

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



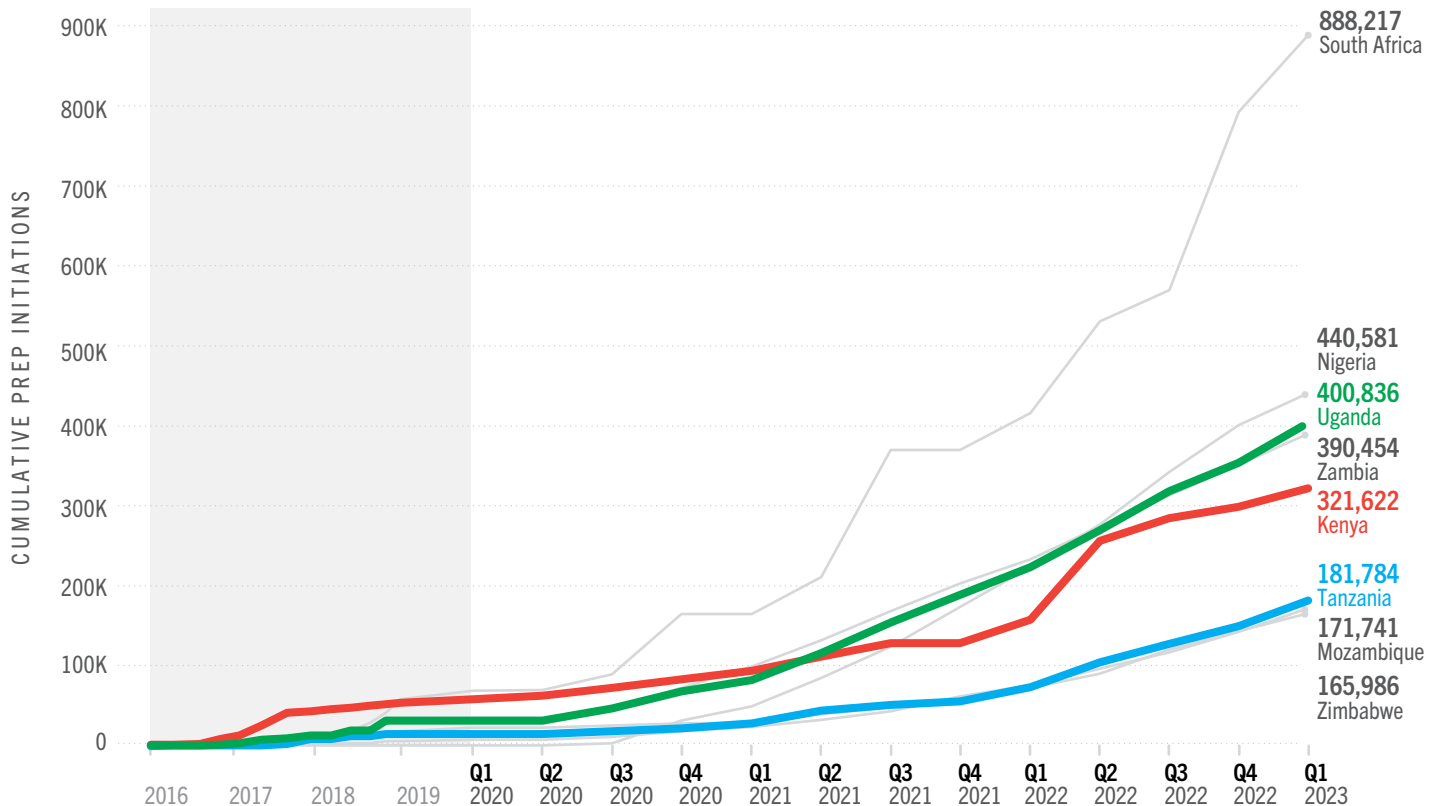
Px Wire is AVAC's quarterly update covering the latest in the field of biomedical HIV prevention research and development, implementation and advocacy. Each issue includes updates, emerging issues and features upcoming events.

PrEP Tracker Data / Progress in PrEP Uptake



Q1 2023 marked 481,237 new global PrEP initiations, which can be attributed to the scale-up of national programs and PEPFAR's commitment to support and closely track PrEP investments. Key countries including Kenya, Nigeria, South Africa, Uganda and Zambia have led in these investments and show marked increases in PrEP initiations. However, discrimination and oppression of basic human rights, including proposed anti-gay legislation in Uganda, Kenya, and Tanzania threaten lives and livelihoods and could roll back substantial progress in the scale-up of PrEP programming.

Trajectory of Countries with Most PrEP Initiations in SSA, 2016-2023



PrEParing for New Products



➔ The Medicines Patent Pool announced the granting of voluntary sub-licenses to three India-based generic manufacturers (Aurobindo, Cipla, and Viartris/Mylan). Importantly, Cipla said they plan to manufacture in South Africa as well. Depending on technology transfer and market demand, it is estimated that the generic product could be available in low- and middle-income countries (LMICs) in three to five years.

➔ In May 2023, the PrEP Ring study in Eswatini officially opened for enrollment. In addition, the *Catalyzing Access to New Prevention Products to Stop HIV (CATALYST)* study is launching in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. This product introduction study of the MOSAIC project will assess the implementation of an enhanced service delivery package that provides a choice of oral PrEP, PrEP ring, and injectable cabotegravir for PrEP among women at PEPFAR delivery sites.

As of May 2023, there are 29 planned or ongoing implementation science (IS) studies exploring injectable cabotegravir for PrEP and/or the dapivirine vaginal ring

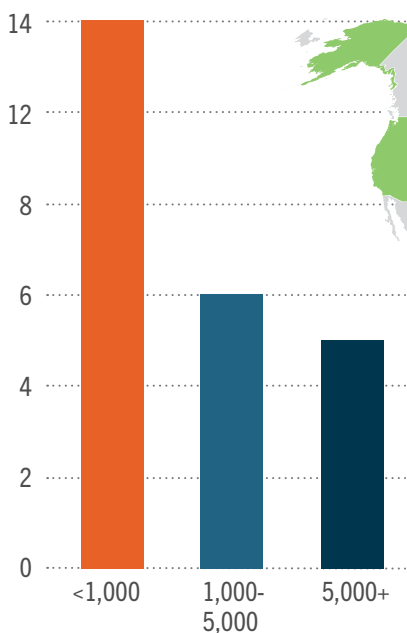
in 22 countries looking at one or more populations. Botswana, Ukraine, and Zambia are the latest countries to plan IS studies and South Africa continues to lead with nine studies planned.

Not all studies have established sample sizes. Of the 25 that do, only five have over 5,000 participants—MOSAIC’s five-country CATALYST study, Wits RHI’s Project PrEP, Desmond Tutu Health Foundation’s FASTPrEP, African Health Research Institute’s Theta Nami Ngithethe Nawe (“Let’s Talk”), and Path to Scale for CAB-LA in Malawi.

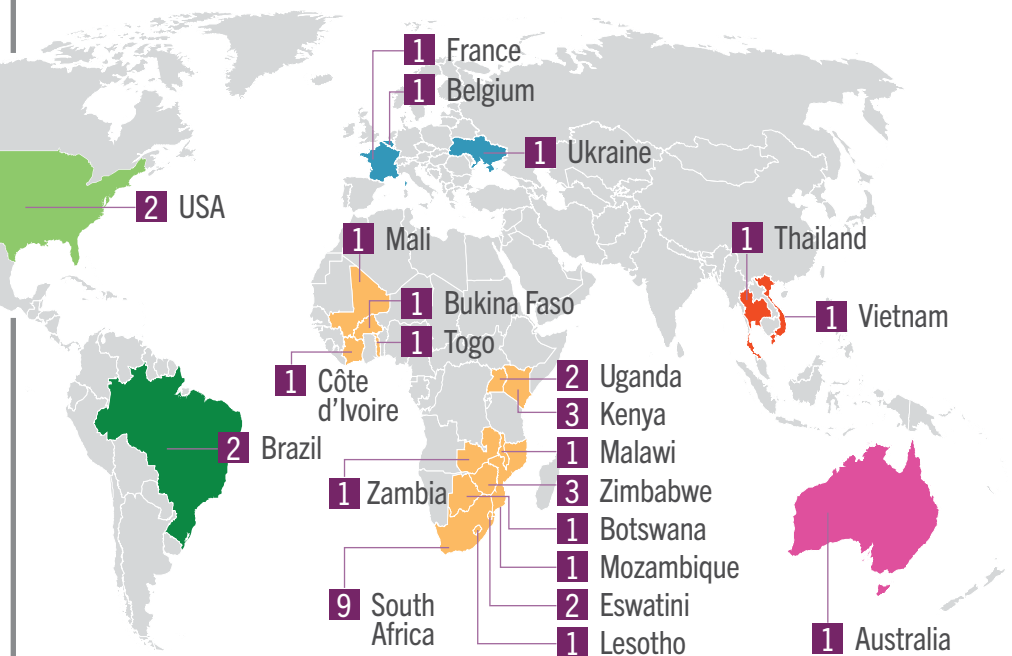
Inclusion of diverse populations in implementation studies is critical to gather evidence around important outcomes like safety and patterns of use across different types of users. Cisgender men and women and gay and bisexual men who have sex with men are all well represented across the planned and ongoing CAB for PrEP and ring studies. Sex workers, trans men, and gender non-conforming people are less well represented, and there are currently no studies planned for people who use drugs or prisoners. See AVAC’s *Integrated Study Tracker* for this data.

CAB for PrEP and DVR Implementation Science Studies

Sample size of studies



Only 25 of 29 studies currently have established sample sizes.



Some studies are happening in more than one country, with a total of 29 studies in 22 countries.

The HIV Prevention Pipeline: The latest in research, development and more



The HIV prevention pipeline has seen major movement in the early part of 2023, with much new data presented at the Conference on Retroviruses and Opportunistic Infections (CROI) 2023 and elsewhere. See AVAC’s CROI roundup for more.

Data on the Mosaico vaccine efficacy trial, which was stopped early due to non-efficacy, confirmed this finding, as well as an alarmingly high HIV incidence rate in both arms of the study, 4.1 percent. The table below summarizes results from multiple HIV prevention placebo-controlled trials, highlighting the persistent high incidence—and the need for new prevention options.

HIV Incidence in Placebo-Controlled Prevention Trials

Trial	Px Modality	Years	Location	Population	Incidence
HVTN 706/Mosaico	Vaccine	2019-23	United States of America, Argentina, Italy, Mexico, Peru, Poland, Spain	Cisgender men and transgender individuals who have sex with cisgender men and/or transgender Individuals	4.1
HVTN 705/Imbokodo	Vaccine	2017-22	Malawi, Mozambique, South Africa, Zambia, Zimbabwe	Cisgender women	4.3
HVTN 704 /HPTN 085/ AMP	Antibody	2017-20	United States of America, Brazil, Peru, Switzerland	Cisgender men and transgender individuals who have sex with cisgender men	3.0
HVTN 703/HPTN 081/AMP	Antibody	2016-21	Botswana, Kenya, Malawi, Mozambique, South Africa, Tanzania, Zimbabwe	Cisgender women	3.1
HVTN 702/Uhambo	Vaccine	2016-20	South Africa	Women and men	4.2 (female), 1.2 (male)
ECHO	Multiple contraceptives	2015-18	Eswatini, Kenya, South Africa, Zambia	Cisgender women	4.2, 3.9, 3.3
ASPIRE	Vaginal ring	2012-15	Malawi, South Africa, Uganda, Zimbabwe	Cisgender women	4.5
Ring Study	Vaginal ring	2012-15	South Africa, Uganda	Cisgender women	6.1
FACTS 001	Microbicide gel	2011-14	South Africa	Cisgender women	4.0
VOICE	Microbicide gel and oral PrEP	2009-13	South Africa, Uganda, Zimbabwe	Cisgender women	4.2
CAP 004	Vaginal ring	2007-10	South Africa	Cisgender women	9.1
HPTN 035	Microbicide gel	2005-09	Malawi, South Africa, Zambia, Zimbabwe	Cisgender women	3.9
MDP 301	Microbicide gel	2005-08	South Africa, Tanzania, Uganda, Zambia	Cisgender women	4.2
MIRA	Vaginal diaphragm	2003-07	South Africa, Zimbabwe	Cisgender women	3.9

Also this quarter:

- ➔ Two studies from the Microbicides Trials Network (MTN)—B-Protected and DELIVER—found the dapivirine vaginal ring (DVR) to be safe for pregnant and lactating people and their babies. An analysis of cabotegravir drug levels in women from the HPTN 084 efficacy trial of injectable CAB for PrEP suggest that women who experienced delays in receiving their dose due to COVID-19 (normally every two months as directed by the protocol) may still have protection against HIV. Delays were up to 6 weeks, and offer potentially some relief for women who cannot adhere perfectly to their dosing schedule.
- ➔ New data show that a rectal suppository combining the antiretrovirals tenofovir alafenamide and elvitegravir was safe in humans, with high concentrations of drug present in rectal tissue. This suppository is also being tested vaginally.

Prevention Playlist

The most effective advocacy is based on smart analysis and accurate information. AVAC develops a wide range of materials to inform decision making and action. Be sure to read, join or listen to the resources below to stay up to date and join the conversation.

JOIN

- ➔ As anti-LGBTQIA+ legislation gains momentum in the US, Africa and elsewhere, [Convening for Equality/ Uganda](#), where draconian legislation has been approved, is leading advocacy to champion LGBTQIA+ rights. Follow [@CFE_Uganda](#) on twitter and reach out to get involved at coordinator@ugandakpc.org.
- ➔ [What's All the Buzz About: mRNA, manufacturing, vaccines access](#). Thursday, June 1 at 10am ET/4pm SAST. Register [here](#).
- ➔ [To bNAb or not to bNAb? The case for broadly neutralizing antibodies](#), June 7, 7 am PST/10am ET/4pm SAST. Register [here](#).
- ➔ [PrEP That Booty: The latest on rectal microbicide research for the back door](#). Thursday, June 29 at 9:00am–10:30am ET, Register [here](#).

READ

- ➔ A new series of articles, [Multipurpose Prevention Technologies for HIV, STIs & Pregnancies](#) published in [Frontiers in Reproductive Health](#).
- ➔ [From the Lab to the Jab Overview](#), a review of a series of upcoming briefs on emerging issues for vaccines R & D and equitable access.
- ➔ An updated FAQ on the DPP highlighting the latest updates and key questions on the DPP and project plans.
- ➔ The DPP Consortium's [strategy for delivering the DPP in the private sector in Kenya and Zimbabwe](#).
- ➔ [Advancing HIV Prevention Research in Pregnant and Lactating People \(PLP\): Think Tank Report and Action Plan](#).
- ➔ [Prevent, Prepare, and Respond: An Analysis of Global Health Architecture for Pandemic Preparedness](#).
- ➔ [Advocates' Guide for PPR in 2023](#).

- ➔ [AVAC Condemns Uganda's Anti-Homosexuality Bill 2023](#).
- ➔ [Highlights from CROI 2023](#).

LISTEN

- ➔ [Global PPR Equity: Why do we need agreements on IP and tech transfers?](#), [Recording](#), [Fifa Rahman Slides](#) / [Fitsum Lakew Slides](#) / [Esteban Burrone Slides](#).
- ➔ [Px Pulse Podcasts](#):
 - [Evolving Strategies for an HIV Vaccine: One researcher explains where the field is going and why?](#)
 - [LGBTQIA+ Advocacy in Uganda: Facing down fear and fighting for justice](#).
 - [PPPR Advocacy 101: Find out what it means to you](#).
 - [The Shape of Pandemic Preparedness is Being Decided. Now is the Time for Collective Action](#).
- ➔ [The Choice Agenda Webinars](#):
 - [PrEP \(In\)equity: Documenting, measuring, and flipping the script towards justice](#), [Recording](#) / [Slides](#) / [Resources](#)
 - [HIV Prevention Plus Plus: Developing options that meet the full range of our sexual and reproductive health needs](#), [Recording](#) / [Slides](#) / [Resources](#)
 - [How to Communicate about Sexual Health and STIs: Sex positivity vs. risk-based language](#), [Recording](#) / [Slides](#) / [Resources](#)
 - [Mpx - Sexual Networks, HIV and Activism](#), [Recording](#) / [Slides](#) / [Resources](#)
 - [Been There, Did That - Research Reflections from CROI 2023](#), [Recording](#) / [Dr. Monica Ghandi's Slides](#) / [Community Educator Slides](#)

About AVAC



AVAC is an international non-profit organization that leverages its independent voice and global partnerships to accelerate ethical development and equitable delivery of effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity. Follow AVAC on Twitter [@HIVpxresearch](#); find more at www.avac.org, www.prepwatch.org and www.stiwatch.org.