

Data Elements for SUSAR report

1. Clinical trial identification:

- Clinical trial identification (EudraCT number, if applicable or the sponsor's trial protocol number),

2. Subject's details :

- Sponsor's subject identification numbers,
- Initials, if applicable,
- Gender,
- Age and/or date of birth,
- Weight,
- Height,

3. Suspected investigational medicinal product(s):

- Name of the IMP 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.
- Reaction(s) in MedDRA terminology¹ (lowest level term)⁶
- Start date (and time) of onset of the reaction,
- Stop date (and time) or duration of the reaction,
- De-challenge and re-challenge information,

- 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 ADR :

- name,
- address,
- telephone number,
- profession (speciality)

7. Administrative and Sponsor details:

- Date of this report
- Source of report: from a clinical trial (provide details if not in Eudract¹, 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,
- identifying regulatory code or number for marketing authorisation dossier or clinical investigation process for the suspected product (for example IND number, NDA number)
- 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 case).

⁵ Data not listed in CPMP/ICH/377/95

⁶ EMEA recommendations and ICH E2B (M).B2i 1 20