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The future of cancer therapy

Avenue E. Mounier 83/11
1200 Brussels
Belgium
Tel: +32 2 774 1611
Email: eortc@eortc.be
www.eortc.org

Statistical Programming for Regular Clinical Data Reporting and Administrative Data Transfers

ST-003-SOP-02
Version 1.0
ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

Author *Lead Statistician* Thierry Gorlia	Signature:	Date: 12/05/2017
Approved by: *Head Statistics Department* Laurence Collette	Signature:	Date: 15/05/2017
Authorized by: *Director General* Denis Lacombe	Signature:	Date: 17 - MAY - 2017

1 PURPOSE

To describe the programming procedure for the preparation of non-confidential administrative or safety reports and for administrative data transfers with third parties during EORTC study conduct.

2 SCOPE

This SOP applies to

- all EORTC data administrative transfers to third parties,
- the production of Adverse Events (AE) listings, graphs and tables for medical review,
- other complex programming needed for the preparation of administrative reports or newsletters (eg. accrual curves, etc.) according to ST-003-SOP-01.

3 POLICY

The present procedure aims to ensure:

- Safe and efficient administrative transfers of EORTC data to third parties;
- Release of AE listings, graphs and tables which facilitate the medical review of the safety of EORTC trials by the Clinical Research Physician (CRP) and assure the consistency of safety reporting through all EORTC analysis reports.
- Release of administrative reports and/or newsletters to monitor the study accrual and to communicate with investigators and external partners about the study conduct.

4 DEFINITIONS

- **EORTC data administrative transfer:** Transfer of EORTC data to third parties (e.g. pharmaceutical company) which does not require a lock of the database and does not include trial endpoints. The content and frequency of these transfers are described in the contract between EORTC and third parties.
- **Data transfer requirements specifications:** The document which describes and specifies the contractual requirements for data transfer of EORTC data to third parties. It includes the transfer type (e.g.cumulative vs incremental) and frequency (e.g. weekly, monthly, other), the list(s) of Case Report Forms and selected patients (e.g. all, discontinued patients,…), any variables and file naming conventions, other specifications.
- **Data transfer guide:** The document which describes how to parametrize the SAS data transfer programs and the process to upload EORTC data via the data transfer platform (e.g. http link, SFTP host name, username and password entry, upload subfolder, other parametrizations).
- **Transfer platform**: An IT solution to securely exchange files with third parties.
- **Transfer platform provider:** The person who provides the service of a transfer platform and is responsible for its maintenance and security.

- **Receiver(s):** The person(s) at third parties who receive(s) the SAS data files.
- **SAS macro:** Parts of SAS programs that are written in the SAS MACRO language and that enable one to substitute text in a program or to repeatedly perform operations without having to repeat the SAS code.
- **EORTC SAS macro:** Programming module with a well-defined functionality that can be used across studies, developed in SAS at the EORTC.

5 PROCEDURE

5.1 Generalities

The SAS programs follow the same procedure for database export, program structure, program documentation, programming conventions and program validation detailed in ST-003-SOP-01.

The data transfer follows ST-009-SOP.

5.2 EORTC data administrative transfer

As soon as the study contract is signed, the Project Manager informs the study Statistician, the Head of data management (DM) department and the statistical analyst(s) that EORTC data administrative transfers are planned. The study Statistician provides:

- The study number,
- Data transfer requirements specifications,
- The name and email of the transfer platform provider (or indicates if data can be transferred through Filebox) and of the receiver(s).

The statistical analyst contacts the transfer platform provider to obtain access codes, starts developing the data transfer guide and saves it in a subfolder labeled S:\DM\Trial Folder\TRANSFER\.

The SAS Clinical Data Manager (SAS CDM) develops the SAS program according to the data transfer requirements specifications with the support of the statistical analyst if needed and completes the data transfer guide to describe how the SAS program must be parameterized before its execution (e.g. macro variable initialization, …). The SAS datasets and outputs generated are stored in a subfolder labeled S:\DM\Trial Folder\TRANSFER\DDMMYYYY.

The SAS program and data transfer guide are reviewed and approved by the study Statistician. The study Statistician signs the Program Approval Form for Regular Reporting and Data Transfer (ST-003-AF-02) and files it and the data transfer specifications in the TMF according to the TMF index. The SAS CDM exports the data from the EORTC database, performs the data transfer according to ST-009-SOP and informs the statistical analyst, the study Statistician and the receiver(s) that the transfer was executed.

The study Statistician informs the SAS CDM and the statistical analyst of any change in the contract or data transfer requirements specifications which might affect the data transfer. The SAS programs and data transfer guide are updated accordingly by the SAS CDM and approved by the study Statistician. The study Statistician signs ST-003-AF-02 and files it and the data transfer specifications in the TMF.

5.3 AE listings, graphs and tables for medical review

For a medical review of the study, the CRP can request a safety report. He/she discusses with the study CDM the AE listings, graphs and tables that should be produced. If AE listings graphs and tables are needed, the study CDM informs the Head of data management (DM) department who assigns a SAS CDM.

The SAS CDM develops and maintains the SAS program (using the EORTC AE and LABTOX SAS Macro) with the support of the study Statistician and consults the statistical analyst if needed.

The SAS program is reviewed and approved by the study Statistician who signs ST-003-AF-02 and files it in the TMF.

The SAS CDM exports the data from the EORTC database, executes the SAS program and provides the outputs to the study CDM that liaises with the CRP.

The SAS dataset and the outputs are stored in a subfolder labeled S:\DM\Trial Folder\SAFETY\DDMMYYYY.

5.4 Administrative reports and newsletters

As soon as the study contract is signed, the Project Manager informs the Head of Data Management (DM) Department and the study Statistician that EORTC data administrative reports and newsletters are planned.

The SAS CDM develops the SAS program for administrative reports and newsletters with the support of the study Statistician and consults the statistical analyst if needed. The SAS program is reviewed and approved by the study Statistician who signs ST-003-AF-02 and files it in the TMF.

The SAS CDM exports the data from the EORTC database, executes the SAS program, generates the outputs and provides them to the HQ study team responsible for generating the administrative report and newsletter.

The SAS dataset is stored in a subfolder labelled S:\DM\Trial Folder\ADRNEWSL\DDMMYYYY.

6 FILING AND ARCHIVING

The SAS programs, databases and outputs generated are stored by the CDM in a subfolder of S:\DM which can be accessed by all SAS CDMs, statistical analysts, Head and associate Head of statistics department.

Each database export is saved in a folder that indicates the aim (Transfer, AE, administrative report or newsletter) and date of the export e.g. S:\DM\Trial folder\SAFETY\DDMMYYYY.

The study Statistician files the ‘Program approval form for Regular reporting and data transfer’ (ST-003-AF-02) and the Data Transfer Specifications in the TMF according to the TMF index.

7 RACI MATRIX

Functions / Activities	Head DM	SAS CDM	Statistical analyst	CDM	Stat	CRP	PM	Study Team	Data Transfer Provider
SAS Program		R	C		A				
Filing (program)		A							
Filing (administrative))					A				
Data transfer									
Contractual data transfer requirements	I		I		A				
Data Transfer Platform set-up		I	A		I				R
Data Transfer Guide		R	R		A				
Data transfer		A	I		I				
Medical review report									
Content	I	I		C	R	A			
Generate output		A		I	I	I			
Administrative reports and newsletters									
Informs team	I				I		A		
Generate output		A		I	I	I	I	I	
R: responsible; A: accountable; C: consulted; I: informed. Use ‘A’ when ‘A’ and ‘R’ are assigned to the same person.									

8 REFERENCES

- ICH Topic E2F: Development Safety Update Report, issued as EMEA/CHMP/ICH/309348/2008

9 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
Statistical Programming	ST-003-SOP-01
Data Transfer	ST-009-SOP
Program approval form for Regular Reporting and Data Transfer	ST-003-AF-02

10 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective Date
1.0	First release	Thierry Gorlia	21 Jun 2017