CRF – Medical Events/Conditions CRF

No.	Question	Response
001	Enter today's date:	_ _ / _ _ / _ _ _ _ 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
004	Date the event/condition was reported:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
005	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:	Enter value 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
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:	`Enter value only if [013 = 2 or 3]` _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y

015	Are any medical records available for review?
	
	Note: document records type in chart notes
		```Select all that apply:```
		
		```0 = No```
		
		```1 = Yes, handheld along with participant report```
		
		```2 = Yes, abstracted from medical records (includes ultrasound results)```

016	Is the event due to study participation and meets SAE criteria?	```0 = No``` ```1 = Yes	Complete SAE form and reporting process```
017	CRF Notes	