

# CABOTEGRAVIR ROUNDTABLE

## DISCUSSION:

### “THE TWINS” (HPTN 083-01/084-01)

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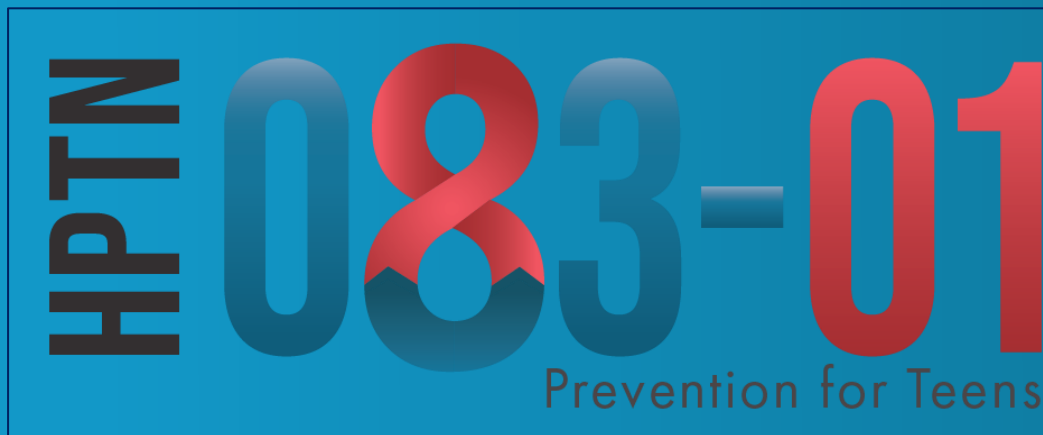
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HPTN  
HIV Prevention  
Trials Network



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

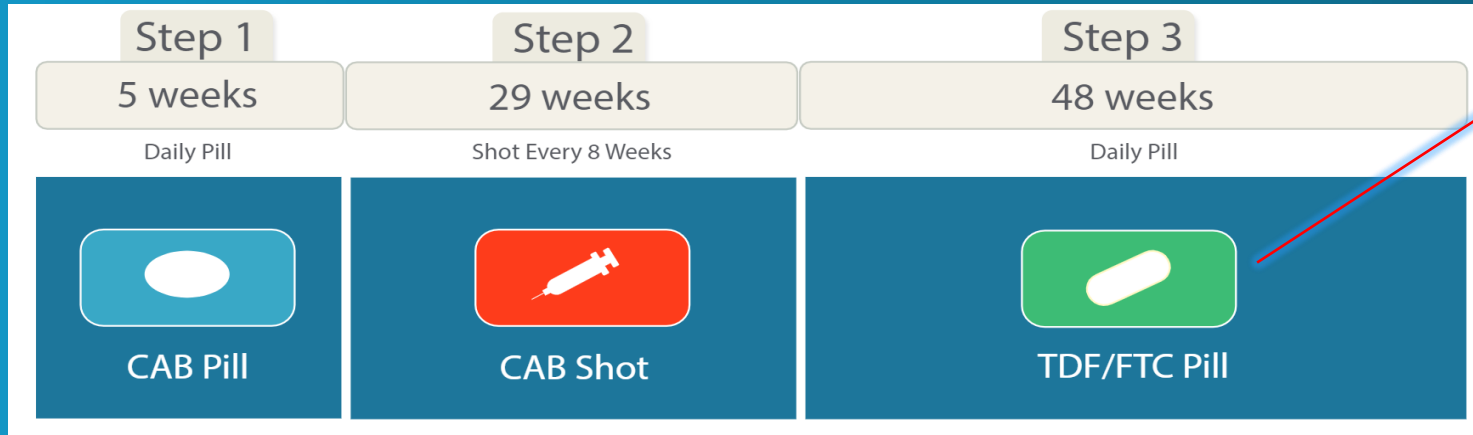


# Objectives of the Adolescent CAB Studies

- 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



Or CAB open label 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

## 083-01 Webpage

HOME ABOUT HPTN 083-01 ABOUT PREP FAQ FOR PARENTS CHECK ELIGIBILITY

### A NEW HIV PREVENTION STUDY FOR TEENS

Examining whether injectable CAB for PrEP is safe and acceptable for adolescents assigned male at birth.

Learn More

<https://inject2protect.org/>

# Acknowledgements

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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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