

C-TRACT Manual of Operations - APPENDIX L
ORCCID Database Modules

Study Visit	Database Modules
Baseline	<p>Baseline Assessment: <i>Demographics (Age, Gender, Ethnicity, Race, Employment)</i> <i>Medical History (Comorbid conditions, Smoking)</i> <i>Treatment (Medications, Stockings, Compression devices)</i> <i>Physical Examination (Height, Weight, Blood pressure, Blood sample collection)</i> <i>Qualifying Leg with DIO-PTS (Index Leg, Ulcer assessment, DVT history)</i> <i>Index Leg Circumference Measurements</i> Villalta PTS Symptoms (Subject) Quality of Life Questionnaire (Subject) – Part 1 and Part 2 Venous Clinical Severity Score (Blinded Clinician) Villalta PTS Signs (Blinded Clinician) CEAP Clinical Classification</p>
Initial Treatment	<p>Initial Stent Procedure</p>
2 Month Follow-up	<p>Follow-Up: <i>Ulcer assessment</i> <i>Current Treatment (Medications, Compression)</i> <i>Resource Utilization</i> <i>Outcome event assessment (DVT/PE, Bleed, Death, AE/SAE)</i></p>
4 Month Follow-up	<p>Follow-up: <i>Current Treatment (Medications, Compression)</i> <i>Resource Utilization</i> <i>Outcome event assessment (DVT/PE, Bleed, Death, AE/SAE)</i></p>
6 Month Follow-up	<p>Follow-up: <i>Ulcer assessment</i> <i>6-month Assessment (Blood sample collection, Smoking, Out-of-pocket costs)</i> <i>Index Leg Circumference Measurements</i> <i>Current Treatment (Medications, Compression)</i> <i>Resource Utilization</i> <i>Outcome event assessment (DVT/PE, Bleed, Death, AE/SAE)</i> Villalta PTS Symptoms (Subject) Quality of Life Questionnaire (Subject) – Part 1 and Part 2 Venous Clinical Severity Score (Blinded Clinician) Villalta PTS Signs (Blinded Clinician)</p>

<p>12 Month Follow-up</p>	<p>Follow-up: <i>Ulcer assessment</i> <i>Index Leg Circumference Measurements</i> <i>Current Treatment (Medications, Compression)</i> <i>Resource Utilization</i> <i>Outcome event assessment (DVT/PE, Bleed, Death, AE/SAE)</i> Villalta PTS Symptoms (Subject) Quality of Life Questionnaire (Subject) – Part 1 and Part 2 Venous Clinical Severity Score (Blinded Clinician) Villalta PTS Signs (Blinded Clinician)</p>
<p>18 Month Follow-up</p>	<p>Follow-up: <i>Index Leg Circumference Measurements</i> <i>Current Treatment (Medications, Compression)</i> <i>Resource Utilization</i> <i>Outcome event assessment (DVT/PE, Bleed, Death, AE/SAE)</i> Villalta PTS Symptoms (Subject) Quality of Life Questionnaire (Subject) – Part 1 and Part 2 Venous Clinical Severity Score (Blinded Clinician) Villalta PTS Signs (Blinded Clinician)</p>
<p>24 Month Follow-up</p>	<p>Follow-up: <i>Index Leg Circumference Measurements</i> <i>Current Treatment (Medications, Compression)</i> <i>Resource Utilization</i> <i>Outcome event assessment (DVT/PE, Bleed, Death, AE/SAE)</i> Villalta PTS Symptoms (Subject) Quality of Life Questionnaire (Subject) – Part 1 and Part 2 Venous Clinical Severity Score (Blinded Clinician) Villalta PTS Signs (Blinded Clinician) End of Study</p>

Supplementary Database Modules	Clinical Scenario
Adverse Events	AE section: Non-serious Adverse Event occurs within 30 days SAE section: Serious Adverse Event occurs within 24 months
Suspected Bleeding Event	Patient experiences bleeding complication Patient is evaluated for suspected bleeding
Subsequent Hospitalization	Patient is hospitalized or attends emergency room
Suspected VTE Event	Patient experiences DVT or PE during follow-up Patient is evaluated for suspected DVT or PE
Late Endovascular Procedure	Non-EVT Arm Patient undergoes stent placement EVT-Arm patient has repeat EVT procedure
Endovenous Ablation Procedure	Patient undergoes ablation procedure
Documentation of Death	Patient dies for any reason
End of Study	Patient dies or elects to withdraw from the study early