

A banner image with a blurred background of books and floating mathematical symbols like pi, infinity, and numbers. The text 'CAPTIVATE Publication Policy' is overlaid in a white, bold, sans-serif font.

CAPTIVATE Publication Policy

Background:

CAPTIVATE is an innovative multi-centre, multi-arm, phase 3, blinded, parallel group, platform randomised controlled trial. The trial has multiple domains within an overarching core protocol allowing us to assess multiple treatments simultaneously and add/remove interventions based on a priori criteria. The trial will be conducted across multiple countries.

Governance:

CAPTIVATE has a robust governance structure to ensure successful delivery of the trial whilst protecting trial participants, ensuring ethical trial conduct, protecting data integrity and quality.

Principles and Confidentiality:

All publications from CAPTIVATE will follow approved authorship criteria. Academic collaborators and investigators may be invited to be authors, as well as industry partners under certain circumstances. All authors are expected to review all manuscripts. Manuscripts may also be sent to CAPTIVATE collaborators who are not named authors for review and comment. All authors and collaborators have full access to the deidentified results from appropriate/relevant analyses.

All manuscripts being submitted for publication will follow the same process. They will be drafted by a writing committee and shared with all named authors for editing. The final draft will be circulated to the wider Steering Committee and other collaborators for review and comment prior to journal submission. The Writing Committee and Steering Committee will be the named authors alongside the reference: “on behalf of the CAPTIVATE Investigators”.

Contributing Investigators Appendix

A *Contributing Investigators Appendix* of all recruiting investigators, study coordinators, steering committee members, data collection sub-committee members, and trial executive management team members will be included in all CAPTIVATE submissions to ensure that every team member is recognised within the publication. This list will be updated and circulated for review before a publication is submitted to ensure accuracy. Editors of journals/PubMed will be requested to index all collaborators individually.

Thresholds for Named Authorship [1, 2]:

Each author is expected to have made substantial contributions to the:

- Conception or design of the work, OR
- Acquisition, analysis, or interpretation of data, OR
- Creation of new software used in the work, AND
- Drafted the work or substantively revised it, AND

- Approved the submitted version (and any substantially modified version that involves the author's contribution to the study), AND
- Agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature

Authorship will not be attributed solely based on the provision of:

- Supervision
- Funding, data, materials, infrastructure, or access to equipment
- Routine technical support
- Editorial assistance
- Technical advice.

Contributions not meeting the threshold of named authorship or inclusion in the Contributing Investigators Appendix, including the contribution of research infrastructure, may be recognised by acknowledgement in the manuscript.

Recruitment Contribution and Named Authorship

CAPTIVATE recognises that high-quality participant recruitment and retention are critical intellectual and operational contributions to successful trial delivery. In addition to meeting the authorship criteria above, the Platform Oversight Committee (POC) and relevant Domain-specific Steering Committee (DSC) may consider outstanding recruitment performance (including sustained recruitment, high data completeness/quality, timely follow-up, and adherence to protocol processes) as a factor supporting eligibility for named authorship, particularly for primary domain manuscripts. The POC/DSC will review recruitment-related contributions during manuscript planning, and where appropriate may invite high-recruiting site Principal Investigators (or site leads) to join the writing group to enable substantive intellectual input, consistent with authorship standards. All contributors will be recognised in the Contributing Investigators Appendix.

Primary Analysis:

The primary analysis manuscript for each domain will be led by the domain specific principal investigators, who will be named first and last authors respectively, with the other members of the corresponding DSC, and POC also listed as named authors. If there are interactions between Domain-specific Appendix (DSAs), the DSCs for all affected DSAs will be involved in preparing the publication. Each draft manuscript will be circulated to the POC and relevant DSC and collaborators for review and comment prior to journal submission. Final approval for submission of the manuscript for publication will be granted by the POC via the chairs of the POC. Principal statisticians leading the analysis will also be included as named authors. All publications will reference: "on behalf of the CAPTIVATE Investigators".

A Contributing Investigators Appendix of ALL Steering Committee Members, Investigators and Study Coordinators involved in CAPTIVATE will be included in the submission to ensure that every team member is acknowledged in the publication. This list will be updated and circulated for review on a periodic basis to ensure accuracy of team member inclusion.

Secondary Analysis:

Specific details of authorship will be decided at the time of proposal development. All manuscripts arising from CAPTIVATE data must be reviewed and approved by the POC and relevant DSC prior to publication submission. The final draft will also be circulated to the relevant DSC and POC for review and comments. Similar to the primary analysis, all secondary analysis papers will list the group of Investigators leading the analysis activity, TGI statisticians involved in the analysis (if applicable), as well as reference “on behalf of the CAPTIVATE Investigators” with the Contributing Investigators Appendix included in the submission.

References:

1. McNutt, M.K., et al., *Transparency in authors' contributions and responsibilities to promote integrity in scientific publication*. Proc Natl Acad Sci U S A, 2018. 115(11): p. 2557-2560.
2. *Authorship: A guide supporting the Australian Code for the Responsible Conduct of Research*. 2019, National Health and Medical Research Council.