Appendix 1

创新药临床试验申请
申报资料要求
模块一

Center for Drug Evaluation, National Medical Products Administration

September 2025

创新药临床试验申请申报资料要求

模块一

Before submitting an Investigational New Drug (IND) application, the applicant should comply with the requirements of the National Medical Products Administration.

Research will be conducted on the relevant requirements of the technical guidelines published by the food safety regulatory authorities, based on...

Overall R&D plan, clinical trial protocol, preliminary research data, risk control, etc., for

Whether the existing data can support the conduct of clinical trials and whether the risks are controllable need to be fully evaluated.

Estimate. According to the current version of "M4: Common Technical Document (CTD) for Human Drug Registration Applications"

The format, numbering, and item order of the "Classification and Application Requirements for Registration of Traditional Chinese Medicine" are organized as follows:

Submit the required materials to apply for a drug clinical trial. Unsuitable items may be reasonably omitted, but should...

Indicate that it is not applicable and explain why.

For applications to comply with the "Public Notice on Optimizing the Review and Approval of Clinical Trials for Innovative Drugs"

For innovative drugs included in the 30-day clinical trial review and approval process, the applicant should submit the application form...

The document specifies a "30-day application period for inclusion in clinical trials" in the current version of the application.

Based on the required documentation, we will focus on the following requirements for writing project documents and provide relevant information.

Material.

I. Chemical Drugs and Biological Products

1.1.3.4.1 Clinical Trial Plan and Protocol

Applicants should provide a clinical trial plan and complete documentation for the proposed indication.

Clinical trials approved and signed by the principal investigator of the lead institution of the Chinese clinical trial organization.

Experimental plan. The specific plan design considerations are as follows:

The determination of indications should be based on product characteristics, research and development objectives, and preliminary research data.

Taking all factors into consideration, the provided clinical trial protocol should be risk-controllable, feasible, and targeted at...

Develop corresponding safety risk control measures for major toxicity findings; key aspects of clinical trials.

The design of elements should be supported by prior non-clinical and/or clinical research data, and should be considered in clinical trials.

The design basis for key elements should be explained in the test plan.

2.1.3.8.7 Research Institution Qualification Certificates

Applicants should provide: (1) Clinical trials conducted by the lead unit of the Chinese clinical trial institution.

(2) Project approval and contract review: receiving supporting documents or review opinions;

The ethics committee of the leading organization reviews and accepts the supporting documents or provides its review opinions.

The applicant should submit a list of review materials to the ethics committee that includes at least the following documents:

Document: Clinical trial protocol signed by the principal investigator of the lead institution of the Chinese clinical trial organization.

Case study, researcher's brochure, draft informed consent form, and risk management plan during research and development.

Documents such as the evaluation report for the application for clinical trials of new drugs.

3.1.3.9 Other product information and related materials

According to the "Announcement on Matters Related to Optimizing the Review and Approval of Clinical Trials for Innovative Drugs",

Applicants should provide a statement confirming their eligibility and relevant supporting documentation, and submit the application.

A commitment letter to initiate clinical trials within 12 weeks of confirmation of approval.

For Phase I and Phase II clinical trial registration applicants, globally synchronized [documents/resources] should be provided.

Supporting documentation such as research and development plans; for Phase III international multicenter clinical trials,

The main Chinese researchers served on the Global Steering Committee/Consultant Committee for International Multicenter Clinical Trials.

The committee members were asked to lead or co-lead early involvement in clinical research and development, and clinical trials.

The plan should include clinical research centers in two or more countries, including my country.

4.1.8.3 Risk Management Plan (RMP)

Applicants should provide relevant documentation of their experience in pharmacovigilance work during clinical trials, as well as...

The applicant and the principal investigator from the lead institution of the Chinese clinical trial jointly signed the confirmation.

A recognized risk management plan during the research and development period.

Explanation of experience in pharmacovigilance work. This includes the following two parts:

(1) Introduction to the pharmacovigilance system: For example, the department responsible for pharmacovigilance activities /

Relevant departments and staffing; pharmacovigilance system; standard operating procedures (SOPs).

Records; Drug Safety Committee, etc.

(2) Quality Management of Pharmacovigilance System: Briefly describe the quality control of pharmacovigilance system.

Indicators and procedures for monitoring and auditing pharmacovigilance systems.

Two Chinese medicines

The requirements for application materials for traditional Chinese medicine registration are in accordance with the "Classification of Traditional Chinese Medicine Registration and Requirements for Application Materials".

Execution. Specifically, 1.3.7.6 Research institution qualification certificates, 1.3.8 Other product information...

The requirements for relevant information materials and risk management plan data in section 1.8.3 are the same as those for chemical and biological products.

According to the product information requirements in sections 1.3.8.7, 1.3.9, and 1.8.3, section 2.1, "Product Overview," should state...

A comparison of Minghe's existing marketed traditional Chinese medicine prescriptions.