Drug Clinical Trial Registration and Information Disclosure Management Standards (Trial)

Chapter 1 General Provisions

Article 1 is to implement the Drug Administration Law and adhere to the rules of drug clinical trials.

Risk management, full-process control, social co-governance, and good information disclosure on drug clinical trials

open, strengthen the supervision and management of drug clinical trials, protect the legitimate rights and interests of subjects, and comply with

Following ethical principles and referring to international common practices, in accordance with the "Measures for the Administration of Drug Registration",

Develop this management practice.

Article 2 The Drug Evaluation Center of the State Drug Administration (hereinafter referred to as

Drug Evaluation Center) is established and maintained in accordance with the overall requirements of the State Drug Administration

and update the “Drug Clinical Trial Registration and Information Disclosure Platform” (hereinafter referred to as the registration

platform), formulate and update the registration platform usage instructions and filling guide.

Article 3 The applicant shall ensure the authenticity and completeness of the drug clinical trial registration information.

Bear overall responsibility. Applicants can do so through authorization or entrustment, etc.

Drug clinical trial information registration, the registration platform does not

bear any legal responsibility for the transfer, authorization or entrustment relationship and registration of approval documents.

legal responsibility.

Article 4 Drug clinical trial registration and information disclosure records will be

Communication, technical review, supervision and inspection during the clinical trial process.

Article 5 The public is exempt from the clinical trial information that has been published on the registration platform.

Free search and retrieval.

Chapter 2 Information Registration and Update

Article 6 If it falls under any of the following circumstances, the applicant shall

Before drug clinical trials, clinical trials should be conducted on the registration platform in accordance with these management specifications.

Information is registered and continuously updated based on clinical trial progress.

(1) Obtained drug clinical trial license documents from the State Drug Administration

and clinical trials conducted in my country;

(2) Those who have completed the chemical drug bioequivalence test registration and obtained the registration number

Clinical Trials;

(3) According to the drug registration certificate or the notice issued by the drug regulatory department

Phase IV clinical trials and post-marketing studies as required;

(4) Other circumstances that require registration according to regulatory requirements.

Article 7 The applicant has obtained the drug clinical trial license document and it is valid

Drug clinical trial information can be registered only within this period; in accordance with the chemical registration management

Drug bioequivalence testing needs to be completed and registered, and registration can only be done after obtaining the registration number;

If registration is required under other circumstances, the applicant should provide relevant supporting documents.

Those that meet relevant requirements will be registered. Drug clinical trial application starts from the date of approval

If no subject signs an informed consent form within three years, the clinical trial of the drug

The license will automatically expire and registration will not be granted.

Article 8 The applicant shall submit drug clinical trial information through account name and password.

information registration and update.

Article 9 A clinical trial corresponds to a clinical trial protocol number, only

A record can be registered. After the registration information is submitted for the first time, a unique medicine will be automatically generated.

clinical trial registration number (CTR).

Article 10 Drug clinical trial registration information is divided into

First-time required items and first-time optional items, updateable items and non-updateable items, public notice items

and undisclosed items.

Article 11 The content registered on the registration platform includes approval to carry out drug clinical trials.

Trial license documents and related information, experimental drug information, applicant information,

Clinical trial protocol information, principal investigator information, participating institutions information, ethics

Management committee information, test status information, test result information, registration contact person

information, related attachments, etc.

Article 12 Applicants should strictly follow the instructions for use of the registration platform and fill in the

The guidelines require registration and updating of drug clinical trial information.

Article 13 Applicants should conduct quality control on the accuracy of registration information,

Once the non-renewable items are announced, applicants cannot modify them on their own.

Article 14 The applicant shall be within the validity period of the drug clinical trial license document.

Fill in all required fields for the first time and complete the first submission. First registration, submission and publication

Instructions should be completed before subject recruitment.

Article 15 After the drug clinical trial information is updated, the applicant shall

Submit updated information within working days. For proactive suspension due to security reasons or

If a clinical trial is terminated, the applicant should update the trial status letter within ten working days.

information; if ordered to suspend or terminate a clinical trial, the Center for Drug Evaluation shall update the trial status

status and make it public immediately. After the clinical trial is completed, the applicant should

Register clinical trial results information on the registration platform within twelve months after the completion date;

For registered clinical trials to support a marketing application, it is recommended that they be completed before the marketing application

Registration of clinical trial results information (whichever occurs earlier). Clinical Trials

The resulting information should contain at least the International Conference on Harmonization of Technologies for the Registration of Medicinal Products for Human Use (ICH)

Clinical research reports stipulated in "E3: Structure and Content of Clinical Research Reports"

Summary content.

Chapter 3 Information Review and Publicity

Article 16: Drug Clinical Trial Information Registered by the Applicant by the Center for Drug Evaluation

Conduct normative and logical reviews. This normative and logical review does not

It means that the Center for Drug Evaluation and the applicant discuss the scientific and reasonable drug clinical trial plan.

To achieve some kind of commitment, recognition or contract through sex.

Article 17 The Center for Drug Evaluation shall, in accordance with current laws and regulations, drug clinical trials

Licensing documents, registration platform filling guide, communication meeting minutes and other requirements are

The drug clinical trial information registered by the applicant will be reviewed.

Article 18 The drug clinical trial information registered by the applicant shall, upon review, comply with

If it meets the requirements for drug clinical trial licensing information and filling guidelines, it will be made public.

The main information disclosed includes basic information about experimental drugs, applicant information, clinical

Basic information of the trial plan, information of the main investigators, information of participating institutions, ethics

management committee information and test status information, but it is stipulated that it is only used for supervision and management and not

Except for information and attachments to be disclosed.

Article 19 The drug clinical trial information registered by the applicant shall not be

If it meets the requirements for drug clinical trial licensing information or filling guidelines, the application will be returned.

Ask someone to make modifications. After all modifications are made, and if they meet the requirements after review, they will be published.

Article 20 For clinical trials of drugs that do not comply with the provisions of these management regulations

Information registration will be returned to the applicant, registration will not be granted, and the applicant will be informed that registration will not be granted.

s reason.

Article 21 If the applicant needs to withdraw the announced drug clinical trial registration

Record information, and the reasons for withdrawing registration must be stated. After review and compliance with the requirements, the withdrawal is agreed.

Register.

Article 22 For drug clinical trial registrations that the applicant voluntarily withdraws,

If the applicant can provide relevant supporting documents to support his registration, he can re-register.

If the application meets the requirements after review, it will be announced to the public.

Article 23 Except for special circumstances, drug clinical trial registration information

The review time limit shall not exceed fifteen working days from the date the applicant submits information.

Article 24 Applicants may follow the communication time specified by the Center for Drug Evaluation

and ways to consult on issues related to drug clinical trial registration and information disclosure.

For inquiries, relevant information can be found on the official website of the Center for Drug Evaluation.

Chapter 4 Supplementary Provisions

Article 25 These management regulations will come into effect on July 1, 2020.