Suspected Outcome Event Form Table of Contents and Instructions

Instructions

Please refer to Protocol Appendix A for detailed definitions of suspected outcome events. Suspected outcome forms do not need to be entered into REDCap Cloud. All suspected outcome forms, associated screening forms and de-identified source documents will uploaded onto a secure CanVECTOR online adjudication platform for independent outcome adjudication.

Form Instructions	
Text	Print all entries in BLOCK CAPITAL LETTERS and avoid writing outside the space provided. English should be used **and abbreviations avoided**.
Answer/ Ticking boxes	Make sure that you answer all relevant questions. Closed boxes are used for "ticking".
Blank Spaces	Please do not leave any answer fields blank. If information is unknown, please write **UNK**. If information is not applicable to this subject, please write **NA**.
Errors	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. **Initial and date each correction.**
Numeric Fields	When the answer to a question is a number, put only one digit in each box with a leading "0" when necessary.
Dates	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).
Times	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.

Symptomatic Venous Thromboembolism (VTE) Outcome Event

Suspected Symptomatic VTE Outcome

1. Date of suspected VTE: D D M M M Y Y Y Y

2. Number of days postpartum: ☐☐ days

3. Please indicate the type of suspected VTE (check all that apply):

- ☐ Proximal deep vein thrombosis (DVT)
- ☐ Pulmonary embolism (PE)
- ☐ Superficial vein thrombosis
- ☐ Distal DVT
- ☐ Subsegmental PE
- ☐ Unusual site thrombosis

If DVT, please indicate the location:

- ☐ Right leg
- ☐ Left leg
- ☐ Right arm
- ☐ Left arm

4. Description of event (describe all relevant information/events preceding and at the time of the suspected event):

5. Was the subject hospitalized or did they visit the Emergency Department relating to the event?

- ☐ **Yes**
- ☐ **No**
  - ☐ Hospitalization
  - ☐ Emergency Department visit only

Available Imaging Studies for Suspected VTE

6. Compression ultrasound:

- ☐ **Yes**
- ☐ **Not done**

Date of ultrasounds, including serial ultrasounds, if applicable:

D D M M M Y Y Y Y

D D M M M Y Y Y Y

D D M M M Y Y Y Y

Results (check all that apply):

Normal:	☐ Left	☐ Right
Superficial vein thrombosis:	☐ Left	☐ Right
Distal vein thrombosis (including veins at trifurcation):	☐ Left	☐ Right
Proximal vein thrombosis (popliteal vein or more proximal):	☐ Left	☐ Right

Other: _____

7. V/Q Scan

☐ **Yes** ☐ **Not done**

Date of V/Q Scan: D D M M M Y Y Y Y

Results reported based on modified PIOPED:

☐ Normal
☐ Intermediate probability V/Q scan
☐ Very low probability V/Q scan
☐ High probability V/Q scan
☐ Low probability V/Q scan

Results reported based on EANM SPECT:

☐ Positive
☐ Negative

8. CT Scan

☐ **Yes** ☐ **Not done**

Date of CT Scan: D D M M M Y Y Y Y

Results:

☐ Normal
☐ Intraluminal filling defect, segmental artery or more proximal
☐ Intraluminal filling defect, subsegmental only

9. MRI Scan

☐ **Yes** ☐ **Not done**

Date of MRI Scan: D D M M M Y Y Y Y

Results:

☐ Normal
☐ Proximal filling defect. If yes, please specify site (check all that apply):
☐ Left Leg ☐ Right Leg

10. Unusual site thrombosis diagnosis:

☐ **Yes** ☐ **No**

Imaging test: _____ D D M M M Y Y Y Y

Imaging test: _____ D D M M M Y Y Y Y

Diagnosis:

☐ Cerebral vein thrombosis
☐ Ovarian vein thrombosis
☐ Splanchnic vein thrombosis
☐ Other, please specify: _____

Available Laboratory Tests for Suspected VTE

11. D-dimer:

☐ **Yes** ☐ **Not done**

Date of D-dimer test: D D M M M Y Y Y Y

Results: ☐ Positive ☐ Negative *(based on local laboratory cutoff)*

☐☐☐☐☐ units: _____

Medication Details

12. Was there any change to the study medication?

- ☐ No change
- ☐ Other, please specify: _____
- ☐ Study medication temporarily discontinued
- ☐ Study medication permanently discontinued

13. Was any medication started after the suspected event?

- ☐ No
- ☐ Anticoagulation, details: _____
- ☐ Other medication, details: _____

Please append VTE screening form and all de-identified source documents supporting this event for adjudication.

Reporting Centre

Delegate's Name: _____ Signature _____

Investigator's Name: _____ Signature _____

Date D D M M M Y Y Y Y

Symptomatic Arterial Thromboembolism (ATE) Outcome Event

Suspected Symptomatic ATE Outcome	
1. Date of suspected ATE:	D D M M M Y Y Y Y
2. Number of days postpartum:	☐☐ days

Details of ATE Event

3. Please indicate the type of ATE that was suspected:

- ☐ Ischemic stroke
- ☐ Transient ischemic attack
- ☐ Myocardial infarction
- ☐ Peripheral arterial embolism

4. Description of event (describe all relevant information/events preceding and at the time of the suspected event):

5. Was the subject hospitalized or did they visit the Emergency Department relating to the event?

- ☐ **Yes** ☐ **No**
  - ☐ Hospitalization
  - ☐ Emergency Department visit

Diagnostic Imaging / Laboratory Results

Please record any relevant imaging or test results below:

Test	Date	Result
	DD/MMM/YYYY	
	DD/MMM/YYYY	
	DD/MMM/YYYY	
	DD/MMM/YYYY	
	DD/MMM/YYYY	

Medication Details

6. Was there any change to the study medication?

- ☐ No change
- ☐ Other, please specify: _____
- ☐ Study medication temporarily discontinued
- ☐ Study medication permanently discontinued

7. Was any medication started or changed after the suspected event?

- ☐ No
- ☐ Anticoagulation/antiplatelet, details: _____
- ☐ Other medication, details: _____

Please append ATE screening form and all de-identified source documents supporting this event for adjudication.

Reporting Centre

Delegate's Name: _____ Signature _____

Investigator's Name: _____ Signature _____

Date D D M M M Y Y Y Y

Suspected Bleeding Outcome Event

Suspected Bleeding Outcome

1. Date of suspected bleed: D D M M M Y Y Y Y

2. Number of days postpartum: ☐☐ days

3. Description of event (describe all relevant information/events preceding and at the time of the suspected event):

4. Location of the bleed:

- ☐ Vaginal
- ☐ Wound (cesarean delivery)
- ☐ Wound (non-vaginal, non-cesarean delivery)
- ☐ Epistaxis
- ☐ Gastrointestinal
- ☐ Hematuria
- ☐ Retroperitoneal
- ☐ Other: _____
- ☐ Subcutaneous tissue
- ☐ Intramuscular (muscle)
- ☐ Intra-articular (joint)
- ☐ Intracranial
- ☐ Intraspinal
- ☐ Intraocular
- ☐ Pericardial

5. Was the subject hospitalized or did they visit the Emergency Department relating to the event?

- ☐ **Yes** ☐ **No**
  - ☐ Hospitalization
  - ☐ Emergency Department visit

Details of Bleeding Event

6. Pre-bleed Hemoglobin: _____ g/L ☐ Not done

Date of most recent pre-bleed hemoglobin: D D M M M Y Y Y Y

7. Post-bleed Hemoglobin: _____ g/L ☐ Not done

Date of most recent post-bleed hemoglobin: D D M M M Y Y Y Y

8. Lowest Post-bleed Hemoglobin: _____ g/L ☐ Not done

Date of lowest post-bleed hemoglobin: D D M M M Y Y Y Y

9. Did the subject receive a blood transfusion as a result of this bleed?

☐ **Yes** ☐ **No**

☐ Packed Red Blood Cells: ☐☐ units

☐ Platelets: ☐☐ units

☐ Fresh Frozen Plasma: ☐☐ units

☐ Other, *please specify type and units*: _____

10. Did the subject require surgery or a procedure as a result of this bleed?

☐ **Yes** ☐ **No**

Date of surgery/procedure: D D M M M Y Y Y Y

Type of surgery/procedure: _____

Medication Details

11. Was there any change to the study medication?

☐ No change

☐ Other, please specify: _____

☐ Study medication temporarily discontinued

☐ Study medication permanently discontinued

12. Was any other medication started or changed after the suspected event?

☐ No

☐ Yes, details: _____

Please append Bleeding screening form and all de-identified source documents supporting this event for adjudication.

Reporting Centre

Delegate's Name: _____ Signature _____

Investigator's Name: _____ Signature _____

Date D D M M M Y Y Y Y

Suspected Postpartum Pre-eclampsia Outcome Event

Suspected Postpartum Preeclampsia Outcome	
1.	**Date of suspected postpartum preeclampsia:** D D M M M Y Y Y Y
2.	**Number of days postpartum:** ☐☐ days
3.	**Description of event (describe all relevant information/events preceding and at the time of the suspected event):**
4.	**Largest amount of proteinuria documented postpartum:** Urine protein / Cr ratio: _____ mg/mmol spot urine **OR** 24-hour urine protein: _____ grams
5.	**Highest blood pressure reading postpartum:** ☐ Blood pressure readings not available Systolic ☐☐☐ mmHg Diastolic: ☐☐☐ mmHg
6.	**Please check criteria for HELLP syndrome** (check all that apply): ☐ Hemolysis: LDH>600 IU/L or serum bilirubin greater than 2xULN ☐ Elevated liver enzymes: AST or ALT greater than 2xULN ☐ Low platelets: Platelet count <100 x 10^9/L

7. Please check criteria for severe preeclampsia (check all that apply):

- ☐ **None**, subject has non-severe preeclampsia
- ☐ SBP ≥ 160 mm Hg and/or DBP ≥ 110 mm Hg
- ☐ Proteinuria > 5 g/24 hours
- ☐ AST, ALT, or bilirubin greater than 2xULN
- ☐ Platelet count <100 x 10^9/L
- ☐ Pulmonary edema diagnosed on chest x-ray
- ☐ Seizures (eclampsia)
- ☐ Headache
  - ☐ Mild: Responsive to non-narcotic analgesics
  - ☐ Severe: Does not improve with non-narcotic analgesics
- ☐ Other neurological manifestations (stroke, intracranial hemorrhage, cerebral edema, hyperreflexia, visual impairment)
  - ☐ Details:_____
    _____
    _____
- ☐ Coagulopathy: Elevated INR/PT or PTT greater than 1.5xULN, or decreased fibrinogen <2 g/L
- ☐ Oliguria <30 mL per hour over at least 3 hours

Medication Details

8. Was there any change to the study medication?

- ☐ No change
- ☐ Other, please specify: _____
- ☐ Study medication temporarily discontinued
- ☐ Study medication permanently discontinued

9. Was any other medication started or changed after the suspected event?

- ☐ No
- ☐ Yes, details: _____

Please append all de-identified source documents supporting this event for adjudication.

Reporting Centre

Delegate's Name: _____ Signature _____

Investigator's Name: _____ Signature _____

Date D D M M M Y Y Y Y

Death Outcome Event

NOTE: Complete a **DEATH EVENT form, along with an SAE form,** as soon as you are aware of the event. Attach all supporting source documents (**with no identifying and study treatment allocation information)** to this form for Death Event Adjudication.

Death Outcome	
1. Date of Death:	D D M M M Y Y Y Y
2. Date of last dose of study medication:	D D M M M Y Y Y Y
3. Description of event (describe all relevant information/events preceding and at the time of death):	

4.	**Description of event (describe all relevant information/events preceding and at the time of death):** ☐ Hospital discharge summary ☐ Hospital chart notes ☐ Death certificate ☐ Other, please specify:
5.	**Was an autopsy performed?** ☐ **No** ☐ **Yes** ***If yes, please attach report to this form.**

Please append all de-identified source documents supporting this event for adjudication.

Reporting Centre			
Delegate's Name:	_____	Signature	_____
Investigator's Name:	_____	Signature	_____
Date	D D M M M Y Y Y Y		