

Sexually Transmitted Infections

Myron S. Cohen, MD

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Dual Prevention Pill

A multisite, open-label, randomized crossover study comparing adherence to a single daily dual prevention pill (DPP) versus FTC/TDF and Combined Oral Contraception separate pill dosing (2PR), given for pre-exposure prophylaxis and pregnancy prevention in people of childbearing potential

Sub-Saharan Africa

- Wits RHI Ward 21 CRS
- Eswatini Prevention Center CRS
- Spilhaus CRS
- Makerere University –Johns Hopkins University (MU-JHU) Research Collaboration CRS



2

Broadly neutralizing antibodies

- A phase 2 clinical trial to evaluate the safety, tolerability, pharmacokinetics, and neutralization of VRC07-523LS, PGT121.414.LS, and PGDM1400LS broadly neutralizing monoclonal antibodies in adult participants without HIV
- Study to be completed in Brazil, Peru, South Africa and United States – Sites are TBD
- Looks to gain data about neutralization and dosing to inform possible phase 3 Combo AMP trial.

3

HPTN STI Studies

- A vanguard study to **test a suite of mHealth tools to increase HIV PrEP uptake and adherence** among young Latino/e/x cisgender men and gender nonbinary persons assigned male at birth (AMAB) who have sex with men
- Will also evaluate the uptake, adherence, and acceptability of **doxycycline for STI post-exposure prophylaxis (doxy-PEP)**
- **N = 400** participants
- **Five sites:** Bronx, UCLA Vine St, Fundacion Huesped, IPEC Fiocruz, San Miguel



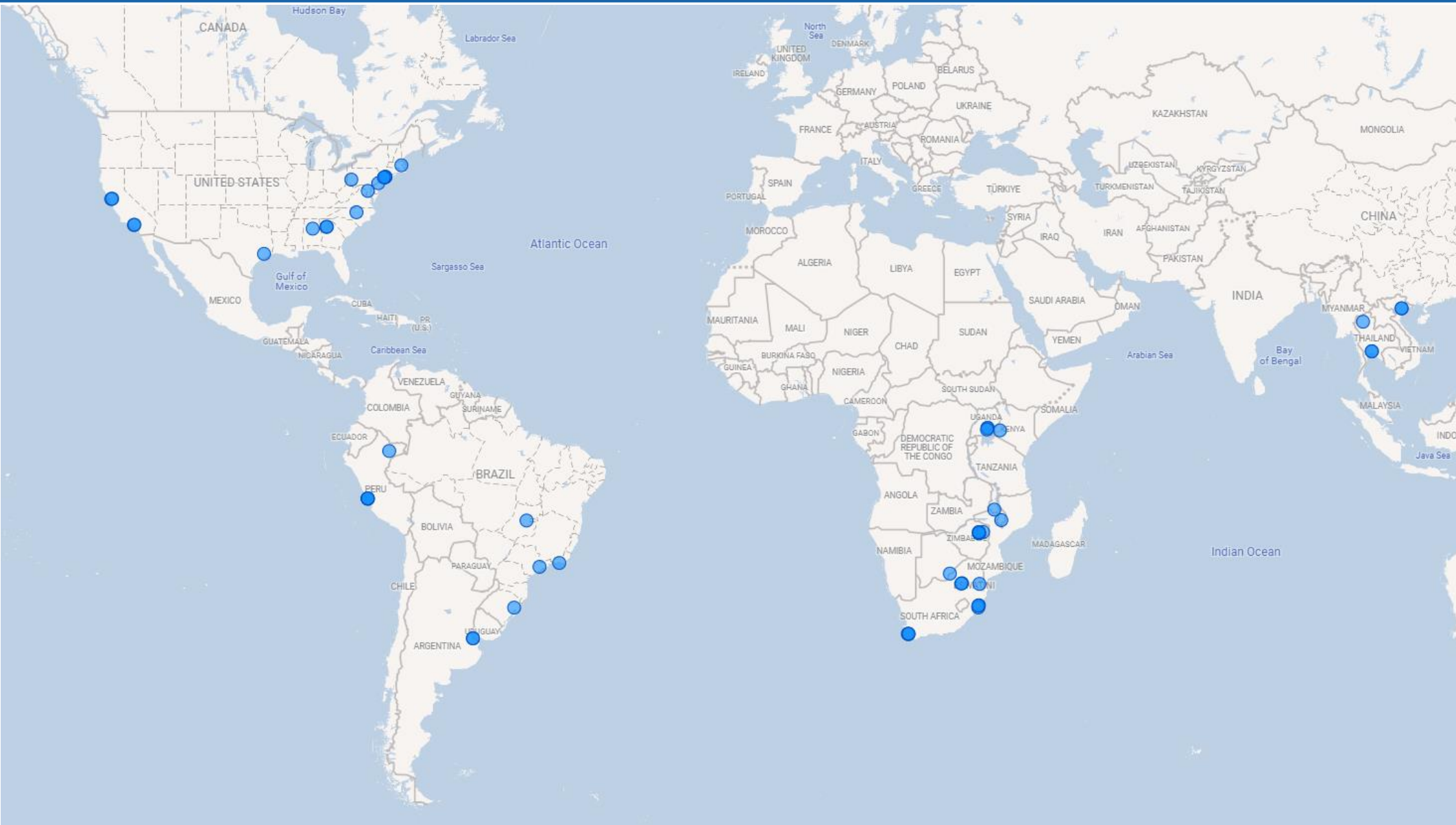
ATN 173/HPTN 115 (foXXy doxy)

- Open-label 3-arm RCT investigating use of DoxyPEP for the prevention of STIs (gonorrhea [GC], chlamydia [CT], and early syphilis).
 - Arms (1:1:1): 1) on-demand doxyPEP; 2) weekly doxyPEP; 3) SOC
 - Population: 759 adolescents and youth aged 13-29 assigned female at birth (AFAB) in the US
 - Aim to enroll 20% transgender and gender diverse individuals AFAB
 - 12 sites across the US have been selected (7 ATN and 5 HPTN)
 - Quarterly visits (1 year) + weekly assessments via Health Mpowerment (HMP) app
 - Objectives include efficacy (all incident and individual incident), acceptability, tolerability, self-reported adherence and objective use, and resistance



- A Phase II trial, open-label, multicenter, non-inferiority, randomized clinical trial to assess the efficacy of doxycycline compared to CDC-recommended IV aqueous penicillin G in the treatment of neurosyphilis and ocular syphilis.
- Approximately 180 participants will be randomized 1:1 to doxycycline or penicillin G across multiple sites in the US and internationally.
- The protocol and site selection process is in development.

HPTN Clinical Research Sites



54

HPTN Sites

13

Countries

21

African Sites

5

Asian Sites

17

North American Sites

11

South American Sites

HPTN Presence in South America

 HPTN 083

 HVTN 704/
HPTN 085 (AMP)

 HPTN 091

 HPTN 113





Thank you

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