FORM NO: 33-DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CT

1. Patient Details:
   Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)*
   Gender
   Age 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 non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).
4. Details of Serious Adverse Event: Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*
   Start date (and time) of onset of event.
   Stop date (and time) or duration of event
   DE challenge 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 or treatment that may have been conducted. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; 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 and Address
   Telephone number\
   Profession (specialty)\
   Date of reporting the event to Central Licencing Authority:
   Date of reporting the event to ethics committee overseeing the site:
   Signature of the Investigator or Sponsor
   Note: Information marked * must be provided