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**PUBLICATION GUIDELINES FOR RETROSPECTIVE
STUDIES, NON-INTERVENTIONAL PROSPECTIVE
TRIALS, AND PROSPECTIVE CLINICAL TRIALS OF
THE EUROPEAN SOCIETY FOR BLOOD AND
MARROW TRANSPLANTATION**

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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 cellular therapies. Authorship on scientific manuscripts is therefore a key means of acknowledging the contribution of EBMT members to prospective clinical trials and retrospective studies.

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I- General Guidelines on Authorship

These guidelines apply to all EBMT publications including abstracts, manuscripts and other forms of scientific communication.

The recommendations of the International Committee of Medical Journal Editors (ICMJE) on defining the role of authors and contributors

(<http://www.icmje.org/recommendations/browse/rolesandresponsibilities/defining-the-roleof-authors-and-contributors.html>) should be considered as the basis of these EBMT publication guidelines. In the event of any uncertainty or conflict, these recommendations provide the basis for their resolution.

Authorship of an EBMT study should be based on the following criteria.

Except in joint studies, all co-authors must:

- I-1)** Be EBMT members or be working in formal co-operation with an elected member of the EBMT board
- I-2)** Have made a substantial contribution to the conception or design of the study or to the acquisition, analysis, or interpretation of data for the study
- I-3)** Have had a substantial role in either writing or critically reviewing the draft manuscript
- I-4)** Have approved the final version prior to journal submission
- I-5)** Be accountable for all aspects of the work and must ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Many journals have guidelines limiting the number of authors allowed on a publication. This may lead to confusion. In general, manuscripts should aim to incorporate as many authors as possible as long as they have met the above eligibility criteria.

Pharmaceutical company representatives

In the case of non-interventional prospective studies and prospective clinical trials, a representative of the pharmaceutical company sponsoring the study may be considered for authorship, if their involvement meets the ICJME criteria.

II- Institutional Review Board approval

Journals increasingly require all submitted studies to have undergone independent Institutional Review Board (IRB) approval. It should be understood that the minutes of the scientific meeting of the relevant Working Party confirming discussion and final approval of the proposal and its 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.

III- Author obligations

As the EBMT has a valid scientific and economic interest in the timely and successful publication of retrospective studies performed using EBMT data and resources, PIs / first authors are obliged to complete manuscripts in a timely manner once the study has been completed and the statistical analysis done.

If the PI fails to deliver a manuscript within a reasonable time frame (in general, three months after having received the results of the statistical analysis), the WP chair may transfer first authorship to another investigator or may complete the manuscript themselves.

IV- Writing Committee

All EBMT studies require the formation of a writing committee. The composition of the writing committee should be decided upon before starting the study and should include the following:

IV-1) Principal Investigator (PI) who originally proposed the study

IV-2) Chair and Secretary of the Working Party

IV-3) Study coordinator / Study statistician

IV-5) Subcommittee chair(s) or vice-chair(s), as appropriate, (as senior author)

IV-6) Additional members of the WP, if they have made significant contributions that qualify for authorship

IV-7) Representatives of centres that will potentially contribute the largest number of patients to the study based on the pre-study feasibility check will be invited to join the Writing Committee

IV-8) Representatives from countries or study groups that wish to collaborate in a formal Joint Study, and who would lead local involvement (“National Coordinator”)

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.

V- Statisticians, Data Managers and Study Coordinators

The role of the statistician as a co-author should be decided upon as the study progresses and will depend on the amount of work involved. In principle, and unless otherwise specified, the statistician does not need to be the second, third or penultimate author of the manuscript.

The role of data managers and/or study coordinators as a co-author should be decided upon as the study progresses and will depend on the amount of work involved.

However, if the amount of work is not considered substantial, their involvement should be formally acknowledged in the relevant section of the manuscript.

When they are co-authors, their names will be included in the middle of the authorship list.

VI- Representatives of participating EBMT centres

Specific considerations:

VI-1) Representation should be as wide as possible, always taking into consideration specific journal author guidelines and the number of patients included in the analysis

VI-2) The authorship position of centre representatives will be based on the number of patients included in the study

VI-3) Two places will be allocated to participating centres that, despite smaller patient numbers, work closely with the EBMT office to provide timely, accurate data (this should be decided upon by the WP chair and the study coordinator)

VI-4) The names of centre representatives who are not included as co-authors due to low numbers of patients will be listed in the Appendix

All investigators in prospective studies as well as all contributors to retrospective studies should be listed in the appendix in an order that reflects the number of patients included in the study. If there are several centres with the same number of patients appearing in the Appendix, they will be listed in alphabetical order.

VII- EBMT attribution

Manuscripts published on behalf of the EBMT must include the following words in the title:

On behalf of the EBMT

Or

On behalf of the xx Working Party of the EBMT

If the title is too long or does not meet the manuscript title guidelines of a given journal, an alternative is to add this phrase after the name of the last author.

This policy is to ensure recognition of the key scientific role of the EBMT in supporting these studies.

VIII- Order of Authors

First author

PI of the manuscript. Two authors could share first authorship. Such an arrangement should be discussed with the WP Chair and agreed upon beforehand.

Last Author

Current WP Chair.

If the study was started during the term of office of the prior WP chair, the final decision as to the last author will be based on how advanced the study was at the end of their term. If data collection had been completed and the study was undergoing statistical analysis or the manuscript was in draft, then the prior WP chair should remain as last author. In this case, the current WP chair should be one of the co-authors. If, however, the majority of the work remained to be done, then the new WP chair should be the last author.

Regardless, the final decision will be made jointly by the prior and current WP chairs.

If it is a joint study, for example with the CIBMTR, the decision as the last author position should be decided in advance between the two parties.

IX- Consensus and Guideline Papers and Reviews

Publication rules should be based on the same principles as apply to retrospective studies

Consensus Papers should follow standard methodological principles as provided by the Statistical Committee

Educational manuscripts and invited reviews

If a WP member has been invited to write one of these types of manuscripts as a representative of EBMT, then the manuscript should reference the scientific activity of the relevant Working Party and should have been reviewed by the WP Chair prior to journal submission.