Regulations Regarding Clinical Drug[1]

Authority: **Ministry of Health of Vietnam**

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Chapter I: GENERAL REGULATIONS

Article 1. Scope of Regulation

1.This Circular provides for:

a) Good Clinical Practice (GCP) as defined in Clause 37, Article 2 of the Law on Pharmacy;

b) Dossiers and procedures for the conduct of clinical trials of medicinal products (hereinafter referred to as "clinical trials") as prescribed in Clause 3, Article 95 of the Law on Pharmacy.

2.This Circular applies to clinical trial establishments, including:

a) Establishments registered to provide clinical trial services;

b) Establishments registered to provide bioequivalence study services;

c) Establishments engaged in pharmaceutical activities for non-commercial purposes that register to conduct clinical trials.

Article 2. Definitions

For the purposes of this Circular, the following terms shall be construed as follows:

1.Clinical drug trials mean scientific activities involving the study of medicinal products in human volunteer subjects for the purpose of investigating or determining the safety and efficacy of a medicinal product; identifying and detecting adverse reactions associated with the use of the medicinal product; and evaluating its absorption, distribution, metabolism, and excretion.

[1]Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

2.Clinical trial institution means an establishment engaged in pharmaceutical activities, whether or not subject to the issuance of a Certificate of Eligibility for Pharmaceutical Business, which conducts one, several, or all phases of clinical drug trials.

3.Good Clinical Practice (GCP) means a set of internationally recognized ethical and scientific quality standards for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials, ensuring that data and reported results are credible and accurate, and that the rights, safety, dignity, and confidentiality of trial participants are protected.

4.Investigator's Brochure (IB) means a compilation of clinical and non-clinical data relating to the investigational medicinal product(s).

5.Case Report Form (CRF) means a printed, electronic, or digital document designed for the systematic recording of all protocol-required information for each trial participant.

6.Placebo means an inert substance or intervention with no intrinsic pharmacological activity, used in controlled clinical trials as a comparator to evaluate the efficacy of investigational medicinal products.

7.Investigational medicinal product (IMP) means any medicinal product (including new products, comparator products, or placebo) being tested or used as a reference in a clinical trial.

8.Multicentre trial means a clinical trial conducted in accordance with a single protocol but implemented at two or more investigational sites.

Chapter II: ISSUING AND PUBLISHING GOOD CLINICAL TRIAL PRACTICES FOR DRUG TRIALS

Article 3. Document on Principles and Standards of Good Clinical Practice for Clinical Drug Trials

1.The principles and standards of Good Clinical Practice for clinical drug trials are hereby promulgated as set out in Appendix I attached to this Circular.

2.Updated documents on Good Clinical Practice principles and standards:

In the event that the World Health Organization (WHO) or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) issues amendments to, or supplements of, the Good Clinical Practice (GCP) principles and standards (hereinafter referred to as the "updated documents") referred to in Clause 1 of this Article, the Department of Science, Technology and Training shall, within three months from the date such

updated documents are published on the official electronic portals of WHO or ICH, disseminate the contents thereof to relevant entities for the purpose of review, updating, and implementation.

The Department of Science, Technology and Training shall further be responsible for organizing the translation of such updated documents and publishing the Vietnamese translation thereof (for reference purposes only) on the electronic portal of the Ministry of Health and on its official website.

Article 4. Application of Good Clinical Practice Principles and Standards for Clinical Drug Trials

1.Clinical trial establishments not engaged in the provision of bioequivalence testing services for commercial purposes shall comply with Good Clinical Practice (GCP) principles and standards as specified in Appendix I issued together with this Circular, and any subsequently updated or amended GCP documents.

2.Enterprises providing bioequivalence testing services shall comply with Good Clinical Practice (GCP) principles and standards as specified in Appendix II issued together with this Circular, and any subsequently updated or amended GCP documents.

Chapter III: EVALUATING RESPONSE TO GOOD CLINICAL TRIAL PRACTICES

Article 5. Cases for evaluating, inspecting, and verifying compliance with Good Clinical Practice for drug trials.

1. Initial assessment shall apply to facilities applying for registration to conduct clinical drug trials for the first time, as follows:

a) In the case of an application for a Certificate of Eligibility for Pharmaceutical Business, the initial assessment shall be carried out concurrently with the issuance of such Certificate;

b) In cases where an application for a Certificate of Eligibility for Pharmaceutical Business is not required, the initial assessment shall be conducted at the time the facility commences the conduct of clinical drug trials.

2. Periodic assessments of compliance with GCP are conducted every three years from the date of signing the assessment report of the previous assessment (excluding unscheduled assessments, inspections, and audits by competent state agencies).

3. Unscheduled assessments of compliance with GCP shall be conducted according to the procedures stipulated in Article 8 of this Circular in the following cases:

a) A drug testing facility complying with GCP level 2 as stipulated in point b, clause 3, Article 8 of this Circular must undergo at least one unscheduled assessment within three years from the date of completion of the previous assessment period in case of recommendations from the Assessment Team in the Assessment Report;

b) Clinical trial facilities that have been inspected or audited by competent state authorities and found to have committed serious violations of GCP principles and standards;

c) There is information reflecting or recommending that clinical trial facilities seriously violate GCP principles and standards;

d) Clinical drug trial facilities that fail to submit activity reports - maintaining compliance with GCP as prescribed in Clause 5, Article 10 of this Circular.

Article 6. Dossier for requesting assessment of compliance with Good Clinical Practice for drug trials.

1. The documentation used as the basis for the assessment of compliance with Good Clinical Practice (GCP) requirements for pharmaceutical business establishments shall consist of the dossiers submitted by such establishments in their application for a Certificate of Eligibility for Pharmaceutical Business, as prescribed in Clause 1, Article 38 of the Law on Pharmacy, specifically as follows:

a) Application for issuance, re-issuance, or adjustment of the Certificate of Eligibility for Pharmaceutical Business according to Forms No. 10,11, and12 in Appendix I issued together with Government Decree No. 163/2025/ND-CP dated June 29, 2025, detailing a number of articles and measures to organize and guide the implementation of the Law on Pharmacy (hereinafter referred to as Decree No. 163/2025/ND-CP);
b) Technical documents as stipulated in point e or point g of Clause 2, Article 20 of Decree No. 163/2025/ND-CP, bearing the seal of the establishment. These documents shall be presented according to the guidelines on the overall dossier specified in Appendix III issued together with this Circular, or the updated overall dossier in case of addition to the scope of activities;

c) Documents proving payment of the appraisal fee as stipulated in Circular No. 41/2023/TT-BTC dated June 12, 2023, of the Minister of Finance regulating the rates, collection, payment, management, and use of fees in the field of pharmaceuticals and cosmetics (hereinafter referred to as Circular No. 41/2023/TT-BTC).

2.The documentation serving as the basis for the assessment of compliance with Good Clinical Practice (GCP) requirements, in cases where a Certificate of Eligibility for Pharmaceutical Business is not required, shall include:

a) The application for the issuance, re-issuance, or adjustment of the Certificate of GCP compliance, made using Form No. 02 as prescribed in Appendix IV issued together with this Circular;

b) Technical documents as specified in Point e or Point g of Clause 2, Article 20 of Decree No. 163/2025/ND-CP, duly stamped by the establishment. Such documents shall be prepared in accordance with the guidance on the general dossier set out in Appendix III issued together with this Circular, or the updated general dossier in the event of any expansion of the scope of activities;

c) Evidence of payment of the appraisal fee as prescribed in Circular No. 41/2023/TT-BTC.

Article 7. Procedures for Evaluation of Compliance with Good Clinical Practice for Clinical Drug Trials

1.Receipt of applications:

Clinical drug trial facilities shall submit one set of dossiers, either directly, via postal service, or through the online submission system, as prescribed in Article 6 of this Circular, to the receiving authority of the Ministry of Health, as follows:

a) The Department of Science, Technology and Training shall receive dossiers from facilities registering solely for clinical drug trials;

b) The Drug Administration of Vietnam, Ministry of Health, shall receive dossiers from facilities registering for clinical drug trials while concurrently applying for other pharmaceutical business services.

2.Receipt and processing of applications:

a) Upon receipt of a complete dossier as prescribed in Article 6 of this Circular, the receiving authority shall issue to the applicant an acknowledgment of receipt in accordance with Form No. 01, Appendix I, issued together with Decree No. 163/2025/ND-CP;

b) Within five working days from the date of receipt of a valid dossier, the receiving authority shall establish an Evaluation Team and issue a decision on the establishment thereof to the clinical trial facility, including the expected schedule for the on-site inspection at the facility;

c) Within fifteen days from the date of issuance of the decision establishing the Evaluation Team, the Evaluation Team shall conduct an on-site assessment at the clinical trial facility.

Article 8. Procedures for Assessment and Classification of Good Clinical Practice Compliance in Clinical Drug Trials

1.Documents used as the basis for the assessment of compliance with GCP shall be those specified in Clause 1, Article 3 of this Circular, corresponding to the clinical drug trial activities conducted by the clinical trial facility.

2.On-site assessment procedure at clinical trial facilities:

a) Step 1: The Evaluation Team shall announce the Decision on the establishment of the Evaluation Team, as well as the purpose, scope, content, and plan of the on-site assessment at the clinical trial facility;

b) Step 2: The clinical trial facility shall present a summary of its organizational structure, personnel, operational activities, implementation of Good Clinical Practice, and any other relevant matters in accordance with the evaluation criteria;

c) Step 3: The Evaluation Team shall conduct an on-site assessment of GCP implementation at the clinical trial facility in accordance with each specific evaluation criterion;

d) Step 4: The Evaluation Team shall hold a meeting with the clinical trial facility to communicate the preliminary assessment results regarding compliance with GCP as prescribed in Clause 3 of this Article, including any non-compliances or deficiencies requiring correction (if any), and shall discuss with the clinical trial facility any points of disagreement regarding the assessment;

e) Step 5: Preparation and signing of the assessment report: The assessment report shall be signed by the Head of the clinical trial facility and the Head of the Evaluation Team. The report shall include the composition of the Evaluation Team, the location, time, and scope of the assessment, as well as any disagreements (if any) between the Evaluation Team and the clinical trial facility regarding the evaluation results. The report shall be made in two copies, one of which shall be retained by the clinical trial facility and one by the receiving authority;

f) Step 6: Finalization of the GCP Assessment Report: Within five working days from the date of signing the assessment report, the Evaluation Team shall prepare a GCP Assessment Report in accordance with Form No. 04 set out in Appendix IV issued together with this Circular and shall send it to the clinical trial facility.

The GCP Assessment Report shall identify, analyze, and classify deficiencies requiring rectification, with reference to the relevant provisions of applicable legal documents and GCP principles and standards, and shall determine the level of GCP compliance of the clinical trial facility. The classification of deficiencies and the determination of the level of GCP compliance shall be carried out in accordance with Form No. 01, Appendix IV issued together with this Circular. The report shall be made in two copies, one of which shall be sent to the clinical trial facility and one retained by the receiving authority.

3.Levels of GCP compliance:

a) Level 1: The clinical trial facility is compliant with GCP;

b) Level 2: The clinical trial facility is partially compliant with GCP;

c) Level 3: The clinical trial facility is non-compliant with GCP.

Article 9. Handling of Results of Assessment of Compliance with Good Clinical Practice for Clinical Drug Trials

1.In cases where the GCP Assessment Report concludes that the clinical trial facility is compliant with GCP at Level 1 as specified in Point a, Clause 3, Article 8 of this Circular:

a) Within seven working days from the date of completion of the GCP Assessment Report, the receiving authority shall submit to the Minister of Health for the issuance of a Certificate of Eligibility for Pharmaceutical Business in accordance with Form No. 13 set out in Appendix I issued together with Decree No. 163/2025/ND-CP, and shall issue a GCP Certificate in accordance with Form No. 05 set out in Appendix IV issued together with this Circular, upon request of the clinical trial facility;

b) The scope of drug testing activities recorded in the Certificate of Eligibility for Pharmaceutical Business of the clinical trial facility shall be determined in accordance with each category of medicinal product that has been assessed for compliance with GCP.

2.In cases where the GCP Assessment Report concludes that the clinical trial facility is compliant with GCP at Level 2 as specified in Point b, Clause 3, Article 8 of this Circular:

a) Within five working days from the date of completion of the GCP Assessment Report, the receiving authority shall issue a written notice requesting the clinical trial facility to rectify and remedy the identified deficiencies, in accordance with Form No. 16 set out in Appendix I issued together with Decree No. 163/2025/ND-CP, together with the GCP Assessment Report;

b) Upon completion of the corrective actions, the clinical trial facility shall submit a written report on the rectification of deficiencies, including a corrective action plan and supporting evidence (including documents, images, videos, certificates, or other relevant materials);

c) Within twenty days from the date of receipt of the report on completion of corrective actions, the receiving authority shall assess the results of such corrective actions on the basis of the documents specified in Clause 1, Article 8 of this Circular, prepare an assessment report on the corrective actions undertaken by the clinical trial facility, and determine the level of compliance with GCP, as follows:

Where the corrective actions are deemed satisfactory and the clinical trial facility is determined to be compliant with GCP, the receiving authority shall submit to the Minister of Health for the issuance of a Certificate of Eligibility for Pharmaceutical Business and shall issue a GCP Certificate (where requested by the facility) in accordance with Form No. 05 set out in Appendix IV issued together with this Circular;

Where the clinical trial facility is determined not to meet GCP requirements, the receiving authority shall notify the facility in writing, clearly stating the reasons therefor;

d) Within six months from the date on which the receiving authority issues the GCP Assessment Report containing requests for corrective actions, the clinical trial facility shall submit the report on corrective actions as prescribed in Point b of this Clause. After the expiry of this period, if the clinical trial facility fails to submit such report, or if, after twelve (12) months from the date of initial submission of the application dossier, the receiving authority determines that the clinical trial facility has not satisfied the GCP requirements, the application dossier shall no longer be valid.

3.In cases where the GCP Assessment Report concludes that the clinical trial facility is compliant with GCP at Level 3 as specified in Point c, Clause 3, Article 8 of this Circular:

Within five working days from the date of completion of the GCP Assessment Report, the receiving authority shall issue a written notice of non-compliance with GCP requirements, in accordance with Form No. 16 set out in Appendix I issued together with Decree No. 163/2025/ND-CP, together with the GCP Assessment Report, and shall not issue a Certificate of Eligibility for Pharmaceutical Business.

4.In the event that a clinical trial facility disagrees with the findings of the GCP assessment, it may, within thirty days from the date of completion of the GCP Assessment Report or the report on the assessment of corrective actions, submit a written request for reconsideration to the receiving authority, together with supporting evidence (including documents, images, videos, certificates, or other relevant materials).

Within ten days from the date of receipt of such request, the receiving authority shall review the GCP Assessment Report and the request submitted by the clinical trial facility. Where necessary, the receiving authority may seek opinions from experts in the relevant field and shall provide a written response to the clinical trial facility, clearly stating whether the request is accepted or rejected and the reasons therefor. The time required for such review shall not be included in the statutory assessment timeline.

5.Within five working days from the date of issuance of the Certificate of Eligibility for Pharmaceutical Business, the receiving authority shall publish the following information on its official website:

a) Name and address of the clinical trial facility;

b) Full name of the person responsible for pharmaceutical expertise, together with the number of their Pharmacy Practice Certificate;

c) Number of the Certificate of Eligibility for Pharmaceutical Business;

d) Scope of pharmaceutical business activities (including the scope of drug testing activities);

e) Number of the GCP Certificate (if any);

f) Validity period of the GCP compliance assessment.

Article 10. Periodic Assessment of the Maintenance of Compliance with Good Clinical Practice for Clinical Drug Trials

1.The periodic assessment of the maintenance of compliance with Good Clinical Practice (GCP) at clinical trial facilities shall be conducted every three years, calculated from the date of signing of the assessment report of the most recent assessment, excluding inspections and audits conducted by competent state authorities.

2.In November of each year, the receiving authority shall review and promulgate a plan for the periodic assessment of the maintenance of GCP compliance of clinical trial facilities for the following year. Such plan shall be published on the official website of the receiving authority.

3.At least thirty days prior to the scheduled periodic assessment of GCP compliance maintenance, as announced by the receiving authority, the clinical trial facility shall submit to the receiving authority a report on clinical drug trial activities and the maintenance of GCP compliance (hereinafter referred to as the "GCP compliance maintenance report") in accordance with Form No. 07 set out in Appendix IV issued together with this Circular, together with updated technical documentation regarding the facility's physical, technical, and personnel conditions (if any changes have occurred).

4.In the event that a clinical trial facility fails to submit the GCP compliance maintenance report within the time limit prescribed in Clause 3 of this Article, the receiving authority shall, within fifteen days from the expiry of such time limit, issue a written request requiring the clinical trial facility to submit the report in accordance with the prescribed requirements.

5.Within forty-five days from the date of issuance of the written request by the receiving authority, the clinical trial facility shall submit the GCP compliance maintenance report, together with an explanation for the delay. If, upon expiry of this period, the clinical trial facility fails to

submit such report, the receiving authority shall conduct an inspection of the facility's compliance with GCP in accordance with Clause 3, Article 5 of this Circular.

6.Upon submission of the GCP compliance maintenance report in accordance with the prescribed requirements, the clinical trial facility may continue to conduct its activities in accordance with the Law on Pharmacy and relevant implementing regulations, within the scope of activities specified in the Certificate of Eligibility for Pharmaceutical Business, except in cases where the competent authority issues a written decision imposing sanctions for non-compliance with GCP. The clinical trial facility shall ensure continuous compliance with GCP throughout its operation. Upon request of the facility, the receiving authority shall issue a written confirmation of receipt of the GCP compliance maintenance report.

7.The sequence, procedures, and classification of results for the assessment of compliance with GCP shall be carried out in accordance with Articles 7 and 8 of this Circular.

8.In the event of an epidemic, natural disaster, catastrophe, or war that restricts the mobility of the receiving authority and prevents the conduct of GCP compliance assessments as prescribed, the receiving authority shall:

a) Issue GCP Certificates to clinical trial facilities that achieved Level 1 compliance in their most recent assessment;

b) Conduct remote assessments for clinical trial facilities that achieved Level 2 compliance in their most recent assessment;

c) Upon cessation of such circumstances, conduct assessments of the maintenance of GCP compliance in accordance with Articles 7 and 8 of this Circular.

Chapter IV: ASSESSING THE MAINTENANCE OF GOOD CLINICAL TRIAL PRACTICES

Article 11. Handling of Results of Periodic Assessment of Compliance with Good Clinical Practice for Clinical Drug Trials

1.In cases where the GCP Assessment Report concludes that the clinical trial facility is compliant with GCP at Level 1 as specified in Point a, Clause 3, Article 8 of this Circular:

a) Within ten days from the date of completion of the GCP Assessment Report, the receiving authority shall update information on the facility's continued compliance with GCP on its official website in accordance with Clause 5, Article 9 of this Circular, and shall issue a GCP Certificate in accordance with Form No. 05 set out in Appendix IV issued together with this Circular, upon request of the clinical trial facility;

b) In the event that a clinical trial facility discontinues one or more clinical drug trial activities within the scope of certification stated in its Certificate of Eligibility for Pharmaceutical Business, the receiving authority shall update information on the maintenance of GCP compliance for the remaining activities assessed as compliant and shall issue a written notice requiring the clinical trial facility to carry out procedures for amendment of its Certificate of Eligibility for Pharmaceutical Business in accordance with Point b, Clause 3, Article 36 of the Law on Pharmacy.

2.In cases where the GCP Assessment Report concludes that the clinical trial facility is compliant with GCP at Level 2 as specified in Point b, Clause 3, Article 8 of this Circular:

a) Within five working days from the date of completion of the GCP Assessment Report, the receiving authority shall issue a written notice requesting the clinical trial facility to remedy and rectify the identified deficiencies, in accordance with Form No. 16 set out in Appendix I issued together with Decree No. 163/2025/ND-CP, together with the GCP Assessment Report, and request submission of a corrective action report;

b) Within forty-five days from the date on which the GCP Assessment Report is issued by the receiving authority, the clinical trial facility shall submit a written report on corrective actions, including a corrective action plan and supporting evidence (including documents, images, videos, certificates, or other relevant materials) demonstrating the rectification of the identified deficiencies;

c) Within twenty days from the date of receipt of the corrective action report, the receiving authority shall assess the results of the corrective actions and determine the level of GCP compliance of the clinical trial facility, as follows:

1.Where the corrective actions are deemed satisfactory, the receiving authority shall update information on the facility's continued compliance with GCP on its official website in accordance with Clause 5, Article 9 of this Circular and shall issue a GCP Certificate in accordance with Form No. 05 set out in Appendix IV issued together with this Circular, upon request of the clinical trial facility;

2.Where the corrective actions are deemed insufficient, the receiving authority shall issue a written notice specifying the additional corrective actions required and request submission of a supplementary report. The period for completion of such additional corrective actions and submission of the report shall be forty-five days from the date of such notice;

d) Within one hundred and thirty-five days from the date of completion of the GCP Assessment Report, if the clinical trial facility fails to submit a corrective action report, or if the results of corrective actions as prescribed in Point c of this Clause remain unsatisfactory, the receiving authority shall issue a written notice of non-compliance with GCP and, depending on the nature

and severity of the deficiencies, shall apply one or more of the measures specified in Points a and b, Clause 3 of this Article.

3.In cases where the GCP Assessment Report concludes that the clinical trial facility is compliant with GCP at Level 3 as specified in Point c, Clause 3, Article 8 of this Circular:

Within five working days from the date of signing of the GCP Assessment Report, and based on the assessment of risks to the quality of the clinical trial, as well as to the health and safety of trial participants, the receiving authority shall issue a written notice of non-compliance with GCP, together with the GCP Assessment Report. Depending on the nature and severity of the violations, the receiving authority shall implement one or more of the following measures:

a) Issue a written decision to temporarily suspend the operation of the clinical trial facility and/or refer the case to the competent authority for administrative sanctions in accordance with the law on handling of administrative violations;

b) Submit to the Minister of Health for a decision to revoke the Certificate of Eligibility for Pharmaceutical Business issued in accordance with Clause 2, Article 40 of the Law on Pharmacy, and to revoke the GCP Certificate (if any).

4.Within five working days from the date of determination that the clinical trial facility meets the requirements for maintaining GCP compliance, or from the date of issuance of the decision to revoke the Certificate of Eligibility for Pharmaceutical Business due to failure to maintain GCP compliance, the receiving authority shall update the status of GCP compliance on its official website in accordance with Clause 5, Article 9 of this Circular, including information on facilities maintaining compliance or, as applicable, information on the revocation of the Certificate of Eligibility for Pharmaceutical Business and the GCP Certificate (if any) for facilities that fail to maintain GCP compliance.

Article 12. Change Control

1.Cases of change control:

a) Changes falling within one of the cases specified in Point b, Clause 1, Article 36 of the Law on Pharmacy;

b) Changes to the location of clinical drug trial activities for clinical trial facilities not subject to the requirement to obtain a Certificate of Eligibility for Pharmaceutical Business;

c) Other cases of change control.

2.In the event that a clinical trial facility undergoes changes as prescribed in Point a, Clause 1 of this Article, the facility shall submit an application for a Certificate of Eligibility for Pharmaceutical Business in accordance with Clauses 2 and 4, Article 38 of the Law on Pharmacy.

The procedures for assessment of compliance with GCP, classification of results, and handling of assessment outcomes shall be carried out in accordance with Articles 7, 8, and 9 of this Circular.

3.In the event that a clinical trial facility undergoes changes as prescribed in Point b, Clause 1 of this Article, the facility shall submit a dossier requesting assessment of compliance with GCP in accordance with Clause 2, Article 6 of this Circular.

The procedures for assessment of compliance with GCP, classification of results, and handling of assessment outcomes shall be carried out in accordance with Articles 7, 8, and 9 of this Circular.

4.In the event that a clinical trial facility undergoes changes as prescribed in Point c, Clause 1 of this Article, the clinical trial facility shall remain fully responsible for maintaining compliance with GCP following such changes and shall submit a report on the changes, together with the relevant technical documentation, to the receiving authority for record-keeping purposes.

Article 13. Assessment of Compliance with, and Maintenance of Compliance with, Good Clinical Practice for Clinical Drug Trial Facilities Not Subject to the Issuance of a Certificate of Eligibility for Pharmaceutical Business

1.Clinical drug trial facilities not subject to the requirement to obtain a Certificate of Eligibility for Pharmaceutical Business (i.e., facilities conducting pharmaceutical activities for non-commercial purposes) shall comply with GCP as prescribed in Point a, Clause 2, Article 35 of the Law on Pharmacy.

2.Such facilities shall submit:

-For initial assessment: a written request for assessment of GCP compliance using Form No. 02 set out in Appendix IV issued together with this Circular, together with technical documentation on the clinical trial facility prepared in accordance with the guidance on the general dossier specified in Appendix III of this Circular;

-For periodic assessment: a report on clinical drug trial activities and the maintenance of GCP compliance of the facility, together with updated technical documentation (if any changes have occurred), in accordance with Clause 3, Article 10 of this Circular.

3.The sequence, procedures, classification of assessment results, and change control relating to GCP compliance for clinical trial facilities not subject to the issuance of a Certificate of Eligibility for Pharmaceutical Business shall be carried out in accordance with the corresponding provisions of Articles 7, 8, and 12 of this Circular.

4.Handling of results of the initial assessment of GCP compliance for such facilities:

a) The sequence and timelines for handling the results of the initial GCP compliance assessment shall be carried out in accordance with Article 9 of this Circular;

b) The receiving authority shall issue a written notification confirming the clinical trial facility's compliance with GCP and shall publish such information on its official website in accordance with Clause 6 of this Article.

5.Handling of results of periodic assessments of maintenance of GCP compliance:

Where the assessment results conclude that the clinical trial facility is compliant with GCP at Level 1, Level 2, or Level 3 as specified in Points a, b, and c, Clause 3, Article 8 of this Circular, the receiving authority shall handle such results in accordance with Clauses 1, 2, and 3, Article 11 of this Circular.

6.Within five working days from the date of determination that the clinical trial facility meets the requirements for maintaining GCP compliance, or from the date of issuance of a decision to revoke the GCP Certificate, the receiving authority shall update the status of GCP compliance on its official website in accordance with Clause 5, Article 9 of this Circular, including, as applicable, information on facilities maintaining compliance or the decision to revoke the GCP Certificate for facilities that fail to maintain compliance.

Chapter V: EVALUATION TEAM ON COMPLIANCE WITH GOOD CLINICAL TRIAL PRACTICES

Article 14. Composition and Criteria of Members of the Evaluation Team

1.The Minister of Health shall decide on the establishment of an Evaluation Team to assess compliance with Good Clinical Practice (GCP). The composition of the Evaluation Team shall include:

a) One representative of the receiving agency, who shall serve as the Head of the delegation;

b) One specialist of the receiving agency, who shall serve as the Secretary of the delegation;

c) Representatives from units under the Ministry of Health (no more than one member from each unit), including: the Department of Medical Examination and Treatment Management; the

Legal Department; the Drug Administration Department; the Department of Science, Technology and Training; and, where applicable in the case of clinical trials involving herbal or traditional medicines, the Department of Traditional Medicine Management;

d) One representative of the Department of Health of the province or centrally governed city (hereinafter referred to as the "Department of Health") where the clinical trial facility is headquartered, in cases where such facility is directly managed by the Department of Health;

e) One representative of the National Ethics Committee for Biomedical Research;

f) Representatives of other relevant agencies or units, where necessary.

2.Members of the Evaluation Team must satisfy the following requirements:

a) Hold a university degree or higher;

b) Possess knowledge of GCP and demonstrate the capacity to conduct GCP evaluations;

c) Act with integrity, objectivity, and in strict compliance with applicable laws and regulations during the evaluation process, and must not have any conflict of interest with the clinical trial facility being evaluated as specified in Clause 3 of this Article;

d) The Head of the delegation must hold at least a university degree in medicine or pharmacy and have a minimum of three years of experience in clinical trial management.

3.A member of the Evaluation Team shall be deemed to have a conflict of interest with the clinical trial facility under evaluation if such member falls under any of the following circumstances:

a) Has been employed by, or has participated in consulting activities for, the clinical trial facility within the preceding five years;

b) Has any financial interest in the clinical trial facility;

c) Has a spouse, child, parent, sibling, parent-in-law, or other immediate family member employed by the clinical trial facility.

Article 15. Responsibilities and Powers of the Evaluation Team

1.The Evaluation Team shall have the following responsibilities:

a) To conduct a comprehensive assessment of the operations of the clinical trial facility in accordance with the applicable GCP standards as prescribed in Article 4 of this Circular, any updated GCP guidelines (if applicable), and relevant technical regulations; to accurately record the assessment findings, including any identified deficiencies; and to prepare a formal evaluation report;

b) To provide clarification or explanation of the GCP evaluation report in cases where the clinical trial facility disputes its contents;

c) To ensure the confidentiality of all information obtained during the evaluation process, including information related to the clinical trial activities of the facility, except where disclosure is authorized by the facility or required by a competent state authority for inspection, examination, or investigation purposes.

2.The Evaluation Team shall have the following powers:

a) To inspect all areas and activities related to clinical trials at the clinical trial facility;

b) To request and review all documents relevant to the clinical trial activities of the facility;

c) To collect documentary evidence, including photocopies, photographs, and video recordings, to substantiate findings identified during the evaluation process;

d) To document violations and request the temporary suspension of clinical trial activities where, during the course of the evaluation, serious non-compliance is identified that may adversely affect the safety and health of trial participants or compromise the accuracy and integrity of research data, and to report such matters to the competent authority for handling in accordance with applicable regulations.

Chapter VI: CLINICAL DRUG TRIAL PROCEDURES AND FILES

Article 16. Clinical Trial Procedures

The conduct of clinical trials shall comply with Article 95 of the Law on Pharmacy. The approval of clinical trial studies shall include: initial approval of the clinical trial study; and approval of amendments during the course of the clinical trial where the clinical trial facility modifies the clinical trial dossier.

Article 17. Documentation for Registration of Clinical Drug Trials

A dossier for registration of a clinical drug trial study shall comprise:

1.An application for registration of the clinical drug trial study, using Form No. 09 as prescribed in Appendix IV issued together with this Circular;

2.Product research information, prepared in accordance with Form No. 18 set out in Appendix IV issued together with this Circular.

Article 18. Dossier for Requesting Approval of Clinical Drug Trials

1.An application for approval of a clinical drug trial study, using Form No. 10 as prescribed in Appendix IV issued together with this Circular.

2.Information dossiers relating to drugs used in clinical trials (investigational products), including:

a) Dossier for investigational new drugs:

-Documentation on the drug, including its formulation, manufacturing process, and certificate of analysis. For chemical drugs, biologicals, herbal medicines, and traditional medicines, a certificate of analysis shall be issued by: a state drug testing establishment meeting Good Laboratory Practice (GLP) standards; or a drug and raw material testing service provider complying with GLP standards within its licensed scope; or a manufacturing establishment meeting Good Manufacturing Practice (GMP) standards in accordance with Circular No. 28/2025/TT-BYT dated 01 July 2025 of the Minister of Health on GMP for drugs and raw materials (hereinafter referred to as "Circular No. 28/2025/TT-BYT").

For vaccines and biological products, a certificate of batch release or a certificate of quality control issued by a national control authority shall be required prior to implementation of the approved study protocol;

-Pre-clinical study documentation, including reports on pharmacodynamics, toxicity, safety, proposed dosage, route of administration, and method of use;

-Documentation from previous phases of clinical trials, where the proposed study is in a subsequent phase and the investigational product is not exempt from earlier-phase trials.

b) Dossier for comparator drugs (if applicable):

-A certificate of analysis issued by the manufacturer confirming compliance with GMP standards in accordance with Circular No. 28/2025/TT-BYT, or documents evidencing the origin and quality control of the comparator drug provided by the supplying organization or individual;

-Documentation demonstrating that the manufacturing facility complies with GMP standards in accordance with Circular No. 28/2025/TT-BYT.

c) Dossier for placebo (if applicable):

-A certificate of analysis issued by the manufacturing facility meeting GMP standards in accordance with Circular No. 28/2025/TT-BYT;

-Documentation demonstrating that the manufacturing facility complies with GMP standards in accordance with Circular No. 28/2025/TT-BYT.

3.Legal documentation relating to the clinical trial drug:

a) A written request from the competent drug regulatory authority requiring Phase IV clinical trials in accordance with Clause 2, Article 87 of the Law on Pharmacy;

b) The approved product information leaflet for drugs proposed for Phase IV clinical trials;

c) Documentation demonstrating that the manufacturing facility of the investigational product complies with GMP standards in accordance with Circular No. 28/2025/TT-BYT;

d) Written confirmations of participation from research institutions in the case of multi-center trials conducted in Vietnam;

e) A certified copy, or a copy bearing the seal of the institution, or a copy presented together with the original for verification, of the document approving the research plan issued by the People's Committee of the relevant province or centrally governed city for field studies conducted within its jurisdiction;

f) A contract or framework agreement governing cooperation in clinical drug trial research between the organization or individual supplying the investigational product and the clinical trial facility.

4.Clinical trial protocol and explanatory documentation:

a) An explanatory document of the clinical trial protocol prepared in accordance with Form No. 11 set out in Appendix IV issued together with this Circular;

b) A Research Information Collection Form or Case Report Form (CRF).

5.The curriculum vitae and a copy of the certificate of completion of Good Clinical Practice (GCP) training of the principal investigator, issued by the Ministry of Health or by an institution authorized to provide GCP training.

6.The participant information sheet and informed consent form for clinical trial subjects, prepared in accordance with Form No. 12 set out in Appendix IV issued together with this Circular.

7.Minutes of the scientific and ethical review conducted by the Institutional Ethics Committee in Biomedical Research; and the minutes of review together with the approval certificate issued by the National Ethics Committee in Biomedical Research.

8.Labelling of investigational products shall comply with Clause 2, Article 88 of the Law on Pharmacy and Clause 4, Article 11 of Circular No. 01/2018/TT-BYT dated 18 January 2018 of the Minister of Health on labelling of drugs, drug substances and package inserts, as amended and supplemented by Circular No. 23/2023/TT-BYT and Circular No. 12/2025/TT-BYT dated 16 May 2025 on registration for marketing authorization of drugs and drug substances.

Article 19. Dossier for Requesting Approval of Amendments to Clinical Drug Trial Studies

1.In the case of administrative amendments, the dossier shall comprise a notification of amendment.

2.In the case of amendments relating to the principal investigator or the clinical trial facility, the dossier shall include:

a) An application for approval of amendments to the clinical drug trial study, using Form No. 13 as prescribed in Appendix IV issued together with this Circular;

b) Supporting documentation relevant to the proposed amendments.

3.For amendments other than those specified in Clauses 1 and 2 of this Article, the dossier shall include:

a) An application for approval of amendments to the clinical drug trial study, using Form No. 13 as prescribed in Appendix IV issued together with this Circular;

b) Updated versions of the relevant documents specified in Point b, Clause 2 of this Article reflecting the proposed amendments;

c) Minutes of review by the Institutional Ethics Committee in Biomedical Research;

d) Either:

-A summary of the assessment results of the amendment application (for amendments that do not affect the safety, rights of clinical trial participants, or the study design); or

-Minutes of scientific and ethical review of the study (for amendments affecting the safety, rights of clinical trial participants, or the study design), together with the approval certificate issued by the National Ethics Committee in Biomedical Research.

Article 20. Dossier for Approval of Clinical Trial Results

The dossier for requesting approval of clinical trial results shall include:

1.An application for approval of clinical trial results, using Form No. 14 as prescribed in Appendix IV issued together with this Circular;

2.A copy of the approved research protocol;

3.A copy of the decision approving the research protocol;

4.Minutes of clinical trial evaluation by the Institutional Ethics Committee in Biomedical Research; and minutes of scientific and ethical review of the study, together with the approval certificate issued by the National Ethics Committee in Biomedical Research;

5.A comprehensive report on clinical trial results of the medicinal product, prepared in accordance with Form No. 16 as prescribed in Appendix IV issued together with this Circular.

Article 21. Requirements on Language, Form, and Legal Validity of Dossiers

1.Language of dossiers

Clinical trial dossiers shall be prepared in the Vietnamese language.

For investigational medicinal product information dossiers, clinical trial protocols, participant information sheets, informed consent forms, and clinical trial results reports in multinational studies, an English version shall be required for reference and comparison purposes.

Where documents are prepared in a language other than Vietnamese or English, a notarised translation into Vietnamese or English shall be required, together with consular legalisation in accordance with Clause 3 of this Article, unless otherwise exempted by law.

2.Form of dossiers

Clinical trial dossiers shall be prepared on A4-size paper, securely bound, and accompanied by a table of contents. Documents shall be arranged in the order set out in the table of contents. Sections shall be clearly separated, labelled, and consecutively numbered to facilitate reference.

3.Legal validity of documents

a) Application forms, requests, and accompanying documents requiring signatures shall be signed and stamped by the legal representative or duly authorised person of the submitting organisation in accordance with applicable law;

b) Documents issued by foreign competent authorities shall be subject to consular legalisation in accordance with regulations on consular legalisation, except where exemption is provided under law;

c) Where legal documents are issued electronically and the clinical trial facility retrieves, prints, and requests certification from a competent foreign authority, such documents shall be subject to consular legalisation in accordance with applicable regulations;

d) Where electronic legal documents do not contain sufficient signatures, names of signatories, or official seals of the competent foreign authority, the clinical trial facility shall submit a self-retrieved copy of the document from the issuing authority's official website, bearing the seal of the facility, together with a document specifying the online access link, to the Department of Science, Technology and Training.

Clinical trial organisations, individuals, and facilities shall be legally responsible for the legality, authenticity, and accuracy of all submitted documents, information, and self-retrieved data.

Article 22. Registration of Clinical Drug Trials

Organisations and individuals possessing medicinal products intended for clinical trials shall submit a written notification of clinical trial registration to the Department of Science, Technology and Training for consolidation and management of information.

Article 23. Procedures for Approval of Clinical Drug Trials

Clinical trial facilities shall submit one set of application dossiers requesting approval of clinical trial studies directly, by post, or via the online submission system to the Department of Science, Technology and Training.

Within seven working days from the date of receipt, the Department of Science, Technology and Training shall review the validity of the dossier.

Where the dossier is invalid, a written notice specifying the required amendments or supplementation shall be issued to the submitting organisation. The dossier may be supplemented and revised a maximum of two times.

The clinical trial facility shall complete the dossier within a maximum period of sixty days from the date of the first notification. Upon expiry of this time limit, the approval procedure shall be re-initiated.

Within seven working days from the date of receipt of a valid dossier, the Department of Science, Technology and Training shall consolidate and submit the dossier to the Minister of Health for consideration and approval of the clinical trial protocol, provided that the dossier meets all requirements.

Where the protocol is not approved or requires revision, written notification stating the reasons shall be issued to the applicant.

Where revision of the clinical trial protocol is required, the clinical trial facility shall coordinate with the Department of Science, Technology and Training to complete the revised dossier within a maximum period of ninety days from the date of notification. Upon expiry of this time limit, the approval procedure shall be re-initiated.

Within seven working days from the date of receipt of the revised and completed dossier in accordance with the notification, the Department of Science, Technology and Training shall review, finalise, and submit the dossier to the Minister of Health for approval of the clinical trial protocol.

Within seven working days from the date of issuance of the decision approving the clinical trial protocol, the clinical trial facility shall update the study information on the Scientific and Technological Information Management and Health Workforce Training System.

Article 24. Procedures for Approval of Amendments to Clinical Drug Trials

1.Administrative amendments

For administrative amendments, clinical trial facilities shall submit a notification of amendment directly, by post, or via the Ministry of Health's online public service portal to the Department of Science, Technology and Training.

The Department of Science, Technology and Training shall receive, record, and manage the submitted information in accordance with applicable regulations.

2.Amendments relating to the principal investigator or clinical trial facility

a) Clinical trial facilities shall submit one set of application dossiers requesting approval of amendments to the clinical trial study directly, by post, or via the Ministry of Health's online public service portal to the Department of Science, Technology and Training;

b) Within seven working days from the date of receipt, the Department of Science, Technology and Training shall review the validity of the dossier.

Where the dossier is invalid, a written notice specifying required amendments or supplementation shall be issued to the applicant. The dossier may be supplemented or revised a maximum of two times.

The clinical trial facility shall coordinate with the Department of Science, Technology and Training to complete the dossier within a maximum period of thirty days from the date of the notification. Upon expiry of this time limit, the amendment approval procedure shall be re-initiated;

c) Within seven working days from the date of receipt of a valid dossier, the Department of Science, Technology and Training shall review, finalise, and submit the dossier to the Minister of Health for consideration and approval of the proposed amendments to the clinical trial protocol.

3.Amendments specified in Clause 3, Article 19 of this Circular

a) Clinical trial facilities shall submit one set of application dossiers requesting approval of amendments to clinical trial studies directly, by post, or via the Ministry of Health's online public service portal to the Department of Science, Technology and Training;

b) Within seven working days from the date of receipt, the Department of Science, Technology and Training shall review the validity of the dossier.

Where the dossier is invalid, a written notice specifying required supplementation shall be issued to the clinical trial facility. The dossier may be supplemented or revised a maximum of two times.

The clinical trial facility shall coordinate with the Department of Science, Technology and Training to complete the dossier within a maximum period of forty-five days from the date of notification. Where an extension is required, the facility shall submit a written request to the Department of Science, Technology and Training for consideration;

c) For amendments that do not affect the safety, rights of clinical trial participants, or the study design, within seven working days from the date of receipt of a valid dossier, the Department of Science, Technology and Training shall review, record, and monitor the amendment;

d) For amendments affecting the safety, rights of clinical trial participants, or the study design, within seven working days from the date of receipt of a valid dossier, the Department of Science, Technology and Training shall review, finalise, and submit the dossier to the Minister of Health for consideration and approval of the proposed amendments.

Within seven working days from the date of issuance of the decision approving the amendments to the clinical trial protocol, or from the date of issuance of the review report for amendments that do not affect the safety, rights of participants, or the study design, the clinical

trial facility shall update the amended information on the Scientific and Technological Information Management and Health Workforce Training System.

Article 25. Conduct of Clinical Drug Trials

Clinical trial facilities shall conduct clinical drug trials in strict accordance with the approved clinical trial protocol and applicable Good Clinical Practice (GCP) standards.

Article 26. Procedures for Approval of Clinical Drug Trial Results

1.Clinical trial facilities shall submit one set of application dossiers requesting approval of clinical trial results directly, by post, or via the Ministry of Health's online public service portal to the Department of Science, Technology and Training.

2.Within five working days from the date of receipt, the Department of Science, Technology and Training shall review the validity of the dossier.

Where the dossier is invalid, a written notice specifying required amendments or supplementation shall be issued to the applicant. The dossier may be supplemented or revised a maximum of two times.

The clinical trial facility shall coordinate with the Department of Science, Technology and Training to complete the dossier within a maximum period of sixty days from the date of notification. Upon expiry of this time limit, the procedure for approval of clinical trial results shall be re-initiated.

3.Within five working days from the date of receipt of a valid dossier, the Director of the Department of Science, Technology and Training shall issue a decision approving the results of the clinical drug trial in accordance with Form No. 17 specified in Appendix IV issued together with this Circular.

Where the evaluation report is satisfactory but requires amendments or supplementation, or where the results do not meet safety or efficacy requirements, the Department of Science, Technology and Training shall issue a written notification to the clinical trial facility clearly stating the reasons.

4.Where amendments or supplementation are required, the clinical trial facility shall coordinate with the Department of Science, Technology and Training to complete the dossier within a maximum period of ninety days from the date of notification. Upon expiry of this time limit, the procedure for approval of clinical trial results shall be re-initiated.

5.Within five working days from the date of receipt of the complete and compliant dossier in accordance with the notification, the Director of the Department of Science, Technology and Training shall issue a decision approving the results of the clinical drug trial.

6.Within five working days from the date of issuance of the decision approving the clinical trial results, the clinical trial facility shall update the study results on the Scientific and Technological Information Management and Health Workforce Training System.

Chapter VII: ENFORCEMENT CLAUSES

Article 27. Effect

1.This Circular shall enter into force as of 27 February 2026.

2.Upon the effective date of this Circular, the following legal instruments shall cease to have effect:

a) Circular No. 29/2018/TT-BYT dated 29 October 2018 of the Minister of Health regulating clinical drug trials;

b) Article 9 of Circular No. 10/2020/TT-BYT dated 11 June 2020 of the Minister of Health providing for bioequivalence testing of medicinal products;

c) Circular No. 08/2014/TT-BYT dated 26 February 2014 of the Minister of Health regulating activities supporting clinical trial research in Vietnam.

Article 28. Reference Clause

Where legal documents cited in this Circular are amended, supplemented, replaced, or superseded, the new or amended documents shall apply.

Article 29. Transitional Provisions

Clinical trial dossiers submitted prior to the effective date of this Circular shall be processed in accordance with Circular No. 29/2018/TT-BYT dated 29 October 2018 of the Minister of Health on clinical drug trials.

However, where organisations or individuals so request, such dossiers may be reviewed and processed in accordance with the provisions of this Circular.

Article 30. Implementation Responsibilities

1.Responsibilities of units under the Ministry of Health

a) The Department of Science, Technology and Training shall take the lead and coordinate with the Drug Administration of Vietnam and other relevant units in:

Organising the implementation, and conducting preliminary and final reviews of the implementation of this Circular nationwide;

Carrying out inspection, supervision, handling of violations, and resolution of difficulties and obstacles arising during implementation in accordance with applicable laws.

b) The Drug Administration of Vietnam shall, within the scope of its functions and assigned duties, organise the implementation of this Circular and coordinate with the Department of Science, Technology and Training in performing the tasks specified in Point a of this Clause.

2.Responsibilities of ministries, ministerial-level agencies, Governmental agencies, and People's Committees of provinces and centrally run cities

a) To take the lead in organising the implementation of this Circular and conduct preliminary and final reviews within the scope of their management;

b) To conduct inspection, handle violations, and resolve difficulties and obstacles arising during the implementation of this Circular in accordance with applicable law.

3.Clinical trial facilities conducting clinical trials not for the purpose of drug registration may apply the provisions of this Circular in a manner appropriate to their operational conditions and practical requirements.

During the implementation process, where difficulties or obstacles arise, agencies, organisations, and individuals shall promptly report them to the Ministry of Health (Department of Science, Technology and Training) for consideration and resolution.