

MTN-003 Publication Plan

1.0 MTN-003 Protocol Team Publication Goals

It is the goal of the MTN-003 Protocol Team to ensure MTN-003 data are cleaned, analyzed, and completed for publication as soon as possible; publications utilizing MTN-003 data are published in a timely fashion; and writing assignments are clearly defined and fairly distributed among the MTN-003 Protocol Team.

2.0 MTN-003 Publication Committee

The MTN-003 Publications Committee (PC) will oversee the MTN-003 publication process. The Publications Committee will include the following individuals: Z. Mike Chirenje (Protocol Co-chair), Jeanne Marrazzo (Protocol Co-chair), Barbra Richardson (SDMC Biostatistician), Jeanna Piper (DAIDS Medical Officer), Kailazarid Gomez (FHI 360 Clinical Research Manager), Karen Patterson (SCHARP Project Manager) and Lisa Noguchi (Protocol Specialist).

- *Note: The MTN-003 Publication Committee may ask other protocol team members for input on publications based on expertise.*

2.1 MTN-003 Publication Committee Responsibilities

The responsibilities of the MTN-003 PC include:

1. Setting priorities for MTN-003 data analyses;
2. Planning, reviewing and approving publication concepts for all protocol-related scientific publications (including journal articles and meeting abstracts, poster and oral presentations)
3. Triaging manuscript development and proposals from study investigators for use of data collected from MTN-003;
4. Determining the appropriate composition of MTN-003 analysis and writing teams;
5. Agreeing on authorship for all MTN-003 publications;
6. Assisting protocol team members in becoming active participants in the analysis and writing process;
7. Reviewing and providing feedback to authors on draft publications;
8. Establishing and monitoring timelines for publication development and review;
9. Approving all study publications prior to submission to the MTN MRC and subsequent journal and/or conference venue
10. Disseminating and publishing as much information as is possible from the data collected during the course of MTN-003.

These objectives will be accomplished using the guidance of the MTN Publications Policy which is located in Section 6 of the MTN Manual of Operational Procedures:

<http://www.mtnstopshiv.org/node/187>

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3.0 MTN-003 Publication Proposal Guidelines

Proposals for publications (abstracts or manuscripts) and presentations should be submitted to the MTN-003 PC, utilizing the *MTN-003 Concept Sheet Form* (See Appendix I). These include proposals for both multi-site and single-site analyses. From these submissions, the MTN-003 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.

In addition, the MTN-003 PC has taken proactive steps to list potential analyses/publications and propose an allocation of these potential analyses/publications to specific members of the MTN-003 team. The MTN-003 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-003 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-003; 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-003 Protocol Chairs
2. All other members of the protocol team and/or staff at the participating MTN-003 institutions
3. All other staff at non-participating MTN-003 institutions but member MTN institutions

4.0 MTN-003 Publication Authorship/Sponsorship Guidelines

The following comprises suggested guidance on authorship for MTN-003 publications. Authorship should be reflective of the multi-site nature of MTN-003, 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.

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Please Note: Authorship priority will be given to staff that collaborated on the MTN-003 study. If a person who did not collaborate on MTN-003 is interested in being included as an author, the MTN-003 PC should be consulted. When communicating with the MTN-003 PC, please provide a rationale as to why the person should be included as a potential author.

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-003 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 360 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 Laboratory Center should be given the option of being included as a co-author on abstracts/manuscripts involving laboratory aspects of the study.
- The SCHARP Project Manager should be given the option of being included as a co-author on all abstracts/manuscripts presenting data on primary and secondary study objectives.

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- A representative from the MTN BRWG should be given the option of being included as a co-author on abstracts/manuscripts involving behavioral aspects/assessments of the study.
- Protocol Chairs should be given the option of being included as co-authors on all abstracts/manuscripts presenting data on primary and secondary study objectives

5.0 MTN-003 Publication Review Process

1. The proposing author will complete and submit the MTN-003 Concept Proposal Form to MTN-003 PC by email (mtn003pubcommittee@mtnstopshiv.org). Note: Site-specific proposals must be reviewed and approved by the site Investigator of Record (IoR) prior to submission to the MTN-003 PC.
2. The MTN-003 PC aims to review and provide written comments on concept proposals within 5 working days. FHI 360 will compile and provide final comments from all reviewers to the lead author and/or will notify the lead author of the MTN-003 PC decision on whether the concept can move forward to development.
3. Upon receipt of MTN-003 PC approval of the proposed concept, the lead author will draft the publication in a timely manner per the timeline outlined in the concept proposal sheet. NOTE: The publication must be formatted in accordance with target journal or conference requirements.
4. All members of the writing team must review and approve the publication prior to submission to the MTN-003 PC.
5. The lead author will submit the publication to the MTN-003 PC by e-mail (mtn003pubcommittee@mtnstopshiv.org), and indicate the target journal or venue (for abstracts and presentations).
6. The MTN-003 PC will review within 10 working days, and comments will be sent to the lead author within 14 working days.
7. Once the lead author receives comments and feedback, she/he will address these in a timely manner and resubmit to the MTN-003 PC for review.
8. The MTN-003 PC will distribute the publication within three working days to DAIDS, CONRAD, and Gilead Sciences, Inc. for review prior to submission to the MTN Manuscript Review Committee (MRC).
9. The MTN-003 PC will compile final comments from all reviewers and submit to the lead author.
10. Once final comments have been received and incorporated, the lead author will send the publication to FHI 360 CRM
11. FHI 360 CRM will upload the publication to Datavision and initiates the MRC review process.
12. Once the review has been completed by the MTN MRC, comments to the lead author will be provided via Datavision. An automated email, generated by Datavision, is sent to the author

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providing a link to the review outcome along with the reviewer's comments and suggested revisions

Please note that an abstract or manuscript may be submitted for presentation/publication only after it has been approved by the MTN-003 PC and MTN MRC and others as appropriate. Once it is submitted for presentation/publication, the lead author is responsible for informing the MTN-003 PC and MTN MRC of the result of the review and the presentation/publication's status.

Note: In the event an author has intention of developing an approved abstract into a manuscript, the lead author should email the MTN-003 PC requesting approval prior to development of the manuscript. At a minimum, the e-mail should include:

- Target journal
- Proposed timeline
- Any additional data/support needed from the MTN Statistical Data and Management Center (SDMC)

6.0 Publication 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 the following statement of support:

MTN-003 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 is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health.

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Appendix I: MTN-003 Concept Proposal Form

Date:

Lead Author/Writer Name:

Lead Author/Writer: Institution:

Lead Author/Writer Email Address:

Lead Author/Writer Role on MTN-003 (VOICE):

This concept proposal should be brief (1-3 pages) and must include the following:

1. Type of publication: (e.g., manuscript or abstract)

Note: If the lead author intends to develop an approved abstract into a manuscript, the lead author should email the VOICE PC requesting approval prior to manuscript development.

2. What venue (Journal, conference, etc.) will this publication be submitted?

3. Submission Deadline (to target venue), if applicable

4. Name of Potential Co-Authors/Writing Team (if known):

NOTE: Authorship priority should be given to staff that collaborated on the VOICE study.

5. Proposed publication title

6. Briefly describe the rationale/hypothesis/objectives for the proposed publication: NOTE: If related to the protocol's study objectives, please explain.

7. 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.

7.a. Is data needed from the MTN Statistical Data and Management Center (SDMC)?

No → specify below what data will be used and how such data will be generated.

Yes → provide a summary of data needed (e.g., lab assay data, CASI, CRF, etc.):

7.b. Is assistance needed with the statistical analysis?

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- No → If no, please describe who will be conducting the statistical analysis or why no statistical analysis is needed:
- Yes → A statistician will be assigned to be a member of the writing team once a concept has been reviewed and approved by the VOICE PC.

8. Proposed timeline for completion of analysis and subsequent submission of draft publication to VOICE PC.

Submit this Concept Sheet proposal to the MTN-003 Publications Committee (PC)
mtn003pubcommittee@mtnstopshiv.org.