

Women & HIV Prevention:
**EXPANDING
THE OPTIONS,
EMPOWERING
WOMEN**

Dear friends and colleagues,



Dr. Zeda F. Rosenberg
Founder and CEO



Dr. James McIntyre
Chair of the Board

Each year, we take stock of progress in HIV prevention research and development. As with all types of product development, the field has seen growth, victories and setbacks. Through it all, women have remained at the core of IPM's mission, given their urgent and unmet need for new prevention options.

Equipping women with the range of tools they need to protect their sexual and reproductive health is vital. We are making strides with the first long-acting HIV prevention product, one that could give women more control in staying HIV-free. In 2017, IPM submitted the first regulatory application for the monthly dapivirine ring, and earlier this year, interim data from two open-label studies of the ring suggested encouraging increases in use and risk reduction.

These milestones toward the ring's potential introduction were possible only through the steadfast and determined efforts of our donors and many partners, and, most important, the women participating in the ring studies. We are proud to work with so many individuals and institutions dedicated to realizing a future where women have choices to stay healthy on their own terms. This shared commitment is essential to making the ring available, if it is approved.

Women's sexual and reproductive health needs are multiple and varied, and their product options should be, too. IPM is prioritizing the development of next-generation microbicides that would expand the spectrum of women's long-acting prevention technologies: a three-month dapivirine-only ring and a three-month dapivirine-contraceptive ring that both entered safety clinical trials in 2017.

We know that products alone cannot change the course of an epidemic as complex as HIV/AIDS. Gender dynamics, cultural norms and socioeconomic factors are significant determinants of risk. Yet without a wider set of prevention tools, HIV will continue to threaten women's lives.

When one woman first enrolled in the Phase III dapivirine ring trials, she discovered that she could use the product discreetly and said, "That means I can use it without compromising." Women should never have to compromise on protecting their health. Together, we can empower women with more options so they won't have to.

A handwritten signature in black ink that reads "Zeda F. Rosenberg".

A handwritten signature in black ink that reads "James McIntyre".

Current prevention products are not doing enough for women. Every day, nearly 2,000 women, many of whom live in sub-Saharan Africa, become infected with HIV. Young women ages 15-24 in the region are more than twice as likely to acquire HIV as young men of the same age.

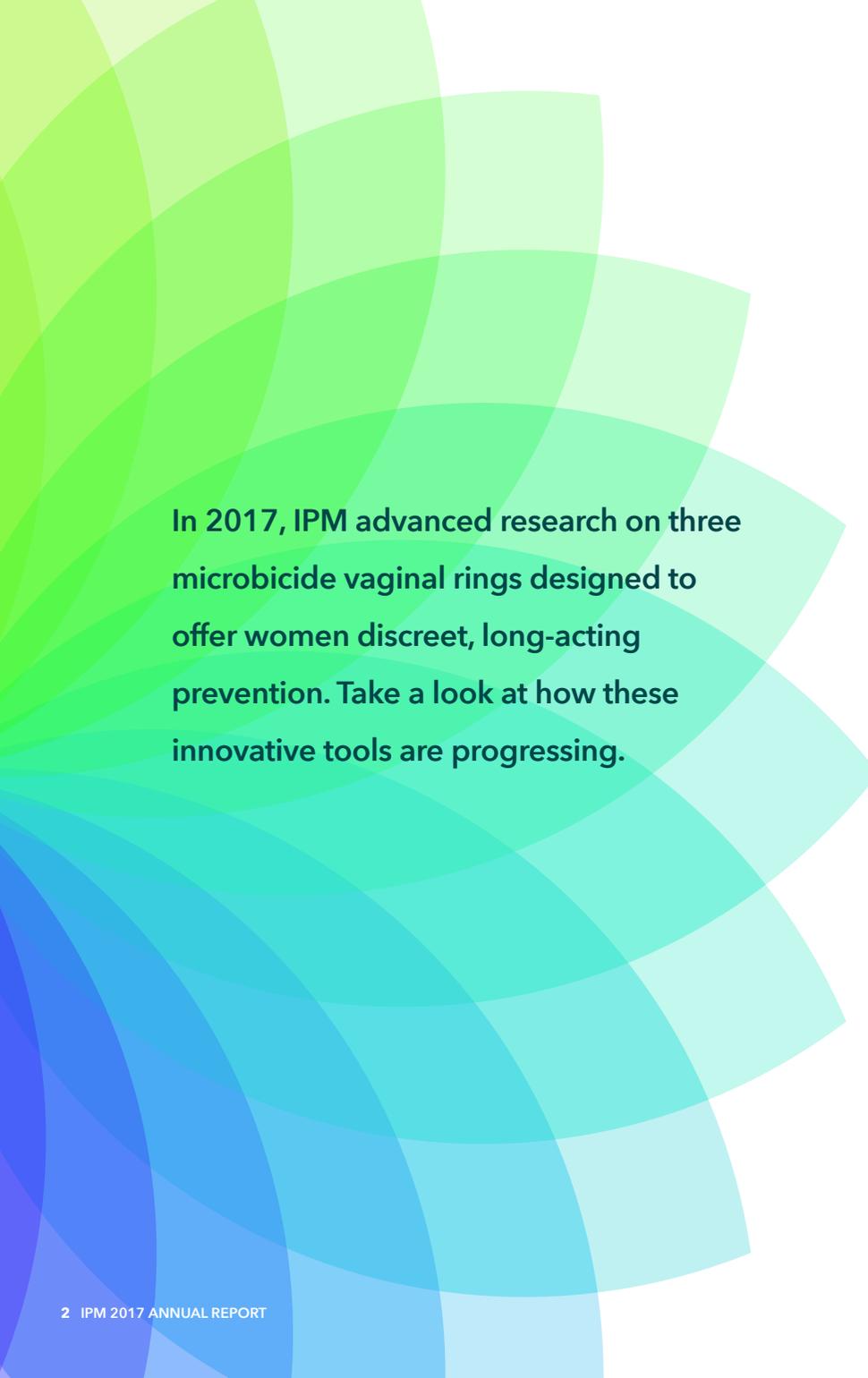
When HIV/AIDS threatens women's health, the well-being of their families and communities also suffer. But when women can protect their sexual and reproductive health, they can better care for their families, tap into educational and economic opportunities for themselves and their children, and pursue their dreams.

That is why IPM remains committed to developing woman-centered technologies that would expand women's prevention options and allow them to stay healthy on their own terms:

BECAUSE

- > women should be able to **choose a method** that meets their needs.
- > women deserve the chance to **live without fear of HIV.**
- > **healthy women are empowered women.**





In 2017, IPM advanced research on three microbicide vaginal rings designed to offer women discreet, long-acting prevention. Take a look at how these innovative tools are progressing.

Woman-centered prevention: Advancing the dapivirine ring

In 2016, a monthly vaginal ring containing the antiretroviral (ARV) drug dapivirine was found to reduce women's HIV risk in two Phase III clinical trials and to be well-tolerated. Women inserted the flexible silicone ring themselves and left it in place for a month. IPM developed the ring and is now leading public health and regulatory efforts to potentially obtain approval for the ring's use and roll out the product in countries where women face high HIV risk.

Strengthening the dapivirine ring evidence base

IPM and its partner, the US National Institutes of Health-funded Microbicide Trials Network (MTN), launched two open-label extension studies in 2016, called DREAM and HOPE, to provide the active ring for one year to former Phase III participants. The IPM-led DREAM and MTN-led HOPE studies are also assessing product adherence and collecting additional safety data.

In February 2018, IPM and MTN presented interim results for the DREAM and HOPE open-label studies at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. As of late 2017:

- Adherence had increased from approximately 80 percent across the Phase III trials to approximately 90 percent across both open-label studies.
- Data suggest that women's HIV risk is being reduced by approximately half in DREAM and HOPE compared to 30 percent in the Phase IIIs. (Because open-label studies do not have placebo groups for comparison, risk reduction was estimated using mathematical modeling.)
- The ring has been well-tolerated in the open-label studies.

Although the data have limitations, they suggest that when women know the ring reduced HIV risk in large clinical trials, they are more likely to use the product and see greater protection. These encouraging results are similar to the results of early open-label studies of oral pre-exposure prophylaxis, or PrEP, a daily pill to prevent HIV, which showed steady increases in adherence and HIV risk reduction compared to Phase III studies. PrEP has since been approved for use and implementation studies and market introduction efforts are under way across sub-Saharan Africa.

It is hoped that the improving adherence and risk reduction trends will continue for the ring as it did in open-label studies of PrEP. DREAM and HOPE will conclude at the end of 2018, with final results expected in 2019.



IPM's clinical research center partners, including the Desmond Tutu HIV Foundation in Masiphumelele, South Africa, are conducting an open-label study of the dapivirine ring to learn how the ring could fit into women's lives.

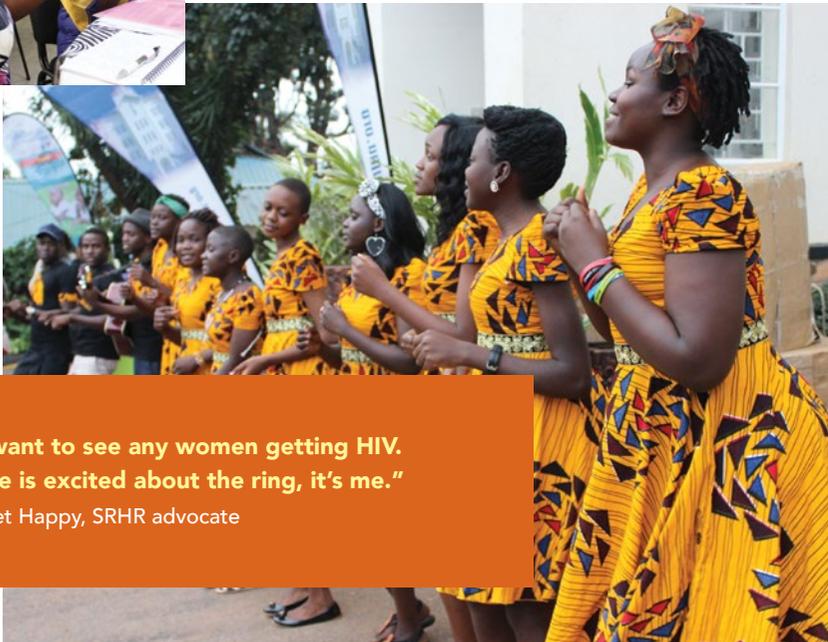


A staff member at the MatCH research center in Edendale, South Africa, demonstrates how to insert a vaginal ring at a journalist training on women's HIV prevention and microbicides.

Ring Use Among Young Women: The dapivirine ring is early on the path to potential introduction, and there is still more to learn about its safety and use, including among adolescent girls and young women. A joint IPM/MTN study among adolescent girls ages 15-17 in the US presented at the 2017 International AIDS Society Conference on HIV Science (IAS 2017) showed that the ring was well-tolerated, and the majority of girls liked the ring and found it easy to use. In addition, MTN, in partnership with IPM, plans to initiate the REACH study in early 2019 to assess adherence to and preferences for the monthly dapivirine ring

and daily oral PrEP among adolescent girls and young women in eastern and southern Africa. REACH will also look at the safety of both products in this high-risk population.

MTN and AVAC, in collaboration with IPM, met with young women, civil society, government representatives, researchers and advocates to gather feedback on the REACH study planned for early 2019 (Courtesy of MTN).



“ I don’t want to see any women getting HIV. If anyone is excited about the ring, it’s me.”

– Margaret Happy, SRHR advocate



Finding Solutions for New and Expecting Mothers:

Recent research suggests that women’s HIV risk is three times higher than normal during pregnancy and four times higher in the six months following birth, when some women are breastfeeding. Yet little research exists on the safety of HIV prevention products during these periods. IPM’s clinical program for the dapivirine ring aims to address this knowledge gap.

Ring Safety in Pregnant and Breastfeeding Women: Results of an IPM/MTN safety study among lactating women in the US, also presented at IAS 2017, found the ring to be well-tolerated, with low dapivirine levels in mothers’ breast milk and blood plasma, and low estimated drug uptake in infants. Based on those encouraging results, IPM and MTN are now planning safety studies among pregnant and breastfeeding women in four countries in Africa, expected to begin in 2019.

Pursuing regulatory approval for the dapivirine ring

Given women's urgent need for discreet, self-initiated HIV prevention options and the dapivirine ring's potential public health impact, IPM is pursuing regulatory approvals for the ring in countries in sub-Saharan Africa with high incidence rates among women.

In June 2017, IPM submitted a regulatory application to the European Medicines Agency (EMA) for the monthly ring under a procedure known as Article 58. That procedure assesses the quality, safety and efficacy of a medicine for high-priority diseases and provides a scientific opinion on the benefit-risk ratio for a medicine's use in low-income countries outside of the European Union, in cooperation with the World Health Organization (WHO).

Dapivirine ring application: By-the-numbers

The EMA submission was the culmination of intensive work assembling a comprehensive dossier of data on both the ring and dapivirine, a new chemical entity that has not undergone previous regulatory review.

250 studies incorporated
260,000 pages in electronic submission
1st regulatory application for a microbicide

A positive opinion from the EMA would facilitate a decision by the WHO on the ring's prequalification, a designation that many national regulatory authorities in Africa use to determine their own product approvals.

IPM's next regulatory steps include plans to submit applications to the South African Health Products Regulatory Authority in 2018, followed by the US Food and Drug Administration and other African regulators.



Access partnerships for potential ring introduction

Maximizing the ring's potential public health impact means ensuring its cost-effectiveness to country governments, and its affordability and availability to women. IPM is working with partners across multiple sectors to share resources and learn from market introduction efforts of other HIV prevention and biomedical products.

IPM continues to deepen its partnership with Johnson & Johnson (J&J), which granted IPM exclusive worldwide rights to dapivirine in 2014 through Janssen Sciences Ireland UC. This landmark agreement builds on the original royalty-free license IPM received from Janssen in 2004 to develop dapivirine as a microbicide. With the assistance of J&J product access experts, IPM refined its ring access strategy in 2017 and planned market research studies to inform future policy and education initiatives.



USAID's Center for Accelerating Innovation and Impact worked with IPM to gather insights from young women that could inform the ring's potential rollout.

In addition, IPM convened 12 experts from different countries and sectors in September 2017 for the first meeting of the Dapivirine Ring Access Advisory Committee. The multidisciplinary group is drawing on extensive product access experience in Africa to help ensure the ring's successful introduction where it is most urgently needed, if it is approved.



2017 Dapivirine Ring Access Advisory Committee Members

Georgina Caswell, MA, Chair
International HIV/AIDS Alliance, South Africa

Bob Mwiinga Munyati, MPH
AIDS Accountability International, South Africa

Diana Amanyire, MPH
Marie Stopes International, Uganda

Brian Ngwira, MBBS
Family Planning Association of Malawi, Malawi

Brenda Facy Azizuyo
International Community of Women Living with HIV, Uganda

Lebogang Ramafoko, MC/MPA
Soul City Institute, South Africa

Manju Chatani, MPH
AVAC, United States

Jens Van Roey, MD
Independent Consultant, Belgium

Frances Cowan, MD, MS, MBBS
Liverpool School of Tropical Medicine and Centre for Sexual Health and HIV/AIDS Research, Zimbabwe

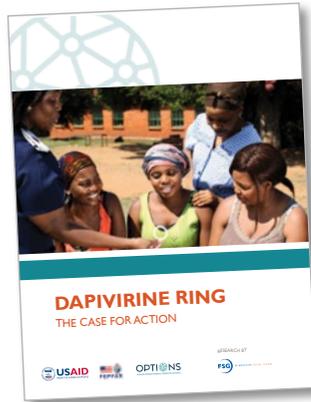
Daniel Were, PhD, MA
Jhpiego, Kenya

Maximina Jokonya
Africaid, Zimbabwe

Samantha Willan, MA
What Works to Prevent Violence Against Women and Girls Programme, South Africa

“ We must all join forces to support the world's young women.”

– Jaak Peeters, global head, Global Public Health, Johnson & Johnson



IPM is also partnering with the OPTIONS project, part of the USAID-funded Microbicide Product Introduction Initiative. In consultation with IPM, OPTIONS developed an investment case for the ring in 2017 to inform public health decision-making. IPM also worked with USAID's Center for Accelerating Innovation and Impact, which in 2017 published a human-centered design guide to encourage ring uptake and consistent use, especially among young women in sub-Saharan Africa. The guide includes insights and tools that can be adapted to design educational outreach and marketing strategies customized to the needs of different groups and contexts.

**Ngoba bathi AIDS ayilapheki,
soyinqoba ngeringi namhlanje yemicrobicides**

**Because they say AIDS is not treatable,
we will defeat it with microbicide ring**

– Song excerpt from DREAM study communities, in Zulu and English



Advancing next-generation microbicides

IPM's efforts to expand women's prevention options do not stop with the monthly dapivirine ring. Women have different needs that change and intersect throughout their lives. Using the monthly ring as a platform, IPM is prioritizing the development of next-generation vaginal rings that could offer women greater convenience and versatility.

A three-month dapivirine ring entered a first Phase I trial in 2017 to assess the ring's safety and pharmacokinetics among women in the US, with results expected in early 2019. This longer-acting ring would help reduce costs and minimize women's visits to a health facility to obtain the product.

Many women have expressed interest in a method that would give them long-acting control over HIV prevention and contraception in a single product. IPM's three-month dapivirine-contraceptive ring also entered a first Phase I trial in 2017, final results of which are expected in 2018. Given encouraging preliminary data, a second Phase I trial began in 2018. A multipurpose ring could have an important impact on the sexual and reproductive health for many of the 214 million women in developing countries who want but lack access to a modern family planning method, many of whom are also at high risk of HIV infection.

Pending study results and the potential rollout of the monthly dapivirine ring, IPM will determine the path forward for these longer-acting next-generation rings.

Empowering women through HIV prevention: Advancing the conversation

Broadening the range of women's sexual and reproductive health tools would not only support the United Nations' target to reduce new adult HIV infections by 90 percent, but also give women more opportunities to thrive, and contribute to the growth of their communities and societies. IPM is raising awareness about the connections between reducing HIV infections among women and global development among scientific, policymaking and general audiences alike—because everyone has a role to play in empowering women to stay healthy.

The intersections between women's empowerment, gender equality and health were featured in discussions at the **61st Commission on the Status of Women** in New York, where IPM organized an event highlighting how innovative HIV prevention technologies could advance young women's economic empowerment. Co-hosted by AVAC, USAID's Center for Accelerating Innovation and Impact, and Dalberg's Design Impact Group, attendees discussed how human-centered design could contribute to the successful introduction of HIV prevention technologies such as PrEP and the dapivirine ring, if it is approved, among young women and adolescent girls.

IPM also organized a satellite session at the **Southern African AIDS Conference** in June 2017 to provide updates on dapivirine ring research and foster discussion on HIV prevention product adherence among women and product options. IPM continued to spread the word about ring results and next steps throughout the year at **outreach events** such as youth and community awareness events in Africa and **meetings with advocates, civil society organizations and governments** in the US, Canada and Europe.



IPM and its global partners were recognized at the Innovation for Impact Awards for their pioneering work to develop the dapivirine vaginal ring.

IPM and the Population Council partnered in November 2017 to hold the first in a **series of webinars** exploring vaginal rings and their role in women's sexual and reproductive health. From multipurpose prevention to long-acting contraception, self-initiated vaginal rings could be important new tools for women.

IPM was honored to accept the Global Health Technologies Coalition's inaugural **Innovation for Impact Partnership Award** on behalf of the many partners that helped us develop and research the dapivirine ring. At the December 2017 awards ceremony, IPM joined representatives from Johnson & Johnson and USAID to discuss how different sectors came together to advance this innovative technology, and the need for continued collaboration to make the product available if it is approved.



IPM CEO Zeda Rosenberg met with Danish Parliament members at the UN High-Level Political Forum.

“Dual-purpose rings like this one, which give women control over their health in intersecting ways, are the leading edge of contraceptive technology. Imagine a world where we don't have to choose between 'good enough' options for staying healthy and planning our futures, because all our options are designed with our needs in mind.”

– Shannon Davis, Knowledge for Health Project



IPM held a variety of community events, including these soccer and netball tournaments, to continue raising awareness about HIV.



At the UN's Commission on the Status of Women, IPM event attendees discuss the links between HIV prevention, product innovation and young women's empowerment.



IPM Donors

2017 Donors

Bill & Melinda Gates Foundation

Ministry of Foreign Affairs of Denmark

Flanders Department of Foreign Affairs

**German Federal Ministry of Education and Research (BMBF)
through the KfW Development Bank**

Irish Aid, Department of Foreign Affairs and Trade

**Ministry of Foreign Affairs of the Netherlands through the
Netherlands Enterprise Agency**

United Kingdom Department for International Development

**United States Agency for International Development through
the United States President's Emergency Plan for AIDS Relief**

Previous Donors

Ackerman Family Foundation

Belgian Development Cooperation

Canadian International Development Agency

European Commission

Federal Ministry for Economic Cooperation and
Development, Germany

M•A•C AIDS Fund

Magee-Womens Research Institute and Foundation

Ministry for Foreign Affairs, Sweden

Ministry of Foreign Affairs and Cooperation, Spain

Ministry of Foreign Affairs, France

Norwegian Agency for Development Cooperation, Norwegian Ministry
of Foreign Affairs

OPEC Fund for International Development, the development finance
institution of OPEC Member States

Rockefeller Foundation

Swedish International Development Agency

United Nations Population Fund

World Bank

2017 Board of Directors

James McIntyre, MBChB, Chair
Anova Health Institute, South Africa

Ayo Ajayi, MD, MPH
Independent Consultant, United States

Pamela W. Barnes, MBA
Independent Consultant, United States

Bruce Burlington, MD, Finance Committee member
Independent Consultant, United States

Alex Coutinho, MBChB, MPH, MSc, DTM&H
Partners in Health, Rwanda

Florence Houn, MD, MPH
Celgene Corporation, United States

Tamar Howson, MS, MBA, Finance Committee member
Independent Consultant, United States

Maureen Luba Milambe
Centre for the Development of People/Malawi Network of People Living with HIV, Malawi

Lebogang Motsumi
HIV Activist, Coach and Speaker, South Africa

Ndola Prata, MD, MSc
University of California, Berkeley School of Public Health, United States

Zeda F. Rosenberg, ScD
IPM, United States

Michael Stevens, Finance Committee Chair
Independent Consultant, United Kingdom

Heidemarie Wiczorek-Zeul
Former Member of Parliament, German Bundestag, Germany

2017 Scientific Advisory Board

Robin Shattock, PhD, Chair
Imperial College London, United Kingdom

David R. Friend, PhD
Daré Bioscience, United States

Sharon Hillier, PhD
Magee-Womens Hospital, University of Pittsburgh School of Medicine, United States

Ruth B. Mer Katz, PhD, RN, FAAN
Population Council, United States

Thomas Moench, MD
ReProtect, Inc., United States

Beth Romach, PhD
ViiV Healthcare, United States

Doug Taylor, PhD
FHI 360, United States

Jim A. Turpin, PhD
National Institute of Allergy and Infectious Diseases, National Institutes of Health, United States

Lut Van Damme, PhD, MD
Bill & Melinda Gates Foundation, United States

Jens Van Roey, MD
Independent Consultant, Belgium

IPM Leadership

Zeda F. Rosenberg, ScD
Founder and Chief Executive Officer

Mike Goldrich, MBA
President and Chief Operating Officer

Brid Devlin, PhD
Executive Vice President, Product Development

Kathy Flynn, MBA
Chief Financial Officer

Patricia R. Mayer, PhD
Executive Vice President, Regulatory Affairs

Annalene Nel, MD, PhD
Executive Vice President, Chief Medical Officer, Clinical Programs

2017 Financial Considerations

IPM's cash, cash equivalents and short-term investments as of Dec. 31, 2017, totaled USD 12 million. In 2017, IPM advanced three major programs:

- **Providing support to clinical research center partners and leading clinical activities to conduct DREAM**, an open-label extension study that launched in July 2016 to provide the monthly dapivirine ring to former Ring Study participants and to learn more about how to support ring adherence. IPM also engaged in chemistry, manufacturing and control activities to support the regulatory filing to the EMA and prepare for the scale-up needed to introduce the ring, if it is approved.
- **Conducting regulatory activities to seek approval for the dapivirine ring's use in African countries where women face high HIV risk.** IPM submitted an application to the EMA under Article 58 in June 2017, and currently plans to submit applications to SAHPRA in late 2018, followed by the FDA in 2019.
- **Advancing next-generation products in IPM's pipeline.** In 2017, IPM initiated the first clinical trial of a three-month dapivirine ring and the first clinical trial of a three-month dapivirine-contraceptive ring. These innovative technologies would expand women's options for self-initiated, long-acting prevention.

In 2017, IPM received support from donors including the Ministry of Foreign Affairs of Denmark, the Flanders Department of Foreign Affairs, the German Federal Ministry of Education and Research, Irish Aid, the Ministry of Foreign Affairs of the Netherlands, DFID, USAID and the Bill & Melinda Gates Foundation. IPM received approximately USD 37.2 million (cash receipts) in 2017.

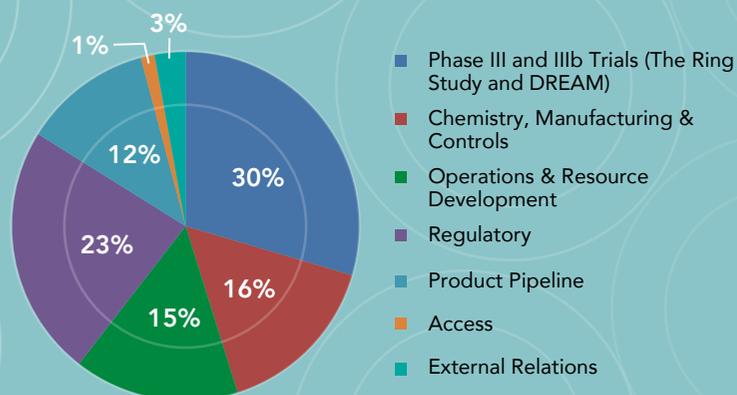
IPM's 2017 financial audits continue a history of full compliance with all financial reporting requirements from all US and international government and private donors. In 2017, IPM again received an unqualified, or clean, audit opinion across its South Africa, US and Belgium offices.

IPM's Board of Directors, management team and staff remain dedicated to efficiently and effectively delivering on our mission to develop HIV prevention and other sexual and reproductive health technologies for women, and to make them available and accessible where they are urgently needed. Given the consistently high rates of new HIV infections among women and girls, especially in sub-Saharan Africa, woman-centered technologies like the dapivirine ring could be a valuable addition to the suite of HIV prevention options. Continued financial support for IPM's work is essential to capitalizing on the promise of microbicides for women's health, and we continue to advocate for increased funds from existing donors and to pursue new funding sources.

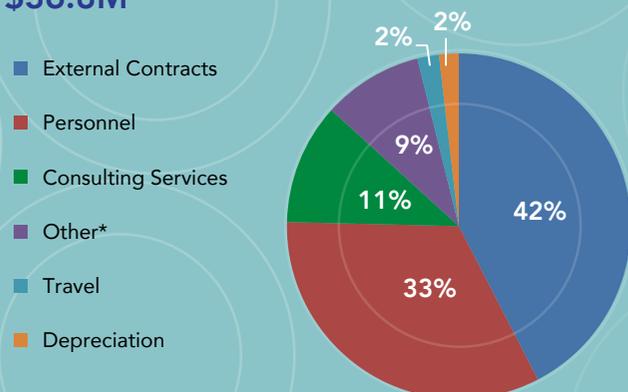
“ Simply put, girls and women are the keys that will unlock sustainable development. They are also at the center of the healthier and more resilient societies we desire.

– Tedros Adhanom Ghebreyesus, director-general, World Health Organization

2017 Expenditures By Activity \$36.8M



2017 Expenditures by Functional Category \$36.8M



* Includes rent, internet/phone, clinical trial insurance, legal fees, audit fees, regulatory fees and miscellaneous.

Statement of Financial Position

December 31, 2017

Assets

Cash and cash equivalents	\$11,761,856
Investments, at fair value	247,161
Grants and accounts receivables	6,653,755
Prepaid expenditures and other assets	692,463
Property and equipment, net	3,694,037

Total assets **\$23,049,272**

Liabilities and net assets

Liabilities

Accounts payable and accrued expenditures	\$3,910,213
Accrued payroll liabilities	649,752
Grant advances and deferred revenue	4,415,411
Deferred rent liability	813,490

Total liabilities **\$9,788,866**

Commitments and contingencies

Net assets:

Without donor restrictions	13,260,406
----------------------------	------------

Total liabilities and net assets **\$23,049,272**



**INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES**

IPM Headquarters

8405 Colesville Road
Suite 600
Silver Spring, MD 20910 USA
Tel: +1-301-608-2221
Fax: +1-301-608-2241

IPM South Africa

63 Main Road
Paarl 7646, South Africa
P.O. Box 3460
Tel: +27-21-860-2300
Fax: +27-21-860-3208/1000

IPM Belgium AISBL

Square de Meeûs 38/40
B1000 Brussels
Belgium



www.IPMglobal.org



Follow us on Twitter
at @IPMicrobicides