Standard for safety information evaluation and management during drug clinical trials (trial)

Chapter 1 General Provisions

Article 1 is to implement the safety information report of the applicant during the clinical trial of the drug.

The main responsibility in reporting and risk management, and do a good job of safety information during drug clinical trials

According to the "Drug Administration Law" and "Drug Registration Administration Office"

Law" to formulate this management standard.

Article 2 During the clinical trial of the drug, the applicant should actively communicate with the clinical trial

Institutions and other relevant parties shall cooperate to strictly implement the main responsibility of security risk management.

Pharmacovigilance systems and systems should be established to carry out risk monitoring, identification, assessment and

Control, discover existing security problems and risks in a timely manner, and take the initiative to take necessary measures

Risk management measures, such as adjusting clinical trial protocols, proactively suspending or terminating clinical trials

bed test, etc. The effectiveness of security risk management measures should also be assessed to ensure that

Minimize the risk of the test subjects and effectively protect the safety of the subjects. for drug clinical trials

If there are any security risk-related issues that arise during the inspection process, the applicant should promptly

Risk and management information shall be reported to the drug supervision and administration department.

Article 3 is related to safety risks arising during drug clinical trials

problem, encourage applicants, clinical trial institutions and the State Drug Administration to drug

The Drug Evaluation Center (hereinafter referred to as the "Drug Evaluation Center") actively communicates with each other.

Chapter 2 Risk Assessment and Management of Security Information

Section 1 Applicant Risk Assessment and Management

Article 4 During the clinical trial, the applicant shall transmit the electronic data through pharmacovigilance

System (PV system) timely submission of suspected and unexpected serious adverse reactions

(SUSAR) case report, submitted on time during the research and development period through the website of the Center for Drug Evaluation

Security Update Report (DSUR), other potentially serious security risk information

Report.

SUSAR case reports, other potentially serious security risk information reports

Relevant requirements are in accordance with the "Safety Data During Drug Clinical Trials" issued by the Center for Drug Evaluation.

Implemented in accordance with the Expedited Reporting Standards and Procedures.

The relevant requirements of DSUR are in accordance with the "Safety During Research and Development" issued by the Center for Drug Evaluation.

Update Report Management Specifications (Trial)" implementation.

Clinical trial protocol changes, non-clinical or pharmaceutical

If there are changes or new discoveries, the applicant should fully evaluate the safety of the subjects

influences. If the assessment does not affect the safety of the subjects, it should be reported in the DSUR;

If it may increase the safety risk of the subjects, a supplementary application should be submitted.

Article 5 During the clinical trial of drugs, the applicant shall conscientiously perform drug clinical trials.

The main responsibility for the safety risk management of the bed test is to carry out risk monitoring and management of safety information.

Identify, assess, and control to detect security issues or other risks in a timely manner

risk, and take timely risk control measures and risk minimization measures, including general

Risk management measures (such as modifying clinical trial protocols, etc.), voluntary suspension or termination

Clinical Trials.

Article 6 The applicant believes that the clinical trial has a certain degree of safety information evaluation.

safety risks, general risk control measures should be taken, such as modifying clinical

The trial protocol, revision of the investigator's manual, revision of the informed consent form, etc.

Article 7 The applicant assesses that there is a greater safety risk in the clinical trial.

If it is dangerous, the clinical trial should be suspended actively. Clinical trials that need to be suspended due to safety risks

Refer to Annex 1 for reference standards and conditions.

Article 8 The applicant assesses that there is a significant safety risk in the clinical trial.

If it is dangerous, the clinical trial should be terminated voluntarily. Clinical trials need to be terminated due to safety risks

Refer to Annex 2 for reference standards and conditions.

Article 9 Applicants shall take risk management measures for security risks and evaluate them.

Evaluate the effectiveness of the implementation of measures to ensure that risks to subjects are minimized. Modify clinical

Information about the trial protocol, active suspension or termination of clinical trials should be posted on the drug in a timely manner.

The clinical trial registration and information publicity platform is updated.

Section 2 Risk Assessment and Management of Drug Administration

Article 10 The Center for Drug Evaluation shall, based on the safety information submitted by the applicant and its evaluation

and risk management information, combined with the specific circumstances of the original review and approval of drug clinical trials,

Evaluate the risk management implemented by the applicant in the clinical trial. assessment that

The risk management measures implemented by the applicant are insufficient, and the clinical trial is still safe

risk, the Center for Drug Evaluation may propose further risk control requirements, such as general

Risk management, suspension of clinical trials, termination of clinical trials, etc.

Article 11 Safety information and risks submitted by the applicant

Management information is evaluated, and it is believed that there are still certain safety risks in clinical trials

If yes, the applicant may be required to take further risk control measures, such as modifying clinical

Trial protocol, revision of investigator handbook, revision of informed consent, or adjustment of research and development

During the period of safety update reporting cycle, etc., the "Clinical Trial Risk Control Notice"

It is sent to the applicant through the website of the Center for Drug Evaluation, and the applicant should inquire and download it in time.

The applicant should take timely measures after receiving the "Clinical Trial Risk Control Notice".

Relevant measures and will be notified through the website of the Center for Drug Evaluation within 20 working days.

Written response to the completion or progress of the implementation.

Article 12 The Center for Drug Evaluation has reviewed the safety information and risks submitted by the applicant

Management information is evaluated, and it is believed that there is a greater safety risk in continuing the clinical trial.

In case of risk, the clinical trial may be suspended.

When the corresponding situation in Annex 1 occurs during the clinical trial, but the applicant has not

If the clinical trial is suspended on its own initiative, the Center for Drug Evaluation may request to suspend the clinical trial.

The Center for Drug Evaluation passed the "Notice of Suspension of Clinical Trials" through the website of the Center for Drug Evaluation

Send it to the applicant, the applicant should inquire and download in time.

Article 13 The Center for Drug Evaluation has reviewed the safety information and risks submitted by the applicant

Management information is assessed and there are significant safety risks to continuing the clinical trial

In case of risk, the clinical trial may be terminated.

When the corresponding situation in Annex 2 occurs during the clinical trial, but the applicant has not

If the clinical trial is terminated voluntarily, the Center for Drug Evaluation may request to terminate the clinical trial; in addition,

When the applicant is still 20 working days after receiving the "Notice of Suspension of Clinical Trials"

If the requirements are not implemented, the Center for Drug Evaluation may request to terminate the clinical trial.

The Center for Drug Evaluation passed the "Notice of Termination of Clinical Trials" through the website of the Center for Drug Evaluation

Send it to the applicant, the applicant should inquire and download in time.

Article 14 Safety information report and risk assessment during clinical trials

The principle of subject protection should be strictly abided by in terms of risk management and related treatment. temporarily

In the case of suspending clinical trials and terminating clinical trials,

Subjects, sponsors and investigators of the drug should ensure their safety and benefits before

Please make appropriate arrangements.

Chapter 3 Procedures for Applying for Resumption of Clinical Trials After Suspension of Clinical Trials

Article 15 For applicants who voluntarily suspend clinical trials due to safety risks

In the case of a trial, the Center for Drug Evaluation may, according to the severity of the risk, require the applicant

After completing the rectification, submit a supplementary application for resumption of drug clinical trials to the Center for Drug Evaluation

Please, the clinical trial of the drug can be resumed only after review and approval. Drug Evaluation Center is not clear

If the applicant is required to make a supplementary application, the applicant may, as needed, follow the

Apply for communication and exchange with the relevant provisions of the Technical Review Communication Management Measures.

Article 16 For those who are held accountable by the drug supervision and administration department due to safety risks

In the case of suspension, the applicant intends to continue the clinical trial, and should

After the modification, a supplementary application for resumption of drug clinical trials was submitted to the Center for Drug Evaluation.

After consent, the clinical trial of the drug can be continued.

Supplementary application materials for resuming clinical trials of drugs should include "Suspension of Clinical Trials".

"Notice of Clinical Trial Suspension", the response to the reasons for suspending clinical trials, the risk control adopted

measures and related technical information.

After the review of the supplementary application for resumption of clinical trials, according to the review conclusion,

The Center for Drug Evaluation will issue the "Notice of Resumption of Clinical Trials" or "Continue Suspension of Clinical Trials".

Inspection Notice" is sent to the applicant through the website of the Center for Drug Evaluation.

Chapter 4 Risk Communication

Article 17 For the safety risks arising in the process of drug clinical trials

For related issues, the applicant may follow the "Drug R&D and Technical Review Communication Management"

According to the relevant provisions of the “Administrative Measures”, the application for communication and exchange is submitted through the website of the Center for Drug Evaluation.

The Center for Drug Evaluation shall handle it in accordance with relevant regulations.

The Center for Drug Evaluation has monitored, evaluated and processed the safety information of clinical trials.

During the process, you can communicate with the applicant by phone, email, etc. general situation

Under these circumstances, after the official issuance of the "Clinical Trial Risk Control Notice", "Clinical Suspension"

Before the "Trial Notice" or "Clinical Trial Termination Notice", the applicant will be notified in advance.

Ask someone to communicate. However, when subjects are at serious risk, drug review

The center can directly order the suspension or termination of clinical trials to control risks in a timely manner.

Keep subjects safe. The Center for Drug Evaluation can also, according to needs, target risk management related issues.

Organize applicants to discuss related matters.

The applicant should strengthen risk management according to the content of the notice, and inform the temporary

Clinical trial institutions, ethics committees, researchers, etc., in order to effectively control clinical trials

risk and protect the safety of subjects.

Chapter V Supplementary Provisions

Article 18 This management standard shall come into force on July 1, 2020.

Attachment: 1. Criteria and Conditions for Suspension of Clinical Trials

2. Criteria and conditions for termination of clinical trials

attachment1

Criteria and Conditions for Suspension of Clinical Trials

The criteria and conditions for suspending clinical trials for safety reasons generally include

(but not limited to) the following situations:

1. Subjects are or will face benefits/risks associated with the trial

an unreasonable and substantial risk of bodily harm;

2. Failure to timely submit to the regulatory agency within the prescribed time limit in accordance with relevant requirements

Submit SUSAR reports, DSURs, or other potentially serious security risk information reports

report, etc.;

3. The clinical trial drugs have quality problems that affect the safety of the subjects;

4. Others may cause subjects to face greater safety problems or hidden risks.

Suffering condition.

Annex 2

Criteria and Conditions for Termination of Clinical Trials

The criteria and conditions for terminating clinical trials due to safety issues generally include (but not limited to) the following situations:

1. Large-scale, unexpected serious adverse reactions occur in clinical trials of drugs;

2. The drugs used in clinical trials have serious quality problems;

3. For other reasons, the drug supervision and administration department believes that it may be possible to continue clinical trials Causes major harm to the health of the subjects or is not in the public interest.