DEEP VEIN THROMBOSIS (DVT) & PULMONARY EMBOLISM (PE)			
Protocol Identifier	**Subject Identifier**		**Visit Description** **Treatment Period ABD** **Visit XYZ**

EVENT DETAILS

Was subject hospitalized due to event? [Y] ☐Yes [N] ☐No

If Yes, admission date and time ☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐☐☐ HR: Min(00:-23:59)

Discharge date and time ☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐☐☐ HR: Min(00:-23:59)

DEEP VEIN THROMBOSIS (DVT)

SIGNS AND SYMPTOMS

Date and time of documented onset of deep vein thrombosis (DVT) ☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐☐☐ HR: Min(00:-23:59)

Leg tenderness/pain [Y] ☐Yes [N] ☐No

Leg swelling [Y] ☐Yes [N] ☐No

palpable cord [Y] ☐Yes [N] ☐No

Skin warmth [Y] ☐Yes [N] ☐No

Skin erythema / discoloration) [Y] ☐Yes [N] ☐No

Other [Y] ☐Yes [N] ☐No

If Yes, please specify_____

RESOLUTION (to be filled out when information available)

Was resolution documented? [Y] ☐Yes [N] ☐No

If Yes, date and time of resolution of deep vein thrombosis (DVT) ☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐☐☐ HR: Min(00:-23:59)

Were there any sequelae? [Y] ☐Yes [N] ☐No

PULMONARY EMBOLISM (PE)

SIGNS AND SYMPTOMS

Date and time of documented onset of pulmonary embolism ☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐☐☐ HR: Min(00:-23:59)

Hypotension [Y] ☐Yes [N] ☐No

Shortness of breath [Y] ☐Yes [N] ☐No

If Yes, complete the following: (this went with SOB)

☐ Mild

☐ Moderate

☐ Severe

Hemoptysis	[Y] ☐Yes	[N] ☐No
Syncope	[Y] ☐Yes	[N] ☐No
Pleuritic chest pain	[Y] ☐Yes	[N] ☐No
Tachycardia, Heart Rate>100/minute	[Y] ☐Yes	[N] ☐No
Other	[Y] ☐Yes	[N] ☐No

If Yes, specify_____

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Risk Factors		
Known hypercoagulable state	[Y] ☐Yes	[N] ☐No
Cancer	[Y] ☐Yes	[N] ☐No
Prolonged immobilization	[Y] ☐Yes	[N] ☐No
Postoperative	[Y] ☐Yes	[N] ☐No
If Yes, complete the following:		
Surgical procedure(s) within the past 12 weeks	[Y] ☐Yes	[N] ☐No
Recent severe trauma	[Y] ☐Yes	[N] ☐No
History of prior DVT,PE or pulmonary infarct	[Y] ☐Yes	[N] ☐No
Use of oral estrogen preparations	[Y] ☐Yes	[N] ☐No
Use of immune globulin products	[Y] ☐Yes	[N] ☐No
Chronic intravenous access (e.g., PICC line)	[Y] ☐Yes	[N] ☐No
Other	[Y] ☐Yes	[N] ☐No
If Yes, please specify_____		

DIAGNOSTIC TESTS (Upload the source documents)

Diagnostic Test Name	**Test Performed** Y=Yes N=No	**Consistent with DVT** Y=Yes N=No E=Equivocal	**Date of Test** Day Month Year	**Time of Test** Hrs: Mins 00:00-23:59
DVT	**e.g., Y**	**Y**	**01 Jan 09**	**10:35**
Impedance plethysmography				
Extremity ultrasound				
Venography				
MRI Scan				

Diagnostic Test Name	**Test Performed** Y=Yes N=No	**Evidence of PE** Y=Yes N=No E=Equivocal	**Date of Test** Day Month Year	**Time of Test** Hrs: Mins 00:00-23:59
PE	**e.g., Y**	**Y**	**01 Jan 09**	**10:35**
CT Scan				
Angiography				

Ventilation-Perfusion Scan				
Diagnostic Test Name	**Test Performed** Y=Yes N=No	**Elevated** Y=Yes N=No	**Date of Test** Day Month Year	**Time of Test** Hrs: Mins 00:00-23:59
	e.g., Y	**Y**	**01 Jan 09**	**10:35**
D-dimer				
Diagnostic Test Name	**Test Performed** Y=Yes N=No	**Elevated** Y=Yes N=No	**Date of Test** Day Month Year	**Time of Test** Hrs: Mins 00:00-23:59
	e.g., Y	**Y**	**01 Jan 09**	**10:35**
D-dimer				

ECHOCARDIOGRAPHY

Was an Echocardiogram performed? [Y] ☐Yes [N] ☐N

If Yes, complete the following:

Date and time of Echocardiogram: **Day** **Month** **Year** **Hrs:Mins (00:00-23:59)**

Evidence of thrombus in a chamber? [Y] ☐Yes [N] ☐No
If Yes, which chamber(s)? [A] ☐Atrial [V] ☐Ventricular
Evidence of right-sided chamber dilatation? [Y] ☐Yes [N] ☐No
If Yes, which chamber(s)? [A] ☐Atrial [V] ☐ Ventricular
Elevated PA pressure [Y] ☐Yes [N] ☐No
Pulmonary hypertension [Y] ☐Yes [N] ☐No
Severe tricuspid regurgitation [Y] ☐Yes [N] ☐No
Other [Y] ☐Yes [N] ☐No
If Yes, specify [Y] ☐Yes [N] ☐No

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MEDICATIONS and PROCEDURES

Did the subject require the following treatment at the time of the event?

Vasopressor support	[Y] ☐Yes	[N] ☐No
Thrombolytics	[Y] ☐Yes	[N] ☐No
Thrombectomy	[Y] ☐Yes	[N] ☐No
Anti-coagulation (e.g., heparin)	[Y] ☐Yes	[N] ☐No
Anti-platelet	[Y] ☐Yes	[N] ☐No
Anti-thrombin (e.g., direct thrombin inhibitors)	[Y] ☐Yes	[N] ☐No
IVC Filter placement	[Y] ☐Yes	[N] ☐No

"Additional Supplemental information (to what has already been highlighted in yellow in the form): Source documents for data requested in the eCRF (e.g., labs, CXR) as well as admission History and Physical and Discharge Summary".