

# Is Injectable PrEP safe and effective? New research findings from HPTN 083



## Key Takeaways:

- A new study has proven the safety and efficacy of a long-acting injectable agent, cabotegravir, for use as pre-exposure prophylaxis (PrEP) for the prevention of HIV.
- The existing options for PrEP (including Truvada) continue to be safe and effective.
- An additional option for PrEP has the potential to improve uptake, but to ensure that HIV disparities narrow and not widen as a result of cabotegravir's introduction, policymakers and other groups must consider key determinants that may influence the drug's accessibility and acceptability

## WHAT IS THE RESEARCH?

HIV Prevention Trials Network (HPTN) 083 is a randomized, active-controlled, double-blind clinical trial that began in December 2016. **The study has compared the safety and efficacy of two drugs for use as PrEP among a population at increased risk of HIV infection:** 4,570 men who have sex with men and transgender women, recruited from Argentina, Brazil, Peru, United States, South Africa, Thailand and Vietnam. A separate trial comparing the efficacy and safety of the same two drugs with cisgender women in Sub-Saharan Africa (HPTN 084), is ongoing.

The two drugs compared in this study are the standard-of-care PrEP agent **Truvada®** (brand name for a formulation combining tenofovir disoproxil fumarate/emtricitabine) and a PrEP regimen of long-acting injectable **cabotegravir (CAB)**. Study participants taking CAB took an oral version of the drug for five weeks, followed by injections of the long-acting injectable version of the drug at 8-week intervals for a median of 1.4 years. Due to the success of the study, the U.S. National Institute of Allergy and Infectious Disease (NIAID) decided to end the blinded, randomized portion of the study two years ahead of schedule and recommended immediate dissemination of results. It did so because **the study had successfully established that CAB is an effective alternative to Truvada® for PrEP.**

## WHAT DO THE RESULTS MEAN?

When the rates of HIV infection for participants who received CAB were compared to those of participants who received daily oral Truvada®, CAB users were found to acquire HIV at rates lower than Truvada® users. CAB was found to be **statistically superior** to oral Truvada®, meaning that **CAB was able to protect more people against acquiring HIV during the study**, and that this difference likely cannot be explained by random chance.

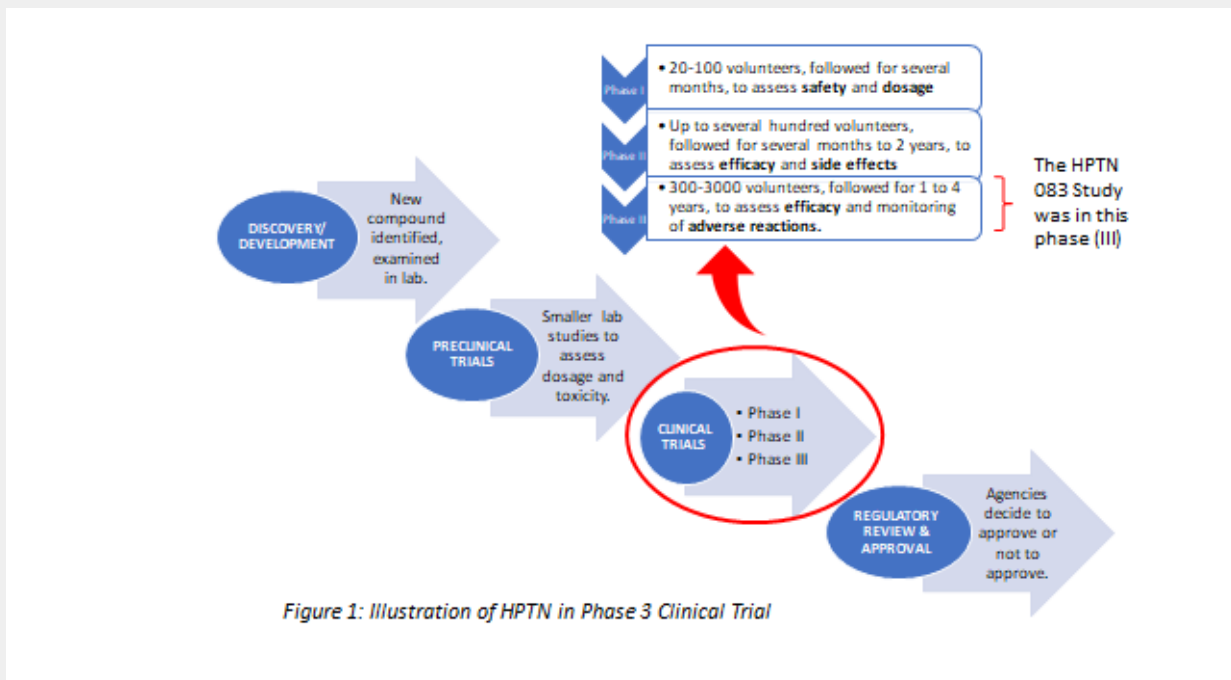
**Importantly, the interpretation of these data is not that Truvada® is unsafe or ineffective. Truvada®, if taken as directed, is a highly effective option for PrEP, suggesting that the efficacy of the CAB regimen is extremely high.**

## WHAT DOES THIS MEAN FOR THE FUTURE OF PREP?

**Cabotegravir as a form of injectable PrEP has the potential to increase uptake and adherence by increasing the choices individuals have for a PrEP medication that fits their needs and lifestyle. There are documented racial/ethnic, age, and gender disparities in PrEP uptake that need to be addressed (1, 2).** Diversity in HIV prevention medications and different ways of delivering them has the potential to help reduce those disparities (3, 4). **However, health disparities may widen** if the new medication isn't equally available across clinical settings for those in need of it (5). Adding a long-acting injectable form of PrEP offers a novel solution to individual-level barriers, such as daily adherence and pill fatigue (6).

# WHEN CAN WE EXPECT CABOTEGRAVIR ON THE MARKET?

It is still too early to know when CAB will be available on the market. HPTN 083 was a Phase III Clinical Trial and, while CAB has been shown to be safe and effective, it is not yet approved by the Food and Drug Administration (FDA) and other regulatory agencies. Figure 1 shows where the study currently stands in the long process a novel drug must take from discovery to market.



## POLICY IMPLICATIONS

With the findings of HPTN 083, individuals will have an additional medication option to take for HIV prevention. Whether this development narrows or widens HIV disparities among different groups depends in large part on how our healthcare delivery system adapts to this new development. In order to determine this, the following questions should be addressed:

- **How will governments, health systems, and community groups spread awareness of CAB** so that those groups at greatest risk are aware of this new option?
- **Will consumers accept CAB?** Will messaging be delivered to them in a culturally competent manner? If the only way to obtain CAB injections is to physically show up to a clinic, will that create barriers, either logistical (e.g., transportation, getting time off work) or social (in terms of concerns regarding HIV stigma)?
- **Will healthcare providers be able to offer injections of CAB as easily** as oral PrEP? Will they have the resources and training they need to administer the drug in clinic if a take-home version is not available? Will they have staffing capacity and the means to accommodate the increased demand for service?
- **Will health insurers cover the new medication and associated staff time?** Will providers have to spend significant time obtaining prior authorization, and will patients be able to afford the cost?

### References

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