EORTC European Organisation for Research and Treatment of Cancer The future of cancer therapy	**Policy on Transparency in Clinical Trials**		
Document owner	HQ Direction	Version number	1.0
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1 Purpose

This policy describes how EORTC promotes transparency and sharing of knowledge about the proceedings and findings of EORTC clinical trials.

2 Scope

This policy applies to clinical trials sponsored by EORTC and to clinical trials where EORTC takes part and there is agreement with the sponsor that EORTC's transparency policy applies.

3 Policy statement

Transparency of health care interventions helps generate further knowledge, build and maintain trust and gives confidence to both those involved in the trial and those who are not. EORTC aims to:

- Ensure transparency within the whole life cycle of the clinical trial
- help guide future research,
- reduce unnecessary duplication of effort,
- enable care to be guided by an up-to-date evidence base,
- support wider efforts to foster potential collaborations, and
- increase informed participation in clinical trials.

Therefore, EORTC commits to timely communication of trial results, regardless of outcome, and to wide provision of relevant information on EORTC clinical studies.

4 Changes since last version

Process step	**Changes since last version**
All	Initial release

5 Policy

5.1 Register research

EORTC registers all clinical trials on at least one broadly recognised clinical trials registry, such as European Union Clinical Trials Register and the United States National Library of Medicine ClinicalTrials.gov.

EORTC publishes information on the EORTC website for all current clinical trials, providing navigation aids, such as filters, to help finding relevant trials for the ones seeking information.

If applicable, clinical trial protocols are posted online on publication following the policy of the journal's publisher. Protocols are also available upon request.

5.2 Disseminate results

According to the World Health Organisation (WHO) draft guidance, once the trial is completed, reports should be publicly available within twelve (12) months. Peer-reviewed publications should describe the study design, methods and results in a clear and transparent manner, regardless of the trial's findings. The 'Publication Policy' of EORTC specifies timelines for manuscript drafting and publication, including fallback mechanisms in case of delays.

EORTC complies with this requirement by reporting and publishing the results of all clinical trials, irrespective of their result, i.e. whether positive, negative, or inconclusive. All clinical trials registered in the EU Clinical Trials Register include a report of the results within twelve (12) months of the end of the clinical trial. These reports may include a layperson summary of the main results of the clinical trial. Clinical trials registered on ClinicalTrials.gov may include a report of the results within twelve (12) months of the end of the clinical trial.

5.3 Share data and tissue

EORTC commits to promote the usage of clinical data and tissue collected during the clinical trial within the scientific community according to 'Policy on Data Sharing' and policy on 'Collection and Use of Human Biological Material', which describe the conditions and are publicly accessible on the EORTC website.

5.4 Disclose funding sources

EORTC's revenue by source is available on the EORTC website. EORTC discloses trial funding to ethics committees and national competent authorities upon clinical trial submission and shares the funding agreement upon request.

Internal clinical trial approval processes are the same irrespective of funder, are publicly available on the EORTC website and promote the scientific independence of EORTC from the trial funder.

6 Definitions

- **Clinical study:** (1) Clinical research with prospective data and need for informed consent; (2) means any investigation in relation to humans intended:
  - to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
  - to identify any adverse reactions to one or more medicinal products; or
  - to study the absorption, distribution, metabolism and excretion of one or more medicinal products; with the objective of ascertaining the safety and/or efficacy of those medicinal products.
- **Clinical trial:** means a clinical study which fulfils any of the following conditions:
  - the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;
  - the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or
  - diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects (as per EU Regulation 536/2014).

7 Associated documents

Process step	Title	Identifier / location
Disseminate results	Publication Policy	J-03-POL-01
Share data and tissue	Policy on Data Sharing	L-01-POL-01
Share data and tissue	Collection and Use of Human Biological Material	POL020

8 References

- WHO Guidance for best practices for clinical trials , section 2.3.3 on Transparency
- EU Clinical Trials Register - About the EU Clinical Trials Register

9 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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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: 05 December 2024 | 15:55:43 CET 457339F472784605806FBD4D54FBD7A4