Publication Policy

1. Aim

A key strategic priority is for ANZUP is to disseminate results of its cancer research projects including clinical trials and translational sub-studies to the scientific community and to the community at large. This ensures that results and data are accessible for future research to further the outcomes for those impacted by urogenital cancers.

The primary method for disseminating these outcomes is through publication in peer-reviewed and globally recognised and reputable journals providing scientific rigor via peer review and acknowledges those who have made an intellectual contribution and taking responsibility for the work. Additionally, presentation of results at medical/scientific meetings provides a potential way that research teams can reveal their findings to a closed audience of their peers and receive comments and feedback before final publication.

A clear publication policy is essential to ensure that each project is reported comprehensively and that authorship is assigned deliberately and transparently. ANZUP's publication policy has been developed to ensure that each project prioritises a patient centred and equitable approach and is reported to the highest level of scientific rigor. This may include, but not be limited to, the reporting of transparent, reproducible, unbiased results that accurately describe study limitations, uses accurate data representation, and aligning conclusions strictly with findings.

2. Scope

This document covers policy and procedures for publication of ANZUP studies in peer-reviewed journals, presentation of results at scientific meetings and elsewhere as applicable.

The document is relevant to ANZUP investigators and committee/sub-committee members, hospital research staff, coordinating centre staff, and collaborating researchers who wish to use ANZUP trial data.

3. Responsibilities

The Scientific Advisory Committee (SAC) will be responsible for:

- Development and approval of the publication policy before going to ANZUP Board for ratification;
- Ensuring compliance with this publication policy.

The study chair & Trial Management Committee (TMC) will be responsible for:

- Developing an initial draft of the manuscript;
- Suggesting a list and sequence of authors with a clearly defined strategy for selecting authors.;
- Finalising the author list after discussion with the relevant Operations Executive Committee;
- Ensuring compliance of authors with Vancouver and ICMJE requirements;
- Suggesting a priority list of journals;
- Reviewing and deciding the authorship list on abstracts, presentations and papers, following transparent reviewing against predefined contribution-based selection criteria.

Where the TMC disagree regarding the proposed authorship list, the final decision will be made by the Study chair.

ANZUP will maintain an up-to-date bibliography of all publications of ANZUP trials or those to which ANZUP has contributed.

The primary author should forward the most recent version of any publications (including posters and abstracts) to ANZUP. Presentations and posters will be recorded when they relate to ANZUP or ANZUP intergroup trials.

ANZUP's bibliography will be published on the ANZUP website.

4. Manuscripts

The study chair or the senior author of the publication will be responsible for ensuring timely production of a scientific manuscript at the completion of the trial. The study chair or the senior author of the publication will liaise with the TMC Chair and agree upon a timeline for the completion of the manuscript. If there is a significant delay in the writing of the manuscript, alternate strategies will be explored. Progress will be reported to the Scientific Advisory Committee.

The manuscript may be written by a writing committee, TMC or individuals associated with the study.

All authors will approve the final content of the manuscript before it is submitted to a journal.

5. Authorship

Authorship recognises the intellectual contributions of investigators and others to a study. It also identifies those who take public responsibility for the study.

ANZUP endorses the guidelines developed by the International Committee of Medical Journal Editors (ICMJE) to ensure that contributors who have made substantive intellectual contributions to a paper are given credit as authors, but also that contributors credited as authors understand their role in taking responsibility and being accountable for what is published.

As per the ICMJE guidelines (www.icmje.org), an 'author' is someone who has made substantive intellectual contributions to a published study. Authorship credit should be based on the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Sub-editing for data quality, provision of technical services and/or materials, participation in, recruitment to, or coordination of a trial are generally not considered sufficient to warrant authorship.

When presenting the primary results of the main study, group authorship should be considered where possible with a list of specific contributions at the end.

ANZUP will be acknowledged in all publications and/or presentations. ANZUP should be named as a group author wherever allowable by the relevant journal/conference.

All funding support must be acknowledged appropriately, including funding support for ANZUP overall.

Authorship will be determined along the following lines:

The study chair or co-chair should be the first (potentially two) author(s) or senior author(s) on the basis that:

- The study chair or co-chair has ensured the success of the study;
- The 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;
- The study chair or co-chair is a guarantor of the study;
- In the event there are two co-chairs on a trial, the arrangements for authorship should be determined in consultation with the TMC on completion of the study;
- In the event there are co-chairs on a trial every effort should be made to ensure there are opportunities for appropriate authorship and recognition.

A template for recording authorship contributions is provided in APPENDIX 1.

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 will (with his or her permission) be acknowledged in an acknowledgments section.

6. Publication plan

A publication plan, including authorship, progressive steps in the development of manuscripts and target dates will be developed by the TMC and agreed to and documented by the potential authors or writing committee at the start of the project.

In general, results of sub studies will not be published before the main results of a trial.

7. Publication of journal articles

Proposals for manuscripts reporting any trial data must be approved by the TMC before data are analysed.

Main trial results

The main trial results should be submitted for publication as soon as possible, or depending on the publication strategy, within a reasonable time [usually 6 months] after the analysis of the data.

All efforts must be made to publish trial results, even if these results are negative, unexpected or disappointing.

Secondary publications and sub studies

Any proposal for a secondary study or sub study must be approved by the TMC. Authorship requirements are the same as for the primary paper.

Approval for submission of secondary study results may be withheld until primary results have been published.

8. Disclosure of results

The journal article reporting the main findings of a trial is the first public disclosure of the results. The results should not be published elsewhere or revealed to the media before journal publication, including through social media. Journal and conference embargo policies must be respected. The content of the manuscript being reviewed by a journal for publication (and the fact that the

manuscript is under review), should not be revealed publicly or to the mass media before the publication embargo time set by the journal.

Presentation of preliminary results at a scientific meeting or published in a conference abstract book or journal is not considered prior publication except where defined by specific journals or conferences.

9. Publication guidelines

The following guidelines relating to publication of research results should be followed:

- National Statement on Ethical Conduct in Human Research 2023: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
- Australian Code for the Responsible Conduct of Research 2018 https://www.nhmrc.gov.au/sites/default/files/documents/attachments/grant%20documents/The-australian-code-for-the-responsible-conduct-of-research-2018.pdf
- International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use Guidelines for Good Clinical Practice ICH E6(R3) January 2025. https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106_ErrorCorrections_2025_1024.pdf

Where relevant, the following guidelines should be considered:

ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals (formally the ("The Uniform Requirements") https://www.icmje.org/recommendations/

And any other relevant institutional guidelines, and the principles for reporting clinical trials described in:

Greater transparency for oncology clinical trials reporting. Collingridge *et al* Lancet Oncol. 2026 Feb;27(2) p147-148. https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(26)00025-2/fulltext?rss=yes

Common Sense Oncology principles for the design, analysis, and reporting of phase 3 randomised clinical trials Bishal Gyawali Lancet Oncol. 2025 Feb;26(2):e80-e89.doi: 10.1016/S1470-2045(24)00451-0. https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(24)00451-0/fulltext

10. Presentation at scientific meetings

Abstracts

The presenting author should carefully review the policies and procedures of the meeting or organisation prior to submission to adhere to all applicable requirements. The presenting author should also take into consideration the review process in accordance with funding agreements and factor this into submission timelines.

Authorship of abstract submissions for conferences that relate to ANZUP trials should include all members of the Trial Management Committee named authors, space permitting and as appropriate to the submission. If the authorship list allows those who have played a significant role in the

conduct of the trial over the duration of the study may be included however, they should not take the space of other investigators or high recruiting sites.

Study results

Proposals to present trial results (including secondary results) at national and international meetings will be approved by the TMC to ensure that this is in accord with the publication plan.

Invited presentations

Invitations to present any results from a trial or discussion of results will be approved by the TMC.

11. Intergroup studies

If the study is a collaborative (intergroup) trial, authorship should be agreed to in the protocol-development phase.

Authorship for intergroup studies led by ANZUP will follow the policy in this document.

Manuscripts for intergroup studies led by ANZUP must be reviewed and approved by the relevant trial operations executive committee and TMC before submission to a journal.

Authorship for intergroup studies where ANZUP is participating but not leading will follow the publication policy of the lead group. The Australian Principal Investigator should liaise with the Australasian TMC and relevant trial operations executive to determine authorship for Australasian investigators and ensure that Australasian contributors are appropriately credited.

This document may be cited in the protocol in a section titled 'Publication Policy'. This policy can accommodate such instances provided that:

- All groups are represented on the TMC;
- The Principal Investigator is clearly designated.

12. Bias in publication of clinical trial data

Incomplete publication of trial results leads to bias in clinical evidence. The main results of all trials should be published without undue delay.

The clinical trial registration number should be included on all manuscripts.

13. Competing interests

Contributors and authors must disclose in writing any conflict of interest (financial or academic) relating to a study or publication when submitting a paper or conference abstract.

Conflict of interest disclosures will be held by ANZUP.

14. ANZUP and Coordinating centres

All ANZUP publications and presentations will acknowledge ANZUP and individual and collective contributions of colleagues/staff where possible.

The lead author should forward a copy of any submitted manuscript or conference abstract to ANZUP and the publications office at the coordinating centre. They will record and track manuscripts being prepared for submission and being reviewed by journals.

15. Role of professional medical writers

Professional medical writers may be employed to facilitate the publication process, by assisting with writing, editing or preparing manuscripts, especially when clinicians and scientists do not have time to produce submissible manuscripts.

In general, medical writers do not contribute to the design and conduct of a study and are not responsible for the content of a paper and therefore do not qualify as authors.

The contribution of any medical writer or other contributor who does not qualify as an author should be acknowledged.

16. Data ownership and location

Study data will remain the property of ANZUP, the sponsor (if not ANZUP), and the coordinating centre where applicable. Researchers who require use of all or part of the data must request approval from the appropriate study chair. Separate arrangements will be made for the physical data in the form of bio specimen acquired via trial activities.

Data will be stored by the study statistician at the coordinating centre, and a copy will be available in ANZUP's secured SharePoint. Any transfer of a database will be fully documented by the study statistician and all associated trial parties informed, including but limited to ANZUP.

In intergroup studies, the groups will have joint ownership of the data unless agreed to otherwise. Although access to data for research projects by ANZUP investigators would not require formal approval from other cooperative groups, these groups should be notified out of courtesy.

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

Analyses and data used in published articles will be retained at the coordinating centre for a minimum of 5 years.

APPENDIX 1

	Authorship Contribution (%)								
Author Name									
Project Task									
Conceptualizing the research									
Refining/crystalizing the research									
Literature searching & summarizing									
Creating the research design									
Measurement/Instrument construction									
Selection of statistical tests/analyses									
Data (statistical/qualitative) analyses									
Interpretation of data (statistical/qualitative)									
Manuscript Content									
Writing Introduction									
Writing Methods									
Overall results collation									
Writing results analysis/ interpretation									
Writing Discussion									
Critical review/supervision									
Reviewing & providing feedback									

Other:									