



Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer The AURORA PROGRAM

Publications and Presentations Policy (Including Abstracts and Posters)

1. Introduction

The Breast International Group (BIG) is conducting a molecular screening program entitled “Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer” (the “Program” or “AURORA”), and this document outlines the Program’s Publication and Presentation Policy.

The principles outlined in this document are based on the BIG publication guidelines and are in accordance with the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts submitted to Biomedical Journals, April 2010 (www.ICMJE.org).

The term “Publication” applies to full manuscripts and abstracts related to these manuscripts.

The term “Presentation” includes oral presentations, posters, or poster discussions, and their corresponding abstracts.

It is assumed that the Program shall have several Publications and Presentations and that a distinction shall be made between those that are “Core” and those that are “Additional”, as defined hereunder.

“Core” are those that report on the primary research questions i.e. on data subsets of the Program analysed by the AURORA Data Analysis Committee (DAC) set up for the Program. This includes Publications and Presentations by the DAC Core Group and by any of the DAC Working Groups. The DAC is composed of individuals with expertise in clinical oncology, genetics, genomics and bioinformatics. The Core Group will be conducting bioinformatic and/or statistical analyses on the AURORA study population as a whole. The Working Groups will be conducting the bioinformatic and/or statistical analyses for specific patient populations, or to answer specific research questions.

“Additional” are those that report on any other analyses approved by the AURORA Steering Committee (SC) i.e. analyses proposed and performed outside the DAC Core Group or the DAC Working Groups. This includes Publications and Presentations

- driven by investigators (Publications and Presentations by BIG Groups/individual institutions reporting on a subset of Program data related to patients from their sites)
- on Research Projects (RP)

All Publications and Presentations should be based on analyses that have used

- data from the Program specific central database – consisting of the clinical database managed by IJB-CTSU and the molecular screening IT platform managed by BIG - that use all relevant patients in the central Program database.
- data derived from the analysis of biological samples in accordance with the AURORA protocol and/or any data generated from any central analysis of the biological samples approved by the SC and/or
- any data generated by RPs approved by the AURORA SC.

2. Core Publications and Presentations

2.1 Governing Body

The AURORA Steering Committee (SC) is the body responsible for all issues related to the reporting of Program related data and results in the form of publications in scientific journals and presentations at conferences.

The SC shall endorse the writing committee (WC) assigned for each Publication and Presentation, and shall ensure that the Program constituencies are appropriately represented in this.

The composition of the WC may differ for each Publication and Presentation and should be kept small.

For each such Publication or Presentation the SC shall:

1. Designate the individual(s) who should lead the activities within each WC (i.e. the first author);
2. For Publications, approve authorship, including who should serve as first and last author. In general, the first author is responsible for the preparation of the first draft manuscript, circulation to and approval by co-authors, liaison with the journal/conference in which the Publication/Presentation should appear or be made, submission of the final approved Publication/Presentation to the journal/conference, collection and submission of conflict of interest forms from all the co-authors, follow upon on any questions related to the Publication, as well as making the Presentation and must therefore be member of the WC at hand;
3. For Presentations, approve the individual who is to make the Presentation, as well as the list of authors;
4. Resolve any disagreements within the WC about authorship.

The mandate of the WC shall be to:

1. Prepare a high quality Publication or Presentation on the topic/subject matter assigned to it;
2. Ensure that the Program Publications and Presentations Policy is applied to the Publication and/or Presentation that is being prepared.

Correspondence between the SC and the WC shall be by email with specified “respond by” dates.

The WC cannot make amendments to this Publications and Presentations Policy document without SC approval.

2.2. Publications and Presentations

- Proposals for specific analyses made by the DAC Working Groups will have a limited period of protected time (9-12 months) from the time of Program Data receipt, in which similar proposals from other investigators are rejected. If after this period no results have been shared with the SC by the DAC

Working Group, a collaboration might be proposed between the DAC Working Group and the other investigators with a similar proposal.

- In the title of the Publications or Presentations it must be made clear that the Program is sponsored by BIG.
- Prior to submission to the journal/conference of a proposed Publication or Presentation, the first author shall share the final draft with the SC coordinator at BIG Headquarters (HQ) (aurora.bighq@bigagainstbc.org) for review by the SC.
- The SC shall review and approve the material to be published or presented within ten (10) working days for a Publication and five (5) working days for a Presentation.

2.3. Authorship, Acknowledgments and Presenters

Authorship should be based on the principle of respect for all partners, groups, investigators and countries/regions involved in the Program. Authorship credit should follow the ICMJE guidelines. In addition, the following recommendations to the WCs and SC are made:

- When allowed by a journal, authorship must be on behalf of the overall Program, publishing in the name of BIG and the groups and investigators involved in the SC, in the DAC Core Group or DAC Working Groups or otherwise participating;
- When individual authors are to be listed, the maximum number of author positions allowed by a journal should be filled;
- Prime authorship positions should be given to those who have provided the most scientific leadership (e.g., clinical, translational, bio-statistical expertise related to hypotheses, design, protocol writing, key scientific expertise) rather than those whose contributions have been more administrative (e.g. Program Management);
- Other author positions should be reserved for:
 - Collaborative groups, allotting authorship in proportion to their contribution to the Program. If allowed by the journal, groups should be named as groups, with individual representatives of groups mentioned in the acknowledgements;
 - The principal investigator at high recruiting sites, in order of recruitment numbers.
 - Individuals involved in the conduct of the Program;
 - The sponsor, being BIG;
 - Any other partner not listed above, who has significantly contributed to the Program.
- Funding bodies must always be listed in the acknowledgment section of any Publication. BIG HQ shall provide a current list of those at any time, including the order in which they must be mentioned, and the grant identification number of the funding bodies, if applicable.
- Those who are not accorded an authorship position and have participated in the Program should appear in the acknowledgments. The number of acknowledgments per participating entity (i.e., partners, groups, investigators and countries/regions) depends on the journal's rules and be based on fair and practical considerations.

- Authorship should be rotated across Publications, e.g. no individual should appear as first author on consecutive Core Publications; constituencies (e.g., institutions) on consecutive Publications should be represented by different individuals who contributed significantly.

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 allocated, it should be the constituency's responsibility to make the selection

For oral Presentations, presenters are approved by the SC. In all cases, presenters should be rotated across Presentations.

3. Publication and Presentation by Groups/Individual Institutions

After the publication of the results of the analyses performed by the DAC Core Group or by any of the DAC Working Groups, groups/individual institutions shall be allowed to publish/present the data and results from their site(s), i.e. clinical data from the Program specific central database and TGS results from the molecular screening IT platform managed by BIG, provided the following conditions are met:

- The proposed Publication/Presentation is in line with the principles outlined in this document and first submitted to the Program SC as follows;
 - Prior to submission to the journal/conference of a proposed Publication or Presentation, the first author shall share the final draft with the SC coordinator at BIG HQ (aurora.bighq@bigagainstbc.org) for review by the SC
 - The SC shall review and approve the material to be published or presented within ten (10) working days for a Publication and five (5) working days for a Presentation.
- The Publication/Presentation is not made in the name of the Program, but properly acknowledges that the data collection was made possible through the Program and all the entities funding the Program (to be asked to BIG HQ at aurora.bighq@bigagainstbc.org) and a reference to BIG as the sponsor of the Program will be made.

4. Publications and Presentation on Research Projects

With regard to Presentations or Publications on Research Projects, approved by the SC, the following principles apply :

- Publications are expected to have a draft version circulated for review to the authors within 2 years of data transfer;
- They should not be presented or published prior to the first Core Publication of the main Program, unless otherwise agreed upon by the SC;
- They shall not use unpublished data;
- Researchers must inform BIG HQ of planned Publication/Presentation before submission to a journal/conference, for review as follows:
 - Two SC members who have been assigned to serve as link between the RP and SC, will review the proposed Publication or Presentation, on behalf of the SC. They will review and approve the material to be published/presented within ten (10) working days for a Publication and five (5) working days for a Presentation. Conditional on their contribution

- to the conduct of the RP and its associated Publication or Presentation, the designated SC members might have an authorship position.
- In addition to the SC members assigned to a RP, the authorship for RP Publication or Presentation is defined by the RP team, as identified in the RP proposal form, to include and acknowledge those contributing to the RP. SC approval of the authorship as defined by the RP team is not required.
 - All Publications and Presentations must acknowledge the Program as the source of the Program Data/RP Biological Samples used in the RP, and the Program partners (BIG, IJB-CTSU and Frontier Science), and all the entities funding the Program (to be asked to BIG HQ at aurora.bighq@bigagainstbc.org) and a reference to BIG as the sponsor of the Program will be made.
 - Copies of all final manuscripts/abstracts arising from the RP which are accepted for Presentation or Publication must be sent to the SC (via BIG HQ) for information.