Transfusion Medicine/H	lemostasis Clinical Trials Network
HR01:	Screening and History Version: A
SECTION A: GENERAL INFORMATION	
A1. Subject ID	
SECTION B: MEDICAL HISTORY	
B1. Did the subject have a +Heparin/PF4 ELISA drawn between 01/21/2008 and 09/25/2008?	O Yes O No
B2. Is the medical record available for the admission during which the +Heparin/PF4 ELISA was obtained?	O Yes O No
B3. History of venous thrombosis prior to this admission (at any point in time)?	 Yes No (Go to B4) Not in record (Go to B4)
If yes, please specify the type of venous throm	bosis. Check all that apply.
a. Was it DVT of arm or leg?	
b. Was it PE?	
c. Was it CVAD (central venous access device) thrombosis?	
d. Was it CNS venous sinus?	
e. Was it Intra-abdominal venous thrombosis	
f. Was it another type of venous thrombosis (specify type)?	
 f1. If another type of venous thrombosis, specify the type. 	<u></u>
B4. History of arterial thrombosis prior to this admission?	 Yes No (Go to B5) No (Go to B5)
If yes, please specify the type of arterial thron	C Not in record (Go to B5)
a. Was it MI?	
b. Was it CVA?	
c. Was it arterial thrombosis of limb?	
d. Was it another type of arterial thrombosis (specify type)?	
d1. If another type of arterial thrombosis, specify the type.	
B5. History of HIT or HIT-T prior to admission?	O Yes O No
	O Not in record
B6. Heparin exposure in the 90 days prior to this hospital admission (only if available in chart)?	 Yes No (Go to B7) Not in record (Go to B7)
a. What type was it?	 Fragmin Lovenox
	C InnohepC Unfractionated Heparin

	O Arixtra
	O Not in record
b. Date of exposure?	(MM/DD/YYYY)
B7. History of active (present within the past 6 months) cancer excluding non-melanoma skin	O Yes
cancer?	No (Go to B8)Not in record (Go to B8)
a. What type was it?	
	 Hematologic Non-hematologic
	O Not in record
Was it treated with (please select all that appl	y):
b1. Hormonal Therapy	
b2. Chemotherapy	
b3. Radiation Therapy	
b4. Surgery	
b5. Other	
If other, specify	
B8. History of estrogen-containing hormonal contraception or replacement therapy use within	O Yes
the last three months?	O No
	O Not in record
B9. Hospital admission within 60 days prior to this admission?	O Yes
	C No C Not in record
a. If yes, date of most recent admission	
(excluding this admission)	(MM/DD/YYYY)
DONE	



Transfusion Medicine/Hemostasis Clinical Trials Network CRF Guide (QxQ Information) Report Date: Wednesday, June 09, 2010 2:37:20 PM



Form HR01, Version A

#	Question	Help Text/QxQ
A1	Subject ID	Please provide the subject's ID number. Must match ID in header.
В1	+Heparin/PF4 ELISA	Please indicate if the subject has a +Heparin/PF4 ELISA drawn between 01/21/2008 and 09/25/2008. Codes: 1 = Yes 2 = No
B2	Medical Record Available	Please indicate if the subject's medical record is available for the admission during which the +Heparin/PF4 ELISA was obtained. Codes: 1 = Yes 2 = No Special Values: -4 = IL:K -9 = MI:O
В3	History of venous thrombosis prior to this admission	Please indicate if the subject has a history of venous thrombosis prior to this admission (at any point in time). Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B3a	DVT of arm or leg	Please indicate if the venous thrombosis prior to this admission was DVT of arm or leg. At least one of B3a-B3f must be checked. Codes: 1 = Checked 2 = Not Checked Special Values: -4 = IL:K -9 = MI:O
B3b	PE	Please indicate if the venous thrombosis prior to this admission was PE. At least one of B3a-B3f must be checked. Codes: 1 = Checked 2 = Not Checked Special Values: -4 = IL:K -9 = MI:O
B3c	CVAD thrombosis	Please indicate if the venous thrombosis prior to this admission was CVAD (central venous access device) thrombosis. At least one of B3a-B3f must be checked. Codes: 1 = Checked 2 = Not Checked Special Values: -4 = IL:K -9 = MI:O
B3d	CNS venous sinus	Please indicate if the venous thrombosis prior to this admission was CNS venous sinus. At least one of B3a-B3f must be checked. Codes: 1 = Checked 2 = Not Checked

		Special Values: -4 = IL:K -9 = MI:O
B3e	Intra-abdominal venous thrombosis	Please indicate if the venous thrombosis prior to this admission was Intra-abdominal venous thrombosis. At least one of B3a-B3f must be checked. Codes:
		1 = Checked 2 = Not Checked
		Special Values: -4 = IL:K -9 = MI:O
B3f	Other type	Please indicate if the venous thrombosis prior to this admission was another type of venous thrombosis. At least one of B3a-B3f must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -4 = IL:K -9 = MI:O
B3f1	If other, specify	If the venous thrombosis was another type than those previously listed, please specify the type.
		Special Values: -4 = IL:K -9 = MI:O
B4	History of arterial thrombosis prior to this admission	Please indicate if the subject has a history of arterial thrombosis prior to this admission? Codes:
		1 = Yes 2 = No -1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B4a	MI	Please indicate if the arterial thrombosis prior to this admission was MI. At least one of B4a-B4d must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -4 = IL:K -9 = MI:O
B4b	CVA	Please indicate if the arterial thrombosis prior to this admission was CVA. At least one of B4a-B4d must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -4 = IL:K -9 = MI:O
B4c	Arterial thrombosis of limb	Please indicate if the arterial thrombosis prior to this admission was arterial thrombosis of limb. At least one of B4a-B4d must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -4 = IL:K -9 = MI:O
B4d	Other type	Please indicate if the arterial thrombosis prior to this admission was another type of arterial thrombosis (specify type). At least one of B4a-B4d must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -4 = IL:K -9 = MI:O

B4d1	If other, specify	If the arterial thrombosis was another type than those previously listed, please specify the type.
		Special Values: -4 = IL:K -9 = MI:O
В5	History of HIT or HIT-T prior to admission	Please indicate if the subject has a history of HIT or HIT-T prior to admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values:
		-4 = IL:K -9 = MI:O
B6	Heparin exposure	Please indicate if the subject was exposed to heparin in the 90 days prior to this hospital admission (only if available in chart). Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B6a	What type was it	Please indicate the type of heparin exposure the subject experienced. Must be Fragmin, Lovenox, Innohep, Unfractionated Heparin, or Arixtra. Codes: 1 = Fragmin
		2 = Lovenox 3 = Innohep 4 = Unfractionated Heparin 5 = Arixtra -1 = Not in record Special Values:
		-4 = IL:K -9 = MI:O
B6b	Date of exposure	Please provide the date of the heparin exposure. Must be in MM/DD/YYYY format. Special Values: 04/04/0404 = IL:K 09/09/0909 = MI:O
Β7	History of active cancer	Please indicate if the subject has a history of active (present within the past 6 months) cancer excluding non-melanoma skin cancer? Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B7a	What type was it	Please indicate the type of active cancer the subject had. Must be hematologic or non- hematologic. Codes: 1 = Hematologic 2 = Non-hematologic -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B7b1	Hormonal Therapy	Please indicate if the cancer treatment was hormonal therapy. At least one of B7b1-B7b5 must be checked. Codes: 1 = Checked 2 = Not Checked Special Values:
BJPD	Chemotherapy	-1 = NN:K -4 = IL:K -9 = MI:O
20102	Chemotherapy	Please indicate if the cancer treatment was chemotherapy. At least one of B7b1-B7b5 must

		be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -1 = NN:K -4 = IL:K -9 = MI:O
B7b3	Radiation Therapy	Please indicate if the cancer treatment was radiation therapy. At least one of B7b1-B7b5 must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -1 = NN:K -4 = IL:K -9 = MI:O
B7b4	Surgery	Please indicate if the cancer treatment was surgery. At least one of B7b1-B7b5 must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -1 = NN:K -4 = IL:K -9 = MI:O
B7b5	Other	Please indicate if the cancer treatment was other than those previously listed. At least one of B7b1-B7b5 must be checked.
		Codes: 1 = Checked 2 = Not Checked
		Special Values: -1 = NN:K -4 = IL:K -9 = MI:O
B7b5a	Specify Other	Please specify the other type of cancer treatment.
		Special Values: -1 = NN:K -4 = IL:K -9 = MI:O
B8	Estrogen	Please indicate if the subject has a history or estrogen-containgin hormonal contraception or replacement therapy use within the last three months?
		Codes: 1 = Yes 2 = No -1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B9	Hospital admission	Please indicate if the subject was admittied to a hospital within 60 days prior to this admission.
		Codes: 1 = Yes 2 = No -1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B9a	Most recent admission date	Please provide the date of the most recent admission (excluding this admission).
		Special Values: 04/04/0404 = IL:K 09/09/0909 = MI:O

OK Back

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			Transfusion	Medicine/H	emostasis	Clinical Tri	als Network	Temporary
				HR02: D	ata for This Adm Version: A	ission		Save Reload
SECT	ION A: GENERA	L INFORMATION						
A1.	Subject ID							
SECT	TION B: ADMISS	ION DATA						
B1.	Admission date fo				(MM/DD/YYY	Y)		
B2.	Discharge date fo				(MM/DD/YY)	Y)		
B3.			ELISA draw (Day 0)	у	ears			
а. B4.	Age in months if · Gender	s 5 years old		·	nonths			
в5.		or weight taken clo	sest to Day 0)		kilograms			
B6.	Height at Day 0 (or height taken clos	est to Day 0)		centimeters			
B7.	Ethnic Origin			C Hisp	anic/Latino			
					Hispanic/Latino in record			
B8.	Race (answer all q	uestions)						
a.		n or Alaska Native		O Yes	O No O Not i	n record		
b.	Asian	A		C Yes	O No O Not i	n record		
c. d.	Black or African	or Other Pacific Isl	ander	C Yes	C No C Not i	n record		
e.	White				O No O Noti			
f.	Other				O No O Noti			
-	f1. Specify Othe	r Race		C Yes	C No C Not i	n record		
				I				
B9.	Reason for this ho	spitalization					•	
a.	Specify other reas	on for hospitalization	on					
		nrolled in the HOT S	Study?	C Yes	C No			
B11.	Positive Heparin/F	F4 ELISA	Date Result Returned	OD Value of	OD Value of Ass	ay Brand Name	of Assay Used	
	(MM/DD/YYYY)		(MM/DD/YYYY)	Positive Result	Cut-Off			
						 GTI Diagnostic 	a Stago	
						O Other	ord	
						If other, speci	fy:	
B12.	Documented thro this admission (D		oarin/PF4 ELISA being dra	awn for C Yes	🔿 No 🔿 Not ii	n record		
	Please select the highlighted types	type of thrombosis (all type of thrombo	prior to when the Heparin osis except for MI, Retinal	/PF4 ELISA was dra Artery, Retinal Vei	wn. Radiographic c n Thrombosis, and	onfirmation is req i Superficial Venous	uired for Thrombosis).	
	Thrombosis Ty	pe	Radiographical Confirmation	Limb	Location	Side	Date (MM/DD/YYYY)	
			• C Yes	O Upper	O Proximal	C Right		
	If other, specify		C No	C Lower C Not in record	DistalNot in record	C Left C Not in record		
	Stocker, specify							
	<u>[</u>							
B13.	ELISA was drawn	(up to Day 45 or di		0 103	🔿 No 🔿 Not ii			
	Please select the	type of thrombosis	after the Heparin/PF4 ELI	SA was drawn. Rad	iographic confirmati	on is required for	r	

Thrombosis Typ		Radiographica Confirmation	LIMD	Location	Side	Date (MM/DD/YYY
	3	• Yes	O Upper	C Proximal	C Right	
		O No	C Lower C Not in record	 Distal Not in record 	C Left C Not in record	
If other, specify	<u> </u>					
Other obvious c thrombocytoper	.e. done in the absence f upper extremity (lim sitive Heparin/PF4 ELIS	of clinical symptom	s) 72 C Yes	C No C Not i	n record	
Location	Side Da	te Found	U Tes		in record	
C Proximal	C Right	M/DD/YYYY)				
O Distal	C Left					
O Not in record	O Not in record					
ultrasound study o	Side Da	s) performed withir	72 72	C No C Not i		
ultrasound study o hours after the pos Was a clot present	f lower extremity (limi sitive Heparin/PF4 ELIS ? Side Da (M	bs) performed withir A was drawn? te Found	72 72			
ultrasound study o hours after the pos Was a clot present C Proximal C Distal C Not in record History of use of cr admission?	f lower extremity (limit sitive Heparin/PF4 ELIS ? Side Da (M C Right C Left	I access devices dur	72 C Yes	C No C Not i	n record	
ultrasound study o hours after the pos Was a clot present C Proximal C Distal C Not in record History of use of cr admission?	f lower extremity (limit sitive Heparin/PF4 ELIS ? Side Da C Right C Left C Not in record	I access devices dur	72 C Yes C Yes Location of devi C Right	C No C Not i C No C Not i ce Limb for dev C Upper	n record n record ice Insertion Da	
ultrasound study o hours after the pos Was a clot present C Proximal C Distal C Not in record History of use of cc admission?	f lower extremity (limi sitive Heparin/PF4 ELIS ? Side Da (M C Right C Left C Not in record entral venous or arterial venous or arterial a	I access devices dur	72 C Yes C Yes Location of devi C Right C Left	C No C Not i	n record ice Insertion Da (MM/DD/YY)	
ultrasound study o hours after the pos Was a clot present C Proximal C Distal C Not in record History of use of cc admission? Type of central If other, specify:	f lower extremity (limi sitive Heparin/PF4 ELIS ? Side Da (M C Right C Left C Not in record entral venous or arterial venous or arterial a	es) performed within A was drawn?	72 C Yes C Yes Location of devi C Right C Left Not in record	C No C Not i C No C Not i ce Limb for dev C Upper C Lower C Not in reco	n record ice Insertion Da (MM/DD/YY) ord	
ultrasound study o hours after the pos Was a clot present Location C Proximal C Distal C Not in record History of use of cc admission? Type of central If other, specify: History of surgical	f lower extremity (limit sitive Heparin/PF4 ELIS ? Side Da (M C Right C Left C Not in record entral venous or arterial entral venous or arterial a venous or arterial a	es) performed within A was drawn?	72 C Yes C Yes Location of devi C Right C Left Not in record	C No C Not i C No C Not i ce Limb for dev C Upper C Lower	n record ice Insertion Da (MM/DD/YY) ord	
ultrasound study o hours after the pos Was a clot present C Proximal C Distal C Not in record History of use of cc admission? Type of central If other, specify: History of surgical Type of surgical	f lower extremity (limit itive Heparin/PF4 ELIS ? Side Da (M C Right C Left C Not in record entral venous or arterial entral venous or arterial a venous or arterial a procedure on this adm procedure on this adm	es) performed within A was drawn? te Found M/DD/YYYY)	72 C Yes ing this C Yes Location of devi C Right C Right C Right C Yes C Yes	C No C Not i C No C Not i ce Limb for dev C Upper C Lower C Not in reco	n record n record ice Insertion Da (MM/DD/YY) ord	

	Invasive Card	iac Intervention								
	Other (specify)								
		,								
	If other, specify:									
	If other, specify.		a							
l.										
B20.	History of limb gan	grene for this admi	ission (Day 0 o	r later).	🖸 Yes 🔿 No	O Not in record				
	Date	Limb	Side							
	(MM/DD/YYYY)									
		O Upper	C Right							
		C Lower	🖸 Left							
		O Not in record	O Not in rec	ord						
l										
B21.	Any bleeding event	s on or after Day () for this admis	sion.		O Not in record				
B21. /	Any bleeding event	s on or after Day () for this admis	sion.	O Yes O No	O Not in record				
) for this admis	Date	Time	C Not in record				
	Any bleeding event) for this admis		Time	C Not in record				
) for this admis	Date	Time	C Not in record				
				Date	Time	C Not in record	I			
) for this admis	Date	Time	C Not in record	I			
				Date	Time	• Not in record	I			
	Type of bleeding			Date	Time	C Not in record	1			
		g event		Date	Time	C Not in record	I			
	Type of bleeding	g event		Date	Time	C Not in record	I			
	Type of bleeding			Date	Time	C Not in record	I			
	Type of bleeding	g event		Date	Time	C Not in record				
	Type of bleeding	g event		Date	Time	C Not in record	I			
	Type of bleeding	g event		Date	Time	C Not in record	I			
	Type of bleeding	g event		Date (MM/DD/YYYY)	Time	C Not in record				
	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock					
	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock	Not in record				
B22.	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock					
B22.	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock					
B22.	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock					
B22.	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock					
B22. a.	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock					
B22.	Type of bleeding	g event		Date (MM/DD/YYYY)	Time (HH:MM) 24-hour clock					



		Form HR02, Version A
#	Question	Help Text/QxQ
A1 B1	Subject ID Admission date for this admission	Please provide the subject's ID number. Must match ID in header. Please provide the admission date for this admission. Must be in MM/DD/YYYY format.
DI	Admission date for this admission	
		Special Values: 01/01/0101 = NR:K
		04/04/0404 = 1L:K 09/09/0909 = MI:O
B2	Discharge date for this admission	Please provide the discharge date for this admission. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K
		04/04/0404 = IL:K
B3	Age at date of Heparin/PF4 ELISA	09/09/0909 = MI:O Please provide the subject's age (in years) at the date the Heparin/PF4 ELISA was drawn (Day 0). If the subject is less than one year old, please enter "0."
	draw (Day 0)	Special Values:
		-1 = NR:K -4 = IL:K
		-9 = MI:O
B3a	Age in months if <3 years	Please provide the subject's age in months if they were less than 3 years old at the date of the Heparin/PF4 ELISA draw.
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B4	Gender	Please provide the subject's gender.
		Codes:
		1 = Male 2 = Female
		Special Values:
		-1 = NR:K -4 = IL:K
		-9 = MI:O
B5	Weight at Day 0	Please provide the subject's weight at (or weight taken closest to) Day 0. Kilograms = pounds X 0.4536. Expected range is between 5.0 kg and 200.0 kg.
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B6	Height at Day 0	Please provide the subject's height at (or height taken closest to) Day 0. Centimeter = inch X 2.54. Expected range is between 40.0 cm and 214.0 cm.
		Special Values:
		-1 = NR:K -4 = IL:K
B7	Ethnic Origin	-9 = MI:O Please indicate if the subject's ethnic origin was Hispanic or not.
07		
		1 = Hispanic/Latino
		2 = Not Hispanic/Latino -1 = Not in record
		Special Values:
		-4 = IL:K -9 = MI:O
B8a	American Indian or Alaska Native	Please indicate if the subjec'ts race was American Indian or Alaska Native.
		Codes: 1 = Yes
		2 = No -1 = Not in record
		Special Values:
		-4 = IL:K -9 = MI:O
B8b	Asian	-9 = MI:O Please indicate if the subject's race was Asian.
		Codes:
		1 = Yes 2 = No
		-1 = Not in record
		Special Values: -4 = IL:K
		-9 = MI:O
B8c	Black or African American	Please indicate if the subject's race was Black or African American.
		Codes: 1 = Yes
		2 = No -1 = Not in record
		Special Values:
		-4 = IL:K -9 = MI:O
B8d	Native Hawaiian or Other Pacific	Please indicate if the subject's race was Native Hawaiian or Other Pacific Islander.
	Islander	Codes:
		1 = Yes 2 = No
		-1 = Not in record
		Special Values: -4 = IL:K
		-9 = MI:O
B8e	White	Please indicate if the subject's race was White.
		Codes: 1 = Yes
		2 = No -1 = Not in record
	1	

		Special Values: -4 = IL:K
B8f	Other	-9 = MI:O Please indicate if the subject's race was one other than those previously listed.
20.		Codes:
		1 = Yes 2 = No
		-1 = Not in record
		Special Values: -4 = IL:K
B8f1	Specify Other Race	-9 = MI:O This field cannot be left blank, nor may it contain only numbers.
		Special Values:
		-1 = NR:K -4 = IL:K
B9	Reason for this hospitalization	-9 = MI:O Please select the reason for this hospitalization.
		Codes: 1 = Cancer-related
		2 = Infection (e.g. pneumonia, urinary tract infection) 3 = Interventional cardiac procedure
		4 = New MI/Unstable Angina 5 = New stroke/TIA
		6 = Psychiatric treatment 7 = Surgery
		8 = Other (specify) -1 = Not in record
		Special Values: -4 = IL:K
		-9 = MI:O
B9a	If other, specify	Please provide the other reason for this hospitalization.
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B10	Subject enrolled in HOT Study	Please indicate if the subject was enrolled in the HOT Study.
		Codes: 1 = Yes
		Special Values: -1 = NR:K -4 = IL:K
		-9 = MI:O
B11a	Date drawn	Please provide the date the positive Heparin/PF4 ELISA was drawn. Must be between 01/21/2008 and 09/25/2008. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K 04/02/014 = NR:K
		04/04/0404 = IL:K 09/09/0909 = MI:O
B11b	Time drawn	Please provide the time the positive Heparin/PF4 ELISA was drawn. Must be in HH:MM format.
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B11c	Date result returned	Please provide the date the positive Heparin/PF4 ELISA was returned. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K
		04/04/0404 = IL:K 09/09/0909 = MI:O
B11d	OD value of subject's positive result	Please provide the OD value of the subject's positive result. Expected range: 0.000 to 9.999.
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B11e	OD value of assay cut-off for this subject's positive test	Please provide the OD value of the assay cut-off used for this subject's positive test. Expected range: 0.000 to 9.999.
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B11f	Brand name of assay used	Please indicate the brand name of the assay used for the subject's positive Heparin PF-4 ELISA test.
		Codes: 1 = GTI
		2 = Diagnostica Stago 3 = Other
		-1 = Not in record
		Special Values: -4 = IL:K
B11f1	Other	-9 = MI:O Please provide the brand name of the assay used for the subject's positive Heparin PF-4 ELISA test.
		Special Values:
		-1 = NR:K -4 = IL:K
B12	Thrombosis prior to Heparin/PF4	-9 = MI:O Please indicate if the subject has documented thrombosis prior to Heparin/PF4 ELISA being drawn for this admission (Day -28 to Day 0). If
DIZ	ELISA	a test required radiographical confirmation (highlighted in red), but it was not done, then do <u>not</u>
		Codes: 1 = Yes
		2 = No -1 = Not in record
		Special Values:
		-4 = II:K -9 = MI:O
B12a	Type of thrombosis	Please select the type of thrombosis prior to the Heparin/PF4 ELISA being drawn.
		Codes: 1 = Abdominal Vasculature
		2 = Aortic Clot 3 = Arterial Thrombosis
		4 = Calf Vein Thrombosis 5 = Central Venous Catheter Thrombosis

		7 = CNS Venous Thrombosis 8 = Deep Venous Thrombosis 9 = Intra-abdominal Clot 10 = Intracardiac Clot 11 = MI 12 = Peripheral Arterial Thrombosis 13 = Pulmonary Embolism 14 = Retinal Vein Thrombosis 15 = Retinal Vein Thrombosis 16 = Superficial Venous Thrombosis 17 = Other (specify) Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
B12a1	If other, specify	Please specify the other type of thrombosis prior to the PF-4 antibody being drawn. This field cannot be left blank, nor may it contain only numbers. Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
B12b	Radiographical confirmation	Please indicate if there is radiographical confirmation for this thrombosis. Codes: 1 = Yes 2 = No Special Values: -4 = IL:K
B12c	Limb	-9 = MI:O Please indicate the limb associated with this thrombosis. Codes: 1 = Upper 2 = Lower -1 = Not in record Special Values: -4 = IL:K
B12d	Location	-9 = MI:O Please indicate the location of this thrombosis. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B12e	Side	Please indicate the side of this thrombosis. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B12f	Date of thrombosis	Please provide the date of this thrombosis. Must be Day -28 to Day 0. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/0404 = 1L:K 09/09/0909 = MI:O
B13	Thrombosis after Heparin/PF4 ELISA	Please indicate if the subject had documented thrombosis during this admission, after the Heparin/PF4 ELISA was drawn (up to Day 45 or discharge). If a test required radiographical confirmation (highlighted in red), but it was not done, then do <u>not</u> record. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B13a	Type of thrombosis	Please select the type of thrombosis after the Heparin/PF4 ELISA was drawn. Codes: 1 = Abdominal Vasculature 2 = Aortic Clot 3 = Arterial Thrombosis 5 = Central Venous Catheter Thrombosis 6 = Cerebral Vascular Accident/Stroke 7 = CNS Venous Thrombosis 8 = Deep Venous Thrombosis 9 = Intra-abdominal Clot 10 = Intracardiac Clot 11 = MI 12 = Peripheral Arterial Thrombosis 13 = Pulmonary Embolism 14 = Retinal Artery 15 = Retinal Vein Thrombosis 16 = Superficial Venous Thrombosis 17 = Other (specify)
B13a1	If other, specify	Special Values: -1 = NR:K -4 = IL:K -9 = MI:O Please specify the other type of thrombosis after the Heparin/PF4 ELISA was drawn. This field cannot be left blank, nor may it contain only numbers. Special Values: -1 = NR:K -4 = IL:K -4 = IL:K
B13b	Radiographical confirmation	-9 = MI:O Please indicate if there is radiographical confirmation for this type of thrombosis. Codes: 1 = Yes 2 = No Special Values: -4 = IL:K
B13c	Limb	-9 = MI:O Please indicate the limb associated with this thrombosis. Codes:

		1 = Upper 2 = Lower
		-1 = Not in record
		Special Values: -4 = IL:K
B13d	Location	-9 = MI:O Please indicate the location of this thrombosis.
5150		Codes:
		1 = Proximal 2 = Distal
		-1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B13e	Side	Please indicate the side of this thrombosis.
		Codes: 1 = Right
		2 = Left -1 = Not in record
		Special Values:
		-4 = IL:K -9 = MI:O
B13f	Date of thrombosis	Please provide the date of this thrombosis. Must be Day 1 to Day 45 (or discharge). Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K
		04/04/0404 = IL:K 09/09/0909 = MI:O
B14	Obvious cause of thrombocytopenia	Please indicate if there was any other obvious cause of thrombocytopenia on Day 0.
		Codes: 1 = Yes
		2 = No -1 = Not in record
		Special Values: -4 = IL:K
		-9 = MI:O
B14a	What cause	Please select the other obvious cause of thrombocytopenia on Day 0. Codes:
		1 = Cardiovascular procedure within the past 5 days 2 = Chemotherapy
		3 = DIC 4 = Drug induced thrombocytopenia
		5 = Infection 6 = Radiation therapy
		7 = Other (specify)
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B14a1	Other	Please specify the other cause of thrombocytopenia on Day 0.
		Special Values: -1 = NR:K -4 = IL:K
		-9 = MI:O
B14b	Other cause date	Please provide the date of any other obvious cause of thrombocytopenia up to Day 0. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K 04/04/0404 = IL:K
D15		09/09/0909 = MI:O
B15	Screening ultrasound study of upper extremity	Please indicate if a screening (i.e. done in the absence of clinical symptoms) ultrasound study of the upper extremity (limbs) was performed within 72 hours after the positive Heparin/PF4 ELISA was drawn.
		Codes: 1 = Yes
		2 = No -1 = Not in record
		Special Values:
		-4 = IL:K -9 = MI:O
B15a	Clot present	Please indicate if a clot was present.
		Codes:
		1 = Yes
		1 = Yes 2 = No -1 = Not in record
		2 = No -1 = Not in record Special Values:
	Learning	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B15b	Location	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot.
B15b	Location	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal
B15b	Location	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes:
B15b	Location	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K
		2 = No -1 = Not in record Special Values: -4 = 1L:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = 1L:K -9 = MI:O
	Location	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the side of the clot. Codes:
		2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the side of the clot. Codes: 1 = Right 2 = Left
		2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the side of the clot. Codes: 1 = Right 2 = Left -1 = Not in record
		2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the side of the clot. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K Special Values: -1 = Not in record Special Values: -1 = Not in record Special Values: -4 = IL:K
B15c		2 = No -1 = Not in record Special Values: -4 = II:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = II:K -9 = MI:O Please indicate the side of the clot. Codes: 1 = Right 2 = Left -1 = Not in record Special Values:
B15c	Side	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the side of the clot. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please provide the side of the clot. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please provide the date the clot was found. Must be within 72 hours after positive PF-4 test drawn. Must be in MM/DD/YYYY format. Special Values: -9 = MI:O
B15c	Side	2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the location of the clot. Codes: 1 = Proximal 2 = Distal -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate the side of the clot. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please provide the date the clot was found. Must be within 72 hours after positive PF-4 test drawn. Must be in MM/DD/YYYY format.

	1	Codes:
		1 = Yes 2 = No -1 = Not in record
		Special Values: -4 = IL:K -9 = M1:O
B16a	Clot present	Please indicate if a clot was present.
		Codes: 1 = Yes 2 = No -1 = Not in record
		Special Values: -4 = 1L:K -9 = M1:O
B16b	Location	Please indicate the location of the clot.
		Codes: 1 = Proximal 2 = Distal -1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B16c	Side	Please indicate the side of the clot.
		Codes: 1 = Right 2 = Left -1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B16d	Date clot found	Please provide the date the clot was found. Must be within 72 hours after positive PF-4 test was drawn. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K 04/04/0404 = IL:K 09/09/0909 = MI:O
B17	History of devices	Please indicate if the subject has a history of use of central venous or arterial access devices during this admission?
		Codes: 1 = Yes 2 = No -1 = Not in record
		Special Values: -4 = 1L:K -9 = MI:O
B17a	Type of device	Please indicate the type of central venous or arterial access device used during this admission.
		Codes: 1 = Arterial Line 2 = CVAD 3 = Dialysis Catheter 4 = Intra-aortic Balloon Pump 5 = PICC Line 6 = Pulmonary Artery Line 7 = Other Central Line (specify)
		Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
B17a1	Other	Please specify the other type of central venous or arterial access device used during this admission. This field cannot be left blank, nor may it contain only numbers.
		Special Values: -1 = NR:K -4 = IL:K
B17b	Location of device	-9 = MI:O Please indicate the location of the device used.
		Codes: 1 = Right 2 = Left -1 = Not in record
		Special Values: -4 = 1L:K -9 = M1:O
B17c	Limb for device	Please indicate the limb the device was used on.
		Codes: 1 = Upper 2 = Lower -1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B17d	Insert date	Please provide the date the device was inserted. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K 04/04/0404 = IL:K 09/09/0909 = MI:O
B17e	Removal date	Please provide the date that the device was removed. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/0404 = IL:K 09/09/0909 = MI:O
B18	Surgical procedure	Please indicate if the subject has a history of a surgical procedure for this admission prior to Day 0.
		Codes: 1 = Yes 2 = No -1 = Not in record
		Special Values: -4 = IL:K -9 = MI:O
B18a	Type of surgical procedure	Please indicate the type of surgical procedure the subject had on this admission prior to Day 0.

	1	Codes:
		1 = Abdominal 2 = Cardiothoracic
		3 = Gynecological
		4 = Orthopedic 5 = Other (specify)
		Special Values:
		-1 = NR:K -4 = IL:K
		-9 = MI:O
B18a1	Other	Please specify the other surgical procedure. This field cannot be left blank, nor may it contain only numbers.
		Special Values: -1 = NR:K
		-4 = IL:K -9 = M:O
B18b	Date of surgical procedure	-9 = M1:0 Please provide the date of the surgical procedure. Must be between the admission date and Day 0. Must be in MM/DD/YYYY format.
0100	bate of bargical procedure	Special Values:
		01/01/0101 = NR:K
		04/04/0404 = IL:K 09/09/0909 = MI:O
B19	Medical procedure	Please indicate if the subject has a history of a medical procedure for this admission prior to Day 0.
		Codes:
		1 = Yes 2 = No
		-1 = Not in record
		Special Values: -4 = IL:K
		-9 = MI:0
B19a	Type of medical procedure	Please indicate the type of medical procedure the subject had on this admission prior to Day 0.
		Codes: 1 = Chemotherapy
		2 = Invasive Cardiac Intervention
		3 = Other (specify)
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B19a1	Other	Please specify the other type of medical procedure. This field cannot be left blank, nor may it contain only numbers.
		Special Values:
		-1 = NR:K -4 = IL:K
		-9 = MI:O
B19b	Date of medical procedure	Please provide the date of the medical procedure. Must be between the admission date and Day 0. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K
		04/04/0404 = IL:K
B20	History of limb gangrops	09/09/0909 = MI:O
620	History of limb gangrene	Please indicate if the subject had a history of limb gangrene for this admission (Day 0 or later).
		Codes: 1 = Yes
		2 = No -1 = Not in record
		Special Values:
		-4 = IL:K
B20a	Date of limb gangrene	-9 = MI:O Please provide the date of this limb gangrene. Must be in MM/DD/YYYY format.
5200	Sate of line gangrene	Special Values:
		01/01/0101 = NR:K
		04/04/0404 = IL:K 09/09/0909 = MI:O
B20b	Limb of limb gangrene	Please indicate the limb of the limb gangrene for this admission.
		Codes:
		1 = Upper 2 = Lower
		-1 = Not in record
		Special Values:
		-4 = IL:K
B20c		-9 = MI:O
DZUC	Side of limb gangrene	-9 = MI:O Please indicate the side of the limb gangrene for this admission.
BZUC	Side of limb gangrene	-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes:
BZUC	Side of limb gangrene	-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left
BZUC	Side of limb gangrene	-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right
BZUC	Side of limb gangrene	-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values:
BZUC	Side of limb gangrene	-9 = MI:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record
	Side of limb gangrene Bleeding events	-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = 1L:K
		-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes:
		-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -9 = MI:O Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No
		-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record
		-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values:
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0
B21		-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -1 = Not in record Special Values: -4 = Nt.K
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = 11:K -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes:
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: -4 = IL:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Drop in hemoglobin by >=2 grams 2 = Prank bleeding at surgical or procedure site
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = N0 -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Yos 2 = N0 -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Drop in hemoglobin by >=2 grams 2 = Frank bleeding at surgical or procedure site 3 = Gross hematuria 4 = Gross hemotypis
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Drop in hemoglobin by >=2 grams 2 = Frank bleeding at surgical or procedure site 3 = Gross hematuria 4 = Gross hematuria 4 = Gross hematuria 4 = Gross hematuria 5 = Intracrenial bleed radiographically confirmed
B21	Bleeding events	-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = N0 -1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Not in record Special Values: -4 = IL:K -9 = MI:O Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Drop in hemoglobin by >=2 grams 2 = Frank bleeding at surgical or procedure site 3 = Gross hemoturia 4 = Gross hemoturia 4 = Gross hemoturia 4 = Gross hemoturia 5 = Intracrenial bleed radiographically confirmed 6 = Line related bleeding 7 = Melena, hematemesis, or hematencesia
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: -1 = Not in record Special Values: -4 = L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Drop in hemoglobin by >=2 grams 2 = Frank bleeding at surgical or procedure site 3 = Gross hemotytysis 5 = Intracranial bleed radiographically confirmed 6 = Line related bleeding 7 = Melena, hematemesis, or hematochezia 8 = Other (specify)
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = N0 -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Prop in hemoglobin by >=2 grams 2 = Frank bleeding at surgical or procedure site 3 = Gross hematuria 4 = Gross hematuria 4 = Gross hematuria 4 = Gross hematuria 7 = Melena, hematemesis, or hematochezia 8 = Other (specify) Special Values: -4 = 1L:K
B21	Bleeding events	-9 = MI:O Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = 1L: K -9 = MI:O Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = L: K -9 = MI:O Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Torp in hemoglobin by >=2 grams 2 = Frank bleeding at surgical or procedure site 3 = Gross hemoglysis 2 = Intracranial bleed radiographically confirmed 6 = Line related bleeding 7 = Melena, hematemesis, or hematochezia 8 = Other (specify) Special Values: -4 = 1L: K -9 = MI:O
B21	Bleeding events	-9 = M1:0 Please indicate the side of the limb gangrene for this admission. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please indicate if the subject had any bleeding events on or after Day 0 for this admission. Codes: 1 = Yes 2 = N0 -1 = Not in record Special Values: -4 = 1L:K -9 = M1:0 Please select the type of bleeding event the subject had on or after Day 0 for this admission. Codes: 1 = Prop in hemoglobin by >=2 grams 2 = Frank bleeding at surgical or procedure site 3 = Gross hematuria 4 = Gross hematuria 4 = Gross hematuria 4 = Gross hematuria 7 = Melena, hematemesis, or hematochezia 8 = Other (specify) Special Values: -4 = 1L:K

		-1 = NR:K -4 = IL:K -9 = MI:O			
B21b	Date of bleeding event	Please provide the date of the bleeding event. Must be on or after Day 0. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/04040 = 1L:K 09/09/0909 = ML:O			
B21c	Time of bleeding event	Please provide the time of the bleeding event. Please use a 24 hour clock to record the time. Must be in HH:MM format. Special Values: -1 = NR:K -4 = IL:K -9 = MI:O			
B22	Has the subject died	Please indicate if the subject has died (through Day 45 or discharge), whichever comes first. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O			
B22a	Date of subject death	Please provide the date of the subject's death. Must be through Day 45 or discharge. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/0404 = IL:K 09/09/0909 = M1:O			
	OK Back				
		Transfusion Medicine/Hemostasis Clinical Trials Network ADEPT Data Management System Wednesday, June 09, 2010 2:45:24 PM			

Transfusion Medicine/Hemostasis Clinical Trials Network				Temporary	
			HR03: Platelet Coo Version: A	unts	Save Reload
SECTION A: GENERAL INFORMA	ATION				
A1. Subject ID					
SECTION B: PLATELET COUNTS	;				
Baseline platelet count (highest plate prior to Day 0. Does not have to be					
B1. Baseline Platelet Count	B1a. Date (MM/DD/YYYY)	B1b. Time (HH:MM) 24-hour clock	B1c. Value (10^3/µl)		
Nadir platelet count (lowest platelet of Does not have to be the first count of B2. Nadir Platelet Count	count within +/- 5 days of the day). B2a. Date (MM/DD/YYYY)	of Day 0. B2b. Time (HH:MM) 24-hour clock	B2c. Value (10^3/µl)		
Daily platelet counts for this admissi Capture daily until discharge or Day B3. Daily Platelet Counts	on (if multiple on same 45 post Heparin/PF4 E B3a. Date (MM/DD/YYYY)	day, only first count o LISA draw, whichever B3b. Time (HH:MM) 24-hour clock	f day). comes first. B3c. Value (10^3/µl)		
	1	·			
DONE					



		Form HR03, Version A
#(Question	Help Text/QxQ
A1	Subject ID	Please provide the subject's ID number. Must match ID in header.
B1a	Date of count	Baseline Platelet count (highest platelet count in record for current hospitalization prior to Day 0. Does not have to be the first count of the day. Please provide the date of the Baseline Platelet count. Must be between the admission date and Day 0. Must be in MM/DD/YYYY format. Special Values:
		04/04/0404 = IL:K 09/09/0909 = MI:O
B1b	Time of count	Please provide the time of the Baseline Platelet count. Must be in HH:MM format.
		Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
B1c	Value	Please provide the Baseline Platelet count. This should be the highest platelet count in record for the current hospitalization prior to Day 1. It does not have to be the first count of the day. Must be between 0 and 9999.
		Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
B2a	Date of count	Nadir Platelet count (lowest platelet count within +/- 5 days of Day 0. Does not have to be the first count of the day).
		Special Values: 01/01/0101 = NR:K 04/04/0404 = IL:K 09/09/0909 = MI:O
B2b	Time of count	Please provide the time of the Nadir Platelet count. Must be in HH:MM format.
	counc	Special Values: -1 = NR:K -4 = I1:K -9 = MI:O
B2c	Value	Please provide the Nadir Platelet count (lowest platelet count within +/- 5 days of Day 0. Does not have to be the first count of the day). Must be between 0 and 9999. Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3a	Date of count	Daily platelet counts for this admission (if multiple on same day, only first count of the day). Capture daily until discharge or Day 45 post PF-4 draw, whichever comes first. > /> Please provide the date of the Daily Platelet counts for this admission (if multiple counts on the same day, only provide the first count of the day). Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K 04/04/0404 = IL:K 09/09/0909 = MI:O
B3b	Time of count	Please provide the time of the Daily Platelet counts. Must be in HH:MM format. Special Values: -1 = NR:K -4 = 1L:K -9 = MI:O
B3c	Value	Please provide the value of the Daily Platelet counts. Must be between 0 and 9999.
		Special Values: -1 = NR:K -4 = 11:K -9 = MI:O
		OK Back
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Transfusion Medicine/Hemostasis Clinical Trials Network							
	HR04: Medications and Interventions						
	Version: A						
SECTI	SECTION A: GENERAL INFORMATION						
SLCH							
A1. Su	bject ID						
SECTI	ON B: MEDICATIONS	AND INTERVENTIO	NS				
B1.	this admission (UFH	osed to heparin durir or LMWH) prior to Da nin (dalteparin), Love nohep (Tinzaparin).	/ 0?				
	🖸 Yes						
	🜔 No (Go to B2)						
	Not in record (Go	o to B2)					
	Type of Exposure	Indicati UFH or			Start Date of Exposure (MM/DD/YYYY)	Stop Date of Exposure (MM/DD/YYYY)	
	O UFH			-			
	C Lovenox	· · · · · · · · · · · · · · · · · · ·					
	🖸 Fragmin	If other, specify:					
	🖸 Innohep						
B2.	 anti-coagulant medic Heparin/PF4 ELISA v 45 or discharge)? Yes No (Go to B3) Not in record (Go 	vas drawn (Day 0 to E o to B3)	-				
	Anti-Coagulant M	ledication			Start Date (MM/DD/YYYY)	Stop Date (MM/DD/YYYY)	
				-			
ВЗ.	 coagulant medication Yes No (Go to B4) Not in record (Go Please select the ar 	o to B4)	anti- tion(s) the subject w	/as disch	harged home on. P	ease check all that	
1	apply. . Aggrenox						
2	. Aspirin						
3	. Fondaparinux (Arixtr	a)					

Lovenox/Enoxaparin, Innohep/Tinzaparin)			
5. Dipyridamole (Persantine)			
6. Clopidogrel (Plavix)			
7 Warfarin (Couradin)			
8. Other (specify)			
If other, specify		×	
Transfusion given after Hepari drawn (Day 0 to Day 45 or dis	in/PF4 ELISA scharge)?		
C Yes			
Not in record (Go to B5)			
		Number of Units Transfused	
 C Yes C No C Not in record 	Jay o through		
Type of Amputation	Side of Amputat	tion Date of Amputation (MM/DD/YYYY) Must be between Day and Day 45	(HH:MM)
Hand or part of hand	C Right		
Hand or part of handFoot or part of foot	C Left		
	 7. Warfarin (Coumadin) 8. Other (specify) If other, specify Transfusion given after Hepardrawn (Day 0 to Day 45 or disense of the second second	 7. Warfarin (Coumadin) 8. Other (specify) If other, specify Transfusion given after Heparin/PF4 ELISA drawn (Day 0 to Day 45 or discharge)? Yes No (Go to B5) Not in record (Go to B5) Type of Transfusion Date of Transfusion (MM/DD/YYYY) Image: Date of transfusion (MM/DD/YYY)	7. Warfarin (Coumadin) 8. Other (specify) If other, specify If other, specify Transfusion given after Heparin/PF4 ELISA drawn (Day 0 to Day 45 or discharge)? • Yes • No (Go to B5) • Not in record (Go to B5) • Not in record (Go to B5) • Limb amputation performed (Day 0 through Day 45, or discharge) • Yes • No • No • No • No tin record Type of Amputation Side of Amputation Date of Amputation



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🗈 **by ?** 🔼

		Form HR04, Version A
#][Question	Help Text/QxQ
A1 B1	Subject ID Exposed to heparin during this	Please provide the subject's ID number. Must match ID in header. Please indicate if the subject was exposed to heparin during this admission (UFH or LMWH) prior to Day 0. LMWH includes Fragmin (dalteparin), Lovenox
DI	admission	(enoxaparin), and Innohep (Tinzaparin). Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI.O
B1a	Type of herparin exposure	Please indicate the type of heparin exposure.
		Codes: 1 = UFH 2 = Lovenox 3 = Fragmin 4 = Innohep Special Values: -4 = IL:K -9 = MI:O -1 = NR:K
B1b	Indications for UFH or LMWH	Please select the indication for the UFH or LMWH for this admission.
		Codes: 1 = Prophylaxis 2 = Treatment of DVT/PE/any other venous clot 3 = Heparin Flush 4 = Procedurer/surgery related 5 = Cardiac (ML, intracardiac clot, unstable angina) 6 = CVA, TLA, other neurological event 7 = Other (specify) Special Values: -4 = IL:K -9 = MI:O -1 = NR:K
B1b1	Specify	Please specify the other indication for the subject's exposure to heparin during this admission.
		Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
B1c	Start date of exposure	Please provide the start date of the heparin exposure. Must be in MM/DD/YYYY format.
		Special Values: 01/01/0101 = NR:K 04/04/0404 = 1L:K 09/09/0909 = MI:O
B1d	Stop date of exposure	Please provide the stop date of the heparin exposure. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/0404 = 1L:K 09/09/0909 = MI:O
B2	Anti-coagulant medications after Heparin/PF4 ELISA	Please indicate if the subject took any of the following anti-coagulant medications after the Heparin/PF4 ELISA was drawn (Day 0 to Day 45 or discharge): Abciximab, Argatroban, Bivalirudin, Eptifibatide, Fondaparinux, Lepirudin, LMWH (Lovenox, Fragmin, Tinzaparin), Tirofiban, Unfractionated Heparin, Warfarin). Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI.O
B2a	Medication	Select the medication that the subject received after their Heparin/PF4 ELISA was drawn (Day 0 to Day 45 or discharge).
		Codes: 1 = Abciximab (ReoPro) 2 = Argatroban 3 = Bivalirudin (Angiomax) 4 = Eptifibatide (Integrilin) 5 = Fondaparinux (Arixtra) 6 = Lepirudin (Refudan, Hirudin) 7 = LMWH (Fragmin/Dalteparin, Lovenox/Enoxaparin, Innohep/Tinzaparin) 8 = Tirofiban (Aggrastat) 9 = Unfractionated Heparin 10 = Warfarin (Coumadin) Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B2b	Start Date	Please record the date the subject began taking the medication. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/0404 = 1L:K 09/09/0909 = MI:O
B2c	Stop Date	Please record the date the subject stopped taking the medication. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/0404 = 1L:K 09/09/0909 = MI:O
B3	Discharged home on any anti-	Please indicate if the subject was discharged home on any anti-coagulant medication(s).
	coagulant medication(s)	Codes: 1 = Yes 2 = No -1 = Not in record

		Special Values:
		-4 = IL:K -9 = MI:O
B3a1	Aggrenox	Please indicate if the subject was discharged home on Aggrenox. Codes:
		1 = Checked 2 = Not checked
		Special Values: -1 = NR:K
		-4 = IL:K -9 = MI:O
B3a2	Aspirin	Please indicate if the subject was discharged home on Aspirin.
		Codes: 1 = Checked 2 = Not checked
		Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3a3	Fondaparinux (Arixtra)	Please indicate if the subject was discharged home on Fondaprinux (Arixtra).
		Codes: 1 = Checked 2 = Not checked
		Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3a4	LMWH (Lovenox Fragmin, Innohep)	Please indicate if the subject was discharged home on LMWH (Fragmin/Dalteparin, Lovenox/Enoxaparin, Innohep/Tinzaparin).
		Codes: 1 = Checked 2 = Not checked
		Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3a5	Dipyridamole (Persantine)	Please indicate if the subject was discharged home on Dipyridamole (Persantine).
		Codes: 1 = Checked 2 = Not checked
		Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3a6	Clopidogrel (Plavix)	Please indicate if the subject was discharged home on Clopidogrel (Plavix).
		Codes: 1 = Checked
		2 = Not checked Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3a7	Warfarin (Coumadin)	Please indicate if the subject was discharged home on Warfarin (Coumadin).
		Codes: 1 = Checked
		2 = Not checked Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3a8	Other (specify)	Please indicate if the subject was discharged home on another anti-coagulant medication.
		Codes: 1 = Checked 2 Nut observed
		2 = Not checked Special Values:
		-1 = NR:K -4 = IL:K -9 = MI:O
B3b	Specify	Please specify the other type of anti-coagulant medication the subject was discharged home on.
		Special Values: -1 = NR:K -1 = V.K
B4	Transfusion -itera - ft	-4 = IL:K -9 = MI:O Places lights if a transfusion was given to the subject after the Hoppin/DE4 EUCA was drawn (Day 0 to Day 4E or discharge)
D4	Transfusion given after Heparin/PF4 ELISA test drawn	Please indicate if a transfusion was given to the subject after the Heparin/PF4 ELISA was drawn (Day 0 to Day 45 or discharge). Codes:
		1 = Yes 2 = No -1 = Not in record
		Special Values:
		-4 = IL:K -9 = MI:O
B4a	Type of transfusion	Please select the type of transfusion the subject was given after the Heparin/PF4 ELISA was drawn. Codes:
		1 = Platelets 2 = RBCs
		3 = FFP 4 = Cryoprecipitate
		Special Values: -1 = NR:K -4 = IL:K
B4b	Date of transfusion	-4 = IL:K -9 = MI:O Please provide the date of the transfusion the subject was given after the Heparin/PF4 ELISA was drawn. Must be in MM/DD/YYYY format.
0+0		Special Values:
		01/01/0101 = NR:K 04/04/0404 = IL:K 09/09/0909 = MI:O
B4c	Number of units	Please provide the number of units transfused to the subject.

		Special Values: 1 = NR:K -4 = IL:K -9 = MI:O
B5	Limb amputation performed	Please indicate if the subject had a limb amputation performed. Codes: 1 = Yes 2 = No -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B5a	Type of limb amputation	Please select the type of amputation the subject had performed. Codes: 1 = Hand or part of hand 2 = Foot or part of foot 3 = Arm 4 = Leg Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
B5b	Side of limb amputation	Please indicate the side the limb was amputated from. Codes: 1 = Right 2 = Left -1 = Not in record Special Values: -4 = IL:K -9 = MI:O
B5c	Date of amputation	Please provide the date the subject's limb amputation was performed. Must be between Day 0 and Day 45. Must be in MM/DD/YYYY format. Special Values: 01/01/0101 = NR:K 04/04/0404 = 1L:K 09/09/0909 = MI:O
B5d	Time of amputation	Please provide the time the subject's limb amputation was performed. Must be in HH:MM format. Special Values: -1 = NR:K -4 = IL:K -9 = MI:O
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