

Registry Number

Data Collection Sheet



Hospital and Patient Information

Hospital:	<input type="text"/>	Data Collection:	<input type="checkbox"/> Retrospective
			<input type="checkbox"/> Contemporaneous
Patient Age:	<input type="text"/>	Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female
		Weight:	<input type="text"/> kg
Hospital Admission:	<input type="text"/> / <input type="text"/> / <input type="text"/>		: <input type="text"/> hrs
ICU Admission:	<input type="text"/> / <input type="text"/> / <input type="text"/>	Ventilation Time:	<input type="text"/> hrs
ICU Discharge:	<input type="text"/> / <input type="text"/> / <input type="text"/>		

Was this patient transferred from another hospital ?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Transferring Hospital :	<input type="text"/>
Is this case related to any other Haemostasis Registry cases ?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Hospital	<input type="text"/> Ref : <input type="text"/>

Case Description

Context of Bleeding (tick only one primary context and one or more secondary contexts as appropriate)

<input type="checkbox"/> <input type="checkbox"/> 1° 2° Trauma	<input type="checkbox"/> <input type="checkbox"/> 1° 2° Obstetric	<input type="checkbox"/> <input type="checkbox"/> 1° 2° Intra-Cranial Haemorrhage
<input type="checkbox"/> <input type="checkbox"/> Cardiac Surgery	<input type="checkbox"/> <input type="checkbox"/> Medical/Other	<input type="checkbox"/> <input type="checkbox"/> Known Coagulopathic State
<input type="checkbox"/> <input type="checkbox"/> Other Surgery	<input type="checkbox"/> <input type="checkbox"/> Haem/Oncology	<input type="checkbox"/> <input type="checkbox"/> Congenital Platelet Disorder

Description of Case (for Trauma cases please include list of injuries)

Date/Time of Bleeding Onset:	<input type="text"/> / <input type="text"/> / <input type="text"/>	:	<input type="text"/> hrs
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Office Use Only:	Input		Verification	
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Case Description (cont.)

Significant Medical History:

 Patient History Not Known No Significant Medical History

Anticoagulant or Thrombolytic Use Pre-Event

 Medications Unknown No relevant medications used Aspirin

Date last used :

 Other antiplatelet drugs including clopidogrel, dipyridamole, abciximab, tirofiban, plavix Warfarin Heparin Low Molecular Weight Heparins incl. fragmin, clexane, orgaran, enoxaparin, lovenox Other _____

rFVIIa administration

No. of doses

	1 st dose	2 nd dose	3 rd dose	4 th dose	5 th dose
Dose Volume	<input type="text"/> mg	<input type="text"/> mg	<input type="text"/> mg	<input type="text"/> mg	<input type="text"/> mg
Date of Dose	<input type="text"/> / /	<input type="text"/> / /	<input type="text"/> / /	<input type="text"/> / /	<input type="text"/> / /
Time of Dose	<input type="text"/> : hrs	<input type="text"/> : hrs	<input type="text"/> : hrs	<input type="text"/> : hrs	<input type="text"/> : hrs
Body Temperature	<input type="text"/> oC	<input type="text"/> oC	<input type="text"/> oC	<input type="text"/> oC	<input type="text"/> oC
pH	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Place of Administration (ED, Theatre, Recovery, ICU, Ward)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Effect on Bleeding (Stopped, Decreased, Unchanged, Increased)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Was this use of rFVIIa part of a clinical trial? Yes No

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Laboratory Test Results

	If applicable					
	Before Dose 1	Between Dose 1 & 2	Between Dose 2 & 3	Between Dose 3 & 4	Between Dose 4 & 5	After final Dose
Date	/ /	/ /	/ /	/ /	/ /	/ /
Time	: hrs	: hrs	: hrs	: hrs	: hrs	: hrs
PT (sec)						
PTT (sec)						
INR						
Platelets (10⁹/L)						
Hb (g/L)						
Haematocrit (%)						
Fibrinogen (g/L)						
Creatinine (mmol/L)						

Replacement Therapy Administration

	If applicable					
	24 hrs pre Dose 1	Between Dose 1 & 2	Between Dose 2 & 3	Between Dose 3 & 4	Between Dose 4 & 5	24 hrs post final Dose
Packed Cells	Units	Units	Units	Units	Units	Units
Cell Saver Cells	ml	ml	ml	ml	ml	ml
FFP	Units	Units	Units	Units	Units	Units
Cryoprecipitate	Units	Units	Units	Units	Units	Units
Platelets	Units	Units	Units	Units	Units	Units
Colloids:						
Albumex	ml	ml	ml	ml	ml	ml
Gelofusine	ml	ml	ml	ml	ml	ml
Haemaccel	ml	ml	ml	ml	ml	ml
Other _____	ml	ml	ml	ml	ml	ml
Total other fluid						
	ml	ml	ml	ml	ml	ml

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Other Therapies

Relevant Medication Given

If applicable

24 hrs pre Dose 1	Between Dose 1 & 2	Between Dose 2 & 3	Between Dose 3 & 4	Between Dose 4 & 5	24 hrs post final Dose
<input type="checkbox"/> unknown	<input type="checkbox"/> unknown	<input type="checkbox"/> unknown	<input type="checkbox"/> unknown	<input type="checkbox"/> unknown	<input type="checkbox"/> unknown
<input type="checkbox"/> no other drug therapy	<input type="checkbox"/> no other drug therapy	<input type="checkbox"/> no other drug therapy	<input type="checkbox"/> no other drug therapy	<input type="checkbox"/> no other drug therapy	<input type="checkbox"/> no other drug therapy
<input type="checkbox"/> Fibrin Sealant	<input type="checkbox"/> Fibrin Sealant	<input type="checkbox"/> Fibrin Sealant	<input type="checkbox"/> Fibrin Sealant	<input type="checkbox"/> Fibrin Sealant	<input type="checkbox"/> Fibrin Sealant
<input type="checkbox"/> Tranexamic acid	<input type="checkbox"/> Tranexamic acid	<input type="checkbox"/> Tranexamic acid	<input type="checkbox"/> Tranexamic acid	<input type="checkbox"/> Tranexamic acid	<input type="checkbox"/> Tranexamic acid
<input type="checkbox"/> Aprotinin	<input type="checkbox"/> Aprotinin	<input type="checkbox"/> Aprotinin	<input type="checkbox"/> Aprotinin	<input type="checkbox"/> Aprotinin	<input type="checkbox"/> Aprotinin
<input type="checkbox"/> Protamine	<input type="checkbox"/> Protamine	<input type="checkbox"/> Protamine	<input type="checkbox"/> Protamine	<input type="checkbox"/> Protamine	<input type="checkbox"/> Protamine
<input type="checkbox"/> Heparin	<input type="checkbox"/> Heparin	<input type="checkbox"/> Heparin	<input type="checkbox"/> Heparin	<input type="checkbox"/> Heparin	<input type="checkbox"/> Heparin
<input type="checkbox"/> DDAVP	<input type="checkbox"/> DDAVP	<input type="checkbox"/> DDAVP	<input type="checkbox"/> DDAVP	<input type="checkbox"/> DDAVP	<input type="checkbox"/> DDAVP
<input type="checkbox"/> Prothrombinex	<input type="checkbox"/> Prothrombinex	<input type="checkbox"/> Prothrombinex	<input type="checkbox"/> Prothrombinex	<input type="checkbox"/> Prothrombinex	<input type="checkbox"/> Prothrombinex
<input type="checkbox"/> Vitamin K	<input type="checkbox"/> Vitamin K	<input type="checkbox"/> Vitamin K	<input type="checkbox"/> Vitamin K	<input type="checkbox"/> Vitamin K	<input type="checkbox"/> Vitamin K
<input type="checkbox"/> Other	<input type="checkbox"/> Other	<input type="checkbox"/> Other	<input type="checkbox"/> Other	<input type="checkbox"/> Other	<input type="checkbox"/> Other

Physical attempts to control bleeding eg returns to theatre, angiographic embolisation, etc.

If applicable

24 hrs pre Dose 1	Between Dose 1 & 2	Between Dose 2 & 3	Between Dose 3 & 4	Between Dose 4 & 5	24 hrs post final Dose
Date <input type="text"/> / <input type="text"/> / <input type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/>
Time <input type="text"/> : <input type="text"/> hrs	Time <input type="text"/> : <input type="text"/> hrs	Time <input type="text"/> : <input type="text"/> hrs	Time <input type="text"/> : <input type="text"/> hrs	Time <input type="text"/> : <input type="text"/> hrs	Time <input type="text"/> : <input type="text"/> hrs
Details <input type="text"/>	Details <input type="text"/>	Details <input type="text"/>	Details <input type="text"/>	Details <input type="text"/>	Details <input type="text"/>

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Complications/Adverse Events (tick one or more below)

NO COMPLICATIONS OR ADVERSE EVENTS WITHIN 28 DAYS

Time after rFVIIa

1 – immediately 5 – 1-2 days
 2 – < 6 hours 6 – 2-7 days
 3 – 6-12 hours 7 – 8-28 days
 4 – 12-24 hours

Causality Assessment

0 – not linked 3 – probably linked
 1 – unlikely to be linked 4 – definitely linked
 2 – possibly linked 5 – unable to assess

<input type="checkbox"/> CVA	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> TIA	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> DVT	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> PE	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> AMI	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> Arterial Thrombosis	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> DIC	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> Multi-organ Failure(MOF)	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> ARDS	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> Allergic	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>
<input type="checkbox"/> Other	Time after rFVIIa	<input type="text"/>	Causality Assessment	<input type="text"/>

Description of Adverse Event/s

Outcome (please follow patient progress to discharge or at least 28 days)

Choose one of the options below:

Patient still in Hospital as at: / /

Patient Discharged date of discharge: / /

discharged to: Home Rehab
 Other Hospital Other _____

Patient Deceased date/time of death: / / : hrs

cause of death:

Other Comments? Please use back of page to record any further information or comments