



PUBLICATIONS GUIDELINES FOR RETROSPECTIVE STUDIES, NON-INTERVENTIONAL PROSPECTIVE TRIALS, AND PROSPECTIVE CLINICAL TRIALS OF THE EUROPEAN GROUP FOR BLOOD AND BONE MARROW TRANSPLANTATION. VERSION JUNE/2012

Publications in peer-reviewed journals represent one of the most important indicators of the scientific contribution of the European Society of Blood and Marrow Transplantation (EBMT) to the field of stem cell transplantation and cell therapy. Thus, authorship on scientific manuscripts is an important recognition of contributions of individuals for the benefit of EBMT prospective clinical trials or retrospective studies.

In this sense, contribution of distinct individuals to the outcome of scientific analysis needs to be properly acknowledged.

General Guidelines

- **Authorship on scientific manuscripts is an important recognition of contributions of individuals for the benefit of EBMT prospective or retrospective studies.** Some journals have guidelines limiting the number of authors allowed on a publication. Such rules dichotomy can eventually create some conflict of interest. In general, manuscripts should aim to incorporate as many authors as possible as long as they have significantly contributed to the manuscript/ study according to international rules.

- **Principles for authorship regarding a specific study should be discussed and decided beforehand** and clearly documented in the study protocol or study specific publication plan. The “Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship” (http://www.icmje.org/ethical_1author.html) has to be considered as the basis of the EBMT Publication Guidelines. Any doubt / conflict should in principle be resolved on the basis of the above mentioned international rules.
- **For joint studies with partner organizations (for instance, CIBMTR), authorship should** fairly reflect the individual contributions of the participating organizations and should be discussed and agreed on beforehand
- **A «writing» committee (or its equivalent) should usually be appointed for the preparation of an EBMT study manuscript**
- **All authors should have had the opportunity to review an advanced version of the manuscript prior to submission**
- **All investigators in prospective studies** as well as all **contributors to retrospective studies should be listed in an appendix** to the manuscript in an order that reflects the number of patients included in the study. In case there are several centers with the same number of patients appearing in the Appendix, they will be listed in alphabetical order
- Manuscripts published on behalf of the EBMT **must have in the title: on behalf of the EBMT / on behalf of the xx Working Party of the EBMT**. If the title seems too long or is not accepted to a specific journal rules, this statement can be included after the name of the last author. This will ensure a proper scientific visibility of the EBMT. In all cases, the best efforts should be made to highlight the role of the EBMT.

Guidelines for Publication of Retrospective Analyses

Retrospective analyses represent > 90% of the scientific output of EBMT. The careful design of the study as well as involvement of relevant people at early stages of its development will ensure the final success of the publication.

Writing Committee

- The writing committee should be invited before start of the study and should be composed by:
 - *Investigator developing the scientific idea, principal investigator (PI)*
 - *WP chairperson*
 - *Study coordinator / Study statistician*
 - *Subcommittee chair(s), if appropriate*
 - *Additional members of the WP, if significant contributions made that qualify for authorship*
 - *Representatives of centres that potentially will contribute the largest patient numbers to the study according to the pre-study feasibility check will be invited to join the Writing committee before the start of the study*
 - *Representatives from countries / Study groups that have many potential contributors to the study, who could promote the study within the National / Study Group community (“National Coordinator”)*

Authorship Position in the Manuscript and Specific Considerations

- **First author.** PI of the manuscript. Eventually two authors could share the first position. This situation should also be discussed and agreed on beforehand
- **Last position.** Present WP Chair unless the WP chair grants senior authorship to somebody else (e.g. subcommittee chair). If this is the case, the WP Chair could be in the one before the last position
 - *If the study was initiated under the supervision of a prior WP chair, the decision of the last position will depend on how developed was the study at the time of change of WP chairpersonship. In any case, this situation should be agreed between the leaving and entering Chairs. Points to consider:*

- Level of development of the study at the time of WP chair change
 - If data collection finished and manuscript in the phase of statistical analysis / writing, last author could be the prior WP Chair. In that case, the entering WP Chair should be one of the co-authors.
 - If still a significant amount of WP study coordinator / staff time is needed for finalization of the study, last author should be the entering WP chair.
 - *If the study is a Joint study (e.g., CIBMTR), last position should be discussed between different groups.*
- **Position for Statistician and Study Coordinator**, to be discussed during the development of the study and will depend on the amount of work done. In principle, and unless otherwise specified neither of them need to be occupying the second / third position in the authorship list of the manuscript.
- **Representatives of the participating centers.** Specific considerations:
 - *This representation should be as wide as possible, always taking into consideration the specific guidelines / requests of the journal and the number of patients included in the analysis*
 - *Position of representative of the centers will depend on the number of patients included in the study*
 - *Centers not being able to appear in the list of co-authors due to low number of patients included will appear appropriately mentioned in the Appendix.*

Author obligations

Given the fact that the EBMT has a scientific and economical interest in a timely and successful publication of retrospective studies performed with EBMT data and resources, PIs / first authors granted with these resources for conducting an EBMT retrospective study should aim at timely preparation of a manuscript draft once the study is closed and the statistical analysis is done.

If the PI fails to deliver a manuscript within a reasonable time frame (usually 3 months after having received the results of the statistical analysis), the WP chair may transfer

manuscript writing responsibility / first authorship to another investigator or take it over by herself/ himself.

Independent Review Board Approval

Some journals are requesting an Independent Review Approval (IRB) of the study before the publication of the manuscript. The scientific meeting of the relevant WP / WPs minutes that indicates the discussion of the proposal, potential modifications and final approval of the protocol could be used for this purpose. WP chairs ensure that all studies are performed in accordance with the principles of the declaration of Helsinki.

Guidelines for Publication of Non-Interventional Prospective Analyses and Prospective Clinical Trials

Presentation of data coming from non-interventional prospective trials and prospective clinical trials also represent a source of scientific output for the EBMT.

- **Publication Plans should be developed at the earliest stages of trial planning** and should follow the same general rules / reference manuscripts as what has been previously described for Retrospective Analyses
- **Authorship criteria should be discussed at the start of the study and should reflect the individual contributions to the trial**
- Rules for being invited to participate in the **Writing Committee**
 - *The investigator coordinating the writing of the manuscript*
 - *Study coordinator*
 - *Study statistician*
 - *National PIs*
 - *Other potential collaborators who have significantly contributed to conception, design, analysis or interpretation of the data*

- *Investigators who have provided a substantial proportion of the study population for the study*
- *WP Chair. Chair of a subcommittee, if applicable*
- *A representative of the pharma company sponsoring the study, if applicable, if he/she fulfils ICJME criteria for authorship*

Authorship Position in the Manuscript and Specific Considerations

Same strategy than Retrospective Studies

Other Types of Scientific Output on Behalf of the EBMT

Invited Reviews, Educational Manuscripts (in general non-peer reviewed manuscripts), Consensus and Guideline Papers

- Active member so the EBMT can be invited to participate in other type of manuscripts, not necessarily “peer-reviewed”: invited reviews, educational manuscripts, guidelines, consensus papers.
- The name of the EBMT should adequately be acknowledged, always reflecting the scientific input that EBMT has provided to the manuscript:
 - Consensus and Guideline Papers. Publication rules should follow the same pathway than Retrospective Analysis
 - Educational Manuscripts, Invited Reviews. This refers to the case that a relevant WP member has been invited to write one of these types of manuscripts. If this is the case and the manuscript is to have the “EBMT Logo” it should contain if possible information coming from the relevant EBMT WP scientific activity and have been reviewed by the Chair of the WP before submission.