



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



héro[♂]es
Ser Gellux

GELLUX CAMPAIGN

Para disfrutar primero
te lo debes aplicar

SOY GELLUX

Y traigo una nueva opción
que nos podría ayudar a
prevenir el VIH...

Los Microbioidas Rectales

herqes

Ser Voluntario

Impacta

INFORMATE MÁS LLAMANDO
AL 0-600-1-7432

f Gellux.Impacta

PHOTON
TE AYUDA A ENTENDER MEJOR
TU CUERPO Y SU RESPUESTA
AL ESTRÉS Y AL DOLOR.

EL SISTEMA
MUSCULAR...
...Y SU RESPUESTA AL
ESTRÉS Y AL DOLOR.
...Y SU RESPUESTA AL
ESTRÉS Y AL DOLOR.

UNA NUEVA OPCIÓN
...Y SU RESPUESTA AL
ESTRÉS Y AL DOLOR.

...Y SU RESPUESTA AL
ESTRÉS Y AL DOLOR.

...Y SU RESPUESTA AL
ESTRÉS Y AL DOLOR.

SOCIAL NETWORKS

Regístrate con una foto de perfil
Las fotos o los logos son más eficaces

Regístrate con una foto de portada
Da un toque de personalidad a tu página

Regístrate información de contacto
Ayuda a que los demás te encuentren fácilmente

**Para disfrutar,
primero te lo debes aplicar**

**Yo Soy
Gellux**

**Gellux Impacta
Comunidad**

Comunicación

Biografía | Información | Fotos | Me gusta | Más ▾

PERSONAS >

HEROES TOUR



HEROES TOUR



GAY PRIDE PARADE



DIA DEL ORGULLO GAY

Actividad Wind
Fuente: Wind
Actividad Wind
Fuente: Wind

Visits to CBO



Visit to CBO (Corazones Chalacos)



VOLUNTADES



Promotors 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)



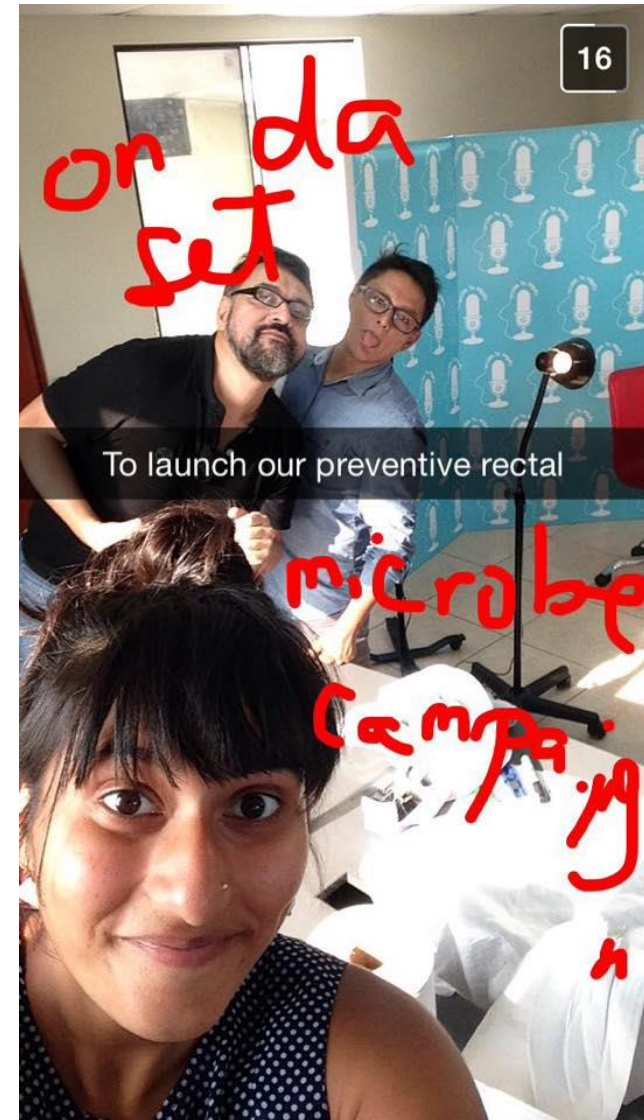
CCB CORAZONES CHALACOS
URB. CIUDAD DEL PESCADOR MZ Y2 LOTE 5 – BELLAVISTA CALLAO
TELEFONO 561 – 1702 E – MAIL corazoneschalacos@gmail.com



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



SAN MIGUEL TEAM





Any Questions?
