Communications Planning:
Study Closeout and Results Dissemination

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ASPIRE Team Meeting
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Overview

- Who does what
- The general plan
- Important considerations
- Communications planning and materials development timeline
Communications Planning Group

For DAIDS/NIAID
- DAIDS Leadership – PO, MO
- NIAID Office of Communications and Government Relations (OCGR)
- DAIDS Workforce Operations, Communications and Reporting Branch (WOCRB)

For MTN
- MTN Leadership – Co-PIs
- MTN Communications and External Relations Director
- ASPIRE Protocol Chair and Co-chair
- FHI 360 Clinical Research Manager

See MOP section titled *Data Access, Public Release and Communications*
Who does what?

- **DAIDS/NIAID:**
  - Directs overall planning
  - Sets timelines, parameters for stakeholder engagement
  - Coordinates with IPM per CTA
  - Issues official press release; directs U.S. media outreach

- **MTN:**
  - Works with sites on plans
  - Ensures plans and timelines align with overall strategy (NIAID, IPM)
  - Develops materials and provides training and support
  - Oversees outreach to key African media, civil society
  - Coordinates communications with other stakeholders as appropriate

See MOP section titled *Data Access, Public Release and Communications*
Cross-Communications Planning Group

**MTN**
- Lisa Rossi  
  *Communications and External Relations Director*

**NIAID/DAIDS**
- Kathy Stover  
  *Chief, News and Science Writing Branch, OCGR, NIAID*
- Rona Siskind  
  *Health Sciences Specialist, WOCRB, DAIDS*

**IPM**
- Holly Seltzer  
  *Communications Director*
- Leonard Solai  
  *Director, External Affairs (Africa)*
The General Plan

- Funders, MTN leadership, Study leadership, IoRs and IPM will be unblinded tentatively mid-November
  - This should be kept confidential

- Results will be announced in a press release within a few weeks of unblinding (early Dec.)
  - Release will not be linked to a publication or meeting
  - Goal still to get manuscript submitted/published ASAP

- What’s the rationale?
  - Waiting to publish or for CROI would be time lost -- if the ring is effective, want to start the approval process for HOPE right away
Practical Implications

There will be no embargo to work around

- Timing will revolve around NIAID release (similar to the way it would be for a DSMB announcement)
- Time zone differences may still be an issue, but MTN will try to accommodate as best we can

We may have only a few weeks to disseminate results

- Timing would be just before the holidays
- Materials will need to be finalized quickly
- Sites – all of us – would need to be ready to spring into action
Critical questions to consider

What about The Ring Study?

- Will The Ring Study have efficacy results when we are ready to report ASPIRE results?
- If both studies have efficacy results, are they or are they not similar? What does it mean if they’re not?
- What do our results (or both sets of results) mean for the future of the ring?

What about HOPE?

- Will results support moving forward?
- Will we have a definitive answer at the time of release?
Different landscape(s) to consider

- After FACTS 001, results of ASPIRE and The Ring Study are now “highly anticipated”
  - The stakes are high; expectations are high

- Phase II trials of long-acting injectables now taking place in Zimbabwe, Malawi and Uganda
  - HPTN 076 – South Africa (Cape Town–Emavundleni); Zimbabwe (Spilhaus)
  - HPTN 077 – Malawi (Lilongwe); South Africa (CAPRISA and PHRU- Soweto)

- HVTN 100 Phase II vaccine trial underway in South Africa

- Partners Demonstration Project ongoing in Uganda; advocacy push for PrEP introduction in several countries
Potential criticism to consider

“Science by press release”

- Potential criticism from the scientific community
  - Not the typical process – not peer review
  - Many journals allow for this, however – and we may have an agreement at the time of release
  - Ethics consultation may be considered

- RV 144 Thai Vaccine experience - Can a press release be trusted?
  - Release: “HIV Vaccine Study First to Show Some Effectiveness in Preventing HIV” cited only mITT result – reduced risk by 31.2%, statistically significant
  - Full analysis published 4 weeks later reported 26% - no statistical significance
  - (Shows also that press coverage does not preclude publication)
  - We intend to provide as much info as possible (appropriate for a news release)
  - May consider additional vehicles for access to data
The Communications Process: 3 (4?) Phases

- Phase 1 - Study close-out
- Phase 2 - Pre-Results
- Phase 3 - Results dissemination
- Phase 4 - Lead-in to HOPE
Study close-out

- Materials available June/July for use before, during and/or after close-out (i.e., into pre-results phase)
  - Updated ASPIRE QA
  - Updated “Sister Studies” Fact Sheet
  - OLEs fact sheet and definitions
  - Anticipating the Results fact sheet
  - Anticipating the Results PowerPoint
  - Updated General Study Messages
- MTN press release when study officially closed
- Engagement with stakeholders and community focused on next steps, timeline for results, possible outcomes
Pre-Results

June - November
- Ongoing engagement with community, stakeholders and participants

August - November
- Intensive planning and preparations

Rossi’s Rules on Readiness for Releasing Ring Results
August / September

Sites to receive communications planning materials

- Communications plan template/survey
  - Focused on both ASPIRE and HOPE
  - Pre-release activities and proposed plans for release
  - Different audiences and groups – e.g., staff, participants, CABs, MoHs, IRB/ECs, civil society, media

- Stakeholders Directory

- Media relations SOP
September/October

- Scenarios and messages distributed
- Dear Colleague letter(s) distributed

At Regional Meeting (Oct. 4-8)

- Media training
- Face-to-face meetings with each site to discuss plans, challenges, needs
October

Possible joint MTN and IPM meetings with:
- Key stakeholders
- Civil society and advocacy representatives
- Select media
November

- Unblinding mid-November??
- Within 1-2 weeks - materials finalized/approved
  - NIAID press release
  - MTN press release
  - QA
  - Understanding the Results fact sheet
  - Understanding the Results PowerPoint
  - Dear Colleague letter (s)
  - Key messages
  - Internal QA
  - Talking points and FAQ for trial staff
  - HOPE QA/fact sheet
December

**Nov. 30 - Dec. 12**
Approximate 2-week window for Results Dissemination

- Things are very preliminary – many details to work out
  - Will likely plan according to Tier 1, Tier 2, Tier 3, etc
  - MoHs and IRB/ECs likely Tier 1
  - Press release likely to coincide with Tier 3

- Process will play out on multiple levels and by multiple players in highly coordinated fashion
  - NIAID
  - MTN
  - IPM
  - Within each country
  - At each site
Summary

- Planning will cover both ASPIRE and HOPE
- Will coordinate very closely with IPM
- Many, many things to consider
- Small window for results dissemination
- Preparation is key!
- Remember…..

Rossi’s Rules on Readiness for Releasing Ring Results
Thank you!

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Questions?