EORTC European Organisation for Research and Treatment of Cancer The future of cancer therapy	**Policy on Data Sharing**		
Document owner	Projects director	Version number	1.2
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1 Purpose

To define the terms and conditions under which EORTC study dataset may be shared with other organizations or individual researchers for the purpose of external scientific research, without the involvement of the EORTC.

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 promoting the responsible use of data generated from EORTC research by the cancer research community to support scientific progress and 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 and obligations specific to the studies

4 Changes since last version

Process step	Changes since last version
All	Clarification and addition of following details: 5.1: Review of data sharing request by study steering committee 5.3: Study steering committee and EORTC group chair to review and approve the data request; 5.4: principle of data minimization and data transfer security; 5.5: purpose for Terms of Use and 5.5.2. specific to publications; Definition: Pseudonymisation & data requestor

5 Policy

5.1 Data availability

EORTC may share data collected as part of ongoing or completed studies, subject to the conditions specified in this policy and any study-specific restrictions.

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).

The study steering committee or study coordinator(s) or group chair should be consulted for any data sharing to ensure alignment with the group's scientific priorities.

5.2 Data request submission

Data applicants are requested to submit a research proposal that should include, at minimum:

- 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,
- the qualification, experience and affiliation of the research team to conduct the proposed research, and
- a description of the data privacy requirements.

5.3 Review of the data request

Once the data request submission is complete and all supporting documents are available, the request 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 coordinator(s), steering committee from the original study, or EORTC group chair, as applicable, are provided the opportunity to 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 the compatibility of the research proposal with the study informed consent under which the 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 concerns identified during this assessment process might result in the request being declined, or in a request for additional information from the researcher. The rationale for the decision shall be communicated 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 their 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 administrative, contractual, and financial requirements governing the data transfer are fulfilled between EORTC, the requester, and any other relevant parties,
- technical arrangements are formalized between EORTC and the requestor in the form of a data transfer specification,

Only data that are necessary for the approved research purpose shall be transferred, and the transfer shall use a secure method appropriate to the sensitivity of the dataset.

5.5 Terms and conditions

EORTC requires the data requestor to comply with a standard set of conditions in the form of an agreement, referred to as 'Terms of Use', which must be electronically acknowledged at time of submission of the request on the EORTC website. Depending on the type of research, applicable study-specific constraints on the requested dataset(s), and the legal and regulatory context,, EORTC may require additional terms to be complied with and/or formalized in a separate agreement.

The Terms of Use (or separate agreement, as applicable), addresses permitted and prohibited use, confidentiality, ethical and data protection requirements, payment of fees, publication and acknowledgement obligations, as well as ownership, liability and indemnification provisions.

5.5.1 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 of Use'.

All questions concerning EORTC data sharing should be addressed to datasharing@eortc.org.

5.5.2 Publication

The researcher shall acknowledge EORTC in any publication or dissemination arising from the shared data, in accordance with the Terms of Use and shall share the publication reference with the EORTC for its records.

6 Definitions

- **EORTC data:** Any and all electronic records of individual data obtained from patients entered in EORTC studies, including but not limited to 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) format). Data does not include human biological material samples. Data shared under this policy are limited to the data necessary for the approved research purpose and shall be pseudonymised, as applicable and legally appropriate.
- **Data requestor**: The organisation or qualified individual researcher requesting access to EORTC data under this policy.
- **Pseudonymisation:** The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

7 Signature

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

Author Marie-Sophie Robert Projects and services director	Signed by: Marie-Sophie Robert Signer Name: Marie-Sophie Robert Signing Reason: I am the author of this document Signing Time: 15 June 2026 | 12:07:17 CEST 615637184FF6416A8054EF70C0260FB3
Approved & authorized by Denis Lacombe Chief executive officer *on behalf of the Board*	Signed by: Denis Lacombe Signer Name: Denis Lacombe Signing Reason: I approve this document Signing Time: 15 June 2026 | 12:39:15 CEST 457339F472784605806FBD4D54FBD7A4