

Changing landscape of PrEP in Africa

Saiqa Mullick, MBBCh PhD (Wits RHI)

HPTN Regional Meeting, Cape Town 27th September 2023

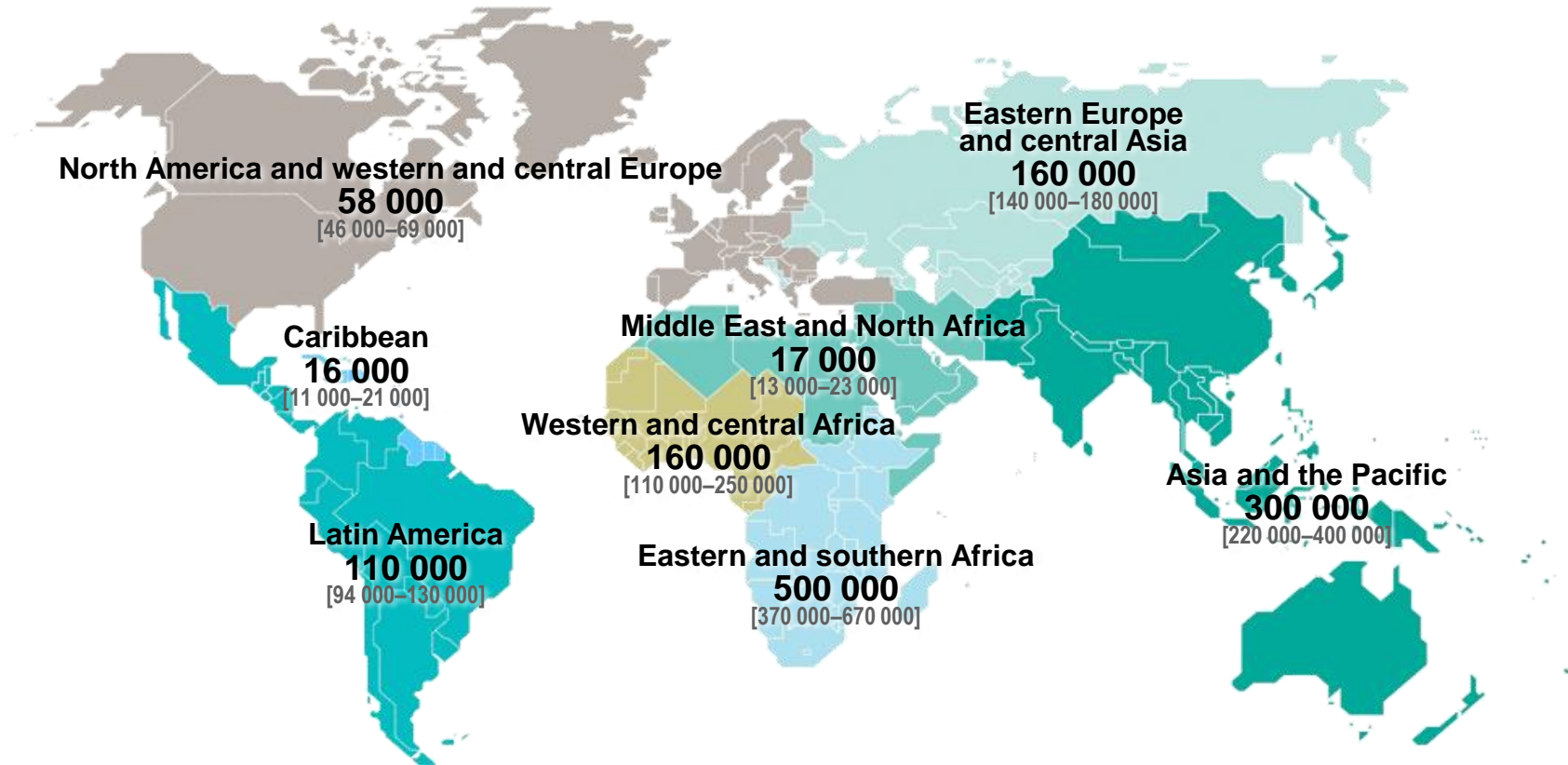


Key takeaways

- **East and Southern Africa bear the highest burden of HIV, although HIV incidence is declining, AGYW and key populations are disproportionately affected**
- **Oral PrEP has been rolled out and uptake has been highest in the Africa region - but below targets**
- **High uptake has been due to many factors including coordination, availability of tools and resources, understanding the value chain for product introduction and many differentiated service delivery models**
- **New long-acting PrEP methods: DVR and CAB-LA approved in several African countries**
- **Many demonstration studies are planned and underway, some of which are large, real-world demonstration projects**
- **Stigma, access for pregnant and breastfeeding people, under 18s, cost, supply chain, scheduling of new methods, and the coexisting burden of STIs and unmet need for contraception remain challenges.**

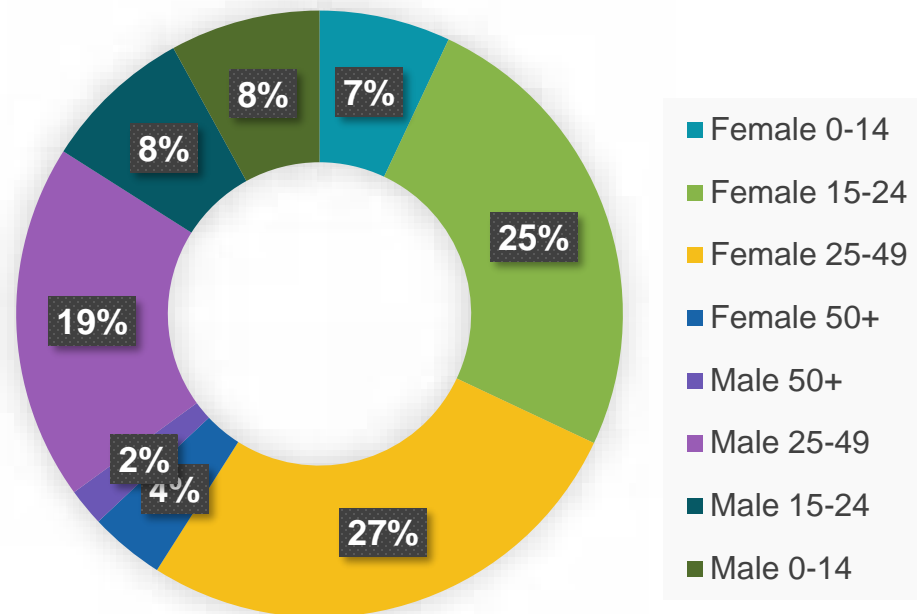
East and Southern Africa bear a high burden of HIV

Estimated number of adults and children newly infected with HIV | 2022

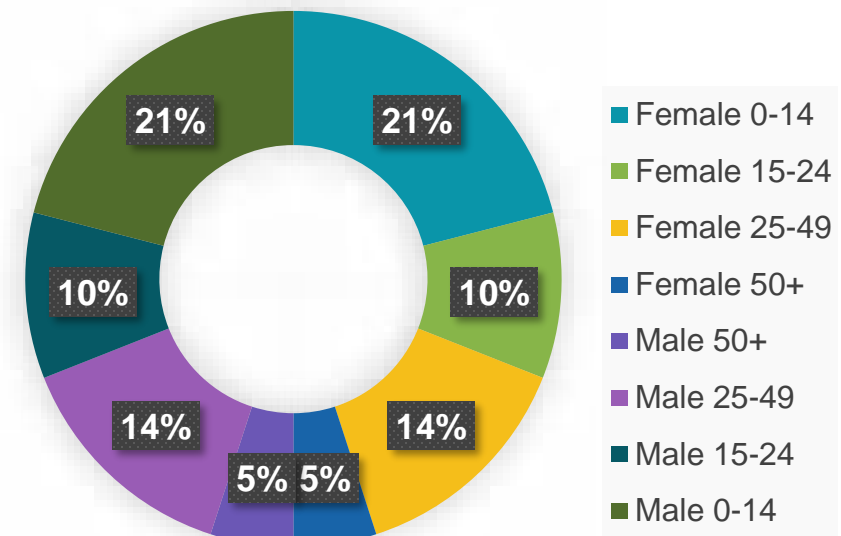


Women and girls bear a disproportionate burden of HIV in sub-Saharan Africa

New HIV infections, sub-Saharan Africa

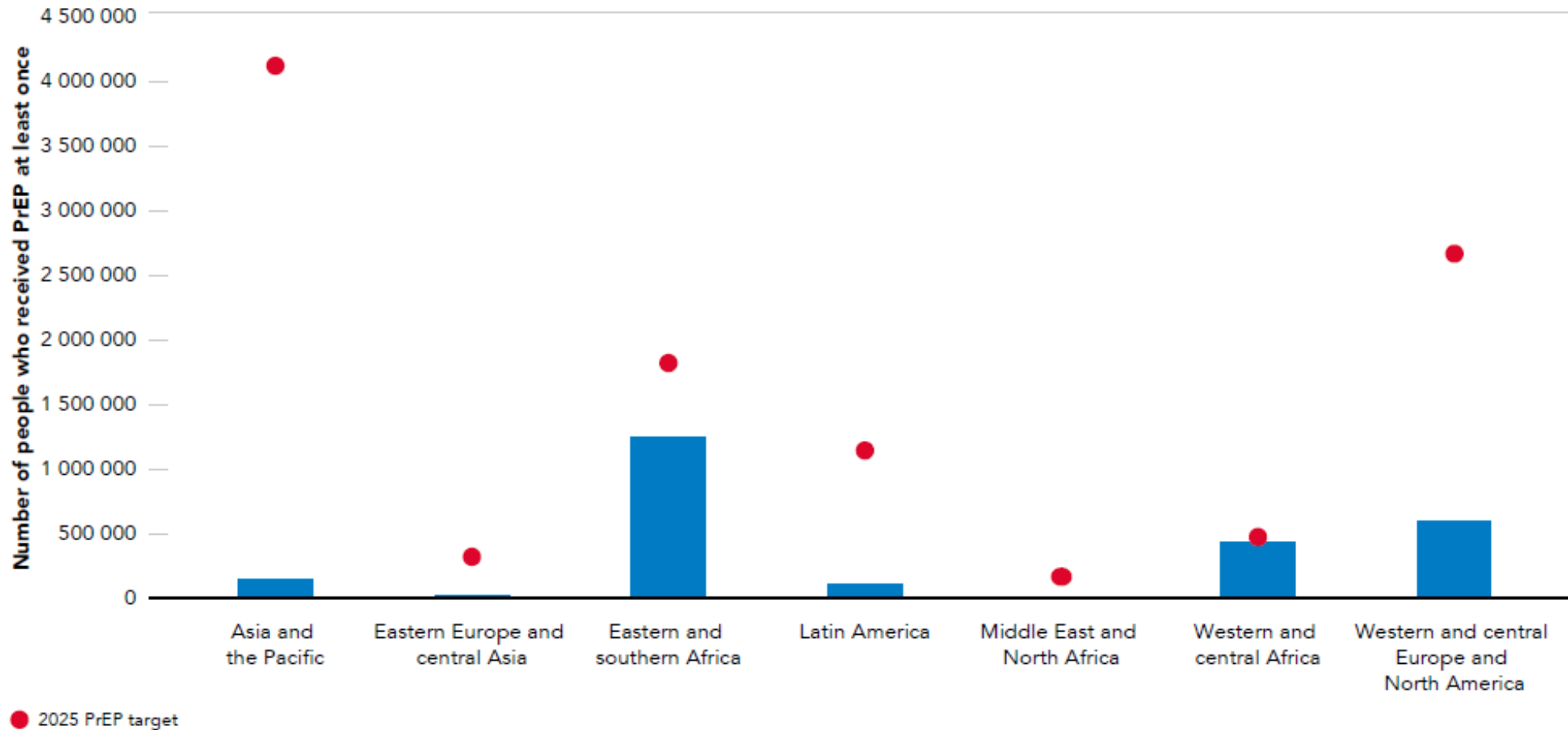


Population distribution, sub-Saharan Africa



Distribution of new HIV infections and of the population, by age and sex, sub-Saharan Africa, 2020

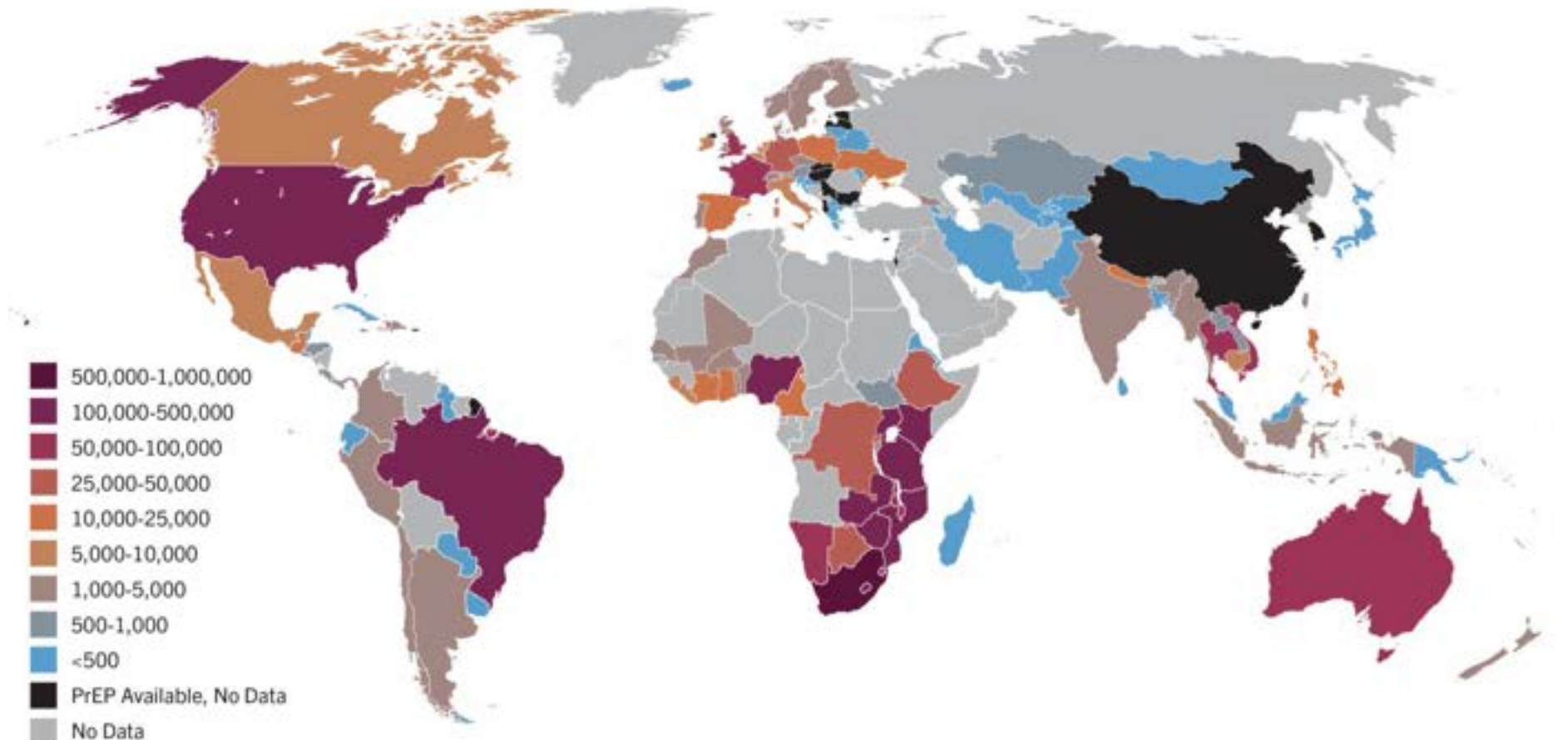
Since 2015, oral PrEP uptake increased exponentially, especially in ESA...



Global PrEP Uptake – 11+ years in

PrEP initiations by country, August 2023

Approximate
total PrEP
initiations: 4.9
million
with strong
increases in
2022



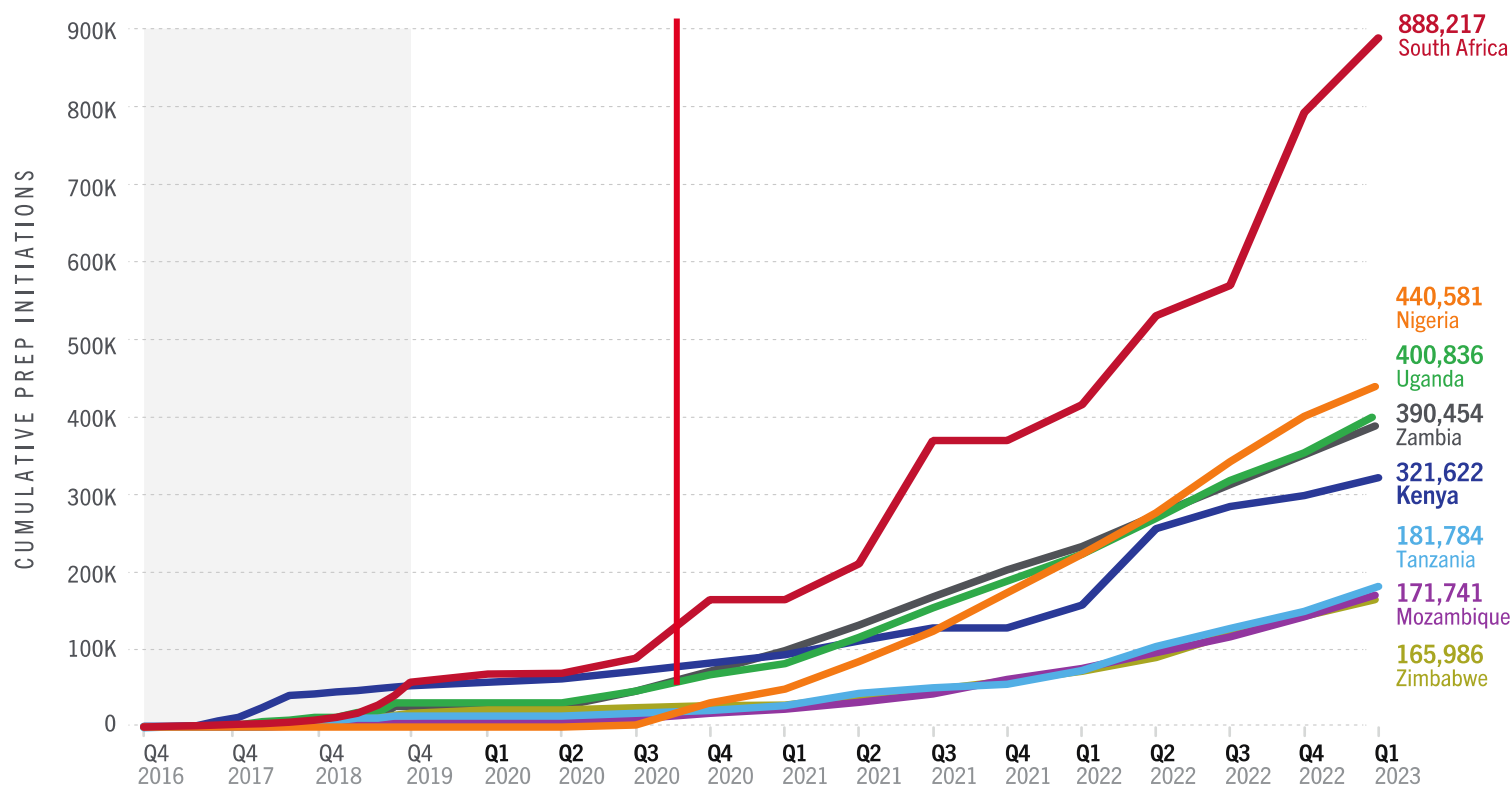
Source: AWAC Global PrEP Tracker, Q2 2023,
<https://www.prepwatch.org/data-by-country/>

Country trends in oral PrEP uptake

- Eight countries in SSA have surpassed 100,000 PrEP initiations, accounting for 91% initiations in the region
- South Africa and Kenya were two of the earliest adopters with national programs scaling up over time
- Zambia, Uganda and Nigeria have seen steep growth since 2021 – nearly 100% of initiations in these countries were PEPFAR-driven

Trajectory of Countries with Most PrEP Initiations in Sub-Saharan Africa (SSA)

2016–2023



Global coordination!

Coalition to Accelerate Access to Long-Acting PrEP July 2022

Convenors:



Secretariat:



Purpose

The **Coalition to Accelerate Access to Long-Acting PrEP** is a new initiative that brings together leading donors, agencies, and advocates to ensure an accelerated, equitable, sustainable and collaborative approach to making longer-acting PrEP options accessible as quickly and as equitably as possible. The Coalition is convened by Unitaid, WHO, UNAIDS, Global Fund and PEPFAR, with AVAC as the Secretariat.

The objective of this coalition is practical: *to coordinate key stakeholder activities on PrEP access, including jointly developing strategies to identify and overcome access challenges for new PrEP options in the near- to medium-term (especially as relates to ViiV's injectable CAB, including generics, and the dapivirine vaginal ring) and the medium- to longer-term (as relates to future PrEP products).*

MOSAIC

Maximizing Options to Advance Informed Choice for HIV Prevention

OPTIONS

OPTIMIZING PREVENTION TECHNOLOGY INTRODUCTION ON SCHEDULE

MATRIX

Advancing R&D of Innovative
HIV Prevention Products for Women

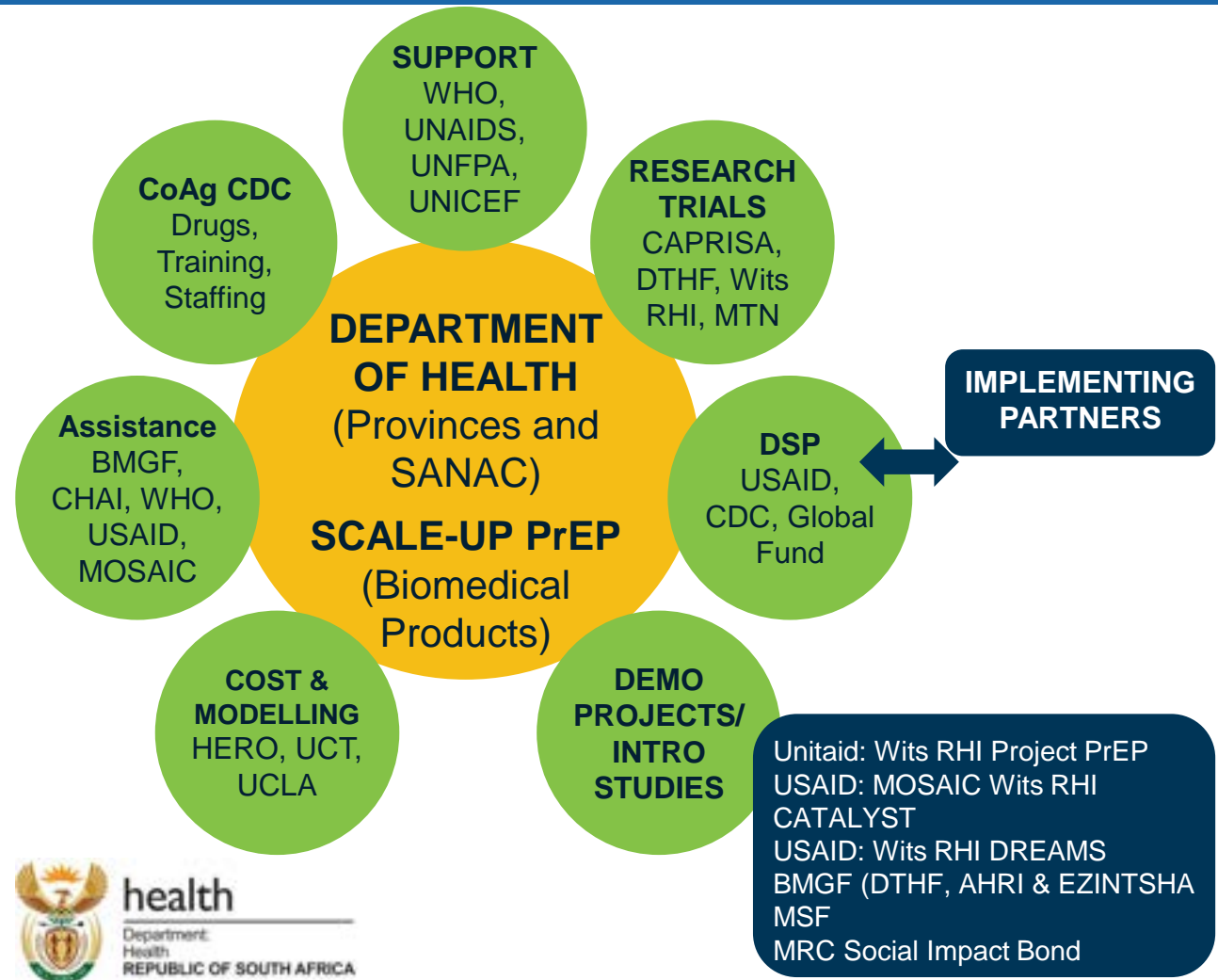
BioPIC

Country-level coordination and collaboration is essential for success

MOSAIC Experience

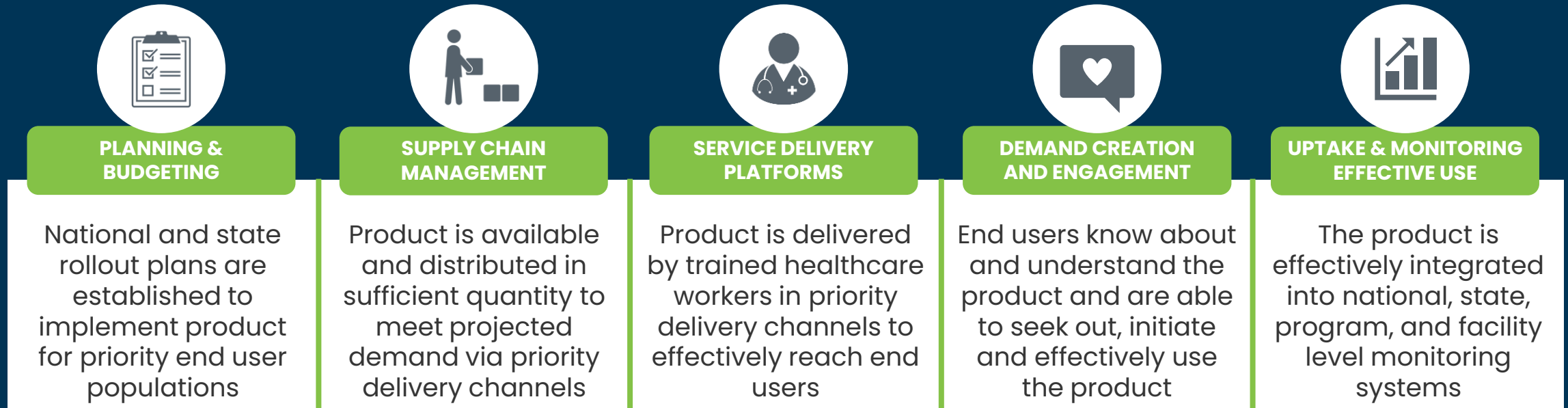
- While oral PrEP scale-up in South Africa has been successful, it was **complex** with many different partners doing different things
- Coordination and collaboration at the country level helps to **avoid duplication**, **identify synergies** and **optimize resources**
- South Africa example of a **collaborative 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

South Africa National Department of Health: Collaborative Framework for PrEP



Clear path from research to national implementation at scale:

The Product Introduction Framework (VALUE CHAIN)



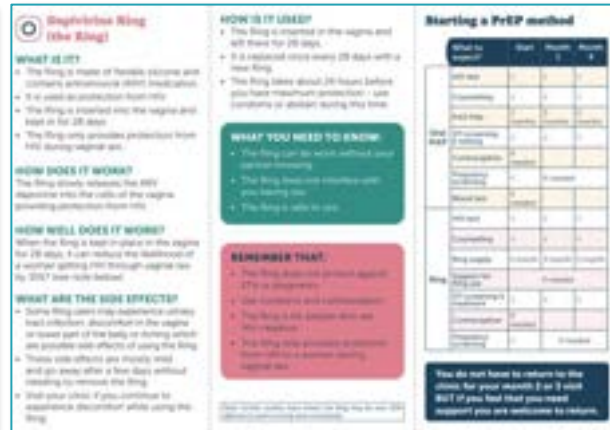
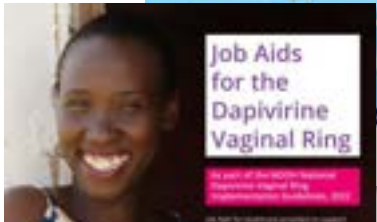
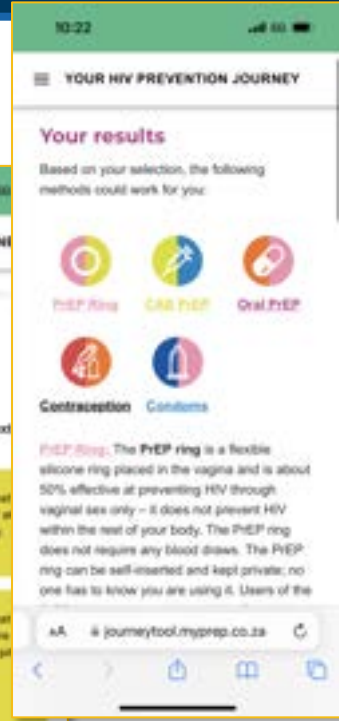
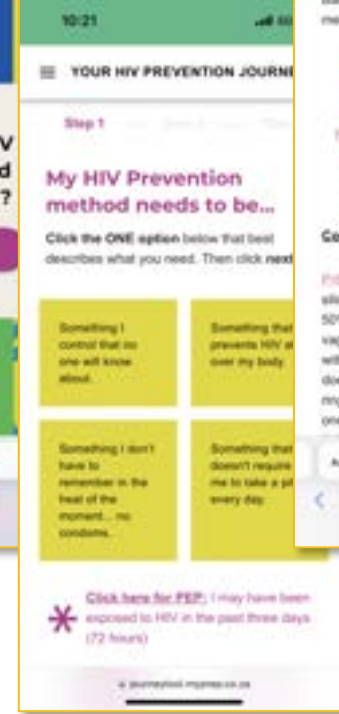
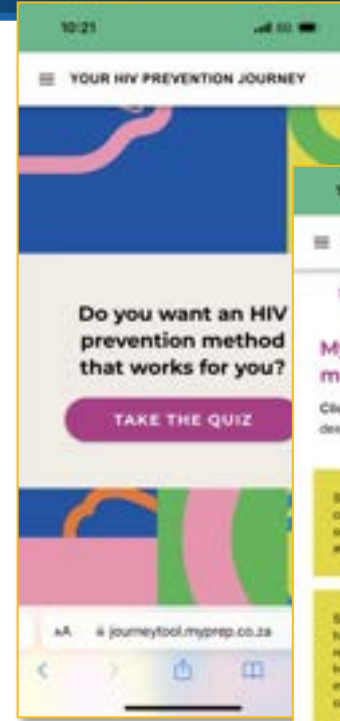
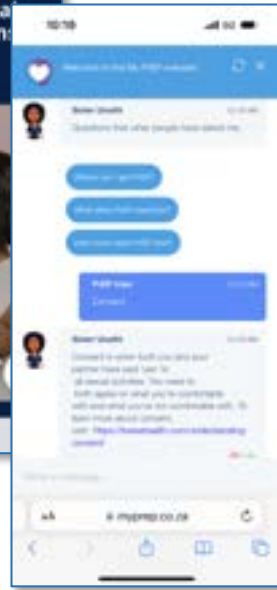
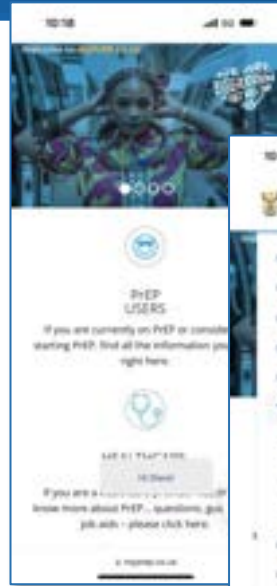
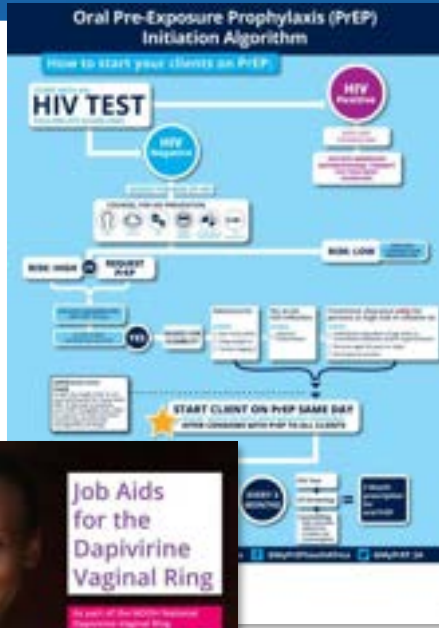
The value chain must be preceded by the finalisation of guidelines, submission to NEML, market shaping and a tender process.

This framework is dependent on product developers to ensure acceptable and affordable options are put forward.

Multiple key tools and resources available along the introduction pathway:

Policy, Plans & Costing	Supply Chain & Market Development	Service Delivery	Uptake & Effective Use	Monitoring & Evaluation	Research
<p>PrEP Guideline Template Supports rapid guideline development, up to date with latest WHO guidance</p> <p>Implementation Plan Template In progress, to support rapid programmatic planning</p> <p>CAB Value Chain Situation Analysis Template Recently finalized to allow IPs/ministries to carry out their own assessments</p>	<p>PrEP-it Ongoing development to ensure good user experience/based on user feedback</p> <p>Supply chain 101 Unpacking the supply chain for biomedical prevention (provided to MATRIX)</p> <p>Regulatory 101 Provides an overview of the regulatory process for new PrEP methods. Provided to MOSAIC countries as requested by Mission/MOH</p>	<p>AHI assessment tool Developed, utilized in CATALYST; non-CATALYST version available for adaptation</p> <p>PrEP ring clinical training Developed, utilized in CATALYST and adapted by select MOSAIC countries</p> <p>Provider training on choice counselling Developed and utilized in CATALYST</p> <p>PrEP for PBFP Provider Training Course Updated to include PrEP ring</p>	<p>HIV Prevention Journey Tool Adapted for country use in CATALYST</p> <p>HIV Prevention Ambassadors Training Package Update for KPs/diverse populations in progress; AGYW version utilized in CATALYST</p> <p>Digital health demand generation resource pack In development- to guide digital health selection for PrEP demand generation</p> <p>Positioning strategy for AGYW In development- validation completed in SA, Kenya and Zimbabwe</p>	<p>HIVDR monitoring tools HIVDR toolkit (developed under GEMS) gets updated with new resources added through MOSAIC</p> <p>Proposed M&E indicators Novel PrEP indicators developed by the MOSAIC M&E WG; 'volume of PrEP prescribed' included as new WHO SI indicator</p>	<p>CATALYST/Ring Study protocol and implementation tools Available for public access; shared widely with ring and CAB researchers (Vietnam, Malawi, Cambodia, Kenya, Nigeria, South Africa)</p>
<p>More information on these resources can be found here: MOSAIC - PrEPWatch</p>					

Examples of available technical resources



Many differentiated service-delivery models are being implemented

- Healthcare facilities
- Mobile clinics at community hotspots
- Gazebos at community hotspots
- Pharmacy models
- Community-Based Organisations (CBOs) as pick-up points
- Universities and TVET colleges
- Service delivery at high schools
- Linkage to care through social media messengers and WhatsApp 4 Business

But we still have a huge burden of disease, especially STIs



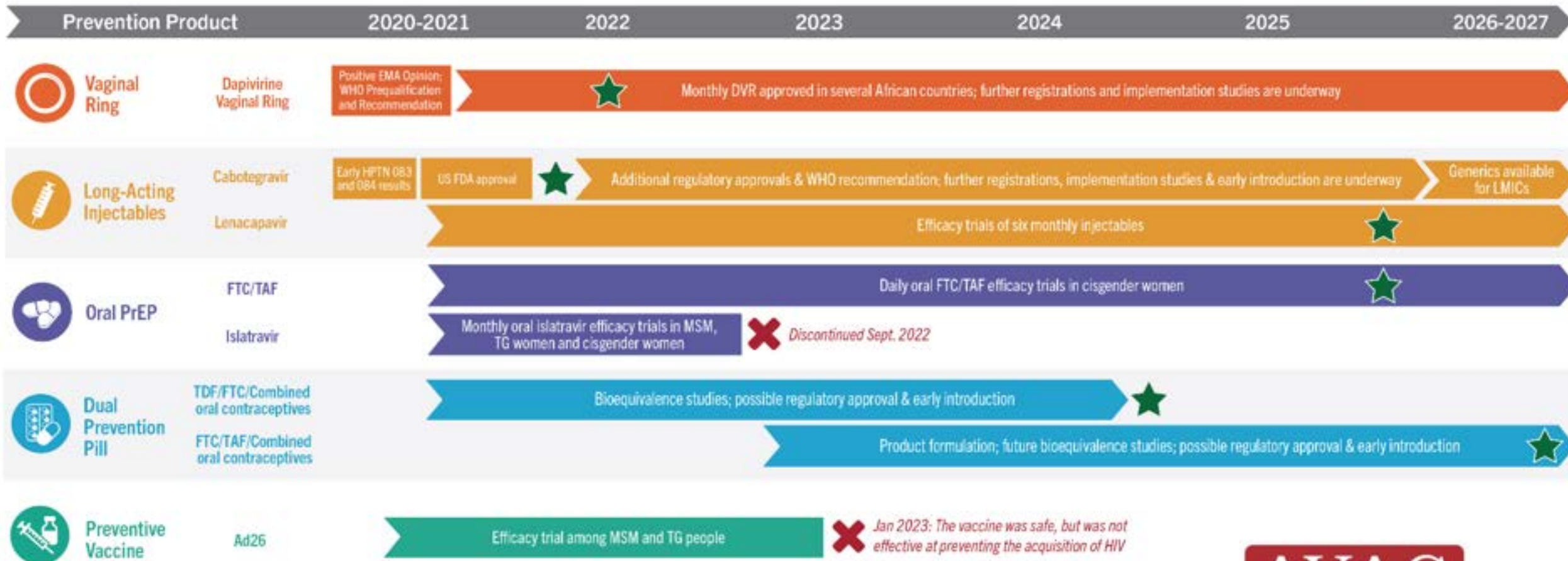


Community and youth engagement are key!

We need a multi-method market

Time to market

★ Earliest time to market
 ✗ Discontinued



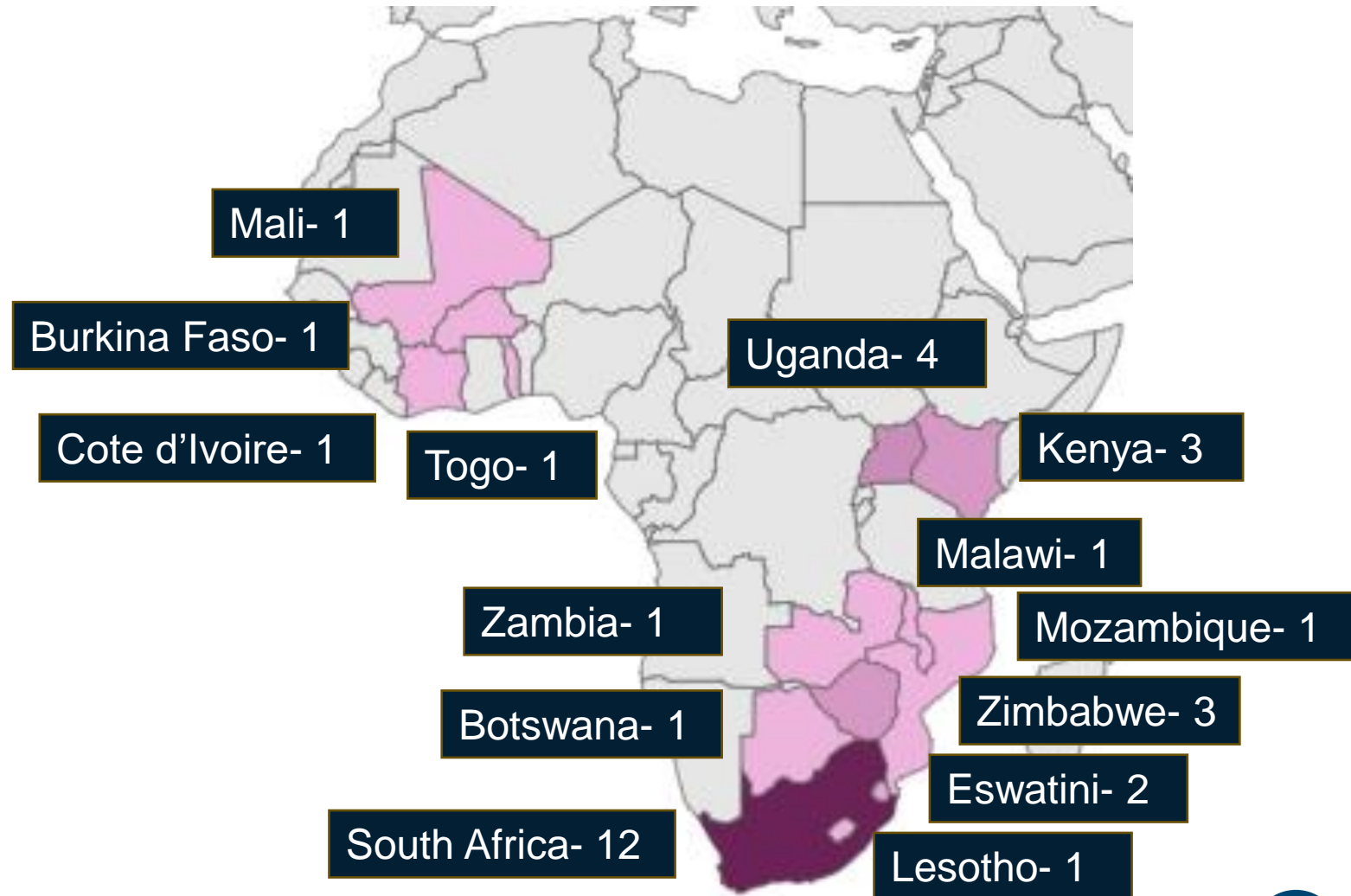
PrEParing for New Products in Africa

Country	CAB for PrEP Regulatory Status	DVR Regulatory Status	HPTN 083/084 Studies	Ring/ASPIRE Studies	PURPOSE 1/2 Studies	PEPFAR CAB Procurement 2023-2025 (# people)	Global Fund PrEP Matching Funds	Approved Implementation Studies	Planned Implementation Studies
Botswana	Approved	Approved						1	
Eswatini	Via South Africa	Approved				Starting 2024/25		1	1
Ethiopia		To file in 2023							
Kenya	Pending	Approved				Priority waitlist	\$3,000,000	3	
Lesotho	Via South Africa	Approved				Starting 2024/25		1	
Malawi	Approved	Pending				10,000		1	
Mozambique	To file in 2023	To file in 2023					\$3,750,000		1
Namibia	Pending	Pending							
Rwanda	Pending	Approved							
South Africa	Approved	Approved				Starting 2024/25	\$5,750,000	11	1
Tanzania	Pending	Under Appeal							
Uganda	Pending	Approved					\$3,000,000	4	
Zambia	Approved	Approved				8,000- 10,000	\$3,000,000	1	
Zimbabwe	Approved	Approved				10,000- 12,000		2	1
Burkina Faso									1
Cote D'Ivoire	Pending								1
Ghana		To file in 2023							
Mali									1
Nigeria	Pending	To file in 2023				Priority waitlist	\$6,500,000		
Togo									1

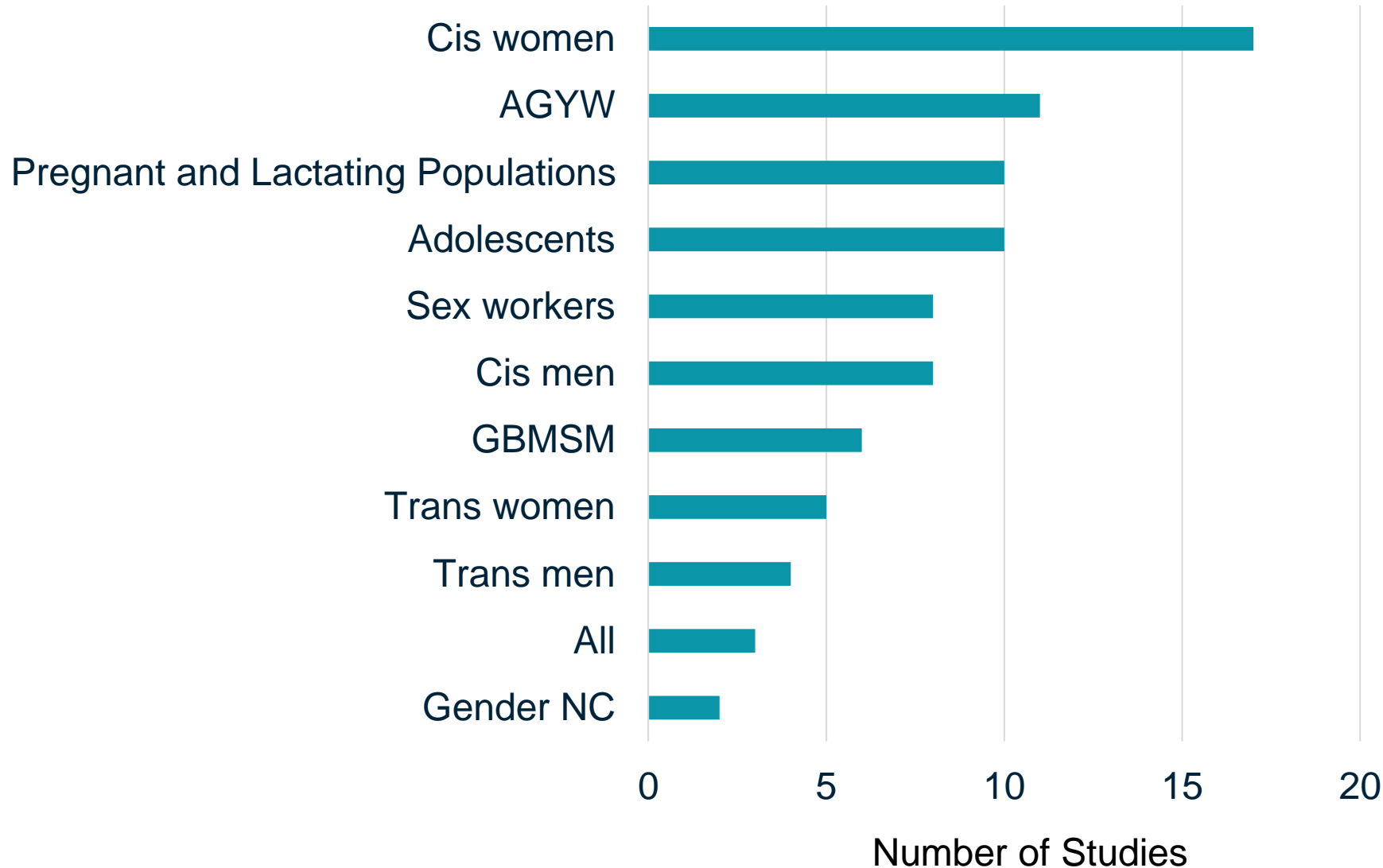
PrEParing for New Products- Geographically

Out of **36** planned and ongoing **CAB for PrEP and Dapivirine Vaginal Ring** implementation studies, **23** are taking place in Africa

**some studies are taking place in more than one country*

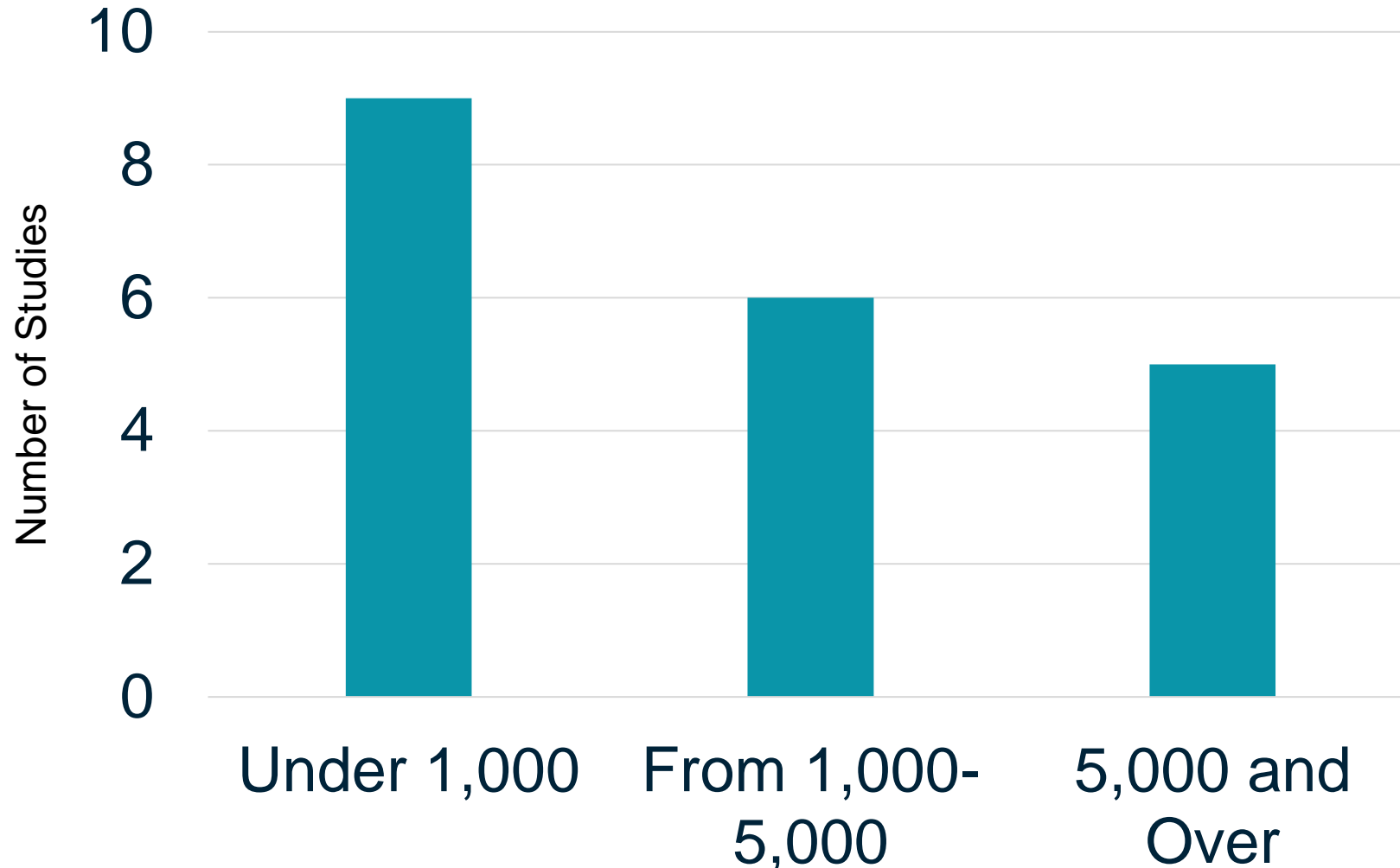


PrEParing for New Products- Study Populations (Africa)



- Cis women, AGYW, PLP, and adolescents well represented
- Trans and gender non conforming people less well represented
- No studies planned for people who use drugs or prisoners
- Inclusion of diverse populations is key to gather evidence around safety, adherence, etc.

PrEParing for New Products- Sample Sizes (Africa)



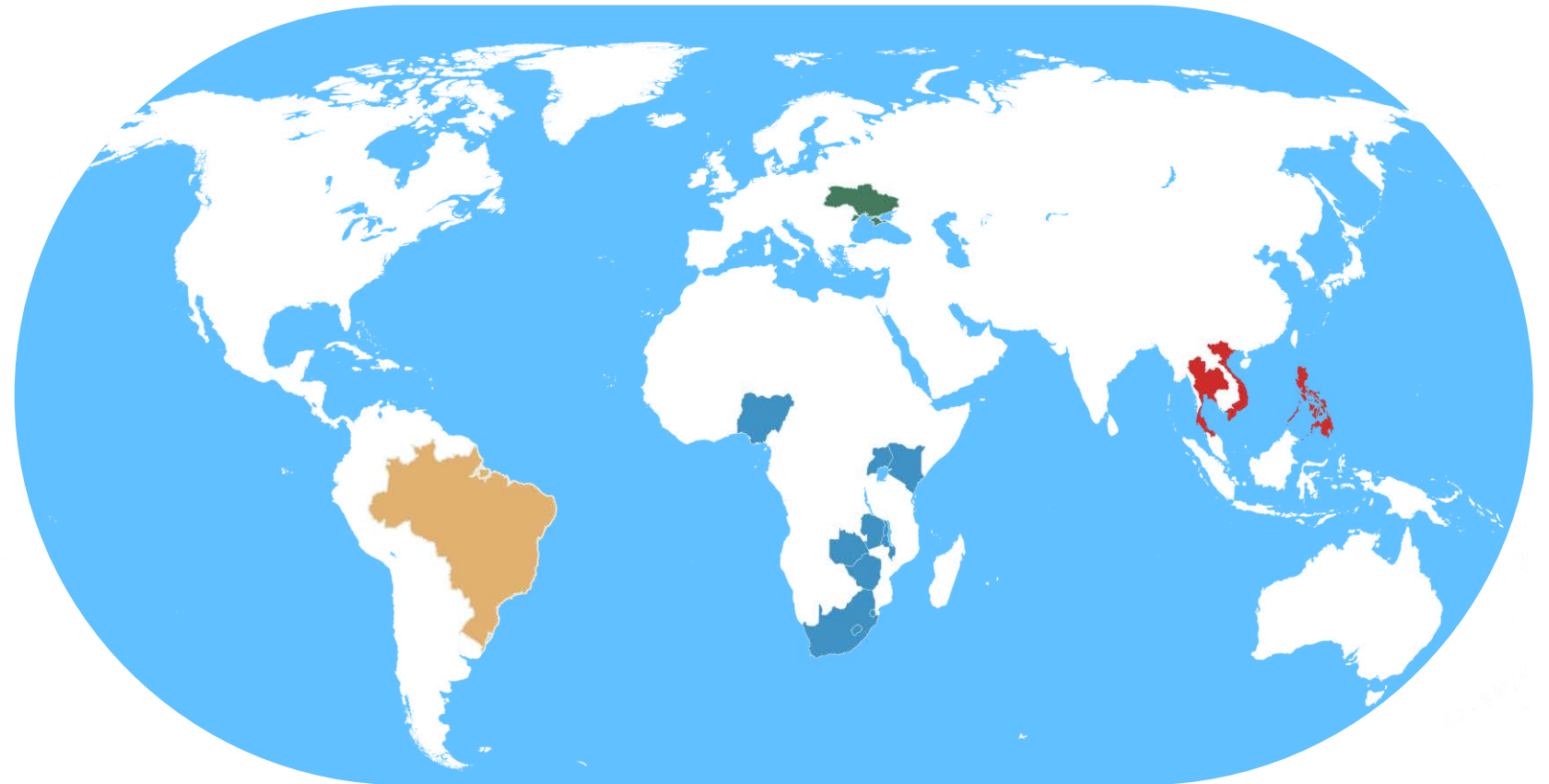
- Not all studies have established sample sizes
- Only five studies with over 5,000 participants: CATALYST (MOSAIC), Project PrEP (Wits RHI), FASTPrEP (DTHF), Theta Nami Ngithethe Nawe (“Let’s Talk”) (AHRI), and Path to Scale for CAB-LA in Malawi (BPS)
- Most studies plan to run 2023- 2025, dependent on approvals and CAB supply

Landscape of CAB PrEP Introduction – as of 09 Sep 2023

2023

8 studies introducing CAB in
6 countries: Brazil, Kenya,
Lesotho, South Africa,
Uganda, Zimbabwe

5 countries receiving CAB
through PEPFAR COP
allocations*: Malawi, Zambia,
Zimbabwe, Ukraine, Vietnam



2024/2025

Likely to start via
COP in first half of
2024*: Eswatini

Other potential countries on PEPFAR COP waiting
list*: Kenya, Lesotho, Nigeria, Philippines, South
Africa, Thailand, and Uganda (currently paused)

20+ studies in
the pipeline:
see [PrEPWatch](#)

**PEPFAR COP allocations may change*

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

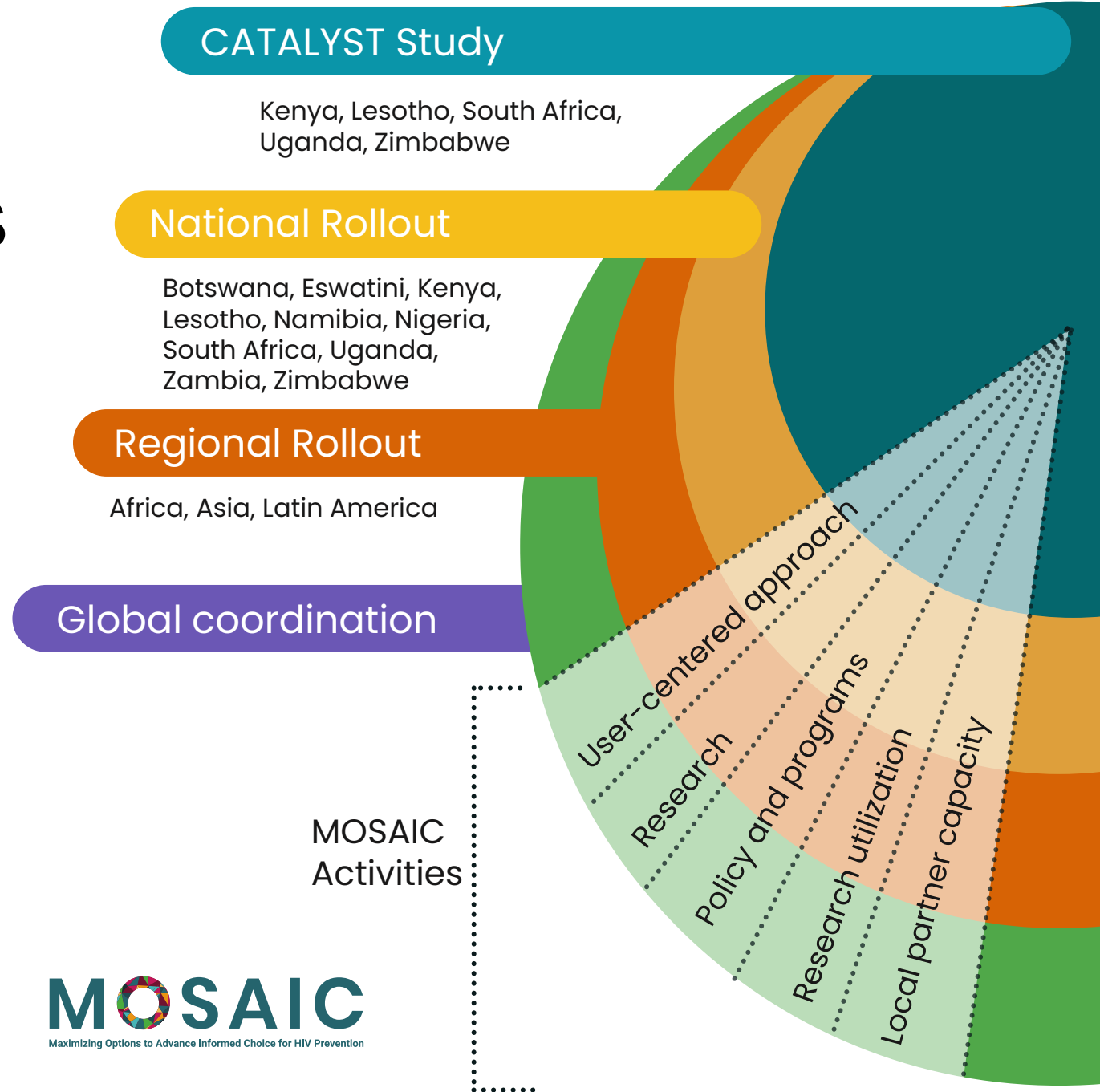
Describe patterns of PrEP use and use effectiveness in the context of PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns

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.



PrEP demonstration sites across regions in South Africa

The planned implementation science studies are spread across all 9 provinces and 18 districts representing a mix of urban, peri urban and rural settings.

Johannesburg Health District, Gauteng

Wits RHI, DREAMS
Wits RHI, CATALYST – Key Populations Sites (FSW and TNBP)
Wits RHI & Shandukani Research, Deliver & B-Protected
AXIS, Ezintsha

Tshwane, Gauteng

Wits RHI, Project PrEP
NACOSA, Global Fund*

Lejweleputswa (FS)

Wits RHI, CATALYST

Thabo Mofutsunyana (FS)

Beyond Zero, Global Fund*

Frances Baard (NC)

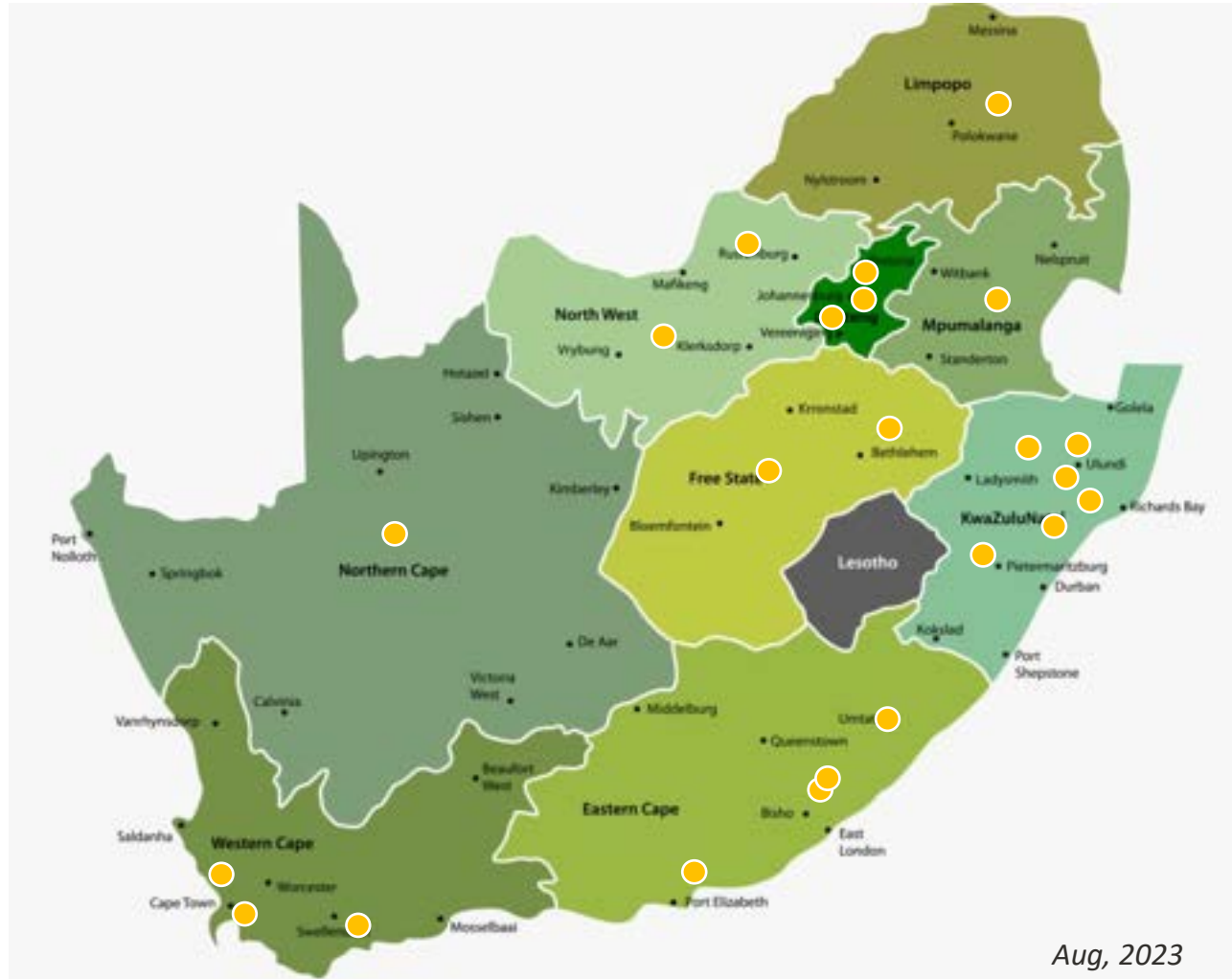
NACOSA, Global Fund*

Klipfontein Mitchell's Plain, Cape Town (WC)

DTHF, FastPrEP
NACOSA, Global Fund*
UTC, UCLA & DTHF, PrEP-PP & SCOPE-PP

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 MyJourney or National SWP

Anticipated coverage of priority research questions

Question	# of studies	Summary
Q1 What is an affordable price and the cost of PrEP delivery across multiple PrEP products?	6	While 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?	10	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?	5	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?	8	Provider attitudes and beliefs will be widely assessed, with several studies including 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?	4	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?	5	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?	12	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?	8	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?	9	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?	5	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 ?	2	Only two studies will aim to strengthen the linkages between PEP and PrEP.
Q12 What is the frequency and characteristics of seroconversion and HIV drug resistance for PrEP users across the new PrEP methods?	9	PrEP efficacy across the methods for specific population groups as well as seroconversion and HIV drug resistance (HIVDR) data are widely tracked..

■ Significant coverage in studies (+7 studies)
 ■ Some studies address topic (3-6 studies)
 ■ 1-2 studies address topic

Remaining challenges

#EndStigma + Laws impeding access for all	The full potential of PrEP, both oral and a category of products, has not yet been realized
PBFP – Limited access	Limited access remains problematic for pregnant and breastfeeding people who have known vulnerability but are often excluded
Under 18s – Limited choice	The full category of products have not yet been approved for under 18s - Most affected yet often excluded
High burden of STIs + contraceptive needs	Unmet contraceptive and STI management needs amongst those using PrEP - Integration and comprehensive services needed now
All current options are ARV-based	Current category are all ARV-based - complex scheduling and delivery, concerns about testing, HIVDR, side effects and more
COST	Affordability = Sustainability and Impact

Acknowledgements

- Kristine Torjesen (FHI 360)
- Hasina Subedar (NDOH South Africa)
- Mitchell Warren (AVAC)
- Sinead Delany-Moretlwe (Wits RHI)
- Thesla Palanee-Philips (Wits RHI)
- Elmari Briedenhann (Wits RHI)
- Nyaradzo Mgodzi (University of Zimbabwe)