Drug clinical trial data management and statistical analysis plan

Guiding Principles

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Guidelines for drug clinical trial data management and statistical analysis plans

I. Introduction

During drug clinical trials, formulating a standardized data management plan can help
Obtain true, accurate, complete and reliable data and rigorous statistical analysis plan
Helps ensure the rationality of statistical analysis methods and the reliability of conclusions. therefore,
The sponsor must conduct data management and statistical analysis in accordance with the clinical trial plan.
Analyze the content and develop a detailed plan.

In recent years, with the development of clinical trial data management and statistical analysis technologies and methods
The continuous development of electronic source data and the widespread application of electronic data collection systems,
and the addition of ICH E9 (R1) "Statistical Principles of Clinical Trials" guidance.
Supplement: The introduction and implementation of "Estimation Target and Sensitivity Analysis in Clinical Trials",
Philosophy and understanding of clinical trial design, implementation, data collection and analysis, etc.
Practice has had an impact. In order to adapt to these new changes, we are now focusing on July 2016
"Plan and Report on Drug Clinical Trial Data Management and Statistical Analysis" released in March
Revise the Guiding Principles and update the data management plan and statistical analysis plan
Technical requirements, and no longer writing data management reports and statistical analysis reports
Put forward technical requirements. For the submission requirements of the above information, the sponsor is recommended to refer to
Application information requirements and relevant guidelines such as ICH E3.

This guideline is mainly applicable to confirmatory clinical trials and can also be used to explore
For reference use in sexual clinical trials.

2. Data Management Plan

(1) General considerations

The data management plan is written by the data manager based on the clinical trial protocol.

Define and document the data management tasks for a specific clinical trial in detail and comprehensively,

Including personnel roles, work content, operating specifications, etc. The data management plan should be in

After the clinical trial plan is determined and before the first subject is screened, the approved

approved version and started execution. During execution, the data management plan can

May need to be updated and revised in a timely manner based on actual operations.

Data management requires the participation of multiple parties, including clinical research institutions and sponsors.

Data management, statistics, programming, monitoring, pharmacovigilance and other departments designated by the author.

The responsibilities of each party are different in each step of data management, which can be divided into responsibility, participation,

Review, approval, etc., the data management plan must clearly define the roles of all parties involved and their personnel

responsibility. At the same time, each step of data management needs to establish and follow corresponding standard operating procedures.

The data management plan should include a list of standard operating procedures to be followed by the project.

(2) Basic content

The data management plan should comprehensively and detailedly describe the data management processes, data

Systems used for collection and management, data management steps and tasks, and data

Quality assurance measures for data management.

1. Overview of the test

Contents related to data management in the clinical trial protocol should be briefly described.

Generally include the purpose and overall design of the study, such as randomization method and blinding (if necessary)

(required), number of subjects, evaluation indicators, key time points of the trial, important

Data analysis nodes and corresponding data requirements, etc.

2. Data management process and data flow

The data management workflow and clinical trial data flow should be described,

Clarify the management of each link. If necessary, graphic representation can be used.

The workflow of data management should include the establishment of data collection/management system (such as

Case report form and database design), data reception and entry, data verification and

Questioning, medical coding, external data management, data review, database locking,

Processes such as data export and transmission, archiving of data and data management files, etc.

The data flow should include all types and sources of data in clinical trials (e.g.

Case report form data, central laboratory test data, pharmacokinetic test data

data, patient-reported outcome data, imaging data, etc.)

input, import, export, archive location, storage period, responsible unit/person and other information.

The process for data of various types and sources should be outlined in detail to facilitate their

Data management.

3. Data collection/management system

Methods for collecting clinical trial data should be listed, such as paper or electronic medical records

Report form, name and version of data collection/management system used. Description system

User's access control plan, or provide corresponding information in the form of an attachment, including

Measures or methods for defining, assigning, monitoring and preventing unauthorized operations,

Revocation of permissions, etc.

The data collection/management system should have audit trails, system security management, rights

It has functions such as limited control and data backup, and has passed complete system verification. Number of electrons

The data collection/management system should also have electronic signatures in addition to the above functions.

Function.

4. Data management steps and tasks

(1) Design of case report form and database

The case report form must be designed to collect the data specified in the clinical trial protocol and meet the needs of statistical analysis. Regardless of whether the case report form is in paper form Whether it is an electronic version, the writing and management of the filling guide need to be elaborated.

The design of the database should be consistent with the annotated case report form and/or database design. be consistent and establish logical verification based on the data verification plan. After the user accepts It can be used online only after passing the test. This process should be briefly described and explained bright.

(2) Data collection

The method and process of data collection should be described, including completion, receipt and entry (or import) etc.

The clinical investigator or clinical research coordinator should complete the case report form Guidelines for filling out case report forms accurately, timely, completely and standardizedly. paper disease The case report form needs to define the sending, transporting and receiving methods of the completed case report form. Such as fax, mail, inspector collection, etc., and also define the collection frequency and recording documents. The format for receiving documents, etc. Paper case report forms are usually entered by two people independently. Compare to control data quality; data entry instructions need to be formulated before data entry. Determine data entry requirements and methods. Electronic case report form prepared by clinical investigators or directly entered by their designated clinical research coordinator or directly from electronic source data. Direct import.

(3) Data verification

Before conducting data verification, a detailed data verification plan should be developed to

Clarify the data verification content, methods and verification requirements. Data verification usually requires several

It is completed jointly by management personnel, supervisors, medical personnel and statisticians. Therefore

The division of responsibilities between different personnel should be clearly defined in the data verification plan.

(4) Medical coding

Medical coding is the process of classifying adverse events and medical diagnoses collected from case report forms.

descriptions of diagnosis, concomitant medications, past medications, past medical history, etc. and in standard dictionaries

The process of matching terms. A medical coding plan should be developed describing the coding flow

procedures, encoding methods, encoding dictionaries and versions, and related standards for performing encoding

document.

(5) External data management

External data are an integral part of the clinical trial database, including but not limited to

Laboratory data, randomization data, etc. For the management of external data, a

Its data transfer protocol describes data categories, data providers, data formats,

Transmission method, transmission frequency and other protocol contents, as well as clear processing of external data

Quality control measures, such as transmission testing, consistency verification, etc. For blind external

Data, such as drug concentration in blood samples or certain key data, need to be described

Processes for the management of such data.

(6) Electronic source data management

At present, the original records of data in various research centers are mostly electronic and direct.

Access input, such as electronic health records, electronic laboratory reports, electronic patient reports

Report results, digital imaging reports, etc. Electronic source data facilitates timely,

Accurate and complete collection enables remote monitoring and real-time data review to avoid certain

Eliminate unnecessary duplicate data entry and reduce data transcription errors. If the number of electron sources

As the direct source of data generated for submission, the sponsor should list in the clinical trial

Computerized systems related to electronic source data used in

measures, de-privacy measures and quality control processes, system access control, and

The process of transmitting electronic data in software and/or hardware systems. Number of electron sources

The data should meet the qualities of traceability, legibility, synchronization, originality and accuracy.

Quantity requirements and regulatory document retention requirements for verification.

(7) Data audit and database locking

In order to ensure data quality, it can be carried out as needed during the clinical trial process.

Conduct multiple data reviews. Generally speaking, data review should deal with data doubts, loss and

Cases of protocol deviations, concomitant medications, and occurrence of adverse events were confirmed.

The requirements for data auditing should be listed and the specific procedures for data auditing operations should be described.

If a clinical trial adopts a blinded design, data review should also be conducted in a blinded manner;

If an open design is used, data reviewers should be blinded.

Data auditing is a prerequisite for database locking. Database locking should be stated

The process, implementation department and standard operating procedure documents executed. should be avoided as much as possible

The unlocking and re-locking of the database after locking should be stipulated and explained in advance.

items and processes.

(8) Data export and transmission

Describe the file format for data export and transmission, export content (database,

variable name and variable value encoding) and transmission media. The transmission media should comply with national laws.

regulations and regulatory requirements.

(9) Archiving requirements for data and data management files

Data, time of entry/import into the database, entry person, and data audit track

and data management files need to be completely saved. Data typically includes but is not limited to:

Clinical trial data, external data, database metadata information, laboratory testing

Reference value range, logic check and derived data change control list, data questioning

Tables and program codes, etc. Data management documents typically include but are not limited to: Data management

management plan, blank case report form, case report form filling guide, completed case

PDF format files of report forms, annotated case report forms, database design instructions,

Database entry instructions, data verification plan, data quality control verification report, etc.

The clinical trial data, management files, media, and ownership that need to be archived should be clearly defined.

File mode and time limit.

5.Quality control

It is necessary to determine the quality control items and quality control methods for data and data management operations.

(such as quality control frequency, sample selection method and sample size, etc.), quality requirements and compliance

standards, remedial measures for failure to meet expected quality standards, etc.

3. Statistical analysis plan

(1) General considerations

Relative to the description of statistical analysis in the clinical trial protocol, the statistical analysis plan

A plan is a separate document with more technical and practical details, including

Details of statistical analysis of estimated targets and other data. Statistical points

The analysis plan should be drafted by a statistical professional and requires a comprehensive description of the clinical trial

Methods of analysis and presentation of data, as well as preset criteria for statistical inference. system

The analysis plan should be formed after the first version of the clinical trial protocol is finalized. if needed,

It can be modified, supplemented and improved during the clinical trial process. at different points in time

It is recommended that the statistical analysis plan be marked with the version and date, and its final draft should be published after the data is unblinded.

completed before. During the clinical trial, if the clinical trial protocol is revised,

The statistical analysis plan can also be adjusted accordingly as needed.

Confirmatory evidence must be statistics specified in advance in the statistical analysis plan.

Analysis content, other analysis content can only be supportive or exploratory. if

Involving interim analysis, the corresponding statistical analysis plan should be prepared at the latest for each interim analysis

Confirm before analysis.

(2) Basic content

The basic content of the statistical analysis plan covers but is not limited to the research purpose, design

Types, types of comparisons, randomization and blinding, definition of estimation objectives, hypothesis testing

Detailed plans for testing, sample size, analysis set definition, validity and safety evaluation

Draw.

1. Overview of the test

A trial overview is a brief description of the clinical trial protocol, which generally includes the following

main content:

(1) Research purpose: the main purpose and secondary purpose of the clinical trial.

(2) Design type: such as parallel design, crossover design, factorial design, single

Arm design etc.

(3) Type of control: such as placebo control, positive control, dose group control,

Target value comparison, etc.

(4) Comparative type: clarify the comparative type of clinical trial, such as superiority testing

test, non-inferiority/equivalence test and its boundary value, etc.

(5) Randomization method and its implementation: clarify the randomization method, such as block randomization

machine, stratified randomization and its stratification factors, etc.

(6) Blinding method and blinding measures: Indicate whether it is single-blind or double-blind, and the blinding measures are

Double-blind single simulations, double-blind double simulations, and methods for performing statistical analyzes in the blind state

Shi et al. If an open design is used, it needs to be stated whether some degree of blinding is adopted.

measure.

2. Estimate goals

The definition of estimated goals should be described in the clinical trial protocol, and each estimated goal

Targets should include treatment (treatment), population, variables (endpoints), concomitant events, and their

Processing strategies, group-level aggregation and other attributes.

(1) Main estimation objectives

Treatment (Treatment): The relevant treatment condition and, where applicable, the comparison

Other treatment conditions. These may be separate interventions or they may be combined

A combination of interventions (e.g. loading therapy), or a complex intervention

The overall program composed of sequences.

Population: The target group for which the clinical question is addressed. Can be the entire clinical trial

The test population can also be a subgroup defined according to certain baseline characteristics, or a specific patient group.

The main layer where events are defined.

Variable (endpoint): Variable obtained from each subject to address the clinical question

(or end point).

Concomitant events and their management strategies: For clinically relevant issues of concomitant events,

Usually therapeutic strategies, hypothetical strategies, composite variable strategies, on-treatment strategies or

Main layer strategy to reflect. Strategies for dealing with some concomitant events can include treatment

(treatment), population, and variable (endpoint). Regardless of

Regardless of the strategy, the sponsor should provide sufficient clinical evidence.

Population-level summary: Population-level summary statistics for variables should be specified,

Provide a basis for comparisons between different treatments, such as mean, median survival time,

response rate, etc.

(2) Secondary estimation target

Reference should be made to the previous description of the main estimation objectives. If there is a key secondary

estimated objectives, they may be described separately from other secondary estimated objectives and placed within these

Before estimating the target.

(3) Exploratory estimation target

If there are exploratory estimation objectives, please refer to the previous main estimation objectives.

describe. If there are no exploratory estimation goals, no description is needed.

3.Sample size

The basis for determining the sample size should be stated, including the sample size estimation method (including

Involved parameters and their basis), software modules used for sample size estimation, etc.,

and sample size adjustment plan, if any. The sample size should be determined to ensure that the main estimates

The evaluation of planning objectives has sufficient verification efficiency.

4. Analysis set

The definition of the analysis set should be described according to the different study objectives. clinical trial points

Analysis sets generally include analysis sets based on random grouping and security analysis sets. based on

Randomized analysis sets are generally suitable for analyzing demographic data and baseline characteristics.

analysis and evaluation of different estimated targets; if used to evaluate the population of estimated targets

If it is not the entire population in the analysis set, then this part of the population should be included in the analysis set.

Row tags, and the conditions for tagging are described in this section. Security analysis set general

Suitable for security analysis. For non-randomized clinical trials, the number of enrollees can be

The group defines the analysis set.

5. Statistical analysis methods

Statistical analysis should be based on true, accurate, complete and reliable clinical trial data

Based on the data, a reasonable selection should be made based on the research purpose, experimental design and estimation objectives, etc.

statistical analysis methods. Descriptions of different types of data and statistical inference methods should be given,

Clarify the one-sided/two-sided test and its test level, and explain the statistical software used

file and version number. For the derived variables involved in statistical analysis, the derived parameters should be described.

Mode. Statistical analysis results are usually presented in the form of statistical analysis tables or graphs, and

Briefly describe the relevant information in text form.

(1) Subject distribution analysis

For analysis of subject distribution, describe the descriptive statistical analysis used

Methods and analysis content, such as screening, allocation, discontinuation of treatment, termination of study, etc.

condition and its reasons.

(2) Demographic data and baseline characteristics analysis

Explain the description used for baseline data such as demographics based on the nature of the data.

Descriptive statistical analysis method.

(3) Compliance and concomitant medication analysis

For analyzes of adherence and concomitant medications, describe the descriptive system used

statistical analysis method, and explain the effectiveness of the method for subjects with poor compliance and concomitant medication.

way of describing the physical condition.

(4) Main estimation target analysis

The main estimation method and the sensitivity estimation method for the main estimation objectives should be described.

ÿMain estimation method

Strategies and related strategies for dealing with concomitant events involved in the main estimation target should be clarified.

Appropriate data processing and analysis methods, including those related to accompanying events and their processing strategies

Handling of missing data. This should be avoided from the previous estimation target definition part.

To repeat, more details on data processing and analysis methods should be provided.

The null hypothesis, alternative hypothesis and their

Inspection standards, etc. Describe the statistical analysis methods used to evaluate the main estimation objectives,

The selection of the corresponding statistical model should pay attention to the type of variables (end points) and their

distribution characteristics. Estimates of treatment effects should include point estimates and interval estimates.

ÿSensitivity analysis method

To explore the robustness of statistical inference results obtained from the main estimation method

It is recommended to use one or more forms of sensitivity analysis for the same estimation target

analysis.

For sensitivity analyses, changing multiple aspects of the main analysis assumptions simultaneously can

It is difficult to determine which assumptions account for the underlying differences observed so far. because

Therefore, whether it is necessary to change multiple assumptions simultaneously should be considered based on the specific circumstances.

Sensitivity analysis. Illuminating the changes in assumptions underlying different sensitivity analyzes will help

to provide a more reasonable explanation for the sensitivity analysis results. The sensitivity analysis method is the same

Need to explain in advance.

(5) Secondary estimation target analysis

The estimation method for secondary estimation objectives should be described and estimates of treatment effects should be given

Out-point estimation and interval estimation. If there is a hypothesis test for the secondary estimation objective,

The original hypothesis, alternative hypothesis and test level should be stated. If relevant

For the key secondary estimation target, please refer to the previous description of the main estimation target analysis.

and are described separately before the analytical methods for other secondary estimation objectives.

(6) Exploratory estimation target analysis

If there is an exploratory estimation target, its estimation method, treatment effect should be described

The estimate of should give both a point estimate and an interval estimate. If there is no exploratory estimation target,

No description is needed.

(7) Security analysis

All safety indicators require great attention in the analysis, and special attention should be paid to

Pay attention to serious adverse events and those related to drug mechanism of action, metabolites and/or disease areas

related security incidents. Adverse events and their severity should be graded using

The Unified Coding Dictionary encodes the code and states its name and version.

For analysis of safety data, the statistical analysis methods used must be stated.

The analysis plan needs to describe the classification of various safety data (such as clinical outcomes, clinical

laboratory test results, vital signs, etc.) and its summary method, such as according to the occurrence of the event

The frequency, frequency and incidence of births can be analyzed, and comparisons between groups can be made if necessary.

The analysis of safety data can also be combined with appropriate graphics and

Show the distribution of an adverse event and its severity among groups, or over time

Trends in segment incidence and cumulative incidence.

(8) Missing data processing

The method and reasons for handling missing data should be explained in advance. should be distinguished from associated

Missing data directly related to the event and its treatment strategy (e.g., under therapy strategy,

data that should have been collected after discontinuation of randomized treatment but were not collected), and related to specific

Estimated goals are directly related but not directly related to accompanying events and their handling strategies

missing data (e.g. when direct withdrawal from the study was not preset as a concomitant event). forward

The treatment method should be described in the analytical methods section of the estimated target, which

The processing method should be described in this section.

(9) Subgroup analysis

Supportive subgroup analyzes are usually required, with the primary purpose of further exploratory testing

The efficacy of the test drug in each subgroup is consistent. When it comes to subgroup analysis, it is necessary to

Give clear definitions of subgroups.

(10) Supplementary analysis

In addition to the above analysis, supplementary analysis can also be performed on the estimated target.

to provide a more comprehensive understanding of efficacy. Supplementary analyzes in interpreting clinical trial results

The role of aspects is usually small, so the necessity and role of supplementary analysis need to be considered.

6. Multiple considerations

If there are multiplicity testing issues, such as multiple estimation targets, multiple groups

Comparison, multi-stage overall decision-making, multiple time-point analysis and confirmation of longitudinal data

Sexual subgroup analysis, etc., the strategies and methods to control the overall type I error rate should be explained.

7. Interim analysis

If an interim analysis plan has been developed in advance, the timing of the interim analysis should be stated.

Points (including calendar time points or information time points), decision-making strategies and total Type I error rate control

Preparation methods, etc. If a data monitoring committee is established, its tasks should be briefly described.

service.

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Appendix 1: Glossary

Electronic Source Data : refers to preliminary data in electronic form

data initially recorded, including data collected before or during the clinical study that can be used to reproduce or

Evaluate the information in the study's original records and their certified copies.

Electronic Data Capture (EDC): It is a computer-based

Computer network technology for clinical trial data collection, through software, hardware, standard operations

The organic combination of operating procedures and staffing can directly collect and transmit clinical data in electronic form.

data.

Access Control (Access Control): refers to the user control according to the clinical trial electronic system

The identity and the identity of a defined group to which it belongs to allow, restrict or prohibit its login to the system.

record or use, or the ability to access, input, modify, and browse certain information resource items in the system

technical control of power.

Audit Trail : It is the basis of computer systems (such as data management systems).

This function. It refers to the system using secure and computer-generated electronic records with time stamps.

records, so that each electronic record entered, modified or deleted by the system user can be independently traced

Date, time, and reason for modification so that the data can be reproduced in the future. any record changes

Neither will cause records of the past to be obscured or lost. As long as the subject's electronic record remains unchanged,

Such audit trail documentation should always be retained and made available for review by regulatory inspections or auditors.

Read and copy.

System Validation : refers to the establishment of a computerized system life cycle

Documented evidence of management to ensure the development, implementation, operation and maintenance of computerized systems

From beginning to end, the maintenance and other aspects can highly meet the various system technical standards and usage preset by it.

Purpose and quality attributes, and quality management procedures that are monitored and implemented

Highly reproducible and maintained system standards and functionality in compliance with regulatory requirements through decommissioning

beg.

Annotated Case Report Form (aCRF): Yes to Blank

Mark the white case report form, record the position of each data item in the case report form and its corresponding

Variable names and encodings in the database.

Data Validation Plan (DVP): also known as Logical Validation Plan

Planning is done by the data manager to check the logic of the data based on the clinical trial plan and system

A system configuration file written for system functions.

Logical check (Edit Check): refers to the review of clinical trial data after it is entered into the computer system.

Data validity check. This verification can be done through the system's program logic, subroutines and data

It is implemented by learning equations and other methods, mainly evaluating the input data domain and its expected numerical logic,

Are there any errors in numerical ranges or numerical properties?

User Acceptance Testing (UAT): User **Acceptance Testing**

It is a detection method performed by users of the clinical data management system. The detection records can be used to

It proves that the designed system has gone through the relevant verification process. Users should thoroughly check all correct and

Error data combination, record detection results. Comprehensive testing documentation should include verification plans, test

Test detailed records, test summary report and verification summary report, etc.

Protocol Deviation : refers to any intentional or unintentional deviation and unintentional

Follow the treatment, examination or data collection procedures stipulated in the clinical trial protocol and have not obtained the ethics committee

actions approved by the committee. Generally speaking, this kind of deviation is only a logical or managerial deviation

The clinical trial plan will not have a substantial effect on the safety and benefit of the subjects, nor will it

Can affect the value of the data collected.

Estimand: A precise description of the treatment effect that reflects the clinical

Clinical questions raised for clinical trial purposes. It aggregates at a population level to compare the same patients across different

Outcomes under the same treatment conditions.

Estimator: Use clinical trial data to calculate an estimate of the estimated target

value analysis method.

Intercurrent Event : An event that occurs after treatment begins and may affect

affect the interpretation or existence of observations relevant to clinical questions. When describing relevant clinical issues,

Concomitant events need to be addressed in order to accurately define the treatment effect that needs to be estimated.

Interim Analysis : refers to the use of experimental data during clinical trials.

Analysis of accumulated data, such as analysis to evaluate effectiveness, analysis to evaluate safety, and

Re-estimation of sample size, etc.

Safety Set (SS): used for safety and tolerability evaluation

The pooled set of subjects is called the safety analysis set. The security analysis set should consider including all

Subjects who received less than one treatment and had safety evaluation.

Missing Data : refers to the analysis that is meaningful and meaningful for the established estimation target.

But the data was not collected. It should be associated with data that does not exist, or was recognized due to accompanying events.

Separate meaningless data.

Sensitivity Analysis : refers to the deviation and sum of model assumptions

Data limitations, a series of analyzes exploring the robustness of statistical inference from the principal estimation method.

Subgroup Analysis : usually refers to classifying subjects according to their characteristics

An analytical strategy that divides variable values into different subgroups and estimates the efficacy and/or safety of each subgroup.

slightly.

Supplementary Analysis : refers to the main analysis and sensitive

A general description of analyzes beyond sexual analysis to learn more about treatment effects.

Appendix 2: Chinese and English comparison table

Chinese	English
Security Analysis Set	Safety Set, SS
accompanying events	Intercurrent Event
Standard Operating	Standard Operation Procedure, SOP
Procedure	Case Report Form, CRF
Case Report	Supplementary Analysis
Form Supplementary Analysis	Electronic Patient Reported Outcome, ePRO
electronic data capture	Electronic Data Capture, EDC
electronic source data	Electronic Source Data Multiplicity
Protocol	Multiplicity
Deviation	Protocol Deviation
Estimation	Estimator
Method	estimating
Estimation Target	Patient Reported Outcome, PRO
Patient-Reported	Audit Trail
Outcomes Audit Trajectory	Clinical Research Coordinator, CRC
Clinical Research	Edit Check
Coordinator Logic	Sensitivity Analysis
Check Sensitivity	Interim Analysis
Analysis Interim	Access Control
Analysis Access	Missing Data
Control Missing Data	Data Management Plan, DMP
Data Management Plan	Data Validation Plan, DVP
Data Verification Plan Data	Data Monitoring Committee, DMC
Monitoring Committee	Statistical Analysis Plan, SAP
Statistical	System Validation
Analysis Plan	Subgroup Analysis
System Validation	User Acceptance Testing, UAT
Subgroup Analysis Users	Annotated Case Report Form, aCRF
Overall Type I Error Rate for Acceptance Test Annotation Case Report Form	Familywise Error Rate, FWER