MD RATING - BASELINE

IRRITABLE BOWEL SYNDROME STUDY

Patient Number [patid]

Date of Study Participant Visit/Contact [visitm] mmm [ ] dd [ ] yyyy

Protocol Number [study]

Institution Code [instn]

Form Week [week] *Seq No. [seqno] **Step No. [stepno] Key Operator Code [keyop]

This area completed by Clinic Staff only.

* Enter a '1' if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.
** Enter the study participant's current study step number. Enter '1' if the study does not have multiple steps.

EXCLUSION CRITERIA			
To be eligible, all answers should be a No response.	***YES*** 1	***NO*** 2	
1. Evidence of current structural or biochemical abnormalities that better explain the patient's IBS symptoms (e.g. IBD).	STOP		mb601
2. Evidence of a current infection or infection of any type within the 2 weeks prior to the study gastroenterologists' evaluation which would obscure the presentation of IBS symptoms. In such cases the baseline can be delayed until 2 weeks after complete recovery.	STOP		mb602
3. Study participant has received antibiotics (e.g. rifaximan and/or neomycin) specifically targeted to treat IBS symptoms. In this instance, eligibility will be suspended 12 weeks from the initial date antibiotics were consumed.	STOP		mb603
4. Study participant has undergone previous abdominal surgery that would have caused significant alteration of the anatomy/physiology of the digestive/GI tract which adequately explains GI symptoms.	STOP		mb604
5. Study participant has been diagnosed and/or treated for malignancy in the past 5 years with exception of localized basal or squamous cell carcinomas of the skin.	STOP		mb605
6. Study participant has an unstable extraintestinal medical condition whose immediate or foreseeable treatment needs (e.g. hospitalization, conflicting physician visits) would realistically interfere with study demands (e.g. consistent attendance at treatment sessions and/or ability to participate in telephone interventions) or may affect the interpretation of clinical efficacy data.	STOP		mb606
7. Study participant has other conditions which in the opinion of the senior clinical staff would influence negatively the conduct of the clinical trial.	STOP		mb607

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mmm dd yyyy

INCLUSION CRITERIA			
To be eligible, all answers should be a Yes response.	***YES*** 1	***NO*** 2	
8. The IBSOS includes all participants of either gender from any ethnic and/ or racial group between the ages of 18-70 (inclusive). Check "Yes" to confirm.		N / A	mb608
9. Does the participant meet Rome III criteria for IBS?		STOP	mb609
10. Does the participant experience moderate to severe IBS symptoms (symptom frequency ≥ 2 days/wk)?		STOP	mb610
11. Is the participant able to understand and provide informed consent?		STOP	mb611
12. With the exception of antibiotics, is the participant taking medications and willing to remain on a stable dose throughout the 4 week pretreatment baseline period prior to randomization?		STOP	mb612
13. Is the participant either not taking medications or if taking medications, is the participant willing to suspend starting any new medications during the initial 4 week pretreatment baseline period?		STOP	mb613
14. Is the participant able to speak and read English at the sixth grade level or higher?		STOP	mb614

FORMAL DIAGNOSIS

15. *Does this patient meet the formal Rome III diagnosis of any of the following:* mb615

1☐ IBS
2☐ Functional Diarrhea
3☐ Functional Constipation
4☐ Functional Abdominal Pain
5☐ Other, please spec mb616
6☐ Provisional diagnos warranted) [70]:

mb617 ______________________________
7☐ NO, specify reason(s) for ineligibility [70]:

mb618 ______________________________

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IBS CLASSIFICATION

16. If the participant meets ROME III criteria for IBS, choose one of the following to describe the subject's predominant stool pattern over the last 3-6 months. (***Check one)***

mb619

1 ☐	**IBS-C (IBS Constipation)**	Hard or lumpy stools greater than or equal to 25% and loose (mushy) or watery stools less than 25% of bowel movements.
2 ☐	**IBS-D (IBS Diarrhea)** ……	Loose (mushy) or watery stools greater than or equal to 25% and hard or lumpy stools less than 25% of bowel movements.
3 ☐	**IBS-M (IBS Mixed)** ……	Hard or lumpy stools greater than or equal to 25% and loose (mushy) or watery stools greater than or equal to 25% of bowel movements.
4 ☐	**IBS-U (IBS Unsubtyped)**	Insufficient abnormality of stool consistency to meet criteria for IBS-C, IBS-D, or IBS-M.

SEVERITY OF ILLNESS

17. Considering the study participant's overall well-being and symptoms of pain / discomfort and altered bowel habits as well as your total clinical experience with patients with IBS, how ill is this study participant now? **(*Check one)***

mb620

1 ☐ Not Assessed
2 ☐ Normal, not ill
3 ☐ Minimally ill
4 ☐ Mildly ill
5 ☐ Moderately ill
6 ☐ Markedly ill
7 ☐ Severely ill
8 ☐ Among the most severely ill

CLINICIAN'S IMPACT RATING

*18. Circle the ONE number that reflects your estimation of the **impact of subject's symptoms** using the scale below. Do not ask patient for self-ratings.*

mb621

0	1	2	3	4	5	6	7	8
None		Slightly disturbing/ not really disturbing		Definitely disturbing/ disabling		Markedly disturbing/ disabling		Very severely disturbing/ disabling

Date Form Keyed (DO NOT KEY): _____ / _____ / _____