

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		
Date started:	<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		
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	
Condition/Diagnosis:	
Action taken with study medication: <input type="checkbox"/> No change <input type="checkbox"/> New medication(s) started: _____ <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"/> Study medication discontinued <input type="checkbox"/> Unknown	

This section to be completed by the Investigator only		
Intensity		
<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Severe
Relationship to study medication/causality		
<input type="checkbox"/> Unrelated	<input type="checkbox"/> Possibly related	<input type="checkbox"/> Related

Reporting Centre										
Delegate's Name:										
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		