WebDCU™ EPISOD **Annotated Form for [Adverse Events (unblinded)]**

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]	No Data Source: [zCodeItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=51 and zItemNb=0]
1	Name of Adverse Event DB Name: [Q01]	*100 char.*
2	Serious DB Name: [Q02]	○ 0 - No ○ 1 - Yes Data Source: [zCodeItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=51]
3	If serious, why? DB Name: [Q03]	○ 1 - Resulted in death ○ 2 - Is life-threatening ○ 3 - Requires hospitalization / prolongation of hospitalization ○ 4 - Resulted in a persistent or significant disability/incapacity Data Source: [zCodeItem] 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]	○ 1 - Not related ○ 2 - Unlikely ○ 3 - Possibly ○ 4 - Probably ○ 5 - Definitely Data Source: [zCodeItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=130]
6	Severity of the non-ERCP related AE DB Name: [Q06]	○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe ○ 4 - Life threatening / Disabling ○ 5 - Death related to AE / Fatal Data Source: [zCodeItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=131]
7	Severity of the ERCP-related AE DB Name: [Q07]	○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe ○ 4 - Fatal Data Source: [zCodeItem] 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]	○ 0 - No ○ 1 - Yes Data Source: [zCodeItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=51]
9	Date of onset of the AE DB Name: [Q09]	*Complete Date*
10	Outcome of the AE DB Name: [Q10]	○ 1 - AE resolved ○ 2 - AE's severity increased/decreased ○ 3 - AE is continuing ○ 4 - Patient died before AE resolved Data Source: [zCodeItem] 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]	*Day Optional*
12	I attest that this SAE was reviewed by the site's PI or designee DB Name: [Q12]	○ 0 - No ○ 1 - Yes Data Source: [zCodeItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=51]
13	Date of PI / Designee review DB Name: [Q13]	*Complete Date*
For Serious Adverse Events Only		

15	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]	*2500 char.*
c	General Comments DB Name: [zNotes]	*250 char.*