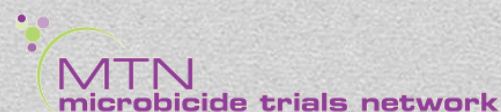


University of Puerto Rico
Medical Sciences Campus
Maternal-Infant Studies Center (CEMI)

Proyecto M

Update for MTN-017

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Presentation Outline

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

Study Progress

- Date of activation: Nov 15, 2013
 - ✓ First Pre-Screenings: Dec 10, 2013
 - ✓ First Screening: Dec 18, 2013
 - ✓ Last Screening: Aug 6, 2013
 - ✓ First Enrollment: Feb 13, 2014
 - ✓ Last Enrollment: Jul 18, 2014

Study Progress

- Pre-Screened: 69
- Screened: 13
 - ✓ 2 screen failure (positive for Chlamydia & Syphilis)
 - ✓ 1 possible allergic reaction to Truvada
 - ✓ 1 decided not to participate
 - ✓ 1 unable to be enrolled because of work
 - ✓ 1 qualified but study was closed for enrollment
- Number of participants enrolled: 7
- S:E ratio: 1:1.9
- Duration of Accrual (months): 15 months
 - May 2013 – Aug 2014

Study Progress: Retention

- No missed visits
- No participants were loss-to-follow up. Study finalized with 100% retention rate for enrolled participants.

Best Study Practices

- Pre-screening participants
- Screening participants that have visited the clinic at least once.
- Participants recommending friends
- Referrals from other clinics

Retention Challenges

- 1. List what, if any, challenges and/or factors encountered that impacted participant retention:**

Even though all participants were 100% adherent to their study visits, challenges were encountered. Some participants changed jobs and encountered difficulties asking for the days to come to the clinic. Others had vacations in other states that required to rescheduled appointments or difficulties with transportation and appointments were adjusted to this reality.

Retention Strategies

List what, if any, strategies and/or efforts that were put in place to improve or enhance retention:

1. Accurate locator information was collected and updated in every visit.
2. Visit reminders methods:
 - Participants were informed of all study visits since the enrollment visit. A calendar was made and dates were discussed to determine the best available dates for the participants.
 - Reminder methods were specific to the participants needs. Printer calendars, cellphone calendar reminders and/or alarms were implemented.

Retention Strategies

List what, if any, strategies and/or efforts that were put in place to improve or enhance retention:

1. Visit reminders methods:
 - Reminders were made 1 week before the appointment and 1 day before the appointment ALWAYS for ALL participants by phone calls or text messages as preferred.
2. An increase in the participant incentive was implemented from \$30 to \$50 per visit.

Adherence Challenges

List what, if any, challenges and/or factors that were encountered that impacted participant adherence:

- Change in daily routines represented the biggest challenge for adherence. Some participants had changes in their working shifts and adherence strategies were reevaluated. Other participants were students and changes in their classes also represented an adherence challenge.
- Participants vacations also represented some challenges in adherence since strategies needed to be tailored to their lifestyles during the time.

Adherence Challenges

List what, if any, challenges and/or factors that were encountered that impacted participant adherence:

- Some adverse events represented adherence challenges for the participants.

Adherence Strategies

List what, if any, strategies and/or efforts that were put in place to improve participant adherence:

Working one-on-one with the participant's particular needs was key. Strategies were developed with each participant to tackle changes in daily routines. The use of technology worked for all participants; reminders via text messages, phone alarms and phone calendar reminders.

Effective communication between the participant and study staff was very important and established a trusting relationship that provided the participant the freedom to ask about adherence issues or other difficulties.

Going Forward

How will your site ensure high data quality is maintained?

- Using the iDataFax provided the opportunity to self-monitored our data quality and learn from the mistakes.
- QC meetings helped identify common mistakes among staff.
- Protocol updates were made available to all study staff as soon as they were sent.

Lessons Learned

- **Pre study implementation:**

Pre-screenings has been a good strategy to maximize funding and resources. Helps to determine better the participants commitment and to start an education process about the study.

- **Post study implementation:**

Having all staff involved in the recruitment process and in the planning of activities has been key to work as one! Best recruitment strategy has been interested participants reaching to staff.

- **Accrual and retention:**

Face-to-face recruitment has been more effective than online recruitment (7.4% only).

Challenges Implementing MTN-017

1. Holidays and local lab closures:

Local laboratories were closed during the Holidays (Thanksgiving 28-29 Nov, Christmas 23-31 Dec, Three Kings Day 1-7 Jan, Other holidays 6, 13 & 20 Jan).

The UPR was closed from December 20, 2013 until January 8, 2014

2. Laboratory Internal Validation:

The local laboratory notified January 31, 2014 they needed to make an internal validation of the processes required to handle the rectal GC/CL samples due to the need for a special media. Rectal GC/CL had to be repeated to the first four participants. This delayed significantly the enrollment dates.

Cultural challenges with Holiday appointments

- Traditionally the Christmas Holidays are extended from mid December until mid January.
 - Some groups (students and some offices) reduce activities after the Thanksgiving Holiday.
 - Most healthy individuals (and even patients with chronic conditions) avoid medical appointments during the Holidays.
 - Forcing appointments for enrollment/screening is counterproductive and might affect our relationship with the community.
 - This reality affects recruitment of participants for prevention studies (since they are considered healthy individuals).
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Strategies to Address these Challenges

1. Holidays and local lab closures:

Coordinate visits around the holidays.

2. Laboratory Internal Validation:

Collaborative agreement to help with the validation process. This will help expedite the process and establish a precedent in the management of the samples in PR. Local lab made arrangements with lab outside PR to process the samples.

No unresolved challenges to disclose.

