The Fenway Institute | Boston
Update for MTN-017

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It’s been a snowy winter…
Presentation Outline

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

- 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

- 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

- 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

- 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

- 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

- **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

- 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

- 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

- 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

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

- 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

- 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

- 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

- 2nd 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 1st rectal period
Fenway MTN Team

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Thank You &
Many Thanks to our Research Participants