AcertaPharma
INNOVATE DEVELOP CURE

Serious Adverse Event (SAE) Worksheet / Product Complaint Worksheet

Check all that apply:

☐ **SAE** ☐ **Product Complaint** ☐ **Initial Report** ☐ **Additional Information**

- For **SAE reporting**, complete entire form
- For **Product Complaint**, complete Narrative section (include detailed description of events) and provide lot number

SUBJECT INFORMATION:

1. Subject No. /Initials: _____ / _____
2. DOB (DD MMM YYYY): _____
3. Sex: ☐Male ☐ Female
4. Most recent weight: _____ ☐ lbs ☐ kg

THERAPY DURATION /STUDY TREATMENT:

PROTOCOL #	TREATMENT OR Blinded Drug # and Dosage	DATE OF FIRST DOSE (DD MMM YYYY)	DATE OF LAST DOSE (DD MMM YYYY)	NUMBER OF DOSES RECEIVED	LOT NUMBER

1. Did SAE abate after stopping drug? ☐Yes ☐No ☐N/A
2. Did SAE reappear after re-introduction? ☐Yes ☐No ☐N/A

3. If event resulted in death, was autopsy conducted? ☐ Yes (please attach report) ☐ No

SAE TERMS	RELATIONSHIP To Drug (Yes/No)	SERIOUS CRITERIA*	ONSET DATE (DD MMM YYYY)

***Serious Criteria Code Key (Use code that best describes the SAE):**

D= Death **L**= Life Threatening **H**= Hospitalization and/or Prolonged Hospitalization **P**= Permanent Disability
C= Congenital Anomaly **M**= Medically Significant

Reminder: The following eCRFs must be completed when submitting this SAE report:

- Medical history ● Adverse Event ● Laboratory Results
- Concomitant medications *(If concomitant med contributed to the adverse event, please describe in Narrative section below.)*

NARRATIVE: Describe the event:

(use additional pages as needed)

PLEASE EMAIL THIS FORM and supporting documentation to Drug Safety at DrugSafety@acerta-pharma.com or FAX to 866.467.0304

Investigator Signature:

_____ Date:_____

(Do **not** delay emailing in SAE report; signature may be emailed with updated report at a later time)

Name of person preparing form:

_____

Date of Report (DD MMM YYYY):

_____