Principles Guiding Publications and Presentations (including Abstracts and Posters)

Related to ALTTO and NEO-ALTTO Studies

Contact for Queries:

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Version 2 to add principle for authorship of translational research (point 7 i) 4 September 2013, 5 Mar 2017
Version 3 to modify the Coordinator of the Publication Committee

Principles Guiding Publications and Presentations (including Abstracts and Posters)

1. The key principles outlined in this document apply to both the ALTTO and Neo-ALTTO trials and are based on the publication guidelines of the lead partners for the trials.

2. The trials will have a body responsible for all issues related to the publication of trial related data in scientific journals or presentation at conferences.
    a. The Executive Committee (EC) will propose membership of the Publication Committee (PC) to the Steering Committee (SC) for approval.
    b. The membership of the PC shall always include the SC and EC chairs, identified principal investigators of the trials, lead trial statistician(s) and others who have been primary contributors to the study design and analysis. The EC in particular shall be well represented on the PC.
    c. The mandate of the PC will be to
        i. Ensure that the Principles Guiding Publications and Presentations are applied to planned publications or presentations, including abstracts and posters.
        ii. For each such publication or presentation,
            1. Coordinate the related activities e.g., in the form of a specific "writing committee", which may differ for each publication but should be kept small and controlled by the PC;
            2. Designate the individuals who will lead the activities, e.g., the Study Chair(s) or Lead Statistician, including but not limited to activities such as liaison with the journal / conference in which the publication / presentation will appear or be made;
            3. For publications, propose authorship, including who will serve as first, last and coordinating author;
            4. For presentations, propose or confirm the individual who is to make the presentation;
            5. Refer any disagreements about authorship to the EC for adjudication if there is no agreement within the PC; if the EC cannot adjudicate successfully, the SC must do so;
        iii. Ensure that all publications, presentations and decisions about authorship are made with SC approval. SC approvals are generally sought by email with specified "respond by" dates.

3. It is assumed that each trial will have several publications and presentations and that a distinction will be made between those that are "major" and those that are "secondary"
    a. "Major" are those that report on the primary research questions (primary endpoints) of the trial. The number of major publications will generally correspond to the number of primary research questions / endpoints in each trial.
    b. "Secondary" are those that report on
        i. Secondary endpoints / exploratory study questions;
        ii. Research of trial related sub-committees (e.g., cardiology, pathology).
    c. With regards to "secondary" presentations or publications, it is assumed that
        i. They should not present unpublished data from the primary research questions / endpoints;

ii. They should not be presented or published prior to the first major publication of the main study unless the SC agrees otherwise.

4. Unless the SC approves otherwise, all major and secondary publications and presentations will be based on analyses that have used data from the BrEAST Data Centre database, that use all relevant patients in the central study database, and that have been performed by the trial's independent statistical team. For research project proposals requesting access to data and/or residual biological material, a statistician from the Independent Statistical Team could perform the analyses if desired by the investigator. Some funding may be required depending on the scope of the project.

5. In the title of the publications and presentations it must be made clear that ALTTO is a BIG and Alliance led trial and Neo-ALTTO a BIG and SOLTI led trial. If this is not possible, for example due to a journal's publication policy, this must be indicated clearly in another suitable part of the publication or presentation.

6. Prior to submission of a publication or any other dissemination of results, including oral presentations, Novartis and the US National Cancer Institute (NCI), as sponsors, shall have the right to review and comment on the content of the material to be published or presented, as stipulated in the main agreement of the trials. A time frame mutually agreed between the PC and the sponsors should be defined to complete the review, this time frame should not exceed 30 calendar days. However, during this review period, Novartis may request delay of submission for an additional period up to a maximum of 90 days from the original submission to the PC. This is for the sole purpose of deciding on patent filing. If such a delay is imposed, Novartis will notify the PC, which will then notify the principal author and the Steering Committee.

7. Authorship shall be based on the principle of respect for all partners, groups, investigators and countries / regions involved in the trials and shall consider the following
    a. When allowed by a journal, authorship must be on behalf of the overall study team (e.g., the ALTTO Study Group); publishing in the name of the group is particularly advocated in the case of electronic publication.
    b. When individual authors are to be listed, the maximum number of author positions allowed by a journal should be filled
    c. Prime authorship positions, especially in the first major publication (s) / presentation (s) (cf. 3a supra), will be given to those who have provided the most scientific leadership (e.g., clinical / translational / biostatistical expertise related to study hypotheses, trial design, protocol writing, medical review, or key scientific committees) rather than those whose contributions have been more administrative (e.g., study management).
    d. Prime authorship positions for secondary publications focusing on cardiology, pathology or other "non-oncology" issues (cf 3 b & c supra) will privilege those specialists (i.e., cardiologists, pathologists, statisticians, other) who have contributed substantially to that research.
    e. Other author positions should be reserved for
        1. collaborative groups, allotting authorship in proportion to their level of patient accrual. If allowed by the journal, groups should be named as groups, with individual representatives of groups mentioned in the acknowledgements

2. the highest recruiting centres (in the name of an individual);
3. individuals involved in the central trial management;
4. young team members (e.g., fellows) contributing significantly to the trial;
5. the trial sponsors (Novartis and US NCI, maximum one each);
6. any other trial partner not listed above.

f. Those who are not accorded an authorship position and have participated in the study should appear in the acknowledgments. The number of acknowledgments per participating entity (i.e., partners, groups, investigators and countries / regions) will depend on the journal rules and be based on fair and practical considerations.
g. Authorship should be rotated across publications, e.g., no individual should appear as first author on consecutive major publications; constituencies (e.g., institutions) on consecutive publications should be represented by different individuals who contributed significantly.
h. If more than one individual would be appropriate to represent a particular constituency on a particular publication / presentation, but only one author position can be given, it shall be the constituency's responsibility to make the selection, whether by "lottery" or other means acceptable to the constituency.
i. Authorship of translational research in ALTTO and NeoALTTO shall consider the following
    1. Prime authorship positions in publication (s) / presentation (s) will be given to those who have provided the most scientific leadership (e.g., translational research, other lab researchers and biostatistical expertise related to research hypotheses).
    2. Authorship should be rotated across publications, e.g., no individual should appear as first or last author on consecutive publications; constituencies (e.g., institutions) on consecutive publications should be represented by different individuals who contributed significantly.
    3. Consider including up to a maximum of 30% of authors not directly involved in the research proposal to acknowledge:
        a. Clinicians involved in the main trials (principal investigators – at least one, any other BIG/Alliance (for ALTTO)/SOLTI (for NeoALTTO) representative who played a major role in the trial design/setup, high recruiters, statistical team, and fellows or young team members);
        b. Representative of collaborative groups, allotting authorship in proportion to their level of patient accrual;
        c. The highest recruiting centres (in the name of an individual in case of independent site);
        d. Individuals involved in the central trial management;
        e. The trial sponsors (Novartis and US NCI, maximum one each).

8. Presenters shall be selected by the Executive Committee (unless otherwise approved by the SC) and should be rotated across presentations. A specific hierarchy of names shall be defined by the PC, taking into account scientific contribution, level of involvement during the study conduct and the ability to give high quality oral presentations.

9. After the publication of the results of the primary research questions/endpoints, groups/ individual institutions might be allowed to publish/present the data and results from their site(s), provided the following conditions are met:

a. The proposed publication/presentation is first submitted to the SC, the National Cancer Institute, and the Sponsor for review and comments, in line with point 6 of this document
b. The publication/presentation cannot be made in the name of the ALTTO or Neo-ALTTO study, but can make reference to the fact that patients had been enrolled in the ALTTO or Neo-ALTTO studies.

Appendix to Principles Guiding Publications and Presentations

Publication Committee Members composition

a. For all publications:

Title	Name	Email	Assistants	Telephone/Fax
Chair	Martine J. Piccart	martine.piccart@bordet.be		Tel: +32 2 541 3206 Fax: +32 2 538 0858
Co-Chair	Alvaro Moreno Aspitia	morenoaspitia.alvaro@mayo.edu		Tel: +1 (904) 953 7291 Fax: +1 (904) 953 2315
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PI Neo-ALTTO	Jens Huober	jens.huober@uniklinik-ulm.de	Sabine.Endres@uniklinik-ulm.de	Tel: +49 (731) 500-58511 / 58509 Fax: +49 (731) 500-58595
Independent / Head Study Statistician, Frontier Science	Richard Gelber	gelber@jimmy.harvard.edu		Tel: +1 617 632 3603 Fax: +1 617 632-2444
Statistician Alliance	Amylou Dueck	dueck.amylou@mayo.edu		Tel: +1 480-301-6159
Medical Director BrEAST	Evandro de Azambuja	evandro.azambuja@bordet.be		Tel: +32 2 541 7244 Fax: +32 2 541 3477
Scientific Director SOLTI	Lorena de la Peña	lorena.delapena@gruposolti.org		Tel: +34 661783471 Fax: +34 937156401
Publication Committee Coordinator	Mihaela Sicoe	mihaela.sicoe@bigagainstbc.org	altto@bigagainstbc.org	Tel: +32 2 486 16 78

b. In the case of the publication includes data from translational research, the following members will be added to the members listed above:

Co-chairs TransALTTO Committee	Nadia Harbeck	nadia.harbeck@med.uni-muenchen.de	sekretariat-prof-harbeck@med.uni-muenchen.de	Tel: +49 89 7095-4531 Fax: +49 89 7095-8892
Co-chairs TransALTTO Committee	Lajos Pusztai	lajos.pusztai@yale.edu	laurene.goode-ade@yale.edu	Tel: +1 203-737-7059 Fax: +1 203-785-4116