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**

CABOTEGRAVIR LONG-ACTING INJECTABLE (CAB-LA)

BioPIC efforts have initially focused on planning for CAB-LA. The long-acting injectable product was proven to be safe and efficacious in two large-scale Phase III trials (HPTN 083 and HPTN 084) in men who have sex with men, transgender women, and cisgender women at risk of HIV infection. In December of 2021 the US FDA approved CAB-LA for HIV prevention, making this product the first injectable PrEP. As a longer-acting highly efficacious agent, CAB-LA has the potential to have a significant impact on lowering HIV incidence, if the field learns the lessons from oral PrEP and invests in smart people-centered rollout.

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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

CABOTEGRAVIR LONG-ACTING INJECTABLE (CAB-LA)

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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