The CATALYST Study
Frequently Asked Questions

CATALYST FAQ
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What is the CATALYST study?

Catalyzing Access to New Prevention Products to Stop HIV (CATALYST) is the flagship HIV prevention product introduction study of Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC). This study will characterize and assess the implementation of providing greater choice in pre-exposure prophylaxis (PrEP) products for women seeking to protect themselves from acquiring HIV. By introducing multiple new PrEP products at select U.S. President's Plan for AIDS Relief (PEPFAR) delivery sites, the CATALYST study will generate usable knowledge for implementing informed PrEP choice at scale.

Currently, PEPFAR delivery sites in Africa offer only one type of PrEP in the form of a daily oral pill. As part of the CATALYST study, participating sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe will offer two new forms of PrEP in addition to the daily pill: injectable cabotegravir for PrEP (also called CAB PrEP) and the dapivirine vaginal ring (PrEP ring). Implementing an informed PrEP choice approach will allow participating women, with support from their providers, to choose the PrEP products that are most effective for them based on their unique needs and preferences. Over the next three years, the study will produce critical evidence to help transform the HIV prevention landscape and inform future scale-up and sustainability of HIV prevention options.

How is the project funded?

The CATALYST study is funded by PEPFAR through the U.S. Agency for International Development (USAID) as part of MOSAIC. ViiV Healthcare is donating cabotegravir for the study.

Why is the study being done?

Despite the expansion of HIV care and treatment, HIV remains a pressing health challenge in many countries in eastern and southern Africa, particularly for specific groups such as adolescent girls and young women (AGYW), pregnant and breastfeeding populations, female sex workers (FSW), and transgender populations.

In recent years, oral PrEP introduced individuals to a powerful tool for HIV prevention. However, barriers to daily adherence required for the pill's efficacy diminish the product's potential for epidemic impact. Newer forms of PrEP with more discreet and less frequent delivery methods have recently been proven safe and effective at preventing HIV in clinical trials, including PrEP ring and CAB PrEP. The best prevention product is the one an individual can use effectively when needed. Providing women choice among PrEP products may

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increase access and effective use of PrEP, but more understanding of real-world experience with these products is needed.

The CATALYST study will provide relevant information on user preferences and PrEP use in the context of informed PrEP choice. These study results will guide HIV prevention policy and programming in scaling up the introduction of new PrEP products.

What products are part of the study?

The CATALYST study will assess informed PrEP choice by offering three PrEP products:

Oral PrEP: Oral PrEP containing tenofovir disoproxil fumarate is delivered by ingestion of a daily pill. While highly effective when used correctly, adhering to the daily dose schedule is often challenging for users in real-world contexts.

PrEP ring: Dapivirine vaginal ring (PrEP ring) is a flexible silicone ring inserted into the vagina that continually releases the antiretroviral drug dapivirine over one month. This discreet, self-inserted PrEP delivery method provides local protection against HIV acquisition during receptive vaginal sex.

CAB PrEP: Injectable long-acting cabotegravir for PrEP (CAB PrEP), is delivered as an intramuscular injection in the buttocks. After a one month loading dose, users receive repeating injections every two months, in addition to regular HIV testing.

The study will be implemented in two stages. Stage I will offer oral PrEP and PrEP ring, which are currently approved for use in the study countries. In each country, Stage II will add CAB PrEP once it has been approved by the national regulatory authority and donated product is available on site.

What organizations are involved?

The CATALYST study is an effort under MOSAIC, a global cooperative agreement led by FHI 360 with core partners Wits Reproductive Health and HIV Institute, Pangaea Zimbabwe AIDS Trust, LCVT Health, Jhpiego, and AVAC.

Within each CATALYST country, a local partner will implement the study in collaboration with the Ministry of Health. Technical partners from Avenir Health, the University of Pittsburgh, and RTI International will provide specialized support in key research functions like laboratory testing, data analysis, and qualitative research.

What perspectives are guiding the study design and implementation?

MOSAIC engaged an extensive network of global and country-based stakeholders to design the study, including policy makers, advocates, program implementers, civil society representatives, and members of communities disproportionately affected by HIV. Their perspectives are helping ensure the study is locally relevant and poised to address pressing policy and program needs.

This network of stakeholders will continue to make substantive contributions during study implementation and results dissemination. For example, PrEP users and health providers will guide potential enhancements

to informed PrEP choice implementation as the study progresses. In addition, interim data analyses will be conducted every 6-9 months with results shared with ministries of health and other country stakeholders to inform national PrEP implementation plans. The NextGen Squad—MOSAIC's youth advisory council—provided input on the CATALYST study during protocol development and will continue to be meaningfully engaged at all phases of the study to ensure the voices of adolescent girls and young women guide PrEP choice policy and practice.

Where is the study taking place?

The CATALYST study will be implemented in 28 PEPFAR-supported service delivery sites across five countries: Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. These countries were selected based on high HIV incidence among women and the current or anticipated addition of PrEP ring and CAB PrEP to existing oral PrEP delivery programs.

Each study site has existing oral PrEP service delivery operations and will begin offering informed PrEP choice with multiple PrEP products during the CATALYST study.

What is the study design?

The CATALYST study includes two main components, in addition to several smaller, nested studies. The collective learnings generated from these studies will provide a breadth of relevant information to optimize HIV prevention programs and policy.

Component I:
In a prospective cohort study, a group of HIV negative women will be followed over time to learn about their preferences, choices, and effective use of the PrEP products offered at CATALYST service delivery sites.

Component II:
A process evaluation will document the implementation of informed PrEP choice, and improvements made, during the life of the CATALYST study and inform a core implementation package for scale-up. This study component involves periodically gathering service statistics, collecting cost data, and conducting qualitative interviews about the acceptability and feasibility of implementing informed PrEP choice.

What are the study demographics?

The participants for the cohort study within CATALYST are HIV-negative women* attending PEPFAR-supported facilities who are interested in learning about HIV prevention options, including the following subgroups:

- Adolescent girls and young women (AGYW) ages 15–24 years old*
- Female sex workers (FSWs) ages ≥18 years
- Individuals assigned female at birth of any gender identity, ages ≥15 years
- Individuals assigned male at birth who identify as women, ages ≥15 years
- Pregnant and breastfeeding populations (PBFP), ages ≥15 year

*For this study, the term "women" is inclusive of individuals assigned female at birth of any gender identity or individuals assigned male at birth who identify as women.

*For participants ages 15–17 years, potential participants under the age of 18 may be excluded from study participation based on each country's individual guidelines and legal age of consent.

What will happen to the participants in the CATALYST study?

Study participants will be counseled on ways to prevent HIV, including condom use, offered a choice of PrEP products, and be fully informed of benefits and potential drawbacks of each method. Participants can decline use of any PrEP methods. Individuals who elect to use PrEP will be followed over the course of the study for data collection. Participants will be allowed to discontinue PrEP or switch PrEP methods at any time during the study for any reason. Participants can decline any study procedure or withdraw from the study at any time.

Any participant who acquires HIV during the study will be provided with post-test HIV counseling and facilitated referral to HIV treatment, including prevention of vertical transmission for pregnant and breastfeeding populations.

Study participants may benefit from the study by gaining access to certain PrEP products, including PrEP ring and CAB PrEP, which might not be available outside of the study context.

Where can I learn more about the CATALYST Study?

More information on the CATALYST study can be found on PrEPWatch, the one-stop online clearinghouse for resources and information on PrEP delivery.

Additional inquiries should be directed to FHI 360 Media Contacts for the CATALYST study:

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Any inquiries about ViiV Healthcare's products, product approval, regulatory information, and product availability should be directed to ViiV's media team:

- **Rachel Jaikaran:** Rachel.s.jaikaran@viivhealthcare.com

Any inquiries about the International Partnership for Microbicides' dapivirine vaginal ring should be directed to the Population Council's media team:

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