

# The Fenway Institute | Boston Update for MTN-017

Ian R Lemieux, RN, MPH, MLS(ASCP)  
Project Director for Biomedical Research

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# It's been a snowy winter...





# Presentation Outline

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- Study Progress
- Best Study Practices
- Study Challenges
- Lessons Learned

# Study Progress

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- Date of site activation: 06 Sep 2013
- First/last screen:
  - 18 Sep 2013 / 13 Jan 2014
- First/last enrollment:
  - 25 Sep 2013 / 29 Jan 2014
- Last follow-up visit: 04 Aug 2014
  - Screened: 12; Enrolled: 7 (1 Replacement)
  - Screen fails: 5 (refused to use condoms, difficult work schedule, 3 x rectal exam findings [hx severe fissures, pilonidal cyst, anal warts requiring treatment])

# Study Progress

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- S:E ratio: 1.7
- 4 month accrual period
- Retention numbers: 86%
  - 1 voluntary withdrawal (military service)
- Missed visits: 1
- Loss to follow-up: 0
- Replacement: 1





# Best Study Practices

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- ❑ Conducting pre-screen consultations, after phone pre-screen and prior to screen visit
- ❑ Splitting screen visits (v1.0a and v1.0b)
- ❑ Engaging past participants
- ❑ Utilizing a consistent visit flow
- ❑ Scheduling staff resources in advance
- ❑ Preparing visit forms, clinical and lab supplies prior to participant arrival



# Best Study Practices

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- Regular clinical supervision for counseling
- Pharmacy labeling/printing system established for MTN-017 study product
- Completing timely visit QC procedures
- Maintaining regular communication with internal and external team members
- Seeking PSRT consultation regarding enrollment eligibility, adverse events, potential clinical hold/resume scenarios



# Retention Challenges + Strategies

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- No particular challenges
  - Site engaged participants regularly and encouraged emails/calls for questions
  - Reminder calls made 48 hours prior to study visits
  - Review of study visit schedule and windows at each visit





# Adherence Challenges + Strategies

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## □ SMS

- Communication with SMS team regarding any challenges with system or reports
- Highlighting the benefit of this system to participants

## □ Product returns

- Reminding participants to bring returns when making appointment reminder calls



# Adherence Challenges + Strategies

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- Applicator transport and use
  - Creating a space for participants to share their experiences and develop plans for use
- Side effects/adverse events
  - Carefully documenting all AEs reported, ensuring timely assessment and follow-up
  - Reviewing product use instructions



# Going Forward

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- Data Quality
  - 1-day turnaround for chart completion
  - Internal chart QC
  - Regular QC report review
  - Internal QA review
  - Review of site statistics
  - Site team review of trends and policies



# Going Forward

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- Participant Retention
  - Thorough participant screening process inclusive of consultations and split screen visits
  - Intra- and inter-visit review of study visit schedules, procedures, and visit windows with participants
  - Regular follow-up by phone during larger visit gaps
  - Share data when able, via community forum, to build interest in microbicide research



# Going Forward

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- Product Use Adherence
  - Importance of a comprehensive approach to product use adherence
    - Returns
    - SMS
    - Counseling
  - Partnering with our clients

# Lessons Learned

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- Pictorial product use instructions were developed by FHI360 and helpful to staff and participants
- SMS system challenges were easily communicated via email alias for support





# Lessons Learned

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- Building off of rectal microbicide and MTN protocol experience with Project Gel (McGowan R01; tenofovir gel study, 18-30 y/o MSM), MTN-007 and MTN-013; SOPs; source docs; supplies
- PBMC processing via existing relationships (courier service and ACTG research lab)
- 48-72hr and 2wk post-initiate visit phone calls were helpful to participants – staff could answer participant questions and review AEs
- Best to maintain participant-counselor consistency throughout study whenever possible



# Lessons Learned

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- Created unique recruiting materials that can be used across media formats
- Screen failures can be unpredictable when recruiting from the general population, queue up additional participants even when near enrollment target
- Maintained regular communication (ie. reminder calls), providing referrals, and establishing rapport with participants



# Lessons Learned

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- 2<sup>nd</sup> rectal period first dose or simulation in clinic seemed redundant, some participants refused given that they had completed this step at the start of their 1<sup>st</sup> rectal period



# Fenway MTN Team

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- Kenneth Mayer, MD
- Lori Panther, MD, MPH
- Ami Multani, MD
- Marcy Gelman, NP, MPH
- Ian Lemieux, RN, MPH, MLS(ASCP)
- Amber Rucker, BS
- Ralph Mele, RPh
- Sinclair Lao, PharmD

***Thank You &  
Many Thanks to our Research  
Participants***

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