

Transfer of EORTC data

ST-009-SOP

Version 2.0

ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

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1 PURPOSE

The purpose of this procedure is to describe the process of electronic transfer of EORTC data from EORTC Headquarters to external organizations or from those bodies to EORTC Headquarters.

2 SCOPE

This procedure applies to all EORTC Headquarters staff members who are involved with clinical trials and projects that require transfer of EORTC data (of any type and in any format) over the Internet covered by EORTC Policy 008 and/or by contractual agreements between EORTC and third parties. Postal mail shipments or any other physical transfers are not covered, nor the transfer of patient information from centers/groups to the EORTC Headquarters in the frame of the regular study data collection.

3 POLICY

It is EORTC policy to ensure that the transfer of EORTC data is realized in the best conditions through secured ways. The authorization of EORTC data release to external partners is governed by the EORTC Data Sharing policy (POL008) and/or by contractual agreements between EORTC and third parties. For any transfer of individual patient data not covered by this document, EORTC nevertheless recommends that transfer is performed through secured ways.

4 DEFINITIONS

- ◆ **EORTC data:** all and any electronic records of human clinical and biological data (included but not limited to genetic, "omics" or other molecular data) or centrally stored imaging data in Digital Imaging and Communications in Medicine (DICOM) file format obtained from patients entered in EORTC studies; i.e. individual patient data. Data does not include human biological material samples. As EORTC works exclusively with coded data, the term "EORTC data" in the present document refer exclusively to coded EORTC data.
- ◆ **Third parties:** any external organization including: other cooperative groups, pharmaceutical, biotechnology or diagnostic companies, contract research organizations, biobanks, central laboratories and registries.
- ◆ **Transfer platform:** an IT solution to 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 EORTC Headquarters or at third parties who receive(s) the data files.
- ◆ **Sender(s):** the person(s) at EORTC Headquarters or at third parties who is/are responsible for the transfer of data files to the receiver(s) through the transfer platform. Sender(s) create data folders, upload data and invite receivers to access these files.

5 PROCEDURE

5.1 Pre-conditions

Method(s) by which EORTC data will be transferred must be agreed upfront with third parties. Method(s) include the type of transfer platform to be used, the file format and the file convention name. For each method, detailed procedure and documentation must be communicated by the transfer platform provider to the sender(s) and receiver(s) so they can accurately and safely proceed to the transfers. Data transfer method(s) are tested and signed off by both parties during the system validation and test phase.

5.2 Data transfer process

The following procedure is undertaken when there has been a specific request for transferring EORTC data to or from third parties:

Files are checked for completeness and gross validation (check to see all data fields have been stored in a complete and consistent manner). Files must be protected by passwords.

Files are stored by the sender(s) on a data transfer platform.

Access instructions are sent separately via emails to the receiver(s). Email notifications ensure that everyone stays current with updates to the available data.

Passwords are mandatory to access the transfer platform. Passwords must be sent in separate emails than access instructions.

Access to files is limited in time. Timelines are agreed by sender(s) and receiver(s) on a case per case basis and managed by the sender(s).

6 FILING AND ARCHIVING

The original EORTC data are archived according to QS-004-SOP like all EORTC data. There is no trail of the transfer of EORTC data.

7 RACI MATRIX

Activities \ Functions	Receiver(s)	Sender(s)	Transfer platform provider
Deciding on process(es) of transfer of EORTC data	R	A	C
Maintaining the transfer platform	I	A	R
Using the transfer platform to send EORTC data	I	R	A
Proceeding to the reception of EORTC data	R	A	I
R: responsible; A: accountable; C: consulted; I: informed. Use 'A' when 'A' and 'R' are assigned to the same person.			

8 REFERENCES

None

9 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
Data Sharing	POL008
Data sharing	ST-008-SOP
Filebox user-guide	http://confluence.eortc.be:8090/display/SUP/Filebox:+EORTC+HQ+file+exchange+platform

10 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.0	Initial release	Thierry Gorlia	07 July 2015
2.0	Clarification of scope	Thierry Gorlia	23 Oct 2015