

		<h1>Publication Policy</h1>	
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## 1 Purpose

To define the EORTC policy regarding release and publication of all results from EORTC clinical studies and research projects.

This policy covers timing of release of results, authorship and acknowledgements rules for abstracts/presentations and peer-reviewed publications, and the process of review by EORTC Headquarters.

Compatible group-specific requirements or contractual agreements may complement the present policy when applicable.

## 2 Scope

The present policy applies to any form of publication or public release of results of EORTC clinical studies or research projects, not including disclosure to regulatory authorities.

Whenever EORTC participates to intergroup studies or research programs led by partner organisations, the publication rules are prospectively agreed and documented, and must be compatible with the present policy.

The development of EORTC Guidelines, expert opinions, and the use of EORTC results in promotional material on cancer care are covered in a separate EORTC policy (“Developing EORTC Guidelines, Expert Opinions, and the use of EORTC Results in Promotional Material on Cancer Care”).

The release of individual patient data for external research is covered in the data sharing policy.

## 3 Policy statement

The EORTC policy is to report results of all its research completely, accurately, objectively, and promptly, irrespective of the findings (positive or negative, statistically significant or not).

The publications must conform to the most recent relevant publication guidelines (CONSORT, CONSORT-PRO, STROBE, TRIPOD, etc., as appropriate; see [www.equator-network.org](http://www.equator-network.org))

Authorship follows the International Committee of Medical Journal Editors guidelines on authorship (<http://www.icmje.org/icmje-recommendations.pdf>). Contributors who do not fulfil the conditions for authorship are acknowledged.

Representatives from the for-profit industry do not generally co-author publications of EORTC clinical studies.

All publications that fall in the scope of the present policy must be reviewed and approved by EORTC Headquarters prior to submission to journal or congress or presentation.

The name “EORTC” must be clearly visible in the publications.

## 4 Changes since last version

Process step	Changes since last version
All	Supersedes Publication policy POL009 v 5.0
	Added measures towards timely publication of results. Clarifications throughout the text.

## 5 Disclosure and dissemination of results

### 5.1 General rule

The timing of analysis and disclosure of results must ensure that the following conditions are met before results are published.

1. The information needed to conduct the analysis generating the results is complete and accurate. In particular, the duration of follow-up in clinical studies must be sufficient to fulfil protocol requirements on analysis of study endpoints.
2. An unbiased and clear interpretation of these results is possible, at the light of the disclosed or already available results.
3. The disclosure of the results shall not jeopardize the future study conduct or cause bias in the future data collection regarding other research endpoints, if any.

The timing of disclosure of the primary and major secondary endpoints of clinical studies is specified in the study protocol. Typically, secondary efficacy endpoints are reported after reporting the primary efficacy endpoint. Any deviation from the plan specified in the protocol, such as premature disclosure of all or part of the efficacy study endpoints on all or a subset of patients, requires authorization by the study IDMC.

Directly ensuring from the above requirements:

- Intermediate results of multiple-stage phase II or phase III studies would not be publicly disseminated.
- Intermediate results of early phase studies (phase I, very early single arm phase II studies) may be published as soon as data completeness is guaranteed.

- Results of translational research of randomized studies may not be disclosed prior to the disclosure of the study final results when they report correlations with the study endpoint in all treatment arms. Likewise in single-arm studies, correlations with the study endpoint may not be disclosed.
- Secondary efficacy endpoints are not disclosed before primary endpoints.
- Interim reports regarding baseline information, treatment compliance and acute toxicity are authorized unless they are by themselves the study endpoints.
- Reporting during the study only on patient and baseline data accumulation to a study are authorized at any time.
- For full-length publications of results from clinical studies, a definitive version of the locked database and a consolidated statistical analysis report must be available.

## 5.2 Abstract publications of results

For abstract-form publications, condition 1 (in 5.1) may be modified to the set of all following 3 conditions:

- Top line results (draft version of the data analysis report) are available.
- The Headquarters study team has determined that inconsistencies and incomplete information in the database shall not affect the conclusions presented in the abstract.
- The database can be cleaned and locked in sufficient time to enable the preparation of the final data analysis report by the time of presentation.

If abstracts are prepared based on the modified conditions, the abstract must clearly stipulate that the results are not definitive and that definitive results shall be presented.

## 5.3 Press release

All press releases about EORTC studies must be prepared by the EORTC communications department.

If an external party undertakes to write such press releases about EORTC studies, it needs to be coordinated with and approved by the EORTC communications department ([communication@eortc.org](mailto:communication@eortc.org)).

Embargoes set by journals, congresses, or other media must be respected.

## 5.4 Publications by individual sites pertaining to patients entered in EORTC clinical studies

Investigators shall not independently publish site-specific results about the study endpoints until results of the whole study are published (or after one year following database lock if there is no publication). Deviations from this rule are authorized by the study IDMC. Exceptions to this rule may be the publication of case reports when these are explicitly authorized in the study protocol.

When publishing information about patients entered in an EORTC clinical study, care is taken to avoid disclosing information that may affect the interpretation or the conduct of the clinical study. To this aim, the proposed publication shall be submitted for review to EORTC headquarters in accordance with the review timelines described under section 8.1.

The EORTC headquarters team in charge of the study must be informed of intended publications.

## 6 Authorship and acknowledgements

For any study or research project, authorship rules must be agreed prospectively and documented in the study protocol or in the research documentation.

In particular, the research leader (principal study coordinator(s) of clinical studies, coordinator of additional research questions to clinical studies, and leader of research projects) must be clearly identified in the research protocol. The research leader directs the writing of the corresponding publication.

### 6.1 Responsibilities of first author

The first author of the publication is responsible for

- Identifying the co-authors of the publication agreeable to all parties involved in the research, in compliance with the present policy and further rules specified in the study protocol or research agreements. The headquarters review coordinator checks compliance of the proposed author list with the present policy.

#### **For full length articles:**

- Drafting the manuscript within 6 months of receipt of the data analysis report produced by the EORTC headquarters, in collaboration with EORTC scientific staff involved in the research (statistician and medical representative for clinical studies, translational research or quality-of-life staff, or else as appropriate)
  - Delays in dissemination of results should be avoided. In case a first draft of the manuscript is not available within this timeline, the Group Chair in collaboration with the involved EORTC scientific staff re-assigns the first author responsibility. The research leader is then given a place in the author list according to his/her contribution to the study and the applicable authorship rules.  
In case of a recurring delay, EORTC may assign the first author responsibility to an EORTC scientific staff member.
- Selecting the journal to which the manuscript shall be submitted, in agreement with co-authors, being aware that the European Journal of Cancer is the official journal of EORTC.
- Submitting the manuscript for review by all co-authors and to the headquarters representatives. Ensuring that all authors have seen and approved the final manuscript before submission.

- Collecting any signatures and disclosure forms requested by the journal.
- Submitting the final manuscript of the article to a peer-reviewed journal as corresponding author.
- Addressing all requests for revision by iterating the above steps until the manuscript is accepted for publication.
- Reviewing the proofs of publication and answering any "letter to the editor" that the publication may have raised.

**For abstracts:**

- Drafting the abstract and circulating it to the co-authors and at least one EORTC headquarters representative (EORTC statistician for clinical studies and EORTC scientific staff involved in the research). EORTC headquarters circulates the manuscript to all external partners of the research in accordance with any contractual agreements.
- Submitting the abstract onto the congress portal
- Informing the Headquarters of the outcome of the submission and, if accepted, the format of the presentation
- Preparing the material for the presentation in collaboration with EORTC headquarters
- Presenting at the conference
- Informing the EORTC headquarters of any planned press releases

**The contents of the publication must always be submitted to the EORTC headquarters for approval.**

## 6.2 Authorship on full length articles

EORTC follows the International Committee of Medical Journal Editors guidelines on authorship. All contributors who do not meet sufficient criteria for authorship are acknowledged in the publication.

The policy of EORTC is to recognize the scientific contribution of the largest possible number of contributors fulfilling the ICMJE guidelines through authorship on primary and/or secondary publications of its clinical studies and research projects, within the limits set by the journal to which the full-length article is submitted.

The following rules apply:

### 6.2.1 Primary publication of clinical studies

- The first author of publication of primary study results is the study coordinator who initiated the study design (being the research leader in this case). Other study coordinators are usually second, third or last author.

- For intergroup studies, at least one authorship position is granted to each contributing group.
- Authorship positions are granted to centres and groups contributing patients to the study on the basis of the number of patients contributing in the published research that they provided and are ordered by decreasing number. Authorship rules shall be specified upfront in the study protocol. Rules may specify minimum number of patients required to qualify as co-author and may attribute additional positions to sites recruiting beyond a specified large number of the patients. Contributing groups and sites select themselves the names of the representatives that appear on the publication.
- Scientific contributors to the trial such as but not limited to central pathologist, persons responsible for integral translational research components of the study (e.g., molecular characterization, genomic analysis), central image reviewer, quality of life specialists also qualify as co-authors as long as the service they provided was not provided in the frame of a paid service agreement.
- Representatives from the industry are generally not co-authors on publications of EORTC study results, except for scientists fulfilling one of the roles specified above. **Deviations from this rule must be authorized by the EORTC Board.**
- Authorship is granted to two to three scientists at EORTC headquarters who contributed to the study (typically, study statistician, medical representative, other scientist involved in the study). This condition does not apply to intergroup studies not led by EORTC.

### 6.2.2 Secondary publication of clinical studies

- The rules listed for primary publications under 6.2.1 generally apply. However, the first authorship (research leadership) may be delegated to another study contributor, in agreement with all parties involved in the study.
- To maximize the number of investigators from contributing sites who are granted authorship, contributors fulfilling the ICMJE conditions who could not co-author the primary publication should preferentially be selected to co-author secondary publications. When the publication pertains to a long-term update of a clinical trial, the clinicians who provided the follow-up information generally replace the initial contributors as author.
- Authorship is granted to two to three scientists at EORTC headquarters who contributed to the study.

### 6.2.3 Publication of research not included in the clinical study protocol

- The scientific leader of the research identified in the research protocol is the first author of the manuscript.

- Authorship is attributed to all scientists who contributed to the research according to the ICMJE guidelines.
- Further authorship is granted to the sites who contributed data, samples, or information that enabled the research (e.g., sites who contributed samples in a TR analysis, RT plans in an RTQA publication or HRQOL forms for an HRQOL publication)
- Authorship is granted to scientists at EORTC headquarters who contributed to the analysis and publication, if any.

### 6.3 Authorship on abstract publications

Although the general rules listed in 6.2 apply, the total number of co-authors allowed on abstract submissions may be limited. If this is the case, the list determined in 6.1 shall be modified as follows

- The study coordinator(s) retain authorship.
- One author from the EORTC headquarters is retained.
- The other co-authors are selected from the list of co-authors starting from the beginning of the list and retaining the maximum possible number of authors.

## 6.4 Acknowledgments

### 6.4.1 Contributors

All clinicians and scientists who contributed patient or data to the research, relevant EORTC headquarters staff, and members of study-specific oversight or review committees who contributed to the research but who are not listed as co-authors are acknowledged in the publication.

Representative(s) from the pharmaceutical companies and other partner organisations (e.g., data repositories) are acknowledged in the publication as per contractual agreements.

Patient representatives who were involved with the research are acknowledged for their contribution.

### 6.4.2 Funding bodies

Sources of funding for the clinical study or research (e.g., pharmaceutical companies, grant providers, financial support for fellowships) must be acknowledged in all related publications. The exact phrasing is supplied by the EORTC Headquarters during the review of the article.

For intergroup trials and other joint research ventures, any additional source of funding that supported partners' contribution to the research need to be identified and acknowledged.

Some journals require explicit statement regarding the role of the funding bodies. The following statement is expected to reflect the role accurately when the study is conducted independently and sponsored by EORTC: *"The funders had no role in study design, data*

*collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication”.*

## 6.5 Affiliation

### 6.5.1 Contributor who changed affiliation

Whenever a contributor changed institution during the study, that contributor is listed with the affiliation he/she had at the time of her participation to the research, with the mention “(now at [new affiliation])”.

### 6.5.2 Contributors from EORTC headquarters

Attribution of a publication to EORTC headquarters via search engines is dependent on the way an author lists their affiliation in the publication. All headquarter staff must be listed with the affiliation “EORTC Headquarters, Brussels, Belgium”, without mention of a specific department or group.

## 7 Data sharing statement

EORTC has a data sharing policy in place which should be referred to as follows

*“Data shall be shared according to the EORTC data release policy (<https://www.eortc.org/data-sharing/>)”.*

## 8 Review and approval of draft publication

All co-authors of publications must have reviewed and approved the manuscript.

Co-authors from the EORTC headquarters take care of the processing of the review within EORTC headquarters. If no EORTC staff co-authors the publication, publications are addressed to the author of the present policy.

Some EORTC groups require additional reviews by a group-specific review committee. Such rules must be adhered to when applicable.

Whenever collaborative groups are involved in a study, their review must comply with intergroup agreements. This review is coordinated by EORTC headquarters.

Whenever a pharmaceutical company sponsors the study, the publication review timelines are documented in the contract with the sponsor. According to the EORTC principles of independence, the final decision to submit the manuscript for publication remains with the EORTC.



## 8.1 Timelines for review of publications

The review from all co-authors and partners must conclude within 15 calendar days for abstracts and within 30 calendar days for full-length articles.

# 9 Publication of perspectives on EORTC clinical trials in European Journal of Cancer

Where a manuscript reporting the primary results of an EORTC clinical study is accepted for publication in another journal with a higher impact factor than that of the European Journal of Cancer, EORTC prepares and submits a perspective to the Journal, to be prepared according to the Journal's Guide for Authors (<http://www.ejcancer.com/content/authorinfo>), and submitted within one (1) month of the publication of the clinical study results. The editorial provides a summary of the clinical study and the impact of the results for the scientific discipline.

## 10 Definitions

- **Primary endpoint(s):** the outcome measure(s) identified as primary endpoint in the study protocol (or research project statistical analysis plan).
- **Secondary endpoint(s):** all other endpoints specified in the study protocol.
- **Publication:** any public release or dissemination of research results or disclosure of any confidential information, including but not limited to intellectual property, but not including disclosure to regulatory authorities. In this document, the terms “full-length publication” include the full range of formats published in peer-reviewed journals (for example, original research articles, short reports, reviews, or letters to the editor) and “abstract publication” includes abstracts, posters, and slides for oral presentations at scientific congresses.
- **Independent data monitoring committee (IDMC):** An independent group of individuals with pertinent expertise 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.
- **Research leader:** can be the principal study coordinator(s) of clinical studies, coordinator of additional research questions to clinical studies, and leader of research projects. He/she must be clearly identified in the research protocol.
- **Headquarters review coordinator:** the scientist at EORTC headquarters who is the main leader on the research

## 11 References

- International Committee of Medical Journal Editors (Vancouver Group) - Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/>)

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- Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP3). Battisti WP, Wager E, Baltzer L, et al. ; International Society for Medical Publication Professionals. Ann Intern Med. 2015 Sep 15;163(6):461-4. doi: 10.7326/M15-0288 ([www.ismpp.org/GPP3](http://www.ismpp.org/GPP3))

## 12 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>  Saskia Litière  Head of statistics	
<b>Approved &amp; authorized by</b>  Denis Lacombe  Chief executive officer	