

90 Day Follow-up Case Report Form

A. Details of Follow-up										
1.	<p>Able to contact subject to complete postpartum follow-up: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, please specify reason why, and sign and date the form.</p> <p><input type="checkbox"/> Unable to contact subject after multiple attempts – <i>see resource manual for contact procedures</i></p> <p><input type="checkbox"/> Subject has died (Please complete End of Study, SAE and Death Outcome forms)</p> <p><input type="checkbox"/> Subject withdrew consent (Please complete End of Study form)</p>									
2.	<p>Date of follow-up: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;">D</td><td style="width: 20px; height: 20px;">D</td><td style="width: 20px; height: 20px;">M</td><td style="width: 20px; height: 20px;">M</td><td style="width: 20px; height: 20px;">M</td><td style="width: 20px; height: 20px;">Y</td><td style="width: 20px; height: 20px;">Y</td><td style="width: 20px; height: 20px;">Y</td><td style="width: 20px; height: 20px;">Y</td></tr></table></p>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
3.	<p>Concomitant Medication Form reviewed? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>									
4.	<p>Has the subject experienced any adverse events since the last visit? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please complete Adverse Event or Serious Adverse Event Form.</p>									
5.	<p>Complete VTE Screening Form for all subjects. <input type="checkbox"/> Completed</p>									
6.	<p>Has the subject had any bleeding since the last visit (other than normal vaginal bleeding*)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If “No” to any bleeding: probe further to confirm response by asking specifically about black stools, blood in stools, blood in urine, nose bleeds, excessive vaginal bleeding and coughing up blood.</p> <p>If yes, complete Bleeding Screening Form.</p>									
7.	<p>Has the subject had any chest symptoms such as shortness of breath or chest pain, or neurological symptoms such as weakness or numbness since the last visit? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, complete ATE Screening Form.</p>									

* Defined as vaginal bleeding equivalent or less in volume to subject’s pre-pregnancy menstrual bleeding and blood flow does not soak through one or more sanitary pads or tampons every hour for several consecutive hours. Normal postpartum vaginal bleeding should diminish in volume and be less red in colour each day when compared to the previous day.

Delegate’s Name

Delegate’s Signature

D	D	M	M	M	Y	Y	Y	Y
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Date