appendix

Guidelines for filling out the annual work summary report of drug clinical trial institutions

This guideline is intended to provide guidance for drug clinical trial institutions in the “Drug Clinical Trial Institution Registration Management”.

Submit the annual work summary report of the drug clinical trial institution on the "Management Information Platform" (hereinafter referred to as

The Annual Report provides guidance and identifies issues to consider when writing and submitting an annual report.

In this guideline, drug clinical trials refer to those conducted for the purpose of drug marketing registration in accordance with the

The drug administration law of the People's Republic of China, the drug registration management regulations and other relevant regulations

Drug clinical trials.

1. Basis for formulation

According to the Drug Administration Law of the People's Republic of China and the Drug Registration Management Measures,

Clinical trials of drugs should be conducted in drug clinical trial institutions that meet the relevant conditions and are registered in accordance with regulations.

On December 1, 2019, the “Regulations on the Administration of Drug Clinical Trial Institutions” came into effect.

The “Drug Clinical Trial Institution Registration Management Information Platform” was launched at the same time.

The Regulations on the Administration of Clinical Trial Institutions require that drug clinical trial institutions should

Recently, a summary report on the drug clinical trials conducted in the previous year was filled out on the registration platform.

2. Main Purpose

In order to unify the format of annual reports, standardize the content of reports and ensure the quality of reports,

Clinical trial supervision and management provides objective, accurate and high-quality data.

Based on previous work experience, this guideline was drafted for use by registered institutions in their

Fill in the annual report on the filing platform to clarify the factors that need to be considered when writing and submitting the annual report.

Key points.

The main purpose of the annual report is to review the relevant information of the institution's drug clinical trials conducted in the previous year.

The content should include the construction of organizational management system, personnel

Staff training, document system changes, quality control implementation, ethics committees,

Seven aspects are explained, including the situation of accepting domestic and overseas inspections and plans for the next year.

3. Basic requirements

The annual report should be concise and to the point.

It is accurate and can cover all the work related to the drug clinical trials in the previous year, ensuring that

Monitor and evaluate the work of the organization based on the annual report.

The data collection period for the annual report should be from the first day to the last day of the previous calendar year.

If it is a new filing institution, the data collection start date of the annual report is the date when the filing is successfully obtained.

The date of the filing number, for example, if the institution’s filing date is May 1, then the first annual

The report should be submitted before January 31 of the following year.

IV. Contents of the Report

The contents of this section should be reflected in the annual report.

The information should be explained.

1. Construction of organizational management system

This section should show the important changes in the key information of the organization in the previous year and the

Drug clinical trial project status, the main contents include:

1. Important changes to the basic information of the organization should be listed:

Whether the name of the organization has changed. If so, list the information before and after the change;

Whether there is any change in the legal person of the institution. If so, list the information before and after the change;

Whether the address of the organization has changed. If so, list the information before and after the change;

Whether there is any change in the head of the organization; if so, list the information before and after the change;

Whether there is any change in the person in charge of the clinical trial management department; if so, please list the changes before and after the change.

information;

Whether the contact person and contact information have changed. If so, list the information before and after the change;

2. List the changes in the registered majors/test sites, including those added, cancelled or

Change of address of specialty/test site; self-assessment of newly added specialty/test site

Overview.

3. List the changes in the principal investigators and list the principal investigators by specialty.

Addition or cancellation of the situation; description of the new principal investigators participating in the 3 drug clinical trials

Condition.

4. The status of drug clinical trial projects conducted in the previous year should be summarized in a table.

status (including projects started and completed in the previous year, as well as other ongoing projects), and collect data

The deadline is December 31 of the previous year. The main contents are as follows:

Clarify the basic information of the trial, including product name, registration applicant, drug registration score,

Category, institution type (specify that the institution is the lead unit or participating unit), drug clinical trial

Registration number, National Bureau drug clinical trial approval number/notification number/bioequivalence test record number

Case number, test protocol name, test protocol number;

Identify key time points, including the signing of the informed consent form by the first subject in the institution

The date of the first trial enrollment, the date of trial termination;

Identify the specialty and principal investigator responsible for the trial;

Clarify the trial status and number of enrolled cases.

If the trial is inspected by the drug supervision and administration department/health and health authority,

Write the inspection results.

2. Personnel training

This section should summarize the organization's training in the previous year. The main contents include:

1. Summarize the total number of people trained by the organization in the previous year; organize and manage the work of the organization

Personnel, researchers, quality management personnel, drug management personnel, ethics committee members, CRC

Number of people who attended the training.

2. The status of various types of training should be tabulated, including the name of the training, the type of training (such as

regulations, professional skills, etc.), departments involved in the training, number of participants in the training, and training assessment results

(if any).

(III) Changes in the file system

This section should list the changes in the file system in a table format, including file name, category,

Type (system, SOP), file name before and after the change, such as the file name before and after the change

If the name is the same, you can fill in the version number and version date to distinguish them; briefly describe the content of the change

Content and reason.

(IV) Implementation of quality control

This section should list the implementation of the institution's quality control in the previous year. The main contents include:

include:

1. Number of quality control projects implemented, percentage of quality control projects implemented to total number of projects, quality

The total number of control implementations.

2. Describe the institution's clinical trial management effectiveness for principal investigators and the clinical trials they undertake

Type and number of projects, number and experience of participating researchers, type and number of subject populations

The matching analysis conducted (such as the evaluation method adopted, evaluation results, etc.), and

The institution's corresponding quality management measures.

3. Briefly describe the main problems found by quality control and their treatment, including risk assessment,

Risk control, improvement measures, etc.

5. Ethics Committee

This section should show the important changes and reviews conducted by the ethics committee in the previous year.

The main contents include:

1. Whether the chairman has changed. If so, list the information before and after the change;

2. Whether the committee members have been replaced. If so, list the names of the committee members before and after the replacement;

3. Are there any new cases of passing ethical certification? If so, please specify the name of the certification

Name and time of certification;

4. Number of annual review projects, specify the total number of drug clinical trial projects reviewed annually

The number of projects reviewed, including initial review, follow-up review, and fast-track review

The number of projects;

5. Briefly describe the issues found in the annual ethical review and how they were handled.

(VI) Acceptance of domestic and overseas inspections

This section should describe the domestic and overseas inspections received by the institution in the previous year, mainly

Contents include:

1. If you have been inspected by domestic drug regulatory authorities, please fill in the number of inspections and use

List the inspections received in a table, including the regulatory agency, inspection type (including first inspections),

Supervision and inspection, routine supervision and inspection, cause-based inspection, drug registration verification, other inspections, etc.),

Inspection date, inspection conclusions, and whether rectification has been completed for any problems found during the inspection.

If rectification is completed, the reasons shall be stated.

2. If you have been inspected by overseas drug regulatory authorities, please fill in the number of inspections and use

List the inspections received in a table, including the regulatory agency, inspection date, and findings during the inspection.

The main problems found, the inspection conclusions and whether rectification has been completed for the problems found during the inspection, such as

If there are any rectifications that have not been completed, please explain the reasons.

(VII) Plans for the next year

Briefly describe which aspects of drug clinical trial institution management will be improved in the next year.

Strengthen or improve.

V. Annual work summary report template for drug clinical trial institutions

Annual work summary report template for drug clinical trial institutions

XX (Organization Name)

XXXX Annual work summary report of drug clinical trial institutions

1. Construction of organizational management system

1. Changes in basic information of the organization

Basic Information	Before the change (the system automatically captures the previous year last updated information before the date)	After change (fill in by yourself)
Institution Name		
Institutional Legal Person		
Institution Address		
Head of Institution		
Head of Clinical Trial Management Department		
Contact		
Contact Details		

2. Changes in the registered specialty/test site (change categories include addition, cancellation, and change of address. If it is addition or cancellation, it is not necessary to fill in The situation before and after the change.)

Before changing the serial number registration specialty/test site change category				After Change

Provide an overview of the self-assessment of the newly added disciplines/test sites

3. Changes in principal investigators (change types include addition and cancellation, indicating the situation of new principal investigators participating in 3 drug clinical trials)

Professional Change Type Name Title				Participation in 3 drug clinical trials

4. Status of drug clinical trial projects conducted in the previous year (including projects initiated and completed in the previous year, as well as other ongoing projects)

Schedule[1]

5. Other information

2. Personnel Training

1. Training organized by this institution

Last year, the total number of trainings organized was 100 (including 100 staff members of the organization and management department, 100 researchers, and 100 quality management personnel).

Personnel person-times, drug management personnel person-times, ethics committee ___ person-times, CRC____ person-times)

2. Status of various types of training (training categories include but are not limited to publicity of laws and regulations, professional skills training, management system training, etc.)

No. Training	Name Training Category Departments Involved Training	Number of People		Training assessment results (such as have)

3. Other information

3. Changes to the Document System

1. List of changes

ÿNo ÿChange

If there are any changes, please fill in the form below:

Before the serial number file name category is changed				After Change	Briefly describe the content and reasons for the change

Note: Categories include system and SOP. Fill in the file names before and after the change. If the file names before and after the change are the same, fill in

Write the version number and version date to distinguish them.

2. Other information

4. Implementation of quality control

1. Statistics on the number of quality control implementations

Number of quality control implementation projects: The percentage of quality control implementation projects to the total number of projects:

Total number of quality control implementations: times

2. Describe the relationship between the institution's clinical trial management effectiveness for principal investigators and the types and number of trial projects it undertakes, the number of participating researchers, and their experience.

The matching analysis of the experiment, the type and number of subjects (such as the evaluation method adopted, the evaluation results, etc.), and the relevant institutions

Applicable quality management measures

3. Briefly describe the main problems found by quality control and their treatment (including risk assessment, risk control, improvement measures, etc.)

4. Other information

V. Ethics Committee

1. Changes in the Chairperson

ÿNo ÿChange

If there is any change, before the change: _____ After the change: _____

2. Change of committee members

ÿNo ÿYes Change of term

If there is a change of term, please upload the list of committee members before and after the change of term (including name, gender, unit, major, position, title)

List before the change of term (appendix: *Word* or *Excel* ÿ

List after the change of term (appendix: *Word* or *Excel* ÿ

3. Newly added ethical certification status

ÿNo ÿYes Certification Name: _____ Certification time: _____

4. Ethical review

Total number of annual review projects: _____

Number of preliminary review projects: _____ Number of follow-up review projects: _____

Number of fast-track projects: _____ Number of meeting review items: _____

5. Briefly describe the problems found in the annual review and how they were handled

6. Other information

VI. Acceptance of domestic and overseas inspections

1. Acceptance of inspections by domestic drug regulatory authorities

ÿNo ÿYes Number of inspections received by domestic drug regulatory authorities: _____ times

If you have been inspected by domestic drug regulatory authorities, please fill in the following form:

No.	Regulatory Agency	Inspection Type	Inspection Date	Inspection Conclusion		Whether it is for inspection Check and find the problem Complete rectification	If there is any unfinished Corrected, said Clear cause

Note: Inspection types include initial supervisory inspection, routine supervisory inspection, cause-based inspection, drug registration verification, and other inspections.

2. Acceptance of inspections by overseas drug regulatory authorities

ÿNo ÿYes Number of inspections received by overseas drug regulatory authorities: times

If you have been inspected by overseas drug regulatory authorities, please fill in the following form:

Serial number	regulatory agency	Check date	Inspection found Main Issues	Inspection conclusion and rectification status	

VII. Plans for the next year

Briefly describe which aspects of the management of drug clinical trial institutions will be strengthened or improved in the next year

Note: Clinical trials of drugs in this table refer to clinical trials of drugs conducted for the purpose of drug marketing registration in accordance with the Drug Administration Law of the People's Republic of China, the Drug Registration Management Measures and other relevant regulations.

Schedule 1

XX (Organization Name)

Status of drug clinical trial projects conducted in XXXX

Serial number	Drug clinical trial registration number	National Bureau Drug Clinical Trial Approval Number/ Notice Number /BE Raw Physical equivalence test registration number	Variety name	Registration applicant	Drug Registration Classification	Organization type (leader unit, participating unit)	Test plan name	Protocol No.	Undertake special Industry	Principal Investigator	The date when the first subject in this institution signed the informed consent form	Date of first enrollment of subject in this institution	Trial termination date	Trial status (e.g., in progress but not recruiting yet, in progress and recruiting, in progress and recruiting completed, completed, etc.)	Number of cases	Accept the inspection results of the drug supervision and administration department/ health and health administration department (if any

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