Interpretation of *the Key Points and Determination Principles for Supervision and Inspection of Medical Device Clinical Trials (for Trial Implementation)*

6 August 2024

Interpretation of *the Key Points and Determination Principles for Supervision and Inspection of Medical Device Clinical Trials (for Trial Implementation)*

6 August 2024

To facilitate the execution of the *Provisions for Medical Device Registration and Filing* and the *Provisions for Medical Device Clinical Trial Organization Supervision and Inspection (for Trial Implementation),* along with other pertinent requirements, the Center for Food and Drug Inspection of the National Medical Products Administration (NMPA) has established the *Key Points and Determination Principles for Supervision and Inspection of Medical Device Clinical Trials (for Trial Implementation).* This framework, which has received approval from the NMPA, will take effect on 1 October 2024.

1. Background

The rapid advancement of the medical device sector and the introduction of innovative products have necessitated elevated standards and requirements for clinical trials. This situation underscores the critical need for a robust and systematic regulatory framework to guarantee the safety and efficacy of medical devices. The release of the *Key Points and Determination Principles for Supervision and Inspection of Medical Device Clinical Trials (for Trial Implementation)* (hereafter referred to as "the Document") offers a comprehensive operational guide for clinical trial practices. Its primary objectives are to standardize and enhance the implementation standards of clinical trials, effectively mitigate potential irregularities, improve the relevance and efficiency of oversight, ensure prompt identification and rectification of issues and ultimately elevate the quality and effectiveness of supervision.

2. Key contents

Overview: the scope of supervision and inspection, principles of determination and implementation and execution

1 The scope of supervision and inspection

- Qualification of institutions and researchers
- Organizational structure and management framework
- Ethical review committee
- Trial design and implementation
- Protection of subjects
- Management of facilities, equipment and materials
- Documentation and archiving

2 Principles of determination

- Compliance determination
- Risk classification
- Failure criteria
- Corrections and judgment results

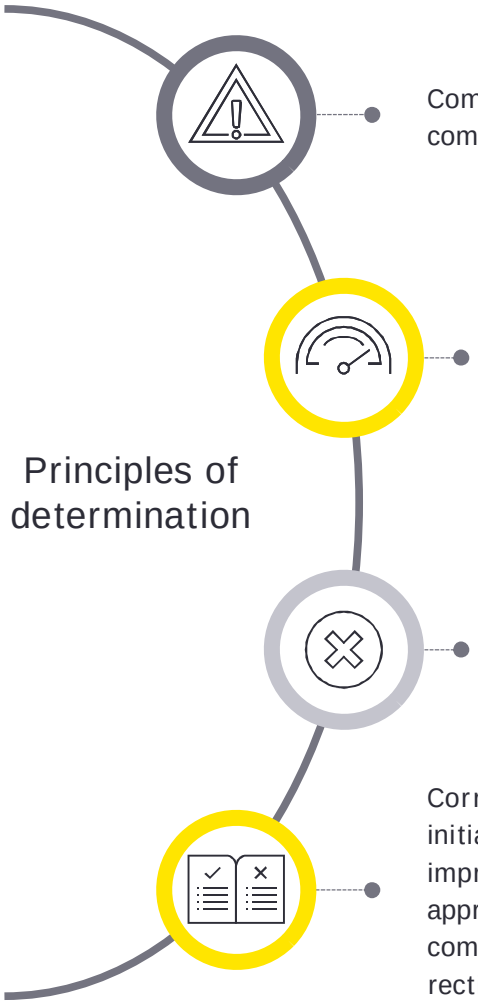
3 Implementation and execution

- On-site inspection and document review
- Problem identification and feedback
- Tracking and verification

(1) The scope of supervision and inspection

- Qualification of institutions and researchers: The qualification assessment of institutions involves verifying their legal registration and filing status, as well as their capacity and conditions for conducting specific types of clinical trials involving medical devices. The evaluation of researchers' qualifications encompasses their professional competencies, training records, ethical education and their capability to implement the trial protocol effectively.
- Organizational structure and management framework: Evaluating the rationality of the institution's organizational structure and the robustness of its management system, which includes the quality management system, risk management mechanism and emergency response protocols.
- Ethical review committee: Examining the composition and functioning of the ethical review committee to ensure that its review processes adhere to national standards and international ethical principles.
- Trial design and implementation: Verifying the scientific validity and rationality of the clinical trial protocol and assessing whether the processes for data collection, recording, storage and analysis during the trial are conducted in a standardized manner.
- Protection of subjects: Reviewing the informed consent documentation, the legality of the consent acquisition process, the adequacy of measures for safeguarding subject privacy and safety and the establishment and execution of procedures for reporting and managing adverse events.
- Management of facilities, equipment and materials: Assessing the compliance of the physical infrastructure at the testing site, along with the calibration and maintenance records of instruments and equipment, as well as the handling of medical devices–including storage, distribution, recycling and disposal.
- Documentation and archiving: Verifying the completeness, authenticity and traceability of all trial-related documentation, which includes trial protocols, raw data, statistical reports and meeting minutes, among others.

(2) Principles of the determination



Compliance determination: Judging whether the organization's operation is compliant based on relevant laws and regulations and technical guidelines.

Risk classification: Each inspection criterion is distinctly evaluated, categorizing critical items that fail to meet standards as serious defects, major items that do not comply as major defects, and general items that are inadequate as general defects. The overall outcome will be determined based on the total number of defects identified. If fewer than 5 general defects are detected, the requirements may still be considered met following a thorough evaluation. Conversely, if the count of general deficiencies is 5 or more, while the number of major deficiencies remains at 3 or fewer, the organization is required to address the deficiencies and undergo a subsequent assessment.

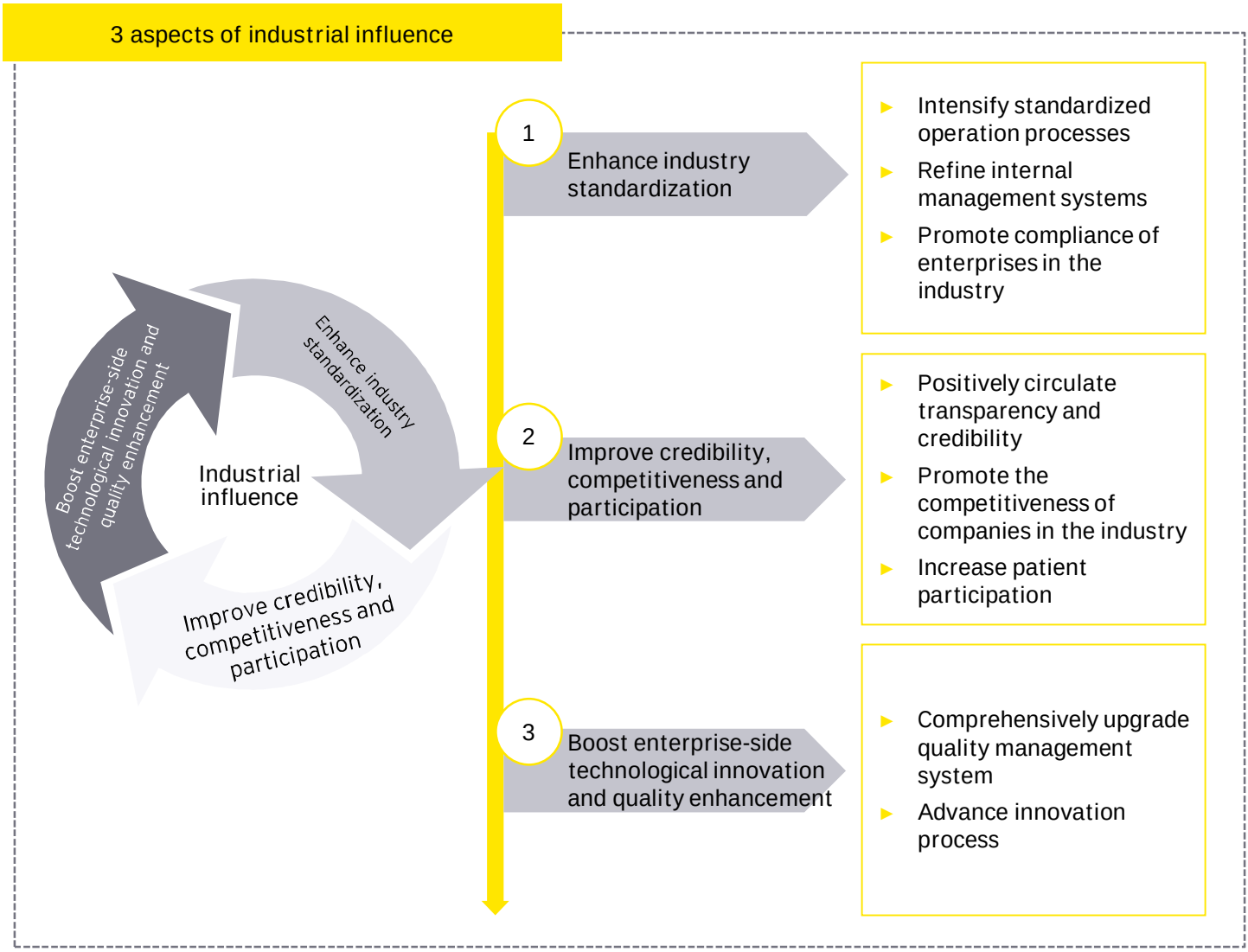
Failure criteria: If there are any serious deficiencies for critical items or more than 3 major deficiencies for major items, or other serious situations (e.g., data falsification, serious violation of ethical principles, unacceptable risk to subjects, etc.), it will be judged as non-compliant.

Corrections and judgment results: Institutions are encouraged to take the initiative to identify and rectify problems through self-inspection and continuous improvement mechanisms. According to the nature and severity of the problems, appropriate management measures are taken. If it is directly judged to be non-compliant with the standards or cannot meet the standards after requesting rectification, it will be finally judged to be non-compliant with the requirements.

(3) Implementation and execution

- On-site inspection and document review: Conducting a thorough assessment of the organization's actual status through site visits, document review and interviews with personnel.
- Problem identification and feedback: Documenting the issues discovered, offering prompt feedback to the organization and necessitating the formulation and execution of corrective actions.
- Tracking and verification: Monitoring the organization's progress in addressing the identified issues, conducting reviews as needed and validating the effectiveness of the corrective measures.

3. Influence on the industry



(1) Enhance industry standardization

- Intensify standardized operation processes: The Document specifies the standard process and checkpoints for clinical trials, promotes the popularization and deepened implementation of standardized processes, strengthens daily operation compliance, pushes the industry toward a unified and efficient model and facilitates the sharing of best practices.
- Refine internal management systems: The Document will prompt enterprises to refine their internal systems, adopt advanced quality management tools, ensure traceability and efficiency of operations and improve management accuracy.
- Promote compliance of enterprises in the industry: The normative enhancement prompts enterprises to shift from passive compliance to active practice, integrating compliance into corporate culture, strategy and daily operation as core competitiveness and continuously promoting the healthy development of the industry.

(2) Improve credibility, competitiveness and participation

- Positively circulate transparency and credibility: The trust of the public, investors and the research community are enhanced through the handling of supervision and inspection results and the disclosure of results within a certain degree. Transparent regulation will enhance the credibility of the industry, which will help attract more investment and participation and promote medical innovation.
- Promote the competitiveness of companies in the industry: Companies that respond positively to the Document will establish an image of high standards, become industry benchmarks and increase brand influence and market share. Transparency and compliance will enhance consumer confidence, expand product demand and solidify customer base.
- Increase patient participation: With the increased transparency and credibility of clinical trials, the increased willingness of patients to participate will further accelerate the research and development (R&D) process of new medical devices.

(3) Boost enterprise-side technological innovation and quality enhancement

- Comprehensively upgrade quality management system: The Document emphasizes the priority of quality, forcing companies to re-examine and optimize their quality management systems. Enterprises may adopt more advanced quality management modes (e.g., digital quality management platforms) to achieve real-time monitoring and rapid response of quality data.
- Advance innovation process: Clear regulatory guidance will allay enterprises' concerns about unclear regulatory standards and help them focus on R&D innovation and quality control. Within the regulatory system, relying on innovative technologies and products, it will promote the overall technological innovation of the industry and enhance the competitive position.

4. Outlook

1

Improvement of the regulatory system

- Enhanced regulatory efficiency
- Policy refinement and implementation
- Risk assessment and prevention
- Emergency response mechanism

An effective regulatory framework can greatly improve the efficacy of regulations, offering clear directives for execution and ensuring the successful application of measures. Advanced risk assessments can foresee and avert breaches and safety hazards, while thoughtfully designed contingency plans can proficiently handle emergencies, protect the well-being of individuals, and reduce negative outcomes.

2

Clarification of legal basis

- Legalization process
- Well-defined responsibilities

The issued document will offer targeted assistance for the legal proceedings, delineate the limits of the rights and responsibilities of all pertinent parties, and efficiently mitigate the emergence of liability conflicts.

3

Optimization of industry ecology

- Healthy competition environment
- Sustainable development

The guidance outlined in the document will facilitate the constructive development of the industry's ecosystem, encourage the establishment of a more favorable competitive landscape, and contribute to the creation of a sustainable health industry framework.

5. Conclusion

In recent years, the pharmaceutical and medical device industries have witnessed a persistent increase in the establishment of regulatory compliance policies and official guidance documents, presenting new challenges for companies. Given the rapidly evolving policy landscape, it is imperative for companies to take a proactive approach to refine their supply chains, suppliers and partner organizations through dynamic and effective compliance management strategies. The objective is to create a robust defense against potential compliance risks that may arise from policy changes and to ensure that operations consistently adhere to the most current regulatory standards.

The EY Consulting team possesses extensive expertise and practical experience in pharmaceutical compliance. We are eager to share valuable insights and success stories with companies across all sectors of the pharmaceutical industry, fostering mutually beneficial collaboration opportunities that promote shared prosperity and growth.

For more information, please contact us:

Felix Fei

Life Sciences and Healthcare Segment Leader
Managing Partner, Assurance, China Central
Ernst & Young Hua Ming LLP
felix.fei@cn.ey.com

Ronald Wang

Executive Director, Consulting
Ernst & Young (China) Advisory Limited
ronald.wang@cn.ey.com

Sharry Wu

Life Sciences and Healthcare Segment Leader
Managing Partner, Management Consulting
Ernst & Young (China) Advisory Limited
sharry.wu@cn.ey.com

Jackson Han

Senior Manager, Consulting
Ernst & Young (China) Advisory Limited
jackson.han@cn.ey.com

Michelle Yan

Partner, Consulting
Ernst & Young (China) Advisory Limited
michelle-xx.yan@cn.ey.com

John Shi

Manager, Business Innovation and Management Transformation Consulting
Ernst & Young (China) Advisory Limited
john.shi@cn.ey.com

Jeffrey Yu

Partner, Consulting
Ernst & Young (China) Advisory Limited
jeffrey.yu@cn.ey.com

Allen Liu

Senior Consultant, Consulting
Ernst & Young (China) Advisory Limited
allen.jm.liu@cn.ey.com

EY | Building a better working world

EY exists to build a better working world, helping to create long-term value for clients, people and society and build trust in the capital markets.

EY embraces innovation and adopts advanced technologies, helping clients identify market trends, capture opportunities and accelerate business transformation through integrated high-quality services.

Working across assurance, consulting, strategy, tax and transactions, EY teams ask better questions to find new answers for the complex issues facing our world today.

APAC no. 03020907
ED None.

ey.com/china

Follow us on WeChat
Scan the QR code and stay up-to-date with the latest EY news.