

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, WOCR, 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....

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on
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Thank you!

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Questions?
