

IPM: Pioneering HIV prevention options for women



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES

Seventeen years ago, the International Partnership for Microbicides (IPM) entered the HIV prevention field with a promise and a clear vision to create products that women in developing countries could use discreetly to prevent HIV and protect their sexual and reproductive health. Every step we have taken since then has brought that vision into sharper focus.

The HIV/AIDS epidemic continues to disproportionately affect women, especially in developing countries. Currently available prevention options are often not practical for many women, who urgently need new self-initiated tools that make sense for their lives. IPM's monthly dapivirine ring and other technologies in development could help empower women with discreet and long-acting tools they can use to protect their health, on their own terms.

Our Progress

Since IPM was founded as a nonprofit organization in 2002, we have leveraged public, philanthropic and private sector resources to accelerate the development of potentially lifesaving technologies for women.

IPM builds on partnerships—with governments, foundations, researchers, pharmaceutical companies, policymakers, advocates and communities—to bring scientific ingenuity, political will and financial resources to bear on all phases of product development. Key achievements include:

- **Developing a monthly ring for women's HIV prevention**

IPM led the development and testing of the dapivirine ring, the first long-acting prevention method shown to help reduce HIV risk in clinical trials. The vaginal ring is designed to deliver the antiretroviral (ARV) drug dapivirine over the course of one month, and women can insert and remove the ring themselves.

By marshalling scientific know-how and resources through partnerships, we brought the ring from concept to Phase III efficacy trials just seven years after acquiring the license for dapivirine.

In 2016, two Phase III trials found that the dapivirine ring helped reduce women's HIV risk and was well-tolerated. In 2019, two subsequent open-label extension (OLE) studies saw increased product use and suggested greater risk reduction. Additional OLE data will help answer questions about how women might use the product in real-world settings.



IPM's monthly dapivirine ring is currently under regulatory review.

Data from other ongoing and planned open-label studies will provide insights into the ring's safety and acceptability among adolescents, and pregnant and breastfeeding women.

- **Negotiating innovative licenses for potent ARVs**

Since our inception, IPM has negotiated royalty-free licenses and an exclusive worldwide rights agreement from five leading pharmaceutical companies to develop nine promising ARVs as microbicides. These licenses ensure future IPM products will be affordable where the need is most urgent.

- **Conducting rigorous research studies**

IPM has worked in 11 countries in Africa, Europe and North America to conduct more than 40 clinical trials to date on a variety of products as well as 13 incidence studies and two acceptability studies, all of which continue to inform our work and the field.





A research staff member demonstrates how to insert a vaginal ring at a journalist training on women's HIV prevention and microbicides.

■ Strengthening medical research capacity in Africa

IPM has collaborated with in-country partners and research staff to build and strengthen capacity at more than 15 research centers across sub-Saharan Africa. We trained more than 600 research center clinical staff, including community engagement teams on microbicide trial implementation. These staff are equipped to conduct rigorous HIV prevention and other clinical trials that contribute to the health of their communities.

■ Streamlining manufacturing processes

IPM led a state-of-the-art manufacturing facility to produce vaginal gel and ring prototypes for early trials, resolving a manufacturing bottleneck and saving costs for more than 10 clinical studies. We transferred dapivirine ring production to an external manufacturer beginning with our Phase III studies to ensure cost-efficiencies for large-scale production, a process that would continue for the ring's potential introduction, to keep costs as low as possible.

Realizing the lifesaving potential of new products for women may be within our reach.

■ Advancing multipurpose tools to address women's overlapping sexual and reproductive health needs

Because HIV and unintended pregnancy are major causes of serious health complications and death for women worldwide, IPM is developing a multipurpose technology: a three-month dapivirine-contraceptive ring designed to offer

both HIV prevention and contraception. Encouraging results from a first Phase I trial supported a second Phase I trial that began in 2018, with results expected in 2020.

What May the Future Hold?

The first long-acting, self-initiated HIV prevention product for women, if it is approved for public use

The monthly dapivirine ring is currently under regulatory review by the European Medicines Agency, with an opinion expected in 2020. Applications are also planned to the US Food and Drug Administration, the South African Health Products Regulatory Authority and other national regulatory authorities in Africa, where women face the highest HIV risk.

Access to products where the need is urgent

IPM is collaborating with global, regional and national partners to determine how the dapivirine ring could fit into prevention programs, and plan for its potential rollout.

Building on dapivirine ring research

IPM is leveraging its ring technology to develop a range of follow-on products that advance the science of HIV prevention. These include a three-month dapivirine-only ring, which entered a Phase I trial in 2017, with results expected in 2019.

From Promise to Product

As women have become the face of HIV, IPM has remained true to its vision by pioneering critically needed microbicide research and development to help fill a gap in women's HIV prevention needs.

IPM extends its deepest thanks to our partners around the world and to our generous donors, all of whom amplify our efforts to improve women's health. Realizing the lifesaving potential of new products for women may be within our reach. But only by continuing to unite scientific discovery with political will and financial commitment, can we meet women's urgent sexual and reproductive health needs globally.