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| SOP No. |  |
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| Author: |  |
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| Document information | |
| Revision period |  |

**1. Purpose**

This Procedure is applied to the process of generating Tables, Listings, and Figures (TLFs) for clinical trial data analysis and reporting.

This Procedure is mandatory for compliance by all statistical programmers involved in the creation, validation, and documentation of TLFs.

The requirements of this Procedure are mandatory for compliance by Biostatisticians, Quality Control Reviewers (QCR), and Project Managers who are responsible for ensuring accuracy, consistency, and adherence to regulatory requirements and sponsor guidelines.

## **2. Scope**

This SOP applies to all statistical programmers involved in the creation, validation, and documentation of TLFs for statistical analysis reports (SARs) clinical study reports (CSRs), regulatory submissions, and other research deliverables.

## **3. Responsibilities**

* **Statistical Programmers (SP)**: Develop, validate, and document TLF programs.
* **Biostatisticians (BST)**: Provide statistical analysis plans (SAPs) and review outputs.
* **Quality Control Reviewers (QCR)**: Perform independent validation and ensure compliance.
* **Project Managers (PM)**: Ensure timelines and deliverables align with study requirements.

## **4. Definitions**

* **ETL: Extract, Transform, Load**
* **TLFs**: Tables, Listings, and Figures summarizing clinical trial data.
* **SAP**: Statistical Analysis Plan, outlining methodology and specifications for TLFs.
* **CDISC**: Clinical Data Interchange Standards Consortium, defining standard data formats.
* **ADaM**: Analysis Data Model, providing datasets used for statistical analysis.

## **5. Procedure**

### **5.1 Preparation**

#### **5.1.1. Review the SAP and study protocol to determine TLF specifications.**

* SP and BST identify key analysis objectives, endpoints, and statistical methodologies.
* SP and BST review planned TLF shells and ensure consistency with SAP requirements.
* BST verify study population definitions and planned analysis sets (e.g., ITT, PP, Safety).
* BST prepare an excel file listing all TLFs for SAR by study endpoint.

#### **5.1.2. Obtain necessary input datasets and metadata**

* SP access and validate datasets.
* SP confirm dataset structures and variable mappings align with the specifications.
* SP check for data integrity issues such as missing values and outliers.
* If quality check is passed, **SP proceed to the next step. If** quality check is failed the code is updated with necessary changes with completion of the respective QC Log.

#### **5.1.3. Define the output structure**

* SP specify table/listing/figure formats based on regulatory or sponsor requirements.
* SP align titles, footnotes, and captions with study reporting guidelines.
* SP ensure consistency in aesthetic presentation in line with corporate identity.

### **5.2 Programming**

#### **5.2.1. Develop ETL (Extract, Transform, Load) script to process raw datasets into clean analysis-ready domains.**

* SP extract and import datasets or other sources.
* SP split, clean, format data to align with study specifications.
* SP load transformed data into structured analysis datasets.

#### **5.2.2. Save analysis datasets separately in appropriate formats**

* SP store datasets in standardized formats (e.g., XPT, CSV).
* SP ensure dataset naming conventions align with company and regulatory standards.

#### **5.2.3. Develop TLFs using R Studio or other statistical software per study requirements**

* SP and BST implement required statistical analyses using necessary programming techniques.
* SP use predefined templates for TLF generation to ensure consistency.

#### **5.2.4. Apply appropriate statistical methods and formatting guidelines**

* SP and BST follow the SAP for applying statistical tests, calculating confidence intervals, and performing subgroup analyses.
* SP implement predefined formatting rules for tables, listings, and figures.
* SP ensure compliance with CDISC and regulatory guidelines.

#### **5.2.5. Ensure traceability by documenting data derivation and transformations**

* SP maintain detailed logs of all data processing steps using version control feature of Git.
* SP store scripts and outputs in version-controlled repositories.
* SP annotate programs to describe key transformations and calculations.

### 5.3 Validation

* SP perform independent double programming.
* BST compare the results of double programming and reviews output against mock shells. If quality check is passed, **the team proceeds to the next step. If** quality check is failed the code is updated with necessary changes with completion of the respective QC Log.
* SP and BST cross-check TLF results with source datasets and statistical analysis requirements.
* SP and BST identify and resolve discrepancies through reconciliation and documentation.

### 5.4 Quality Control (QC) and Review

1. SP and BST conduct QC checks for accuracy, completeness, and consistency.
2. SP and BST ensure adherence to CDISC standards and regulatory requirements.
3. SP and BST maintain version control and archive validated outputs.

### 5.5 Submission and Reporting

1. SP format TLFs per sponsor and regulatory guidelines.
2. SP integrate TLFs into study reports and electronic submission packages.
3. SP store final validated TLFs in the appropriate repository.

## **6. Documentation and Compliance**

* SP maintain logs of programming activities and validation reports.
* SP and BST ensure compliance with Good Clinical Practice (GCP) and company SOPs.
* SP and BST archive final datasets and programs per project documentation archiving SOPs.

## **7. References**

* Statistical Analysis Plan (SAP)
* Clinical Study Protocol
* CDISC ADaM and SDTM Guidelines
* Regulatory Guidance Documents (e.g., FDA, EMA)

## **8. Related SOPs**

* SOP-DM-17

## **9. Supporting documents**

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| **No.** | **Name** | **SD No.** |
| 1. | Detailed log of data processing steps with version control by Git |  |

## **10. Revision History**

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| **Version** | **Effective date** | **Reason for changes / description** |
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