

	<b>EORTC Guidelines and Expert Opinions</b>		
	Document owner	Executive Office	Version number
Effective date	2023-12-19	Identifier	POL019

## 1 Purpose

EORTC as a clinical research organisation needs to create a structure for the development and approval of documents that are published as recommendations. These documents are encouraged, as they increase the EORTC's visibility and quality of cancer care and should be published in a peer reviewed journal.

## 2 Scope

This policy applies to all EORTC guidelines, expert opinions and promotional material that are published as recommendations.

This policy does not apply to individual studies but to the recommendations dedicated to a specific clinical or methodological situation.

## 3 Policy statement

The forms of these recommendations need to comply with international references for level of evidence and be in compliance with EORTC missions.

## 4 Changes since last version

Process step	Changes since last version
NA	Update to reflect current organization chart. Removal of definitions.

## 5 Policy

Guidelines are usually referred to recommendations which are developed to assist clinicians in improving quality of care and patient outcomes. EORTC as a clinical research organisation does not issue, in principle, clinical practice guidelines and considers these are the remit of the professional societies or regulatory competent bodies. EORTC however may issue guidelines related to clinical research operation and methodology i.e., guidelines for time-to-event definitions. EORTC may as well join forces with other organizations for specific guidelines i.e., RECIST (Response Evaluation Criteria in Solid Tumors). Compliance with the criteria and levels of evidence recommended by the Center for Evidence Based Medicine (CEBM) is always recommended as applicable.

For certain pathologies (organ based), techniques, or treatment and/or diagnostic modalities, EORTC group(s) may produce documents presenting their views regarding a particular aspect of the disease management; such documents are called EORTC expert opinions. EORTC expert opinions are developed on behalf of EORTC group(s) to assist clinicians in improving quality of care and patient outcomes.

### 5.1 Expert review and board approval

The EORTC chief executive officer must be informed upfront of the preparation of EORTC guidelines, expert opinions, and promotional material.

EORTC guidelines are official EORTC documents requiring EORTC board approval. However, guidelines addressing methodology may fall in the remit of EORTC Headquarters and may not need board approval. Guideline proposals need to be assessed by the chief executive officer whether they need board approval or not. They are reviewed by external experts in the concerned topic involved in the guidelines. The external experts are proposed by the working group involved in producing the guidelines and subject to the approval of the EORTC board. The EORTC board may also propose external experts.

Once the guidelines have been reviewed by the external experts, they are then submitted to the EORTC board together with the comments of the external experts for final review and approval by the board.

Links (Digital Object Identifier (DOI) links) to approved EORTC guidelines are published on the EORTC website in the research tools section.

EORTC expert opinions produced by EORTC group(s) do require EORTC board approval. EORTC expert opinions should be reviewed by external experts in the field and approved by the steering committee of the concerned group prior to publication.

### 5.2 Funding

The EORTC recommends that EORTC guidelines and expert opinions be produced independently of industry support. If external funding/sponsorship from the pharmaceutical industry is needed, this should be provided by several companies rather than a single

sponsor. Sponsorship and funding sources are to be approved by the EORTC board prior to initiation of the project; external support should be disclosed in the manuscript.

Financial contributions from pharmaceutical industry companies should be deposited on the EORTC headquarters account, with expenses for travel and meetings being reimbursed from this account. All financial contributions received from pharmaceutical industry companies to produce EORTC guidelines or expert opinions shall be in the form of unrestricted educational grants.

Pharmaceutical industry companies providing unrestricted educational grants have a limited time to review the manuscript (30 days). They are not to comment on the guidelines themselves, but they may draw the attention of the authors on relevant published data that might not have been mentioned or reviewed. While the manuscript should not be written by a pharmaceutical industry employee, it is permitted to obtain the support of a medical writer from an independent communication agency.

### **5.3 Conflict of interest**

A conflict-of-interest statement must appear in the EORTC guidelines or expert opinions document as an appendix. The disclosure of conflict of interest must follow the EORTC policy on 'Conflict of Interest, Bribery and Confidentiality'. No employees of any pharmaceutical company can be involved as authors of EORTC guidelines or expert opinions, but if relevant, employees of the pharmaceutical company may be acknowledged.

## **5.4 Document requirements**

### **5.4.1 Disclaimer**

EORTC guidelines and expert opinions must include a disclaimer.

The model hereunder could serve as a basis.

*Disclaimer: These recommendations reflect the state of knowledge, current at the time of publication, on effective and appropriately validated data, as well as clinical consensus judgments when knowledge is lacking. The inevitable changes in the state of scientific information and technology mandate that periodic review, updating, and revisions can be needed. Guidelines/expert opinions users always are urged to seek out newer information that might impact the diagnostic and treatment recommendations contained within. These guidelines/ expert opinions do not apply to all patients and must be adapted and tailored to each individual patient. Proper use, adaptation modifications or decisions to disregard these or other guidelines, in whole or in part, are entirely the responsibility of the clinician who uses the guidelines/ expert opinions. Ultimately, healthcare professionals must make their own treatment decisions about care on a case-by-case basis, after consultation with their patients, using their clinical judgment, knowledge, and expertise. A guideline/expert opinion is not intended to take the place of physician or a researcher judgment in diagnosing and treatment of particular patients or in conducting specific research activities.*

*Guidelines/ experts opinions may not be complete or accurate. The EORTC and members of their boards, officers and employees disclaim all liability for the accuracy or completeness of a guideline/ expert opinion, and disclaim all warranties, express or implied to their incorrect use.*

## 5.4.2 Acknowledgement

EORTC guidelines and expert opinions must include an acknowledgment section which cites all unrestricted educational grants received.

## 5.4.3 Methodology

The coordinator or person responsible for the EORTC guidelines or expert opinions should prepare and include a section within the publication dedicated to “methodology for producing the guidelines and recommendations”. For each recommendation in a guideline, the level of scientific evidence and the grade of the recommendation must be indicated.

## 5.5 Periodic review

Periodic review of guidelines/ expert opinions is needed as new data or scientific evidence become available. A section must be included in the EORTC guidelines or expert opinions document stating the plans for periodic review and updating of the guidelines.

## 5.6 Promotional materials

Pharmaceutical industry companies wishing to use EORTC results, publications or presentations as promotional material should request an approval from the EORTC chief executive officer prior to dissemination.

## 6 Associated documents

Process step	Title	Identifier / location
Policy	Policy on Conflict of Interest, Bribery and Confidentiality	POL001
	EORTC Guidelines	<a href="https://www.eortc.org/guidelines/">https://www.eortc.org/guidelines/</a>

# 7 Signature

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

<b>Author</b>  Denis Lacombe  Chief Executive Officer	
<b>Approved &amp; authorized by</b>  Denis Lacombe  Chief Executive Officer  <i>On behalf of the Board</i>	