

ADVERSE EVENTS

IRRITABLE BOWEL SYNDROME STUDY

Page 1 of 3

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.

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.

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

<p>³ Unexpected or Expected Event</p> <p>1-Unexpected: the nature, severity, or frequency of the event is not consistent with either:</p> <p style="margin-left: 20px;">a. the known or foreseeable risk of adverse events associated with the procedures described in protocol-related documents</p> <p style="margin-left: 20px;"><i>or</i></p> <p style="margin-left: 20px;">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.</p> <p>2-Expected: any event that does not meet the definition of unexpected adverse event.</p>
--

<p>⁴ Relationship to Protocol Treatment</p> <p>1-Reasonable possibility 2-Not reasonable possibility</p>	<p>⁵ Serious Adverse Event Criteria</p> <p>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</p>	<p>⁶ Serious Adverse Event Final Outcome</p> <p>1-Resolved 2-Resolved, with sequelae 3-Ongoing 4-Death</p>
--	---	--

CONTINUE ON NEXT PAGE

04-10-10/06-15-10



