CIBMTR Study Proposal Guidance

Dear Potential Investigator,

We have created this CIBMTR study proposal guidance to assist you in the development of your proposal. Each year, fewer than a third of proposals are selected, and this document is designed to assist in making your proposal successful. Please review each of the following to determine if your study question is best answered through the CIBMTR:

- **Which working committee(s) might be best to consider your proposal?**
  The CIBMTR proposals are sent to a specific working committee to consider. The list of those committees is available at:
  https://www.cibmtr.org/About/WhoWeAre/Committees/wc/Pages/default.aspx
  To determine which committee might be best, look at the recent meeting minutes on the committee's homepage to understand what types of studies have recently been performed by each committee.
  *Please note that Cellular and Immunotherapy for Cancer Working Committee and Graft Sources and Manipulation Working Committee are no longer accepting proposals. Please direct proposals to the committee that best fits based on disease, population or topic.
  *Donor Health and Safety and Health Services and International Studies will be a merged committee moving forward. Please choose the merged committee choice on the proposal form if proposing a study through either committee.

- **What are your outcomes of interest?**
  One common issue with proposals is that some investigators will list all potential outcomes which sometimes limits feasibility. When considering your overall study question, consider the most important primary outcome and 1-3 secondary outcomes. Once this is narrowed down, it may become more apparent which working committee is most appropriate.

- **Has the question been previously answered?**
  The use of CIBMTR data has resulted in over 1500 publications since 1972. As part of your literature search, see if CIBMTR or other organizations (e.g. EBMT) have asked similar questions recently. Look at the meeting minutes from the past 5 CIBMTR meetings for the working group(s) that your proposal might fit with and see if they have accepted similar proposals previously. Additionally, look at the list of recently published manuscripts by potential working groups:
  https://www.cibmtr.org/Studies/Observational/StudyLists/pages/index.aspx

- **Is CIBMTR already thinking about your question?**
  Reviewing the meeting minutes from previous working committee meetings may also reveal that previous proposals that were like your own may not have been accepted due to feasibility issues. Often times these feasibility issues will continue to exist, but at times changes in transplant practice or forms may make a study feasible at a later date (i.e. a study on haploidentical recipients may not

have been feasible due to low numbers several years ago, but with the increased incidence of haploidentical transplant this question may now be feasible).

- **Does CIBMTR have the data you need to answer the study question?**

  Data Forms

  CIBMTR collects data on donor and recipients with two general sets of forms. Transplant Essential Data (TED) forms collect less data and are collected pre- and post- BMT and Cellular Therapy on all patients. If you would like to conduct a study that requires a large group of patients, these forms may be best. Comprehensive Report Forms (CRF) are collected on a weighted subset of patients and contain much more detailed information. For example, graft sources are collected in the TED forms, but specific late-effects are likely only captured via CRF forms.

  Look at the current CIBMTR forms to see if the data you need is collected by CIBMTR:
  https://www.cibmtr.org/DataManagement/DataCollectionForms/Pages/index.aspx
  Additionally, forms are updated from time to time, and fields that are presently collected may not have been previously. When considering your study population, also review retired forms to see if the data you need was collected during the timeframe you are considering:
  https://www.cibmtr.org/DataManagement/DataCollectionForms/Pages/Investigators.aspx
  If you have additional questions regarding past and present forms, you may choose to reach out to working committee leadership for additional guidance when preparing your proposal.

  Available (prepared) Datasets

  Recently, CIBMTR has released datasets of previously published studies. If you have a similar question to a recently published CIBMTR project that was not previously answered, the dataset is available to you outside of this proposal framework and can be analyzed using your institutional statisticians. This may be a simpler and quicker alternative to a formal proposal.
  https://cibmtr.org/CIBMTR/Resources/Publicly-Available-Datasets

- **Have you been in touch with the working group chair or scientific director?**

  If you have questions about the feasibility of your study after completing the above steps, you can certainly reach out to the working group chairs or scientific director of the committee your study best fits with. Contact information for individuals is available on the individual working committee webpages: *https://www.cibmtr.org/About/WhoWeAre/Committees/wc/Pages/default.aspx*

  Please note, you are not obligated to contact the committee or a chair prior to submission.

- **Do you need additional data or materials beyond what has already been collected by the CIBMTR?**

  Immunobiology Specimens

In addition to retrospective data on donors and recipients of hematopoietic stem cell transplantation or cellular therapy, the CIBMTR also collects several types of specimens and houses them in a tissue repository. Information on available samples is here:
https://www.cibmtr.org/Samples/Pages/index.aspx
For studies that do not require clinical outcome data you can follow this link to request specimens:
https://www.cibmtr.org/Samples/Inventory/Requests/Pages/index.aspx
Studies that also require clinical data are processed through the CIBMTR study proposal process via the Immunobiology working committee:
https://www.cibmtr.org/About/WhoWeAre/Committees/wc/Immunobiology/Pages/default.aspx
If you are interested in proposing a study via the Immunobiology working committee, we strongly recommend you contact the Co-Chairs or scientific directors prior to submission.

Patient Reported Outcomes
The CIBMTR also collects patient reported outcomes on symptoms, functioning, and other quality of life attributes (e.g., financial toxicity, return to work). For additional information on what PRO measures have been collected and timepoints of collection, please reach out to the PRO leadership:
https://cibmtr.org/CIBMTR/Studies/Research-Programs/Patient-Reported-Outcomes-PRO-Data-Collection

Supplemental Data
At times, retrospective data of interest is not presently available from the CIBMTR, but additional supplemental forms can be sent to individual centers to collect needed data fields. These proposals are considered on a case-by-case basis, and additional funding to support these activities is typically required. If you are interested in proposing a study that requires additional data collection, we strongly recommend you contact the Co-Chairs or scientific directors of the relevant working committees prior to submission to get a better understanding of feasibility. In certain situations, the working committee may be able to provide letters of support for outside funding proposals, etc.

The CIBMTR has also worked on various projects linking databases with other organizations to provide a more diverse dataset. For example, EBMT, SWOG, ECOG, etc. If this is something of interest, we again would recommend discussing with the Co-Chairs or scientific directors of the relevant working committees prior to submission.