

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.

SAE report type										
<input type="checkbox"/> Initial	<input type="checkbox"/> Follow-up									
<input type="checkbox"/> Final										
Participant or infant?	<input type="checkbox"/> Participant <input type="checkbox"/> Infant									
SAE report date:	<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		
Condition/Diagnosis:										
SAE Term (MedDRA Coding):										
<p>Event Description: 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>										

Serious Adverse Event Information										
Date of onset:	<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		
Date when event became serious:	<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		
Date SAE ended:	<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>SAE category:</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			
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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

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This section to be completed by the Investigator only		
Severity/Intensity		
<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Severe
Causality		
<input type="checkbox"/> Unrelated	<input type="checkbox"/> Possibly related	<input type="checkbox"/> Related
Expectedness		
<input type="checkbox"/> Expected/Anticipated	<input type="checkbox"/> Unexpected/Unanticipated	
Gravity		
<input type="checkbox"/> Non-serious	<input type="checkbox"/> Serious	
Possible causes of the event (check all that apply):		
<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):	_____	

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

Coordinating Trial Centre									
Principal Investigator:									
Signature:									
Date:	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 and alexandra.garven@ucalgary.ca to confirm receipt of the SAE electronic CRF.