1 Purpose

To define the terms and conditions under which individual electronic records of patients from EORTC studies may be shared with other organizations or individual researchers for the purpose of scientific research.

2 Scope

This policy relates to the transfer of electronic data from all or from a subset of the patients from EORTC studies, requested by other organizations or qualified individual researchers for the purpose of their own scientific research.

Not covered by this policy

- Data transfers to third parties agreed in the scope of EORTC research (e.g., agreed data transfers at the end of and EORTC led study, agreed data transfers in the frame of an EORTC research project).
- Transfer of data from studies in which EORTC is not the legal sponsor, unless such right has been contractually granted to EORTC by the study sponsor.
- Sharing of human biological material, which is driven by EORTC policy on 'Human biological material collection and use'.
- Requests that necessitate further data collection, which are subject to the EORTC policy on selection, development and approval of EORTC studies.

3 Policy statement

EORTC is committed to promote the use of the data generated from EORTC research by the cancer research community to deliver patient benefit.

It is EORTC's policy to consider for sharing upon request from qualified scientific and medical researchers, for the purpose of legitimate research, all data generated from EORTC studies within the limits of:

- rights and privacy of patients who participated to the studies,
- applicable laws and regulations,
- intellectual property, contractual and confidentiality rights specific to the studies
4 Changes since last version

<table>
<thead>
<tr>
<th>Process step</th>
<th>Changes since last version</th>
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<tbody>
<tr>
<td>All</td>
<td>Superseding POL008 version 3.0</td>
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<tr>
<td></td>
<td>Changes include full re-shaping of the policy and clarification of scope.</td>
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<td>5.7 Useful links</td>
<td>Administrative release: removal of hyperlinks.</td>
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5 Policy

5.1 Data availability

EORTC shares data collected in the frame of current or past studies.

EORTC shall not release the data of a study until the primary study results have been published.

In exceptional circumstances, EORTC may consider sharing data before primary study results have been published provided that authorization for release has been granted by the study independent data monitoring committee (IDMC).

5.2 Data request submission

Data applicants are requested to submit a research proposal that should include amongst other:

- a description of the intended research, including the rationale supporting the research, the hypothesis to be tested, the analysis plan,
- a description of the requested data, and
- qualification and experience of the research team to conduct the proposed research.

5.3 Review of the data request

Once the request is complete and all supporting documents are available, it is scientifically evaluated, and feasibility shall be assessed before EORTC grants access to the data.

Recognizing that timely communication, and decision-making is of high value to the involved parties, EORTC strives to provide information and feedback to requestor in a reasonable timeline.

The study coordinators and the officers of the EORTC groups that participated to the study review and approve the data request, including the research proposal. EORTC reserves the right to deny access to data if the research proposal overlaps with EORTC research. If required by a specific study contract or study charter, other groups/stakeholders having participated to the study are informed or requested for review and/or approval.
A check shall be performed to safeguard the rights of research participants, including compatibility of the research proposal with study informed consent under which data and samples were provided by the research participants.

A legal and regulatory compliance check shall be performed to ensure that nothing prevents EORTC from sharing the data for this research proposal with respect to contractual agreements and legal or regulatory requirements, to ensure compliance with applicable legislation, including but not limited to EU General Data Protection Regulation.

Any concern identified during this assessment process might result in decline of the request, or a request for further information from the researcher. The rationale is provided to the requestor.

The EORTC review is solely meant to check that the data can be shared for the specific purpose of the requestor's research proposal. It is the responsibility of the requestor to ensure that his/her research can be conducted by seeking all applicable scientific, legal, regulatory and ethical approvals for the research proposal itself.

5.4 Data release

Data are released by EORTC HQ in electronic format when:

- the data request is approved,
- all needed administrative, contractual and financial arrangements for the data transfer are set up between EORTC, the requestor, and any other relevant parties,
- technical arrangements are set up between EORTC and the requestor in the form of a data transfer specification signed by both parties.

5.5 Terms and conditions

EORTC mandates the data requestor to comply with a standard set of conditions in the format of an agreement, referred to as ‘Terms of Use’, which needs to be electronically acknowledged at time of submission of the request on the EORTC website. Depending on the type of research and potential constraints on the requested dataset(s) in the scope of the original study, EORTC may require additional terms to be complied with and/or formalized in a separate agreement.

5.6 Administrative fee

EORTC is entitled to ask for a financial compensation to cover the administrative and data transfer costs. Financial terms are defined in the ‘Terms and Conditions’.

All questions concerning EORTC data sharing should be addressed to Datasharing@eortc.org.
6 Definitions

- **EORTC data**: Any and all electronic records of individual data obtained from patients entered in EORTC studies, including but not limited to human clinical data, biological data (included but not limited to genetic, any -omic or other molecular data) or imaging data (centrally stored in Digital Imaging and Communications in Medicine (DICOM) file format). Data does not include human biological material samples.

7 Signature

This document will be electronically signed.
The signatories acknowledge that electronic signature is legally binding and equivalent to a handwritten signature.

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<tr>
<th>Author</th>
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<td>Pascale Baltus</td>
<td>Projects and services director</td>
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<td>Denis Lacombe</td>
<td>Chief executive officer on behalf of the Board</td>
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