

# After The Ring Study: DREAM

## An open-label study of IPM's dapivirine ring

**What is the dapivirine ring?** The dapivirine vaginal ring, a monthly HIV prevention product developed by the nonprofit International Partnership for Microbicides (IPM), is the first long-acting technology designed for women [found](#) to help reduce HIV-1 risk in large-scale Phase III trials: The Ring Study and ASPIRE. The ring slowly releases the ARV dapivirine over the course of a month. Women insert and replace the ring themselves.

**What is DREAM?** DREAM (Dapivirine Ring Extended Access and Monitoring) was an open-label extension study launched by IPM in July 2016 to provide the active dapivirine ring for one year to approximately 940 HIV-negative women who participated in The Ring Study. (A similar open-label study called [HOPE](#) was conducted by the Microbicide Trials Network to provide the ring to former ASPIRE participants.) HOPE completed in October 2018 and DREAM completed in January 2019.

**Why DREAM?** In addition to offering former Ring Study participants access to the ring for one year, DREAM collected extended safety information and explored when, why and how women use the ring. DREAM also gathered information on product adherence to help identify new ways to support ring use.

**What are the results so far?** The Phase III trials found the product reduced HIV risk by about 30 percent overall. In addition, HIV risk was cut by 45 percent among participants who used the ring at least some of the time. Interim analyses of DREAM found increased product use, with over 90 percent of women using the ring at least some of the time, and data modeling suggest a 59 percent reduction in HIV risk. Although these findings are limited by a lack of a placebo comparison group, they suggest that when women know the ring helped reduce HIV risk in clinical trials, they are more likely to use it and see greater protection. Final results are expected in 2019.

### DREAM highlights

- Provided active dapivirine ring to former Ring Study participants who remained HIV-negative
- Gained insight into how women used the ring once Phase III results were known
- Collected extended safety data
- Collected data on adherence and its influence on risk reduction
- Explored the feasibility of three-month follow-up visits to obtain the monthly ring

Open-label studies of a daily oral ARV pill (known as PrEP) also showed increases in adherence and risk reduction over Phase III trials, a trend IPM hopes will continue for the ring. Adherence support was a key feature of DREAM.



**Where is DREAM being conducted?** DREAM was conducted at six former Ring Study sites: one site in Uganda, which is the MRC/UVRI Uganda Research Unit on AIDS in Masaka, as well as five sites in South Africa, which are the Desmond Tutu HIV Foundation in Masiphumelele; Madibeng Centre for Research in Brits; Maternal, Adolescent and Child Health (MatCH) in KwaZulu-Natal; Ndlovu Care Group in Elandsdoorn, Limpopo; and Qhakaza Mbokodo Research Clinic in KwaZulu-Natal.

**DREAM study design:** DREAM included numerous measures to monitor and protect the safety and well-being of participants. Potential study participants provided informed consent to be screened and to enroll in the study. Participants visited the clinic once per month for their first three months, receiving one ring per visit; thereafter, women visited the clinic once every three months, inserting one ring at the clinic and receiving two additional rings until their next visit (with the option to return monthly). Participants also received ongoing HIV risk-reduction counseling, male and/or female condoms, diagnosis and treatment of sexually transmitted infections, pregnancy testing and family planning services, as well as treatment or referrals for medical conditions. Any women in the study who tested positive for HIV immediately stopped using the ring and were referred to local health facilities for care and treatment, with an option to enroll in a follow-up study to assess the ring's impact, if any, on HIV treatment outcomes.