

# Coordinating Implementation Science for CAB for PrEP: Early Insights from EBONI and PILLAR

## AVAC/BioPIC

8 February 2024, 9am- 10.30am EDT

### Background/Rationale

As of February 2024, there are [38 planned or ongoing cabotegravir \(CAB\) for PrEP implementation science \(IS\) studies](#). These studies will evaluate a variety of modalities for delivering CAB for PrEP in real-life situations, outside of clinical trials, with many offering a choice of PrEP methods to understand user preferences. Information gathered from these studies will be used to establish best practices for CAB for PrEP delivery, which will then be applied to wider scale-up across national PrEP programmes, ensuring programmes are effective in reaching all who want to use CAB for PrEP. While the majority of studies are only just starting to deliver CAB for PrEP, two implementation studies in the USA led by ViiV Healthcare, the manufacturer of CAB for PrEP, were able to start in 2022, approximately a year and half after approval by the local regulator, the US Food and Drug Administration, in December 2021. In these studies, known as [EBONI](#) and [PILLAR](#), participants utilise commercially available CAB for PrEP, meaning that they acquire the product through whichever means they would in the real world (e.g. public or private insurance or patient assistance programs), rather than ViiV providing product as would be the case in a clinical trial.

This provides a great opportunity for other researchers studying implementation of CAB for PrEP, as well as ministries of health beginning to rollout CAB for PrEP directly, to learn from the early insights generated from the EBONI and PILLAR studies and apply them to their own activities.

### Meeting Objectives:

1. Share and discuss early insights from the EBONI and PILLAR studies, with a greater focus on PILLAR which is further along in implementation
2. Identify insights which can help improve delivery of CAB for PrEP via IS studies and PrEP programmes

### Insights to Action- Key Takeaways and Implications for CAB for PrEP Rollout

EBONI/PILLAR Insight	Opportunity/Recommendations
ViiV uses the <a href="#">Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions-Implementation Strategies</a> (FRAME-IS), a ten-item questionnaire, to track modifications to the EBONI and PILLAR studies on a monthly basis. A thematic analysis of modifications is then mapped onto the <a href="#">Consolidated Framework for Implementation Research</a> (CFIR) to identify and assess the contextual factors impacting implementation.	FRAME-IS and CFIR are open-source resources that can be used by implementation researchers to understand how real-world conditions impact CAB for PrEP delivery, and to further refine and identify context-specific best practices.  For support using these resources, researchers can contact <a href="#">Nanlesta Pilgrim</a> at ViiV who can connect them to the co-author of the FRAME-IS tool.

## EBONI/PILLAR Insight

In PILLAR, most modifications to date have focused on supporting the feasibility of CAB for PrEP integration into a clinical setting, with the primary goal of improving client management and speeding up the injection/implementation process. Modifications have centred around updating clinical systems and processes to be more efficient, adding staff to administer injections and coordinate clients, spending additional time on client and staff education, streamlining the screening and enrolment process, and changing facilities' approach to management of private insurance.

ViiV designed the sexual health assessment and education materials for EBONI specifically for and with Black women to ensure relevance and acceptability to study participants.

ViiV trained PrEP champions from within the community to encourage Black women's engagement in PrEP.

Healthcare providers participating in EBONI were trained on sexual health care for Black women in addition to PrEP service delivery.

More advanced participant education and engagement was required in the EBONI study than the PILLAR study as the EBONI study includes Black women, who have historically been excluded from PrEP provision in the USA, in contrast with gay and bisexual men who have sex with men (GBMSM), the population eligible for the PILLAR study, and historically the focus community for PrEP campaigns in the USA.

For HIV testing, the study protocols outlined that study sites were to follow the US Centres for Disease Control (CDC) guidelines and the product label. In practice, study sites made adaptations to

## Opportunity/Recommendations

Where feasible, other IS studies and programs rolling out CAB can identify and act on opportunities to streamline service delivery and improve client experience as early as possible in the implementation process to improve feasibility of CAB for PrEP delivery and prepare for a wider scale-up. This may include reviewing and revising existing systems or adding additional resources.

It's paramount to engage members of the community you're intending to serve to co-design study materials and ensure they resonate within the community. Specific guidance on stakeholder engagement in research can be found in the [Good Participatory Practice Guidelines](#), with further guidance available in the online course [Unlocking the Potential of Implementation Science and Good Participatory Practices](#). Similar practices should be done with programmatic introduction and scale-up.

Involve community members as PrEP champions to encourage and support uptake- many tools exist for this, including MOSAIC's [HIV Prevention Ambassador toolkit](#), for adolescent girls and young women in east and southern Africa.

Provider training for PrEP needs to go beyond service delivery and include best practices for serving specific populations, such as key populations or adolescents, to ensure providers know how best to engage with users and that services are acceptable to users.

Implementers introducing CAB for PrEP into communities that have historically been excluded from PrEP provision need to ensure their study and/or programs include additional time and investment for education and sensitisation to the concept of biomedical HIV prevention.

It is important to follow the locally approved product label and guidelines. Several ongoing implementation science studies are assessing the appropriate testing algorithms for CAB for PrEP.

## EBONI/PILLAR Insight

their own testing strategies to support same-day initiation to comply with guidelines with some choosing to employ an initial rapid antigen/antibody test and then drawing blood for a nucleic acid antigen test (NAAT) to be run following the visit.

Study sites use oral lead-in according to their own standard of care, and ViiV is tracking whether oral lead-ins are a provider choice or a user choice when they are offered.

Eligibility for EBONI and PILLAR is based on both gender identity and sex assigned at birth, so that trans and cisgender women are included in the same study, as are trans and cisgender men. ViiV is tracking which modifications are being done to better serve these populations.

Providers across both studies have noted an immense level of gratitude amongst users, who note that they recognise how important having access to HIV prevention is, and that they want more of it.

## Opportunity/Recommendations

In settings where a confirmatory negative NAAT is required for CAB for PrEP initiation, implementers can consider conducting a rapid antigen/antibody test and draw blood for NAAT prior to the injection. If the rapid test is negative, they can initiate and then continue or discontinue the user from CAB for PrEP as appropriate based on the NAAT results.

In settings where an oral lead-in is optional and available, implementers should track who is using it and why to add to the body of evidence around use and reason for use of the oral lead-in.

To remain inclusive and respect the gender identity of study participants, implementers segregating studies by male and female should take into consideration the gender identity of individuals.

Recognising the importance of and demand for HIV prevention, implementers should aim to scale up CAB for PrEP as quickly as possible.

## PILLAR Study Summary

[\*A Study Evaluating Implementation Strategies for the Delivery of Cabotegravir in Low and High-Volume PrEP Sites in the United States\*](#) (PILLAR) is evaluating the process of integrating CAB for PrEP into the standard of care at existing PrEP delivery sites, comparing routine and dynamic implementation and looking at feasibility, acceptability, reach, fidelity, and utility. The study, which began in May 2022 and is planned to run through August 2024, has enrolled 220 cis and transgender men who have sex with men in California, Connecticut, Florida, Massachusetts, Missouri, New York, Pennsylvania, South Carolina, Texas, Washington, and Washington, D.C.

## EBONI Study Summary

[\*A Study Evaluating Implementation Strategies for the Delivery of Apretude for Black Cis- and Transgender Women in United States Ending the HIV Epidemic Territories\*](#) (EBONI) is evaluating the process of integrating CAB for PrEP into clinical settings where HIV negative Black women receive routine healthcare, including women's health clinics and general primary care, looking at appropriateness, adoption, feasibility, fidelity, and acceptability. The study, which began in October 2022 and is planned to run through May 2025, is currently enrolling 160 Black cis and transgender women in Florida, Georgia, Michigan, Nevada, New York, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and Washington, D.C.

For more information on EBONI or PILLAR, contact [nanlesta.a.pilgrim@viivhealthcare.com](mailto:nanlesta.a.pilgrim@viivhealthcare.com).

## Global PrEP Tracker

- [AVAC's Global PrEP Tracker](#) provides an accurate picture of worldwide PrEP initiations, by country and PrEP method, and is trusted and used by researchers, implementers, advocates, and other HIV stakeholders around the world.
- Data is collected quarterly via a survey, with all information aggregated at country level, and sources kept anonymous.
- To ensure it remains accurate and up to date, it's important that all implementers delivering PrEP submit their information via the survey, including for services delivered via CAB for PrEP and other product implementation studies.
- Please be in touch with [preptracker@avac.org](mailto:preptracker@avac.org) or [janki@avac.org](mailto:janki@avac.org) if you are able to provide data.

### Additional Resources:

- [EBONI on clinicaltrials.gov](#)
- [PILLAR on clinicaltrials.gov](#)
- [CAB for PrEP Integrated Study Tracker](#)
- [BioPIC Think Tank Notes](#)
- [WHO Guidelines on Long-Acting Injectable Cabotegravir for HIV Prevention, July 2022](#)
- [A Plan for accelerating access and introduction of injectable CAB for PrEP, June 2022](#)
- [An Advocates' Primer on Injectable Cabotegravir for PrEP: Trials, Approvals, Rollout and More, February 2022](#)
- [Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions-Implementation Strategies](#)
- [Consolidated Framework for Implementation Research](#)
- [HIV Prevention Ambassador Toolkit](#)
- [Global PrEP Tracker](#)
- [PrEPWatch Country Pages/Data](#)