CInMED
Institute for Medicines and Medical Devices of Montenegro

DOCUMENTATION REQUIRED FOR APPROVAL OF A CLINICAL TRIAL

The documentation for approval of a clinical trial contains:

1. cover letter from the applicant;
2. completed application form for approval of a clinical trial;
3. Protocol of a clinical trial (hereinafter: Protocol);
4. summary of the Protocol;
5. positive opinion of the Ethics Committee or a statement that identical documentation is submitted to the Ethics Committee as well;
6. Brochure for the investigator;
7. Investigational medicinal Product Dossier (IMPD), in case that a medicine has not been granted a marketing authorisation;
8. Summary of Product Characteristics for a medicine that has been granted a marketing authorisation;
9. written statement of a professional collegium, director or other authorised person in authorised institution in which a clinical trial shall be conducted, giving consent to the appointment of the principal investigator and investigating team, to the use of premises, staff and equipment during the course of a clinical trial, and providing the principal investigator with the conditions to conduct a clinical trial and undisturbed smooth operation of the auditor, monitor and inspector of Good Clinical Practice in a clinical trial;
10. signed statement by the principal investigator that he/she is familiar with the properties of an investigational medicine and with the objective of the trial, and that the trial shall be conducted in accordance with the Protocol and applicable regulations and Guidelines of Good Clinical Practice;
11. brief biography and references of the principal investigator;
12. valid Good Manufacturing Practice certificate (GMP certificate) of an investigational medicine;
13. valid GMP certificate for the site of manufacture of biologically active substance, or a statement of a person qualified for batch release confirming that the biologically active substance is manufactured in accordance with GMP;
14. proof of insurance of the subject against possible hazardous consequences of a clinical trial;
15. informed consent form, other written information for the subject, as well as the original text, if a translation is in question;
16. report on known adverse reactions to the investigational medicine, if any, if it is not part of the Investigator's brochure;
17. list of countries in which the medicine has been granted a marketing authorization, if available;
18. list of countries in which the same clinical trial has been approved, i.e. approvals of authorised bodies;
19. list of centers in which the same clinical trial is conducted, if a multicenter clinical trial is in question;

20. list of submitted documentation, indicating versions and dates;
21. sample of the test list/CRF;
22. TSE certificate confirming that the material of animal or human origin used in the manufacture of a medicine does not pose a risk for transmissible spongiform encephalopathy, if required;
23. verified copy of the contract on transfer of authorisation from the sponsor of the clinical trial to the applicant, if they differ;
24. proof that prescribed fees have been paid to the Institute;
25. additional information relating to health protection of the subject, at the request of the Institute;
26. additional requirements for medicines for advanced therapy.

The documentation shall be submitted both in electronic and written form.

Original documents must be submitted, or their copies verified by a notary from Montenegro or from other country having a notary service, or, in case of countries with no such service, by local authorities (for example, by court, or municipal authority).

An application with documentation for approval of a clinical trial shall be submitted in language which is in official use in Montenegro. Notwithstanding, documentation referred to in items 3, 6, 7, 12, 13, 16, 21, 22 and 26 of this Article may be submitted in English.

The form for approval of a clinical trial, referred to in item 2, is published on the website of the Institute in the section Legislation/Templates.