Appendix 2

Question and Answer Document on Good Clinical Practice for Drug Clinical Trials (2026 Revision)

I. What is the background for revising the Good Clinical Practice (GCP) for drug clinical trials?

Drug clinical trials are a crucial step in drug development. The CPC Central Committee and the State Council attach great importance to this.

We attach great importance to the development of the biopharmaceutical industry, and promote it with the support of national policies and the joint efforts of the industry.

During the 14th Five-Year Plan period, my country's clinical research and development system accelerated its development and became deeply embedded in the global clinical research and development system.

The global R&D industry chain has seen a significant increase in the number of clinical trials for innovative drugs, contributing to global clinical R&D.

Its proportion in the market has steadily increased.

In recent years, with the accelerated globalization of the global biopharmaceutical industry, the industry and regulators...

Regulatory agencies continuously update clinical research and development technologies and concepts, and strive to improve the quality of drug clinical trials.

Quantity and efficiency. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) conducts drug clinical trials.

Technical harmonization of test quality management specifications, published in January 2025, is outlined in E6 (R3):

Technical Guidelines for Good Clinical Practice (ICH GCP) for Drug Clinical Trials

To better guide flexible experimental design, emphasizing that quality stems from design, meets objectives, and is risk-averse.

The core concept is proportionality between risk and reward. Our bureau was deeply involved in coordinating this guiding principle in the early stages, and in 2026…

Fully implemented after March 31, 2019.

my country's Good Clinical Practice (GCP) guidelines are used to guide drug research and development.

Issue important normative documents that are scientifically compliant and whose regulatory enforcement conforms to international standards. The existing...

Since the implementation of the 2020 version of GCP, it has played a significant role in the standardized development of drug clinical trials in my country.

It has played a crucial role and effectively guided the implementation and regulatory practices of clinical trials in my country. To further optimize...

To improve the quality management of drug clinical trials in my country, it is necessary to review and summarize the pre-clinical trial procedures in my country.

Based on the experience gained in the implementation phase, further absorb the development of global clinical trial technologies and updated concepts, and for

The 2020 version of GCP has been revised.

II. How GCP integrates with laws, regulations, other normative documents, and technical guidelines

Then how to connect?

The Good Clinical Practice for Drug Clinical Trials is a normative document that guides regulatory authorities, sponsors, drug clinical trial institutions, and other entrusted institutions in conducting drug clinical trials and serves as the basis for regulatory enforcement.

At the legal and regulatory level, it is consistent with the "Drug Administration Law", "Vaccine Administration Law", and "Drug Management Regulations".

Align with the relevant requirements of higher-level laws such as the "Regulations for the Implementation of the Law on Drug Registration" and the "Measures for Drug Registration Management".

At the level of normative documents, it is consistent with the "Regulations on the Management of Drug Clinical Trial Institutions", the "Measures for Supervision and Inspection of Drug Clinical Trial Institutions (Trial)" and the "Measures for Ethical Review of Life Science and Medical Research Involving Humans" (Guo Wei Ke Jiao Fa [2023] No. 4) issued by the National Health Commission and other four departments. The content stipulated in the existing special normative documents will not be repeated, and interfaces can be left in GCP.

At the guiding principles level, the focus is on ensuring alignment with ICH E6(R3), refining and improving regulatory rules, and maintaining consistency in basic principles and requirements; for E6(R3) provisions that comply with local regulatory requirements, further clarify the regulatory requirements; for E6(R3) provisions that are operational details, recommended practices, and conceptual descriptions, they will not be included in my country's GCP, but will be implemented in full as E6(R3), reserving room for flexibility in clinical trial implementation; the key points for verification and inspection, as well as other relevant technical guidelines in my country, will be aligned with GCP and E6(R3) to strengthen implementation guidance.

III. What are the adjustments and considerations for each chapter of the GCP revision?

The revised GCP is divided into six chapters and fifty-four articles: General Provisions, Ethics Review Committee, Principal Investigators and Clinical Trial Institutions, Sponsors, Data Governance, and Supplementary Provisions. Compared with the 2020 version of GCP, a data governance chapter has been added. Given that E6(R3) already provides detailed explanations of trial protocols, investigator's manuals, required document management, terminology, and their definitions, to reduce unnecessary repetition and further strengthen alignment with ICH E6(R3), the revised GCP has removed the original chapters on trial protocols, investigator's manuals, and required document management. The terminology section has been simplified, retaining only terms related to trial participants and those applicable to clinical trial practices in my country. Specific implementation details should refer to the Chinese version of E6(R3). The requirements for writing investigator's manuals for traditional Chinese medicine and ethnic minority medicines in the 2020 version of GCP will be incorporated into subsequent technical guidance principles. IV. What are the conceptual adjustments in the revised GCP?

my country's revised Good Clinical Practice (GCP) fully incorporates the core principles of ICH E6 (R3)—quality by design, conformity to purpose, and proportionality to risk—into the general principles section, and sets forth guiding principles for their application in all stages of drug clinical trials. Simultaneously, to support the application of new technologies and methods in clinical trials, the general principles section defines the boundaries for their application, stipulating that their use in clinical trials must comply with current ethical, scientific, and relevant legal and regulatory requirements.

V. The revised GCP draft further strengthens the main responsibility and protects the participants in the experiment. What measures have been taken to optimize management requirements?

Regarding principal responsibility, considering the reality that drug clinical trials in my country are all conducted by teams, and in conjunction with the E6(R3) definition of principal investigator, the revised draft clarifies that the principal investigator is the ultimate responsible party on-site in the clinical trial, and specifies matters that the principal investigator should not, in principle, delegate. At the same time, it clarifies that the sponsor is the most responsible party for clinical trial-related activities.

The principal investigator and sponsor bear ultimate responsibility for the activities they authorize and entrust.

Regarding the protection of trial participants, the general principles section further clarifies the important role of ethical review and informed consent in safeguarding the rights and safety of trial participants; strengthens the review by the ethics review committee on issues involving special groups, informed consent, and serious and persistent non-compliance; the sponsor section clarifies that sponsors should update the trial protocol, investigator's manual, and informed consent materials as necessary based on the safety information assessment results during the trial, and that the informed consent form should be sufficient, complete, easy to understand, and comply with relevant ethical review requirements; and clarifies the requirements for principal investigators to report serious adverse events to the ethics review committee.

In terms of optimizing management, the document addresses the specific needs of all participants in clinical trials, further streamlining processes and clarifying responsibilities. For example, the section on ethics review committees requires that their ethical review work comply with the relevant regulations of the health authorities, and improves the requirements for the content and methods that ethics review committees should focus on reviewing; it optimizes the reporting process for safety information and clarifies the relevant responsible parties; the section on sponsors improves the requirements for maintaining blinding at all stages of the trial and adds requirements for sponsors to implement risk management in clinical trials; and it clarifies the requirements and status of electronic signatures, etc.

VI. How does the revised GCP strengthen quality management requirements?

The design and implementation quality of drug clinical trials directly affect the rights and safety of trial participants, as well as the reliability of clinical trial results. This revision clarifies that quality management should be integrated throughout the entire drug clinical trial process and adds terminology related to drug clinical trial quality management and drug clinical trial quality management system. This aims to unify understanding among all parties, clarify the goals, pathways, and methods of drug clinical trial quality management, and guide sponsors and drug clinical trial institutions to conduct quality management work scientifically and efficiently.