

CRF – Medical Events/Conditions CRF		
No.	Question	Response
001	Enter date event/condition was reported to site staff:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
002	Is the event/condition related to:	0 = Maternal participant 1 = Fetus/unenrolled infant 2 = Enrolled infant
003	Type of visit that the event/condition was first reported:	0 = Enrollment Visit (V101) 1 = Antenatal Visit 1 (V102) 2 = Antenatal Visit 2 (V103) 3 = Antenatal Visit 3 (V104) 4 = Pregnancy Outcome Visit (V201) 5 = Postnatal Visit 1 (V202) 6 = Postnatal Visit 2 (V203) 97 = Interim Visit
005a	Brief 1-3 word description of the event/condition:	
005b	Description of the event/condition:	

006	Affected body system:	0 = Constitutional 1 = Cardiovascular 2 = Digestive 3 = Endocrine 4 = Hemic/Lymphatic 5 = Metabolic/Nutritional 6 = Musculoskeletal 7 = Nervous 8 = Respiratory 9 = Skin/Appendages 10 = Special Senses (Seeing, hearing, smelling, touch, taste, equilibrium) 11 = Urogenital 12 = Infection 13 Head, Ears, Eyes, Nose, Throat 14 = Obstetric 15 = Mental health 16 = Other Specify in 007
007	Specify the 'other' body system effected by medical event:	Respond only if [006 = 16]
008	Date the event took place, or of onset, start, or diagnosis:	-- -- / -- -- / -- -- -- -- D D / M M / Y Y Y Y
009	Were medications prescribed as part of the treatment for the event/condition?	0 = No 1 = Yes Document on Medications CRF if taken during the pregnancy/study participation

010	Were there any hospitalizations, prolongation of hospitalizations or deaths associated with the event.	0 = No 1 = Yes
011	Describe any relevant information from the participant's medical history that could explain the event (past occurrences, medications use or risk factors)?	
012	What is the current status of the event/condition?	0 = Not recovered/not resolved or ongoing. Skip to 015 1 = In the process of recovering/resolving. Skip to 015 2 = Fully recovered/resolved with no sequelae. 3 = Fully recovered/resolved with sequelae Specify in 013 4 = Resulted in death.
013	Please describe the sequelae associated with the event/condition:	Respond only if [013 = 3]

014	Date when the event/condition ended or was resolved:	<p>Enter value only if [013 = 2, 3, 4]</p> <p>-- / -- / ----- D D / M M / Y Y Y Y</p>
015	<p>Are any medical records available for review?</p> <p>Note: document records type in chart notes</p>	<p>Select all that apply:</p> <p>0 = No</p> <p>1 = Yes, handheld along with participant report Document records type in chart notes</p> <p>2 = Yes, abstracted from medical records (includes ultrasound results) Document records type in chart notes</p>
016	Is the event due to study participation and meets SAE criteria?	<p>0 = No</p> <p>1 = Yes See SSP section 6 for SAE criteria and reporting guidance</p>
017	CRF Notes	