

MTN 004 Publication Guidance

MTN 004 Protocol Team Publication Goals

It is the intent of the MTN 004 Protocol Team to ensure:

1. Publications utilizing MTN 004 data are published in a timely fashion and contain accurate information.
2. Writing assignments are clearly defined and fairly distributed among the MTN 004 Protocol Team.

MTN 004 Publication Committee

The MTN 004 Publications Committee (PC) will oversee the MTN 004 publication process. The Publications Committee will include the following individuals:

1. Ian McGowan (Protocol Chair)
2. Barbra Richardson (SDMC Biostatistician)
3. Jeanna Piper (DAIDS Medical Officer)
4. Kailazarid Gomez (FHI Clinical Research Manager)

MTN 004 Publication Committee Responsibilities

The responsibilities of the MTN 004 PC include:

1. Setting priorities for MTN 004 data analyses;
2. Triaging proposals from study investigators for use of data collected from MTN 004;
3. Determining the appropriate composition of MTN 004 analysis and writing teams;
4. Agreeing on authorship for all MTN 004 publications;
5. Assisting protocol team members in becoming active participants in the analysis and writing process;
6. Reviewing and providing feedback to authors on draft publications;
***NOTE:** The MTN-004 Publication Committee may ask other protocol team members for input on publications based on expertise.*
7. Establishing timelines for publication development and review
8. Disseminating and publishing as much information as is possible from the data collected during the course of MTN 004.

These objectives will be accomplished using the guidance of the MTN Publications Policy.

<http://mtnstopshiv.org/sites/default/files/attachments/MOP2009Appendix.pdf>

MTN 004 Publication Proposal Guidelines

Proposals for publications (abstracts or manuscripts), and presentations should be submitted to the MTN 004 PC, utilizing the attached form. These include proposals for both multi-site and single-site analyses.

From these submissions, the MTN 004 PC will compile a list of all requests for analyses/publications and will work to ensure that each concept on the list is appropriately evaluated.

The MTN 004 PC will assign lead writing roles among the project investigators/team members based on the above-listed principles, the expressed interest of the specific investigators/team members, and a desire to distribute lead writing assignments as equally as possible among the investigators and the team.

Note: *Investigators/team members who accept a lead writing assignment will be expected to produce their manuscripts in a timely fashion. For those failing to do so, the MTN 004 Publications Committee has the authority to re-assign lead writing assignments.*

Priority will be given to analyses addressing primary and secondary study objectives of MTN 004; however, other analysis proposals will be considered on their merits. In general, access to data will be made available according to a plan that allows access in the following sequence:

1. MTN 004 Protocol Chair
2. All other members of the protocol team and/or staff at the participating MTN 004 institutions
3. All other members of the protocol team and/or staff at non-004 but member MTN institutions

MTN 004
Concept Sheet Form

Date: _____
Investigator/team member name: _____
Investigator/team member institution: _____
Investigator/team member email address: _____

This concept proposal should include the following:

1. Proposed abstract/manuscript title and names of the lead writer as well as potential participating investigators (if known).

2. Briefly describe the rationale for the proposed publication.

3. List specific research hypothesis and how it relates to the primary or secondary objectives of MTN 004.

4. Provide a summary of the analysis plan. List analysis variables including dependent variables, independent variables of primary interest, and other variables to control in the analysis.

5. Proposed timeline for completion of analysis.

6. **OPTIONAL:** Statistical methods/approaches anticipated for the manuscript (unless the statistical analyses have already been determined and/or are to be done outside of SCHARP, an statistician will be assigned to be a member of the writing team once a concept has been reviewed and approved by the MTN 004 Publications Committee).

Submit this Concept Sheet proposal to the MTN 004 Publications Committee
mtn004pubcommittee@mtnstopshiv.org

MTN 004 Publication Authorship/Sponsorship Guidelines

The following comprises suggested guidance on authorship for MTN 004 publications:

Authorship should be reflective of the multi-site nature of MTN 004, MTN publication policies, and generally accepted authorship guidelines. Authorship should be based on the collaborative contributions of all investigators; from conception and design, or acquisition of data, or analysis and interpretation of data; drafting the abstract or revising it critically for important intellectual content; and final approval of the version to be presented/published.

Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. Everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work to take public responsibility for appropriate portions of the content.

The following approach for operationalizing these guidelines will be implemented:

- The person leading the data analysis, data interpretation, and writing of the abstract/manuscript should be the first author.
- Team members who contributed substantially to the conceptualization, design, and/or implementation of specific aspects of the study should be included as first author or co-author on abstracts/manuscripts related to that aspect of the study (e.g., safety measures, behavioral measures).
- If data from more than one site are included in an abstract/manuscript, a representative from each site should be included as a co-author whenever possible. When abstract submission guidelines limit the number of co-authors, the Publication Committee will facilitate decision-making on site representation in the authorship team, making every effort to ensure fairness across sites over time.
- All authorship lists for abstracts/manuscripts that include data from more than one site should include “on behalf of the MTN 004 Protocol Team” at the end of the authorship list.
- The SCHARP statistician who works with the first author to analyze the data for the abstract/manuscript should be included as a co-author. The Protocol Statisticians are responsible for designating the most appropriate SCHARP staff member to the authorship team.
- A representative from FHI should be given the option of being included as a co-author on all abstracts/manuscripts presenting data on primary and secondary study objectives or describing study design and conduct.
- A representative from the MTN Network Laboratory should be given the option of being included as a co-author on abstracts/manuscripts involving laboratory aspects of the study.

- For abstracts/manuscripts presenting data on primary and secondary study objectives, the Protocol Chair should be given the option of being included as a co-author.
- For abstracts/manuscripts presenting data on primary and secondary study objectives, the SCHARP Project Manager should be given the option of being included as a co-author
- For abstracts/manuscripts presenting data on behavioral assessment should include a representative from the Behavioral Working Group.
- Acknowledgments: All publications and presentations will include a statement acknowledging the MTN's and NIH's support for the work and listing the applicable cooperative agreement numbers, unless the journal's policy precludes such an acknowledgment. The acknowledge section for publications should include:
 - Study sponsors: US National Institutes of Health (R Black, B Kapogiannis, J Piper); Starpharma Pty Ltd. (J Paull, C Price)
 - Protocol Chair (I McGowan)
 - Tampa, USA: (P Emmanuel)
 - San Juan, Puerto Rico: (I Febo)
 - Pittsburgh, USA: (B Chen)
 - Coordinating Center: (K Bunge, A Carballo-Diequez, R Cranston, L Levy, L Noguchi, K Gomez, M Shah, R White)
 - Statistical Center: (M Cianciola, M Husnik, B Masse, K Patterson, B Richardson)
 - Network Laboratory: (C Dezzutti, S Hillier, E Livant, L Rabe)

MTN 004 was sponsored by the US National Institutes of Health (NIH); and co-sponsored by CONRAD and Gilead Sciences, Inc. The study was designed and implemented by the Microbicide Trials Network (MTN). The MTN (U01AI068633) has been funded by NIAID, NICHD, and NIMH. MTN-004 was also funded through NICHD awards to the Adolescent Trials Network (U01 HD040533 and U01 HD040474) co-funded by NIMH and NIDA.

MTN 004 Publication Review Process

Any presentation, abstract, or manuscript will be submitted to the MTN Manuscript Review Committee, DAIDS, NICHD, and Starpharma Pty Ltd. for review prior to submission for publication.