Unanticipated/Serious Adverse Events Reporting Form

Terminology:

Serious Adverse Event (SAE): A serious adverse event (SAE) in human drug trials is defined as:

1. Any untoward medical occurrence that at any dose results in
2. Death
3. Is life-threatening
4. Requires inpatient hospitalization or prolongation of existing hospitalization
5. Results in persistent or significant disability/incapacity, or
6. Is a congenital anomaly/birth defect.

Procedure for reporting:

All interventional trials approved by the IEC of Samarth will come under the purview of this policy (drugs, devices, and behavioral or educational interventions; single or multiple armed trials, randomized or non-randomized).

For all SAE reports: Within 24 hours of learning about an unanticipated or serious adverse event, the principal investigator is responsible for notifying the DCGI, the Study Sponsor (if external), the **Ethics Committee (samarthethics@gmail.com).** A hard copy of this document must also be sent to the IEC Member Secretary, 100 Warren Road, Mylapore, Chennai – 600004, Tamil Nadu.

Within 10 days the principal investigator is to submit a follow up report to the same list of people as above.

SERIOUS ADVERSE EVENT FORM

PROTOCOL TITLE:	**Protocol ID No.:**	**Centre:**

Subject's Study No.	**Investigation Product:**	**Report type**
Occupation:		**1.0 = Initial** **2.1 = follow up 1** **2.2 = follow up 2 etc**

Patient Initials:	**Date of birth dd/mm/yy**	**Age Years**	**Sex**	**Height (cm)**	**Weight (Kg)**

Event onset (dd/mm/yy)	**Adverse Event in MEDICAL TERMS:**

Tick ✓ all appropriate to the Event

Patient Died Date: dd/mm/yy	**Life Threatening**	**Prolonged Hospitalization**	**Significant Disability**	**Congenital Abnormality**	**Other SAE**

Description:

Suspected Product(s):	**Daily Dose at onset of event:**	**Route of Administration:**

Indication for use:

Therapy dates (from/to), dd/mm/yy):

Therapy duration until onset of SAE

Was the product stopped? Yes / No
If yes, did the event abate after stopping the product? Yes / No/ Not Applicable

Were Relevant Concomitant Drugs administered? Yes / No
If Yes, give names and details:

Drug Name	**Dose & Route**	**Date Started (dd/mm/yy)**	**Continued Y or N**	**Date Discontinued (dd/mm/yy)**	**Reason For use**

Other Relevant History, laboratory findings and action taken.
Medical History (please attach an additional sheet if this space is inadequate):

Relevant test / Laboratory findings

Laboratory test	Unit	Date	Value	Comments on laboratory finding

Action taken by the Investigator: Please tick appropriate box

	None		Concomitant drug discontinued
	Trial dosage changed		New drug therapy added
	Trial drug discontinued		Prolonged hospitalization
	Non-drug Therapy		

Outcome: Please tick appropriate box

	Completely recovered on (dd/mm/yy)		Condition deteriorated
	Recovered with sequel		Death, autopsy done (attach summary)
	Condition improving		Death, autopsy not done
	Condition still unchanged		

Casuality Assessment by investigator (is there any relationship with the test product?):

	Not related		Probable
	Unlikely		Most probably
	Possible		Insufficient data to assess

Could the SAE be related to the study procedure?:

	Not related		Probable

	Unlikely		Most probably
	Possible		Insufficient data to assess

What is the long-term prognosis for the patient and will the patient continue to receive treatment? Will the costs of treatment be covered by insurance or other arrangements? (Please describe in detail the arrangements that will be made)

Was the protocol followed in recruitment of the participant? Yes / No

Did the participant meet the exclusion / inclusion criteria of the protocol? Yes / No

Was informed consent obtained as outlined in the protocol? Yes / No …… If no please explain:

In your opinion, does this report require that the consent form for participants to be revised? Yes / No

If Yes, submit revised consent forms (one soft copy of each and one hard copy).

Name, address, telephone and e-mail address of the investigator

Name:_____ Profession (speciality): _____

Tel: _____ e-mail: _____

Signature of the Investigator reporting the event: _____

Reporting date (dd/mm/yy) PLEASE NOTE THAT THIS DATE MUST BE COMPLETED ON THE FORM
_____

Date Received by the IEC Member Secretary: _____

Signature of the receiver: _____