

**Patient Demography**

(\*) Mandatory fields

Patient Reference (UPN No) *	:	
Date of Birth (dd/mm/yyyy) *	:	
Weight *	:	Kgs
Height *	:	Cms
BSA	:	M <sup>2</sup>
Age*	:	Years
Sex	:	<input type="checkbox"/> Male <input type="checkbox"/> Female

**Clinical Information**

Hospitalized from * (dd/mm/yyyy)	:	Hospital Number :
Hospitalized Until * (dd/mm/yyyy)	:	
Hospital/Institution*	:	
Department/Division *	:	
Doctor in Charge	:	

**Clinical History**

Sl. no	Symptoms	Duration
1 *		
2		
3		
4		
5		

(Duration is in hours, days, weeks and months)

Sl.no	Salient features
1	
2	
3	
4	
5	

Sl.no	Final Diagnosis
1 *	
2	
3	
4	
5	



Other Relevant scores <input type="checkbox"/> APACHE, <input type="checkbox"/> SOFA, <input type="checkbox"/> SAPS II <input type="checkbox"/> TRISS	Value
Comments	

### Blood Loss

Last 6hr *	in ml	<input type="checkbox"/> Not Applicable
Last 12hr *	in ml	<input type="checkbox"/> Not Applicable
Last 24hr *	in ml	<input type="checkbox"/> Not Applicable

### Laboratory Parameters

Laboratory Parameters	Onset of Bleeding	Before use of NovoSeven™	After use of NovoSeven™
PT(sec) *			
aPTT(sec) *			
Fibrinogen (g/l)			
Thrombin Time (s)			
D-Dimer (ng/ml)			
FDP			
Platelet Count (x10 <sup>9</sup> /L) *			
Hb (10 <sup>gm</sup> /dL) *			
Total WBCs (X 10 <sup>9</sup> /L)			

Sodium (mEq/L)			
Potassium(mEq/L)			
Creatinine(mg/dL)			
Calcium(mg/dL)			

LFT (Mandatory if Liver Disease) \*

Laboratory Parameters	At admission/Onset of Bleeding	Before use of NovoSeven™	After use of NovoSeven™
Total bilirubin (mg/dl)			
Direct bilirubin (mg/dl)			
Total protein (gm/dl)			
Albumin (gm/dL)			
SGOT (U/L)			
SGPT(U/L)			
Alkaline Phosphatase(U/L)			
Body Temperature(°F)			
Acid Base Status(pH)			
Other Test			

**Blood products / Haemostatic measures before use of NovoSeven**

Packed Red cell units	:
Whole blood	:
<input type="checkbox"/> Platelet Concentrates <ul style="list-style-type: none"> <li><input type="radio"/> Random Donor :</li> <li><input type="radio"/> Single Donor :</li> </ul> <input type="checkbox"/> FFP Units :	
<input type="checkbox"/> Cryoprecipitate units	:

<input type="checkbox"/> Prothrombin Complex concentrate	:
<input type="checkbox"/> FVIII/VWF Concentrate (Units)	:
<input type="checkbox"/> DDAVP (micrograms)	:
<input type="checkbox"/> Tranexamic Acid (milligrams)	:
<input type="checkbox"/> Aprotinin (KIU)	:
Others (specify)	

### NovoSeven Therapy

No. of injection	Time since bleeding (In hrs)	Dose (microgm/kg)	Dose administered (mg)
1 <sup>st</sup> dose*			
2 <sup>nd</sup> dose			
3 <sup>rd</sup> dose			
4 <sup>th</sup> does			
5 <sup>th</sup> dose			
Further doses (specify dose, frequency and duration)			
Cumulative dose (in mg)			

### Response to NovoSeven

Time of 1 <sup>st</sup> assessment * (after last dose) (in minutes)	:
6hrs. assessment	:
12hrs.assessment	:
Day 2 assessment	:
Day 5 assessment	:
<b>(Options: 1. Bleeding stopped, 2. Minimal bleeding (not requiring transfusion of blood products), 3. Bleeding reduced (requiring further transfusion of blood products), 4. Bleeding did not reduce)</b>	

Surgical Intervention to Control Bleeding       Yes       No

Specify

Overall Impression
<input type="checkbox"/> Bleeding stopped <input type="checkbox"/> Minimal bleeding (not requiring transfusion of blood products), <input type="checkbox"/> Bleeding reduced (requiring further transfusion of blood products), <input type="checkbox"/> Bleeding did not reduce
Time until control of bleeding * after last dose (in hours)

**Blood products / Haemostatic measures after use of NovoSeven™**

Packed Red cell units	:
Whole blood	:
<input type="checkbox"/> Platelet Concentrates	
○ Random Donor	:
○ Single Donor	:
<input type="checkbox"/> FFP Units	:
<input type="checkbox"/> Cryoprecipitate units	:
<input type="checkbox"/> Prothrombin Complex concentrate	:
<input type="checkbox"/> FVIII/VWF Concentrate (Units)	:
<input type="checkbox"/> DDAVP (micrograms)	:

<input type="checkbox"/> Tranexamic Acid (milligrams)	:	:
<input type="checkbox"/> Aprotinin (KIU)	:	:
Others (specify)		

Number of Treatment Days *	:	:
Number of Doses *	:	:

### NovoSeven Related Complications

Adverse effects within 7 days of discharge <input type="checkbox"/> Yes <input type="checkbox"/> No		
Adverse Event Type	Time after rFVIIa	Causality Assessment
	1. immediately 2. <6 hours 3. 6 -12 hours 4. 12 -24 hours 5. 1 - 2 days 6. 2 - 7 days	0 - not linked 1 - unlikely to be linked 2 - possibly linked 3 - probably linked 4 - definitely linked 5 - unable to assess causality
<b>Thromboembolic Phenomenon</b>		
<input type="checkbox"/> CVA	:	:
<input type="checkbox"/> Stroke	:	:
<input type="checkbox"/> DVT	:	:
<input type="checkbox"/> PE	:	:
<input type="checkbox"/> AMI	:	:
<input type="checkbox"/> Peripheral	:	:
<input type="checkbox"/> Arterial	:	:
<input type="checkbox"/> DIC	:	:
<input type="checkbox"/> Allergic	:	:
<input type="checkbox"/> Multi-Organ Failure	:	:
<input type="checkbox"/> ARDS	:	:
<input type="checkbox"/> Others(Specify)	:	:
Description of adverse events(specify):		

**Outcome**

Patient Still in Hospital      Date:  
(tick if applicable)

Discharged      Date:  
(tick if applicable)

Death      Date:  
(tick if applicable)

Cause of death  
(mandatory if patient dies)

Impact of rFVIIa on outcome \*  
(tick the most appropriate response)

- The patient's outcome was improved by the use of rFVIIa
- The patient would have died without the use of rFVIIa
- I am unable to tell if rFVIIa affected the patient's outcome
- rFVIIa made no difference to the outcome
- The patient's outcome was worsened by the use of rFVIIa

Name of the person completing this form \*:

Date \* :

Date of Submission :