Telling a story – manuscripts

MTN Regional Meeting
Laboratory Breakout 2016
Have an idea?

• Is there a gap in the information available?
• Do you have a testable hypothesis?
• What testing / data analysis is needed?

• Ancillary study – investigations that are not described in the original protocol
• Data request – data is available, but need to crunch the numbers.
Write it up!

• Develop your hypothesis / study design and talk with the LC, SCHARP, and FHI360 folks familiar with that study.

• As you fill-in the ancillary concept / data request application (http://www.mtnstopshiv.org/node/5647), please keep-in mind logistical considerations.
Logistics

- What types of samples are available from which visits? Review Study protocol and SSP first.
- Do your ethics committees need to approve your proposal?
- Will I only be analyzing data or will I need samples?
- Will I use samples only from my site or should I expand to include other sites?
- How will I identify samples needed for my concept? Talk with SCHARP.
- Will samples need to be shipped?
- How will shipping, testing, and other aspects of my concept be funded?
- How will the data be analyzed?
Your concept

• Make sure your application addresses all elements and is clearly written.

• Once ready, send your form, and any additional information, to the FHI 360 Clinical Research Manager (CRM) for that study to start the approval process.
Approval process

- FHI360 CRM
- Protocol Team
- Working Groups
  - Community
  - Biomedical Science
  - Behavioral Research
- Protocol Chair / co-chair(s)

1. Questions/clarifications for investigator
2. Protocol Team
3. Working Groups
4. Protocol Chair / co-chair(s)
5. Stop

- Not approve
- Comments/concerns
- Not approve
- Stop

Not approve path leads to Stop.
Approval process

Protocol Chair / co-chair(s)

Operational review

MTN Executive Committee

Approved pending modifications
Approved
Denied

(Redesign application?)

Investigator informed of the outcome.
Don’t delay

• Novel findings need to be written up well and quickly...
• ... otherwise others will publish them.
  OR
• ... the information will no longer be relevant.
• MTN leaders are applying for a Fogerty Global Health Fellowship to work with you on developing publications – funded in 2018?
Once your paper is written

• Send the draft to the CRM for review by collaborators and protocol publication committee(s).

• Consider the feedback
  – Make edits as necessary or
  – Explain why they’re not needed.

• After protocol team approval, paper needs to be cleared by MTN Manuscript Review Committee (MRC).
Submit to a journal

• Outcomes:
  – Provisionally accepted pending rebuttal
  – Rejected
• Regardless should have valuable comments.
• Resubmit – don’t quite!
• Once accepted, notify the MTN MRC and make sure you obtain the PMCID number.
Congratulations!