

Px Wire is AVAC's quarterly update covering the latest in the field of biomedical HIV prevention research and development, implementation and advocacy. Each issue includes updates, emerging issues and features upcoming events.

More than 40 years into this epidemic—and in the midst of multiple pandemics and persistent inequities—2022 brought a rare opportunity to fundamentally reshape and reimagine HIV prevention, if everyone does their part.

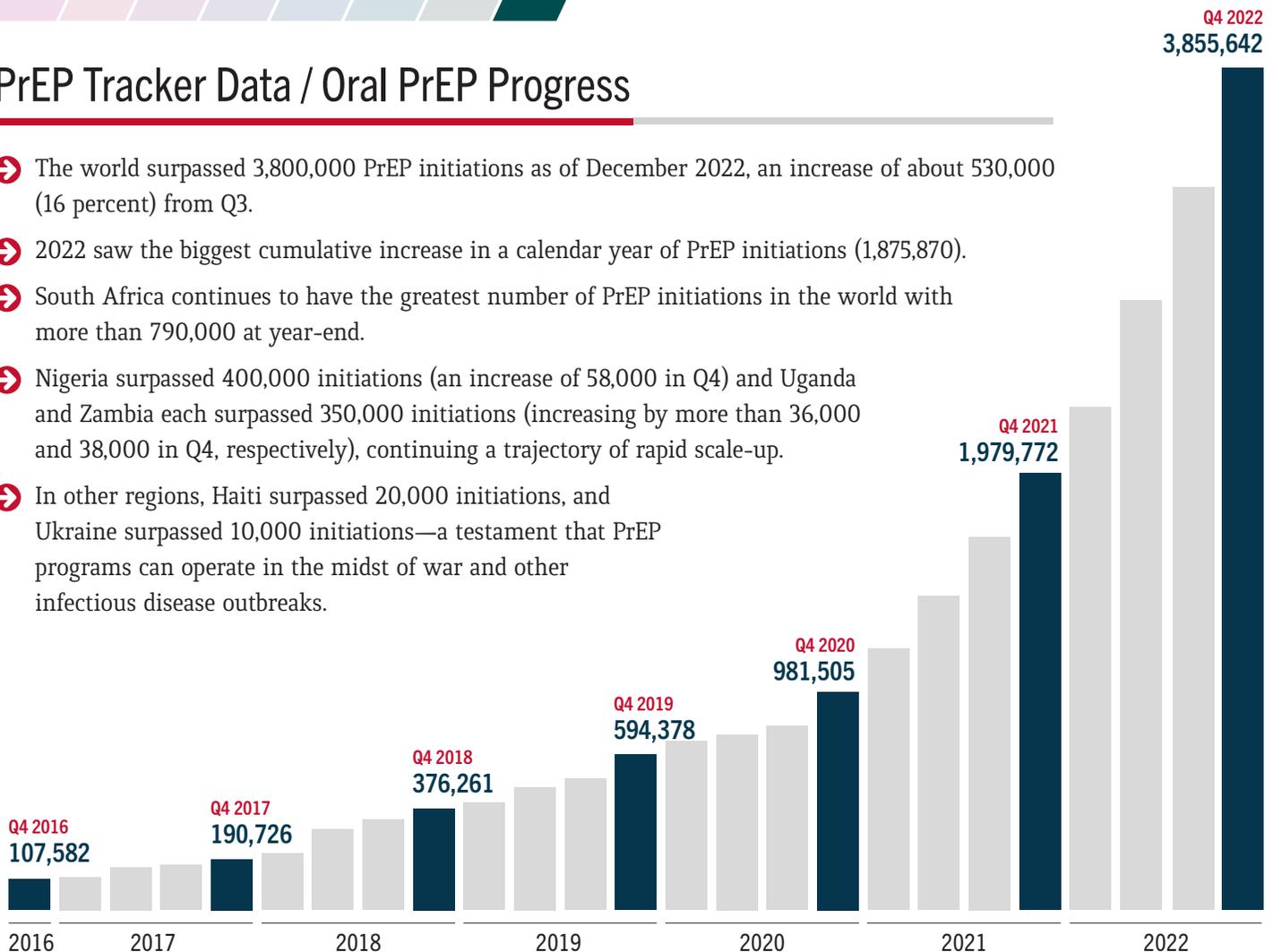
This issue offers data from Q4 of 2022, when South Africa became the fourth country in the world to approve injectable cabotegravir (CAB) for PrEP; the dapivirine

vaginal ring (DVR) was approved in a growing number of countries; and oral PrEP use was on the rise, passing the mark of 3.8 million initiations. For the first time, the world has multiple biomedical interventions to offer choice, and it's essential to develop the programs that bring the fruits of science to the communities facing public health threats, while continuing to invest in developing new options to meet diverse needs.



PrEP Tracker Data / Oral PrEP Progress

- ➔ The world surpassed 3,800,000 PrEP initiations as of December 2022, an increase of about 530,000 (16 percent) from Q3.
- ➔ 2022 saw the biggest cumulative increase in a calendar year of PrEP initiations (1,875,870).
- ➔ South Africa continues to have the greatest number of PrEP initiations in the world with more than 790,000 at year-end.
- ➔ Nigeria surpassed 400,000 initiations (an increase of 58,000 in Q4) and Uganda and Zambia each surpassed 350,000 initiations (increasing by more than 36,000 and 38,000 in Q4, respectively), continuing a trajectory of rapid scale-up.
- ➔ In other regions, Haiti surpassed 20,000 initiations, and Ukraine surpassed 10,000 initiations—a testament that PrEP programs can operate in the midst of war and other infectious disease outbreaks.



PrEP Introduction Country Planning Matrix

This chart shows the trajectory of regulatory approvals and implementation science studies for CAB for PrEP and the dapivirine vaginal ring (DVR), in the context of oral PrEP programs.

COUNTRY	CAB Regulatory Status	DVR Regulatory Status	HPTN 083/084 Studies	Ring/ ASPIRE Studies	Oral PrEP approved	Oral PrEP Initiations in 2022	Cumulative PrEP Initiations since launch	Global Fund PrEP Matching Funds	CAB & DVR Projects: Approved	CAB & DVR Projects: Planned
Argentina	To file by Q2, 2023		●			—	129			
Botswana	Pending	Pending	●		2016	10,214	21,972			
Brazil	Pending		●		2017	41,589	89,410		● ImPrEP; ● PrEP 1519	
Colombia	To file by Q2, 2023					N/A	N/A			
Cote D'Ivoire	To file by Q2, 2023					7,080	10,138			● CohMSM (also in Burkina Faso, Mali, Togo)
Eswatini	Via SA		●			28,603	57,340			● Ring Intro
Kenya	Pending	Approved	●		2015	170,551	298,455	\$3,000,000	●● Catalyst/ MOSAIC; ● SEARCH	●● PrEP-PP
Lesotho	Via SA	Approved				27,235	82,147		●● Catalyst/ MOSAIC	
Malawi	Pending	Pending	●	●	2017	30,807	37,498			● MOH/BPS
Malaysia	Pending					—	130			
Mozambique	To file by Q2, 2023	Pending				81,038	142,351	\$3,750,000		●● MSF
Myanmar	Pending					2,922	3,556			
Namibia	To file by Q2, 2023	Pending				20,187	68,762			
Nigeria	To file by Q2, 2023				2017	227,478	401,110	\$6,500,000		
Peru	Pending		●		2021	—	2,931			
Philippines	Pending					6,763	8,494			
Rwanda	To file by Q2, 2023	Approved				7,430	21,239			
South Africa	Approved	Approved	●	●	2015	422,239	792,434	\$5,750,000	●● Catalyst/ MOSAIC; ●● Project PrEP; ● Fast PrEP; ● Axis; ● Let's Talk	● PICASSO; ● CAB in Private Pharmacies; ● PrEP-PP; ● Mobile Men
Tanzania	To file by Q2, 2023	Pending			2020	93,767	149,687			
Thailand	Pending		●		2016	11,764	51,072			● IHRI Key-Pop
Uganda	Pending	Approved	●	●	2017	165,500	353,974	\$3,000,000	●● Catalyst/ MOSAIC; ● SEARCH	● Mobile Men
Ukraine	To file by Q2, 2023					5,690	11,065			
Vietnam	Pending		●		2015	21,238	50,265			● STEPS
Zambia	To file by Q2, 2023	Approved			2017	148,503	351,207	\$3,000,000		
Zimbabwe	Approved	Approved	●	●	2017	83,580	143,498		●● Catalyst/ MOSAIC; ● PSI Ring	

See Global PrEP Tracker for more details about oral PrEP uptake, <https://www.prepwatch.org/data-by-country/>

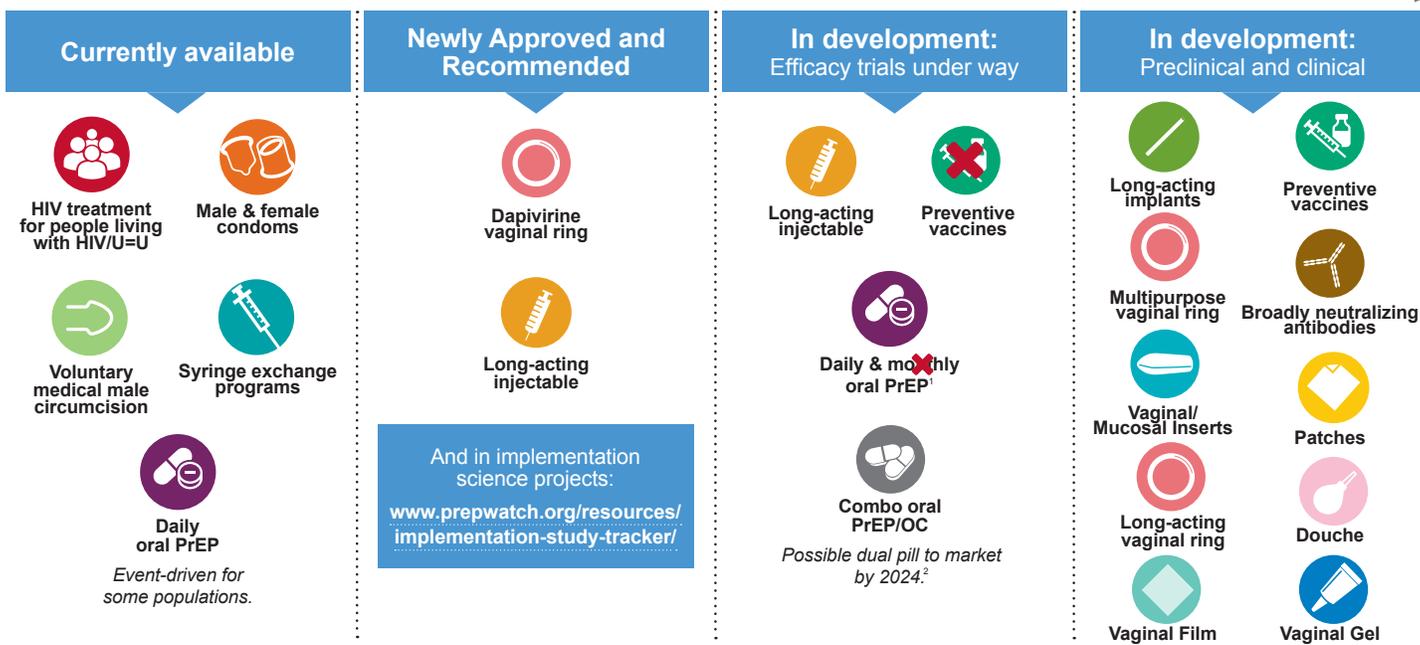
See Implementation Study Tracker for more details on implementation science studies of new PrEP products, <https://www.prepwatch.org/resources/implementation-study-tracker/>



HIV Prevention & Cure Pipeline

Just as this issue was going to press, the Mosaico vaccine efficacy trial was stopped early for non-efficacy (see here for more information and here for a recording of a webinar to unpack the results). The remaining HIV preventive vaccine efficacy trial, PrEPVacc, is a large efficacy study that will contribute to evidence about both PrEP (TDF/FTC and TAF/FTC) and two different vaccine concepts, but it will not lead to licensure in either case. We've updated our infographics and materials on the HIV prevention pipeline, including this pipeline overview:

The HIV Prevention Pipeline



¹In 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.

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



Additional updated materials include:

- ➔ Time to Market Graphic
- ➔ Years Ahead in Biomedical HIV Prevention Graphic
- ➔ Biomedical HIV Prevention Research in 2022 and Beyond

Other important R&D updates:

- ➔ Stakeholders from Kenya, South Africa and Zimbabwe came together to share feedback on the MATRIX pipeline of early phase and pre-clinical products. The country consultations are establishing a foundation for future engagement through the lifecycle of product development.

- ➔ Results from a Phase 1 vaccine proof of concept study (IAVI G001), using a germline-targeting strategy supports further development of the approach, with the goal of inducing broadly neutralizing antibodies to prevent HIV acquisition.

- ➔ Substudies of the HPTN 084 open label extension trial were extended by 48 weeks to allow for inclusion of adolescents and pregnant and lactating people and their infants. HPTN 084 is designed to test if an injection of CAB given once every two months works better than a Truvada pill taken every day for PrEP.

Prevention Playlist

The most effective advocacy is based on smart analysis and accurate information. AVAC develops a wide range of materials and resources to inform decision making and action. Be sure to read, join or listen to these essential resources for HIV prevention and global health equity.



JOIN

- ➔ Subscribe to AVAC's *Advocates' Network*, timely updates about developments in the biomedical HIV prevention field.
- ➔ Subscribe to AVAC's podcast, *Px Pulse* on Apple, Spotify, Google or wherever you listen to podcasts!
- ➔ Join the DRM Advocacy Learning Collaborative, where advocates come together to advance domestic investment in R&D across Africa. Email john@avac.org to learn more.
- ➔ Consider applying to AVAC's Navigator program, a training and mentorship program for developing advocates. Learn more [here](#).
- ➔ Upcoming Choice Agenda webinars include: *Ready, Set, CROI 2023—Prepare for the 30th Year of CROI*, Monday, February 13 at 9:00am ET / 2:00 pm GMT; *Decolonizing Global Public Health—What Will it Take to Dismantle Racism and White Supremacy?*, Thursday, February 16 at 9:00am ET/2:00 pm GMT.



READ

- ➔ A third major HIV vaccine to end early for no efficacy announced it was stopping in early January 2023. AVAC's Advocates' Network provides context and links to Janssen, HVTN and AVAC statements: *Mosaico HIV Vaccine Study Stopped Early for Non-Efficacy*.
- ➔ AVAC's year-end letter, *HIV Prevention and Equity in 2022 & Beyond*, rounds up key advocacy from 2022 as the field faces a turning point. The right commitments in funding, policy and programming, spelled out in *AVAC in 2023: A Year of Action*, define an advocacy agenda for the year ahead.
- ➔ An initiative out of South Africa to repeal punitive laws against sex workers is underway. Read our blog to learn about the work of AVAC Fellow, Liyema Somnono to fight for the *Decriminalization of Sex Work Prevents HIV: South Africa could overturn its outdated laws*.
- ➔ New research published in the journal *PLOS*, by AVAC and COMPASS partners shows the impact of policy to increase the uptake of HIV prevention services, including PrEP. *Correlates Key Policies with PrEP Uptake*.

- ➔ G20 leaders launched the Pandemic Fund at their November meeting in Indonesia. Learn more about how this fund is intended to mitigate global health threats, and the advocacy to keep it on target, in our blog, *The Pandemic Fund: What you need to know*.
- ➔ The World Health Summit took on COVID, future pandemics, funding, community engagement and more in October. Get the big picture in our blog, *The World Health Summit: Hitting the target, or missing the mark?*



LISTEN

- ➔ AVAC's latest *Px Pulse* podcast, *New Products are Needed and a New Paradigm is Essential: A new era in prevention?* explores how to match proven products with the programs, policies and political will needed to deliver them. In it, PEPFAR Ambassador Dr. John Nkengasong, Executive Director of HEPS-Uganda and former AVAC Advocacy Fellow Kenneth Mwehonge and Lilian Benjamin Mwakyosi, the Executive Director of DARE and former AVAC Advocacy Fellow, talk about how to scale up access to prevention options and show impact.
- ➔ AVAC's November 2022 webinar, *Much Accomplished, Much to Do: A Conversation Looking Back & Looking Ahead with Tony Fauci*, explores what the future looks like for NIAID, for Dr. Fauci and for pandemic preparedness.
- ➔ Study investigators and community representatives discuss the outcome of the Mosaico study, and discuss next steps in AVAC's webinar, *Where Are We Now and What's Next?: Mosaico Study Update*.
- ➔ AVAC and FP2030's webinar explores opportunities for the private sector to deliver the Dual Prevention Pill, and lessons learned from the family planning field. These insights could inform the introduction of multi-purpose prevention technologies in the private sector. *Meeting summary /Recording/Slides*.
- ➔ This TCA webinar dives into the *Transgender Manifesto*, a scorecard on trans-inclusive HIV research to date, and more. *Trans Inclusion: Charting HIV Research into the Future: A Manifesto and Scorecard for Advocates and Researchers*. *Recording/Slides/Resources*.

About AVAC



Founded in 1995, AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of HIV prevention options, as part of a comprehensive and integrated pathway to global health equity. Follow AVAC on Twitter [@HIVpxresearch](#) and find more at www.avac.org and www.prepwatch.org.