

**ADVERSE EVENTS**

IRRITABLE BOWEL SYNDROME STUDY

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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.

**INSTRUCTIONS:**

- Use this form to describe all adverse events.
- The "Specify" line must include a description of the event, the body system site (if applicable), and the pathogen (if applicable).
- Estimate any incomplete date according to the "Date Conventions" if the complete "Date of Onset" or "Date of Resolution" is not known.

<sup>1</sup> Severity	<sup>2</sup> Status
1-Mild	1-New
2-Moderate	2-Resolved
3-Severe	3-New and resolved in same interval
4-Life-threatening	4-Ongoing

<b><sup>3</sup> Unexpected or Expected Event</b>
<b>1-Unexpected:</b> the nature, severity, or frequency of the event is not consistent with either: a. the known or foreseeable risk of adverse events associated with the procedures described in protocol-related documents <b>or</b> b. the expected natural progression of the underlying disease, disorder, or condition of the participant(s) experiencing the adverse event and the participant's predisposing risk factor profile for the adverse event. <b>2-Expected:</b> any event that does not meet the definition of unexpected adverse event.

<sup>4</sup> Relationship to Protocol Treatment	<sup>5</sup> Serious Adverse Event Criteria	<sup>6</sup> Serious Adverse Event Final Outcome
1-Reasonable possibility 2-Not reasonable possibility	1-Death 2-Life-threatening 3-Hospitalization (initial or prolonged) 4-Persistent or significant disability or incapacity 5-Congenital anomaly or birth defect 6-Medically important condition that requires intervention to prevent permanent impairment or damage	1-Resolved 2-Resolved, with sequelae 3-Ongoing 4-Death

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04-10-10/06-15-10



## ADVERSE EVENTS

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Pt. No.	<input type="text"/>	*Seq. No.	<input type="text"/>	**Step No.	<input type="text"/>	Date	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
						mmm	dd	yyyy			

mb301

1. Indicate the type of report: ..... 1-AE/ SAE Report  
If 2, STOP. 2-No AE/ SAE to report; participant's  
If 1, continue. study follow-up completed

*Use the Tab Key after the last entry.*

<b>Event Number</b> (Use this same number whenever referring to this event)	<b>Specify Event [70]:</b>				<b>Recorder's Initials</b>	<b>Severity <sup>1</sup></b>	
a.	<input type="text"/>	<input type="text"/>				<input type="text"/>	<input type="text"/>
<b>Status <sup>2</sup></b>	<b>Unexpected or Expected Event <sup>3</sup></b>	<b>Relationship to Protocol Treatment <sup>4</sup></b>	<b>Is This a Serious Adverse Event (SAE)? (1-Yes, 2-No)</b>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				
<b>SAE Criteria for this SAE <sup>5</sup></b>	<b>SAE Final Outcome if Resolved or at Off Study <sup>6</sup></b>	<b>Date of Death (if Applicable) (mmm/dd/yyyy)</b>	<b>Time of Death (if Applicable) (hh:mm)</b>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

<b>Event Number</b> (Use this same number whenever referring to this event)	<b>Specify Event [70]:</b>				<b>Recorder's Initials</b>	<b>Severity <sup>1</sup></b>	
b.	<input type="text"/>	<input type="text"/>				<input type="text"/>	<input type="text"/>
<b>Status <sup>2</sup></b>	<b>Unexpected or Expected Event <sup>3</sup></b>	<b>Relationship to Protocol Treatment <sup>4</sup></b>	<b>Is This a Serious Adverse Event (SAE)? (1-Yes, 2-No)</b>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				
<b>SAE Criteria for this SAE <sup>5</sup></b>	<b>SAE Final Outcome if Resolved or at Off Study <sup>6</sup></b>	<b>Date of Death (if Applicable) (mmm/dd/yyyy)</b>	<b>Time of Death (if Applicable) (hh:mm)</b>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

<b>Event Number</b> (Use this same number whenever referring to this event)	<b>Specify Event [70]:</b>				<b>Recorder's Initials</b>	<b>Severity <sup>1</sup></b>	
c.	<input type="text"/>	<input type="text"/>				<input type="text"/>	<input type="text"/>
<b>Status <sup>2</sup></b>	<b>Unexpected or Expected Event <sup>3</sup></b>	<b>Relationship to Protocol Treatment <sup>4</sup></b>	<b>Is This a Serious Adverse Event (SAE)? (1-Yes, 2-No)</b>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				
<b>SAE Criteria for this SAE <sup>5</sup></b>	<b>SAE Final Outcome if Resolved or at Off Study <sup>6</sup></b>	<b>Date of Death (if Applicable) (mmm/dd/yyyy)</b>	<b>Time of Death (if Applicable) (hh:mm)</b>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

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Pt. No.	<input type="text"/>	*Seq. No.	<input type="text"/>	**Step No.	<input type="text"/>	Date	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
							mmm	dd	yyyy		

2. Print and key the name of the responsible clinician whose signature is below:

CLINICIAN REVIEW:

*I have reviewed this case and all supporting data.*

\_\_\_\_\_  
Clinician's Signature

\_\_\_\_\_  
Date

Print and key the name of the reviewing clinician

LAST NAME

FIRST NAME

04-10-10/06-15-10

Date Form Keyed (DO NOT KEY): \_\_\_\_ / \_\_\_\_ / \_\_\_\_

