SOP 002_06

Title	File Transfer
SOP Code	SOP 002_06
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the steps required during the transfer of external files to and from the study database to preserve the integrity of transmitted data and the study database.

2.0 SCOPE

This SOP is applicable to all data files that are part of the study data set and which are transmitted from another site to be included in the study database. This SOP is also applicable to those personnel responsible for the transmission, such as all the Data Management and Information Technology (IT) personnel, unless otherwise stated in the study contract or data management plan.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator, Data Management and IT personnel (if applicable) are responsible for ensuring that the processes involved in all database file transfers, from or to the study database, meet all of the applicable regulatory, International Conference on Harmonisation (ICH), Good Clinical Practice (GCP), Sponsor, and local requirements.

Any or all parts of this procedure may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the Sponsor, Sponsor-Investigator and/or Qualified Investigator (QI)/Investigator.

4.0 DEFINITIONS

Database: The term database applies to all computer software which is used to format, manipulate or control storage of the electronic data for the study. This may be one computer file or a system of files which are maintained as the study database.

See also, “CDISC Clinical Research Glossary, Version 8.0” and “N2 Glossary of Terms”.

5.0 PROCEDURE

5.1 Treatment Coding and Blinding

5.1.1. Where necessary, maintain the blinding of the treatment coding in released datasets. This may mean removing the treatment codes or replacing the treatment codes with mock codes. Document the recoding and include notification of the re-coding/blinding with the transmitted file.

5.2 Data Security

5.2.1. Maintain appropriate authorizations for access to data to be transferred/ received.

5.2.2. Ensure that the receiving site is aware of privacy legislation regarding the use of linked data.

5.2.3. Encrypt files for transfer using local encryption methods and software. Files may also be transferred as password protected compressed archives or transferred directly using encrypted file transfer.

5.2.4. Ensure that the original data files that are to be received by the data centre and that are to be transferred into the study data base are write protected and are included in the data archiving process.

5.2.5. Maintain a copy of all files of the originating study database before they are transmitted externally. Ensure the copy is write protected and is included in the data archiving process.

5.2.6. Point-to-point file transfers or utilization of authorized “drop file” facilities are used when available. File drop/exchange services, provided by many institutions, utilize file encryption and secure transmission. File transfer via an email message is a secondary option.

5.2.7. Passwords are always sent to the recipient of the data files in a separate transmission

5.3 Documentation and Verification

5.3.1. Ensure that the data file is accompanied by documentation of the content and format.
• If applicable use export/import functions for creating/reading transport files and ensure that the appropriate documentation is associated to the transport.
• The minimum information should include:
- The column positions or delimiter
- The column headings
- The field formats for all columns
- The field lengths for all columns

5.3.2. In cases where transferred data are converted to a different format, verify the data conversion by comparing the transferred fields to original field specifications.

5.3.3. When feasible, provide/verify the number of observations (rows) and number of variables (columns) in the transferred file.

5.3.4. Request documentation from the receiving site or provide documentation to the transmitting site to ensure that the file was received and verified.

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

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CDISC Clinical Research Glossary, Version 8.0, Glossary. December 2009.

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US Department of Health and Human Services. Food and Drug Administration. Office of the Commissioner. Guidance for Industry, Computerized Systems Used in Clinical Investigations. Guideline. May 2007.

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The Society for Clinical Data Management, GCDMP Committee, Good Clinical Data Management Practices. December 2009 Ed. WHO Drug Dictionary, Uppsala Monitoring Centre (UMC).