

## IPM: A decade of progress advancing HIV prevention for women

Ten years ago, IPM entered the HIV prevention field with a promise and a clear vision to create products that women in developing countries could use to prevent HIV and protect their sexual and reproductive health. Every step we have taken since has brought that vision into sharper focus. Today, we are as optimistic about our mission as we have ever been.

The HIV epidemic continues to disproportionately affect women in developing countries, and yet they lack practical tools they can use on their own, without the involvement of a male partner. IPM's monthly microbicide ring and other technologies in development could help empower women with discreet and long-acting tools they can use to protect their own health.

### Ten Years of Progress

Since IPM was founded as a nonprofit organization in 2002, we have leveraged public, philanthropic and private sector resources to spur development of safe and effective life-saving 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. IPM's key achievements over the past 10 years include:

- **Negotiating royalty-free licenses for ARV drugs.** Recent studies have validated the potential of antiretroviral (ARV) drugs to prevent HIV infection and save millions of lives. Since our inception, IPM has negotiated non-exclusive, royalty-free licenses from five pharmaceutical companies to develop eight different ARV drugs as microbicides. These licenses are essential to ensuring IPM products will be affordable where the need is most urgent.
- **Developing the monthly dapivirine ring and advancing it to Phase III efficacy trials.** IPM developed an easy-to-use monthly vaginal ring that delivers the ARV dapivirine slowly over time that could help women protect themselves against HIV. After acquiring the license for dapivirine, we brought the ring from concept to Phase III efficacy and long-term safety trials, now underway, in just seven years.
- **Conducting research studies.** IPM has worked in 11 countries in Africa, Europe and North America to conduct 17 clinical trials on a variety of products, 13 incidence studies and two product acceptability studies, all of which continue to inform our work and the field more broadly.
- **Strengthening medical research capacity in Africa.** IPM has helped build and strengthen capacity at over 10 research centers in seven countries in Africa, and trained 600 clinic staff and community advisors on microbicide trial implementation. These centers are now equipped to conduct high-quality clinical trials for IPM and other organizations, and many provide other needed services to their communities.
- **Streamlining manufacturing processes.** IPM led a state-of-the-art manufacturing facility to accelerate production of prototype gels and rings for early trials, resolving a bottleneck in manufacturing capacity and

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HIV PREVENTION FOR WOMEN

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saving costs for more than 10 clinical studies. We successfully transferred ring production for our Phase III program to a manufacturer to ensure cost-efficiencies for large-scale production.

- **Expanding the pipeline with MPTs to address women’s multiple sexual and reproductive health needs.** Because high rates of HIV and unintended pregnancy are significant causes of health complications and death for women worldwide, IPM is building on its ring technology to advance a new multipurpose prevention technology (MPT) — a 60-day dapivirine-contraceptive ring that would offer both HIV protection and contraception.
- **Developing the first combination ARV ring.** IPM is also developing the first combination ARV vaginal ring, the dapivirine-maraviroc ring, now in Phase I clinical trials. Combining ARVs with different mechanisms of action may provide greater protection against HIV than a single drug alone.
- **Maintaining a singular focus on the health needs of women.** IPM has remained true to its vision by staying focused on women’s unique sexual and reproductive health needs. As women have increasingly become the face of HIV over the past decade, IPM’s pioneering work to develop a safe and effective microbicides remains timely and critically needed. New tools like IPM’s 60-day MPT ring reflect that women’s overlapping health needs must be addressed through integrated products, policies and services.

## What does the future hold?

- **The first long-acting, female-initiated HIV prevention technology brought to market, pending study results.** IPM’s dapivirine ring is now in two parallel Phase III studies, the first efficacy studies of a microbicide ring for HIV prevention. These two “sister studies” — IPM’s Ring Study along with the ASPIRE study being conducted by our partner the Microbicide Trials Network — are designed to provide the strength of evidence needed for IPM to obtain licensure for the ring, pending results in 2015.
- **Access to products where the need is most urgent.** IPM collaborates with global partners to help ensure women in developing countries will have affordable access to its products in the future. We are working to expedite the potential roll-out, availability and affordability of the dapivirine ring. This includes optimizing manufacturing processes and scale-up to minimize production costs and exploring distribution and financing mechanisms. IPM works with regulatory authorities in developing countries, the European Medicines Agency and the U.S. Food and Drug Administration to guide regulatory pathways for our products.
- **An innovative pipeline of products and novel mechanisms of action.** In addition to the monthly dapivirine ring, the MPT ring and the combination ARV ring, IPM is advancing other products in a variety of novel formulations to accelerate the science of HIV prevention and expand women’s options. These include multiple ARV drugs with different mechanisms of action, such as a gp120 binder and entry inhibitors like maraviroc, alone and in combination. IPM is also working to extend the current monthly dapivirine ring formulation to 60 days or longer.

## From Promise to Product

The possibility of putting life-saving products in millions of women’s hands is within our reach. 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. We also highlight the need for additional political and financial support to ensure that the pace of product development meets the urgency of women’s health needs globally.