

INFORMATION on completing the clinical trial (CT) report

The CT report shall be completed by the applicant (holder of registration certificate) in the Ukrainian based on the information provided in registration dossier.

If multiple clinical trial results are required, a special CT report shall be completed for each clinical trial and a sequential number shall be provided for each CT report.

The dates in the CT report shall be stated in the following order: date, month, year.

Item 1 shall indicate the name of medicinal product for which the clinical trial report has been submitted (registration certificate №, if available). The name of the medicinal product shall correspond to the name in registration certificate.

Item 2 shall indicate the applicant/holder of registration certificate.

Item 3 shall indicate the manufacturer of medicinal product.

Item 4 shall indicate whether the clinical trials have been conducted. If no, please indicate, why CT has not been conducted. Subitem 1 shall specify the type of medicinal product according to which the registration has been conducted or is planned.

Item 5 shall specify the full title of clinical trial and the coded number of clinical trial protocol assigned by the sponsor, latest version and date.

Item 6 shall indicate the phase of clinical trial - I, II, III, IV (for generic medicinal products - bioequivalence study or comparative clinical trial).

Item 7 shall specify the period during which the clinical trial has been conducted.

Item 8 shall indicate all countries where this clinical trial has been conducted.

Item 9 shall indicate the total number of trial subjects that the sponsor planned to bring to the clinical trial in accordance with the protocol and the actual total number of trial subjects.

Item 10 shall set out the main objective and secondary endpoints of the study.

Item 11 shall specify the design of clinical trial (e.g., a randomized placebo-controlled double-blind trial). Examples of trial design also include parallel, crossover, factorial, etc.

In item 12, the patient population and their inclusion criteria shall be indicated - characteristics that potential subjects must have in order to be included in clinical trials (age range, sex, underlying and concomitant diseases, etc.).

Item 13 shall indicate the name of investigational medicinal product, route of administration and strength. If there was no trade name at the time of clinical trial, the code assigned by the sponsor, which was used to identify the investigational medicinal product in the clinical trial documentation, should be indicated. The international non-proprietary name or the proposed international non-proprietary name should be specified, if it was at the time of the clinical trial.

Item 14 shall indicate the name of comparator, route of administration and strength. The international non-proprietary name of the comparator shall be mentioned as well. If placebo was used, this should be noted.

Item 15 should list the medicinal products (pharmacotherapeutic group) that were allowed to be taken (in addition to the investigational medicinal product) while clinical trial.

Item 16 shall specify the criteria for evaluating efficacy of investigational medicinal product.

Item 17 shall indicate the criteria for evaluating safety of investigational medicinal product.

Item 18 shall list the statistical methods that have been used to evaluate the results of clinical trial.

Item 19 shall set out the main demographic indicators of the population studied, including sex, age, race, etc.

In item 20, the applicant shall provide the results of efficacy analysis, showing the difference in the effect size of products together with the appropriate confidence intervals, as well as the results of hypothesis test, if any. It is important to summarize the main conclusions about the efficacy of investigational medicinal product, considering the primary and secondary endpoints.

Item 21 shall require the applicant to provide an overall safety assessment of investigational medicinal product with particular attention to the serious adverse reactions that have led to death or withdrawal of therapy with investigational medicinal product.

In item 22 the overall study results shall be specified and the benefit-risk ratio shall be concisely described. The conclusion shall not be a simple repetition of results description, it shall not indicate new data. In conclusion, all new or unexpected events shall be clearly specified, their severity commented, and

any potential problems discussed. Clinical consistency and significance of results shall be discussed in light of other available data. Each specific benefit or specific warning that shall be considered for individual patients or risk groups, as well as any conclusions that are relevant for future study, shall be noted.