ASPIRE Publications: Approach and Overview

Jared Baeten

Katie Schwartz

MTN Regional Meeting: October 2015

Goals for ASPIRE publications

- Collaboration

- High quality manuscripts

- Timely reporting and wide dissemination

- Capacity building of young investigators

- Compliance with ethics and with authorship integrity

ASPIRE
A Study to Prevent Infection
with a Ring for Extended Use

Process (1)

- Concept Development:
  - Lead author and mentor identified
  - Specify if submitting for conference or manuscript development
  - Analysis plan- tell us the story you want to tell with this data! Will you need SCHARP support?

Process (2)

- PPC Review:
  - Ensure support is identified as needed
  - Making a needed scientific contribution to the field?
  - Is there overlap with other concept proposals?
  - What is appropriate timeline given analysis priorities?
  - Who is appropriate to include on the writing team?

Operations (1)

- All concepts must first be approved by the MTN-020 Publications Committee. Site-level concepts and abstracts should be approved by the IoR first.

- Lead author will manage ASPIRE Pubs Com and MTN MRC approvals and track all timelines
  - Lead authors with relatively limited manuscript experience should have mentoring

- FHI 360 will manage sponsor (IPM) approvals

- It is the lead author's responsibility to provide FHI 360 and the MTN MRC will all final versions (oral presentation, poster, or manuscript)

ASPIRE
A Study to Prevent Infection
with a Ring for Extended Use

Operations (2)

- Manuscript/Abstract Development:
  - Work closely with mentor (if suggested by PPC) to ensure efficiency and overall positive experience for all involved
  - Lead authors (site staff): Report back on progress to site IoR in advance of ASPIRE publications calls
  - Lead authors (non-site staff): Join pubs calls to provide updates to PPC on progress and timeline

Making the goals a reality

- Manuscript concepts are robust and result in collaborative, efficient analysis;

- Publications utilizing MTN-020 data are written and revised in a timely fashion;

- All team members are provided an opportunity to develop and participate in the development of MTN-020 manuscripts.

Authorship Guidelines

- ICMJE:
  - 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 revising 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.

ASPIRE
A Study to Prevent Infection
with a Ring for Extended Use

Authorship

- Our approach:
  - The Pubs Com will help finalize writing teams for each ASPIRE manuscript
  - Authorship suggestions from the Pubs Com will be based on interest expressed (based on discussions or similar concepts submitted by other individuals), involvement in the topic area, or role/responsibilities in ASPIRE
  - ICMJE criteria will be used.

ASPIRE
A Study to Prevent Infection
with a Ring for Extended Use

Timelines

- As we all know, when the trial was ongoing we did not analyze post-randomization data.

- We have completed the baseline manuscript (submitted!) and the first publication will be the primary efficacy and safety manuscript (late 2015 submission…!). Thereafter, we will move through a priority list.

Manuscript Expectations

- Priorities and manuscripts in development will be reviewed on periodic publications calls.

- Once analysis is underway, forward progress is expected on manuscript development. If progress is not made, the Pubs Comm could assign a new lead author to the manuscript.

Current Manuscript Concepts

- 14 manuscript concepts submitted to ASPIRE PPC
  - 3 approved
  - 4 still under review by PPC
  - 6 are being revised by lead authors/next steps being determined based on PPC review
- 3 are known in development (not yet received by committee)

Next Steps

- Discuss proposed manuscript ideas and brainstorm new ones

- Determine authorship list on first set of manuscripts

- Establish regular publications calls for ASPIRE with site IoR representing the site
  - Track concepts in progress
  - Discuss/brainstorm new areas for manuscript development
  - Ensure timelines are kept, ideas are moving forward and authors are supported in process