



Pitt CRS

Update for MTN-017

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Presentation Outline

- Study Progress
- Best Study Practices
- Challenges Implementing MTN-017
- Strategies to Address These Challenges
- Lessons Learned

Study Progress

- Date of activation- 9/27/13
- First enrollment- 10/24/13



↳ 2 ineligible (1 Rectal Ct; 1 Rectal abnormality)
3 Pending Eligibility

- 4 (screen): 3 (enrolled) ratio

Best Study Practices

- Recruitment success due to:
 - Prior participants excited for study
 - Pre-activation wait list
 - Active research registry
 - Word of mouth



Best Study Practices

- We're in our Rectal Groove:
 - Site experience with rectal microbicide/PrEP studies (Staff, Pharmacy, Physicians, etc.)
 - Research Savvy Participants “Rectal Rock Stars”



Challenges Implementing MTN-017

- Pool of recycled participants needing to adhere to strict wash-out periods
 - We know our participants well and carefully determined washout periods
- Clinicians had difficulty “taking off their clinical hat” and counselling
 - Rita brought on as main counselor; Minimize clinician/counselor overlap





Lessons Learned

- Pre-study implementation
 - Intense and recurrent community outreach finds the most appropriate, motivated, and dedicated research participants
 - Recruitment starts long before site activation: Wait list and research registry pool of potential participants helped to get study started promptly
 - Creating packets helps streamline each visit



Lessons Learned

- Post study implementation
 - First participant handpicked to ensure a smooth first visit
 - 1 visit vs. 2 visits screening
 - Participants use smartphones for product reminders
- Accrual and retention
 - Having research savvy previous participants has helped get the study off to a good start
 - Good rapport = good retention



Other Issues

- Issues we have come across
 - Participants concerns with product
 - Rectal leakage
 - BM after rectal product use
 - SMS system downtime/issues
 - Participants to notify us with SMS issues
 - No other pharmacy, laboratory, behavioral, or counselling issues have been identified

Any Questions?
