AUSTRALASIAN GASTRO-INTESTINAL TRIALS GROUP

Publications Policy

General Principles

1. The aim of the Publication Policy is to ensure appropriate dissemination of AGITG clinical research programme results to the scientific community and the population at large.

   1.1. The results are categorised as:

   - Reports of primary outcomes of studies
   - Reports of secondary outcomes and analyses of studies
   - Reports of sub-studies.

2. Publication of AGITG data without adhering to this policy is not permitted without the prior written consent of the Chair of the AGITG Scientific Advisory Committee (SAC).

3. AGITG requires an opportunity to **review and approve** all publications (journal article and/or presentation) **prior** to submission to a Journal or Conference.

4. AGITG will be acknowledged in **all** publications (including conference presentations, media releases and abstracts).

5. The AGITG Corporate Governance Committee (CGC) is responsible for approving the Publication Policy.

6. The SAC will ensure compliance with this Publication Policy via internal reports detailing a list of all publications and presentations.

7. AGITG will maintain a current bibliography of all publications notified to the AGITG, CTC Publications Officer and OEC. The bibliography will be published on the AGITG website.

Study Chair and Trial Management Committee (TMC)

1. Ensure timely production of a scientific manuscript at the completion of the trial. If there is a significant delay in the writing of the manuscript, alternate strategies will be explored.

   1.1. **Timeframe for publication** – if the study data is not published **within 3 years** of study closure, the Study Chair will provide the final analysis as a Study Report to the Operations Executive Committee (OEC) and/or AGITG. The Study Report will be publicly available on the AGITG website.

   1.2. **Studies that are published** – a Lay Summary of the publication will be provided by the Study Chair to AGITG. The summary will be made available on the AGITG website following Consumer Advisory Panel (CAP) review and feedback.

2. For studies coordinated by the NHMRC Clinical Trials Centre (CTC), the manuscript will be drafted in liaison with the CTC Associate Oncology Program Manager (AOPM) and Publications Officer.

3. Ensure the manuscript is written by a writing committee, TMC or individuals associated with the study.

4. Suggest a list of authors.

5. Finalise the author list.
6. Ensure all authors have approved the final content of the manuscript before it is submitted to a journal.
7. Suggest a priority list of journals to submit to.
8. Forward the publication to AGITG, AOPM or CTC Publications Officer.
9. Ensure that the OEC monitor the timeliness of the publication of trial results.

Authorship

1. Presentation of the primary results of the main study should include group authorship where possible with a list of specific contributions at the end.
2. AGITG will be acknowledged in all publications (including conference presentations, medial releases and abstracts).
3. As per the ICMJE guidelines (www.icmje.org), an 'author' is considered to be someone who has made substantive intellectual contributions to a published study. Authorship credit should be based on:
    3.1. Substantial contributions to the conception and design, or acquisition of data, or analysis and interpretation of data
    3.2. Drafting the article or revising it critically for important intellectual content
    3.3. Final approval of the version to be published.
    3.4. Authors should meet conditions 1, 2 and 3 above.
4. Eligibility for authorship will be based on the following factors:
    4.1. Substantial contribution to the trial design and protocol development,
    4.2. Substantial contribution to the management and conduct of the trial,
    4.3. Substantial contribution to the analysis and interpretation of the data,
    4.4. Level of contribution of participants to the study.
5. **Study Chair** or **Co-Chair** should be the first (potentially two) author(s) on the basis that:
    - Study Chair or Co-Chair has ensured the success of the study.
    - Study Chair or Co-Chair has made significant contributions to the scientific ideas on which the study was based and to the writing of the manuscript.
    - Study Chair or Co-Chair is a guarantor of the study.

    5.1. In the event there are two Co-Chairs on a trial, the arrangements for authorship should be determined in consultation with the Trial Management and the Operations Executive committees before commencement of the study.
    5.2. In the event there are Co-Chairs on a trial, every effort should be made to ensure there are opportunities for more than one publication and that both Co-Chairs can have a first-author publication.
    5.3. A Co-Chair who is not the first author should choose whether to be second author or last author.
6. **Statistician** should be a principal author (second, third or fourth author) on the basis that:
    - The Statistician has made a significant contribution to the scientific principles of the study.

- The Statistician has 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.)
- The Statistician guarantees the scientific integrity of the study.

7. **AGITG-CTC Group Coordinator** should be considered as an author to reflect their contribution throughout the lifecycle of the trial (development, conduct, analysis and publication) for studies coordinated by the NHMRC CTC, if in compliance with the policy criteria.
8. **SAC Chair** should be considered as an author to reflect their contribution throughout the lifecycle of the trial (development, conduct, analysis and publication), if in compliance with the policy criteria.
9. Subsequent authors will comprise clinicians or other scientists who have made scientific or intellectual contributions to the study question or the study conduct and meet the journal's requirements for authorship, including members of the TMC.
10. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
11. Contributors listed in Acknowledgements:
    - Any person who contributes to the success of the study or the progress of the manuscript but does not qualify for authorship should (with his/her permission) be acknowledged in the acknowledgements section.
    - All participating sites and the coordinating centre will be acknowledged in the manuscript.

Sub-studies

1. Various sub-study publications are likely to result from any major trial or study. These may involve a distinct subset of patients or may look at specific features.
2. All sub-studies should:
    - be approved by the TMC and OEC before they are started
    - have draft publications approved as detailed in section 5
    - Acknowledge the AGITG trial involved and any sponsors of the trial.
3. Authorship of sub-studies will follow the general policy as detailed in section 6. The sub-study chair will generally be the primary author.

Intergroup Cooperative Studies

1. If the study is a collaborative (intergroup) trial, authorship should be agreed to in the protocol development phase.
2. Authorship for AGITG led intergroup studies will follow the general policy as detailed in section 6.
3. Authorship for Intergroup studies where AGITG are participating but not leading will follow the publication policy of the lead group. The Australian Principal Investigator in consultation with the Australian TMC will determine authorship for Australian investigators. Authorship will be finalised after discussion with the OEC.
4. The agreement about authorship will be included in the protocol in a section titled 'Publication Policy'.
5. This policy can accommodate such instances provided that:
    - All groups are represented on the trial management committee

- The Principal Investigator is clearly designated.

6. Manuscripts for AGITG led intergroup studies must be reviewed and scientific content approved by the OEC prior to submission.
7. Manuscripts for intergroup studies where AGITG are participating but not leading must be reviewed and scientific content approved by the OEC. The Australian Principal Investigator should liaise with the OEC to facilitate this process.
8. Reference to this policy on authorship should be included as the publications policy in all intergroup trial protocols in which the AGITG participates.
9. During the development of intergroup protocols, the publication policy should be circulated to the Protocol Development Group to facilitate discussion and resolution on this issue.

Abstracts, Presentations and Posters

1. Study participants are encouraged to write and present abstracts based on the scientific information available from the study.
2. Authorship will follow the general policy as detailed in section 6.
3. Abstracts and other presentations would generally not require OEC approval. However the following procedures are mandatory:
   3.1. Before submission, abstracts to be submitted must be referred to the study Statistician who will ensure that information disclosed is appropriate and will not compromise the main study.
   3.2. The final abstract will be sent by the primary author to the relevant Trial Coordinator or Project Manager for dissemination to the OEC.
4. Copies of submitted abstracts and presented posters, with details of the pertinent scientific meeting, should be provided to the AGITG or CTC Publications Officer by the primary author.

Ownership of Trial Data

1. Study data will usually remain the property of the AGITG (and University of Sydney when the trial is coordinated by NHMRC CTC). Researchers who require use of all or part of the data must obtain approval from the appropriate study chair.
2. Studies conducted jointly with other groups will generally have joint ownership of the data unless agreed to otherwise. Although access to data for research projects by AGITG investigators would not require formal approval from the cooperative groups, professional courtesy would ensure that notification of such projects to these groups is given.
3. Ownership of data generated in trials funded by the pharmaceutical industry will remain with the AGITG (and University of Sydney when the trial is coordinated by NHMRC CTC). The use of data by industry funders will be in accordance with the terms and conditions set out in the funding agreement. Decisions regarding the use of data will be made on an individual trial basis and incorporate the commitment from each party which will be outlined in the funding agreement.
4. In some instances both funders and the AGITG may make agreement for joint ownership after some time period has elapsed, after the termination of the study (for example 2 years). In this period, the AGITG would prepare all its reports and manuscripts. After this period the AGITG would reserve the right to use the data for further analyses in research and teaching without necessarily seeking the approval of the funder.

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

Funders

1. Funding or other contributions to the study such as drug product will be acknowledged in all publications, presentations and posters.
2. Any financial relationship between the funder, or a funder's competitor, and any author must be disclosed on publications or in the submission letter to the journal.

Disputes

1. Disputes that cannot be resolved by discussion will be referred to an independent sub-group of the SAC for resolution. This committee will be chaired by SAC Chair. In cases where there is a conflict of interest, the committee will be chaired by the SAC Deputy Chair.

Glossary of Terms

Operations Executive:	AGITG Chair, Group Coordinator, CTC Director, CTC Clinical Trial Director, Research Fellow, AGITG Chief Executive Officer, CTC Associate Oncology Program Managers, AGITG Clinical Research Manager.
Study Chair:	A person, or persons, usually clinicians, taking primary responsibility for the conception, conduct, monitoring and completion of the trial or research project.
Statistician:	The statistician taking primary responsibility for the statistical considerations of the trial. Usually the group statistician or his or her designate.
Trial Coordinator:	The person responsible for the running of the trial on a day-to-day basis. Responsibilities include randomisation, documentation, data processing, data cleaning, adverse event monitoring, quality control, liaison with site staff and preparation of reports.
Project Manager:	Used interchangeably with the term Trial Coordinator.
Principal Investigator:	Person identified at each participating institution responsible for the conduct of the trial or research project within that institution.
Reviewed:	Appraised of the content of the manuscript or abstract to ensure that the validity of the trial, the objectives of the group, and the interpretation of the data are maintained.
Commented:	Provided written feedback to the principal investigator, first author or coordinating centre to indicate that the review is complete.
Approved:	Signed off on the manuscript or abstract after review, with or without comment, and conveying this in writing to the principal investigator, first author or coordinating centre.