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## FACT SHEET

### The Microbicide Trials Network

#### Fast Facts

- The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases, with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health.
- The MTN brings together international investigators and community and industry partners whose work is focused on the rigorous evaluation of promising microbicides – products applied inside the vagina or rectum to prevent the sexual transmission of HIV – and of dual-purpose products for preventing both HIV and unintended pregnancy.
- MTN studies are designed specifically to support the potential licensure and regulatory approval of these products for different high-risk populations. Because effectiveness of a product is also dependent on use, behavioral science is integrated throughout MTN’s unique research portfolio.
- The MTN is led by Sharon Hillier, Ph.D., of the University of Pittsburgh and Magee-Womens Research Institute, who is principal investigator, and by Jared Baeten, M.D., Ph.D., of the University of Washington, who serves as co-principal investigator. The MTN is comprised of a Leadership and Operations Center; a Laboratory Center with expertise in immunology, virology and microbiology; and a Statistical and Data Management Center.
- More than 25 clinical research sites on four continents have partnered with the MTN in the conduct of its clinical trials. Collectively, more than 11,000 research participants have taken part in MTN studies.

#### Research Highlights

- **ASPIRE and other MTN studies are key components in bid for regulatory approval of dapivirine vaginal ring** – The dapivirine ring is the first biomedical HIV prevention product developed specifically for women that was shown to be safe and help protect against HIV in two independently conducted Phase III trials. [ASPIRE](#), also known as MTN-020, was conducted by the MTN, while its sister study, The Ring Study, was conducted by the International Partnership for Microbicides (IPM), a non-profit organization that also developed the dapivirine ring. The ring, which women can insert and replace themselves, contains an antiretroviral (ARV) drug called dapivirine that is slowly released during the month it is worn. Based on the results of these trials and several smaller studies, including studies conducted by the MTN, IPM is seeking regulatory approval of the dapivirine ring. In parallel, MTN continues to conduct studies to help understand issues important for broader implementation of the dapivirine ring should it be approved. Among these is [HOPE](#) (MTN-025), an open-label extension study for former participants of ASPIRE. HOPE will provide additional safety data and greater insight into the relationship between ring use and HIV protection.
- **Addressing the needs of adolescent girls and young women** – Adolescent girls and young women are among those at highest risk of HIV in sub-Saharan Africa. While oral pre-exposure prophylaxis (PrEP) and the dapivirine ring, should it eventually receive regulatory approval, could help curtail the rate of new infections, neither approach can be effective if not used with sufficient adherence. Studies have shown adherence to be particularly challenging for younger women. Reducing HIV incidence in this vulnerable population is clearly a global priority. The [REACH](#) study (MTN-034/IPM 045) will help answer key

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questions about the safety and use of Truvada as daily oral PrEP and the monthly dapivirine ring by adolescent girls and young women ages 16-21, as well as their preferences for either or both approaches. The MTN has already completed a study called [MTN-023 /IPM 030](#) that evaluated the safety and drug absorption qualities of the dapivirine ring in 96 adolescent girls in the United States. The REACH study will contribute important data about the ring in African girls.

- **The next generation of vaginal rings: Dual-purpose rings and 90-day rings** – While a ring used for a month at a time may appeal to some women, others may prefer a product they replace every three months, or a ring that provides contraception in addition to protecting against HIV. Toward this end, [MTN-030/IPM 041](#) is the first study of a three-month dual-purpose ring containing both the ARV dapivirine and a hormonal contraceptive (levonorgestrel). As a Phase I study, MTN-030 is designed to assess the safety of the combination ring and how each active ingredient is taken up in the body in the presence of the other. Additional trials of rings used for three-months at a time – one containing dapivirine (MTN-036/IPM 047) and another containing tenofovir (MTN-038) – are also planned for the coming year.
- **Leading the way to a rectal microbicide** – MTN’s rectal microbicide research agenda is focused on evaluating diverse products and delivery methods as HIV prevention options for people who practice anal sex. Just as women have multiple options for contraception based on their needs and lifestyles, rectal microbicides – formulated as gels, douches or even fast-dissolving suppository-like inserts – could provide additional ways to reduce the risk of HIV infection from anal sex. The MTN has conducted three trials of tenofovir-based gel as a rectal microbicide, including [MTN-017](#), the first Phase II study of a rectal microbicide product. Additional products and formulations will be evaluated in five new studies the MTN plans to implement during 2017 and 2018.
- **Not to be forgotten: Pregnant and breastfeeding women** – The MTN has long recognized that women need products that will be safe and effective to use during all stages of life. As such, included in its scientific portfolio is a comprehensive research program purposefully designed to take incremental steps in determining whether HIV prevention products are safe to use by women during pregnancy and breastfeeding, when the risk of acquiring HIV from an infected partner may be particularly high. Researchers will soon report results of the first such study of the dapivirine ring (MTN-029/IPM 039), which looked at whether drug released from the ring into the vagina gets absorbed by breastmilk. Additional studies of the dapivirine ring are planned in both breastfeeding and pregnant women in Africa.
- **Product use and adherence: Insights and lessons learned** – MTN’s first flagship trial, [VOICE](#), found none of the daily products tested (oral Truvada, oral tenofovir and tenofovir vaginal gel) was effective. In fact, the study’s results, first reported in 2013, found most women had not used their assigned products, making clear the need for approaches that fit better within the context of these women’s lives and are less challenging to use. Behavioral sub-studies and subsequent research provided important insight into the reasons women did not use the products and is helping to inform the design and conduct of current and future HIV prevention trials.

### About Microbicides

- Microbicides are products applied inside the vagina or rectum to protect against HIV through sex. Unlike condoms, these products are controlled by the user, not his or her sexual partner. And unlike other biomedical approaches that rely on systemic delivery of anti-HIV drugs, microbicides deliver drugs directly to the site of potential infection. Microbicide products could offer an additional option for people who, for various reasons, may not want to or cannot access proven methods, such as condoms or daily use of Truvada as PrEP to reduce their risk of HIV.
- Several microbicide products are in various stages of clinical evaluation, with the monthly dapivirine ring the furthest along and possibly the first product to receive regulatory approval. Other vaginal formulations being evaluated include three-month rings, fast-dissolving films and tablet-like inserts. Rectal microbicide formulations currently being developed and evaluated include gels, douches and fast-dissolving suppository-like inserts.

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### Why Microbicides Are Needed

- Worldwide, nearly 37 million people are living with HIV. Almost 78 million people have been infected with HIV and about 35 million have died of HIV-related causes since the epidemic started in the early 1980s.
- Although significant strides have been made in the treatment of HIV, now, more than 30 years after HIV was first identified, the prevention of new infections continues to be great a challenge. More than 2 million new HIV infections occur annually – about 5,700 every day – a figure than has remained unchanged between 2010 and 2015. Approximately one-third of new infections are among people ages 15-24.
- Women represent more than half (51 percent) of all people living with HIV worldwide, and account for 60 percent of those with HIV in sub-Saharan Africa.
- Across the globe, gay men and other men who have sex with men and transgender women continue to be at very high-risk, with condomless anal sex the primary driver for the high prevalence in these populations. By some estimates, the risk of acquiring HIV through condomless receptive anal intercourse – which is practiced by both men and women – is at least 20 times greater than through condomless vaginal sex.

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More information about HIV can be found in the [UNAIDS report AIDS by the Numbers 2016](#), the Kaiser Family Foundation [Global HIV/AIDS Epidemic](#) fact sheet; and the amfAR [Worldwide Statistics](#) fact sheet.

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