

Global Mapping of PrEP Ring Implementation Research and Programmatic Pilots

NOVEMBER 2023



MOSAIC Project Overview

- 5-year global project funded by PEPFAR through USAID (2021–2026)
- Focuses on introduction of and access to new biomedical prevention products to prevent HIV for women in sub-Saharan Africa
- Works across multiple countries — Botswana, Eswatini, Lesotho, Kenya, Namibia, Nigeria, South Africa, Uganda, Zambia, and Zimbabwe
- Supports a multi-product market with informed choice for HIV prevention as new products enter the market
- Collaborates closely with ministries of health, missions, implementing partners, civil society, end users, providers, other local and global stakeholders, and product developers

VALUES

Country-led

Women-focused
with emphasis
on AGYW

Informed choice

Equitable co-
leadership

Intentionality

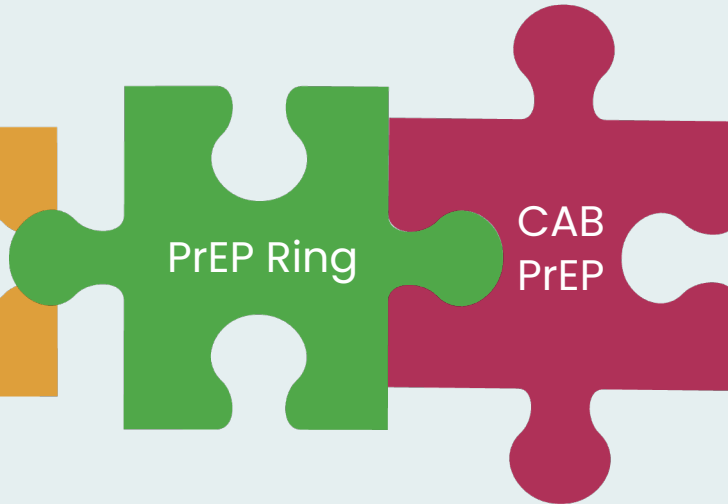
MOSAIC's goal is to accelerate access to new products

MOSAIC works to accelerate and expand introduction of new HIV prevention products, including those in and near to market, and to lay the groundwork for introduction of products in the research pipeline.

IN MARKET



NEAR-TO-MARKET



PIPELINE PRODUCTS



...toward a multi-method market

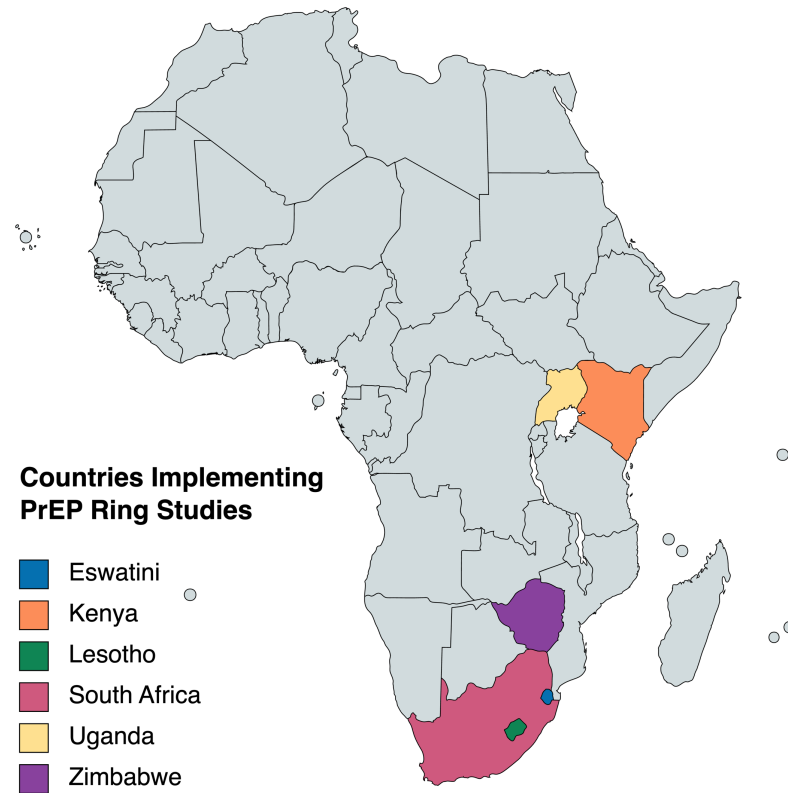
Mapping of PrEP ring introduction research and programmatic pilots

- With the upcoming availability of the dapivirine ring (PrEP ring or PrEP ring) and long-acting injectable cabotegravir (CAB PrEP), there remain some questions about how to introduce these new HIV prevention methods in the market.
- Several introduction studies across the globe are looking at real world introduction of the new prevention methods in order to plan for rollout of these new products.
- Our aim for the mapping of the PrEP ring implementation research and programmatic pilots is to understand which research questions will or will not be addressed by the current slate of ongoing or planned introduction studies as well as provide a timeline of when the research findings will be available.
- This analysis provides an overview of the 13 introduction studies that include the PrEP ring as one of the PrEP products under investigation alongside oral PrEP and/or CAB PrEP. All of the PrEP ring studies are conducted in Sub-Saharan Africa and focus primarily on adolescent girls and young women (AGYW) as well as female sex workers (FSW) and women engaged in transactional sex.

Overview of PrEP ring introduction studies

Countries implementing PrEP ring introduction studies

There are 13 studies have been recently completed or underway that focus on the introduction of the PrEP ring, all in the Sub-Sahara Africa region.*



Projects including the PrEP ring	Countries implemented
CATALYST	Kenya, Lesotho, South Africa, Uganda and Zimbabwe
Project PrEP	South Africa
DREAMS PrEP Choice	South Africa
Let's Talk & LAPIS	South Africa
FastPrEP & PrEPared	South Africa
DO PrEP	South Africa
My Journey	South Africa
National SWP	South Africa
Imagine	South Africa
MSF PrEP Ring Study	Eswatini
MOSAIC / GOKE PrEP Ring Study	Eswatini
CeSHHAR PrEP Study	Zimbabwe
Going the Last Mile	Zimbabwe

* Note: UCSF, Uganda IDRC, and KEMRI will begin the SEARCH / SEARCH Sapphire B sub-study in Uganda and Kenya; however this study was not included in the mapping due to early stages of development.

Many of the PrEP ring introduction study sites are across South Africa

In South Africa, there are 9 introduction studies for the PrEP ring underway. They are spread across all nine provinces and 18 districts representing a mix of urban, peri urban and rural settings.

Johannesburg Health District, Gauteng

Wits RHI, DREAMS PrEP Choice
Wits RHI, CATALYST – Key Populations Sites (FSWs and TNBP)

Tshwane, Gauteng

Wits RHI, Project PrEP
NACOSA, Global Fund*

Lejweleputswa (FS)

Wits RHI, CATALYST

Thabo Mofutsunyana (FS)

Beyond Zero, Global Fund*

Frances Baard (NC)

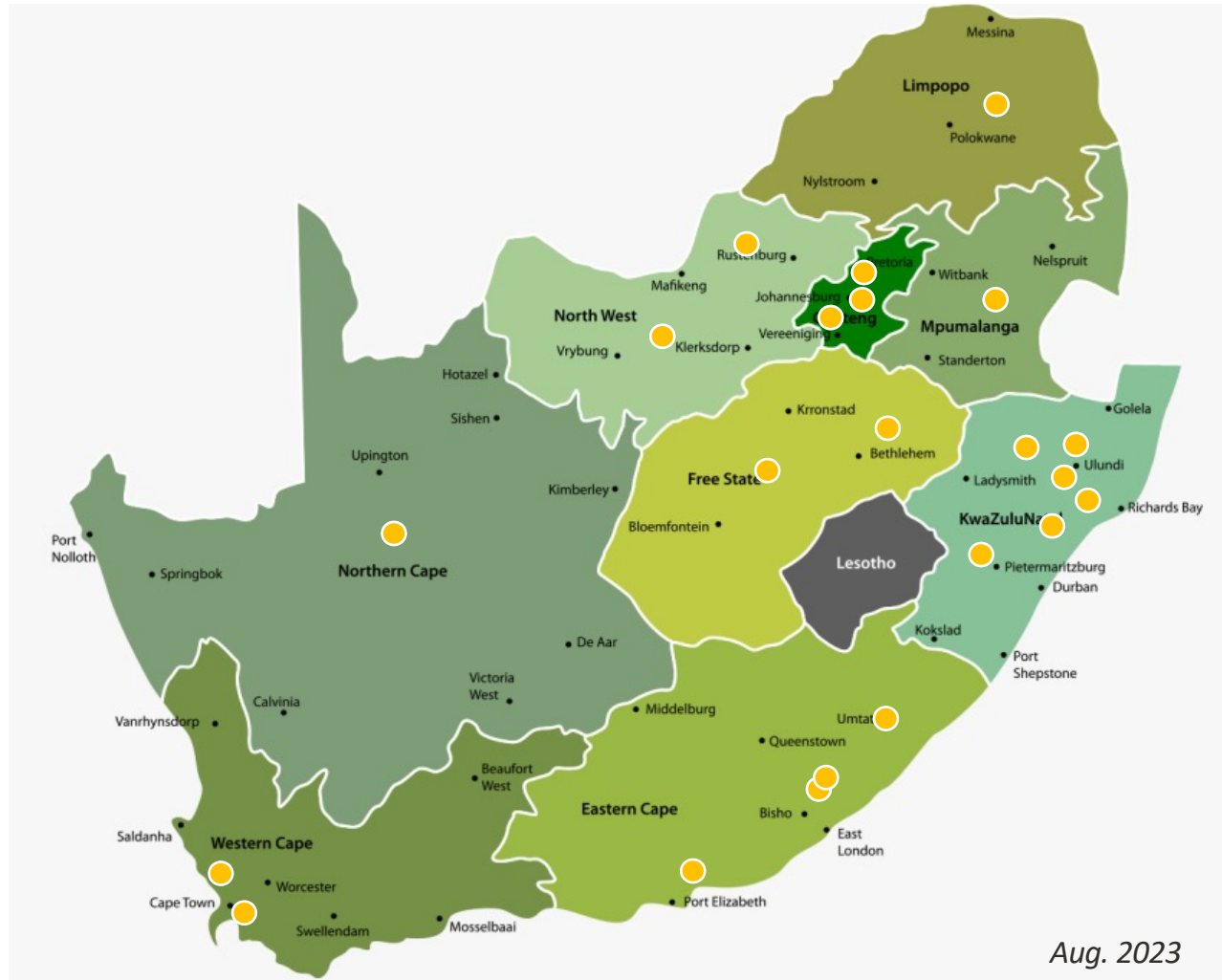
NACOSA, Global Fund*

Klipfontein Mitchell’s Plain, Cape Town (WC)

DTHF, FastPrEP
NACOSA, Global Fund*

Gqeberha

Wits RHI, Project PrEP



Aug. 2023

King Cetshwayo & Zululand (KZN); Ehlanzeni and Gert Sibande (MP), Sekhukhune (LP)

AFSA & Beyond Zero, Global Fund*

Newcastle, KZN and Moretele, Northwest

SA MRC & NACOSA, Imagine

Hlabisa, uMkhanyakude (KZN)

AHRI, Let’s Talk & LAPIS

Msunduzi, Umgungundlovu (KZN)

HSRC & MGH, DO PrEP

eThekweni (KZN)

Wits RHI, Project PrEP

Nelson Mandela & Oliver Tambo (EC)

Beyond Zero, Global Fund*

Nelson Mandela, King Dalindyebo (EC)

Wits RHI, Project PrEP

Mthatha (EC)

Wits RHI, Project PrEP

*Global Fund-funded program My Journey or National SWP

Projects included in this mapping (1/2)

Project Name	Reference name	Project goals
CATALYST	Catalyzing Access to New Prevention Products to Stop HIV (CATALYST)	To describe the implementation of an enhanced service delivery package providing choice of PrEP products among women at PEPFAR/USAID delivery sites in Kenya, Lesotho, South Africa , Uganda, and Zimbabwe.
Project PrEP	Project PrEP: Integrating PrEP into Comprehensive Services for AGYW	To improve the understanding of uptake and continuation of PrEP among AGYW and at-risk groups in real world settings and inform delivery models for service integration by expanding PrEP choice through the introduction and integration of new biomedical prevention options into comprehensive SRH services
DREAMS PrEP Choice	DREAMS PrEP Choice Study	To examine the acceptability and feasibility of providing additional PrEP options (PrEP ring) to AGYW accessing services through DREAMS community-based delivery
Thetha Nami ngithethe nawe (Let's Talk) & LAPIS	Social mobilization into integrated sexual and reproductive health (SRH)/HIV care (Let's talk) Long-Acting PrEP Integrated with SRH (LAPIS)	<ol style="list-style-type: none"> 1) To evaluate effect of peer-led youth mobilization in community-based integrated SRH/HIV service on sexually transmissible HIV and uptake of risk-informed HIV 2) To evaluate effect of choice of long-acting antiretroviral-based PrEP within community-based nurse-led SRH for youth on uptake and retention of effective HIV prevention amongst adolescents and youth in rural KwaZulu-Natal (KZN), South Africa.
FastPrEP & PrEPared to Choose substudy	FastPrEP & PrEPared substudy	To distinguish PrEP persistence patterns across different PrEP modalities (vaginal, oral, and injectable) and identify successful implementation strategies that will aid the provision of PrEP choice to adolescents and young people in South Africa from multiple delivery platforms
DO PrEP	Delivery Optimization for Pre-Exposure Prophylaxis (DO PrEP) Study	To test an end-to-end decentralized delivery service for PrEP to safely increase PrEP access and use among priority populations in a high-HIV prevalence setting.
My Journey	Global Fund KP Programmes (AYP for 3 Principle Recipients)	To provide an alternative method for HIV prevention among AGYW, aligned to national guidelines; raise awareness and sensitize stakeholders on new prevention methods; support the National Department of Health (NDOH) to collect data for early learning; and create demand for uptake of PrEP ring by key populations (KPs)

Projects included in this mapping (2/2)

Project Name	Reference name	Project goals
National Sex Work Plan (SWP)	National Sex Work Plan (SWP)	To provide an alternative method for HIV prevention amongst female sex workers; to raise awareness and sensitize stakeholders on new prevention methods; and to create demand for uptake by key populations
Imagine	Imagine Social Outcomes Based Contract	To improve HIV and sexually transmitted infection (STI) health outcomes among young women; to improve pregnancy health outcomes among young women.
CeSHHAR PrEP Study	Long-acting cabotegravir (CAB LA) for HIV prevention among female, male and transgender sex workers in Harare and Mutare, Zimbabwe: a values and preferences study	The aim of the study is to explore values and preferences for long-acting PrEP choices and delivery options among female, male and transgender sex workers in Zimbabwe.
Going the Last Mile	Going the Last Mile for HIV Epidemic Control: Feasibility and Acceptability of the DPV ring among AGYW	To measure proportion of AGYW accept and effectively use the PrEP ring compared to oral PrEP.
MSF PrEP Ring Study	A qualitative exploration of women's choices and experiences of using oral and vaginal HIV pre-exposure prophylaxis in Eswatini.	<p>The overall objective of this study was to explore the perceptions of women aged 18 and above who were eligible for PrEP towards the vaginal PrEP ring and to elicit the factors which influenced their choices between oral PrEP, the PrEP ring or no PrEP use. The specific objectives were:</p> <ol style="list-style-type: none"> 1) To understand the experiences of women newly initiated on the PrEP ring, including facilitators and barriers to PrEP initiation, adherence, and retention in care. 2) To explore the decision-making processes underlying choices of women who are eligible for PrEP. 3) To explore anticipated barriers and facilitating factors associated with injectable PrEP combined with contraception. 4) To understand how the different PrEP options influence partner disclosure patterns and conversations about HIV prevention among PrEP users and their partners.
MOSAIC / GOKE PrEP Ring Study	Increasing PrEP options for women in Eswatini: A prospective mixed method study on the introduction of the PrEP vaginal ring.	The overall goal of the study is to characterize and assess the feasibility, acceptability, uptake, patterns of use, and clinical outcomes of an enhanced service delivery package providing fully informed choice of oral PrEP and the PrEP ring among women, especially adolescent girls and young women, in Eswatini.

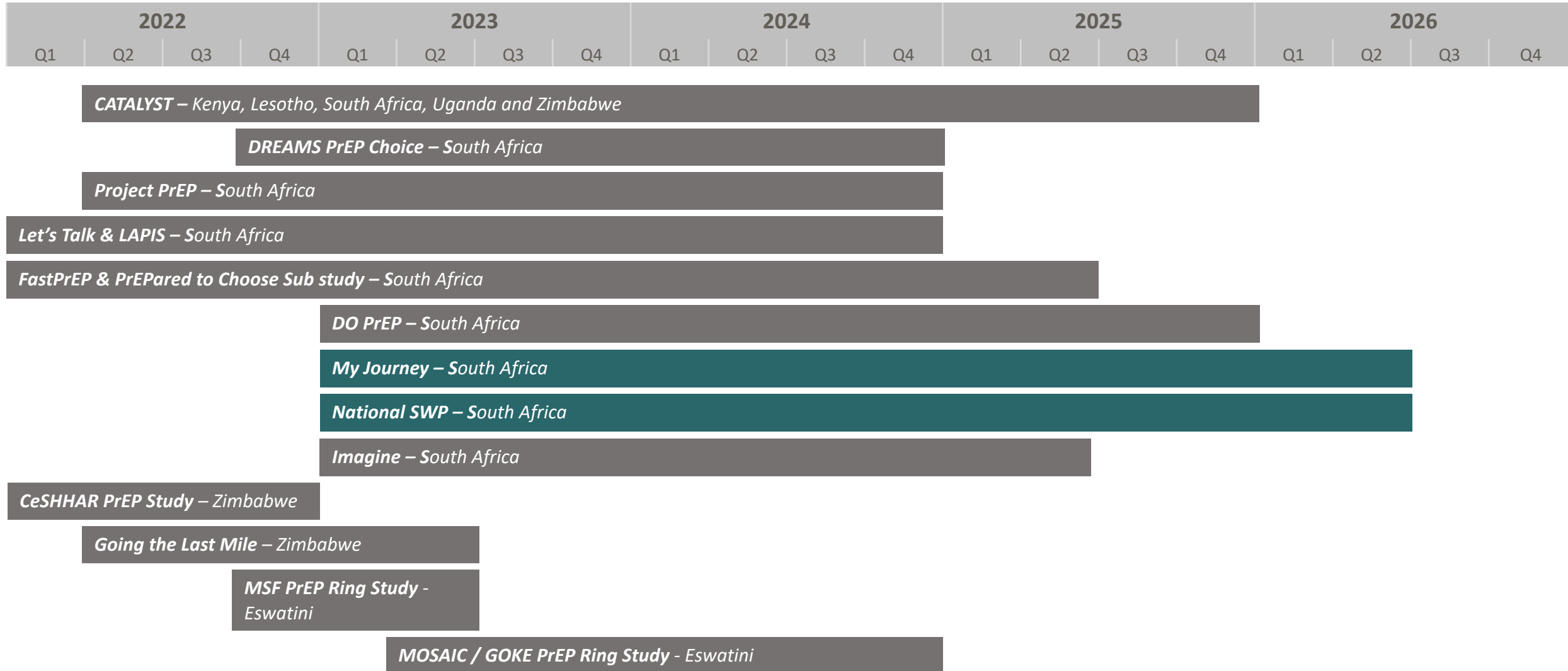
Project background information (1/2)

Project Name	Countries	Project design	Lead Org.	Donor	PrEP method	Target population for monitoring and evaluation (M&E)
CATALYST	Kenya, Lesotho, South Africa, Uganda and Zimbabwe	Introduction research	FHI 360, Wits RHI, Jhpiego, LVCT Health, and PZAT	USAID	Oral PrEP, PrEP ring and CAB PrEP	End users: AGYW (years 18+ years), FSWs, women engaged in transactional sex, transgender and nonbinary people (TNBP), pregnant and breastfeeding people (PBFP) Key influencers: Policymakers, health care providers, community health service providers, community leaders, community members, CSOs, key population-led organizations, parents, partners, and caregivers
Project PrEP	South Africa	Introduction research	Wits RHI	Unitaid	Oral PrEP, PrEP ring, and CAB PrEP	End users: Female, male, and transgender people who are 15 years and older, with a focus on AGYW Key influencers: (included in implementation activities and evaluation): health care providers, community members, and community-based organizations
DREAMS PrEP Choice	South Africa	Introduction research	Wits RHI	USAID	Oral PrEP and PrEP ring	End users: Sexually active women of reproductive age 18+ years accessing PrEP or SRH at a community-based site Key influencers: Health care providers who provide SRH and PrEP at DREAMS sites; key informants (NDOH, Provincial and District Prevention and youth TWG representatives) and community gate keepers
Let's Talk / LAPIS	South Africa	Introduction research	AHRI	BMGF	Oral PrEP, PrEP ring and CAB PrEP (also will include PEP)	End users: Adolescents and youth ages 15–30 years in a rural community and including key populations
FastPrEP / PrEPared to Choose sub-study	South Africa	Introduction research	DTHF	BMGF	Oral PrEP, PrEP ring and CAB PrEP	End users: AGYW; young men who have sex with men (MSM); TNBP, PBFP, male partners of AGYW Key influencers (included in implementation activities and evaluation): health care providers, facility managers, provincial and city health representatives
DO PrEP	South Africa	Introduction research	MGH/HSRC	BMGF	Oral PrEP, PrEP ring and CAB PrEP	End users: Priority populations (adolescents and young people, including sexual minority men, ages 16–30 years)
My Journey	South Africa	Program pilot	AFSA, Beyond Zero, NACOSA	GFATM	Oral PrEP and PrEP ring	End users: AGYW ages 18–24 years who are unable or unwilling to take oral PrEP
National SWP	South Africa	Program pilot	AFSA	GFATM	Oral PrEP and PrEP ring	End users: Sex workers assigned female at birth who are 18+ years and unable or unwilling to take oral PrEP

Project background information (2/2)

Project Name	Countries	Study design	Lead Org.	Donor	PrEP method	Target population for monitoring and evaluation (M&E)
Imagine	South Africa	Introduction research	SA MRC & NACOSA	GoSA, Aids Fdn SA	Oral PrEP, PrEP ring and CAB PrEP	End users: AGYW ages 15–24 years; high school learners
CeSHHAR PrEP Study	Zimbabwe	Introduction research	CeSHHAR Zimbabwe	World Health Organization	PrEP ring and CAB PrEP	End users: FSW, women who engage in transaction sex, and transgender sex workers Key influencers: HCWs and community members
Going the Last Mile	Zimbabwe	Introduction research	Populations Services International (PSI) and Population Solutions for Health; partnering with FACT and Matebeleland AIDS Council	USAID; supplied by International Partnership for Microbicides (IPM)	Oral PrEP and PrEP ring	End users: AGYW, adolescent and young people, FSW, women engaged in transactional sex Key influencers: Providers and other site staff
MSF PrEP Ring Study Eswatini	Eswatini	Introduction research	Médecins sans Frontières (MSF) and Ministry of Health (MoH) of Eswatini	MSF Operational Centre Geneva (OCG)	Oral PrEP and PrEP ring	End users: AGYW, FSW, and women engaged in transactional sex Key influencers: Providers and other site staff, male partners, and community leaders
MOSAIC / GOKE PrEP Ring Study	Eswatini	Introduction research	FHI 360 and MoH of Eswatini (Government of the Kingdom of Eswatini, GOKE)	USAID	Oral PrEP and PrEP ring	End users: AGYW, AYP, FSW, women engaged in transactional sex, TNBP Key influencers: Providers and other site staff

Timeline of PrEP ring introduction studies



Note: Timelines include preparatory phases (protocol development, ministry and donor concurrence, protocol consultations and approvals) through to study closeout. Dates for planned projects are subject to change (pending research ethics committee and site approvals). Information may be missing for studies.

PrEP methods included in introduction studies

All the introduction studies include either the PrEP ring and/or CAB PrEP in addition to oral PrEP implementation.

Nov. 2023

Project Name	Countries implemented	Oral PrEP	PrEP ring	CAB PrEP	Sample size across PrEP methods	Ethics approval
CATALYST	Kenya, Lesotho, South Africa, Uganda and Zimbabwe	✓	✓	✓	Approximately 11,265 (2253/country) across Stage 1 (choice between oral and PrEP ring) and Stage 2 (choice between oral, PrEP ring, CAB PrEP)	Approved
Project PrEP	South Africa	✓	✓	✓	7,400 participants across all three products; estimated 1,500 users on PrEP ring, 2,600 on CAB PrEP, and 3,300 on oral PrEP	Approved
DREAMS PrEP Choice	South Africa	✓	✓		804 PrEP users across oral PrEP and PrEP ring – equally distributed	Approved
Let's Talk & LAPIS	South Africa	✓	✓	✓	26,000 15–30-year-olds; ~3,000 PrEP users overall; 1,300 CAB PrEP and ~100 PrEP ring	Let's Talk approved; LAPIS approved
FastPrEP & PrEPared	South Africa	✓	✓	✓	FastPrEP will have 20,000 young people for oral PrEP; 1,800 on PrEPared to Choose substudy of PrEP ring and CAB PrEP	Approved
DO PrEP	South Africa	✓	✓	✓	2,000 young people on oral PrEP (100 AGYW on ring; TBC for CAB)	Approved
My Journey*	South Africa	✓	✓		AGYW on the PrEP ring across the 3 Principle Recipients (PRs): 581 (ASFA); 387 (Beyond Zero); 467 (NASCOSA)	Not applicable
National SWP*	South Africa	✓	✓		FSW on the PrEP ring: 946 (AFSA)	Not applicable
Imagine	South Africa	✓	✓	✓	Year 1 will reach 334 AGYW; Year 2 will reach 480; and Year 3 will reach 136	Pending as of Mar 2023
CeSHHAR PrEP Study	Zimbabwe		✓	✓	50 FSW in the pilot; 435 FSW recruited in the pilot survey; and 199 female, male and transgender sex workers in qualitative focus group discussions	Approved
Going the Last Mile	Zimbabwe	✓	✓		1,100 participants on the PrEP ring	Approved
MSF PrEP Ring Study	Eswatini	✓	✓		6 women opted for oral PrEP; 5 women chose PrEP ring	Approved
MOSAIC PrEP Ring Study	Eswatini	✓	✓		At least 500 PrEP ring users	Approved

* My Journey and National SWP are programmatic pilots, therefore ethics approval is not applicable.

Target populations of introduction studies

Introduction studies focus primarily on AGYW, with some other priority groups included as end users. Only a few studies also include PrEP influencers as a target population for monitoring and evaluation.

* End user for oral PrEP or CAB PrEP
 ** Included in the study for SRH services; however, not a target population for PrEP initiation
 *** Will track pregnancy outcomes if an end user falls pregnant while on PrEP

	END USERS							PrEP INFLUENCERS				
	Adolescent girls and young women (AGYW)	Adolescents and young people (AYP)	Pregnant and breastfeeding people (PBF) and their infants	Female sex workers (FSWs)	Women engaged in transactional sex	Transgender and nonbinary people (TNBP)	Men who have sex with men (MSM)*	Male partners (e.g., of AGYW)*	Providers and other site staff	Partners	Parents and / or caregivers	Community members and leaders
CATALYST	✓		✓	✓	✓	✓			✓	✓	✓	✓
Project PrEP	✓	✓	**			✓		✓	✓	✓	✓	✓
DREAMS	✓								✓			✓
Let's Talk & LAPIS		✓		✓	✓	✓	✓		✓			✓
FastPrEP & PrEPared to Choose	✓		✓			✓	✓	✓	✓			✓
DO PrEP		✓	***		✓		✓	✓	✓			✓
My Journey	✓											
National SWP				✓								
Imagine	✓		**									
CeSHHAR PrEP Study				✓	✓	✓			✓			✓
Going the Last Mile	✓	✓		✓	✓				✓			
MSF PrEP Ring Study	✓			✓	✓				✓	✓		✓
MOSAIC / GOKE PrEP Ring Study	✓	✓		✓	✓	✓			✓			

PrEP delivery channels of introduction studies (1/2)

Introduction studies also cover a variety of delivery channels, with a focus on differentiated service delivery.

Project Name	Countries implemented	Priority delivery channel approach	Fixed public HIV ART clinics	Public mobile clinics	Community-based models	Nonprofit health clinics	Private health clinics/pharmacies	SRH/FP services
CATALYST	Kenya, Lesotho, South Africa, Uganda and Zimbabwe	PEPFAR/USAID-funded public HIV facilities and nongovernmental organization (NGO) implementing partner (IP) sites. Some countries will study PrEP within community-based models (e.g., Lesotho) as well as PrEP services integrated into a SRH/FP facility (e.g., Zimbabwe).	✓		✓	✓		✓
Project PrEP	South Africa	Fixed public health facilities and mobile clinics, including fixed decentralized service points for comprehensive SRH services	✓	✓	✓		✓	✓
DREAMS PrEP Choice	South Africa	Mobile clinics and gazebos linked to community-based sites (TVETs, universities, community safe spaces layering with DREAMS IPs).	✓		✓	✓		✓
Let's Talk & LAPIS	South Africa	Community models with peer navigators, nurse-led mobile clinics, and fixed public facilities with connection to existing government-led HIV models.	✓		✓			✓
FastPrEP & PrEPared to Choose	South Africa	PrEP initiation through public health facilities and community-focused models (e.g., mobile clinics, local clinics, schools, courier service, youth clubs, quick PrEP depots at pharmacies)	✓	✓	✓	✓	✓	
DO PrEP	South Africa	Community-based delivery with linkages to public HIV facility and mobile	✓	✓	✓			✓

Primary PrEP delivery channel
 Connection to private or public HIV facility
 Linkage for follow-up support

PrEP delivery channels of introduction studies (2/2)

Introduction studies also cover a variety of delivery channels, with a focus on differentiated service delivery.

Project Name	Countries implemented	Priority delivery channel approach	Fixed public HIV ART clinics	Public mobile clinics	Community-based models	Nonprofit health clinics	Private health clinics/ pharmacies	SRH/FP services
My Journey	South Africa	Integration in provincial DOH facilities and through community mobile units with a registered nurse	✓	✓				
National SWP	South Africa	Mobile clinics in hot spot areas and linked to provincial DOH facilities	✓	✓				
Imagine	South Africa	In-school youth-friendly clinic and social spaces that also offer SRH services through social impact funding models			✓			✓
CeSHHAR PrEP Study	Zimbabwe	Nonprofit health clinics and SRH / FP services				✓		✓
Going the Last Mile	Zimbabwe	Public mobile clinics, community-based models, nonprofit health clinics, and SRH / FP services		✓	✓	✓		✓
MSF PrEP Ring Study	Eswatini	Fixed public HIV / ART clinics, community-based models, nonprofit health clinics, and SRH / FP services	✓		✓	✓		✓
MOSAIC / GOKE PrEP Ring Study	Eswatini	Fixed public HIV / ART clinics as well as community-based models (DREAMS on Wheels outreach, fixed mobile sites), nonprofit health clinics, private health clinics, and SRH / FP services	✓	✓	✓	✓		✓

Primary PrEP delivery channel
 Connection to private or public HIV facility
 Linkage for follow-up support

Anticipated insights from PrEP ring introduction studies

PrEP introduction framework to scale new and existing biomedical prevention products

This product introduction framework has been used across countries to support planning for the introduction of PrEP products. It identifies necessary steps for PrEP introduction and scale-up across five major categories and priority delivery channels.

This framework can also be used to map research priorities across the implementation studies.

PrEP Introduction Framework



PLANNING & BUDGETING

National and subnational plans are established to introduce and scale-up PrEP products.



SUPPLY CHAIN MANAGEMENT

PrEP products are available and distributed in sufficient quantity to meet projected demand via priority delivery channels.



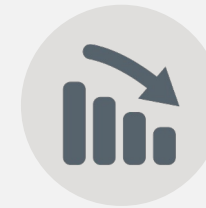
DELIVERY PLATFORMS

PrEP products are delivered by trained providers in priority delivery channels to effectively reach end users.



UPTAKE & EFFECTIVE USE

End users know about and understand PrEP products and know how to access and effectively use them.



MONITORING, EVALUATION, & LEARNING

PrEP products are effectively integrated into national, subnational, facility, community, and program monitoring systems.

Research priorities across introduction studies



PLANNING & BUDGETING

1. What does PrEP delivery **cost** and how does it vary across PrEP products?



SUPPLY CHAIN MANAGEMENT - *Primarily answered through secondary research after introduction studies are completed*



PREP DELIVERY PLATFORMS

2. Which **delivery platforms and/or models** will best reach populations who need PrEP?
3. How should new PrEP methods be **integrated within oral PrEP provision** and/or existing PrEP programming?
4. What are the **service readiness and delivery requirements** for new PrEP methods?
5. What are **provider attitudes and beliefs** about the new PrEP methods, and what are we learning about how to inform or shape them?



UPTAKE & EFFECTIVE USE

6. What **demand generation strategies** effectively support uptake and effective use of new PrEP methods?
7. What are **end user preferences** across PrEP methods, and how are end users making decisions among methods?
8. What **tools effectively support choice** among the PrEP methods?
9. How do **key influencers** affect the uptake and effective use of new PrEP methods and how can they be effectively engaged?
10. To what extent is there evidence of **social harms associated with PrEP use**, particularly for the PrEP ring?
11. What are the most effective approaches to strengthen linkages between PrEP and **post-exposure prophylaxis (PEP)**?



MONITORING, EVALUATION & LEARNING

12. What are the **characteristics and frequency of seroconversion and HIV drug resistance (HIVDR)** among users of new PrEP methods?

Anticipated coverage of priority research questions

Question	# of studies	Summary
Q1 What does PrEP delivery cost and how does it vary across PrEP products?	5	The cost of delivery will be widely assessed across delivery channels, but a gap remains for affordable pricing, particularly for CAB PrEP.
Q2 Which delivery platforms and/or models will best reach populations who need PrEP?	10	The effectiveness of delivery channels to reach priority populations as well as the comparison across delivery platforms are widely covered.
Q3 How should the new PrEP methods be integrated within oral PrEP provision and/or existing PrEP programming?	8	The integration of the new PrEP methods, particularly the PrEP ring, within oral PrEP provision is widely covered across delivery channels.
Q4 What are the service readiness and delivery requirements for the new PrEP methods?	7	Several studies focus on service readiness and delivery requirements for the new PrEP methods.
Q5 What are provider attitudes and beliefs about the new PrEP methods, and what are we learning about how to inform or shape them?	8	Provider attitudes and beliefs will be widely assessed, with several studies including health care workers as a target population for evaluation.
Q6 What demand generation strategies are most effective to support uptake and effective use of the new PrEP methods?	5	Although each study includes demand generation approaches, only a few will assess the effectiveness of the strategies leveraged for PrEP uptake.
Q7 What are end-user preferences across PrEP methods, and how are they making decisions among methods?	13	Several studies will track end-user preferences (patterns of use, method switching, discontinuation and restart, etc.) for the PrEP ring.
Q8 What tools effectively support choice among the PrEP methods?	7	Several studies will assess the effectiveness of support approaches for PrEP choice.
Q9 How do key influencers affect the uptake and effective use of the new PrEP methods, and how can they be engaged effectively?	8	Many of the studies will focus on understanding key influencer attitudes and beliefs as well as how to effectively engage them.
Q10 To what extent is there evidence of social harms associated with PrEP use , particularly for the PrEP ring?	8	Social harms will be tracked across several studies as a subcomponent for monitoring negative consequences of PrEP use, particularly for the PrEP ring.
Q11 What are the most effective approaches to strengthening linkages between PEP and PrEP ?	1	Only two studies will aim to strengthen the linkages between PEP and PrEP.
Q12 What are the characteristics and frequency of seroconversion and HIVDR among PrEP users across the new PrEP methods?	7	PrEP efficacy across the methods for specific population groups as well as seroconversion and HIVDR data are widely tracked.

■ Significant coverage in studies (+8 studies)
 ■ Some studies address topic (3–7 studies)
 ■ 1–4 studies address topic

Affordable price and cost of PrEP delivery across multiple PrEP products



Research question:

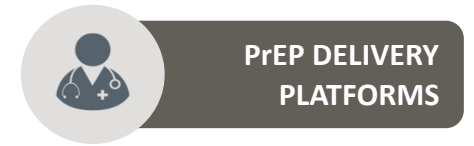
What does PrEP delivery **cost** and how does it vary across PrEP products?

Study	PrEP methods	Research objectives
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will assess the cost of PrEP implementation for the new PrEP methods in existing USAID PrEP service delivery sites; sites will be selected in accordance with government guidelines. Data will be collected yearly with interim analysis to identify sites with high and low performance.
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will conduct a cost analysis assessment in collaboration with the Health Economics and Epidemiology Research Office (HERO) to understand what is the most cost-effective decentralized and simple service delivery model for HIV prevention services into comprehensive SRH services. The assessment will be based on financial and M&E data.
Let's Talk & LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> LAPIS will assess the affordability and cost-effectiveness of decentralized HIV prevention programming that is integrated with SRH services for the PrEP ring, CAB PrEP, PEP, and oral PrEP. The study will also assess what resources are needed for program scale-up at the provider and health systems level.
FastPrEP & PrEPared to Choose	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> FastPrEP will conduct a cost analysis in collaboration with HERO to understand what is the most cost-effective decentralized and simple service delivery model for PrEP.
CeSHHAR PrEP Study	PrEP ring and CAB PrEP	<ul style="list-style-type: none"> CeSHHAR PrEP Study collected data on participant willingness to pay for the PrEP ring or CAB PrEP, including minimum and maximum prices for each product.

Insights expected across studies:

- **Several studies will assess the affordability across the PrEP methods and the cost of delivery as a study subcomponent** (i.e., the cost analysis will not be the primary objective).
- After completion of the studies, there will be greater understanding on the **cost of delivery for all three PrEP products (oral PrEP, PrEP ring, and CAB PrEP) across multiple service delivery channels:**
 - CATALYST will provide insights on cost of delivery in USAID-funded sites (e.g., public HIV facilities and NGO IPs) for oral PrEP, the PrEP ring, and CAB PrEP.
 - Project PrEP will have an in-depth cost analysis of PrEP integration into comprehensive SRH services through fixed facilities and decentralized, community-based mobile clinics for oral PrEP, the PrEP ring, and CAB PrEP.
 - Let's Talk & LAPIS will study affordable pricing and the cost of delivery for PrEP and SRH integration for the PrEP ring, CAB PrEP, PEP and oral PrEP.
 - FastPrEP will assess the cost-effectiveness of decentralized and simple service delivery for PrEP.
 - CeSHHAR PrEP Study will give insight on how much clients are willing to pay for the PrEP ring and CAB PrEP.

Delivery platforms and/or models that reach priority populations



Research question:

Which **delivery platforms and/or models** will best reach populations who need PrEP?

Study	PrEP methods	Research objectives	Type of assessment
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will assess the acceptability of delivery for the new PrEP methods across USAID sites to determine if they are successful at reaching priority populations: AGYW, FSWs, women engaged in transactional sex, TBNP, and PBFP. 	<i>Effectiveness of delivery platform to reach priority populations</i>
Let's Talk & LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Let's Talk & LAPIS will study whether peer-led mobilization into decentralized SRH services with and without a choice of long-acting PrEP are effective channels for engaging young people (15–30 years) and KPs in rural areas. 	
Imagine	PrEP ring and CAB PrEP	<ul style="list-style-type: none"> Imagine will assess the effectiveness of reaching AGYW (15–24 years) within school programming by tracking the lessons learned on which subgroups of AGYW were reached, why, and whether they were the intended end user. 	
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will assess the uptake and use of PrEP across fixed facility, mobile, and decentralized service delivery platforms. 	<i>Comparative analysis across delivery channels</i>
DREAMS PrEP Choice	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> DREAMS PrEP Choice will compare uptake of the PrEP ring across differentiated service delivery models within community-based DREAMS sites. 	
LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> LAPIS will provide a comparative analysis on PrEP uptake and continuation in community-based settings. 	
FastPrEP & PrEPared to Choose	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> FastPrEP will assess which follow-up implementation strategies across hub-and-spokes models (e.g., mobile clinics, local clinics, schools, courier service, youth clubs, quick PrEP depots at pharmacies) are most effective at ensuring prevention effective use of the PrEP ring by tracking whether PrEP users are following up and continuing PrEP at 6 and 18 months from initiation at a HIV clinic. 	
DO PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> DO PrEP will assess whether home- and community-based initiation, refills, and monitoring of PrEP achieves high PrEP access, effective use, and persistence among priority populations compared to clinic-based PrEP delivery. 	
My Journey	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> My Journey will compare the effectiveness of community-based models (e.g., mobile units vs. fixed space in a HIV clinic) to reach AGYW (18–24 years). The study will measure ease of access and patterns of use of PrEP across AGYW with different service delivery platforms. 	
CeSHHAR PrEP Study	PrEP ring and CAB PrEP	<ul style="list-style-type: none"> CeSHHAR PrEP Study compared FSW acceptability to receive long-acting PrEP methods in nonprofit health clinics, government hospitals, private pharmacies and home delivery through peer models. 	

Insights expected across studies:

- Across all of the studies, there is be a **comprehensive view on both the effectiveness of the delivery channels to reach priority populations as well as how delivery platforms compare** for PrEP uptake and continuation across these population groups.
- CATALYST, Let's Talk, and Imagine will focus on the **effectiveness of different delivery models to reach priority groups** (e.g., USAID sites, PrEP integration in SRH/ANC/PNC, and in school programming) across the PrEP methods.
- Project PrEP, DREAMS PrEP Choice, Fast PrEP, DO PrEP, LAPIS, My Journey, and CeSHHAR PrEP Study will provide **comparative analyses on PrEP uptake and continuation across delivery models and PrEP methods**, particularly to highlight whether community-based models are more effective for reaching priority groups than HIV clinic settings.

Integration of the new PrEP methods within oral PrEP provision (1/2)



Research question:

How should new PrEP methods be **integrated within oral PrEP provision** and/or existing PrEP programming?

Project	PrEP methods	Research objectives
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will assess facility- and health system-level facilitators of and barriers to the implementation of the new PrEP methods, building on the existing PrEP service delivery within existing USAID-funded sites in public health facilities and NGO IP sites that are in accordance with government guidelines. The study will include a quality improvement (QI) approach to adapt the enhanced service delivery package for PrEP choice throughout the duration of the study, including a QI Collaborative to facilitate knowledge sharing and stakeholder advisory mechanisms.
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will assess the integration of the PrEP ring and CAB PrEP within comprehensive SRH services in fixed and mobile facilities as well as conduct a substudy on the integration of PrEP into STI management.
LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> LAPIS will explore the effectiveness and real-world implementation of adding the choice of CAB PrEP, the PrEP ring, and PEP to community-based, integrated SRH and PrEP delivery models (acceptability, feasibility, practical implementation issues, and safety).
FastPrEP & PrEPared to Choose	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> FastPrEP will assess facility-level facilitators and barriers to PrEP product implementation, including testing models of providing PrEP choice counseling



Integration of the new PrEP methods within oral PrEP provision (2/2)

Research question:

How should new PrEP methods be **integrated within oral PrEP provision** and/or existing PrEP programming?

Project	PrEP methods	Research objectives
MSF PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none">The MSF PrEP Ring Study aims to inform key decision making for PrEP service programming for the PrEP ring in Eswatini as well as internationally.
CeSHHAR PrEP Study	PrEP ring and CAB PrEP	<ul style="list-style-type: none">CeSHHAR PrEP Study assessed integration of the PrEP ring in existing PrEP programming provided at nonprofit sex worker health clinics.
Going the Last Mile	Oral PrEP and PrEP ring	<ul style="list-style-type: none">Going the Last Mile will assess the integration of the PrEP ring in existing oral PrEP programming in public mobile clinics, community-based models, nonprofit health clinics, and SRH / FP services.
MOSAIC / GOKE PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none">The MOSAIC PrEP Ring Study will assess important implementation considerations on the integration of the PrEP ring within existing HIV prevention and SRH services.

Insights expected across studies:

- Most studies will build on existing oral PrEP infrastructure and provision; however, **only four will study the integration of the new PrEP methods within oral PrEP provision** as a core component of the study (CATALYST, PrEP PrEP and MSF PrEP Ring Study).
 - CATALYST and the MOSAIC / GOKE PrEP Ring Study will provide insights on **integration of the PrEP ring and CAB PrEP within existing oral PrEP programming in public health facilities and NGO clinics** that reach AGYW, FSWs, women engaged in transactional sex, TNBP, and PFBF.
 - Project PrEP will provide insights on the **integration of the PrEP ring and CAB PrEP within fixed HIV facilities, mobile clinics, and other fixed, decentralized service points**. Project PrEP will also provide insights on the integration of PrEP within STI management.
 - MSF PrEP Ring Study will provide insights on **integration of the PrEP ring in fixed HIV facilities, community-based sites, nonprofit health clinics and SRH / FP services**.
 - CeSHHAR PrEP Study will provide insights on integration of the PrEP ring in **nonprofit sex worker health clinics and SRH / FP services**.
 - Going the Last Mile will provide insights on the PrEP ring integration in **differentiated service delivery channels such as public mobile clinics, community-based models, nonprofit health services and SRH / FP services**.
- FastPrEP will provide insights on the facility-level **facilitators of and barriers to PrEP implementation within public health facilities and community-based models**.
- LAPIS will provide insights into adding in the **choice of CAB PrEP, the PrEP ring, and PEP to community-based integrated SRH and PrEP delivery models**.



Service readiness and delivery requirements for the new PrEP methods

Research question:

What are the **service readiness and delivery requirements** for the new PrEP methods?

Project	PrEP method	Research objectives
CATALYST	Oral PrEP, PrEP ring and CAB PrEP	<ul style="list-style-type: none"> CATALYST will assess the readiness and feasibility of USAID-funded facilities (public and NGO IPs) to implement and offer PrEP choice for oral PrEP, PrEP ring and CAB PrEP. Data will be regularly monitored with bi-annual reports; an interim analysis will identify sites with high and low performance.
DREAMS PrEP Choice	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> DREAMS PrEP will study the service readiness for implementation in communities.
Project PrEP	Oral PrEP, PrEP ring and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will assess the feasibility and service delivery requirements for integrating new PrEP methods into existing SRH services. Project PrEP will assess the facilitators and barriers to new PrEP method introduction within routine primary care settings.
LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> LAPIS will explore the effectiveness and real-world implementation of adding in the choice of PrEP methods to community-based integrated SRH and PrEP delivery models (including practical implementation issues and safety).
FastPrEP & PrEPared to Choose	Oral PrEP, PrEP ring and CAB PrEP	<ul style="list-style-type: none"> FastPrEP/PrEPared will assess what are the characteristics of delivery sites (e.g., the size and type of facility across mobile sites, clinics and HIV service providers) to accept an invitation to receive training for the integration of PrEP programming and subsequently compare which delivery sites follow through to integrate PrEP post-training (e.g., tracking PrEP delivery, initiation and continuation within these sites post-training). FastPrEP/PrEPared will also track what program modifications were needed across the intervention and why they occurred, specifically considering PrEP ring provision and CAB PrEP administration.
CeSHHAR PrEP Study	PrEP ring and CAB PrEP	<ul style="list-style-type: none"> CeSHHAR PrEP Study assessed service readiness and delivery requirements for the PrEP methods, including the PrEP ring.
MOSAIC PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The MOSAIC PrEP Ring Study will assess service readiness and delivery requirements through health system feasibility and delivery acceptability among users/providers.

Insights expected across studies:

- The studies CATALYST, DREAMS PrEP Choice, Project PrEP, LAPIS, FastPrEP/ PrEPared, CeSHHAR PrEP Study will provide insights on:
 - Service readiness for USAID-funded PrEP access points** (e.g., public health facilities and NGO IP sites) to integrate the new PrEP methods
 - Lessons learned about PrEP provider training and program modifications** that are needed to ensure PrEP integration within mobile sites and HIV clinics (e.g., based on size, type of facility) for PrEP ring and CAB integration
 - The feasibility and service readiness and delivery requirements** for the PrEP integration in existing HIV prevention and SRH services
 - Operational improvements for service delivery** at private pharmacies
- It is unclear whether the studies track the service readiness to support PrEP choice across priority populations.** Nevertheless, the combined studies to reach a wide range of target populations: AGYW, AGYW male partners, FSW, young MSM, women engaged in transactional sex, TBNP, and PBFP.

Provider attitudes and beliefs about the new PrEP methods



Research question:

What are **provider attitudes and beliefs** about the new PrEP methods, and what are we learning about how to inform or shape them?

Project	PrEP methods	Research objectives
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will assess the provider factors and barriers to the implementation process (e.g., including acceptability of the new PrEP methods among providers) for integrating the new PrEP methods, including health care providers as a target population for assessment in the study. A clinic committee will advise on the planning, development, and implementation of the study as well as provide input and feedback to convey questions and concerns to the research team.
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will explore provider experiences, perceived acceptability of service delivery components, and facilitators and barriers to new PrEP product delivery, as well as provider needs to implement new PrEP products, including capacity development requirements.
DREAMS PrEP Choice	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> DREAMS PrEP Choice will assess the factors that influence choice and uptake of the different PrEP methods, including health care providers who provide SRH and PrEP at DREAMS sites as a target population for assessment in the study.
Let's Talk & LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Let's Talk & LAPIS will explore the feasibility from a provider perspective of adding in the choice of CAB PrEP, PrEP ring, and PrEP to community-based, integrated SRH and PrEP delivery models
Imagine	PrEP ring and CAB PrEP	<ul style="list-style-type: none"> Imagine will study the acceptability of the PrEP ring, PrEP choice, and the service delivery package among providers.
MSF PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The MSF PrEP Ring Study collected data about HCW experiences to provide oral PrEP and PrEP ring services, including sharing their own perceptions and recommendations for the products.
Going the Last Mile	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> Going the Last Mile will assess provider attitudes and beliefs about the PrEP ring.
MOSAIC / GOKE PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The MOSAIC PrEP Ring Study will assess provider knowledge, practice, and attitudes around delivery of the PrEP choice.

Insights expected across studies:

- While several studies (CATALYST, DREAMS PrEP Choice, and Imagine) will provide insights on the provider-level factors and barriers to PrEP choice and uptake, **only CATALYST, Project PrEP, DREAMS PrEP Choice, Let's Talk, LAPIS, MSF PrEP Ring Study, and Going the Last Mile will include HCWs as a target population to understand acceptability among providers.**
- CATALYST, Project PrEP, MSF Ring Study, Going the Last Mile, and the MOSAIC / GOKE PrEP Ring Study will provide a deeper understand of **provider attitudes and beliefs within fixed and mobile public health facilities, as well as in sites of donor-funded NGO IPs** that already have existing infrastructure for oral PrEP. This will give insights on provider attitudes and acceptability to offer PrEP choice for the PrEP ring and CAB PrEP across a wide range of population groups (AGYW, FSWs, etc.).
- Going the Last Mile and MSF PrEP Ring Study will also cover differentiated service delivery sites such as **community-based models, nonprofit health clinics, and SRH / FP services.**
- DREAMS will assess how **health care providers who provide SRH and PrEP at DREAMS sites influence choice and uptake among end users** for oral PrEP and the PrEP ring. This will give insights on health care provider attitudes and beliefs for those who are familiar to give SRH services for AGYW in youth-friendly spaces.
- Although health care providers are not a target population within the study assessment, Imagine will provide insights on the acceptability of the PrEP choice among **school-based health care providers** who offer both PrEP and SRH services as an integrated package for AGYW.



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Demand generation strategies (1/2)

Research question:

What **demand generation strategies** are most effective to support uptake and effective use of the new PrEP methods?

Project	Research objectives	Demand generation strategies
CATALYST	<i>No clear research objective defined</i>	<ul style="list-style-type: none"> Add PrEP choice to existing community engagement and demand generation activities Align stakeholders around a common AGYW positioning strategy for PrEP Apply the positioning strategy to refresh national demand creation strategies and campaigns Roll out interventions with influencers—parents, peers, providers—to normalize PrEP Adapt user-support tools and strengthen the capacity of ambassadors in PEPFAR-supported programming, including DREAMS
Project PrEP	Project PrEP will determine the most effective demand creation and messaging strategies for increasing uptake and promoting effective use of PrEP.	<p>Demand generation will be undertaken only for oral PrEP and HIV prevention services until the new PrEP methods are widely available. Strategies implemented will include:</p> <ul style="list-style-type: none"> Print, digital, and mass media Social mobilization targeting AGYW (e.g., community celebration events, network of AGYW HIV prevention ambassadors, community information agents who mobilize AGYW, etc.) Client support for continuation (in-person and digitally)
DREAMS PrEP Choice	DREAMS PrEP Choice will study increased demand for services through targeted demand creation activities in communities to support the normalization and buy-in of PrEP as an effective prevention tool.	<ul style="list-style-type: none"> Dialogues with communities supported by CBOs HIV prevention ambassadors engaging AGYW in communities Addressing ward councilors, traditional leaders, chiefs Radio interviews on African local radio stations Social media posts (e.g., targeted and boosted posts using the MyPrEP Facebook page)
Let's Talk & LAPIS	Let's Talk & LAPIS will study which social mobilization approaches will attract young people to create demand for risk-informed HIV prevention.	<ul style="list-style-type: none"> Peer-led social mobilization Structured needs assessment and support Referral into community-based integrated HIV/SRH services through mobile clinics
FastPrEP & PrEPared sub-study	<i>No clear research objective defined</i>	<ul style="list-style-type: none"> Leveraging existing Youth Reference Group (of PrEP users and PrEP-naïve members) Recruiting existing FastPrEP clients and previous ring study participants PrEP ambassadors Designing materials to help women make informed decisions across the PrEP methods Digital, social and print media on oral and new PrEP modalities



Demand generation strategies (2/2)

Research question:

What **demand generation strategies** are most effective to support uptake and effective use of the new PrEP methods?

Project	Research objectives	Demand generation strategies
DO PrEP	<i>No clear research objective defined</i>	<ul style="list-style-type: none">• Motorcades/load hailing• Community events and mobilization• Partnerships with HIV counseling and testing centers and programs• Home-based and mobile HIV testing programs• Family planning clinics, youth clinics, post-abortion clinics• Pharmacies that provide emergency contraception and PEP (e.g., for sexual assault)• Social media platforms popular among young people
My Journey	My Journey will study the effectiveness of social mobilization strategies to increase uptake by AGYW.	<ul style="list-style-type: none">• Information, education, and communication materials• Contacting existing My Hope cohorts• Information shared in local newspaper and radio• Create demand in targeted areas of implementation (community and facilities)• AYP ambassadors/influencers• Community dialogues• Focus group discussions
National SWP	<i>No clear research objective defined</i>	<ul style="list-style-type: none">• Meetings with local stakeholders and gatekeepers• Program awareness creation meetings for sex workers, health campus teams• Community engagement with traditional leaders, community strengthening systems (CSSs), implementing organizations (IPOs)
Imagine	Imagine will assess the role of key influencers (e.g., parents) within demand creation and PrEP education models.	<ul style="list-style-type: none">• Engage AGYW in gamification approaches post screening within school programming

Insights expected across studies:

- Although most of the studies deploy demand generation strategies, **only a few will measure the effectiveness of the demand generation strategies** to increase prevention/effective PrEP use and continuation.
- Global and national stakeholders will have **lessons on the effectiveness of demand generation strategies** across several studies: DREAMS, LAPIS, DO PrEP, My Journey, and Imagine.
- Most of the studies focus on **reaching AGYW and other priority groups** through community mobilizers and dialogues, peer influencers, partner counseling, and mass media campaigns (e.g., radio, TV, social media platforms).

End-user preferences across the PrEP methods (1/2)



Research question:

What are **end-user preferences** across PrEP methods, and how are they making decisions among methods?

Project	PrEP methods	Research objectives and / or research question
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will conduct in-depth assessments of end-user preferences and how they are making decisions among methods through: <ul style="list-style-type: none"> Assessment of patterns of PrEP use and use effectiveness in the context of PrEP choice (i.e., preventive effective use) as well as an assessment of sociodemographic and contraceptive use correlation to PrEP use patterns Assessment of how end users use PrEP, including continuation, method switching, and restart and discontinuation patterns Assessment of PrEP method acceptability among PrEP users and which product end users prefer when offered choice Service statistics (monthly disaggregated facility-level data on PrEP use) will assess change in PrEP uptake over the course of the study.
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will study the uptake and continuation of PrEP among AGYW and other priority groups (e.g., transgender) in fixed and mobile SRH services to understand: <ul style="list-style-type: none"> The factors that influence choice and uptake of the different PrEP methods The frequency of and reasons for switching between PrEP products The rates of PrEP continuation, as well as the factors that affect continuation and how they differ by PrEP product
DREAMS PrEP Choice	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> DREAMS PrEP Choice will study the uptake, preference, and patterns of long-acting method use among women of reproductive age at the DREAMS site. <ul style="list-style-type: none"> Assessment of whether offering additional choice influences coverage of PrEP for AGYW Assessment of the frequency of and reasons for switching between PrEP products Assessment of the rates of PrEP continuation among PrEP ring users and the factors that affect discontinuation across PrEP products
LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	LAPIS will explore the acceptability, preferences, reach, and retention of long-acting PrEP among end users.
FastPrEP & PrEPared sub-study	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> FastPrEP will assess the demographic, risk profile, and clinical characteristics of early PrEP adopters for the new methods (PrEP ring and CAB PrEP) compared to oral PrEP. FastPrEP will also measure the time required for end users to self-select to adopt PrEP ring or CAB PrEP as opposed to other PrEP modalities.
DO PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> DO PrEP will study participant experiences of the PrEP ring over time (access, effective use, and persistence) as well as their preferences and experiences with PrEP delivery approaches and products.

End-user preferences across the PrEP methods (2/2)



Research question:

What are **end-user preferences** across PrEP methods, and how are they making decisions among methods?

Project	PrEP methods	Research objectives
My Journey	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> My Journey will assess the acceptability and uptake of and stigma associated with PrEP ring use by AGYW. My Journey will also study end-user perceptions of the concurrent use of PrEP ring and tampons.
National SWP	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The National SWP program will study the acceptability of the PrEP ring among the sex worker community, based on learning from how the introduction of the menstrual cup may influence preference for the PrEP ring among the sex worker community.
Imagine	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Imagine will assess service quality perceptions from end users, building on insights from other interventions similar to the PrEP ring (e.g., such as vaginal products like the menstrual cup and diaphragm). Imagine will also look at the values and preferences underlying PrEP method choice and use as well as PrEP uptake, continuation/discontinuation, patterns of use/prevention effective use, concomitant use, and switching patterns between oral PrEP and PrEP ring.
MSF PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The MSF PrEP Ring Study collected data around factors that influenced end-user choice of PrEP method as well as whether end users decided not to take up PrEP.
CeSHHAR PrEP Study	PrEP ring and CAB PrEP	<ul style="list-style-type: none"> CeSHHAR PrEP Study will assess end-user opinions, attitudes, acceptability, ease of use, comfort, adherence, and side effects regarding the new PrEP methods.
Going the Last Mile	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> Going the Last Mile will assess end-user preferences for the PrEP ring.
MOSAIC/GOKE PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> MOSAIC PrEP Ring Study will assess patterns of PrEP use in the context of informed PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns.

Insights expected across studies:

- As a core research objective across all studies, there will be a **wide range of insights on end-user preferences for the PrEP ring** as well as for oral PrEP and CAB PrEP.
- The **most common insights that the studies track include:**
 - Acceptability of PrEP among AGYW (and in some instances for PBFP)
 - Patterns of PrEP use and use effectiveness in the context of PrEP choice (i.e., prevention effective use) with sociodemographic and contraceptive use correlation to PrEP use patterns
 - Continuation, method switching, and restart and discontinuation patterns
 - PrEP method acceptability among PrEP users and which product end users prefer when offered choice
 - PrEP acceptability and patterns of use within private pharmacies across client socioeconomic factors, as well as across oral PrEP and CAB PrEP
 - Sociodemographic and contraceptive use correlates of PrEP use patterns



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Tools to effectively support choice among the PrEP methods

Research question:

What tools effectively support choice among the PrEP methods?

Project	PrEP method	Research objectives
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will develop user-support tools for PrEP choice (e.g., job aids) and strengthen the capacity of ambassadors in PEPFAR-supported programming, including DREAMS. The study will include a QI approach to adapt the enhanced service delivery package for PrEP choice throughout the duration of the study, including a QI Collaborative to facilitate knowledge sharing and stakeholder advisory mechanisms.
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will implement the support tools developed and recommended in the South Africa’s NDOH guidelines. A formal evaluation of client and provider tools is not planned but would be explored through qualitative data collection.
Let’s Talk & LAPIS	Oral PrEP, PrEP ring and CAB PrEP	<ul style="list-style-type: none"> Let’s Talk & LAPIS will study the effectiveness of a peer-led REDCap based needs assessment and tailored psychosocial support to increase uptake, retention, and adherence to HIV prevention among young people (15–30 years).
FastPrEP and PrEPared to Choose	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> FastPrEP & PrEPared to Choose will co-create a PrEP choice counseling script with key stakeholders (youth, PrEP providers, peer navigators) and sexual health product choice experts. The aim will be to identify potential enablers and barriers to the implementation of the PrEP choice counseling process at the level of the community, health care facility, PrEP provider, and PrEP user.
Imagine	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Imagine will study the effectiveness of client support interventions/tools to support continued use of PrEP among AGYW in schools, including an assessment of what investments improve uptake and the needed system-, provider-, and user-level supports to support informed choice and prevention effective use of the PrEP ring.
MSF PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The MSF PrEP Ring Study will assess the strategies and tools to support choice between oral PrEP and the PrEP ring for AGYW, FSW, and women engaged in transactional sex.
MOSAIC / GOKE PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The MOSAIC PrEP Ring Study will assess strategies and tools to support choice between oral PrEP and the PrEP ring through PrEP counseling.

Insights expected across studies:

- The studies will provide insights on the **most effective user-support tools for PrEP choice**, particularly for the PrEP ring.
- CATALYST will employ a quality improvement approach to adapt the enhanced service delivery package for PrEP choice throughout implementation. Global and national stakeholders will have insights on **how to adapt support tools that are designed for USAID-funded HIV facilities and IPs**.
- Let’s Talk, LAPIS, and Imagine will provide lessons on the **effectiveness of peer-led support tools that are designed for adolescents and youth in community-based models** (e.g., community mobile sites, in-school youth-friendly clinics).
- FastPrEP & PrEPared to Choose will identify the **enablers and barriers to PrEP choice counseling at the individual, community, and health care facility levels** within fixed and mobile HIV clinics.

Key influencer attitudes and engagement models (1/2)



Research question:

How do **key influencers** affect the uptake and effective use of the new PrEP methods, and how can they be engaged effectively?

Project	PrEP method	Research objectives
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will assess the attitudes of key influencers and community members (e.g., among partners, parents, and caregivers). The study will establish or leverage existing stakeholder advisory mechanisms, including community advisory boards and youth advisory mechanisms
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will study the factors that influence choice and uptake of the different PrEP methods, which may include key influencer attitudes; however, this is a not a core component of the study. Several key influencer engagement models will be deployed: <ul style="list-style-type: none"> Planned 22 community engagement activities with AGYW, as well as parents and other community members, including traditional and religious leaders Facilitating 2 large engagements with AGYW and their male peers, including Generation PrEP! Simunye Ambassadors and community informant agents
DREAMS PrEP Choice	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> DREAMS PrEP Choice will study the factors that influence choice and uptake of the different PrEP methods, particularly to understand community considerations from community gatekeepers.
My Journey	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> My Journey will study male sex partner perceptions of PrEP ring use by their AGYW partners and how they influence AGYW. The program will engage key influencers, such as ward counselors, civil society organizations, and traditional and religious leaders as well as CSS IPOs.
National SWP	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The National SWP program will engage key influencers, such as traditional leaders, CSS IPOs, and gatekeepers in hot spots, to raise awareness and sensitize stakeholders on the new PrEP methods. Furthermore, the program will assess whether sexual partners are able to feel the ring.

Key influencer attitudes and engagement models (2/2)



Research question:

How do **key influencers** affect the uptake and effective use of the new PrEP methods, and how can they be engaged effectively?

Project	PrEP method	Research objectives
Imagine	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Imagine will assess the most effective engagement models for parents in education and demand creation to get their support for PrEP as an empowerment option for young women.
MSF PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The MSF PrEP Ring Study conducted three focus group discussions with community members to ascertain attitudes towards PrEP options.
Going the Last Mile	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> Going the Last Mile will assess the impact of key influencer attitudes and beliefs on the PrEP ring uptake and effective use.

Insights expected across studies:

- Studies will provide a **broad understanding of key influencer attitudes and beliefs, as well as the engagement models to effectively educate and sensitize them** on the new PrEP methods.
- Key influencer groups that will be engaged include:
 - **Parents and caregivers**
 - **Male partners of AGYW and PBFP**
 - **Community members such as traditional and/or religious leaders**
 - **Community health volunteers/ ward counselors**
 - **Sex worker gatekeepers**
- The insights from the studies will inform **how key influencer attitudes and beliefs affect a wide range of end users:** AGYW, AGYW male partners, FSWs, young MSM, women engaged in transactional sex, TBNP, and PBFP.

Social harms associated with PrEP use

Research question:

To what extent is there evidence of **social harms associated with PrEP use**, particularly for the PrEP ring?

Project	PrEP method	Research objectives and / or research question
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will include job aids for health care workers to support gender-based violence (GBV) response as a part of the enhanced service delivery package.
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will document and analyze the proportion and types of social harms experienced by participants using PrEP (by PrEP method). Routine screening for GBV and mental health is conducted for all Project PrEP participants.
DREAMS PrEP Choice	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> Collection of social harms experienced by study participants DREAMS PrEP Choice will conduct a series of in-depth interviews and focus group discussions after enrollment where participants will be screened for mental health disorders, GBV, and substance use.
LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> LAPIS will explore social harms and the safety of delivering a choice of CAB PrEP, the PrEP ring, and oral PrEP (as well as PEP) within community-based integrated SRH and PrEP delivery models through a mixture of quantitative and qualitative data collection.
FastPrEP & PrEPared to Choose	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> While assessing social harms is not a core component of the study, FastPrEP/PrEPared will also monitor the negative consequences of PrEP use in young people, based on self-report at each in-person visit. These data may elevate evidence of social harms, particularly related to PrEP ring use by AGYW.
My Journey	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The My Journey program includes GBV and intimate partner violence (IPV) awareness as a component of the service delivery package; however, monitoring social harms for PrEP use is not a core research objective.
National SWP	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> The National SWP program includes GBV awareness and screening as a core component of its layered services; however, monitoring social harms for PrEP use is not a core research objective.
MOSAIC / GOKE PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> MOSAIC PrEP Ring Study will collect data on serious adverse events (SAEs) and social harms for study participants, including product-related and non-product-related events.

Insights expected across studies:

- A number of studies include gender-based violence and intimate partner violence awareness as a component of the service delivery package.
- Furthermore, **several studies will provide deeper insights on the negative consequences of PrEP use** through participant interviews at each in-person visit, particularly for the PrEP ring (e.g., DREAMS PrEP Choice, Project PrEP, LAPIS, FastPrEP/PrEPared, and MOSAIC / GOKE PrEP Ring Study).
- There is an opportunity for further research to track social harms across the studies, especially considering that **monitoring any evidence of social harms associated with PrEP use is a priority for national government regulatory authorities**, particularly to move forward with the approval of the PrEP ring.

Linkages between PEP and PrEP



Research question:

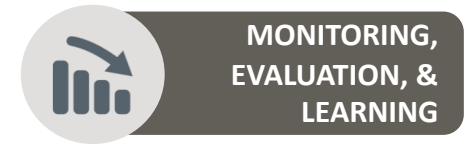
What are the most effective approaches to strengthen linkages between PrEP and **post-exposure prophylaxis (PEP)**?

Study	PrEP method	Research objectives
LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> LAPIS will explore the uptake of PEP packs amongst adolescents and youth who are eligible but choose not to take up oral or long-acting PrEP. Describe patterns of PEP use Describe PEP into PrEP journeys

Insights expected across studies:

- **Only LAPIS studies will track the linkages between PrEP and PEP.**
- LAPIS will study several research objectives that will provide the global and national stakeholders with **insights on patterns of use for PEP and the journey from PEP to PrEP.** These insights will help key actors understand the **linkages between PEP and PrEP use within community models**, nurse-led mobile clinics, and fixed public facilities.

Frequency and characteristics of seroconversion and HIV drug resistance across the PrEP methods



Research question:

What are the **characteristics and frequency of seroconversion and HIV drug resistance** among PrEP users across the new PrEP methods?

Study	PrEP methods	Research objectives
CATALYST	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> CATALYST will include an in-depth HIV drug resistance and monitoring study to describe clinically relevant indicators among PrEP users, including rates of HIV infection and drug resistance among PrEP users who acquire HIV following PrEP exposure. <ul style="list-style-type: none"> Which combination of HIV testing works best in detecting HIV among CAB PrEP users The number of PrEP users who seroconvert The proportion and rates of HIVDR mutations among PrEP users who acquire HIV The side effects that are frequently reported across the PrEP methods
DREAMS PrEP Choice	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> DREAMS PrEP Choice includes an HIVDR sub-study in most recent modifications (currently in approvals as of October 2023).
Project PrEP	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Project PrEP will monitor the incidence of HIV, as well as the associated HIV viral load and resistance patterns, among PrEP users across the PrEP methods.
LAPIS	Oral PrEP, PrEP ring, and CAB PrEP	<ul style="list-style-type: none"> Let's Talk & LAPIS will monitor drug resistance and virological suppression in all seroconverters.
My Journey	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> My Journey will monitor seroconversions among AGYW using PrEP ring.
Going the Last Mile	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> Going the Last Mile will measure HIV incidence for end users participating in the study, particularly comparing HIV incidence and HIV seroconversion for PrEP ring users.
MOSAIC / GOKE PrEP Ring Study	Oral PrEP and PrEP ring	<ul style="list-style-type: none"> MOSAIC PrEP Ring Study will collect data on HIV incidence among participants as well as the proportion and rate of HIV drug resistance mutations among PrEP users who acquire HIV.

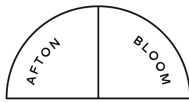
Insights expected across studies:

- Many studies will track the **frequency and characteristics of seroconversion and side effects across the priority population groups as well as the service delivery channels.**
- CATALYST, DREAMS PrEP Choice sub-study, Project PrEP, LAPIS, Going the Last Mile, and the MOSAIC / GOKE PrEP Ring Study are the only studies that are specifically tracking HIVDR.
- The data across the studies will be of great value to national regulatory authorities, considering this is a key research question for the approval of the new PrEP methods.

PrEP Ring – Anticipated Data from Completed Clinical Research

Study	Summary of Data Available	Available or Anticipated Data
MTN-042 (DELIVER)	<p>Approximately 550 pregnant individuals in 3 gestational age cohorts randomized to use PrEP ring or Oral PrEP through delivery:</p> <p>Cohort 1 (36-37 weeks), N=150 (101 PrEP ring, 49 Oral) Cohort 2 (30-35 weeks), N=157 (106 PrEP ring, 51 Oral) Cohort 3 (12-29 weeks), N=251 (202 PrEP ring, 49 Oral)</p>	<p>Interim results from Cohort 1 presented at IAS 2021, and Cohort 2 presented at CROI 2023.</p> <p>Final safety manuscript from Cohorts 1 and 2 published in Sept 2023 in JAIDS.</p> <p><i>Cohort 3 results accepted to CROI 2024</i> <i>Final Cohort 3 paper in development, anticipate submission Q2 2024</i></p>
MTN-043 (B-PROTECTED)	<p>197 breastfeeding parent/infant pairs enrolled 6-12 weeks after delivery randomized to use PrEP ring or Oral PrEP for 12 weeks (148 PrEP ring, 49 Oral)</p>	<p>Interim results presented at AIDS 2022 and final results presented at CROI 2023 and FIGO 2023.</p> <p><i>Paper in development, anticipate submission Q4 2023</i></p>

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