



# Bridge HIV | SFDPH Update for MTN-017

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Albert Liu, MD, MPH  
Site Principal Investigator

# Hello from Bridge HIV!

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# Presentation Outline

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- Study Progress
- Best Study Practices
- Study Challenges
- Lessons Learned



# Study Progress: Milestones

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- Date of First and Last Screening
  - 8 Oct 2013 – 12 Nov 2014
- Date of First and Last Enrollment
  - 29 Oct 2013 – 18 Nov 2014
- Date of Last Follow Up Visit (Projected)
  - Last scheduled visit 19 May 2015
  - Last possible visit window closes 1 Jun 2015

# Study Progress: Accrual

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- Number of Participants Screened:
  - Info sessions: 181
  - Screen 1: 100
  - Screen 2: 82
- 38 Participants enrolled
  - 2 replacements
    - 1 found the gel too uncomfortable and declined to use it
    - 1 missed too many visits
- Overall Screening to Enrollment Ratio: 2.5:1
  - We had estimated a ratio of 2:1
- Duration of Accrual: 13 months



# Study Progress: Retention

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- Missed Visits to date – 13 out of 271
  - 4 of those for the participant who was replaced  
[He did come in for his final visit, the other replaced participant didn't miss visits, just didn't use gel]
- Loss-to-Follow Up to date – No one has missed their final visit



# Best Practices

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- Schedule out all visits at enrollment
- Frequent communication with participants (giving business cards, open to questions/calls even not at a visit date, mid period check ins) – allowed us to keep them engaged and to air out any concerns about product
- Maintain friendly staff environment so participants feel welcome



# Retention Challenges

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- Gel fatigue
  - One person tried the gel and really didn't like it and refused to use the gel for the 2<sup>nd</sup> regimen
- End period visit windows were very short
- Trans participants in SF may have additional challenges





# Retention Strategies

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- Clear communication about goals of study at screening
- Careful selection of participants, including those from previous studies
- Scheduling all visits at enrollment
- Offer evening visits
- Text reminders for visits
- Mid-period check in
- Postings on FB/Twitter
- Invitations to events – PrEP forum in Sep 2014
- Supportive relationship with each participant
- We make rectal procedures fun!



# Adherence Challenges

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- Gel fatigue
  - Multiple steps
  - Applicator uncomfortable, looked like syringe
  - Excessive packaging
  - Needing privacy
  - Gel felt “dirty”
  - A few participants stopped having receptive anal sex to avoid using the product



# Adherence Challenges, cont.

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- Participants on PrEP (20/38)
  - Some were reluctant to use the gel (or forgot) because they were already on PrEP
  - Others were more dedicated and did it anyway
  - PK results weren't that useful for them



# Adherence Strategies

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- Emphasize that each regimen is just 2 months long: “the end is near” message – especially at mid period visit
- SMS messages serve as a reminder to use product, in addition to report use, also functioned as a log to track use of gel
- Most people committed to idea of gel even if they don't like the product



# Going Forward

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- We have 8 active participants
- We will ensure high data quality, high participant retention, visit and product use adherence by continuing to use the strategies that have worked for us throughout the study

# Lessons Learned – Study Product

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## □ Gel

- Participants would prefer as lube or as a suppository

## □ Applicator

- Shape and size were difficult to use
  - Could be like a lube shooter
  - Plunger should be part of applicator
  - Have gel come out the sides of the applicator
- Less packaging/more green

# Lessons Learned – Study Design

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- Requirement to agree to condom use and specific condoms
  - Problematic for those on PrEP
  - People didn't like the study condoms
    - Original packaging was “embarrassing”
    - Trojans were only choice, some people don't like that brand
    - Some prefer non-latex condoms
  - Maybe better to just measure condom use in future studies



# Lessons Learned – Study Design

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- DCI process
  - Discrepant numbers made some participants defensive
  - Maybe design to capture more of participant experience
  - Consider making part of the CASI instead of a face to face interview
- Use before RAI
  - Hard for people to figure out “Am I going to have sex today?”
  - Could possibly be administered as post-dose?
  - Hard to carry around the product



Thank you.

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Any Questions?

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