

Opportunities, Controversies & Cruel Ironies

What's New & Next in HIV Prevention

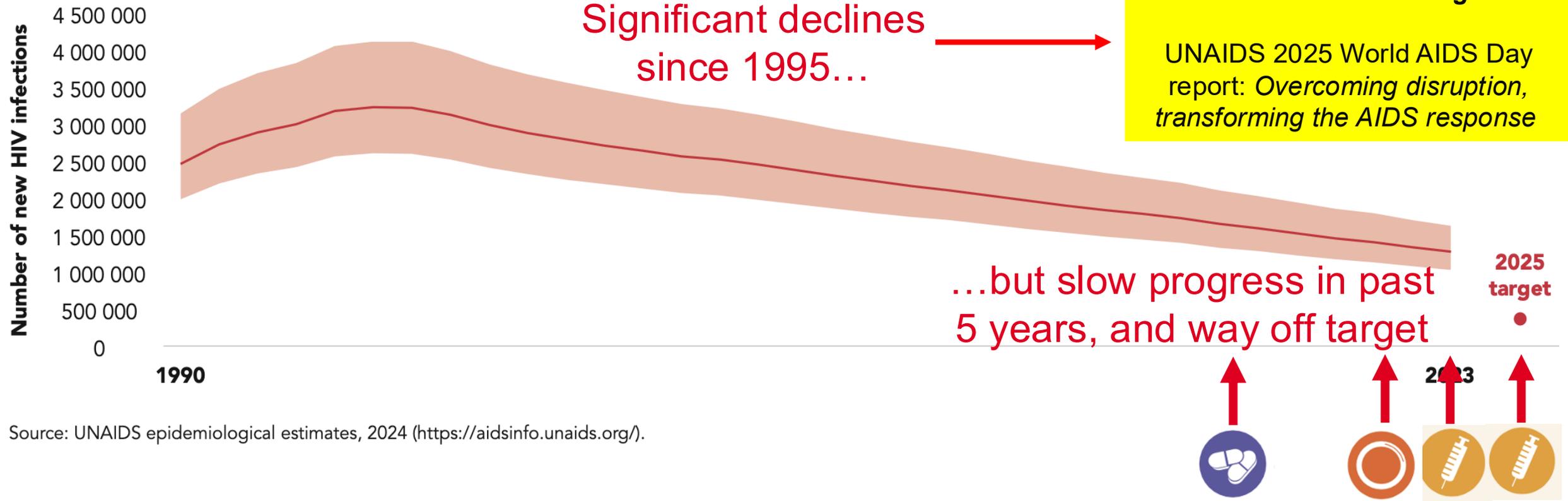
Mitchell Warren, Executive Director

20 March 2026

Forward in SYNChronicity through Research and Care

Tracking against UNAIDS 2025 targets

Figure 0.1 Number of new HIV infections, global, 1990–2023, and 2025 target



Source: UNAIDS epidemiological estimates, 2024 (<https://aidsinfo.unaids.org/>).

The End of the World As We Know It

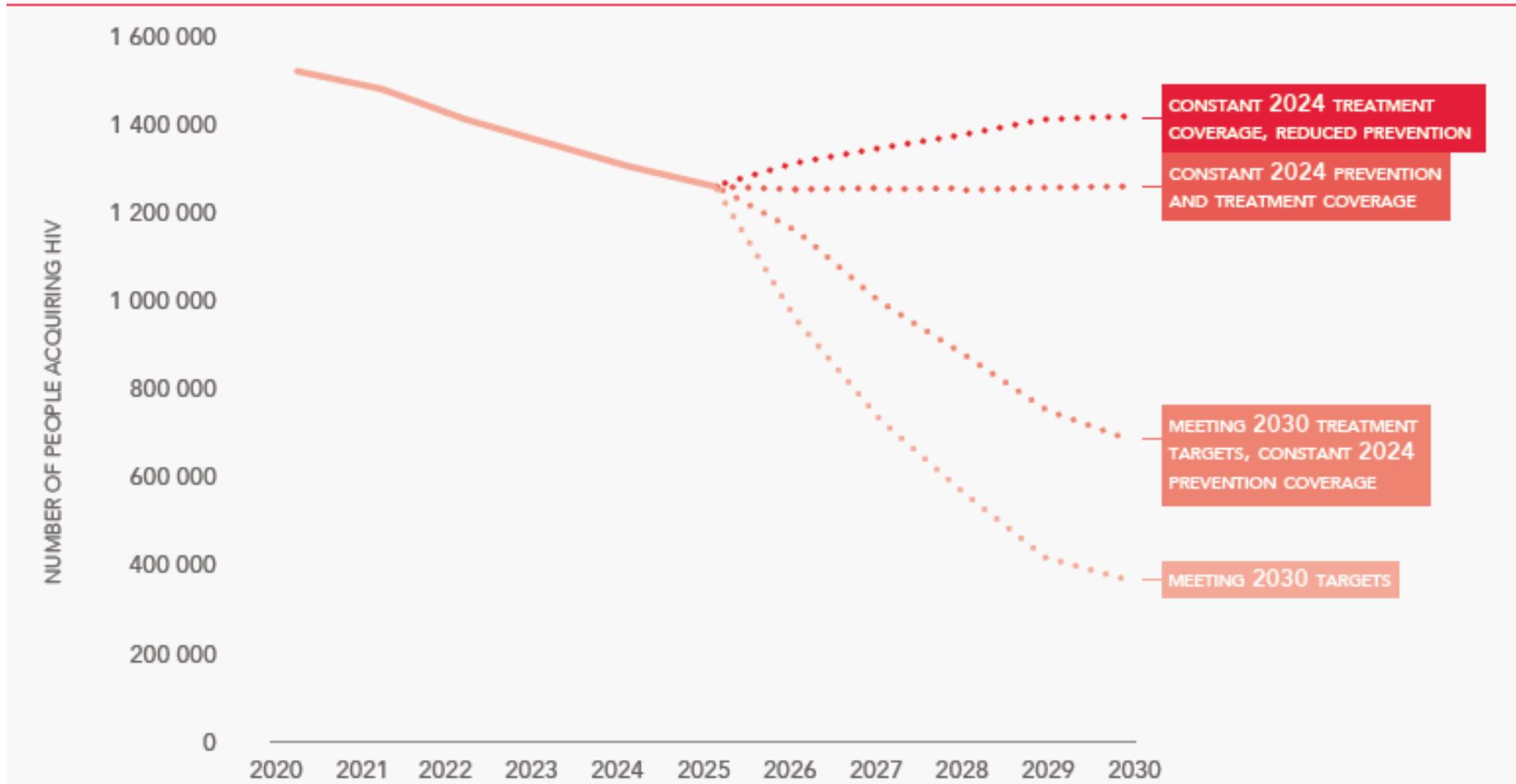
How It Started



What Could Happen Now

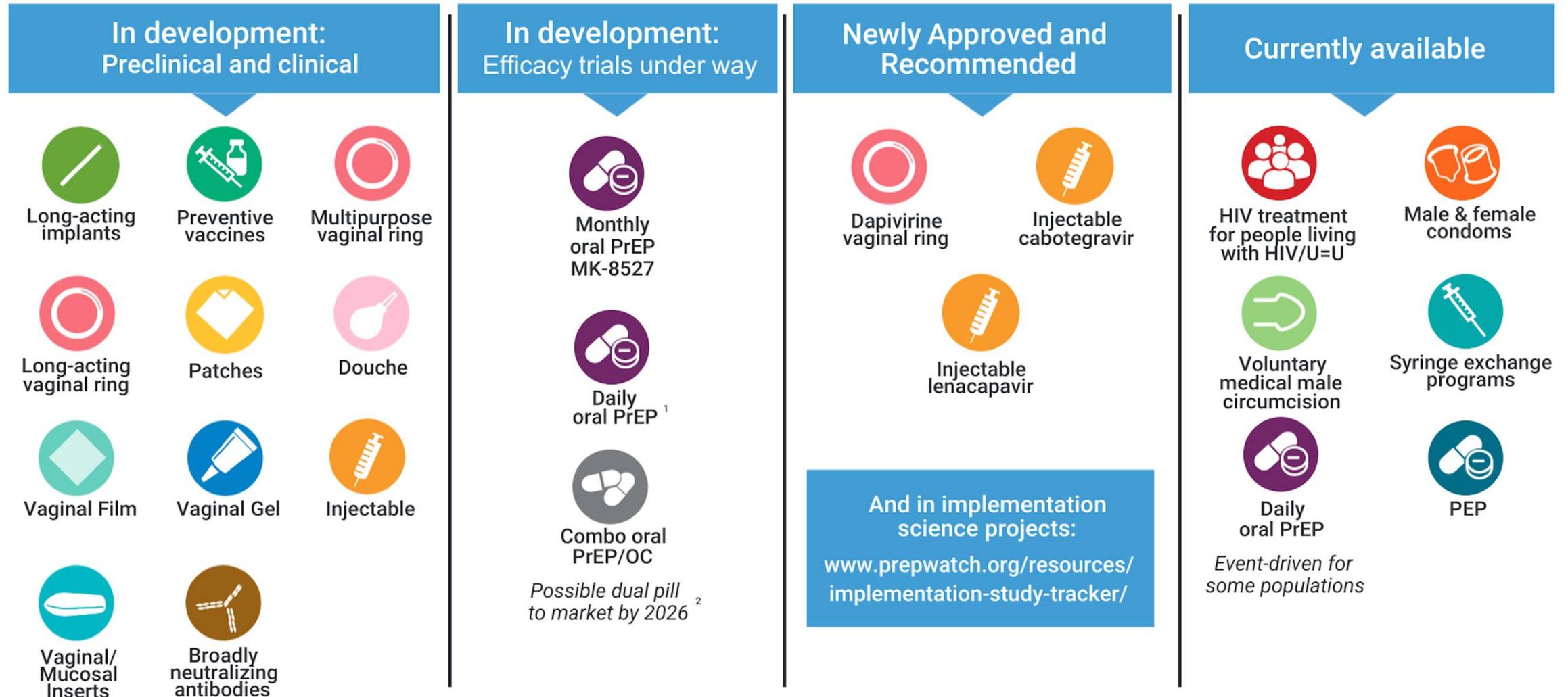
FIGURE 3.1

Figure 3.1. Number of people acquiring HIV, 2020–2024, and projected scenarios, 2025–2030, global.



Source: 2025 UNAIDS epidemiological estimates and Goals projections

Overview of Biomedical Px Pipeline (circa 2026)



¹ In Oct 2019, US FDA approved F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex; still in development for cisgender women.

² Efficacy trials not required; bioequivalency of the two approved products when dosed together may be all that is required.

Pipeline in Crisis: Impact of USAID & NIH Cuts

**In development:
Preclinical and clinical**

USAID cancelled funding for pre-clinical and clinical trials, stunting critical early progress on multiple upstream HIV prevention products

NIH terminated HIV vaccine research, including research on vaccine candidates and bNabs

Long-acting implants, Long-acting vaginal ring, Purpose vaginal ring, Preventive vaccines, Daily oral PrEP, Vaginal Mucosal Inserts, neutralizing antibodies

**In development:
Efficacy & IS trials under way**

NIH and USAID terminated implementation science and acceptability studies which could impact product introduction

lenacapavir, Daily oral PrEP, Combo oral PrEP/OC, Possible dual pill to market by 2025?

Newly Approved and Recommended

Introduction of promising new products in development and newly approved is at risk if USAID does not honor procurement commitments and fund prevention programs

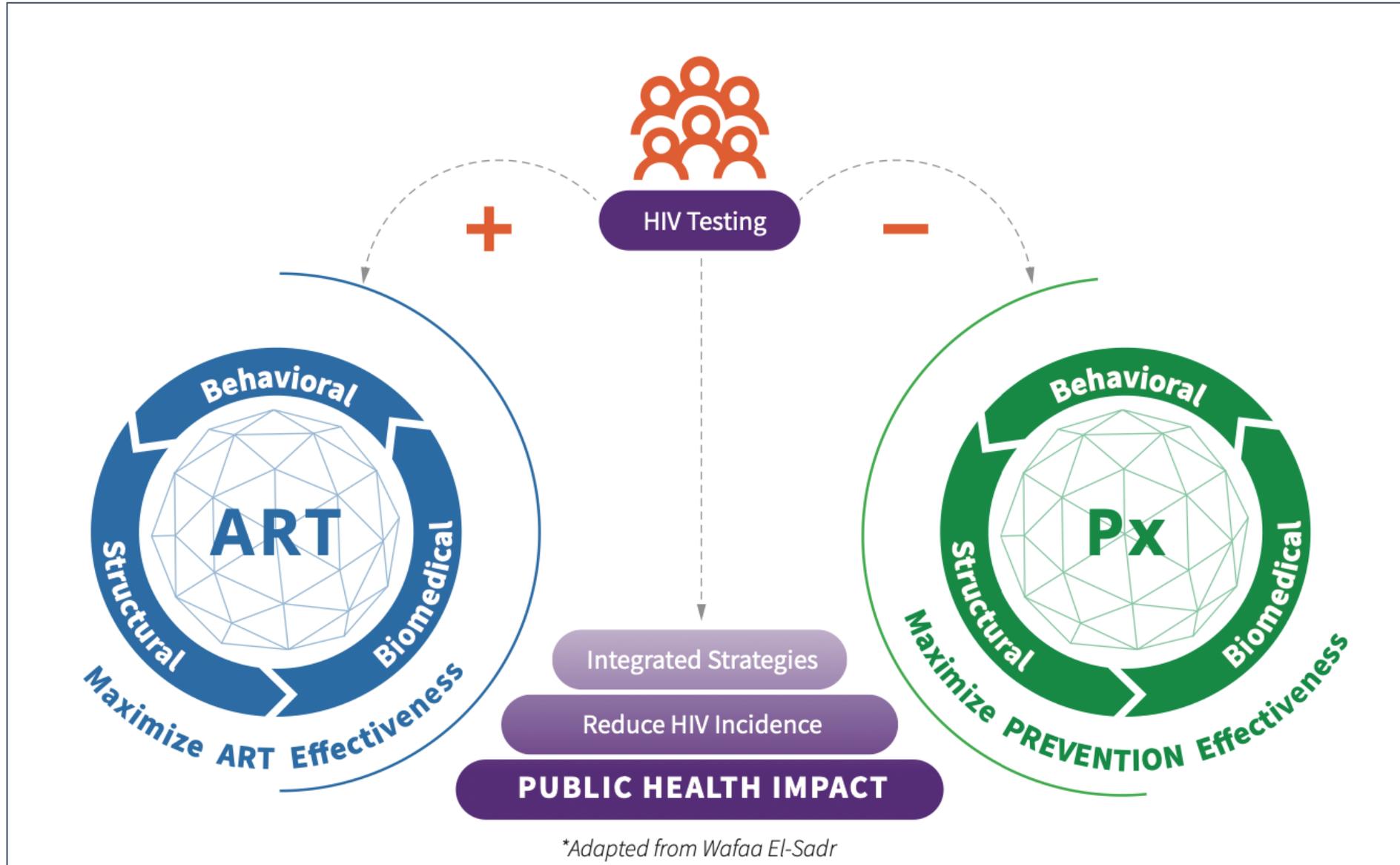
Injectable, vaginal ring

Currently available

Cuts to USAID's PEPFAR funding for prevention products and programs may impact access to available products, but the extent is not yet known

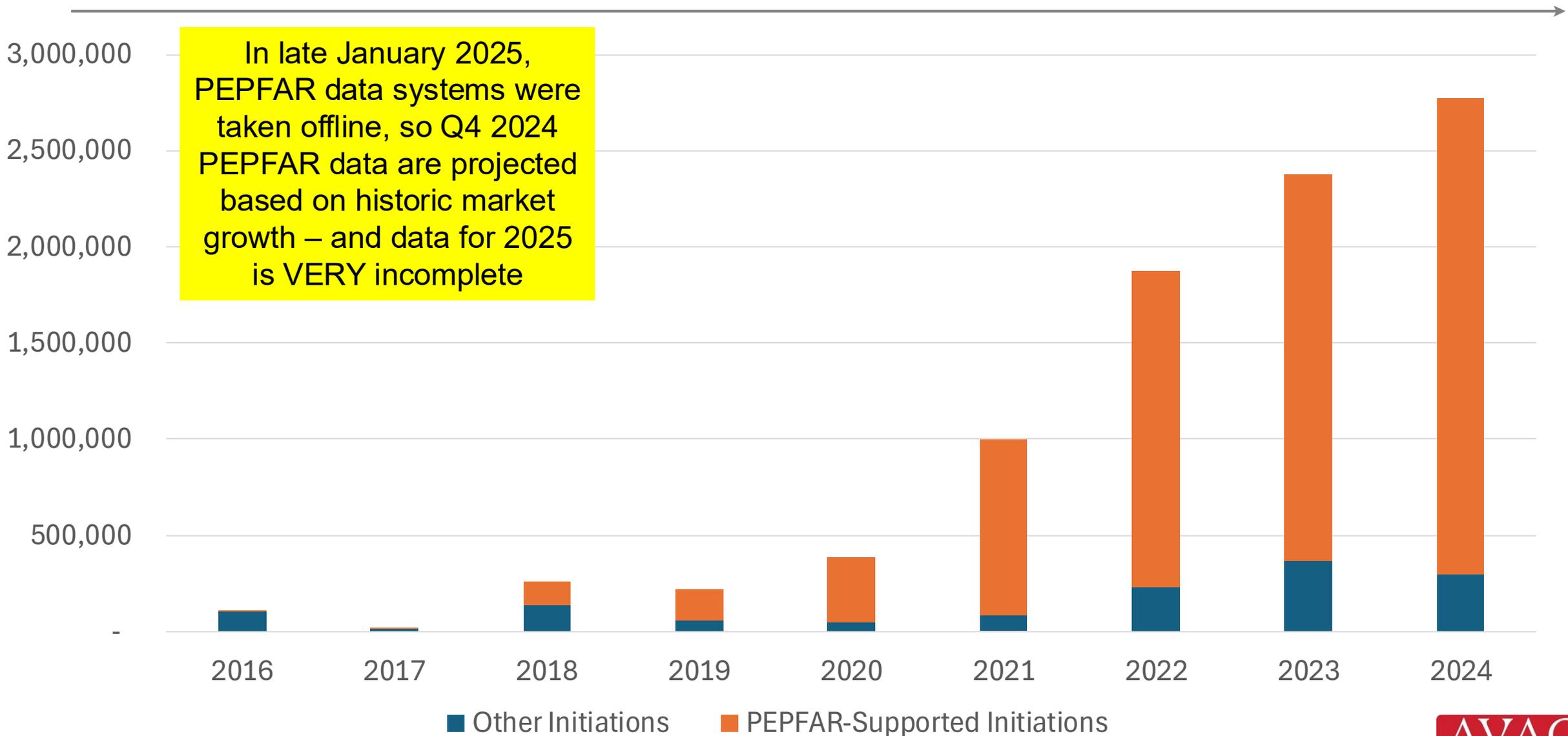
HIV treatment for people living with HIV, Male & female condoms, Voluntary medical male circumcision programs, Daily oral PrEP, PEP, Event-driven for some populations.

Universal Test & Connect



**Adapted from Wafaa El-Sadr*

PrEP Initiations to 2024



PEPFAR Stop Work Orders: Major Impacts

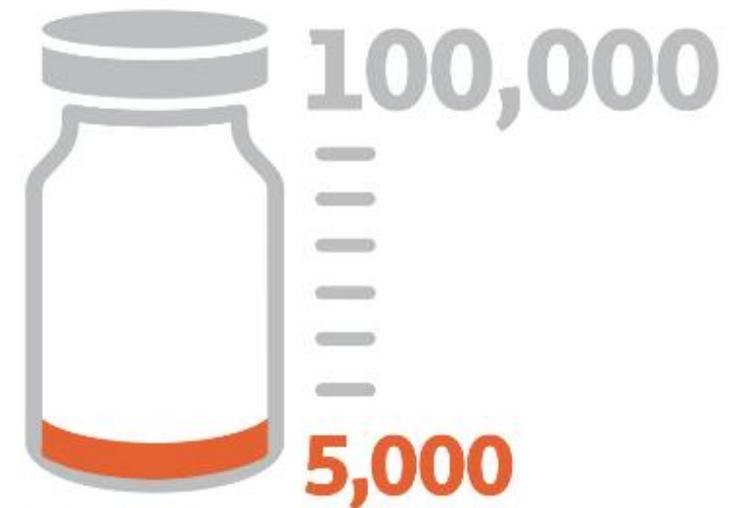
<https://www.prepwatch.org/pepfar-stop-work/>



Number of new **PrEP users** in 2024 who have **lost access to PEPFAR-supported PrEP services**

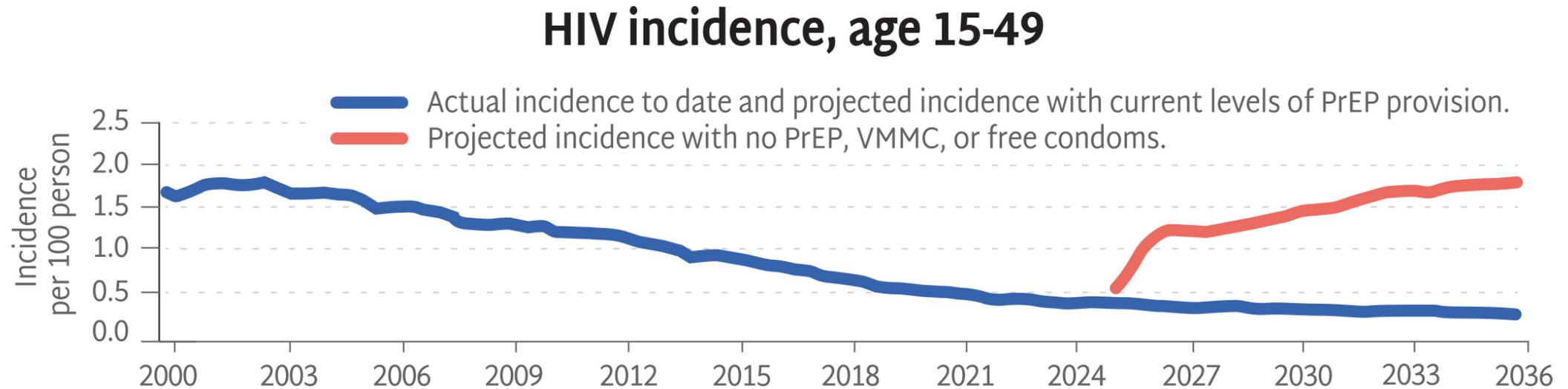


Number of people identifying as **Key Populations** who have **lost access to HIV prevention programming** under PEPFAR



Off Target: The PEPFAR goal of **people initiating CAB for PrEP** in 2025 is falling far short – **5k instead of 100k**

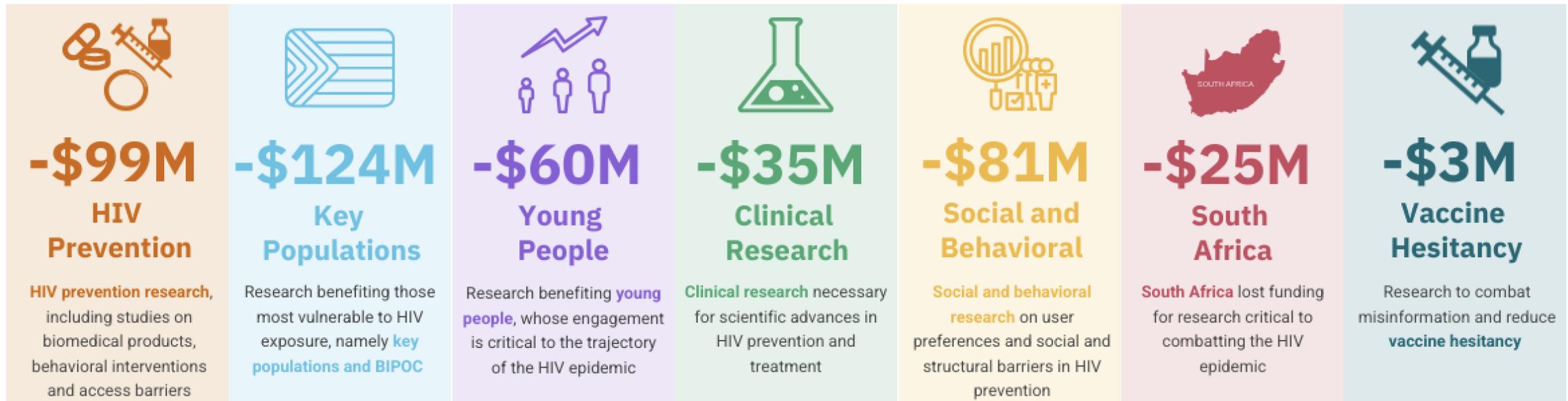
A World Without HIV Prevention



[HIV Synthesis model](#), developed by the HIV Modelling Consortium

The Cost of Cutting HIV Research

NIH terminated 191 HIV-specific grants in 2025, slashing over \$200 million from key HIV prevention research grants¹



¹Grants may cover more than one research area, so total across categories shown here exceeds \$200 million in total funding lost

Potential Fallout from Cuts to HIV Prevention

Impacts on trials, including those sponsored by non-USG funders

- USG funding is the scaffold on which pharma, philanthropies and other governments invest in transformative HIV & TB science
- Trials sponsored by other research funders build on top of core and other funding provided to clinical trials units and research sites through NIH awards
- USG cuts risk infrastructure, staff/talent, training the next generation of scientists, community engagement, data sharing, biorepositories, etc.
- If South African and other international study sites and participants are excluded from enrollment, follow-up, study completion, and data collection and analysis, ongoing and planned trials are likely underpowered to produce meaningful results, wasting years of work and tens or hundreds millions of dollars
- Trials no longer able to enroll internationally will face delays and increased costs as they seek new sites and study participants elsewhere

The Truly Global Nature of HIV Research

HEALTH AFFAIRS FOREFRONT | GLOBAL HEALTH POLICY

RELATED TOPICS:

HIV/AIDS | TREATMENT | CLINICAL TRIALS | ORGANIZATION OF CARE | SYSTEMS OF CARE
| PRESCRIPTION DRUGS | HEALTH OUTCOMES | CLINICS | QUALITY OF LIFE
| POPULATIONS

The Benefits To Americans Of US-Supported International HIV Research

[Judith Auerbach](#), [Jirair Ratevosian](#), [Mitchell Warren](#)

MARCH 13, 2026

10.1377/forefront.20260310.289132



Timeline of US-Funded International HIV Research—Recent Milestones and US Impact

Male circumcision efficacy trials 2006

Kenya, South Africa, Uganda

Three clinical trials showed approximately 60 percent reduction in heterosexual acquisition of HIV among men receiving medical male circumcision. This provided evidence of the efficacy of a prevention intervention bridging biological and cultural factors in different settings.

First trials of Truvada for oral PrEP efficacy 2010

Brazil, Ecuador, Kenya, Peru, South Africa, Thailand, Uganda, United States.

The iPrEx, Partners PrEP, and TDF2 trials demonstrated the safety and efficacy of daily oral PrEP with TDF/FTC for significantly reducing the risk for HIV acquisition, leading to FDA approval in 2012 for Americans at elevated risk.

First randomized controlled trial to assess the efficacy of Treatment as Prevention 2011

13 sites in 9 countries in Africa, Asia, Latin America, United States

HPTN 052 demonstrated that early ART for the HIV-positive partner dramatically reduces sexual transmission in serodiscordant couples, providing foundational scientific support for the Undetectable=Untransmittable movement and affecting clinical practice in the US.

Trial examining the efficacy of long-acting injectable PrEP for HIV prevention in cisgender men and transgender women 2016

Asia, Africa, Latin America, United States

HPTN 083 showed that long-acting injectable PrEP with CAB-LA given every 8 weeks was superior to daily oral TDF/FTC for HIV prevention among cisgender men and transgender women who have sex with men, providing the first definitive evidence that injectable PrEP could outperform oral PrEP and expanding prevention options for cisgender men and transgender women.

Implementation of research on the efficacy of differentiated service delivery models 2022

Many African countries

Multiple studies showed that reimagining care delivery helped decongest clinics, reduce patient burden, and improve retention and viral suppression in resource-constrained settings. These models have informed US efforts to adapt HIV care delivery, particularly in under-resourced, rural, or hard-to-reach communities.

First antiretroviral-based microbicide effectiveness trial in women 2010

South Africa

Caprisa 004 demonstrated that a user-controlled prevention tool (tenofovir microbicide gel) could reduce HIV acquisition risk among women in high-incidence contexts, reinforcing the need for multiple prevention options beyond condoms and behavior change. This expanded the prevention toolbox for women globally.

Trial to determine the efficacy of immediate ART initiation 2011

215 sites in 35 countries in Africa, Asia, Europe, Latin America, United States

The Strategic Timing of Antiretroviral Treatment (START) trial found that immediate ART (regardless of CD4 count) significantly reduced serious AIDS and non-AIDS events versus delayed ART. The data supported the shift to treat all globally, influencing US ART guidelines.

Cluster-randomized trial to test the efficacy of “test-and-treat” plus combination prevention at a community scale 2013

South Africa, Zambia

HPTN 071 (PopART) was a large trial of comprehensive HIV prevention plus universal ART. It showed that high levels of testing, linkage, and treatment in a real-world setting could significantly reduce community incidence, providing empirical backing for incidence-reduction programs worldwide, including Ending the HIV Epidemic in the US.

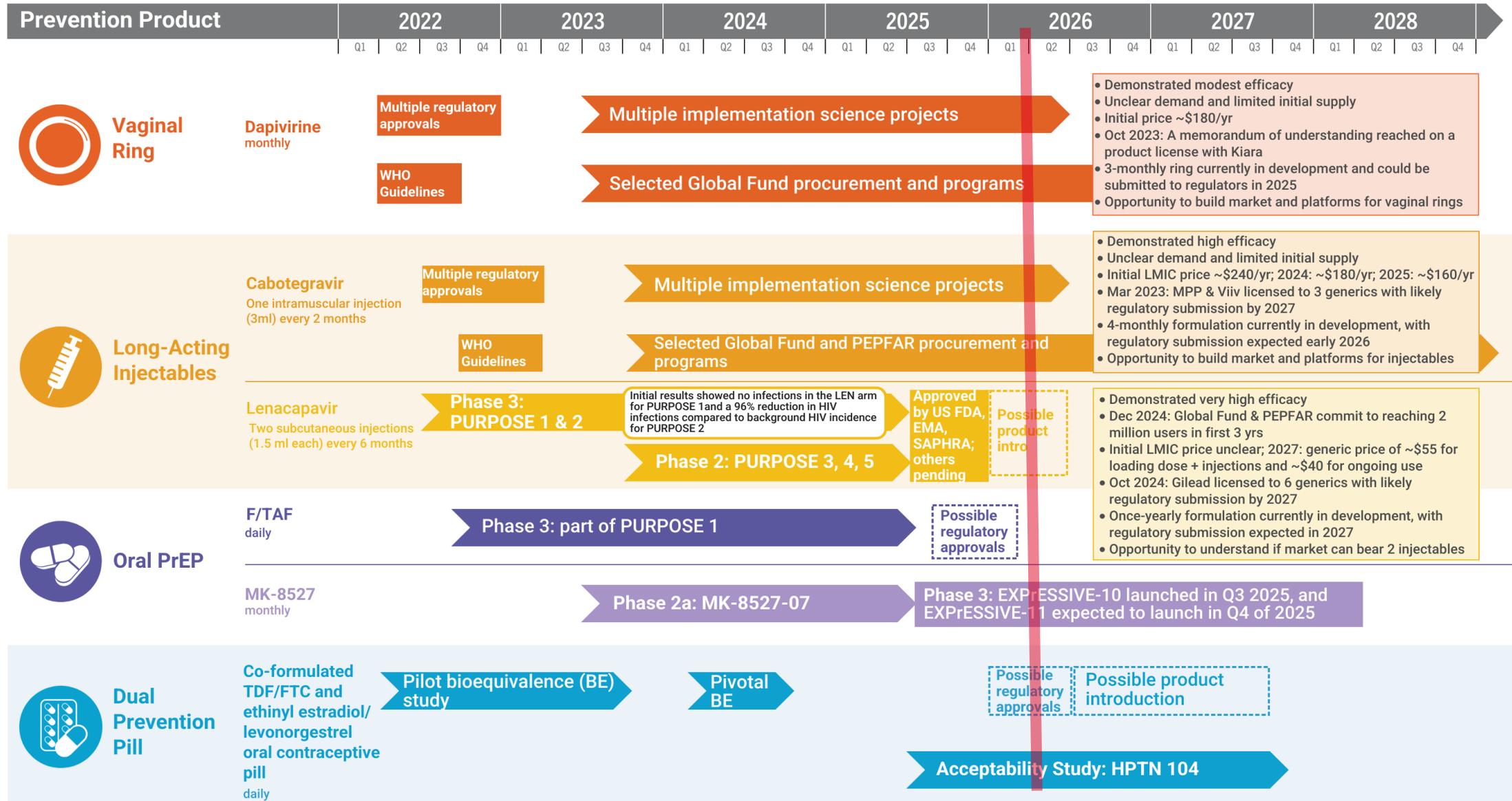
Trial examining the efficacy of long-acting injectable PrEP for HIV prevention in cisgender women 2020

7 sub-Saharan African countries

HPTN 084 showed that CAB-LA injected every 8 weeks was superior to daily oral TDF/FTC for the prevention of HIV infection in cisgender women. Along with findings from HPTN 083, this led to FDA approval of CAB-LA in 2021, expanding HIV prevention options for women and men in the US.

<https://www.healthaffairs.org/content/forefront/benefits-americans-us-supported-international-hiv-research>

PrEP Pipeline



- Demonstrated modest efficacy
- Unclear demand and limited initial supply
- Initial price ~\$180/yr
- Oct 2023: A memorandum of understanding reached on a product license with Kiara
- 3-monthly ring currently in development and could be submitted to regulators in 2025
- Opportunity to build market and platforms for vaginal rings

- Demonstrated high efficacy
- Unclear demand and limited initial supply
- Initial LMIC price ~\$240/yr; 2024: ~\$180/yr; 2025: ~\$160/yr
- Mar 2023: MPP & Viiv licensed to 3 generics with likely regulatory submission by 2027
- 4-monthly formulation currently in development, with regulatory submission expected early 2026
- Opportunity to build market and platforms for injectables

- Demonstrated very high efficacy
- Dec 2024: Global Fund & PEPFAR commit to reaching 2 million users in first 3 yrs
- Initial LMIC price unclear; 2027: generic price of ~\$55 for loading dose + injections and ~\$40 for ongoing use
- Oct 2024: Gilead licensed to 6 generics with likely regulatory submission by 2027
- Once-yearly formulation currently in development, with regulatory submission expected in 2027
- Opportunity to understand if market can bear 2 injectables

The Time Is Now

THE LEDE

THE DRUG THAT COULD REVOLUTIONIZE THE FIGHT AGAINST H.I.V.

World leaders are dismantling global health programs and cutting back foreign aid. Will an extraordinary new medicine be able to outpace the damage?

By Jon Cohen

June 24, 2025

“At least conceptually, this is one of the most transformational moments in H.I.V. prevention ever.” -- Mitchell Warren, AVAC

THE
NEW YORKER

Getting to Zero

June 20, 2024

Gilead's Twice-Yearly Lenacapavir Demonstrated 100% Efficacy and Superiority to Daily Truvada® for HIV Prevention

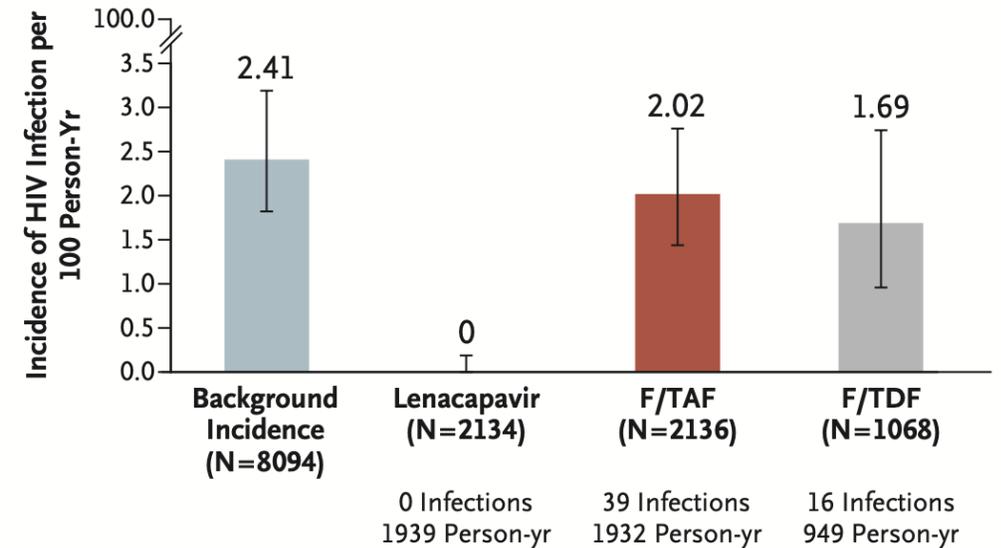
ORIGINAL ARTICLE

Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women

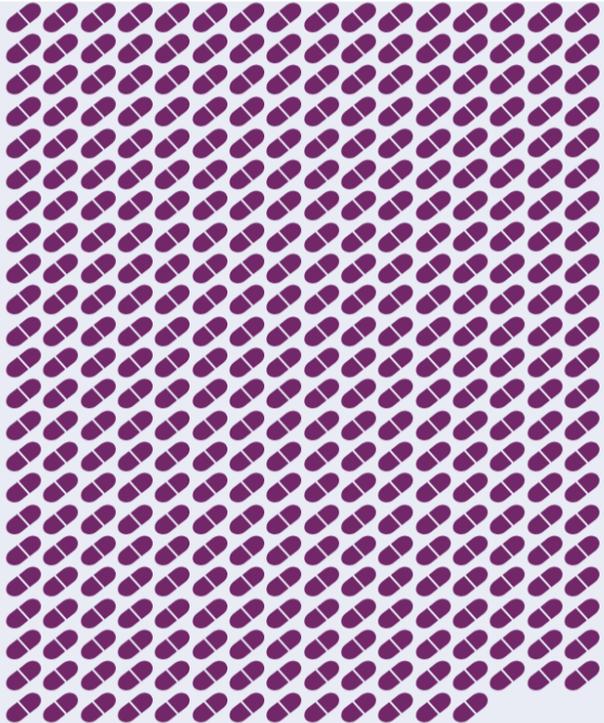
September 12, 2024

Gilead's Twice-Yearly Lenacapavir for HIV Prevention Reduced HIV Infections by 96% and Demonstrated Superiority to Daily Truvada® in Second Pivotal Phase 3 Trial

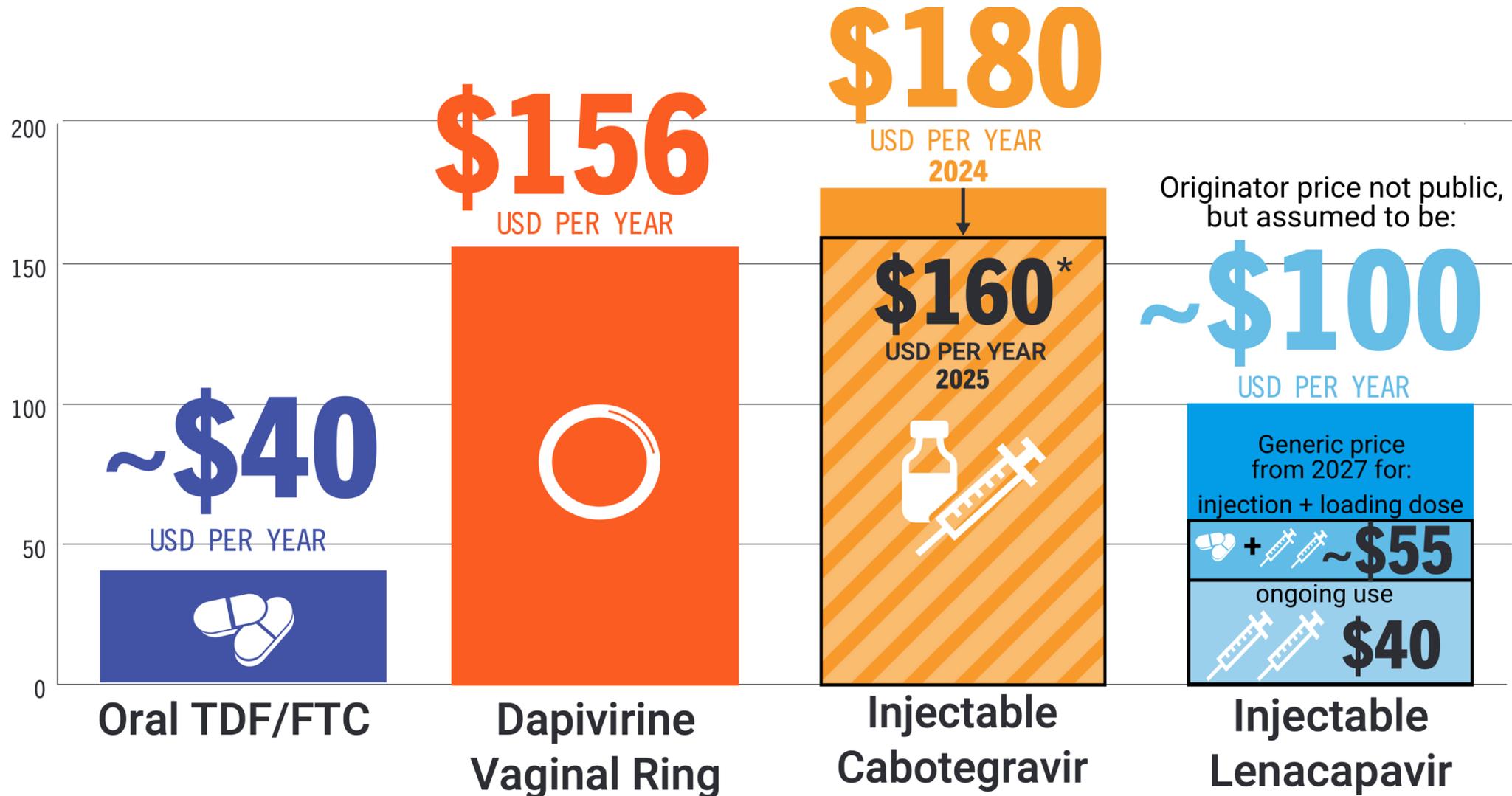
A Background HIV Incidence and HIV Incidence in Lenacapavir, F/TAF, and F/TDF Groups



What Is a “Person Year of Protection”?

	Tenofovir-based (FTC + TDF or TAF)	Dapivirine (DVR)	Cabotegravir (CAB)	Lenacapavir (LEN)
PrEP Dosing for One Year of Protection	One pill every day for all populations (with possibility of event-driven dosing of 2-1-1 for some)	One ring every month	First injection followed by a second one month later, then every 2 months	First injection along with two oral tablets, followed by two more tablets on day 2 and then injections every 6 months
			Day 1:  1 month:  3 month:  5 month:  7 month:  9 month:  11 month: 	Day 1:    Day 2:  6 month:  

PrEP Price Comparison for LMICs



*The actual price per vial is quoted in UK Pounds but converted to US Dollars for comparison purposes. The price is down from \$180 in 2024 to \$160 in 2025.

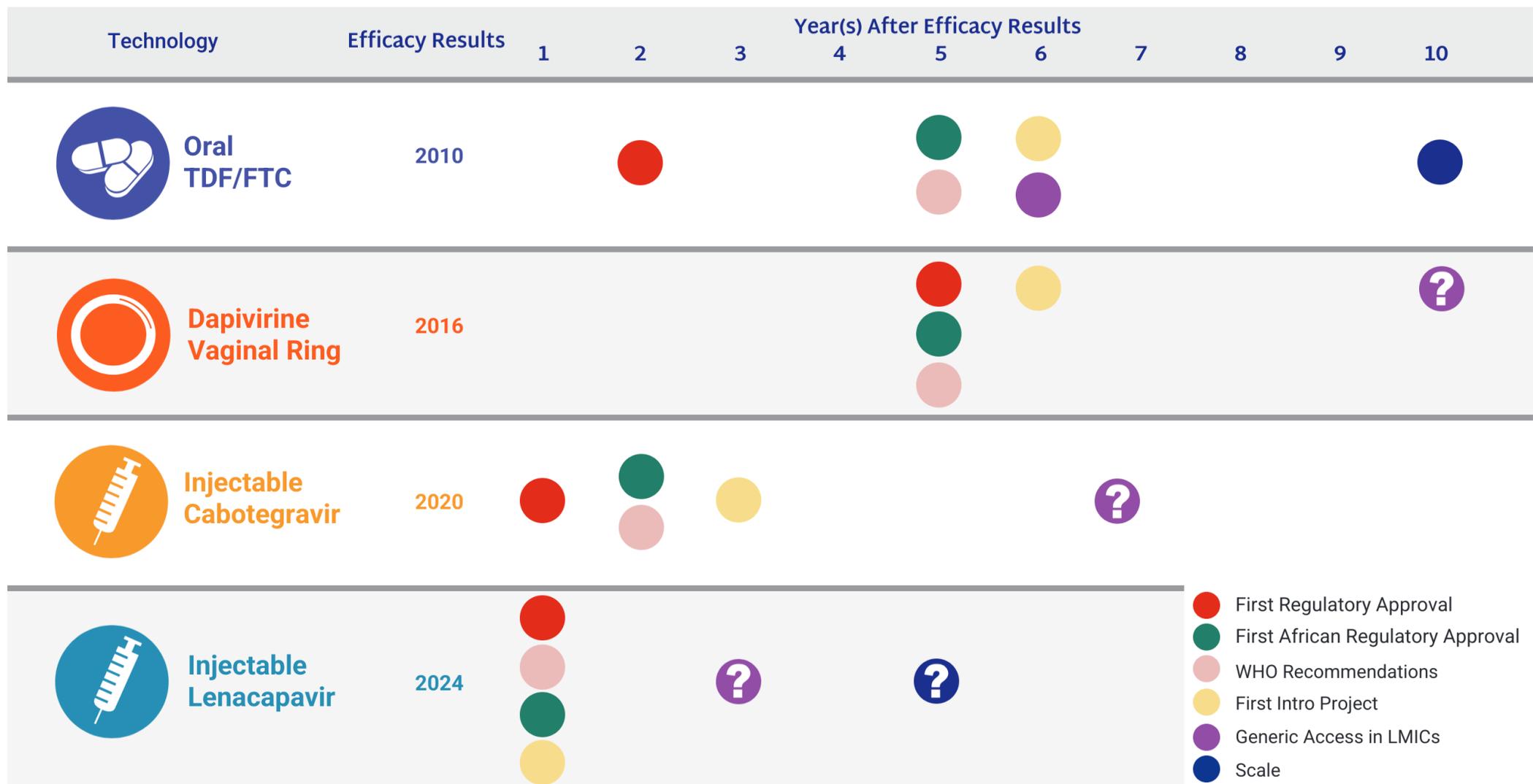
Gears of Lenacapavir for PrEP Rollout

The Gear Framework for Lenacapavir for PrEP Rollout

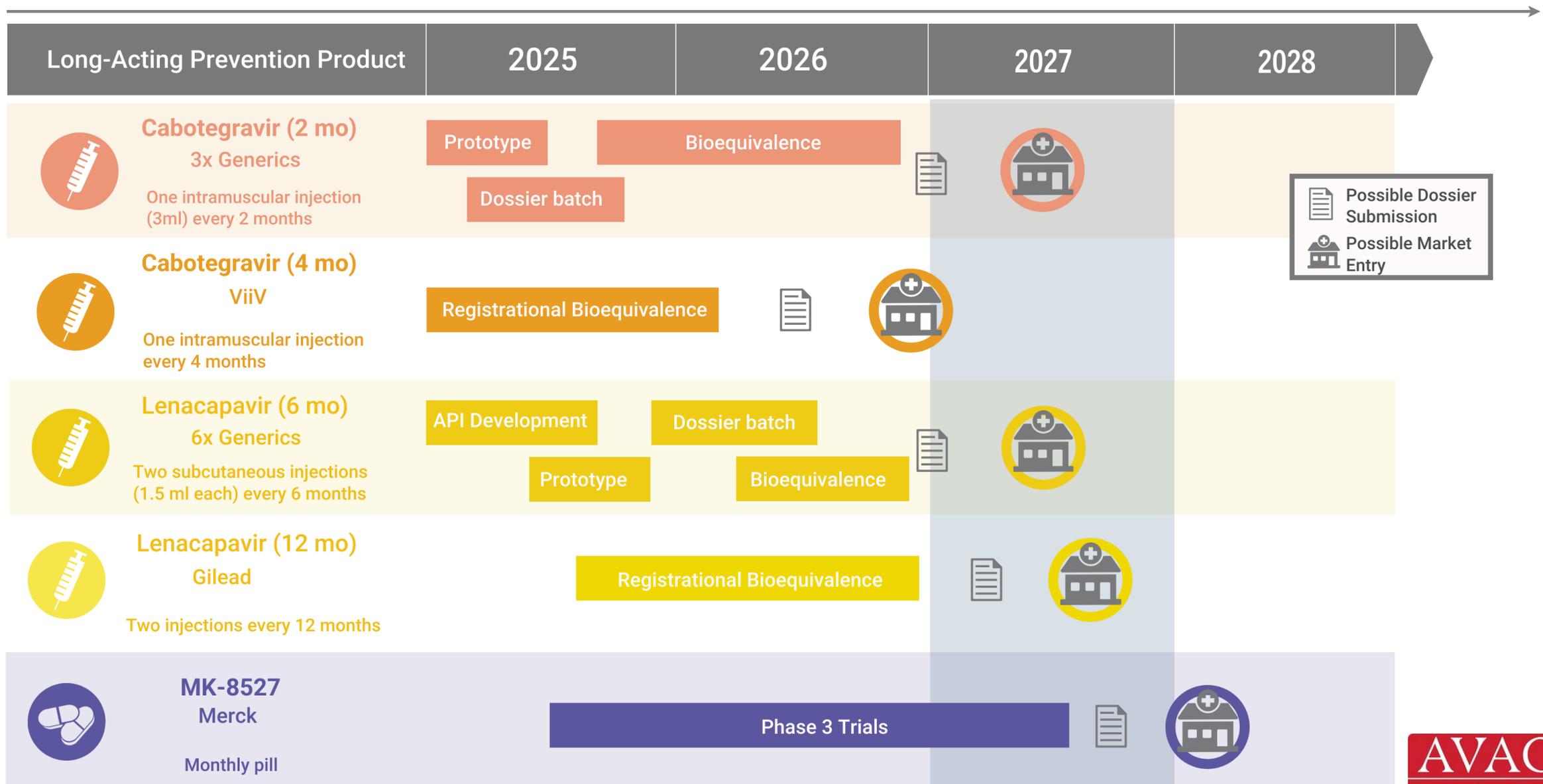


The rollout of lenacapavir represents not just a scientific breakthrough, but a pivotal moment in global health equity. Stakeholders must act decisively to seize this opportunity, ensuring that all populations—regardless of geography, income, or identity—benefit from this innovative prevention tool.

Moving a Product to the Real World

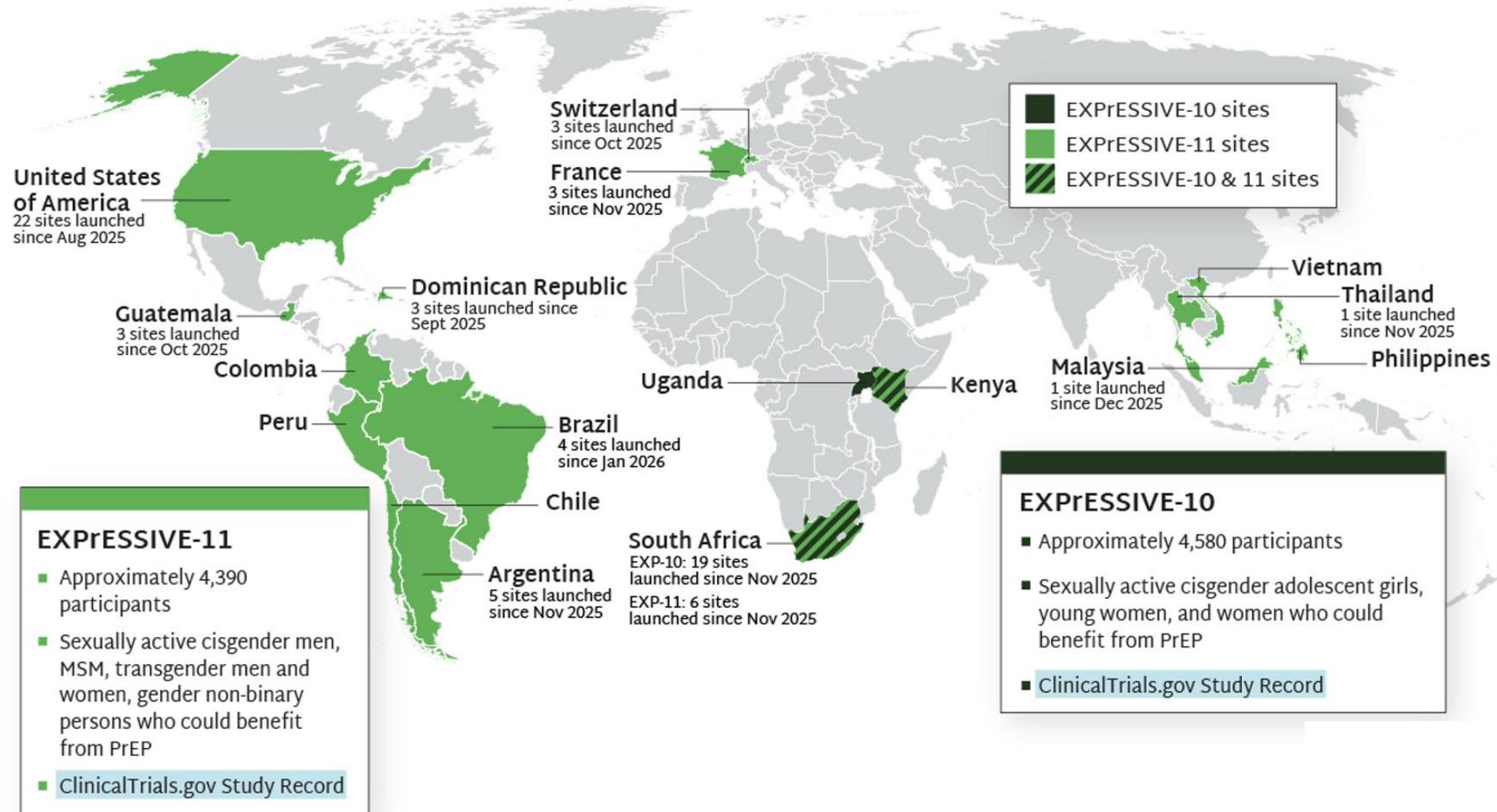


Looking to the Future: Innovation Pile-Up



EXPrESSIVE Phase 3 Trial Countries of MK-8527

17 countries hosting sites for Phase 3 trials of monthly PrEP pill, MK-8527; EXPrESSIVE-11 launched Aug 2025; EXPrESSIVE-10 launched Nov 2025.



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

The Way(s) Forward

- We are not going back to 19 January 2025...



"SIX WEEKS ON THE JOB! HAS IT BEEN THAT LONG ALREADY?"

The Way(s) Forward

- ...must build for the future

Science

SCIENCEINSIDER | HEALTH

Trump has blown a massive hole in global health funding—and no one can fill it

Other countries, foundations, international groups are unable to replace billions lost in U.S. cuts

8 APR 2025 · 4:18 PM ET · BY [IDA JOOSTE](#)

“We are in the middle of a massive earthquake. When buildings fall, we can’t just build back what we had before. We need a whole new global health funding architecture, but we won’t be able to build it fast enough to avoid significant harm.”

<https://www.science.org/content/article/trump-has-blown-massive-hole-global-health-funding-and-no-one-can-fill-it>

The Way(s) Forward

Some guiding principles

- Prioritize, Prioritize, Prioritize – like we've never prioritized before
- Don't miss out on innovation
- Think health systems – not disease- or product-specific
- Think and collaborate differently – in new ways and with different stakeholders
- Re-define sustainability – and make sure it is not just about money, and that prevention is a solid part of it
- Local ownership & leadership

Further Resources

- [People's Research Agenda](#) and online pipeline tracker
- Weekly [Global Health Watch](#)
- [PEPFAR Stop Work Order Tracker](#) – a live version of this slide deck
- [HIV Prevention R&D at Risk](#) – highlighting the impact of US cuts on the pipeline of HIV prevention R&D
- [PrEPWatch.org](#) – data, information, and PrEP resources
- [Global PrEP Tracker](#) – tracking PrEP initiations by country over time
- [All things LEN](#)



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- Hasina Subedar
- Kristine Torjesen
- Jacque Wambui

Gates Foundation

CIF CHILDREN'S INVESTMENT FUND FOUNDATION

HIV Prevention Market Manager
Accelerating Product Introduction
Informing Product Development
Reducing Time to Impact

AVAC
CLINTON HEALTH ACCESS INITIATIVE
Supported by the Bill & Melinda Gates Foundation

BioPIC Biomedical Prevention Implementation Collaborative

ELTON JOHN AIDS FOUNDATION

COMPASS

Coalition to Accelerate and Support Prevention Research (CASPR)

Cooperative Agreement No. AID-OAA-A-16-00031
HIV Vaccine and Biomedical Prevention Research Project—Objective 3

MATRIX
Advancing R&D of Innovative HIV Prevention Products for Women