

**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
- Challenges Implementing MTN-017
- Strategies to Address These Challenges
- Lessons Learned
- Updates (Pharmacy, Behavioral, Lab & Counseling)

Study Progress

- Date of activation: Nov 15, 2013
 - ✓ First Pre-Screenings: Dec 10, 2013
 - ✓ First Screening: Dec 18, 2013
 - ✓ First Enrollment: Feb 13, 2014
- Pre-Screened: 27
- Screened: 5
 - ✓ 1 screen failure (positive GC/CL)*
- Enrolled: 3
 - ✓ 1 more enrollment Mar 4, 2014
- S:E ratio: 1:0.8
- Retention numbers: 100%

¿SABÍAS QUÉ?



**...una pastilla diaria
puede prevenir que te
infectes con el VIH.**

**...se está desarrollando
un gel que puede
reducir el riesgo
de infectarte
con el VIH.**



Study Progress

Pre-Screenings profile (27):

- 14.8% (4/27) Not interested in the pill regimen
- 48.1% (13/27) Not eligible
 - ✓ 2/13 HIV + (15%)
 - ✓ 4/13 Only active
 - ✓ 3/13 No RAI in the past three months
 - ✓ 2/13 STIs requiring treatment (15%)
 - ✓ 1/13 Conflicting medications
 - ✓ 1/13 <18 years old
- 14.8% (4/27) Enrolled (4th enrollment Mar 7, 2014)
- 3.7% (1/27) Doesn't have a cellphone at the moment
- 18.5% (5/27) In the pipeline for screening*

Best Study Practices

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

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.

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).

Updates:

Pharmacy:

- No issues to disclose

Laboratory:

- No issues to disclose

Counseling:

- No concerns or difficulties when providing protocol HIV/STI Risk Reduction Counseling or Product Use/Adherence Counseling.
- Participants expressed that the educational materials developed by MTN were very useful (Informed Consent Booklet & Product Use Instructions).

Behavioral Update

Site's experience and/or any challenge(s) with the following:

- CASI Administration:
No problems disclosed by participants.
- SMS System:
Great technical support by Rebecca Giguere. Use reports have been updated frequently.
- PK Data and Data Convergence Interviews & Phone Interviews:
Not done yet





Prepárate Para el Futuro

TOMA EL CONTROL

Existe una nueva forma para mantenerte seguro mientras continúas divirtiéndote.

Nuestro objetivo es determinar si una pastilla o un gel rectal pueden ayudarte a reducir las posibilidades de contagiarte con el VIH.

SE VOLUNTARIO EN UN ESTUDIO PARA LA PREVENCIÓN

DEL **VIH**

Proyecto M
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Requisitos:

- ♦ Tener 18 años o más
- ♦ Estar activo sexualmente
- ♦ Hombre que tiene sexo con hombre

Serás compensado por tu participación



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