ETOP·IBCSG PARTNERS

Foundation for International
Cancer Research

ETOP IBCSG Partners Foundation Publication Guidelines for ETOP trials

1. Purpose

To define the policy regarding the release and publication of results from ETOP clinical trials and translational research projects sponsored and led by ETOP IBCSG Partners Foundation.

This guideline covers timing of release of results, authorship and acknowledgement rules for abstracts/presentations and peer-reviewed publications on study data.

Rules for the dissemination of data from individual participating centres are covered in the contractual agreements with the centres.

2. General Policy Statement

It is ETOP IBCSG Partners policy to publish the results from all clinical trials and from all research projects done on collected biological material completely, accurately, objectively and promptly, irrespective of the findings (positive or negative, statistically significant or not). The results should be published in an adequate scientific journal and the results presented or disclosed in a manner that fairly reflects the evidence supported by the data.

3. Governing Bodies

3.1. Foundation Board

The ETOP IBCSG Partners Foundation Board is the governing body of the ETOP IBCSG Partners Foundation, which is a foundation under Swiss law. The Foundation Board is responsible for the strategy, finances, the management structure, overall supervision and the mission of the Group.

3.2. Executive Committee

The Executive Committee is a subgroup of the Foundation Board that supervises the execution of the resolutions, initiates and implements the scientific activities together with the Scientific Committees, and supports and oversees the Director of the ETOP IBCSG Partners Foundation.

3.3. Scientific Committee (Thoracic)

The primary role of the ETOP Scientific Committee is to actively support and advise the Foundation Board on all scientific matters relating to the purpose and the activities of the Foundation. The Committee's principal tasks include the initiation, evaluation, planning and monitoring of clinical trials and translational research projects. For trials/projects without a trial/project-specific Steering Committee, the Scientific Committee may have an advisory role to

support the Foundation Board and the Executive Committee for trial/project oversight and review of manuscripts, abstracts and presentations.

3.4. Steering Committees

Most ETOP-sponsored clinical trials and translational research projects are governed by a Steering Committee with roles defined in the trial/project-specific Steering Committee Guidelines.

The Steering Committee is advisory to the Foundation Board. These ETOP Publication Guidelines are presumed to have been accepted by the trial/project-specific Steering Committee; a trial/project-specific publication and presentation guideline would supersede these Guidelines.

3.5. Translational Research Working Group (Thoracic)

The Translational Research Working Group is a self-governing group of scientists whose primary responsibility is to ensure that the ETOP biobank is used appropriately for scientifically-sound research proposals. The Translational Research Working Group is advisory to the Foundation Board and assesses the scientific value and the priority of biomaterial based research projects and ensures the proper use of the material.

4. Publications of Main Study Results

4.1. Preparation of Main Publication

4.1.1. A main publication refers to any publication on the primary and secondary endpoints of a clinical trial or a research project on biological material.

4.1.2. Results associated with the primary and secondary endpoints are not to be communicated or published until the trial data is mature for the primary analysis, unless recommended by the ETOP IBCSG Partners Independent Data Monitoring Committee Thoracic (ETOP IDMC) and authorized by the Steering Committee.

4.1.3. The main publications primarily serve the initial dissemination of the key results from a clinical trial or findings of a translational research project.

4.1.4. Based on the statistical report of the analysis, the Steering Committee discusses the results of the clinical trial or translational research project and how to present the results in the publication.

4.1.5. The Steering Committee will establish a writing committee that will assume primary responsibility for preparing the manuscript. The writing committee should include Study Chairs and Statistician, Scientific Committee (thoracic) Chair, Head Trial Activities/Head Translational Research Coordination, as well as primary contributors to the study design, implementation, conduct or analysis (e.g. pathologist, medical reviewer, biologist, etc.).

4.1.6. Manuscript preparation is coordinated by the Head Trial Activities/Head Translational Research Coordination. Manuscript writing is done by the Study Chair(s), based on the statistical report(s), in conjunction with the statistician, with active participation from the writing committee.

4.1.7. The list of co-authors is prepared as per criteria listed in Section 2. The Steering Committee may decide on further authorship of the manuscript.

4.1.8. The Steering Committee will decide on the appropriate journal to submit.

4.1.9. No main publication should be submitted for publication until approved by the Steering Committee.

4.1.10. The Head Trial Activities or Head Translational Research Coordination will submit the manuscript of the main publications to the journal and is responsible for keeping the writing committee and Steering Committee informed about the status of the submission. Either one of the first or senior authors will serve as corresponding author.

4.1.11. The final publication will be distributed and posted on the website by the Head Trial Activities/Head Translational Research Coordination.

4.1.12. None of the collaborators (individual investigators or collaborative groups) should publish data on therapy results from their own patients, before the publication of the main results.

4.1.13. In the event that the main results have not been published within one year after trial/project completion or termination, investigators from participating sites or collaborative groups may publish the results from their patients included in the trial/project. Such a manuscript must be reviewed and approved by the Steering Committee beforehand.

4.2. Guidelines for authorship of main publications

The below guidelines will be followed to draft a preliminary authorship list. Potential disagreements with the author list that cannot be resolved among the proposed authors themselves, will be resolved by the Steering Committee.

- First author or co-first authors: The person(s) who take(s) primary responsibility for writing the manuscript, usually the Study Chair(s).
- Second author: The statistician (may be first author if fulfils role) who takes primary responsibility for data analysis, preparation of the statistical methods and results section of the manuscript and assuring data and manuscript integrity.
- Scientific Committee (thoracic) Chair
- Head Trial Activities (for clinical trials) or Head Translational Research Coordination (for TR projects)
- Further authorships may be assigned to major contributors to the trial/project and/or to manuscript preparation, for example:
    a. Person(s) who designed and/or defined the research question addressed in the sub-study
    b. PI of institutions contributing a large number of patients (in case of PI change, the institution is responsible to determine the PI for authorship)
    c. Coordinating PIs of participating countries and representative of collaborative group (if applicable)
    d. Major contributors to the design and/or overall conduct of the trial/project
    e. Co-worker(s) from the coordinating centre or from the statistical office, for extraordinary involvement such as regulatory submissions, trial or translational research coordination and/or data management, or medical review and/or pharmacovigilance/safety activities
    f. Person who does extra work for editing or polishing the manuscript.

  If the journal limits the number of authors, authors a - d take priority over e - f.

- Senior author or co-senior authors: could be Steering Committee Chair, ETOP IBCSG Partners Foundation Board President, or other appropriate person.
- The author list should be followed by “(list of authors), *results from the ETOP XXX trial*/project.” The Trial Participants List should be included as an appendix (if applicable).

5. Sub-study Publications

5.1. Preparation of sub-study publications

5.1.1. Publications from sub-studies include all non-main publications. Sub-study publications are based on data generated from a clinical trial, other than the results of the primary endpoint that is published in the initial publication. Examples of sub-study publications are results from translational research or quality of life sub-projects.

5.1.2. In general, sub-study publications follow the main publication and do not precede the main publication on the primary results. Exceptions have to be agreed by the Steering Committee.

5.1.3. In the event that a sub-study publication precedes a major publication, it should not include the results of the primary endpoint.

5.1.4. Sub-study publications should be prepared in conjunction with the Study/Project Chairs and Statistician, with the involvement of the Head Translational Research Coordination or the Head Trial Activities.

5.1.5. Sub-study publications must be reviewed and approved by the Steering Committee, and the Steering Committee must be informed about the status of the manuscript.

5.1.6. The final publication from the sub-study will be forwarded to the ETOP IBCSG Partners Foundation coordinating centre for distribution and posting on the website.

5.1.7. Publications of results on data provided to external collaborators and analysis without the involvement of the ETOP IBCSG Partners Foundation should follow the relevant points mentioned in this section.

6. Meeting abstracts and presentations

6.1. Meeting abstracts

6.1.1. No abstracts on main or sub-study results should be submitted to scientific congresses before the main publication is in planning. Abstracts for “trials in progress” presentations are exempted.

6.1.2. Abstracts on main or sub-study results must be reviewed and approved by the Steering Committee.

6.1.3. Acceptance of invitations to scientific meetings by individuals is encouraged. However, presentation should not include uncoded data of therapy results, before publication of these results. The Study Chair(s) and the Steering Committee should be consulted for advice and approval before accepting such an invitation.

6.1.4. Abstracts of results on data provided to external collaborators and for analysis without the involvement of the ETOP IBCSG Partners Foundation must be reviewed and approved by the Steering Committee.

6.2. Presentations

6.2.1. Presentations of ETOP trials at internal meetings from collaborative groups or individual investigators sites are encouraged. However, on all such presentations ETOP IBCSG Partners Foundation should clearly appear as sponsor and lead coordinator of the trial.

6.2.2. The final slide set of all such presentations should be sent to the ETOP IBCSG Partners Foundation coordinating centre. They will be announced in ETOP IBCSG Partners Foundation communications and may be posted on the website.