



ASPIRE CWG Considerations for Study Closeout

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Outline

- Community Perceptions of the Vaginal Ring
- Considerations for ASPIRE Closeout
- Strategies for Success



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

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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