MINISTRY OF HEALTH

No: 29/2018/TT-BYT

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

Hanoi, October 29, 2018

CIRCULARS

REGULATIONS ON CLINICAL TRIAL DRUGS

Pursuant to Law No. 105/2016/QH13 dated April 6, 2016 on pharmacy;

Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the proposal of the Director of the Department of Science, Technology and Training, Ministry of Health; The Minister of Health promulgates a Circular on clinical trial of drugs.

Chapter I

GENERAL RULES

Article 1. Scope

1. This Circular stipulates the promulgation and application of Good Clinical Practice; assess the response to Good Clinical Practice and clinical trial records and procedures.

2. Clinical trial activities related to medical examination and treatment, apart from complying with the provisions of this Circular, must also comply with the provisions of the law on medical examination and treatment.

Article 2. Subjects of application

This Circular applies to:

1. Clinical trial drug establishment, including:

a) A clinical trial service business establishment is an establishment that has been granted a certificate of eligibility for pharmacy business with the scope of clinical trial.

b) Establishment providing bioequivalence testing service of drugs is an establishment that has been granted a certificate of eligibility for pharmacy business with the scope of bioequivalence testing of drugs.

c) Establishments not subject to issuance of certificates of eligibility for pharmacy business specified in Clause 1, Article 35 of the Law on Pharmacy are medical examination and treatment establishments or scientific research establishments that conduct clinical trials of drugs. clinical trials, bioequivalence testing of drugs and other establishments engaged in clinical trials and bioequivalence testing of drugs for non-commercial purposes.

2. Agencies, organizations and individuals involved in clinical drug trial activities.

Article 3. Interpretation of terms

1. ***Clinical trial*** means a scientific activity of researching drugs on volunteers in order to explore or determine the safety and effectiveness of drugs; recognize and detect adverse reactions due to the effects of drugs; absorption, distribution, metabolism and elimination of drugs.

2. ***Good Clinical Practice (GCP)*** is a set of principles and standards for the design, organization, implementation, monitoring, inspection, recording, analysis and reporting. clinical trial reports in order to ensure the reliability and accuracy of data and report research results, protect the rights, safety and confidentiality of research subjects' information.

3. ***International regulations on clinical drug trials recognized by the Ministry of Health*** as Guidelines for good practice in clinical drug testing are specified in the General Guidelines of the International Conference on Harmonization of Technical Requirements. for the registration of pharmaceutical products for human use (International Conference on I Iamonization of Technical Requiments for Registration of Pharmaceuticals for Human use (ICH), World Health Organization Good Practice Guidelines for Clinical Trials) Organization - WHO) and the guidelines on clinical trial of the reference management agencies specified in Clause 5 of this Article.

4. ***Product profile for researchers*** (Investigator's Brochure - IB) is a document containing information and data on preclinical research and clinical trials of research drugs.

5. ***Reference*** regulatory agencies specified in this Circular include: European Medicines Agency (EMA), USA, Japan, France, Germany, Sweden, UK, Switzerland, Australia, Canada, Belgium, Austria, Ireland, Denmark and the Netherlands.

6. ***Research Information Collection Form or*** Case Report Form (CRF) is a paper or electronic tool designed to collect research data of participants in clinical trials.

chapter II

Issuance and application of good practice in clinical trials

Article 4. Principles and standards of Good clinical practice for drug testing

1. To promulgate principles and standards of Good clinical practice in clinical trial in Appendix I to this Circular and updated documents specified in Clause 2 of this Article on the basis of reference to the guidance of ICH, WHO and the reference management agencies specified in Clause 5, Article 3 of this Circular.

2. In case ICH and WHO amend and supplement GCP principles and standards (updated documents), the Department of Science, Technology and Training shall update and publish the updated documents on the Ministry's web portal. Health and the website of the Department of Science, Technology and Training for relevant subjects to look up, update and apply.

Article 5. Subjects of application of principles and standards of Good clinical practice in drug testing

1. Clinical trial facilities apply and satisfy GCPs specified in Appendix I issued with this Circular and updated documents.

2. In case a business providing bioequivalence testing services of drugs and establishments conducting bioequivalence testing activities of drugs for non-commercial purposes fails to satisfy the GCP for the clinical research stage. Clinical trials must sign a contract or joint document with a GCP-compliant clinical trial facility specified in Appendix I issued together with this Circular and updated documents to carry out clinical research. .

3. Clinical drug trial establishments shall apply updated GCP documents as prescribed in Clause 2, Article 4 of this Circular within 12 months if there is a request for change in facilities serving the trial. medicine or 06 months for other updates, counting from the time the updated document is published by the Department of Science, Technology and Training on the website of the Ministry of Health and the website of the Department of Public Science. Technology and Training.

Chapter III

GENERAL PROVISIONS ON ASSESSMENT OF CLINICAL TRIAL GOOD PRACTICE

Article 6. Cases of assessment, inspection and examination of compliance with Good Practice in Clinical Drug Trial

1. The initial drug assessment shall be carried out together with the grant of a certificate of eligibility for pharmacy business to a clinical trial service provider and a drug bioequivalence testing service provider (after this is referred to as a drug trial service business establishment). For a clinical trial drug establishment specified at Point c, Clause 1, Article 2 of this Circular, the initial assessment shall be carried out when the facility has carried out clinical trial activities.

2. Periodic assessment of maintenance of GCP satisfaction shall be carried out every 3 years from the date of signing the audit minutes of the previous audit (excluding unexpected audits, inspections and inspections of Ministry of Health, Department of Health).

3. Unscheduled assessment of GCP compliance shall comply with the provisions of Clause 1, Article 15 of this Circular.

4. Inspection and examination of the maintenance of GCP compliance of clinical trial drug establishments shall comply with the provisions of the law on inspection and examination.

Article 7. Compliance with Good clinical practice

The assessment of GCP compliance of a clinical trial facility follows three levels:

1. Level 1: A clinical trial facility that meets GCP in case there is no content to be remedied or corrected.

2. Level 2: A clinical trial facility still has contents that must be corrected or corrected to meet GCP in case the content to be corrected or corrected does not affect research quality and safety. health of drug trial participants.

3. Level 3: A clinical trial facility fails to meet GCP in the following cases:

a) There is content that is inconsistent with GCP standards, which may affect the quality of research and/or the health and safety of drug trial participants;

b) Fraud, forgery, modification of data, data and documents.

Chapter IV

FIRST ASSESSMENT OF CLINICAL TRIAL GOOD PRACTICE Response

Article 8. Dossier of request for initial assessment of compliance with Good Clinical Practice

1. Dossier as a basis for assessing GCP satisfaction for a drug trial service provider is an application for a certificate of eligibility for pharmacy business (to be submitted when applying for a certificate of eligibility for pharmacy business). For pharmaceutical business conditions, drug trial service providers are not required to submit this additional application) as prescribed in Article 38 of the Law on Pharmacy and Article 32 of Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government detailing a number of articles and measures to implement the Law on Pharmacy (hereinafter referred to as Decree No. 54/2017/ND-CP). In case a drug trial service provider is subject to special control, it shall comply with the provisions of Article 38 of the Law on Pharmacy and Article 49 of Decree No. 54/2017/ND-CP;

Technical documents on drug testing service providers as prescribed in Article 38 of the Law on Pharmacy and Article 32 of Decree No. 54/2017/ND CP are presented in accordance with the instructions on the overall profile specified in Appendix II. Appendix II promulgated together with this Circular or the updated master file in case of additional operation scope, bearing the seal of the drug testing service provider.

In case a drug trial service business establishment applies for a GCP certificate together with a certificate of eligibility for pharmacy business, the drug testing service provider needs to clearly state this content in the application for a drug trial certificate. meet the conditions for pharmacy business.

2. Dossier as a basis for assessment of GCP response for clinical drug registration establishments specified at Point c, Clause 1, Article 2 of this Circular includes:

a) An application for assessment of GCP satisfaction, made according to Form No. 01 specified in Appendix III to this Circular. In case the establishment applies for a GCP certificate, this content must be clearly stated in the application;

b) Technical documents on the facility are presented according to the instructions on the master file specified in Appendix II to this Circular, bearing the seal of the owner.
basis.

Article 9. Order of receipt of dossiers for assessment of compliance with Good Clinical Practice

1. Receipt of dossiers:

a) Establishments providing clinical trial services and establishments conducting clinical trials for non-commercial purposes shall submit 01 set of documents as prescribed in Article 8 of this Circular, together with an assessment fee. according to the regulations of the Minister of Finance on the fee for evaluation of standards and conditions for clinical trial to the Department of Science, Technology and Training, the Ministry of Health;

b) Establishments providing bioequivalence testing services of drugs and establishments conducting bioequivalence testing of drugs for non-commercial purposes shall submit 1 set of dossiers as prescribed in Article 8 of this Circular. together with the appraisal fee as prescribed by the Minister of Finance on the fee for appraisal of standards and conditions for bioequivalence testing of drugs to the Drug Administration of Vietnam, the Ministry of Health. The Drug Administration of Vietnam shall act as the focal point to receive dossiers and coordinate with the Department of Science, Technology and Training in organizing the assessment of the response to good practice in clinical drug testing.

2. The order of receipt and appraisal of dossiers shall comply with the provisions of:

a) Clauses 2, 3, 4, 5 and 6, Article 50 of Decree No. 54/2017/ND-CP, applicable to clinical trial establishments of narcotic drugs, psychotropic drugs, precursor drugs and medicinal ingredients are narcotic active ingredients, psychotropic active ingredients, drug precursors, radioactive drugs; combination drugs containing narcotic active ingredients, combination drugs containing psychotropic active ingredients, and combination drugs containing precursors;

b) Clauses 2, 3, 4 and 5, Article 51 of Decree No. 54/2017/ND-CP, applicable to establishments conducting clinical trials of toxic drugs and toxic medicinal ingredients; drugs and active ingredients on the list of drugs and active ingredients on the list of substances banned from use in a number of industries and fields;

c) Clauses 2, 4 and 5, Article 33 of Decree No. 54/2017/ND-CP, for establishments that do not fall into the cases specified at Points a and b of this Clause.

3. Within 05 working days from the day on which the complete application is received, the Department of Science, Technology and Training or the Drug Administration of Vietnam (hereinafter referred to as the application-receiving agency) shall set up a team to assess the satisfaction of the application. respond to the GCP (hereinafter referred to as the Evaluation Team), notify in writing the clinical trial establishment of the Evaluation Team and the estimated actual time of the assessment at the facility.

Within 15 days from the date of the written notice, the assessment team shall conduct the actual assessment at the establishment according to the provisions of Article 10 of this Circular.

Article 10. Procedures for assessing the response to Good Practice in Clinical Drug Trial

1. Evaluation process:

a) Step 1. The audit team announces the decision to establish the audit team; purpose, content and plan of evaluation at clinical trial establishments;

b) Step 2. The clinical trial establishment briefly presents the organization, personnel, implementation and application of GCP or other issues according to the assessment content;

c) Step 3. The assessment team conducts a practical assessment of the application of GCP at the clinical trial facility according to each specific assessment content;

d) Step 4. The evaluation team meets with the clinical trial facility to inform the clinical trial facility's GCP compliance as prescribed in Article 7 of this Circular, the unsatisfactory contents , need to overcome, repair discovered during the assessment process (if any); discuss with the clinical trial facility in case the facility disagrees with the Delegation's assessment for each content.

dd) Step 5. Make and sign the assessment minutes:

The evaluation minutes are signed and certified by the leader of the clinical trial facility and the head of the evaluation team; The minutes must show the composition of the assessment team, location, time, scope of assessment, issues of disagreement (if any), between the evaluation team and the clinical trial facility related to the assessment. GCP compliance. The minutes are made in 03 copies: 01 copy is kept at the clinical trial facility, 02 copies are kept at the application-receiving agency.

2. GCP . compliance assessment report

a) Immediately after completing the actual assessment at the clinical drug trial establishment, the assessment team is responsible for making a report on assessment of GCP compliance according to Form No. 02 specified in Appendix III issued together with This Circular, listing and specifically analyzing unsatisfactory contents that clinical trial establishments need to overcome and correct (if any) compares them with corresponding provisions of legal documents, assess the GCP compliance of the clinical trial facility according to the provisions of Article 7 of this Circular;

b) In case the clinical trial establishment disagrees with the evaluation content, within 30 days from the date of signing the evaluation record, the clinical trial establishment shall give a written explanation. send to the application-receiving agency with evidence (documents, photos, videos, certificates) related to the assessment content;

c) Within 10 days from the date of receipt of the written explanation from the clinical trial facility, the application-receiving agency shall consider the GCP assessment report and the clinical trial establishment's explanation. , consult experts in the relevant field (if necessary) and reply in writing to the clinical trial facility. The written response must clearly state the content of approval or disapproval of the explanation of the clinical trial establishment. This time does not count towards the assessment period.

Article 11. Handling of response assessment results Good clinical trial practice

1. In case the report on assessment of GCP compliance concludes that the clinical trial facility meets the GCP as prescribed in Clause 1, Article 7 of this Circular:

Within 10 working days from the date of signing the evaluation minutes, the application-receiving agency shall submit to the Minister of Health for granting a certificate of eligibility for pharmacy business and issue a certificate of GCP achievement according to the Form No. No. 03 specified in Appendix III to this Circular if the establishment has made a request in the application for a certificate of eligibility for pharmacy business. If the facility does not apply for a GCP certificate, the GCP compliance assessment report that concludes that the clinical trial facility meets the GCP is valid for certifying that the clinical trial facility meets the GCP and is used in the clinical trial. be used as a basis for submitting to the Minister of Health for a certificate of eligibility for pharmacy business or as a basis for conducting clinical trial activities for clinical drug trial establishments specified at Point c, Clause 1 of this Article. 1 Article 2 of this Circular.

In case a clinical trial facility conducts drug trials and trades drugs subject to special control, within 20 days from the date of completion of the actual assessment at the clinical trial establishment and sign the assessment record, if the establishment has a request in the application, the application-receiving agency shall issue a certificate of GCP achievement according to Form No. 03 specified in Appendix III issued together with this Circular (concurrently with the issuance of certificates of eligibility for pharmaceutical business).

2. In case the report on assessment of GCP satisfaction concludes that the clinical trial establishment needs to remedy or repair according to the provisions of Clause 2, Article 7 of this Circular:

a) Within 05 working days after finishing the actual assessment at the clinical trial facility and signing the evaluation minutes, the application-receiving agency shall send a report on assessment of GCP compliance. enclosed with a written notice of the contents that need to be corrected or corrected to the clinical trial drug establishment.

In case a clinical trial facility conducts drug testing and trades drugs subject to special control, within 15 days from the date of completion of the actual assessment at the clinical trial establishment and After signing the evaluation record, the application-receiving agency shall send a report on assessment of GCP compliance, enclosed with a written notice of the contents that need to be corrected or corrected, to the clinical trial facility.

b) After completing the remedy or repair, the clinical drug testing establishment must submit a written report with evidence (documents, photos, videos, certificates) proving that the drug has been completed. the correction and correction of the contents recorded in the evaluation report;

c) Within 20 days from the date of receiving the remedial and repair report from the clinical trial facility, the application-receiving agency shall consider the remedial report of the drug testing establishment and draw conclusions about it. Clinical trial facility's GCP response status:

- In case the clinical trial facility's remedial and repair work has met the requirements: The application-receiving agency shall comply with the provisions of Clause 1 of this Article.

- In case the clinical trial facility's remedial and repair work has not yet met the requirements: the application-receiving agency shall issue a written request to continue to remedy, correct or supplement until the requirements are met. .

d) Within 06 months from the date the application-receiving agency issues a written request for remedy or repair, the clinical drug trial establishment must submit a report on remedial and corrective action as required. After the above time limit, the clinical trial establishment does not correct or repair the drug or after 12 months,

From the date of first submission of the application, if the application for remedial work fails to meet the requirements, the submitted application is no longer valid.

3. In case the report on assessment of GCP satisfaction concludes that the clinical trial establishment does not meet the GCP according to the provisions of Clause 3, Article 7 of this Circular:

Within 5 working days after finishing the actual assessment at the clinical trial facility and signing the evaluation minutes, the application-receiving agency shall issue a written notice of non-compliance. The GCP is attached to the GCP Assessment Report for the clinical trial facility that does not issue a GCP certificate.

4. Within 05 working days from the date of issuance of the certificate of eligibility for pharmacy business or the certificate of GCP attainment, the application-receiving agency shall publish it on the website of the Ministry of Health and The website of the application-receiving agency contains the following information:

a) Name and address of a clinical trial facility that meets GCP;

b) Full name of person in charge of professional practice, number of practice certificate;

c) Number of business eligibility certificate and GCP certificate number (if any);

d) Expiration time of GCP response assessment and next periodic audit date;

d) Operational scope of the clinical trial facility.

Chapter V

ASSESSMENT OF CLINICAL TRIAL GOOD PRACTICE RESPONSIBILITY MAINTENANCE

Article 12. Periodic assessment of response to Good Clinical Trial Practice

1. Every November, the application-receiving agency publishes on the website's website of the dossier-receiving agency the plan to periodically evaluate the clinical trial facility's maintenance of GCP compliance during the clinical trial period. next year and send this plan to the clinical trial facilities named in the plan.

2. Based on the periodic assessment plan announced by the application-receiving agency, the clinical drug trial establishment shall submit a dossier of request for periodic assessment as prescribed in Clause 6 of this Article together with the appraisal fee according to the provisions of Clause 6 of this Article. regulations of the Minister of Finance on the application-receiving agency within at least 30 days, before the scheduled assessment time announced by the dossier-receiving agency.

3. In case a clinical trial facility fails to submit an application for periodic assessment by the time limit specified in Clause 2 of this Article within 15 days from the date the facility must submit the application, the receiving agency the dossier contains a written request to the establishment to submit the dossier as prescribed.

4. Within 45 days from the date the application-receiving agency issues a written request, the clinical drug trial establishment must submit a dossier enclosed with an explanation for the delay in submitting the dossier as prescribed.

5. After submitting the application for periodic assessment of the maintenance of GCP satisfaction within the prescribed time, the clinical drug testing establishment may continue to conduct clinical trial activities within the scope specified in the certificate. receive the eligibility for pharmacy business or the certificate of GCP achievement, for the clinical trial drug establishment specified at Point c, Clause 1, Article 2 of this Circular, from the date of submission of the dossier until the results of the quantitative assessment are available. period.

6. Dossier to request periodic assessment of the maintenance of GCP compliance includes:

a) An application form for periodical assessment of the maintenance of GCP compliance, made according to Form No. 04 specified in Appendix III to this Circular;

b) A summary report on the clinical trial activities of the clinical trial establishment within the last 3 years from the time of the preceding evaluation (excluding unexpected evaluations, , inspection by the Ministry of Health, Department of Health) to the date of request for periodic assessment;

c) Updated technical documents on physical, technical and personnel conditions of the clinical trial facility (if any);

7. The process and handling of GCP compliance assessment results shall comply with the provisions of Articles 9, 10 and 13 of this Circular.

Article 13. Processing results of periodical assessment of response to Good clinical practice

1. In case the GCP assessment report concludes that the clinical trial facility meets the GCP as prescribed in Clause 1, Article 7 of this Circular:

Within 10 days from the date of completion of the actual assessment at the clinical trial facility and signing the evaluation minutes, the application-receiving agency shall issue the GCP certificate according to Form No. 03. specified in Appendix III issued with this Circular if the establishment makes a request in the application; If the facility does not request a GCP certificate, the GCP compliance assessment report that concludes that the clinical trial facility meets the GCP is valid for certifying that the clinical trial facility meets the GCP and is used used as a basis for the clinical trial establishment to continue conducting clinical drug trial activities.

2. In case the GCP assessment report concludes that the clinical trial establishment needs to remedy or repair according to the provisions of Clause 2, Article 7 of this Circular:

a) Within 05 working days from the date of completion of the actual assessment at the clinical trial facility and signing the evaluation record, the application-receiving agency shall send a written request to the drug-testing establishment. clinically carry out remedial work, correct existing problems, and send remedial reports to the application-receiving agency;

b) Within 45 days from the day on which the application-receiving agency issues a written request, the clinical trial establishment must complete the remedial work and make corrections and send a written report enclosed with evidence. proof (documents, photos, videos, certificates) have completed the remedial work, the existing repair is recorded in the assessment report;

c) Within 20 days from the date of receipt of the report on remedial or repair, together with proofs (documents, photos, videos, certificates), the application-receiving agency shall: evaluate the remedial results of the clinical trial establishment and conclude on the GCP response status of the clinical trial establishment as follows:

- In case the clinical trial establishment's remedy has met the requirements: The application-receiving agency shall issue the GCP certificate according to Form No. 03 specified in Appendix III issued with this Circular. this private;

- In case the clinical trial facility's remedial work has not met the requirements: The application-receiving agency shall issue a written request for the content to be further corrected, corrected and submitted an additional report. The extension period to continue to remedy, repair and report is 45 days from the date of written request.

d) Within 90 days from the date of completion of the actual assessment, the clinical trial establishment does not report on remedial measures, or after remedying according to the provisions of Point c of this Clause, the remedial results are not reported. If the application continues to be unsatisfactory, the application-receiving agency shall issue a written notice of non-compliance with the GCP and, depending on the nature and seriousness of the violation, the application-receiving agency shall take one or more measures. as prescribed at Points a and b, Clause 3 of this Article.

3. In case the GCP assessment report concludes that the clinical trial establishment does not satisfy the GCP as prescribed in Clause 3, Article 7 of this Circular:

Within 05 working days from the date of completion of the assessment at the clinical trial facility and signing the evaluation minutes, on the basis of assessment of the detected existential risks to research quality, health and safety. health and safety of drug trial participants, the application-receiving agency shall issue a written notice of non-compliance with the GCP and, depending on the nature and severity of the violation, the application-receiving agency shall make a decision. or the following measures:

a) Sanction according to their competence (if any) or propose competent agencies to sanction administrative violations according to the provisions of law on handling of administrative violations;

b) Submit to the Minister of Health for issue a decision on revocation of the granted certificate of eligibility for pharmacy business and/or perform the revocation of the certificate of GCP attainment (if any) according to the provisions of Article 40 of the Law on Pharmacy. .

4. Within 05 working days from the date of conclusion that the clinical trial establishment is assessed to maintain compliance with GCP or from the date of issuance of the Decision on revocation of the granted certificate of eligibility for pharmacy business. Because the drug trial service provider fails to maintain GCP compliance, the application-receiving agency shall update the dossier-receiving agency's website on its GCP-satisfactory status according to the contents specified in Clause 1 of this Article. 4 Article 11 of this Circular for clinical drug testing establishments that satisfy GCP or information on the revocation of the certificate of eligibility for pharmacy business or the certificate of GCP attainment (if any) granted to the establishment drug testing service business does not maintain GCP compliance.

Article 14. Change control

1. In the interval between periodic evaluations, a clinical trial facility must carry out the procedures for applying for a certificate of eligibility for pharmacy business according to the provisions of Point b, Clause 1, Article 36 of the Law. Pharmacy or Dossier of application for assessment of GCP compliance or change report, made according to Form No. 05 specified in Appendix III issued with this Circular if it falls into one of the following cases:

a) The change falls into one of the cases specified at Point b, Clause 1, Article 36 of the Law on Pharmacy;

b) Change of drug testing location for clinical drug testing establishments specified at Point c, Clause 1, Article 2 of this Circular;

c) Changing the location of one of the technical rooms serving clinical drug testing (clinic, treatment, emergency room, laboratory, phase 1 clinical trial area) at the same business location. sales/trials;

d) Adding one of the technical rooms for clinical drug testing (clinic, treatment, emergency room, laboratory, phase 1 clinical trial area) at a new location at the same location. point of sale/drug testing;

dd) Expand one of the technical rooms for clinical drug testing (clinic, treatment, emergency room, laboratory, phase 1 clinical trial area) on the basis of the already established room structure. yes;

e) Repair or major structural change, arrange in one of the technical rooms for clinical drug testing (clinic, treatment, emergency room, laboratory, clinical trial area). state 1).

2. If there is a change in the drug testing service provider as prescribed at Point a, Clause 1 of this Article, the drug testing service provider must submit an application for the Certificate of eligibility for pharmacy business. according to the provisions of Clauses 2 and 4, Article 38 of the Law on Pharmacy.

The order of assessment of GCP compliance, classification of results and handling of GCP compliance assessment results comply with the provisions of Articles 9, 10 and 11 of this Circular.

3. In case a clinical trial drug establishment specified at Point c, Clause 1, Article 2 of this Circular changes according to the provisions of Point b, Clause 1 of this Article, the establishment must send a dossier of request for assessment of GCP satisfaction. as prescribed in Clause 2, Article 8 of this Circular.

The order of assessment of GCP compliance, classification of results and handling of GCP compliance assessment results comply with the provisions of Articles 9, 10 and 11 of this Circular.

4. In case a clinical drug trial establishment has changes in one of the cases specified at Points c and d, Clause 1 of this Article, the clinical trial establishment must submit a change report enclosed with technical documents. corresponding to the change in the agency receiving the dossier.

a) The application-receiving agency conducts the actual assessment at the clinical trial facility. If the clinical trial facility meets the requirements, the application-receiving agency shall in writing agree with the change of the clinical drug trial establishment;

b) The order of assessment, classification of results, and handling of evaluation results for clinical trial establishments that are changed according to the provisions of Point c, Clause 1 of this Article shall comply with the provisions of Article 9. , 10 and 13 of this Circular;

c) The order of assessment, classification of results and handling of evaluation results for clinical trial establishments that are changed according to the provisions of Point d, Clause 1 of this Article shall comply with the provisions of Article 9. , 10 and 11 of this Circular.

5. In case a clinical drug trial establishment experiences a change in one of the cases specified at Points dd and e, Clause 1 of this Article, the clinical trial establishment must submit a change report enclosed with technical documents. corresponding to the change in the agency receiving the dossier. The application-receiving agency shall evaluate the change report of the clinical trial establishment.

a) Within 10 days from the date of receipt of the written notice, the application-receiving agency shall issue a written notice of its agreement with the changed content in case the change meets the requirements;

b) Within 10 days from the day on which the written notice is received, the application-receiving agency shall issue a written notice of the contents to be corrected or corrected in case the requirements are not satisfied;

c) Within 45 days from the day on which the application-receiving agency issues a written notice, the clinical trial establishment must complete the remedy and repair and issue a written notice together with evidence proof (documents, photos, videos, certificates) have completed the remedial work, the existing repair mentioned in the written notice;

d) Within 10 days from the date of receipt of the remedial report together with evidencing evidence (documents, photos, videos, certificates), the dossier-receiving agency shall evaluate the remedial results. clinical trial establishment's recovery and conclusions on the clinical trial facility's GCP response status:

- In case the remedial work has met the requirements: The application-receiving agency shall issue a written notice of its agreement with the changed content;

- In case the remedial work has not met the requirements: The application-receiving agency shall conduct an unscheduled assessment and handle the evaluation results according to the provisions of Article 15 of this Circular.

Article 15. Unscheduled assessment of response to Good Clinical Trial Practice

1. At the request of the Ministry of Health and the Department of Health, based on the level of risk of effects of reagents on the health of drug trial participants, the level of GCP compliance specified in Article 7 of this Circular The application-receiving agency shall conduct an unscheduled assessment of the maintenance of GCP response at a clinical trial facility in one of the following cases:

a) The remedial clinical trial facility fails to meet the requirements specified at Point d, Clause 5, Article 14 of this Circular;

b) Clinical drug trial establishments complying with GCP at level 2 specified in Clause 2, Article 7 of this Circular must undergo a surprise assessment at least once within 3 years from the end of the periodical assessment. before;

c) A clinical trial drug establishment has the results of inspection and examination by competent authorities and concludes that there is a serious violation of GCP principles and standards;

d) There is information to report or recommend that the clinical trial facility seriously violates GCP principles and standards;

dd) The clinical trial facility fails to submit the application for assessment of the maintenance of GCP compliance as prescribed in Clause 4, Article 12 of this Circular.

2. The composition of the evaluation team is decided by the Director of the application-receiving agency according to the scope and purpose of conducting the assessment.

3. Dossier, order and process of ad hoc assessment at clinical drug trial establishments shall comply with the provisions of Clauses 6 and 7, Article 12 of this Circular.

Chapter VI

CLINICAL TRIAL GOOD PRACTICE ASSESSMENT TEAM

Article 16. Composition and criteria of members of the audit team

1. The Minister of Health shall decide to establish a GCP meeting assessment team. Its composition includes:

a) Representative 01 leader of the agency receiving the application as the Head of the Delegation;

b) 01 specialist from the receiving agency to act as the Secretary of the Union;

c) Representatives of units under the Ministry of Health (each unit may not have more than 01 member), including: Department of Medical Examination and Treatment; Legal services; National Council on Ethics in Biomedical Research; Drug Administration; Department of Science, Technology and Training; The Department of Management of Traditional Medicine and Pharmacy Long, in the case of establishments providing testing services for herbal drugs and traditional drugs;

d) 01 member is the representative of the Department of Health of the province or city directly under the Central Government (hereinafter referred to as the Department of Health) where the clinical drug trial establishment is headquartered, in case the facility is directly under the control of the Ministry of Health. Health service Dept;

d) Members of relevant agencies and units in case of necessity.

2. Officers participating in the assessment team must meet the following criteria:

a) Having a university degree or higher;

b) Have been trained on GCP, GCP assessment;

c) To be honest, objective and strictly abide by regulations and legal regulations during the assessment process, there is no conflict of interest with the assessed drug testing service business as prescribed in Clause 3 of Article 3 of this Law. this;

d) The team leader must have a university degree in medicine, pharmacy or higher and have experience in clinical trial management for at least 5 years.

3. Principle of assessment of conflict of interest: A member of the Evaluation Team is considered to have a conflict of interest with the assessed clinical trial facility if falling into one of the following cases:

a) Having worked within the last 5 years for an evaluated clinical trial facility;

b) Participated in consulting activities within the last 5 years for the clinical trial establishment to be evaluated;

c) Having a financial interest in the evaluated clinical trial facility;

d) Having a spouse, child, father or mother, siblings of father or mother or spouse or child working for an evaluated clinical trial facility.

Article 17. Responsibilities and powers of the assessment team

1. Responsibilities of the Evaluation Team:

a) Evaluate the entire operation of the clinical trial facility according to the corresponding GCP in Article 4 of this Circular, updated GCP documents (if any) and relevant professional and technical regulations; specifically record the contents of the assessment, detect any problems, make an assessment report and minutes;

b) Prepare or explain the report on GCP assessment results in case the clinical trial establishment disagrees with the content of the report;

c) Confidentiality of all information related to the evaluation and all information related to the clinical trial activities of the clinical trial establishment; except for the case with the consent of the establishment or at the request of a competent State agency to serve the inspection, examination and investigation.

2. Powers of the Evaluation Team:

a) Inspect the entire area related to clinical drug testing activities of the clinical trial facility;

b) Request for the provision of documents related to the clinical trial activities of the clinical trial establishment;

c) Collect documents and evidence (copy documents, take photos, record videos) to prove existence detected during the assessment process;

d) Make a record and request the clinical trial establishment to suspend its clinical trial activities if during the assessment the team detects that the clinical trial establishment commits a violation that seriously affects the safety of the drug. , health of participants in clinical trials or the accuracy and truthfulness of research data and reports to authorized persons for handling according to regulations.

Chapter VII

DOCUMENTATION, PROCEDURES FOR Clinical Trial of Drugs

Article 18. Clinical trial of drugs

Clinical trial of drugs includes stages and procedures as prescribed in Articles 86 and 95 of the Law on Pharmacy and is specified as follows:

1. Registering for clinical trial drug research;

2. Approval of clinical drug research includes initial approval and approval of changes in the course of clinical trial when the clinical trial establishment changes the drug trial protocol above. clinical trial or research information supply and volunteer research form of participants in clinical trials;

3. Organize clinical trials of drugs;

4. Approve clinical trial results.

Article 19. Dossier of clinical trial of drugs

A clinical trial drug application file includes a clinical trial drug registration application file; Dossier of application for approval of clinical trial drug research; Dossier of application for approval of changes to clinical trial drug research; Dossier of application for approval of clinical trial results shall be specified as follows:

1. An application for registration of a clinical trial of a drug includes:

a) An application form for clinical trial drug research, made according to Form No. 06 specified in Appendix III issued with this Circular;

b) Research product information profile (general information about clinical reagents: name, composition, indications, physical, chemical, pharmaceutical properties and other relevant information); preclinical research papers; research documents on clinical trials in previous stages) in Vietnamese or in English together with a summary in Vietnamese.

2. An application for approval of a clinical trial drug study includes:

a) An application form for approval of clinical drug research, made according to Form No. 07 specified in Appendix III issued with this Circular;

b) A dossier of information on a clinical trial drug includes:

- Research documents on drugs: ingredients, formula, production process, quality standards, drug test sheet (for chemical drugs, herbal drugs, traditional drugs: test report of the testing establishment: State-owned drugs that meet GLP or a GLP-compliant drug and drug ingredient testing service business within the scope of implementation or of a manufacturer that meets the Good Manufacturing Practice (GMP) standard. ; for vaccines: the quality control report issued by the national inspection agency or the ex-factory certificate for batches of vaccines and biological products);

-Preclinical research documents of the drug to be tested: research reports on pharmacological effects, toxicity, safety, recommendations on dosage, route of administration, usage;

- Research documents on clinical trial of the drug in previous stages (if the clinical trial is proposed at the next stage and the drug is not eligible for exemption from testing in the previous stages).

c) Legal dossiers of clinical trial drugs include:

- A copy of the written approval for registration of clinical drug research from the Department of Science, Technology and Training, Ministry of Health.

- A certified copy or a copy with the seal of the establishment that presents the original for comparison of the written request for phase 4 clinical trial of the competent pharmacy authority for the drug to be tested. clinical stage 4;

- The instruction sheet has been licensed for circulation for the drugs proposed for phase 4 clinical trial;

- A certified true copy or a copy stamped by the establishment that presents the original for comparison of the certificate of eligibility for pharmacy business of the drug trial service provider;

- Written confirmation of participation of research organizations for multi-center research in Vietnam;

- A certified copy or a copy with the seal of the establishment presenting the original for comparison, the written consent for participation in the research of the People's Committee of the province or city directly under the Central Government for actual research. geography;

- A cooperation contract in clinical drug research between agencies, organizations and individuals that have reagents and a clinical trial service provider; a cooperation contract between an organization or individual having reagents and a research support organization (if any).

d) The clinical trial research outline and the explanation include:

- An explanation of the clinical trial research protocol using the Form No. 08 specified in Appendix III to this Circular;

- Research information collection form or Research medical record (Case Report Form - CRF);

dd) Scientific curriculum vitae and a copy of the certificate of completion of the Good Clinical Practice course of the main investigator issued by the Ministry of Health.
Medical or issued by establishments with GCP training functions;

e) A copy of research information supply and volunteer research form of participants in clinical trials, made according to Form No. 09 specified in Appendix III issued together with this Circular;

g) Minutes of evaluation on science and ethics in research by the Ethics Council in biomedical research at grassroots level;

h) Research drug labels according to Circular No. 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health on regulations on labeling of drugs, medicinal ingredients and instructions for drug use.

3. Dossier to request approval for change of clinical trial drug research includes:

a) An application form for approval of changes to clinical drug research, made according to Form No. 10 specified in Appendix III to this Circular;

b) Updated versions of the respective documents specified in Clause 2 of this Article have been changed;

c) Minutes of appraisal of the Ethics Committee in biomedical research at grassroots level for changes in clinical drug research that have a significant impact on the health and interests of drug trial participants or affect research design, processes, and procedures
assist.

4. An application for approval of clinical trial results includes:

a) An application form for approval of clinical trial results, made according to Form No. 11 specified in Appendix III to this Circular;

b) A copy of the approved research protocol;

c) A copy of the decision approving the approved research protocol;

d) Minutes of evaluation of clinical trial results of the ethics committee in biomedical research at grassroots level;

dd) A report on the full text of the clinical trial research results using the Form No. 12 specified in Appendix III to this Circular.

Article 20. Requirements on language, form and legality of documents

1. Language of profile:

Dossiers of clinical trial must be written in Vietnamese or English. In case the document cannot be expressed in Vietnamese or English, a notarized translation of that document into Vietnamese or English is required (including the content of consular certification and legalization).

2. Application form:

The clinical trial drug file must be prepared on A4 size paper, firmly bound, with a table of contents, documents arranged in the correct order of the table of contents, with separation and instructions between sections, sections. Separators must be numbered for easy reference.

3. Legality of the dossier:

a) The registration application form and the contents of the registration dossier must be registered and stamped by the legal representative or lawfully authorized person of the registration organization;

b) Papers issued by foreign management agencies must be consularly legalized in accordance with the law on consular legalization, except for cases exempted by law.

Article 21. Procedures and order for registration of clinical drug research studies

1. Organizations and individuals that have drugs for clinical trial shall send, directly or by post, 01 set of registration dossiers for clinical drug research to the Department of Science, Technology and Training, the Ministry of Health.

2. The Department of Science, Technology and Training, the Ministry of Health shall check the validity of the application within 05 working days from the date of receipt of the application. In case the dossier is invalid, there must be a written notice and specific instructions for the organization or individual to supplement until the dossier is valid.

3. Organizations and individuals having clinical reagents are responsible for coordinating with the Department of Science, Technology and Training, the Ministry of Health to complete the dossier within a maximum of 60 days from the date of receipt of the written notification. newspaper. Past this time limit, the submitted application is no longer valid.

4. Within 05 working days from the date of receipt of a complete and valid application, the Director of the Department of Science, Technology and Training shall issue a written approval for clinical drug research using the Form No. 13 specified in the Appendix. III promulgated together with this Circular. In case of disapproval, a written reply must be given clearly stating the reason.

Article 22. Procedures and order for approving clinical drug research studies

1. A clinical drug trial establishment shall send 01 set of application dossiers for approval of clinical drug research directly or by post to the Department of Science, Technology and Training, the Ministry of Health.

2. The Department of Science, Technology and Training, the Ministry of Health shall check the validity of the application within 05 working days from the date of receipt of the application. In case the dossier is invalid, there must be a written notice and specific instructions for the establishment to supplement the dossier until the dossier is valid.

The clinical trial facility is responsible for coordinating with the Department of Science, Technology and Training, the Ministry of Health to complete the dossier within a maximum of 60 days from the date of receipt of the written notice. Past this time limit, the research approval procedure must start from the beginning.

3. Within 25 days from the date of receipt of complete and valid dossiers, the Ministry of Health shall hold a meeting of the National Ethics Council in Biomedical Research (hereinafter referred to as the National Ethics Council) and there is a record of evaluation of the clinical trial protocol.

4. Within 05 working days from the date of receipt of the appraisal minutes from the National Ethical Council, the Department of Science, Technology and Training synthesizes, completes the dossier and submits it to the Minister of Health for approval decision. approve the clinical drug research protocol if the clinical trial protocol meets the requirements. In case the research proposal is not approved or needs correction, the Department of Science, Technology and Training shall notify in writing the institution and clearly state the reason.

5. In case the clinical drug research outline needs to be corrected, the clinical trial establishment is responsible for coordinating with the Department of Science, Technology and Training, the Ministry of Health to complete the dossier within the maximum time limit. up to 90 days from the date of receipt of the written notice. Past this time limit, the research protocol approval procedure must start from the beginning.

6. Within 05 working days from the date of receipt of the completed research outline according to the notification, the Department of Science, Technology and Training, the Ministry of Health summarizes, completes the application and submits it. The Minister of Health shall decide to approve the clinical trial research protocol.

Article 23. Procedures and order for approving changes to clinical trial research protocol

1. A clinical trial drug establishment shall send 01 set of application dossiers for approval to change the clinical trial research protocol directly or by post to the Department of Science, Technology and Training, the Ministry of Health.

2. The Department of Science, Technology and Training, the Ministry of Health shall check the validity of the application within 05 working days from the date of receipt of the application. In case the dossier is invalid, there must be a written notice and specific instructions for the establishment to supplement the dossier until the dossier is valid.

The clinical trial facility is responsible for coordinating with the Department of Science, Technology and Training, the Ministry of Health to complete the dossier within a maximum of 60 days from the date of receipt of the written notice. Past this time limit, the research approval procedure must start from the beginning.

3. Within 25 days from the date of receipt of complete and valid dossiers, the Ministry of Health shall hold a meeting of the National Ethics Council and issue a minutes of appraisal of changes to the clinical trial research protocol.

4. Within 05 working days from the date of receipt of the appraisal minutes from the National Ethical Council, the Department of Science, Technology and Training synthesizes, completes the dossier and submits it to the Minister of Health for approval decision. approve amendments and supplements to the clinical trial research protocol if the clinical drug trial protocol meets the requirements. In case the research proposal is not approved or needs correction, the Department of Science, Technology and Training shall notify in writing the institution and clearly state the reason.

5. In case the clinical drug research outline needs to be corrected, the clinical trial establishment is responsible for coordinating with the Department of Science, Technology and Training, the Ministry of Health to complete the dossier within the maximum time limit. up to 90 days from the date of receipt of the written notice. Past this time limit, the research protocol approval procedure must start from the beginning.

6. Within 05 working days from the date of receipt of the completed research outline according to the notification, the Department of Science, Technology and Training, the Ministry of Health summarizes, completes the application and submits it. The Minister of Health shall decide to approve amendments and supplements to the clinical trial research protocol.

Article 24. Organization of clinical trial of drugs

The clinical trial facility shall organize the clinical trial according to the approved research outline and guidelines.
GCP.

Article 25. Procedures and order for approving clinical trial results

1. A clinical trial facility shall send 01 set of application dossiers for approval of clinical drug trial results in Vietnamese directly or by post to the Department of Science, Technology and Training, the Ministry of Health.

2. The Department of Science, Technology and Training, the Ministry of Health shall check the validity of the application within 05 working days from the date of receipt of the application. In case the dossier is invalid, there must be a written notice and specific instructions for the establishment to supplement the dossier until the dossier is valid.

The clinical trial facility is responsible for coordinating with the Department of Science, Technology and Training, the Ministry of Health to complete the dossier within a maximum of 60 days from the date of receipt of the written notice. Past this time limit, the procedure for approving clinical trial results must start from the beginning.

3. Within 25 days from the date of receipt of complete and valid dossiers, the Ministry of Health shall hold a meeting of the National Ethics Council and issue a record of acceptance of the clinical trial of the drug, which must contain a satisfactory conclusion. request; satisfactory but need to be corrected, supplemented or not met the requirements.

4. Within 05 working days from the date of receipt of the acceptance report meeting the safety and effectiveness requirements of the National Ethical Council, the Director of the Department of Science, Technology and Training shall decide to approve the results. clinical trial using the Form No. 14 specified in Appendix III to this Circular. In case the minutes of acceptance test pass but need to be corrected or supplemented or fail to meet the requirements for safety and effectiveness, the Department of Science, Technology and Training shall notify in writing the establishment and clearly state the reasons therefor.

5. In case the acceptance record is passed but needs to be corrected or supplemented, the establishment is responsible for coordinating with the Department of Science, Technology and Training and the Ministry of Health to complete the dossier within a maximum time limit of 90 days from the date of delivery. from the date of receipt of the written notice. Past this time limit, the procedure for approving clinical trial results must start from the beginning.

6. Within 05 working days from the date of receipt of the completed dossier according to the notification, the Director of the Department of Science, Technology and Training shall decide to approve the clinical trial results.

Chapter VIII

TERMS ENFORCEMENT

Article 26. Effect

1. This Circular takes effect from January 1, 2019.

2. Article 2, Article 3, Article 4, Chapter III, Chapter IV, Chapter V, Chapter VI, Chapter VII, Chapter VIII, Article 39, Article 40 of the Circular No. 03/2012/TT-BYT dated 02/ 02/2012 of the Minister of Health guiding on clinical trials and Decision No. 799/QD-BYT dated 07/03/2008 of the Minister of Health on the promulgation of "Guidelines for good practice in clinical drug testing" from the effective date of this Circular.

Article 27. Terms of Reference

In case the documents referenced in this Circular are replaced or amended or supplemented, the replaced or amended or supplemented document shall prevail.

Article 28. Transitional provisions

Clinical trial dossiers submitted before the effective date of this Circular shall be considered and appraised in accordance with the Minister of Health's Circular No. 03/2012/TT BYT dated February 2, 2012 guiding the clinical trial. drugs in clinical practice or according to the provisions of this Circular in case the establishment so requests.

Article 29. Implementation organization

1. Department of Science, Technology and Training , Ministry of Health is responsible for:

a) Act as the focal point to assess the response to Good Clinical Practice by clinical trial service business establishments and establishments that conduct clinical trials for non-clinical purposes. commercial purposes;

b) Assume the prime responsibility for, and coordinate with relevant units in, disseminating and guiding the contents of this Circular;

c) Act as the focal point and coordinate with relevant units in guiding the implementation to the Department of Health, branch health and clinical trial facilities within the scope of their assigned functions and tasks;

d) Summarize and publish on the website of the Department of Science, Technology and Training a list of establishments providing clinical drug testing services and those that have activities of receiving clinical drug trials because: for commercial purposes nationwide have been granted a certificate of eligibility for pharmacy business, a certificate of GCP attainment, an update on the status of the certificate of eligibility for pharmacy business, a certificate of GCP attainment, the status of meeting GCP and other information as prescribed in Clause 4, Article 11 of this Circular, within the scope of assigned functions and tasks;

dd) Publish GCP update documents on the website of the Ministry of Health and the website of the Department of Science, Technology and Training;

e) To act as a focal point or coordinate with the Inspector of the Ministry of Health and relevant units of the Ministry of Health in inspecting and inspecting the compliance with the regulations. GCP and handle violations according to its competence;

g) Receive and examine clinical trial drug dossiers, guide organizations and individuals with clinical trial drugs and clinical trial establishments to strictly comply with the provisions of this Circular and other regulations of law. relevant laws;

h) Act as a focal point to help the Ministry of Health organize meetings of the National Ethics Council to evaluate clinical trial research protocols, change clinical trial research protocols, and accept clinical trials. clinical trial of drugs; carry out the approval of clinical trial results;

i) Organize periodic or irregular monitoring and inspection of the clinical trial process.

2. Drug Administration of Vietnam, Ministry of Health is responsible for:

a) Act as the focal point to assess the response to Good Clinical Practice of Drugs by business establishments providing bioequivalence testing services of drugs and establishments engaged in bioequivalence testing activities. of drugs for non-commercial purposes;

b) Cooperate with relevant units in disseminating the contents and guiding the implementation of this Circular;

c) Summarize and publish on the website of the Drug Administration of Vietnam a list of establishments providing bioequivalence testing services of drugs and those that conduct bioequivalence testing of drugs. for commercial purposes nationwide have been granted a certificate of eligibility for pharmacy business, a certificate of GCP achievement, updated status of certificate of eligibility for pharmacy business, certificate of GCP attainment, status of compliance GCP response and other information as prescribed in Clause 4, Article 11 of this Circular, within the scope of assigned functions and tasks;

d) To act as a focal point for and coordinate with relevant units under the Ministry of Health in inspecting and inspecting the compliance with GCP requirements of establishments providing bioequivalence testing services of drugs and medical establishments. have activities to receive bioequivalence testing of drugs for non-commercial purposes and handle violations according to their competence.

3. The Department of Health is responsible for:

a) Cooperate with relevant units in disseminating this Circular and guiding its implementation to units in the locality;

b) Join the inspection team to assess the GCP compliance; supervise and handle violations according to their competence of GCP compliance for clinical drug trial establishments in their respective management areas.

4. Clinical drug trial establishments are responsible for:

a) Organize the implementation of this Circular in accordance with the reality of the establishment;

b) Ensure to meet GCP principles and standards throughout the operation of the establishment;

c) Carry out clinical trial activities in accordance with the licensed scope on the basis of compliance with the provisions of law;

d) Comply with regulations on time limit, dossier and procedures for assessment of GCP satisfaction according to the provisions of this Circular;

d) Subject to irregular inspection, examination and assessment of the maintenance of GCP compliance by competent state agencies in accordance with law.

Article 30. Responsibilities for implementation

Director of Department of Science, Technology and Training, Director of Drug Administration of Vietnam, Chief of Office of the Ministry, Chief Inspector of the Ministry, Director, Director, General Director of Departments, Departments, General Departments under the Ministry of Health, Prime Minister Heads of units under the Ministry of Health, relevant organizations and individuals are responsible for the implementation of this Circular.

In the course of implementation, if there are any difficulties or problems, agencies, organizations and individuals should promptly report them to the Ministry of Health (the Department of Science, Technology and Training) for consideration and settlement./.

KT. MINISTER VICE MINISTER

Truong Quoc Cuong

Recipients: -
Committee on Social Affairs of the National Assembly (for reporting); - Office of the Government (Cong Bao, Portal of the Government); - Minister (for reporting); - The Deputy Ministers of Health; - Ministries, ministerial-level agencies, agencies under the Government; - Ministry of Justice (Department for Examination of Legal Documents); - Departments of Health of provinces and centrally run cities; - Health ministries, branches; - Units under and under the Ministry of Health; - Vietnam Pharmaceutical Corporation - Joint Stock Company; - Pharmaceutical business associations Vietnam; - Vietnam Pharmaceutical Association; - Portal of the Ministry of Health; - Website of the Department of Science, Technology and Investment; - Save: VT, PC, K2DT (05).

APPENDIX I

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(Issued together with the Circular No. 29/2018/ TT-BYT dated October 29, 2018 of the Minister of Health providing for clinical trial of drugs)

Chapter I

TERMS AND PRINCIPLES IN CLINICAL TRIAL GOOD PRACTICE

Article 1. Terminology

1. ***Organizations and individuals that have clinical trial drugs*** are organizations or individuals that own research drugs, have a need for clinical trials and commit to provide financial support for clinical trials.

2. ***Researcher*** is the person responsible for conducting research at the research site.

3. ***The main*** researcher is the directing researcher, directly responsible for the completion of the research and directly reporting the research process and results to the sponsor.

4. ***Standard Operating Procedures (Standard Operation Procedure - SOP)*** is a detailed guide to achieve consistency in the performance of a specific job or task in clinical drug research.

5. ***Research monitoring and supervision*** is the process of checking and monitoring the research progress, the researcher's compliance with the approved outline and the provisions of the law on research.

6. ***Examination of the Ethics Council or examination of organizations and individuals having clinical reagents (audit)*** is a systematic and independent examination of activities and documents related to drug trial research. clinical trials to determine whether the activities related to the evaluated clinical trial are conducted, whether the data are accurately recorded, analyzed, and reported in accordance with the protocol, the SOPs of the funding, GCP and legal regulations.

7. ***Inspection*** is an activity by a regulatory authority to conduct a formal review of research-related documents, facilities, records, and other resources. clinical trial of drugs. Testing by the Regulatory Authority may be conducted at the testing site, the facility of an organization or individual that has clinical reagents or a research support organization, or at other facilities deemed by the regulatory authority to be Fit.

8. ***An adverse event (AE)*** is a medical event or condition including any sign, symptom, medical condition, or adverse test result that occurs during, Clinical trial duration affects clinical trial participants, with or without clinical trial involvement.

9. A ***serious adverse event (SAE)*** is an adverse event that can lead to one of the following situations in a clinical trial participant:

a) Death;

b) Threats to life;

c) Hospitalization or prolonged hospital stay;

d) Permanent or serious disability or injury;

dd) Birth defects or malformations in the fetus of a drug trial participant;

e) A situation where appropriate medical intervention is required to prevent or avoid one of the situations specified at Points a, b, c, d, dd of this Clause or other situations of medical significance. faculty according to the opinion of the researcher at the study site.

10. ***Unexpected adverse events in a clinical trial study (unexpected adverse event - unexpected SAE)*** are adverse events occurring in a clinical trial, of which nature or the severity or specificity or patient outcome of the event was not as described or detailed previously in the protocol or relevant literature.

Article 2. Principles of Good Practice in Clinical Trial

1. Principle 1:

Clinical trials must be conducted in accordance with the basic principles of biomedical research ethics in the Declaration of Helsinki, first adopted by the World Medical Association (WMA) in 2016. 1964 in Helsinki (Finland) and updated periodically.

2. Principle 2:

The benefits and risks or inconveniences to clinical trial participants, to society or to the general population need to be considered, fully and carefully considered before commencing a study. clinical trial of drugs on the basis of ensuring the safety, health and interests of clinical trial participants.

3. Principle 3:

Clinical trials only begin if the anticipated benefits to the clinical trial participants and to society outweigh the possible risks. The scientific and social benefits need to be considered, fully and carefully considered on the basis of ensuring the safety, health and interests of participants in clinical trials.

4. Principle 4:

Clinical trials must be conducted on the basis of strict adherence to the research protocol and procedures approved by the Ethics Council, the Scientific Council and approved by the competent regulatory agency. Any changes in the research protocol or process must be promptly reported and fully approved by the competent authority.

5. Principle 5:

The review of clinical trial studies should be comprehensive and thorough on the basis of being provided with sufficient preclinical, clinical and other relevant results. to reagents (if any).

6. Principle 6:

Participants in clinical drug trials are guaranteed the following rights: to provide all relevant information using Form No. 09 in Appendix III to this Circular; request explanation and clarification of research-related information when necessary; respecting the specific characteristics of culture and habits of individuals, regions and ethnic groups and deciding whether to participate or not to participate in clinical drug trials; provide appropriate medical services free of charge; Research participants who are underage, have limited civil act capacity or have lost their civil act capacity must obtain the consent of their representatives as prescribed by law on participating in drug trials on clinical.

7. Principle 7:

Establishments that receive clinical trials are responsible for arranging appropriately qualified doctors to provide medical care and make medical decisions for participants in clinical trials in clinical trials. necessary and in accordance with the law.

8. Principle 8:

Each individual participating in the conduct of clinical drug trials should ensure standards of professional qualifications, training, retraining and experience in order to perform their respective tasks in clinical trials. .

9. Principle 9:

All information on clinical trials must be recorded, handled, managed and kept in accordance with regulations in order to be able to accurately report, interpret, monitor, and check the accuracy and reliability of such information. clinical trial information and data.

10. Principle 10:

Records used to identify participants in clinical trials must be protected and kept to ensure their right to be kept private in accordance with the provisions of law.

11. Principle 11:

Reagents must be manufactured, managed as prescribed, stored in accordance with relevant good practice guidelines, and used only for research in accordance with an approved study protocol.

12. Principle 12:

The quality assurance system and methods to ensure quality in clinical trials must be fully and accurately implemented in accordance with the quality assurance provisions of this guideline and legal regulations. on quality assurance of drugs used in research.

13. Principle 13:

Respect the culture, identity, traditions and customs of the population in which clinical trials are conducted.

chapter II

RIGHTS AND RESPONSIBILITIES OF ORGANIZATIONS AND INDIVIDUALS IN CLINICAL TRIAL RESEARCH

Article 3. Rights and responsibilities of organizations and individuals having clinical trial drugs

Rights and responsibilities of individuals and organizations having clinical trial drugs comply with Article 92 of the Law on Pharmacy No. 105/2016/QH13.

Article 4. Rights and responsibilities of clinical trial recipients

The rights and responsibilities of a clinical trial receiving facility shall comply with the provisions of Article 93 of the Law on Pharmacy No. 105/2016/QH13.

Article 5. Rights and responsibilities of researchers

1. Researcher has the following rights:

a) Enjoy financial benefits according to agreements with organizations and individuals having clinical trial drugs;

b) Sign a research contract with the main researcher or the clinical trial receiving facility to coordinate in performing a number of specific contents of the clinical trial on the basis of compliance with the above drug trial research protocol. clinically approved;

c) Propose to the principal investigator to change the clinical trial research protocol in case of necessity;

d) Propose to the principal investigator to stop or prematurely terminate the clinical trial if an adverse event is detected that seriously affects the safety and health of the trial participants or the community.

2. Researcher has the following responsibilities:

a) Contribute to the clinical trial drug research outline, research information supply form and the participant's volunteer participation form in the clinical trial together with relevant documents;

b) Coordinating with clinical trials receiving establishments and organizations and individuals having clinical trial drugs in formulating and completing dossiers of application for approval for clinical drug research;

c) Carry out the tasks assigned by the main researcher related to the research implementation; selection of drug trial participants; record and keep source documents and essential documents; periodic and extraordinary reports as prescribed; monitor and supervise the implementation of research according to the approved research protocol and current regulations;

d) Adhere to the approved research protocol and procedures, except where immediate changes are needed to ensure the safety of the trial participants;

d) Propose the main researcher to change the research proposal in case of necessity. The implementation of the revised outline can only be carried out after it has been approved by a competent agency or organization;

e) Compensation for damage to drug trial participants when an adverse event causes serious damage to the safety and health of drug trial participants because the researcher violates the research protocol ;

g) Cooperate with organizations and individuals that have clinical trial drugs to complete the application for approval of clinical trial results and submit them to competent agencies for appraisal and approval.

Article 6. Rights and responsibilities of principal investigator

1. Principal investigator has the following rights:

a) Enjoy financial benefits according to agreements with organizations and individuals having clinical trial drugs;

b) Propose units to coordinate and list researchers with organizations and individuals having clinical reagents and management agencies;

c) Proposing a laboratory with a quality assurance system suitable for clinical drug research with organizations and individuals having clinical reagents and management agencies;

d) Sign research contracts with agencies, organizations and individuals to coordinate in implementing a number of specific contents of clinical drug trials on the basis of compliance with the approved research outline;

dd) Proposing organizations or individuals having clinical reagents to change the research protocol in case of necessity;

e) Stop or terminate the study early if an adverse event is detected that seriously affects the safety and health of the trial participants or the community;

g) Publish research results according to agreements with organizations and individuals having clinical trial drugs.

2. Principal investigator has the following responsibilities:

a) Take the highest responsibility for the safety and health of drug trial participants at the clinical trial receiving facility;

b) Design or contribute to the research proposal, research information sheet and research volunteer form and related research documents;

c) Coordinating with clinical drug trial establishments and organizations and individuals having clinical trial drugs in formulating and completing dossiers of application for approval of clinical drug research studies;

d) Organizing research implementation; selection of drug trial participants; record and keep source documents and essential documents; periodic and extraordinary reports as prescribed; monitor and supervise the implementation of research according to the approved research protocol and current regulations;

dd) Comply with the approved research outline and process, except in cases where it is necessary to change immediately to ensure the safety of drug trial participants;

e) Make payments to drug trial participants according to the contents of the approved research information supply and the approved research volunteer form;

g) Propose organizations and individuals having clinical reagents to change the research protocol in case of necessity. The implementation of the revised outline can only be carried out after it has been approved by a competent agency or organization;

h) Provide dossiers and documents related to clinical trial of drugs to competent agencies and organizations upon request for examination, supervision and research inspection;

i) Compensation for damage to drug trial participants when an adverse event causes serious damage to the safety and health of drug trial participants which is caused by the main researcher's violation of the study protocol. assist;

k) Cooperate with organizations and individuals that have clinical trial drugs to complete the application for approval of clinical trial results and submit them to competent agencies for appraisal and approval.

Article 7. Rights and obligations of participants in clinical trials

Rights and obligations of participants in clinical trials shall comply with the provisions of Article 91 of the Law on Pharmacy No. 105/2016/QH13.

Chapter III

OUTLINE OF THE CLINICAL TRIAL RESEARCH

Article 8. Clinical trial drug research outline

1. Organizations and individuals that have drugs for clinical trial shall coordinate with the main researcher to develop a clinical trial drug research protocol.

2. The clinical trial research protocol must be approved by the Ethical Council in Biomedical Research at the grassroots level, the National Ethical Council in Biomedical Research and the competent authority before proceeding. research practice.

3. Changing the clinical trial research protocol:

a) For administrative changes: the facility receiving the clinical trial shall report in writing to the Ethics Council at all levels and the competent management agency.

b) For changes that do not affect the health, interests of drug trial participants, research designs, processes and procedures: it is necessary to be approved by the Ethics Committee in Biomedical Research at grassroots level, the Association National Biomedical Research Ethics Committee peer-reviewed and approved. Dossier and appraisal process are made according to the provisions of Circular No. 45/2017/TT-BYT dated November 16, 2017 of the Minister of Health stipulating the establishment, functions, tasks and powers of the Ethics Council in biomedical research.

c) For changes that affect the health and interests of drug trial participants or affect the research design, process and procedures: must be approved by the competent management agency. Dossier of application for approval of changes and procedures for and order of approval for changes in clinical trial research protocols shall comply with the provisions of Articles 19 and 23 of this Circular.

Article 9. Design of clinical drug trial studies

The design of clinical trial drug research should ensure the scientific, feasible and suitable for each research stage as well as the reagent's characteristics, specifically as follows:

1. Phase 1 clinical trial is performed on healthy volunteers or patients. The selection of a group of people to participate in a drug trial must be justified based on the consideration of the risks and benefits of the study drug.

2. Phase 2, 3, and 4 clinical trials are conducted on patients (for research to evaluate treatment effects) or participants in drug trials at high risk of disease (for researches to evaluate treatment effects). cost of prophylactic effect). In case the participation of other target groups is required, there must be a suitable explanation.

3. The selection of control and comparison groups in clinical trial studies should be considered and rationally explained among the following methods:

a) Compare the control with placebo;

b) Compare the control with the group without treatment with study drug;

c) Comparison of controls between different dose levels;

d) Compare the control with another active ingredient;

d) Compare and contrast with historical data.

4. Phase 3 clinical trial studies to serve the purpose of drug registration must be designed in a randomized, double-blind, controlled grouping design. Where randomized, double-blind or control grouping is not feasible, an appropriate rationale must be provided.

5. For studies that confirm safety and efficacy in a phase 3 clinical trial, the following principles can be applied in study design to minimize bias:

a) Blinding in a phase 3 study is required in cases where the main study variable is subjective or difficult to measure accurately (e.g. pain, mass response). u on magnetic resonance imaging...) but is not required for studies where the key variable can be objectively and accurately measured. In case blinding is not possible, there must be a reasonable explanation of how to control and minimize errors used in the study.

b) Randomization is an important requirement for phase 3 clinical studies to ensure objectivity in grouping.
The case where random grouping is not possible must have a reasonable explanation.

6. For drugs from herbal ingredients, traditional drugs, depending on experience, understanding and convincing level of evidence on safety and effectiveness of herbal ingredients, design in each phase The research section will be considered based on each specific profile and protocol.

7. Phase 4 clinical trial is the research after the drug has been licensed for circulation. The phase 4 study can be designed as a non-interventional observational study; a safety surveillance study based on existing medical databases or safety surveillance reporting systems, or rigorously designed as a phase 3 clinical trial to confirm safety or effectiveness of the drug under actual conditions of use.

Article 10. Research sample size

1. The sample size needs to be calculated and explained in a reasonable way to achieve the research objectives. Assumptions to be included in the calculation of the research sample size need to clearly state the source of the reference, it is necessary to perform a sensitivity analysis of the sample size according to the variation of the assumed parameters.

2. In the course of research, if it is found that the assumptions to be included in the calculation of sample size are significantly different from the reality, the sample size must be recalculated and reported to the competent authority for approval.

3. The sample size in the phase 1 study should be carefully considered based on the results of preclinical studies. The recommended sample size is 10-30 subjects (including intervention and control groups, if any). In case the sample size is less, a reasonable explanation must be given.

4. Sample size in phase 2 is recommended to be at least 50 subjects (including intervention and control groups, if any). For drugs from medicinal herbs, traditional drugs, the minimum recommended sample size is at least 30 subjects. In case the sample size is less, a reasonable explanation must be given.

5. The sample size in the phase 3 study must be fully calculated and justified. The sample size of the phase 3 study must be large enough to allow scientific verification of the efficacy and safety of the study drug. The recommended sample size is at least 100 subjects (including intervention and control groups, if applicable). For drugs from medicinal herbs and traditional drugs, the recommended minimum sample size is at least 50 subjects.
In case the sample size is less, a reasonable explanation must be given.

6. The sample size in the phase 4 study must be made at the request of the regulatory agency or fully calculated and justified.
The sample size should be large enough to allow continued scientific testing of the study drug's efficacy and safety. The recommended sample size is at least 200 subjects (including intervention and control groups, if applicable). In case the sample size is less, a reasonable explanation must be given.

Chapter IV

IMPLEMENTATION OF Clinical Trial of Drugs

Article 11. Conducting clinical drug trial research

a) Clinical trials of drugs are only allowed to be carried out when approved by a competent regulatory agency;

b) The implementation of research on drug trial participants can only begin after the research information is fully informed to the drug trial participants and the trial participants or their legal representatives have signed. The research information sheet and the research volunteer form;

c) The research team, the facility receiving the clinical trial is responsible for organizing and conducting the research in accordance with the approved research outline and research process;

d) Essential documents before conducting, during the implementation and after the end of the clinical trial study, made according to Forms 01, 02 and 03 issued together with this Appendix;

dd) The Ministry of Health encourages principal researchers to register and publish research on reputable databases at home and abroad.
country.

Article 12. Technical standards of facilities serving clinical trial of drugs

1. The clinical area of the facility receiving the clinical trial (or according to the contract/document associated with the medical examination and treatment facility in case the vaccine receiving facility does not have a clinical area) must meet the requirements. the following technical standards:

a) The reception area must have enough seats for at least 30 people to participate in the drug trial, ensuring that it can be shaded from rain, sun and well ventilated;

b) The counseling area ensures privacy for drug trial participants with sufficient temperature, light and ventilation conditions;

c) Clinical clinics and treatment rooms ensure privacy for drug trial participants;

d) The injection room, procedure room, and treatment room must be airtight, ventilated and warm enough for the subject;

dd) The emergency room has enough area for emergency services as prescribed by the Minister of Health;

e) Room for keeping participants in drug trials to monitor adverse events after using research drugs (for vaccine studies) must have adequate temperature, light and ventilation conditions; enough area to save the object;

g) Separate male and female restrooms for drug trial participants;

h) Ensure hygiene and safety conditions for fire prevention and fighting and comply with the collection, management and treatment of medical waste in accordance with law;

i) The phase 1 clinical trial area or bioequivalence trial should be closed and controlled with at least 12 beds for inpatient treatment; 24-hour central physiological monitoring room; medicine preparation room; recreation room, dining room; lockers for personal belongings of trial participants.

2. The laboratory of the facility receiving the clinical trial (or according to the contract/document associated with the specialized facility in case the vaccine receiving establishment does not have a laboratory) must meet the standards after:

a) Sufficient area to arrange professional equipment, documents and working space for staff in accordance with the scale of clinical trial activities;

b) Having an appropriate laboratory quality assurance system.

3. Area for preservation of biological samples and research drugs; The area for storing research files and documents of a clinical trial receiving facility must meet the following standards:

a) A separate area for storing researched drugs, with limited access, ensuring conditions of temperature, humidity, light, area and volume to meet the requirements for drug preservation;

b) The place where samples are taken, handled and preserved must be sterile and meet the requirements for sample handling and preservation as prescribed;

c) Areas for preservation of records and documents ensure confidentiality, restricted access, fire and explosion prevention and control; Avoid the adverse effects of light, temperature, humidity, penetration of insects and other animals.

4. The clinical trial management department is responsible for supervising, managing and coordinating the departments in the clinical trial receiving facility, which must meet the following standards:

- Having working rooms, meeting rooms that are qualified in terms of area, tables and chairs;

- Enough office equipment, computers with internet connection, security and limited access.

5. The grassroots-level office of the Ethical Council in Biomedical Research of the facility receiving the clinical trial must meet the following standards:
or:

- Having working rooms, meeting rooms that are qualified in terms of area, tables and chairs;

- Enough office equipment, computers with internet connection, security and limited access.

6. Equipment for clinical trial must meet the following standards:

a) Having enough basic equipment to serve the assessment and monitoring of the health of research participants;

b) Having enough specialized equipment to apply to clinical trials of drugs in specialized fields;

c) Having adequate emergency equipment according to regulations of the Ministry of Health;

d) Having testing equipment meeting the list of tests registered for clinical trial;

dd) Having sufficient equipment to preserve and monitor the storage conditions of the research drug in accordance with the storage requirements stated on the label;

e) Having enough injection equipment, tools, chemicals for disinfection, medical waste containers and necessary supplies according to regulations of the Ministry of Health;

g) Having sufficient equipment to meet the requirements on preservation of biological samples;

h) Having equipment to monitor temperature at the place of storage and during transportation of research drugs;

i) Equipment for testing, preserving research drugs, preserving biological samples must be arranged, appraised, used and maintained in accordance with the purpose of use, calibrated and periodically checked by appropriate method;

k) Having an emergency power backup system, ensuring uninterrupted power supply for important stages of the research; suitable alarm and monitoring system for storage devices for research drugs, biological samples, and testing equipment;

l) For the phase 1 clinical trial: a physiological monitoring system at the bedside is required; surveillance camera system to support safety monitoring and appropriate drug preparation equipment;

m) Having equipment to preserve records and documents to avoid adverse effects of light, temperature and humidity; intrusion of insects and other animals and ensure fire prevention and fighting safety.

Article 13. Professional, technical, and quality management documents for clinical trial of drugs

1. Professional and technical documents must meet the following standards:

a) Having adequate standards, guidelines and standard practice procedures for activities performed in clinical drug trials;

b) Having a document showing the scope of professional activities suitable to the field of clinical drug registration;

c) Having sufficient legal documents and instructions on clinical trial of drugs;

d) Having a document on management and handling of conflicts of interest in clinical trials;

dd) Having personnel files and training records of researchers updated at least once a year;

e) Having electronic records and databases managing clinical trial studies;

g) Having sufficient source documents and essential documents of clinical trial studies.

2. The quality management system applied in clinical drug trials meets ISO 9001 or equivalent standards or higher.

Article 14. Professional standards for personnel

1. Professional standards of researchers:

a) Having a professional diploma or certificate issued or recognized in Vietnam suitable to the job position;

b) Having a valid practicing certificate suitable to the assigned work (for jobs specified that the performer must have a practicing certificate);

c) Having a certificate of completion of the GCP course issued by the Ministry of Health or an establishment with the GCP training function, which is updated every 3 years;

d) Having a certificate of completion of the safety reporting course in clinical drug trial under GCP issued by the Ministry of Health or an establishment with the function of training in safety reporting in clinical drug trial, issued and updated. once every 3 years;

dd) The team of researchers has sufficient number and composition suitable to the assigned work and has enough time for research.

2. Criteria of principal investigator:

a) Having a professional diploma or certificate issued or recognized in Vietnam suitable to the job position;

b) Having a valid practicing certificate suitable to the assigned work (for jobs specified that the performer must have a practicing certificate);

c) Having a certificate of completion of the GCP course issued by the Ministry of Health or an establishment with the GCP training function, which is updated every 3 years;

d) Having a certificate of completion of the safety reporting course in clinical drug trial under GCP issued by the Ministry of Health or an establishment with the function of training in safety reporting in clinical drug trial, issued and updated. once every 3 years;

dd) Having sufficient specialized knowledge, clinical experience, practical ability to ensure GCP principles, mastering regulations on clinical drug trial, being able to implement research protocol. fully and on schedule;

e) At the same time, each principal investigator must not lead more than 03 clinical trial studies.

3. Member of clinical trial management department:

a) Having a university degree or higher in the field of health;

b) Having a certificate of completion of the GCP course issued by the Ministry of Health or an establishment with the GCP training function, which is updated every 3 years.

4. Ethical council in biomedical research at grassroots level shall comply with the provisions of Circular No. 45/2017/TT-BYT dated November 16, 2017 of the Minister of Health stipulating the establishment, functions, tasks and powers of the Ethics Council in biomedical research.

Article 15. Recording, reporting and statistical analysis

a) Record and report:

The principal investigator is responsible for ensuring the accuracy, truthfulness, confidentiality, integrity and verifiability of the research data. The correction of data must be in accordance with the regulations: without deleting the original data, the researcher is assigned to name, sign for confirmation and clearly state the date of correction. The lead investigator must submit an encrypted list of trial participants to the regulatory agency after the clinical trial ends. The retention and submission of the list of participants after decryption must be kept. secret.

b) Statistical analysis:

- The planning and performance of statistical analysis should be carried out and validated by a qualified and experienced statistician;

- The statistical analysis plan must fully and detail describe the descriptive or inferential statistics of the variables to be performed in the study according to the approved protocol; must describe the means to ensure data blindness in the case of studies using a design where the statistical analyst is partially blinded to the study data;

- The statistical analysis needs to comply with the analysis plan. In case the statistical analysis has changed from the plan, detailed description and appropriate explanation should be provided. The mid-term analysis (if applicable) must be clearly defined in the statistical analysis outline and plan;

- The results of statistical analysis must be consistent with the research objectives and answer the research question.

Article 16. Supervision and examination of clinical drug research studies

1. Monitoring:

a) Purpose: to protect the rights and health of drug trial participants; ensure the accuracy, completeness and truthfulness of research data; ensure that drug trials are conducted in compliance with the study protocol, GCP and relevant legal regulations.

b) Supervision authority:

- Organizations and individuals having clinical trial drugs shall appoint supervisors to periodically supervise the research. Supervisors are appointed by organizations or individuals with clinical reagents and comply with the provisions of Circular No. 08/2014/TT-BYT dated February 26, 2014 of the Minister of Health regulating activities to support clinical trial research in Vietnam. During the monitoring process, if a serious protocol violation is detected that harms the safety of subjects or the accuracy and truthfulness of data, organizations and individuals having clinical reagents are entitled to stop the research and send notices to the Ethics Councils at all levels and regulatory agencies, and at the same time notify the establishments receiving clinical trials and research
main member.

- The Ethics Committee irregularly or periodically supervises the study.

c) Monitoring process:

- Organizations and individuals that have clinical trial drugs or the Ethics Council send a notice of the surveillance phase to the clinical trial receiving facility and the main researcher at least 5 days before the monitoring time.

- Monitoring minutes or reports should be completed and sent to the clinical trial recipient and the main investigator no later than 20 days after the end of monitoring.

d) Scale and frequency of supervision:

Based on the objective, purpose, design, complexity, blinding technique, scale and outcome of the study, organizations and individuals having clinical reagents and the Ethics Committee decide on the scale and frequency of monitoring before, during, and after a clinical trial.

d) Supervision contents:

- Resources of the facility receiving the clinical trial before conducting the clinical trial;

- The research information sheet and the research volunteer form, the process of collecting the volunteer form to participate in the research;

- Dossiers, source documents, essential documents of the research;

- Research drugs (expiry date, storage conditions, management, and distribution to drug trial participants);

- Compliance with the research protocol (including protocol changes) approved by the investigator;

- Record and report adverse events in clinical trials;

- Other contents related to the research.

2. Inspection by organizations or individuals having clinical reagents or the Ethics Council:

a) Purpose: to assess the appropriateness of clinical trial performance with the study's quality system, with the study's SOPs, study protocol, GCP and related legal requirements. Inspection as part of quality assurance should focus on systematic and possibly quality control of supervision.

b) Authority:

- Organizations and individuals having clinical trial drugs shall appoint inspectors to periodically check the research. Inspectors shall be appointed by organizations or individuals having clinical reagents and shall comply with the provisions of Circular No. 08/2014/TT-BYT dated February 26, 2014 of the Minister of Health regulating activities to support clinical trial research in Vietnam. During the examination, if a serious protocol violation is detected, affecting the safety of subjects or the accuracy and truthfulness of data, organizations and individuals that have clinical reagents are entitled to stop the research and send notices to the Ethics Councils at all levels and regulatory agencies, and at the same time notify the establishments receiving clinical trials and research
main member.

- The Ethics Committee for irregular or periodic inspection of the study.

c) Process:

- Organizations and individuals that have clinical reagents or the Ethics Council shall send a notice of the inspection to the clinical trial receiving facility and the main researcher at least 05 days before the time of testing.

- The inspection record or report should be completed and sent to the clinical trial recipient and the main investigator no later than 20 days after the end of the test.

d) Scale and frequency:

Based on the objective, purpose, design, complexity, blinding technique, scale and outcome of the study, organizations and individuals having clinical reagents and the Ethics Committee decide on the scale and frequency of checking before, during and after drug testing on sieves.

d) Inspection contents:

The contents are similar to the supervision content in Clause 1, point dd of this Article

3. Inspection by competent management agencies:

a) Purpose: to ensure the rights and health of drug trial participants, to ensure the quality and integrity of research data, to ensure that the responsibilities of stakeholders in the research are carried out in accordance with regulations. , promptly detect research protocol violations.

b) Authority: Department of Science, Technology and Training - Ministry of Health shall preside over clinical trial testing in Vietnam.

c) Process:

- The Ministry of Health shall send a notice of the inspection to organizations and individuals having clinical trial drugs and establishments receiving clinical trial at least 05 days before the time of inspection.

- The inspection record should be completed and sent to the organization or individual that has the drug in clinical trial and the facility that receives the drug in clinical trial no later than 20 days after the end of the test.

d) Scale and frequency: based on the objective, purpose, design, complexity, blinding technique, scale and outcome of the study, the Ministry of Health decides the scale and frequency of examination. before, during, and after a clinical trial.

d) Content:

- For establishments that receive drugs in clinical trials: resources for research; The research information sheet and the research volunteer form, the process of obtaining consent for volunteering to participate in the research; collect research data; recording and archiving source and essential documents; contents related to research drugs (management, preservation, inventory, use...). oh

- For organizations and individuals having clinical reagents: resources for research, supervision and inspection activities of organizations and individuals having reagents; compliance with SOPs; keep records, research materials; manage research data and other relevant information.

- The activities of the coordinating establishment related to the clinical trial of drugs;

- Supervision and inspection activities of the Ethics Council and organizations and individuals having clinical reagents.

Article 17. Management of adverse events (AEs) in clinical drug trials in Vietnam

1. In the event of an AE that is dangerous, life-threatening or fatal to a drug trial participant in a clinical trial, the principal investigator and the facility receiving the clinical trial must immediately stop the drug trial. on that subject, give first aid, remedy and deal with consequences, make a record in case of death, and immediately report urgently by phone or email to the Ethics Council in acute biomedical research. establishments, the National Ethical Council in Biomedical Research, the Department of Science, Technology and Training - Ministry of Health and the National Center for Drug Information, monitoring of adverse drug reactions and reporting by documents as prescribed in Article 18 of this Appendix.

2. In case an AE occurs leading to health damage to a drug participant in a clinical trial, the principal investigator or assigned researcher must treat and monitor the subject's health developments. until stabilized, record and report events in accordance with Article 18 of this Annex.

Article 18. AE reports in clinical drug trials in Vietnam

1. Contents of AE reporting in clinical drug trial research in Vietnam include:

a) Monitor, detect and report information related to AEs in clinical drug trials implemented in Vietnam or multinational trials in which Vietnam participates;

b) Collect and process information about reported AEs; assessment of benefits, risks, and risk management associated with clinical trials with reported AEs;

c) Publication of conclusions of competent authorities on issues related to monitoring AE reports of clinical trial studies.

2. Reporting scope:

a) All SAEs that occurred at the study sites in Vietnam, especially those that resulted in fatal, life-threatening, or unexpected SAEs.
These SAEs include situations where the study protocol failed to have a therapeutic effect that was fatal, life-threatening, or required medical interventions to prevent these outcomes, except for SAE that has been approved by the relevant authority in the study protocol as non-reporting;

b) SAEs occurring at research sites outside Vietnam of multinational studies involving Vietnam that lead to termination, suspension of research, withdrawal of subjects from the study, or change of topic research outline;

c) All other AEs in clinical trials at research sites in Vietnam.

3. Regulations on reporting

a) For SAE cases occurring at study sites in Vietnam:

- All SAEs occurring at research sites in Vietnam during clinical trials must be reported according to Form No. 04 attached to this Appendix to the Ethics Committee in Biomedical Research. National Administration of Science, Technology and Training - Ministry of Health and the National Center for Drug Information and Adverse Drug Reaction Monitoring;

- Reporting deadlines: Fatal or life-threatening SAEs must be reported urgently within 07 working days of receiving information about the SAE. Other SAEs must be reported within 15 business days of receiving information about the SAE. Information on SAE progress should continue to be updated in supplemental reports until the trial participant has recovered or is stable;

b) For SAE cases occurring at study sites outside of Vietnam:

- All SAEs occurring at research sites outside Vietnam of multinational studies involving Vietnam that lead to study termination, suspension, withdrawal of drug trial participants from the study, or Research protocol changes must be reported to
Department of Science, Technology and Training - Ministry of Health, National Ethics Council in Biomedical Research and National Center for Drug Information and Adverse Drug Reactions Monitoring;

- The time limit for reporting is not more than 10 working days from the date of decision to stop, suspend the research, withdraw drug trial participants from the study or change the research protocol;

c) Non-serious AEs occurring in Vietnam must be recorded, summarized and reported briefly in periodic reports and full-text reports on clinical trial research results to the Department of Science and Technology and Training - Ministry of Health and National Ethics Council in Biomedical Research.

4. Responsibilities of parties in reporting AEs in clinical drug trials in Vietnam:

a) Principal investigator and researcher at the study site: detect and treat AEs in a timely manner, ensuring the safety of drug trial participants; fully monitor and record information; report SAE and periodically update information on AE and SAE for organizations and individuals with clinical reagents, Ethics Council in biomedical research at grassroots level, Ethics Council in biomedical research National Agency for Science, Technology and Training - Ministry of Health and National Center for Drug Information and Monitoring of Drug Adverse Reactions within the prescribed time limit. In case the level and frequency of AEs and SAEs exceed the allowable limits, the researcher can propose to organizations and individuals having clinical reagents, the Ethics Committee and temporary competent regulatory agencies. stop clinical drug trial;

b) Establishments that receive clinical trials: manage and supervise the detection, handling and monitoring of AE and SAE reports at the research site to ensure safety for drug trial participants.

c) The grassroots ethics committee: to review and give professional opinions on AEs and SAEs occurring at the research site, ensuring absolute safety for drug trial participants;

d) Organizations and individuals that have clinical reagents and authorized research support organizations:

- Coordinate with the main researcher to report AEs and SAEs occurring at research sites in Vietnam to the grassroots level biomedical research ethics council of the clinical trial recipient, the Council ethics in national biomedical research, Department of Science, Technology and Training - Ministry of Health, National Center for Drug Information and Adverse Drug Reaction Monitoring;

- Report on SAEs occurring at research sites outside of Vietnam that lead to termination, suspension of research, withdrawal of drug trial participants from the study or change of research protocols of multinational studies to which Vietnam participates;

- Synthesize data of AEs and SAEs;

Report findings from clinical trial studies, epidemiological studies, animal studies, in vitro studies, information in the literature, and from other sources that may lead to a serious risk associated with the study drug;

d) National Ethical Council in Biomedical Research:

- Review, evaluate, and, if necessary, provide feedback on individual SAE reports and information on SAE in annual progress reports and full-text reports on clinical trial results;

- Organize supervision and inspection of research sites in case of necessity;

- Advise the regulatory agency to promptly direct the clinical trial recipient, the organization or individual that has the clinical trial drug in order to ensure absolute safety for the drug trial participants;

e) The National Center for Drug Information and Adverse Drug Reactions Monitoring receives SAE reports in clinical trial studies; coordinate with the National Council on Ethics in Biomedical Research to review and evaluate the SAE report; statistics, data analysis of SAE reports in clinical trials; report, advise and propose competent authorities on contents related to ensuring safety for drug trial participants.

Article 19. Finance and payment for drug trial participants in clinical drug trial

1. Funding for clinical trial drug research:

a) Funds for clinical drug trial research, including professional contracting, consumables, support for drug trial participants, insurance, etc., shall be provided by the main researcher, the facility receiving the above drug trial. clinical cooperation with organizations and individuals having clinical trial drugs to discuss, develop and sign contracts;

b) Funds for management and supervision of clinical drug trial research for the following activities: survey and evaluation of research sites; research-related meetings, conferences and seminars; training for research staff; supervision, examination, inspection... by the main researcher, clinical trial receiving facility in collaboration with organizations and individuals having clinical reagents to discuss, develop and sign contracts;

c) Organizations and individuals that have drugs for clinical trial are responsible for paying expenses for research into clinical trials.

2. The payment and compensation for damage (if any) for clinical trial participants must be clearly shown in the research information provision and the trial participant's volunteer form. in clinical practice and in research protocols.

Article 20. Termination of clinical drug trial studies

1. At the end of the research, the lead researcher must inventory the research drugs, make payment for the funding, and coordinate with the organizations and individuals having clinical reagents in formulating and completing research dossiers and documents. according to the list of necessary documents after finishing the research in Form No. 03 issued together with this Appendix.

2. Research dossiers and documents should be archived and preserved according to the contract between the organization or individual having the drug for clinical trial and the facility receiving the clinical trial. For research and development of new products, documentation needs to be kept for at least 10 years.

3. Organizations and individuals that have clinical trial drugs are responsible for storing research drug samples after clinical trials are completed in accordance with current regulations. drive

4. Organizations and individuals having clinical trial drugs shall coordinate with clinical trial receiving establishments to recall and destroy residual drugs in accordance with current regulations.

Article 21. Reporting and publication of research results.

1. For clinical trial of drugs for the purpose of registration of drug circulation in Vietnam, within 01 year from the date on which the last trial participant finishes the last visit, the establishment receives the drug trial on The clinician has the responsibility to coordinate with the organization or individual having the drug in clinical trial to complete the application for approval of the clinical trial result and submit it to the competent management agency for approval.

2. The full report on clinical trial results should be presented according to Form No. 12 in Appendix III issued with this Circular. For multinational studies, in addition to analyzing the general results, separate analyzes of the main safety and efficacy variables in the Asian or Vietnamese study populations for drugs that are weak Racial factors are considered to affect efficacy and safety.

3. The publication of research results must be made within 03 years from the date of issuance of the decision approving the clinical trial results from the competent regulatory agency and must comply with the regulations on the nature of the drug. authorship in the publication of research results.

4. Encourage principal researchers to publish research results in prestigious national and international journals.

Form 01 - List of essential documents before conducting clinical drug research studies

STT	file name	Purpose	Requirements for		Reference
			Principal investigator/Clinical trial receiving facility	organization, fish patients with clinical trial drugs	
1.1	Application for registration of clinical trial of drugs ready	Provide summary information about the product to be tested and proposed to the principal investigator/ recipient of the clinical trial To demonstrate that the scientific information related to the clinical drug has		ÿ	Form No. 05 Appendix III (issued together with This circular)
1.2	Product Information Profile (IB)	been provided to the Study main lifeguard	ÿ	ÿ	
1.3	Application for approval of a clinical trial of a drug 1.4 Explanation of the drug trial protocol A detailed research outline according		ÿ		Form No. 06 Appendix III ÿ Form
	to regulations, standard practice procedures, clinical evidence and sample of follow-up research records, monitoring, demonstrate financial agreement between the lead investigator/clinical recipient and the organization to To confirm consent to participate in the study 1.6 A written confirmation of participation in the study for clinical	between the parties involved, e.g. research in	ÿ		No. 07 Appendix III
1.5	Clinical trial contract between an organization or individual having a clinical trial drug and the main researcher/facility receiving the clinical trial drug	accordance with current regulations.	ÿ	ÿ	
	- Principal researcher - Branch principal investigator and organizations and individuals having clinical reagents.		ÿ ÿ	ÿ ÿ (where required)	
	- Lead researcher/clinical trial recipient and local authority at the study site (if required).		ÿ		
1.7	Information provided to participants in clinical trials: - Research information sheet and Form - To confirm voluntary participation in the study (including research participants. all information	appropriate information to convey to the audience).	ÿ	ÿ	Form No. 08 Appendix III
			ÿ	ÿ	

	- Any other information in written form copy.	- To demonstrate that drug trial participants will be provided with relevant information in written form (content and wording) to fully support their decision to sign a Voluntary Study Participation Form.	ÿ	ÿ	
	Notice of selection of subjects to participate in the trial To demonstrate drug selection methods (if used). selection is appropriate and not coercive, ensuring ethics in research. To protect drug trial participants are compensated if they are injured during clinical trial participation.		ÿ		
1.8 Insurance contract			ÿ	ÿ	
1.9 Certificate of Approval Board Evidence of approval of ethical consent in biomedical research at all levels by	the Ethical Council in Biomedical Research at all levels. To confirm that the clinical trial of the drug by the	Ethics Council at all levels for the drug trials has been appraised by the Ethics Committee at			
1.10 Date the document was approved/commented	approved. To confirm the version number and approval date of the document (documents) - Research outline (including revised version); - Case report - Voluntary form to participate in drug trial - Other information in written form is provided to drug trial participants - Notice of participant selection (if used) - Compensation for participants (if any) - Any other document showing approval/approval 1.11 Decision to establish an Ethics Committee in	all levels and given the following approval/opinion:	ÿ	ÿ	Certificate of approval from the Ethics Council at all levels
To demonstrate that the national and grassroots biomedical research ethics committees in medical research	biologics was established in accordance with the requirements of the GCP and relevant regulations 1.12	Authoritative approval for formal approval of the research protocol authority. authority before commencing clinical trials under current regulations	ÿ	ÿ (where	Decision to establish the Council
		onion.	ÿ	requested)	Decision approving the outline of Minister of BYT
background and GCP certificate issued by the Ministry of Health of the forest investigator (including managers)	drug trials on the forest investigator (including managers) Principal Investigator and sub 1.13 Scientific drug trial participants, laboratories, etc.)	Proving capacity and suitability to conduct clinical trials, monitor and supervise medical care for dependents, pharmacists, nurses, technicians with	ÿ	ÿ	
1.14 GCP-certified clinical trial facility (Area To demonstrate the clinical trial facility's capacity, record-keeping area,	drug-prescribing area, equipment to meet monitoring and supervision, laboratory data, equipment for appropriate quality standards for research and testing. (standard laboratories approved by the Ministry of Health for clinical trial drug establishments.	conducting, recording, and reporting procedures.) are provided to the trial	ÿ	ÿ	
1.15 Sample of reagent label attached to clinical reagent	composition	To demonstrate compliance with relevant labeling regulations and the appropriateness of instructions provided to drug trial participants.		ÿ	
1.16 Guidelines for Reagent Administration To demonstrate the necessary instructions			ÿ	ÿ	

	clinical and related materials for the storage, packaging, reconstitution, testing (if not included in the protocol or destruction of clinical reagents and materials in the production with clinical related regulations. To demonstrate shipping date, batch number reagents and shipping related materials. Allows lot number tracking, verification of shipping				
1.17	Records of the shipment of clinically tested products and materials related to the drug trial	conditions and accountability. To prove the type, purity and strength of the product will be clinically tested. To demonstrate in an emergency. Blinded trial products can be disclosed without breaking the blinding principle to the remaining subjects being	ÿ	ÿ	
1.18	Certification of analysis of tested products	treated.		ÿ	
1.19	Re-coding procedures for blind clinical trials		ÿ	ÿ	
1.20	Standard Practices (SOPs) for the techniques used in the study	Prove and ensure the uniformity, science, objectivity, accuracy of the techniques used in the research.			
1.21	Random process or list	To demonstrate the method of random selection of test subjects.		ÿ	

Form 02 - List of essential documents in the process of conducting clinical drug research research

STT	file name	Purpose	Requirements for		Reference
			Researcher main individuals/receiving having drug reagents in clinical trials	Organizations, establishments	
2.1	Product Profile Updates	To demonstrate that researchers are promptly informed of information related to the study drug. To demonstrate that changes in clinical		ÿ	
2.2	Any changes to: - Research proposal - Voluntary form to participate in the study assist - Any other written information provided to trial participants - Notice for the selection of drug trial participants (if any)	trial-related records are in effect throughout the trial.	ÿ	ÿ	
2.3	Approval decision/certificate To demonstrate that the changes have been approved by the regulatory body/Regulatory body/Ethics Board under the following items: approval/approval. - Change of research proposal - Changes to: + Voluntary form to participate in the study assist + Any other information provided in writing to participants	To determine the version number and date of the lake Sister	ÿ	ÿ	

	+ Notice for the selection of participants (if any) + Any other documents giving consent + Annual appraisal 2.4			
Curriculum vitae, GCP Certificate Proving capacity and researchers to conduct clinical drug trials and medical supervisors adjusted normally in the medical/laboratory/engi	suitability to be issued by the Ministry of Health of clinical supervisors/managers 2.5 Laboratory/	ÿ	ÿ	
Medical facilities/laboratory/technical procedures/tests	during the test experience. Research outline 2.6	ÿ	ÿ	
	- Certificate - Established quality control and/or external quality assessment - Other validations 2.7	To demonstrate that testing remains appropriately maintained throughout the testing period.	ÿ	ÿ
Documentation of the shipment of test products and test-related materials 2.8 Test certificates for new batches of test products			ÿ	ÿ
				ÿ
2.9 Reporting on monitoring sessions		To demonstrate the monitoring and the results of the monitoring sessions. To record any		ÿ
communication other than substantial discussion of field AE/SAE report. - Letters - Meeting memos - Call Memorandums 2.11 Research	agreements and arrangements 2.10 Other forms of	protocol violations, conducting drug trials, reporting	ÿ	ÿ
Information Statement and To Prove the Eligibility of the and protocol, signed prior to the subject taking pa document includes original information regarding	Voluntary Form The study volunteer form with GCP To prove the existence of signed consent directly. with the data obtained through tests and the Subject's medical history. To demonstrate that the investigator		ÿ	
2.12 Source documents		or an authorized member of the Principal Investigator takes notes to confirm observations. To substantiate all changes/additions or corrections to the medical record after data collection commenced were recorded.		
2.13 Signed, signed and completed medical records			ÿ (copy)	ÿ (original)
2.14 Documentation of medical record correction			ÿ (copy)	ÿ (original)
2.15 SAE reporting to sponsors		SAE report of the main investigator for organizations and individuals having clinical reagents.	ÿ	ÿ
2.16 SAE reporting to the Ethics Council SAE reports of		organizations and individuals have	ÿ	ÿ

		clinical reagents and principal investigator for the Ethics Council Notice of organizations and			
2.17	Notice of organizations and individuals having to researchers about safety information about information safety of reagents and concurrent drugs.	individuals having clinical reagents for clinical trials	ÿ	ÿ (where required)	
2.18	Midterm or annual reports Ethics Committee and to the co-ethical and governing body. physical.	Midterm or annual reports to the Society to the	ÿ	ÿ (where required)	
2.19	Subject Identifier List To demonstrate that the primary investigator/recipient of the clinical trial maintains	a confidential list of trial participants' names associated with trial numbers to identify participants drug trial.	ÿ		
2.20	Logs where the number of subjects participated To demonstrate participation in order	duration of subjects by trial number 2.21 Explanation of study product in place To demonstrate that the trial	ÿ		
product	was used according to protocol. To verify the signatures and initials of those authorized to participate identification of stored samples if experiments need to be repeated.	and/or edit medical records. To confirm storage and	ÿ	ÿ	
2.22	List of signatures		ÿ	ÿ	
2.23	Records of tissue/biological fluid samples have been archived (if needed)		ÿ	ÿ	

Form 03 - List of essential documents after the end of clinical trial studies

Upon completion or cessation of testing, all documents identified in sections 1 and 2 should be documented with the following sections:

STT	file name	Purpose	Requirements for		Reference
			Research staff with research facility ÿ	organization, fish main drug/clinical	
3.1	Explanation of research products To demonstrate that clinical reagents used at the trial site were in accordance with the study protocol, were received at the study site, were distributed to subjects, were	paid by the subjects in return, have been returned to organizations or individuals that have clinical trial drugs. To confirm the destruction of unused clinical reagents is carried out by the organization or individual (if canceling at the place of			
3.2	Disposal of clinical reagents	clinical reagents or at the place of research and research) in accordance with current regulations.	ÿ	ÿ	
3.3	List of identifiers To allow identification of all subjects who participated ÿ completed subjects in the trial in the event that follow-up is required. This list must be kept confidential for an agreed time. To demonstrate that all required documents assist	for trial termination have been completed, and copies of activities conducted have been maintained in the appropriate files.			
3.4	Monitoring report on the end of drug trial			ÿ	
3.5	Periodic and irregular monitoring reports	Demonstrate the trial's compliance with the study protocol, GCP, and relevant regulatory requirements. In order for organizations and individuals with clinical reagents to know	ÿ	ÿ	
in	properly performing grouping, as well as to know the necessary cases of decoding for blind decoding appropriate when a serious adverse event occurs.	and 3.6 Guidelines for treatment grouping and unblinding		ÿ	
3.7	Written reports and proposals To confirm completion of a drug trial		ÿ		

	approval of drug test results on the clinical of the study main member to the Religious Council ethics and governing bodies	on clinical.			
3.8	Full text report of results clinical trial of drugs ready	To confirm the results and interpret the trial clinical drugs.	ÿ	ÿ	Model No. 12 Appendix III
3.9	Patient database Vietnam (in case there are request)	To check the accuracy and truthfulness of the results research.	ÿ	ÿ	

Form 04 - Report of a serious adverse event in a clinical trial

Reporting number of the unit: ……

SAMPLE FOR REPORTING SERIOUS ADVERSE EVENTS (SAE) IN CLINICAL TRIAL RESEARCH

1. SUMMARY OF REPORT

Report Type: ÿFirst Report ÿAdditional report

Classification according to the severity of the event:

ÿ Death
ÿ Life threatening
Hospitalization/prolonged hospital stay Birth defects/fetal malformations
ÿ Disability/permanent/serious disability
ÿ Requires medical intervention to prevent one of the situations on or judged to be medically significant by the investigator or principal investigator

Research name ……..

……

Study Design If this is a blinded study, will SAE lead to an open-blind?
ÿ Open label ÿ Single blind ÿDouble Blind
Yes No No information available

Donors ……

Name of principal investigator ……

SAE . recognized research points ……

When to receive information about SAE ……

Time of appearance of SAE ……..

SAE end time (or check ***"Ongoing"*** box if SAE is ongoing) …… ÿ Ongoing

SAE name (diagnosis of SAE or major symptoms of SAE) ……

……

Abbreviated name of participant in clinical trial Participant's number in clinical trial **2. DESCRIPTION OF CHARACTERISTICS AND MANAGEMENT of SAE**

Provide information on signs, clinical symptoms, laboratory tests related to SAE, measures to manage SAE if any (including including discontinuing/ reducing the clinical trial drug/ research protocol), developments after taking such measures, and information needed other equipment with specific timelines (if any).

……

……

……

……

……

Result after SAE treatment:

ÿ Recovering without sequelae ÿ Recovering but leaving sequelae **3. CLINICAL TRIAL** ÿ Recovering Not Recovering ÿ Death (date of death: ……..) No information available

PARTICIPANTS

Date of birth ……

Age ……

Sex Male Female For women: ÿ Pregnant (week ...)

Weight (Kg) ……

Medical history related to SAE……

……

4. CLINICAL TRIAL DRUGS/RESEARCH PROGRAMS

TT	Clinical reagents or research protocol save(a)	Dosage form, content	Route of Administration Dosage		Date *(day month Year)*	
					Begin	End
I						
II						
III						
IV						
IN						
WE						

(a) Specify the clinical trial drug/research protocol used by the clinical trial participant. With blind studies and SAE no leading to blind/unidentifiable clinical reagents/research protocols used by clinical trial participants, recording specify the protocol to be applied in the study and arm of the clinical trial participant (described in section 2) (if have information).

5. INTERVENTION FOR CLINICAL TRIAL DRUG/RESEARCH REGION AFTER SAE Occurrence

STT (b)	Is it possible to stop/reduce the dose of reagents? clinical/research protocol on drug trial participants on Clinically experiencing SAE?		If stopping/reducing the dose of a clinical trial drug clinical trial/protocol (or open-blind), Has the severity of SAE been improved? are not?			If reusing clinical reagents/research protocols, Did the event happen again?			
	Have	No	Have	No	Not available information	Have	No	There is no information believe	Do not reuse use
I	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ
II	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ
III	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ
IV	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ
IN	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ
WE	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ	ÿ

(b) The serial number (STT) corresponding to item 4.

6. MEDICATIONS/PRODUCTS CONTRAINDICATIONS MAY BE INDIRECTED TO SAE BY RESEARCH TABLETS (excluding drugs used to manage SAE)

STT	Concomitant drug/preparation (name original, trade name)	Dosage form, strength Dosage route Dosage Date of use *(day/ month/ year)*				
					Begin	End
1						
2						
3						

4						
5						
6						

7. ASSESSMENT OF THE RESEARCH AND MEDICAL STUDENT RESEARCH CLINICAL TRIAL/RESEARCH RECOGNITION

STT (b)	Evaluation of the cause-and-effect relationship between SAE and clinical drugs research protocol/plan			If relevant, is this an expected or unexpected reaction? opinion of the clinical trial drug/research protocol?(c)	
	May be related	Not related Not yet concluded		Known/expected	Out of expectation
i	ÿ	ÿ	ÿ	ÿ	ÿ
ii	ÿ	ÿ	ÿ	ÿ	ÿ
iii	ÿ	ÿ	ÿ	ÿ	ÿ
iv	ÿ	ÿ	ÿ	ÿ	ÿ
in	ÿ	ÿ	ÿ	ÿ	ÿ
we	ÿ	ÿ	ÿ	ÿ	ÿ

(b) The serial number (STT) corresponding to item 4.

(c) Whether SAE is ***"expected"*** or ***"unexpected"*** should be assessed against the literature relevant to the clinical trial/protocol study as the most up-to-date study protocol if the clinical trial is not yet licensed, or the version is new of the User's Guide if the clinical reagent has been approved for marketing registration.

- Explain the rationale for the causal assessment and the predictive nature of the SAE:

……

……

……

- How many SAEs or similar AEs have occurred in this study up to the time of reporting:

+ At the study site, SAE/AE mentioned in this report was recorded: ……

+ At other research sites: ……..

8. OPINION OF THE REPRESENTATIVE OF THE Ethics Council/Scientific Council of the FOREST REPRESENTATIVE DRUG TRIAL COUNCIL READY (if any)

Recommendations for participants in clinical trials *(not applicable in case of death of clinical trial participants):*

ÿ Continue to participate in research ÿ Pause to participate in the study ÿ Withdrawal from the study

Recommendations for research:

ÿ Continue to research **other Proposals** ÿ Suspension of research implementation ÿ Stop conducting research

(if any):

……

……

……

9. REPORTER (lead researcher or authorized researcher)

Signature: ……..

Date of signing ***(day/ month/ year):*** ……..

Full name: ……..

Position, department/department: ……..

Phone number: ……..

Email address: ……..

REPRESENTATIVE OF THE Ethics Council / SCIENTIFIC COMMITTEE OF THE BASIC RECEIVING THE CLINICAL TRIAL *(signature, full name)(d)* (d)Applicable only if there are opinions in section 8.

BASIS LEADERSHIP RECEIVE CLINICAL TRIAL *(signature, full name and stamp)*

APPENDIX II

GENERAL DOCUMENTATION ON CLINICAL DRUG BASIS

(Issued together with Circular No. 29/2018/ TT-BYT dated October 29, 2018 of the Minister of Health)

I. Overview of the overall profile of the clinical trial facility

II. Overall profile content:

1. General information about the establishment (administrative, legal and related information);

2. Dossier on technical standards of facilities serving clinical trial of drugs;

3. Professional and technical documents, standard practice procedures (SOPs) serving clinical trials;

4. Records of personnel serving clinical trials;

5. Quality management system applied in clinical drug trial;

6. Internal supervision.

I. OVERVIEW OF THE GENERAL DOCUMENTATION OF THE ESTABLISHMENT

A drug trial facility master file is a document prepared by a clinical trial establishment and includes clear and specific information on the technical and professional standards for clinical trials, quality management policy, quality control for drug testing activities carried out at the establishment to serve the management, planning, inspection and assessment of GCP compliance effectively.

The overall profile must include complete information, but it should preferably not exceed 25 - 30 pages including the attached appendix. Focus should be on general information, general drawings and layout diagrams of the facility rather than verbal descriptions.

The clinical trial establishment's master record is part of the establishment's quality management system documentation and should be updated on a regular basis. The overall record should be reviewed periodically to ensure it is up-to-date and representative of the establishment's current operations, clearly marked with the version number, effective date, and date reviewed. . Each addendum can have its own effective date making the annex update process independent.

The update and revision history of the Master Profile is considered a part of the Master Profile, which summarizes the changes to the content of the Master Profile and its appendices, the time of the change, the reason for the change. change.

II. GENERAL PROFILE CONTENT

1. General information about clinical trial facilities

1.1. Contact information of drug testing facility

- The official name and address of the establishment;

- Name and detailed address of the facility where the drug is being clinically tested;

- Contact information of the establishment, including the 24-hour phone number of the person responsible for ensuring the safety and health of drug trial participants;

- Other positioning information (if any): GPS coordinates, postal code...

1.2. Licensed activity of the establishment

- A copy of the operation license, the business registration certificate (if any), legal documents on the establishment and functions and duties of the non-commercial clinical trial facility, the certificate receive the eligibility for pharmacy business (if any) granted by a competent authority;

- Brief description of drug trial activities and other activities approved by the competent regulatory authority (if any), including those assessed by the foreign regulatory authority, information information about the scope not specified in the certificate of eligibility for pharmacy business;

- A list of GCP-responsive tests and assessments conducted at the facility during the past 5 years, including information on the date and name of the agency competent to conduct the inspection. Copy of current GCP Certificate (if any).

1.3. Other related activities performed at the facility

- Description of clinical trials of non-drug products at the site (if any).

2. Dossier on technical standards of facilities serving clinical trial of drugs

- Brief description of the facility: List, address, area of areas, rooms/offices/departments;

- Simple description information about clinical area, laboratory, storage area for biological samples, research drugs, storage area for records, research documents, clinical trial management department clinical, Ethics Council office, area for phase 1 clinical trial or bioequivalence trial (if applicable);

- Design drawings, layout of clinical area, laboratory, storage area for biological samples/research drugs, storage area for documents, clinical trial management department, office Chamber of Ethics Council in Biomedical Research at grassroots level and phase 1 clinical trial area (if any);

- Description of the laboratory quality assurance system;

- List of main equipment for clinical trial;

- Other relevant information in case of necessity as prescribed in Article 12, Appendix I of this Circular.

3. Professional and technical documents, standard practice procedures for clinical trial of drugs

- Brief description of the documentation system at the establishment (eg electronic document system, hard copy);

- A list of regulations, dossiers and documents related to drug activities as prescribed in Article 13, Appendix I of this Circular;

- List of standard practice procedures for activities in clinical trials;

- For documents and records preserved or stored off-site: List of types of documents/records, name and address of information storage facility, calculate the amount of time required to retrieve information from those external documents.

4. Profile of personnel serving clinical trials

- A preliminary description of the number of personnel involved in the management and implementation of clinical trials;

- List of personnel of the institution as prescribed in Article 14, Appendix I of this Circular: name, title, academic title/diploma (if any), diploma, professional certificate, certificate of course completion GCP study, course completion certificate, clinical trial safety reporting, clinical trial assignment, and other relevant information;

- Dossier of ethics council in biomedical research at grassroots level as prescribed in Circular No. 45/2017/TT-BYT November 16, 2017 by the Minister of Health.

5. Quality management system applied in clinical drug trial

5.1. Quality management system of the establishment

- Brief description of the establishment's quality management system and applicable standards;

- responsibilities related to the maintenance of the quality system, including senior management;

- Information on activities that have been audited, including the date and content of the certification, and the name of the certification body;

- The personnel chart should show the arrangement of personnel in the quality management system, the main positions of responsibility, including senior management and trained/authorized personnel (manager positions). quality control, quality control, etc.).

5.2. Management of affiliate contract facilities (in case of association with other establishments)

- Summary of the affiliate facility and external audit program (if any);

- Summary of the affiliate contract basis rating system;

- Summary of responsibility sharing between the contractor and the contract recipient for compliance with quality assurance regulations.

5.3. Quality risk management

- Brief description of the Quality Risk Management (QRM) method used at the establishment: purpose,
work...

6. Internal monitoring

Brief description of the establishment's monitoring system, self-monitoring results, and the establishment's GCP self-assessment, focusing on the following areas: monitored according to the plan, regulations and monitoring activities.

Appendix I:	Copy of Operation License, Business Registration Certificate, Legal documents on establishment and function duties of a non-commercial clinical trial facility, Certificate of eligibility for business pharmacy (if any), copy of current GCP certificate (if any).
Appendix II:	Schematic drawing of facilities for drug testing.
Appendix III:	List of main equipment for drug testing.
Appendix IV:	List of SOPs for related activities in drug testing.
Appendix V:	Organization chart, personnel, drug testing service, copies of diplomas, certificates and related certifications.
Appendix VI:	List of affiliate contract establishments (address, contact information, specialized fields of contract...).

APPENDIX III

TEXT FORM

(Attached to Circular No. 29/2018/ TT-BYT dated October 29, 2018 of the Minister of Health)

Model number 01	Application for GCP . Satisfaction Assessment
Model number 02	Sample report on assessment of response to Good Clinical Practice
Model number 03	Certificate of GCP
Model number 04	Application for periodic assessment of maintenance of GCP
Model number 05	Change report
Model number 06	Application for registration of a clinical trial of a drug
Model number 07	Application for approval of a clinical trial of a drug
Model number 08	Explanation of clinical trial research protocol
Model number 09	Research information sheet and volunteer research form of participants in clinical trials ready
Model No. 10	Application for approval of changes to clinical trial drug research
Model No. 11	Application for approval of clinical trial results
Model No. 12	Full text report on clinical trial results
Model No. 13	Written approval of clinical trial drug research
Model No. 14	Decision approving clinical trial results

Form No. 01 - Application for assessment of GCP satisfaction

NAME OF MANAGER UNIT
FACILITY NAME

Number: ……/…….

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

……, day ….. month… year 20…

APPLICATION FOR CLINICAL TRIAL GOOD PRACTICE RESPONSE ASSESSMENT

Dear: Department of Science, Technology and Training/Drug Administration - Ministry of Health

Name of establishment: ....

Address: ....

Phone/fax/email: ....

Contact person: …….. Title: …… .....

Phone/fax/email: ....

Implement Circular No. /2018/TT-BYT dated ... month ... 2018 of the Ministry of Health stipulating on clinical trial of drugs, after conducting self-assessment to meet GCP requirements dated ... month ... year..., respectfully request the Ministry of Health (Department of Science, Technology and Training/Drug Administration) to be assessed for GCP satisfaction and granted a GCP Certificate for the scope in regulations on our mission function.

[Name of establishment] attach the following documents to this application:

1. Legal documents on the establishment and functions of the unit;

2. Overall profile of the clinical trial facility.

Head of the facility
(Signature, full name, stamp)

Form No. 02 -Form of Assessment Report on Good Practice in Clinical Trials

MINISTRY OF HEALTH
PUBLIC SCIENCE DEPARTMENT
TURMERIC
AND TRAINING/
DRUG ADMINISTRATION

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom
- Happiness

……, date… month… year 20….

EVALUATION REPORT

“GOOD PRACTICE OF DRUG CLASSIFICATIONS”

I. GENERAL INFORMATION OF THE ESTABLISHMENT

- Name of establishment: ...

- Address of premises to be checked: ...

- Phone:...

- Establishment Decision No.: ...

- Legal representative: ...

Professional responsible person:...

II. GENERAL INFORMATION OF REVIEW BOOKING

- Evaluation time: ....

- Last pre-assessment time: ...

- Evaluation form:...

- Scope of assessment: ...

III. INFORMATION ABOUT THE ASSESSMENT TEAM

- Decision No. ……., dated …….. by the Director of the Department of Science, Technology and Training/Drug Administration, Ministry of Health on the establishment of the GCP meeting assessment team, at...

- The composition of the evaluation team includes: ...

IV. ACTUAL ASSESSMENT

After appraising the dossier, listening to the facility's report and conducting the actual assessment, the assessment team had some comments as follows:

The facility has implemented activities according to the principles and standards of "Good clinical practice" of the Ministry of Health, specifically:

1. Facilities:

a) Clinical area:

b) Laboratory:

c) Area to preserve biological samples and research drugs; archiving research files and documents:

d) Clinical trial management department:

e) Office of the Ethics Council in Biomedical Research at the grassroots level:

f) Equipment for clinical trials:

2. Professional technical documents, quality management:

a) Professional and technical documents:

b) Quality management system applied in clinical drug trial according to standards appropriate to the type of research

3. Human Resources

a) Professional standards of researchers

b) Criteria of the principal investigator

c) Member of clinical trial management department

d) Ethical Council in grassroots biomedical research

4. Other content (if any)

V. LIST OF EXISTS

The detected shortcomings must be listed, classified and referenced to the articles and clauses in the Circular on clinical trial of drugs.

STT	Exist	Reference	classification
1.	**Infrastructure**		
1.1.			
2.	**Technical documentation**		
2.1.			
3.	**Personnel**		
3.1.			
4.	**Other existence (if any)**		
4.1.			
Summary of the problems:	Serious: 0 Weight: 0 Light: 0 Recommendation: 0		

BECAUSE. CONCLUSION OF THE ASSESSMENT

TEAM LIVE

VII. OPINION OF FACILITIES

……

……

……

The audit minutes are read, approved and agreed upon between the evaluation team and the establishment. The assessment record is made in 03 copies: The establishment keeps 01 copies, the evaluation team keeps 02 copies./.

Evaluation team **Representative of grassroots leadership**

Secretary **Team manager**

Form No. 03 - Certificate of GCP

MINISTRY OF HEALTH
DEPARTMENT OF SCIENCE AND TECHNOLOGY AND TRAINING/ DRUG ADMINISTRATION

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No./ No.: _ _ _/_ _ _/GCN-K2ÿT/QLD

CERTIFICATE OF GCP

Pursuant to Circular No. ……/2018/TT-BYT dated.../.../2018 of the Minister of Health providing for clinical trial of drugs

The Department of Science, Technology and Training/Drug Administration certifies:

Name of clinical trial facility: ...

Facility address:...

Number of Business Eligibility Certificate (if any): number of days month year

List of clinical areas/laboratory (in case the vaccine testing facility has a cooperation contract with a specialized facility):

Based on the report on assessment of GCP compliance of a clinical trial facility made on a date...the clinical trial is recognized as five ..., drug testing facility in the forest meeting the standards of Good Clinical Practice (GCP) according to regulations. Decree No. .../2018/TT-BYT dated ... may ... of the Minister of Health.

This certificate represents the clinical trial facility's GCP compliance status at the time of the above assessment and is not valid. more than 3 years from the date of the most recent assessment. However, the validity period of the Certificate may be shortened or extended depending on the specific cases as prescribed in Circular No. .../2018/TT-BYT dated ... month ... five ... of the Minister of Health.

……/……/……

Recipients: **DIRECTOR**

Form No. 04 - Application for periodic assessment of response to Good Clinical Practice

NAME OF MANAGER UNIT
FACILITY NAME

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number: …… / ……..

……, date …… month ….. 20…….

APPLICATION FOR ASSESSMENT OF RESPONSIBILITIES

Uh oh oh oh oh oh oh

GOOD PRACTICE IN CLINICAL DRUG TRIAL

Dear: Department of Science, Technology and Training/Drug Administration - Ministry of Health

Facility name:

Address:

Phone/fax/email:

Contact: Title:

Phone/fax/email:

Implement Circular No. /2018/TT-BYT dated ... month ... 2018 of the Minister of Health on regulations on clinical trial of drugs, after being granted GCP Certificate No.../ GCN-K2ÿT/QLD dated ... month ... ..., respectfully request the Ministry of Health (Department of Science, Technology and Training/Drug Administration) to periodically evaluate the maintenance of GCP compliance. ***(and issue a GCP Certificate - if the facility requests it).***

[Name of facility] enclose this application with the following documents:

1. Updated technical documents on the facility's physical, technical and personnel conditions (if any);

2. A summary report on the establishment's clinical trial activities in the last 3 years from the time of the preceding evaluation.

Head of the facility
(Signature, full name, stamp)

Form No. 05 - Change report

NAME OF MANAGER UNIT
FACILITY NAME

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

Number: …… / ……..

……, date …… month ….. 20…….

CHANGE REPORT

ON CLINICAL TRIAL GOOD PRACTICE

Dear: Department of Science, Technology and Training/Drug Administration

Name of establishment: ....

Address: ....

Phone/fax/email: ....

Contact person: …….. Title: ……

Phone/fax/email: ....

Professional person in charge: ……., Year of Birth: .....

Number of medical/pharmaceutical practice certificates:

Issued by ……; year of issue ……, valid up to ……(if any)

Has been granted the Certificate of eligibility for business (if any) number…….date…….month…….year with the scope:

GCP Certificate No..date....month...year has been granted:

The establishment reports the following changes:

Content changes	List of documents related to the change

1.	
2.	

We undertake to fully comply with relevant legal documents, regulations and regulations on clinical drug testing. Request the Department of Science, Technology and Training/Drug Administration to consider and evaluate the facility's GCP compliance with the above changes.

[Name of establishment] attach the following documents to this application:

1. A copy of the Certificate of GCP attainment;

2. A copy of the business registration certificate (or legal document on the establishment and functions and duties of the non-commercial clinical trial drug establishment);

3. The establishment's overall profile has been updated with the changes.

Head of the facility
(Signature, full name, stamp)

Form No. 06 - Application for registration of clinical trial of drugs

SOCIALIST REPUBLIC OF VIETNAM Independence -
Freedom - Happiness

……, day month Year

APPLICATION FOR A CLINICAL TRIAL TRIAL

To: **Ministry of Health (Department of Science, Technology and Training)**

Organizations and individuals having drugs for clinical trial:

Trading address:

Phone: Fax:

Email:

Register for a clinical trial drug study with the following contents:

Drug name:

- Concentration:

- Content:

- Dosage forms:

- Usage route:

Classify:

- Pharmaceutical drugs:

- Medicinal drugs:

- Traditional medicine:

- Vaccine:

- Biosimilar drugs:

- Medical biologicals used to treat:

Suggested clinical trial phase:

or suggest a clinical trial from: to stage:

The drug completed the study at the stage:

Proposal of principal investigator:

Proposal for a business providing clinical trial services:

Attached documents include:

…

Representative of an organization or individual having drugs for clinical trial *(signature and seal)*

Form No. 07 - Application for approval of a clinical trial of a drug

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

……, day month Year ...

APPROVAL FOR APPROVAL TRIAL RESEARCH IN CLINICAL DRUG

To: **Ministry of Health (Department of Science, Technology and Training)**

Full name of the principal investigator:

Clinical trial facilities:

Work address:

Phone: Fax:

Email:

Proposing the Ministry of Health to approve a clinical trial of the drug:

Drug name:

- Lot number:

- Concentration:

- Content:

- Dosage forms:

- Usage route:

- Due date:

Classify:

- Pharmaceutical drugs:

- Medicinal drugs:

- Traditional medicine:

- Vaccine:

- Biosimilar drugs:

- Medical biological products:

Suggested clinical trial phase:

or suggest a clinical trial from: to stage:

The drug completed the study at the stage:

Attached documents include:

1.

2.

3.

The main researcher and the clinical trial establishment commit to absolutely not having any conflicts of interest between the parties involved in the clinical trial, strictly complying with the research protocol approved by the Ministry of Health. approval and principles of Good Clinical Practice.

Principal investigator
(signature)

Head of clinical
trial facility *(signature, stamp)*

Form No. 08 - Explanation of the clinical trial research protocol

Outline explanation

clinical trial study

I. General information about clinical trial studies (TNLS)

1. *Research name* …….. ……..	**2. *Code*** ***……*** ***……***
3. *Implementation time:* (From month ...../20... to month ...../20....)	**4. *Management level*** NN The set/ CS Conscious

5. *Funding*

Total: ……

In which, from the Budget of SNKH: ……

From other sources (specify source): ……

6 Request for a phased TNLS research (specify): Or request to be researched in different stages (specify):		

7 *Principal Researcher*

First and last name: ……

Academic title, degree: ……..

Scientific title: ……

Phone: …….. (CQ)/ …….. (NR) …….. Fax: ……

Mobile: ……

E-mail: ……

Work address: ……..

Home address: ……..

8 ***Business establishments providing clinical trial services***

Name of agency or organization: ……..

Phone: …….. Fax: ……. E-mail: ……..

Address: ……..

9 ***Agency or individual that orders clinical trial of drugs (is an agency that has the right to use the copyright on the product to launch a trial and use the results of the trial to be able to put the product into production or put it to use in the real world). economy, or included in research at the next s***

Organization Name: ……

Phone: …….. Fax: …….. E-mail: ……

Work address: ……..

Full name (if individual ordering):

Academic title, degree: ……

Scientific title: ……

Phone: …….. (CQ)/…….. (NR) ……..Fax: ……..

Mobile: ……

E-mail: ……

Work address: ……

Home address: ……..

****Note:***

In the event that organizations and individuals find it necessary to present, supplement and clarify certain items of this Note, a longer presentation can be made, with an unlimited number of pages of the Note.

II. S&T content of research

(Explain the sections required by the Clinical Trials Regulations with content by trial phases)

10 ***Objectives of the study***

11 ***Research situation at home and abroad •***

Overview of research products

• Clinical trial study overview:

Foreign:

Domestic:

12 ***Approaches, methods and content of research, techniques will be used: Please present clear arguments for approach, research design, sampling method, sample size, and criteria for selecting research subjects. , research methods, techniques to be used, standard operating procedures (SOPs) for each technique used in the study - comparison with other similar resolution methods, research objectives , technical means, equipment to determine the research evaluation criteria)*** **12.1 Research location:**

12.2 Research time:

12.3 Research Methods: Describe the type of trial (randomized, blind, open), design of the trial (parallel groups, paired technique), blind technique (double-blind, single-blind), and random selection methods and procedures.

12.4 Research subjects: Description of research subjects (selection and exclusion criteria of potential subjects), standard practice procedures (SOPs) for the selection of research subjects: methods , criteria and time of assigning subjects to study groups.

12.5 Sample size: The number of subjects needed to achieve the test objective, based on statistical calculations.

12.6 Research drug regimen: Developing standard operating procedures (SOPs): Describe and clearly describe route of administration, dose, interval of administration and duration of treatment for the study product and the product compared. compare. Person in charge, technique and manipulator of drug administration. Monitoring and evaluation metrics. The dose-response relationship should be considered.

12.7 Concomitant treatment: Any other treatment that may have been identified or authorized for concomitant use.

12.8 Tests used: Development of Standard Procedures (SOPs): Clinical and laboratory tests, pharmacological analysis, etc... tests performed. Responsible person, sampling procedure, storage, technique. Evaluation criteria, compare results.

12.9 Assessment of adverse reactions: Description of how response is documented (describe and evaluate method and frequency of measurement), monitoring and measurement procedures to determine compliance treatment among the study subjects.

12.10 Subject Exclusion Criteria During Study: Exclusion criteria for study subjects and indications for termination of the entire study or part of the study.

12.11 Recording and reporting side effects: Methods for recording and reporting reactions or incidents, and provisions relating to compliance.

12.12 Blinding and Identity Protection Techniques: Procedures for maintaining identification lists, treatment records, randomization lists, and/or field report forms composites (CRFs). Records should allow for individual identification of patients or participants as well as for examination and reconstruction of data.

12.13 Unlocking Regulations: Information on setting up test codes, where to keep lists and who, when, and how to unlock them in an emergency.

12.14 Research Product Storage: Measures taken to ensure the safe packaging and storage of study and comparative products if used, and to promote and determine regulatory compliance treatment and other instructions.

12.15 Outcome Evaluation Method: Describes the method used to evaluate outcomes, (including statistical methods) and reports on patients or participants who dropped out of the trial.

12.16 Methods of dealing with adverse events

12.17 How information is provided to subjects: Information presented to test subjects, including how they will be informed about the trial, and when and how their consent was obtained.

12.18 Training for Research Teams: Training for researchers involved in clinical trials (including: Project manager, branch project manager, coordinator, researchers, pharmacists, nurses, technicians) including: Basic content research publications, information on how to conduct trials, and standard practices (SOPs) for drug administration and use.

12.19 Ethical issues: Ethical considerations and measures related to testing.

12.20 Post-trial medical care: Medical care provided after the trial, post-trial treatment.

12.21 Implementation plan

12.22 Monitoring, supervision and inspection plan:

- Supervision of Principal Investigator and research team

- Sponsor's supervision

- Supervision and inspection by the Management Authority, the Ethics Council.

12.23. Standard Practice Procedures (SOPs) of the study

Ethical issues in biomedical research:

(Including: Information about the study, Information sheet and volunteer form to participate in the research, Commitment to implementing the guidelines) ethical guidelines in research)

13 *International Cooperation*

Collaborative content	Partner name

14 *Implementation progress*

TT	Main contents and tasks performed **(Main milestones)**	Products must pass	Time (BD-KT)	Person or agency implementing
1	*2*	*3*	*4*	*5*

III. Results of the study

15 *Type of expected outcome of the study*

I	II	III
ÿ	ÿ	ÿ Diagram
ÿ	ÿ	ÿData Table
ÿ	ÿ	ÿ Analysis report
ÿ	ÿ	ÿ Forecast document
ÿ		ÿ Treatment Procedures
ÿ		ÿ

IV. Organizations/individuals participating in the research

16	***Activities of coordinating organizations participating in the implementation of the research*** (Insert all organizations that cooperate in carrying out the research and content of work involved in the study)		
TT	Organization Name	Address	Activity/contribution to research
1			
2			
3			

17 ***Team of Researcher - Collaborator - Research Coordinator***

TT	First and last name	Scientific title- Working agency	Proof take already medicine dig create about GCP
A Principal Researcher			
B Staff participating in the study			
1			
2			
3…			

V. Funding for research and funding sources (for a detailed explanation, please see the attached appendix)

Unit: million VND

18 ***Funding for conducting research by expenditures***

TT	Funding	total	In there				
			Contract hire specialize	Raw materials, things whether, power quantity	Machinery equipment hook	Construction, repair small cure	Other expenses
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*
	Total cost						
	In there:						
1	SNKH budget						
2	Other sources of capital (specify)						
	-Sponsorship, orders from organizations and individuals						
	- Other (mobilized capital, own capital...)						

……., day month Year 20....

Chief
clinical trial facility
(Full name, signature and seal)

Principal Investigator
(Full name, first name and signature)

……, date ….. month …… year 20....

Director
Department of Science, Technology and Training

RESEARCH ESTIMATES

Unit: million dong

TT	Contents of expenses	*total*		*Capital*		

	Expense	Ratio (%)	NSSNKH	Sponsor	Other
1. Professional contracting					
2. Raw materials, materials, energy					
3. Specialized equipment and machinery					1
4. Construction and minor repair					
5. Other expenses					
total					

Explanation of expenses

(Million dong)

Clause 1. Professional contracting

TT	Contract content	Total cost	Capital		
			NSSNKH	Sponsor	Other
Add					

Clause 2. Raw materials and energy

TT	Content	Unit of measure	Quantity	Unit Price	To Money	Capital		
						NSSNKH	Sponsorship	Other
2.1 Raw materials, materials								

2.2 Tools and spare parts							
2.3 Energy, fuel							
- Than							
- Electricity	kW / h						
- Petroleum							
- Other fuels							
2.4 Water	m^3						
2.5 Buy books, documents, data							
Add							

Clause 3. Specialized equipment and machinery

TT	Content	Unit of measure	Quantity	Unit Price	To Money	Capital	
						NSSNKH Sponsorship	Other
3.1 Purchase of technological equipment							
3.2 Purchase of test and measurement equipment							
3.3 Equipment depreciation							
3.4 Equipment rental							
3.5 Transport and installation							
							\ i mi

Add								

Clause 4. Construction and minor repair

TT	***Content***	***Expense***	***Capital***		
			NSSNKH	***Sponsor***	***Other***
	laboratory 4.1 Construction cost of maintenance workshop,				
	repair 4.3 Cost of installation of electrical and water systems				
	4.4 Other expenses				
	Add				

Clause 5. Other expenses

TT	***Content***	***Expense***	***Capital***		
			NSSNKH	***Sponsor***	***Other***
	5.1 Business expenses				
	5.2 Facility management				
	5.3 Cost of assessment, inspection and				
	acceptance - Cost of appraisal - Cost of				
	application review				
	- Cost of supervision				
	- Cost of intermediate inspection and acceptance				
	- Cost of internal acceptance				
	- Official acceptance fee				
	5.4 Other expenses				
	- Train				
	- Conference				
	- Printing documents, stationery				
	- Document translation				
	……				
	5.5 Researcher allowance Plus				

Form No. 09 -

The research information sheet and the participant's volunteer form to participate in the study in clinical trials (ICF)

Research name:

Version: ICF Day ……/……/……...

Name of organization or individual having drugs in clinical trial:

Subject code: ……..

This document is fully communicated to the study participants, no pages or sections of this document should be omitted.
The contents of this document need to be clearly explained orally to the study participants.

1. State the issues related to the study, the purpose of the study, the expected duration, the method of conducting (specify what is being tested)

2. Object selection criteria

3. Exclusion criteria from the study

4. Who will evaluate the personal and medical information to select you/... to participate in this study?

5. Number of people who will participate in the study

6. Describe the risks or disadvantages

7. Describe the benefit to the audience or to others

8. What you/yourself/... was paid in the research

9. Alternative method or treatment

10. How to keep personal records confidential

11. Specify the subjects to be approached to inspect, check and monitor your records...

12. Compensation or care, treatment if a health incident occurs

13. Person to contact when you have questions related to research

Specifying that participation is voluntary, you have the right to refuse to participate or stop participating at any time during the study period while still being guaranteed medical care.

Signature of the subject participating in the study

Voluntary ballot signing date

Volunteer application

I,

_____

Confirm that

• I have read the information provided about the study……. in the research brochure and the research volunteer form, version, date ..../…/….., …… Page). I was well explained by the research staff about the study and the procedures for volunteering to participate in the study.

• I have had the opportunity to ask questions about the research and I am satisfied with the answers given.

• I had the time and opportunity to consider participating in this study.

• I have understood that I have a right to access to the information described in the Research Information Sheet.

• I understand that I have the right to withdraw from the study at any time for any reason

• I agree that the doctors who are treating me (if any) will be notified of my participation in the study.

Tick the appropriate box:

Have: ☐ **No:** ☐

I agree to participate in this study.

Participant's signature ……	Day month Year ……

Necessary,	
*Signature of witness ……..	Day month Year ……
* Name of witness ……..	Day month Year ……
Signature of the person taking the research information sheet and the volunteer form to participate in the study assist ……..	Day month Year ……
The name of the person who received the Research Information Sheet and the research volunteer form ……..	

Form No. 10 - Application for approval of changes to clinical trial drug research

**SOCIALIST REPUBLIC OF VIETNAM Independence -
Freedom - Happiness**

……., day month Year ····

APPROVAL APPROVAL

CHANGES IN CLINICAL TRIAL RESEARCH

To: **Ministry of Health (Department of Science, Technology and Training)**

Full name of the principal investigator:

Clinical trial facilities:

Work address:

Phone: Fax:

Email:

Has been approved by the Ministry of Health to conduct clinical trial [name of research] in Decision No. /QD-BYT dated five

The establishment reports the following changes:

Content changes	Explanation of changes	List of documents related to the change
1.		
2.		
3.		

Attached documents include:

….

After studying the Circular No. /2018/TT-BYT dated / /2018 regulations on clinical drug trials and related regulations, we commit to fully comply with legal documents, specialized regulations. related subjects, ethical compliance in research. Request the Department of Science, Technology and Training to consider and approve the above changes of the establishment.

Principal investigator
(signature)

Head of clinical trial facility *(signature, stamp)*

Form No. 11 - Application for approval of clinical trial results

Ò

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

……., day month Year ...

APPLICATION FOR APPROVAL OF CLINICAL TRIAL RESULTS

To: **Ministry of Health (Department of Science, Technology and Training)**

Principal Investigator:

Clinical trial facilities:

Research collaboration facilities:

Request the Ministry of Health to consider and approve clinical trial results:

Research name:

Name of study drug:

Name of organization or individual having drugs in clinical trial:

Research code:

Research stage:

Research time:

Attached documents include:

……..

Principal Investigator
sign

Head of clinical trial drug facility
sign, stamp

Form No. 12 - Full text report on clinical trial results

Cover page 1

MINISTRY OF HEALTH

REPORT

RESULTS OF CLINICAL TRIAL RESEARCH

Research name:

Principal Investigator:

Clinical trial facilities:

Management level: Ministry of Health

Implementation period: from month ... year ... to the month ... five ...

Total funding for research implementation In …….. million dong

which: budget for scientific research Other …….. million dong

sources (if any) …….. million dong

Title page

REPORT

RESULTS OF CLINICAL TRIAL RESEARCH

1. Research name

2. Name of the drug used in the study

3. Research content (if the name of the study is not shown, briefly describe (1-2 sentences) the design, comparison, drug duration, dose and patient population..

4. Name of organization or individual having drugs for clinical trial

5. Research code

6. Research phase.

7. Research start date

8. Study End Date

9. Name and title of principal investigator

10. Supervisor's name.

11. Commit to GCP-compliant research.

12.Report date

Page 3

RESEARCH SUMMARY

Page 4

Abbreviations

Page 5

TABLE OF CONTENTS

CONTENTS NEEDED IN THE SUMMARY REPORT

3.5. Describe data quality assurance methods

3.6. Statistical methods mentioned in the protocol and sample size determination

3.7. Changes in research performance and analysis according to the research plan.

4. Research subjects (patients/volunteers)

4.1. Status of patients participating in the study

4.2. Errors compared to the outline

5. Evaluating the effectiveness

5.1. Analytical data

The exact patients included in the efficacy analysis, and exclusions, must be identified.

5.2. Anthropological and other baseline characteristics Make a summary table of the demographic characteristics of each patient

5.3. Determination of drug suitability

Summarize and analyze any results that assess the suitability of individual patients to study dosing regimens such as drug concentrations in biological fluids over time.

5.4. Treatment effectiveness and patient data table

a) Performance analysis

b) Analysis/statistics

c) Make a table of response data of each patient

d) Drug dose, drug concentration and relationship to response

d) Drug-drug, drug-disease interactions

e) Present the data of each patient

g) Conclusion about effectiveness

6. Safety rating

Analysis of safety-related data is considered at three levels:

- The level of exposure (dose, duration of administration, number of patients) should be examined to determine the safety of the study.

- Adverse events that need attention, factors affecting the frequency of adverse events.

- Serious adverse events regardless of whether they were related to the study drug or not.

7. Level of exposure

Exposure to study drug, control drug, or placebo should be assessed according to the number of patients who received the drug, the duration of the drug, and the dose level used.

8. Adverse Event (AE)

Summary of AE

Presentation of AEs

Analysis of AE

List AEs by patient

9. Death and serious adverse events (SAE)

List of deaths and SAEs

Report of a fatality, SAE

Analysis and discussion of mortality, the SAE

10. Test evaluation

List each patient's laboratory values (appendix) and abnormal values.

Evaluate each test parameter

11. Vital signs, physiological manifestations and other observations related to safety.

Analyze vital signs, physiological manifestations, and observed changes.

12. Conclusion of safety

Summary of drug safety, with particular attention to dose-induced variability, AEs leading to drug discontinuation, medical intervention, or death...

13. Discussion and Conclusion

General assessment of drug safety and efficacy, and the relationship between benefits and risks.

14. Related tables, charts, graphs

15. List of References

16. Appendix

List the list of appendices included in the report.

Form 13 - Written approval of clinical trial drug research

MINISTRY OF HEALTH
PUBLIC SCIENCE DEPARTMENT
TURMERIC
AND TRAINING

SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

Number: /K2ÿT-TNLS
Approval of the policy of developing clinical trial records

Hanoi Day Month Year ...

Dear: [name of organization or individual having clinical reagents]

The Department of Science, Technology and Training (Department of Science, Technology and Investment) has received an application from [name of organization or individual with clinical reagents] for the implementation of a clinical trial drug study [name of research]. . After considering, the Department of Science, Technology and Investment made the following comments:

Approving in principle the preparation, development of dossiers and protocol for clinical trial [study name]. It is requested that organizations and individuals that have clinical reagents coordinate with the research units proposed in the application and the main researchers to develop research dossiers in accordance with regulations promulgated in Circular No. /2018/TT-BYT dated / /2018 of the Minister of Health Regulations on clinical trial of drugs and basis for submission to the Ministry of Health for consideration and approval.

Please notify so that organizations and individuals that have drugs in clinical trials can know and implement them.

Head of Department

Recipients:
- As above;
- TT in charge (for reporting); -
Director (for reporting); -
Organization to receive the proposal (for implementation); - Save: VT, TNLS (02 copies).

Form 14 - Certificate of clinical trial results

MINISTRY OF HEALTH

SOCIAL REPUBLIC ONLY

DEPARTMENT OF SCIENCE TECHNOLOGY AND TRAINING	**MEANING OF VIETNAM Independence - Freedom - Happiness**
Number: /CN-K2ÿT	***Hanoi Day Month Year*** ...

CERTIFICATE

Clinical trial results

Pursuant to Decision No. .../QD-BYT dated …/…/… of the Minister of Health on defining the functions, tasks, powers and organizational structure of the Department of Science, Technology and Training under the Ministry of Health;

Pursuant to Decision No. .../QD-BYT dated …/…/… of the Minister of Health on approval of clinical trial research protocol;

Pursuant to the minutes No. .../BB-BDÿÿ dated …/…/… of the National Ethics Council in Biomedical Research on evaluation and acceptance of clinical trial research results;

The Department of Science, Technology and Training certifies the completion and acceptance of the research:

1. Research name:

2. Research phase:

3. Principal researcher:

4. Clinical trial facilities:

5. Organizations and individuals having drugs for clinical trial:

6. Deployment location:

7. Research object:

8. Number of objects:

9. Research time:

10. Product name:

11. Manufacturer:

12. Dose and regimen for using products in research: according to the research protocol approved in Decision No. .../QD-BYT dated …/.../… of the Ministry of Health.

13. Date of meeting of the Acceptance Council:

14. Conclusions on acceptance of research results of the National Ethics Council in biomedical research ethical issues in biomedical research Ministry of Health:

Certification date: day ... month ... year ...

Head of Department

Recipients:
- TT in charge (for reporting);
- Director (for reporting);
- Relevant Department/Department (for coordination);
- Principal investigator (for implementation);
- Organization of testing (for implementation);
- Organizations and individuals that have drugs for clinical trial (for implementation);
- Save: VT, TNLS (02 copies);