

MOSAIC: The mountain to implementation


MATRIX INVESTIGATOR MEETING
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Presentation Outline

- Overview of MOSAIC
 - Looking Back to Move Forward – The OPTIONS experience
 - Applying the value chain lens – CAB-LA experience
 - Challenges and considerations across the value chain
 - The winding road from product development to product introduction and scale
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MOSAIC Project Overview

- 5-year \$85M global project funded by PEPFAR through USAID (2021–2026)
- Focuses on introduction and access for new biomedical prevention products to prevent HIV for women in sub-Saharan Africa
- Works across multiple countries – Eswatini, Lesotho, Kenya, Namibia, Nigeria, South Africa, Uganda, Zambia, 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

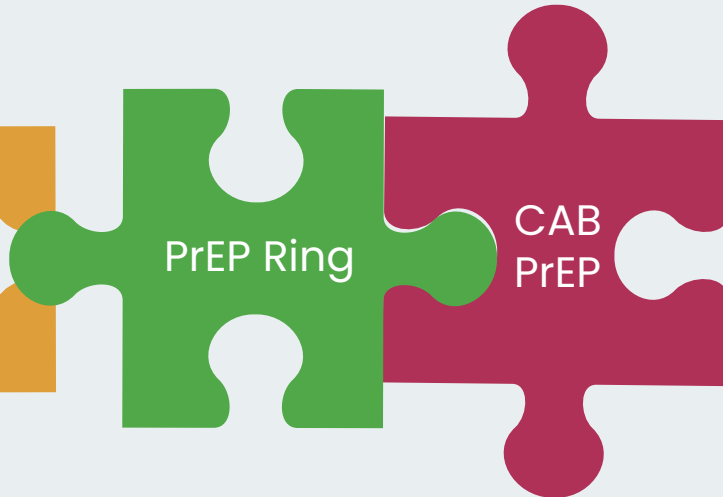
MOSAIC's goal is to accelerate access to new products

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 those products in the research pipeline.

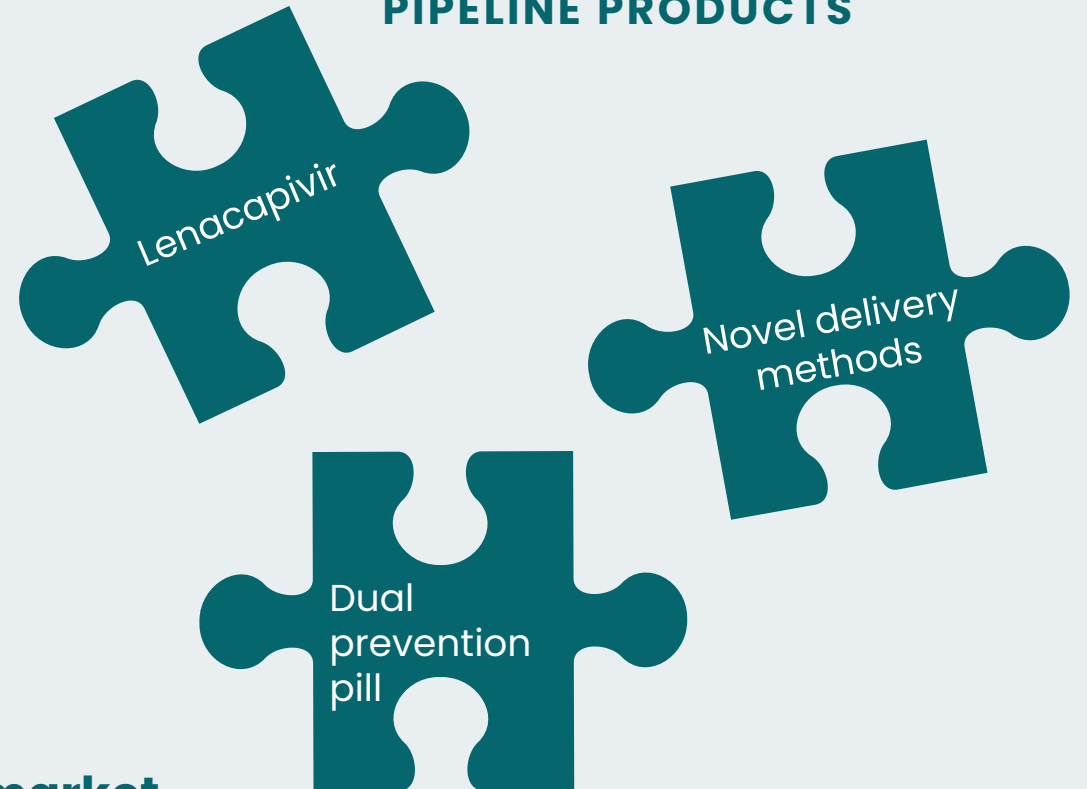
IN MARKET



NEAR-TO-MARKET



PIPELINE PRODUCTS



...towards a multi-method market

We need a multi-method market...

- Every product has **strengths and weaknesses** that individual users should have the opportunity to weigh.
- Choice allows potential users to move between products as their lives change, and as periods of risk change.
- The best product is the one an individual can use effectively when needed.
- Each product has unique implementation considerations and potential for epidemic impact if made widely accessible.

...to achieve impact.

“

I think people should be given all the information, then they make an informed decision as to which method they should use.

HCP Zimbabwe, 2021

Having multiple options will help us support our patients who want to take care of their health without having to change their lifestyle so much because I think that's where adherence becomes the problem.

HCP South Africa, 2021

”

MOSAIC will accelerate access to a multi-method market through five strategic priorities



User-centered Approach

Promote a user-centered approach



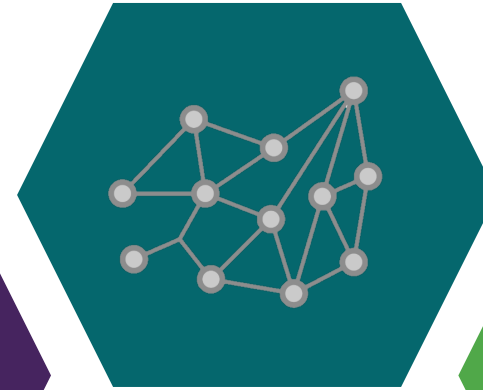
Research

Conduct research on how to enhance product availability, acceptability, uptake, and effective use



Policy & Programs

Coordinate and provide TA on regulatory review, policy, resource mobilization, supply chain, delivery, M&E, surveillance, and demand generation



Research Utilization

Implement research utilization activities and establish mechanisms for rapid, effective knowledge exchange



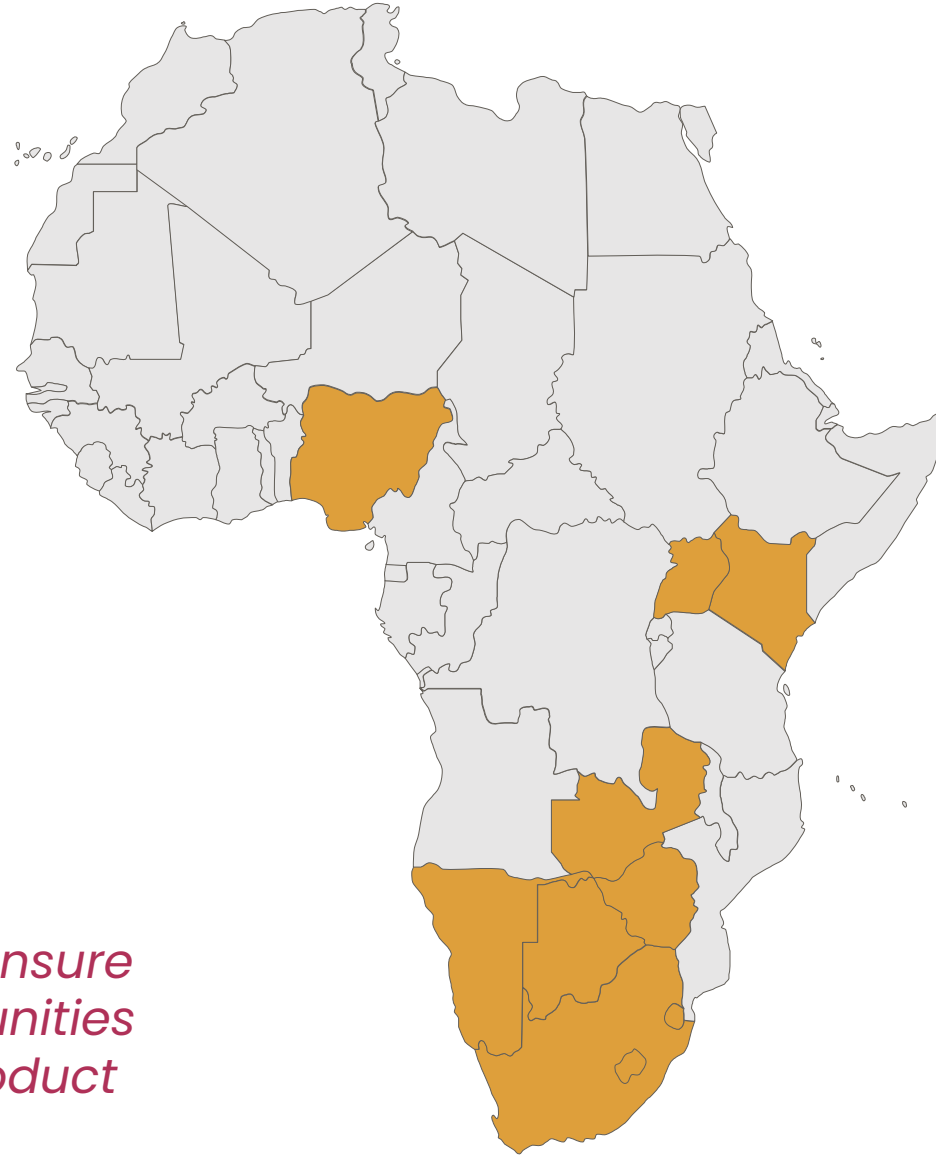
Local Partner Capacity

Strengthen and sustain local partner capacity to advocate for, design, and implement product introduction activities and research

OUR VISION

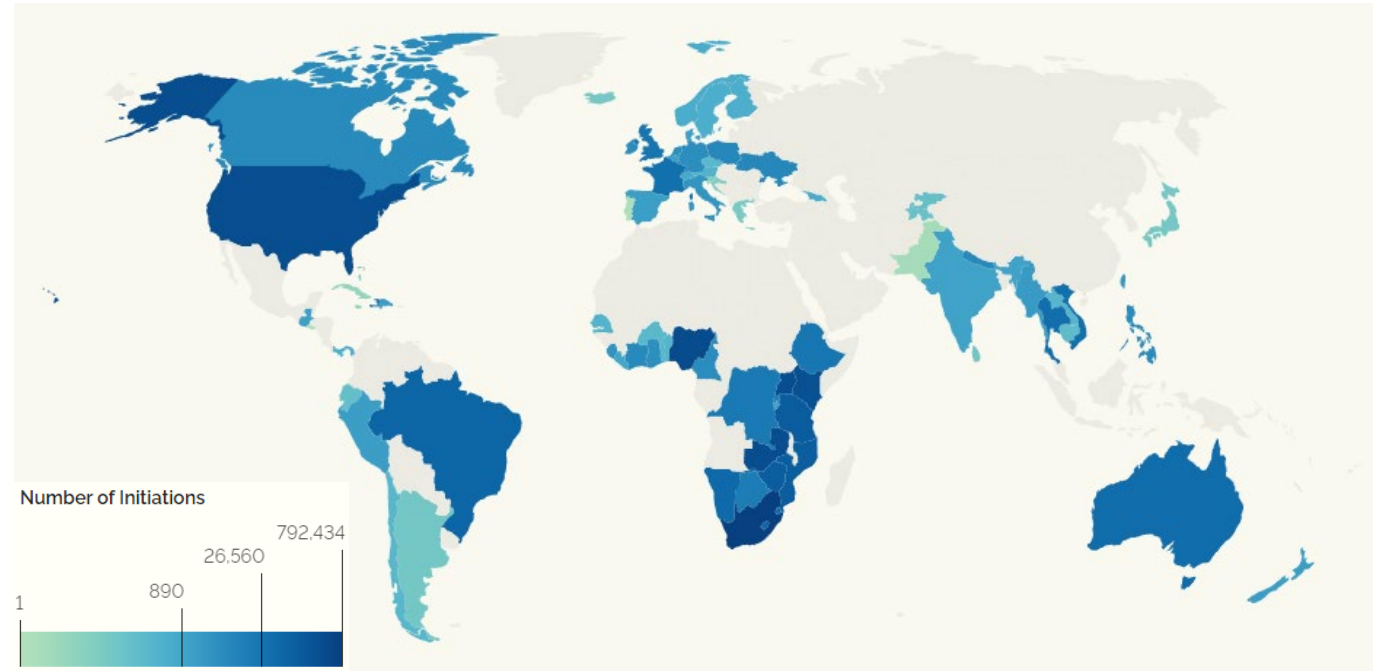
By project end, there will be **product introduction expertise** across the value chain **in each MOSAIC country** and these local leaders will provide national, regional and global expertise to **guide the introduction of *future PrEP products**

**Working closely with MATRIX, MOSAIC will ensure that health systems, end users and communities are engaged early to ensure successful product introduction and scale*



Globally, oral PrEP initiations reached more than 3.8 million; however, there is still a high unmet need for prevention

- Oral PrEP effectiveness lower in real-world than in clinical trials
- Access did not translate into uptake and use
- Many PrEP products are in the pipeline; three are in the market or nearing introduction
 - Oral PrEP
 - PrEP ring
 - CAB PrEP
- Lessons from oral PrEP can inform future product introduction



Source: <https://www.prepwatch.org>

CONTEXT

38.4 million people living with HIV and 1.5 million people became newly infected with HIV in 2021

OPTIONS (2015-2020) – Catalytic Investment for PrEP introduction and scale up

- Funded at a critical time
- Shaped the market in priority early adopter countries for new PrEP products in the pipeline – **established a clear path from research to national implementation at scale**
- **Principles** – Collaboration, rapid learning, responsiveness to local needs (gov'ts and communities), building bridges between across different parts of a complex system to ensure translation of research and policy into implementation, and leveraging diverse skills and assets.

1 Established **product introduction framework and tools** to adopt a comprehensive systems approach to PrEP roll out

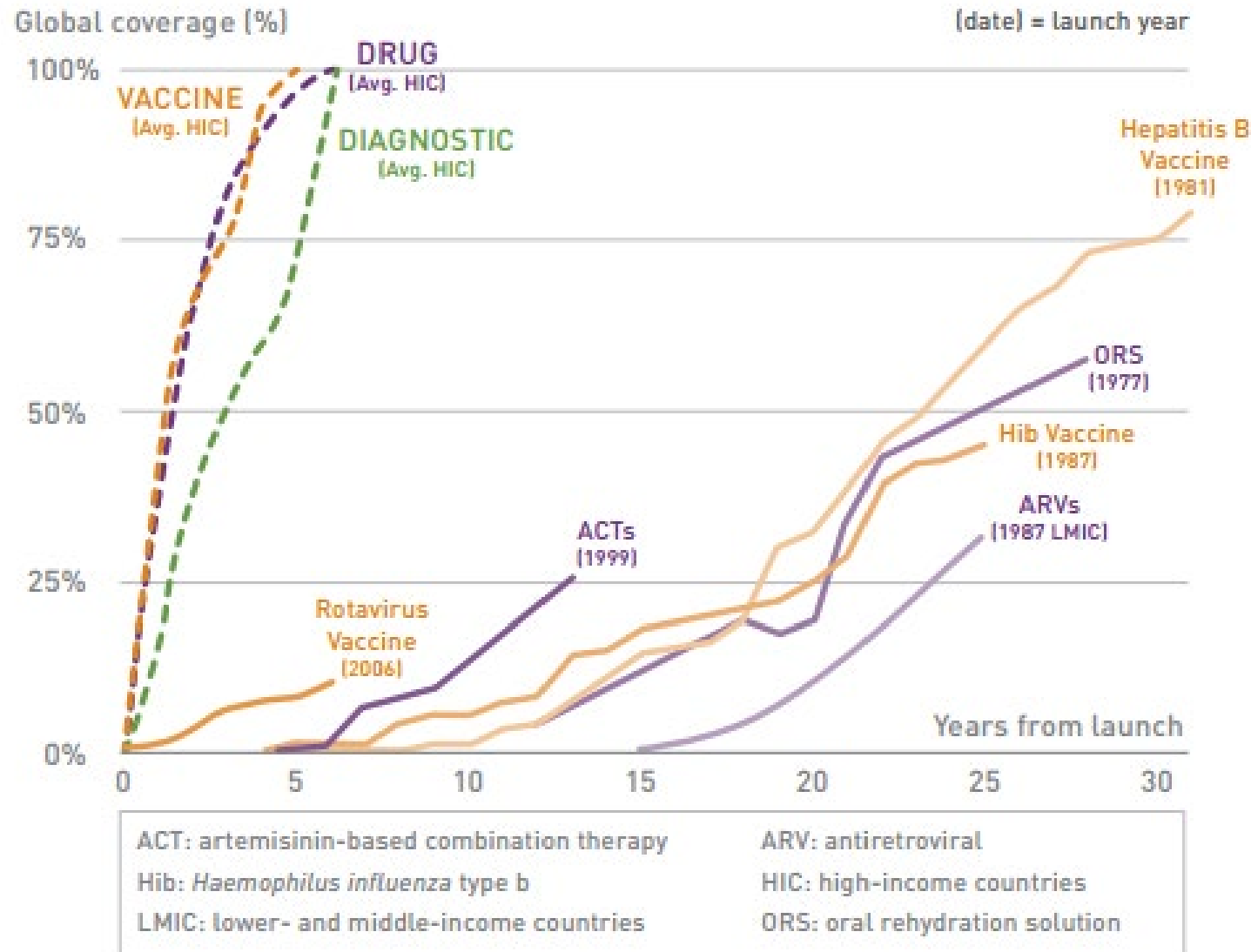
2 Catalyzed momentum and facilitated **multi-stakeholder, cross-partner action and learning** to support PrEP rollout at the national, regional, and global levels

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.

4 Shaped the market in priority early adopter countries for **new PrEP products in the pipeline**, specifically for the Dapivirine vaginal ring.

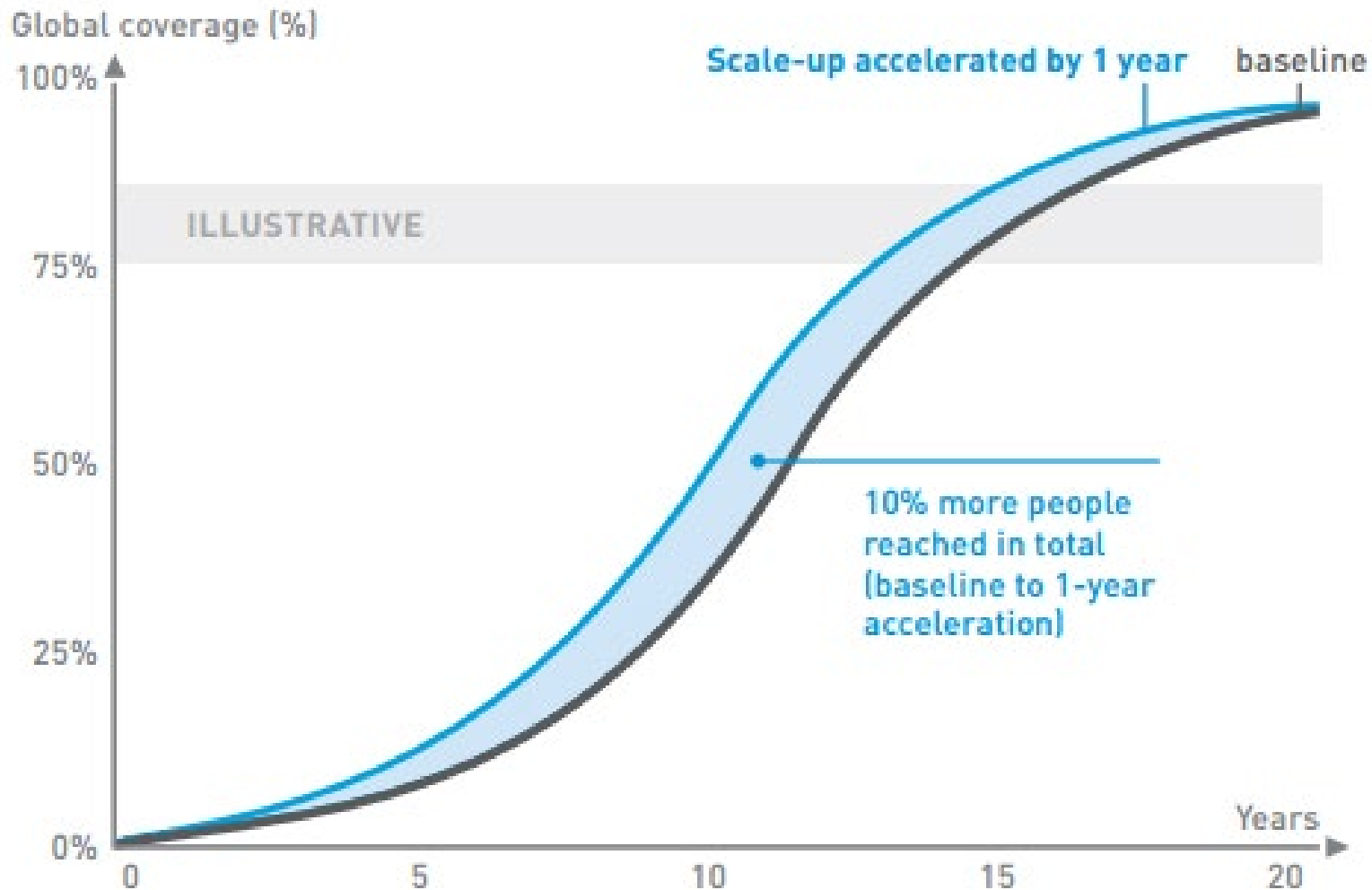
However, there is an unfinished agenda on PrEP – strengthening oral PrEP implementation whilst leveraging the existing program delivery platform to accelerate the introduction of new products

Delay between trial results, implementation and access



In the past, diffusion-dissemination strategies have resulted in about 14% use of evidence-based programs after about **17 years**

Source: USAID (2015) *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations*



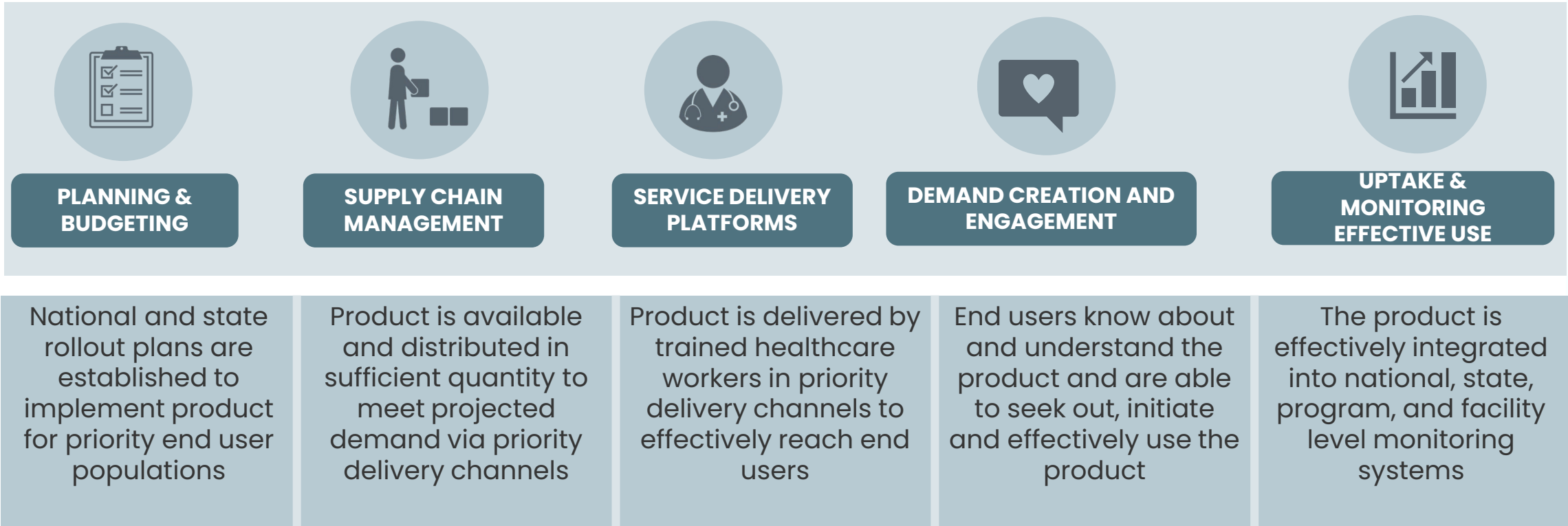
Benefits of accelerated scale; however can only be achieved through rapid learning and understanding of what impedes or facilitates programme implementation (incl. how products are developed and delivered)

Accelerating scale-up by just one year can result in an increased reach of 10 percent of the target population per year.

Source: Dalberg Global Development Advisors

Source: USAID (2015) *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations*

What is required to scale new and existing biomedical prevention products – the Product Introduction Framework



The value chain below must be preceded by the finalisation of guidelines, submission to NEML, market shaping and tender process

*****This framework is dependant on mechanisms like MATRIX to ensure acceptable and affordable options are put forward*****

SNAPSHOT OF MOSAIC'S CAB PREP WORK ALONG THE INTRODUCTION PATHWAY

Policy, Plans & Costing	Supply Chain & Market Development	Service Delivery	Uptake & Effective Use	Monitoring & Evaluation	Cross-Cutting Activities
<p>Global guidance & national guidelines Contributing updates to WHO PrEP Implementation Tool, developing template guidelines for CAB PrEP, supporting adoption of national guidelines for CAB PrEP, integration with PMTCT and FP guidelines</p> <p>Implementation plans & national strategies Developing implementation plans and integrating CAB PrEP into national strategies, including support for target setting and forecasting (PrEP-it)</p> <p>Costing Conducting costing studies and analyses to inform implementation planning and budgeting</p>	<p>Market shaping Contributing to market shaping efforts to address supply-side barriers and global demand</p> <p>Demand forecasting Conducting analyses for demand forecasting</p> <p>Private sector Developing private sector engagement roadmap</p> <p>Supply chain Assessing product stockouts, supply chain readiness</p>	<p>Implementation research Conducting studies to assess implementation, acceptability, choice, uptake, patterns of use, prevention effective use, and cost; strengthening integrated and client-centered service delivery through quality improvement collaborative</p> <p>Provider training/ job aids/ counseling materials Developing and integrating CAB PrEP into national PrEP curricula, job aids and counseling materials</p> <p>Research and program collaborations Collaborating to identify common study indicators, pregnancy registry study; rapid data sharing to inform program scale-up</p>	<p>End-user engagement Implementing strategy to meaningfully engage potential end-users</p> <p>Positioning Strategy Expanding PrEP positioning strategy to include providers and key influencers</p> <p>Demand generation strategies & tools Providing technical guidance on integration of CAB PrEP into demand creation national strategies and integrating CAB PrEP into demand creation tools, including the HIV Prevention Ambassador Training</p>	<p>Resistance surveillance Supporting inclusion of CAB PrEP in HIV drug resistance surveillance platforms</p> <p>Routine M&E Assessing feasibility and acceptability of novel PrEP indicators for multi-product M&E, supporting system improvements/integration</p> <p>Laboratory strengthening Increasing capacity for HIVDR testing</p>	<p>Civil society engagement Developing and strengthening civil society partnerships, engagement, and advocacy</p> <p>Global collaborations Building and strengthening global collaborations with programs, networks, product developers, and funders</p> <p>Situation analyses Conducting value chain situation analyses to build on lessons learned from oral PrEP to inform rollout of CAB PrEP</p> <p>Capacity strengthening Strengthening local partner capacity to design and implement biomedical prevention product introduction activities and research</p> <p>Evidence & Resources Synthesizing and sharing CAB PrEP evidence and resources</p>

Implementation Technical Assistance provided at all stages of VC and all levels of governance

Early reflections from MOSAIC on supporting the introduction of DVR and CAB-LA*?

■ Supply chain

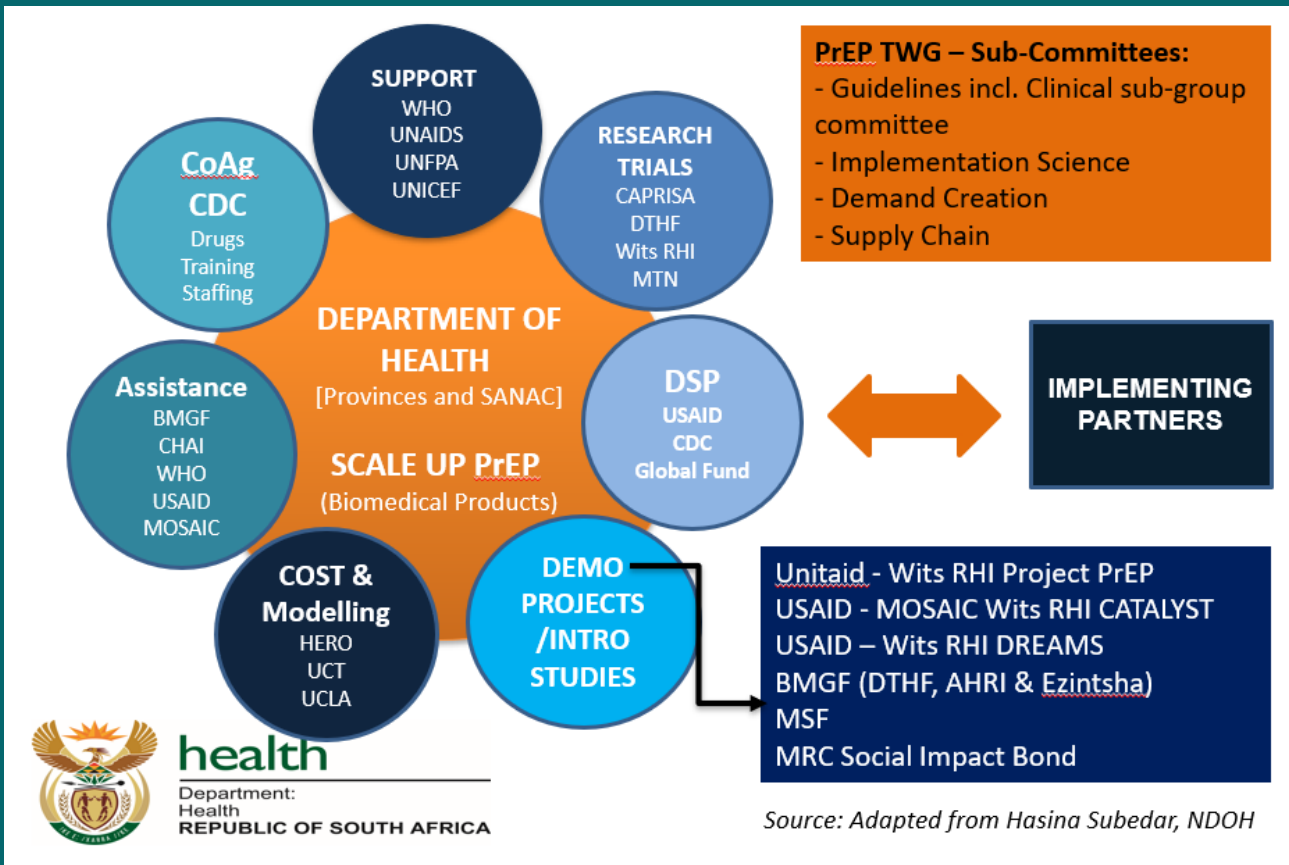
- Bridging the gap between trial result and product introduction and access must involve the product developers
- Communities understanding of regulatory process (DVR)
- Post study access messaging
- Early engagement with potential regulatory and supply chain partners to unpack acceptable strategies and pathways (SAHPRA experience)
- Use of authorised routes to ensure commercial import of products – Market Authorisation Holders (MAH)
- Cost – impediment to inclusion on National Essential Medicines list

■ Policy, Coordination and Costing

- Establishing pricing to support demand forecasting and costing for national governments
- National coordination is essential – MOH need local data, standard implementation and training package, guidelines, messaging and IEC, reporting system and indicators,



Example: Country-level coordination and collaboration



South Africa National Department of Health
Collaborative Framework for PrEP

MOSAIC EXPERIENCE

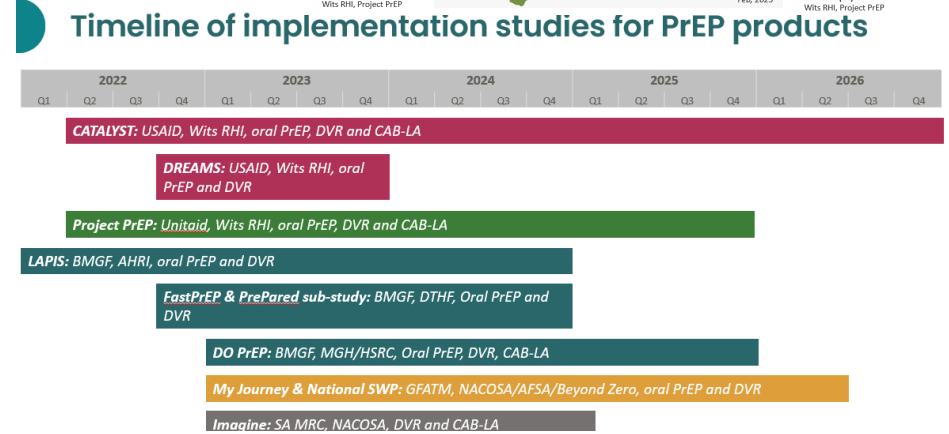
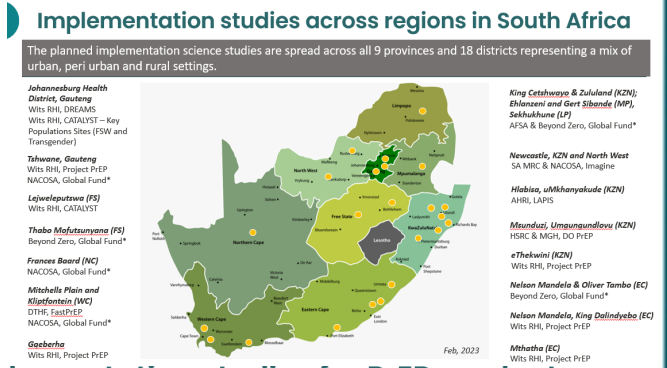
- While oral PrEP scale-up in South Africa has been successful, it was **complex** with many different partners doing different things
- Coordination and collaboration at the country level helps to **avoid duplication, identify synergies** and **optimize resources**
- South Africa example of a **collaborative framework** for PrEP led by the NDOH
 - Includes interagency partners working together on a shared agenda
 - MOSAIC co-leads PrEP TWG sub-committees on guidelines, implementation science and demand creation, and supports the supply chain subcommittee

A healthcare worker in a white lab coat is seated at a desk, gesturing with her hands while talking to a patient. The patient is wearing a headscarf and a patterned shawl. The desk is cluttered with papers, a blue container, and other medical supplies. The background shows a window with green curtains and a poster on the wall.

**Service Delivery:
Implementation
Research, provider
training, job aids and
counselling materials**

Collaboration with Afton Bloom to conduct an analysis of Priority Research Questions and Study Mapping in South Africa

- Building on from work started by Wits RHI – study mapping and priority research questions, with Afton Bloom synthesising information to inform current and future priorities
- Objectives of the synthesis:**
- A number of questions remain around how to best introduce the new biomedical HIV prevention methods for AGYW and FSW in South Africa.
- This analysis aims to:
 - Investigate which questions will / will not be addressed by the current slate of ongoing or planned implementation science.
 - Provide an understanding of when insights across key questions will become available, to help inform the rollout planning for the new PrEP methods in South Africa



Anticipated coverage of priority research questions

Question	Status	Summary
Q1 What is an affordable price and the cost of PrEP delivery across multiple PrEP products?	Some studies address topic	The cost of delivery will be widely assessed across delivery channels; there remains a gap for affordable pricing, particularly for CAB-LA.
Q2 Which delivery platforms and / or models will best reach populations who need PrEP?	Significant coverage in studies	The effectiveness of delivery channels to reach priority populations as well as the comparison across delivery platforms are widely covered.
Q3 What are the service readiness and delivery requirements for the new PrEP methods?	Some studies address topic	Several studies focusing on service readiness and delivery requirements for the new PrEP methods.
Q4 What are provider attitudes and beliefs about the new PrEP methods and what are we learning about how to inform or shape them?	Some studies address topic	Several studies assess provider attitudes and beliefs, including a few that include healthcare workers as a target population for evaluation.
Q5 How should the new PrEP methods be integrated within oral PrEP provision and / or existing PrEP programming?	Some studies address topic	Several studies focus on the integration of the new PrEP methods within oral PrEP provision; yet more coverage is needed across delivery channels.
Q6 Which demand generation strategies are most effective to support uptake and effective use of the new PrEP methods?	Some studies address topic	While 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 between them?	Significant coverage in studies	End user preferences (patterns of use, method switching, discontinuation and restart, etc.) are widely covered across all studies for all of the PrEP methods.
Q8 How do key influencers affect the uptake and effective use of the new PrEP methods, and how can they effectively be engaged?	Significant coverage in studies	A large number of the studies will focus on understanding key influencer attitudes and beliefs as well as how to effectively engage them.
Q9 What evidence of social harms associated with PrEP use has emerged, particularly for the PrEP ring?	Some studies address topic	Social harms will be tracked across several studies as a subcomponent for monitoring negative consequences of PrEP use.
Q10 What tools effectively support choice between the PrEP methods?	Some studies address topic	A few studies will study the effectiveness of support approaches for PrEP choice.
Q11 What approaches are most effective to strengthen linkages between PEP and PrEP?	No studies address topic	No studies focus on the linkages between PEP and PrEP programming.
Q12 What is the frequency and characteristics of seroconversion and HIV drug resistance for PrEP users across the new PrEP methods?	Significant coverage in studies	PrEP efficacy across the methods for specific population groups as well as seroconversion and HIV drug resistance (HIVDR) data are widely tracked..

Legend: Significant coverage in studies (Green), Some studies address topic (Yellow), No studies address topic (Pink)

Catalyzing access to new prevention products to stop HIV

The CATALYST study, under the MOSAIC project, will use mixed methods to characterize and assess the implementation of an enhanced service delivery package providing choice of PrEP products among women at PEPFAR delivery sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe.

STUDY DESIGN

- Implementation of **an enhanced service delivery package that supports choice** among the PrEP products that have regulatory approval in each country, such as oral PrEP, PrEP ring and injectable cabotegravir for PrEP.
- Includes components at the individual, provider, facility and community levels
- Uses **quality improvement methods** to refine components and identify a core service delivery package for PrEP choice

OBJECTIVE 1

Characterize the implementation of an enhanced service delivery package for PrEP choice and assess individual-, provider-, facility-, community- and health system-level facilitators and barriers of the implementation process

OBJECTIVE 2

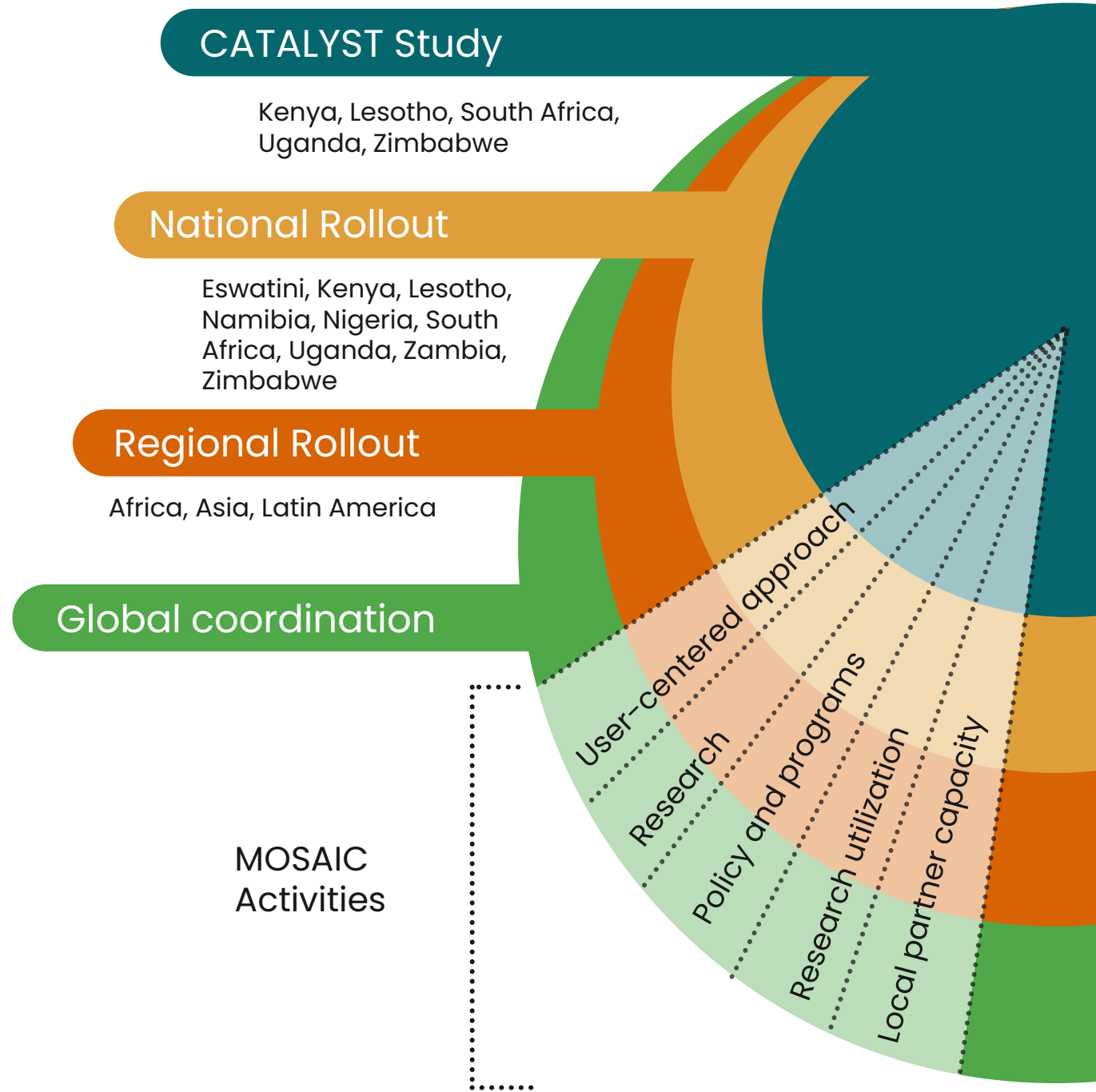
Describe patterns of PrEP use and use effectiveness in the context of PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns

OBJECTIVE 3

Describe clinically relevant indicators among PrEP users, including rates of HIV infection and drug resistance among PrEP users who acquire HIV following PrEP exposure

CATALYST functions as a learning lab

CATALYST serves as a **learning laboratory** for new product introduction. Learnings from CATALYST and MOSAIC activities **flow** across national, regional and global levels.



Uptake and effective use:

- Acceptability, to who?
- Providers – route of administration – How easy to use/implement – e.g. CAB and testing algorithm for identifying seroconversions and acute HIV
- End user engagement – young people want simplified and self care (product development that resonates with the needs around frequency, integration with contraception etc)
- End users and health system feedback is crucial so that only promising technologies move forward with limited resources
- Demand generation
 - a balance of creating awareness with demand in early stage roll out/introduction
 - Refreshing the image of existing messaging for HIV prevention – positioning strategies
 - Understanding the concerns with messaging at community level – risks to product introduction and scale
- Monitoring uptake and use – alignment of indicators and data harmonization



The road from product development to introduction and access

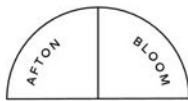
“Product development, however, is only half the equation – these products must efficiently reach, and be used by, those most at-risk to contribute toward HIV epidemic control”



ACKNOWLEDGMENTS

Would like to acknowledge partners of the MOSAIC consortium, National Ministries who continue to support this critical work and our communities and health providers who remind us of what is needed to ensure access.

For more information, contact Kristine Tjoresen; ktorjesen@fhi360.org



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