PEDIATRIC HYDROXYUREA CLINICAL TRIAL BABY HUG Form 31

STUDY VISIT

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PART I: IDENTIFYING INFORMATION

1.	Patient's ID Number	7:	D 2. C	urrent Clinic:		SITE	
3.	Patient's Letter Cod	e:	INITS 4. Vi	sit:	sequence - 0 0	# SEQNO	
5.	Visit Start Date:	Month -	Day -	Year	VIS_DT		
PA	RT II: PHYSICAL EX	AMINATION AND	MEDICAL REV	/IEW			
1.	Spleen (00 if not pal	pable):					
	A. Midclavicular line		cm	SPLNMDCL		(1) N/D	SPLNMCND
	B. Anterior axillary li	ne	cm	SPLNINTC		(1) N/D	SPLNICND
2.	A. Temperature	TEMP		degr	PMEAS ees F (1) ees C (2)	(1) N/D	TEMPND
	B. Pulse	PULSE		/min		(1) N/D	PULSEND
	C. Respiration	RESP		/min		(1) N/D	RESPND
3.	Child's recumbent le	ength					
	A. Measurement #1	l		cm	HEIGHT1	(1) N/D	HEIGHTND
	B. Measurement #2	2		cm	HEIGHT2		
	C. Measurement #3 (If #1 and #2 diffe	3 er by more than 0.5	5 cm)	cm	HEIGHT3		
	·			height = HEIGHT			
	D. Rate hair style i None Some Not noted	nterference on chil	d's length	(1) (2) (3)	HAIRHGHT		

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4.	Ch	ild's weight			_				
	A.	Measurement #1	WEIGHT1	<u> </u>	kg	(1) N/D	WEIGHTND		
	B.	Measurement #2	WEIGHT2		kg				
	C.	Measurement #3	WEIGHT3		kg				
		(If #1 and #2 differ by n	- ·	rerage weight = WEIGHT					
5.	Ch	Child's head circumference							
	A.	Measurement #1	HEADC1		cm	(1) N/D	HEADCND		
	B.	Measurement #2	HEADC2		cm				
	C.	Measurement #3 (If #1 and #2 differ by r	HEADC3 nore than 0.4 cm)		cm				
		Average head circumference = HEADC							
	D.	Rate hair style interfere None	nce on child's head ci	cumference (1)		HAIR			
		Some Not noted		(2) (3)					
6.		mber of reportable events ce last completed study v			EVTS	(1) N/A	V_EVTSNA		
		•	e Form 50, Reportable or Hospitalization.	Event					
7.	Sir	nce last visit?		Yes	s No	N/A			
	A. B.	Any vaccinations since If yes, update Vaccin	e last visit?	(1)			FEVER31 VACCINE		
			ID Nun	nber	Visit	Seq	7		
						-			

8.	Ro	outine treatments since last visit?	Yes	No	o N/A			
	A.	Did the child take their night-time dose of twice daily prophylactic penicillin last night? *1. If no, did the child take another antibiotic?	(1) (1) [†]	(2 (2				
		[†] a. Specify:	_		ANANT_SP			
	В.	How many doses of twice daily prophylactic penicillin or similar antibiotic were missed in the last week?	PENDOSE		(1) PENNA			
9.		r 3-month, 9-month, 15-month or 21-month visit, s Form 33 been completed?	Yes (1)		o N/A whchvis 2) (3)			
PAI	RT II	I: STUDY TREATMENT REVIEW AND BLOOD SPEC	IMEN COL	LECT	ION			
1.	Re	trieve study treatment from last visit						
		RECORDRX Not Re	turned	Lost				
	A.	Record Rx # (1)	ı	(2)	RXNORET			
	В.	Approximately how much volume VOLLFT CC (1) is left?						
	C.	Any irregular treatment administration since (1) last visit?		No (2)	IRRTRT			
		If YES, complete Form 66 (Study Treatment Dosing Irregularity)						
2.	We	re blood specimens collected for this visit? (1)	(2)	BLOODCOL			
		If NO , answer 2A.						
		If YES , Skip to 2B.						
	A.	Reason blood specimens not collected today.						
		1. Difficulty with blood drawing (1)	(2)	DIFBLDDW			
		2. Patient/Family refusal (1)	(2)	PATRFUSL			
		3. Other (1)*	(2)	OTHNOBLD			
		*a. Specify:						
		Skip to PART IV.						
		ID Number	<u>-</u>	Visi	t Seq			

2.	В.	B. Routine study visit blood collection1. Hematology (required)	HBF31 HBF31ND
		(0.5 ml EDTA lavender-top)	(1) N/D (2) NA
		Biochemistry (check child's schedule) (1.0 ml red top)	(1) N/D (2) N/A BIOCHND
3.	A.	A. Is there any reason you would NOT recommend study treatment to this child today?	(1) Tx (2) Not OK
	B.	3. 1. If Tx OK , dispense study treatment and record bottle number	TXBOTNO
		2. Daily dose a.	. mg TXDDOSMG
		b	. ml TXDDOSML
		3. Volume dispensed	CC VOLDISP
	C.	C. If NOT OK , or treatment not dispensed for other reason, check here to confirm that study treatment was not dispensed	(1) тхноток
PA	RT IV	IV: COORDINATION	
1.	Che	hecked for completeness and accuracy:	
	A.	Certification number: -	CERT_NO
	B.	Signature:	CERT_SIG
	C.	General Comments:	GEN_CMNT
2.	Ir	Individual who prescribed or withheld study treatn	ment - SCERT_NO
		ID Numb	per Visit Seq