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PHN-06

Safety Laboratory Findings

Form A112

Form A112: Safety Laboratory Findings

INSTRUCTIONS: This form must be completed for all consenting subjects at the time of entry into the Marfan Trial, at study drug initiation for subjects <18 months of age, and at the end of up-titration. If multiple labs were performed for a visit, report only the final labs.

	Section	A: KEY IDEN	TIFYING INFORM	IATION							
A1.	Study Identification Numb	er		<del></del>							
A2.	Study visit		BASELINE 0								
			STUDY DRUG II	NITIATION*5 (A3)							
			END OF UPTITE	RATION 6 <b>(A3)</b>							
	*All subjects <18 months of a check prior to starting uptitra		drug initiation will be required to have a safety lab								
	a. What number screen	ing is this?									
A3.	Date of form completion		/	D / Y Y Y Y							
A4.	Name of person completing form		PRINT FULL NAME	INITIALS							
A5.	Date of sample		$\overline{M} = \overline{M} = $								
A6.	Location where the labs w	ere drawn	PHN SITE	1							
			OTHER CLINIC/	MD2							
Section B: HEMATOLOGY											
	1										
		<b>a.</b>		b.							
		U.S.	. Units	International Units							
B1.	Platelet count		x 10³ cells/mm³ x 10³ cells/uL x 10° cells/L K/uL	x 10 <sup>9</sup> cells/L							
B2.	Hemoglobin		g/dL	g/L							
B3.	Hematocrit		%	·							
B4.	White blood cell count (WBC)	•	x 10³ cells/mm³ x 10³ cells/uL x 10° cells/L K/uL	x 10 <sup>9</sup> cells/L							

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	Affix N	/larfan Trial Subj	ect ID:	<u></u>				
	Section	C: BLOOD CH	EMISTRY					
		a.		b.				
		U.S. Units		International Units				
C1.	Potassium (K <sup>+</sup> )	·	meq/L mmol/L	·	mmol/L			
C2.	Creatinine (Cr)	• mg/dL		umol/L				
C3.	ALT	u/L		umol/L				
C4.	AST		u/L _		umol/L			
If the study visit reported in question A2. > 0, skip section D and go to question Z1.								
Section D: TRIAL ELIGIBILITY								
			YES	NO	UNKNOWN			
D1.		ased on the baseline safety lab results, does e subject have renal dysfunction (Creatinine > per limit of age-related normal values)?		2	-8			
D2.	Were any of the baseline safety lab results abnormal?		1	2	-8			
D3.	Is the subject currently pregnant per results of serum HCG test?		1	2	-8			
	S or UNKNOWN to any D1 or D3 ening.	3, subject is NO	T eligible for	the Trial. <u>E</u>	nd Baseline			
D4.	D4. Is the subject eligible to proceed with screening? YES							
Section Z: TIME TO COMPLETE FORM								
Z1.	Z1. How long did it take to complete this form? minutes							
END OF FORM								

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