

FORMAT OF FINAL CLINICAL TRIAL REPORT

Structure of final clinical trial report is unified; it can be used for description of clinical trial of any therapeutic, prophylactic and diagnostic agent conducted in trial subjects, in which the clinical and statistical description, data analysis is presented in a single report, incorporating tables and figures into the main text of the report or at its end. In addition, annexes contain data about trial subjects and detailed statistical information. The basic principles and structure of the report can be applied to different kinds of clinical trials (e.g., clinical pharmacology trials). The following items are to be included in the report.

1. Title page shall contain:

Report title; name of investigational medicinal product; clinical trial identification; brief design description, comparison, duration of clinical trial, dosing of medicinal product and trial subject population (if not indicated in the title); clinical trial sponsor's name; clinical trial protocol identification; type/phase of clinical trial; clinical trial start date, clinical trial end date; statement of compliance with GCP (if applicable); date of report. Name of principal or coordinating investigator or representative of the clinical trial sponsor.

2. Summary (brief description of clinical trial with numeric data to show results).

3. Table of contents (including list and location of annexes and tables of CRF)

4. List of abbreviations and definition of terms.

5. Ethic issues.

6. Investigators and clinical trial administrative organization (name, address, contact telephone number).

7. Introduction.

8. Purpose of trial.

9. Investigational plan.

9.1. Overall study plan (design) and clinical trial description plan; a schematic diagram of clinical trial stages and procedures.

9.2. Validation of clinical trial plan (design) including choice of control groups.

9.3. Selection of study population:

Inclusion criteria;

Exclusion criteria;

Exclusion of patients from trial or analysis.

9.4. Treatment:

Treatment prescribed;

Identity of investigational medicinal products;

Methods of assigning trial subject to groups (randomization);

Selection of doses for study;

Selection and timing of doses of medicinal product for each study patient;

“blinding” (if used);

Previous and concomitant therapy;

Compliance of treatment regimen by trial subject.

9.5. Efficacy and safety information (assessment and schedule for efficacy and safety characterization).

9.6. Data of quality assurance (document conforming the audit conducted, if applicable).

9.7. Statistical methods specified in the clinical trial protocol.

9.8. Changes in the planned conduct of the clinical trial or analyses.

10. Information about trial subjects.

10.1. Distribution of trial subjects.

10.2. Deviations from clinical trial protocol.

11. Efficacy evaluation.

11.1. Data sets analyzed.

11.2. Demographic and/or other baseline characteristics.

11.3. Characteristics of compliance of treatment regimen by trial subject.

11.4. Efficacy results and tabulations of individual patient data:

Analysis of efficacy;

Statistical/analytical issues;

Tabulation of individual response data of trial subjects to treatment;

Medicinal product dose, medicinal product concentration and their relationship to patient response to medicinal product;

Drug-drug, drug-disease interactions (if studied);

Efficacy conclusions.

12. Safety evaluation.

12.1. Adverse events:

Brief summary of adverse events;

Information about adverse events;

Analysis of adverse events;

Listing of adverse events in each patient.

12.2. Death.

12.3. Other serious adverse events as well as serious adverse reactions.

12.4. Evaluation of clinical laboratory characteristics:

Listing of individual laboratory values by patients and each abnormal laboratory value;

Evaluation of each laboratory value;

Laboratory values over the course of study;

Changes in individual patient values;

Individual clinically significant abnormalities.

12.5. Parameters of organism's essential functions, data of objective study and other safety-related observations.

12.6. Conclusions regarding safety.

13. Discussions and overall conclusions.

14. Tables, figures and graphs referenced to but not included in the text.

14.1. Demographic data (summary figures and tables).

14.2. Efficacy data (summary figures and tables).

14.3. Safety data (summary figures and tables):

Data on adverse events;

Listing of serious adverse events;

Description of serious adverse events;

Abnormal laboratory value listing (each trial subject).

15. Reference list.

16. Annexes.

16.1. Clinical trial information:

Clinical trial protocol and clinical trial protocol amendments;

Template of case report form;

Ethics-related pages and ethics committee's at HCS approval, written information for patients and informed consent;

List and description of investigators and other responsible officers;

Signatures of clinical trial principal investigator or coordinating investigator;

Analytical documentation – certificates of analysis for batch of investigational medicinal product;

Randomization scheme and codes (trial subject identification and treatment assigned);

Document conforming the audit conducted (if applicable);

Documentation of statistical methods;

Documents of laboratory standardization of methods and assurance of the quality of procedures, if available;

Publications based on clinical trial;

Important publications referenced in report.

16.2. Trial subject data listings:

Dropped out trial subjects;

Clinical trial protocol deviations;

Trial subjects excluded from the efficacy analysis;

Demographic data;

Compliance with treatment regimen and/or data on concentration of medicinal product (if available);

Individual efficacy response data;

Adverse events listing (for each trial subject);

Listing of individual laboratory values by trial subjects (if necessary)

16.3. Case report forms:

Case report forms of death, other serious adverse events and cases of exclusion from investigation due to development of serious adverse events;

Other case report forms submitted to the State Expert Center MoH Ukraine for review.

16.4. Listing of each trial subject data.

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