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Disclosure of Results and Publication Policy

POL009

Version 4.2

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

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

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1 PURPOSE

To describe the policy of EORTC regarding the publications of results from the EORTC study protocols with respect to the timing of the release of results from the EORTC central database, publication in a peer-reviewed journal, the authorship rules, the rules for acknowledging contributors to the study and sources of funding and the review process within the EORTC Headquarters.

To define for each type of study the exact conditions under which publication of safety data, translational research endpoints or results of ancillary studies attached to the protocol may be published or presented to the medical community before the final results of the study have been published, and to describe the associated authorization process.

To define the terms and conditions for the publication of research results that arise from the use of biological material from EORTC clinical studies. All recipients of patient material from EORTC studies must therefore comply with the present policy.

The present policy however does not define a general EORTC rule for selecting authors among the clinical study contributors, as each EORTC group has defined its own set of rules regarding this aspect. The present policy rather addresses specific problems (relation between Headquarters staff and EORTC Groups) or situations (i.e. intergroup, meta-analysis). It also proposes a clear statement with regards to the acknowledgment of contributors and sources of funding.

2 SCOPE

The present policy is applicable to all EORTC studies and to Intergroup trials for which EORTC is the coordinating group.

2.1 Intergroup studies

Intergroup studies coordinated by a non-EORTC Group will usually follow the policy of the Coordinating group and are prospectively specified in the protocol specific Intergoup Agreement. This agreement should enforce that any publication of Intergroup study results that involve data from EORTC patients should be prospectively agreed.

2.2 Publications by individual sites

Centers or investigators will not independently publish their own site-specific results using the study data from the patients that they entered in this study before the EORTC multi-center paper is published according to the present policy.

However, (i) after such joint publication of the study results has been made or (ii) if no joint publication of the study results (at minimum in abstract form) has been made within 12 months of the study database lock or (iii) if the study has been terminated prior to its completion and no joint publication is to be made, participating centers and investigators shall have the right to publish its site-specific study results according to the following provisions:

- The center or investigator shall submit the draft of the intended publication to the Head of the EORTC Statistics Department for review and comment at least 30 days prior to submission to a publisher or disclosure to any third party
- If within this 30 day period the Head of the EORTC Statistics Department notifies the investigator in writing that EORTC reasonably believes that prior to such publication or presentation it must take action

to protect its intellectual property interests, such as the filing of a patent application claiming an invention, the investigator shall either delay such publication or presentation for an additional 60 days or until the foregoing action(s) have been taken, whichever occurs first; or if the investigator is unwilling to delay the publication or presentation, the investigator will remove from the publication or presentation the information which the Head of the EORTC Statistics Department has specified it reasonably believes would jeopardize its intellectual property interests.

♦ The participating centers or investigator shall properly acknowledge EORTC in all publications or presentations resulting from the performance of the Study.

3 DEFINITIONS

- **Primary endpoint(s):** the outcome measure(s) that forms the basis of the statistical design and sample size of the study. In most protocols, one single endpoint is specified as primary endpoint.
- **Secondary endpoint(s):** all other endpoints of the protocol.
- **Study maturity:** a study is considered mature for analysis when the criteria specified in the protocol for the analysis of the primary endpoint(s) has been reached. This criteria is typically expressed in terms of observed number of events for phase III studies with time to event endpoints, or number of patients assessed for the primary study endpoint (for phase I and II studies and feasibility studies)
- **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. These may be translational research studies planned within a clinical study protocol, quality assurance studies, prognostic or predictive factor analyses, pathology review studies or other.
- **EORTC endorsed translational research project:** translational research project involving patient biological material from an EORTC study that was approved by one of the official EORTC bodies (EORTC Protocol Review Committee, EORTC Board, EORTC Translational Research Advisory Committee)
- **Publication**: any public release or dissemination of study results (abstracts, oral presentations, posters, full length article, chapters in books, press release) or disclosure of any confidential information, including but not limited to intellectual property.
- **IDMC:** EORTC Independent Data Monitoring Committee, an independent committee of clinicians and Statisticians whose task is to review the status of a clinical study and make recommendations to the clinical research group concerning the study's continuation, modification and/or publication

4 POLICY

The results of all EORTC studies and all research results arising from the use of biological material from EORTC clinical studies are published, irrespective of the findings (both positive and negative, statistically significant or not). These results should be published in appropriate scientific journals, presented or disclosed in a manner that fairly reflects the evidence supported by the results.

The publications conform to the CONSORT guidelines and to the International Committee of Medical Journal Editors guidelines on authorship.

Without any exception, all publications of results related to EORTC studies (protocol endpoints, ancillary research, translational research on biological material from EORTC studies or any other) must be submitted to the EORTC Headquarters for review prior to their submission to a journal, a congress or any presentation. The name “EORTC” must be visible in the publication's header of publications clinical study results and ancillary research to EORTC protocols conducted by EORTC members.

RESPONSIBILITIES OF THE FIRST AUTHOR OF A FULL-LENGTH ARTICLE

The first author of a full-length article is responsible for;

- Writing a first draft manuscript of the full-length article, within 6 months of receiving the corresponding Analysis Report produced by the EORTC Headquarters and sending it to the EORTC Study Statistician for review and approval by the EORTC Headquarters, and to all co-authors. Ensuring that all authors have seen and approved the final manuscript prior to submission
- Submitting the final manuscript of the article to a peer-reviewed journal once it has been approved by all-co-authors and EORTC Headquarters, until is it accepted for publication.
- Reviewing the proofs of publication and answering any "letter to the editor" that the publication may have raised.
- The Study Coordinator is usually the first author of the primary study publication. However, if the study coordinator fails to meet the above specified 6-month timeline for writing the draft manuscript, a replacement may be designated by the EORTC Group

5 RELEASE OF EORTC STUDY RESULTS

5.1 Phase III studies

The results of EORTC phase III studies pertaining to the primary endpoint and to the secondary efficacy study endpoints are not disseminated or published until the study data are mature for the final analysis of the primary study endpoint (as "end of study" as defined by the protocol), unless it is authorized by an Independent Data Monitoring Committee (IDMC).

However, for the purpose of submission of abstracts to congresses that do not allow late-breaking abstract submissions, a draft version of the analysis report may be generated, if EORTC Headquarters team determines, prior to the abstract submission, that the inconsistencies remaining in the database will not affect the conclusions of the study, and that the database can be cleaned and locked in sufficient time to enable the preparation of the final statistical report by the time of presentation. In this case, the abstract should clearly stipulate that the results are not definitive and that definitive results will be presented at the congress.

In general, publication of results before the end of the study must be authorized by an IDMC, with the exception of the items listed below, that may be authorized by the Headquarters Clinical Research Physician and Statistician in charge of the study:

5.1.1 Toxicity and treatment compliance

Toxicity data and data relating to treatment compliance may be published before the publication of the primary endpoint of the study, provided

- 1) the follow-up is long enough* to guarantee that reliable information on those aspects of the treatment is available and

- 2) there is no direct relationship between toxicity, treatment compliance or treatment duration and efficacy endpoints. *Guidelines for adequate duration of follow-up

** For a publication on late side effects, a median follow-up equal to the median expected time to occurrence of the side effects is mandatory. For acute toxicity data, a minimum follow-up of 3 months after the end of the treatment is required for all patients. For data pertaining to the compliance and feasibility of the treatment, all patients must have finished treatment.*

Although not recommended, in very large studies (>1000) the publication may be restricted to a large enough subset of patients selected on the basis of objective pre-randomization criteria (entry date, institution, …).

5.1.2 Quality Assurance/Quality Control

Protocol-specific quality programs may be separately published at any time of the recruitment or follow-up period provided they do not relate to any efficacy endpoint of the study.

5.1.3 Quality of life results

These results shall not be published until ahead of the primary study endpoint. This is to allow their interpretation in light of the therapeutic efficacy of the randomized treatments.

5.1.4 Ancillary studies

The development of predictive models or of prognostic models involving the experimental treatment arm, surrogate marker studies and outcome research studies shall not be performed or published before the data are mature for the primary study endpoint, as these directly relate to the study endpoints and/or treatment comparison

Results of translational research studies (on baseline or follow-up material) that are part of the clinical study protocol may be published before the study data is mature for the primary study endpoint, provided the data maturity is sufficient to carry out the planned ancillary studies; and provided they do not disclose relation to endpoint by randomized treatment (e.g. studies involving only patients in the reference arm of the study). If they do not fulfill either condition, their publication is subject to authorization by the IDMC.

5.2 Phase II studies

Results of EORTC phase II studies are not publicly disseminated or published until the study data are mature for the final analysis of the primary study endpoint(s) (as defined by the protocol).

However, for the purpose of submission of abstracts to congresses, a draft version of the analysis report may be generated, if EORTC Headquarters team determines, prior to the abstract submission, that the inconsistencies remaining in the database will not affect the conclusions of the study, and that the database can be cleaned and locked in sufficient time to enable the preparation of the final statistical report by the time of presentation. In this case, the abstract should clearly stipulate that the results are not definitive and that definitive results will be presented at the congress.

In addition, preliminary results may be confidentially disclosed to a restricted committee for the purpose of designing a follow-up study.

In multi-stage studies, the study maturity is defined on the basis of the last planned stage of the study. No data are released after intermediate stages, unless the conditions for ending the study specified in the study protocol are met.

For parallel phase II studies (i.e. phase II that are built as a series of independent phase II study in a single protocol), data maturity is defined separately for each cohort in the study protocol, thus a separate publication pertaining to that cohort is allowed.

Phase II-III studies and feasibility/phase III studies, results of the phase II or feasibility part may be released pending the conditions for data maturity for that part of the study are met. However, the primary endpoint of the phase III can never be released before the conditions specified for phase III are met. The published results will report only on those patients entered during the corresponding phase of the study. Once the study is in its phase III phase, the rules specified for phase III apply.

The publication of the results of ancillary studies (e.g. translational research) is authorized at any time provided they do not mention the primary study endpoint (usually response). Otherwise, they are subject to authorization by the IDMC.

5.3 Phase I studies

The interim publication of study results is authorized at any time during the course of the study. However, the data analysis needed for any such publication(s) is subject to the condition that the database can be cleaned and locked in sufficient time to enable the preparation of the data analysis report needed for the publication.

6 TIMING OF PREPARATION OF PUBLICATIONS

It is the responsibility of the Study Coordinator or first author of a publication to submit a draft manuscript of the full-length article within maximum 6 months of the issue of the corresponding statistical analysis report by the EORTC Headquarters.

It is customary to present the study results to the EORTC Group before the data are presented at international congresses.

7 REVIEW AND APPROVAL OF DRAFT PUBLICATIONS

The first author is responsible for ensuring that all co-authors have seen and approved the final version of the publication prior to submission.

7.1 Clinical study results and ancillary research

All publications reporting results of EORTC studies must be reviewed and approved by the EORTC Statistician and Clinical Research Physician in charge of the study.
All publications reporting results of EORTC studies must be reviewed and approved by the Study Coordinator(s).

Depending on the EORTC Group statutes, selected or all members of the Group Executive/Steering committee must be informed of all publications.

All co-authors review and approve the manuscript s before their submission.

Whenever an academic third party is involved in a study (collaborative group), an intergroup agreement may further detail the process of submission of the draft manuscript for review by the academic third party. The communication with the academic third parties is made via the EORTC Headquarters Project Manager.

Whenever a pharmaceutical company supports the study, it will be offered the possibility to review and comment on the manuscript. However, according to the EORTC principles of independence, the final decision to submit the manuscript for publication will remain with the EORTC.

7.2 Research on biological material collected in EORTC studies

For research that was prospectively defined as one of the objectives of an EORTC study protocol, for translational research projects for which the statistical analysis was produced at the EORTC Headquarters and for translational research projects that were submitted through the EORTC External Research Project procedure (EORTC POL008) by EORTC members, the review process specified in chapter 7.2 applies and the Head of the EORTC Translational Research Unit must be informed of the publication.

For translational research projects that were submitted through EORTC External Research Project procedure (EORTC POL008) by non EORTC members, the review process specified in POL008 applies, and chapters 7 and chapter 8 of this policy are also super-seeded by the terms agreed with POL008.

In addition, for all publications of results that were obtained using biological material from EORTC patients, the terms of the EORTC policies covering biological material collection and bio-banking apply.

7.3 Timelines for review of manuscript

A maximum delay is allowed to the co-authors to perform their review and to feed-back their comments.

This delay is prospectively agreed in the study specific contracts with pharmaceutical companies when such company financially supports the trial, or in the intergroup agreement, for intergroup collaboration.

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

- Abstracts: a maximum of 7 calendar days
- Full-length articles: a maximum of one month

8 STUDY AUTHORSHIP

In accordance with the International Committee of Medical Journal Editors, each author on an EORTC publication should have participated sufficiently in the work to take public responsibility for the content.

All other contributors (clinicians, pathologists, …) who do not meet sufficient criteria for authorship will be acknowledged in the publication

8.1 Publication of the primary study results (primary endpoint)

8.1.1 Authors from the EORTC Groups

The first author of publication of primary study results is the Study Coordinator who initiated the study design. Other Study Coordinators are usually second, third or last author. Coordinators of integrated translational research components of the study (e.g. molecular characterization, pathology review, or imaging that form part of the clinical trial design (e.g. biomarkers/imaging markers used in stratification, randomization or clinical trial endpoints) or pathologists responsible for the central pathology review that is part of the study also qualify as co-author. Further co-author positions are attributed to the EORTC members who contributed most patients to the study, according to the EORTC Group specific Statutes.

8.1.2 Authors from the EORTC Headquarters

Two EORTC Headquarters representatives are co-authors. These two co-authors will usually be the Statistician and the Clinical Research Physician who were in charge of and contributed to the study of the group. Under specific circumstances either the Statistician or the Clinical Research Physician can be substituted as co-author and replaced by a statistically or medically qualified person (fellows, clinical coordinators..).

8.1.3 Authors from Quality of Life Group/Quality of Life Department, when applicable

Whenever Health Related Quality of Life (HRQOL) is a secondary endpoint and is not the subject of a separate paper but HRQOL results are included in the primary study publication, the EORTC Group member who was leading the design and interpretation of the HRQOL part of the study is co-author on the primary publication, or alternatively, if no such person is available within the EORTC Group, a representative from the EORTC Headquarters' Quality of Life Department is co-author.

8.1.4 Authors from pharmaceutical companies in EORTC studies supported (in part or in full) by pharmaceutical companies

Representatives from the industry are generally not co-authors on publications of EORTC study results. Their scientific contribution in name may be acknowledged with that of other scientific contributors to reflect their active scientific contribution to the study. This should be discussed and agreed upon unanimously between EORTC and the pharmaceutical company.

Deviations from this rule must be agreed by the EORTC Board.

8.1.5 Authors from collaborative groups in intergroup studies with non-EORTC groups

The protocol specific "Intergroup Agreement" should prospectively specify the authorship policy agreed between the participating groups.

EORTC's principles vis-à-vis authorship in Intergroup studies are as follows:

- The first author on the publication of Intergroup studies is the Study Coordinator from the Coordinating Group.
- At least one author position will be attributed to each participating Group that contributed patients to the study.
- For additional co-authors or for a fixed total number of co-authors, the number of co-authors from a given Group is proportionate to the total number of patients that the Group contributed to the study.
- In addition, two representatives from the coordinating Data Center should be included as co-authors.
- Other rules regarding acknowledgement and visibility of "EORTC" in the title also apply.

8.2 Other publications (secondary endpoints, ancillary studies…)

The person who took the lead in conducting the ancillary study or research project is the first author of the publication. EORTC Headquarters' staff who contributed to the analysis and publication, if any, are also co-

authors. Other co-authors are selected amongst the other scientific contributors to the research project and EORTC members who contributed patient and data to the study.

The list of co-authors must be approved by the following parties: Study steering committee, if it exists, Executive Committee of the EORTC Group(s) who conducted the study otherwise

Whenever HRQOL is a secondary study endpoint which is the subject of separate publication, the first author of that publication will preferably be the person who took the lead on the design and interpretation of the HRQOL part of the study. Whenever no such person is available within the EORTC Group, the paper will be written by personnel from the EORTC Headquarters, usually from the Quality of Life Department. Co-authors will include at least representative from the EORTC Quality of Life Department, the Study Coordinator, and the EORTC Statistician who performed the statistical analysis of the HRQOL data.

9 ACKNOWLEDGEMENTS IN FULL-LENGTH ARTICLES

The acknowledgements will be supplied by the EORTC Headquarters during the review of the article that report results linked to clinical data of EORTC studies.

9.1 Contributors to the study

ALL EORTC members who contributed patients to the study (i.e. clinicians) or contributed scientifically to the study (i.e. pathologists, collaborators from the same institutions, ..) are acknowledged in the publication. The acknowledgement list should include the name of all participating institutions and the name of the clinicians and other scientists involved with the study at that institution. Whenever a study participant has moved from one institution to another in the course of the study, that participant is listed with the institution to which he/she was affiliated at the time of starting his/her participation to the study, with the mention "(now at (new affiliation))"

EORTC Headquarters staff that made a substantial scientific contribution to the study but are not co-authors should be mentioned in the acknowledgement section (i.e. data managers, monitors, project managers fellows…).

When appropriate, and following the rules prospectively agreed representative(s) from the pharmaceutical company(ies) supporting the study financially will also be acknowledged in the publication.

9.2 Sources of funding and supporting bodies

Sources of funding and supporting bodies will be acknowledged in the publications. The exact phrasing will be supplied by the EORTC statistician in charge of the study.

10 REFERENCES

- International Committee of Medical Journal Editors (Vancouver Group) - Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org/)
- Revised 2010 CONSORT statement (http://www.consort-statement.org/consort-statement)

11 DOCUMENT HISTORY

Version number	Brief description of change	Author	Issue Date
1.0	Initial Release (Authorship)	Patrick Therasse Richard Sylvester	Oct 2001
2.0	Modification to add the section on Release of results	Laurence Collette Richard Sylvester PatrickTherasse	Oct 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 PatrickTherasse	02 Sep 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 Apr 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 Jan 2005
2.4	Addition of the acknowledgement of the National Cancer Leagues	Laurence Collette	25 Nov 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 Sep 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	Laurence Collette	02 Mar 2009

	chapter "Responsibilities of the first author" were added. Other chapters were renumbered. The definitions were simplified.		
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 Oct 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 Nov 2011
4.02	Clarification of section 2.2 and 8.1.4	Laurence Collette	19 Mar 2012
4.2	EORTC Executive Committee updated into EORTC Board.	Laurence Collette	06 Mar 2015
4.2	No change	Laurence Collette	05 Mar 2018