90 Day Follow-up Case Report Form

A. Details of Follow-up		
1.	**Able to contact subject to complete postpartum follow-up:** ☐ Yes ☐ No If no, please specify and then go to end of form: ☐ Unable to contact subject after multiple attempts – *see resource manual for contact procedures* ☐ Subject has died (Please complete **End of Study, SAE and Death Outcome Event forms**) ☐ Subject withdrew consent (Please complete **End of Study CRF**)
2.	**Date of follow-up:** D D M M M Y Y Y Y
3.	Were there any changes to medications since the last visit? ☐ Yes ☐ No **If yes, please complete Concomitant Medication Form.**
4.	Has the subject experienced any adverse events since the last visit? ☐ Yes ☐ No **If yes, please complete Adverse Event or Serious Adverse Event Form(s).**
5.	**Screening Forms:**
	A) Complete VTE Screening Form for all subjects
	B) Other than normal vaginal bleeding*, has the subject had any bleeding since the last visit? ☐ Yes ☐ No If "No" to any bleeding: probe further to confirm response by asking specifically about black stools, blood in stools, blood in urine, nose bleeds, excessive vaginal bleeding and coughing up blood. **If yes, complete Bleeding Screening Form.**
	C) Has the subject had any chest symptoms or neurological symptoms such as weakness or numbness since the last visit? ☐ Yes ☐ No **If yes, complete ATE Screening Form.**

* Defined as vaginal bleeding equivalent or less in volume to subject's pre-pregnancy menstrual bleeding and blood flow does not soak through one or more sanitary pads or tampons every hour for several consecutive hours. Normal postpartum vaginal bleeding should diminish in volume and be less red in colour each day when compared to the previous day.

Delegate's Name

Delegate's Signature

D D M M M Y Y Y Y
Date

Concomitant Medication Form

NSAID Use Postpartum: ☐ Yes ☐ No

	NSAID Name	Average Dose & Frequency	Date Started (dd/mmm/yyyy)	Date Stopped (dd/mmm/yyyy) Or N/A for ongoing	Investigator / Delegate Initials and Date
Baseline visit					
6-week visit					
90-day visit					
Unscheduled					

Other Medication Use: ☐ Yes ☐ No If yes, please complete table. Includes prescriptions, vitamins, supplements, and over the counter medications.

Medication Name	Dose & Frequency	Date Started Postpartum (dd/mmm/yyyy)	Date Stopped (dd/mmm/yyyy) Or N/A for ongoing	Investigator / Delegate Initials and Date

Follow-up Screening: VTE

VTE Screening				
1. Follow-Up Visit / Phone or Video Call: ☐ 6 weeks (Visit/call) ☐ 90 days (Call) ☐ Unscheduled (Visit/Call)				
2. Follow-Up Date: 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): ☐ L leg ☐ R leg ☐ L arm ☐ R arm	☐	☐	☐	☐
Swelling in limb(s): ☐ L leg ☐ R leg ☐ L arm ☐ R arm	☐	☐	☐	☐
Tenderness of the leg(s): • Along the path of the deep vein (groin, thigh, behind the knee and/or in the deep calf) ☐ L leg ☐ R leg	☐	☐	☐	☐
Tenderness of the arm(s): • In the armpit, under the clavicle and/or in the neck ☐ L arm ☐ R arm	☐	☐	☐	☐
Warmth in the limb(s): ☐ L leg ☐ R leg ☐ L arm ☐ R arm	☐	☐	☐	☐
Redness or purple discoloration of the skin in the limb(s): ☐ L leg ☐ R leg ☐ L arm ☐ R arm	☐	☐	☐	☐
4. Pulmonary Embolism (PE) Symptoms:	None	New	Worse	Same
Shortness of breath	☐	☐	☐	☐
Pain in the chest	☐	☐	☐	☐
Rapid pulse or racing heart	☐	☐	☐	☐
Cough with blood in sputum	☐	☐	☐	☐
Fainting or near fainting episodes	☐	☐	☐	☐
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.

Follow-up Screening: ATE

ATE Screening				
1. Follow-Up Visit / Phone or Video Call: ☐ 6 weeks (Visit/Call) ☐ 90 days (Call) ☐ Unscheduled (Visit/Call)				
2. Follow-Up Date: 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. Myocardial Infarction Symptoms:	None	New	Worse	Same
Pressure, tightness or pain in chest • Arm or jaw radiation	☐	☐	☐	☐
Shortness of breath	☐	☐	☐	☐
Nausea or vomiting	☐	☐	☐	☐
Cold sweat (Diaphoresis)	☐	☐	☐	☐
Fainting or near fainting episodes	☐	☐	☐	☐
4. Stroke / TIA Symptoms:	None	New	Worse	Same
Weakness of the face, arms or legs	☐	☐	☐	☐
Numbness or tingling to the face, arms or legs	☐	☐	☐	☐
Slurred speech, trouble speaking or understanding speech	☐	☐	☐	☐
Sudden vision loss	☐	☐	☐	☐
Sudden loss of balance or coordination	☐	☐	☐	☐

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

Follow-up Screening: Bleeding

Expected postpartum vaginal bleeding (lochia) is not included.

Bleeding Screening

1. Follow-Up Visit/ Phone or Video Call:

☐ 6 weeks (Visit/Call) ☐ 90 days (Call) ☐ Unscheduled (Visit/Call)

2. Follow-Up Date: D D M M M Y Y Y Y

Instructions:
Complete the following interview script for bleeding events. **Expected postpartum vaginal bleeding (lochia) is not included as a bleeding event.** Normal postpartum vaginal bleeding should diminish in volume and be less red in colour each day when compared to the previous day.

3. Bleeding:

1. Did you seek any medical attention for bleeding since the last study visit? ☐ Yes* ☐ No

   If yes, specify why? _____

   Where / from whom was medical attention given? _____

2. Were you hospitalized for bleeding since the last study visit? ☐ Yes* ☐ No

   If yes, specify why? _____

   Where were you hospitalized? _____

3. Have you had any bleeding since the last study visit? ☐ Yes ☐ No

3.3a. Where was the bleeding, specify location(s)? _____

3.3b. Was it external (i.e., you saw the blood)? ☐ Yes ☐ No

3.3c. Did the bleeding last longer than 10 minutes? ☐ Yes* ☐ No

*Indicate date and time bleeding started: D D M M M Y Y Y Y H H M M

*Indicate date and time bleeding stopped: D D M M M Y Y Y Y H H M M

3.3d. Did the bleed stop on its own? ☐ Yes ☐ No

3.3e. Did the bleeding cause discomfort or pain? ☐ Yes ☐ No

3.3f. Did the bleeding have an effect on your usual daily ctivities? ☐ Yes ☐ No

If yes, specify why? _____

3.3g. Were you taking the study drug when the bleeding started? ☐ Yes ☐ No

3.3h. Description of bleeding event (describe all relevant information/events preceding and at the time of the bleed):

Important: If MEDICAL ATTENTION was sought or patient was hospitalized, then study personnel will collect all pertinent source documents to diagnose or exclude bleeding as indicated in the Protocol, including arranging for patient assessment if required.