

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):	
Event Description: 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.	
Action taken with study medication: <input type="checkbox"/> No change <input type="checkbox"/> Other medication(s) started for AE: _____ <input type="checkbox"/> Study medication temporarily discontinued <input type="checkbox"/> Study medication permanently discontinued <input type="checkbox"/> Other, please specify: _____	
Clinical outcome: <input type="checkbox"/> Recovered/resolved <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Unknown <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Study medication discontinued	

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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*	

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

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