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Developing EORTC Guidelines, Expert Opinions, and the use of EORTC Results in Promotional Material on Cancer Care

POL019

Version 2.0

ALWAYS REFER TO THE EORTC INTERNET WEBSITE TO CHECK THE VALIDITY OF THIS DOCUMENT

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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 will increase the EORTC's visibility and quality of cancer care and should be published in a peer reviewed journal. The forms of these recommendations need to comply with international references for level of evidence and be in compliance with EORTC missions. This policy does not apply to individual studies but to the recommendations dedicated to a specific clinical or methodological situation.

2 DEFINITIONS

2.1 EORTC Guidelines

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.

EORTC Guidelines are official EORTC documents requiring EORTC Board approval. Recommendations in EORTC Guidelines should be assessed according to their level of scientific evidence and subsequently graded to balance the quality of that evidence against its benefits and burdens. Compliance with the criteria and levels of evidence recommended by the Center for Evidence Based medicine (CEBM) is always recommended as applicable. www.cebm.net/index.aspx?o=1025.

2.2 EORTC Expert Opinions

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.

The EORTC Director General must be informed in advance about Expert Opinions in preparation, and Expert Opinions produced by a specific pathology or modality oriented group should be approved by the Steering Committee of the concerned group.

2.3 Promotional Material

Promotional Material is any documents / tools provided by pharmaceutical industry using EORTC results to support recommendations for cancer care.

3 POLICY

- 1) The EORTC Director General must be informed upfront of the preparation of EORTC Guidelines, Expert Opinions, and Promotional Material.
- 2) 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 Director General 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 (DOI links) to approved EORTC Guidelines are published on the EORTC website:

www.eortc.org/investigators-area/guidelines .

3) 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.

4) 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.

5) Financial contributions from pharmaceutical industry companies should be deposited in 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 will be in the form of unrestricted educational grants.

6) Pharmaceutical industry companies providing unrestricted educational grants will 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 communications agency.

7) 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 (POL 001). There will be no employees of any pharmaceutical company involved as authors of EORTC Guidelines or Expert Opinions, but if relevant, employees of the pharmaceutical company may be acknowledged.

8) 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 will 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.

9) EORTC Guidelines and Expert Opinions must include an acknowledgment section which cites all unrestricted educational grants received.

10) 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.

11) 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.

12) Pharmaceutical industry companies wishing to use EORTC results, publications or presentations as promotional material should request an approval from the EORTC Director General prior to dissemination.

4 DOCUMENT HISTORY

Version number	Brief description of change	Author	Effective date
1.00	Initial release	Françoise Meunier	20 Jun 2008
1.01	Addition of levels of evidence for EORTC guidelines.	Françoise Meunier	26 Jun 2012
2.0	Updating EORTC responsibilities towards position statement for treatment recommendations	Denis Lacombe	24 Feb 2017