

No.	Data Item	Data Value
The Inclusion Exclusion Criteria CRF must be submitted and all eligibility criteria met (unless a protocol exemption is granted) or randomization will be blocked.		
a	Date of assessment DB Name: [zFormDate]	Complete Date
Inclusion Criteria: To be eligible, all questions in this section should be answered YES or Protocol Exemption Granted		
Questionnaires		
28	For which version of the protocol does your site have IRB approval? Answer the questions below depending upon which version is approved. Refer to the version column adjacent to each question for guidance. DB Name: [Q28]	<input type="radio"/> 5 - Version 5 <input type="radio"/> 6 - Version 6 <input type="radio"/> 7 - Version 7 Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=383 and zItemNb>=5]
29	V3 & V4 & V5 & V6 & V7: Has the patient been diagnosed with the clinical syndrome of SOD, as defined by the Modified Functional Biliary Disorders Module of the Rome III Criteria? (In order to be eligible Form 2: FBDM: Q09 must be "Yes" Q10 must be "Sometimes" or "Often", or "Most of the time", or "Always" AND (In order to be eligible Form 2: FBDM the subject must meet the following 5 criteria with one and only one of the criteria listed below being "Sometimes" Q02 must be "Often", "Most of the time", or "Always" Q03 must be "Often", "Most of the time", or "Always" Q05 must be "Never or Rarely" Q07 must be "Never or Rarely" Q08 must be "None or Rarely" DB Name: [Q29]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384]
30	V3 & V4 & V5 & V6 & V7: Does the patient have a pain burden of Grade 3 or higher on the RAPID	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384]

	<p>Questionnaire? (In order to be eligible Form 12: RAPID, Q22 must be greater than or equal to 11) DB Name: [Q30]</p>	
31	<p>V3 & V4 & V5 & V6 & V7: Has the patient had a cholecystectomy more than 90 days before enrollment? (In order to be eligible Form 39: RAPID Start, Q01 must be greater than 90 days prior to date of enrollment) DB Name: [Q31]</p>	<p> <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodeltem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384] </p>
Tests		
4	<p>V2 & V5 & V6 & V7: Has the patient had an upper endoscopy examination without findings to explain the pain? DB Name: [Q04]</p>	<p> <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodeltem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384] </p>
5	<p>Has the patient had normal abdominal imaging by CT or MR/MRCP with bile duct reported at = 9mm? (In order to be eligible Form 10: Abdominal Imaging, Q37 & Q47 must be less than or equal 9mm) DB Name: [Q05]</p>	<p> <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodeltem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384] </p>
37	<p>V4 & V5 & V6 & V7: Do results of blood tests taken within 1 week preceding the baseline visit and any others available from the preceding 6 months (post-cholecystectomy) meet the following criteria? Direct bilirubin, alkaline phosphatase, amylase and lipase results must no greater than 2 X upper level of normal (ULN). (In order to be eligible Form 08: Liver Function Test, Q11, Q12, Q15, Q16 must be within 2X the upper limit of normal limits) Transaminase levels can be no more than 3 X upper limit of normal (ULN). (In order to be eligible, Form 08:</p>	<p> <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodeltem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384] </p>

	Liver Function Test, Q13 & Q14 must be within 3X the upper limit of normal) DB Name: [Q37]	
Medication		
33	V3 & V4 & V5 & V6 & V7: Does the patient have pain persisting despite a trial of acid suppressant medications for one month (if tolerated)? DB Name: [Q33]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384]
34	V3 & V4 & V5 & V6 & V7: Does the patient have pain persisting despite a trial of PRN antispasmodics? DB Name: [Q34]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384]
8	If the patient is on antidepressants for pain control (not required), has he/she been taking them for a minimum of one month prior to the baseline assessment? (In order to be eligible Form 04: Prior Medications if patient has taken antidepressants for pain control, the patient must have taken for 30 or more days prior to enrollment) DB Name: [Q08]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 3 - Not applicable <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=385]
9	If this patient has SOD with depressive and/or anxiety disorders and is receiving psychopharmacologic treatment, has he/she been on a stable medication dose for at least 6 weeks? DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 3 - Not applicable <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=385]
35	V3 & V4 & V5 & V6 & V7: The total number of days in the previous 3 months that the patient has taken prescription analgesics due to episodes of abdominal pain is not greater than the total number of days the subject has episodes of pain. (In order to be eligible (Form 04: Prior Medications , QE) - Total days taking	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted Data Source: [zCodelItem] Data Field: [zItemNb] Label Field: [zItemNm] Filter: [zGroupID=384]

	<p>prescription analgesics must be less than total days of episodes of pain (Form 12: RAPID, Q16))</p> <p>DB Name: [Q35]</p>	
Personal Information		
11	<p>Does the patient have access to a telephone?</p> <p>DB Name: [Q11]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
12	<p>Is the patient able to speak, read, and write English?</p> <p>DB Name: [Q12]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
13	<p>Has the patient signed and dated the informed consent? (In order to be eligible Form 00: Subject Enrollment, Q03 must be dated prior or equal to enrollment date)</p> <p>DB Name: [Q13]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
Exclusion Criteria: To be eligible, all questions in this section should be answered NO or Protocol Exemption Granted.		
Demographic Information		
15	<p>Is the patient's age less than 18 or greater than 65? (In order to be eligible Form 00: Subject Enrollment, Q05 must be between 18 and 65)</p> <p>DB Name: [Q15]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
16	<p>Is the patient pregnant? (In order to be eligible Form 09: HCG Blood Serum Test, Q03 must be "Negative")</p> <p>DB Name: [Q16]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
Prior Events		
17	<p>Does the patient have known pancreas divisum, (complete or partial)?</p> <p>DB Name: [Q17]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
18	<p>Has the patient had prior gastric resection or surgery involving biliary diversion?</p> <p>DB Name: [Q18]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
19	<p>Has the patient had prior ERCP treatment?</p> <p>DB Name: [Q19]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>

20	<p>Has the patient had prior diagnosis of acute pancreatitis (lipase >3 x ULN) including post-ERCP pancreatitis, or of chronic pancreatitis by radiological imaging, EUS 5 or more criteria, or Cambridge criteria moderate or more on ERCP?</p> <p>DB Name: [Q20]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
Medications		
22	<p>Has the patient used prescription analgesics daily over the previous month? (In order to be eligible Form 04: Prior Medications must not have used daily prescription analgesics within 30 days of enrollment)</p> <p>DB Name: [Q22]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
Psychiatric Disorders		
<p>Does the patient have any of the following significant psychiatric disorders?</p> <p>Lifetime psychotic disorders, bipolar disorder;</p> <p>(In order to be eligible Form 11: MINI, Q19, Q20, Q27, Q28 must be "No")</p> <p>Substance use disorders within 6 months; (In order to be eligible Form 11: MINI, Q15-Q18 must be "No")</p> <p>Eating disorders within 2 years; (In order to be eligible Form 11: MINI, Q21-Q23 must be "No")</p>		
<p>Moderate & severe depression defined by BDI-2 cutoff score of >22, unless there is evidence of an appropriate assessment of their condition by a mental health professional who has establish that the patient is being appropriately managed and is clinically stable (In order to be eligible Form 13: BDI-II, Q22 must be less than or equal to 22 or have document psychological therapy for past 6 weeks, if higher than 22. Data enter therapy information on concomitant procedures form, Form22) and/or, Suicidal risk (equal to or greater than "low") using MINI suicide section or a score of greater than 0 on question 9 of the BDI. (In order to be eligible Form 11: MINI, Q04 must be "No" & Form 13: BDI-II, Q22 must be less than or equal to 22)</p>		
38	<p>V5 & V6 & V7: Does the patient have any of the following significant psychiatric disorders?</p> <p>DB Name: [Q38]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
Eligibility Confirmation		
24	<p>Does the patient have any condition that, in the investigator's or designee's opinion, makes him/her unsuitable for study participation?</p> <p>DB Name: [Q24]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Unknown <input type="radio"/> 99 - Protocol Exemption Granted</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=384]</p>
26	<p>Date of PI/Designee review</p> <p>DB Name: [Q26]</p>	<p><i>Complete Date</i></p>
27	<p>I attest that this subject's eligibility was reviewed by the site's PI or designee.</p> <p>DB Name: [Q27]</p>	<p><input type="radio"/> 0 - No <input type="radio"/> 1 - Yes</p> <p>Data Source: [zCodelItem]</p> <p>Data Field: [zItemNb]</p> <p>Label Field: [zItemNm]</p> <p>Filter: [zGroupID=51]</p>

b	General Comments DB Name: [zNotes]	250 char.
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