

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 2 - Consent Withdrawn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