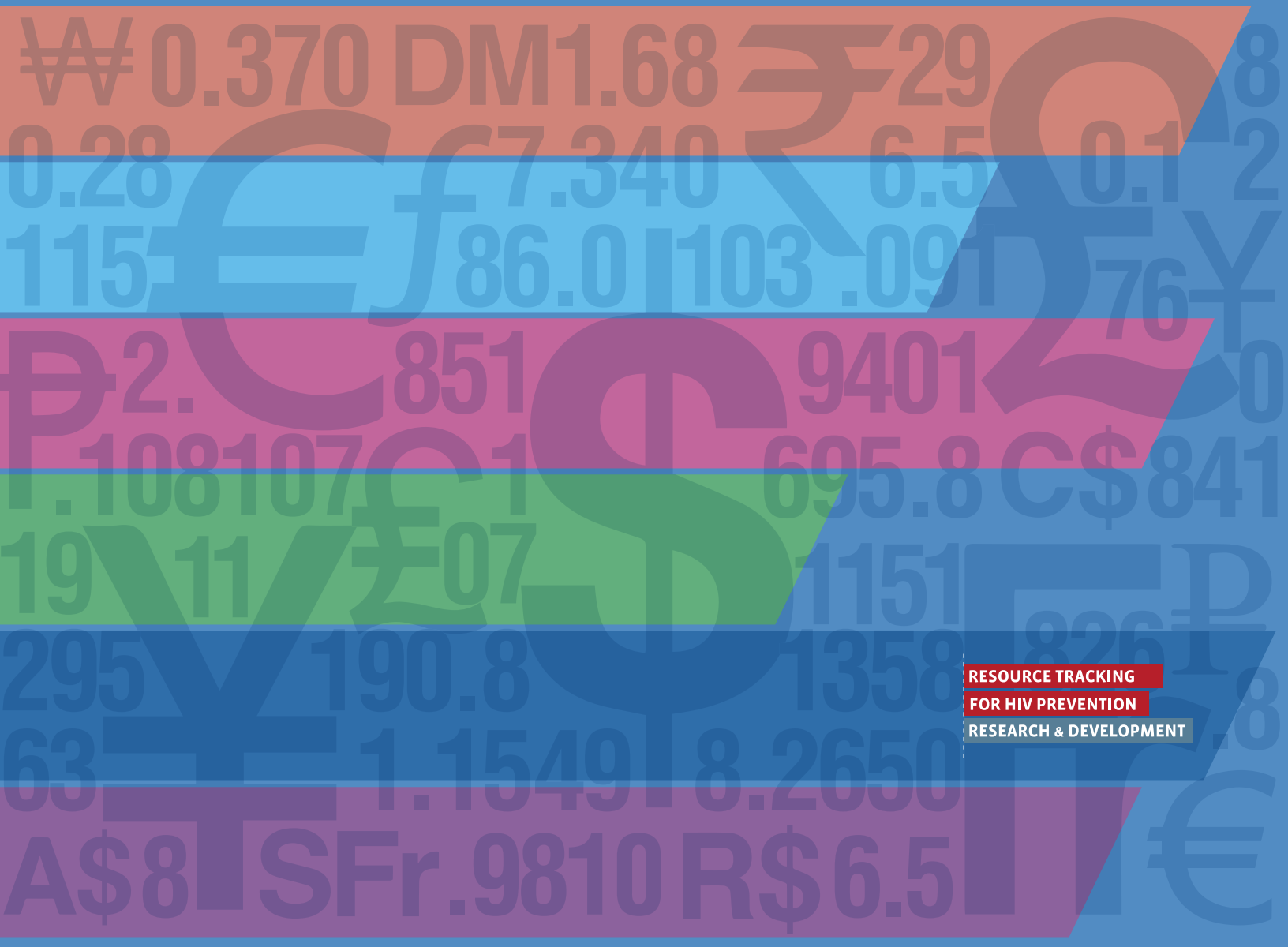
HIV Prevention Research & Development Investments 2017

Investing to End the Epidemic



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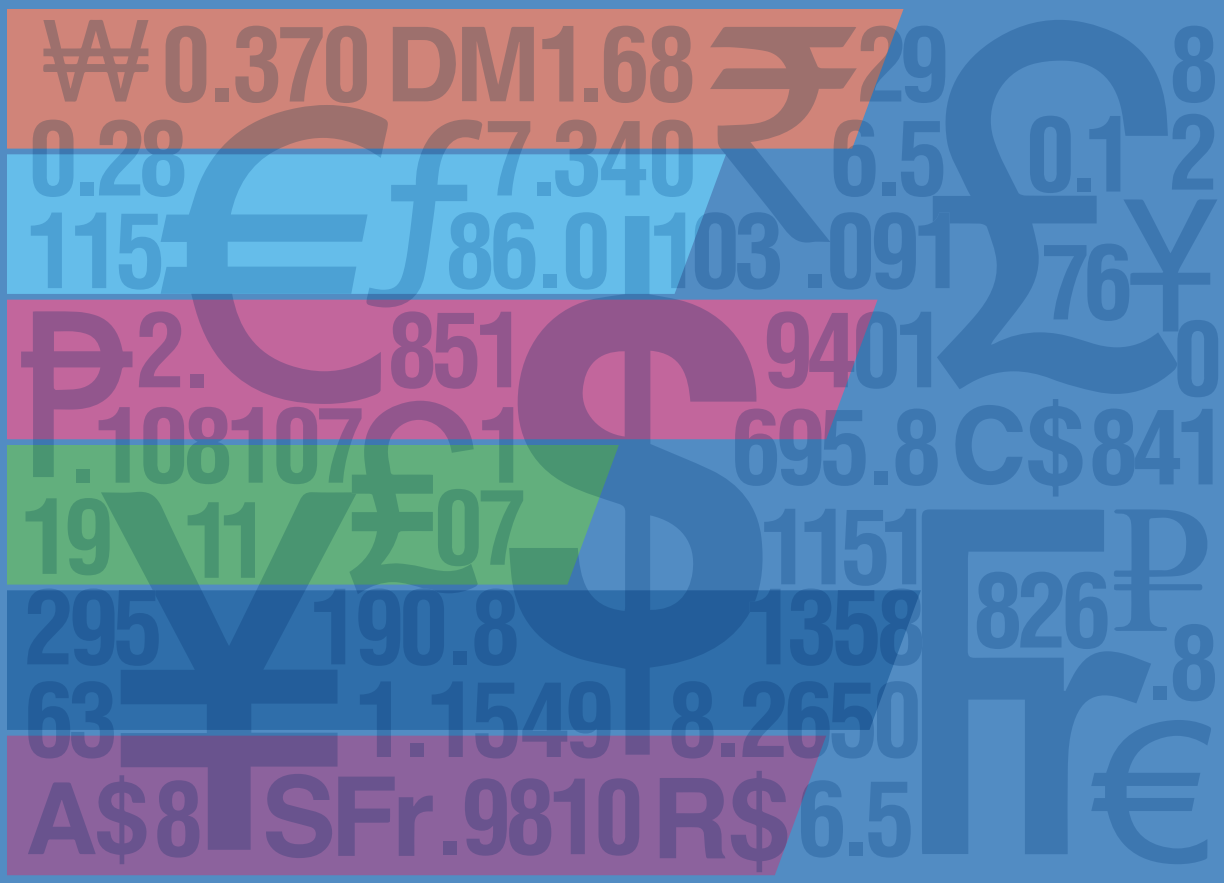
Investing to End the Epidemic



Resource Tracking for HIV Prevention Research & Development

OCTOBER 2018

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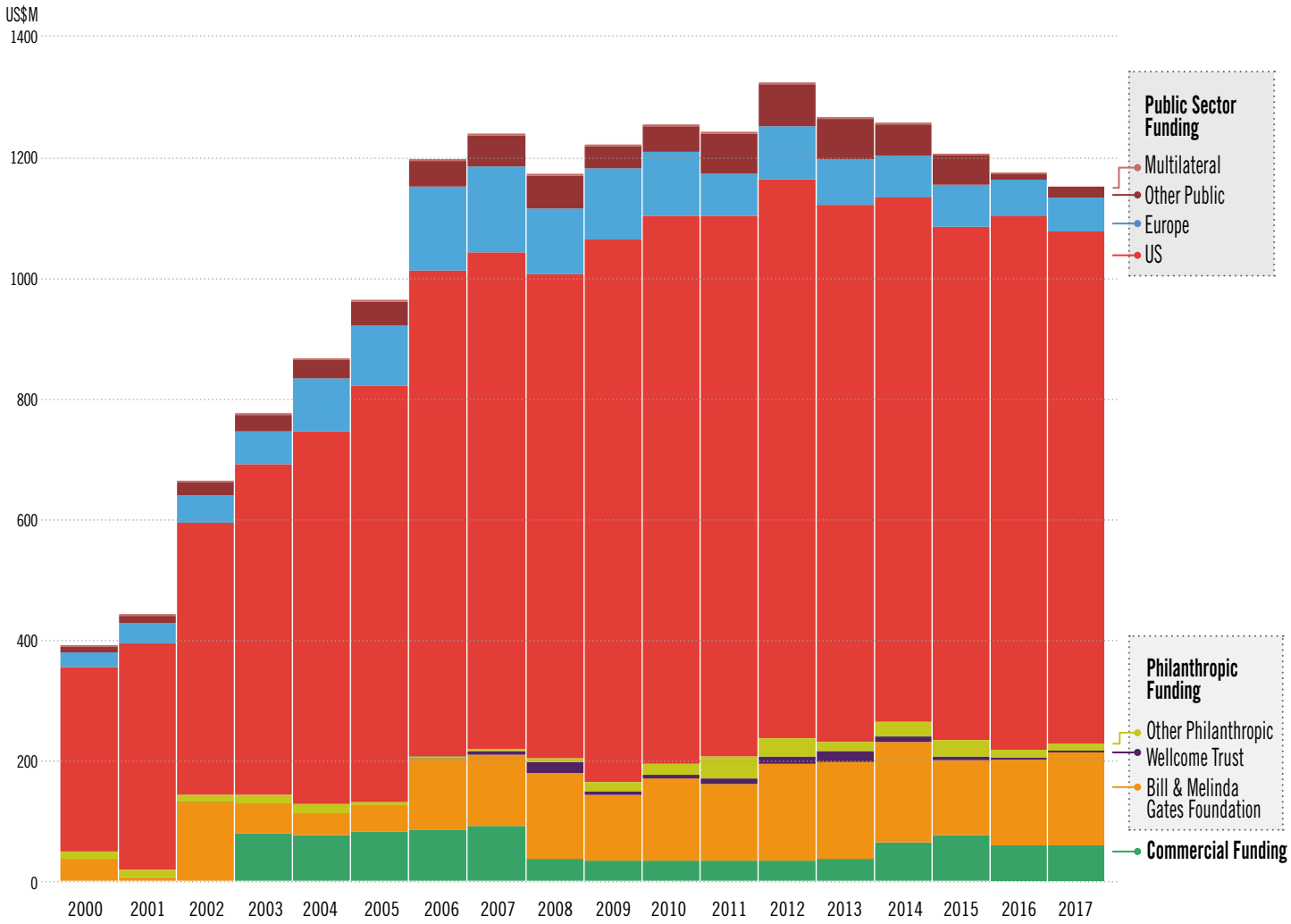
Introduction

In its 14th annual report, the Resource Tracking for HIV Prevention Research & Development Working Group ("Working Group") documents research and development spending for the calendar year 2017 and analyzes funding trends spanning seventeen years.

Since 2004, the Working Group has employed a standardized and comprehensive methodology to generate HIV prevention research and development (R&D[1]) estimates, and to track investment trends for biomedical HIV prevention options, including AIDS vaccines, microbicides, pre-exposure prophylaxis (PrEP), treatment as prevention (TasP), voluntary medical male circumcision (VMMC), female condoms, prevention of vertical transmission (PMTCT) and multipurpose prevention technologies. The Working Group also tracks expenditures in HIV cure and therapeutic AIDS vaccine research[2].

By generating investment estimates that can be compared from year to year and across prevention options, funding sources and strategies, the Working Group helps assess the impact of relevant public policies and marshals data for use in advocacy. The over-US$18 billion tracked by the Group to date has also enhanced transparency for funders, HIV/AIDS advocates and policy makers, and has aided in their understanding of global investment flows and trends *(Figure 1)*.

FIGURE 1 **Global Funding Sources for HIV Prevention R&D, 2000-2017** (US$ millions)

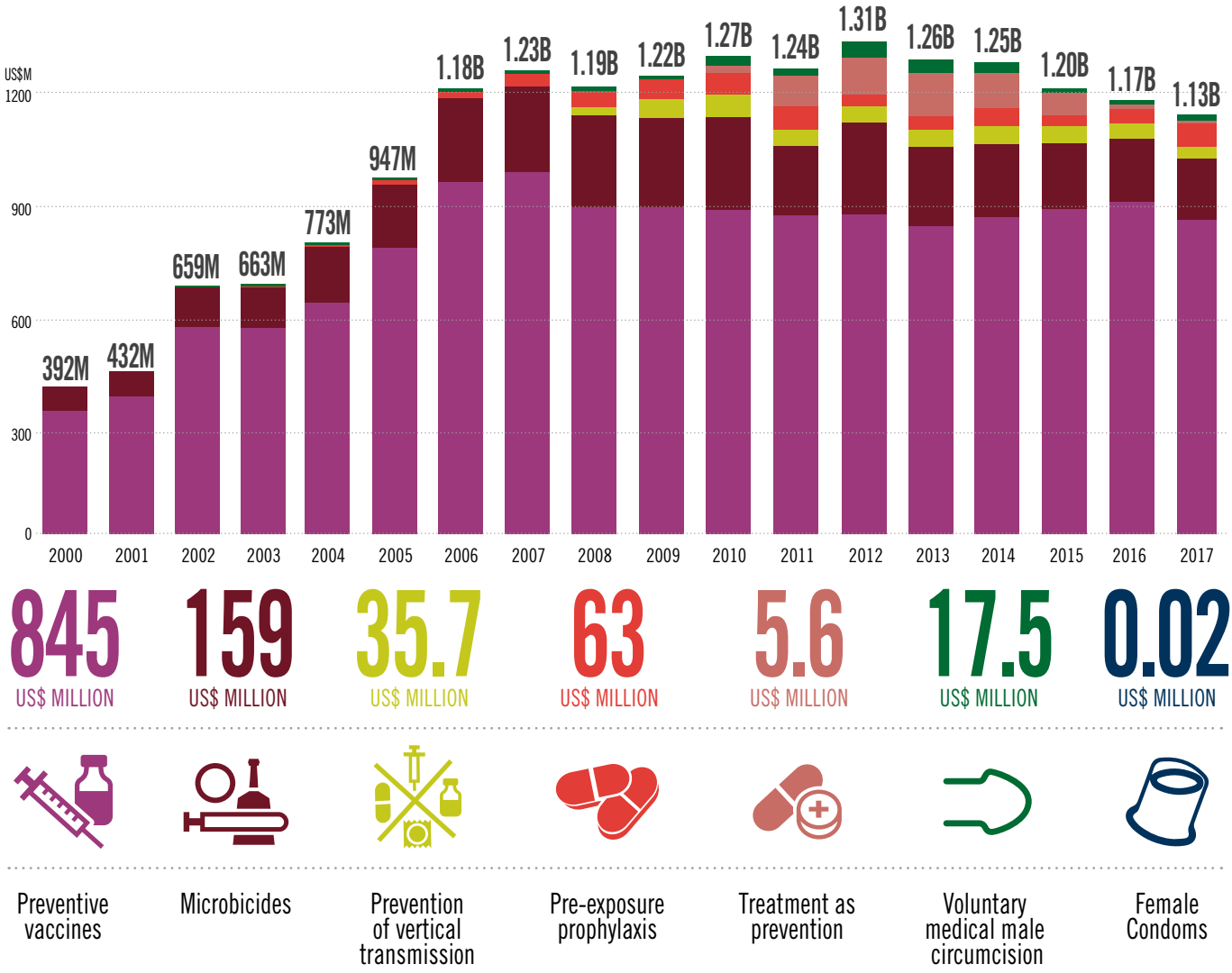


Trends in HIV Prevention Research and Development (R&D)

In July of 2018, UNAIDS released its *Global AIDS Update*. The "Miles to go..." report highlighted both a "prevention crisis" and a broader "funding crisis" impeding the global AIDS response. *Emblematic of the lack of political commitment and funding for primary prevention, incidence rates have increased in around 50 countries, and new HIV infections are not decreasing rapidly enough to meet the prevention Fast-Track milestone by 2020*[3]. Compounding the insufficient scale-up of prevention services is the declining funding for the global AIDS response, with no significant new donor commitments.

The end of AIDS as a global public health threat aims at significant reductions in the annual new HIV infections and AIDS related deaths, but the elimination of HIV is not feasible with the existing technologies. Getting to zero new infections will not only require the expansion of existing options like VMMC and PrEP but also the development of innovative new products capable of complementing current treatment efforts by preventing HIV infection. Hence, the significance of tracking the levels and trends of funding for HIV prevention R&D.

FIGURE 2 **Global HIV Prevention R&D Investment by Technology Category, 2000-2017** (US$ millions)



[a] Tracking funding for female condom and treatment as prevention research began in 2010

[b] Tracking funding for prevention of vertical transmission began in 2008

[c] Tracking funding for pre-exposure prophylaxis began in 2002

[d] Tracking funding for medical male circumcision began in 2001

FIGURE 3 **Total Global HIV Prevention R&D Investment by Prevention Option, 2016-2017**

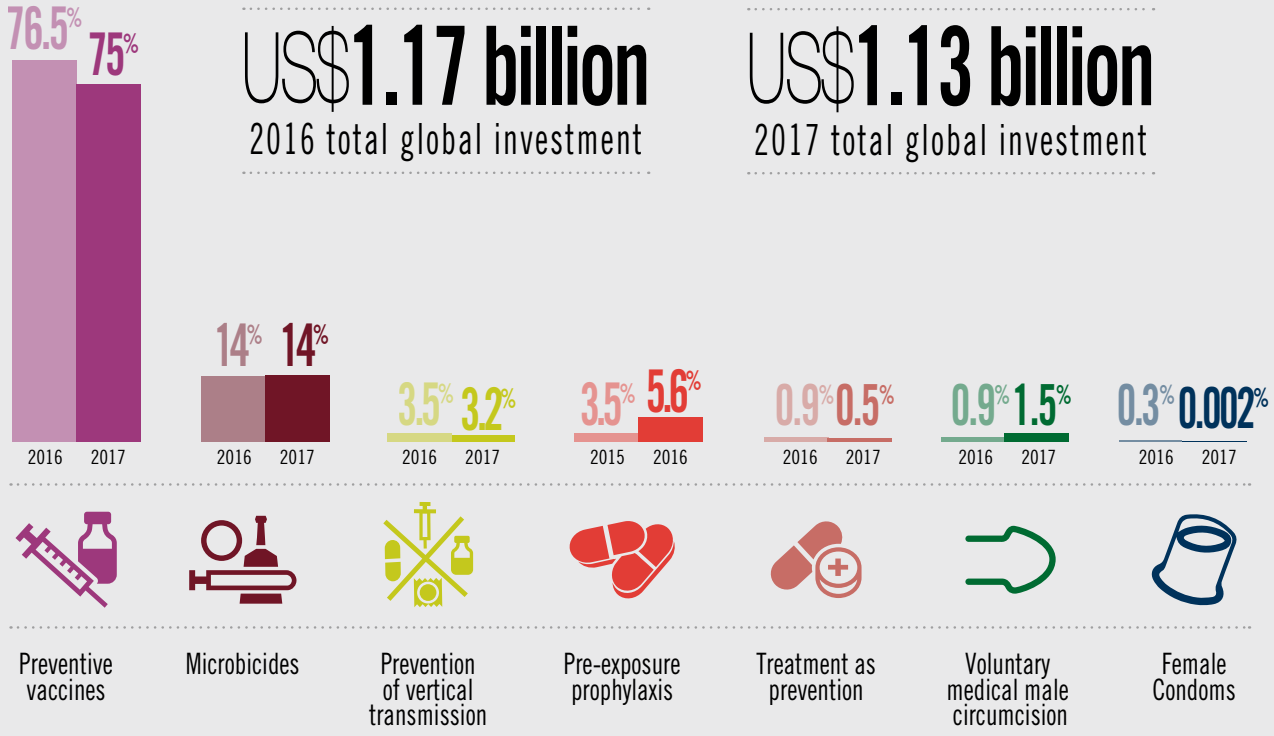
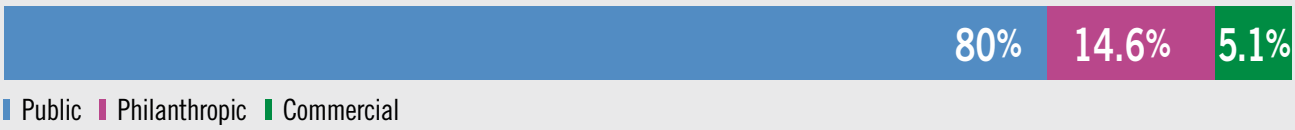
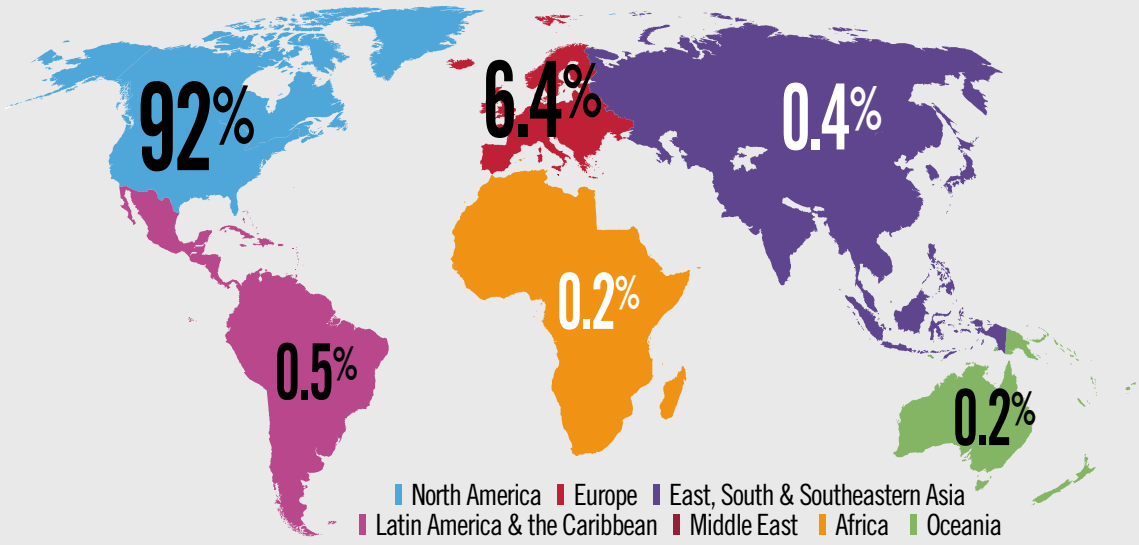


FIGURE 4 **Total Global HIV Prevention R&D Investment by Sector & Region, 2017**

2017 HIV prevention R&D investments by sector



2017 public sector investments by region



- In 2017, reported funding for HIV prevention R&D decreased by 3.5 percent (US$40 million) from the previous year, falling to US$1.13 billion *(Figure 2)*. *This is the fifth consecutive year of decreasing annual investment, with 2017 levels representing the lowest funding since 2005.* There was variation in investment by technology category: R&D funding increased for PrEP and VMMC, while preventive vaccines, microbicides, PMTCT, female condoms and TasP saw a decline from the previous year *(Figure 3)*.
- While public funding continued to be the predominant sector (funding 80 percent of total investment or US$905 million), overall levels dropped by five percent from 2016. The US made up the bulk of public sector funding at US$830 million (92 percent), while the European region came in second at US$58 million (6.4 percent). Other

FIGURE 5A **US Public Sector Investments in HIV Prevention R&D, Compared to All Other Funding, 2013-2017** (US$ billions)

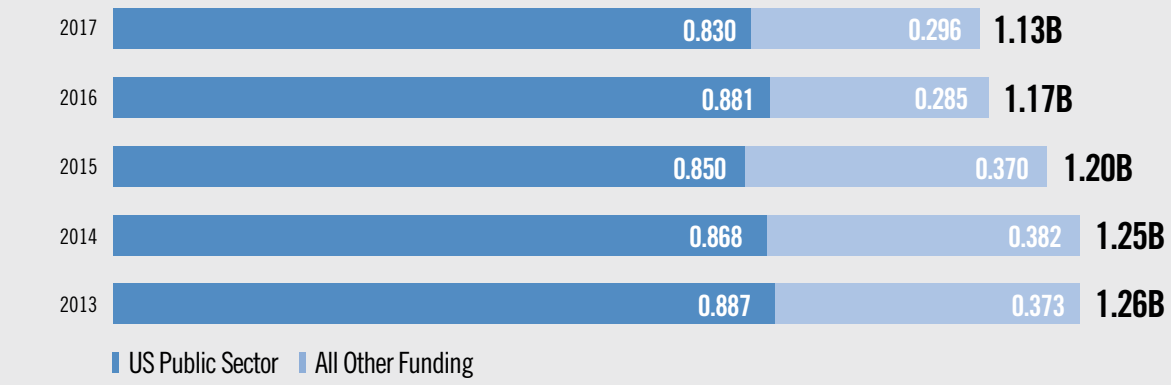
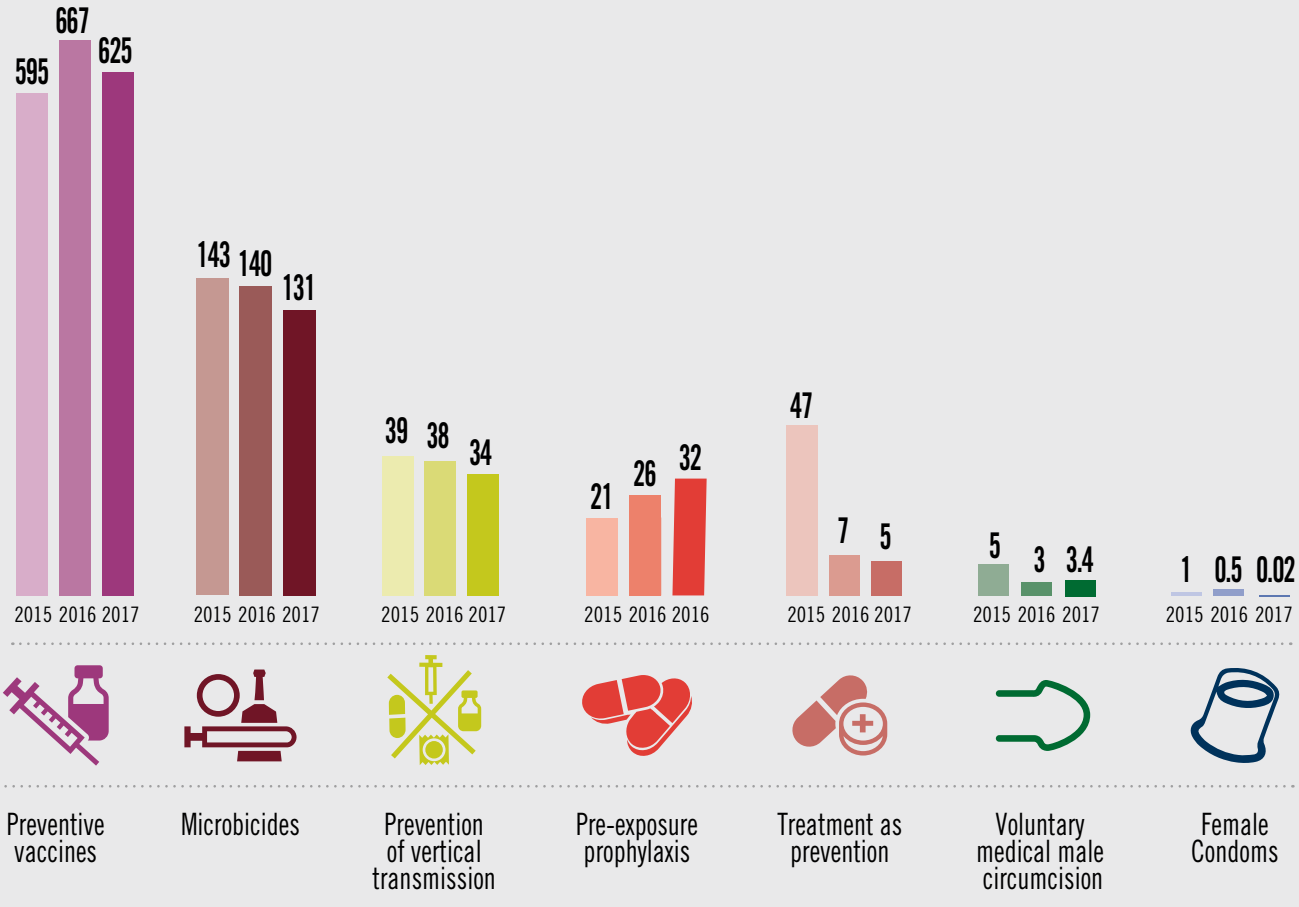


FIGURE 5B **US Public Sector Investments in HIV Prevention R&D, by Technology, 2015-2017** (US$ millions)



countries contributed US$16.4 million, which constituted 1.8 percent of cumulative public sector funding. Philanthropic investment increased by 14.6 percent to US$164 million, while private sector funding increased slightly by 1.2 percent, to a value of US$57 million *(Figure 4)*.

- US public sector investment decreased by 5.8 percent in 2017, falling from US$881 million to US$830 million *(Figure 5A)*. Declining US investment in 2017 was largely attributed to the 6.5 percent (US$49 million) decrease in funding from the National Institutes of Health (NIH). The Centers for Disease Control and Prevention (CDC) also had a notable 13 percent decrease in investment, from US$11.3 million in 2016 to US$9.9 million in 2017. While US public investment for PrEP and VMMC increased by 21 percent and 19 percent, respectively, contributions to all other prevention options declined *(Figure 5B)*.

FIGURE 6A **European Public Sector Investments in HIV Prevention R&D, Compared to All Other Funding, 2013-2017** (US$ billions)

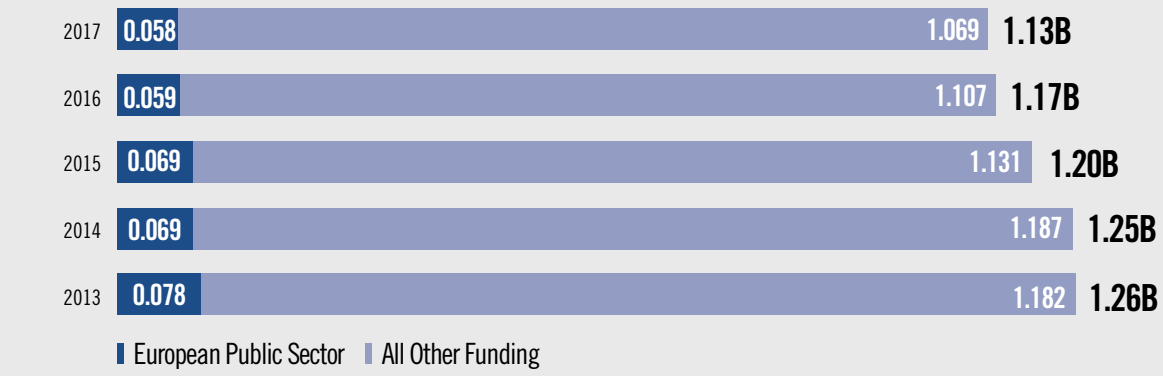
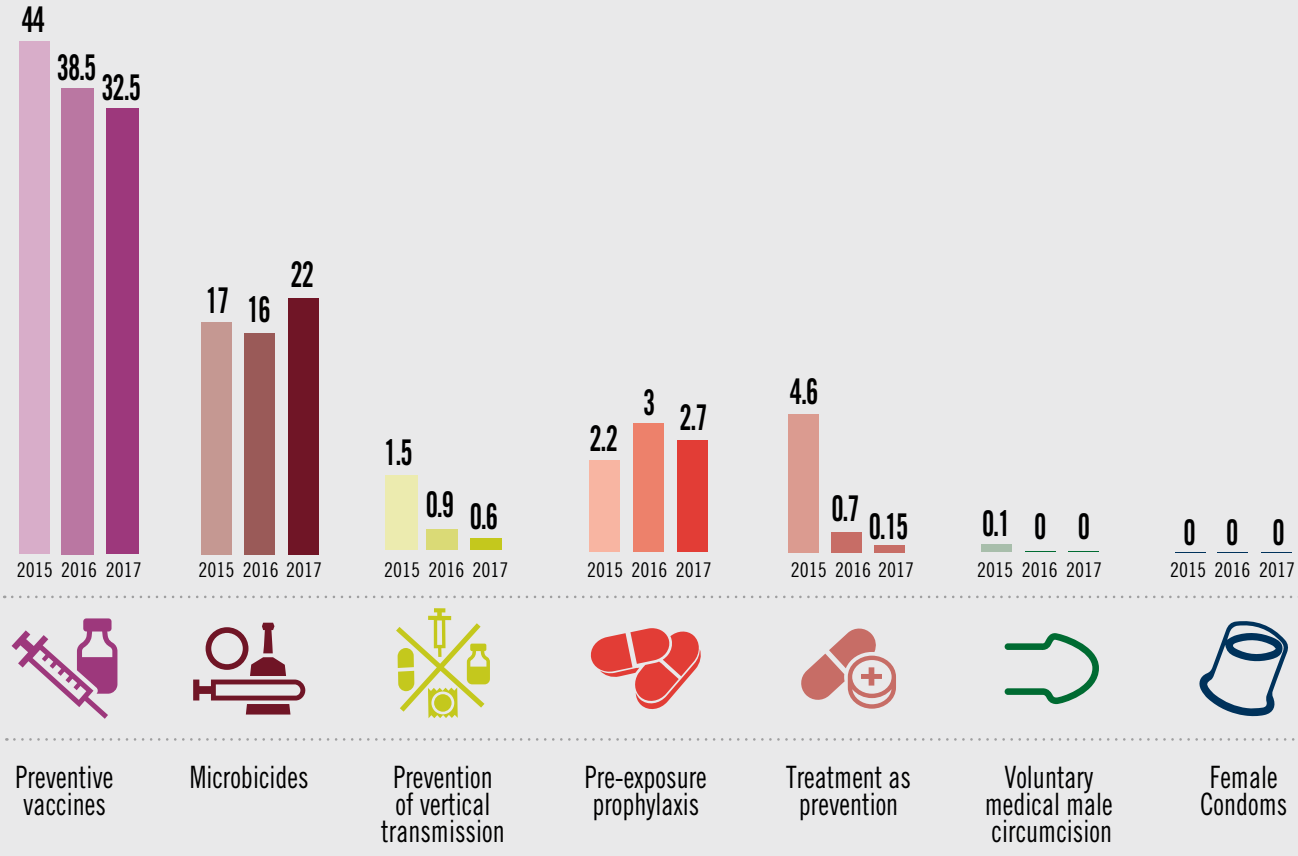


FIGURE 6B **European Public Sector Investments in HIV Prevention R&D, by Technology, 2015-2017** (US$ millions)



- The European public sector contributed US$58 million in 2017, a two percent decrease from the previous year and the lowest funding observed in a decade *(Figure 6A)*. Despite this, European funding made up a larger proportion of overall public-sector funding (6.4 percent in 2017 versus six percent in 2016). Excluding microbicides, European investment in all other prevention options decreased in 2017 *(Figure 6B)*.
- Global philanthropic funding increased by 4.1 percent from 2016 levels and amounted to US$164 million, or 14.6 percent of overall funding *(Figure 7A)*. The Bill and Melinda Gates Foundation (BMGF) remained the largest funder and increased its contribution by 6.6 percent, to US$150.2 million. Wellcome Trust investment fell for the fifth consecutive year to an annual US$2 million *(Figure 7B)*.

FIGURE 7A **Investment in HIV Prevention R&D by Top Philanthropic Funders in 2017** (US$ millions)

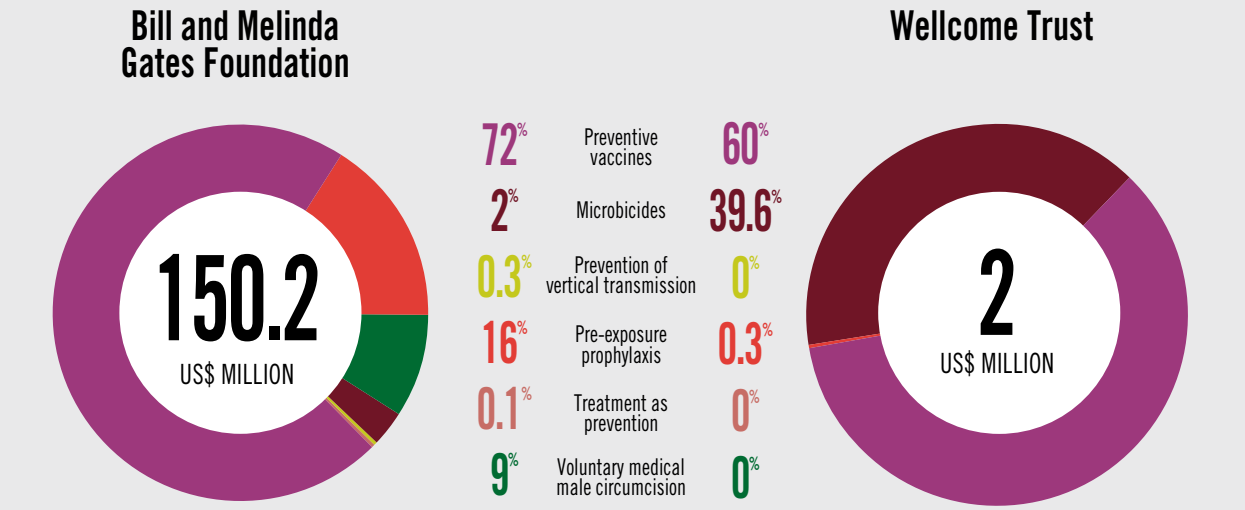
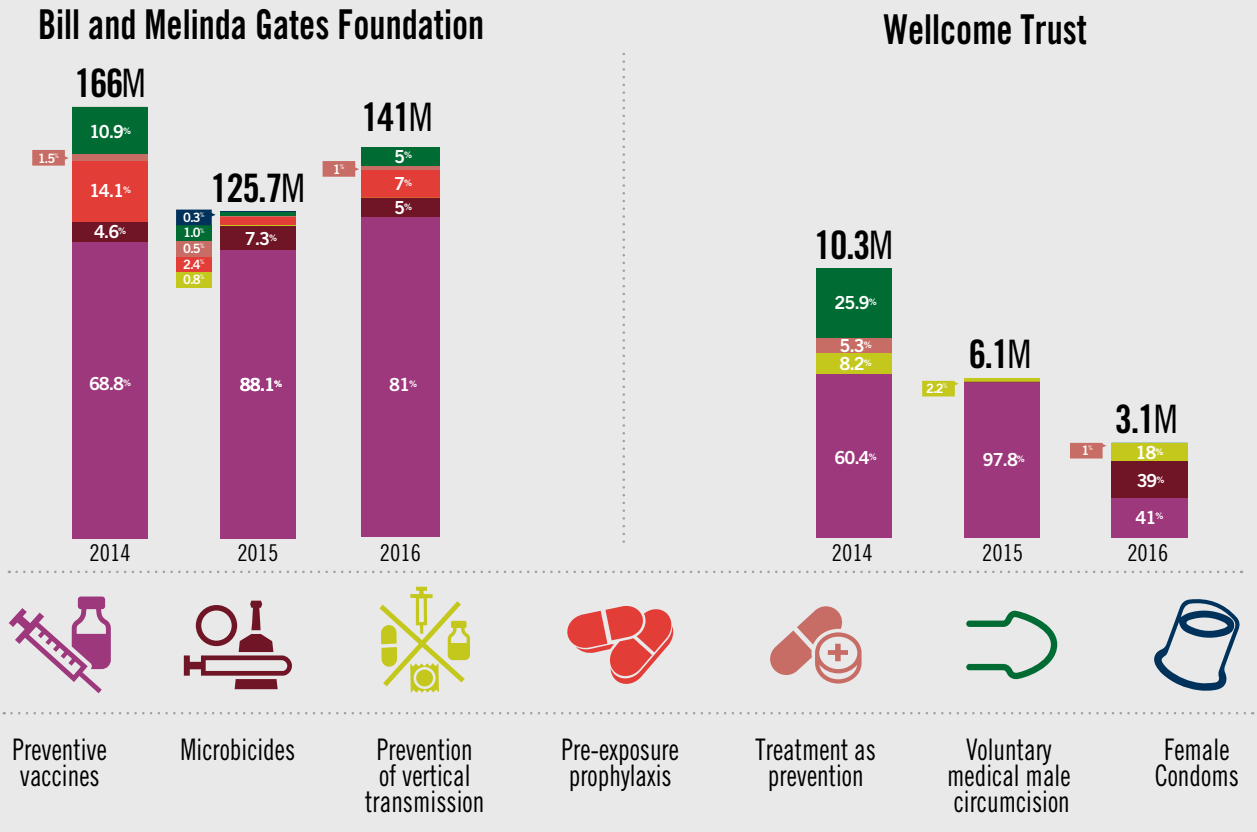


FIGURE 7B **Investments in HIV Prevention R&D by Top Philanthropic Funders, 2014-2016** (US$ millions)



Key Findings

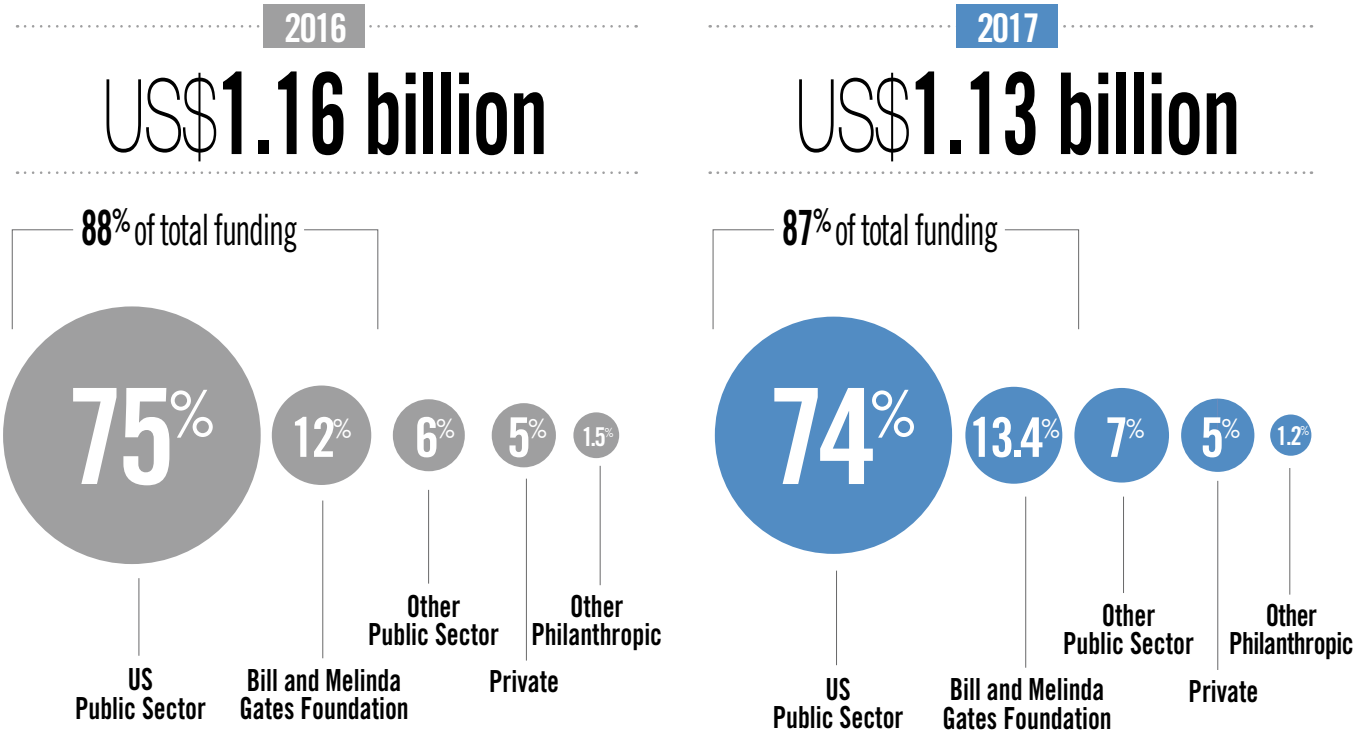
Dominant funders and their field-wide influence

In 2017, the previous years' trend of funding being concentrated in a small number of large investors has endured. The US public sector contributed almost three-fourths of all global funding (US$830 million out of US$1.13 billion), while the BMGF remained the principal philanthropic donor, accounting for 91 percent (US$150.2 million out of US$164 million) of all sector investment. Combined, investments by the two leading donors were valued at almost a billion dollars and accounted for 87 percent of overall funding, a marginal decrease from 2016 levels *(Figure 8)*.

In drawing attention to the funding imbalance within the HIV prevention R&D landscape, this report has frequently cautioned against the disproportionate impact of shifting donor priorities on cutting-edge research. *Predictably, 85 percent of the US$50 million decrease in vaccine R&D in 2017 can be traced back to a reduction in US public-sector investment.* Similarly, the 67 percent increase in VMMC funding in 2017 is due largely to enhanced investment from BMGF, which makes up 79 percent of all VMMC funding. Investment in female condom research decreased by 99 percent in 2017, as the leading donor, the Female Health Company, made no commitments.

Diversifying the funding base is vital not only for the long-term sustainability of the field, but also to ensure that decades of gains made in scientific innovation and billions of dollars spent are not lost to shifting donor priorities.

FIGURE 8 **Composition of the Global HIV Prevention R&D Investment Base, 2016-2017**



* *Other public sector* includes funding outside the US public sector;
other philanthropic includes funding outside the Bill and Melinda Gates Foundation

Emerging players outside of the US public sector

Funding outside the US public sector totaled US$71 million in 2016, with 16 countries accounting for six percent of the overall funding for that calendar year. This number increased to US$74 million in 2017, and the 15 contributing countries represented seven percent of overall funding. Prominent increases came from Canada (from US$2.6M to US$5M), Brazil (from US$0.19M to US$4M) and the Netherlands (from US$8.6M to US$11.2M) *(Figure 9)*. Investment by Australia and Japan increased by 2.4 percent and 37 percent, respectively, in 2017, while funding from France remained unchanged from 2016 levels *(Figure 10)*. The big decrease outside the US public sector came from the European Commission, with funding levels dropping by 47 percent, from US$14.4 million in 2016 to US$7.6 million in 2017.

FIGURE 9 **Top Countries Investing in HIV Prevention R&D, 2016-2017** (US$ millions)

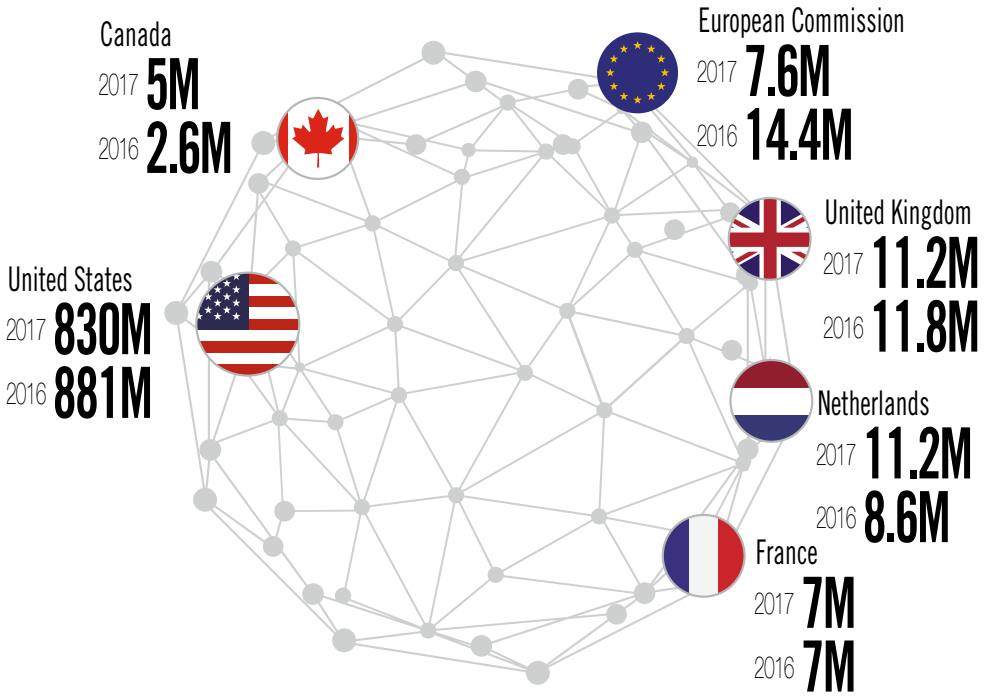
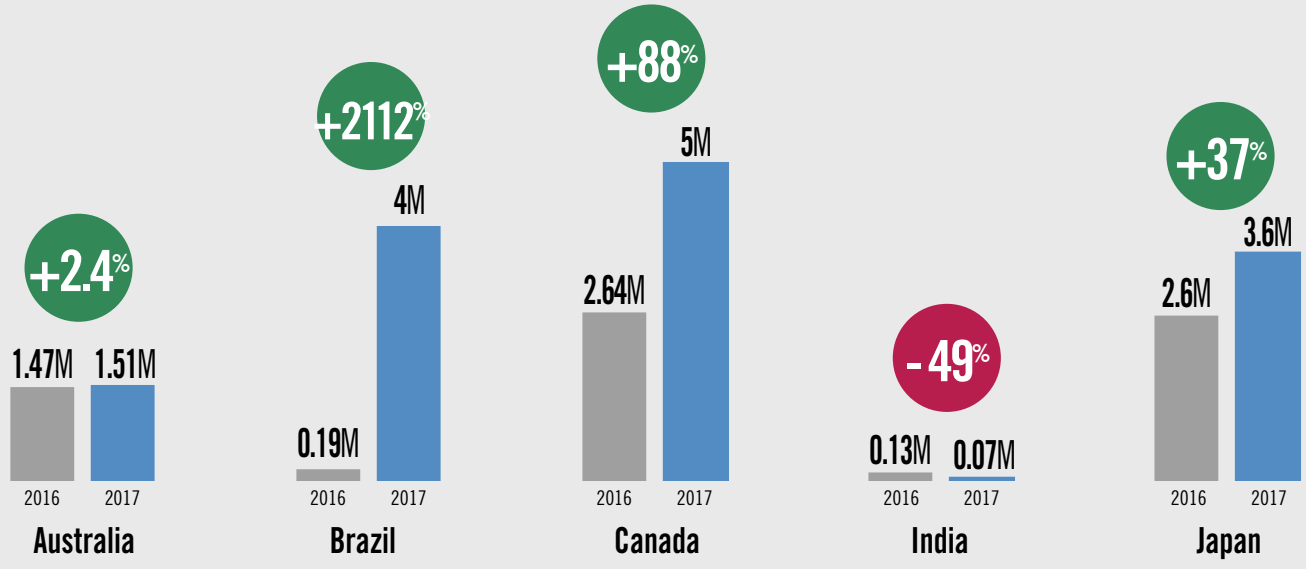


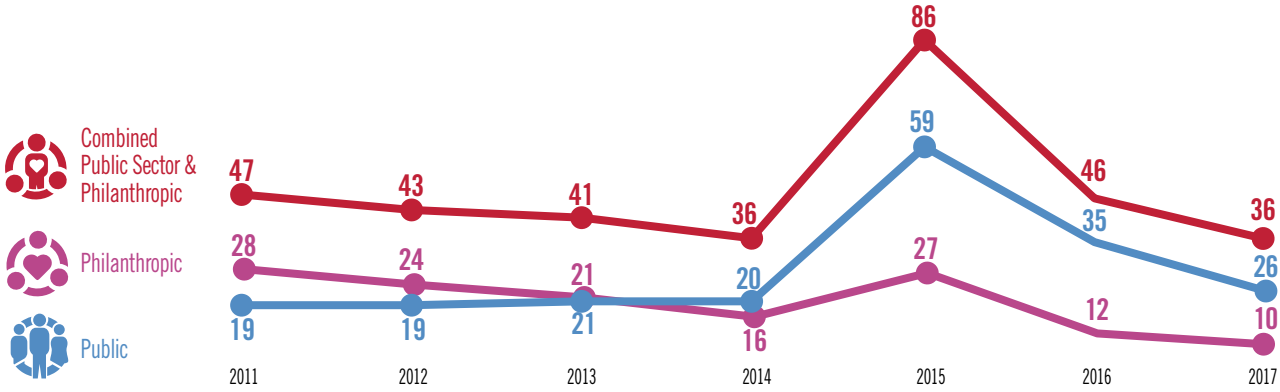
FIGURE 10 **Changes in Public Sector Investment Outside the US and Europe, 2016-2017** (US$ millions)



Decrease in the number of philanthropic funders engaged

Philanthropic funding increased by 4.1 percent in 2017, a statistic that masks the decreasing number of philanthropies being consistently engaged in HIV prevention research. In what is now a continuous trend since 2010, the number of philanthropic funders decreased from 12 to 10 in 2017 *(Figure 11)*.

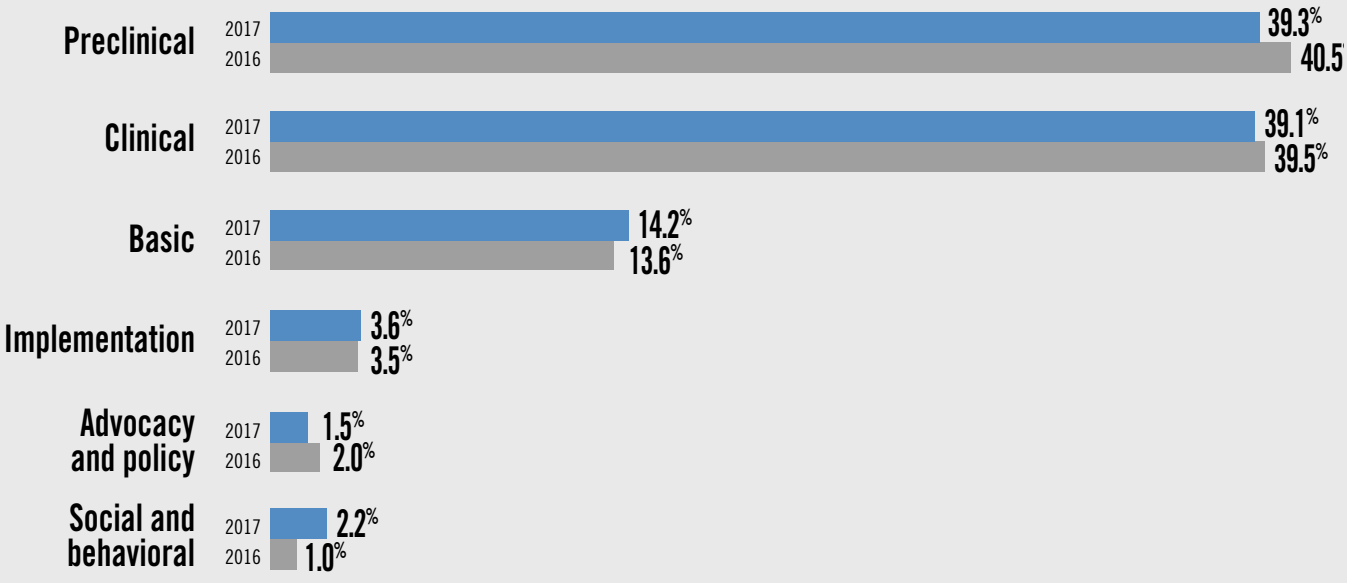
FIGURE 11 **Number of Public Sector and Philanthropic Funders Investing in HIV Prevention R&D, 2011-2017**



The unfinished agenda for social and behavioral research

Mirroring trends from previous years, preclinical and clinical research received the bulk of investment (39 percent each) in 2017. As for biomedical options backed by empirical evidence, such as PrEP and VMMC, the emphasis remained on the "science of delivery" or implementation science. Approximately $28 million (50 percent) of PrEP funding and US$9.7 million (56 percent) of VMMC funding was allocated to demonstration projects aimed at service delivery and rollout. The most significant shift was in funding for social and behavioral research; investment more than doubled, increasing from US$9 million in 2016 to US$25 million in 2017. This is a promising development, albeit modest, when considering the US$1.13 billion invested in HIV prevention R&D overall *(Figure 12)*.

FIGURE 12 **Research to Rollout: Investment by Research Stage, 2016-2017**

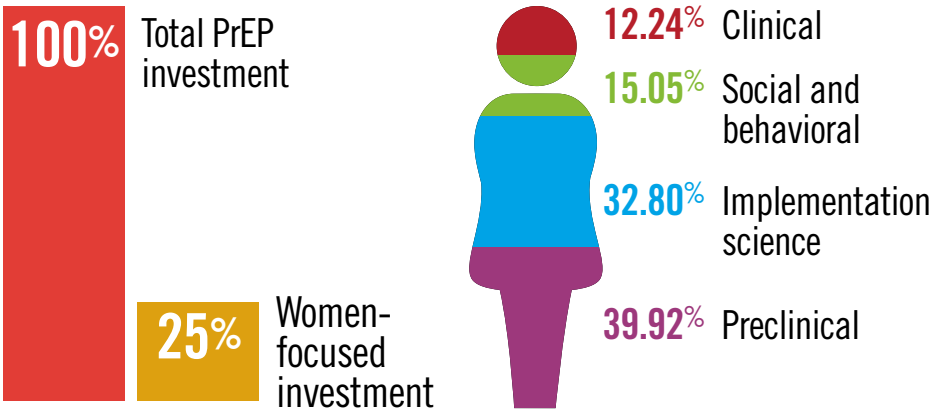


Women-focused PrEP research

Adolescent girls and young women have a heightened risk for HIV: 7,000 new infections are recorded every week, and girls aged 15-19 years make up three out of every four new HIV cases in sub-Saharan Africa[3]. This disproportionate burden calls for the development of women-controlled HIV prevention options that are not only effective, but are also processed from bench to bedside with the unique intersecting needs of women in mind.

One such option is PrEP, which is currently being refined for scale-up and improved adherence in women. Out of the US$63 million invested in PrEP overall, US$16 million (or 25 percent) was for research explicitly focused on women. Most of this research was preclinical, with an emphasis on discreet products with long-acting formulations, e.g., PrEP implant studies and long-acting injectables. Almost 30 percent of the implementation studies focused on the uptake of and adherence to oral PrEP in high-risk women, and 15 percent focused on PrEP for pregnant and breastfeeding women *(Figure 13)*.

FIGURE 13 **Investment in Women-Focused PrEP R&D, 2017**



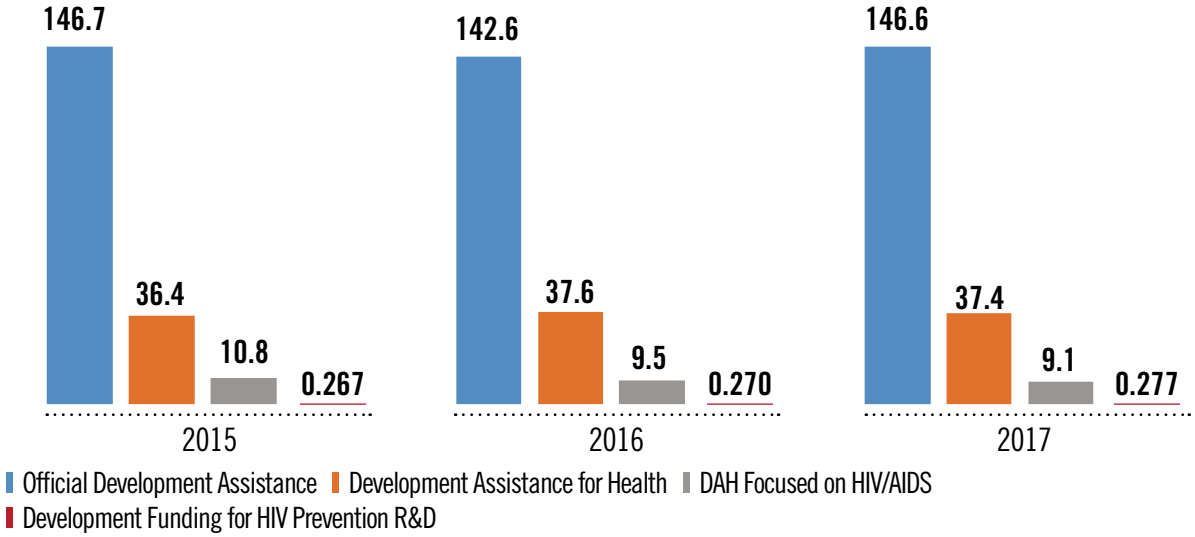
Two-thirds of preclinical research was focused on PrEP implant studies, while **16**% was dedicated to exploring long-acting PrEP formulations

Almost **30**% of the research was dedicated to improving PrEP adherence and uptake in high-risk women, including those with drug or substance abuse. Delivering PrEP to pregnant and breastfeeding women made up **15**% of the women-focused implementation science budget.

Spending on HIV/AIDS in the global context

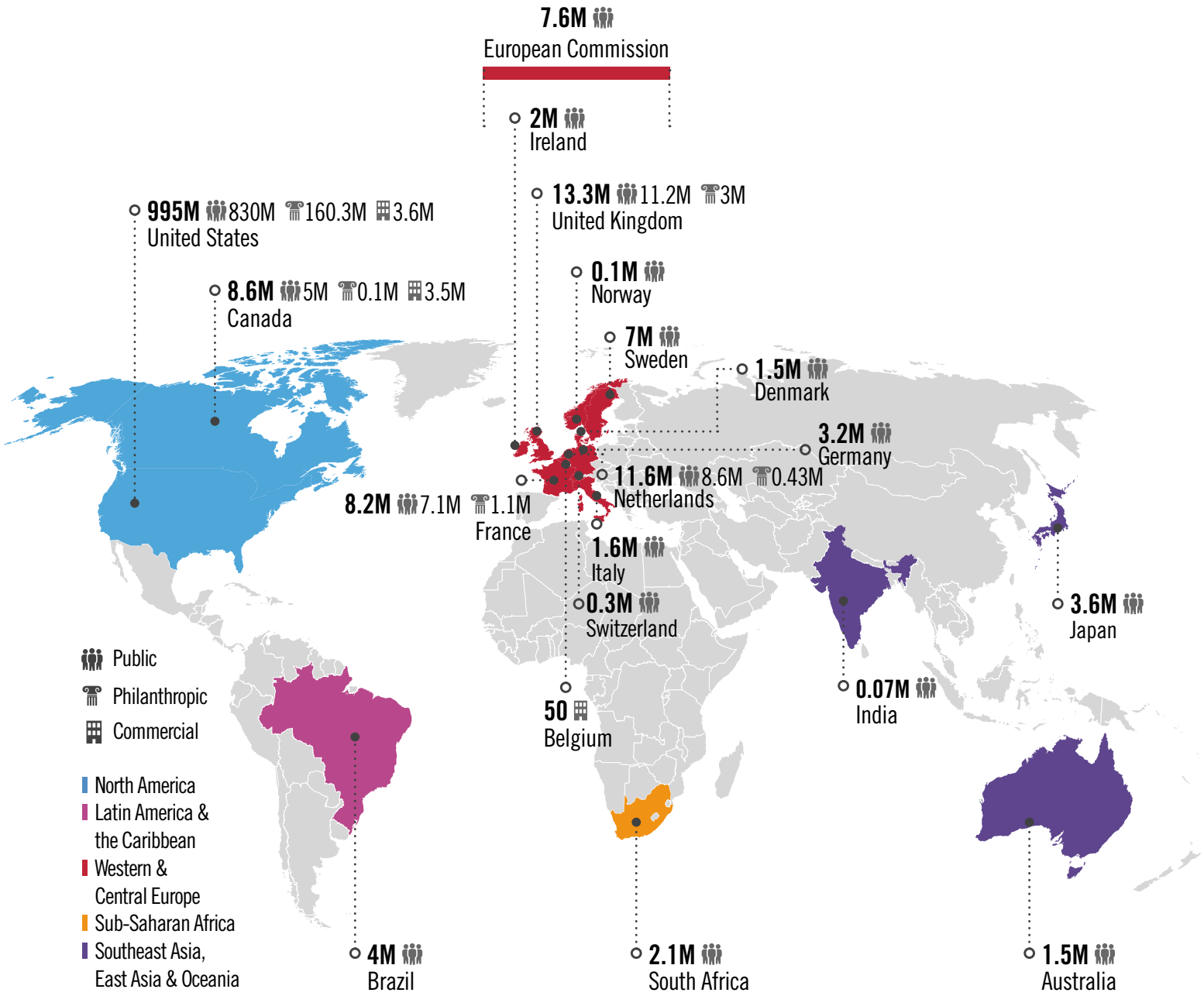
HIV/AIDS has been positioned prominently in the global health agenda: it was initially featured in the Millennium Development Goals (specifically MDG 6) and, more recently, the Sustainable Development Agenda (specifically SDG 3). The prioritization of HIV/AIDS attracted large funding for treatment and prevention programs, totaling up

FIGURE 14 **HIV Prevention R&D in the Context of Development Assistance for Health and Total Official Development Assistance, 2015-2017** (US$ billions)



to US$562 billion spent between 2000 and 2015[5]. This includes Development Assistance for Health (DAH), which is the financial or in-kind support from development agencies to low– and middle-income countries in order to maintain or improve health. Following the growth observed at the turn of the millennium, DAH for HIV/AIDS has been declining annually at a rate of 1.4 percent since 2011. This trend continued in 2017, with DAH focused on HIV/AIDS falling from US$9.5 billion to US$9.1 billion. Around 16.8 percent of the total DAH for HIV/AIDS was spent on prevention programs, and 2.4 percent (or US$277 million) on HIV prevention R&D *(Figure 14) (Figure 15)*.

FIGURE 15 **Total Global Investment in HIV Prevention R&D by Country, 2017** (US$ millions)



* Information collected includes funding from those countries that responded to the Working Group's annual survey, or where public information on sources of funding was available. Totals include public, philanthropic and commercial sector funding from each country. Commercial-sector investments are allocated to a country based on the location of corporate headquarters and are underestimated due to a lack of reporting by companies. Not all commercial-sector estimates are able to be allocated by country.

Trial Participation

Participation of volunteers and the engagement of communities in which trials take place is essential to conducting HIV prevention research. In 2017, there were nearly 600,000 participants in HIV prevention research trials globally, mostly originating from sub-Saharan Africa, Europe, North America and Asia *(Figure 16A)*.

A majority of participants were enrolled in research investigating TasP and PrEP, and while there are trials aimed specifically at men who have sex with men (MSM), transgender individuals and people who inject drugs (PWID), most of the studies do not specify the need to include members of key populations (KPs) *(Figure 16B)*.

FIGURE 16A **HIV Prevention R&D Trial Participants by Region in 2017** (thousands)

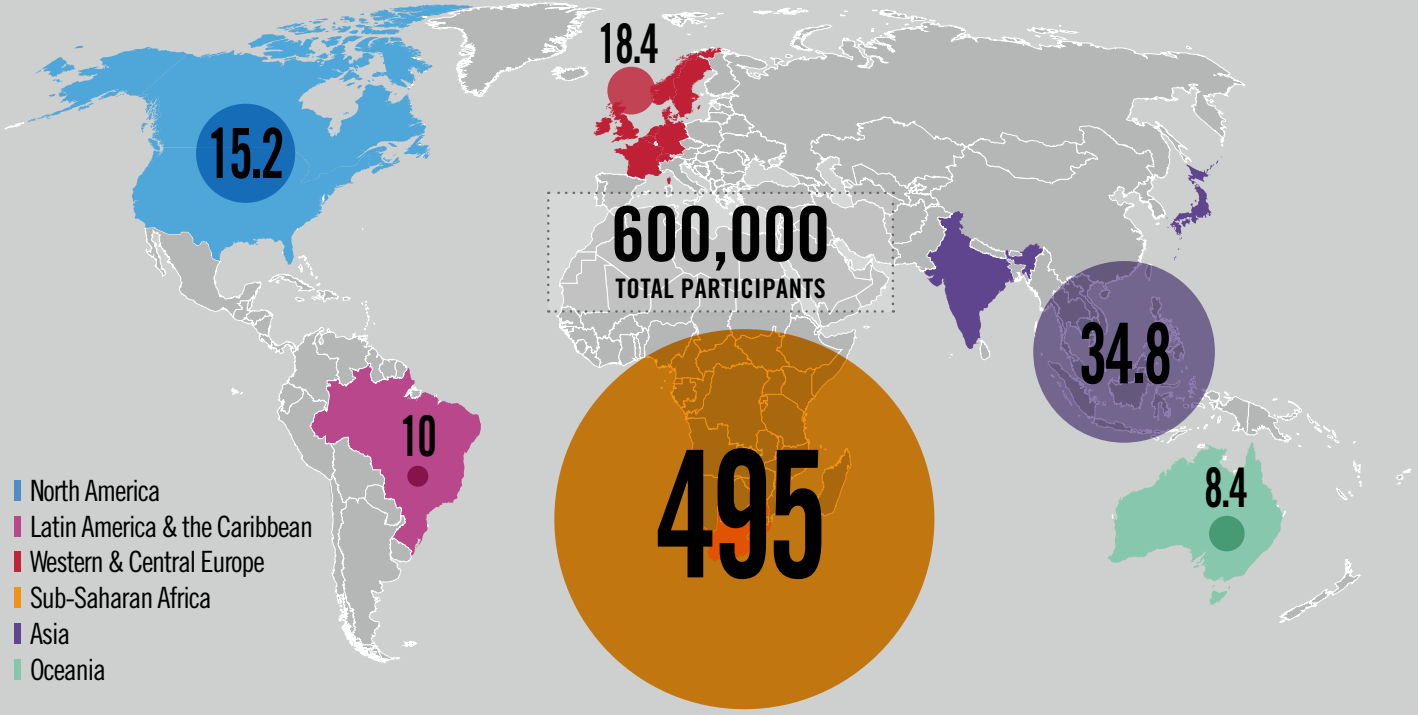


FIGURE 16B **Trial Participants, 2017**

TRIAL PARTICIPANTS BY PREVENTION RESEARCH AREA

Preventative vaccines	2.6%
Microbicides	1.3%
Prevention of vertical tranmission	4.2%
Pre-exposure prophylaxis	14.4%
Treatment as prevention	78.4%
Voluntary madical male circumcision	0.2%

KEY POPULATION REPRESENTATION IN CLINICAL TRIALS

Gay men, men who have sex with men and transgender women	8.4%
People who inject drugs	0.12%
Sex workers	0.6%
Women	49%
Non-KP specific	41.7%

Collection and Analysis Methodology

In order to generate investment estimates that can be compared from year to year, from one technology to another and across funding sources, a systematic approach to data collection and collation was developed at the establishment of this collaborative project in 2004. Its fundamental premise is that monitoring HIV prevention R&D investment trends permits the identification of investment needs, prioritization of research areas and assessment of the impact of public policies that increase or decrease investments. Investment data also provide the fact base for advocacy around spending levels, resource allocations, the value of sustained investments in research building on trial successes, attracting novel HIV prevention candidates to the pipeline and follow-on trials to assure the safety, immunogenicity, efficacy and acceptability of new HIV prevention products. The same methods were employed to generate the estimates of funding for R&D presented in this year's report.

R&D data were collected on annual disbursements by public, private and philanthropic funders for product development, clinical trials and trial preparation, community education and policy and advocacy efforts to estimate annual investments in HIV prevention R&D. Investment trends were assessed and compared by year, prevention type, research phase, funder category and geographic location. Comprehensive and consistent use of this methodology enables data comparisons across organizations, countries and years. The Working Group makes every effort to maintain a comparable data set, while allowing for the limitations inherent to global investment tracking styles and timing. Its primary limitation is that data collection largely depends on the response rate of public, private and philanthropic funders, and year-to-year variability is partly a reflection of this response rate. Funds were allocated to the year in which they were disbursed by the donor, irrespective of whether the funds were expended by the recipient in that year or in future years. Investment figures are rounded throughout the report. In order to minimize double-counting, the Working Group distinguishes between primary funders and intermediary organizations. "Intermediary" organizations receive resources from multiple funders and use these resources to fund their own work, as well as the work of others.

All figures in the report are given in current US dollars and have not been adjusted for inflation. Because of this, investments in later years may be overvalued relative to investments in earlier years due to inflation. From a total of 215 surveyed organizations, institutions and companies, 70 funders reported their investments. A total of 410 grants were allocated to HIV prevention research, with an average grant size of US$2.7 million.

TABLE 1 Global Investments in HIV Prevention R&D: 2017 Funding Map

2017 totals in US$ millions *(2016 investments, percent change[a])*

Funding type	2016	2017	% Change 2016-2017	Funder	Total 2017	Total 2016	% Change	Preventive AIDS vaccines			Microbicides			Prevention of vertical transmission			Pre-exposure prophylaxis			Treatment as prevention			Voluntary medical male circumcision			Female condoms		
								2017	2016	Change	2017	2016	Change	2017	2016	Change	2017	2016	Change	2017	2016	Change	2017	2016	Change	2017	2016	Change
US Public Sector	**$881 million**	**$830 million**	**-5.8%**	NIH	$713.0	$762.0	-6.5%	*$561.8*	*$605.0*	*-7.2%*	*$95.0*	*$96.9*	*-2.0%*	*$34.3*	*$37.7*	*-8.9%*	*$20.1*	*$20.6*	*-2.4%*	—	—	—	*$1.7*	*$0.8*	*131%*	*$0.02*	*$0.5*	*-95%*
				USAID/PEPFAR	$74.7	$73.9	1.1%	*$30.0*	*$28.7*	*4.1%*	*$34.9*	*$42.8*	*-18.5%*	—	—	—	*$10.0*	*$2.4*	*315.4%*	—	—	—	—	—	—	—	—	—
				CDC	$9.9	$11.3	-13%	—	—	—	*$1.6*	*$0.4*	*308%*	—	—	—	*$1.7*	*$2.6*	*-33.5%*	*$4.9*	*$6.2*	*-21.7%*	*$1.6*	*$2.0*	*-22%*	—	—	—
				MHRP	$33.0	$33.0	0.0%	*$33.0*	*$33.0*		—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
European Public Sector	**$59 million**	**$58 million**	**-2.10%**	Belgium	—	$0.2	—	—	—	—	—	*$0.2*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Denmark	$1.5	$0.7	103%	*$0.7*	*$0.7*	*0.0%*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				EC	$7.6	$14.4	-47%	*$7.5*	*$12.1*	*-38%*	*$0.01*	*$1.7*	*-93%*	—	*$0.6*	—	—	—	—	—	—	—	—	—	—	—	—	—
				France	$7.1	$7.0	1.4%	*$3.6*	*$5.3*	*-33%*	*$0.2*	*$0.2*	*0.0%*	*$0.5*	*$0.3*	*66%*	*$2.7*	*$0.5*	*472%*	*$0.1*	*$0.7*	*-80%*	—	—	—	—	—	—
				Germany	$3.2	*$1.4*	*130.5%*	—	*$0.01*	—	*$3.2*	*$1.4*	*132%*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Ireland	$2.1	$2.0	5.1%	*$0.6*	*$0.9*	*-38%*	*$1.6*	*$1.1*	*40%*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Italy	*$1.6*	—	—	*$1.6*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Netherlands	$11.2	$8.6	31%	*$3.7*	*$3.6*	*2%*	*$7.5*	*$5.0*	*52%*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Norway	—	$0.1	—	—	—	—	—	*$0.1*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Spain	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Sweden	$7.2	$7.2	0.0%	*$6.0*	*$6.0*	*0%*	*$1.1*	*$1.1*	*0%*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Switzerland	$0.31	$0.28	12.6%	*$0.31*	*$0.28*	*13%*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				UK	$11.2	$11.8	-5.1%	*$4.5*	*$6.5*	*-31%*	*$6.7*	*$5.3*	*27%*	*$0.02*	*$0.05*	*-63%*	—	—	—	—	—	—	—	—	—	—	—	—
Other Countries	**$50 million**	**$11.5 million**	**-334.70%**	Australia	$1.51	$1.47	2%	*$0.9*	*$1.3*	*-37%*	*$0.2*	—	—	*$0.06*	—	—	*$0.03*	—	—	*$0.2*	*$0.2*	*0.0%*	*$0.2*	—	—	—	—	—
				Brazil	$4.1	$0.2	2112%	*$0.06*	*$0.03*	*61%*	—	—	—	*$0.4*	—	—	*$4.0*	*$0.1*	*2556%*	—	—	—	—	—	—	—	—	—
				Canada	$5.0	$2.6	88%	*$3.8*	*$0.9*	*326%*	*$0.8*	*$0.7*	*9%*	*$0.2*	*$0.3*	*-16%*	—	*$0.4*	—	*$0.09*	*$0.2*	*-62%*	—	*$0.1*	—	—	—	—
				China	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Cuba	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				India	$0.07	$0.13	-49%	*$0.07*	*$0.04*	*85%*	—	*$0.1*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Israel	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Japan	$3.6	$2.6	37%	*$3.6*	*$2.6*	*37%*	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Russia	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				South Africa	$2.1	$4.4	-52%	*$1.6*	*$3.9*	*-58.0%*	*$0.2*	*$0.5*	*-54.0%*	—	—	—	*$0.2*	—	—	—	—	—	—	—	—	—	—	—
				Taiwan	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Thailand	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Philanthropic	**$157 million**	**$164 million**	**4.4%**	BMGF	$150.2	$141.0	6.6%	*$107.9*	*$113.8*	*-5%*	*$3.3*	*$7.6*	*-56%*	*$0.4*	*$0.1*	*272%*	*$24.0*	*$10.3*	*134%*	*$0.2*	*$1.5*	*-87%*	*$13.9*	*$7.5*	*84%*	—	—	—
				Wellcome Trust	$2.0	$3.1	-34%	*$1.2*	*$1.3*	*-4%*	*$0.8*	*$1.2*	*-34%*	—	*$0.6*	—	*$0.005*	—	—	—	*$0.04*	—	—	—	—	—	—	—	—
				Other	$11.8	$13.5	-12%	*$11.2*	*$11.0*	*9%*	*$0.1*	*$0.4*	*-65%*	—	*$1.2*	—	*$0.40*	*$0.43*	*-7%*	*$0.1*	*$0.5*	*-78%*	—	—	—	—	—	—
Industry	**56.4 million**	**$57 million**	**1.2%**	Commercial Sector	$57.1	$56.4	1%	*$56.9*	*$53.6*	*6%*	**$0.2**	**$0.4**	**-52%**	—	—	—	—	—	—	—	—	—	—	—	—	—	*$2.4*	—
Total	**$1.17 billion**	**$1.13 billion**	**-3.5%**	**HIV prevention option totals**	1.13 billion	1.17 billion	-3.5%	**$845.0**	**$894.0**	**-5.6%**	**$159.0**	**$167.0**	**-4.8%**	**$35.7**	**$41.0**	**-12.8%**	**$63.0**	**$40.5**	**56%**	**$5.6**	**$10.3**	**-45%**	**$17.5**	**$10.4**	**67%**	**$0.02**	**$2.8**	**-99%**
				% Change 2016–2017		**-3.5%**			-5.6%			-4.8%			-12.8%			56%			-45%			67%			-99%	

[a] All figures are rounded. See Appendix for a detailed methodology section, including the limitations of data collection.

AIDS Vaccines

1.0 Global investment in preventive AIDS vaccines R&D

In 2017, funding for preventive AIDS vaccines R&D decreased by 5.6 percent, or US$50 million, from the previous year, to a total of US$845 million *(Figure 17)*. The public sector accounted for 79 percent of overall investment at US$667 million, with the philanthropic and commercial sectors contributing 14 percent and 6.7 percent, respectively. At US$624.7 million (or 93 percent) of all public-sector funding, the US remained the largest donor for preventive vaccine research globally. This distinction remained, despite the 6.3 percent decrease in US public-sector funding, largely resulting from the US$43 million reduction in investment from the NIH *(Figure 18 and Table 2)*.

FIGURE 17 **AIDS Vaccine Funding from 2000 - 2017** (US$ millions)

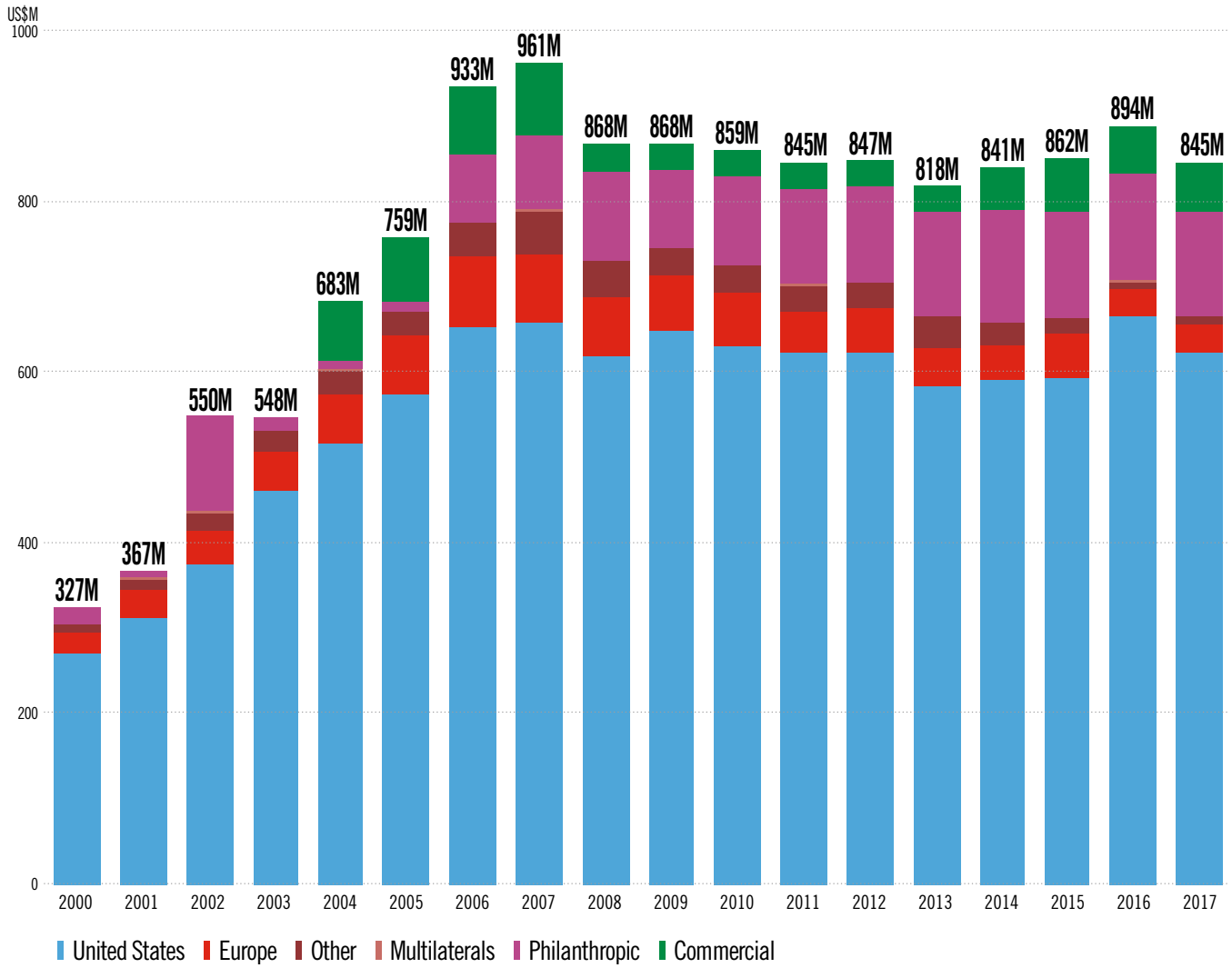
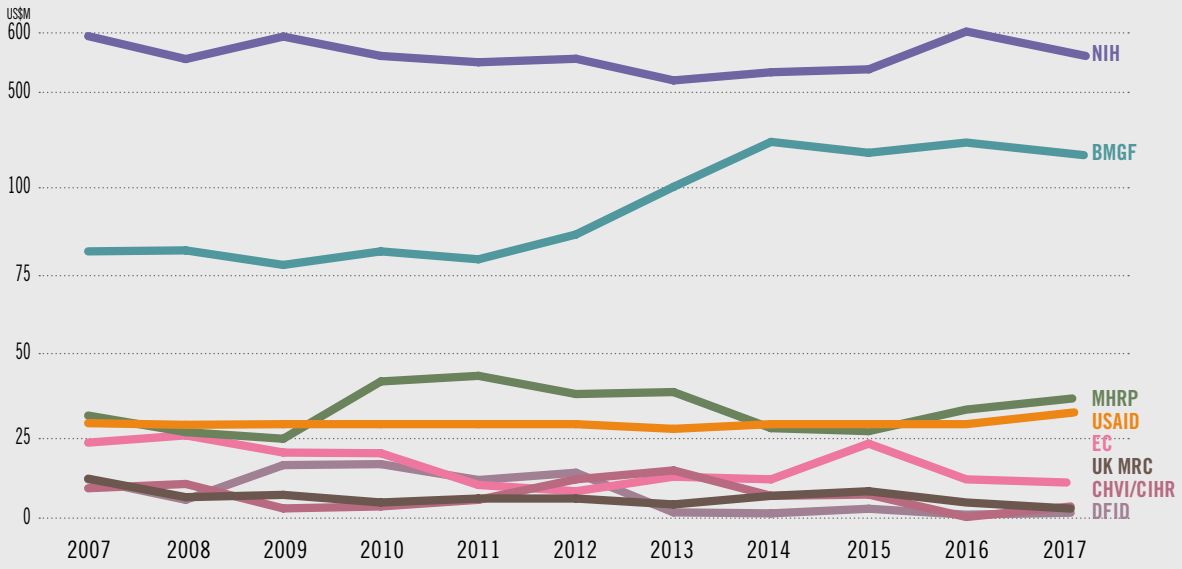


TABLE 2 Annual Investment in AIDS Vaccine R&D,2000-2017 (US$ millions)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
US	272	314	376	463	516	574	654	659	620	649	632	615	623	584	591	595	667	624.7
Europe	23	32	39	44	57	69	82	79	69	65	61	48.5	52	44	40	44	38.5	32.5
Other Countries	10	12	21	24	28	27	38	49	41	31	32	30	31	38	27	26	7.8	10.1
Multilaterals	2	2	2	2	2	2	2	2	1	1	1	0.5	0.5	0.5	0.5	0.5	0.5	0
Total Public	307	359	436	532	602	672	776	789	731	746	726	702	707	667	653	655	714	667
Total Philanthropic	20	7	112	15	12	12	78	88	104	92	103	113	110	120.5	131	132	126	120.7
Total Commercial	–	–	–	–	68	75	79	84	33	30	30	30	30	31	51	62	54	57
Total Global Investment	**327**	**366**	**548**	**547**	**682**	**759**	**933**	**961**	**868**	**868**	**859**	**845**	**847**	**818**	**840**	**859**	**894**	**844.9**

FIGURE 18 Top AIDS Vaccine Funder Trends, 2007-2017 (US$ millions)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NIH	596.8	556.1	596	561.6	550.4	556.6	518.2	532.7	537.9	605	561.8
BMGF	80.9	81.2	76.8	80.9	78.5	86	100.4	114	110.7	113.8	108
USAID	29	28.5	28.7	28.7	28.7	28.7	27.3	28.7	28.7	28.7	30
MHRP	31.3	26.3	24.3	41.6	43.3	37.8	38.4	27.5	26.6	33.1	33
EC	23.1	25.3	20.1	19.9	10.3	8.4	12.8	12	22.8	12	7.5
DFID	12	5.8	16.3	16.6	11.8	14	2	1.7	3.1	1.3	1.3
CHVI/CIHR	9.3	10.6	3.2	3.8	5.8	12	14.7	7	7.4	0.6	3.8
UK MRC	12.2	6.6	7.3	5	6.2	6.2	4.4	7	8.4	5	3.2



European investment in preventive vaccines R&D decreased by six percent, from US$38.5 million in 2016 to US$32.5 million, signaling the lowest levels of European investment since 2001. Funding from the European Commission also declined, from US$12 million to US$7.5 million. Philanthropic contributions decreased by US$5.7 million, down to US$120 million, in 2017, with the BMGF remaining the largest philanthropic funder of vaccine research, at US$108 million *(Table 3)*. The commercial sector contributed US$57 million, representing a six percent increase from the previous year.

Japan, Italy, Switzerland, the Netherlands and Canada all increased their commitments in 2017, which helped cushion against the decrease in funding from France, Ireland, the UK, Australia and the US *(Table 4)*.

TABLE 3 Philanthropic Investment in AIDS Vaccine R&D by Foundations and Commercial Philanthropy in 2017 (US$ millions)

Amount	Investors
US$108 million	Bill and Melinda Gates Foundation
US$1 million to US$10 million	Ragon Institute, Wellcome Trust
US$250,000 to <US$1 million	Institut Pasteur
<US$250,000	Aidsfonds, Sidaction

TABLE 4 Top AIDS Vaccine Funders for 2011-2017 (US$ millions)[a,b]

	2011		2012		2013		2014		2015		2016		2017	
Rank	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount
1	NIH	550.4	NIH	557	NIH	518.2	NIH	532.7	NIH	538	NIH	605	NIH	561.8
2	BMGF	78.5	BMGF	86	BMGF	100.4	BMFG	114	BMFG	103	BMGF	114	BMGF	108
3	MHRP	43.3	MHRP	37.8	MHRP	38.4	USAID	28.7	USAID	28.7	MHRP	33	MHRP	33
4	USAID	28.7	USAID	28.7	USAID	27.3	MHRP	27.5	MHRP	26.6	USAID	29	USAID	30
5	DFID	11.8	DFID	14	CHVI[c]	14.7	EC	12	EC	22.3	EC	12	Ragon Institute	10
6	EC	10.3	CHVI	12	EC	12.8	Ragon Institute	10	Ragon Institute	10	Ragon Institute	10	EC	7.5
7	Ragon Institute	10	Ragon Institute	10	Ragon Institute	10	CHVI	7	UK MRC	8.3	Swedish Research Council	6	EDCTP	5
8	ANRS	7.3	EC	8.4	Wellcome Trust	7.7	China[d]	7	CHVI	7.2	ANRS	5.3	CIHR	3.8
9	China	6.9	Wellcome Trust	8.2	China[d]	7	UK MRC	7	China[d]	7	UK MRC	5	Dutch PDP	3.7
10	Wellcome Trust	6.5	China	7	NHMRC	6.8	Wellcome Trust	6.2	Wellcome Trust	6	Dutch PDP	3.6	ANRS	3.6
11	UK MRC	6.2	MRC	6.2	ANRS	5.3	Nether-lands	5.1	Institut Pasteur	5.5	EDCTP	3	Sumagen Canada, Inc.	3.5
12	CHVI	5.8	Institute Pasteur	4.8	The Netherlands	4.9	Institute Pasteur	3.9	South Africa DST/ SAMRC	3.9	South Africa DST/ SAMRC	3.9	VIR Biotech-nology	3.4
13	CIDA	4.9	Netherlands	4.8	Institute Pasteur	4.8	Sumagen Canada Inc.	2.8	DFID	3.1	Sumagen Canada Inc.	1.4	UK MRC	3.2
14	NMHRC	3.9	NHMRC	4.4	UK MRC	4.4	ANRS	2.7	Japan AMED	2.4	DFID	1.3	World Bank (Japan)	2
15	The Netherlands	3.8	ANRS	4	DANIDA	2.2	South Africa DST/DOH	2.5	CIHR	2.4	Wellcome Trust	1.3	SAMRC	1.6

[a] See Appendix for list of acronyms.

[b] A portion of the significantly lower contribution to AIDS vaccine R&D by DFID in 2013 can be attributed to a difference in funding cycles: a £5m disbursement was recognized as 2012 funding according to Working Group methodology.

[c] Participating CHVI Government of Canada departments and agencies are: the Canadian International Development Agency (CIDA), the Public Health Agency of Canada (PHAC), Industry Canada, the Canadian Institutes of Health Research (CIHR) and Health Canada. CIHR grants are reported separately.

[d] The Working Group could not obtain a response from China for investments made in 2012-2015. Thus, an estimate was developed and sent to China's National Center for AIDS/STD Control and Prevention. The estimate was developed based on public information submitted by the National Center for AIDS/STD Control and Prevention and China's Center for Disease Control and Prevention on *clinicaltrials.gov*, with regards to a Phase II preventive AIDS vaccine trial that started in August 2012 and other research that is underway.

1.1 Development in the field of AIDS vaccine research

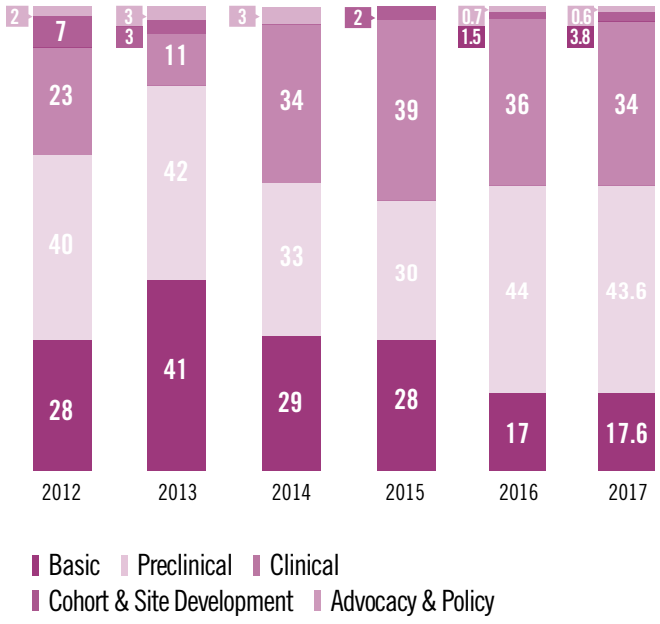
It is an unprecedented time for vaccine research with multiple late-stage vaccine efficacy trials underway. Some of them include:

- The AMP Study (HVTN 703/HPTN 081 and HVTN 704/HPTN 085), which comprises two "sister" Phase II safety and efficacy trials, is currently recruiting participants[6,7]. These proof-of-concept trials are testing the administration of the VRC01 monoclonal antibody in HIV-negative women in several African countries, and in MSM and transgender men and women in North and South America. Study results are expected in 2020.
- The Phase IIb/III HVTN 702 study is ongoing and planning to enroll 5,400 men and women in South Africa8. Driven by the Pox-Protein Public Private Partnership, or P5, HVTN702 is evaluating the efficacy, safety and tolerability of a clade C subtype vaccine candidate. Results of the study are expected in July 2021.
- HPX2008/HVTN 705 is the Phase IIb proof-of-concept study ongoing in five countries across sub-Saharan Africa9. The trial will enroll 2600 women and is testing a mosaic immunogen designed to confer protection from more than one clade of HIV. Results are anticipated sometime after 2022.

1.2 Funding allocations for preventive AIDS vaccine R&D

Funding for HIV vaccine R&D was allocated to the following areas in 2017: basic research (17.6 percent), preclinical (43.6 percent), clinical (34 percent), cohort and site development (3.8 percent), advocacy and policy (0.6 percent) and social and behavioral (0.02 percent). These allocations are reflective of the increasing focus on preclinical research since 2015, with lesser investment recorded for clinical trials. At 3.8 percent of total funding, this is the largest allocation for cohort and site development in five years, and could be attributed to planned large-scale HIV vaccine trials as well as those that are currently underway *(Figure 19)*.

FIGURE 19 **AIDS Vaccine Funding Allocations, 2012-2017**



Microbicides

2.0 Global investment in microbicide R&D

Investment in microbicide R&D totaled US$159 million in 2017, a 4.8 percent (US$8 million) decrease from 2016 funding levels. This is the fifth consecutive year of declining microbicide funding and the lowest investment level recorded since 2004 *(Figure 20)*. The majority of funding originated from the public sector (96 percent), while philanthropic and commercial funding trailed at 3.4 percent and 0.1 percent, respectively *(Figure 21)*. Philanthropic funding decreased by

FIGURE 20 **Microbicide Funding from 2000-2017** (US$ millions)

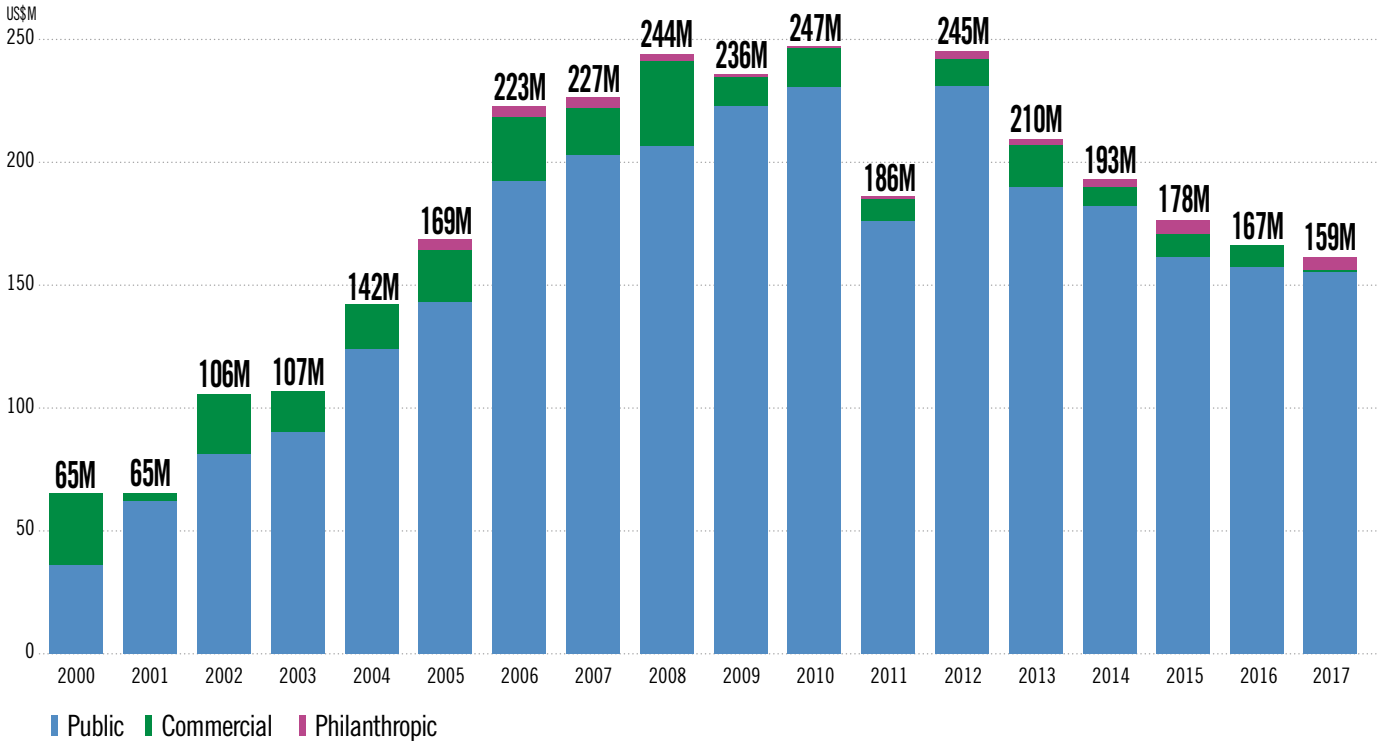
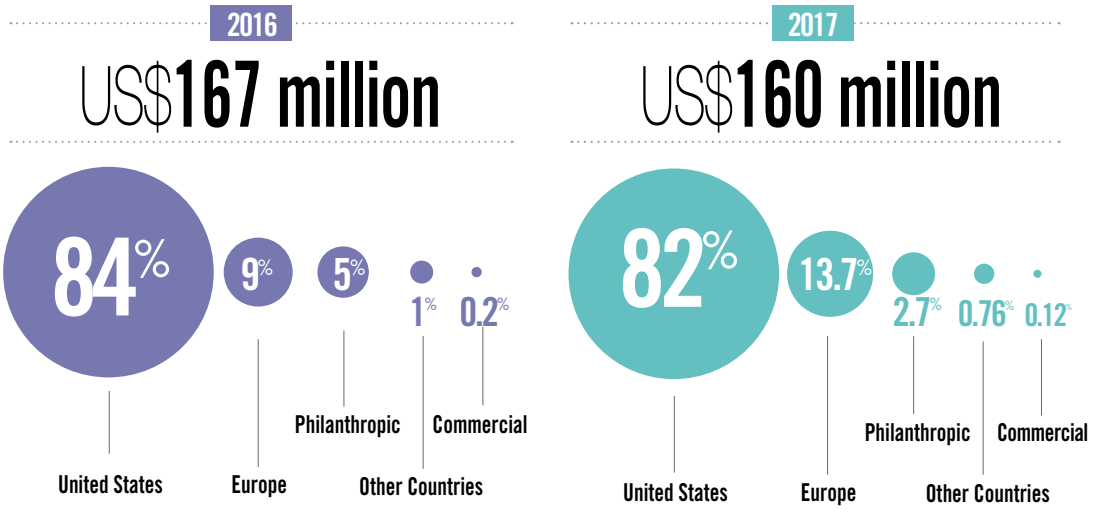


FIGURE 21 **The Funding Base for Microbicide R&D by Percentage, 2016-2017** (US$ millions)



53 percent and commercial by 52 percent, although this could also be a function of reduced reporting from commercial and philanthropic funders. Despite a 6.4 percent decrease in investment, the US public sector remained the predominant funder, at US$131 million *(Table 5)*. European funding grew by 23.9 percent, to US$22 million, boosted mainly by increased investments from the German Federal Ministry of Education and Research (BMBF, up 132 percent), the Netherlands Ministry of Foreign Affairs (up 52 percent), Irish Aid (up 40 percent) and the UK Department of International Development (DFID, up 51 percent) *(Figure 22 and Table 6)*.

The list of philanthropic funders engaged in microbicide research remained unchanged in 2017, with all involved decreasing their investment from the previous year (i.e., BMGF, Institut Pasteur, Sidaction and Wellcome Trust). Investments totaling US$1.3 million were also made in rectal microbicide research by the CDC and Wellcome Trust.

TABLE 5 Annual Investment in Microbicide R&D by Sector, 2007-2017 (US$ millions)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
US	140	154	173	182	148	173	155	154	143	140	131
Europe	60	40	44	40	16	27	27	23	17	16	22
Other Countries	3.4	12	5.7	8.3	12	17	5	4.5	2.4	1.3	1.2
Multilaterals	0.2	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0
Total Public	203	207	223	230	176	217	187	182	162	157	154.7
Total Philanthropic	19	35	12	16	9	25	20	20	9.3	9	4.3
Total Commercial	4.5	2.5	1	1	1	3	3	3	6	0.4	0.2
Total Global Investment	**227**	**244**	**236**	**247**	**186**	**245**	**210**	**193**	**178**	**167**	**159**

FIGURE 22 Top Microbicide Funder Trends, 2007-2017 (US$ millions)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
NIH	99	116	133	147	112	130	111	108	106	97	95
USAID	40	38	39	38	36	43	43	45	35	43	34.9
BMGF	15	35	7	17	7	23	19	8	9	7.6	3.3
DFID	21	13	22	16	3	5	8	8	5.2	4.4	6.7
EC	12	5	7	7	1	14	7	7	4	1.7	0.12
UK MRC	8	4	4	3	1	2	1	0.5	1.2	0.8	0

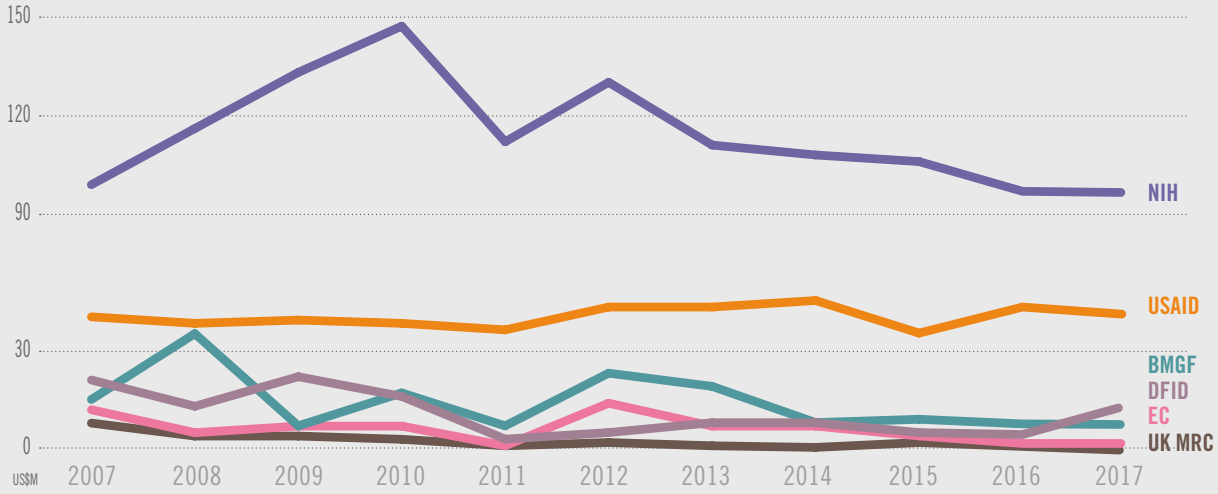


TABLE 6 **Top Microbicide R&D Funders, 2011-2017** (US$ millions)

	2011		2012		2013		2014		2015		2016		2017	
Rank	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount
1	NIH	111.8	NIH	129.9	NIH	111.2	NIH	107.8	NIH	106.3	NIH	97	NIH	95
2	USAID	36	USAID	43.2	USAID	42.8	USAID	45	USAID	45.2	USAID	43	USAID	34.9
3	South African DST/DOH	10	BMGF	22.9	BMGF	19.2	BMGF	7.6	BMGF	8.9	BMGF	7.6	Netherlands Ministry of Foreign Affairs	7.5
4	BMGF	7	EC	13.6	DFID	8.4	DFID	7.4	DFID	5.2	Netherlands Ministry of Foreign Affairs	5	DFID	6.7
5	DfID	3.2	CHVI19	9.2	EC	6.7	EC	5.7	EC	3.9	DFID	4.4	BMGF	3.3
6	Netherlands	2.7	South Africa	7	Netherlands	3.6	Sweden	3.2	Sweden	2.9	EC	1.7	BMBF	3.2
7	NORAD	2.5	DFID	4. 7	South Africa DST/ DOH	2.3	Nether-lands	3	DANIDA	1.4	BMBF	1.4	CDC	1.6
8	Wellcome Trust	1.6	UK MRC	2.2	Denmark	2.2	ICMR	2.3	UK MRC	1.2	Wellcome Trust	1.2	Irish Aid	1.6
9	Irish Aid	1.4	Netherlands	1.7	EDCTP	2.2	Ireland	1.3	IrishAid	1.1	Swedish Research Council	1.2	Wellcome Trust	0.8
10	UK MRC	1.3	Ireland	1.2	Norway	1.5	CDC	1.2	CDC	0.9	IrishAID	1.1	CIHR	0.8
11	Denmark	0.9	Norway	1	US CDC	1.5	NORAD	1	CIHR	0.8	UK MRC	0.8	DANIDA	0.8
12	NHMRC	0.6	OPEC	1	Ireland	1.3	DANIDA	0.8	NORAD	0.8	CIHR	0.7	SAMRC	0.2
13	OFID	0.5	Denmark	0.9	UK MRC	0.8	CIHR	0.8	South Africa DST/ SAMRC	0.5	South Africa DST/ SAMRC	0.5	NHMRC	0.2
14	Spain	0.4	NHMRC	0.5	NHMRC	0.5	UK MRC	0.5	ANRS	0.2	CDC	0.4	MAPP Biopharma-ceutical	0.2
15	ARC	0.4	Wellcome Trust	0.5	Wellcome Trust	0.3	South Africa DST/DOH	0.4	NHMRC	0.2	Osel Inc.	0.2	ANRS	0.2

2.1 Developments in the field of microbicide research

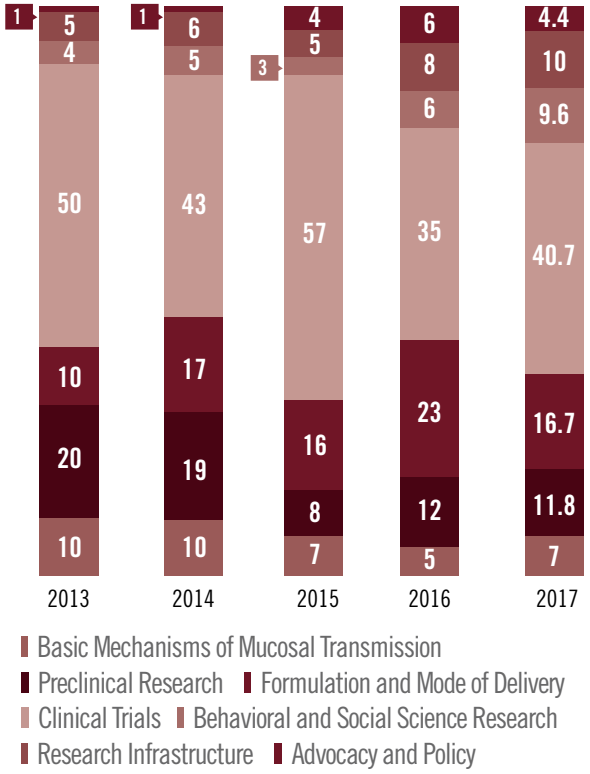
- The open-label trials assessing the safety and adherence of the dapivirine intravaginal ring in nearly 3000 participants, HOPE (MTN-025) and DREAM (IPM 032), have closed to accrual. Interim results from HOPE were presented at CROI 2018, where it was revealed that 90 percent of women were using the monthly ring at least some of the time. Modelling estimates also predicted that the dapivirine ring could cut the rates of HIV acquisition in women by half[10].
- The silicone intravaginal ring investigated in HOPE and DREAM (see above) is the first microbicide to be submitted for regulatory approval. The ring's developer, the International Partnership for Microbicides (IPM), is pursuing approval from the European Medicines Agency (EMA) for the ring's use by women in high-incidence countries. A verdict on the application is expected in late 2018[11].

- A new Phase I study (MTN-037) launched in the US in June 2018 that is testing the safety of the on-demand gel PC-1005. The product will be administered rectally and the study will enroll both cisgender and transgender men and women[12]. If proven effective, PC-1005 would be the first product to confer protection against three sexually transmitted infections (STIs): HIV, herpes simplex virus (HSV) and human papillomavirus (HPV).

2.2 Funding allocations for microbicide R&D

Allocations for microbicide R&D were as follows: basic mechanisms of mucosal transmission (seven percent), preclinical research (11.8 percent), formulations and modes of delivery (16.7 percent), clinical trials (40.7 percent), behavioral and social science research (9.6 percent), research infrastructure (10 percent) and advocacy and policy (4.4 percent) *(Figure 23)*. Investment in clinical trials was up from 2016 levels, and made up the bulk of microbicide R&D, at 40.7 percent. This is attributed largely to the topical microbicides, intravaginal rings (with active drugs tenofovir, tenofovir/levonorgestrel and dapivirine) and intravaginal films that are currently in clinical testing. Investment in social and behavioral research also rose in 2017 (9.6 percent versus six percent in 2016) and encompassed end-user market research as well as studies around access and the introduction of the dapivirine vaginal ring.

FIGURE 23 **Microbicide R&D Funding Allocations by Percentage, 2013-2017**



The ECHO Trial

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) study is an open-label randomized clinical trial ongoing in 7800 women across South Africa, Kenya, Swaziland and Zambia since 2015[13]. The study is investigating the relationship between the use of three highly effective contraceptive options (i.e. injectable depot-medroxyprogesterone acetate (DMPA), levonorgestrel-containing Jadelle implant and the copper intrauterine device) and the risk of acquiring HIV. While more than 150 million women use modern contraception worldwide, the study's results are particularly significant for sub-Saharan Africa where widespread DMPA use coincides with high levels of HIV incidence[14]. This study addresses a critical gap in women's intersecting reproductive and sexual health needs, and will provide the evidence needed for women to make informed decisions about contraception. The study is closed to accrual and results are expected in 2019.

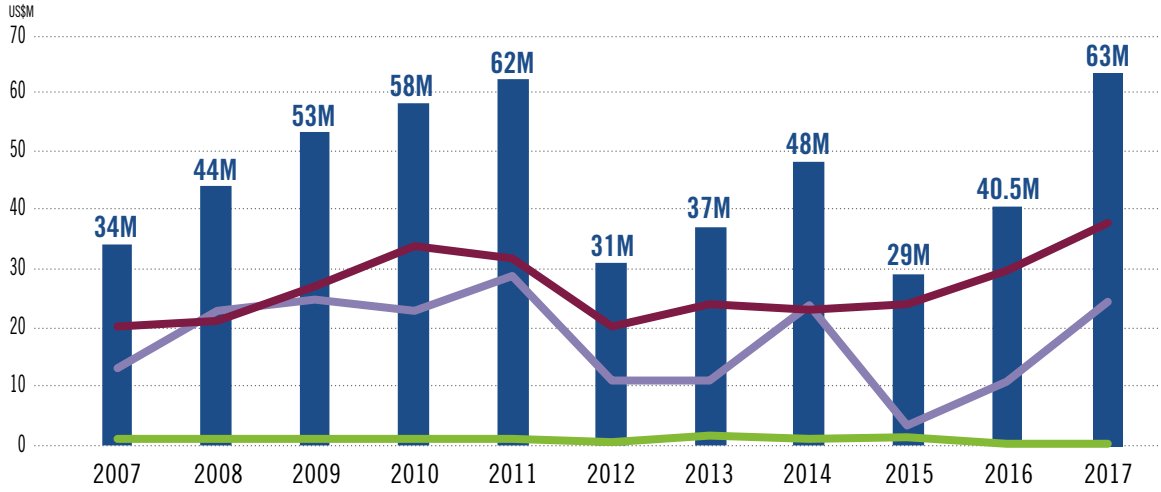
Other HIV Prevention Options

3.0 Global investment in R&D related to PrEP

In 2017, global investment in PrEP R&D amounted to US$63 million. This is a 56 percent increase from 2016 and the highest funding recorded in more than a decade *(Figure 24)*. This surge was driven by increases from both the public sector (up by 30 percent) and the philanthropic sector (up by 128 percent). The leading funder, the BMGF, more than doubled investment in PrEP R&D and made up 98 percent of all philanthropic funding (US$24 million). It is worth mentioning that a large portion of PrEP funding is now focused on aspects such as guidelines development and delivery mechanisms that are outside the scope of this report.

FIGURE 24 **Investments in Pre-Exposure Prophylaxis by Sector, 2007-2017** (US$ millions)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Public	20	21	27	34	32	20	24	23	24	29.8	38.7
Philanthropic	13	23	25	23	29	11	11	24	3.2	10.7	24.4
Commercial	1.3	1.3	1.3	1.3	1.3	0.5	2	1.2	1.6	0	0
Total Funding	34	44	53	58	62	31	37	48	29	40.5	63



3.1 Developments in the field of PrEP research

The global demand for oral PrEP is growing; Truvada (FDF/FTC) has been approved in 42 countries, with another eight having submitted applications for regulatory approval[15]. As access expands, the research leans towards implementation and demonstration studies that address questions around delivery, uptake and adherence. Other ARV-based PrEP products are also in the pipeline and are being investigated with different active drugs and delivery systems. Some of these include:

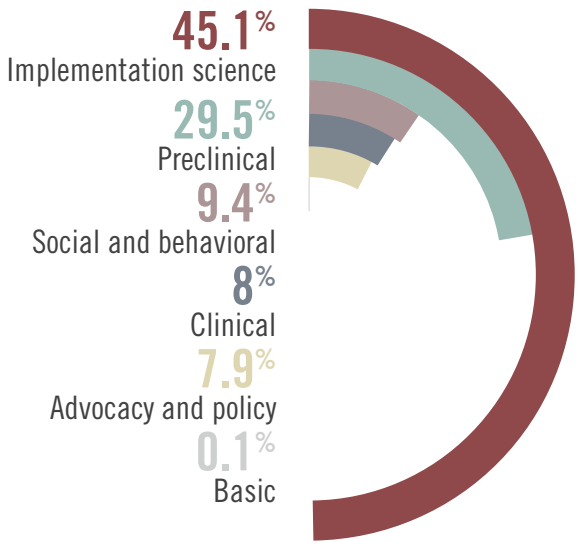
- Two phase III trials investigating the safety and efficacy of the long-acting injectable drug cabotegravir as a pre-exposure prophylaxis agent are currently recruiting participants. HPTN 083 is ongoing in 4500 HIV uninfected cisgender men and transgender women who have sex with men (MSM and TGW) in the Americas, Asia and South Africa[16]. HPTN 084 is recruiting 3200 women at high risk in sub-Saharan Africa[17].
- PrEP Impact trial: This implementation study is sponsored by the NHS in England and is assessing PrEP use in groups at high risk, as well as questions around eligibility, uptake and the duration of use. The study began in September 2017 and will end in 2020, after enrolling 10,000 participants on oral PrEP[18].

- MSF Swaziland PrEP Demonstration Project: Ongoing in eSwatini and funded by Medecins Sans Frontieres, this study aims to increase the understanding of the tolerability, feasibility and the acceptability of daily PrEP use among key population members[18].

3.2 Funding allocations for PrEP R&D

PrEP in oral form is an established HIV prevention tool and has been endorsed by the World Health Organization for use by individuals in communities of high HIV incidence. This is why most of contemporary PrEP research (45 percent) is geared toward implementation science or improvement in the delivery, adherence and scale-up of PrEP *(Figure 25)*. Investment allocated for early-stage research, i.e., basic and preclinical research, increased in 2017 and is a function of the investigations into long-acting PrEP formulations in implant and injectable forms.

FIGURE 25 **PrEP R&D Funding Allocations by Percentage in 2017**



Implantable Antiretrovirals as PrEP in Women

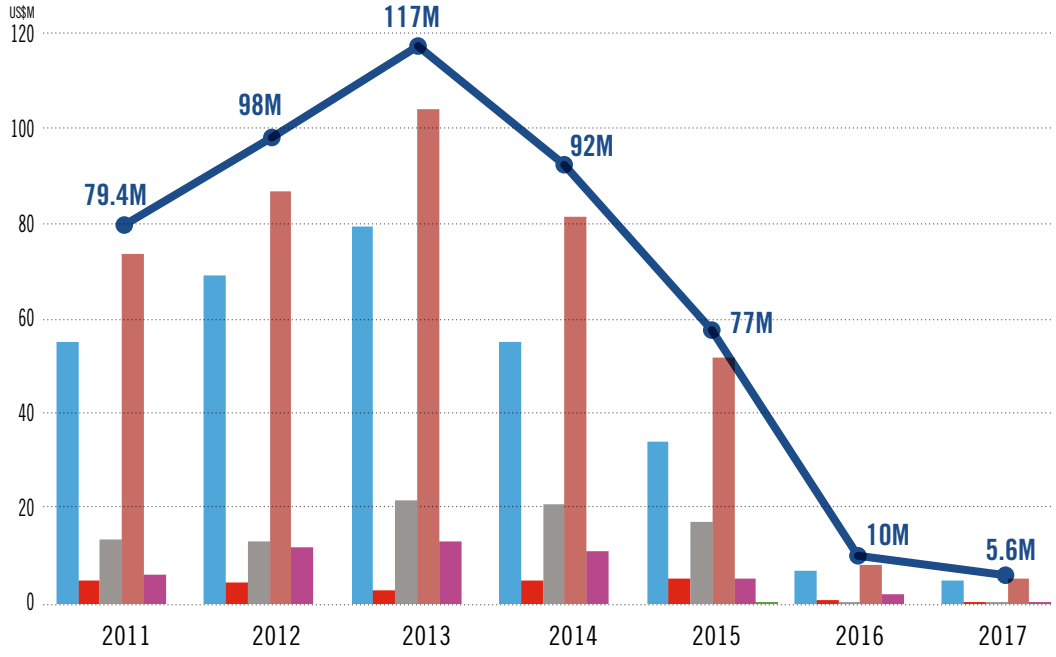
Implants present a longer-acting and more discreet mode of HIV prevention for individuals at high risk, particularly women. Although still early in the 'bench to bedside' continuum, one candidate proved effective in preclinical testing and is now being developed as a product to confer protection from HIV for one year. That candidate is the long-acting thin film biodegradable implant by developer RTI International, which safely biodegrades after releasing a steady dose of ARVs into the bloodstream[19]. Another innovation is the microarray or the microneedle patch currently under development by PATH. This adhesive patch contains micron-scale projections that painlessly pierce the skin for the intradermal delivery of long-acting cabotegravir (up to three months)[20].

4.0 Global investment in R&D related to treatment as prevention (TasP)

After a 45 percent decrease from 2016 levels, funding for TasP totaled US$5.6 million in 2017. Funding decreased across the board for sectors and countries alike, and the largest donor, the CDC, made up 86.7 percent of overall funding, at US$4.9 million *(Figure 26)*. The efficacy of TasP as an HIV prevention strategy has been proven in multiple large-scale trials, such as HPTN 052, PARTNER, Opposites Attract and PARTNER 2[21]. The success of this body of research likely explains the sharp decline in R&D investment for TasP since 2015.

FIGURE 26 **Investment in Treatment as Prevention by Sector, 2011-2017** (US$ millions)

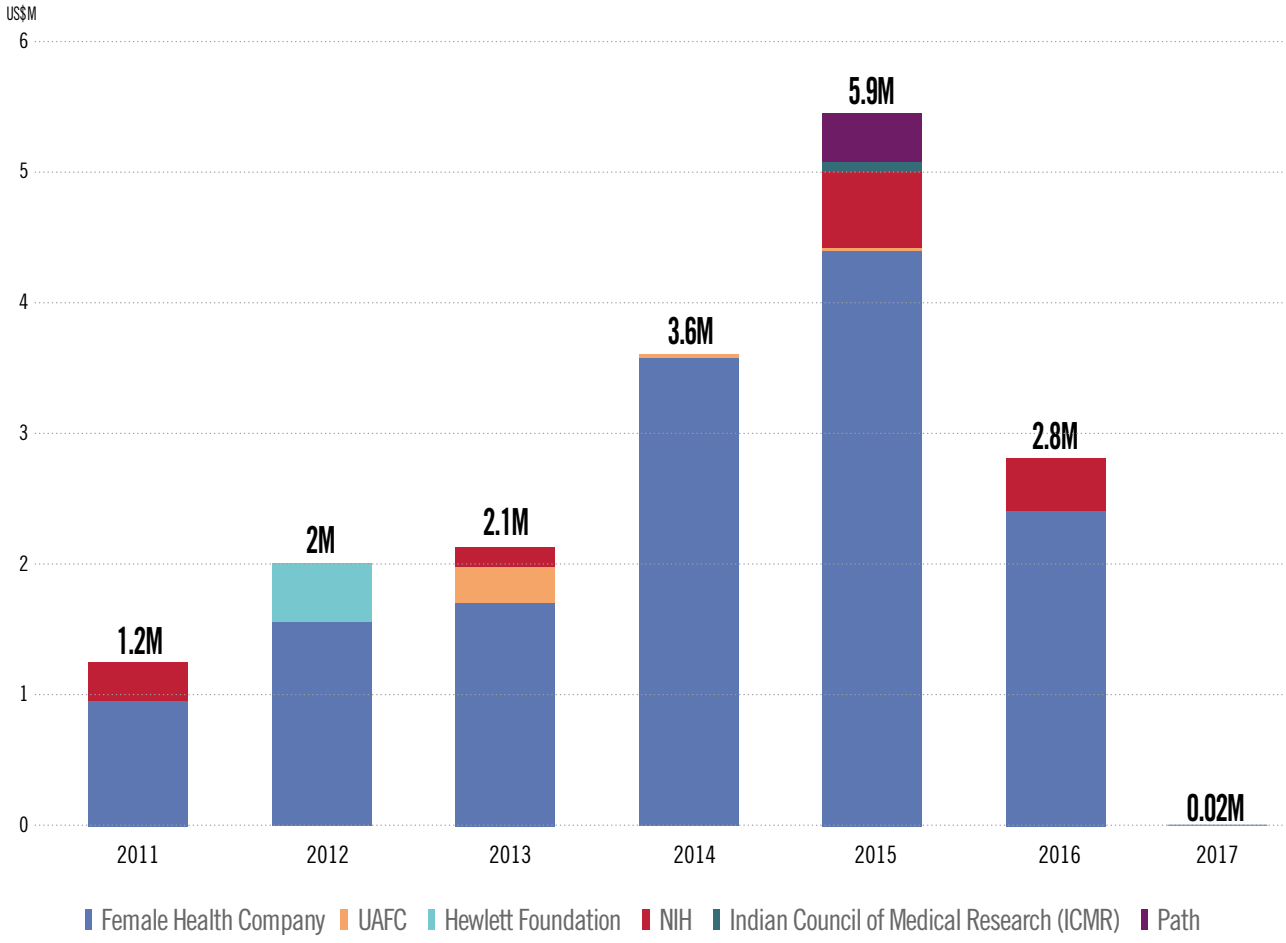
	2011	2012	2013	2014	2015	2016	2017
US	55	68.6	79	55	47	7	4.9
Europe	4.7	4.6	3	5	4.6	0.7	0.1
Other Countries	13.5	13	21.5	21	20	0.4	0.3
Total Public	73.2	86.2	103.5	81	71	8	5.3
Total Philanthropic	6.2	11.8	13.1	11	5.5	2	0.3
Total Commercial	–	–	–	–	<0.1	–	–
Total Global Investment	79.4	98	117	92	77	10	5.6



5.0 Global investment in female condom R&D

Investment in female condom research decreased by 99 percent in 2017, adding to the irregularity of the last two years of funding *(Figure 27)*. The Female Health Company, traditionally the preeminent sponsor of female condom research, did not report any relevant investments. The US public sector was the lone funder in 2017, with one disbursement amounting to US$0.02 million.

FIGURE 27 **Investments in the Female Condom, 2011-2017** (US$ millions)



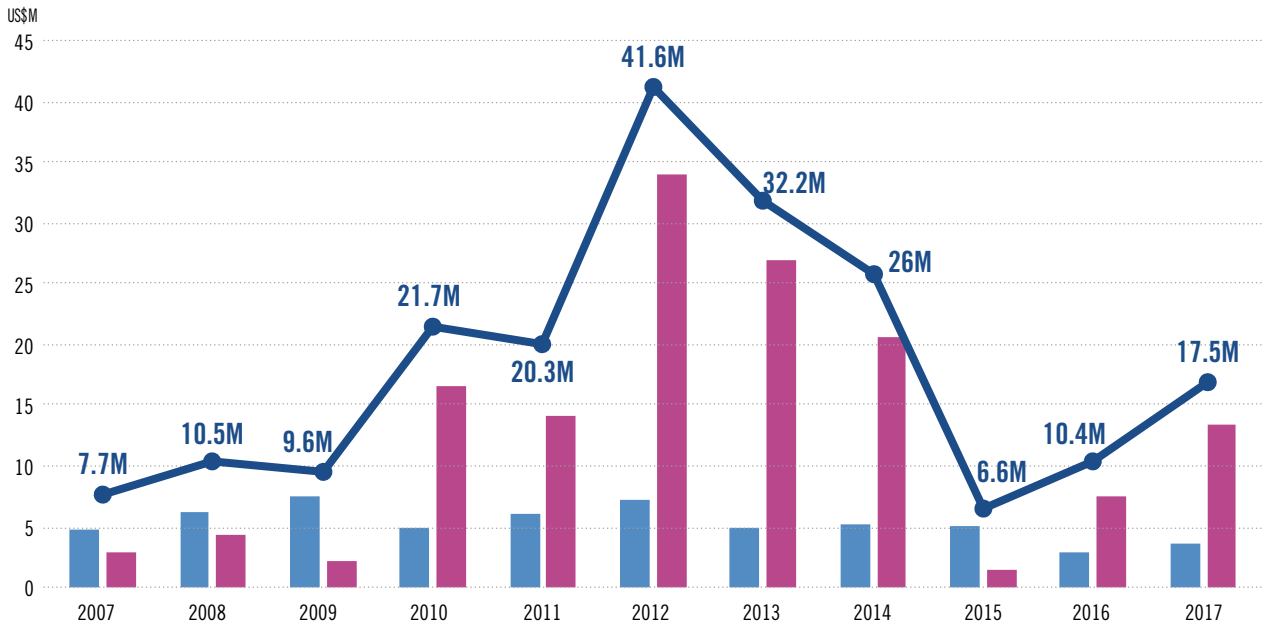
6.0 Global investment in the implementation of voluntary medical male circumcision (VMMC)

Investment in VMMC increased by 67 percent in 2017, from US$10.4 million to US$17.5 million *(Figure 28)*. As in 2016, the BMGF was the largest donor, at US$13.9 million or 79 percent of overall funding. The US public sector followed with funding worth US$3.4 million, with contributions from the CDC (US$1.6 million) and NIH (US$1.8 million).

Sufficient empirical studies have already affirmed the efficacy of VMMC as a prevention option, which is likely why 56 percent of the research is allocated to implementation science and the scale-up of services in underserved populations. Other areas of focus include social and behavioral studies (21 percent), clinical trials (14.4 percent) and advocacy and policy development (eight percent).

FIGURE 28 **Investment in Voluntary Medical Male Circumcision by Sector, 2007-2017** (US$ millions)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total Public	4.8	6.2	7.5	5	6.1	7.2	5	5.2	5.1	2.9	3.6
Total Philanthropic	2.9	4.3	2.1	16.7	14.2	34.4	27.2	20.8	1.4	7.5	13.9
Total Global Investment	7.7	10.5	9.6	21.7	20.3	41.6	32.2	26	6.6	10.4	17.5



7.0 Global investment in research related to the prevention of mother to child transmission (PMTCT)

Funding for PMTCT decreased by 12.8 percent in 2017, falling from US$41 million in 2016 to US$35.7 million *(Table 7)*. The majority of funding (over 98.8 percent) was derived from the public sector, with the US being the largest funder through the NIH, at the annual contribution of US$34.4 million. European funding decreased from US$0.96 million to US$0.57 million, while philanthropic investment was reduced by 77 percent, down to US$0.4 million.

TABLE 7 **Annual Investment in Prevention of Vertical Transmission by Sector, 2008-2017** (US$ millions)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
US	10.3	44.6	56.9	36.2	34.6	42	44.9	39.1	37.7	34.3
Europe	7.3	5.9	1.5	1.1	1.7	0.1	1.2	2.1	0.9	0.5
Other Countries	–	–	1.3	5.1	6.7	0.2	–	0.8	–	0.3
Total Public	17.6	50.5	59.7	42.6	42.9	42.4	46.6	41.3	39	35.3
Total Philanthropic	3.6	0.9	0	0.5	0.8	1.7	2.5	2.3	1.7	0.4
Total Commercial	0	0	0	0	0	0	0.5	0.5	–	–
Total Global Investment	**21.2**	**51.4**	**59.7**	**43.1**	**43.7**	**44.1**	**49**	**44.1**	**41**	**35.7**

8.0 Global investments in multipurpose prevention technology R&D

Multipurpose prevention technologies (MPTs) are products that simultaneously offer protection from unintended pregnancy and/or one or more sexually transmitted infections. Since 2013, the Working Group has collaborated with CAMI Health, Secretariat to the Initiative for MPTs (IMPT), to track the volume and annual trends in funding towards the advancement of MPT research. For this year's effort, data on grants for MPT R&D in 2017 was collected and analyzed, and 2016 funding levels revised based on retroactive reporting from some investors.

Investment in MPT R&D in 2016 was updated from the previously reported US$40 million to US$51.2 million. In 2017, overall investments totaled US$50.3 million, a 1.7 percent decrease from 2016 levels. The public sector accounted for half of overall funding at US$25.2 million, with the commercial sector close behind at 48 percent or US$24 million, and the philanthropic sector trailing at 2 percent or US$0.9 million *(Figure 29)*. The US public sector made up 99 percent of public sector investment at US$25 million, largely derived from grants by the predominant funders, NIH and USAID. European funding decreased by 20 percent, from US$1.5 million in 2016 to US$1.2 million (Figure 30). Philanthropic estimates signaled a 77 percent decrease from the past year, with the Bill and Melinda Gates Foundation decreasing investment from US$3.5 million to US$0.4 million. Commercial investment increased by 36 percent and amounted to US$24 million in 2017.

Recipients of public sector support for MPT R&D continue to be nonprofit entities such as CONRAD, Population Council, the International Partnership for Microbicides, and academic research groups, such as Boston University, Dartmouth College and the University of Louisville.

FIGURE 29 **Investment in MPT R&D by Sector, 2017**

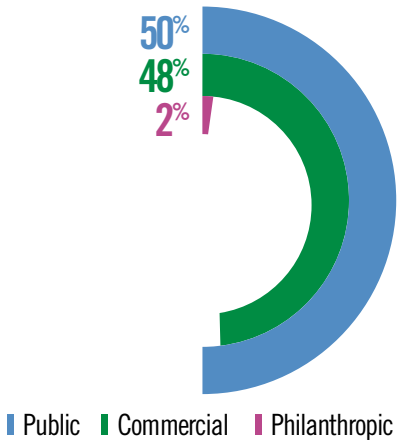
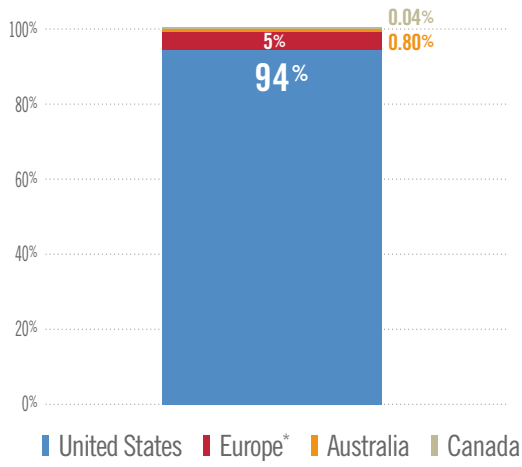


FIGURE 30 **Investment in in MPT R&D by Funder, 2017**



* European public-sector investments represent estimates.

9.0 Investment in cure and therapeutic vaccine R&D

The Working Group estimates that in 2017, US$288.8 million was invested in cure research, representing an 8% increase over the US$268 million invested in 2016, and an increase of 228% over the US$88.1 million invested in 2012. The majority of investments (US$272.4 million) came from the public sector with US$16.3 million invested by philanthropies such as Aidsfonds, amfAR, the Bill and Melinda Gates Foundation, CANFAR, the Campbell Foundation, the Fair Foundation and Sidaction. Despite outreach by the Working Group this year, few companies responded to the survey, whilst several companies are known to have active cure research programmes, resulting in a significant underestimation for commercial investment in cure research.

In 2017, the United States through the US National Institutes of Health contributed the majority of public funding, with France, Canada, the European Commission, Italy, the United Kingdom, Australia, the Netherlands, Switzerland, Germany and Cuba also being contributors to HIV cure research. The successful implementation of the Global Scientific Strategy plan will require improved international scientific collaborative research teams and institutions at the international level to ensure an optimal use of resources. Active initiatives include:

- **IAS Towards an HIV cure initiative**

  The revised IAS Global Scientific Strategy: Towards an HIV Cure 2016, published in Nature Medicine, was launched in Durban at the AIDS 2016 conference.

- **Martin Delaney Collaboratory**

  The National Institutes of Health has awarded $30 million in annual funding among six research collaborations working to advance basic medical science toward an HIV cure.

- **amfAR Countdown to a Cure for AIDS**

  amfAR focuses investments aimed at finding the scientific underpinnings of a cure by 2020.

Endnotes

[1] For the purposes of this report, the terms "research and development, or "R&D" and "research" are used interchangeably and all refer to the entire spectrum of research activities.

[2] See Appendix for more information.

[3] UNAIDS. *Miles To Go—Closing Gaps, Breaking Barriers, Righting Injustices.* Geneva; 2018. http://www.unaids.org/sites/default/files/media_asset/miles-to-go_en.pdf. Accessed September 25, 2018.

[4] Please refer to the Appendix for a comprehensive exploration of data collection methodology used and the associated limitations.

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Appendix: Methodology

This report was prepared by Fatima Riaz (AVAC), with contributions from Kevin Fisher (AVAC), Jennifer Maple (IAVI), UNAIDS staff and Mitchell Warren (AVAC) of the Resource Tracking for HIV Research and Development Working Group (herein referred to as "the Working Group"), with contributions from Emily Hayman. The Working Group developed and has utilized a systematic approach to data collection and collation since 2004. These methods were employed to generate the estimates of funding for R&D presented in this report. A detailed explanation of the methodology can be found on the Working Group website (www.hivresourcetracking.org). Categories used to describe different R&D activities—one for AIDS vaccines and one for HIV microbicides—were derived from those developed by the US NIH and are shown in the following tables.

TABLE 8 Public, Philanthropic and Commercial Sector Primary Funders

Total responders: 70	
Sector	**Type of Responders**
Public	• National governments (including government research bodies, international development assistance agencies and other government funding agencies) • European Commission • Multilateral agencies
Philanthropic	• Private, not-for-profit organizations (e.g., foundations, trusts and non-governmental organizations) • Charities • Corporate donations
Commercial	• Pharmaceutical companies • Biotechnology companies

Data Collection Methods and Fluctuation in Investment Levels

HIV prevention R&D investment figures are collected annually by the Resource Tracking for HIV Prevention R&D Working Group through an email survey. For the present report, the Working Group reached out from February to August 2018 to 215 funders in the public, philanthropic and commercial sectors and collected information on investments that the Group then allocated to HIV prevention R&D.

Two different types of resource flows were tracked: investments, defined as annual disbursements by funders; and, when available, expenditures, defined as the level of resources directly spent on R&D activities by funding recipients in a particular year. The main reasons for differentiating between these two resource flows were: (1) some funders may forward fund (i.e., disburse funding in one year to be expended over multiple years); (2) research projects may be delayed and (3) entities such as the increasingly important product development public-private partnerships (PDPs) often receive funds in one year but expend them over a period of time or may hold funds to sustain multiyear contracts. Investment figures were based on estimates of the level of funds disbursed each year and generated from the perspective of the funder. As such, funds were allocated to the year in which they were disbursed by the donor, irrespective of whether the funds were expended by the recipient in that year or in future years.

In order to minimize double-counting, the Working Group distinguished between primary funders and intermediary organizations. "Intermediary" organizations receive resources from multiple funders and use these resources to fund their own work as well as the work of others. All identified primary funders were categorized as public, (such as government research bodies, international development agencies and multilaterals), philanthropic, (such as foundations, charities and corporate donors) or commercial, (pharmaceutical and biotechnology companies) sector funders.

While limitations exist in developing a method for breaking down funding allocations by type of activity or stage of product development, the Working Group allocates resources into categories based on NIH definitions. As the largest funder of HIV prevention R&D and thus, with the majority of grants toward HIV prevention research allocated based on NIH definitions, this allows for the most accurate possible analysis of the largest portion of grants. For grants received outside of NIH funding, the allocation of funding was based on the information provided by the intermediaries or funders. When this information was not available, the Working Group reviewed the descriptions of the projects funded and, based on the description of each project, allocated the funds across the expenditure categories.

All figures in the report are given in current US dollars and have not been adjusted for inflation. Funding information in other currencies was converted into US dollars using the appropriate International Monetary Fund (IMF) annual average exchange rate for July 1, 2017, except for those funds where we had access to the actual rate received.

Every effort was made to obtain a comprehensive set of data that was comparable across organizations and countries. However, the data presented in this report are subject to a number of limitations:

- Requests for information were directed to all public, philanthropic and commercial organizations identified as providing funding for HIV prevention R&D. However, not all entities contacted responded or provided financial information with their response. For the private sector, annual investments and funding estimates were extrapolated based on qualitative data collection on R&D programs and expert opinions.
- The Working Group provides R&D allocation definitions in the survey sent to funders. However, most funders and intermediary organizations do not break down their expenditures and investments by type of activity or stage of product development, and definitions often vary among funders.
- The Working Group attempted to reduce the potential for double-counting and to distinguish between funders and recipients of funding. However, all financial information is "self-reported" by organizations and not independently verified.

Data Collection Categories:

- Preventive AIDS vaccines
- Microbicides
- Multipurpose prevention technologies
- Pre-exposure prophylaxis (PrEP)
- Treatment as prevention
- Male circumcision
- Female condom
- Prevention of vertical transmission
- HIV cure
- Therapeutic AIDS vaccines

Preventive and therapeutic AIDS vaccine R&D	
Category	**Definition**
Basic research	Studies to increase scientific knowledge through research on protective immune responses and host defenses against HIV.
Preclinical research	Efforts to improve preventive AIDS vaccine design, development and animal testing.
Clinical trials	Support for Phase I, II and III trials (including the costs of candidate products).
Cohort and site development	Support to identify trial sites, build capacity, ensure adequate performance of trials and address the prevention needs of the trial communities.
Advocacy and policy development	Education and mobilization of public and political support for preventive AIDS vaccines and the targeting of potential regulatory, financial, infrastructural or political barriers to their rapid development and use.

Microbicides R&D	
Category	**Definition**
Basic mechanisms of mucosal transmission	Elucidate basic mechanisms of HIV transmission at mucosal/epithelial surfaces.
Discovery, development and preclinical testing	Target R&D efforts at the discovery, development and pre-clinical evaluation of topical microbicides alone and or in combination.
Formulations and modes of delivery	Develop and assess acceptable formulations and modes of delivery for microbicides.
Clinical trials	Support for Phase I, II and III trials of candidate microbicides for safety, acceptability and effectiveness (including costs of candidate products).
Behavioral and social science research	Conduct applied behavioral and social science research to inform and optimize microbicide development, testing and acceptability and use.
Microbicide research infrastructure	Establish and maintain the appropriate infrastructure (including training) needed to conduct research.
Advocacy and policy development	Education and mobilization of public and political support for microbicides, and the targeting of potential regulatory, financial, infrastructural or political barriers to their rapid development.

Other prevention tools: male circumcision, treatment as prevention, treatment of herpes simplex virus type 2 (HSV-2), cervical barriers and pre-exposure prophylaxis (PrEP)	
Category	**Definition**
Basic research	Studies to increase scientific knowledge through research on protective immune responses and host defenses against HIV.
Preclinical research	Efforts to improve design, development and animal testing of experimental interventions.
Clinical trials	Support for Phase I, II and III trials (including the costs of candidate products).
Cohort and site development	Support to identify trials sites, build capacity, ensure adequate performance of trials and address the prevention needs of the trial communities.
Advocacy and policy development	Education and mobilization of public and political support for new HIV prevention tools and the targeting of potential regulatory, financial, infrastructural or political barriers to their rapid development and use.

Definitions	
Category	**Definition**
Treatment as prevention research	Research evaluating the impact of early/expanded ART (at any CD4 count), ART initiation strategies (e.g., Seek, Test, Treat and Retain) or ART adherence strategies on HIV incidence, HIV transmission risk, HIV risk behavior and/or community viral load; and impact of ART at CD4 count ≥ 350 cells/mm3 on HIV and/or TB-related morbidity and mortality or HIV transmission.
Multipurpose Prevention Technologies (MPTs)	Combine protection to prevent at least two sexual and reproductive health risks: unintended pregnancy and HIV and other sexually transmitted infections (STIs). Indications of interest include: • HIV • HSV • Pregnancy • Bacterial Vaginosis (BV) • Chlamydia • Gonorrhea • Hepatitis • HPV • Syphilis • Trichomoniasis • Urinary Tract Infections (UTI) • Other STIs
Cure research	Research conducted on viral latency, elimination of viral reservoirs, immune system and other biological approaches, as well as therapeutic strategies that may lead to either a functional (control of virus rather than elimination, without requirement for therapy) or sterilizing (permanent remission in absence of requirement for therapy) cure of HIV infection.

Toward a Cure Program Definition: US NIH eradication of viral reservoirs

Research conducted on viral latency, elimination of viral reservoirs, immune system and other biological approaches, as well as therapeutic strategies that may lead to either a functional (control of virus rather than elimination, without requirement for therapy) or sterilizing (permanent remission in absence of requirement for therapy) cure of HIV infection.

Pathogenesis studies

Basic research on viral reservoirs, viral latency and viral persistence, including studies on genetic factors associated with reactivation of the virus, and other barriers to HIV eradication.

Animal models

Identification and testing of various animal and cellular models to mimic the establishment and maintenance of viral reservoirs. These studies are critical for testing novel or unique strategies for HIV reactivation and eradication.

Drug development and preclinical testing

Programs to develop and preclinically test new and better antiretroviral compounds capable of entering viral reservoirs, including the central nervous system.

Clinical trials

Studies to evaluate lead compounds, drug regimens and immune-based strategies capable of a sustained response to HIV, including clinical studies of drugs and novel approaches capable of eradicating HIV-infected cells and tissues.

Therapeutic vaccines

Design and testing of vaccines thatwould be capable of suppressing viral replication and preventing disease progression.

Adherence/compliance

Development and testing of strategies to maintain adherence/compliance to treatment, in order to improve treatment outcomes and reduce the risk of developing HIV drug resistance.

Appendix: List of acronyms

amfAR	The Foundation for AIDS Research
ANRS	National Agency for Research on AIDS and Viral Hepatitis (France)
ARC	Australian Research Council
ART	Anti-retroviral therapy
ARV	Anti-retroviral
ASPIRE	A Study to Prevent Infection with a Ring for Extended Use
BMGF	Bill & Melinda Gates Foundation
BMS	Bristol-Meyers Squibb
bNAB	Broadly neutralizing antibody
BV	Bacterial vaginosis
CANFAR	Canadian Foundation for AIDS Research
CDC	US Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness
CHVI	Canadian HIV Vaccine Initiative
CIDA	Canadian International Development Agency
CIHR	Canadian Institutes of Health Research
COP	Country Operational Plan
CROI	Conference on Retroviruses and Opportunistic Infections
DAH	Development assistance for health
DANIDA	Danish International Development Agency
DBT	Department of Biotechnology at India's Ministry of Science and Technology
DFID	UK Department for International Development
DIB	Development Impact Bond
DOH	Department of Health
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women
DST	Department of Science and Technology, South Africa
EAVI2020	European AIDS Vaccine Initiative
EC	European Commission
ECHO	Evidence for Contraceptive Options and HIV Outcomes
EDCTP	European and Developing Countries Clinical Trials Partnership
EHVA	European HIV Vaccine Alliance
EIMC	Early infant male circumcision
FDA	US Food and Drug Administration
FRESH	Females Rising through Education, Support, and Health
FSW	Female sex workers
GIS	Geographic information systems
GSK	Glaxo SmithKline
HOPE	HIV Open-label Prevention extension trial
HPTN	HIV Prevention Trials Network
HPV	Human papillomavirus
HSV	Herpes simplex virus
HVTN	HIV Vaccine Trials Network
IAS	International AIDS Society
IAVI	International AIDS Vaccine Initiative
ICMR	Indian Council of Medical Research
IHME	Institute for Health Metrics and Evaluation
IMF	International Monetary Fund
IMPT	Initiative for Multipurpose Prevention Technologies
IPM	International Partnership for Microbicides
KP	Key population
LAI	Long-acting injectable
LMIC	Lower-middle-income country
MDG	Millennium Development Goal
MHRP	US Military HIV Research Program
MPT	Multipurpose prevention technology
MRC	UK Medical Research Council
MSM	Men who have sex with men
MTN	Microbicide Trials Network
NEMAPP	National Evaluation of Malawi's PMTCT programme
NHMRC	Australian National Health & Medical Research Council
NIAID	US National Institute of Allergy and Infectious Diseases
NIH	US National Institutes of Health
Norad	Norwegian Agency for Development Cooperation
OAR	US NIH Office of AIDS Research
ODA	Official Development Assistance
OECD	Organisation for Economic Co-operation and Development
OFID	OPEC Fund for International Development
OHTN	Ontario HIV Treatment Network
OPEC	Organization of the Petroleum Exporting Countries
P5	Pox-Protein Public-Private Partnership
PDP	Product development partnership
PEPFAR	US President's Emergency Plan for AIDS Relief
PHAC	Public Health Agency of Canada
PMTCT	Prevention of vertical transmission
POWER	Prevention Options for Women's Evaluation Research
PrEP	Pre-exposure prophylaxis
R&D	Research & development
SA DOH	South African Department of Health
SDG	Sustainable Development Goal
SIDA	Swedish Agency for International Cooperation Development
SIDACTION	Association de lutte contre le sida
SNSF	Swiss National Science Foundation
START	Strategic Timing of AntiRetroviral Treatment study
TasP	Treatment as prevention
TDF	Tenofovir
TDF/FTC	Tenofovir/Emtricitabine
TEMPRANO	A Trial of Early Antiretrovirals and Isoniazid Preventive Therapy in Africa
TPP	Target Product Profiles
UAFC	Universal Access to Female Condoms Joint Programme
UK	United Kingdom
UMIC	Upper-middle-income country
UNAIDS	Joint United Nations Programme on HIV/AIDS
US	United States
USAID	US Agency for International Development
USD	United States dollar
UTI	Urinary tract infections
VMMC	Voluntary Medical Male Circumcision
VOICE	Vaginal and Oral Interventions to Control the Epidemic
VRC	US Vaccine Research Center
WHO	World Health Organization

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To order copies of this report, please contact the Secretariat of the Working Group:

AVAC
423 West 127th Street, 4th Floor
New York, NY 10027, USA
Telephone: +1 646 369 1458
Email: *avac@avac.org*
www.avac.org

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