Appendix 1

Good Clinical Practice for Drug Clinical Trials (Revised 2026)

Chapter 1 General Provisions

Article 1. This standard is 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 *Regulations for the Implementation of the Drug Administration Law of the People's Republic of China*, and the *Measures for Drug Registration Administration* to ensure the standardization of drug clinical trial procedures, protect the rights and safety of trial participants, and ensure that data and results are scientific, truthful, and reliable. Article 2. This standard applies to drug clinical trials conducted for the purpose of drug development and approval by the State Council's drug regulatory department. All activities related to drug clinical trials shall comply with this standard.

Article 3. Good Clinical Practice (GCP) guidelines for drug clinical trials are the ethical, scientific, and quality standards that must be followed throughout the entire process of drug clinical trials. The entire process of drug clinical trials includes planning, initiation, execution, recording, monitoring, evaluation, analysis, and reporting.

Article 4. Clinical trials of drugs shall comply with the principles of the World Medical Association's Declaration of Helsinki and related ethical requirements. The rights and safety of trial participants shall be the primary consideration, taking precedence over scientific and social benefits. Ethical review and informed consent are important measures to protect the rights and safety of trial participants.

Article 5 Drug clinical trials shall be scientifically sound and reasonable, weighing the expected risks and benefits for trial participants and society. A clinical trial may only be initiated or continued when the expected benefits are reasonably proportionate to the risks. Article 6 The design and implementation of clinical trials shall incorporate quality-by-design principles.

The method involves identifying key quality factors and related risks of the trial, and adopting appropriate risk control measures to protect the rights and safety of trial participants and ensure reliable results. Article 7: The clinical trial

protocol should be clear, concise, scientifically sound, and operable, and can only be implemented after obtaining approval from the ethics review committee. During the implementation of the clinical trial, to ensure its ethical and scientific rigor, the trial protocol may be adjusted as necessary, and can only be implemented after obtaining approval from the ethics review committee again.

Article 8. All parties involved in clinical trials shall possess the relevant educational background, training, and practical experience to undertake clinical trial work, and shall adhere to the trial protocol during the clinical trial process. Roles and responsibilities in clinical trials shall be clearly defined and properly documented. All medical judgments or decisions shall be made by qualified clinicians. Article 9. All paper and electronic data from clinical trials shall be properly recorded,

processed, and stored to ensure data reliability and traceability. The privacy and personal information of trial participants shall be protected, complying with relevant Chinese requirements regarding personal information protection. Systems and processes used for data collection, management, and analysis shall meet their intended purpose.

And commensurate with the risks to trial participants and the importance of the data collected.

Article 10 The preparation of drugs for clinical trials shall comply with the relevant requirements of Good Manufacturing Practice (GMP) for clinical trial drugs, and their use and management shall comply with laws and regulations and the requirements of the trial

protocol and related documents. Article 11 Quality management of drug clinical trials shall be implemented throughout the entire clinical trial process to protect the rights and safety of trial participants, ensure the reliability of clinical trial results, and comply with relevant laws and regulations.

Article 12 The implementation of drug clinical trials shall adhere to the principle of conflict of interest avoidance to prevent any impact on the rights and safety of trial participants and the reliability of trial results.

Article 13

The application of new technologies and methods in drug clinical trials shall comply with...

It complies with ethical, scientific, and relevant legal and regulatory requirements.

Chapter Two Ethics Review Committee

Article Fourteen The responsibilities of the ethics review committee are to protect the rights and safety of trial participants. The ethics review committee shall review the ethical and scientific rigor of clinical trials, with particular attention to the protection of vulnerable trial participants. The ethics review committee shall conduct its ethical review work in accordance with the relevant regulations of the health authorities and the requirements of this standard.

(a) The documents reviewed by the ethics review committee include: the trial protocol, informed consent form, methods and information for recruiting trial participants, other materials provided to trial participants, investigator's manual and current scientific information, safety data, documents containing information on compensation for trial participants, qualification documents of the principal investigator, reports of significant protocol deviations, progress and completion reports, and other documents required by the ethics review committee to perform its duties.

(ii) The ethics review committee shall pay particular attention to the following special circumstances to review whether the rights and safety of trial participants are adequately

protected: In clinical trials where no expected benefit is expected, informed consent is given by the participant's legal representative.

The trial participant is a person without civil capacity or with limited civil capacity.

When minors are involved, the ethics review committee should review the informed consent information for minors and take into account the age characteristics, cognitive maturity, psychological state, and applicable legal requirements of the participants.

The trial protocol clearly outlines the roles of trial participants and their legal representatives in emergency situations. Enrollment is permitted when no participant is able to sign an informed consent form before

the trial. (III) The ethics review committee shall review the case to ensure that there are no circumstances in which participants are coerced or induced to participate in the clinical trial. The ethics review committee shall review the informed consent form to ensure that it does not contain any content requiring participants or their legal representatives to waive their legal rights, nor does it contain any content that exempts the principal investigator, clinical trial institution, sponsor, and related service providers from liability.

(iv) The ethics review committee shall ensure that informed consent forms are provided to trial participants. The information on trial participant compensation contained in other materials of the participants, including the method, amount and plan of compensation, is reasonable.

(V) The ethics review committee shall pay close attention to and review the following situations in a timely manner: serious adverse events reported by the principal investigator in the clinical trial; deviations or modifications to the trial protocol made during the implementation of the clinical trial to eliminate urgent harm to the trial participants; serious and persistent non-compliance issues; changes that increase the risk to the trial participants or significantly affect the implementation of the clinical trial; and new information that may have an adverse impact on the safety of the trial participants or the implementation of the clinical trial.

The ethics review committee should review information on suspected and unexpected serious adverse reactions reported by sponsors, other potential serious safety risks, and information related to safety updates during drug development in a manner commensurate with the urgency of the measures required and the changes in the safety characteristics of the investigational drug.

(vi) The ethics review committee shall regularly review ongoing clinical trials. The frequency of the review shall be determined according to the risk level of the trial, and the time interval shall not exceed 12 months.

(vii) The ethics review committee shall complete the review or filing process of clinical trial-related materials within a reasonable timeframe and provide a clear written review opinion or filing receipt containing information on the version of the reviewed documents. The ethics review committee's review opinions include: approval, disapproval, approval after modification, re-review after modification, continuation of study, suspension or termination of study.

(viii) The ethics review committee has the right to suspend or terminate clinical trials that are not conducted in accordance with relevant requirements or where trial participants experience unexpected serious harm. (ix) The ethics review committee shall accept and properly handle all complaints from trial participants.

Regarding the demands.

Article 15 The ethics review committee shall establish an ethics review system and standards. Establish standardized operating procedures, improve conflict of interest management mechanisms and ethical review quality control mechanisms, and ensure that the ethical review process is independent, objective, and impartial.

Article 16 The ethics review committee shall retain all records of the ethics review, including written records of the ethics review, information of committee members, submitted documents, meeting minutes, and relevant correspondence. For clinical trials used to apply for drug registration, all records shall be kept for at least 5 years after the investigational drug is approved for marketing; for clinical trials used to apply for drug registration but the investigational drug has not been approved, and for clinical trials not used to apply for drug registration, all records shall be kept for at least 5 years after the termination of the clinical trial.

Article 17 The ethics review committee shall promptly provide the principal investigator and sponsor with relevant written review documents, including the name and address of the ethics review committee, and the names of the participants.

The project review should include a list of ethics review committee members, review opinions, and a statement confirming compliance with these guidelines and relevant laws and regulations. If necessary, the principal investigator, sponsor, or drug regulatory authority may request the ethics review committee to provide its standard operating procedures.

Chapter 3 Principal Investigators and Drug Clinical Trial Institutions

Article 18. Drug clinical trial institutions conducting drug clinical trials shall establish a drug clinical trial quality management system and ensure its effective operation. Article 19. The principal investigator

is the ultimate responsible person at the clinical trial site and is responsible for the rights and safety of trial participants and the quality of the clinical trial. The principal investigator shall possess the corresponding professional qualifications at the clinical trial institution, have the necessary educational background, training experience, and practical experience for clinical trials; be familiar with the trial protocol, investigator's manual, and relevant information on the clinical trial drug provided by the sponsor; be familiar with relevant technical guidelines for clinical trials, and comply with this standard and relevant laws and regulations.

Article 20. Principal investigators and clinical trial institutions that authorize individuals or entities to undertake relevant responsibilities and functions in clinical trials shall establish complete working systems and implement effective supervision and management to ensure that such authorizations possess the corresponding qualifications and are able to correctly perform their responsibilities and functions. If principal investigators and clinical trial institutions need to entrust entities other than clinical trial institutions to undertake relevant responsibilities and functions in clinical trials, they must obtain the sponsor's consent in advance. Principal investigators and clinical trial institutions bear ultimate responsibility for the matters they authorize and entrust. In principle, decisions made by the principal investigator regarding clinical trials, key validations, and formal reports to the ethics review committee, the drug clinical trial institution, and the sponsor shall not be delegated.

Article 21. Principal investigators and clinical trial institutions shall be qualified to complete clinical trials. The necessary conditions for a clinical trial

are: (i) The principal investigator has sufficient time and capacity to organize and conduct the clinical trial, and to enroll a sufficient number of participants who meet the trial protocol within the timeframe stipulated in the clinical trial contract. (ii) The

principal investigator has the authority to use the facilities required for the clinical trial, and has the right to direct and supervise the researchers involved in the clinical trial to ensure the correct and safe conduct of the clinical trial.

Article 22. Communication between the principal investigator and the ethics review committee includes:

(i) Before initiating a clinical trial, the principal investigator must obtain approval for the clinical trial project from the ethics review committee. (ii) Before,

during, and after the clinical trial, the principal investigator must report to the ethics review committee as required and provide all necessary documents for the ethics review.

document.

(iii) The principal investigator shall promptly implement the review opinions of the ethics review committee. See.

Article 23 The principal investigator and his/her authorized investigators shall comply with the trial Clinical trial

protocol. (a) Clinical trials shall be conducted in accordance with the trial protocol approved by the ethics review committee. Any deviation from the trial protocol shall be recorded, significant deviations explained, appropriate corrective and preventive measures taken, and reported to the ethics review committee and the sponsor.

(ii) In order to eliminate imminent harm to trial participants, if the trial protocol is deviated from without the consent of the ethics review committee, the principal investigator should promptly report to the ethics review committee.

(iii) The principal investigator shall unblind the trial in accordance with the requirements

of the trial protocol. In the event of unexpected unblinding or emergency unblinding, it shall be recorded immediately, and the reasons shall be explained to the sponsor in writing. Article 24 If a clinical trial is terminated or suspended early, the principal

investigator shall promptly notify the trial participants and provide them with appropriate treatment and follow-up. If the principal investigator, sponsor, or ethics review committee terminates or suspends a clinical trial early, the principal investigator shall immediately report to the sponsor, the non-sponsor on the ethics review committee, and the clinical trial institution, and provide a written explanation.

Article 25. The principal investigator with clinical physician qualifications or a clinical physician authorized by the principal investigator shall provide appropriate medical treatment to the trial participants and assume responsibility for medical judgment or medical decisions related to the clinical trial.

Article 26 The safety report of the principal investigator shall meet the following requirements:

(i) Safety reports shall be submitted to the sponsor in accordance with the requirements and time limits of the test protocol. Evaluation of adverse events and abnormal test results required.

(ii) Except for serious adverse events that do not require immediate reporting as specified in the trial protocol or other documents (such as the investigator's manual), the principal investigator shall immediately report all serious adverse events in writing to the sponsor and the ethics review committee upon learning of them, and shall subsequently provide a detailed, written follow-up report in a timely manner.

(iii) Regarding reports of deaths, if the sponsor, ethics review committee, or drug regulatory authority requests other necessary materials, such as autopsy reports or final medical reports, the principal investigator shall provide them promptly upon receipt. (iv) If the principal investigator receives information from the sponsor regarding suspected and

unexpected serious adverse reactions, other potential serious safety risks, or safety concerns during drug development...

After receiving new reports containing relevant safety information, participants should promptly sign and review them, and consideration should be given to whether their treatment should be adjusted accordingly. If necessary, participants should be communicated with as early as possible.

Article 27 The implementation of informed consent shall comply with the ethical principles of the Declaration of Helsinki, ensure that trial participants are participating in clinical trials voluntarily, and ensure that they receive sufficient information through the informed consent process: (a) Before participating in a clinical trial,

the principal investigator or his/her authorized researcher shall fully inform the trial participants or their legal representatives of matters related to the clinical trial, obtain and record the informed consent of the trial participants or their legal representatives, and use the latest version of the informed consent form approved by the ethics review committee and other information provided to the trial participants.

(ii) When the principal investigator obtains new information that may affect a participant's willingness to continue participating in the clinical trial, the principal investigator shall promptly inform the participant or their legal representative and make a corresponding record. If necessary, the informed consent form shall be signed again.

(iii) The principal investigator and his/her authorized investigators shall not use coercion or bribery. Inappropriate methods may be used to influence participants to participate in or continue participating in clinical trials.

(iv) Informed consent forms and other materials provided to trial participants shall be in plain language and easy to understand, so that the trial participants or their legal representatives or impartial witnesses can easily understand them.

(v) Before signing the informed consent form, the principal investigator or its authorized investigator shall give the trial participants or their legal representatives sufficient time and opportunity to understand the details of the clinical trial and answer in detail any questions raised by the trial participants or their legal representatives related to the clinical trial.

(vi) The trial participant or their legal representative, as well as the researcher executing the informed consent, shall sign and date the informed consent form. If the signature is not given by the trial participant, the relationship shall be noted. The specific time and person giving the informed consent shall be recorded in the medical record. (vii) If the trial participant or their legal representative

lacks reading ability, a notary public shall witness the entire informed consent process. The contents of the informed consent form and other materials shall be explained in detail to the trial participant, their legal representative, and the notary public. If the trial participant or their legal representative verbally agrees to participate in the clinical trial, they shall, to the extent possible, sign the informed consent form. The notary public shall also sign and date the informed consent form to prove that the trial participant or their legal representative has received an accurate interpretation of the informed consent form and other materials, understands the relevant content, and agrees to participate in the clinical trial.

(viii) Participants in the trial or their legal representatives shall receive the original signed and dated informed consent form and other materials provided to them, and shall continue to receive updated versions of the information during the trial period. (ix) If a participant in the trial is a person

without civil capacity, they shall obtain their legal representative's consent.

Written informed consent from the agent is required; if the trial participant is a person with limited civil capacity, written informed consent from both the person and their legal representative is required. When a legal representative gives informed consent on behalf of the trial participant, they should inform the participant of relevant information about the clinical trial to the extent that the participant can understand, and should, as far as possible, have the participant personally sign the informed consent form and

indicate the date. For minors as trial participants, informed consent from their legal representative is required, and the legal representative must sign the informed consent form. When a minor is capable of giving consent to participate in a clinical trial...

When making a decision, the minor's consent must be obtained. If a minor participant does not agree to participate in the clinical trial or decides to withdraw midway, even if their legal guardian has agreed to participate or is willing to continue participating, the minor participant's decision shall prevail. However, in therapeutic clinical trials for serious or life-threatening diseases, if the principal investigator or legal guardian believes that the minor participant's life would be endangered if they do not participate, the legal guardian's consent may suffice for the participant to participate or continue. If a minor participant meets the conditions for signing an informed consent form during the clinical trial, they must sign the form before the trial can continue. After a person with limited civil capacity regains their civil capacity, informed consent must be obtained again to obtain their voluntary consent to continue or withdraw from the relevant clinical trial.

(x) In emergency situations where informed consent cannot be obtained from a trial participant before participation in a clinical trial, their legal representative may provide informed consent on their behalf. If the legal representative is also not present, the enrollment procedures for the trial participant must be clearly stated in the trial protocol approved in writing by the ethics review committee and other documents. Trial information should be communicated to the trial participant or their legal representative as soon as possible, and informed consent should be obtained in a timely m agree.

(xi) Participants in clinical trials for which no expected benefit should, in principle, [leave the trial]. Informed consent must be signed by the trial participant.

Article 28. Principal investigators and clinical trial institutions shall provide sponsors with...

The principal investigator and the clinical trial institution shall bear management

responsibility for the supplied clinical trial drugs. (a) The principal investigator and the clinical trial institution shall appoint qualified personnel...

Clinical trial drugs shall be managed by designated personnel. Clinical trial institutions shall comply with relevant regulations and maintain records regarding the receipt, processing, storage, distribution, use, recycling, return, and destruction of clinical trial drugs. The principal investigator shall ensure that clinical trial drugs are used in accordance with the trial protocol and explain the correct usage of clinical trial drugs to trial participants. (II) The principal investigator shall randomly sample clinical trial drugs used in bioequivalence trials and retain the samples for at least two years after the drug's market launch, and shall establish corresponding management systems. Clinical trial institutions may entrust qualified independent third parties to retain the samples, but they shall not return them to the sponsor or any third party with a related interest.

Article 29 The records and reports of clinical trials shall meet the following requirements:

(i) The principal investigator shall supervise data collection at the trial site and ensure that all researchers fulfill their responsibilities to guarantee data reliability. (ii) The principal investigator shall ensure that all clinical trial data are obtained from the source records of the clinical trial and guarantee their reliability and traceability. Source records shall be attributable, readable, synchronic, original, accurate, and complete. Modifications to source records shall be traceable, shall not obscure the original records, and the reasons for the modifications shall be recorded. For clinical trials involving patients as participants, relevant medical records shall be entered into the outpatient or inpatient medical record system.

(III) Principal investigators and clinical trial institutions shall properly preserve trial documents in accordance with the relevant management requirements of the drug regulatory authorities. For clinical trials used to apply for drug registration, the essential records of the clinical trial shall be kept for at least 5 years after the investigational drug is approved for marketing; for clinical trials used to apply for drug registration but the investigational drug has not been approved, and for clinical trials not used to apply for drug registration, the essential records shall be kept for at least 5 years after the termination of the clinical trial.

(iv) During the processing of clinical trial data and participant information, care should be taken to avoid illegal or unauthorized collection, storage, use, correction, transmission, provision, publication, deletion, etc. The recording, processing, and preservation of clinical trial data should ensure the security of records and participant information. (v) The transfer of

ownership of essential records must comply with the requirements of relevant laws and regulations.

Article 30 The principal investigator shall provide a clinical trial report.

(i) The principal investigator shall submit progress and completion reports as required by the ethics review committee. (ii)

Upon completion of the clinical trial, the principal investigator shall promptly submit a written report to the clinical trial institution.

(iii) The principal investigator shall provide the sponsor with the relevant clinical trial reports required by the drug regulatory authority.

Article 31 The principal investigator and clinical trial institution shall accept the monitoring and auditing organized by the sponsor, as well as the inspection by the drug regulatory authority, and cooperate in providing the necessary records related to the clinical trial.

Chapter Four: Applicants

Article 32 The sponsor is ultimately responsible for all activities related to clinical trials. Protecting the rights and safety of trial participants and ensuring the reliability of data should be fundamental considerations in clinical trials.

Article 33: Sponsors designing clinical trial protocols must be based on sufficient safety and efficacy data, incorporate quality-by-design methods, and ensure the scientific rigor, reliability, and operability of the clinical trials.

Article 34. Sponsors shall select appropriately qualified personnel based on the needs of clinical trials.

The sponsor shall establish a research and management team to conduct clinical trials, guide and supervise the entire process. The sponsor shall establish effective communication channels to ensure timely communication among all participants throughout the clinical trial and record key communication content. The sponsor shall also assign medical personnel to promptly answer medical questions related to the clinical trial. Article 35: The sponsor shall conduct a prior assessment and select a qualified principal

investigator.

Researchers and drug clinical trial institutions are needed to meet the requirements for conducting clinical trials.

Article 36 The service provider entrusted by the applicant shall meet the following requirements:

(i) Sponsors may delegate some or all of their clinical trial tasks to qualified service providers, but shall supervise and manage the service providers and their further subcontracted activities and bear ultimate responsibility. If the delegated party engages in subcontracting, it shall obtain the sponsor's prior written consent.

(ii) Before the commencement of clinical trial activities, the sponsor shall sign a clinical trial contract with all relevant parties participating in the clinical trial, including the principal investigator, the clinical trial institution, and its entrusted service providers. The contract shall clearly define the roles, responsibilities, rights, and obligations of each party, as well as any potential conflicts of interest that should be avoided. The clinical trial contract shall be clear and complete in its terms, and the trial funding shall be reasonable and in accordance with market principles.

(III) The requirements for applicants in this specification apply to those undertaking the relevant work of the applicant. Service providers for the task. Article 37

The applicant is responsible for selecting laboratories that meet relevant regulations and possess the corresponding qualifications to undertake the testing and analysis of biological samples, and for supervising the laboratory's management, testing and analysis, transportation, storage and disposal of biological samples collected in clinical trials throughout the entire process.

Quality Management. Conducting biological sample testing (such as genetic testing) unrelated to the trial protocol approved by the ethics review committee is prohibited. Sponsors should clearly state in the informed consent form the continued preservation or potential future use of remaining biological samples after the clinical trial, including preservation time, data confidentiality issues, and under what circumstances data and biological samples can be shared.

Article 38 Before commencing a clinical trial, the sponsor shall submit relevant clinical trial data to the State Drug Administration and obtain a clinical trial permit or complete the bioequivalence trial filing. The sponsor shall promptly obtain relevant records from the ethics review committee and comply with the ethics review opinions as required.

Article 39. Sponsors shall develop and update trial protocols, researcher handbooks, informed consent materials, and other relevant documents in a timely manner, and provide the latest documents to principal investigators and the ethics review committee. Informed consent forms shall be comprehensive, complete, and easily understandable, and shall comply with relevant ethical review requirements.

Article 40. Sponsors shall, based on risk and employing an appropriate system, conduct quality management throughout the entire clinical trial process, effectively design and implement clinical trials, and supervise the entire clinical trial process. The scope and extent of the sponsor's supervisory measures shall be appropriate to the purpose and commensurate with the complexity and risks of the clinical trial. Article 41. Sponsors shall implement

quality assurance and quality control measures for clinical trials.

control.

(i) The sponsor is responsible for establishing, implementing and updating in a timely manner the written standard operating procedures related to clinical trial quality assurance and quality control, to ensure that the implementation of clinical trials, as well as the generation, recording and reporting of data, comply with the trial protocol and meet the requirements of this regulation and regulatory requirements.

(ii) Quality assurance should be implemented throughout the entire clinical trial process, and a risk-based strategy should be adopted to identify serious non-compliance with the trial protocol and the causes of violations of this guideline and regulatory requirements, so as to take corrective and preventive measures.

Sponsors should conduct audits in a manner commensurate with the risks associated with the implementation of the clinical trial. Sponsor audits are independent of routine monitoring or quality control functions and aim to assess whether trial management, implementation, and related stakeholders comply with the trial protocol, these guidelines, and regulatory requirements.

(III) Sponsors shall employ a risk-based approach to quality control at every stage and in every aspect of clinical trial implementation to ensure process standardization and data reliability. Monitoring and data management are key quality control activities in clinical trials. Sponsors shall appoint qualified monitors to monitor clinical trials. Article 42 Sponsors shall conduct risk management for clinical trials.

(i) The sponsor shall identify risks that may have a meaningful impact on key quality factors before the start of the trial and throughout the trial, and assess the likelihood of such risks occurring, their detectability, their impact on the protection of trial participants and the reliability of the trial results.

(ii) Risk control should be commensurate with the importance of the risk to the rights and safety of trial participants and the reliability of trial results. When critical quality factors that may affect the safety of trial participants or the reliability of trial results are involved, the sponsor should pre-determine an acceptable range for risk control. If the risk exceeds the pre-determined range, an assessment should be made as to whether measures are necessary. (iii) The sponsor should record the identified risks and

corresponding mitigation measures and communicate them with personnel involved in taking measures or affected by such activities.

(iv) Sponsors shall periodically review risk control measures based on new knowledge and experience gained during clinical trials to ensure the effectiveness and applicability of current quality management activities, and consider implementing additional risk control measures as needed. (v) Sponsors shall

summarize and report important quality aspects in the clinical trial report.

Problems, including deviations from pre-defined acceptable ranges, and remedial measures. Article 43:

Sponsors shall ensure compliance with clinical trials.

(a) Staff of principal investigators, clinical trial institutions, and sponsors.

Or, if the service provider fails to comply with the trial protocol, standard operating procedures, this guideline, and regulatory requirements during the clinical trial, appropriate corrective measures shall be

taken. (II) If non-compliance issues are found that have or may have a significant impact on the rights and safety of trial participants or on the reliability of trial results, the sponsor shall promptly analyze the root cause, take appropriate and sufficient corrective and preventive measures, and promptly report in writing to the ethics review committee. (III) If serious and persistent non-

compliance issues are found, the sponsor shall consider termination.

The principal investigator, clinical trial institution, or service provider must continue to participate in the clinical trial, promptly submit a written report to the ethics review committee, and take measures to minimize the impact on trial participants and the reliability of trial results. If the violation of the trial protocol or these guidelines is serious, the sponsor may hold the relevant personnel accountable and report the matter to the drug regulatory authority.

Management department.

Article 44 The sponsor shall conduct continuous [testing/monitoring] during the drug clinical trial.

Safety assessments should be conducted and reported as required and within

the stipulated timeframes. (a) Sponsors should review and evaluate existing safety information. Any new safety findings that may affect the safety or willingness of trial participants, or may impact the clinical trial, should be reported.

For any issues that may change the approval opinion of the ethics review committee, the principal investigator, clinical trial institution, and ethics review committee should be notified in a timely manner to ensure that trial participants are informed in a timely manner, and necessary updates should be made to the trial protocol, investigator's manual, informed consent materials, and other documents as required.

(ii) Upon receiving any safety-related information from any source, the sponsor shall immediately analyze and evaluate it, including its severity, relevance to the investigational drug, and whether it is as expected.

Events, etc.

(III) Sponsors shall promptly report any suspected and unexpected serious adverse reactions or other potential serious safety risks to the Center for Drug Evaluation of the National Medical Products Administration (NMPA), and the method of rapid reporting shall meet the requirements. The method by which sponsors submit reports of suspected and unexpected serious adverse reactions to the principal investigator and the ethics review committee shall be commensurate with the urgency of the required action and the changes in the safety characteristics of the investigational drug. Risk handling requirements from drug regulatory authorities, information on other potential serious safety risks, and urgent safety issues requiring immediate attention or action shall be reported to the ethics review committee and the principal investigator within the time limits required for rapid reporting.

(iv) The sponsor shall regularly submit safety update reports during drug development to the Center for Drug Evaluation of the National Medical Products Administration, and notify the principal investigator and ethics review committee of relevant information as required.

(v) During the clinical trial of the drug, if safety issues or other risks are discovered...

If the trial is deemed risky, the sponsor should promptly adjust the trial protocol, suspend or terminate the clinical trial, and report to the Center for Drug Evaluation of the National Medical Products Administration.

Article 45. Sponsors shall provide clinical trial drugs to trial participants free of charge and pay for medical testing costs related to the clinical trial. Sponsors shall adopt...

Appropriate measures should be taken to ensure that trial participants and principal investigators are compensated or indemnified.

(i) The sponsor shall provide legal and financial insurance or guarantee to compensate or indemnify damages related to the clinical trial, and such insurance shall be commensurate with the nature and degree of risk of the clinical trial, but shall not include damages caused by the negligence of the principal investigator or the clinical trial institution itself.

(II) The sponsor shall bear the medical expenses incurred by trial participants for any harm related to their participation in the clinical trial, as well as corresponding compensation or damages. (III) The

sponsor and principal investigator shall promptly pay the compensation or damages to the trial participants. The methods of providing compensation or damages shall comply with relevant laws and regulations. Article 46 The sponsor is responsible for

providing the clinical trial drugs to the principal investigator and the drug clinical trial institution. The preparation, supply, and management of clinical trial drugs shall meet the following requirements:

(i) Sponsors shall ensure that clinical trial drugs are manufactured and released under conditions that meet the relevant requirements of Good Manufacturing Practice (GMP) for clinical trial drugs; the labels of clinical trial drugs shall indicate that they are for clinical trials only, clinical trial information and clinical trial drug information; and the clinical trial drugs shall be able to remain blinded in blinded trials.

(II) The sponsor shall clearly specify the storage and transportation conditions, expiration date, and method of use of the clinical trial drug to ensure that the drug is not contaminated or deteriorated during transportation and storage, and provide corresponding written explanations to the principal investigator and clinical trial institution, while retaining relevant records. If the clinical trial drug is a vaccine, its procurement, storage, transportation, and administration shall also comply with relevant vaccine management regulations. (III) The clinical trial shall be approved by the ethics review

committee and the State Council's drug supervision department.

After obtaining permission or filing from the regulatory authorities, the applicant shall promptly provide the principal investigator and clinical trial institution with the drugs for clinical trials.

(iv) Sponsors shall establish procedures for the supply and management of clinical trial drugs, including systems for the receipt, processing, storage, distribution, use, recycling, and destruction of clinical trial drugs. Clinical trial drugs recovered from trial participants or unused within the clinical trial facility shall be returned to the sponsor or disposed of in other ways authorized by the sponsor. All management processes for clinical trial drugs shall be documented in writing, and all records shall be accurate throughout the process.

(v) In blinded trials, procedures and mechanisms for emergency unblinding should be established to enable rapid identification of the clinical trial drug in the event of an emergency medical situation requiring unblinding, while maintaining blinding of treatment allocation for other trial participants. (vi)

Sponsors should take measures to ensure the stability of the clinical trial drug during the clinical trial, ensure that it is provided only within its expiration date, and retain a sufficient number of clinical trial drug samples. The quantity, method, and time limit of sample retention should meet the relevant requirements.

Article 47 In blinded trials, the sponsor shall establish a working system to ensure...
To maintain blinding at all applicable phases of clinical trials and to prevent and identify unblinding.

Article 48. Applicants shall fulfill their data governance responsibilities and ensure the security of data. Reliability, traceability, and security.

(i) Sponsors shall ensure that the electronic data management system deployed or used in the clinical trial meets the requirements of a computerized system; and confirm that the computerized system used by the principal investigator and their authorized researchers, and the drug clinical trial institution, meets the requirements of the clinical trial. (ii)

Sponsors shall not change the principal investigator and their authorized researchers or...

Unless there is a legitimate reason, data entered by trial participants should be subject to written consent from the principal investigator and recorded before any modifications are made.

(iii) Sponsors shall use trial participant identification codes to identify all clinical trial data for each trial participant. After the clinical trial is unblinded, the sponsor shall provide the principal investigator with the treatment information of the trial participants in the blinded trial. (iv) Sponsors shall develop a statistical

analysis plan that conforms to the trial protocol and perform statistical analysis accordingly. Implement appropriate quality management and record the programming, data processing, and analysis processes.

(v) Sponsors shall retain all necessary records related to clinical trials in accordance with regulatory requirements and shall inform the principal investigator, clinical trial institution, and service provider in writing of the requirements for the retention

of trial records. Article 49 Sponsors shall clearly define the access rights for trial records.

(i) The sponsor shall specify in the trial protocol or other written contract that the principal investigator, clinical trial institution and service provider shall allow monitors, auditors, ethics review committee reviewers and drug regulatory authorities to directly access source records related to the clinical trial.

(II) The sponsor shall confirm that each trial participant has given written consent to allow the monitors, auditors, ethics review committee reviewers, and inspectors from the drug regulatory authority to directly access source records related to the clinical trial. Article 50. Any change to the sponsor during a clinical trial

shall be approved by the State Council's drug regulatory authority as required. If the sponsor suspends or prematurely terminates an ongoing clinical trial, or if a change occurs during the clinical trial, the sponsor shall promptly notify the principal investigator, the clinical trial institution, and the ethics review committee in writing, explaining the reasons.

Sponsors shall submit clinical trial reports to the drug regulatory authorities in accordance with regulatory requirements. Clinical trial reports shall comprehensively, completely, and accurately reflect the clinical trial results, and the clinical trial data shall be consistent with the source records.

Chapter 5 Data Governance

Article 51 Sponsors, principal investigators, and clinical trial institutions shall, within their respective responsibilities, assume data governance responsibilities. Data governance shall be implemented throughout the entire lifecycle of clinical trial data to ensure the accurate reporting, verification, and interpretation of clinical trial-related information.

(a) Data obtained from any source, including directly in a computerized system

The collected data should be accompanied by corresponding metadata, including the investigation trajectory.

(ii) Sponsors, principal investigators, and clinical trial institutions shall use appropriate methods to apply, evaluate, access, and manage metadata, and shall establish procedures for reviewing data and metadata. (iii) Sponsors and clinical trial institutions shall establish

relevant procedures for correcting data errors, and sponsors and principal investigators shall promptly correct data errors that may affect the reliability of trial results and ensure the traceability of the correction process.

(iv) Sponsors, principal investigators and clinical trial institutions shall establish validated processes to ensure the reliability, traceability and security of electronic data (including related metadata) transmitted between computerized systems, and to prevent data loss or tampering.

(v) Sponsors shall define interim and final analysis data that meet quality standards, and adopt timely and reliable processes for data collection, verification, validation, auditing and error correction, and, where possible, make corrections to safety requirements for trial participants.

The omission of data could significantly impact the reliability of experimental results. Before statistical analysis, the dataset should be finalized according to a pre-established procedure. Data extraction and the determination of the analysis set should follow the statistical analysis plan and be documented.

Article 52 In blinded trials, the blinding integrity shall be maintained at all stages of the clinical trial and appropriate blinding management measures shall be taken to prevent accidental unblinding from causing trial bias.

Before the commencement of a clinical trial, all relevant parties shall define their roles, responsibilities, and procedures for accessing unblinded information and maintain records. During the trial, any instances of unblinding or unexpected unblinding shall be recorded, their impact on the trial results assessed, and appropriate necessary measures taken. Article 53. All parties involved in a clinical trial shall

ensure that calculations used in the clinical trial are properly performed.

The mechanized system meets the requirements for the reliability, traceability, and security of test data.

(i) Standard operating procedures for the setup, installation, and use of computerized systems should be established, clearly defining the responsibilities of all parties involved in clinical trials when using computerized systems, and ensuring the correct use of computerized systems during the collection, processing, and management of clinical trial data. All personnel using computerized systems should receive training. (ii) Data security management of

computerized systems should cover the entire data lifecycle of trial data and records, ensuring security controls are implemented on computerized systems, and continuously taking measures to prevent, detect, and reduce security vulnerabilities.

Test data generated by computerized systems should be backed up promptly and thoroughly, and recorded in the system. Take emergency measures in case of system failure to prevent data loss or inaccessibility.

(iii) The computerized systems used by all parties in the clinical trial shall be reliably validated, meet their intended use and pre-set technical performance, in order to ensure the accuracy of trial data.

The reliability of the data is ensured, and the system remains in a valid state throughout the entire test.

(iv) All parties involved in the clinical trial shall establish a workflow to record, evaluate and manage problems that arise in the computerized system, and regularly review the collected problems to identify recurring or systemic problems and take appropriate action according to the severity of the problems.

(v) Computerized systems should have robust user management, access control, and audit tracking mechanisms to ensure that only authorized users can access and use the system, and that access and operations are traceable. If electronic signatures are used, they should comply with relevant Chinese requirements regarding electronic signatures. User permissions should align with their duties, legal settings, and the organization to which they belong. Authorized users and their permissions should be clearly recorded, maintained, and preserved.

Chapter Six Supplementary Provisions

Article 54. The following terms in this standard have the following

meanings: (1) Trial participant, i.e., subject, refers to an individual participating in a drug clinical trial.

They are expected to receive the experimental drug or be included in the control group.

(ii) The principal investigator is the clinical trial research team of the drug clinical trial institution. The person in charge is responsible for the rights and safety of trial participants and the reliability of clinical trial data during the implementation of clinical trials.

(iii) Other potential serious safety risks refer to information that significantly affects the assessment of drug benefit risks, may change the use of the drug, or affect the overall drug development process.

(iv) Quality management of drug clinical trials: This involves managing the quality of drug clinical trials, including establishing a quality management system and conducting specific quality management activities.

It is to protect the rights and safety of the participants in the experiment, ensure that the data and results are scientific, true and reliable, and that the entire experiment process follows the experimental protocol, this specification and relevant laws and regulations.

(v) The quality management system for drug clinical trials refers to the mechanism for quality management of the entire process of clinical trials. It focuses on the protection of trial participants and the reliability of data, clarifies responsibilities, standards and procedures, prevents, identifies and handles abnormal events based on risks, and continuously improves to achieve the set quality management goals.

In addition to the terms and definitions included in this clause, other terms and definitions used in this specification shall also apply. The definitions can be found in the glossary of Chinese version of ICH E6(R3). This specification

will come into effect on September 1, 2026.