ICS 11.040
CCS C30

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0297-2026

Replacing YY/T 0297-1997

General requirements for clinical investigation of medical devices

医疗器械临床试验质量通用要求

Issued on: March 9, 2026 **Implemented on: March 1, 2027**

Issued by: National Medical Products Administration

Table of Contents

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. This document replaces YY/T 0297-1997 "Clinical Investigation of Medical Devices". Compared with YY/T 0297-1997, the main differences are in structural adjustments and compilation. Aside from the logical changes, the main technical changes are as follows:

---The scope has been changed (see Chapter 1, Chapter 1 of the.1997 edition);

---Terminology and definitions have been changed (see Chapter 3, Chapter 3 of the.1997 edition);

---The clauses concerning ethical considerations have been revised and added (see Chapter 4, Chapter 4 of the.1997 edition);

---The relevant clauses of the clinical trial protocol have been revised and added (see Chapter 5, Chapter 5 of the.1997 edition);

---The provisions related to the implementation of clinical trials have been revised and added (see Chapter 6, Chapter 6 of the.1997 edition);

---The provisions regarding the suspension, termination, and closure of clinical trials have been revised and added (see Chapter 7, Chapter 7 of the.1997 edition);

---Added responsibilities for the applicant (see Chapter 8);

---Added the responsibilities of the principal investigator (see Chapter 9);

---The researcher's manual has been revised (see Appendix A, Appendix A of the.1997 edition). Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the national technical standardization authority for clinical evaluation of medical devices. This document was drafted by: the Center for Medical Device

Evaluation, National Medical Products Administration; and the Food and Drug Evaluation Center, National Medical Products Administration. Inspection Center, Shandong Provincial Institute for Inspection and Testing of Medical Devices and Pharmaceutical Packaging, Peking University Third Hospital. The main drafters of this document are. Liu Yinghui, Liu Lu, Cheng Weilu, Cui Xinyue, Wang Jianan, Yan Juan, Shi Yanping, Liu Chenghu, Sun Xiaoxia, and Li Haiyan. Wang Yupeng. The release history of this document and the document it replaces is as follows:

---First released in.1997 as YY/T 0297-1997;

---This is the first revision.

This document is based on the regulatory framework of the "Good Clinical Practice for Medical Devices" and references ISO 14155.2020 "Medical devices for human use in medical settings". The "Good Clinical Practice for Medical Devices" standardizes the entire process of clinical trials for medical devices seeking registration conducted within China. Require. General requirements for the quality of clinical trials of medical devices

1 Scope

YY/T 0297 is the good clinical practice standard for medical device trials in China. It specifies the general quality requirements for the entire pre-market clinical trial process of a medical device: protocol design, implementation, monitoring, auditing and inspection, and the collection, recording, storage, analysis, summarisation and reporting of the data. It is the device counterpart of the pharmaceutical GCP rules and the general text from which the sector-specific documents descend, including YY/T 1998 on in vitro diagnostic reagent trials and YY/T 1997 on biological sample management. For a manufacturer running a clinical trial in China, or bringing foreign trial data to a Chinese submission, this is the standard the trial file is inspected against, and the document that decides whether the evidence will be accepted at all.

This document specifies the general quality requirements for the entire pre-market clinical trial process for medical devices, including the design of the clinical trial protocol. Planning, implementation, monitoring, auditing, inspection, as well as data collection, recording, storage, analysis, summarization, and reporting. This document applies to clinical trials of medical devices for registration purposes. This document does not apply to in vitro diagnostic reagents.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 42062 Application of Risk Management for Medical Devices

YY/T 1930 Terminology and Definitions for Clinical Evaluation of Medical Devices

3 Terms and Definitions

The terms and definitions defined in YY/T 1930 apply to this document.

4 Ethical considerations

4.1 General Requirements The following principles should be followed in clinical trials of medical devices.

a) Clinical trials of medical devices should comply with the ethical guidelines of the Declaration of Helsinki of the World Medical Congress and national biomedical protocols involving human subjects. Research relevant ethical norms. (b) Clinical trials of medical devices should be based on sufficient scientific evidence and have a clear trial objective, balancing the risks to participants and societal expectations. Risks and benefits. Clinical trials can only be implemented or continued if the expected benefits outweigh the risks.

c) The rights and safety of the participants take precedence over all other interests, such as scientific and social interests.

d) The non-clinical and clinical information available for the investigational medical device should be sufficient to support the proposed clinical trial.

e) The scientific basis should be clearly and thoroughly described in the clinical trial protocol.

f) Clinical trials should be conducted in accordance with the clinical trial protocol approved by the ethics committee and subject to regulatory approval (if applicable).

g) Providing medical services to the subjects and making medical decisions on their behalf are always the responsibility of qualified medical personnel.

h) Personnel involved in the design, execution, recording, and reporting of clinical trials should have relevant education, training, and experience.

i) Informed consent should be obtained from each participant before they participate in a clinical trial. Note

1.There may be some exceptions (see 4.8.3).

j) All information relating to clinical trials shall be recorded, processed, and securely documented, interpreted, monitored, audited, and verified in a manner that ensures accurate reporting, interpretation, monitoring, auditing, and verification. Data storage

should ensure that it is authentic, accurate, complete, and traceable.

k) Privacy and confidentiality principles should be respected, and the confidentiality of records of identifiable subjects should be protected.