

## Annexure 12

### 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 Investigator\*

Name

Address

Telephone number

Profession (specialty)

Date of reporting the event to Licensing Authority:

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

Signature of the Investigator

Note: Information marked \* must be provided.”