

Annexure 7

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

Initials & other relevant identifier (hospital/OPD record number etc.)*

Gender

Age and/or date of birth Weight

Height

2. Suspected Drug(s)

Generic name of the drug*

Indication(s) for which suspect drug was

prescribed or tested Dosage form and strength

Daily dose and regimen (specify units - e.g., mg,

ml, mg/kg) Route of administration

Starting date and time of day

Stopping date and time, or duration of treatment

3. Other Treatment(s)

Provide the same information for concomitant drugs (including nonprescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*

Start date (and time) of onset

of reaction Stop date (and time)

or duration of reaction

Dechallenge and rechallenge
information

Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. Outcome

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator⁸ – Name, Address, Phone, Profession (specialty)

Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator

*Note: Information marked * must be provided."*