Document Type	|	Policy
Index Number	|	EBMT 68
Version Number	|	4.0
Title	|	EBMT Authorship Policy
Author	|	Marco Bressers
Authorised By	|	Claudia Ramirez
Authorised On	|	31-Oct-2024
Release Date:		14-Nov-2024

PUBLICATION GUIDELINES FOR ALL STUDIES OF THE EUROPEAN SOCIETY FOR BLOOD and MARROW TRANSPLANTATION, THE GO-CART COALITION AND JOINT STUDIES WITH THE WBMT AND OTHER SOCIETIES

VERSION 4.0

Author: Dr Donal McLornan and Fabio Ciceri

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), the GoCART coalition and the WBMT to the field of stem cell transplantation and cellular therapies. Authorship of scientific manuscripts is therefore a key means of acknowledging the contribution of EBMT members and collaborators to prospective clinical trials and retrospective studies across these areas and collaborations.

Content

I- Background and General Guidelines on Authorship

These guidelines apply to all EBMT, GoCART and WBMT (involving EBMT data) 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

(https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-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 where applicable.

The wider EBMT community, local and global partners and the public's trust in the academic research output from our society rely upon all those involved in conducting such research and publication adhering to the highest ethical standards in disseminating findings and conclusions in any form. Authorship implies responsibility and accountability for any published work. Eligibility for authorship does not equate to guaranteed authorship. Eligible authors must still make substantive contributions, including careful review and contributions to the draft manuscript.

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or reviewing it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors should have confidence concerning the transparent contributions of their co-authors.

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors but should be acknowledged.

Authorship of any EBMT study should hence be based on the following criteria

Except in formally approved 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 or a WP member when there is oversight from an EBMT WP chair.

I-2) Have made a substantial contribution to the conception or design of the study or the acquisition, analysis, or interpretation of data for the study

I-3) Have had a substantial role in either writing or critically reviewing the meeting abstract or full manuscript when circulated

I-4) Have approved the final version before meeting or 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 authorship eligibility criteria and as agreed by the original writing committee.

Pharmaceutical company representatives:

In the case of non-interventional prospective studies, prospective clinical trials and some retrospective 'matched control' based studies, a representative (s) of the pharmaceutical company sponsoring the study may be considered for authorship only if their involvement meets the ICJME criteria i.e. they have contributed significant input to study design and manuscript preparation. This should be discussed and agreed at the outset of the project and documented.

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 the discussion and final approval of the proposal and its protocol could be used for this purpose. WP chairs ensure that all studies are performed under the principles of the Declaration of Helsinki. If further review is required, this could be with an alternative WP or the Executive Committee for an independent review.

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 promptly once the study has been completed and the statistical analysis is done.

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

IV- Writing Committee

All EBMT studies require the formation of a writing committee (WC) which is a decision taken within each working party. The composition of the writing committee **must** be decided upon **before** starting the study* and this is normally generated following discussion between the PI, WP chair, WP secretary and subcommittee groups as appropriate. The frequency of meetings is dependent on the working patterns of each particular WP. Progress is monitored during the formal and informal operational meetings within each WP.

* Clearly the contributing centres cannot often be correctly assigned at this point and will be assigned based upon data contribution thereafter as the study progresses. Fair representation of the contributing centres to the study should be preserved. The WP chairs are elected members who should ensure equitable representation of the wider EBMT community who have contributed to the study.

The WC should include the following:

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

IV-2) Chair and Secretary/Co-secretaries of the Working Parties involved.

IV-3) Study coordinator(s), data managers and study statistician(s)

IV-4) Subcommittee chair(s) or vice-chair(s), as appropriate, dependent on the topic and structure of the Working Parties involved, as long as they have made significant contribution to the study.

IV-5) Additional members of the involved WP(s), if they have made significant contributions that qualify for authorship and meet the ICMJE criteria as above

IV-6) Representatives of centres that contribute the largest number of patients to the study based on the pre-study feasibility check will be invited to join the Writing Committee in addition to, where possible, the addition of two smaller centres who have contributed to the study data acquisition with timely and accurate data. These centres are frequently identified as the study progresses and data is obtained hence will be invited to the WC at a later point.

IV-7) 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. This should be documented and recorded by the data management team on behalf the EBMT contribution. We must also take into consideration that the authorship policy of other organisations such as CIBMTR differ than that of the EBMT so a mutually agreed author byline is essential at the time of study commencement.

V- Statisticians, Data Managers and Study Coordinators

The role of the statistician to meet inclusion as a co-author should be for those statisticians who perform the primary and subsequent revision analyses and must be decided upon at the time of the study proposal and kept under review as the study progresses. Given the scientific input into the study analyses and manuscript preparation, in general, when the WC is being established the statistician is most commonly second author after the PI. If it is a study led directly by a statistician (for example a comparative methodology paper or expert opinion on statistical analyses in cellular therapy) then they could function as PI or senior author if appropriate to the subject matter. This must, as per all studies, be decided in advance and agreed by the WP chair and the wider WC. It is mandated that the clinical input from the WP and the contributing centres must be recognized in such papers.

Data manager(s) and/or study coordinator(s) are co-authors as per the WC guidance in section IV. Those involved should be decided upon at the time of study proposal, as the study progresses and on completion of the study.

If either the statistician or data manager/ study coordinator changes before the study conclusion then a discussion must be had by the WP chair/s and writing committee to review the relative contribution and if one/ both still meet authorship criteria as per section I. If such a situation arises, this discussion must be documented and sent to the relative study unit. However, if the amount of work is not considered substantial to meet authorship criteria, their involvement must be formally acknowledged in the relevant section of the manuscript.

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. It is recognized that at the time of the writing committee proposal, this detail may not be known.

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. This should follow the standard format of name of the PI, centre name, city and country in alphabetical order of surname. The centre attributed is where the subject of interest occurred.

VI-5) Centre representatives will initially be the Principal Investigator (PI) as listed on the EBMT membership list. However, upon the PI's request, this can be altered to another representative of the same centre. Frequently different individuals within centres may be responsible for aspects of the clinical care of patients rather than the PI. If this is the case, it is the responsibility of the individual centres to alert the WC of the abstract/ paper that an alternative author should be included. The formal invite to be involved in the study or any communication thereafter should include a statement '**it is the responsibility of the centre PI to ascertain if another individual from their centre should be the representative author of the study'.**

VI-6) Surveys are a differing project in that all responding centres contribute equally to the collated responses. Dependent on the survey, attempts should be made to include all contributing PIs to the authorship list if the target journal allows such. If not, then normal practice would be to have the authorship as per the WC and all contributing centres must be listed in an appendix in alphabetical order of surname.

VI-7) Those PI/members of centres not reporting consecutive CART cell data to the EBMT registry should not be PIs or co-PIs of any project focused on CART-related work from the EBMT registry. This is to encourage timely reporting to the EBMT registry.

All investigators in prospective studies as well as all contributors to retrospective studies who are not listed as a co-author 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. Of note, some journals will ask for the full composition of the relevant working party as an addendum. This policy is to ensure recognition of the key scientific role of the EBMT in supporting these studies.

VIII- Order of Authors

The criteria used to determine the order in which authors are listed on the byline must be discussed following acceptance of the study on the portfolio, agreed upon and documented in advance and collectively by the writing committee. The order of authorship should be a joint decision and authors should be prepared to explain the order in which authors are listed. Each working party, or all involved working parties if a joint or transversal paper, should keep a document detailing this discussion, including the date and detail of those involved in the decision-making process to provide transparency. In the case of a joint or transversal paper the authorship order, first and last author (s) should be agreed between both/all working party chairs in advance. Operationally, this will be the agreed EBMT study proposal template (Section 12a). The final version should be kept by the WP secretaries and also must be sent to the relevant Paris or Leiden study unit. This document should be referred to in the situation of any dispute over authorship order or authorship seniority. The writing committee lead(s)/ WP chair(s) should reconfirm who meets the criteria for being attributed as an author before submitting the manuscript for publication and periodically throughout the project lifespan as required.

First author:

PI of the manuscript. Two authors could share the first authorship, if appropriate. Such an arrangement should be discussed with the WP Chair and agreed upon before the study commences. This **must** be documented on the study proposal template. Requests to add a co-first author after the study commences do not follow normal practice and are at the discretion of the WP chair/s who should discuss it with the entire writing committee. This situation should not arise if the WC is agreed in advance.

Last author:

In general, the current WP Chair has overall responsibility for the scientific output of the group under the umbrella of the EBMT. They should meet all criteria for authorship and have had a senior position in study development and/or completion within the writing committee. There is the possibility of joint senior authorship if appropriate. The position of the last author/s for all studies must be **discussed and agreed** upon before the project commences. This will be recorded on the study proposal template once the study has been accepted and the writing committee agreed. A written authorship agreement provides a useful tool to minimize subsequent authorship disputes.

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 the 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 the last author. In this case, the current WP chair should be one of the co-authors. If, however, the majority of the work remains 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 or WBMT where EBMT has made a significant contribution of data management resource, statistical expert and patient numbers, the decision as the last author position and overall study authorship list should be decided in advance between the two parties.

In certain specific situations, there may be a request that another author other than the WP chair be the last author of the study abstract/ manuscript. Discussion of authorship order should begin

at the inception of a research project, as discussed above, and involve a purposeful, mutually respectful and thoughtful examination of the expected contributions of the individuals involved in the project. Such discussions should be transparent, honest, and conducted professionally. If such a request arises for the last authorship position, then a review and documentation of the reasoning and rationale should be made between the members of the writing committee. Such a request must have scientific reasoning and this must be timely. It would not be normal practice that a request to change the senior author is made after study conception and agreement of the writing committee, apart from a changeover in WP chair/ key contributors over study gestation as discussed above. 'Last minute' requests are not acceptable. All discussions should be documented.

IX- Authorship Disputes

If a dispute arises concerning the first author/s, last author position or author order byline and continues despite the above points of reference, in the first instance this should be discussed with the Chair and Co-Chair of the Scientific Council to provide senior oversight, advice and aid in resolution/ mediation. This should be a transparent and documented process. If this process fails or is in on going contest, or one of the scientific chairs/ co-chair is directly involved, it should be elevated to the Executive Committee for discussion/ resolution. Dated documentation should be kept and recorded in the relevant study unit at all stages.

X- 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 if appropriate.

Guidelines and best practice papers being produced by the Practice Harmonization and Guidelines Committee or individual Working Parties should in the vast majority of cases be candidates for publication in the journal of the EBMT 'BMT'. The possibility of dual publication can be discussed with the BMT editorial board were deemed necessary.

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 before journal submission.

XI- Go-CART Coalition Guidance

i. The title should contain: "…On behalf of the Go-CART Coalition". This sentence could be added at the end of the authorship list. If there is specific involvement from a WP then it should also include: 'on behalf of XX WP'.

ii. Authorship rules should follow the international regulations (ICMJE) as detailed above and relevant EBMT authorship guidelines and should include the relevant stakeholders.

iii. Of note, PI of centres not reporting consecutive CART cell data to the EBMT registry should not be PIs or co-PIs of any project related to the GoCART Coalition or CART-related work from the EBMT registry. This is to encourage timely reporting to the EBMT registry.

iv. An audit of adherence to the guidance above should be performed by the relevant data management team yearly for all Go-CART projects.

XII- PASS Study Guidance

PASS studies were developed as a request of the EU competent authorities (EMA) to the pharmaceutical companies to better understand long-term efficacy and/or safety issues related to the use of CART cell constructs in the real world. The EBMT registry received a positive opinion of EMA to be used for this purpose back in February 2019.

Analysis and publication of data of patients included in the PASS represents a significant effort of many different people within the structure of the EBMT and this needs to be recognised in the authorship list.

Authorship rules should follow the international regulations (ICMJE) as detailed above and relevant EBMT authorship guidelines and should include the relevant stakeholders.

These representatives should be included in the authorship list:

- Representatives of the relevant WPs (disease-oriented, transversal WPs, CTIWP) depending on the topic

- If the PASS study has been developed within two different WP chair terms, the inclusion of both chairs should be considered (see also section VIII)
- The WP chair should have the capacity to delegate the authorship position to another member of the WP if necessary/relevant
- Data manager (s) involved in PASS studies
- Statistician(s)
- Medical Officer
- PI of centres that have included a relevant number of patients
- Representatives of the pharmaceutical company

The main author order should be agreed in advance. An audit of adherence to the guidance as above should be performed by the relevant data management team yearly for all projects.

XIII- EBMT 'Mega-file' Study Guidance

i. The title should contain: "…an EBMT mega-file study". This sentence should be added at the end of the authorship list

ii. Authorship rules should follow the international regulations (ICMJE) as detailed above and relevant EBMT authorship guidelines and should include all the relevant stakeholders. This includes the EBMT president, secretary and treasurer as representatives of the executive committee responsible for the EBMT.

iii. Of note, for all 'Mega-file' studies representatives of each WP that has contributed data to the study must be included in the authorship list.

XIV- Joint EBMT-WBMT studies

i. Authorship rules should follow the international regulations (ICMJE) as detailed above and relevant EBMT authorship guidelines and should include all relevant stakeholders. This includes the EBMT president, secretary and treasurer as representatives of the executive committee responsible for the overall output of the EBMT.

ii. Of note, for all WBMT studies representatives of each WP that has contributed data to the study should be included in the authorship list.

iii. Where the EBMT has contributed significant patients numbers to a particular joint study then the weighting of the author byline should reflect this. This is particularly the case where EBMT data resource and statistical support has been utilized for WBMT studies. A good example of this is the WAUSTIM studies which are heavily supported by the EBMT

iv. The writing committee of the joint studies should be agreed in advance and reflect contribution. The last author can be either a WBMT and/ or an EBMT member or joint. It is essential that the contribution of the EBMT centres is also recognized in such work by inclusion based on numbers of patients included in the analysis.

v. An audit of adherence to the guidance above should be performed by the relevant data management teams yearly for all projects.