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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 47336-2026

Specification for quality control in traditional Chinese medicine clinical trials

中医药临床研究质量控制规范

Issued on: March 31, 2026 **Implemented on: July 1, 2026**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

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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. 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 State Administration of Traditional Chinese Medicine. This document is under the jurisdiction of the National Technical Committee on Standardization of Traditional Chinese Medicine (SAC/TC478). This document was drafted by: Xiyuan Hospital of China Academy of Chinese Medical Sciences, China Academy of Chinese Medical Sciences, and China Food and Drug Enterprises Quality and Safety Promotion Association. China Association of Traditional Chinese Medicine, First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine, Affiliated Hospital of Chengdu University of Traditional Chinese Medicine, and Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine Hospitals, the First Affiliated Hospital of Hunan University of Traditional Chinese Medicine, the Second Affiliated Hospital of Heilongjiang University of Traditional Chinese Medicine, and the First Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine Dongfang Hospital of Beijing University of Chinese Medicine, Beijing Institute of Chinese Medicine, Dongzhimen Hospital of Beijing University of Chinese Medicine, and Longmen Affiliated Hospital of Shanghai University of Chinese Medicine Huazhong University of Science and Technology, Wangjing Hospital of China Academy of Chinese Medical Sciences, Affiliated Hospital of Shandong University of Traditional Chinese Medicine, Xiamen Municipal Hospital of Traditional Chinese Medicine, Jiangsu Provincial

Hospital of Traditional Chinese Medicine, Henan University of Traditional Chinese Medicine The First Affiliated Hospital of Shanghai Pharmaceutical University, Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, and Yueyang Hospital of Integrated Traditional Chinese and Western Medicine affiliated to Shanghai University of Traditional Chinese Medicine. Tasly Pharmaceutical Group Co., Ltd., Shijiazhuang Yiling Pharmaceutical Co., Ltd., Chia Tai Qingchunbao Pharmaceutical Co., Ltd., Jiangsu Famaisheng Medical Technology Co., Ltd. The main drafters of this document are. Gao Rui, Tang Xudong, Mao Zhenbin, Su Xiangfei, Wang Baohe, Tang Jianyuan, Yuan Weian, Zhao Yanling, Zhang Miao, and Yang Zhongqi. Lu Fang, Liu Wenna, Li Bo, Wu Shengxian, Yang Ming, Wei Xu, Peng Wei, Li Xiaohui, Zou Chong, Li Bin, Zi Mingjie, Li Min, Geng Lin, He Yi, Gao Xuedong Wang Mulan, Yin Qingfeng, Zhang Haoling, Liu Pengwei, Li Qingna, Qiu Panbo, Li Rui, Qian Zhenzhen.

Clinical research is one of the important scientific methods for evaluating the effectiveness and safety of traditional Chinese medicine. In recent years, the number of clinical studies of traditional Chinese medicine in my country has increased significantly. The volume is showing a rapid growth trend. However, traditional Chinese medicine, due to its unique theoretical system, diverse diagnostic and treatment methods, and complex drug compatibility rules, still faces challenges. Due to the unique characteristics of traditional Chinese medicine (TCM), it is difficult to establish unified and universally applicable standards in the field of TCM clinical research. Therefore, the standardization of TCM clinical research has been... The process is particularly complex, and producing high-quality clinical research results presents a significant challenge. To strengthen clinical research management and standardize clinical research practices... To promote the healthy development of clinical research, the National Health Commission, the National Medical Products Administration, and the State Administration of Traditional Chinese Medicine have successively issued relevant policies. The guidelines include the "Good Clinical Practice for Drug Clinical Trials", "Good Clinical Practice for Medical Device Clinical Trials", "General Principles of Clinical Research of New Traditional Chinese Medicines", and "Medical..." A series of policy documents, such as the "Administrative Measures for Researcher-Initiated Clinical Research Conducted by Medical and Health Institutions," have clarified the management of project initiation procedures and the responsibilities of all parties involved in cooperation. Detailed implementation rules for drug registration, clinical research registration, data security supervision, and record management will be established to comprehensively promote modern drug regulatory practices and enhance the capabilities of drug regulatory agencies. The construction of a scientific regulatory system for traditional Chinese medicine with Chinese characteristics. Good quality control is an important guarantee for the authenticity and reliability of clinical research data. Quality control in traditional Chinese medicine clinical research must comply with national standards. While adhering to the basic requirements of international and national clinical trial quality management standards, attention should also be paid to the unique characteristics of

traditional Chinese medicine. Therefore, it is necessary to formulate and promote scientific and feasible TCM clinical trial quality management standards. The Good Clinical Practice Guidelines for Pharmaceutical Clinical Research are helpful in guiding the establishment and implementation of quality control measures in traditional Chinese medicine clinical research and improving the quality of traditional Chinese medicine clinical research. It is of great significance to improve the overall quality and level of traditional Chinese medicine, promote innovation and transformation of achievements in traditional Chinese medicine, and promote international recognition of clinical research results in traditional Chinese medicine. This document draws upon the latest international methods and concepts for quality control in drug clinical trials, and is consistent with the laws and regulations issued by relevant national regulatory authorities. Within the framework of this technical document, taking into full account the characteristics of traditional Chinese medicine and the current state of the industry, the aim is to provide technical support for the quality control process of clinical research in traditional Chinese medicine. guide. Standards for Quality Control of Clinical Research in Traditional Chinese Medicine

1 Scope

GB/T 47336-2026 is the Chinese national standard covering quality control in a TCM clinical trial - the syndrome differentiation that has to be recorded reproducibly, the standardisation of the intervention, the blinding where it is possible, the outcome measures and the monitoring and data management. First edition, in force since 1 July 2026, under the National Administration of Traditional Chinese Medicine. It was issued on 31 March 2026 and has been in force since 1 July 2026, as a first edition. This page is published from the official record of the 2026 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document specifies the general requirements, quality control personnel, quality control plan, and primary quality control for quality control in clinical research of traditional Chinese medicine. This includes secondary quality control, tertiary quality control (when necessary), and record management. This document applies to clinical research projects in traditional Chinese medicine, clinical research on traditional Chinese medicine/medical devices for registration purposes, and the marketing of traditional Chinese medicine. Quality control work in post-clinical studies, etc.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Traditional Chinese medicine, originating in China, is characterized by holism and dialectical reasoning. It encompasses the medicine of the Han Chinese and ethnic minorities. A general term for traditional Chinese medicine. [Source: GB/T 38324-2019, 3.1]

3.2 Clinical research; CR Scientific studies conducted on humans or human samples to assess the safety and effectiveness of drugs or medical devices.

3.3 Clinical Trial of Drug (CTD) Human trials (patients or healthy subjects) aim to discover or validate the clinical, pharmacological, and clinical efficacy of an investigational drug. Other pharmacodynamic effects, adverse reactions, or the absorption, distribution, metabolism, and excretion of the investigational drug are used to determine the efficacy and safety of the drug. Systematic test.

3.4 In qualified institutions, the safety and... (The sentence is incomplete and requires more context to be translated accurately.) The process of confirming validity.

3.5 Quality control (QC) In a clinical research quality assurance system, the techniques implemented to verify that all relevant activities in a clinical research study meet quality requirements are... Activity.

3.6 Key data; CD Data used to ensure the reliability of clinical research results and the safety of subjects.