

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"/>	<b>Protocol Deviation:</b> 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"/>	<b>Protocol Violation:</b> 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)										
<b>Date of deviation or violation:</b>	<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		
<b>Categories:</b> <ul style="list-style-type: none"><li><input type="checkbox"/> Informed consent process error</li><li><input type="checkbox"/> Participant did not meet Inclusion/Exclusion Criteria</li><li><input type="checkbox"/> Randomization error</li><li><input type="checkbox"/> Study visit<ul style="list-style-type: none"><li><input type="checkbox"/> Incomplete visit</li><li><input type="checkbox"/> Outside of study window</li><li><input type="checkbox"/> Missed visit</li></ul></li><li><input type="checkbox"/> Study booklet<ul style="list-style-type: none"><li><input type="checkbox"/> Incomplete study booklet</li><li><input type="checkbox"/> Failed to return study booklet</li></ul></li><li><input type="checkbox"/> Study medication<ul style="list-style-type: none"><li><input type="checkbox"/> Dispensing error</li><li><input type="checkbox"/> Dosing error</li><li><input type="checkbox"/> Use of prohibited medication</li><li><input type="checkbox"/> Stopped medication early</li><li><input type="checkbox"/> Failed to return study medication</li></ul></li><li><input type="checkbox"/> Improper breaking of the blind</li><li><input type="checkbox"/> Unreported SAE</li><li><input type="checkbox"/> Other: _____</li></ul>										
<b>Event description:</b> <p>Please provide details of the deviation or violation. Include any other relevant information not captured elsewhere on the form.</p>										
<b>Actions taken to reconcile the deviation or violation and prevent future occurrences:</b>										

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

<b>Reporting Centre</b>										
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		