IMPACTA San Miguel CRS
Update for MTN-017

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Presentation Outline

- Study Progress
- Best Study Practices
- Study Challenges
- Lessons Learned
LIMA-PERÚ
LIMA-PERU
SAN MIGUEL SITE
Study Progress: Milestones

- Date of First and Last Screening
  Site Activation: 01/15/2014
  First Screening: 01/16/2014
  Last Screening: 11/05/2014

- Date of First and Last Enrollment
  First Enrollment: 01/23/2014
  Last Enrollment: 11/10/2014

- Date of Last Follow Up Visit (Projected)
  05/11/2015
Study Progress: Accrual

- **Number of Participants Screened**
  - Projected: 72
  - Actual: 55

- **Number of Participants Enrolled**: 38 (Two TG women)
  - Two participants replaced

- **Overall Screening to Enrollment Ratio**: 1.4

- **Duration of Accrual**: 10 months
Study Progress: Retention

- Missed Visits to date: 8 visits
- Loss-to-Follow Up to date: None
Best Practices

- Pre-Screening
- HEROES campaign
- IMPACTA software: Siscitas
- Experience of the clinic, pharmacy, laboratory and data staff.
GELLUX CAMPAIGN
GELLUX CAMPAIGN
SOCIAL NETWORKS
HEROES TOUR
HEROES TOUR
GAY PRIDE PARADE
Visits to CBO
Visit to CBO (Corazones Chalacos)
VOLUNTADES
Promoters from the MoH Centers
Promoters of MoH
Continuous Information

CENTRO COMUNITARIO
CORAZONES CHALACOS

Continuando con nuestra línea de difundir información actualizada sobre las investigaciones en VIH, les informamos que el día Miércoles 29 de Enero a horas 7.00 p.m. y con el apoyo de la ONG IMPACTA se estará tratando el tema de Microbicidas, en el marco del Proyecto MTN017.

A los asistentes se les hará entrega de O1 Kit preventivo (Condomes y Lubricantes).

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Appreciation Event
New Campaign: Chapa tu Micro
Best Practices – Data Management

Given the time windows provided for this study, we adapted our procedures accordingly:

a) We assigned a Data Manager (90%) for MTN-017

b) PTIDs assignment and randomization procedures was requested via e-mail to the MTN Data Manager, but also to all the other Data Managers (in case the main Data Manager was not available)
Best Practices- Data Management

c) We applied a QC “en route” for all source documents and adverse events

d) QA was performed on day 4 (faxing should occur on day 7)

e) During those 3 extra days, the Data Management coordinator performed an additional electronic control
Best Practices Data Management

c) Automatic alerts were sent following the central day (ideal day) of the visit window; these provided extra days before faxing limit date

d) We used review scripts and routing sheets

e) The Study Coordinator did the follow-up for the results transcription
Counseling

- CASI Administration
- SMS System
- PK Data and Data Convergence Interviews
- In-Depth Phone Interview
Retention Challenges

- Time to complete the visits
- New job, an example are the participants that were replaced
Retention Strategies

- SISCITAS software
- Reminder calls
- Appreciation Event
- Multiple points of study staff contact
- Participant engagement in new campaign
Pharmacy

- Importation issues.
  - Tenofovir gel
  - Truvada

- Replaced participants did not returned the study product.
Adherence Strategies

- All study staff involve in adherence.
- Data convergence interview (PK)
- Remaining in all visits the adequate use of the product.
Lessons Learned

- Regulatory issues

- Post study implementation:
  Continuous participant motivation.
- Accrual and retention: A continue information to the community about a probably new prevention strategy. Clinic staff promoted that the participant can invite friends.
- Recruiting participants that the staff knows.
- Meetings and continuous training of the staff.
- Clinical: Work as a TEAM.
Recruitment and Retention team
Any Questions?