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Site No. 

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Subject No. 

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<b>Instructions</b>	
<b>Text</b>	Print all entries in <b>BLOCK CAPITAL LETTERS</b> and avoid writing outside the space provided. English should be used <b>and abbreviations avoided</b> .
<b>Answer/ Ticking boxes</b>	Make sure that you answer all relevant questions. Closed boxes are used for “ticking”.
<b>Blank Spaces</b>	Please do not leave any answer fields blank. If information is unknown, please write <b>UNK</b> . If information is not applicable to this subject, please write <b>NA</b> .
<b>Errors</b>	Cross-out the error with a single horizontal line and write correction next to it. Make sure that the error, although crossed out, remains legible. <b>Initial and date each correction</b> .
<b>Numeric Fields</b>	When the answer to a question is a number, put only one digit in each box with a leading “0” when necessary.
<b>Dates</b>	Record the actual date of the visit. The order of the entry in the date format is day, month, year (01/JAN/2011). Day and year are to be expressed numerically; month is to be expressed textually using the first 3 letters of the month (JAN, FEB, MAR, APR, MAY and so on).
<b>Times</b>	The 24-hour clock time designation should be used (hours: 2 digits and minutes: 2 digits). For example, two thirty in the afternoon should be reported as 14:30 hours.

**Confirmation of Eligibility: France Site**

Screening No.

Inclusion Criteria	YES	NO
<b>At risk for thromboembolism for <u>ONE</u> of the following reasons:</b>		
<b>1. Known inherited thrombophilia</b> (diagnosed prior to enrolment) <ul style="list-style-type: none"> <li><input type="checkbox"/> Heterozygous factor V Leiden</li> <li><input type="checkbox"/> Heterozygous prothrombin gene variant</li> <li><input type="checkbox"/> Protein C deficiency</li> <li><input type="checkbox"/> Protein S deficiency</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2. Antepartum immobilization (strict bedrest) for <math>\geq 7</math> days at any time during pregnancy</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b><u>OR</u> At risk for thromboembolism for any <u>TWO</u> of the following reasons:</b>		
<b>3. Pre-pregnancy BMI <math>\geq 30</math> kg/m<sup>2</sup></b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4. Smoking <math>\geq 5</math> cigarettes/day pre-pregnancy</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>5. Previous clinical history of superficial vein thrombosis</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>6. Pre-eclampsia</b> (blood pressure $\geq 140$ and/or 90 mmHg on at least one occasion <u>and</u> proteinuria of $\geq 0.3$ grams/24 hours or $\geq 30$ mg/mmol in a random urine sample)	<input type="checkbox"/>	<input type="checkbox"/>
<b>7. Current pregnancy ending in stillbirth</b> (pregnancy loss $> 20$ weeks gestation)	<input type="checkbox"/>	<input type="checkbox"/>
<b>8. Emergency cesarean delivery</b> (emergency = not previously planned)	<input type="checkbox"/>	<input type="checkbox"/>
<b>9. Small-for-gestational-age infant at time of delivery</b> ( $< 3^{\text{rd}}$ percentile adjusted for gestational age and sex)	<input type="checkbox"/>	<input type="checkbox"/>
<b>10. Postpartum infection</b> (temperature $\geq 38.3^{\circ}\text{C}$ <u>and</u> elevated WBC <u>or</u> neutrophil count <u>or</u> positive blood cultures)	<input type="checkbox"/>	<input type="checkbox"/>
<b>11. Postpartum hemorrhage</b> ( $> 1000$ mL of blood loss, regardless of delivery mode)	<input type="checkbox"/>	<input type="checkbox"/>

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Exclusion Criteria	YES	NO
1. <b>More than 48 hours since delivery of the placenta at the time of randomization</b>	<input type="checkbox"/>	<input type="checkbox"/>
2. <b>Received more than 2 doses of LMWH since delivery of the placenta</b>	<input type="checkbox"/>	<input type="checkbox"/>
3. <b>Need for postpartum LMWH prophylaxis or systemic anticoagulation as judged by the local investigator. May include but is not limited to the conditions below. If yes, please specify:</b> <input type="checkbox"/> Documented history of provoked or unprovoked VTE <input type="checkbox"/> Mechanical heart valve(s) <input type="checkbox"/> Known antiphospholipid syndrome (APS) <input type="checkbox"/> Known high-risk inherited thrombophilia <input type="checkbox"/> Antithrombin deficiency <input type="checkbox"/> Homozygous factor V Leiden <input type="checkbox"/> Homozygous prothrombin gene mutation <input type="checkbox"/> Compound heterozygosity factor V Leiden and prothrombin gene mutation <input type="checkbox"/> More than 1 thrombophilia: any combination of 2 or more: factor V Leiden, prothrombin gene mutation, protein C deficiency, protein S deficiency, antithrombin deficiency <input type="checkbox"/> Other: _____	<input type="checkbox"/>	<input type="checkbox"/>
4. <b>Need for postpartum ASA as judged by the local investigator. May include but is not limited to:</b> <input type="checkbox"/> Documented history of myocardial infarction <input type="checkbox"/> Documented history of ischemic stroke or transient ischemic attack (TIA) <input type="checkbox"/> Other: _____	<input type="checkbox"/>	<input type="checkbox"/>
5. <b>History of known ASA allergy</b>	<input type="checkbox"/>	<input type="checkbox"/>
6. <b>Documented history of a gastrointestinal ulcer</b>	<input type="checkbox"/>	<input type="checkbox"/>
7. <b>Known platelet count <math>&lt;50 \times 10^9/L</math> at any time during the current pregnancy or postpartum</b>	<input type="checkbox"/>	<input type="checkbox"/>
8. <b>Active bleeding at any site, excluding normal vaginal bleeding, at the time of randomization</b>	<input type="checkbox"/>	<input type="checkbox"/>
9. <b>Most recent known hemoglobin <math>\leq 70</math> g/L documented during the current pregnancy or postpartum</b>	<input type="checkbox"/>	<input type="checkbox"/>
10. <b>Known severe hypertension (SBP <math>&gt;200</math> mmHg and/or DBP <math>&gt;120</math> mmHg) during the current pregnancy or postpartum</b>	<input type="checkbox"/>	<input type="checkbox"/>
11. <b>Known severe hepatic dysfunction</b>	<input type="checkbox"/>	<input type="checkbox"/>
12. <b>Known severe renal dysfunction</b>	<input type="checkbox"/>	<input type="checkbox"/>
13. <b>Known severe bleeding disorder/coagulopathy</b>	<input type="checkbox"/>	<input type="checkbox"/>
14. <b>Known severe heart failure</b>	<input type="checkbox"/>	<input type="checkbox"/>
15. <b>History of a hemorrhagic cerebrovascular accident (CVA)</b>	<input type="checkbox"/>	<input type="checkbox"/>
16. <b><math>&lt;18</math> years of age</b>	<input type="checkbox"/>	<input type="checkbox"/>
17. <b>Unable to give or refused consent</b>	<input type="checkbox"/>	<input type="checkbox"/>

PILOT PARTUM: Eligibility

Site No.

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Subject No.

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Eligibility Criteria		YES	NO									
1.	All eligibility criteria have been met and the subject will be enrolled into the study	<input type="checkbox"/>	<input type="checkbox"/>									
2.	Version date of the consent form signed by subject:	<table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>		D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y				

**Please review with the Investigator/Co-Investigator prior to randomization:**

I \_\_\_\_\_ (Investigator/Co-Investigator) confirm that I have reviewed all relevant reports, results and annotations and find the potential subject to meet all eligibility criteria. This subject may be randomized to the pilot PARTUM trial.

\_\_\_\_\_  
Investigator/Co-Investigator Signature

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Date

PILOT PARTUM: Randomization

Site No.

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Subject No.

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## Randomization Case Report Form

Randomization Details										
Date of randomization:	<table border="1"><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
<input type="checkbox"/> Randomization code obtained and matched with study medication										
Medication randomization code (Drug ID):	<table border="1"><tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr></table>									

Study Medication										
Date of subject's first dose:	<table border="1"><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
Time of subject's first dose:	<table border="1"><tr><td>H</td><td>H</td><td>M</td><td>M</td></tr></table>	H	H	M	M					
H	H	M	M							
Study medication delivered by:	_____									
Study medication and booklet reviewed with the subject:	<input type="checkbox"/> Completed									

\_\_\_\_\_  
Delegate's Name

\_\_\_\_\_  
Delegate's Signature

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Date

## Baseline Assessment Case Report Form

A. Demographic Data														
<b>1. Date of baseline visit:</b>	<table border="1" style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">D</td><td style="width: 12.5%;">D</td><td style="width: 12.5%;">M</td><td style="width: 12.5%;">M</td><td style="width: 12.5%;">M</td><td style="width: 12.5%;">Y</td><td style="width: 12.5%;">Y</td><td style="width: 12.5%;">Y</td><td style="width: 12.5%;">Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y				
D	D	M	M	M	Y	Y	Y	Y						
<b>2. Age at randomization:</b>	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> Years													
<b>3. Race/Ethnicity</b> (may choose more than one):	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><input type="checkbox"/> White/Caucasian</td> <td style="width: 33%;"><input type="checkbox"/> Black/African Heritage</td> <td style="width: 33%;"><input type="checkbox"/> Indigenous</td> </tr> <tr> <td><input type="checkbox"/> Asian/South East Asian</td> <td><input type="checkbox"/> Hispanic/Latino</td> <td><input type="checkbox"/> Pacific Islander</td> </tr> </table>	<input type="checkbox"/> White/Caucasian	<input type="checkbox"/> Black/African Heritage	<input type="checkbox"/> Indigenous	<input type="checkbox"/> Asian/South East Asian	<input type="checkbox"/> Hispanic/Latino	<input type="checkbox"/> Pacific Islander							
<input type="checkbox"/> White/Caucasian	<input type="checkbox"/> Black/African Heritage	<input type="checkbox"/> Indigenous												
<input type="checkbox"/> Asian/South East Asian	<input type="checkbox"/> Hispanic/Latino	<input type="checkbox"/> Pacific Islander												
<b>4. Height and weight prior to this pregnancy (can be reported by the subject):</b>	Pre-pregnancy weight: _____ <input type="checkbox"/> kg <input type="checkbox"/> lbs Height: _____ <input type="checkbox"/> cm <input type="checkbox"/> feet/inches Pre-pregnancy BMI: _____ (kg/m <sup>2</sup> ) <i>If pre-pregnancy weight unknown, use subject's reported weight in 1st trimester</i>													
<b>5. Current maternal weight (can be reported by the subject):</b>	_____ <input type="checkbox"/> kg <input type="checkbox"/> lbs													
<b>6. Smoking history:</b>	Smoked in the last year? <input type="checkbox"/> Yes <input type="checkbox"/> No Average number of cigarettes per day during pregnancy? <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> Average number of cigarettes per day in the 3 months prior to pregnancy? <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> Previous smoker? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, quit date: <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 12.5%;">M</td><td style="width: 12.5%;">M</td><td style="width: 12.5%;">M</td><td style="width: 12.5%;">Y</td><td style="width: 12.5%;">Y</td><td style="width: 12.5%;">Y</td><td style="width: 12.5%;">Y</td> </tr> </table> Number of cigarettes per day (average over year prior to quitting): <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>					M	M	M	Y	Y	Y	Y		
M	M	M	Y	Y	Y	Y								
B. Medical History														
<b>1. Has any related family members had a VTE?</b>	<input type="checkbox"/> No <input type="checkbox"/> First degree relative <input type="checkbox"/> Second degree relative													
<b>2. Prior medical issues?</b>	<input type="checkbox"/> <b>No prior medical issues</b> <input type="checkbox"/> <b>Yes, please check all that apply:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Systemic lupus erythematosus (SLE, lupus)</td> <td style="width: 50%;"><input type="checkbox"/> Sickle cell disease</td> </tr> <tr> <td><input type="checkbox"/> Inflammatory bowel disease</td> <td><input type="checkbox"/> Hypertension (prior to pregnancy)</td> </tr> <tr> <td><input type="checkbox"/> Type 1 diabetes (prior to pregnancy)</td> <td><input type="checkbox"/> Type 2 diabetes (prior to pregnancy)</td> </tr> <tr> <td><input type="checkbox"/> Known kidney disease: _____</td> <td><input type="checkbox"/> Known cardiac disease: _____</td> </tr> <tr> <td><input type="checkbox"/> Asthma</td> <td><input type="checkbox"/> Other inflammatory or autoimmune disorders(s): _____</td> </tr> </table>	<input type="checkbox"/> Systemic lupus erythematosus (SLE, lupus)	<input type="checkbox"/> Sickle cell disease	<input type="checkbox"/> Inflammatory bowel disease	<input type="checkbox"/> Hypertension (prior to pregnancy)	<input type="checkbox"/> Type 1 diabetes (prior to pregnancy)	<input type="checkbox"/> Type 2 diabetes (prior to pregnancy)	<input type="checkbox"/> Known kidney disease: _____	<input type="checkbox"/> Known cardiac disease: _____	<input type="checkbox"/> Asthma	<input type="checkbox"/> Other inflammatory or autoimmune disorders(s): _____			
<input type="checkbox"/> Systemic lupus erythematosus (SLE, lupus)	<input type="checkbox"/> Sickle cell disease													
<input type="checkbox"/> Inflammatory bowel disease	<input type="checkbox"/> Hypertension (prior to pregnancy)													
<input type="checkbox"/> Type 1 diabetes (prior to pregnancy)	<input type="checkbox"/> Type 2 diabetes (prior to pregnancy)													
<input type="checkbox"/> Known kidney disease: _____	<input type="checkbox"/> Known cardiac disease: _____													
<input type="checkbox"/> Asthma	<input type="checkbox"/> Other inflammatory or autoimmune disorders(s): _____													



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<b>3. Previous history of superficial vein thrombosis?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, confirmed by ultrasound?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, pregnancy or postpartum related?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, exogenous estrogen related?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>4. Previous history of varicose veins?</b> <i>(soft, dilated, large superficial veins)</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

**C. Obstetrical History**

<b>1. Parity:</b>			
Number of pregnancies carried past 20 weeks gestation (including current pregnancy):	<table border="1" style="display: inline-table;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>		
<b>2. Prior cesarean delivery</b> (not including current pregnancy)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>3. Did the subject have any complications during <u>PRIOR pregnancies</u>?</b>			
<input type="checkbox"/> <b>No complications</b> <input type="checkbox"/> <b>Yes <u>PRIOR</u> complications</b> , please check all that apply:			
<input type="checkbox"/> Gestational hypertension			
<input type="checkbox"/> Pre-eclampsia			
Largest amount of proteinuria documented if known:			
Urine protein / Cr ratio: _____ mg/mmol spot urine			
<b>OR</b> 24-hour urine protein: _____ grams			
<input type="checkbox"/> Eclampsia (seizures)			
<input type="checkbox"/> HELLP syndrome			
<input type="checkbox"/> Gestational diabetes			
<input type="checkbox"/> Intrauterine growth restriction or small-for gestational age			
<input type="checkbox"/> Placental abruption			
<input type="checkbox"/> Intrapartum infection (e.g. chorioamnionitis)			
<input type="checkbox"/> Postpartum infection			
<b>4. Did the subject have any prior pregnancy losses?</b>			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
<input type="checkbox"/> <10 weeks gestation	Number of losses: <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>		
<input type="checkbox"/> 10-20 weeks gestation	Number of losses: <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>		
<input type="checkbox"/> >20 weeks gestation	Number of losses: <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>		
<input type="checkbox"/> Unknown timing	Number of losses: <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>		

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**D. Current Pregnancy**

**1. Method of conception:**

- Spontaneous                       Ovulation induction with medical therapy  
 Intrauterine insemination       In vitro fertilisation (IVF) or Intracytoplasmic sperm injection

**2. Aspirin use in current pregnancy:**       Yes    No

If yes, dose per day: \_\_\_\_\_ mg

Gestational age when aspirin started: 

--	--

 weeks + 

--

 days

Date of last dose:

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

**3. Immobilization in current pregnancy:**

Any type of bedrest at any point during pregnancy?       Yes    No

If yes, total days immobilized during this pregnancy: 

--	--

Bedrest at home?       Yes    No

Hospitalized for bedrest?       Yes    No

Type of bedrest (choose all that apply):

- Strict bedrest (>90% of time, bathroom privileges)  
 Modified bedrest (Limited walking, restricted activities)

Reason for bedrest: \_\_\_\_\_

Number of episodes of bedrest: 

--	--

Gestational age at **start** of bedrest closest to delivery: 

--	--

 weeks + 

--

 days

Gestational age at **end** of bedrest closest to delivery: 

--	--

 weeks + 

--

 days

**E. Delivery Details**

**1. Date of admission for labor/delivery:**

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

**2. Date of delivery of infant:**

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

**3. Date and time of delivery of placenta (24 hr clock):**

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	M	M
---	---	---	---

**4. Gestational age at delivery:**

--	--

 weeks + 

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 days

**5. Singleton or multiple pregnancy:**       Single    Multiple pregnancy





PILOT PARTUM: Baseline

Site No.

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Subject No.

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**3. Since delivery, has the subject received low-molecular-weight-heparin (LMWH) or unfractionated heparin (UFH)?**

- Yes**, please specify dose of LMWH or UFH:                       **No**
- Enoxaparin                      \_\_\_\_\_ mg                       Dalteparin                      \_\_\_\_\_ IU
- Tinzaparin                      \_\_\_\_\_ IU                       Nadroparin                      \_\_\_\_\_ IU/mg
- Unfractionated heparin                      \_\_\_\_\_ IU

Frequency of doses given:                       Q24H                       Q12H                       Q8H

Number of doses given since delivery:                       1                       2

Date of last dose:                      

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Time of last dose:                      

H	H	M	M
---	---	---	---

**4. Hospital discharge date:**

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

\_\_\_\_\_  
Delegate's Name

\_\_\_\_\_  
Delegate's Signature

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Date

PILOT PARTUM: Medication

Site No.

Subject No.

### Concomitant Medication Form

Visit Type	Date of Visit	Delegate's Name	Delegate's Signature
<input type="checkbox"/> Baseline	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
<input type="checkbox"/> 6-week visit	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
<input type="checkbox"/> 90-day visit	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
<input type="checkbox"/> Unscheduled visit	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

NSAID Use Postpartum:  Yes  No

NSAID Name	Average Dose & Frequency	Date Started (dd/mmm/yyyy)	Date Stopped (dd/mmm/yyyy)	Ongoing at final visit?
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes

PILOT PARTUM: Medication

Site No. 

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Subject No. 

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**Other Medication Use:**       Yes       No      Includes prescriptions, vitamins, supplements, and over the counter medications.

Medication Name	Dose & Frequency	Date Started Postpartum (dd/mmm/yyyy)	Date Stopped (dd/mmm/yyyy)	Ongoing at final visit?
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes
				<input type="checkbox"/> Yes

## 6 Week Follow-up Case Report Form

A. Details of Follow-up			
<b>1.</b>	<b>Able to contact subject to complete follow-up:</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	If no, please specify reason why, and sign and date the form:		
	<input type="checkbox"/> Unable to contact subject after multiple attempts – see resource manual for contact procedures <input type="checkbox"/> Subject has died (Please complete End of Study, SAE and Death Outcome Event forms) <input type="checkbox"/> Subject withdrew consent (Please complete End of Study CRF)		
<b>2.</b>	<b>Date of follow up:</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
<b>3.</b>	<b>Type of follow up:</b>	<input type="checkbox"/> In person	<input type="checkbox"/> Phone call
		<input type="checkbox"/> Video call	
<b>4.</b>	<b>Study medication:</b>	Subject's booklet collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No
		Study medication bottle collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No
		Pill count (confirmed by research team member):	<input type="text"/> <input type="text"/>
		Number of days missed (based on subject's booklet):	<input type="text"/> <input type="text"/>
		Number of days NSAIDs taken (based on subject's booklet):	<input type="text"/> <input type="text"/>
	Canadian sites only: Which study medication does the subject think they received?		
	<input type="checkbox"/> Aspirin <input type="checkbox"/> Placebo <input type="checkbox"/> Unsure <input type="checkbox"/> N/A		
	Canadian sites only: Which study medication does the research coordinator think the subject received?		
	<input type="checkbox"/> Aspirin <input type="checkbox"/> Placebo <input type="checkbox"/> Unsure <input type="checkbox"/> N/A		
<b>5.</b>	<b>Concomitant Medication Form reviewed?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>6.</b>	Has the subject experienced any adverse events since the last visit? <b>If yes, please complete Adverse Event or Serious Adverse Event Form.</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>7.</b>	Has the subject's infant experienced any adverse events since the last visit? <b>If yes, please complete Adverse Event or Serious Adverse Event Form.</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>8a.</b>	Is the infant receiving the subject's breastmilk (e.g. breastfeeding or pumping)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>8b.</b>	If yes, has the infant received the subject's breastmilk on average 50% or more of the time during the last 6 weeks?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>9.</b>	Has the subject been diagnosed with a postpartum wound complication requiring a procedure?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>10.</b>	Does the subject have a diagnosed wound separation or dehiscence?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>11.</b>	Has the subject been diagnosed with a postpartum wound infection requiring antibiotics?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>12.</b>	Has the subject been diagnosed with new high blood pressure requiring medication or new protein in the urine postpartum? <b>If yes, please complete Postpartum Pre-eclampsia Outcome Form.</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No



<b>13.</b>	<b>Complete VTE Screening Form for all subjects.</b>	<input type="checkbox"/> Completed		
<b>14.</b>	How long did the subject’s vaginal bleeding (lochia) last for?	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> days <input type="checkbox"/> Ongoing		
<b>15.</b>	Has the subject had any bleeding since the last visit? (other than normal vaginal bleeding*)  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. <b>If yes, complete Bleeding Screening Form.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>16.</b>	Has the subject experienced a serious bruise (hematoma)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>17.</b>	Has the subject had any chest symptoms such as shortness of breath or chest pain, or neurological symptoms such as weakness or numbness since the last visit? <b>If yes, complete ATE Screening Form.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		

\*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
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Date

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## 90 Day Follow-up Case Report Form

A. Details of Follow-up										
<b>1.</b>	<p><b>Able to contact subject to complete postpartum follow-up:</b> <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span></p> <p>If no, please specify reason why, and sign and date the form.</p> <p><input type="checkbox"/> Unable to contact subject after multiple attempts – <i>see resource manual for contact procedures</i></p> <p><input type="checkbox"/> Subject has died (Please complete <b>End of Study, SAE and Death Outcome forms</b>)</p> <p><input type="checkbox"/> Subject withdrew consent (Please complete <b>End of Study form</b>)</p>									
<b>2.</b>	<p><b>Date of follow-up:</b> <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 150px; height: 20px;"> <tr> <td style="width: 15px;">D</td><td style="width: 15px;">D</td><td style="width: 15px;">M</td><td style="width: 15px;">M</td><td style="width: 15px;">M</td><td style="width: 15px;">Y</td><td style="width: 15px;">Y</td><td style="width: 15px;">Y</td><td style="width: 15px;">Y</td> </tr> </table></p>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
<b>3.</b>	<p><b>Concomitant Medication Form reviewed?</b> <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span></p>									
<b>4.</b>	<p>Has the subject experienced any adverse events since the last visit? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span></p> <p><b>If yes, please complete Adverse Event or Serious Adverse Event Form.</b></p>									
<b>5.</b>	<p><b>Complete VTE Screening Form for all subjects.</b> <span style="float: right;"><input type="checkbox"/> Completed</span></p>									
<b>6.</b>	<p>Has the subject had any bleeding since the last visit (other than normal vaginal bleeding*)? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span></p> <p>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.</p> <p><b>If yes, complete Bleeding Screening Form.</b></p>									
<b>7.</b>	<p>Has the subject had any chest symptoms such as shortness of breath or chest pain, or neurological symptoms such as weakness or numbness since the last visit? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span></p> <p><b>If yes, complete ATE Screening Form.</b></p>									

\* 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
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Date



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## End of Study Case Report Form

A. Study Completion										
<b>1. Date of study termination:</b>	<table border="1" style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;">D</td><td style="width: 15%;">D</td><td style="width: 15%;">M</td><td style="width: 15%;">M</td><td style="width: 15%;">M</td><td style="width: 15%;">Y</td><td style="width: 15%;">Y</td><td style="width: 15%;">Y</td><td style="width: 15%;">Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
<b>2. Reason for study termination:</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Routine study termination, study protocol completed</li> <li><input type="checkbox"/> Early study termination, due to:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> Lost to follow up</li> <li><input type="checkbox"/> Death*</li> <li><input type="checkbox"/> Withdrawal of subject's consent**:                                     <ul style="list-style-type: none"> <li><input type="checkbox"/> Subject allows data collection to continue</li> <li><input type="checkbox"/> Subject refuses further data collection</li> </ul> </li> <li><input type="checkbox"/> Other, please specify: _____</li> </ul> </li> </ul> <p style="color: red; margin-top: 10px;"><b>*If selected, please complete Death Outcome Form and SAE form</b></p> <p style="color: red;"><b>**Reason(s) subject has withdrawn consent:</b></p>									

B. Suspected Secondary Outcome Events						
<p><b>1. Did the subject have one or more suspected outcome events listed below that will undergo adjudication? (check all that apply)*:</b></p> <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> <p style="color: red; margin-top: 10px;"><b>*If yes, please ensure corresponding Outcome Event and SAE form(s) are completed.</b></p>	<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				

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="width: 100%; text-align: center; border-collapse: collapse; margin-left: 20px;"> <tr> <td style="width: 15%;">D</td><td style="width: 15%;">D</td><td style="width: 15%;">M</td><td style="width: 15%;">M</td><td style="width: 15%;">M</td><td style="width: 15%;">Y</td><td style="width: 15%;">Y</td><td style="width: 15%;">Y</td><td style="width: 15%;">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

<b>VTE Screening</b>													
<b>1. Follow-Up Visit / Phone or Video Call:</b>													
<input type="checkbox"/> 6 weeks (Visit/call) <input type="checkbox"/> 90 days (Call) <input type="checkbox"/> Unscheduled (Visit/Call)													
<b>2. Follow-Up Date:</b>													
<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					
<b>Instructions:</b> Use the following categories to rate each symptom. Choose the one best answer. <b>None:</b> Patient is not experiencing this symptom today. <b>New:</b> Patient has this symptom today, but did not have it at her last study visit. <b>Worse:</b> Patient had this symptom at her last study visit and it has gotten worse. <b>Same:</b> Patient had this symptom at her last study visit and it has not changed.													
<b>3. Deep Vein Thrombosis (DVT) Symptoms:</b>													
	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"> <li>• Along the path of the deep vein (groin, thigh, behind the knee and/or in the deep calf)</li> </ul> <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"> <li>• In the armpit, under the clavicle and/or in the neck</li> </ul> <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													
<b>4. Pulmonary Embolism (PE) Symptoms:</b>													
	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"/>									
<b>If the subject responds 'New' or 'Worse' to any chest symptoms, complete the ATE Screening Form.</b>													

**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.

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## Follow-up Screening: ATE

<b>ATE Screening</b>													
<b>1. Follow-Up Visit / Phone or Video Call:</b> <input type="checkbox"/> 6 weeks (Visit/Call) <input type="checkbox"/> 90 days (Call) <input type="checkbox"/> Unscheduled (Visit/Call)													
<b>2. Follow-Up Date:</b> <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 150px; height: 20px;"> <tr> <td style="width: 15px;">D</td><td style="width: 15px;">D</td><td style="width: 15px;">M</td><td style="width: 15px;">M</td><td style="width: 15px;">M</td><td style="width: 15px;">Y</td><td style="width: 15px;">Y</td><td style="width: 15px;">Y</td><td style="width: 15px;">Y</td> </tr> </table>					D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y					
<b>Instructions:</b> Use the following categories to rate each symptom. Choose the one best answer. <b>None:</b> Patient is not experiencing this symptom today. <b>New:</b> Patient has this symptom today, but did not have it at her last study visit. <b>Worse:</b> Patient had this symptom at her last study visit and it has gotten worse. <b>Same:</b> Patient had this symptom at her last study visit and it has not changed.													
<b>3. Myocardial Infarction Symptoms:</b>	None	New	Worse	Same									
Pressure, tightness or pain in chest <input type="checkbox"/> Arm or jaw radiation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Shortness of breath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Nausea or vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Cold sweat (Diaphoresis)	<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"/>									
<b>4. Stroke / TIA Symptoms:</b>	None	New	Worse	Same									
Weakness of the face, arms or legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Numbness or tingling to the face, arms or legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Slurred speech, trouble speaking or understanding speech	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Sudden vision loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
Sudden loss of balance or coordination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									

**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.

<b>Bleeding Screening</b>														
<b>1.</b>	<b>Follow-Up Visit/ Phone or Video Call:</b> <input type="checkbox"/> 6 weeks (Visit/Call) <input type="checkbox"/> 90 days (Call) <input type="checkbox"/> Unscheduled (Visit/Call)													
<b>2.</b>	<b>Follow-Up Date:</b> <table border="1" style="display: inline-table; vertical-align: middle;"><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						
<b>Instructions:</b> Complete the following interview script for bleeding events. <b>Expected postpartum vaginal bleeding (lochia) is not included as a bleeding event.</b> Normal postpartum vaginal bleeding should diminish in volume and be less red in colour each day when compared to the previous day.														
<b>3. Bleeding:</b>														
1.	Did you seek any medical attention for bleeding since the last study visit? <input type="checkbox"/> Yes* <input type="checkbox"/> No If yes, specify why? _____ Where / from whom was medical attention given? _____													
2.	Were you hospitalized for bleeding since the last study visit? <input type="checkbox"/> Yes* <input type="checkbox"/> No If yes, specify why? _____ Where were you hospitalized? _____													
3.	Have you had any bleeding since the last study visit? <input type="checkbox"/> Yes <input type="checkbox"/> No													
3.3a.	Where was the bleeding, specify location(s)? _____													
3.3b.	Was it external (i.e., you saw the blood)? <input type="checkbox"/> Yes <input type="checkbox"/> No													
3.3c.	Did the bleeding last longer than 10 minutes? <input type="checkbox"/> Yes* <input type="checkbox"/> No													
*Indicate date and time bleeding started:	<table border="1" style="display: inline-table; vertical-align: middle;"><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><td style="width: 20px; height: 20px;">H</td><td style="width: 20px; height: 20px;">H</td><td style="width: 20px; height: 20px;">M</td><td style="width: 20px; height: 20px;">M</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y	H	H	M	M
D	D	M	M	M	Y	Y	Y	Y	H	H	M	M		
*Indicate date and time bleeding stopped:	<table border="1" style="display: inline-table; vertical-align: middle;"><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><td style="width: 20px; height: 20px;">H</td><td style="width: 20px; height: 20px;">H</td><td style="width: 20px; height: 20px;">M</td><td style="width: 20px; height: 20px;">M</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y	H	H	M	M
D	D	M	M	M	Y	Y	Y	Y	H	H	M	M		
3.3d.	Did the bleed stop on its own? <input type="checkbox"/> Yes <input type="checkbox"/> No													
3.3e.	Did the bleeding cause discomfort or pain? <input type="checkbox"/> Yes <input type="checkbox"/> No													
3.3f.	Did the bleeding have an effect on your usual daily activities? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, specify why? _____													
3.3g.	Were you taking the study drug when the bleeding started? <input type="checkbox"/> Yes <input type="checkbox"/> 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.

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## Protocol Deviation / Violation Form

Type of Event	
<input type="checkbox"/>	<b>Protocol Deviation:</b> non-compliance with the protocol that is <u>unlikely</u> to have a significant impact on the patient’s rights, safety and welfare, or on the integrity of the data.
<input type="checkbox"/>	<b>Protocol Violation:</b> non-compliance with the protocol that may have a <u>significant</u> impact on the patient’s rights, safety and welfare, or on the integrity of the data <u>and</u> can cause the coordinating centre to exclude the patient from the eligibility analysis and/or discontinue the patient from the study.

Protocol Deviation / Violation / Unanticipated Risk Involving Participant (UaP)										
<b>Date of deviation or violation:</b>	<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="width: 20px; text-align: center;">D</td> <td style="width: 20px; text-align: center;">D</td> <td style="width: 20px; text-align: center;">M</td> <td style="width: 20px; text-align: center;">M</td> <td style="width: 20px; text-align: center;">M</td> <td style="width: 20px; text-align: center;">Y</td> <td style="width: 20px; text-align: center;">Y</td> <td style="width: 20px; text-align: center;">Y</td> <td style="width: 20px; text-align: center;">Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
<b>Categories:</b>										
<input type="checkbox"/> Informed consent process error <input type="checkbox"/> Participant did not meet Inclusion/Exclusion Criteria <input type="checkbox"/> Randomization error <input type="checkbox"/> Study visit <ul style="list-style-type: none"> <li><input type="checkbox"/> Incomplete visit</li> <li><input type="checkbox"/> Outside of study window</li> <li><input type="checkbox"/> Missed visit</li> </ul> <input type="checkbox"/> Study booklet <ul style="list-style-type: none"> <li><input type="checkbox"/> Incomplete study booklet</li> <li><input type="checkbox"/> Failed to return study booklet</li> </ul> <input type="checkbox"/> Study medication <ul style="list-style-type: none"> <li><input type="checkbox"/> Dispensing error</li> <li><input type="checkbox"/> Dosing error</li> <li><input type="checkbox"/> Use of prohibited medication</li> <li><input type="checkbox"/> Stopped medication early</li> <li><input type="checkbox"/> Failed to return study medication</li> </ul> <input type="checkbox"/> Improper breaking of the blind <input type="checkbox"/> Unreported SAE <input type="checkbox"/> Other: _____										
<b>Event description:</b>										
Please provide details of the deviation or violation. Include any other relevant information not captured elsewhere on the form.										
<b>Actions taken to reconcile the deviation or violation and prevent future occurrences:</b>										



PILOT PARTUM: Serious Adverse Event

Site No.

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Subject No.

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**Protocol Violations ONLY**

Please complete this section only if the non-compliance is a violation.

**Did the violation impact subject's rights and/or safety?**

Yes  No

**Reporting Centre**

Delegate's Name:

Signature:

Investigator's Name:

Signature:

Date:

D	D	M	M	M	Y	Y	Y	Y
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PILOT PARTUM: Adverse Event

Site No.

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Subject No.

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## Adverse Event Form

If the AE meets the definition of a SAE, please complete a Serious Adverse Event Form.  
(Do not complete this form)

Timeline of Adverse Event										
AE report date:	<table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
AE start date:	<table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
AE end date:	<input type="checkbox"/> Ongoing <table border="1"> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		

Adverse Event Information	
Participant or infant?	<input type="checkbox"/> Participant <input type="checkbox"/> Infant
Condition/Diagnosis:	
AE Term (MedDRA Coding):	
<b>Event Description:</b> Include a history of the event chronologically including signs and characteristics, severity, dates and outcomes and any other relevant information not captured elsewhere on the form. Include relevant tests/data, treatment/procedures, medical history, treatment history.	
<b>Action taken with study medication:</b> <input type="checkbox"/> No change <input type="checkbox"/> Study medication temporarily discontinued <input type="checkbox"/> Other medication(s) started for AE: _____ <input type="checkbox"/> Study medication permanently discontinued <input type="checkbox"/> Other, please specify: _____	
<b>Clinical outcome:</b> <input type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Study medication discontinued <input type="checkbox"/> Unknown	

PILOT PARTUM: Adverse Event

Site No. 

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Subject No. 

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<b>This section to be completed by the Investigator only</b>		
<b>Severity/Intensity</b>		
<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Severe
<b>Causality</b>		
<input type="checkbox"/> Unrelated	<input type="checkbox"/> Possibly related	<input type="checkbox"/> Related
<b>Expectedness</b>		
<input type="checkbox"/> Expected/Anticipated	<input type="checkbox"/> Unexpected/Unanticipated	
<b>Gravity</b>		
<input type="checkbox"/> Non-serious	<input type="checkbox"/> Serious*	

\*If the AE meets the definition of an SAE, complete the SAE form instead

<b>Reporting Centre</b>									
Delegate's Name:									
Signature:									
Investigator's Name:									
Signature:									
Date: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y	

PILOT PARTUM: Serious Adverse Event

Site No.

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Subject No.

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## Serious Adverse Event Form

Complete one form for each SAE. Submit all supporting source documents (with no identifying information). The source documents must be signed and dated by the investigator.

<b>SAE report type</b>										
<input type="checkbox"/> <b>Initial</b>	<input type="checkbox"/> <b>Follow-up</b>									
<input type="checkbox"/> <b>Final</b>										
<b>Participant or infant?</b>	<input type="checkbox"/> Participant <input type="checkbox"/> Infant									
<b>SAE report date:</b>	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <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		
<b>Condition/Diagnosis:</b>										
<b>SAE Term (MedDRA Coding):</b>										
<p><b>Event Description:</b>                  Include a history of the event chronologically including signs and characteristics, severity, dates and outcomes of hospitalization and any other relevant information not captured elsewhere on the form. Include relevant tests/data, treatment/procedures, medical history, treatment history.</p>										

<b>Serious Adverse Event Information</b>										
<b>Date of onset:</b>	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <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		
<b>Date when event became serious:</b>	<table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <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		
<b>Date SAE ended:</b>	<input type="checkbox"/> Ongoing <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <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		
<p><b>SAE category:</b></p> <table style="width: 100%;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Death</td> <td style="width: 50%;"><input type="checkbox"/> Persistent or significant disability/incapacity</td> </tr> <tr> <td><input type="checkbox"/> Life-threatening</td> <td><input type="checkbox"/> Other medically relevant condition judged or defined as serious</td> </tr> <tr> <td><input type="checkbox"/> Other, please specify: _____</td> <td><input type="checkbox"/> New or prolonged hospitalization</td> </tr> </table> <p style="text-align: center; margin-top: 10px;"><i>*As per the Protocol, congenital anomalies or birth defects will not be reported as an SAE</i></p>		<input type="checkbox"/> Death	<input type="checkbox"/> Persistent or significant disability/incapacity	<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Other medically relevant condition judged or defined as serious	<input type="checkbox"/> Other, please specify: _____	<input type="checkbox"/> New or prolonged hospitalization			
<input type="checkbox"/> Death	<input type="checkbox"/> Persistent or significant disability/incapacity									
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Other medically relevant condition judged or defined as serious									
<input type="checkbox"/> Other, please specify: _____	<input type="checkbox"/> New or prolonged hospitalization									

PILOT PARTUM: Serious Adverse Event

Site No.

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Subject No.

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**SAE status/clinical outcome:**

- Death
- Not yet recovered
- Recovered with sequelae
- Recovered/Resolved
- Unknown

**Relevant Information to SAE**

Have relevant source documents been attached?

Yes  No

**Study Medication**

Date of first dose:

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Date of last dose prior to SAE:

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

**Action taken with study medication:**

- No change
- Study medication temporarily discontinued
- Study medication permanently discontinued
- Other medication(s) started for AE/SAE: \_\_\_\_\_
- Other, please specify: \_\_\_\_\_

**If the study medication was temporarily or permanently discontinued:**

Study medication stopped on:

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

N/A

Study medication restarted on:

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

N/A

**Did the event resolve after study medication stopped?**

Yes  No  N/A

**Did event reappear after reintroducing study medication?**

Yes  No  N/A

**Concomitant medications:** Source documents have been attached?  
(Exclude those used to treat reaction)

Yes  No

PILOT PARTUM: Serious Adverse Event

Site No.

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Subject No.

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<b>This section to be completed by the Investigator only</b>
<b>Severity/Intensity</b>
<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
<b>Causality</b>
<input type="checkbox"/> Unrelated <input type="checkbox"/> Possibly related <input type="checkbox"/> Related
<b>Expectedness</b>
<input type="checkbox"/> Expected/Anticipated <input type="checkbox"/> Unexpected/Unanticipated
<b>Gravity</b>
<input type="checkbox"/> Non-serious <input type="checkbox"/> Serious
<b>Possible causes of the event (check all that apply):</b>
<input type="checkbox"/> Pre-existing/Underlying disease: _____
<input type="checkbox"/> Study treatment: _____
<input type="checkbox"/> Other treatment: _____
<input type="checkbox"/> Other (e.g. accident, new or intercurrent illness): _____

<b>Reporting Centre</b>									
Delegate's Name									
Delegate's Signature									
Investigator's Name:									
Signature:									
Date: <table border="1"><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y	

<b>Coordinating Trial Centre</b>									
Principal Investigator:									
Signature:									
Date: <table border="1"><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y	

**In the occurrence of an SAE, the Sponsor is to be notified within 24 hours of awareness of the event. The SAE CRF should be uploaded via the secure REDCap cloud electronic data management system along with all de-identified source documents, with an email to [laskeith@ucalgary.ca](mailto:laskeith@ucalgary.ca) and [alexandra.garven@ucalgary.ca](mailto:alexandra.garven@ucalgary.ca) to confirm receipt of the SAE electronic CRF.**