IMPACTA-SAN MIGUEL
Update for MTN-017

Dr. Pedro Gonzales
Site Investigator of Record
Presentation Outline

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

- Date of training: December 9-10
  December 20-21
- Date of activation: January 15
- First Screening: January 16, 2014
- First enrollment: January 23, 2014
# Study Progress

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<th>Participants</th>
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<tr>
<td>Screened</td>
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<tr>
<td>Screening Stopped</td>
<td>1</td>
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<tr>
<td>Enrolled</td>
<td>5</td>
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<tr>
<td>In screening</td>
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**Ratio : Screened/Enrolled : 1/ 1**

Retention
Best Study Practices

- Prescreening
- HEROES campaign
- IMPACTA software: Siscitas
- Experience of the clinic, pharmacy, laboratory and data staff.
RECRUITMENT

- Gellux
- Social Networks
- CBO
- Promoters of sexual health centers
- Other organizations
Recruitment

Presentación a la Comunidad
Recruitment

Comunidad - Tour de Héroes
Recruitment
Recruitment

Comunidad – OBC Voluntades

Voluntades Lima Norte

PRESENTA:
Este VIERNES 21 de FEBRERO
a las 7:30pm

Investigación en Microbicidas Rectales en Perú:
La Revolución de la prevención de VIH en Hombres Gay

El Centro Comunitario "VOLUNTADES LIMA NORTE"
PRESENTA: Este VIERNES 21 de FEBRERO a las 7:30pm
Investigación en Microbicidas Rectales en Perú:
... Ver más — con Miguel Ecltronic Rave, Lessly Coffiure D Jer Jey, Lyzbeth Yalezka Gonzales Romero, Sianinne Kriss Ampudia, Paloma Martinez Lopez, Jhair Enrique, Paola Alvarez y Lucho Castro.
Challenges Implementing MTN-017

- Regulatory issues.
- Study product importation.
- Completion of site activation checklist.
- Laboratory issues.
Strategies to Address These Challenges

- Regulatory
- Laboratory
- Pharmacy
- Activation checklist
Lessons Learned

- Regulatory issues
- Post study implementation:
  Participant motivation.
- Accrual and retention: A continue information to the community about a probably new prevention strategy. Clinic staff promotes that the participant can invite friends
- Clinical : Work as a TEAM, the PI and study coordinator must be involved in ALL study procedures.
Pharmacy Update

- Importation issues
- Study enrollment: All procedures according to study SSP.
- Study Follow-Up
- Product use: Participant didn’t report any issue with the study product use. Applicator were easy to use.
Behavioral Update

- CASI Administration
- SMS System
- PK Data and Data Convergence Interviews
- In-Depth Phone Interview
## SMS-ADHERENCE

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<th># Reminders Sent</th>
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### Period 1, Mid-Period

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### Period 1, End-Period

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Laboratory Update

- No problem with specimen collection.
  Laboratory chart.
  Laboratory staff well trained to perform lab procedures.
Counseling Update

- **Barriers:**
  - Some participants said that it will better to have a direct communication.
  - Time that they spent in the visits.

- **Advantages:**
  - Counselors are psychologists. Experience in risk reduction, motivation, etc.
  - Adherence counseling centered in the participant
  - Easy communication
  - Facilities and private rooms for counseling, clinic procedures.
Counselors Training
THANK YOU - GRACIAS
MTN 017

ANY QUESTION?