# Regulations on the Quality Management of Drug Clinical Trials (Revised Draft for Opinions)[1]

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## Chapter I: General Provisions

### Article 1- Purpose

In order to ensure the standardized conduct of drug clinical trials, protect the rights, safety, and well-being of trial participants, and ensure that data and results are scientific, authentic, and reliable, these standards are formulated in accordance with the Drug Administration Law of the People's Republic of China, the Vaccine Administration Law of the People's Republic of China, the Implementation Regulations of the Drug Administration Law of the People's Republic of China, and the Measures for the Administration of Drug Registration.

### Article 2- Scope of Application

These standards apply to drug clinical trials conducted for the purpose of applying for drug registration and approved or filed by the drug regulatory authority under the State Council. All activities related to drug clinical trials shall comply with these standards.

### Article 3- Scope of Coverage

This document defines the ethical, scientific, and quality standards that must be followed throughout the entire process of drug clinical trials. The entire process of a drug clinical trial

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includes planning, initiation, conduct, documentation, supervision, evaluation, analysis, and reporting.

Article 4- Compliance with the Declaration of Helsinki

Principles Drug clinical trials shall comply with the principles of the Declaration of Helsinki adopted by the World Medical Association and other relevant ethical requirements. The rights, safety, and well-being of trial participants are the primary considerations, taking precedence over scientific and social benefits. Ethical review and informed consent are important measures to protect the rights and well-being of trial participants.

Article 5- Principles of Scientific Validity and Benefit in Clinical Trials

Drug clinical trials shall be scientifically and reasonably designed, balancing the anticipated risks and benefits to trial participants and society. Clinical trials may only be conducted or continued if the expected benefits outweigh the risks.

Article 6- Concept of Trial Design and Proportionality of Risk

The design and conduct of clinical trials shall incorporate the concept of Quality by Design, identify critical quality factors and related risks of the trial, and adopt risk-control measures proportionate to those risks. These measures shall protect the rights and safety of trial participants and ensure the reliability of trial results.

Article 7- Clinical Trial Protocol

The clinical trial protocol shall be clear, concise, scientifically sound, and feasible. It may be implemented only after obtaining approval from an ethics review committee. During the implementation of the clinical trial, the protocol may be adjusted when necessary to ensure scientific and ethical integrity, and any adjusted protocol shall again be approved by the ethics review committee before implementation.

Article 8- Qualifications of Investigators

All personnel involved in the clinical trial shall have the educational background, training, and practical experience necessary to undertake clinical trial work, and shall follow the trial protocol during the trial. Any medical judgment or clinical decision involved shall be made by clinical physicians.

Article 9- Principles for Data Recording, Handling, and Preservation

All paper or electronic materials of a clinical trial shall be properly recorded, handled, and preserved to ensure the reliability and traceability of the data. The privacy and personal information of trial participants shall be protected in accordance with the relevant requirements of China's personal information protection regulations. Systems and processes used for data collection, management, and analysis shall be fit for their intended purpose and proportionate to both participant risk and the importance of the data collected.

Article 10- Investigational Product Principles

The preparation of investigational products shall comply with the relevant requirements for the Good Manufacturing Practice of clinical trial drugs. The use and management of investigational products shall comply with the trial protocol and applicable laws and regulations.

Article 11- Quality Management Principles

Quality management of drug clinical trials shall run through the entire trial process to protect the rights and safety of trial participants, ensure the reliability of trial results, and comply with relevant laws and regulations.

Article 12- Principle of Avoiding Conflicts of Interest

All parties involved in drug clinical trials shall take management measures, such as avoidance or control, for any potential conflicts of interest, to prevent impacts on the protection of trial participants and the reliability of trial results.

Article 13- Principle of Using New Technologies

The application of new technologies or new methods in drug clinical trials shall comply with ethical standards, scientific principles, and relevant laws and regulations.

**Chapter II: Ethics Review Committee**

Article 14- Responsibilities

The responsibility of the Ethics Review Committee (ERC) is to protect the rights, safety, and well-being of trial participants. The ERC shall review the scientific and ethical aspects of clinical trials, with particular attention to the protection of vulnerable participants. The ERC shall conduct ethical reviews in accordance with relevant regulations issued by health authorities and the supervisory requirements of the drug regulatory authorities.

1-Checklist of Documents for Review

The documents reviewed by the ERC include:

-The clinical trial protocol

-Informed consent forms

-Methods and information for recruiting trial participants

-Other written materials provided to participants

-Investigator's brochure

-Safety data

-Documents containing participant compensation information

-Qualification documents of principal investigators

-Reports of significant protocol deviations

-Summary reports

-Other documents necessary for the ERC to fulfill its responsibilities

2-Ethical Review in Special Circumstances

The ERC shall pay special attention to the following situations, reviewing whether the protection of participants' rights, safety, and well-being is adequate:

-Trials in which participants are not expected to benefit, and informed consent is provided by their legally authorized representatives.

-Participants who are legally incapacitated or have limited legal capacity.

-Trials involving minors, in which the ERC shall review the informed consent information for minors and consider the participant's age, cognitive maturity, psychological state, and applicable legal requirements.

-Trials in which the protocol specifies that, in emergency situations, the participant or their legally authorized representative is unable to sign the informed consent form before participation.

3-Prevention of Coercion and Waiver of Liability

The Ethics Review Committee (ERC) shall review whether there are situations in which participants are influenced to join the clinical trial through coercion, inducement, or other inappropriate means. The ERC shall also review whether the informed consent form contains any clauses requiring participants or their legally authorized representatives to waive their legal rights. It shall not include content that exempts the principal investigator, clinical trial institution, sponsor, or their agents from responsibilities they are legally obliged to bear.

4-Compensation Mechanism

The ERC shall ensure that the informed consent form and other written materials provided to participants clearly describe the compensation information for participants, including the method, amount, and plan of compensation.

5-Review of Safety Events

The ERC shall pay special attention to and review promptly the following situations:

-Serious adverse events reported by the principal investigator during the clinical trial.

-Deviations or modifications to the trial protocol implemented to eliminate urgent risks to participants.

-Serious or persistent non-compliance issues.

-Changes that increase participant risk or significantly impact trial implementation.

-New information that may adversely affect participant safety or trial conduct.

-Other potential serious safety risk information.

For suspected and unexpected serious adverse reactions reported by the sponsor, as well as safety updates during drug development, the ERC's review process shall be proportional to the urgency of necessary measures and the changing safety characteristics of the investigational drug.

6- Ongoing Review

The Ethics Review Committee (ERC) shall conduct periodic follow-up reviews of ongoing clinical trials. The frequency of such reviews shall be determined according to the level of risk to participants, and the interval between reviews shall not exceed 12 months.

7- Types and Content of Review Opinions

The ERC shall complete the review or filing of clinical trial-related materials within a reasonable timeframe and provide clear written review opinions. ERC review opinions may include: approval, disapproval, approval after modification, re-review after modification, continuation of research, suspension, or termination of the study.

8- Suspension/Termination of Trials

The ERC has the authority to suspend or terminate clinical trials that are not conducted in accordance with relevant requirements or in which participants experience unexpected serious harm.

9- Handling Participant Complaints

The ERC shall accept and properly address complaints or concerns raised by trial participants.

Article 15- Composition and Operational Requirements

The Ethics Review Committee (ERC) shall establish work systems and standard operating procedures for ethical review, improve mechanisms for managing conflicts of interest, and implement quality control mechanisms for ethical review to ensure that the review process is independent, objective, and fair.

Article 16- Document Retention

The ERC shall retain all records of ethical review, including written review records, committee member information, submitted documents, meeting minutes, and related correspondence. For clinical trials used to support drug registration applications, all records shall be kept for at least 5 years after the investigational drug is approved for marketing. For clinical trials not used for drug registration, all records shall be kept for at least 5 years after the termination of the trial.

Article 17- Transparency Requirements

The ERC shall provide relevant written records to principal investigators and sponsors, including the ERC's name and address, the list of members involved in the review of the project, written review opinions, and review statements in compliance with this standard and applicable laws and regulations. If necessary, principal investigators, sponsors, or drug regulatory authorities may request the ERC to provide its standard operating procedures.

**Chapter III: Principal Investigators and Drug Clinical Trial Institutions**

Article 18- Qualification Requirements for Clinical Trial Institutions

Drug clinical trial institutions shall establish a quality management system for drug clinical trials and ensure its effective operation when conducting drug clinical trials.

Article 19- Qualifications and Requirements for Principal Investigators

The principal investigator is the ultimate responsible person at the clinical trial site and shall be accountable for the rights, safety, and welfare of trial participants as well as the quality of the clinical trial. The qualifications and requirements for a principal investigator shall include:

1-Qualifications

The principal investigator shall possess the relevant professional qualifications at the clinical trial institution and shall have the educational background, training experience, and practical experience necessary for conducting clinical trials.

2-Requirements

The principal investigator shall be familiar with the clinical trial protocol, investigator's brochure, and information regarding the investigational drug provided by the sponsor.

3-Requirements

The principal investigator shall be familiar with relevant technical guidelines for clinical trials and shall comply with this standard as well as applicable laws and regulations.

Article 20- Outsourcing of Services

The principal investigator and the clinical trial institution shall establish comprehensive operational systems to ensure fulfillment of their responsibilities and functions in relation to the clinical trial. If any individual or entity is authorized to undertake responsibilities or functions of the clinical trial, the principal investigator and the clinical trial institution shall ensure that such individual or entity possesses the requisite qualifications and shall provide appropriate supervision.

Article 21- Necessary Conditions for Conducting Trials

The principal investigator and the clinical trial institution shall possess the necessary conditions to successfully conduct the clinical trial:

1-Time and Capacity for Participant Enrollment

The principal investigator shall have sufficient time and capability, within the period specified in the clinical trial protocol, to enroll an adequate number of participants who meet the protocol requirements.

2-Facilities and Resources for Trial Completion

The principal investigator shall have access to and authority over the facilities required for the clinical trial, the ability to direct and supervise personnel involved in the trial, and the capacity to conduct the trial correctly and safely.

Article 22- Communication with the Ethics Review Committee

The communication between the principal investigator and the Ethics Review Committee (ERC) shall include the following:

1-Prior to the initiation of the clinical trial, the principal investigator shall obtain approval from the ERC. Participant screening shall not commence before such approval is obtained.

2-Before, during, and after the clinical trial, the principal investigator shall report to the ERC as required and provide all documents necessary for ethical review.

3-The principal investigator shall promptly implement the review opinions issued by the ERC.

Article 23- Compliance with the Protocol

The principal investigator shall comply with the clinical trial protocol.

1-Protocol Deviations

The principal investigator shall conduct the clinical trial in accordance with the protocol approved by the ERC. Any deviation from the protocol by the principal investigator or authorized research personnel shall be recorded and explained. Where necessary, appropriate corrective and preventive measures shall be implemented, and the ERC shall be notified in a timely manner.

2-Protocol Deviations in Response to Urgent Hazards

To eliminate urgent risks to trial participants, if the principal investigator modifies or deviates from the protocol without prior ERC approval, the principal investigator shall promptly report to the ERC and the sponsor, providing a clear explanation of the reasons.

3-Emergency Unblinding

The principal investigator shall perform unblinding in accordance with the requirements of the trial protocol. In the event of accidental or emergency unblinding, the principal investigator shall immediately document the occurrence and provide the sponsor with a written explanation of the reasons.

Article 24- Early Termination or Suspension of a Clinical Trial

In the event of early termination or suspension of a clinical trial, the principal investigator shall promptly inform trial participants and provide appropriate treatment and follow-up. If the clinical trial is terminated or suspended early by the principal investigator, the sponsor, or the Ethics Review Committee (ERC), the principal investigator shall immediately report to the sponsor, the non-initiating members of the ERC, and the clinical trial institution, and shall provide a written explanation.

Article 25- Medical Care

The principal investigator, if a clinical physician, or a clinical physician authorized by the principal investigator, shall provide appropriate medical care to trial participants and shall bear responsibility for medical decisions related to the clinical trial.

Article 26- Safety Reporting

The principal investigator's safety reporting shall comply with the following requirements:

1-Adverse Events

The principal investigator shall report adverse events and/or abnormal test results necessary for safety evaluation to the sponsor in accordance with the clinical trial protocol and specified timelines.

2-Serious Adverse Events

Except for serious adverse events that the protocol or other documents (such as the investigator's brochure) specify do not require immediate reporting, the principal investigator shall immediately submit written reports of all serious adverse events to the sponsor and ERC upon becoming aware of them, and shall subsequently provide detailed written follow-up reports in a timely manner.

3-Deaths

For reports involving deaths, if the sponsor, ERC, or drug regulatory authority requests additional materials, such as autopsy reports or final medical reports, the principal investigator shall provide them promptly upon receipt.

4-Suspected Unexpected Serious Adverse Reactions (SUSARs), Other Potential Serious Safety Risk Information, and Development Safety Update Reports (DSURs)

Upon receiving safety information from the sponsor, including SUSARs, other potential serious safety risks, or DSURs during drug development, the principal investigator shall promptly review the information and consider whether adjustments to participants' treatment are warranted. Where necessary, the principal investigator shall communicate with trial participants at the earliest opportunity.

Article 27- Informed Consent

The principal investigator shall implement informed consent in accordance with the ethical principles of the Declaration of Helsinki, ensuring that trial participants voluntarily participate in clinical trials and are provided with sufficient information through the informed consent process:

1-Obtaining Informed Consent

Before participating in a clinical trial, the principal investigator shall fully inform the trial participants of matters related to the clinical trial, obtain their informed consent, and make a record thereof. The latest version of the informed consent form and other materials provided to the trial participants, approved by the ethics committee, shall be used.

2-Informing Participants of New Information

When the principal investigator obtains new information that may affect the trial participant's continued participation in the clinical trial, the participant or their legal representative shall be promptly informed, and a record shall be made. If necessary, the informed consent form shall be re-signed.

3-No Coercion or Inducement

Researchers shall not use coercion, inducement, or other improper means to influence the trial participants to participate or continue participating in the clinical trial.

4-Comprehensible Informed Consent Materials

The informed consent form and other materials provided to the trial participants shall be written in plain and understandable language, enabling the participants, their legal representatives, and any witnesses to easily comprehend the content.

5-Adequate Time for Consideration

Prior to signing the informed consent form, the principal investigator or an authorized researcher shall provide the trial participants or their legal representatives with adequate time and opportunity to understand the details of the clinical trial, and shall thoroughly answer any questions they may have regarding the clinical trial.

6-Signing of Informed Consent

The trial participant or their legal representative, as well as the researcher obtaining informed consent, shall sign and date the informed consent form. If the form is not signed by the trial participant personally, the relationship shall be specified. The medical record shall document the specific time and personnel involved in obtaining informed consent from the trial participant.

7-Informed Consent When Reading Ability is Lacking

If the trial participant or their legal representative is unable to read, an impartial witness shall be present for the entire informed consent process. The content of the informed consent form and other written materials shall be explained in detail to the trial participant or their legal representative and the witness. If the trial participant provides verbal consent, they shall, to the extent possible, sign the informed consent form when able. The witness shall also sign and date the informed consent form to certify that the trial participant or their legal representative received an accurate explanation of the form and other materials, understood the relevant content, and agreed to participate in the clinical trial.

8-Obtaining a Copy of the Informed Consent

The trial participant or their legal representative shall receive a copy or the original of the signed and dated informed consent form, along with any other materials provided to the trial participant, as well as any subsequent updated versions.

9-Informed Consent for Persons Without or with Limited Civil Capacity

If the trial participant is legally incapable of civil conduct, written informed consent shall be obtained from their legal representative. If the trial participant has limited civil capacity, written informed consent shall be obtained from both the participant and their legal representative. When a legal representative provides informed consent on behalf of the trial participant, the principal investigator shall explain relevant information about the clinical trial to the participant to the extent they can understand and shall, to the greatest extent possible, allow the participant to personally sign and date the informed consent form. Minors as Trial Participants: Written informed consent shall be obtained from the minor's legal representative and signed accordingly. If the minor is capable of making a decision regarding participation in the clinical trial, their personal consent shall also be obtained. If the minor participant does not agree to

participate or decides to withdraw from the clinical trial, their decision shall prevail, even if the legal representative has consented.

Exception: In therapeutic clinical trials for serious or life-threatening conditions, if the principal investigator and the legal representative determine that non-participation would endanger the minor's life, the legal representative's consent alone may allow the minor to participate or continue participation.

During the trial, if the minor reaches the capacity to sign the informed consent form, continued participation requires the minor's own signature on the form.

If a participant with previously limited civil capacity regains full civil capacity, informed consent shall be obtained again from the participant themselves to confirm voluntary continuation or withdrawal from the clinical trial.

10-Informed Consent in Emergency Situations

In emergency situations where informed consent cannot be obtained from the participant prior to trial participation, their legal representative may provide consent on their behalf. If the legal representative is also unavailable, the method of enrolling the participant shall be clearly specified in the trial protocol and other documents, and written approval shall be obtained from the ethics committee. Informed consent from the participant or their legal representative shall be obtained as soon as possible to confirm continued participation in the trial.

11-Informed Consent in Trials Without Anticipated Benefit

For clinical trials in which no direct benefit is expected for the participant, informed consent shall, in principle, be obtained from the participant personally.

Article 28- Drug Management

The principal investigator and the clinical trial institution are responsible for managing investigational drugs provided by the sponsor.

1-Designated Personnel and Management Procedures

The principal investigator and the clinical trial institution shall appoint qualified personnel specifically responsible for managing investigational drugs. The clinical trial institution shall comply with applicable regulations when receiving, handling, storing, dispensing, using, collecting, and returning investigational drugs, and shall maintain records of these activities. The principal investigator shall ensure that investigational drugs are used in accordance with

the trial protocol and shall instruct trial participants on the correct use of the investigational drugs.

2-Retention of Samples for Bioequivalence Trials

The principal investigator shall randomly retain samples of investigational drugs used in bioequivalence trials, and such samples shall be preserved for at least two years after the drug is marketed. Appropriate management procedures shall be established for these retained samples. The clinical trial institution may entrust qualified independent third parties with the storage of retained samples, but these samples shall not be returned to the sponsor or to any third party with an interest in the sponsor.

Article 29- Records and Reporting

Records and reporting of clinical trials shall comply with the following requirements:

1-Supervision to Ensure Data Reliability

The principal investigator shall supervise the collection of data at the trial site and monitor the performance of each research staff member to ensure the reliability of the data.

2-Clinical Trial Data Recording, Modification, Traceability, and Preservation

The principal investigator shall ensure that all clinical trial data are derived from source documents and that their reliability and traceability are maintained. Source documents shall be attributable, legible, contemporaneous, original, accurate, and complete. Any modifications to source documents shall be traceable, must not obscure the original data, and the reason for the modification shall be recorded. For clinical trials involving patients as participants, relevant medical records shall be entered into outpatient or inpatient medical record systems.

3-Retention Period of Documents

The principal investigator and the clinical trial institution shall properly preserve trial documents in accordance with the relevant requirements of the drug regulatory authority. For clinical trials used to support drug registration applications, essential trial records shall be retained for at least five years after the investigational drug is approved for marketing. For clinical trials not used to support drug registration applications, essential records shall be retained for at least five years after the termination of the clinical trial.

4-Protection of Personal Information

In processing clinical trial data and trial participant information, illegal or unauthorized collection, storage, use, correction, transmission, provision, disclosure, or deletion shall be avoided. The recording, handling, and preservation of clinical trial data shall ensure the security of the records and participant information.

5-Transfer of Ownership

The transfer of ownership of essential records shall comply with applicable laws and regulations.

Article 30- Progress Reports

The principal investigator shall provide reports on the progress of the trial.

1-The principal investigator shall submit progress reports and summaries of clinical trial results in accordance with the requirements of the ethics committee.

2-Upon completion of the clinical trial, the principal investigator shall promptly report to the clinical trial site.

3-The principal investigator shall provide the sponsor with clinical trial-related reports as required by the drug regulatory authority.

Article 31- Cooperation with Monitoring, Auditing, and Inspections

The principal investigator and the clinical trial site shall accept monitoring and auditing organized by the sponsor, as well as inspections conducted by the drug regulatory authority, and shall cooperate in providing all records and information related to the clinical trial as requested.

**Chapter IV: Sponsor**

Article 32- Fundamental Considerations

As the party ultimately responsible for activities related to a clinical trial, the sponsor shall regard the protection of the rights, safety, and well-being of trial participants, as well as the reliability of trial data, as fundamental considerations in the conduct of clinical trials.

Article 33- Trial Design

When designing a clinical trial protocol, the sponsor shall ensure that the route of administration, dosage, and duration of administration are supported by adequate safety and efficacy data. The protocol design shall follow the principles of quality by design to ensure the scientific integrity, reliability, and operational feasibility of the clinical trial.

Article 34- Resources, Qualifications, and Training

The sponsor's team shall meet the following requirements:

1-The sponsor shall select appropriately qualified personnel according to the needs of the clinical trial, establish research and management teams for the trial, and provide guidance and oversight throughout the entire clinical trial process.

2-The sponsor shall engage appropriately qualified personnel in the conduct of the clinical trial, including activities related to trial design, implementation, processes, information and data handling, data verification, statistical analysis, and preparation of the trial summary report.

3-The sponsor shall assign medical personnel to promptly address medical issues related to the clinical trial.

4-The sponsor shall establish effective communication channels to ensure timely communication among all personnel involved in the trial throughout its entire course and shall maintain records of key communications.

Article 35- Sponsor's Blinding Maintenance System

In blinded trials, the sponsor shall establish working procedures to ensure that blinding is maintained throughout the entire clinical trial process and to prevent and identify unblinding.

Article 36- Contracts

A sponsor's engagement of service providers shall comply with the following requirements:

1-The sponsor may entrust or authorize a service provider to undertake part or all of the tasks of a clinical trial, but shall supervise and manage the service provider. If the entrusted party intends to subcontract any tasks, prior written consent from the sponsor must be obtained.

2-Before the commencement of clinical trial activities, the sponsor shall enter into clinical trial agreements with all relevant parties involved, including principal investigators, clinical trial sites, and service providers. Such agreements shall clearly define each party's role, responsibilities, rights, and obligations, as well as potential and avoidable conflicts of interest. Updates to the clinical trial agreements shall be made as necessary. The agreements shall contain clear and

comprehensive provisions, and trial funding shall be reasonable and in accordance with market practices.

3-Requirements imposed on the sponsor under these standards shall also apply to service providers performing tasks on behalf of the sponsor.

Article 37- Selection of Principal Investigators

The sponsor is responsible for selecting suitable principal investigators and clinical trial sites to meet the requirements of the clinical trial. The sponsor shall prepare a Investigator's Brochure and update it in a timely manner, providing both the trial protocol and the most recent Investigator's Brochure to the principal investigators and the ethics review committee.

Investigator's Brochure for Traditional Chinese Medicine (TCM) and Ethnic Medicine:

The TCM and ethnic medicine Investigator's Brochure shall specify the theoretical basis of the formulation, screening information, drug compatibility, functions, indications, existing human usage experience, botanical origins of the medicinal materials, and their provenance. For compound preparations derived from classical formulas, the source shall be clearly cited. Relevant materials on medicinal herbs and prescriptions shall also be included.

Article 38- Selection of Laboratories

The sponsor is responsible for selecting laboratories that comply with relevant regulations and possess the necessary qualifications to conduct sample testing involving medical judgments. The sponsor shall supervise the laboratories in quality management of the entire process, including the collection, testing, transport, and storage of clinical trial specimens. It is prohibited to conduct biological sample testing unrelated to the protocol approved by the ethics review committee (e.g., genetic testing).

After the conclusion of the clinical trial, any continued storage or potential future use of remaining specimens must be clearly described in the informed consent signed by the participants, including the duration of storage, confidentiality of data, and circumstances under which data and specimens may be shared with other principal investigators.

Article 39- Communication with Ethics Committees and Regulatory Authorities

Before the commencement of a clinical trial, the sponsor shall submit relevant clinical trial documents to the drug regulatory authority under the State Council and obtain clinical trial approval or complete the required registration/filing. Submitted documents shall clearly indicate the version number and version date. The sponsor shall promptly obtain relevant records from the ethics committee and implement the ethics committee's opinions as required.

Article 40- Sponsor Oversight

The sponsor shall supervise the entire clinical trial process, establish clear work standards and procedures, ensure that the trial is conducted in accordance with the protocol and other relevant documents, comply with applicable laws and regulations, and follow ethical standards. The scope and extent of sponsor oversight shall be appropriate to the purpose and proportional to the complexity and risk of the clinical trial.

Article 41- Quality Management

The sponsor shall implement quality management for the entire clinical trial process based on risk, using an appropriate system to effectively design and conduct the trial.

Article 42- Risk Management

The sponsor shall conduct risk management throughout the clinical trial.

1-Risk Identification and Assessment

The sponsor shall identify risks that may meaningfully affect critical quality factors before the trial begins and throughout the trial. The sponsor shall assess the likelihood of harm, the detectability of risks, and the potential impact on participant protection and the reliability of trial results.

2-Risk Control

Risk control measures shall be proportionate to the significance of the risk in relation to the rights and safety of trial participants and the reliability of trial results. For critical quality factors that may affect participant safety or the reliability of trial results, the sponsor shall predefine acceptable risk control limits. When these predefined limits are exceeded, the sponsor shall assess whether additional measures are necessary.

3-Risk Communication

The sponsor shall document identified risks and corresponding mitigation measures and communicate them to personnel involved in implementing the measures or affected by such activities.

4-Risk Review

The sponsor shall periodically review risk control measures in light of new knowledge and experience acquired during the clinical trial to ensure the effectiveness and applicability of ongoing quality management activities. Additional risk control measures shall be considered as necessary.

5-Risk Reporting

The sponsor shall summarize and report significant quality issues in the clinical trial report, including deviations from predefined acceptable risk limits and any remedial actions taken.

Article 43- Quality Assurance and Quality Control

The sponsor shall implement quality assurance and quality control for the conduct of clinical trials.

1- Responsibilities of the sponsor

The sponsor shall establish, implement, and promptly update written standard operating procedures (SOPs) related to clinical trial quality assurance and quality control, to ensure that the conduct of the clinical trial, as well as the generation, recording, and reporting of data, comply with the trial protocol and conform to this standard and regulatory requirements.

2-Quality Assurance

Quality assurance shall be applied throughout the duration of the clinical trial. A risk-based strategy shall be employed to identify the causes of significant noncompliance with the trial protocol, as well as violations of this standard and regulatory requirements, so as to implement corrective and preventive actions.

3-Audit

The sponsor shall conduct audit activities in a manner proportionate to the risks associated with the conduct of the clinical trial. Audits shall be independent of routine monitoring or

quality control functions, and are intended to evaluate whether the processes for trial management and conduct comply with the trial protocol, this standard, and regulatory requirements.

4-Quality Control

The sponsor shall apply risk-based quality control measures at each stage and step of the clinical trial to ensure procedural compliance and data reliability. Monitoring and data management are the primary quality control activities in clinical trials. The sponsor shall designate qualified monitors to oversee the conduct of the clinical trial.

Article 44- Compliance Issues

The sponsor shall ensure compliance in the conduct of the clinical trial:

1-The sponsor shall take appropriate measures to correct any instances of noncompliance with the trial protocol, standard operating procedures (SOPs), this standard, or regulatory requirements by principal investigators, clinical trial sites, sponsor personnel, or service providers involved in the clinical trial.

2-Upon identifying noncompliance issues that have, or may have, a significant impact on the rights and safety of trial subjects or on the reliability of trial results, the sponsor shall promptly conduct a root cause analysis, implement appropriate and sufficient corrective and preventive actions, and submit a written report to the ethics committee in a timely manner.

3-In the event of serious or persistent noncompliance, the sponsor shall consider terminating the participation of the relevant principal investigator, clinical trial site, or service provider in the trial. The sponsor shall promptly submit a written report to the ethics committee and take measures to minimize any impact on trial subjects and the reliability of trial results. Where violations of the trial protocol or this standard are serious, the sponsor may hold responsible personnel accountable and shall report to the relevant drug regulatory authority.

Article 45- Safety Assessment and Reporting

The sponsor shall conduct ongoing safety assessments throughout the drug clinical trial and shall report in accordance with required formats and timelines:

1-Issues Potentially Affecting Safety

The sponsor shall review and evaluate existing safety information and shall promptly inform trial subjects, principal investigators, clinical trial sites, and the ethics committee of any new findings in the clinical trial that may: Affect the safety or willingness of trial participants, Impact the conduct of the clinical trial, or Alter the opinion or approval of the ethics committee.

2-Safety Assessment

Upon receipt of any safety-related information from any source, the sponsor shall immediately analyze and evaluate it, including considerations of severity, relationship to the investigational product, and whether it constitutes an expected event.

3-SUSARs and Other Potential Serious Safety Risk Information Reporting

The sponsor shall promptly report suspected unexpected serious adverse reactions (SUSARs) and other potential serious safety risk information to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in a manner that complies with applicable requirements.

Reports of suspected unexpected serious adverse reactions submitted to principal investigators and ethics committees shall be proportional to the urgency of required actions and any changes in the safety profile of the investigational product.

Requirements for risk management issued by the drug regulatory authority, other potential serious safety risk information, and urgent safety issues requiring immediate attention or action shall be reported to the ethics committee and principal investigators within the rapid reporting timelines and shall not be unreasonably delayed.

4-DSUR Reporting

The sponsor's Development Safety Update Reports (DSURs) during the drug development period shall include a risk-benefit assessment of the clinical trial and shall be communicated to principal investigators, the ethics committee, and the CDE of the NMPA.

Article 46- Insurance/Compensation/Reimbursement for Trial Participants and Principal Investigators

The sponsor shall adopt appropriate measures to ensure that compensation or reimbursement can be provided to trial participants and principal investigators:

1-The sponsor shall provide legal and financial insurance or guarantees to compensate for damages related to the clinical trial, in a manner proportionate to the nature and degree of

trial risks. This does not cover damages caused by the negligence of principal investigators or clinical trial sites.

2-The sponsor shall bear the medical treatment costs and provide corresponding compensation for damages incurred by trial participants as a result of participation in the clinical trial.

3-The sponsor and principal investigators shall promptly disburse any compensation or reimbursement owed to trial participants. The methods and procedures for providing compensation shall comply with applicable laws and regulations.

4-The sponsor shall provide the investigational product free of charge to trial participants and cover the costs of any medical examinations related to the clinical trial.

Article 47- Investigational Medicinal Products

The preparation, supply, and management of investigational medicinal products (IMPs) shall comply with the following requirements:

1-Manufacture and Labeling

The sponsor shall ensure that IMPs are manufactured and released in accordance with applicable Good Manufacturing Practice (GMP) requirements for clinical trial drugs. The labeling of IMPs shall indicate that they are for clinical trial use only and shall include relevant clinical trial and IMP information. For blinded trials, the IMPs shall maintain the blind.

2-Storage, Transportation, Shelf-Life, and Administration

The sponsor shall clearly specify storage and transportation conditions, shelf-life, and administration methods to ensure that the IMPs are not contaminated or degraded during storage or transport. Written instructions shall be provided to principal investigators and clinical trial sites, and relevant records shall be maintained. For vaccines, procurement, storage, transportation, and administration shall also comply with applicable national regulations.

3-Delivery of IMPs to Sites

Following ethics committee approval of the clinical trial and authorization or filing with the relevant drug regulatory authority, the sponsor shall timely provide IMPs to principal investigators and clinical trial sites.

4-Sponsor IMP Management SOP

The sponsor shall establish standard operating procedures (SOPs) for IMP management, including receipt, handling, storage, distribution, administration, return, and destruction. IMPs returned from trial participants or unused by study personnel shall be returned to the sponsor or otherwise disposed of under sponsor authorization. All IMP management processes shall be documented in writing, and inventory counts shall be accurate throughout.

5-Emergency Unblinding Mechanism

In blinded trials, procedures and mechanisms for emergency unblinding shall be established to allow rapid identification of IMPs in urgent medical situations while maintaining blinding for other trial participants.

6-Retention of IMP Samples

The sponsor shall take measures to ensure the stability of IMPs during the clinical trial and provide IMPs only within their shelf-life. Sufficient samples of IMPs shall be retained, with quantities, methods, and retention periods in accordance with applicable requirements.

Article 48- Data and Records

The sponsor shall fulfill its responsibilities for data governance to ensure the reliability, traceability, and security of data. The sponsor shall ensure that any electronic data management systems deployed or used in the clinical trial meet the requirements for computerized systems. The sponsor shall also confirm that computerized systems used by principal investigators or clinical trial sites meet the requirements of the clinical trial.

1-The sponsor shall not alter data entered by the principal investigator or trial participants, except for valid reasons. Any modification must be approved by the principal investigator before the change and properly documented.

2-The sponsor shall use subject identification codes to identify all clinical trial data for each participant. After unblinding, the sponsor shall provide the principal investigator with the treatment information for participants in the blinded trial.

3-The sponsor shall develop a statistical analysis plan that complies with the trial protocol. Appropriate quality management and documentation shall be applied to statistical programming, data processing, and analysis.

4-The sponsor shall retain essential clinical trial records in accordance with regulatory requirements and shall provide written instructions to the principal investigator, clinical trial site, and service providers regarding the requirements for trial record retention.

Article 49- Access to Trial Records

The sponsor shall clearly define the access rights to trial records.

The sponsor shall specify, in the trial protocol or other written agreements, that the principal investigator, clinical trial site, and service providers permit the sponsor to directly access relevant source records of the clinical trial during monitoring, auditing, ethics review, and inspections by the drug regulatory authority.

The sponsor shall confirm that each trial participant has provided written consent allowing the sponsor to directly access the relevant original medical records during monitoring, auditing, ethics review, and inspections by the drug regulatory authority.

Article 50- Reporting

If the sponsor suspends or prematurely terminates an ongoing clinical trial, or if the sponsor undergoes a change during the trial, the sponsor shall promptly inform the principal investigator, clinical trial site, ethics committee, and drug regulatory authority, providing the reasons for such action.

The sponsor shall submit a clinical trial report to the drug regulatory authority in accordance with regulatory requirements. The clinical trial report shall fully, completely, and accurately reflect the trial results, and the clinical trial data shall be consistent with the source data.

**Chapter V: Data Governance**

Article 51- Data Lifecycle

The sponsor, principal investigator, and clinical trial site shall assume responsibilities for data governance within their respective roles. Data governance applies throughout the entire lifecycle of clinical trial data to ensure accurate reporting, verification, and interpretation of information related to the clinical trial.

1-During the clinical trial, the sponsor, principal investigator, and clinical trial site shall enter collected data into computerized systems along with the corresponding metadata, including audit trails.

2-They shall apply, evaluate, access, manage, and review metadata using appropriate methods.

3-The sponsor and clinical trial site shall establish procedures for correcting data errors, and the sponsor and principal investigator shall promptly correct any data errors that may affect the reliability of trial results, ensuring that the correction process is fully traceable.

4-The sponsor, principal investigator, and clinical trial site shall establish validated processes to ensure the reliability, traceability, and security of electronic data, including relevant metadata, transmitted between computerized systems, and to prevent data loss or tampering.

5-The sponsor shall define interim and final analysis datasets that meet quality standards and shall implement timely and reliable procedures for data collection, verification, validation, review, error correction, and, where applicable, correction of omissions that may significantly affect participant safety or the reliability of trial results. Prior to statistical analysis, datasets shall be finalized according to pre-established procedures. Data extraction and determination of analysis datasets shall follow the statistical analysis plan and be properly documented.

Article 52- Maintaining Blinding in Data Governance

In blinded clinical trials, the integrity of blinding shall be maintained throughout all stages of the trial, and appropriate measures shall be taken to prevent accidental unblinding that could introduce bias into the trial. Before the trial begins, all relevant parties shall define the roles, responsibilities, and procedures for accessing unblinded information and shall document these arrangements. During the trial, any instances of unblinding or breaking of the blind shall be recorded, the impact on trial results shall be assessed, and any necessary corrective measures shall be implemented.

Article 53- Computerized Systems

All parties to a clinical trial shall ensure that the computerized systems used for the trial meet the requirements for data reliability, traceability, and security.

1-Rules for Use of Computerized Systems and Training

Standard operating procedures shall be established for the configuration, installation, and use of computerized systems, and the responsibilities of all parties in using such systems shall be clearly defined. These measures shall ensure the proper use of computerized systems during the collection, processing, and management of clinical trial data. All personnel operating computerized systems shall receive appropriate training.

2-Security Management of Computerized Systems

Data security management for computerized systems shall cover the entire data lifecycle, ensuring the implementation of security controls and the adoption of continuous measures to

prevent, detect, and mitigate security vulnerabilities. Trial data generated by computerized systems shall be backed up in a timely manner, and contingency measures shall be taken in the event of system failure to prevent data loss or inaccessibility.

3-Validation of Computerized Systems

Computerized systems used by all parties to a clinical trial shall undergo reliable system validation to ensure conformity with their intended use and predefined technical performance specifications, thereby ensuring data reliability and maintaining the validated state of the system throughout the trial.

4-Technical Support

All parties to a clinical trial shall establish workflows for documenting, assessing, and managing issues arising within computerized systems, and shall periodically review the collected issues to identify recurring or systemic problems. Issues shall be addressed according to their severity.

5-User Management

Computerized systems shall have robust user management, access control, and audit trail capabilities to ensure that only authorized users may access and operate the system, and to ensure full traceability of access and operations. Where electronic signatures are used, they shall comply with relevant national requirements on electronic signatures. User permissions shall align with their job responsibilities, blinding requirements, and organizational affiliation. Authorized users and their permissions shall be clearly documented, maintained, and preserved.

## Chapter VI: Supplementary Provisions

Article 54- Definitions of Terms

1-Principal Investigator refers to the head of the clinical trial implementation team at the drug clinical trial site, who is responsible for the rights and safety of trial participants on site, as well as the reliability of clinical trial data during trial conduct.

2-Other Potential Serious Safety Risk Information refers to information that clearly affects the benefit-risk assessment of the investigational drug, may alter its usage, or impact the overall drug development process.

3-Quality Management of Drug Clinical Trials refers to the management of quality throughout drug clinical trials, including establishing a quality management system and carrying out specific quality management activities.

4-Quality Management System of Drug Clinical Trials refers to the mechanism for managing quality throughout the entire clinical trial process, with the protection of trial participants and data reliability as its core. It clearly defines and implements the responsibilities and division of duties of all parties, enables timely identification, prevention, and handling of abnormal

events based on risk, continuously promotes quality improvement, and ensures compliance throughout the clinical trial process.

This standard shall come into effect on [XXXX Year X Month X].