

PILOT PARTUM: Protocol Deviation/Violation

Site No.

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Subject No.

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Protocol Deviation / Violation Form

Type of Event	
<input type="checkbox"/>	Protocol Deviation: non-compliance with the protocol that is <u>unlikely</u> to have a significant impact on the patient's rights, safety and welfare, or on the integrity of the data.
<input type="checkbox"/>	Protocol Violation: non-compliance with the protocol that may have a <u>significant</u> impact on the patient's rights, safety and welfare, or on the integrity of the data <u>and</u> can cause the coordinating centre to exclude the patient from the eligibility analysis and/or discontinue the patient from the study.

Protocol Deviation / Violation Information										
Date of deviation or violation:	<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		
Event description: Please provide details of the deviation or violation. Include any other relevant information not captured elsewhere on the form.										
Reason for the deviation or violation:										
Actions taken to reconcile the deviation or violation and prevent future occurrences:										

Protocol Violations ONLY	
Please complete this section only if the non-compliance is a violation.	
Did the violation impact subject's rights and/or safety?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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		