

EORTC POLICY FOR PRODUCING EORTC GUIDELINES/EXPERT OPINIONS/PROMOTIONAL MATERIAL ON CANCER CARE

The EORTC Board (October 12, 2007) agreed that there is a need to create a structure for the coordination and approval of documents that are published either as EORTC Guidelines or Expert Opinions (on behalf of the EORTC or an EORTC group). The content of those documents is under the responsibility of the EORTC Board.

Both types of documents are encouraged as they will increase the EORTC's visibility and quality of cancer care and should be considered for publication in the EJC.

A. Guidelines

Evidence based guidelines assist clinicians in improving quality of care and patient outcomes. The EORTC can contribute to this effort either by EORTC Guidelines which should be conceived and prepared according to rigorous scientific methodologies, similar to those of ASCO and ASH or other relevant established levels of evidence and grades of recommendations (for example for opportunistic infectious diseases occurring during cancer treatment).

Guidelines will be official EORTC documents requiring Board approval following a review by external experts and/or relevant PRC members, who are experts in the concerned topic involved in the guidelines.

The EORTC Executive Committee will have to approve the panel of experts reviewing the guidelines once they have been proposed by the working groups involved in producing the guidelines. The guidelines will then be circulated to the Board with the external Expert Opinions for approval.

B. Expert Opinions

For certain pathologies (organ based) an EORTC group may produce documents which should be called "Expert Opinions". Those documents would not need the Board's review and approval, however, the Executive Committee has to be informed in advance and therefore the Director General should be informed about Expert Opinions in preparation.

Expert Opinions produced by a specific or modality oriented group should follow a similar procedure with external review prior to publication; those Expert Opinions documents should be approved by the full Steering Committee of the concerned groups.

General Principles

- 1) The Board recommends that guidelines or expert opinions documents are produced preferably 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 Executive Committee prior to initiation of the project, external support should be disclosed in the manuscript.

- 2) For EORTC Guidelines, the support from pharmaceutical industry should be paid on the EORTC Headquarters account and the expenses to be covered for travel and meetings will be reimbursed from the EORTC Headquarters account. All support received from pharmaceutical industries to produce either EORTC Guidelines or Expert Opinions will be in the form of unrestricted educational grants.
- 3) The pharmaceutical industry providing those unrestricted educational grants will have a limited time to review the manuscript (4 weeks). They are not to comment on the recommendations given in the manuscript but may attract attention to any published data that might not have been mentioned or reviewed. While the manuscript should not be written by a pharmaceutical industry person, it is accepted to get the support of a medical writer from an independent communications agency.
- 4) A conflict of interest statement must appear for both documents as an appendix. The disclosure of conflict of interest statement should be similar to the one requested for publication in major journals such as JCO or the NEJM for example. There will be no employees of any pharmaceutical company involved as authors of either EORTC Guidelines or Expert Opinions produced by EORTC groups but if relevant, employees of the pharmaceutical company may be acknowledged.
- 5) For both types of documents (EORTC Guidelines or Expert Opinions), there is a need to establish a disclaimer. It is crucially important for many of oncological activities including the production of Treatment Guidelines and Expert Opinions.

The model hereunder could serve as a basis.

Disclaimer: These guidelines reflect the state of knowledge, current at the time of publication, on effective and appropriate care, 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. These guidelines do not apply to all patients, and each 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.

- 6) In both types of documents, an acknowledgment section will also have to be mentioned with appropriate acknowledgement to the unrestricted educational grants received.
- 7) The coordinator or responsible person for the EORTC Guidelines or Expert Opinions should also prepare and include a section within the publication dedicated to “methodology of producing the documents”.

Scientific and methodological rigor is crucial in Guideline development. Integrity and balance of the Guidelines are essential. There are clinical questions for which there is an absence of definitive evidence and therefore, consensus based statements will need to be provided as guidance to clinicians. Therefore, evidence based guidelines versus consensus based statements have to be clearly identified in all documents produced. Periodical review may be needed as new data or scientific evidence becomes available. Transparency in Guidelines/Expert Opinions development is also needed and those principles of transparency will be dealt with in an appropriate acknowledgement section, declaration of potential conflict of interest and financial relationship with industry.

C. Promotional Material

Pharmaceutical industry willing to use EORTC data, publication or presentations as promotional material should request an approval prior dissemination, from the EORTC group having published the guidelines/experts opinions or having made the presentations. Information should be provided to the EORTC Director General.