BCT PUBLICATION GUIDELINES

WI-T-14

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1. BCT PUBLICATION GUIDELINES

In general, BCT claims publication rights for all data (and other activities) produced in the course of its business, and uses an equitable publication and authorship policy consistent with the Australian Code for the Responsible Conduct of Research, the NHMRC Open Access Policy and NHMRC Open Access Policy – Further Guidance.

In this Guideline, "scientific publication" means manuscripts, editorials, abstracts, posters or related materials presented and/or published in the scientific arena.

1.1. PUBLICATION OF BCT-LED TRIALS

BCT-led trials are defined as trials originated by members of BCT and led by BCT.

In general, BCT owns all data associated with BCT-led trials and publishes results in accordance with internal BCT SOP-T-15 Trial Reporting and Publication, these guidelines, any prevailing clinical trial agreement, and the trial protocol.

1.1.1. Publication Responsibilities

Operational Executive Committee (OEC):

- Has oversight of BCT's publication processes
- Determines timelines for preparation and submission of scientific publications in discussion with the Study Chair (or Sub-study Chair) (see Section 1.1.2)
- Approves the final scientific content of all scientific publications before peer reviewed journal submission or presentation at a scientific meeting or conference.

Study Chair:

- Reviews reports of trial outcomes to participants and participating sites
- With DoR, COO-R and BCT Clinical Operations:
    - Complies with the timelines set by the OEC for publication of trial results, and, where agreed, engaging the assistance of the BCT Medical Advisor or a Medical Writer to meet publication deadlines
    - Drafts scientific publications/presentations of trial outcomes
    - Provides a shortlist of journals, scientific meetings or conferences to which the scientific publication will be submitted for approval by the OEC
    - Proposes and finalises authorship lists in accord with Section 1.1.3
    - Circulates draft scientific publications to the Trial Steering Committee, Trial Statistician, BCT Clinical Operations, nominated authors, and pharmaceutical partners/other relevant parties (as per contractual requirements) for review, comment and approval
    - Finalises scientific publications after review and approval by the Trial Steering Committee, Trial Statistician, nominated authors and pharmaceutical partners/other relevant parties (as per contractual requirements)

- Submits the scientific publication to the approved shortlist of journals, scientific meetings or conferences
- Circulates publications to the SAC after they are accepted for publication/presentation.

Trial Steering Committee:

- Reviews draft publications and presentations.

1.1.2. Timelines for Publication

The publication of the main study analysis in a peer reviewed medical journal is an alternative to the clinical study report for a collaborative group trial. All BCT-led trials will be reported and published, including trials that do not meet their recruitment targets, primary endpoints etc.

General timelines:

- Preliminary results will be presented to the SAC within four months of available results (or at the next SAC meeting)
- Primary endpoint publication will be submitted within one year of analysis
- BCT Clinical Operations will notify Principal Investigators at participating sites and trial participants as soon as the primary endpoint publication is available as per the relevant BCT Trials Department SOP(s).

1.1.3. Authorship Rules for Scientific Publication of Primary Study Results

When publishing the primary results of a BCT-led study, the agreed authorship list will be augmented, where possible, with the phrase “on behalf of Breast Cancer Trials”, or internationally “Breast Cancer Trials, Australia and New Zealand”.

Authorship credit will be based on meeting the 4 conditions below (ICMJE criteria):

1. Substantial contributions to the conception and design, or acquisition of data, or analysis and interpretation of data
2. Drafting the article or revising it critically for important intellectual content
3. Final approval of the version to be published
4. Agreement to be accountable for all aspects of the work related to the accuracy or integrity of any of the work.

See Section 1.1.3.4 for additional requirements for authorship eligibility for BCT publications.

Authorship will be determined as follows:

1.1.3.1. Study Chair

The Study Chair will choose to be the first (lead) author or last (senior) author on the basis that:

- The Study Chair has taken responsibility for scientific leadership of the study
- The Study Chair has made significant contributions to the scientific ideas on which the study was based and to the writing of the scientific publication

- In the event there are co-chairs for a trial, the arrangements for authorship will be determined in consultation with OEC before study start. Every effort will be made to ensure there are opportunities for more than one publication and that both co-chairs can have a first or last author publication
- A Co-Chair/Deputy Chair will choose which position of authorship they prefer following the decision of the Study Chair
- The Study Chair may offer the first author position to the person who drafts the manuscript (if not the Study Chair).

1.1.3.2. Trial Statistician

The Trial Statistician will be a principal author (second, third or fourth author) on the basis that:

- They have made a significant contribution to the scientific principles of the study
- They have been a prime contributor to the study design, determination of sample size and scientific conduct of the study (unblinding principles, analysis principles, interpretation of results, compliance etc.).

1.1.3.3. Additional Authors

- Subsequent authors will include Principal Investigators or other scientists who have made scientific or intellectual contributions to the study question or the study conduct and meet a journal's requirements for authorship. This may include members of the Trial Steering Committee, other clinical investigators, members of the OEC and/or members of the BCT Trial Team.
- All who qualify for authorship because of their intellectual contribution will be named
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship
- The Study Chair in consultation with the Trial Steering Committee and assisted by the BCT Trial Team, will develop a key authorship list. The list will be finalised after approval by the OEC.

1.1.3.4. Authorship Eligibility

Eligibility for authorship will be based on the following factors:

- Substantial contribution to the trial design and protocol development
- Substantial contribution to the management and conduct of the trial
- Substantial contribution to the analysis and interpretation of the data including key BCT staff members
- Level of contribution of participants to the study (up to a maximum of five top recruiters, where allowed by the journal format).

The Study Chair will invite a key authorship list, which will include those who contribute to both the analysis of the study and manuscript development at an early stage.

If there is more than one publication from a study, every effort will be made to ensure that all potential authors are given the opportunity to contribute as an author at least once.

To build a track record for contributing early career researchers, senior investigators will consider taking second or last author positions, particularly where multiple publications arise from a study.

1.1.4. Contributors Listed in Acknowledgements

Any investigator, institution or Group who contributes to the success of the study or the progress of the manuscript but does not qualify for authorship will (with his/her/its permission) be named in an acknowledgements section. Principal and co-investigators from all participating institutions and key staff members from BCT will be acknowledged in the manuscript.

Where appropriate, BCT donors will be acknowledged as providing financial support, along with any relevant external granting body or other funder.

1.1.5. Design and Formatting Requirements

General design and formatting requirements follow BCT Style Guidelines.

The BCT Communications Manager or Trials Department will provide approved templates (e.g. poster, PowerPoint presentation) and review and approve drafts to ensure the preferred BCT format is used e.g. the correct logo for international presentations or Australian presentations.

1.2. ANCILLARY RESEARCH PROJECTS DERIVED FROM BCT LED TRIALS

Ancillary research projects may develop from any major trial or study. These may involve a distinct subset of patients or may look at specific features or translational endpoints.

All ancillary research projects (including substudies) will:

- Be endorsed by the SAC before starting (refer to internal BCT SOP-T-01 Protocol Development)
- Acknowledge BCT and any sponsors, funders or other contributors.

Authorship selection for scientific publications from ancillary research projects will be as per Section 1.1.2, unless otherwise agreed. The lead researcher will generally be the primary author, and where possible, also a BCT member.

1.3. PUBLICATION OF INTERGROUP COOPERATIVE/COLLABORATIVE TRIALS

Publication and authorship processes will be agreed to during the protocol development phase and form part of the clinical trial agreement which governs the conduct of the study. In general, BCT has the right to present research data and results at investigator meetings and closed scientific meetings for trials in which BCT collaborates. However, all relevant study agreements must be reviewed in light of each proposed publication.

The BCT Study Chair in consultation with the International Trial Steering Committee, and in accordance with the study publication policy, will determine authorship for BCT and its investigators, provided all groups are represented on the International Trial Steering Committee and the BCT Study Chair is clearly designated. BCT authorship will be finalised after discussion with the OEC.

Manuscripts for intergroup trials where BCT is participating but not leading will be reviewed, commented on and scientific content approved by the BCT Study Chair, in consultation with the OEC, and where permitted by the applicable publication policy.

1.4. DISCLOSURES/CONFLICT OF INTEREST

Publications should be published with statements or supporting documents (e.g. disclosure form) declaring:

- Authors' relationships and activities. Any financial relationship between a study sponsor (if this is not BCT) or their competitor, or a study funder and any author on a BCT scientific publication must be disclosed in the publications or in the submission letter to the journal.
- Sources of support for the work, including sponsor names along with explanations of the role of those sources (if any) in study design; collection, analysis, and interpretation of data; writing of the manuscript; any restrictions regarding the submission for publication; or a statement declaring that the supporting source had no such involvement or restrictions regarding publication. Sponsorship or financial support of a study will be acknowledged in all publications according to the policies, guidelines or agreements which govern these arrangements.
- Whether the authors had access to the study data, with an explanation of the nature and extent of access, including whether access is on-going.

1.5. PROMOTION OF TRIAL RESULTS

Promotion of trial results including media releases will be managed by the BCT Communications Manager in consultation with the DoR, OEC, BCT Study Chair (or international collaborative group, as applicable) and COO-Research. Promotional activities will be managed in line with publication embargos and any other applicable requirements.

BCT maintains a current list of all BCT publications on its website. This list is accessible and searchable by both the public and BCT Members.

1.6. DISPUTES REGARDING PUBLICATION

Disputes regarding publication that cannot be resolved by discussion will be referred to the Director of Research or delegate for resolution. The Director of Research or delegate will liaise with appropriate members of the OEC and SAC to resolve the issue. In cases where the Director of Research or delegate has a conflict of interest, the matter will be referred to the SAC Deputy Chair or OEC for resolution.

1.7. OWNERSHIP OF TRIAL DATA

Trial data from BCT-led trials is the property of BCT. Researchers who require use of all or part of the data must obtain approval from BCT by submitting a request to the Study Chair and OEC.

Trial data from trials conducted jointly with other Groups will generally be jointly owned unless otherwise agreed. The ownership and use of trial data from intergroup trials will be governed by the terms of the clinical trial agreement for the study. Access to trial data from intergroup trials for

research projects by BCT investigators will require formal approval from all Groups with data ownership rights.

Trial data from trials conducted with the pharmaceutical industry will generally be the property of BCT unless otherwise agreed. The ownership and use of trial data from trials conducted with the pharmaceutical industry will be governed by the terms of the clinical trial agreement for the study; and

Individual sites retain ownership of their own patient data (that is, data recorded about patients randomised or registered by investigators at that site).