



HPTN
HIV Prevention
Trials Network



HPTN 083

#GivePrEPaSHOT

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Study Rationale

- Daily oral TDF/FTC is highly effective when taken as prescribed
- Some individuals find it challenging to take oral tablets daily
- CAB is an investigational integrase inhibitor being developed for
 - HIV treatment (in combination with other ARVs)
 - HIV prevention (alone, as a single drug)
- CAB is available both as a daily pill and as a long-acting intramuscular injection given every 1-2 months

Study Design and Duration

- Randomized, double-blind active-controlled comparison of daily oral TDF/FTC and injectable CAB
 - 5 week oral “lead in” – 2 tablets daily
 - ~3.5 year injectable phase – injections + daily tablets
 - 1 year “open-label phase” – everyone receives HIV prevention package + daily oral TDF/FTC

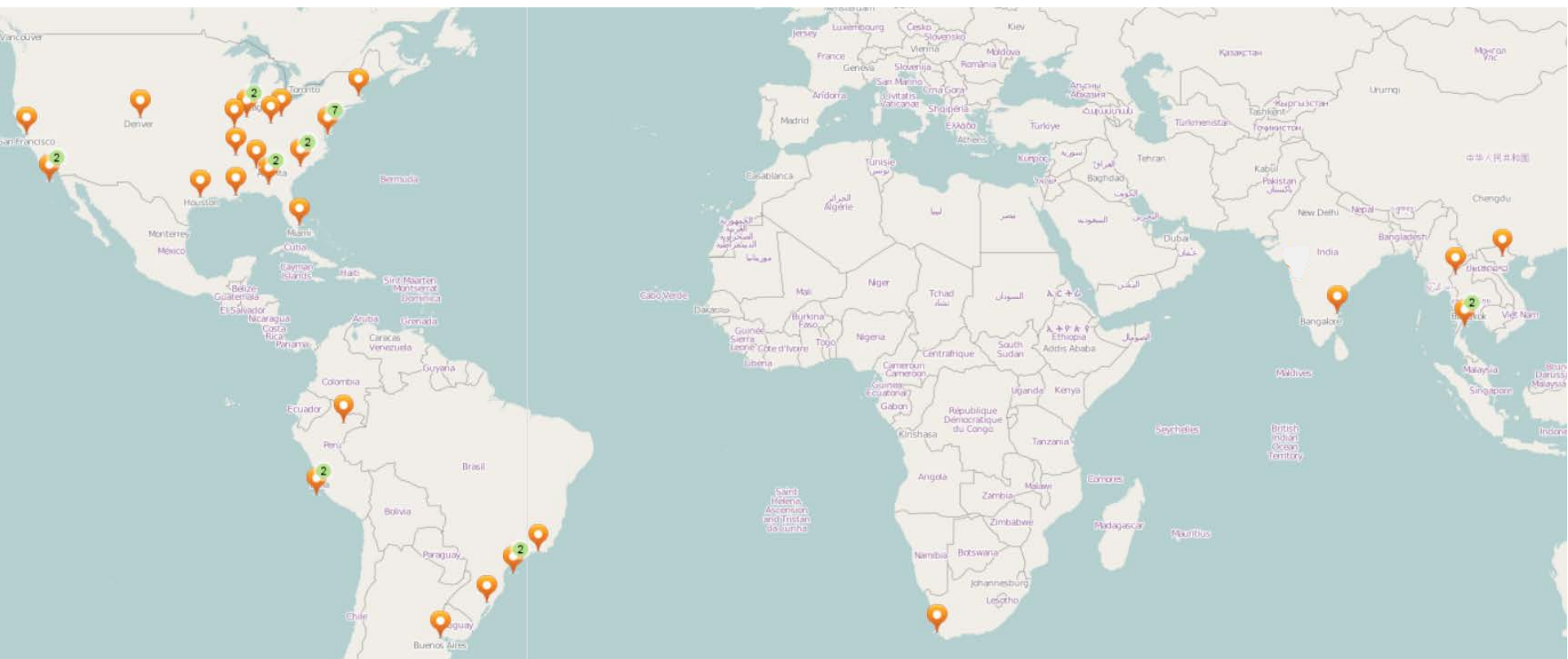
Study Population and Size

- >18 yo, HIV-uninfected, increased risk MSM and TGW
- 4500 participants
 - 45 sites in 8 countries
 - >50% under age 30
 - >50% of US enrollment BMSM
 - >10% TGW

Study Objectives

- Efficacy of injectable CAB compared to daily oral TDF/FTC for HIV prevention
- Safety of injectable CAB compared to daily oral TDF/FTC
- Acceptability and preferences for injectable vs. oral PrEP
- Compare rates and types of drug resistance in people who acquire HIV after taking TDF/FTC or CAB

Clinical Research Sites



45 sites in 8 Countries

Current Study Status

- Open to enrollment December, 2016
- First enrollment: December 19, 2016
- Sites Activated:
 - US:
 - Non-US:
- Currently Enrollment
- Estimated Completion of Enrollment:
- Estimated Results Available: 2021

Community Engagement

- Initial concept review, inclusion/exclusion criteria review, science review
- Community preparedness meetings (regionally focused)
- Central resource development
- Site CEWP development/review
- CPM 6 meetings with protocol team; 2 community workshops
- Cultural responsiveness training (PAT)
- 6 national/international external stakeholder events at scientific meetings

ACKNOWLEDGEMENTS

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