

MD RATING - BASELINE

IRRITABLE BOWEL SYNDROME STUDY

Page 1 of 3

Patient Number	[patid] [] [] []	Date of Study Participant	[visitm] [] [] [] [] []
Protocol Number	[study] [] [] [] []	Visit/Contact	mmm dd yyyy
Form Week	[week] [] []	*Seq No.	[seqno] **Step No.
			[stepno] Key Operator Code [keyop] []
		Institution Code	[instn] [] [] [] []

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		
<i>To be eligible, all answers should be a No response.</i>	YES 1	NO 2
1. Evidence of current structural or biochemical abnormalities that better explain the patient's IBS symptoms (e.g. IBD).	STOP	
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 <u>the baseline can be delayed until 2 weeks after complete recovery.</u>	STOP	
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	
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	
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	
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	
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	

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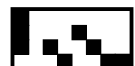
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04-10-10/06-15-10/08-30/10



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Pt. No. *Seq. No. **Step No. Date
mmm dd yyyy

INCLUSION CRITERIA

<i>To be eligible, all answers should be a Yes response.</i>	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
9. Does the participant meet Rome III criteria for IBS?		STOP
10. Does the participant experience moderate to severe IBS symptoms (symptom frequency ≥ 2 days/wk)?		STOP
11. Is the participant able to understand and provide informed consent?		STOP
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
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
14. Is the participant able to speak and read English at the sixth grade level or higher?		STOP

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FORMAL DIAGNOSIS

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

- 1 IBS
- 2 Functional Diarrhea
- 3 Functional Constipation
- 4 Functional Abdominal Pain
- 5 Other, please specify _____
- 6 Provisional diagnosis (if not warranted) [70]:

- 7 NO, specify reason(s) for ineligibility [70]:

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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)**

- 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.

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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)**

- 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

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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.

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

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