

**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.</b>   | <b>Known inherited thrombophilia</b> (diagnosed prior to enrolment)  |                          |                          |
|   | <input type="checkbox"/> Heterozygous factor V Leiden  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | <input type="checkbox"/> Heterozygous prothrombin gene variant   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | <input type="checkbox"/> Protein C deficiency  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | <input type="checkbox"/> Protein S deficiency  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>2.</b>   | <b>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.</b>   | <b>Pre-pregnancy BMI <math>\geq 30</math> kg/m<sup>2</sup></b>   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>4.</b>   | <b>Smoking <math>\geq 5</math> cigarettes/day pre-pregnancy</b>  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>5.</b>   | <b>Previous clinical history of superficial vein thrombosis</b>  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>6.</b>   | <b>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.</b>   | <b>Current pregnancy ending in stillbirth</b> (pregnancy loss $> 20$ weeks gestation)  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>8.</b>   | <b>Emergency cesarean delivery</b> (emergency = not previously planned)  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>9.</b>   | <b>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.</b>  | <b>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.</b>  | <b>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><br><input type="checkbox"/> Documented history of provoked or unprovoked VTE<br><input type="checkbox"/> Mechanical heart valve(s)<br><input type="checkbox"/> Known antiphospholipid syndrome (APS)<br><input type="checkbox"/> Known high-risk inherited thrombophilia<br><input type="checkbox"/> Antithrombin deficiency<br><input type="checkbox"/> Homozygous factor V Leiden<br><input type="checkbox"/> Homozygous prothrombin gene mutation<br><input type="checkbox"/> Compound heterozygosity factor V Leiden and prothrombin gene mutation<br><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<br><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><br><input type="checkbox"/> Documented history of myocardial infarction<br><input type="checkbox"/> Documented history of ischemic stroke or transient ischemic attack (TIA)<br><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