

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 / Unanticipated Risk Involving Participant (UaP)										
Date of deviation or violation:	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
Categories: <ul style="list-style-type: none"><input type="checkbox"/> Informed consent process error<input type="checkbox"/> Participant did not meet Inclusion/Exclusion Criteria<input type="checkbox"/> Randomization error<input type="checkbox"/> Study visit<ul style="list-style-type: none"><input type="checkbox"/> Incomplete visit<input type="checkbox"/> Outside of study window<input type="checkbox"/> Missed visit<input type="checkbox"/> Study booklet<ul style="list-style-type: none"><input type="checkbox"/> Incomplete study booklet<input type="checkbox"/> Failed to return study booklet<input type="checkbox"/> Study medication<ul style="list-style-type: none"><input type="checkbox"/> Dispensing error<input type="checkbox"/> Dosing error<input type="checkbox"/> Use of prohibited medication<input type="checkbox"/> Stopped medication early<input type="checkbox"/> Failed to return study medication<input type="checkbox"/> Improper breaking of the blind<input type="checkbox"/> Unreported SAE<input type="checkbox"/> Other: _____										
Event description: <p>Please provide details of the deviation or violation. Include any other relevant information not captured elsewhere on the form.</p>										
Actions taken to reconcile the deviation or violation and prevent future occurrences:										

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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" style="display: inline-table;"><tr><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">D</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">M</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td><td style="width: 20px; height: 20px; text-align: center;">Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		