UCT Clinical Trial Unit
Groote Schuur Hospital CRS
Update for MTN-017

Ben Brown
Programme Manager

MTN Annual Meeting
15 March 2015
Overview

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

11 March 2014

Screening

20 Oct 2014

10 April 2014

Enrollment

30 Oct 2014

Final Follow Up

30 April 2015
Study Progress: Accrual

- Projected Screening: 50
- Screened: 40
- Enrolled: 18
Study Progress: Accrual and Retention

- Total Duration of Accrual: 7 Months
- Enrollment Ratio: 2.2 : 1
- Total Missed Visits: 9
Best Practices

Initial Screening Results

All HIV/STI + participants were referred to care
Best Practices

We developed an anal STI pre-screening protocol to address the prevalent asymptomatic STIs that were increasing our screening to enrollment ratio.
Anal Pre-Screening Protocol

Complete basic demographic form and contact information

Receives HIV test from study counselor

Visual and Digital Anal Exam

Anoscopy and Sample Collection

Return in +/- 1 week for results
Anal Pre-Screening Protocol

Pre-Screening, Screening, and Enrollments
August - October 2014
Retention Challenges

- Extended holidays to the Eastern Cape during the Dec - Jan Festive Season.

- Our team coordinated visits around these expected travel dates.

- Still resulted in missed visits due to participants unable to organize transport back to Cape Town
Retention Strategies

- Bi-weekly/Weekly Meetings in each community group
- Dissemination of HIV prevention information and supplies
- Events across different communities
- Monthly activities in each community including sports and debate
- Full community programme events
Adherence

- Challenges: using and storing product in family settings when disclosure has not occurred.

- Strategies: client centered approaches developed with experienced counselors. Participants valued alarms and visual reminders including the study SMS message.

Research Assistants in charge of adherence counseling, Daniel Ndzuzo and Lindsay Gcwabe
Lessons Learned

Additional Pre-Screening Procedures were required

Extensive Education was needed to introduce microbicides

Recruitment benefited from having strong community-led strategies in place
Comprehensive education about microbicides and phase II studies was required to successfully reach participants.
Barriers to engagement

- Participants had not been exposed to microbicides previously.

- Some participants were skeptical of the microbicide application.

- Other participants were nervous or afraid of the anoscopy procedure.
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<th>Education Activity</th>
<th>2011</th>
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<td>RM Discussions</td>
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Opportunities for Education

Community Outreach

- Meet with Outreach worker at event
- Meet with senior outreach worker one on one

Pre Screening

- Discussion with Counselor
- Discussion with Doctor

Screening and Enrollment

- Discussion with Counselor
- Discussion with SCO
- Discussion with Doctor
Recruitment had to be a comprehensive community-driven process lead by MSM peers
Team Structure and Capacity Building

- Research Assistant
- Counselor
- Senior Outreach Worker
- Outreach Worker
- Outreach Intern
- Community Leader
- Community Member
Community Member
Community Leader
Outreach Intern
Outreach Worker
Senior Outreach Worker
Counselor
Research Assistant

Clinic

Community

Community Member
Community Leader
Outreach Intern
Outreach Worker
Senior Outreach Worker
Counselor
Research Assistant
Going Forward

- Ensuring high data quality and strong retention is an important goal for our site.
- Driven by a strong integrated team approach.
- Each file is reviewed for QA.
- Monitor for trends from data queries and address through staff refresher trainings.

Senior outreach worker, Xolani Mvula; Research Assistant, Daniel Ndzuza; SCO Karen Dominguez; Research Assistant Brian Kanyemba; Research Nurse, Jo Sage
Going Forward

- Everyone on our team is involved in participant retention.
- Clinic team build meaningful relationships with participants and outreach team implement regular visits to sustain contact between visits.
- Adherence is driven by counseling team and enforced outside of the clinic with retention officers.

Senior outreach worker, Xolani Mvula; Research Assistant, Daniel Ndzuzo; SCO Karen Dominguez; Research Assistant Brian Kanyemba; Research Nurse, Jo Sage
Any Questions?