

The logo graphic for HPTN consists of several blue lines radiating from a central point, resembling a stylized sunburst or fan.

HPTN

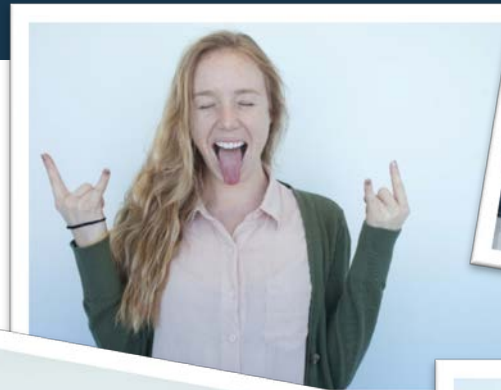
HIV Prevention
Trials Network



HVTN 704/HPTN 085

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Who are we?



Who are we?

- Located in **Newark, NJ**
- Funded in 2007 as 1 of 10 Clinical Research Sites in the Terry Beirn CPCRA CTU (*Fred Gordin, MD, PI*)
- Re-funded in 2013 as **Joint CTU** with Well-Cornell Medical Center (*Trip Gulick, MD, PI*)
- Current clinical research activity: **ACTG, INSIGHT, HPTN**, pharma and investigator initiated studies
- Co-located in the Infectious Disease Practice (IDP)



RUTGERS
New Jersey Medical School



What is AMP?

- AMP stands for
Antibody Mediated Prevention
- Using an antibody against HIV that was made in a lab and given to people as an intravenous infusion
- “IV” or “getting a drip”



Study Rationale

- <https://www.youtube.com/watch?v=e91JxLxZImg>

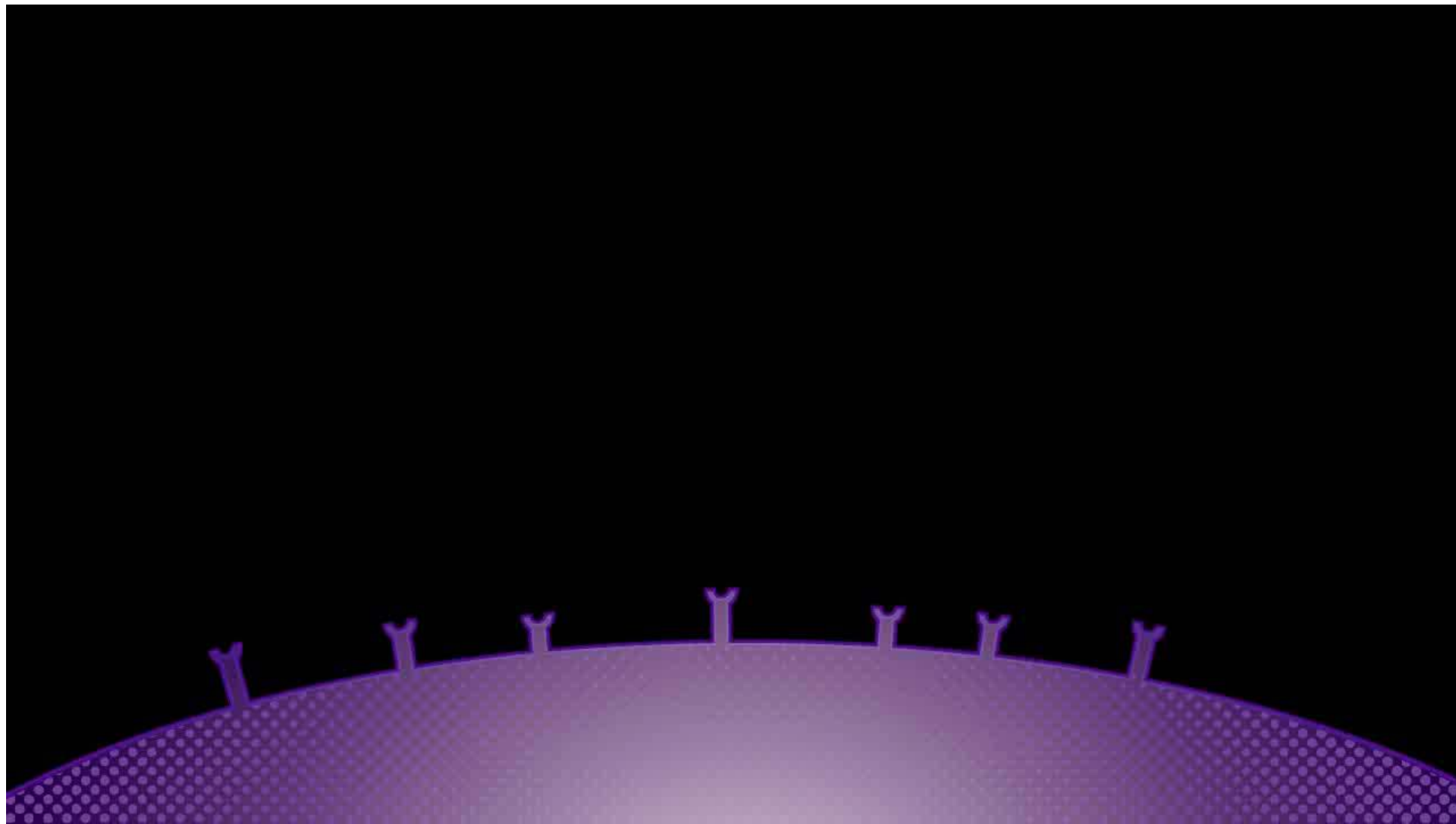
Study Objectives

PRIMARY

- **Safety & Tolerability of VRC01 infusion**
 - Reactogenicity, AEs, SAEs, discontinuation rates
- **Efficacy to prevent HIV infection**
 - HIV infection by week 80 in those HIV-negative at enrollment

SECONDARY

-
- **Develop a marker(s) of VRC01 that correlates with the level and antigenic specificity of efficacy**
 - Serum VRC01 concentration
 - Serum mAb effector functions
 - Breakthrough HIV viral sequences in infected people
 - VRC01 neutralization sensitivity of, & effector functions against, HIV strains from infected trial participants



Study Population and Size

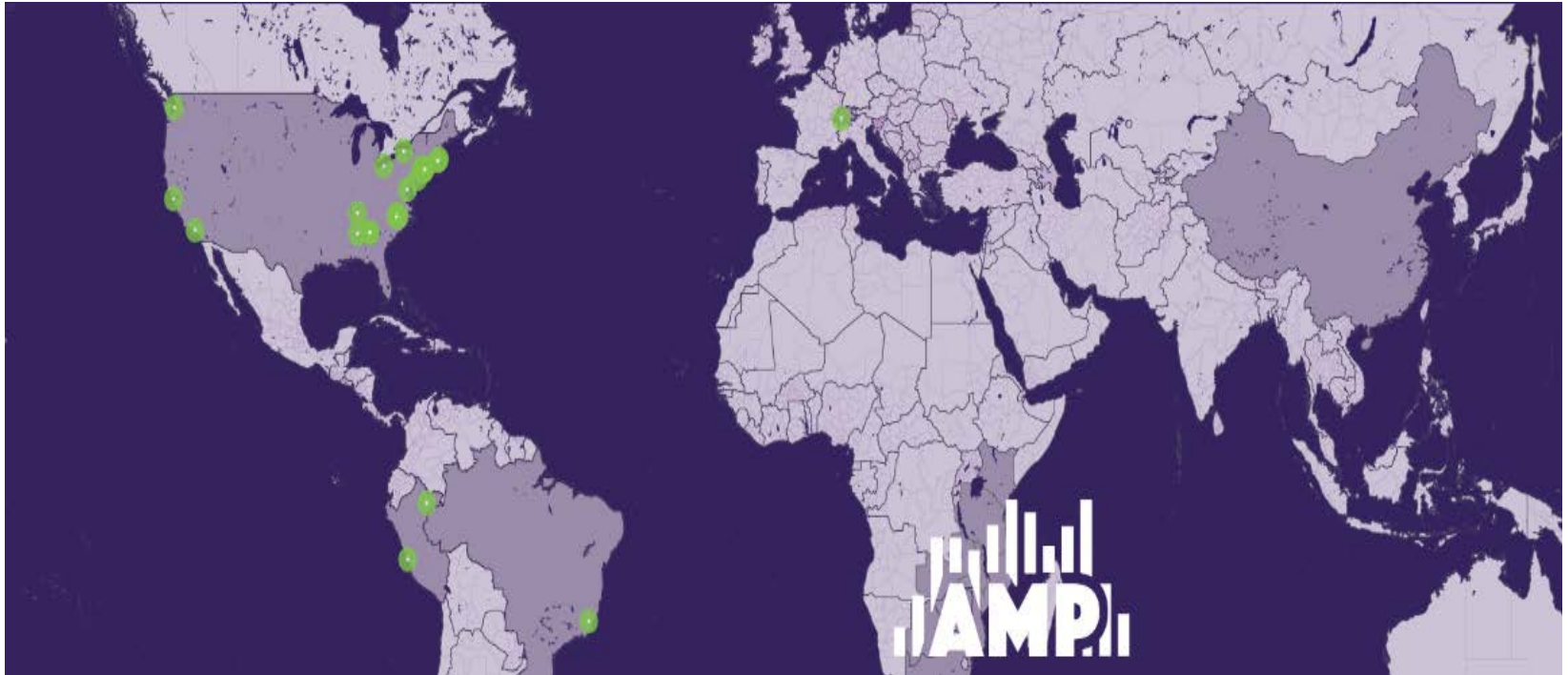
- N=2700
- 18-50 years old
- HIV-1- uninfected MSM and TG persons who have sex with men or TG persons



*Trans
Pride*



Clinical Research Sites



Clinical Research Sites

United States

- Atlanta, GA (2 clinic locations)
- Birmingham, AL
- Boston, MA (2 clinic locations)
- Chapel Hill, NC
- Cleveland, OH
- Los Angeles, CA
- Nashville, TN
- **Newark, NJ**
- New York City, NY (4 clinic locations)
- Philadelphia, PA
- Rochester, NY
- San Francisco, CA
- Seattle, WA
- Washington, DC

South America

- Peru (4 sites)
- Brazil

Switzerland

Current Study Status



- **31 March 2016**
 - Protocol Opened
- **06 Apr 2016**
 - 1st Participant Enrolled
- **04 Apr 2017**
 - **958 Participants Enrolled**
 - 24 Participants Randomized

Newark Enrollment Status

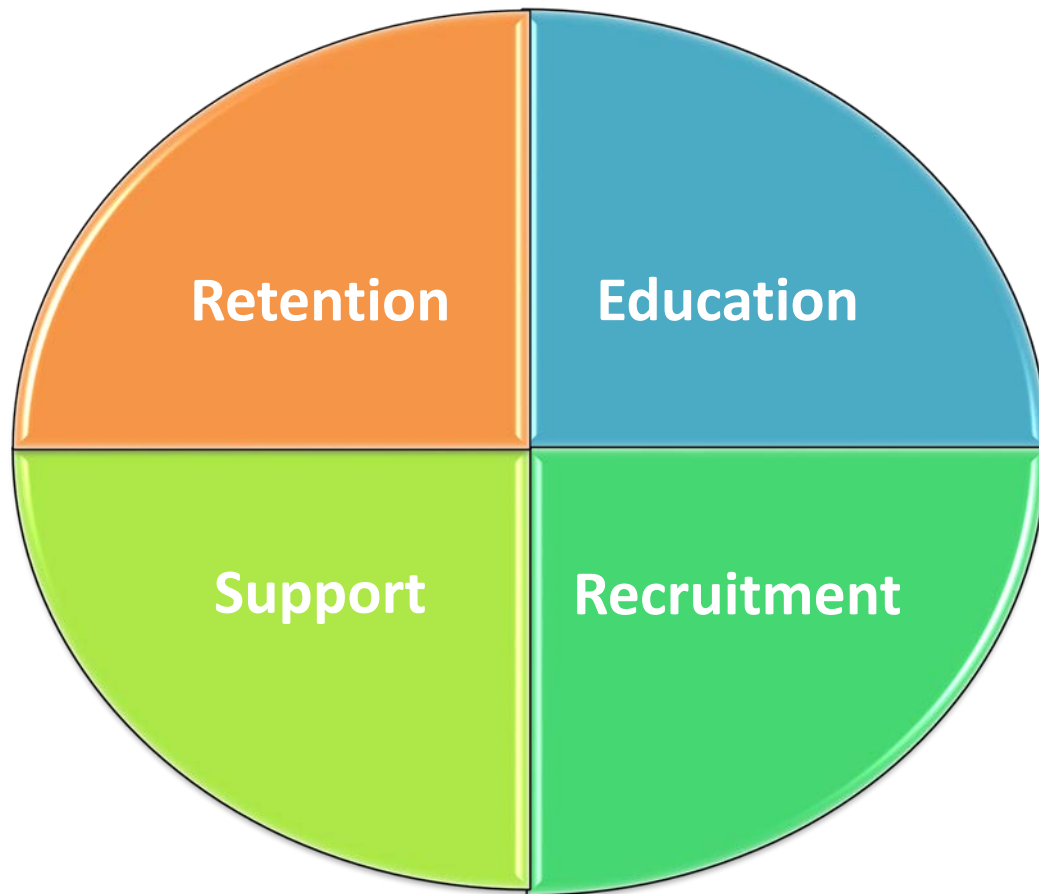
- 330 Potential Candidates
- **26 Jul 16**
 - **First Participant Enrolled**
- 50 Candidates Consented
- 13 Failed Screening
 - 5 Preliminary Positive Results
 - 2 Diabetes
 - 1 ALT >2.5XULN
 - 1 BMI >40
 - 2 Medical History
 - 2 Sexual Risk
- **35 Enrolled**
 - **2 pending**



What is Community Engagement?



Engagement Domains



Education

- Provide information about research studies
- Share interactive videos about study rationale and procedures
- Discuss HIV prevention methods and the current state of research
- Review Truvada as PrEP, safer sex practices, sex positive messages
- Other topics as needed or requested by CBOs or other organizations/groups
- **Goals**
 - Raise awareness about HIV and prevention studies
 - Provide knowledge about HIV, methods of transmission and other sexual health related topics
 - Establish our site as an ally and resource to community

Recruitment

- Presentation directed and provided to target population in group facilitated or discussion setting
- Study specific recruitment materials (ie. business cards, chochkis, pre-screeners) are available
- Some education is provided but focus is on engaging potential clients to be pre-screened, discussing HIV prevention research, and focusing on being a part of the next phase of HIV prevention
- **Goal**
 - ENROLLMENTS!

Retention

- Activities focused on maintaining interest in study participation as well as ensuring our participants are appreciated for their participation
 - Events are informal and do not involve study specific information or presentations
- **Goals**
 - Encourage retention in our study activities and adherence to schedule of events
 - Foster sense of community among participants and staff

Support

- Activities engage NJMS CRC staff with the populations we serve by attending local events without actively recruiting
 - Houseball competitions
 - Facilitated discussions
 - Task force meetings
- **Goals**
 - Collaborative efforts
 - Foster sense of community
 - Remain connected to local events and cultural shifts



ACKNOWLEDGEMENTS

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