

## What to Watch in 2015

Welcome to the New Year! Wondering where to put your attention and advocacy energy for the next 12 months? AVAC doesn't presume to have all the answers, but here's a highly selective list of ten issues, events and developments to hold attention and spark action in 2015—and beyond. Want to see the bigger picture? Check out our updated timeline in the centerspread!

### **1** Data from the IPERGAY and PROUD PrEP Trials

In October 2014, both of these trials of oral TDF/FTC (brand name Truvada) as PrEP in gay men and other men who have sex with men reported great success—but without any data. How's that, you say? The data were reviewed by each trial's independent monitoring board. Each board determined that that daily and “on-demand” (before and after sex) PrEP was so effective that all trial participants—regardless of which study arm they were in—should be offered this PrEP strategy. That's happening now. The initial, eagerly awaited data from these studies are expected as late-breaker abstracts at the upcoming CROI meeting in late February. The IPERGAY team will announce the first data on non-daily use of TDF/FTC as PrEP. These data plus PROUD results represent information that could push PrEP access in Europe and beyond.

### **2** Data from the FACTS 001 Trial

In July 2010, the CAPRISA 004 trial team reported that 1% tenofovir vaginal gel reduced HIV risk in South African women by 39 percent—and also cut the risk of HSV-2 infection by about half. This was the first evidence that a microbicide could reduce women's risk of HIV. The CAPRISA finding triggered the FACTS 001 trial, which tested the same product and dosing regimen in South Africa, and these data are also expected in a late-breaker abstract at CROI. Regardless of the result, there will be a lot for advocates and others across the HIV prevention field to consider, debate, discuss and act on.

### **3** Launch of the ECHO Trial

ECHO is the name of the long-awaited (for some), much-debated (by all) randomized trial that aims to test how different contraceptive methods affect HIV risk among African women. The trial team has been choosing its words with tremendous care ever since a funding shortfall

made it seem like there might not be any ECHO trial at all. But as *Px Wire* went to press, the signs were hopeful for a start date in 2015. Once this is confirmed, stakeholder engagement will be more urgent than ever to ensure that women make informed decisions about whether to enroll or stay in the trial.

### **4** Launch of Two Phase II Long-Acting Injectable ARV Trials

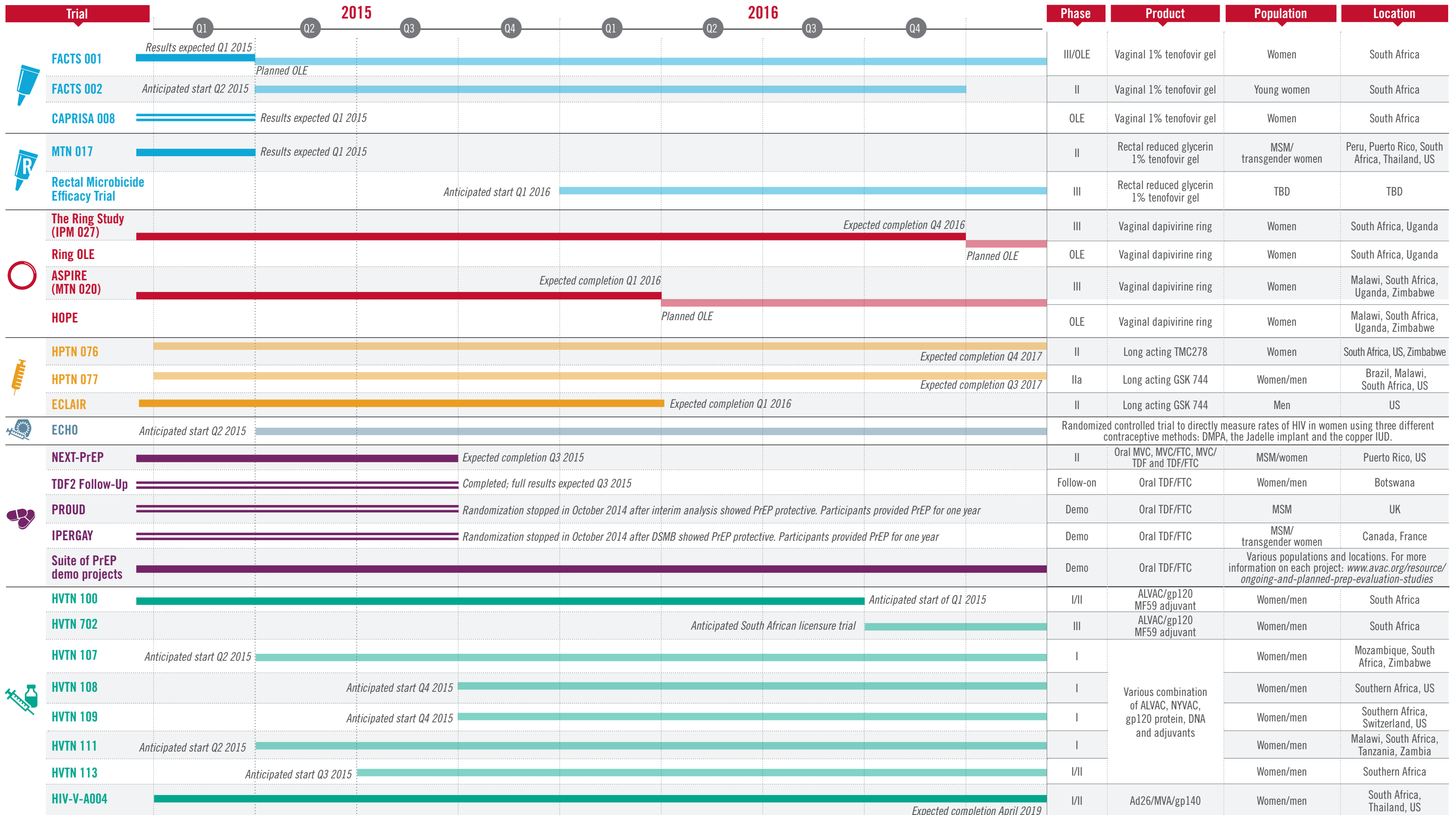
AIDS treatment has come a long way from the early regimens that involved handfuls of pills. Today's fixed-dose combinations have simplified antiretroviral treatment (ART) to one pill a day. Could it get even simpler with an injection every two or three months for people who've achieved virologic suppression? And what if that same drug or drugs could be used as long-acting PrEP? We won't have all the answers in 2015, but trial activity will heat up, with HPTN 076 and 077 phase II trials of two different products starting in the first quarter. Now's a great time for advocates to follow this field in more detail.

### **5** Continuation of the Early-Treatment “Cure” Strategy Trial in Infants

The IMPAACT network (the US-funded trial network focused on HIV research in pre- and post-partum mothers, infants, children and adolescents) has recently started the P1115 clinical trial, a proof-of-concept study that identifies HIV-positive pregnant women at the time of labor and asks them for consent to start their newborns on ART immediately after birth. Enrollment is open at sites in the US and multiple countries in Africa and Latin America. The hope is that immediate triple combination treatment will lead to “remission”, as seen in the case of the “Mississippi Baby” who was born with HIV, started on ART and appeared to have been HIV-free. She later stopped ART. HIV eventually returned in this child, but the long period of undetectable virus raised intriguing questions about how early ART could be used as part of cure strategies in newborns. This is just one example of an ambitious and complex strategy that will be happening in communities all over the globe in 2015. To learn more and get hooked into the new “CUREicculum”—contact us at [avac@avac.org](mailto:avac@avac.org).

### **6** HVTN 100 Continues AIDS Vaccine Research and Development

This trial is the next in the stepwise southern African series that seeks to improve on the vaccine protection seen



> *Continued from front*

in the Thai RV144 trial. Already, the HVTN 097 trial has shown that the actual RV144 regimen had similar immunological effects in South Africans as it did in Thais, in spite of differences in average body mass and other parameters. HVTN 100 is a Phase I/II study that will test a vaccine combination similar to that used in RV144 but adapted for improved efficacy and to match the viral subtype found in southern Africa. Results from this trial will be used to decide whether this vaccine can proceed into a Phase III licensure study. It is a long road to efficacy, but many of the short- and mid-term steps have been mapped out by the P5 consortium behind this vaccine strategy. Now is the time for advocates to track these trials, seeking transparency in timelines and clarity in messages.

## **7** Global Fund Concept Notes Translated into Grants—and Action

As 2015 gets under way, countries that meet the Global Fund to Fight AIDS, Tuberculosis and Malaria classification of “high burden” will be among those submitting concept notes. If advocates at every level have done their jobs in-country, these documents should be full of ambitious, high-impact strategies. Will the concept notes turn into funded grants, and will these grants get implemented as they were originally written—or will funds shift around based on politics or problematic policies? These are key questions for advocates interested in whether UNAIDS Prevention Targets (see item no. 9 on our list) mean anything at all.

## **8** A New Round of PEPFAR Country Operating Plans

PEPFAR Country Operating Plans dictate the activities that are funded and the targets that are set at a country level. This year’s planning process will be in full swing during the first quarter of the year, with plans finalized for submission to Washington, DC, by March or April. PEPFAR is placing an increased emphasis on civil society engagement throughout this process—so it’s up to informed civil society to ask for genuine opportunities to review proposed plans, provide input and hear about how their feedback has been incorporated. At a global level, now is also the time to push PEPFAR to set specific funding, coverage and impact targets.

## **9** Launch of UNAIDS Prevention and Non-Discrimination Targets

Last year UNAIDS released its treatment-focused “90-90-90” target. 90-90-90 is, of course, a combination treatment and prevention target since virologic suppression preserves health and reduces the risk of

HIV transmission. AVAC and others have been asking for targets with similar specificity and ambition for non-ART prevention—including attention to stigma, discrimination and criminalization, since rights-based delivery of services is essential. UNAIDS shared draft prevention and non-discrimination targets in late-2014 and took comments on them. Many advocates weighed in with substantial comments, and we’ll be watching to see whether the revisions reflect our concerns!

## **10** Ebola Vaccine Trials

When is it ethical or feasible to conduct research without a placebo? What is the best strategy for stakeholder engagement when the epidemic in question is fluctuating in intensity and relates to a disease that has a rapid, often fatal course? This year will see Ebola vaccine trials launch in the context of discussion about these and other questions. AIDS researchers, ethicists and advocates are deeply engaged in the vaccine development process. This area offers a crucial and fascinating insight into the ways that the work the AIDS field has done—e.g., on the Good Participatory Practice Guidelines for stakeholder engagement—translates in other fields.



This year’s Conference on Retroviruses and Opportunistic Infections (CROI) will be held from

February 23 to February 26, 2015, in Seattle, Washington. It brings together researchers and advocates from around the world to share the latest studies, important developments and best research methods in the ongoing battle against HIV/AIDS and related infectious diseases. Several studies described above will be presented at CROI 2015. Webcasts, abstracts, electronic posters and other electronic resources from CROI 2015 will be available online at [www.croiconference.org](http://www.croiconference.org).

## About AVAC



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 biomedical prevention options as part of a comprehensive response to the pandemic.

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