

MD RATING - FOLLOW-UP
IRRITABLE BOWEL SYNDROME STUDY

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] [][][][]

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.

FORMAL DIAGNOSIS

Does this participant meet the formal Rome III diagnosis for any of the following: (1-Yes, 2-No)

- 1. IBS [mb701]
 - If No, complete questions 2-5 and go to question 7.
 - If Yes, complete 'a' and go to question 6.
 - a. Is the participant's IBS in remission?..... [mb714]
 - 2. Functional diarrhea [mb702]
 - 3. Functional constipation [mb703]
 - 4. Functional abdominal pain [mb704]
 - 5. Other, specify [mb705]
- [70]: [mb706]

IBS CLASSIFICATION

6. 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) [mb715]
- 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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04-10-10/02-15-11/06-03-11



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

SEVERITY OF ILLNESS

7. 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 study participants with IBS, how ill is this study participant now?

Not Assessed	Normal (shows no symptoms of IBS)	Borderline symptoms of IBS	Mild IBS	Moderate IBS	Marked IBS	Severe IBS	Very severe; among the most extreme cases of IBS	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	mb711
1	2	3	4	5	6	7	8	

CLINICIAN'S IMPACT RATING

8. Circle the ONE number that reflects your estimation of the **impact of the participant's symptoms** using the scale below. Do not ask the participant for a self-rating.

0	1	2	3	4	5	6	7	8	
None		Slightly disturbing/ not really disabling		Definitely disturbing/ disabling		Markedly disturbing/ disabling		Very severely disturbing/ disabling	mb712

CLINICAL IMPRESSION OF CHANGE

9. Rate how much the patient's overall well-being, symptoms of abdominal pain/discomfort and altered bowel symptoms have improved or worsened compared to your impression of the way s/he felt before entering the study:

- 1-Very much improved
- 2-Much improved
- 3-Minimally improved
- 4-No change
- 5-Minimally worse
- 6-Much worse
- 7-Very much worse

mb713

