STOP II TRIAL

QUARTERLY MEDICAL RECORD REVIEW

AFFIX PATIENT'S LABEL HERE

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): ☐☐☐

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

A3. Date Quarterly Progress Report completed (Month/Day/Year) ___ ___/___ ___/___ ___ ___ ___

A4. STOP II Patient group: ☐ **1. POTENTIAL CANDIDATE** ☐ **2. RANDOMIZED PATIENT**

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	Event Documented 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. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
B2. TIA	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
B3. Seizures	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
B4. Splenic Sequestration	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐

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**

☐ ML ☐ DE

Event	Event Documented 1. NO	Event Documented 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
B5. Aplastic Crisis	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
B6. Hand-Foot Syndrome	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
B7. Vaso-occlusive pain event for which patient was hospitalized	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
				k. __ __/__ __/__ __ __ __	l. ☐	m. ☐	☐
B8. Fever ≥ 101°F (39°C)	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
				k. __ __/__ __/__ __ __ __	l. ☐	m. ☐	☐
B9. Septicemia	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
B10. Pneumonia/ Acute Chest Syndrome	☐	☐ →	a. ☐	b. __ __/__ __/__ __ __ __	c. ☐	d. ☐	☐
				e. __ __/__ __/__ __ __ __	f. ☐	g. ☐	☐
				h. __ __/__ __/__ __ __ __	i. ☐	j. ☐	☐
				k. __ __/__ __/__ __ __ __	l. ☐	o. ☐	☐

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FOR A POTENTIAL CANDIDATE:
- **Complete FORM Q30 for each documented neurological event**

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
B11. Meningitis or Encephalitis	☐	☐	→	a.	☐	b.	__ __/__ __/__ __ __ __	c.	☐	d. ☐	☐
						e.	__ __/__ __/__ __ __ __	f.	☐	g. ☐	☐
B12. Osteomyelitis	☐	☐	→	a.	☐	b.	__ __/__ __/__ __ __ __	c.	☐	d. ☐	☐
						e.	__ __/__ __/__ __ __ __	f.	☐	g. ☐	☐
B13. Priapism	☐	☐	→	a.	☐	b.	__ __/__ __/__ __ __ __	c.	☐	d. ☐	☐
						e.	__ __/__ __/__ __ __ __	f.	☐	g. ☐	☐
B14. Transfusion Reaction	☐	☐	→	a.	☐	b.	__ __/__ __/__ __ __ __	c.	☐	d. ☐	☐
						e.	__ __/__ __/__ __ __ __	f.	☐	g. ☐	☐
B15. Other	☐	☐	→	a.	☐						

IF YES, specify event(s) below

a.1 ______________________________	b.1 __ __/__ __/__ __ __ __	c.1 ☐	d.1 ☐	☐
a.2 ______________________________	b.2 __ __/__ __/__ __ __ __	c.2 ☐	d.2 ☐	☐
a.3 ______________________________	b.3 __ __/__ __/__ __ __ __	c.3 ☐	d.3 ☐	☐

B16. Transfusion	☐	☐	→	a.	☐	b.	__ __/__ __/__ __ __ __	c.	☐	d. ☐	☐
						e.	__ __/__ __/__ __ __ __	f.	☐	g. ☐	☐
						h.	__ __/__ __/__ __ __ __	i.	☐	j. ☐	☐
						k.	__ __/__ __/__ __ __ __	l.	☐	m. ☐	☐
						n.	__ __/__ __/__ __ __ __	o.	☐	p. ☐	☐
B17. Surgery	☐	☐	→	a.	☐						

IF YES, specify surgical procedures below

a.1 ____________________________	b.1 __ __/__ __/__ __ __ __	c.1 ☐	d.1 ☐	☐
a.2 ____________________________	b.2 __ __/__ __/__ __ __ __	c.2 ☐	d.2 ☐	☐
a.3 ____________________________	b.3 __ __/__ __/__ __ __ __	c.3 ☐	d.3 ☐	☐

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FOR A POTENTIAL CANDIDATE:
*** Complete FORM Q30 for each documented neurological event**