

No.	Data Item	Data Value
1	Date of study termination DB Name: [ Q01 ]	<i>Complete Date</i>
3	Did the subject complete the Month 12 Visit? DB Name: [ Q03 ]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=51 ]
10	Did the subject take prescription analgesics for abdominal pain during months 10, 11, or 12. DB Name: [ Q10 ]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=51 ]
4	Primary reason for early study termination DB Name: [ Q04 ]	<input type="radio"/> 1 - Adverse Event (Complete Adverse Event CRF) <input type="radio"/> 2 - Consent Withdrawn <input type="radio"/> 3 - Lost to follow up <input type="radio"/> 4 - Failed randomization (EPISOD subjects only) <input type="radio"/> 5 - Screen failure <input type="radio"/> 6 - Failed at ERCP (EPISOD2 subjects only) <input type="radio"/> 98 - Other  Data Source: [ zCodeltem ] Data Field: [ zItemNb ] Label Field: [ zItemNm ] Filter: [ zGroupID=145 ]
9-1	If Failed randomization, specify:	<input type="checkbox"/> Found to be ineligible for study during ERCP due to pancreas divisum (complete or partial). <input type="checkbox"/> Found to be ineligible for study due to pathology discovered during ERCP. <input type="checkbox"/> Found to be ineligible for study due to failed pancreatic manometry.
5	If "Other", please specify DB Name: [ Q05 ]	<i>250 char.</i>
6	Last name of principal investigator DB Name: [ Q06 ]	<i>50 char.</i>
8	PI signature date DB Name: [ Q08 ]	<i>Complete Date</i>
c	General Comments DB Name: [ zNotes ]	<i>250 char.</i>