Guideline on Data Management Plan and Statistical Analysis Plan of Drug Clinical Trials

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1. Overview

In clinical trials, a standardized data management plan is helpful to ensure authenticity, accuracy, integrity and reliability of data, and a rigorous statistical analysis plan is helpful to ensure the rationality of statistical analysis methods and the reliability of conclusions. Therefore, it is necessary for the sponsor to develop a detailed plan for data management and statistical analysis according to the clinical trial protocol.

With the continuous development of techniques and methods for data management and statistical analysis of clinical trials in recent years, such as the widespread use of electronic source data and electronic data capture systems, as well as the release and implementation of the ICH E9 (R1) Guideline *Addendum on Estimands and Sensitivity Analysis in Clinical Trials to the Guideline on Statistical Principles for Clinical Trials* (November 2019), the concepts and practices in the design, conduct, data collection and analysis of clinical trials have been affected. In order to adapt to these new changes, *Guideline for the Planning and Reporting of Data Management and Statistical Analysis of Drug Clinical Trials* (July 2016) is hereby revised to update the technical requirements for data management plan and statistical analysis plan, and no

technical requirements are proposed for the data management report and statistical analysis report. For the submission requirements of the above documents, it is recommended that sponsors refer to the requirements for application dossiers and relevant guidelines such as ICH E3.

This guideline is mainly applicable to confirmatory clinical trials and can also be used as a reference for exploratory clinical trials.

2. Data Management Plan

2.1 General Considerations

The data management plan shall be developed by data manager according to the protocol, and the data management tasks of clinical trial shall be specified and recorded in detail and comprehensively, including personnel role, work content and specifications. The data management plan shall be developed after the protocol is finalized and before the first subject is screened and be implemented after approved by the sponsor. During its implementation, the data management plan may need to be updated and revised in a timely manner according to actual operation.

Data management requires multi-function participation, involving the data management, biostatistics, statistical programming, clinical monitoring, pharmacovigilance and other departments designated by the clinical investigator institution and the sponsor. The responsibilities of all functions are

different in the data management work, which can be divided into responsibility, participation, review and approval. The data management plan shall specify the responsibilities of all parties involved and their personnel. Meanwhile, each data management step shall establish and follow the corresponding standard operating procedures. The data management plan shall list the standard operating procedures followed by the project.

2.2 Basic Contents

The data management plan shall describe the data management process, the systems used for data collection and data management, various steps and tasks of data management as well as the quality assurance approaches for data management comprehensively and in detail.

2.2.1 Trial Overview

The contents related to data management in the protocol shall be briefly described, generally including study purpose and overall design, such as randomization method and blinding method (if necessary), number of subjects, endpoints, key milestones of the trial, critical statistical analysis time points and corresponding requirements for data.

2.2.2 Data Management Process and Data Process

The working process of data management shall be described, and each step shall be specified. Graphical approaches may be adopted if necessary.

The workflow of data management shall include the processes of data

capture/management system establishment (such as the design of case report form (CRF) and database), data collection and entry, data verification and query, medical coding, external data management, data review, database lock, data export and transfer, archiving of data and data management documents.

The clinical data flow shall include the generation, acquisition, transmission, import, export, archiving location, the term of storage, responsible unit/person, and all types and sources of data in the clinical trial (such as CRF data, central laboratory test data, pharmacokinetic test data, patient reported outcome data, imaging data, etc.). Processes for various types and sources of data should be detailed to facilitate data management.

2.2.3 Data Collection/Management System

It is required to list the method for collecting clinical trial data, such as paper or electronic case report form, and the data collection/management system used and its version. Describe the authorization control plan for system users, or provide the corresponding information in the form of appendix, including the measures or methods for authorization definition, assignment, monitoring and prevention of unauthorized operation, authorization revocation, etc.

The data collection/management system shall have such functions as audit trail, system security management, authorization control and data backup, and complete system verification. The electronic data capture/management system shall also have an electronic signature function in addition to the above

functions.

2.2.4 Data Management Steps and Tasks

1) Case report form and database design

The CRF must be designed to ensure the collection of data specified in the clinical trial protocol and meeting the statistical analysis requirements. Whether the CRF is paper or electronic, the development and management of the CRF completion guidelines should be described.

The database design shall be consistent with annotated CRF and/or database design specification. Edit check shall be set up according to the data verification plan. The data can only be put online after passed the user acceptance test (UAT). This process should be described briefly.

2) Data collection

The method and process of data collection shall be described, including filling, receiving and entry (or importing).

The clinical investigator or clinical research coordinator should complete the CRF in an accurate, timely, complete and standardized manner according to the CRF completion guidelines. Paper CRFs should be defined with respect to the method of sending, transporting and receiving the completed CRFs, such as fax, mailing, monitor collection, etc., and the frequency of collection and the format in which documents are received. The paper CRFs are usually entered in the system via two independent persons to control the data quality. Before data entry,

data entry instructions shall be developed to specify the requirements and methods for data entry. Electronic case report forms were entered directly by the clinical investigator or designated clinical research coordinator or imported directly from the electronic source data.

3) Data verification

Before data verification, a detailed data verification plan shall be developed to clarify the content, mode and requirements of data verification. Data verification usually needs to be jointly completed by data management personnel, monitors, medical personnel and statisticians. Therefore, the division of responsibilities of different personnel shall be clarified in the data verification plan.

4) Medical coding

Medical coding is the process of matching the descriptions of adverse events, medical diagnoses, concomitant medications, prior medications, past medical history etc. collected on the CRF with the terms in the standard dictionary. A medical coding plan shall be developed to describe the coding process, coding method, coding dictionary and version, and relevant standard documents for coding.

5) External data management

External data are part of the clinical trial database, including but not limited to laboratory data, randomization data, etc. For the management of external data,

the data transmission protocol shall be developed to describe the data category, data provider, data format, transmission mode, transmission frequency and other protocol contents, as well as the measures for quality control over external data, such as transmission test and reconciliation. For blinded external data, such as drug concentration in blood samples or some key data, the management process of such data shall be described.

6) Electronic source data management

Currently, the original records of data in various research centers are more directly recorded electronically, e.g., electronic health records, electronic laboratory reports, electronic patient reported outcomes, digital image reports, etc. Electronic source data facilitate timely, accurate and complete collection of data, realize remote monitoring and real-time data review, avoid some unnecessary data re-entry, and reduce data transcription errors. If the electronic source data is used as the direct source for data generation and submission, the sponsor should list the computerized systems related to electronic source data, data security measures, de-privacy measures and quality control processes, system access control, and electronic data transfer processes in the software and/or hardware system that are used in the clinical trial. Electronic source data should meet the quality requirements for traceability, legibility, synchrony, originality, accuracy, and regulatory document retention requirements for verification.

7) Data review and database lock

In order to ensure the quality of data, it is recommended to conduct multiple data reviews during the clinical trial. In general, the occurrence of data queries, cases of dropouts and protocol deviations, concomitant medications and adverse events should be finally confirmed during data review. The requirements for data review shall be listed, and the specific process of data review operation shall be described. If the blind design is adopted in the clinical trial, the data review shall also be conducted under blind state; if the open design is adopted, the data review personnel shall be kept blind.

Data review is a pre-requisite for database lock. The process of database lock, the department performing the database, and the standard operating procedure documents implemented should be described. Unlocking and re-locking after database lock should be avoided to the greatest extent possible, and the conditions and process should be defined and described in advance.

8) Data export and transmission

Describe the file format of data export and transmission, export contents (database, variable name and variable value code) and transmission medium. The transmission medium shall meet the requirements of national regulations and regulatory authorities.

9) Filing requirements for data and data management documents

Data and the time of data entry/import into the database, the data entry personnel,

data audit trail and the documents formed in the data management process shall be completely preserved. Data usually include but are not limited to clinical trial data, external data, database metadata information, reference range of laboratory tests, logical test and derived data change control list, data query table and program code. Data management documents usually include but are not limited to data management plan, blank case report form, case report form filling guidelines, completed case report form in PDF format, annotated case report form, database design description, database entry description, data verification plan, data quality control verification report, etc.

Clarify the time limit of clinical trial data, management documents, media and archiving mode to be archived.

2.2.5 Quality Control

It is required to determine the quality control items of data and data management operation process, quality control methods (such as quality control frequency, sample selection method and sample size, etc.), quality requirements and compliance criteria, and remedial measures for the failure to meet the expected quality standards.

3. Statistical Analysis Plan

3.1 General Considerations

Compared to the description of statistical analysis in the clinical trial protocol,

the statistical analysis plan is an independent document with more technical and practical operation details, including the details of statistical analysis on estimands and other data. The statistical analysis plan shall be drafted by the professionals in statistics, and it is required to comprehensively state the analysis methods and presentations of clinical trial data as well as the prespecified statistical inference criteria. The statistical analysis plan should be developed after finalization of the first version of the clinical trial protocol. If necessary, it can be modified, supplemented and improved during the clinical trial. Statistical analysis plans for different time points are recommended to be marked with version and date, and its final version should be completed before unblinding. During the clinical trial, if the clinical trial protocol is revised, the statistical analysis plan can also be revised accordingly as needed.

Analyses for confirmatory evidence must be pre-specified in the statistical analysis plan, and other analyses may only be supportive or exploratory. If an interim analysis is involved, the corresponding statistical analysis plan should be finalized at the latest prior to each interim analysis.

3.2 Basic Contents

The basic contents of statistical analysis plan include but are not limited to study objective, type of study design, type of comparison, randomization and blinding, definition of estimands, hypothesis testing, sample size, definition of analysis sets, and detailed plan for efficacy and safety evaluation.

3.2.1 Trial Overview

The trial overview is a brief description of the clinical trial protocol, which generally includes the following main contents:

1) Study objectives: The primary and secondary objectives of the clinical trial.

2) Type of design: such as parallel design, crossover design, factorial design, single-arm design, etc.

3) Type of control: such as placebo control, active control, dose group control and objective performance criteria control.

4) Type of comparison: such as superiority test, non-inferiority/equivalence test and the margins.

5) Randomization and its implementation: such as block randomization, stratified randomization and the stratification factors.

6) Blinding and blinding method: explain whether it is single-blind or double-blind, whether the blinding method is double-blind single-dummy, or double-blind double-dummy, and approaches to maintain blinding while performing statistical analysis. In an open label study, it should be stated if some degree of blinding has been taken.

3.2.2 Estimand

The definition of estimands should be described in the clinical trial protocol. Each estimand should include the attributes of treatment, population, variable (endpoint), intercurrent event and its handling strategy, and population-level

summary, etc.

1) Primary estimand

Treatments: treatment condition of interest and, as appropriate, the alternative treatment condition to which comparison will be made. These might be individual interventions, combinations of interventions administered concurrently, e.g., as add-on to standard of care, or might consist of an overall regimen involving a complex sequence of interventions.

Population: The population of patients targeted by the clinical question. This will be represented by the entire trial population, a subgroup defined by a particular characteristic measured at baseline, or a principal stratum defined by the occurrence of a specific intercurrent event.

Variable (endpoint): to be obtained for each patient that is required to address the clinical question.

Intercurrent events and their handling strategies: For intercurrent events relevant to the clinical question of interest, treatment policy strategy, hypothetical strategy, composite variable strategy, while on treatment strategy, or principal stratum strategy are usually used to address them. The handling strategy for some intercurrent events can be addressed by the precise specification of treatment, population, and variables (endpoints). No matter which strategy is used, the sponsor should provide sufficient clinical justification.

Population-level summary: Population-level summary statistics of variables should be specified to provide the basis for comparison between different treatments, such as mean, median survival time, response rate, etc.

2) Secondary estimand

Refer to the description of the primary estimand above. If there are key secondary estimands, they can be described separately from the other secondary estimands and before those secondary estimands.

3) Exploratory estimand

If there are exploratory estimands, please refer to the description of the primary estimand above. If there are no exploratory estimands, no description is needed.

3.2.3 Sample Size

The determination of sample size shall be described, including sample size calculation (including the parameters involved and the rational), the software used for sample size calculation as well as the sample size re-estimation plan (if any). The sample size should be determined to ensure adequate power for the evaluation of the primary estimand.

3.2.4 Analysis Sets

The definition of analysis sets should be described according to different study objectives. The analysis sets of clinical trials generally include analysis sets based on randomization and safety analysis sets. The analysis set based on randomization is generally applicable to the analysis of demographic data and

baseline characteristics as well as the evaluation of different estimands; if the population used for evaluation of estimands is not the whole population of this analysis set, this population shall be flagged in the analysis set, and the flag conditions shall be described in this section. The safety analysis set is generally applicable to the safety analysis. For non-randomized clinical trials, analysis sets may be defined based on the enrolled population.

3.2.5 Statistical Analysis Methods

Statistical analysis shall be based on the authentic, accurate, complete and reliable clinical trial data, and reasonable statistical analysis methods shall be selected according to the study objectives, trial design and estimands. It is necessary to provide the description for different types of data as well as the statistical inference method, specify the one-sided/two-sided hypothesis testing as well as the testing level and describe the statistical software with the version number. For the derived variables involved in statistical analysis, the derivation formula shall be described. Statistical analysis results are usually presented in the form of statistical analysis tables or figures, and relevant information is briefly described in the form of text.

1) Subject disposition

For the analysis of subject disposition, the descriptive statistical analysis methods and analysis contents shall be described, such as screening, allocation, discontinuation of treatment and discontinuation of study with reasons.

2) Demographic and baseline characteristics

Describe the descriptive statistical analysis methods used for demographic and other baseline information according to the nature of data.

3) Compliance and concomitant medication

For analysis of compliance and concomitant medications, specify descriptive statistics and describe how subjects with poor compliance and concomitant medications will be described.

4) Analysis of the primary estimand

The primary estimator and sensitivity estimator of the primary estimand should be clearly described.

① Primary estimator

The handling strategy and the corresponding data handling and analysis methods for intercurrent events involved in the primary estimand should be described, including the handling of missing data related to intercurrent events and their corresponding handling strategies. Duplication with the previous definition section of estimands should be avoided here, and more details on data processing and analysis methods should be provided.

The null and alternative hypothesis, and the significance level of the hypothesis test of the primary estimand should be defined. The statistical analysis method used to evaluate the primary estimand should be described. And the type of variable (endpoint) and its distribution characteristics shall be considered for

the selection of corresponding statistical model. Estimation of the treatment effect should include point estimate and confidence interval.

② Sensitivity estimator

In order to explore the robustness of the statistical inference results obtained from the primary estimator, one or more sensitivity analyses are recommended for the same estimand.

When planning and conducting a sensitivity analysis, altering multiple aspects of the main analysis simultaneously can make it challenging to identify which assumptions, if any, are responsible for any potential differences observed. Therefore, the need for analyses varying multiple assumptions simultaneously should be considered on a case-by-case basis. Clarifying the assumption changes behind the different sensitivity analysis will help make a more reasonable interpretation of the results of the sensitivity analyses. Sensitivity analysis methods also need to be prespecified.

5) Analysis of the secondary estimands

Estimators for the secondary estimands should be described, and point estimate and confidence interval should be provided for the estimation of treatment effects. If hypothesis test is to be performed for the secondary estimands, the null and alternative hypothesis, and significance level of statistical test should be specified. If there are key secondary estimands, refer to the description of the analysis of the primary estimand as described above and place them before the

description of estimators of the other secondary estimands.

6) Analysis of the exploratory estimands

If there are exploratory estimands, the estimators should be clearly described, and the estimation of the treatment effect should include point estimates and confidence intervals. If there are no exploratory estimands, they do not need to be described.

7) Safety analysis

All the safety signals should be highly valued in the analysis, and special attention should be paid to serious adverse events, and adverse events of special interest related to drug mechanism of action, metabolites and/or disease area. Adverse events and their severity should be coded using a uniform coding dictionary with the name and version.

For the analysis of safety data, the statistical analysis methods shall be described. The analysis plan shall describe the classification of various safety data (such as clinical outcomes, laboratory test results, vital signs, etc.) as well as the method for summarization thereof, such as performing analysis according to the number, frequency and incidence rate of events, and make inter-group comparison when necessary.

For the analysis of safety data, it is also feasible to use appropriate figures to show the distribution of a certain adverse event and its severity among different groups or the trends in incidence rates and cumulative incidence rates in

different time intervals.

8) Handling of missing data

Missing data handling approach and its rational should be pre-specified. Missing data that is directly related to intercurrent events and corresponding handling strategies should be distinguished (e.g., under treatment policy strategy, data needed to be collected after treatment discontinuation but actually not collected) with the missing data related to an estimand, but not directly related to intercurrent events and their handling strategies (e.g., study withdrawal was not prespecified as an intercurrent event). The handling of the former type of missing data should be described in the section of the analysis of estimands, and the method for handling of the latter type of missing data should be described in this section.

9) Subgroup analysis

Supportive subgroup analyses are usually required to further explore the consistency of efficacy of the investigational drug across subgroups. When subgroup analyses are involved, clear definitions of subgroups are required.

10) Supplementary Analysis

In addition to the above analyses, additional analyses may be performed on the estimands to provide a more comprehensive understanding of efficacy. The role of supplemental analyses in interpreting clinical trial results is usually limited, so the necessity and role of supplemental analyses should be considered.

3.2.6 Multiplicity Considerations

If there are multiplicity issues, such as multiple estimands, multiple inter-group comparisons, multi-stage overall decision-making, analysis of longitudinal data at multiple timepoints, confirmatory subgroup analysis, etc., the strategies and methods for controlling the overall type I error rate should be described.

3.2.7 Interim Analysis

If an interim analysis was planned, the timepoints for interim analyses (including calendar timepoints or information timepoints), decision criteria and method for controlling overall type I error rate should be described. If a Data Monitoring Committee is established, its tasks should be described briefly.

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Appendix 1: Glossary

Electronic Source Data: refers to data initially recorded electronically, including information collected prior to or during the initiation of a clinical study from source records and their certified copies that can be used to reproduce or evaluate the study.

Electronic Data Capture (EDC): is a computer-based technology for clinical trial data collection that directly collects and transmits clinical data in an electronic form through an organic combination of software, hardware, standard operating procedures, and staffing.

Access Control: refers to the technical control of the ability to allow, restrict or prohibit the login or use of a clinical trial electronic system according to the user identity of the clinical trial electronic system and the identity of a defined group to which he/she belongs. In addition, it may refer to the control of the right of access, input, modification and browsing of an information resource item in the system.

Audit Trail: An essential function of a computer system, such as a data management system. It refers to the electronic record with time mark generated by the system using secure and computer, which helps the system user to independently trace the date and time of entering, modify or delete each electronic record. Besides, with the reason for modification recorded, it helps to facilitate the reproduction of data in the future. Any changes to the

recording will not obscure past records. As long as the subject's electronic records remain unchanged, such audit trail documentation should always be retained at all times and can be reviewed and copied by regulatory inspectors or auditors.

System Validation: refers to the establishment of documented evidence for the lifecycle management of computerized systems, so as to ensure that the development, implementation, operation and maintenance of computerized systems can highly meet their pre-set technical standards, intended uses and quality attributes of systems from beginning to end, and be in the monitored quality management procedures, and can highly reproduce and maintain the standards and functions of the system in accordance with the regulatory requirements until they are put into use.

Annotated Case Report Form (aCRF): It is a statement of the blank CRF, recording the location of each data item in the CRF and its variable name and code in the corresponding database.

Data Validation Plan (DVP): also known as edit check plan, is a system setting document prepared by Data Administrator to check the logic of data according to the clinical trial protocol and system functions.

Edit Check: refers to the check of data validity after the clinical trial data are input into the computer system. This verification can be realized through the program logic, subroutine and mathematical equation of the system. It mainly

evaluates whether there are errors in the input data domain and its expected numerical logic, numerical range or numerical attribute.

User Acceptance Testing (UAT): User acceptance testing is a test performed by the user of a clinical data management system in which test records are available to demonstrate that the system is designed to undergo the associated verification process. The user should comprehensively test all correct and erroneous data combinations and record the test results. Comprehensive testing documentation shall include verification protocols, test instruction records, test summary reports, and verification summary reports.

Protocol Deviation: refers to any behavior that intentionally or unintentionally deviates from and fails to follow the treatment, examination or data collection procedures specified in the clinical trial protocol without the approval of the Ethics Committee. In general, such deviations are only logically or administrative deviations from the clinical trial protocol and do not substantially affect the safety and benefits of the subjects or the value of the data collected.

Estimand: A precise description of the treatment effect reflecting the clinical question posed by the trial objective. It summarizes and compares the outcomes of the same patients under different treatment conditions at a population-level.

Estimator: A method of analysis to compute an estimate value of the estimand with clinical trial data.

Intercurrent Event: Events that occur after treatment initiation can affect the

interpretation or the existence of the measurements associated with the clinical question of interest. It is necessary to address intercurrent events when describing the clinical question of interest in order to precisely define the treatment effect that is to be estimated.

Interim Analysis: refers to the analysis using the accumulated data during the clinical trial, such as the analysis to evaluate the effectiveness, the analysis to evaluate the safety, and the re-estimation of sample size.

Safety Set (SS): In the evaluation of safety and tolerability, the set of subjects used for aggregation is called safety analysis set. The safety analysis set should be considered to include all subjects who received at least one treatment and had safety evaluation.

Missing Data: Data that would be meaningful for the analysis of a given estimand but were not collected. They should be distinguished from data that do not exist or data that are not considered meaningful because of an intercurrent event.

Sensitivity Analysis: A series of analyses conducted with the intent to explore the robustness of inferences from the main estimator to deviations from its underlying modelling assumptions and limitations in the data.

Subgroup Analysis: Generally, it refers to the analysis strategy to divide the subjects into different subgroups according to their characteristic variable values and estimate the efficacy and/or safety of each subgroup.

Supplementary Analysis: A general description for analyses that are conducted in addition to the main and sensitivity analysis with the intent to provide additional insights into the understanding of the treatment effect.

Appendix 2: Chinese-English Vocabulary

Chinese	English
安全性分析集	Safety Set, SS
伴发事件	Intercurrent Event
标准操作规程	Standard Operation Procedure, SOP
病例报告表	Case Report Form, CRF
补充分析	Supplementary Analysis
电子患者报告结局	Electronic Patient Reported Outcome, ePRO
电子数据采集	Electronic Data Capture, EDC
电子源数据	Electronic Source Data
多重性	Multiplicity
方案偏离	Protocol Deviation
估计方法	Estimator
估计目标	Estimand
患者报告结局	Patient Reported Outcome, PRO
稽查轨迹	Audit Trail
临床试验质量管理规范	Good Clinical Practice, GCP
临床研究协调员	Clinical Research Coordinator, CRC
逻辑核查	Edit Check
敏感性分析	Sensitivity Analysis
期中分析	Interim Analysis
权限控制	Access Control
缺失数据	Missing Data
数据管理计划	Data Management Plan, DMP
数据核查计划	Data Validation Plan, DVP
数据监查委员会	Data Monitoring Committee, DMC
统计分析计划	Statistical Analysis Plan, SAP
系统验证	System Validation
亚组分析	Subgroup Analysis
用户接受测试	User Acceptance Testing, UAT
注释病例报告表	Annotated Case Report Form, aCRF
总 I 类错误率	Familywise Error Rate, FWER