

## DEMONSTRATE

### Invest in an oral PrEP-driven paradigm shift

*AVAC Report* has tracked the development of daily oral pre-exposure prophylaxis (PrEP) using tenofovir-based drugs (TDF/FTC and TDF, brand names Truvada and Viread) for a decade now. We have developed information and advocacy from the early days of research controversies through the cascade of research results that led to approval of daily TDF/FTC as PrEP by the US Food and Drug Administration and WHO guidance. We have consistently called for plans to act on evidence of efficacy. We have called for a comprehensive suite of demonstration projects. We have called attention to inaction and to areas of progress. As we have issued our recommendations and worked to make them a reality with partners everywhere from the US to Uganda, Thailand, South Africa and Zimbabwe, we've been frustrated by the slow momentum, lack of coordination and inadequate funding.

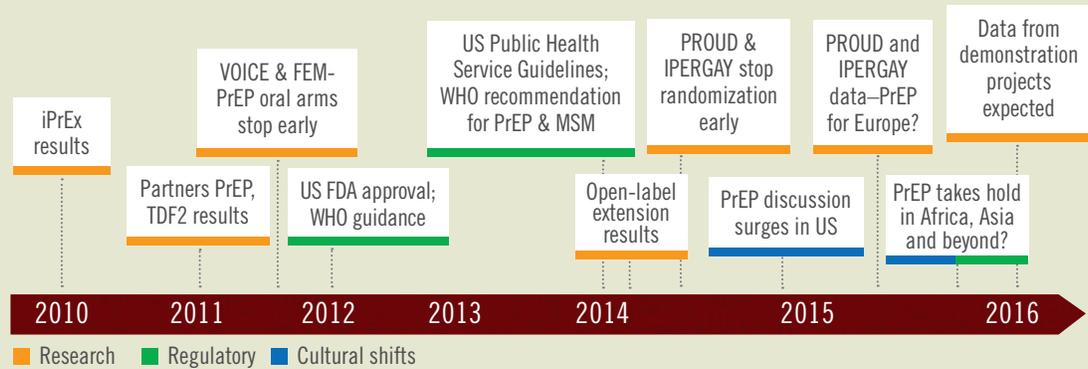
This year, we're still frustrated, but we're also thrilled and excited by the ways that the conversation about this PrEP strategy has changed. Even as funders and governments have been slow to define and implement a comprehensive suite of PrEP demonstration projects, individuals living with HIV and HIV-negative people living in contexts and communities where they feel their

prevention needs are unmet, have begun to demand PrEP. They have initiated a dynamic, even revolutionary dialogue about the right to this life-saving strategy. The discussion has moved far beyond the boundaries of the relatively small HIV prevention advocacy sphere, and the even smaller sphere of biomedical prevention research advocacy. It is part of a wide-ranging conversation about the right to sex without fear or judgment and about ways that HIV-positive and HIV-negative

#### More Positive PrEP Data in 2014/15

In October 2014, both the UK PROUD study and the French IPERGAY trial of oral PrEP in gay men and other men who have sex with men stopped randomization early after independent data monitoring committees saw evidence of overwhelming benefit. The data from these trials hadn't yet been released as *AVAC Report* went to press, but are forthcoming and will include information on behavior, condom use and adherence. Comparable types of data are expected from the Partners PrEP demo project in East Africa. These data will complement data from iPrEx OLE, the open-label extension trial among gay men, other MSM and transwomen, which found high rates of adherence, particularly in participants who reported higher rates of unprotected anal sex and other high-risk behaviors.

## From Proof-of-Concept to Prevention Phenomenon in Five Years



Has the global action on daily oral PrEP been as fast as possible? No. But there has been tremendous activity over the past five years. This timeline can be used to anticipate and speed action on the next generation of ARV-based prevention options.

people can share agency and responsibility as they negotiate their respective options for using ARVs for prevention. In other words, PrEP has become a cause and a rallying cry. But it is not yet a reality for everyone who needs or wants it correctly and consistently. And that is why one key recommendation for 2015 is a call to funders, national governments, implementing agencies and civil society groups working across identities and issues to **invest time and money in an oral PrEP-driven paradigm shift.**

The data all point the same way: daily oral PrEP works if you take it. (It appears that adherence may need to be higher in women whose risk is primarily via vaginal sex compared to individuals whose risk is via anal sex because of differences in how the drug is absorbed in vaginal and rectal tissues).

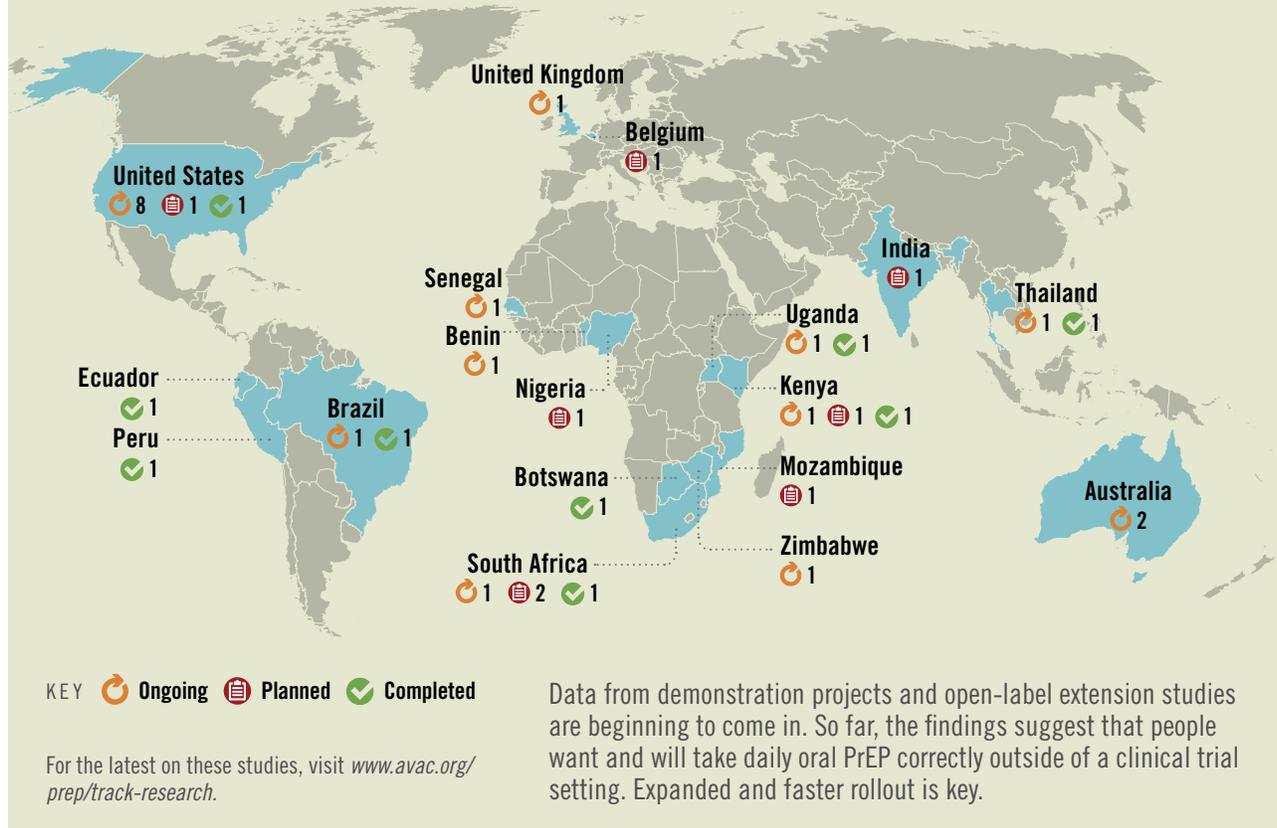
It is time for scale-up to keep up with this demand. This is true both because daily oral PrEP can save lives today and

because learning how to implement this strategy will lay the groundwork for new prevention options, especially ARV-based microbicides, if and when they are demonstrated to be efficacious in clinical trials. The following steps are key to achieving the PrEP-driven paradigm shift:

➤ **Implement large-scale pilots linked to national programs for oral PrEP.**

Daily oral PrEP alone can not address the complex social and structural forces that put individuals at risk (see section starting on page 14). This is why oral PrEP needs to be evaluated in large-scale pilots that provide a range of prevention services and that gather information and trigger action on the factors that help or hinder HIV testing, adherence and disclosure for people who test HIV-positive. Such programs can also serve as platforms for potential introduction of topical microbicides or vaginal rings (see page 23). Countries should initiate activities such as pilots or targeted programs in

## Planned, Ongoing and Completed PrEP Evaluation Studies (December 2014)



the context of multi-year national plans to ensure that there is phased expansion, inclusion in national strategic plans and sufficient funding, including via PEPFAR and GFATM.

➤ **Include a PrEP recommendation for women and adolescents in the next revision of the WHO Guidance on ARVs.**

It is quite possible that by mid-2015, the UNAIDS Prevention Targets document will recommend PrEP for women and adolescent girls, while the WHO consolidated guidelines on the use of on ARVs will not. Bringing these documents into alignment is essential, especially since the WHO

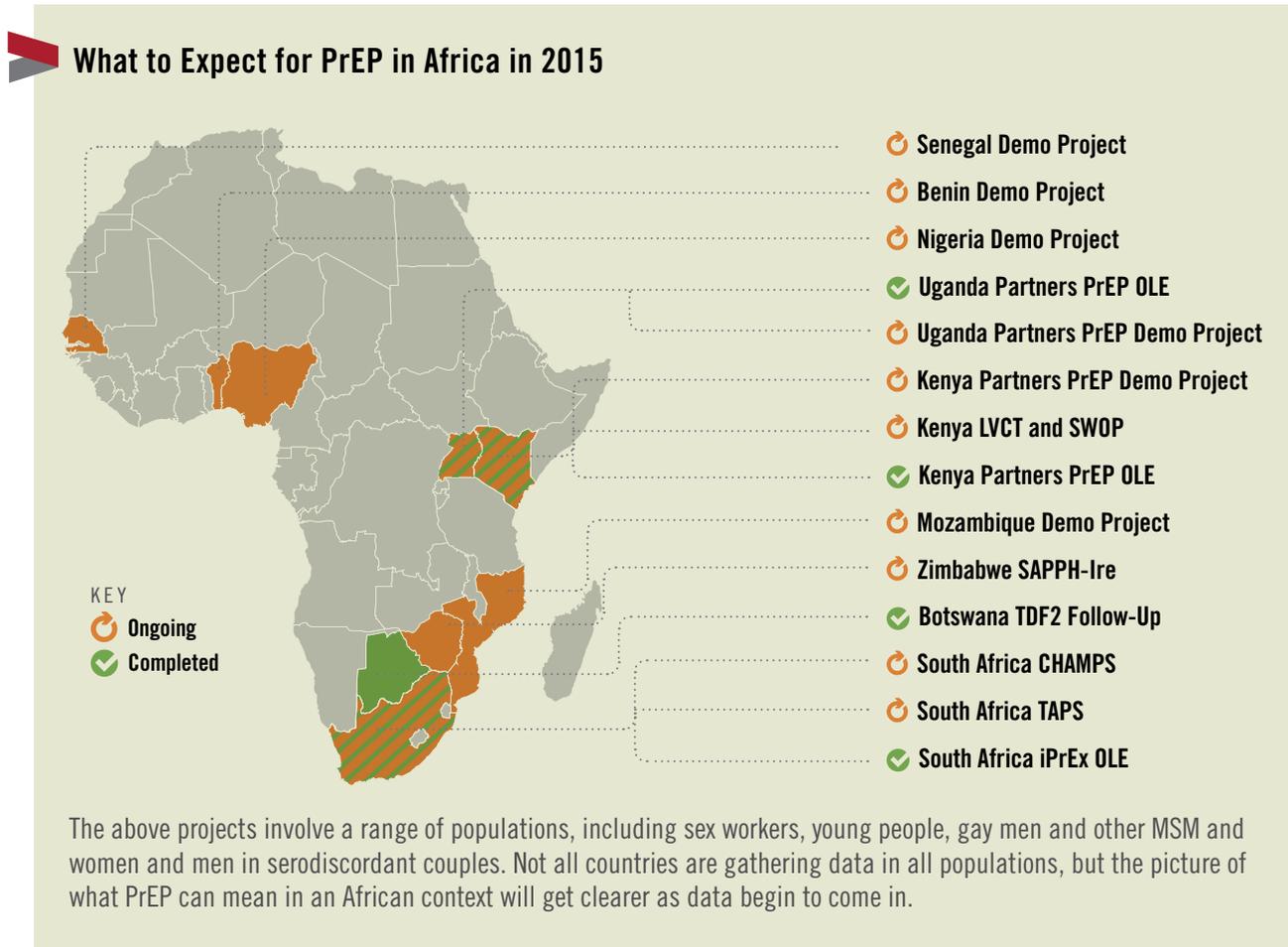
guidance carries far more weight when it comes to national plans and processes. Having clear, consistent guidance on PrEP's utility for women is key.

➤ **Plan and program around rollout of other ARV-based prevention options.**

As we discuss on page 23, the next 18 months will bring results from trials of tenofovir gel and the dapivirine ring. Even if there is evidence of efficacy for either product, there will be a delay between the end of the trial and the launch of pilot projects that make the products available outside of open-label extension trials. But it is possible to project two or three years into the future and envision scaled-up oral PrEP

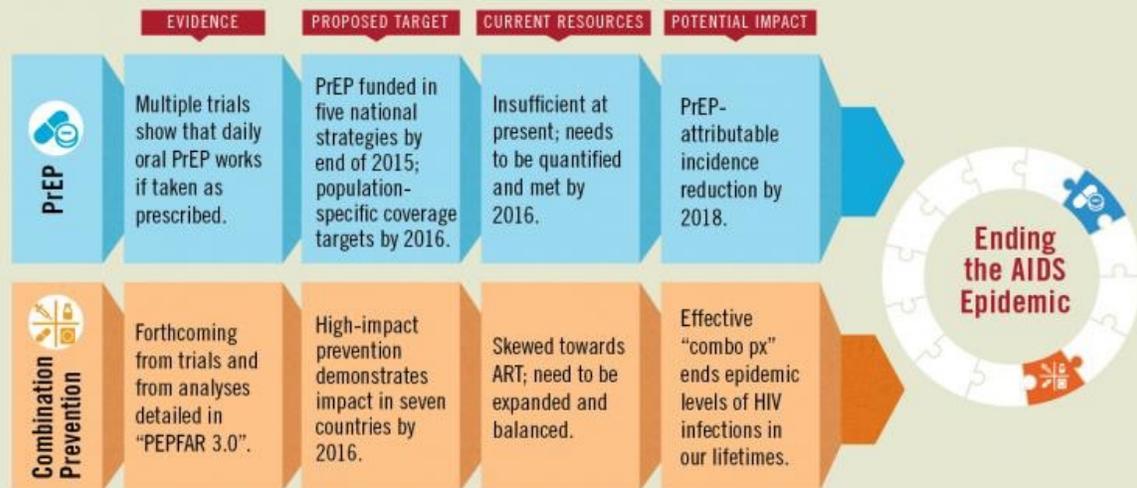
programs that also serve as a platform for piloting other ARV-based prevention strategies for HIV-negative individuals. That planning should start now and be reflected in coordinated multi-year strategies developed by microbicide and oral PrEP stakeholders. Oral PrEP

rollout should be harmonized with ART for HIV-positive individuals. Linking PrEP and ART provision is one option for creative programming that emphasizes options and agency for HIV-positive and HIV-negative people.



## Targets that Require Work: PrEP and Combination Prevention

Targets are urgently needed for daily oral PrEP and combination prevention. Here are proposed goals, along with what's in place and what is missing today.



References available at [www.avac.org/infographic/targets](http://www.avac.org/infographic/targets).

AVAC Report 2014/15: Prevention on the Line  
[www.avac.org/report2014-15/graphics](http://www.avac.org/report2014-15/graphics)