**Data Elements for Suspected Unexpected Serious Adverse Reaction (SUSAR) / Serious Adverse Event (SAE) report**

1. ERC protocol number:

2. Subject’s details:

- Sponsor’s subject identification number

- Initials, if applicable

- Gender

- Age and/or date of birth

- Weight

- Height

3. Suspected investigational medicinal product(s):

- Name of the investigational medicinal product or brand name as reported

- International non-proprietary name (INN)

- Batch number

- Indication(s) for which suspect investigational medicinal product 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

- Unblinding: yes/no/not applicable; results:

∗ Investigator’s causality assessment

∗ Sponsor’s causality assessment

∗ Comments, if relevant (e.g. causality assessment if the sponsor disagrees with the reporter; concomitant medications suspected to play a role in the reactions directly or by interaction; indication treated with suspect drug(s).

4. Other treatment(s):

- For concomitant medicinal products (including non prescription/OTC medicinal products) and non-medicinal product therapies provide the same information as listed above for the suspected investigational medicinal product.

5. 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 should be given. In addition to a description of the reported signs and symptoms, whenever possible attempts should be made to establish a specific diagnosis for the reaction,

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

- Outcome: information on recovery and any sequelae; what specific tests and/or treatment may have been required and their results; for a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction should be provided. Any autopsy or other post-mortem findings (including a coroner’s report) should also be provided when available,

- 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.

6. Details on reporter of event/suspected adverse reactions:

- Name,

- Address,

- Telephone number,

- Email address

- Profession (speciality).

7. Administrative and Sponsor details:

- Date of this report,

- Source of report: from a clinical trial, from the literature (provide copy), spontaneous, other,

- Date event report was first received by sponsor,

- Country in which reaction occurred,

- Type of report filed to authorities: initial or follow-up (first, second, etc),

- Name and address of sponsor/manufacturer/company,

- Name, address, telephone number and fax number of contact person in reporting sponsor,

- Case reference number (sponsor’s/manufacturer’s identification number for the case) (this number must be the same for the initial and follow-up reports on the same