



**PrEPARING
ASIA 2025**



PrEP Now

The latest on PrEP, in all its forms

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PrEPARING ASIA 2025: Making PrEP choice a reality



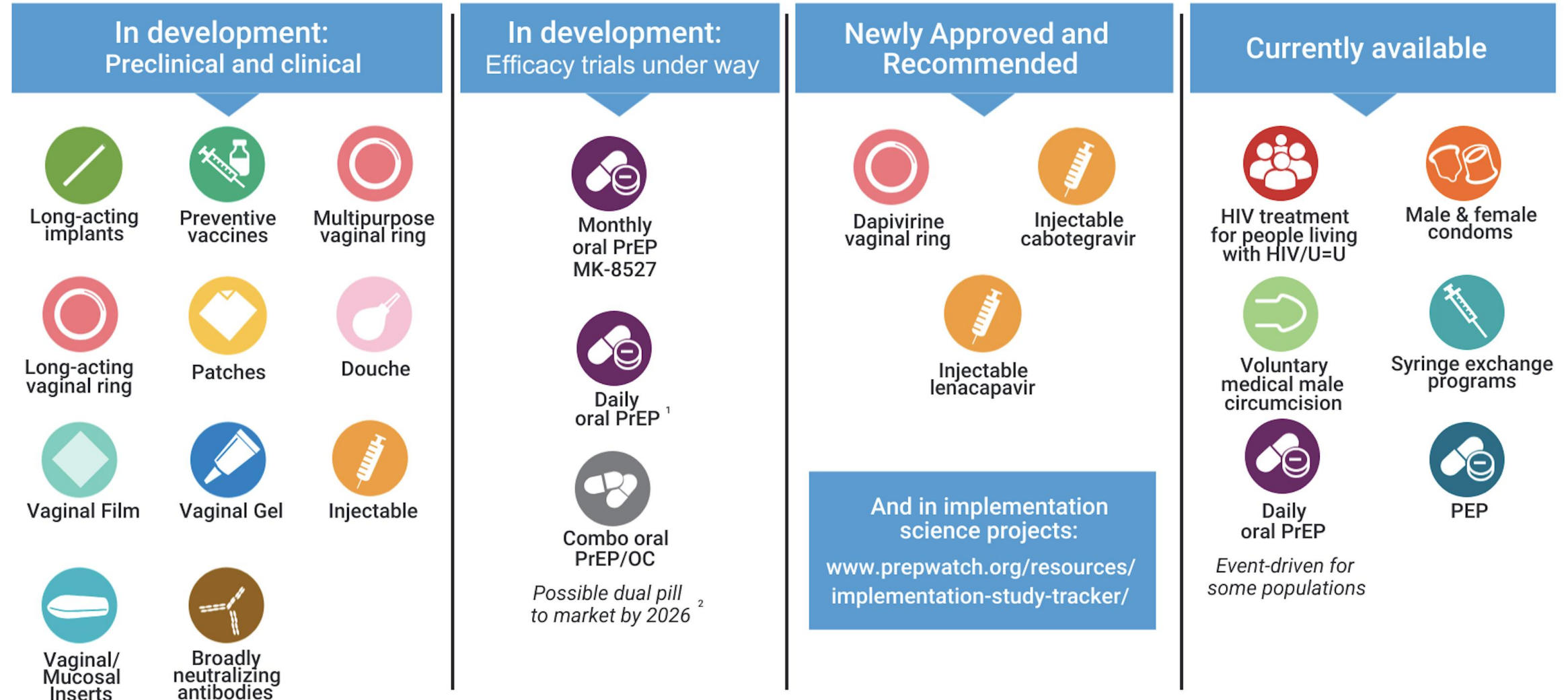
Prevention Paradigm circa 2006

Different Strokes for Different Folks		
Method	Contraception	HIV Prevention
Behavior	✓	✓
Barrier Methods	✓	✓
Gels	✓	
Rings	✓	
Oral pill	✓	
Injectables	✓	
Implants	✓	
Surgical procedures	✓	
Treatment		

Prevention Paradigm 2025 and beyond

Different Strokes for Different Folks		
Method	Contraception	HIV Prevention
Behavior	✓	✓
Barrier Methods	✓	✓
Gels	✓	✓ – not registered
Rings	✓	✓ (monthly) ? – 3-month & dual px in development
Oral pill	✓	✓ (daily) ✓ (<i>event-driven for some</i>) ? – monthly, dual px in development
Injectables	✓	✓ – ARV (every 2 and 6 months) ? – every 4 and 12 month formulations; other ARVs, bNAb, vax in development
Implants	✓	? – multiple in preclinical
Surgical procedures	✓	✓
Treatment		✓

Overview of Biomedical Px Pipeline (circa 2025)



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.

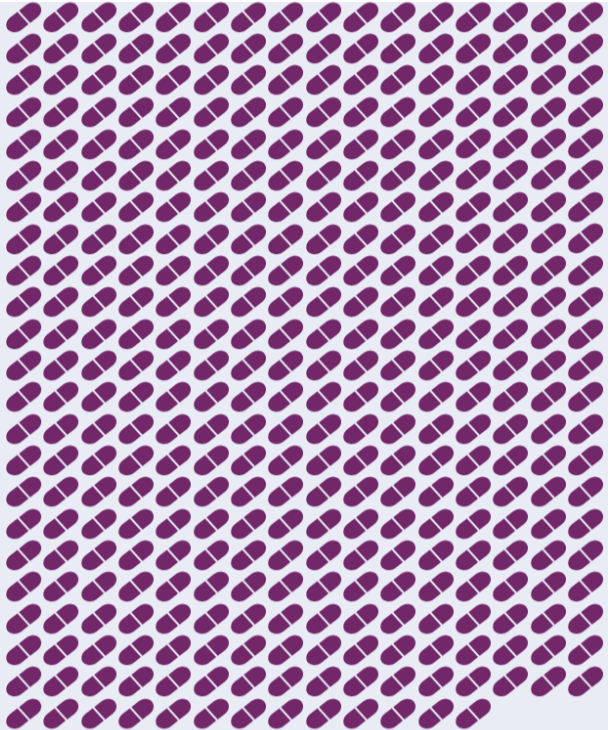
² Efficacy trials not required; bioequivalency of the two approved products when dosed together may be all that is required.

	Tenofovir-based (FTC + TDF or TAF)	Dapivirine (DVR)	Cabotegravir (CAB)	Lenacapavir (LEN)
ARV Drug Class	Nucleoside reverse transcriptase inhibitor (NRTI)	Non-nucleoside reverse transcriptase inhibitor (NNRTI)	Integrase strand transfer inhibitor (ISTI)	Capsid inhibitor
Efficacy Established	2010, 2011	2016	2020	2024
Delivery site	Oral	Vaginal ring	Intramuscular injection in gluteal muscle (buttocks)	Subcutaneous injection in abdomen
Volume	Tablet with 300mg (TDF) or 25mg (TAF) with 200mg emtricitabine (FTC)	25 mg ring	One 3 ml injection	Two 1.5 ml injections
Frequency	Daily ; on-demand dosing for people assigned male at birth also recommended	Monthly (<i>3-monthly ring in development</i>)	First injection followed by a second one month later, then every 2 months (<i>every 4 month dose in development</i>)	First injection along with two oral tablets, followed by two more tablets on day 2 and then injections every 6 months
Efficacy	High efficacy among all populations; highly adherent-dependent	Moderate efficacy among cisgender women; highly adherent-dependent	Very high efficacy in all populations	Very high efficacy in all populations
Regulatory	±100 approvals since 2012; recommended by WHO in 2015	11 approvals as of Nov 2024; recommended by WHO in 2021	27 approvals as of Oct 2024; recommended by WHO in 2022	US FDA approved June 2024; additional submissions ongoing; guidance anticipated in 2025
Commodity Cost in LMICs, per person per yr	±\$40	\$156	≈\$160 (actual cost in UK Pounds)	≈\$100 at launch, with generics to \$55 beginning in 2027
Developer	Gilead Sciences	IPM/PopCouncil	ViiV Healthcare	Gilead Sciences
Generic	15+ suppliers all over the world	MOU with Kiara in SA; details to come on license and timelines	3 licenses via MPP, expected earliest market access in 2027	6 direct licenses, expected earliest market access in 2027

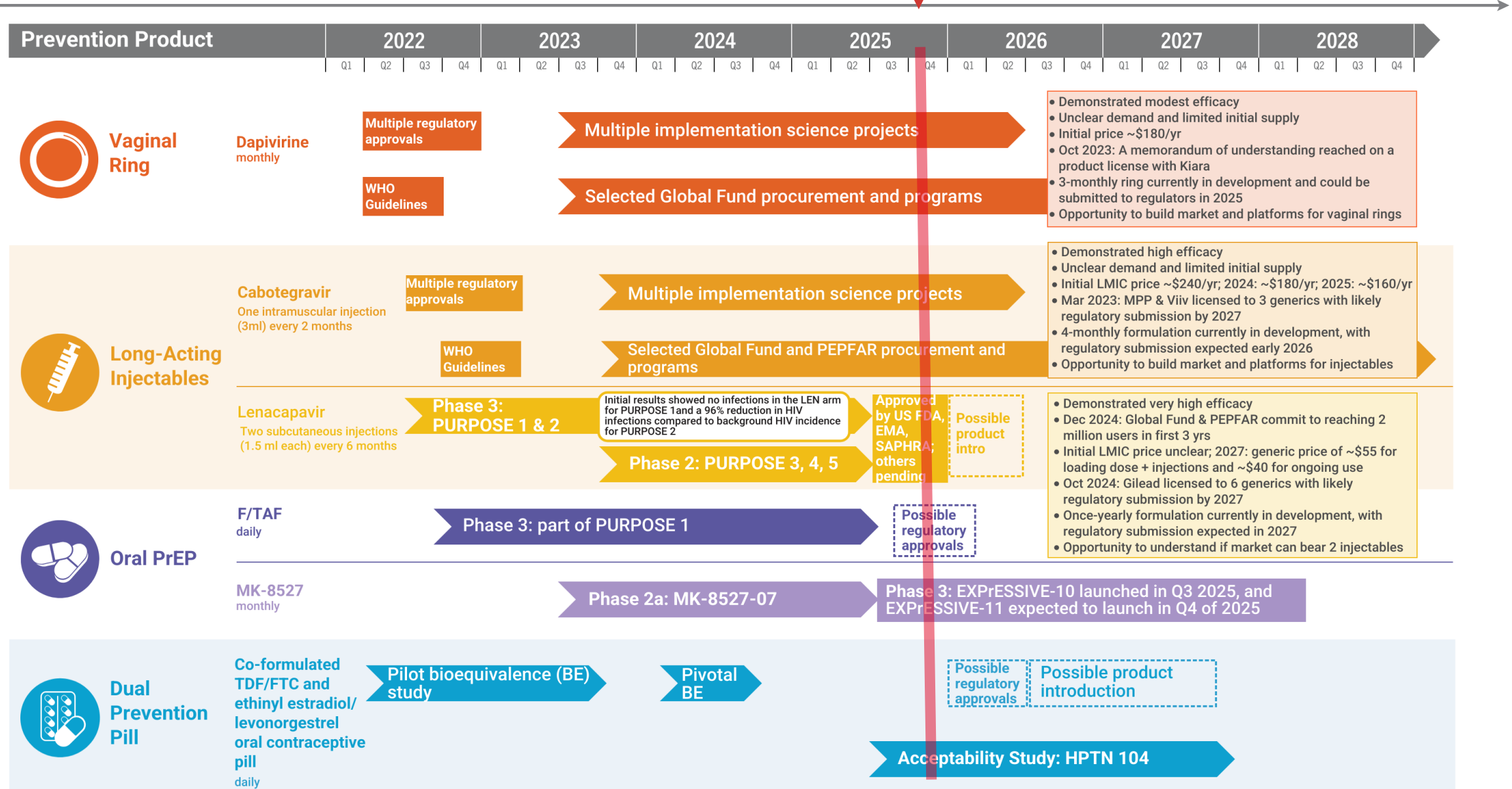
Px Options – Comparative Efficacy

	Tenofovir-based (FTC + TDF or TAF)	Dapivirine (DVR)	Cabotegravir (CAB)	Lenacapavir (LEN)
Efficacy	High efficacy among all populations; highly adherent-dependent ±90% with 7 doses per week	Moderate efficacy among cisgender women; highly adherent-dependent 35% risk reduction in primary efficacy trials; recent OLEs show 50%+ reduction with consistent use	Very high efficacy in all populations 89% higher effectiveness in cisgender women and 66% in MSM, TGW compared to oral PrEP	Very high efficacy in all populations 100% efficacy among cisgender women and 96% reduction compared to a background incidence of HIV among cisgender men and trans and non-binary people
WHO recommendation	2015: “offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches” (<i>strong recommendation, high-quality evidence</i>)	2021: “recommended as an additional choice for cisgender women who are at substantial risk for HIV acquisition and cannot or choose not to use oral PrEP” (<i>conditional recommendation</i>)	2022: “offered as an additional prevention choice for people at substantial risk of HIV infection (<i>conditional recommendation; moderate certainty of evidence</i>)	2025: “offered as an additional prevention choice for people at risk of HIV (<i>strong recommendation, moderate to high certainty of evidence</i>)

What Is a “Person Year of Protection”?

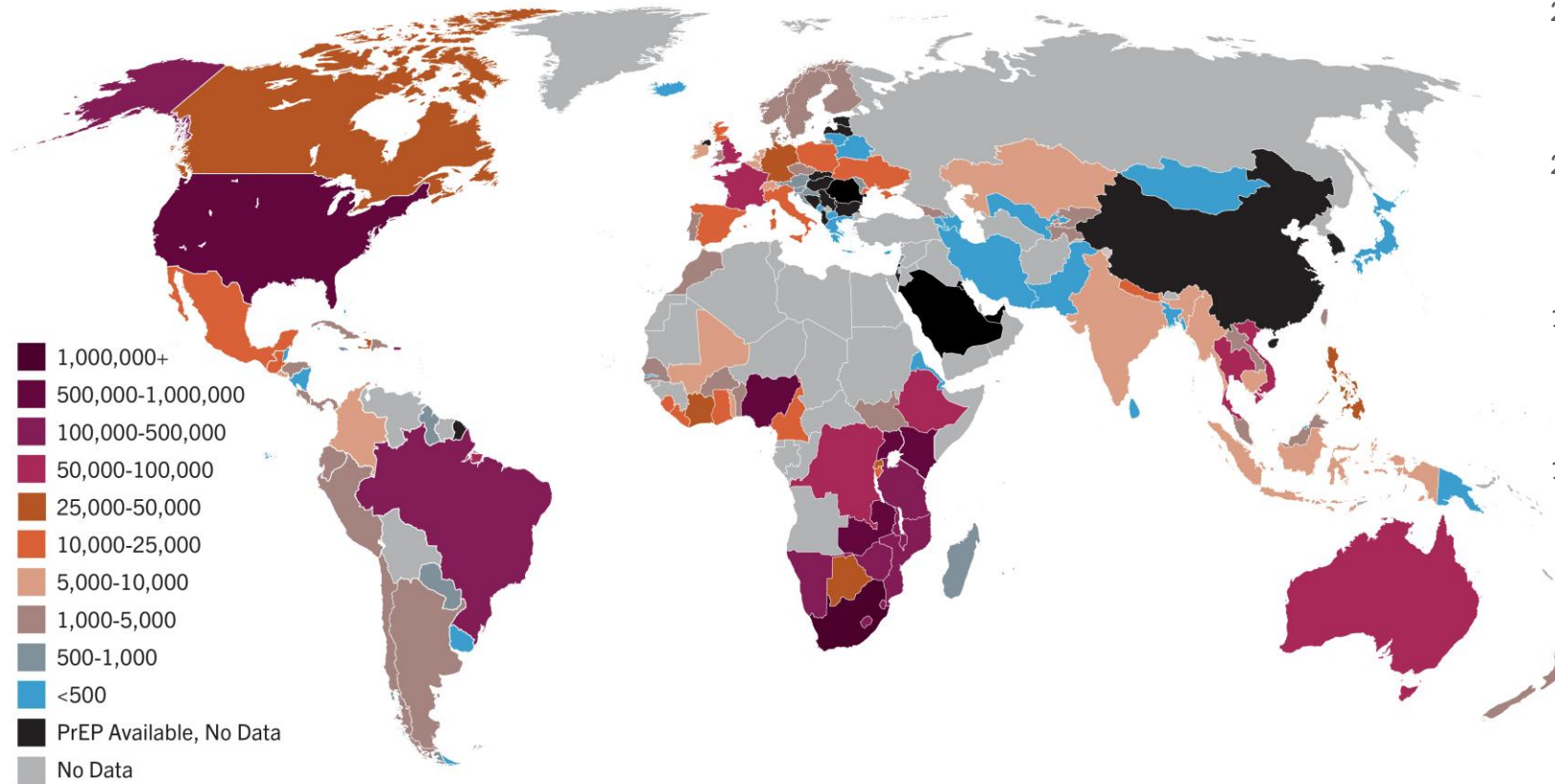
	Tenofovir-based (FTC + TDF or TAF)	Dapivirine (DVR)	Cabotegravir (CAB)	Lenacapavir (LEN)
PrEP Dosing for One Year of Protection	One pill every day for all populations (with possibility of event-driven dosing of 2-1-1 for some)	One ring every month	First injection followed by a second one month later, 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 Pipeline



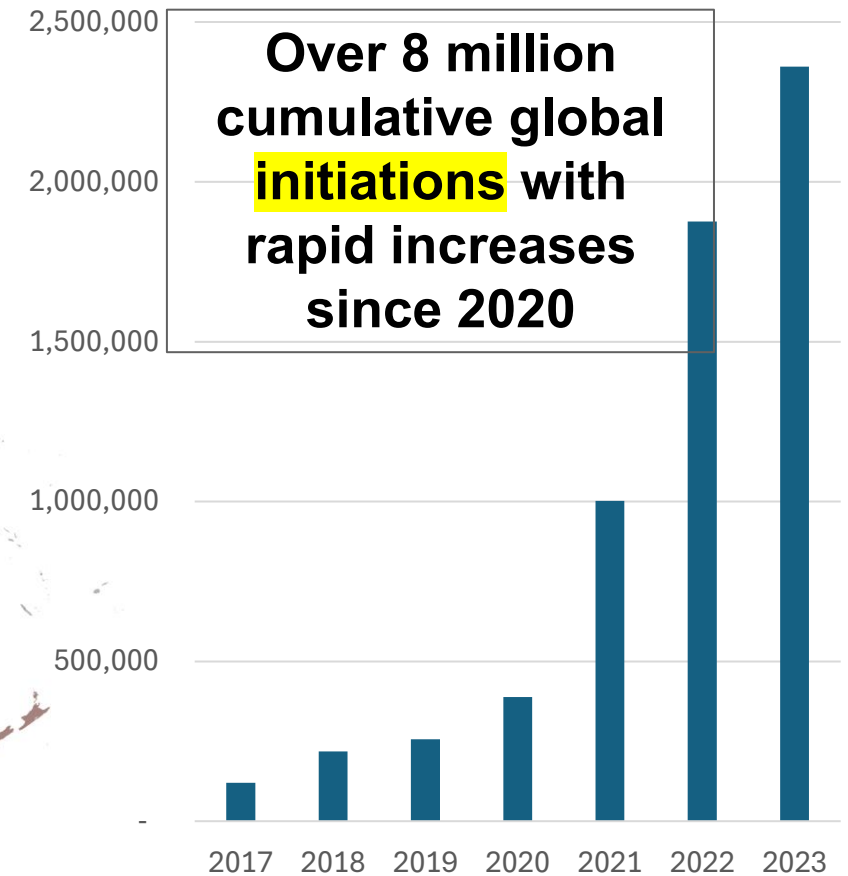
Global PrEP Uptake – 12+ years in

PrEP Initiations by Country, November 2024

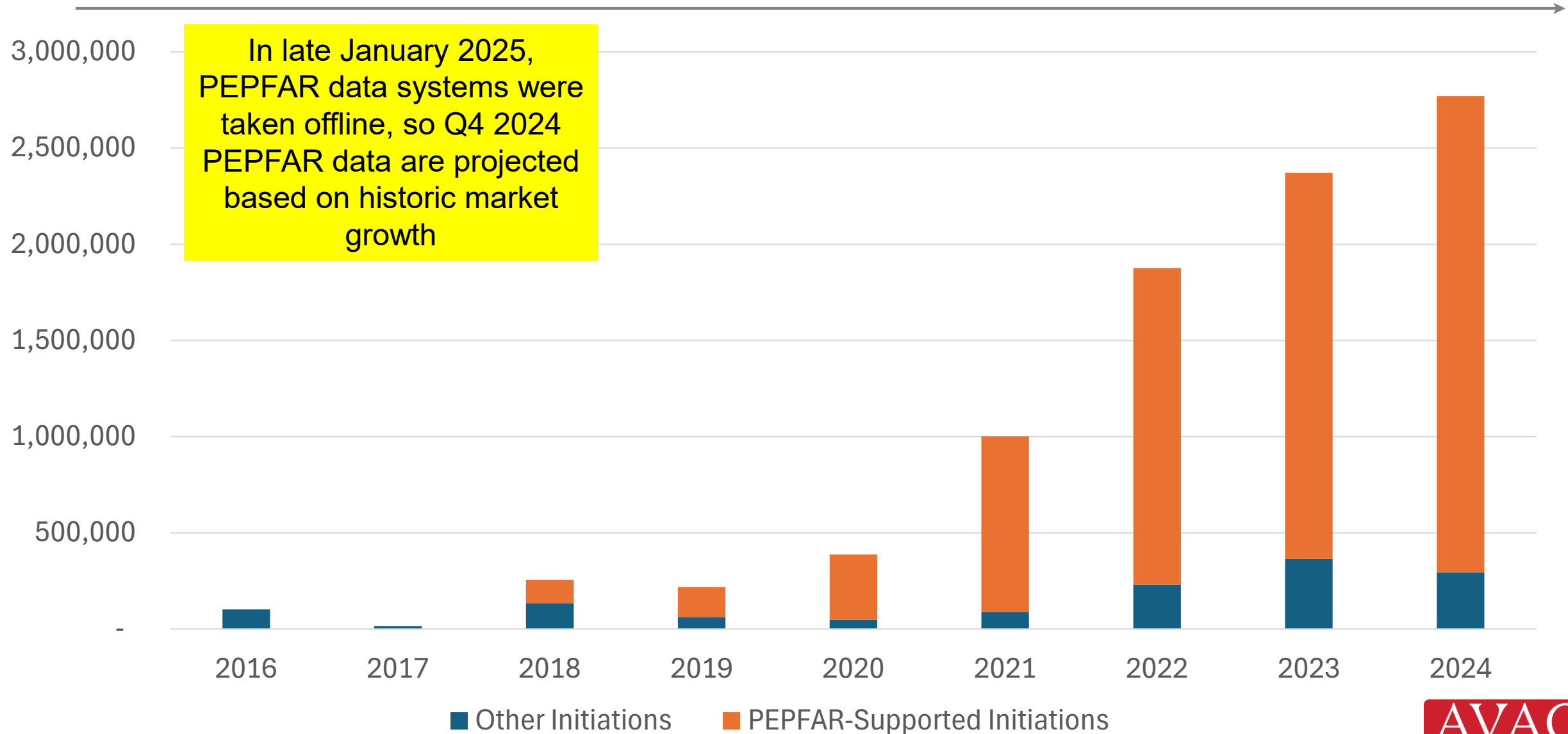


Source: AVAC Global PrEP Tracker, Q3 2024,
<https://www.prepwatch.org/data-by-country/>

PrEP Initiations Over Time



PrEP Initiations to 2024

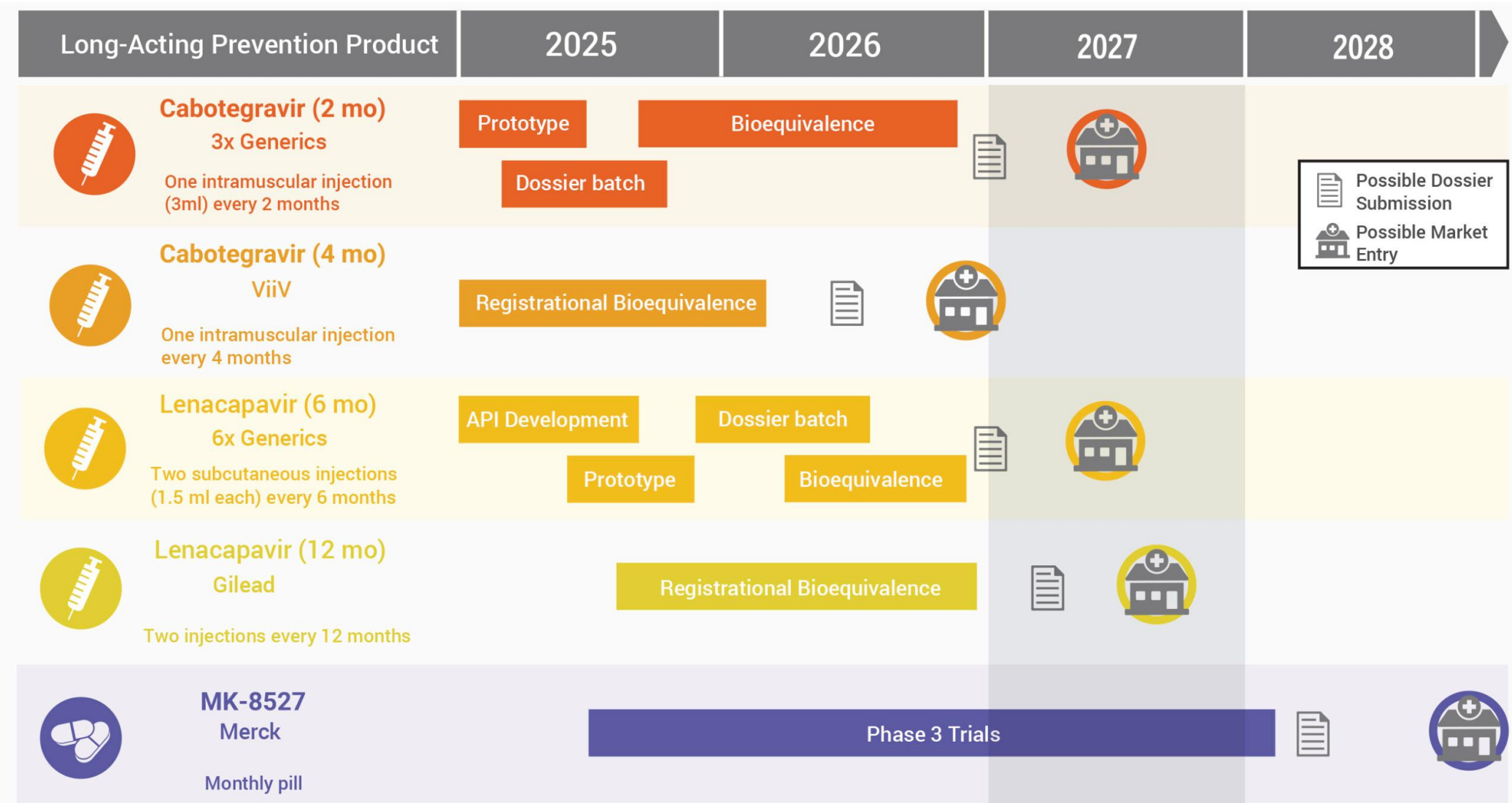


EXPrESSIVE Phase 3 Trial Countries of MK-8527

17 countries hosting sites for Phase 3 trials of monthly PrEP pill, MK-8527; EXPrESSIVE-11 launched in August 2025; EXPrESSIVE 10 to launch in Q4



Long-Acting PrEP of the Future



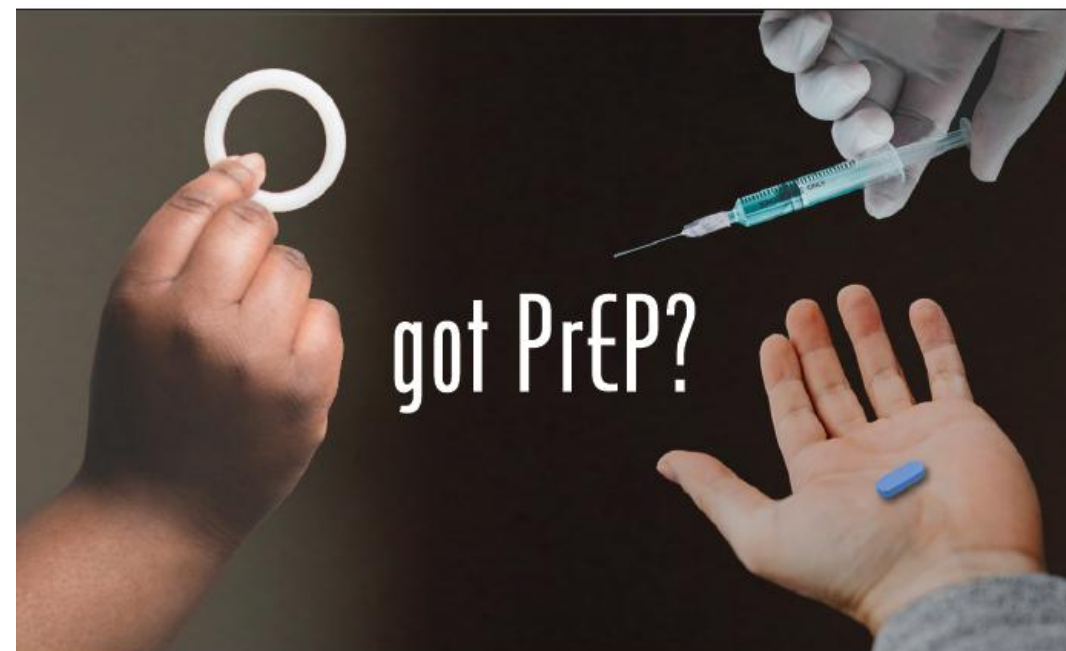
Conclusion

Much accomplished; much to do

- Fill the **product introduction gaps**
 - Accelerate time from regulatory approval to intro to impact
 - Demand-creation and program platforms for prevention generally
 - Differentiated (and integrated) service delivery for px
- Fill the **product development gaps**
 - Longer-acting & event-driven
 - User-friendly & developed WITH users
 - Dual-purpose & multi-purpose methods

Further Resources

- [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
- Weekly [Global Health Watch](#)
- [All things LEN](#)



For the last 8 years, AVAC has proudly worked with PEPFAR to document PrEP uptake and its impact around the world. That stopped in January with a stop work order from the US government. But protecting access to PrEP is vital. Are you leading a PrEP program? Whether supported by PEPFAR or not, we invite you to work with us to ensure global data on PrEP is not lost.