

REQUIREMENTS

to notification about suspected unexpected serious adverse reaction

1. Identification of clinical trial

Identification of clinical trial (clinical trial sponsor's protocol number, EudraCT¹ number, if available).

EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database.

2. Trial subject identification

2.1. Trial subject identification number.

2.2. Initials.

2.3. Gender.

2.4. Age and/or date of birth.

2.5. Weight.

2.6. Height.

3. Information about suspected medicinal product

3.1. Name of investigational medicinal product (or trade name).

3.2. International non-proprietary name.

3.3. Batch number.

3.4. Indications for use or investigation.

3.5. Pharmaceutical form, dosage.

3.6. Daily dose and dosage regimen.

3.7. Method of administration.

3.8. Date and time of starting therapy.

3.9. Date and time of ending therapy or therapy duration.

3.10. Disclosure of blinding: yes/no/hasn't been used, results:

Assessment of casual relation given by investigator;

Assessment of casual relation given by clinical trial sponsor;

Specialists comments, if necessary (e.g., if clinical trial sponsor's assessment of relation to suspected unexpected serious adverse reaction does not correspond to investigator's assessment, a role played by concomitant medicinal products in reaction development directly or as a result of interaction may be suspected).

4. Concomitant treatment

For concomitant medicinal products (including OTC products) and non-medication therapy the same information shall be provided as that for investigational medicinal product, including data about manufacturer, if available.

5. Information about suspected unexpected serious adverse reaction

5.1. Full description of reaction.

5.2. Date and time of the reaction onset.

5.3. Date and time of end or duration of reaction.

5.4. Information about withdrawal or reintroduction of suspected medicinal product.

5.5. Place, where reaction developed (hospital, out-patient clinic, home).

5.6. Outcome: information about recovery or any sequela, any conducted specific tests and/or treatment and their results.

In case of death – reason and comments on possible causative relation with suspected investigational medicinal product shall be given.

5.7. Any information that can be useful for assessment of suspected unexpected serious adverse reaction (concomitant disease, history of allergy, alcohol dependence, etc.).

6. Information about investigator, who submitted the initial information

6.1. Full name

6.2. Trial site.

6.3. Telephone number.

6.4. Position.

7. Information about clinical trial sponsor/applicant and administrative data

7.1. Date of the given report.

7.2. Source of information:

7.3. Date of receiving the report by clinical trial sponsor/applicant.

7.4. Country, where reaction occurred.

7.5. Type of report (initial, additional).

7.6. Name of legal person/full name of natural person and location of legal person/address of natural person.

7.7. Full name, position, contact telephone and fax of contact person in charge of the information about adverse reaction.

7.8. Clinical trial sponsor's/applicant's identification number of unexpected serious adverse reaction (unique number for initial and follow-up reports about the same case).

*{Annex in wording of MoH Order № 523 of
12.07.2012}*