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 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.

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 be 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 “CURIEcculum”—contact us at 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...
## Status of Selected Biomedical HIV Prevention Clinical Trials

<table>
<thead>
<tr>
<th>Phase</th>
<th>Product</th>
<th>Population</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>III/OLE</td>
<td>Vaginal 1% tenofovir gel</td>
<td>Women</td>
<td>South Africa</td>
</tr>
<tr>
<td>II</td>
<td>Vaginal 1% tenofovir gel</td>
<td>Young women</td>
<td>South Africa</td>
</tr>
<tr>
<td>OLE</td>
<td>Vaginal 1% tenofovir gel</td>
<td>Women</td>
<td>South Africa</td>
</tr>
<tr>
<td>II</td>
<td>Rectal reduced glycerin 1% tenofovir gel</td>
<td>MSM/Transgender women</td>
<td>Peru, Puerto Rico, South Africa, Thailand, US</td>
</tr>
<tr>
<td>III</td>
<td>Rectal reduced glycerin 1% tenofovir gel</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>III</td>
<td>Vaginal dapivirine ring</td>
<td>Women</td>
<td>South Africa, Uganda</td>
</tr>
<tr>
<td>OLE</td>
<td>Vaginal dapivirine ring</td>
<td>Women</td>
<td>South Africa, Uganda</td>
</tr>
<tr>
<td>III</td>
<td>Vaginal dapivirine ring</td>
<td>Women</td>
<td>Malawi, South Africa, Uganda, Zimbabwe</td>
</tr>
<tr>
<td>OLE</td>
<td>Vaginal dapivirine ring</td>
<td>Women</td>
<td>Malawi, South Africa, Uganda, Zimbabwe</td>
</tr>
<tr>
<td>II</td>
<td>Long-acting TMC278</td>
<td>Women</td>
<td>South Africa, US, Zimbabwe</td>
</tr>
<tr>
<td>Ha</td>
<td>Long-acting GSK 744</td>
<td>Women/men</td>
<td>Brazil, Malawi, South Africa, US</td>
</tr>
<tr>
<td>II</td>
<td>Long-acting GSK 744</td>
<td>Men</td>
<td>US</td>
</tr>
</tbody>
</table>

### Randomized Controlled Trials to Directly Measure Rates of HIV in Women Using Three Different Contraceptive Methods: DMPA, the Jadelle Implant and the Copper IUD

- **IV/IV** Oral MVC, MVC/FTC, MVC/TDF and TDF/FTC
  - Women/men
  - Puerto Rico, US
- **Follow-on** Oral TDF/FTC
  - Women/men
  - Botswana
- **Demo** Oral TDF/FTC
  - MSM
  - UK

### Demonstration Projects/Label Extension (OLE)/Follow-on

- **Demo** Oral TDF/FTC
  - MSM/Transgender women
  - Canada, France
- **Demo** Oral TDF/FTC
  - Various populations and locations. For more information on each project, visit: www.avac.org/resource/ ongoing-and-planned-prep-evaluation-studies

### Phase I/II

- **ASPIRE (MTN 020)**
  - Anticipated start Q2 2015
  - Expected completion Q1 2016
- **ECLAIR**
  - Anticipated start Q3 2015
  - Expected completion Q1 2016
- **NEXT-PreP**
  - Anticipated start Q2 2015
  - Planned OLE
- **IPERGAY**
  - Anticipated start Q4 2015
  - Planned OLE
- **HOPE**
  - Anticipated start Q2 2015
  - Planned OLE
- **Vaginal Gel Rectal Gel**
  - Vaginal, Ring
  - Long-acting injectable PrEP
  - Hormonal Contraceptives and HIV
  - Oral PrEP
  - Preventive HIV vaccines

### Clinical Trials

- **FACTS 001**
  - Results expected Q1 2015
- **FACTS 002**
  - Anticipated start Q2 2015
- **CAPRISA 008**
  - Results expected Q1 2015
- **MTN 017**
  - Results expected Q1 2015
  - Anticipated start Q1 2016
  - Results expected Q1 2015
  - Expected completion Q4 2016
- **The Ring Study (IPM 027)**
  - Anticipated start Q2 2015
  - Expected completion Q1 2016
- **PROUD**
  - Randomization stopped in October 2014 after interim analysis showed PrEP protective. Participants provided PrEP for one year
- **IPERGAY**
  - Randomization stopped in October 2014 after DSMB showed PrEP protective. Participants provided PrEP for one year
- **Suite of PrEP demo projects**
  - Anticipated start Q2 2015
  - Anticipated South African licensure trial
- **HVTN 100**
  - Anticipated start Q2 2015
  - Anticipated start of Q1 2015
- **HVTN 702**
  - Anticipated start Q2 2015
  - Anticipated African licensure trial
- **HVTN 107**
  - Anticipated start Q4 2015
  - Anticipated start Q4 2015
- **HVTN 108**
  - Anticipated start Q4 2015
- **HVTN 109**
  - Anticipated start Q4 2015
- **HVTN 111**
  - Anticipated start Q2 2015
  - Anticipated start Q3 2015
- **HVTN 113**
  - Anticipated start Q3 2015
- **HIV-V-A004**
  - Anticipated start Q3 2015
  - Anticipated start Q3 2015
  - Expected completion April 2019
- **FACTS 002**
  - Results expected Q1 2015
- **FACTS 003**
  - Anticipated start Q2 2015
- **CAPRISA 008**
  - Results expected Q1 2015
- **MTN 017**
  - Results expected Q1 2015
- **Rectal Microbicide Efficacy Trial**
  - Anticipated start Q2 2015
  - Expected completion Q1 2016
- **The Ring Study (IPM 027)**
  - Anticipated start Q2 2015
  - Expected completion Q1 2016
- **HOPE**
  - Anticipated start Q3 2015
  -Expected completion April 2019
Continued from front

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.

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