EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

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Publication Policy

POL009
Version 5.0

ALWAYS REFER TO THE INTRANET
TO CHECK THE VALIDITY OF THIS DOCUMENT

Name/Title	Signature/Date
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Authorized by: *Director General on behalf of the Board* Denis Lacombe	

Signature Statement

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"I regard my electronic signature as legally binding equivalent to my handwritten signatures"

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1 PURPOSE

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

This policy covers timing of release of results, authorship and acknowledgements rules for both abstracts/presentations and peer reviewed publications as well as 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 publications and/or public release of results of EORTC clinical studies or research projects.

Whenever EORTC participates to intergroup studies or research programs led by partner organisations, the publication policy is prospectively agreed and documented, and must be compatible with the rules set forth in 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 (POL019).

The publication of individual patient data is covered in the data sharing policy (POL008).

3 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.
- **Ancillary studies (also called correlative studies):** Separate research that is attached to a clinical study protocol but addresses different objectives than the study protocol itself.
- **Publication**: any public release or dissemination of study results or disclosure of any confidential information, including but not limited to intellectual property. 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 ancillary research questions to clinical studies, and leader of research projects.
  He/she must be clearly identified in the research protocol.
  The research leader will lead the writing of the corresponding publication.

4 POLICY

The EORTC policy is to report results of all its research in a complete, accurate, balanced, and timely manner, irrespective of the findings (both positive and 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**)**

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 condition for authorship are acknowledged.

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

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

The name "EORTC" must be clearly visible in the publications.

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. The data analyst (e.g. statistician, bioinformatician, data scientist) is best able to inform if the conditions are met.

1. The information needed to conduct the analysis generating the results is complete and accurate. In particular, for clinical studies follow-up duration 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 will 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 protocol specified plan (such as premature disclosure of all or part of the efficacy study endpoints on all or a subset of patients) require authorization by the study IDMC.

Directly ensuing from the above requirements:

- Intermediate results of multiple-stage phase II or phase III studies would not be publically 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 studies to randomized studies would not be disclosed prior to the disclosure of the study final results when they report correlations with the study endpoint in both treatments. Likewise in single arm studies, correlations with the study endpoint could not be disclosed
- Secondary efficacy endpoints are not disclosed prior to primary endpoints
- Interim reports regarding baseline information, treatment compliance and acute toxicity are authorized unless they are by themselves the study endpoints.
- The Trials in Progress reporting only on patient and baseline data accumulation to a study are authorized at any time.

Disclosure of results of research projects is conditioned solely by the availability of the data and corresponding data analysis reports.

For full-length publications of results clinical studies, condition 1 requires that a definitive version of the locked database and a consolidated statistical analysis report 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 and
- the Headquarters study team has determined that inconsistencies and incomplete information in the database will 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 on the basis of the modified conditions, the abstract must clearly stipulate that the results are not definitive and that definitive results will be presented.

5.3 Press release

All press releases about EORTC studies should be compiled by the EORTC Communication 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 communication department (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 will 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 reporting information about patients entered in an EORTC clinical study in a publication, care will be taken to avoid disclosing information that may affect the interpretation or the conduct of the clinical study. To this aim, the proposed publication will be submitted for review to EORTC 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 ancillary research questions to clinical studies, and leader of research projects) must be clearly identified in the research protocol. The research leader will lead 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 HQ review coordinator will check 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, TR or HRQOL staff, or else as appropriate)
- Selecting the journal to which the manuscript will be submitted, in accordance with co-authors (see paragraph …) -- please be aware that the EJC 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 prior to 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 (medical representative for clinical studies, TR or HRQOL staff, or else as appropriate). (The EORTC Headquarter project manager and/or COM will circulate the manuscript to all external partners of the research or clinical study in accordance to 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 the EORTC Headquarter staff
- Presenting at the conference
- Informing the EORTC of any planned press releases

The contents of the publication must always be prospectively 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 will be 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 project, within the limits of number of co-authors 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 (= 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 centres recruiting beyond a specified large number of the patients. Contributing groups and centers 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.**
- Two to three scientific headquarters staff 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 lead by EORTC.

6.2.2 Secondary publication of clinical studies (secondary endpoints, long term updates)

- 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 centers 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 will generally replace the initial contributors as author.
- Two to three scientific headquarters staff who contributed to the study

6.2.3 Ancillary research (including quality of life, QART, translational research…) and research projects

- The scientific leader of the research identified in the study protocol is the first author of the manuscript
- Authorship is attributed to all scientists who contributed to the research as per ICMJE
- Further authorship is granted to the centers who contributed the data / samples / information that enabled the research (e.g. centers who contributed samples in a TR analysis, RT plans in an RTQA publication or HRQOL forms for an HRQOL publication …)
- EORTC Headquarters scientific staff who contributed to the analysis and publication, if any, are also co-authors.

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 will be modified as follows

- The study coordinator(s) retain authorship
- One author from the EORTC Headquarter 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 who contributed patient or data to the research and the scientists (incl. HQ staff), members of study-specific oversight or review committees who contributed to the research but who are not listed as co-author of the publication 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…) must be acknowledged in all related publications. Likewise, grants supporting the contribution of EORTC fellows or Headquarter staff must be acknowledged in the publication. The exact phrasing will be 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 the partner's contribution to the research need to be identified and acknowledged as well.

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 in the course of 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 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 will be shared according to the EORTC data release policy (*https://www.eortc.org/data-sharing/*)"*.

8 REVIEW AND APPROVAL OF DRAFT PUBLICATIONS

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

All publications must be reviewed and approved by the EORTC headquarters staff co-authoring the publication. This person will take care of the processing of the review within EORTC headquarter. 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 group specific review committee. Such rules must be adhered to when applicable.

Whenever an academic third party is involved in a study (collaborative group), review by the academic third parties must comply with intergroup agreements. This review is coordinated by the EORTC Headquarters Project Manager or COM.

Whenever a pharmaceutical company supports the study, the publication review timelines will be documented in the contract with the sponsor. According to the EORTC principles of independence, the final decision to submit the manuscript for publication will remain with the EORTC.

8.1 Timelines for review of publications

A delay is allowed to perform the review and to feed-back comments.

The following maximum delays are envisaged for the review of the publications:

- Abstracts: 15 calendar days
- Full-length articles: 30 calendar days

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, the EORTC will prepare and submit 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 paper. The editorial will provide a precis of the clinical study and the impact of the results for the scientific discipline.

10 REFERENCES

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

11 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.0	Initial Release (Authorship)	Patrick Therasse Richard Sylvester	October 2001
2.0	Modification to add the section on Release of results.	Laurence Collette Richard Sylvester Patrick Therasse	October 2002
2.1	Clarification of the rules for the release of data from side studies in phase II and phase III. Addition of the chapter regarding the timing of the publications. Addition of the chapter on the NCI grants/sources of funding. "Medical Advisor" changed into "Coordinating Physician".	Laurence Collette Richard Sylvester Patrick Therasse	02/09/2003
2.2	Addition to section 4.1 of a mention of "EORTC" in titles of major publications, in authorship list if not possible	Laurence Collette	09/04/2004
2.3	Revamping of the introductory section 1. Expansion of section 6 to cover more sources of funding (TR funds, fellowship etc..) Clarification of section 4.1 pertaining to the list of study participants. Addition of section 4.3 pertaining to secondary study publications. Removal of references to HE unit in section 4.5. Other non-substantial editing of the text.	Laurence Collette	20/01/2005

2.4	Addition of the acknowledgement of the National Cancer Leagues	Laurence Collette	25/11/2005
2.5	Addition of definition of DM, CP, Stat, SC and DC Team. Addition of the section 4.7 dealing with authorship for Data Center staff member who left the DC	Laurence Collette	06/09/2006
3.0	Simplification of the text: sections 4.5 (HE) and 4.6 (meta-analyses) were deleted section 4.7 was moved to the new ST-007-WIN-01, definitions were deleted, a new chapter "Policy" and a new chapter "Responsibilities of the first author" were added. Other chapters were renumbered. The definitions were simplified.	Laurence Collette	02/03/2009
4.0	Integration of the "research on biological material". Clarification of the rules for phase I studies (need for database lock). Clarification of the section on release of results pertaining to prognostic factors involving only the reference arm of phase III studies.	Laurence Collette	14/10/2010
4.1	New chapter 2 "Scope" added, to clarify position with respect to publications by individual centers about their own patients. Introduction of chapter 4 about intergroup studies moved into new chapter 2. Paragraph added to chapter 4 allowing submission of abstracts based on draft version of analysis for phase III reports when no late-breaking abstract submission is possible. Clarification of authorship for coordinators of integrated TR or imaging or central path review.	Laurence Collette	29/11/2011
4.02	Clarification of section 2.2 and 8.1.4	Laurence Collette	19/03/2012
4.2	EORTC Executive Committee updated into EORTC Board	Laurence Collette	06/03/2015
5.0	Major modification to cover all research conducted by EORTC	Laurence Collette	23 Nov 2020