

End of Study Case Report Form

| A. Study Completion | | | | | | | | | | |
|--|--|---|---|---|---|---|---|---|---|---|
| 1. Date of study termination: | <table border="1" style="display: inline-table; text-align: center; width: 100%;"><tr><td style="width: 15px; height: 15px;">D</td><td style="width: 15px; height: 15px;">D</td><td style="width: 15px; height: 15px;">M</td><td style="width: 15px; height: 15px;">M</td><td style="width: 15px; height: 15px;">M</td><td style="width: 15px; height: 15px;">Y</td><td style="width: 15px; height: 15px;">Y</td><td style="width: 15px; height: 15px;">Y</td><td style="width: 15px; height: 15px;">Y</td></tr></table> | D | D | M | M | M | Y | Y | Y | Y |
| D | D | M | M | M | Y | Y | Y | Y | | |
| 2. Reason for study termination: | | | | | | | | | | |
| <input type="checkbox"/> Routine study termination, study protocol completed <input type="checkbox"/> Early study termination, due to: <ul style="list-style-type: none"> <input type="checkbox"/> Lost to follow up <input type="checkbox"/> Death* <input type="checkbox"/> Withdrawal of subject's consent**: <ul style="list-style-type: none"> <input type="checkbox"/> Subject allows data collection to continue <input type="checkbox"/> Subject refuses further data collection <input type="checkbox"/> Other, please specify: _____ | | | | | | | | | | |
| <p>*If selected, please complete Death Outcome Form and SAE form</p> <p>**Reason(s) subject has withdrawn consent:</p> | | | | | | | | | | |

| B. Suspected Secondary Outcome Events | | | | | | |
|--|---|---|--|---------------------------------|---|---|
| 1. Did the subject have one or more suspected outcome events listed below that will undergo adjudication? (check all that apply)*: | | | | | | |
| <table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><input type="checkbox"/> None</td> <td style="width: 33%;"><input type="checkbox"/> Symptomatic venous thromboembolism</td> <td style="width: 33%;"><input type="checkbox"/> Bleeding/Hematoma</td> </tr> <tr> <td><input type="checkbox"/> Death*</td> <td><input type="checkbox"/> Symptomatic arterial thromboembolism</td> <td><input type="checkbox"/> Postpartum pre-eclampsia</td> </tr> </table> | <input type="checkbox"/> None | <input type="checkbox"/> Symptomatic venous thromboembolism | <input type="checkbox"/> Bleeding/Hematoma | <input type="checkbox"/> Death* | <input type="checkbox"/> Symptomatic arterial thromboembolism | <input type="checkbox"/> Postpartum pre-eclampsia |
| <input type="checkbox"/> None | <input type="checkbox"/> Symptomatic venous thromboembolism | <input type="checkbox"/> Bleeding/Hematoma | | | | |
| <input type="checkbox"/> Death* | <input type="checkbox"/> Symptomatic arterial thromboembolism | <input type="checkbox"/> Postpartum pre-eclampsia | | | | |
| <p>*If yes, please ensure corresponding Outcome Event and SAE form(s) are completed.</p> | | | | | | |

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| Delegate's Name: | | | | | | | | | |
| Signature: | | | | | | | | | |
| I have reviewed all entries on the Case Report Forms. All information entered onto the Case Report Form for this subject is, to the best of my knowledge, correct. | | | | | | | | | |
| Investigator's Name: | | | | | | | | | |
| Signature: | | | | | | | | | |
| Date: <table border="1" style="display: inline-table; text-align: center; width: 100%;"><tr><td style="width: 15px; height: 15px;">D</td><td style="width: 15px; height: 15px;">D</td><td style="width: 15px; height: 15px;">M</td><td style="width: 15px; height: 15px;">M</td><td style="width: 15px; height: 15px;">M</td><td style="width: 15px; height: 15px;">Y</td><td style="width: 15px; height: 15px;">Y</td><td style="width: 15px; height: 15px;">Y</td><td style="width: 15px; height: 15px;">Y</td></tr></table> | D | D | M | M | M | Y | Y | Y | Y |
| D | D | M | M | M | Y | Y | Y | Y | |

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Follow-up Screening: VTE

| VTE Screening | | | | | | | | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|---|---|---|---|---|---|---|---|---|
| 1. Follow-Up Visit / Phone or Video Call: | | | | | | | | | | | | | |
| <input type="checkbox"/> 6 weeks (Visit/Call) <input type="checkbox"/> 90 days (Call) <input type="checkbox"/> Unscheduled (Visit/Call) | | | | | | | | | | | | | |
| 2. Follow-Up Date: | | | | | | | | | | | | | |
| <table border="1" style="margin: auto;"> <tr> <td style="width: 20px; height: 20px;">D</td> <td style="width: 20px; height: 20px;">D</td> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> </tr> </table> | | | | | D | D | M | M | M | Y | Y | Y | Y |
| D | D | M | M | M | Y | Y | Y | Y | | | | | |
| Instructions: Use the following categories to rate each symptom. Choose the one best answer. None: Patient is not experiencing this symptom today. New: Patient has this symptom today, but did not have it at her last study visit. Worse: Patient had this symptom at her last study visit and it has gotten worse. Same: Patient had this symptom at her last study visit and it has not changed. | | | | | | | | | | | | | |
| 3. Deep Vein Thrombosis (DVT) Symptoms: | | | | | | | | | | | | | |
| | None | New | Worse | Same | | | | | | | | | |
| Pain in limb(s): | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| <input type="checkbox"/> L leg <input type="checkbox"/> R leg <input type="checkbox"/> L arm <input type="checkbox"/> R arm | | | | | | | | | | | | | |
| Swelling in limb(s): | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| <input type="checkbox"/> L leg <input type="checkbox"/> R leg <input type="checkbox"/> L arm <input type="checkbox"/> R arm | | | | | | | | | | | | | |
| Tenderness of the leg(s): | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| <ul style="list-style-type: none"> • Along the path of the deep vein (groin, thigh, behind the knee and/or in the deep calf) <input type="checkbox"/> L leg <input type="checkbox"/> R leg | | | | | | | | | | | | | |
| Tenderness of the arm(s): | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| <ul style="list-style-type: none"> • In the armpit, under the clavicle and/or in the neck <input type="checkbox"/> L arm <input type="checkbox"/> R arm | | | | | | | | | | | | | |
| Warmth in the limb(s): | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| <input type="checkbox"/> L leg <input type="checkbox"/> R leg <input type="checkbox"/> L arm <input type="checkbox"/> R arm | | | | | | | | | | | | | |
| Redness or purple discoloration of the skin in the limb(s): | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| <input type="checkbox"/> L leg <input type="checkbox"/> R leg <input type="checkbox"/> L arm <input type="checkbox"/> R arm | | | | | | | | | | | | | |
| 4. Pulmonary Embolism (PE) Symptoms: | | | | | | | | | | | | | |
| | None | New | Worse | Same | | | | | | | | | |
| Shortness of breath | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| Pain in the chest | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| Rapid pulse or racing heart | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| Cough with blood in sputum | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| Fainting or near fainting episodes | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | |
| If the subject responds 'New' or 'Worse' to any chest symptoms, complete the ATE Screening Form. | | | | | | | | | | | | | |

Important: Any NEW or WORSE leg or chest symptoms will prompt response of study personnel to collect all pertinent source documents to diagnose or exclude VTE as indicated in the Protocol, including arranging for patient assessment if required.