EORTC European Organisation for Research and Treatment of Cancer The future of cancer therapy	**Policy on Patient Involvement**		
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1 Purpose

This policy outlines principles of involving patients and caregivers in the clinical studies and research projects led by EORTC. It describes activities where patients' voices should be integrated when developing and conducting research.

2 Scope

The policy applies to the activities conducted within the EORTC HQ, as well as EORTC disease-oriented groups, cross-discipline groups, Older Adult Council, Radiation Oncology Science Council, and the Protocol Review Committee and Independent Data Monitoring Committee.

This policy does not apply to the groups such as Imaging, Pathobiology, Pharmacology, Molecular Mechanisms, unless otherwise needed, and studies conducted not under the legal sponsorship of EORTC.

3 Policy statement

Given the societal shift and the importance of the patient voice in healthcare decision-making, patient involvement within clinical research became not only valuable, but also vital. Involving patients and caregivers in oncology research has demonstrated to improve the relevance of the research for the patients, its applicability in clinical settings, as well as to enhance access to and inclusion in clinical studies.

Secondly, patient involvement echoes the EORTC mission that aims to increase survival and quality of life of cancer patients. This mission cannot be achieved without systematic and embedded patient involvement across the entire spectrum of EORTC activities.

Lastly, involving patients is a requirement of the Clinical Trial Regulation No. 536/2014 applicable to clinical studies on medicinal products for human use.

4 Changes since last version

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

5 Policy

5.1 Key principles of patient involvement

- **Co-creation:**
  patient partners are invited to get involved throughout the study at every level: from the conception to the dissemination of study results.

- **Respect and recognition**:
  each contributor from the patient community shall be respected and recognised for the unique expertise they bring to the table; patient partners shall be considered as equal partners around the table.

- **Mutual learning**:
  study coordinators, group chairs/members, and HQ representatives provide feedback to the patient partners on their contributions and updates on the progress of the studies or a single activity where patients' input was sought. Patient partners are also welcome to share their feedback on their involvement experience and offer suggestions for further improvement of the processes.

- **Discretion and respect for privacy**:
  patient involvement, besides reviews, also implies sharing personal stories; such stories are supposed to be treated confidentially and with the consent of the person concerned**.**

- **Diversity**:
  EORTC shall make reasonable efforts to ensure that involved patient partners represent diverse population groups and have diverse backgrounds and perspectives.

5.2 Patient involvement in EORTC groups

Each group should appoint at least one patient partner who is invited to provide their patient perspectives throughout the entire lifecycle of each study led by EORTC: from the formulation of the research question to the dissemination of the study results. These can be different patient partners (i.e. not necessarily one partner for the entire study), but patient perspective should be integral when conducting research at EORTC.

Recruitment of patient partners or patient organisations is done by the HQ upon request of each group. Groups can also propose their candidates, communication with whom can be facilitated by the EORTC Patient relationship manager.

EORTC expects groups to secure a budget for patient involvement when planning to conduct a new study. These costs can cover travel expenses of patient partner(s) to the group or any other research-related meetings.

5.3 Potential areas for collaboration

Study phases and activities where patient partners' input will be sought:

Pre-development

- co-define research priorities and formulate research questions
- co-define outcomes relevant to patients

Development:

- review of protocol synopses
- co-writing of lay summary of protocol
- review of patient information sheet and informed consent (incl. the template)
- review of some sections of the protocol, namely:
    - risks and benefits of the treatment
    - planned visits and examinations schedule
    - recruitment strategy

For academic studies that apply for research grants, patient partners should also be involved in the grant application process.

Conduct:

- participation in the study steering committee meetings (optional)
- work in partnership on recruitment-related and drop-off-related issues
- participation in the (ad hoc) study-related meetings or focus group discussions
- participation in the Independent Data Monitoring Committee meetings or offering patient perspectives on the safety of research participants (upon request of the IDMC chair)

Dissemination of study results:

- dissemination of study results on websites and social media with the help of patient organisations or patient groups to ensure wider outreach
- share patients' perspectives on the side effects of the investigated treatment
- help place the study results in the context of real-life patient experience
- contribute to and co-author publications.

5.4 Patient involvement in quality-of-life studies

Unlike clinical studies, quality of life modules aims to improve the sensitivity and specificity of assessments of quality of life in specific groups of patients and are primarily designed to be implemented in oncology studies or other research settings. While quality of life module studies generates new data to develop a module, non-module studies generate new data to apply or further refine the existing EORTC quality of life measures in a clinical or methodological context.

One of the requisites of the module and non-module development and validation is patient experience. It is captured mainly through interviews and questionnaires. However, other

activities taking place within each phase of the module non-module development also leave space for incorporating patients' voices, namely:

Phase 1

- selection of the quality-of-life issues
- selection of the interview questions
- assisting patients who participate in the interviews
- co-analysis of the interview data

Phase 2

- review of the list of items (retention/deletion)
- assessment of the wording of the items

Phase 3

- selection of questions for the pre-testing interview
- review of the list of items (retention/deletion)

Phase 4

- development of the protocol
- assisting patients who participate in the debriefing questionnaire
- contribution to the final publication.

Involving patient partners to contribute to the following activities would help identify new items, offer first-hand perspectives on the disease, help evaluate item wording, and address potential issues such as omissions, redundancies, or duplications.

5.5 EORTC Patient Panel

The EORTC Patient Panel is an advisory board of independent patient advocates, patients, and caregivers of different age, gender, and with different personal experiences.

The Patient Panel members are expected to be actively involved in the activities of the EORTC groups or be group members and able to offer their patient perspectives on and experiences of a specific cancer.

Their role lies in

- advising on the EORTC patient involvement strategy
- advising on the format and content of EORTC communication with the lay audience
- guiding researchers and medical experts in involving patient partners at different stages of the studies
- co-developing programs for training courses for the lay audience
- offer mentorship to other patient partners.

Members of the EORTC Patient Panel assemble twice a year. Their work is supported by a medical oncologist and EORTC Patient relationship manager.

5.6 Training opportunities for patient partners

Every two years, EORTC organises a training course, EORTC Patient Days, aiming to provide cancer patients and their family members with a stimulating experience leading to a much better understanding of cancer, cancer treatments, and research. This course is conducted in English.

The EORTC Patient Days programme committee is composed of experienced patient advocates and EORTC experts whose mission is to encourage education for cancer patients and their family members and increase public awareness and understanding of clinical research.

5.7 Reimbursement of expenses

When attending group or study-related meetings, patient partners' travel and accommodation expenses are reimbursed by the respective group provided that the meeting attendance has been approved by the group chair and/or principal investigator and communicated to the EORTC HQ representative.

5.8 EORTC resources

Currently, patient involvement activities at EORTC are managed by one full-time employee.

6 Definitions

- **Patient partner**: an individual with lived experience of cancer, a family member of a cancer patient, caregiver, or a patient representative who helps to shape the research activities.
- **Patient advocate**: an individual usually working with a recognised (national) organisation (charity, support group), who brings insights from working with patients but may not be a patient themselves.
- **Patient involvement**: a process of co-production of research with patient partners. It differs from the term "patient participation" referring to individuals who voluntarily take part in clinical studies.
- **EORTC Patient Panel**: an advisory board of experienced patient partners whose goal is to provide patient perspective and work with EORTC to co-develop its patient involvement processes.
- **Independent Data Monitoring Committee (IDMC)**: an independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial. (ICH GCP E6(R2))
- **Protocol Review Committee (PRC):** an independent standing committee that will review a selection of proposed studies based on the submitted protocol synopsis and assess their scientific value.

7 References

- EU Regulations No 536/2014, Rec. 18 and Art. 29/6 ‘Informed consent’

8 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: 27 August 2024 | 11:28:17 CEST 457339F472784605806FBD4D54FBD7A4