# Notice by the China National Medical Products Administration of Issuing the Pilot Work Plan for Optimizing the Review and Approval of Clinical Trials of Innovative Drugs[1]

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## Introduction

To implement the directives of the CCP Central Committee and the State Council on accelerating the development of new productive forces and to further deepen the reform of the drug evaluation and approval system while enhancing the efficiency of drug evaluation and approval to support innovative drug research and development, the National Medical Products Administration has formulated the *Pilot Program for Optimizing the Evaluation and Approval of Clinical Trials for Innovative Drugs*. This document is hereby issued to the Drug Administration Departments of all Provinces, Autonomous Regions, Municipalities directly under the Central Government, and the Xinjiang Production and Construction Corps. Please implement it conscientiously in accordance with local conditions.

China National Medical Products Administration

July 31, 2024

## I. Work Objectives

The review and approval mechanism for clinical trials of innovative drugs shall be optimized, and the primary responsibility of applicants for the clinical trial of drugs ("applicants") shall be strengthened. The capacity of drug clinical trial stakeholders to identify and manage the risks of clinical trials of innovative drugs shall be improved and the establishment of a working system and mechanism for comprehensively improving the quality and efficiency of drug clinical trials shall be explored. The review and approval of clinical trial applications for innovative drugs shall be completed within 30 working days to shorten the time for initiation of drug clinical trials.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

## II. Relevant requirements for inclusion in the pilot program

1.Pilot regions

The pilot program shall be launched in eligible provinces (Autonomous Regions and Municipalities). The governments of pilot provinces (Autonomous Regions and Municipalities directly under the Central Government), attaching great importance to pharmaceutical R&D and innovation, have introduced relatively complete supporting management and support policies for clinical trials of drugs. The governments of pilot provinces have established and improved a multi-sectoral collaboration mechanism and established a supporting work system according to the tasks of the pilot work.

2. Pilot projects

Pilot projects are targeted at clinical trial applications for Class 1 innovative drugs (except products for cell and gene therapy, vaccine products and so forth). Applicants are free from regional limitations and shall have received approval for at least three clinical trial applications for innovative drugs, both domestically and internationally. They shall have considerable experience in clinical trial implementation and pharmacovigilance management. They shall be able to conduct a comprehensive risk assessment of clinical trial projects before submitting clinical trial applications and develop effective risk management plans.

3. Institutions engaging in the clinical trial of pilot drugs ("pilot institutions")

(1) A pilot institution shall be a national medical center or national clinical medical research center in a pilot region, and it shall have established a working system for providing services such as clinical trial project initiation, ethical review and contract review before applicants submit applications for the clinical trial of new drugs. The pilot institution responsible for the relevant specialties of the pilot project shall have been filed with the Information Platform for the Filing of Institutions Engaging in Drug Clinical Trials and have completed at least three clinical trials for innovative drugs as a lead institution in that specialty.

(2) The ethics committee of the pilot institution shall have the ability to conduct an initial review of the risk management plan for the clinical trial project submitted by the applicant and conduct a follow-up review of the implementation of clinical trial risk management measures during the implementation of the clinical trial.

(3) The principal investigator, as the principal investigator of a lead institution, shall have presided over at least three clinical trials of innovative drugs, be able to participate in the risk assessment of the pilot project in the stage of preparation for a clinical trial application and complete the review and confirmation of the pilot project plan before the clinical trial application is submitted.

## III. Implementation steps for the pilot's work

1.Application by pilot regions

For eligible Provinces (Autonomous Regions and Municipalities directly under the Central Government) that are eligible to launch the pilot program after self-assessment, the Provincial Medicinal Products Administrative Department shall submit a pilot application to the China National Medical Products Administration, which grants approval according to the review.

2. Application for pilot institutions

A clinical trial institution in a pilot region shall establish and improve relevant working systems and submit a pilot application to the provincial medicinal products administrative department where the clinical trial institution is located. The Provincial Medicinal Products Administrative Department shall review and confirm the application.

3. Application for pilot projects

(1) Making an application: An eligible applicant voluntarily applies for a pilot project. The lead institution for the pilot project shall be an institution that has been included in the pilot program. The applicant shall submit the application form for the pilot project and the following materials to the Provincial Medicinal Products Administrative Department in the pilot region: the contract review opinion or acceptance form of the pilot institution, the clinical trial protocol reviewed and signed by the principal investigator, the review opinion or acceptance form from the ethics committee and the risk management plan for the clinical trial project jointly confirmed by the applicant, the principal investigator and the ethics committee. Before submitting a project application, the applicant may, as needed, request a consultation with the Center for Drug Evaluation of the National Medical Products Administration regarding the clinical trial application for the new drug.

(2) Confirming the application: Within five working days of receipt of the pilot application, the Provincial Medicinal Products Administrative Department in the pilot region shall, in consultation with the Center for Drug Evaluation, send a letter of project confirmation to the pilot-project applicant who grants the recommendation and a copy to the pilot institution. A clinical trial project for which the project confirmation fails to be received within five working days shall not be included in the pilot program and the applicant may apply for drug clinical trials in accordance with provisions in force.

4. Review and approval

The Center for Drug Evaluation shall complete the review and approval within 30 working days of receipt of the clinical trial application and notify the applicant of the approval results on the website of the Center for Drug Evaluation.

5. Initiating drug clinical trials

The applicant shall develop efficient cooperation with the pilot institution, initiate the clinical trial within 12 weeks after the clinical trial application is approved (the first subject signs the informed consent) and implement risk management throughout the clinical trial process.

## IV. Schedule and expected results

The pilot program lasts for one year. Before the end of August 2024, the confirmation of pilot regions and pilot institutions shall be completed and pilot project applications shall be initiated; in January 2025 a mid-term assessment shall be carried out; in July 2025 the experience of the pilot work shall be summarized.

During the pilot period, clinical trial applications for at least ten varieties shall be reviewed and approved in the pilot region and clinical trials shall be initiated. The Center for Drug Evaluation shall establish work measures for optimizing the review and approval of clinical trials of innovative drugs and formulate and improve systems and mechanisms; the pilot region shall summarize and analyze the work related to improving the efficiency of clinical trial initiation, clinical trial quality, and risk management capabilities, and obtain the replicable and extensively applicable experience in drug clinical trial management.

## V. Guarantee measures

1. Strictly fulfilling the responsibilities of all parties involved: The China National Medical Products Administration strengthens guidance and overall coordination. The Center for Drug Evaluation shall carry out review and approval in strict accordance with the technical requirements in force. Provincial Medicinal Products Administrative Departments shall continue to strengthen the day-to-day regulation of drug clinical trial institutions. All parties involved in clinical trials shall strictly abide by Good Clinical Practice, earnestly perform their respective duties, scientifically design clinical trials in a well-regulated manner, identify risks in a timely manner and implement risk management measures.

2. Ensuring fairness and justice: All entities and personnel shall strictly adhere to work discipline and relevant systems for preventing integrity risks and conflicts of interest. All entities and personnel shall carry out various tasks in accordance with laws and regulations, and strengthen supervision, so as to ensure the fairness and justice of the pilot program.

3. Strengthening technical training: The Center for Drug Evaluation shall provide personnel training for clinical trial institutions (including pilot institutions and non-pilot institutions) in pilot regions to improve the technical capabilities of clinical trial institutions in, among other things, project initiation, protocol review and risk assessment. Provincial medicinal products administrative departments may, as needed, assign personnel with expertise in pharmacy and pharmacology and toxicology to participate in the training. The management system for personnel training shall be established by the Center for Drug Evaluation.