The Fenway Institute | Boston
Update for MTN-017

Ian R Lemieux, RN, MPH, MLS(ASCP)
Clinical Project Manager

Presentation Outline

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

Study Progress

- Date of activation: 06 Sep 2013
- First enrollment: 25 Sep 2013
- How many participants screened and how many enrolled:
  - Screened: 12
  - Enrolled: 7
  - Screen fails: 5 (refused to use condoms, difficult work schedule, 3 x rectal exam findings)
- S:E ratio: 1.7
- Retention numbers: 86%
  - 1 voluntary withdrawal (military service)

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

Challenges Implementing MTN-017

- Product use instructions for Rectal RAI period
  - Contacted FHI360; suggested a pictorial flow sheet of product use be developed
- SMS reminder errors: received late, not received, no response to messages sent
  - Continue to utilize the alias email for support: mtn017sms@mtnstopshiv.org
  - Include related documentation and correspondence in participant charts

Unresolved Challenges

- None

Lessons Learned

- Pre study implementation
  - 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)
- Post study implementation
  - 48-72hr and 2wk post-initiate visit phone calls are helpful to participants – staff can answer participant questions and review AEs
  - Best to maintain participant-counselor consistency throughout study whenever possible

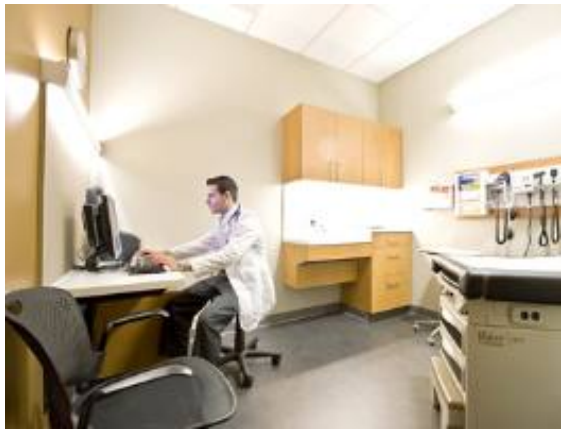
Lessons Learned

- Accrual and retention
  - Create unique recruiting materials that can be used across media formats
  - Screen failures can be unpredictable when recruiting from the general population
  - Maintaining regular communication (ie. reminder calls), providing referrals, and establishing rapport with/for participants

Recruitment Material Design

Lessons Learned

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



Pharmacy Update

- None

Behavioral Update

- CASI Administration – no problems
- SMS System – as noted
- PK Data and Data Convergence Interviews – no problems; site acknowledges time required to prepare for, conduct, and closeout each session
- In-Depth Phone Interview – no problems; 1 completed to date

Laboratory Update

- Specimen collection – no problems
- Processing – no problems
- Shipping – request for clarification regarding process for return of empty STP/dry ice shippers to site
- Receipt of results – no problems; all results have been received prior to PK convergence

Counseling Update

- Protocol – no problems
- HIV/STI – no problems
- Product Use – as noted
- Adherence – as related to PK convergence: how to promote discussion when PK results are ‘detectable’; reviewed with Ivan
- Clinical supervision helpful to site staff

Any Questions?