

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 CLINICAL TRIAL 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;
Trial 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 clinical trial sponsor or official representative of the clinical trial 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*.

* 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 Order № 523 of
12.07.2012}*