

No.	Data Item	Data Value
This CRF should only be completed if the subject experiences an Adverse Event (AE) . You can print additional copies of this form, as needed, from WebDCU.		
For EPISOD subjects, all adverse events should be documented in the Adverse Event CRF. For EPISOD2 subjects, only ERCP related adverse events and serious adverse events should be documented in the Adverse Event CRF.		
This form must be data entered and submitted in WebDCU within 24 hours if the adverse event was serious.		
	Blinded DB Name: [ Blinded ]	Yes Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=51 and zItemNb=1 ]
1	Name of Adverse Event DB Name: [ Q01 ]	<div style="border: 1px solid black; height: 20px; width: 100%;"></div> <div style="text-align: right; font-size: small;">100 char.</div>
2	Serious DB Name: [ Q02 ]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=51 ]
3	If serious, why? DB Name: [ Q03 ]	<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  Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=129 ]
16	Date of hospital admission DB Name: [ Q16 ]	Complete Date
17	Date of hospital discharge DB Name: [ Q17 ]	Complete Date
4	What is the relationship of the AE to the study treatment? DB Name: [ Q04 ]	<input type="radio"/> 1 - Not related <input type="radio"/> 2 - Unlikely <input type="radio"/> 3 - Possibly <input type="radio"/> 4 - Probably <input type="radio"/> 5 - Definitely  Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=130 ]
6	Severity of the non-ERCP related AE DB Name: [ Q06 ]	<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  Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=131 ]
7	Severity of the ERCP-related AE DB Name: [ Q07 ]	<input type="radio"/> 1 - Mild <input type="radio"/> 2 - Moderate <input type="radio"/> 3 - Severe <input type="radio"/> 4 - Fatal Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=132 ]

8	Did the AE related to ERCP prevent the completion of the ERCP? DB Name: [ Q08 ]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=51 ]
9	Date of onset of the AE DB Name: [ Q09 ]	<input type="text"/> / <input type="text"/> / <input type="text"/> <i>Complete Date</i>
10	Outcome of the AE DB Name: [ Q10 ]	<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  Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=133 ]
11	Date of resolution or date that the AE's severity increased/decreased DB Name: [ Q11 ]	<input type="text"/> / <input type="text"/> / <input type="text"/> <i>Day Optional</i>
12	I attest that this SAE was reviewed by the site's PI or designee DB Name: [ Q12 ]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=51 ]
13	Date of PI / Designee review DB Name: [ Q13 ]	<input type="text"/> / <input type="text"/> / <input type="text"/> <i>Complete Date</i>
For Serious Adverse Events Only		

15	<p>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: [ Q15 ]</p>	<p>2500 char.</p>
c	<p>General Comments DB Name: [ zNotes ]</p>	<p>250 char.</p>