
Pre-exposure prophylaxis (PrEP) for HIV prevention

WHO guidelines and guidance

Michelle Rodolph
WHO
rodolphm@who.int

WHO PrEP recommendations and guidance

HIVAIDS Programme

PrEP for SDC, MSM & TG (**conditional** rec in the context of demo projects)

GUIDANCE ON PRE-EXPOSURE ORAL PROPHYLAXIS (PrEP) FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV. Recommendations for use in the context of demonstration projects.

July 2012

2012

World Health Organization

PrEP for people at substantial HIV risk (**strong** rec)

GUIDELINES

GUIDELINE ON WHEN TO START ANTIRETROVIRAL THERAPY AND ON PRE-EXPOSURE PROPHYLAXIS FOR HIV

SEPTEMBER 2015

2015/16

TECHNICAL BRIEF

ED-PrEP

WHAT'S THE 2+1+1?

EVENT-DRIVEN ORAL PRE-EXPOSURE PROPHYLAXIS TO PREVENT HIV FOR MEN WHO HAVE SEX WITH MEN: UPDATE TO WHO'S RECOMMENDATION ON ORAL PrEP

JULY 2019

2019

World Health Organization

Updates on oral PrEP + dapivirine vaginal ring

GUIDELINES

CONSOLIDATED GUIDELINES ON HIV PREVENTION, TESTING, TREATMENT, SERVICE DELIVERY AND MONITORING: RECOMMENDATIONS FOR A PUBLIC HEALTH APPROACH

AUG 2021

2021

Differentiated and simplified pre-exposure prophylaxis for HIV prevention

Update to WHO implementation guidance

TECHNICAL BRIEF

2022

WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection

Provider module for oral and long-acting PrEP

2024

PrEP for MSM (**strong** rec); other KP (**conditional** rec) no recommendation for PWID

GUIDELINES

CONSOLIDATED GUIDELINES ON HIV PREVENTION, DIAGNOSIS, TREATMENT AND CARE FOR KEY POPULATIONS

JULY 2014

KEY POPULATIONS



Imp tool

MODULE 1 CLINICAL

WHO IMPLEMENTATION TOOL FOR PRE-EXPOSURE PROPHYLAXIS (PrEP) OF HIV INFECTION

JULY 2017

DPV-VR

WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection

CAB-LA

World Health Organization

GUIDELINES ON LONG-ACTING INJECTABLE CABOTEGRAVIR FOR HIV PREVENTION

WHO guidelines on PrEP and PEP for HIV



GUIDELINES

CONSOLIDATED GUIDELINES ON
**HIV PREVENTION, TESTING,
TREATMENT, SERVICE
DELIVERY AND MONITORING:**
RECOMMENDATIONS FOR A
PUBLIC HEALTH APPROACH

JULY 2021



GUIDELINES ON
**LONG-ACTING
INJECTABLE
CABOTEGRAVIR FOR
HIV PREVENTION**



Pre-exposure prophylaxis (PrEP)

2015. Daily Oral PrEP containing **tenofovir** as an additional prevention choice

2019. Event-driven PrEP for cisgender men & MSM

2021. Dapivirine vaginal ring for cisgender women at substantial risk of HIV infection

2022. Long-acting injectable cabotegravir (CAB-LA) as an additional prevention choice

Dapivirine vaginal ring (DVR)

Recommendations (2021)

The dapivirine vaginal ring may be offered as an additional prevention choice for women^a at substantial risk of HIV infection as part of combination prevention approaches (*conditional recommendation, moderate-certainty evidence*).

^aFor the recommendation on the dapivirine vaginal ring, the term women applies to cisgender women, meaning women assigned female at birth. There is no research at this time to support the dapivirine vaginal ring for other populations.

Source: *Guidelines: updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring (12)*.

- **A discreet** prevention choice for **women** that is **woman controlled**
- Phase III trial evidence support **safety** and **efficacy** (~30%)
- Open label extension studies suggest **higher efficacy** (~50 – 70%)
- **Safe:** Adverse events are **rare** and **no effect** on **contraceptives**
- Studies in **pregnant** and **breastfeeding women** support safety and acceptability
- Studies in **Asia-Pacific** support acceptability and feasibility



26 January 2021 | Departmental news

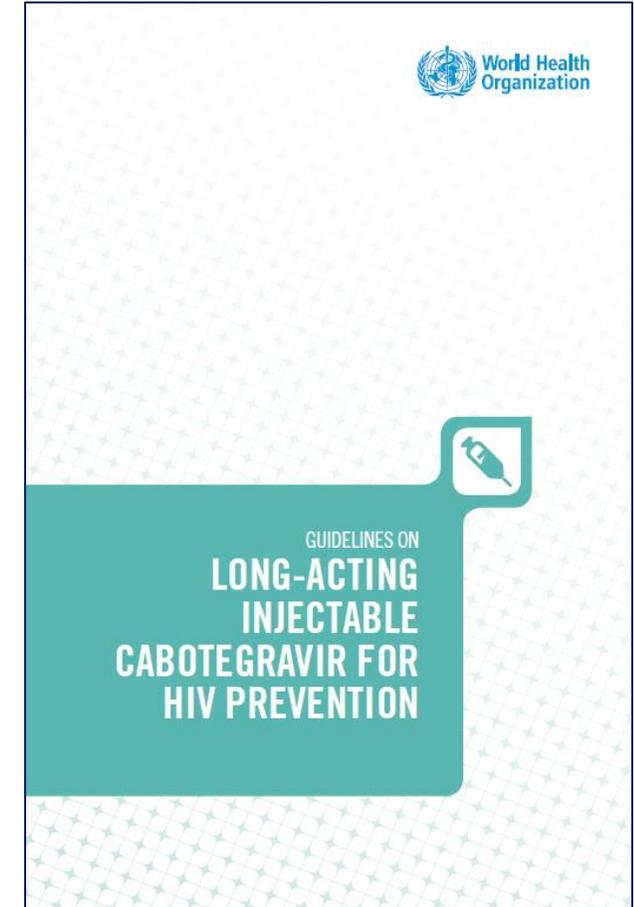
WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection

Long-acting injectable cabotegravir (CAB-LA)

Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (*conditional recommendation; moderate certainty of evidence*).

Critical gaps and outstanding issues

- Real-world data is just beginning
- Data lacking for **certain populations** e.g. sex workers, trans men
- **Supply, Cost, Generics**
- Need more research
 - Safety during **pregnancy** and **breastfeeding**
 - **HIV testing** and
 - **Drug resistance**
 - Product **switching** and **stopping** CAB-LA



New Provider Module for Oral and Long-Acting PrEP

Handy “quick reference” guide

Quick reference guide for PrEP providers

This section provides an overview of this provider module for oral and long-acting PrEP. Please refer to each section in the module for more information. PrEP providers can include physicians, nurses, clinical officers, community health workers, pharmacists, lay and peer providers and other cadres, in either clinical or community settings.

WHO-recommended PrEP products

 Oral PrEP (tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg OR TDF 300 mg + lamivudine (3TC) 300 mg tablets)	 DVR (25 mg dapivirine impregnated silicone ring) – long-acting	 CAB-LA (500 mg cabotegravir extended-release injectable suspension) – long-acting
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PrEP should be offered to HIV-negative individuals who are at substantial risk of HIV acquisition as part of combination HIV prevention approaches. PrEP is not suitable (contraindicated) for:

- people living with HIV
- people indicated for post-exposure prophylaxis (PEP)
- people with suspected acute HIV infection (AHI) with a potential HIV exposure in the previous 14 days
- people with a contraindication, allergy or hypersensitivity to the PrEP product.

Initial PrEP visit (most people can start the same day they come to the service)

1. Identify individuals who could benefit from PrEP, for example:
 - a. Individuals who request PrEP; OR
 - b. Individuals with likely ongoing HIV exposure, which may include any of the following:
 - i. a sexual partner living with HIV who is not virally suppressed on HIV treatment;
 - ii. recent or probable future inconsistent use of condoms for vaginal or anal sex;
 - iii. a recent sexually transmitted infection (STI);
 - iv. recent PEP use for sexual exposure to HIV, especially for individuals who have used PEP more than once.
2. Test for HIV (only individuals who return a negative test result should be offered PrEP).
3. Assess for PEP (offer PEP if there is a probable exposure in the previous 72 hours).
4. Assess for AHI and probable recent exposure (assess any signs and symptoms in the context of probable exposures to HIV in the previous 14 days – decisions to initiate PrEP or defer should be made on a case-by-case basis).
5. Provide information on PrEP (for example, discuss client's concerns and goals, PrEP products and how to take them, side-effects, procedures for receiving PrEP and additional services that can be offered).
6. Assess for contraindications, allergies and hypersensitivities to PrEP.
7. Discuss PrEP products that are available.
8. Confirm willingness to use PrEP as directed and provide the chosen PrEP product.
9. Provide (or refer for) any of the suggested additional services appropriate to the PrEP product and client, for example STI screening. (Only the results of an HIV test are needed to start PrEP. Waiting for other tests should not delay starting PrEP as these may be performed and/or the results provided at a later visit).

Follow-up PrEP visits (timing will depend on the PrEP product)

1. Test for HIV (only clients who have a negative test result should continue PrEP).
2. HIV self-testing (HVST) may be appropriate for people using oral PrEP or the DVR to support effective use.
3. Check-in with the client (for example, discuss sexual health concerns and goals, key messages about PrEP, side-effects and intention to continue PrEP).
4. Assess for effective use of PrEP (assess for AHI and PEP if PrEP use was not effective).
5. Provide the chosen PrEP product.
6. Provide, or refer for, any of the suggested additional services appropriate to the PrEP product and client, for example, STI screening. (Only the results of an HIV test are required to continue PrEP. Waiting for other tests should not interrupt PrEP as these may be performed and/or the results provided at a later visit).

Key counselling messages

- All PrEP choices are effective HIV prevention options¹.
- Effective use is important to prevent HIV acquisition (this means using PrEP according to the dosing schedule during periods of HIV risk).
- PrEP does not offer prevention against other STIs or pregnancy.
- PrEP products are generally safe and well tolerated. Side-effects are typically mild and resolve on their own and can be treated symptomatically. Severe side-effects should be reported to the PrEP provider without delay.
- Regular follow-up is important to support effective PrEP use and to provide other services including HIV testing. The follow-up visit schedule will depend on the PrEP product chosen.

Key messages for PrEP providers

- Task sharing is a key component of differentiated service delivery (DSD) for PrEP and a variety of providers can safely and effectively deliver PrEP. More experienced or qualified PrEP providers have an important role in supporting other cadres.
- PrEP is not a lifelong commitment. People using PrEP can generally stop, start and restart PrEP as their needs and circumstances change. PrEP providers should empower clients to use PrEP effectively, including appropriate starting, stopping and restarting. PrEP providers should support clients who want to switch products and provide information about how to do this safely and effectively.
- Consider simplified and DSD options for PrEP to support persistent and effective use by increasing accessibility and acceptability for clients.
- Oral PrEP is safe during pregnancy and breastfeeding. Although there are limited data on the use of CAB-LA and DVR in pregnancy and breastfeeding, there has been no safety signal and neither product is contraindicated.
- Adopting a person-centered approach, where the PrEP service is tailored to the needs and preferences of the client, is important. Some people, such as adolescents and young people, may require additional support and benefit from more frequent contact with PrEP providers. Others could have additional considerations. For example, people who use drugs should be supported to receive harm reduction services alongside PrEP. Alternatively, some people may only want services directly related to PrEP. These needs and preferences may also change over time.

¹ Specific efficacy varies by PrEP product. Using PrEP as directed according to the dosing schedule for the specific PrEP product is important for high effectiveness.

WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection

Provider module for oral and long-acting PrEP



Oral PrEP – Dosing regimen (EVERYONE)

- **Who is it for?**

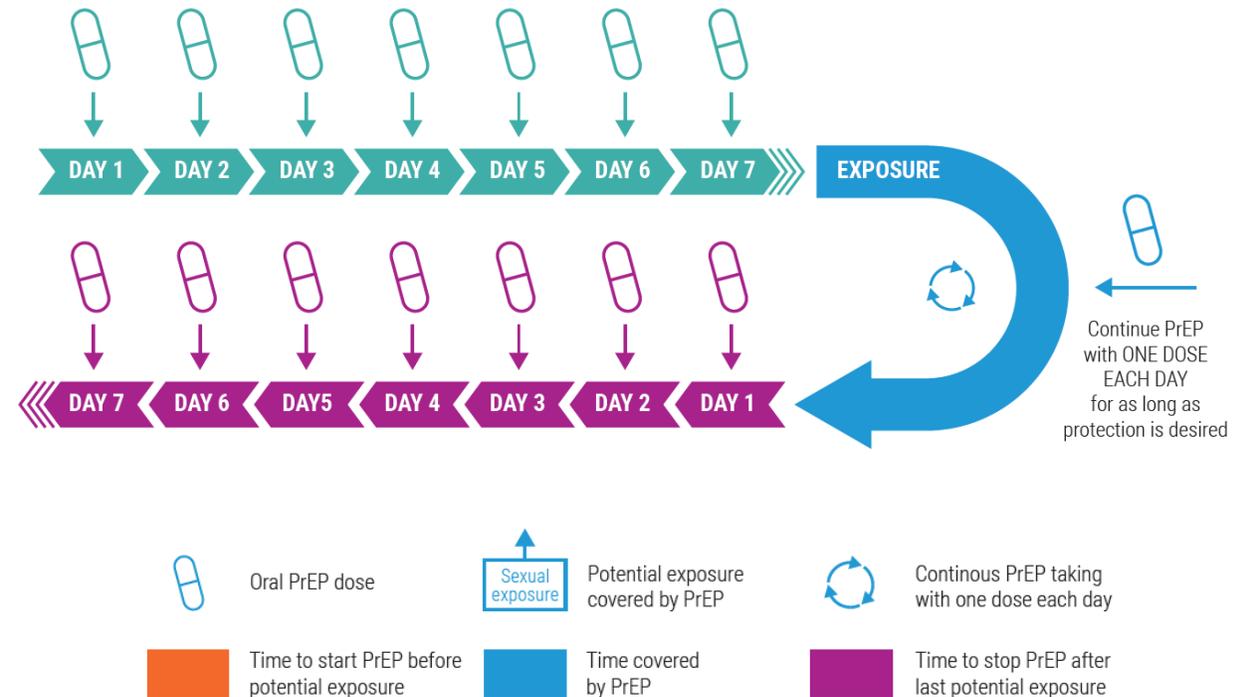
- EVERYONE who could benefit from PrEP
 - Women, men, transgender men, transgender women, people who use drugs, people who use gender-affirming hormones, and people who do not gender identify

- **How do you take it?**

- Start with 1 dose per day for 7 days
- Continue with 1 dose per day for as long as oral PrEP use is desired
- Stop by taking 1 dose per day for at least 7 days after the last potential exposure

- **What else?**

- Is effective for sexual exposure and exposure through injecting drug use
- This guidance only applies to TDF-based oral PrEP



Oral PrEP – Dosing regimen (cisgender men*)

- **Who is it for?**

- men* and transgender women who are not taking gender affirming hormones

- **How do you take it?**

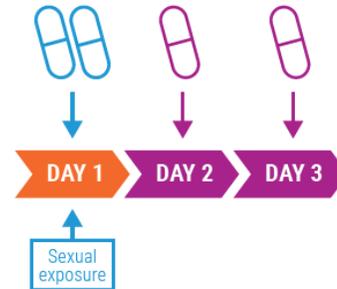
Whether for a single event, a short time or a long time

- **Start** with 2 doses 2-24 hours prior to the first exposure
- **Continue** with 1 dose per day for as long as oral PrEP use is desired
- **Stop** by taking 1 dose per day for at least 2 days after the last potential exposure

- **What else?**

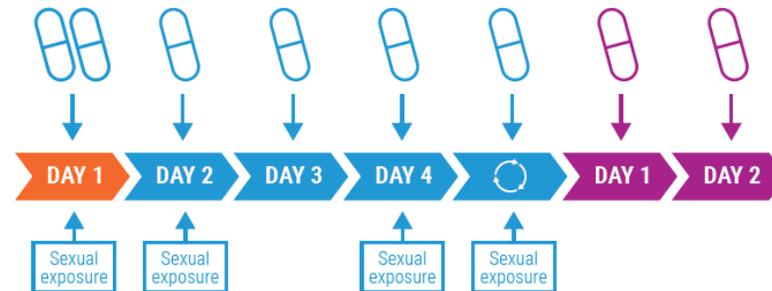
- Kidney impairment (CrCl <60ml/min) is a contraindication

PrEP for a single event e.g. sex on 1 day

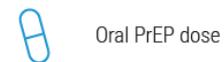


No longer using the term ED-PrEP to describe this dosing regimen

PrEP for multiple events or daily



Continue PrEP with ONE DOSE EACH DAY for as long as protection is desired



Oral PrEP dose



Potential exposure covered by PrEP



Continuous PrEP taking with one dose each day



Time to start PrEP before potential exposure



Time covered by PrEP



Time to stop PrEP after last potential exposure

HIVST for oral PrEP

New recommendation

HIV self-testing may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation (*conditional recommendation, low-certainty evidence*).

- WHO recommends offering HIVST for oral PrEP
 - **Initiation, Continuation and Re-starting**
- HIVST can also be used to reassure people without HIV that their prevention practices are effective.
- HIVST can be used with oral PrEP and the dapivirine vaginal ring.
- Further research on using HIVST with CAB-LA is needed.



Kidney function monitoring for oral PrEP

Impaired kidney function, indicated by eGFR<60*, is a contraindication for using oral PrEP containing TDF.

Comorbidities	Age	Initiation		Follow-up
No	<30	Optional	Very low risk	Optional (until age 30 or kidney-related comorbidities develop) If baseline done and CrCl<60, conduct follow-up ever 6-12 months
No	30-49	Optional	Low risk, particularly 30-39 years. Screening optional.	If CrCl≥60, optional (until age 50 or kidney-related comorbidities develop)
		Conduct once within 1-3 months after oral PrEP initiation		If CrCl<60, screening every 6-12 months
Yes	Any age	Conduct once within 1-3 months after oral PrEP initiation		Screening every 6-12 months
No	50+	Conduct once within 1-3 months after oral PrEP initiation		Screening every 6-12 months

This guidance only applies to TDF-based oral PrEP.

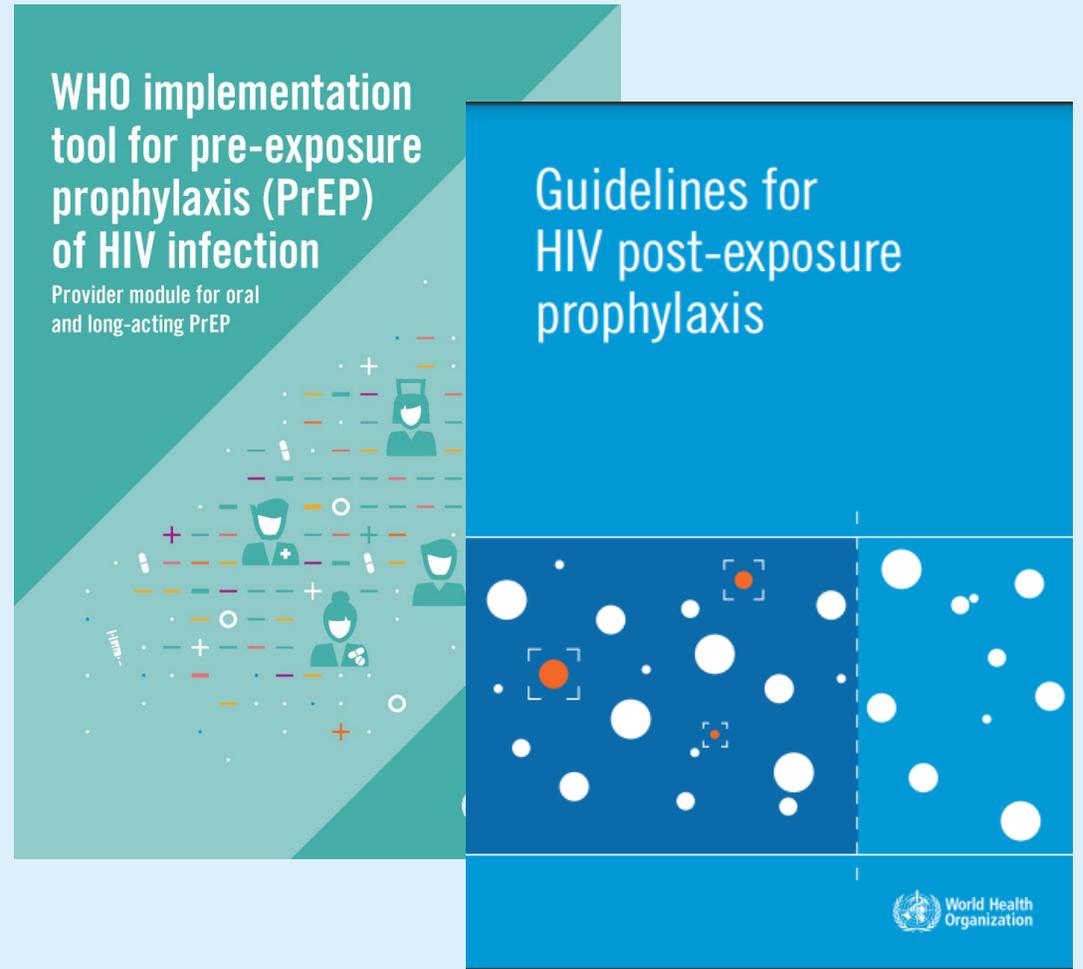
Thank you

Acknowledgements

Rachel Baggaley

Mateo Prochazka

Heather-Marie Schmidt



The Promise of Prevention

Global PrEP Landscape

Mitchell Warren,
Executive Director, AVAC
2024 Africa Regional PrEP Workshop
9 September 2024

Outline

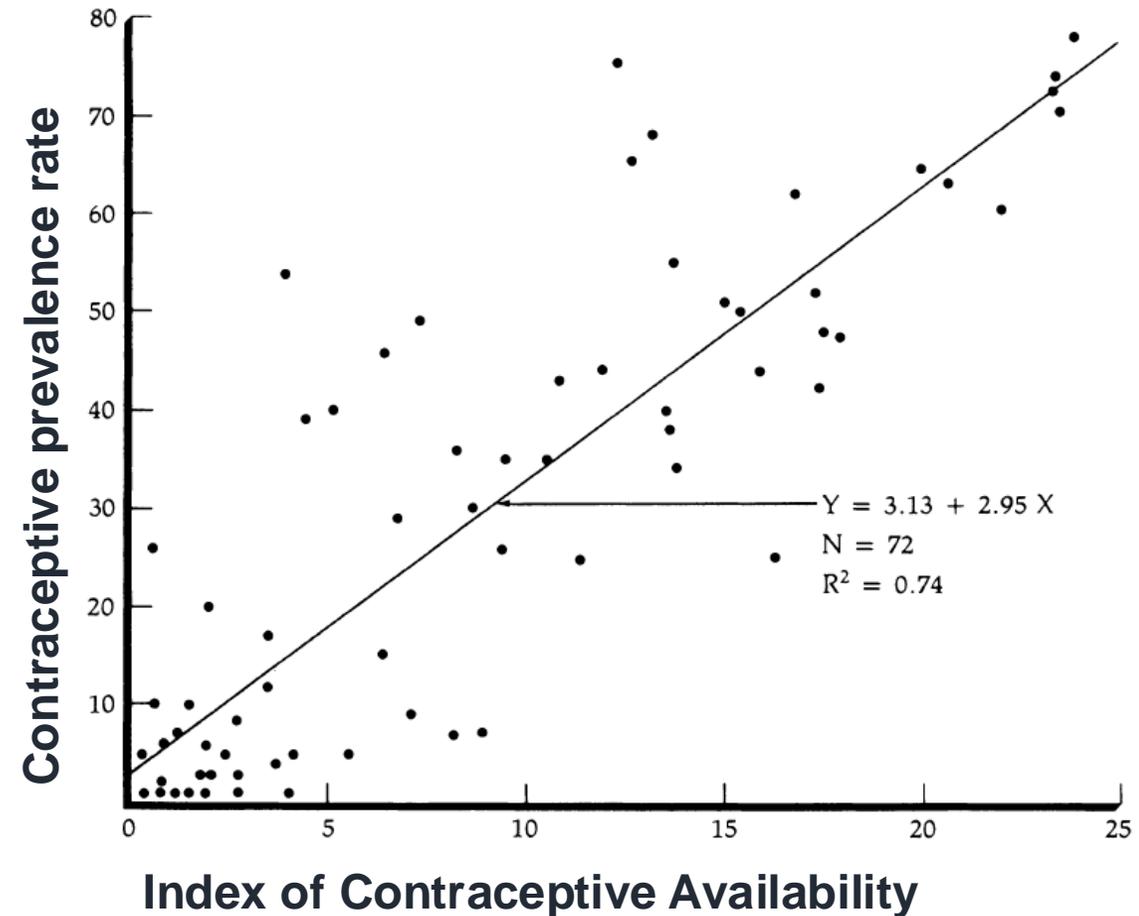
- From Options to Choices
- The product pipeline
- The oral PrEP experience – and the potential of a “prevention platform”
- Getting Rollout Right This Time

Language Check

- Options
 - Biomedical methods that are safe and effective
 - Requires R&D of additional options to add to the “method mix”
- Choice
 - The ability for an individual to select from an array of options
 - Requires policy makers, donors, governments & implementers to make the “mix” available, accessible & affordable

Choice Matters

- WHO systematic review (231 articles) showed increased choice associated with:
 - **Increased persistence** on chosen method
 - **Better health outcomes**
 - **12% increase in contraceptive prevalence for each additional method**
- Similar to contraceptive needs: different people have different HIV prevention needs at different times



Voices for Choice

African Women Prevention Community Accountability Board

The HIV Prevention Choice Manifesto For Women and Girls In Africa



Introduction:

The HIV Prevention Choice Manifesto is a collection of voices of African women and girls in all their diversity, feminists and HIV prevention advocates across Southern and Eastern Africa who are united in calling for continued political and financial support for HIV prevention choice.

Biomedical HIV prevention is at a historic turning

Options vs. Choice

- Effective and safe biomedical methods
- Requires R&D of additional options to add to the "method mix"



- The ability for an individual to select from an array of options
- Requires policy makers, donors, governments & implementers to make the "mix" available, accessible & affordable

▶ [HIV Prevention Choice Manifesto](#)

Global Key Population HIV Prevention Advisory Group

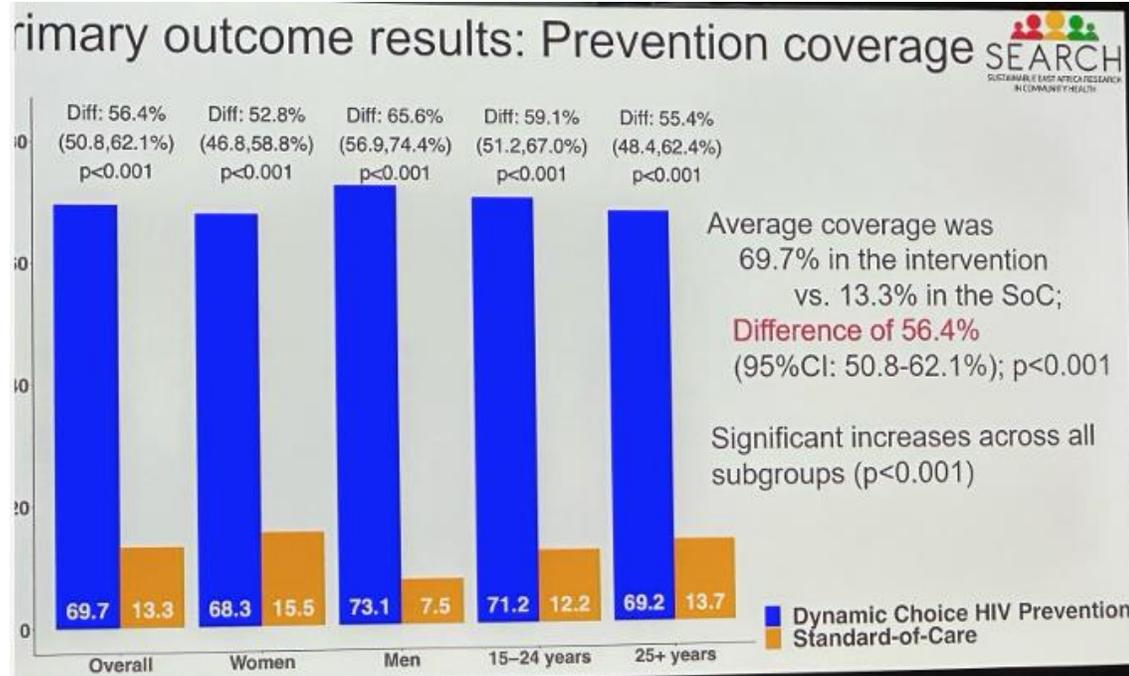
DECEMBER 2023

Global HIV Prevention Roadmap for Key Populations

This roadmap outlines a strategy for the equitable expansion and delivery of HIV prevention services to key populations (KPs) globally and regionally. It introduces a critical, coordinated approach led by KPs to accelerate the implementation of existing and new HIV prevention interventions.

▶ [Global HIV Prevention Roadmap for Key Populations](#)

Choice Matters



Secondary outcome: HIV incident infection

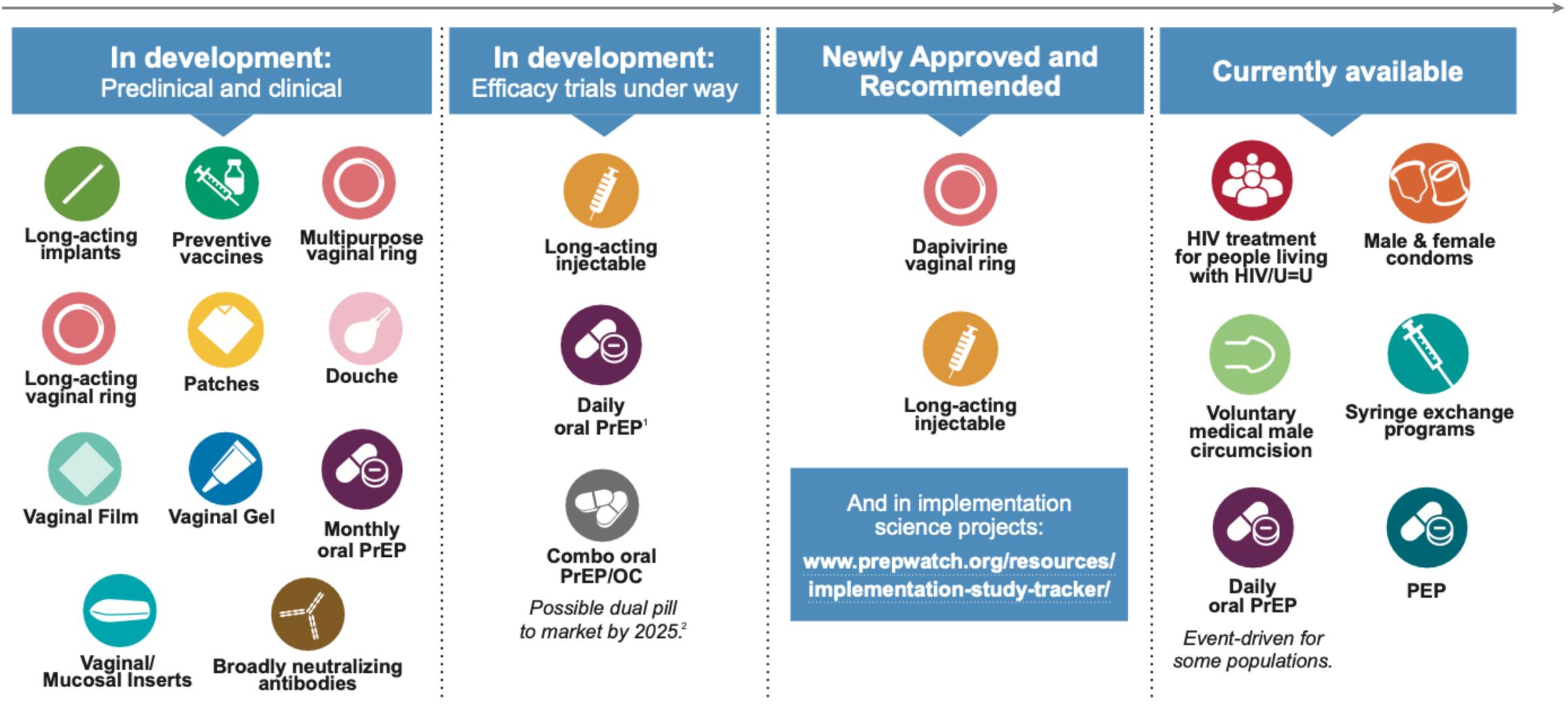
	Dynamic Choice HIV Prevention intervention	Standard of Care
Overall	0/400 PY	7/390 PY
Women	0/293 PY	5/283 PY
Men	0/107 PY	2/106 PY
15-24 years	0/113 PY	1/122 PY
25+ years	0/287 PY	6/268 PY

- 7 participants in the SoC and 0 in intervention had incident HIV infection
- Incidence rate was 0% in the intervention vs. 1.8% in the SoC
- Difference of -1.8% (p=0.01)
- In addition, 1 infant born to participant in SoC was infected
 - Not included in incidence

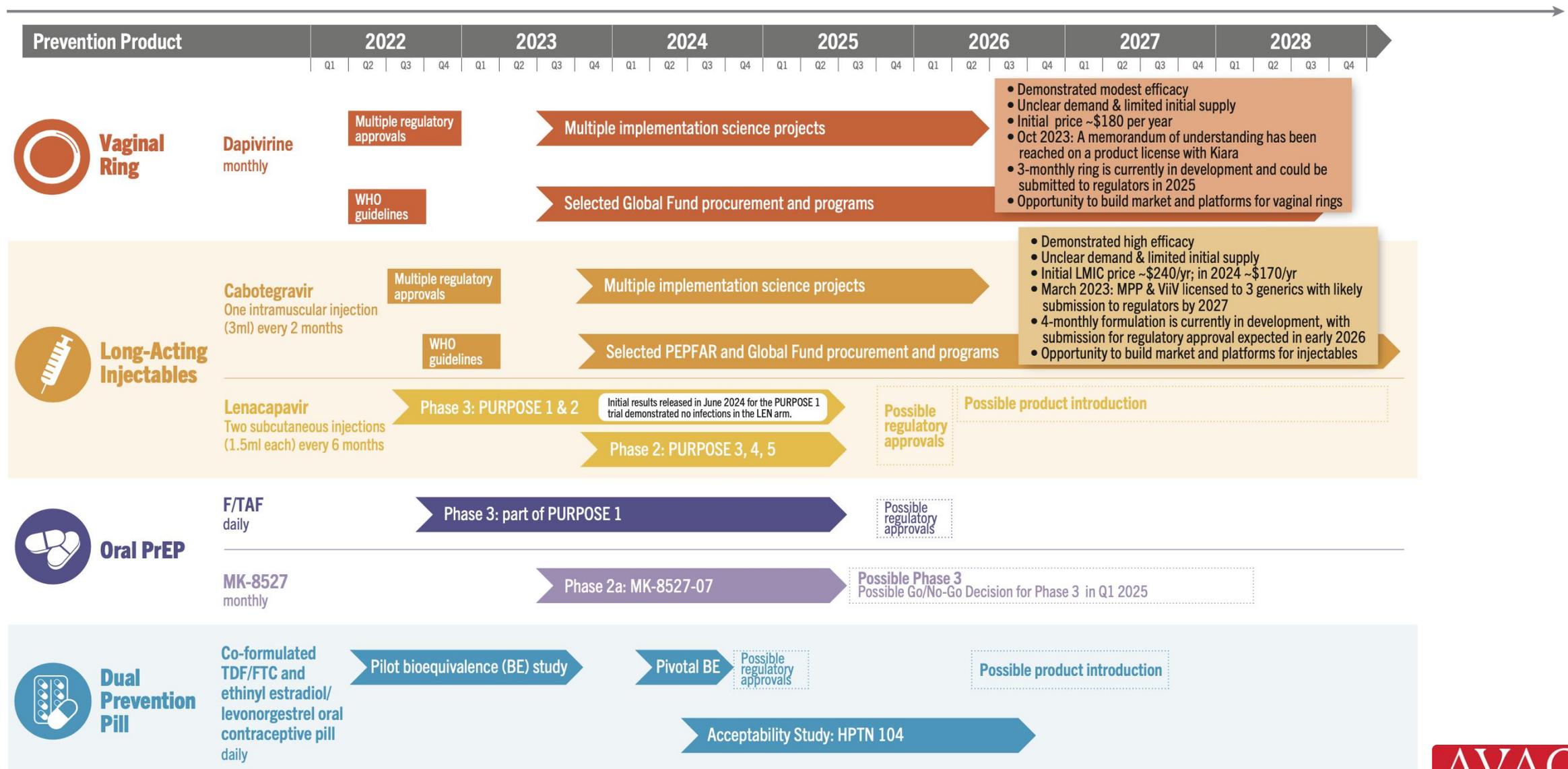
Ever use	Dynamic Choice HIV Prevention intervention	Standard of Care
CAB-LA	56%	0%
Oral PrEP	53%	19%
PEP	2%	1%
2+ products	28%	0.4%

- Over half of participants in intervention arm used CAB-LA during the study (both men and women)
- Of those starting CAB-LA at baseline, 42% were not on any prevention product in the prior month
- 28% of intervention participants used at least 2 different products during the study

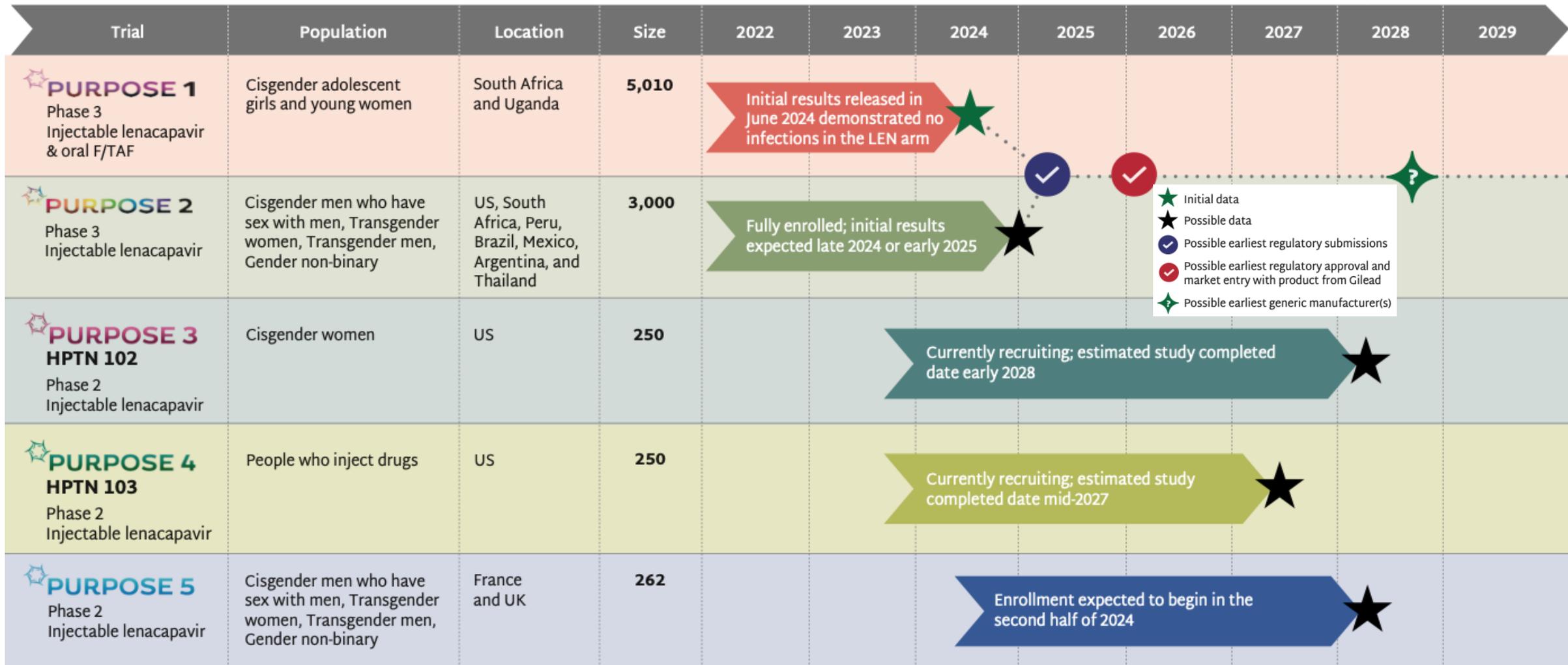
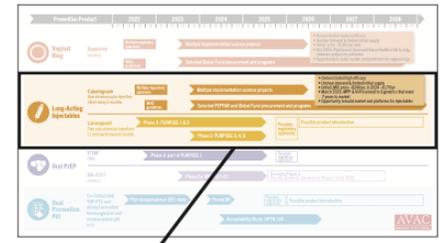
Overview of Biomedical Prevention Pipeline



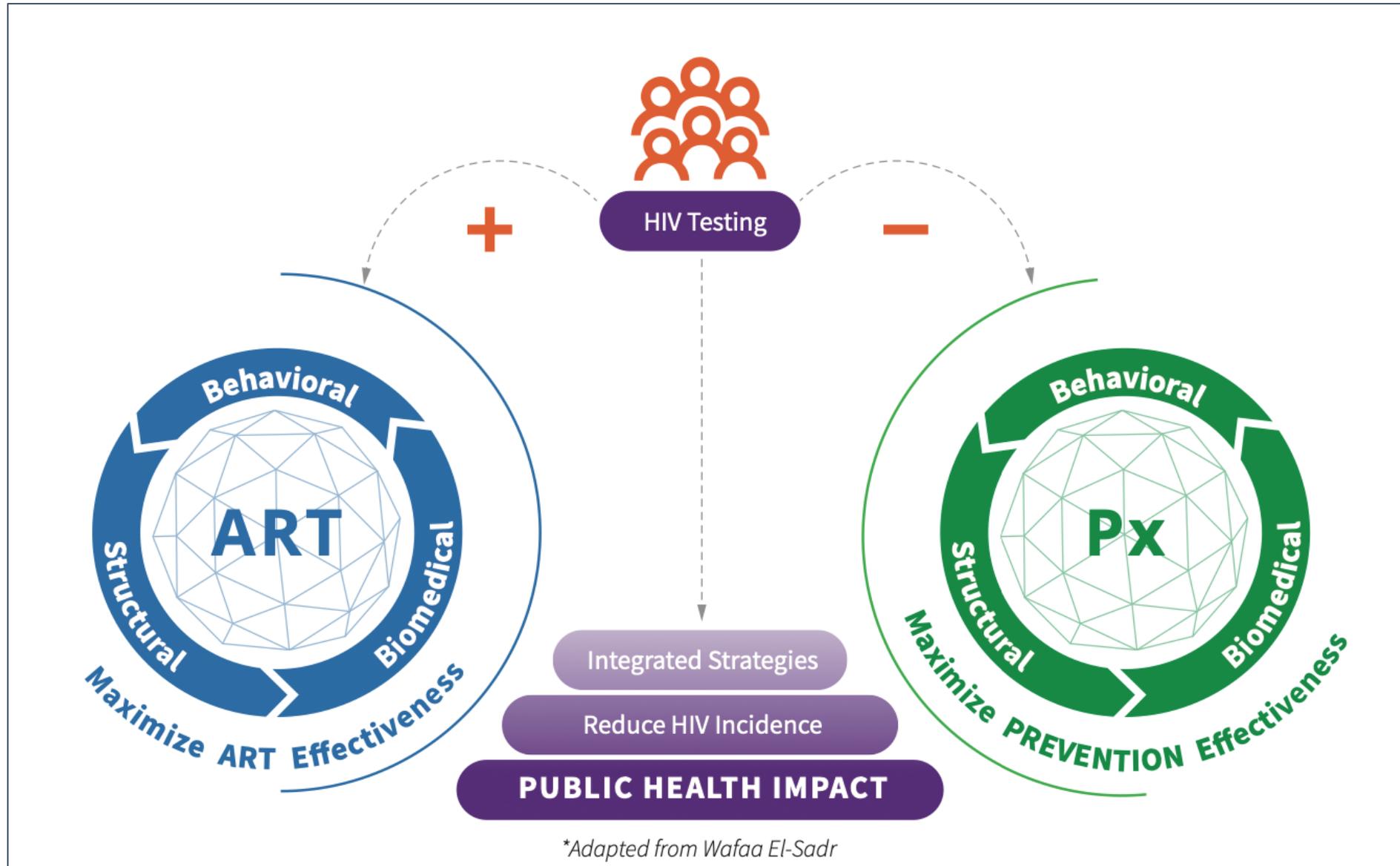
Updated Pipeline



Planning for Injectable Lenacapavir



Universal Test & Connect



Product Considerations

For each product, understand and balance:

Clinical	Policy & Programs	Personal & Social
<ul style="list-style-type: none">■ Biologic efficacy■ Dosing/duration■ Reversibility■ Side effect profile■ Systemic/Topical	<ul style="list-style-type: none">■ Delivery channel(s)■ Health system burden■ Product cost■ Program cost■ Provider training■ Demand creation	<ul style="list-style-type: none">■ User effectiveness■ User preference■ User burden■ Discretion of use■ Contribution to stigma

It's never just "the product" – it's the program;
new options can't solve for everything

Product Considerations

For each product, understand and balance:

Clinical

Policy & Programs

Personal & Social

Spoiler Alert:
**There is no – and never will
be a – miracle drug!!**

- Demand creation

It's never just "the product" – it's the program;
new options can't solve for everything

UNAIDS 2020 Targets: Where we landed

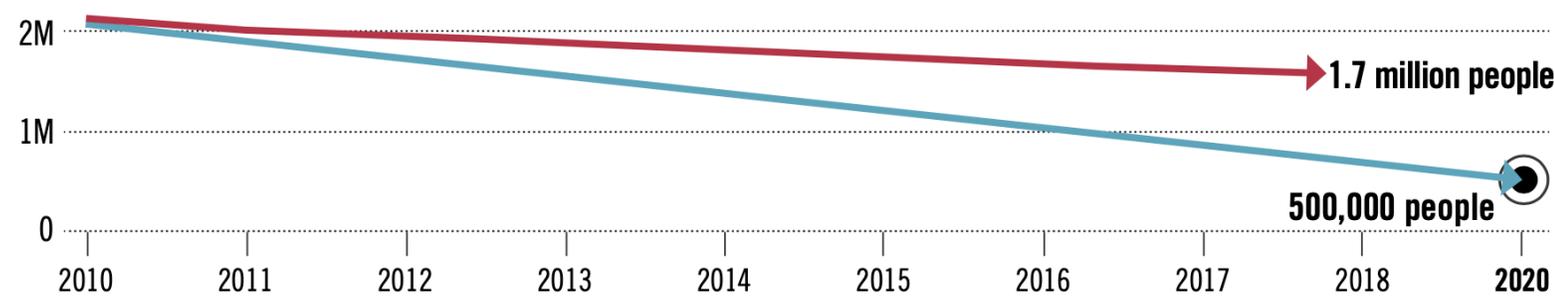


What Model Assumed

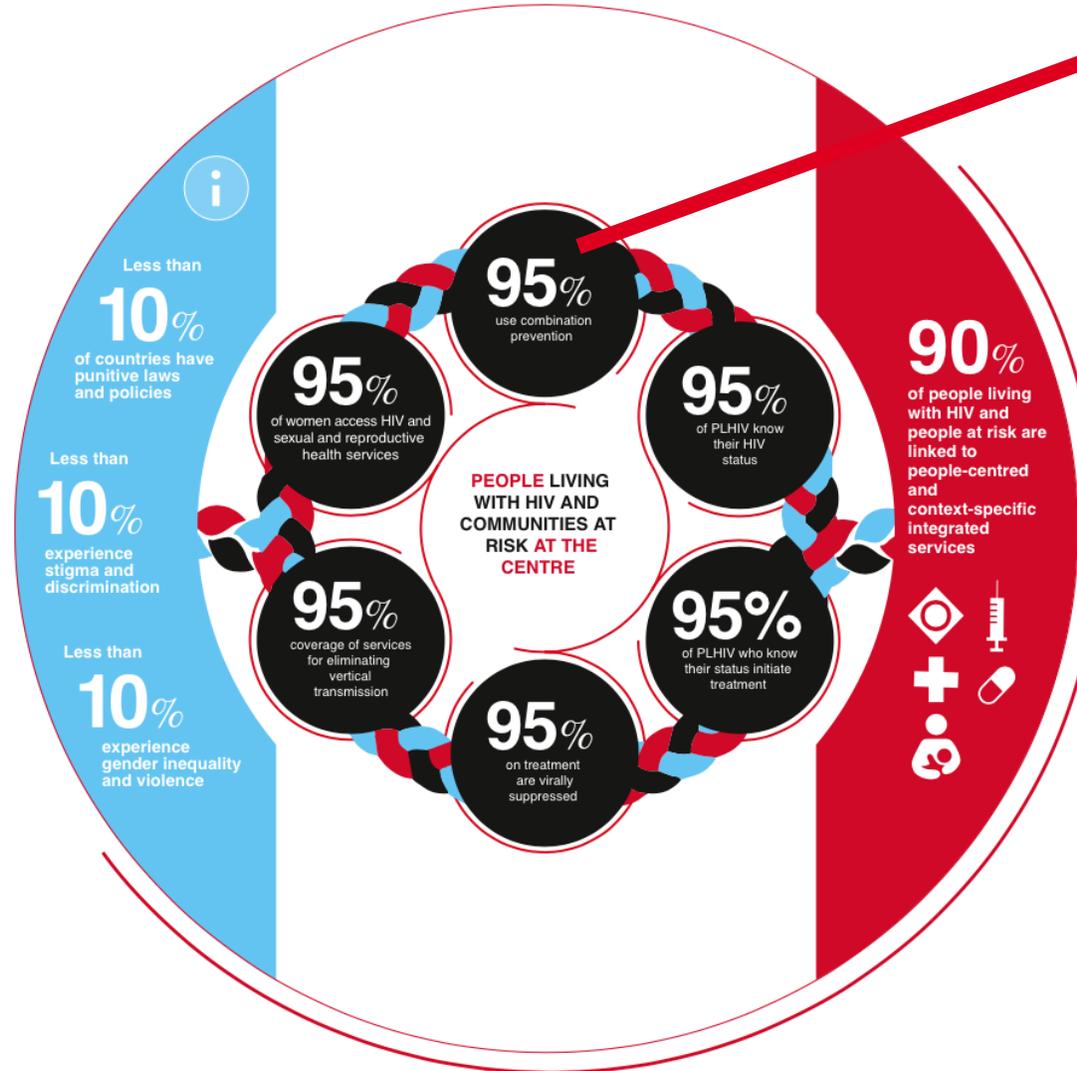
- 90% key population covered
- 90% of AGYW (key locations)
- >6bn condoms (SSA) per year
- 3m PrEP**
- 5m VMMC per year
- Funding (additional \$6.5bn per year)
- Testing, treatment, virologic suppression in PLHIV worldwide: 90-90-90

What Was Implemented

- 47% for sex workers • 33% for gay men & other MSM • 32% for PWID*
- 34% of AGYW in key locations covered**
- <3bn condoms (SSA)*** per year
- Approx 385,000 PrEP******
- 4.1m VMMC per year in 2018
- Flat funding
- Testing, treatment, virologic suppression in PLHIV worldwide: 79-78-86 with large disparities



UNAIDS 2025 Targets: Where we're trying to land

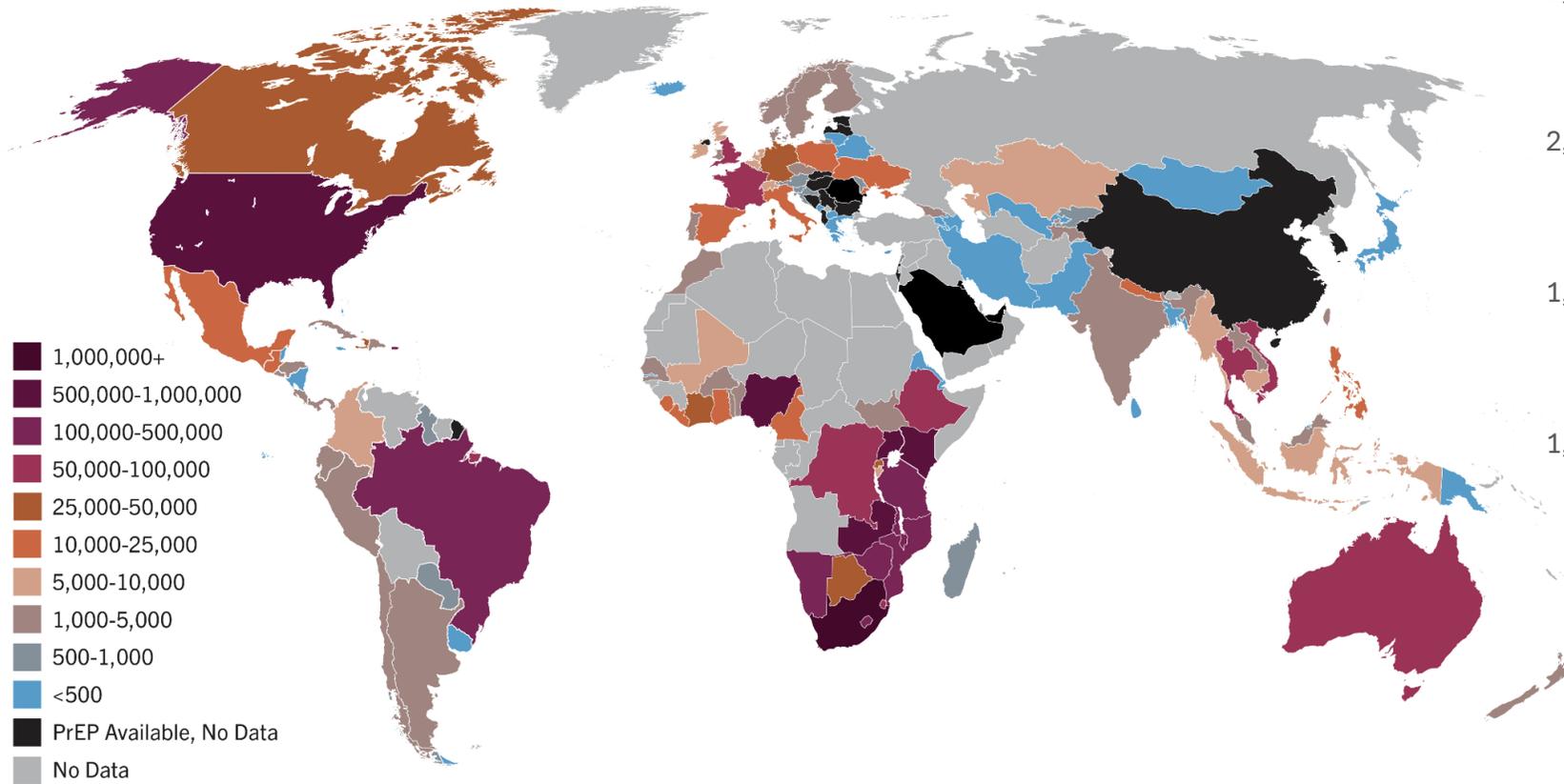


No single “PrEP target”:
2025 targets for combo px
are arranged in population-
specific service packages
that aim to provide
individuals at higher risk
with a choice of prevention
options that work best in
specific circumstances.”

But overall model calls for
**10 million person years of
PrEP protection** each year

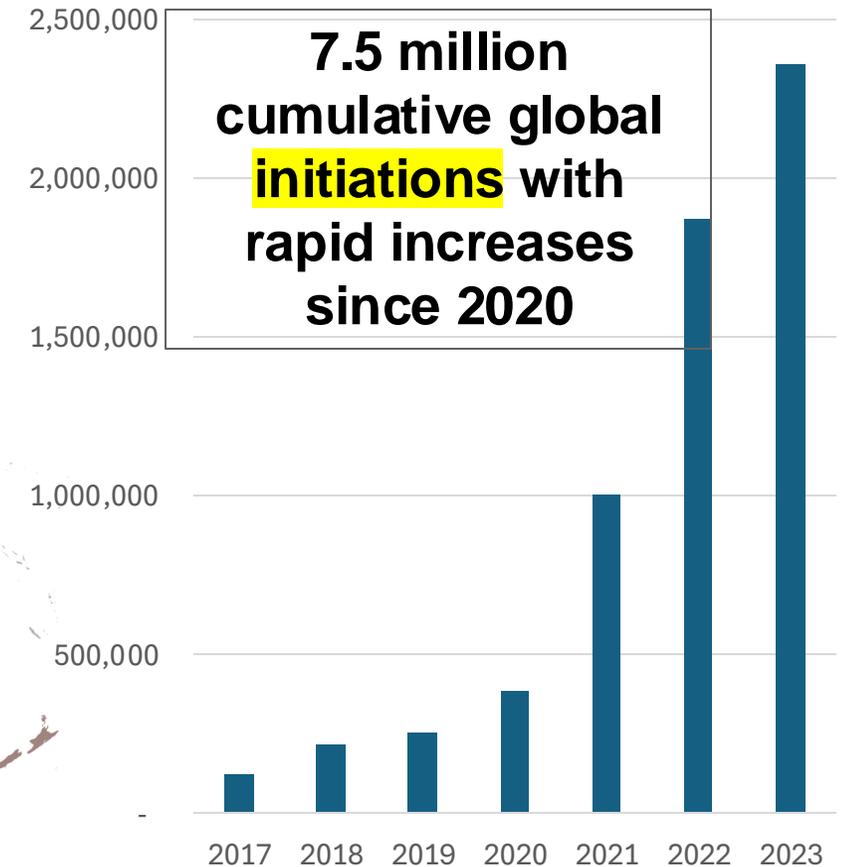
Global PrEP Uptake – 12+ years in

PrEP Initiations by Country, August 2024



Source: AVAC Global PrEP Tracker, Q2 2024, <https://www.prepwatch.org/data-by-country/>

PrEP Initiations Over Time

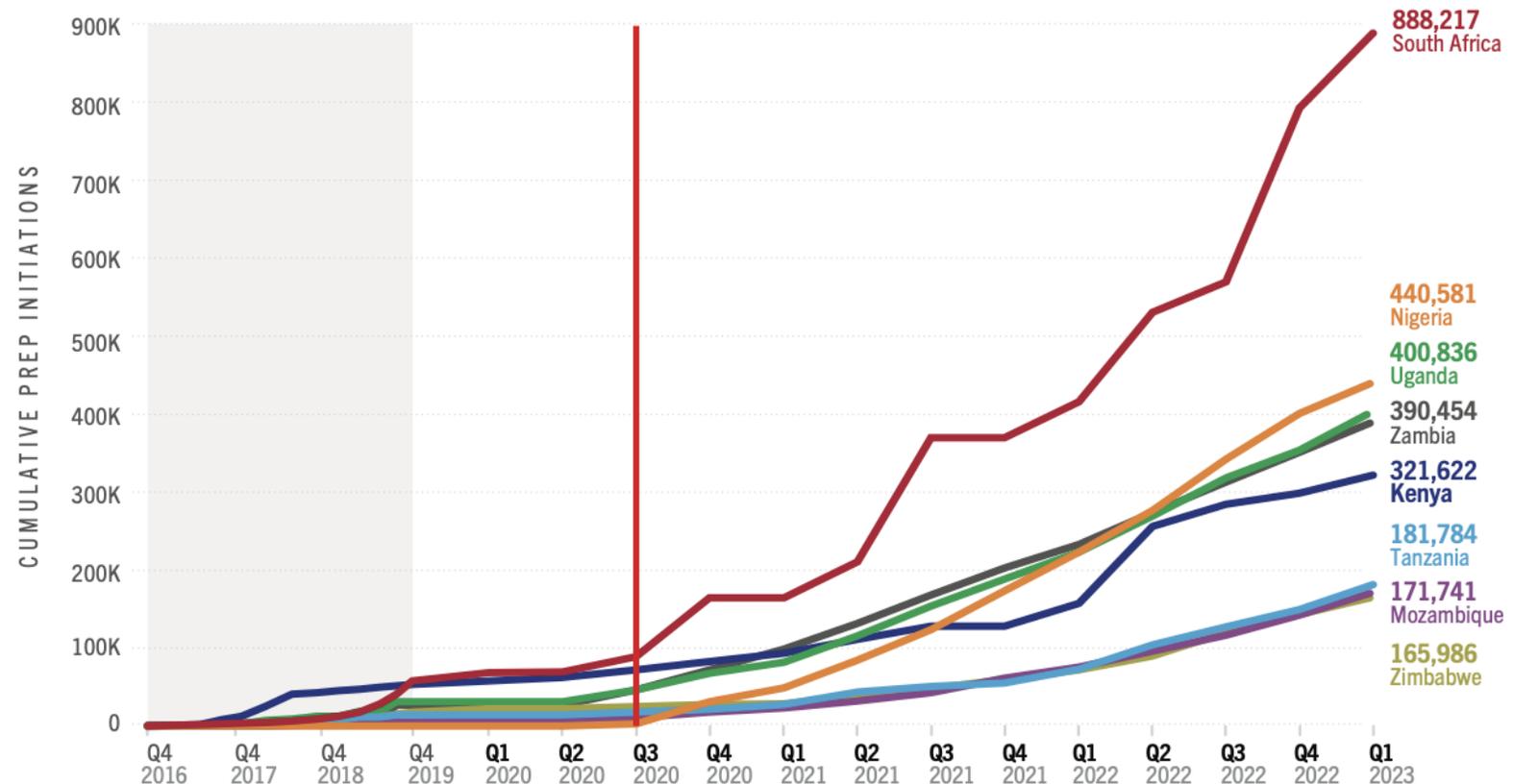


Country trends in oral PrEP uptake

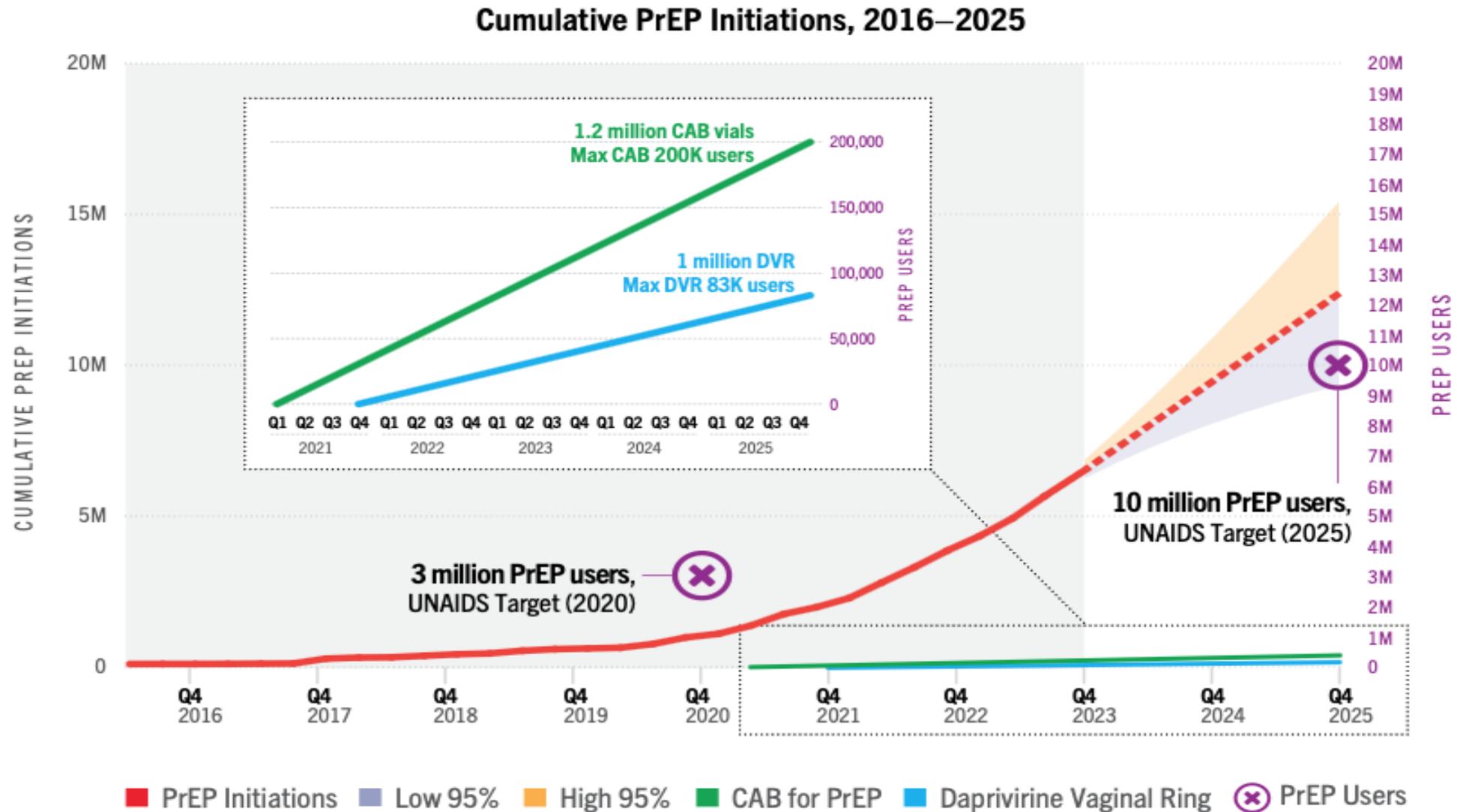
- Eight countries in SSA have surpassed 100,000 PrEP initiations, accounting for 91% initiations in the region
- South Africa and Kenya were two of the earliest adopters with national programs scaling up over time
- Zambia, Uganda and Nigeria have seen steep growth since 2021 – nearly 100% of initiations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

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

2016–2023



Cumulative PrEP Initiations – and the Targets



Long-Acting PrEP Quarterly Dashboard

Posted in Support of the Coalition to Accelerate Access to Long-Acting PrEP

Long-Acting PrEP—Current Status as of June 2024

	CAB	DVR	LEN
Product (pricing, manufacturing, generics)	Current LIC price from ViiV made public: £23.50/vial (approx. \$180/year). Voluntary license granted from MPP to 3 generics – expected in market by 2027	Current price from PopCouncil is approx. \$156/years. MOU signed with Kiara Health to manufacture in South Africa but no clear timeline for local manufacturing	In June 2024, Gilead announced early review of PURPOSE 1 trial data: LEN was safe and effective, with no infections in LEN arm. PURPOSE 2 to readout later in 2024.
Regulatory Approval & Normative Guidance	19 regulatory approvals (including EMA); pending in 9 countries; WHO pre-qualification in 2023	Approved in 11 countries; 2 pending review/appeal; 3 submissions in preparation; WHO pre-qualification in 2021	Possible regulatory submissions by early 2025, pending additional data and review
Planning & Budgeting	Total 2023-2025 volume: 1.2M doses for non-commercial supply (955k for programs; remainder for studies)	750k rings available 2023-2024, 250k to be manufactured by end of 2025	
Delivery & Supply Chain	Approx. 12,000 initiations as of Q2 2024	Approx 1,800 initiations as of Q2 2024	
Stakeholder Engagement	Establishment of the Coalition's Civil Society (CS) Caucus; facilitating reoccurring meetings with product owners and other stakeholders		
Research	42 implementation studies ongoing or planned	15 implementation studies ongoing or planned	
Monitoring & Evaluation	Continued monitoring and assessment of initiations via trackers and think tanks. Understand country-specific product introduction issues to inform programmatic rollout		

Long-Acting PrEP Quarterly Status Update

Long-Acting PrEP—Proposed Priorities for H2 2024

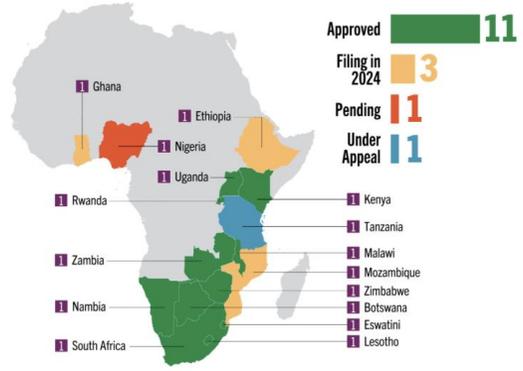
	CAB	DVR	LEN
Product (pricing, manufacturing, generics)	Collaborate with ViiV to understand procurement plans, build demand and accelerate generics progress	Collaborate with PopCouncil on price/volume for 2024/25 & plans for local mfg with Kiara; track development of 3-monthly & dual-purpose rings	Engage with Gilead now to encourage transparency on pricing and access, and to grant non-exclusive licenses to multiple generic manufacturers by end of 2024
Regulatory Approval & Normative Guidance	Monitor progress on the need to remove oral CAB development and registration from sublicense agreements	Advocate for additional submission in high-burden countries	Engage with Gilead to ensure timely sharing of PURPOSE 1 data and begin submission to WHO and regulatory agencies. WHO and national agencies to review data asap.
Planning & Budgeting	Build demand in country and develop long-term demand forecast	Build demand in country and develop long-term demand forecast; understand what data PEPFAR may need to consider programmatic procurement	PEPFAR and the Global Fund to work with other donors and MoH to negotiate price and volume guarantees. MoHs to integrate into national guidelines asap.
Delivery & Supply Chain	Track current implementation studies and share early insights; continue to identify and address evidence gaps	Track current implementation studies and share early insights; continue to identify and address evidence gaps	MoHs, policy makers and donors to collaboratively design a comprehensive introduction strategy to speed up introduction
Stakeholder Engagement	Create collective advocacy strategies, continue to integrate civil society perspectives and support implementation of HIV Prevention Choice Manifesto		Create collective commitment to expedite comprehensive access strategy; joint CS statement issued in July
Research	Ensure further studies are planned to research long-term effects, and continue to identify gaps in product introduction by country	Advocate for further research on long-term effects and use in conjunction with other prevention methods	Identify implementation science priorities that can be embedded in programmatic rollout and/or run in parallel in anticipation of approval & recommendations
Monitoring & Evaluation	Continue to coordinate modeling exercises; assess gaps in in product introduction by country. Push to advance a learning agenda for programmatic rollout	Continue to assess gaps in in product introduction by country. Push to advance a learning agenda for programmatic rollout	Anticipate gaps in in product introduction by country; push to advance a learning agenda for programmatic rollout

Long-Acting PrEP Quarterly Dashboard

Posted in Support of the Coalition to Accelerate Access to Long-Acting PrEP

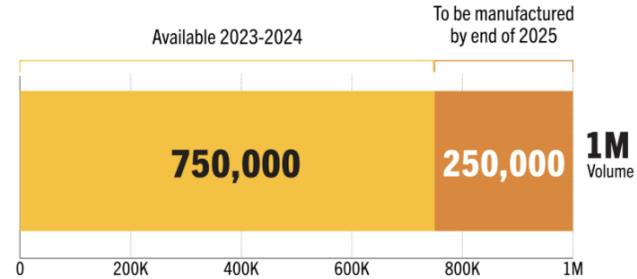
DVR REGULATORY APPROVAL >

11 regulatory approvals; 1 pending and 3 submissions in preparation as of June 2024



DVR VOLUME >

Allocation of Non-Commercial DVR for PrEP Supply in Low- and Middle-Income Countries, 2023-2025



DVR IMPLEMENTATION >

15 ongoing & planned implementation studies in 10 countries as of June 2024



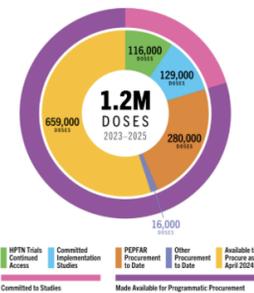
CAB REGULATORY APPROVAL >

20 regulatory approvals (EMA approval counting as 1); 9 pending as of June 2024

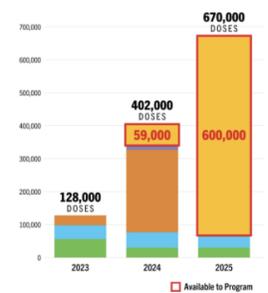


CAB VOLUME >

Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025 — BY CATEGORY



Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025 — BY YEAR

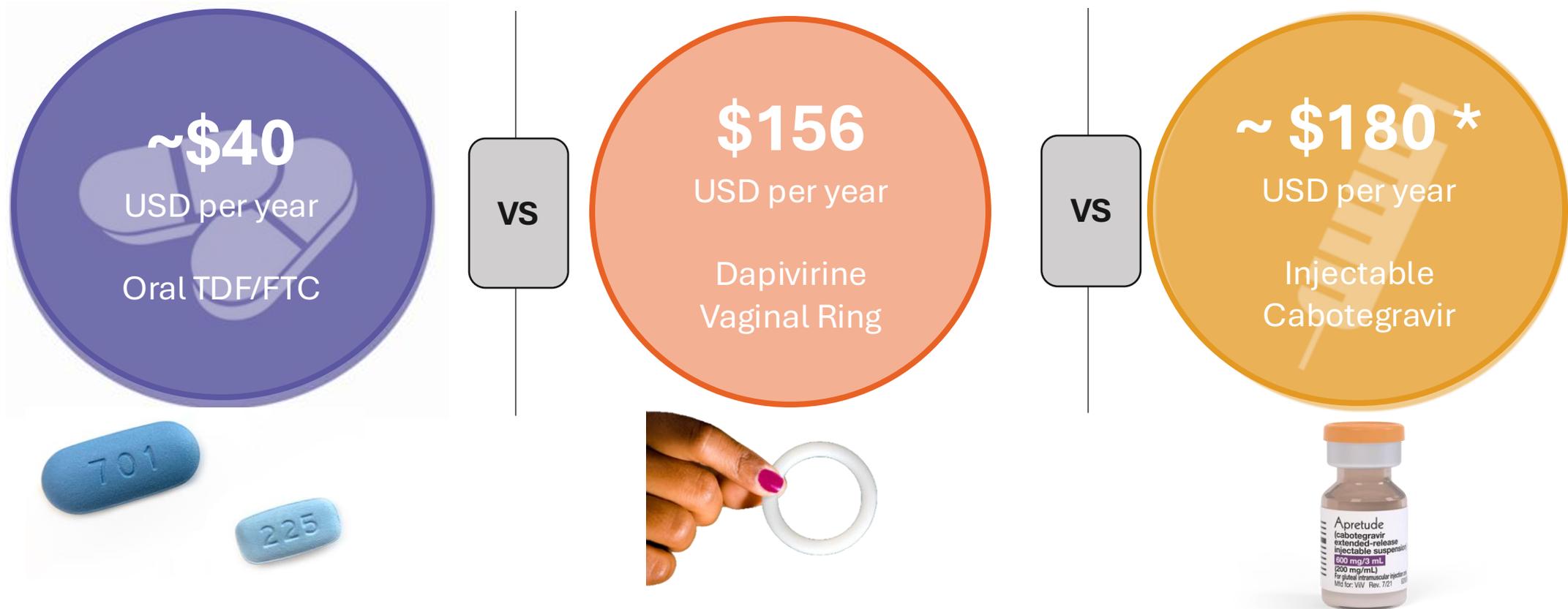


CAB IMPLEMENTATION >

42 ongoing & planned implementation studies in 23 countries as of June 2024

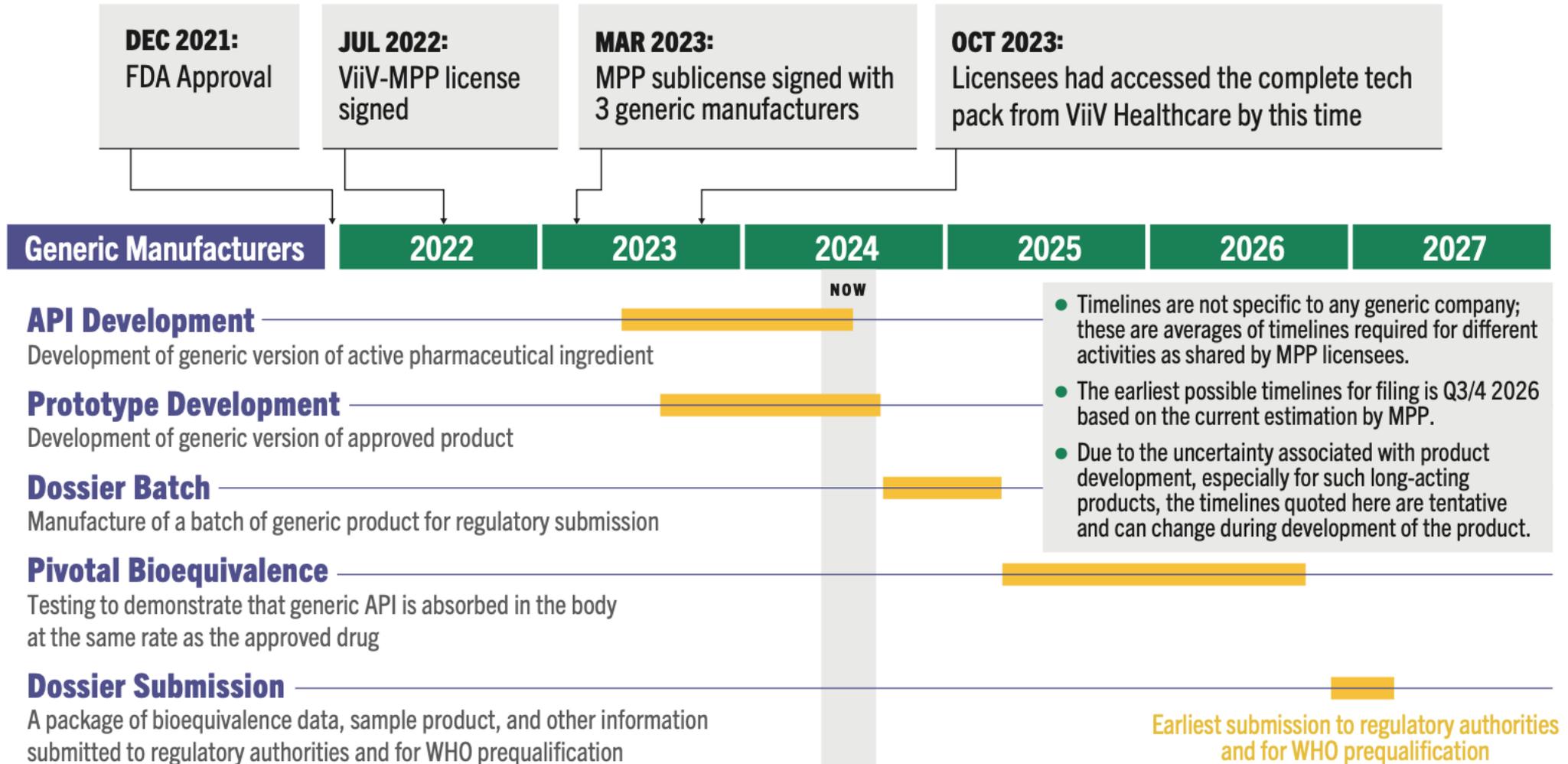


PrEP Prices in LMICs



* £23.50 / vial as confirmed by ViiV in October 2023.

Development Timeline for Generic CAB for PrEP



Source: Medicines Patent Pool, May 2024.

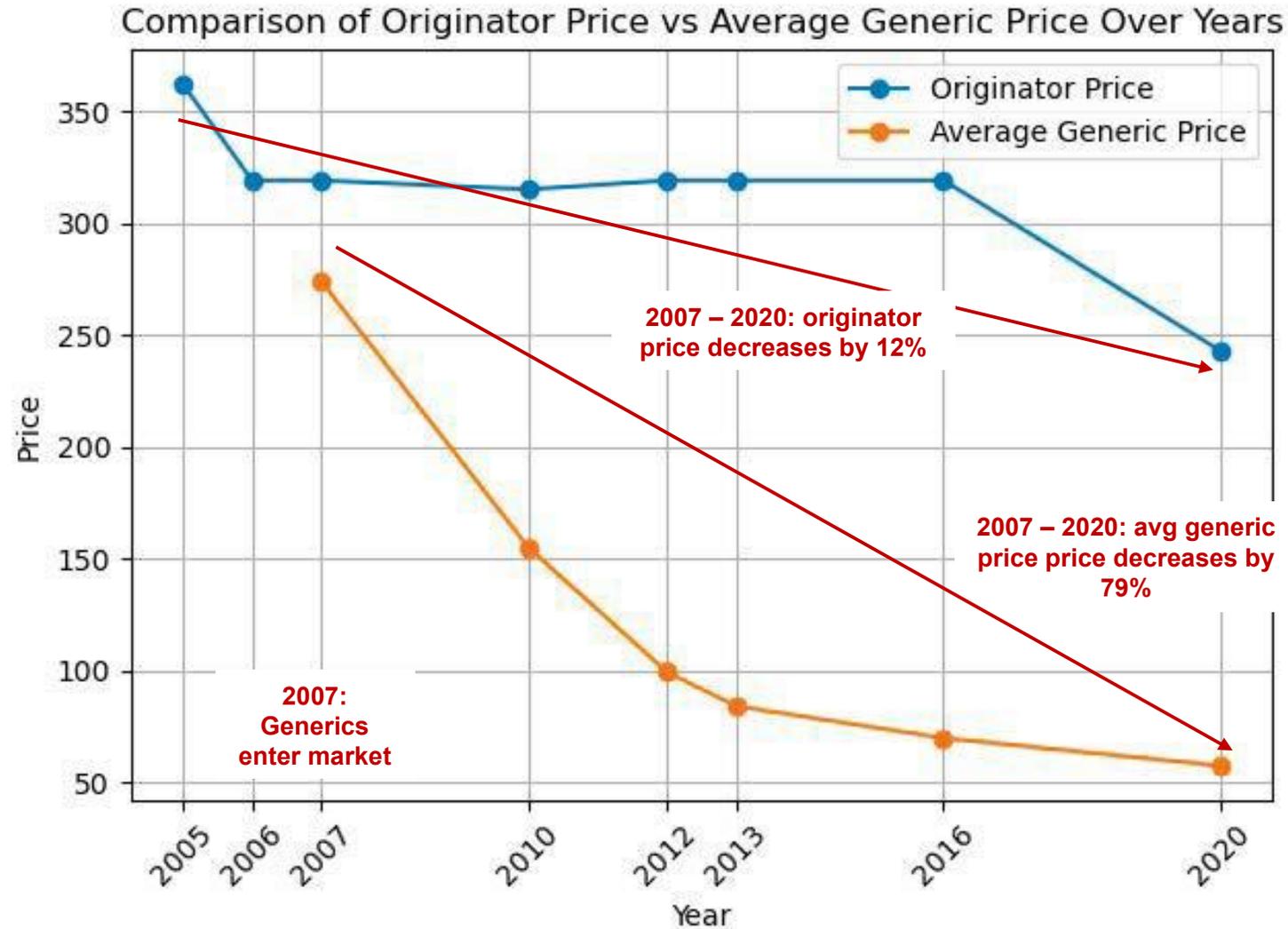
PrEP Prices in LMICs

And Costs, And Costs of Infections Averted, And Time to Generics

- Price
- Cost/Cost of Goods
- Cost-effectiveness
- Cost per infection averted
- Time to generics – and time to low prices:
 - Low prices = volume + time to build volume + multiple generics

PrEP Prices in LMICs

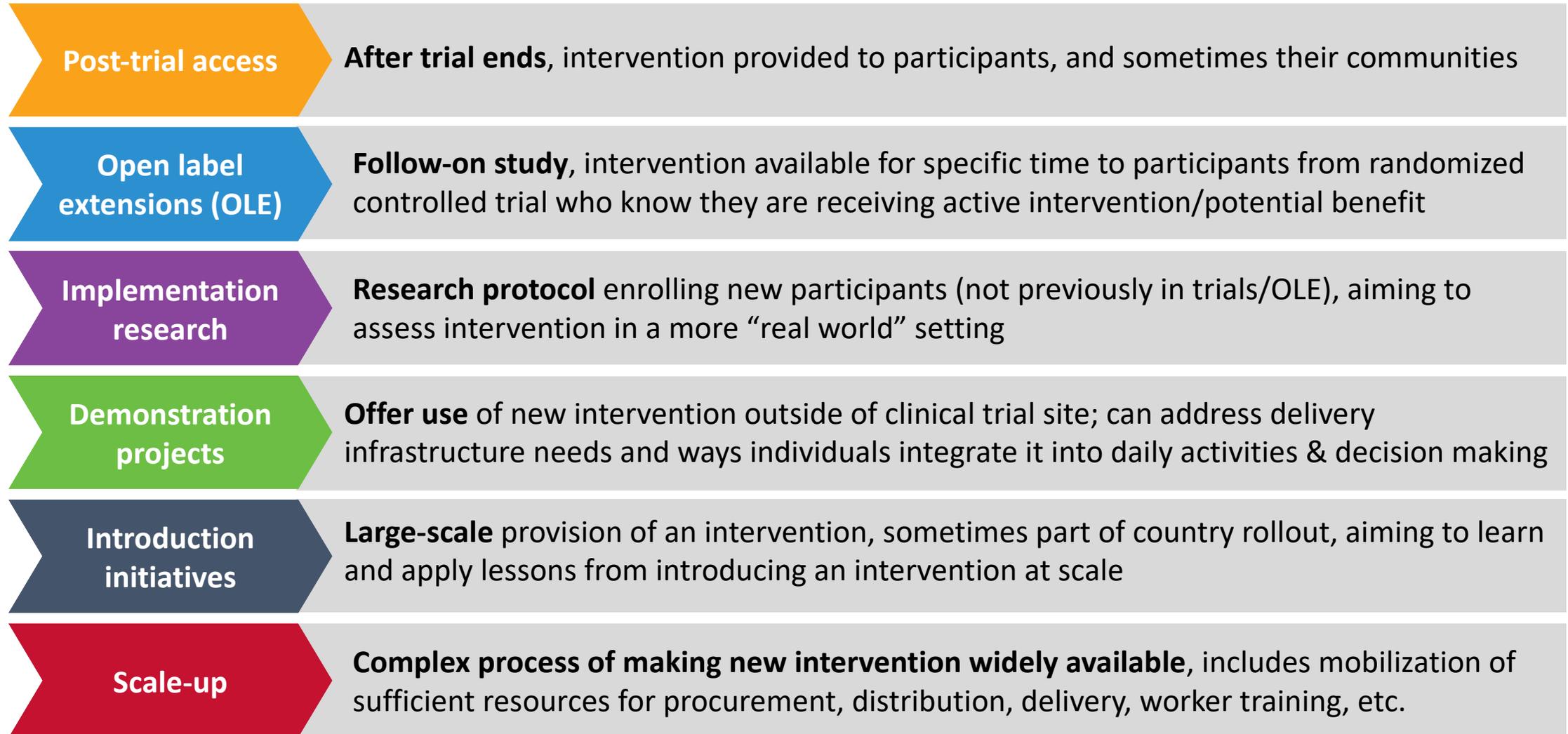
And Costs, And Costs of Infections Averted, And Time to Generics



Moving a Product to the “Real World”



Moving a Product to the “Real World”



Getting Rollout Right This Time

Speed + Scale + Equity = Impact

Acknowledgements

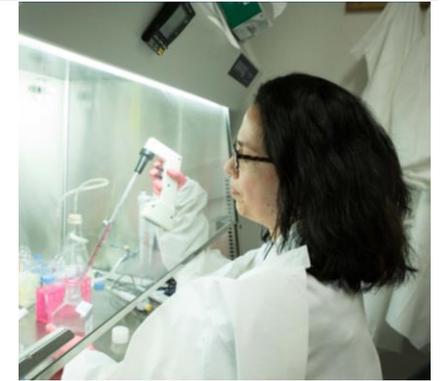
- Carolyn Amole
- Rachel Baggaley
- Linda-Gail Bekker
- Susan Buchbinder
- Connie Celum
- Sinead Delany-Moretlwe
- Kim Green
- Beatriz Grinsztejn
- Sharon Hillier
- Brian Kanyemba
- Grace Kumwenda
- Raphy Landovitz
- Kenneth Mwehonge
- Definate Nhamo
- Nittaya Phanuphak
- Yvette Raphael
- Helen Rees
- Zeda Rosenberg
- Kenly Sikwese
- Kristine Torjesen
- Jacque Wambui



Dapivirine Vaginal Ring - PrEP Ring - DapiRing

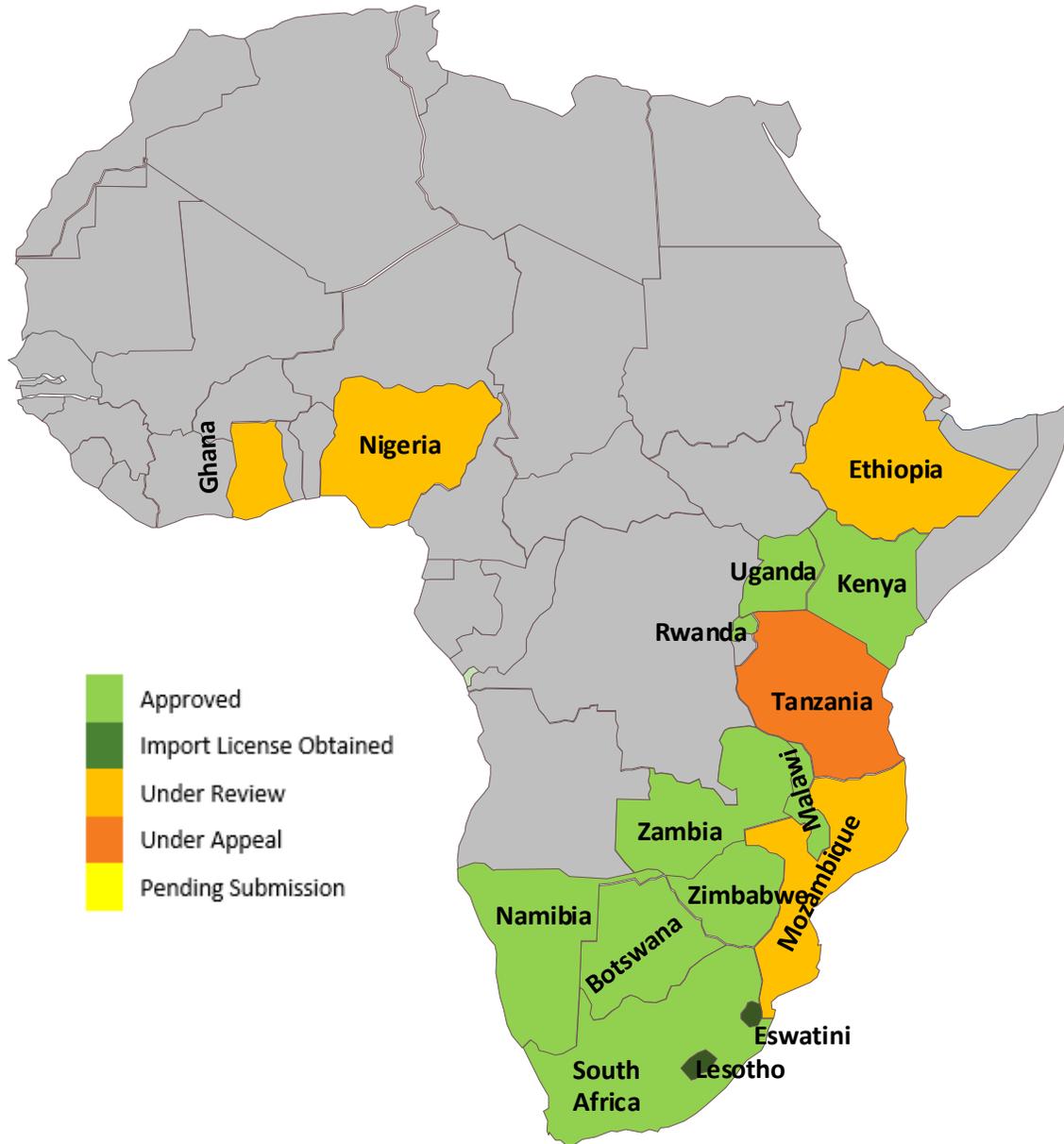
Regulatory and Access Update

Leonard Solai
September 2024



The Monthly Dapivirine Vaginal Ring (DVR)/DapiRing[®]

Monthly DVR Registrations – 11 countries



	Submission Date	Status
South Africa	Final Submission 26-Mar-2021	Product Registration 08-March-2022
Zimbabwe	03-February-2021	Product Registration 06-July-2021
Rwanda	11-February-2021	Approved by RFDA 10 Feb 2023
Uganda	17-February-2021	Product Registration 05-October-2021
Malawi	22-February-2021	
Tanzania	11-March-2021	On 12-April-2022 TMDA rejected the registration of DapiRing. An appeal was submitted.
Zambia	05-March-2021	Product Registration 10-May-2021
Kenya	23-March-2021	Product Registration 16-July-2021
Namibia	01-September-2021	Product Registration 27-July-2023
Botswana	08-September-2021	Product Registration 21 December 2022
Mozambique	28-June-2024	Under Review
Ghana	8-August-2024	Under Review
Ethiopia	TBD	Submission in progress
Nigeria	On hold	Requirement for clinical data in West African populations in discussion with Nigerian FDA
Eswatini and Lesotho	Import licenses have been issued	

Type II Clinical Variations - EMA



Monthly DVR

- Breast Feeding - APPROVED – B Protected Data
- Women older than 16 - AGYW - indication change: submission planned Oct 2024; soonest approval Jan 2025
- Pregnancy - : current submission plan Q4 2025, but depends on CSR availability (being confirmed) – DELIVER data – CSR submission with first trimester infant follow up

CIFF / Global Fund Ring Purchase

- Purchase of approximately 150 000 monthly DVR for Global Fund countries
- Application process and country decision – Chris Obermeyer
- Timeline : October 2024 for delivery end 2024 / begin 2025.
- Order mechanism

Expanding Access and the Continued Need for Choice

CIFF To Propel PrEP Revolution with up to US\$2 Million for Immediate Access to PrEP Rings

21 July 2024

MUNICH – The Children’s Investment Fund Foundation (CIFF), in partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), announced on 21 July at the 25th International AIDS Conference an initiative of up to US\$2 million over the 2024–2025 period for the purchase of approximately 150,000 dapivirine vaginal rings in countries that implement Global Fund grants to fight HIV and AIDS. The PrEP ring is a long-acting HIV pre-exposure prophylaxis (PrEP) option for women.

[Bis zu 2 Millionen US-Dollar der CIFF für sofortigen Zugang zu PrEP-Ringen revolutionieren Präexpositionsprophylaxe](#)

[[download in Deutsch](#)]

IDEAS

YVETTE RAPHAEL | The basket of HIV prevention options needs to be filled

The dapivirine vaginal ring symbolises a shift towards truly empowering women in HIV prevention

25 July 2024 - 08:30

BY YVETTE RAPHAEL



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DVR being integrated into IPPF Service Delivery

- Initiative underway to integrate new biomedical HIV prevention products into IPPF service delivery platforms
- First rings arrived at FLAS (Family Life Association of Eswatini)
- Other Member Associations across several countries to follow



Three-month DVR and Contraceptive- DVR

3 Month DVR: 2024 progress and next steps

2024 Progress

The Pivotal Bridging Trial – Complete!

- Initiated Q3 2022; LPLV April 2024
- Data includes participant interviews to understand acceptability, perceptions and preferences of 3 month vs. monthly DVR

Manufacturing Process Validation (1X scale)

- Complete!
- Results are sufficient for regulatory review
- The produced rings can be utilized as initial commercial supply

Next Steps

Bridging Trial Reporting

- Late Breaker Presentation at HIV R4P
- Study reports complete Q4 2024

Optimize Manufacturing at 5X scale and Tech Transfer to Kiara Health

- Optimization complete by end of 2025
- Tech transfer complete by end of 2027

Prepare and submit regulatory dossiers

- Submission to the EMA as a line-extension (Mid/late 2025)

Advocacy and Access Activities

- Conduct community engagement and other market access activities to prepare for market introduction

Contraceptive-DVR: 2024 progress and next steps

2024 Progress

Phase Ib Clinical Trial (IPM-056)

- Last participant enrolled June 2024, LPLV expected October 2024
- Early data analyses expected early/mid-2025 (through in-kind support from NICHD)

Next Steps

Regulatory strategy for an MPT to prevent HIV and unintended pregnancy

- Expected mid-2025

HIV-efficacy bridging and Phase III contraceptive clinical trials

- Will initiate after regulatory feedback received

Manufacturing Optimization

- Expected to complete mid-2026

Community engagement and access plan

- Ongoing

CBR and IPM South Africa Direct and In-Kind Funders

