

VOICE Publication Plan

VOICE Team Meeting

MTN Annual Meeting, February 2012



VAGINAL + ORAL INTERVENTIONS
TO CONTROL THE EPIDEMIC

Where do we start?

- Initial list of manuscript topics generated by protocol chairs, study statisticians (Tier 1) — underway
- Establish lead author, lead statistician
- Establish writing team
- Goal: ready to submit Tier 1 when data presented

Topic	Lead Author(s)	Writing Team
Primary safety & efficacy	Protocol co-chairs, study statistician	Representatives from DAIDS, FHI, SCHARP, NL, Sites Investigators
“Baseline paper:” study design, accrual process, key baseline characteristic of enrollees	Protocol co-chairs, study statistician, FHI	Representatives from DAIDS, FHI, SCHARP, NL, Sites Investigators



Next step: Tier 2 (Protocol Objectives)

- Behavioral
- Seroconverters
- Safety
- Reproductive outcomes
- Pharmacokinetics
- Acquisition of HSV-2 (herpes simplex virus)

Next step: Tier 2 (Protocol Objectives)

□ Behavioral

Topic	Lead Author(s)
Adherence	BRWG
Sexual behavior	BRWG

□ Seroconversion

Topic	Lead Author(s)
HIV drug resistance	Network lab
Delayed seroconversion	TBD

Next step: Tier 2 (Protocol Objectives)

□ Safety

Topic	Lead Author(s)
Baseline renal, hepatic, metabolic characteristics	Safety Physicians
Specific safety secondary analysis on study (e.g. proteinuria, creatinine, hypophosphatemia, genital AEs)	Safety Physicians

□ Reproductive Outcomes

Topic	Lead Author(s)
Pregnancy incidence & associated outcomes (contraceptive use, association with HIV risk)	TBD

Next step: Tier 2 (Protocol Objectives)

□ pK / pD

Topic	Lead Author(s)
pK / pD analyses	Pharmacology core

□ Reproductive Outcomes

Topic	Lead Author(s)
Pregnancy incidence & associated outcomes (contraceptive use, association with HIV risk)	TBD

Next step: Tier 2

□ STI

Topic	Lead Author(s)
Incidence of genital herpes (HSV-2)	Protocol co-chairs
Incidence of other STI	TBD
Hepatitis B: baseline data, uptake of immunization, incidence in unvaccinated	

□ Community involvement

Topic	Lead Author(s)
Community efforts	CWG



Next steps...

- Distribution of publication list
- Designation of site staff for MS writing teams
- Consideration of site proposals for additional papers
 - MTN process
 - VOICE Publication Committee: Mike Chirenje, Kaila Gomez, Barb Richardson, Jeanne Marrazzo, Lisa Noguchi, Jeanna Piper



VOICE Publication Plan

- Describes process for publication submissions from the point of submitting proposed ideas to the VOICE Publication Committee to the approval process.
- Goal: ensure that data are cleaned and analyzed, published in a timely fashion; writing assignments are clearly defined and fairly distributed among team
- Proposals submitted to the MTN-003 PC, using MTN-003 Concept Sheet Form. 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



VOICE Publication Plan

- MTN-003 PC will oversee the writing assignment among the project investigators/team members
- Authorship should
 - Reflect multi-site nature of MTN-003, MTN publication policies, and generally accepted authorship guidelines.
 - Be based on collaborative contributions of all investigators; from conception and design, or acquisition of data, or analysis and interpretation of data; drafting the work 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
 - All authors should have made a substantial, direct, intellectual contribution to the work to take public responsibility for appropriate portions of the content.

Authorship Guidelines

First Author

- Person leading data analysis, interpretation and writing should be first author

Co-authors

- Team members who contributed substantially to conceptualization, design, and/or implementation of the aspect of the study covered
- A representative from each site if data from more than one site are included
- SDMC statistician who oversees data analysis



First Review: Site Leader

- 1) Submit concept, outline, or draft abstract to site leader or designee for approval and identifies an appropriate journal for submission
- 2) Work with site leader to develop a more detailed abstract



Second Review: Protocol Chair

- 1) Submit draft abstract to Protocol Chair for review
- 2) The Protocol Chair reviews the abstract, discusses with statistician (or statistician and protocol publications committee) and informs author of their decision which may be any of the following:
 - 1) Yes, this would make a **good journal article**, so please move forward with writing a paper (if there are many papers moving forward, the statisticians and protocol chair need to create a prioritization list – which analyses to be done first)
 - 2) Yes, this would make a **good abstract to submit to the conference**; please continue working on the abstract (suggested edits included in the draft)
 - 3) No, this should not move forward

Second Review: Protocol Chair

3) If approved:

Journal article: the author talks with Chair about possible target journals and moves forward with writing the manuscript (working with statistician)

Abstract to be submitted to a conference:, **the author** investigates the conference abstract guidelines and deadlines; revises abstract as requested and resubmits for Chair approval and reviews

4) Protocol Chair (or lead author) works with the Medical Officer to ensure all sponsor representatives have the opportunity to review the abstract/manuscript per the Clinical Trials Agreement for the study

Third Review: MTN Manuscript Review Committee (MRC)

- 1) Once approved by the Protocol Chair and DAIDS Medical Officer, the author submits to the MTN Manuscript Review Committee via the links on the MTN website

Checklist prior to submitting to MRC:

Methods and rationale are clearly described, and as are the conclusions

Numbers in tables and graphs agree with text

Number of words meets criteria of journal or conference