Management Specifications for Security Update Reports During Research and Development (Trial)

Chapter 1 General Provisions

The first article is to standardize the safety update report during research and development (hereinafter referred to as The writing and management of DSUR) are based on the relevant requirements of the "Measures for the Administration of Drug Registration". Develop this management practice.

Article 2 The main purpose of DSUR is for drug registration applicants (hereinafter referred to as Applicants, including sponsors) for information collected during the reporting period related to the drug (none conduct a comprehensive and in-depth annual review and review of relevant safety information (whether listed or not) Evaluate.

Chapter 2 Basic Principles

Article 3 Applicants shall comply with the requirements of the International Conference on Technical Coordination of Registration of Pharmaceuticals for Human Use. (hereinafter referred to as ICH) E2F "Safety Update Report during Research and Development" (hereinafter referred to as Prepare, write and submit a DSUR in accordance with the requirements of the E2F Guidelines.

Applicants can entrust a third party (such as a contract research organization) to conduct DSUR Prepare, write, and submit work, but applicants remain concerned about the content, quality, and The main body is responsible for the submission time. For joint development and other situations involving multiple parties, Applicants should follow the “Responsibilities of Parties” section of the ICH E2F Guidelines for DSUR approval. Separate responsibilities for preparation and submission.

Article 4 When preparing the DSUR, the applicant needs to include information related to all dosage forms and Relevant to strengths, all indications, and patient populations receiving study drug in the study

data (chemical drugs and biological products should be based on the same active ingredient, traditional Chinese medicine should be based on prepared with the same prescription). If the relevant information is not available (e.g. the applicant has not yet data), the applicant should explain this in the preamble to the DSUR.

Article 5 Applicants are allowed to carry out drug (including traditional Chinese medicine, chemical medicine and biological medicines) After clinical trials, all medical products should submit to the National Medical Products Administration for drug review Center (hereinafter referred to as the Center for Drug Evaluation) submits the DSUR.

Article 6 DSUR In principle, drug clinical trials should be carried out domestically or globally The date when clinical trial approval was first obtained (i.e., the “International R&D Birth Date”, hereinafter referred to as The month and day (called DIBD) are used as the starting date of the annual reporting cycle. First mention The submission shall be completed within two months after the first DIBD after the domestic clinical trial is approved. If successful, subsequent submissions should also be based on DIBD.

Article 7 DSUR shall be continuously submitted to the last domestic marketing authorization authority for the drug. The application can be submitted, or until R&D is no longer continued within the country. last one The first submission should be accompanied by an explanatory document stating that this submission is the last one within the country. DSUR, and indicate whether the applicant is continuing to undergo clinical studies in other countries or regions. bed test.

Article 8 When a drug has obtained marketing authorization at home and abroad, if the applicant needs If necessary, you can obtain marketing approval on the first date in the world (i.e. the "international birthday", Prepare and submit the DSUR based on the IBD). Adjusted first mention The reporting period should not exceed one year.

Chapter 3 Writing Requirements

Article 9 Applicants should include the following documents when submitting the DSUR:

1. Full text and attachments of DSUR;

2. Drug clinical trials that the applicant believes will not affect the safety of subjects during the reporting period

Changes in clinical trial protocols or new clinical, non-clinical or pharmaceutical discoveries

Changes or newly discovered supporting information.

Applicants should also submit the DSUR along with the

Submit necessary explanatory documents.

Article 10 Applicants should strictly follow the ICH E2F guiding principles and apply one by one.

Chapters are fully written in the DSUR and attachments. For chapters with no progress/no findings or

Attachments should be described under the corresponding items and cannot be omitted.

When organizing the DSUR, the applicant should include in the “Region-Specific Information” section

, during the reporting period, combined with relevant regulations, technical guidelines and other requirements, we will conduct

changes in drug clinical trial protocols or new clinical discoveries, non-clinical

Or whether pharmaceutical changes or new discoveries may increase subject safety risks.

Summarize the risk assessment results and declaration status, and submit supporting information.

The DSUR should not be used as the initial reporting avenue for new important safety information, or

Ways to detect security issues.

Article 11 DSUR is reported in Chinese. For “during the reporting period

"Serious Adverse Reaction Line List" can be reported in Chinese or English.

Article 12 When writing the DSUR, the applicant must include “regional specific information”.

Provide the following information under "Information" or as a DSUR area attachment:

1. Cumulative summary table of serious adverse reactions (SAR);

2. List of subjects who died in the country during the reporting period;

3. Withdrawal from clinical trials due to any adverse events in the country during the reporting period

Subject list;

4. Changes in drug clinical trial protocols or clinical trials that occurred during the reporting period

New discoveries, non-clinical or pharmaceutical changes, or summary tables of new discoveries;

5. Summary of the overall research plan for the next reporting period.

For detailed writing requirements, please refer to Attachments 1 to 5 and the attached table.

Chapter 4 Submission and Other Requirements

Article 13 Applicants can apply through the drug evaluation center website and other prescribed channels.

Path to submit DSUR. After review, it is considered necessary to remind or require the applicant (for example, to

Request the applicant to change the DSUR reporting period, supplement and correct information or remind the application

(People should strengthen subject safety measures, etc.), the Center for Drug Evaluation will submit it in the DSUR

The applicant will be notified within 180 working days after submission. Applicants should pass drug review

Check and download relevant notices or reminders from the Evaluation Center website. For those who need additional updates,

In the case of correct information, the applicant should complete the work within five working days from the date of receiving the supplementary opinions.

Submit supplementary information in one go within the day.

Article 14 These management regulations will come into effect on July 1, 2020.

Attachment: 1. Cumulative summary of serious adverse reactions (SAR)

2. List of subjects who died during the reporting period

3. Withdrawal from clinical practice due to any adverse events in the country during the reporting period

List of subjects for the trial

4. Changes in drug clinical trial protocols that occurred during the reporting period or

or new clinical discoveries, non-clinical or pharmaceutical changes or new

Discovery summary table

5. Summary of the overall research plan for the next reporting period

attachment1

Serious Adverse Reaction (SAR) Cumulative Summary Table

The SAR cumulative summary table should indicate the number of all SARs since DIBD, Need to be classified as follows:

1. System Organ Classification (SOC);

2. Terminology of adverse reactions;

3. Treatment group (if applicable).

At the same time, terms for unexpected adverse reactions should be labeled.

Applicants should refer to Appendix R1 of the "E2F DSUR Example Commercial Sponsor" to write.

Attachment 2

List of subjects who died within the reporting period

The list of subjects who died in the country during clinical trials should at least include: subjects Patient number, treatment plan (which may still be blinded), and each subject death s reason. If any safety issues are identified during the evaluation of subject deaths issues should be addressed on a case-by-case basis in DSUR Section 18 “Overall Safety Assessment” explained in .

Applicants may refer to Appendix R2 of "E2F DSUR Example Commercial Sponsor" to write. If using this format, please fill in also under "Test Number" The clinical trial was registered in the "Drug Clinical Trial Registration and Information Disclosure Platform" mark" (such as CTR20XXXXXX).

Annex 3

Domestic subjects who withdraw from clinical trials due to any adverse events during the reporting period

list

The list should include any in-country withdrawals due to adverse events during the reporting period

All subjects in clinical trials, whether drug related or not. If you are tested on

Any security issues identified during the assessment of the applicant's withdrawal should be addressed on a case-by-case basis.

Described in DSUR Section 18 “Overall Security Assessment”.

Applicants may refer to Appendix R3 of "E2F DSUR Example Commercial Sponsor"

to write. If using this format, please fill in also under "Test Number"

The clinical trial was registered in the "Drug Clinical Trial Registration and Information Disclosure Platform"

mark" (e.g., CTR20XXXXXX).

Annex 4

Changes in drug clinical trial protocols or clinical changes that occurred during the reporting period

Summary table of new discoveries, non-clinical or pharmaceutical changes, or new findings

Applicants should list the drug clinical trials that occurred during the reporting period.

summarize changes in trial protocols, non-clinical or pharmaceutical changes, or new findings,

See Appendix 1 for examples.

For items that may increase the risk to subject safety, the applicant should follow the pharmaceutical

changes or new discoveries, non-clinical changes or new discoveries, drug clinical trials

three categories: changes in trial protocols or new clinical discoveries, and summarizes the submitted

Supplementary application acceptance number, application matters, processing date and whether it was approved (yes/no

/under trial). No supporting information is required.

For those that the applicant assesses as not affecting the safety of the subjects, the applicant should

According to pharmaceutical changes or new discoveries, non-clinical changes or new discoveries, drugs

Three categories: changes in clinical trial protocols or new clinical discoveries, summarize the

Content, time, category, and indicate the application information items corresponding to supporting information

No. or Common Technical Document for Human Drug Registration Application (hereinafter referred to as CTD)

Module and chapter number in . Applicants should refer to chemical drugs, biological products and Chinese

Drug registration classification and application dossier requirements, CTD and other requirements, and prepare corresponding support

Sexual information is submitted with the DSUR. For relevant information that has been submitted during the reporting period

Information (such as information used for communication, due to subsequent phased drug clinical trials)

test, the drug clinical trial plan and support that have been submitted on the Center for Drug Evaluation website

sexual information), the submission method, time and reference number should be indicated in the remarks column (such as

(Communicate application number, etc.), no need to submit again.

Schedule 1

Changes in drug clinical trial protocols or new clinical discoveries, non-clinical or pharmaceutical changes that occurred during the reporting period, or

Summary table of new findings

1. May increase risks to subject safety

1. Changes or new discoveries in medicine

Supplementary application acceptance number	application matters	Whether the hosting date is approved (yes/no/under review)	

2. Non-clinical changes or new findings

Supplementary application acceptance number	application matters	Whether the hosting date is approved (yes/no/under review)	

3. Changes in drug clinical trial protocols or new clinical discoveries

Supplementary application acceptance number	application matters	Whether the hosting date is approved (yes/no/under review)	

2. Does not affect the safety of subjects

1. Changes or new discoveries in medicine

date category		A brief summary of the content	Supporting information is in the application data item number/ Module and chapter numbers in CTD	Remark

2. Non-clinical changes or new findings

date category		A brief summary of the content	Supporting information is in the application data item number/ Module and chapter numbers in CTD	Remark

3. Changes in drug clinical trial protocols or new clinical discoveries

date category		A brief summary of the content	Supporting information is in the application data item number/ Module and chapter numbers in CTD	Remark

Annex 5

Summary of the overall research plan for the next reporting period

Applicants should briefly provide the following:

1. Summary of the overall clinical research plan for the next reporting period

(1) Basis for establishing the topic;

Applicants should briefly describe the clinical trials planned for the next reporting period.

The basis for establishing the subject of the test.

(2) Indications to be studied;

Applicants should list the unlisted products that they plan to study in the next reporting period.

Indications.

(3) The overall path followed when evaluating drugs;

Briefly describe the planned sequence of clinical trials in the next reporting period or

The author provides a brief description of the patient population planned for the study.

(4) Clinical trials to be carried out in the next reporting cycle;

Briefly describe the clinical trials planned for the next reporting period

Design (applicant should indicate if no full-year plan is in place).

(5) The expected number of subjects;

Estimated number of subjects in clinical trials planned for the next reporting period

Number of people;

(6) Anticipated risks.

Based on animal toxicology or data from previous human trials, any

Any serious or serious risks associated with the drug or related drugs.

2. Summary of the overall non-clinical research plan in the next reporting cycle

Briefly describe what is planned to be newly developed or continued in the next reporting period.

Non-clinical research.

3. Summary of the overall pharmaceutical research plan in the next reporting period

Briefly describe what is planned to be newly developed or continued in the next reporting period.

Pharmaceutical research.