



HPTN
HIV Prevention
Trials Network



HPTN 083: Give PrEP a Shot!

Audio Conference Information:

Dial-In Number(s):

U.S. & Canada: 866.740.1260 (Toll Free)

U.S.: 303.248.0285 (Toll)

Brazil: 01149497302 (Toll)

Brazil: 08008918965 (Toll Free)

Access the link below for a list of global toll-free numbers:

<http://www.readytalk.com/an.php?tfnum=8667401260>

Access Code: 4011527

#HPTN083

#GivePrEPaShot

HPTN 083: Give PrEP a Shot!

- Overview of HPTN 083
- Community Engagement in HPTN 083
- Questions/Answers



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OVERVIEW OF HPTN 083

Phase 2B/3 Injectable Cabotegravir Compared to Daily Oral
TDF/FTC for PrEP in Cisgender Men and Transgender
Women Who Have Sex With Men

Raphael J. Landovitz, MD MSc

Associate Professor of Medicine

UCLA Center for Clinical AIDS Research & Education

HPTN 083 Protocol Chair

Agenda

- Background
- HPTN 083 (Phase 2b/3)
- Training, Timelines, and Community Engagement

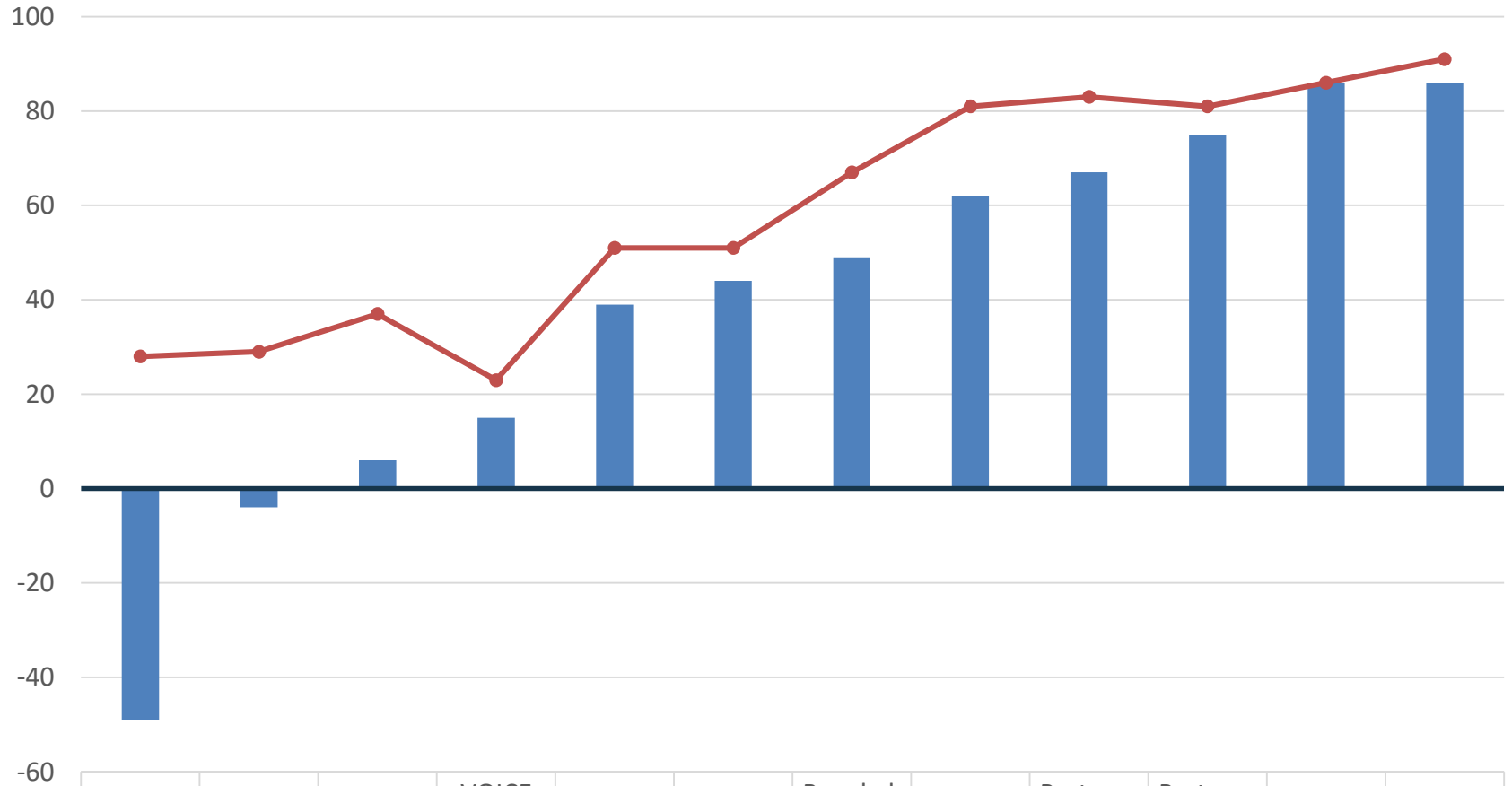
Cabotegravir: HIV Integrase Inhibitor



INJECTABLE CABOTEGRAVIR

Cabotegravir

- Experimental
- GSK1265744 = Cabotegravir
- Integrase inhibitor – Prevents HIV from combining its genetic material into the host cell's genetic material
- Well-suited for long-acting injectable
- Being evaluated for injectable PrEP and HIV treatment



	VOICE Tenofovir	VOICE Truvada	Fem PrEP	VOICE Tenofovir Gel	CAPRISA 004	iPrEX	Bangkok Tenofovir Study	TDF2	Partners PrEP Tenofovir	Partners PrEP Truvada	PROUD	IPERGAY
Efficacy	-49	-4	6	15	39	44	49	62	67	75	86	86
Adherence	28	29	37	23	51	51	67	81	83	81	86	91

■ Efficacy ● Adherence

Safety Overview

- Approximately 1500 exposures across Phase 1 and 2 clinical trials
 - ~ 640 volunteers at very low risk for HIV infection
 - ~ 500 HIV-infected
 - ~ 500 with long acting cabotegravir
- Generally safe and well tolerated



Advantages

Disadvantages

Injection could help address adherence issues

Medicine cannot be removed once given

Fewer (or different) side effects

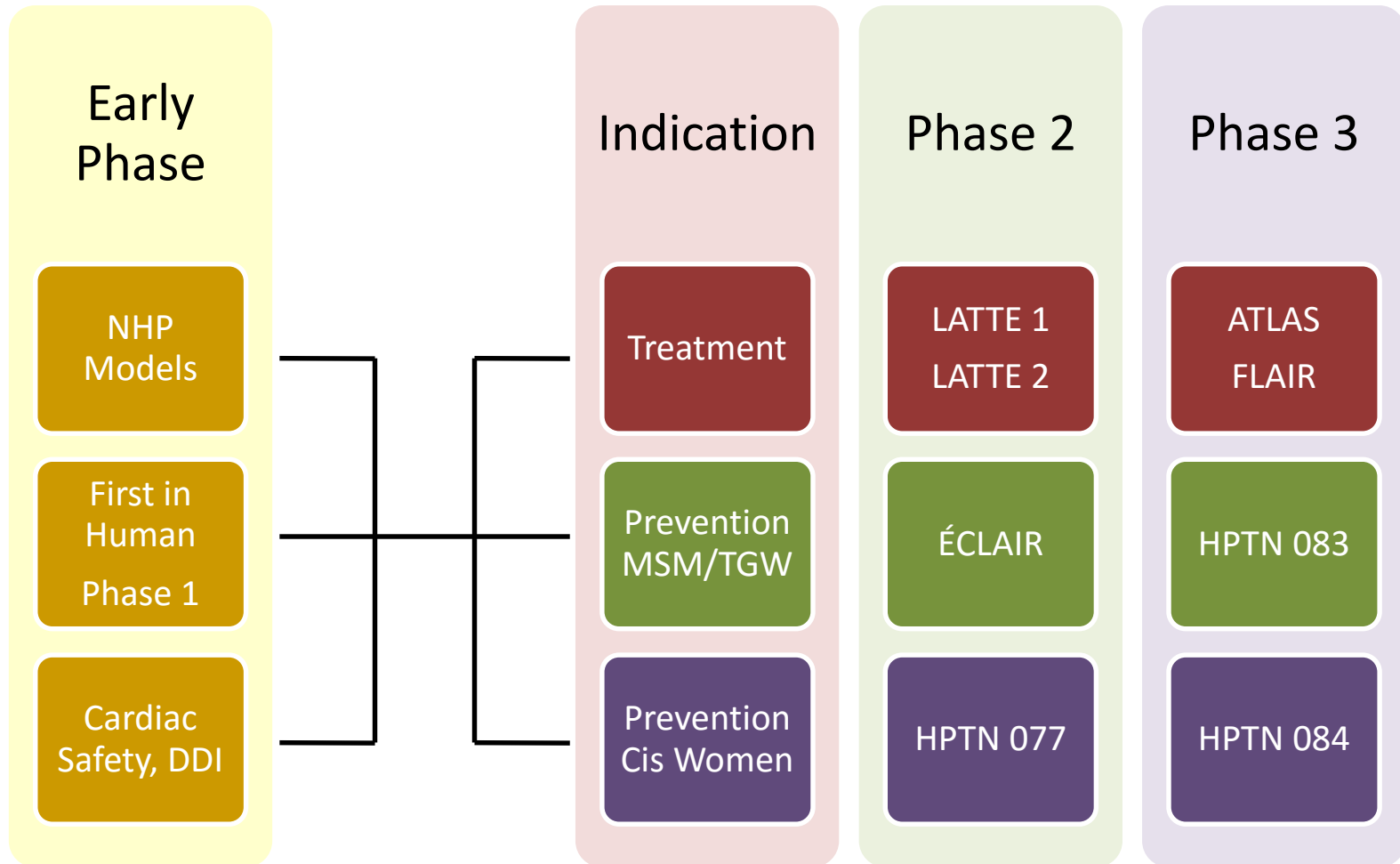
Some people may not like injections

Don't have to swallow pills daily (after first 5 weeks)

Potential long lasting side effects

Medicine may be in the body for more than a year after injections stop

Cabotegravir Development



*Includes both men and women

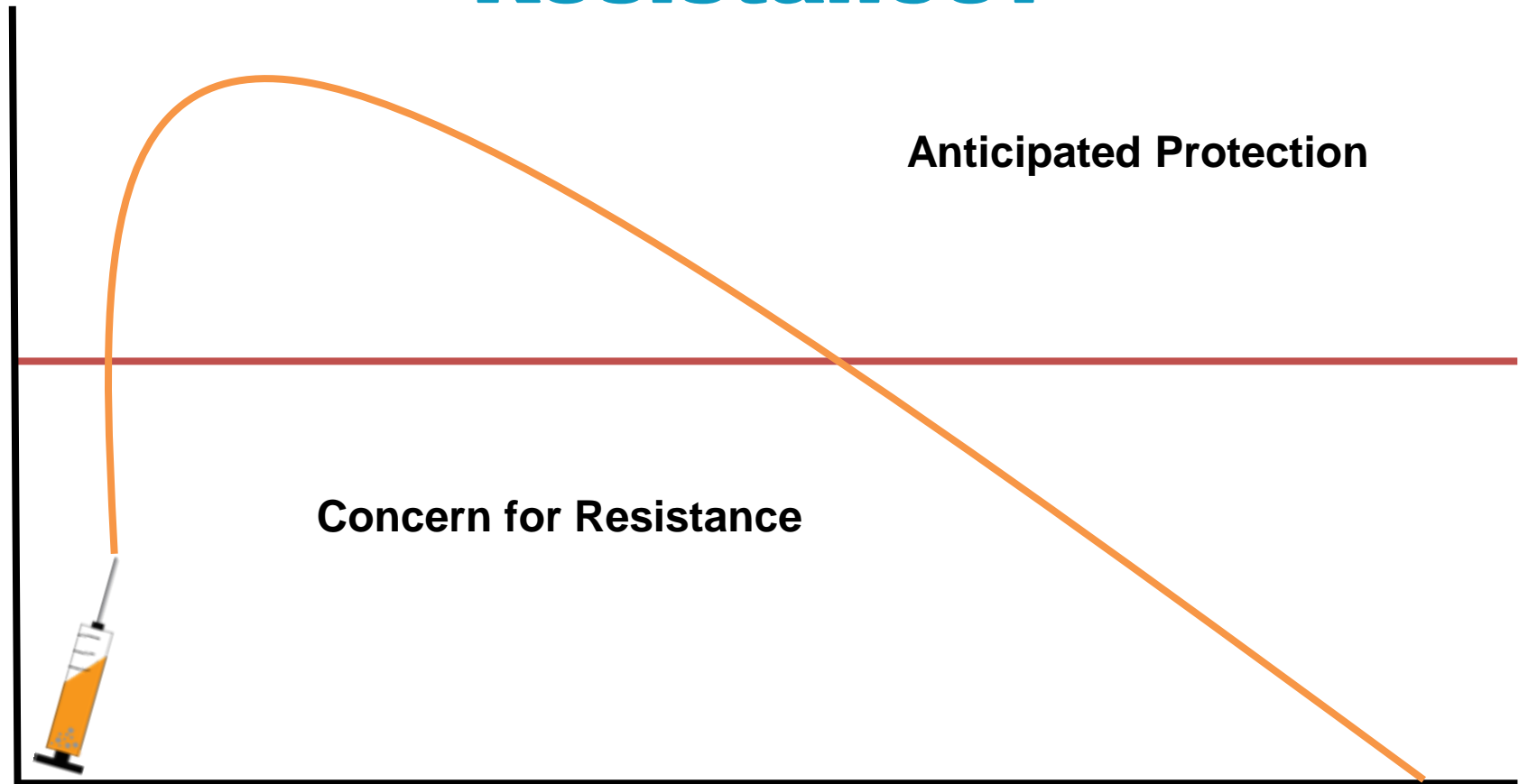
The PK Tail: Concern for Resistance?

Anticipated Protection

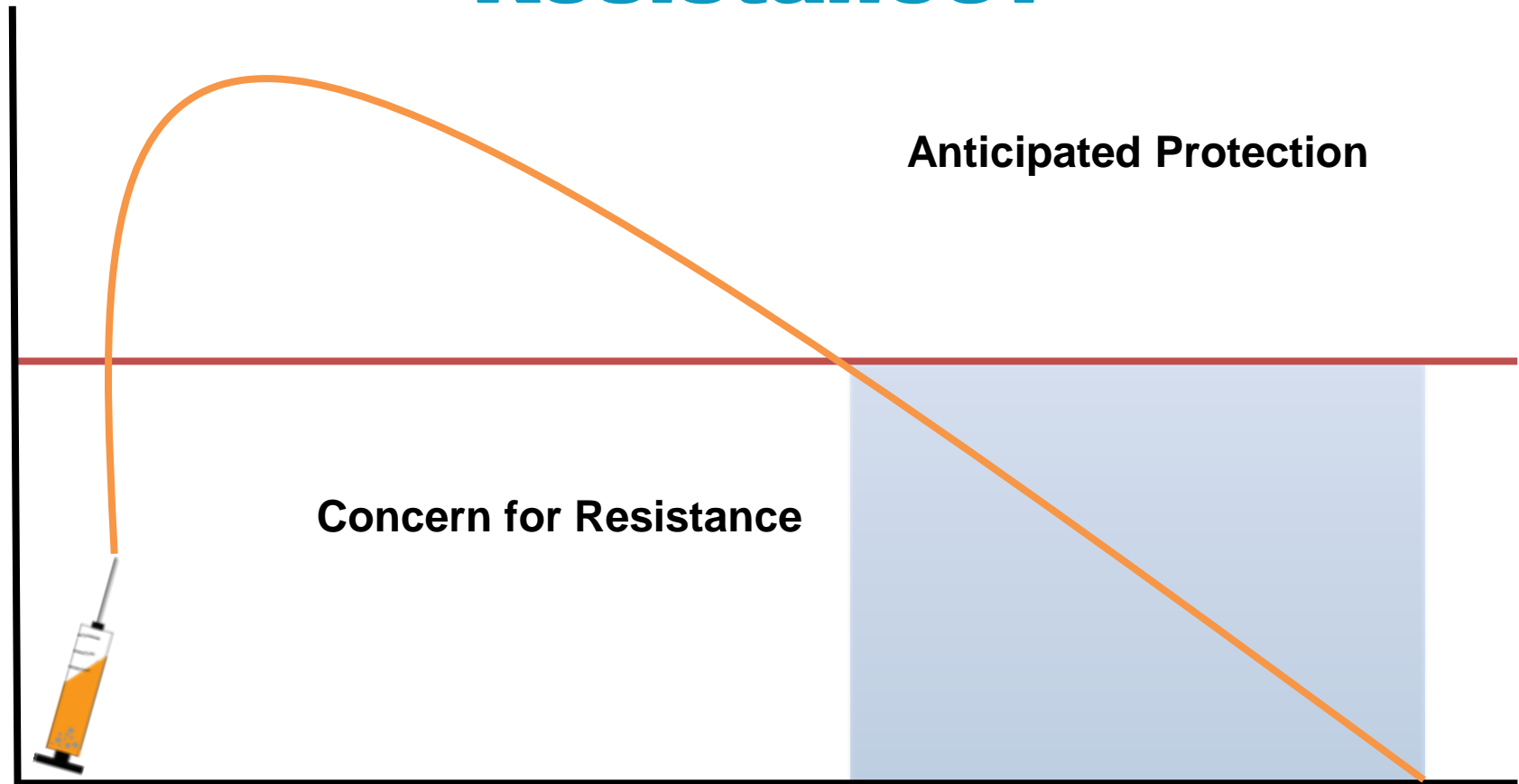
Concern for Resistance



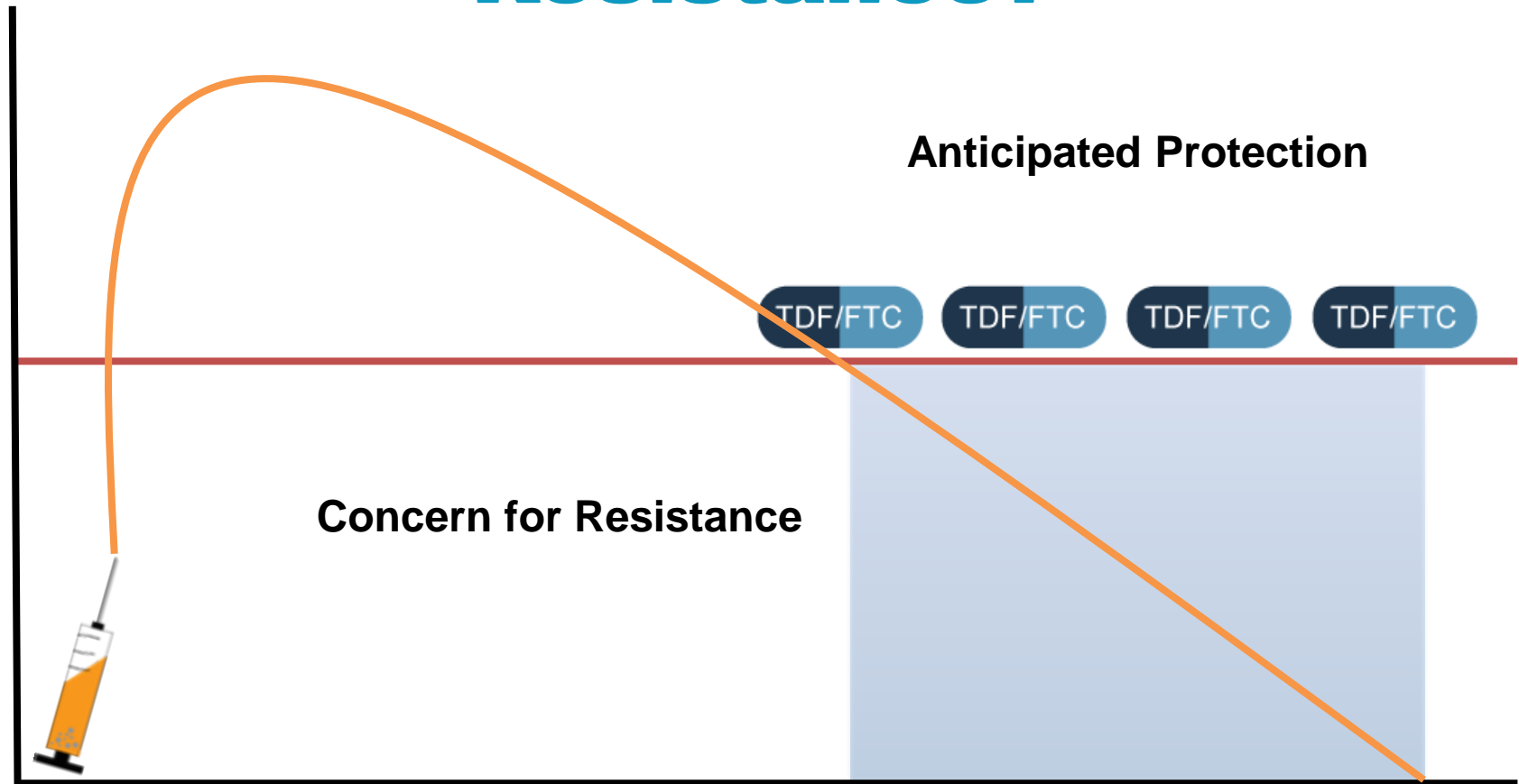
The PK Tail: Concern for Resistance?



The PK Tail: Concern for Resistance?



The PK Tail: Concern for Resistance?



HPTN 083: Injectable Cabotegravir vs Oral Truvada®

HPTN

083

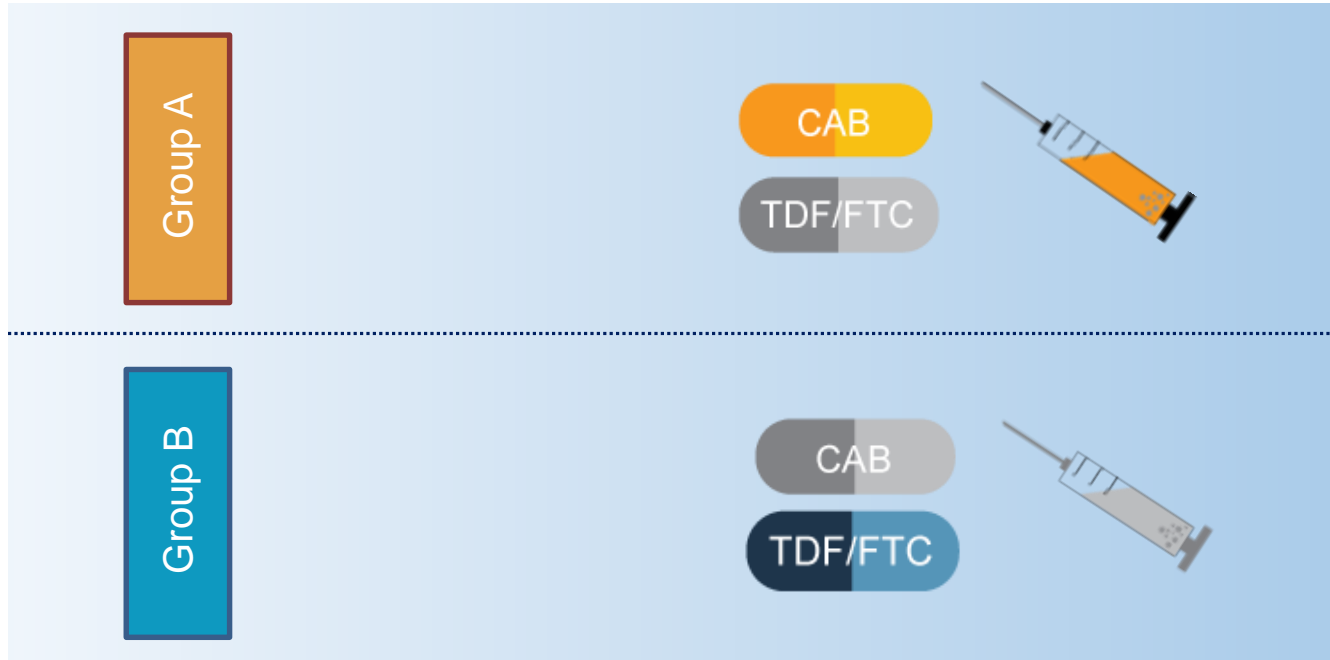


an **HIV prevention** clinical trial

HPTN 083 Study Design

- Phase 2b/3 trial
- Comparing once daily oral PrEP (Truvada®) to injectable PrEP (Cabotegravir)
- Randomized
- All study volunteers receive one active and one inactive product

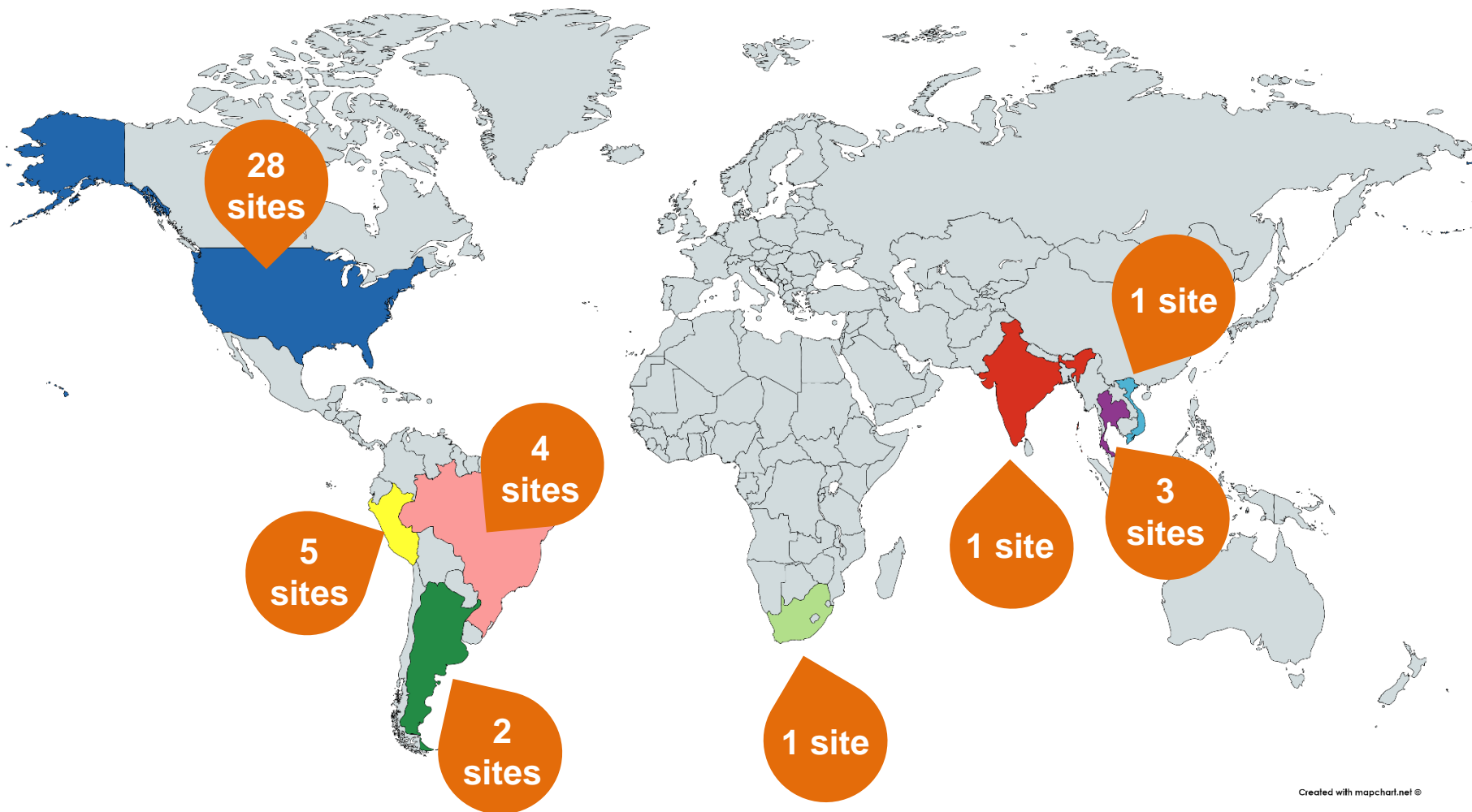
Volunteer Groups



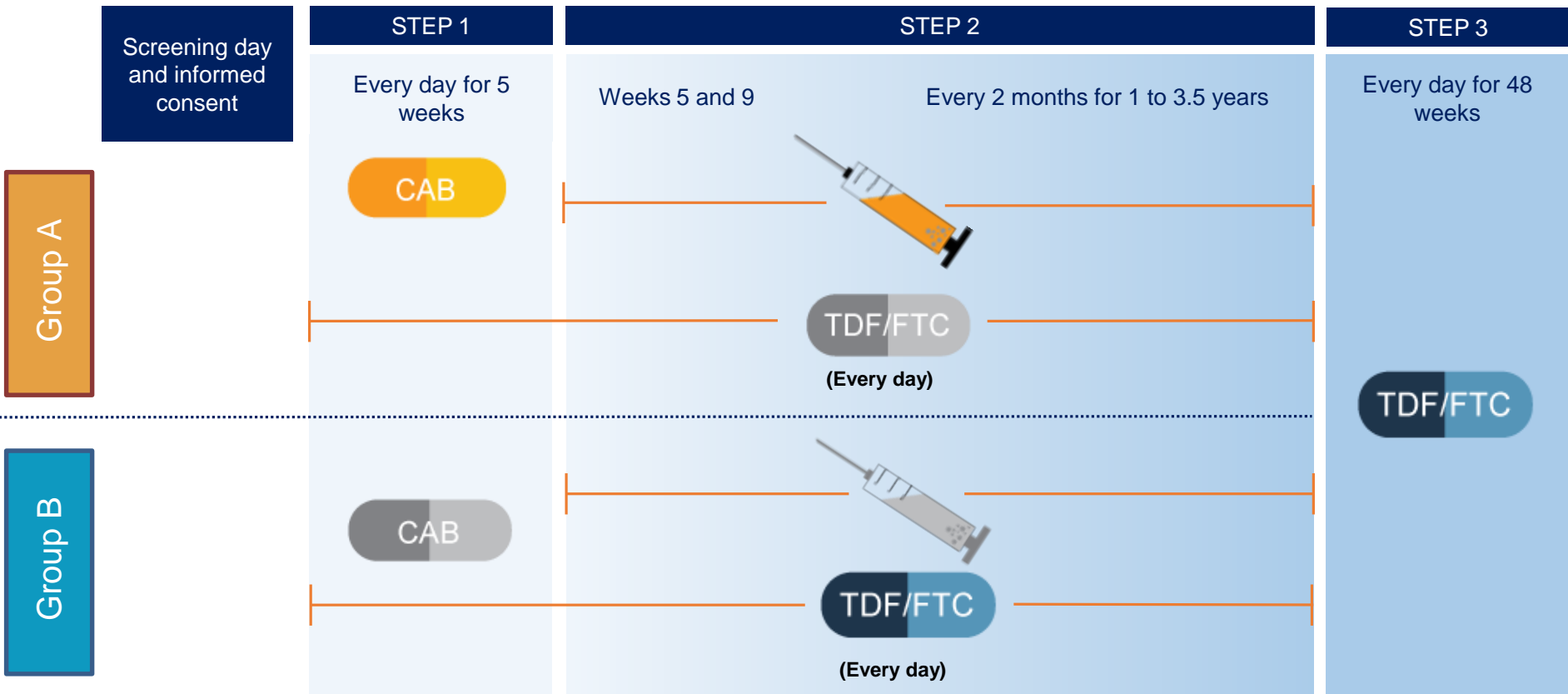
-  TDF/FTC pill
-  Cabotegravir (CAB) injection
-  Placebo for TDF/FTC pill
-  Placebo for cabotegravir (CAB) injection
-  Cabotegravir (CAB) pill
-  Placebo for cabotegravir (CAB) pill

Study Population

- 4500 cisgender-MSM and TGW who have sex with men
 - Minimum overall target 10% TGW (~450)
 - Minimum overall target > 50% YMSM under age 30
 - Minimum target 50% Black MSM in the United States (~950)
- Research sites in North and South America, South Africa and Asia



Created with mapchart.net ©



-  TDF/FTC pill
-  Cabotegravir (CAB) injection
-  Placebo for TDF/FTC pill
-  Placebo for cabotegravir (CAB) injection
-  Cabotegravir (CAB) pill
-  Placebo for cabotegravir (CAB) pill

Study Questions

- How effective is cabotegravir when compared to Truvada®?
 - Overall effectiveness
 - Effectiveness in sub-groups
- How safe is cabotegravir when compared to Truvada®?
 - Overall safety
 - Kidney, liver and bone safety
- Cabotegravir injections or oral Truvada®
 - Which do study participants prefer to use?
 - Which do study participants find more acceptable?

Study Questions

- What is the HIV incidence rate of study participants based on product adherence?
 - Rates, patterns, and correlates of adherence
- What is the rate of ART resistance in seroconverters on cabotegravir compared to Truvada[®]?
- Are there changes in sexual risk behavior?
- Would cabotegravir be a cost effective method for HIV prevention?

Study Volunteers

Cisgender-MSM and TGW who consent to participate and meet the study criteria are eligible for this study. This criteria includes:

- 18 years of age or older
- HIV negative
- Sexually active with males and at increased risk of HIV infection
- Willing to provide comprehensive and current locator information
- In general good health per clinical and laboratory assessments
- Willing to undergo all study procedures

Final Thoughts

Final Thoughts

- We are sincerely hopeful that the results from HPTN 083 will prove that injectable CAB is as effective or more effective than oral PrEP.
- There is a strong need for prevention options for diverse communities worldwide.
- We need ALL HIV AFFECTED COMMUNITIES involved and engaged.



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Community Engagement in HPTN 083

Cheryl D. Blanchette, PMD Pro

Community Program Manager

HIV Prevention Trials Network Leadership and Operations Center

Overview

- Community Engagement in the HPTN
- Community Engagement in HPTN 083
 - Internal Community / Network Engagement
 - External Community / National Engagement

Partnership in Research

- An important aspect of conducting research is ensuring the community partners have a role in the research process.
- Continuum of an evolving partnership

**Advisors/
Consultants**



**Partners/
Collaborators**

Internal Community Engagement

Activities focused within the various
levels of the HPTN



HPTN 083 COMMUNITY WORKING GROUP

Facilitating, directing, and advocating for inclusion of the research community as partners in HPTN 083.

CWG - Protocol Development

- Critical reviews
 - Initial concept review March 2015
 - Inclusion/Exclusion criteria review May 2015
 - Science Review Committee review December 2015
- Community feedback resulted in protocol modifications regarding inclusion/exclusion criteria and risk language

CWG - Community Preparedness

- Discussions of key considerations that needed to be addressed for successful community engagement of HPTN 083 in each region – Africa, Asia, South America, and the United States
- Provided feedback on any assistance and tools related to education and recruitment that would be needed for successful implementation of HPTN 083 for each region.



HPTN 083

Give PrEP a Shot

A NEW KIND OF RESEARCH STUDY

HPTN 083 is a research study that compares the effectiveness of injections and oral tablets as pre-exposure prophylaxis (PrEP) to prevent HIV.



Give PrEP a Shot!

Learn more about HPTN 083,
a research study comparing
the effectiveness of injections
and oral tablets to prevent HIV

WWW.GIVEPREPASHOT.ORG





Give
PrEP
a Shot!



PROJECT
achieve

Injectable
PrEP

A Butt Shot
Worth Trying.

HIV negative men,
18 or older wanted for a
paid injectable PrEP project.



PROJECT
achieve
GIVE PREP A SHOT

iprep

PROJECT ACHIEVE IS LOOKING FOR MEN
TO JOIN AN INJECTABLE PREP STUDY (HPTN 083)
TO HELP DEVELOP THE NEXT GENERATION OF PREP.

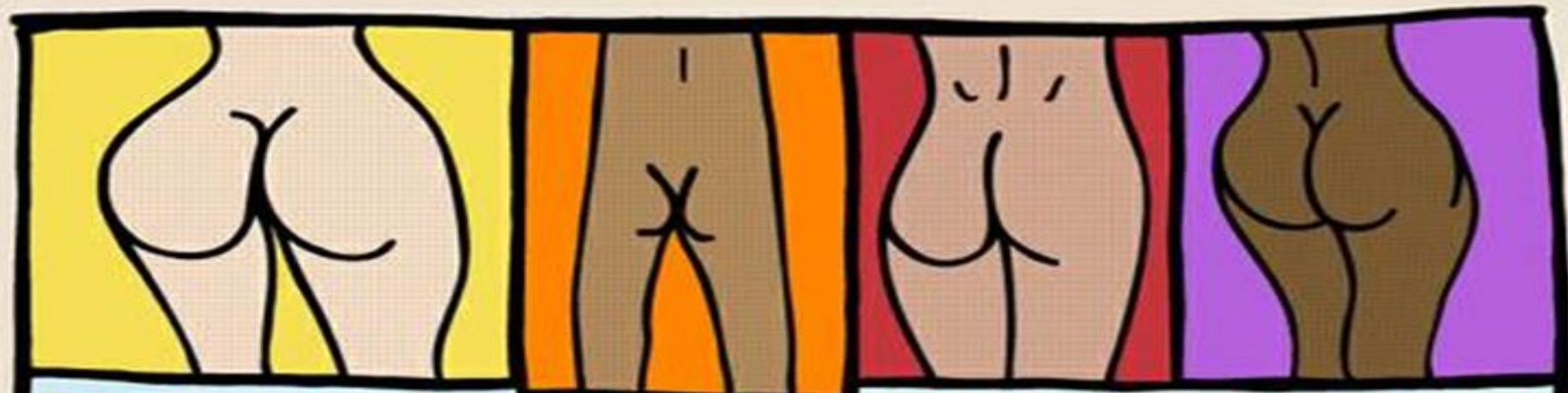


PROJECT
achieve

IPREP

GIVE PREP
A SHOT





PrEP IS A PILL THAT PREVENTS HIV.

COULD IT ALSO *be a shot?*

SHOW US YER CHEEKS

**VOLUNTEER FOR A PrEP RESEARCH STUDY
& HELP US FIND OUT.**

JOINPREP.ORG

UCLA CARE CENTER & BASH LA INVITES YOU TO
SUNDAY, FEBRUARY 5TH



"COME AND LEARN ABOUT AN HIV PREVENTION STUDY!"

B.A.S.H.

HPTN 083

RAGE

8011 SANTA MONICA BLVD.
WEST HOLLYWOOD, CA 90061

- FOOD & DRINKS WILL BE SERVED -

COMPLIMENTARY RSVP AT GIVEPREPASHOT.EVENTBRITE.COM

CWG - Community Preparedness

- Community Engagement Work Plans (CEWP)
 - Required for study activation and are to have the joint input, feedback, and support of the community educator, principal investigator, clinic coordinator, and CAB representative(s).

CWG - Trainings and Capacity Building

- Two conference calls and four face-to-face meetings/sessions with the HPTN 083 protocol chair and clinical research managers to discuss the science that supports cabotegravir and the study design of HPTN 083.
- Two community workshops with focus on best practices for recruitment and retention of MSM, TGW, and minority populations

Other Trainings and Capacity Building

- Cultural Responsiveness Training: *A Presence at the Table*
 - Facilitated with US site staff who have direct contact with study participants (recruiters, study coordinators, nurses, investigators, etc.)
 - Designed to engage, develop, and increase understandings of the perspectives of colleagues and research participants.

External Community Engagement

National Engagement with Stakeholders

National Community Engagement

- Black MSM Consultation, November 2015
- NAESM Conference – January 2016 and 2017
- YBGLI Policy and Advocacy Summit – April 2016
- Saving Ourselves Symposium – June 2016
- National Trans Health Conference – November 2016
- National HIV PreP Summit – December 2016

Stakeholder Consultations and Meetings

- HPTN Transgender Workshop, June 2015
 - Attended by HPTN Scientific Committee members, NIH project officers, and invited key researchers and community leaders
 - Purposed to inform the HPTN on how best to develop and conduct new, culturally-tailored interventions for transgender men and women

Final Thoughts

Final Thoughts

- The HPTN supports community engagement throughout all stages of the research process
- Collaboration with, and inclusion of, community representatives in the research process help to
 - build trust
 - increase the likelihood that affected communities are invested in and supportive of the research

Questions

THANK YOU

Additional Information

- 083CPM@hptn.org
- www.hptn.org
 - www.facebook.com/HIVptn
 - www.twitter.com/HIVptn
- www.nih.gov

Acknowledgements

- The HPTN 083 Community Working Group
- The HPTN 083 Study Team
- The HPTN Black Caucus
- FHI 360 Community Program Management Team

ACKNOWLEDGEMENTS

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