

From Research to Rollout: A Look at Where We are in HIV Prevention

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 news, emerging issues and features upcoming events.



The HIV field gathers for its first hybrid International AIDS Conference (IAC) since the start of the COVID-19 pandemic at a pivotal moment in HIV prevention. Across research to rollout—accelerated product access,

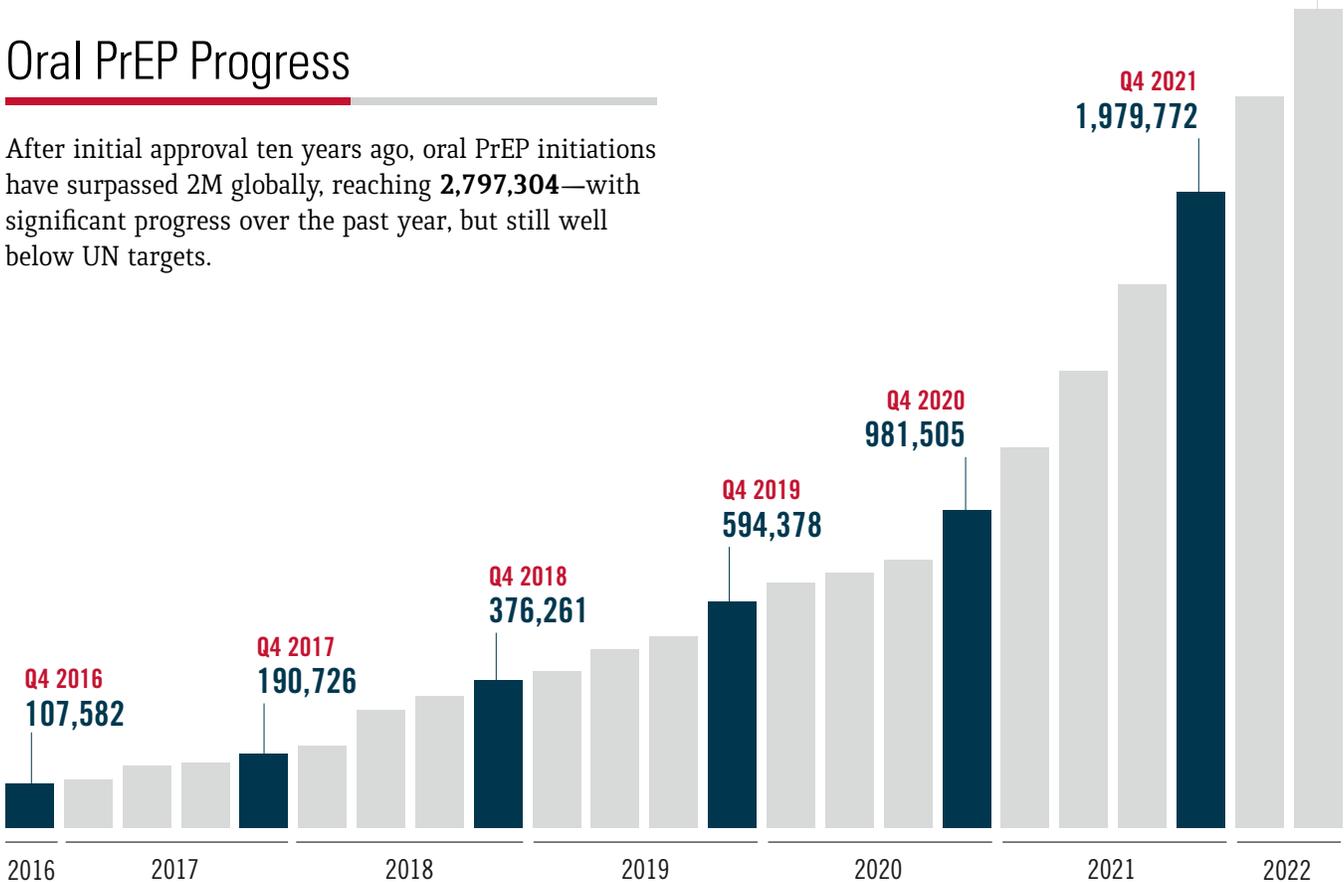
new products reaching the market, new trials starting (and pausing) and recent research results—the ability to deliver two new proven PrEP methods will be determined by conversations and decisions happening now.



Q2 2022
2,797,304

Oral PrEP Progress

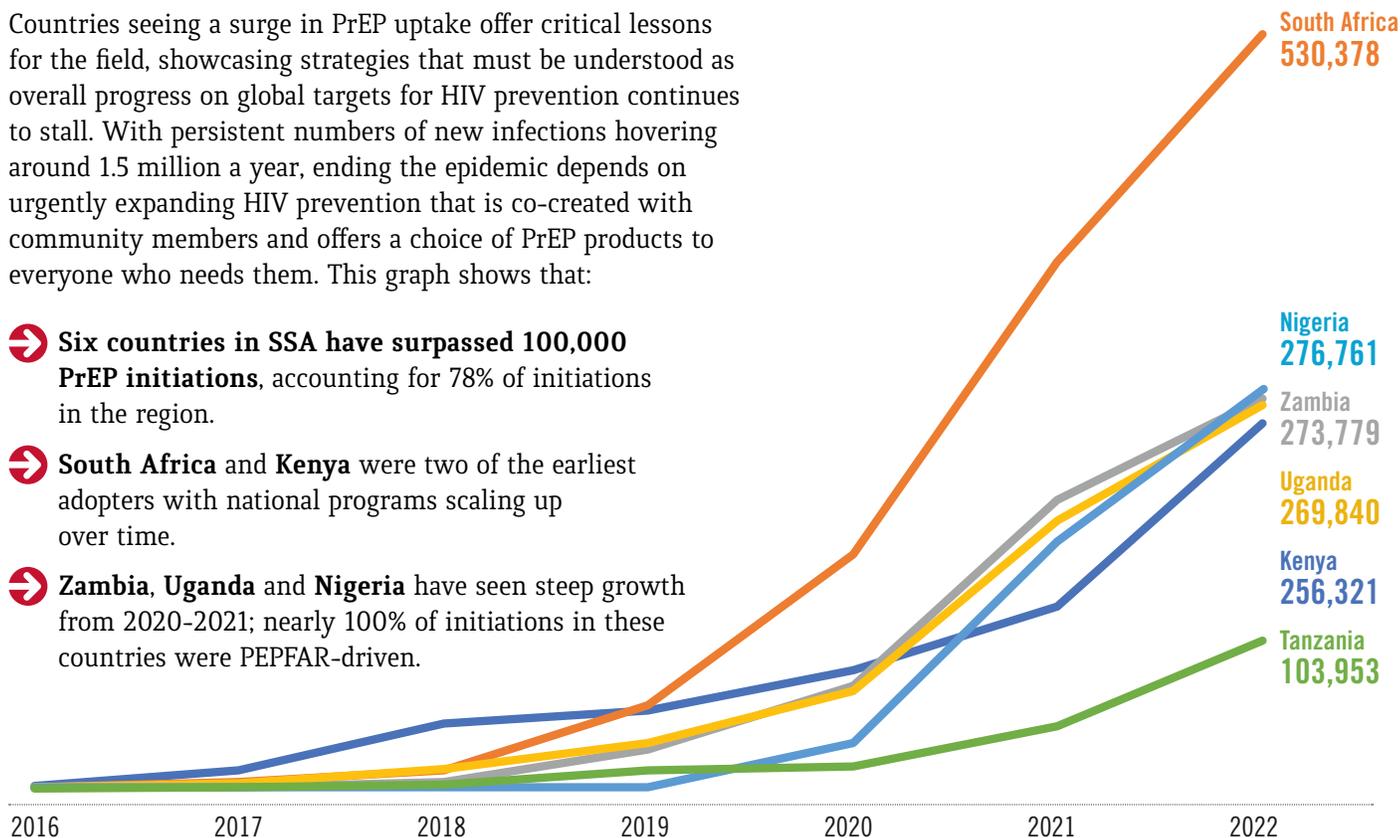
After initial approval ten years ago, oral PrEP initiations have surpassed 2M globally, reaching **2,797,304**—with significant progress over the past year, but still well below UN targets.



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Countries seeing a surge in PrEP uptake offer critical lessons for the field, showcasing strategies that must be understood as overall progress on global targets for HIV prevention continues to stall. With persistent numbers of new infections hovering around 1.5 million a year, ending the epidemic depends on urgently expanding HIV prevention that is co-created with community members and offers a choice of PrEP products to everyone who needs them. This graph shows that:

- ➔ **Six countries in SSA have surpassed 100,000 PrEP initiations**, accounting for 78% of 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 from 2020-2021; nearly 100% of initiations in these countries were PEPFAR-driven.



PrEParing for New Products

These numbers are just a beginning and one the world cannot squander. To reach the millions of people who need access to PrEP products today, HIV prevention must include real choices. Transforming options into choices requires funders, drug-makers, regulators and policy-makers to define and execute the steps of the process, from research to rollout, with advocates, civil society, trial participants and most importantly of all, the communities who need prevention most, as equal partners.



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Countries have approved the PrEP ring—Kenya, Lesotho, South Africa, Uganda, Zimbabwe.



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Country (US) approved cabotegravir for PrEP (CAB for PrEP).
Additional national regulatory agencies are currently reviewing applications.

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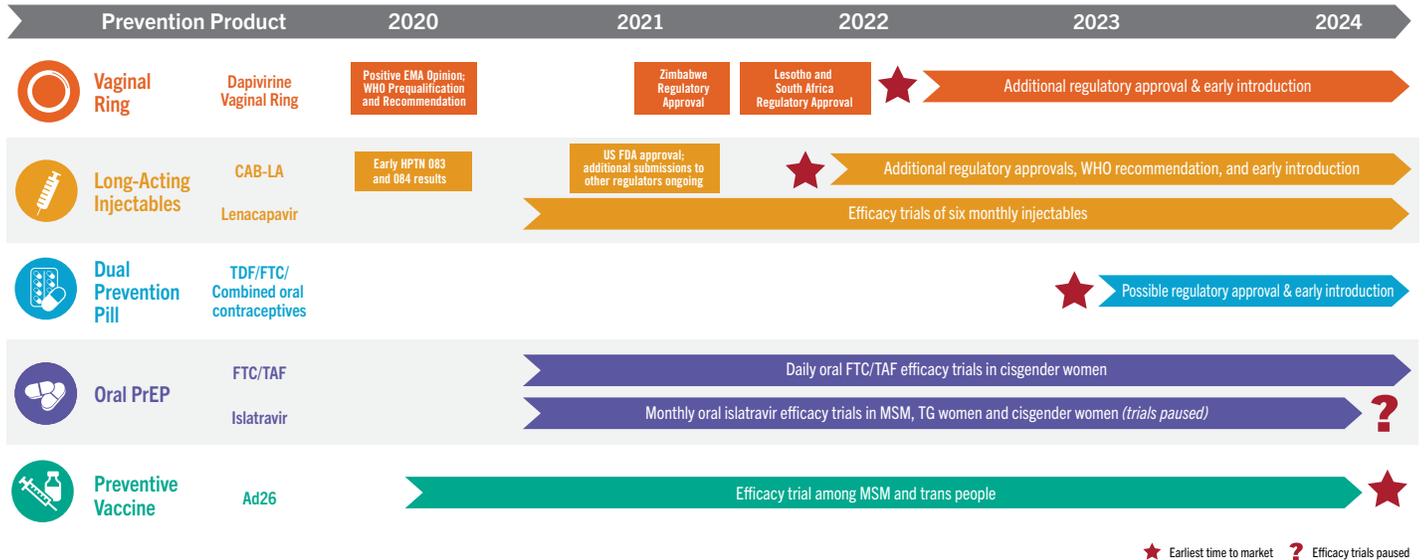
Implementation studies are planned with CAB for PrEP and/or PrEP ring, 4 in South Africa, 2 in Brazil, 2 in the US, 1 regional study in East and Southern Africa, 1 one in West and Central Africa and 1 study each in Australia, France, Thailand and Vietnam.

WHO guidelines on the dapivirine vaginal ring were released in January 2021, and on injectable CAB for PrEP in July 2022.

Phase I Phase II/Ib Phase III

HIV Prevention Pipeline

This timeline shows the potential time points when the next-generation of HIV prevention options might find their way into new programs.



UPDATES ON PRODUCTS UPSTREAM AND IN CLINICAL TRIALS



The **Dual Prevention Pill** is undergoing bioequivalence testing with submission to the US FDA for approval expected in early 2024. For more information read [a summary and FAQs](#).



Two efficacy trials (PURPOSE 1 and 2) assessing the safety and efficacy of **six-monthly injectable lenacapavir for PrEP** started in 2021, but were then put on hold. They resumed in May 2022, following the US FDA's decision to lift the clinical hold.

Efficacy trials of **once-monthly oral lenacapavir** for PrEP, which also started in 2021 remain on clinical hold.



The **Mosaico Adeno-26** vaccine efficacy trial in gay men, transgender individuals and other men who have sex with men, is fully enrolled with data collection ongoing and an estimated completion date in 2024. Imbokodo, the sibling trial of the Adeno-26 vaccine in women, was stopped early for non-efficacy in July 2021.



In early 2022, both the International AIDS Vaccine Initiative (IAVI) and the NIH announced initiation of early trials testing HIV vaccine candidates based on **mRNA** technology. mRNA has been a successful platform for COVID-19 vaccines, but has not been used to test HIV vaccine candidates in human clinics trials until now.

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 in on what AVAC sees as essential to the current HIV prevention and global health equity conversations of the quarter.



JOIN

- ➔ AVAC's [Advocates' Network](#) is an electronic network for organizations and individuals interested in receiving timely updates about developments in the biomedical HIV prevention field. Sign up today.
- ➔ The new Choice Agenda webinar series kicked off with lessons from contraception ([Efficacy is Not the Only HIV Prevention Attribute that Matters—Lessons from Contraception](#)) and the important role of pleasure (...). Check out recordings and join the list serve.
- ➔ Join the Choice Agenda for a webinar, [Faster, Smarter and More Equitable—Accelerating Roll Out and Uptake of CAB for PrEP](#), Monday, August 8 at 9:00am ET / 1:00pm GMT / 15:00 SAST. [Register here](#).
- ➔ Join AVAC and partners for a webinar to showcase the new [PrEPWatch](#) website, the one-stop online repository for all things PrEP. Date/time is forthcoming.



READ

- ➔ [Getting Rollout Right](#): This collection of resources distills some of the most important insights from studies using human centered design and findings from real world experience delivering oral PrEP. Read the [full report](#) and [issue briefs](#).
- ➔ Advocates are calling for widespread access to the dapivirine vaginal ring (the PrEP ring) and comprehensive engagement. Check out [this statement](#) raising the voices of advocates for women's HIV prevention.

- ➔ AVAC's [Plan for Accelerating Access and Introduction of Injectable CAB for PrEP](#) provides a view of all the moving parts. Learn how and why funding commitments, creating demand, WHO guidelines, implementation studies, technology transfer and more must be coordinated and expedited now.

- ➔ An ongoing series of think tanks, conducted by [The BioPIC](#), are generating key insights for people-centered product delivery. Topics cover: [HIV testing](#), [coordination of pilot studies](#), [planning for next generation PrEP](#), and [modelling the impact of CAB for PrEP on drug resistance](#), with more to come.



LISTEN

- ➔ Tune into this [Px Pulse](#) podcast, which discusses and builds on principles from the rollout of oral PrEP in the past to inform how we equitably and effectively deliver the PrEP ring and injectable CAB for PrEP.
- ➔ Some vaccines are easier to develop than others. COVID-19 vaccines were developed with unprecedented speed, taking a matter of months to become available. Listen to this [Px Pulse](#) podcast on what's the challenge and what's the science of HIV vaccines.

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](#).