CABOTEGRAVIR ROUNDTABLE DISCUSSION:
“THE TWINS” (HPTN 083-01/084-01)

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HPTN 083-01 and HPTN 084-01: Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescents
Objectives of the Adolescent CAB Studies

- **GOAL:** Concurrent (or as close as possible) licensure of CAB LA for adolescents and adults

- **Primary Objective**
  - To evaluate the safety, tolerability and acceptability of CAB LA in healthy HIV-uninfected adolescents aged below 18 years.

- **Secondary Objectives**
  - To examine adherence to and timeliness of injections over time
  - To examine patterns of sexual risk behavior over time
  - To evaluate the safety of CAB LA for up to 48 weeks of follow-up after final injection
  - To characterize the pharmacokinetics of CAB LA
Study Design/Population

• A single arm, open label bridging study

- 083-01: 50 cisgender men or transgender women; 084-01: 50 cisgender women
- Under the age of 18
- Sexually-active, HIV-negative, generally healthy adolescents
- Weigh at least 35kg (77 pounds)
- If currently on oral PrEP, willing to switch to LA CAB during the study
Study Sites

• 083-01 sites were activated Feb-March 2020 then immediately put on pause due to COVID.
  • Re-opened for enrollment in July (Chicago), August (Boston), and September (Memphis)

• 084-01 sites were activated in November 2020 (Ward 21 & MU-JHU) and March 2021 (Spilhaus)

083-01 Study Sites

**Boston**
Fenway Health – The Fenway Institute

**Chicago**
Adolescent/Young Adult Research – CORE Center

**Memphis**
St. Jude Children’s Research Hospital

084-01 Study Sites

**Johannesburg, South Africa**
Ward 21 CRS, WRHI

**Kamplala, Uganda**
MU-JHU Research Collaboration CRS

**Harare, Zimbabwe**
Spilhaus CRS
Screening and Enrollment

- Enrollment continues through November 2021 for both studies.
- Recruitment/enrollment affected by COVID
  - But improving as restrictions decrease
- As expected, parental consent can be a barrier
  - Sexual minority youth given that many have not disclosed their sexual orientation to parents/guardians;
  - Youth in general may not have disclosed sexual activity to their parents/guardians;
  - Youth may face harm should they be required to disclose in order to participate in the study.
- Contraception requirement for very young women a barrier
- To date, screened 40 and enrolled 22 across both studies

https://inject2protect.org/
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• The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
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