Pitt CRS
Our MTN–017 Experience

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Study Summary

- Date of activation: 9/27/13
- First enrollment: 10/24/13
- Last enrollment: 11/10/14

- 45 Pts Screened
- 33 Pts Enrolled (19 TS)
- 4 Withdrawals
- 0 Lost to follow-up

- 12 ineligible (5 Rectal GC/CT; 4 Rectal abnormality; 3 Other)
- 4 (screen): 3 (enrolled) ratio
Recruitment Methods

HIV Prevention Research Registry

Have You Thought about Participating in HIV Prevention Research?

You can be part of local research efforts to prevent HIV worldwide. Anyone 18 or older may join our Research Registry to be contacted to participate in HIV prevention research studies.

If you’re a man, a woman, or transgender person—if you’re straight, gay, or bisexual—if you’re HIV-negative, HIV-positive, or don’t know your status—you’re welcome to join. For basic information about the clinical research process, click here.

Completing this consent form enrolls you into this Research Registry and gives your permission for us to match you with research studies you may be interested in and to use information provided by you. You will be mailed a password-protected link so you can answer some medical and social questions. Our studies mostly look at developing new ways to prevent HIV such as using microbicides, vaccines, and PrEP (pre-exposure prophylaxis).

There is no compensation for joining this Registry. But, if you are enrolled in a study you will be compensated for your time and travel. Every study compensates differently based on what is involved in participation.

Only members of the HIV Prevention Research Registry staff will have access to your identifiable, self-reported medical information and use this information in a confidential, HIPAA-directed manner. However, just as with the use of your medical information for health care purposes, we cannot guarantee its privacy. Thank you.

1. Please use your full legal name:

   First Name: ____________________________
   Middle Initial: _______________________
   Last Name: ____________________________

2. Email address [ ]

   Please check each box if you have an email address:
   [ ] I have a personal email address
   [ ] I have a work email address
   [ ] I don’t have email, please call instead

3. Phone [ ]

   Please enter a phone number in the format (000)000-0000

4. I was born ____________ [ ] Male [ ] Female

5. Date of Birth [ ] (MM/DD/YYYY)

   Press to Confirm your Permission to Enroll in this Research Registry

For additional information, email HIVReg@pitt.edu, call 412-956-9686, or write to HIV Prevention Research Registry, 3520 Fifth Ave., Ste. 510, Pittsburgh, PA 15213.

The Registry is supported by funding from the National Institutes of Health (NIH) and the Registry’s Director is Ian McGowan, MD, PhD.

You may withdraw from the Registry by email at HIVReg@pitt.edu or writing to the address above. Questions you have about research participant rights are answered by the Human Subject Protection Advocate at the University of Pittsburgh IRB Office at 866-212-2669.

University of Pittsburgh

IRB Number: PRO11110371
Approval Date: 1/2/2013
Renewal Date: 1/1/2014

A373

Be A Hero
by taking part in an
HIV Prevention Research Study
www.hivregis.pitt.edu
University of Pittsburgh
Registry (continued)

McGowan Research Group Data Portal

Welcome sherrikaras! [Change]

Participants Studies Reports

From       To

(From MM/DD/YYYY)       (To MM/DD/YYYY)

Reload

Participant Reports

1028 currently enrolled in HIVRegis
1238 currently enrolled in system
960 sent email invitations to complete interview
470 who have completed interview
0 with pending interviews (sent email, have not completed, have not exceeded 30 day window)
490 who have not completed interview in 30 day window

HIVRegis Dates Enrolled

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Enrolled</th>
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11:11 AM 2/24/2015
Registry (continued)

- Community Events: 53%
- Social Media: 11%
- Other: 22%
- Friend Referral: 7%
Other Recruitment Methods

- Community Outreach
Other Recruitment Methods

- Past Participants
- Word Of Mouth
- Craigslist/ Social Media
Product Use Challenges

- Tenofovir Gel and Applicator
  - Few issues reported
  - Reports of gel leakage and applicator discomfort usually resolved with counseling, i.e. take your time and ensure you are inserting deeply enough
  - “Easy” discharge of gel was resolved by counseling to leave cap on until just before insertion

[Image of Tenoforir Gel and Applicator] + [Image of Gel Packets] = ?
Product Use Challenges

- Truvada tablet
  - Widely accepted
  - Few reports of nausea and bloated feeling
Better adherence with daily regimens
In general, very good adherence and positive PKs, making motivational interviewing a challenge
Daily texts very often cited as the main reminder to use product, but some participants had frequent issues with the system (certain networks)
Lessons Learned

- Product Use vs Procedure Counseling
  - Rectal biopsies while on gel
- Follow-Up Contact
  - Telephone vs email or text
- Doin’ It for the Cause
  - Participants who had PrEP knowledge and interest in Truvada had a more difficult time accepting the gel
Thank You

- Awesome Participants!
- MTN Protocol and Behavioral Team, FHI360, SCHARP
- Lab and Pharmacy Staff
- Site Staff – Coordinators and Data
Any Questions?