Announcement of the National Medical Products Administration, the National Health Commission, the National Administration of Traditional Chinese Medicine, and the National Disease Control and Prevention Administration on Issuing the Good Clinical Practice for Drug Trials [1]

Authorities: **National Medical Products Administration, National Health Commission, National Administration of Traditional Chinese Medicine, National Disease Control and Prevention Administration.**

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Chapter I General Provisions

Article 1

These Specifications are formulated in accordance with the *Drug Administration Law of the People's Republic of China*, the *Vaccines 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 the Administration of Drug Registration*, for the purpose of ensuring the standardized conduct of drug clinical trials, protecting the rights, interests, and safety of trial participants, and ensuring that data and results are scientific, authentic, and reliable.

Article 2

These Specifications shall apply to drug clinical trials conducted for the purpose of drug development that have been approved or filed with the drug regulatory authority under the State Council. All activities related to drug clinical trials shall comply with these Specifications.

Article 3

Good Clinical Practice (GCP) for drug clinical trials refers to ethical, scientific, and quality standards that shall be followed throughout the entire process of drug clinical trials. The full

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

clinical trial process includes planning, initiation, conduct, recording, monitoring, evaluation, analysis, and reporting.

Article 4

Drug clinical trials shall comply with the principles of the World Medical Association's Declaration of Helsinki and relevant ethical requirements. The rights, interests, and safety of trial participants shall be the primary consideration, taking precedence over scientific and societal benefits. Ethical review and informed consent constitute essential safeguards for protecting the rights and safety of trial participants.

Article 5

Drug clinical trials shall be scientifically designed and appropriately justified, with due consideration given to the anticipated risks and benefits to trial participants and society. Clinical trials may only be initiated or continued when the anticipated benefits are justified in relation to the risks.

Article 6

The design and conduct of clinical trials shall incorporate a quality-by-design approach, identifying critical quality factors and associated risks, and implementing risk control measures proportionate to such risks, so as to protect the rights and safety of trial participants and ensure the reliability of results.

Article 7

Clinical trial protocols shall be clear, concise, scientifically sound, and operationally feasible, and may only be implemented upon approval by an ethics review committee. During the conduct of a clinical trial, the protocol may be modified when necessary to ensure ethical and scientific validity, provided that such modifications are subject to re-approval by the ethics review committee prior to implementation.

Article 8

All personnel involved in clinical trials shall possess appropriate educational background, training, and practical experience sufficient to undertake clinical trial responsibilities, and shall comply with the trial protocol throughout the course of the study. Roles and responsibilities in

clinical trials shall be clearly defined and properly documented. Any medical judgment or clinical decision-making shall be performed by qualified clinical physicians.

Article 9

All paper-based and electronic records relating to clinical trials shall be appropriately documented, processed, and retained to ensure the reliability and traceability of data. The privacy of trial participants and the security of their personal information shall be protected in accordance with the applicable requirements of the People's Republic of China concerning personal information protection.

Systems and processes used for data collection, management, and analysis shall be fit for their intended purpose and proportionate to the risks posed to trial participants and the significance of the data collected.

Article 10

The manufacture of investigational medicinal products shall comply with the applicable requirements for Good Manufacturing Practice relating to investigational medicinal products. Their use and management shall be conducted in accordance with applicable laws and regulations and shall comply with the requirements of the clinical trial protocol and related documentation.

Article 11

Quality management of drug clinical trials shall be implemented throughout the entire clinical trial lifecycle in order to protect the rights, safety, and well-being of trial participants, ensure the reliability of clinical trial results, and maintain compliance with applicable laws and regulations.

Article 12

The conduct of drug clinical trials shall adhere to the principle of avoiding conflicts of interest so as to prevent any adverse impact on the rights and safety of trial participants or on the reliability of trial results.

Article 13

The application of new technologies and novel methodologies in the conduct of drug clinical trials shall comply with ethical principles, scientific standards, and applicable laws and regulations.

Chapter II Ethics Review Committee

Article 14

The Ethics Review Committee shall be responsible for safeguarding the rights, safety, and well-being of trial participants. The Ethics Review Committee shall review the ethical and scientific aspects of clinical trials and shall give particular consideration to the protection of vulnerable trial participants. The conduct of ethical review by the Ethics Review Committee shall comply with the relevant provisions of the competent health authorities and the requirements of these Specifications.

1. The documents subject to review by the Ethics Review Committee shall include: the clinical trial protocol; the informed consent form; methods and materials for the recruitment of trial participants; other information to be provided to trial participants; the Investigator's Brochure and current scientific information; safety information; documents containing information on compensation for trial participants; qualification documents of the Principal Investigator; reports of significant protocol deviations; progress reports and final reports; and any other documents necessary for the Ethics Review Committee to discharge its responsibilities.

2. The Ethics Review Committee shall pay particular attention to the following circumstances and shall assess whether adequate measures have been taken to protect the rights and safety of trial participants: clinical trials in which trial participants are not expected to derive direct benefit and informed consent is provided by their legally authorized representatives on their behalf; trial participants who lack civil capacity or have limited civil capacity; clinical trials involving minors, in which case the Ethics Review Committee shall review the information provided for obtaining informed consent from minors and shall take into account the participants' age, cognitive maturity, psychological condition, and applicable legal requirements; clinical trial protocols that provide for the enrolment of participants in emergency situations where neither the participant nor the participant's legally authorized representative is able to provide informed consent prior to enrolment.

3. The Ethics Review Committee shall ensure that no coercion, undue influence, or improper inducement is used to affect a trial participant's decision to participate in a clinical trial. The Ethics Review Committee shall also ensure that informed consent forms do not contain any provision requiring trial participants or their legally authorized representatives to waive their lawful rights, nor any provision purporting to release the Principal Investigator, the clinical trial institution, the sponsor, or any relevant service provider from liability.

4. The Ethics Review Committee shall ensure that information concerning compensation for trial participants contained in informed consent forms and other materials provided to trial

participants, including the method, amount, and schedule of compensation, is reasonable and appropriate.

5. The Ethics Review Committee shall give priority attention to, and conduct timely review of, the following matters: serious adverse events reported by the Principal Investigator during the clinical trial; protocol deviations or modifications implemented to eliminate immediate hazards to trial participants during the conduct of the clinical trial; serious or persistent non-compliance; changes that increase risks to trial participants or significantly affect the conduct of the clinical trial; and new information that may adversely affect the safety of trial participants or the conduct of the clinical trial.

With respect to suspected unexpected serious adverse reactions (SUSARs), other information concerning potentially significant safety risks reported by the sponsor, and information contained in Development Safety Update Reports (DSURs), the review procedures adopted by the Ethics Review Committee shall be proportionate to the urgency of any required action and the nature of any changes in the safety profile of the investigational product.

6. The Ethics Review Committee shall conduct continuing review of ongoing clinical trials at regular intervals. The frequency of such review shall be determined according to the level of risk associated with the trial and the interval between reviews shall not exceed 12 months.

7. The Ethics Review Committee shall complete the review or filing procedures for clinical trial-related documentation within a reasonable timeframe and shall issue a clear written opinion or filing acknowledgement specifying the versions of the documents reviewed. The opinions of the Ethics Review Committee may include: approval; disapproval; approval subject to modifications; re-review following modifications; continuation of the study; suspension of the study; or termination of the study.

8. The Ethics Review Committee shall have the authority to suspend or terminate a clinical trial that is not conducted in accordance with applicable requirements or where trial participants have suffered unexpected serious harm.

9. The Ethics Review Committee shall receive and appropriately address complaints, concerns, and other requests submitted by trial participants.

Article 15

The Ethics Review Committee shall establish an ethics review system and standard operating procedures, improve mechanisms for the management of conflicts of interest and the quality control of ethics reviews, and ensure that the ethics review process is conducted independently, objectively, and impartially.

Article 16

The Ethics Review Committee shall retain all records relating to ethics reviews, including written review records, information on committee members, submitted documents, meeting minutes, and relevant correspondence records.

For clinical trials conducted for the purpose of a drug registration application, all such records shall be retained for at least 5 years after the investigational drug has been approved for marketing. For clinical trials conducted for the purpose of a drug registration application where the investigational drug is not approved, and for clinical trials not conducted for the purpose of a drug registration application, all such records shall be retained 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 the Sponsor with relevant written review documents, including the name and address of the Ethics Committee, the list of Ethics Committee members who participated in the review of the project, the review opinion, and a statement confirming that the review was conducted in compliance with these Specifications and applicable laws and regulations.

Where necessary, the Principal Investigator, the Sponsor, or the drug regulatory authority may require the Ethics Committee to provide its standard operating procedures.

Chapter III Principal Investigator and Drug Clinical Trial Institution

Article 18

A drug clinical trial institution conducting a drug clinical trial shall establish a quality management system for drug clinical trials and ensure its effective operation.

Article 19

The Principal Investigator is the person ultimately responsible at the clinical trial site and shall be responsible for the rights, safety, and well-being of trial participants, as well as the quality of the clinical trial.

The Principal Investigator shall possess the appropriate professional qualifications required to practice at the clinical trial institution and shall have the educational background, training, and practical experience necessary for the conduct of the clinical trial. The Principal Investigator shall be familiar with the protocol, Investigator's Brochure, and relevant information and materials concerning the investigational product provided by the Sponsor; shall be familiar with the applicable technical guidelines for clinical trials; and shall comply with these Specifications and all applicable laws and regulations.

Article 20

Where the Principal Investigator or the clinical trial institution authorizes an individual or entity to undertake specific responsibilities and functions relating to a clinical trial, a comprehensive management system shall be established, and effective oversight and supervision shall be implemented to ensure that such individual or entity possesses the requisite qualifications and is capable of properly performing the delegated clinical trial responsibilities and functions.

Where it is necessary for the Principal Investigator or the clinical trial institution to entrust a party outside the clinical trial institution with clinical trial-related responsibilities and functions, the prior consent of the Sponsor shall also be obtained. The Principal Investigator and the clinical trial institution shall bear ultimate responsibility for all authorized and delegated matters. As a general principle, clinical trial decisions, critical confirmations, and formal reports to the Ethics Review Committee, the drug clinical trial institution, and the Sponsor that fall under the responsibility of the Principal Investigator shall not be delegated.

Article 21

The Principal Investigator and the clinical trial institution shall possess the necessary conditions required to complete the clinical trial, including:

1.The Principal Investigator has sufficient time and capability to organize and conduct the clinical trial and to enroll, within the time period specified in the clinical trial agreement, an adequate number of trial participants who satisfy the requirements of the protocol.

2.The Principal Investigator has the authority to access and use the facilities required for the clinical trial, and has the authority to direct and supervise the research personnel participating in the clinical trial, thereby ensuring the proper and safe conduct of the clinical trial.

Article 22

Communications between the Principal Investigator and the Ethics Review Committee shall include the following:

1.Prior to the initiation of a clinical trial, the Principal Investigator shall obtain approval of the clinical trial project from the Ethics Review Committee.

2. Before, during, and after the conduct of the clinical trial, the Principal Investigator shall report to the Ethics Review Committee as required and shall provide all documents necessary for ethics review.

3. The Principal Investigator shall promptly implement the review opinions and decisions of the Ethics Review Committee.

Article 23

The Principal Investigator and the research personnel authorized by the Principal Investigator shall comply with the protocol.

1. The clinical trial shall be conducted in accordance with the protocol approved by the Ethics Review Committee. Any deviation from the protocol shall be documented. Significant protocol deviations shall be explained, appropriate corrective and preventive actions shall be taken, and such deviations shall be reported to the Ethics Committee and the Sponsor.

2. Where a deviation from the protocol is necessary to eliminate an immediate hazard to a trial participant without prior approval from the Ethics Review Committee, the Principal Investigator shall promptly report the deviation to the Ethics Review Committee and the Sponsor and provide the reasons therefor.

3. The Principal Investigator shall implement unblinding in accordance with the requirements of the protocol. In the event of accidental unblinding or emergency unblinding, the circumstances shall be documented immediately, and the reasons therefor shall be provided to the Sponsor in writing.

Article 24

Where a clinical trial is terminated prematurely or suspended, the Principal Investigator shall promptly notify the trial participants and provide them with appropriate medical treatment and follow-up care. Where the Principal Investigator, the Sponsor, or the Ethics Review Committee terminate or suspend a clinical trial prematurely, the Principal Investigator shall immediately report such termination or suspension to the Sponsor, the non-initiating members of the Ethics Committee, and the clinical trial institution, and shall provide a written explanation thereof.

Article 25

The Principal Investigator who is qualified as a licensed clinician, or a clinician authorized by the Principal Investigator, shall provide trial participants with appropriate medical care and shall assume responsibility for medical judgments and medical decision-making related to the clinical trial.

Article 26

The Principal Investigator's safety reporting shall comply with the following requirements:

1.The Principal Investigator shall report adverse events and abnormal examination findings required for safety evaluation to the Sponsor in accordance with the requirements and timelines specified in the trial protocol.

2.Except for serious adverse events that, pursuant to the trial protocol or other documents (such as the Investigator's Brochure), are not required to be reported immediately, the Principal Investigator shall, upon becoming aware of such events, immediately submit a written report of all serious adverse events to the Sponsor and the Ethics Review Committee, and shall subsequently provide detailed written follow-up reports in a timely manner.

3.With respect to reports involving deaths, where the Sponsor, the Ethics Review Committee, or the drug regulatory authority requires additional documentation, such as an autopsy report or a final medical report, the Principal Investigator shall provide such materials promptly upon obtaining them.

4. Upon receipt from the Sponsor of safety information, including suspected unexpected serious adverse reactions (SUSARs), other potential serious safety risks, and information related to Development Safety Update Reports (DSURs), the Principal Investigator shall review and acknowledge such information in a timely manner, consider whether corresponding adjustments to the treatment of trial participants are necessary, and, where appropriate, communicate with trial participants as early as possible.

Article 27

The informed consent process shall comply with the ethical principles set forth in the Declaration of Helsinki, ensuring that trial participants voluntarily participate in the clinical trial and that, through the informed consent process, they are provided with sufficient information regarding the trial:

1.Prior to participation in the clinical trial, the Principal Investigator or research personnel authorized by the Principal Investigator shall fully inform the trial participant or his/her legally authorized representative of matters relating to the clinical trial, obtain and document the informed consent of the trial participant or his/her legally authorized representative, and use the latest version of the informed consent form and other participant materials approved by the Ethics Review Committee.

2.Where the Principal Investigator obtains new information that may affect a trial participant's willingness to continue participation in the clinical trial, the Principal Investigator shall promptly inform the trial participant or his/her legally authorized representative and make corresponding records thereof. Where necessary, the informed consent form shall be re-executed.

3.The Principal Investigator and research personnel authorized by the Principal Investigator shall not use coercion, undue influence, inducement, or any other improper means to influence a trial participant's decision to participate in or continue participating in the clinical trial.

4.The informed consent form and other materials provided to trial participants shall be written in clear and understandable language and presented in a manner that is readily comprehensible to the trial participant, his/her legally authorized representative, and any impartial witness.

5.Prior to the signing of the informed consent form, the Principal Investigator or research personnel authorized by the Principal Investigator shall provide the trial participant or his/her legally authorized representative with sufficient time and opportunity to understand the details of the clinical trial and shall thoroughly answer any questions relating to the clinical trial raised by the trial participant or his/her legally authorized representative.

6.The trial participant or his/her legally authorized representative, as well as the research personnel conducting the informed consent process, shall each sign and date the informed consent form. Where the informed consent form is signed by a person other than the trial participant, the relationship between the signatory and the trial participant shall be specified. The participant's medical records shall document the specific date and time at which informed consent was obtained, as well as the identities of the individuals involved in the informed consent process.

7. Where the trial participant or his/her legally authorized representative is unable to read, an impartial witness shall be present throughout the entire informed consent process. The contents of the informed consent form and other relevant materials shall be explained in detail to the trial participant or his/her legally authorized representative and to the impartial witness. Where the trial participant or his/her legally authorized representative orally agrees to participate in the clinical trial, he/she shall, where capable, sign the informed consent form whenever possible. The impartial witness shall also sign and date the informed consent form to attest that the information contained in the informed consent form and other materials was accurately explained to the trial participant or his/her legally authorized representative, that the relevant contents were understood, and that consent to participate in the clinical trial was given.

8. The trial participant or his/her legally authorized representative shall be provided with an original copy of the informed consent form bearing the signatures and dates of execution, as well as any other materials provided to trial participants, and shall continue to receive updated versions thereof throughout the duration of participation in the trial.

9. Where a trial participant lacks civil capacity, the written informed consent of his/her legal guardian or legally authorized representative shall be obtained. Where a trial participant has limited civil capacity, the written informed consent of both the participant and his/her legal guardian or legally authorized representative shall be obtained. When a legal guardian or legally authorized representative provides informed consent on behalf of a trial participant, information relating to the clinical trial shall be provided to the trial participant to the extent that he or she is capable of understanding, and the trial participant should, whenever possible, personally sign and date the informed consent form.

Where a minor serves as a trial participant, the informed consent of the minor's legal guardian or legally authorized representative shall be obtained, and the informed consent form shall be signed accordingly. Where the minor is capable of making a decision regarding participation in the clinical trial, the minor's assent or consent shall also be obtained. If the minor participant

does not agree to participate in the clinical trial or decides to withdraw from the clinical trial during its course, the decision of the minor participant shall prevail, notwithstanding the consent of the legal guardian or legally authorized representative to participation or continued participation.

However, in a therapeutic clinical trial involving a serious or life-threatening disease, where the Principal Investigator and the legal guardian or legally authorized representative determine that the minor participant's life would be endangered if he or she does not participate in the clinical trial, the consent of the legal guardian or legally authorized representative alone may permit the participant to enroll in or continue participating in the clinical trial.

Where, during the course of the clinical trial, a minor participant subsequently attains the capacity to sign an informed consent form, the participant shall personally sign the informed consent form before further participation in the clinical trial may continue.

A participant with limited civil capacity who subsequently regains full civil capacity shall undergo a renewed informed consent process, and his or her voluntary consent shall be obtained regarding whether to continue participation in or withdraw from the clinical trial.

10. In emergency circumstances where it is not possible to obtain the informed consent of a trial participant prior to enrollment in the clinical trial, the participant's legally authorized representative may provide informed consent on the participant's behalf. Where the legally authorized representative is also unavailable, the procedures and conditions for enrolling the trial participant shall be clearly specified in the trial protocol and other relevant documents that have received prior written approval from the Ethics Review Committee. The trial participant or his/her legally authorized representative shall be informed of the trial-related information as soon as possible, and informed consent shall be obtained at the earliest appropriate opportunity.

11. As a general principle, where a trial participant is enrolled in a clinical trial from which no direct benefit is anticipated, the informed consent form shall be signed by the trial participant personally.

Article 28

The Principal Investigator and the clinical trial institution shall be responsible for the management of investigational products provided by the Sponsor.

1. The Principal Investigator and the clinical trial institution shall designate appropriately qualified personnel to manage investigational products. The receipt, handling, storage, dispensing, use, recovery, return, and destruction of investigational products by the clinical trial institution shall comply with applicable requirements and be appropriately documented. The Principal Investigator shall ensure that investigational products are used in accordance with the trial protocol and shall instruct trial participants on the proper use of the investigational products.

2. The Principal Investigator shall randomly select and retain samples of investigational products used in bioequivalence studies and shall preserve such retained samples for at least two years after the drug has been approved for marketing. Appropriate management procedures shall be established for such retained samples. The clinical trial institution may entrust the storage of retained samples to an independent qualified third party; however, such samples shall not be returned to the Sponsor or to any third party having an interest affiliated with the Sponsor.

Article 29

The records and reports of a clinical trial shall comply with the following requirements:

1. The Principal Investigator shall supervise data collection at the trial site and monitor the performance of duties by study personnel to ensure the reliability of the data.

2. The Principal Investigator shall ensure that all clinical trial data are derived from source records and shall ensure their reliability and traceability. Source records shall be attributable, legible, contemporaneous, original, accurate, and complete. Any modification to source records shall be traceable, shall not obscure the original entry, and shall include documentation of the reason for the modification. For clinical trials involving patients as trial participants, relevant medical records shall be incorporated into the outpatient or inpatient medical record system, as applicable.

3. The Principal Investigator and the clinical trial institution shall properly retain trial documentation in accordance with the relevant requirements of the drug regulatory authorities.

For clinical trials conducted to support an application for drug registration, the essential records shall be retained for at least five years after the investigational drug has been approved for marketing.

For clinical trials conducted to support an application for drug registration where the investigational drug is not approved, as well as clinical trials not conducted to support an application for drug registration, the essential records shall be retained for at least five years after termination of the clinical trial.

4. During the processing of clinical trial data and trial participant information, measures shall be taken to prevent any unlawful or unauthorized collection, storage, use, correction, transmission, disclosure, publication, deletion, or other handling of such data and information. The recording, processing, and retention of clinical trial data shall ensure the security of records and trial participant information.

5. Any transfer of ownership of essential records shall comply with the requirements of applicable laws and regulations.

Article 30

The Principal Investigator shall provide clinical trial reports.

1. The Principal Investigator shall submit progress reports and a final report to the Ethics Review Committee in accordance with its requirements.

2. Upon completion of the clinical trial, the Principal Investigator shall promptly submit a written report to the clinical trial institution.

3. The Principal Investigator shall provide the Sponsor with clinical trial-related reports required by the drug regulatory authorities.

Article 31

The Principal Investigator and the clinical trial institution shall accept monitoring and auditing organized by the Sponsor, as well as inspections conducted by the drug regulatory authorities, and shall cooperate by providing all records related to the clinical trial as required.

Chapter IV Sponsor

Article 32

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

Article 33

The Sponsor shall design the clinical trial protocol on the basis of adequate safety and efficacy data and shall incorporate a Quality-by-Design (QbD) approach to ensure the scientific validity, reliability, and operational feasibility of the clinical trial.

Article 34

The Sponsor shall select appropriately qualified personnel according to the needs of the clinical trial and establish a clinical trial research and management team to conduct the clinical trial and to direct and oversee the entire clinical trial process.

The Sponsor shall establish effective communication channels to ensure that all personnel involved in the clinical trial are able to communicate in a timely manner throughout the conduct of the trial and shall document key communications.

The Sponsor shall appoint or retain qualified medical personnel to provide timely responses to medical questions arising in connection with the clinical trial.

Article 35

The Sponsor shall conduct a prior assessment and select qualified Principal Investigator(s) and clinical trial institution(s) that meet the applicable requirements and are capable of fulfilling the needs of the clinical trial.

Article 36

Where the Sponsor engages a service provider, the following requirements shall apply:

(1) The Sponsor may delegate part or all of its clinical trial-related duties and responsibilities to a qualified service provider. However, the Sponsor shall supervise and manage the activities of the service provider, including any activities further subcontracted by the service provider, and shall retain ultimate responsibility for the clinical trial. Where the entrusted party intends to subcontract any delegated task, the Sponsor's prior written consent shall be obtained.

(2) Prior to the commencement of clinical trial activities, the Sponsor shall enter into clinical trial agreements with the Principal Investigator(s), clinical trial institution(s), commissioned service provider(s), and all other relevant parties participating in the clinical trial. Such agreements shall clearly define the roles, responsibilities, rights, and obligations of each party, as well as any actual or potential conflicts of interest that should be avoided. Clinical trial agreements shall contain clear and complete terms, and trial-related funding shall be reasonable and consistent with market practices.

(3) The requirements applicable to Sponsors under these Good Clinical Practice provisions shall also apply to service providers performing Sponsor-related duties and responsibilities.

Article 37

The Sponsor shall be responsible for selecting laboratories that comply with applicable requirements and possess the necessary qualifications to conduct the testing and analysis of biological samples. The Sponsor shall oversee the laboratory's quality management throughout the entire lifecycle of biological samples collected during the clinical trial, including sample management, testing and analysis, transportation, storage, and destruction.

The conduct of any testing of biological samples that is unrelated to the trial protocol approved by the Ethics Review Committee (including, but not limited to, genetic testing) is prohibited.

The Sponsor shall clearly specify in the informed consent form the arrangements regarding the continued retention and/or potential future use of any remaining biological samples after

completion of the clinical trial, including the retention period, data confidentiality considerations, and the circumstances under which data and biological samples may be shared.

Article 38

Prior to the commencement of a clinical trial, the Sponsor shall submit the relevant clinical trial documentation to the drug regulatory authority under the State Council and obtain approval for the clinical trial or complete the filing procedures for a bioequivalence study, as applicable. The Sponsor shall promptly obtain the relevant records of the Ethics Review Committee and implement the Ethics Review Committee's opinions and requirements in accordance with applicable provisions.

Article 39

The Sponsor shall prepare and maintain documents including, but not limited to, the clinical trial protocol, Investigator's Brochure, and informed consent materials, and shall update such documents in a timely manner. The Sponsor shall provide the most current versions of these documents to the Principal Investigator(s) and the Ethics Review Committee.

The informed consent form shall be adequate, complete, and readily understandable, and shall comply with the requirements of ethical review and other applicable requirements.

Article 40

The Sponsor shall establish and apply an appropriate risk-based system for quality management throughout the entire clinical trial lifecycle, so as to ensure the effective design, conduct, and oversight of the clinical trial. The scope and extent of the Sponsor's oversight activities shall be fit for purpose and proportionate to the complexity and risks of the clinical trial.

Article 41

The Sponsor shall implement quality assurance and quality control measures for the clinical trial.

1. The Sponsor shall be responsible for establishing, implementing, and timely updating written standard operating procedures relating to quality assurance and quality control of clinical trials, to ensure that the conduct of the clinical trial and the generation, recording, and reporting of data are performed in accordance with the trial protocol, these Good Clinical Practice requirements, and applicable regulatory requirements.

2. Quality assurance activities shall be integrated throughout the entire clinical trial process and shall adopt a risk-based approach to identify significant protocol non-compliance and the causes of non-compliance with these Good Clinical Practice requirements and applicable regulatory requirements, thereby enabling the implementation of appropriate corrective and preventive actions (CAPA).

Where the Sponsor conducts audits, such audits shall be performed in a manner proportionate to the risks associated with the conduct of the clinical trial. Sponsor audits shall be independent of routine monitoring and quality control functions and shall be conducted for the purpose of evaluating whether trial management, trial conduct, and the activities of relevant participating parties comply with the protocol, these Good Clinical Practice requirements, and applicable regulatory requirements.

3. The Sponsor shall apply risk-based quality control measures at each stage and for each critical process of the clinical trial to ensure procedural compliance and data reliability. Monitoring and data management are the primary quality control activities in a clinical trial. The Sponsor shall appoint qualified monitors to oversee the conduct of the clinical trial.

Article 42

The Sponsor shall implement risk management throughout the conduct of the clinical trial.

1. Prior to the initiation of the trial and throughout its duration, the Sponsor shall identify risks that may have a meaningful impact on critical quality factors and shall assess the likelihood of harm arising from such risks, the extent to which such risks can be detected, and their potential impact on the protection of trial participants and the reliability of trial results.

2. Risk control measures shall be proportionate to the significance of the risks with respect to the rights, safety, and well-being 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 establish predefined acceptable limits for risk control. Where such predefined limits are exceeded, the Sponsor shall evaluate whether corrective actions are required.

3. The Sponsor shall document identified risks and corresponding risk mitigation measures and shall communicate such information to personnel involved in implementing the measures or otherwise affected by such activities.

4.Taking into account new knowledge and experience gained during the conduct of the clinical trial, the Sponsor shall periodically review risk control measures to ensure the effectiveness and appropriateness of ongoing quality management activities and shall, where necessary, consider the implementation of additional risk control measures.

5. The Sponsor shall summarize and report significant quality issues in the clinical trial report, including issues involving deviations from predefined acceptable limits and the remedial actions taken in response thereto.

Article 43

The Sponsor shall ensure compliance throughout the conduct of the clinical trial.

1.The Sponsor shall take appropriate corrective measures in response to any failure by the Principal Investigator, clinical trial institution, Sponsor personnel, or service provider to comply with the trial protocol, standard operating procedures, these Good Clinical Practice requirements, or applicable regulatory requirements.

2. Where non-compliance is identified that has had, or may have, a significant impact on the rights, safety, or well-being of trial participants, or on the reliability of the trial results, the Sponsor shall promptly conduct a root cause analysis, implement appropriate and adequate corrective and preventive actions (CAPA), and promptly submit a written report to the Ethics Review Committee.

3. Where serious or persistent non-compliance is identified, the Sponsor shall consider terminating the continued participation of the Principal Investigator, clinical trial institution, or service provider in the clinical trial, promptly submit a written report to the Ethics Review Committee, and take measures to minimize any impact on trial participants and the reliability of the trial results. Where violations of the protocol or these Good Clinical Practice requirements are serious, the Sponsor may pursue accountability against the responsible personnel and shall report such matters to the drug regulatory authority.

Article 44

The Sponsor shall conduct ongoing safety evaluations throughout the duration of the clinical trial and shall submit reports in accordance with applicable requirements and prescribed timelines.

1. The Sponsor shall review and evaluate available safety information. Any newly identified information that may affect the safety of trial participants or their willingness to continue participation, may affect the conduct of the clinical trial, or may require modification of the Ethics Review Committee's approval, shall be promptly communicated to the Principal Investigator, the clinical trial institution, and the Ethics Review Committee. The Sponsor shall ensure that trial participants are informed in a timely manner and shall, as required, make necessary updates to the trial protocol, Investigator's Brochure, informed consent materials, and other relevant documents.

2. Upon receipt of any safety-related information from any source, the Sponsor shall promptly conduct an analysis and assessment thereof, including an evaluation of severity, causality with the investigational medicinal product, and whether the event is expected.

3. The Sponsor shall rapidly 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). Such rapid reporting shall be conducted in accordance with applicable requirements. The method by which SUSAR reports are submitted to the Principal Investigator(s) and the Ethics Review Committee shall be proportionate to the urgency of the required actions and to any changes in the safety profile of the investigational medicinal product.

Risk management requirements 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 Review Committee and Principal Investigator(s) in accordance with the prescribed timelines for expedited reporting.

4. The Sponsor shall submit periodic Development Safety Update Reports (DSURs) to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA), and shall, as required, communicate relevant information to the Principal Investigator(s) and the Ethics Committee.

5. Where safety issues or other risks are identified during the conduct of a clinical trial, the Sponsor shall promptly amend the trial protocol, suspend or terminate the clinical trial, and report such actions to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA).

Article 45

The Sponsor shall provide investigational medicinal products free of charge to trial participants and shall bear the costs of medical examinations related to the clinical trial. The Sponsor shall adopt appropriate measures to ensure that compensation and/or indemnification can be provided to trial participants and the Principal Investigator.

1. The Sponsor shall provide legal and financial insurance or guarantees for the purpose of compensation or indemnification for harm arising in connection with the clinical trial. Such insurance or guarantees shall be commensurate with the nature and level of risk of the clinical trial; however, they shall not cover harm resulting from negligence attributable to the Principal Investigator or the clinical trial institution.

2. The Sponsor shall bear the costs of diagnosis and treatment for any harm incurred by trial participants as a result of participation in the clinical trial, as well as the corresponding compensation or indemnification.

3. The Sponsor and the Principal Investigator shall ensure the timely payment of any compensation or indemnification due to trial participants. The methods and procedures for providing such compensation or indemnification shall comply with applicable laws and regulations.

Article 46

The Sponsor shall be responsible for providing investigational medicinal products to the Principal Investigator and the clinical trial institution. The preparation, supply, and management of investigational medicinal products shall comply with the following requirements:

1.The Sponsor shall ensure that investigational medicinal products are manufactured and released under conditions that comply with applicable Good Manufacturing Practice (GMP) requirements for investigational medicinal products. The labeling of investigational medicinal products shall clearly indicate “For Clinical Trial Use Only,” as well as relevant clinical trial information and investigational product information. In blinded trials, measures shall be taken to maintain the blinding of treatment allocation.

2. The Sponsor shall clearly define the storage and transportation conditions, shelf life, and method of use of investigational medicinal products, and shall ensure that such products are not contaminated or degraded during transportation and storage. The Sponsor shall provide written instructions to the Principal Investigator and clinical trial institution and retain relevant records. Where the investigational medicinal product is a vaccine, its procurement, storage, transportation, and administration shall also comply with applicable vaccine regulatory requirements.

3. After approval by the Ethics Review Committee and authorization or filing with the drug regulatory authority under the State Council has been obtained, the Sponsor shall promptly provide investigational medicinal products to the Principal Investigator and the clinical trial institution.

4. The Sponsor shall establish standard operating procedures for the supply and management of investigational medicinal products, including procedures governing receipt, handling, storage, distribution, use, return, and destruction. Investigational medicinal products returned by trial participants and unused products within the clinical trial institution shall be returned to the Sponsor or disposed of by other methods authorized by the Sponsor. All handling of investigational medicinal products shall be documented in writing, and accountability for all quantities shall be maintained throughout the entire process.

5. In blinded trials, procedures and mechanisms for emergency unblinding shall be established to ensure that investigational medicinal products can be rapidly identified when unblinding is required for urgent medical reasons, while preserving the blinding of treatment allocation for other trial participants.

6. The Sponsor shall take measures to ensure the stability of investigational medicinal products during the clinical trial, ensure that only products within their valid shelf life are used, and retain sufficient reserve samples. The quantity, method, and duration of retention of such samples shall comply with applicable requirements.

Article 47

In blinded clinical trials, the Sponsor shall establish standard operating procedures to ensure that blinding is maintained at all applicable stages of the clinical trial, and to prevent and detect any instances of unblinding.

Article 48

The Sponsor shall fulfill its responsibilities for data governance and ensure the reliability, traceability, and security of clinical trial data.

1. The Sponsor shall ensure that any electronic data management systems deployed or used in the clinical trial comply with applicable requirements for computerized systems. The Sponsor shall confirm that the computerized systems used by the Principal Investigator(s), their authorized staff, and the clinical trial institution meet the requirements of the clinical trial.

2. The Sponsor shall not alter data entered by the Principal Investigator(s), their authorized staff, or trial participants, unless there is a justified reason. In such cases, prior written approval from the Principal Investigator shall be obtained, and all modifications shall be properly documented.

3. The Sponsor shall use subject identification codes to identify all clinical trial data relating to each trial participant. Following unblinding of the clinical trial, the Sponsor shall provide the Principal Investigator with treatment allocation information for trial participants in blinded studies.

4. The Sponsor shall develop a statistical analysis plan consistent with the trial protocol and shall implement appropriate quality management and documentation for statistical programming, data processing, and data analysis activities.

5. The Sponsor shall retain essential clinical trial records in accordance with applicable regulatory requirements and shall provide written notification to the Principal Investigator, clinical trial institution, and service providers regarding record retention requirements for trial documentation.

Article 49

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

1. The Sponsor shall specify in the clinical trial protocol or other written agreements that the Principal Investigator(s), clinical trial institution(s), and service providers shall permit monitors, auditors, inspectors from Ethics Review Committees, and inspectors from drug regulatory

authorities to have direct access to source documents and source data related to the clinical trial.

2. The Sponsor shall ensure that each trial participant has provided written informed consent permitting monitors, auditors, Ethics Review Committee reviewers, and regulatory inspectors to directly access source documents and source data related to the clinical trial.

Article 50

Where there is a change of Sponsor during the conduct of a clinical trial, prior approval shall be obtained from the drug regulatory authority under the State Council in accordance with applicable requirements.

Where the Sponsor suspends or prematurely terminates an ongoing clinical trial, or where a change of Sponsor occurs during the conduct of the clinical trial, the Sponsor shall promptly notify the Principal Investigator(s), clinical trial institution(s), and Ethics Review Committee in writing, and shall provide the reasons therefor.

The Sponsor shall submit clinical trial reports to the drug regulatory authority in accordance with regulatory requirements. Clinical trial reports shall be comprehensive, complete, and accurate in reflecting the trial results, and clinical trial data shall be consistent with source records.

Chapter V Data Governance

Article 51

The Sponsor, Principal Investigator(s), and clinical trial institution(s) shall, within their respective scopes of responsibility, assume data governance obligations. Data governance shall be applied throughout the entire lifecycle of clinical trial data to ensure the accurate reporting, verification, and interpretation of clinical trial-related information.

1. Data obtained from any source, including data captured directly within computerized systems, shall be accompanied by corresponding metadata, including audit trails.

2. The Sponsor, Principal Investigator(s), and clinical trial institution(s) shall adopt appropriate methods for the use, assessment, access, and management of metadata, and shall establish procedures for the review of both data and metadata.

3. The Sponsor and clinical trial institution(s) shall establish procedures for the correction of data errors. The Sponsor and Principal Investigator(s) shall promptly correct data errors that may affect the reliability of trial results and shall ensure that such corrections are fully traceable.

4. The Sponsor, Principal Investigator(s), and clinical trial institution(s) shall establish validated processes to ensure the reliability, traceability, and security of electronic data (including

associated metadata) transferred between computerized systems, and to prevent data loss or unauthorized alteration.

5. The Sponsor shall define interim and final analysis datasets that meet applicable quality standards and shall implement timely and reliable processes for data collection, verification, validation, review, and error correction. Where feasible, omissions that may have a material impact on participant safety or the reliability of trial results shall be corrected. Prior to statistical analysis, datasets shall be finalized in accordance with pre-established procedures. The extraction of data and definition of analysis datasets shall be conducted in accordance with the statistical analysis plan and shall be duly documented.

Article 52

In blinded clinical trials, blinding integrity shall be maintained at all applicable stages of the clinical trial, and appropriate blinding management measures shall be implemented to prevent accidental unblinding and resultant bias in trial outcomes.

Prior to the commencement of the clinical trial, all relevant parties shall define and document the roles, responsibilities, and procedures for access to unblinded information. During the conduct of the trial, instances of unblinding or accidental unblinding shall be documented, their potential impact on trial results shall be assessed, and necessary corrective measures shall be implemented where appropriate.

Article 53

All parties involved in the clinical trial shall ensure that computerized systems used for the clinical trial comply with requirements for the reliability, traceability, and security of trial data.

1. Standard operating procedures shall be established for the configuration, installation, and use of computerized systems, clearly defining the responsibilities of all parties in relation to their use. Proper use of computerized systems shall be ensured in the collection, processing, and management of clinical trial data. All personnel using computerized systems shall be appropriately trained.

2. Data security management of computerized systems shall cover the entire data lifecycle of trial data and records, ensuring the implementation of appropriate security controls and the continuous adoption of measures to prevent, detect, and mitigate security vulnerabilities.

Adequate backup of trial data generated by computerized systems shall be performed in a timely manner, and contingency measures shall be implemented in the event of system failure to prevent data loss or loss of accessibility.

3. Computerized systems used by all parties in the clinical trial shall be validated through reliable system validation processes, ensuring fitness for intended use and predefined technical

performance specifications, thereby safeguarding the reliability of trial data. Systems shall remain in a validated state throughout the entire duration of the clinical trial.

4. All parties shall establish procedures for the recording, evaluation, and management of issues arising within computerized systems, and shall periodically review collected issues to identify recurring or systemic problems. Appropriate actions shall be taken based on the severity of identified issues.

5. Computerized systems shall incorporate robust user management, access control, and audit trail functionalities to ensure that only authorized users may access and operate the system, thereby enabling full traceability of access and actions. Where electronic signatures are used, they shall comply with applicable Chinese requirements on electronic signatures. User access rights shall correspond to assigned duties, blinding requirements, and organizational roles. Authorized users and their access privileges shall be clearly documented, maintained, and retained.

Chapter VI Supplementary Provisions

Article 54

The terms used in these Good Clinical Practice (GCP) provisions shall have the following meanings:

1. “Trial participant” refers to an individual who participates in a clinical trial of a medicinal product and is expected to receive the investigational medicinal product or be assigned to a control group.

2. “Principal Investigator” refers to the person in charge of the clinical trial research team at a clinical trial institution, who is responsible for the rights and safety of trial participants at the trial site during the conduct of the clinical trial, as well as for the reliability of clinical trial data.

3. “Other potential serious safety risk information” refers to information that may significantly affect the benefit–risk assessment of a medicinal product, may lead to changes in the use of the product, or may impact the overall drug development process.

4. “Quality management of clinical trials” refers to the management of quality in clinical trials, including the establishment of a quality management system and the implementation of specific quality management activities. Its purpose is to protect the rights and safety of trial participants, ensure that data and results are scientifically valid, authentic, and reliable, and ensure that the entire clinical trial process complies with the protocol, these provisions, and applicable laws and regulations.

5. “Clinical trial quality management system” refers to the mechanism for quality management throughout the entire clinical trial process, which places participant protection and data reliability at its core, defines responsibilities, standards, and procedures, and adopts a risk-

based approach to prevent, identify, and address deviations and incidents, continuously improve performance, and achieve defined quality objectives.

Except for the terms and definitions set out in this Article, other terms used in these provisions may refer to the glossary of the Chinese version of International Council for Harmonisation E6(R3). These Good Clinical Practice provisions shall come into force on 1 September 2026.