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|  | Annex 9  to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials |

# List of aspects of clinical trial which may be amended SUBSTANTIALLY by sponsor

**1. Amendments related to clinical trial protocol:**

Purpose of trial;

Trial design;

Code number and version of CT protocol;

Informed consent;

Recruitment procedure;

Efficacy indices;

Schedule of sampling for laboratory tests;

Addition or exclusion of tests or indices;

Subjects age range;

Inclusion criteria;

Exclusion criteria;

Safety control;

Duration of effect of investigational medicinal product(s);

Correction of dosage of investigational medicinal product(s);

Change of comparator;

Statistical analysis.

**2. Amendments related to organization of clinical trial:**

Change of principal investigator or involving new principal investigator/clinical trial site;

Change in the number of trial subjects in Ukraine;

Change of coordinating investigator;

Change of sponsor or official representative of the sponsor;

Change of contract research organization responsible for important tasks within the clinical trial;

Change of specification related to the end of clinical trial.

**3. Amendments related to investigational medicinal product:**

Change in quality data of investigational medicinal product related to:

Change in the name or code of investigational medicinal product;

Primary packaging material\*;

Manufacturer(s) of active substance\*;

Manufacturing process of active substance\*;

Specification of active substance\*;

Manufacture of medicinal product\*;

Specification of medicinal product\*;

Specification of excipients when the effect of medicinal product may be influenced\*;

Shelf-life, including storage after first opening and dilution\*;

Essential changes in composition of investigational medicinal product\*;

Storage conditions\*;

Methods of investigation of active substance\*;

Methods of investigation of medicinal product\*;

Methods of investigation of non-pharmacopoeial excipients\*;

Changes in labelling of investigational medicinal product\*.

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\* Appropriate amendments shall be submitted only to the State Expert Center MoH Ukraine

**4. Amendments to pre-clinical, pharmacological, toxicological study data related to current clinical trials (i.e., change in assessment of risk/benefit ratio).** For example:

Results of new pharmacological studies;

New interpretation of present pharmacological studies;

Results of new toxicological studies;

New interpretation of present toxicological studies;

Results of new investigations of drug interactions.

**5. Amendments to clinical trial, data on experience of use of medicinal product in humans, which are important to current clinical trials (i.e. change in assessment of risk/benefit ratio)**

For example, related to:

Safety of clinical trial or experience of using investigational medicinal product;

Results of new clinical/pharmacological studies;

New interpretation of present clinical/pharmacological studies;

New data on experience of using investigational medicinal product;

New interpretation of present data on experience of using investigational medicinal product.

{Annex in wording of MoH Ukraine Order [№ 523 as of 12.07.2012](http://zakon4.rada.gov.ua/laws/show/z1235-12/paran388#n388)}