



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

	Participants
Screened	9
Screening Stopped	1
Enrolled	5
In screening	3

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
- Promotors of sexual health centers
- Other organizations

Recruitment

Presentación a la Comunidad



Recruitment

Comunidad - Tour de Héroes



Recruitment

Comunidad – Corazones Chalacos



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**



Voluntades Lima Norte

Me gusta · 16 de febrero

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 Ektronic Rave, Lessly Coffiure D Jer Jey, Lyzbeth Yalezka Gonzales Romero, Slainne Kriss Ampudia, Paloma Martinez Lopez, Jhair Enrique, Paola Alvarez y Lucho Castro.

Me gusta · Comentar · Compartir

A Lucho Castro, Voluntades Lima Norte y 2 personas más les gusta esto.

4 compartidos



Voluntades Lima Norte: Nose olviden chicos, es un tema muy importante !!!

Me gusta · Responder · Hace 21 horas



Escribe un comentario...



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

Lima SMS Data Summary 21.02.14 - Microsoft Excel

1	A	B	PERIOD 1, MID-PERIOD					PERIOD 1, END-PERIOD					M	
			C	D	E	F	G	H	I	J	K	L		
2	Contraseña	PTID	# Times Product Used	# Reports Completed	Start Date/End Date	# Reminders Sent	Bonus	# Times Product Used	# Reports Completed	Start Date/End Date	# Reminders Sent	Bonus	# Times Product Used	#
3	LM1	334-00001-3	28	28	23/01/14-19/02/14	28	Y	2	2	20/02/14-21/02/14	2	Y		
4	LM2	334-00002-4	5	5	17/02/14-21/02/14	5	Y							
5	LM3	334-00003-8	0	1	20/02/14-20/02/14	1	Y							
6	LM4	334-00004-6	3	2	18/02/14-20/02/14	3	N							
7	LM6	334-00006-0	1	1	21/02/14-21/02/14	1	Y							
8														
9														
10														
11														
12														
13														
14														
15														
16														
17														
18														
19														
20														
21														



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 psicologist. Experience in risk reduction, motivation, etc.
- Adherence counseling centered in the participant
- Easy communication
- Facilities and private rooms for counseling, clinic procedures.

LIMA TRAINING



Counselors Training



THANK YOU- GRACIAS





MTN 017

ANY QUESTION?