

PILOT PARTUM: Protocol Deviation/Violation Site No.

--	--

Subject No.

--	--	--

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:	Please provide details of the deviation or violation. Include any other relevant information not captured elsewhere on the form.									
Actions taken to reconcile the deviation or violation and prevent future occurrences:										

PILOT PARTUM: Protocol Deviation/Violation Site No.

--	--

Subject No.

--	--	--

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		