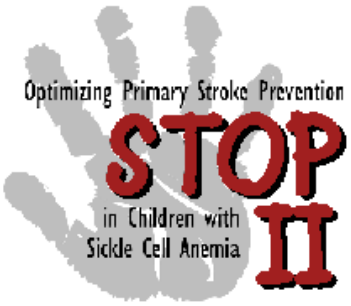

Optimizing Primary Stroke Prevention in Children with Sickle Cell Anemia STOP II

[National Heart, Lung, and Blood Institute Grant Numbers: U01 HL 052193 and U01 HL 052016]

Documentation for the Limited Access Datasets March 2006

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Section 1: OVERVIEW

OPTIMIZING PRIMARY STROKE PREVENTION IN CHILDREN WITH SICKLE CELL ANEMIA (STOP II)

SECTION 1: OVERVIEW

1.1 STUDY SYNOPSIS

Funding agency: National Heart, Blood and Lung Institute
Grant Numbers: U01 HL 052193 and U01 HL 052016
Funding period: 7/1/00 – 5/31/06 (with extension)

Study Design: STOP II was a randomized, controlled, multi-center clinical trial to evaluate whether prophylactic transfusion can be safely halted after 30 months of treatment during which patients at high risk for stroke (as determined by transcranial Doppler ultrasound (TCD) prior to the start of transfusion) changed from high risk to low risk of stroke as demonstrated by a change from abnormal to normal TCD.

A synopsis of key elements of the Study and Trial follows;

- **Primary outcome (composite endpoint)**: Stroke (cerebral infarction or intracranial hemorrhage), return to abnormal TCD, or 3 consecutive inadequate TCDs accompanied by evidence of new stenosis on MRA.
- **Secondary outcome**: Assessment of potential predictors of response to withdrawal of transfusion (age at entry, baseline Magnetic Resonance Imaging (MRI) status, pretreatment TCD velocity, duration of transfusion) in the subgroup of patients randomized to discontinue transfusion.
- **Number of clinical sites**: 28
- **TCD screening period for "new" abnormal TCD patients and recruitment of "Potential" Trial patients (those who started transfusion as a result of STOP II TCD screening results) :** 18 months
- **Planned randomization period**: 48 months
- **Number of patients screened with TCD**: 2,474
- **Number enrolled as Potential (observation) patients for randomization**: 210
- **Number randomized**: 79
- **Central Laboratory**: Serology Core Laboratory and Serum and DNA Repository
- **Central Reading Panels**: TCD Reading Center, Stroke Adjudication Panel, MRI/MRA Reading Panel
- **Trial Results**: The Trial was halted for safety concerns at the fourth interim analysis after 79 of a planned 100 children were randomized. Sixteen patients had reached endpoints (14 reversions to abnormal TCD and 2 strokes). All were observed in children randomized to discontinue transfusion.
- **Main Results Publication:** Adams RJ, Brambilla D; Optimizing Primary Stroke Prevention in Sickle Cell Anemia (STOP 2) Trial Investigators. Discontinuing prophylactic transfusions used to prevent stroke in sickle cell disease. *N Engl J Med* 2005;353:2769-78.

1.2 INTRODUCTION AND OVERVIEW OF STUDY AND DOCUMENTATION

INTRODUCTION

This manual provides documentation for the SAS datasets which contain data collected for the Optimizing Primary Stroke Prevention in Children with Sickle Cell Anemia Trial (STOP II). Data for the study were collected between December 2000 and May 2004. The study was conducted at 28 clinical centers. The Central Administrative Center was located at the Medical College of Georgia in Augusta, Georgia and the Data Coordinating Center for the study was located at New England Research Institutes (NERI), Watertown, MA. The TCD Training and Reading Centers as well as the Core Laboratory were also located at the Medical College of Georgia. The study was funded by the National Heart, Lung and Blood Institute (NHLBI).

BACKGROUND

The Stroke Prevention Trial in Sickle Cell Anemia (STOP) conducted between December 1994 and September 1997 demonstrated that transfusions prevent initial strokes in children who are found to be at risk for stroke based on abnormal (high risk) transcranial Doppler (TCD) ultrasound results. However, long-term use of transfusions can result in iron overload, alloimmunization, and other problems. The STOP II trial was designed as a follow-up to the STOP trial to examine whether transfusions could be safely stopped, using TCD surveillance to detect return of high stroke risk, rather than required indefinitely.

STUDY DESIGN

In STOP II, children and young adults with sickle cell anemia who were at risk for stroke based on abnormal TCD and had at least 30 months of transfusions, during which the TCD became normal, were randomized to either continue or withdraw from transfusions. There were three levels of involvement in this study:

1. Screening by TCD to determine stroke risk prior to transfusion therapy (administered clinically),
2. Enrollment in an observational phase as a “potential subject” who elected to receive clinical transfusion for stroke prevention based on TCD screening; and
3. Trial participation as a randomized subject.

Each level involved different inclusion criteria and surveillance. Randomization procedures were similar to those used in STOP. Surveillance of subjects randomized to the study included at least quarterly TCD. The primary outcome of the trial was a composite endpoint that consisted of the occurrence of stroke, reversion to high stroke risk based on abnormal TCD, or three consecutive inadequate TCDs, involving at least two examiners, accompanied by evidence of new stenosis on MRA.

TCD CLASSIFICATION

Each TCD exam was classified by the STOP II TCD Reading Center into one of five mutually exclusive categories:

1. Normal: all time-averaged maximum mean (TAMM) velocities in the selected cerebral arteries (M1, MCA, BIF, dICA, ACA, PCA, TOB, basilar segment) are <170 cm/sec;

2. Conditional: at least one TAMM velocity of 170-199 cm/sec and no velocities ≥200 cm/sec in the M1, MCA, BIF, or dICA arterial segments OR at least one TAMM velocity ≥170 in the PCA, TOB, basilar or ACA segments.

   Conditional exams were sub-classified as:
   2A (Conditional A) if the qualifying velocity is in the MI, MCA, BIF, or dICA segment;
   2B (Conditional B) if the qualifying velocity is in the PCA, TOB, or basilar segment;
   OR
   2C (Conditional C) if the velocity is in the ACA.

   If multiple velocities between 170 and 199 in M1, MCA, BIF, or dICA arterial segments or > 170 in the PCA, TOB, basilar or ACA segments are recorded, then Conditional A takes priority over Conditional B and both take priority over Conditional C. Conditional A exams with velocities between 180 and 199 cm/sec are considered "high" Conditional A and those between 170 and 179 are considered "low" Conditional A.

3. Abnormal: at least one TAMM velocity of at least 200 cm/sec in M1, MCA, BIF, or dICA segments; and

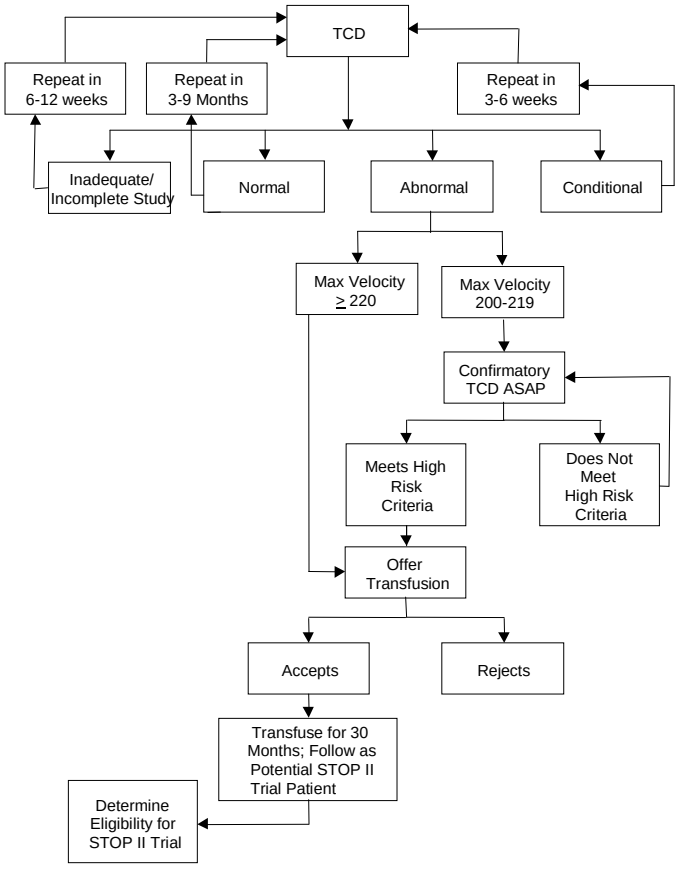
4. Inadequate: unreadable or incomplete due to presence of a poor ultrasound window or complete or nearly complete occlusion of an arterial segment. Caveat: incomplete exams with at least one velocity ≥200 cm/sec in the M1, MCA, BIF, or dICA segments are considered abnormal.

5. Inadequate (technical): uninterpretable due to technical reasons, such as improper adjustments of the TCD machine, motion of child, poor TCD examiner technique.

SCHEDULE OF MEASUREMENTS

A1. TCD Exam Schedule for Screening Patients

STOP II TCD SCREENING FLOWCHART



A2. STOP II Form Completion Schedule for Screening Patients

		When Completed			
Form #	& Name	Each TCD Exam Visit *	Notification of Eligibility for Clinical Transfusions	Annual Follow-up **	Suspected Neuro Event
01A	Eligibility Questionnaire for TCD Screening Exam	X			
02	Transcranial Doppler (TCD) Examination Form	X			
03	Treatment Decision by Parent-Guardian of Newly Identified Child With Two Abnormal TCDs or One Abnormal TCD With TAMM Velocity ≥ 220 CM/SEC		X		
Q30	Quasi-Adjudication Neurological Event Form				X

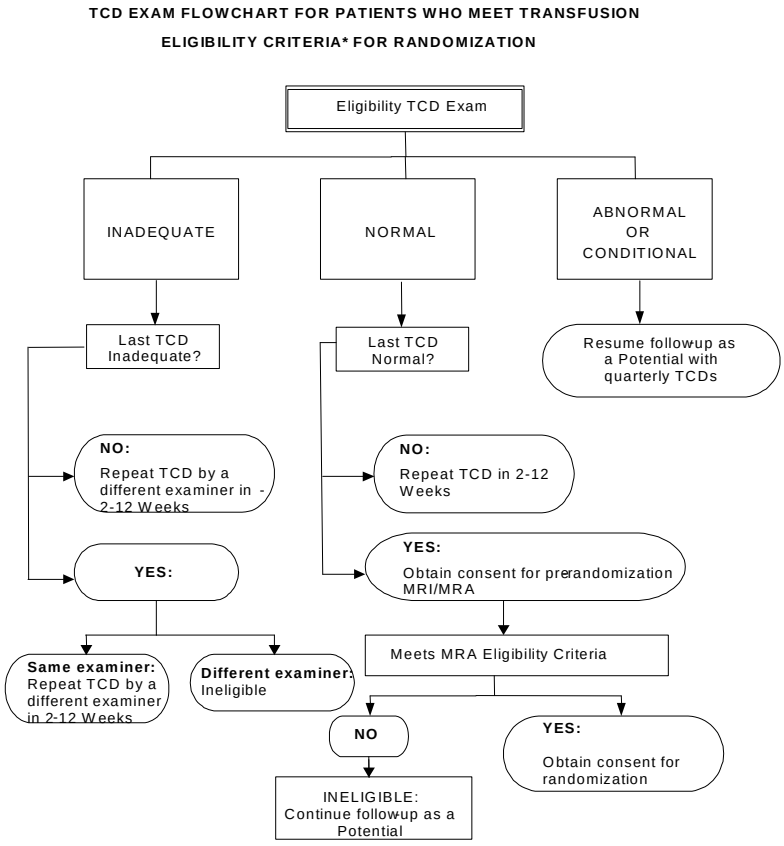
* See A1 for detailed TCD exam follow-up schedule
** Discontinued June 2003

B1. Schedule of Measurements for Potential (observation) Patients

	When Completed			
	Entry	Quarterly	Neurological Event	Transfusion
Vital Statistics/History	X	X	X	
CBC (local)	X	X		X
Quantitative Hb Analysis (local)	X	X		X
Ferritin (local)	X	X		
Liver Profile (ALT, GGT, LDH, bilirubin) (local)	X	X		
TCD	X	X *	X	
Neurology Consult Report			X	
MRI/MRA Reports			X	
Progress Reports		X		
Transfusion Information	X			X

* Schedule determined by time on transfusion and previous results; see B2

B2. TCD Exam Schedule for Potential Patients



* Adequate participation in a transfusion program was defined as at least 24 transfusions in the 30-month evaluation period with a maximum average interval of 5.4 weeks between transfusions, pre-transfusion Hb S $\leq$ 40% in at least two-thirds of the measurements obtained during the 30-month evaluation period, and no interruption in transfusion that exceeded 6 consecutive months.

B3. STOP II Form Completion Schedule for Potential Patients

Form # and Name		When Completed			
		"Entry" Visit	Quarterly Visit	Transfusion	Suspected Neuro Event
01B	Eligibility Questionnaire for Patients on Transfusion For Primary Stroke Prevention for < 30 Months	X			
01C	Pre-Randomization Eligibility Questionnaire (for patients on transfusion for ≥ 30 months)	X			
02	Transcranial Doppler (TCD) Examination Form	X	X[2]		
11	Intake History Form	X			
12	Physical Examination	X	X		
13B	Local Laboratory Form for Non-Randomized Patients Receiving Transfusions	X	X	X	
15	Head MRI Scan		X[3]		
16B	Quarterly Progress Report for Non-Randomized Patients Receiving Transfusions		X		
16R	Quarterly Medical Record Review		X		
19	MRA Scan		X[3]		
22	Transfusion History Log	X[1]			
Q30	Quasi-Adjudication Neurological Event Form				X

[1] Not required for STOP randomized patients if DCC had information for all transfusions prior to "entry" visit

[2] See B2

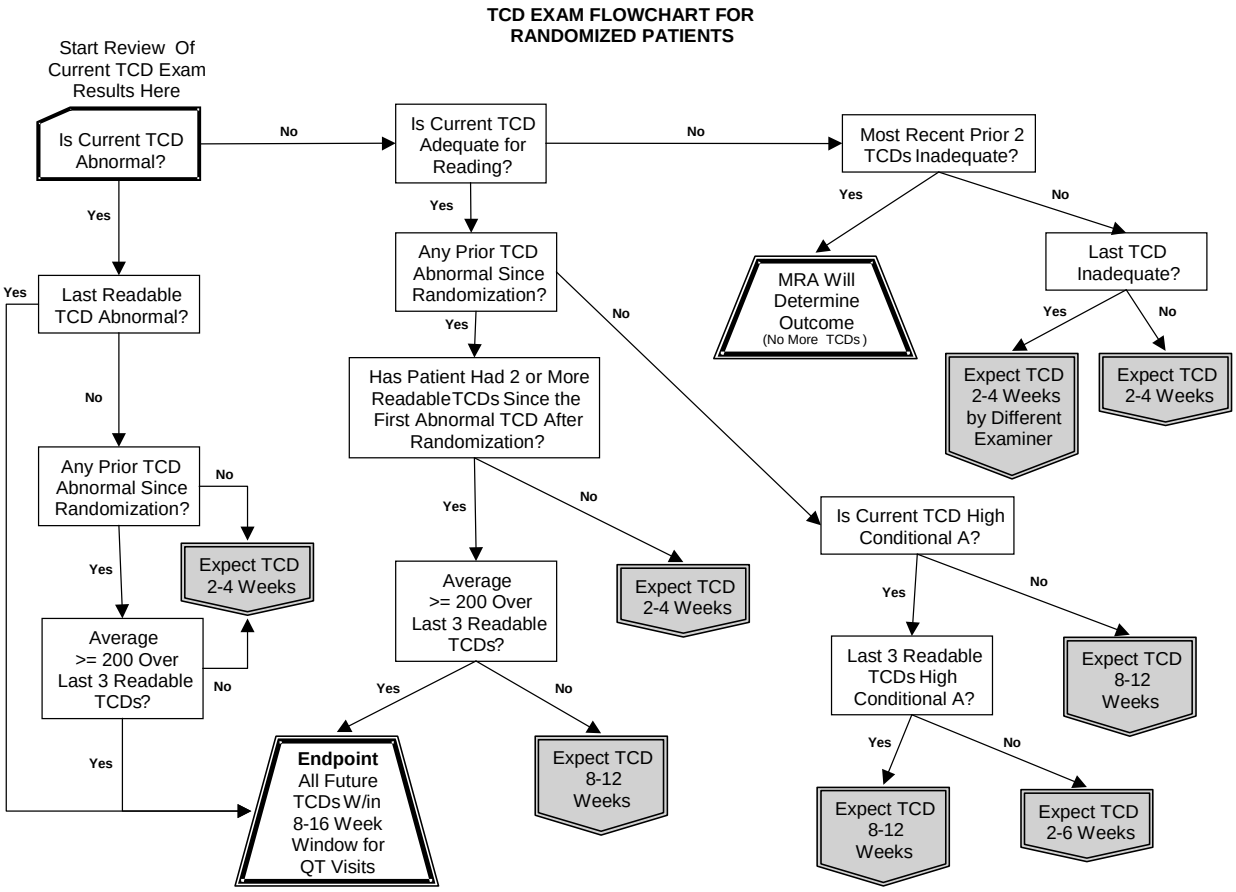
[3] Part of pre-randomization evaluation; scheduled once patient met pre-randomization TCD and transfusion eligibility criteria for randomization

C1. Schedule of Measurements for Randomized Patients

	When Completed					
	Entry	Quarterly	Every TX	Annual	Neurological Event	Study Exit
Vital Stats/History	X	X	X	X	X	X
CBC w/diff, retics, platelets	X	X	X	X	X	X
Serum Bank Sample	X	X		X	X	X
DNA Bank Sample	X					
Quantitative Hb Analysis	X	X	X	X	X	X
Ferritin	X	X		X		X
Liver Profile (ALT,GGT, LDH, bilirubin)	X			X		X
Hepatitis B & C Antibody Tests	X					X[1]
TCD		X[2]		X[2]	X	X[2]
MRI/MRA		[2]		X	X	X
DWI					X	
Neurological Exam	X			X	X	
Progress Report		X		X	X	X

[1] Only hepatitis C tested, and only if previous test was negative.
[2] See C2 for detailed schedule for TCD monitoring.

C2. TCD Exam Schedule for Randomized Patients



C3. STOP II Form Completion Schedule for Randomized Patients

		When Completed								
Form #	and Name	Trial Entry Visit	Quarterly Visit	Annual Visit	Endpoint/ Exit Visit	Transfusion	Suspected Neuro Event	Non-Neuro Event	Delayed Transfusion Reaction	Death
02	Transcranial Doppler (TCD) Examination Form		X[1]	X	X		X			
10	Trial Randomization Form	X								
12	Physical Examination	X	X	X	X					
13	Core Laboratory Form	X	X	X	X	X[4]	X			
14	Neurological Consultant Report	X		X	X		X			
15	Head MRI Scan		[2]	X[3]	X		X			
15A	Event CT Scan						X (if done)			
16	Quarterly Progress Report for Randomized Patients	X	X	X	X					
16R	Quarterly Medical Record Review	X	X	X	X					
19	MRA Scan		[2]	X[3]	X		X			
20	Transfusion Form					X				
21	Blood Unit Form					X				
30	Neurological Event Form						X			
31	Non-Neurological Event Form							X		
32	Delayed Transfusion Reaction Form								X	
33	Outcome of Hospitalization for Stroke, Meningitis, or Head Injury						X	X[5]		
40	Cause of Death Form									X

(1) See C2 for detailed monitoring schedule
(2) required following three inadequate TCD exams by at least two examiners
(3) required every 6 months if patient has history of repeated inadequate exams without moderate to severe arterial disease on MRA
(4) required only if randomized to continuation of transfusion arm
(5) required if event is meningitis or head injury

DATA AND DOCUMENTATION FILES

Two versions of data and documentation were produced:

- one version for STOP II investigators that includes data for all patients who participated in the screening, observation, and/or randomized phase of the study and
- one version for public use that includes data for only Trial (randomized) patients.

The STOP II investigator version includes date variables in all datasets. In the public use (limited data access version), date variables have been converted to days from randomization or, in some cases, dropped from the dataset. The table below provides the following information about each data file that is on the CD that accompanies this manual:

- Data source (data collection form);
- Name of the SAS dataset;
- Name of the SAS user-defined format file associated with the SAS dataset;
- Number of records (observations) in dataset;
- Number of patients with records in dataset;
- Number of variables in dataset;
- Dates of Oracle data export and finalization of codebook.

Electronic copies of blank STOP II data collection forms are included in a separate subdirectory on both the investigator and public use (limited data access) CDs.

List of STOP II Data and Documentation Files on CD

FORM NAME	FORM #	SAS DATASET (**.sas7bdat**) FILE	SAS FORMATS (**.txt**) FILE	# OF RECORDS (PTS) IN DATASET	# OF VARIABLES IN DATASET	ORACLE DATA EXPORT DATE FOR CODEBOOK	**DATE FINAL CODEBOOK PRODUCED**
Patient Roster		Prst2_final	Rst2fmts	79 (79)	12	03/09/06	**03/15/06**
Randomization Table		PRand_table _final	Rand_ tablefmts	79 (79)	19	02/27/06	**03/10/06**
Eligibility Questionnaire for TCD Screening Exam	1A	P01a_final	F01Afmts	42 (17)	20	01/20/06	**01/27/06**
Eligibility Questionnaire for Patients on Transfusion for Primary Stroke Prevention for < 30 months	1B	P01b_final	F01Bfmts	33 (33)	24	09/21/05	**01/27/06**
Pre-Randomization Eligibility Questionnaire	1C	P01c_final	F01Cfmts	79 (79)	24	02/03/06	**02/06/06**
Transcranial Doppler (TCD) Examination Form	2	P002_final	F002fmts	1349 (79)	119	02/06/06	**03/21/06**
Non-STOP II TCD Exams		PnonSTOP2 TCDs_final	N/A	16 (9)	4	11/07/05	**02/23/06**
Treatment Decision by Parent/Guardian of Newly Identified Child with Two Abnormal TCDs or One Abnormal TCD with TAMM Velocity ≥ 220 cm/sec	3	P003_final	F003fmts	17 (17)	12	09/01/05	**01/27/06**
Signed Acknowledgement of New Information About the STOP II Study	5	P005_final	N/A	69 (69)	8	08/05/05	**01/27/06**
Post-Trial Treatment Decision Form	6	P006_final	F006fmts	70 (70)	11	08/05/05	**01/27/06**
Trial Randomization Form	10	P010_final	F010fmts	80 (79)	32	08/08/05	**03/08/06**
Intake History Form	11	P011_final	F011fmts	79 (79)	128	02/03/06	**02/06/06**
Physical Examination	12	P012_final	F012fmts	1162 (79)	42	12/02/05	**01/27/06**
Core Laboratory Form	13	P013_final	F013fmts	1530 (79)	60	01/09/06	**03/08/06**

FORM NAME	FORM #	SAS DATASET (**.sas7bdat**) FILE	SAS FORMATS (**.txt**) FILE	# OF RECORDS (PTS) IN DATASET	# OF VARIABLES IN DATASET	ORACLE DATA EXPORT DATE FOR CODEBOOK	**DATE FINAL CODEBOOK PRODUCED**
Local Laboratory Form for Non-Randomized Patients Receiving Transfusions	13B	P13B_final	F13Bfmts	1703 (79)	36	10/03/05	**03/08/06**
Neurological Consultant Report	14	P014_final	F014fmts	248 (77)	152	01/20/06	**03/08/06**
Head MRI Scan	15	P015_final	F015fmts	227 (79)	93	03/29/06	**04/18/06**
Event CT Scan	15A	P15A_final	F15Afmts	1 (1)	21	09/13/05	**02/20/06**
Quarterly Progress Report for Randomized Patients	16	P016_final	F016fmts	740 (79)	191	12/02/05	**03/09/06**
Quarterly Progress Report for Non-Randomized Patients Receiving Transfusions	16B	P16b_final	F16Bfmts	344 (79)	124	02/16/06	**03/09/06**
Quarterly Medical Record Review	16R	P16r_final	F16Rfmts	2083 (198)	129	01/20/06	**03/17/06**
Missed Follow-Up Visit for Trial Patients	18	P018_final	F018fmts	45 (29)	12	10/04/05	**02/15/06**
Reason for Overdue TCD Exam Visit for Randomized Patient	18T	P18t_final	F18Tfmts	75 (38)	15	08/09/05	**02/17/06**
MRA Scan	19	P019_final	F019fmts	226 (79)	70	03/24/06	**03/28/06**
Transfusion Form	20	P020_final	F020fmts	1996 (67)	103	09/20/05	**03/09/06**
Blood Unit Form	21	P021_final	F021fmts	5020 (67)	30	01/04/06	**03/09/06**
Transfusion History Log for Patients on Transfusion for Primary Stroke Prevention who were not STOP Randomized Patients	22	P022_final	F022fmts	558 (21)	15	01/09/06	**02/15/06**
Chelation Questionnaire for STOP II Randomized Patients	23A	P23a_final	F23Afmts	49 (49)	13	11/29/05	**03/10/06**
Transfusion History Log for Pre-STOP II Transfusions that Are Not in FOXPRO or ADEPT for STOP Randomized Patients	24	P024_final	N/A	240 (33)	7	06/06/05	**02/16/06**
Neurological Event Form	30	P030_final	F030fmts	14 (11)	62	01/06/06	**02/17/06**
Non-Neurological Event Form	31	P031_final	F031fmts	555 (62)	44	11/21/05	**03/15/06**

FORM NAME	FORM #	SAS DATASET (**.sas7bdat**) FILE	SAS FORMATS (**.txt**) FILE	# OF RECORDS (PTS) IN DATASET	# OF VARIABLES IN DATASET	ORACLE DATA EXPORT DATE FOR CODEBOOK	**DATE FINAL CODEBOOK PRODUCED**
Delayed Transfusion Reaction Form	32	P032_final	F032fmts	2 (2)	80	08/24/05	**03/02/06**
Outcome of Hospitalization for Stroke, Meningitis, or Head Injury	33	P033_final	F033fmts	6 (5)	17	01/06/06	**03/10/06**
Cause of Death Form	40	P040_final	F040fmts	1 (1)	19	09/22/05	**02/17/06**
Endpoint Adjudication Decision	52	P052_final	F052fmts	14 (11)	19	01/23/06	**02/17/06**
Quasi-Neurological Event Form	Q30	PQ30_final	FQ30fmts	1 (1)	53	01/06/06	**02/20/06**
Quasi-Adjudication Consensus	Q52	PQ52_final	FQ52fmts	1 (1)	12	01/30/06	**02/17/06**

IDENTIFIER LINK DATASET

An identifier "link" dataset, which provides a link between the original STOP II subject ID numbers and the new blinded ID numbers that were randomly assigned, is included on a separate CD **for NHLBI use only**. The original STOP II subject ID numbers (**MASTER_ID**) were structured as 11-222-3, where digits 1-2 denote the STOP II site number, digits 3-5 denote the patient number, and digit 6 denotes a check digit used to validate ID numbers in the data entry process. The new 10-character blinded ID numbers (**LDU_ID**) have references to site and patient removed. The link dataset "RANDIDLINK_FINAL.sas7bdat" also has the original site ID number. The number of records in the dataset matches the number of randomized patients (N=79).

SAS DATASET (**.sas7bdat**) FILE	SAS FORMATS (**.txt**) FILE	# OF RECORDS (PTS) IN DATASET	# OF VARIABLES IN DATASET
RANDIDLINK_FINAL	N/A	79 (79)	3

```
Data Set Name        PUBDS.RANDIDLINK_FINAL          Observations          79
Member Type          DATA                            Variables             3
Engine               V9                              Indexes               0
Created              Saturday, April 22,             Observation Length    24
                     2006 12:58:55 PM
Protection                                           Compressed            NO
Data Set Type                                        Sorted                YES
Data Representation  WINDOWS_32
Encoding             wlatin1  Western (Windows)

                      Engine/Host Dependent Information

Data Set Page Size          4096
Number of Data Set Pages    1
First Data Page             1
Max Obs per Page            168
Obs in First Data Page      79
Number of Data Set Repairs  0
File Name                   p:\stop2\data manual\public use\pu
                            data sets\randidlink_final.sas7bdat
Release Created             9.0101M3
Host Created                XP_PRO

                Alphabetic List of Variables and Attributes

# Variable   Type Len Format Informat Label

1 MASTER_ID  Char   6 $6.    $6.      Original STOP II Subject ID Number
2 ldu_id     Char  10                 ID Number (de-identified)
                                      for Public Use Datasets
3 site_      Num    8                 Original STOP II Site Number
  number
                           Sort Information
                          Sortedby       ldu_id
                          Validated      YES
                          Character Set  ANSI
```

DATA EXCLUDED OR MODIFIED

- **Confidentiality Considerations**

1. As noted above, in the public use datasets, date variables have either been converted to days from randomization or dropped.

2. In the public use datasets, patient ID numbers have been replaced with anonymized ID numbers (**LDU_ID**).

3. Clinical site, which was embedded in the original patient ID number and extracted from the ID number as a 2-digit integer code, has been dropped from the public use datasets.

4. All initials and/or names of clinical site staff have been dropped from the public use datasets.

5. Some fields have been dropped, recoded, or modified in the public use because they contained information which might be used to identify a particular patient.

MERGING ACROSS DATASETS (FORMS)

The table below provides information about what variables should be used to link across (merge) datasets (forms). Before merging, make sure that each of the datasets to be merged is sorted by the merge (linking) variable(s), as applicable.

Forms to be Linked	Applicable for Datasets	Link Datasets by
Routine Visit Forms		**LDU_ID, VISTYPE**
1A	P01a_final	
2	P002_ final (applicable only if EX_TYPE=QT, RT or CS)	
10	P010_final	
11	P011_final	
12	P012_final	
13	P013_final (applicable only if EX_TYPE=QT)	
13B	P013B_final (applicable only if EX_TYPE=QT)	
14	P014_final (applicable only if EX_TYPE=QT)	
15	P015_final (applicable only if EX_TYPE=QT) *	
16	P016_final	
16B	P16b_final	
16R	P16r_final	
18	P018_final	
19	P019_final *	

Forms to be Linked	Applicable for Datasets	Link Datasets By
Transfusion/Laboratory		
20 with 21	P020_final with P021_final *	**LDU_ID, EX_NUM**
20 with 13	P020_final with P013_final	**LDU_ID, tran_datfrmrand (P013)/comp_dfrmrand (P020) ****
20 with 13B	P020_final with P13b_final	**LDU_ID, tran_datfrmrand (P13b)/comp_dfrmrand (P020) ****
Events		
30 with 15	P030_final with P015_final * (where EX_TYPE=NE)	**LDU_ID, VISTYPE**
30 with 15A	P030_final with P15a_final (where EX_TYPE=NE)	**LDU_ID, VISTYPE**
30 with 19	P030_final with P019_final * (where EX_TYPE=NE)	**LDU_ID, VISTYPE**
30 with 52	P030_final with P052_final	**LDU_ID, VISTYPE**
30 with 33	P030_final with P033_final	**LDU_ID, VISTYPE**
Q30 with Q52	Pq30_final with Pq52_final	**LDU_ID, VISTYPE**

* Dataset contains multiple observations with same BY variables

**** IMPORTANT:** In order to merge P013 & P020 datasets or P13b & P020 datasets, the variable comp_dfrmrand in the P020 dataset will need to be **renamed** tran_datfrmrand before merging.

IMPORTANT – SPECIAL ALERT:

Before merging datasets, some variable names in the datasets to be merged may need to be renamed in cases where the **same variable name** is used in both datasets but for different items – e.g., **comp_dfrmrand** is the variable name for "date of physical exam" in the **P012_final** dataset and the variable name for "date core lab sections completed" in the **P013_final** dataset. To avoid inappropriate overwriting of a value when the datasets are merged, these variables should be renamed with a unique variable name in one or both datasets before merging.

DATA CODEBOOKS – OVERVIEW OF CONTENTS AND ORGANIZATION

Each codebook has the following components as applicable:

1. **Codebook Summary**
2. **Contents of the SAS Dataset**
3. **SAS Formats**
4. **Data Codebook**

1. The **Codebook Summary** contains the following information:

   FORM XX: the form name

   A. Collection Information: information detailing which patient groups the form was required for, which visits or events precipitated form completion, how frequently a form was collected, and other details pertaining to form collection.

   B. Data Collection Period: the study dates between which the form was collected.

   C. Form Version Dates: the date a form was created or modified, with a summary of changes made from the previous version of the form. For the few forms with more than one version, a variable **VER_ID** exists in the dataset to identify which version was used for the data collection.

   D. Files Used to Store Information: the file name of the final SAS dataset

   E. Unique Record Identifiers: the variable names in the SAS dataset by which the data are sorted and by which individual records can be identified.

   F. Number of Observations (Patients) in SAS Dataset: the number of unique records in the dataset. As many of the forms were completed at multiple time points, the number of patients in the dataset is listed in parenthesis following the number of observations.

   G. Contents of SAS Dataset: a report generated by SAS of the contents of the dataset, including number of observations, number of variables, date of file creation, etc. Variables are listed first alphabetically, and then listed by their position in the dataset.

   H. Formats: information about the name of the external text file with SAS user-defined formats for categorical variables in the dataset and a description of the format naming convention used.

   I. Codes for Missing Values: specific codes used to identify reasons that a response for a variable is missing.

   J. Date Variables: notes about the collection and formatting of dates in the dataset.

   K. Notes about Selected Variables: information for selected variables describing what data a variable collected, details about value codes, out of range values, unique situation disclaimers, details about value recoding, or information on variable creation.

2. The **Contents of the SAS Dataset** is a report generated by SAS detailing the contents of the dataset, including the dataset name, number of observations, number of variables, date of file creation, sort information, etc. Variables are listed first alphabetically, and then listed by their position in the dataset**.**

   FORMSTAT_ID - This variable is a unique 6-digit code number assigned to each form entered into the ADEPT DMS

3. User-defined **SAS Formats** assigned to categorical variables in the dataset are included in the codebook and in a separate file on the CD. The naming convention for the individual format file associated with a dataset is <form #>fmts.txt (e.g., F010fmts.txt is the name of the format file on the CD that is associated with Form 10). This text file can be inserted into SAS programs to associate values for categorical variables with their descriptions during a SAS session or permanently saved to a format catalog (Refer to SAS documentation for details related to methods for associating formats with variables).

The following conventions were used for assigning format labels for variables:

- Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF.

- Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF.

4. The **Data Codebook** contains the statistical tables for each variable embedded in the data collection form.

The first section of the data codebook is the form header and patient label information:

FORM 16
VERSION A – 11/15/2000

STOP II TRIAL
QUARTERLY PROGRESS REPORT FOR RANDOMIZED PATIENTS

***** AFFIX PATIENT LABEL HERE*****

Patient labels were generated by the DCC for use on study forms, and contained variables for the patient ID number, acrostic, date of birth, gender, and visit information:

11-222-3 ABCDE DOB: 01/01/1980 Male Quarterly Visit: QT Visit Number: 201 Complete between: 07/29/2002 - 09/23/2002

MASTER_ID - The patient ID number was structured as a 6-character variable (11-222-3), where digits 1-2 denote the STOP II site, digits 3-5 denote an assigned patient number, and digit 6 denotes a check digit used to validate ID numbers in the data entry process. For the public use versions, original ID numbers were replaced by a 10-character variable (**LDU_ID**) beginning with the letter 'P'. These blinded ID numbers have all references to site and patient removed.

ACROSTIC - This variable is a 5-character variable that was to be constructed as follows: first 3 letters of the patient's LAST name, followed by the first 2 letters of the patient's FIRST name. This variable was dropped from the public use datasets.

Patient ID, acrostic, date of birth and gender were taken from the Patient Roster. Expected completion windows were generated by the ADEPT data management system for coordinator information, and were not data entered.

How to Read a Codebook

Related questions on forms are generally presented in horizontal rows. As shown in Example 1 below, the flow of questions would lead from C1.a to C1.b to C1.c to C1.d to C1.e for item 1. Stroke/TIA before continuing to C1.a for item 2. New Onset of Seizures.

EXAMPLE 1.

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
1. **Stroke/TIA**	☐	☐	☐	__ __/__ __ __ __	☐
2. **New Onset of Seizures**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: An event which a doctor called a stroke or cerebrovascular accident (CVA) which involved loss of consciousness, paralysis, visual, speech, or motor difficulties)*

*(**PROBE**: Any fits or convulsions that were not associated with a stroke or meningitis (brain infection))*

Data tables are generally arranged beneath each question or group of questions in the order of the question flow, as indicated in Example 2 below. Notes in each codebook indicate where variables have been dropped from the dataset or where data tables are not included (Example 3.)

EXAMPLE 2.

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
1. **Stroke/TIA**				__ __/__ __ __	

*(**PROBE**: An event which a doctor called a stroke or cerebrovascular accident (CVA) which involved loss of consciousness, paralysis, visual, speech, or motor difficulties)*

C1a1. Stroke/TIA

STROKE	Frequency	Percent	Cum Freq	Cum Percent
1	736	99.46	736	99.46
2	4	0.54	740	100.00

C1b1. Number of events:stroke

STROKTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	736	99.46	736	99.46
1	4	0.54	740	100.00

C1c1. Number of events treated:stroke

TREATSTR	Frequency	Percent	Cum Freq	Cum Percent
-2	736	99.46	736	99.46
0	1	0.14	737	99.59
1	3	0.41	740	100.00

Analysis Variable : strok_dtfrmrand <created variable> C1d1. Date of stroke as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	177.0	76.4	125.0	131.0	146.5	223.0	290.0

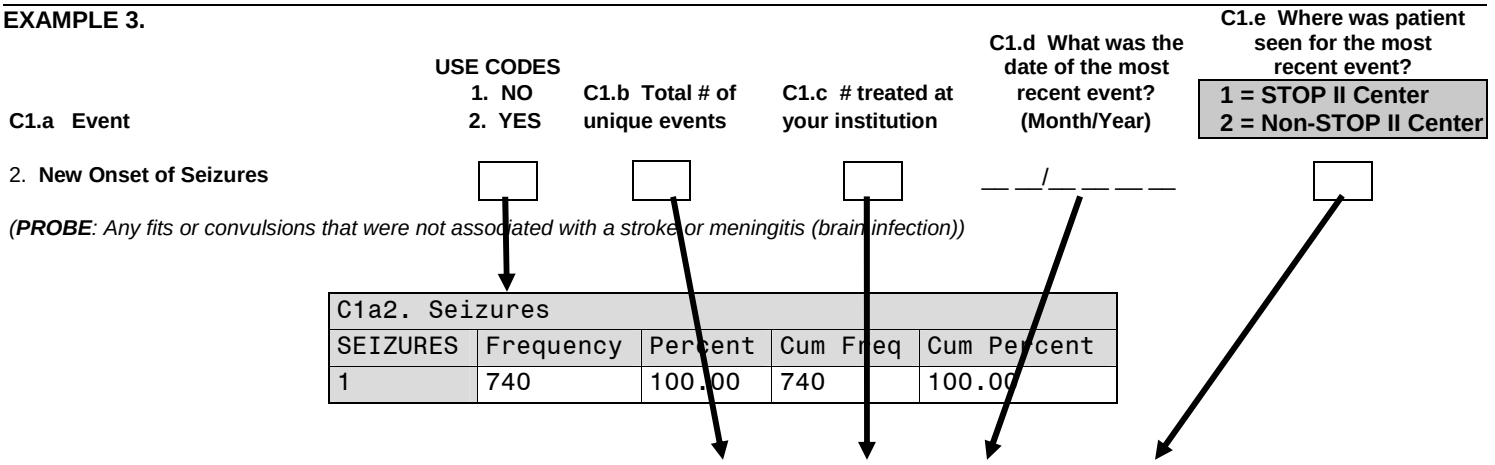
<created variable> C1d1. Date of stroke as days from RAND visit

strok_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	736	100.00	736	100.00

C1e1. Location seen at for stroke

SEENSTRK	Frequency	Percent	Cum Freq	Cum Percent
-2	736	99.46	736	99.46
1	3	0.41	739	99.86
2	1	0.14	740	100.00

EXAMPLE 3.

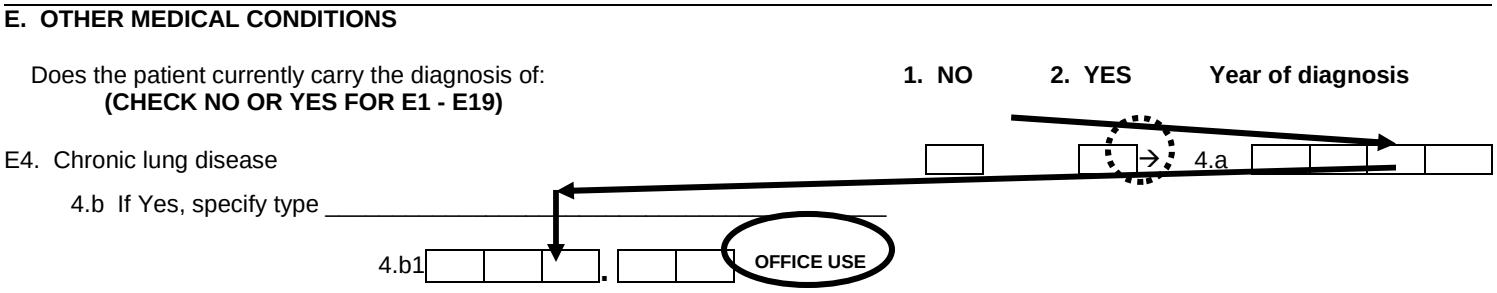


C1a2. Seizures				
SEIZURES	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

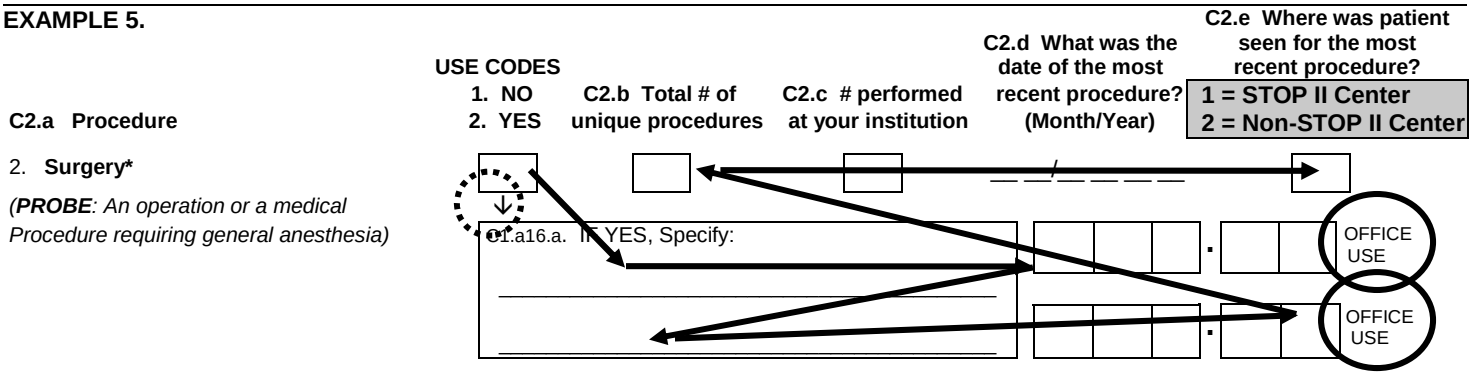
[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

Forms also included variables to capture other events or procedures not otherwise listed. These incidents needed further specification and were associated with the applicable code from the International Classification of Diseases manual (ICD-9-CM). ICD coding was completed by the DCC and listed in boxes labeled "Office Use" (circled below). The question flow on the form and in the database followed one of two paths: the question flow proceeded as above from the NO/YES response horizontally before continuing to the specify field, or the question flow proceeded from the NO/YES response to the specify field before continuing to the other variables. The arrows on the form (dotted circles in Examples 4 and 5 below) indicated which pattern was used for a particular question.

EXAMPLE 4.

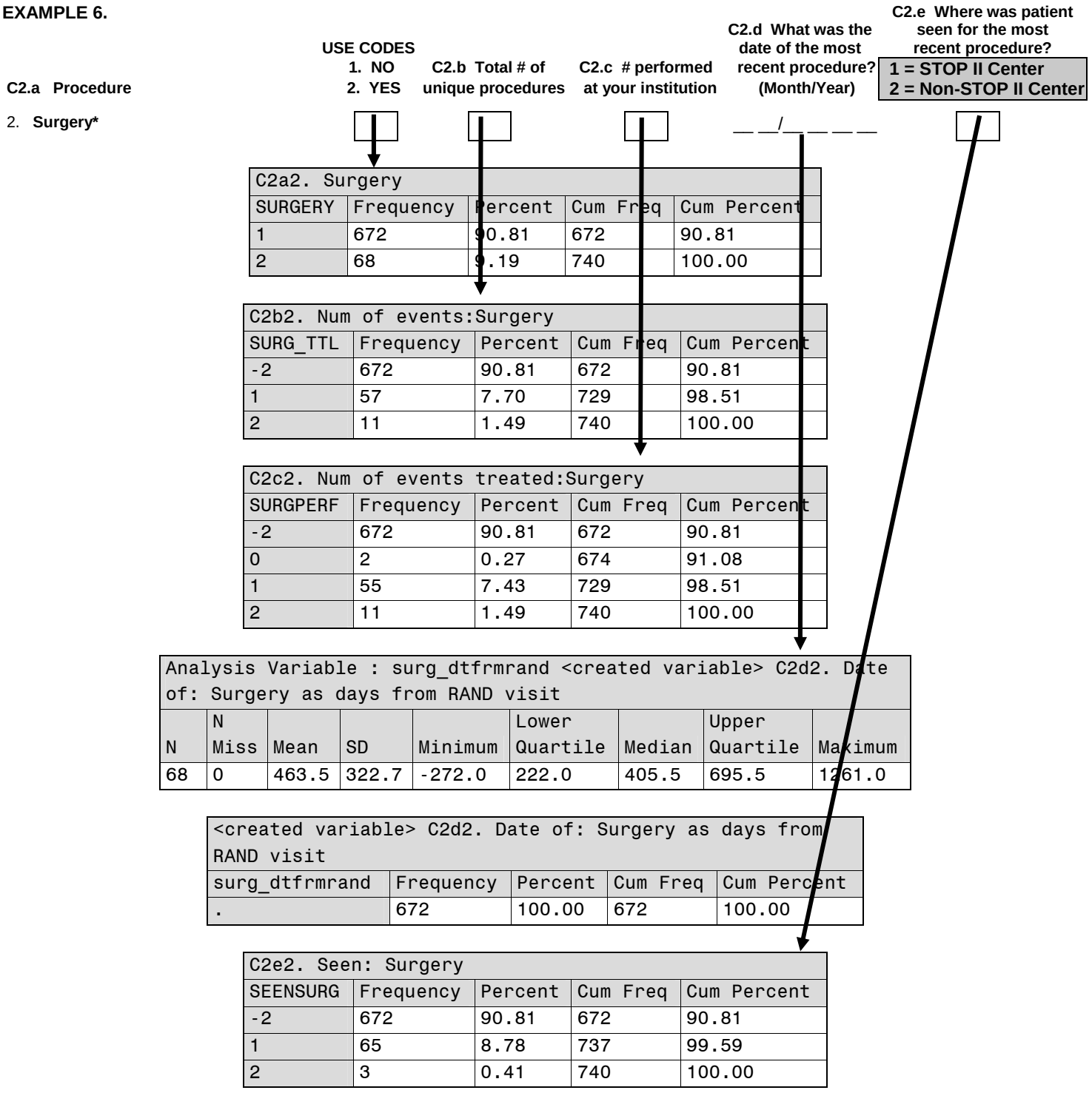


EXAMPLE 5.



The ICD code and its associated specify field were combined into one table in the codebook. Specify field tables were placed for ease of codebook formatting and readability rather than by question flow, and are shown beneath their related question on the form as in Example 6 below.

EXAMPLE 6.



C2a2. Surgery

SURGERY	Frequency	Percent	Cum Freq	Cum Percent
1	672	90.81	672	90.81
2	68	9.19	740	100.00

C2b2. Num of events:Surgery

SURG_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	672	90.81	672	90.81
1	57	7.70	729	98.51
2	11	1.49	740	100.00

C2c2. Num of events treated:Surgery

SURGPERF	Frequency	Percent	Cum Freq	Cum Percent
-2	672	90.81	672	90.81
0	2	0.27	674	91.08
1	55	7.43	729	98.51
2	11	1.49	740	100.00

Analysis Variable : surg_dtfrmrand <created variable> C2d2. Date of: Surgery as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
68	0	463.5	322.7	-272.0	222.0	405.5	695.5	1261.0

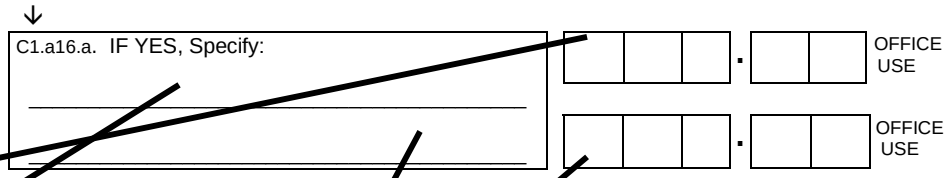
<created variable> C2d2. Date of: Surgery as days from RAND visit

surg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	672	100.00	672	100.00

C2e2. Seen: Surgery

SEENSURG	Frequency	Percent	Cum Freq	Cum Percent
-2	672	90.81	672	90.81
1	65	8.78	737	99.59
2	3	0.41	740	100.00

*(**PROBE**: An operation or a medical Procedure requiring general anesthesia)*



surgrecode	surg_recodespc	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	672	90.81	672	90.81
38.93	CENTRAL LINE PLACEMENT	1	0.14	673	90.95
38.93	Fermoral line for exchang	1	0.14	674	91.08
38.93	MEDIPORT PLACEMENT	1	0.14	675	91.22
38.93	Port-a-cath insertion	7	0.95	682	92.16
50.11	Liver biopsy	33	4.46	715	96.62
51.04	gallbladder removal	2	0.27	717	96.89
51.22	Cholecystectomy	3	0.41	720	97.30
51.23	Cholecystectomy	2	0.27	722	97.57
51.23	Lap. cholecystectomy	5	0.68	727	98.24
97.89	Hickman line removal	1	0.14	728	98.38
97.89	Mediport removal	1	0.14	729	98.51
97.89	Port-a-cath removal	4	0.54	733	99.05
99.99	OTHER	7	0.95	740	100.00

surgrecode2	surg_recodesp2	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	672	90.81	672	90.81
-1	-1	56	7.57	728	98.38
38.93	Hickman placement	1	0.14	729	98.51
38.93	Port-a-cath insertion	3	0.41	732	98.92
50.11	Liver biopsy	3	0.41	735	99.32
51.23	Cholecystectomy	1	0.14	736	99.46
51.23	Lap. cholecystectomy	1	0.14	737	99.59
97.89	Port-a-cath removal	3	0.41	740	100.00

Data for missing values are represented by special codes as defined under the Codes for Missing Values section on each codebook summary sheet. A variable may have a missing value when the value was not applicable, when a test or measurement was not done, when the value was unknown, or when the item was left blank on the form. Values may also be missing if the data management system was programmed to skip a question based on previous data on the form.

Missing value data for categorical variables are included in the main data table for a variable (circled in Example 7 below). (Missing values shown here by negative number codes.)

EXAMPLE 7.

C1. General Appearance ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C1. General appearance				
GENAPPER	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	3	0.26	4	0.34
1	1104	95.01	1108	95.35
2	54	4.65	1162	100.00

Missing value data for continuous variables have been separated from the main table so the special codes are not calculated in the means statistics as real numbers. As such, NMiss=0 in the main table (dotted circle) is NOT the true count of missing values. Missing values for data are shown in a separate table (circled below). Example 8 shows tables for a date variable (missing values shown by ".".) Example 9 shows tables for a lab result (missing values shown by negative number codes).

EXAMPLE 8.

B2. Date Blood Drawn for Hemoglobin S (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

Analysis Variable : hbs_dtfrmrand <created variable> B2. Date blood drawn for HB S as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1642	0	-401.1	290.5	-1343	-623.0	-337.5	-151.0	-1.0

<created variable> B2. Date blood drawn for HB S as days from RAND visit				
hbs_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	61	100.00	61	100.00

EXAMPLE 9.

D. LABORATORY TEST RESULTS

D1. Hemoglobin Analysis:

a. % S ☐☐ . ☐

Analysis Variable : HBA_S D1a. Hemoglobin analysis: %% S								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1634	0	26.7	12.9	0.0	18.2	25.1	33.4	99.9

D1a. Hemoglobin analysis: % S				
HBA_S	Frequency	Percent	Cum Freq	Cum Percent
-9	2	2.90	2	2.90
-3	67	97.10	69	100.00

Variables that were programmed to be skipped by the data management system during data entry received a value of -2. (E.g. where no event was reported, variables for date of event and number of event were skipped.) This may apply to an individual variable for an individual observation, in which case the -2 would be listed as per the special value guidelines in Examples 7 and 8 above.

In cases where a variable was skipped for all observations, tables contained only a value of -2 as shown in Example 10. Tables for these cases were often indicated with a note that the data are not shown in the codebook, or the variable was dropped from the dataset completely, also indicated in the codebook with a note. (Example 11.)

EXAMPLE 10.

Does the patient currently carry the diagnosis of: **(CHECK NO OR YES FOR E1 - E19)**

1. NO **2. YES** **Year of diagnosis**

E8. Chronic renal disease ☐ ☐→ 8.a ☐☐☐☐

8.b If Yes, specify type: _____

8.b1 ☐☐☐.☐☐ **OFFICE USE**

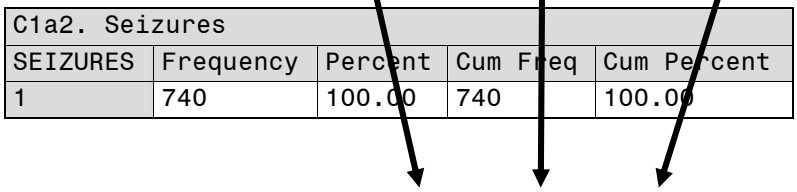
E8. Chronic Renal Disease				
CHR_RNLD	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

E8b. Type of Chronic Renal Disease				
C_RNLTYP	Frequency	Percent	Cum Freq	Cum Percent
-2	79	100.00	79	100.00

EXAMPLE 11.

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
2. **New Onset of Seizures**				__ __/__ __ __ __	

*(**PROBE**: Any fits or convulsions that were not associated with a stroke or meningitis (brain infection))*



C1a2. Seizures				
SEIZURES	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

Section 2: STOP II CODEBOOKS

STOP II
PATIENT ROSTER

A. Collection Information:
The full **Patient Roster** dataset contains identification, demographic, and study status information on more than 6,000 patients who were on the original STOP roster (including those who were screened in STOP or the STOP ancillary study) as well as those identified by the clinical sites in STOP II as possible candidates for evaluation to participate in the STOP II study. The final SAS roster dataset includes only the subset of patients on the roster who completed screening or "potential" patient eligibility forms in combination with submission of source documents confirming their hemoglobin diagnosis as SS or S/β^0 thalassemia.

B. Data Collection Period: December 2000 through August 2002

C. Form Version Dates: n/a

D. Files Used to Store Information:

SAS System File: **prst2_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 79 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 6
- Listing of Variables by Position: See p. 7

H. Formats:
The file **rst2fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the formal label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 8.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **WHICHGRP** - This variable indicates which patient group(s) a patient participated in during STOP II. The value for this variable was calculated, based on information from multiple STOP II form sources, and includes the prefix "<created variable>" in the variable label.

  The three patient groups are:

  - **SCRN** - **Screening Patients** were patients on the STOP II clinical center rosters who were not participating in a chronic transfusion program and met the following eligibility criteria: hemoglobin diagnosis of HbSS or HbS/β^0 thalassemia, age 2 through 16 years, and no history of prior stroke. These patients were screened with Transcranial Doppler (TCD) exams for high stroke risk. Screening patients determined to be at high risk (i.e. a single abnormal TCD exam with a qualifying value $\geq$ 220 cm/sec or two separate abnormal TCD exams each with a qualifying value $\geq$ 200 cm/sec) were offered chronic transfusion for primary stroke prevention and participation as a STOP II Potential patient.

  - **POT - Potential Patients** were patients on chronic transfusion for primary stroke prevention that met the following eligibility criteria: hemoglobin diagnosis of HbSS or HbS/β^0 thalassemia, age 2 through 20 years, and 2 TCDs $\geq$ 200 cm/sec (or 1 TCD $\geq$ 220 cm/sec) prior to starting transfusions. These were patients identified in the screening phase of STOP II or previously identified in the STOP study or those who started transfusion based on local TCD results and submitted the qualifying TCDs to the STOP II TCD Reading Center for transfusion eligibility confirmation. Patients on transfusion for < 30 months were not yet eligible for the full pre-randomization evaluation and were considered Potential 1 patients. Patients on transfusion for $\geq$ 30 months met the TCD requirements for starting transfusion and were considered Potential 2 patients. Pre-randomization evaluation included TCD to confirm reversion to normal TCD while on transfusion and MRA to verify that the patient was free of moderate to severe intracranial arterial disease. Potential 2 patients who met eligibility requirements were offered randomization and participation in the randomized trial phase of STOP II.

  - **RAND - Randomized Patients** were Potential 2 patients that met all randomization eligibility requirements and consented to randomization to either the Continue Transfusion arm or the Discontinue Transfusion arm. Review of source documents related to and confirmation of the following eligibility requirements by Drs. Adams and Brambilla were required prior to randomization. Also see contents of "rand_table" and "f010" datasets.

Operational definitions prior to 6/1/2002	Operational definitions on or after 6/1/2002
Qualifying TCDs prior to start of transfusion	
1. The patient had two TCD examinations with flow velocities≥ 200 cm/sec or one exam with flow velocities≥ 220 cm/sec prior to starting transfusions for primary stroke prevention & the results were based on STOP/STOP II TRC readings.	1. same
Qualifying hemoglobin diagnosis	
2. The diagnosis of HbSS or HbSβ^0 thalassemia was documented by the STOP Core Lab or local laboratory	2. same
Qualifying age criteria	
3. The patient's age is in the range of 4.5 through 20 years of age	3. same
Qualifying TCDs on transfusion	
4. The patient had two normal TCD examinations while on transfusion, at least two weeks apart with the most recent one being on ___ ___/___ ___/___ ____ which is within six months of today's date.	4. The patient had two consecutive normal TCD examinations while on transfusion, at least two weeks apart and no more than 24 weeks apart with the most recent one being on ___ ___/___ ___/___ ____ which is within four months of today's date.
Qualifying transfusion eligibility criteria	
5. The patient meets the following transfusion eligibility criteria for randomization:	5.
a. Patient has had at least 24 transfusions in the previous 30 months (Maximum average interval between transfusions: 5.4 weeks)	a. same
b. Patient's HbS has been < 30% for at least 20 of the 30 months	b. No more than 1/3 of patient's pre-transfusion HbS values have been ≥ 41% during the preceding 30 months
c. There has been no interruption in transfusion longer than 6 consecutive months during the previous 30 months	c. same
-- --	d. The most recent transfusion was received within the last 4 weeks (or will occur on the date of randomization)
Qualifying MRA criteria	
6. The patient has had an MRA within the preceding 4 months which shows no evidence of moderate to severe arterial disease or occlusion in the qualifying arteries	6. same

Confirmation of infarct status needed for randomization stratification

- **LDU_ID** - This variable is the patient's blinded ID for the public use datasets. It is a 10-character variable beginning with the letter 'P'. The original subject ID was structured as a 6-character variable (11-222-3), where digits 1-2 denote the STOP II site, digits 3-5 denote an assigned patient number, and digit 6 denotes a check digit used to validate ID numbers in the data entry process. The blinded ID numbers have all references to site and patient removed. The SAS "link" dataset RANDIDXREF.sas7bdat, provided to NHLBI, has the original and blinded ID numbers and is for NHLBI use only.

- **HB_DIAG** - This is a patient's hemoglobin diagnosis. Only patients with a hemoglobin diagnosis of HbSS or HbS/β^0 thalassemia were eligible to participate in the STOP II study.

- **TXBEGIND_FRMRAND** - For patients receiving transfusion for stroke prevention (TXTOPREV=2), this is the variable for transfusion start date, calculated as days from randomization. Values were updated for 6 patients AFTER the dataset for the final results paper was created, as summarized in the table below.

LDU_ID	Previous TXBEGIND_FRMRAND	Revised TXBEGIND_FRMRAND	Source for revised date
P513261385	-1871	-1864	Changed per F01C data
P659528155	-960	-959	Changed per F22 data
P438374416	-1567	-1596	Changed per F22 data
P946227653	-1076	-1892	Changed per F01C and F22 data
P677528414	-1323	-1325	Changed per F22 data
P091993715	-966	-991	Changed per F22 data

- **FRSTSCRND_FRMRAND** - This is the date of the first screening TCD exam visit for a patient ("F002_Screening" dataset, vistype=RT-101), calculated as days from randomization. This variable is only applicable where WHICHGRP=SCRN, SCRN+POT or SCRN+POT+RAND. This variable is not stored in the original roster dataset and is indicated in the contents by "<created variable>" in the label.

- **FRSTPOTD_FRMRAND** - This is the date of a patient's first visit as a potential patient (see “f002_rand_pot” and f012 datasets, vistype=QT-201 or QT-301), calculated as days from randomization. This variable is only applicable where WHICHGRP=SCRN+POT, SCRN+POT+RAND, POT or POT+RAND. This variable is not stored in the original roster dataset and is indicated in the contents by "<created variable>" in the label.

- **FRSTPOTFORM** - This is the form number that the date of a patient's first visit as potential patient (FRSTPOTD) was taken from. This variable is only applicable where WHICHGRP=SCRN+POT, SCRN+POT+RAND, POT or POT+RAND. This variable is not stored in the original roster dataset and is indicated in the contents by "<created variable>" in the label.

- **RACE** - This is the patient's race. This variable was compiled from other sources (forms 1A, 1B and/or 1C) and is not stored in the original roster dataset. This is indicated in the contents by "<summary variable>" in the label.

- **STOPRAND** - This variable indicates whether a patient was randomized in the first STOP trial. This variable was compiled from other sources and is not stored in the original roster dataset. This is indicated in the contents by "<summary variable>" in the label.

Data Set Name	PUBDS.PRST2_FINAL	Observations	79
Member Type	DATA	Variables	12
Engine	V9	Indexes	0
Created	Wednesday, March 15, 2006 09:25:56 AM	Observation Length	96
Last Modified	Wednesday, March 15, 2006 09:25:56 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	8192
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	84
Obs in First Data Page	55
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\prst2_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
4	ANY_SIBS	Num	8	3.	8. Other siblings on roster
2	GENDER	Num	8	3.	5. Gender
3	HB_DIAG	Num	8	3.	6. Hemoglobin Diagnosis
6	RACE	Num	8	3.	<summary variable> Race (sources: Forms 1A, 1B, or 1C)
9	age_rand	Num	8		<created variable> 4. Date of birth as age at randomization in years
11	frstpotd_frmrand	Num	8		<created variable> First visit (enrollment) as a potential patient as days from randomization
5	frstpotform	Num	8		<created variable> Form source for first potential visit date
12	frstscrnd_frmrand	Num	8		<created variable> First TCD screening visit as days from randomization
8	ldu_id	Char	10		ID for public use datasets
7	stoprand	Char	1		<summary variable> Was the patient a STOP randomized patient?
10	txbegind_frmrand	Num	8		<created variable> 11. Transfusion start date as days from randomization
1	whichgrp	Char	13		<created variable> Patient groups in which patient participated

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	whichgrp	Char	13		<created variable> Patient groups in which patient participated
2	GENDER	Num	8	3.	5. Gender
3	HB_DIAG	Num	8	3.	6. Hemoglobin Diagnosis
4	ANY_SIBS	Num	8	3.	8. Other siblings on roster
5	frstpotform	Num	8		<created variable> Form source for first potential visit date
6	RACE	Num	8	3.	<summary variable> Race (sources: Forms 1A, 1B, or 1C)
7	stoprand	Char	1		<summary variable> Was the patient a STOP randomized patient?
8	ldu_id	Char	10		ID for public use datasets
9	age_rand	Num	8		<created variable> 4. Date of birth as age at randomization in years
10	txbegind_frmrand	Num	8		<created variable> 11. Transfusion start date as days from randomization
11	frstpotd_frmrand	Num	8		<created variable> First visit (enrollment) as a potential patient as days from randomization
12	frstscrnd_frmrand	Num	8		<created variable> First TCD screening visit as days from randomization

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*Rst2fmts.txt;

proc format;

   value GENDERF
    1='1: Female'
    2='2: Male';

  value HB_DIAGF
    1='1: SS'
    2='2: SB0 Thalassemia';

  value ANY_SIBSF
    1='1: No'
    2='2: Yes';

*  formats for variables added to rst2 dataset;

 value RACEF
    1='1: Black/African American/not Latin origin'
    2='2: Black/African American/of Latin origin'
    3='3: White/not of Latin origin'
    4='4: White/of Latin origin'
    5='5: Asian American/Pacific Islander'
    6='6: Native American/Alaskan Native'
    7='7: Other';

* format gender genderf. hb_diag hb_diagf. any_sibs any_sibsf. race racef.;
```

Optimizing Primary Stroke Prevention in Children with Sickle Cell Anemia
Patient Roster for STOP II

<created variable> Patient groups in which patient participated				
whichgrp	Frequency	Percent	Cum Freq	Cum Percent
POT+RAND	62	78.48	62	78.48
SCRN+POT+RAND	17	21.52	79	100.00

1.	Patient ID:	__ __ __ __ __ __

[Data not shown for LDU_ID.]

2.	Acrostic:	__ __ __ __ __

[Variable NOT included in dataset.]

3.	Line number on Roster Sheet:	__ __

[Variable NOT included in dataset.]

4.	Date of birth:	__ __ / __ __ / __ __ __ __

Analysis Variable : age_rand <created variable> 4. Date of birth as age at randomization in years								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
79	0	12.2	3.2	6.1	9.8	11.7	14.3	20.4

5.	Gender:	1. FEMALE 2. MALE

5. Gender				
GENDER	Frequency	Percent	Cum Freq	Cum Percent
1	46	58.23	46	58.23
2	33	41.77	79	100.00

6.	Hemoglobin Diagnosis:	1. SS 2. HbS β^0 Thalassemia

6. Hemoglobin Diagnosis				
HB_DIAG	Frequency	Percent	Cum Freq	Cum Percent
1	78	98.73	78	98.73
2	1	1.27	79	100.00

7.	Has diagnosis been confirmed?	1. NO 2. YES

[Variable NOT included in dataset.]

8.	Are there other siblings on the roster?	1. NO 2. YES

8. Other siblings on roster				
ANY_SIBS	Frequency	Percent	Cum Freq	Cum Percent
1	63	79.75	63	79.75
2	16	20.25	79	100.00

	a. Sibling ID #1:	__ __ __ __ __ __
	b. Sibling ID #2:	__ __ __ __ __ __
	c. Sibling ID #3:	__ __ __ __ __ __
	d. Sibling ID #4:	__ __ __ __ __ __

[Variables NOT included in dataset.]

9.	Is patient expected to be screened in STOP II?	1. NO, NOT ELIGIBLE 2. NO 3. YES

[Variable NOT included in dataset.]

10.	Is the patient on transfusion for primary stroke prevention?	1. NO 2. YES

[Variable NOT included in dataset.]

11.	Begin Date of transfusions:	__ __ / __ __ / __ __ __ __

Analysis Variable : txbegind_frmrand <created variable> 11. Transfusion start date as days from randomization								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
79	0	-1534	478.8	-2777	-1988	-1426	-1021	-938.0

12.	End Date of transfusions:	__ __ / __ __ / __ __ __ __

[Variable NOT included in dataset.]

13.	Old STOP ID number of patient:	__ __ __ __ __ __

[Variable NOT included in dataset.]

14.	Did patient enroll as a Potential patient?	1. NO 2. YES

[Variable NOT included in dataset.]

15.	Did patient discontinue f/u as a Potential patient?		1. NO 2. YES
		a. Date discontinued:	__ __ / __ __ / __ __ __ __
		b. Reason discontinued:	_____

[Variables NOT included in dataset.]

16.	Comments: _____

[Variable NOT included in dataset.]

Analysis Variable : frstscrnd_frmrand <created variable> First TCD screening visit as days from randomization								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
17	0	-1119	98.8	-1310	-1157	-1120	-1048	-992.0

<created variable> First TCD screening visit as days from randomization				
frstscrnd_frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	62	100.00	62	100.00

Analysis Variable : frstpotd_frmrand <created variable> First visit (enrollment) as a potential patient as days from randomization								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
79	0	-515.9	360.2	-1343	-938.0	-350.0	-202.0	-64.0

<created variable> Form source for first potential visit date				
frstpotform	Frequency	Percent	Cum Freq	Cum Percent
2	49	62.03	49	62.03
12	30	37.97	79	100.00

RACE

☐ 1. Black/African American/not Latin origin ☐ 2. Black/African American/of Latin Origin

☐ 3. White/not of Latin origin ☐ 4. White/of Latin origin

☐ 5. Asian American/Pacific Islander ☐ 6. Native American/Alaskan Native

☐ 7. Other → SPECIFY: _____

<summary variable> Race (sources: Forms 1A, 1B, or 1C)				
RACE	Frequency	Percent	Cum Freq	Cum Percent
1	73	92.41	73	92.41
4	1	1.27	74	93.67
7	5	6.33	79	100.00

<summary variable> Was the patient a STOP randomized patient?				
stoprand	Frequency	Percent	Cum Freq	Cum Percent
N	38	48.10	38	48.10
Y	41	51.90	79	100.00

STOP II
RANDOMIZATION RECORD

A. Collection Information:
The **Randomization Record** dataset contains the following information from NERI's proprietary VERANDI randomization system for each STOP II randomized patient: randomization date, time, and confirmation number; DCC staff member who randomized the patient, and randomization stratification information (infarct status). This dataset also stores treatment outcome summary information, including endpoint, crossover, and dropout status.

B. Data Collection Period: April 2001 to March 2005

C. Form Version Dates: n/a

D. Files Used to Store Information:

SAS System File: **rand_table_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 79 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 16
- Listing of Variables by Position: See p. 17

H. Formats:
The file **Rand_tablefmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 18.

I. Special Value Codes: none

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:
- **INFARCT** - is the variable name for infarct status based the pre-randomization MRI as determined by the STOP II MR Reading Panel.

- **EP** - is the variable name for whether or not a subject met the criteria for any one of the three components of the composite endpoint:
  1. Stroke (cerebral infarction or intracranial hemorrhage),
  2. Reversion to abnormal TCD, or
  3. Three consecutive inadequate TCDs accompanied by evidence of new moderate to severe stenosis on MRA.

- **EPWHY** - is the variable name for type of endpoint. Endpoints are categorized into one of four categories.

  1. Reversion to abnormal TCD defined as 2 consecutive abnormal TCD exams (TAMM velocity $\geq$ 200 cm/sec on both),

  2. Reversion to abnormal TCD defined as a moving average of the TAMM velocities of the three most recent readable exams that reaches or exceeds 200 cm/sec following the first abnormal TCD.

  3. Stroke
     a. Cerebral infarction defined as focal neurological symptoms consistent with stroke supported by the presence of new MR findings consistent with cerebral infraction and anatomically appropriate to the patient's symptoms and/or clear and compelling evidence of new neurological deficit consistent with stroke on clinical examination based on the Neurological Consultant Report, OR
     b. Intracranial hemorrhage defined as an event associated with either focal or non-focal neurological symptoms that arise in the presence of acute subarachnoid, intraparenchymal, or intraventricular bleeding and are not associated with head injury.

  The determination of whether or not a patient had a stroke was made by the STOP II Endpoint Adjudication Panel based on their review of the neurological event & neurological consultant report forms completed for the event and review of MRI results on STOP II forms filled out by STOP II MR Reading Panel members and other relevant source documents.

  4. Three consecutive inadequate TCDs, involving at least two different examiners, with evidence of new moderate to severe stenosis on MRA.

  Also see documentation sections for Forms 2 (results of post-randomization TCD exams), 14, 15, 19, and 52.

- **EPD_FRMRAND** - is the variable name for endpoint date, calculated as days from randomization. Endpoint dates were defined as follows:

  1. For patients with two consecutive abnormal TCDs, EPD_FRMRAND=date of first abnormal TCD.

  2. For patients with an endpoint based on a moving TAMM velocity average of $\geq$ 200 cm/sec, EPD_FRMRAND=midpoint between the first and third examinations in the series of three with an average velocity of $\geq$ 200 cm/sec.

3. For patients who had a stroke as determined by the STOP II Endpoint Adjudication Panel, EPD_FRMRAND=date of stroke.
4. For patients with an endpoint based on inadequate TCDs + new moderate to severe stenosis on MRA, EPD_FRMRAND=time point at which the first of the three consecutive inadequate TCDs occurred.

- **EPDECLARED_FRMRAND** - is the variable name for the date an endpoint was declared, calculated as days from randomization.
  1. For patients with two consecutive abnormal TCDs, EPDECLARED_FRMRAND=date of the second of the two consecutive abnormal TCDs.
  2. For patients with an endpoint based on a moving TAMM velocity average of $\geq$ 200 cm/sec, EPDECLARED_FRMRAND=midpoint between the first and third examinations in the series of three with an average velocity of $\geq$ 200 cm/sec.
  3. For patients who had a stroke as determined by the STOP II Endpoint Adjudication Panel, EPDECLARED_FRMRAND=date of stroke.
  4. For patients with an endpoint based on inadequate TCDs + new moderate to severe stenosis on MRA, EPDECLARED_FRMRAND=time point at which the first of the three consecutive inadequate TCDs occurred.

- **XOVER** - is the variable name for whether a subject left the assigned treatment arm for any reason other than an endpoint by choosing to either stop chronic transfusion or resume chronic transfusion. Once a subject was determined to be a crossover patient, he/she retained crossover status for study purposes regardless of further clinical treatment decisions.

- **POSTXO_EP** - is the variable name for reversion to abnormal TCD after crossover.

- **DROPOUT** - is the variable name for subjects who dropped out of the study and/or were lost to follow up.

- **Q6M_MRAS** - is the variable name for bi-annual MRA monitoring. Subjects considered unTCDable, as defined by three consecutive TCD exams deemed "inadequate" and no evidence of moderate to severe arterial disease on MRA, were monitored every 6 months with MRA.

- **GOTOMRA_DFRMRAND** - is the variable name for date MRA monitoring began, calculated as days from randomization.

Data Set Name	PUBDS.PRAND_TABLE_FINAL	Observations	79
Member Type	DATA	Variables	19
Engine	V9	Indexes	0
Created	Friday, March 10, 2006 02:11:59 PM	Observation Length	376
Last Modified	Friday, March 10, 2006 02:11:59 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	3
First Data Page	1
Max Obs per Page	43
Obs in First Data Page	33
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\prand_table_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
8	DROPOUT	Num	8	3.	Did patient drop out of the study?
4	EP	Num	8	3.	Did patient have an endpoint?
6	EPCOMMENT	Char	130		<recoded variable> Endpoint comments
5	EPWHY	Num	8	2.	Type of endpoint
1	INFARCT	Num	8	3.	Infarct status
10	POSTXO_EP	Num	8	3.	Reversion to abnormal TCD post-crossover?
9	Q6M_MRAS	Num	8	3.	Was patient monitored with MRA rather than TCD?
3	RAND_BY	Char	12	$12.	DCC staff who randomized the patient
2	TREATMENT	Num	8	3.	Treatment arm
7	XOVER	Num	8	3.	Did patient cross over?
18	drop_reasrecode	Char	50		<recoded variable> Reason for dropout
15	dropout_dfrmand	Num	8		<created variable> Dropout date as days from RAND visit
12	epd_frmrand	Num	8		<created variable> Endpoint date as days from RAND visit
13	epdeclared_frmrand	Num	8		<created variable> Date endpoint declared as days from RAND visit
17	gotomra_dfrmrand	Num	8		<created variable> Date MRA monitoring replaced TCD monitoring as days from RAND visit
11	ldu_id	Char	10		ID for public use datasets
16	postxo_epdfrmrand	Num	8		<created variable> Date of reversion to abn TCD post-crossover as days from RAND visit
14	xover_dfrmrand	Num	8		<created variable> Crossover date as days from RAND visit
19	xover_reasrecode	Char	60		<recoded variable> Reason for crossover

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	INFARCT	Num	8	3.	Infarct status
2	TREATMENT	Num	8	3.	Treatment arm
3	RAND_BY	Char	12	$12.	DCC staff who randomized the patient
4	EP	Num	8	3.	Did patient have an endpoint?
5	EPWHY	Num	8	2.	Type of endpoint
6	EPCOMMENT	Char	130		<recoded variable> Endpoint comments
7	XOVER	Num	8	3.	Did patient cross over?
8	DROPOUT	Num	8	3.	Did patient drop out of the study?
9	Q6M_MRAS	Num	8	3.	Was patient monitored with MRA rather than TCD?
10	POSTXO_EP	Num	8	3.	Reversion to abnormal TCD post-crossover?
11	ldu_id	Char	10		ID for public use datasets
12	epd_frmrand	Num	8		<created variable> Endpoint date as days from RAND visit
13	epdeclared_frmrand	Num	8		<created variable> Date endpoint declared as days from RAND visit
14	xover_dfrmrand	Num	8		<created variable> Crossover date as days from RAND visit
15	dropout_dfrmand	Num	8		<created variable> Dropout date as days from RAND visit
16	postxo_epdfrmrand	Num	8		<created variable> Date of reversion to abn TCD post-crossover as days from RAND visit
17	gotomra_dfrmrand	Num	8		<created variable> Date MRA monitoring replaced TCD monitoring as days from RAND visit
18	drop_reasrecode	Char	50		<recoded variable> Reason for dropout
19	xover_reasrecode	Char	60		<recoded variable> Reason for crossover

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*Rand_tablefmts.txt;

proc format;

value INFARCTF
 1='1: No Infarct'
 2='2: Infarct';

value TREATMENTF
 1='1: Continue Transfusions'
 2='2: Discontinue Transfusions';

value DROPOUTF
 1='1: No'
 2='2: Yes';

value EPF
1='1: No'
2='2: Yes';

value EPWHYF
 1='1: 2 consecutive abnormal TCDs'
 2='2: Moving average >=200 cm/sec'
 3='3: Stroke'
 4='4: Three consecutive inadequate TCDs + mod.-severe stenosis on MRA';

value XOVERF
 1='1: No'
 2='2: Yes';

value POSTXO_EPF
 1='1: No'
 2='2: Yes';

value Q6M_MRASF
 1='1: No'
 2='2; Yes';

* format infarct infarctf. treatment treatmentf. dropout dropoutf. ep epf. epwhy epwhyf.
  xover xoverf. postxo_ep postxo_epf. q6m_mras q6m_mrasf.;
```

Infarct status				
INFARCT	Frequency	Percent	Cum Freq	Cum Percent
1: No Infarct	58	73.42	58	73.42
2: Infarct	21	26.58	79	100.00

Treatment arm				
TREATMENT	Frequency	Percent	Cum Freq	Cum Percent
1: Continue Transfusions	38	48.10	38	48.10
2: Discontinue Transfusions	41	51.90	79	100.00

DCC staff who randomized the patient				
RAND_BY	Frequency	Percent	Cum Freq	Cum Percent
dgallagher	31	39.24	31	39.24
lenos	12	15.19	43	54.43
robertl	2	2.53	45	56.96
sdellagr	26	32.91	71	89.87
tmansolf	8	10.13	79	100.00

Did patient have an endpoint?				
EP	Frequency	Percent	Cum Freq	Cum Percent
1: No	63	79.75	63	79.75
2: Yes	16	20.25	79	100.00

Analysis Variable : epd_frmrand <created variable> Endpoint date as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
16	0	136.6	79.5	64.0	82.0	97.5	176.0	307.0

<created variable> Endpoint date as days from RAND visit				
epd_frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	63	100.00	63	100.00

Analysis Variable : epdeclared_frmrand <created variable> Date endpoint declared as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
16	0	155.4	79.4	83.0	102.5	119.0	193.0	335.0

<created variable> Date endpoint declared as days from RAND visit				
epdeclared_frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	63	100.00	63	100.00

Type of endpoint				
EPWHY	Frequency	Percent	Cum Freq	Cum Percent
.	63	79.75	63	79.75
1: 2 consecutive abnormal TCDs	10	12.66	73	92.41
2: Moving average >=200 cm/sec	4	5.06	77	97.47
3: Stroke	2	2.53	79	100.00

<recoded variable> Endpoint comments				
EPCOMMENT	Frequency	Percent	Cum Freq	Cum Percent
	73	92.41	73	92.41
1st abn TCD 136 days after randomization, stroke 144 days after, conf abn TCD 147 days after	1	1.27	74	93.67
1st abn TCD 281 days after ranodmization, stroke & conf abn TCD 295 days after randomization	1	1.27	75	94.94
Moving average determined by TCD results 198, 254, 270 days after randomization, 1st abn 144 days after	1	1.27	76	96.20
Moving average determined by TCD results 67, 72, 92 days after randomization	1	1.27	77	97.47
Moving average determined by TCD results 71, 92, 113 days after randomization	1	1.27	78	98.73
Moving average determined by TCD results 88, 104, 118 days after randomization	1	1.27	79	100.00

Did patient cross over?				
XOVER	Frequency	Percent	Cum Freq	Cum Percent
1: No	65	82.28	65	82.28
2: Yes	14	17.72	79	100.00

Analysis Variable : xover_dfrmrand <created variable> Crossover date as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
14	0	466.9	304.1	90.0	183.0	466.0	599.0	980.0

<created variable> Crossover date as days from RAND visit				
xover_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	65	100.00	65	100.00

Did patient drop out of the study?				
DROPOUT	Frequency	Percent	Cum Freq	Cum Percent
1: No	71	89.87	71	89.87
2: Yes	8	10.13	79	100.00

<recoded variable> Reason for dropout				
drop_reasrecode	Frequency	Percent	Cum Freq	Cum Percent
	71	89.87	71	89.87
Death	1	1.27	72	91.14
Family decision/refusal to continue	2	2.53	74	93.67
Relocated	5	6.33	79	100.00

Was patient monitored with MRA rather than TCD?				
Q6M_MRAS	Frequency	Percent	Cum Freq	Cum Percent
1: No	78	98.73	78	98.73
2: Yes	1	1.27	79	100.00

Analysis Variable : gotomra_dfrmrand <created variable> Date MRA monitoring replaced TCD monitoring as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	120.0	.	120.0	120.0	120.0	120.0	120.0

<created variable> Date MRA monitoring replaced TCD monitoring as days from RAND visit				
gotomra_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	78	100.00	78	100.00

Reversion to abnormal TCD post-crossover?				
POSTXO_EP	Frequency	Percent	Cum Freq	Cum Percent
1: No	76	96.20	76	96.20
2: Yes	3	3.80	79	100.00

Analysis Variable : postxo_epdfrmrand <created variable> Date of reversion to abn TCD post-crossover as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	466.0	158.1	288.0	288.0	520.0	590.0	590.0

<created variable> Date of reversion to abn TCD post-crossover as days from RAND visit				
postxo_epdfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	76	100.00	76	100.00

STOP II

FORM 1A: ELIGIBILITY QUESTIONNAIRE FOR TCD SCREENING EXAM

(TO DETERMINE ELIGIBILITY FOR TRANSFUSION)

A. Collection Information:
The **Eligibility Questionnaire for TCD Screening Exam** (Form 1A) was to be completed at each TCD screening visit during the STOP II screening period.

B. Data Collection Period: December 2000 through June 2002

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p01a_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 42 (17)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 26
- Listing of Variables by Position: See p. 27

H. Formats:
The file **f01Afmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 28.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPEs for Form 1A are:
  - RT for routine visits - Initial TCD screening exam, and all subsequent TCD exams for patients with no previous abnormal TCD results.
  - CS for confirmatory visits - all subsequent TCD screening exams for patients with a previous exam with abnormal results that were between 200-219 cm/sec.

- **EX_NUM** – is the variable name for exam number. Valid EX_NUMs for Form 1A are:
  - 100 series numbers were assigned to “Screening” patient visits – i.e., TCD screening visits completed before the patient started transfusions and enrolled as a potential trial patient.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **DOB_COR**, **GEN_COR** - A value of -1 for these variables indicates that the form did not have a pre-printed label affixed to it.

Data Set Name	PUBDS.P01A_FINAL	Observations	42
Member Type	DATA	Variables	20
Engine	V9	Indexes	0
Created	Friday, January 27, 2006 02:54:19 PM	Observation Length	408
Last Modified	Friday, January 27, 2006 02:54:19 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	40
Obs in First Data Page	30
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p01a_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
10	AGE2_16	Num	8	3.	C2. Is the patient's age in the range of 2 through 20 years?
12	BONE_MAR	Num	8	3.	C4. Has the patient received a bone marrow transplant?
14	CONSNT_S	Num	8	3.	D2. Has legal guardian read and signed informed consent?
6	COR_GEND	Num	8	3.	B3a. Correct gender of patient
17	DESTATUS	Char	1	$1.	DESTATUS
4	DOB_COR	Num	8	3.	B2. Is the birthdate info on label provided by DCC correct
13	ELIG_TCD	Num	8	3.	D1. Is the patient eligible for TCD screening?
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
16	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
5	GEND_COR	Num	8	3.	B3. Is the gender info on patient label provided by DCC correct
9	HBS_DIAG	Num	8	3.	C1. Diagnosis of HbSS or HbS/b0 Thalassemia?
3	PREVF1A	Num	8	3.	B1. Has form 01A been completed previously for this patient
7	RACE	Num	8	3.	B4. Race of patient
15	SP_CONST	Char	200	$200.	D2a. Reason no consent obtained.
8	SP_RACE	Char	75	$75.	B4a. Specify other race of patient
11	STROKE_H	Num	8	3.	C3. Does the patient have a prior history of stroke?
20	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
19	ldu_id	Char	10		ID for public use datasets
18	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	PREVF1A	Num	8	3.	B1. Has form 01A been completed previously for this patient
4	DOB_COR	Num	8	3.	B2. Is the birthdate info on label provided by DCC correct
5	GEND_COR	Num	8	3.	B3. Is the gender info on patient label provided by DCC correct
6	COR_GEND	Num	8	3.	B3a. Correct gender of patient
7	RACE	Num	8	3.	B4. Race of patient
8	SP_RACE	Char	75	$75.	B4a. Specify other race of patient
9	HBS_DIAG	Num	8	3.	C1. Diagnosis of HbSS or HbS/b0 Thalassemia?
10	AGE2_16	Num	8	3.	C2. Is the patient's age in the range of 2 through 20 years?
11	STROKE_H	Num	8	3.	C3. Does the patient have a prior history of stroke?
12	BONE_MAR	Num	8	3.	C4. Has the patient received a bone marrow transplant?
13	ELIG_TCD	Num	8	3.	D1. Is the patient eligible for TCD screening?
14	CONSNT_S	Num	8	3.	D2. Has legal guardian read and signed informed consent?
15	SP_CONST	Char	200	$200.	D2a. Reason no consent obtained.
16	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
17	DESTATUS	Char	1	$1.	DESTATUS
18	vistype	Char	7		<created variable> VISIT TYPE
19	ldu_id	Char	10		ID for public use datasets
20	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*F01Afmts.txt;

proc format;

  value RACEF
    1='1: Black/African American/not Latin origin'
    2='2: Black/African American/of Latin origin'
    3='3: White/not of Latin origin'
    4='4: White/of Latin origin'
    5='5: Asian American/Pacific Islander'
    6='6: Native American/Alaskan Native'
    7='7: Other';

  value HBS_DIAGF
    1='1: No'
    2='2: Yes';

  value BONE_MARF
    1='1: No'
    2='2: Yes';

  value PREVF1AF
    1='1: No'
    2='2: Yes';

  value DOB_CORF
    1='1: No'
    2='2: Yes';

  value GEND_CORF
    1='1: No'
    2='2: Yes';

  value COR_GENDF
    1='1: Female'
    2='2: Male';

  value STROKE_HF
    1='1: No'
    2='2: Yes';

  value ELIG_TCDF
    1='1: No'
    2='2: Yes';

  value CONSNT_SF
    1='1: No'
    2='2: Yes';

  value AGE2_16F
    1='1: No'
    2='2: Yes';

* format race racef. hbs_diag hbs_diagf. bone_mar bone_marf. prevf1a prevf1af. dob_cor dob_corf.
gend_cor gend_corf. cor_gend cor_gendf. stroke_h stroke_hf. elig_tcd elig_tcdf. consnt_s consnt_sf.
age2_16 age2_16f.;
```

STOP II

ELIGIBILITY QUESTIONNAIRE FOR TCD SCREENING EXAM

(TO DETERMINE ELIGIBILITY FOR TRANSFUSION)

AFFIX PATIENT LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	42	100.00	42	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
CS-102	9	21.43	9	21.43
CS-103	6	14.29	15	35.71
CS-104	2	4.76	17	40.48
CS-105	1	2.38	18	42.86
RT-101	17	40.48	35	83.33
RT-102	4	9.52	39	92.86
RT-103	2	4.76	41	97.62
RT-104	1	2.38	42	100.00

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
42	0	-1069	88.7	-1310	-1121	-1054	-1016	-915.0

B. PATIENT ID INFORMATION

B1. Has a STOP II Form 01A been completed previously for this patient? ☐ 1. NO ☐ 2. YES

↓

GO TO SECTION C

B1. Has form 01A been completed previously for this patient				
PREVF1A	Frequency	Percent	Cum Freq	Cum Percent
1	17	40.48	17	40.48
2	25	59.52	42	100.00

B2. Is the birthdate information on the pre-printed patient label provided by the DCC correct? ☐ 1. NO ☐ 2. YES

↓

B2.a If NO, list correct birthdate
___ ___/___ ___/___ ___ ___ ___

B2. Is the birthdate info on label provided by DCC correct				
DOB_COR	Frequency	Percent	Cum Freq	Cum Percent
-2	25	59.52	25	59.52
-1	3	7.14	28	66.67
2	14	33.33	42	100.00

[Variable for correct birthdate NOT included in dataset.]

B3. Is the gender information on the pre-printed patient label provided by the DCC correct? ☐ 1. NO ☐ 2. YES

↓

B3.a If NO, check correct gender:

☐ 1. FEMALE

☐ 2. MALE

B3. Is the gender info on patient label provided by DCC correct				
GEND_COR	Frequency	Percent	Cum Freq	Cum Percent
-2	25	59.52	25	59.52
-1	3	7.14	28	66.67
2	14	33.33	42	100.00

[No data for variable COR_GEND.]

B4. Race

(READ BOLDED SENTENCES TO PARENT/GUARDIAN OR CHILD IF AGE APPROPRIATE AND SHOW CARD WITH CHOICES)

NIH monitors enrollment of minorities to ensure their adequate representation in all research studies funded by NIH. Please identify the race of the child among the following choices [SHOW CARD]:

☐ **1. Black/African American/not Latin origin** ☐ **2. Black/African American/of Latin Origin**

☐ **3. White/not of Latin origin** ☐ **4. White/of Latin origin**

☐ **5. Asian American/Pacific Islander** ☐ **6. Native American/Alaskan Native**

☐ **7. Other** → B4.a SPECIFY: _____

B4. Race of patient				
RACE	Frequency	Percent	Cum Freq	Cum Percent
-2	25	59.52	25	59.52
1	14	33.33	39	92.86
4	1	2.38	40	95.24
7	2	4.76	42	100.00

B4a. Specify other race of patient				
SP_RACE	Frequency	Percent	Cum Freq	Cum Percent
-2	40	95.24	40	95.24
LATINO	2	4.76	42	100.00

C. INCLUSION/EXCLUSION CRITERIA

C1. Does the patient have a diagnosis of HbSS or HbS/β^0 thalassemia? ☐ **1. NO** ☐ **2. YES**

C1. Diagnosis of HbSS or HbS/b0 Thalassemia?				
HBS_DIAG	Frequency	Percent	Cum Freq	Cum Percent
2	42	100.00	42	100.00

C2. Is the patient's age in the range of 2 through 16 years? ☐ 1. NO ☐ 2. YES

C2. Is the patient's age in the range of 2 through 20 years?				
AGE2_16	Frequency	Percent	Cum Freq	Cum Percent
2	42	100.00	42	100.00

IF THE ANSWER TO EITHER C1 OR C2 IS NO, THE PATIENT IS NOT ELIGIBLE FOR STUDY.
GO TO SECTION D

C3. Does the patient have a prior history of stroke? ☐ 1. NO ☐ 2. YES

C3. Does the patient have a prior history of stroke?				
STROKE_H	Frequency	Percent	Cum Freq	Cum Percent
1	42	100.00	42	100.00

C4. Has the patient received a bone marrow transplant? ☐ 1. NO ☐ 2. YES

C4. Has the patient received a bone marrow transplant?				
BONE_MAR	Frequency	Percent	Cum Freq	Cum Percent
1	42	100.00	42	100.00

IF THE ANSWER TO EITHER C3 OR C4 IS YES, THE PATIENT IS NOT ELIGIBLE FOR STUDY.
GO TO SECTION D

D. ELIGIBILITY DISPOSITION FOR TCD SCREENING

D1. Is the patient eligible for TCD screening?

☐ 1. NO → **STOP – FORM COMPLETE**

☐ 2. YES → **CONTINUE TO QUESTION D2**

D1. Is the patient eligible for TCD screening?				
ELIG_TCD	Frequency	Percent	Cum Freq	Cum Percent
2	42	100.00	42	100.00

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for TCD screening?

☐ **1. NO** → D2.a Please specify reason:

_____

STOP – FORM COMPLETE

☐ **2. YES** → **PROCEED WITH TCD EXAMINATION AND COMPLETE TCD EXAM FORM**

D2. Has legal guardian read and signed informed consent?				
CONSNT_S	Frequency	Percent	Cum Freq	Cum Percent
2	42	100.00	42	100.00

D2a. Reason no consent obtained.				
SP_CONST	Frequency	Percent	Cum Freq	Cum Percent
-2	42	100.00	42	100.00

Signature of Study Coordinator:_____ Date: ___ ___/___ ___/___ ___ ___ ___

STOP II

FORM 01B: ELIGIBILITY QUESTIONNAIRE FOR PATIENTS ON TRANSFUSION FOR PRIMARY STROKE PREVENTION FOR < 30 MONTHS

A. Collection Information:

The **Eligibility Questionnaire for Patients on Transfusion for Primary Stroke Prevention for < 30 Months** (Form 01B) was to be completed at the entry quarterly visit (QT-201) for patients on transfusion for less than 30 months to determine eligibility of participation as a Potential 1 patient.

B. Data Collection Period: December 2000 through September 2002

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p01b_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 33 (33)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 36-37
- Listing of Variables by Position: See p. 37

H. Formats:

The file **f01Bfmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 38-39.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip Code
-3 = Not Done
-8 = Unknown
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPE for Form 01B is QT for quarterly visit.

- **EX_NUM** – is the variable name for exam number.
  - EX_NUM=201 is the entry quarterly visit for Potential 1 patients (patients on transfusion for less than 30 months)

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

Data Set Name	PUBDS.P01B_FINAL	Observations	33
Member Type	DATA	Variables	24
Engine	V9	Indexes	0
Created	Friday, January 27, 2006 02:59:28 PM	Observation Length	440
Last Modified	Friday, January 27, 2006 02:59:28 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	37
Obs in First Data Page	27
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p01b_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
13	ABN_TCDS	Num	8	3.	C4b. Did patient have 2 abnormal TCDs or 1 abn of velocity 220
11	AGE2_20	Num	8	3.	C3. Is patient's age in the range of 2 through 20 years
15	BONE_MAR	Num	8	3.	C6. Has patient received bone marrow transplant
17	CONSENT	Num	8	3.	D2. Has guardian read and signed informed consent document
18	CONSNT_R	Char	200	$200.	D2a. Reason for no consent
6	COR_GEND	Num	8	3.	B3a. Check correct gender
20	DESTATUS	Char	1	$1.	DESTATUS
4	DOB_COR	Num	8	3.	B2. Is birthdate info on label correct
16	ELIG_P1	Num	8	3.	D1. Is patient eligible for follow-up as a potential candidate
2	EX_NUM	Char	4	$4.	X4. Exam number
1	EX_TYPE	Char	2	$2.	X3. Exam type
19	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
5	GEND_COR	Num	8	3.	B3. Is gender info on label correct
10	HBS_DIAG	Num	8	3.	C2. Does patient have diagnosis of HbSS or HbS/b0 Thalassemia
14	H_STROKE	Num	8	3.	C5. Does patient have prior history of stroke
3	PREVF1B	Num	8	3.	B1. Form 01A or F01B previously completed for patient
9	PRE_RAND	Num	8	3.	C1. Is patient a previously STOP randomized patient
7	RACE	Num	8	3.	B4. Race of patient
8	SP_RACE	Char	75	$75.	B4a. Specify other race
12	TX_RECPT	Num	8	3.	C4. Currently receiving transfusions for primary stroke prevention

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
23	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
22	ldu_id	Char	10		ID for public use datasets
24	tx_startfrmrand	Num	8		<created variable> C4a. Date transfusion started as days from RAND visit
21	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam number
3	PREVF1B	Num	8	3.	B1. Form 01A or F01B previously completed for patient
4	DOB_COR	Num	8	3.	B2. Is birthdate info on label correct
5	GEND_COR	Num	8	3.	B3. Is gender info on label correct
6	COR_GEND	Num	8	3.	B3a. Check correct gender
7	RACE	Num	8	3.	B4. Race of patient
8	SP_RACE	Char	75	$75.	B4a. Specify other race
9	PRE_RAND	Num	8	3.	C1. Is patient a previously STOP randomized patient
10	HBS_DIAG	Num	8	3.	C2. Does patient have diagnosis of HbSS or HbS/b0 Thalassemia
11	AGE2_20	Num	8	3.	C3. Is patient's age in the range of 2 through 20 years
12	TX_RECPT	Num	8	3.	C4. Currently receiving transfusions for primary stroke prevention
13	ABN_TCDS	Num	8	3.	C4b. Did patient have 2 abnormal TCDs or 1 abn of velocity 220
14	H_STROKE	Num	8	3.	C5. Does patient have prior history of stroke
15	BONE_MAR	Num	8	3.	C6. Has patient received bone marrow transplant
16	ELIG_P1	Num	8	3.	D1. Is patient eligible for follow-up as a potential candidate
17	CONSENT	Num	8	3.	D2. Has guardian read and signed informed consent document
18	CONSNT_R	Char	200	$200.	D2a. Reason for no consent
19	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
20	DESTATUS	Char	1	$1.	DESTATUS
21	vistype	Char	7		<created variable> VISIT TYPE
22	ldu_id	Char	10		ID for public use datasets
23	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
24	tx_startfrmrand	Num	8		<created variable> C4a. Date transfusion started as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F01Bfmts.txt;

proc format;

  value H_STROKEF
    1='1: No'
    2='2: Yes';

  value BONE_MARF
    1='1: No'
    2='2: Yes';

  value ELIG_P1F
    1='1: No'
    2='2: Yes';

  value RACEF
    1='1: Black/African American/not Latin origin'
    2='2: Black/African American/of Latin origin'
    3='3: White/not of Latin origin'
    4='4: White/of Latin origin'
    5='5: Asian American/Pacific Islander'
    6='6: Native American/Alaskan Native'
    7='7: Other';

  value HBS_DIAGF
    1='1: No'
    2='2: Yes';

  value ABN_TCDSF
    1='1: No'
    2='2: Yes';

  value CONSENTF
    1='1: No'
    2='2: Yes';

  value GEND_CORF
    1='1: No'
    2='2: Yes';

  value PREVF1BF
    1='1: No'
    2='2: Yes';

  value DOB_CORF
    1='1: No'
    2='2: Yes';

  value COR_GENDF
    1='1: Female'
    2='2: Male';
```

```
value PRE_RANDF
   1='1: No'
   2='2: Yes';

  value AGE2_20F
   1='1: No'
   2='2: Yes';

  value TX_RECPTF
   1='1: No'
   2='2: Yes';

* format h_stroke h_strokef. bone_mar bone_marf. elig_p1 elig_p1f. race racef. hbs_diag hbs_diagf.
abn_tcds abn_tcdsf. consent consentf. gend_cor gend_corf. prevf1b prevf1bf. dob_cor dob_corf.
cor_gend cor_gendf. pre_rand pre_randf. age2_20 age2_20f. tx_recpt tx_recptf.;
```

STOP II

ELIGIBILITY QUESTIONNAIRE FOR PATIENTS ON TRANSFUSION FOR PRIMARY STROKE PREVENTION FOR < 30 MONTHS

AFFIX PATIENT LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	32	96.97	32	96.97
P	1	3.03	33	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-201	33	100.00	33	100.00

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
33	0	-845.3	267.1	-1343	-995.0	-959.0	-824.0	-151.0

B. PATIENT ID INFORMATION

B1. Has a STOP II Form 01A or 01B been completed previously for this patient? ☐ **1. NO** ☐ **2. YES** ↓

B1. Form 01A or F01B previously completed for patient				
PREVF1B	Frequency	Percent	Cum Freq	Cum Percent
1	16	48.48	16	48.48
2	17	51.52	33	100.00

GO TO SECTION C

B2. Is the birthdate information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B2.a If NO, list correct birthdate
___ ___/___ ___/___ ___ ___ ___

B2. Is birthdate info on label correct				
DOB_COR	Frequency	Percent	Cum Freq	Cum Percent
-2	17	51.52	17	51.52
-1	2	6.06	19	57.58
2	14	42.42	33	100.00

[Variable for correct birthdate NOT included in dataset.]

B3. Is the gender information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B3.a If NO, check correct gender:

☐ **1. FEMALE**

☐ **2. MALE**

B3. Is gender info on label correct				
GEND_COR	Frequency	Percent	Cum Freq	Cum Percent
-2	17	51.52	17	51.52
-1	2	6.06	19	57.58
2	14	42.42	33	100.00

[No data for variable COR_GEND.]

B4. Race

(READ BOLDED SENTENCES TO PARENT/GUARDIAN OR CHILD IF AGE APPROPRIATE AND SHOW CARD WITH CHOICES)

NIH monitors enrollment of minorities to ensure their adequate representation in all research studies funded by NIH. Please identify the race of the child among the following choices
[SHOW CARD]:

☐ **1. Black/African American/not Latin origin** ☐ **2. Black/African American/of Latin Origin**

☐ **3. White/not of Latin origin** ☐ **4. White/of Latin origin**

☐ **5. Asian American/Pacific Islander** ☐ **6. Native American/Alaskan Native**

☐ **7. Other** →B4.a. Please specify _____

B4. Race of patient				
RACE	Frequency	Percent	Cum Freq	Cum Percent
-2	17	51.52	17	51.52
1	15	45.45	32	96.97
7	1	3.03	33	100.00

B4a. Specify other race				
SP_RACE	Frequency	Percent	Cum Freq	Cum Percent
-2	32	96.97	32	96.97
LATINO	1	3.03	33	100.00

C. INCLUSION/EXCLUSION CRITERIA

C1. Is the patient a previously STOP randomized patient? ☐ **1. NO** ☐ **2. YES**

↓

GO TO QUESTION C3

C1. Is patient a previously STOP randomized patient				
PRE_RAND	Frequency	Percent	Cum Freq	Cum Percent
1	33	100.00	33	100.00

C2. Does the patient have a diagnosis of HbSS or HbS/β^0 thalassemia? ☐ **1. NO** ☐ **2. YES**

C2. Does patient have diagnosis of HbSS or HbS/b0 Thalassemia				
HBS_DIAG	Frequency	Percent	Cum Freq	Cum Percent
2	33	100.00	33	100.00

C3. Is the patient's age in the range of 2 through 20 years? ☐ **1. NO** ☐ **2. YES**

C3. Is patient's age in the range of 2 through 20 years				
AGE2_20	Frequency	Percent	Cum Freq	Cum Percent
2	33	100.00	33	100.00

C4. Is the patient currently receiving transfusions for primary stroke prevention? ☐ **1. NO** ☐ **2. YES**

C4. Currently receiving transfusions for primary stroke prevention				
TX_RECPT	Frequency	Percent	Cum Freq	Cum Percent
2	33	100.00	33	100.00

C4.a Date transfusions started (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

C4.b. Did the STOP/STOP II TCD Reading Center determine that the patient had 2 abnormal TCDs or 1 abnormal TCD with time averaged maximum mean velocity ≥ 220 cm prior to starting transfusions?

☐ **1. NO** ☐ **2. YES**

Analysis Variable : tx_startfrmrand <created variable> C4a. Date transfusion started as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
33	0	-1124	242.6	-1892	-1258	-1009	-985.0	-938.0

[Note: A Form F01B, rather than a Form F01C – Pre-randomization Eligibility Form (for patients on transfusion for ≥ 30 months), was completed for one patient [P946227653] who had been on transfusion for more than 30 months at the time of enrollment as a Potential patient. The transfusion start date was originally reported on Form F01B as being 845 days (about 28 months) prior the Potential enrollment date (1076 days before the randomization visit). However, after study end, review of the transfusion history documentation indicated that the patient had been on transfusion for 1661 days (about 54 months) prior to enrollment. As a result, the TX_STARTfrmRAND was updated from -1076 to -1892 days in the final dataset.]

C4b. Did patient have 2 abnormal TCDs or 1 abn of velocity 220

ABN_TCDS	Frequency	Percent	Cum Freq	Cum Percent
2	33	100.00	33	100.00

IF THE ANSWER TO ANY OF QUESTIONS C2 – C4.b IS NO, THE PATIENT IS NOT ELIGIBLE FOR FOLLOW-UP AS A POTENTIAL CANDIDATE FOR RANDOMIZATION. GO TO SECTION D

C5. Does the patient have a prior history of stroke? ☐ **1. NO** ☐ **2. YES**

C5. Does patient have prior history of stroke

H_STROKE	Frequency	Percent	Cum Freq	Cum Percent
1	33	100.00	33	100.00

C6. Has the patient received a bone marrow transplant? ☐ **1. NO** ☐ **2. YES**

C6. Has patient received bone marrow transplant

BONE_MAR	Frequency	Percent	Cum Freq	Cum Percent
1	33	100.00	33	100.00

IF THE ANSWER TO EITHER C5 OR C6 IS YES, THE PATIENT IS NOT ELIGIBLE FOR STUDY. GO TO SECTION D

D. DETERMINATION OF ELIGIBILITY

D1. Is the patient eligible for follow-up as a potential candidate for randomization?
(Answers to C2 – C4b = YES, Answers to C5 – C6 = NO)

☐ **1. NO** → **STOP – FORM COMPLETE**

☐ **2. YES** → **CONTINUE TO QUESTION D2**

D1. Is patient eligible for follow-up as a potential candidate				
ELIG_P1	Frequency	Percent	Cum Freq	Cum Percent
2	33	100.00	33	100.00

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for follow-up as a potential candidate for randomization?

☐ **1. NO** → D2.a. Please specify reason:

_____

STOP – FORM COMPLETE

☐ **2. YES** → **COMPLETE ENTRY FORMS**

D2. Has guardian read and signed informed consent document				
CONSENT	Frequency	Percent	Cum Freq	Cum Percent
2	33	100.00	33	100.00

D2a. Reason for no consent				
CONSNT_R	Frequency	Percent	Cum Freq	Cum Percent
-2	33	100.00	33	100.00

Signature of Study Coordinator:_____ Date: ___ ___/___ ___/___ ___ ___ ___

STOP II

FORM 1C: PRE-RANDOMIZATION ELIGIBILITY QUESTIONNAIRE

A. Collection Information:
The **Pre-Randomized Eligibility Questionnaire** (Form 1C) was to be completed at the entry quarterly visit (QT-301) for patients on transfusion for greater than 30 months to determine eligibility of participation as a Potential 2 patient and further pre-randomization requirements.

B. Data Collection Period: December 2000 through October 2004

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p01c_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 79 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 47-48
- Listing of Variables by Position: See p. 48

H. Formats:
The file **f01Cfmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 49-50.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPE for Form 1C is QT for quarterly visit.

- **EX_NUM** – is the variable name for exam number.
  - EX_NUM=301 is the entry quarterly visit for Potential 2 patients (patients on transfusion for greater than 30 months)

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **COMP_DFRMRAND** - is the variable name for form completion date, calculated as days from randomization. The 3 Form 1Cs with comp_dfrmrand > 0 represent forms that were completed after randomization based on information in the medical records at the time the parent/patient consented to participation as a Potential 2 subject.

Data Set Name	PUBDS.P01C_FINAL	Observations	79
Member Type	DATA	Variables	24
Engine	V9	Indexes	0
Created	Monday, February 06, 2006 03:17:21 PM	Observation Length	440
Last Modified	Monday, February 06, 2006 03:17:21 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	3
First Data Page	1
Max Obs per Page	37
Obs in First Data Page	27
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p01c_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
13	ABN_TCDS	Num	8	3.	C3a2. Did patient have abnormal TCD readings prior to transfusions
10	AGE4_20	Num	8	3.	C2. Is the patient's age in the range of 4.5 through 20 years
15	BONE_MAR	Num	8	3.	C5. Has the patient received a bone marrow transplant
17	CONSENT	Num	8	3.	D2. Has patient's guardian read and signed inform consent doc
18	CONSNT_R	Char	200	$200.	D2a. Specify reason for no consent
6	COR_GEND	Num	8	3.	B3a. Check correct gender of patient
20	DESTATUS	Char	1	$1.	DESTATUS
4	DOB_COR	Num	8	3.	B2. Is birthdate information on label provided by DCC correct
16	ELIG_PR	Num	8	3.	D1. Is the patient eligible for pre-randomization evaluation
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
19	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
5	GEND_COR	Num	8	3.	B3. Is the gender information on label provided by DCC correct
9	HBS_DIAG	Num	8	3.	C1. A diagnosis of HbSS or HbS/b0 Thalassemia?
14	H_STROKE	Num	8	3.	C4. Does the patient have a prior history of stroke
3	PREVF1C	Num	8	3.	B1. Has Form 01A, 01B, or 01C been completed previously
7	RACE	Num	8	3.	B4. Race
8	SP_RACE	Char	75	$75.	B4a. Specify other race of patient
12	TX_ADQT	Num	8	3.	C3a. Was patient adequately transfused during last 30 months
11	TX_RECPT	Num	8	3.	C3. Currently receiving trans for primary stroke prevention
23	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
22	ldu_id	Char	10		ID for public use datasets

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
24	tx_startfrmrand	Num	8		<created variable> C3a1. Date transfusion started as days from RAND visit
21	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	PREVF1C	Num	8	3.	B1. Has Form 01A, 01B, or 01C been completed previously
4	DOB_COR	Num	8	3.	B2. Is birthdate information on label provided by DCC correct
5	GEND_COR	Num	8	3.	B3. Is the gender information on label provided by DCC correct
6	COR_GEND	Num	8	3.	B3a. Check correct gender of patient
7	RACE	Num	8	3.	B4. Race
8	SP_RACE	Char	75	$75.	B4a. Specify other race of patient
9	HBS_DIAG	Num	8	3.	C1. A diagnosis of HbSS or HbS/b0 Thalassemia?
10	AGE4_20	Num	8	3.	C2. Is the patient's age in the range of 4.5 through 20 years
11	TX_RECPT	Num	8	3.	C3. Currently receiving trans for primary stroke prevention
12	TX_ADQT	Num	8	3.	C3a. Was patient adequately transfused during last 30 months
13	ABN_TCDS	Num	8	3.	C3a2. Did patient have abnormal TCD readings prior to transfusions
14	H_STROKE	Num	8	3.	C4. Does the patient have a prior history of stroke
15	BONE_MAR	Num	8	3.	C5. Has the patient received a bone marrow transplant
16	ELIG_PR	Num	8	3.	D1. Is the patient eligible for pre-randomization evaluation
17	CONSENT	Num	8	3.	D2. Has patient's guardian read and signed inform consent doc
18	CONSNT_R	Char	200	$200.	D2a. Specify reason for no consent
19	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
20	DESTATUS	Char	1	$1.	DESTATUS
21	vistype	Char	7		<created variable> VISIT TYPE
22	ldu_id	Char	10		ID for public use datasets
23	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
24	tx_startfrmrand	Num	8		<created variable> C3a1. Date transfusion started as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F01Cfmts.txt;

proc format;

  value PREVF1CF
    1='1: No'
    2='2: Yes';

  value AGE4_20F
    1='1: No'
    2='2: Yes';

  value TX_ADQTF
    1='1: No'
    2='2: Yes';

  value H_STROKEF
    1='1: No'
    2='2: Yes';

  value RACEF
    1='1: Black/African American/not Latin origin'
    2='2: Black/African American/of Latin origin'
    3='3: White/not of Latin origin'
    4='4: White/of Latin origin'
    5='5: Asian American/Pacific Islander'
    6='6: Native American/Alaskan Native'
    7='7: Other';

  value HBS_DIAGF
    1='1: No'
    2='2: Yes';

  value ABN_TCDSF
    1='1: No'
    2='2: Yes';

  value CONSENTF
    1='1: No'
    2='2: Yes';

  value ELIG_PRF
    1='1: No'
    2='2: Yes';

  value BONE_MARF
    1='1: No'
    2='2: Yes';

  value TX_RECPTF
    1='1: No'
    2='2: Yes';

  value COR_GENDF
    1='1: Female'
    2='2: Male';
```

```
  value GEND_CORF
    1='1: No'
    2='2: Yes';

  value DOB_CORF
    1='1: No'
    2='2: Yes';

* format prevf1c prevf1cf. age4_20 age4_20f. tx_adqt tx_adqtf. h_stroke h_strokef. race racef. hbs_diag
hbs_diagf. abn_tcds abn_tcdsf. consent consentf. elig_pr elig_prf. bone_mar bone_marf. tx_recpt
tx_recptf. cor_gend cor_gendf. gend_cor gend_corf. dob_cor dob_corf.;
```

STOP II

PRE-RANDOMIZATION ELIGIBILITY QUESTIONNAIRE

AFFIX PATIENT LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	78	98.73	78	98.73
P	1	1.27	79	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-301	79	100.00	79	100.00

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
79	0	-188.3	177.6	-832.0	-301.0	-154.0	-75.0	378.0

B. PATIENT ID INFORMATION

B1. Has a STOP II Form 01A, B, or C been completed previously for this patient? ☐ 1. NO ☐ 2. YES

↓

GO TO SECTION C

B1. Has Form 01A, 01B, or 01C been completed previously				
PREVF1C	Frequency	Percent	Cum Freq	Cum Percent
1	46	58.23	46	58.23
2	33	41.77	79	100.00

B2. Is the birthdate information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B2.a If NO, list correct birthdate
___ ___/___ ___/___ ___ ___ ___

B2. Is birthdate information on label provided by DCC correct				
DOB_COR	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
-2	33	41.77	34	43.04
-1	2	2.53	36	45.57
2	43	54.43	79	100.00

[Variable for correct birthdate NOT included in dataset.]

B3. Is the gender information on the pre-printed patient label provided by the DCC correct? ☐ **1. NO** ☐ **2. YES**

↓

B3.a If NO, check correct gender:

☐ **1. FEMALE**

☐ **2. MALE**

B3. Is the gender information on label provided by DCC correct				
GEND_COR	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
-2	33	41.77	34	43.04
-1	2	2.53	36	45.57
2	43	54.43	79	100.00

[No data for variable COR_GEND.]

B4. Race

(READ BOLDED SENTENCES TO PARENT/GUARDIAN OR CHILD IF AGE APPROPRIATE AND SHOW CARD WITH CHOICES)

NIH monitors enrollment of minorities to ensure their adequate representation in all research studies funded by NIH. Please identify the race of the child among the following choices [SHOW CARD]:

☐ **1. Black/African American/not Latin origin** ☐ **2. Black/African American/ of Latin Origin**

☐ **3. White/not of Latin origin** ☐ **4. White/of Latin origin**

☐ **5. Asian American/Pacific Islander** ☐ **6. Native American/Alaskan Native**

☐ **7. Other** → B4.a Please specify _____

B4. Race				
RACE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
-2	33	41.77	34	43.04
1	43	54.43	77	97.47
7	2	2.53	79	100.00

B4a. Specify other race of patient				
SP_RACE	Frequency	Percent	Cum Freq	Cum Percent
-2	77	97.47	77	97.47
LATINO	2	2.53	79	100.00

C. INCLUSION/EXCLUSION CRITERIA

C1. Does the patient have a diagnosis of HbSS or HbS/β^0 thalassemia? ☐ **1. NO** ☐ **2. YES**

C1. A diagnosis of HbSS or HbS/b0 Thalassemia?				
HBS_DIAG	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

C2. Is the patient's age in the range of 4.5 through 20 years? ☐ **1. NO** ☐ **2. YES**

C2. Is the patient's age in the range of 4.5 through 20 years				
AGE4_20	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

C3. Is the patient currently receiving transfusions for primary stroke prevention? ☐ **1. NO** ☐ **2. YES**

↓

C3. Currently receiving trans for primary stroke prevention				
TX_RECPT	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

C3.a Was the patient adequately transfused during the last 30 months?

☐ **1. NO**

☐ **2. YES**

↓

C3a. Was patient adequately transfused during last 30 months				
TX_ADQT	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

C3.a1 Date transfusion started:

___ ___/___ ___/___ ___ ___ ___

C3.a2 Did the STOP/STOP II TCD Reading Center determine that the patient had 2 abnormal TCDs or 1 abnormal TCD with time averaged maximum mean velocity ≥ 220 cm prior to starting transfusions?

☐ **1. NO**

☐ **2. YES**

Analysis Variable : tx_startfrmrand <created variable> C3a1. Date transfusion started as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
79	0	-1548	473.9	-2777	-1988	-1475	-1035	-938.0

C3a2. Did patient have abnormal TCD readings prior to transfusions				
ABN_TCDS	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

IF THE ANSWER TO ANY OF C1 - C3.a2 IS NO, THE PATIENT IS NOT ELIGIBLE FOR STUDY. GO TO SECTION D

C4. Does the patient have a prior history of stroke? ☐ **1. NO** ☐ **2. YES**

C4. Does the patient have a prior history of stroke				
H_STROKE	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

C5. Has the patient received a bone marrow transplant? ☐ **1. NO** ☐ **2. YES**

C5. Has the patient received a bone marrow transplant				
BONE_MAR	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

IF THE ANSWER TO EITHER C4 OR C5 IS YES, THE PATIENT IS NOT ELIGIBLE FOR STUDY. GO TO SECTION D

D. ELIGIBILITY DISPOSITION FOR PRE-RANDOMIZATION EVALUATION

D1. Is the patient eligible for pre-randomization evaluation?
(Answers to questions C1 – C3.a2 = YES,
Answers to questions C4 and C5 = NO)

☐ **1. NO** → **STOP – FORM COMPLETE**

☐ **2. YES**

D1. Is the patient eligible for pre-randomization evaluation				
ELIG_PR	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for pre-randomization evaluation?

☐ **1. NO** → D2.a Please specify reason:

_____

STOP – FORM COMPLETE

☐ **2. YES** → **PROCEED WITH TCD EXAMINATION AND COMPLETE TCD EXAM FORM**

D2. Has patient's guardian read and signed inform consent doc				
CONSENT	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

D2a. Specify reason for no consent				
CONSNT_R	Frequency	Percent	Cum Freq	Cum Percent
-2	79	100.00	79	100.00

Signature of Study Coordinator:_____ Date: ___ ___/___ ___/___ ___ ___ ___

STOP II
FORM 02: TRANSCRANIAL DOPPLER (TCD) EXAMINATION FORM

A. Collection Information:
The **Transcranial Doppler (TCD) Examination Form** (Form 02) was to be completed for all TCD examination visits.

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p002_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, TCD_SEQ**

Records in the dataset are sorted by LDU_ID and TCD sequence number (TCD_SEQ).

Other unique identifiers in the dataset are FNAME (blinded ID # of TCD exam) vs. LDU_ID, exdated_frmrand vs. LDU_ID, examdt_frmrand vs. LDU_ID, EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 1,349 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 61-64
- Listing of Variables by Position: See pp. 65-67

H. Formats:
The file **f002fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this the dataset are listed on page 68.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **FNAME** – is the variable name for the blinded ID # that was assigned to the TCD exam prior to submitting the exam to the TCD Reading Center.

- **EX_TYPE** - is the variable name for type of visit. Valid EX_TYPEs for Form 2 - Randomized and Potential Patient subset are:
  - RT for routine visits - Initial TCD screening exam, and all subsequent TCD exams for patients with no abnormal TCD results.
  - CS for confirmatory visits - all subsequent TCD screening exams for patients with a previous exam with abnormal results and TAMM velocity between 200-219 cm/sec.
  - QT: for quarterly visits
  - EX: for randomized patient TCD visits
  - NE: for neurological events

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 2 are:
  For EX_TYPE=RT or CS,
  - 100 series numbers were assigned to “Screening” patient visits – i.e., TCD screening visits completed before the patient started transfusions and enrolled as a potential trial patient.

  For EX_TYPE=QT,
  - 200 & 300 series numbers indicate visits that were completed prior to randomization.
    - 200 series numbers were assigned to “Potential 1” visits – i.e., quarterly visits completed while the patient was on transfusion for < 30 months
    - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months
  - EX_NUM=401 indicates an extra TCD completed at the randomization visit for randomized patients

  For EX_TYPE=EX
  - Numbers from 001-022 were used for randomized patient TCD visits.

  For EX_TYPE=NE
  - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **EXAM_INTP** – is the variable name for exam interpretation. Each TCD exam was classified by the STOP II TCD Reading Center into one of five mutually exclusive categories:

  1. Normal: all time-averaged maximum mean (TAMM) velocities in the selected cerebral arteries (M1, MCA, BIF, dICA, ACA, PCA, TOB, basilar segment) are <170 cm/sec;

  2. Conditional: at least one TAMM velocity of 170-199 cm/sec and no velocities ≥200 cm/sec in the M1, MCA, BIF, or dICA arterial segments OR at least one TAMM velocity ≥170 in the PCA, TOB, basilar or ACA segments.

  Conditional exams are classified as:

  2A (Conditional A) if the qualifying velocity is in the MI, MCA, BIF, or dICA segment;
  2B (Conditional B) if the qualifying velocity is in the PCA, TOB, or basilar segment; OR
  2C (Conditional C) if the velocity is in the ACA.

  If multiple velocities between 170 and 199 in M1, MCA, BIF, or dICA arterial segments or > 170 in the PCA, TOB, basilar or ACA segments are recorded, then Conditional A takes priority over Conditional B and both take priority over Conditional C. Conditional A exams with velocities between 180 and 199 cm/sec are considered “high” Conditional A and those between 170 and 179 are considered “low” Conditional A.

  3. Abnormal: at least one TAMM velocity of at least 200 cm/sec in M1, MCA, BIF, or dICA segments; and

  4. Inadequate: unreadable or incomplete due to presence of a poor ultrasound window or complete or nearly complete occlusion of an arterial segment. Caveat: incomplete exams with at least one velocity ≥200 cm/sec in the M1, MCA, BIF, or dICA segments are considered abnormal.

  5. Inadequate (technical): uninterpretable due to technical reasons, such as improper adjustments of the TCD machine, motion of child, or poor TCD examiner technique.

- **MAXVELL** – is a variable name for TAMM velocity - left side and was calculated as the maximum of LMCAVM, LM1VM, LBIFVM, LDICAVM. A value was not calculated for this variable if the EXAM_INTP was 4 or 5.

- **MAXVELR** – is the variable name for TAMM velocity – right side and was calculated as the maximum of RMCAVM**,** RM1VM**,** RBIFVM**,** RDICAVM. A value was not calculated for this variable if the EXAM_INTP was 4 or 5.

- **MAXVEL** – is the variable name for TAMM velocity and was calculated as the maximum of the LMCAVM**,** LM1VM**,** LBIFVM**,** LDICAVM**,** RMCAVM**,** RM1VM**,** RBIFVM**,** RDICAVM. A value was not calculated for this variable if the EXAM_INTP was 4 or 5.

Data Set Name	PUBDS.P002_FINAL	Observations	1349
Member Type	DATA	Variables	119
Engine	V9	Indexes	0
Created	Tuesday, March 21, 2006 10:04:47 AM	Observation Length	920
Last Modified	Tuesday, March 21, 2006 10:04:47 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	81
First Data Page	2
Max Obs per Page	17
Obs in First Data Page	17
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p002_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
100	BASD	Num	8	18.4	BAS - depth
104	BASPI	Num	8	16.2	BAS - pulsatility index
105	BASRI	Num	8	16.2	BAS - resistivity index
103	BASVD	Num	8	18.4	BAS - peak diastolic velocity
101	BASVM	Num	8	18.4	BAS - TAMM velocity
102	BASVS	Num	8	18.4	BAS - peak systolic velocity
9	DESTATUS	Char	1	$1.	DESTATUS
14	EXAM_INTP	Char	2	$2.	Exam interpretation
4	EXAM_RSN	Num	8	3.	B2. Reason for examination
11	EX_AMPM	Num	8	18.4	Exam time - AM/PM
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
10	FNAME	Char	8	$8.	Blinded TCD exam file name
8	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
15	HEAD_DI	Num	8	18.4	Head diameter
7	HEMAT	Num	8	5.1	D1c. Hematocrit (%)
6	HEMOGLOB	Num	8	5.1	D1b. Hemoglobin (g/dl)
5	H_H_DRAW	Num	8	3.	D1. Was a sample for hemoglobin/hematrocrit drawn at this visit
58	LACAD	Num	8	18.4	L ACA - depth
62	LACAPI	Num	8	16.2	L ACA - pulsatility index
63	LACARI	Num	8	16.2	L ACA - resistivity index
61	LACAVD	Num	8	18.4	L ACA - peak diastolic velocity
59	LACAVM	Num	8	18.4	L ACA - TAMM velocity
60	LACAVS	Num	8	18.4	L ACA - peak systolic velocity
46	LBIFD	Num	8	18.4	L BIF - depth

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
50	LBIFPI	Num	8	16.2	L BIF - pulsatility index
51	LBIFRI	Num	8	16.2	L BIF - resistivity index
49	LBIFVD	Num	8	18.4	L BIF - peak diastolic velocity
47	LBIFVM	Num	8	18.4	L BIF - TAMM velocity
48	LBIFVS	Num	8	18.4	L BIF - peak systolic velocity
70	LDICAD	Num	8	18.4	L dICA - depth
74	LDICAPI	Num	8	16.2	L dICA - pulsatility index
75	LDICARI	Num	8	16.2	L dICA - resistivity index
73	LDICAVD	Num	8	18.4	L dICA - peak diastolic velocity
71	LDICAVM	Num	8	18.4	L dICA - TAMM velocity
72	LDICAVS	Num	8	18.4	L dICA - peak systolic velocity
22	LM1D	Num	8	18.4	L M1 - depth
26	LM1PI	Num	8	16.2	L M1 - pulsatility index
27	LM1RI	Num	8	16.2	L M1 - resistivity index
25	LM1VD	Num	8	18.4	L M1 - peak diastolic velocity
23	LM1VM	Num	8	18.4	L M1 - TAMM velocity
24	LM1VS	Num	8	18.4	L M1 - peak systolic velocity
34	LMCAD	Num	8	18.4	L MCA - depth
38	LMCAPI	Num	8	16.2	L MCA - pulsatility index
39	LMCARI	Num	8	16.2	L MCA - resistivity index
37	LMCAVD	Num	8	18.4	L MCA - peak diastolic velocity
35	LMCAVM	Num	8	18.4	L MCA - TAMM velocity
36	LMCAVS	Num	8	18.4	L MCA - peak systolic velocity
82	LPCAD	Num	8	18.4	L PCA - depth
86	LPCAPI	Num	8	16.2	L PCA - pulsatility index
87	LPCARI	Num	8	16.2	L PCA - resistivity index
85	LPCAVD	Num	8	18.4	L PCA - peak diastolic velocity
83	LPCAVM	Num	8	18.4	L PCA - TAMM velocity
84	LPCAVS	Num	8	18.4	L PCA - peak systolic velocity
94	LTOBD	Num	8	18.4	L TOB - depth
98	LTOBPI	Num	8	16.2	L TOB - pulsatility index
99	LTOBRI	Num	8	16.2	L TOB - resistivity index
97	LTOBVD	Num	8	18.4	L TOB - peak diastolic velocity
95	LTOBVM	Num	8	18.4	L TOB - TAMM velocity
96	LTOBVS	Num	8	18.4	L TOB - peak systolic velocity
12	PREAD_INIT	Char	3	$3.	Primary reader(READER-1)initials
52	RACAD	Num	8	18.4	R ACA - depth
56	RACAPI	Num	8	16.2	R ACA - pulsatility index
57	RACARI	Num	8	16.2	R ACA - resistivity index
55	RACAVD	Num	8	18.4	R ACA - peak diastolic velocity
53	RACAVM	Num	8	18.4	R ACA - TAMM velocity
54	RACAVS	Num	8	18.4	R ACA - peak systolic velocity
40	RBIFD	Num	8	18.4	R BIF - depth
44	RBIFPI	Num	8	16.2	R BIF - pulsatility index
45	RBIFRI	Num	8	16.2	R BIF - resistivity index
43	RBIFVD	Num	8	18.4	R BIF - peak diastolic velocity
41	RBIFVM	Num	8	18.4	R BIF - TAMM velocity
42	RBIFVS	Num	8	18.4	R BIF - peak systolic velocity
64	RDICAD	Num	8	18.4	R dICA - depth
68	RDICAPI	Num	8	16.2	R dICA - pulsatility index
69	RDICARI	Num	8	16.2	R dICA - resistivity index

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
67	RDICAVD	Num	8	18.4	R dICA - peak diastolic velocity
65	RDICAVM	Num	8	18.4	R dICA - TAMM velocity
66	RDICAVS	Num	8	18.4	R dICA - peak systolic velocity
16	RM1D	Num	8	18.4	R M1 - depth
20	RM1PI	Num	8	16.2	R M1 - pulsatility index
21	RM1RI	Num	8	16.2	R M1 - resistivity index
19	RM1VD	Num	8	18.4	R M1 - peak diastolic velocity
17	RM1VM	Num	8	18.4	R M1 - TAMM velocity
18	RM1VS	Num	8	18.4	R M1 - peak systolic velocity
28	RMCAD	Num	8	18.4	R MCA - depth
32	RMCAPI	Num	8	16.2	R MCA - pulsatility index
33	RMCARI	Num	8	16.2	R MCA - resistivity index
31	RMCAVD	Num	8	18.4	R MCA - peak diastolic velocity
29	RMCAVM	Num	8	18.4	R MCA - TAMM velocity
30	RMCAVS	Num	8	18.4	R MCA - peak systolic velocity
76	RPCAD	Num	8	18.4	R PCA - depth
80	RPCAPI	Num	8	16.2	R PCA - pulsatility index
81	RPCARI	Num	8	16.2	R PCA - resistivity index
79	RPCAVD	Num	8	18.4	R PCA - peak diastolic velocity
77	RPCAVM	Num	8	18.4	R PCA - TAMM velocity
78	RPCAVS	Num	8	18.4	R PCA - peak systolic velocity
88	RTOBD	Num	8	18.4	R TOB- depth
92	RTOBPI	Num	8	16.2	R TOB - pulsatility index
93	RTOBRI	Num	8	16.2	R TOB - resistivity index
91	RTOBVD	Num	8	18.4	R TOB - peak diastolic velocity
89	RTOBVM	Num	8	18.4	R TOB- TAMM velocity
90	RTOBVS	Num	8	18.4	R TOB - peak systolic velocity
13	SREAD_INIT	Char	3	$3.	Secondary reader(READER-2)initials
3	TCD_SEQ	Num	8	3.	X5. TCD sequence number
111	compdfrmrand	Num	8		<created variable> A2. Date Form 2 completed as days from RAND visit
112	daterand_dfrmrand	Num	8		<created variable> Date blinded TCD exam sent to MCG as days from RAND visit
113	dumpdt_frmrand	Num	8		<created variable> Date TCD exam results received as days from RAND visit
114	eventdt_frmrand	Num	8		<created variable> B2a. Date of neurological event as days from RAND visit
115	examdt_frmrand	Num	8		<created variable> B1. Date of TCD exam from Form 2 as days from RAND visit
116	exdated_frmrand	Num	8		<created variable> Date of TCD exam in TCD files as days from RAND
117	hhdate_frmrand	Num	8		<created variable> D1a. Date sample for CBC drawn as days from RAND visit
110	ldu_id	Char	10		ID for public use datasets
106	maxvel	Num	8		<created variable> TAMM velocity (M1,MCA,dICA,BIF)
107	maxvell	Num	8		<created variable> TAMM velocity - left side (M1,MCA,dICA,BIF)
108	maxvelr	Num	8		<created variable> TAMM velocity - right side (M1,MCA,dICA,BIF)
118	preaddte_frmrand	Num	8		<created variable> Date of TCD exam reading by Primary reader as days from RAND visit

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
119	sreaddte_frmrand	Num	8		<created variable> Date of TCD exam reading by Secondary reader as days from RAND visit
109	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	TCD_SEQ	Num	8	3.	X5. TCD sequence number
4	EXAM_RSN	Num	8	3.	B2. Reason for examination
5	H_H_DRAW	Num	8	3.	D1. Was a sample for hemoglobin/hematrocrit drawn at this visit
6	HEMOGLOB	Num	8	5.1	D1b. Hemoglobin (g/dl)
7	HEMAT	Num	8	5.1	D1c. Hematocrit (%)
8	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
9	DESTATUS	Char	1	$1.	DESTATUS
10	FNAME	Char	8	$8.	Blinded TCD exam file name
11	EX_AMPM	Num	8	18.4	Exam time - AM/PM
12	PREAD_INIT	Char	3	$3.	Primary reader(READER-1)initials
13	SREAD_INIT	Char	3	$3.	Secondary reader(READER-2)initials
14	EXAM_INTP	Char	2	$2.	Exam interpretation
15	HEAD_DI	Num	8	18.4	Head diameter
16	RM1D	Num	8	18.4	R M1 - depth
17	RM1VM	Num	8	18.4	R M1 - TAMM velocity
18	RM1VS	Num	8	18.4	R M1 - peak systolic velocity
19	RM1VD	Num	8	18.4	R M1 - peak diastolic velocity
20	RM1PI	Num	8	16.2	R M1 - pulsatility index
21	RM1RI	Num	8	16.2	R M1 - resistivity index
22	LM1D	Num	8	18.4	L M1 - depth
23	LM1VM	Num	8	18.4	L M1 - TAMM velocity
24	LM1VS	Num	8	18.4	L M1 - peak systolic velocity
25	LM1VD	Num	8	18.4	L M1 - peak diastolic velocity
26	LM1PI	Num	8	16.2	L M1 - pulsatility index
27	LM1RI	Num	8	16.2	L M1 - resistivity index
28	RMCAD	Num	8	18.4	R MCA - depth
29	RMCAVM	Num	8	18.4	R MCA - TAMM velocity
30	RMCAVS	Num	8	18.4	R MCA - peak systolic velocity
31	RMCAVD	Num	8	18.4	R MCA - peak diastolic velocity
32	RMCAPI	Num	8	16.2	R MCA - pulsatility index
33	RMCARI	Num	8	16.2	R MCA - resistivity index
34	LMCAD	Num	8	18.4	L MCA - depth
35	LMCAVM	Num	8	18.4	L MCA - TAMM velocity
36	LMCAVS	Num	8	18.4	L MCA - peak systolic velocity
37	LMCAVD	Num	8	18.4	L MCA - peak diastolic velocity
38	LMCAPI	Num	8	16.2	L MCA - pulsatility index
39	LMCARI	Num	8	16.2	L MCA - resistivity index
40	RBIFD	Num	8	18.4	R BIF - depth
41	RBIFVM	Num	8	18.4	R BIF - TAMM velocity
42	RBIFVS	Num	8	18.4	R BIF - peak systolic velocity
43	RBIFVD	Num	8	18.4	R BIF - peak diastolic velocity
44	RBIFPI	Num	8	16.2	R BIF - pulsatility index
45	RBIFRI	Num	8	16.2	R BIF - resistivity index
46	LBIFD	Num	8	18.4	L BIF - depth
47	LBIFVM	Num	8	18.4	L BIF - TAMM velocity
48	LBIFVS	Num	8	18.4	L BIF - peak systolic velocity
49	LBIFVD	Num	8	18.4	L BIF - peak diastolic velocity
50	LBIFPI	Num	8	16.2	L BIF - pulsatility index

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
51	LBIFRI	Num	8	16.2	L BIF - resistivity index
52	RACAD	Num	8	18.4	R ACA - depth
53	RACAVM	Num	8	18.4	R ACA - TAMM velocity
54	RACAVS	Num	8	18.4	R ACA - peak systolic velocity
55	RACAVD	Num	8	18.4	R ACA - peak diastolic velocity
56	RACAPI	Num	8	16.2	R ACA - pulsatility index
57	RACARI	Num	8	16.2	R ACA - resistivity index
58	LACAD	Num	8	18.4	L ACA - depth
59	LACAVM	Num	8	18.4	L ACA - TAMM velocity
60	LACAVS	Num	8	18.4	L ACA - peak systolic velocity
61	LACAVD	Num	8	18.4	L ACA - peak diastolic velocity
62	LACAPI	Num	8	16.2	L ACA - pulsatility index
63	LACARI	Num	8	16.2	L ACA - resistivity index
64	RDICAD	Num	8	18.4	R dICA - depth
65	RDICAVM	Num	8	18.4	R dICA - TAMM velocity
66	RDICAVS	Num	8	18.4	R dICA - peak systolic velocity
67	RDICAVD	Num	8	18.4	R dICA - peak diastolic velocity
68	RDICAPI	Num	8	16.2	R dICA - pulsatility index
69	RDICARI	Num	8	16.2	R dICA - resistivity index
70	LDICAD	Num	8	18.4	L dICA - depth
71	LDICAVM	Num	8	18.4	L dICA - TAMM velocity
72	LDICAVS	Num	8	18.4	L dICA - peak systolic velocity
73	LDICAVD	Num	8	18.4	L dICA - peak diastolic velocity
74	LDICAPI	Num	8	16.2	L dICA - pulsatility index
75	LDICARI	Num	8	16.2	L dICA - resistivity index
76	RPCAD	Num	8	18.4	R PCA - depth
77	RPCAVM	Num	8	18.4	R PCA - TAMM velocity
78	RPCAVS	Num	8	18.4	R PCA - peak systolic velocity
79	RPCAVD	Num	8	18.4	R PCA - peak diastolic velocity
80	RPCAPI	Num	8	16.2	R PCA - pulsatility index
81	RPCARI	Num	8	16.2	R PCA - resistivity index
82	LPCAD	Num	8	18.4	L PCA - depth
83	LPCAVM	Num	8	18.4	L PCA - TAMM velocity
84	LPCAVS	Num	8	18.4	L PCA - peak systolic velocity
85	LPCAVD	Num	8	18.4	L PCA - peak diastolic velocity
86	LPCAPI	Num	8	16.2	L PCA - pulsatility index
87	LPCARI	Num	8	16.2	L PCA - resistivity index
88	RTOBD	Num	8	18.4	R TOB- depth
89	RTOBVM	Num	8	18.4	R TOB- TAMM velocity
90	RTOBVS	Num	8	18.4	R TOB - peak systolic velocity
91	RTOBVD	Num	8	18.4	R TOB - peak diastolic velocity
92	RTOBPI	Num	8	16.2	R TOB - pulsatility index
93	RTOBRI	Num	8	16.2	R TOB - resistivity index
94	LTOBD	Num	8	18.4	L TOB - depth
95	LTOBVM	Num	8	18.4	L TOB - TAMM velocity
96	LTOBVS	Num	8	18.4	L TOB - peak systolic velocity
97	LTOBVD	Num	8	18.4	L TOB - peak diastolic velocity
98	LTOBPI	Num	8	16.2	L TOB - pulsatility index
99	LTOBRI	Num	8	16.2	L TOB - resistivity index
100	BASD	Num	8	18.4	BAS - depth
101	BASVM	Num	8	18.4	BAS - TAMM velocity

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
102	BASVS	Num	8	18.4	BAS - peak systolic velocity
103	BASVD	Num	8	18.4	BAS - peak diastolic velocity
104	BASPI	Num	8	16.2	BAS - pulsatility index
105	BASRI	Num	8	16.2	BAS - resistivity index
106	maxvel	Num	8		<created variable> TAMM velocity (M1,MCA,dICA,BIF)
107	maxvell	Num	8		<created variable> TAMM velocity - left side (M1,MCA,dICA,BIF)
108	maxvelr	Num	8		<created variable> TAMM velocity - right side (M1,MCA,dICA,BIF)
109	vistype	Char	7		<created variable> VISIT TYPE
110	ldu_id	Char	10		ID for public use datasets
111	compdfrmrand	Num	8		<created variable> A2. Date Form 2 completed as days from RAND visit
112	daterand_dfrmrand	Num	8		<created variable> Date blinded TCD exam sent to MCG as days from RAND visit
113	dumpdt_frmrand	Num	8		<created variable> Date TCD exam results received as days from RAND visit
114	eventdt_frmrand	Num	8		<created variable> B2a. Date of neurological event as days from RAND visit
115	examdt_frmrand	Num	8		<created variable> B1. Date of TCD exam from Form 2 as days from RAND visit
116	exdated_frmrand	Num	8		<created variable> Date of TCD exam in TCD files as days from RAND
117	hhdate_frmrand	Num	8		<created variable> D1a. Date sample for CBC drawn as days from RAND visit
118	preaddte_frmrand	Num	8		<created variable> Date of TCD exam reading by Primary reader as days from RAND visit
119	sreaddte_frmrand	Num	8		<created variable> Date of TCD exam reading by Secondary reader as days from RAND visit

Sort Information

Sortedby	ldu_id TCD_SEQ
Validated	YES
Character Set	ANSI

```
*F002fmts.txt;

proc format;

  value H_H_DRAWF
    1='1: No'
    2='2: Yes';

  value EXAM_RSNF
    1='1: Routine TCD Screening Examination to determine eligibility for transfusion'
    2='2: Confirmatory TCD Examination to determine eligibility for transfusion'
    3='3: TCD Screening Examination to determine eligibility for randomization'
    4='4: Confirmatory TCD Screening Examination to determine eligibility for randomization'
    5='5: Entry/Quarterly Visit for potential subject'
    6='6: Quarterly or 6 week Follow-up Visit for trial patient'
    7='7: Neurological Event';

  value $EXAM_INTF
    "1"="1: Normal"
    "2A"="2A: Conditional A"
    "2B"="2B: Conditional B"
    "2C"="2C: Conditional C"
    "3"="3: Abnormal"
    "4"="4: Inadequate"
    "5"="5: Inadequate (technical)";

* format h_h_draw h_h_drawf. exam_rsn exam_rsnf. exam_intp $exam_intf.;
```

STOP II TRIAL

TRANSCRANIAL DOPPLER (TCD) EXAMINATION FORM

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1340	99.33	1340	99.33
P	9	0.67	1349	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
CS-102	9	0.67	9	0.67
CS-103	6	0.44	15	1.11
CS-104	2	0.15	17	1.26
CS-105	1	0.07	18	1.33
CS-106	1	0.07	19	1.41
EX-001	79	5.86	98	7.26
EX-002	78	5.78	176	13.05
EX-003	71	5.26	247	18.31
EX-004	66	4.89	313	23.20
EX-005	63	4.67	376	27.87
EX-006	59	4.37	435	32.25
EX-007	55	4.08	490	36.32
EX-008	52	3.85	542	40.18
EX-009	45	3.34	587	43.51
EX-010	41	3.04	628	46.55
EX-011	39	2.89	667	49.44
EX-012	38	2.82	705	52.26
EX-013	35	2.59	740	54.86
EX-014	31	2.30	771	57.15
EX-015	32	2.37	803	59.53
EX-016	24	1.78	827	61.30
EX-017	16	1.19	843	62.49
EX-018	13	0.96	856	63.45
EX-019	9	0.67	865	64.12
EX-020	5	0.37	870	64.49
EX-021	2	0.15	872	64.64
EX-022	1	0.07	873	64.71
QT-201	14	1.04	887	65.75
QT-202	27	2.00	914	67.75
QT-203	22	1.63	936	69.38
QT-204	26	1.93	962	71.31
QT-205	24	1.78	986	73.09
QT-206	22	1.63	1008	74.72
QT-207	17	1.26	1025	75.98

<created variable> VISIT TYPE (continued)				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-208	18	1.33	1043	77.32
QT-209	18	1.33	1061	78.65
QT-210	16	1.19	1077	79.84
QT-210A	1	0.07	1078	79.91
QT-301	78	5.78	1156	85.69
QT-301A	40	2.97	1196	88.66
QT-301B	2	0.15	1198	88.81
QT-302	30	2.22	1228	91.03
QT-302A	10	0.74	1238	91.77
QT-302B	1	0.07	1239	91.85
QT-303	21	1.56	1260	93.40
QT-303A	2	0.15	1262	93.55
QT-304	20	1.48	1282	95.03
QT-304A	3	0.22	1285	95.26
QT-304B	1	0.07	1286	95.33
QT-305	11	0.82	1297	96.15
QT-305A	1	0.07	1298	96.22
QT-306	6	0.44	1304	96.66
QT-306A	1	0.07	1305	96.74
QT-307	2	0.15	1307	96.89
QT-307A	1	0.07	1308	96.96
QT-308	3	0.22	1311	97.18
QT-308A	1	0.07	1312	97.26
QT-309	2	0.15	1314	97.41
QT-309A	1	0.07	1315	97.48
QT-310	1	0.07	1316	97.55
QT-401	9	0.67	1325	98.22
RT-101	17	1.26	1342	99.48
RT-102	4	0.30	1346	99.78
RT-103	2	0.15	1348	99.93
RT-104	1	0.07	1349	100.00

SECTIONS A, B and D TO BE COMPLETED BY STUDY COORDINATOR
SECTION C TO BE COMPLETED BY TCD EXAMINER

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year) ____ ____/____ ____/____ ____ ____ ____

Analysis Variable : compdfrmrand <created variable> A2. Date Form 2 completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1349	0	169.5	559.8	-1343	-169.0	175.0	573.0	1399.0

B. TCD EXAMINATION INFORMATION

B1. Date of examination (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

Analysis Variable : examdt_frmrand <created variable> B1. Date of TCD exam from Form 2 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1349	0	167.6	559.4	-1343	-170.0	174.0	569.0	1399.0

B2. Reason for examination:

- ☐ **1. Routine TCD Screening Examination to determine eligibility for transfusion**
- ☐ **2. Confirmatory TCD Examination to determine eligibility for transfusion**
- ☐ **3. TCD Screening Examination to determine eligibility for randomization**
- ☐ **4. Confirmatory TCD Screening Examination to determine eligibility for randomization**
- ☐ **5. Entry/Quarterly Visit for potential subject**
- ☐ **6. Quarterly or 6 week Follow-up Visit for trial patient**
- ☐ **7. Neurological Event**

B2. Reason for examination				
EXAM_RSN	Frequency	Percent	Cum Freq	Cum Percent
1	24	1.78	24	1.78
2	19	1.41	43	3.19
3	56	4.15	99	7.34
4	60	4.45	159	11.79
5	327	24.24	486	36.03
6	863	63.97	1349	100.00

B2.a Date of Event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

[Note: No TCDs submitted as 7. Neurological Event only. No data for this variable.]

C. TCD EXAMINATION

SECTION C TO BE COMPLETED BY TCD EXAMINER

C1. Name of examiner: _____ (Initials): | | | |

[Variable NOT included in dataset.]

C2. TCD machine serial number: | |

[Variable NOT included in dataset.]

C3. Examiner comments: _____

[Variable NOT included in dataset.]

SECTION D TO BE COMPLETED BY STUDY COORDINATOR

D. CBC INFORMATION (OPTIONAL)

1. NO **2. YES**

D1. Was a sample for hemoglobin/hematocrit drawn at this visit? ☐ ☐

D1. Was a sample for hemoglobin/hematrocrit drawn at this visit				
H_H_DRAW	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.37	5	0.37
1	735	54.48	740	54.86
2	609	45.14	1349	100.00

D1.a. Date drawn (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

D1.b. Hemoglobin (g/dl) ☐☐.☐

D1.c Hematocrit (%) ☐☐.☐

Analysis Variable : hhdate_frmrand <created variable> D1a. Date sample for CBC drawn as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
609	0	141.0	565.6	-1310	-253.0	147.0	558.0	1399.0

<created variable> D1a. Date sample for CBC drawn as days from RAND visit				
hhdate_frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	740	100.00	740	100.00

Analysis Variable : HEMOGLOB D1b. Hemoglobin (g/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
600	0	9.4	1.2	5.8	8.6	9.4	10.1	14.2

D1b. Hemoglobin (g/dl)				
HEMOGLOB	Frequency	Percent	Cum Freq	Cum Percent
-9	9	1.20	9	1.20
-2	740	98.80	749	100.00

Analysis Variable : HEMAT D1c. Hematocrit (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
600	0	27.4	3.8	16.1	25.1	27.7	29.8	42.4

D1c. Hematocrit (%)				
HEMAT	Frequency	Percent	Cum Freq	Cum Percent
-9	9	1.20	9	1.20
-2	740	98.80	749	100.00

TCD RESULTS REPORT:

TCD VELOCITY AND INTERPRETATION REPORT

MASTER ID TCD SEQUENCE # ACROSTIC EXAM DATE TIME

__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ / __ __ / __ __ __ __ __ __ : __ __ : __ __

X5. TCD sequence number				
TCD_SEQ	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	77	5.71	77	5.71
2	76	5.63	153	11.34
3	76	5.63	229	16.98
4	79	5.86	308	22.83
5	78	5.78	386	28.61
6	78	5.78	464	34.40
7	75	5.56	539	39.96
8	75	5.56	614	45.52
9	76	5.63	690	51.15
10	75	5.56	765	56.71
11	73	5.41	838	62.12
12	69	5.11	907	67.23
13	65	4.82	972	72.05
14	62	4.60	1034	76.65
15	59	4.37	1093	81.02
16	54	4.00	1147	85.03
17	54	4.00	1201	89.03
18	47	3.48	1248	92.51
19	33	2.45	1281	94.96
20	25	1.85	1306	96.81
21	20	1.48	1326	98.30
22	10	0.74	1336	99.04
23	7	0.52	1343	99.56
24	3	0.22	1346	99.78
25	3	0.22	1349	100.00

TCD VELOCITY AND INTERPRETATION REPORT

MASTER ID TCD SEQUENCE # ACROSTIC EXAM DATE TIME

__ __ __ __ __ __ __ __ __ __ __ __ / __ __ / __ __ __ __ __ __ : __ __ : __ __

[Data not shown.]

READER-1 DATE READER-2 DATE HEAD-DIAMETER (mm)

__ __ __ __ __ / __ __ / __ __ __ __ __ __ __ __ / __ __ / __ __ __ __ __ __ __

Analysis Variable : exdated_frmrand <created variable> Date of TCD exam in TCD files as days from RAND									
N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
1349	167.61	559.40	-1343.00	-894.00	-170.00	174.00	569.00	1070.00	1399.00

Primary reader (READER-1) initials				
PREAD_INIT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
ACM	252	18.71	252	18.71
DSR	41	3.04	293	21.75
JPL	667	49.52	960	71.27
LSB	386	28.66	1346	99.93
RJA	1	0.07	1347	100.00

Frequency Missing = 2

Analysis Variable : preaddte_frmrand <created variable> Date of TCD exam reading by Primary reader as days from RAND visit									
N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
1344	176.19	559.33	-1303.00	-867.00	-161.00	181.00	577.50	1079.00	1406.00

Secondary reader (READER-2) initials				
SREAD_INIT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
FTN	18	1.34	18	1.34
RJA	1328	98.66	1346	100.00

Frequency Missing = 3

TCD VELOCITY AND INTERPRETATION REPORT

READER-1 DATE READER-2 DATE HEAD-DIAMETER (mm)
__ __ __ __ __ / __ __ / __ __ __ __ __ __ __ __ __ __ / __ __ / __ __ __ __ __ __ __

EXAM INTERPRETATION: __ __

1=Normal 2A=Conditional A 2B=Conditional B 2C=Conditional C 3=Abnormal 4=Inadequate
5=Inadequate (Technical)

Analysis Variable : sreaddte_frmrand <created variable> Date of TCD exam reading by Secondary reader as days from RAND visit									
N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
1346	178.33	558.57	-1303.00	-866.00	-158.00	182.00	579.00	1083.00	1409.00

Analysis Variable : HEAD_DI Head diameter									
N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
1225	128.72	6.82	110.00	116.00	124.00	130.00	134.00	140.00	154.00

Exam interpretation				
EXAM_INTP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	1201	89.03	1201	89.03
2B	2	0.15	1203	89.18
2C	15	1.11	1218	90.29
3	100	7.41	1318	97.70
4	25	1.85	1343	99.56
5	6	0.44	1349	100.00

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
RM1D	R M1 - depth	1336	37.56	2.41	26.00	32.00	36.00	38.00	40.00	40.00	48.00
RM1VM	R M1 - TAMM velocity	1336	98.78	27.73	34.00	56.00	79.00	97.00	117.00	145.00	205.00
RM1VS	R M1 - peak systolic velocity	1336	139.35	35.69	49.00	82.00	114.00	139.00	163.00	199.00	270.00
RM1VD	R M1 - peak diastolic velocity	1336	66.73	21.34	20.00	35.00	50.00	65.00	80.00	103.00	159.00
RM1PI	R M1 - pulsatility index	1336	0.75	0.15	0.40	0.54	0.65	0.74	0.84	1.02	1.43
RM1RI	R M1 - resistivity index	1336	0.52	0.07	0.32	0.42	0.48	0.52	0.57	0.63	0.73

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
RMCAD	R MCA - depth	1344	49.54	3.79	36.00	42.00	48.00	50.00	52.00	56.00	64.00
RMCAVM	R MCA - TAMM velocity	1344	136.76	27.86	50.00	97.00	117.00	133.00	153.00	189.00	237.00
RMCAVS	R MCA - peak systolic velocity	1344	188.49	34.52	71.00	138.00	165.00	186.00	210.00	250.00	312.00
RMCAVD	R MCA - peak diastolic velocity	1344	94.61	22.49	34.00	62.00	79.00	92.00	107.00	139.00	180.00
RMCAPI	R MCA - pulsatility index	1344	0.70	0.13	0.38	0.50	0.61	0.69	0.78	0.92	1.22
RMCARI	R MCA - resistivity index	1344	0.50	0.06	0.32	0.40	0.46	0.50	0.54	0.60	0.67

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
RBIFD	R BIF - depth	1341	54.35	3.22	44.00	50.00	52.00	54.00	56.00	60.00	70.00
RBIFVM	R BIF - TAMM velocity	1341	128.47	27.31	49.00	88.00	111.00	126.00	144.00	178.00	222.00
RBIFVS	R BIF - peak systolic velocity	1341	177.03	32.81	71.00	124.00	154.00	177.00	198.00	232.00	282.00
RBIFVD	R BIF - peak diastolic velocity	1341	88.64	22.09	32.00	58.00	74.00	86.00	102.00	130.00	174.00
RBIFPI	R BIF - pulsatility index	1341	0.70	0.13	0.35	0.51	0.61	0.69	0.78	0.93	1.47
RBIFRI	R BIF - resistivity index	1341	0.50	0.06	0.30	0.40	0.46	0.50	0.54	0.60	0.76

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
RACAD	R ACA - depth	1282	58.77	3.35	50.00	54.00	56.00	58.00	60.00	64.00	74.00
RACAVM	R ACA - TAMM velocity	1282	-104.85	30.13	-259.00	-158.00	-123.00	-102.00	-84.00	-61.00	-32.00
RACAVS	R ACA - peak systolic velocity	1282	-145.26	36.49	-297.00	-208.00	-169.00	-142.00	-120.00	-88.00	-47.00
RACAVD	R ACA - peak diastolic velocity	1282	-71.56	24.55	-214.00	-117.00	-85.00	-68.00	-55.00	-37.00	-13.00
RACAPI	R ACA - pulsatility index	1282	0.73	0.15	0.30	0.50	0.62	0.72	0.82	0.99	1.58
RACARI	R ACA - resistivity index	1282	0.51	0.07	0.27	0.40	0.47	0.51	0.56	0.62	0.80

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
RDICAD	R dICA - depth	1313	58.49	3.36	48.00	54.00	56.00	58.00	60.00	64.00	74.00
RDICAVM	R dICA - TAMM velocity	1313	118.85	29.23	34.00	77.00	97.00	117.00	135.00	175.00	231.00
RDICAVS	R dICA - peak systolic velocity	1313	164.32	35.58	50.00	111.00	139.00	162.00	186.00	231.00	300.00
RDICAVD	R dICA - peak diastolic velocity	1313	81.97	23.53	20.00	49.00	66.00	79.00	95.00	129.00	171.00
RDICAPI	R dICA - pulsatility index	1313	0.71	0.13	0.35	0.51	0.62	0.70	0.79	0.95	1.25
RDICARI	R dICA - resistivity index	1313	0.50	0.06	0.29	0.40	0.46	0.50	0.55	0.61	0.69

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
RPCAD	R PCA - depth	1301	61.57	3.68	48.00	56.00	60.00	62.00	64.00	68.00	82.00
RPCAVM	R PCA - TAMM velocity	1301	85.72	24.38	32.00	50.00	68.00	83.00	100.00	129.00	195.00
RPCAVS	R PCA - peak systolic velocity	1301	119.59	31.68	46.00	72.00	97.00	117.00	138.00	175.00	249.00
RPCAVD	R PCA - peak diastolic velocity	1301	58.35	18.68	19.00	32.00	46.00	56.00	70.00	92.00	141.00
RPCAPI	R PCA - pulsatility index	1301	0.73	0.14	0.41	0.54	0.63	0.71	0.80	0.98	1.53
RPCARI	R PCA - resistivity index	1301	0.51	0.06	0.33	0.42	0.47	0.51	0.55	0.63	0.74

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
RTOBD	R TOB- depth	1245	64.59	3.43	54.00	60.00	62.00	64.00	66.00	70.00	84.00
RTOBVM	R TOB- TAMM velocity	1245	83.45	22.99	25.00	50.00	67.00	80.00	99.00	124.00	172.00
RTOBVS	R TOB - peak systolic velocity	1245	116.32	29.97	39.00	71.00	95.00	112.00	135.00	169.00	236.00
RTOBVD	R TOB - peak diastolic velocity	1245	56.69	17.44	16.00	31.00	44.00	55.00	68.00	88.00	130.00
RTOBPI	R TOB - pulsatility index	1245	0.73	0.14	0.44	0.54	0.63	0.71	0.81	0.97	1.45
RTOBRI	R TOB - resistivity index	1245	0.51	0.06	0.36	0.42	0.47	0.51	0.55	0.62	0.77

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
BASD	BAS - depth	1310	75.06	2.07	62.00	72.00	74.00	74.00	76.00	78.00	82.00
BASVM	BAS - TAMM velocity	1310	-87.30	22.62	-233.00	-127.00	-101.00	-85.00	-72.00	-56.00	-19.00
BASVS	BAS - peak systolic velocity	1310	-117.02	28.35	-276.00	-165.00	-134.00	-115.00	-97.00	-77.00	-28.00
BASVD	BAS - peak diastolic velocity	1310	-62.11	17.85	-192.00	-93.00	-72.00	-60.00	-50.00	-37.00	-14.00
BASPI	BAS - pulsatility index	1310	0.64	0.11	0.26	0.47	0.56	0.63	0.71	0.85	1.13
BASRI	BAS - resistivity index	1310	0.47	0.06	0.23	0.38	0.43	0.47	0.51	0.57	0.68

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
LM1D	L M1 - depth	1326	37.74	2.37	28.00	34.00	36.00	38.00	40.00	40.00	44.00
LM1VM	L M1 - TAMM velocity	1326	96.96	26.13	23.00	56.00	77.00	97.00	114.00	142.00	192.00
LM1VS	L M1 - peak systolic velocity	1326	136.00	34.00	35.00	80.00	112.00	136.00	159.00	193.00	250.00
LM1VD	L M1 - peak diastolic velocity	1326	66.32	20.39	13.00	36.00	52.00	65.00	79.00	102.00	147.00
LM1PI	L M1 - pulsatility index	1326	0.73	0.14	0.38	0.54	0.64	0.72	0.81	0.99	1.42
LM1RI	L M1 - resistivity index	1326	0.52	0.06	0.31	0.42	0.47	0.51	0.55	0.62	0.75

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
LMCAD	L MCA - depth	1342	50.19	3.61	40.00	44.00	48.00	50.00	52.00	56.00	62.00
LMCAVM	L MCA - TAMM velocity	1342	142.89	28.98	45.00	97.00	123.00	141.00	162.00	192.00	261.00
LMCAVS	L MCA - peak systolic velocity	1342	195.35	35.96	63.00	136.00	171.00	195.00	220.00	255.00	326.00
LMCAVD	L MCA - peak diastolic velocity	1342	100.16	23.68	33.00	65.00	85.00	99.00	114.00	144.00	208.00
LMCAPI	L MCA - pulsatility index	1342	0.68	0.11	0.38	0.50	0.60	0.67	0.75	0.88	1.15
LMCARI	L MCA - resistivity index	1342	0.49	0.06	0.32	0.40	0.45	0.49	0.53	0.58	0.67

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
LBIFD	L BIF - depth	1339	54.50	3.18	44.00	50.00	52.00	54.00	56.00	60.00	70.00
LBIFVM	L BIF - TAMM velocity	1339	136.17	28.90	48.00	92.00	115.00	133.00	157.00	186.00	274.00
LBIFVS	L BIF - peak systolic velocity	1339	185.95	34.49	67.00	132.00	162.00	184.00	211.00	243.00	330.00
LBIFVD	L BIF - peak diastolic velocity	1339	95.24	23.70	34.00	59.00	79.00	92.00	109.00	136.00	223.00
LBIFPI	L BIF - pulsatility index	1339	0.68	0.12	0.37	0.49	0.60	0.67	0.75	0.89	1.21
LBIFRI	L BIF - resistivity index	1339	0.49	0.06	0.31	0.39	0.46	0.49	0.53	0.58	0.69

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
LACAD	L ACA - depth	1296	59.01	3.31	46.00	54.00	56.00	58.00	62.00	64.00	74.00
LACAVM	L ACA - TAMM velocity	1296	-105.57	28.77	-228.00	-154.00	-124.00	-106.00	-83.00	-61.00	-34.00
LACAVS	L ACA - peak systolic velocity	1296	-145.84	35.31	-274.00	-204.00	-169.00	-147.00	-120.50	-89.00	-50.00
LACAVD	L ACA - peak diastolic velocity	1296	-72.53	23.15	-172.00	-112.00	-88.00	-71.00	-55.00	-39.00	-13.00
LACAPI	L ACA - pulsatility index	1296	0.71	0.15	0.30	0.50	0.61	0.70	0.81	0.97	1.96
LACARI	L ACA - resistivity index	1296	0.51	0.07	0.26	0.39	0.46	0.51	0.55	0.62	0.84

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
LDICAD	L dICA - depth	1300	58.58	3.26	48.00	54.00	56.00	58.00	60.00	64.00	78.00
LDICAVM	L dICA - TAMM velocity	1300	122.06	30.97	50.00	74.00	100.00	120.00	141.00	178.00	238.00
LDICAVS	L dICA - peak systolic velocity	1300	167.85	37.91	67.00	105.00	141.00	168.00	192.00	234.00	303.00
LDICAVD	L dICA - peak diastolic velocity	1300	84.76	25.00	29.00	49.00	67.00	82.00	99.00	133.00	193.00
LDICAPI	L dICA - pulsatility index	1300	0.70	0.13	0.34	0.50	0.61	0.69	0.77	0.92	1.34
LDICARI	L dICA - resistivity index	1300	0.50	0.06	0.30	0.40	0.46	0.50	0.54	0.60	0.71

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
LPCAD	L PCA - depth	1291	61.62	3.53	50.00	56.00	60.00	62.00	64.00	68.00	76.00
LPCAVM	L PCA - TAMM velocity	1291	85.06	23.51	35.00	52.00	67.00	83.00	99.00	127.00	178.00
LPCAVS	L PCA - peak systolic velocity	1291	118.28	30.32	46.00	73.00	95.00	116.00	137.00	171.00	226.00
LPCAVD	L PCA - peak diastolic velocity	1291	58.33	18.52	21.00	31.00	44.00	56.00	70.00	92.00	139.00
LPCAPI	L PCA - pulsatility index	1291	0.72	0.14	0.39	0.53	0.61	0.70	0.81	0.97	1.49
LPCARI	L PCA - resistivity index	1291	0.51	0.07	0.32	0.41	0.46	0.50	0.55	0.62	0.73

	RIGHT						LEFT					
VESSEL	Depth	Vm	Vs	Vd	PI	RI	Depth	Vm	Vs	Vd	PI	RI
M1	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
MCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BIF	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
ACA	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __
DICA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
PCA	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
TOB	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __	__ __	__ __ __	__ __ __	__ __ __	__ . __ __	__ . __ __
BAS	__ __	- __ __ __	- __ __ __	- __ __ __	__ . __ __	__ . __ __						

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
LTOBD	L TOB - depth	1249	64.65	3.30	54.00	60.00	62.00	64.00	66.00	70.00	78.00
LTOBVM	L TOB - TAMM velocity	1249	82.63	22.41	31.00	50.00	67.00	80.00	96.00	123.00	162.00
LTOBVS	L TOB - peak systolic velocity	1249	114.42	28.66	43.00	70.00	93.00	112.00	133.00	166.00	210.00
LTOBVD	L TOB - peak diastolic velocity	1249	56.90	17.70	19.00	31.00	45.00	55.00	68.00	89.00	129.00
LTOBPI	L TOB - pulsatility index	1249	0.71	0.14	0.39	0.51	0.61	0.69	0.78	0.96	1.27
LTOBRI	L TOB - resistivity index	1249	0.51	0.07	0.33	0.40	0.46	0.50	0.55	0.62	0.72

Variable	Label	N	Mean	Std Dev	Minimum	5th Ptcl	25th Pctl	Median	75th Pctl	95th Pctl	Maximum
Maxvelr	<created variable> TAMM velocity - right side (M1,MCA,dICA,BIF)	1318	141.44	27.92	68.00	102.00	121.00	138.00	157.00	195.00	237.00
maxvell	<created variable> TAMM velocity - left side (M1,MCA,dICA,BIF)	1318	147.49	29.38	74.00	102.00	127.00	146.00	166.00	201.00	274.00
maxvel	<created variable> TAMM velocity (M1,MCA,dICA,BIF)	1318	154.51	28.45	83.00	112.00	135.00	151.00	172.00	205.00	274.00

STOP II
NON-STOP II TRANSCRANIAL DOPPLER (TCD) EXAMS

A. Collection Information:
The **non-STOP II Transcranial Doppler (TCD) exam** dataset includes results of non-STOP/non-STOP II abnormal TCD exams completed prior to the start of transfusion for Potential patients who had no STOP or STOP II TCDs prior to starting transfusion. TCDs qualifying patients for treatment with transfusion for this subgroup of patients were sent to the STOP II TCD Reading Center for central reading. Electronic files containing STOP II ID information, date of the TCD, centrally interpreted TCD results (max velocity, location of the max velocity) for each TCD were sent to the Data Coordinating Center. Only patients with documented abnormal STOP or STOP II TCDs prior to the start of transfusion OR those whose non-STOP/STOP II TCDs prior to the start of transfusion were determined to be abnormal (using STOP II criteria) by the STOP II Reading Center were eligible for enrollment as Potential patients in STOP II.

B. Data Collection Period: July 1998 through October 2000

C. Form Version Dates: n/a

D. Files Used to Store Information:

SAS System File: **PnonSTOP2TCDs_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EXAM_DATFRMRAND**

Records in the dataset are sorted by LDU_ID and EXAM_DATFRMRAND.

F. Number of Observations (Patients) in SAS Dataset: 16 (9)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 86
- Listing of Variables by Position: See p. 86

H. Formats: N/A

I. Special Value Codes: N/A

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables: N/A

Data Set Name	PUBDS.PNONSTOP2TCDS_FINAL	Observations	16
Member Type	DATA	Variables	4
Engine	V9	Indexes	0
Created	Thu, Feb 23, 2006 03:50:06 PM	Observation Length	40
Last Modified	Thu, Feb 23, 2006 03:50:06 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	4096
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	101
Obs in First Data Page	16
Number of Data Set Repairs	0
File Name	P:\Stop2\Data Manual\Public Use\PU Data Sets\pnonstop2tcds_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
1	MAX_VEL	Num	8	12.	Maximum Velocity
2	VESSEL	Char	12		Vessel with Maximum Velocity
4	exam_datfrmrand	Num	8		<created variable> Date of TCD exam as days from RAND visit
3	ldu_id	Char	10		ID for public use datasets

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	MAX_VEL	Num	8	12.	Maximum Velocity
2	VESSEL	Char	12		Vessel with Maximum Velocity
3	ldu_id	Char	10		ID for public use datasets
4	exam_datfrmrand	Num	8		<created variable> Date of TCD exam as days from RAND visit

Sort Information

Sortedby	ldu_id exam_datfrmrand
Validated	YES
Character Set	ANSI

Analysis Variable : exam_datfrmrand <created variable> Date of TCD exam as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
16	0	-1291	204.0	-1640	-1388	-1327	-1111	-1000

Analysis Variable : MAX_VEL Maximum Velocity								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
16	0	207.7	11.0	200.0	200.0	203.0	211.5	240.0

Vessel with Maximum Velocity				
VESSEL	Frequency	Percent	Cum Freq	Cum Percent
LBIF	1	6.25	1	6.25
LMCA	11	68.75	12	75.00
LdICA	1	6.25	13	81.25
RMCA	3	18.75	16	100.00

STOP II

FORM 03: TREATMENT DECISION BY PARENT-GUARDIAN OF NEWLY IDENTIFIED CHILD WITH TWO ABNORMAL TCDS OR ONE ABNORMAL TCD WITH TAMM VELOCITY ≥ 220 CM/SEC

A. Collection Information:
The **Treatment Decision by Parent-Guardian** (Form 03) was to be completed during the screening period for any STOP II Roster patient not yet on chronic transfusion that was newly identified as having two abnormal TCDs or one abnormal TCD with TAMM velocity ≥ 220 cm/sec.

B. Data Collection Period: December 2000 through July 2002

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p003_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 17 (17)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 90
- Listing of Variables by Position: See p. 91

H. Formats:
The file **f003fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 92.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPEs for Form 3 are:
  - RT for routine visits - Initial TCD screening exam, and all subsequent TCD exams for patients with no prior abnormal TCD results. Form 3s with EX_TYPE=RT indicate patients whose first abnormal TCD exam was one where the associated TCD velocity was ≥ 220 cm/sec, qualifying the patient for transfusion without a confirmatory (CS) TCD exam.
  - CS for confirmatory visits - all subsequent TCD screening exams for patients with a previous exam with abnormal results that were between 200-219 cm/sec.

- **EX_NUM** – is the variable name for exam number. The valid EX_NUMs for Form 3 are:
  - 100 series numbers were assigned to “Screening” patient visits – i.e., TCD screening visits completed before the patient started transfusions and enrolled as a potential trial patient. The EX_NUM on Form 3 corresponds with the EX_NUM of the TCD exam which qualified the patient for transfusion.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

Data Set Name	PUBDS.P003_FINAL	Observations	17
Member Type	DATA	Variables	12
Engine	V9	Indexes	0
Created	Friday, January 27, 2006 03:07:00 PM	Observation Length	176
Last Modified	Friday, January 27, 2006 03:07:00 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	92
Obs in First Data Page	17
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p003_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
5	DECISION	Num	8	3.	B1. Transfusion elected for primary stroke prevention?
4	DESTATUS	Char	1	$1.	DESTATUS
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
3	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
6	REASON1	Num	8	3.	B1a1. Reason for decision (1)
7	REASON2	Num	8	3.	B1a2. Reason for decision (2)
8	REASON3	Num	8	3.	B1a3. Reason for decision (3)
9	SP_OTHR	Char	100	$100.	B1a4. Specify other reason child not placed on transfusion
12	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
11	ldu_id	Char	10		ID for public use datasets
10	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
4	DESTATUS	Char	1	$1.	DESTATUS
5	DECISION	Num	8	3.	B1. Transfusion elected for primary stroke prevention?
6	REASON1	Num	8	3.	B1a1. Reason for decision (1)
7	REASON2	Num	8	3.	B1a2. Reason for decision (2)
8	REASON3	Num	8	3.	B1a3. Reason for decision (3)
9	SP_OTHR	Char	100	$100.	B1a4. Specify other reason child not placed on transfusion
10	vistype	Char	7		<created variable> VISIT TYPE
11	ldu_id	Char	10		ID for public use datasets
12	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F003fmts.txt;

proc format;

  value DECISIONF
    1='1: No'
    2='2: Yes';

  value REASON1F
    1='1: Concerns about transfusion safety'
    2='2: Difficulty participating in program/anticipated compliance problems'
    3='3: Family/patient not convinced that transfusion is needed'
    4='4: Other';

  value REASON2F
    1='1: Concerns about transfusion safety'
    2='2: Difficulty participating in program/anticipated compliance problems'
    3='3: Family/patient not convinced that transfusion is needed'
    4='4: Other';

  value REASON3F
    1='1: Concerns about transfusion safety'
    2='2: Difficulty participating in program/anticipated compliance problems'
    3='3: Family/patient not convinced that transfusion is needed'
    4='4: Other';

* format decision decisionf. reason1 reason1f. reason2 reason2f. reason3 reason3f.;
```

STOP II

TREATMENT DECISION BY PARENT-GUARDIAN OF NEWLY IDENTIFIED CHILD WITH TWO ABNORMAL TCDS OR ONE ABNORMAL TCD WITH TAMM VELOCITY ≥ 220 CM/SEC

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	17	100.00	17	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
CS-102	5	29.41	5	29.41
CS-103	4	23.53	9	52.94
CS-104	2	11.76	11	64.71
CS-106	1	5.88	12	70.59
RT-101	4	23.53	16	94.12
RT-103	1	5.88	17	100.00

A1. Person completing form (Name) _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
17	0	-990.4	40.6	-1105	-1008	-985.0	-960.0	-939.0

B. TREATMENT DECISION

B1. Did the parent/guardian elect to place child on transfusion for primary stroke prevention?

☐ **1. NO** →

B1.a Reason:

- ☐ **1. Concerns about transfusion safety**
- ☐ **2. Difficulty participating in program/ anticipated compliance problems**
- ☐ **3. Family/patient not convinced that transfusion is needed**
- ☐ **4. Other:** _____

☐ **2. YES** →

COMPLETE STOP II ELIGIBILITY QUESTIONNAIRE (FORM 01B)

B1. Transfusion elected for primary stroke prevention?

DECISION	Frequency	Percent	Cum Freq	Cum Percent
2	17	100.00	17	100.00

B1a1. Reason for decision (1)

REASON1	Frequency	Percent	Cum Freq	Cum Percent
-2	17	100.00	17	100.00

B1a2. Reason for decision (2)

REASON2	Frequency	Percent	Cum Freq	Cum Percent
-2	17	100.00	17	100.00

B1a3. Reason for decision (3)

REASON3	Frequency	Percent	Cum Freq	Cum Percent
-2	17	100.00	17	100.00

B1a4. Specify other reason child not placed on transfusion

SP_OTHR	Frequency	Percent	Cum Freq	Cum Percent
-2	17	100.00	17	100.00

STOP II

FORM 5: SIGNED ACKNOWLEDGEMENT OF NEW INFORMATION ABOUT THE STOP II STUDY

A. Collection Information:

The **Signed Acknowledgement of New Information about the STOP II Study** (Form 5) was to be completed for randomized patients who were active at the time the trial ended on MM/DD/YY to confirm receipt of new information concerning the early termination of the study and exit visit requirements. At the end of the trial on MM/DD/YY, 72 randomized patients were active.

B. Data Collection Period: November 2004 through March 2005

C. Form Version Dates: 11/15/04

D. Files Used to Store Information:

SAS System File: **p005_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 69 (69)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 97
- Listing of Variables by Position: See p. 98

H. Formats: N/A

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

Data Set Name	PUBDS.P005_FINAL	Observations	69
Member Type	DATA	Variables	8
Engine	V9	Indexes	0
Created	Friday, January 27, 2006 03:19:32 PM	Observation Length	64
Last Modified	Friday, January 27, 2006 03:19:32 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	8192
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	127
Obs in First Data Page	69
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p005_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
2	DESTATUS	Char	1	$1.	DESTATUS
1	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
4	copytoptfrmrand	Num	8		<created variable> A1. Date copy given to parent as days from RAND visit
8	daterecfrmrand	Num	8		<created variable> A5. Date received as days from RAND visit
3	ldu_id	Char	10		ID for public use datasets
5	parentsigfrmrand	Num	8		<created variable> A2. Date parent signed acknowledgement as days from RAND visit
6	patientsigfrmrand	Num	8		<created variable> A3. Date patient signed acknowledgement as days from RAND visit
7	picompdfrmrand	Num	8		<created variable> A4. Date PI signed acknowledgement as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
2	DESTATUS	Char	1	$1.	DESTATUS
3	ldu_id	Char	10		ID for public use datasets
4	copytoptfrmrand	Num	8		<created variable> A1. Date copy given to parent as days from RAND visit
5	parentsigfrmrand	Num	8		<created variable> A2. Date parent signed acknowledgement as days from RAND visit
6	patientsigfrmrand	Num	8		<created variable> A3. Date patient signed acknowledgement as days from RAND visit
7	picompdfrmrand	Num	8		<created variable> A4. Date PI signed acknowledgement as days from RAND visit
8	daterecfrmrand	Num	8		<created variable> A5. Date received as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

STOP II
Randomized Patients

SIGNED ACKNOWLEDGEMENT OF NEW INFORMATION ABOUT THE STOP II STUDY

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	69	100.00	69	100.00

PATIENT ID # _____ *[Data not shown for variable LDU_ID.]* _____ _____

ACROSTIC _____ *[Variable NOT included in dataset.]* _____ _____

BIRTHDATE: _____ *[Not entered in Form 5 dataset. See Roster dataset.]* _____

The above STOP II Randomized patient was given a copy of the 11/22/04 "Acknowledgement of New Information about the STOP II Study" on ___ ___ / ___ ___ / ___ ___ ___ ___.

Analysis Variable : copytoptfrmrand <created variable> A1. Date copy given to parent as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
69	0	779.9	437.7	73.0	363.0	1005.0	1145.0	1330.0

☐ The Parent/Legal Guardian of the patient signed the 11/22/04 "Acknowledgement of New Information about the STOP II Study" on ___ ___ / ___ ___ / ___ ___ ___ ___ ☐ Check here if not signed because of subject's age

Analysis Variable : parentsigfrmrand <created variable> A2. Date parent signed acknowledgement as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
60	0	738.7	439.5	73.0	283.0	861.0	1129.5	1330.0

<created variable> A2. Date parent signed acknowledgement as days from RAND visit				
parentsigfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	9	100.00	9	100.00

☐ The Patient signed the 11/22/04 "Acknowledgement of New Information About the STOP II Study" on
___ ___ / ___ ___ / ___ ___ ___ ___ ☐ Check here if not signed because of subject's age

Analysis Variable : patientsigfrmrand <created variable> A3. Date patient signed acknowledgement as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
44	0	856.5	409.3	97.0	406.5	1037.0	1172.5	1330.0

<created variable> A3. Date patient signed acknowledgement as days from RAND visit				
patientsigfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	25	100.00	25	100.00

Comments (optional):
[Not entered in Form 5 dataset.]

Signature of STOP II Principal Investigator _____

Date form completed: ___ ___ / ___ ___ / ___ ___ ___ ___

Analysis Variable : picompdfrmrand <created variable> A4. Date PI signed acknowledgement as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
69	0	784.7	437.6	73.0	365.0	1005.0	1153.0	1330.0

Fax completed form to: Dianne Gallagher • Fax Number: 617-923-4176

Date received at DCC: ___ ___ / ___ ___ / ___ ___ ___ ___

Analysis Variable : daterecfrmrand <created variable> A5. Date received as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
69	0	788.3	438.9	73.0	365.0	1006.0	1153.0	1330.0

STOP II
FORM 6: POST-TRIAL TREATMENT DECISION FORM

A. Collection Information:
The **Post-Trial Treatment Decision Form** (Form 6) was to be completed for randomized patients who were active at the time the trial ended on MM/DD/YY to document their treatment decisions after the end of the study. At the end of the trial on MM/DD/YY, 72 randomized patients were active.

B. Data Collection Period: December 2004 through March 2005

C. Form Version Dates: 12/15/04

D. Files Used to Store Information:

SAS System File: **p006_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 70 (70)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 103
- Listing of Variables by Position: See p. 104

H. Formats:
The file **f006fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 105.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

Data Set Name	PUBDS.P006_FINAL	Observations	70
Member Type	DATA	Variables	11
Engine	V9	Indexes	0
Created	Friday, January 27, 2006 03:59:45 PM	Observation Length	88
Last Modified	Friday, January 27, 2006 03:59:45 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	8192
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	92
Obs in First Data Page	63
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p006_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
6	CUR_CHEL	Num	8	3.	C3. Is patient currently receiving chelation
5	CUR_HU	Num	8	3.	C2. Is patient currently receiving hydroxyurea
8	DESTATUS	Char	1	$1.	DESTATUS
7	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
1	RECREGTR	Num	8	3.	B1. On MM/DD/YY, was patient receiving regular transfusions
4	REC_HU	Num	8	3.	C1. On MM/DD/YY, was patient receiving hydroxyurea
2	TX_DEC1	Num	8	3.	B1a. Treatment decision for this patient was
3	TX_DEC2	Num	8	3.	B1b. Treatment decision for this patient was
10	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
11	hu_datefrmrand	Num	8		<created variable> C2a. Date hydroxyurea started as days from RAND visit
9	ldu_id	Char	10		ID for public use datasets

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	RECREGTR	Num	8	3.	B1. On MM/DD/YY, was patient receiving regular transfusions
2	TX_DEC1	Num	8	3.	B1a. Treatment decision for this patient was
3	TX_DEC2	Num	8	3.	B1b. Treatment decision for this patient was
4	REC_HU	Num	8	3.	C1. On MM/DD/YY, was patient receiving hydroxyurea
5	CUR_HU	Num	8	3.	C2. Is patient currently receiving hydroxyurea
6	CUR_CHEL	Num	8	3.	C3. Is patient currently receiving chelation
7	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
8	DESTATUS	Char	1	$1.	DESTATUS
9	ldu_id	Char	10		ID for public use datasets
10	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
11	hu_datefrmrand	Num	8		<created variable> C2a. Date hydroxyurea started as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F006fmts.txt;

proc format;

  value CUR_CHELF
    1='1: No'
    2='2: Yes';

  value CUR_HUF
    1='1: No'
    2='2: Yes';

  value REC_HUF
    1='1: No'
    2='2: Yes';

  value RECREGTRF
    1='1: No'
    2='2: Yes';

  value TX_DEC1F
    1='1: Restart transfusions'
    2='2: Remain off of transfusions';

  value TX_DEC2F
    1='1: Continue transfusions'
    2='2: Discontinue transfusions';

* format cur_chel cur_chelf. cur_hu cur_huf. rec_hu rec_huf. recregtr recregtrf. tx_dec1 tx_dec1f. tx_dec2
tx_dec2f.;
```

STOP II

TREATMENT DECISION AFTER TRIAL END

AFFIX PATIENT LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	70	100.00	70	100.00

A1. Person completing form (Name): _____ ___ ___ ___
PRINT FULL NAME INITIALS

[Variable NOT included in dataset.]

A2. Date of form completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
70	0	821.3	432.4	115.0	392.0	1028.0	1174.0	1399.0

B. TREATMENT BEFORE AND AFTER TRIAL END ON MM/DD/YY

B1. On MM/DD/YY, was the patient receiving regular transfusions?

NO ..... 1 (**GO TO B1a**) YES ..... 2 (**SKIP TO B1b**)

B1. On MM/DD/YY, was patient receiving regular transfusions				
RECREGTR	Frequency	Percent	Cum Freq	Cum Percent
1	22	31.43	22	31.43
2	48	68.57	70	100.00

a. After the trial end, the treatment decision for this patient was to

RESTART TRANSFUSIONS.....1

REMAIN OFF OF TRANSFUSIONS.....2

SKIP TO C1

B1a. Treatment decision for this patient was				
TX_DEC1	Frequency	Percent	Cum Freq	Cum Percent
-2	48	68.57	48	68.57
1	11	15.71	59	84.29
2	11	15.71	70	100.00

b. After the trial end, the treatment decision for this patient was to

CONTINUE TRANSFUSIONS.....1

DISCONTINUE TRANSFUSIONS.....2

B1b. Treatment decision for this patient was				
TX_DEC2	Frequency	Percent	Cum Freq	Cum Percent
-2	22	31.43	22	31.43
1	42	60.00	64	91.43
2	6	8.57	70	100.00

C. OTHER TREATMENT

C1. On MM/DD/YY, was the patient receiving hydroxyurea?

NO ..... 1 YES 2

C1. On MM/DD/YY, was patient receiving hydroxyurea				
REC_HU	Frequency	Percent	Cum Freq	Cum Percent
1	64	91.43	64	91.43
2	6	8.57	70	100.00

C2. Is the patient currently receiving hydroxyurea?

NO ..... 1 (**SKIP TO C3**) YES 2

a. Date hydroxyurea started ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

C2. Is patient currently receiving hydroxyurea				
CUR_HU	Frequency	Percent	Cum Freq	Cum Percent
1	60	85.71	60	85.71
2	10	14.29	70	100.00

Analysis Variable : hu_datefrmrand <created variable> C2a. Date hydroxyurea started as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
10	0	753.6	458.7	105.0	203.0	979.5	1085.0	1320.0

<created variable> C2a. Date hydroxyurea started as days from RAND visit				
hu_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	60	100.00	60	100.00

C3. Is the patient currently receiving chelation?

NO.....1 YES.....2

C3. Is patient currently receiving chelation				
CUR_CHEL	Frequency	Percent	Cum Freq	Cum Percent
1	24	34.29	24	34.29
2	46	65.71	70	100.00

STOP II
FORM 10: TRIAL RANDOMIZATION FORM

A. Collection Information:
The **Trial Randomization Form** (Form 10) was to be completed at the time of randomization to confirm patient eligibility and consent to participate in the trial.

B. Data Collection Period: April 2001 through October 12, 2004

C. Form Version Dates (**VER_ID**): "A" 11/15/00
"B" 01/12/04

SUMMARY OF VERSION DIFFERENCES

Version Date	
01/12/04	• Question B6. "Did the patient have two normal TCD exams..." wording changed from "with the most recent one being within 6 months of today's date?" to "being within 4 months". • Added question D2.b. "Has the patient/patient's parent or legal guardian agreed to allow serum and DNA samples to be collected, stored, and used for sickle cell research?" • Removed Section F: Follow-up Status of Patients who are Ineligible for Randomization

D. Files Used to Store Information:

SAS System File: **p010_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 80 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 111-112
- Listing of Variables by Position: See pp. 112-113

H. Formats:
The file **f010fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + “F” – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are “$”+variable name+”F” – e.g., the format label for a variable named “RATING” where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 114-115.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPE for Form 10 is QT for quarterly or entry visits.

- **EX_NUM** – is the variable name for exam number.
  - For Form 10 an EX_NUM=401 is the randomization visit.
  - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months.
    - For Form 10, any EX_NUM with a 300 series number indicates a form completed for a Potential 2 patient that was ineligible for or refused randomization at the time the form was completed.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **DNA_SAMP, DNASAMP1** - are the variable names for serum and DNA sample consent. This question (D2.b) was new on version B of Form 10. Variable DNA_SAMP displays responses from question D2.b for patients randomized with form version B. Variable DNASAMP1 is a created variable (indicated in the contents by "<created variable>" in the label) that captures serum and DNA consent information for all randomized patients as collected in an external source file compiled by the Core Laboratory.

Data Set Name	PUBDS.P010_FINAL	Observations	80
Member Type	DATA	Variables	32
Engine	V9	Indexes	0
Created	Wednesday, March 08, 2006 09:42:13 AM	Observation Length	232
Last Modified	Wednesday, March 08, 2006 09:42:13 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	70
Obs in First Data Page	46
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p010_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
5	ABN_CONF	Num	8	3.	B3. Has the DCC confirmed qualifying TCD exams?
6	AGE_RANG	Num	8	3.	B4. Is the patient's age 4.5 - 20 years?
10	BAD_MRA	Num	8	3.	C2. Evidence on MRA of moderate to severe disease?
20	CONF_NUM	Num	8	5.	E4. Confirmation number
16	CONSENT	Num	8	3.	D2. Informed consent document for randomization read and signed?
17	CONSREAS	Num	8	3.	D2a. Please specify reason
22	CONS_POT	Num	8	3.	F1a. Consent for follow-up as potential candidate signed?
23	CONT_POT	Num	8	3.	F1b. Consent for continuing follow-up as potential patient?
25	DESTATUS	Char	1	$1.	DESTATUS
4	DIAG_HBS	Num	8	3.	B2. Was the diagnosis confirmed?
29	DNASAMP1	Char	3	$3.	<created variable> D2b. Has patient's parent agreed to allow serum and DNA samples?
26	DNA_SAMP	Num	8	3.	D2b. Has patient's parent agreed to allow serum and DNA samples?
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
24	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
19	GROUP2	Num	8	3.	E3. Trial group assigned
9	HX_STROK	Num	8	3.	C1. Prior history of clinical stroke (adjudicated)?
14	MED_CND2	Num	8	3.	C6. Any medical condition preventing continuation?
13	MED_COND	Num	8	3.	C5. Any other condition precluding discontinuation?
8	NORMCONF	Num	8	3.	B6. Did patient have two normal TCD exams, one within 4 months
11	OTH_PROT	Num	8	3.	C3. Patient participating in any other study?
12	OTH_RX	Num	8	3.	C4. Patient receiving clinical treatment?

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
18	PIS_CONF	Num	8	3.	E1. Was eligibility confirmed by Principal Investigators?
21	PREV_POT	Num	8	3.	F1. Patient previously enrolled as a potential patient?
15	PT_ELIG	Num	8	3.	D1. Is the patient eligible for randomization?
3	STOPRAND	Num	8	3.	B1. Was the patient randomized in the STOP Trial?
7	TR_CONF	Num	8	3.	B5. Has the DCC confirmed compliance with transfusion?
28	VER_ID	Char	1	$1.	Form Version
31	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
30	ldu_id	Char	10		ID for public use datasets
32	random_dfrmrand	Num	8		<created variable> E2. Date patient randomized as days from RAND visit
27	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	STOPRAND	Num	8	3.	B1. Was the patient randomized in the STOP Trial?
4	DIAG_HBS	Num	8	3.	B2. Was the diagnosis confirmed?
5	ABN_CONF	Num	8	3.	B3. Has the DCC confirmed qualifying TCD exams?
6	AGE_RANG	Num	8	3.	B4. Is the patient's age 4.5 - 20 years?
7	TR_CONF	Num	8	3.	B5. Has the DCC confirmed compliance with transfusion?
8	NORMCONF	Num	8	3.	B6. Did patient have two normal TCD exams, one within 4 months
9	HX_STROK	Num	8	3.	C1. Prior history of clinical stroke (adjudicated)?
10	BAD_MRA	Num	8	3.	C2. Evidence on MRA of moderate to severe disease?
11	OTH_PROT	Num	8	3.	C3. Patient participating in any other study?
12	OTH_RX	Num	8	3.	C4. Patient receiving clinical treatment?
13	MED_COND	Num	8	3.	C5. Any other condition precluding discontinuation?
14	MED_CND2	Num	8	3.	C6. Any medical condition preventing continuation?
15	PT_ELIG	Num	8	3.	D1. Is the patient eligible for randomization?
16	CONSENT	Num	8	3.	D2. Informed consent document for randomization read and signed?
17	CONSREAS	Num	8	3.	D2a. Please specify reason
18	PIS_CONF	Num	8	3.	E1. Was eligibility confirmed by Principal Investigators?
19	GROUP2	Num	8	3.	E3. Trial group assigned
20	CONF_NUM	Num	8	5.	E4. Confirmation number
21	PREV_POT	Num	8	3.	F1. Patient previously enrolled as a potential patient?
22	CONS_POT	Num	8	3.	F1a. Consent for follow-up as potential candidate signed?
23	CONT_POT	Num	8	3.	F1b. Consent for continuing follow-up as potential patient?
24	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
25	DESTATUS	Char	1	$1.	DESTATUS
26	DNA_SAMP	Num	8	3.	D2b. Has patient's parent agreed to allow serum and DNA samples?
27	vistype	Char	7		<created variable> VISIT TYPE
28	VER_ID	Char	1	$1.	Form Version
29	DNASAMP1	Char	3	$3.	<created variable> D2b. Has patient's parent agreed to allow serum and DNA samples?

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
30	ldu_id	Char	10		ID for public use datasets
31	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
32	random_ dfrmrand	Num	8		<created variable> E2. Date patient randomized as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*F010fmts.txt;

proc format;

  value STOPRANDF
    1='1: No'
    2='2: Yes';

  value DIAG_HBSF
    1='1: No'
    2='2: Yes';

  value ABN_CONFF
    1='1: No'
    2='2: Yes';

  value AGE_RANGF
    1='1: No'
    2='2: Yes';

  value TR_CONFF
    1='1: No'
    2='2: Yes';

  value NORMCONFF
    1='1: No'
    2='2: Yes';

  value HX_STROKF
    1='1: No'
    2='2: Yes';

  value BAD_MRAF
    1='1: No'
    2='2: Yes';

  value OTH_PROTF
    1='1: No'
    2='2: Yes';

  value OTH_RXF
    1='1: No'
    2='2: Yes';

  value MED_CONDF
    1='1: No'
    2='2: Yes';

  value MED_CND2F
    1='1: No'
    2='2: Yes';

  value PT_ELIGF
    1='1: No'
    2='2: Yes';
```

```
value CONSENTF
  1='1: No'
  2='2: Yes';

value CONSREASF
  1='1: Fear of stroke'
  2='2: Other';

value PIS_CONFF
  1='1: No'
  2='2: Yes';

value GROUP2F
  1='1: Continuation of transfusion'
  2='2: Discontinuation of transfusion';

value PREV_POTF
  1='1: No'
  2='2: Yes';

value CONS_POTF
  1='1: No'
  2='2: Yes';

value CONT_POTF
  1='1: No'
  2='2: Yes';

value DNA_SAMPF
  1='1: No'
  2='2: Yes';

* format stoprand stoprandf. diag_hbs diag_hbsf. abn_conf abn_conff. age_rang age_rangf. tr_conf
tr_conff. normconf normconff. hx_strok hx_strokf. bad_mra bad_mraf. oth_prot oth_protf. oth_rx oth_rxf.
med_cond med_condf. med_cnd2 med_cnd2f. pt_elig pt_eligf. consent consentf. consreas consreasf.
pis_conf pis_conff. group2 group2f. prev_pot prev_potf. cons_pot cons_potf. cont_pot cont_potf.
dna_samp dna_sampf.;
```

STOP II TRIAL

TRIAL RANDOMIZATION FORM

****AFFIX PATIENT LABEL HERE*****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	80	100.00	80	100.00

Form Version				
VER_ID	Frequency	Percent	Cum Freq	Cum Percent
A	62	77.50	62	77.50
B	18	22.50	80	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-304	1	1.25	1	1.25
QT-401	79	98.75	80	100.00

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
80	0	-2.7	24.3	-217.0	0.0	0.0	0.0	0.0

******PLEASE ANSWER NO OR YES TO EACH OF THE QUESTIONS IN SECTIONS B & C******

B. INCLUSION CRITERIA

1. NO **2. YES**

B1. Was the patient randomized in the STOP Trial?

B1. Was the patient randomized in the STOP Trial?				
STOPRAND	Frequency	Percent	Cum Freq	Cum Percent
1	38	47.50	38	47.50
2	42	52.50	80	100.00

↓
GO TO B4

B2. Was the diagnosis of HbSS or HbS/β^0 thalassemia confirmed?

B2. Was the diagnosis confirmed?				
DIAG_HBS	Frequency	Percent	Cum Freq	Cum Percent
-2	42	52.50	42	52.50
2	38	47.50	80	100.00

B3. Has the DCC confirmed that the patient had two TCD examinations with flow velocities $\geq$ 200 cm/second or one exam with velocity $\geq$ 220 cm/second determined by the STOP/STOP II TCD Reading Center before starting transfusions?

B3. Has the DCC confirmed qualifying TCD exams?				
ABN_CONF	Frequency	Percent	Cum Freq	Cum Percent
-2	42	52.50	42	52.50
2	38	47.50	80	100.00

B4. Is the patient's age in the range of 4.5 through 20 years?

B4. Is the patient's age 4.5 - 20 years?				
AGE_RANG	Frequency	Percent	Cum Freq	Cum Percent
2	80	100.00	80	100.00

B5. Has the STOP II DCC confirmed compliance with transfusion for $\geq$ 30 months as specified in the research protocol?

B5. Has the DCC confirmed compliance with transfusion?				
TR_CONF	Frequency	Percent	Cum Freq	Cum Percent
2	80	100.00	80	100.00

B6. Did the patient have two normal TCD exams as determined by the STOP/STOP II TCD Reading Center, at least two weeks apart, while on transfusion with the most recent one being within 4 months of today's date?

[Comment: On version A of form used prior to 01/12/04, question was whether most recent TCD was "within 6 months."]

B6. Did patient have two normal TCD exams, one within 4 months				
NORMCONF	Frequency	Percent	Cum Freq	Cum Percent
2	80	100.00	80	100.00

IF THE ANSWER TO ANY OF QUESTIONS B2-B6 IS NO, THE PATIENT IS NOT ELIGIBLE FOR RANDOMIZATION. GO TO SECTION D

[Section C specify field variables NOT included in dataset.]

C. EXCLUSION CRITERIA

1. NO 2. YES

C1. Does the patient have a prior history of clinical stroke adjudicated by the STOP or STOP II Endpoint Adjudication Panel?

C1. Prior history of clinical stroke (adjudicated)?				
HX_STROK	Frequency	Percent	Cum Freq	Cum Percent
1	80	100.00	80	100.00

C2. Does the patient have evidence on MRA of moderate to severe intracranial arterial disease as determined by the STOP II MR Review Panel?

C2. Evidence on MRA of moderate to severe disease?				
BAD_MRA	Frequency	Percent	Cum Freq	Cum Percent
1	80	100.00	80	100.00

C3. Is the patient participating in any study involving treatments which might confound the interpretation of the results of STOP II?

C3.a. **IF YES**, specify study _____

C3. Patient participating in any other study?				
OTH_PROT	Frequency	Percent	Cum Freq	Cum Percent
1	80	100.00	80	100.00

1. NO **2. YES**

C4. Is the patient receiving clinical treatment which might confound the interpretation of the results of STOP II? ☐ ☐

C4.a. **IF YES**, specify treatment _____

C4. Patient receiving clinical treatment?				
OTH_RX	Frequency	Percent	Cum Freq	Cum Percent
1	80	100.00	80	100.00

C5. Does the patient have any other medical condition which would preclude discontinuation of transfusion? ☐ ☐

C5.a. **IF YES**, specify condition _____

C5. Any other medical condition precluding discontinuation?				
MED_COND	Frequency	Percent	Cum Freq	Cum Percent
1	80	100.00	80	100.00

C6. Does the patient have any medical condition that would prevent continuation of transfusion? ☐ ☐

C6.a. **IF YES**, specify condition _____

C6. Any medical condition preventing continuation?				
MED_CND2	Frequency	Percent	Cum Freq	Cum Percent
1	80	100.00	80	100.00

IF THE ANSWER TO ANY OF THE QUESTIONS IN SECTION C IS YES, THE PATIENT IS NOT ELIGIBLE FOR RANDOMIZATION. GO TO SECTION D

D. DETERMINATION OF RANDOMIZATION ELIGIBILITY

D1. Is the patient eligible for randomization?

☐ **1. NO** → **STOP - FORM COMPLETE**

☐ **2. YES** → **CONTINUE TO QUESTION D2**

D1. Is the patient eligible for randomization?				
PT_ELIG	Frequency	Percent	Cum Freq	Cum Percent
2	80	100.00	80	100.00

[Comment: On version A of form used prior to 01/12/04, if D1=1 then form proceeded to Section F.]

D2. Has the patient/patient's parent or legal guardian read and signed the informed consent document for randomization?

☐ **1. NO** →

D2.a. **Please specify reason:**

☐ **1. Fear of stroke**

☐ **2. Other** → D2.a1. Specify _____

STOP - FORM COMPLETE

[Specify field variable NOT included in dataset.]

☐ **2. YES** →

D2.b. Has the patient/patient's parent or legal guardian agreed to allow serum and DNA samples to be collected, stored, and used for sickle cell research?

☐ **1. NO**

☐ **2. YES**

D2. Informed consent document for randomization read and signed?				
CONSENT	Frequency	Percent	Cum Freq	Cum Percent
1	1	1.25	1	1.25
2	79	98.75	80	100.00

D2a. Please specify reason				
CONSREAS	Frequency	Percent	Cum Freq	Cum Percent
-2	79	98.75	79	98.75
2	1	1.25	80	100.00

D2.b. Has the patient/patient's parent or legal guardian agreed to allow serum and DNA samples to be collected, stored, and used for sickle cell research?

☐ **1. NO**

☐ **2. YES**

[Comment: Question D2.b was not on version A. Variable DNA_SAMP displays reponses from question D2.b for patients randomized with form version B. Variable DNASAMP1 was created to capture serum and DNA consent information for all randomized patients as collected in an external source file compiled by the Core Laboratory.]

D2b. Has patient's parent agreed to allow serum and DNA samples?				
DNA_SAMP	Frequency	Percent	Cum Freq	Cum Percent
.	62	77.50	62	77.50
1	1	1.25	63	78.75
2	17	21.25	80	100.00

<created variable> D2b. Has patient's parent agreed to allow serum and DNA samples?				
DNASAMP1	Frequency	Percent	Cum Freq	Cum Percent
no	14	17.50	14	17.50
yes	66	82.50	80	100.00

E. RANDOMIZATION (ELIGIBLE PATIENTS ONLY) – TO BE COMPLETED AT TIME OF CALL TO DCC TO RANDOMIZE PATIENTS

E1. Was eligibility confirmed by the CAC and DCC Principal Investigators?
(YES to questions B2 – B6, and NO to all questions in Section C)

☐ **1. NO** → **STOP - FORM COMPLETE**

☐ **2. YES** → **CONTINUE TO QUESTION E2**

E1. Was eligibility confirmed by Principal Investigators?				
PIS_CONF	Frequency	Percent	Cum Freq	Cum Percent
-2	1	1.25	1	1.25
2	79	98.75	80	100.00

E2. Date Patient Randomized ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : random_dfrmrand <created variable> E2. Date patient randomized as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
79	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

<created variable> E2. Date patient randomized as days from RAND visit				
random_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

E3. Trial Group Assigned ☐ **1. Continuation of Transfusion** ☐ **2. Discontinuation of Transfusion**

E3. Trial group assigned				
GROUP2	Frequency	Percent	Cum Freq	Cum Percent
-2	1	1.25	1	1.25
1	38	47.50	39	48.75
2	41	51.25	80	100.00

E4. Confirmation Number ☐☐☐☐

[Variable NOT included in dataset.]

[Comment: Section F was removed on Version B dated 01/12/04.]

SECTION F. FOLLOW-UP STATUS OF PATIENTS WHO ARE INELIGIBLE FOR RANDOMIZATION

F1. Was the patient previously enrolled as a Potential patient (consent form signed)?

☐ **1. NO** →

F1.a Did the patient's parent or legal guardian read and sign the informed consent document for follow-up as a potential candidate for randomization?

☐ **1. NO**

☐ **2. YES**

☐ **2. YES** →

F1.b Did the patient/parent consent to continuing follow-up as a Potential patient?

☐ **1. NO**

☐ **2. YES**

F1. Patient previously enrolled as a potential patient?

PREV_POT	Frequency	Percent	Cum Freq	Cum Percent
.	18	22.50	18	22.50
-2	62	77.50	80	100.00

F1a. Consent for follow-up as potential candidate signed?

CONS_POT	Frequency	Percent	Cum Freq	Cum Percent
.	18	22.50	18	22.50
-2	62	77.50	80	100.00

F1b. Consent for continuing follow-up as potential patient?

CONT_POT	Frequency	Percent	Cum Freq	Cum Percent
.	18	22.50	18	22.50
-2	62	77.50	80	100.00

Signature of Study Coordinator: _____Date: ___ ___/___ ___/___ ___ ___ __

STOP II

FORM 11: INTAKE HISTORY FORM FOR PATIENTS ENROLLED AS POTENTIALS OR RANDOMIZED PATIENTS

A. Collection Information:
The **Intake History Form for Patients Enrolled as Potentials or Randomized Patients** (Form 11) was to be completed once at a patient's first entry visit as a Potential 1 (QT-201) or Potential 2 (QT-301) patient. Potential patients were enrolled between December 2000 and July 2002.

B. Data Collection Period: December 2000 through July 2002.

C. Form Version Dates: "11/15/00"
"12/15/00"

SUMMARY OF VERSION DIFFERENCES

Version Date	
12/15/00	• Question numbers corrected for C3.a1-C3.c8 • Section title added "D. Family History of Stroke" • Question E4.b1 added • Question numbers added for E6.b1, E7.b1, E8.b1, E13.b1, E19.b2, E19.c2 • Questions E19.b1 and E19.c1 added • Question numbers corrected in section F2 • Added "Attach Red Cell Phenotype Report" after section F2

D. Files Used to Store Information:

SAS System File: **p011_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 79 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 127-129
- Listing of Variables by Position: See pp. 130-132

H. Formats:

The file **f011fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + “F” – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are “$”+variable name+”F” – e.g., the format label for a variable named “RATING” where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 133-140.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The only valid EX_TYPE for Form 11 is QT.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 11 are:
  - EX_NUM=201 is the entry quarterly visit for Potential 1 patients (patients on transfusion for less than 30 months)
  - EX_NUM=301 is the entry quarterly visit for Potential 2 patients (patients on transfusion for greater than 30 months)

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **OT1_MEDS, OT2_MEDS** - are the variable names for other medication. Where more than one medication is listed on a line that were taken for a different number of months as listed for OT1_MTHS or OT2 _MTHS, the medication taken for a shorter time was listed second and months taken were annotated as (#) after the medication name.

- **LUNGCODE, CHD_CODE, CLD_CODE, RENALCOD** - are the variable names for ICD-9 codes for other medical conditions. These variables require the ICD-9 Codebook Diseases section for interpretation. Code boxes are labeled "Office Use" on the form.

Data Set Name	PUBDS.P011_FINAL	Observations	79
Member Type	DATA	Variables	128
Engine	V9	Indexes	0
Created	Monday, February 06, 2006 03:31:10 PM	Observation Length	1520
Last Modified	Monday, February 06, 2006 03:31:10 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	9
First Data Page	2
Max Obs per Page	10
Obs in First Data Page	10
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p011_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
22	ACS	Num	8	3.	C1. 2 or more episodes of Acute Chest Syndrome (pneumonia)
48	ANECROS	Num	8	3.	E2. Aseptic Necrosis
106	ANTI_C	Num	8	3.	G1b. anti-C
105	ANTI_D	Num	8	3.	G1a. anti-D
107	ANTI_E	Num	8	3.	G1c. anti-E
111	ANTI_FYA	Num	8	3.	G1g. anti-Fya
112	ANTI_FYB	Num	8	3.	G1h. anti-Fyb
113	ANTI_JKB	Num	8	3.	G1i. anti-Jkb
110	ANTI_K	Num	8	3.	G1f. anti-K (Kell)
114	ANTI_LEA	Num	8	3.	G1j. anti-Lea
115	ANTI_LEB	Num	8	3.	G1k. anti-Leb
108	ANTI_M	Num	8	3.	G1d. anti-M
116	ANTI_OTH	Num	8	3.	G1l. Other antibody
109	ANTI_S	Num	8	3.	G1e. anti-S
5	ANY_MEDS	Num	8	3.	B1. Patient currently taking medication.
28	APLASTIC	Num	8	3.	C3a3. Aplastic Crisis
54	ASTHMA	Num	8	3.	E5. Asthma
4	A_T_VERI	Num	8	3.	A4. Address and telephone verified
76	BLOODGRP	Num	8	3.	F2a. ABO Blood Group
55	CHD	Num	8	3.	E6. Chronic Heart Disease
57	CHD_CODE	Num	8	7.2	E6b1. Code for Chronic Heart Disease
56	CHD_TYPE	Char	50	$50.	E6b. Type of Chronic Heart Disease
51	CHR_LUNG	Num	8	3.	E4. Chronic Lung Disease
58	CHR_LVRD	Num	8	3.	E7. Chronic Liver Disease
61	CHR_RNLD	Num	8	3.	E8. Chronic Renal Disease
60	CLD_CODE	Num	8	7.2	E7b1. Code for Chronic Liver Disease

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
59	C_LVRTYP	Char	50	$50.	E7b. Type of Chronic Liver Disease
62	C_RNLTYP	Char	50	$50.	E8b. Type of Chronic Renal Disease
125	DESTATUS	Char	1	$1.	DESTATUS
67	DIABETES	Num	8	3.	E10. Diabetes
64	DIALYSIS	Num	8	3.	E8c. Currently receiving Dialysis
90	DUF_FYA	Num	8	3.	F2d1. Fya
91	DUF_FYB	Num	8	3.	F2d2. Fyb
71	ELEVLEAD	Num	8	3.	E15. Elevated Blood Lead Level
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
66	FERRITIN	Num	8	6.	E9b. Highest level of Ferritin
11	FOLATE	Num	8	3.	B1a3. Taking Folate
12	FOL_MTHS	Num	8	4.	B1b3. Number of months taking Folate
124	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
121	HEPBVACC	Num	8	3.	H1. Hepatitis B vaccination
72	HEP_B	Num	8	3.	E16. Hepatitis B
73	HEP_C	Num	8	3.	E17. Hepatitis C
13	HU	Num	8	3.	B1a4. Taking Hydroxyurea
14	HU_MTHS	Num	8	4.	B1b4. Number of months taking Hydroxyurea
30	H_F_SYND	Num	8	3.	C3a4. Hand-Foot Syndrome
3	INTERVIW	Num	8	3.	A3. Person interviewed
15	IRONCHEL	Num	8	3.	B1a5. Taking Iron Chelators (Desferoxamine)
16	IRON_MTH	Num	8	4.	B1b5. Number of months taking Iron Chelators (Desferoxamine)
65	IRON_OL	Num	8	3.	E9. Iron Overload
86	KELL_JSA	Num	8	3.	F2c3. Jsa
87	KELL_JSB	Num	8	3.	F2c4. Jsb
85	KELL_K	Num	8	3.	F2c2. k
84	KELL_KEL	Num	8	3.	F2c1. K (Kell)
88	KELL_KPA	Num	8	3.	F2c5. Kpa
89	KELL_KPB	Num	8	3.	F2c6. Kpb
92	KID_JKA	Num	8	3.	F2e1. Jka
93	KID_JKB	Num	8	3.	F2e2. Jkb
47	LEGULCER	Num	8	3.	E1. Leg Ulcers
94	LEW_LEA	Num	8	3.	F2f1. Lea
95	LEW_LEB	Num	8	3.	F2f2. Leb
41	LIVER_BX	Num	8	3.	C4b. Had a Liver Biopsy
53	LUNGCODE	Num	8	7.2	E4b1. Code for Chronic Lung Disease
52	LUNGTYPE	Char	50	$50.	E4b. Type of Chronic Lung Disease
98	LUTH_LU3	Num	8	3.	F2g3. Lu3
96	LUTH_LUA	Num	8	3.	F2g1. Lua
97	LUTH_LUB	Num	8	3.	F2g2. Lub
24	MENINGIT	Num	8	3.	C3a1. Meningitis
103	MNS_A_S	Num	8	3.	F2i4. s
100	MNS_M	Num	8	3.	F2i1. M
101	MNS_N	Num	8	3.	F2i2. N
102	MNS_S	Num	8	3.	F2i3. S
104	MNS_U	Num	8	3.	F2i5. U
49	NECR_LOC	Char	50	$50.	E2b. Location of Aseptic Necrosis
122	NONSTSIT	Num	8	3.	I1. Seen at Non-STOP II site
34	OSTEOMYL	Num	8	3.	C3a6. Osteomyelitis
18	OT1_MEDS	Char	75	$75.	B1a6a. Specify Other Medication

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
19	OT1_MTHS	Num	8	4.	B1b6a. Number of months taking medication
20	OT2_MEDS	Char	75	$75.	B1a6b. Specify other medication
21	OT2_MTHS	Num	8	4.	B1b6b. Number of months taking medication
74	OTHCOND	Num	8	3.	E19. Other Chronic Medical Condition
117	OTHER1	Char	50	$50.	G1l1. Specify first other antibody
118	OTHER2	Char	50	$50.	G1l2. Specify second other antibody
119	OTHER3	Char	50	$50.	G1l3. Specify third other antibody
8	OTH_ANTI	Num	8	3.	B1a2. Taking other Antibiotic
17	OTH_MEDS	Num	8	3.	B1a6. Taking Other Medication
10	O_ANTMTH	Num	8	4.	B1b2. Months taking other Antibiotic
9	O_ANTSPE	Char	50	$50.	B1a2a. Specify other Antibiotic
99	P1_ANTIG	Num	8	3.	F2h1. P1
23	PAINHOSP	Num	8	3.	C2. Number of times hospitalized for pain events
6	PENICILN	Num	8	3.	B1a1. Taking Penicillin
7	PEN_MTHS	Num	8	4.	B1b1. Number of months taking penicillin
123	PHEN_SRC	Num	8	3.	J1. Red cell phenotyping report
42	PORTCATH	Num	8	3.	C5. Have a Portacath
70	PRIAPISM	Num	8	3.	E14. Priapism
36	PRIAPSM	Num	8	3.	C3a7. Priapism
63	RENALCOD	Num	8	7.2	E8b1. Code for Chronic Renal Disease
81	RHANT_C	Num	8	3.	F2b5. Rh Antigens c
80	RHANT_E	Num	8	3.	F2b4. Rh Antigens e
68	RHEU_FVR	Num	8	3.	E11. Rheumatic Fever
78	RH_ANT_C	Num	8	3.	F2b2. Rh Antigens C
77	RH_ANT_D	Num	8	3.	F2b1. Rh Antigens D
79	RH_ANT_E	Num	8	3.	F2b3. Rh Antigens E
82	RH_ANT_F	Num	8	3.	F2b6. Rh Antigens f
83	RH_ANT_V	Num	8	3.	F2b7. Rh AntigensV
50	SC_RETIN	Num	8	3.	E3. Sickle Cell Retinopathy
29	SEENAPLS	Num	8	3.	C3c3. Where seen for Aplastic Crisis
31	SEENHFS	Num	8	3.	C3c4. Where seen for Hand-Foot Syndrome
25	SEENMENI	Num	8	3.	C3c1. Where seen for Meningitis
35	SEENOSTE	Num	8	3.	C3c6. Where seen for Osteomyelitis
37	SEENPRIA	Num	8	3.	C3c7. Where seen for Priapism
39	SEENREAC	Num	8	3.	C3c8. Where seen for Transfusion Reaction
33	SEENSEPT	Num	8	3.	C3c5. Where seen for Septicemia
27	SEENSPLN	Num	8	3.	C3c2. Where seen for Splenic Sequestration
32	SEPTICEM	Num	8	3.	C3a5. Septicemia
40	SPLENECT	Num	8	3.	C4a. Had a Splenectomy
26	SPLENICS	Num	8	3.	C3a2. Splenic Sequestration
75	STOPRAND	Num	8	3.	F1. Randomized in STOP
45	STR_BROT	Num	8	3.	D1c. Child's brother had a stroke
44	STR_FATH	Num	8	3.	D1b. Child's father had a stroke
43	STR_MOTH	Num	8	3.	D1a. Child's mother had a stroke
46	STR_SIST	Num	8	3.	D1d. Child's sister had a stroke
120	TRANREAC	Num	8	3.	G3. Transfusion Reaction
69	TUBERCUL	Num	8	3.	E12. Tuberculosis
38	T_REACTN	Num	8	3.	C3a8. Transfusion Reaction
128	comp_ dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
127	ldu_id	Char	10		ID for public use datasets
126	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	INTERVIW	Num	8	3.	A3. Person interviewed
4	A_T_VERI	Num	8	3.	A4. Address and telephone verified
5	ANY_MEDS	Num	8	3.	B1. Patient currently taking medication.
6	PENICILN	Num	8	3.	B1a1. Taking Penicillin
7	PEN_MTHS	Num	8	4.	B1b1. Number of months taking penicillin
8	OTH_ANTI	Num	8	3.	B1a2. Taking other Antibiotic
9	O_ANTSPE	Char	50	$50.	B1a2a. Specify other Antibiotic
10	O_ANTMTH	Num	8	4.	B1b2. Months taking other Antibiotic
11	FOLATE	Num	8	3.	B1a3. Taking Folate
12	FOL_MTHS	Num	8	4.	B1b3. Number of months taking Folate
13	HU	Num	8	3.	B1a4. Taking Hydroxyurea
14	HU_MTHS	Num	8	4.	B1b4. Number of months taking Hydroxyurea
15	IRONCHEL	Num	8	3.	B1a5. Taking Iron Chelators (Desferoxamine)
16	IRON_MTH	Num	8	4.	B1b5. Number of months taking Iron Chelators (Desferoxamine)
17	OTH_MEDS	Num	8	3.	B1a6. Taking Other Medication
18	OT1_MEDS	Char	75	$75.	B1a6a. Specify Other Medication
19	OT1_MTHS	Num	8	4.	B1b6a. Number of months taking medication
20	OT2_MEDS	Char	75	$75.	B1a6b. Specify other medication
21	OT2_MTHS	Num	8	4.	B1b6b. Number of months taking medication
22	ACS	Num	8	3.	C1. 2 or more episodes of Acute Chest Syndrome (pneumonia)
23	PAINHOSP	Num	8	3.	C2. Number of times hospitalized for pain events
24	MENINGIT	Num	8	3.	C3a1. Meningitis
25	SEENMENI	Num	8	3.	C3c1. Where seen for Meningitis
26	SPLENICS	Num	8	3.	C3a2. Splenic Sequestration
27	SEENSPLN	Num	8	3.	C3c2. Where seen for Splenic Sequestration
28	APLASTIC	Num	8	3.	C3a3. Aplastic Crisis
29	SEENAPLS	Num	8	3.	C3c3. Where seen for Aplastic Crisis
30	H_F_SYND	Num	8	3.	C3a4. Hand-Foot Syndrome
31	SEENHFS	Num	8	3.	C3c4. Where seen for Hand-Foot Syndrome
32	SEPTICEM	Num	8	3.	C3a5. Septicemia
33	SEENSEPT	Num	8	3.	C3c5. Where seen for Septicemia
34	OSTEOMYL	Num	8	3.	C3a6. Osteomyelitis
35	SEENOSTE	Num	8	3.	C3c6. Where seen for Osteomyelitis
36	PRIAPSM	Num	8	3.	C3a7. Priapism
37	SEENPRIA	Num	8	3.	C3c7. Where seen for Priapism
38	T_REACTN	Num	8	3.	C3a8. Transfusion Reaction
39	SEENREAC	Num	8	3.	C3c8. Where seen for Transfusion Reaction
40	SPLENECT	Num	8	3.	C4a. Had a Splenectomy
41	LIVER_BX	Num	8	3.	C4b. Had a Liver Biopsy
42	PORTCATH	Num	8	3.	C5. Have a Portacath
43	STR_MOTH	Num	8	3.	D1a. Child's mother had a stroke
44	STR_FATH	Num	8	3.	D1b. Child's father had a stroke
45	STR_BROT	Num	8	3.	D1c. Child's brother had a stroke
46	STR_SIST	Num	8	3.	D1d. Child's sister had a stroke
47	LEGULCER	Num	8	3.	E1. Leg Ulcers
48	ANECROS	Num	8	3.	E2. Aseptic Necrosis
49	NECR_LOC	Char	50	$50.	E2b. Location of Aseptic Necrosis
50	SC_RETIN	Num	8	3.	E3. Sickle Cell Retinopathy
51	CHR_LUNG	Num	8	3.	E4. Chronic Lung Disease

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
52	LUNGTYPE	Char	50	$50.	E4b. Type of Chronic Lung Disease
53	LUNGCODE	Num	8	7.2	E4b1. Code for Chronic Lung Disease
54	ASTHMA	Num	8	3.	E5. Asthma
55	CHD	Num	8	3.	E6. Chronic Heart Disease
56	CHD_TYPE	Char	50	$50.	E6b. Type of Chronic Heart Disease
57	CHD_CODE	Num	8	7.2	E6b1. Code for Chronic Heart Disease
58	CHR_LVRD	Num	8	3.	E7. Chronic Liver Disease
59	C_LVRTYP	Char	50	$50.	E7b. Type of Chronic Liver Disease
60	CLD_CODE	Num	8	7.2	E7b1. Code for Chronic Liver Disease
61	CHR_RNLD	Num	8	3.	E8. Chronic Renal Disease
62	C_RNLTYP	Char	50	$50.	E8b. Type of Chronic Renal Disease
63	RENALCOD	Num	8	7.2	E8b1. Code for Chronic Renal Disease
64	DIALYSIS	Num	8	3.	E8c. Currently receiving Dialysis
65	IRON_OL	Num	8	3.	E9. Iron Overload
66	FERRITIN	Num	8	6.	E9b. Highest level of Ferritin
67	DIABETES	Num	8	3.	E10. Diabetes
68	RHEU_FVR	Num	8	3.	E11. Rheumatic Fever
69	TUBERCUL	Num	8	3.	E12. Tuberculosis
70	PRIAPISM	Num	8	3.	E14. Priapism
71	ELEVLEAD	Num	8	3.	E15. Elevated Blood Lead Level
72	HEP_B	Num	8	3.	E16. Hepatitis B
73	HEP_C	Num	8	3.	E17. Hepatitis C
74	OTHCOND	Num	8	3.	E19. Other Chronic Medical Condition
75	STOPRAND	Num	8	3.	F1. Randomized in STOP
76	BLOODGRP	Num	8	3.	F2a. ABO Blood Group
77	RH_ANT_D	Num	8	3.	F2b1. Rh Antigens D
78	RH_ANT_C	Num	8	3.	F2b2. Rh Antigens C
79	RH_ANT_E	Num	8	3.	F2b3. Rh Antigens E
80	RHANT_E	Num	8	3.	F2b4. Rh Antigens e
81	RHANT_C	Num	8	3.	F2b5. Rh Antigens c
82	RH_ANT_F	Num	8	3.	F2b6. Rh Antigens f
83	RH_ANT_V	Num	8	3.	F2b7. Rh AntigensV
84	KELL_KEL	Num	8	3.	F2c1. K (Kell)
85	KELL_K	Num	8	3.	F2c2. k
86	KELL_JSA	Num	8	3.	F2c3. Jsa
87	KELL_JSB	Num	8	3.	F2c4. Jsb
88	KELL_KPA	Num	8	3.	F2c5. Kpa
89	KELL_KPB	Num	8	3.	F2c6. Kpb
90	DUF_FYA	Num	8	3.	F2d1. Fya
91	DUF_FYB	Num	8	3.	F2d2. Fyb
92	KID_JKA	Num	8	3.	F2e1. Jka
93	KID_JKB	Num	8	3.	F2e2. Jkb
94	LEW_LEA	Num	8	3.	F2f1. Lea
95	LEW_LEB	Num	8	3.	F2f2. Leb
96	LUTH_LUA	Num	8	3.	F2g1. Lua
97	LUTH_LUB	Num	8	3.	F2g2. Lub
98	LUTH_LU3	Num	8	3.	F2g3. Lu3
99	P1_ANTIG	Num	8	3.	F2h1. P1
100	MNS_M	Num	8	3.	F2i1. M
101	MNS_N	Num	8	3.	F2i2. N
102	MNS_S	Num	8	3.	F2i3. S

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
103	MNS_A_S	Num	8	3.	F2i4. s
104	MNS_U	Num	8	3.	F2i5. U
105	ANTI_D	Num	8	3.	G1a. anti-D
106	ANTI_C	Num	8	3.	G1b. anti-C
107	ANTI_E	Num	8	3.	G1c. anti-E
108	ANTI_M	Num	8	3.	G1d. anti-M
109	ANTI_S	Num	8	3.	G1e. anti-S
110	ANTI_K	Num	8	3.	G1f. anti-K (Kell)
111	ANTI_FYA	Num	8	3.	G1g. anti-Fya
112	ANTI_FYB	Num	8	3.	G1h. anti-Fyb
113	ANTI_JKB	Num	8	3.	G1i. anti-Jkb
114	ANTI_LEA	Num	8	3.	G1j. anti-Lea
115	ANTI_LEB	Num	8	3.	G1k. anti-Leb
116	ANTI_OTH	Num	8	3.	G1l. Other antibody
117	OTHER1	Char	50	$50.	G1l1. Specify first other antibody
118	OTHER2	Char	50	$50.	G1l2. Specify second other antibody
119	OTHER3	Char	50	$50.	G1l3. Specify third other antibody
120	TRANREAC	Num	8	3.	G3. Transfusion Reaction
121	HEPBVACC	Num	8	3.	H1. Hepatitis B vaccination
122	NONSTSIT	Num	8	3.	I1. Seen at Non-STOP II site
123	PHEN_SRC	Num	8	3.	J1. Red cell phenotyping report
124	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
125	DESTATUS	Char	1	$1.	DESTATUS
126	vistype	Char	7		<created variable> VISIT TYPE
127	ldu_id	Char	10		ID for public use datasets
128	comp_ dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F011fmts.txt;

proc format;

  value INTERVIWF
    1='1: Patient'
    2='2: Parent'
    3='3: Legal Guardian'
    4='4: Other';

  value A_T_VERIF
    1='1: No'
    2='2: Yes';

  value ANY_MEDSF
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    2='2: Yes';

  value OTH_ANTIF
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    2='2: Yes';

  value FOLATEF
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    2='2: Yes';

  value HUF
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    2='2: Yes';

  value IRONCHELF
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    2='2: Yes';

  value OTH_MEDSF
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    2='2: Yes'

  value ACSF
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    2='2: Yes';

  value MENINGITF
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    2='2: Yes';

  value PENICILNF
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    2='2: Yes';

  value SEENMENIF
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    2='2: Non-STOP II Center';
```

```
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  2='2: Yes';

value SEENSPLNF
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  2='2: Non-STOP II Center';

value APLASTICF
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  2='2: Yes';

value SEENAPLSF
  1='1: STOP II Center'
  2='2: Non-STOP II Center';

value H_F_SYNDF
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  2='2: Yes';

value SEENHFSF
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  2='2: Non-STOP II Center';

value SEPTICEMF
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  2='2: Yes';

value SEENSEPTF
  1='1: STOP II Center'
  2='2: Non-STOP II Center';

value OSTEOMYLF
  1='1: No'
  2='2: Yes';

value SEENOSTEF
  1='1: STOP II Center'
  2='2: Non-STOP II Center';

value SEENPRIAF
  1='1: STOP II Center'
  2='2: Non-STOP II Center';

value T_REACTNF
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  2='2: Yes';

value SEENREACF
  1='1: STOP II Center'
  2='2: Non-STOP II Center';

value SPLENECTF
  1='1: No'
  2='2: Yes';
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```
value LIVER_BXF
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  2='2: Yes';

value PORTCATHF
  1='1: No'
  2='2: Yes';

value STR_MOTHF
  1='1: No'
  2='2: Yes'
  3='3: Don't know';

value STR_FATHF
  1='1: No'
  2='2: Yes'
  3='3: Don't know';

value STR_BROTF
  1='1: No'
  2='2: Yes'
  3='3: Don't know'
  4='4: NA- no brothers';

value STR_SISTF
  1='1: No'
  2='2: Yes'
  3='3: Don't know'
  4='4: NA- no sisters';

value LEGULCERF
  1='1: No'
  2='2: Yes';

value ANECROSF
  1='1: No'
  2='2: Yes';

value SC_RETINF
  1='1: No'
  2='2: Yes';

value CHR_LUNGF
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  2='2: Yes';

value ASTHMAF
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  2='2: Yes';

value CHDF
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  2='2: Yes';
```

```
value CHR_LVRDF
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  2='2: Yes';

value CHR_RNLDF
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value DIALYSISF
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value IRON_OLF
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  2='2: Yes';

value DIABETESF
  1='1: No'
  2='2: Yes';

value RHEU_FVRF
  1='1: No'
  2='2: Yes';

value TUBERCULF
  1='1: No'
  2='2: Yes';

value ELEVLEADF
  1='1: No'
  2='2: Yes';

value HEP_CF
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  2='2: Yes';

value OTHCONDF
  1='1: No'
  2='2: Yes';

value STOPRANDF
  1='1: No'
  2='2: Yes';

value BLOODGRPF
  1='1: A'
  2='2: B'
  3='3: AB'
  4='4: O';

value RH_ANT_DF
  1='1: Absent'
  2='2: Present';
```

```
value RH_ANT_CF
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value RH_ANT_EF
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  2='2: Present';

value RHANT_EF
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  2='2: Present';

value RHANT_CF
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  2='2: Present';

value RH_ANT_FF
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  2='2: Present';

value RH_ANT_VF
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  2='2: Present';

value KELL_KELF
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  2='2: Present';

value KELL_KF
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value KELL_JSAF
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  2='2: Present';

value KELL_JSBF
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  2='2: Present';

value KELL_KPAF
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  2='2: Present';

value KELL_KPBF
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  2='2: Present';

value DUF_FYAF
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  2='2: Present';

value DUF_FYBF
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  2='2: Present';
```

```
value KID_JKAF
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  2='2: Present';

value KID_JKBF
  1='1: Absent'
  2='2: Present';

value LEW_LEAF
  1='1: Absent'
  2='2: Present';

value LEW_LEBF
  1='1: Absent'
  2='2: Present';

value LUTH_LUAF
  1='1: Absent'
  2='2: Present';

value LUTH_LUBF
  1='1: Absent'
  2='2: Present';

value LUTH_LU3F
  1='1: Absent'
  2='2: Present';

value P1_ANTIGF
  1='1: Absent'
  2='2: Present';

value MNS_MF
  1='1: Absent'
  2='2: Present';

value MNS_NF
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  2='2: Present';

value MNS_SF
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  2='2: Present';

value MNS_A_SF
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  2='2: Present';

value MNS_UF
  1='1: Absent'
  2='2: Present';

value ANTI_DF
  1='1: No'
  2='2: Yes';
```

```
value ANTI_CF
  1='1: No'
  2='2: Yes';

value ANTI_EF
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  2='2: Yes';

value ANTI_MF
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  2='2: Yes';

value ANTI_SF
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  2='2: Yes';

value ANTI_KF
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  2='2: Yes';

value ANTI_FYAF
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  2='2: Yes';

value ANTI_FYBF
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  2='2: Yes';

value ANTI_JKBF
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value ANTI_LEAF
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value ANTI_LEBF
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  2='2: Yes';

value ANTI_OTHF
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  2='2: Yes';

value TRANREACF
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  2='2: Yes'
  3='3: Don't Know';

value HEPBVACCF
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  2='2: Yes';

value NONSTSITF
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  2='2: Yes';
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```
 value PHEN_SRCF
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 value HEP_BF
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   2='2: Yes';

 value PRIAPISMF
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   2='2: Yes';

 value PRIAPSMF
   1='1: No'
   2='2: Yes';
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* format interviw interviwf. a_t_veri a_t_verif. any_meds any_medsf. oth_anti oth_antif. folate folatef. hu huf. ironchel ironchelf. oth_meds oth_medsf. acs acsf. meningit meningitf. peniciln penicilnf. seenmeni seenmenif. splenics splenicsf. seenspln seensplnf. aplastic aplasticf. seenapls seenaplsf. h_f_synd h_f_syndf. seenhfs seenhfsf. septicem septicemf. seensept seenseptf. osteomyl osteomylf. seenoste seenostef. seenpria seenpriaf. t_reactn t_reactnf. seenreac seenreacf. splenect splenectf. liver_bx liver_bxf. portcath portcathf. str_moth str_mothf. str_fath str_fathf. str_brot str_brotf. str_sist str_sistf. legulcer legulcerf. anecros anecrosf. sc_retin sc_retinf. chr_lung chr_lungf. asthma asthmaf. chd chdf. chr_lvrd chr_lvrdf. chr_rnld chr_rnldf. dialysis dialysisf. iron_ol iron_olf. diabetes diabetesf. rheu_fvr rheu_fvrf. tubercul tuberculf. elevlead elevleadf. hep_c hep_cf. othcond othcondf. stoprand stoprandf. bloodgrp bloodgrpf. rh_ant_d rh_ant_df. rh_ant_c rh_ant_cf. rh_ant_e rh_ant_ef. rhant_e rhant_ef. rhant_c rhant_cf. rh_ant_f rh_ant_ff. rh_ant_v rh_ant_vf. kell_kel kell_kelf. kell_k kell_kf. kell_jsa kell_jsaf. kell_jsb kell_jsbf. kell_kpa kell_kpaf. kell_kpb kell_kpbf. duf_fya duf_fyaf. duf_fyb duf_fybf. kid_jka kid_jkaf. kid_jkb kid_jkbf. lew_lea lew_leaf. lew_leb lew_lebf. luth_lua luth_luaf. luth_lub luth_lubf. luth_lu3 luth_lu3f. P1_antig P1_antigf. mns_m mns_mf. mns_n mns_nf. mns_s mns_sf. mns_a_s mns_a_sf. mns_u mns_uf. anti_d anti_df. anti_c anti_cf. anti_e anti_ef. anti_m anti_mf. anti_s anti_sf. anti_k anti_kf. anti_fya anti_fyaf. anti_fyb anti_fybf. anti_jkb anti_jkbf. anti_lea anti_leaf. anti_leb anti_lebf. anti_oth anti_othf. tranreac tranreacf. hepbvacc hepbvaccf. nonstsit nonstsitf. phen_src phen_srcf. hep_b hep_bf. priapism priapismf. priapsm priapsmf.;

STOP II

INTAKE HISTORY FORM FOR PATIENTS ENROLLED AS POTENTIALS OR RANDOMIZED PATIENTS

***** AFFIX PATIENT LABEL HERE *****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	76	96.20	76	96.20
P	3	3.80	79	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-201	33	41.77	33	41.77
QT-301	46	58.23	79	100.00

A1. Person completing form (Name):_____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of interview (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
79	0	-488.9	377.4	-1343	-931.0	-334.0	-170.0	225.0

A3. Person interviewed (Choose **ONE** for person providing majority of answers to sections B-D):

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Legal Guardian** ☐ **4. Other** → A3.a (specify): _____

A3. Person interviewed				
INTERVIW	Frequency	Percent	Cum Freq	Cum Percent
1	6	7.59	6	7.59
2	65	82.28	71	89.87
4	8	10.13	79	100.00

[Specify field variable NOT included in dataset.]

A4. Were address and telephone information verified for this patient? ☐ **1. NO** ☐ **2. YES**

A4. Address and telephone verified				
A_T_VERI	Frequency	Percent	Cum Freq	Cum Percent
2	79	100.00	79	100.00

QUESTIONS IN SECTIONS B THROUGH D ARE TO BE ANSWERED BY THE PERSON INTERVIEWED; QUESTIONS IN SECTIONS E THROUGH I ARE TO BE ANSWERED BY MEDICAL PERSONNEL.

B. MEDICATIONS

B1. Is the patient currently taking, on a regular basis, any medications prescribed by a physician?

☐ **1. NO** ☐ **2. YES**

B1. Patient currently taking medication.				
ANY_MEDS	Frequency	Percent	Cum Freq	Cum Percent
1	12	15.19	12	15.19
2	67	84.81	79	100.00

↓

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
1. Penicillin	☐	☐	1. ☐☐☐

B1a1. Taking Penicillin				
PENICILN	Frequency	Percent	Cum Freq	Cum Percent
-2	12	15.19	12	15.19
1	32	40.51	44	55.70
2	35	44.30	79	100.00

Analysis Variable : PEN_MTHS B1b1. Number of months taking penicillin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
35	0	85.4	43.3	8.0	60.0	72.0	115.0	185.0

B1b1. Number of months taking penicillin				
PEN_MTHS	Frequency	Percent	Cum Freq	Cum Percent
-2	44	100.00	44	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
2. Other antibiotic	☐	☐	2. ☐☐☐

↓

B1.a2.a SPECIFY:_____

B1a2. Taking other Antibiotic				
OTH_ANTI	Frequency	Percent	Cum Freq	Cum Percent
-2	12	15.19	12	15.19
1	66	83.54	78	98.73
2	1	1.27	79	100.00

B1a2a. Specify other Antibiotic				
O_ANTSPE	Frequency	Percent	Cum Freq	Cum Percent
-2	78	98.73	78	98.73
Amoxicillin/erythromycin	1	1.27	79	100.00

Analysis Variable : O_ANTMTH B1b2. Months taking other Antibiotic								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	98.0	.	98.0	98.0	98.0	98.0	98.0

B1b2. Months taking other Antibiotic				
O_ANTMTH	Frequency	Percent	Cum Freq	Cum Percent
-2	78	100.00	78	100.00

3. Folate	☐	☐	3. ☐☐☐

B1a3. Taking Folate				
FOLATE	Frequency	Percent	Cum Freq	Cum Percent
-2	12	15.19	12	15.19
1	38	48.10	50	63.29
2	29	36.71	79	100.00

Analysis Variable : FOL_MTHS B1b3. Number of months taking Folate								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
29	0	91.2	64.4	9.0	48.0	80.0	120.0	270.0

B1b3. Number of months taking Folate				
FOL_MTHS	Frequency	Percent	Cum Freq	Cum Percent
-2	50	100.00	50	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

1. NO **2. YES**

4. Hydroxyurea ☐ ☐ 4. ☐☐☐

B1a4. Taking Hydroxyurea				
HU	Frequency	Percent	Cum Freq	Cum Percent
-2	12	15.19	12	15.19
1	64	81.01	76	96.20
2	3	3.80	79	100.00

Analysis Variable : HU_MTHS B1b4. Number of months taking Hydroxyurea								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	12.3	2.5	10.0	10.0	12.0	15.0	15.0

B1b4. Number of months taking Hydroxyurea				
HU_MTHS	Frequency	Percent	Cum Freq	Cum Percent
-2	76	100.00	76	100.00

5. Iron Chelators (Desferoxamine) ☐ ☐ 5. ☐☐☐

B1a5. Taking Iron Chelators (Desferoxamine)				
IRONCHEL	Frequency	Percent	Cum Freq	Cum Percent
-2	12	15.19	12	15.19
1	35	44.30	47	59.49
2	32	40.51	79	100.00

Analysis Variable : IRON_MTH B1b5. Number of months taking Iron Chelators (Desferoxamine)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
32	0	30.8	14.5	1.0	24.0	34.5	41.0	54.0

B1b5. Number of months taking Iron Chelators (Desferoxamine)				
IRON_MTH	Frequency	Percent	Cum Freq	Cum Percent
-2	47	100.00	47	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
6. Other	☐	☐	6.a ☐☐☐
		↓	6.b ☐☐☐

B1.a6.a SPECIFY:_____

B1.a6.b SPECIFY: _____

B1a6. Taking Other Medication				
OTH_MEDS	Frequency	Percent	Cum Freq	Cum Percent
-2	12	15.19	12	15.19
1	46	58.23	58	73.42
2	21	26.58	79	100.00

B1a6a. Specify Other Medication				
OT1_MEDS	Frequency	Percent	Cum Freq	Cum Percent
-2	58	73.42	58	73.42
Advil	1	1.27	59	74.68
Albuterol	2	2.53	61	77.22
Aspirin	1	1.27	62	78.48
Baby aspirin	4	5.06	66	83.54
Elavil	1	1.27	67	84.81
Flonase	1	1.27	68	86.08
Flovent	1	1.27	69	87.34
Nasonex	3	3.80	72	91.14
Singulair	1	1.27	73	92.41
Singulair, tilade	1	1.27	74	93.67
Vitamin C	2	2.53	76	96.20
Zoloft	1	1.27	77	97.47
Zyrtec	2	2.53	79	100.00

Analysis Variable : OT1_MTHS B1b6a. Number of months taking medication								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
19	0	15.2	18.1	1.0	5.0	8.0	18.0	75.0

B1b6a. Number of months taking medication				
OT1_MTHS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.67	1	1.67
-8	1	1.67	2	3.33
-2	58	96.67	60	100.00

B1a6b. Specify other medication				
OT2_MEDS	Frequency	Percent	Cum Freq	Cum Percent
-1	8	10.13	8	10.13
-2	58	73.42	66	83.54
ASA	1	1.27	67	84.81
Albuterol	3	3.80	70	88.61
Albuterol, flovent	1	1.27	71	89.87
Clonidine	1	1.27	72	91.14
Flovent	1	1.27	73	92.41
Percocet	1	1.27	74	93.67
Periactin	1	1.27	75	94.94
Singulair	2	2.53	77	97.47
Zyrtec	2	2.53	79	100.00

Analysis Variable : OT2_MTHS B1b6b. Number of months taking medication								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
12	0	17.0	17.7	1.0	4.5	11.0	27.5	60.0

B1b6b. Number of months taking medication				
OT2_MTHS	Frequency	Percent	Cum Freq	Cum Percent
-8	1	1.49	1	1.49
-2	66	98.51	67	100.00

[Section C date variables NOT included in dataset.]

C. CLINICAL EVENT HISTORY

C1. Has the patient had 2 or more episodes of Acute Chest Syndrome (pneumonia) in the past year? ☐ **1. NO** ☐ **2. YES**

(**PROBE:** An infection or blockage of blood flow in the lungs)

C1. 2 or more episodes of Acute Chest Syndrome (pneumonia)				
ACS	Frequency	Percent	Cum Freq	Cum Percent
1	76	96.20	76	96.20
2	3	3.80	79	100.00

C2. How many times was the patient <u>hospitalized</u> for sickle cell painful episodes in the last 2 years? ☐☐

(**PROBE:** Pain in the bones of arms, legs, or vertebrae**)**

C2. Number of times hospitalized for pain events				
PAINHOSP	Frequency	Percent	Cum Freq	Cum Percent
0	59	74.68	59	74.68
1	11	13.92	70	88.61
2	3	3.80	73	92.41
3	3	3.80	76	96.20
6	1	1.27	77	97.47
9	1	1.27	78	98.73
10	1	1.27	79	100.00

1. Meningitis ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: Infection of the brain**)**

C3a1. Meningitis				
MENINGIT	Frequency	Percent	Cum Freq	Cum Percent
1	76	96.20	76	96.20
2	3	3.80	79	100.00

C3c1. Where seen for Meningitis				
SEENMENI	Frequency	Percent	Cum Freq	Cum Percent
-2	76	96.20	76	96.20
1	1	1.27	77	97.47
2	2	2.53	79	100.00

C3.a Has the patient ever been seen by a doctor for any of the following events?

C3.b **What was date of Recent event (month/year)**

C3.c **Where seen for most recent event?**
1 = STOP II Center
2 = Non-STOP II Center

2. Splenic Sequestration ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: Enlargement of the spleen with trapping of blood in it)

C3a2. Splenic Sequestration				
SPLENICS	Frequency	Percent	Cum Freq	Cum Percent
1	66	83.54	66	83.54
2	13	16.46	79	100.00

C3c2. Where seen for Splenic Sequestration				
SEENSPLN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
-2	66	83.54	67	84.81
1	11	13.92	78	98.73
2	1	1.27	79	100.00

3. Aplastic Crisis ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: A drop in the blood count which required a transfusion)

C3a3. Aplastic Crisis				
APLASTIC	Frequency	Percent	Cum Freq	Cum Percent
1	68	86.08	68	86.08
2	11	13.92	79	100.00

C3c3. Where seen for Aplastic Crisis				
SEENAPLS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
-2	68	86.08	69	87.34
1	8	10.13	77	97.47
2	2	2.53	79	100.00

C3.a Has the patient ever been seen by a doctor for any of the following events?

C3.b **What was date of most recent event (month/year)**

C3.c **Where seen for most recent event?**
1 = STOP II Center
2 = Non-STOP II Center

4. Hand-Foot Syndrome ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: Pain, tenderness, with or without swelling, in the hands and/or feet only)

C3a4. Hand-Foot Syndrome				
H_F_SYND	Frequency	Percent	Cum Freq	Cum Percent
1	68	86.08	68	86.08
2	11	13.92	79	100.00

C3c4. Where seen for Hand-Foot Syndrome				
SEENHFS	Frequency	Percent	Cum Freq	Cum Percent
-2	68	86.08	68	86.08
1	8	10.13	76	96.20
2	3	3.80	79	100.00

5. Septicemia ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: An infection in the blood stream**)**

C3a5. Septicemia				
SEPTICEM	Frequency	Percent	Cum Freq	Cum Percent
1	69	87.34	69	87.34
2	10	12.66	79	100.00

C3c5. Where seen for Septicemia				
SEENSEPT	Frequency	Percent	Cum Freq	Cum Percent
-2	69	87.34	69	87.34
1	10	12.66	79	100.00

6. Osteomyelitis ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: Infection in the bones)

C3a6. Osteomyelitis				
OSTEOMYL	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

C3c6. Where seen for Osteomyelitis				
SEENOSTE	Frequency	Percent	Cum Freq	Cum Percent
-2	79	100.00	79	100.00

C3.a Has the patient ever been seen by a doctor for any of the following events?

C3.b **What was date of most recent Recent event (month/year)**

C3.c **Where seen for most recent event?**
1 = STOP II Center
2 = Non-STOP II Center

7. Priapism ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: A painful, unwanted erection of the penis lasting more than one hour)

C3a7. Priapism				
PRIAPSM	Frequency	Percent	Cum Freq	Cum Percent
1	78	98.73	78	98.73
2	1	1.27	79	100.00

C3c7. Where seen for Priapism				
SEENPRIA	Frequency	Percent	Cum Freq	Cum Percent
-2	78	98.73	78	98.73
1	1	1.27	79	100.00

8. Transfusion Reaction ☐ **1. NO** ☐ **2. YES** → ___ ___/___ ___ ___ ___ ☐

(PROBE: Complication of a transfusion within 2 weeks after the transfusion was given)

C3a8. Transfusion Reaction				
T_REACTN	Frequency	Percent	Cum Freq	Cum Percent
1	70	88.61	70	88.61
2	9	11.39	79	100.00

C3c8. Where seen for Transfusion Reaction				
SEENREAC	Frequency	Percent	Cum Freq	Cum Percent
-2	70	88.61	70	88.61
1	9	11.39	79	100.00

C4. Has the patient had any of the following surgical procedures?

a. Splenectomy ☐ **1. NO** ☐ **2. YES** → C4.a1 Date: (month/year) ___ ___/___ ___ ___ ___

C4a. Had a Splenectomy				
SPLENECT	Frequency	Percent	Cum Freq	Cum Percent
1	65	82.28	65	82.28
2	14	17.72	79	100.00

b. Liver Biopsy ☐ **1. NO** ☐ **2. YES** → C4.b1 Date: (month/year) ___ ___/___ ___ ___ ___

C4.b2 Date: (month/year) ___ ___/___ ___ ___ ___

C4.b3 Date: (month/year) ___ ___/___ ___ ___ ___

C4b. Had a Liver Biopsy				
LIVER_BX	Frequency	Percent	Cum Freq	Cum Percent
1	60	75.95	60	75.95
2	19	24.05	79	100.00

C5. Does the patient currently have a portacath? ☐ **1. NO** ☐ **2. YES**

C5. Have a Portacath				
PORTCATH	Frequency	Percent	Cum Freq	Cum Percent
1	71	89.87	71	89.87
2	8	10.13	79	100.00

D. FAMILY HISTORY OF STROKE

D1. Have any of the following members of the child's family ever had a stroke?

a. Mother ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW

D1a. Child's mother had a stroke				
STR_MOTH	Frequency	Percent	Cum Freq	Cum Percent
1	76	96.20	76	96.20
2	1	1.27	77	97.47
3	2	2.53	79	100.00

b. Father ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW

D1b. Child's father had a stroke				
STR_FATH	Frequency	Percent	Cum Freq	Cum Percent
1	75	94.94	75	94.94
2	1	1.27	76	96.20
3	3	3.80	79	100.00

c. Brothers ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW ☐ 4. NA - no brothers

↓

D1c. Child's brother had a stroke				
STR_BROT	Frequency	Percent	Cum Freq	Cum Percent
1	68	86.08	68	86.08
2	2	2.53	70	88.61
3	1	1.27	71	89.87
4	8	10.13	79	100.00

c1. # of brothers who had stroke ☐☐

[Variable NOT included in dataset.]

d. Sisters ☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW ☐ 4. NA - no sisters

↓

D1d. Child's sister had a stroke				
STR_SIST	Frequency	Percent	Cum Freq	Cum Percent
1	65	82.28	65	82.28
2	4	5.06	69	87.34
3	1	1.27	70	88.61
4	9	11.39	79	100.00

d1. # of sisters who had stroke ☐☐

[Variable NOT included in dataset.]

*******SECTIONS E THROUGH I TO BE COMPLETED BY MEDICAL PERSONNEL*******

[Section E date variables NOT included in dataset.]

E. OTHER MEDICAL CONDITIONS

Does the patient currently carry the diagnosis of: **(CHECK NO OR YES FOR E1 - E19)** — **1. NO** — **2. YES** — **Year of diagnosis**

E1. Leg ulcers ☐ ☐→ 1.a ☐☐☐☐

E1. Leg Ulcers				
LEGULCER	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

E2. Aseptic necrosis ☐ ☐→ 2.a ☐☐☐☐

2.b If Yes, specify location(s) _____

E2. Aseptic Necrosis				
ANECROS	Frequency	Percent	Cum Freq	Cum Percent
1	78	98.73	78	98.73
2	1	1.27	79	100.00

E2b. Location of Aseptic Necrosis				
NECR_LOC	Frequency	Percent	Cum Freq	Cum Percent
-2	78	98.73	78	98.73
Left and Right hips.	1	1.27	79	100.00

E3. Sickle cell retinopathy ☐ ☐→ 3.a ☐☐☐☐

E3. Sickle Cell Retinopathy				
SC_RETIN	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

Does the patient currently carry the diagnosis of: **1. NO** **2. YES** **Year of diagnosis**
(CHECK NO OR YES FOR E1 - E19)

E4. Chronic lung disease ☐ ☐→ 4.a ☐☐☐☐

4.b If Yes, specify type _____

4.b1 ☐☐☐.☐☐ **OFFICE USE**

E4. Chronic Lung Disease				
CHR_LUNG	Frequency	Percent	Cum Freq	Cum Percent
1	78	98.73	78	98.73
2	1	1.27	79	100.00

LUNGCODE	LUNGTYPE	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	78	98.73	78	98.73
518.82	S/PACS, ARDS	1	1.27	79	100.00

E5. Asthma ☐ ☐→ 5.a ☐☐☐☐

E5. Asthma				
ASTHMA	Frequency	Percent	Cum Freq	Cum Percent
1	67	84.81	67	84.81
2	12	15.19	79	100.00

E6. Chronic heart disease ☐ ☐→ 6.a ☐☐☐☐

6.b If Yes, specify type: _____

6.b1 ☐☐☐.☐☐ **OFFICE USE**

E6. Chronic Heart Disease				
CHD	Frequency	Percent	Cum Freq	Cum Percent
1	77	97.47	77	97.47
2	2	2.53	79	100.00

CHD_CODE	CHD_TYPE	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	77	97.47	77	97.47
429.3	cardio megaly	1	1.27	78	98.73
785.2	heart murmur	1	1.27	79	100.00

Does the patient currently carry the diagnosis of: **1. NO** **2. YES** **Year of diagnosis**
(CHECK NO OR YES FOR E1 - E19)

E7. Chronic liver disease ☐ ☐→ 7.a ☐☐☐☐

7.b If Yes, specify type: _____

7.b1 ☐☐☐.☐☐ **OFFICE USE**

E7. Chronic Liver Disease				
CHR_LVRD	Frequency	Percent	Cum Freq	Cum Percent
1	78	98.73	78	98.73
2	1	1.27	79	100.00

CLD_CODE	C_LVRTYP	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	78	98.73	78	98.73
70.9	hemosiderosis grade 2, stage 4, hepatitis with cir	1	1.27	79	100.00

E8. Chronic renal disease ☐ ☐→ 8.a ☐☐☐☐

8.b If Yes, specify type: _____

8.b1 ☐☐☐.☐☐ **OFFICE USE**

E8. Chronic Renal Disease				
CHR_RNLD	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

E8b. Type of Chronic Renal Disease				
C_RNLTYP	Frequency	Percent	Cum Freq	Cum Percent
-2	79	100.00	79	100.00

E8b1. Code for Chronic Renal Disease				
RENALCOD	Frequency	Percent	Cum Freq	Cum Percent
-2	79	100.00	79	100.00

8.c If Yes, is patient receiving dialysis? ☐ **1. NO** ☐ **2. YES**

E8c. Currently receiving Dialysis				
DIALYSIS	Frequency	Percent	Cum Freq	Cum Percent
-2	79	100.00	79	100.00

Does the patient currently carry the diagnosis of: **(CHECK NO OR YES FOR E1 - E19)**

1. NO **2. YES** **Year of diagnosis**

E9. Iron overload ☐ ☐→ 9.a ☐☐☐☐

9.b If yes, highest ferritin level (ng/ml) ☐☐☐☐☐

E9. Iron Overload				
IRON_OL	Frequency	Percent	Cum Freq	Cum Percent
1	25	31.65	25	31.65
2	54	68.35	79	100.00

Analysis Variable : FERRITIN E9b. Highest level of Ferritin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
50	0	3828.3	2638.7	411.0	2215.0	3475.0	4510.0	13900

E9b. Highest level of Ferritin				
FERRITIN	Frequency	Percent	Cum Freq	Cum Percent
-9	2	6.90	2	6.90
-8	1	3.45	3	10.34
-3	1	3.45	4	13.79
-2	25	86.21	29	100.00

E10. Diabetes ☐ ☐→ 10.a ☐☐☐☐

E10. Diabetes				
DIABETES	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

E11. Rheumatic fever ☐ ☐→ 11.a ☐☐☐☐

E11. Rheumatic Fever				
RHEU_FVR	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

E12. Tuberculosis ☐ ☐→ 12.a ☐☐☐☐

E12. Tuberculosis				
TUBERCUL	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

Does the patient currently carry the diagnosis of: **(CHECK NO OR YES FOR E1 - E19)** | **1. NO** | **2. YES** | **Year of diagnosis**

E13. Cancer ☐ ☐→ 13.a ☐☐☐☐

13.b If Yes, specify type: _____

13.b1 ☐☐☐.☐☐ **OFFICE USE**

[Variables NOT included in dataset.]

E14. Priapism ☐ ☐→ 14.a ☐☐☐☐

E14. Priapism				
PRIAPISM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	77	97.47	78	98.73
2	1	1.27	79	100.00

E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?) ☐ ☐→ 15.a ☐☐☐☐

E15. Elevated Blood Lead Level				
ELEVLEAD	Frequency	Percent	Cum Freq	Cum Percent
1	79	100.00	79	100.00

E16. Hepatitis B ☐ ☐→ 16.a ☐☐☐☐

E16. Hepatitis B				
HEP_B	Frequency	Percent	Cum Freq	Cum Percent
1	78	98.73	78	98.73
2	1	1.27	79	100.00

E17. Hepatitis C ☐ ☐→ 17.a ☐☐☐☐

E17. Hepatitis C				
HEP_C	Frequency	Percent	Cum Freq	Cum Percent
1	78	98.73	78	98.73
2	1	1.27	79	100.00

E18. HIV ☐ ☐→ 18.a ☐☐☐☐

[Variables NOT included in dataset.]

Does the patient currently carry the diagnosis of: **1. NO** **2. YES** **Year of diagnosis**
(CHECK NO OR YES FOR E1 - E19)

E19. Any other chronic medical condition? ☐ ☐

E19. Other Chronic Medical Condition				
OTHCOND	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	75	94.94	76	96.20
2	3	3.80	79	100.00

19.b If Yes, specify type: _____ 19.b1 ☐☐☐☐

19.b2 ☐☐☐.☐☐ **OFFICE USE**

19.c If Yes, specify type: _____ 19.c1 ☐☐☐☐

19.c2 ☐☐☐.☐☐ **OFFICE USE**

[Variables NOT included in dataset.]

F. RED CELL PHENOTYPING (COMPLETION NOT REQUIRED FOR PATIENTS RANDOMIZED IN STOP)

F1. Was the patient randomized in STOP? ☐ **1. NO** ☐ **2. YES** → **GO TO SECTION G**

F1. Randomized in STOP				
STOPRAND	Frequency	Percent	Cum Freq	Cum Percent
1	37	46.84	37	46.84
2	42	53.16	79	100.00

F2.a. ABO Blood Group

☐ **1. A** ☐ **2. B** ☐ **3. AB** ☐ **4. O**

F2a. ABO Blood Group				
BLOODGRP	Frequency	Percent	Cum Freq	Cum Percent
-2	42	53.16	42	53.16
1	11	13.92	53	67.09
2	7	8.86	60	75.95
3	2	2.53	62	78.48
4	17	21.52	79	100.00

F2.b Rh Antigens	1. ABSENT	2. PRESENT
1. D	☐	☐

F2b1. Rh Antigens D				
RH_ANT_D	Frequency	Percent	Cum Freq	Cum Percent
-3	5	6.33	5	6.33
-2	42	53.16	47	59.49
1	9	11.39	56	70.89
2	23	29.11	79	100.00

2. C	☐	☐

F2b2. Rh Antigens C				
RH_ANT_C	Frequency	Percent	Cum Freq	Cum Percent
-3	2	2.53	2	2.53
-2	42	53.16	44	55.70
1	26	32.91	70	88.61
2	9	11.39	79	100.00

F2.b Rh Antigens	1. ABSENT	2. PRESENT
3. E	☐	☐

F2b3. Rh Antigens E				
RH_ANT_E	Frequency	Percent	Cum Freq	Cum Percent
-3	2	2.53	2	2.53
-2	42	53.16	44	55.70
1	28	35.44	72	91.14
2	7	8.86	79	100.00

4. e	☐	☐

F2b4. Rh Antigens e				
RHANT_E	Frequency	Percent	Cum Freq	Cum Percent
-3	4	5.06	4	5.06
-2	42	53.16	46	58.23
1	9	11.39	55	69.62
2	24	30.38	79	100.00

F2.b Rh Antigens	1. ABSENT	2. PRESENT
5. c	☐	☐

F2b5. Rh Antigens c				
RHANT_C	Frequency	Percent	Cum Freq	Cum Percent
-3	4	5.06	4	5.06
-2	42	53.16	46	58.23
1	9	11.39	55	69.62
2	24	30.38	79	100.00

6. f	☐	☐

F2b6. Rh Antigens f				
RH_ANT_F	Frequency	Percent	Cum Freq	Cum Percent
-3	29	36.71	29	36.71
-2	42	53.16	71	89.87
1	7	8.86	78	98.73
2	1	1.27	79	100.00

7. V	☐	☐

F2b7. Rh AntigensV				
RH_ANT_V	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

F2.c Kell Antigens	1. ABSENT	2. PRESENT
1. K (Kell)	☐	☐

F2c1. K (Kell)				
KELL_KEL	Frequency	Percent	Cum Freq	Cum Percent
-3	3	3.80	3	3.80
-2	42	53.16	45	56.96
1	30	37.97	75	94.94
2	4	5.06	79	100.00

F2.c Kell Antigens **1. ABSENT** **2. PRESENT**

2. k ☐ ☐

F2c2. k				
KELL_K	Frequency	Percent	Cum Freq	Cum Percent
-3	18	22.78	18	22.78
-2	42	53.16	60	75.95
1	10	12.66	70	88.61
2	9	11.39	79	100.00

3. Js^a ☐ ☐

F2c3. Jsa				
KELL_JSA	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

4. Js^b ☐ ☐

F2c4. Jsb				
KELL_JSB	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

5. Kp^a ☐ ☐

F2c5. Kpa				
KELL_KPA	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

6. Kp^b ☐ ☐

F2c6. Kpb				
KELL_KPB	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

F2.d Duffy Antigens

1. Fy^a

F2d1. Fya				
DUF_FYA	Frequency	Percent	Cum Freq	Cum Percent
-3	7	8.86	7	8.86
-2	42	53.16	49	62.03
1	28	35.44	77	97.47
2	2	2.53	79	100.00

2. Fy^b

F2d2. Fyb				
DUF_FYB	Frequency	Percent	Cum Freq	Cum Percent
-3	8	10.13	8	10.13
-2	42	53.16	50	63.29
1	24	30.38	74	93.67
2	5	6.33	79	100.00

F2.e Kidd Antigens

1. Jk^a

F2e1. Jka				
KID_JKA	Frequency	Percent	Cum Freq	Cum Percent
-3	8	10.13	8	10.13
-2	42	53.16	50	63.29
1	8	10.13	58	73.42
2	21	26.58	79	100.00

2. Jk^b

F2e2. Jkb				
KID_JKB	Frequency	Percent	Cum Freq	Cum Percent
-3	8	10.13	8	10.13
-2	42	53.16	50	63.29
1	17	21.52	67	84.81
2	12	15.19	79	100.00

F2.f Lewis Antigens

1. Le^a

F2f1. Lea				
LEW_LEA	Frequency	Percent	Cum Freq	Cum Percent
-3	17	21.52	17	21.52
-2	42	53.16	59	74.68
1	16	20.25	75	94.94
2	4	5.06	79	100.00

2. Le^b

F2f2. Leb				
LEW_LEB	Frequency	Percent	Cum Freq	Cum Percent
-3	17	21.52	17	21.52
-2	42	53.16	59	74.68
1	13	16.46	72	91.14
2	7	8.86	79	100.00

F2.g Lutheran Antigens

1. Lu^a

F2g1. Lua				
LUTH_LUA	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

2. Lu^b

F2g2. Lub				
LUTH_LUB	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

3. Lu^3

F2g3. Lu3				
LUTH_LU3	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

F2.h P Antigens	1. ABSENT	2. PRESENT
1. P_1	☐	☐

F2h1. P1				
P1_ANTIG	Frequency	Percent	Cum Freq	Cum Percent
-3	17	21.52	17	21.52
-2	42	53.16	59	74.68
1	7	8.86	66	83.54
2	13	16.46	79	100.00

F2.i MNS Antigens		
1. M	☐	☐

F2i1. M				
MNS_M	Frequency	Percent	Cum Freq	Cum Percent
-3	12	15.19	12	15.19
-2	42	53.16	54	68.35
1	11	13.92	65	82.28
2	14	17.72	79	100.00

2. N	☐	☐

F2i2. N				
MNS_N	Frequency	Percent	Cum Freq	Cum Percent
-3	12	15.19	12	15.19
-2	42	53.16	54	68.35
1	12	15.19	66	83.54
2	13	16.46	79	100.00

3. S	☐	☐

F2i3. S				
MNS_S	Frequency	Percent	Cum Freq	Cum Percent
-3	11	13.92	11	13.92
-2	42	53.16	53	67.09
1	21	26.58	74	93.67
2	5	6.33	79	100.00

F2.i MNS Antigens	1. ABSENT	2. PRESENT
4. s	☐	☐

F2i4. s				
MNS_A_S	Frequency	Percent	Cum Freq	Cum Percent
-3	11	13.92	11	13.92
-2	42	53.16	53	67.09
1	9	11.39	62	78.48
2	17	21.52	79	100.00

5. U	☐	☐

F2i5. U				
MNS_U	Frequency	Percent	Cum Freq	Cum Percent
-3	30	37.97	30	37.97
-2	42	53.16	72	91.14
1	7	8.86	79	100.00

***** ATTACH RED CELL PHENOTYPE REPORT ******

[Section G date variables NOT included in dataset.]

G. RED CELL ANTIBODIES AND TRANSFUSION COMPLICATIONS

G1. Is the patient known by your blood bank to have any of the following red cell antibodies?

(CHECK NO OR YES FOR EACH OF G1 a - l)

	1.NO	2. YES	G2. Date first identified
a. anti-D	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1a. anti-D				
ANTI_D	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	76	96.20	77	97.47
2	2	2.53	79	100.00

b. anti-C	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1b. anti-C				
ANTI_C	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	77	97.47	78	98.73
2	1	1.27	79	100.00

c. anti-E	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1c. anti-E				
ANTI_E	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	77	97.47	78	98.73
2	1	1.27	79	100.00

d. anti-M	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1d. anti-M				
ANTI_M	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	77	97.47	78	98.73
2	1	1.27	79	100.00

G1. Is the patient known by your blood bank to have any of the following red cell antibodies?

(CHECK NO OR YES FOR EACH OF G1 a - l)

	1.NO	2. YES	G2. Date first identified
e. anti-S	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1e. anti-S				
ANTI_S	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	78	98.73	79	100.00

f. anti-K (Kell)	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1f. anti-K (Kell)				
ANTI_K	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	76	96.20	77	97.47
2	2	2.53	79	100.00

g. anti-Fv^{a}	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1g. anti-Fya				
ANTI_FYA	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	76	96.20	77	97.47
2	2	2.53	79	100.00

h. anti-Fv^{b}	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1h. anti-Fyb				
ANTI_FYB	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	78	98.73	79	100.00

i. anti-Jk^{b}	☐	☐→	___ ___/___ ___/___ ___ ___ ___

G1i. anti-Jkb				
ANTI_JKB	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	77	97.47	78	98.73
2	1	1.27	79	100.00

G1. Is the patient known by your blood bank to have any of the following red cell antibodies?

(CHECK NO OR YES FOR EACH OF G1 a - l)

G2. Date first identified

1.NO **2. YES**

i. anti-Le[a] ☐ ☐→ ___ ___/___ ___/___ ___ ___ ___

G1j. anti-Lea				
ANTI_LEA	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	76	96.20	77	97.47
2	2	2.53	79	100.00

k. anti-Le[b] ☐ ☐→ ___ ___/___ ___/___ ___ ___ ___

G1k. anti-Leb				
ANTI_LEB	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	78	98.73	79	100.00

l. Other ☐ ☐

G1l. Other antibody				
ANTI_OTH	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.27	1	1.27
1	70	88.61	71	89.87
2	8	10.13	79	100.00

↓

List Antibody: **Date first identified:**

G1.l1 _____ G1.l1.a ___ ___/___ ___/___ ___ ___ ___

G1l1. Specify first other antibody				
OTHER1	Frequency	Percent	Cum Freq	Cum Percent
-2	71	89.87	71	89.87
Anti-H	1	1.27	72	91.14
Anti-Lu(A)	1	1.27	73	92.41
Anti-V	2	2.53	75	94.94
JSA	1	1.27	76	96.20
KN, MC	1	1.27	77	97.47
anti JKa	1	1.27	78	98.73
auto antibody	1	1.27	79	100.00

List Antibody:	Date first identified:
G1.l2 _____	G1.l2.a ___ ___/___ ___/___ ___ ___ ___

G1l2. Specify second other antibody				
OTHER2	Frequency	Percent	Cum Freq	Cum Percent
-1	6	7.59	6	7.59
-2	71	89.87	77	97.47
Anti-G	1	1.27	78	98.73
UN	1	1.27	79	100.00

G1.l3 _____ G1.l3.a ___ ___/___ ___/___ ___ ___ ___

G1l3. Specify third other antibody				
OTHER3	Frequency	Percent	Cum Freq	Cum Percent
-2	77	97.47	77	97.47
HL	1	1.27	78	98.73
warm auto antibody	1	1.27	79	100.00

G3. Has the patient ever had a transfusion reaction? ☐ **1. NO** ☐ **2. YES** ☐ **3. DON'T KNOW**

G3. Transfusion Reaction				
TRANREAC	Frequency	Percent	Cum Freq	Cum Percent
1	70	88.61	70	88.61
2	9	11.39	79	100.00

↓

G3.a Describe

_____

_____

_____

[Variable NOT included in dataset.]

H. VACCINATIONS

H1. Has the patient received Hepatitis B vaccination?

☐ **1. NO** ☐ **2. YES**

H1. Hepatitis B vaccination				
HEPBVACC	Frequency	Percent	Cum Freq	Cum Percent
-8	3	3.80	3	3.80
1	8	10.13	11	13.92
2	68	86.08	79	100.00

↓

H1.a Date of most recent vaccination (Month/Day/Year)

___ ___/___ ___/___ ____ ___ ___

[Variable NOT included in dataset.]

I. GENERAL

I1. Is the patient seen for most of his/her clinical events at a NON-STOP II study site because of third party payment restrictions, distance from clinic, some other reason? ☐ **1. NO** ☐ **2. YES**

I1. Seen at Non-STOP II site				
NONSTSIT	Frequency	Percent	Cum Freq	Cum Percent
1	76	96.20	76	96.20
2	3	3.80	79	100.00

Signature of Study Coordinator: _____ Date: ____ ___/___ ___/___ ___ ___ ___

SECTION J. FOR OFFICE USE

J1. Local red cell phenotyping report received?

☐ **1. NO**

☐ **2. YES**

☐ **-1. NA**

J1. Red cell phenotyping report				
PHEN_SRC	Frequency	Percent	Cum Freq	Cum Percent
-9	4	5.06	4	5.06
-1	42	53.16	46	58.23
1	2	2.53	48	60.76
2	31	39.24	79	100.00

STOP II
FORM 12: PHYSICAL EXAMINATION

A. Collection Information:

The **Physical Examination** (Form 12) was to be completed at entry and quarterly visits for Potential Patients and at entry, quarterly, annual, and exit visits for Randomized Patients.

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p012_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 1,162 (79)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 173-174
- Listing of Variables by Position: See p. 175

H. Formats:

The file **f012fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 176-178.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The only valid EX_TYPE for Form 12 is QT for quarterly visits.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 12 are:
    - 200 & 300 series numbers indicate visits that were completed prior to randomization.
        - 200 series numbers were assigned to “Potential 1” visits – i.e., quarterly visits completed while the patient was on transfusion for < 30 months
        - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months
    - 400 series numbers indicate visits completed after randomization
        - 401=randomization visit
        - 405, 409, or 413=annual visits

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

Data Set Name	PUBDS.P012_FINAL	Observations	1162
Member Type	DATA	Variables	42
Engine	V9	Indexes	0
Created	Friday, January 27, 2006 03:34:06 PM	Observation Length	320
Last Modified	Friday, January 27, 2006 03:34:06 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	24
First Data Page	1
Max Obs per Page	51
Obs in First Data Page	32
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p012_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
23	ABDOMEN	Num	8	3.	C7. Abdomen
6	BP_DIAS	Num	8	4.	B3b. Diastolic blood pressure
5	BP_SYST	Num	8	4.	B3a. Systolic blood pressure
39	DESTATUS	Char	1	$1.	DESTATUS
25	DIST_SPL	Num	8	5.1	C8a. Distance below LCM at MCL (cm)
12	EARS	Num	8	3.	C3. Ears
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
11	EYES	Num	8	3.	C2. Eyes
38	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
10	GENAPPER	Num	8	3.	C1. General appearance
3	HEIGHT	Num	8	6.1	B1. Height (cm)
29	LEFTHIP	Num	8	3.	C10a2. Left hip (pain or limitation of motion)
32	LEGULCER	Num	8	3.	C10b. Leg ulcer
34	LE_EDEMA	Num	8	3.	C10c. Lower extremity edema
26	LIVER	Num	8	3.	C9. Liver
37	L_NODES	Num	8	3.	C12. Lymph nodes enlarged?
31	L_SHOLDR	Num	8	3.	C10a4. Left shoulder (pain or limitation of motion)
21	MURMUR	Num	8	3.	C6b. Heart murmur
18	M_BREATH	Num	8	3.	C5d. Mouth breathing
13	N_T_M	Num	8	3.	C4. Nose/Throat/Mouth
22	OTHERABN	Num	8	3.	C6c. Other abnormality (heart)
19	OTH_ABN	Num	8	3.	C5e. Other lung/respiratory abnormality
7	PULSE	Num	8	4.	B4. Pulse (beats/min)
15	RALES	Num	8	3.	C5a. Rales
8	RESPRATE	Num	8	4.	B5. Respiration rate (rate/min)

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
16	RHONCHI	Num	8	3.	C5b. Rhonchi
20	RHYTHM	Num	8	3.	C6a. Rhythm abnormality
28	RIGHTHIP	Num	8	3.	C10a1. Right hip (pain or limitation of motion)
30	R_SHOLDR	Num	8	3.	C10a3. Right shoulder (pain or limitation of motion)
36	SKIN	Num	8	3.	C11. Skin
24	SPLEEN	Num	8	3.	C8. Spleen
9	TEMPERAT	Num	8	5.1	B6. Temperature (degrees C)
27	TENDER	Num	8	3.	C9a. Liver tenderness
14	TONSILS	Num	8	3.	C4b. Tonsils
4	WEIGHT	Num	8	6.1	B2. Weight (kg)
17	WHEEZE	Num	8	3.	C5c. Wheeze
33	WHICHLEG	Num	8	3.	C10b1. Which leg (leg ulcer)
35	WHICH_LE	Num	8	3.	C10c1. Which leg (lower extremity edema)
42	comp_ dfrmrand	Num	8		<created variable> A2. Date of physical exam as days from RAND visit
41	ldu_id	Char	10		ID for public use datasets
40	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	HEIGHT	Num	8	6.1	B1. Height (cm)
4	WEIGHT	Num	8	6.1	B2. Weight (kg)
5	BP_SYST	Num	8	4.	B3a. Systolic blood pressure
6	BP_DIAS	Num	8	4.	B3b. Diastolic blood pressure
7	PULSE	Num	8	4.	B4. Pulse (beats/min)
8	RESPRATE	Num	8	4.	B5. Respiration rate (rate/min)
9	TEMPERAT	Num	8	5.1	B6. Temperature (degrees C)
10	GENAPPER	Num	8	3.	C1. General appearance
11	EYES	Num	8	3.	C2. Eyes
12	EARS	Num	8	3.	C3. Ears
13	N_T_M	Num	8	3.	C4. Nose/Throat/Mouth
14	TONSILS	Num	8	3.	C4b. Tonsils
15	RALES	Num	8	3.	C5a. Rales
16	RHONCHI	Num	8	3.	C5b. Rhonchi
17	WHEEZE	Num	8	3.	C5c. Wheeze
18	M_BREATH	Num	8	3.	C5d. Mouth breathing
19	OTH_ABN	Num	8	3.	C5e. Other lung/respiratory abnormality
20	RHYTHM	Num	8	3.	C6a. Rhythm abnormality
21	MURMUR	Num	8	3.	C6b. Heart murmur
22	OTHERABN	Num	8	3.	C6c. Other abnormality (heart)
23	ABDOMEN	Num	8	3.	C7. Abdomen
24	SPLEEN	Num	8	3.	C8. Spleen
25	DIST_SPL	Num	8	5.1	C8a. Distance below LCM at MCL (cm)
26	LIVER	Num	8	3.	C9. Liver
27	TENDER	Num	8	3.	C9a. Liver tenderness
28	RIGHTHIP	Num	8	3.	C10a1. Right hip (pain or limitation of motion)
29	LEFTHIP	Num	8	3.	C10a2. Left hip (pain or limitation of motion)
30	R_SHOLDR	Num	8	3.	C10a3. Right shoulder (pain or limitation of motion)
31	L_SHOLDR	Num	8	3.	C10a4. Left shoulder (pain or limitation of motion)
32	LEGULCER	Num	8	3.	C10b. Leg ulcer
33	WHICHLEG	Num	8	3.	C10b1. Which leg (leg ulcer)
34	LE_EDEMA	Num	8	3.	C10c. Lower extremity edema
35	WHICH_LE	Num	8	3.	C10c1. Which leg (lower extremity edema)
36	SKIN	Num	8	3.	C11. Skin
37	L_NODES	Num	8	3.	C12. Lymph nodes enlarged?
38	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
39	DESTATUS	Char	1	$1.	DESTATUS
40	vistype	Char	7		<created variable> VISIT TYPE
41	ldu_id	Char	10		ID for public use datasets
42	comp_dfrmrand	Num	8		<created variable> A2. Date of physical exam as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
* F012fmts.txt;

proc format;

  value GENAPPERF
    1='1: Normal'
    2='2: Abnormal';

  value EYESF
    1='1: Normal'
    2='2: Abnormal';

  value EARSF
    1='1: Normal'
    2='2: Abnormal';

  value N_T_MF
    1='1: Normal'
    2='2: Abnormal';

  value TONSILSF
    1='1: Normal'
    2='2: Enlarged'
    3='3: Absent';

  value RALESF
    1='1: Absent'
    2='2: Present';

  value RHONCHIF
    1='1: Absent'
    2='2: Present';

  value WHEEZEF
    1='1: Absent'
    2='2: Present';

  value M_BREATHF
    1='1: Absent'
    2='2: Present';

  value OTH_ABNF
    1='1: Absent'
    2='2: Present';

  value RHYTHMF
    1='1: Absent'
    2='2: Present';

  value MURMURF
    1='1: Absent'
    2='2: Present';

  value OTHERABNF
    1='1: Absent'
    2='2: Present';
```

```
value ABDOMENF
  1='1: Normal'
  2='2: Abnormal';

value SPLEENF
  1='1: Not Enlarged'
  2='2: Enlarged'
  3='3: N/A Splenectomy';

value LIVERF
  1='1: Not Enlarged'
  2='2: Enlarged';

value TENDERF
  1='1: Absent'
  2='2: Present';

value RIGHTHIPF
  1='1: No'
  2='2: Yes';

value LEFTHIPF
  1='1: No'
  2='2: Yes';

value R_SHOLDRF
  1='1: No'
  2='2: Yes';

value L_SHOLDRF
  1='1: No'
  2='2: Yes';

value LEGULCERF
  1='1: Absent'
  2='2: Present';

value WHICHLEGF
  1='1: Right'
  2='2: Left'
  3='3: Both';

value LE_EDEMAF
  1='1: Absent'
  2='2: Present';

value WHICH_LEF
  1='1: Right'
  2='2: Left'
  3='3: Both';

value SKINF
  1='1: Normal'
  2='2: Abnormal';
```

```
  value L_NODESF
    1='1: No'
    2='2: Yes';
```

* format genapper genapperf. eyes eyesf. ears earsf. n_t_m n_t_mf. tonsils tonsilsf. rales ralesf. rhonchi rhonchif. wheeze wheezef. m_breath m_breathf. oth_abn oth_abnf. rhythm rhythmf. murmur murmurf. otherabn otherabnf. abdomen abdomenf. spleen spleenf. liver liverf. tender tenderf. righthip righthipf. lefthip lefthipf. r_sholdr r_sholdrf. l_sholdr l_sholdrf. legulcer legulcerf. whichleg whichlegf. le_edema le_edemaf. which_le which_lef. skin skinf. l_nodes l_nodesf.;

STOP II

PHYSICAL EXAMINATION

AFFIX PATIENT'S LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1153	99.23	1153	99.23
P	9	0.77	1162	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-201	33	2.84	33	2.84
QT-202	28	2.41	61	5.25
QT-203	24	2.07	85	7.31
QT-204	26	2.24	111	9.55
QT-205	26	2.24	137	11.79
QT-206	22	1.89	159	13.68
QT-207	20	1.72	179	15.40
QT-208	18	1.55	197	16.95
QT-209	17	1.46	214	18.42
QT-210	16	1.38	230	19.79
QT-301	78	6.71	308	26.51
QT-302	41	3.53	349	30.03
QT-303	24	2.07	373	32.10
QT-304	21	1.81	394	33.91
QT-305	12	1.03	406	34.94
QT-306	6	0.52	412	35.46
QT-307	3	0.26	415	35.71
QT-308	3	0.26	418	35.97
QT-309	2	0.17	420	36.14
QT-310	2	0.17	422	36.32
QT-401	79	6.80	501	43.12
QT-402	75	6.45	576	49.57
QT-403	75	6.45	651	56.02
QT-404	66	5.68	717	61.70
QT-405	62	5.34	779	67.04
QT-406	54	4.65	833	71.69
QT-407	48	4.13	881	75.82
QT-408	50	4.30	931	80.12
QT-409	44	3.79	975	83.91
QT-410	43	3.70	1018	87.61

<created variable> VISIT TYPE (continued)				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-411	39	3.36	1057	90.96
QT-412	36	3.10	1093	94.06
QT-413	33	2.84	1126	96.90
QT-414	18	1.55	1144	98.45
QT-415	13	1.12	1157	99.57
QT-416	5	0.43	1162	100.00

A1. Person performing physical examination (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of Physical Exam (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of physical exam as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1162	0	160.2	551.8	-1343	-201.0	152.5	557.0	1399.0

B. MEASUREMENTS

B1. Height (cm): | | | | . | |

Analysis Variable : HEIGHT B1. Height (cm)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1066	0	148.5	17.1	95.0	136.1	149.2	161.3	189.5

B1. Height (cm)				
HEIGHT	Frequency	Percent	Cum Freq	Cum Percent
-8	4	4.17	4	4.17
-3	92	95.83	96	100.00

B2. Weight (kg): | | | | . | |

Analysis Variable : WEIGHT B2. Weight (kg)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1100	0	43.7	17.5	14.4	30.1	40.5	53.3	108.8

B2. Weight (kg)				
WEIGHT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.61	1	1.61
-8	1	1.61	2	3.23
-3	60	96.77	62	100.00

B3. Blood Pressure (Supine, before blood drawing): a. [ ][ ][ ] b. [ ][ ][ ]

Systolic Diastolic

Analysis Variable : BP_SYST B3a. Systolic blood pressure								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1133	0	113.9	13.5	74.0	105.0	112.0	122.0	175.0

B3a. Systolic blood pressure				
BP_SYST	Frequency	Percent	Cum Freq	Cum Percent
-8	3	10.34	3	10.34
-3	26	89.66	29	100.00

Analysis Variable : BP_DIAS B3b. Diastolic blood pressure								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1132	0	60.9	8.7	37.0	55.0	60.0	67.0	98.0

B3b. Diastolic blood pressure				
BP_DIAS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	3.33	1	3.33
-8	3	10.00	4	13.33
-3	26	86.67	30	100.00

B4. Pulse (beats/min): [ ][ ][ ]

Analysis Variable : PULSE B4. Pulse (beats/min)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1116	0	89.3	12.7	50.0	80.0	89.0	97.0	149.0

B4. Pulse (beats/min)				
PULSE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	2.17	1	2.17
-8	1	2.17	2	4.35
-3	44	95.65	46	100.00

B5. Respiration rate/min: [ ][ ][ ]

Analysis Variable : RESPRATE B5. Respiration rate (rate/min)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1081	0	20.7	3.0	10.0	20.0	20.0	22.0	60.0

B5. Respiration rate (rate/min)				
RESPRATE	Frequency	Percent	Cum Freq	Cum Percent
-9	2	2.47	2	2.47
-8	4	4.94	6	7.41
-3	75	92.59	81	100.00

B6. Temperature (°C): [ ][ ] . [ ]

Analysis Variable : TEMPERAT B6. Temperature (degrees C)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1126	0	36.6	0.5	35.0	36.2	36.7	37.0	38.6

B6. Temperature (degrees C)				
TEMPERAT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	5.56	2	5.56
-8	1	2.78	3	8.33
-3	33	91.67	36	100.00

C. PHYSICAL EXAMINATION

[Specify field variables NOT included in dataset.]

C1. General Appearance [ ] **1. NORMAL** [ ] **2. ABNORMAL** → a. Describe _____

C1. General appearance				
GENAPPER	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	3	0.26	4	0.34
1	1104	95.01	1108	95.35
2	54	4.65	1162	100.00

C2. Eyes [ ] **1. NORMAL** [ ] **2. ABNORMAL** → a. Describe _____

C2. Eyes				
EYES	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	4	0.34	5	0.43
1	853	73.41	858	73.84
2	304	26.16	1162	100.00

C3. Ears ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C3. Ears				
EARS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-8	1	0.09	2	0.17
-3	9	0.77	11	0.95
1	1114	95.87	1125	96.82
2	37	3.18	1162	100.00

C4. Nose/Throat/Mouth ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C4. Nose/Throat/Mouth				
N_T_M	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	6	0.52	7	0.60
1	1093	94.06	1100	94.66
2	62	5.34	1162	100.00

b. Tonsils ☐ **1. NORMAL** ☐ **2. ENLARGED** ☐ **3. ABSENT**

C4b. Tonsils				
TONSILS	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.17	2	0.17
-3	9	0.77	11	0.95
1	999	85.97	1010	86.92
2	117	10.07	1127	96.99
3	35	3.01	1162	100.00

C5. Lungs **1. ABSENT** **2. PRESENT**

a. Rales ☐ ☐

C5a. Rales				
RALES	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	2	0.17	3	0.26
1	1157	99.57	1160	99.83
2	2	0.17	1162	100.00

b. Rhonchi ☐ ☐

C5b. Rhonchi				
RHONCHI	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	2	0.17	3	0.26
1	1156	99.48	1159	99.74
2	3	0.26	1162	100.00

c. Wheezing ☐ ☐

C5c. Wheeze				
WHEEZE	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	2	0.17	3	0.26
1	1156	99.48	1159	99.74
2	3	0.26	1162	100.00

d. Mouth Breathing ☐ ☐

C5d. Mouth breathing				
M_BREATH	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	3	0.26	4	0.34
1	1151	99.05	1155	99.40
2	7	0.60	1162	100.00

e. Other lung/respiratory abnormality ☐ ☐ → e1. Specify _____

C5e. Other lung/respiratory abnormality				
OTH_ABN	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	4	0.34	5	0.43
1	1151	99.05	1156	99.48
2	6	0.52	1162	100.00

C6. Heart **1. ABSENT** **2. PRESENT**

a. Rhythm abnormality ☐ ☐ → a1. Specify type:_____

C6a. Rhythm abnormality				
RHYTHM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-8	1	0.09	2	0.17
-3	4	0.34	6	0.52
1	1147	98.71	1153	99.23
2	9	0.77	1162	100.00

b. Heart murmur ☐ ☐ → b1. Specify type:_____

C6b. Heart murmur				
MURMUR	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-8	1	0.09	2	0.17
-3	5	0.43	7	0.60
1	769	66.18	776	66.78
2	386	33.22	1162	100.00

c. Other abnormality ☐ ☐ → c1. Specify type:_____

C6c. Other abnormality (heart)				
OTHERABN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-8	2	0.17	3	0.26
-3	7	0.60	10	0.86
1	1142	98.28	1152	99.14
2	10	0.86	1162	100.00

C7. Abdomen ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C7. Abdomen				
ABDOMEN	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	2	0.17	3	0.26
1	1129	97.16	1132	97.42
2	30	2.58	1162	100.00

C8. Spleen ☐ 1. NOT ENLARGED ☐ 2. ENLARGED ☐ 3. N/A: S/P splenectomy

↓

C8.a Distance below LCM at MCL (cm) ☐☐ . ☐

C8. Spleen				
SPLEEN	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	4	0.34	5	0.43
1	980	84.34	985	84.77
2	27	2.32	1012	87.09
3	150	12.91	1162	100.00

Analysis Variable : DIST_SPL C8a. Distance below LCM at MCL (cm)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
27	0	4.0	2.1	1.0	2.0	3.5	6.0	8.0

C8a. Distance below LCM at MCL (cm)				
DIST_SPL	Frequency	Percent	Cum Freq	Cum Percent
-2	1135	100.00	1135	100.00

C9. Liver ☐ 1. NOT ENLARGED ☐ 2. ENLARGED

C9. Liver				
LIVER	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	3	0.26	4	0.34
1	1107	95.27	1111	95.61
2	51	4.39	1162	100.00

a. Tenderness ☐ 1. ABSENT ☐ 2. PRESENT

C9a. Liver tenderness				
TENDER	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.34	4	0.34
-8	1	0.09	5	0.43
-3	17	1.46	22	1.89
1	1138	97.93	1160	99.83
2	2	0.17	1162	100.00

C10. Extremities

a. Pain or limitation of motion in **1. NO** **2. YES**

1. Right hip? ☐ ☐

C10a1. Right hip (pain or limitation of motion)				
RIGHTHIP	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	5	0.43	6	0.52
1	1147	98.71	1153	99.23
2	9	0.77	1162	100.00

2. Left hip? ☐ ☐

C10a2. Left hip (pain or limitation of motion)				
LEFTHIP	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	5	0.43	6	0.52
1	1148	98.80	1154	99.31
2	8	0.69	1162	100.00

3. Right shoulder? ☐ ☐

C10a3. Right shoulder (pain or limitation of motion)				
R_SHOLDR	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	5	0.43	6	0.52
1	1152	99.14	1158	99.66
2	4	0.34	1162	100.00

4. Left shoulder? ☐ ☐

C10a4. Left shoulder (pain or limitation of motion)				
L_SHOLDR	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	5	0.43	6	0.52
1	1154	99.31	1160	99.83
2	2	0.17	1162	100.00

b. Leg ulcer ☐ **1. ABSENT** ☐ **2. PRESENT** → b1. ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

C10b. Leg ulcer				
LEGULCER	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	4	0.34	5	0.43
1	1157	99.57	1162	100.00

C10b1. Which leg (leg ulcer)				
WHICHLEG	Frequency	Percent	Cum Freq	Cum Percent
-2	1162	100.00	1162	100.00

c. Lower extremity edema ☐ **1. ABSENT** ☐ **2. PRESENT** → c1. ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

C10c. Lower extremity edema				
LE_EDEMA	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	4	0.34	5	0.43
1	1157	99.57	1162	100.00

C10c1. Which leg (lower extremity edema)				
WHICH_LE	Frequency	Percent	Cum Freq	Cum Percent
-2	1162	100.00	1162	100.00

C11. Skin ☐ **1. NORMAL** ☐ **2. ABNORMAL** → a. Describe _____

C11. Skin				
SKIN	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	5	0.43	6	0.52
1	1038	89.33	1044	89.85
2	118	10.15	1162	100.00

C12. Lymph nodes enlarged? ☐ **1. NO** ☐ **2. YES** → a. Specify _____

C12. Lymph nodes enlarged?				
L_NODES	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.09	1	0.09
-3	4	0.34	5	0.43
1	1107	95.27	1112	95.70
2	50	4.30	1162	100.00

Signature of Study Coordinator:_____ Date: ___ ___/___ ___/___ ___ ___ ___

STOP II
FORM 13: CORE LABORATORY FORM

A. Collection Information:

The **Core Laboratory Form** (Form 13) was to be completed for Randomized Patients at entry, quarterly, annual, transfusion, and exit visits, and at the time of suspected neurological event. After July 2003, Form 13 was no longer required at transfusion only visits for randomized patients after cross-over or an endpoint.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: "A" 11/15/00
"B" 01/10/02

SUMMARY OF VERSION DIFFERENCES

Version Date	
01/10/02	• Added question A3.a1 for Office Use to record TX_NUM. Variable was retrospectively added to all version A forms in the database.

D. Files Used to Store Information:

SAS System File: **p013_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype), LAV_D_DTFRMRAND**

Records in the dataset are sorted by LDU_ID, EX_TYPE, EX_NUM (vistype) and LAV_D_DTFRMRAND.

F. Number of Observations (Patients) in SAS Dataset: 1,530 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 193-194
- Listing of Variables by Position: See pp. 195-196

H. Formats:

The file **f013fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + “F” – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are “$”+variable name+”F” – e.g., the format label for a variable named “RATING” where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 197.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. Valid EX_TYPEs for Form 13 are:
  - QT: for quarterly and annual visits
  - TR: for transfusion visits
  - NE: for neurological events

  If the visit is a combined TR & QT visit, QT was assigned as the EX_TYPE.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 13 are:

  For EX_TYPE=QT,
  - 400 series numbers indicate visits completed after randomization
    - 401=randomization visit
    - 405, 409, or 413=annual visits

  For EX_TYPE=TR
  - No EX_NUM was required

  For EX_TYPE=NE
  - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

- **TX_NUM** - is the variable name for transfusion number. This three digit field is question A3.a1 labeled "Office Use" on the form 13. For Form 13:
    - Completed on all transfusion Form 13s (REASON1=5 or REASON2=5)
    - 500 series numbers indicate transfusions received on or after the randomization visit
    - TX_NUM=599 was used when a transfusion number was unknown, or (after July 2003) to indicate transfusions for randomized patients after cross-over or an endpoint

- **HAPLOTYP** - is the variable name for β^S haplotype. This information is stored in the **QT-401** visit Form 13. For patients previously randomized in the STOP trial, haplotype "ban" is the same as haplotype "car" used in STOP. Haplotyping was not completed for 24 STOP II randomized patients.

- **ALPHGENE** - is the variable name for number of α genes. This information is stored in the **QT-401** visit Form 13 (or the QT-402 Form 13 for one patient that did not complete a QT-401 Form 13.)

- **HEPATI_B** - is the variable name for Hepatitis B Surface Antibody. This test was to be completed at the entry visit for randomized patients. This information is stored in the **QT-401** visit Form 13 (or the QT-402 Form 13 for one patient that did not complete a QT-401 Form 13.) Results reflect one patient that was screened twice, once at the entry visit and once at a subsequent annual visit (QT-409).

- **HEPATI_C** - is the variable name for Hepatitis C Surface Antibody. This test was to be completed initially at the entry visit for all randomized patients, and repeated at the exit visit for active randomized patients. Results reflect one patient that was screened three times, once at the entry visit, once at a subsequent annual visit (QT-409), and once at the exit visit.

- **S_REPOSI** - is the variable name for serum repository sample. Samples were to be sent at entry, quarterly, annual, and exit visits, and for neurological events.

Data Set Name	PUBDS.P013_FINAL	Observations	1530
Member Type	DATA	Variables	60
Engine	V9	Indexes	0
Created	Wednesday, March 08, 2006 11:14:14 AM	Observation Length	512
Last Modified	Wednesday, March 08, 2006 11:14:14 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	50
First Data Page	1
Max Obs per Page	31
Obs in First Data Page	14
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p013_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
44	ALPHGENE	Char	10	$10.	D12. Number alpha genes
30	BANDS	Num	8	3.	D8b. Bands (%)
34	BASO	Num	8	3.	D8f. Basophils (%)
22	CBC_HEMA	Num	8	5.1	D5d. Hematocrit (%)
21	CBC_HEMO	Num	8	5.1	D5c. Hemoglobin (g/dl)
24	CBC_MCH	Num	8	5.1	D5f. Mean cell hemoglobin (pg)
25	CBC_MCHC	Num	8	5.1	D5g. Mean cell hemoglobin concentration (g/dl)
23	CBC_MCV	Num	8	4.	D5e. Mean cell volume (fl)
20	CBC_RBC	Num	8	5.2	D5b. Red cell count
26	CBC_RDW	Num	8	5.1	D5h. RDW (%)
19	CBC_WBC	Num	8	5.1	D5a. White cell count (uncorrected for nRBC's)
10	C_INITS	Char	3	$3.	D1. Core lab person completing form
49	DESTATUS	Char	1	$1.	DESTATUS
42	D_BILI	Num	8	5.1	D10e. Direct bilirubin (mg/dl)
33	EOSINO	Num	8	3.	D8e. Eosinophils (%)
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
37	FERRITIN	Num	8	6.	D9. Serum ferritin
48	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
39	GGT	Num	8	5.	D10b. GGT (U/I)
43	HAPLOTYP	Char	25	$25.	D11. Haplotype
14	HBA_A	Num	8	5.1	D4d. Percent A
13	HBA_A2	Num	8	4.1	D4c. Percent A2
12	HBA_F	Num	8	5.1	D4b. Percent F
15	HBA_OTH	Num	8	5.1	D4e. Percent other
17	HBA_PHEN	Num	8	3.	D4f. Hemoglobin phenotype

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
11	HBA_S	Num	8	5.1	D4a. Percent S
16	HB_OTH_S	Char	25	$25.	D4e1. Percent other hemoglobin, specify:
45	HEPATI_B	Num	8	5.1	D13a. Hepatitis B surface antibody
46	HEPATI_C	Num	8	5.1	D13b. Hepatitis C antibody
6	LAV_RECV	Num	8	3.	B1c. Number of tubes received in good condition (lavender)
5	LAV_TUBE	Num	8	3.	B1b. Number of tubes enclosed (lavender)
40	LDH	Num	8	5.	D10c. LDH (U/I)
31	LYMPHOCY	Num	8	3.	D8c. Lymphocytes (%)
32	MONO	Num	8	3.	D8d. Monocytes (%)
36	NRBC	Num	8	4.	D8h. Nucleated red blood cells (/100 WBC)
35	OTH_WBC	Num	8	3.	D8g. Other (%)
18	PHENSPEC	Char	25	$25.	D4f1. Hemoglobin phenotype, specify:
28	PLAT_CT	Num	8	5.	D7. Platelet count
3	REASON1	Num	8	3.	A3.1. Reason for collection
4	REASON2	Num	8	3.	A3.2. Reason for collection
8	RED_RECV	Num	8	3.	B2c. Number of tubes received in good condition (red)
7	RED_TUBE	Num	8	3.	B2b. Number of tubes enclosed (red)
27	RETICULO	Num	8	5.1	D6. Reticulocyte count (%)
38	SGPT	Num	8	5.	D10a. ALT (SGPT) (U/I)
47	S_REPOSI	Num	8	5.1	D14. Serum repository sample received
9	TRANSF_4	Num	8	3.	C1. Transfused during the last 4 months?
50	TX_NUM	Char	4	$4.	A3a1. Transfusion number
41	T_BILI	Num	8	5.1	D10d. Total bilirubin (mg/dl)
29	WBC_PMN	Num	8	3.	D8a. PMN (%)
53	comp_dfrmrand	Num	8		<created variable> D3. Date core lab section completed as days from RAND visit
56	event_dtfrmrand	Num	8		<created variable> A3b. Date of event as days from RAND visit
57	lav_d_dtfrmrand	Num	8		<created variable> B1a. Date blood drawn (lav-top tube) as days from RAND visit
52	ldu_id	Char	10		ID for public use datasets
60	recv_dtfrmrand	Num	8		<created variable> D2. Date blood received at core lab as days from RAND visit
58	red_d_dtfrmrand	Num	8		<created variable> B2a. Date blood drawn (red-top tube) as days from RAND visit
54	ship_dtfrmrand	Num	8		<created variable> A2. Date samples shipped as days from RAND visit
55	tran_datfrmrand	Num	8		<created variable> A3a. Date of transfusion as days from RAND visit
59	transf_dfrmrand	Num	8		<created variable> C1a. Date of last transfusion as days from RAND visit
51	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	REASON1	Num	8	3.	A3.1. Reason for collection
4	REASON2	Num	8	3.	A3.2. Reason for collection
5	LAV_TUBE	Num	8	3.	B1b. Number of tubes enclosed (lavender)
6	LAV_RECV	Num	8	3.	B1c. Number of tubes received in good condition (lavender)
7	RED_TUBE	Num	8	3.	B2b. Number of tubes enclosed (red)
8	RED_RECV	Num	8	3.	B2c. Number of tubes received in good condition (red)
9	TRANSF_4	Num	8	3.	C1. Transfused during the last 4 months?
10	C_INITS	Char	3	$3.	D1. Core lab person completing form
11	HBA_S	Num	8	5.1	D4a. Percent S
12	HBA_F	Num	8	5.1	D4b. Percent F
13	HBA_A2	Num	8	4.1	D4c. Percent A2
14	HBA_A	Num	8	5.1	D4d. Percent A
15	HBA_OTH	Num	8	5.1	D4e. Percent other
16	HB_OTH_S	Char	25	$25.	D4e1. Percent other hemoglobin, specify:
17	HBA_PHEN	Num	8	3.	D4f. Hemoglobin phenotype
18	PHENSPEC	Char	25	$25.	D4f1. Hemoglobin phenotype, specify:
19	CBC_WBC	Num	8	5.1	D5a. White cell count (uncorrected for nRBC's)
20	CBC_RBC	Num	8	5.2	D5b. Red cell count
21	CBC_HEMO	Num	8	5.1	D5c. Hemoglobin (g/dl)
22	CBC_HEMA	Num	8	5.1	D5d. Hematocrit (%)
23	CBC_MCV	Num	8	4.	D5e. Mean cell volume (fl)
24	CBC_MCH	Num	8	5.1	D5f. Mean cell hemoglobin (pg)
25	CBC_MCHC	Num	8	5.1	D5g. Mean cell hemoglobin concentration (g/dl)
26	CBC_RDW	Num	8	5.1	D5h. RDW (%)
27	RETICULO	Num	8	5.1	D6. Reticulocyte count (%)
28	PLAT_CT	Num	8	5.	D7. Platelet count
29	WBC_PMN	Num	8	3.	D8a. PMN (%)
30	BANDS	Num	8	3.	D8b. Bands (%)
31	LYMPHOCY	Num	8	3.	D8c. Lymphocytes (%)
32	MONO	Num	8	3.	D8d. Monocytes (%)
33	EOSINO	Num	8	3.	D8e. Eosinophils (%)
34	BASO	Num	8	3.	D8f. Basophils (%)
35	OTH_WBC	Num	8	3.	D8g. Other (%)
36	NRBC	Num	8	4.	D8h. Nucleated red blood cells (/100 WBC)
37	FERRITIN	Num	8	6.	D9. Serum ferritin
38	SGPT	Num	8	5.	D10a. ALT (SGPT) (U/I)
39	GGT	Num	8	5.	D10b. GGT (U/I)
40	LDH	Num	8	5.	D10c. LDH (U/I)
41	T_BILI	Num	8	5.1	D10d. Total bilirubin (mg/dl)
42	D_BILI	Num	8	5.1	D10e. Direct bilirubin (mg/dl)
43	HAPLOTYP	Char	25	$25.	D11. Haplotype
44	ALPHGENE	Char	10	$10.	D12. Number alpha genes
45	HEPATI_B	Num	8	5.1	D13a. Hepatitis B surface antibody
46	HEPATI_C	Num	8	5.1	D13b. Hepatitis C antibody
47	S_REPOSI	Num	8	5.1	D14. Serum repository sample received
48	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
49	DESTATUS	Char	1	$1.	DESTATUS
50	TX_NUM	Char	4	$4.	A3a1. Transfusion number
51	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
52	ldu_id	Char	10		ID for public use datasets
53	comp_dfrmrand	Num	8		<created variable> D3. Date core lab section completed as days from RAND visit
54	ship_dtfrmrand	Num	8		<created variable> A2. Date samples shipped as days from RAND visit
55	tran_datfrmrand	Num	8		<created variable> A3a. Date of transfusion as days from RAND visit
56	event_dtfrmrand	Num	8		<created variable> A3b. Date of event as days from RAND visit
57	lav_d_dtfrmrand	Num	8		<created variable> B1a. Date blood drawn (lav-top tube) as days from RAND visit
58	red_d_dtfrmrand	Num	8		<created variable> B2a. Date blood drawn (red-top tube) as days from RAND visit
59	transf_dfrmrand	Num	8		<created variable> C1a. Date of last transfusion as days from RAND visit
60	recv_dtfrmrand	Num	8		<created variable> D2. Date blood received at core lab as days from RAND visit

Sort Information

Sortedby	ldu_id vistype lav_d_dtfrmrand
Validated	YES
Character Set	ANSI

```
*F013fmts.txt;

proc format;

  value REASON1F
    1='1: Baseline visit'
    2='2: Quarterly visit'
    3='3: Annual visit'
    4='4: Exit from study'
    5='5: Transfusion'
    6='6: Neurological event';

  value REASON2F
    1='1: Baseline visit'
    2='2: Quarterly visit'
    3='3: Annual visit'
    4='4: Exit from study'
    5='5: Transfusion'
    6='6: Neurological event';

  value TRANSF_4F
    1='1: No'
    2='2: Yes';

  value HBA_PHENF
    1='1: SS'
    2='2: S-Beta thalassemia'
    3='3: Other';

  value HEPATI_BF
    1='1: Negative'
    2='2: Positive';

  value HEPATI_CF
    1='1: Negative'
    2='2: Positive';

  value S_REPOSIF
    1='1: No'
    2='2: Yes';

* format reason1 reason1f. reason2 reason2f. transf_4 transf_4f. hba_phen hba_phenf. hepati_b
hepati_bf. hepati_c hepati_cf. s_reposi s_reposif.;
```

STOP II TRIAL
CORE LABORATORY FORM

*****AFFIX PATIENT LABEL HERE*****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1525	99.67	1525	99.67
P	5	0.33	1530	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	2	0.13	2	0.13
QT-401	78	5.10	80	5.23
QT-402	74	4.84	154	10.07
QT-403	75	4.90	229	14.97
QT-404	66	4.31	295	19.28
QT-405	59	3.86	354	23.14
QT-406	54	3.53	408	26.67
QT-407	46	3.01	454	29.67
QT-408	50	3.27	504	32.94
QT-409	45	2.94	549	35.88
QT-410	42	2.75	591	38.63
QT-411	39	2.55	630	41.18
QT-412	36	2.35	666	43.53
QT-413	32	2.09	698	45.62
QT-414	17	1.11	715	46.73
QT-415	13	0.85	728	47.58
QT-416	5	0.33	733	47.91
QT-417	1	0.07	734	47.97
TR-	796	52.03	1530	100.00

A1. On-site person completing page 1 of form: _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date samples shipped (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : ship_dtfrmrand <created variable> A2. Date samples shipped as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1530	0	478.1	338.3	-2.0	195.0	423.0	736.0	1399.0

A3. Reason for Collection:

☐ **1. Baseline Visit** ☐ **2. Quarterly Visit**

☐ **3. Annual Visit** ☐ **4. Exit from study**

☐ **5. Transfusion** → A3.a Date of Transfusion (Month/Day/Year): ___ ___/___ ___/___ ___ ___ __

For Office Use A3.a1 ☐☐☐

☐ **6. Neurological Event** → A3.b Date of Event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ __

Table of REASON1 by REASON2							
REASON1(A3.1. Reason for collection)	REASON2(A3.2. Reason for collection)						
Frequency	-1	2	3	4	5	6	Total
1	35	0	0	0	43	0	78
2	195	0	0	0	276	1	472
3	32	0	0	1	64	0	97
4	45	0	0	0	23	0	68
5	799	13	1	0	0	1	814
6	0	0	0	0	1	0	1
Total	1106	13	1	1	407	2	1530

A3a1. Transfusion number				
TX_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	309	20.20	309	20.20
-9	3	0.20	312	20.39
501	56	3.66	368	24.05
502	35	2.29	403	26.34
503	42	2.75	445	29.08
504	37	2.42	482	31.50
505	41	2.68	523	34.18
506	42	2.75	565	36.93
507	35	2.29	600	39.22
508	38	2.48	638	41.70
509	37	2.42	675	44.12
510	37	2.42	712	46.54
511	32	2.09	744	48.63
512	34	2.22	778	50.85
513	32	2.09	810	52.94
514	33	2.16	843	55.10
515	32	2.09	875	57.19
516	28	1.83	903	59.02
517	27	1.76	930	60.78
518	26	1.70	956	62.48
519	26	1.70	982	64.18
520	25	1.63	1007	65.82
521	25	1.63	1032	67.45

A3a1. Transfusion number (continued)				
TX_NUM	Frequency	Percent	Cum Freq	Cum Percent
522	21	1.37	1053	68.82
523	19	1.24	1072	70.07
524	21	1.37	1093	71.44
525	20	1.31	1113	72.75
526	18	1.18	1131	73.92
527	20	1.31	1151	75.23
528	21	1.37	1172	76.60
529	21	1.37	1193	77.97
530	20	1.31	1213	79.28
531	19	1.24	1232	80.52
532	18	1.18	1250	81.70
533	18	1.18	1268	82.88
534	18	1.18	1286	84.05
535	18	1.18	1304	85.23
536	15	0.98	1319	86.21
537	19	1.24	1338	87.45
538	17	1.11	1355	88.56
539	14	0.92	1369	89.48
540	15	0.98	1384	90.46
541	10	0.65	1394	91.11
542	12	0.78	1406	91.90
543	12	0.78	1418	92.68
544	11	0.72	1429	93.40
545	10	0.65	1439	94.05
546	7	0.46	1446	94.51
547	6	0.39	1452	94.90
548	4	0.26	1456	95.16
549	4	0.26	1460	95.42
550	2	0.13	1462	95.56
551	1	0.07	1463	95.62
554	1	0.07	1464	95.69
555	1	0.07	1465	95.75
556	1	0.07	1466	95.82
599	64	4.18	1530	100.00

☐ **5. Transfusion** → A3.a Date of Transfusion (Month/Day/Year): ___ ___/___ ___/___ ___ ___ __

☐ **6. Neurological Event** → A3.b Date of Event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ __

Analysis Variable : tran_datfrmrand <created variable> A3a. Date of transfusion as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1221	0	479.6	325.5	-2.0	211.0	428.0	731.0	1351.0

<created variable> A3a. Date of transfusion as days from RAND visit

tran_datfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	309	100.00	309	100.00

Analysis Variable : event_dtfrmrand <created variable> A3b. Date of event as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	203.3	80.1	147.0	147.0	168.0	295.0	295.0

<created variable> A3b. Date of event as days from RAND visit

event_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1527	100.00	1527	100.00

B. SPECIMENS:

Type of Visit	Specimens Required (# in parentheses = # of tubes required) Routine Hematology (Lavender Top)	Serum Chemistries (Red Top)	Serum Repository (Red Top)
Trial Entry	(2) 5 ml	(2) 5 ml*	(1) 5 ml
Quarterly	(1) 5 ml		(1) 5 ml
Annual	(1) 5 ml	(1) 5 ml*	(1) 5 ml
Exit from study	(1) 5 ml	(1) 5 ml*	(1) 5 ml
Transfusion (pre)	(1) 5 ml		
Neurological Event	(1) 5 ml		(1) 5 ml

*** Will also be used for infection panel**

Amount and type of tube	*To be completed by Study Coordinator* Date blood Drawn	# of tubes Enclosed	*For Core Lab use* # of tubes received In good condition
B1. 5 ml lavender-top tube	a. ___ ___/___ ___/___ ___ ___ ___	b. _____	c. _____

Analysis Variable : lav_d_dtfrmrand <created variable> B1a. Date blood drawn (lav-top tube) as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1530	0	477.6	338.4	-3.0	195.0	423.0	735.0	1399.0

B1b. Number of tubes enclosed (lavender)

LAV_TUBE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.07	1	0.07
0	1	0.07	2	0.13
1	867	56.67	869	56.80
2	625	40.85	1494	97.65
3	33	2.16	1527	99.80
4	2	0.13	1529	99.93
5	1	0.07	1530	100.00

B1c. Number of tubes received in good condition (lavender)

LAV_RECV	Frequency	Percent	Cum Freq	Cum Percent
0	1	0.07	1	0.07
1	869	56.80	870	56.86
2	622	40.65	1492	97.52
3	35	2.29	1527	99.80
4	2	0.13	1529	99.93
5	1	0.07	1530	100.00

	To be completed by Study Coordinator		*For Core Lab use*
Amount and type of tube	Date blood Drawn	# of tubes Enclosed	# of tubes received In good condition
B2. 5 ml red-top tube	a. ___ ___/___ ___/___ ___ ___ ___	b. _____	c. _____

Analysis Variable : red_d_dtfrmrand <created variable> B2a. Date blood drawn (red-top tube) as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1056	0	467.8	344.5	-3.0	175.0	410.0	725.5	1399.0

<created variable> B2a. Date blood drawn (red-top tube) as days from RAND visit

red_d_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	474	100.00	474	100.00

B2b. Number of tubes enclosed (red)

RED_TUBE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.07	1	0.07
-3	1	0.07	2	0.13
-2	468	30.59	470	30.72
0	6	0.39	476	31.11
1	638	41.70	1114	72.81
2	256	16.73	1370	89.54
3	144	9.41	1514	98.95
4	14	0.92	1528	99.87
5	2	0.13	1530	100.00

B2c. Number of tubes received in good condition (red)

RED_RECV	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.07	1	0.07
-2	468	30.59	469	30.65
0	8	0.52	477	31.18
1	639	41.76	1116	72.94
2	254	16.60	1370	89.54
3	144	9.41	1514	98.95
4	14	0.92	1528	99.87
5	2	0.13	1530	100.00

C. TRANSFUSION STATUS

C1. Has patient been transfused during the last 4 months? ☐ 1. NO ☐ 2. YES

C1. Transfused during the last 4 months?				
TRANSF_4	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.13	2	0.13
1	120	7.84	122	7.97
2	1408	92.03	1530	100.00

C1.a Date of Last Transfusion: ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : transf_dfrmrand <created variable> C1a. Date of last transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1406	0	440.9	336.1	-87.0	160.0	388.5	698.0	1352.0

<created variable> C1a. Date of last transfusion as days from RAND visit				
transf_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	124	100.00	124	100.00

D. LABORATORY TEST RESULTS (To be completed by MCG Core Lab)

D1. Core Lab person completing form: _____ (Initials): ☐ ☐ ☐

D1. Core lab person completing form				
C_INITS	Frequency	Percent	Cum Freq	Cum Percent
JBH	1530	100.00	1530	100.00

D2. Date shipment received (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : recv_dtfrmrand <created variable> D2. Date blood received at core lab as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1530	0	479.2	338.3	-2.0	197.0	424.5	737.0	1399.0

D3. Date Core Lab sections completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> D3. Date core lab section completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1530	0	489.3	338.4	2.0	206.0	432.5	748.0	1413.0

D4. Hemoglobin Analysis:

a. % S ☐☐ . ☐

Analysis Variable : HBA_S D4a. Percent S								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1526	0	32.0	21.5	0.9	19.3	26.0	36.0	95.3

D4a. Percent S				
HBA_S	Frequency	Percent	Cum Freq	Cum Percent
-9	4	100.00	4	100.00

b. % F ☐☐ . ☐

Analysis Variable : HBA_F D4b. Percent F								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1526	0	3.4	3.4	0.7	1.0	2.4	4.4	39.6

D4b. Percent F				
HBA_F	Frequency	Percent	Cum Freq	Cum Percent
-9	4	100.00	4	100.00

c. %A_2 ☐☐ . ☐

Analysis Variable : HBA_A2 D4c. Percent A2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1526	0	2.5	0.3	1.0	2.3	2.5	2.6	4.1

D4c. Percent A2				
HBA_A2	Frequency	Percent	Cum Freq	Cum Percent
-9	4	100.00	4	100.00

d. %A ☐☐ . ☐

Analysis Variable : HBA_A D4d. Percent A								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1526	0	62.3	23.6	0.0	58.7	68.8	75.9	96.7

D4d. Percent A				
HBA_A	Frequency	Percent	Cum Freq	Cum Percent
-9	4	100.00	4	100.00

e. % other ☐☐ . ☐

Analysis Variable : HBA_OTH D4e. Percent other								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1526	0	0.1	0.8	0.0	0.0	0.0	0.0	14.0

D4e. Percent other				
HBA_OTH	Frequency	Percent	Cum Freq	Cum Percent
-9	4	100.00	4	100.00

D4.e1. **SPECIFY:** _____

D4e1. Percent other hemoglobin, specify:				
HB_OTH_S	Frequency	Percent	Cum Freq	Cum Percent
-2	1477	96.54	1477	96.54
HbC	43	2.81	1520	99.35
HbD	3	0.20	1523	99.54
HbX	1	0.07	1524	99.61
Unidentified variant	6	0.39	1530	100.00

f. Hemoglobin Phenotype

☐ **1. SS** ☐ **2. Sβ^o thal** ☐ **3. Other** → D4.f1. **SPECIFY:** _____

[Note: HbA_PHEN not done]

D5. CBC

a. White Cell Count (x 10 ^{9}/l) (uncorrected for nRBCs) ☐☐ . ☐ Reference Range 3.5 - 22.5

Analysis Variable : CBC_WBC D5a. White cell count (uncorrected for nRBC's)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	12.2	4.0	2.7	9.6	12.1	14.4	32.0

D5a. White cell count (uncorrected for nRBC's)				
CBC_WBC	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

b. Red Cell Count (x10^{12}/l) ☐ . ☐☐ 1.5 - 5

Analysis Variable : CBC_RBC D5b. Red cell count								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	3.1	0.5	1.5	2.8	3.1	3.4	5.0

D5b. Red cell count				
CBC_RBC	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

Reference Range

c. Hemoglobin (g/dl) ____ . ____ 5 - 12

Analysis Variable : CBC_HEMO D5c. Hemoglobin (g/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	9.3	1.2	4.8	8.5	9.4	10.1	13.3

D5c. Hemoglobin (g/dl)				
CBC_HEMO	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

d. Hematocrit (%) ____ . ____ 14 - 36

Analysis Variable : CBC_HEMA D5d. Hematocrit (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	27.5	3.7	13.2	25.2	27.7	29.9	39.8

D5d. Hematocrit (%)				
CBC_HEMA	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

e. Mean Cell Volume (fl) ____ 60 - 110

Analysis Variable : CBC_MCV D5e. Mean cell volume (fl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	88.6	5.3	68.0	86.0	88.0	91.0	132.0

D5e. Mean cell volume (fl)				
CBC_MCV	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

Reference Range
22 - 35

f. Mean Cell Hemoglobin (pg) ____ . ____

Analysis Variable : CBC_MCH D5f. Mean cell hemoglobin (pg)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	30.0	2.2	22.3	28.8	29.8	30.9	44.8

D5f. Mean cell hemoglobin (pg)				
CBC_MCH	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

g. Mean Cell Hemoglobin Concentration (g/dl) ____ . ____

Analysis Variable : CBC_MCHC D5g. Mean cell hemoglobin concentration (g/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	33.8	0.9	24.1	33.3	33.7	34.3	38.8

D5g. Mean cell hemoglobin concentration (g/dl)				
CBC_MCHC	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

h. RDW (%) ____ . ____

Analysis Variable : CBC_RDW D5h. RDW (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1420	0	18.8	3.0	13.1	16.7	18.3	20.2	36.4

D5h. RDW (%)				
CBC_RDW	Frequency	Percent	Cum Freq	Cum Percent
-9	109	99.09	109	99.09
-3	1	0.91	110	100.00

D6. Reticulocyte Count (%) ☐☐ . ☐

Reference Range
0 - 30

Analysis Variable : RETICULO D6. Reticulocyte count (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1418	0	8.8	4.6	0.1	5.9	8.3	10.2	35.1

D6. Reticulocyte count (%)				
RETICULO	Frequency	Percent	Cum Freq	Cum Percent
-9	112	100.00	112	100.00

D7. Platelet Count ($x10^9$/l) ☐☐☐☐

100 - 750

Analysis Variable : PLAT_CT D7. Platelet count								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1413	0	391.8	109.9	108.0	310.0	398.0	463.0	1344.0

D7. Platelet count				
PLAT_CT	Frequency	Percent	Cum Freq	Cum Percent
-9	116	99.15	116	99.15
-3	1	0.85	117	100.00

D8. WBC Differential/Nucleated RBCs

a. PMN (%) ☐☐

Analysis Variable : WBC_PMN D8a. PMN (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	39.4	17.4	0.0	27.0	40.0	51.0	88.0

D8a. PMN (%)				
WBC_PMN	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

b. Bands (%)

Analysis Variable : BANDS D8b. Bands (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	2.4	4.1	0.0	0.0	1.0	3.0	62.0

D8b. Bands (%)				
BANDS	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

c. Lymphocytes (%)

Analysis Variable : LYMPHOCY D8c. Lymphocytes (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	44.1	16.5	3.0	32.0	43.0	55.0	98.0

D8c. Lymphocytes (%)				
LYMPHOCY	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

d. Monocytes (%)

Analysis Variable : MONO D8d. Monocytes (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	9.4	5.7	0.0	5.0	8.0	12.0	56.0

D8d. Monocytes (%)				
MONO	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

e. Eosinophils (%)

Analysis Variable : EOSINO D8e. Eosinophils (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	3.7	3.8	0.0	1.0	3.0	5.0	35.0

D8e. Eosinophils (%)				
EOSINO	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

f. Basophils (%)

Analysis Variable : BASO D8f. Basophils (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	0.8	1.1	0.0	0.0	0.0	1.0	6.0

D8f. Basophils (%)				
BASO	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

g. Other (includes atypical cells, myelocytes, metamyelocytes) (%)

Analysis Variable : OTH_WBC D8g. Other (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	0.3	0.8	0.0	0.0	0.0	0.0	14.0

D8g. Other (%)				
OTH_WBC	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

h. Nucleated Red Blood Cells (/100 WBC)

Analysis Variable : NRBC D8h. Nucleated red blood cells (/100 WBC)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1392	0	3.8	12.5	0.0	0.0	1.0	4.0	323.0

D8h. Nucleated red blood cells (/100 WBC)				
NRBC	Frequency	Percent	Cum Freq	Cum Percent
-9	137	99.28	137	99.28
-3	1	0.72	138	100.00

D9. Serum Ferritin (ng/ml)

Analysis Variable : FERRITIN D9. Serum ferritin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1028	0	3226.1	1944.0	5.0	1786.5	2966.5	4250.5	14518

D9. Serum ferritin				
FERRITIN	Frequency	Percent	Cum Freq	Cum Percent
-9	15	2.99	15	2.99
-3	4	0.80	19	3.78
-1	483	96.22	502	100.00

D10. Serum chemistries

a. ALT (SGPT) (U/l)

Reference Range
0 - 75

Analysis Variable : SGPT D10a. ALT (SGPT) (U/I)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
265	0	35.8	31.5	5.0	19.0	30.0	41.0	329.0

D10a. ALT (SGPT) (U/I)				
SGPT	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.32	4	0.32
-3	6	0.47	10	0.79
-1	1255	99.21	1265	100.00

Reference Range

b. GGT (U/l) | | | | | 12 - 89

Analysis Variable : GGT D10b. GGT (U/I)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
264	0	26.5	27.5	1.0	15.0	19.0	29.5	317.0

D10b. GGT (U/I)				
GGT	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.39	5	0.39
-3	6	0.47	11	0.87
-1	1255	99.13	1266	100.00

c. LDH (U/l) | | | | | 50 - 1000

Analysis Variable : LDH D10c. LDH (U/I)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
263	0	464.1	212.8	152.0	330.0	406.0	563.0	1822.0

D10c. LDH (U/I)				
LDH	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.39	5	0.39
-3	8	0.63	13	1.03
-1	1254	98.97	1267	100.00

d. Total Bilirubin (mg/dl) | | | . | | .5 - 10

Analysis Variable : T_BILI D10d. Total bilirubin (mg/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
266	0	2.9	2.0	0.6	1.7	2.5	3.4	12.9

D10d. Total bilirubin (mg/dl)				
T_BILI	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.32	4	0.32
-3	7	0.55	11	0.87
-1	1253	99.13	1264	100.00

e. Direct Bilirubin (mg/dl) ☐☐.☐

Reference Range
0 - 1.0

Analysis Variable : D_BILI D10e. Direct bilirubin (mg/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
265	0	0.4	0.2	0.0	0.3	0.4	0.5	1.8

D10e. Direct bilirubin (mg/dl)				
D_BILI	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.32	4	0.32
-3	7	0.55	11	0.87
-1	1254	99.13	1265	100.00

D11. β^S Haplotype: _____

D11. Haplotype				
HAPLOTYP	Frequency	Percent	Cum Freq	Cum Percent
-1	11	0.72	11	0.72
-3	1464	95.69	1475	96.41
ban/ ?	5	0.33	1480	96.73
ban/ban	5	0.33	1485	97.06
ben/ ?	3	0.20	1488	97.25
ben/ban	13	0.85	1501	98.10
ben/ben	19	1.24	1520	99.35
cam/ben	1	0.07	1521	99.41
sen/ ?	2	0.13	1523	99.54
sen/ban	1	0.07	1524	99.61
sen/ben	6	0.39	1530	100.00

[Note: For patients previously randomized in the STOP trial, haplotype "ban" is the same as haplotype "car" used in STOP. Test not completed for 24 STOP II randomized patients.]

D12. Number α Genes: ☐

D12. Number alpha genes				
ALPHGENE	Frequency	Percent	Cum Freq	Cum Percent
-1	11	0.72	11	0.72
-3	1440	94.12	1451	94.84
-a/-a	1	0.07	1452	94.90
-a/aa	17	1.11	1469	96.01
aa/aa	61	3.99	1530	100.00

D13. Infection Panel:

a. Hepatitis B Surface Antibody ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D13a. Hepatitis B surface antibody				
HEPATI_B	Frequency	Percent	Cum Freq	Cum Percent
-1	1450	94.77	1450	94.77
1	22	1.44	1472	96.21
2	58	3.79	1530	100.00

b. Hepatitis C Antibody ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D13b. Hepatitis C antibody				
HEPATI_C	Frequency	Percent	Cum Freq	Cum Percent
-1	1382	90.33	1382	90.33
1	147	9.61	1529	99.93
2	1	0.07	1530	100.00

D14. Serum repository sample received ☐ **1. NO** ☐ **2. YES**

D14. Serum repository sample received				
S_REPOSI	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.13	2	0.13
-1	717	46.86	719	46.99
1	121	7.91	840	54.90
2	690	45.10	1530	100.00

STOP II
FORM 13B: LOCAL LABORATORY FORM FOR NON-RANDOMIZED PATIENTS RECEIVING TRANSFUSIONS

A. Collection Information:

The **Local Laboratory Form for Non-Randomized Patients Receiving Transfusions** (Form 13B) was to be completed at entry and quarterly visits, and prior to each transfusion for Potential Patients.

B. Data Collection Period: December 2000 through November 2004

C. Form Version Dates (**VER_ID**): "A" 11/15/00
"B" 01/14/02

SUMMARY OF VERSION DIFFERENCES

Version Date	
01/14/02	• Added question A3.a1 for Office Use to record TX_NUM. Variable was retrospectively added to all version A forms in the database.

D. Files Used to Store Information:

SAS System File: **p13b_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype), TRAN_DATFRMRAND**

Records in the dataset are sorted by LDU_ID, EX_TYPE, EX_NUM (vistype), and TRAN_DATFRMRAND.

F. Number of Observations (Patients) in SAS Dataset: 1,703 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 220-221
- Listing of Variables by Position: See p. 222

H. Formats:

The file **f13Bfmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + “F” – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are “$”+variable name+”F” – e.g., the format label for a variable named “RATING” where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 223.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. Valid EX_TYPEs for Form 13B are:
  - QT: for quarterly visits
  - TR: for transfusion visits

  If the visit is a combined TR & QT visit, QT was assigned as the EX_TYPE.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 13B are:

  For EX_TYPE=QT,
  - 200 & 300 series numbers indicate visits that were completed prior to randomization.
    - 200 series numbers were assigned to “Potential 1” visits – i.e., quarterly visits completed while the patient was on transfusion for < 30 months
    - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months

  For EX_TYPE=TR
  - No EX_NUM was required

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

- **TRAN_DATFRMRAND** - is the variable name for transfusion date, calculated as days from randomization. A few retrospectively completed Form 13Bs remain in the dataset for transfusions received by patients previously randomized in STOP after the end of STOP but prior to enrollment as STOP II Potential patients.

- **TX_NUM** - is the variable name for transfusion number. This three digit field is question A3.a1 labeled "Office Use" on the form 13B. For Form 13B:
    - Completed on all transfusion Form 13Bs (REAS1=3 or REAS2=3)
    - Blank TX_NUMs indicate previously data entered Version A forms that were not updated
    - 001-150 series numbers indicate transfusions received by patients previously randomized in STOP after the end of STOP but prior to enrollment as STOP II Potential patients
    - 300 series numbers indicate transfusions received by patients previously randomized in STOP after enrollment as STOP II Potential patients.
    - TX_NUM=199 indicates transfusions for STOP II Potential patients who were not randomized in STOP

Data Set Name	PUBDS.P13B_FINAL	Observations	1703
Member Type	DATA	Variables	36
Engine	V9	Indexes	0
Created	Wednesday, March 08, 2006 01:44:16 PM	Observation Length	272
Last Modified	Wednesday, March 08, 2006 01:44:16 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	29
First Data Page	1
Max Obs per Page	60
Obs in First Data Page	38
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p13b_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
10	CBC_HEMA	Num	8	5.1	D2d. CBC: Hematocrit (%)
9	CBC_HEMO	Num	8	5.1	D2c. CBC: Hemoglobin (g/dl)
12	CBC_MCH	Num	8	5.1	D2f. CBC: Mean cell hemoglobin (pg)
13	CBC_MCHC	Num	8	5.1	D2g. CBC: Mean cell hemoglobin concentration (g/dl)
11	CBC_MCV	Num	8	4.	D2e. CBC: Mean cell volume (fl)
8	CBC_RBC	Num	8	5.2	D2b. CBC: Red cell count
14	CBC_RDW	Num	8	5.1	D2h. CBC: RDW (%)
21	CBC_SRCE	Num	8	3.	E1. Local CBC report received
7	CBC_WBC	Num	8	5.1	D2a. CBC: White cell count
26	DESTATUS	Char	1	$1.	DESTATUS
20	D_BILI	Num	8	5.1	D4e. Serum chemistries: Direct bilirubin (mg/dl)
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
15	FERRITIN	Num	8	6.	D3. Serum ferritin (ng/ml)
23	FERRSRCE	Num	8	3.	E3. Serum ferritin report received
25	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
17	GGT	Num	8	5.	D4b. Serum chemistries: GGT (U/l)
6	HBA_S	Num	8	5.1	D1a. Hemoglobin analysis: % S
22	HBS_SRCE	Num	8	3.	E2. Hemoglobin analysis report received
18	LDH	Num	8	5.	D4c. Serum chemistries: LDH (U/l)
24	LFT_SRCE	Num	8	3.	E4. Liver profile report received
3	REAS1	Num	8	3.	A3.1. Reason for completion
4	REAS2	Num	8	3.	A3.2. Reason for completion
16	SGPT	Num	8	5.	D4a. Serum chemistries: ALT (SGPT) (U/l)
5	TRANSF_4	Num	8	3.	C1. Has patient been transfused during last 4 months?
27	TX_NUM	Num	8		A3a1. Transfusion number

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
19	T_BILI	Num	8	5.1	D4d. Serum chemistries: Total bilirubin (mg/dl)
32	cbc_dtfrmrand	Num	8		<created variable> B1. Date blood drawn for CBC as days from RAND visit
30	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
34	ferr_dtfrmrand	Num	8		<created variable> B3. Date blood drawn for ferritin as days from RAND visit
33	hbs_dtfrmrand	Num	8		<created variable> B2. Date blood drawn for HB S as days from RAND visit
29	ldu_id	Char	10		ID for public use datasets
35	lft_dtfrmrand	Num	8		<created variable> B4. Date blood drawn for liver profile as days from RAND visit
31	tran_datfrmrand	Num	8		<created variable> A3a. Date of transfusion as days from RAND visit
36	transf_dfrmrand	Num	8		<created variable> C1a. Date of last transfusion as days from RAND visit
28	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	REAS1	Num	8	3.	A3.1. Reason for completion
4	REAS2	Num	8	3.	A3.2. Reason for completion
5	TRANSF_4	Num	8	3.	C1. Has patient been transfused during last 4 months?
6	HBA_S	Num	8	5.1	D1a. Hemoglobin analysis: % S
7	CBC_WBC	Num	8	5.1	D2a. CBC: White cell count
8	CBC_RBC	Num	8	5.2	D2b. CBC: Red cell count
9	CBC_HEMO	Num	8	5.1	D2c. CBC: Hemoglobin (g/dl)
10	CBC_HEMA	Num	8	5.1	D2d. CBC: Hematocrit (%)
11	CBC_MCV	Num	8	4.	D2e. CBC: Mean cell volume (fl)
12	CBC_MCH	Num	8	5.1	D2f. CBC: Mean cell hemoglobin (pg)
13	CBC_MCHC	Num	8	5.1	D2g. CBC: Mean cell hemoglobin concentration (g/dl)
14	CBC_RDW	Num	8	5.1	D2h. CBC: RDW (%)
15	FERRITIN	Num	8	6.	D3. Serum ferritin (ng/ml)
16	SGPT	Num	8	5.	D4a. Serum chemistries: ALT (SGPT) (U/l)
17	GGT	Num	8	5.	D4b. Serum chemistries: GGT (U/l)
18	LDH	Num	8	5.	D4c. Serum chemistries: LDH (U/l)
19	T_BILI	Num	8	5.1	D4d. Serum chemistries: Total bilirubin (mg/dl)
20	D_BILI	Num	8	5.1	D4e. Serum chemistries: Direct bilirubin (mg/dl)
21	CBC_SRCE	Num	8	3.	E1. Local CBC report received
22	HBS_SRCE	Num	8	3.	E2. Hemoglobin analysis report received
23	FERRSRCE	Num	8	3.	E3. Serum ferritin report received
24	LFT_SRCE	Num	8	3.	E4. Liver profile report received
25	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
26	DESTATUS	Char	1	$1.	DESTATUS
27	TX_NUM	Num	8		A3a1. Transfusion number
28	vistype	Char	7		<created variable> VISIT TYPE
29	ldu_id	Char	10		ID for public use datasets
30	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
31	tran_datfrmrand	Num	8		<created variable> A3a. Date of transfusion as days from RAND visit
32	cbc_dtfrmrand	Num	8		<created variable> B1. Date blood drawn for CBC as days from RAND visit
33	hbs_dtfrmrand	Num	8		<created variable> B2. Date blood drawn for HB S as days from RAND visit
34	ferr_dtfrmrand	Num	8		<created variable> B3. Date blood drawn for ferritin as days from RAND visit
35	lft_dtfrmrand	Num	8		<created variable> B4. Date blood drawn for liver profile as days from RAND visit
36	transf_dfrmrand	Num	8		<created variable> C1a. Date of last transfusion as days from RAND visit

Sort Information

Sortedby	ldu_id vistype tran_datfrmrand
Validated	YES
Character Set	ANSI

```
*F13Bfmts.txt;

proc format;

  value REAS1F
    1='1: Entry Visit'
    2='2: Quarterly Visit'
    3='3: Pre-transfusion';

  value REAS2F
    1='1: Entry Visit'
    2='2: Quarterly Visit'
    3='3: Pre-transfusion';

  value TRANSF_4F
    1='1: No'
    2='2: Yes';

  value CBC_SRCEF
    1='1: No'
    2='2: Yes';

  value HBS_SRCEF
    1='1: No'
    2='2: Yes';

  value FERRSRCEF
    1='1: No'
    2='2: Yes';

  value LFT_SRCEF
    1='1: No'
    2='2: Yes';

* format reas1 reas1f. reas2 reas2f. transf_4 transf_4f. cbc_srce cbc_srcef. hbs_srce hbs_srcef. ferrsrce
ferrsrcef. lft_srce lft_srcef.;
```

STOP II
LOCAL LABORATORY FORM FOR NON-RANDOMIZED
PATIENTS RECEIVING TRANSFUSIONS

AFFIX PATIENT LABEL

HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1695	99.53	1695	99.53
P	8	0.47	1703	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-201	33	1.94	33	1.94
QT-202	28	1.64	61	3.58
QT-203	24	1.41	85	4.99
QT-204	26	1.53	111	6.52
QT-205	26	1.53	137	8.04
QT-206	22	1.29	159	9.34
QT-207	20	1.17	179	10.51
QT-208	18	1.06	197	11.57
QT-209	17	1.00	214	12.57
QT-210	16	0.94	230	13.51
QT-301	78	4.58	308	18.09
QT-302	41	2.41	349	20.49
QT-303	24	1.41	373	21.90
QT-304	20	1.17	393	23.08
QT-305	12	0.70	405	23.78
QT-306	6	0.35	411	24.13
QT-307	3	0.18	414	24.31
QT-308	3	0.18	417	24.49
QT-309	2	0.12	419	24.60
QT-310	2	0.12	421	24.72
TR-	1282	75.28	1703	100.00

A1. Person completing form: _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1703	0	-366.7	306.7	-1343	-602.0	-301.0	-112.0	652.0

A3. Reason for Completion:

☐ **1. Entry Visit** ☐ **2. Quarterly Visit** For Office Use

☐ **3. Pre-transfusion** → A3.a Date of Transfusion (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ A3.a1 | | |

Table of REAS1 by REAS2					
REAS1(A3.1. Reason for completion)	REAS2(A3.2. Reason for completion)				
Frequency	-1	1	2	3	Total
1	12	0	0	59	71
2	23	0	0	312	335
3	1287	2	8	0	1297
Total	1322	2	8	371	1703

Analysis Variable : tran_datfrmrand <created variable> A3a. Date of transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1668	0	-401.4	289.9	-1343	-620.0	-341.5	-152.0	0.0

<created variable> A3a. Date of transfusion as days from RAND visit				
tran_datfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	35	100.00	35	100.00

A3a1. Transfusion number				
TX_NUM	Frequency	Percent	Cum Freq	Cum Percent
.	353	20.73	353	20.73
-2	13	0.76	366	21.49
33	1	0.06	367	21.55
34	1	0.06	368	21.61
36	1	0.06	369	21.67
37	1	0.06	370	21.73
38	2	0.12	372	21.84
39	2	0.12	374	21.96
40	3	0.18	377	22.14
41	4	0.23	381	22.37
42	3	0.18	384	22.55
43	2	0.12	386	22.67
44	1	0.06	387	22.72
45	2	0.12	389	22.84
46	2	0.12	391	22.96
47	2	0.12	393	23.08
48	2	0.12	395	23.19
49	1	0.06	396	23.25
50	1	0.06	397	23.31
51	1	0.06	398	23.37
56	1	0.06	399	23.43
57	1	0.06	400	23.49
58	1	0.06	401	23.55
59	1	0.06	402	23.61
60	1	0.06	403	23.66
61	2	0.12	405	23.78
62	3	0.18	408	23.96
63	3	0.18	411	24.13
64	2	0.12	413	24.25
65	4	0.23	417	24.49
66	6	0.35	423	24.84
67	7	0.41	430	25.25
68	6	0.35	436	25.60
69	3	0.18	439	25.78
70	2	0.12	441	25.90
71	1	0.06	442	25.95
72	3	0.18	445	26.13
73	2	0.12	447	26.25
74	2	0.12	449	26.37
75	1	0.06	450	26.42
76	1	0.06	451	26.48
77	1	0.06	452	26.54
78	1	0.06	453	26.60
79	1	0.06	454	26.66
80	1	0.06	455	26.72
81	1	0.06	456	26.78
82	1	0.06	457	26.83
83	1	0.06	458	26.89
84	1	0.06	459	26.95
199	864	50.73	1323	77.69

A3a1. Transfusion number (continued)				
TX_NUM	Frequency	Percent	Cum Freq	Cum Percent
301	36	2.11	1359	79.80
302	37	2.17	1396	81.97
303	38	2.23	1434	84.20
304	34	2.00	1468	86.20
305	30	1.76	1498	87.96
306	30	1.76	1528	89.72
307	27	1.59	1555	91.31
308	20	1.17	1575	92.48
309	18	1.06	1593	93.54
310	17	1.00	1610	94.54
311	14	0.82	1624	95.36
312	9	0.53	1633	95.89
313	6	0.35	1639	96.24
314	7	0.41	1646	96.65
315	5	0.29	1651	96.95
316	5	0.29	1656	97.24
317	5	0.29	1661	97.53
318	4	0.23	1665	97.77
319	4	0.23	1669	98.00
320	4	0.23	1673	98.24
321	4	0.23	1677	98.47
322	3	0.18	1680	98.65
323	3	0.18	1683	98.83
324	3	0.18	1686	99.00
325	2	0.12	1688	99.12
326	1	0.06	1689	99.18
327	1	0.06	1690	99.24
328	1	0.06	1691	99.30
329	1	0.06	1692	99.35
330	1	0.06	1693	99.41
331	1	0.06	1694	99.47
332	1	0.06	1695	99.53
333	1	0.06	1696	99.59
334	1	0.06	1697	99.65
335	1	0.06	1698	99.71
336	1	0.06	1699	99.77
337	1	0.06	1700	99.82
338	1	0.06	1701	99.88
339	1	0.06	1702	99.94
340	1	0.06	1703	100.00

B. TESTS REQUIRED

Test Required

Type of Visit:	CBC	HBS	Ferritin	Liver Profile
Entry	X	X	X	X
Quarterly	X	X	X	X
Transfusion (pre)	X	X		

B1. Date Blood Drawn for CBC (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

Analysis Variable : cbc_dtfrmrand <created variable> B1. Date blood drawn for CBC as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1699	0	-402.8	290.8	-1343	-623.0	-341.0	-153.0	-1.0

<created variable> B1. Date blood drawn for CBC as days from RAND visit

cbc_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	4	100.00	4	100.00

B2. Date Blood Drawn for Hemoglobin S (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

Analysis Variable : hbs_dtfrmrand <created variable> B2. Date blood drawn for HB S as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1642	0	-401.1	290.5	-1343	-623.0	-337.5	-151.0	-1.0

<created variable> B2. Date blood drawn for HB S as days from RAND visit

hbs_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	61	100.00	61	100.00

B3. Date Blood Drawn for Ferritin (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

Analysis Variable : ferr_dtfrmrand <created variable> B3. Date blood drawn for ferritin as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
749	0	-395.4	277.1	-1237	-599.0	-345.0	-160.0	-1.0

<created variable> B3. Date blood drawn for ferritin as days from RAND visit

ferr_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	954	100.00	954	100.00

B4. Date Blood Drawn for Liver Profile (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___ ☐ -1. **NOT DONE**

Analysis Variable : lft_dtfrmrand <created variable> B4. Date blood drawn for liver profile as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
586	0	-423.8	290.4	-1237	-649.0	-378.0	-168.0	-4.0

<created variable> B4. Date blood drawn for liver profile as days from RAND visit				
lft_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1117	100.00	1117	100.00

C. TRANSFUSION STATUS

C1. Has patient been transfused during the last 4 months? ☐ **1. NO** ☐ **2. YES**

C1. Has patient been transfused during last 4 months?				
TRANSF_4	Frequency	Percent	Cum Freq	Cum Percent
1	17	1.00	17	1.00
2	1686	99.00	1703	100.00

↓

C1.a Date of Last Transfusion: ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : transf_dfrmrand <created variable> C1a. Date of last transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1684	0	-422.0	285.5	-1373	-637.0	-363.0	-175.5	-22.0

<created variable> C1a. Date of last transfusion as days from RAND visit				
transf_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	19	100.00	19	100.00

D. LABORATORY TEST RESULTS

D1. Hemoglobin Analysis:

a. % S ☐☐ . ☐

Analysis Variable : HBA_S D1a. Hemoglobin analysis: %% S								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1634	0	26.7	12.9	0.0	18.2	25.1	33.4	99.9

D1a. Hemoglobin analysis: % S				
HBA_S	Frequency	Percent	Cum Freq	Cum Percent
-9	2	2.90	2	2.90
-3	67	97.10	69	100.00

D2. CBC

Reference Range

a. White Cell Count (x 10 ^{9}/l) (uncorrected for nRBCs) ☐☐ . ☐ 3.5 - 22.5

Analysis Variable : CBC_WBC D2a. CBC: White cell count								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1687	0	12.7	3.7	4.4	10.1	12.3	14.5	36.2

D2a. CBC: White cell count				
CBC_WBC	Frequency	Percent	Cum Freq	Cum Percent
-9	3	18.75	3	18.75
-3	13	81.25	16	100.00

b. Red Cell Count (x10^{12}/l) ☐ . ☐☐ 1.5 - 5

Analysis Variable : CBC_RBC D2b. CBC: Red cell count								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1684	0	3.2	0.4	1.7	3.0	3.2	3.4	5.6

D2b. CBC: Red cell count				
CBC_RBC	Frequency	Percent	Cum Freq	Cum Percent
-9	2	10.53	2	10.53
-8	1	5.26	3	15.79
-3	16	84.21	19	100.00

Reference Range

c. Hemoglobin (g/dl) [ ][ ] . [ ] 5 - 12

Analysis Variable : CBC_HEMO D2c. CBC: Hemoglobin (g/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1696	0	9.4	0.9	6.0	8.8	9.4	10.0	14.2

D2c. CBC: Hemoglobin (g/dl)				
CBC_HEMO	Frequency	Percent	Cum Freq	Cum Percent
-9	2	28.57	2	28.57
-3	5	71.43	7	100.00

d. Hematocrit (%) [ ][ ] . [ ] 14 - 36

Analysis Variable : CBC_HEMA D2d. CBC: Hematocrit (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1697	0	27.6	2.8	17.0	25.9	27.7	29.4	42.4

D2d. CBC: Hematocrit (%)				
CBC_HEMA	Frequency	Percent	Cum Freq	Cum Percent
-9	2	33.33	2	33.33
-3	4	66.67	6	100.00

e. Mean Cell Volume (fl) [ ][ ][ ] 60 - 110

Analysis Variable : CBC_MCV D2e. CBC: Mean cell volume (fl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1686	0	86.6	3.7	70.0	85.0	87.0	89.0	113.0

D2e. CBC: Mean cell volume (fl)				
CBC_MCV	Frequency	Percent	Cum Freq	Cum Percent
-9	2	11.76	2	11.76
-8	1	5.88	3	17.65
-3	14	82.35	17	100.00

Reference Range
22 - 35

f. Mean Cell Hemoglobin (pg) ____ . ____

Analysis Variable : CBC_MCH D2f. CBC: Mean cell hemoglobin (pg)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1621	0	29.4	1.5	22.1	28.5	29.4	30.4	38.3

D2f. CBC: Mean cell hemoglobin (pg)				
CBC_MCH	Frequency	Percent	Cum Freq	Cum Percent
-9	2	2.44	2	2.44
-8	1	1.22	3	3.66
-3	77	93.90	80	97.56
-1	2	2.44	82	100.00

g. Mean Cell Hemoglobin Concentration (g/dl) ____ . ____

Analysis Variable : CBC_MCHC D2g. CBC: Mean cell hemoglobin concentration (g/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1673	0	34.0	1.0	28.0	33.3	34.0	34.6	39.8

D2g. CBC: Mean cell hemoglobin concentration (g/dl)				
CBC_MCHC	Frequency	Percent	Cum Freq	Cum Percent
-9	2	6.67	2	6.67
-8	1	3.33	3	10.00
-3	26	86.67	29	96.67
-1	1	3.33	30	100.00

h. RDW (%) ____ . ____

Analysis Variable : CBC_RDW D2h. CBC: RDW (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1591	0	17.4	2.3	10.3	15.9	17.0	18.4	30.0

D2h. CBC: RDW (%)				
CBC_RDW	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.89	1	0.89
-8	1	0.89	2	1.79
-3	104	92.86	106	94.64
-1	6	5.36	112	100.00

D3. Serum Ferritin (ng/ml) | | | | | |

Analysis Variable : FERRITIN D3. Serum ferritin (ng/ml)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
746	0	2258.4	1330.2	1.0	1377.0	2089.0	2940.0	8719.0

D3. Serum ferritin (ng/ml)				
FERRITIN	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.31	3	0.31
-3	103	10.76	106	11.08
-1	851	88.92	957	100.00

D4. Serum chemistries

Reference Range

a. ALT (SGPT) (U/l) | | | | | 0 - 75

Analysis Variable : SGPT D4a. Serum chemistries: ALT (SGPT) (U/l)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
574	0	30.2	22.8	3.0	19.0	26.0	34.0	372.0

D4a. Serum chemistries: ALT (SGPT) (U/l)				
SGPT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.18	2	0.18
-3	126	11.16	128	11.34
-1	1001	88.66	1129	100.00

b. GGT (U/l) | | | | | 12 - 89

Analysis Variable : GGT D4b. Serum chemistries: GGT (U/l)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
289	0	23.0	9.4	6.0	17.0	22.0	27.0	75.0

D4b. Serum chemistries: GGT (U/l)				
GGT	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.21	3	0.21
-3	248	17.54	251	17.75
-1	1163	82.25	1414	100.00

Reference Range

c. LDH (U/l) [ ][ ][ ][ ] 50 - 1000

Analysis Variable : LDH D4c. Serum chemistries: LDH (U/l)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
307	0	871.4	570.5	194.0	412.0	712.0	1269.0	4840.0

D4c. Serum chemistries: LDH (U/l)				
LDH	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.14	2	0.14
-3	240	17.19	242	17.34
-1	1154	82.66	1396	100.00

d. Total Bilirubin (mg/dl) [ ][ ] . [ ] .5 - 10

Analysis Variable : T_BILI D4d. Serum chemistries: Total bilirubin (mg/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
570	0	2.4	1.1	0.1	1.5	2.2	2.9	7.7

D4d. Serum chemistries: Total bilirubin (mg/dl)				
T_BILI	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.18	2	0.18
-3	125	11.03	127	11.21
-1	1006	88.79	1133	100.00

e. Direct Bilirubin (mg/dl) [ ][ ] . [ ] 0 - 1.0

Analysis Variable : D_BILI D4e. Serum chemistries: Direct bilirubin (mg/dl)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
489	0	0.2	0.2	0.0	0.1	0.2	0.3	2.4

D4e. Serum chemistries: Direct bilirubin (mg/dl)				
D_BILI	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.16	2	0.16
-3	150	12.36	152	12.52
-1	1062	87.48	1214	100.00

ATTACH LABORATORY REPORTS FOR ALL TESTS PERFORMED

Signature of Study Coordinator: _____ Date: ___ ___/___ ____/___ ___ ___ ___

E. FOR OFFICE USE

E1. Local CBC report received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NOT APPLICABLE**

E1. Local CBC report received				
CBC_SRCE	Frequency	Percent	Cum Freq	Cum Percent
-1	2	0.12	2	0.12
1	11	0.65	13	0.76
2	1690	99.24	1703	100.00

E2. Hemoglobin analysis report received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NOT APPLICABLE**

E2. Hemoglobin analysis report received				
HBS_SRCE	Frequency	Percent	Cum Freq	Cum Percent
-1	4	0.23	4	0.23
1	69	4.05	73	4.29
2	1630	95.71	1703	100.00

E3. Serum ferritin report received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NOT APPLICABLE**

E3. Serum ferritin report received				
FERRSRCE	Frequency	Percent	Cum Freq	Cum Percent
-1	861	50.56	861	50.56
1	106	6.22	967	56.78
2	736	43.22	1703	100.00

E4. Liver profile report received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NOT APPLICABLE**

E4. Liver profile report received				
LFT_SRCE	Frequency	Percent	Cum Freq	Cum Percent
-1	1008	59.19	1008	59.19
1	118	6.93	1126	66.12
2	577	33.88	1703	100.00

STOP II
FORM 14: NEUROLOGICAL CONSULTANT REPORT

A. Collection Information:

The **Neurological Consultant Report** (Form 14) was to be completed for Randomized Patients at entry/baseline, annual and exit visits, within 48 hours of reporting of a suspected neurological event, and 3-4 weeks post-discharge for head injury or meningitis events.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p014_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 248 (77)

Two patients have no STOP II neurological consultant forms: one was a patient who discontinued f/u < 3 months after randomization and another was a patient who was on study less than a year at the time the Trial was halted. The coordinator reported both changes in coordinator and missed appointments as reasons that neither the baseline nor the exit exam was completed.

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 238-241
- Listing of Variables by Position: See pp. 242-245

H. Formats:

The file **f014fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + “F” – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are “$”+variable name+”F” – e.g., the format label for a variable named “RATING” where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 246-255.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. Valid EX_TYPEs for Form 14 are:
  - QT: for quarterly and annual visits
  - NE: for neurological events

- **EX_NUM** – is the variable name for exam number. Valid EX_NUMs for Form 14 are:

  For EX_TYPE=QT,
  - 400 series numbers indicate visits completed after randomization
    - 401=randomization visit. The window for completion of the "randomization" neurological evaluation was within ± 90 days of the randomization date. Eight of the 79 randomized patients have no neurological evaluation associated with the randomization visit; 4 neuro exams associated with the QT-401 visit were completed >90 days after randomization.
    - 405, 409, or 413=annual visits

  For EX_TYPE=NE
  - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

Data Set Name	PUBDS.P014_FINAL	Observations	248
Member Type	DATA	Variables	152
Engine	V9	Indexes	0
Created	Wednesday, March 08, 2006 03:08:49 PM	Observation Length	1224
Last Modified	Wednesday, March 08, 2006 03:08:49 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	21
First Data Page	2
Max Obs per Page	13
Obs in First Data Page	10
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p014_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
47	ABDOMEN	Num	8	3.	C3e. Abdomen
33	ABN_MOVE	Num	8	3.	B9i. Abnormal movements
104	ANKLE_LT	Num	8	3.	D14b1. Left: ankle jerk
103	ANKLE_RT	Num	8	3.	D14b. Right: ankle jerk
30	ARMLEFT	Num	8	3.	B9h3b. Arm: left
29	ARMRIGHT	Num	8	3.	B9h3. Arm: right
19	ARM_LT	Num	8	3.	B9c3b. Arm: left
18	ARM_RT	Num	8	3.	B9c3. Arm: right
49	ARRHYTHM	Num	8	3.	C3f2. Cardiovascular: Arrhythmias
120	ATAXLARM	Num	8	3.	D15f3. Appendicular ataxia: Left arm
121	ATAXLLEG	Num	8	3.	D15f4. Appendicular ataxia: Left leg
118	ATAXRARM	Num	8	3.	D15f1. Appendicular ataxia: Right arm
119	ATAXRLEG	Num	8	3.	D15f2. Appendicular ataxia: Right leg
114	BALANC_L	Num	8	3.	D15b. Coordination: Can the patient balance on the left foot?
115	BALANC_R	Num	8	3.	D15c. Coordination: Can the patient balance on the right foot?
106	BICEP_LT	Num	8	3.	D14c1. Left: biceps jerk
105	BICEP_RT	Num	8	3.	D14c. Right: biceps jerk
37	BP_DIAS	Num	8	4.	C1c2. Blood pressure
36	BP_SYST	Num	8	4.	C1c1. Blood pressure (mmHg) (sys/dia)
110	BRACH_LT	Num	8	3.	D14e1. Left: brachioradialis
109	BRACH_RT	Num	8	3.	D14e. Right: brachioradialis
45	CHEST	Num	8	3.	C3c. Chest
24	CLUMSINS	Num	8	3.	B9f. Clumsiness
3	COMPAMPM	Num	8	3.	A2b. A.M./P.M.

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
55	COMPAPPR	Num	8	3.	D3b. Is comprehension appropriate for age?
54	COMPRTTL	Num	8	3.	D3a. Total correct
13	CONCIOS	Num	8	3.	B9a. Alteration of level of consciousness
52	CONFRTTL	Num	8	3.	D2a. Total correct
51	CONS_ABN	Num	8	3.	D1a. Abnormal
116	COORDINL	Num	8	3.	D15d. Coordination: The fine motor coordination of the left hand
117	COORDINR	Num	8	3.	D15e. Coordination: The fine motor coordination of the right hand
72	CORNEAL	Num	8	3.	D10g. Corneal reflexes
148	DESTATUS	Char	1	$1.	DESTATUS
65	DRAWAPPR	Num	8	3.	D8b. Is drawing appropriate for age?
64	DRAWTTL	Num	8	3.	D8. Total correct
82	DYSARTHR	Num	8	3.	D10n. Dysarthria
6	EXAMTYPE	Num	8	3.	A5. Type of exam
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
28	FACELEFT	Num	8	3.	B9h2a. Face: left
27	FACERIGT	Num	8	3.	B9h2. Face: right
17	FACE_LT	Num	8	3.	B9c2a. Face: left
16	FACE_RT	Num	8	3.	B9c2. Face: right
71	FACIAL_S	Num	8	3.	D10f. Facial sensation
147	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
78	GAG	Num	8	3.	D10j. Gag
113	GAIT	Num	8	3.	D15a. Coordination: gait
70	GAZE	Num	8	3.	D10e. Gaze
4	GENDER	Num	8	3.	A3. Patient gender
14	HEADACHE	Num	8	3.	B9b. Headache
44	HEADNECK	Num	8	3.	C3b. Head and neck
41	HEAD_CIR	Num	8	5.1	C1g. Head circumference (cm)
77	HEARING	Num	8	3.	D10i. Hearing
39	HEIGHT	Num	8	6.1	C1e. Height (cm)
15	HEMIPARE	Num	8	3.	B9c. Hemiparesis or other weakness
95	HOPLFOOT	Num	8	3.	D12e. Can the patient hop on the left foot?
96	HOPRFOOT	Num	8	3.	D12f. Can the patient hop on the right foot?
7	INTERVIE	Num	8	3.	B1. Person interviewed
102	KNEE_LT	Num	8	3.	D14a1. Left: knee jerk
101	KNEE_RT	Num	8	3.	D14a. Right: knee jerk
92	LARMDIST	Num	8	3.	D12c.d. Strength: Left arm distal
127	LARMPINP	Num	8	3.	D16c1. Sensation: Left arm pinprick
143	LARMPROP	Num	8	3.	D16c3. Sensation: Left arm proprioception
91	LARMPROX	Num	8	3.	D12c.p. Strength: Left arm proximal
126	LARMTOUC	Num	8	3.	D16c. Sensation: Left arm light touch
142	LARMVIB	Num	8	3.	D16c2. Sensation: Left arm vibration
32	LEGLEFT	Num	8	3.	B9h4c. Leg: left
31	LEGRIGHT	Num	8	3.	B9h4. Leg: right
21	LEG_LT	Num	8	3.	B9c4c. Leg: left
20	LEG_RT	Num	8	3.	B9c4. Leg: right
50	LEV_CONS	Num	8	3.	D1. Level of consciousness
135	LFACEPIN	Num	8	3.	D16g1. Sensation: Left face pinprick
134	LFACE_T	Num	8	3.	D16g. Sensation: Left face light touch

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
94	LLEGDIST	Num	8	3.	D12d.d. Strength: Left leg distal
129	LLEGPINP	Num	8	3.	D16d1. Sensation: Left leg pinprick
145	LLEGPROP	Num	8	3.	D16d3. Sensation: Left leg proprioception
93	LLEGPROX	Num	8	3.	D12d.p. Strength: Left leg proximal
128	LLEGTOUC	Num	8	3.	D16d. Sensation: Left leg light touch
144	LLEGVIB	Num	8	3.	D16d2. Sensation: Left leg vibration
75	LL_FACE	Num	8	3.	D10h3. Left lower face
137	LTRUNKPP	Num	8	3.	D16h1. Sensation: Left trunk pinprick
136	LTRUNK_T	Num	8	3.	D16h. Sensation: Left trunk light touch
76	LU_FACE	Num	8	3.	D10h4. Left upper face
48	MURMUR	Num	8	3.	C3f1. Cardiovascular: Murmurs
53	NAMEAPPR	Num	8	3.	D2b. Is naming approriate for age?
69	OCULARMV	Num	8	3.	D10d. Extra ocular movements
99	ONHEELS	Num	8	3.	D12h. Can the patient walk on heels?
9	ONSET_AP	Num	8	3.	B5b. A.M./P.M.
63	ORIENAPP	Num	8	3.	D7b. Is right/left orientation appropriate for age?
62	ORIENTTL	Num	8	3.	D7. Total correct
12	PAIN_CRI	Num	8	3.	B8. Was patient also experiencing a pain crisis/medical illness?
79	PALATELV	Num	8	3.	D10k. Palate elevation
67	PAPILLED	Num	8	3.	D10b. Papilledema
112	PLANTR_L	Num	8	3.	D14f2. Plantar responses: Left
111	PLANTR_R	Num	8	3.	D14f1. Plantar responses: Right
25	POS_SEIZ	Num	8	3.	B9g. Possible seizure
42	PTHANDED	Num	8	3.	C2. Is patient right or left handed?
5	PT_AGE	Num	8	3.	A4. Patient age
34	PULSE	Num	8	4.	C1a. Pulse (beats/minute)
68	PUPILS	Num	8	3.	D10c. Pupils
88	RARMDIST	Num	8	3.	D12a.d. Strength: Right arm distal
123	RARMPINP	Num	8	3.	D16a1. Sensation: Right arm pinprick
139	RARMPROP	Num	8	3.	D16a3. Sensation: Right arm proprioception
87	RARMPROX	Num	8	3.	D12a.p.. Strength: Right arm proximal
122	RARMTOUC	Num	8	3.	D16a. Sensation: Right arm light touch
138	RARMVIB	Num	8	3.	D16a2. Sensation: Right arm vibration
59	READAPPR	Num	8	3.	D5b. Is reading appropriate for age?
58	READTTL	Num	8	3.	D5a. Total correct
57	REPITAPP	Num	8	3.	D4b. Is repetition appropriate for age?
56	REPITTTL	Num	8	3.	D4a. Total correct
35	RESPRATE	Num	8	4.	C1b. Respirations (breaths/minute)
131	RFACEPIN	Num	8	3.	D16e1. Sensation: Right face pinprick
130	RFACE_T	Num	8	3.	D16e. Sensation: Right face light touch
90	RLEGDIST	Num	8	3.	D12b.d. Strength: Right leg distal
125	RLEGPINP	Num	8	3.	D16b1. Sensation: Right leg pinprick
141	RLEGPROP	Num	8	3.	D16b3. Sensation: Right leg proprioception
89	RLEGPROX	Num	8	3.	D12b.p. Strength: Right leg proximal
124	RLEGTOUC	Num	8	3.	D16b. Sensation: Right leg light touch
140	RLEGVIB	Num	8	3.	D16b2. Sensation: Right leg vibration
73	RL_FACE	Num	8	3.	D10h1. Right lower face
133	RTRUNKPP	Num	8	3.	D16f1. Sensation: Right trunk pinprick
132	RTRUNK_T	Num	8	3.	D16f. Sensation: Right trunk light touch
74	RU_FACE	Num	8	3.	D10h2. Right upper face

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
26	SENS_DIS	Num	8	3.	B9h. Numbness or other sensory disturbance
43	SKIN	Num	8	3.	C3a. Skin
23	SPEECH	Num	8	3.	B9e. Alteration of speech
46	SPINE	Num	8	3.	C3d. Spine
146	STROKE	Num	8	3.	D17. Was this event a stroke?
11	SYM_BEFR	Num	8	3.	B7. Has patient had these symptoms before?
10	SYM_LAST	Char	25	$25.	B6. How long did symptoms last?
38	TEMPERAT	Num	8	6.1	C1d. Temperature
97	TIPTOES	Num	8	3.	D12g. Can the patient walk on tip toes?
85	TONELARM	Num	8	3.	D11c. Left arm
86	TONELLEG	Num	8	3.	D11d. Left leg
83	TONERARM	Num	8	3.	D11a. Right arm
84	TONERLEG	Num	8	3.	D11b. Right leg
81	TONGUE_S	Num	8	3.	D10m. Tongue strength
80	TRAPEZIS	Num	8	3.	D10.l. Trapezius strength
108	TRICEP_L	Num	8	3.	D14d1. Left: triceps jerk
107	TRICEP_R	Num	8	3.	D14d. Right: triceps jerk
66	VISUAL_C	Num	8	3.	D10a. Visual fields to confrontation
22	VIS_LOSS	Num	8	3.	B9d. Loss of vision
98	WCHFOOT	Num	8	3.	D12g1. If no, the problem is with which foot?
40	WEIGHT	Num	8	6.1	C1f. Weight (kg)
100	WHATFOOT	Num	8	3.	D12h1. If no, the problem is with which foot?
8	WITNES_E	Num	8	3.	B2. Did person interviewed witness the event?
61	WRITAPPR	Num	8	3.	D6b. Is writing appropriate for age?
60	WRITETTL	Num	8	3.	D6. Total correct
151	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
150	ldu_id	Char	10		ID for public use datasets
152	onset_dtfrmrand	Num	8		<created variable> B5. Date of onset as days from RAND visit
149	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	COMPAMPM	Num	8	3.	A2b. A.M./P.M.
4	GENDER	Num	8	3.	A3. Patient gender
5	PT_AGE	Num	8	3.	A4. Patient age
6	EXAMTYPE	Num	8	3.	A5. Type of exam
7	INTERVIE	Num	8	3.	B1. Person interviewed
8	WITNES_E	Num	8	3.	B2. Did person interviewed witness the event?
9	ONSET_AP	Num	8	3.	B5b. A.M./P.M.
10	SYM_LAST	Char	25	$25.	B6. How long did symptoms last?
11	SYM_BEFR	Num	8	3.	B7. Has patient had these symptoms before?
12	PAIN_CRI	Num	8	3.	B8. Was patient also experiencing a pain crisis/medical illness?
13	CONCIOS	Num	8	3.	B9a. Alteration of level of consciousness
14	HEADACHE	Num	8	3.	B9b. Headache
15	HEMIPARE	Num	8	3.	B9c. Hemiparesis or other weakness
16	FACE_RT	Num	8	3.	B9c2. Face: right
17	FACE_LT	Num	8	3.	B9c2a. Face: left
18	ARM_RT	Num	8	3.	B9c3. Arm: right
19	ARM_LT	Num	8	3.	B9c3b. Arm: left
20	LEG_RT	Num	8	3.	B9c4. Leg: right
21	LEG_LT	Num	8	3.	B9c4c. Leg: left
22	VIS_LOSS	Num	8	3.	B9d. Loss of vision
23	SPEECH	Num	8	3.	B9e. Alteration of speech
24	CLUMSINS	Num	8	3.	B9f. Clumsiness
25	POS_SEIZ	Num	8	3.	B9g. Possible seizure
26	SENS_DIS	Num	8	3.	B9h. Numbness or other sensory disturbance
27	FACERIGT	Num	8	3.	B9h2. Face: right
28	FACELEFT	Num	8	3.	B9h2a. Face: left
29	ARMRIGHT	Num	8	3.	B9h3. Arm: right
30	ARMLEFT	Num	8	3.	B9h3b. Arm: left
31	LEGRIGHT	Num	8	3.	B9h4. Leg: right
32	LEGLEFT	Num	8	3.	B9h4c. Leg: left
33	ABN_MOVE	Num	8	3.	B9i. Abnormal movements
34	PULSE	Num	8	4.	C1a. Pulse (beats/minute)
35	RESPRATE	Num	8	4.	C1b. Respirations (breaths/minute)
36	BP_SYST	Num	8	4.	C1c1. Blood pressure (mmHg) (sys/dia)
37	BP_DIAS	Num	8	4.	C1c2. Blood pressure
38	TEMPERAT	Num	8	6.1	C1d. Temperature
39	HEIGHT	Num	8	6.1	C1e. Height (cm)
40	WEIGHT	Num	8	6.1	C1f. Weight (kg)
41	HEAD_CIR	Num	8	5.1	C1g. Head circumference (cm)
42	PTHANDED	Num	8	3.	C2. Is patient right or left handed?
43	SKIN	Num	8	3.	C3a. Skin
44	HEADNECK	Num	8	3.	C3b. Head and neck
45	CHEST	Num	8	3.	C3c. Chest
46	SPINE	Num	8	3.	C3d. Spine
47	ABDOMEN	Num	8	3.	C3e. Abdomen
48	MURMUR	Num	8	3.	C3f1. Cardiovascular: Murmurs
49	ARRHYTHM	Num	8	3.	C3f2. Cardiovascular: Arrhythmias
50	LEV_CONS	Num	8	3.	D1. Level of consciousness

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
51	CONS_ABN	Num	8	3.	D1a. Abnormal
52	CONFRTTL	Num	8	3.	D2a. Total correct
53	NAMEAPPR	Num	8	3.	D2b. Is naming approriate for age?
54	COMPRTTL	Num	8	3.	D3a. Total correct
55	COMPAPPR	Num	8	3.	D3b. Is comprehension appropriate for age?
56	REPITTTL	Num	8	3.	D4a. Total correct
57	REPITAPP	Num	8	3.	D4b. Is repetition appropriate for age?
58	READTTL	Num	8	3.	D5a. Total correct
59	READAPPR	Num	8	3.	D5b. Is reading appropriate for age?
60	WRITETTL	Num	8	3.	D6. Total correct
61	WRITAPPR	Num	8	3.	D6b. Is writing appropriate for age?
62	ORIENTTL	Num	8	3.	D7. Total correct
63	ORIENAPP	Num	8	3.	D7b. Is right/left orientation appropriate for age?
64	DRAWTTL	Num	8	3.	D8. Total correct
65	DRAWAPPR	Num	8	3.	D8b. Is drawing appropriate for age?
66	VISUAL_C	Num	8	3.	D10a. Visual fields to confrontation
67	PAPILLED	Num	8	3.	D10b. Papilledema
68	PUPILS	Num	8	3.	D10c. Pupils
69	OCULARMV	Num	8	3.	D10d. Extra ocular movements
70	GAZE	Num	8	3.	D10e. Gaze
71	FACIAL_S	Num	8	3.	D10f. Facial sensation
72	CORNEAL	Num	8	3.	D10g. Corneal reflexes
73	RL_FACE	Num	8	3.	D10h1. Right lower face
74	RU_FACE	Num	8	3.	D10h2. Right upper face
75	LL_FACE	Num	8	3.	D10h3. Left lower face
76	LU_FACE	Num	8	3.	D10h4. Left upper face
77	HEARING	Num	8	3.	D10i. Hearing
78	GAG	Num	8	3.	D10j. Gag
79	PALATELV	Num	8	3.	D10k. Palate elevation
80	TRAPEZIS	Num	8	3.	D10.l. Trapezius strength
81	TONGUE_S	Num	8	3.	D10m. Tongue strength
82	DYSARTHR	Num	8	3.	D10n. Dysarthria
83	TONERARM	Num	8	3.	D11a. Right arm
84	TONERLEG	Num	8	3.	D11b. Right leg
85	TONELARM	Num	8	3.	D11c. Left arm
86	TONELLEG	Num	8	3.	D11d. Left leg
87	RARMPROX	Num	8	3.	D12a.p.. Strength: Right arm proximal
88	RARMDIST	Num	8	3.	D12a.d. Strength: Right arm distal
89	RLEGPROX	Num	8	3.	D12b.p. Strength: Right leg proximal
90	RLEGDIST	Num	8	3.	D12b.d. Strength: Right leg distal
91	LARMPROX	Num	8	3.	D12c.p. Strength: Left arm proximal
92	LARMDIST	Num	8	3.	D12c.d. Strength: Left arm distal
93	LLEGPROX	Num	8	3.	D12d.p. Strength: Left leg proximal
94	LLEGDIST	Num	8	3.	D12d.d. Strength: Left leg distal
95	HOPLFOOT	Num	8	3.	D12e. Can the patient hop on the left foot?
96	HOPRFOOT	Num	8	3.	D12f. Can the patient hop on the right foot?
97	TIPTOES	Num	8	3.	D12g. Can the patient walk on tip toes?
98	WCHFOOT	Num	8	3.	D12g1. If no, the problem is with which foot?
99	ONHEELS	Num	8	3.	D12h. Can the patient walk on heels?
100	WHATFOOT	Num	8	3.	D12h1. If no, the problem is with which foot?
101	KNEE_RT	Num	8	3.	D14a. Right: knee jerk

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
102	KNEE_LT	Num	8	3.	D14a1. Left: knee jerk
103	ANKLE_RT	Num	8	3.	D14b. Right: ankle jerk
104	ANKLE_LT	Num	8	3.	D14b1. Left: ankle jerk
105	BICEP_RT	Num	8	3.	D14c. Right: biceps jerk
106	BICEP_LT	Num	8	3.	D14c1. Left: biceps jerk
107	TRICEP_R	Num	8	3.	D14d. Right: triceps jerk
108	TRICEP_L	Num	8	3.	D14d1. Left: triceps jerk
109	BRACH_RT	Num	8	3.	D14e. Right: brachioradialis
110	BRACH_LT	Num	8	3.	D14e1. Left: brachioradialis
111	PLANTR_R	Num	8	3.	D14f1. Plantar responses: Right
112	PLANTR_L	Num	8	3.	D14f2. Plantar responses: Left
113	GAIT	Num	8	3.	D15a. Coordination: gait
114	BALANC_L	Num	8	3.	D15b. Coordination: Can the patient balance on the left foot?
115	BALANC_R	Num	8	3.	D15c. Coordination: Can the patient balance on the right foot?
116	COORDINL	Num	8	3.	D15d. Coordination: The fine motor coordination of the left hand
117	COORDINR	Num	8	3.	D15e. Coordination: The fine motor coordination of the right hand
118	ATAXRARM	Num	8	3.	D15f1. Appendicular ataxia: Right arm
119	ATAXRLEG	Num	8	3.	D15f2. Appendicular ataxia: Right leg
120	ATAXLARM	Num	8	3.	D15f3. Appendicular ataxia: Left arm
121	ATAXLLEG	Num	8	3.	D15f4. Appendicular ataxia: Left leg
122	RARMTOUC	Num	8	3.	D16a. Sensation: Right arm light touch
123	RARMPINP	Num	8	3.	D16a1. Sensation: Right arm pinprick
124	RLEGTOUC	Num	8	3.	D16b. Sensation: Right leg light touch
125	RLEGPINP	Num	8	3.	D16b1. Sensation: Right leg pinprick
126	LARMTOUC	Num	8	3.	D16c. Sensation: Left arm light touch
127	LARMPINP	Num	8	3.	D16c1. Sensation: Left arm pinprick
128	LLEGTOUC	Num	8	3.	D16d. Sensation: Left leg light touch
129	LLEGPINP	Num	8	3.	D16d1. Sensation: Left leg pinprick
130	RFACE_T	Num	8	3.	D16e. Sensation: Right face light touch
131	RFACEPIN	Num	8	3.	D16e1. Sensation: Right face pinprick
132	RTRUNK_T	Num	8	3.	D16f. Sensation: Right trunk light touch
133	RTRUNKPP	Num	8	3.	D16f1. Sensation: Right trunk pinprick
134	LFACE_T	Num	8	3.	D16g. Sensation: Left face light touch
135	LFACEPIN	Num	8	3.	D16g1. Sensation: Left face pinprick
136	LTRUNK_T	Num	8	3.	D16h. Sensation: Left trunk light touch
137	LTRUNKPP	Num	8	3.	D16h1. Sensation: Left trunk pinprick
138	RARMVIB	Num	8	3.	D16a2. Sensation: Right arm vibration
139	RARMPROP	Num	8	3.	D16a3. Sensation: Right arm proprioception
140	RLEGVIB	Num	8	3.	D16b2. Sensation: Right leg vibration
141	RLEGPROP	Num	8	3.	D16b3. Sensation: Right leg proprioception
142	LARMVIB	Num	8	3.	D16c2. Sensation: Left arm vibration
143	LARMPROP	Num	8	3.	D16c3. Sensation: Left arm proprioception
144	LLEGVIB	Num	8	3.	D16d2. Sensation: Left leg vibration
145	LLEGPROP	Num	8	3.	D16d3. Sensation: Left leg proprioception
146	STROKE	Num	8	3.	D17. Was this event a stroke?
147	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
148	DESTATUS	Char	1	$1.	DESTATUS

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
149	vistype	Char	7		<created variable> VISIT TYPE
150	ldu_id	Char	10		ID for public use datasets
151	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
152	onset_dtfrmrand	Num	8		<created variable> B5. Date of onset as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*F014fmts.txt;

proc format;

  value ABDOMENF
    1='1: Normal'
    2='2: Abnormal';

  value ABN_MOVEF
    1='1: No'
    2='2: Yes';

  value ARM_LTF
    1='1: No'
    2='2: Yes';

  value ARM_RTF
    1='1: No'
    2='2: Yes';

  value ARMLEFTF
    1='1: No'
    2='2: Yes';

  value ARMRIGHTF
    1='1: No'
    2='2: Yes';

  value ARRHYTHMF
    1='1: Absent'
    2='2: Present';

  value ATAXLARMF
    1='1: Absent'
    2='2: Present';

  value ATAXLLEGF
    1='1: Absent'
    2='2: Present';

  value ATAXRARMF
    1='1: Absent'
    2='2: Present';

  value ATAXRLEGF
    1='1: Absent'
    2='2: Present';

  value BALANC_LF
    1='1: No'
    2='2: Yes';

  value BALANC_RF
    1='1: No'
    2='2: Yes';
```

```
value CHESTF
  1='1: Normal'
  2='2: Abnormal';

value CLUMSINSF
  1='1: No'
  2='2: Yes';

value COMPAMPMF
  1='1: AM'
  2='2: PM';

value COMPAPPRF
  1='1: No'
  2='2: Yes';

value CONCIOSF
  1='1: No'
  2='2: Yes';

value CONS_ABNF
  1='1: Lethargy'
  2='2: Stupor'
  3='3: Coma'
  4='4: Other';

value COORDINLF
  1='1: Normal'
  2='2: Abnormal';

value COORDINRF
  1='1: Normal'
  2='2: Abnormal';

value CORNEALF
  1='1: Normal'
  2='2: Abnormal';

value DRAWAPPRF
  1='1: No'
  2='2: Yes';

value DYSARTHRF
  1='1: Absent'
  2='2: Mild'
  3='3: Moderate'
  4='4: Severe';

value EXAMTYPEF
  1='1: Baseline'
  2='2: Annual'
  3='3: Neurological event'
  4='4: Post-Meningitis'
  5='5: Post-head injury';
```

```
value FACE_LTF
  1='1: No'
  2='2: Yes';

value FACE_RTF
  1='1: No'
  2='2: Yes';

value FACELEFTF
  1='1: No'
  2='2: Yes';

value FACERIGTF
  1='1: No'
  2='2: Yes';

value FACIAL_SF
  1='1: Normal'
  2='2: Abnormal';

value GAGF
  1='1: Normal'
  2='2: Abnormal';

value GAITF
  1='1: Normal'
  2='2: Abnormal';

value GAZEF
  1='1: Normal'
  2='2: Abnormal';

value GENDERF
  1='1: Male'
  2='2: Female';

value HEADACHEF
  1='1: No'
  2='2: Yes';

value HEADNECKF
  1='1: Normal'
  2='2: Abnormal';

value HEARINGF
  1='1: Normal'
  2='2: Abnormal';

value HEMIPAREF
  1='1: No'
  2='2: Yes';

value HOPLFOOTF
  1='1: No'
  2='2: Yes';
```

```
value HOPRFOOTF
  1='1: No'
  2='2: Yes';

value INTERVIEF
  1='1: Patient'
  2='2: Parent'
  3='3: Legal guardian'
  4='4: Other';

value LARMDISTF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value LARMPINPF
  1='1: Normal'
  2='2: Abnormal';

value LARMPROPF
  1='1: Normal'
  2='2: Abnormal';

value LARMPROXF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value LARMTOUCF
  1='1: Normal'
  2='2: Abnormal';

value LARMVIBF
  1='1: Normal'
  2='2: Abnormal';

value LEG_LTF
  1='1: No'
  2='2: Yes';

value LEG_RTF
  1='1: No'
  2='2: Yes';

value LEGLEFTF
  1='1: No'
  2='2: Yes';
```

```
value LEGRIGHTF
  1='1: No'
  2='2: Yes';

value LEV_CONSF
  1='1: Normal'
  2='2: Abnormal';

value LFACE_TF
  1='1: Normal'
  2='2: Abnormal';

value LFACEPINF
  1='1: Normal'
  2='2: Abnormal';

value LL_FACEF
  1='1: Normal'
  2='2: Weak';

value LLEGDISTF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value LLEGPINPF
  1='1: Normal'
  2='2: Abnormal';

value LLEGPROPF
  1='1: Normal'
  2='2: Abnormal';

value LLEGPROXF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value LLEGTOUCF
  1='1: Normal'
  2='2: Abnormal';

value LLEGVIBF
  1='1: Normal'
  2='2: Abnormal';

value LTRUNK_TF
  1='1: Normal'
  2='2: Abnormal';
```

```
value LTRUNKPPF
  1='1: Normal'
  2='2: Abnormal';

value LU_FACEF
  1='1: Normal'
  2='2: Weak';

value MURMURF
  1='1: Absent'
  2='2: Present';

value NAMEAPPRF
  1='1: No'
  2='2: Yes';

value OCULARMVF
  1='1: Normal'
  2='2: Abnormal';

value ONHEELSF
  1='1: No'
  2='2: Yes';

value ONSET_APF
  1='1: AM'
  2='2: PM';

value ORIENAPPF
  1='1: No'
  2='2: Yes';

value PAIN_CRIF
  1='1: No'
  2='2: Yes';

value PALATELVF
  1='1: Normal'
  2='2: Abnormal';

value PAPILLEDF
  1='1: Absent'
  2='2: Present';

value PLANTR_LF
  1='1: Normal'
  2='2: Abnormal';

value PLANTR_RF
  1='1: Normal'
  2='2: Abnormal';

value POS_SEIZF
  1='1: No'
  2='2: Yes';
```

```
value PTHANDEDF
  1='1: Right'
  2='2: Left'
  3='3: Ambidexterous'
  4='4: Undetermined';

value PUPILSF
  1='1: Normal'
  2='2: Abnormal';

value RARMDISTF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value RARMPINPF
  1='1: Normal'
  2='2: Abnormal';

value RARMPROPF
  1='1: Normal'
  2='2: Abnormal';

value RARMPROXF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value RARMTOUCF
  1='1: Normal'
  2='2: Abnormal';

value RARMVIBF
  1='1: Normal'
  2='2: Abnormal';

value READAPPRF
  1='1: No'
  2='2: Yes';

value REPITAPPF
  1='1: No'
  2='2: Yes';

value RFACE_TF
  1='1: Normal'
  2='2: Abnormal';
```

```
value RFACEPINF
  1='1: Normal'
  2='2: Abnormal';

value RL_FACEF
  1='1: Normal'
  2='2: Weak';

value RLEGDISTF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value RLEGPINPF
  1='1: Normal'
  2='2: Abnormal';

value RLEGPROPF
  1='1: Normal'
  2='2: Abnormal';

value RLEGPROXF
  0='0: No contraction'
  1='1: Flicker or trace of contraction'
  2='2: Active movement, with gravity eliminated'
  3='3: Active movement against gravity'
  4='4: Active movement against gravity and resistance'
  5='5: Normal power';

value RLEGTOUCF
  1='1: Normal'
  2='2: Abnormal';

value RLEGVIBF
  1='1: Normal'
  2='2: Abnormal';

value RTRUNK_TF
  1='1: Normal'
  2='2: Abnormal';

value RTRUNKPPF
  1='1: Normal'
  2='2: Abnormal';

value RU_FACEF
  1='1: Normal'
  2='2: Weak';

value SENS_DISF
  1='1: No'
  2='2: Yes';
```

```
value SKINF
  1='1: Normal'
  2='2: Abnormal';

value SPEECHF
  1='1: No'
  2='2: Yes';

value SPINEF
  1='1: Normal'
  2='2: Abnormal';

value STROKEF
  1='1: Definitely yes'
  2='2: Probably yes'
  3='3: Unclear'
  4='4: Probably not'
  5='5: Definitely not';

value SYM_BEFRF
  1='1: No'
  2='2: Yes';

value TIPTOESF
  1='1: No'
  2='2: Yes';

value TONELARMF
  1='1: Normal'
  2='2: Increased'
  3='3: Decreased';

value TONELLEGF
  1='1: Normal'
  2='2: Increased'
  3='3: Decreased';

value TONERARMF
  1='1: Normal'
  2='2: Increased'
  3='3: Decreased';

value TONERLEGF
  1='1: Normal'
  2='2: Increased'
  3='3: Decreased';

value TONGUE_SF
  1='1: Normal'
  2='2: Abnormal';

value TRAPEZISF
  1='1: Normal'
  2='2: Abnormal';
```

```
value VIS_LOSSF
  1='1: No'
  2='2: Yes';

value VISUAL_CF
  1='1: Normal'
  2='2: Abnormal';

value WCHFOOTF
  1='1: Right'
  2='2: Left'
  3='3: Both';

value WHATFOOTF
  1='1: Right'
  2='2: Left'
  3='3: Both';

value WITNES_EF
  1='1: No'
  2='2: Yes';

value WRITAPPRF
  1='1: No'
  2='2: Yes';
```

* format abdomen abdomenf. abn_move abn_movef. arm_lt arm_ltf. arm_rt arm_rtf. armleft armleftf. armright armrightf. arrhythm arrhythmf. ataxlarm ataxlarmf. ataxlleg ataxllegf. ataxrarm ataxrarmf. ataxrleg ataxrlegf. balanc_l balanc_lf. balanc_r balanc_rf. chest chestf. clumsins clumsinsf. compampm compampmf. compappr compapprf. concios conciosf. cons_abn cons_abnf. coordinl coordinlf. coordinr coordinrf. corneal cornealf. drawappr drawapprf. dysarthr dysarthrf. examtype examtypef. face_lt face_ltf. face_rt face_rtf. faceleft faceleftf. facerigt facerigtf. facial_s facial_sf. gag gagf. gait gaitf. gaze gazef. gender genderf. headache headachef. headneck headneckf. hearing hearingf. hemipare hemiparef. hoplfoot hoplfootf. hoprfoot hoprfootf. intervie intervief. larmdist larmdistf. larmpinp larmpinpf. larmprop larmpropf. larmprox larmproxf. larmtouc larmtoucf. larmvib larmvibf. leg_lt leg_ltf. leg_rt leg_rtf. legleft legleftf. legright legrightf. lev_cons lev_consf. lface_t lface_tf. lfacepin lfacepinf. ll_face ll_facef. llegdist llegdistf. llegpinp llegpinpf. llegprop llegpropf. llegprox llegproxf. llegtouc llegtoucf. llegvib llegvibf. ltrunk_t ltrunk_tf. ltrunkpp ltrunkppf. lu_face lu_facef. murmur murmurf. nameappr nameapprf. ocularmv ocularmvf. onheels onheelsf. onset_ap onset_apf. orienapp orienappf. pain_cri pain_crif. palatelv palatelvf. papilled papilledf. plantr_l plantr_lf. plantr_r plantr_rf. pos_seiz pos_seizf. pthanded pthandedf. pupils pupilsf. rarmdist rarmdistf. rarmpinp rarmpinpf. rarmprop rarmpropf. rarmprox rarmproxf. rarmtouc rarmtoucf. rarmvib rarmvibf. readappr readapprf. repitapp repitappf. rface_t rface_tf. rfacepin rfacepinf. rl_face rl_facef. rlegdist rlegdistf. rlegpinp rlegpinpf. rlegprop rlegpropf. rlegprox rlegproxf. rlegtouc rlegtoucf. rlegvib rlegvibf. rtrunk_t rtrunk_tf. rtrunkpp rtrunkppf. ru_face ru_facef. sens_dis sens_disf. skin skinf. speech speechf. spine spinef. stroke strokef. sym_befr sym_befrf. tiptoes tiptoesf. tonelarm tonelarmf. tonelleg tonellegf. tonerarm tonerarmf. tonerleg tonerlegf. tongue_s tongue_sf. trapezis trapezisf. vis_loss vis_lossf. visual_c visual_cf. wchfoot wchfootf. whatfoot whatfootf. witnes_e witnes_ef. writappr writapprf.;

STOP II TRIAL
NEUROLOGICAL CONSULTANT REPORT

AFFIX PATIENT LABEL

HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	235	94.76	235	94.76
P	13	5.24	248	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	6	2.42	6	2.42
NE-102	1	0.40	7	2.82
QT-401	71	28.63	78	31.45
QT-402	1	0.40	79	31.85
QT-403	15	6.05	94	37.90
QT-404	3	1.21	97	39.11
QT-405	59	23.79	156	62.90
QT-408	4	1.61	160	64.52
QT-409	39	15.73	199	80.24
QT-411	1	0.40	200	80.65
QT-412	4	1.61	204	82.26
QT-413	31	12.50	235	94.76
QT-415	8	3.23	243	97.98
QT-416	5	2.02	248	100.00

A1. Name of Examiner: _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date and time of interview (Month/Day/Year): ___ ___/___ ___/___ ___ A2.a Time:____:____

Analysis Variable : comp_dfrmrand <created variable> A2. Date of interview as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
248	0	482.9	425.1	-56.0	71.0	364.5	774.0	1399.0

[Note: Mean number of days between Randomization and the baseline neurological consult (QT-401 visit) equals 30.7 ± 42.3 days. Median number of days equals 22.0 days.]

[Time variable NOT included in dataset.]

A2.b ☐ **1. A.M.** ☐ **2. P.M.**

A2b. A.M./P.M.				
COMPAMPM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
1	113	45.56	114	45.97
2	134	54.03	248	100.00

A3. Patient is: ☐ **1. Male** ☐ **2. Female** A4. Patients age: ☐☐ Years

A3. Patient gender				
GENDER	Frequency	Percent	Cum Freq	Cum Percent
1	104	41.94	104	41.94
2	144	58.06	248	100.00

Analysis Variable : PT_AGE A4. Patient age								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
248	0	13.1	3.3	6.0	11.0	13.0	15.0	23.0

A5. Type of exam

☐ **1. BASELINE →** **GO TO SECTION C**

☐ **2. ANNUAL →** **GO TO SECTION C**

☐ **3. NEUROLOGICAL EVENT →** **GO TO SECTION B**

☐ **4. POST-MENINGITIS →**

A5.a Date of event (month/day/year): ___ ___/___ ___/___ ___

A5.b Date of discharge(month/day/year): ___ ___/___ ___/___ ___

GO TO SECTION C

☐ **5. POST-HEAD INJURY →**

A5.c Date of event (month/day/year): ___ ___/___ ___/___ ___

A5.d Date of discharge(month/day/year): ___ ___/___ ___/___ ___

GO TO SECTION C

A5. Type of exam				
EXAMTYPE	Frequency	Percent	Cum Freq	Cum Percent
1	72	29.03	72	29.03
2	169	68.15	241	97.18
3	7	2.82	248	100.00

[Date variables NOT included in dataset.]

B EVENT HISTORY

B1. Person interviewed (Choose **ONE** for person providing majority of answers to questions in Section B):

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Legal Guardian** ☐ **4. Other →** B1.a (specify): _____

B1. Person interviewed				
INTERVIE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	4	1.61	246	99.19
2	2	0.81	248	100.00

[Specify variable NOT included in dataset.]

B2. Did person interviewed witness the event? ☐ **1. NO** ☐ **2. YES**

B2. Did person interviewed witness the event?				
WITNES_E	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
2	6	2.42	248	100.00

PERSON INTERVIEWED SHOULD ANSWER QUESTIONS B3 - B10

B3. Why did the patient come to the hospital?

[Variable NOT included in dataset.]

B4. Describe the development of symptoms in detail:

[Variable NOT included in dataset.]

B5. Specific date and time of onset: (Month/Day/Year): ___ ___/___ ___/___ ___ B5.a Time:____:____

Analysis Variable : onset_dtfrmrand <created variable> B5. Date of onset as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6	0	300.0	347.4	51.0	144.0	159.5	295.0	991.0

<created variable> B5. Date of onset as days from RAND visit				
onset_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	242	100.00	242	100.00

[Time variable NOT included in dataset.]

B5.b ☐ **1. A.M.** ☐ **2. P.M.**

B5b. A.M./P.M.				
ONSET_AP	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.81	2	0.81
-2	241	97.18	243	97.98
1	1	0.40	244	98.39
2	4	1.61	248	100.00

B6. How long did symptoms last? _____

B6. How long did symptoms last?				
SYM_LAST	Frequency	Percent	Cum Freq	Cum Percent
-2	241	97.18	241	97.18
-9	1	0.40	242	97.58
1 week	1	0.40	243	97.98
30 minutes	1	0.40	244	98.39
4 days	1	0.40	245	98.79
dizzy 30 m, blurry 5.5 hr	1	0.40	246	99.19
up to 1 week	1	0.40	247	99.60
weakness persists LU limb	1	0.40	248	100.00

B7. Has patient had these symptoms before? ☐ **1. NO** ☐ **2. YES**

B7. Has patient had these symptoms before?				
SYM_BEFR	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	3	1.21	245	98.79
2	3	1.21	248	100.00

B8. Was the patient also experiencing a pain crisis or medical illness? ☐ **1. NO** ☐ **2. YES**

↓

B8.a Specify type of event**:**
[Variable NOT included in dataset.]

B8. Was patient also experiencing a pain crisis/medical illness?				
PAIN_CRI	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	3	1.21	245	98.79
2	3	1.21	248	100.00

B9. Did the patient experience any of the following symptoms?

	1. NO	2. YES	GIVE DETAILS IF YES
B9.a Alteration of Level of Consciousness	☐	☐	B9.a1. *[Variable NOT included in dataset.]*

B9a. Alteration of level of consciousness				
CONCIOS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	6	2.42	248	100.00

B9.b Headache ☐ ☐ B9.b1. *[Variable NOT included in dataset.]*

B9b. Headache				
HEADACHE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	3	1.21	245	98.79
2	3	1.21	248	100.00

B9.c Hemiparesis or other weakness ☐ ☐ B9.c1. *[Variable NOT included in dataset.]*

↓

B9c. Hemiparesis or other weakness				
HEMIPARE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	3	1.21	245	98.79
2	3	1.21	248	100.00

LOCATION	RIGHT		LEFT	
B9.c2. Face	☐ 1. NO	☐ 2. YES	a. ☐ 1. NO	☐ 2. YES

B9c2. Face: right				
FACE_RT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	3	1.21	248	100.00

B9c2a. Face: left				
FACE_LT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	3	1.21	248	100.00

LOCATION	RIGHT		LEFT	
B9.c3. Arm	☐ 1. NO	☐ 2. YES	b. ☐ 1. NO	☐ 2. YES

B9c3. Arm: right				
ARM_RT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	2	0.81	247	99.60
2	1	0.40	248	100.00

B9c3b. Arm: left				
ARM_LT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	1	0.40	246	99.19
2	2	0.81	248	100.00

B9.c4. Leg	☐ 1. NO	☐ 2. YES	c. ☐ 1. NO	☐ 2. YES

B9c4. Leg: right				
LEG_RT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	3	1.21	248	100.00

B9c4c. Leg: left				
LEG_LT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	3	1.21	248	100.00

B9. (cont'd) Did the patient experience any of the following symptoms?

	1. NO	2. YES	GIVE DETAILS IF YES
B9.d Loss of vision	☐	☐	B9.d1. [*Variable NOT included in dataset.]*

B9d. Loss of vision				
VIS_LOSS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	5	2.02	247	99.60
2	1	0.40	248	100.00

B9. (cont'd) Did the patient experience any of the following symptoms?

	1. NO	2. YES	GIVE DETAILS IF YES
B9.e Alteration of speech	☐	☐	B9.e1. [*Variable NOT included in dataset.]*

B9e. Alteration of speech				
SPEECH	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	6	2.42	248	100.00

B9.f Clumsiness	☐	☐	B9.f1. [*Variable NOT included in dataset.]*

B9f. Clumsiness				
CLUMSINS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	5	2.02	247	99.60
2	1	0.40	248	100.00

B9.g Possible seizure	☐	☐	B9.g1. [*Variable NOT included in dataset.]*

B9g. Possible seizure				
POS_SEIZ	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	6	2.42	248	100.00

B9.h Numbness or other sensory disturbance	☐	B9.h1. [*Variable NOT included in dataset.]*

↓

B9h. Numbness or other sensory disturbance				
SENS_DIS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	3	1.21	245	98.79
2	3	1.21	248	100.00

LOCATION	RIGHT	LEFT
B9.h2. Face	☐ 1. NO ☐ 2. YES	a. ☐ 1. NO ☐ 2. YES

B9h2. Face: right				
FACERIGT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	3	1.21	248	100.00

B9h2a. Face: left				
FACELEFT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	3	1.21	248	100.00

B9.h3. Arm ☐ 1. NO ☐ 2. YES b. ☐ 1. NO ☐ 2. YES

B9h3. Arm: right				
ARMRIGHT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	1	0.40	246	99.19
2	2	0.81	248	100.00

B9h3b. Arm: left				
ARMLEFT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	2	0.81	247	99.60
2	1	0.40	248	100.00

B9.h4. Leg ☐ 1. NO ☐ 2. YES c. ☐ 1. NO ☐ 2. YES

B9h4. Leg: right				
LEGRIGHT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	3	1.21	248	100.00

B9h4c. Leg: left				
LEGLEFT	Frequency	Percent	Cum Freq	Cum Percent
-2	245	98.79	245	98.79
1	2	0.81	247	99.60
2	1	0.40	248	100.00

B9.i Abnormal Movements **1. NO** ☐ **2. YES** ☐ ↓

B9.i1. **GIVE DETAILS** [*Variable NOT included in dataset.]*

B9i. Abnormal movements				
ABN_MOVE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-2	241	97.18	242	97.58
1	6	2.42	248	100.00

B10. PLEASE PROVIDE ANY OTHER INFORMATION THAT MAY HELP DETERMINE THE NATURE OF THE EVENT:
[*Variable NOT included in dataset.]*

C. GENERAL PHYSICAL EXAM

C1. Record Vital Signs and Measurements:

C1.a Pulse (beats/minute) ☐☐☐

Analysis Variable : PULSE C1a. Pulse (beats/minute)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
229	0	87.7	13.5	58.0	78.0	88.0	96.0	128.0

C1a. Pulse (beats/minute)				
PULSE	Frequency	Percent	Cum Freq	Cum Percent
-9	4	21.05	4	21.05
-3	15	78.95	19	100.00

C1.b Respirations (breaths/minute) | | | |

Analysis Variable : RESPRATE C1b. Respirations (breaths/minute)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
191	0	19.2	3.4	12.0	16.0	20.0	20.0	36.0

C1b. Respirations (breaths/minute)				
RESPRATE	Frequency	Percent	Cum Freq	Cum Percent
-9	7	12.28	7	12.28
-3	50	87.72	57	100.00

C1.c Blood Pressure (mmHg) (sys/dia) c1. | | | | / c2. | | | |

Analysis Variable : BP_SYST C1c1. Blood pressure (mmHg) (sys/dia)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
225	0	112.3	13.3	78.0	103.0	110.0	120.0	159.0

C1c1. Blood pressure (mmHg) (sys/dia)				
BP_SYST	Frequency	Percent	Cum Freq	Cum Percent
-9	6	26.09	6	26.09
-3	17	73.91	23	100.00

Analysis Variable : BP_DIAS C1c2. Blood pressure								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
224	0	60.7	8.8	41.0	54.0	61.0	66.0	92.0

C1c2. Blood pressure				
BP_DIAS	Frequency	Percent	Cum Freq	Cum Percent
-9	6	25.00	6	25.00
-3	18	75.00	24	100.00

C1.d Temperature (C°) ☐☐☐.☐

Analysis Variable : TEMPERAT C1d. Temperature								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
184	0	36.8	0.5	35.0	36.5	36.9	37.1	38.0

C1d. Temperature				
TEMPERAT	Frequency	Percent	Cum Freq	Cum Percent
-9	11	17.19	11	17.19
-3	53	82.81	64	100.00

C1.e Height (cm) ☐☐☐.☐

Analysis Variable : HEIGHT C1e. Height (cm)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
224	0	152.5	14.1	114.6	142.7	152.7	163.0	185.4

C1e. Height (cm)				
HEIGHT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	8.33	2	8.33
-3	22	91.67	24	100.00

C1.f Weight (kg) ☐☐☐.☐

Analysis Variable : WEIGHT C1f. Weight (kg)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
231	0	47.5	17.2	22.3	32.9	44.9	58.0	109.8

C1f. Weight (kg)				
WEIGHT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	11.76	2	11.76
-3	15	88.24	17	100.00

C1.g Head Circumference (cm) ☐☐ . ☐ (Measure at baseline and annual visits)

Analysis Variable : HEAD_CIR C1g. Head circumference (cm)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
197	0	54.7	2.3	50.0	53.0	54.7	56.3	60.0

C1g. Head circumference (cm)				
HEAD_CIR	Frequency	Percent	Cum Freq	Cum Percent
-9	4	7.84	4	7.84
-3	47	92.16	51	100.00

C2. Is the patient right or left handed? ☐ **1. Right** ☐ **2. Left** ☐ **3. Ambidexterous** ☐ **4. Undetermined**

C2. Is patient right or left handed?				
PTHANDED	Frequency	Percent	Cum Freq	Cum Percent
-3	6	2.42	6	2.42
1	209	84.27	215	86.69
2	24	9.68	239	96.37
3	6	2.42	245	98.79
4	3	1.21	248	100.00

C3. Assess condition of the following: **1. NORMAL** **2. ABNORMAL** **GIVE DETAILS IF ABNORMAL**

C3.a Skin ☐ ☐ C3.a1 [*Variable NOT included in dataset.]*

C3a. Skin				
SKIN	Frequency	Percent	Cum Freq	Cum Percent
-3	11	4.44	11	4.44
1	222	89.52	233	93.95
2	15	6.05	248	100.00

1. NORMAL **2. ABNORMAL** **GIVE DETAILS IF ABNORMAL**

C3.b Head and Neck ☐ ☐ C3.b1 [*Variable NOT included in dataset.]*

C3b. Head and neck				
HEADNECK	Frequency	Percent	Cum Freq	Cum Percent
-3	11	4.44	11	4.44
1	229	92.34	240	96.77
2	8	3.23	248	100.00

1. NORMAL 2. ABNORMAL GIVE DETAILS IF ABNORMAL

C3.c Chest ☐ ☐ C3.c1 [*Variable NOT included in dataset.]*

C3c. Chest				
CHEST	Frequency	Percent	Cum Freq	Cum Percent
-3	13	5.24	13	5.24
1	228	91.94	241	97.18
2	7	2.82	248	100.00

1. NORMAL 2. ABNORMAL GIVE DETAILS IF ABNORMAL

C3.d Spine ☐ ☐ C3.d1 [*Variable NOT included in dataset.]*

C3d. Spine				
SPINE	Frequency	Percent	Cum Freq	Cum Percent
-3	15	6.05	15	6.05
1	230	92.74	245	98.79
2	3	1.21	248	100.00

1. NORMAL 2. ABNORMAL GIVE DETAILS IF ABNORMAL

C3.e Abdomen ☐ ☐ C3.e1 [*Variable NOT included in dataset.]*

C3e. Abdomen				
ABDOMEN	Frequency	Percent	Cum Freq	Cum Percent
-3	19	7.66	19	7.66
1	219	88.31	238	95.97
2	10	4.03	248	100.00

C3.f Cardiovascular: **1. ABSENT 2. PRESENT GIVE DETAILS IF PRESENT**

C3.f1 Murmurs: ☐ ☐ C3.f1.a [*Variable NOT included in dataset.]*

C3f1. Cardiovascular: Murmurs				
MURMUR	Frequency	Percent	Cum Freq	Cum Percent
-3	18	7.26	18	7.26
1	169	68.15	187	75.40
2	61	24.60	248	100.00

	1. ABSENT	2. PRESENT	GIVE DETAILS IF PRESENT
C3.f2 Arrhythmias	☐	☐	C3.f2.a [*Variable NOT included in dataset.]*

C3f2. Cardiovascular: Arrhythmias				
ARRHYTHM	Frequency	Percent	Cum Freq	Cum Percent
-3	21	8.47	21	8.47
1	227	91.53	248	100.00

D. NEUROLOGICAL EXAMINATION

D1. Level of Consciousness ☐ **1. NORMAL** ☐ **2. ABNORMAL**

↓

D1.a
- ☐ **1. Lethargy**
- ☐ **2. Stupor**
- ☐ **3. Coma**
- ☐ **4. Other:** D1.a1 specify [*Variable NOT included in dataset.]*

D1. Level of consciousness				
LEV_CONS	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.40	1	0.40
1	247	99.60	248	100.00

D1a. Abnormal				
CONS_ABN	Frequency	Percent	Cum Freq	Cum Percent
-2	248	100.00	248	100.00

D2. **NAMING TO CONFRONTATION** **(SHOW PATIENT DRAWINGS ON PAGE 11)**

(check if response correct)

Clock ☐
Pencil ☐
Skateboard ☐
Shirt ☐
Ball ☐
Bicycle ☐

D2.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D2.b Is naming appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D2a. Total correct				
CONFRTTL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	1	0.40	2	0.81
3	1	0.40	3	1.21
4	1	0.40	4	1.61
5	1	0.40	5	2.02
6	243	97.98	248	100.00

D2b. Is naming approriate for age?				
NAMEAPPR	Frequency	Percent	Cum Freq	Cum Percent
-3	4	1.61	4	1.61
-2	2	0.81	6	2.42
2	242	97.58	248	100.00

D3. **COMPREHENSION**

(check if response correct)

Ask patient to:

1. Close your eyes ☐
2. Touch your nose ☐
3. Point to the floor and then point to the ceiling ☐

D3.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D3.b Is comprehension appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D3a. Total correct				
COMPRTTL	Frequency	Percent	Cum Freq	Cum Percent
2	1	0.40	1	0.40
3	247	99.60	248	100.00

D3b. Is comprehension appropriate for age?				
COMPAPPR	Frequency	Percent	Cum Freq	Cum Percent
-3	6	2.42	6	2.42
2	242	97.58	248	100.00

D4. **REPETITION**

(check if response correct)
Ask patient to repeat:

1. Stop. ☐
2. Stop and go. ☐
3. If it rains we play inside ☐
4. The President lives in Washington ☐

D4.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D4.b Is comprehension appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D4a. Total correct				
REPITTTL	Frequency	Percent	Cum Freq	Cum Percent
1	3	1.21	3	1.21
4	245	98.79	248	100.00

D4b. Is repetition appropriate for age?				
REPITAPP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	8	3.23	9	3.63
2	239	96.37	248	100.00

D5. **READING** **(SHOW PATIENT SENTENCES ON PAGE 12)**

(check if response correct)
Ask patient to read:

1. Stop. ☐
2. See the dog run. ☐
3. Little children like to play outdoors ☐

D5.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D5.b Is reading appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D5a. Total correct				
READTTL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
1	2	0.81	3	1.21
2	7	2.82	10	4.03
3	238	95.97	248	100.00

D5b. Is reading appropriate for age?				
READAPPR	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.81	2	0.81
-3	8	3.23	10	4.03
1	8	3.23	18	7.26
2	230	92.74	248	100.00

D6. **WRITING** **(SPACES PROVIDED ON PAGE 13)**

(check if response correct)
Ask patient to write:

1. The patient's signature ☐
2. Cat ☐
3. The cat is black ☐

D6.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D6.b Is writing appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D6. Total correct				
WRITETTL	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.40	1	0.40
1	4	1.61	5	2.02
2	21	8.47	26	10.48
3	222	89.52	248	100.00

D6b. Is writing appropriate for age?				
WRITAPPR	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.81	2	0.81
-3	7	2.82	9	3.63
1	10	4.03	19	7.66
2	229	92.34	248	100.00

D7. **RIGHT/LEFT ORIENTATION**

(check if response correct)
Ask patient to:

1. Show me your left hand ☐
2. Show me your right hand ☐

D7.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D7.b Is right/left orientation appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D7. Total correct				
ORIENTTL	Frequency	Percent	Cum Freq	Cum Percent
0	3	1.21	3	1.21
1	1	0.40	4	1.61
2	244	98.39	248	100.00

D7b. Is right/left orientation appropriate for age?				
ORIENAPP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	9	3.63	10	4.03
1	4	1.61	14	5.65
2	234	94.35	248	100.00

D8. **DRAWING** **(SHOW PATIENT DRAWINGS ON PAGE 14)**

(check if response is correct)
Ask patient to copy:

1. Circle ☐
2. Triangle ☐
3. Maltese cross ☐
4. Bisecting lines ☐

D8.a Total Correct: ☐ ☐ **-8. NE** ☐ **-1. NA**

D8.b Is drawing appropriate for age? ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D8. Total correct				
DRAWTTL	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.40	1	0.40
2	6	2.42	7	2.82
3	20	8.06	27	10.89
4	221	89.11	248	100.00

D8b. Is drawing appropriate for age?				
DRAWAPPR	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.81	2	0.81
-3	7	2.82	9	3.63
1	12	4.84	21	8.47
2	227	91.53	248	100.00

D9. SUMMARIZE THE ABNORMALITIES/COMMENTS:

[*Variable NOT included in dataset.]*

D10. CRANIAL NERVES:

D10.a Visual fields to confrontation ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAL →** **B10.a1 GIVE DETAILS IF ABNORMAL**

[*Variable NOT included in dataset.]*

D10a. Visual fields to confrontation				
VISUAL_C	Frequency	Percent	Cum Freq	Cum Percent
1	247	99.60	247	99.60
2	1	0.40	248	100.00

D10.b Papilledema ☐ **-8. NE** ☐ **1. ABSENT** ☐ **2. PRESENT**

D10b. Papilledema				
PAPILLED	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
-3	2	0.81	4	1.61
1	242	97.58	246	99.19
2	2	0.81	248	100.00

CRANIAL NERVES III, IV, VI **-8. NE** **1. NORMAL** **2. ABNORMAL**

GIVE DETAILS IF ABNORMAL

D10.c Pupils ☐ ☐ ☐ →**c1.** [*Variable NOT included in dataset.]*

D10c. Pupils				
PUPILS	Frequency	Percent	Cum Freq	Cum Percent
1	247	99.60	247	99.60
2	1	0.40	248	100.00

D10.d Extra Ocular Movements ☐ ☐ ☐ →**d1.** [*Variable NOT included in dataset.]*

D10d. Extra ocular movements				
OCULARMV	Frequency	Percent	Cum Freq	Cum Percent
1	248	100.00	248	100.00

D10.e Gaze ☐ ☐ ☐ →**e1.** [*Variable NOT included in dataset.]*

D10e. Gaze				
GAZE	Frequency	Percent	Cum Freq	Cum Percent
1	248	100.00	248	100.00

CRANIAL NERVES V. **-8. NE** **1. NORMAL** **2. ABNORMAL**

GIVE DETAILS IF ABNORMAL

D10.f Facial Sensation ☐ ☐ ☐ →**f1.** [*Variable NOT included in dataset.]*

D10f. Facial sensation				
FACIAL_S	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
1	246	99.19	247	99.60
2	1	0.40	248	100.00

	-8. NE	1. NORMAL	2. ABNORMAL	GIVE DETAILS IF ABNORMAL
D10.g. Corneal Reflexes	☐	☐	☐	→**g1.** [*Variable NOT included in dataset.]*

D10g. Corneal reflexes				
CORNEAL	Frequency	Percent	Cum Freq	Cum Percent
-8	31	12.50	31	12.50
-3	7	2.82	38	15.32
1	210	84.68	248	100.00

CRANIAL NERVE VII	-8. NE	1. NORMAL	2. WEAK	GIVE DETAILS IF WEAK
D10.h Facial Strength				
D10.h1 Right Lower Face	☐	☐	☐	→**h1.a** [*Variable NOT included in dataset.]*

D10h1. Right lower face				
RL_FACE	Frequency	Percent	Cum Freq	Cum Percent
1	245	98.79	245	98.79
2	3	1.21	248	100.00

D10.h2 Right Upper Face	☐	☐	☐	→**h2.a** [*Variable NOT included in dataset.]*

D10h2. Right upper face				
RU_FACE	Frequency	Percent	Cum Freq	Cum Percent
1	248	100.00	248	100.00

D10.h3 Left Lower Face	☐	☐	☐	→**h3.a** [*Variable NOT included in dataset.]*

D10h3. Left lower face				
LL_FACE	Frequency	Percent	Cum Freq	Cum Percent
1	247	99.60	247	99.60
2	1	0.40	248	100.00

D10.h4 Left Upper Face	☐	☐	☐	→**h4.a** [*Variable NOT included in dataset.]*

D10h4. Left upper face				
LU_FACE	Frequency	Percent	Cum Freq	Cum Percent
1	247	99.60	247	99.60
2	1	0.40	248	100.00

CRANIAL NERVES VIII **-8. NE** **1. NORMAL** **2. ABNORMAL**

GIVE DETAILS IF ABNORMAL

D10.i Hearing ☐ ☐ ☐ **→i1.** [*Variable NOT included in dataset.]*

D10i. Hearing				
HEARING	Frequency	Percent	Cum Freq	Cum Percent
-8	4	1.61	4	1.61
1	237	95.56	241	97.18
2	7	2.82	248	100.00

CRANIAL NERVES IX, X

D10.j Gag ☐ ☐ ☐ **→j1.** [*Variable NOT included in dataset.]*

D10j. Gag				
GAG	Frequency	Percent	Cum Freq	Cum Percent
-8	29	11.69	29	11.69
-3	3	1.21	32	12.90
1	216	87.10	248	100.00

-8. NE **1. NORMAL** **2. WEAK**

GIVE DETAILS IF WEAK

D10.k Palate elevation ☐ ☐ ☐ **→k1.** [*Variable NOT included in dataset.]*

D10k. Palate elevation				
PALATELV	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
1	246	99.19	248	100.00

CRANIAL NERVE XI

D10.l Trapezius strength ☐ ☐ ☐ **→l1.** [*Variable NOT included in dataset.]*

D10.l. Trapezius strength				
TRAPEZIS	Frequency	Percent	Cum Freq	Cum Percent
1	248	100.00	248	100.00

CRANIAL NERVE XII

D10.m Tongue strength ☐ ☐ ☐ **→m1.** [*Variable NOT included in dataset.]*

D10m. Tongue strength				
TONGUE_S	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
1	247	99.60	248	100.00

D10.n Dysarthria ☐ -8. NE ☐ 1. ABSENT ☐ 2. MILD ☐ 3. MODERATE ☐ 4. SEVERE

D10n. Dysarthria				
DYSARTHR	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
1	205	82.66	206	83.06
2	42	16.94	248	100.00

D11. MOTOR FUNCTION - TONE

-8. NE 1. NORMAL 2. INCREASED 3. DECREASED

D11.a Right arm ☐ ☐ ☐ ☐

D11a. Right arm				
TONERARM	Frequency	Percent	Cum Freq	Cum Percent
1	245	98.79	245	98.79
2	2	0.81	247	99.60
3	1	0.40	248	100.00

D11.b Right leg ☐ ☐ ☐ ☐

D11b. Right leg				
TONERLEG	Frequency	Percent	Cum Freq	Cum Percent
1	246	99.19	246	99.19
2	1	0.40	247	99.60
3	1	0.40	248	100.00

D11.c Left arm ☐ ☐ ☐ ☐

D11c. Left arm				
TONELARM	Frequency	Percent	Cum Freq	Cum Percent
1	245	98.79	245	98.79
2	1	0.40	246	99.19
3	2	0.81	248	100.00

-8. NE 1. NORMAL 2. INCREASED 3. DECREASED

D11.d Left Leg ☐ ☐ ☐ ☐

D11d. Left leg				
TONELLEG	Frequency	Percent	Cum Freq	Cum Percent
1	246	99.19	246	99.19
2	1	0.40	247	99.60
3	1	0.40	248	100.00

D11.e. DESCRIBE ANY ABNORMAL MOVEMENTS:

[*Variable NOT included in dataset.]*

D12. STRENGTH (Circle Appropriate MRC Grade*)

MRC GRADE

0 = No contraction
1 = Flicker or trace of contraction
2 = Active movement, with gravity eliminated
3 = Active movement against gravity
4 = Active movement against gravity and resistance
5 = Normal power

D12.a Right arm 12a.p proximal **NE 0 1 2 3 4 5**

D12a.p.. Strength: Right arm proximal				
RARMPROX	Frequency	Percent	Cum Freq	Cum Percent
2	1	0.40	1	0.40
5	247	99.60	248	100.00

12a.d distal **NE 0 1 2 3 4 5**

D12a.d. Strength: Right arm distal				
RARMDIST	Frequency	Percent	Cum Freq	Cum Percent
5	248	100.00	248	100.00

D12.b Right leg 12b.p. proximal **NE 0 1 2 3 4 5**

D12b.p. Strength: Right leg proximal				
RLEGPROX	Frequency	Percent	Cum Freq	Cum Percent
4	2	0.81	2	0.81
5	246	99.19	248	100.00

12b.d distal **NE 0 1 2 3 4 5**

D12b.d. Strength: Right leg distal				
RLEGDIST	Frequency	Percent	Cum Freq	Cum Percent
4	1	0.40	1	0.40
5	247	99.60	248	100.00

D12.c Left arm 12c.p proximal **NE 0 1 2 3 4 5**

D12c.p. Strength: Left arm proximal				
LARMPROX	Frequency	Percent	Cum Freq	Cum Percent
4	1	0.40	1	0.40
5	247	99.60	248	100.00

D12. (continued) **STRENGTH** (Circle Appropriate MRC Grade*)

12c.d distal **NE 0 1 2 3 4 5**

D12c.d. Strength: Left arm distal				
LARMDIST	Frequency	Percent	Cum Freq	Cum Percent
4	2	0.81	2	0.81
5	246	99.19	248	100.00

D12.d Left Leg 12d.p proximal **NE 0 1 2 3 4 5**

D12d.p. Strength: Left leg proximal				
LLEGPROX	Frequency	Percent	Cum Freq	Cum Percent
4	2	0.81	2	0.81
5	246	99.19	248	100.00

12d.d distal **NE 0 1 2 3 4 5**

D12d.d. Strength: Left leg distal				
LLEGDIST	Frequency	Percent	Cum Freq	Cum Percent
4	2	0.81	2	0.81
5	246	99.19	248	100.00

D12.e Can the patient hop on the left foot? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

D12e. Can the patient hop on the left foot?				
HOPLFOOT	Frequency	Percent	Cum Freq	Cum Percent
-8	3	1.21	3	1.21
2	245	98.79	248	100.00

D12.f Can the patient hop on the right foot? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

D12f. Can the patient hop on the right foot?				
HOPRFOOT	Frequency	Percent	Cum Freq	Cum Percent
-8	3	1.21	3	1.21
1	1	0.40	4	1.61
2	244	98.39	248	100.00

D12.g Can the patient walk on tip toes? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

↓

D12.g1. **IF NO**, the problem is with which foot? ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

D12g. Can the patient walk on tip toes?				
TIPTOES	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
2	246	99.19	248	100.00

D12g1. If no, the problem is with which foot?				
WCHFOOT	Frequency	Percent	Cum Freq	Cum Percent
-2	248	100.00	248	100.00

D12.h Can the patient walk on heels? ☐ **-1. NA** ☐ **-8 NE** ☐ **1. NO** ☐ **2. YES**

↓

D12.h1. **IF NO**, the problem is with which foot? ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

D12h. Can the patient walk on heels?				
ONHEELS	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
-3	3	1.21	5	2.02
1	1	0.40	6	2.42
2	242	97.58	248	100.00

D12h1. If no, the problem is with which foot?				
WHATFOOT	Frequency	Percent	Cum Freq	Cum Percent
-2	247	99.60	247	99.60
1	1	0.40	248	100.00

D13. IF ANY MOTOR ITEMS ARE NOT EVALUABLE, EXPLAIN WHY:

[*Variable NOT included in dataset.]*

D14. TENDON REFLEXES

Circle response:

RIGHT **LEFT**

D14.a Knee Jerk **NE 0 1 2 3 4** a1. **NE 0 1 2 3 4**

D14a. Right: knee jerk				
KNEE_RT	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
-3	2	0.81	3	1.21
0	8	3.23	11	4.44
1	60	24.19	71	28.63
2	161	64.92	232	93.55
3	15	6.05	247	99.60
4	1	0.40	248	100.00

D14a1. Left: knee jerk				
KNEE_LT	Frequency	Percent	Cum Freq	Cum Percent
-3	2	0.81	2	0.81
0	10	4.03	12	4.84
1	56	22.58	68	27.42
2	164	66.13	232	93.55
3	15	6.05	247	99.60
4	1	0.40	248	100.00

D14.b Ankle Jerk **NE 0 1 2 3 4** b1. **NE 0 1 2 3 4**

D14b. Right: ankle jerk				
ANKLE_RT	Frequency	Percent	Cum Freq	Cum Percent
-3	3	1.21	3	1.21
0	14	5.65	17	6.85
1	62	25.00	79	31.85
2	160	64.52	239	96.37
3	8	3.23	247	99.60
4	1	0.40	248	100.00

D14b1. Left: ankle jerk				
ANKLE_LT	Frequency	Percent	Cum Freq	Cum Percent
-3	3	1.21	3	1.21
0	15	6.05	18	7.26
1	61	24.60	79	31.85
2	159	64.11	238	95.97
3	9	3.63	247	99.60
4	1	0.40	248	100.00

RIGHT **LEFT**

D14.c Biceps Jerk **NE 0 1 2 3 4** c1. **NE 0 1 2 3 4**

D14c. Right: biceps jerk				
BICEP_RT	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.40	1	0.40
-1	1	0.40	2	0.81
0	19	7.66	21	8.47
1	75	30.24	96	38.71
2	140	56.45	236	95.16
3	11	4.44	247	99.60
4	1	0.40	248	100.00

D14c1. Left: biceps jerk				
BICEP_LT	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.40	1	0.40
0	20	8.06	21	8.47
1	73	29.44	94	37.90
2	142	57.26	236	95.16
3	11	4.44	247	99.60
4	1	0.40	248	100.00

D14.d Triceps Jerk **NE 0 1 2 3 4** d1. **NE 0 1 2 3 4**

D14d. Right: triceps jerk				
TRICEP_R	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
-3	2	0.81	3	1.21
-1	1	0.40	4	1.61
0	19	7.66	23	9.27
1	73	29.44	96	38.71
2	145	58.47	241	97.18
3	6	2.42	247	99.60
4	1	0.40	248	100.00

D14d1. Left: triceps jerk				
TRICEP_L	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
-3	2	0.81	3	1.21
0	19	7.66	22	8.87
1	73	29.44	95	38.31
2	145	58.47	240	96.77
3	7	2.82	247	99.60
4	1	0.40	248	100.00

RIGHT **LEFT**

D14.e Brachioradialis **NE 0 1 2 3 4** e1. **NE 0 1 2 3 4**

D14e. Right: brachioradialis				
BRACH_RT	Frequency	Percent	Cum Freq	Cum Percent
-3	2	0.81	2	0.81
0	18	7.26	20	8.06
1	77	31.05	97	39.11
2	144	58.06	241	97.18
3	6	2.42	247	99.60
4	1	0.40	248	100.00

D14e1. Left: brachioradialis				
BRACH_LT	Frequency	Percent	Cum Freq	Cum Percent
-3	2	0.81	2	0.81
0	19	7.66	21	8.47
1	75	30.24	96	38.71
2	145	58.47	241	97.18
3	6	2.42	247	99.60
4	1	0.40	248	100.00

D14.f. Plantar Responses:

D14.f1. Right ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAL**

D14f1. Plantar responses: Right				
PLANTR_R	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
-3	1	0.40	2	0.81
1	245	98.79	247	99.60
2	1	0.40	248	100.00

D14.f2. Left ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAL**

D14f2. Plantar responses: Left				
PLANTR_L	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
-3	1	0.40	2	0.81
1	246	99.19	248	100.00

D15. COORDINATION

D15.a Gait ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAI**

D15a. Coordination: gait				
GAIT	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
1	246	99.19	247	99.60
2	1	0.40	248	100.00

D15.b Can the patient balance on the left foot? ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D15b. Coordination: Can the patient balance on the left foot?				
BALANC_L	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-8	2	0.81	3	1.21
-3	1	0.40	4	1.61
1	4	1.61	8	3.23
2	240	96.77	248	100.00

D15.c Can the patient balance on the right foot? ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NO** ☐ **2. YES**

D15c. Coordination: Can the patient balance on the right foot?				
BALANC_R	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-8	1	0.40	2	0.81
-3	1	0.40	3	1.21
1	4	1.61	7	2.82
2	241	97.18	248	100.00

D15.d The fine motor coordination of the left hand is ☐ **-1. NA** ☐ **-8. NE** ☐ **1. NORMAL** ☐ **2. ABNORMAI**

D15d. Coordination: The fine motor coordination of the left hand				
COORDINL	Frequency	Percent	Cum Freq	Cum Percent
-3	2	0.81	2	0.81
1	240	96.77	242	97.58
2	6	2.42	248	100.00

D15.e The fine motor coordination of the right hand is ☐ -1. NA ☐ -8. NE ☐ 1. NORMAL ☐ 2. ABNORMAI

D15e. Coordination: The fine motor coordination of the right hand				
COORDINR	Frequency	Percent	Cum Freq	Cum Percent
-3	2	0.81	2	0.81
1	244	98.39	246	99.19
2	2	0.81	248	100.00

D15.f Appendicular Ataxia?

D15.f1. Right Arm ☐ -8. NE ☐ 1. ABSENT ☐ 2. PRESENT

D15f1. Appendicular ataxia: Right arm				
ATAXRARM	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.40	1	0.40
1	246	99.19	247	99.60
2	1	0.40	248	100.00

D15.f2. Right Leg ☐ -8. NE ☐ 1. ABSENT ☐ 2. PRESENT

D15f2. Appendicular ataxia: Right leg				
ATAXRLEG	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.40	1	0.40
-3	2	0.81	3	1.21
1	244	98.39	247	99.60
2	1	0.40	248	100.00

D15.f3. Left Arm ☐ -8. NE ☐ 1. ABSENT ☐ 2. PRESENT

D15f3. Appendicular ataxia: Left arm				
ATAXLARM	Frequency	Percent	Cum Freq	Cum Percent
-3	1	0.40	1	0.40
1	245	98.79	246	99.19
2	2	0.81	248	100.00

D15.f4. Left Leg ☐ -8. NE ☐ 1. ABSENT ☐ 2. PRESENT

D15f4. Appendicular ataxia: Left leg				
ATAXLLEG	Frequency	Percent	Cum Freq	Cum Percent
-3	2	0.81	2	0.81
1	245	98.79	247	99.60
2	1	0.40	248	100.00

D15.g DESCRIBE ANY ABNORMALITIES WITH COORDINATION:

[*Variable NOT included in dataset.]*

D16. SENSATION

	Light Touch	Pinprick
D16.a Right Arm	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	a1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16a. Sensation: Right arm light touch				
RARMTOUC	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	1	0.40	2	0.81
1	245	98.79	247	99.60
2	1	0.40	248	100.00

D16a1. Sensation: Right arm pinprick				
RARMPINP	Frequency	Percent	Cum Freq	Cum Percent
-8	9	3.63	9	3.63
-3	3	1.21	12	4.84
1	234	94.35	246	99.19
2	2	0.81	248	100.00

D16.b Right Leg	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	b1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16b. Sensation: Right leg light touch				
RLEGTOUC	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	1	0.40	2	0.81
1	245	98.79	247	99.60
2	1	0.40	248	100.00

D16b1. Sensation: Right leg pinprick				
RLEGPINP	Frequency	Percent	Cum Freq	Cum Percent
-8	9	3.63	9	3.63
-3	3	1.21	12	4.84
1	234	94.35	246	99.19
2	2	0.81	248	100.00

Light Touch **Pinprick**

D16.c Left Arm ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal | c1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16c. Sensation: Left arm light touch				
LARMTOUC	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	1	0.40	2	0.81
1	243	97.98	245	98.79
2	3	1.21	248	100.00

D16c1. Sensation: Left arm pinprick				
LARMPINP	Frequency	Percent	Cum Freq	Cum Percent
-8	9	3.63	9	3.63
-3	3	1.21	12	4.84
1	232	93.55	244	98.39
2	4	1.61	248	100.00

D16.d Left Leg ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal | d1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16d. Sensation: Left leg light touch				
LLEGTOUC	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	1	0.40	2	0.81
1	245	98.79	247	99.60
2	1	0.40	248	100.00

D16d1. Sensation: Left leg pinprick				
LLEGPINP	Frequency	Percent	Cum Freq	Cum Percent
-8	9	3.63	9	3.63
-3	3	1.21	12	4.84
1	234	94.35	246	99.19
2	2	0.81	248	100.00

Light Touch **Pinprick**

D16.e Right Face | ☐ **-1. NA** ☐ **-8. NE** ☐ **1. Normal** ☐ **2. Abnormal** | e1. ☐ **-8. NE** ☐ **1. Normal** ☐ **2. Abnormal**

D16e. Sensation: Right face light touch				
RFACE_T	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-3	1	0.40	2	0.81
1	245	98.79	247	99.60
2	1	0.40	248	100.00

D16e1. Sensation: Right face pinprick				
RFACEPIN	Frequency	Percent	Cum Freq	Cum Percent
-8	9	3.63	9	3.63
-3	3	1.21	12	4.84
1	234	94.35	246	99.19
2	2	0.81	248	100.00

D16.f Right Trunk | ☐ **-1. NA** ☐ **-8. NE** ☐ **1. Normal** ☐ **2. Abnormal** | f1. ☐ **-8. NE** ☐ **1. Normal** ☐ **2. Abnormal**

D16f. Sensation: Right trunk light touch				
RTRUNK_T	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-8	2	0.81	3	1.21
-3	2	0.81	5	2.02
1	242	97.58	247	99.60
2	1	0.40	248	100.00

D16f1. Sensation: Right trunk pinprick				
RTRUNKPP	Frequency	Percent	Cum Freq	Cum Percent
-8	10	4.03	10	4.03
-3	4	1.61	14	5.65
1	232	93.55	246	99.19
2	2	0.81	248	100.00

	Light Touch	Pinprick
D16.g Left Face	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	g1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16g. Sensation: Left face light touch				
LFACE_T	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-8	1	0.40	2	0.81
-3	1	0.40	3	1.21
1	244	98.39	247	99.60
2	1	0.40	248	100.00

D16g1. Sensation: Left face pinprick				
LFACEPIN	Frequency	Percent	Cum Freq	Cum Percent
-8	9	3.63	9	3.63
-3	3	1.21	12	4.84
1	234	94.35	246	99.19
2	2	0.81	248	100.00

D16.h Left Trunk	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	h1. ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16h. Sensation: Left trunk light touch				
LTRUNK_T	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.40	1	0.40
-8	1	0.40	2	0.81
-3	2	0.81	4	1.61
1	243	97.98	247	99.60
2	1	0.40	248	100.00

D16h1. Sensation: Left trunk pinprick				
LTRUNKPP	Frequency	Percent	Cum Freq	Cum Percent
-8	10	4.03	10	4.03
-3	4	1.61	14	5.65
1	232	93.55	246	99.19
2	2	0.81	248	100.00

	Vibration	Proprioception
D16.a2. Right Arm	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	a3. ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16a2. Sensation: Right arm vibration				
RARMVIB	Frequency	Percent	Cum Freq	Cum Percent
-8	5	2.02	5	2.02
-3	5	2.02	10	4.03
-1	1	0.40	11	4.44
1	234	94.35	245	98.79
2	3	1.21	248	100.00

D16a3. Sensation: Right arm proprioception				
RARMPROP	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
-3	5	2.02	7	2.82
1	240	96.77	247	99.60
2	1	0.40	248	100.00

D16.b2. Right Leg ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal | b3. ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16b2. Sensation: Right leg vibration				
RLEGVIB	Frequency	Percent	Cum Freq	Cum Percent
-8	5	2.02	5	2.02
-3	4	1.61	9	3.63
-1	1	0.40	10	4.03
1	235	94.76	245	98.79
2	3	1.21	248	100.00

D16b3. Sensation: Right leg proprioception				
RLEGPROP	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
-3	4	1.61	6	2.42
1	241	97.18	247	99.60
2	1	0.40	248	100.00

	Vibration	Proprioception
D16.c2. Left Arm / c3.	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16c2. Sensation: Left arm vibration				
LARMVIB	Frequency	Percent	Cum Freq	Cum Percent
-8	5	2.02	5	2.02
-3	5	2.02	10	4.03
-1	1	0.40	11	4.44
1	234	94.35	245	98.79
2	3	1.21	248	100.00

D16c3. Sensation: Left arm proprioception				
LARMPROP	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
-3	5	2.02	7	2.82
1	240	96.77	247	99.60
2	1	0.40	248	100.00

D16.d2. Left Leg	☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal	d3. ☐ -1. NA ☐ -8. NE ☐ 1. Normal ☐ 2. Abnormal

D16d2. Sensation: Left leg vibration				
LLEGVIB	Frequency	Percent	Cum Freq	Cum Percent
-8	5	2.02	5	2.02
-3	4	1.61	9	3.63
-1	1	0.40	10	4.03
1	235	94.76	245	98.79
2	3	1.21	248	100.00

D16d3. Sensation: Left leg proprioception				
LLEGPROP	Frequency	Percent	Cum Freq	Cum Percent
-8	2	0.81	2	0.81
-3	4	1.61	6	2.42
1	241	97.18	247	99.60
2	1	0.40	248	100.00

D16.i If sensation is not evaluable, explain why: [*Variable NOT included in dataset.]*

D. EXAMINERS ASSESSMENT - <u>FOR EVENT ONLY</u>:

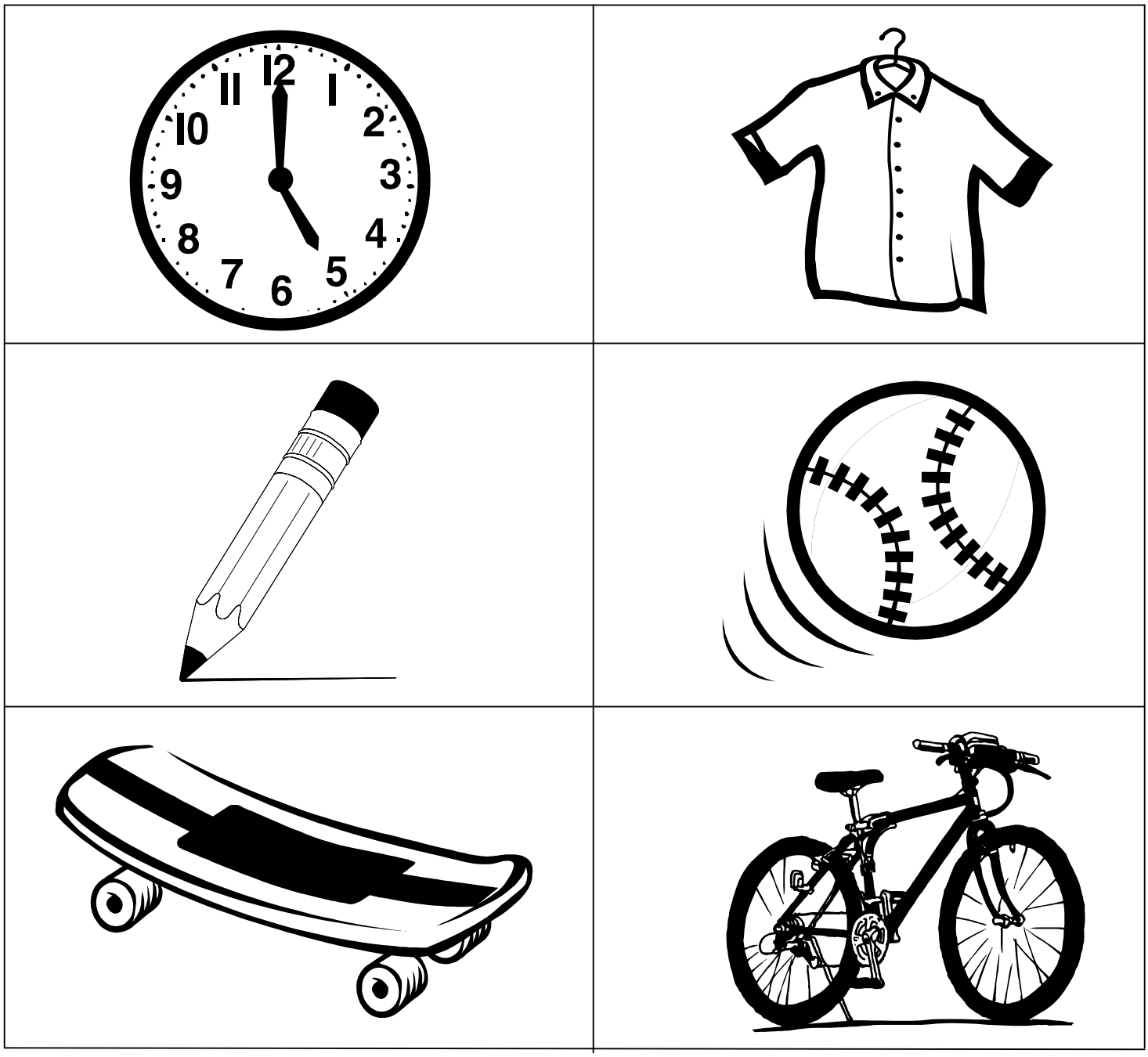
D17. Was this event a stroke (pick one)?

- ☐ **1. Definitely yes**
- ☐ **2. Probably yes**
- ☐ **3. Unclear**
- ☐ **4. Probably not**
- ☐ **5. Definitely not**

D17. Was this event a stroke?				
STROKE	Frequency	Percent	Cum Freq	Cum Percent
-1	241	97.18	241	97.18
1	2	0.81	243	97.98
2	1	0.40	244	98.39
4	1	0.40	245	98.79
5	3	1.21	248	100.00

D2. Naming to Confrontation

Ask patient to identify:



D5. Reading

Ask the patient to read:

1. Stop.

2. See the dog run.

3. Little children like to play outdoors.

D6. Writing

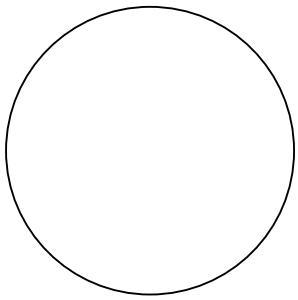
1. _____

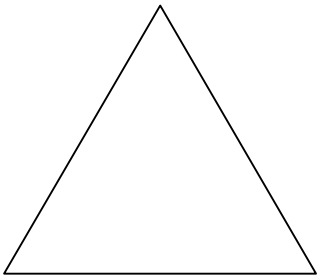
2. _____

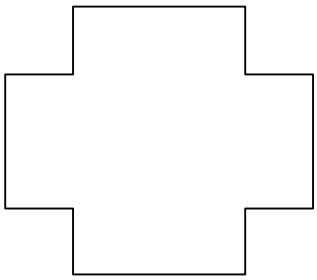
3. _____

D7. Drawing

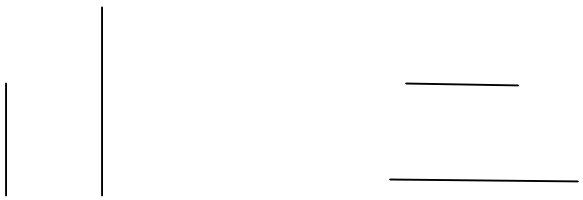
Ask patient to copy these drawings:







Ask patient to place an “X” in the middle of these lines:



STOP II

FORM 15A: EVENT CT SCAN

A. Collection Information:

The **Event CT Scan** (Form 15A) was to be completed for randomized patients when a CT scan (but no MRI) was performed following a neurological event, for intracranial hemorrhage event CT scans, or if the Principal Investigator felt that a CT scan was critical to understanding a neurological event. F15J refers to the portion of Form 15A completed by the readers.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p15a_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 1 (1)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 300
- Listing of Variables by Position: See p. 301

H. Formats:

The file **f15Afmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 302.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPE for Form 15A is NE for neurological events.

- **EX_NUM** – is the variable name for exam number. For Form 15A:
  - 100 series numbers indicate neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

Data Set Name	PUBDS.P15A_FINAL	Observations	1
Member Type	DATA	Variables	21
Engine	V9	Indexes	0
Created	Monday, February 20, 2006 06:00:47 PM	Observation Length	176
Last Modified	Monday, February 20, 2006 06:00:47 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	92
Obs in First Data Page	1
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p15a_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
11	ACCEPTAB	Num	8	3.	B3. Study acceptable for interpretation?
13	ATROPHYJ	Num	8	3.	C1. Atrophy on CT scan
15	COMMENT1	Char	8		Reader comments 1
16	COMMENT2	Char	41		Reader comments 2
7	DESTATUS	Char	1	$1.	DESTATUS
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
6	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
14	INTHEMOR	Num	8	3.	C2. CT scan evidence of intracranial hemorrhage?
4	INTR_HEM	Num	8	3.	A4b. Did the patient have intracranial hemorrhage
3	MRI_PERF	Num	8	3.	A4a. Was an MRI performed
5	PI_REV	Num	8	3.	A4c. Did the principal Investigator request a review
9	READER1	Char	3	$3.	B1a. Reader 1 initials
10	READER2	Char	3	$3.	B1b. Reader 2 initials
12	SCANQUAL	Num	8	3.	B4. Scan quality
19	comp_dfrmrand	Num	8		<created variable> A2. Date of CT scan as days from RAND visit
17	ldu_id	Char	10		ID for public use datasets
18	lesions	Num	8		<created variable> C3. Number of lesions listed in CT Scan lesion table
20	neuro_dtfrmrand	Num	8		<created variable> A3. Date of neurological event as days from RAND visit
21	read_dtfrmrand	Num	8		<created variable> B2. Date CT scan read as days from RAND visit
8	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	MRI_PERF	Num	8	3.	A4a. Was an MRI performed
4	INTR_HEM	Num	8	3.	A4b. Did the patient have intracranial hemorrhage
5	PI_REV	Num	8	3.	A4c. Did the principal Investigator request a review
6	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
7	DESTATUS	Char	1	$1.	DESTATUS
8	vistype	Char	7		<created variable> VISIT TYPE
9	READER1	Char	3	$3.	B1a. Reader 1 initials
10	READER2	Char	3	$3.	B1b. Reader 2 initials
11	ACCEPTAB	Num	8	3.	B3. Study acceptable for interpretation?
12	SCANQUAL	Num	8	3.	B4. Scan quality
13	ATROPHYJ	Num	8	3.	C1. Atrophy on CT scan
14	INTHEMOR	Num	8	3.	C2. CT scan evidence of intracranial hemorrhage?
15	COMMENT1	Char	8		Reader comments 1
16	COMMENT2	Char	41		Reader comments 2
17	ldu_id	Char	10		ID for public use datasets
18	lesions	Num	8		<created variable> C3. Number of lesions listed in CT Scan lesion table
19	comp_dfrmrand	Num	8		<created variable> A2. Date of CT scan as days from RAND visit
20	neuro_dtfrmrand	Num	8		<created variable> A3. Date of neurological event as days from RAND visit
21	read_dtfrmrand	Num	8		<created variable> B2. Date CT scan read as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F15Afmts.txt;

proc format;

  value INTR_HEMF
    1='1: No'
    2='2: Yes';

  value MRI_PERFF
    1='1: No'
    2='2: Yes';

  value PI_REVF
    1='1: No'
    2='2: Yes';

  value ACCEPTABF
    1='1: No'
    2='2: Yes';

  value ATROPHYJF
    1='1: No atrophy'
    2='2: Atrophy'
    3='3: Equivocal';

  value INTHEMORF
    1='1: No'
    2='2: Yes';

  value SCANQUALF
    1='1: Excellent'
    2='2: Slight artifact/motion,Adequate'
    3='3: Severe artifact/motion,Inadequate';

* format intr_hem intr_hemf. mri_perf mri_perff. pi_rev pi_revf. acceptab acceptabf. atrophyj atrophyjf.
inthemor inthemorf. scanqual scanqualf.;
```

STOP II TRIAL

EVENT CT SCAN

AFFIX PATIENT'S LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1	100.00	1	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	1	100.00	1	100.00

SUBMIT THIS FORM AND FOUR COPIES (ORIGINALS IF AVAILABLE) OF EACH CT FILM OF HEAD ONLY IF:

1) CT SCAN (BUT NO MRI) WAS PERFORMED FOLLOWING A NEUROLOGICAL EVENT

2) PATIENT HAD AN INTRACRANIAL HEMORRHAGE

3) PRINCIPAL INVESTIGATOR FEELS CT SCAN IS CRITICAL TO UNDERSTANDING THE EVENT

THIS FORM IS TO BE COMPLETED BY PRINCIPAL INVESTIGATOR OR STUDY COORDINATOR

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of CT scan (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of CT scan as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	325.0	.	325.0	325.0	325.0	325.0	325.0

A3. Date of Neurological Event for which CT scan was performed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : neuro_dtfrmrand <created variable> A3. Date of neurological event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	325.0	.	325.0	325.0	325.0	325.0	325.0

A4. Reason CT films submitted **(CHECK NO OR YES FOR EACH OF a THROUGH c)**

a. Was an MRI performed? ☐ **1. NO** ☐ **2. YES**

A4a. Was an MRI performed				
MRI_PERF	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

↓

A4.a1. **IF NO**, specify reason

[Variable NOT included in dataset.]

b. Did the patient have an intracranial hemorrhage? ☐ **1. NO** ☐ **2. YES**

A4b. Did the patient have intracranial hemorrhage				
INTR_HEM	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

c. Did the Principal Investigator request a review? ☐ **1. NO** ☐ **2. YES**

A4c. Did the principal Investigator request a review				
PI_REV	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

↓

A4.c1. **IF YES**, specify reason

[Variable NOT included in dataset.]

SECTIONS B - C TO BE COMPLETED BY READERS (F15J)

B1. Readers: a. (Name): _____ (Initials): ☐☐☐

b. (Name): _____ (Initials): ☐☐☐

B1a. Reader 1 initials				
READER1	Frequency	Percent	Cum Freq	Cum Percent
JAB	1	100.00	1	100.00

B1b. Reader 2 initials				
READER2	Frequency	Percent	Cum Freq	Cum Percent
-1	1	100.00	1	100.00

B2 Date read (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : read_dtfrmrand <created variable> B2. Date CT scan read as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	362.0	.	362.0	362.0	362.0	362.0	362.0

B3. Study acceptable for interpretation? ☐ 1. NO ☐ 2. YES

↓

B3.a. Reason: *[Variable NOT included in dataset.]*

B3. Study acceptable for interpretation?				
ACCEPTAB	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

B4. **SCAN QUALITY (CHECK ONE):**

☐ 1. Excellent

☐ 2. Slight Artifact/Motion, Adequate

☐ 3. Severe Artifact/Motion, Inadequate

B4. Scan quality				
SCANQUAL	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

C1. ATROPHY ON CT SCAN (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

C1. Atrophy on CT scan				
ATROPHYJ	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

[Variables NOT included in dataset for type of atrophy. Fields had no data.]

Type of atrophy:

a1. GENERAL: ☐ 1. NO ☐ 2. YES

- a. Sulcal ☐ 1. NO ☐ 2. YES
- b. Ventricular ☐ 1. NO ☐ 2. YES
- c. Level of severity ☐ 1. MILD ☐ 2. MODERATE ☐ 3. SEVERE

a2. FOCAL: ☐ 1. NO ☐ 2. YES

- a. Sulcal ☐ 1. NO ☐ 2. YES
- b. Ventricular ☐ 1. NO ☐ 2. YES
- c. Specify Area(s): c1. _____

C2. Does the CT scan show evidence of intracranial hemorrhage? ☐ 1. NO ☐ 2. YES

C2. CT scan evidence of intracranial hemorrhage?				
INTHEMOR	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

[Variables NOT included in dataset for type of hemorrhage. Fields had no data.]

Type:	1. NO	2. YES
a. Subarachnoid	☐	☐
b. Intraventricular	☐	☐
c. Subdural	☐	☐
d. Epidural	☐	☐
e. Intraparenchymal	☐	☐

C3. DISCRETE FINDINGS ON CT SCAN (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (Punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Acute B = Subacute C = Chronic

	a.	b.	c.	d.	e.	f.	g.	h.
				LOCATION(S)				
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	STATUS
1.								
2.								
3.								
4.								
5.								
6.								
7.								

<created variable> C3. Number of lesions listed in CT Scan lesion table

lesions	Frequency	Percent	Cum Freq	Cum Percent
0	1	100.00	1	100.00

C4. COMMENTS:

Reader comments 1		
COMMENT1	Frequency	Cum Freq
Bones nl	1	1

Reader comments 2		
COMMENT2	Frequency	Cum Freq
probable Ca++ choroid in fourth ventricle	1	1

STOP II
FORM 16: QUARTERLY PROGRESS REPORT FOR RANDOMIZED PATIENTS

A. Collection Information:
The **Quarterly Progress Report for Randomized Patients** (Form 16) was to be completed at entry, quarterly, annual, and exit visits for Randomized Patients.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p016_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 740 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 312-317
- Listing of Variables by Position: See pp. 318-322

H. Formats:
The file **f016fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 323-330.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The only valid EX_TYPE for Form 16 is QT: for quarterly and annual visits

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 16 are:
    - 400 series numbers indicate visits completed after randomization
        - 401=randomization visit
        - 405, 409, or 413=annual visits

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **SP_INT** - is the variable name for the specify other person interviewed field. This variable has been recoded to standardize or anonymize findings as indicated in the contents by "<recoded>" in the label.

- **SPLENICS** - is the variable name for splenic sequestration events. Cases where this variable is coded "-1:Not Applicable" refer to patients who have had a splenectomy. This code was not standardized for this variable and does not capture all patients or all records for patients who had a splenectomy.

- **PRIAPISM, PRIAP** - are the variable names for priapism events. Cases where these variables are coded "-1:Not Applicable" refer to patients who are female. This code was not standardized for these variables and does not capture all patients or all records for patients who are female.

- **O_RECODE1, O_RECODE2** - are the variable names for ICD-9 codes for other clinical events as indicated in the preceding specify fields (OTH_RECODESPC1, OTH_RECODESPC2 respectively). These variables require the ICD-9 Codebook Diseases section for interpretation. Code boxes are labeled "Office Use" on the form. Specific codes and associated diagnosis text are included for only those events that are frequently associated with sickle cell disease or treatment with transfusion. Other disease codes were recoded as 999.99 (OTHER). In a few cases, procedure/procedure code values were entered for these variables. The text “<recoded>” in the labels for this set of variables indicates that recoding of some of the original values has occurred.

- **SURGRECODE, SURGRECODE2** - are the variable names for ICD-9 codes for surgeries as indicated in the preceding specify fields (SURGRECODESPC, SURGRECODESP2 respectively). These variables require the ICD-9 Codebook Procedures section for interpretation. Code boxes are labeled "Office Use" on the form. Specific codes and associated procedure text are included for only those procedures that are frequently associated with sickle cell disease or treatment with transfusion. Other procedure codes were recoded as 99.99 (OTHER). The text “<recoded>” in the labels for this set of variables indicates that recoding of some of the original values has occurred.

Data Set Name	PUBDS.P016_FINAL	Observations	740
Member Type	DATA	Variables	191
Engine	V9	Indexes	0
Created	Thursday, March 09, 2006 04:42:29 PM	Observation Length	1792
Last Modified	Thursday, March 09, 2006 04:42:29 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	84
First Data Page	2
Max Obs per Page	9
Obs in First Data Page	3
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p016_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
6	ANYMEDS	Num	8	3.	B1. Patient taking any medications
30	APLASTIC	Num	8	3.	C1a6. Aplastic Crisis
31	APLASTTL	Num	8	3.	C1b6. Number of events:aplastic
126	ASTHMA	Num	8	3.	E5. Asthma
122	A_NECROS	Num	8	3.	E2. Aseptic necrosis
5	A_T_VERI	Num	8	3.	A4. Address and telephone info verified
135	CANCER	Num	8	3.	E13. Cancer
127	CHD	Num	8	3.	E6. Chronic heart disease
128	CHRLIVER	Num	8	3.	E7. Chronic liver disease
129	CHRRENAL	Num	8	3.	E8. Chronic renal disease
125	CHR_LUNG	Num	8	3.	E4. Chronic lung disease
79	DESTATUS	Char	1	$1.	DESTATUS
132	DIABETES	Num	8	3.	E10. Diabetes
115	DIFFUNDR	Num	8	3.	D9. Any difficulty talking or understanding what was said
117	DIF_UNDS	Num	8	3.	D9a2. Difficulty understanding
87	DIZZINESS	Num	8	3.	D3. Dizziness
88	DIZZY_EP	Num	8	3.	D3a. Number of episodes: Dizziness
89	D_VISION	Char	2	$2.	D4a. Double vision
137	ELEV_BLD	Num	8	3.	E15. Elevated blood lead level
118	EXPRESS	Num	8	3.	D9a3. Expressing
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
131	FERRITIN	Num	8	6.	E9b. Ferritin
42	FEVER	Num	8	3.	C1a9. Fever
43	FEVERTTL	Num	8	3.	C1b9. Number of events:Fever
11	FOLATE	Num	8	3.	B1a3. Folate

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
12	FOLAT_MT	Num	8	4.	B1b3. Months taking: Folate
78	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
113	HANDCHNG	Num	8	3.	D8. Hand change
81	HEADACHE	Num	8	3.	D1. Has the patient complained of headaches?
82	HEADFREQ	Num	8	3.	D1a. Is the frequency < 1 per month or >= 1 per month
28	HEADINJR	Num	8	3.	C1a4. Head injury
84	HEAD_LOC	Char	50	$50.	D1c. Describe location and type of pain
83	HEAD_MTH	Num	8	4.	D1b. How long has the patient had them
141	HEPBVACC	Num	8	3.	F1. HepB Vaccination
35	HFS_TTL	Num	8	3.	C1b7. Number of events:Hand foot syndrome
13	HYDROXYU	Num	8	3.	B1a4. Hydroxyurea
14	HYDRX_MT	Num	8	4.	B1b4. Months taking: Hydroxyurea
34	H_F_SYND	Num	8	3.	C1a7. Hand-Foot Syndrome
3	INT_TYPE	Num	8	3.	A3. Person interviewed
91	INVOLMOV	Char	2	$2.	D5. Involuntary movements
144	INV_REV	Num	8	3.	H1a. Did STOPII Investigators review results of both reports?
15	IRONCHEL	Num	8	3.	B1a5. Iron Chelators
130	IRONOVER	Num	8	3.	E9. Iron overload
16	IRON_MTH	Num	8	4.	B1b5. Months taking: Iron chelators
119	LANGFUNC	Num	8	3.	D1O. Unable to perform a muscle or language function
120	LANG_SPC	Char	50	$50.	D1Oa. Language function: Specify
85	LOSSCONS	Num	8	3.	D2. Has (s)he experienced loss of consciousness
86	LOSSEPIS	Num	8	3.	D2a. Number of episodes: Lost consciousness
121	LULCERS	Num	8	3.	E1. Leg ulcers
27	MENINGIT	Num	8	3.	C1a3. Meningitis
93	MOVELARM	Num	8	3.	D5b1. Left arm
95	MOVELLEG	Num	8	3.	D5b3. Left leg
94	MOVERARM	Num	8	3.	D5b2. Right arm
96	MOVERLEG	Num	8	3.	D5b4. Right leg
92	MOVE_SPC	Char	50	$50.	D5a. Describe type of movements
97	MOVLFACE	Num	8	3.	D5b5. Left face
98	MOVRFACE	Num	8	3.	D5b6. Right face
123	NECROSPC	Char	25	$25.	E2b. Aseptic necrosis, specify
143	NEWNEURO	Num	8	3.	H1. Any new neurological
146	NEWREPRT	Num	8	3.	H1a2b. Were new symptoms reported on a STOP II Event Form
142	NON_STOP	Num	8	3.	G1. Is patient seen at non-STOP II sites
100	NUMBLARM	Num	8	3.	D6a1. Numb: Left arm
102	NUMBLLEG	Num	8	3.	D6a3. Numb: Left leg
99	NUMBNESS	Num	8	3.	D6. Numbness
101	NUMBRARM	Num	8	3.	D6a2. Numb: Right arm
103	NUMBRLEG	Num	8	3.	D6a4. Numb: Right leg
104	NUMLFACE	Num	8	3.	D6a5. Numb: Left face
105	NUMRFACE	Num	8	3.	D6a6. Numb:Right face
54	OSTEOMYL	Num	8	3.	C1a12. Osteomyelitis
55	OSTEOTTL	Num	8	3.	C1b12. Number of events:Osteomyelitis
10	OTHANTMT	Num	8	4.	B1b2. Months taking: Other
140	OTHCOND	Num	8	3.	E17. Other condition
9	OTH_ANTI	Num	8	3.	B1a2. Other antibiotic
66	OTH_EVNT	Num	8	3.	C1a15. Other event
17	OTH_MED	Num	8	3.	B1a6. Other medication(s)
67	OTH_TTL	Num	8	3.	C1b15. Number of events:Other

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
19	O_MD2_MT	Num	8	4.	B1b6b. Months taking: Other 2
20	O_MD3_MT	Num	8	4.	B1b6c. Months taking: Other 3
21	O_MD4_MT	Num	8	4.	B1b6d. Months taking: Other 4
18	O_MED_MT	Num	8	4.	B1b6a. Months taking: Other 1
7	PENCILLN	Num	8	3.	B1a1. Pencillin
8	PEN_MTHS	Num	8	4.	B1b1. Months taking: Pencillin
50	PNEUMONI	Num	8	3.	C1a11. Acute Chest Syndrome/Pneumonia
51	PNEUMTTL	Num	8	3.	C1b11. Number of events:ACS/pneumonia
136	PRIAP	Num	8	3.	E14. Priapism
58	PRIAPISM	Num	8	3.	C1a13. Priapism
59	PRIAPTTL	Num	8	3.	C1b13. Number of events:Priapism
138	RBCANTI	Num	8	3.	E16. New red cell antibody
139	RBC_SPC1	Char	25	$25.	E16a1. New red cell antibody,specify
63	REACTTTL	Num	8	3.	C1b14. Number of events:Transfusion reaction
133	RHEUMATC	Num	8	3.	E11. Rheumatc fever
124	SC_RETIN	Num	8	3.	E3. Sickle cell retinopathy
33	SEENAPLS	Num	8	3.	C1e6. Location seen at for aplastic
45	SEENFEVR	Num	8	3.	C1e9. Location seen at for fever
37	SEENHFS	Num	8	3.	C1e7. Location seen at for hand foot syndrome
57	SEENOSTE	Num	8	3.	C1e12. Location seen at for osteomyelitis
69	SEENOTH	Num	8	3.	C1e15. Location seen at for other
53	SEENPNEU	Num	8	3.	C1e11. Location seen at for ACS/pneumonia
61	SEENPRIA	Num	8	3.	C1e13. Location seen at for priapism
65	SEENREAC	Num	8	3.	C1e14. Location seen at for transfusion reaction
49	SEENSEPT	Num	8	3.	C1e10. Location seen at for septicemia
25	SEENSTRK	Num	8	3.	C1e1. Location seen at for stroke
77	SEENSURG	Num	8	3.	C2e2. Seen: Surgery
73	SEENTRAN	Num	8	3.	C2e1. Seen: Transfusion
41	SEENVASO	Num	8	3.	C1e8. Location seen at for vaso-occlusive pain
26	SEIZURES	Num	8	3.	C1a2. Seizures
46	SEPTICEM	Num	8	3.	C1a10. Septicemia
47	SEPT_TTL	Num	8	3.	C1b10. Number of events:Septicemia
145	SIGNEURO	Num	8	3.	H1a2. Patient has deveoped significant new neurological symptoms
116	SLURRING	Num	8	3.	D9a1. Slurring
29	SPLENICS	Num	8	3.	C1a5. Splenic sequestration
4	SP_INT	Char	75	$75.	<recoded> A3a. Person interviewed, specify
22	STROKE	Num	8	3.	C1a1. Stroke/TIA
23	STROKTTL	Num	8	3.	C1b1. Number of events:stroke
74	SURGERY	Num	8	3.	C2a2. Surgery
76	SURGPERF	Num	8	3.	C2c2. Num of events treated:Surgery
75	SURG_TTL	Num	8	3.	C2b2. Num of events:Surgery
70	TRANFUSN	Num	8	3.	C2a1. Transfusion
72	TRANPERF	Num	8	3.	C2c1. Num of events treated:Transfusion
71	TRAN_TTL	Num	8	3.	C2b1. Num of events:Transfusion
32	TREATAPL	Num	8	3.	C1c6. Number of events treated:aplastic
44	TREATFEV	Num	8	3.	C1c9. Number of events treated:Fever
36	TREATHFS	Num	8	3.	C1c7. Number of events treated:Hand foot syndrome
56	TREATOST	Num	8	3.	C1c12. Number of events treated:Osteomyelitis
68	TREATOTH	Num	8	3.	C1c15. Number of events treated:Other
52	TREATPNE	Num	8	3.	C1c11. Number of events treated:ACS/pneumonia

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
60	TREATPRI	Num	8	3.	C1c13. Number of events treated:Priapism
64	TREATREA	Num	8	3.	C1c14. Number of events treated:Transfusion reaction
48	TREATSEP	Num	8	3.	C1c10. Number of events treated:Septicemia
24	TREATSTR	Num	8	3.	C1c1. Number of events treated:stroke
40	TREATVAS	Num	8	3.	C1c8. Number of events treated:Vaso-occlusive pain
134	TUBERCUL	Num	8	3.	E12. Tuberculosis
62	T_REACTN	Num	8	3.	C1a14. Transfusion reaction
38	VASOPAIN	Num	8	3.	C1a8. Vaso-occlusive pain
39	VASO_TTL	Num	8	3.	C1b8. Number of events:Vaso-occlusive pain
90	VISION_L	Char	2	$2.	D4b. Loss of vision or blind spots
107	WEAKLARM	Num	8	3.	D7a1. Weak: Left arm
111	WEAKLFACE	Num	8	3.	D7a5. Weak: Left face
109	WEAKLLEG	Num	8	3.	D7a3. Weak: Left leg
106	WEAKNESS	Num	8	3.	D7. Weakness
108	WEAKRARM	Num	8	3.	D7a2. Weak: Right arm
112	WEAKRFACE	Num	8	3.	D7a6. Weak: Right face
110	WEAKRLEG	Num	8	3.	D7a4. Weak: Right leg
114	WHCHHAND	Num	8	3.	D8a. Hand change: Which hand
151	aplast_ dfrmrand	Num	8		<created variable> C1d6. Date of aplastic crisis as days from RAND visit
148	comp_ dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
163	dizzy_ dtfrmrand	Num	8		<created variable> D3b. Date of most recent episode: Dizziness as days from RAND visit
164	expres_ dfrmrand	Num	8		<created variable> D9a3a. Date: Expressing as days from RAND visit
152	fever_ dtfrmrand	Num	8		<created variable> C1d9. Date of fever as days from RAND visit
153	hfs_ datefrmrand	Num	8		<created variable> C1d7. Date of hand foot syndrome as days from RAND visit
147	ldu_id	Char	10		ID for public use datasets
165	loss_ dtfrmrand	Num	8		<created variable> D2b. Date of most recent episode: Lost consciousness as days from RAND visit
166	mlarm_ dtfrmrand	Num	8		<created variable> D5b1a. Date: Left arm as days from RAND visit
167	mlleg_ dtfrmrand	Num	8		<created variable> D5b3a. Date: Left leg as days from RAND visit
168	mrarm_ dtfrmrand	Num	8		<created variable> D5b2a. Date: Right arm as days from RAND visit
169	mrleg_ dtfrmrand	Num	8		<created variable> D5b4a. Date: Right leg as days from RAND visit
170	neuro_ dtfrmrand	Num	8		<created variable> H1a2c. Date of Neurological Event as days from RAND visit
171	nlarm_ dtfrmrand	Num	8		<created variable> D6a1a. Date: Numb: left arm as days from RAND visit
172	nlface_ dfrmrand	Num	8		<created variable> D6a5a. Date: Numb: left face as days from RAND visit
173	nlleg_ dtfrmrand	Num	8		<created variable> D6a3a. Date: Numb: Left leg as days from RAND visit
174	nrarm_ dtfrmrand	Num	8		<created variable> D6a2a. Date: Numb: right arm as days from RAND visit

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
175	nrleg_dtfrmrand	Num	8		<created variable> D6a4a. Date: Numb: Right leg as days from RAND visit
184	o_recode1	Num	8		<recoded variable> C1a15a1. Other code 1
186	o_recode2	Num	8		<recoded variable> C1a15b1. Other code 2
154	osteo_dtfrmrand	Num	8		<created variable> C1d12. Date of osteomyelitis as days from RAND visit
155	oth_evdtfrmrand	Num	8		<created variable> C1d15. Date of other event as days from RAND visit
185	oth_recodespc1	Char	25		<recoded variable> C1a15a. Other event 1, specify
187	oth_recodespc2	Char	25		<recoded variable> C1a15b. Other event 2, specify
156	pneum_dtfrmrand	Num	8		<created variable> C1d11. Date of ACS/pneumonia as days from RAND visit
157	priap_dtfrmrand	Num	8		<created variable> C1d13. Date of priapism as days from RAND visit
176	qtrrpt2frmrand	Num	8		<created variable> D. Quarterly Report Date as days from RAND visit
149	qtrrptfrmrand	Num	8		<created variable> C1. Date of last report as days from RAND visit
177	rbcant_dfrmrand	Num	8		<created variable> E16b. Date first identified as days from RAND visit
158	react_dtfrmrand	Num	8		<created variable> C1d14. Date of transfusion reaction as days from RAND visit
159	septi_dtfrmrand	Num	8		<created variable> C1d10. Date of septicemia as days from RAND visit
178	slur_dtfrmrand	Num	8		<created variable> D9a1a. Date: Slurring as days from RAND visit
150	strok_dtfrmrand	Num	8		<created variable> C1d1. Date of stroke as days from RAND visit
160	surg_dtfrmrand	Num	8		<created variable> C2d2. Date of: Surgery as days from RAND visit
191	surg_recodesp2	Char	25		<recoded variable> C1a16b. Surgery 2, specify
189	surg_recodespc	Char	25		<recoded variable> C1a16a. Surgery 1, specify
188	surgrecode	Num	8		<recoded variable> C2a2a1. Surgery code 1
190	surgrecode2	Num	8		<recoded variable> C2a2b1. Surgery code 2
161	transf_dfrmrand	Num	8		<created variable> C2d1. Date of: Transfusion as days from RAND visit
179	vacc_dtfrmrand	Num	8		<created variable> F1a. Vaccination date as days from RAND visit
162	vaso_dtfrmrand	Num	8		<created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit
80	vistype	Char	7		<created variable> VISIT TYPE
180	wlarm_dtfrmrand	Num	8		<created variable> D7a1a. Date: Weak: Left arm as days from RAND visit
181	wlleg_dtfrmrand	Num	8		<created variable> D7a3a. Date: Weak: Left leg as days from RAND visit
182	wrarm_dtfrmrand	Num	8		<created variable> D7a2a. Date: Weak: Right arm as days from RAND visit

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
183	wrleg_dtfrmrand	Num	8		<created variable> D7a4a. Date: Weak: Right leg as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	INT_TYPE	Num	8	3.	A3. Person interviewed
4	SP_INT	Char	75	$75.	<recoded> A3a. Person interviewed, specify
5	A_T_VERI	Num	8	3.	A4. Address and telephone info verified
6	ANYMEDS	Num	8	3.	B1. Patient taking any medications
7	PENCILLN	Num	8	3.	B1a1. Pencillin
8	PEN_MTHS	Num	8	4.	B1b1. Months taking: Pencillin
9	OTH_ANTI	Num	8	3.	B1a2. Other antibiotic
10	OTHANTMT	Num	8	4.	B1b2. Months taking: Other
11	FOLATE	Num	8	3.	B1a3. Folate
12	FOLAT_MT	Num	8	4.	B1b3. Months taking: Folate
13	HYDROXYU	Num	8	3.	B1a4. Hydroxyurea
14	HYDRX_MT	Num	8	4.	B1b4. Months taking: Hydroxyurea
15	IRONCHEL	Num	8	3.	B1a5. Iron Chelators
16	IRON_MTH	Num	8	4.	B1b5. Months taking: Iron chelators
17	OTH_MED	Num	8	3.	B1a6. Other medication(s)
18	O_MED_MT	Num	8	4.	B1b6a. Months taking: Other 1
19	O_MD2_MT	Num	8	4.	B1b6b. Months taking: Other 2
20	O_MD3_MT	Num	8	4.	B1b6c. Months taking: Other 3
21	O_MD4_MT	Num	8	4.	B1b6d. Months taking: Other 4
22	STROKE	Num	8	3.	C1a1. Stroke/TIA
23	STROKTTL	Num	8	3.	C1b1. Number of events:stroke
24	TREATSTR	Num	8	3.	C1c1. Number of events treated:stroke
25	SEENSTRK	Num	8	3.	C1e1. Location seen at for stroke
26	SEIZURES	Num	8	3.	C1a2. Seizures
27	MENINGIT	Num	8	3.	C1a3. Meningitis
28	HEADINJR	Num	8	3.	C1a4. Head injury
29	SPLENICS	Num	8	3.	C1a5. Splenic sequestration
30	APLASTIC	Num	8	3.	C1a6. Aplastic Crisis
31	APLASTTL	Num	8	3.	C1b6. Number of events:aplastic
32	TREATAPL	Num	8	3.	C1c6. Number of events treated:aplastic
33	SEENAPLS	Num	8	3.	C1e6. Location seen at for aplastic
34	H_F_SYND	Num	8	3.	C1a7. Hand-Foot Syndrome
35	HFS_TTL	Num	8	3.	C1b7. Number of events:Hand foot syndrome
36	TREATHFS	Num	8	3.	C1c7. Number of events treated:Hand foot syndrome
37	SEENHFS	Num	8	3.	C1e7. Location seen at for hand foot syndrome
38	VASOPAIN	Num	8	3.	C1a8. Vaso-occlusive pain
39	VASO_TTL	Num	8	3.	C1b8. Number of events:Vaso-occlusive pain
40	TREATVAS	Num	8	3.	C1c8. Number of events treated:Vaso-occlusive pain
41	SEENVASO	Num	8	3.	C1e8. Location seen at for vaso-occlusive pain
42	FEVER	Num	8	3.	C1a9. Fever
43	FEVERTTL	Num	8	3.	C1b9. Number of events:Fever
44	TREATFEV	Num	8	3.	C1c9. Number of events treated:Fever
45	SEENFEVR	Num	8	3.	C1e9. Location seen at for fever
46	SEPTICEM	Num	8	3.	C1a10. Septicemia
47	SEPT_TTL	Num	8	3.	C1b10. Number of events:Septicemia
48	TREATSEP	Num	8	3.	C1c10. Number of events treated:Septicemia
49	SEENSEPT	Num	8	3.	C1e10. Location seen at for septicemia
50	PNEUMONI	Num	8	3.	C1a11. Acute Chest Syndrome/Pneumonia
51	PNEUMTTL	Num	8	3.	C1b11. Number of events:ACS/pneumonia

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
52	TREATPNE	Num	8	3.	C1c11. Number of events treated:ACS/pneumonia
53	SEENPNEU	Num	8	3.	C1e11. Location seen at for ACS/pneumonia
54	OSTEOMYL	Num	8	3.	C1a12. Osteomyelitis
55	OSTEOTTL	Num	8	3.	C1b12. Number of events:Osteomyelitis
56	TREATOST	Num	8	3.	C1c12. Number of events treated:Osteomyelitis
57	SEENOSTE	Num	8	3.	C1e12. Location seen at for osteomyelitis
58	PRIAPISM	Num	8	3.	C1a13. Priapism
59	PRIAPTTL	Num	8	3.	C1b13. Number of events:Priapism
60	TREATPRI	Num	8	3.	C1c13. Number of events treated:Priapism
61	SEENPRIA	Num	8	3.	C1e13. Location seen at for priapism
62	T_REACTN	Num	8	3.	C1a14. Transfusion reaction
63	REACTTTL	Num	8	3.	C1b14. Number of events:Transfusion reaction
64	TREATREA	Num	8	3.	C1c14. Number of events treated:Transfusion reaction
65	SEENREAC	Num	8	3.	C1e14. Location seen at for transfusion reaction
66	OTH_EVNT	Num	8	3.	C1a15. Other event
67	OTH_TTL	Num	8	3.	C1b15. Number of events:Other
68	TREATOTH	Num	8	3.	C1c15. Number of events treated:Other
69	SEENOTH	Num	8	3.	C1e15. Location seen at for other
70	TRANFUSN	Num	8	3.	C2a1. Transfusion
71	TRAN_TTL	Num	8	3.	C2b1. Num of events:Transfusion
72	TRANPERF	Num	8	3.	C2c1. Num of events treated:Transfusion
73	SEENTRAN	Num	8	3.	C2e1. Seen: Transfusion
74	SURGERY	Num	8	3.	C2a2. Surgery
75	SURG_TTL	Num	8	3.	C2b2. Num of events:Surgery
76	SURGPERF	Num	8	3.	C2c2. Num of events treated:Surgery
77	SEENSURG	Num	8	3.	C2e2. Seen: Surgery
78	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
79	DESTATUS	Char	1	$1.	DESTATUS
80	vistype	Char	7		<created variable> VISIT TYPE
81	HEADACHE	Num	8	3.	D1. Has the patient complained of headaches?
82	HEADFREQ	Num	8	3.	D1a. Is the frequency < 1 per month or >= 1 per month
83	HEAD_MTH	Num	8	4.	D1b. How long has the patient had them
84	HEAD_LOC	Char	50	$50.	D1c. Describe location and type of pain
85	LOSSCONS	Num	8	3.	D2. Has (s)he experienced loss of consciousness
86	LOSSEPIS	Num	8	3.	D2a. Number of episodes: Lost consciousness
87	DIZZINESS	Num	8	3.	D3. Dizziness
88	DIZZY_EP	Num	8	3.	D3a. Number of episodes: Dizziness
89	D_VISION	Char	2	$2.	D4a. Double vision
90	VISION_L	Char	2	$2.	D4b. Loss of vision or blind spots
91	INVOLMOV	Char	2	$2.	D5. Involuntary movements
92	MOVE_SPC	Char	50	$50.	D5a. Describe type of movements
93	MOVELARM	Num	8	3.	D5b1. Left arm
94	MOVERARM	Num	8	3.	D5b2. Right arm
95	MOVELLEG	Num	8	3.	D5b3. Left leg
96	MOVERLEG	Num	8	3.	D5b4. Right leg
97	MOVLFACE	Num	8	3.	D5b5. Left face
98	MOVRFACE	Num	8	3.	D5b6. Right face
99	NUMBNESS	Num	8	3.	D6. Numbness
100	NUMBLARM	Num	8	3.	D6a1. Numb: Left arm
101	NUMBRARM	Num	8	3.	D6a2. Numb: Right arm
102	NUMBLLEG	Num	8	3.	D6a3. Numb: Left leg

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
103	NUMBRLEG	Num	8	3.	D6a4. Numb: Right leg
104	NUMLFACE	Num	8	3.	D6a5. Numb: Left face
105	NUMRFACE	Num	8	3.	D6a6. Numb:Right face
106	WEAKNESS	Num	8	3.	D7. Weakness
107	WEAKLARM	Num	8	3.	D7a1. Weak: Left arm
108	WEAKRARM	Num	8	3.	D7a2. Weak: Right arm
109	WEAKLLEG	Num	8	3.	D7a3. Weak: Left leg
110	WEAKRLEG	Num	8	3.	D7a4. Weak: Right leg
111	WEAKLFACE	Num	8	3.	D7a5. Weak: Left face
112	WEAKRFACE	Num	8	3.	D7a6. Weak: Right face
113	HANDCHNG	Num	8	3.	D8. Hand change
114	WHCHHAND	Num	8	3.	D8a. Hand change: Which hand
115	DIFFUNDR	Num	8	3.	D9. Any difficulty talking or understanding what was said
116	SLURRING	Num	8	3.	D9a1. Slurring
117	DIF_UNDS	Num	8	3.	D9a2. Difficulty understanding
118	EXPRESS	Num	8	3.	D9a3. Expressing
119	LANGFUNC	Num	8	3.	D10. Unable to perform a muscle or language function
120	LANG_SPC	Char	50	$50.	D10a. Language function: Specify
121	LULCERS	Num	8	3.	E1. Leg ulcers
122	A_NECROS	Num	8	3.	E2. Aseptic necrosis
123	NECROSPC	Char	25	$25.	E2b. Aseptic necrosis, specify
124	SC_RETIN	Num	8	3.	E3. Sickle cell retinopathy
125	CHR_LUNG	Num	8	3.	E4. Chronic lung disease
126	ASTHMA	Num	8	3.	E5. Asthma
127	CHD	Num	8	3.	E6. Chronic heart disease
128	CHRLIVER	Num	8	3.	E7. Chronic liver disease
129	CHRRENAL	Num	8	3.	E8. Chronic renal disease
130	IRONOVER	Num	8	3.	E9. Iron overload
131	FERRITIN	Num	8	6.	E9b. Ferritin
132	DIABETES	Num	8	3.	E10. Diabetes
133	RHEUMATC	Num	8	3.	E11. Rheumatc fever
134	TUBERCUL	Num	8	3.	E12. Tuberculosis
135	CANCER	Num	8	3.	E13. Cancer
136	PRIAP	Num	8	3.	E14. Priapism
137	ELEV_BLD	Num	8	3.	E15. Elevated blood lead level
138	RBCANTI	Num	8	3.	E16. New red cell antibody
139	RBC_SPC1	Char	25	$25.	E16a1. New red cell antibody,specify
140	OTHCOND	Num	8	3.	E17. Other condition
141	HEPBVACC	Num	8	3.	F1. HepB Vaccination
142	NON_STOP	Num	8	3.	G1. Is patient seen at non-STOP II sites
143	NEWNEURO	Num	8	3.	H1. Any new neurological
144	INV_REV	Num	8	3.	H1a. Did STOPII Investigators review results of both reports?
145	SIGNEURO	Num	8	3.	H1a2. Patient has deveoped significant new neurological symptoms
146	NEWREPRT	Num	8	3.	H1a2b. Were new symptoms reported on a STOP II Event Form
147	ldu_id	Char	10		ID for public use datasets
148	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
149	qtrrptfrmrand	Num	8		<created variable> C1. Date of last report as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
150	strok_dtfrmrand	Num	8		<created variable> C1d1. Date of stroke as days from RAND visit
151	aplast_dfrmrand	Num	8		<created variable> C1d6. Date of aplastic crisis as days from RAND visit
152	fever_dtfrmrand	Num	8		<created variable> C1d9. Date of fever as days from RAND visit
153	hfs_datefrmrand	Num	8		<created variable> C1d7. Date of hand foot syndrome as days from RAND visit
154	osteo_dtfrmrand	Num	8		<created variable> C1d12. Date of osteomyelitis as days from RAND visit
155	oth_evdtfrmrand	Num	8		<created variable> C1d15. Date of other event as days from RAND visit
156	pneum_dtfrmrand	Num	8		<created variable> C1d11. Date of ACS/pneumonia as days from RAND visit
157	priap_dtfrmrand	Num	8		<created variable> C1d13. Date of priapism as days from RAND visit
158	react_dtfrmrand	Num	8		<created variable> C1d14. Date of transfusion reaction as days from RAND visit
159	septi_dtfrmrand	Num	8		<created variable> C1d10. Date of septicemia as days from RAND visit
160	surg_dtfrmrand	Num	8		<created variable> C2d2. Date of: Surgery as days from RAND visit
161	transf_dfrmrand	Num	8		<created variable> C2d1. Date of: Transfusion as days from RAND visit
162	vaso_dtfrmrand	Num	8		<created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit
163	dizzy_dtfrmrand	Num	8		<created variable> D3b. Date of most recent episode: Dizziness as days from RAND visit
164	expres_dfrmrand	Num	8		<created variable> D9a3a. Date: Expressing as days from RAND visit
165	loss_dtfrmrand	Num	8		<created variable> D2b. Date of most recent episode: Lost consciousness as days from RAND visit
166	mlarm_dtfrmrand	Num	8		<created variable> D5b1a. Date: Left arm as days from RAND visit
167	mlleg_dtfrmrand	Num	8		<created variable> D5b3a. Date: Left leg as days from RAND visit
168	mrarm_dtfrmrand	Num	8		<created variable> D5b2a. Date: Right arm as days from RAND visit
169	mrleg_dtfrmrand	Num	8		<created variable> D5b4a. Date: Right leg as days from RAND visit
170	neuro_dtfrmrand	Num	8		<created variable> H1a2c. Date of Neurological Event as days from RAND visit
171	nlarm_dtfrmrand	Num	8		<created variable> D6a1a. Date: Numb: left arm as days from RAND visit
172	nlface_dfrmrand	Num	8		<created variable> D6a5a. Date: Numb: left face as days from RAND visit
173	nlleg_dtfrmrand	Num	8		<created variable> D6a3a. Date: Numb: Left leg as days from RAND visit
174	nrarm_dtfrmrand	Num	8		<created variable> D6a2a. Date: Numb: right arm as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
175	nrleg_dtfrmrand	Num	8		<created variable> D6a4a. Date: Numb: Right leg as days from RAND visit
176	qtrrpt2frmrand	Num	8		<created variable> D. Quarterly Report Date as days from RAND visit
177	rbcant_dfrmrand	Num	8		<created variable> E16b. Date first identified as days from RAND visit
178	slur_dtfrmrand	Num	8		<created variable> D9a1a. Date: Slurring as days from RAND visit
179	vacc_dtfrmrand	Num	8		<created variable> F1a. Vaccination date as days from RAND visit
180	wlarm_dtfrmrand	Num	8		<created variable> D7a1a. Date: Weak: Left arm as days from RAND visit
181	wlleg_dtfrmrand	Num	8		<created variable> D7a3a. Date: Weak: Left leg as days from RAND visit
182	wrarm_dtfrmrand	Num	8		<created variable> D7a2a. Date: Weak: Right arm as days from RAND visit
183	wrleg_dtfrmrand	Num	8		<created variable> D7a4a. Date: Weak: Right leg as days from RAND visit
184	o_recode1	Num	8		<recoded variable> C1a15a1. Other code 1
185	oth_recodespc1	Char	25		<recoded variable> C1a15a. Other event 1, specify
186	o_recode2	Num	8		<recoded variable> C1a15b1. Other code 2
187	oth_recodespc2	Char	25		<recoded variable> C1a15b. Other event 2, specify
188	surgrecode	Num	8		<recoded variable> C2a2a1. Surgery code 1
189	surg_recodespc	Char	25		<recoded variable> C1a16a. Surgery 1, specify
190	surgrecode2	Num	8		<recoded variable> C2a2b1. Surgery code 2
191	surg_recodesp2	Char	25		<recoded variable> C1a16b. Surgery 2, specify

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

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    3='3: Legal guardian'
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```

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STOP II TRIAL
QUARTERLY PROGRESS REPORT FOR RANDOMIZED PATIENTS

*** AFFIX PATIENT LABEL HERE***

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	729	98.51	729	98.51
P	11	1.49	740	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-401	79	10.68	79	10.68
QT-402	75	10.14	154	20.81
QT-403	75	10.14	229	30.95
QT-404	66	8.92	295	39.86
QT-405	62	8.38	357	48.24
QT-406	54	7.30	411	55.54
QT-407	48	6.49	459	62.03
QT-408	50	6.76	509	68.78
QT-409	44	5.95	553	74.73
QT-410	43	5.81	596	80.54
QT-411	39	5.27	635	85.81
QT-412	36	4.86	671	90.68
QT-413	33	4.46	704	95.14
QT-414	18	2.43	722	97.57
QT-415	13	1.76	735	99.32
QT-416	5	0.68	740	100.00

A1. Person completing form (Name):_____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of interview (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of interview as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
740	0	487.0	368.1	-14.0	168.5	441.0	790.0	1399.0

A3. Person interviewed (Choose **ONE** for person providing majority of answers to sections B-D):

☐ 1. Patient ☐ 2. Parent ☐ 3. Legal Guardian ☐ 4. Other → A3.a (specify): _____

A3. Person interviewed				
INT_TYPE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
1	213	28.78	214	28.92
2	417	56.35	631	85.27
3	15	2.03	646	87.30
4	94	12.70	740	100.00

<recoded> A3a. Person interviewed, specify				
SP_INT	Frequency	Percent	Cum Freq	Cum Percent
-2	646	87.30	646	87.30
Aunt	1	0.14	647	87.43
Case worker	5	0.68	652	88.11
Foster parent	2	0.27	654	88.38
Grandmother	1	0.14	655	88.51
Medical personnel	80	10.81	735	99.32
Retrospective chart review	1	0.14	736	99.46
Sister	3	0.41	739	99.86
Social Worker	1	0.14	740	100.00

A4. Were address and telephone information verified for this patient? ☐ **1. NO** ☐ **2. YES**

A4. Address and telephone info verified				
A_T_VERI	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.68	5	0.68
-8	1	0.14	6	0.81
1	9	1.22	15	2.03
2	725	97.97	740	100.00

QUESTIONS IN SECTIONS B THROUGH D ARE TO BE ANSWERED BY THE PERSON INTERVIEWED; QUESTIONS IN SECTIONS E THROUGH H ARE TO BE ANSWERED BY MEDICAL PERSONNEL.

B. MEDICATIONS

B1. Is the patient currently taking, on a regular basis, any medications prescribed by a physician?

☐ **1. NO** ☐ **2. YES**

B1. Patient taking any medications				
ANYMEDS	Frequency	Percent	Cum Freq	Cum Percent
1	103	13.92	103	13.92
2	637	86.08	740	100.00

↓

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
1. Penicillin	☐	☐	1. ☐☐☐

B1a1. Pencillin				
PENCILLN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	103	13.92	104	14.05
1	358	48.38	462	62.43
2	278	37.57	740	100.00

Analysis Variable : PEN_MTHS B1b1. Months taking: Pencillin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
277	0	117.6	54.6	1.0	90.0	121.0	156.0	229.0

B1b1. Months taking: Pencillin				
PEN_MTHS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.22	1	0.22
-8	1	0.22	2	0.43
-2	461	99.57	463	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
2. Other antibiotic	☐	☐	2. ☐☐☐

↓

B1.a2.a SPECIFY:_____

B1a2. Other antibiotic				
OTH_ANTI	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	103	13.92	104	14.05
1	608	82.16	712	96.22
2	28	3.78	740	100.00

Analysis Variable : OTHANTMT B1b2. Months taking: Other								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
22	0	84.4	59.4	1.0	1.0	110.5	130.0	143.0

B1b2. Months taking: Other				
OTHANTMT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.28	2	0.28
-2	711	99.03	713	99.30
-1	1	0.14	714	99.44
0	4	0.56	718	100.00

[Variable NOT included in dataset for specify field.]

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

1. NO **2. YES**

3. Folate ☐ ☐ 3. ☐☐☐

B1a3. Folate				
FOLATE	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.27	2	0.27
-2	103	13.92	105	14.19
1	334	45.14	439	59.32
2	301	40.68	740	100.00

Analysis Variable : FOLAT_MT B1b3. Months taking: Folate								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
293	0	79.2	67.9	1.0	15.0	77.0	130.0	282.0

B1b3. Months taking: Folate				
FOLAT_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.89	4	0.89
-8	6	1.34	10	2.24
-2	437	97.76	447	100.00

4. Hydroxyurea ☐ ☐ 4. ☐☐☐

B1a4. Hydroxyurea				
HYDROXYU	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.54	4	0.54
-2	103	13.92	107	14.46
1	613	82.84	720	97.30
2	20	2.70	740	100.00

Analysis Variable : HYDRX_MT B1b4. Months taking: Hydroxyurea								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
18	0	4.2	4.4	1.0	1.0	2.0	4.0	16.0

B1b4. Months taking: Hydroxyurea				
HYDRX_MT	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.14	1	0.14
-2	720	99.72	721	99.86
0	1	0.14	722	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
5. Iron Chelators (Desferoxamine)	☐	☐	5. ☐☐☐

B1a5. Iron Chelators				
IRONCHEL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	103	13.92	104	14.05
1	190	25.68	294	39.73
2	446	60.27	740	100.00

Analysis Variable : IRON_MTH B1b5. Months taking: Iron chelators								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
440	0	36.0	28.4	1.0	15.0	30.5	51.0	199.0

B1b5. Months taking: Iron chelators				
IRON_MTH	Frequency	Percent	Cum Freq	Cum Percent
-9	3	1.00	3	1.00
-8	2	0.67	5	1.67
-2	293	97.67	298	99.33
0	2	0.67	300	100.00

6. Other ☐ ☐ → 6.a ☐☐☐ 6.b ☐☐☐

B1.a6.a SPECIFY:_____

B1.a6.b SPECIFY: _____

B1a6. Other medication(s)				
OTH_MED	Frequency	Percent	Cum Freq	Cum Percent
-2	103	13.92	103	13.92
1	326	44.05	429	57.97
2	311	42.03	740	100.00

[Variables NOT included in dataset for specify fields.]

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
6. Other	☐	☐	6.a ☐☐☐
			6.b ☐☐☐

Analysis Variable : O_MED_MT B1b6a. Months taking: Other 1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
298	0	33.6	41.5	1.0	7.0	18.0	42.0	188.0

B1b6a. Months taking: Other 1				
O_MED_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	5	1.13	5	1.13
-8	3	0.68	8	1.81
-3	2	0.45	10	2.26
-2	429	97.06	439	99.32
-1	1	0.23	440	99.55
0	2	0.45	442	100.00

Analysis Variable : O_MD2_MT B1b6b. Months taking: Other 2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
141	0	37.0	47.9	1.0	6.0	18.0	42.0	182.0

B1b6b. Months taking: Other 2				
O_MD2_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	6	1.00	6	1.00
-8	3	0.50	9	1.50
-3	1	0.17	10	1.67
-2	588	98.16	598	99.83
0	1	0.17	599	100.00

Analysis Variable : O_MD3_MT B1b6c. Months taking: Other 3								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
34	0	11.6	10.2	1.0	3.0	8.0	18.0	36.0

B1b6c. Months taking: Other 3				
O_MD3_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.42	3	0.42
-8	1	0.14	4	0.57
-3	1	0.14	5	0.71
-2	700	99.15	705	99.86
0	1	0.14	706	100.00

B1.a TYPE OF MEDICATION: (CHECK NO OR YES FOR EACH OF B1.a1-6)	1. NO	2. YES	B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?
6. Other	☐	☐	6.a ☐☐☐ 6.b ☐☐☐

Analysis Variable : O_MD4_MT B1b6d. Months taking: Other 4								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
23	0	14.4	9.0	1.0	6.0	14.0	24.0	36.0

B1b6d. Months taking: Other 4				
O_MD4_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.28	2	0.28
-8	1	0.14	3	0.42
-2	713	99.44	716	99.86
0	1	0.14	717	100.00

C. CLINICAL EVENTS

Since the last quarterly report (or entry interview if this is the first quarterly report) on _____/_____/_____, has the patient been seen by a doctor or nurse for any of the following:

Analysis Variable : qtrrptfrmrand <created variable> C1. Date of last report as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
739	0	393.9	363.7	-370.0	71.0	342.0	693.0	1253.0

<created variable> C1. Date of last report as days from RAND visit				
qtrrptfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
1. **Stroke/TIA**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: An event which a doctor called a stroke or cerebrovascular accident (CVA) which involved loss of consciousness, paralysis, visual, speech, or motor difficulties)*

C1a1. Stroke/TIA				
STROKE	Frequency	Percent	Cum Freq	Cum Percent
1	736	99.46	736	99.46
2	4	0.54	740	100.00

C1b1. Number of events:stroke				
STROKTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	736	99.46	736	99.46
1	4	0.54	740	100.00

C1c1. Number of events treated:stroke				
TREATSTR	Frequency	Percent	Cum Freq	Cum Percent
-2	736	99.46	736	99.46
0	1	0.14	737	99.59
1	3	0.41	740	100.00

Analysis Variable : strok_dtfrmrand <created variable> C1d1. Date of stroke as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	177.0	76.4	125.0	131.0	146.5	223.0	290.0

<created variable> C1d1. Date of stroke as days from RAND visit				
strok_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	736	100.00	736	100.00

C1e1. Location seen at for stroke				
SEENSTRK	Frequency	Percent	Cum Freq	Cum Percent
-2	736	99.46	736	99.46
1	3	0.41	739	99.86
2	1	0.14	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
2. **New Onset of Seizures**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Any fits or convulsions that were not associated with a stroke or meningitis (brain infection))*

C1a2. Seizures				
SEIZURES	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

IF RESPONSE TO C1.a1 or C1.a2 IS YES, SUBMIT NEUROLOGICAL EVENT FORM (FORM 30), NEUROLOGICAL CONSULTANT REPORT (FORM 14), HEAD MRI SCAN (FORM 15), SUPPORTING HOSPITAL SUMMARIES, AND SCANS AND REPORTS FOR ALL IMAGING TESTS PERFORMED

3. **Meningitis**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Infection of the brain)*

c1.f3 **IF YES,** Date of discharge ___ ___/___ ___/___ ___ ___ ___

C1a3. Meningitis				
MENINGIT	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event, where seen or date discharged.]

4. **Head Injury with loss of consciousness**	☐	☐	☐	__ __/__ __ __ __	☐

c1.f4 **IF YES,** Date of discharge ___ ___/___ ___/___ ___ ___ ___

C1a4. Head injury				
HEADINJR	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event, where seen or date discharged.]

IF RESPONSE TO C1.a3 or C1.a4 IS YES, SUBMIT NON-NEUROLOGICAL EVENT FORM (FORM 31), AND SCHEDULE NEUROLOGICAL EXAM BY STOP II NEUROLOGIST (COMPLETE FORM 14) AND HEAD MRI SCAN (COMPLETE FORM 15), 2-3 WEEKS AFTER PATIENT'S DISCHARGE FROM HOSPITAL.

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
5. **Splenic Sequestration***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Enlargement of the spleen with trapping of blood in it)*

C1a5. Splenic sequestration				
SPLENICS	Frequency	Percent	Cum Freq	Cum Percent
-1	10	1.35	10	1.35
1	730	98.65	740	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

6. **Aplastic Crisis***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: A drop in the blood count which required a transfusion)*

C1a6. Aplastic Crisis				
APLASTIC	Frequency	Percent	Cum Freq	Cum Percent
1	737	99.59	737	99.59
2	3	0.41	740	100.00

C1b6. Number of events:aplastic				
APLASTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	737	99.59	737	99.59
1	3	0.41	740	100.00

C1c6. Number of events treated:aplastic				
TREATAPL	Frequency	Percent	Cum Freq	Cum Percent
-2	737	99.59	737	99.59
0	1	0.14	738	99.73
1	2	0.27	740	100.00

Analysis Variable : aplast_dfrmrand <created variable> C1d6. Date of aplastic crisis as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	444.7	365.1	85.0	85.0	434.0	815.0	815.0

<created variable> C1d6. Date of aplastic crisis as days from RAND visit				
aplast_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	737	100.00	737	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
6. **Aplastic Crisis***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: A drop in the blood count which required a transfusion)*

C1e6. Location seen at for aplastic				
SEENAPLS	Frequency	Percent	Cum Freq	Cum Percent
-2	737	99.59	737	99.59
1	2	0.27	739	99.86
2	1	0.14	740	100.00

7. **Hand-Foot Syndrome*** ☐ ☐ ☐ __ __/__ __ __ __ ☐

*(**PROBE**: Pain, tenderness, with or without swelling, in the hands and/or feet only)*

C1a7. Hand-Foot Syndrome				
H_F_SYND	Frequency	Percent	Cum Freq	Cum Percent
1	739	99.86	739	99.86
2	1	0.14	740	100.00

C1b7. Number of events:Hand foot syndrome				
HFS_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
1	1	0.14	740	100.00

C1c7. Number of events treated:Hand foot syndrome				
TREATHFS	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
0	1	0.14	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
7. **Hand-Foot Syndrome***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Pain, tenderness, with or without swelling, in the hands and/or feet only)*

Analysis Variable : hfs_datefrmrand <created variable> C1d7. Date of hand foot syndrome as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	1073.0	.	1073.0	1073.0	1073.0	1073.0	1073.0

<created variable> C1d7. Date of hand foot syndrome as days from RAND visit

hfs_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

C1e7. Location seen at for hand foot syndrome

SEENHFS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	739	99.86	740	100.00

8. **Vaso-occlusive pain event for which the patient was hospitalized***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: An acute episode of pain in the arms, legs, back, chest, and/or abdomen, lasting at least two hours for which no other explanation was found)*

C1a8. Vaso-occlusive pain

VASOPAIN	Frequency	Percent	Cum Freq	Cum Percent
1	645	87.16	645	87.16
2	95	12.84	740	100.00

C1b8. Number of events:Vaso-occlusive pain

VASO_TTL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	645	87.16	646	87.30
1	64	8.65	710	95.95
2	26	3.51	736	99.46
3	4	0.54	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
8. **Vaso-occlusive pain event for which the patient was hospitalized***				__ __/__ __ __ __	

(***PROBE**: An acute episode of pain in the arms, legs, back, chest, and/or abdomen, lasting at least two hours for which no other explanation was found)*

C1c8. Number of events treated:Vaso-occlusive pain

TREATVAS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	645	87.16	646	87.30
0	12	1.62	658	88.92
1	60	8.11	718	97.03
2	18	2.43	736	99.46
3	4	0.54	740	100.00

Analysis Variable : vaso_dtfrmrand <created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
93	0	487.9	359.5	-103.0	155.0	451.0	743.0	1307.0

<created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit

vaso_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	647	100.00	647	100.00

C1e8. Location seen at for vaso-occlusive pain

SEENVASO	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	645	87.16	646	87.30
1	78	10.54	724	97.84
2	16	2.16	740	100.00

*** IF RESPONSE TO ANY OF C1.a5 – C1.a8 IS YES, COMPLETE A NON-NEUROLOGICAL EVENT (FORM 31) FOR EACH UNIQUE EVENT**

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
9. **Fever***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: A temperature greater than 101° F (39° C)*

C1a9. Fever				
FEVER	Frequency	Percent	Cum Freq	Cum Percent
1	657	88.78	657	88.78
2	83	11.22	740	100.00

C1b9. Number of events:Fever				
FEVERTTL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	657	88.78	658	88.92
1	67	9.05	725	97.97
2	13	1.76	738	99.73
3	2	0.27	740	100.00

C1c9. Number of events treated:Fever				
TREATFEV	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.27	2	0.27
-2	657	88.78	659	89.05
0	14	1.89	673	90.95
1	55	7.43	728	98.38
2	11	1.49	739	99.86
3	1	0.14	740	100.00

Analysis Variable : fever_dtfrmrand <created variable> C1d9. Date of fever as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
82	0	395.1	348.0	-89.0	116.0	296.0	639.0	1307.0

<created variable> C1d9. Date of fever as days from RAND visit				
fever_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	658	100.00	658	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
9. **Fever***	☐	☐	☐	__ __/__ __ __ __	☐

(***PROBE**: A temperature greater than 101° F (39° C)*

C1e9. Location seen at for fever				
SEENFEVR	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.27	2	0.27
-2	657	88.78	659	89.05
1	62	8.38	721	97.43
2	19	2.57	740	100.00

10. **Septicemia*** ☐ ☐ ☐ __ __/__ __ __ __ ☐

*(**PROBE**: An infection in the blood stream)*

C1a10. Septicemia				
SEPTICEM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
1	731	98.78	732	98.92
2	8	1.08	740	100.00

C1b10. Number of events:Septicemia				
SEPT_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	732	98.92	732	98.92
1	7	0.95	739	99.86
2	1	0.14	740	100.00

C1c10. Number of events treated:Septicemia				
TREATSEP	Frequency	Percent	Cum Freq	Cum Percent
-2	732	98.92	732	98.92
1	7	0.95	739	99.86
2	1	0.14	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
10. **Septicemia***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: An infection in the blood stream)*

Analysis Variable : septi_dtfrmrand <created variable> C1d10. Date of septicemia as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
8	0	179.1	266.5	-89.0	-2.5	135.0	250.0	757.0

<created variable> C1d10. Date of septicemia as days from RAND visit

septi_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	732	100.00	732	100.00

C1e10. Location seen at for septicemia

SEENSEPT	Frequency	Percent	Cum Freq	Cum Percent
-2	732	98.92	732	98.92
1	8	1.08	740	100.00

11. **Acute Chest Syndrome/Pneumonia *** ☐ ☐ ☐ __ __/__ __ __ __ ☐

*(**PROBE:** An infection or blockage of blood flow in the lung(s))*

C1a11. Acute Chest Syndrome/Pneumonia

PNEUMONI	Frequency	Percent	Cum Freq	Cum Percent
1	710	95.95	710	95.95
2	30	4.05	740	100.00

C1b11. Number of events:ACS/pneumonia

PNEUMTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	710	95.95	710	95.95
1	29	3.92	739	99.86
2	1	0.14	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
11. **Acute Chest Syndrome/Pneumonia ***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE:** An infection or blockage of blood flow in the lung(s))*

C1c11. Number of events treated:ACS/pneumonia

TREATPNE	Frequency	Percent	Cum Freq	Cum Percent
-2	710	95.95	710	95.95
0	4	0.54	714	96.49
1	25	3.38	739	99.86
2	1	0.14	740	100.00

Analysis Variable : pneum_dtfrmrand <created variable> C1d11. Date of ACS/pneumonia as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
30	0	358.8	306.0	-89.0	147.0	252.5	487.0	1307.0

<created variable> C1d11. Date of ACS/pneumonia as days from RAND visit

pneum_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	710	100.00	710	100.00

C1e11. Location seen at for ACS/pneumonia

SEENPNEU	Frequency	Percent	Cum Freq	Cum Percent
-2	710	95.95	710	95.95
1	26	3.51	736	99.46
2	4	0.54	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
12. **Osteomyelitis***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Infection in the bones)*

C1a12. Osteomyelitis				
OSTEOMYL	Frequency	Percent	Cum Freq	Cum Percent
1	739	99.86	739	99.86
2	1	0.14	740	100.00

C1b12. Number of events:Osteomyelitis				
OSTEOTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
1	1	0.14	740	100.00

C1c12. Number of events treated:Osteomyelitis				
TREATOST	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
1	1	0.14	740	100.00

Analysis Variable : osteo_dtfrmrand <created variable> C1d12. Date of osteomyelitis as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	478.0	.	478.0	478.0	478.0	478.0	478.0

<created variable> C1d12. Date of osteomyelitis as days from RAND visit				
osteo_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

C1e12. Location seen at for osteomyelitis				
SEENOSTE	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
1	1	0.14	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
13. **Priapism***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: A painful, unwanted erection of the penis lasting more than one hour)*

C1a13. Priapism

PRIAPISM	Frequency	Percent	Cum Freq	Cum Percent
-1	403	54.46	403	54.46
1	336	45.41	739	99.86
2	1	0.14	740	100.00

C1b13. Number of events:Priapism

PRIAPTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
1	1	0.14	740	100.00

C1c13. Number of events treated:Priapism

TREATPRI	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
1	1	0.14	740	100.00

Analysis Variable : priap_dtfrmrand <created variable> C1d13. Date of priapism as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	369.0	.	369.0	369.0	369.0	369.0	369.0

<created variable> C1d13. Date of priapism as days from RAND visit

priap_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

C1e13. Location seen at for priapism

SEENPRIA	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
1	1	0.14	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
14. **Transfusion reaction**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Complication of a transfusion within 2 weeks after the transfusion was given*

IF RESPONSE TO C1.14 IS YES, SUBMIT DELAYED TRANSFUSION REACTION FORM (FORM 32)

C1a14. Transfusion reaction

T_REACTN	Frequency	Percent	Cum Freq	Cum Percent
1	735	99.32	735	99.32
2	5	0.68	740	100.00

C1b14. Number of events:Transfusion reaction

REACTTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	5	0.68	740	100.00

C1c14. Number of events treated:Transfusion reaction

TREATREA	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	5	0.68	740	100.00

Analysis Variable : react_dtfrmrand <created variable> C1d14. Date of transfusion reaction as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
5	0	497.4	357.1	29.0	290.0	489.0	757.0	922.0

<created variable> C1d14. Date of transfusion reaction as days from RAND visit

react_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	735	100.00	735	100.00

C1e14. Location seen at for transfusion reaction

SEENREAC	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	4	0.54	739	99.86
2	1	0.14	740	100.00

C1. Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)
15. **Other***	☐	☐	☐	__ __/__ __ __ __	☐

C1a15. Other event				
OTH_EVNT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.27	2	0.27
1	621	83.92	623	84.19
2	117	15.81	740	100.00

C1b15. Number of events:Other				
OTH_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	623	84.19	623	84.19
1	77	10.41	700	94.59
2	29	3.92	729	98.51
3	8	1.08	737	99.59
6	1	0.14	738	99.73
7	1	0.14	739	99.86
12	1	0.14	740	100.00

C1c15. Number of events treated:Other				
TREATOTH	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	623	84.19	624	84.32
0	16	2.16	640	86.49
1	73	9.86	713	96.35
2	17	2.30	730	98.65
3	7	0.95	737	99.59
6	1	0.14	738	99.73
7	1	0.14	739	99.86
12	1	0.14	740	100.00

Analysis Variable : oth_evdtfrmrand <created variable> C1d15. Date of other event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
117	0	452.0	354.5	-76.0	124.0	402.0	703.0	1261.0

<created variable> C1d15. Date of other event as days from RAND visit				
oth_evdtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	623	100.00	623	100.00

C1e15. Location seen at for other				
SEENOTH	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.27	2	0.27
-2	623	84.19	625	84.46
-1	1	0.14	626	84.59
1	98	13.24	724	97.84
2	16	2.16	740	100.00

*(**PROBE**: Was the child seen for any Other clinical events? What events?)*

C1.a15.a. IF YES, Specify:

_____

_____

OFFICE USE

OFFICE USE

IF RESPONSE TO C1.a9 - C1.a13 OR C1.a15 IS YES, COMPLETE A NON-NEUROLOGICAL EVENT FORM (FORM 31) FOR EACH UNIQUE EVENT

o_recode1	oth_recodespc1	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	623	84.19	623	84.19
51.23	Cholecystectomy	1	0.14	624	84.32
51.23	Lap. cholecystectomy	1	0.14	625	84.46
99.29	Desferal infusion	2	0.27	627	84.73
99.29	Desferal injections	2	0.27	629	85.00
282.62	Pain crisis in ER	2	0.27	631	85.27
282.62	Pain crisis with fever	1	0.14	632	85.41
282.62	VOC -lower back pain	1	0.14	633	85.54
282.62	VOC R. ankle - not hosp.	1	0.14	634	85.68
282.62	pain crisis	1	0.14	635	85.81
282.62	pain crisis x2	1	0.14	636	85.95
574.2	Cholelithiasis	2	0.27	638	86.22
574.2	Gallstones	2	0.27	640	86.49
575.1	Cholecystitis	1	0.14	641	86.62
575.9	Gallstones RUQ pain	1	0.14	642	86.76
780.2	Syncope	1	0.14	643	86.89
780.7	INCREASED TIREDNESS/SLEEP	1	0.14	644	87.03
782	Tingling, Numbness	1	0.14	645	87.16
784	Headache	6	0.81	651	87.97
999.99	OTHER	89	12.03	740	100.00

o_recode2	oth_recodespc2	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	623	84.19	623	84.19
-1	-1	83	11.22	706	95.41
99.29	Desferal infusion	1	0.14	707	95.54
282.62	VOC w/o hospitalization	1	0.14	708	95.68
575.1	CHOLECYSTITIS	1	0.14	709	95.81
575.9	Gallstones RUQ pain	1	0.14	710	95.95
784	Headaches	1	0.14	711	96.08
999.99	OTHER	29	3.92	740	100.00

C2.a Procedure	USE CODES 1. NO 2. YES	C2.b Total # of unique procedures	C2.c # performed at your institution	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
1. **Transfusion**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Injection of blood into the bloodstream)*

IF RESPONSE TO C2.a1 IS YES, SUBMIT TRANSFUSION FORMS(FORMS 20 AND 21) FOR EACH TRANSFUSION GIVEN

C2a1. Transfusion				
TRANFUSN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-8	2	0.27	3	0.41
1	168	22.70	171	23.11
2	569	76.89	740	100.00

C2b1. Num of events:Transfusion				
TRAN_TTL	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.27	2	0.27
-2	171	23.11	173	23.38
1	72	9.73	245	33.11
2	119	16.08	364	49.19
3	189	25.54	553	74.73
4	102	13.78	655	88.51
5	53	7.16	708	95.68
6	21	2.84	729	98.51
7	4	0.54	733	99.05
8	5	0.68	738	99.73
9	1	0.14	739	99.86
12	1	0.14	740	100.00

C2c1. Num of events treated:Transfusion				
TRANPERF	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.27	2	0.27
-8	1	0.14	3	0.41
-2	171	23.11	174	23.51
0	11	1.49	185	25.00
1	71	9.59	256	34.59
2	111	15.00	367	49.59
3	191	25.81	558	75.41
4	98	13.24	656	88.65
5	53	7.16	709	95.81
6	20	2.70	729	98.51
7	4	0.54	733	99.05
8	5	0.68	738	99.73
9	1	0.14	739	99.86
12	1	0.14	740	100.00

C2.a Procedure	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
1. **Transfusion**	__ __/__ __ __ __	

Analysis Variable : transf_dfrmrand <created variable> C2d1. Date of: Transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
567	0	463.6	367.0	-144.0	150.0	421.0	755.0	1334.0

<created variable> C2d1. Date of: Transfusion as days from RAND visit				
transf_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	173	100.00	173	100.00

C2e1. Seen: Transfusion				
SEENTRAN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	171	23.11	172	23.24
1	552	74.59	724	97.84
2	16	2.16	740	100.00

C2.a Procedure	USE CODES 1. NO 2. YES	C2.b Total # of unique procedures	C2.c # performed at your institution	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
2. **Surgery***	☐	☐	☐	__ __/__ __ __ __	☐

C2a2. Surgery				
SURGERY	Frequency	Percent	Cum Freq	Cum Percent
1	672	90.81	672	90.81
2	68	9.19	740	100.00

C2b2. Num of events:Surgery				
SURG_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	672	90.81	672	90.81
1	57	7.70	729	98.51
2	11	1.49	740	100.00

C2c2. Num of events treated:Surgery				
SURGPERF	Frequency	Percent	Cum Freq	Cum Percent
-2	672	90.81	672	90.81
0	2	0.27	674	91.08
1	55	7.43	729	98.51
2	11	1.49	740	100.00

Analysis Variable : surg_dtfrmrand <created variable> C2d2. Date of: Surgery as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
68	0	463.5	322.7	-272.0	222.0	405.5	695.5	1261.0

<created variable> C2d2. Date of: Surgery as days from RAND visit				
surg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	672	100.00	672	100.00

C2e2. Seen: Surgery				
SEENSURG	Frequency	Percent	Cum Freq	Cum Percent
-2	672	90.81	672	90.81
1	65	8.78	737	99.59
2	3	0.41	740	100.00

*(**PROBE**: An operation or a medical Procedure requiring general anesthesia)*

C1.a16.a. IF YES, Specify:

_____

_____

OFFICE USE

OFFICE USE

surgrecode	surg_recodespc	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	672	90.81	672	90.81
38.93	CENTRAL LINE PLACEMENT	1	0.14	673	90.95
38.93	Fermoral line for exchang	1	0.14	674	91.08
38.93	MEDIPORT PLACEMENT	1	0.14	675	91.22
38.93	Port-a-cath insertion	7	0.95	682	92.16
50.11	Liver biopsy	33	4.46	715	96.62
51.04	gallbladder removal	2	0.27	717	96.89
51.22	Cholecystectomy	3	0.41	720	97.30
51.23	Cholecystectomy	2	0.27	722	97.57
51.23	Lap. cholecystectomy	5	0.68	727	98.24
97.89	Hickman line removal	1	0.14	728	98.38
97.89	Mediport removal	1	0.14	729	98.51
97.89	Port-a-cath removal	4	0.54	733	99.05
99.99	OTHER	7	0.95	740	100.00

surgrecode2	surg_recodesp2	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	672	90.81	672	90.81
-1	-1	56	7.57	728	98.38
38.93	Hickman placement	1	0.14	729	98.51
38.93	Port-a-cath insertion	3	0.41	732	98.92
50.11	Liver biopsy	3	0.41	735	99.32
51.23	Cholecystectomy	1	0.14	736	99.46
51.23	Lap. cholecystectomy	1	0.14	737	99.59
97.89	Port-a-cath removal	3	0.41	740	100.00

*** IF RESPONSE TO C2.a2 IS YES, COMPLETE A NON-NEUROLOGICAL EVENT FORM (FORM 31) FOR EACH UNIQUE EVENT**

NOTE: FOR VISITS AT A NON-STOP STUDY SITE, ASK PARENT TO SIGN A MEDICAL RECORD RELEASE FORM FOR EACH UNIQUE EVENT REMEMBER TO SUBMIT MEDICAL RECORD REVIEW FORM (FORM 16R)

D. NEUROLOGICAL SIGNS AND SYMPTOMS

D1. Since the last quarterly report (or entry interview if this is the first quarterly report) on ___ ___/___ ___/___ ___ ___ ___, has the patient complained of headaches?

Analysis Variable : qtrrpt2frmrand <created variable> D. Quarterly Report Date as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
739	0	394.7	363.5	-190.0	71.0	343.0	693.0	1253.0

<created variable> D. Quarterly Report Date as days from RAND visit

qtrrpt2frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

☐ **1. NO** ☐ **2. YES**

D1. Has the patient complained of headaches?

HEADACHE	Frequency	Percent	Cum Freq	Cum Percent
1	571	77.16	571	77.16
2	169	22.84	740	100.00

D1.a Is the frequency < 1 per month or ≥ 1 per month?

☐ 1. < 1 per month ☐ 2. ≥ 1 per month

D1.b How long has the patient had them? ☐☐☐ months

D1.c Describe location and type of pain

_____

_____

D1a. Is the frequency < 1 per month or >= 1 per month

HEADFREQ	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-2	571	77.16	572	77.30
1	44	5.95	616	83.24
2	124	16.76	740	100.00

Analysis Variable : HEAD_MTH D1b. How long has the patient had them								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
144	0	8.4	16.2	1.0	2.0	3.0	6.5	130.0

D1b. How long has the patient had them				
HEAD_MTH	Frequency	Percent	Cum Freq	Cum Percent
-9	9	1.51	9	1.51
-8	10	1.68	19	3.19
-3	1	0.17	20	3.36
-2	571	95.81	591	99.16
0	5	0.84	596	100.00

[Note: HEAD_LOC data not shown. Representative sample below.]

HEAD_LOC	Frequency	Percent
"whole head", sharp pain	1	0.14
at least 3-4 times per month	1	0.14
Bilateral temporal area - pounding. lasts ~2 hrs	1	0.14
Bitemporal non-radiating throbbing	1	0.14
Bitemporal, frontal throbbing non radiating	1	0.14
center of forehead; dull pain	1	0.14
front and sides, sharp pain last a few minutes	1	0.14
frontal	1	0.14
Frontal + temporal - usually in AM till noon	1	0.14
Frontal pain, dull pain. HA with sinus + car sickn	1	0.14
generalized headaches ~2 day before transfusion	1	0.14
HA was R sided pounding woke him from sleep 1 time	1	0.14
left side of head	1	0.14
Loc. unspecified. Throb. pain.No aura/sight issues	1	0.14
mild-sharp, frontal H/A - relief with Ibuprofen	1	0.14
Mostly around front and sides of head	1	0.14
patient can't recall	1	0.14
R side around ear	1	0.14
right side pounding	1	0.14
sharp pain, side	1	0.14
sides, shooting and dull pain	1	0.14
SUBJECT HAS A HA TODAY. RELIEVES W/IBROFEN &LIQUID	1	0.14
Temporal, pounding	1	0.14
top & middle of head; dull-lasted a few days	1	0.14
Varies, frontal and temporal	1	0.14

D2. Since the last report, has (s)he experienced loss of consciousness?

☐ 1. NO ☐ 2. YES

D2. Has (s)he experienced loss of consciousness				
LOSSCONS	Frequency	Percent	Cum Freq	Cum Percent
1	738	99.73	738	99.73
2	2	0.27	740	100.00

↓

D2.a Number of episodes ☐☐

D2.b Date of most recent episode (month/day/year) ___ ___/___ ___/___ ___ ___ ___

D2a. Number of episodes: Lost consciousness				
LOSSEPIS	Frequency	Percent	Cum Freq	Cum Percent
-2	738	99.73	738	99.73
1	2	0.27	740	100.00

Analysis Variable : loss_dtfrmrand <created variable> D2b. Date of most recent episode: Lost consciousness as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	382.0	291.3	176.0	176.0	382.0	588.0	588.0

<created variable> D2b. Date of most recent episode: Lost consciousness as days from RAND visit				
loss_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	738	100.00	738	100.00

D3. Since the last report, has (s)he experienced any episodes of dizziness?

☐ 1. NO ☐ 2. YES

D3. Dizziness				
DIZZINESS	Frequency	Percent	Cum Freq	Cum Percent
1	706	95.41	706	95.41
2	34	4.59	740	100.00

↓

D3.a Number of episodes ☐☐

D3.b Date of most recent episode (month/day/year) ___ ___/___ ___/___ ___ ___ ___

D3a. Number of episodes: Dizziness				
DIZZY_EP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
-8	1	0.14	2	0.27
-2	706	95.41	708	95.68
1	13	1.76	721	97.43
2	12	1.62	733	99.05
3	4	0.54	737	99.59
4	2	0.27	739	99.86
5	1	0.14	740	100.00

Analysis Variable : dizzy_dtfrmrand <created variable> D3b. Date of most recent episode: Dizziness as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
24	0	484.2	372.6	-8.0	147.0	439.0	838.0	1168.0

<created variable> D3b. Date of most recent episode: Dizziness as days from RAND visit				
dizzy_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	716	100.00	716	100.00

D4. Since the last report, has (s)he experienced the following vision difficulties:

D4.a Double vision? ☐ **1. NO** ☐ **2. YES**

D4a. Double vision				
D_VISION	Frequency	Percent	Cum Freq	Cum Percent
1	738	99.73	738	99.73
2	2	0.27	740	100.00

D4.b Loss of vision or blind spots? ☐ **1. NO** ☐ **2. YES**

D4b. Loss of vision or blind spots				
VISION_L	Frequency	Percent	Cum Freq	Cum Percent
1	736	99.46	736	99.46
2	4	0.54	740	100.00

D5. Since the last report, has the child had any unusual or involuntary movements of the face, arms, or legs? ☐ 1. NO ☐ 2. YES

D5. Involuntary movements				
INVOLMOV	Frequency	Percent	Cum Freq	Cum Percent
1	735	99.32	735	99.32
2	5	0.68	740	100.00

D5.a Describe type of movements and duration of episode(s)

D5a. Describe type of movements				
MOVE_SPC	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
Hands twitch and then start hurting. See Field Com	1	0.14	736	99.46
Pt. was unable to open door or write a sentence	1	0.14	737	99.59
VERY BRIEF QUICK JERK OF A FOOT WHEN RELAXED	1	0.14	738	99.73
has occasional twitching of right leg only. See FC	1	0.14	739	99.86
myoclonic jerks of left leg occured x1.	1	0.14	740	100.00

D5.b Where did patient exhibit these movements?

(CHECK NO OR YES BOX FOR EACH OF D5.b1 - D5.b6) **1. NO** **2. YES** Date of most recent episode (month/year)

1. Left arm ☐ ☐ → 1.a __ __/__ __ __ __

D5b1. Left arm				
MOVELARM	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	4	0.54	739	99.86
2	1	0.14	740	100.00

Analysis Variable : mlarm_dtfrmrand <created variable> D5b1a. Date: Left arm as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-82.0	.	-82.0	-82.0	-82.0	-82.0	-82.0

<created variable> D5b1a. Date: Left arm as days from RAND visit				
mlarm_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

D5.b Where did patient exhibit these movements?

(CHECK NO OR YES BOX FOR EACH OF D5.b1 - D5.b6) **1. NO** **2. YES** Date of most recent episode (month/year)

2. Right arm ☐ ☐→ 2.a __ __/__ __ __ __

D5b2. Right arm				
MOVERARM	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	3	0.41	738	99.73
2	2	0.27	740	100.00

Analysis Variable : mrarm_dtfrmrand <created variable> D5b2a. Date: Right arm as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	27.5	154.9	-82.0	-82.0	27.5	137.0	137.0

<created variable> D5b2a. Date: Right arm as days from RAND visit				
mrarm_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	738	100.00	738	100.00

3. Left leg ☐ ☐→ 3.a __ __/__ __ __ __

D5b3. Left leg				
MOVELLEG	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	2	0.27	737	99.59
2	3	0.41	740	100.00

Analysis Variable : mlleg_dtfrmrand <created variable> D5b3a. Date: Left leg as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-82.0	.	-82.0	-82.0	-82.0	-82.0	-82.0

<created variable> D5b3a. Date: Left leg as days from RAND visit				
mlleg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

D5.b Where did patient exhibit these movements?

(CHECK NO OR YES BOX FOR EACH OF D5.b1 - D5.b6) **1. NO** **2. YES** Date of most recent episode (month/year)

4. Right leg ☐ ☐ → 4.a __ __/__ __ __ __

D5b4. Right leg				
MOVERLEG	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	2	0.27	737	99.59
2	3	0.41	740	100.00

Analysis Variable : mrleg_dtfrmrand <created variable> D5b4a. Date: Right leg as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	301.0	541.6	-82.0	-82.0	301.0	684.0	684.0

<created variable> D5b4a. Date: Right leg as days from RAND visit				
mrleg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	738	100.00	738	100.00

5. Left face ☐ ☐ → 5.a __ __/__ __ __ __

D5b5. Left face				
MOVLFACE	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	5	0.68	740	100.00

[Variable NOT included in dataset for date.]

6. Right face ☐ ☐ → 6.a __ __/__ __ __ __

D5b6. Right face				
MOVRFACE	Frequency	Percent	Cum Freq	Cum Percent
-2	735	99.32	735	99.32
1	5	0.68	740	100.00

[Variable NOT included in dataset for date.]

D6. Since the last report, has the patient had any episode of numbness and/or tingling in his arms, legs, or face which lasted for at least an hour?

☐ **1. NO** ☐ **2. YES**

D6. Numbness				
NUMBNESS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
1	729	98.51	730	98.65
2	10	1.35	740	100.00

↓

D6.a Location(s) of numbness or tingling

(CHECK NO OR YES BOX FOR EACH OF D6.a1 - D6.a6) **1. NO** **2. YES** Date of most recent episode (month/year)

1. Left arm ☐ ☐ → 1.a __ __/__ __ __ __

D6a1. Numb: Left arm				
NUMBLARM	Frequency	Percent	Cum Freq	Cum Percent
-2	730	98.65	730	98.65
1	4	0.54	734	99.19
2	6	0.81	740	100.00

Analysis Variable : nlarm_dtfrmrand <created variable> D6a1a. Date: Numb: left arm as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6	0	133.7	353.5	-149.0	-149.0	34.0	309.0	723.0

<created variable> D6a1a. Date: Numb: left arm as days from RAND visit				
nlarm_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	734	100.00	734	100.00

(CHECK NO OR YES BOX FOR EACH OF D6.a1 - D6.a6) **1. NO** **2. YES** Date of most recent episode (month/year)

2. Right arm ☐ ☐→ 2.a __ __/__ __ __ __

D6a2. Numb: Right arm				
NUMBRARM	Frequency	Percent	Cum Freq	Cum Percent
-2	730	98.65	730	98.65
1	9	1.22	739	99.86
2	1	0.14	740	100.00

Analysis Variable : nrarm_dtfrmrand <created variable> D6a2a. Date: Numb: right arm as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	977.0	.	977.0	977.0	977.0	977.0	977.0

<created variable> D6a2a. Date: Numb: right arm as days from RAND visit				
nrarm_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

3. Left leg ☐ ☐→ 3.a __ __/__ __ __ __

D6a3. Numb: Left leg				
NUMBLLEG	Frequency	Percent	Cum Freq	Cum Percent
-2	730	98.65	730	98.65
1	7	0.95	737	99.59
2	3	0.41	740	100.00

Analysis Variable : nlleg_dtfrmrand <created variable> D6a3a. Date: Numb: Left leg as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	352.3	554.6	-82.0	-82.0	162.0	977.0	977.0

<created variable> D6a3a. Date: Numb: Left leg as days from RAND visit				
nlleg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	737	100.00	737	100.00

(CHECK NO OR YES BOX FOR EACH OF D6.a1 - D6.a6) **1. NO** **2. YES** Date of most recent episode (month/year)

4. Right leg ☐ ☐→ 4.a __ __/__ __ __ __

D6a4. Numb: Right leg				
NUMBRLEG	Frequency	Percent	Cum Freq	Cum Percent
-2	730	98.65	730	98.65
1	8	1.08	738	99.73
2	2	0.27	740	100.00

Analysis Variable : nrleg_dtfrmrand <created variable> D6a4a. Date: Numb: Right leg as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	40.0	172.5	-82.0	-82.0	40.0	162.0	162.0

<created variable> D6a4a. Date: Numb: Right leg as days from RAND visit				
nrleg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	738	100.00	738	100.00

5. Left face ☐ ☐→ 5.a __ __/__ __ __ __

D6a5. Numb: Left face				
NUMLFACE	Frequency	Percent	Cum Freq	Cum Percent
-2	730	98.65	730	98.65
1	9	1.22	739	99.86
2	1	0.14	740	100.00

Analysis Variable : nlface_dfrmrand <created variable> D6a5a. Date: Numb: left face as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	1064.0	.	1064.0	1064.0	1064.0	1064.0	1064.0

<created variable> D6a5a. Date: Numb: left face as days from RAND visit				
nlface_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

(CHECK NO OR YES BOX FOR EACH OF D6.a1 - D6.a6)	1. NO	2. YES	Date of most recent episode (month/year)
6. Right face	☐	☐ → 6.a	__ __/__ __ __ __

D6a6. Numb:Right face				
NUMRFACE	Frequency	Percent	Cum Freq	Cum Percent
-2	730	98.65	730	98.65
1	10	1.35	740	100.00

[Variable NOT included in dataset for date.]

D7. Since the last report, has the patient had any episodes of weakness in his arms, legs or face?

☐ **1. NO** ☐ **2. YES**

D7. Weakness				
WEAKNESS	Frequency	Percent	Cum Freq	Cum Percent
1	725	97.97	725	97.97
2	15	2.03	740	100.00

↓

D7.a Location(s) of weakness (CHECK NO OR YES BOX FOR EACH OF D7.a1 - D7.a6)	1. NO	2. YES	Date of most recent episode (month/year)
1. Left arm	☐	☐ → 1.a	__ __/__ __ __ __

D7a1. Weak: Left arm				
WEAKLARM	Frequency	Percent	Cum Freq	Cum Percent
-2	725	97.97	725	97.97
1	5	0.68	730	98.65
2	10	1.35	740	100.00

Analysis Variable : wlarm_dtfrmrand <created variable> D7a1a. Date: Weak: Left arm as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
10	0	513.2	350.7	125.0	217.0	410.5	769.0	1104.0

<created variable> D7a1a. Date: Weak: Left arm as days from RAND visit				
wlarm_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	730	100.00	730	100.00

2. Right arm	☐	☐ → 2.a	__ __/__ __ __ __

D7a2. Weak: Right arm				
WEAKRARM	Frequency	Percent	Cum Freq	Cum Percent
-2	725	97.97	725	97.97
1	12	1.62	737	99.59
2	3	0.41	740	100.00

Analysis Variable : wrarm_dtfrmrand <created variable> D7a2a. Date: Weak: Right arm as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	265.7	213.4	137.0	137.0	148.0	512.0	512.0

<created variable> D7a2a. Date: Weak: Right arm as days from RAND visit				
wrarm_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	737	100.00	737	100.00

D7.a Location(s) of weakness (CHECK NO OR YES BOX FOR EACH OF D7.a1 - D7.a6)	1. NO	2. YES	Date of most recent episode (month/year)
3. Left leg	☐	☐ → 3.a	__ __/__ __ __ __

D7a3. Weak: Left leg				
WEAKLLEG	Frequency	Percent	Cum Freq	Cum Percent
-2	725	97.97	725	97.97
1	11	1.49	736	99.46
2	4	0.54	740	100.00

Analysis Variable : wlleg_dtfrmrand <created variable> D7a3a. Date: Weak: Left leg as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	322.3	296.5	-113.0	134.0	445.0	510.5	512.0

<created variable> D7a3a. Date: Weak: Left leg as days from RAND visit				
wlleg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	736	100.00	736	100.00

4. Right leg	☐	☐ → 4.a	__ __/__ __ __ __

D7a4. Weak: Right leg				
WEAKRLEG	Frequency	Percent	Cum Freq	Cum Percent
-2	725	97.97	725	97.97
1	10	1.35	735	99.32
2	5	0.68	740	100.00

Analysis Variable : wrleg_dtfrmrand <created variable> D7a4a. Date: Weak: Right leg as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
5	0	346.4	262.4	-113.0	381.0	443.0	509.0	512.0

<created variable> D7a4a. Date: Weak: Right leg as days from RAND visit				
wrleg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	735	100.00	735	100.00

(CHECK NO OR YES BOX FOR EACH OF D7.a1 - D7.a6)	1. NO	2. YES	Date of most recent episode (month/year)
5. Left face	☐	☐ → 5.a	__ __/__ __ __ __

D7a5. Weak: Left face				
WEAKLFACE	Frequency	Percent	Cum Freq	Cum Percent
-2	725	97.97	725	97.97
1	15	2.03	740	100.00

[Variable NOT included in dataset for date.]

6. Right face	☐	☐ → 6.a	__ __/__ __ __ __

D7a6. Weak: Right face				
WEAKRFACE	Frequency	Percent	Cum Freq	Cum Percent
-2	725	97.97	725	97.97
1	15	2.03	740	100.00

[Variable NOT included in dataset for date.]

D8. Since the last report, has the patient changed the hand (s)he uses to feed herself/himself?
*(**Probe:** Did the child use one hand to feed himself/herself previously and now uses the other one?)*

☐ **1. NO** ☐ **2. YES**

D8. Hand change				
HANDCHNG	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

↓

D8.a Which hand does (s)he now use to feed herself/himself?

☐ **1. RIGHT** ☐ **2. LEFT**

D8a. Hand change: Which hand				
WHCHHAND	Frequency	Percent	Cum Freq	Cum Percent
-2	740	100.00	740	100.00

D9. Since the last report, has the patient had any unexpected difficulty talking or understanding what was said to him/her?

☐ **1. NO** ☐ **2. YES**

D9. Any difficulty talking or understanding what was said				
DIFFUNDR	Frequency	Percent	Cum Freq	Cum Percent
1	737	99.59	737	99.59
2	3	0.41	740	100.00

↓

D9.a What type of difficulty?

(CHECK NO OR YES BOX FOR EACH OF D9.a1 - D9.a3) **1. NO** **2. YES** Date of most recent episode (month/year)

1. Slurring of words ☐ ☐→ 1.a __ __/__ __ __ __

D9a1. Slurring				
SLURRING	Frequency	Percent	Cum Freq	Cum Percent
-2	737	99.59	737	99.59
1	1	0.14	738	99.73
2	2	0.27	740	100.00

Analysis Variable : slur_dtfrmrand <created variable> D9a1a. Date: Slurring as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	574.0	.	574.0	574.0	574.0	574.0	574.0

<created variable> D9a1a. Date: Slurring as days from RAND visit				
slur_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	739	100.00	739	100.00

2. Difficulty understanding what was said to him/her ☐ ☐→ 2.a __ __/__ __ __ __

D9a2. Difficulty understanding				
DIF_UNDS	Frequency	Percent	Cum Freq	Cum Percent
-2	737	99.59	737	99.59
1	2	0.27	739	99.86
2	1	0.14	740	100.00

[Variable NOT included in dataset for date.]

D9.a What type of difficulty? (CHECK NO OR YES BOX FOR EACH OF D9.a1 - D9.a3)	1. NO	2. YES	Date of most recent episode (month/year)
3. Problems expressing himself/herself	☐	☐ →	3.a __ __/__ __ __ __

D9a3. Expressing				
EXPRESS	Frequency	Percent	Cum Freq	Cum Percent
-2	737	99.59	737	99.59
1	2	0.27	739	99.86
2	1	0.14	740	100.00

[Variable NOT included in dataset for date.]

D10. Since the last report, has the patient become unable to perform a muscle or language function that (s)he was able to do before?

☐ **1. NO** ☐ **2. YES →** D10.a Explain _____

_____

_____

D10. Unable to perform a muscle or language function				
LANGFUNC	Frequency	Percent	Cum Freq	Cum Percent
1	739	99.86	739	99.86
2	1	0.14	740	100.00

D10a. Language function: Specify				
LANG_SPC	Frequency	Percent	Cum Freq	Cum Percent
-2	739	99.86	739	99.86
very weak in L. hand. Could not open things ..cont	1	0.14	740	100.00

NOTE: THE PERSON CONDUCTING THE INTERVIEW MUST COMPARE THE RESPONSES TO QUESTIONS IN SECTION D TO RESPONSES GIVEN TO THESE QUESTIONS AT THE PREVIOUS QUARTERLY VISIT BEFORE THE PATIENT IS SEEN BY THE STOP II INVESTIGATOR - SEE SECTION H

E. OTHER MEDICAL CONDITIONS

(QUESTIONS IN SECTIONS E – H TO BE COMPLETED BY MEDICAL PERSONNEL

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E1. Leg ulcers ☐ ☐

E1. Leg ulcers				
LULCERS	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

E2. Aseptic necrosis ☐ ☐

2.b If Yes, specify location(s) _____

E2. Aseptic necrosis				
A_NECROS	Frequency	Percent	Cum Freq	Cum Percent
1	738	99.73	738	99.73
2	2	0.27	740	100.00

E2b. Aseptic necrosis, specify				
NECROSPC	Frequency	Percent	Cum Freq	Cum Percent
-2	738	99.73	738	99.73
R. hip	1	0.14	739	99.86
shoulder	1	0.14	740	100.00

E3. Sickle cell retinopathy ☐ ☐

E3. Sickle cell retinopathy				
SC_RETIN	Frequency	Percent	Cum Freq	Cum Percent
1	739	99.86	739	99.86
2	1	0.14	740	100.00

E4. Chronic lung disease ☐ ☐

4.b If Yes, specify type _____

E4. Chronic lung disease				
CHR_LUNG	Frequency	Percent	Cum Freq	Cum Percent
1	739	99.86	739	99.86
2	1	0.14	740	100.00

[Variable NOT included in dataset for specify field.]

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E5. Asthma ☐ ☐

E5. Asthma				
ASTHMA	Frequency	Percent	Cum Freq	Cum Percent
1	728	98.38	728	98.38
2	12	1.62	740	100.00

E6. Chronic heart disease ☐ ☐

6.b If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E6. Chronic heart disease				
CHD	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for specify or code fields.]

E7. Chronic liver disease ☐ ☐

7.b If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E7. Chronic liver disease				
CHRLIVER	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for specify or code fields.]

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E8. Chronic renal disease ☐ ☐

8.b If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E8. Chronic renal disease				
CHRRENAL	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for specify or code fields.]

8.c If Yes, is patient receiving dialysis? ☐ **1. NO** ☐ **2. YES**

[Variable NOT included in dataset.]

E9. Iron overload ☐ ☐

9.b If yes, highest ferritin level (ng/ml) ☐☐☐☐☐

E9. Iron overload				
IRONOVER	Frequency	Percent	Cum Freq	Cum Percent
1	617	83.38	617	83.38
2	123	16.62	740	100.00

Analysis Variable : FERRITIN E9b. Ferritin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
121	0	4279.5	2790.0	714.0	2414.0	3694.0	5884.0	23000

E9b. Ferritin				
FERRITIN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.16	1	0.16
-3	1	0.16	2	0.32
-2	617	99.68	619	100.00

E10. Diabetes ☐ ☐

E10. Diabetes				
DIABETES	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E11. Rheumatic fever ☐ ☐

E11. Rheumatc fever				
RHEUMATC	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

E12. Tuberculosis ☐ ☐

E12. Tuberculosis				
TUBERCUL	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

E13. Cancer ☐ ☐

13b. If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E13. Cancer				
CANCER	Frequency	Percent	Cum Freq	Cum Percent
1	740	100.00	740	100.00

[Variables NOT included in dataset for specify or code fields.]

E14. Priapism ☐ ☐

E14. Priapism				
PRIAP	Frequency	Percent	Cum Freq	Cum Percent
-1	402	54.32	402	54.32
1	338	45.68	740	100.00

E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?) ☐ ☐

E15. Elevated blood lead level				
ELEV_BLD	Frequency	Percent	Cum Freq	Cum Percent
-3	11	1.49	11	1.49
1	729	98.51	740	100.00

Since the last quarterly report was the patient **newly** diagnosed with:

	1. NO	2. YES
E16. New red cell antibody	☐	☐

↓

E16.a. SPECIFY:
a1. _____
a2. _____
a3. _____
a4. _____

E16.b. Date first identified: __ __/__ __/__ __ __ __

IF RESPONSE TO E16 IS YES, ATTACH COPIES OF RESULTS OF INDIRECT (ANTIBODY SCREEN) AND DIRECT ANTIGLOBULIN TESTS AND BLOOD BANK PANEL SHEETS DOCUMENTING IDENTIFICATION OF ANTIBODY (IES) IF NOT SUBMITTED PREVIOUSLY WITH A FORM 20.

E16. New red cell antibody				
RBCANTI	Frequency	Percent	Cum Freq	Cum Percent
1	737	99.59	737	99.59
2	3	0.41	740	100.00

[Variables NOT included in dataset for specify fields.]

Analysis Variable : rbcant_dfrmrand <created variable> E16b. Date first identified as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	648.3	550.4	117.0	117.0	612.0	1216.0	1216.0

<created variable> E16b. Date first identified as days from RAND visit				
rbcant_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	737	100.00	737	100.00

E17. Any other chronic medical condition? ☐ ☐

17.a. If Yes, specify type: a1. _____
a2. _____

☐☐☐.☐☐ **OFFICE USE**

☐☐☐.☐☐ **OFFICE USE**

E17. Other condition				
OTHCOND	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
1	715	96.62	716	96.76
2	24	3.24	740	100.00

[Variables NOT included in dataset for specify or code fields.]

F. VACCINATIONS

F1. Since the last quarterly report, has the patient received Hepatitis B vaccination?

☐ 1. NO ☐ 2. YES

F1. HepB Vaccination				
HEPBVACC	Frequency	Percent	Cum Freq	Cum Percent
1	731	98.78	731	98.78
2	9	1.22	740	100.00

↓

F1.a Date of vaccination (Month/Day/Year)

___ ___/___ ___/___ ___ ___ ___

Analysis Variable : vacc_dtfrmrand <created variable> F1a. Vaccination date as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	457.7	724.6	-331.0	-331.0	610.0	1094.0	1094.0

<created variable> F1a. Vaccination date as days from RAND visit				
vacc_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	737	100.00	737	100.00

G. GENERAL

G1. Is the patient seen for most of his/her clinical events at a NON-STOP II study site because of third party payment restrictions, distance from clinic, some other reason? ☐ 1. NO ☐ 2. YES

G1. Is patient seen at non-STOP II sites				
NON_STOP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.14	1	0.14
1	718	97.03	719	97.16
2	21	2.84	740	100.00

H. DETERMINATION OF INTERVAL CHANGE IN PATIENT'S NEUROLOGICAL SYMPTOMS

IN ORDER TO COMPLETE THIS SECTION, RESPONSES TO QUESTIONS D2, D5, D6, D7, D8, D9, AND D10 OF THIS REPORT MUST BE COMPARED TO RESPONSES TO THESE SAME QUESTIONS IN THE PREVIOUS REPORT

H1. Since the last report were any new neurological symptoms reported? . ☐ **1. NO** ☐ **2. YES**

H1. Any new neurological				
NEWNEURO	Frequency	Percent	Cum Freq	Cum Percent
1	720	97.30	720	97.30
2	20	2.70	740	100.00

↓

REVIEW RESULTS WITH STOP II INVESTIGATOR

H1.a Did the STOP II Investigator review results of both reports? ☐ **1. NO** → H1a.1 Reason _____

☐ **2. YES**

↓

H1a. Did STOPII Investigators review results of both reports?				
INV_REV	Frequency	Percent	Cum Freq	Cum Percent
-2	720	97.30	720	97.30
2	20	2.70	740	100.00

[Variable NOT included in dataset for specify field.]

H1.a2. Did the STOP II Investigator determine that the patient has developed significant new neurological symptoms since the last report?

☐ **1. NO** → H1.a2.a Explain _____

☐ **2. YES**

H1a2. Patient has deveoped significant new neurological symptoms				
SIGNEURO	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.14	1	0.14
-2	720	97.30	721	97.43
1	10	1.35	731	98.78
2	9	1.22	740	100.00

[Variable NOT included in dataset for specify field.]

↓

H1.a2.b Were these "new" symptoms reported on a STOPII Neurological Event Form which was submitted for adjudication since the last quarterly report?

☐ **1. NO →** **COMPLETE AND SUBMIT NEUROLOGICAL EVENT FORM (FORM 30), NEUROLOGICAL CONSULTANT REPORT (FORM 14), MRI AND MRA FORMS (FORM 15 AND 19), SCANS AND REPORTS FOR ALL IMAGING TESTS PERFORMED**

☐ **2. YES →** H1.a2c Date of neurological event recorded on Neurological Event Form (month/day/year) ___ ___/___ ___/___ ___ ___ ___

H1a2b. Were new symptoms reported on a STOP II Event Form				
NEWREPRT	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.14	1	0.14
-2	730	98.65	731	98.78
1	2	0.27	733	99.05
2	7	0.95	740	100.00

[Variable NOT included in dataset for date.]

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___

I. FOR OFFICE USE

I1.a IAT/DAT Reports Received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA**

[Variable NOT included in dataset.]

I1.b Blood Bank Panel Sheets Received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA**

[Variable NOT included in dataset.]

STOP II

FORM 16B: QUARTERLY PROGRESS REPORT FOR NON-RANDOMIZED PATIENTS RECEIVING TRANSFUSIONS

A. Collection Information:
The **Quarterly Progress Report for Non-Randomized Patients Receiving Transfusions** (Form 16B) was to be completed at post-enrollment quarterly visits for Potential Patients.

B. Data Collection Period: December 2000 through November 10, 2004

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p16b_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 344 (79)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 385-388
- Listing of Variables by Position: See pp. 389-391

H. Formats:
The file **f16Bfmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + “F” – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are “$”+variable name+”F” – e.g., the format label for a variable named “RATING” where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 392-396.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The only valid EX_TYPE for Form 16B is QT.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 16B are:
  For EX_TYPE=QT,
  - 200 & 300 series numbers indicate visits that were completed prior to randomization.
    - 200 series numbers were assigned to “Potential 1” visits – i.e., quarterly visits completed while the patient was on transfusion for < 30 months
    - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months
  - Baseline medical history data was collected on Form 11 at the entry visit for Potential patients (QT-201 or QT-301) rather than form 16B.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **O_MED_SP, O_MD2_SP** - are the variable names for other medication. Where more than one medication is listed on a line that were taken for a different number of months as listed for O_MED_MT or O_MD2_MT, the medication taken for a shorter time was listed second and months taken were annotated as (#) after the medication name.

- **SPLENICS** - is the variable name for splenic sequestration events. Cases where this variable is coded "-1:Not Applicable" refer to patients who have had a splenectomy. This code was not standardized for this variable and does not capture all patients or all records for patients who had a splenectomy.

- **PRIAPISM, PRIAP** - are the variable names for priapism events. Cases where these variables are coded "-1:Not Applicable" refer to patients who are female. This code was not standardized for these variables and does not capture all patients or all records for patients who are female.

- **O_RECODE1, O_RECODE2** - are the variable names for ICD-9 codes for other clinical events as indicated in the preceding specify fields (OTH_RECODESPC1, OTH_RECODESPC2 respectively). These variables require the ICD-9 Codebook Diseases section for interpretation. Code boxes are labeled "Office Use" on the form. Specific codes and associated diagnosis text are included for only those events that are frequently associated with sickle cell disease or treatment with transfusion. Other disease codes were recoded as 999.99 (OTHER). In a few cases, procedure/procedure code values were entered for these variables. The text “<recoded>” in the labels for this set of variables indicates that recoding of some of the original values has occurred.

- **SURGRECODE, SURGRECODE2** - are the variable names for ICD-9 codes for surgeries as indicated in the preceding specify fields (SURGRECODESPC, SURGRECODESP2 respectively). These variables require the ICD-9 Codebook Procedures section for interpretation. Code boxes are labeled "Office Use" on the form. Specific codes and associated procedure text are included for only those procedures that are frequently associated with sickle cell disease or treatment with transfusion. Other procedure codes were recoded as 99.99 (OTHER). The text “<recoded>” in the labels for this set of variables indicates that recoding of some of the original values has occurred.

Data Set Name	PUBDS.P16B_FINAL	Observations	344
Member Type	DATA	Variables	124
Engine	V9	Indexes	0
Created	Thursday, March 09, 2006 01:42:37 PM	Observation Length	1232
Last Modified	Thursday, March 09, 2006 01:42:37 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	28
First Data Page	2
Max Obs per Page	13
Obs in First Data Page	12
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p16b_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
6	ANYMEDS	Num	8	3.	B1. Patient taking any medications
31	APLASTIC	Num	8	3.	C1a6. Aplastic Crisis
32	APLASTTL	Num	8	3.	C1b6. Number of events:aplastic
80	ASTHMA	Num	8	3.	E5. Asthma
76	A_NECROS	Num	8	3.	E2. Aseptic necrosis
5	A_T_VERI	Num	8	3.	A4. Address and telephone info verified
89	CANCER	Num	8	3.	E13. Cancer
81	CHD	Num	8	3.	E6. Chronic heart disease
82	CHRLIVER	Num	8	3.	E7. Chronic liver disease
83	CHRRENAL	Num	8	3.	E8. Chronic renal disease
79	CHR_LUNG	Num	8	3.	E4. Chronic lung disease
100	DESTATUS	Char	1	$1.	DESTATUS
86	DIABETES	Num	8	3.	E10. Diabetes
91	ELEV_BLD	Num	8	3.	E15. Elevated blood lead level
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
85	FERRITIN	Num	8	6.	E9b. Ferritin
40	FEVER	Num	8	3.	C1a9. Fever
41	FEVERTTL	Num	8	3.	C1b9. Number of events:Fever
12	FOLATE	Num	8	3.	B1a3. Folate
13	FOLAT_MT	Num	8	4.	B1b3. Months taking: Folate
99	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
26	HEADINJR	Num	8	3.	C1a4. Head injury
97	HEPBVACC	Num	8	3.	F1. HepB Vaccination
14	HYDROXYU	Num	8	3.	B1a4. Hydroxyurea
15	HYDRX_MT	Num	8	4.	B1b4. Months taking: Hydroxyurea

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
35	H_F_SYND	Num	8	3.	C1a7. Hand-Foot Syndrome
3	INT_TYPE	Num	8	3.	A3. Person interviewed
16	IRONCHEL	Num	8	3.	B1a5. Iron Chelators
84	IRONOVER	Num	8	3.	E9. Iron overload
17	IRON_MTH	Num	8	4.	B1b5. Months taking: Iron chelators
75	LULCERS	Num	8	3.	E1. Leg ulcers
25	MENINGIT	Num	8	3.	C1a3. Meningitis
77	NECROSPC	Char	25	$25.	E2b. Aseptic necrosis, specify
74	NEWNEURO	Num	8	3.	D1. Neurological signs and symptoms
98	NON_STOP	Num	8	3.	G1. Is patient seen at non-STOP II sites
52	OSTEOMYL	Num	8	3.	C1a12. Osteomyelitis
11	OTHANTMT	Num	8	4.	B1b2. Months taking: Other
96	OTHCOND	Num	8	3.	E17. Other condition
9	OTH_ANTI	Num	8	3.	B1a2. Other antibiotic
61	OTH_EVNT	Num	8	3.	C1a15. Other event
18	OTH_MED	Num	8	3.	B1a6. Other medication(s)
62	OTH_TTL	Num	8	3.	C1b15. Number of events:Other
10	O_ANT_SP	Char	25	$25.	B1a2a. Other antibiotic, specify
22	O_MD2_MT	Num	8	4.	B1b6b. Months taking: Other 2
21	O_MD2_SP	Char	25	$25.	B1a6b. Other medication 2, specify
20	O_MED_MT	Num	8	4.	B1b6a. Months taking: Other 1
19	O_MED_SP	Char	25	$25.	B1a6a. Other medication, specify
7	PENCILLN	Num	8	3.	B1a1. Pencillin
8	PEN_MTHS	Num	8	4.	B1b1. Months taking: Pencillin
48	PNEUMONI	Num	8	3.	C1a11. Pneumonia/Acute Chest Syndrome
49	PNEUMTTL	Num	8	3.	C1b11. Number of events: pneumonia/ACS
73	PORTACTH	Num	8	3.	C3. Does patient have a portacath
90	PRIAP	Num	8	3.	E14. Priapism
53	PRIAPISM	Num	8	3.	C1a13. Priapism
54	PRIAPTTL	Num	8	3.	C1b13. Number of events:Priapism
92	RBCANTI	Num	8	3.	E16. New red cell antibody
93	RBC_SPC1	Char	25	$25.	E16a1. New red cell antibody,specify
94	RBC_SPC2	Char	25	$25.	E16a2. New red cell antibody 2,specify
95	RBC_SPC3	Char	25	$25.	E16a3. New red cell antibody 3,specify
58	REACTTTL	Num	8	3.	C1b14. Number of events:Transfusion reaction
87	RHEUMATC	Num	8	3.	E11. Rheumatc fever
78	SC_RETIN	Num	8	3.	E3. Sickle cell retinopathy
34	SEENAPLS	Num	8	3.	C1e6. Location seen at for aplastic
43	SEENFEVR	Num	8	3.	C1e9. Location seen at for fever
64	SEENOTH	Num	8	3.	C1e15. Location seen at for other
51	SEENPNEU	Num	8	3.	C1e11. Location seen at for pneumonia/ACS
56	SEENPRIA	Num	8	3.	C1e13. Location seen at for priapism
60	SEENREAC	Num	8	3.	C1e14. Location seen at for transfusion reaction
47	SEENSEPT	Num	8	3.	C1e10. Location seen at for septicemia
30	SEENSPLN	Num	8	3.	C1e5. Location seen at for splenic
72	SEENSURG	Num	8	3.	C2e2. Seen: Surgery
68	SEENTRAN	Num	8	3.	C2e1. Seen: Transfusion
39	SEENVASO	Num	8	3.	C1e8. Location seen at for vaso-occlusive pain
24	SEIZURES	Num	8	3.	C1a2. Seizures
44	SEPTICEM	Num	8	3.	C1a10. Septicemia
45	SEPT_TTL	Num	8	3.	C1b10. Number of events:Septicemia

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
27	SPLENICS	Num	8	3.	C1a5. Splenic sequestration
28	SPLENTTL	Num	8	3.	C1b5. Number of events:splenic
4	SP_INT	Char	75	$75.	<recoded> A3a. Person interviewed, specify
23	STROKE	Num	8	3.	C1a1. Stroke/TIA
69	SURGERY	Num	8	3.	C2a2. Surgery
71	SURGPERF	Num	8	3.	C2c2. Num of events treated:Surgery
70	SURG_TTL	Num	8	3.	C2b2. Num of events:Surgery
65	TRANFUSN	Num	8	3.	C2a1. Transfusion
67	TRANPERF	Num	8	3.	C2c1. Num of events treated:Transfusion
66	TRAN_TTL	Num	8	3.	C2b1. Num of events:Transfusion
33	TREATAPL	Num	8	3.	C1c6. Number of events treated:aplastic
42	TREATFEV	Num	8	3.	C1c9. Number of events treated:Fever
63	TREATOTH	Num	8	3.	C1c15. Number of events treated:Other
50	TREATPNE	Num	8	3.	C1c11. Number of events treated: pneumonia/ACS
55	TREATPRI	Num	8	3.	C1c13. Number of events treated:Priapism
59	TREATREA	Num	8	3.	C1c14. Number of events treated:Transfusion reaction
46	TREATSEP	Num	8	3.	C1c10. Number of events treated:Septicemia
29	TREATSPL	Num	8	3.	C1c5. Number of events treated:splenic
38	TREATVAS	Num	8	3.	C1c8. Number of events treated:Vaso-occlusive pain
88	TUBERCUL	Num	8	3.	E12. Tuberculosis
57	T_REACTN	Num	8	3.	C1a14. Transfusion reaction
36	VASOPAIN	Num	8	3.	C1a8. Vaso-occlusive pain
37	VASO_TTL	Num	8	3.	C1b8. Number of events:Vaso-occlusive pain
106	aplast_dfrmrand	Num	8		<created variable> C1d6. Date of aplastic crisis as days from RAND visit
103	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
107	fever_dtfrmrand	Num	8		<created variable> C1d9. Date of fever as days from RAND visit
102	ldu_id	Char	10		ID for public use datasets
117	o_recode1	Num	8		<recoded variable> C1a15a1. Other code 1
119	o_recode2	Num	8		<recoded variable> C1a15b1. Other code 2
108	oth_evdtfrmrand	Num	8		<created variable> C1d15. Date of other event as days from RAND visit
118	oth_recodespc1	Char	25		<recoded variable> C1a15a. Other event 1, specify
120	oth_recodespc2	Char	25		<recoded variable> C1a15b. Other event 2, specify
109	pneum_dtfrmrand	Num	8		<created variable> C1d11. Date of ACS/pneumonia as days from RAND visit
110	priap_dtfrmrand	Num	8		<created variable> C1d13. Date of priapism as days from RAND visit
104	qtrrptfrmrand	Num	8		<created variable> C1. Date of last report as days from RAND visit
111	react_dtfrmrand	Num	8		<created variable> C1d14. Date of transfusion reaction as days from RAND visit
112	septi_dtfrmrand	Num	8		<created variable> C1d10. Date of septicemia as days from RAND visit
105	splen_dtfrmrand	Num	8		<created variable> C1d5. Date of splenic sequestration as days from RAND visit

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
113	surg_dtfrmrand	Num	8		<created variable> C2d2. Date of: Surgery as days from RAND visit
124	surg_recodesp2	Char	25		<recoded variable> C2a2b. Surgery 2, specify
122	surg_recodespc	Char	25		<recoded variable> C2a2a. Surgery 1, specify
121	surgrecode	Num	8		<recoded variable> C2a2a1. Surgery code 1
123	surgrecode2	Num	8		<recoded variable> C2a2b1. Surgery code 2
114	transf_dfrmrand	Num	8		<created variable> C2d1. Date of: Transfusion as days from RAND visit
116	vacc_dtfrmrand	Num	8		<created variable> F1a. Vaccination date as days from RAND visit
115	vaso_dtfrmrand	Num	8		<created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit
101	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	INT_TYPE	Num	8	3.	A3. Person interviewed
4	SP_INT	Char	75	$75.	<recoded> A3a. Person interviewed, specify
5	A_T_VERI	Num	8	3.	A4. Address and telephone info verified
6	ANYMEDS	Num	8	3.	B1. Patient taking any medications
7	PENCILLN	Num	8	3.	B1a1. Pencillin
8	PEN_MTHS	Num	8	4.	B1b1. Months taking: Pencillin
9	OTH_ANTI	Num	8	3.	B1a2. Other antibiotic
10	O_ANT_SP	Char	25	$25.	B1a2a. Other antibiotic, specify
11	OTHANTMT	Num	8	4.	B1b2. Months taking: Other
12	FOLATE	Num	8	3.	B1a3. Folate
13	FOLAT_MT	Num	8	4.	B1b3. Months taking: Folate
14	HYDROXYU	Num	8	3.	B1a4. Hydroxyurea
15	HYDRX_MT	Num	8	4.	B1b4. Months taking: Hydroxyurea
16	IRONCHEL	Num	8	3.	B1a5. Iron Chelators
17	IRON_MTH	Num	8	4.	B1b5. Months taking: Iron chelators
18	OTH_MED	Num	8	3.	B1a6. Other medication(s)
19	O_MED_SP	Char	25	$25.	B1a6a. Other medication, specify
20	O_MED_MT	Num	8	4.	B1b6a. Months taking: Other 1
21	O_MD2_SP	Char	25	$25.	B1a6b. Other medication 2, specify
22	O_MD2_MT	Num	8	4.	B1b6b. Months taking: Other 2
23	STROKE	Num	8	3.	C1a1. Stroke/TIA
24	SEIZURES	Num	8	3.	C1a2. Seizures
25	MENINGIT	Num	8	3.	C1a3. Meningitis
26	HEADINJR	Num	8	3.	C1a4. Head injury
27	SPLENICS	Num	8	3.	C1a5. Splenic sequestration
28	SPLENTTL	Num	8	3.	C1b5. Number of events:splenic
29	TREATSPL	Num	8	3.	C1c5. Number of events treated:splenic
30	SEENSPLN	Num	8	3.	C1e5. Location seen at for splenic
31	APLASTIC	Num	8	3.	C1a6. Aplastic Crisis
32	APLASTTL	Num	8	3.	C1b6. Number of events:aplastic
33	TREATAPL	Num	8	3.	C1c6. Number of events treated:aplastic
34	SEENAPLS	Num	8	3.	C1e6. Location seen at for aplastic
35	H_F_SYND	Num	8	3.	C1a7. Hand-Foot Syndrome
36	VASOPAIN	Num	8	3.	C1a8. Vaso-occlusive pain
37	VASO_TTL	Num	8	3.	C1b8. Number of events:Vaso-occlusive pain
38	TREATVAS	Num	8	3.	C1c8. Number of events treated:Vaso-occlusive pain
39	SEENVASO	Num	8	3.	C1e8. Location seen at for vaso-occlusive pain
40	FEVER	Num	8	3.	C1a9. Fever
41	FEVERTTL	Num	8	3.	C1b9. Number of events:Fever
42	TREATFEV	Num	8	3.	C1c9. Number of events treated:Fever
43	SEENFEVR	Num	8	3.	C1e9. Location seen at for fever
44	SEPTICEM	Num	8	3.	C1a10. Septicemia
45	SEPT_TTL	Num	8	3.	C1b10. Number of events:Septicemia
46	TREATSEP	Num	8	3.	C1c10. Number of events treated:Septicemia
47	SEENSEPT	Num	8	3.	C1e10. Location seen at for septicemia
48	PNEUMONI	Num	8	3.	C1a11. Pneumonia/Acute Chest Syndrome
49	PNEUMTTL	Num	8	3.	C1b11. Number of events: pneumonia/ACS
50	TREATPNE	Num	8	3.	C1c11. Number of events treated: pneumonia/ACS
51	SEENPNEU	Num	8	3.	C1e11. Location seen at for pneumonia/ACS

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
52	OSTEOMYL	Num	8	3.	C1a12. Osteomyelitis
53	PRIAPISM	Num	8	3.	C1a13. Priapism
54	PRIAPTTL	Num	8	3.	C1b13. Number of events:Priapism
55	TREATPRI	Num	8	3.	C1c13. Number of events treated:Priapism
56	SEENPRIA	Num	8	3.	C1e13. Location seen at for priapism
57	T_REACTN	Num	8	3.	C1a14. Transfusion reaction
58	REACTTTL	Num	8	3.	C1b14. Number of events:Transfusion reaction
59	TREATREA	Num	8	3.	C1c14. Number of events treated:Transfusion reaction
60	SEENREAC	Num	8	3.	C1e14. Location seen at for transfusion reaction
61	OTH_EVNT	Num	8	3.	C1a15. Other event
62	OTH_TTL	Num	8	3.	C1b15. Number of events:Other
63	TREATOTH	Num	8	3.	C1c15. Number of events treated:Other
64	SEENOTH	Num	8	3.	C1e15. Location seen at for other
65	TRANFUSN	Num	8	3.	C2a1. Transfusion
66	TRAN_TTL	Num	8	3.	C2b1. Num of events:Transfusion
67	TRANPERF	Num	8	3.	C2c1. Num of events treated:Transfusion
68	SEENTRAN	Num	8	3.	C2e1. Seen: Transfusion
69	SURGERY	Num	8	3.	C2a2. Surgery
70	SURG_TTL	Num	8	3.	C2b2. Num of events:Surgery
71	SURGPERF	Num	8	3.	C2c2. Num of events treated:Surgery
72	SEENSURG	Num	8	3.	C2e2. Seen: Surgery
73	PORTACTH	Num	8	3.	C3. Does patient have a portacath
74	NEWNEURO	Num	8	3.	D1. Neurological signs and symptoms
75	LULCERS	Num	8	3.	E1. Leg ulcers
76	A_NECROS	Num	8	3.	E2. Aseptic necrosis
77	NECROSPC	Char	25	$25.	E2b. Aseptic necrosis, specify
78	SC_RETIN	Num	8	3.	E3. Sickle cell retinopathy
79	CHR_LUNG	Num	8	3.	E4. Chronic lung disease
80	ASTHMA	Num	8	3.	E5. Asthma
81	CHD	Num	8	3.	E6. Chronic heart disease
82	CHRLIVER	Num	8	3.	E7. Chronic liver disease
83	CHRRENAL	Num	8	3.	E8. Chronic renal disease
84	IRONOVER	Num	8	3.	E9. Iron overload
85	FERRITIN	Num	8	6.	E9b. Ferritin
86	DIABETES	Num	8	3.	E10. Diabetes
87	RHEUMATC	Num	8	3.	E11. Rheumatc fever
88	TUBERCUL	Num	8	3.	E12. Tuberculosis
89	CANCER	Num	8	3.	E13. Cancer
90	PRIAP	Num	8	3.	E14. Priapism
91	ELEV_BLD	Num	8	3.	E15. Elevated blood lead level
92	RBCANTI	Num	8	3.	E16. New red cell antibody
93	RBC_SPC1	Char	25	$25.	E16a1. New red cell antibody,specify
94	RBC_SPC2	Char	25	$25.	E16a2. New red cell antibody 2,specify
95	RBC_SPC3	Char	25	$25.	E16a3. New red cell antibody 3,specify
96	OTHCOND	Num	8	3.	E17. Other condition
97	HEPBVACC	Num	8	3.	F1. HepB Vaccination
98	NON_STOP	Num	8	3.	G1. Is patient seen at non-STOP II sites
99	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
100	DESTATUS	Char	1	$1.	DESTATUS
101	vistype	Char	7		<created variable> VISIT TYPE
102	ldu_id	Char	10		ID for public use datasets

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
103	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
104	qtrrptfrmrand	Num	8		<created variable> C1. Date of last report as days from RAND visit
105	splen_dtfrmrand	Num	8		<created variable> C1d5. Date of splenic sequestration as days from RAND visit
106	aplast_dfrmrand	Num	8		<created variable> C1d6. Date of aplastic crisis as days from RAND visit
107	fever_dtfrmrand	Num	8		<created variable> C1d9. Date of fever as days from RAND visit
108	oth_evdtfrmrand	Num	8		<created variable> C1d15. Date of other event as days from RAND visit
109	pneum_dtfrmrand	Num	8		<created variable> C1d11. Date of ACS/pneumonia as days from RAND visit
110	priap_dtfrmrand	Num	8		<created variable> C1d13. Date of priapism as days from RAND visit
111	react_dtfrmrand	Num	8		<created variable> C1d14. Date of transfusion reaction as days from RAND visit
112	septi_dtfrmrand	Num	8		<created variable> C1d10. Date of septicemia as days from RAND visit
113	surg_dtfrmrand	Num	8		<created variable> C2d2. Date of: Surgery as days from RAND visit
114	transf_dfrmrand	Num	8		<created variable> C2d1. Date of: Transfusion as days from RAND visit
115	vaso_dtfrmrand	Num	8		<created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit
116	vacc_dtfrmrand	Num	8		<created variable> F1a. Vaccination date as days from RAND visit
117	o_recode1	Num	8		<recoded variable> C1a15a1. Other code 1
118	oth_recodespc1	Char	25		<recoded variable> C1a15a. Other event 1, specify
119	o_recode2	Num	8		<recoded variable> C1a15b1. Other code 2
120	oth_recodespc2	Char	25		<recoded variable> C1a15b. Other event 2, specify
121	surgrecode	Num	8		<recoded variable> C2a2a1. Surgery code 1
122	surg_recodespc	Char	25		<recoded variable> C2a2a. Surgery 1, specify
123	surgrecode2	Num	8		<recoded variable> C2a2b1. Surgery code 2
124	surg_recodesp2	Char	25		<recoded variable> C2a2b. Surgery 2, specify

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

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*F16Bfmts.txt;

proc format;

  value SEPTICEMF
    1='1: No'
    2='2: Yes';

  value SEIZURESF
    1='1: No'
    2='2: Yes';

  value A_NECROSF
    1='1: No'
    2='2: Yes';

  value A_T_VERIF
    1='1: No'
    2='2: Yes';

  value ANYMEDSF
    1='1: No'
    2='2: Yes';

  value APLASTICF
    1='1: No'
    2='2: Yes';

  value ASTHMAF
    1='1: No'
    2='2: Yes';

  value CANCERF
    1='1: No'
    2='2: Yes';

  value CHDF
    1='1: No'
    2='2: Yes';

  value CHR_LUNGF
    1='1: No'
    2='2: Yes';

  value CHRLIVERF
    1='1: No'
    2='2: Yes';

  value CHRRENALF
    1='1: No'
    2='2: Yes';

  value DIABETESF
    1='1: No'
    2='2: Yes';
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value ELEV_BLDF
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  2='2: Yes';

value FEVERF
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  2='2: Yes';

value FOLATEF
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  2='2: Yes';

value H_F_SYNDF
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  2='2: Yes';

value HEADINJRF
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  2='2: Yes';

value HEPBVACCF
  1='1: No'
  2='2: Yes';

value HYDROXYUF
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value INT_TYPEF
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  2='2: Parent'
  3='3: Legal guardian'
  4='4: Other';

value IRONCHELF
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value IRONOVERF
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value LULCERSF
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value MENINGITF
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value NEWNEUROF
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```

```
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 value OSTEOMYLF
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 value OTH_ANTIF
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  2='2: Yes';

 value OTH_EVNTF
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  2='2: Yes';

 value OTH_MEDF
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 value OTHCONDF
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  2='2: Yes';

 value PENCILLNF
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 value PNEUMONIF
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 value PORTACTHF
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  2='2: Yes';

 value PRIAPF
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  2='2: Yes';

 value PRIAPISMF
  1='1: No'
  2='2: Yes';

 value RBCANTIF
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  2='2: Yes';

 value RHEUMATCF
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  2='2: Yes';

 value SC_RETINF
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  2='2: Yes';
```

```
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  2='2: Non-STOP II Center';

value SEENFEVRF
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  2='2: Non-STOP II Center';

value SEENOTHF
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value SEENPNEUF
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  2='2: Non-STOP II Center';

value SEENPRIAF
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  2='2: Non-STOP II Center';

value SEENREACF
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  2='2: Non-STOP II Center';

value SEENSEPTF
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  2='2: Non-STOP II Center';

value SEENSPLNF
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  2='2: Non-STOP II Center';

value SEENSURGF
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  2='2: Non-STOP II Center';

value SEENTRANF
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  2='2: Non-STOP II Center';

value SEENVASOF
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value SPLENICSF
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value STROKEF
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```

```
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 value TUBERCULF
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   2='2: Yes';

 value VASOPAINF
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   2='2: Yes';
```

* format septicem septicemf. seizures seizuresf. a_necros a_necrosf. a_t_veri a_t_verif. anymeds anymedsf. aplastic aplasticf. asthma asthmaf. cancer cancerf. chd chdf. chr_lung chr_lungf. chrliver chrliverf. chrrenal chrrenalf. diabetes diabetesf. elev_bld elev_bldf. fever feverf. folate folatef. h_f_synd h_f_syndf. headinjr headinjrf. hepbvacc hepbvaccf. hydroxyu hydroxyuf. int_type int_typef. ironchel ironchelf. ironover ironoverf. lulcers lulcersf. meningit meningitf. newneuro newneurof. non_stop non_stopf. osteomyl osteomylf. oth_anti oth_antif. oth_evnt oth_evntf. oth_med oth_medf. othcond othcondf. pencilln pencillnf. pneumoni pneumonif. portacth portacthf. priap priapf. priapism priapismf. rbcanti rbcantif. rheumatc rheumatcf. sc_retin sc_retinf. seenapls seenaplsf. seenfevr seenfevrf. seenoth seenothf. seenpneu seenpneuf. seenpria seenpriaf. seenreac seenreacf. seensept seenseptf. seenspln seensplnf. seensurg seensurgf. seentran seentranf. seenvaso seenvasof. splenics splenicsf. stroke strokef. surgery surgeryf. t_reactn t_reactnf. tranfusn tranfusnf. tubercul tuberculf. vasopain vasopainf.;

STOP II TRIAL
QUARTERLY PROGRESS REPORT FOR NON-RANDOMIZED PATIENTS RECEIVING TRANSFUSIONS

*** AFFIX PATIENT LABEL HERE***

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	341	99.13	341	99.13
P	3	0.87	344	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-202	28	8.14	28	8.14
QT-203	24	6.98	52	15.12
QT-204	26	7.56	78	22.67
QT-205	26	7.56	104	30.23
QT-206	22	6.40	126	36.63
QT-207	20	5.81	146	42.44
QT-208	18	5.23	164	47.67
QT-209	17	4.94	181	52.62
QT-210	16	4.65	197	57.27
QT-301	32	9.30	229	66.57
QT-302	42	12.21	271	78.78
QT-303	24	6.98	295	85.76
QT-304	21	6.10	316	91.86
QT-305	12	3.49	328	95.35
QT-306	6	1.74	334	97.09
QT-307	3	0.87	337	97.97
QT-308	3	0.87	340	98.84
QT-309	2	0.58	342	99.42
QT-310	2	0.58	344	100.00

A1. Person completing form (Name):_____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of interview (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of interview as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
344	0	-386.5	274.8	-1237	-600.5	-343.0	-140.5	-5.0

A3. Person interviewed (Choose **ONE** for person providing majority of answers to sections B-F):

☐ 1. Patient ☐ 2. Parent ☐ 3. Legal Guardian ☐ 4. Other → A3.a (specify): _____

A3. Person interviewed				
INT_TYPE	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	43	12.50	46	13.37
2	267	77.62	313	90.99
3	1	0.29	314	91.28
4	30	8.72	344	100.00

<recoded> A3a. Person interviewed, specify				
SP_INT	Frequency	Percent	Cum Freq	Cum Percent
-2	314	91.28	314	91.28
Aunt	2	0.58	316	91.86
Case worker	2	0.58	318	92.44
Foster parent	2	0.58	320	93.02
Foster parents	1	0.29	321	93.31
Grandmother	2	0.58	323	93.90
Medical personnel	15	4.36	338	98.26
Medical personnel and record review	1	0.29	339	98.55
Medical record review	1	0.29	340	98.84
Retrospective chart review	1	0.29	341	99.13
Sister	1	0.29	342	99.42
Transfusion nurse	2	0.58	344	100.00

A4. Were address and telephone information verified for this patient? ☐ **1. NO** ☐ **2. YES**

A4. Address and telephone info verified				
A_T_VERI	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	7	2.03	10	2.91
2	334	97.09	344	100.00

QUESTIONS IN SECTIONS B THROUGH D ARE TO BE ANSWERED BY THE PERSON INTERVIEWED; QUESTIONS IN SECTIONS E THROUGH G ARE TO BE ANSWERED BY MEDICAL PERSONNEL.

B. MEDICATIONS

B1. Is the patient currently taking, on a regular basis, any medications prescribed by a physician?

☐ **1. NO** ☐ **2. YES**

B1. Patient taking any medications				
ANYMEDS	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	64	18.60	67	19.48
2	277	80.52	344	100.00

↓

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
1. Penicillin	☐	☐	1. ☐☐☐

B1a1. Pencillin				
PENCILLN	Frequency	Percent	Cum Freq	Cum Percent
-2	67	19.48	67	19.48
1	142	41.28	209	60.76
2	135	39.24	344	100.00

Analysis Variable : PEN_MTHS B1b1. Months taking: Pencillin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
134	0	89.6	43.2	1.0	65.0	88.0	117.0	190.0

B1b1. Months taking: Pencillin				
PEN_MTHS	Frequency	Percent	Cum Freq	Cum Percent
-2	209	99.52	209	99.52
-1	1	0.48	210	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
2. Other antibiotic	☐	☐	2. ☐☐☐

↓

B1.a2.a SPECIFY:_____

B1a2. Other antibiotic				
OTH_ANTI	Frequency	Percent	Cum Freq	Cum Percent
-2	67	19.48	67	19.48
1	271	78.78	338	98.26
2	6	1.74	344	100.00

B1a2a. Other antibiotic, specify				
O_ANT_SP	Frequency	Percent	Cum Freq	Cum Percent
-2	338	98.26	338	98.26
-9	1	0.29	339	98.55
Amoxil	1	0.29	340	98.84
Augmentin	1	0.29	341	99.13
Septra	3	0.87	344	100.00

Analysis Variable : OTHANTMT B1b2. Months taking: Other								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	2.5	1.9	1.0	1.0	2.0	4.0	5.0

B1b2. Months taking: Other				
OTHANTMT	Frequency	Percent	Cum Freq	Cum Percent
-8	1	0.29	1	0.29
-2	338	99.41	339	99.71
0	1	0.29	340	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
3. Folate	☐	☐	3. ☐☐☐

B1a3. Folate				
FOLATE	Frequency	Percent	Cum Freq	Cum Percent
-2	67	19.48	67	19.48
1	140	40.70	207	60.17
2	137	39.83	344	100.00

Analysis Variable : FOLAT_MT B1b3. Months taking: Folate								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
131	0	72.4	51.4	1.0	21.0	78.0	105.0	236.0

B1b3. Months taking: Folate				
FOLAT_MT	Frequency	Percent	Cum Freq	Cum Percent
-8	5	2.35	5	2.35
-3	1	0.47	6	2.82
-2	207	97.18	213	100.00

4. Hydroxyurea	☐	☐	4. ☐☐☐

B1a4. Hydroxyurea				
HYDROXYU	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.29	1	0.29
-2	67	19.48	68	19.77
1	275	79.94	343	99.71
2	1	0.29	344	100.00

Analysis Variable : HYDRX_MT B1b4. Months taking: Hydroxyurea								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	16.0	.	16.0	16.0	16.0	16.0	16.0

B1b4. Months taking: Hydroxyurea				
HYDRX_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.29	1	0.29
-2	342	99.71	343	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
5. Iron Chelators (Desferoxamine)	☐	☐	5. ☐☐☐

B1a5. Iron Chelators				
IRONCHEL	Frequency	Percent	Cum Freq	Cum Percent
-2	67	19.48	67	19.48
1	150	43.60	217	63.08
2	127	36.92	344	100.00

Analysis Variable : IRON_MTH B1b5. Months taking: Iron chelators								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
126	0	15.4	13.2	1.0	6.0	11.0	21.0	51.0

B1b5. Months taking: Iron chelators				
IRON_MTH	Frequency	Percent	Cum Freq	Cum Percent
-2	217	99.54	217	99.54
0	1	0.46	218	100.00

6. Other ☐ ☐ → 6.a ☐☐☐

6.b ☐☐☐

B1.a6.a SPECIFY:_____

B1.a6.b SPECIFY:_____

B1a6. Other medication(s)				
OTH_MED	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.29	1	0.29
-2	67	19.48	68	19.77
1	142	41.28	210	61.05
2	134	38.95	344	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
6. Other	☐	☐	6.a ☐☐☐
			6.b ☐☐☐

B1.a6.a SPECIFY:_____

B1.a6.b SPECIFY:_____

B1a6a. Other medication, specify				
O_MED_SP	Frequency	Percent	Cum Freq	Cum Percent
-2	209	60.76	209	60.76
-9	1	0.29	210	61.05
Albuterol	6	1.74	216	62.79
Aspirin	2	0.58	218	63.37
Baby aspirin	36	10.47	254	73.84
CLARITIN	1	0.29	255	74.13
CONCERTA	1	0.29	256	74.42
Children's motrin	1	0.29	257	74.71
Claritin, nasonex	1	0.29	258	75.00
Digoxin	7	2.03	265	77.03
EYEDROPS FOR INFLAMMATION	1	0.29	266	77.33
Ear drops for otitis exte	1	0.29	267	77.62
Flonase	4	1.16	271	78.78
Flovent	8	2.33	279	81.10
Flovent/nebulizer	1	0.29	280	81.40
Halotestin, methotrexate	1	0.29	281	81.69
Ibuprofen	3	0.87	284	82.56
Motrin	6	1.74	290	84.30
Nasarel	1	0.29	291	84.59
Nasonex	4	1.16	295	85.76
Nebulizers	1	0.29	296	86.05
PERIACTIN	1	0.29	297	86.34
Panaz	1	0.29	298	86.63
Percocet	1	0.29	299	86.92
RUGRATS VITAMINS	1	0.29	300	87.21
Rhinocort Aqua	1	0.29	301	87.50
SINGULAIR,ALBUTEROL	1	0.29	302	87.79
Singulair	24	6.98	326	94.77
Singulair Flovent Nebuliz	1	0.29	327	95.06
Singulair, albuterol	1	0.29	328	95.35
Singulair, flovent	1	0.29	329	95.64
Singulair, fovent, tilade	1	0.29	330	95.93
Tofranil	1	0.29	331	96.22
Tylenol	4	1.16	335	97.38
Vitamin C	5	1.45	340	98.84
Zoloft	3	0.87	343	99.71
Zyrtec	1	0.29	344	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
6. Other	☐	☐	6.a ☐☐☐
		↓	6.b ☐☐☐

B1.a6.a SPECIFY:_____

B1.a6.b SPECIFY:_____

Analysis Variable : O_MED_MT B1b6a. Months taking: Other 1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
126	0	27.4	26.0	1.0	11.0	21.5	34.0	129.0

B1b6a. Months taking: Other 1				
O_MED_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.92	2	0.92
-8	5	2.29	7	3.21
-2	209	95.87	216	99.08
-1	2	0.92	218	100.00

B1a6b. Other medication 2, specify				
O_MD2_SP	Frequency	Percent	Cum Freq	Cum Percent
-1	82	23.84	82	23.84
-2	209	60.76	291	84.59
ALLEGRA	1	0.29	292	84.88
Albuterol	9	2.62	301	87.50
Allergy shots	1	0.29	302	87.79
Aspirin	2	0.58	304	88.37
Eyedrops, steroids/eyes	1	0.29	305	88.66
Flovent	10	2.91	315	91.57
Flovent, tilade	1	0.29	316	91.86
Ibuprofen	1	0.29	317	92.15
Multivitamin	2	0.58	319	92.73
Nasonex	3	0.87	322	93.60
Nebulizer treatments	1	0.29	323	93.90
Percocet	7	2.03	330	95.93
Rhinocort	4	1.16	334	97.09
Risperdal	3	0.87	337	97.97
Ritalin	1	0.29	338	98.26
Ritalin, Miralax (3 mth)	1	0.29	339	98.55
SINGULAIR,NASONEX	1	0.29	340	98.84
Singulair	2	0.58	342	99.42
Singulair(15);miralax(1)	1	0.29	343	99.71
Tilade,Albuterol	1	0.29	344	100.00

B1.a TYPE OF MEDICATION:
(CHECK **NO** OR **YES** FOR EACH OF B1.a1-6)

B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?

	1. NO	2. YES	
6. Other	☐	☐	6.a ☐☐☐
		↓	6.b ☐☐☐

B1.a6.a SPECIFY:_____

B1.a6.b SPECIFY:_____

Analysis Variable : O_MD2_MT B1b6b. Months taking: Other 2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
49	0	20.6	17.7	1.0	8.0	15.0	29.0	63.0

B1b6b. Months taking: Other 2				
O_MD2_MT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.34	1	0.34
-8	3	1.02	4	1.36
-2	291	98.64	295	100.00

C. CLINICAL EVENTS

Since the last quarterly report (or entry interview if this is the first quarterly report) on ___/___ ___/___ ___ ___ ___, has the patient been seen by a doctor or nurse for any of the following:

Analysis Variable : qtrrptfrmrand <created variable> C1. Date of last report as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
344	0	-483.7	274.6	-1237	-692.5	-440.0	-246.5	-42.0

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
1. **Stroke/TIA**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: An event which a doctor called a stroke or cerebrovascular accident (CVA) which involved loss of consciousness, paralysis, visual, speech, or motor difficulties)*

C1a1. Stroke/TIA				
STROKE	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	341	99.13	344	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
2. **New Onset of Seizures**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Any fits or convulsions that were not associated with a stroke or meningitis (brain infection))*

IF RESPONSE TO C1.a1 or C1.a2 IS YES, SUBMIT QUASI-ADJUDICATION NEUROLOGICAL EVENT FORM Q30, NEUROLOGICAL EVALUATION REPORT, MRI REPORT, CT SCAN REPORT (IF DONE), AND SUPPORTING HOSPITAL SUMMARIES

C1a2. Seizures				
SEIZURES	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	341	99.13	344	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

3. **Meningitis** ☐ ☐ ☐ __ __/__ __ __ __ ☐

*(**PROBE**: Infection of the brain)*

c1.f3 **IF YES,** Date of discharge ___ ___/___ ___/___ ___ ___ ___

C1a3. Meningitis				
MENINGIT	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	341	99.13	344	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event, where seen or date discharged.]

4. **Head Injury with loss of consciousness** ☐ ☐ ☐ __ __/__ __ __ __ ☐

c1.f4 **IF YES,** Date of discharge ___ ___/___ ___/___ ___ ___ ___

C1a4. Head injury				
HEADINJR	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	341	99.13	344	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event, where seen or date discharged.]

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
5. **Splenic Sequestration***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Enlargement of the spleen with trapping of blood in it)*

C1a5. Splenic sequestration				
SPLENICS	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
-1	7	2.03	10	2.91
1	333	96.80	343	99.71
2	1	0.29	344	100.00

C1b5. Number of events:splenic				
SPLENTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

C1c5. Number of events treated:splenic				
TREATSPL	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

Analysis Variable : splen_dtfrmrand <created variable> C1d5. Date of splenic sequestration as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-350.0	.	-350.0	-350.0	-350.0	-350.0	-350.0

<created variable> C1d5. Date of splenic sequestration as days from RAND visit				
splen_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	343	100.00	343	100.00

C1e5. Location seen at for splenic				
SEENSPLN	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
6. **Aplastic Crisis***	☐	☐	☐	__ __/__ __ __ __	☐

(***PROBE**: A drop in the blood count which required a transfusion)*

C1a6. Aplastic Crisis				
APLASTIC	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	340	98.84	343	99.71
2	1	0.29	344	100.00

C1b6. Number of events:aplastic				
APLASTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

C1c6. Number of events treated:aplastic				
TREATAPL	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

Analysis Variable : aplast_dfrmrand <created variable> C1d6. Date of aplastic crisis as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-918.0	.	-918.0	-918.0	-918.0	-918.0	-918.0

<created variable> C1d6. Date of aplastic crisis as days from RAND visit				
aplast_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	343	100.00	343	100.00

C1e6. Location seen at for aplastic				
SEENAPLS	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
7. **Hand-Foot Syndrome***	☐	☐	☐	__ __/__ __ __ __	☐

(***PROBE**: Pain, tenderness, with or without swelling, in the hands and/or feet only)*

C1a7. Hand-Foot Syndrome				
H_F_SYND	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	341	99.13	344	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

8. **Vaso-occlusive pain event for which the patient was hospitalized*** ☐ ☐ ☐ __ __/__ __ __ __ ☐

(***PROBE**: An acute episode of pain in the arms, legs, back, chest, and/or abdomen, lasting at least two hours for which no other explanation was found)*

C1a8. Vaso-occlusive pain				
VASOPAIN	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	331	96.22	334	97.09
2	10	2.91	344	100.00

C1b8. Number of events:Vaso-occlusive pain				
VASO_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	334	97.09	334	97.09
1	8	2.33	342	99.42
2	1	0.29	343	99.71
3	1	0.29	344	100.00

C1c8. Number of events treated:Vaso-occlusive pain				
TREATVAS	Frequency	Percent	Cum Freq	Cum Percent
-2	334	97.09	334	97.09
1	8	2.33	342	99.42
2	1	0.29	343	99.71
3	1	0.29	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
8. **Vaso-occlusive pain event for which the patient was hospitalized***	☐	☐	☐	__ __/__ __ __ __	☐

(***PROBE**: An acute episode of pain in the arms, legs, back, chest, and/or abdomen, lasting at least two hours for which no other explanation was found)*

Analysis Variable : vaso_dtfrmrand <created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
10	0	-472.1	326.4	-971.0	-795.0	-417.5	-149.0	-105.0

<created variable> C1d8. Date of vaso-occlusive pain as days from RAND visit

vaso_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	334	100.00	334	100.00

C1e8. Location seen at for vaso-occlusive pain

SEENVASO	Frequency	Percent	Cum Freq	Cum Percent
-2	334	97.09	334	97.09
1	10	2.91	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
9. **Fever***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: A temperature greater than 101° F (39° C)*

C1a9. Fever				
FEVER	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	310	90.12	313	90.99
2	31	9.01	344	100.00

C1b9. Number of events:Fever				
FEVERTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	313	90.99	313	90.99
1	26	7.56	339	98.55
2	4	1.16	343	99.71
6	1	0.29	344	100.00

C1c9. Number of events treated:Fever				
TREATFEV	Frequency	Percent	Cum Freq	Cum Percent
-2	313	90.99	313	90.99
0	7	2.03	320	93.02
1	21	6.10	341	99.13
2	2	0.58	343	99.71
6	1	0.29	344	100.00

Analysis Variable : fever_dtfrmrand <created variable> C1d9. Date of fever as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
31	0	-474.3	268.6	-985.0	-681.0	-441.0	-270.0	-76.0

<created variable> C1d9. Date of fever as days from RAND visit				
fever_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	313	100.00	313	100.00

C1e9. Location seen at for fever				
SEENFEVR	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.29	1	0.29
-2	313	90.99	314	91.28
1	22	6.40	336	97.67
2	8	2.33	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
10. **Septicemia***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: An infection in the blood stream)*

C1a10. Septicemia				
SEPTICEM	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	340	98.84	343	99.71
2	1	0.29	344	100.00

C1b10. Number of events:Septicemia				
SEPT_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

C1c10. Number of events treated:Septicemia				
TREATSEP	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

Analysis Variable : septi_dtfrmrand <created variable> C1d10. Date of septicemia as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-985.0	.	-985.0	-985.0	-985.0	-985.0	-985.0

<created variable> C1d10. Date of septicemia as days from RAND visit				
septi_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	343	100.00	343	100.00

C1e10. Location seen at for septicemia				
SEENSEPT	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
11. **Acute Chest Syndrome/Pneumonia ***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE:** An infection or blockage of blood flow in the lung(s))*

C1a11. Pneumonia/Acute Chest Syndrome				
PNEUMONI	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	340	98.84	343	99.71
2	1	0.29	344	100.00

C1b11. Number of events: pneumonia/ACS				
PNEUMTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

C1c11. Number of events treated: pneumonia/ACS				
TREATPNE	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
0	1	0.29	344	100.00

Analysis Variable : pneum_dtfrmrand <created variable> C1d11. Date of ACS/pneumonia as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-513.0	.	-513.0	-513.0	-513.0	-513.0	-513.0

<created variable> C1d11. Date of ACS/pneumonia as days from RAND visit				
pneum_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	343	100.00	343	100.00

C1e11. Location seen at for pneumonia/ACS				
SEENPNEU	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
2	1	0.29	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
12. **Osteomyelitis***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Infection in the bones)*

C1a12. Osteomyelitis				
OSTEOMYL	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	341	99.13	344	100.00

[Variables NOT included in dataset for number of unique events, number treated, date of event or where seen.]

13. **Priapism*** ☐ ☐ ☐ __ __/__ __ __ __ ☐

*(**PROBE**: A painful, unwanted erection of the penis lasting more than one hour)*

C1a13. Priapism				
PRIAPISM	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
-1	214	62.21	217	63.08
1	126	36.63	343	99.71
2	1	0.29	344	100.00

C1b13. Number of events:Priapism				
PRIAPTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
5	1	0.29	344	100.00

C1c13. Number of events treated:Priapism				
TREATPRI	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
5	1	0.29	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
13. **Priapism***	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: A painful, unwanted erection of the penis lasting more than one hour)*

Analysis Variable : priap_dtfrmrand <created variable> C1d13. Date of priapism as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-395.0	.	-395.0	-395.0	-395.0	-395.0	-395.0

<created variable> C1d13. Date of priapism as days from RAND visit

priap_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	343	100.00	343	100.00

C1e13. Location seen at for priapism

SEENPRIA	Frequency	Percent	Cum Freq	Cum Percent
-2	343	99.71	343	99.71
1	1	0.29	344	100.00

14. **Transfusion reaction** ☐ ☐ ☐ __ __/__ __ __ __ ☐

*(**PROBE**: Complication of a transfusion within 2 weeks after the transfusion was given*

C1a14. Transfusion reaction

T_REACTN	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	338	98.26	341	99.13
2	3	0.87	344	100.00

C1b14. Number of events:Transfusion reaction

REACTTTL	Frequency	Percent	Cum Freq	Cum Percent
-2	341	99.13	341	99.13
1	1	0.29	342	99.42
2	1	0.29	343	99.71
8	1	0.29	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
14. **Transfusion reaction**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Complication of a transfusion within 2 weeks after the transfusion was given*

C1c14. Number of events treated:Transfusion reaction

TREATREA	Frequency	Percent	Cum Freq	Cum Percent
-2	341	99.13	341	99.13
0	1	0.29	342	99.42
1	2	0.58	344	100.00

Analysis Variable : react_dtfrmrand <created variable> C1d14. Date of transfusion reaction as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	-352.7	328.9	-707.0	-707.0	-294.0	-57.0	-57.0

<created variable> C1d14. Date of transfusion reaction as days from RAND visit

react_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	341	100.00	341	100.00

C1e14. Location seen at for transfusion reaction

SEENREAC	Frequency	Percent	Cum Freq	Cum Percent
-2	341	99.13	341	99.13
1	3	0.87	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
15. **Other*** *(**PROBE**: Was the child seen for any other clinical events? What events?)*	☐ ↓	☐	☐	__ __/__ __ __ __	_____

C1.a15.a. IF YES, Specify:

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C1a15. Other event				
OTH_EVNT	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	312	90.70	315	91.57
2	29	8.43	344	100.00

o_recode1	oth_recodespc1	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	315	91.57	315	91.57
282.62	Pain crisis in ER	1	0.29	316	91.86
999.99	OTHER	28	8.14	344	100.00

o_recode2	oth_recodespc2	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	315	91.57	315	91.57
-1	-1	20	5.81	335	97.38
282.62	Pain crisis in legs	1	0.29	336	97.67
282.62	pain crisis	1	0.29	337	97.97
999.99	OTHER	7	2.03	344	100.00

C1b15. Number of events:Other				
OTH_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	315	91.57	315	91.57
1	23	6.69	338	98.26
2	3	0.87	341	99.13
3	2	0.58	343	99.71
4	1	0.29	344	100.00

C1c15. Number of events treated:Other				
TREATOTH	Frequency	Percent	Cum Freq	Cum Percent
-2	315	91.57	315	91.57
0	8	2.33	323	93.90
1	21	6.10	344	100.00

C1.a Event	USE CODES 1. NO 2. YES	C1.b Total # of unique events	C1.c # treated at your institution	C1.d What was the date of the most recent event? (Month/Year)	C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center
15. **Other*** *(**PROBE**: Was the child seen for any other clinical events? What events?)*	☐ ↓	☐	☐	__ __/__ __ __ __	_____

C1.a15.a. IF YES, Specify:

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Analysis Variable : oth_evdtfrmrand <created variable> C1d15. Date of other event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
29	0	-431.7	257.5	-959.0	-614.0	-384.0	-262.0	-49.0

<created variable> C1d15. Date of other event as days from RAND visit				
oth_evdtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	315	100.00	315	100.00

C1e15. Location seen at for other				
SEENOTH	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.29	1	0.29
-2	315	91.57	316	91.86
1	19	5.52	335	97.38
2	9	2.62	344	100.00

C2.a Procedure	USE CODES 1. NO 2. YES	C2.b Total # of unique procedures	C2.c # performed at your institution	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
1. **Transfusion**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Injection of blood into the bloodstream)*

C2a1. Transfusion				
TRANFUSN	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	12	3.49	15	4.36
2	329	95.64	344	100.00

C2b1. Num of events:Transfusion				
TRAN_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	15	4.36	15	4.36
1	7	2.03	22	6.40
2	48	13.95	70	20.35
3	123	35.76	193	56.10
4	74	21.51	267	77.62
5	38	11.05	305	88.66
6	24	6.98	329	95.64
7	7	2.03	336	97.67
8	3	0.87	339	98.55
9	3	0.87	342	99.42
11	2	0.58	344	100.00

C2c1. Num of events treated:Transfusion				
TRANPERF	Frequency	Percent	Cum Freq	Cum Percent
-2	15	4.36	15	4.36
0	3	0.87	18	5.23
1	7	2.03	25	7.27
2	48	13.95	73	21.22
3	120	34.88	193	56.10
4	74	21.51	267	77.62
5	38	11.05	305	88.66
6	24	6.98	329	95.64
7	7	2.03	336	97.67
8	3	0.87	339	98.55
9	3	0.87	342	99.42
11	2	0.58	344	100.00

C2.a Procedure	USE CODES 1. NO 2. YES	C2.b Total # of unique procedures	C2.c # performed at your institution	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
1. **Transfusion**	☐	☐	☐	__ __/__ __ __ __	☐

*(**PROBE**: Injection of blood into the bloodstream)*

Analysis Variable : transf_dfrmrand <created variable> C2d1. Date of: Transfusion as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
329	0	-428.5	277.5	-1275	-642.0	-374.0	-197.0	-25.0

<created variable> C2d1. Date of: Transfusion as days from RAND visit

transf_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	15	100.00	15	100.00

C2e1. Seen: Transfusion

SEENTRAN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.29	1	0.29
-2	15	4.36	16	4.65
1	325	94.48	341	99.13
2	3	0.87	344	100.00

C2.a Procedure	USE CODES 1. NO 2. YES	C2.b Total # of unique procedures	C2.c # performed at your institution	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
2. **Surgery*** *(**PROBE**: An operation or a medical procedure requiring general anesthesia)*	☐ ↓	☐	☐	__ __/__ __ __ __	☐

C2.a2.a. IF YES, Specify:

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C2a2. Surgery				
SURGERY	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	322	93.60	325	94.48
2	19	5.52	344	100.00

surgrecode	surg_recodespc	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	325	94.48	325	94.48
38.93	FEMORAL LINE REPLACEMENT	1	0.29	326	94.77
38.93	Port-a-cath placement	2	0.58	328	95.35
38.93	infusaport placement x2	1	0.29	329	95.64
41.5	Splenectomy	1	0.29	330	95.93
50.11	Liver biopsy	5	1.45	335	97.38
51.23	Lap. cholecystectomy	1	0.29	336	97.67
97.89	Port-a-cath removal	3	0.87	339	98.55
99.99	OTHER	5	1.45	344	100.00

surgrecode2	surg_recodesp2	Frequency	Percent	Cum Freq	Cum Percent
-2	-1	15	4.36	15	4.36
-2	-2	325	94.48	340	98.84
38.93	Port-a-cath placement	2	0.58	342	99.42
38.93	port replacement	1	0.29	343	99.71
99.99	OTHER	1	0.29	344	100.00

C2b2. Num of events:Surgery				
SURG_TTL	Frequency	Percent	Cum Freq	Cum Percent
-2	325	94.48	325	94.48
1	16	4.65	341	99.13
2	2	0.58	343	99.71
3	1	0.29	344	100.00

C2.a Procedure	USE CODES 1. NO 2. YES	C2.b Total # of unique procedures	C2.c # performed at your institution	C2.d What was the date of the most recent procedure? (Month/Year)	C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center
2. **Surgery*** *(**PROBE**: An operation or a medical procedure requiring general anesthesia)*	☐ ↓	☐	☐	__ __/__ __ __ __	☐

C2.a2.a. IF YES, Specify:
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Analysis Variable : surg_dtfrmrand <created variable> C2d2. Date of: Surgery as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
19	0	-523.1	281.6	-974.0	-742.0	-502.0	-299.0	-93.0

<created variable> C2d2. Date of: Surgery as days from RAND visit

surg_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	325	100.00	325	100.00

C2e2. Seen: Surgery

SEENSURG	Frequency	Percent	Cum Freq	Cum Percent
-2	325	94.48	325	94.48
1	19	5.52	344	100.00

C3. Does the patient currently have a portacath? ☐ **1. NO** ☐ **2. YES**

C3. Does patient have a portacath

PORTACTH	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	316	91.86	319	92.73
2	25	7.27	344	100.00

NOTE: FOR VISITS AT A NON-STOP II STUDY SITE, ASK PARENT TO SIGN A MEDICAL RECORD RELEASE FORM FOR EACH UNIQUE EVENT AND REMEMBER TO SUBMIT MEDICAL RECORD REVIEW FORM (FORM 16R)

D. NEUROLOGICAL SIGNS AND SYMPTOMS

D1. Has the patient developed a new neurologic problem, been hospitalized for a neurological event, or been seen by a neurologist because of a new neurologic problem?

☐ **1. NO** ☐ **2. YES**

D1. Neurological signs and symptoms				
NEWNEURO	Frequency	Percent	Cum Freq	Cum Percent
-3	3	0.87	3	0.87
1	337	97.97	340	98.84
2	4	1.16	344	100.00

↓

D1.a. Please give brief details: _____

[Variable NOT included in dataset for specify field.]

E. OTHER MEDICAL CONDITIONS

(SECTIONS E – G TO BE COMPLETED BY MEDICAL PERSONNEL)

Since the last quarterly report was the patient **newly** diagnosed with: **(CHECK NO OR YES FOR EACH OF E1 - E17)**

1. NO **2. YES**

E1. Leg ulcers ☐ ☐

E1. Leg ulcers				
LULCERS	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

E2. Aseptic necrosis ☐ ☐

2.b If Yes, specify location(s) _____

E2. Aseptic necrosis				
A_NECROS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.29	1	0.29
1	343	99.71	344	100.00

E2b. Aseptic necrosis, specify				
NECROSPC	Frequency	Percent	Cum Freq	Cum Percent
-2	344	100.00	344	100.00

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E3. Sickle cell retinopathy ☐ ☐

E3. Sickle cell retinopathy				
SC_RETIN	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

E4. Chronic lung disease ☐ ☐

4.b If Yes, specify type _____

E4. Chronic lung disease				
CHR_LUNG	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

[Variable NOT included in dataset for specify field.]

E5. Asthma ☐ ☐

E5. Asthma				
ASTHMA	Frequency	Percent	Cum Freq	Cum Percent
1	339	98.55	339	98.55
2	5	1.45	344	100.00

E6. Chronic heart disease ☐ ☐

6.b If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E6. Chronic heart disease				
CHD	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

[Variables NOT included in dataset for specify and code fields.]

E7. Chronic liver disease ☐ ☐

7.b If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E7. Chronic liver disease				
CHRLIVER	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

[Variables NOT included in dataset for specify and code fields.]

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E8. Chronic renal disease ☐ ☐

8.b If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E8. Chronic renal disease				
CHRRENAL	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

[Variables NOT included in dataset for specify and code fields.]

8.c If Yes, is patient receiving dialysis? ☐ **1. NO** ☐ **2. YES**

[Variable NOT included in dataset.]

E9. Iron overload ☐ ☐

E9. Iron overload				
IRONOVER	Frequency	Percent	Cum Freq	Cum Percent
1	273	79.36	273	79.36
2	71	20.64	344	100.00

9.b If yes, highest ferritin level (ng/ml) ☐☐☐☐☐

Analysis Variable : FERRITIN E9b. Ferritin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
71	0	3010.2	1286.9	776.0	2053.0	2928.0	3850.0	7092.0

E9b. Ferritin				
FERRITIN	Frequency	Percent	Cum Freq	Cum Percent
-2	273	100.00	273	100.00

E10. Diabetes ☐ ☐

E10. Diabetes				
DIABETES	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

E11. Rheumatic fever ☐ ☐

E11. Rheumatc fever				
RHEUMATC	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E12. Tuberculosis ☐ ☐

E12. Tuberculosis				
TUBERCUL	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

E13. Cancer ☐ ☐

13b. If Yes, specify type: _____

☐☐☐.☐☐ **OFFICE USE**

E13. Cancer				
CANCER	Frequency	Percent	Cum Freq	Cum Percent
1	344	100.00	344	100.00

[Variables NOT included in dataset for specify and code fields.]

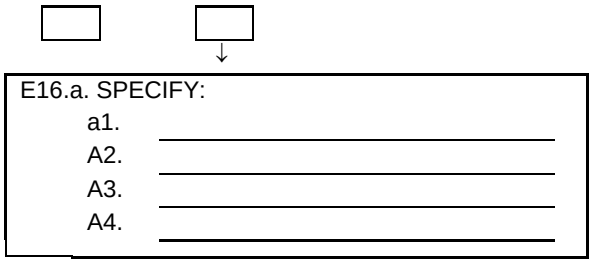
E14. Priapism ☐ ☐

E14. Priapism				
PRIAP	Frequency	Percent	Cum Freq	Cum Percent
-1	213	61.92	213	61.92
1	131	38.08	344	100.00

E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?) ☐ ☐

E15. Elevated blood lead level				
ELEV_BLD	Frequency	Percent	Cum Freq	Cum Percent
-3	7	2.03	7	2.03
-1	1	0.29	8	2.33
1	336	97.67	344	100.00

E16. New red cell antibody



E16. New red cell antibody				
RBCANTI	Frequency	Percent	Cum Freq	Cum Percent
1	338	98.26	338	98.26
2	6	1.74	344	100.00

E16a1. New red cell antibody,specify				
RBC_SPC1	Frequency	Percent	Cum Freq	Cum Percent
+W direct	1	0.29	1	0.29
-2	338	98.26	339	98.55
Anti E	1	0.29	340	98.84
anti RH10	1	0.29	341	99.13
auto antibody	2	0.58	343	99.71
warm auto antibody	1	0.29	344	100.00

E16a2. New red cell antibody 2,specify				
RBC_SPC2	Frequency	Percent	Cum Freq	Cum Percent
-1	4	1.16	4	1.16
-2	338	98.26	342	99.42
anti CW - Indirect	1	0.29	343	99.71
anti RH8	1	0.29	344	100.00

E16a3. New red cell antibody 3,specify				
RBC_SPC3	Frequency	Percent	Cum Freq	Cum Percent
-1	6	1.74	6	1.74
-2	338	98.26	344	100.00

[Variable NOT included in dataset for A4 specify field. Field contained no data.]

Since the last quarterly report was the patient **newly** diagnosed with:
(CHECK NO OR YES FOR EACH OF E1 - E17)

1. NO **2. YES**

E17. Any other chronic medical condition? ☐ ☐

17.a. If Yes, specify type: a1. _____
a2. _____

☐☐☐.☐☐ **OFFICE USE**

☐☐☐.☐☐ **OFFICE USE**

E17. Other condition				
OTHCOND	Frequency	Percent	Cum Freq	Cum Percent
1	337	97.97	337	97.97
2	7	2.03	344	100.00

[Variables NOT included in dataset for specify and code fields.]

F. VACCINATIONS

F1. Since the last quarterly report, has the patient received Hepatitis B vaccination?

☐ **1. NO** ☐ **2. YES**

F1. HepB Vaccination				
HEPBVACC	Frequency	Percent	Cum Freq	Cum Percent
1	340	98.84	340	98.84
2	4	1.16	344	100.00

↓

F1.a Date of vaccination (Month/Day/Year)

___ ___/___ ___/___ ___ ___ ___

Analysis Variable : vacc_dtfrmrand <created variable> F1a. Vaccination date as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	-562.3	290.8	-785.0	-767.0	-656.5	-357.5	-151.0

<created variable> F1a. Vaccination date as days from RAND visit				
vacc_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	340	100.00	340	100.00

G. GENERAL

G1. Is the patient seen for most of his/her clinical events at a NON-STOP II study site because of third party payment restrictions, distance from clinic, some other reason? ☐ **1. NO** ☐ **2. YES**

G1. Is patient seen at non-STOP II sites				
NON_STOP	Frequency	Percent	Cum Freq	Cum Percent
1	336	97.67	336	97.67
2	8	2.33	344	100.00

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___

STOP II
FORM 16R: QUARTERLY MEDICAL RECORD REVIEW

A. Collection Information:

The **Quarterly Medical Record Review** (Form 16R) was to be completed for patients enrolled as Potential patients at quarterly visits and for Randomized patients at quarterly, yearly, and exit visits.

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p16r_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 2,083 (198)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 433-436
- Listing of Variables by Position: See pp. 437-440

H. Formats:

The file **f16Rfmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 441-446.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The only valid EX_TYPE for Form 16R is QT: for quarterly and annual visits

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 16R are:
  - 200 series numbers were assigned to “Potential 1” visits – i.e., quarterly visits completed while the patient was on transfusion for < 30 months (prior to randomization)
  - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months (prior to randomization)
  - 400 series numbers indicate visits completed after randomization
    - 401=randomization visit
    - 405, 409, or 413=annual visits

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

- **SPLENSEQ** - is the variable name for splenic sequestration events. Cases where this variable is coded "-1:Not Applicable" refer to patients who have had a splenectomy. This code was not standardized for this variable and does not capture all patients or all records for patients who had a splenectomy.

- **PRIAPISM** - is the variable name for priapism events. Cases where this variable is coded "-1:Not Applicable" refer to patients who are female. This code was not standardized for this variable and does not capture all patients or all records for patients who are female.

- **Section B. Documentation of Clinical Events** - A limited number of event date fields were allowed for each type of event in section B as listed in the table below. Where the number of events exceeded the allotted date fields for that event, the most recent dates of events prior to the QT visit were listed.

Question #	# of Events Variable Name	# of Date Fields
B1a	STROKNUM	2
B2a	TIA_NUM	2
B3a	SEIZ_NUM	2
B4a	SPLN_NUM	2
B5a	APLA_NUM	2
B6a	HFSY_NUM	2
B7a	VASO_NUM	4
B8a	FEVR_NUM	4
B9a	SEPT_NUM	3
B10a	PNEU_NUM	4
B11a	MENI_NUM	2
B12a	OSTE_NUM	2
B13a	PRIA_NUM	2
B14a	REAC_NUM	2
B15a	OTHR_NUM	3
B16a	TRANSNUM	5
B17a	SURG_NUM	3

Data Set Name	PUBDS.P16R_FINAL	Observations	1077
Member Type	DATA	Variables	129
Engine	V9	Indexes	0
Created	Friday, March 17, 2006 03:08:43 PM	Observation Length	1568
Last Modified	Friday, March 17, 2006 03:08:43 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	109
First Data Page	2
Max Obs per Page	10
Obs in First Data Page	7
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p16r_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
17	APLASTIC	Num	8	3.	B5. Event Documented: Aplastic Crisis
20	APLAS_C1	Num	8	3.	B5d. STOP II event form completed: Aplastic Crisis
18	APLA_NUM	Num	8	3.	B5a. # of Events: Aplastic Crisis
19	APLSEEN1	Num	8	3.	B5c. Where was patient seen for event 1: Aplastic Crisis
91	DESTATUS	Char	1	$1.	DESTATUS
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
30	FEVER	Num	8	3.	B8. Event Documented: Fever greater than or equal to 101
33	FEVER_C1	Num	8	3.	B8d. STOP II event form completed: Fever > or = 101
35	FEVER_C2	Num	8	3.	B8g. STOP II event form completed: Fever > or = 101
37	FEVER_C3	Num	8	3.	B8j. STOP II event form completed: Fever > or = 101
39	FEVER_C4	Num	8	3.	B8m. STOP II event form completed: Fever > or = 101
31	FEVR_NUM	Num	8	3.	B8a. # of Events: Fever greater than or equal to 101
32	FEVSEEN1	Num	8	3.	B8c. Where was patient seen for event 1: Fever > or = 101
34	FEVSEEN2	Num	8	3.	B8f. Where was patient seen for event 2: Fever > or = 101
36	FEVSEEN3	Num	8	3.	B8i. Where was patient seen for event 3: Fever > or = 101
38	FEVSEEN4	Num	8	3.	B8l. Where was patient seen for event 4: Fever > or = 101
21	HF_SYND	Num	8	3.	B6. Event Documented: Hand-Foot Syndrome
50	MENINGIT	Num	8	3.	B11. Event Documented: Meningitis
51	OSTEOMYE	Num	8	3.	B12. Event Documented: Osteomyelitis
54	OSTEO_C1	Num	8	3.	B12d. STOP II event form completed: Osteomyelitis
52	OSTE_NUM	Num	8	3.	B12a. # of Events: Osteomyelitis
53	OSTSEEN1	Num	8	3.	B12c. Where was patient seen for event 1: Osteomyelitis
63	OTHER	Num	8	3.	B15. Event Documented: Other
66	OTHER_C1	Num	8	3.	B15d.1. STOP II event form completed: Other
68	OTHER_C2	Num	8	3.	B15d.2. STOP II event form completed: Other

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
70	OTHER_C3	Num	8	3.	B15d.3. STOP II event form completed: Other
64	OTHR_NUM	Num	8	3.	B15a. # of Events: Other
65	OTHSEEN1	Num	8	3.	B15c.1. Where was patient seen for event 1: Other
67	OTHSEEN2	Num	8	3.	B15c.2. Where was patient seen for event 2: Other
69	OTHSEEN3	Num	8	3.	B15c.3. Where was patient seen for event 3: Other
46	PNEUMONA	Num	8	3.	B1O. Event Documented: Pneumonia
48	PNEUSEN1	Num	8	3.	B1Oc. Where was patient seen for event 1: Pneumonia/ACS
47	PNEU_NUM	Num	8	3.	B1Oa. # of Events: Pneumonia/ACS
49	PNUEM_C1	Num	8	3.	B1Od. STOP II event form completed: Pneumonia/ACS
55	PRIAPISM	Num	8	3.	B13. Event Documented: Priapism
58	PRIAP_C1	Num	8	3.	B13d. STOP II event form completed: Priapism
56	PRIA_NUM	Num	8	3.	B13a. # of Events: Priapism
57	PRISEEN1	Num	8	3.	B13c. Where was patient seen for event 1: Priapism
3	PTGROUP	Num	8	3.	A4. STOP II Patient Group
61	RCTSEEN1	Num	8	3.	B14c. Where was patient seen for event 1: Transfusion Reaction
62	REACT_C1	Num	8	3.	B14d. STOP II event form completed: Transfusion Reaction
60	REAC_NUM	Num	8	3.	B14a. # of Events: Transfusion Reaction
12	SEIZURES	Num	8	3.	B3. Event Documented: Seizures
42	SEPSEEN1	Num	8	3.	B9c. Where was patient seen for event 1: Septicemia
44	SEPSEEN2	Num	8	3.	B9f. Where was patient seen for event 2: Septicemia
43	SEPTC_C1	Num	8	3.	B9d. STOP II event form completed: Septicemia
45	SEPTC_C2	Num	8	3.	B9g. STOP II event form completed: Septicemia
40	SEPTICEM	Num	8	3.	B9. Event Documented: Septicemia
41	SEPT_NUM	Num	8	3.	B9a. # of Events: Septicemia
13	SPLENSEQ	Num	8	3.	B4. Event Documented: Splenic Sequestration
14	SPLN_NUM	Num	8	3.	B4a. # of Events: Splenic Sequestration
15	SPLSEEN1	Num	8	3.	B4c. Where was patient seen for event 1: Splenic Sequestration
16	SPLSEQC1	Num	8	3.	B4d. STOP II event form completed: Splenic Sequestration
4	STROKE	Num	8	3.	B1. Event Documented: Stroke
5	STROKNUM	Num	8	3.	B1a. # of Events: Stroke
7	STROK_C1	Num	8	3.	B1d. STOP II event form completed: Stroke
6	STRSEEN1	Num	8	3.	B1c. Where was patient seen for event 1: Stroke
83	SURGERY	Num	8	3.	B17. Event Documented: Surgery
85	SURGSEN1	Num	8	3.	B17c.1. Where was patient seen for surgery 1
87	SURGSEN2	Num	8	3.	B17c.2. Where was patient seen for surgery 2
89	SURGSEN3	Num	8	3.	B17c.3. Where was patient seen for surgery 3
86	SURG_C1	Num	8	3.	B17d.1. STOP II event form completed
88	SURG_C2	Num	8	3.	B17d.2. STOP II event form completed
90	SURG_C3	Num	8	3.	B17d.3. STOP II event form completed
84	SURG_NUM	Num	8	3.	B17a. # of Events: Surgery
8	TIA	Num	8	3.	B2. Event Documented: TIA
10	TIASEEN1	Num	8	3.	B2c. Where was patient seen for event 1: TIA
11	TIA_C1	Num	8	3.	B2d. STOP II event form completed: TIA
9	TIA_NUM	Num	8	3.	B2a. # of Events: TIA
74	TRANF_C1	Num	8	3.	B16d. STOP II event form completed: Transfusion
76	TRANF_C2	Num	8	3.	B16g. STOP II event form completed: Transfusion
78	TRANF_C3	Num	8	3.	B16j. STOP II event form completed: Transfusion
80	TRANF_C4	Num	8	3.	B16m. STOP II event form completed: Transfusion
82	TRANF_C5	Num	8	3.	B16p. STOP II event form completed: Transfusion

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
71	TRANSFSN	Num	8	3.	B16. Event Documented: Transfusion
72	TRANSNUM	Num	8	3.	B16a. # of Events: Transfusion
73	TRNSEEN1	Num	8	3.	B16c. Where was patient seen for event 1: Transfusion
75	TRNSEEN2	Num	8	3.	B16f. Where was patient seen for event 2: Transfusion
77	TRNSEEN3	Num	8	3.	B16i. Where was patient seen for event 3: Transfusion
79	TRNSEEN4	Num	8	3.	B16l. Where was patient seen for event 4: Transfusion
81	TRNSEEN5	Num	8	3.	B16o. Where was patient seen for event 5: Transfusion
59	T_REACTN	Num	8	3.	B14. Event Documented: Transfusion Reaction
22	VASOPAIN	Num	8	3.	B7. Event Documented: Vaso-occlusive pain
25	VASOP_C1	Num	8	3.	B7d. STOP II event form completed: Vaso-occlusive pain
27	VASOP_C2	Num	8	3.	B7g. STOP II event form completed: Vaso-occlusive pain
29	VASOP_C3	Num	8	3.	B7j. STOP II event form completed: Vaso-occlusive pain
24	VASOSEN1	Num	8	3.	B7c. Where was patient seen for event 1: Vaso-occlusive pain
26	VASOSEN2	Num	8	3.	B7f. Where was patient seen for event 2: Vaso-occlusive pain
28	VASOSEN3	Num	8	3.	B7i. Where was patient seen for event 3: Vaso-occlusive pain
23	VASO_NUM	Num	8	3.	B7a. # of Events: Vaso-occlusive pain
99	aplas_d1frmrand	Num	8		<created variable> B5b. 1st Date of Event: Aplastic Crisis as days from RAND visit
94	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
103	fever_d1frmrand	Num	8		<created variable> B8b. 1st Date of Event: Fever greater than or equal to 101 as days from RAND visit
104	fever_d2frmrand	Num	8		<created variable> B8e. 2nd Date of Event: Fever greater than or equal to 101 as days from RAND visit
105	fever_d3frmrand	Num	8		<created variable> B8h. 3rd Date of Event: Fever greater than or equal to 101 as days from RAND visit
106	fever_d4frmrand	Num	8		<created variable> B8k. 4th Date of Event: Fever greater than or equal to 101 as days from RAND visit
93	ldu_id	Char	10		ID for public use datasets
110	osteo_d1frmrand	Num	8		<created variable> B12b. 1st Date of Event: Osteomyelitis as days from RAND visit
113	other_d1frmrand	Num	8		<created variable> B15b.1. Date of Event 1: Other as days from RAND visit
114	other_d2frmrand	Num	8		<created variable> B15b.2. Date of Event 2: Other as days from RAND visit
115	other_d3frmrand	Num	8		<created variable> B15b.3. Date of Event 3: Other as days from RAND visit
124	othspec1_recode	Char	100		<recoded variable> B15a.1. Specify 1: Other
125	othspec2_recode	Char	100		<recoded variable> B15a.2. Specify 2: Other
126	othspec3_recode	Char	100		<recoded variable> B15a.3. Specify 3: Other
109	pnuem_d1frmrand	Num	8		<created variable> B10b. 1st Date of Event: Pneumonia/ACS as days from RAND visit
111	priap_d1frmrand	Num	8		<created variable> B13b. 1st Date of Event: Priapism as days from RAND visit
95	qrtrpt_dfrmrand	Num	8		<created variable> A3. Date Quarterly Progress Report Completed as days from RAND visit
112	react_d1frmrand	Num	8		<created variable> B14b. 1st Date of Event: Transfusion Reaction as days from RAND visit

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
107	septc_d1frmrand	Num	8		<created variable> B9a. # of Events: Septicemia as days from RAND visit
108	septc_d2frmrand	Num	8		<created variable> B9e. 2nd Date of Event: Septicemia as days from RAND visit
98	spls_d1frmrand	Num	8		<created variable> B4b. 1st Date of Event: Splenic Sequestration as days from RAND visit
96	strok_d1frmrand	Num	8		<created variable> B1b. 1st Date of Event: Stroke as days from RAND visit
121	surg_d1frmrand	Num	8		<created variable> B17b.1. Date of Surgery 1 as days from RAND visit
122	surg_d2frmrand	Num	8		<created variable> B17b.2. Date of Surgery 2 as days from RAND visit
123	surg_d3frmrand	Num	8		<created variable> B17b.3. Date of Surgery 3 as days from RAND visit
127	surgery1_recode	Char	100		<recoded variable> B17a.1. Surgery 1
128	surgery2_recode	Char	100		<recoded variable> B17a.2. Surgery 2
129	surgery3_recode	Char	100		<recoded variable> B17a.3. Surgery 3
97	tia_dt1frmrand	Num	8		<created variable> B2b. 1st Date of Event: TIA as days from RAND visit
116	tranf_d1frmrand	Num	8		<created variable> B16b. 1st Date of Event: Transfusion as days from RAND visit
117	tranf_d2frmrand	Num	8		<created variable> B16e. 2nd Date of Event: Transfusion as days from RAND visit
118	tranf_d3frmrand	Num	8		<created variable> B16h. 3rd Date of Event: Transfusion as days from RAND visit
119	tranf_d4frmrand	Num	8		<created variable> B16k. 4th Date of Event: Transfusion as days from RAND visit
120	tranf_d5frmrand	Num	8		<created variable> B16n. 5th Date of Event: Transfusion as days from RAND visit
100	vasop_d1frmrand	Num	8		<created variable> B7b. 1st Date of Event: Vaso-occlusive pain as days from RAND visit
101	vasop_d2frmrand	Num	8		<created variable> B7e. 2nd Date of Event: Vaso-occlusive pain as days from RAND visit
102	vasop_d3frmrand	Num	8		<created variable> B7h. 3rd Date of Event: Vaso-occlusive pain as days from RAND visit
92	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	PTGROUP	Num	8	3.	A4. STOP II Patient Group
4	STROKE	Num	8	3.	B1. Event Documented: Stroke
5	STROKNUM	Num	8	3.	B1a. # of Events: Stroke
6	STRSEEN1	Num	8	3.	B1c. Where was patient seen for event 1: Stroke
7	STROK_C1	Num	8	3.	B1d. STOP II event form completed: Stroke
8	TIA	Num	8	3.	B2. Event Documented: TIA
9	TIA_NUM	Num	8	3.	B2a. # of Events: TIA
10	TIASEEN1	Num	8	3.	B2c. Where was patient seen for event 1: TIA
11	TIA_C1	Num	8	3.	B2d. STOP II event form completed: TIA
12	SEIZURES	Num	8	3.	B3. Event Documented: Seizures
13	SPLENSEQ	Num	8	3.	B4. Event Documented: Splenic Sequestration
14	SPLN_NUM	Num	8	3.	B4a. # of Events: Splenic Sequestration
15	SPLSEEN1	Num	8	3.	B4c. Where was patient seen for event 1: Splenic Sequestration
16	SPLSEQC1	Num	8	3.	B4d. STOP II event form completed: Splenic Sequestration
17	APLASTIC	Num	8	3.	B5. Event Documented: Aplastic Crisis
18	APLA_NUM	Num	8	3.	B5a. # of Events: Aplastic Crisis
19	APLSEEN1	Num	8	3.	B5c. Where was patient seen for event 1: Aplastic Crisis
20	APLAS_C1	Num	8	3.	B5d. STOP II event form completed: Aplastic Crisis
21	HF_SYND	Num	8	3.	B6. Event Documented: Hand-Foot Syndrome
22	VASOPAIN	Num	8	3.	B7. Event Documented: Vaso-occlusive pain
23	VASO_NUM	Num	8	3.	B7a. # of Events: Vaso-occlusive pain
24	VASOSEN1	Num	8	3.	B7c. Where was patient seen for event 1: Vaso-occlusive pain
25	VASOP_C1	Num	8	3.	B7d. STOP II event form completed: Vaso-occlusive pain
26	VASOSEN2	Num	8	3.	B7f. Where was patient seen for event 2: Vaso-occlusive pain
27	VASOP_C2	Num	8	3.	B7g. STOP II event form completed: Vaso-occlusive pain
28	VASOSEN3	Num	8	3.	B7i. Where was patient seen for event 3: Vaso-occlusive pain
29	VASOP_C3	Num	8	3.	B7j. STOP II event form completed: Vaso-occlusive pain
30	FEVER	Num	8	3.	B8. Event Documented: Fever greater than or equal to 101
31	FEVR_NUM	Num	8	3.	B8a. # of Events: Fever greater than or equal to 101
32	FEVSEEN1	Num	8	3.	B8c. Where was patient seen for event 1: Fever > or = 101
33	FEVER_C1	Num	8	3.	B8d. STOP II event form completed: Fever > or = 101
34	FEVSEEN2	Num	8	3.	B8f. Where was patient seen for event 2: Fever > or = 101
35	FEVER_C2	Num	8	3.	B8g. STOP II event form completed: Fever > or = 101
36	FEVSEEN3	Num	8	3.	B8i. Where was patient seen for event 3: Fever > or = 101
37	FEVER_C3	Num	8	3.	B8j. STOP II event form completed: Fever > or = 101
38	FEVSEEN4	Num	8	3.	B8l. Where was patient seen for event 4: Fever > or = 101
39	FEVER_C4	Num	8	3.	B8m. STOP II event form completed: Fever > or = 101
40	SEPTICEM	Num	8	3.	B9. Event Documented: Septicemia
41	SEPT_NUM	Num	8	3.	B9a. # of Events: Septicemia
42	SEPSEEN1	Num	8	3.	B9c. Where was patient seen for event 1: Septicemia
43	SEPTC_C1	Num	8	3.	B9d. STOP II event form completed: Septicemia
44	SEPSEEN2	Num	8	3.	B9f. Where was patient seen for event 2: Septicemia
45	SEPTC_C2	Num	8	3.	B9g. STOP II event form completed: Septicemia
46	PNEUMONA	Num	8	3.	B10. Event Documented: Pneumonia
47	PNEU_NUM	Num	8	3.	B10a. # of Events: Pneumonia/ACS
48	PNEUSEN1	Num	8	3.	B10c. Where was patient seen for event 1: Pneumonia/ACS
49	PNUEM_C1	Num	8	3.	B10d. STOP II event form completed: Pneumonia/ACS
50	MENINGIT	Num	8	3.	B11. Event Documented: Meningitis

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
51	OSTEOMYE	Num	8	3.	B12. Event Documented: Osteomyelitis
52	OSTE_NUM	Num	8	3.	B12a. # of Events: Osteomyelitis
53	OSTSEEN1	Num	8	3.	B12c. Where was patient seen for event 1: Osteomyelitis
54	OSTEO_C1	Num	8	3.	B12d. STOP II event form completed: Osteomyelitis
55	PRIAPISM	Num	8	3.	B13. Event Documented: Priapism
56	PRIA_NUM	Num	8	3.	B13a. # of Events: Priapism
57	PRISEEN1	Num	8	3.	B13c. Where was patient seen for event 1: Priapism
58	PRIAP_C1	Num	8	3.	B13d. STOP II event form completed: Priapism
59	T_REACTN	Num	8	3.	B14. Event Documented: Transfusion Reaction
60	REAC_NUM	Num	8	3.	B14a. # of Events: Transfusion Reaction
61	RCTSEEN1	Num	8	3.	B14c. Where was patient seen for event 1: Transfusion Reaction
62	REACT_C1	Num	8	3.	B14d. STOP II event form completed: Transfusion Reaction
63	OTHER	Num	8	3.	B15. Event Documented: Other
64	OTHR_NUM	Num	8	3.	B15a. # of Events: Other
65	OTHSEEN1	Num	8	3.	B15c.1. Where was patient seen for event 1: Other
66	OTHER_C1	Num	8	3.	B15d.1. STOP II event form completed: Other
67	OTHSEEN2	Num	8	3.	B15c.2. Where was patient seen for event 2: Other
68	OTHER_C2	Num	8	3.	B15d.2. STOP II event form completed: Other
69	OTHSEEN3	Num	8	3.	B15c.3. Where was patient seen for event 3: Other
70	OTHER_C3	Num	8	3.	B15d.3. STOP II event form completed: Other
71	TRANSFSN	Num	8	3.	B16. Event Documented: Transfusion
72	TRANSNUM	Num	8	3.	B16a. # of Events: Transfusion
73	TRNSEEN1	Num	8	3.	B16c. Where was patient seen for event 1: Transfusion
74	TRANF_C1	Num	8	3.	B16d. STOP II event form completed: Transfusion
75	TRNSEEN2	Num	8	3.	B16f. Where was patient seen for event 2: Transfusion
76	TRANF_C2	Num	8	3.	B16g. STOP II event form completed: Transfusion
77	TRNSEEN3	Num	8	3.	B16i. Where was patient seen for event 3: Transfusion
78	TRANF_C3	Num	8	3.	B16j. STOP II event form completed: Transfusion
79	TRNSEEN4	Num	8	3.	B16l. Where was patient seen for event 4: Transfusion
80	TRANF_C4	Num	8	3.	B16m. STOP II event form completed: Transfusion
81	TRNSEEN5	Num	8	3.	B16o. Where was patient seen for event 5: Transfusion
82	TRANF_C5	Num	8	3.	B16p. STOP II event form completed: Transfusion
83	SURGERY	Num	8	3.	B17. Event Documented: Surgery
84	SURG_NUM	Num	8	3.	B17a. # of Events: Surgery
85	SURGSEN1	Num	8	3.	B17c.1. Where was patient seen for surgery 1
86	SURG_C1	Num	8	3.	B17d.1. STOP II event form completed
87	SURGSEN2	Num	8	3.	B17c.2. Where was patient seen for surgery 2
88	SURG_C2	Num	8	3.	B17d.2. STOP II event form completed
89	SURGSEN3	Num	8	3.	B17c.3. Where was patient seen for surgery 3
90	SURG_C3	Num	8	3.	B17d.3. STOP II event form completed
91	DESTATUS	Char	1	$1.	DESTATUS
92	vistype	Char	7		<created variable> VISIT TYPE
93	ldu_id	Char	10		ID for public use datasets
94	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
95	qrtrpt_dfrmrand	Num	8		<created variable> A3. Date Quarterly Progress Report Completed as days from RAND visit
96	strok_d1frmrand	Num	8		<created variable> B1b. 1st Date of Event: Stroke as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
97	tia_dt1frmrand	Num	8		<created variable> B2b. 1st Date of Event: TIA as days from RAND visit
98	spls_d1frmrand	Num	8		<created variable> B4b. 1st Date of Event: Splenic Sequestration as days from RAND visit
99	aplas_d1frmrand	Num	8		<created variable> B5b. 1st Date of Event: Aplastic Crisis as days from RAND visit
100	vasop_d1frmrand	Num	8		<created variable> B7b. 1st Date of Event: Vaso-occlusive pain as days from RAND visit
101	vasop_d2frmrand	Num	8		<created variable> B7e. 2nd Date of Event: Vaso-occlusive pain as days from RAND visit
102	vasop_d3frmrand	Num	8		<created variable> B7h. 3rd Date of Event: Vaso-occlusive pain as days from RAND visit
103	fever_d1frmrand	Num	8		<created variable> B8b. 1st Date of Event: Fever greater than or equal to 101 as days from RAND visit
104	fever_d2frmrand	Num	8		<created variable> B8e. 2nd Date of Event: Fever greater than or equal to 101 as days from RAND visit
105	fever_d3frmrand	Num	8		<created variable> B8h. 3rd Date of Event: Fever greater than or equal to 101 as days from RAND visit
106	fever_d4frmrand	Num	8		<created variable> B8k. 4th Date of Event: Fever greater than or equal to 101 as days from RAND visit
107	septc_d1frmrand	Num	8		<created variable> B9a. # of Events: Septicemia as days from RAND visit
108	septc_d2frmrand	Num	8		<created variable> B9e. 2nd Date of Event: Septicemia as days from RAND visit
109	pnuem_d1frmrand	Num	8		<created variable> B10b. 1st Date of Event: Pneumonia/ACS as days from RAND visit
110	osteo_d1frmrand	Num	8		<created variable> B12b. 1st Date of Event: Osteomyelitis as days from RAND visit
111	priap_d1frmrand	Num	8		<created variable> B13b. 1st Date of Event: Priapism as days from RAND visit
112	react_d1frmrand	Num	8		<created variable> B14b. 1st Date of Event: Transfusion Reaction as days from RAND visit
113	other_d1frmrand	Num	8		<created variable> B15b.1. Date of Event 1: Other as days from RAND visit
114	other_d2frmrand	Num	8		<created variable> B15b.2. Date of Event 2: Other as days from RAND visit
115	other_d3frmrand	Num	8		<created variable> B15b.3. Date of Event 3: Other as days from RAND visit
116	tranf_d1frmrand	Num	8		<created variable> B16b. 1st Date of Event: Transfusion as days from RAND visit
117	tranf_d2frmrand	Num	8		<created variable> B16e. 2nd Date of Event: Transfusion as days from RAND visit
118	tranf_d3frmrand	Num	8		<created variable> B16h. 3rd Date of Event: Transfusion as days from RAND visit
119	tranf_d4frmrand	Num	8		<created variable> B16k. 4th Date of Event: Transfusion as days from RAND visit
120	tranf_d5frmrand	Num	8		<created variable> B16n. 5th Date of Event: Transfusion as days from RAND visit
121	surg_d1frmrand	Num	8		<created variable> B17b.1. Date of Surgery 1 as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
122	surg_d2frmrand	Num	8		<created variable> B17b.2. Date of Surgery 2 as days from RAND visit
123	surg_d3frmrand	Num	8		<created variable> B17b.3. Date of Surgery 3 as days from RAND visit
124	othspec1_recode	Char	100		<recoded variable> B15a.1. Specify 1: Other
125	othspec2_recode	Char	100		<recoded variable> B15a.2. Specify 2: Other
126	othspec3_recode	Char	100		<recoded variable> B15a.3. Specify 3: Other
127	surgery1_recode	Char	100		<recoded variable> B17a.1. Surgery 1
128	surgery2_recode	Char	100		<recoded variable> B17a.2. Surgery 2
129	surgery3_recode	Char	100		<recoded variable> B17a.3. Surgery 3

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

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value OSTEOMYEF
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  2='2: Yes';

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  2='2: Non-STOP II Center';

value OTHSEEN3F
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STOP II TRIAL

QUARTERLY MEDICAL RECORD REVIEW

AFFIX PATIENT'S LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1061	98.51	1061	98.51
P	16	1.49	1077	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-202	27	2.51	27	2.51
QT-203	24	2.23	51	4.74
QT-204	26	2.41	77	7.15
QT-205	26	2.41	103	9.56
QT-206	22	2.04	125	11.61
QT-207	20	1.86	145	13.46
QT-208	18	1.67	163	15.13
QT-209	17	1.58	180	16.71
QT-210	16	1.49	196	18.20
QT-301	32	2.97	228	21.17
QT-302	42	3.90	270	25.07
QT-303	23	2.14	293	27.21
QT-304	21	1.95	314	29.16
QT-305	12	1.11	326	30.27
QT-306	6	0.56	332	30.83
QT-307	3	0.28	335	31.10
QT-308	3	0.28	338	31.38
QT-309	2	0.19	340	31.57
QT-310	2	0.19	342	31.75
QT-401	79	7.34	421	39.09
QT-402	75	6.96	496	46.05
QT-403	74	6.87	570	52.92
QT-404	65	6.04	635	58.96
QT-405	60	5.57	695	64.53
QT-406	54	5.01	749	69.55
QT-407	48	4.46	797	74.00
QT-408	50	4.64	847	78.64
QT-409	44	4.09	891	82.73
QT-410	43	3.99	934	86.72
QT-411	38	3.53	972	90.25
QT-412	36	3.34	1008	93.59
QT-413	33	3.06	1041	96.66
QT-414	18	1.67	1059	98.33
QT-415	13	1.21	1072	99.54
QT-416	5	0.46	1077	100.00

THIS FORM IS TO BE COMPLETED AS SOON AS POSSIBLE AFTER EACH QUARTERLY PROGRESS REPORT IS COMPLETED. PLEASE REVIEW MEDICAL RECORDS FOR THE TIME PERIOD COVERED BY THE QUARTERLY PROGRESS REPORT IN ORDER TO CORROBORATE THE OCCURRENCE/NON-OCCURRENCE OF EVENTS LISTED ON PAGES 2 AND 3 OF THE QUARTERLY PROGRESS REPORT. IF THE PATIENT WAS SEEN FOR AN EVENT AT A NON-STOP II STUDY SITE, MEDICAL RECORDS FROM THAT SITE SHOULD ALSO BE CHECKED AND/OR APPROPRIATE MEDICAL PERSONNEL CONTACTED. PLEASE MAKE SURE TO COMPLETE THE APPROPRIATE STOP II STUDY EVENT FORM*:

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of interview as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1076	0	220.1	528.9	-1237	-103.0	180.5	629.5	1399.0

<created variable> A2. Date of interview as days from RAND visit

comp_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

A3. Date Quarterly Progress Report completed (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : qrtrpt_dfrmrand <created variable> A3. Date Quarterly Progress Report Completed as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1077	0	210.4	530.9	-1237	-119.0	175.0	623.0	1399.0

A4. STOP II Patient group: ☐ **1. POTENTIAL CANDIDATE** ☐ **2. RANDOMIZED PATIENT**

A4. STOP II Patient Group

PTGROUP	Frequency	Percent	Cum Freq	Cum Percent
1	345	32.03	345	32.03
2	732	67.97	1077	100.00

B. DOCUMENTATION OF CLINICAL EVENTS

During the period covered in the Quarterly Progress Report, indicate if the occurrence of each of the following events was documented by medical records and/or medical personnel:

Event	Event Documented 1. NO 2. YES	# of Events	Date of Event	Where was patient seen for event? 1 = STOP II Center 2 = Non-STOP II Center	Was STOP II event form* completed? (see below) 1. NO 2. YES
B1. Stroke	☐ ☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B1. Event Documented: Stroke				
STROKE	Frequency	Percent	Cum Freq	Cum Percent
1	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

B1a. # of Events: Stroke				
STROKNUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

Analysis Variable : strok_d1frmrand <created variable> B1b. 1st Date of Event: Stroke as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	295.0	.	295.0	295.0	295.0	295.0	295.0

<created variable> B1b. 1st Date of Event: Stroke as days from RAND visit				
strok_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1076	100.00	1076	100.00

B1c. Where was patient seen for event 1: Stroke				
STRSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

B1d. STOP II event form completed: Stroke				
STROK_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

e. __ __/__ __/__ __ __ __ f. ☐ g. ☐ ☐

[No other stroke reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B2. TIA	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B2. Event Documented: TIA				
TIA	Frequency	Percent	Cum Freq	Cum Percent
1	1075	99.81	1075	99.81
2	2	0.19	1077	100.00

B2a. # of Events: TIA				
TIA_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1075	99.81	1075	99.81
1	2	0.19	1077	100.00

Analysis Variable : tia_dt1frmrand <created variable> B2b. 1st Date of Event: TIA as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	147.5	4.9	144.0	144.0	147.5	151.0	151.0

<created variable> B2b. 1st Date of Event: TIA as days from RAND visit

tia_dt1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1075	100.00	1075	100.00

B2c. Where was patient seen for event 1: TIA				
TIASEEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1075	99.81	1075	99.81
1	1	0.09	1076	99.91
2	1	0.09	1077	100.00

B2d. STOP II event form completed: TIA				
TIA_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1075	99.81	1075	99.81
2	2	0.19	1077	100.00

e. __ __/__ __/__ __ __ __ f. ☐ g. ☐ ☐

[No other TIA reported. Variables NOT included in dataset.]

Event	Event Documented		# of Events	Date of Event	Where was patient seen for event? 1 = STOP II Center 2 = Non-STOP II Center	Was STOP II event form* completed? (see below)	
	1. NO	2. YES				1. NO	2. YES
B3. Seizures	☐	☐ → a. ☐		b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐

B3. Event Documented: Seizures				
SEIZURES	Frequency	Percent	Cum Freq	Cum Percent
1	1077	100.00	1077	100.00

[No seizures reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B4. Splenic Sequestration	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B4. Event Documented: Splenic Sequestration				
SPLENSEQ	Frequency	Percent	Cum Freq	Cum Percent
-1	6	0.56	6	0.56
1	1070	99.35	1076	99.91
2	1	0.09	1077	100.00

B4a. # of Events: Splenic Sequestration				
SPLN_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

Analysis Variable : spls_d1frmrand <created variable> B4b. 1st Date of Event: Splenic Sequestration as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-510.0	.	-510.0	-510.0	-510.0	-510.0	-510.0

<created variable> B4b. 1st Date of Event: Splenic Sequestration as days from RAND visit				
spls_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1076	100.00	1076	100.00

B4c. Where was patient seen for event 1: Splenic Sequestration				
SPLSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

B4d. STOP II event form completed: Splenic Sequestration				
SPLSEQC1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

e. __ __/__ __/__ __ __ __ f. ☐ g. ☐ ☐

[No other splenic sequestration reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B5. Aplastic Crisis	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B5. Event Documented: Aplastic Crisis				
APLASTIC	Frequency	Percent	Cum Freq	Cum Percent
1	1074	99.72	1074	99.72
2	3	0.28	1077	100.00

B5a. # of Events: Aplastic Crisis				
APLA_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1074	99.72	1074	99.72
1	3	0.28	1077	100.00

Analysis Variable : aplas_d1frmrand <created variable> B5b. 1st Date of Event: Aplastic Crisis as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	461.0	369.0	92.0	92.0	461.0	830.0	830.0

<created variable> B5b. 1st Date of Event: Aplastic Crisis as days from RAND visit				
aplas_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1074	100.00	1074	100.00

B5c. Where was patient seen for event 1: Aplastic Crisis				
APLSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1074	99.72	1074	99.72
1	2	0.19	1076	99.91
2	1	0.09	1077	100.00

B5d. STOP II event form completed: Aplastic Crisis				
APLAS_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1074	99.72	1074	99.72
1	1	0.09	1075	99.81
2	2	0.19	1077	100.00

e. __ __/__ __/__ __ __ __ f. ☐ g. ☐ ☐

[No other aplastic crisis reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)	
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO	2. YES
B6. Hand-Foot Syndrome	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐

B6. Event Documented: Hand-Foot Syndrome				
HF_SYND	Frequency	Percent	Cum Freq	Cum Percent
1	1077	100.00	1077	100.00

[No hand-foot syndrome reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B7. Vaso-occlusive pain event for which patient was hospitalized	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B7. Event Documented: Vaso-occlusive pain				
VASOPAIN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
1	976	90.62	977	90.71
2	100	9.29	1077	100.00

B7a. # of Events: Vaso-occlusive pain				
VASO_NUM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	977	90.71	978	90.81
1	73	6.78	1051	97.59
2	21	1.95	1072	99.54
3	5	0.46	1077	100.00

Analysis Variable : vasop_d1frmrand <created variable> B7b. 1st Date of Event: Vaso-occlusive pain as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
98	0	410.9	459.8	-948.0	128.0	417.0	751.0	1319.0

<created variable> B7b. 1st Date of Event: Vaso-occlusive pain as days from RAND visit				
vasop_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	979	100.00	979	100.00

B7c. Where was patient seen for event 1: Vaso-occlusive pain				
VASOSEN1	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	977	90.71	978	90.81
1	87	8.08	1065	98.89
2	12	1.11	1077	100.00

B7d. STOP II event form completed: Vaso-occlusive pain				
VASOP_C1	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	977	90.71	978	90.81
1	26	2.41	1004	93.22
2	73	6.78	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B7. Vaso-occlusive pain event for which patient was hospitalized			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐

Analysis Variable : vasop_d2frmrand <created variable> B7e. 2nd Date of Event: Vaso-occlusive pain as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
26	0	459.3	388.7	-377.0	204.0	495.0	747.0	1123.0

<created variable> B7e. 2nd Date of Event: Vaso-occlusive pain as days from RAND visit				
vasop_d2frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1051	100.00	1051	100.00

B7f. Where was patient seen for event 2: Vaso-occlusive pain				
VASOSEN2	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	1051	97.59	1052	97.68
1	22	2.04	1074	99.72
2	3	0.28	1077	100.00

B7g. STOP II event form completed: Vaso-occlusive pain				
VASOP_C2	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	1051	97.59	1052	97.68
1	7	0.65	1059	98.33
2	18	1.67	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B7. Vaso-occlusive pain event for which patient was hospitalized			h. __ __/__ __/__ __ __ __	i. ☐	j. ☐ ☐

Analysis Variable : vasop_d3frmrand <created variable> B7h. 3rd Date of Event: Vaso-occlusive pain as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	568.5	572.5	-125.0	114.5	614.0	1022.5	1171.0

<created variable> B7h. 3rd Date of Event: Vaso-occlusive pain as days from RAND visit				
vasop_d3frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1073	100.00	1073	100.00

B7i. Where was patient seen for event 3: Vaso-occlusive pain				
VASOSEN3	Frequency	Percent	Cum Freq	Cum Percent
-2	1073	99.63	1073	99.63
1	4	0.37	1077	100.00

B7j. STOP II event form completed: Vaso-occlusive pain				
VASOP_C3	Frequency	Percent	Cum Freq	Cum Percent
-2	1073	99.63	1073	99.63
1	2	0.19	1075	99.81
2	2	0.19	1077	100.00

k. __ __/__ __/__ __ __ __ l. ☐ m. ☐ ☐

[No other vaso-occlusive pain event reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)	
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO	2. YES
B8. Fever ≥ 101°F (39°C)	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐

B8. Event Documented: Fever greater than or equal to 101				
FEVER	Frequency	Percent	Cum Freq	Cum Percent
1	961	89.23	961	89.23
2	116	10.77	1077	100.00

B8a. # of Events: Fever greater than or equal to 101				
FEVR_NUM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	961	89.23	962	89.32
1	96	8.91	1058	98.24
2	17	1.58	1075	99.81
3	1	0.09	1076	99.91
4	1	0.09	1077	100.00

Analysis Variable : fever_d1frmrand <created variable> B8b. 1st Date of Event: Fever greater than or equal to 101 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
110	0	174.7	505.0	-963.0	-127.0	168.0	515.0	1325.0

<created variable> B8b. 1st Date of Event: Fever greater than or equal to 101 as days from RAND visit				
fever_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	967	100.00	967	100.00

B8c. Where was patient seen for event 1: Fever > or = 101				
FEVSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-2	961	89.23	963	89.42
1	88	8.17	1051	97.59
2	26	2.41	1077	100.00

B8d. STOP II event form completed: Fever > or = 101				
FEVER_C1	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-2	961	89.23	963	89.42
1	44	4.09	1007	93.50
2	70	6.50	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B8. Fever ≥ 101°F (39°C)		e. __ __/__ __/__ __ __ __		f. ☐	g. ☐ ☐

Analysis Variable : fever_d2frmrand <created variable> B8e. 2nd Date of Event: Fever greater than or equal to 101 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
18	0	214.1	427.9	-859.0	66.0	189.5	529.0	826.0

<created variable> B8e. 2nd Date of Event: Fever greater than or equal to 101 as days from RAND visit				
fever_d2frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1059	100.00	1059	100.00

B8f. Where was patient seen for event 2: Fever > or = 101				
FEVSEEN2	Frequency	Percent	Cum Freq	Cum Percent
-2	1058	98.24	1058	98.24
1	14	1.30	1072	99.54
2	5	0.46	1077	100.00

B8g. STOP II event form completed: Fever > or = 101				
FEVER_C2	Frequency	Percent	Cum Freq	Cum Percent
-2	1058	98.24	1058	98.24
1	8	0.74	1066	98.98
2	11	1.02	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)	
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO	2. YES
B8. Fever ≥ 101°F (39°C)			h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐

Analysis Variable : fever_d3frmrand <created variable> B8h. 3rd Date of Event: Fever greater than or equal to 101 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	168.0	7.1	163.0	163.0	168.0	173.0	173.0

<created variable> B8h. 3rd Date of Event: Fever greater than or equal to 101 as days from RAND visit				
fever_d3frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1075	100.00	1075	100.00

B8i. Where was patient seen for event 3: Fever > or = 101				
FEVSEEN3	Frequency	Percent	Cum Freq	Cum Percent
-2	1075	99.81	1075	99.81
2	2	0.19	1077	100.00

B8j. STOP II event form completed: Fever > or = 101				
FEVER_C3	Frequency	Percent	Cum Freq	Cum Percent
-2	1075	99.81	1075	99.81
1	1	0.09	1076	99.91
2	1	0.09	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B8. Fever ≥ 101°F (39°C)			k. __ __/__ __/__ __ __ __	l. ☐	m. ☐ ☐

Analysis Variable : fever_d4frmrand <created variable> B8k. 4th Date of Event: Fever greater than or equal to 101 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	165.0	.	165.0	165.0	165.0	165.0	165.0

<created variable> B8k. 4th Date of Event: Fever greater than or equal to 101 as days from RAND visit				
fever_d4frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1076	100.00	1076	100.00

B8l. Where was patient seen for event 4: Fever > or = 101				
FEVSEEN4	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

B8m. STOP II event form completed: Fever > or = 101				
FEVER_C4	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B9. Septicemia	☐ ☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B9. Event Documented: Septicemia				
SEPTICEM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
1	1070	99.35	1071	99.44
2	6	0.56	1077	100.00

B9a. # of Events: Septicemia				
SEPT_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1071	99.44	1071	99.44
1	5	0.46	1076	99.91
2	1	0.09	1077	100.00

Analysis Variable : septc_d1frmrand <created variable> B9a. # of Events: Septicemia as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6	0	-1.0	558.5	-963.0	-63.0	45.5	163.0	766.0

<created variable> B9a. # of Events: Septicemia as days from RAND visit				
septc_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1071	100.00	1071	100.00

B9c. Where was patient seen for event 1: Septicemia				
SEPSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1071	99.44	1071	99.44
1	6	0.56	1077	100.00

B9d. STOP II event form completed: Septicemia				
SEPTC_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1071	99.44	1071	99.44
1	4	0.37	1075	99.81
2	2	0.19	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B9. Septicemia			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐

Analysis Variable : septc_d2frmrand <created variable> B9e. 2nd Date of Event: Septicemia as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	193.0	.	193.0	193.0	193.0	193.0	193.0

<created variable> B9e. 2nd Date of Event: Septicemia as days from RAND visit				
septc_d2frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1076	100.00	1076	100.00

B9f. Where was patient seen for event 2: Septicemia				
SEPSEEN2	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

B9g. STOP II event form completed: Septicemia				
SEPTC_C2	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

h. __ __/__ __/__ __ __ __ i. ☐ j. ☐ ☐

[No other septicemia reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B10. Pneumonia/ Acute Chest Syndrome	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B10. Event Documented: Pneumonia				
PNEUMONA	Frequency	Percent	Cum Freq	Cum Percent
1	1046	97.12	1046	97.12
2	31	2.88	1077	100.00

B10a. # of Events: Pneumonia/ACS				
PNEU_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1046	97.12	1046	97.12
1	31	2.88	1077	100.00

Analysis Variable : pnuem_d1frmrand <created variable> B10b. 1st Date of Event: Pneumonia/ACS as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
31	0	388.3	353.6	-513.0	154.0	301.0	664.0	1325.0

<created variable> B10b. 1st Date of Event: Pneumonia/ACS as days from RAND visit				
pnuem_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1046	100.00	1046	100.00

B10c. Where was patient seen for event 1: Pneumonia/ACS				
PNEUSEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1046	97.12	1046	97.12
1	27	2.51	1073	99.63
2	4	0.37	1077	100.00

B10d. STOP II event form completed: Pneumonia/ACS				
PNUEM_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1046	97.12	1046	97.12
1	4	0.37	1050	97.49
2	27	2.51	1077	100.00

Event	Event Documented 1. NO 2. YES	# of Events	Date of Event	Where was patient seen for event? 1 = STOP II Center 2 = Non-STOP II Center	Was STOP II event form* completed? (see below) 1. NO 2. YES
B10. Pneumonia/ Acute Chest Syndrome			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐
			h. __ __/__ __/__ __ __ __	i. ☐	j. ☐ ☐
			k. __ __/__ __/__ __ __ __	l. ☐	o. ☐ ☐

[No other pneumonia reported. Variables NOT included in dataset.]

Event	Event Documented 1. NO 2. YES	# of Events	Date of Event	Where was patient seen for event? 1 = STOP II Center 2 = Non-STOP II Center	Was STOP II event form* completed? (see below) 1. NO 2. YES
B11. Meningitis or Encephalitis	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐
			e. __ __/__ __/__ __ __ __	f. ☐	g. ☐ ☐

B11. Event Documented: Meningitis				
MENINGIT	Frequency	Percent	Cum Freq	Cum Percent
1	1077	100.00	1077	100.00

[No meningitis reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B12. Osteomyelitis	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B12. Event Documented: Osteomyelitis				
OSTEOMYE	Frequency	Percent	Cum Freq	Cum Percent
1	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

B12a. # of Events: Osteomyelitis				
OSTE_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

Analysis Variable : osteo_d1frmrand <created variable> B12b. 1st Date of Event: Osteomyelitis as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	490.0	.	490.0	490.0	490.0	490.0	490.0

<created variable> B12b. 1st Date of Event: Osteomyelitis as days from RAND visit				
osteo_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1076	100.00	1076	100.00

B12c. Where was patient seen for event 1: Osteomyelitis				
OSTSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

B12d. STOP II event form completed: Osteomyelitis				
OSTEO_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

e. __ __/__ __/__ __ __ __ f. ☐ g. ☐ ☐

[No other osteomyelitis reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B13. Priapism	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B13. Event Documented: Priapism				
PRIAPISM	Frequency	Percent	Cum Freq	Cum Percent
-1	440	40.85	440	40.85
1	636	59.05	1076	99.91
2	1	0.09	1077	100.00

B13a. # of Events: Priapism				
PRIA_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

Analysis Variable : priap_d1frmrand <created variable> B13b. 1st Date of Event: Priapism as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	382.0	.	382.0	382.0	382.0	382.0	382.0

<created variable> B13b. 1st Date of Event: Priapism as days from RAND visit				
priap_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1076	100.00	1076	100.00

B13c. Where was patient seen for event 1: Priapism				
PRISEEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
1	1	0.09	1077	100.00

B13d. STOP II event form completed: Priapism				
PRIAP_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1076	99.91	1076	99.91
2	1	0.09	1077	100.00

e. __ __/__ __/__ __ __ __ f. ☐ g. ☐ ☐

[No other priapism reported. Variables NOT included in dataset.]

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B14. Transfusion Reaction	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B14. Event Documented: Transfusion Reaction				
T_REACTN	Frequency	Percent	Cum Freq	Cum Percent
1	1069	99.26	1069	99.26
2	8	0.74	1077	100.00

B14a. # of Events: Transfusion Reaction				
REAC_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	1069	99.26	1069	99.26
1	8	0.74	1077	100.00

Analysis Variable : react_d1frmrand <created variable> B14b. 1st Date of Event: Transfusion Reaction as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
8	0	217.8	564.3	-707.0	-150.5	175.5	737.5	924.0

<created variable> B14b. 1st Date of Event: Transfusion Reaction as days from RAND visit				
react_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1069	100.00	1069	100.00

B14c. Where was patient seen for event 1: Transfusion Reaction				
RCTSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	1069	99.26	1070	99.35
1	7	0.65	1077	100.00

B14d. STOP II event form completed: Transfusion Reaction				
REACT_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	1069	99.26	1069	99.26
1	2	0.19	1071	99.44
2	6	0.56	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed? (see below)
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B14. Transfusion Reaction		e. __ __/__ __/__ __ __ __		f. ☐	g. ☐ ☐

[No other transfusion reaction reported. Variables NOT included in dataset.]

B15. Other ☐ ☐ → a. ☐

B15. Event Documented: Other				
OTHER	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
1	907	84.22	908	84.31
2	169	15.69	1077	100.00

B15a. # of Events: Other				
OTHR_NUM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	908	84.31	909	84.40
1	116	10.77	1025	95.17
2	25	2.32	1050	97.49
3	18	1.67	1068	99.16
4	5	0.46	1073	99.63
5	1	0.09	1074	99.72
6	1	0.09	1075	99.81
8	1	0.09	1076	99.91
10	1	0.09	1077	100.00

IF YES, specify event(s) below

a.1 _____ b.1 __ __/__ __/__ __ __ __ c.1 ☐ d.1 ☐ ☐

<recoded variable> B15a.1. Specify 1: Other				
othspec1_recode	Frequency	Percent	Cum Freq	Cum Percent
	908	84.31	908	84.31
ABDOM PAIN D/T GALLSTONE	1	0.09	909	84.40
ACUTE PHARYNGITIS	3	0.28	912	84.68
CELLULITIS OF PORT SITE	1	0.09	913	84.77
CHEST DISCOMFORT/SORE THROAT	1	0.09	914	84.87
CHOLECYSTITIS	1	0.09	915	84.96
CHOLELITHIASIS	4	0.37	919	85.33
CHOLELITHIASIS W/ PANCREATITIS	1	0.09	920	85.42
DESFERAL INFUSION	4	0.37	924	85.79
DESFERAL INJECTION	1	0.09	925	85.89
GALLSTONES	2	0.19	927	86.07
GALLSTONES RUQ PAIN	1	0.09	928	86.17
HAS + DIRECT COOMBS DUE TO WARM AUTO ANTIBODY	1	0.09	929	86.26
HEADACHE	5	0.46	934	86.72
HEADACHE X 1 WEEK	1	0.09	935	86.82
HEADACHES - MIGRAINE	1	0.09	936	86.91
HEADACHES DUE TO CHRONIC ALLERGIES	1	0.09	937	87.00
LIVER BIOPSY	1	0.09	938	87.09
NONFUNCTIONAL PORT	1	0.09	939	87.19
NUMBNESS/TINGLING LT. FOOT, RT. HAND	1	0.09	940	87.28
OTHER	112	10.40	1052	97.68
PAIN CRISIS	3	0.28	1055	97.96
PAIN CRISIS IN ER	1	0.09	1056	98.05
PHARYNGITIS	1	0.09	1057	98.14
PORT INFECTION	2	0.19	1059	98.33
POSS STREP THROAT	1	0.09	1060	98.42
RESOLVING PAIN CRISIS	1	0.09	1061	98.51
SORE THROAT	3	0.28	1064	98.79
SORE THROAT WITH FEVER	1	0.09	1065	98.89
SORE THROAT, COUGH, NASAL CONGESTION	1	0.09	1066	98.98
STREP PHARYNGITIS	1	0.09	1067	99.07
STREP THROAT	1	0.09	1068	99.16
STREP THROAT (PHARYNGITIS)	1	0.09	1069	99.26
STREP THROAT/ABDOMINAL PAIN	1	0.09	1070	99.35
UPPER QUADRANT PAIN. SLUDGE IN GALLBLADDER	1	0.09	1071	99.44
VASO-OCCLUSIVE PAIN	1	0.09	1072	99.54
VOC (PAIN WITH FEVER)NOT HOSPITALIZED	1	0.09	1073	99.63
VOC - ER VISIT	1	0.09	1074	99.72
VOC - LOWER BACK PAIN	1	0.09	1075	99.81
VOC - NOT ADMITTED	1	0.09	1076	99.91
VOC R ANKLE NOT HOSP	1	0.09	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			**1 = STOP II Center 2 = Non-STOP II Center**	**1. NO 2. YES**
B15. Other	☐	☐ → a. ☐			

IF YES, specify event(s) below

a.1 _____ b.1 __ __/__ __/__ __ __ __ c.1 ☐ d.1 ☐ ☐

Analysis Variable : other_d1frmrand <created variable> B15b.1. Date of Event 1: Other as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
167	0	295.8	488.1	-948.0	22.0	273.0	662.0	1278.0

<created variable> B15b.1. Date of Event 1: Other as days from RAND visit

other_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	910	100.00	910	100.00

B15c.1. Where was patient seen for event 1: Other

OTHSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	908	84.31	909	84.40
1	143	13.28	1052	97.68
2	25	2.32	1077	100.00

B15d.1. STOP II event form completed: Other

OTHER_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	908	84.31	908	84.31
1	69	6.41	977	90.71
2	100	9.29	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			**1 = STOP II Center 2 = Non-STOP II Center**	**1. NO 2. YES**
B15. Other	☐	☐ → a. ☐			

IF YES, specify event(s) below

a.2 _____ b.2 __ __/__ __/__ __ __ __ c.2 ☐ d.2 ☐ ☐

<recoded variable> B15a.2. Specify 2: Other				
othspec2_recode	Frequency	Percent	Cum Freq	Cum Percent
	1022	94.89	1022	94.89
ACUTE PHARYNGITIS AND CONJUNCTIVITIS	1	0.09	1023	94.99
CHOLECYSTITIS	1	0.09	1024	95.08
CHOLELITHIASIS	2	0.19	1026	95.26
DESFERAL INFUSION	4	0.37	1030	95.64
DESFERAL INJECTION	1	0.09	1031	95.73
FEVER - SEROUS OTITIS MEIDA - ACUTE SINUSITIS - PHARYNGITIS	1	0.09	1032	95.82
GALLSTONES RUQ PAIN	1	0.09	1033	95.91
HEADACHE	1	0.09	1034	96.01
HEADACHE, ABDOMINAL PAIN	1	0.09	1035	96.10
INFUSE PORT DEVICE COMPLICATIONS	1	0.09	1036	96.19
JOINT PAIN/VASOOCCLUSIVE	1	0.09	1037	96.29
MALFUNCTION OF PORT	1	0.09	1038	96.38
OCC. SORE THROAT	1	0.09	1039	96.47
OTHER	36	3.34	1075	99.81
PAIN CRISIS	2	0.19	1077	100.00

Event	Event Documented **1. NO 2. YES**	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center** **2 = Non-STOP II Center**	Was STOP II event form* completed? **1. NO 2. YES**
B15. Other	☐	☐ → a. ☐			

IF YES, specify event(s) below

a.2 _____ b.2 __ __/__ __/__ __ __ __ c.2 ☐ d.2 ☐ ☐

Analysis Variable : other_d2frmrand <created variable> B15b.2. Date of Event 2: Other as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
54	0	359.4	429.0	-631.0	104.0	300.5	631.0	1288.0

<created variable> B15b.2. Date of Event 2: Other as days from RAND visit

other_d2frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1023	100.00	1023	100.00

B15c.2. Where was patient seen for event 2: Other

OTHSEEN2	Frequency	Percent	Cum Freq	Cum Percent
-2	1022	94.89	1022	94.89
1	49	4.55	1071	99.44
2	6	0.56	1077	100.00

B15d.2. STOP II event form completed: Other

OTHER_C2	Frequency	Percent	Cum Freq	Cum Percent
-2	1022	94.89	1022	94.89
1	23	2.14	1045	97.03
2	32	2.97	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B15. Other	☐	☐ → a. ☐			

IF YES, specify event(s) below

a.3 _____ b.3 __ __/__ __/__ __ __ __ c.3 ☐ d.3 ☐ ☐

<recoded variable> B15a.3. Specify 3: Other				
othspec3_recode	Frequency	Percent	Cum Freq	Cum Percent
	1047	97.21	1047	97.21
ACUTE PHARYNGITIS/STREP THROAT	1	0.09	1048	97.31
CHOLELITHIASIS	1	0.09	1049	97.40
DESFERAL INFUSION	2	0.19	1051	97.59
DESFERAL INJECTION	1	0.09	1052	97.68
FEVER - SROUS OTITIS MEDIA - SINUSITIS - PHARYNGITIS	1	0.09	1053	97.77
HEADACHE	1	0.09	1054	97.86
INFUSE PORT DEVICE COMPLICATIONS	1	0.09	1055	97.96
OTHER	20	1.86	1075	99.81
PAIN CRISIS	1	0.09	1076	99.91
SORE THROAT, RUNNY NOSE	1	0.09	1077	100.00

Analysis Variable : other_d3frmrand <created variable> B15b.3. Date of Event 3: Other as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
29	0	237.5	357.4	-603.0	120.0	206.0	440.0	1043.0

<created variable> B15b.3. Date of Event 3: Other as days from RAND visit				
other_d3frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1048	100.00	1048	100.00

B15c.3. Where was patient seen for event 3: Other				
OTHSEEN3	Frequency	Percent	Cum Freq	Cum Percent
-2	1047	97.21	1047	97.21
1	26	2.41	1073	99.63
2	4	0.37	1077	100.00

B15d.3. STOP II event form completed: Other				
OTHER_C3	Frequency	Percent	Cum Freq	Cum Percent
-2	1047	97.21	1047	97.21
1	13	1.21	1060	98.42
2	17	1.58	1077	100.00

Event	Event Documented **1. NO 2. YES**	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center** **2 = Non-STOP II Center**	Was STOP II event form* completed? **1. NO 2. YES**
B16. Transfusion	☐ → ☐	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

B16. Event Documented: Transfusion				
TRANSFSN	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-8	2	0.19	3	0.28
1	169	15.69	172	15.97
2	905	84.03	1077	100.00

B16a. # of Events: Transfusion				
TRANSNUM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	172	15.97	173	16.06
1	85	7.89	258	23.96
2	174	16.16	432	40.11
3	287	26.65	719	66.76
4	190	17.64	909	84.40
5	106	9.84	1015	94.24
6	39	3.62	1054	97.86
7	10	0.93	1064	98.79
8	6	0.56	1070	99.35
9	4	0.37	1074	99.72
10	1	0.09	1075	99.81
11	1	0.09	1076	99.91
12	1	0.09	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B16. Transfusion	☐	☐ → a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐ ☐

Analysis Variable : tranf_d1frmrand <created variable> B16b. 1st Date of Event: Transfusion as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
905	0	123.7	543.4	-1237	-249.0	106.0	538.0	1336.0

<created variable> B16b. 1st Date of Event: Transfusion as days from RAND visit

tranf_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	172	100.00	172	100.00

B16c. Where was patient seen for event 1: Transfusion

TRNSEEN1	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.28	3	0.28
-2	172	15.97	175	16.25
1	884	82.08	1059	98.33
2	18	1.67	1077	100.00

B16d. STOP II event form completed: Transfusion

TRANF_C1	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-8	1	0.09	3	0.28
-2	172	15.97	175	16.25
1	265	24.61	440	40.85
2	637	59.15	1077	100.00

Event	Event Documented **1. NO 2. YES**	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center** **2 = Non-STOP II Center**	Was STOP II event form* completed? **1. NO 2. YES**
B16. Transfusion			e. __ __/__ __/__ __ __ __	f.	g.

Analysis Variable : tranf_d2frmrand <created variable> B16e. 2nd Date of Event: Transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
820	0	108.1	553.2	-1296	-277.5	56.0	522.0	1324.0

<created variable> B16e. 2nd Date of Event: Transfusion as days from RAND visit				
tranf_d2frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	257	100.00	257	100.00

B16f. Where was patient seen for event 2: Transfusion				
TRNSEEN2	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.28	3	0.28
-2	257	23.86	260	24.14
1	804	74.65	1064	98.79
2	13	1.21	1077	100.00

B16g. STOP II event form completed: Transfusion				
TRANF_C2	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.28	3	0.28
-8	1	0.09	4	0.37
-2	257	23.86	261	24.23
1	236	21.91	497	46.15
2	580	53.85	1077	100.00

Event	Event Documented **1. NO 2. YES**	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center** **2 = Non-STOP II Center**	Was STOP II event form* completed? **1. NO 2. YES**
B16. Transfusion		h. __ __/__ __/__ __ __ __	i.	j.	

Analysis Variable : tranf_d3frmrand <created variable> B16h. 3rd Date of Event: Transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
645	0	70.0	559.7	-1317	-334.0	41.0	497.0	1352.0

<created variable> B16h. 3rd Date of Event: Transfusion as days from RAND visit				
tranf_d3frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	432	100.00	432	100.00

B16i. Where was patient seen for event 3: Transfusion				
TRNSEEN3	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-2	432	40.11	434	40.30
1	639	59.33	1073	99.63
2	4	0.37	1077	100.00

B16j. STOP II event form completed: Transfusion				
TRANF_C3	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-2	432	40.11	434	40.30
1	165	15.32	599	55.62
2	478	44.38	1077	100.00

Event	Event Documented **1. NO 2. YES**	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center** **2 = Non-STOP II Center**	Was STOP II event form* completed? **1. NO 2. YES**
B16. Transfusion		k. __ __/__ __/__ __ __ __	l.	m.	

Analysis Variable : tranf_d4frmrand <created variable> B16k. 4th Date of Event: Transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
357	0	37.8	545.6	-1225	-353.0	-18.0	414.0	1289.0

<created variable> B16k. 4th Date of Event: Transfusion as days from RAND visit				
tranf_d4frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	720	100.00	720	100.00

B16l. Where was patient seen for event 4: Transfusion				
TRNSEEN4	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-2	720	66.85	722	67.04
1	352	32.68	1074	99.72
2	3	0.28	1077	100.00

B16m. STOP II event form completed: Transfusion				
TRANF_C4	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	720	66.85	721	66.95
1	93	8.64	814	75.58
2	263	24.42	1077	100.00

Event	Event Documented **1. NO 2. YES**	# of Events	Date of Event	Where was patient seen for event? **1 = STOP II Center** **2 = Non-STOP II Center**	Was STOP II event form* completed? **1. NO 2. YES**
B16. Transfusion		n. __ __/__ __/__ __ __ __	o.	p.	

Analysis Variable : tranf_d5frmrand <created variable> B16n. 5th Date of Event: Transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
166	0	-29.1	532.9	-1233	-441.0	-87.0	350.0	1287.0

<created variable> B16n. 5th Date of Event: Transfusion as days from RAND visit				
tranf_d5frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	911	100.00	911	100.00

B16o. Where was patient seen for event 5: Transfusion				
TRNSEEN5	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-2	911	84.59	913	84.77
1	162	15.04	1075	99.81
2	2	0.19	1077	100.00

B16p. STOP II event form completed: Transfusion				
TRANF_C5	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	911	84.59	912	84.68
1	41	3.81	953	88.49
2	124	11.51	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B17. Surgery	☐	☐ → a. ☐			

B17. Event Documented: Surgery				
SURGERY	Frequency	Percent	Cum Freq	Cum Percent
1	995	92.39	995	92.39
2	82	7.61	1077	100.00

B17a. # of Events: Surgery				
SURG_NUM	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.19	2	0.19
-2	995	92.39	997	92.57
1	68	6.31	1065	98.89
2	11	1.02	1076	99.91
3	1	0.09	1077	100.00

IF YES, specify surgical procedures below

a.1 _____ b.1 __ __/__ __/__ __ __ __ c.1 ☐ d.1 ☐ ☐

<recoded variable> B17a.1. Surgery 1				
surgery1_recode	Frequency	Percent	Cum Freq	Cum Percent
	995	92.39	995	92.39
CENTRAL LINE PLACEMENT	1	0.09	996	92.48
CHOLECYSTECTOMY	8	0.74	1004	93.22
GALL BLADDER REMOVAL	1	0.09	1005	93.31
INFUSAPORT PLACEMENT	1	0.09	1006	93.41
INFUSAPORT REMOVAL	1	0.09	1007	93.50
LAP CHOLECYSTECTOMY	5	0.46	1012	93.96
LIVER BIOPSY	36	3.34	1048	97.31
MEDIPORT PLACEMENT	1	0.09	1049	97.40
OTHER	12	1.11	1061	98.51
PORT REPLACEMENT	1	0.09	1062	98.61
PORT-A-CATH	1	0.09	1063	98.70
PORT-A-CATH PLACEMENT	8	0.74	1071	99.44
PORT-A-CATH REMOVAL	5	0.46	1076	99.91
SPLENECTOMY	1	0.09	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B17. Surgery	☐	☐ →	a. ☐		

IF YES, specify surgical procedures below

a.1 _____ b.1 __ __/__ __/__ __ __ __ c.1 ☐ d.1 ☐ ☐

Analysis Variable : surg_d1frmrand <created variable> B17b.1. Date of Surgery 1 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
82	0	282.0	496.3	-1010	37.0	296.5	654.0	1287.0

<created variable> B17b.1. Date of Surgery 1 as days from RAND visit				
surg_d1frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	995	100.00	995	100.00

B17c.1. Where was patient seen for surgery 1				
SURGSEN1	Frequency	Percent	Cum Freq	Cum Percent
-2	995	92.39	995	92.39
1	80	7.43	1075	99.81
2	2	0.19	1077	100.00

B17d.1. STOP II event form completed				
SURG_C1	Frequency	Percent	Cum Freq	Cum Percent
-2	995	92.39	995	92.39
1	29	2.69	1024	95.08
2	53	4.92	1077	100.00

a.2 _____ b.2 __ __/__ __/__ __ __ __ c.2 ☐ d.2 ☐ ☐

<recoded variable> B17a.2. Surgery 2				
surgery2_recode	Frequency	Percent	Cum Freq	Cum Percent
	1064	98.79	1064	98.79
GALLBLADDER REMOVAL	1	0.09	1065	98.89
HICKMAN PLACEMENT	1	0.09	1066	98.98
INFUSAPORT REMOVAL	1	0.09	1067	99.07
LAP CHOLECYSTECTOMY	1	0.09	1068	99.16
LIVER BIOPSY	2	0.19	1070	99.35
OTHER	1	0.09	1071	99.44
PORT-A-CATH INSERTION	4	0.37	1075	99.81
PORT-A-CATH REMOVAL	2	0.19	1077	100.00

Event	Event Documented	# of Events	Date of Event	Where was patient seen for event?	Was STOP II event form* completed?
	1. NO 2. YES			1 = STOP II Center 2 = Non-STOP II Center	1. NO 2. YES
B17. Surgery	☐	☐ →	a. ☐		

IF YES, specify surgical procedures below

a.2 _____ b.2 __ __/__ __/__ __ __ __ c.2 ☐ d.2 ☐ ☐

Analysis Variable : surg_d2frmrand <created variable> B17b.2. Date of Surgery 2 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
12	0	322.9	553.0	-951.0	171.5	316.0	674.0	1114.0

<created variable> B17b.2. Date of Surgery 2 as days from RAND visit				
surg_d2frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1065	100.00	1065	100.00

B17c.2. Where was patient seen for surgery 2				
SURGSEN2	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	1064	98.79	1065	98.89
1	11	1.02	1076	99.91
2	1	0.09	1077	100.00

B17d.2. STOP II event form completed				
SURG_C2	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.09	1	0.09
-2	1064	98.79	1065	98.89
1	6	0.56	1071	99.44
2	6	0.56	1077	100.00

Event	Event Documented 1. NO 2. YES	# of Events	Date of Event	Where was patient seen for event? 1 = STOP II Center 2 = Non-STOP II Center	Was STOP II event form* completed? 1. NO 2. YES
B17. Surgery	☐	☐ → a. ☐			

IF YES, specify surgical procedures below

a.3 _____ b.3 __ __/__ __/__ __ __ __ c.3 ☐ d.3 ☐ ☐

<recoded variable> B17a.3. Surgery 3				
surgery3_recode	Frequency	Percent	Cum Freq	Cum Percent
	1075	99.81	1075	99.81
INFUSAPORT PLACEMENT	1	0.09	1076	99.91
PORT-A-CATH INSERTION	1	0.09	1077	100.00

Analysis Variable : surg_d3frmrand <created variable> B17b.3. Date of Surgery 3 as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	-814.5	173.2	-937.0	-937.0	-814.5	-692.0	-692.0

<created variable> B17b.3. Date of Surgery 3 as days from RAND visit				
surg_d3frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1075	100.00	1075	100.00

B17c.3. Where was patient seen for surgery 3				
SURGSEN3	Frequency	Percent	Cum Freq	Cum Percent
-2	1075	99.81	1075	99.81
1	2	0.19	1077	100.00

B17d.3. STOP II event form completed				
SURG_C3	Frequency	Percent	Cum Freq	Cum Percent
-2	1075	99.81	1075	99.81
1	2	0.19	1077	100.00

FOR A RANDOMIZED PATIENT:
*** Complete FORM 30 for each documented neurological event (stroke, TIA, or seizures)**
*** Complete FORMS 20 and 21 for each documented transfusion**
*** Complete FORM 32 for each documented delayed transfusion reaction**
*** Complete FORM 31 for all other types of documented clinical events**
FOR A POTENTIAL CANDIDATE:
*** Complete FORM Q30 for each documented neurological event**

STOP II
FORM 18: MISSED FOLLOW-UP VISIT FOR POTENTIAL OR RANDOMIZED PATIENTS

A. Collection Information:
The **Missed Follow-Up Visit for Potential or Randomized Patients** (Form 18) was to be completed as soon as the last date in the scheduling window had passed without completion of any quarterly visit requirements within that window. Quarterly visit requirements for Potential patients were: TCD exam, physical exam, local laboratory tests, quarterly medical history interview, and quarterly medical record review (with appropriate forms). Quarterly visit requirements for randomized patients were: physical exam, core laboratory tests, quarterly medical history interview, and quarterly medical record review (with appropriate forms) and MRI, MRA and neurological consultation (for annual visits only). The TCD schedule for randomized patients was dependent on previous TCD results. Beginning in November 2002, missed TCD visits for randomized patients were captured on the form 18T (Reason for Overdue TCD Exam Visit for Randomized Patient.)

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p018_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 45 (29)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 487
- Listing of Variables by Position: See p. 488

H. Formats:
The file **f018fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the formal label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 489.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The only valid EX_TYPE for Form 18 is QT for quarterly visits.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 18 are:
  - 200 & 300 series numbers indicate visits that were completed prior to randomization.
    - 200 series numbers were assigned to “Potential 1” visits – i.e., quarterly visits completed while the patient was on transfusion for < 30 months
    - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months
  - 400 series numbers indicate visits completed after randomization
    - 401=randomization visit
    - 405, 409, or 413=annual visits

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

Data Set Name	PUBDS.P018_FINAL	Observations	45
Member Type	DATA	Variables	12
Engine	V9	Indexes	0
Created	Wed, Feb 15, 2006 01:56:33 PM	Observation Length	80
Last Modified	Wed, Feb 15, 2006 01:56:33 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	8192
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	101
Obs in First Data Page	45
Number of Data Set Repairs	0
File Name	v:\Stop2\Data Manual\Public Use\PU Data Sets\p018_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
8	DESTATUS	Char	1	$1.	DESTATUS
5	DROP_OUT	Num	8	3.	B3. Did patient withdraw consent to continue follow-up study?
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
6	LOST_FUP	Num	8	3.	B4. Was patient lost to follow-up?
4	MISS_TCD	Num	8	3.	B2. Did patient miss a TCD exam?
3	MISS_VST	Num	8	3.	B1. Did patient miss a quarterly visit?
7	PT_DIE	Num	8	3.	B5. Did patient die?
11	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
12	death_dtfrmrand	Num	8		<created variable> B5a. Date of death
10	ldu_id	Char	10		ID for public use datasets
9	vistype	Char	7		VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	MISS_VST	Num	8	3.	B1. Did patient miss a quarterly visit?
4	MISS_TCD	Num	8	3.	B2. Did patient miss a TCD exam?
5	DROP_OUT	Num	8	3.	B3. Did patient withdraw consent to continue follow-up study?
6	LOST_FUP	Num	8	3.	B4. Was patient lost to follow-up?
7	PT_DIE	Num	8	3.	B5. Did patient die?
8	DESTATUS	Char	1	$1.	DESTATUS
9	vistype	Char	7		VISIT TYPE
10	ldu_id	Char	10		ID for public use datasets
11	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
12	death_dtfrmrand	Num	8		<created variable> B5a. Date of death

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*F018fmts.txt;

proc format;

  value DROP_OUTF
    1='1: No'
    2='2: Yes';

  value LOST_FUPF
    1='1: No'
    2='2: Yes';

  value MISS_TCDF
    1='1: No'
    2='2: Yes';

  value MISS_VSTF
    1='1: No'
    2='2: Yes';

  value PT_DIEF
    1='1: No'
    2='2: Yes';

* format drop_out drop_outf. lost_fup lost_fupf. miss_tcd miss_tcdf. miss_vst miss_vstf. pt_die pt_dief.;
```

STOP II TRIAL

MISSED FOLLOW-UP VISIT FOR POTENTIAL OR RANDOMIZED PATIENTS

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	45	100.00	45	100.00

VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QT-202	2	4.44	2	4.44
QT-203	7	15.56	9	20.00
QT-204	3	6.67	12	26.67
QT-205	1	2.22	13	28.89
QT-302	5	11.11	18	40.00
QT-303	7	15.56	25	55.56
QT-306	1	2.22	26	57.78
QT-307	1	2.22	27	60.00
QT-402	2	4.44	29	64.44
QT-403	1	2.22	30	66.67
QT-404	1	2.22	31	68.89
QT-405	1	2.22	32	71.11
QT-406	1	2.22	33	73.33
QT-407	3	6.67	36	80.00
QT-408	1	2.22	37	82.22
QT-409	2	4.44	39	86.67
QT-410	2	4.44	41	91.11
QT-411	3	6.67	44	97.78
QT-412	1	2.22	45	100.00

A1. Person completing form (Name):_____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of interview as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
45	0	101.6	594.9	-794.0	-288.0	-65.0	589.0	1119.0

B1. Did patient miss a quarterly visit? ☐ 1. NO ☐ 2. YES

B1.a **IF YES**, reason_____

B1. Did patient miss a quarterly visit?				
MISS_VST	Frequency	Percent	Cum Freq	Cum Percent
2	45	100.00	45	100.00

[Variable NOT included in dataset for specify field.]

B2. Did patient miss a TCD exam? ☐ 1. NO ☐ 2. YES

B2.a **IF YES**, reason_____

B2. Did patient miss a TCD exam?				
MISS_TCD	Frequency	Percent	Cum Freq	Cum Percent
1	2	4.44	2	4.44
2	43	95.56	45	100.00

[Variable NOT included in dataset for specify field.]

B3. Did patient withdraw consent to continue follow-up in study? ☐ 1. NO ☐ 2. YES

B3.a **IF YES**, reason_____

B3. Did patient withdraw consent to continue follow-up study?				
DROP_OUT	Frequency	Percent	Cum Freq	Cum Percent
1	43	95.56	43	95.56
2	2	4.44	45	100.00

[Variable NOT included in dataset for specify field.]

B4. Was patient lost to follow-up (address and telephone number unknown)? ☐ 1. NO ☐ 2. YES

B4. Was patient lost to follow-up?				
LOST_FUP	Frequency	Percent	Cum Freq	Cum Percent
1	43	95.56	43	95.56
2	2	4.44	45	100.00

B5. Did patient die? ☐ 1. NO ☐ 2. YES

↓

B5.a Date of death (month/day/year): ___ ___/___ ___/___ ___ ___ ___

COMPLETE CAUSE OF DEATH FORM

B5. Did patient die?				
PT_DIE	Frequency	Percent	Cum Freq	Cum Percent
1	44	97.78	44	97.78
2	1	2.22	45	100.00

Analysis Variable : death_dtfrmrand <created variable> B5a. Date of death

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	815.0	.	815.0	815.0	815.0	815.0	815.0

<created variable> B5a. Date of death				
death_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	44	100.00	44	100.00

STOP II
FORM 18T: REASON FOR OVERDUE TCD EXAM VISIT FOR RANDOMIZED PATIENT

A. Collection Information:
The **Reason for Overdue TCD Exam Visit for Randomized Patient** (Form 18T) was to be completed for randomized patients who had an overdue or missed TCD exam visit.

B. Data Collection Period: November 2002 through November 2004

C. Form Version Dates: 10/25/02

D. Files Used to Store Information:

SAS System File: **p18t_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 75 (38)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 495
- Listing of Variables by Position: See p. 496

H. Formats:
The file **f18Tfmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 497.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The only valid EX_TYPE for Form 18T is EX for Randomized patient TCD exam visits.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 18T are:
  - 001-050 series numbers indicate TCD exams completed after randomization.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

Data Set Name	PUBDS.P18T_FINAL	Observations	75
Member Type	DATA	Variables	15
Engine	V9	Indexes	0
Created	Friday, February 17, 2006 03:45:10 PM	Observation Length	152
Last Modified	Friday, February 17, 2006 03:45:10 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	12288
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	80
Obs in First Data Page	61
Number of Data Set Repairs	0
File Name	v:\Stop2\Data Manual\Public Use\PU Data Sets\p18t_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
12	DESTATUS	Char	1	$1.	DESTATUS
6	EXNOTRPT	Num	8	3.	B1.b. Number of missed TCD exam visits
2	EX_NUM	Char	4	$4.	A3. Exam number
1	EX_TYPE	Char	2	$2.	X3. Exam type
3	FIRST18T	Num	8	3.	A4. Is this the first Form 18T
11	NEWVISIT	Num	8	3.	B2. Has patient been rescheduled for exam
8	OTHER1	Char	50	$50.	B1.b1.c. Specify reason if other
7	REASMIS1	Num	8	3.	B1.b1.b. Reason exam was missed
9	REASMIS2	Num	8	3.	B1.b2.b. Reason exam was missed
10	REASMIS3	Num	8	3.	B1.b3.b. Reason exam was missed
5	REAS_NOT	Num	8	3.	B1.a. Reason TCD exam not scheduled
4	TCDSCHED	Num	8	3.	B1. Was a TCD exam scheduled
15	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit
14	ldu_id	Char	10		ID for public use datasets
13	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	A3. Exam number
3	FIRST18T	Num	8	3.	A4. Is this the first Form 18T
4	TCDSCHED	Num	8	3.	B1. Was a TCD exam scheduled
5	REAS_NOT	Num	8	3.	B1.a. Reason TCD exam not scheduled
6	EXNOTRPT	Num	8	3.	B1.b. Number of missed TCD exam visits
7	REASMIS1	Num	8	3.	B1.b1.b. Reason exam was missed
8	OTHER1	Char	50	$50.	B1.b1.c. Specify reason if other
9	REASMIS2	Num	8	3.	B1.b2.b. Reason exam was missed
10	REASMIS3	Num	8	3.	B1.b3.b. Reason exam was missed
11	NEWVISIT	Num	8	3.	B2. Has patient been rescheduled for exam
12	DESTATUS	Char	1	$1.	DESTATUS
13	vistype	Char	7		<created variable> VISIT TYPE
14	ldu_id	Char	10		ID for public use datasets
15	comp_dfrmrand	Num	8		<created variable> A2. Date of interview as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*F18Tfmts.txt;

proc format;

  value FIRST18TF
    1='1: No'
    2='2: Yes';

  value NEWVISITF
    1='1: No'
    2='2: Yes';

  value REAS_NOTF
    1='1: Patient Lost-To-Follow-Up'
    2='2: Patient Refusing'
    3='3: Patient Moved'
    4='4: Patient Ill'
    5='5: TCD Examiner Not Available'
    99='99: Other';

  value REASMIS1F
    1='1: Patient Did Not Show'
    2='2: Patient Ill'
    3='3: Patient Lost To Follow-Up'
    4='4: Patient Moved'
    5='5: TCD Examiner Not Available'
    6='6: TCD Machine Malfunction'
    99='99: Other';

  value REASMIS2F
    1='1: Patient Did Not Show'
    2='2: Patient Ill'
    3='3: Patient Lost To Follow-Up'
    4='4: Patient Moved'
    5='5: TCD Examiner Not Available'
    6='6: TCD Machine Malfunction'
    99='99: Other';

  value REASMIS3F
    1='1: Patient Did Not Show'
    2='2: Patient Ill'
    3='3: Patient Lost To Follow-Up'
    4='4: Patient Moved'
    5='5: TCD Examiner Not Available'
    6='6: TCD Machine Malfunction'
    99='99: Other';

  value TCDSCHEDF
    1='1: No'
    2='2: Yes';

* format first18t first18tf. newvisit newvisitf. reas_not reas_notf. reasmis1 reasmis1f. reasmis2 reasmis2f.
reasmis3 reasmis3f. reasmis4 reasmis4f. tcdsched tcdschedf.;
```

STOP II TRIAL

REASON FOR OVERDUE TCD EXAM VISIT FOR RANDOMIZED PATIENT

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	73	97.33	73	97.33
P	2	2.67	75	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
EX-001	2	2.67	2	2.67
EX-002	1	1.33	3	4.00
EX-003	3	4.00	6	8.00
EX-004	4	5.33	10	13.33
EX-005	2	2.67	12	16.00
EX-006	8	10.67	20	26.67
EX-007	10	13.33	30	40.00
EX-008	7	9.33	37	49.33
EX-009	10	13.33	47	62.67
EX-010	7	9.33	54	72.00
EX-011	3	4.00	57	76.00
EX-012	4	5.33	61	81.33
EX-013	3	4.00	64	85.33
EX-015	3	4.00	67	89.33
EX-016	1	1.33	68	90.67
EX-017	5	6.67	73	97.33
EX-018	2	2.67	75	100.00

A. OVERDUE TCD EXAM IDENTIFIER INFORMATION

A1. Person completing form (Initials) | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of interview as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
75	0	651.9	265.9	72.0	500.0	632.0	836.0	1176.0

A3. TCD exam number of overdue TCD EX- ___ ___ ___

[Data not shown. Included in VISTYPE above.]

A4. Is this the first Form 18T submitted for this exam number?

NO .....1 (**SKIP TO B1.b**)

YES 2

A4. Is this the first Form 18T				
FIRST18T	Frequency	Percent	Cum Freq	Cum Percent
1	10	13.33	10	13.33
2	65	86.67	75	100.00

B. REASON FOR OVERDUE OR MISSED TCD EXAM

B1. Was a TCD exam scheduled?

NO..... 1

YES..... 2 (**SKIP TO Q. B1.b**)

B1. Was a TCD exam scheduled				
TCDSCHED	Frequency	Percent	Cum Freq	Cum Percent
-2	10	13.33	10	13.33
1	11	14.67	21	28.00
2	54	72.00	75	100.00

B1.a. Reason that TCD exam was not scheduled

PATIENT LOST-TO -FOLLOW-UP .....1 **[STOP- FORM COMPLETE]**

PATIENT REFUSING.....2

PATIENT MOVED .....3 [**STOP – FORM COMPLETE]**

PATIENT ILL.....4

TCD EXAMINER NOT AVAILABLE TO PERFORM STUDY 5

OTHER 99

B1.a. Reason TCD exam not scheduled				
REAS_NOT	Frequency	Percent	Cum Freq	Cum Percent
-2	64	85.33	64	85.33
3	2	2.67	66	88.00
5	2	2.67	68	90.67
99	7	9.33	75	100.00

B1.a1. If OTHER, specify _____

[Variable NOT included in dataset.]

(**GO TO Q. B.2**)

B1.b. Number of missed TCD exam visits for this exam number that were not previously reported: ____

B1.b. Number of missed TCD exam visits				
EXNOTRPT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.33	1	1.33
-8	2	2.67	3	4.00
-2	11	14.67	14	18.67
0	28	37.33	42	56.00
1	21	28.00	63	84.00
2	11	14.67	74	98.67
3	1	1.33	75	100.00

a. Date of Scheduled TCD Exam Visit	b. Reason TCD Exam Visit was Missed (See code list below)	c. Specify reason if "Other"
1. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	

[Variable NOT included in dataset for date.]

B1.b1.b. Reason exam was missed				
REASMIS1	Frequency	Percent	Cum Freq	Cum Percent
-8	1	1.33	1	1.33
-2	11	14.67	12	16.00
1	41	54.67	53	70.67
2	2	2.67	55	73.33
4	1	1.33	56	74.67
5	5	6.67	61	81.33
6	1	1.33	62	82.67
99	13	17.33	75	100.00

Reason for Missed TCD Exam Visit Code List **(Enter code for primary reason patient missed TCD exam visit)**
01 Patient did not show up for scheduled visit
02 Patient was ill or experiencing or recovering from an acute event on the date of the scheduled visit
03 Patient lost to follow-up
04 Patient moved
05 TCD examiner was not available to perform TCD
06 TCD machine malfunction
99 Other (if Other, specify reason in Column c)

a. Date of Scheduled TCD Exam Visit	b. Reason TCD Exam Visit was Missed (See code list below)	c. Specify reason if "Other"
1. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	

B1.b1.c. Specify reason if other				
OTHER1	Frequency	Percent	Cum Freq	Cum Percent
-2	62	82.67	62	82.67
BLOOD NOT AVAILABLE, DATE OF TRANSFUSION POSTPONED	1	1.33	63	84.00
Insurance issues regarding TR	1	1.33	64	85.33
Mother not able to take off from work.	1	1.33	65	86.67
Patient out of town	1	1.33	66	88.00
Pt. no show possible b/c of move?	1	1.33	67	89.33
Scheduled for surgery, went early and missed TCD	1	1.33	68	90.67
Snowstorm - pt unable to get to hosp	1	1.33	69	92.00
TCD machine being repaired	1	1.33	70	93.33
Transportation Problems	1	1.33	71	94.67
family issues	1	1.33	72	96.00
snow/ice; unable to bring pt b/c road conditions	1	1.33	73	97.33
transportation unavailable	1	1.33	74	98.67
ward of state - case worker unable to make trip	1	1.33	75	100.00

2. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	

B1.b2.b. Reason exam was missed				
REASMIS2	Frequency	Percent	Cum Freq	Cum Percent
-9	1	1.33	1	1.33
-2	62	82.67	63	84.00
1	9	12.00	72	96.00
5	2	2.67	74	98.67
99	1	1.33	75	100.00

[Variables NOT included in dataset for date or specify fields.]

Reason for Missed TCD Exam Visit Code List
(Enter code for primary reason patient missed TCD exam visit)

01 Patient did not show up for scheduled visit
02 Patient was ill or experiencing or recovering from an acute event on the date of the scheduled visit
03 Patient lost to follow-up
04 Patient moved
05 TCD examiner was not available to perform TCD
06 TCD machine malfunction
99 Other (if Other, specify reason in Column c)

a. Date of Scheduled TCD Exam Visit	b. Reason TCD Exam Visit was Missed (See code list below)	c. Specify reason if "Other"
3. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	

B1.b3.b. Reason exam was missed				
REASMIS3	Frequency	Percent	Cum Freq	Cum Percent
-2	74	98.67	74	98.67
1	1	1.33	75	100.00

[Variables NOT included in dataset for date or specify fields.]

4. ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y	___ ___	

[Variables NOT included in dataset. Fields had no data.]

Reason for Missed TCD Exam Visit Code List **(Enter code for primary reason patient missed TCD exam visit)**
01 Patient did not show up for scheduled visit
02 Patient was ill or experiencing or recovering from an acute event on the date of the scheduled visit
03 Patient lost to follow-up
04 Patient moved
05 TCD examiner was not available to perform TCD
06 TCD machine malfunction
99 Other (if Other, specify reason in Column c)

B2. Has the patient been scheduled/rescheduled for a TCD exam visit?

NO..... 1

YES..... 2

B2. Has patient been rescheduled for exam				
NEWVISIT	Frequency	Percent	Cum Freq	Cum Percent
-2	2	2.67	2	2.67
1	14	18.67	16	21.33
2	59	78.67	75	100.00

B2.a Date of next scheduled TCD exam visit (Month/Day/Year):

__ __ / __ __ / __ __ __ __

[Variable NOT included in dataset.]

STOP II
FORM 19: MRA SCAN

A. Collection Information:

The **MRA Scan** (Form 19) was to be completed when a study-related MRA was performed for a Potential or Randomized patient. Potential patients were required to have an MRA performed at their pre-randomization evaluation visit only. After randomization, MRAs were required

1) at annual visits,
2) at the exit visit,
3) within 1-7 days after a suspected neurological event,
4) within 2-3 weeks after discharge for a head injury associated with loss of consciousness,
5) at the first quarterly visit after a stroke or TCD endpoint,
6) after three consecutive inadequate TCDs involving at least 2 examiners. If the MRA did not show moderate or severe arterial disease in the "qualifying" segments, an MRA was to be repeated every 6 months.

MRA scans were sent for reading by a central STOP II MRI/MRA Reading Panel comprised of three neuroradiologists, two from non-STOP II institutions and one from a STOP II institution. The member located at a STOP II institution did not (in general) do the central readings of studies from his own institution. Each study (with the exception of those completed for events) was read by two panel members. In cases of disagreement, the third member of the panel adjudicated the differences.

Pre-randomization MRA studies, and q 6 month MRA studies for "un-TCDable" patients were to be read in "real" time - i.e. films for these studies were sent to two central reviewers simultaneously upon receipt of the films at the DCC. All other studies were to be read at batch reviews at a central location 2-4 times yearly. However, as the study (and technology) progressed, sites began to go "filmless" (except for producing films for the STOP II study) and, as a result, disposed of the large alternators needed for loading and review of large numbers of films. Because of this change, central batch readings were not feasible – i.e., it was necessary for the vast majority of all MRA studies (including annual & exit studies) to be sent to readers individually. As a result, it was not possible to obtain readings for all of the studies. Although **ALL exit studies were read**, 45 annual (11 1st annual, 24 2nd annual, and 10 3rd annual) studies distributed among 30 patients were not read and, therefore, are not included in the dataset.

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p019_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype), R_DATEFRMRAND**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype) and R_DATEFRMRAND.

F. Number of Observations/Unique MRAs (Patients) in SAS Dataset: 226/225 (79)

As noted above, 45 unread annual studies for 30 patients are not included in this dataset.

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 506-507
- Listing of Variables by Position: See pp. 508-509

H. Formats:

The file **f019fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 510.

I. Special Value Codes:

- Non-Date Variables:
  -1 = Not Applicable
  -2 = Programmed Skip
  -3 = Not Done/Not Recorded
  -8 = Don't Know
  -9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form. 48 exams submitted to the DCC were not read by the STOP II MR Reader Panel. All pre-randomization and exit visit studies were read.

- **EX_TYPE –** is the variable name for type of visit. Valid EX_TYPEs for Form 19 are:
    - QT: for quarterly and annual visits
    - NE: for neurological events

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 19 are:
  For EX_TYPE=QT,
    - 300 series numbers were assigned to “Potential 2” visits – i.e., quarterly visits completed after the patient was on transfusion for at least 30 months
    - 400 series numbers indicate visits completed after randomization
        - 401=randomization visit
        - 405, 409, or 413=annual visits

  For EX_TYPE=NE
    - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **"xxxxRATE"** (for MCA, ICA, ACA, PCA, basilar) - are variable names for blood flow rate in the selected cerebral arteries being evaluated for stenosis. The criteria below were used for scoring the degree of stenosis.
    - Normal: No narrowing or flow gap noted
    - Mild stenosis: < 25% narrowing or flow gap in the apparent lumen
    - Moderate stenosis: 25-75% narrowing or flow gap in the apparent lumen
    - Severe stenosis: >75 and < 100% narrowing or flow gap in the apparent lumen
    - Occlusion: 100% flow gap.

Data Set Name	PUBDS.P019_FINAL	Observations	226
Member Type	DATA	Variables	70
Engine	V9	Indexes	0
Created	Tuesday, March 28, 2006 11:02:30 AM	Observation Length	424
Last Modified	Tuesday, March 28, 2006 11:02:30 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	NO
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	7
First Data Page	1
Max Obs per Page	38
Obs in First Data Page	13
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p019_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
3	ADEQUATE	Num	8	3.	A4. MRA study adequate for interpretation?
4	AD_REASN	Num	8	3.	A4a. Reason MRA not study adequate
51	BASLBASE	Char	2	$2.	E9b1. Basilar compared to pre-randomization
52	BASLPREV	Char	2	$2.	E9b2. Basilar compared to previous study
50	BASLRATE	Num	8	3.	E9a. Basilar rating
17	COMPPREV	Num	8	3.	C1. Is this MRA scan being compared to a previous scan?
15	DESTATUS	Char	1	$1.	DESTATUS
7	ECHOTIME	Num	8	4.1	A7. Echo time (MS)
14	EV_TYPE	Num	8	3.	B1b. Type of neurological event
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
10	FOV	Num	8	3.	A9a. Field of view (square)
45	LACABASE	Char	2	$2.	E7b1. Left ACA compared to pre-randomization
46	LACAPREV	Char	2	$2.	E7b2. Left ACA compared to previous study
44	LACARATE	Num	8	3.	E7a. Left ACA rating
63	LHROBBAS	Char	2	$2.	E13b1. Left hemisphere blood flow compared to pre-randomization
64	LHROBPRV	Char	2	$2.	E13b2. Left hemisphere blood flow compared to previous study
62	LHROBRAT	Num	8	3.	E13a. Robustness of left hemisphere blood flow
39	LICABASE	Char	2	$2.	E5b1. Left ICA compared to pre-randomization
40	LICAPREV	Char	2	$2.	E5b2. Left ICA compared to previous study
38	LICARATE	Num	8	3.	E5a. Left ICA rating
42	LMCABASE	Char	2	$2.	E6b1. Left MCA compared to pre-randomization
43	LMCAPREV	Char	2	$2.	E6b2. Left MCA compared to previous study
41	LMCARATE	Num	8	3.	E6a. Left MCA rating
48	LPCABASE	Char	2	$2.	E8b1. Left PCA compared to pre-randomization

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
49	LPCAPREV	Char	2	$2.	E8b2. Left PCA compared to previous study
47	LPCARATE	Num	8	3.	E8a. Left PCA rating
57	LPCOABAS	Char	2	$2.	E11b1. Left PCoA compared to pre-randomization
58	LPCOAPRV	Char	2	$2.	E11b2. Left PCoA compared to previous study
56	LPCOARAT	Num	8	3.	E11a. Left PCoA rating
6	MANUFACT	Num	8	3.	A6a. MRA machine manufacturer
21	NOK_REAS	Char	30	$30.	D3a. Reason study not acceptable for interpretation?
33	RACABASE	Char	2	$2.	E3b1. Right ACA compared to pre-randomization
34	RACAPREV	Char	2	$2.	E3b2. Right ACA compared to previous study
32	RACARATE	Num	8	3.	E3a. Right ACA rating
13	REAS_MRA	Num	8	3.	B1. Reason for MRA procedure
5	REAS_SPC	Char	30	$30.	A4b. Specify reason MRA not study adequate
11	RECTFVA	Num	8	3.	A9b1. Field of view (rectangular) dimension 1
12	RECTFVB	Num	8	3.	A9b2. Field of view (rectangular) dimension 2
60	RHROBBAS	Char	2	$2.	E12b1. Right hemisphere blood flow compared to pre-randomization
61	RHROBPRV	Char	2	$2.	E12b2. Right hemisphere blood flow compared to previous study
59	RHROBRAT	Num	8	3.	E12a. Robustness of right hemisphere blood flow
27	RICABASE	Char	2	$2.	E1b1. Right ICA compared to pre-randomization
28	RICAPREV	Char	2	$2.	E1b2. Right ICA compared to previous study
26	RICARATE	Num	8	3.	E1a. Right ICA rating
30	RMCABASE	Char	2	$2.	E2b1. Right MCA compared to pre-randomization
31	RMCAPREV	Char	2	$2.	E2b2. Right MCA compared to previous study
29	RMCARATE	Num	8	3.	E2a. Right MCA rating
36	RPCABASE	Char	2	$2.	E4b1. Right PCA compared to pre-randomization
37	RPCAPREV	Char	2	$2.	E4b2. Right PCA compared to previous study
35	RPCARATE	Num	8	3.	E4a. Right PCA rating
54	RPCOABAS	Char	2	$2.	E10b1. Right PCoA compared to pre-randomization
55	RPCOAPRV	Char	2	$2.	E10b2. Right PCoA compared to previous study
53	RPCOARAT	Num	8	3.	E10a. Right PCoA rating
18	R_INITS1	Char	3	$3.	D1a. Reader 1 initials
19	R_INITS2	Char	3	$3.	D1b. Reader 2 initials
22	SCANQUAL	Num	8	3.	D4. Scan quality
23	SOURCEAV	Num	8	3.	D5a. Source images available for review?
8	SPATRESA	Num	8	4.	A8a. Matrix dimension 1
9	SPATRESB	Num	8	4.	A8b. Matrix dimension 2
20	STUDY_OK	Num	8	3.	D3. Study acceptable for interpretation?
24	TARGETAV	Num	8	3.	D5b. Targeted MIP images available for review?
25	UNSEGMAV	Num	8	3.	D5c. Unsegmented paraxial images available for review?
66	comp_dfrmrand	Num	8		<created variable> A2. Date of MRA procedure as days from RAND visit
68	dbasescn_frmrand	Num	8		<created variable> C1a. Date of pre-randomization study as days from RAND visit
69	dprevscn_frmrand	Num	8		<created variable> C1b. Date of previous study as days from RAND visit
67	event_dtfrmrand	Num	8		<created variable> B1a. Date of neurological event as days from RAND visit
65	ldu_id	Char	10		ID for public use datasets
70	r_datefrmrand	Num	8		<created variable> D2. Date read as days from RAND visit
16	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	ADEQUATE	Num	8	3.	A4. MRA study adequate for interpretation?
4	AD_REASN	Num	8	3.	A4a. Reason MRA not study adequate
5	REAS_SPC	Char	30	$30.	A4b. Specify reason MRA not study adequate
6	MANUFACT	Num	8	3.	A6a. MRA machine manufacturer
7	ECHOTIME	Num	8	4.1	A7. Echo time (MS)
8	SPATRESA	Num	8	4.	A8a. Matrix dimension 1
9	SPATRESB	Num	8	4.	A8b. Matrix dimension 2
10	FOV	Num	8	3.	A9a. Field of view (square)
11	RECTFVA	Num	8	3.	A9b1. Field of view (rectangular) dimension 1
12	RECTFVB	Num	8	3.	A9b2. Field of view (rectangular) dimension 2
13	REAS_MRA	Num	8	3.	B1. Reason for MRA procedure
14	EV_TYPE	Num	8	3.	B1b. Type of neurological event
15	DESTATUS	Char	1	$1.	DESTATUS
16	vistype	Char	7		<created variable> VISIT TYPE
17	COMPPREV	Num	8	3.	C1. Is this MRA scan being compared to a previous scan?
18	R_INITS1	Char	3	$3.	D1a. Reader 1 initials
19	R_INITS2	Char	3	$3.	D1b. Reader 2 initials
20	STUDY_OK	Num	8	3.	D3. Study acceptable for interpretation?
21	NOK_REAS	Char	30	$30.	D3a. Reason study not acceptable for interpretation?
22	SCANQUAL	Num	8	3.	D4. Scan quality
23	SOURCEAV	Num	8	3.	D5a. Source images available for review?
24	TARGETAV	Num	8	3.	D5b. Targeted MIP images available for review?
25	UNSEGMAV	Num	8	3.	D5c. Unsegmented paraxial images available for review?
26	RICARATE	Num	8	3.	E1a. Right ICA rating
27	RICABASE	Char	2	$2.	E1b1. Right ICA compared to pre-randomization
28	RICAPREV	Char	2	$2.	E1b2. Right ICA compared to previous study
29	RMCARATE	Num	8	3.	E2a. Right MCA rating
30	RMCABASE	Char	2	$2.	E2b1. Right MCA compared to pre-randomization
31	RMCAPREV	Char	2	$2.	E2b2. Right MCA compared to previous study
32	RACARATE	Num	8	3.	E3a. Right ACA rating
33	RACABASE	Char	2	$2.	E3b1. Right ACA compared to pre-randomization
34	RACAPREV	Char	2	$2.	E3b2. Right ACA compared to previous study
35	RPCARATE	Num	8	3.	E4a. Right PCA rating
36	RPCABASE	Char	2	$2.	E4b1. Right PCA compared to pre-randomization
37	RPCAPREV	Char	2	$2.	E4b2. Right PCA compared to previous study
38	LICARATE	Num	8	3.	E5a. Left ICA rating
39	LICABASE	Char	2	$2.	E5b1. Left ICA compared to pre-randomization
40	LICAPREV	Char	2	$2.	E5b2. Left ICA compared to previous study
41	LMCARATE	Num	8	3.	E6a. Left MCA rating
42	LMCABASE	Char	2	$2.	E6b1. Left MCA compared to pre-randomization
43	LMCAPREV	Char	2	$2.	E6b2. Left MCA compared to previous study
44	LACARATE	Num	8	3.	E7a. Left ACA rating
45	LACABASE	Char	2	$2.	E7b1. Left ACA compared to pre-randomization
46	LACAPREV	Char	2	$2.	E7b2. Left ACA compared to previous study
47	LPCARATE	Num	8	3.	E8a. Left PCA rating
48	LPCABASE	Char	2	$2.	E8b1. Left PCA compared to pre-randomization
49	LPCAPREV	Char	2	$2.	E8b2. Left PCA compared to previous study
50	BASLRATE	Num	8	3.	E9a. Basilar rating
51	BASLBASE	Char	2	$2.	E9b1. Basilar compared to pre-randomization

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
52	BASLPREV	Char	2	$2.	E9b2. Basilar compared to previous study
53	RPCOARAT	Num	8	3.	E10a. Right PCoA rating
54	RPCOABAS	Char	2	$2.	E10b1. Right PCoA compared to pre-randomization
55	RPCOAPRV	Char	2	$2.	E10b2. Right PCoA compared to previous study
56	LPCOARAT	Num	8	3.	E11a. Left PCoA rating
57	LPCOABAS	Char	2	$2.	E11b1. Left PCoA compared to pre-randomization
58	LPCOAPRV	Char	2	$2.	E11b2. Left PCoA compared to previous study
59	RHROBRAT	Num	8	3.	E12a. Robustness of right hemisphere blood flow
60	RHROBBAS	Char	2	$2.	E12b1. Right hemisphere blood flow compared to pre-randomization
61	RHROBPRV	Char	2	$2.	E12b2. Right hemisphere blood flow compared to previous study
62	LHROBRAT	Num	8	3.	E13a. Robustness of left hemisphere blood flow
63	LHROBBAS	Char	2	$2.	E13b1. Left hemisphere blood flow compared to pre-randomization
64	LHROBPRV	Char	2	$2.	E13b2. Left hemisphere blood flow compared to previous study
65	ldu_id	Char	10		ID for public use datasets
66	comp_dfrmrand	Num	8		<created variable> A2. Date of MRA procedure as days from RAND visit
67	event_dtfrmrand	Num	8		<created variable> B1a. Date of neurological event as days from RAND visit
68	dbasescn_frmrand	Num	8		<created variable> C1a. Date of pre-randomization study as days from RAND visit
69	dprevscn_frmrand	Num	8		<created variable> C1b. Date of previous study as days from RAND visit
70	r_datefrmrand	Num	8		<created variable> D2. Date read as days from RAND visit

```
*F019fmts.txt;

proc format;

  value ADEQUATEF
    1='1: No'
    2='2: Yes';

  value AD_REASNF
    1='1: Incomplete study'
    2='2: Motion artifact'
    3='3: Other';

  value MANUFACTF
    1='1: GE'
    2='2: Siemens'
    3='3: Picker Edge'
    4='4: Marconi'
    5='5: Phillips'
    6='6: Other';

  value REAS_MRAF
    1='1: Pre-randomization study'
    2='2: Routine follow-up study'
    3='3: Exit from study'
    4='4: TCD endpoint or 3 inadequte TCD exams'
    5='5: New neurological event'
    6='6: Post-meningitis event'
    7='7: Post-head injury event';

  value EV_TYPEF
    1='1: TIA'
    2='2: Cerebral infarction'
    3='3: Intracranial hemorrhage'
    4='4: Other';


* format adequate adequatef. ad_reasn ad_reasnf. manufact manufactf. reas_mra reas_mraf. ev_type
ev_typef.;
```

STOP II TRIAL
MRA SCAN

AFFIX PATIENT LABEL

HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	225	99.56	225	99.56
P	1	0.44	226	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	8	3.54	8	3.54
NE-102	1	0.44	9	3.98
QT-301	20	8.85	29	12.83
QT-301A	14	6.19	43	19.03
QT-302	11	4.87	54	23.89
QT-302A	4	1.77	58	25.66
QT-302B	1	0.44	59	26.11
QT-303	7	3.10	66	29.20
QT-303A	1	0.44	67	29.65
QT-304	13	5.75	80	35.40
QT-304B	1	0.44	81	35.84
QT-305	3	1.33	84	37.17
QT-306	2	0.88	86	38.05
QT-306A	1	0.44	87	38.50
QT-307	1	0.44	88	38.94
QT-308B	1	0.44	89	39.38
QT-309	1	0.44	90	39.82
QT-309A	1	0.44	91	40.27
QT-403	19	8.41	110	48.67
QT-404	5	2.21	115	50.88
QT-405	50	22.12	165	73.01
QT-407	1	0.44	166	73.45
QT-408	4	1.77	170	75.22
QT-409	18	7.96	188	83.19
QT-411	2	0.88	190	84.07
QT-412	2	0.88	192	84.96
QT-413	19	8.41	211	93.36
QT-415	10	4.42	221	97.79
QT-416	5	2.21	226	100.00

SECTION A TO BE COMPLETED BY STOP II NEURORADIOLOGIST

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of MRA procedure (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of MRA procedure as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
226	0	366.5	446.2	-483.0	-33.0	296.5	708.0	1399.0

A3. Was the patient's MRA data copied to a STOP II optical disk? ☐ **1. NO** ☐ **2. YES**

↓

A3.a What is the file name of the patient's MR study on the STOP II optical disk?

_____

[Variables NOT included in dataset.]

A4. Is the MRA study adequate for interpretation? ☐ **1. NO** ☐ **2. YES**

A4. MRA study adequate for interpretation?				
ADEQUATE	Frequency	Percent	Cum Freq	Cum Percent
1	6	2.65	6	2.65
2	220	97.35	226	100.00

A4.a. Reason:

☐ 1. Incomplete Study ☐ 2. Motion Artifact ☐ 3. Other → A4.b Specify:_____

RESCHEDULE STUDY WITHIN 2 WEEKS _____

A4a. Reason MRA not study adequate				
AD_REASN	Frequency	Percent	Cum Freq	Cum Percent
-2	220	97.35	220	97.35
2	2	0.88	222	98.23
3	4	1.77	226	100.00

A4b. Specify reason MRA not study adequate				
REAS_SPC	Frequency	Percent	Cum Freq	Cum Percent
-2	222	98.23	222	98.23
Braces	1	0.44	223	98.67
metallic artifact lt.	1	0.44	224	99.12
sig. dental metallic artif.	1	0.44	225	99.56
technical factors	1	0.44	226	100.00

A5. Name of Imaging Center: _____

[Variable NOT included in dataset.]

A6. Machine/Model: _____

A6a. MRA machine manufacturer				
MANUFACT	Frequency	Percent	Cum Freq	Cum Percent
1=GE	104	46.02	104	46.02
2=SIEMENS	68	30.09	172	76.11
3=PICKER EDGE	32	14.16	204	90.27
5=PHILLIPS	22	9.73	226	100.00

[Variables NOT included in dataset for specify other manufacturer or model name.]

A7. Echo Time (ms): ☐☐ . ☐☐

Analysis Variable : ECHOTIME A7. Echo time (MS)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
218	0	3.9	1.1	2.0	2.8	3.5	4.9	9.0

A7. Echo time (MS)				
ECHOTIME	Frequency	Percent	Cum Freq	Cum Percent
-9	8	100.00	8	100.00

A8. Matrix: ☐☐☐ **X** ☐☐☐

Analysis Variable : SPATRESA A8a. Matrix dimension 1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
219	0	303.0	108.8	160.0	256.0	256.0	258.0	512.0

A8a. Matrix dimension 1				
SPATRESA	Frequency	Percent	Cum Freq	Cum Percent
-9	7	100.00	7	100.00

Analysis Variable : SPATRESB A8b. Matrix dimension 2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
219	0	304.6	108.0	160.0	256.0	256.0	256.0	512.0

A8b. Matrix dimension 2				
SPATRESB	Frequency	Percent	Cum Freq	Cum Percent
-9	7	100.00	7	100.00

A9. Field-of-View (range: 6 - 20 cm): a. [ ][ ] (if square)

Analysis Variable : FOV A9a. Field of view (square)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
116	0	19.2	2.7	11.0	18.0	20.0	20.0	30.0

A9a. Field of view (square)				
FOV	Frequency	Percent	Cum Freq	Cum Percent
-9	6	5.45	6	5.45
-1	104	94.55	110	100.00

A9. Field-of-View (range: 6 - 20 cm): b. [ ][ ] **X** [ ][ ] (if rectangular)

Analysis Variable : RECTFVA A9b1. Field of view (rectangular) dimension 1								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
104	0	19.8	5.0	13.0	18.0	20.0	21.0	60.0

A9b1. Field of view (rectangular) dimension 1				
RECTFVA	Frequency	Percent	Cum Freq	Cum Percent
-2	122	100.00	122	100.00

Analysis Variable : RECTFVB A9b2. Field of view (rectangular) dimension 2								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
104	0	17.6	2.4	14.0	15.0	17.0	20.0	24.0

A9b2. Field of view (rectangular) dimension 2				
RECTFVB	Frequency	Percent	Cum Freq	Cum Percent
-2	122	100.00	122	100.00

SECTION B TO BE COMPLETED BY STUDY COORDINATOR

B1. Reason for MRA procedure:

1. Pre-Randomization Study
2. Routine Follow-up Study
3. Exit from Study
4. TCD Endpoint or 3 inadequate TCD exams by at least 2 examiners
5. New Neurological Event

B1. Reason for MRA procedure				
REAS_MRA	Frequency	Percent	Cum Freq	Cum Percent
1	80	35.40	80	35.40
2	69	30.53	149	65.93
3	55	24.34	204	90.27
4	14	6.19	218	96.46
5	8	3.54	226	100.00

B1.a. Date of event (Month/Day Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : event_dtfrmrand <created variable> B1a. Date of neurological event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
8	0	302.9	315.6	51.0	110.0	172.0	408.5	991.0

<created variable> B1a. Date of neurological event as days from RAND visit				
event_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	218	100.00	218	100.00

B1.b. Type of event:

1. TIA 2. Cerebral Infarction

3. Intracranial Hemorrhage → B1.b1. Type 1. Intraparenchymal 2. Subarachnoid 3. Intraventricula

4. Other: B1.b2. Specify: _____

6. Post-meningitis event → B1.c. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ __

B1.d. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ __

7. Post-head injury event → B1.e. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ __

B1.f. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ __

B1b. Type of neurological event				
EV_TYPE	Frequency	Percent	Cum Freq	Cum Percent
-2	218	96.46	218	96.46
1	2	0.88	220	97.35
2	1	0.44	221	97.79
4	5	2.21	226	100.00

[No Post meningitis or Post-head injury events reported. Date variables NOT included in dataset.]

[Variables NOT included in dataset for B1.b1 Type or B1.b2 Other: Specify.]

B2. Date optical disk with MRA study sent to the STOP II Data Coordinating Center (Month/Day/Year): ___ ___/___ ___/___ ___ ___ __

[Variable NOT included in dataset.]

SECTION C TO BE COMPLETED BY DCC DATA MANAGER

C1. Is this MRA scan being compared to a previous scan? ☐ **1. NO** ☐ **2. YES**

C1. Is this MRA scan being compared to a previous scan?				
COMPPREV	Frequency	Percent	Cum Freq	Cum Percent
1	82	36.28	82	36.28
2	144	63.72	226	100.00

↓

Which Scan(s)?
C1.a. Pre-randomization study dated ___ ___/___ ___/___ ___ ___ ___

C1.b. Previous scan dated ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : dbasescn_frmrand <created variable> C1a. Date of pre-randomization study as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
144	0	-44.0	21.2	-116.0	-56.0	-40.0	-28.0	-16.0

<created variable> C1a. Date of pre-randomization study as days from RAND visit

dbasescn_frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	82	100.00	82	100.00

Analysis Variable : dprevscn_frmrand <created variable> C1b. Date of previous study as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
45	0	476.2	300.1	83.0	216.0	365.0	734.0	1106.0

<created variable> C1b. Date of previous study as days from RAND visit

dprevscn_frmrand	Frequency	Percent	Cum Freq	Cum Percent
.	181	100.00	181	100.00

SECTIONS D - F TO BE COMPLETED BY READERS

D1. Readers: a. (Name): _____ (Initials): | | | |

b. (Name): _____ (Initials): | | | |

D1a. Reader 1 initials				
R_INITS1	Frequency	Percent	Cum Freq	Cum Percent
FM	11	4.87	11	4.87
JAB	41	18.14	52	23.01
RZ	174	76.99	226	100.00

D1b. Reader 2 initials				
R_INITS2	Frequency	Percent	Cum Freq	Cum Percent
-1	3	1.33	3	1.33
FM	156	69.03	159	70.35
JAB	59	26.11	218	96.46
RZ	8	3.54	226	100.00

D2. Date read (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : r_datefrmrand <created variable> D2. Date read as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
226	0	588.6	582.6	-463.0	-15.0	570.0	1230.0	1697.0

D3. Study acceptable for interpretation? ☐ **1. NO** ☐ **2. YES**

D3. Study acceptable for interpretation?				
STUDY_OK	Frequency	Percent	Cum Freq	Cum Percent
1	2	0.88	2	0.88
2	224	99.12	226	100.00

D3.a. Reason: _____

_____

D3a. Reason study not acceptable for interpretation?				
NOK_REAS	Frequency	Percent	Cum Freq	Cum Percent
-2	224	99.12	224	99.12
artifacts due to braces	1	0.44	225	99.56
marked artifact - no detail	1	0.44	226	100.00

D4. Scan Quality (check one):

☐ 1. Excellent

☐ 2. Slight Artifact/Motion, Adequate

☐ 3. Severe Artifact/Motion, Inadequate

D4. Scan quality				
SCANQUAL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.44	1	0.44
1	7	3.10	8	3.54
2	215	95.13	223	98.67
3	3	1.33	226	100.00

[-9: P823360074 *QT-302 exam. Reader Comments: RZ - "too white"; JB - "Moderate Artifact"]*

D5. Are the following available for review?

	1. NO	2. YES
a. Source images	☐	☐

D5a. Source images available for review?				
SOURCEAV	Frequency	Percent	Cum Freq	Cum Percent
1	22	9.73	22	9.73
2	204	90.27	226	100.00

b. Targeted MIP images ☐ ☐

D5b. Targeted MIP images available for review?				
TARGETAV	Frequency	Percent	Cum Freq	Cum Percent
1	17	7.52	17	7.52
2	209	92.48	226	100.00

c. Unsegmented paraxial images ☐ ☐

D5c. Unsegmented paraxial images available for review?				
UNSEGMAV	Frequency	Percent	Cum Freq	Cum Percent
1	14	6.19	14	6.19
2	212	93.81	226	100.00

E. CENTRAL REVIEW INTERPRETATION (COMPLETE TABLE FOR MRA USING THE CODES BELOW)

a. RATING	b. STATUS
1 = NORMAL 2 = STENOSIS, MILD 3 = STENOSIS, MODERATE 4 = STENOSIS, SEVERE 5 = OCCLUSION 6 = NOT ASSESSABLE 7 = DEPHASING ARTIFACT, LIKELY NORMAL	A = IMPROVED B = SAME (NO PROGRESSION) C = WORSE (PROGRESSION) D = CANNOT DETERMINE E = N/A

		RATING	STATUS COMPARED TO Pre-rand. Study	STATUS COMPARED TO Previous Study
E1.	RIGHT ICA	a.	b1.	b2.

E1a. Right ICA rating				
RICARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.88	2	0.88
1	213	94.25	215	95.13
2	2	0.88	217	96.02
4	3	1.33	220	97.35
6	1	0.44	221	97.79
7	5	2.21	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.
-9: P088161782 QT-409 exam. Reader Comments: not read - artifacts due to braces.]

E1b1. Right ICA compared to pre-randomization				
RICABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	139	61.50	221	97.79
C	3	1.33	224	99.12
D	2	0.88	226	100.00

E1b2. Right ICA compared to previous study				
RICAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL **2 = STENOSIS, MILD** **3 = STENOSIS, MODERATE** **4 = STENOSIS, SEVERE** **5 = OCCLUSION** **6 = NOT ASSESSABLE** **7 = DEPHASING ARTIFACT, LIKELY NORMAL**	**A = IMPROVED** **B = SAME (NO PROGRESSION)** **C = WORSE (PROGRESSION)** **D = CANNOT DETERMINE** **E = N/A**

		RATING	**STATUS COMPARED TO Pre-rand. Study**	**STATUS COMPARED TO Previous Study**
E2.	RIGHT MCA	a. ☐	b1. ☐	b2. ☐

E2a. Right MCA rating				
RMCARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.88	2	0.88
1	222	98.23	224	99.12
6	1	0.44	225	99.56
7	1	0.44	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.
-9: P088161782 QT-409 exam. Reader Comments: not read - artifacts due to braces.]

E2b1. Right MCA compared to pre-randomization				
RMCABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	142	62.83	224	99.12
D	2	0.88	226	100.00

E2b2. Right MCA compared to previous study				
RMCAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL **2 = STENOSIS, MILD** **3 = STENOSIS, MODERATE** **4 = STENOSIS, SEVERE** **5 = OCCLUSION** **6 = NOT ASSESSABLE** **7 = DEPHASING ARTIFACT, LIKELY NORMAL**	**A = IMPROVED** **B = SAME (NO PROGRESSION)** **C = WORSE (PROGRESSION)** **D = CANNOT DETERMINE** **E = N/A**

		RATING	**STATUS COMPARED TO Pre-rand. Study**	**STATUS COMPARED TO Previous Study**
E3.	RIGHT ACA	a. ☐	b1. ☐	b2. ☐

E3a. Right ACA rating				
RACARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.88	2	0.88
1	215	95.13	217	96.02
3	4	1.77	221	97.79
6	3	1.33	224	99.12
7	1	0.44	225	99.56
8	1	0.44	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.
-9: P088161782 QT-409 exam. Reader Comments: not read - artifacts due to braces.]

E3b1. Right ACA compared to pre-randomization				
RACABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	141	62.39	223	98.67
D	3	1.33	226	100.00

E3b2. Right ACA compared to previous study				
RACAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL 2 = STENOSIS, MILD 3 = STENOSIS, MODERATE 4 = STENOSIS, SEVERE 5 = OCCLUSION 6 = NOT ASSESSABLE 7 = DEPHASING ARTIFACT, LIKELY NORMAL	A = IMPROVED B = SAME (NO PROGRESSION) C = WORSE (PROGRESSION) D = CANNOT DETERMINE E = N/A

		RATING	STATUS COMPARED TO Pre-rand. Study	STATUS COMPARED TO Previous Study
E4.	RIGHT PCA	a.	b1.	b2.

E4a. Right PCA rating				
RPCARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.44	1	0.44
1	223	98.67	224	99.12
6	1	0.44	225	99.56
7	1	0.44	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.]

E4b1. Right PCA compared to pre-randomization				
RPCABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	142	62.83	224	99.12
D	2	0.88	226	100.00

E4b2. Right PCA compared to previous study				
RPCAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL **2 = STENOSIS, MILD** **3 = STENOSIS, MODERATE** **4 = STENOSIS, SEVERE** **5 = OCCLUSION** **6 = NOT ASSESSABLE** **7 = DEPHASING ARTIFACT, LIKELY NORMAL**	**A = IMPROVED** **B = SAME (NO PROGRESSION)** **C = WORSE (PROGRESSION)** **D = CANNOT DETERMINE** **E = N/A**

		RATING	**STATUS COMPARED TO Pre-rand. Study**	**STATUS COMPARED TO Previous Study**
E5.	LEFT ICA	a. ☐	b1. ☐	b2. ☐

E5a. Left ICA rating				
LICARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.88	2	0.88
1	218	96.46	220	97.35
6	2	0.88	222	98.23
7	4	1.77	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.
-9: P088161782 QT-409 exam. Reader Comments: not read - artifacts due to braces.]

E5b1. Left ICA compared to pre-randomization				
LICABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	141	62.39	223	98.67
D	3	1.33	226	100.00

E5b2. Left ICA compared to previous study				
LICAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL **2 = STENOSIS, MILD** **3 = STENOSIS, MODERATE** **4 = STENOSIS, SEVERE** **5 = OCCLUSION** **6 = NOT ASSESSABLE** **7 = DEPHASING ARTIFACT, LIKELY NORMAL**	**A = IMPROVED** **B = SAME (NO PROGRESSION)** **C = WORSE (PROGRESSION)** **D = CANNOT DETERMINE** **E = N/A**

		RATING	**STATUS COMPARED TO Pre-rand. Study**	**STATUS COMPARED TO Previous Study**
E6.	LEFT MCA	a.	b1.	b2.

E6a. Left MCA rating				
LMCARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.88	2	0.88
1	220	97.35	222	98.23
2	1	0.44	223	98.67
6	2	0.88	225	99.56
7	1	0.44	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.
-9: P088161782 QT-409 exam. Reader Comments: not read - artifacts due to braces.]

E6b1. Left MCA compared to pre-randomization				
LMCABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	141	62.39	223	98.67
D	3	1.33	226	100.00

E6b2. Left MCA compared to previous study				
LMCAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL 2 = STENOSIS, MILD 3 = STENOSIS, MODERATE 4 = STENOSIS, SEVERE 5 = OCCLUSION 6 = NOT ASSESSABLE 7 = DEPHASING ARTIFACT, LIKELY NORMAL	A = IMPROVED B = SAME (NO PROGRESSION) C = WORSE (PROGRESSION) D = CANNOT DETERMINE E = N/A

		RATING	STATUS COMPARED TO Pre-rand. Study	STATUS COMPARED TO Previous Study
E7.	LEFT ACA	a. [ ]	b1. [ ]	b2. [ ]

E7a. Left ACA rating				
LACARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	4	1.77	4	1.77
1	209	92.48	213	94.25
2	1	0.44	214	94.69
3	3	1.33	217	96.02
4	1	0.44	218	96.46
5	1	0.44	219	96.90
6	6	2.65	225	99.56
7	1	0.44	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.
-9: P088161782 QT-409 exam. Reader Comments: not read - artifacts due to braces.
-9: P091993715 QT-405 exam. Reader Comments: congenitally small.
-9: P091993715 QT-409 exam. Reader Comments: congenitally small.]

E7b1. Left ACA compared to pre-randomization				
LACABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	139	61.50	221	97.79
D	5	2.21	226	100.00

E7b2. Left ACA compared to previous study				
LACAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL 2 = STENOSIS, MILD 3 = STENOSIS, MODERATE 4 = STENOSIS, SEVERE 5 = OCCLUSION 6 = NOT ASSESSABLE 7 = DEPHASING ARTIFACT, LIKELY NORMAL	A = IMPROVED B = SAME (NO PROGRESSION) C = WORSE (PROGRESSION) D = CANNOT DETERMINE E = N/A

		RATING	STATUS COMPARED TO Pre-rand. Study	STATUS COMPARED TO Previous Study
E8.	LEFT PCA	a.	b1.	b2.

E8a. Left PCA rating				
LPCARATE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.44	1	0.44
1	222	98.23	223	98.67
6	2	0.88	225	99.56
7	1	0.44	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.]

E8b1. Left PCA compared to pre-randomization				
LPCABASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	141	62.39	223	98.67
D	3	1.33	226	100.00

E8b2. Left PCA compared to previous study				
LPCAPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

a. RATING	b. STATUS
1 = NORMAL 2 = STENOSIS, MILD 3 = STENOSIS, MODERATE 4 = STENOSIS, SEVERE 5 = OCCLUSION 6 = NOT ASSESSABLE 7 = DEPHASING ARTIFACT, LIKELY NORMAL	A = IMPROVED B = SAME (NO PROGRESSION) C = WORSE (PROGRESSION) D = CANNOT DETERMINE E = N/A

		RATING	STATUS COMPARED TO Pre-rand. Study	STATUS COMPARED TO Previous Study
E9.	BASILAR	a.	b1.	b2.

E9a. Basilar rating				
BASLRATE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.44	1	0.44
1	222	98.23	223	98.67
6	2	0.88	225	99.56
7	1	0.44	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: E1-E9 all visualized but can't exclude mild abnormality. No mod. or severe stenosis is present.]

E9b1. Basilar compared to pre-randomization				
BASLBASE	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	142	62.83	224	99.12
D	2	0.88	226	100.00

E9b2. Basilar compared to previous study				
BASLPREV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

1. NORMAL **2. SMALL** **3. NOT VISUALIZED**

E10.a RIGHT PCoA ☐ ☐ ☐ b1. ☐ b2. ☐

E10a. Right PCoA rating				
RPCOARAT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.88	2	0.88
-1	1	0.44	3	1.33
1	168	74.34	171	75.66
2	40	17.70	211	93.36
3	15	6.64	226	100.00

[-9: P946227653 QT-302 exam. Reader Comments: one reader coded RPCoA as 2. Small.
-9: P088161782 QT-409 exam. Reader Comments: artifacts due to braces.
-1: P896225781 QT-403 exam. Reader Comments: barely acceptable MRA.]

E10b1. Right PCoA compared to pre-randomization				
RPCOABAS	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	141	62.39	223	98.67
C	1	0.44	224	99.12
D	2	0.88	226	100.00

E10b2. Right PCoA compared to previous study				
RPCOAPRV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
A	1	0.44	182	80.53
B	40	17.70	222	98.23
C	1	0.44	223	98.67
D	3	1.33	226	100.00

1. NORMAL **2. SMALL** **3. NOT VISUALIZED**

E11.a LEFT PCoA ☐ ☐ ☐ b1. ☐ b2. ☐

E11a. Left PCoA rating				
LPCOARAT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.88	2	0.88
-1	1	0.44	3	1.33
1	183	80.97	186	82.30
2	32	14.16	218	96.46
3	8	3.54	226	100.00

[-9: P946227653 QT-302 exam. Reader Comments: one reader coded RPCoA as 2. Small.
-9: P088161782 QT-409 exam. Reader Comments: artifacts due to braces.
-1: P896225781 QT-403 exam. Reader Comments: barely acceptable MRA.]

E11b1. Left PCoA compared to pre-randomization				
LPCOABAS	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	142	62.83	224	99.12
D	2	0.88	226	100.00

E11b2. Left PCoA compared to previous study				
LPCOAPRV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

		1. GOOD	**2. POOR**	**3. INDETERMINATE**		
E12.a	Robustness of R. hemisphere blood flow	☐	☐	☐	b1. ☐	b2. ☐

E12a. Robustness of right hemisphere blood flow				
RHROBRAT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.44	1	0.44
-1	1	0.44	2	0.88
1	222	98.23	224	99.12
3	2	0.88	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: artifacts due to braces.
-1: P896225781 QT-403 exam. Reader Comments: barely acceptable MRA]

E12b1. Right hemisphere blood flow compared to pre-randomization				
RHROBBAS	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	142	62.83	224	99.12
D	2	0.88	226	100.00

E12b2. Right hemisphere blood flow compared to previous study				
RHROBPRV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

1. GOOD 2. POOR 3. INDETERMINATE

E13.a Robustness of L. hemisphere Blood flow ☐ ☐ ☐ b1. ☐ b2. ☐

E13a. Robustness of left hemisphere blood flow				
LHROBRAT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.44	1	0.44
-1	1	0.44	2	0.88
1	222	98.23	224	99.12
3	2	0.88	226	100.00

[-9: P704156254 QT-301A exam. Reader Comments: artifacts due to braces.
-1: P896225781 QT-403 exam. Reader Comments: barely acceptable MRA]

E13b1. Left hemisphere blood flow compared to pre-randomization				
LHROBBAS	Frequency	Percent	Cum Freq	Cum Percent
-2	82	36.28	82	36.28
B	142	62.83	224	99.12
D	2	0.88	226	100.00

E13b2. Left hemisphere blood flow compared to previous study				
LHROBPRV	Frequency	Percent	Cum Freq	Cum Percent
-2	181	80.09	181	80.09
B	42	18.58	223	98.67
D	3	1.33	226	100.00

F. COMMENTS:

[Variable NOT included in dataset.]

STOP II
FORM 20: TRANSFUSION FORM

A. Collection Information:
The **Transfusion Form** (Form 20) was to be completed for STOP II Potential patients previously randomized in the STOP trial and for STOP II Randomized patients to document each received transfusion. Form 20s with completion dates prior to December 2000 are forms for patients previously randomized in STOP that were collected in the interim period between the end of STOP and the beginning of STOP II. After July 2003, collection of Form 20 was discontinued for STOP II cross-over and endpoint patients. Transfusion information for non-STOP patients who started transfusion prior to enrollment was collected on Form 22 (Transfusion History Log) at enrollment. Form 13B (Local Laboratory Form for Non-Randomized Patients Receiving Transfusions) was used to collect transfusion information at and after enrollment of non-STOP potential patients for each transfusion.

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p020_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, COMP_DFRMRAND**

Records in the dataset are sorted by LDU_ID and COMP_DFRMRAND.

F. Number of Observations (Patients) in SAS Dataset: 1,996 (67)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 535-537
- Listing of Variables by Position: See pp. 538-540

H. Formats:
The file **f020fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 541-547.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The valid EX_TYPE for Form 20 is TR - for transfusion visits

- **EX_NUM** - is the variable name for exam number. For Form 20, this is the transfusion number as indicated by:
  - 001-150 series numbers indicate transfusions received by patients previously randomized in STOP after the end of STOP but prior to enrollment as STOP II Potential patients. This number is the transfusion number since the patient started transfusions in STOP.
  - EX_NUM=199 was used when a Potential patient transfusion number was unknown.
  - 300 series numbers indicate transfusions received by patients previously randomized in STOP after enrollment as STOP II Potential patients.
  - 500 series numbers indicate transfusions received by STOP II Randomized patients on or after the randomization visit
  - EX_NUM=599 was used when a Randomized patient transfusion number was unknown

Data Set Name	PUBDS.P02O_FINAL	Observations	1996
Member Type	DATA	Variables	103
Engine	V9	Indexes	0
Created	Thursday, March 09, 2006 02:25:46 PM	Observation Length	952
Last Modified	Thursday, March 09, 2006 02:25:46 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	119
First Data Page	1
Max Obs per Page	17
Obs in First Data Page	2
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p02O_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
79	ALL2	Num	8	3.	E1d. Other allergic reactions
80	ALL2_DAP	Num	8	3.	E1d2. AM PM designation: Other allergic reactions
81	ALL2_RAP	Num	8	3.	E1d4. AM PM designation: Other allergic reactions
76	ALLERGIC	Num	8	3.	E1c. Severe anaphylaxis
77	ALL_DAP	Num	8	3.	E1c2. AM PM designation: Severe anaphylaxis
78	ALL_RAP	Num	8	3.	E1c4. AM PM designation: Severe anaphylaxis
90	ANTIG_AP	Num	8	3.	E2a1. AM PM designation
27	ANTI_C	Num	8	3.	D5d2. Antibody C
33	ANTI_C2	Num	8	3.	D5d5. Antibody c
25	ANTI_D	Num	8	3.	D5d1. Antibody D
29	ANTI_E	Num	8	3.	D5d3. Antibody E
31	ANTI_E2	Num	8	3.	D5d4. Antibody e
34	ANTI_F2	Num	8	3.	D5d6. Antibody f
53	ANTI_FYA	Num	8	3.	D5d19. Antibody Fya
55	ANTI_FYB	Num	8	3.	D5d20. Antibody Fyb
64	ANTI_I	Num	8	3.	D5d26. Antibody I
56	ANTI_JKA	Num	8	3.	D5d21. Antibody Jka
58	ANTI_JKB	Num	8	3.	D5d22. Antibody Jkb
46	ANTI_JSA	Num	8	3.	D5d15. Antibody Jsa
48	ANTI_JSB	Num	8	3.	D5d16. Antibody Jsb
51	ANTI_K2	Num	8	3.	D5d18. Antibody k
49	ANTI_KEL	Num	8	3.	D5d17. Antibody K (Kell)
43	ANTI_KPA	Num	8	3.	D5d13. Antibody Kpa
45	ANTI_KPB	Num	8	3.	D5d14. Antibody Kpb
60	ANTI_LEA	Num	8	3.	D5d23. Antibody Lea
61	ANTI_LEB	Num	8	3.	D5d24. Antibody Leb

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
36	ANTI_M	Num	8	3.	D5d8. Antibody M
37	ANTI_N	Num	8	3.	D5d9. Antibody N
65	ANTI_OTH	Num	8	3.	D5d27. Antibody -- Other
62	ANTI_P1	Num	8	3.	D5d25. Antibody P1
38	ANTI_S	Num	8	3.	D5d10. Antibody S
39	ANTI_S2	Num	8	3.	D5d11. Antibody s
41	ANTI_U	Num	8	3.	D5d12. Antibody U
35	ANTI_V	Num	8	3.	D5d7. Antibody V
91	A_DIR_H	Num	8	3.	E2b. Direct Antiglobulin Test (DAT)
92	A_IND_H	Num	8	3.	E2c. Indirect Antiglobulin Test (IAT)
8	BP_DIAS	Num	8	4.	B2b. Diastolic blood pressure (supine)
7	BP_SYS	Num	8	4.	B2a. Systolic blood pressure (supine)
69	COMPNOTE	Num	8	3.	E1. Transfusion complications noted during transfusion visit?
94	DESTATUS	Char	1	$1.	DESTATUS
23	DIRECT_A	Num	8	3.	D5b. Direct Antiglobulin Test (DAT)
2	EX_NUM	Num	3		X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
73	FEBRILE	Num	8	3.	E1b. Febrile, nonhemolytic (fever, chills)
74	FEB_DAP	Num	8	3.	E1b2. AM PM designation: Febrile, nonhemolytic
75	FEB_RAP	Num	8	3.	E1b4. AM PM designation: Febrile, nonhemolytic
82	FLUID	Num	8	3.	E1e. Fluid overload
18	HEMAT	Num	8	5.1	D1c. Hematocrit
17	HEMOG	Num	8	5.1	D1b. Hemoglobin
70	HEMOLYT	Num	8	3.	E1a. Hemolytic immediate
71	HEM_DAP	Num	8	3.	E1a2. AM PM designation: Hemolytic immediate
72	HEM_RAP	Num	8	3.	E1a4. AM PM designation: Hemolytic immediate
93	HOSP	Num	8	3.	E5. Patient hospitalized because of a transfusion complication?
83	HYPERTEN	Num	8	3.	E1f. Hypertension
84	HYP_DAP	Num	8	3.	E1f2. AM PM designation: Hypertension
85	HYP_RAP	Num	8	3.	E1f4. AM PM designation: Hypertension
24	INDIR_A	Num	8	3.	D5c. Indirect Antiglobulin Test (IAT)
28	NEW_C	Num	8	3.	D5e2. New Antibody C
26	NEW_D	Num	8	3.	D5e1. New Antibody D
30	NEW_E	Num	8	3.	D5e3. New Antibody E
32	NEW_E2	Num	8	3.	D5e4. New Antibody e
54	NEW_FYA	Num	8	3.	D5e19. New Antibody Fya
57	NEW_JKA	Num	8	3.	D5e21. New Antibody Jka
59	NEW_JKB	Num	8	3.	D5e22. New Antibody Jkb
47	NEW_JSA	Num	8	3.	D5e15. New Antibody Jsa
52	NEW_K2	Num	8	3.	D5e18. New Antibody k
50	NEW_KEL	Num	8	3.	D5e17. New Antibody K (Kell)
44	NEW_KPA	Num	8	3.	D5e13. New Antibody Kpa
66	NEW_OTH	Num	8	3.	D5e27. New Other Antibody
63	NEW_P1	Num	8	3.	D5e25. New Antibody P1
40	NEW_S2	Num	8	3.	D5e11. New Antibody s
42	NEW_U	Num	8	3.	D5e12. New Antibody U
86	OTHCOMPL	Num	8	3.	E1g. Other
87	OTH_DAP	Num	8	3.	E1g2. AM PM designation: Other
88	OTH_RAP	Num	8	3.	E1g4. AM PM designation: Other
22	PCT_HBS	Num	8	3.	D4b. Percent HbS

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
10	PHYS_EX	Num	8	3.	B4. Physical Examination
21	PL_CNT	Num	8	7.1	D3. Platelet Count
20	RET_CNT	Num	8	5.1	D2. Reticulocyte Count
9	SPLEENSZ	Num	8	3.	B3. Spleen size (distance below LCM at MCL)
67	SP_ANTI	Char	25	$25.	D5d27a. Specify Other Antibody
89	SP_COMPL	Char	60	$60.	E1g5. Specify Other complication
68	SP_REFL	Char	60	$60.	D5f1. Reason the specimen were not sent to reference lab
15	TOT_VOL	Num	8	3.	C4. Was total planned volume given?
14	TRE_AMPM	Num	8	3.	C3a. AM PM designation
13	TRS_AMPM	Num	8	3.	C2a. AM PM designation
12	TR_CC_IN	Num	8	5.	C1a. Total mL of units transfused
11	TR_N_UN	Num	8	3.	C1. Total number of units transfused
16	VOL_REAS	Char	25	$25.	C4a. Reason total planned volume was not given?
19	WC_COUNT	Num	8	5.1	D1d. White cell count
6	WEIGHT	Num	8	6.1	B1. Weight(kg)
3	WHYTRAN1	Num	8	3.	A3a. Reason for this transfusion
4	WHYTRAN2	Num	8	3.	A3b. Second reason for this transfusion
5	WHYTRAN3	Num	8	3.	A3c. Third reason for this transfusion
96	comp_dfrmrand	Num	8		<created variable> A2. Date of transfusion as days from RAND visit
102	d_admfrmrand	Num	8		<created variable> E5a. Date of hospital admission as days from RAND visit
103	d_disfrmrand	Num	8		<created variable> E5b. Date of hospital discharge as days from RAND visit
100	dt_antigfrmrand	Num	8		<created variable> D5a. Date blood drawn for antiglobulin tests as days from RAND visit
98	dt_cbcfrmrand	Num	8		<created variable> D1a. Date blood drawn as days from RAND visit
99	dt_hemfrmrand	Num	8		<created variable> D4a. Date blood drawn for hb analysis as days from RAND visit
95	ldu_id	Char	10		ID for public use datasets
97	prior_trfrmrand	Num	8		<created variable> A4. Date of most recent prior transfusion as days from RAND visit
101	reflab_dfrmrand	Num	8		<created variable> D5f. Date specimen sent to reference lab as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Num	3		X4. Exam Number
3	WHYTRAN1	Num	8	3.	A3a. Reason for this transfusion
4	WHYTRAN2	Num	8	3.	A3b. Second reason for this transfusion
5	WHYTRAN3	Num	8	3.	A3c. Third reason for this transfusion
6	WEIGHT	Num	8	6.1	B1. Weight(kg)
7	BP_SYS	Num	8	4.	B2a. Systolic blood pressure (supine)
8	BP_DIAS	Num	8	4.	B2b. Diastolic blood pressure (supine)
9	SPLEENSZ	Num	8	3.	B3. Spleen size (distance below LCM at MCL)
10	PHYS_EX	Num	8	3.	B4. Physical Examination
11	TR_N_UN	Num	8	3.	C1. Total number of units transfused
12	TR_CC_IN	Num	8	5.	C1a. Total mL of units transfused
13	TRS_AMPM	Num	8	3.	C2a. AM PM designation
14	TRE_AMPM	Num	8	3.	C3a. AM PM designation
15	TOT_VOL	Num	8	3.	C4. Was total planned volume given?
16	VOL_REAS	Char	25	$25.	C4a. Reason total planned volume was not given?
17	HEMOG	Num	8	5.1	D1b. Hemoglobin
18	HEMAT	Num	8	5.1	D1c. Hematocrit
19	WC_COUNT	Num	8	5.1	D1d. White cell count
20	RET_CNT	Num	8	5.1	D2. Reticulocyte Count
21	PL_CNT	Num	8	7.1	D3. Platelet Count
22	PCT_HBS	Num	8	3.	D4b. Percent HbS
23	DIRECT_A	Num	8	3.	D5b. Direct Antiglobulin Test (DAT)
24	INDIR_A	Num	8	3.	D5c. Indirect Antiglobulin Test (IAT)
25	ANTI_D	Num	8	3.	D5d1. Antibody D
26	NEW_D	Num	8	3.	D5e1. New Antibody D
27	ANTI_C	Num	8	3.	D5d2. Antibody C
28	NEW_C	Num	8	3.	D5e2. New Antibody C
29	ANTI_E	Num	8	3.	D5d3. Antibody E
30	NEW_E	Num	8	3.	D5e3. New Antibody E
31	ANTI_E2	Num	8	3.	D5d4. Antibody e
32	NEW_E2	Num	8	3.	D5e4. New Antibody e
33	ANTI_C2	Num	8	3.	D5d5. Antibody c
34	ANTI_F2	Num	8	3.	D5d6. Antibody f
35	ANTI_V	Num	8	3.	D5d7. Antibody V
36	ANTI_M	Num	8	3.	D5d8. Antibody M
37	ANTI_N	Num	8	3.	D5d9. Antibody N
38	ANTI_S	Num	8	3.	D5d10. Antibody S
39	ANTI_S2	Num	8	3.	D5d11. Antibody s
40	NEW_S2	Num	8	3.	D5e11. New Antibody s
41	ANTI_U	Num	8	3.	D5d12. Antibody U
42	NEW_U	Num	8	3.	D5e12. New Antibody U
43	ANTI_KPA	Num	8	3.	D5d13. Antibody Kpa
44	NEW_KPA	Num	8	3.	D5e13. New Antibody Kpa
45	ANTI_KPB	Num	8	3.	D5d14. Antibody Kpb
46	ANTI_JSA	Num	8	3.	D5d15. Antibody Jsa
47	NEW_JSA	Num	8	3.	D5e15. New Antibody Jsa
48	ANTI_JSB	Num	8	3.	D5d16. Antibody Jsb
49	ANTI_KEL	Num	8	3.	D5d17. Antibody K (Kell)
50	NEW_KEL	Num	8	3.	D5e17. New Antibody K (Kell)
51	ANTI_K2	Num	8	3.	D5d18. Antibody k

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
52	NEW_K2	Num	8	3.	D5e18. New Antibody k
53	ANTI_FYA	Num	8	3.	D5d19. Antibody Fya
54	NEW_FYA	Num	8	3.	D5e19. New Antibody Fya
55	ANTI_FYB	Num	8	3.	D5d20. Antibody Fyb
56	ANTI_JKA	Num	8	3.	D5d21. Antibody Jka
57	NEW_JKA	Num	8	3.	D5e21. New Antibody Jka
58	ANTI_JKB	Num	8	3.	D5d22. Antibody Jkb
59	NEW_JKB	Num	8	3.	D5e22. New Antibody Jkb
60	ANTI_LEA	Num	8	3.	D5d23. Antibody Lea
61	ANTI_LEB	Num	8	3.	D5d24. Antibody Leb
62	ANTI_P1	Num	8	3.	D5d25. Antibody P1
63	NEW_P1	Num	8	3.	D5e25. New Antibody P1
64	ANTI_I	Num	8	3.	D5d26. Antibody I
65	ANTI_OTH	Num	8	3.	D5d27. Antibody -- Other
66	NEW_OTH	Num	8	3.	D5e27. New Other Antibody
67	SP_ANTI	Char	25	$25.	D5d27a. Specify Other Antibody
68	SP_REFL	Char	60	$60.	D5f1. Reason the specimen were not sent to reference lab
69	COMPNOTE	Num	8	3.	E1. Transfusion complications noted during transfusion visit?
70	HEMOLYT	Num	8	3.	E1a. Hemolytic immediate
71	HEM_DAP	Num	8	3.	E1a2. AM PM designation: Hemolytic immediate
72	HEM_RAP	Num	8	3.	E1a4. AM PM designation: Hemolytic immediate
73	FEBRILE	Num	8	3.	E1b. Febrile, nonhemolytic (fever, chills)
74	FEB_DAP	Num	8	3.	E1b2. AM PM designation: Febrile, nonhemolytic
75	FEB_RAP	Num	8	3.	E1b4. AM PM designation: Febrile, nonhemolytic
76	ALLERGIC	Num	8	3.	E1c. Severe anaphylaxis
77	ALL_DAP	Num	8	3.	E1c2. AM PM designation: Severe anaphylaxis
78	ALL_RAP	Num	8	3.	E1c4. AM PM designation: Severe anaphylaxis
79	ALL2	Num	8	3.	E1d. Other allergic reactions
80	ALL2_DAP	Num	8	3.	E1d2. AM PM designation: Other allergic reactions
81	ALL2_RAP	Num	8	3.	E1d4. AM PM designation: Other allergic reactions
82	FLUID	Num	8	3.	E1e. Fluid overload
83	HYPERTEN	Num	8	3.	E1f. Hypertension
84	HYP_DAP	Num	8	3.	E1f2. AM PM designation: Hypertension
85	HYP_RAP	Num	8	3.	E1f4. AM PM designation: Hypertension
86	OTHCOMPL	Num	8	3.	E1g. Other
87	OTH_DAP	Num	8	3.	E1g2. AM PM designation: Other
88	OTH_RAP	Num	8	3.	E1g4. AM PM designation: Other
89	SP_COMPL	Char	60	$60.	E1g5. Specify Other complication
90	ANTIG_AP	Num	8	3.	E2a1. AM PM designation
91	A_DIR_H	Num	8	3.	E2b. Direct Antiglobulin Test (DAT)
92	A_IND_H	Num	8	3.	E2c. Indirect Antiglobulin Test (IAT)
93	HOSP	Num	8	3.	E5. Patient hospitalized because of a transfusion complication?
94	DESTATUS	Char	1	$1.	DESTATUS
95	ldu_id	Char	10		ID for public use datasets
96	comp_ dfrmrand	Num	8		<created variable> A2. Date of transfusion as days from RAND visit
97	prior_ trfrmrand	Num	8		<created variable> A4. Date of most recent prior transfusion as days from RAND visit
98	dt_ cbcfrmrand	Num	8		<created variable> D1a. Date blood drawn as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
99	dt_hemfrmrand	Num	8		<created variable> D4a. Date blood drawn for hb analysis as days from RAND visit
100	dt_antigfrmrand	Num	8		<created variable> D5a. Date blood drawn for antiglobulin tests as days from RAND visit
101	reflab_dfrmrand	Num	8		<created variable> D5f. Date specimen sent to reference lab as days from RAND visit
102	d_admfrmrand	Num	8		<created variable> E5a. Date of hospital admission as days from RAND visit
103	d_disfrmrand	Num	8		<created variable> E5b. Date of hospital discharge as days from RAND visit

Sort Information

Sortedby	ldu_id comp_dfrmrand
Validated	YES
Character Set	ANSI

```
*F020fmts.txt;

proc format;

  value NEW_DF
    1='1: No'
    2='2: Yes';

  value NEW_CF
    1='1: No'
    2='2: Yes';

  value NEW_EF
    1='1: No'
    2='2: Yes';

  value NEW_E2F
    1='1: No'
    2='2: Yes';

    value NEW_S2F
    1='1: No'
    2='2: Yes';

  value NEW_UF
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    2='2: Yes';

  value NEW_KPAF
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    2='2: Yes';

  value NEW_JSAF
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    2='2: Yes';

  value ANTI_JSBF
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    2='2: Yes';

  value ANTI_KELF
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    2='2: Yes';

  value NEW_KELF
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    2='2: Yes';

  value ANTI_K2F
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    2='2: Yes';

  value NEW_K2F
    1='1: No'
    2='2: Yes';
```

```
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  2='2: Yes';

value NEW_FYAF
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  2='2: Yes';

value ANTI_FYBF
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  2='2: Yes';

value ANTI_JKAF
  1='1: No'
  2='2: Yes';

value ANTI_JSAF
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  2='2: Yes';

value NEW_JKAF
  1='1: No'
  2='2: Yes';

value ANTI_JKBF
  1='1: No'
  2='2: Yes';

value NEW_JKBF
  1='1: No'
  2='2: Yes';

value ANTI_LEAF
  1='1: No'
  2='2: Yes';

value ANTI_LEBF
  1='1: No'
  2='2: Yes';

value DIRECT_AF
  1='1: Negative'
  2='2: Positive';

value INDIR_AF
  1='1: Negative'
  2='2: Positive';

value ANTI_DF
  1='1: No'
  2='2: Yes';
```

```
value ANTI_CF
  1='1: No'
  2='2: Yes';

 value ANTI_EF
  1='1: No'
  2='2: Yes';

 value ANTI_E2F
  1='1: No'
  2='2: Yes';

 value ANTI_C2F
  1='1: No'
  2='2: Yes';

 value ANTI_F2F
  1='1: No'
  2='2: Yes';

 value ANTI_VF
  1='1: No'
  2='2: Yes';

 value ANTI_MF
  1='1: No'
  2='2: Yes';

 value ANTI_NF
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  2='2: Yes';

 value ANTI_SF
  1='1: No'
  2='2: Yes';

 value ANTI_S2F
  1='1: No'
  2='2: Yes';

 value ANTI_UF
  1='1: No'
  2='2: Yes';

 value ANTI_KPAF
  1='1: No'
  2='2: Yes';

 value ANTI_KPBF
  1='1: No'
  2='2: Yes';
```

```
value WHYTRAN1F
  1='1: STOP II Trial transfusion for primary stroke prevention'
  2='2: Acute Anemic Episode'
  3='3: Acute Chest Event'
  4='4: CVA'
  5='5: Surgery'
  6='6: Priapism'
  7='7: Other';

 value WHYTRAN2F
  1='1: STOP II Trial transfusion for primary stroke prevention'
  2='2: Acute Anemic Episode'
  3='3: Acute Chest Event'
  4='4: CVA'
  5='5: Surgery'
  6='6: Priapism'
  7='7: Other';

 value WHYTRAN3F
  1='1: STOP II Trial transfusion for primary stroke prevention'
  2='2: Acute Anemic Episode'
  3='3: Acute Chest Event'
  4='4: CVA'
  5='5: Surgery'
  6='6: Priapism'
  7='7: Other';

 value PHYS_EXF
  1='1: Normal'
  2='2: Abnormal';

 value TRS_AMPMF
  1='1: AM'
  2='2: PM';

 value TOT_VOLF
  1='1: No'
  2='2: Yes';

 value ANTI_P1F
  1='1: No'
  2='2: Yes';

 value NEW_P1F
  1='1: No'
  2='2: Yes';

 value ANTI_IF
  1='1: No'
  2='2: Yes';

 value ANTI_OTHF
  1='1: No'
  2='2: Yes';
```

```
value NEW_OTHF
  1='1: No'
  2='2: Yes';

value COMPNOTEF
  1='1: No'
  2='2: Yes';

value HEMOLYTF
  1='1: No'
  2='2: Yes';

value HEM_DAPF
  1='1: AM'
  2='2: PM';

value FEBRILEF
  1='1: No'
  2='2: Yes';

value FEB_DAPF
  1='1: AM'
  2='2: PM';

value ALLERGICF
  1='1: No'
  2='2: Yes';

value ALL_DAPF
  1='1: AM'
  2='2: PM';

value ALL_RAPF
  1='1: AM'
  2='2: PM';

value ALL2F
  1='1: No'
  2='2: Yes';

value ALL2_DAPF
  1='1: AM'
  2='2: PM';

value ALL2_RAPF
  1='1: AM'
  2='2: PM';

value FLUIDF
  1='1: No'
  2='2: Yes';

value HYPERTENF
  1='1: No'
  2='2: Yes';
```

```
value HYP_DAPF
  1='1: AM'
  2='2: PM';

value HYP_RAPF
  1='1: AM'
  2='2: PM';

value OTHCOMPLF
  1='1: No'
  2='2: Yes';

value OTH_DAPF
  1='1: AM'
  2='2: PM';

value OTH_RAPF
  1='1: AM'
  2='2: PM';

value ANTIG_APF
  1='1: AM'
  2='2: PM';

value A_DIR_HF
  1='1: Negative'
  2='2: Positive';

value A_IND_HF
  1='1: Negative'
  2='2: Positive';

value HOSPF
  1='1: No'
  2='2: Yes';

value FEB_RAPF
  1='1: AM'
  2='2: PM';

value HEM_RAPF
  1='1: AM'
  2='2: PM';

value TRE_AMPMF
  1='1: AM'
  2='2: PM';
```

* format new_d new_df. new_c new_cf. new_e new_ef. new_e2 new_e2f. new_s2 new_s2f. new_u new_uf. new_kpa new_kpaf. new_jsa new_jsaf. anti_jsb anti_jsbf. anti_kel anti_kelf. new_kel new_kelf. anti_k2 anti_k2f. new_k2 new_k2f. anti_fya anti_fyaf. new_fya new_fyaf. anti_fyb anti_fybf. anti_jka anti_jkaf. anti_jsa anti_jsaf. new_jka new_jkaf. anti_jkb anti_jkbf. new_jkb new_jkbf. anti_lea anti_leaf. anti_leb anti_lebf. direct_a direct_af. indir_a indir_af. anti_d anti_df. anti_c anti_cf. anti_e anti_ef. anti_e2 anti_e2f. anti_c2 anti_c2f. anti_f2 anti_f2f. anti_v anti_vf. anti_m anti_mf. anti_n anti_nf. anti_s anti_sf. anti_s2 anti_s2f. anti_u anti_uf. anti_kpa anti_kpaf. anti_kpb anti_kpbf. whytran1 whytran1f. whytran2 whytran2f. whytran3 whytran3f. phys_ex phys_exf. trs_ampm trs_ampmf. tot_vol tot_volf. anti_p1 anti_p1f. new_p1 new_p1f. anti_i anti_if. anti_oth anti_othf. new_oth new_othf. compnote compnotef. hemolyt hemolytf. hem_dap hem_dapf. febrile febrilef. feb_dap feb_dapf. allergic allergicf. all_dap all_dapf. all_rap all_rapf. all2 all2f. all2_dap all2_dapf. all2_rap all2_rapf. fluid fluidf. flu_dap flu_dapf. flu_rap flu_rapf. hyperten hypertenf. hyp_dap hyp_dapf. hyp_rap hyp_rapf. othcompl othcomplf. oth_dap oth_dapf. oth_rap oth_rapf. antig_ap antig_apf. a_dir_h a_dir_hf. a_ind_h a_ind_hf. hosp hospf. feb_rap feb_rapf. hem_rap hem_rapf. tre_ampm tre_ampmf.;

STOP II TRIAL

TRANSFUSION FORM

***** AFFIX PATIENT LABEL HERE *****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1901	95.24	1901	95.24
P	95	4.76	1996	100.00

X3. Exam Type				
EX_TYPE	Frequency	Percent	Cum Freq	Cum Percent
TR	1996	100.00	1996	100.00

X4. Exam Number				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
27	2	0.10	2	0.10
28	3	0.15	5	0.25
29	3	0.15	8	0.40
30	3	0.15	11	0.55
31	2	0.10	13	0.65
32	4	0.20	17	0.85
33	4	0.20	21	1.05
34	4	0.20	25	1.25
35	6	0.30	31	1.55
36	5	0.25	36	1.80
37	7	0.35	43	2.15
38	7	0.35	50	2.51
39	7	0.35	57	2.86
40	5	0.25	62	3.11
41	6	0.30	68	3.41
42	4	0.20	72	3.61
43	4	0.20	76	3.81
44	4	0.20	80	4.01
45	5	0.25	85	4.26
46	5	0.25	90	4.51
47	7	0.35	97	4.86
48	6	0.30	103	5.16
49	5	0.25	108	5.41
50	5	0.25	113	5.66
51	4	0.20	117	5.86
52	3	0.15	120	6.01
53	3	0.15	123	6.16
54	1	0.05	124	6.21
55	1	0.05	125	6.26
56	3	0.15	128	6.41

X4. Exam Number (continued)				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
57	3	0.15	131	6.56
58	5	0.25	136	6.81
59	6	0.30	142	7.11
60	6	0.30	148	7.41
61	8	0.40	156	7.82
62	8	0.40	164	8.22
63	7	0.35	171	8.57
64	6	0.30	177	8.87
65	6	0.30	183	9.17
66	9	0.45	192	9.62
67	8	0.40	200	10.02
68	7	0.35	207	10.37
69	3	0.15	210	10.52
70	3	0.15	213	10.67
71	3	0.15	216	10.82
72	4	0.20	220	11.02
73	3	0.15	223	11.17
74	3	0.15	226	11.32
75	3	0.15	229	11.47
76	4	0.20	233	11.67
77	4	0.20	237	11.87
78	3	0.15	240	12.02
79	2	0.10	242	12.12
80	2	0.10	244	12.22
81	2	0.10	246	12.32
82	2	0.10	248	12.42
83	2	0.10	250	12.53
84	2	0.10	252	12.63
85	1	0.05	253	12.68
86	1	0.05	254	12.73
87	1	0.05	255	12.78
88	1	0.05	256	12.83
92	1	0.05	257	12.88
93	1	0.05	258	12.93
94	1	0.05	259	12.98
95	1	0.05	260	13.03
96	1	0.05	261	13.08
97	1	0.05	262	13.13
98	1	0.05	263	13.18
199	1	0.05	264	13.23
301	38	1.90	302	15.13
302	39	1.95	341	17.08
303	40	2.00	381	19.09
304	36	1.80	417	20.89
305	32	1.60	449	22.49
306	31	1.55	480	24.05
307	28	1.40	508	25.45
308	22	1.10	530	26.55
309	18	0.90	548	27.45

X4. Exam Number (continued)				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
310	18	0.90	566	28.36
311	16	0.80	582	29.16
312	12	0.60	594	29.76
313	10	0.50	604	30.26
314	9	0.45	613	30.71
315	6	0.30	619	31.01
316	6	0.30	625	31.31
317	5	0.25	630	31.56
318	6	0.30	636	31.86
319	4	0.20	640	32.06
320	4	0.20	644	32.26
321	4	0.20	648	32.46
322	4	0.20	652	32.67
323	3	0.15	655	32.82
324	3	0.15	658	32.97
325	2	0.10	660	33.07
326	1	0.05	661	33.12
327	1	0.05	662	33.17
328	1	0.05	663	33.22
329	1	0.05	664	33.27
330	1	0.05	665	33.32
331	1	0.05	666	33.37
332	1	0.05	667	33.42
333	1	0.05	668	33.47
334	1	0.05	669	33.52
335	1	0.05	670	33.57
336	1	0.05	671	33.62
337	1	0.05	672	33.67
338	1	0.05	673	33.72
339	1	0.05	674	33.77
340	1	0.05	675	33.82
501	63	3.16	738	36.97
502	61	3.06	799	40.03
503	58	2.91	857	42.94
504	57	2.86	914	45.79
505	49	2.45	963	48.25
506	48	2.40	1011	50.65
507	44	2.20	1055	52.86
508	42	2.10	1097	54.96
509	40	2.00	1137	56.96
510	41	2.05	1178	59.02
511	41	2.05	1219	61.07
512	40	2.00	1259	63.08
513	37	1.85	1296	64.93
514	35	1.75	1331	66.68
515	33	1.65	1364	68.34
516	33	1.65	1397	69.99
517	30	1.50	1427	71.49
518	30	1.50	1457	73.00

X4. Exam Number (continued)				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
519	29	1.45	1486	74.45
520	28	1.40	1514	75.85
521	26	1.30	1540	77.15
522	24	1.20	1564	78.36
523	23	1.15	1587	79.51
524	21	1.05	1608	80.56
525	22	1.10	1630	81.66
526	21	1.05	1651	82.72
527	22	1.10	1673	83.82
528	20	1.00	1693	84.82
529	20	1.00	1713	85.82
530	20	1.00	1733	86.82
531	18	0.90	1751	87.73
532	19	0.95	1770	88.68
533	19	0.95	1789	89.63
534	20	1.00	1809	90.63
535	19	0.95	1828	91.58
536	18	0.90	1846	92.48
537	18	0.90	1864	93.39
538	17	0.85	1881	94.24
539	16	0.80	1897	95.04
540	16	0.80	1913	95.84
541	13	0.65	1926	96.49
542	12	0.60	1938	97.09
543	12	0.60	1950	97.70
544	11	0.55	1961	98.25
545	10	0.50	1971	98.75
546	8	0.40	1979	99.15
547	5	0.25	1984	99.40
548	4	0.20	1988	99.60
549	3	0.15	1991	99.75
550	2	0.10	1993	99.85
554	1	0.05	1994	99.90
555	1	0.05	1995	99.95
599	1	0.05	1996	100.00

A1. Person completing form (Name): _____ (Initials):

[Variable NOT included in dataset.]

A2. Date of transfusion (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1996	0	206.2	447.3	-1136	-122.0	197.5	527.5	1253.0

A3. Reason for this transfusion:

- ☐ **1. STOP II TRIAL Transfusion for Primary Stroke Prevention**
- ☐ **2. Acute Anemic Episode**
- ☐ **3. Acute Chest Event**
- ☐ **4. CVA**
- ☐ **5. Surgery**
- ☐ **6. Priapism**
- ☐ **7. Other Reason (SPECIFY):** A3.a _____

A3a. Reason for this transfusion				
WHYTRAN1	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.15	3	0.15
1	1832	91.78	1835	91.93
2	19	0.95	1854	92.89
3	26	1.30	1880	94.19
4	4	0.20	1884	94.39
5	21	1.05	1905	95.44
6	1	0.05	1906	95.49
7	90	4.51	1996	100.00

A3b. Second reason for this transfusion				
WHYTRAN2	Frequency	Percent	Cum Freq	Cum Percent
-2	90	4.51	90	4.51
-1	1875	93.94	1965	98.45
2	2	0.10	1967	98.55
3	2	0.10	1969	98.65
5	8	0.40	1977	99.05
7	19	0.95	1996	100.00

A3c. Third reason for this transfusion				
WHYTRAN3	Frequency	Percent	Cum Freq	Cum Percent
-2	1984	99.40	1984	99.40
-1	8	0.40	1992	99.80
7	4	0.20	1996	100.00

A4. Date of most recent prior transfusion: ___ ___/___ ___/___ ___ ___ ___ ☐ **UNKNOWN**

Analysis Variable : prior_trfrmrand <created variable> A4. Date of most recent prior transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1995	0	175.1	446.7	-1168	-152.0	159.0	494.0	1217.0

<created variable> A4. Date of most recent prior transfusion as days from RAND visit				
prior_trfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

B. PHYSICAL EXAMINATION PRIOR TO TRANSFUSION

B1. Weight (kg) ☐☐☐.☐

Analysis Variable : WEIGHT B1. Weight(kg)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1830	0	47.4	16.6	20.4	33.7	46.3	56.7	107.4

B1. Weight(kg)				
WEIGHT	Frequency	Percent	Cum Freq	Cum Percent
-9	17	10.24	17	10.24
-8	7	4.22	24	14.46
-3	142	85.54	166	100.00

B2. Blood pressure (supine) (Sys/Dia) a. ☐☐☐ / b. ☐☐☐

Analysis Variable : BP_SYS B2a. Systolic blood pressure (supine)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1977	0	116.8	14.2	78.0	106.0	115.0	127.0	183.0

B2a. Systolic blood pressure (supine)				
BP_SYS	Frequency	Percent	Cum Freq	Cum Percent
-9	10	52.63	10	52.63
-8	1	5.26	11	57.89
-3	8	42.11	19	100.00

Analysis Variable : BP_DIAS B2b. Diastolic blood pressure (supine)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1974	0	60.3	9.1	22.0	54.0	60.0	66.0	104.0

B2b. Diastolic blood pressure (supine)				
BP_DIAS	Frequency	Percent	Cum Freq	Cum Percent
-9	11	50.00	11	50.00
-8	2	9.09	13	59.09
-3	9	40.91	22	100.00

B3. Spleen size (distance below LCM at MCL) ☐☐ cm

Analysis Variable : SPLEENSZ B3. Spleen size (distance below LCM at MCL)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
794	0	0.1	0.6	0.0	0.0	0.0	0.0	5.0

B3. Spleen size (distance below LCM at MCL)				
SPLEENSZ	Frequency	Percent	Cum Freq	Cum Percent
-9	88	7.32	88	7.32
-8	69	5.74	157	13.06
-3	691	57.49	848	70.55
-1	354	29.45	1202	100.00

B4. Physical Examination ☐ **1. NORMAL** ☐ **2. ABNORMAL** ↓

B4. Physical Examination				
PHYS_EX	Frequency	Percent	Cum Freq	Cum Percent
-9	16	0.80	16	0.80
-8	1	0.05	17	0.85
-3	92	4.61	109	5.46
1	1292	64.73	1401	70.19
2	595	29.81	1996	100.00

B4.a **List Abnormalities**

[Variable NOT included in dataset.]

C. TRANSFUSION SUMMARY

C1. Total number of units transfused [ ][ ] → **COMPLETE FORM 21 FOR EACH**

C1. Total number of units transfused				
TR_N_UN	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.15	3	0.15
1	524	26.25	527	26.40
2	786	39.38	1313	65.78
3	272	13.63	1585	79.41
4	182	9.12	1767	88.53
5	87	4.36	1854	92.89
6	68	3.41	1922	96.29
7	53	2.66	1975	98.95
8	17	0.85	1992	99.80
9	3	0.15	1995	99.95
14	1	0.05	1996	100.00

C1.a Total mL in [ ][ ][ ][ ]

Analysis Variable : TR_CC_IN C1a. Total mL of units transfused								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1929	0	719.6	482.2	0.0	350.0	590.0	913.0	3000.0

C1a. Total mL of units transfused				
TR_CC_IN	Frequency	Percent	Cum Freq	Cum Percent
-9	30	44.78	30	44.78
-8	12	17.91	42	62.69
-3	25	37.31	67	100.00

C2. Time transfusion started [ ][ ] : [ ][ ] C2.a [ ] **1. AM** [ ] **2. PM**

[Variable NOT included in dataset for time.]

C2a. AM PM designation				
TRS_AMPM	Frequency	Percent	Cum Freq	Cum Percent
-9	28	1.40	28	1.40
-8	4	0.20	32	1.60
-3	4	0.20	36	1.80
1	1314	65.83	1350	67.64
2	646	32.36	1996	100.00

C3. Time transfusion stopped ☐☐ : ☐☐ C3.a ☐ 1. AM ☐ 2. PM

[Variable NOT included in dataset for time.]

C3a. AM PM designation				
TRE_AMPM	Frequency	Percent	Cum Freq	Cum Percent
-9	39	1.95	39	1.95
-8	5	0.25	44	2.20
-3	8	0.40	52	2.61
1	348	17.43	400	20.04
2	1596	79.96	1996	100.00

C4. Was total planned volume given? ☐ 1. NO ☐ 2. YES

↓

C4.a Reason: _____

C4. Was total planned volume given?				
TOT_VOL	Frequency	Percent	Cum Freq	Cum Percent
-9	17	0.85	17	0.85
-8	1	0.05	18	0.90
-3	1	0.05	19	0.95
1	65	3.26	84	4.21
2	1912	95.79	1996	100.00

C4a. Reason total planned volume was not given?				
VOL_REAS	Frequency	Percent	Cum Freq	Cum Percent
-2	1931	96.74	1931	96.74
1 unit avail - antibodies	1	0.05	1932	96.79
1st unit - bag tore	1	0.05	1933	96.84
2 units not avail.	1	0.05	1934	96.89
2nd unit ran short	1	0.05	1935	96.94
2nd unit short by 9 cc	1	0.05	1936	96.99
3U DIDNT TOTAL PLAN VOLUM	1	0.05	1937	97.04
900cc ordered - 845 avail	1	0.05	1938	97.09
900cc ordered - 860 avail	1	0.05	1939	97.14
900cc ordered, 895 avail.	1	0.05	1940	97.19
932cc avail.- antibodies	1	0.05	1941	97.24
Blood not available	2	0.10	1943	97.34
H/H was up	1	0.05	1944	97.39
HbS 17%	1	0.05	1945	97.44
Hgbs up, ret. for pheresi	1	0.05	1946	97.49
IV infiltrate	2	0.10	1948	97.60
Mother had to go to work	1	0.05	1949	97.65
Mother had to leave early	1	0.05	1950	97.70
Mother said she had to go	1	0.05	1951	97.75
Multiple antibodies	3	0.15	1954	97.90
NEEDED 1/2 U OF 2ND BAG	1	0.05	1955	97.95
POOR IV ACCESS	1	0.05	1956	98.00

C4a. Reason total planned volume was not given? (continued)				
VOL_REAS	Frequency	Percent	Cum Freq	Cum Percent
PRBC's late & unit return	1	0.05	1957	98.05
PRETRANSFUSION HGB 9.8	1	0.05	1958	98.10
PRETRANSFUSION HGB/HCT UP	1	0.05	1959	98.15
Pt. had skin reaction	1	0.05	1960	98.20
Pt. refused 2nd unit	1	0.05	1961	98.25
Small units	1	0.05	1962	98.30
UNABLE TO APHERESED	1	0.05	1963	98.35
access	1	0.05	1964	98.40
access problems	1	0.05	1965	98.45
access to vein failed	1	0.05	1966	98.50
acute asthma attack	1	0.05	1967	98.55
blood needed for emergenc	1	0.05	1968	98.60
mistake	1	0.05	1969	98.65
multiple antibodies	6	0.30	1975	98.95
not avail. b/c antibodies	1	0.05	1976	99.00
not enough blood	1	0.05	1977	99.05
only 1 unit available	1	0.05	1978	99.10
only 2 units available	1	0.05	1979	99.15
only 4 units available	1	0.05	1980	99.20
only 780cc avail - antibd	1	0.05	1981	99.25
only 830ml available	1	0.05	1982	99.30
only 897cc avail - antibd	1	0.05	1983	99.35
ordered 3 units, late ord	1	0.05	1984	99.40
pheresis unsucessful	1	0.05	1985	99.45
poor access. pheresis sto	1	0.05	1986	99.50
possible reaction	1	0.05	1987	99.55
pre transfusion HbS 28.0	1	0.05	1988	99.60
problems with IV line	1	0.05	1989	99.65
pt. c/o itching	1	0.05	1990	99.70
pt. lost IV	1	0.05	1991	99.75
small volume units	1	0.05	1992	99.80
unable to crossmatch	1	0.05	1993	99.85
units smaller than normal	1	0.05	1994	99.90
units volume too small	1	0.05	1995	99.95
unknown	1	0.05	1996	100.00

D. PRE-TRANSFUSION LABORATORY TEST RESULTS:

D1. CBC *

D1.a Date blood drawn (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : dt_cbcfrmrand <created variable> D1a. Date blood drawn as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1985	0	206.5	444.8	-1137	-121.0	198.0	526.0	1252.0

<created variable> D1a. Date blood drawn as days from RAND visit				
dt_cbcfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

D1.b Hemoglobin (g/dl) ☐☐ . ☐

Analysis Variable : HEMOG D1b. Hemoglobin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1984	0	9.3	1.1	4.3	8.7	9.4	10.0	13.9

D1b. Hemoglobin				
HEMOG	Frequency	Percent	Cum Freq	Cum Percent
-9	6	50.00	6	50.00
-3	6	50.00	12	100.00

D1.c Hematocrit (%) ☐☐ . ☐

Analysis Variable : HEMAT D1c. Hematocrit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1984	0	27.6	3.5	11.3	25.7	27.7	29.5	42.2

D1c. Hematocrit				
HEMAT	Frequency	Percent	Cum Freq	Cum Percent
-9	6	50.00	6	50.00
-3	6	50.00	12	100.00

D1.d White Cell Count (x 10 ^{9}/l) (corrected for nRBCs) ☐☐ . ☐

Analysis Variable : WC_COUNT D1d. White cell count								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1983	0	12.9	4.1	2.0	10.4	12.6	14.8	42.9

D1d. White cell count				
WC_COUNT	Frequency	Percent	Cum Freq	Cum Percent
-9	6	46.15	6	46.15
-3	7	53.85	13	100.00

D2. Reticulocyte Count (%) ☐☐ . ☐

Analysis Variable : RET_CNT D2. Reticulocyte Count								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1817	0	9.0	4.6	0.2	5.9	8.5	11.6	52.0

D2. Reticulocyte Count				
RET_CNT	Frequency	Percent	Cum Freq	Cum Percent
-9	7	3.91	7	3.91
-8	1	0.56	8	4.47
-3	171	95.53	179	100.00

D3. Platelet Count (x10^{9}/l) ☐☐☐☐

Analysis Variable : PL_CNT D3. Platelet Count								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1972	0	393.3	106.5	50.0	309.0	403.0	468.0	1152.0

D3. Platelet Count				
PL_CNT	Frequency	Percent	Cum Freq	Cum Percent
-9	8	33.33	8	33.33
-3	16	66.67	24	100.00

D4. Hemoglobin Analysis*

D4.a Date blood drawn (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : dt_hemfrmrand <created variable> D4a. Date blood drawn for hb analysis as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1873	0	210.3	443.6	-1137	-119.0	200.0	530.0	1252.0

<created variable> D4a. Date blood drawn for hb analysis as days from RAND visit				
dt_hemfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	123	100.00	123	100.00

D4.b % HbS ☐☐

Analysis Variable : PCT_HBS D4b. Percent HbS								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1849	0	27.6	12.8	0.0	20.0	27.0	33.0	99.0

D4b. Percent HbS				
PCT_HBS	Frequency	Percent	Cum Freq	Cum Percent
-9	15	10.20	15	10.20
-8	1	0.68	16	10.88
-3	131	89.12	147	100.00

ATTACH COPIES OF LOCAL LABORATORY REPORTS

D5. Antiglobulin Tests

D5.a Date blood drawn (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : dt_antigfrmrand <created variable> D5a. Date blood drawn for antiglobulin tests as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1967	0	210.1	443.4	-1137	-119.0	201.0	530.0	1252.0

<created variable> D5a. Date blood drawn for antiglobulin tests as days from RAND visit				
dt_antigfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	29	100.00	29	100.00

D5.b Direct Antiglobulin Test (DAT) ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D5b. Direct Antiglobulin Test (DAT)				
DIRECT_A	Frequency	Percent	Cum Freq	Cum Percent
-9	21	1.05	21	1.05
-3	1149	57.57	1170	58.62
1	789	39.53	1959	98.15
2	37	1.85	1996	100.00

D5.c Indirect Antiglobulin Test (IAT) ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D5c. Indirect Antiglobulin Test (IAT)				
INDIR_A	Frequency	Percent	Cum Freq	Cum Percent
-9	37	1.85	37	1.85
-8	2	0.10	39	1.95
-3	27	1.35	66	3.31
1	1775	88.93	1841	92.23
2	155	7.77	1996	100.00

ATTACH COPY OF ANTIGLOBULIN TEST RESULTS REPORT

IF BOTH D5.b AND D5.c ARE NEGATIVE, GO TO E1

IF EITHER D5.b OR D5.c IS POSITIVE, CONTINUE TO D5.d

***NOTE: A pre-transfusion sample for hb, hct, and hemoglobin analysis by the Core Lab must also be drawn for patients randomized to the Transfusion arm.**

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
1. Anti - D	☐	☐ →	☐	☐

D5d1. Antibody D				
ANTI_D	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	37	1.85	79	3.96
-2	1760	88.18	1839	92.13
1	147	7.36	1986	99.50
2	10	0.50	1996	100.00

D5e1. New Antibody D				
NEW_D	Frequency	Percent	Cum Freq	Cum Percent
-2	1986	99.50	1986	99.50
1	10	0.50	1996	100.00

2. Anti - C	☐	☐ →	☐	☐

D5d2. Antibody C				
ANTI_C	Frequency	Percent	Cum Freq	Cum Percent
-9	33	1.65	33	1.65
-8	5	0.25	38	1.90
-3	46	2.30	84	4.21
-2	1760	88.18	1844	92.38
1	107	5.36	1951	97.75
2	45	2.25	1996	100.00

D5e2. New Antibody C				
NEW_C	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.10	2	0.10
-2	1951	97.75	1953	97.85
1	41	2.05	1994	99.90
2	2	0.10	1996	100.00

D5.d Antibodies	D5.e Newly Identified?			
	1. NO	2. YES	1. NO	2. YES
3. Anti - E	☐	☐ →	☐	☐

D5d3. Antibody E				
ANTI_E	Frequency	Percent	Cum Freq	Cum Percent
-9	36	1.80	36	1.80
-8	4	0.20	40	2.00
-3	46	2.30	86	4.31
-2	1760	88.18	1846	92.48
1	148	7.41	1994	99.90
2	2	0.10	1996	100.00

D5e3. New Antibody E				
NEW_E	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1994	99.90	1995	99.95
1	1	0.05	1996	100.00

4. Anti - e	☐	☐ →	☐	☐

D5d4. Antibody e				
ANTI_E2	Frequency	Percent	Cum Freq	Cum Percent
-9	37	1.85	37	1.85
-8	4	0.20	41	2.05
-3	46	2.30	87	4.36
-2	1760	88.18	1847	92.54
1	148	7.41	1995	99.95
2	1	0.05	1996	100.00

D5e4. New Antibody e				
NEW_E2	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
1	1	0.05	1996	100.00

5. Anti - c	☐	☐ →	☐	☐

D5d5. Antibody c				
ANTI_C2	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	46	2.30	88	4.41
-2	1760	88.18	1848	92.59
1	148	7.41	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
6. Anti - f	☐	☐ →	☐	☐

D5d6. Antibody f				
ANTI_F2	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	47	2.35	89	4.46
-2	1760	88.18	1849	92.64
1	147	7.36	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

7. Anti - V	☐	☐ →	☐	☐

D5d7. Antibody V				
ANTI_V	Frequency	Percent	Cum Freq	Cum Percent
-9	35	1.75	35	1.75
-8	3	0.15	38	1.90
-3	46	2.30	84	4.21
-2	1760	88.18	1844	92.38
1	116	5.81	1960	98.20
2	36	1.80	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

8. Anti - M	☐	☐ →	☐	☐

D5d8. Antibody M				
ANTI_M	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	3	0.15	41	2.05
-3	46	2.30	87	4.36
-2	1760	88.18	1847	92.54
1	149	7.46	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
9. Anti - N	☐	☐ →	☐	☐

D5d9. Antibody N				
ANTI_N	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	3	0.15	41	2.05
-3	46	2.30	87	4.36
-2	1760	88.18	1847	92.54
1	149	7.46	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

10. Anti - S ☐ ☐ → ☐ ☐

D5d10. Antibody S				
ANTI_S	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	3	0.15	41	2.05
-3	46	2.30	87	4.36
-2	1760	88.18	1847	92.54
1	149	7.46	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

11. Anti - s ☐ ☐ → ☐ ☐

D5d11. Antibody s				
ANTI_S2	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	46	2.30	88	4.41
-2	1760	88.18	1848	92.59
1	148	7.41	1996	100.00

D5e11. New Antibody s				
NEW_S2	Frequency	Percent	Cum Freq	Cum Percent
-2	1996	100.00	1996	100.00

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
12. Anti - U	☐	☐ →	☐	☐

D5d12. Antibody U				
ANTI_U	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	47	2.35	89	4.46
-2	1760	88.18	1849	92.64
1	147	7.36	1996	100.00

D5e12. New Antibody U				
NEW_U	Frequency	Percent	Cum Freq	Cum Percent
-2	1996	100.00	1996	100.00

13. Anti - Kp[a] ☐ ☐ → ☐ ☐

D5d13. Antibody Kpa				
ANTI_KPA	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	47	2.35	89	4.46
-2	1760	88.18	1849	92.64
1	144	7.21	1993	99.85
2	3	0.15	1996	100.00

D5e13. New Antibody Kpa				
NEW_KPA	Frequency	Percent	Cum Freq	Cum Percent
-2	1993	99.85	1993	99.85
2	3	0.15	1996	100.00

14. Anti - Kp[b] ☐ ☐ → ☐ ☐

D5d14. Antibody Kpb				
ANTI_KPB	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	3	0.15	41	2.05
-3	47	2.35	88	4.41
-2	1760	88.18	1848	92.59
1	148	7.41	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
15. Anti - Js[a]	☐	☐ →	☐	☐

D5d15. Antibody Jsa				
ANTI_JSA	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	3	0.15	41	2.05
-3	47	2.35	88	4.41
-2	1760	88.18	1848	92.59
1	138	6.91	1986	99.50
2	10	0.50	1996	100.00

D5e15. New Antibody Jsa				
NEW_JSA	Frequency	Percent	Cum Freq	Cum Percent
-2	1986	99.50	1986	99.50
1	9	0.45	1995	99.95
2	1	0.05	1996	100.00

16. Anti - Js[b]	☐	☐ →	☐	☐

D5d16. Antibody Jsb				
ANTI_JSB	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	47	2.35	89	4.46
-2	1760	88.18	1849	92.64
1	147	7.36	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

17. Anti - K (Kell)	☐	☐ →	☐	☐

D5d17. Antibody K (Kell)				
ANTI_KEL	Frequency	Percent	Cum Freq	Cum Percent
-9	36	1.80	36	1.80
-8	4	0.20	40	2.00
-3	37	1.85	77	3.86
-2	1760	88.18	1837	92.03
1	131	6.56	1968	98.60
2	28	1.40	1996	100.00

D5e17. New Antibody K (Kell)				
NEW_KEL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1968	98.60	1969	98.65
1	25	1.25	1994	99.90
2	2	0.10	1996	100.00

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
18. Anti - k	☐	☐ →	☐	☐

D5d18. Antibody k				
ANTI_K2	Frequency	Percent	Cum Freq	Cum Percent
-9	37	1.85	37	1.85
-8	4	0.20	41	2.05
-3	46	2.30	87	4.36
-2	1760	88.18	1847	92.54
1	148	7.41	1995	99.95
2	1	0.05	1996	100.00

D5e18. New Antibody k				
NEW_K2	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
1	1	0.05	1996	100.00

19. Anti - Fy[a] ☐ ☐ → ☐ ☐

D5d19. Antibody Fya				
ANTI_FYA	Frequency	Percent	Cum Freq	Cum Percent
-9	35	1.75	35	1.75
-8	4	0.20	39	1.95
-3	46	2.30	85	4.26
-2	1760	88.18	1845	92.43
1	146	7.31	1991	99.75
2	5	0.25	1996	100.00

D5e19. New Antibody Fya				
NEW_FYA	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1991	99.75	1992	99.80
1	3	0.15	1995	99.95
2	1	0.05	1996	100.00

20. Anti - Fy[b] ☐ ☐ → ☐ ☐

D5d20. Antibody Fyb				
ANTI_FYB	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	46	2.30	88	4.41
-2	1760	88.18	1848	92.59
1	148	7.41	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
21. Anti - Jk[a]	☐	☐ →	☐	☐

D5d21. Antibody Jka				
ANTI_JKA	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	46	2.30	88	4.41
-2	1760	88.18	1848	92.59
1	146	7.31	1994	99.90
2	2	0.10	1996	100.00

D5e21. New Antibody Jka				
NEW_JKA	Frequency	Percent	Cum Freq	Cum Percent
-2	1994	99.90	1994	99.90
1	2	0.10	1996	100.00

22. Anti - Jk[b]	☐	☐ →	☐	☐

D5d22. Antibody Jkb				
ANTI_JKB	Frequency	Percent	Cum Freq	Cum Percent
-9	35	1.75	35	1.75
-8	4	0.20	39	1.95
-3	46	2.30	85	4.26
-2	1760	88.18	1845	92.43
1	148	7.41	1993	99.85
2	3	0.15	1996	100.00

D5e22. New Antibody Jkb				
NEW_JKB	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1993	99.85	1994	99.90
1	2	0.10	1996	100.00

23. Anti - Le[a]	☐	☐ →	☐	☐

D5d23. Antibody Lea				
ANTI_LEA	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	5	0.25	43	2.15
-3	47	2.35	90	4.51
-2	1760	88.18	1850	92.69
1	146	7.31	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
24. Anti - Le^b	☐	☐ →	☐	☐

D5d24. Antibody Leb				
ANTI_LEB	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	5	0.25	43	2.15
-3	47	2.35	90	4.51
-2	1760	88.18	1850	92.69
1	146	7.31	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

25. Anti - P_1	☐	☐ →	☐	☐

D5d25. Antibody P1				
ANTI_P1	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	5	0.25	43	2.15
-3	46	2.30	89	4.46
-2	1760	88.18	1849	92.64
1	146	7.31	1995	99.95
2	1	0.05	1996	100.00

D5e25. New Antibody P1				
NEW_P1	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
2	1	0.05	1996	100.00

26. Anti - I	☐	☐ →	☐	☐

D5d26. Antibody I				
ANTI_I	Frequency	Percent	Cum Freq	Cum Percent
-9	38	1.90	38	1.90
-8	4	0.20	42	2.10
-3	46	2.30	88	4.41
-2	1760	88.18	1848	92.59
1	148	7.41	1996	100.00

[Variable NOT included in dataset. No newly identified reported.]

D5.d Antibodies			D5.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
27. Anti - Other → D5.d27.a Specify_____	☐	☐ →	☐	☐

D5d27. Antibody -- Other				
ANTI_OTH	Frequency	Percent	Cum Freq	Cum Percent
-9	37	1.85	37	1.85
-8	4	0.20	41	2.05
-3	46	2.30	87	4.36
-2	1760	88.18	1847	92.54
1	78	3.91	1925	96.44
2	71	3.56	1996	100.00

D5e27. New Other Antibody				
NEW_OTH	Frequency	Percent	Cum Freq	Cum Percent
-2	1925	96.44	1925	96.44
1	66	3.31	1991	99.75
2	5	0.25	1996	100.00

D5d27a. Specify Other Antibody				
SP_ANTI	Frequency	Percent	Cum Freq	Cum Percent
-2	1925	96.44	1925	96.44
Anti Lua	1	0.05	1926	96.49
Anti-G, warm auto	1	0.05	1927	96.54
Anti-KNMC	1	0.05	1928	96.59
Anti-Knops, anti-McCoy	1	0.05	1929	96.64
BS, IGG	1	0.05	1930	96.69
HEMOGLUTIN	1	0.05	1931	96.74
HLA	1	0.05	1932	96.79
HLA HEMOGLUTIN	6	0.30	1938	97.09
HTLA	3	0.15	1941	97.24
IGG, BS	1	0.05	1942	97.29
LU (A)	1	0.05	1943	97.34
Lua	12	0.60	1955	97.95
Non-specific	1	0.05	1956	98.00
Warm auto, anti-G	1	0.05	1957	98.05
anti-G, warm auto	1	0.05	1958	98.10
unidentified	5	0.25	1963	98.35
warm antiab	1	0.05	1964	98.40
warm auto	30	1.50	1994	99.90
weak non-specific unident	1	0.05	1995	99.95
weak warm auto	1	0.05	1996	100.00

IF THE RESPONSE TO ANY OF D5.e1-27 IS YES, SEND SPECIMEN TO REFERENCE LAB FOR CONFIRMATION.

D5.f Date specimen sent to reference lab (Month/Day/Year) :__ __/__ __ /__ __ __ __ ☐ **-1. NOT SENT**

Analysis Variable : reflab_dfrmrand <created variable> D5f. Date specimen sent to reference lab as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	393.5	467.4	-255.0	52.0	540.0	735.0	749.0

<created variable> D5f. Date specimen sent to reference lab as days from RAND visit				
reflab_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1992	100.00	1992	100.00

D5.f.1 Reason:

_____

_____

D5f1. Reason the specimen were not sent to reference lab				
SP_REFL	Frequency	Percent	Cum Freq	Cum Percent
-2	1989	99.65	1989	99.65
Hospital lab does not send specimens out	1	0.05	1990	99.70
Not able to obtain sample	1	0.05	1991	99.75
RESULTS OF LOCAL LAB SATISFACTORY	1	0.05	1992	99.80
Specimen unavailable from core lab	1	0.05	1993	99.85
Unknown, not answered	1	0.05	1994	99.90
insufficient amount of sample	1	0.05	1995	99.95
transfusion services states prob handled at our lab	1	0.05	1996	100.00

E. COMPLICATIONS

E1. Were any of the following transfusion complications noted <u>during</u> the transfusion visit? ☐ **1. NO** ☐ **2. YES**

E1. Transfusion complications noted during transfusion visit?				
COMPNOTE	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
1	1976	99.00	1982	99.30
2	14	0.70	1996	100.00

1 Time Complication Detected | 2 | 3 Time Complication Resolved | 4

1. NO **2. YES**

E1.a Hemolytic immediate ☐ ☐ → ☐☐:☐☐ ☐ **1. AM** ☐ **2. PM** ☐☐:☐☐ ☐ **1. AM** ☐ **2. PM**

E1a. Hemolytic immediate				
HEMOLYT	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
-2	1976	99.00	1982	99.30
1	13	0.65	1995	99.95
2	1	0.05	1996	100.00

[Variables NOT included in dataset for time detected or time resolved.]

E1a2. AM PM designation: Hemolytic immediate				
HEM_DAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
2	1	0.05	1996	100.00

E1a4. AM PM designation: Hemolytic immediate				
HEM_RAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
1	1	0.05	1996	100.00

	1. NO	2. YES	1 Time Complication Detected	2	3 Time Complication Resolved	4
E1.b Febrile, nonhemolytic (fever, chills)	☐	☐ →	☐☐:☐☐	☐ 1. AM ☐ 2. PM	☐☐:☐☐	☐ 1. AM ☐ 2. PM

E1b. Febrile, nonhemolytic (fever, chills)				
FEBRILE	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
-2	1976	99.00	1982	99.30
1	11	0.55	1993	99.85
2	3	0.15	1996	100.00

[Variables NOT included in dataset for time detected or time resolved.]

E1b2. AM PM designation: Febrile, nonhemolytic				
FEB_DAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1993	99.85	1993	99.85
2	3	0.15	1996	100.00

E1b4. AM PM designation: Febrile, nonhemolytic				
FEB_RAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1993	99.85	1993	99.85
1	1	0.05	1994	99.90
2	2	0.10	1996	100.00

		1. NO	2. YES	1 Time Complication Detected	2	3 Time Complication Resolved	4
E1.c	Severe anaphylaxis (dyspnea, chest constriction, cyanosis, pulse variations, convulsions)	☐	☐ →	☐☐:☐☐ ☐ 1. AM ☐ 2. PM		☐☐:☐☐ ☐ 1. AM ☐ 2. PM	

E1c. Severe anaphylaxis				
ALLERGIC	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
-2	1976	99.00	1982	99.30
1	13	0.65	1995	99.95
2	1	0.05	1996	100.00

[Variables NOT included in dataset for time detected or time resolved.]

E1c2. AM PM designation: Severe anaphylaxis				
ALL_DAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
2	1	0.05	1996	100.00

E1c4. AM PM designation: Severe anaphylaxis				
ALL_RAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
2	1	0.05	1996	100.00

	1. NO	2. YES	1 Time Complication Detected	2	3 Time Complication Resolved	4
E1.d Other allergic reactions (redness of skin, Itching, urticaria)	☐	☐ →	☐☐:☐☐	☐ 1. AM ☐ 2. PM	☐☐:☐☐	☐ 1. AM ☐ 2. PM

E1d. Other allergic reactions				
ALL2	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
-2	1976	99.00	1982	99.30
1	8	0.40	1990	99.70
2	6	0.30	1996	100.00

[Variables NOT included in dataset for time detected or time resolved.]

E1d2. AM PM designation: Other allergic reactions				
ALL2_DAP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1990	99.70	1991	99.75
1	2	0.10	1993	99.85
2	3	0.15	1996	100.00

E1d4. AM PM designation: Other allergic reactions				
ALL2_RAP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1990	99.70	1991	99.75
1	1	0.05	1992	99.80
2	4	0.20	1996	100.00

	1. NO	2. YES	1 Time Complication Detected	2	3 Time Complication Resolved	4
E1.e Fluid overload	☐	☐ →	☐☐:☐☐ ☐ 1. AM ☐ 2. PM		☐☐:☐☐ ☐ 1. AM ☐ 2. PM	

E1e. Fluid overload				
FLUID	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
-2	1976	99.00	1982	99.30
1	14	0.70	1996	100.00

[Variables NOT included in dataset for time or AM/PM. Fields had no data.]

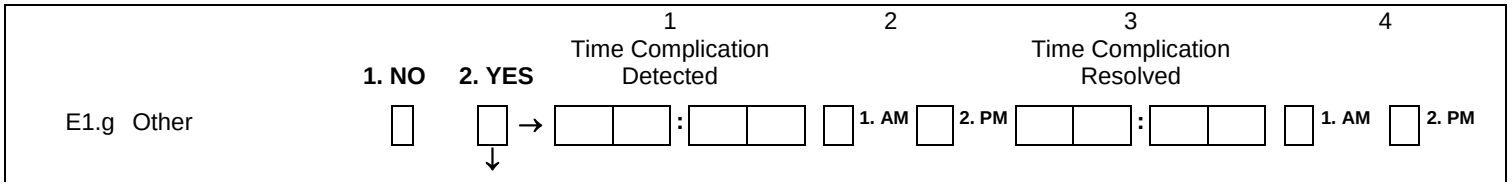
E1.f Hypertension (increase of >=30 mm Hg over baseline BP)	☐	☐ →	☐☐:☐☐ ☐ 1. AM ☐ 2. PM	☐☐:☐☐ ☐ 1. AM ☐ 2. PM

E1f. Hypertension				
HYPERTEN	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
-2	1976	99.00	1982	99.30
1	13	0.65	1995	99.95
2	1	0.05	1996	100.00

[Variables NOT included in dataset for time detected or time resolved.]

E1f2. AM PM designation: Hypertension				
HYP_DAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
2	1	0.05	1996	100.00

E1f4. AM PM designation: Hypertension				
HYP_RAP	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
2	1	0.05	1996	100.00



E1g. Other				
OTHCOMPL	Frequency	Percent	Cum Freq	Cum Percent
-9	5	0.25	5	0.25
-8	1	0.05	6	0.30
-2	1976	99.00	1982	99.30
1	8	0.40	1990	99.70
2	6	0.30	1996	100.00

[Variables NOT included in dataset for time detected or time resolved.]

E1g2. AM PM designation: Other				
OTH_DAP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1990	99.70	1991	99.75
1	2	0.10	1993	99.85
2	3	0.15	1996	100.00

E1g4. AM PM designation: Other				
OTH_RAP	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.05	1	0.05
-2	1990	99.70	1991	99.75
1	1	0.05	1992	99.80
2	4	0.20	1996	100.00

SPECIFY:

E1.g5 _____

E1g5. Specify Other complication				
SP_COMPL	Frequency	Percent	Cum Freq	Cum Percent
-2	1990	99.70	1990	99.70
1 large hive	1	0.05	1991	99.75
IV infiltrate	1	0.05	1992	99.80
Lower back pain	1	0.05	1993	99.85
Restlessness, tingling, dizzy, ionized CA .85	1	0.05	1994	99.90
venous access difficulties	1	0.05	1995	99.95
vomiting once	1	0.05	1996	100.00

IF PATIENT HAD AN IMMEDIATE HEMOLYTIC TRANSFUSION REACTION, COMPLETE QUESTION E2; OTHERWISE GO TO QUESTION E4

E2. Antiglobulin Tests

E2.a Time sample collected ☐☐:☐☐ a1. ☐ **1. AM** ☐ **2. PM**

[Variable NOT included in dataset for time.]

E2a1. AM PM designation				
ANTIG_AP	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
2	1	0.05	1996	100.00

E2.b Direct Antiglobulin Test (DAT) ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

E2b. Direct Antiglobulin Test (DAT)				
A_DIR_H	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
1	1	0.05	1996	100.00

E2.c Indirect Antiglobulin Test (IAT) ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

E2c. Indirect Antiglobulin Test (IAT)				
A_IND_H	Frequency	Percent	Cum Freq	Cum Percent
-2	1995	99.95	1995	99.95
1	1	0.05	1996	100.00

ATTACH COPY OF ANTIGLOBULIN TEST RESULTS REPORT

IF BOTH E2.b AND E2.c ARE NEGATIVE, GO TO E4

IF EITHER E2.b OR E2.c IS POSITIVE, CONTINUE TO E2.d

[Note: Both E2.b and E2.c were negative in all cases. No data for sections E2.d through E3.]

E2.d Antibodies			E2.e Newly Identified?	
	1. NO	2. YES	1. NO	2. YES
1. Anti - D	☐	☐ →	☐	☐
2. Anti - C	☐	☐ →	☐	☐
3. Anti - E	☐	☐ →	☐	☐
4. Anti - e	☐	☐ →	☐	☐
5. Anti - c	☐	☐ →	☐	☐
6. Anti - f	☐	☐ →	☐	☐
7. Anti - V	☐	☐ →	☐	☐
8. Anti - M	☐	☐ →	☐	☐
9. Anti - N	☐	☐ →	☐	☐
10. Anti - S	☐	☐ →	☐	☐
11. Anti - s	☐	☐ →	☐	☐
12. Anti - U	☐	☐ →	☐	☐
13. Anti - Kp^a	☐	☐ →	☐	☐
14. Anti - Kp^b	☐	☐ →	☐	☐
15. Anti - Js^a	☐	☐ →	☐	☐
16. Anti - Js^b	☐	☐ →	☐	☐
17. Anti - K (Kell)	☐	☐ →	☐	☐
18. Anti - k	☐	☐ →	☐	☐
19. Anti - Fy^a	☐	☐ →	☐	☐
20. Anti - Fy^b	☐	☐ →	☐	☐
21. Anti - Jk^a	☐	☐ →	☐	☐
22. Anti - Jk^b	☐	☐ →	☐	☐
23. Anti - Le^a	☐	☐ →	☐	☐
24. Anti - Le^b	☐	☐ →	☐	☐
25. Anti - P_1	☐	☐ →	☐	☐
26. Anti - I	☐	☐ →	☐	☐
27. Anti - Other → E2.d27.a Specify_____	☐	☐ →	☐	☐

IF RESPONSE TO ANY OF E2.e1-27 IS YES, SEND SPECIMEN TO REFERENCE LAB FOR CONFIRMATION.

E3. Date specimen sent to reference lab (Month/Day/Year) :__ __/__ __ /__ __ __ __ ☐ **-1. NOT SENT**

↓

E3.a Reason:

_____

_____

E4. Describe pertinent details of each complication and its management

[Variable NOT included in dataset.]

ATTACH TRANSFUSION SUMMARY NOTES

E5. Was patient hospitalized because of a complication from this transfusion?

☐ **1. NO** ☐ **2. YES →**

E5.a Date of admission (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

E5.b Date of discharge (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

E5. Patient hospitalized because of a transfusion complication?				
HOSP	Frequency	Percent	Cum Freq	Cum Percent
-9	17	0.85	17	0.85
1	1977	99.05	1994	99.90
2	2	0.10	1996	100.00

Analysis Variable : d_admfrmrand <created variable> E5a. Date of hospital admission as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	712.0	.	712.0	712.0	712.0	712.0	712.0

<created variable> E5a. Date of hospital admission as days from RAND visit				
d_admfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1995	100.00	1995	100.00

E5.a Date of admission (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

E5.b Date of discharge (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : d_disfrmrand <created variable> E5b. Date of hospital discharge as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	714.0	.	714.0	714.0	714.0	714.0	714.0

<created variable> E5b. Date of hospital discharge as days from RAND visit				
d_disfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1995	100.00	1995	100.00

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___

F. FOR OFFICE USE:

[Variables NOT included in dataset.]

F1. Local hematology laboratory reports received: ☐ **1. NO** ☐ **2. YES**

F2. Blood Bank antiglobulin test report received: ☐ **1. NO** ☐ **2. YES**

F3. Blood Bank Panel sheets received: ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA**

F4. Transfusion notes received: ☐ **1. NO** ☐ **2. YES**

F5. Reference lab report received: ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA**

STOP II
FORM 21: BLOOD UNIT FORM

A. Collection Information:
The **Blood Unit Form** (Form 21) was to be completed for each unit of blood received by a Randomized patient during a transfusion visit, as well as, potential patients if randomized in STOP. Form 21s with transfusion dates prior to December 2000 are forms for patients previously randomized in STOP that were collected in the interim period between the end of STOP and the beginning of STOP II.

B. Data Collection Period: December 2000 through November 2004

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p021_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, TR_DATEFRMRAND, EX_UNUM**

Records in the dataset are sorted by LDU_ID, TR_DATEFRMRAND and EX_UNUM.

F. Number of Observations (Patients) in SAS Dataset: 5,020 (67)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 585-586
- Listing of Variables by Position: See p. 586

H. Formats:
The file **f021fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 587.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The valid EX_TYPE for Form 21 is TR for transfusion visits

- **EX_NUM** - is the variable name for exam number. For Form 21, this is the transfusion number as indicated by:
  - 001-150 series numbers indicate transfusions received by patients previously randomized in STOP after the end of STOP but prior to enrollment as STOP II Potential patients
  - EX_NUM=199 was used when a Potential patient transfusion number was unknown
  - 300 series numbers indicate transfusions received by patients previously randomized in STOP after enrollment as STOP II Potential patients.
  - 500 series numbers indicate transfusions received by STOP II Randomized patients on or after the randomization visit
  - EX_NUM=599 was used when a Randomized patient transfusion number was unknown

- **EX_UNUM** – is the variable name for the blood unit transfusion sequence number.

- **BAG_UNUM** – is the variable name for blood unit id information.

Data Set Name	PUBDS.P021_FINAL	Observations	5020
Member Type	DATA	Variables	30
Engine	V9	Indexes	0
Created	Thursday, March 09, 2006 03:23:37 PM	Observation Length	312
Last Modified	Thursday, March 09, 2006 03:23:37 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	97
First Data Page	1
Max Obs per Page	52
Obs in First Data Page	36
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p021_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
7	ANT_C	Num	8	3.	B2a. Was the unit negative for the C antigen?
8	ANT_E	Num	8	3.	B2b. Was the unit negative for the E antigen?
9	ANT_KELL	Num	8	3.	B2c. Was the unit negative for the Kell antigen?
10	ANT_OTH	Num	8	3.	B3. Was the unit known to be negative for any other antigens?
11	ANT_OTH1	Char	20	$20.	B3a1. Specify antigens
12	ANT_OTH2	Char	20	$20.	B3a2. Specify antigen
13	ANT_OTH3	Char	20	$20.	B3a3. Specify antigens
14	ANT_OTH4	Char	20	$20.	B3a4. Specify antigen(s)
3	BL_PROD	Num	8	3.	B1. Blood product
24	DELIVR_F	Num	8	3.	C1b3a. Delivery
27	DESTATUS	Char	1	$1.	DESTATUS
28	EX_NUM	Num	8		X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_UNUM	Num	8	3.	X4.1. Blood unit transfusion sequence number
20	FULL_EX	Num	8	3.	C1b. Exchange transfusion
26	HEMAT_RV	Num	8	5.1	C1b4b. Hematocrit of blood removed (%)
25	HEMAT_TR	Num	8	5.1	C1b4a. Hematocrit of blood transfused (%)
16	LEUKPROC	Char	2	$2.	B4a. Filtering process
17	LEUKP_SP	Char	25	$25.	B4a1. Other filter, specify
15	LEUK_FLT	Num	8	3.	B4. Was a Third Generation Leukodepletion Filter used?
23	METHOD_F	Num	8	3.	C1b3. Method
21	ML_IN_F	Num	8	5.	C1b1. Total mL in
19	ML_IN_S	Num	8	5.	C1a1. Number of mL in
22	ML_OUT_F	Num	8	5.	C1b2. Total mL out
4	REC_WITH	Num	8	3.	B1a. Blood product reconstituted with
18	SIMPL_TR	Num	8	3.	C1a. Simple transfusion

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
6	SP_BL_PR	Char	20	$20.	B1c. Other specify
5	SP_REC	Char	20	$20.	B1b. Specify
29	ldu_id	Char	10		ID for public use datasets
30	tr_datefrmrand	Num	8		<created variable> A2. Date of transfusion as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_UNUM	Num	8	3.	X4.1. Blood unit transfusion sequence number
3	BL_PROD	Num	8	3.	B1. Blood product
4	REC_WITH	Num	8	3.	B1a. Blood product reconstituted with
5	SP_REC	Char	20	$20.	B1b. Specify
6	SP_BL_PR	Char	20	$20.	B1c. Other specify
7	ANT_C	Num	8	3.	B2a. Was the unit negative for the C antigen?
8	ANT_E	Num	8	3.	B2b. Was the unit negative for the E antigen?
9	ANT_KELL	Num	8	3.	B2c. Was the unit negative for the Kell antigen?
10	ANT_OTH	Num	8	3.	B3. Was the unit known to be negative for any other antigens?
11	ANT_OTH1	Char	20	$20.	B3a1. Specify antigens
12	ANT_OTH2	Char	20	$20.	B3a2. Specify antigen
13	ANT_OTH3	Char	20	$20.	B3a3. Specify antigens
14	ANT_OTH4	Char	20	$20.	B3a4. Specify antigen(s)
15	LEUK_FLT	Num	8	3.	B4. Was a Third Generation Leukodepletion Filter used?
16	LEUKPROC	Char	2	$2.	B4a. Filtering process
17	LEUKP_SP	Char	25	$25.	B4a1. Other filter, specify
18	SIMPL_TR	Num	8	3.	C1a. Simple transfusion
19	ML_IN_S	Num	8	5.	C1a1. Number of mL in
20	FULL_EX	Num	8	3.	C1b. Exchange transfusion
21	ML_IN_F	Num	8	5.	C1b1. Total mL in
22	ML_OUT_F	Num	8	5.	C1b2. Total mL out
23	METHOD_F	Num	8	3.	C1b3. Method
24	DELIVR_F	Num	8	3.	C1b3a. Delivery
25	HEMAT_TR	Num	8	5.1	C1b4a. Hematocrit of blood transfused (%)
26	HEMAT_RV	Num	8	5.1	C1b4b. Hematocrit of blood removed (%)
27	DESTATUS	Char	1	$1.	DESTATUS
28	EX_NUM	Num	8		X4. Exam Number
29	ldu_id	Char	10		ID for public use datasets
30	tr_datefrmrand	Num	8		<created variable> A2. Date of transfusion as days from RAND visit

Sort Information

Sortedby	ldu_id tr_datefrmrand EX_UNUM
Validated	YES
Character Set	ANSI

```
*F021fmts.txt;

proc format;

  value ANT_CF
    1='1: No'
    2='2: Yes';

  value ANT_EF
    1='1: No'
    2='2: Yes';

  value ANT_OTHF
    1='1: No'
    2='2: Yes';

  value SIMPL_TRF
    1='1: No'
    2='2: Yes';

  value FULL_EXF
    1='1: No'
    2='2: Yes';

  value METHOD_FF
    1='1: Manual'
    2='2: Red Cell Pheresis';

  value DELIVR_FF
    1='1: Intermittent'
    2='2: Continuous';

  value REC_WITHF
    1='1: Saline'
    2='2: Albumin'
    3='3: Plasma'
    4='4: Other';

  value LEUK_FLTF
    1='1: No'
    2='2: Yes';

  value ANT_KELLF
    1='1: No'
    2='2: Yes';

  value $LEUKPROCF
    "A"="A: Prestorage leukodepletion"
    "B"="B: Leukodepletion in blood bank"
    "C"="C: Bedside filtration"
    "D"="D: Other";

* format ant_c ant_cf. ant_e ant_ef. ant_oth ant_othf. simpl_tr simpl_trf. full_ex full_exf. method_f
method_ff. delivr_f delivr_ff. rec_with rec_withf. leuk_flt leuk_fltf. ant_kell ant_kellf. leukproc $leukprocf.;
```

STOP II TRIAL
BLOOD UNIT FORM

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	4978	99.16	4978	99.16
P	42	0.84	5020	100.00

X3. Exam Type				
EX_TYPE	Frequency	Percent	Cum Freq	Cum Percent
TR	5020	100.00	5020	100.00

X4. Exam Number				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
27	3	0.06	3	0.06
28	6	0.12	9	0.18
29	5	0.10	14	0.28
30	5	0.10	19	0.38
31	4	0.08	23	0.46
32	8	0.16	31	0.62
33	8	0.16	39	0.78
34	8	0.16	47	0.94
35	12	0.24	59	1.18
36	11	0.22	70	1.39
37	18	0.36	88	1.75
38	22	0.44	110	2.19
39	22	0.44	132	2.63
40	13	0.26	145	2.89
41	14	0.28	159	3.17
42	10	0.20	169	3.37
43	4	0.08	173	3.45
44	6	0.12	179	3.57
45	9	0.18	188	3.75
46	10	0.20	198	3.94
47	16	0.32	214	4.26
48	14	0.28	228	4.54
49	14	0.28	242	4.82
50	10	0.20	252	5.02
51	9	0.18	261	5.20
52	6	0.12	267	5.32
53	6	0.12	273	5.44

X4. Exam Number (continued)				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
54	1	0.02	274	5.46
55	1	0.02	275	5.48
56	4	0.08	279	5.56
57	4	0.08	283	5.64
58	7	0.14	290	5.78
59	10	0.20	300	5.98
60	10	0.20	310	6.18
61	14	0.28	324	6.45
62	14	0.28	338	6.73
63	11	0.22	349	6.95
64	13	0.26	362	7.21
65	14	0.28	376	7.49
66	17	0.34	393	7.83
67	16	0.32	409	8.15
68	10	0.20	419	8.35
69	7	0.14	426	8.49
70	5	0.10	431	8.59
71	5	0.10	436	8.69
72	6	0.12	442	8.80
73	4	0.08	446	8.88
74	2	0.04	448	8.92
75	3	0.06	451	8.98
76	7	0.14	458	9.12
77	7	0.14	465	9.26
78	5	0.10	470	9.36
79	4	0.08	474	9.44
80	4	0.08	478	9.52
81	4	0.08	482	9.60
82	5	0.10	487	9.70
83	5	0.10	492	9.80
84	6	0.12	498	9.92
85	2	0.04	500	9.96
86	2	0.04	502	10.00
87	2	0.04	504	10.04
88	1	0.02	505	10.06
92	1	0.02	506	10.08
93	1	0.02	507	10.10
94	1	0.02	508	10.12
95	1	0.02	509	10.14
96	1	0.02	510	10.16
97	1	0.02	511	10.18
98	1	0.02	512	10.20
199	2	0.04	514	10.24
301	75	1.49	589	11.73
302	84	1.67	673	13.41
303	81	1.61	754	15.02

X4. Exam Number (continued)				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
304	79	1.57	833	16.59
305	66	1.31	899	17.91
306	65	1.29	964	19.20
307	56	1.12	1020	20.32
308	45	0.90	1065	21.22
309	40	0.80	1105	22.01
310	42	0.84	1147	22.85
311	31	0.62	1178	23.47
312	25	0.50	1203	23.96
313	21	0.42	1224	24.38
314	18	0.36	1242	24.74
315	15	0.30	1257	25.04
316	16	0.32	1273	25.36
317	11	0.22	1284	25.58
318	16	0.32	1300	25.90
319	10	0.20	1310	26.10
320	10	0.20	1320	26.29
321	10	0.20	1330	26.49
322	11	0.22	1341	26.71
323	7	0.14	1348	26.85
324	7	0.14	1355	26.99
325	6	0.12	1361	27.11
326	2	0.04	1363	27.15
327	2	0.04	1365	27.19
328	1	0.02	1366	27.21
329	1	0.02	1367	27.23
330	1	0.02	1368	27.25
331	1	0.02	1369	27.27
332	2	0.04	1371	27.31
333	2	0.04	1373	27.35
334	1	0.02	1374	27.37
335	1	0.02	1375	27.39
336	1	0.02	1376	27.41
337	1	0.02	1377	27.43
338	1	0.02	1378	27.45
339	1	0.02	1379	27.47
340	2	0.04	1381	27.51
353	1	0.02	1382	27.53
392	1	0.02	1383	27.55
501	138	2.75	1521	30.30
502	135	2.69	1656	32.99
503	125	2.49	1781	35.48
504	132	2.63	1913	38.11
505	113	2.25	2026	40.36
506	108	2.15	2134	42.51
507	105	2.09	2239	44.60

X4. Exam Number (continued)				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
508	89	1.77	2328	46.37
509	90	1.79	2418	48.17
510	93	1.85	2511	50.02
511	99	1.97	2610	51.99
512	98	1.95	2708	53.94
513	91	1.81	2799	55.76
514	82	1.63	2881	57.39
515	85	1.69	2966	59.08
516	86	1.71	3052	60.80
517	79	1.57	3131	62.37
518	82	1.63	3213	64.00
519	77	1.53	3290	65.54
520	92	1.83	3382	67.37
521	77	1.53	3459	68.90
522	71	1.41	3530	70.32
523	75	1.49	3605	71.81
524	68	1.35	3673	73.17
525	59	1.18	3732	74.34
526	64	1.27	3796	75.62
527	75	1.49	3871	77.11
528	70	1.39	3941	78.51
529	68	1.35	4009	79.86
530	63	1.25	4072	81.12
531	65	1.29	4137	82.41
532	59	1.18	4196	83.59
533	62	1.24	4258	84.82
534	73	1.45	4331	86.27
535	61	1.22	4392	87.49
536	58	1.16	4450	88.65
537	69	1.37	4519	90.02
538	65	1.29	4584	91.31
539	64	1.27	4648	92.59
540	63	1.25	4711	93.84
541	49	0.98	4760	94.82
542	42	0.84	4802	95.66
543	45	0.90	4847	96.55
544	42	0.84	4889	97.39
545	41	0.82	4930	98.21
546	32	0.64	4962	98.84
547	15	0.30	4977	99.14
548	14	0.28	4991	99.42
549	12	0.24	5003	99.66
550	10	0.20	5013	99.86
554	2	0.04	5015	99.90
555	2	0.04	5017	99.94
599	3	0.06	5020	100.00

X4.1. Blood unit transfusion sequence number				
EX_UNUM	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.02	1	0.02
1	1990	39.64	1991	39.66
2	1464	29.16	3455	68.82
3	681	13.57	4136	82.39
4	409	8.15	4545	90.54
5	229	4.56	4774	95.10
6	142	2.83	4916	97.93
7	74	1.47	4990	99.40
8	21	0.42	5011	99.82
9	4	0.08	5015	99.90
10	1	0.02	5016	99.92
11	1	0.02	5017	99.94
12	1	0.02	5018	99.96
13	1	0.02	5019	99.98
14	1	0.02	5020	100.00

A1. Person completing form (Name): _____ Initials: | | | |

[Variable NOT included in dataset.]

A2. Date of Transfusion (Month/Day/Year): ____ ___/____ ___/____ ___ ___ ___

Analysis Variable : tr_datefrmrand <created variable> A2. Date of transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
5020	0	292.4	461.4	-1136	-46.0	294.5	648.0	1253.0

A3. Unit Number: _____

[Variable NOT included in dataset.]

B1. Blood Product:

☐ 1. HbS negative packed red cells

☐ 2. HbS negative packed red cells reconstituted with → B1.a

B1.a
- ☐ **1. saline**
- ☐ **2. albumin**
- ☐ **3. plasma**
- ☐ **4. other** → B1.b Specify: _____

☐ 3. Other → B1.c Specify: _____

B1. Blood product				
BL_PROD	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.08	4	0.08
-8	717	14.28	721	14.36
-3	1	0.02	722	14.38
1	4103	81.73	4825	96.12
2	59	1.18	4884	97.29
3	136	2.71	5020	100.00

B1a. Blood product reconstituted with				
REC_WITH	Frequency	Percent	Cum Freq	Cum Percent
-2	4961	98.82	4961	98.82
1	20	0.40	4981	99.22
2	5	0.10	4986	99.32
4	34	0.68	5020	100.00

B1b. Specify				
SP_REC	Frequency	Percent	Cum Freq	Cum Percent
-2	4986	99.32	4986	99.32
anticoagulant	34	0.68	5020	100.00

B1c. Other specify				
SP_BL_PR	Frequency	Percent	Cum Freq	Cum Percent
-2	4884	97.29	4884	97.29
packed RBCs	3	0.06	4887	97.35
unwashed packed RBCs	8	0.16	4895	97.51
washed RBCs	2	0.04	4897	97.55
washed packed RBCs	123	2.45	5020	100.00

B2. Was the unit NEGATIVE for the following antigens? **1. NO** **2. YES**

B2.a C ☐ ☐

B2a. Was the unit negative for the C antigen?				
ANT_C	Frequency	Percent	Cum Freq	Cum Percent
-9	112	2.23	112	2.23
-8	32	0.64	144	2.87
-3	15	0.30	159	3.17
1	1163	23.17	1322	26.33
2	3698	73.67	5020	100.00

B2.b E ☐ ☐

B2b. Was the unit negative for the E antigen?				
ANT_E	Frequency	Percent	Cum Freq	Cum Percent
-9	112	2.23	112	2.23
-8	32	0.64	144	2.87
-3	18	0.36	162	3.23
1	887	17.67	1049	20.90
2	3971	79.10	5020	100.00

B2.c Kell ☐ ☐

B2c. Was the unit negative for the Kell antigen?				
ANT_KELL	Frequency	Percent	Cum Freq	Cum Percent
-9	112	2.23	112	2.23
-8	32	0.64	144	2.87
-3	15	0.30	159	3.17
1	309	6.16	468	9.32
2	4552	90.68	5020	100.00

B3. Was the unit known to be negative for any other antigens? ☐ ☐

B3. Was the unit known to be negative for any other antigens?				
ANT_OTH	Frequency	Percent	Cum Freq	Cum Percent
-9	110	2.19	110	2.19
-8	33	0.66	143	2.85
-3	12	0.24	155	3.09
1	3265	65.04	3420	68.13
2	1600	31.87	5020	100.00

↓

SPECIFY ANTIGEN(S):	
B3.a1	
B3.a2	
B3.a3	
B3.a4	

B3a1. Specify antigens				
ANT_OTH1	Frequency	Percent	Cum Freq	Cum Percent
-2	3420	68.13	3420	68.13
-9	1	0.02	3421	68.15
Cw	11	0.22	3432	68.37
D	24	0.48	3456	68.84
Fya	900	17.93	4356	86.77
Fya, Fyb	3	0.06	4359	86.83
Fyb	87	1.73	4446	88.57
Jka	125	2.49	4571	91.06
Jkb	184	3.67	4755	94.72
Jsa	7	0.14	4762	94.86
Kpa	2	0.04	4764	94.90
Lea	40	0.80	4804	95.70
Leb	1	0.02	4805	95.72
M	37	0.74	4842	96.45
N	1	0.02	4843	96.47
S	164	3.27	5007	99.74
V	3	0.06	5010	99.80
small c	7	0.14	5017	99.94
small e	2	0.04	5019	99.98
small s	1	0.02	5020	100.00

↓

SPECIFY ANTIGEN(S):	
B3.a1	
B3.a2	
B3.a3	
B3.a4	

B3a2. Specify antigen				
ANT_OTH2	Frequency	Percent	Cum Freq	Cum Percent
-1	704	14.02	704	14.02
-2	3421	68.15	4125	82.17
Cw	5	0.10	4130	82.27
Fya	128	2.55	4258	84.82
Fya, Fyb	1	0.02	4259	84.84
Fyb	54	1.08	4313	85.92
Jka	131	2.61	4444	88.53
Jka, Jkb	1	0.02	4445	88.55
Jkb	266	5.30	4711	93.84
Jsa	99	1.97	4810	95.82
Lea	7	0.14	4817	95.96
Leb	1	0.02	4818	95.98
M	2	0.04	4820	96.02
S	188	3.75	5008	99.76
small c	6	0.12	5014	99.88
small f	1	0.02	5015	99.90
small s	5	0.10	5020	100.00

↓

SPECIFY ANTIGEN(S):	
B3.a1	
B3.a2	
B3.a3	
B3.a4	

B3a3. Specify antigens				
ANT_OTH3	Frequency	Percent	Cum Freq	Cum Percent
-1	483	9.62	483	9.62
-2	4125	82.17	4608	91.79
Cw	1	0.02	4609	91.81
Fya	6	0.12	4615	91.93
Fya, Fyb	1	0.02	4616	91.95
Fyb	13	0.26	4629	92.21
Jka	37	0.74	4666	92.95
Jkb	22	0.44	4688	93.39
Jsa	2	0.04	4690	93.43
Jsa, Jsb	1	0.02	4691	93.45
M	5	0.10	4696	93.55
S	144	2.87	4840	96.41
V	171	3.41	5011	99.82
Wra	1	0.02	5012	99.84
small c	3	0.06	5015	99.90
small k	1	0.02	5016	99.92
small s	4	0.08	5020	100.00

B3a4. Specify antigen(s)				
ANT_OTH4	Frequency	Percent	Cum Freq	Cum Percent
--1	1	0.02	1	0.02
-1	379	7.55	380	7.57
-2	4608	91.79	4988	99.36
Cw	2	0.04	4990	99.40
Fyb	1	0.02	4991	99.42
Jka	1	0.02	4992	99.44
Jkb	2	0.04	4994	99.48
Lea	1	0.02	4995	99.50
M	6	0.12	5001	99.62
N	1	0.02	5002	99.64
S	14	0.28	5016	99.92
S, Fyb	1	0.02	5017	99.94
S, V	2	0.04	5019	99.98
V	1	0.02	5020	100.00

B4. Was a Third Generation Leukodepletion Filter used? ☐ **1. NO** ☐ **2. YES**

B4. Was a Third Generation Leukodepletion Filter used?				
LEUK_FLT	Frequency	Percent	Cum Freq	Cum Percent
-9	8	0.16	8	0.16
1	418	8.33	426	8.49
2	4594	91.51	5020	100.00

↓

B4.a Filtering Process:

☐ A **PRESTORAGE LEUKODEPLETION**

☐ B **LEUKODEPLETION IN BLOOD BANK**

☐ C **BEDSIDE FILTRATION**

☐ D **OTHER**

D1. If other, specify: _____

B4a. Filtering process				
LEUKPROC	Frequency	Percent	Cum Freq	Cum Percent
-2	426	8.49	426	8.49
-8	1	0.02	427	8.51
-9	2	0.04	429	8.55
A	2949	58.75	3378	67.29
B	1375	27.39	4753	94.68
C	261	5.20	5014	99.88
D	6	0.12	5020	100.00

B4a1. Other filter, specify				
LEUKP_SP	Frequency	Percent	Cum Freq	Cum Percent
-2	5014	99.88	5014	99.88
Pall Filter	1	0.02	5015	99.90
both A and C	2	0.04	5017	99.94
both A and C checked	3	0.06	5020	100.00

C. TRANSFUSION TYPE AND DELIVERY

C1. Type of transfusion for this unit:

C1.a **Simple** ☐ **1. NO** ☐ **2. YES** → C1.a1 Number of mL in ☐☐☐☐

C1a. Simple transfusion				
SIMPL_TR	Frequency	Percent	Cum Freq	Cum Percent
-9	9	0.18	9	0.18
1	2696	53.71	2705	53.88
2	2315	46.12	5020	100.00

Analysis Variable : ML_IN_S C1a1. Number of mL in								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2161	0	273.4	83.3	29.0	242.0	280.0	310.0	2881.0

C1a1. Number of mL in				
ML_IN_S	Frequency	Percent	Cum Freq	Cum Percent
-9	97	3.39	97	3.39
-8	17	0.59	114	3.99
-6	1	0.03	115	4.02
-3	39	1.36	154	5.39
-2	2705	94.61	2859	100.00

C1.b **Exchange** ☐ **1. NO** ☐ **2. YES** → C1.b1 Total mL in: ☐☐☐☐

C1b. Exchange transfusion				
FULL_EX	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.08	4	0.08
1	2320	46.22	2324	46.29
2	2696	53.71	5020	100.00

Analysis Variable : ML_IN_F C1b1. Total mL in								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2432	0	296.0	46.6	28.0	280.0	293.0	322.0	1189.0

C1b1. Total mL in				
ML_IN_F	Frequency	Percent	Cum Freq	Cum Percent
-9	245	9.47	245	9.47
-8	19	0.73	264	10.20
-2	2324	89.80	2588	100.00

C1.b2 Total mL out: ☐☐☐☐

Analysis Variable : ML_OUT_F C1b2. Total mL out								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
711	0	1134.2	804.4	0.0	400.0	1110.0	1575.0	4165.0

C1b2. Total mL out				
ML_OUT_F	Frequency	Percent	Cum Freq	Cum Percent
-9	1975	45.83	1975	45.83
-8	7	0.16	1982	46.00
-6	3	0.07	1985	46.07
-2	2324	53.93	4309	100.00

C1.b3 Method ☐ **1. Manual** ☐ **2. Red Cell Pheres**

C1b3. Method				
METHOD_F	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.02	1	0.02
-2	2324	46.29	2325	46.31
1	442	8.80	2767	55.12
2	2253	44.88	5020	100.00

↓

C1.b3.a Delivery

☐ **1. Intermittent**

☐ **2. Continuous**

C1b3a. Delivery				
DELIVR_F	Frequency	Percent	Cum Freq	Cum Percent
-2	2767	55.12	2767	55.12
1	284	5.66	3051	60.78
2	1969	39.22	5020	100.00

C1.b4 Hematocrit of

a. blood transfused (%) ☐☐.☐ ☐ **-1. NOT AVAILABLE**

Analysis Variable : HEMAT_TR C1b4a. Hematocrit of blood transfused (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1032	0	59.8	4.1	27.0	57.5	60.0	60.0	90.0

C1b4a. Hematocrit of blood transfused (%)				
HEMAT_TR	Frequency	Percent	Cum Freq	Cum Percent
-2	2767	69.38	2767	69.38
-1	1221	30.62	3988	100.00

b. blood removed (%) ☐☐.☐ ☐ **-1. NOT AVAILABLE**

Analysis Variable : HEMAT_RV C1b4b. Hematocrit of blood removed (%%)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1000	0	40.0	6.3	1.0	35.7	39.7	44.0	60.0

C1b4b. Hematocrit of blood removed (%)				
HEMAT_RV	Frequency	Percent	Cum Freq	Cum Percent
-2	2767	68.83	2767	68.83
-1	1253	31.17	4020	100.00

ATTACH COPY OF THE TRANSFUSION TAG FOR THIS BLOOD UNIT.

Signature of Study Coordinator: _____ Date: ____ ___/___ ____/___ ___ ___ ___

D. FOR OFFICE USE

D1. Transfusion tag received: ☐ **1.NO** ☐ **2.YES** ☐ ML ☐ DE

[Variable NOT included in dataset.]

FORM 22: TRANSFUSION HISTORY LOG FOR PATIENTS ON TRANSFUSION FOR PRIMARY STROKE PREVENTION WHO WERE NOT STOP RANDOMIZED PATIENTS

A. Collection Information:

The **Transfusion History Log for Patients on Transfusion for Primary Stroke Prevention who were not STOP Randomized Patients** (Form 22) was to be completed at the time of enrollment for Potential patients who started transfusions > 1 month before enrollment. (Transfusion data was also collected on Forms 20 and 21 for STOP Randomized patients, Form 13B for STOP II Potential patients, and Forms 13, 20 and 21 for STOP II Randomized patients.)

B. Data Collection Period: December 2000 through July 2002

C. Form Version Dates: 12/15/00

D. Files Used to Store Information:

SAS System File: **p022_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID, and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 558 (21)

Each transfusion listed on Form 22 was output as a separate record. Questions B1-B3a were set to missing for all records except the first record for each patient (EX_NUM=01.)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 604
- Listing of Variables by Position: See p. 605

H. Formats:

The file **f022fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 606.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPE for Form 22 is TR for transfusion visits.

- **EX_NUM** – is the variable name for exam number. For Form 22 this is the transfusion number as indicated by the numbering in section B4.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

Data Set Name	PUBDS.P022_FINAL	Observations	558
Member Type	DATA	Variables	15
Engine	V9	Indexes	0
Created	Wed, Feb 15, 2006 02:33:20 PM	Observation Length	120
Last Modified	Wed, Feb 15, 2006 02:33:20 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	12288
Number of Data Set Pages	6
First Data Page	1
Max Obs per Page	102
Obs in First Data Page	76
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p022_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
5	DESTATUS	Char	1	$1.	DESTATUS
1	EX_TYPE	Char	2	$2.	X3. Exam Type
8	FERRITIN	Num	8	6.	B4c. Ferritin (ng/ml)
7	HB_S	Num	8	3.	B4b. % Hb S
4	ON_CHEL	Num	8	3.	B3. Patient receiving chelation
3	SPEC_RSN	Char	25	$25.	B2a. Specify other reason for transfusions
2	TX_REASN	Num	8	3.	B2. Reason for transfusions
13	chel_begfrmrand	Num	8		<created variable> B3a. Date chelation started as days from RAND visit
11	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
15	datedrawfrmrand	Num	8		<created variable> B4d. Date blood drawn as days from RAND visit
6	ex_num	Char	3		B4. Exam number
10	ldu_id	Char	10		ID for public use datasets
14	tx_datefrmrand	Num	8		<created variable> B4a. Date of transfusion as days from RAND visit
12	tx_startfrmrand	Num	8		<created variable> B1. Date transfusion started as days from RAND visit
9	vistype	Char	6		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	TX_REASN	Num	8	3.	B2. Reason for transfusions
3	SPEC_RSN	Char	25	$25.	B2a. Specify other reason for transfusions
4	ON_CHEL	Num	8	3.	B3. Patient receiving chelation
5	DESTATUS	Char	1	$1.	DESTATUS
6	ex_num	Char	3		B4. Exam number
7	HB_S	Num	8	3.	B4b. % Hb S
8	FERRITIN	Num	8	6.	B4c. Ferritin (ng/ml)
9	vistype	Char	6		<created variable> VISIT TYPE
10	ldu_id	Char	10		ID for public use datasets
11	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
12	tx_startfrmrand	Num	8		<created variable> B1. Date transfusion started as days from RAND visit
13	chel_begfrmrand	Num	8		<created variable> B3a. Date chelation started as days from RAND visit
14	tx_datefrmrand	Num	8		<created variable> B4a. Date of transfusion as days from RAND visit
15	datedrawfrmrand	Num	8		<created variable> B4d. Date blood drawn as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
* F022fmts.txt;

proc format;

  value TX_REASNF
    1='1: Primary stroke prevention'
    2='2: Other';

  value ON_CHELF
    1='1: No'
    2='2: Yes';


      * format tx_reasn tx_reasnf. on_chel on_chelf.;
```

STOP II
TRANSFUSION HISTORY LOG FOR PATIENTS ON TRANSFUSION FOR PRIMARY STROKE PREVENTION WHO WERE NOT STOP RANDOMIZED PATIENTS

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	471	84.41	471	84.41
P	87	15.59	558	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
TR-01	21	3.76	21	3.76
TR-02	21	3.76	42	7.53
TR-03	21	3.76	63	11.29
TR-04	21	3.76	84	15.05
TR-05	21	3.76	105	18.82
TR-06	20	3.58	125	22.40
TR-07	19	3.41	144	25.81
TR-08	19	3.41	163	29.21
TR-09	19	3.41	182	32.62
TR-10	19	3.41	201	36.02
TR-11	19	3.41	220	39.43
TR-12	19	3.41	239	42.83
TR-13	17	3.05	256	45.88
TR-14	17	3.05	273	48.92
TR-15	17	3.05	290	51.97
TR-16	15	2.69	305	54.66
TR-17	14	2.51	319	57.17
TR-18	12	2.15	331	59.32
TR-19	11	1.97	342	61.29
TR-20	10	1.79	352	63.08
TR-21	10	1.79	362	64.87
TR-22	9	1.61	371	66.49
TR-23	9	1.61	380	68.10
TR-24	9	1.61	389	69.71
TR-25	9	1.61	398	71.33
TR-26	9	1.61	407	72.94
TR-27	8	1.43	415	74.37
TR-28	7	1.25	422	75.63
TR-29	7	1.25	429	76.88
TR-30	7	1.25	436	78.14
TR-31	7	1.25	443	79.39
TR-32	7	1.25	450	80.65
TR-33	7	1.25	457	81.90

<created variable> VISIT TYPE (continued)				
vistype	Frequency	Percent	Cum Freq	Cum Percent
TR-34	7	1.25	464	83.15
TR-35	7	1.25	471	84.41
TR-36	7	1.25	478	85.66
TR-37	7	1.25	485	86.92
TR-38	7	1.25	492	88.17
TR-39	7	1.25	499	89.43
TR-40	5	0.90	504	90.32
TR-41	5	0.90	509	91.22
TR-42	4	0.72	513	91.94
TR-43	4	0.72	517	92.65
TR-44	4	0.72	521	93.37
TR-45	4	0.72	525	94.09
TR-46	4	0.72	529	94.80
TR-47	4	0.72	533	95.52
TR-48	4	0.72	537	96.24
TR-49	4	0.72	541	96.95
TR-50	2	0.36	543	97.31
TR-51	2	0.36	545	97.67
TR-52	2	0.36	547	98.03
TR-53	2	0.36	549	98.39
TR-54	2	0.36	551	98.75
TR-55	2	0.36	553	99.10
TR-56	2	0.36	555	99.46
TR-57	1	0.18	556	99.64
TR-58	1	0.18	557	99.82
TR-59	1	0.18	558	100.00

A1. Person completing log (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
558	0	-446.7	344.0	-1125	-820.0	-304.0	-190.0	240.0

B. TRANSFUSION HISTORY SECTION

B1. Date Transfusion Started (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : tx_startfrmrand <created variable> B1. Date transfusion started as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
21	0	-1405	329.7	-2120	-1596	-1391	-1138	-959.0

<created variable> B1. Date transfusion started as days from RAND visit				
tx_startfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	537	100.00	537	100.00

B2. Reason for Transfusions:

☐ **1. PRIMARY STROKE PREVENTION**

☐ **2. OTHER→** B2.a. Specify: _____ _____

B2. Reason for transfusions				
TX_REASN	Frequency	Percent	Cum Freq	Cum Percent
1	20	95.24	20	95.24
2	1	4.76	21	100.00

B2a. Specify other reason for transfusions				
SPEC_RSN	Frequency	Percent	Cum Freq	Cum Percent
-2	20	95.24	20	95.24
stroke pre & chronic lung	1	4.76	21	100.00

B3. Is Patient Receiving Chelation? ☐ **1. NO** ☐ **2. YES→** B3.a Date Started ___ ___/___ ___/___ ___ ___ ___

B3. Patient receiving chelation				
ON_CHEL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	4.76	1	4.76
1	13	61.90	14	66.67
2	7	33.33	21	100.00

Analysis Variable : chel_begfrmrand <created variable> B3a. Date chelation started as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
7	0	-1231	203.0	-1511	-1432	-1218	-1063	-964.0

<created variable> B3a. Date chelation started as days from RAND visit				
chel_begfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	551	100.00	551	100.00

B4. Transfusion Visits Since Chronic Transfusion Program Started (List most recent transfusion first):

		Pre-transfusion		
a. Date of Transfusion	b. %Hb S	c. Ferritin (ng/ml)	d. Date Blood Drawn	e. OFFICE USE
1. __ __/__ __/__ __ __ __			__ __/__ __/__ __ __ __	

Analysis Variable : tx_datefrmrand <created variable> B4a. Date of transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
557	0	-995.2	397.3	-2120	-1265	-992.0	-712.0	-154.0

<created variable> B4a. Date of transfusion as days from RAND visit				
tx_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

Analysis Variable : HB_S B4b. %% Hb S								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
528	0	36.7	16.6	6.0	26.0	34.0	43.0	99.0

B4b. % Hb S				
HB_S	Frequency	Percent	Cum Freq	Cum Percent
-3	30	100.00	30	100.00

Analysis Variable : FERRITIN B4c. Ferritin (ng/ml)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
203	0	1430.7	1039.5	13.0	678.0	1191.0	1924.0	5221.0

B4c. Ferritin (ng/ml)				
FERRITIN	Frequency	Percent	Cum Freq	Cum Percent
-3	355	100.00	355	100.00

Analysis Variable : datedrawfrmrand <created variable> B4d. Date blood drawn as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
543	0	-988.6	394.7	-2120	-1252	-989.0	-707.0	-155.0

<created variable> B4d. Date blood drawn as days from RAND visit				
datedrawfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	15	100.00	15	100.00

[Variable NOT included in dataset for Office Use field.]

STOP II
FORM 23A: CHELATION QUESTIONNAIRE FOR STOP II RANDOMIZED PATIENTS

A. Collection Information:
The **Chelation Questionnaire** (Form 23A) was to be completed once for patients randomized before February 2003.

B. Data Collection Period: February 2003

C. Form Version Dates: 02/01/03

D. Files Used to Store Information:

SAS System File: **p23a_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 49 (49)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See p. 613
- Listing of Variables by Position: See p. 614

H. Formats:
The file **f23Afmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 615.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

Data Set Name	PUBDS.P23A_FINAL	Observations	49
Member Type	DATA	Variables	13
Engine	V9	Indexes	0
Created	Friday, March 10, 2006 10:06:51 AM	Observation Length	104
Last Modified	Friday, March 10, 2006 10:06:51 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	12288
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	117
Obs in First Data Page	49
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p23a_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
6	ADMN	Num	8	3.	B2.d. Current prescription for chelation: Where administered
9	CH_THPY	Num	8	3.	D1. Did patient ever receive chelation therapy?
10	CMNTS	Num	8	3.	E1. Do you want to add additional comments?
2	CURRCHEL	Char	2	$2.	B1. Is patient currently being chelated?
8	DEG_COMP	Char	2	$2.	C1. Rate the degree of compliance at this time
1	DESTATUS	Char	1	$1.	DESTATUS
3	DOSE	Num	8	4.	B2.a. Current prescription for chelation: Dose
4	FREQUENCY	Num	8	3.	B2.b. Current prescription for chelation: Frequency
5	METHOD	Num	8	3.	B2.c. Current prescription for chelation: Method of delivery
7	OTH_SP	Char	25	$25.	B2.d1. If OTHER, specify
12	comp_ dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
13	disc_ dtfrmrand	Num	8		<created variable> D1a. If YES, most recent date discontinued as days from RAND visit
11	ldu_id	Char	10		ID for public use datasets

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	DESTATUS	Char	1	$1.	DESTATUS
2	CURRCHEL	Char	2	$2.	B1. Is patient currently being chelated?
3	DOSE	Num	8	4.	B2.a. Current prescription for chelation: Dose
4	FREQUENCY	Num	8	3.	B2.b. Current prescription for chelation: Frequency
5	METHOD	Num	8	3.	B2.c. Current prescription for chelation: Method of delivery
6	ADMN	Num	8	3.	B2.d. Current prescription for chelation: Where administered
7	OTH_SP	Char	25	$25.	B2.d1. If OTHER, specify
8	DEG_COMP	Char	2	$2.	C1. Rate the degree of compliance at this time
9	CH_THPY	Num	8	3.	D1. Did patient ever receive chelation therapy?
10	CMNTS	Num	8	3.	E1. Do you want to add additional comments?
11	ldu_id	Char	10		ID for public use datasets
12	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
13	disc_dtfrmrand	Num	8		<created variable> D1a. If YES, most recent date discontinued as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F23Afmts.txt;

proc format;

  value ADMNF
    1='1: At home'
    2='2: In clinic'
    3='3: In hospital'
    9='9: Other';

  value CH_THPYF
    1='1: No'
    2='2: Yes';

  value CMNTSF
    1='1: No'
    2='2: Yes';

  value $CURRCHELF
    "1"="1: Yes"
    "2"="2: No";

  value $DEG_COMPF
    "1"="1: High"
    "2"="2: Moderate"
    "3"="3: Poor";

  value METHODF
    1='1: Subcutaneous'
    2='2: Intravenous'
    3='3: Intramuscular';

* format admn admnf. ch_thpy ch_thpyf. cmnts cmntsf. currchel $currchelf. deg_comp $deg_compf.
method methodf.;
```

STOP II TRIAL

CHELATION QUESTIONNAIRE FOR STOP II RANDOMIZED PATIENTS

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	49	100.00	49	100.00

Section A: KEY IDENTIFYING INFORMATION

A1. Person completing form _____ ___ ___ ___
PRINT FULL NAME INITIALS

[Variable NOT included in dataset.]

A2. Date form completed ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
49	0	467.3	138.6	144.0	372.0	469.0	580.0	674.0

Section B: CHELATION PRESCRIPTION INFORMATION

B1. Is patient <u>currently</u> being chelated? NO ..... 1 YES ..... 2 UNKNOWN ... -8

IF NO, SKIP TO SECTION D

IF UNKNOWN, SKIP TO SECTION D

B1. Is patient currently being chelated?				
CURRCHEL	Frequency	Percent	Cum Freq	Cum Percent
1	20	40.82	20	40.82
2	29	59.18	49	100.00

B2. Current prescription for chelation

a. Dose ___ ___ ___ mg/kg/day

Analysis Variable : DOSE B2.a. Current prescription for chelation: Dose								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
26	0	43.8	15.6	13.0	40.0	40.0	50.0	100.0

B2.a. Current prescription for chelation: Dose				
DOSE	Frequency	Percent	Cum Freq	Cum Percent
-9	3	13.04	3	13.04
-2	20	86.96	23	100.00

b. Frequency ___ days/week

B2.b. Current prescription for chelation: Frequency				
FREQUENCY	Frequency	Percent	Cum Freq	Cum Percent
-9	3	6.12	3	6.12
-2	20	40.82	23	46.94
1	1	2.04	24	48.98
4	1	2.04	25	51.02
5	17	34.69	42	85.71
6	2	4.08	44	89.80
7	5	10.20	49	100.00

c. Method of delivery

SUBCUTANEOUS 1

INTRAVENOUS 2

INTRAMUSCULAR 3

B2.c. Current prescription for chelation: Method of delivery				
METHOD	Frequency	Percent	Cum Freq	Cum Percent
-2	20	40.82	20	40.82
1	24	48.98	44	89.80
2	5	10.20	49	100.00

d. Where administered

AT HOME 1
IN CLINIC (OUTPATIENT)..... 2
IN HOSPITAL (INPATIENT)..... 3
OTHER 9

1. If OTHER, specify

_____

B2.d. Current prescription for chelation: Where administered				
ADMN	Frequency	Percent	Cum Freq	Cum Percent
-2	20	40.82	20	40.82
1	25	51.02	45	91.84
2	2	4.08	47	95.92
3	2	4.08	49	100.00

B2.d1. If OTHER, specify				
OTH_SP	Frequency	Percent	Cum Freq	Cum Percent
-2	49	100.00	49	100.00

Section C: CURRENT PATIENT COMPLIANCE IN CHELATION PROGRAM

C1. Rate the degree of compliance <u>at this time</u>

HIGH 1
MODERATE 2
POOR..... 3
UNKNOWN ..... -8

C1. Rate the degree of compliance at this time				
DEG_COMP	Frequency	Percent	Cum Freq	Cum Percent
-2	20	40.82	20	40.82
-8	3	6.12	23	46.94
1	7	14.29	30	61.22
2	14	28.57	44	89.80
3	5	10.20	49	100.00

COMPLETE SECTION D ONLY IF THE PATIENT IS NOT BEING CHELATED CURRENTLY OR THE PATIENT'S CURRENT CHELATION STATUS IS UNKNOWN.

Section D: PAST HISTORY OF CHELATION

D1. Did patient ever receive chelation therapy? NO ..... 1 YES 2

D1. Did patient ever receive chelation therapy?				
CH_THPY	Frequency	Percent	Cum Freq	Cum Percent
-2	29	59.18	29	59.18
1	11	22.45	40	81.63
2	9	18.37	49	100.00

a. If YES, most recent date discontinued

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

E1. Do you want to add additional comments?				
CMNTS	Frequency	Percent	Cum Freq	Cum Percent
1	31	63.27	31	63.27
2	18	36.73	49	100.00

Section E: COMMENTS

E1. Do you want to add any additional comments about the patient's current or past chelation treatment? NO ..... 1 YES 2

a. If YES, please **PRINT** comments in space provided below:

[Variable NOT included in dataset.]

STOP II

"FORM" 24: TRANSFUSION HISTORY LOG FOR PRE-STOP II TRANSFUSIONS THAT ARE NOT IN FOXPRO OR ADEPT FOR STOP RANDOMIZED PATIENTS

A. Collection Information:

The **Transfusion History Log for Pre-STOP II Transfusions That Are Not in FOXPRO or ADEPT** ("Form" 24) was to be completed for STOP II Randomized patients previously randomized in STOP for transfusion data collected on Form 20A (STOP Trial Transfusion Form.) Form 20A was completed for transfusions received in the interim period between STOP and STOP II and data entered into FOXPRO, the data management system used during STOP. The data collected on Form 20As were not previously data entered in the FOXPRO database and were transferred to "Form" 24 for data entry into ADEPT.

B. Data Collection Period: September 1999 to December 2000

C. Form Version Dates: 11/10/04

D. Files Used to Store Information:

SAS System File: **p024_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, TX_DATEFRMRAND**

Records in the dataset are sorted by LDU_ID and TX_DATEFRMRAND.

F. Number of Observations (Patients) in SAS Dataset: 240 (33)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 622
- Listing of Variables by Position: See pp. 622-623

H. Formats: N/A

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_NUM** – is the variable name for transfusion number as recorded on the Form 20A. This number reflects the number of transfusions since the patient started transfusions in STOP.

Data Set Name	PUBDS.P024_FINAL	Observations	240
Member Type	DATA	Variables	7
Engine	V9	Indexes	0
Created	Thu, Feb 16, 2006 01:50:17 PM	Observation Length	56
Last Modified	Thu, Feb 16, 2006 01:50:17 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	8192
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	145
Obs in First Data Page	110
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p024_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
1	DESTATUS	Char	1	$1.	DESTATUS
2	EX_NUM	Num	8	4.	B1b. Exam number
3	HB_S	Num	8	3.	B1c. % Hb S
5	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
7	datedrawfrmrand	Num	8		<created variable> B1d. Date blood drawn as days from RAND visit
4	ldu_id	Char	10		ID for public use datasets
6	tx_datefrmrand	Num	8		<created variable> B1a. Date of transfusion as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	DESTATUS	Char	1	$1.	DESTATUS
2	EX_NUM	Num	8	4.	B1b. Exam number
3	HB_S	Num	8	3.	B1c. % Hb S
4	ldu_id	Char	10		ID for public use datasets
5	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
6	tx_datefrmrand	Num	8		<created variable> B1a. Date of transfusion as days from RAND visit
7	datedrawfrmrand	Num	8		<created variable> B1d. Date blood drawn as days from RAND visit

Sort Information

Sortedby	ldu_id tx_datefrmrand
Validated	YES
Character Set	ANSI

STOP II
TRANSFUSION HISTORY LOG FOR PRE-STOP II TRANSFUSIONS THAT ARE NOT IN FOXPRO OR ADEPT FOR STOP RANDOMIZED PATIENTS
[Forms 20A & 21 completed]

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	234	97.50	234	97.50
P	6	2.50	240	100.00

A1. Person completing log (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
240	0	1171.6	99.6	962.0	1087.0	1200.0	1267.0	1319.0

B. TRANSFUSION HISTORY SECTION

List Transfusion Visits Recorded on STOP Form 20A That Are Not in FOXPRO or ADEPT:

a. Date of Transfusion	b. Foxpro TR Number	c. Pre-Transfusion HbS (%)	d. Date Blood Drawn	e. OFFICE USE
1. ___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __

Analysis Variable : tx_datefrmrand <created variable> B1a. Date of transfusion as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
238	0	-505.4	137.7	-831.0	-602.0	-497.0	-410.0	-210.0

<created variable> B1a. Date of transfusion as days from RAND visit				
tx_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	2	100.00	2	100.00

B1b. Exam number				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
24	1	0.42	1	0.42
25	1	0.42	2	0.83
26	1	0.42	3	1.25
27	2	0.83	5	2.08
28	1	0.42	6	2.50
29	3	1.25	9	3.75
30	5	2.08	14	5.83
31	5	2.08	19	7.92
32	6	2.50	25	10.42
33	7	2.92	32	13.33
34	8	3.33	40	16.67
35	7	2.92	47	19.58
36	5	2.08	52	21.67
37	4	1.67	56	23.33
38	4	1.67	60	25.00
39	5	2.08	65	27.08
40	5	2.08	70	29.17
41	5	2.08	75	31.25
42	4	1.67	79	32.92
43	3	1.25	82	34.17
44	3	1.25	85	35.42
45	3	1.25	88	36.67
46	3	1.25	91	37.92
48	1	0.42	92	38.33
49	1	0.42	93	38.75
50	1	0.42	94	39.17
51	3	1.25	97	40.42
52	6	2.50	103	42.92
53	6	2.50	109	45.42
54	6	2.50	115	47.92
55	6	2.50	121	50.42
56	5	2.08	126	52.50
57	5	2.08	131	54.58
58	4	1.67	135	56.25
59	4	1.67	139	57.92
60	5	2.08	144	60.00
61	4	1.67	148	61.67
62	4	1.67	152	63.33
63	8	3.33	160	66.67
64	8	3.33	168	70.00
65	9	3.75	177	73.75
66	6	2.50	183	76.25
67	5	2.08	188	78.33
68	5	2.08	193	80.42
69	6	2.50	199	82.92

B1b. Exam number (continued)				
EX_NUM	Frequency	Percent	Cum Freq	Cum Percent
70	6	2.50	205	85.42
71	6	2.50	211	87.92
72	5	2.08	216	90.00
73	4	1.67	220	91.67
74	4	1.67	224	93.33
75	3	1.25	227	94.58
76	1	0.42	228	95.00
77	1	0.42	229	95.42
78	1	0.42	230	95.83
79	1	0.42	231	96.25
80	1	0.42	232	96.67
81	1	0.42	233	97.08
85	1	0.42	234	97.50
86	1	0.42	235	97.92
87	1	0.42	236	98.33
88	1	0.42	237	98.75
89	1	0.42	238	99.17
90	1	0.42	239	99.58
91	1	0.42	240	100.00

a. Date of Transfusion	b. Foxpro TR Number	c. Pre-Transfusion HbS (%)	d. Date Blood Drawn	e. OFFICE USE
1. ___ ___ / ___ ___ / ___ ___ ___ ___	__ __	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	__ __

Analysis Variable : HB_S B1c. %% Hb S								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
224	0	29.3	12.2	6.0	21.0	30.0	36.0	97.0

B1c. % Hb S				
HB_S	Frequency	Percent	Cum Freq	Cum Percent
-9	8	50.00	8	50.00
-3	8	50.00	16	100.00

Analysis Variable : datedrawfrmrand <created variable> B1d. Date blood drawn as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
223	0	-504.4	136.8	-831.0	-598.0	-499.0	-415.0	-210.0

<created variable> B1d. Date blood drawn as days from RAND visit				
datedrawfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	17	100.00	17	100.00

[Variable NOT included in dataset for Office Use field.]

STOP II

FORM 30: NEUROLOGICAL EVENT FORM

A. Collection Information:

The **Neurological Event Form** (Form 30) was to be completed for Randomized patients immediately following clinic awareness of a suspected neurological event by direct clinic involvement in treatment, by notification from another clinic, or by a positive response to a key question on the Quarterly Progress Report (Form 16) completed at a quarterly or annual visit.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p030_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 14 (11)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 630-631
- Listing of Variables by Position: See pp. 632-633

H. Formats:

The file **f030fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 634-637.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The only valid EX_TYPE for Form 30 is NE for neurological event.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 30:
  - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

Data Set Name	PUBDS.P030_FINAL	Observations	14
Member Type	DATA	Variables	62
Engine	V9	Indexes	0
Created	Friday, February 17, 2006 10:10:59 AM	Observation Length	600
Last Modified	Friday, February 17, 2006 10:10:59 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	27
Obs in First Data Page	11
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p030_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
29	ANESTHES	Num	8	3.	C3e. General anesthesia
40	ARTERIOG	Num	8	3.	D5. Arteriogram
28	A_ANEMIA	Num	8	3.	C3d. Acute anemia
27	A_CHEST	Num	8	3.	C3c. Acute Chest Syndrome
25	A_FEBRIL	Num	8	3.	C3a. Acute febrile event
30	A_PRIAPISM	Num	8	3.	C3f. Priapism
20	BEHAVIOR	Num	8	3.	B3k. Change in behavior
6	CHG_MENT	Num	8	3.	B3b. Change in mental status
21	COORDINA	Num	8	3.	B3l. Change in gait or coordination
37	CT_BRAIN	Num	8	3.	D2. CT scan of brain
50	DESTATUS	Char	1	$1.	DESTATUS
7	DIF_SPEK	Num	8	3.	B3c. Loss of or difficulty with speech
13	DIZZINES	Num	8	3.	B3g. Loss of balance or dizziness
10	DSWALLOW	Num	8	3.	B3e. Difficulty with swallowing
36	DWI_PERF	Num	8	3.	D1b. Was DWI performed?
11	D_VISION	Num	8	3.	B3f. Difficulty with vision
48	EV_TYPE	Num	8	3.	G1. Type of neurological event:
34	EXPRSPEC	Char	50	$50.	C3i1. Specify other experience
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
15	HEADACHE	Num	8	3.	B3i. Headache
31	HEAD_INJ	Num	8	3.	C3g. Head injury with loss of consciousness
16	HEAD_LOC	Num	8	3.	B3i1. Location
17	HEAD_SPEC	Char	25	$25.	B3i1a. Specify headache location
23	INTERVIE	Num	8	3.	C1. Person interviewed:
5	LOSSCONS	Num	8	3.	B3a. Loss of consciousness

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
39	MRABRAIN	Num	8	3.	D4. MRA of brain
35	MRIBRAIN	Num	8	3.	D1. MRI of brain
44	NEUREVAL	Num	8	3.	E1. Was a neurological evaluation performed ...?
43	OTHIMAGE	Char	25	$25.	D7a. Specify other imaging
33	OTH_EXPR	Num	8	3.	C3i. Other experience
45	O_EVENTS	Num	8	3.	F1. Were there other events associated with this neuro. event?
42	O_IMAGE	Num	8	3.	D7. Other imaging
26	PAINFUL	Num	8	3.	C3b. Painful event
38	PETBRAIN	Num	8	3.	D3. PET scan of brain
47	PT_DIE	Num	8	3.	F3. Did the patient die as a complication of this event?
22	PT_HOSP	Num	8	3.	B4. Was patient hospitalized for this event?
46	PT_TRANS	Num	8	3.	F2. Was this patient transfused for this neurological event?
14	SEIZURE	Num	8	3.	B3h. Seizure
18	SENSDIST	Num	8	3.	B3j. New sensory disturbance
19	SENSSIDE	Num	8	3.	B3j1. Side of sensory disturbance
4	SYMPRPTD	Num	8	3.	B2. Were signs and symptoms first reported at a quarterly visit?
41	TRANSDOP	Num	8	3.	D6. Transcranial Doppler
32	TRANSFUS	Num	8	3.	C3h. Transfusion
49	TYPESPEC	Char	50	$50.	G1a. Specify other type of neurological event
12	VIS_SIDE	Num	8	3.	B3f1. Side with vision loss
8	WEAKNESS	Num	8	3.	B3d. Paralysis or weakness
9	WEAKSIDE	Num	8	3.	B3d1. Side of weakness
3	WHERSEEN	Num	8	3.	B1. Where was the patient first seen for this event?
24	WITNES_E	Num	8	3.	C2. Did person interviewed witness suspected event?
53	comp_dfrmrand	Num	8		<created variable> A2. Date of neurological event as days from RAND visit
58	ct_datefrmrand	Num	8		=<created variable> D2a. Date CT scan of brain performed as days from RAND visit
55	hospadmtfrmrand	Num	8		<created variable> B4a. Date of hospital admission as days from RAND visit
56	hospdiscfrmrand	Num	8		<created variable> B4b. Date of hospital discharge as days from RAND visit
61	image_dtfrmrand	Num	8		<created variable> D7a. Date other imaging performed as days from RAND visit
52	ldu_id	Char	10		ID for public use datasets
59	mra_datefrmrand	Num	8		<created variable> D4a. Date MRA performed as days from RAND visit
57	mri_datefrmrand	Num	8		<created variable> D1a. Date MRI performed as days from RAND visit
62	neuro_dtfrmrand	Num	8		<created variable> E1a. Date neuro evaluation performed as days from RAND visit
54	qtr_datefrmrand	Num	8		<created variable> B2a. Date of Quarterly Progress Report as days from RAND visit
60	tcd_datefrmrand	Num	8		<created variable> D6a. Date TCD performed as days from RAND visit
51	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	WHERSEEN	Num	8	3.	B1. Where was the patient first seen for this event?
4	SYMPRPTD	Num	8	3.	B2. Were signs and symptoms first reported at a quarterly visit?
5	LOSSCONS	Num	8	3.	B3a. Loss of consciousness
6	CHG_MENT	Num	8	3.	B3b. Change in mental status
7	DIF_SPEK	Num	8	3.	B3c. Loss of or difficulty with speech
8	WEAKNESS	Num	8	3.	B3d. Paralysis or weakness
9	WEAKSIDE	Num	8	3.	B3d1. Side of weakness
10	DSWALLOW	Num	8	3.	B3e. Difficulty with swallowing
11	D_VISION	Num	8	3.	B3f. Difficulty with vision
12	VIS_SIDE	Num	8	3.	B3f1. Side with vision loss
13	DIZZINES	Num	8	3.	B3g. Loss of balance or dizziness
14	SEIZURE	Num	8	3.	B3h. Seizure
15	HEADACHE	Num	8	3.	B3i. Headache
16	HEAD_LOC	Num	8	3.	B3i1. Location
17	HEAD_SPEC	Char	25	$25.	B3i1a. Specify headache location
18	SENSDIST	Num	8	3.	B3j. New sensory disturbance
19	SENSSIDE	Num	8	3.	B3j1. Side of sensory disturbance
20	BEHAVIOR	Num	8	3.	B3k. Change in behavior
21	COORDINA	Num	8	3.	B3l. Change in gait or coordination
22	PT_HOSP	Num	8	3.	B4. Was patient hospitalized for this event?
23	INTERVIE	Num	8	3.	C1. Person interviewed:
24	WITNES_E	Num	8	3.	C2. Did person interviewed witness suspected event?
25	A_FEBRIL	Num	8	3.	C3a. Acute febrile event
26	PAINFUL	Num	8	3.	C3b. Painful event
27	A_CHEST	Num	8	3.	C3c. Acute Chest Syndrome
28	A_ANEMIA	Num	8	3.	C3d. Acute anemia
29	ANESTHES	Num	8	3.	C3e. General anesthesia
30	A_PRIAPISM	Num	8	3.	C3f. Priapism
31	HEAD_INJ	Num	8	3.	C3g. Head injury with loss of consciousness
32	TRANSFUS	Num	8	3.	C3h. Transfusion
33	OTH_EXPR	Num	8	3.	C3i. Other experience
34	EXPRSPEC	Char	50	$50.	C3i1. Specify other experience
35	MRIBRAIN	Num	8	3.	D1. MRI of brain
36	DWI_PERF	Num	8	3.	D1b. Was DWI performed?
37	CT_BRAIN	Num	8	3.	D2. CT scan of brain
38	PETBRAIN	Num	8	3.	D3. PET scan of brain
39	MRABRAIN	Num	8	3.	D4. MRA of brain
40	ARTERIOG	Num	8	3.	D5. Arteriogram
41	TRANSDOP	Num	8	3.	D6. Transcranial Doppler
42	O_IMAGE	Num	8	3.	D7. Other imaging
43	OTHIMAGE	Char	25	$25.	D7a. Specify other imaging
44	NEUREVAL	Num	8	3.	E1. Was a neurological evaluation performed ...?
45	O_EVENTS	Num	8	3.	F1. Were there other events associated with this neuro. event?
46	PT_TRANS	Num	8	3.	F2. Was this patient transfused for this neurological event?
47	PT_DIE	Num	8	3.	F3. Did the patient die as a complication of this event?
48	EV_TYPE	Num	8	3.	G1. Type of neurological event:
49	TYPESPEC	Char	50	$50.	G1a. Specify other type of neurological event

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
50	DESTATUS	Char	1	$1.	DESTATUS
51	vistype	Char	7		<created variable> VISIT TYPE
52	ldu_id	Char	10		ID for public use datasets
53	comp_dfrmrand	Num	8		<created variable> A2. Date of neurological event as days from RAND visit
54	qtr_datefrmrand	Num	8		<created variable> B2a. Date of Quarterly Progress Report as days from RAND visit
55	hospadmtfrmrand	Num	8		<created variable> B4a. Date of hospital admission as days from RAND visit
56	hospdiscfrmrand	Num	8		<created variable> B4b. Date of hospital discharge as days from RAND visit
57	mri_datefrmrand	Num	8		<created variable> D1a. Date MRI performed as days from RAND visit
58	ct_datefrmrand	Num	8		=<created variable> D2a. Date CT scan of brain performed as days from RAND visit
59	mra_datefrmrand	Num	8		<created variable> D4a. Date MRA performed as days from RAND visit
60	tcd_datefrmrand	Num	8		<created variable> D6a. Date TCD performed as days from RAND visit
61	image_dtfrmrand	Num	8		<created variable> D7a. Date other imaging performed as days from RAND visit
62	neuro_dtfrmrand	Num	8		<created variable> E1a. Date neuro evaluation performed as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

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*F030fmts.txt;

proc format;

  value A_ANEMIAF
    1='1: No'
    2='2: Yes'
    3='3: Don't Know';

  value A_CHESTF
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    2='2: Yes'
    3='3: Don't Know';

  value A_FEBRILF
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  value COORDINAF
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    2='2: Yes';

  value CT_BRAINF
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    2='2: Done';

  value D_VISIONF
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value EV_TYPEF
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  2='2: Intracranial Hemorrhage'
  3='3: TIA'
  4='4: Seizure'
  5='5: Other';

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  2='2: Yes'
  3='3: Don't Know';

value HEAD_LOCF
  1='1: Diffuse'
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value HEADACHEF
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  2='2: Yes';

value INTERVIEF
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  2='2: Parent'
  3='3: Other';

value LOSSCONSF
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  2='2: Yes';

value MRABRAINF
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  2='2: Done';

value MRIBRAINF
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  2='2: Done';
```

```
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  2='2: Yes';

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value O_IMAGEF
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  2='2: Done';

value OTH_EXPRF
  1='1: No'
  2='2: Yes'
  3='3: Don't Know';

value PAINFULF
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  2='2: Yes'
  3='3: Don't Know';

value PETBRAINF
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  2='2: Done';

value PT_DIEF
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  2='2: Yes';

value PT_HOSPF
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  2='2: Yes';

value PT_TRANSF
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  2='2: Yes';

value SEIZUREF
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  2='2: Yes';

value SENSDISTF
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  2='2: Yes';

value SENSSIDEF
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  2='2: Left'
  3='3: Both';

value SYMPRPTDF
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  2='2: Yes';
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```
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   2='2: Done';

value TRANSFUSF
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   3='3: Don't Know';

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   3='3: Both';

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   3='3: Both';

 value WHERSEENF
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   2='2: Other';

 value WITNES_EF
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   2='2: Yes';

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dwi_perff. ev_type ev_typef. head_inj head_injf. head_loc head_locf. headache headachef. intervie
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```

STOP II TRIAL

NEUROLOGICAL EVENT FORM

AFFIX PATIENT LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	12	85.71	12	85.71
P	2	14.29	14	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	11	78.57	11	78.57
NE-102	2	14.29	13	92.86
NE-103	1	7.14	14	100.00

Person completing form (Name): _____ _____ _____

[Variable NOT included in dataset.]

A2. Date of neurological event (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

Analysis Variable : comp_dfrmrand <created variable> A2. Date of neurological event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
14	0	350.4	303.9	51.0	144.0	235.0	522.0	991.0

B. PRESENTATION

B1. Where was the patient first seen for this event? ☐ **1. STOP II Center** → B1.a ☐☐

☐ **2. Other** → B1.b _____

B1. Where was the patient first seen for this event?				
WHERSEEN	Frequency	Percent	Cum Freq	Cum Percent
1	13	92.86	13	92.86
2	1	7.14	14	100.00

[Variables NOT included in dataset for specify fields.]

B2. Were signs or symptoms first reported at a quarterly visit? ☐ **1. NO** ☐ **2. YES**

B2. Were signs and symptoms first reported at a quarterly visit?				
SYMPRPTD	Frequency	Percent	Cum Freq	Cum Percent
1	9	64.29	9	64.29
2	5	35.71	14	100.00

↓

B2.a Date of Quarterly Progress Report (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

Analysis Variable : qtr_datefrmrand <created variable> B2a. Date of Quarterly Progress Report as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
5	0	333.8	435.9	0.0	0.0	69.0	673.0	927.0

<created variable> B2a. Date of Quarterly Progress Report as days from RAND visit				
qtr_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	9	100.00	9	100.00

B3. What signs or symptoms occurred?

(CHECK NO OR YES BOX FOR EACH OF B3.

1. NO **2. YES**

B3.a Loss of consciousness ☐ ☐

B3a. Loss of consciousness				
LOSSCONS	Frequency	Percent	Cum Freq	Cum Percent
1	12	85.71	12	85.71
2	2	14.29	14	100.00

1.NO **2. YES**

B3.b Change in mental status ☐ ☐

B3b. Change in mental status				
CHG_MENT	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

1.NO **2. YES**

B3.c Loss of or difficulty with speech ☐ ☐

B3c. Loss of or difficulty with speech				
DIF_SPEK	Frequency	Percent	Cum Freq	Cum Percent
1	12	85.71	12	85.71
2	2	14.29	14	100.00

1.NO **2. YES**

B3.d Paralysis or weakness ☐ ☐ → B3.d1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

B3d. Paralysis or weakness				
WEAKNESS	Frequency	Percent	Cum Freq	Cum Percent
1	10	71.43	10	71.43
2	4	28.57	14	100.00

B3d1. Side of weakness				
WEAKSIDE	Frequency	Percent	Cum Freq	Cum Percent
-2	10	71.43	10	71.43
1	1	7.14	11	78.57
2	3	21.43	14	100.00

1.NO **2. YES**

B3.e Difficulty with swallowing ☐ ☐

B3e. Difficulty with swallowing				
DSWALLOW	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

B3.f Difficulty with vision **1.NO** ☐ **2. YES** ☐ → B3.f1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

B3f. Difficulty with vision				
D_VISION	Frequency	Percent	Cum Freq	Cum Percent
1	13	92.86	13	92.86
2	1	7.14	14	100.00

B3f1. Side with vision loss				
VIS_SIDE	Frequency	Percent	Cum Freq	Cum Percent
-2	13	92.86	13	92.86
2	1	7.14	14	100.00

B3.g Loss of balance or dizziness **1.NO** ☐ **2. YES** ☐

B3g. Loss of balance or dizziness				
DIZZINES	Frequency	Percent	Cum Freq	Cum Percent
1	9	64.29	9	64.29
2	5	35.71	14	100.00

B3.h Seizure **1.NO** ☐ **2. YES** ☐

B3h. Seizure				
SEIZURE	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

B3.i Headache **1.NO** ☐ **2. YES** ☐ → B3.i1 LOCATION: ☐ **1. DIFFUSE** ☐ **2. FOCAL** ↓

B3i. Headache				
HEADACHE	Frequency	Percent	Cum Freq	Cum Percent
1	6	42.86	6	42.86
2	8	57.14	14	100.00

B3i1. Location				
HEAD_LOC	Frequency	Percent	Cum Freq	Cum Percent
-9	1	7.14	1	7.14
-2	6	42.86	7	50.00
1	3	21.43	10	71.43
2	4	28.57	14	100.00

B3.i1a SPECIFY: _____

B3i1a. Specify headache location				
HEAD_SPEC	Frequency	Percent	Cum Freq	Cum Percent
-2	10	71.43	10	71.43
Frontal	1	7.14	11	78.57
forehead	1	7.14	12	85.71
frontal/temporal bilatera	1	7.14	13	92.86
left frontal	1	7.14	14	100.00

1.NO **2. YES**

B3.j New sensory disturbance ☐ ☐ → B3.j1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

B3j. New sensory disturbance				
SENSDIST	Frequency	Percent	Cum Freq	Cum Percent
1	11	78.57	11	78.57
2	3	21.43	14	100.00

B3j1. Side of sensory disturbance				
SENSSIDE	Frequency	Percent	Cum Freq	Cum Percent
-2	11	78.57	11	78.57
1	1	7.14	12	85.71
2	1	7.14	13	92.86
3	1	7.14	14	100.00

1.NO **2. YES**

B3.k Change in behavior ☐ ☐

B3k. Change in behavior				
BEHAVIOR	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

1.NO **2. YES**

B3.l Change in gait or coordination ☐ ☐

B3l. Change in gait or coordination				
COORDINA	Frequency	Percent	Cum Freq	Cum Percent
1	13	92.86	13	92.86
2	1	7.14	14	100.00

B4. Was patient hospitalized for this event?

☐ **1. NO** ☐ **2. YES** →

B4.a Date of Hospital Admission (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.b Date of Hospital Discharge (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.c Where was patient hospitalized?

_____

_____

B4. Was patient hospitalized for this event?				
PT_HOSP	Frequency	Percent	Cum Freq	Cum Percent
1	7	50.00	7	50.00
2	7	50.00	14	100.00

Analysis Variable : hospdiscfrmrand <created variable> B4b. Date of hospital discharge as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
7	0	220.0	151.2	51.0	75.0	170.0	329.0	469.0

<created variable> B4b. Date of hospital discharge as days from RAND visit				
hospdiscfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	7	100.00	7	100.00

[Variable NOT included in dataset for specify field.]

C. HISTORY

C1. Person interviewed **(SELECT PERSON PROVIDING MAJORITY OF RESPONSES)**

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Other** → C1.a Specify: _____

C1. Person interviewed:				
INTERVIE	Frequency	Percent	Cum Freq	Cum Percent
1	8	57.14	8	57.14
2	6	42.86	14	100.00

[Variable NOT included in dataset for specify field.]

C2. Did person interviewed witness suspected event? ☐ **1. NO** ☐ **2. YES**

C2. Did person interviewed witness suspected event?				
WITNES_E	Frequency	Percent	Cum Freq	Cum Percent
1	1	7.14	1	7.14
2	13	92.86	14	100.00

C3. Did the patient experience any of the following during the two weeks prior to the neurological event?

(CHECK NO OR YES BOX FOR EACH OF C3.a - i) **1. NO** **2. YES** **3. DON'T KNOW**

C3.a Acute febrile event ☐ ☐ ☐

C3a. Acute febrile event				
A_FEBRIL	Frequency	Percent	Cum Freq	Cum Percent
1	11	78.57	11	78.57
2	3	21.43	14	100.00

1. NO **2.YES** **3. DON'T KNOW**

C3.b Painful event ☐ ☐ ☐

C3b. Painful event				
PAINFUL	Frequency	Percent	Cum Freq	Cum Percent
1	8	57.14	8	57.14
2	6	42.86	14	100.00

1. NO **2.YES** **3. DON'T KNOW**

C3.c Acute Chest Syndrome ☐ ☐ ☐

C3c. Acute Chest Syndrome				
A_CHEST	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

1. NO **2.YES** **3. DON'T KNOW**

C3.d Acute anemia ☐ ☐ ☐

C3d. Acute anemia				
A_ANEMIA	Frequency	Percent	Cum Freq	Cum Percent
1	13	92.86	13	92.86
2	1	7.14	14	100.00

1. NO **2.YES** **3. DON'T KNOW**

C3.e General anesthesia ☐ ☐ ☐

C3e. General anesthesia				
ANESTHES	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

1. NO **2.YES** **3. DON'T KNOW**

C3.f Priapism ☐ ☐ ☐

C3f. Priapism				
A_PRIAPISM	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

1. NO 2.YES 3. DON'T KNOW

C3.g Head injury with loss of consciousness ☐ ☐ ☐

C3g. Head injury with loss of consciousness				
HEAD_INJ	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

1. NO 2.YES 3. DON'T KNOW

C3.h Transfusion ☐ ☐ ☐

↓

COMPLETE TRANSFUSION FORM

C3h. Transfusion				
TRANSFUS	Frequency	Percent	Cum Freq	Cum Percent
1	13	92.86	13	92.86
2	1	7.14	14	100.00

1. NO 2.YES 3. DON'T KNOW

C3.i Other ☐ ☐ ☐

↓

C3.i1 Specify _____
_____

C3i. Other experience				
OTH_EXPR	Frequency	Percent	Cum Freq	Cum Percent
1	11	78.57	11	78.57
2	3	21.43	14	100.00

C3i1. Specify other experience				
EXPRSPEC	Frequency	Percent	Cum Freq	Cum Percent
-2	11	78.57	11	78.57
Headache	2	14.29	13	92.86
UTI, Asthma	1	7.14	14	100.00

C4. DESCRIBE PERTINENT CLINICAL DETAILS OF CLINICAL EVENTS WHICH OCCURRED WITHIN THE TWO WEEKS PRECEDING THE NEUROLOGICAL EVENT

[Variable NOT included in dataset.]

D. RESULTS OF IMAGING AND ULTRASOUND TESTS PERFORMED TO EVALUATE THIS EVENT: (CHECK APPROPRIATE BOX FOR EACH OF D1 - 7)

D1. MRI of brain ☐ **1. NOT DONE** ☐ **2. DONE**

D1. MRI of brain				
MRIBRAIN	Frequency	Percent	Cum Freq	Cum Percent
1	3	21.43	3	21.43
2	11	78.57	14	100.00

↓

D1.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ __

D1.b Was DWI performed? ☐ **1. NO** ☐ **2. YES**

Analysis Variable : mri_datefrmrand <created variable> D1a. Date MRI performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
11	0	377.6	330.9	83.0	153.0	199.0	550.0	1000.0

<created variable> D1a. Date MRI performed as days from RAND visit				
mri_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	3	100.00	3	100.00

D1b. Was DWI performed?				
DWI_PERF	Frequency	Percent	Cum Freq	Cum Percent
-9	1	7.14	1	7.14
-2	3	21.43	4	28.57
1	2	14.29	6	42.86
2	8	57.14	14	100.00

D2. CT scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

D2. CT scan of brain				
CT_BRAIN	Frequency	Percent	Cum Freq	Cum Percent
1	8	57.14	8	57.14
2	6	42.86	14	100.00

D2.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : ct_datefrmrand =<created variable> D2a. Date CT scan of brain performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6	0	194.2	100.7	51.0	151.0	171.5	295.0	325.0

=<created variable> D2a. Date CT scan of brain performed as days from RAND visit				
ct_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	8	100.00	8	100.00

D3. PET scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

D3. PET scan of brain				
PETBRAIN	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

D3.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

[Variable NOT included in dataset. Field had no data.]

D4. MRA of brain ☐ **1. NOT DONE** ☐ **2. DONE**

D4. MRA of brain				
MRABRAIN	Frequency	Percent	Cum Freq	Cum Percent
1	5	35.71	5	35.71
2	9	64.29	14	100.00

D4.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : mra_datefrmrand <created variable> D4a. Date MRA performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
9	0	298.3	283.4	83.0	153.0	182.0	297.0	955.0

<created variable> D4a. Date MRA performed as days from RAND visit				
mra_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	5	100.00	5	100.00

D5. Arteriogram ☐ **1. NOT DONE** ☐ **2. DONE**

D5. Arteriogram				
ARTERIOG	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

D5.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

[Variable NOT included in dataset. Field had no data.]

D6. Transcranial Doppler ☐ **1. NOT DONE** ☐ **2. DONE**

D6. Transcranial Doppler				
TRANSDOP	Frequency	Percent	Cum Freq	Cum Percent
1	8	57.14	8	57.14
2	6	42.86	14	100.00

D6.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : tcd_datefrmrand <created variable> D6a. Date TCD performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6	0	294.2	325.0	56.0	147.0	164.0	295.0	939.0

<created variable> D6a. Date TCD performed as days from RAND visit				
tcd_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	8	100.00	8	100.00

D7. Other → D7.a Specify_____

☐ **1. NOT DONE** ☐ **2. DONE**

D7. Other imaging				
O_IMAGE	Frequency	Percent	Cum Freq	Cum Percent
1	11	78.57	11	78.57
2	3	21.43	14	100.00

D7a. Specify other imaging				
OTHIMAGE	Frequency	Percent	Cum Freq	Cum Percent
-2	11	78.57	11	78.57
CT sinuses	1	7.14	12	85.71
Skull Xray/Sinuses	1	7.14	13	92.86
cardiology evaluation	1	7.14	14	100.00

D7.b Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : image_dtfrmrand <created variable> D7a. Date other imaging performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	528.7	418.2	146.0	146.0	465.0	975.0	975.0

<created variable> D7a. Date other imaging performed as days from RAND visit				
image_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	11	100.00	11	100.00

E. NEUROLOGICAL EVALUATION

E1. Was a neurological evaluation performed by the STOP Neurology Consultant?

☐ **1. NO →** **SCHEDULE EVALUATION BY STOP NEUROLOGY CONSULTANT**

☐ **2. YES →** E1.a Date of exam (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

E1. Was a neurological evaluation performed ...?				
NEUREVAL	Frequency	Percent	Cum Freq	Cum Percent
1	6	42.86	6	42.86
2	8	57.14	14	100.00

Analysis Variable : neuro_dtfrmrand <created variable> E1a. Date neuro evaluation performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
8	0	311.9	314.5	71.0	128.0	164.0	423.5	993.0

<created variable> E1a. Date neuro evaluation performed as days from RAND visit				
neuro_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	6	100.00	6	100.00

F. MANAGEMENT AND COMPLICATIONS

F1. Were there other events associated with this neurological event? ☐ **1. NO** ☐ **2. YES**

COMPLETE A SEPARATE NON-NEUROLOGICAL EVENT FORM FOR EACH UNIQUE ASSOCIATED EVENT

F1. Were there other events associated with this neuro. event?				
O_EVENTS	Frequency	Percent	Cum Freq	Cum Percent
1	10	71.43	10	71.43
2	4	28.57	14	100.00

F2. Was the patient transfused for this neurological event ? ☐ **1. NO** ☐ **2. YES**

F2. Was this patient transfused for this neurological event?				
PT_TRANS	Frequency	Percent	Cum Freq	Cum Percent
1	7	50.00	7	50.00
2	7	50.00	14	100.00

COMPLETE TRANSFUSION FORM

F3. Did the patient die as a complication of this event ? ☐ **1. NO** ☐ **2. YES**

F3. Did the patient die as a complication of this event?				
PT_DIE	Frequency	Percent	Cum Freq	Cum Percent
1	14	100.00	14	100.00

COMPLETE CAUSE OF DEATH FORM

G. FINAL LOCAL DIAGNOSIS

G1. Type of neurological event:

☐ **1. Cerebral Infarction** ☐ **2. Intracranial Hemorrhage** ☐ **3. TIA** ☐ **4. Seizure** ☐ **5. Other**

G1. Type of neurological event:				
EV_TYPE	Frequency	Percent	Cum Freq	Cum Percent
1	1	7.14	1	7.14
3	3	21.43	4	28.57
5	10	71.43	14	100.00

G1.a _____

G1a. Specify other type of neurological event				
TYPESPEC	Frequency	Percent	Cum Freq	Cum Percent
-2	4	28.57	4	28.57
Parasthesia NOS	1	7.14	5	35.71
Pseudotumor cerebri	1	7.14	6	42.86
dizzy spells, pulmonary stenosis	1	7.14	7	50.00
headache	1	7.14	8	57.14
headache r/t anemia	1	7.14	9	64.29
loss of consciousness; pssble reaction to Rocephin	1	7.14	10	71.43
migraine	1	7.14	11	78.57
migraine HA	1	7.14	12	85.71
subtle weakness	1	7.14	13	92.86
syncope due to Amitryptyline	1	7.14	14	100.00

Signature of Study Coordinator:_____ Date: ___ ___/___ ___/___ ___ ___ ___

H. FOR OFFICE USE

[Variables NOT included in dataset.]

H1. Imaging/ultrasound reports received:	☐ **1. NO**	☐ **2. YES**
H2. Optical disk with MR data received:	☐ **1. NO**	☐ **2. YES**
H3. Imaging films received:	☐ **1. NO**	☐ **2. YES**
H4. TCD received:	☐ **1. NO**	☐ **2. YES**

STOP II

FORM 31: NON-NEUROLOGICAL EVENT FORM

A. Collection Information:
The **Non-Neurological Event Form** (Form 31) was to be completed within one week of the discharge date whenever a Randomized Patient was seen in the emergency room or clinic or was hospitalized for a clinical event which was not classified as a suspected neurological event (stroke, TIA, or seizure) or a delayed transfusion reaction. A separate event form was completed for each type of event, even if the patient experienced multiple types of events concurrently.

B. Data Collection Period: April 2001 through November 2004

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p031_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EVENT_DTFRMRAND, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID, EVENT_DTFRMRAND, EX_TYPE, and EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 555 (62)

G. Contents of SAS Dataset:
- Alphabetical Listing of Variables: See pp. 665-666
- Listing of Variables by Position: See p. 667

H. Formats:
The file **f031fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 669-670.

I. Special Value Codes:
-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPE for Form 31 is NN for non-neurological events

- **EX_NUM** – is the variable name for exam number. EX_NUMs for Form 31 refer to the type of non-neurological event. EX_NUM uses the same event codes as EV_CODE1 codes as listed in the table on page 1 of form 31

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

- **EV_CODE1** – is the variable name for type of non-neurological event. This field is the three digit code box for question A4. Event Name on the form, and is labeled "Office Use". EV_CODE1 codes are listed in the table on page 1 of form 31. Codes 044, 063, 090, 124, and 160 require further specification.

- **EV_RECODE2, EV_RECODE3** - are the variable names for ICD-9 codes for further specified non-neurological events and procedures when EV_CODE1=044, 063, 090, 124, or 160. These fields are the 5 digit code boxes following question A4. Event Name and the EV_CODE1 code box on the form. Code boxes are labeled "Office Use" on the form. These variables require the ICD-9 Codebook for interpretation. Codes for EV_CODE1=090 Surgery are found in the Procedures section. Codes for EV_CODE1=044, 063, 124, or 160 are found in the Diseases section. Specific codes and associated diagnosis text are included for only those events that are frequently associated with sickle cell disease or treatment with transfusion, or are common during childhood and adolescence (e.g. pharyngitis). Other events were recoded as 99.99 (OTHER EVENT). In a few cases, procedure/procedure code values were entered for these variables. The text “<recoded>” in the labels for this set of variables indicates that recoding of some of the original values has occurred.

- **CODECUL1, CODECUL2, CODECUL3, CODECUL4** - are the variable names for positive culture organism codes. A code list for specified pathogens is attached. These four digit code boxes follow question B1c. Specify Organism and are labeled "Office Use" on the form.

STOP II PATHOGEN LIST

Applies to Form 31 questions
B1.d1 CODECUL1, B1.d2 CODECUL2,
B1.d3 CODECUL3, B1.d4 CODECUL4

Code	
	I. Aerobic and Facultative Anaerobic Bacteria
0100, 0105	A. Gram positive cocci
0110	1. Staphylococcus aureus
0120	2. Staphylococcus epidermis
0130	3. Streptococcus viridans
0140	4. Streptococcus, Beta hemolytic Group A
0150	5. Streptococcus, Beta hemolytic Group D
0160	6. Streptococcus, Beta hemolytic Group non A, non D
0170	7. Streptococcus pneumoniae
0180	8. Streptococcus, unspecified
0200	B. Gram positive rods
0201	1. Listeria species
0202	2. Bacillus species
0203	3. Corynebacterium species
0300	C. Gram negative cocci
0301	1. Neisseria meningitidis
0302	2. Neisseria gonorrhoeae
0400	D. Gram negative rods
	1. Enterobacteriaceae
0401	a. Escherichia coli
0402	b. Shigella species
0403	c. Edwardsiella species
0404	d. Salmonella typi
0405	e. Salmonella non-typi
0406	f. Arizona species
0407	g. Citrobacter
0408	h. Klebsiella pneumoniae
0409	i. Klebsiella other _____
0410	j. Enterobacter species
0411	k. Serratia species
0412	l. Proteus species
0413	m. Providencia species
0414	n. CDC Groups – I, II, III, IV, V non-fermentive
0500	2. Yersinia species
0600	3. Vibrio species
0700	4. Pasturella species
0800	5. Pseudomonas species
0900	6. Acinetobacter species
1000	7. Alcaligenes species
1100	8. Brucella species
1200	9. Hemophilus influenzae
1300	10. Hemophilus parainfluenzae
1400	11. Hemophilus other _____
1500	12. Bordetella Pertussis
1600	13. Actinobacillus species

STOP II PATHOGEN LIST (CONT.)

Code	
	II. Anaerobic Bacteria
2100	A. Clostridia species
2200	B. Bacteroides species
	III. Acid-Fast Bacteria
3100	A. Mycobacterium tuberculosis
3200	B. Nocardia species
3300	C. Actinomyces species
	IV. Spirochetes
4100	A. Leptospira species
4200	B. Berellia species
4300	C. Treponema pallidum
	V. Other Cell-Associated
	A. Mycoplasma
5110	1. Mycoplasma hominis
5120	2. Mycoplasma pneumoniae
5130	3. Mycoplasma other _____
5200	B. Chlamydia species
5300	C. Rickettsia species
	IV. Viruses
6100	A. Influenza Type A
6200	B. Influenza Type B
6300	C. Respiratory Syncytial virus
6400	D. Parainfluenza virus type O
6500	E. Adenovirus, type OO
6600	F. Mumps
6700	G. Measles
	H. Enterovirus
6801	1. Echo, type OO
6802	2. Coxsackie, Type A OO
6803	3. Coxsackie, Type B OO
6804	4. Polio, type 1-3
6805	5. Togavirus, type A
6806	6. Togavirus, type B
6807	7. Herpes Simplex
6808	8. Cytomegalovirus
6809	9. Varicella-zoster virus
6810	10. Epstein-Barr virus
6811	11. Hepatitis – A
6812	12. Hepatitis – B
6813	13. Hepatitis – non A, non B

STOP II PATHOGEN LIST (CONT.)

Code	
	VII. Parasites
7100	A. Plasmodium species
7200	B. Ascaris
7300	C. Strongyloides
7400	D. Giardia
7500	E. Toxoplasma
7600	F. Pneumocystic
7700	G. Necator
7800	H. Ancyloctoma
7900	I. Trichuris
8000	J. Enterobius
8100	K. Scabies
Code	
8200	L. Microfilaria
8300	M. Trematodes
9000	Other
9700	Contaminated
9800, 9998	Mixed
9999	Unclassified
-1	Negative
-8	Not done

Non-Neurological Event Definitions

Acute anemia:

Reduction of hemoglobin level by at least 30% from the usual level OR reduction of hemoglobin level by at least 20% accompanied by acute increase in spleen size. Acute anemic events should be classified into one of the following 3 categories: splenic sequestration, aplastic crisis, or other anemia using the following criteria:

Splenic sequestration crisis: The event is characterized by an increase in spleen size and firmness with reduction of hemoglobin level by at least 20%, platelet count is often low. This event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Splenic sequestration".

Aplastic crisis: This event is characterized by a decrease in reticulocyte count before or concurrent with falling hemoglobin level (≥ 30% reduction from usual level). The reticulocyte count is usually < 1% and there are nucleated red cells and reticulocytes in peripheral blood as the marrow recovers. This event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Aplastic crisis".

Other anemia: Reduction of hemoglobin because of blood loss or hyperhemolytic crisis should be classified as 'other anemia'. A hyperhemolytic episode is characterized by normal or increased reticulocyte counts and nucleated RBC count during an episode of falling hemoglobin and increase in indirect bilirubin level over the usual value. 'Other anemia' events should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Other anemia - blood loss secondary to _____", or "Other anemia - hyperhemolytes episode." The Transfusion Form (20) or Delayed Transfusion Reaction Form (32) should be used to report acute anemic events which are due to a transfusion reaction.

Acute Chest Syndrome:

A new pulmonary infiltrate which is demonstrable on a chest x-ray at a time when the patient presents with acute symptoms of respiratory illness is an acute chest event. If pain is the only symptom and an x-ray shows no new abnormality, the episode will be considered a pain crisis and recorded as such on the non-neurological event form. An acute chest syndrome event as defined above would be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Acute Chest Syndrome".

Aplastic crisis: See “Acute anemia”

Aseptic necrosis:

Early radiographic findings of subepiphyseal lucency and widening of the joint space or late radiographic changes of flattening of the epiphysis and sclerosis with fragmentation. An event form should be completed for each **newly diagnosed site** of aseptic necrosis regardless of whether the patient is hospitalized. The site **MUST** be specified. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "New aseptic necrosis" - (list site(s) - e.g., “Left hip”)

Cholecystitis:

Inflammatory condition of the gallbladder that may or may not be associated with gallstones. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Cholecystitis".

Cholelithiasis:

Formation or presence of calculi or bilestones in the gallbladder or common bile duct. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Cholelithiasis".

Choledocholithiasis:

Clinical findings indicating biliary tract obstruction, even if only partial or temporary.

Fever without source:

Elevation of temperature greater than 38.3° centigrade orally or 38.9° centigrade rectally which is documented by medical personnel, is not associated with a positive culture from any source, is not associated with signs or symptoms of an Infection (see below), and is not associated with any other special event. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Fever Without Source".

Hematuria:

A history of blood in the urine, confirmed by a member of the medical team OR > 20 RBC/HPF from urinalysis. The event should be listed as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Hematuria". A NON-NEUROLOGICAL EVENT FORM should be completed when the condition is newly diagnosed regardless of whether the patient is hospitalized and whenever the patient is admitted to the hospital **because of** this condition.

Hyperhemolytic crisis: See “Acute anemia”

Infection (other):

Inflammatory process, by a pathogenic agent, which may or may not be accompanied by fever. Sepsis, meningitis, osteomyelitis, and urinary tract infections are **NOT INCLUDED** in this category since they are categorized elsewhere on the NON-NEUROLOGICAL EVENT FORM. 'Other infection' includes cellulitis, abscesses, lymphangitis, lymphadenitis, upper respiratory infection, viral syndrome, chicken pox, measles, throat infections, mastoiditis, otitis, gastroenteritis, pelvic inflammatory disease, septic arthritis among many other conditions. Some of these conditions are defined below. The event should be specified as follows for Question

A4 on the NON-NEUROLOGICAL EVENT FORM: "Other Infection (list type of infection)". **The type of infection must be specified**. If an organism is identified, it must be specified in Question B1c. and the source of the culture should be specified in Question B1a.

Abscess: Infection associated with breakdown of tissues and formation of localized mass of pus.

Cellulitis: Acute infection of skin and deeper tissues.

Gastroenteritis: Inflammation of the stomach and intestinal tract. Signs include nausea, vomiting, and/or diarrhea lasting at least 8 hours.

Lymphadenitis: Infection in regional lymph nodes draining the primary site of infection.

Lymphangitis: Localized infection spreading into lymphatic channels draining the site of inflammation.

Mastoiditis: Infection of the mastoid bone behind the lower half of the ear.

Orbital cellulitis: Infection of the tissues surrounding the eye including the space behind the eye.

Otitis media: Infection of the middle ear associated with erythema of ear drum or bulging of ear drum with loss of landmarks and often ear pain.

Pelvic inflammatory Disease (PID): Ascending infection from the vagina or cervix to the uterus, fallopian tubes, and broad ligaments. Symptoms include vaginal discharge in association with lower abdominal pain on one or both sides and tenderness of adnexae on pelvic examination.

Pharyngitis: Redness of pharyngeal and tonsillar mucosa with or without exudate or pain.

Septic arthritis: Bacterial infection of a joint, requires positive culture.

Upper respiratory infection (URI): An imprecise term for almost any kind of infectious disease process involving the nasal passages, pharynx and bronchi. Cold, rhinorrhea, nasal stuffiness, running nose, sneezing, coughing may be listed in history of patient's complaints. The etiological agent may be bacterial or viral and is rarely accurately known.

Leg ulcer:

Ulceration of the skin of the lower legs, especially on the medial and/or lateral surfaces with or without trauma, which fails to heal in a period of two weeks. If the ulcer is **newly diagnosed**, the event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "New leg ulcer".

Meningitis:

Inflammation of the membranes of the spinal cord or brain usually caused by an infectious agent, as demonstrated by lumbar puncture abnormalities and culture. The event should be listed as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Meningitis". The causative agent should be listed as well (e.g., Pneumococcal Meningitis, Viral Meningitis, etc.). You MUST answer the questions in Section B. The organism isolated must be listed (Question B1c) if the response to B1 is answered YES.

Osteomyelitis:

Infection of bone requiring long-term antibiotics. The event would be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Osteomyelitis". The causative agent, if known should be listed as well (e.g., Osteomyelitis, Salmonella). You MUST answer the questions in Section B. The organism isolated must be listed (Question B1c) if the response to B1 is answered YES.

Other event not specified:

Includes any medical complaint for which a patient is hospitalized or seen in a clinic, doctor's office, or emergency room that is not included in the list of the events specified on the NON-NEUROLOGICAL EVENT FORM **EXCEPT FOR A NEUROLOGICAL EVENT**; a NEUROLOGICAL EVENT FORM should be completed if the event is a NEUROLOGICAL EVENT.

Priapism:

A painful erection of the penis lasting for more than one hour. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Priapism". The event should be reported on an event form when the condition is newly diagnosed regardless of whether or not the patient is hospitalized and whenever the patient is admitted to the hospital because of the condition.

Proteinuria:

3+ or 4+ protein reaction on two consecutive early AM urine specimens (< 1 month apart) measured by dip stick in the absence of gross hematuria. This event should be listed as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Proteinuria". If a quantitative 24 hour urine test was performed, attach results to the form. The event should be reported on an event form when the condition is newly diagnosed regardless of whether the patient was hospitalized and whenever the patient is admitted **because of** the condition.

Renal insufficiency:

A 20% increase in serum creatinine followed by a two-hour creatinine clearance of < 100 cc/minute. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Renal Insufficiency". This condition should be reported when it is newly diagnosed and whenever the patient is admitted to the hospital **because of** the condition.

Sepsis/Bacteremia:

Positive blood culture. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Sepsis". In addition, the organism cultured in blood may be listed in the space provided (e.g., Sepsis - strep pneumoniae or Sepsis-staph aureus, etc.). You MUST answer the questions in Section B. The organism isolated must be listed (Question B1c) if the response to B1 is answered YES.

Splenic sequestration: See “Acute anemia”

Surgery:

Any operative procedure. The procedure(s) performed should be listed in addition to the general event type for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Surgery - (list of operative procedures)"; (Surgery - cholecystectomy, liver biopsy).

Urinary tract infection (UTI):

Sterilely-collected specimen resulting in the growth in culture of more than 10^5 colonies of bacteria /ml. The event should be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Urinary tract infection" or "UTI". The organism isolated in the urine culture MUST be specified in Question B1c.

Vasoocclusive Pain:

Pain in the extremities, back, abdomen, chest, or head, for which no other explanation can be found, which is not classified as one of the other special events and for which medical attention is sought. The pain shall have lasted for at least 2 hours. Irritability in a young child accompanied by pain on palpation shall be considered appropriate evidence. The event would be specified as follows for Question A4 on the NON-NEUROLOGICAL EVENT FORM: "Pain".

Data Set Name	PUBDS.P031_FINAL	Observations	555
Member Type	DATA	Variables	44
Engine	V9	Indexes	0
Created	Wednesday, March 15, 2006 10:29:55 AM	Observation Length	608
Last Modified	Wednesday, March 15, 2006 10:29:55 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	22
First Data Page	1
Max Obs per Page	26
Obs in First Data Page	15
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p031_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
26	ACUTEINF	Num	8	3.	B2b. Were any of results indicative of an acute infection?
6	ADMITTED	Num	8	3.	A6. Was patient admitted because of this event?
11	CODECUL1	Num	8	5.	B1d1. Code 1:
15	CODECUL2	Num	8	5.	B1d2. Code 2:
19	CODECUL3	Num	8	5.	B1d3. Code 3:
23	CODECUL4	Num	8	5.	B1d4. Code 4:
5	CONT_EVT	Num	8	3.	A5a. Do the present hx, symptoms, and/or physical exam indicate this event is a continuation of previous event?
7	CULTSAMP	Num	8	3.	B1. Were samples for any cultures obtained?
8	CULTURE1	Char	25	$25.	B1a1. Culture 1:
12	CULTURE2	Char	25	$25.	B1a2. Culture 2:
16	CULTURE3	Char	25	$25.	B1a3. Culture 3:
20	CULTURE4	Char	25	$25.	B1a4. Culture 4:
31	DAYSVENT	Num	8	3.	C2a. Number of days
34	DESTATUS	Char	1	$1.	DESTATUS
33	DIE_EVNT	Num	8	3.	C4. Did the patient die as a result of this event?
28	EVID_ACI	Char	100	$100.	B2b2. What was the evidence that this was an acute infection?
3	EV_CODE1	Char	3	$3.	A4. Event code 1:
2	EX_NUM	Char	3	$3.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam Type
27	INFAGENT	Char	25	$25.	B2b1. What was the infectious agent?
29	OTHEVENT	Num	8	3.	C1. Were there other events associated with this event?
32	PT_TRANF	Num	8	3.	C3. Was the patient transfused for this event?
9	RESULT1	Num	8	3.	B1b1. Result 1:
13	RESULT2	Num	8	3.	B1b2. Result 2:
17	RESULT3	Num	8	3.	B1b3. Result 3:

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
21	RESULT4	Num	8	3.	B1b4. Result 4:
4	SAME_EVT	Num	8	3.	A5. Has patient been seen for same type of event within ...?
25	SERL_POS	Num	8	3.	B2a. Were the results of any of these studies positive?
24	SEROLOGY	Num	8	3.	B2. Were any serological studies performed?
10	SPECORG1	Char	25	$25.	B1c1. Specify Organism 1:
14	SPECORG2	Char	25	$25.	B1c2. Specify Organism 2:
18	SPECORG3	Char	25	$25.	B1c3. Specify Organism 3:
22	SPECORG4	Char	25	$25.	B1c4. Specify Organism 4:
30	VENTILAT	Num	8	3.	C2. Did the patient require ventilator support?
43	adm_datefrmrand	Num	8		<created variable> A6a. Date of hospital admission as days from RAND visit
41	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
44	dis_datefrmrand	Num	8		<created variable> A6b. Date of hospital discharge as days from RAND visit
37	ev_recode2	Num	8		<recoded variable> A4a. Event code 2
39	ev_recode3	Num	8		<recoded variable> A4b. Event code 3
38	ev_recodenm1	Char	25		<recoded variable> A4a1. Event name for event code 2
40	ev_recodenm2	Char	25		<recoded variable> A4b1. Event name for event code 3
42	event_dtfrmrand	Num	8		<created variable> A3. Date of event as days from RAND visit
36	ldu_id	Char	10		ID for public use datasets
35	vistype	Char	6		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	EX_NUM	Char	3	$3.	X4. Exam Number
3	EV_CODE1	Char	3	$3.	A4. Event code 1:
4	SAME_EVT	Num	8	3.	A5. Has patient been seen for same type of event within ...?
5	CONT_EVT	Num	8	3.	A5a. Do the present hx, symptoms, and/or physical exam indicate this event is a continuation of previous event?
6	ADMITTED	Num	8	3.	A6. Was patient admitted because of this event?
7	CULTSAMP	Num	8	3.	B1. Were samples for any cultures obtained?
8	CULTURE1	Char	25	$25.	B1a1. Culture 1:
9	RESULT1	Num	8	3.	B1b1. Result 1:
10	SPECORG1	Char	25	$25.	B1c1. Specify Organism 1:
11	CODECUL1	Num	8	5.	B1d1. Code 1:
12	CULTURE2	Char	25	$25.	B1a2. Culture 2:
13	RESULT2	Num	8	3.	B1b2. Result 2:
14	SPECORG2	Char	25	$25.	B1c2. Specify Organism 2:
15	CODECUL2	Num	8	5.	B1d2. Code 2:
16	CULTURE3	Char	25	$25.	B1a3. Culture 3:
17	RESULT3	Num	8	3.	B1b3. Result 3:
18	SPECORG3	Char	25	$25.	B1c3. Specify Organism 3:
19	CODECUL3	Num	8	5.	B1d3. Code 3:
20	CULTURE4	Char	25	$25.	B1a4. Culture 4:
21	RESULT4	Num	8	3.	B1b4. Result 4:
22	SPECORG4	Char	25	$25.	B1c4. Specify Organism 4:
23	CODECUL4	Num	8	5.	B1d4. Code 4:
24	SEROLOGY	Num	8	3.	B2. Were any serological studies performed?
25	SERL_POS	Num	8	3.	B2a. Were the results of any of these studies positive?
26	ACUTEINF	Num	8	3.	B2b. Were any of results indicative of an acute infection?
27	INFAGENT	Char	25	$25.	B2b1. What was the infectious agent?
28	EVID_ACI	Char	100	$100.	B2b2. What was the evidence that this was an acute infection?
29	OTHEVENT	Num	8	3.	C1. Were there other events associated with this event?
30	VENTILAT	Num	8	3.	C2. Did the patient require ventilator support?
31	DAYSVENT	Num	8	3.	C2a. Number of days
32	PT_TRANF	Num	8	3.	C3. Was the patient transfused for this event?
33	DIE_EVNT	Num	8	3.	C4. Did the patient die as a result of this event?
34	DESTATUS	Char	1	$1.	DESTATUS
35	vistype	Char	6		<created variable> VISIT TYPE
36	ldu_id	Char	10		ID for public use datasets
37	ev_recode2	Num	8		<recoded variable> A4a. Event code 2
38	ev_recodenm1	Char	25		<recoded variable> A4a1. Event name for event code 2
39	ev_recode3	Num	8		<recoded variable> A4b. Event code 3
40	ev_recodenm2	Char	25		<recoded variable> A4b1. Event name for event code 3
41	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
42	event_dtfrmrand	Num	8		<created variable> A3. Date of event as days from RAND visit
43	adm_datefrmrand	Num	8		<created variable> A6a. Date of hospital admission as days from RAND visit
44	dis_datefrmrand	Num	8		<created variable> A6b. Date of hospital discharge as days from RAND visit

Sort Information

Sortedby	ldu_id event_dtfrmrand vistype
Validated	YES
Character Set	ANSI

```
*F031fmts.txt;

proc format;

  value ACUTEINFF
    1='1: No'
    2='2: Yes'
    3='3: Don't know';

  value ADMITTEDF
    1='1: No'
    2='2: Yes';

  value CONT_EVTF
    1='1: No'
    2='2: Yes'
    9='9: Don't know';

  value CULTSAMPF
    1='1: No'
    2='2: Yes';

  value DAYSVENTF
    1='1: No'
    2='2: Yes';

  value DIE_EVNTF
    1='1: No'
    2='2: Yes';

  value OTHEVENTF
    1='1: No'
    2='2: Yes';

  value PT_TRANFF
    1='1: No'
    2='2: Yes';

  value RESULT1F
    1='1: Negative'
    2='2: Positive';

  value RESULT2F
    1='1: Negative'
    2='2: Positive';

  value RESULT3F
    1='1: Negative'
    2='2: Positive';

  value RESULT4F
    1='1: Negative'
    2='2: Positive';
```

```
  value SAME_EVTF
    1='1: No'
    2='2: Yes';

  value SERL_POSF
    1='1: No'
    2='2: Yes';

  value SEROLOGYF
    1='1: No'
    2='2: Yes';

  value VENTILATF
    1='1: No'
    2='2: Yes';
```

* format acuteinf acuteinff. admitted admittedf. cont_evt cont_evtf. cultsamp cultsampf. daysvent daysventf. die_evnt die_evntf. othevent otheventf. pt_tranf pt_tranff. result1 result1f. result2 result2f. result3 result3f. result4 result4f. same_evt same_evtf. serl_pos serl_posf. serology serologyf. ventilat ventilatf.;

STOP II TRIAL

NON-NEUROLOGICAL EVENT FORM

AFFIX PATIENT LABEL HERE

INSTRUCTIONS

COMPLETE THIS FORM WHENEVER THE PATIENT IS SEEN IN THE EMERGENCY ROOM OR CLINIC OR IS HOSPITALIZED FOR A CLINICAL EVENT WHICH IS NOT A STROKE, TIA, SEIZURE, OR DELAYED TRANSFUSION REACTION.
A SEPARATE EVENT FORM SHOULD BE COMPLETED FOR EACH EVENT TYPE.

IF THE PATIENT IS SEEN FOR A SUSPECTED STROKE, TIA, OR SEIZURES, COMPLETE THE NEUROLOGICAL EVENT FORM.

IF THE PATIENT IS SEEN FOR A DELAYED TRANSFUSION REACTION, COMPLETE THE DELAYED TRANSFUSION REACTION FORM.

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	552	99.46	552	99.46
P	3	0.54	555	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NN-010	142	25.59	142	25.59
NN-020	34	6.13	176	31.71
NN-030	39	7.03	215	38.74
NN-041	7	1.26	222	40.00
NN-043	1	0.18	223	40.18
NN-044	29	5.23	252	45.41
NN-060	8	1.44	260	46.85
NN-062	1	0.18	261	47.03
NN-063	1	0.18	262	47.21
NN-070	15	2.70	277	49.91
NN-080	1	0.18	278	50.09
NN-090	66	11.89	344	61.98
NN-111	1	0.18	345	62.16
NN-120	6	1.08	351	63.24
NN-121	5	0.90	356	64.14
NN-122	1	0.18	357	64.32
NN-160	198	35.68	555	100.00

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
555	0	521.7	305.2	-53.0	251.0	528.0	766.0	1318.0

A3. Date of event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : event_dtfrmrand <created variable> A3. Date of event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
555	0	471.3	295.2	-71.0	208.0	476.0	702.0	1237.0

A4. Event name (see choices below):_____ | | | |

A4. Event code 1:				
EV_CODE1	Frequency	Percent	Cum Freq	Cum Percent
010	142	25.59	142	25.59
020	34	6.13	176	31.71
030	39	7.03	215	38.74
041	7	1.26	222	40.00
043	1	0.18	223	40.18
044	29	5.23	252	45.41
060	8	1.44	260	46.85
062	1	0.18	261	47.03
063	1	0.18	262	47.21
070	15	2.70	277	49.91
080	1	0.18	278	50.09
090	66	11.89	344	61.98
111	1	0.18	345	62.16
120	6	1.08	351	63.24
121	5	0.90	356	64.14
122	1	0.18	357	64.32
160	198	35.68	555	100.00

Code	Type of Event	Code	Type of Event	Code	Type of Event
010	**Vasoocclusive Pain**	061	**Splenic Sequestration**	111	**New Aseptic Necrosis, Shoulder**
020	**Acute Chest Syndrome (with new pulmonary infiltrate)**	062	**Aplastic Crisis**	120	**Urinary Tract Infection**
030	**Fever without source**	063	**Other anemia (SPECIFY TYPE)**	121	**Hematuria**
041	**Sepsis**	070	**Cholecystitis or cholelithiasis**	122	**Proteinuria**
042	**Meningitis**	080	**Priapism**	123	**Renal Insufficiency**
043	**Osteomyelitis**	090	**Surgery (SPECIFY TYPE)**	124	**Other Renal Complication (SPECIFY TYPE)**
044	**Other Infection (SPECIFY TYPE)**	100	**New Leg Ulcer**	130	**Head Injury with loss of consciousness**
060	**Acute Anemia (unspecified)**	110	**New Aseptic Necrosis, Hip**	160	**Other event (SPECIFY TYPE)**

OFFICE USE

OFFICE USE | | | | . | |

OFFICE USE | | | | . | |

First Specified Type for EV_CODE1=044 Other Infection

ev_recode2	ev_recodenm1	Frequency	Percent	Cum Freq	Cum Percent
8.8	Gastroenteritis - viral	1	3.45	1	3.45
8.8	Intestinal virus	1	3.45	2	6.90
31.9	M. abscessus (infusaport)	1	3.45	3	10.34
34	Strep pharyngitis	1	3.45	4	13.79
34	Strep throat	2	6.90	6	20.69
41.7	Psuedomonas - L. ear	1	3.45	7	24.14
78.3	Cat scratch disease	1	3.45	8	27.59
79.99	Viral infection	1	3.45	9	31.03
79.99	Viral syndrome	1	3.45	10	34.48
112.9	Candida albicans	1	3.45	11	37.93
381.01	Serous otitis media	1	3.45	12	41.38
381.01	Serous otitis media bilat	1	3.45	13	44.83
382.9	Middle ear infection	1	3.45	14	48.28
382.9	Otitis media - NOS	1	3.45	15	51.72
461.9	Acute sinusitis	1	3.45	16	55.17
461.9	Sinusitis	2	6.90	18	62.07
462	Acute pharyngitis	1	3.45	19	65.52
462	Pharyngitis	1	3.45	20	68.97
465.9	Acute URI	4	13.79	24	82.76
465.9	URI	3	10.34	27	93.10
682.8	Cellulitis at Port-a-cath	1	3.45	28	96.55
683	Cervical lymphadonitis	1	3.45	29	100.00

First Specified Type for EV_CODE1=063 Other Anemia

ev_recode2	ev_recodenm1	Frequency	Percent	Cum Freq	Cum Percent
285.9	Hyperhemolytic event	1	100.00	1	100.00

First Specified Type for EV_CODE1=090 Surgery

ev_recode2	ev_recodenm1	Frequency	Percent	Cum Freq	Cum Percent
38.93	Port-a-cath insertion	7	10.61	7	10.61
50.11	Liver biopsy	36	54.55	43	65.15
51.04	Gallbladder removal	1	1.52	44	66.67
51.22	Cholecystectomy	1	1.52	45	68.18
51.22	Cholecystectomy - total	1	1.52	46	69.70
51.23	Lap. cholecystectomy	8	12.12	54	81.82
97.89	Mediport removal	1	1.52	55	83.33
97.89	Port-a-cath removal	6	9.09	61	92.42
99.99	OTHER PROCEDURE	5	7.58	66	100.00

First Specified Type for EV_CODE1=160 Other Event

ev_recode2	ev_recodenm1	Frequency	Percent	Cum Freq	Cum Percent
38.93	Femoral line placement	1	0.51	1	0.51
99.29	Desferal challenge	3	1.52	4	2.02
99.29	Desferal infusion	87	43.94	91	45.96
99.29	IV chelation	7	3.54	98	49.49
282.62	Resolving pain crisis	1	0.51	99	50.00
307.81	Headaches - tensional	1	0.51	100	50.51
346.9	Migraine	2	1.01	102	51.52
462	Acute pharyngitis	2	1.01	104	52.53
462	Pharyngitis	1	0.51	105	53.03
462	Sore throat	2	1.01	107	54.04
574.3	Choledocholithiasis	1	0.51	108	54.55
733.42	AN R hip - prev. dx	1	0.51	109	55.05
733.9	Bone pain	1	0.51	110	55.56
780.6	Febrile illness	1	0.51	111	56.06
780.6	Fever	2	1.01	113	57.07
780.6	Fever w/ chills	1	0.51	114	57.58
784	Headache	9	4.55	123	62.12
784	Headache w/ dizziness	1	0.51	124	62.63
787.02	Nausea	1	0.51	125	63.13
787.03	Vomiting	2	1.01	127	64.14
787.3	Abdom. pain - "gas"	1	0.51	128	64.65
789	Abdom. pain	7	3.54	135	68.18
789	Abdom. pain - lower	1	0.51	136	68.69
789	Lower stomach pain	1	0.51	137	69.19
789.01	Abdom. pain - RUQ	3	1.52	140	70.71
789.02	Abdom. pain - LUQ	2	1.01	142	71.72
789.03	Abdom. pain- RLQ	1	0.51	143	72.22
789.04	Abdom. pain - LLQ	1	0.51	144	72.73
789.3	Abd. pain R. adnexal mass	1	0.51	145	73.23
799	Hypoxia	1	0.51	146	73.74
799	Severe hypoxemia	1	0.51	147	74.24
996.59	Blood clot @ PICC line	1	0.51	148	74.75
996.59	Port-a-cath access prob	1	0.51	149	75.25
999.99	OTHER EVENT	49	24.75	198	100.00

Second Specified Type for EV_CODE1=044 Other Infection

ev_recode3	ev_recodenm2	Frequency	Percent	Cum Freq	Cum Percent
-1	-2	16	55.17	16	55.17
372	Conjunctivitis	1	3.45	17	58.62
462	Pharyngitis	2	6.90	19	65.52
462	Sore throat	1	3.45	20	68.97
535.5	Gastritis	1	3.45	21	72.41
780.6	Fever	7	24.14	28	96.55
787.01	Vomiting w/ nausea	1	3.45	29	100.00

Second Specified Type for EV_CODE1=063 Other Anemia

ev_recode3	ev_recodenm2	Frequency	Percent	Cum Freq	Cum Percent
-1	-2	1	100.00	1	100.00

Second Specified Type for EV_CODE1=090 Surgery

ev_recode3	ev_recodenm2	Frequency	Percent	Cum Freq	Cum Percent
-1	-2	63	95.45	63	95.45
38.93	Port-a-cath insertion	1	1.52	64	96.97
50.11	Liver biopsy	1	1.52	65	98.48
97.89	Port-a-cath removal	1	1.52	66	100.00

Second Specified Type for EV_CODE1=160 Other Event

ev_recode3	ev_recodenm2	Frequency	Percent	Cum Freq	Cum Percent
-1	-2	172	86.87	172	86.87
780.6	Fever	6	3.03	178	89.90
784	Headache	1	0.51	179	90.40
787.02	Nausea	1	0.51	180	90.91
787.03	Vomiting	3	1.52	183	92.42
787.91	Diarrhea, dehydration	1	0.51	184	92.93
789	Abdom. pain - L	1	0.51	185	93.43
999.99	OTHER EVENT	13	6.57	198	100.00

A5. Has the patient been seen for the same type of event within the week preceding this visit?

☐ **1. NO** ☐ **2. YES →**

A5.a Do the present history, symptoms, and/or physical exam indicate that this event is a continuation of the previous event?

☐ **1. NO** ☐ **2. YES** ☐ **9. DK**

A5. Has patient been seen for same type of event within ...?				
SAME_EVT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.18	1	0.18
1	512	92.25	513	92.43
2	42	7.57	555	100.00

A5a. Do the present hx, symptoms, and/or physical exam indicate this event is a continuation of previous event?				
CONT_EVT	Frequency	Percent	Cum Freq	Cum Percent
-2	512	92.25	512	92.25
1	4	0.72	516	92.97
2	30	5.41	546	98.38
9	9	1.62	555	100.00

A6. Was the patient admitted to the hospital ***because of this event***?

☐ **1. NO** ☐ **2. YES →**

A6.a Date of hospital admission (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

A6.b Date of hospital discharge (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

A6. Was patient admitted because of this event?				
ADMITTED	Frequency	Percent	Cum Freq	Cum Percent
1	200	36.04	200	36.04
2	355	63.96	555	100.00

Analysis Variable : adm_datefrmrand <created variable> A6a. Date of hospital admission as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
355	0	482.9	279.6	-72.0	251.0	492.0	695.0	1237.0

<created variable> A6a. Date of hospital admission as days from RAND visit

adm_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	200	100.00	200	100.00

Analysis Variable : dis_datefrmrand <created variable> A6b. Date of hospital discharge as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
355	0	486.7	279.6	-69.0	254.0	499.0	697.0	1239.0

<created variable> A6b. Date of hospital discharge as days from RAND visit

dis_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	200	100.00	200	100.00

B. LABORATORY STUDIES FOR SUSPECTED INFECTIONS

B1. Were samples for any cultures obtained? ☐ 1. NO ☐ 2. YES

B1. Were samples for any cultures obtained?				
CULTSAMP	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.72	4	0.72
1	365	65.77	369	66.49
2	186	33.51	555	100.00

↓

B1.a CULTURE	B1.b RESULTS (1. NEGATIVE 2. POSITIVE)	B1.c SPECIFY ORGANISM
1. _____ →	☐	☐ → _____ ☐☐☐☐

B1a1. Culture 1:				
CULTURE1	Frequency	Percent	Cum Freq	Cum Percent
-2	365	65.77	365	65.77
-8	1	0.18	366	65.95
-9	4	0.72	370	66.67
Blood	115	20.72	485	87.39
Bronchial lavage	6	1.08	491	88.47
Cerebrospinal fluid	1	0.18	492	88.65
L. ear drain	1	0.18	493	88.83
Nose	2	0.36	495	89.19
Port - blood	4	0.72	499	89.91
Portacath	1	0.18	500	90.09
Portacath site	1	0.18	501	90.27
Sputum	4	0.72	505	90.99
Stool	3	0.54	508	91.53
Throat	9	1.62	517	93.15
Urine	38	6.85	555	100.00

B1b1. Result 1:				
RESULT1	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.72	4	0.72
-2	365	65.77	369	66.49
1	153	27.57	522	94.05
2	33	5.95	555	100.00

CODECUL1	SPECORG1	Frequency	Percent	Cum Freq	Cum Percent
-9	-9	4	0.72	4	0.72
-2	-2	518	93.33	522	94.05
100	Gram+ cocci in clusters	2	0.36	524	94.41
100	Staph - coagulase neg.	1	0.18	525	94.59
100	Staph hominis	1	0.18	526	94.77
110	Staph	2	0.36	528	95.14
110	Staph aureus	8	1.44	536	96.58
110	Staph coag neg B-lact pos	1	0.18	537	96.76
130	Strep viridans	1	0.18	538	96.94
140	Strep	1	0.18	539	97.12
155	BHS, non-A	1	0.18	540	97.30
170	Strep pneumoniae	2	0.36	542	97.66
401	Pansensitive E. coli	1	0.18	543	97.84
408	Klebsiella pneumoniae	1	0.18	544	98.02
800	Pseudomonas	1	0.18	545	98.20
9000	Candida albicans	3	0.54	548	98.74
9000	Mycobacterium abscessus	2	0.36	550	99.10
9000	Usual upper resp. flora	2	0.36	552	99.46
9800	Alpha strep, diphtheroids	1	0.18	553	99.64
9800	Mixed urogenital flora	1	0.18	554	99.82
9800	Urogenital flora	1	0.18	555	100.00

B1.a CULTURE	B1.b RESULTS	B1.c SPECIFY ORGANISM
	1. NEGATIVE 2. POSITIVE	
2. _____ →	☐ ☐ →	_____ OFFICE USE ☐☐☐☐

B1a2. Culture 2:				
CULTURE2	Frequency	Percent	Cum Freq	Cum Percent
-1	100	18.02	100	18.02
-2	365	65.77	465	83.78
Blood	29	5.23	494	89.01
CSF	1	0.18	495	89.19
IV line	5	0.90	500	90.09
IV tube	1	0.18	501	90.27
Mediport	1	0.18	502	90.45
Port - blood	4	0.72	506	91.17
Sputum	1	0.18	507	91.35
Stool (occult blood)	1	0.18	508	91.53
Surgical Wound	1	0.18	509	91.71
Throat	9	1.62	518	93.33
Urine	35	6.31	553	99.64
Wound	2	0.36	555	100.00

B1b2. Result 2:				
RESULT2	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.18	1	0.18
-2	465	83.78	466	83.96
1	74	13.33	540	97.30
2	15	2.70	555	100.00

CODECUL2	SPECORG2	Frequency	Percent	Cum Freq	Cum Percent
-9	-9	1	0.18	1	0.18
-2	-2	539	97.12	540	97.30
100	Gram+ cocci in clusters	1	0.18	541	97.48
110	Staph aureus	2	0.36	543	97.84
110	Staph coag neg B-lact pos	3	0.54	546	98.38
180	Streptococcus	1	0.18	547	98.56
203	Corynebacterium	2	0.36	549	98.92
401	E. coli	1	0.18	550	99.10
9000	Mycobacterium abscessus	2	0.36	552	99.46
9000	Usual upper resp. flora	2	0.36	554	99.82
9700	Mixed gram positive	1	0.18	555	100.00

B1.a CULTURE	B1.b RESULTS	B1.c SPECIFY ORGANISM
	1. NEGATIVE 2. POSITIVE	
3. _____ →	[ ] [ ] → _____	OFFICE USE [ ] [ ] [ ] [ ]

B1a3. Culture 3:				
CULTURE3	Frequency	Percent	Cum Freq	Cum Percent
-1	54	9.73	54	9.73
-2	465	83.78	519	93.51
Blood	4	0.72	523	94.23
Catheter tip	4	0.72	527	94.95
Foley (urine)	6	1.08	533	96.04
Nasopharynx	1	0.18	534	96.22
Sputum	2	0.36	536	96.58
Throat	8	1.44	544	98.02
Urine	10	1.80	554	99.82
VRE Surveillance	1	0.18	555	100.00

B1b3. Result 3:				
RESULT3	Frequency	Percent	Cum Freq	Cum Percent
-2	519	93.51	519	93.51
1	29	5.23	548	98.74
2	7	1.26	555	100.00

CODECUL3	SPECORG3	Frequency	Percent	Cum Freq	Cum Percent
-2	-2	548	98.74	548	98.74
110	Staph coag neg	4	0.72	552	99.46
140	BHS - Grp A	2	0.36	554	99.82
9700	Mixed, pos. contamination	1	0.18	555	100.00

B1.a CULTURE	B1.b RESULTS	B1.c SPECIFY ORGANISM
	1. NEGATIVE 2. POSITIVE	
4. _____ →	☐ ☐ →	_____ OFFICE USE ☐☐☐☐

B1a4. Culture 4:				
CULTURE4	Frequency	Percent	Cum Freq	Cum Percent
-1	14	2.52	14	2.52
-2	519	93.51	533	96.04
Blood	6	1.08	539	97.12
CSF	1	0.18	540	97.30
MRSA Surveillance	1	0.18	541	97.48
Mycobacterium	1	0.18	542	97.66
Port - blood	1	0.18	543	97.84
Port tip	2	0.36	545	98.20
Sputum	1	0.18	546	98.38
Throat	1	0.18	547	98.56
Trach. tube	6	1.08	553	99.64
Urine	2	0.36	555	100.00

B1b4. Result 4:				
RESULT4	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.18	1	0.18
-2	533	96.04	534	96.22
1	17	3.06	551	99.28
2	4	0.72	555	100.00

CODECUL4	SPECORG4	Frequency	Percent	Cum Freq	Cum Percent
-9	-9	1	0.18	1	0.18
-2	-2	550	99.10	551	99.28
100	Gram+ cocci in clusters	1	0.18	552	99.46
9000	Candida albicans	3	0.54	555	100.00

B2. Were any serological studies performed? ☐ 1. NO ☐ 2. YES

B2. Were any serological studies performed?				
SEROLOGY	Frequency	Percent	Cum Freq	Cum Percent
-9	3	0.54	3	0.54
1	496	89.37	499	89.91
2	56	10.09	555	100.00

↓

B2.a. Were the results of any of these studies positive? ☐ 1. NO ☐ 2. YES

B2a. Were the results of any of these studies positive?				
SERL_POS	Frequency	Percent	Cum Freq	Cum Percent
-9	4	0.72	4	0.72
-2	496	89.37	500	90.09
1	31	5.59	531	95.68
2	24	4.32	555	100.00

↓

B2.b. Were any of the results indicative of an **acute** infection?

☐ 1. NO ☐ 2. YES ☐ 3. DON'T KNOW

B2b. Were any of results indicative of an acute infection?				
ACUTEINF	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.36	2	0.36
-2	527	94.95	529	95.32
1	14	2.52	543	97.84
2	10	1.80	553	99.64
3	2	0.36	555	100.00

↓

B2.b1 What was the infectious agent?_____

B2b1. What was the infectious agent?				
INFAGENT	Frequency	Percent	Cum Freq	Cum Percent
-2	543	97.84	543	97.84
-9	2	0.36	545	98.20
? mycoplasmal infection	1	0.18	546	98.38
Bartonella hensalae	1	0.18	547	98.56
Mycobacterium abscessus	2	0.36	549	98.92
Pansensitive E. coli	1	0.18	550	99.10
Staph	1	0.18	551	99.28
Staph aureus	2	0.36	553	99.64
Strep pneumoniae	2	0.36	555	100.00

B2.b2 What was the evidence that this was an acute infection?

B2b2. What was the evidence that this was an acute infection?				
EVID_ACI	Frequency	Percent	Cum Freq	Cum Percent
-2	543	97.84	543	97.84
-9	2	0.36	545	98.20
1. cold agglutinin pos 1:256; 2. parvovirus IgG 1:160; 3. parvovirus IgM <1:10	1	0.18	546	98.38
BLOODY URINE, NO PAIN	1	0.18	547	98.56
FEVER, ABD. PAIN, EMESIS, HEADACHE	2	0.36	549	98.92
Port blood culture negative weeks preceding [current] culture	2	0.36	551	99.28
elevation of IgM titer	1	0.18	552	99.46
fever	3	0.54	555	100.00

C. MANAGEMENT AND COMPLICATIONS

C1. Were there other events associated with this event? ☐ **1. NO** ☐ **2. YES**

↓

COMPLETE SEPARATE EVENT FORM FOR EACH EVENT TYPE

C1. Were there other events associated with this event?				
OTHEVENT	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.36	2	0.36
1	377	67.93	379	68.29
2	176	31.71	555	100.00

C2. Did the patient require ventilator support? ☐ **1. NO** ☐ **2. YES**

C2. Did the patient require ventilator support?				
VENTILAT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.18	1	0.18
1	547	98.56	548	98.74
2	7	1.26	555	100.00

↓

C2.a Number of days ☐☐

C2a. Number of days				
DAYSVENT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.18	1	0.18
-2	547	98.56	548	98.74
1	1	0.18	549	98.92
13	6	1.08	555	100.00

[Note: Records with DAYSVENT=13 refer to one hospitalization for one patient with ventilation required for 13 days. The 6 observations reflect 6 concurrent events during that hospitalization each requiring a separate form 31 to be completed.]

C3. Was the patient transfused for this event? ☐ **1. NO** ☐ **2. YES**

↓

COMPLETE TRANSFUSION FORMS

C3. Was the patient transfused for this event?				
PT_TRANF	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.18	1	0.18
1	401	72.25	402	72.43
2	153	27.57	555	100.00

C4. Did patient die as a result of this event? ☐ **1. NO** ☐ **2. YES**

↓

COMPLETE CAUSE OF DEATH FORM

C4. Did the patient die as a result of this event?				
DIE_EVNT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.18	1	0.18
1	553	99.64	554	99.82
2	1	0.18	555	100.00

IF THIS FORM IS BEING COMPLETED FOR EITHER A <u>MENINGITIS</u> OR A <u>HEAD INJURY</u> EVENT, AN MRI AND NEUROLOGICAL EXAMINATION BY THE STOP NEUROLOGICAL CONSULTANT MUST BE PERFORMED 3-4 WEEKS AFTER HOSPITAL DISCHARGE. FORMS 14 AND 15 MUST BE COMPLETED AT THAT TIME.

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___

STOP II
FORM 32: DELAYED TRANSFUSION REACTION FORM

A. Collection Information:

The **Delayed Transfusion Reaction Form** (Form 32) was to be completed for Randomized patients within one week after discharge from Hospital or ER/ Clinic for a delayed transfusion reaction.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p032_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, REACT_DTFRMRAND**

Records in the dataset are sorted by LDU_ID and REACT_DTFRMRAND.

F. Number of Observations (Patients) in SAS Dataset: 2 (2)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 687-689
- Listing of Variables by Position: See pp. 690-691

H. Formats:

The file **f032fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 692-696.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

Data Set Name	PUBDS.P032_FINAL	Observations	2
Member Type	DATA	Variables	80
Engine	V9	Indexes	0
Created	Thursday, March 02, 2006 10:48:22 AM	Observation Length	704
Last Modified	Thursday, March 02, 2006 10:48:22 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	23
Obs in First Data Page	2
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p032_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
54	ADM_REA	Num	8	3.	E1. Was patient admitted to the hospital because of the reaction
5	ANA_MILD	Num	8	3.	C4. Mild anaphylasis
4	ANA_SEV	Num	8	3.	C3. Severe anaphylaxis
17	ANTIB_C	Num	8	3.	D1e5. Anti-c
16	ANTIB_E	Num	8	3.	D1e4. Anti-e
18	ANTIB_F	Num	8	3.	D1e6. Anti-f
31	ANTIB_K	Num	8	3.	D1e18. Anti-k
23	ANTIB_S	Num	8	3.	D1e11. Anti-s
24	ANTIB_U	Num	8	3.	D1e12. Anti-U
41	ANTISPE	Char	25	$25.	D1e27a. Specify other antibody
14	ANTI_C	Num	8	3.	D1e2. Anti-C
13	ANTI_D	Num	8	3.	D1e1. Anti-D
15	ANTI_E	Num	8	3.	D1e3. Anti-E
32	ANTI_FC	Num	8	3.	D1e19. Anti-Fya
33	ANTI_FY	Num	8	3.	D1e20. Anti-Fyb
39	ANTI_I	Num	8	3.	D1e26. Anti-I
27	ANTI_JB	Num	8	3.	D1e15. Anti-Jsa
34	ANTI_JD	Num	8	3.	D1e21. Anti-Jka
35	ANTI_JK	Num	8	3.	D1e22. Anti-Jkb
28	ANTI_JS	Num	8	3.	D1e16. Anti-Jsb
29	ANTI_K	Num	8	3.	D1e17. Anti-K (Kell)
25	ANTI_KA	Num	8	3.	D1e13. Anti-Kpa
26	ANTI_KP	Num	8	3.	D1e14. Anti-Kpb
37	ANTI_LE	Num	8	3.	D1e24. Anti-Leb
36	ANTI_LF	Num	8	3.	D1e23. Anti-Lea

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
20	ANTI_M	Num	8	3.	D1e8. Anti-M
21	ANTI_N	Num	8	3.	D1e9. Anti-N
40	ANTI_OT	Num	8	3.	D1e27. Anti-Other
38	ANTI_P1	Num	8	3.	D1e25. Anti-P1
22	ANTI_S	Num	8	3.	D1e10. Anti-S
19	ANTI_V	Num	8	3.	D1e7. Anti-V
61	BBA_REC	Num	8	3.	F2. Blood Bank antiglobulin report received
62	BBP_REC	Num	8	3.	F3. Blood Bank panels sheet received
44	CBC	Num	8	3.	D3. CBC
60	CBC_REC	Num	8	3.	F1. CBC report received
64	CHEM_REC	Num	8	3.	F5. Serum chemistries report received
9	COOMBS	Num	8	3.	D1. Antiglobulin Test
2	DEL_HEM	Num	8	3.	C1. Delayed hemolytic
69	DESTATUS	Char	1	$1.	DESTATUS
11	DIRECT	Num	8	3.	D1c. Direct coombs
49	DIR_BIL	Num	8	4.1	D4c. Direct bilirubin
67	DISC_SU	Num	8	3.	F8. Hospital discharge summary received
66	ERNOTES	Num	8	3.	F7. Clinic/ER notes received
3	FEBRILE	Num	8	3.	C2. Febrile, nonhemolytic
6	FLD_OVL	Num	8	3.	C5. Fluid overload
1	FORMCOM	Num	8	3.	B2. Were STOP II Transfusion Forms completed
68	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
46	HEMAT	Num	8	5.1	D3c. Hematocrit
45	HEMOGLO	Num	8	5.1	D3b. Hemoglobin
55	HYDRATN	Num	8	3.	E2a. Hydration
7	HYPERTE	Num	8	3.	C6. Hypertension
12	INDIREC	Num	8	3.	D1d. Indirect coombs
63	LABRPTS	Num	8	3.	F4. Reference lab report received
50	LDH	Num	8	5.	D4d. LDH
30	NEW_K	Num	8	3.	D1f17. Newly Identified Anti-K (Kell)
42	NEW_OTH	Num	8	3.	D1f27. Newly Identified other antibody
8	OTHREAC	Num	8	3.	C7. Other
57	OTHTREA	Num	8	3.	E2c. Other
59	PT_DIE	Num	8	3.	E3. Did patient die
53	RED_CEL	Num	8	5.	D5c. Number of Red Cells per HPF
47	SER_CHE	Num	8	3.	D4. Serum Chemistries
10	SPECOOM	Char	25	$25.	D1a. Specify reason
43	SP_REFL	Char	25	$25.	D2a. Specify reason
56	TRANSFU	Num	8	3.	E2b. Transfusion
58	TREASPE	Char	25	$25.	E2c1. Specify other
48	TTL_BIL	Num	8	5.1	D4b. Total bilirubin
51	URINALY	Num	8	3.	D5. Urinalysis
52	URINHEM	Num	8	3.	D5b. Hemoglobin
65	URIN_REC	Num	8	3.	F6. Urinalysis report received
79	adm_datfrmrand	Num	8		<created variable> E1a. Date of hospital admission as days from RAND visit
76	cbc_datfrmrand	Num	8		<created variable> D3a. Date of CBC as days from RAND visit
77	chemdatfrmrand	Num	8		<created variable> D4a. Date of serum chemistries as days from RAND visit

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
71	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
74	coomb_dfrmrand	Num	8		<created variable> D1b. Date of coombs test as days from RAND visit
80	dis_datfrmrand	Num	8		<created variable> E1b. Date of hospital discharge as days from RAND visit
70	ldu_id	Char	10		ID for public use datasets
73	prevtrafrmrand	Num	8		<created variable> B1. Date of most recent transfusion preceding reaction as days from RAND visit
72	react_dtfrmrand	Num	8		<created variable> A3. Date of tranfusion reaction as days from RAND visit
75	reflab_dfrmrand	Num	8		<created variable> D2. Date specimen sent to reference lab as days from RAND visit
78	urindatfrmrand	Num	8		<created variable> D5a. Date of urinalysis as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	FORMCOM	Num	8	3.	B2. Were STOP II Transfusion Forms completed
2	DEL_HEM	Num	8	3.	C1. Delayed hemolytic
3	FEBRILE	Num	8	3.	C2. Febrile, nonhemolytic
4	ANA_SEV	Num	8	3.	C3. Severe anaphylaxis
5	ANA_MILD	Num	8	3.	C4. Mild anaphylasis
6	FLD_OVL	Num	8	3.	C5. Fluid overload
7	HYPERTE	Num	8	3.	C6. Hypertension
8	OTHREAC	Num	8	3.	C7. Other
9	COOMBS	Num	8	3.	D1. Antiglobulin Test
10	SPECOOM	Char	25	$25.	D1a. Specify reason
11	DIRECT	Num	8	3.	D1c. Direct coombs
12	INDIREC	Num	8	3.	D1d. Indirect coombs
13	ANTI_D	Num	8	3.	D1e1. Anti-D
14	ANTI_C	Num	8	3.	D1e2. Anti-C
15	ANTI_E	Num	8	3.	D1e3. Anti-E
16	ANTIB_E	Num	8	3.	D1e4. Anti-e
17	ANTIB_C	Num	8	3.	D1e5. Anti-c
18	ANTIB_F	Num	8	3.	D1e6. Anti-f
19	ANTI_V	Num	8	3.	D1e7. Anti-V
20	ANTI_M	Num	8	3.	D1e8. Anti-M
21	ANTI_N	Num	8	3.	D1e9. Anti-N
22	ANTI_S	Num	8	3.	D1e10. Anti-S
23	ANTIB_S	Num	8	3.	D1e11. Anti-s
24	ANTIB_U	Num	8	3.	D1e12. Anti-U
25	ANTI_KA	Num	8	3.	D1e13. Anti-Kpa
26	ANTI_KP	Num	8	3.	D1e14. Anti-Kpb
27	ANTI_JB	Num	8	3.	D1e15. Anti-Jsa
28	ANTI_JS	Num	8	3.	D1e16. Anti-Jsb
29	ANTI_K	Num	8	3.	D1e17. Anti-K (Kell)
30	NEW_K	Num	8	3.	D1f17. Newly Identified Anti-K (Kell)
31	ANTIB_K	Num	8	3.	D1e18. Anti-k
32	ANTI_FC	Num	8	3.	D1e19. Anti-Fya
33	ANTI_FY	Num	8	3.	D1e20. Anti-Fyb
34	ANTI_JD	Num	8	3.	D1e21. Anti-Jka
35	ANTI_JK	Num	8	3.	D1e22. Anti-Jkb
36	ANTI_LF	Num	8	3.	D1e23. Anti-Lea
37	ANTI_LE	Num	8	3.	D1e24. Anti-Leb
38	ANTI_P1	Num	8	3.	D1e25. Anti-P1
39	ANTI_I	Num	8	3.	D1e26. Anti-I
40	ANTI_OT	Num	8	3.	D1e27. Anti-Other
41	ANTISPE	Char	25	$25.	D1e27a. Specify other antibody
42	NEW_OTH	Num	8	3.	D1f27. Newly Identified other antibody
43	SP_REFL	Char	25	$25.	D2a. Specify reason
44	CBC	Num	8	3.	D3. CBC
45	HEMOGLO	Num	8	5.1	D3b. Hemoglobin
46	HEMAT	Num	8	5.1	D3c. Hematocrit
47	SER_CHE	Num	8	3.	D4. Serum Chemistries
48	TTL_BIL	Num	8	5.1	D4b. Total bilirubin
49	DIR_BIL	Num	8	4.1	D4c. Direct bilirubin
50	LDH	Num	8	5.	D4d. LDH
51	URINALY	Num	8	3.	D5. Urinalysis

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
52	URINHEM	Num	8	3.	D5b. Hemoglobin
53	RED_CEL	Num	8	5.	D5c. Number of Red Cells per HPF
54	ADM_REA	Num	8	3.	E1. Was patient admitted to the hospital because of the reaction
55	HYDRATN	Num	8	3.	E2a. Hydration
56	TRANSFU	Num	8	3.	E2b. Transfusion
57	OTHTREA	Num	8	3.	E2c. Other
58	TREASPE	Char	25	$25.	E2c1. Specify other
59	PT_DIE	Num	8	3.	E3. Did patient die
60	CBC_REC	Num	8	3.	F1. CBC report received
61	BBA_REC	Num	8	3.	F2. Blood Bank antiglobulin report received
62	BBP_REC	Num	8	3.	F3. Blood Bank panels sheet received
63	LABRPTS	Num	8	3.	F4. Reference lab report received
64	CHEM_REC	Num	8	3.	F5. Serum chemistries report received
65	URIN_REC	Num	8	3.	F6. Urinalysis report received
66	ERNOTES	Num	8	3.	F7. Clinic/ER notes received
67	DISC_SU	Num	8	3.	F8. Hospital discharge summary received
68	FORMSTAT_ID	Num	8	7.	FORMSTAT_ID
69	DESTATUS	Char	1	$1.	DESTATUS
70	ldu_id	Char	10		ID for public use datasets
71	comp_dfrmrand	Num	8		<created variable> A2. Date form completed as days from RAND visit
72	react_dtfrmrand	Num	8		<created variable> A3. Date of tranfusion reaction as days from RAND visit
73	prevtrafrmrand	Num	8		<created variable> B1. Date of most recent transfusion preceding reaction as days from RAND visit
74	coomb_dfrmrand	Num	8		<created variable> D1b. Date of coombs test as days from RAND visit
75	reflab_dfrmrand	Num	8		<created variable> D2. Date specimen sent to reference lab as days from RAND visit
76	cbc_datfrmrand	Num	8		<created variable> D3a. Date of CBC as days from RAND visit
77	chemdatfrmrand	Num	8		<created variable> D4a. Date of serum chemistries as days from RAND visit
78	urindatfrmrand	Num	8		<created variable> D5a. Date of urinalysis as days from RAND visit
79	adm_datfrmrand	Num	8		<created variable> E1a. Date of hospital admission as days from RAND visit
80	dis_datfrmrand	Num	8		<created variable> E1b. Date of hospital discharge as days from RAND visit

Sort Information

Sortedby	ldu_id react_dtfrmrand
Validated	YES
Character Set	ANSI

```
*F032fmts.txt;

proc format;

  value ADM_REAF
    1='1: No'
    2='2: Yes';

  value ANA_MILDF
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    2='2: Yes';

  value ANA_SEVF
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    2='2: Yes';

  value ANTI_CF
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    2='2: Yes';

  value ANTI_DF
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    2='2: Yes';

  value ANTI_EF
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    2='2: Yes';

  value ANTI_FCF
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    2='2: Yes';

  value ANTI_FYF
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    2='2: Yes';

  value ANTI_JBF
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    2='2: Yes';

  value ANTI_JDF
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    2='2: Yes';

  value ANTI_JKF
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    2='2: Yes';

  value ANTI_JSF
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    2='2: Yes';

  value ANTI_KF
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value ANTIB_EF
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  2='2: Yes';

value ANTIB_KF
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value ANTIB_UF
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  2='2: Yes';

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value BBP_RECF
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  2='2: Yes';

value CBCF
  1='1: Not Done'
  2='2: Done';

value CBC_RECF
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value CHEM_RECF
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value COOMBSF
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value DEL_HEMF
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  2='2: Yes';

value DIRECTF
  1='1: Negative'
  2='2: Positive';

value DISC_SUF
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  2='2: Yes';

value ERNOTESF
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  2='2: Yes';

value FEBRILEF
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  2='2: Yes';

value FLD_OVLF
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  2='2: Yes';
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```
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value HYPERTEF
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value INDIRECF
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value NEW_KF
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value NEW_OTHF
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value OTHREACF
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value OTHTREAF
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  2='2: Yes';

value PT_DIEF
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  2='2: Yes';

value SER_CHEF
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value TRANSFUF
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  2='2: Yes';

value URIN_RECF
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value URINALYF
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```

```
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   2='2: Trace'
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   4='4: 2+'
   5='5: 3+'
   6='6: 4+';

* format adm_rea adm_reaf. ana_mild ana_mildf. ana_sev ana_sevf. anti_c anti_cf. anti_d anti_df. anti_e
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cbc cbcf. cbc_rec cbc_recf. chem_rec chem_recf. coombs coombsf. del_hem del_hemf. direct directf.
disc_su disc_suf. ernotes ernotesf. febrile febrilef. fld_ovl fld_ovlf. formcom formcomf. hydratn hydratnf.
hyperte hypertef. indirec indirecf. labrpts labrptsf. new_k new_kf. new_oth new_othf. othreac othreacf.
othtrea othtreaf. pt_die pt_dief. ser_che ser_chef. transfu transfuf. urin_rec urin_recf. urinaly urinalyf.
urinhem urinhemf.;
```

STOP II TRIAL

DELAYED TRANSFUSION REACTION FORM

AFFIX PATIENT LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	2	100.00	2	100.00

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date form completed (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date form completed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	793.0	63.6	748.0	748.0	793.0	838.0	838.0

A3. Date of transfusion reaction (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : react_dtfrmrand <created variable> A3. Date of tranfusion reaction as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	734.0	33.9	710.0	710.0	734.0	758.0	758.0

B. TRANSFUSION HISTORY

B1. Date of most recent transfusion preceding date of transfusion reaction (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : prevtrafrmrand <created variable> B1. Date of most recent transfusion preceding reaction as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	727.5	26.2	709.0	709.0	727.5	746.0	746.0

B2. Were STOP II Transfusion Forms completed for this transfusion? ☐ 1. NO ☐ 2. YES

↓

COMPLETE TRANSFUSION FORMS

B2. Were STOP II Transfusion Forms completed				
FORMCOM	Frequency	Percent	Cum Freq	Cum Percent
1	2	100.00	2	100.00

C. TYPE OF REACTION

1. NO 2. YES

C1. Delayed hemolytic ☐ ☐

C1. Delayed hemolytic				
DEL_HEM	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

C2. Febrile, nonhemolytic (fever, chills) ☐ ☐

C2. Febrile, nonhemolytic				
FEBRILE	Frequency	Percent	Cum Freq	Cum Percent
1	2	100.00	2	100.00

C3. Severe anaphylaxis (dyspnea, chest constriction, cyanosis, pulse variations, convulsions) ☐ ☐

C3. Severe anaphylaxis				
ANA_SEV	Frequency	Percent	Cum Freq	Cum Percent
1	2	100.00	2	100.00

C4. Mild anaphylasis (redness of skin, itching, urticaria) ☐ ☐

C4. Mild anaphylasis				
ANA_MILD	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

C5. Fluid overload ☐ ☐

C5. Fluid overload				
FLD_OVL	Frequency	Percent	Cum Freq	Cum Percent
1	2	100.00	2	100.00

C6. Hypertension ☐ ☐

C6. Hypertension				
HYPERTE	Frequency	Percent	Cum Freq	Cum Percent
1	2	100.00	2	100.00

C7. Other

1. NO ☐ **2. YES** ☐ ↓

C7. Other				
OTHREAC	Frequency	Percent	Cum Freq	Cum Percent
1	2	100.00	2	100.00

C7.a Specify: *[Variable NOT included in dataset.]*

C8. DESCRIBE PERTINENT CLINICAL DETAILS OF THE REACTION:

[Variable NOT included in dataset.]

D. LABORATORY TESTS

D1. Antiglobulin Test

☐ **1. NOT DONE** →

D1.a Specify reason:

GO TO D2

☐ **2. DONE** ↓

D1. Antiglobulin Test				
COOMBS	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

D1a. Specify reason				
SPECOOM	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
Pt did not come to hosp	1	50.00	2	100.00

D1.b Date of test (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : coomb_dfrmrand <created variable> D1b. Date of coombs test as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	759.0	.	759.0	759.0	759.0	759.0	759.0

<created variable> D1b. Date of coombs test as days from RAND visit				
coomb_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

D1.c Direct ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D1c. Direct coombs				
DIRECT	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
2	1	50.00	2	100.00

D1.d Indirect ☐ **1. NEGATIVE** ☐ **2. POSITIVE**

D1d. Indirect coombs				
INDIREC	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
2	1	50.00	2	100.00

IF BOTH D1.c AND D1.d ARE NEGATIVE, GO TO D3

IF EITHER D1.c OR D1.d ARE POSITIVE, CONTINUE TO D1.e

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
1. Anti - D	☐	☐ →	☐	☐

D1e1. Anti-D				
ANTI_D	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

2. Anti – C ☐ ☐ → ☐ ☐

D1e2. Anti-C				
ANTI_C	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
3. Anti – E	☐	☐ →	☐	☐

D1e3. Anti-E				
ANTI_E	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

4. Anti – e ☐ ☐ → ☐ ☐

D1e4. Anti-e				
ANTIB_E	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

5. Anti – c ☐ ☐ → ☐ ☐

D1e5. Anti-c				
ANTIB_C	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

6. Anti – f ☐ ☐ → ☐ ☐

D1e6. Anti-f				
ANTIB_F	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
7. Anti – V	☐	☐ →	☐	☐

D1e7. Anti-V				
ANTI_V	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

8. Anti – M	☐	☐ →	☐	☐

D1e8. Anti-M				
ANTI_M	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

9. Anti – N	☐	☐ →	☐	☐

D1e9. Anti-N				
ANTI_N	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

10. Anti – S	☐	☐ →	☐	☐

D1e10. Anti-S				
ANTI_S	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
11. Anti – s	☐	☐ →	☐	☐

D1e11. Anti-s				
ANTIB_S	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

12. Anti – U ☐ ☐ → ☐ ☐

D1e12. Anti-U				
ANTIB_U	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

13. Anti - Kp[a] ☐ ☐ → ☐ ☐

D1e13. Anti-Kpa				
ANTI_KA	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

14. Anti - Kp[b] ☐ ☐ → ☐ ☐

D1e14. Anti-Kpb				
ANTI_KP	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
15. Anti - Js[a]	☐	☐ →	☐	☐

D1e15. Anti-Jsa				
ANTI_JB	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

16. Anti - Js[b]	☐	☐ →	☐	☐

D1e16. Anti-Jsb				
ANTI_JS	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

17. Anti - K (Kell)	☐	☐ →	☐	☐

D1e17. Anti-K (Kell)				
ANTI_K	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
2	1	50.00	2	100.00

D1f17. Newly Identified Anti-K (Kell)				
NEW_K	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

18. Anti – k	☐	☐ →	☐	☐

D1e18. Anti-k				
ANTIB_K	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
19. Anti - Fy[a]	☐	☐ →	☐	☐

D1e19. Anti-Fya				
ANTI_FC	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

20. Anti - Fy[b]	☐	☐ →	☐	☐

D1e20. Anti-Fyb				
ANTI_FY	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

21. Anti - Jk[a]	☐	☐ →	☐	☐

D1e21. Anti-Jka				
ANTI_JD	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

22. Anti - Jk[b]	☐	☐ →	☐	☐

D1e22. Anti-Jkb				
ANTI_JK	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
23. Anti - Le^a	☐	☐ →	☐	☐

D1e23. Anti-Lea				
ANTI_LF	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

24. Anti - Le^b	☐	☐ →	☐	☐

D1e24. Anti-Leb				
ANTI_LE	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

25. Anti - P_1	☐	☐ →	☐	☐

D1e25. Anti-P1				
ANTI_P1	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

26. Anti – I	☐	☐ →	☐	☐

D1e26. Anti-I				
ANTI_I	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
1	1	50.00	2	100.00

[Variable NOT included in dataset. No newly identified]

D1.e Antibodies			D1.f Newly Identified?	
	1. NO	**2. YES**	**1. NO**	**2. YES**
27. Anti - Other → D5.e27.a Specify_____	☐	☐ →	☐	☐

D1e27. Anti-Other				
ANTI_OT	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
2	1	50.00	2	100.00

D1e27a. Specify other antibody				
ANTISPE	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
IgG+ compliment	1	50.00	2	100.00

D1f27. Newly Identified other antibody				
NEW_OTH	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
2	1	50.00	2	100.00

IF THE RESPONSE TO ANY OF D1.f1-27 IS YES, SEND SPECIMEN TO REFERENCE LAB FOR CONFIRMATION

D2. Date specimen sent to reference lab (Month/Day/Year) : __ __/__ __ /__ __ __ __ ☐ **-1. NOT SENT**

<created variable> D2. Date specimen sent to reference lab as days from RAND visit				
reflab_dfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	2	100.00	2	100.00

↓

D2.a Reason:

_____

_____

D2a. Specify reason				
SP_REFL	Frequency	Percent	Cum Freq	Cum Percent
Pt did not come to hosp	1	50.00	1	50.00
specimen not obtained	1	50.00	2	100.00

D3. CBC ☐ 1. NOT DONE → GO TO D4 ☐ 2. DONE

D3. CBC				
CBC	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

D3.a. Date of test (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : cbc_datfrmrand <created variable> D3a. Date of CBC as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	758.0	.	758.0	758.0	758.0	758.0	758.0

<created variable> D3a. Date of CBC as days from RAND visit				
cbc_datfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

D3.b. Hemoglobin (g/dl) ☐☐.☐

Analysis Variable : HEMOGLO D3b. Hemoglobin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	7.4	.	7.4	7.4	7.4	7.4	7.4

D3b. Hemoglobin				
HEMOGLO	Frequency	Percent	Cum Freq	Cum Percent
-2	1	100.00	1	100.00

D3.c Hematocrit (%) ☐☐.☐

Analysis Variable : HEMAT D3c. Hematocrit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	21.0	.	21.0	21.0	21.0	21.0	21.0

D3c. Hematocrit				
HEMAT	Frequency	Percent	Cum Freq	Cum Percent
-2	1	100.00	1	100.00

D4. Serum Chemistries ☐ 1. NOT DONE ☐ 2. DONE

GO TO D5

D4. Serum Chemistries				
SER_CHE	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

D4.a Date of test (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : chemdatfrmrand <created variable> D4a. Date of serum chemistries as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	760.0	.	760.0	760.0	760.0	760.0	760.0

<created variable> D4a. Date of serum chemistries as days from RAND visit				
chemdatfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

D4.b Total bilirubin ☐☐.☐

Analysis Variable : TTL_BIL D4b. Total bilirubin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	2.9	.	2.9	2.9	2.9	2.9	2.9

D4b. Total bilirubin				
TTL_BIL	Frequency	Percent	Cum Freq	Cum Percent
-2	1	100.00	1	100.00

D4.c Direct bilirubin ☐☐.☐

Analysis Variable : DIR_BIL D4c. Direct bilirubin								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	0.7	.	0.7	0.7	0.7	0.7	0.7

D4c. Direct bilirubin				
DIR_BIL	Frequency	Percent	Cum Freq	Cum Percent
-2	1	100.00	1	100.00

D4.d LDH ☐☐☐☐

D4d. LDH				
LDH	Frequency	Percent	Cum Freq	Cum Percent
-3	1	50.00	1	50.00
-2	1	50.00	2	100.00

D5. Urinalysis ☐ **1. NOT DONE** → **GO TO SECTION E** ☐ **2. DONE**

D5. Urinalysis				
URINALY	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

D5.a Date of test (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : urindatfrmrand <created variable> D5a. Date of urinalysis as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	759.0	.	759.0	759.0	759.0	759.0	759.0

<created variable> D5a. Date of urinalysis as days from RAND visit				
urindatfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

D5.b Hemoglobin ☐ **1. NEG** ☐ **2. TRACE** ☐ **3. 1+** ☐ **4. 2+** ☐ **5. 3+** ☐ **6. 4+**

D5b. Hemoglobin				
URINHEM	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
4	1	50.00	2	100.00

D5.c Number of Red Cells per HPF ☐☐☐☐

D5c. Number of Red Cells per HPF				
RED_CEL	Frequency	Percent	Cum Freq	Cum Percent
-9	1	50.00	1	50.00
-2	1	50.00	2	100.00

****ATTACH LABORATORY OR BLOOD BANK REPORTS FOR EACH OF THE ABOVE TESTS THAT WERE PERFORMED****

E. MANAGEMENT AND OUTCOME

E1. Was the patient admitted to the hospital because of the reaction?

☐ **1. NO** ☐ **2. YES →** E1.a Date of hospital admission (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

E1. Was patient admitted to the hospital because of the reaction				
ADM_REA	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

Analysis Variable : adm_datfrmrand <created variable> E1a. Date of hospital admission as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	758.0	.	758.0	758.0	758.0	758.0	758.0

<created variable> E1a. Date of hospital admission as days from RAND visit				
adm_datfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

E1.b Date of hospital discharge (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : dis_datfrmrand <created variable> E1b. Date of hospital discharge as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	773.0	.	773.0	773.0	773.0	773.0	773.0

<created variable> E1b. Date of hospital discharge as days from RAND visit				
dis_datfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	1	100.00	1	100.00

E2. What types of treatment did the patient receive? **1. NO** **2. YES**

E2.a Hydration ☐ ☐

E2a. Hydration				
HYDRATN	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

E2.b Transfusion ☐ ☐ → **COMPLETE TRANSFUSION FORM**

E2b. Transfusion				
TRANSFU	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

E2.c Other ☐ ☐ ↓

E2c. Other				
OTHTREA	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

E2.c1 Specify _____

E2c1. Specify other				
TREASPE	Frequency	Percent	Cum Freq	Cum Percent
-2	1	50.00	1	50.00
IV antibiotics	1	50.00	2	100.00

E3. Did patient die? ☐ **1. NO** ☐ **2. YES** ↓

COMPLETE CAUSE OF DEATH FORM

E3. Did patient die				
PT_DIE	Frequency	Percent	Cum Freq	Cum Percent
1	2	100.00	2	100.00

****ATTACH CLINIC/ER NOTES (AND HOSPITAL DISCHARGE SUMMARY IF PATIENT WAS HOSPITALIZED)****

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___

F. FOR OFFICE USE:

F1. CBC report received ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA**

F1. CBC report received				
CBC_REC	Frequency	Percent	Cum Freq	Cum Percent
-1	1	50.00	1	50.00
2	1	50.00	2	100.00

F2. Blood Bank antiglobulin report received: ☐ 1. NO ☐ 2. YES ☐ -1. NA

F2. Blood Bank antiglobulin report received				
BBA_REC	Frequency	Percent	Cum Freq	Cum Percent
-1	1	50.00	1	50.00
1	1	50.00	2	100.00

F3. Blood Bank panel sheets received: ☐ 1. NO ☐ 2. YES ☐ -1. NA

F3. Blood Bank panels sheet received				
BBP_REC	Frequency	Percent	Cum Freq	Cum Percent
-1	1	50.00	1	50.00
2	1	50.00	2	100.00

F4. Reference lab report received: ☐ 1. NO ☐ 2. YES ☐ -1. NA

F4. Reference lab report received				
LABRPTS	Frequency	Percent	Cum Freq	Cum Percent
-1	2	100.00	2	100.00

F5. Serum chemistries report received: ☐ 1. NO ☐ 2. YES ☐ -1. NA

F5. Serum chemistries report received				
CHEM_REC	Frequency	Percent	Cum Freq	Cum Percent
-1	1	50.00	1	50.00
2	1	50.00	2	100.00

F6. Urinalysis report received: ☐ 1. NO ☐ 2. YES ☐ -1. NA

F6. Urinalysis report received				
URIN_REC	Frequency	Percent	Cum Freq	Cum Percent
-1	2	100.00	2	100.00

F7. Clinic/ER notes received: ☐ 1. NO ☐ 2. YES

F7. Clinic/ER notes received				
ERNOTES	Frequency	Percent	Cum Freq	Cum Percent
2	2	100.00	2	100.00

F8. Hospital discharge summary received: ☐ 1. NO ☐ 2. YES

F8. Hospital discharge summary received				
DISC_SU	Frequency	Percent	Cum Freq	Cum Percent
1	1	50.00	1	50.00
2	1	50.00	2	100.00

STOP II

FORM 33: OUTCOME OF HOSPITALIZATION FOR STROKE, MENINGITIS, OR HEAD INJURY

A. Collection Information:

The **Outcome of Hospitalization for Stroke, Meningitis, or Head Injury** (Form 33) was to be completed for Randomized patients after discharge from the hospital for a stroke, meningitis, or head injury event.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p033_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID, and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 6 (5)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 716
- Listing of Variables by Position: See p. 717

H. Formats:

The file **f033fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 718.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. The valid EX_TYPE for Form 33 is NE for neurological event**.**

- **EX_NUM** – is the variable name for exam number. Valid EX_NUMs for Form 33:
  - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

Data Set Name	PUBDS.P033_FINAL	Observations	6
Member Type	DATA	Variables	17
Engine	V9	Indexes	0
Created	Friday, March 10, 2006 12:07:38 PM	Observation Length	120
Last Modified	Friday, March 10, 2006 12:07:38 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	12288
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	102
Obs in First Data Page	6
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p033_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
10	BACTERI	Num	8	3.	C4a. Bacterial
8	BRAINED	Num	8	3.	C3. Brain edema with worsening symptoms
13	DESTATUS	Char	1	$1.	DESTATUS
5	DISAB_S	Num	8	3.	B2. Disability status at discharge
2	EX_NUM	Char	3	$3.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
9	INFECTI	Num	8	3.	C4. Infection
12	OTH_INF	Num	8	3.	C4c. Other type of infection
4	PT_DISC	Num	8	3.	B1. Patient discharged to
3	REASON	Num	8	3.	A2. Reason for hospitalization
7	SEIZURE	Num	8	3.	C2. Seizure
6	STROKRE	Num	8	3.	C1. Recurrent stroke
11	VIRAL	Num	8	3.	C4b. Viral
16	admit_dfrmrand	Num	8		<created variable> A3a. Date of first hospital admission for event as days from RAND visit
17	disch_dfrmrand	Num	8		<created variable> A3b. Date of hospital discharge as days from RAND visit
15	ldu_id	Char	10		ID for public use datasets
14	vistype	Char	6		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	3	$3.	X4. Exam Number
3	REASON	Num	8	3.	A2. Reason for hospitalization
4	PT_DISC	Num	8	3.	B1. Patient discharged to
5	DISAB_S	Num	8	3.	B2. Disability status at discharge
6	STROKRE	Num	8	3.	C1. Recurrent stroke
7	SEIZURE	Num	8	3.	C2. Seizure
8	BRAINED	Num	8	3.	C3. Brain edema with worsening symptoms
9	INFECTI	Num	8	3.	C4. Infection
10	BACTERI	Num	8	3.	C4a. Bacterial
11	VIRAL	Num	8	3.	C4b. Viral
12	OTH_INF	Num	8	3.	C4c. Other type of infection
13	DESTATUS	Char	1	$1.	DESTATUS
14	vistype	Char	6		<created variable> VISIT TYPE
15	ldu_id	Char	10		ID for public use datasets
16	admit_dfrmrand	Num	8		<created variable> A3a. Date of first hospital admission for event as days from RAND visit
17	disch_dfrmrand	Num	8		<created variable> A3b. Date of hospital discharge as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*F033fmts.txt;

proc format;

  value BACTERIF
    1='1: No'
    2='2: Yes';

  value BRAINEDF
    1='1: No'
    2='2: Yes';

  value DISAB_SF
    1='1: No symptoms'
    2='2: Symptoms but no disability'
    3='3: Mild-moderate disability'
    4='4: Major disability';

  value INFECTIF
    1='1: No'
    2='2: Yes';

  value OTH_INFF
    1='1: No'
    2='2: Yes';

  value PT_DISCF
    1='1: Home'
    2='2: Rehabilitation center'
    3='3: Chronic care facility'
    4='4: Died during hospitalization';

  value REASONF
    1='1: Neurological Event'
    2='2: Meningitis'
    3='3: Head injury';

  value SEIZUREF
    1='1: No'
    2='2: Yes';

  value STROKREF
    1='1: No'
    2='2: Yes';

  value VIRALF
    1='1: No'
    2='2: Yes';

* format bacteri bacterif. brained brainedf. disab_s disab_sf. infecti infectif. oth_inf oth_inff. pt_disc
pt_discf. reason reasonf. seizure seizuref. strokre strokref. viral viralf.;
```

STOP II TRIAL

OUTCOME OF HOSPITALIZATION FOR STROKE, MENINGITIS, OR HEAD INJURY

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	6	100.00	6	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	5	83.33	5	83.33
NE-102	1	16.67	6	100.00

A1. Person completing form (Name):_____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Reason for hospitalization:

☐ 1. Neurological Event (stroke) → **COMPLETE FORM 30**

☐ 2. Meningitis → **COMPLETE FORM 31**

☐ 3. Head Injury → **COMPLETE FORM 31**

A2. Reason for hospitalization				
REASON	Frequency	Percent	Cum Freq	Cum Percent
1	6	100.00	6	100.00

A3.a. Date of first hospital admission for event (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

Analysis Variable : admit_dfrmrand <created variable> A3a. Date of first hospital admission for event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6	0	176.3	112.9	51.0	72.0	157.5	295.0	325.0

b. Date of hospital discharge (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

Analysis Variable : disch_dfrmrand <created variable> A3b. Date of hospital discharge as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6	0	178.5	113.9	51.0	75.0	159.0	298.0	329.0

c. Name and address of hospital *[Variable NOT included in dataset.]*

_____

_____

B. DISCHARGE STATUS

B1. Patient discharged to:

☐ 1. Home
☐ 2. Rehabilitation center
☐ 3. Chronic care facility
☐ 4. Died during hospitalization

↓

COMPLETE FORM 40

B1. Patient discharged to				
PT_DISC	Frequency	Percent	Cum Freq	Cum Percent
1	6	100.00	6	100.00

B2. Disability status at discharge (Modified Rankin Disability Scale):

☐ 1. No symptoms
☐ 2. Symptoms but no disability (no interference with daily activities)
☐ 3. Mild-moderate disability (mostly independent functioning and some interference with daily activities)
☐ 4. Major disability (requires help with most or all activities; has limited mobility)

B2. Disability status at discharge				
DISAB_S	Frequency	Percent	Cum Freq	Cum Percent
1	1	16.67	1	16.67
2	5	83.33	6	100.00

B2.a. Name and Title of person who determined disability status:

[Variable NOT included in dataset.]

_____

_____

C. COMPLICATIONS DURING HOSPITALIZATION (Please answer all items):

	1. NO	2. YES
C1. Recurrent Stroke	☐	☐

C1. Recurrent stroke				
STROKRE	Frequency	Percent	Cum Freq	Cum Percent
1	6	100.00	6	100.00

C2. Seizure	☐	☐

C2. Seizure				
SEIZURE	Frequency	Percent	Cum Freq	Cum Percent
1	6	100.00	6	100.00

C3. Brain edema with worsening of symptoms	☐	☐

C3. Brain edema with worsening symptoms				
BRAINED	Frequency	Percent	Cum Freq	Cum Percent
1	6	100.00	6	100.00

C4. Infection	☐	☐

C4. Infection				
INFECTI	Frequency	Percent	Cum Freq	Cum Percent
1	5	83.33	5	83.33
2	1	16.67	6	100.00

↓

a. Bacterial ☐ **1. NO** ☐ **2. YES** → **COMPLETE FORM 31**

C4a. Bacterial				
BACTERI	Frequency	Percent	Cum Freq	Cum Percent
-2	5	83.33	5	83.33
2	1	16.67	6	100.00

b. Viral ☐ **1. NO** ☐ **2. YES** → **COMPLETE FORM 31**

C4b. Viral				
VIRAL	Frequency	Percent	Cum Freq	Cum Percent
-2	5	83.33	5	83.33
1	1	16.67	6	100.00

c. Other type of infection ☐ **1. NO** ☐ **2. YES** → **COMPLETE FORM 31**

C4c. Other type of infection				
OTH_INF	Frequency	Percent	Cum Freq	Cum Percent
-2	5	83.33	5	83.33
1	1	16.67	6	100.00

↓

c1. Specify Type: _____

[Variable NOT included in dataset for specify field.]

Signature of Study Coordinator:

Date: ___ ___ / ___ ___ / ___ ___ ___ ___

STOP II

FORM 40: CAUSE OF DEATH FORM

A. Collection Information:

The **Cause of Death Form** (Form 40) was to be completed soon after being notified of the death of a Randomized patient.

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p040_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID**

Records in the dataset are sorted by LDU_ID.

F. Number of Observations (Patients) in SAS Dataset: 1 (1)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 725
- Listing of Variables by Position: See p. 726

H. Formats:

The file **f040fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 727.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:

All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The only valid EX_TYPE for Form 40 is NN for non-neurological event.

- **CODED1** - is the variable name for ICD-9 code for conditions diagnosed at hospital admission as indicated in the preceding specify field. This variable requires the ICD-9 Codebook Diseases section for interpretation. The code box is labeled "Office Use" on the form.

Data Set Name	PUBDS.P040_FINAL	Observations	1
Member Type	DATA	Variables	19
Engine	V9	Indexes	0
Created	Friday, February 17, 2006 01:43:52 PM	Observation Length	176
Last Modified	Friday, February 17, 2006 01:43:52 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	92
Obs in First Data Page	1
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p040_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
2	ADDRESS	Num	8	3.	A5. This is the address of
11	AUTOPSY	Num	8	3.	B3. Was the autopsy performed
12	CAUSCLAS	Num	8	3.	C1. Classification of cause of death
14	CAUSSPEC	Char	25	$25.	C1d. Specify other cause of death
13	CAUSTYPE	Num	8	3.	C1a. Type of neurological event
5	CODED1	Num	8	7.2	A6b1a. Admitting diagnosis: code 1
3	DEATH_TM	Num	8	3.	A6. Time of death in relation to presentation at hospital
15	DESTATUS	Char	1	$1.	DESTATUS
4	DIAGNOS1	Char	25	$25.	A6b1. Admitting diagnosis: specify 1
6	DTH_CERT	Num	8	3.	B1. Is a copy of the death certificate available
1	EX_TYPE	Char	2	$2.	X3. Exam Type
7	IMFAMILY	Num	8	3.	B2a. Member of immediate family
10	INFO_OTH	Num	8	3.	B2d. Other
8	MED_PERS	Num	8	3.	B2b. Medical Personnel
9	MED_RECS	Num	8	3.	B2c. Medical Records
19	admit_dtfrmrand	Num	8		<created variable> A6a. Date of admission as days from RAND visit
18	death_dtfrmrand	Num	8		<created variable> A3. Date of death as days from RAND visit
16	ldu_id	Char	10		ID for public use datasets
17	notif_dtfrmrand	Num	8		<created variable> A2. Date of clinic notification of death as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam Type
2	ADDRESS	Num	8	3.	A5. This is the address of
3	DEATH_TM	Num	8	3.	A6. Time of death in relation to presentation at hospital
4	DIAGNOS1	Char	25	$25.	A6b1. Admitting diagnosis: specify 1
5	CODED1	Num	8	7.2	A6b1a. Admitting diagnosis: code 1
6	DTH_CERT	Num	8	3.	B1. Is a copy of the death certificate available
7	IMFAMILY	Num	8	3.	B2a. Member of immediate family
8	MED_PERS	Num	8	3.	B2b. Medical Personnel
9	MED_RECS	Num	8	3.	B2c. Medical Records
10	INFO_OTH	Num	8	3.	B2d. Other
11	AUTOPSY	Num	8	3.	B3. Was the autopsy performed
12	CAUSCLAS	Num	8	3.	C1. Classification of cause of death
13	CAUSTYPE	Num	8	3.	C1a. Type of neurological event
14	CAUSSPEC	Char	25	$25.	C1d. Specify other cause of death
15	DESTATUS	Char	1	$1.	DESTATUS
16	ldu_id	Char	10		ID for public use datasets
17	notif_dtfrmrand	Num	8		<created variable> A2. Date of clinic notification of death as days from RAND visit
18	death_dtfrmrand	Num	8		<created variable> A3. Date of death as days from RAND visit
19	admit_dtfrmrand	Num	8		<created variable> A6a. Date of admission as days from RAND visit

Sort Information

Sortedby	ldu_id
Validated	YES
Character Set	ANSI

```
*F040fmts.txt;

proc format;

  value ADDRESSF
    1='1: A STOP Hospital'
    2='2: A non-STOP Hospital'
    3='3: A chronic care facility'
    4='4: The patient's home'
    5='5: Other';

  value AUTOPSYF
    1='1: No'
    2='2: Yes'
    9='9: DK';

  value CAUSCLASF
    1='1: Neurological Event'
    2='2: Other'
    3='3: Unkown - Sudden Death'
    4='4: Unknown - No Information';

  value CAUSTYPEF
    1='1: Cerebral Infarction'
    2='2: Intracranial Hemorrhage'
    3='3: Other';

  value DEATH_TMF
    1='1: Pronounced dead on arrival at hospital'
    2='2: Died in emergency room or within 24 hours of admission'
    3='3: Died more than 24 hours after admission';

  value DTH_CERTF
    1='1: No'
    2='2: Yes';

  value IMFAMILYF
    1='1: No'
    2='2: Yes';

  value INFO_OTHF
    1='1: No'
    2='2: Yes';

  value MED_PERSF
    1='1: No'
    2='2: Yes';

  value MED_RECSF
    1='1: No'
    2='2: Yes';

* format address addressf. autopsy autopsyf. causclas causclasf. caustype caustypef. death_tm
death_tmf. dth_cert dth_certf. imfamily imfamilyf. info_oth info_othf. med_pers med_persf. med_recs
med_recsf.;
```

STOP II TRIAL

CAUSE OF DEATH FORM

AFFIX PATIENT'S LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1	100.00	1	100.00

X3. Exam Type				
EX_TYPE	Frequency	Percent	Cum Freq	Cum Percent
NN	1	100.00	1	100.00

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of Clinic's notification of the death (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : notif_dtfrmrand <created variable> A2. Date of clinic notification of death as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	815.0	.	815.0	815.0	815.0	815.0	815.0

A3. Date of death (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : death_dtfrmrand <created variable> A3. Date of death as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	815.0	.	815.0	815.0	815.0	815.0	815.0

A4. Place of Death:

Address:

Number _____ Street _____ | |

a. City _____ b. County _____ c. State

[Variables NOT included in dataset.]

A5. This is the address of

☐ 1. A STOP Hospital A5.a STOP Center code # ☐☐

☐ 2. A non-STOP Hospital * → **GO TO A5.b**

☐ 3. A chronic care facility* → **GO TO A5.b**

☐ 4. The patient's home

☐ 5. Other → **GO TO A5.b**

A5.b Specify Name:_____

A5. This is the address of				
ADDRESS	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

[Variable NOT included in dataset for STOP Center code or specify field.]

6. If the place of death was a hospital, what was the time of death in relationship to the time of the patient's presentation at the hospital?

☐ 1. Pronounced dead on arrival at hospital

☐ 2. Died in emergency room or within 24 hours of admission

☐ 3. Died more than 24 hours after admission

A6. Time of death in relation to presentation at hospital				
DEATH_TM	Frequency	Percent	Cum Freq	Cum Percent
3	1	100.00	1	100.00

A6.a Date of admission Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : admit_dtfrmrand <created variable> A6a. Date of admission as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	805.0	.	805.0	805.0	805.0	805.0	805.0

A6.b Admitting diagnosis:

OFFICE USE

a. _____ | | | | . | |

A6b1. Admitting diagnosis: specify 1				
DIAGNOS1	Frequency	Percent	Cum Freq	Cum Percent
ACS/pneumonia	1	100.00	1	100.00

A6b1a. Admitting diagnosis: code 1				
CODED1	Frequency	Percent	Cum Freq	Cum Percent
486	1	100.00	1	100.00

b. _____ | | | | . | |

c. _____ | | | | . | |

d. _____ | | | | . | |

[Variables NOT included in dataset for Admitting diagnosis b-d specify or code fields. Fields had no data.]

* **Obtain signed RELEASE OF INFORMATION form from next of kin and request records**

****ATTACH HOSPITALIZATION SUMMARY**** | |

OFFICE USE

[Variable NOT included in dataset.]

B1. Is a copy of the death certificate available?

| | **1. NO** | | **2. YES**

B1. Is a copy of the death certificate available				
DTH_CERT	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

The cause of death as reported on the Death Certificate was:

OFFICE USE

a. immediate _____ | | | | . | |

b. due to _____ | | | | . | |

c. due to _____ | | | | . | |

[Variables NOT included in dataset. Fields had no data.]

Other significant conditions reported on the Death Certificate were:

OFFICE USE

d. _____ | | | | . | |

e. _____ | | | | . | |

f. _____ | | | | . | |

****ATTACH A COPY OF THE DEATH CERTIFICATE**** ☐

OFFICE USE

[Variables NOT included in dataset. Fields had no data]

B2. The information regarding the circumstances surrounding the death was obtained from:
(CHECK NO OR YES FOR EACH OF a - d)

1. NO **2. YES**

a. Member of immediate family ☐ ☐ ↓

B2a. Member of immediate family				
IMFAMILY	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

a1. Specify _____

[Variable NOT included in dataset for specify field.]

b. Medical Personnel ☐ ☐

B2b. Medical Personnel				
MED_PERS	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

c. Medical Records ☐ ☐

B2c. Medical Records				
MED_RECS	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

d. Other ☐ ☐ ↓

B2d. Other				
INFO_OTH	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

d1. Specify _____

[Variable NOT included in dataset for specify field.]

B3. Was an autopsy performed?

☐ **1. NO**

☐ **2. YES →** **ATTACH A COPY OF THE COMPLETE REPORT**

☐ **9. DK**

☐ **OFFICE USE**

B3. Was the autopsy performed				
AUTOPSY	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C1. Classification of cause of death by STOP II Center Investigator

☐ **1. NEUROLOGICAL EVENT →**

C1.a Type

☐ **1. Cerebral Infarction**

☐ **2. Intracranial Hemorrhage**

C1.b Specify type: *[Variable NOT included in dataset.]*

☐ **3. Other →** C1.c Specify: *[Variable NOT included in dataset.]*

☐ **2. OTHER →** C1.d Specify _____

☐ **3. UNKNOWN – SUDDEN DEATH (EXPLAIN BELOW)**

☐ **4. UNKNOWN - NO INFORMATION**

C1. Classification of cause of death				
CAUSCLAS	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

C1a. Type of neurological event				
CAUSTYPE	Frequency	Percent	Cum Freq	Cum Percent
-2	1	100.00	1	100.00

C1d. Specify other cause of death				
CAUSSPEC	Frequency	Percent	Cum Freq	Cum Percent
suspect pulmon. embolism	1	100.00	1	100.00

Continue to C2

C2. STOP II Investigator's summary of sequence of events and/or circumstances surrounding the patient's death:

_____

[Variable NOT included in dataset.]

_____

****ATTACH COPIES OF DEATH CERTIFICATE, AUTOPSY REPORT, AND HOSPITAL SUMMARY WHEN AVAILABLE****
SUBMIT APPROPRIATE STOP EVENT FORMS FOR EACH EVENT SURROUNDING THE PATIENT'S DEATH:

FORM 30 FOR NEUROLOGICAL EVENT
FORM 31 FOR EACH NON-NEUROLOGICAL EVENT
FORMS 20 AND 21 FOR EACH TRANSFUSION
FORM 32 FOR DELAYED TRANSFUSION REACTION

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___

STOP II
FORM 52: ENDPOINT ADJUDICATION DECISION

A. Collection Information:

The **Endpoint Adjudication Decision** (Form 52) was to be completed by the Endpoint Adjudication Panel Chair after completing a Form 51 (Endpoint Assessment) and receiving a Form 51 from a second panel member and reading of MRI/DWI by a STOP II MRI/MRA Reading Panel member.

B. Data Collection Period: April 2001 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **p052_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 14 (11)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 736
- Listing of Variables by Position: See p. 737

H. Formats:

The file **f052fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 738.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The only valid EX_TYPE for Form 52 is NE for neurological event.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 52:
  - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

- **SUMMARY** - is the variable name for summary of teleconference and is a concatenation of three shorter summary field variables that were then dropped**.** This new variable is indicated in the contents by "<created variable>" in the label.

Data Set Name	PUBDS.P052_FINAL	Observations	14
Member Type	DATA	Variables	19
Engine	V9	Indexes	0
Created	Friday, February 17, 2006 03:50:35 PM	Observation Length	568
Last Modified	Friday, February 17, 2006 03:50:35 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	28
Obs in First Data Page	14
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p052_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
14	COMMENTS	Char	200	$200.	D3. Comments:
15	DESTATUS	Char	1	$1.	DESTATUS
2	EX_NUM	Char	3	$3.	A2b. Exam Number
1	EX_TYPE	Char	2	$2.	A2a. Exam Type
3	INITS1	Char	3	$3.	B1. Reviewer #1
5	INITS2	Char	3	$3.	B2. Reviewer #2
7	INITS3	Char	3	$3.	B3. Reviewer #3
11	NCSN_SP	Char	25	$25.	D1a4. Non-CNS event - Specify:
9	NEWSTROK	Num	8	3.	D1. Is the group consensus that the patient had a new stroke?
10	NSTRKDX	Num	8	3.	D1a. If NO, type of event:
13	NSTRK_SP	Num	8	3.	D1b. If YES, type:
12	OTHER_SP	Char	25	$25.	D1a5. Other - Specify:
4	STROK1	Num	8	3.	B1a. Did patient have a new stroke?
6	STROK2	Num	8	3.	B2a. Did patient have a new stroke?
8	STROK3	Num	8	3.	B3a. Did patient have a new stroke?
17	SUMMARY	Char	225		<created variable> C1. Summary of teleconference
18	ldu_id	Char	10		ID for public use datasets
19	neuro_ dtfrmrand	Num	8		<created variable> A3. Date of neurological event as days from RAND visit
16	vistype	Char	6		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	A2a. Exam Type
2	EX_NUM	Char	3	$3.	A2b. Exam Number
3	INITS1	Char	3	$3.	B1. Reviewer #1
4	STROK1	Num	8	3.	B1a. Did patient have a new stroke?
5	INITS2	Char	3	$3.	B2. Reviewer #2
6	STROK2	Num	8	3.	B2a. Did patient have a new stroke?
7	INITS3	Char	3	$3.	B3. Reviewer #3
8	STROK3	Num	8	3.	B3a. Did patient have a new stroke?
9	NEWSTROK	Num	8	3.	D1. Is the group consensus that the patient had a new stroke?
10	NSTRKDX	Num	8	3.	D1a. If NO, type of event:
11	NCSN_SP	Char	25	$25.	D1a4. Non-CNS event - Specify:
12	OTHER_SP	Char	25	$25.	D1a5. Other - Specify:
13	NSTRK_SP	Num	8	3.	D1b. If YES, type:
14	COMMENTS	Char	200	$200.	D3. Comments:
15	DESTATUS	Char	1	$1.	DESTATUS
16	vistype	Char	6		<created variable> VISIT TYPE
17	SUMMARY	Char	225		<created variable> C1. Summary of teleconference
18	ldu_id	Char	10		ID for public use datasets
19	neuro_dtfrmrand	Num	8		<created variable> A3. Date of neurological event as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*F052fmts.txt;

proc format;

  value NEWSTROKF
    1='1: No'
    2='2: Yes';

  value NSTRK_SPF
    1='1: Infraction'
    2='2: Intraparenchymal Hemorrhage'
    3='3: Subarachnoid Hemorrhage'
    4='4: Intraventricular Hemorrhage';

  value NSTRKDXF
    1='1: TIA'
    2='2: Seizure'
    3='3: Migraine'
    4='4: Non-CNS event'
    5='5: Other'
    6='6: Cannot determine';

  value STROK1F
    1='1: No'
    2='2: Yes';

  value STROK2F
    1='1: No'
    2='2: Yes';

  value STROK3F
    1='1: No'
    2='2: Yes';

* format newstrok newstrokf. nstrk_sp nstrk_spf. nstrkdx nstrkdxf. strok1 strok1f. strok2 strok2f. strok3
strok3f.;
```

STOP II TRIAL
ENDPOINT ADJUDICATION DECISION

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	14	100.00	14	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	11	78.57	11	78.57
NE-102	2	14.29	13	92.86
NE-103	1	7.14	14	100.00

A1. Patient ID # ☐☐ - ☐☐☐ - ☐

A2. ACROSTIC ☐☐☐☐☐

A3 Date of neurological event (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

Analysis Variable : neuro_dtfrmrand <created variable> A3. Date of neurological event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
14	0	350.4	303.9	51.0	144.0	235.0	522.0	991.0

B. SUMMARY AND CONSENSUS FOR NEW STROKE

Individual assessments: Did patient have a new stroke?

1. Reviewer #1 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

B1. Reviewer #1				
INITS1	Frequency	Percent	Cum Freq	Cum Percent
ESR	14	100.00	14	100.00

B1a. Did patient have a new stroke?				
STROK1	Frequency	Percent	Cum Freq	Cum Percent
1	12	85.71	12	85.71
2	2	14.29	14	100.00

Individual assessments: Did patient have a new stroke?

2. Reviewer #2 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

B2. Reviewer #2				
INITS2	Frequency	Percent	Cum Freq	Cum Percent
DD	5	35.71	5	35.71
LC	9	64.29	14	100.00

B2a. Did patient have a new stroke?				
STROK2	Frequency	Percent	Cum Freq	Cum Percent
1	12	85.71	12	85.71
2	2	14.29	14	100.00

Individual assessments: Did patient have a new stroke?

3. Reviewer #3 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

B3. Reviewer #3				
INITS3	Frequency	Percent	Cum Freq	Cum Percent
-1	4	28.57	4	28.57
FM	2	14.29	6	42.86
JAB	4	28.57	10	71.43
RZ	4	28.57	14	100.00

B3a. Did patient have a new stroke?				
STROK3	Frequency	Percent	Cum Freq	Cum Percent
-2	4	28.57	4	28.57
1	9	64.29	13	92.86
2	1	7.14	14	100.00

C. SUMMARY OF TELECONFERENCE (If applicable):

<created variable> C1. Summary of teleconference				
SUMMARY	Frequency	Percent	Cum Freq	Cum Percent
-1	12	85.71	12	85.71
Both neurologists agree that there was not a stroke - ESR noted as TIA, LC noted as "other" (ie recrudescence of old Sx during fever). (Per email.) I do not consider this to be a significant disagreement.	1	7.14	13	92.86
N/A. 2 small white matter lesions on recent scan. One of these can be seenon an earlier scan and neither are compatible with patients sx.	1	7.14	14	100.00

D. GROUP CONSENSUS FOR NEW STROKE

D1. Is the group consensus that the patient had a new stroke?

☐ **1. NO** ☐ **2. YES**

D1. Is the group consensus that the patient had a new stroke?				
NEWSTROK	Frequency	Percent	Cum Freq	Cum Percent
1	12	85.71	12	85.71
2	2	14.29	14	100.00

↓

D1.a If NO, type of event:

☐ 1. TIA

☐ 2. Seizure

☐ 3. Migraine

☐ 4. Non-CNS event:
Specify _____

☐ 5. Other:
Specify _____

☐ 6. Cannot determine

D1a. If NO, type of event:				
NSTRKDX	Frequency	Percent	Cum Freq	Cum Percent
-2	2	14.29	2	14.29
1	1	7.14	3	21.43
3	3	21.43	6	42.86
4	1	7.14	7	50.00
5	4	28.57	11	78.57
6	3	21.43	14	100.00

D1a4. Non-CNS event - Specify:				
NCSN_SP	Frequency	Percent	Cum Freq	Cum Percent
-2	13	92.86	13	92.86
cardiac arrest w/hypotens	1	7.14	14	100.00

D1a5. Other - Specify:				
OTHER_SP	Frequency	Percent	Cum Freq	Cum Percent
-2	10	71.43	10	71.43
Episodic dizziness	1	7.14	11	78.57
TIA v. incr. Sx w/ fever	1	7.14	12	85.71
possible migraine	1	7.14	13	92.86
syncope	1	7.14	14	100.00

↓

D1.b If YES, type:

- ☐ 1. Infarction
- ☐ 2. Intraparenchymal Hemorrhage
- ☐ 3. Subarachnoid Hemorrhage
- ☐ 4. Intraventricular Hemorrhage

D1b. If YES, type:				
NSTRK_SP	Frequency	Percent	Cum Freq	Cum Percent
-2	12	85.71	12	85.71
1	2	14.29	14	100.00

D3. Comments:				
COMMENTS	Frequency	Percent	Cum Freq	Cum Percent
-1	14	100.00	14	100.00

Signature of Endpoint Adjudication Panel Chair: _____ Date ___ ___ / ___ ___ / ___ ___ ___ ___

STOP II

FORM Q30: QUASI-ADJUDICATION NEUROLOGICAL EVENT FORM

A. Collection Information:

The **Quasi-Adjudication Neurological Event Form** (Form Q30) was to be completed for non-randomized STOP II patients for any neurological event that occurred between their first screening/enrollment visit in STOP II and randomization or the end of the study, if not randomized.

B. Data Collection Period: December 2000 through October 2004

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System File: **pq30_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID, EX_TYPE and EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 1 (1)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 745-746
- Listing of Variables by Position: See pp. 747-748

H. Formats:

The file **fQ30fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 749-752.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The only valid EX_TYPE for Form Q30 is QN.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form Q30 are 100 series numbers.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

Data Set Name	PUBDS.PQ30_FINAL	Observations	1
Member Type	DATA	Variables	53
Engine	V9	Indexes	0
Created	Monday, February 20, 2006 04:06:58 PM	Observation Length	456
Last Modified	Monday, February 20, 2006 04:06:58 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	35
Obs in First Data Page	1
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\pq30_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
25	ANESTHES	Num	8	3.	C3e. General anesthesia
35	ARTERIOG	Num	8	3.	D5. Arteriogram
24	A_ANEMIA	Num	8	3.	C3d. Acute anemia
23	A_CHEST	Num	8	3.	C3c. Acute Chest Syndrome
21	A_FEBRIL	Num	8	3.	C3a. Acute febrile event
26	A_PRIAPISM	Num	8	3.	C3f. Priapism
16	BEHAVIOR	Num	8	3.	B3k. Change in behavior
6	CHG_MENT	Num	8	3.	B3b. Change in mental status
17	COORDINA	Num	8	3.	B3l. Change in gait or coordination
32	CT_BRAIN	Num	8	3.	D2. CT scan of brain
44	DESTATUS	Char	1	$1.	DESTATUS
7	DIF_SPEK	Num	8	3.	B3c. Loss of or difficulty with speech
12	DIZZINES	Num	8	3.	B3g. Loss of balance or dizziness
10	DSWALLOW	Num	8	3.	B3e. Difficulty with swallowing
31	DWI_PERF	Num	8	3.	D1b. Was DWI performed?
11	D_VISION	Num	8	3.	B3f. Difficulty with vision
42	EV_TYPE	Num	8	3.	G1. Type of neurological event:
2	EX_NUM	Char	4	$4.	X4. Exam Number
1	EX_TYPE	Char	2	$2.	X3. Exam type
14	HEADACHE	Num	8	3.	B3i. Headache
27	HEAD_INJ	Num	8	3.	C3g. Head injury with loss of consciousness
19	INTERVIE	Num	8	3.	C1. Person interviewed:
5	LOSSCONS	Num	8	3.	B3a. Loss of consciousness
34	MRABRAIN	Num	8	3.	D4. MRA of brain
30	MRIBRAIN	Num	8	3.	D1. MRI of brain
38	NEUREVAL	Num	8	3.	E1. Was a neurological evaluation performed ...?

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
29	OTH_EXPR	Num	8	3.	C3i. Other
39	O_EVENTS	Num	8	3.	F1. Were there other events associated with this neuro. event?
37	O_IMAGE	Num	8	3.	D7. Other
22	PAINFUL	Num	8	3.	C3b. Painful event
33	PETBRAIN	Num	8	3.	D3. PET scan of brain
41	PT_DIE	Num	8	3.	F3. Did the patient die as a complication of this event?
18	PT_HOSP	Num	8	3.	B4. Was patient hospitalized for this event?
40	PT_TRANS	Num	8	3.	F2. Was this patient transfused for this neurological event?
13	SEIZURE	Num	8	3.	B3h. Seizure
15	SENSDIST	Num	8	3.	B3j. New sensory disturbance
4	SYMPRPTD	Num	8	3.	B2. Were signs and symptoms first reported at a quarterly visit?
36	TRANSDOP	Num	8	3.	D6. Transcranial Doppler
28	TRANSFUS	Num	8	3.	C3h. Transfusion
43	TYPESPEC	Char	50	$50.	G1a. Specify:
8	WEAKNESS	Num	8	3.	B3d. Paralysis or weakness
9	WEAKSIDE	Num	8	3.	B3d1. Side:
3	WHERSEEN	Num	8	3.	B1. Where was the patient first seen for this event?
20	WITNES_E	Num	8	3.	C2. Did person interviewed witness suspected event?
47	comp_dfrmrand	Num	8		<created variable> A2. Date of neurological event as days from RAND visit
49	hospadmtfrmrand	Num	8		<created variable> B4a. Date of hospital admission as days from RAND visit
50	hospdiscfrmrand	Num	8		<created variable> B4b. Date of hospital discharge as days from RAND visit
46	ldu_id	Char	10		ID for public use datasets
52	mra_datefrmrand	Num	8		<created variable> D4a. Date MRA performed as days from RAND visit
51	mri_datefrmrand	Num	8		<created variable> D1a. Date MRI performed as days from RAND visit
53	neuro_dtfrmrand	Num	8		<created variable> E1a. Date neuro evaluation performed as days from RAND visit
48	qtr_datefrmrand	Num	8		<created variable> B2a. Date of Quarterly Progress Report as days from RAND visit
45	vistype	Char	7		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	X3. Exam type
2	EX_NUM	Char	4	$4.	X4. Exam Number
3	WHERSEEN	Num	8	3.	B1. Where was the patient first seen for this event?
4	SYMPRPTD	Num	8	3.	B2. Were signs and symptoms first reported at a quarterly visit?
5	LOSSCONS	Num	8	3.	B3a. Loss of consciousness
6	CHG_MENT	Num	8	3.	B3b. Change in mental status
7	DIF_SPEK	Num	8	3.	B3c. Loss of or difficulty with speech
8	WEAKNESS	Num	8	3.	B3d. Paralysis or weakness
9	WEAKSIDE	Num	8	3.	B3d1. Side:
10	DSWALLOW	Num	8	3.	B3e. Difficulty with swallowing
11	D_VISION	Num	8	3.	B3f. Difficulty with vision
12	DIZZINES	Num	8	3.	B3g. Loss of balance or dizziness
13	SEIZURE	Num	8	3.	B3h. Seizure
14	HEADACHE	Num	8	3.	B3i. Headache
15	SENSDIST	Num	8	3.	B3j. New sensory disturbance
16	BEHAVIOR	Num	8	3.	B3k. Change in behavior
17	COORDINA	Num	8	3.	B3l. Change in gait or coordination
18	PT_HOSP	Num	8	3.	B4. Was patient hospitalized for this event?
19	INTERVIE	Num	8	3.	C1. Person interviewed:
20	WITNES_E	Num	8	3.	C2. Did person interviewed witness suspected event?
21	A_FEBRIL	Num	8	3.	C3a. Acute febrile event
22	PAINFUL	Num	8	3.	C3b. Painful event
23	A_CHEST	Num	8	3.	C3c. Acute Chest Syndrome
24	A_ANEMIA	Num	8	3.	C3d. Acute anemia
25	ANESTHES	Num	8	3.	C3e. General anesthesia
26	A_PRIAPISM	Num	8	3.	C3f. Priapism
27	HEAD_INJ	Num	8	3.	C3g. Head injury with loss of consciousness
28	TRANSFUS	Num	8	3.	C3h. Transfusion
29	OTH_EXPR	Num	8	3.	C3i. Other
30	MRIBRAIN	Num	8	3.	D1. MRI of brain
31	DWI_PERF	Num	8	3.	D1b. Was DWI performed?
32	CT_BRAIN	Num	8	3.	D2. CT scan of brain
33	PETBRAIN	Num	8	3.	D3. PET scan of brain
34	MRABRAIN	Num	8	3.	D4. MRA of brain
35	ARTERIOG	Num	8	3.	D5. Arteriogram
36	TRANSDOP	Num	8	3.	D6. Transcranial Doppler
37	O_IMAGE	Num	8	3.	D7. Other
38	NEUREVAL	Num	8	3.	E1. Was a neurological evaluation performed ...?
39	O_EVENTS	Num	8	3.	F1. Were there other events associated with this neuro. event?
40	PT_TRANS	Num	8	3.	F2. Was this patient transfused for this neurological event?
41	PT_DIE	Num	8	3.	F3. Did the patient die as a complication of this event?
42	EV_TYPE	Num	8	3.	G1. Type of neurological event:
43	TYPESPEC	Char	50	$50.	G1a. Specify:
44	DESTATUS	Char	1	$1.	DESTATUS
45	vistype	Char	7		<created variable> VISIT TYPE
46	ldu_id	Char	10		ID for public use datasets
47	comp_dfrmrand	Num	8		<created variable> A2. Date of neurological event as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
48	qtr_datefrmrand	Num	8		<created variable> B2a. Date of Quarterly Progress Report as days from RAND visit
49	hospadmtfrmrand	Num	8		<created variable> B4a. Date of hospital admission as days from RAND visit
50	hospdiscfrmrand	Num	8		<created variable> B4b. Date of hospital discharge as days from RAND visit
51	mri_datefrmrand	Num	8		<created variable> D1a. Date MRI performed as days from RAND visit
52	mra_datefrmrand	Num	8		<created variable> D4a. Date MRA performed as days from RAND visit
53	neuro_dtfrmrand	Num	8		<created variable> E1a. Date neuro evaluation performed as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*FQ30fmts.txt;

proc format;

  value A_ANEMIAF
    1='1: No'
    2='2: Yes'
    3='3: Don't Know';

  value A_CHESTF
    1='1: No'
    2='2: Yes'
    3='3: Don't Know';

  value A_FEBRILF
    1='1: No'
    2='2: Yes'
    3='3: Don't Know';

  value A_PRIAPISMF
    1='1: No'
    2='2: Yes'
    3='3: Don't Know';

  value ANESTHESF
    1='1: No'
    2='2: Yes'
    3='3: Don't Know';

  value ARTERIOGF
    1='1: Not Done'
    2='2: Done';

  value BEHAVIORF
    1='1: No'
    2='2: Yes';

  value CHG_MENTF
    1='1: No'
    2='2: Yes';

  value COORDINAF
    1='1: No'
    2='2: Yes';

  value CT_BRAINF
    1='1: Not Done'
    2='2: Done';

  value D_VISIONF
    1='1: No'
    2='2: Yes';
```

```
value DIF_SPEKF
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  2='2: Yes';

value DIZZINESF
  1='1: No'
  2='2: Yes';

value DSWALLOWF
  1='1: No'
  2='2: Yes';

value DWI_PERFF
  1='1: No'
  2='2: Yes';

value EV_TYPEF
  1='1: Cerebral Infarction'
  2='2: Intracranial Hemorrhage'
  3='3: TIA'
  4='4: Seizure'
  5='5: Other';

value HEAD_INJF
  1='1: No'
  2='2: Yes'
  3='3: Don't Know';

value HEADACHEF
  1='1: No'
  2='2: Yes';

value INTERVIEF
  1='1: Patient'
  2='2: Parent'
  3='3: Other';

value LOSSCONSF
  1='1: No'
  2='2: Yes';

value MRABRAINF
  1='1: Not Done'
  2='2: Done';

value MRIBRAINF
  1='1: Not Done'
  2='2: Done';

value NEUREVALF
  1='1: No'
  2='2: Yes';
```

```
value O_EVENTSF
  1='1: No'
  2='2: Yes';

value O_IMAGEF
  1='1: Not Done'
  2='2: Done';

value OTH_EXPRF
  1='1: No'
  2='2: Yes'
  3='3: Don't Know';

value PAINFULF
  1='1: No'
  2='2: Yes'
  3='3: Don't Know';

value PETBRAINF
  1='1: Not Done'
  2='2: Done';

value PT_DIEF
  1='1: No'
  2='2: Yes';

value PT_HOSPF
  1='1: No'
  2='2: Yes';

value PT_TRANSF
  1='1: No'
  2='2: Yes';

value SEIZUREF
  1='1: No'
  2='2: Yes';

value SENSDISTF
  1='1: No'
  2='2: Yes';

value SYMPRPTDF
  1='1: No'
  2='2: Yes';

value TRANSDOPF
  1='1: Not Done'
  2='2: Done';

value TRANSFUSF
  1='1: No'
  2='2: Yes'
  3='3: Don't Know';
```

```
  value WEAKNESSF
    1='1: No'
    2='2: Yes';

  value WEAKSIDEF
    1='1: Right'
    2='2: Left'
    3='3: Both';

  value WHERSEENF
    1='1: Stop II Center'
    2='2: Other';

  value WITNES_EF
    1='1: No'
    2='2: Yes';

* format a_anemia a_anemiaf. a_chest a_chestf. a_febril a_febrilf. a_priapism a_priapismf. anesthes
anesthesf. arteriog arteriogf. behavior behaviorf. chg_ment chg_mentf. coordina coordinaf. ct_brain
ct_brainf. d_vision d_visionf. dif_spek dif_spekf. dizzines dizzinesf. dswallow dswallowf. dwi_perf
dwi_perff. ev_type ev_typef. head_inj head_injf. headache headachef. intervie intervief. losscons
lossconsf. mrabrain mrabrainf. mribrain mribrainf. neureval neurevalf. o_events o_eventsf. o_image
o_imagef. oth_expr oth_exprf. painful painfulf. petbrain petbrainf. pt_die pt_dief. pt_hosp pt_hospf.
pt_trans pt_transf. seizure seizuref. sensdist sensdistf. symprptd symprptdf. transdop transdopf. transfus
transfusf. weakness weaknessf. weakside weaksidef. wherseen wherseenf. witnes_e witnes_ef.;
```

STOP II TRIAL

QUASI-ADJUDICATION NEUROLOGICAL EVENT FORM

AFFIX PATIENT LABEL HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1	100.00	1	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QN-101	1	100.00	1	100.00

A1. Person completing form (Name): _____(Initials): ☐☐☐

[Variable NOT included in dataset.]

A2. Date of neurological event (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

Analysis Variable : comp_dfrmrand <created variable> A2. Date of neurological event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-138.0	.	-138.0	-138.0	-138.0	-138.0	-138.0

B. PRESENTATION

B1. Where was the patient first seen for this event? ☐ **1. STOP II Center** → B1.a. Center # ☐☐

☐ **2. Other** → B1.b _____

B1. Where was the patient first seen for this event?				
WHERSEEN	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

[Variable NOT included in dataset for Center # or specify field.]

B2. Were signs or symptoms first reported at a quarterly visit? ☐ **1. NO** ☐ **2. YES**
↓

B2. Were signs and symptoms first reported at a quarterly visit?				
SYMPRPTD	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

B2.a Date of Quarterly Progress Report (Month/Day/Year): ____ ____/____ ____/____ ____ ____ ____

Analysis Variable : qtr_datefrmrand <created variable> B2a. Date of Quarterly Progress Report as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-135.0	.	-135.0	-135.0	-135.0	-135.0	-135.0

B3. What signs or symptoms occurred?

(CHECK NO OR YES BOX FOR EACH OF B3.

	1. NO	**2. YES**
B3.a Loss of consciousness	☐	☐

B3a. Loss of consciousness				
LOSSCONS	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B3.b Change in mental status ☐ ☐

B3b. Change in mental status				
CHG_MENT	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B3.c Loss of or difficulty with speech ☐ ☐

B3c. Loss of or difficulty with speech				
DIF_SPEK	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B3.d Paralysis or weakness ☐ ☐ → B3.d1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

B3d. Paralysis or weakness				
WEAKNESS	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

B3d1. Side:				
WEAKSIDE	Frequency	Percent	Cum Freq	Cum Percent
3	1	100.00	1	100.00

1. NO **2. YES**

B3.e Difficulty with swallowing ☐ ☐

B3e. Difficulty with swallowing				
DSWALLOW	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B3.f Difficulty with vision ☐ ☐ → B3.f1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

B3f. Difficulty with vision				
D_VISION	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

[Variable NOT included in dataset for side.]

B3.g Loss of balance or dizziness ☐ ☐

B3g. Loss of balance or dizziness				
DIZZINES	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

B3.h Seizure ☐ ☐

B3h. Seizure				
SEIZURE	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B3.i Headache ☐ ☐ → B3.i1 LOCATION: ☐ **1. DIFFUSE** ☐ **2. FOCAL** ↓

B3i. Headache				
HEADACHE	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B3.i1a SPECIFY: _____

[Variables NOT included in dataset for location or specify fields.]

1. NO **2. YES**

B3.j New sensory disturbance ☐ ☐ → B3.j1 SIDE: ☐ **1. RIGHT** ☐ **2. LEFT** ☐ **3. BOTH**

B3j. New sensory disturbance				
SENSDIST	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

[Variable NOT included in dataset for side.]

B3.k Change in behavior ☐ ☐

B3k. Change in behavior				
BEHAVIOR	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B3.l Change in gait or coordination ☐ ☐

B3l. Change in gait or coordination				
COORDINA	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

B4. Was patient hospitalized for this event?

☐ **1. NO** ☐ **2. YES →**

B4.a Date of Hospital Admission (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.b Date of Hospital Discharge (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

B4.c Where was patient hospitalized? _____

_____

B4. Was patient hospitalized for this event?				
PT_HOSP	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

Analysis Variable : hospadmtfrmrand <created variable> B4a. Date of hospital admission as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-138.0	.	-138.0	-138.0	-138.0	-138.0	-138.0

Analysis Variable : hospdiscfrmrand <created variable> B4b. Date of hospital discharge as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-135.0	.	-135.0	-135.0	-135.0	-135.0	-135.0

[Variable NOT included in dataset for specify field.]

C. HISTORY

C1. Person interviewed **(SELECT PERSON PROVIDING MAJORITY OF RESPONSES)**

☐ **1. Patient** ☐ **2. Parent** ☐ **3. Other** → C1.a Specify: _____

C1. Person interviewed:				
INTERVIE	Frequency	Percent	Cum Freq	Cum Percent
3	1	100.00	1	100.00

[Variable NOT included in dataset for specify field.]

C2. Did person interviewed witness suspected event? ☐ **1. NO** ☐ **2. YES**

C2. Did person interviewed witness suspected event?				
WITNES_E	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3. Did the patient experience any of the following during the two weeks prior to the neurological event?

(CHECK NO OR YES BOX FOR EACH OF C3.a - i) **1. NO** **2. YES** **3. DON'T KNOW**

C3.a Acute febrile event ☐ ☐ ☐

C3a. Acute febrile event				
A_FEBRIL	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3.b Painful event ☐ ☐ ☐

C3b. Painful event				
PAINFUL	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

(CHECK NO OR YES BOX FOR EACH OF C3.a - i) 1. NO 2. YES 3. DON'T KNOW

C3.c Acute Chest Syndrome ☐ ☐ ☐

C3c. Acute Chest Syndrome				
A_CHEST	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3.d Acute anemia ☐ ☐ ☐

C3d. Acute anemia				
A_ANEMIA	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3.e General anesthesia ☐ ☐ ☐

C3e. General anesthesia				
ANESTHES	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3.f Priapism ☐ ☐ ☐

C3f. Priapism				
A_PRIAPISM	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3.g Head injury with loss of consciousness ☐ ☐ ☐

C3g. Head injury with loss of consciousness				
HEAD_INJ	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3.h Transfusion ☐ ☐ ☐

C3h. Transfusion				
TRANSFUS	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

(CHECK NO OR YES BOX FOR EACH OF C3.a - i) **1. NO** **2. YES** **3. DON'T KNOW**

C3.i Other ☐ ☐ ☐

C3i. Other				
OTH_EXPR	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

C3.i1 Specify _____

_____

[Variable NOT included in dataset for specify field.]

C4. DESCRIBE PERTINENT CLINICAL DETAILS OF CLINICAL EVENTS WHICH OCCURRED WITHIN THE TWO WEEKS PRECEDING THE NEUROLOGICAL EVENT

[Variable NOT included in dataset.]

D. RESULTS OF IMAGING AND ULTRASOUND TESTS PERFORMED TO EVALUATE <u>THIS EVENT</u>: (CHECK APPROPRIATE BOX FOR EACH OF D1 - 7)

D1. MRI of brain ☐ **1. NOT DONE** ☐ **2. DONE**

D1. MRI of brain				
MRIBRAIN	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

D1.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

D1.b Was DWI performed? ☐ **1. NO** ☐ **2. YES**

Analysis Variable : mri_datefrmrand <created variable> D1a. Date MRI performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-138.0	.	-138.0	-138.0	-138.0	-138.0	-138.0

D1b. Was DWI performed?				
DWI_PERF	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

D2. CT scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D2. CT scan of brain				
CT_BRAIN	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

D2.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

[Variable NOT included in dataset. Field had no data.]

D3. PET scan of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D3. PET scan of brain				
PETBRAIN	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

D3.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

[Variable NOT included in dataset. Field had no data.]

D4. MRA of brain ☐ **1. NOT DONE** ☐ **2. DONE**

↓

D4. MRA of brain				
MRABRAIN	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

D4.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : mra_datefrmrand <created variable> D4a. Date MRA performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-138.0	.	-138.0	-138.0	-138.0	-138.0	-138.0

D5. Arteriogram ☐ **1. NOT DONE** ☐ **2. DONE**
↓

D5. Arteriogram				
ARTERIOG	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

D5.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

[Variable NOT included in dataset. Field had no data.]

D6. Transcranial Doppler ☐ **1. NOT DONE** ☐ **2. DONE**
↓

D6. Transcranial Doppler				
TRANSDOP	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

D6.a Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

[Variable NOT included in dataset. Field had no data.]

D7. Other → D7.a Specify_____

☐ **1. NOT DONE** ☐ **2. DONE**
↓

D7. Other				
O_IMAGE	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

D7.b Date performed (month/day/year): ___ ___/___ ___/___ ___ ___ ___

[Variables NOT included in dataset for specify or date fields. Fields had no data.]

ATTACH COPIES OF LOCAL REPORTS FOR ALL IMAGING STUDIES COMPLETED

E. NEUROLOGICAL EVALUATION

E1. Was a neurological evaluation performed by the STOP II Neurology Consultant?

☐ **1. NO**

☐ **2. YES →** E1.a Date of exam (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

E1. Was a neurological evaluation performed ...?				
NEUREVAL	Frequency	Percent	Cum Freq	Cum Percent
2	1	100.00	1	100.00

Analysis Variable : neuro_dtfrmrand <created variable> E1a. Date neuro evaluation performed as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-98.0	.	-98.0	-98.0	-98.0	-98.0	-98.0

F. MANAGEMENT AND COMPLICATIONS

F1. Were there other events associated with this neurological event? ☐ **1. NO** ☐ **2. YES**

F1. Were there other events associated with this neuro. event?				
O_EVENTS	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

F2. Was the patient transfused for this neurological event ? ☐ **1. NO** ☐ **2. YES**

F2. Was this patient transfused for this neurological event?				
PT_TRANS	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

F3. Did the patient die as a complication of this event ? ☐ **1. NO** ☐ **2. YES**

F3. Did the patient die as a complication of this event?				
PT_DIE	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

G. FINAL LOCAL DIAGNOSIS

G1. Type of neurological event:

☐ **1. Cerebral Infarction** ☐ **2. Intracranial Hemorrhage** ☐ **3. TIA** ☐ **4. Seizure** ☐ **5. Other**
↓

G1. Type of neurological event:				
EV_TYPE	Frequency	Percent	Cum Freq	Cum Percent
5	1	100.00	1	100.00

G1.a _____

G1a. Specify:				
TYPESPEC	Frequency	Percent	Cum Freq	Cum Percent
Atypical pain crisis	1	100.00	1	100.00

Signature of Study Coordinator:_____ Date: ___ ___/___ ___/___ ___ ___ ___

H. FOR OFFICE USE

[Variables NOT included in dataset.]

H1. Imaging/ultrasound reports received: ☐ **1. NO** ☐ **2. YES**

H2. TCD received: ☐ **1. NO** ☐ **2. YES** ☐ **-1. NA (Not Done)**

STOP II
FORM Q52: QUASI-ADJUDICATION CONSENSUS

A. Collection Information:

The **Quasi-Adjudication Consensus** (Form Q52) was completed by Dr. Robert Adams for all neurological events reported for Screening and Potential patients on Form Q30 (Quasi-Adjudication Neurological Event Form.)

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 07/15/02

D. Files Used to Store Information:

SAS System File: **pq52_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, EX_TYPE, EX_NUM (vistype)**

Records in the dataset are sorted by LDU_ID and EX_TYPE, EX_NUM (vistype).

F. Number of Observations (Patients) in SAS Dataset: 1 (1)

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See p. 766
- Listing of Variables by Position: See p. 767

H. Formats:

The file **fQ52fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + "F" – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are "$"+variable name+"F" – e.g., the format label for a variable named "RATING" where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on page 768.

I. Special Value Codes:

-1 = Not Applicable
-2 = Programmed Skip
-3 = Not Done/Not Recorded
-8 = Don't Know
-9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:

- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** - is the variable name for type of visit. The only valid EX_TYPE for Form Q52 is QN.

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form Q52 are between 101-115.

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label

Data Set Name	PUBDS.PQ52_FINAL	Observations	1
Member Type	DATA	Variables	12
Engine	V9	Indexes	0
Created	Friday, February 17, 2006 04:55:25 PM	Observation Length	72
Last Modified	Friday, February 17, 2006 04:55:25 PM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	8192
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	113
Obs in First Data Page	1
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\pq52_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Informat	Label
9	DESTATUS	Char	1	$1.	DESTATUS
2	EX_NUM	Char	3	$3.	A2b. Exam Number
1	EX_TYPE	Char	2	$2.	A2a. Exam Type
3	INITS1	Char	3	$3.	B1. Reviewer #1
5	INITS2	Char	3	$3.	B2. Reviewer #2
7	NEWSTROK	Num	8	3.	D1. Is the group consensus that the patient had a new stroke?
8	NSTRKDX	Num	8	3.	D1a. If NO, type of event:
4	STROK1	Num	8	3.	B1a. Did patient have a new stroke?
6	STROK2	Num	8	3.	B2a. Did patient have a new stroke?
11	ldu_id	Char	10		ID for public use datasets
12	neuro_dtfrmrand	Num	8		<created variable> A3. Date of neurological event as days from RAND visit
10	vistype	Char	6		<created variable> VISIT TYPE

Variables in Creation Order

#	Variable	Type	Len	Informat	Label
1	EX_TYPE	Char	2	$2.	A2a. Exam Type
2	EX_NUM	Char	3	$3.	A2b. Exam Number
3	INITS1	Char	3	$3.	B1. Reviewer #1
4	STROK1	Num	8	3.	B1a. Did patient have a new stroke?
5	INITS2	Char	3	$3.	B2. Reviewer #2
6	STROK2	Num	8	3.	B2a. Did patient have a new stroke?
7	NEWSTROK	Num	8	3.	D1. Is the group consensus that the patient had a new stroke?
8	NSTRKDX	Num	8	3.	D1a. If NO, type of event:
9	DESTATUS	Char	1	$1.	DESTATUS
10	vistype	Char	6		<created variable> VISIT TYPE
11	ldu_id	Char	10		ID for public use datasets
12	neuro_dtfrmrand	Num	8		<created variable> A3. Date of neurological event as days from RAND visit

Sort Information

Sortedby	ldu_id vistype
Validated	YES
Character Set	ANSI

```
*FQ52fmts.txt;

proc format;

  value NEWSTROKF
    1='1: No'
    2='2: Yes';

  value NSTRKDXF
    1='1: TIA'
    2='2: Seizure'
    3='3: Migraine'
    4='4: Non-CNS event'
    5='5: Other'
    6='6: Cannot determine';

  value STROK1F
    1='1: No'
    2='2: Yes';

  value STROK2F
    1='1: No'
    2='2: Yes';

* format newstrok newstrokf. nstrkdx nstrkdxf. strok1 strok1f. strok2 strok2f.;
```

STOP II TRIAL
QUASI-ADJUDICATION CONSENSUS

****AFFIX PATIENT LABEL HERE****

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	1	100.00	1	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
QN-101	1	100.00	1	100.00

A1. Patient ID # ☐☐ - ☐☐☐ - ☐

A2. ACROSTIC ☐☐☐☐☐

A3 Date of neurological event (Month/Day/Year): ___ ___ / ___ ___ / ___ ___ ___ ___

Analysis Variable : neuro_dtfrmrand <created variable> A3. Date of neurological event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1	0	-138.0	.	-138.0	-138.0	-138.0	-138.0	-138.0

B. SUMMARY AND CONSENSUS FOR NEW STROKE

Individual assessments: Did patient have a new stroke?

1. Reviewer #1 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

B1. Reviewer #1				
INITS1	Frequency	Percent	Cum Freq	Cum Percent
RJA	1	100.00	1	100.00

B1a. Did patient have a new stroke?				
STROK1	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

2. Reviewer #2 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

B2. Reviewer #2				
INITS2	Frequency	Percent	Cum Freq	Cum Percent
S R	1	100.00	1	100.00

B2a. Did patient have a new stroke?				
STROK2	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

3. Reviewer #3 _____ (Initials) ☐☐☐ ☐ **1. NO** ☐ **2. YES**

[Variables NOT included in dataset. No third reviewer on any form.]

C. SUMMARY OF TELECONFERENCE (If applicable):

[Variable NOT included in dataset.]

D. GROUP CONSENSUS FOR NEW STROKE

D1. Is the group consensus that the patient had a new stroke?

☐ **1. NO** ☐ **2. YES**

D1. Is the group consensus that the patient had a new stroke?				
NEWSTROK	Frequency	Percent	Cum Freq	Cum Percent
1	1	100.00	1	100.00

D1.a If NO, type of event:

- ☐ 1. TIA
- ☐ 2. Seizure
- ☐ 3. Migraine
- ☐ 4. Non-CNS event: Specify _____
- ☐ 5. Other: Specify _____
- ☐ 6. Cannot determine

D1.b If YES, type:

- ☐ 1. Infarction
- ☐ 2. Intraparenchymal Hemorrhage
- ☐ 3. Subarachnoid Hemorrhage
- ☐ 4. Intraventricular Hemorrhage

D1a. If NO, type of event:				
NSTRKDX	Frequency	Percent	Cum Freq	Cum Percent
6	1	100.00	1	100.00

[Variables NOT included in dataset for D1.a specify fields or D1.b. Fields had no data.]

STOP II

FORM 15: HEAD MRI SCAN

A. Collection Information:

The **Head MRI Scan** (Form 15) was to be completed when a study-related MRI was performed for a Potential or Randomized patient. Potential patients were required to have an MRI performed at their pre-randomization evaluation visit only. After randomization, MRIs were required

1) at annual visits,
2) at the exit visit,
3) within 1-7 days after a suspected neurological event,
4) within 2-3 weeks after discharge for a head injury associated with loss of consciousness, and
5) at the first quarterly visit after a stroke or TCD endpoint.

For patients who became un-TCDable (defined as 3 consecutive inadequate TCDs involving at least 2 examiners) after randomization, MRIs were to be performed in conjunction with the q 6 month MRAs used to assess arterial disease in the "qualifying" segments.

MRI scans were sent for reading by a central STOP II MRI/MRA Reading Panel comprised of three neuroradiologists, two from non-STOP II institutions and one from a STOP II institution. The member located at a STOP II institution did not (in general) do the central readings of studies from his own institution. Each study (with the exception of those completed for events) was read by two panel members. In cases of disagreement, the third member of the panel adjudicated the differences.

Pre-randomization MRI studies were to be read in "real" time - i.e., films for these studies were sent to two central reviewers simultaneously upon receipt of the films at the DCC. Neurological event MRIs were also to be read in "real" time by a single central reviewer (the central reading results for the neurological event MRIs were included in the packets of materials sent to the Stroke Adjudication Panel). All other studies were to be read at batch reviews at a central location 2-4 times yearly. However, as the study (and technology) progressed, sites began to go "filmless" (except for producing films for the STOP II study) and, as a result, disposed of the large alternators needed for loading and review of large numbers of films. Because of this change, central batch readings were not feasible – i.e., it was necessary for the vast majority of all MRI studies (including annual & exit studies) to be sent to readers individually. As a result, it was not possible to obtain readings for all of the studies. Although **ALL exit studies were read**, 46 annual (11 1st annual, 25 2nd annual, and 10 3rd annual) studies distributed among 30 patients were not read and, therefore, are not included in the dataset.

Three Randomized patients (P461673108, P513261385, P330094697) have more than one pre-randomization MRI/MRA. The pre-randomization MRI/MRA closest to the randomization date is the one that is considered the baseline MRI/MRA and used for comparison with f/u studies. Three Randomized patients who were active at the end of the Trial did not complete exit MRI/MRAs: P457488024, P861919693, P250348385.

B. Data Collection Period: December 2000 through March 2005

C. Form Version Dates: 11/15/00

D. Files Used to Store Information:

SAS System Files: **p015_final.sas7bdat**

E. Unique Record Identifier Variables: **LDU_ID, COMP_DFRMRAND, READ_DTFRMRAND, les_num**

Records in the dataset are sorted by LDU_ID, COMP_DFRMRAND (MRI date), READ_DTFRMRAND, and les_num. An alternate set of unique identifiers in the dataset is LDU_ID, EX_TYPE, EX_NUM (vistype), READ_DTFRMRAND, and les_num.

The first record for each MRI (i.e., records with LES_NUM=0 or LES_NUM=1) is the "summary" record which includes values for all non-lesion fields on Form 15 + information about the first lesion in cases where there is at least one lesion. Subsequent records (those with LES_NUM>1) include values for only the unique record identifier variables and the lesion information for the specified lesion number (les_num). The values for all other fields are set to missing.

F. Number of Observations/Unique MRIs/Patients in SAS Dataset:

# of observations: 350 ("summary" record + separate record for each unique lesion)
# of MRI studies: 227
# of unique MRI studies: 226
# of patients: 79

As noted above, 46 unread annual studies for 30 patients are not included in this dataset.

G. Contents of SAS Dataset:

- Alphabetical Listing of Variables: See pp. 776-778
- Listing of Variables by Position: See pp. 779-781

H. Formats:
The file **f015fmts.txt** contains the format labels for numeric or character codes used for categorical variables in the dataset. Format names for numerical variables are the variable name + “F” – e.g., the format label for a variable named GENDER where 1=Female & 2=Male would be GENDERF. Format names for character variables are “$”+variable name+”F” – e.g., the format label for a variable named “RATING” where A=Excellent, B=Good, etc. would be $RATINGF. Format names for categorical variables in this dataset are listed on pages 782-790.

I. Special Value Codes:
- Non-Date Variables:
  -1 = Not Applicable
  -2 = Programmed Skip
  -3 = Not Done/Not Recorded
  -8 = Don't Know
  -9 = Missing

J. Date Variables:
All date variables have been calculated as days from randomization date.

K. Notes About Selected Variables:
- **DESTATUS** - is the variable name for form completion status. "C" indicates all the data on the form is complete. "P" indicates there is a pending edit (missing or unresolved data) on one or more questions on the form.

- **EX_TYPE** – is the variable name for type of visit. Valid EX_TYPEs for Form 15 are:
  - QT: for quarterly and annual visits
  - NE: for neurological events

- **EX_NUM** - is the variable name for exam number. Valid EX_NUMs for Form 15 are:
  For EX_TYPE=QT,
  - 300 series numbers were assigned to “Potential 2” visit MRIs – i.e., MRIs completed as part of the pre-randomization evaluation after a patient was on transfusion for at least 30 months and had had two consecutive normal TCDs.
  - 400 series numbers indicate visits completed after randomization
    - 401=randomization visit
    - 405, 409, or 413=annual visits

  For EX_TYPE=NE
  - 100 series numbers were used for neurological events

- **VISTYPE** - is the variable name for visit type and is a concatenation of the visit type **EX_TYPE** and visit number **EX_NUM.** This new variable is indicated in the contents by "<created variable>" in the label.

- **REASON_P** - reason for the MRI procedure. At study end, randomized patients were required to have an "Exit" MRI. If a patient had completed a routine follow-up study within 4 months of the study end date, this routine exam was counted as an exit exam and a new exit MRI was not required. Therefore, not all exit studies have a code of 3. "Exit from Study."

- **LES_NUM** - lesion number. Lesions were reported individually in a separate table in the DMS and linked to their originating form. This variable is the number of the lesion as reported on the form and is indicated in the contents by "<created variable>" in the label. If no lesions were reported, there is a single ("summary") record associated with the MRI where LES_NUM=0. If a patient had only 1 lesion, there is a single ("summary") record associated with the MRI where LES_NUM=1. If a patient had more than 1 lesion, the number of records associated with the MRI will be equal to the total number of lesions (see LES_TOT). The value of LES_NUM will be 1 in the first ("summary") record.

- **LESION** - lesion location summary. The summary variable LESION has a 14-character value, which is a re-ordered concatenation of the values of 6 variables (SIDE_F, SIZE_F, LOC1_F, LOC2_F, LOC3_F, LOC4_F) that are not individually shown in the codebook but have been retained in the dataset. This new variable is indicated in the contents by "<summary variable>" in the label. The composition of the value is as follows:

  - Position 1 is the side of the lesion: **L**=Left, **R**=Right
  - Position 3: value will be '**F**' if anatomic location is Frontal (i.e., one of LOC1-4 codes=0) or '_' if it's not
  - Position 4: value will be '**T**' if anatomic location is Temporal (i.e., one of LOC1-4 codes=1) or '_' if it's not
  - Position 5: value will be '**P**' if anatomic location is Parietal (i.e., one of LOC1-4 codes=2) or '_' if it's not
  - Position 6: value will be '**O**' if anatomic location is Occipital (i.e., one of LOC1-4 codes=3) or '_' if it's not
  - Position 7: value will be '**B**' if anatomic location is Basal ganglia (i.e., one of LOC1-4 codes=4) or '_' if it's not
  - Position 8: value will be '**A**' if anatomic location is Capsular/corona (i.e., one of LOC1-4 codes=6) or '_' if it's not
  - Position 9: value will be '**E**' if anatomic location is Cerebellum (i.e., one of LOC1-4 codes=9) or '_' if it's not
  - Position 11: value will be '**C**' if lesion extent is Cortex (i.e., one of LOC1-4 codes=5) or '_' if it's not
  - Position 12: value will be '**W**' if lesion extent is White matter/Periventricular (i.e., one of LOC1-4 codes=7) or '_' if it's not
  - Position 14: is the size of the lesion: **S**=Small (i.e., SIZE_F=0), **M**=Medium (i.e., SIZE_F=1), **L**=Large (i.e., SIZE_F=2)

- Size definitions: small (punctuate) = a few mm, medium (ovoid) = 0.5-1.5 cm, large (geographic) = ≥ 1.5 cm

- **FRONTAL, TEMPORAL, PARIETAL, OCCIPITA, BASALGAN, CORTEX, CAPSULAR, WHITEMAT, BRAINSTE, CEREBELL, CORTWHIT** - variables created using the discrete findings in LOC1_F, LOC2_F, LOC3_F and LOC4_F for each reported lesion. These variables were concatenated with the values for SIDE_F and SIZE_F in the summary variable LESION, and are not individually shown in the codebook. These new variables are indicated in the contents by "<created variable>" in the label. If a lesion was present in the location, a value of 1 was assigned. If there was no lesion in the location, the value has a SAS missing value code of '.'.

- **LES_TOT** - the total number of lesions reported on an individual study. This variable is a summary variable and has a value equal to the highest LES_NUM for a particular study. The value for this variable is stored with all lesion records but, in the summary table in this codebook, LES_TOT is counted only once using just the first record associated with an MRI visit (i.e., those with LES_NUM=0 or LES_NUM=1.) This new variable is indicated in the contents by "<summary variable>" in the label.

- **LES_CHNGFRMBASE** - This variable summarizes the change status of lesions compared to the baseline study. If at least one lesion was new, the overall lesion change status was coded as 2 (Yes, new lesion). If there were no new lesions but at least one lesion was coded as worse than at baseline, the overall lesion change status was coded as 3 (Yes, worse but no new lesion). If there was no change from baseline in the lesion status, the overall lesion change status was coded as 1 (No). The value for this variable is stored only with the first record of a follow-up (post-randomization) MRI visit (i.e., VISTYPE=QT-4xx or NE-xxx with LES_NUM=0 or LES_NUM=1.) This new variable is indicated in the contents by "<summary variable>" in the label.

- **"XXXX_SIDE"** (for frontal, parietal, temporal, occipital, basal ganglia, capsular, cerebellar) - These variables summarize the side and lobe locations of lesions; each of these variables is assigned a value of 0 (no lesion at location), 1 (left side only), 2 (right side only), or 3 (both right & left sides). The value for these variables is stored with only the first lesion record associated with an MRI visit (i.e., those with LES_NUM=0 or LES_NUM=1.) These new variables are indicated in the contents by "<summary variable>" in the label.

Data Set Name	PUBDS.P015_FINAL	Observations	350
Member Type	DATA	Variables	93
Engine	V9	Indexes	0
Created	Tuesday, April 18, 2006 09:31:12 AM	Observation Length	720
Last Modified	Tuesday, April 18, 2006 09:31:12 AM	Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	YES
Label			
Data Representation	WINDOWS_32		
Encoding	wlatin1 Western (Windows)		

Engine/Host Dependent Information

Data Set Page Size	16384
Number of Data Set Pages	17
First Data Page	1
Max Obs per Page	22
Obs in First Data Page	3
Number of Data Set Repairs	0
File Name	p:\Stop2\Data Manual\Public Use\PU Data Sets\p015_final.sas7bdat
Release Created	9.0101M3
Host Created	XP_PRO

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Format	Informat	Label
19	ACCEPTAB	Num	8		3.	D3. Study acceptable for interpretation?
22	ATROPHY	Num	8		3.	E1. Atrophy
6	BADFSPEC	Char	25		$25.	A5b. Specify other reason MRI study not adequate
5	BAD_FILM	Num	8		3.	A5a. Reason MRI study not adequate
45	BASILAR	Num	8		3.	G6. Basilar artery
46	BLD_VESS	Num	8		3.	G7. Collateral blood vessels
50	BONT_SPC	Char	25		$25.	H1a. Specify focal abnormality
49	BONYCHNG	Num	8		3.	H1. Bony changes
51	BONY_BAS	Char	2		$2.	H2a. Status of bony changes compared to pre-rand study
52	BONY_PRE	Char	2		$2.	H2b. Status of bony changes compared to previous study
62	BSTAT_F	Char	2	$2.	$2.	Status of lesion compared to pre-randomization study
11	COMPREV	Num	8		3.	C1. Is this MRI scan being compared to a previous scan?
9	DESTATUS	Char	1		$1.	DESTATUS
21	DWI_FILM	Num	8		3.	D5a. Are DWI films available for review for this study?
3	DWI_PER	Num	8		3.	A4. Was DWI performed?
16	ENCL_SPC	Char	25		$25.	C4c1. Specify other reason event CT enclosed for review
8	EV_TYPE	Num	8		3.	B1b. Type of neurological event
2	EX_NUM	Char	4		$4.	X4. Exam Number
1	EX_TYPE	Char	2		$2.	X3. Exam type
4	FILMS_OK	Num	8		3.	A5. MRI study adequate for interpretation?
53	FILM_REV	Num	8		3.	J1. Were CT films reviewed?
27	FOCAL	Num	8		3.	E3. Type of atrophy: Focal
30	FOCALSPC	Char	25		$25.	E3c. Specify areas of focal atrophy
33	FSTAT_B	Char	2		$2.	E5a. Status of focal atrophy compared to pre-randomization study
34	FSTAT_P	Char	2		$2.	E5b. Status of focal atrophy compared to previous study

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Format	Informat	Label
28	F_SULCAL	Num	8		3.	E3a. Focal atrophy: Sulcal
29	F_VENTR	Num	8		3.	E3b. Focal atrophy: Ventricular
23	GENERAL	Num	8		3.	E2. Type of atrophy: General
31	GSTAT_B	Char	2		$2.	E4a. Status of general atrophy compared to pre-rand study
32	GSTAT_P	Char	2		$2.	E4b. Status of general atrophy compared to previous study
26	G_SEV	Num	8		3.	E2c. General atrophy: Level of severity
24	G_SULCAL	Num	8		3.	E2a. General atrophy: Sulcal
25	G_VENTR	Num	8		3.	E2b. General atrophy: Ventricular
54	INTHEMOR	Num	8		3.	J3. CT scan evidence of intracranial hemorrhage?
14	INTRAHEM	Num	8		3.	C4b. Reason event CT scans enclosed: Intracranial hemorrhage?
42	LACA	Num	8		3.	G4b. Left ACA
36	LICCAVER	Num	8		3.	G1b. Left internal carotid: cavernous
38	LIC_SUPR	Num	8		3.	G2b. Left internal carotid: supraclinoid
40	LMCA	Num	8		3.	G3b. Left MCA
58	LOC1_F	Num	8	3.	3.	Discrete findings: Lesion location 1
59	LOC2_F	Num	8	3.	3.	Discrete findings: Lesion location 2
60	LOC3_F	Num	8	3.	3.	Discrete findings: Lesion location 3
61	LOC4_F	Num	8	3.	3.	Discrete findings: Lesion location 4
44	LPCA	Num	8		3.	G5b. Left PCA
13	MRI_PERF	Num	8		3.	C4a. Reason event CT scan enclosed for review
15	OTH_REAS	Num	8		3.	C4c. Reason event CT scans enclosed: Other reason?
63	PSTAT_F	Char	2	$2.	$2.	Status of lesion compared to previous study
41	RACA	Num	8		3.	G4a. Right ACA
17	READER1	Char	3		$3.	D1a. Reader 1 initials
18	READER2	Char	3		$3.	D1b. Reader 2 initials
7	REASON_P	Num	8		3.	B1. Reason for MRI procedure
35	RICCAVER	Num	8		3.	G1a. Right internal carotid: cavernous
37	RIC_SUPR	Num	8		3.	G2a. Right internal carotid: supraclinoid
39	RMCA	Num	8		3.	G3a. Right MCA
43	RPCA	Num	8		3.	G5a. Right PCA
12	SCANENCL	Num	8		3.	C2. Are event CT scans enclosed?
20	SCANQUAL	Num	8		3.	D4. Scan quality
55	SIDE_F	Char	2	$2.	$2.	Discrete findings: Lesion side
57	SIZE_F	Num	8	3.	3.	Discrete findings: Lesion size
56	TYPE_F	Char	2	$2.	$2.	Discrete findings: Lesion type
47	VASC_BAS	Char	2		$2.	G8a. Status of vasculature compared to pre-rand study
48	VASC_PRE	Char	2		$2.	G8b. Status of vasculature compared to previous study
69	basalgan	Num	8			<created variable> Location: Basal ganglia or Thalamic
83	basalgan_side	Num	8			<summary variable> Any basal ganglia lesion on scan?
89	basel_dtfrmrand	Num	8			<created variable> C1a. Date of pre-randomization study as days from RAND visit
73	brainste	Num	8			<created variable> Location: Brain stem
71	capsular	Num	8			<created variable> Location: Capsular/Corona
84	capsular_side	Num	8			<summary variable> Any capsular lesion on scan?
74	cerebell	Num	8			<created variable> Location: Cerebellum

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Format	Informat	Label
85	cerebell_side	Num	8			<summary variable> Any cerebellar lesion on scan?
87	comp_dfrmrand	Num	8			<created variable> A2. Date of MRI procedure as days from RAND visit
70	cortex	Num	8			<created variable> Location: Cortex
75	cortwhit	Num	8			<created variable> Location: Cortex and/or white matter
91	ct_datefrmrand	Num	8			<created variable> C2a. Date of CT scan as days from RAND visit
88	event_dtfrmrand	Num	8			<created variable> B1a. Date of event as days from RAND visit
65	frontal	Num	8			<created variable> Location: Frontal
79	frontal_side	Num	8			<summary variable> Any frontal lesion on scan?
86	ldu_id	Char	10			ID for public use datasets
78	les_chngfrbase	Num	8			<summary variable> Any lesion changes on scan since baseline study?
64	les_num	Num	8			<created variable> Lesion number
77	les_tot	Num	8			<summary variable> Total number of lesions reported for MRI study
76	lesion	Char	14			<summary variable> Lesion location summary
92	neuro_dtfrmrand	Num	8			<created variable> C2b. Date of neurological event as days from RAND visit
68	occipita	Num	8			<created variable> Location: Occipital
82	occipita_side	Num	8			<summary variable> Any occipital lesion on scan?
67	parietal	Num	8			<created variable> Location: Parietal
80	parietal_side	Num	8			<summary variable> Any parietal lesion on scan?
90	prev_dtfrmrand	Num	8			<created variable> C1b. Date of previous study as days from RAND visit
93	read_dtfrmrand	Num	8			<created variable> D2. Date read as days from RAND visit
66	temporal	Num	8			<created variable> Location: Temporal
81	temporal_side	Num	8			<summary variable> Any temporal lesion on scan?
10	vistype	Char	7			<created variable> VISIT TYPE
72	whitemat	Num	8			<created variable> Location: Deep white matter/perivent

Variables in Creation Order

#	Variable	Type	Len	Format	Informat	Label
1	EX_TYPE	Char	2		$2.	X3. Exam type
2	EX_NUM	Char	4		$4.	X4. Exam Number
3	DWI_PER	Num	8		3.	A4. Was DWI performed?
4	FILMS_OK	Num	8		3.	A5. MRI study adequate for interpretation?
5	BAD_FILM	Num	8		3.	A5a. Reason MRI study not adequate
6	BADFSPEC	Char	25		$25.	A5b. Specify other reason MRI study not adequate
7	REASON_P	Num	8		3.	B1. Reason for MRI procedure
8	EV_TYPE	Num	8		3.	B1b. Type of neurological event
9	DESTATUS	Char	1		$1.	DESTATUS
10	vistype	Char	7			<created variable> VISIT TYPE
11	COMPREV	Num	8		3.	C1. Is this MRI scan being compared to a previous scan?
12	SCANENCL	Num	8		3.	C2. Are event CT scans enclosed?
13	MRI_PERF	Num	8		3.	C4a. Reason event CT scan enclosed for review
14	INTRAHEM	Num	8		3.	C4b. Reason event CT scans enclosed: Intracranial hemorrhage?
15	OTH_REAS	Num	8		3.	C4c. Reason event CT scans enclosed: Other reason?
16	ENCL_SPC	Char	25		$25.	C4c1. Specify other reason event CT enclosed for review
17	READER1	Char	3		$3.	D1a. Reader 1 initials
18	READER2	Char	3		$3.	D1b. Reader 2 initials
19	ACCEPTAB	Num	8		3.	D3. Study acceptable for interpretation?
20	SCANQUAL	Num	8		3.	D4. Scan quality
21	DWI_FILM	Num	8		3.	D5a. Are DWI films available for review for this study?
22	ATROPHY	Num	8		3.	E1. Atrophy
23	GENERAL	Num	8		3.	E2. Type of atrophy: General
24	G_SULCAL	Num	8		3.	E2a. General atrophy: Sulcal
25	G_VENTR	Num	8		3.	E2b. General atrophy: Ventricular
26	G_SEV	Num	8		3.	E2c. General atrophy: Level of severity
27	FOCAL	Num	8		3.	E3. Type of atrophy: Focal
28	F_SULCAL	Num	8		3.	E3a. Focal atrophy: Sulcal
29	F_VENTR	Num	8		3.	E3b. Focal atrophy: Ventricular
30	FOCALSPC	Char	25		$25.	E3c. Specify areas of focal atrophy
31	GSTAT_B	Char	2		$2.	E4a. Status of general atrophy compared to pre-rand study
32	GSTAT_P	Char	2		$2.	E4b. Status of general atrophy compared to previous study
33	FSTAT_B	Char	2		$2.	E5a. Status of focal atrophy compared to pre-randomization study
34	FSTAT_P	Char	2		$2.	E5b. Status of focal atrophy compared to previous study
35	RICCAVER	Num	8		3.	G1a. Right internal carotid: cavernous
36	LICCAVER	Num	8		3.	G1b. Left internal carotid: cavernous
37	RIC_SUPR	Num	8		3.	G2a. Right internal carotid: supraclinoid
38	LIC_SUPR	Num	8		3.	G2b. Left internal carotid: supraclinoid
39	RMCA	Num	8		3.	G3a. Right MCA
40	LMCA	Num	8		3.	G3b. Left MCA
41	RACA	Num	8		3.	G4a. Right ACA
42	LACA	Num	8		3.	G4b. Left ACA
43	RPCA	Num	8		3.	G5a. Right PCA
44	LPCA	Num	8		3.	G5b. Left PCA
45	BASILAR	Num	8		3.	G6. Basilar artery
46	BLD_VESS	Num	8		3.	G7. Collateral blood vessels
47	VASC_BAS	Char	2		$2.	G8a. Status of vasculature compared to pre-rand study

Variables in Creation Order

#	Variable	Type	Len	Format	Informat	Label
48	VASC_PRE	Char	2		$2.	G8b. Status of vasculature compared to previous study
49	BONYCHNG	Num	8		3.	H1. Bony changes
50	BONT_SPC	Char	25		$25.	H1a. Specify focal abnormality
51	BONY_BAS	Char	2		$2.	H2a. Status of bony changes compared to pre-rand study
52	BONY_PRE	Char	2		$2.	H2b. Status of bony changes compared to previous study
53	FILM_REV	Num	8		3.	J1. Were CT films reviewed?
54	INTHEMOR	Num	8		3.	J3. CT scan evidence of intracranial hemorrhage?
55	SIDE_F	Char	2	$2.	$2.	Discrete findings: Lesion side
56	TYPE_F	Char	2	$2.	$2.	Discrete findings: Lesion type
57	SIZE_F	Num	8	3.	3.	Discrete findings: Lesion size
58	LOC1_F	Num	8	3.	3.	Discrete findings: Lesion location 1
59	LOC2_F	Num	8	3.	3.	Discrete findings: Lesion location 2
60	LOC3_F	Num	8	3.	3.	Discrete findings: Lesion location 3
61	LOC4_F	Num	8	3.	3.	Discrete findings: Lesion location 4
62	BSTAT_F	Char	2	$2.	$2.	Status of lesion compared to pre-randomization study
63	PSTAT_F	Char	2	$2.	$2.	Status of lesion compared to previous study
64	les_num	Num	8			<created variable> Lesion number
65	frontal	Num	8			<created variable> Location: Frontal
66	temporal	Num	8			<created variable> Location: Temporal
67	parietal	Num	8			<created variable> Location: Parietal
68	occipita	Num	8			<created variable> Location: Occipital
69	basalgan	Num	8			<created variable> Location: Basal ganglia or Thalamic
70	cortex	Num	8			<created variable> Location: Cortex
71	capsular	Num	8			<created variable> Location: Capsular/Corona
72	whitemat	Num	8			<created variable> Location: Deep white matter/perivent
73	brainste	Num	8			<created variable> Location: Brain stem
74	cerebell	Num	8			<created variable> Location: Cerebellum
75	cortwhit	Num	8			<created variable> Location: Cortex and/or white matter
76	lesion	Char	14			<summary variable> Lesion location summary
77	les_tot	Num	8			<summary variable> Total number of lesions reported for MRI study
78	les_chngfrbase	Num	8			<summary variable> Any lesion changes on scan since baseline study?
79	frontal_side	Num	8			<summary variable> Any frontal lesion on scan?
80	parietal_side	Num	8			<summary variable> Any parietal lesion on scan?
81	temporal_side	Num	8			<summary variable> Any temporal lesion on scan?
82	occipita_side	Num	8			<summary variable> Any occipital lesion on scan?
83	basalgan_side	Num	8			<summary variable> Any basal ganglia lesion on scan?
84	capsular_side	Num	8			<summary variable> Any capsular lesion on scan?
85	cerebell_side	Num	8			<summary variable> Any cerebellar lesion on scan?
86	ldu_id	Char	10			ID for public use datasets
87	comp_dfrmrand	Num	8			<created variable> A2. Date of MRI procedure as days from RAND visit
88	event_dtfrmrand	Num	8			<created variable> B1a. Date of event as days from RAND visit

Variables in Creation Order

#	Variable	Type	Len	Format	Informat	Label
89	basel_dtfrmrand	Num	8			<created variable> C1a. Date of pre-randomization study as days from RAND visit
90	prev_dtfrmrand	Num	8			<created variable> C1b. Date of previous study as days from RAND visit
91	ct_datefrmrand	Num	8			<created variable> C2a. Date of CT scan as days from RAND visit
92	neuro_dtfrmrand	Num	8			<created variable> C2b. Date of neurological event as days from RAND visit
93	read_dtfrmrand	Num	8			<created variable> D2. Date read as days from RAND visit

Sort Information

Sortedby	ldu_id comp_dfrmrand read_dtfrmrand les_num
Validated	YES
Character Set	ANSI

```
*F015.txt;

proc format;

  value BAD_FILMF
    1='1: Incomplete study'
    2='2: Motion artifact'
    3='3: Other';

  value DWI_PERF
    1='1: No'
    2='2: Yes';

  value EV_TYPEF
    1='1: TIA'
    2='2: Cerebral infarction'
    3='3: Intracranial hemorrhage'
    4='4: Other';

  value FILMS_OKF
    1='1: No'
    2='2: Yes';

  value REASON_PF
    1='1: Pre-randomization study'
    2='2: Routine follow-up study'
    3='3: Exit from study'
    4='4: TCD endpoint or 3 inadequate TCD exams'
    5='5: New neurological event'
    6='6: Post-meningitis event'
    7='7: Post-head injury event';

  value ACCEPTABF
    1='1: No'
    2='2: Yes';

  value ATROPHYF
    1='1: No atrophy'
    2='2: Atrophy'
    3='3: Equivocal';

  value BASILARF
    0='0: Not seen (technically)'
    1='1: Visualized (Patent)'
    2='2: Occluded';

  value BLD_VESSF
    1='1: Right'
    2='2: Left'
    3='3: Both'
    4='4: Not present';
```

```
value $BONY_BASF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value $BONY_PREF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value BONYCHNGF
  1='1: Normal'
  2='2: Diffuse thickening'
  3='3: Focal abnormality';

value $BSTAT_FF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value COMPREVF
  1='1: No'
  2='2: Yes';

value DWI_FILMF
  1='1: No'
  2='2: Yes';

value F_SULCALF
  1='1: No'
  2='2: Yes';

value F_VENTRF
  1='1: No'
  2='2: Yes';

value FILM_REVF
  1='1: No'
  2='2: Yes';

value FOCALF
  1='1: No'
  2='2: Yes';
```

```
value $FSTAT_BF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value $FSTAT_PF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value G_SEVF
  1='1: Mild'
  2='2: Moderate'
  3='3: Severe';

value G_SULCALF
  1='1: No'
  2='2: Yes';

value G_VENTRF
  1='1: No'
  2='2: Yes';

value GENERALF
  1='1: No'
  2='2: Yes';

value $GSTAT_BF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value $GSTAT_PF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value INTHEMORF
  1='1: No'
  2='2: Yes';
```

```
value INTRAHEMF
  1='1: Not Checked'
  2='2: Checked';

value LACAF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value LIC_SUPRF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value LICCAVERF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value LMCAF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value LOC1_FF
  0='0: Frontal'
  1='1: Temporal'
  2='2: Parietal'
  3='3: Occipital'
  4='4: Basal ganglia or Thalamic'
  5='5: Cortex'
  6='6: Capsular/Corona'
  7='7: Deep white mattter or periventricular'
  8='8: Brain stem'
  9='9: Cerebellum'
  10='10: Subarachnoid'
  11='11: Intraventricular';

value LOC2_FF
  0='0: Frontal'
  1='1: Temporal'
  2='2: Parietal'
  3='3: Occipital'
  4='4: Basal ganglia or Thalamic'
  5='5: Cortex'
  6='6: Capsular/Corona'
  7='7: Deep white mattter or periventricular'
  8='8: Brain stem'
  9='9: Cerebellum'
  10='10: Subarachnoid'
  11='11: Intraventricular';
```

```
value LOC3_FF
  0='0: Frontal'
  1='1: Temporal'
  2='2: Parietal'
  3='3: Occipital'
  4='4: Basal ganglia or Thalamic'
  5='5: Cortex'
  6='6: Capsular/Corona'
  7='7: Deep white mattter or periventricular'
  8='8: Brain stem'
  9='9: Cerebellum'
  10='10: Subarachnoid'
  11='11: Intraventricular';

value LOC4_FF
  0='0: Frontal'
  1='1: Temporal'
  2='2: Parietal'
  3='3: Occipital'
  4='4: Basal ganglia or Thalamic'
  5='5: Cortex'
  6='6: Capsular/Corona'
  7='7: Deep white mattter or periventricular'
  8='8: Brain stem'
  9='9: Cerebellum'
  10='10: Subarachnoid'
  11='11: Intraventricular';

value LPCAF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value MRI_PERFF
  1='1: Not Checked'
  2='2: Checked';

value OTH_REASF
  1='1: Not Checked'
  2='2: Checked';

value $PSTAT_FF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";

value RACAF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';
```

```
value RIC_SUPRF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value RICCAVERF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value RMCAF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value RPCAF
  0='0: Not seen (technically)'
  1='1: Visualized (Patent)'
  2='2: Occluded';

value SCANENCLF
  1='1: No'
  2='2: Yes';

value SCANQUALF
  1='1: Excellent'
  2='2: Adequate, slight artifact/motion'
  3='3: Inadequate, severe artifact/motion';

value $SIDE_FF
  "R"="R: Right"
  "L"="L: Left";

value SIZE_FF
  0='0: Small (punctate)'
  1='1: Medium (ovoid)'
  2='2: Large (geographic)';

value $TYPE_FF
  "H"="H: Hemorrhage"
  "I"="I: Infarct"
  "HI"="HI: Hemorrhagic infarct";

value $VASC_BASF
  "A"="A: Improved"
  "B"="B: Same"
  "C"="C: New"
  "D"="D: Worse"
  "E"="E: Cannot Determine"
  "F"="F: N/A";
```

```
  value $VASC_PREF
    "A"="A: Improved"
    "B"="B: Same"
    "C"="C: New"
    "D"="D: Worse"
    "E"="E: Cannot Determine"
    "F"="F: N/A";

value frontalF
    1='1: Yes'
     .= '.: No';

value temporalF
    1='1: Yes'
     .= '.: No';

value parietalF
    1='1: Yes'
     .= '.: No';

value occipitaF
    1='1: Yes'
     .= '.: No';

value basalganF
    1='1: Yes'
     .=  '.: No';

value capsularF
    1='1: Yes'
     .= '.: No';

value brainsteF
    1='1: Yes'
     .=  '.: No';

value cerebellF
    1='1: Yes'
     .=  '.: No';

value cortexF
    1='1: Yes'
    .= '.: No';

value whitematF
    1='1: Yes'
     .=  '.: No';

value cortwhiteF
    1='1: Yes
    .=  '.: No';
```

```
value les_chngfrbaseF
    1='1: No'
    2='2: Yes, new lesion'
    3='3: Yes, worse but no new lesion';

value frontal_sideF
     0='0: No'
     1='1: Left'
     2='2: Right'
     3='3: Both Left & Right';

value parietal_sideF
     0='0: No'
     1='1: Left'
     2='2: Right'
     3='3: Both Left & Right';

value temporal_sideF
    0='0: No'
    1='1: Left'
    2='2: Right'
    3='3: Both Left & Right';

value occipita_sideF
     0='0: No'
     1='1: Left'
     2='2: Right'
     3='3: Both Left & Right';

value basalgan_sideF
     0='0: No'
    1='1: Left'
    2='2: Right'
    3='3: Both Left & Right';

value capsular_sideF
     0='0: No'
    1='1: Left'
     2='2: Right'
     3='3: Both Left & Right';

 value cerebell_sideF
     0='0: No'
     1='1: Left'
     2='2: Right'
     3='3: Both Left & Right';


* format bad_film bad_filmf. dwi_per dwi_perf. ev_type ev_typef. films_ok films_okf. on_disk reason_p
reason_pf. acceptab acceptabf. atrophy atrophyf. basilar basilarf. bld_vess bld_vessf. bony_bas
$bony_basf. bony_pre $bony_pref. bonychng bonychngf. bstat_f $bstat_ff. comprev comprevf. dwi_film
dwi_filmf. f_sulcal f_sulcalf. f_ventr f_ventrf. film_rev film_revf. focal focalf. fstat_b $fstat_bf. fstat_p
$fstat_pf. g_sev g_sevf. g_sulcal g_sulcalf. g_ventr g_ventrf. general generalf. gstat_b $gstat_bf. gstat_p
$gstat_pf. inthemor inthemorf. intrahem intrahemf. laca lacaf. lic_supr lic_suprf. liccaver liccaverf. lmca
lmcaf. loc1_f loc1_ff. loc2_f loc2_ff. loc3_f loc3_ff. loc4_f loc4_ff. lpca lpcaf. mri_perf mri_perff. oth_reas
oth_reasf. pstat_f $pstat_ff. raca racaf. ric_supr ric_suprf. riccaver riccaverf. rmca rmcaf. rpca rpcaf.
```

scanencl scanenclf. scanqual scanqualf. side_f $side_ff. size_f size_ff. type_f $type_ff. vasc_bas $vasc_basf. vasc_pre $vasc_pref. frontal frontalF. temporal temporalF. parietal parietalF. occipita occipitaF. basalgan basalganF. capsular capsularF. brainste brainsteF. cerebell cerebellF. cortex cortexF. whitemat whitematF. cortwhite cortwhiteF. les_chngfrbase les_chngfrbaseF. frontal_side frontal_sideF. parietal_side parietal_sideF. temporal_side temporal_sideF. occipita_side occipita_sideF. basalgan_side basalgan_sideF. capsular_side capsular_sideF. cerebell_side cerebell_sideF.;

STOP II TRIAL
HEAD MRI SCAN

AFFIX PATIENT LABEL

HERE

DESTATUS				
DESTATUS	Frequency	Percent	Cum Freq	Cum Percent
C	227	100.00	227	100.00

<created variable> VISIT TYPE				
vistype	Frequency	Percent	Cum Freq	Cum Percent
NE-101	28	8.00	28	8.00
NE-102	1	0.29	29	8.29
QT-301	31	8.86	60	17.14
QT-301A	22	6.29	82	23.43
QT-302	11	3.14	93	26.57
QT-302A	4	1.14	97	27.71
QT-302B	1	0.29	98	28.00
QT-303	12	3.43	110	31.43
QT-303A	1	0.29	111	31.71
QT-304	18	5.14	129	36.86
QT-304B	1	0.29	130	37.14
QT-305	5	1.43	135	38.57
QT-306	2	0.57	137	39.14
QT-306A	1	0.29	138	39.43
QT-307	4	1.14	142	40.57
QT-308B	5	1.43	147	42.00
QT-309	1	0.29	148	42.29
QT-309A	1	0.29	149	42.57
QT-403	29	8.29	178	50.86
QT-404	5	1.43	183	52.29
QT-405	80	22.86	263	75.14
QT-407	1	0.29	264	75.43
QT-408	9	2.57	273	78.00
QT-409	29	8.29	302	86.29
QT-411	2	0.57	304	86.86
QT-412	3	0.86	307	87.71
QT-413	25	7.14	332	94.86
QT-415	13	3.71	345	98.57
QT-416	5	1.43	350	100.00

SECTION A TO BE COMPLETED BY STOP II NEURORADIOLOGIST

A1. Person completing form (Name): _____ (Initials): | | | |

[Variable NOT included in dataset.]

A2. Date of MRI procedure (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : comp_dfrmrand <created variable> A2. Date of MRI procedure as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
350	0	341.4	424.5	-483.0	-36.0	296.5	623.0	1399.0

A3. Was the patient's MRI data copied to a STOP II optical disk? ☐ **1. NO** ☐ **2. YES**

↓

A3.a What is the file name of the patient's MR study on the STOP II Optical Disk?

_____

[Variables NOT included in dataset.]

A4. Was DWI performed (<u>required</u> only for suspected neurological events)? ☐ **1. NO** ☐ **2. YES** ☐ **-1 N/A**

A4. Was DWI performed?				
DWI_PER	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-1	23	6.57	146	41.71
1	42	12.00	188	53.71
2	162	46.29	350	100.00

A5. Is the MRI study adequate for interpretation? ☐ **1. NO** ☐ **2. YES**

A5. MRI study adequate for interpretation?				
FILMS_OK	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	5	1.43	128	36.57
2	222	63.43	350	100.00

A5.a. Reason
☐ 1. Incomplete Study
☐ 2. Motion Artifact
☐ 3. Other
↓
A5.b Specify:_____
_____

RESCHEDULE STUDY WITHIN 2 WEEKS

A5a. Reason MRI study not adequate				
BAD_FILM	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	222	63.43	345	98.57
1	1	0.29	346	98.86
2	1	0.29	347	99.14
3	3	0.86	350	100.00

A5b. Specify other reason MRI study not adequate				
BADFSPEC	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	224	64.00	347	99.14
Braces	1	0.29	348	99.43
braces artifact	1	0.29	349	99.71
dental, metalic, artifact	1	0.29	350	100.00

A6. Is there evidence for any of the following?

A6.a. Aneurysm ☐ 1. NO ☐ 2. YES
↓
A6.a1. Location: _____

[Variables NOT included in dataset.]

A6.b. Arteriovenous malformation ☐ 1. NO ☐ 2. YES
↓
A6.b1. Location: _____

[Variables NOT included in dataset.]

A6.c. Tumor ☐ 1. NO ☐ 2. YES
↓
A6.c1. Location: _____

[Variables NOT included in dataset.]

****IF THE ANSWER TO ANY OF QUESTIONS A6.a. – A6.c. IS YES, PLEASE CONTACT CENTER INVESTIGATOR ****

SECTION B TO BE COMPLETED BY STUDY COORDINATOR

B1. Reason for MRI procedure:

☐ 1. Pre-Randomization Study ☐ 2. Routine Follow-up Study

☐ 3. Exit from Study ☐ 4. TCD Endpoint or 3 inadequate TCD exams by at least 2 examiners

☐ 5. New Neurological Event

B1. Reason for MRI procedure				
REASON_P	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	83	23.71	206	58.86
2	65	18.57	271	77.43
3	55	15.71	326	93.14
4	14	4.00	340	97.14
5	10	2.86	350	100.00

B1.a. Date of event (Month/Day Year) ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : event_dtfrmrand <created variable> B1a. Date of event as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
10	0	361.1	335.5	51.0	151.0	235.0	522.0	991.0

<created variable> B1a. Date of event as days from RAND visit				
event_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	340	100.00	340	100.00

B1.b. Type of event:

☐ 1. TIA

☐ 2. Cerebral Infarction

☐ 3. Intracranial Hemorrhage →B1.b1. Type ☐ 1. Intraparenchymal ☐ 2. Subarachnoid ☐ 3. Intraventricular

☐ 4. Other: → B1.b2. Specify: _____

☐ 6. Post-meningitis event → B1.c. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.d. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

☐ 7. Post-head injury event → B1.e. Date of event (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1.f. Date of discharge from hospital (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

B1b. Type of neurological event				
EV_TYPE	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	217	62.00	340	97.14
1	2	0.57	342	97.71
2	2	0.57	344	98.29
4	6	1.71	350	100.00

[No intracranial hemorrhage reported. Variable for question B1.b1 Type NOT included in dataset.]

[Variable NOT included in dataset for question B1.b2. Other: Specify.]

[No post-meningitis or post-head injury events reported. Variables for date fields NOT included in dataset.]

B2. Date optical disk with MRI study sent to the STOP II Data Coordinating Center (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

[Variable NOT included in dataset.]

SECTION C TO BE COMPLETED BY DCC DATA MANAGER

C1. Is this MRI scan being compared to a previous scan? ☐ 1. NO ☐ 2. YES

C1. Is this MRI scan being compared to a previous scan?				
COMPREV	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	82	23.43	205	58.57
2	145	41.43	350	100.00

↓

Which Scan(s)?
C.1.a. Pre-randomization scan dated ___ ___/___ ___/___ ___ ___ ___

C.1.b. Previous scan dated ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : basel_dtfrmrand <created variable> C1a. Date of pre-randomization study as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
145	0	-45.4	21.8	-121.0	-56.0	-42.0	-29.0	-16.0

<created variable> C1a. Date of pre-randomization study as days from RAND visit				
basel_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	205	100.00	205	100.00

Analysis Variable : prev_dtfrmrand <created variable> C1b. Date of previous study as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
46	0	483.3	301.2	83.0	216.0	366.0	734.0	1114.0

<created variable> C1b. Date of previous study as days from RAND visit				
prev_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	304	100.00	304	100.00

C2. Are event CT scans enclosed? ☐ 1. NO ☐ 2. YES

C2. Are event CT scans enclosed?				
SCANENCL	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	225	64.29	348	99.43
2	2	0.57	350	100.00

C2.a. Date of CT scan (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

C2.b. Date of neurological event (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : ct_datefrmrand <created variable> C2a. Date of CT scan as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	173.0	172.5	51.0	51.0	173.0	295.0	295.0

<created variable> C2a. Date of CT scan as days from RAND visit

ct_datefrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	348	100.00	348	100.00

Analysis Variable : neuro_dtfrmrand <created variable> C2b. Date of neurological event as days from RAND visit

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	173.0	172.5	51.0	51.0	173.0	295.0	295.0

<created variable> C2b. Date of neurological event as days from RAND visit

neuro_dtfrmrand	Frequency	Percent	Cum Freq	Cum Percent
.	348	100.00	348	100.00

C3. Type of neurological event:

- ☐ 1. TIA
- ☐ 2. Cerebral Infarction
- ☐ 3. Intracranial Hemorrhage → C3.a. Type
  - ☐ 1. Intraparenchymal
  - ☐ 2. Subarachnoid
  - ☐ 3. Intraventricular
- ☐ 4. Other: → C3.b Specify: _____

[Variables NOT included in dataset.]

C4. Reason event CT scan enclosed for review (CHECK ALL APPLICABLE):

☐ 1. MRI was not performed

☐ 2. Patient had an intracranial hemorrhage

☐ 3. Other: → C4.a Specify: _____

C4a. Reason event CT scan enclosed for review				
MRI_PERF	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	225	64.29	348	99.43
1	2	0.57	350	100.00

C4b. Reason event CT scans enclosed: Intracranial hemorrhage?				
INTRAHEM	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	225	64.29	348	99.43
1	2	0.57	350	100.00

C4c. Reason event CT scans enclosed: Other reason?				
OTH_REAS	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	225	64.29	348	99.43
2	2	0.57	350	100.00

C4c1. Specify other reason event CT enclosed for review				
ENCL_SPC	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	225	64.29	348	99.43
ordered	1	0.29	349	99.71
ordered by clinic	1	0.29	350	100.00

SECTIONS D - J TO BE COMPLETED BY READERS

D1. Readers: a. (Name): _____ (Initials): | | | |

b. (Name): _____ (Initials): | | | |

D1a. Reader 1 initials				
READER1	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
FM	9	2.57	132	37.71
JAB	45	12.86	177	50.57
RZ	173	49.43	350	100.00

D1b. Reader 2 initials				
READER2	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-1	8	2.29	131	37.43
FM	151	43.14	282	80.57
JAB	54	15.43	336	96.00
RZ	14	4.00	350	100.00

D2 Date read (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

Analysis Variable : read_dtfrmrand <created variable> D2. Date read as days from RAND visit								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
350	0	582.2	580.4	-463.0	-16.0	557.0	1212.0	1691.0

D3. Study acceptable for interpretation? ☐ 1. NO ☐ 2. YES

D3. Study acceptable for interpretation?				
ACCEPTAB	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
2	227	64.86	350	100.00

↓

D3.a. Reason: *[Variable NOT included in dataset.]*

D4. **SCAN QUALITY (CHECK ONE):**

☐ 1. Excellent

☐ 2. Slight Artifact/Motion, Adequate

☐ 3. Severe Artifact/Motion, Inadequate

D4. Scan quality				
SCANQUAL	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	8	2.29	131	37.43
2	218	62.29	349	99.71
3	1	0.29	350	100.00

D5. **DWI**

D5.a Are DWI films available for review for this study? ☐ **1. NO**

☐ **2. YES**

D5a. Are DWI films available for review for this study?				
DWI_FILM	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	57	16.29	180	51.43
2	170	48.57	350	100.00

E1. ATROPHY (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

E1. Atrophy				
ATROPHY	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	212	60.57	335	95.71
2	15	4.29	350	100.00

↓

Type of atrophy:

E2. GENERAL: ☐ 1. NO ☐ 2. YES

E2. Type of atrophy: General				
GENERAL	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	212	60.57	335	95.71
1	13	3.71	348	99.43
2	2	0.57	350	100.00

↓

a. Sulcal ☐ 1. NO ☐ 2. YES

E2a. General atrophy: Sulcal				
G_SULCAL	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	225	64.29	348	99.43
1	2	0.57	350	100.00

b. Ventricular ☐ 1. NO ☐ 2. YES

E2b. General atrophy: Ventricular				
G_VENTR	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	225	64.29	348	99.43
2	2	0.57	350	100.00

c. Level of severity ☐ 1. MILD ☐ 2. MODERATE ☐ 3. SEVERE

E2c. General atrophy: Level of severity				
G_SEV	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	225	64.29	348	99.43
1	2	0.57	350	100.00

E3. FOCAL: ☐ 1. NO ☐ 2. YES

E3. Type of atrophy: Focal				
FOCAL	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	212	60.57	335	95.71
1	2	0.57	337	96.29
2	13	3.71	350	100.00

↓

a. Sulcal ☐ 1. NO ☐ 2. YES

E3a. Focal atrophy: Sulcal				
F_SULCAL	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	214	61.14	337	96.29
1	2	0.57	339	96.86
2	11	3.14	350	100.00

b. Ventricular ☐ 1. NO ☐ 2. YES

E3b. Focal atrophy: Ventricular				
F_VENTR	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	214	61.14	337	96.29
1	8	2.29	345	98.57
2	5	1.43	350	100.00

c. Specify Area(s): c1. _____

E3c. Specify areas of focal atrophy				
FOCALSPC	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	214	61.14	337	96.29
L. frontal horn	1	0.29	338	96.57
L. lat. vent. front. horn	1	0.29	339	96.86
R .TEMP. POST- AVM RESECT	1	0.29	340	97.14
R Parietal; R Post-Temora	1	0.29	341	97.43
R TEMPORAL POST AVM RESEC	1	0.29	342	97.71
R TEMPORAL POST-AVM RESEC	1	0.29	343	98.00
R Temp 2dry to AVM repair	2	0.57	345	98.57
R parietal concavity	1	0.29	346	98.86
R post temp occ, R pariet	1	0.29	347	99.14
Right Post Temporal	1	0.29	348	99.43
Right Temporal	1	0.29	349	99.71
Right parietal medially	1	0.29	350	100.00

USE THE FOLLOWING CODES FOR QUESTIONS E4 AND E5

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

E4. Status of *Generalized* atrophy compared to: **(Enter Code)**

a. Pre-randomization Study [ ]

b. Previous Study [ ]

E4a. Status of general atrophy compared to pre-rand study				
GSTAT_B	Frequency	Percent	Cum Freq	Cum Percent
	121	34.57	121	34.57
-2	82	23.43	203	58.00
B	147	42.00	350	100.00

E4b. Status of general atrophy compared to previous study				
GSTAT_P	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	82	23.43	205	58.57
B	47	13.43	252	72.00
F	98	28.00	350	100.00

USE THE FOLLOWING CODES FOR QUESTIONS E4 AND E5

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

	a. Pre-randomization Study	b. Previous Study
E5. Status of *Focal* atrophy compared to: **(Enter Code)**		
If NEW, specify new area(s):	a1. _____	b1. _____
	a2. _____	b2. _____
	a3. _____	b3. _____

E5a. Status of focal atrophy compared to pre-randomization study

FSTAT_B	Frequency	Percent	Cum Freq	Cum Percent
	121	34.57	121	34.57
-2	82	23.43	203	58.00
B	147	42.00	350	100.00

E5b. Status of focal atrophy compared to previous study

FSTAT_P	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	82	23.43	205	58.57
B	47	13.43	252	72.00
F	98	28.00	350	100.00

[No new atrophy reported. Variables for specify fields NOT included in dataset.]

F. DISCRETE FINDINGS (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Improved B = Same (no progression) C = NEW lesion D = Worse (progression) E = Cannot determine F = N/A

	a.	b.	c.	d.	e.	f.	g.	h.	i.
				LOCATION(S)				STATUS COMPARED TO	
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	Pre-rand. Study	Previous Study
1.									
2.									
3.									
4.									
5.									
6.									
7.									

<summary variable> Total number of lesions reported for MRI study

les_tot	Frequency	Percent	Cum Freq	Cum Percent
0	161	70.93	161	70.93
1	23	10.13	184	81.06
2	7	3.08	191	84.14
3	14	6.17	205	90.31
4	10	4.41	215	94.71
5	5	2.20	220	96.92
6	4	1.76	224	98.68
7	3	1.32	227	100.00

[The value for LES_TOT is stored with all lesion records but, for the summary table, LES_TOT is counted only once using just the first record associated with an MRI visit (i.e., those with LES_NUM=0 or LES_NUM=1)]

Lesion summary table						
		N & % of Total # of MRI studies read				
Variable Label	Variable Name	0: No	1: Left	2: Right	3: Both Left & Right	Total # of MRI studies
<summary variable> Any **basal ganglia** lesion on scan?	basalgan_side	217 95.59	8 3.52	2 1.88	0 0.00	227
<summary variable> Any **capsular** lesion on scan?	capsular_side	224 98.68	3 1.32	0 0.00	0 0.00	227
<summary variable> Any **cerebellar** lesion on scan?	cerebell_side	227 100.00	0 0.00	0 0.00	0 0.00	227
<summary variable> Any **frontal** lesion on scan?	frontal_side	172 75.77	14 6.17	17 7.49	24 10.57	227
<summary variable> Any **occipital** lesion on scan?	occipita_side	224 98.68	0 0.00	3 1.32	0 0.00	227
<summary variable> Any **parietal** lesion on scan?	parietal_side	181 79.74	17 7.49	20 8.81	9 3.96	227
<summary variable> Any **temporal** lesion on scan?	temporal_side	221 97.36	2 0.88	4 1.76	0 0.00	227

[The values for these summary variables are stored with the first record associated with an MRI visit (i.e., those with LES_NUM=0 or LES_NUM=1)]

<summary variable> Any lesion changes on scan since baseline study?				
les_chngfrbase	Frequency	Percent	Cum Freq	Cum Percent
1	142	97.93	142	97.93
2	3	2.07	145	100.00

[LES_CHNGFRBASE Codes: 1 - No; 2 - Yes, new lesion; 3 - Yes, worse but no new lesion]

	a.	b.	c.	d.	e.	f.	g.	h.	i.
				LOCATION(S)				STATUS COMPARED TO	
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	Pre-rand. Study	Previous Study
(LES_NUM)	(SIDE_F)	(TYPE_F)	(SIZE_F)	(LOC1_F)	(LOC1_F)	(LOC1_F)	(LOC1_F)	(BSTAT_F)	(PSTAT_F)
1.									

[The summary variable LESION has a 14-character value, which is a re-ordered concatenation of the values of 6 variables (SIDE_F, SIZE_F, LOC1_F, LOC2_F, LOC3_F, LOC4_F) that are not individually shown in the codebook but have been retained in the dataset. The composition of the value is as follows:

Position 1 is the side of the lesion: **L**=Left, **R**=Right
Position 3: value will be '**F**' if anatomic location is Frontal (i.e., one of LOC1-4 codes=0) or '_' if it's not
Position 4: value will be '**T**' if anatomic location is Temporal (i.e., one of LOC1-4 codes=1) or '_' if it's not
Position 5: value will be '**P**' if anatomic location is Parietal (i.e., one of LOC1-4 codes=2) or '_' if it's not
Position 6: value will be '**O**' if anatomic location is Occipital (i.e., one of LOC1-4 codes=3) or '_' if it's not
Position 7: value will be '**B**' if anatomic location is Basal ganglia (i.e., one of LOC1-4 codes=4) or '_' if it's not
Position 8: value will be '**A**' if anatomic location is Capsular/corona (i.e., one of LOC1-4 codes=6) or '_' if it's not
Position 9: value will be '**E**' if anatomic location is Cerebellum (i.e., one of LOC1-4 codes=9) or '_' if it's not
Position 11: value will be '**C**' if lesion extent is Cortex (i.e., one of LOC1-4 codes=5) or '_' if it's not
Position 12: value will be '**W**' if lesion extent is White matter/Periventricular (i.e., one of LOC1-4 codes=7) or '_' if it's not
Position 14: is the size of the lesion: **S**=Small (i.e., SIZE_F=0), **M**=Medium (i.e., SIZE_F=1), **L**=Large (i.e., SIZE_F=2)
Size definitions: small (punctuate) = a few mm, medium (ovoid) = 0.5-1.5 cm, large (geographic) = ≥ 1.5 cm]

<summary variable> Lesion location summary

lesion	Frequency	Percent	Cum Freq	Cum Percent
_____	161	46.00	161	46.00
L_F_____C__S	2	0.57	163	46.57
L_F_____W_M	16	4.57	179	51.14
L_F_____W_S	33	9.43	212	60.57
L__TP_____W_S	1	0.29	213	60.86
L__T___A____M	1	0.29	214	61.14
L___P_____W_L	2	0.57	216	61.71
L___P_____W_M	11	3.14	227	64.86
L___P_____W_S	20	5.71	247	70.57
L____B_____M	3	0.86	250	71.43
L____B_____S	9	2.57	259	74.00
L_____A___W_S	1	0.29	260	74.29
L_____A____M	1	0.29	261	74.57
L_____W_L	2	0.57	263	75.14
R_F_P_____W_M	2	0.57	265	75.71
R_F_P_____W_S	2	0.57	267	76.29
R_F_P_____M	2	0.57	269	76.86
R_F_P_____S	2	0.57	271	77.43
R_F_____C__S	1	0.29	272	77.71
R_F_____W_M	10	2.86	282	80.57
R_F_____W_S	29	8.29	311	88.86
R__T_____W_S	1	0.29	312	89.14

<summary variable> Lesion location summary (continued)				
lesion	Frequency	Percent	Cum Freq	Cum Percent
R___PO_____W_S	2	0.57	314	89.71
R___P_____CW_L	2	0.57	316	90.29
R___P_____W_L	1	0.29	317	90.57
R___P_____W_M	18	5.14	335	95.71
R___P_____W_S	12	3.43	347	99.14
R_____B_____S	3	0.86	350	100.00

Discrete findings: Lesion type				
TYPE_F	Frequency	Percent	Cum Freq	Cum Percent
	161	46.00	161	46.00
I	189	54.00	350	100.00

Status of lesion compared to pre-randomization study				
BSTAT_F	Frequency	Percent	Cum Freq	Cum Percent
	161	46.00	161	46.00
B	116	33.14	277	79.14
C	9	2.57	286	81.71
D	3	0.86	289	82.57
F	61	17.43	350	100.00

Status of lesion compared to previous study				
PSTAT_F	Frequency	Percent	Cum Freq	Cum Percent
	161	46.00	161	46.00
A	1	0.29	162	46.29
B	30	8.57	192	54.86
C	1	0.29	193	55.14
F	157	44.86	350	100.00

G. VASCULATURE (COMPLETE THE TABLE USING THE FOLLOWING CODES):

DESCRIPTION CODES:
0 = NOT SEEN (Technically)
1 = VISUALIZED - PATENT
2 = OCCLUDED
3 = DISEASED

	a. RIGHT	b. LEFT
G1. Internal carotid: cavernous		

G1a. Right internal carotid: cavernous				
RICCAVER	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	2	0.57	125	35.71
1	225	64.29	350	100.00

G1b. Left internal carotid: cavernous				
LICCAVER	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	2	0.57	125	35.71
1	225	64.29	350	100.00

G2. Internal carotid: supraclinoid		

G2a. Right internal carotid: supraclinoid				
RIC_SUPR	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	2	0.57	125	35.71
1	225	64.29	350	100.00

G2b. Left internal carotid: supraclinoid				
LIC_SUPR	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	2	0.57	125	35.71
1	225	64.29	350	100.00

DESCRIPTION CODES:

0 = NOT SEEN (Technically)
1 = VISUALIZED - PATENT
2 = OCCLUDED
3 = DISEASED

G3. MCA

a. RIGHT **b. LEFT**

G3a. Right MCA				
RMCA	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
0	1	0.29	125	35.71
1	225	64.29	350	100.00

G3b. Left MCA				
LMCA	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
0	1	0.29	125	35.71
1	225	64.29	350	100.00

G4. ACA

G4a. Right ACA				
RACA	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
1	226	64.57	350	100.00

G4b. Left ACA				
LACA	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
1	226	64.57	350	100.00

DESCRIPTION CODES:

0 = NOT SEEN (Technically)
1 = VISUALIZED - PATENT
2 = OCCLUDED
3 = DISEASED

G5. PCA

a. RIGHT **b. LEFT**

G5a. Right PCA				
RPCA	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
0	1	0.29	125	35.71
1	225	64.29	350	100.00

G5b. Left PCA				
LPCA	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
0	2	0.57	126	36.00
1	224	64.00	350	100.00

G6. Basilar

G6. Basilar artery				
BASILAR	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
1	226	64.57	350	100.00

G7. Collateral Blood Vessels **(CHECK ONE):** 1. RIGHT 2. LEFT 3. BOTH 4. NOT PRESENT

G7. Collateral blood vessels				
BLD_VESS	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-9	1	0.29	124	35.43
1	1	0.29	125	35.71
3	1	0.29	126	36.00
4	224	64.00	350	100.00

USE THE CODES TO THE RIGHT FOR QUESTION G8

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

	a. Pre-rand. Study	b. Previous Study
G8. Status of vasculature compared to: **(Enter Code)**		

G8a. Status of vasculature compared to pre-rand study				
VASC_BAS	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	82	23.43	205	58.57
B	145	41.43	350	100.00

G8b. Status of vasculature compared to previous study				
VASC_PRE	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	82	23.43	205	58.57
B	46	13.14	251	71.71
F	99	28.29	350	100.00

H1. BONY CHANGES (CHECK ONE):

☐ 1. Normal ☐ 2. Diffuse thickening ☐ 3. Focal abnormality

H1. Bony changes				
BONYCHNG	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	165	47.14	288	82.29
2	44	12.57	332	94.86
3	18	5.14	350	100.00

↓

H1.a. Specify: _____
_____
_____

H1a. Specify focal abnormality				
BONT_SPC	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	209	59.71	332	94.86
PARIETAL	2	0.57	334	95.43
Parietal	4	1.14	338	96.57
Slight parietal	1	0.29	339	96.86
bilateral parietal	1	0.29	340	97.14
clival marrow replacement	1	0.29	341	97.43
frontal	1	0.29	342	97.71
mild occipital	2	0.57	344	98.29
minimal occip. narrowing	1	0.29	345	98.57
parietal	3	0.86	348	99.43
slight parietal	2	0.57	350	100.00

USE THE CODES TO THE RIGHT FOR QUESTION H2

CODES
A. IMPROVED
B. SAME
C. NEW
D. WORSE
E. CANNOT DETERMINE
F. N/A

H2. Status of bony changes compared to: **(Enter Code)**

a. Pre-rand. Study [ ]

b. Previous Study [ ]

H2a. Status of bony changes compared to pre-rand study				
BONY_BAS	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	82	23.43	205	58.57
B	143	40.86	348	99.43
D	1	0.29	349	99.71
E	1	0.29	350	100.00

H2b. Status of bony changes compared to previous study				
BONY_PRE	Frequency	Percent	Cum Freq	Cum Percent
	123	35.14	123	35.14
-2	82	23.43	205	58.57
B	46	13.14	251	71.71
F	99	28.29	350	100.00

I. COMMENTS:

[Variable NOT included in dataset.]

J. EVENT CT SCANS

J1. Were CT films reviewed? ☐ 1. NO → **FORM COMPLETE** ☐ 2. YES → **CONTINUE TO J2**

J1. Were CT films reviewed?				
FILM_REV	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
1	225	64.29	348	99.43
2	2	0.57	350	100.00

J2. ATROPHY ON CT SCAN (CHECK ONE):

☐ 1. No atrophy ☐ 2. Atrophy ☐ 3. Equivocal

↓

Type of atrophy:

a1. GENERAL: ☐ 1. NO ☐ 2. YES

↓

a. Sulcal	☐	1. NO	☐	2. YES	
b. Ventricular	☐	1. NO	☐	2. YES	
c. Level of severity	☐	1. MILD	☐	2. MODERATE	☐ 3. SEVERE

a2. FOCAL: ☐ 1. NO ☐ 2. YES

↓

a. Sulcal	☐	1. NO	☐	2. YES
b. Ventricular	☐	1. NO	☐	2. YES

c. Specify Area(s): c1. _____

[Variables NOT included in dataset.]

J3. Does the CT scan show evidence of intracranial hemorrhage? ☐ 1. NO ☐ 2. YES

J3. CT scan evidence of intracranial hemorrhage?

INTHEMOR	Frequency	Percent	Cum Freq	Cum Percent
.	123	35.14	123	35.14
-2	225	64.29	348	99.43
1	2	0.57	350	100.00

↓

Type:	**1. NO**	**2. YES**
a. Subarachnoid	☐	☐
b. Intraventricular	☐	☐
c. Subdural	☐	☐
d. Epidural	☐	☐
e. Intraparenchymal	☐	☐

[Variables NOT included in dataset.]

J4. DISCRETE FINDINGS ON CT SCAN (COMPLETE TABLE FOR UP TO 7 LESIONS USING THE CODES BELOW)

SIDE:	TYPE:	SIZE:	LOCATION:	STATUS:
R = Right L = Left	H = Hemorrhage I = Infarct HI = Hemorrhagic Infarct	0 = Small (Punctate) (few mm) 1 = Medium (ovoid) (0.5 - 1.5 cm) 2 = Large (geographic) (≥ 1.5 cm)	0 = Frontal 1 = Temporal 2 = Parietal 3 = Occipital 4 = Basal ganglia or Thalamic (caudate, putamen, globus pallidus) 5 = Cortex 6 = Capsular/Corona 7 = Deep white matter or periventricular 8 = Brain stem 9 = Cerebellum 10 = Subarachnoid 11 = Intraventricular	A = Acute B = Subacute C = Chronic

	a.	b.	c.	d.	e.	f.	g.	h.
				LOCATION(S)				
LESION NUMBER	SIDE	TYPE	SIZE	1	2	3	4	STATUS
1.								
2.								
3.								
4.								
5.								
6.								
7.								

[Variables NOT included in dataset.]