ASPIRE CWG Considerations for Study Closeout

Jason Naidoo
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Outline

• Community Perceptions of the Vaginal Ring
• Considerations for ASPIRE Closeout
• Strategies for Success
Community Perceptions of the Vaginal Ring (VR) • At start of ASPIRE, reaction to VR was concern, skepticism, and misconceptions; a 'foreign concept' • Now through continuous sensitization, the VR is accepted as a prevention tool for women; an 'immediate hope' – Support from men/partners has increased, but concern about not being consulted for approval prior to ring use remains
Considerations for ASPIRE Closeout

- Convene appreciation events for participants
- Prepare referral system for access to standard of care
- Consider quarterly visits between end of ASPIRE and start of HOPE to maintain contact, provide counseling/social support, and provide condoms
Considerations for ASPIRE Closeout

• Develop an easy-to-understand closeout plan for participants, partners, the CAB and other stakeholders that includes:
  – a timeline of activities for period between closeout and release of study results
  – various study result scenarios
  – a regulatory pathway presentation/poster
  – plans for post-trial access to the ring
Strategies for Success

Activities to Continue

• Participant engagement
• One-on-one counseling
• Male partner-specific meetings
• Non-study specific sensitization and community meetings for updates
Strategies for Success

New and Enhanced Approaches

• Provide incentives for retention milestones and consistent visit adherence
• More frequent courtesy calls to stay in touch between visits
• Organize waiting room discussions around topics relevant to participants’ lives
Strategies for Success

New and Enhanced Approaches

• Organize recreational/social events between participants, male partners and study staff away from clinic and without any study-related discussion

• Improve the overall clinic experience
Summary

- Community sensitization and timely response to misinformation has been important toward achieving a positive and optimistic community perception of the ring
- Closeout plan should include continued contact with participants during bridge period and establishing means for access to standard of care
Summary

• Continue current participant engagement and support activities
• Consider staff/participant recreational activities and increase phone contacts to achieve/maintain high visit adherence, ring enthusiasm, and ring adherence
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