BSBMTCT
BRITISH SOCIETY OF BLOOD AND MARROW TRANSPLANTATION & CELLULAR THERAPY

Clinical Trials Sub-committee Terms of Reference

1. Context

1.1. As per the vision and mission of the BSBMTCT, there is a need for a dedicated sub-committee to focus on registry data to provide a platform for clinical research to improve lives of those undergoing transplant and cell therapy.

1.2. Additionally such a sub-committee creates a dedicated forum for healthcare professionals to contribute to academic research and represent the voice of the BSBMTCT in the development of clinical trials in the area of transplant and cell therapy.

2. Purpose

2.1. To provide guidance for the development of retrospective and prospective clinical trials to transplant and cell therapy physicians.

2.2. To analyse and publish BSBMTCT registry data with regard to retrospective trial questions.

2.3. To assist with survey questions of interest to the transplant and cell therapy community and to use this information to guide practice or develop clinical trials.

2.4. To liaise with other academic clinical trial units (CTUs) and/or commercial and non-commercial organisations and registries and represent BSBMTCT both within the UK and internationally.

3. Aims

3.1. To provide a collaborative forum whereby clinical research is discussed and promoted.

3.2. To actively utilise registry data for the development of retrospective studies that contribute meaningfully to changes in practice and advances in patient care.

3.3. To ensure the BSBMTCT continues to publish in peer reviewed journals and contributes to scientific literature in the field of transplantation and cell therapy.

3.4. To actively contribute to the development of UK prospective clinical trials.

3.5. To foster the development of younger clinicians with respect to involvement in clinical research and continue to building the research community.

4. Membership and appointment

4.1. The aim of this Sub-Committee is for membership to be inclusive as possible and hence is open to the entire transplant and cell therapy community.

4.2. The core membership group will comprise the Chair, Secretary, Head of Registry, and the lead BSBMTCT statistician.

5. Appointment of Chair/Secretary

5.1. Only BSBMTCT members will be eligible to be nominated and stand for election as Sub-Committee Chair.

5.2. The Sub-Committee Chair and Secretary will be elected by the BSBMTCT membership for a term of three years.

5.3. Once elected the Sub-Committee Chair and Secretary may hold office for a period of three years from the 1st January following their election, and may be re-elected for one further three year term, making a maximum term of six consecutive years. Once the term of office of Chair expires, the Secretary automatically assumes the role of Chair for a period of 3 years and a new election is conducted for Secretary

5.4. The Chair of the Sub-Committee shall nominate a Vice Chair in the event that the Chair is unavailable. If the Chair, for whatever reason is unable to do that, then the Secretary will act as Chair until return of the Chair.

6. Meetings

6.1. Meetings of the entire membership will be held twice a year; usually in February/March and October/November.

6.2. The quorum for the above consists of the Chair, Secretary, Head of Registry, and the lead BSBMTCT Statistician.

6.3. The Chair, Secretary, Head of Registry, Statistician(s) and Data Managers where applicable will meet quarterly to progress registry studies between the bi-annual meetings.

6.4. Additional meetings will be convened by agreement with the BSBMTCT Executive with other UK trial groups to ensure representation of the BSBMTCT in the development of other UK clinical trials.

7. Minutes

7.1. The Sub-Committee will choose a member to act as minute taker and this may be rotated to share the administrative burden.

7.2. Minutes of each sub-committee meeting will be taken and circulated within 1 month of the date of each meeting.

8. Reporting mechanism

8.1. The Sub-Committee Chair will be accountable to the BSBMTCT Executive Committee and/or the Board of Trustees.

8.2. The Chair of the Clinical Trials Sub-Committee will report to the biannual BSBMTCT Executive Committee meeting.

9. Process for reviewing effectiveness

9.1. Review of output will occur bi-annually at the BSBMTCT meetings and reported to the executive.

9.2. As a minimum of once per year, the Sub-Committee will include an agenda item to consider its overall effectiveness in the preceding year, and any changes that may further strengthen its work and outcomes.

10. Conflicts of Interest

10.1. Under the BSBMTCT Conflicts of Interest Policy, perceived or actual conflicts of interest must be declared using the Society's form. These will then be added to Register of Interests for the Sub-Committee. (Policy will be provided for guidance)

10.2. The Register of Interests will be presented as the first item on the agenda at the start of each Sub-Committee meeting.

10.3. All attendees must declare if they have any conflicts of interest pertaining to agenda items for each meeting.

10.4. Where a conflict of interests pertaining to an agenda item exists, Sub-Committee members will withdraw from the room/not contribute/mute when meetings are virtual in nature.

10.5. Members of the Sub-Committee must advise the Chair and Society when their interests change to ensure the Register of Interests is updated in a timely manner.

10.6. The Register of Interests will be formally reviewed annually.

11. Study Conduct

11.1. A call for new studies and surveys where applicable will occur ahead the biannual meetings. Study Principle Investigators (PI)s will be asked to present the proposal at the following meeting for discussion.

11.2. The authority for the selection of studies for further development rests with the core BSBMTCT group consisting of the Chair, Secretary, Head of Registry and Lead Statistician. This core group should consider feedback from members when making decisions regarding study selection.

11.3. Each study selected for development will be sent for external review. Following this external review, the PI of the study will be invited to complete and submit a full trial protocol before going to transplant centres for data collection.

11.4. All approved studies and surveys accepted by this Clinical Trials Sub-Committee will be allocated a study number.

11.5. The PI will be required to sign a “Study Chair commitment for Studies” document which outlines the responsibilities of the PI.

11.6. Full details on the study process can be found in the document BSBMTCT CTSC SOP for Registry studies.

12. Publications

12.1. Once data collection is completed, the study PI is responsible for drafting manuscripts for circulation around the study authors including the BSBMTCT core group. It is expected that the final manuscript is submitted to a peer reviewed journal for publication.

12.2. Authorship is defined as per the Clinical Trials Sub-Committee publication policy with representation of the Chair, Secretary, Head of Registry, Statistician(s) and data managers as part of the authorship. The Chair would normally be accorded last author unless otherwise agreed prior to study commencement.

12.3. The positions of other authors are defined in the document named “BSBMTCT CTSC Authorship Policy” which can be found on the BSBMTCT website.

13. Review of Terms of Reference (ToR)

13.1. The suitability/contents these Sub-Committee ToR will be reviewed annually.

13.2. Date approved by sub-committee:

13.3. Date approved by the Board of Trustees/Executive Committee:

13.4. Future date for review by the Clinical Trials Sub-Committee:

13.5. Version CTSCv1 15022023.