ADVERSE EVENTS

IRRITABLE BOWEL SYNDROME STUDY

Patient Number [patid]

Protocol Number [study]

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

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.

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.

[1] Severity
1-Mild
2-Moderate
3-Severe
4-Life-threatening

[2] Status
1-New
2-Resolved
3-New and resolved in same interval
4-Ongoing

[3] Unexpected or Expected Event

1-Unexpected: 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

or

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.

2-Expected: any event that does not meet the definition of unexpected adverse event.

[4] Relationship to Protocol Treatment
1-Reasonable possibility
2-Not reasonable possibility

[5] Serious Adverse Event Criteria
1-Death
2-Life-threatening
3-Hospitalzation (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

[6] Serious Adverse Event Final Outcome
1-Resolved
2-Resolved, with sequelae
3-Ongoing
4-Death

CONTINUE ON NEXT PAGE

ADVERSE EVENTS

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

mb301

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

Use the Tab Key after the last entry.

Event Number (Use this same number whenever referring to this event)

a. mb302 **Specify Event [70]:** mb303 **Recorder's Initials** mb304 **Severity** [1] mb305

Status [2] mb306 **Unexpected or Expected Event** [3] mb307 **Relationship to Protocol Treatment** [4] mb308 **Is This a Serious Adverse Event (SAE)?** (1-Yes, 2-No) mb309

SAE Criteria for this SAE [5] mb310 **SAE Final Outcome if Resolved or at Off Study** [6] mb311 **Date of Death (if Applicable) (mmm/dd/yyyy)** mb312 ☐☐ ☐☐☐☐ **Time of Death (if Applicable) (hh:mm)** mb315 : mb316

Event Number (Use this same number whenever referring to this event)

b. mb317 **Specify Event [70]:** mb318 **Recorder's Initials** mb319 **Severity** [1] mb320

Status [2] mb321 **Unexpected or Expected Event** [3] mb322 **Relationship to Protocol Treatment** [4] mb323 **Is This a Serious Adverse Event (SAE)?** (1-Yes, 2-No) mb324

SAE Criteria for this SAE [5] mb325 **SAE Final Outcome if Resolved or at Off Study** [6] mb326 **Date of Death (if Applicable) (mmm/dd/yyyy)** mb327 ☐☐ ☐☐☐☐ **Time of Death (if Applicable) (hh:mm)** mb330 : mb331

Event Number (Use this same number whenever referring to this event)

c. mb332 **Specify Event [70]:** mb333 **Recorder's Initials** mb334 **Severity** [1] mb335

Status [2] mb336 **Unexpected or Expected Event** [3] mb337 **Relationship to Protocol Treatment** [4] mb338 **Is This a Serious Adverse Event (SAE)?** (1-Yes, 2-No) mb339

SAE Criteria for this SAE [5] mb340 **SAE Final Outcome if Resolved or at Off Study** [6] mb341 **Date of Death (if Applicable) (mmm/dd/yyyy)** mb342 ☐☐ ☐☐☐☐ **Time of Death (if Applicable) (hh:mm)** mb345 : mb346

CONTINUE ON NEXT PAGE

Pt. No. | *Seq. No. | **Step No. | Date 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 mb347

FIRST NAME mb348

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