



# Developing and Introducing a Dual Prevention Pill

## Combined oral PrEP & oral contraceptive for HIV and pregnancy prevention

January 2025

### Background

A coalition of partners is developing a novel Dual Prevention Pill (DPP) for prevention of pregnancy and HIV acquisition in high-need countries. In East and Southern Africa — where the DPP is initially planned for introduction — 65 percent of new HIV infections are amongst women aged 15 and over, and 15 percent of women of reproductive age have an unmet need for contraception.<sup>1</sup> The results of the Evidence for Contraceptive Options in HIV Outcomes (ECHO) Trial, released in June 2019, found that HIV incidence rates were alarming among women using widely available forms of contraception who were receiving a comprehensive HIV prevention package.<sup>3</sup> The findings underscore the urgent need to optimize access to HIV prevention and contraception for African women.

Multipurpose prevention technologies (MPTs) have the potential to overcome adherence and uptake challenges seen with oral pre-exposure prophylaxis (PrEP) and stigma associated with HIV service delivery. The DPP, an MPT comprising oral PrEP and oral contraception, will offer significant advantages. It will be highly effective at preventing both HIV and pregnancy when used daily, feasible to deliver in various settings, with the potential to deliver public health impact by expanding choice and method mix. Adding an MPT to the available prevention toolkit could empower users with choices that better fit their needs and lives.

In the near-term, the DPP could increase the uptake of PrEP — decreasing new infections among women in high-burden settings — and reduce the number of unintended pregnancies. The DPP could also lay the groundwork for the development and rollout of other MPTs in the research pipeline, such as vaginal rings, injectables, implants and films.

### Project Goal

#### Successfully introduce a daily oral pill for HIV and pregnancy prevention.

AVAC, Clinton Health Access Initiative (CHAI), Viartis and the Population Council are implementing the DPP project. These efforts are supported by the Children's Investment Fund Foundation (CIFF), Gates Foundation, USAID, NIMH, and the HIV Prevention Trials Network (HPTN). The project is guided by the DPP [Market Preparation and Introduction Strategy](#).

### The Product

The DPP is a single, co-formulated, daily pill containing oral PrEP and combined oral contraception (COC). DPP packs will contain a total of 28 tablets — 21 combination PrEP/COC tablets and 7 PrEP-only tablets (corresponding to the placebo/iron pill days of a COC regimen, which will need to be taken to maintain protection against HIV during the last week of the month/cycle). The DPP will be in a blister pack, similar to a COC pack.



### Geographic Scope

Settings that demonstrate **need** (high HIV incidence and high unmet need for modern contraception), **potential demand** (current oral PrEP and contraceptive use) and **enabling policy and regulatory environments** will be prioritized for early DPP introduction. Early estimates indicate a potential market of 251,000-1.25 million women in 15 countries in sub-Saharan Africa.<sup>4</sup>



Prioritized Countries				
Indicator	Kenya	South Africa	Zambia	Zimbabwe
HIV Incidence (per 1,000 women 15+) <sup>5</sup>	0.54	4.86	2.54	1.66
New HIV Infections, (# women 15+) <sup>5</sup>	9,100	89,000	13,000	7,500
Unmet Need for Contraception (%) <sup>6</sup>	11	11	15	8
Adolescent Birth Rate (per 1,000 girls 15-19) <sup>6</sup>	44	71	135	87
Oral Contraceptive Use (% of method mix) <sup>7</sup>	12.6	10.5	14.4	56.5
Total PrEP Initiations (#) <sup>8</sup>	544,524	1,324,154	895,585	337,010

# Key Milestones for Dual Prevention Pill Development



## Product Development

**Single, co-formulated tablet** containing active pharmaceutical ingredients for oral PrEP and COC was successfully developed.

**Bioequivalence study** comparing the bioavailability of the co-formulated DPP tablet to oral PrEP and COC separately was successfully completed, with the DPP found to be bioequivalent to its separate components.

**DPP branding and packaging** was developed, with input from civil society.

**DPP dossier filed** with WHO pre-qualifications for regulatory approval, with national regulatory filings planned in 2025.



## End-User Research

**Human-centered design research** was conducted in Kenya, South Africa and Zimbabwe on perceptions, barriers, and motivators of end users, male partners and healthcare providers on the DPP to shape product development and demand creation approaches.

**Clinical cross-over acceptability studies** with an over-encapsulated DPP were conducted in South Africa and Zimbabwe to compare women's experiences (acceptability, adherence, preference) using a DPP to two separate oral PrEP and COC pills.

**HPTN 104 study** is planned in Eswatini, South Africa, Uganda and Zimbabwe to evaluate adherence to the DPP vs. a two-pill regimen.



## Market Preparation

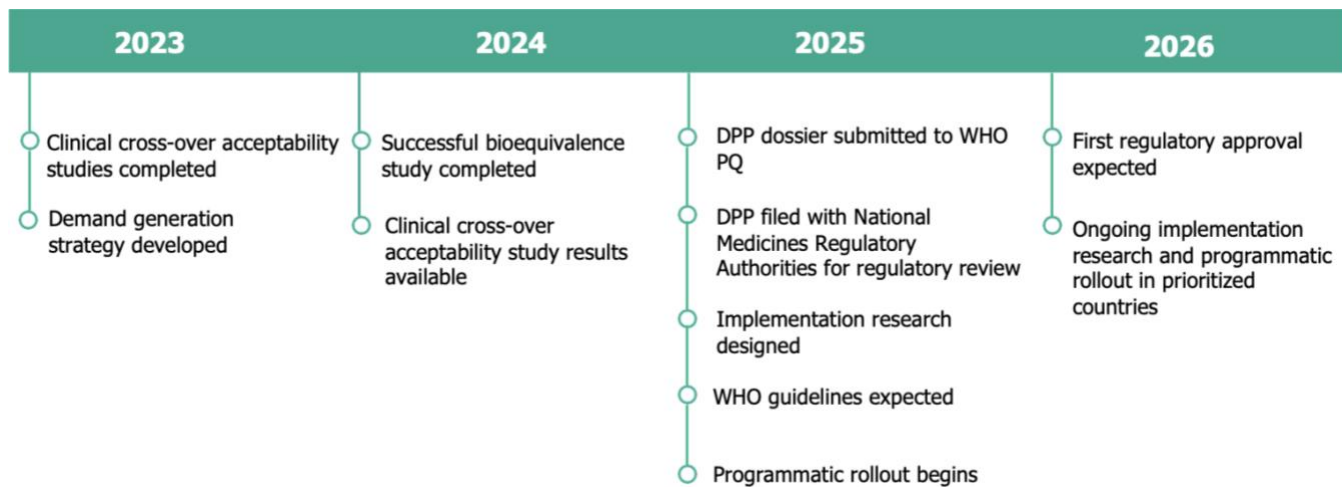
**Market Preparation and Introduction Strategy** was developed to guide rollout.

**Cost-effectiveness modeling** was conducted in Kenya, South Africa and Zimbabwe to inform country decision-making.

**Provider counseling recommendations** developed to support DPP service delivery.

**Private sector delivery opportunities** were analyzed to identify DPP channels, leveraging where COC is delivered.

**Engagement with policymakers, civil society and implementers** is underway to develop country introduction roadmaps and prepare for implementation.



For inquiries, updates and resources on the development of the DPP, please visit [prepwatch.org/dpp](http://prepwatch.org/dpp).

<sup>1</sup> UNFPA, State of the World Population Report 2024 and UNAIDS 2024 data.

<sup>2</sup> UNAIDS, The Youth Bulge and HIV, 2018.

<sup>3</sup> ECHO Trial Consortium, HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomised, multicentre, open-label trial. *Lancet* 2019;394(10195):303-313.

<sup>4</sup> Begg L, Brodsky R, Friedland B, et al Estimating the market size for a dual prevention pill: adding contraception to pre-exposure prophylaxis (PrEP) to increase uptake. *BMJ Sexual & Reproductive Health* 2021;47:166-172.

<sup>5</sup> UNAIDS 2024 data.

<sup>6</sup> UNFPA, State of the World Population Report 2024.

<sup>7</sup> FP2030 Data Hub.

<sup>8</sup> AVAC, Global PrEP Tracker, October 2024.

