

BioPIC

BIOMEDICAL
PREVENTION
IMPLEMENTATION
COLLABORATIVE

A Collaborative Approach to HIV Prevention Product Introduction

The HIV prevention product pipeline offers exciting potential to curb HIV incidence. But we know from previous products that **translating trial efficacy to population impact is challenging** without coordinated effort.

Oral PrEP Product Introduction Experience

Without advanced planning and coordination, the introduction and impact of an effective biomedical prevention tool was delayed in low- and middle-income countries (LMICs).



Key components of product introduction were **not well-timed**, causing delays in introduction and scale.



Due to a **complex, fragmented stakeholder landscape**, post-approval studies were not designed to answer critical questions.

Ideal Product Introduction Experience

To support rapid, successful introduction of HIV prevention products, BioPIC aims to forge a new path forward for future products.



Plan in parallel to clinical trials to shorten the time between regulatory approval and large-scale, phased implementation projects in LMICs.



Coordinate stakeholders in advance to ensure projects are well-designed to provide evidence to quickly build from small pilots to scale.

THE BIOPIC APPROACH:

Using CAB-LA as a focal product and example, BioPIC takes an innovative, collaborative approach to product introduction to ensure activities are well-designed, well-timed, and well-funded to meet the needs of global and country decision-makers.

Objectives

1. Using CAB-LA as an initial example, develop an adaptable HIV prevention product introduction framework.
2. In parallel to clinical trials, develop a shared introduction and access strategy for CAB-LA.

Members

BioPIC has engaged diverse stakeholders including civil society, donors, researchers, policy makers, normative agencies, and implementers.

100+ HIV Prevention Experts
80+ Organizations
20+ Countries

FOCAL PRODUCT: CABOTEGRAVIR LONG-ACTING INJECTABLE (CAB-LA)

BioPIC efforts have initially focused on planning for CAB-LA. The long-acting injectable product is currently being evaluated in two large-scale Phase III efficacy trials (HPTN 083 and HPTN 084) to explore its safety and efficacy for HIV prevention in men who have sex with men, transgender women, and cisgender women at risk of HIV infection. Due to the COVID-19 pandemic, both the HPTN 083 and 084 trials are currently pausing screening and enrollment, which may impact trial completion timelines. If the trials demonstrate that CAB-LA is safe and effective and if regulators approve it, CAB-LA is anticipated to be **one of the first long-acting prevention methods on the market**. This product would be an important, additional HIV prevention option with the potential to have a significant impact on lowering HIV incidence.

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A Shared Strategy for Cabotegravir Long-Acting Injectable

By reviewing decision-maker needs across the research-to-rollout continuum, BioPIC has developed a product introduction strategy for CAB-LA, which identifies activities critical to product introduction. To rapidly and successfully introduce CAB-LA, stakeholders must work to address the following needs.

SUMMARY OF PRIORITIES IDENTIFIED BY BIOPIC:



Ensure global and national bodies have sufficient evidence and safety assurance:

- Plan in advance to obtain safety data for pregnant and breastfeeding women
- Plan in advance and bolster systems to monitor resistance
- Conduct research for additional populations not included in clinical trials
- Support efficient regulatory review and development of normative guidance



Establish evidence to understand resource needs and the impact of CAB-LA:

- Model impact on multiple end-points and in different country contexts
- Build consensus and align methods on indicators, monitoring, and target-setting
- Conduct cost and payer analyses to inform budgeting
- Coordinate and align procurement



Enable programs to quickly move from small projects to scale:

- Conduct delivery channel analyses to identify operational opportunities and barriers prior to early implementation projects
- Support development of guidance and tools during early implementation
- Consolidate implementation questions in fewer, larger-scale projects



Identify methods to support high uptake and continued use:

- Engage and build community mechanisms to refine program design and implementation
- Conduct human-centered design research to understand barriers and enablers for providers, communities, and priority populations

NEXT STEPS FOR BIOPIC: CAB-LA INTRODUCTION AND FUTURE PRODUCTS

BioPIC aims to leverage the shared product introduction strategy for CAB-LA to forge a new path forward for HIV prevention and catalyze more rapid LMIC access to a growing portfolio of products.

BioPIC will continue to serve as a coordination structure, **tracking progress against the strategy** and disseminating learnings for CAB-LA and HIV prevention more broadly.

BioPIC will distill learnings from the CAB-LA strategy into an **adaptable product introduction framework** and define optimal coordination mechanisms for future products.

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