

EPISOD Data Collection Schedule v7																									
Form #	Case Report Form	Baseline	EPISOD														Treatment	EPISOD 2					End of Study		
			Randomization & Treatment	1 Week FU +/- 3 d	1 Month FU +/- 7 d	2 Month FU +/- 7 d	3 Month FU +/- 7 d	4 Month FU +/- 7 d	5 Month FU +/- 7 d	6 Month FU +/- 7 d	7 Month FU +/- 7 d	8 Month FU +/- 7 d	9 Month FU +/- 7 d	10 Month FU +/- 7 d	11 Month FU +/- 7 d	12 Month FU +/- 7 d		Unscheduled Visit	1 Month FU +/- 7 d	6 Month FU +/- 7 d	9 Month FU +/- 7 d	12 Month FU +/- 7 d		EPISOD2 Re-Intervention +/- 7 d	
00	Subject Enrollment Form	X																							
01	Inclusion Exclusion Criteria	X																							
03	Medical History	X																							
04	Prior Medications	X																							
05	Physical Examination	X														X									
06	Vitals	X														X									
07	Complete Blood Count (Baseline)	XM																							
08	Liver/Pancreas Test (Baseline)	XM																							
09	HCG Blood Serum-H.Pylori Test	X																							
10	Abdominal Imaging	X																							
11	MINI International Neuropsychiatric Interview	X																							
12	RAPID	X					X			X						X		X			X				
46	Monthly Abdominal Pain Assessment			X	X	X	X	X	X	X	X	X	X	X	X										
36	RAPID– Central Caller										X				X				X	X					
13	Beck's Depression Inventory II	X					X			X		X			X			X	X	X					
02	Functional Biliary Disorders Module	X																							
14	HADS	X					X			X		X			X			X	X	X					
19	Trauma Scale	X																							
20	Coping	X																							
16	Rome III Diagnostic Module	X																							
15	SF-36 (v2)	X					X			X		X			X	X		X	X	X					
21	Baseline Resource Utilization Questionnaire	X																X	X	X					
39	RAPID START	X																							
38	Subject Personal Contact Information	X																							
34	Subject Follow-Up Contact Log	X																							
37	Subject Randomization Form– Unblinded		X																						
17	Sphincter of Oddi Manometry– Unblinded		X													X									
18	ERCP– Unblinded		X													X									
22	Concomitant Treatment/Procedure for SOD III		X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X				
23	Concomitant Medications		X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X				
25	Adverse Events	OR	OR	OR	OR	OR	OR	OR	OR	OR	OR	OR	OR	OR	OR	OR		OR	OR	OR	OR	OR			
45	Adverse Events- Unblinded		OR																						
41	Subject Treatment Form- Unblinded		X																						
40	Post Procedure Labs		X																						
26	Follow Up Resource Utilization Questionnaire						X			X		X			X				X	X					
27	Review for Re-Intervention															X									
28	Liver/Pancreas Test (Follow Up)															X					X				
29	Complete Blood Count (Follow Up)															X									
30	Best Guess (Study Coordinator)			X	X		X			X		X			X	X									
31	Best Guess (Subject)			X	X		X			X		X			X	X									
32	Best Guess (Evaluating Physician)															X									
33	Unscheduled Clinic Assessment															X					X				
42	EPISOD2 Subject Treatment Form																X				X				
43	EPISOD2 Sphincter of Oddi Manometry																X				X				
44	EPISOD2 ERCP																X				X				
24	Bill Tracking (UB-04)																								
35	End of Study																						X		