

# OPTIONS

## *A value proposition for investment in a central platform for PrEP introduction and scale-up*

### WHY? | OPTIONS is a catalytic investment.

#### *The HIV prevention challenge*

Long-term investments in HIV prevention research and development are finally yielding results, with new technologies like oral PrEP in the market, the dapivirine vaginal ring under regulatory review, and long-acting injectable cabotegravir (CAB-LA) in late-efficacy trials. Product development, however, is only half the equation – these products must efficiently reach, and be used by, those most at-risk to contribute toward HIV epidemic control.

With all new products, introduction is just the beginning of a long and challenging path to impact, requiring sustained product access, uptake, and effective use – and this is true for oral PrEP. Oral PrEP was shown to be safe and effective in multiple populations in 2010-11 and was approved by the US FDA in 2012. In 2015, when OPTIONS began, oral PrEP had just been included in the World Health Organization (WHO) guidelines, but had not been approved by a national regulatory authority nor included in national HIV prevention guidelines in any sub-Saharan African country. Though numerous demonstration projects were ongoing, no country had established a clear path from research to national implementation at scale.

#### *A role for OPTIONS*

The OPTIONS Consortium represents a unique and effective way to bridge the gap between research, product introduction and scale-up. OPTIONS was designed to be an adaptable product delivery platform to support expedited access, uptake and sustained use of new ARV-based HIV prevention products, particularly among adolescent girls and young women (AGYW).

OPTIONS created this platform in close partnership with a broad range of stakeholders, including national governments, donors, implementers, communities and potential PrEP users who work together to catalyze action, identify and fill critical gaps, and share learnings to accelerate and expand access to new HIV prevention technologies.

## OPTIONS

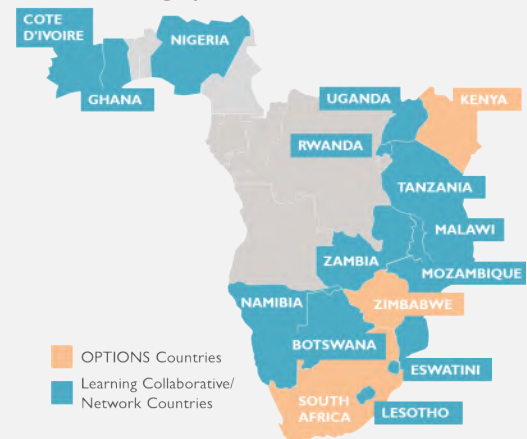
The OPTIONS (Optimizing Prevention Technology Introduction on Schedule) Consortium is one of five interlinked, five-year projects funded in 2015 by the U.S. Agency for International Development (USAID), in partnership with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), to expedite and sustain access to antiretroviral-based HIV prevention products.

OPTIONS includes nine partners:

- FHI 360
- AVAC
- Wits RHI
- LVCT Health
- Pangaia Zimbabwe AIDS Trust (PZAT)
- Avenir Health
- FSG
- London School of Hygiene and Tropical Medicine
- McCann Global Health

OPTIONS has worked with national ministries and their implementing partners in 16 countries.

#### OPTIONS Geographic Reach



## HOW? | OPTIONS plays a unique role in HIV prevention.

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OPTIONS plays a unique role in HIV prevention, leveraging five distinctive approaches:

- **OPTIONS is highly collaborative.** The core purpose of OPTIONS is to support and facilitate policymakers and implementers working on PrEP introduction, including donors, national governments, and implementing partners, to meet national and PEPFAR PrEP targets. This approach is central to how OPTIONS operates as a convener and translator for evidence across partners, projects, and geographies.
- **OPTIONS enables rapid learning to support PrEP introduction and scale-up.** While many national governments and their partners are working on PrEP introduction in-country, OPTIONS functions as a cross-country information “clearinghouse,” conducting rapid research, synthesizing evidence and translating findings into tools and resources, sharing lessons learned across implementation settings, helping national governments translate research to practice, developing new resources to fill gaps, and facilitating cross-country, cross-project learning to improve the quality and efficiency of PrEP policy and programming.
- **OPTIONS is responsive to the needs of national governments.** OPTIONS work is primarily guided by needs identified by national governments and, as such, directly informs and supports national oral PrEP rollout and scale-up. Through its in-depth work in Kenya, South Africa and Zimbabwe, OPTIONS collaborates closely with national ministries of health (MOH) and in-country technical working groups (TWGs) to identify areas where OPTIONS can fill gaps to move PrEP implementation forward. OPTIONS is also guided by needs identified by stakeholders from its extended network of countries, especially for work related to tool development and learning events that involve a broader range of national program representatives.
- **OPTIONS builds bridges.** The introduction of oral PrEP requires action from many components of a large and complex system, including global donors and normative bodies, national governments, product developers, health facility administrators and health care providers, implementing partners, advocates, communities, and the end users themselves. OPTIONS is one of the few projects that acts as a neutral, third-party bridge across these different parts of the system, ensuring that global and national policy is translated to implementers and that experiences with PrEP implementation and the voices of PrEP users inform policy, strategy, and resourcing decisions.
- **OPTIONS leverages diverse skills and assets.** The OPTIONS team comprises nine private and public-sector partners with diverse and complementary skillsets. At the core are three local partners in Kenya (LVCT Health), South Africa (Wits RHI), and Zimbabwe (PZAT) who have deep relationships with national ministries, meaningful engagement on HIV prevention TWGs, and direct experience delivering HIV prevention and oral PrEP. As a complement, OPTIONS also includes global partners with functional expertise in strategy (FSG), communications (McCann Global Health), modeling and costing (Avenir, London School of Hygiene and Tropical Medicine) and technical expertise in HIV prevention and advocacy (FHI 360 and AVAC). Nearly all partners bring expertise in programmatic research. This composition enables OPTIONS to leverage complementary assets, ensure alignment with in-country priorities, and take a comprehensive systems approach to PrEP rollout and scale-up.

“We didn’t have much time – we had about six months to get everything ready [to launch PrEP]. Having timely information, the tools, and the support from OPTIONS really helped. It made it all possible.”  
– NASCOP, Kenya



## WHAT? | OPTIONS is a platform to expedite HIV prevention product introduction and scale-up.

Over the life of the project, OPTIONS has become an effective platform for HIV prevention product introduction and scale-up, with an established network of core partners who collaborate efficiently, a broad extended network of PrEP policymakers and implementers across 16 African countries, a library of evidence-informed tools and resources, and a reputation as a transparent, collaborative, cross-project, cross-country facilitator. OPTIONS has played four major roles to accelerate and support PrEP introduction and scale-up.

**#1** | Established a **product introduction framework** and related set of tools to support PrEP policymakers and technical working groups to take a comprehensive systems approach to PrEP rollout.

*Example: The Plan 4 PrEP Toolkit in Kenya, Years 1-2*

The [OPTIONS Plan 4 PrEP Toolkit](#) is a set of six tools to guide PrEP rollout, developed based on experiences in the three OPTIONS countries. In Kenya, NASCOP and the PrEP TWG used the tools to plan for oral PrEP introduction, make investment decisions about where and how to roll out PrEP in a phased approach, track lessons learned from demonstration projects, prioritize areas for further implementation research, and provide an assessment tool for districts/counties to consider readiness and areas of investment for PrEP. The tools proved so useful to NASCOP that they repurposed them to guide the introduction of HIV self-testing in Kenya.

“The tools have helped us systematically plan for the implementation of PrEP. The Situation Analysis gave us a barometer of where we are and helped us consolidate across a lot of different things. It helped us finalize our PrEP framework.”  
– Learning Collaborative workshop participant, Zambia

**#2** | Catalyzed momentum and facilitated **multi-stakeholder, cross-partner action and learning** to support PrEP rollout at the national, regional, and global levels.

*Example: Support for the national PrEP TWG in Zimbabwe, Years 1-2*

OPTIONS, led by PZAT, played a critical role on Zimbabwe’s PrEP TWG in the earliest stages of PrEP introduction, catalyzing early action and serving as the TWG’s secretariat through initial rollout. OPTIONS supported TWG meetings and brought resources to accelerate planning, including analyses from the OPTIONS Plan 4 PrEP Toolkit as well as resources from other countries (e.g., draft guidelines and training for health care providers from South Africa). Without this support, PrEP may not have been introduced at scale so quickly or may not have been made immediately available to young women.

“OPTIONS has done well to provide technical advice and guidance to the Technical Working Group. They have also been a good advocate to mobilize PrEP for certain populations. OPTIONS was at the forefront of PrEP for young women, and they influenced the policy.”  
– PrEP TWG member, Zimbabwe

*Example: Regional PrEP Learning Collaboratives/Network, Years 3-4*

In a series of learning events held in Malawi, South Africa, and Zimbabwe, OPTIONS facilitated learning meetings for groups of stakeholders across countries in the midst of PrEP introduction and scale-up to share lessons learned and discuss common challenges. Demand for and attendance at the sessions have grown over the series, with participation from 16 African countries, as well as donors and normative bodies, such as USAID, the

“The meeting really helped us, because we learned from what others have done and we don’t need to repeat the same mistakes that others made. It lifted our confidence, which facilitated fast-tracking the [PrEP introduction] process.”  
– Learning Collaborative workshop participant, Tanzania



Office of the U.S. Global AIDS Coordinator (OGAC), and the WHO. Evaluations of the sessions demonstrate a high value to participants, who gain insights and tangible tools and resources. The latest [learning workshop in Malawi](#) in November 2019 was attended by 129 participants and was rated 4.59 out of 5 in terms of usefulness for PrEP implementation by participants.

“OPTIONS has created an amazing platform for stakeholders to get connected and share information”  
– Team member, CHARISMA

*Example: MPii Global Extended Network, Years 1-4*

OPTIONS assumed and sustained a lead role in convening global stakeholders engaged in PrEP rollout to share regular updates. The 30-40 regular call participants include representatives from research projects, product developers, implementers, donors and normative bodies.

**#3** | Tracked emerging challenges with PrEP scale-up and generated, synthesized and disseminated relevant [evidence-informed, open-access tools and resources](#) to unlock further progress.

*Example: PrEP Communications Accelerator, Year 3*

The [PrEP Communications Accelerator](#) is a digital guide to developing a PrEP communications strategy targeted to key audiences (e.g., AGYW, FSW). The resource was developed in close collaboration with in-country partners and was informed by primary market research, stakeholder interviews, and in-country testing. Use of the Accelerator in Zimbabwe in Year 4 has yielded tremendous results – a communications campaign developed with the Accelerator and launched in Chitungwiza, Zimbabwe, has resulted in a 47% increase in PrEP uptake among AGYW and a 113% increase in overall PrEP uptake (including adolescent boys and young men) in the three months following the launch of the campaign. As a result of this impact, the Ministry of Health and Child Care in Zimbabwe recently integrated campaign components (e.g., posters, a flyer, and the video) into a national PrEP campaign.

“Without the Accelerator, it would have been like dancing in the dark because there would have been no structure to work with. We could have missed some critical stages and set ourselves up for failure. We’re discussing the PrEP campaign with the Ministry, who asked us about a similar campaign on a national level.”  
– PZAT, Zimbabwe

*Example: OPTIONS HIV Prevention Ambassador Training Package, Year 4*

The [OPTIONS Ambassador Training Package](#) provides a guide for building the knowledge and skills of AGYW to meaningfully support oral PrEP rollout in their communities. The package includes a toolkit of resources for AGYW to use in their discussions with peers and in their communities. The toolkit is available in English, Kiswahili, and Shona. The package itself was developed in response to a significant gap identified across the three OPTIONS countries around training for youth to effectively talk about oral PrEP. The resource is evidence-informed and was co-designed with AGYW PrEP users. While the tool is new, there is already evidence of its impact. Oral PrEP uptake among AGYW increased by 26% after the training was field tested in one Zimbabwe district. In addition, significant demand has been shown for the training, with over 150 ambassadors trained to date, engaging more than 10 projects across the three OPTIONS countries. The training package is referenced in PEPFAR COP 2020 draft guidance, with a focus on how it can help PrEP implementers address gender-based violence.

"When we walk in our communities, they ask you for information but deep down inside you know you know nothing. Now [after the Ambassador training], I feel confident knowing I actually have content."  
– Peer Educator, Kenya



*Example: PrEP-it, Years 3-4*

[PrEP-it](#) (PrEP Implementation, Monitoring and Evaluation Tool) was developed in direct response to demand from national policymakers seeking support to set national and PEPFAR PrEP targets, track the continuum of PrEP delivery, and estimate PrEP program costs and impact. The tool was developed and tested in consultation with policymakers across countries to ensure relevance and ease of use, including pilot sessions at OPTIONS learning collaborative meetings. While the tool was just released in September 2019, two countries – Eswatini and Malawi – have already used it to set PrEP targets, the Zimbabwe MOHCC is planning to use the tool to set targets for the 2021 – 2025 period, and there is significant interest from national, county and project stakeholders in other tool components. PrEP-it is referenced in PEPFAR COP 2020 draft guidance.

“This is a very useful tool. We will use it for planning, estimating capacity, and monitoring our program.”  
– County HIV lead,  
Kenya

**#4** | Shaped the market in priority early adopter countries for [new PrEP products in the pipeline](#), specifically for the dapivirine vaginal ring.

*Example: Dapivirine Ring Seven Country Stakeholder Analysis – Year 3*

OPTIONS has established a close partnership with the International Partnership for Microbicides (IPM) to support early planning for access in the event of a positive regulatory opinion on the dapivirine vaginal ring. As part of a larger suite of products, OPTIONS conducted interviews with key stakeholders and analyzed perspectives on the ring across seven priority countries (Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zimbabwe). The purpose of the work was twofold: (1) to build awareness for the ring with national stakeholders, and (2) to ensure the perspectives and questions of national policymakers heavily informed early introduction planning – a significant gap in the introduction of oral PrEP.

“The work is just really well done, and the speed with which it was done was impressive. It’s been very helpful – we will use it to inform our strategy and market introduction work. We have an excellent collaboration [with OPTIONS], with a great openness to sharing information.” – IPM

“This work is important and informative.” – WHO

## LOOKING AHEAD | An ongoing need for a central PrEP platform.

While tremendous strides have been made on oral PrEP introduction over the past four years, there is much left to be done to ensure PrEP is an effective tool for reaching HIV epidemic control and to support further expansion to new countries and with new formulations. Several critical areas require continued support to maintain momentum and progress on PrEP, especially in light of a simultaneous push on universal test and treat:



- Completing the **“unfinished agenda” on PrEP** to support countries to transition from product introduction to product scale-up and to meet PEPFAR targets. This includes exploration of emerging questions that will need to be addressed in scale-up, including strengthening the linkage of those who test HIV negative to HIV prevention options, integrating PrEP into sexual and reproductive health services, building community awareness and acceptance of PrEP, expanding PrEP for pregnant and breastfeeding women, and delineating differentiated costs of PrEP scale-up. It also includes continued support for countries using OPTIONS tools and resources to inform their PrEP implementation (e.g., for PrEP-it, OPTIONS HIV Prevention Ambassador Training, and the PrEP Communications Accelerator) and support for countries newly introducing PrEP.
- Continuing to create opportunities for **cross-project and cross-country learning** as countries move into oral PrEP scale-up. Governments and implementers are experiencing common challenges and highlight how much they can learn from one another and from the developers of PrEP implementation tools. These opportunities for improvement and greater efficiency will help countries as they work to meet larger PEPFAR PrEP targets in coming years.
- Leveraging the oral PrEP experience to **accelerate introduction of new HIV prevention products**, such as the dapivirine ring or CAB-LA. There is an opportunity to leverage the significant learnings, strong networks, and catalogue of tools and resources developed for oral PrEP to accelerate the introduction of new HIV prevention products and support countries to develop effective approaches for an **HIV prevention method mix**.

“I would like to express my gratitude for the opportunity to attend the very rich and empowering PrEP Learning Network Regional Workshop in Malawi. I am convinced that what I learned (e.g., good practices, challenges and possible solutions) will be very useful to boost the ongoing PrEP process in Ivory Coast. I really benefited from learning from PrEP scale-up experiences in other countries.”  
 – Learning Network workshop participant, Cote d’Ivoire

The OPTIONS experience demonstrates the value of investment in a central platform to support product introduction and scale-up. For PrEP, OPTIONS technical support proved to be an important follow-on to investments in product development and a valuable complement to investments in program delivery. OPTIONS helped catalyze action for initial oral PrEP rollout, ensured rapid research translation and learning, and filled gaps critical for oral PrEP scale-up. A similar platform will be needed in the years ahead, as PrEP expansion continues and includes new countries, new populations, and new formulations.

