

No.	Item Description	Data Value
<p style="text-align: center;">This CRF should only be completed if the subject experiences a Serious Adverse Event (SAE) . You can print additional copies of this form, as needed, from WebDCU.</p> <p style="text-align: center; color: red; font-weight: bold;">This form must be data entered and submitted in WebDCU within 24 hours.</p>		
1	Name of the adverse event DB Name: [Q01]	(100 char.)
2	If serious, why? DB Name: [Q02]	<input type="radio"/> 1 - Resulted in death <input type="radio"/> 2 - Is life-threatening <input type="radio"/> 3 - Requires hospitalization / prolongation of hospitalization <input type="radio"/> 4 - Resulted in a persistent or significant disability/incapacity
3	Date of hospital admission: DB Name: [Q03]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
4	Date of hospital discharge: DB Name: [Q04]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
5	Severity: Refer to NCI Common Terminology Criteria for Adverse Events (CTCAE) in EPISOD MoP. DB Name: [Q05]	<input type="radio"/> 1 - Mild <input type="radio"/> 2 - Moderate <input type="radio"/> 3 - Severe <input type="radio"/> 4 - Life threatening / Disabling <input type="radio"/> 5 - Death related to AE / Fatal
6	Date of AE onset DB Name: [Q06]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
7	Outcome of the AE: DB Name: [Q07]	<input type="radio"/> 1 - AE resolved <input type="radio"/> 2 - AE's severity increased/decreased <input type="radio"/> 3 - AE is continuing <input type="radio"/> 4 - Patient died before AE resolved
8	Date of resolution or date that the AE's severity increased/decreased: DB Name: [Q08]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
9	Describe the event in detail: Include a description of what happened and a summary of all relevant clinical information (medical status prior to the event, signs and/or symptoms, differential diagnosis for the event in question, clinical course, treatment outcome, etc) DO NOT identify any subject, physician, or institution by name. DB Name: [Q09]	(2500 char.)

10	I attest that this SAE was reviewed by the site's PI or designee. DB Name: [Q10]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
11	Date of PI / Designee review: DB Name: [Q11]	<input type="text"/>  (dd-mmm-yyyy) Complete
B	General Comments DB Name: [zNotes]	<input type="text"/> (500 char.)