Study: ATTRACT

CRF : ACOAGCHG - ANTICOAGULATION CHANGE

Section A: Change from Warfarin to Another Anticoagulant

Warfarin has changed to another anticoagulant? WarfarinChangedTo

Date of last warfarin dose: DateLastWarfarinDose

Date new anticoagulant started: DateNewAnticoagStarted

Name of new anticoagulant: TypeAnticoag Specify: OtherAnticoagSpecify

Reason for changing anticoagulant: ReasonChangeAnticoag

Specify: OtherReasonAnticoagSpecify

Section B: Anticoagulant Therapy Stopped

All anticoagulant therapy was stopped and subject will stay off it long-term. AnticoagStopped

Date of last dose of anticoagulant therapy: DateLastDoseAnticoag

Primary reason why anticoagulant therapy was stopped. PrimaryReasonStopped

New contraindication for anticoagulant therapy, specify: NewContraindication Specify: OtherRiskSpecify

Other Reason, specify: OtherPrimReasonSpecify

Section C: Anticoagulant Therapy Started

Anticoagulant therapy was started in a subject who had stopped taking anticoagulants, and subject will remain on it long-term. AnticoagLongTerm

Date anticoagulant therapy started: DateAnticoagStarted

Primary reason why anticoagulant therapy was started and will be continued long-term (>= 6 weeks). PrimaryReasonLongTerm

New indication for anticoagulant therapy, specify: NewIndicationAnticoag Specify: OtherIndicationSpecify

Study: ATTRACT

CRF : ACOAGCHG - ANTICOAGULATION CHANGE

Other Reason, specify: OtherLongTermSpecify

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : ACOAGTX - INITIAL ANTICOAGULATION THERAPY

Section A: Pre-Randomization Anticoagulant Therapy

Has subject received anticoagulant therapy pre-randomization? ReceivedAnticoagPreRand

Type of anticoagulant therapy: TypeAnticoag ⊘ Specify: OtherAnticoagSpecify ⊘

Date of first dose: ⊘ DateFirstDoseAnticoag

Was warfarin given? ⊘ WarfarinGivenPreRand

Date of first dose: ⊘ DateWarfarinPreRand

Section B: Post-Randomization Anticoagulant Therapy

Initial ATTRACT protocol anticoagulant therapy administered after enrollment:

UFH UFH	Bolus given: Units ⊘ UFHBolusGiven	Initial infusion rate: U/hr ⊘ UFHInfusionRate	
Enoxaparin Enoxaparin	Initial dose: ⊘ EnoxaparinIniDoes	mg BID ⊘ EnoxaparinDoseBID	mg QD ⊘ EnoxaparinDoseQD
Dalteparin Dalteparin	Initial dose: ⊘ DalteBIDOrQD	IU BID ⊘ DalteparinDoseBID	IU QD ⊘ DalteparinDoseQD
Tinzaparin Tinzaparin	Initial dose: IU QD ⊘ TinzaparinDose		

Date and time of first dose: DateAnticoagFirstDose TimeAnticoagFirstDose 24 hour clock

Was warfarin given? WarfarinGivenPostRand

Date of first dose: ⊘ DateWarfarinPostRand

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : ADJBLEED - ADJUDICATION OF SUSPECTED BLEEDING

Date of onset of event: DateOnsetBleed

Results of adjudication: ResultsAdjudication TypeBleed ⊘

- ☐ Associated with >= 2.0 g/dL drop in hemoglobin ⊘ DropHemo
- ☐ Transfusion of 2 units of red blood cells ⊘ Transfusion
- ☐ Critical site, specify: ⊘ CriticalSite CriticalSiteSpecify ⊘ OtherSiteSpecify ⊘

Date of Adjudication: DateAdjudication

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : ADJDEATH - Death Adjudication

Date of Death: DateDeath

Results of adjudication: ResultsAdjudication

- ☐ Diagnosed with recurrent VTE shortly before death and subsequent clinical course suggests death from PE ⊘ DiagRecurrentVTE
- ☐ Autopsy-proven PE without another more obvious cause of death ⊘ AutopsyProvenPE
- ☐ Clinical presentation suggests that PE was the most likely cause of death, but objective testing was not performed ClinPECauseDeath ⊘
- ☐ Sudden death without an associated clinical description and no history of cardiac disease or another more likely cause of death SuddenDeath ⊘
- ☐ Meets criteria for Major Bleed and no other more likely cause of death ⊘ MajorBleedCauseDeath
- ☐ Meets criteria for Major Bleed and bleeding judged to have caused another condition that led to death (e.g., MI) MajorBleedCauseLedDeath ⊘

  Specify: SpecifyOtherCondition ⊘

- ☐ Overt bleeding (includes at autopsy) and no other more likely cause of death ⊘ OvertBleeding

Specify alternative diagnosis: SpecifyAlternativeDiag ⊘

Date of Adjudication: DateAdjudication

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : ADJDVT - ADJUDICATION OF SUSPECTED DVT

Date of onset of event: DateOnsetEvent

Specify location: Location

Results of adjudication: ResultsAdjudication

- ☐ A new non-compressible common femoral or popliteal vein ⊘ NewNonCompFemPop
- ☐ A >= 4 mm increase in compressed thrombus diameter at the common femoral or popliteal site (without a new non-compressible vein) FourmmIncrease ⊘
  - Increase at popliteal: mm ⊘ IncreasePopliteal
  - Increase at common femoral: mm ⊘ IncreaseFemoral
- ☐ A >= 10 cm extension of thrombus margin (without a new non-compressible vein) ⊘ ExtThrombusMargin
  - Increase in margin of cm ⊘ IncreaseThrombusMargin
- ☐ Venogram (ascending or CT) showing a new ILFD in a proximal vein ⊘ VenogramNewILFD

New (recurrent) DVT is: NewDVTIs ⊘

Provoked, specify:
- ☐ Cancer ⊘ ProvokedCancer
- ☐ Surgery within three months ⊘ ProvokedSurgery
- ☐ Other ⊘ ProvokedOther
- Specify: ⊘ OtherProvokedSpecify

Date of Adjudication: DateAdjudication

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : ADJPE - ADJUDICATION OF SUSPECTED PE

Date of onset of event: DateOnsetEvent

Results of adjudication: ResultsAdjudication

- [ ] A (new) ILFD involving a segmental, or more central, pulmonary artery on CTPA NewILFD
- [ ] A (new) ILFD involving a segmental pulmonary artery on catheter pulmonary angiogram NewILFDSegPulmArtery
- [ ] A (new) high-probability perfusion defect on V/Q lung scan NewPerfDefectVQScan
- [ ] Meets criteria for diagnosis of acute proximal DVT with a non-diagnostic CTPA (includes no ILFD) or V/Q scan MeetsCritDiagAcuteDVT

New (recurrent) PE is: NewPEIs

Provoked, specify:
- [ ] Cancer ProvokedCancer
- [ ] Surgery within three months ProvokedSurgery
- [ ] Other ProvokedOther

Specify: OtherProvokedSpecify

Date of Adjudication: DateAdjudication

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : ADJVENGM - ADJUDICATION OF VENOGRAMS

Date of Venography: DateVenography

Specify Venogram: SpecifyVenogram **Leg:** VenogramLeg

Marder Score (Points)

Venous Segments	Maximal Value	Check if cannot assess	Actual Value
Iliac (External and Common)	6	IliacCantAssess	IliacValue
Common Femoral	4	CommonFemoralCantAssess	CommonFemoralValue
Femoral	10	FemoralCantAssess	FemoralValue
Popliteal	4	PoplitealCantAssess	PoplitealValue
		Total Marder Score =	**/ 24** TotalScore

Quality of Venogram: QualityVenogram

Specify reason(s): ReasonUnsatVenogram

Date of Adjudication: DateAdjudication

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : AE - Adverse Event

AE Name: AEName

SAE ○No ○Yes SAE **SAE ID** SAEID **Adverse Event ID** AEID

AE Onset Date AEOnsetDate

Resolution date AEResolutionDate **OR** ☐ Ongoing AEOngoing

AE Severity: AESeverity

Action Taken: AEActionTaken

Outcome AEOutcome

Relationship to use of study drug (rt-PA): AERelationStudyDrug

Relationship to participation in Research Study: AERelationResStudy

Expectedness: Expectedness

Please refer to Protocol Section 13.3 for definition of criteria used for Adverse Event categorization.

SIR Classification

*Please indicate the **most severe** subject consequences resulting from this adverse event.*

AEMostSevere

- ○ No therapy and no consequences
- ○ Minor therapy and no consequences (includes <24 hour admission for observation only)
- ○ Moderate therapy or hospitalization for <48 hours for any treatment or admission for observation for 24-48 hours
- ○ Major therapy or unplanned increase in level of care or hospitalization for >48 hours
- ○ Permanent adverse sequelae

Does this event qualify as an Unanticipated Problem per the definition in Protocol ***Section 13.1.3*** EventQualify

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : BASE - Baseline

Section A: Demographics

Age in years: AgeYears

Gender: Gender

Ethnicity: Ethnicity

Race as reported by the subject:

- American Indian or Alaska Native RaceAboriginal
- Asian RaceAsian
- Black or African American RaceBlackAfrican
- Native Hawaiian or Other Pacific Islander RaceNativeHawaiianIslander
- White RaceWhite
- Not reported or refused RaceNotReportRefused

Employment status: EmploymentStatus

Section B: Medical History

Comorbid Condition		
Hypertension Hypertension	Diabetes Diabetes	HighCholesterol High Cholesterol
Asthma Asthma	COPD COPD	AnginaMI Angina/MI
CHF Congestive Heart Failure		

Other active conditions, *specify:*

OtherConditionSpecify

Section C: Physical Examination/Vital Signs

Height: Height HeightType

Weight: Weight WeightType

Systolic blood pressure: SystolicBP mmHg

Diastolic blood pressure: DiastolicBP mmHg

Study: ATTRACT

CRF : BASE - Baseline

Section D: Qualifying Episode of DVT

Date of diagnosis of qualifying episode of DVT: DateQualifyingVTE

Qualifying episode of DVT:

Specify leg: DVTLeg

Common Femoral Vein and/or Iliac vein involved: CommonFemoralVein

Did the subject have a previous DVT and/or PE? PreviousDVTPE

☐ DVT ⊘ PreviousDVT

Total number of previous episodes: ⊘ NumPrevEpisodes

☐ ***Ipsilateral*** leg previously affected ⊘ DVTIndexLeg

Date last episode diagnosed: DateDVTIndexLeg ⊘ **OR** ☐ Date unknown ⊘ IndexLegUnknown

☐ ***Contralateral*** leg previously affected ⊘ DVTContralateral

Date last episode diagnosed: DateDVTContralateral ⊘ **OR** ☐ Date unknown ⊘ ContralateralUnknown

☐ PE ⊘ PreviousPE

Total number of previous episodes: ⊘ PENumPrevEpisodes

Date last episode diagnosed: DatePEPrevEpisodes ⊘ ☐ Date unknown ⊘ PEPrevUnknown

Did DVT diagnosis occur within 6 weeks of:

MajorSurgery Major surgery (>= 30 minutes duration)	Hospitalization Hospitalization
PlasterCastImmob Plaster cast immobilization	Childbirth Childbirth

Was the subject an inpatient when qualifying event of DVT was diagnosed? InpatientQualifyDVT

When did symptoms of qualifying episode of DVT start? DateSymptomsDVTStart

Are there symptoms suggestive of PE? SymptomsSuggestivePE

Was PE diagnosed using objective testing (e.g., Spiral CT Scan, Ventilation-perfusion Scan)? PEDiagnosedObjTesting

Has the subject taken any aspirin during the 7 days immediately prior to randomization? TakenAspirin

Study: ATTRACT

CRF : BASE - Baseline

Section E: Completeness of Questionnaires

Has the subject answered the Villalta PTS Symptoms questionnaire completely? VillaltaPTSSymptoms

Specify: VillaltaPTSQuestComplete

Other, specify: OtherVillaltaSpecify

Has the subject answered the "Your Health and Well-Being" (i.e., SF-36, VEINES) questionnaire completely? YourHealthWellBeing

Specify: YourHealthWellBeingComplete

Other, specify: OtherYourHealthSpecify

Section G: Required Source Documentation

Submitted	Source Document	FOR DCC USE ONLY Date Received
☐ SubmittedBaseCUSLocal	Baseline Compression Ultrasound local report	DateReceivedBaseCUSLocal
☐ SubmittedCUSForm	Compression Ultrasound Form	DateReceivedCUSForm
☐ SubmittedVenogramLocal	Venogram local report, if performed	DateReceivedVenogramLocal
☐ SubmittedCTVenogram	CT Venogram local report, if performed	DateReceivedCTVenogram
☐ SubmittedLegPainForm	Leg Pain Severity Form (Subject)	DateReceivedLegPainForm
☐ SubmittedVillaltaSubject	Villalta PTS (Symptoms) Form (Subject)	DateReceivedVillaltaSubject
☐ SubmittedQOL	Quality of Life Questionnaire (Subject)	DateReceivedQOL
☐ SubmittedVillaltaNurse	Villalta PTS (Signs) Form (Blinded Clinician)	DateReceivedVillaltaNurse
☐ SubmittedLabReports	Laboratory reports	DateReceivedLabReports

CRF Comment (Optional)

Study: ATTRACT

CRF : BASE - Baseline

CRFComment

Study: ATTRACT

CRF : BLEED - SUSPECTED BLEEDING EVENT

Section A: Details of Bleeding Event

Date of onset of bleeding: DateOnsetBleeding

Was bleeding clinically overt? BleedingClinicallyOvert

Site of Bleeding: SiteBleeding Specify: OtherSiteBleeding

Section B: Diagnostic Testing

Was objective testing performed for this bleeding event? TestingPerformed

No/Yes	Diagnostic Test	Date Performed
CTScan	CT Scan	DateCTScan
MRI	MRI	DateMRI
Ultrasound	Ultrasound	DateUS
Endoscopy	Upper endoscopy	DateEndoscopy
Colonoscopy	Colonoscopy	DateColonoscopy
Bronchoscopy	Bronchoscopy	DateBronchoscopy

Other test, *specify:*	Date Performed
OtherDiagnosticTest	DateOtherDiagnosticTest

Section C: Hemoglobin

Was there a decrease in hemoglobin associated with this bleeding event? DecreaseHemoglobin

	Date Sample Obtained	Time Sample Obtained	Result	Not Done
Most recent Hemoglobin obtained **prior to** bleeding event	DateRecentHemoglobin	TimeRecentHemoglobin	RecentResultHemoglobin mg/dL	NotDoneRecentHemoglobin

Study: ATTRACT

CRF : BLEED - SUSPECTED BLEEDING EVENT

	Date Sample Obtained	Time Sample Obtained	Result Not Done
Lowest hemoglobin result obtained after bleeding event started	DateLowestHemoglobin	TimeLowestHemoglobin	LowestResultHemoglobin mg/dL NotDoneLowestHemoglobin

Number of units of blood (whole blood or PRBCs) transfused before lowest hemoglobin result was obtained: NumUnitsBeforeLowHemo

Section D: Blood Transfusions

Did the subject receive a transfusion of whole blood or PRBCs for this bleeding event? ReceiveTransfusion

Blood product	Date transfusion given	Time transfusion given	Number of units	Hemoglobin value
BloodProduct	DateTransfusionGiven	TimeTransfusionGiven	NumberUnits	HemoglobinValue mg/dL

Section E: Risk Factors for Bleeding

Date sample collected	Time sample collected	Not done
DateSampleCollected	TimeTransfusionCollected	HemoglobinNotDone

Was an INR obtained? INRObtained

Result of first INR after event was suspected: ResultINR

Date and time INR performed: DateINRPerformed TimeINRPerformed

Was an aPTT obtained? aPTTObtained

Result of first aPTT after event was suspected: ResultaPTTSeconds

Date and time aPTT performed: DateaPTTPerformed TimeaPTTPerformed

Was a Factor Xa assay obtained FactorXa

Result of first Factor Xa assay after event was suspected: FirstFactorXa

Date and time Factor Xa assay performed: DateFactorXa TimeFactorXa

Within the preceding 7 days before the suspected event, did the subject take any of the following?

Medication	Date Last Taken

Study: ATTRACT

CRF : BLEED - SUSPECTED BLEEDING EVENT

Medication	Date Last Taken
Warfarin — Warfarin	DateWarfarin
UFH — UFH	DateUFH
LMWH — LMWH	DateLMWH
Fondaparinux — Fondaparinux	DateFondaparinux
OtherAnticoag — Other anticoagulant, *specify*: OtherAnticoagSpecify	DateOtherAnticoag
ASA — Aspirin (ASA)	DateASA
Clopidogrel — Clopidogrel or Ticlopidine	DateClopidogrel
NSAID — NSAID	DateNSAID

Did the subject have any of the following risk factors for bleeding?

Risk Factors	
TraumaWithin1Month — Trauma within 1 month	
SurgeryWithin1Month — Surgery within 1 month	
Other Risk Factors	⊕
OtherRiskFactorSpecify	⊖

Section F: Consequences of Bleeding

Did any of the following occur because of the bleeding?

Consequence
VisitedDoctor — Visited a doctor
AttendedEmergency — Attended an emergency room

Study: ATTRACT

CRF : BLEED - SUSPECTED BLEEDING EVENT

Consequence	
AdmittedToHospital	Admitted to hospital, *specify:* HospitalSpecify ⊘
AdmittedCC	Admitted to cardiac or critical care unit
RequiredSurgery	Required surgery, *describe:* DescribeRequiredSurgery ⊘
AnticogTherapyStopped	Anticoagulant therapy was permanently stopped
PermanentDisability	Permanent disability, *describe:* DescribePermanentDisability ⊘
Death	Death

Section G: Required Source Documentation

Submitted	Source Document	FOR DCC USE ONLY Date Received
SubmittedDiagnosticTestResults	Diagnostic test results, if performed	DateReceivedDiagTests
SubmittedHemoLabReports	Hemoglobin lab reports, if performed	DateReceivedHemoReports
SubmittedTransfusion	Transfusion records, if applicable	DateReceivedTransfusion
SubmittedOperativeReports	Operative reports, if applicable	DateReceivedOperative
SubmittedClinicNotes	All clinic notes relating to the suspected bleeding event	DateReceivedClinicNotes
SubmittedAdjEventTrans	Adjudication Event Transmittal Form - Suspected Bleeding	DateReceivedAdjEventTrans

CRF Comment (Optional)

Study: ATTRACT

CRF : BLEED - SUSPECTED BLEEDING EVENT

CRFComment

Study: ATTRACT

CRF : COMPUS - COMPRESSION ULTRASOUND

Date Compression Ultrasound performed: DateCUSPerformed

Right Leg RightLeg

Common Femoral Vein
Fully compressible ⊘ RightLegCFV

Residual diameter mm ⊘ RightLegCFVDiameter

Femoral Vein
Fully compressible ⊘ RightLegFemoralVein

Popliteal Vein
Fully compressible ⊘ RightLegPopVein

Residual diameter mm ⊘ RightLegPopVeinDiameter

Left Leg LeftLeg

Common Femoral Vein
Fully compressible ⊘ LeftLegCFV

Residual diameter mm ⊘ LeftLegCFVDiameter

Femoral Vein
Fully compressible ⊘ LeftLegFemoralVein

Popliteal Vein
Fully compressible ⊘ LeftLegPopVein

Residual diameter mm ⊘ LeftLegPopVeinDiameter

Other findings/comments: Comments

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : DEATH - DEATH

Section A: Details of Death

Date of death: DeathDate

Primary cause of death: PrimaryCauseDeath

Other cause, *specify*: OtherCauseSpecify

Was an autopsy performed? AutopsyPerformed

Section B: Required Source Documentation

Submitted	Source Document	FOR DCC USE ONLY Date Received
SubmittedDoctorNotes	Doctor`s notes in hospital chart, if applicable	DateReceivedDoctorsNotes
SubmittedNurseNotes	Nurse`s notes in hospital chart, if applicable	DateReceivedNursesNotes
SubmittedHospDischarge	Hospital discharge summary, if applicable	DateReceivedHospDischarge
SubmittedInfoPhysician	Information from subject`s physician, if applicable	DateReceivedInfoPhysician
SubmittedDescriptionFamily	Description from family or other contact, if applicable	DateReceivedDescFamily
SubmittedAutopsyReport	Autopsy report, if applicable	DateReceivedAutopsy
SubmittedAdjEventTrans	Adjudication Event Transmittal Form - Death	DateReceivedAdjEventTrans

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : EOS - End of Study

Date of termination: DateTermination

Reason: ReasonStudyTermination

Early termination details: EarlyTermination

Other, *specify*: OtherReasonTermination

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : FUP - Follow-up

Section A: Completeness of Questionnaires

Has the subject answered the Villalta PTS Symptoms questionnaire completely? VillaltaQuestCompleted

VillaltaNotCompleted ⊘

Other, specify: OtherVillaltaSpecify ⊘

Has the subject answered the Quality of Life Questionnaire (Subject) completely? YourHealthQuestCompleted

YourHealthNotCompleted ⊘

Other, specify: OtherYourHealthSpecify ⊘

Section B: Employment History (All Visits Except Day 10)

Employment status: EmploymentStatus

Number of workdays missed since last visit due to leg problems: **OR** ☐ Not Applicable WorkdaysMissedNotApp

NumWorkdaysMissed

Since the last visit, what are the weekly number of hours that the subject`s family spent providing care to the subject (estimate): NumHoursFamCare

Since the last visit, what is the number of workdays that the subject`s family missed due to providing care to the subject (estimate): NumWordaysFamMissed

Section C: Compression Stockings Use (All visits Except Day 10)

Since the last study visit, which of the following describes the subject`s use of graduated elastic compression stockings? UseStockings

ResultWearingStockings ⊘

When worn, average number of hours in a day: hrs ⊘ NumHoursDayStockings

Section D: Change in Anticoagulant Therapy (AC)

Since the last study visit: ChangeAnticoagTherapy ℹ

Study: ATTRACT

CRF : FUP - Follow-up

Section E: Current Medications

Is the subject currently taking any of the following medications? CurrentlyTakingMeds

Medication	
Warfarin	Warfarin
UFH	UFH
LMWH	LMWH
Fondaparinux	Fondaparinux
Other anticoagulant, specify:	OtherAnticoag
	OtherAnticoagSpecify
Aspirin (ASA)	Aspirin
Clopidogrel or ticlopidine	Clopidogrel
NSAID (one or more doses per day)	NSAID

Is the subject currently taking any of the following medications? MedsLegPain

Medication	Frequency of Use if Yes
NonAnalgesia Non-prescription analgesia	FrequencyNonAnalgesia
NarcoticAnalgesia Narcotic analgesia	FrequencyNarcotic
NSAIDLegPain NSAID	FrequencyNSAID
Other (e.g., analgesics, antidepressants), *specify:*	
OtherMedsSpecify	FrequencyOtherMeds

Section F: INRs Collected Since Last Study Assessment

Study: ATTRACT

CRF : FUP - Follow-up

Since the last study visit, has the subject had any INRs collected? INRsCollected

Date Sample Obtained	INR Result
⊘	⊘

INRResult

DateINRSampleObtained

Section G: Outcome Event Assessment

Since the last study visit, has the subject been diagnosed with, or had any new signs/symptoms of DVT or PE? NewSignsSymptomsDVT

Since the last study visit, has the subject been diagnosed with, or had any new signs/symptoms of bleeding? NewSignsSymptomsBleeding

Since the last study visit, has the subject had any invasive procedures related to DVT treatment (e.g., PCDT, IVC filter placement, other)? InvasiveProcedures

Since the last study visit, has the subject been hospitalized? SubjectHospitalized

Since the last study visit, has the subject experienced an Adverse Event? ExperiencedAE

Since the last study visit, has the subject died? SubjectDied

Section H: Medical Care Resource Utilization Related to Leg Problem(s) (Since the Last Visit)

Number of Emergency Room visits (related to leg), NOT resulting in hospitalization: NumEmergRoomVisits

Number of outpatient physician/nurse visits (related to leg): NumOutpatientVisits

Number of days with home health service: NumDaysHomeHealth

Number of days at a rehabilitation hospital/facility: NumDaysRehab

Number of days at a skilled nursing facility: NumDaysNursingFacility

Number of days at another chronic care facility: NumDaysChronicCare

Specify type: ChronicCareSpecify

Number of intermittent pneumatic compression devices (IPCs) purchased for leg problem: NumIPCsPurchased

Study: ATTRACT

CRF : FUP - Follow-up

List any garments purchased for PTS: GarmentsPurchased

Section I: 10-Day Follow-Up Visit

Is the subject still receiving LMWH or UFH? ReceivingLMWHUFH10Day

When was last dose of LMWH given or UFH stopped: DateLMWHUFH10Day

Platelet Count Result

Date sample obtained: DatePlateletHemoObtained

Platelet count: x 10^9/L PlateletCountResult

Is heparin induced thrombocytopenia suspected or has it been diagnosed since enrollment? HeparinInducedThrombo

Describe: DescribeHeparinThrombo

Section J: 30-Day Follow-Up Visit

If subject was receiving LMWH or UFH at the 10-day visit, are they still receiving it? ReceivingLMWHUFH30Day

Date last dose of LMWH given or UFH stopped: DateLMWHUFHDay30

Indicate reason subject is still receiving LMWH or UFH: ReasonReceivingLMWHUFH

Date 30-Day compression Ultrasound (CUS) performed: Date30DayCUSPerformed

Section K: 12 Month Follow-up Visit

Is the subject part of the Ultrasound Sub-study? USSubStudy

Section L: Required Source Documentation

Submitted	Source Document	FOR DCC USE ONLY Date Received
SubmittedINRReports	INR reports, if applicable	DateReceivedINRReports
Submitted10DayCBC	10-day Visit platelet count, if applicable	DateReceived10DayCBC

Study: ATTRACT

CRF : FUP - Follow-up

Submitted	Source Document	FOR DCC USE ONLY Date Received
☐ Submitted30DayCUS	30-day Compression Ultrasound Form	DateReceived30DayCUS
☐ Submitted12MonthCUS	12-month Compression Ultrasound Form (Substudy)	DateReceived12MonthC US

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : IHF - Initial Hospitalization

Initial Hospitalization

Was the subject an inpatient at any time from randomization to completion of initial therapy? SubjectInitialTherapy

Fill out from beginning of hospital stay (first admit date should be first hospital admission date).

Sequence of Stay	Date	Time	Hospital Unit Type
StaySequence	HospatialDate	HospatialTime	HospitalUnitType

Subject was discharged to: DischargedTo

Specify: OtherDischargeSpecify

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : LATEEND - ATTRACT Late Endovascular Procedure

Indicate which of the following has been performed: IndicatePerformance

Section A: Endovascular Therapy

Before the procedure, complete all of the following:

- ☐ Villalta PTS Symptoms (Subject) ⊘ VillaltaPTSSymptoms
- ☐ Quality of Life Questionnaire (Subject) ⊘ HealthWellBeing
- ☐ Villalta PTS Signs (Blinded Clinician) ⊘ VillaltaPTSSigns

Date and time procedure started: DateEndovascularStarted ⊘ TimeEndovascularStarted ⊘

Justification for performing procedure: ⊘ JustificationProcedure

Procedure performed:

TrellisPCDT	Trellis PCDT ⊘
AngioJetPCDT	AngioJet--PCDT used to deliver rt-PA ⊘
InfusionFirstPCDT	Infusion-first PCDT ⊘
AngioJetAspirate	AngioJet--used to aspirate thrombus (rheolytic thrombectomy) ⊘
BalloonMaceration	Balloon Maceration ⊘
AspirationThrombectomy	Aspiration Thrombectomy (with large bore catheter) ⊘
BalloonAngio	Balloon angioplasty ⊘
StentPlacement	Stent placement ⊘
EndovenousAblation	Endovenous ablation to eliminate reflux. ⊘
GreatSaphenousVein	☐ Great saphenous vein ⊘
SmallSaphenousVein	☐ Small saphenous vein ⊘
OtherEndovenous	☐ Other ⊘
OtherEndovenousSpecify	⊘

Total dose of tPA: TotalDoseTPA mg ⊘

Section B: IVC Filter Placement/Removal

Study: ATTRACT

CRF : LATEEND - ATTRACT Late Endovascular Procedure

Was an IVC filter placed during follow-up? IVCFilterPlaced

Date of filter placement: DateFilterPlacement

Type of filter: TypeFilter specify: RetrievableSpecify

Reason for placement: ReasonPlacement

Specify: OtherReasonSpecify

Was an IVC filter removed (or attempted to be removed) during follow-up? IVCFilterRemoved

Date of filter removal: DateFilterRemoval

Specify: SpecifyFilter

Section C: Complications of Procedures

Indicate if any of the following complications occurred:

- Suspected bleeding event SuspectedBleedingEvent
- Suspected pulmonary embolism SuspectedPE
- OtherComplication Other OtherComplicationSpecify

Section D: Endovascular Resources Used

Total number of endovascular procedure sessions requiring separate cath lab kits: NumberCathKits

Cath Lab Sessions	Date	Time admitted to cath lab	Time discharged from cath lab	
CathSessions	DateCathLabSession	TimeAdmittedLab	TimeDischargedLab	

Document total number of device packages used for each type used during each cath lab session:

Session Number	Device Type	Specify	Number of Device Packages	

Study: ATTRACT

CRF : LATEEND - ATTRACT Late Endovascular Procedure

Session Number	Device Type	Specify	Number of Device Packages	
DeviceSessionNumber	DeviceType	DeviceSpecify	NumDevicePackages	

Section E: Required Source Documentation

Submitted	Source Document	FOR DCC USE ONLY Date Received
SubmittedOperativeReport	Operative report	DateReceivedOperative

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : LegPain - LEG PAIN SEVERITY (Subject)

Date completed: DateCompleted

LEG PAIN SEVERITY

Please rate the overall intensity of PAIN or DISCOMFORT that you have felt in your leg during the past 24 hours by circling ONE response in the following scale:

Right leg:

RtLegPainDiscomfort

Left leg:

LtLegPainDiscomfort

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Date PCDT procedure started: DatePCDTProcedure

Treating Endovascular Physician Identification Number: IdenficationNum

Section A: Anticoagulant Therapy During PCDT Procedure

Dose of anticoagulant therapy administered during the PCDT procedure AnticoagAdministered

UFH

Initial infusion rate UFHChoice

UFHInfusionRate U/hr

UFH U

Date of last dose prior to start of PCDT: DateUFHLastDose

Time of last dose prior to start of PCDT: TimeUFHLastDose

Date of last aPTT or Factor Xa before PCDT: DateUFHaPTTXa

Time of last aPTT or Factor Xa before PCDT: TimeUFHaPTTXa

- Last aPTT prior to start of PCDT therapy
- Last Factor Xa prior to start of PCDT therapy

aPTTOrXaPriorPCDT

sec UFHLastaPTTSeconds

IU/mL UFHLastFactorXa

Enoxaparin

Dose mg BID EnoxaparinDoseBID

Date of last dose prior to start of PCDT: DateEnoxaparinPriorPCDT

Time of last dose prior to start of PCDT: TimeEnoxaparinStartPCDT

Dalteparin

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Dalteparin		
Dose:	⊘	DalteparinDose
	IU BID ⊘	DalteparinDoseBID
	IU QD ⊘	DalteparinIUQD
Date of last dose prior to start of PCDT:	⊘	DateDalteparinPriorPCDT
Time of last dose prior to start of PCDT:	⊘	TimeDalteparinStartPCDT

Tinzaparin		
Dose:	IU QD ⊘	TinzaparinDoseIUQD
Date of last dose prior to start of PCDT:	⊘	DateTinzaparinPriorPCDT
Time of last dose prior to start of PCDT:	⊘	TimeTinzaparinStartPCDT

Section B: IVC Filter Placement

Was a retrievable IVC filter placed in conjunction with PCDT? RetrievableIVCFilter

Section C: Procedure Initiation

Last INR before PCDT procedure:

Not Done	Laboratory Test	Date Sample Obtained	Results
INRNotDone ☐	International Normalized Ratio (INR)	DateINRObtained	INRResults

Start time of PCDT procedure (skin puncture): TimeStartPCDT

Veins that were accessed:

- ☐ Ipsilateral popliteal vein IpsilateralPopVein
- ☐ Ipsilateral tibial vein IpsilateralTibialVein
- ☐ Ipsilateral common femoral vein IpsilateralFemoralVein
- ☐ Internal jugular vein InteralJuglarVein
- ☐ Other, specify OtherVein

OtherVeinsSpecify ⊘

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Which PCDT strategy was used for the initial intrathrombus delivery of rt-PA? PCDTStrategy	Infusion segment length: TechniqueAInfusionLength
	Method: Method
	Reason: TechniqueCPopVein Popliteal vein thrombus TechniqueCIVC IVC thrombus Infusion segment length: TechniqueCInfusionLength cm Catheter type/brand, specify: CatheterTypeSpecify

Section D: Administration of rt-PA

Date and time rt-PA started: DateRTPAStarted TimeRTPAStarted

Date and time rt-PA stopped: DateRTPAStopped TimeRTPAStopped

Total dose given: mg TotalDoseRTPA

Bolus doses given (i.e., less than 15 minutes duration):

Dose Number	Dose Given	Route of Administration	
	mg		

BolusDoseNumber BolusDoseGiven BolusRoute

Infusions given (i.e., longer than 15 minutes duration):

Dose Number	Dose Given	Infusion Duration	Concurrent UFH Infusion		
InfusionDoseNumber	mg	InfusionDuration hr		ResultUFHInfusion U/hr	

InfusionDose ConcurrentUFHInfusion

Section E: Adjunctive Endovascular Procedures

Was Balloon Maceration used? BalloonMacerationUsed

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Was Balloon Maceration used? BalloonMacerationUsed

- Inferior vena cava ⊘ BalloonMacIVC
- Common iliac vein ⊘ BalloonMacCIV
- External iliac vein ⊘ BalloonMacEIV
- Common femoral vein ⊘ BalloonMacCFV
- Femoral vein ⊘ BalloonMacFemoralVein
- Popliteal vein ⊘ BalloonMacPopVein
- Tibial vein ⊘ BalloonMacTibialVein

Was Aspiration Thrombectomy with a large-bore catheter used? AspirationThrombectomy

- Inferior vena cava ⊘ AspThrombIVC
- Common iliac vein ⊘ AspThrombCIV
- External iliac vein ⊘ AspThrombEIV
- Common femoral vein ⊘ AspThrombCFV
- Femoral vein ⊘ AspThrombFemoralVein
- Popliteal vein ⊘ AspThrombPopVein
- Tibial vein ⊘ AspThrombTibialVein

Was Rheolytic Thrombectomy (AngioJet) used? RheolyticThrombectomy

- Inferior vena cava ⊘ RheolyticThrombIVC
- Common iliac vein ⊘ RheolyticThrombCIV
- External iliac vein ⊘ RheolyticThrombEIV
- Common femoral vein ⊘ RheolyticThrombCFV
- Femoral vein ⊘ RheolyticThrombFemoralVein
- Popliteal vein ⊘ RheolyticThrombPopVein
- Tibial vein ⊘ RheolyticThrombTibialVein

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Was Trellis PCDT repeated in a subject who was initially treated with Technique A? TrellisPCDTRepeated

- Inferior vena cava ⊘ TrellisPCDTIVC
- Common iliac vein ⊘ TrellisPCDTCIV
- External iliac vein ⊘ TrellisPCDTEIV
- Common femoral vein ⊘ TrellisPCDTCFV
- Femoral vein ⊘ TrellisPCDTFemoralVein
- Popliteal vein ⊘ TrellisPCDTPopVein

Was Balloon Angioplasty performed? BalloonAngioplastyPerformed

- Inferior vena cava ⊘ BalloonAngioIVC
- Common iliac vein ⊘ BalloonAngioCIV
- External iliac vein ⊘ BalloonAngioEIV
- Common femoral vein ⊘ BalloonAngioCFV
- Femoral vein ⊘ BalloonAngioFemoralVein
- Popliteal vein ⊘ BalloonAngioPopVein
- Tibial vein ⊘ BalloonAngioTibialVein

Was a stent placed? StentPlaced

- Inferior vena cava ⊘ StentIVC
- Common iliac vein ⊘ StentCIV
- External iliac vein ⊘ StentEIV
- Common femoral vein ⊘ StentCFV
- Femoral vein ⊘ StentFemoralVein

Diameter: Largest: mm ⊘ StentDiameterLargest Smallest: mm ⊘ StentDiameterSmallest

Indication(s)

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Indication(s)	
Stenosis ⊘	Stenosis
Residual thrombus ⊘	ResidualThrombus
Extrinsic compression ⊘	ExtrinsicCompression
Indeterminate ⊘	Indeterminate

Section F: End of Procedure Assessments

When was the last component of the PCDT procedure completed? DatePCDTProcedureCompleted TimePCDTProcedureCompleted

Treating endovascular physician's estimate of clot lysis in all proximal veins: EstimateClotLysis

Is there anterograde flow in both the iliac vein and common femoral vein? AnterogradeFlow

Is there anterograde flow in both the femoral vein and popliteal vein? AnterogradeFlowBothVeins

Section G: Procedure Complications

Indicate if any of the following complications occurred:

Complication	
Procedure was stopped prematurely. ℹ	ComplicationProcedure
Specify: ⊘	ProcedureStopped
⊘	OtherProcedureSpecify
Suspected bleeding ℹ	ComplicationSuspectedBleed
Suspected pulmonary embolism ℹ	ComplicationSuspectedPE
Other, *specify:*	ComplicatitonOther
⊘	OtherComplicationSpecify

Section H: Post Procedure Anticoagulant Therapy

Indicate if each of the following were used within 24 hours of completing the procedure:

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Anticoagulant Therapy	
☐ I.V. UFH that was continued for >= 4 hours after procedure	TherapyIVUFHContinued
☐ Enoxaparin, dalteparin, or tinzaparin	TherapyEnoxaparin
☐ Warfarin	TherapyWarfarin
☐ Other anticoagulant, *specify:*	TherapyOtherAnticoag
⊘	OtherAnticoagSpecify

Section I: Endovascular Resources Used

Total number of endovascular procedure sessions requiring separate cath lab kits: NumberCathKits

Provide dates and times for each cath lab session:

Cath Lab Sessions	Date	Time admitted to cath lab	Time discharged from cath lab	⊕
CathSessions	DateCathLabSession	TimeAdmittedLab	TimeDischargedLab	⊖

Document total number of device packages used for each type used during each cath lab session:

Session Number	Device Type	Specify	Number of Device Packages	⊕
DeviceSessionNumber	DeviceType	DeviceSpecify ⊘	NumDevicePackages	⊖

Section J: Required Source Documentation

Submitted	Source Document	FOR DCC USE ONLY Date Received
☐ SubmittedINRReport	INR report	DateReceivedINR
☐ SubmittedOperativeReport	Operative report	DateReceivedOperative

Study: ATTRACT

CRF : PCDT - INITIAL PCDT Therapy

Submitted	Source Document	FOR DCC USE ONLY Date Received
☐ SubmittedLastaPTT	Last aPTT or Factor Xa report before procedure, if applicable	DateReceivedLastaPTT
☐ SubmittedVenogramStartPCDT	Venogram images documenting thrombus before start of PCDT from popliteal vein to IVC	DateReceivedVenoStartPCDT
☐ SubmittedVenogramEndPCDT	Venogram images documenting thrombus at end of PCDT and Adjunctive procedures	DateReceivedVenoEndPCDT
☐ SubmittedVenogramTrans	Venogram Transmittal Form	DateReceivedVenogramTrans

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : QOL - Quality Of Life Questionnaire (Subject)

Date Questionnaire was completed: DateQuestCompleted

Your Health and Well-Being

1. In general, would you say your health is: GeneralHealth

2. Compared to one year ago, how would you rate your health in general now? GeneralHealthNow

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a. **Vigorous activities** VigorousActivities

b. **Moderate activities** ModerateActivities

c. Lifting or carrying groceries LiftingCarryingGroceries

d. Climbing **several** flights of stairs ClimbingFlightsStairs

e. Climbing **one** flight of stairs ClimbingOneFlightStairs

f. Bending, kneeling, or stooping BendingKneelingStooping

g. Walking **more than a mile** WalkingMoreThanMile

h. Walking **several hundred yards** WalkingSeveralYards

i. Walking **one hundred yards** Walking100Yards

j. Bathing or dressing yourself BathinDressingYourself

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down on the **amount of time** you spent on work or other activities PhysicalCutDownTimeWork

b. **Accomplished less** than you would like PhysicalAccomplishedLess

c. Were limited in the **kind** of work or other activities PhysicalLimitedWorkActivities

d. Had **difficulty** performing the work or other activities PhysicalDifficultyPerformWork

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a. Cut down the **amount of time** you spent on work or other activities EmotionalCutDownTimeWork

b. **Accomplished less** than you would like EmotionalAccomplishedLess

c. Did work or other activities as **less carefully** than usual EmotionalActivLessCarefully

Study: ATTRACT

CRF : QOL - Quality Of Life Questionnaire (Subject)

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, neighbors, or groups? InterferredSocialActiv

7. How much bodily pain have you had during the past 4 weeks? BodilyPainPast4Weeks

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? HowMuchDidPainInterfere

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

a. Did you feel full of life? FeelFullOfLife

b. Have you been very nervous? NervousPerson

c. Have you felt so down in the dumps that nothing could cheer you up? FeltDownInDumps

d. Have you felt calm and peaceful? FeltCalmPeaceful

e. Did you have a lot of energy? DidHaveAlotEnergy

f. Have you felt downhearted and depressed? FeltDownhearted

g. Did you feel worn out? FeelWornOut

h. Have you been a happy? BeenHappy

i. Did you feel tired? DidYouFeelTired

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? Past4WeeksHealthInterfered

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people SickEasierOtherPeople

b. I am as healthy as anybody I know HealthyAsAnybody

c. I expect my health to get worse ExpectHealthGetWorse

d. My health is excellent MyHealthExcellent

12. During the past 4 weeks, how often have you had any of the following leg problems?

a. Heavy legs HeavyLegs

b. Aching legs AchingLegs

c. Swelling Swelling

d. Night cramps NightCramps

e. Heat or burning sensation HeatBurningSensation

Study: ATTRACT

CRF : QOL - Quality Of Life Questionnaire (Subject)

f. Restless legs — RestlessLegs

g. Throbbing — Throbbing

h. Itching — Itching

i. Tingling sensation — TinglingSensation

13. At what time of day is your leg problem most intense? — TimeDayLegIntense

14. Compared to one year ago, how would you rate your leg problem in general now? — RateLegProblemNow

15. The following items are about activities that you might do in a typical day. Does your leg problem now limit you in these activities? If so, how much?

a. Daily activities at work — DailyActivitiesWork

b. Daily activities at home — DailyActivitiesHome

c. Social or leisure activities in which you are **standing** for long periods — SocialActivitiesStanding

d. Social or leisure activities in which you are **sitting** for long periods — SocialActivitiesSitting

16. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your leg problem?

a. Cut down on the **amount of time** you spent on work or other activities — CutDownTimeSpentWork

b. **Accomplished less** than you would like — AccomplishedLess

c. Were limited in the **kind** of work or other activities — LimitedWorkActivities

d. Had **difficulty** performing the work or other activities — DifficultyPerformWork

17. During the past 4 weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbors or groups? — LegProblemInterfered

18. How much leg pain have you had during the past 4 weeks? — LegPainPast4Weeks

19. These questions are about how you feel and how things have been with you during the past 4 weeks as a result of your leg problem. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

a. Have you felt concerned about the appearance of your leg(s)? — ConcernedAppearanceLegs

b. Have you felt irritable? — FeltIrritable

c. Have you felt a burden to your family or friends? — FeltBurdenFamily

d. Have you been worried about bumping into things? — WorriedBumpingThings

e. Has the appearance of your leg(s) influenced your choice of clothing? — InfluencedChoiceClothing

Study: ATTRACT

CRF : QOL - Quality Of Life Questionnaire (Subject)

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : REVCEAP - REVISED CEAP CLASSIFICATION (BLINDED CLINICIAN)

Date completed: DateCEAPCompleted

"C" (CLINICAL) CLASSIFICATION

Finding on Physical Exam	Right Leg	Left Leg
Telangiectasias (spider veins) or reticular	RightLegTelangiectasias	LeftLegTelangiectasias
Varicose veins	RightLegVaricose	LeftLegVaricose
Edema	RightLegEdema	LeftLegEdema
Skin changes - pigmentation or venous eczema	RightLegSkinChangePig	LeftLegSkinChangePig
Skin changes-lipodermatosclerosis	RightLegSkinChangeLip	LeftLegSkinChangeLip
Healed venous ulcer	RightLegHealedUlcer	LeftLegHealedUlcer
Active venous ulcer	RightLegActiveUlcer	LeftLegActiveUlcer

If you checked Absent to all, please check to confirm:
There are no visible or palpable signs of venous disease in either leg ☐ NoSignsVenousDisease

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : SAE - SERIOUS ADVERSE EVENT FORM

PLEASE REMEMBER TO PRINT THIS SAE REPORT, SIGN AND DATE AND THEN FAX OR E-MAIL IMMEDIATELY TO THE CCC.

1. SAE ID: SAEID

2. Report number: SAEReportNumber

3. Report type: SAEReport

4. Report date: SAEReportDate

Section A: Subject Information

1. Age in Years: AgeYears

2. Gender: Gender

3. Height: Height HeightType

4. Weight: Weight WeightType

Section B: Serious Adverse Event Summary

1. Event: SAEName

2. Seriousness

a. FDA	
FDAResultDeath Resulted in death	Resulted in persistent or significant disability/incapacity FDAPersistantDisability
FDALifeThreatening Life-threatening	Congenital anomaly/birth defect FDACongenitalAnomaly

Study: ATTRACT

CRF : SAE - SERIOUS ADVERSE EVENT FORM

a. FDA	
Required or prolonged inpatient hospitalization FDAHospitalization	Other medically important condition FDAOtherCondition
b. Study-specific	
Required unplanned increase in level of care UnplannedIncreaseCare	Resulted in pregnancy abortion (accidental, therapeutic, or spontaneous) PregnancyAbortion
RequiredHospitalization Required or prolonged hospitalization: HospitalizationHours ⊘	Seriously jeopardized subject`s health JeopardizedSubjectsHealth
Required aggressive intervention to prevent subject harm AggressiveIntervention	Cancer in a neonate/infant born to female subject CancerInNeonate

3. Maximum severity since last submitted report MaximumSeverity ℹ

4. Date/time event started: SAEStartDate SAEStartTime **OR** Time not known SAEStartTimeNotKnown

5. Date/time event became serious: SAEBecameSeriousDate SAEBecameSeriousTime **OR** Time not known SAEBecameSeriousTimeNotKnown

6. Date/time event known to investigator: SAEKnownDate SAEKnownTime **OR** Time not known SAEKnownTimeNotKnown

7. Date/time event resolved: SAEResolveDate SAEResolveTime **OR** Time not known SAEResolveTimeNotKnown **OR** Ongoing SAEOngoing

8. Did the subject die? DidSubjectDie

Study: ATTRACT

CRF : SAE - SERIOUS ADVERSE EVENT FORM

a. Date/time of death DateOfDeath TimeDeath **OR** Time not known TimeNotKnown

b. Cause of death: DeathCause

c. Was an autopsy performed? Autopsy

Section C: Details of Serious Adverse Event

1. Full chronological description of reaction, including body site, setting (e.g., hospital, home), signs and symptoms: SAEDescription

2. Specific diagnosis of event: SAEDiagnosis

No change since last SAE report NoChangeDiagnosis

3. Treatment given for event and outcome of treatment: SAEOutcomeTreatment

SAETreatment

No action taken since last SAE report NoAction

4. Relevant medical history, including allergy, drug or alcohol abuse, family history: SAEMedicalHistoryNone

SAERelevantMedicalHistory

5. Relevant laboratory/diagnostic tests/investigational findings: SAELabFindings

No additional relevant findings since last SAE report NoNewFindings

6. Outcome at time of this report SAEOutcome

Section D: Relationship to Study Drug and Participation in Research Study

Study: ATTRACT

CRF : SAE - SERIOUS ADVERSE EVENT FORM

1. Date of enrollment: DateEnrollment

2. a) Relationship of event to use of the study drug (rt-PA) (for FDA reporting). StudyDrug
b) Relationship of event to participation in the Research Study (per OHRP Guidelines). ParticipationInStudy

3. Is this SAE expected? SAEExpected

4. Provide details of last administration of rt-PA at time of or before event: ☐ Not Applicable DetailsNotApplicable

Date/Time of Administration (Study Drug = rt-PA): DateAdministration TimeAdministration

Lot Number: LotNumber

Expiration Date: DateDrugExpiration

Dose: Dose Unit: DoseUnit

Section E: Concomitant Medications

1. Concomitant medications. *Exclude medications used to treat event:* ☐ No new information since last SAE report NoNewInfoMedicatitons

Generic Name of Medication	Indication	Start Date	Stop Date	Ongoing	Was SAE possibly related to use of this medication?*	Batch Number	Dose Form & Strength	Route of Administration
MedicationName	Indication	MedicationStartDate	MedicationStopDate	MedicationOngoing	SAERelatedMedication	BatchNumber	DoseStrength	RouteAdministration
				☐				

Study: ATTRACT

CRF : SAE - SERIOUS ADVERSE EVENT FORM

Investigator/Reporter	
Name:	ReporterName
Address:	ReporterAddress
Telephone:	ReporterTelephone
Profession/Specialty:	ReporterProfession
Signature date:	SignatureDate

OtherRouteSpecify

Specify	Time of Administration

TimeRelatedMedAdmin

PLEASE REMEMBER TO PRINT THIS SAE REPORT, SIGN AND DATE AND THEN FAX OR E-MAIL IMMEDIATELY TO THE CCC.

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : SUBHOSP - SUBSEQUENT HOSPITALIZATION

Section A: Details of Hospitalization

Admit date: DateAdmit

Discharge date: DateDischarge

Hospital: Hospital

Name of hospital: NameHospital

City, State/Province: HospitalCityState

Country: HospitalCountry

Was subject transferred to or from another acute care hospital? TransferredAcuteHospital

Fill out from beginning of hospital stay (first admit date should be hospital admission date). Include any transfers between different care units within the hospital (i.e., ICU, medical/Surgical and Step-down Unit). Final date represents discharge from hospital.

Sequence of Stay	Date	Hospital Unit Type
Hospital Admission DateHospitalAdmission		HospitalUnitType
Transfer	**Date**	**Hospital Unit Type**
Transfer DateHospitalTransfer		HospitalTransferUnitType
Sequence of Stay	**Date**	**Hospital Unit Type**
Hospital Discharge DateHospitalDischarge		

Subject was discharged to: DischargedTo

Specify: OtherDischargeSpecify

Primary indication for hospitalization. *Include discharge summary.* PrimaryHospitalization

Specify: OtherPrimarySpecify

Section B: Hospital Summary

Study: ATTRACT

CRF : SUBHOSP - SUBSEQUENT HOSPITALIZATION

Procedure Code	Specify	Date	
ProcedureCodes	OtherProcedureSpecify	DateHospitalProcedure	

Section C: Subject Diagnostic Information

Discharge diagnosis: DischargeDiagnosis

A copy of the discharge summary for this hospitalization must be included. If none available, complete narrative below. Please submit all requisite forms for these hospitalizations. CopyDischargeSummary

Narrative: DischargeNarrative

Section D: Required Source Documentation

Submitted	Source Document	FOR DCC USE ONLY Date Received
SubmittedDischarge	Discharge summary	DateReceivedDischarge
SubmittedLegDoppler	Leg Doppler/duplex ultrasound report, if applicable	DateReceivedLegDoppler
SubmittedVenogram	Venogram report, if applicable	DateReceivedVenogram
SubmittedCTAngiogram	CT angiogram report if applicable	DateReceivedCTAngiogram
SubmittedVQScan	VQ Scan report, if applicable	DateReceivedVQScan
SubmittedEchocardiogram	Echocardiogram report, if applicable	DateReceivedEchocardiogram
SubmittedCTScan	CT Scan report, if applicable	DateReceivedCTScan
SubmittedOperativeReport	Operative report, if applicable	DateReceivedOperative
SubmittedUpEndoscopy	Upper endoscopy report, if applicable	DateReceivedUpEndoscopy

Study: ATTRACT

CRF : SUBHOSP - SUBSEQUENT HOSPITALIZATION

Submitted	Source Document	FOR DCC USE ONLY Date Received
☐ SubmittedColonoscopy	Colonoscopy report, if applicable	DateReceivedColonoscopy
☐ SubmittedSigmoidoscopy	Sigmoidoscopy report, if applicable	DateReceivedSigmoidoscopy
☐ SubmittedBronchoscopy	Bronchoscopy report, if applicable	DateReceivedBronchoscopy
☐ SubmittedTransfusion	Transfusion record, if applicable	DateReceivedTransfusion

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : VasCore - VasCore Case Report Form

Index Limb: IndexLimb

Diagnostic: Diagnostic

Reflux Venous Segment		Reflux Score	
CFV RvsCFVResult	⊘	RvsCFVScore ⊘	
FV RvsFVResult	⊘	RvsFVScore ⊘	
Profunda FV RvsProfundaFVResult	⊘	RvsProfundaFVScore ⊘	R - Reflux N - No reflux U - Unknown
Pop RvsPopResult	⊘	RvsPopScore ⊘	
GSV RvsGSVResult	⊘	RvsGSVScore ⊘	
SSV RvsSSVResult	⊘	RvsSSVScore ⊘	
Obstruction Venous Segment		**Obstruction Score**	
CFV OvsCFVResult	⊘	OvsCFVScore ⊘	
FV OvsFVResult	⊘	OvsFVScore ⊘	
Profunda FV OvsProfundaFVResult	⊘	OvsProfundaFVScore ⊘	O - Obstructed P - Patent U - Unknown
Pop OvsPopResult	⊘	OvsPopScore ⊘	
GSV (AK) OvsGSVResult	⊘	OvsGSVScore ⊘	

Study: ATTRACT

CRF : VasCore - VasCore Case Report Form

Obstruction Venous Segment	Obstruction Score	
Iliac OvsIliacResult ⊘	OvsIliacScore ⊘	

Comments: Comments

VasCore Reviewer: VasCoreReviewer

Review Date: ReviewDate

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : VCSS - VENOUS CLINICAL SEVERITY SCORE-VCSS (BLINDED CLINICIAN)

Date completed: DateVillaltaCompleted

Symptom/Sign	Right Leg	Left Leg
Pain	RightLegPain	LeftLegPain
Varicose Veins	RightLegVaricose	LeftLegVaricose
Venous Edema	RightLegVenousEdema	LeftLegVenousEdema
Skin Pigmentation	RightLegSkinPig	LeftLegSkinPig
Inflammation	RightLegInflammation	LeftLegInflammation
Induration	RightLegInduration	LeftLegInduration
Active Ulcers Number	RightLegUlcersNumber	LeftLegUlcersNumber
Active Ulcers Duration	RightLegUlcersDuration	LeftLegUlcersDuration
Active Ulcers Size (diameter)	RightLegUlcersSize	LeftLegUlcersSize

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : VILLSIGN - VILLALTA PTS SIGNS (BLINDED CLINICIAN)

Date completed: DateVillaltaCompleted

Assessment of Clinical Signs of PTS (VILLALTA)

Signs (complete for both legs)

This form is to be completed by the blinded clinician performing assessment of PTS. Blinded Clinician must be blind to responses to previous Symptoms questions.

Sign	Right Leg	Left Leg
Pretibial edema	RightLegPretibialEdema	LeftLegPretibialEdema
Skin induration	RightSkinInduration	LeftSkinInduration
Hyperpigmentation	RightLegHyperpig	LeftLegHyperpig
Venous ectasia	RightLegVenousEctasia	LeftLegVenousEctasia
Redness	RightLegRedness	LeftLegRedness
Pain during calf compression	RightLegPainCalfComp	LeftLegPainCalfComp
Is an ulcer present?	RightLegUlcer	LeftLegUlcer
Circumference 10 cm below tibial tuberosity	cm RightLegCircumference	cm LeftLegCircumference

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : VILLSYMP - VILLALTA PTS SYMPTOMS (SUBJECT)

Date completed: DateVillaltaCompleted

ASSESSMENT of SYMPTOMS of PTS (VILLALTA)

Symptoms (complete for both legs)

Symptom	Right Leg	Left Leg
Cramps	RightLegCramps	LeftLegCramps
Itching	RightLegItching	LeftLegItching
Pins and needles	RightLegPinsNeedles	LeftLegPinsNeedles
Leg heaviness	RightLegHeaviness	LeftLegHeaviness
Pain	RightLegPain	LeftLegPain

CRF Comment (Optional)

CRFComment

Study: ATTRACT

CRF : VTE - SUSPECTED VENOUS THROMBOEMBOLIC EVENT (VTE)

Date of VTE Event: DateVTEEvent

Section A: Risk Factors for VTE

Risk Factors for VTE RiskFactorsVTE

Risk Factors for VTE		Specify
MajorSurgery	Major surgery (>=30 minutes duration) within the past 6 weeks, *specify:*	MajorSurgerySpecify
Hospitalized	Hospitalized within the past 6 weeks, *specify:*	HospitalizedSpecify
PlasterCast	Plaster cast immobilization within the past 6 weeks, *specify:*	PlasterCastSpecify
ActiveCancer	Active cancer, *specify:*	ActiveCancerSpecify

Other Risk Factors for VTE

OtherRiskFactorsSpecify

Section B: Recent and Current Anticoagulant Status

Has the subject stopped anticoagulant therapy for more than 3 consecutive days within the past month? StoppedAnticoagTherapy

Date anticoagulant therapy most recently stopped: DateAnticoagStopped

Date anticoagulant therapy most recently restarted: DateAnticoagRestarted Not Applicable AnticoagNotApplicable

Was an INR obtained? INRObtained

Result of INR after event was suspected: ResultINR

Date and time INR performed: DateINRPerformed TimeINRPerformed

Section C: Type of Suspected VTE

Study: ATTRACT

CRF : VTE - SUSPECTED VENOUS THROMBOEMBOLIC EVENT (VTE)

TypeVTE

- ○ DVT only. Complete Section D.
- ○ PE only. Complete Section E.
- ○ DVT and PE. Complete Section D, then Section E.

Section D: Suspected DVT

Does the subject have new or worsening symptoms of DVT? ⊘ NewWorseSymptomsDVT

Specify symptomatic leg(s): ⊘ SymptomaticLeg

Date of onset of first clinical signs/symptoms of recurrent DVT: ⊘ DateFirstSignsDVT

Evaluate each of the following subject`s symptoms and signs:

New Onset or Increase of Symptoms or Signs of DVT	Result	
Swelling	⊘	Legswelling
Pain	⊘	Legpain
Discolouration	⊘	Legdiscolouration
Pitting edema	⊘	Legpittingedema
Tenderness (knee and above)	⊘	Legtendernessproximal
Tenderness (below knee)	⊘	Legtendernessdistal
Warmth	⊘	Legwarmth

Other, Specify	Result
OtherSymptomSpecify ⊘	LegOther ⊘

Physician`s clinical suspicion of DVT BEFORE diagnostic testing: SuspicionDVTBeforeTest ⊘

Diagnostic tests for suspected DVT.

Diagnostic Test	Date Performed	Test Result
DVTDDimer D-Dimer ⊘	DateDVTDDimer ⊘	ResultDVTDDimer ⊘

Study: ATTRACT

CRF : VTE - SUSPECTED VENOUS THROMBOEMBOLIC EVENT (VTE)

Diagnostic Test	Date Performed	Test Result
DVTInitialCUS Initial Compression Ultrasound	DateDVTInitialCUS	ResultDVTInitialCUS
DVTSerialDay7CUS Serial (Day 7) Compression Ultrasound	DateDVTSerialDay7CUS	ResultDVTSerialDay7CUS
DVTVenogram Venogram	DateDVTVenogram	ResultDVTVenogram
DVTCTVenogram CT Venogram	DateDVTCTVenogram	ResultDVTCTVenogram

Section E: Suspected PE

Does the subject have symptoms of PE? SymptomsPE

Date of onset of first clinical signs/symptoms of PE: DateFirstSymptomsPE

Evaluate each of the following subject`s symptoms and signs:

New Onset or Increase of Symptoms or Signs of PE	Specify
ChestPain Chest pain. If Yes, *specify:*	ChestPainSpecify
Dyspnea Dyspnea	
Hemoptysis Hemoptysis	
Syncope Syncope/Light-headedness/Dizziness	

Other New Onset or Increase of Symptoms or Signs of PE
OtherSymptomsPESpecify

Physician`s clinical suspicion of PE BEFORE diagnostic testing: SuspicionPEBeforeTest

Diagnostic tests for suspected PE.

Diagnostic Test	Date Performed	Test Result
PEDDimer D-Dimer	DatePEDDimer	ResultPEDDimer

Study: ATTRACT

CRF : VTE - SUSPECTED VENOUS THROMBOEMBOLIC EVENT (VTE)

Diagnostic Test	Date Performed	Test Result
PELungScan Ventilation/Perfusion Lung Scan ⊘	DatePELungScan ⊘	ResultPELungScan ⊘
PESpiralCTScan Spiral CT Scan ⊘	DatePESpiralCTScan ⊘	ResultPESpiralCTScan ⊘ If Acute PE not diagnosed, did Spiral CT Scan yield alternate diagnosis? SpiralCTAltDiagnosis ⊘ ℹ SpiralCTScanSpecify ⊘
PEPulmAngio Pulmonary Angiography ⊘	DatePEPulmAngio ⊘	ResultPEPulmAngio ⊘
PEInitialCUS Initial Compression Ultrasound ⊘	DatePEInitialCUS ⊘	ResultPEInitialCUS ⊘ ℹ
PESerialCUS Serial Compression Ultrasound ⊘	DatePESerialCUS ⊘	ResultPESerialCUS ⊘ ℹ
PEChestXRay Chest X-Ray ⊘	DatePEChestXRay ⊘	ResultPEChestXray ⊘ ℹ AbnormalChestSpecify ⊘

Section F: Final Assessment

Clinical center evaluation of Suspected VTE: EvaluationSuspectedVTE

If anticoagulant therapy was restarted or changed from warfarin to LMWHs, complete **Anticoagulation Change Form.**

If IVC Filter placement or venous recanalization procedure was performed, complete **Late Endovascular Procedure Form.**

Was subject admitted to hospital? ℹ AdmittedHospital

Was subject seen in a hospital (e.g., Emergency Room)? SeenInHospital

Section G: Required Source Documentation

Study: ATTRACT

CRF : VTE - SUSPECTED VENOUS THROMBOEMBOLIC EVENT (VTE)

Submitted	Source Document	FOR DCC USE ONLY Date Received
☐ SubmittedDDDimerReport	D-Dimer report, if performed	DateReceivedDDimer
☐ SubmittedRecentCUSReport	Most recent Compression Ultrasound report and images of symptomatic leg before Suspected VTE	DateReceivedRecentCUS
☐ SubmittedCUSReport	Initial Compression Ultrasound report, form and images, if performed	DateReceivedCUS
☐ SubmittedSerialCUSReport	Serial Compression Ultrasound report, form and images, if performed	DateReceivedSerialCUS
☐ SubmittedVenographyReport	Venogram report and images, if performed	DateReceivedVenogram
☐ SubmittedVentilationReport	Ventilation/Perfusion Lung Scan report and images, if performed	DateReceivedLungScan
☐ SubmittedSpiralCTReport	Spiral CT Scan report and images, if performed	DateReceivedSpiralCT
☐ SubmittedPulmonaryAngioReport	Pulmonary Angiography report and images, if performed	DateReceivedPulmAngio
☐ SubmittedCTVenogram	CT Venogram local report and images, if performed	DateReceivedCTVenogram
☐ SubmittedChestXRayReport	Chest X-Ray report, if performed	DateReceivedChestXRay
☐ SubmittedClinicNotes	All clinic notes relating to the suspected VTE event	DateReceivedClinicNotes
☐ SubmittedINRReport	INR report, if performed	DateReceivedINR
☐ SubmittedAdjEventTrans	Adjudication Event Transmittal Form - Suspected Symptomatic DVT and/or Suspected Symptomatic PE	DateReceivedAdjEventTrans

CRF Comment (Optional)

CRFComment