LIST OF DOCUMENTS REQUIRED FOR CLINICAL TRIALS AUTHORIZATION

1. Application for clinical trial authorization, with description of the type of clinical trial, the investigational medicinal product, and information on the attached documents.
2. Application for compassionate use authorization, with a description of the disease, the investigational medicinal product being used, and information on the attached documents.
3. A package of documents (Investigational medicinal product dossier (IMPD)) on the quality, safety and efficacy of investigational medicinal product(s) in a format adopted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), except for clinical trials conducted during the post-registration use of the medicinal product in Armenia. The application for the investigational medicinal product used for compassionate treatment should include a Good Manufacturing Practices (GMP) compliance certificate for the manufacturing site(s), and any other documents specified in this section, if available.
4. A color sample of label(s) attached to investigational product container(s).
5. Data on the authorization of the clinical trial or compassionate treatment by the competent authorities of other countries (if available).
6. Study protocol of the clinical trial or compassionate treatment in Armenian (the original version should be attached, if translated).
7. Case Report Form (CRF).
8. Description of the investigational medicinal product for the investigator (Investigator's Brochure) or the summary of product characteristics of the registered medicinal product in Armenian (the original version should be attached, if translated).
9. Informed Consent Form in Armenian (the original version should be attached, if translated).
10. Additional information provided to the subject in Armenian (if available).

11. Information regarding the investigator(s) (Curriculum Vitae) in Armenian, including details about their professional education and work experience.
12. Information regarding the medical or veterinary institution(s) involved in the clinical trial (compassionate treatment), including the name, license number, and a copy of the license should be provided.
13. Draft agreement between the Sponsor and/or Contract Research Organization(s) and the investigator medical or veterinary institution(s) involved in the clinical trial.
14. Copy of the document confirming the subject's insurance (with a minimum insurance coverage of 500 000 AMD), except for clinical trials conducted during the post-registration use of the medicinal product.
15. Document confirming the payment of the state duty for the assessment of clinical trial documents.
16. Agreement to conduct inspections to assess compliance with the rules of Good Clinical Practice after the termination or completion of clinical trials.
17. Description of the actions (advertisements or other activities) taken to recruit subjects to participate in the trial.
18. Information of payments or compensation to subjects (if any).