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A quick way the of quality control in statistical programming process using SAS

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ABSTRACT

In order to highlight the importance of the quality continuum in the design and conduct of clinical trials in China, the National Medical Products Administration and the National Health Commission have jointly revised and issued the "Good Clinical Practice", which came into effect on July 1, 2020. According to current ICH E6(R3) guidelines, sponsors are required to maintain statistical programming records pertaining to data included or utilized in test results reports, encompassing quality control/validation activities. Therefore, this paper introduces a method utilizing SAS software from a programmatic perspective to ensure the quality of statistical programming within projects and guarantee accurate and reliable final statistical analysis results.

INTRODUCTION

The China Medical Quality Management Association's official website released the group standard "Key Points for Quality Verification of Clinical Trial Data Management" (T/CQAP3013-2023) on January 11, 2024. This standard, organized and drafted by the association, took effect from January 10, 2024. The release of this group standard aims to promote standardized development in clinical trial data management, enhance data quality management, ensure the accuracy and reliability of clinical trial results, and address gaps in the supervision field of key points in clinical trial data management quality verification. However, as described in the GCP, statistical analysis is also important in clinical trials, in addition to data management. So we should think about what we can do at statistical analysis.

APPROACH

In the clinical trial process, we currently generally use independent dual programming to ensure the correctness of the results. But that alone doesn't make sure results are right. What else can we do? The following table is the sample results of our statistical programming checks. Let’s talk about some key points according to the following table.

final20231125 Analysis File Summary

File	The number of source program files	The number of quality check program files
Project Schedule Table	1	NA
Project Team Member Table	1	NA
Project Issue Tracking Table	1	NA
SDTM aCRF[2]	1	NA
SDTM aCRF Check List[2]	1	NA
Raw data Comparison Results[1]	1	NA
Logical verification results of lock database data creation date and lock database date	Pass	NA
SDTM DDT[2]	1	NA
Active Datasets in SDTM DDT[2]	27	27
SDTM Datasets[2]	27	27
SDTM SUPP Datasets[2]	19	19
Dataset Check List	1	NA
The Programs for SDTM Datasets[2]	27	27
The logs for SDTM Datasets[2]	27	27

File	The number of source program files	The number of quality check program files
The log Summary Report for SDTM Datasets[2]	1	1
There is no ERROR, WARNING or Special Notes in the log Summary Report for SDTM Datasets.[2]	Pass	Pass
SDTM Datasets Comparison Results[2]	46	46
SDTM Datasets Validation Report[2]	1	NA
The log for SDTM Dataset Check List[2]	Pass	NA
ADaM DDT	1	NA
Active Datasets in ADaM DDT	9	9
ADaM Datasets	9	9
The Programs for ADaM Datasets	9	9
The logs for ADaM Datasets	9	9
The log Summary Report for ADaM Datasets	1	1
There is no ERROR, WARNING or Special Notes in the log Summary Report for ADaM Datasets.	Pass	Pass
ADaM Datasets Comparison Results	9	9
ADaM Datasets Validation Report	1	NA
The log for ADaM Dataset Check List	Pass	NA
Tracker	1	NA
Active TFLs in Tracker	273	273
TFL(Table/Figure/Listing)	273	36
TFLs Check List	1	1
The Programs for TFL	273	36
The Logs for TFL	273	36
The log Summary Report for TFLs	1	1
There is no ERROR, WARNING or Special Notes in the log Summary Report for TFL Datasets.	Pass	Pass

[1]If the raw data is XPT data, the data needs to be Cutoff, or the data needs to be transcoded (for example, the data is converted from UTF-8 to EUC-CN), source programmers and QC programmers need to compare the processed data.
[2]Only to the CDISC project.

MAKE SURE THE DATA FLOW AND TIME SEQUENCE ARE CLEAR

In clinical trials, the standard process should be, firstly lock the database, then obtain the data set, then unblind and finally generate statistical charts. We can verify this by obtaining the modification date of the file and going through certain logical checks.

CHECK FOR DRYRUN RECORDS

Before obtaining the final lock time, we usually verify that the results of our program are correct using different stages of data. Through multiple verification and defensive verification of the data that may occur, we can ensure that we can submit the results quickly and accurately after obtaining the locked data set.

CONCLUSION

In the project verification, the program verification is assisted to effectively reduce possible omissions and save more time costs. At the same time, if we establish the work flow of project verification, we will be able to cope with the audit of both the sponsor and CDE organizations.

REFERENCES

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