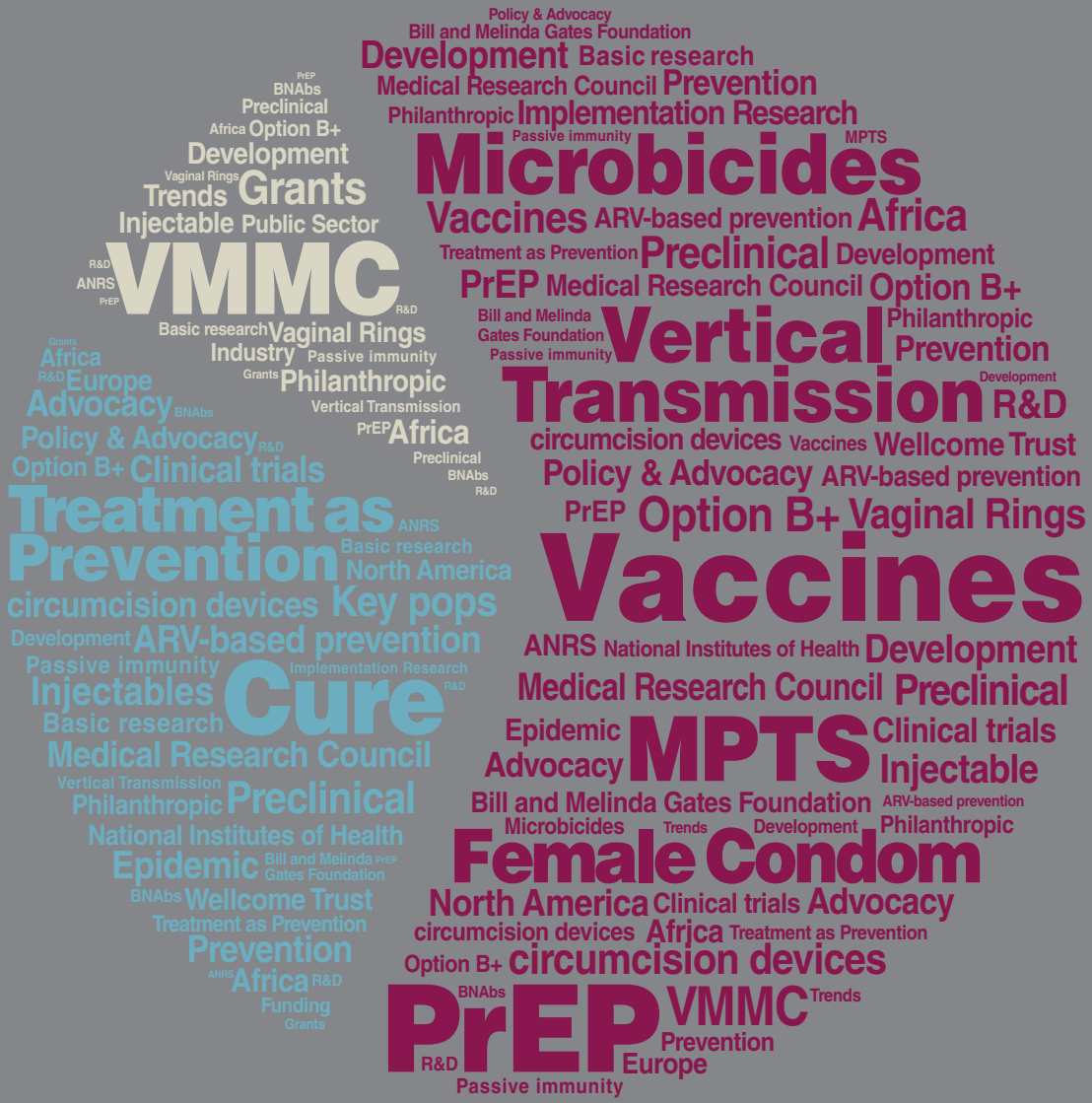
HIV Prevention Research & Development Investments 2000–2016

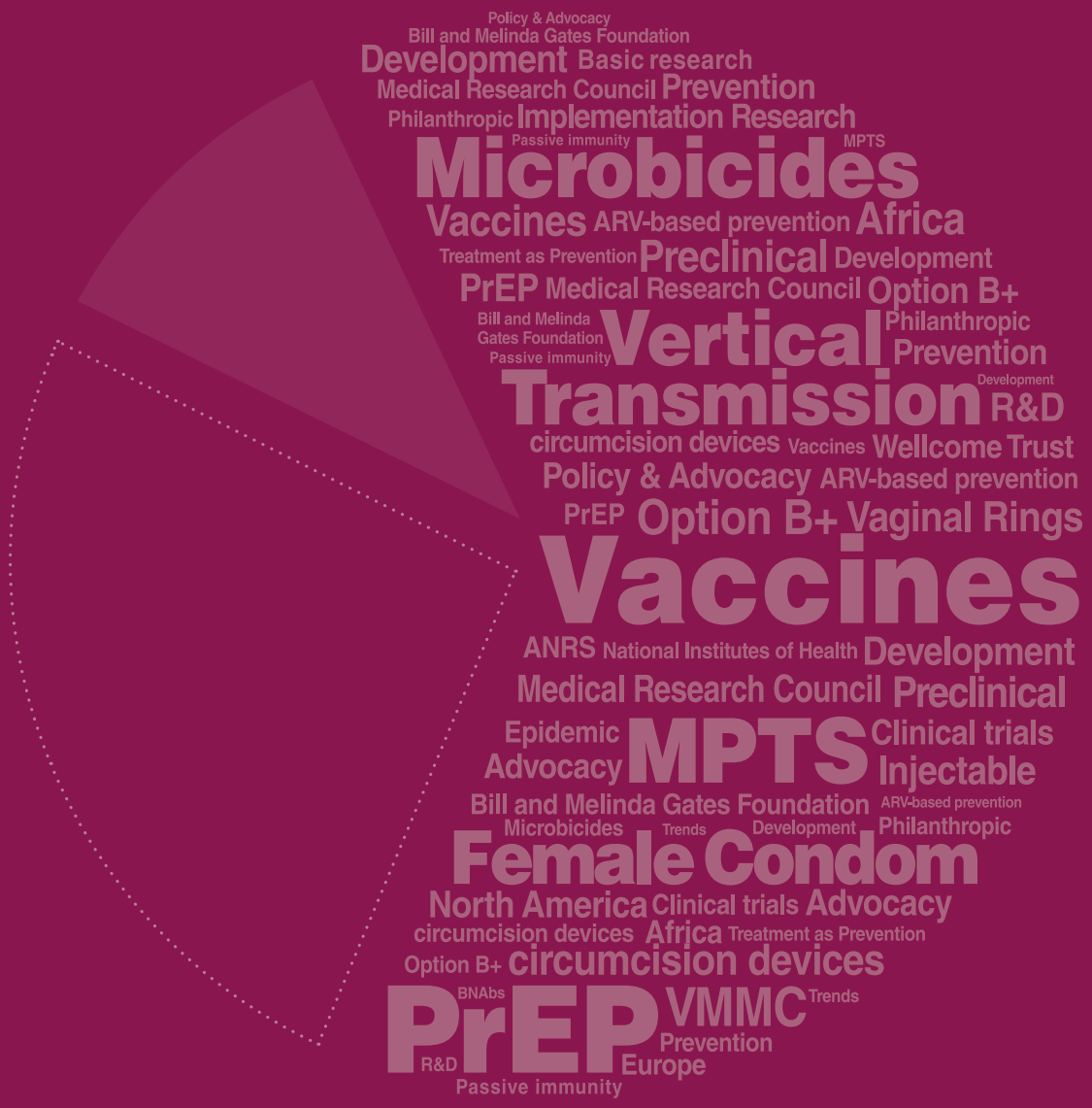
Investment priorities to fund innovation in a challenging global health landscape



RESOURCE TRACKING
FOR HIV PREVENTION
RESEARCH & DEVELOPMENT

HIV Prevention Research & Development Investments, 2000–2016

Investment priorities to fund innovation in a challenging global health landscape



Resource Tracking for HIV Prevention Research & Development

JULY 2017

Table of Contents

FIGURES

TABLES

BOXES

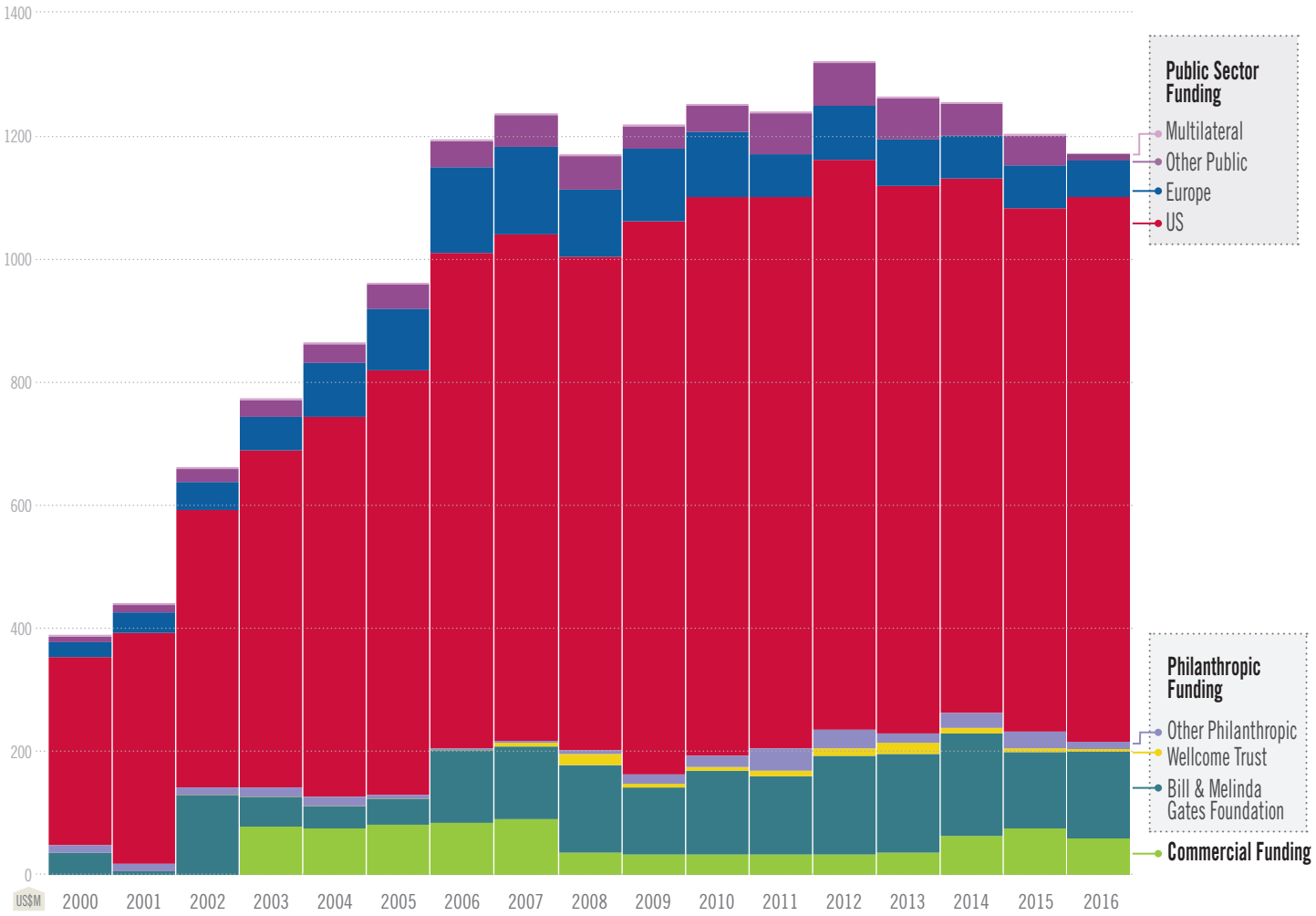
Introduction

In its 13th annual report, the Resource Tracking for HIV Prevention Research & Development Working Group ("Working Group") documents research and development spending for the calendar year 2016 and analyzes funding trends spanning 16 years.

Between 2000 and 2016, the Working Group has tracked over US$17 billion in investment towards biomedical HIV prevention research and development (R&D[1]) *(Figure 1)*. The 2016 report analyzes over 600 donor-identified disbursements, as well as R&D spending trends for the following prevention options: AIDS vaccines, microbicides, pre-exposure prophylaxis (PrEP), treatment as prevention (TasP), medical male circumcision (VMMC), female condoms, prevention of vertical transmission (PMTCT) and HSV-2 vaccines. Cure research and therapeutic vaccine investments were also tracked as part of a comprehensive analysis of the HIV R&D landscape[2].

In a constantly evolving field, the Working Group estimates serve as a comparative cross-sectional and retrospective analysis of interventions, funding sources and strategies to evaluate the impact of public policies and to provide support for advocacy. This work also provides the transparency needed for funders, policy makers and HIV/AIDS advocates to best understand HIV prevention R&D investment flows and to generate strategies for the future.

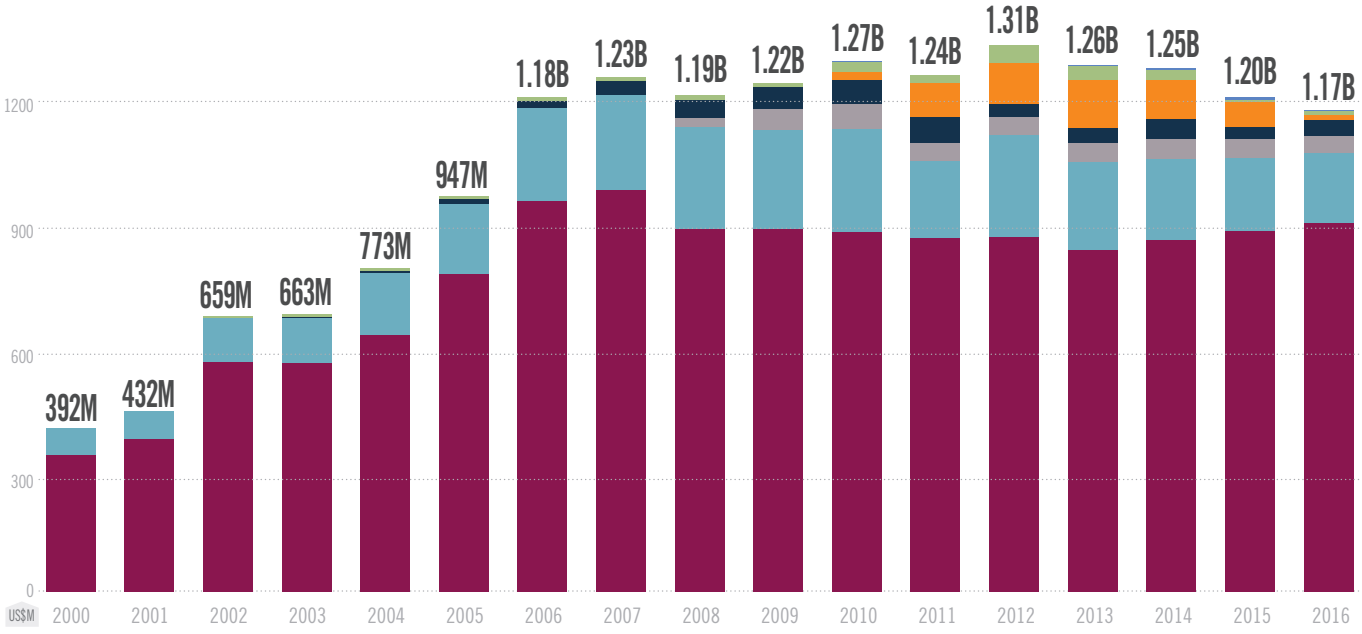
FIGURE 1 **Global Funding Sources for HIV Prevention R&D, 2000-2016** (US$ millions)



Trends in HIV Prevention Research and Development

- In 2016, funding for HIV prevention R&D decreased by 3 percent (US$35 million) from the previous year, falling to US$1.17 billion. Overall funding in the last ten years averaged US$1.23 billion annually with a high of US$1.31 billion in 2012 and a low of US$1.17 billion in 2016 *(Figure 2)*. It is worth noting that funding in 2016 signals the lowest annual investment in HIV prevention R&D in more than a decade. Investment varied further by technology category: funding increased for research into preventive vaccines, PrEP and VMMC, while TasP, microbicides, female condoms and PMTCT saw a decline from 2015 levels *(Figure 3)*.
- Mirroring past trends, the public sector made up the bulk of total 2016 funding at US$953 million (81 percent), with the lion's share coming from the US public sector at US$881 million (75 percent). The European public sector contributed US$59 million (5 percent), and investments from other countries came in at US$12 million, or one percent of the overall funding *(Figure 4)*. Philanthropic investment held steady at US$157 million (13.6 percent), and the commercial sector contributed US$56 million (5 percent).

FIGURE 2 **Global HIV Prevention R&D Investment by Technology Category, 2000-2016** (US$ millions)



Preventive vaccines	Microbicides	Prevention of vertical transmission	Pre-exposure prophylaxis	Treatment as prevention	Voluntary medical male circumcision	Female Condoms
894 US$ MILLION	167 US$ MILLION	41 US$ MILLION	40.5 US$ MILLION	10.3 US$ MILLION	10.4 US$ MILLION	2.8 US$ MILLION

[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, 2015-2016**

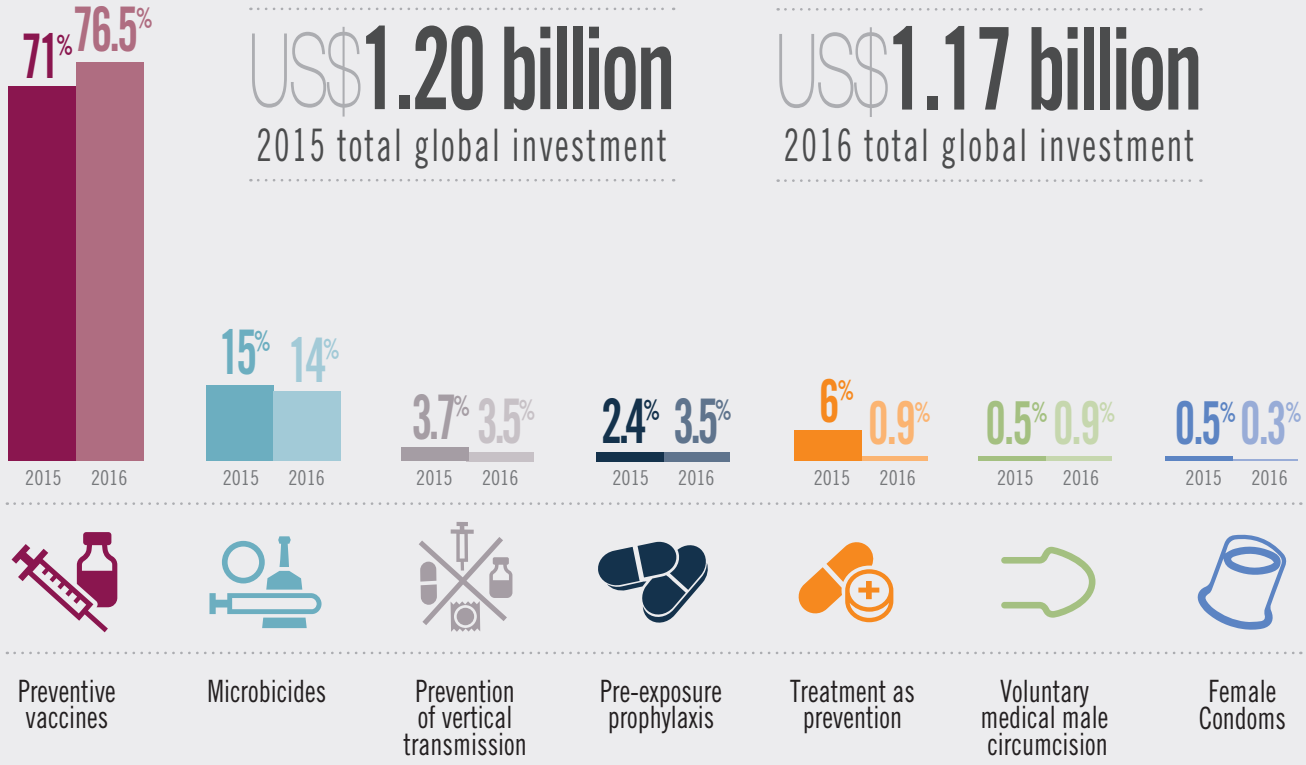
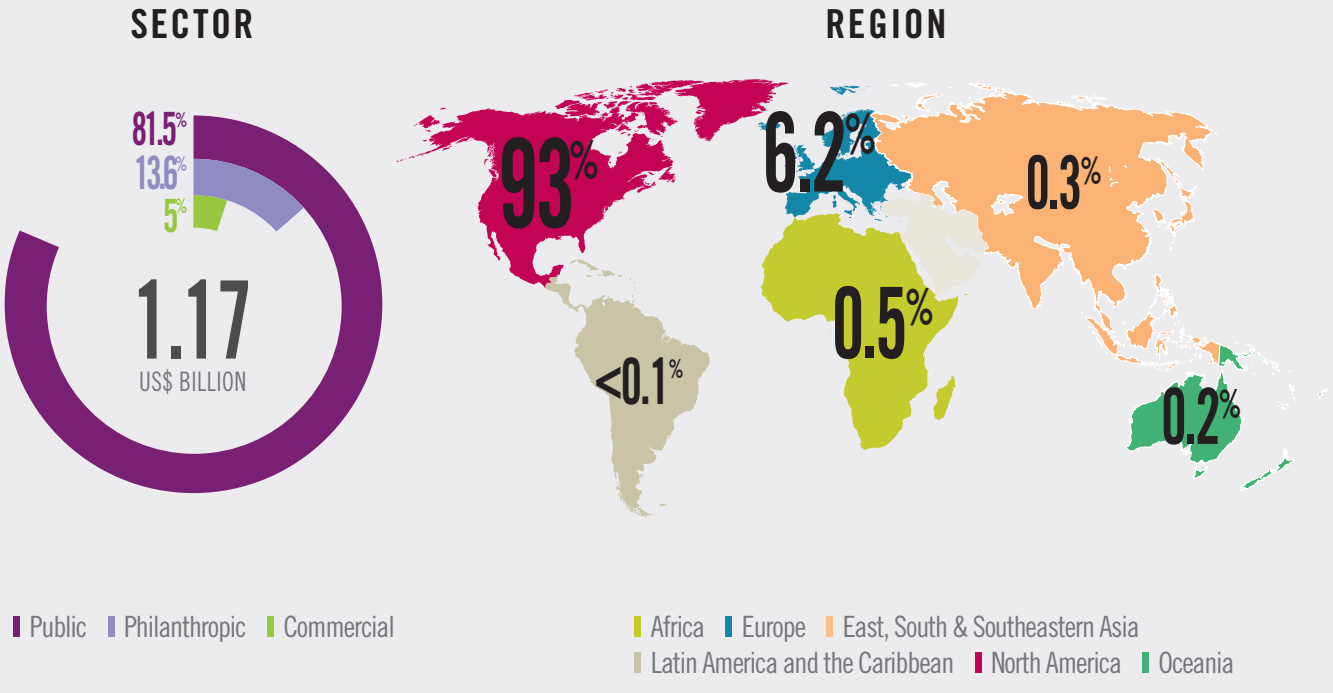


FIGURE 4 **Total Global HIV Prevention R&D Investment by Sector and Region, 2016**



- US public sector investment increased by 3.6 percent in 2016, from US$850 million to US$881 million. This is largely due to the four percent increase in US National Institutes of Health (NIH) funding, which gave HIV prevention R&D an additional US$32 million from 2015. While US public funding for preventive vaccines and PrEP increased by 12 percent and 24 percent, respectively, contributions to all other technology options tracked by the Working Group declined *(Figure 5)*.

FIGURE 5A **US Public Sector Investment in HIV Prevention R&D, Compared to All Other Funding, 2012-2016** (US$ billions)

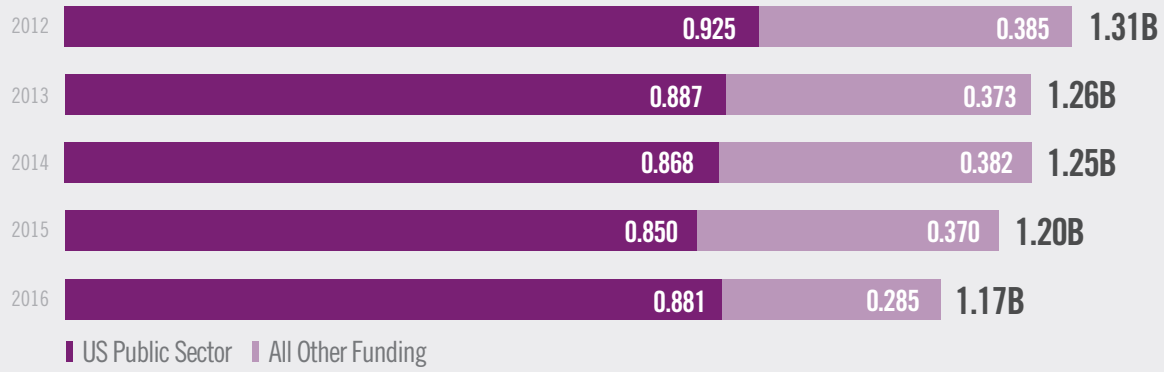
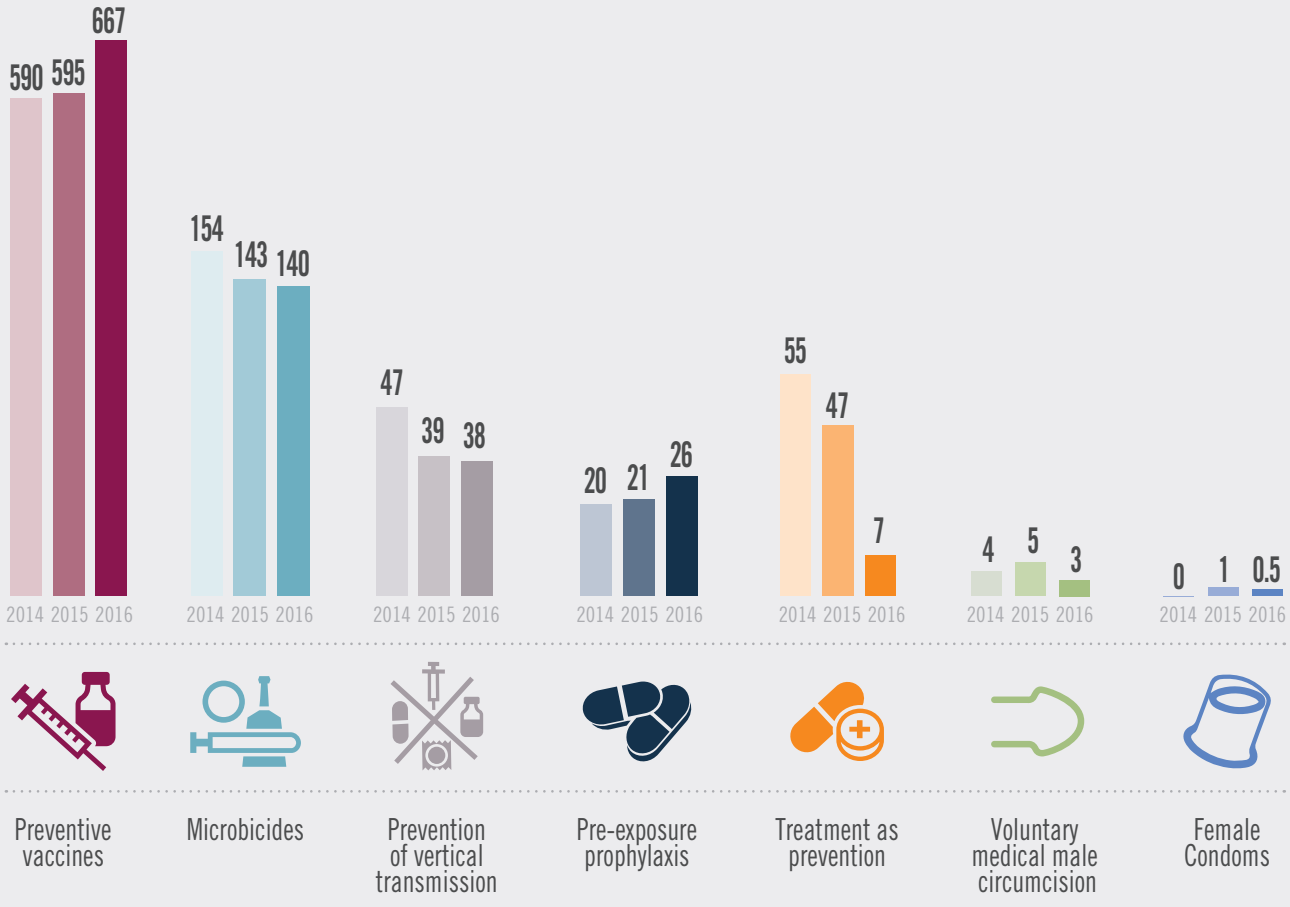


FIGURE 5B **US Public Sector Investment in HIV Prevention R&D, by Technology, 2014-2016** (US$ millions)



- European public sector funding decreased by US$10 million from last year, and at US$59 million, it accounted for 6 percent of all public-sector investment[3]. This is the lowest European funding recorded in the last decade and is a 52 percent decrease from peak funding (US$124 million) in 2009. Excluding PrEP, which had a modest increase of US$0.8 million, European public investment in preventive vaccines, microbicides, PMTCT and TasP declined by 12 percent, 6 percent, 40 percent and 85 percent, respectively. Furthermore, European funding for female condoms and VMMC zeroed out in 2016 *(Figure 6)*.

FIGURE 6A **European Public Sector Investment in HIV Prevention R&D, Compared to All Other Funding, 2012-2016** (US$ billions)

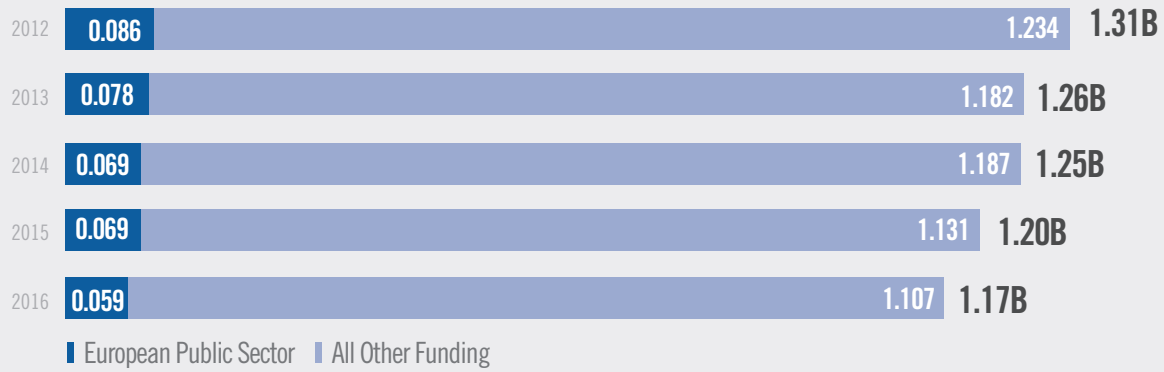
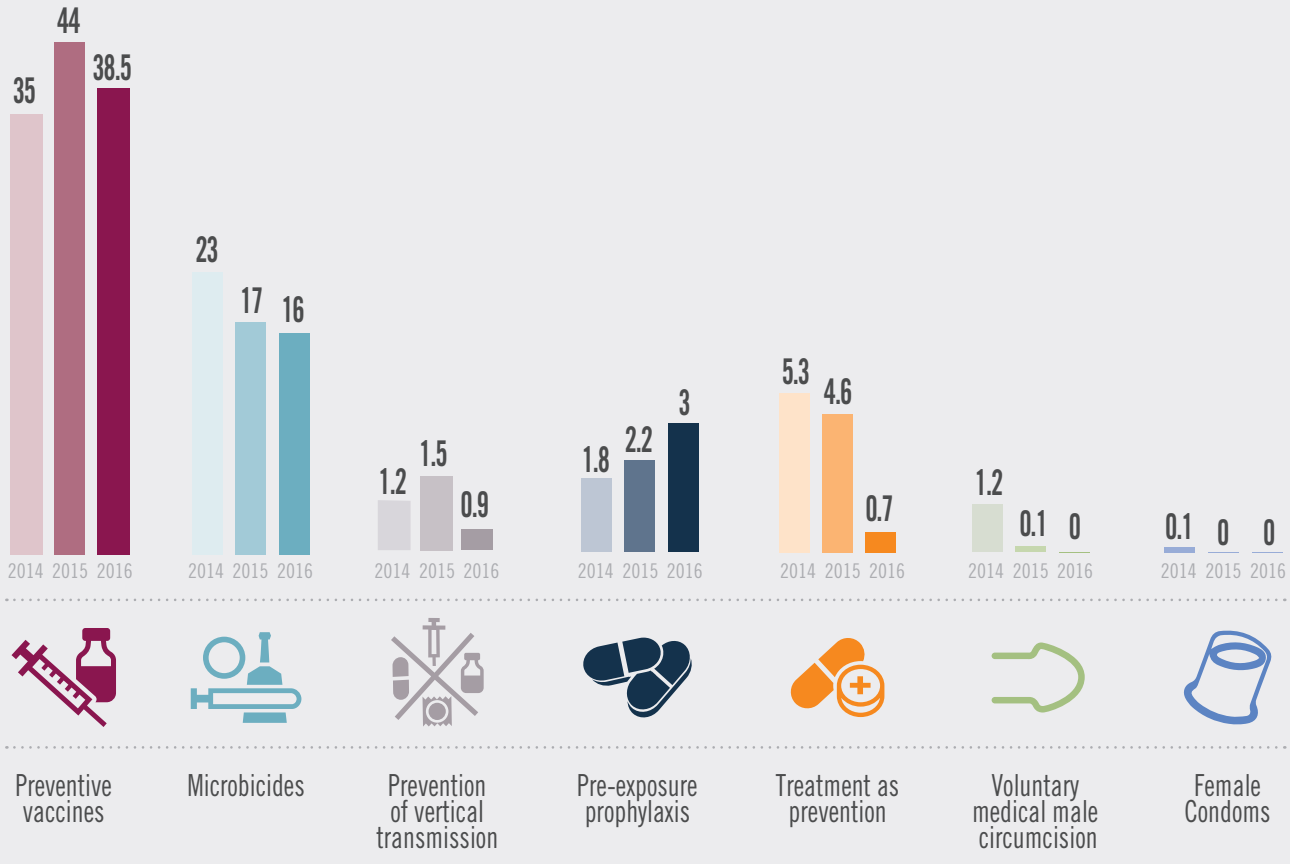


FIGURE 6B **European Public Sector Investment in HIV Prevention R&D, by Technology, 2014-2016** (US$ millions)



- In 2016, total philanthropic investment amounted to US$157 million, or 13.6 percent of the overall funding. Compared to the prior year, philanthropic support essentially flat-funded. The Bill and Melinda Gates Foundation (BMGF) remained the largest funder and increased its contribution by 12 percent, to US$141 million *(Figure 7)*. Wellcome Trust investment fell for the fourth consecutive year as it committed half of the amount that it contributed in 2015 (down from US$6 million to US$3 million).

FIGURE 7A **Investment in R&D Prevention by Top Philanthropic Funders, 2016** (US$ millions)

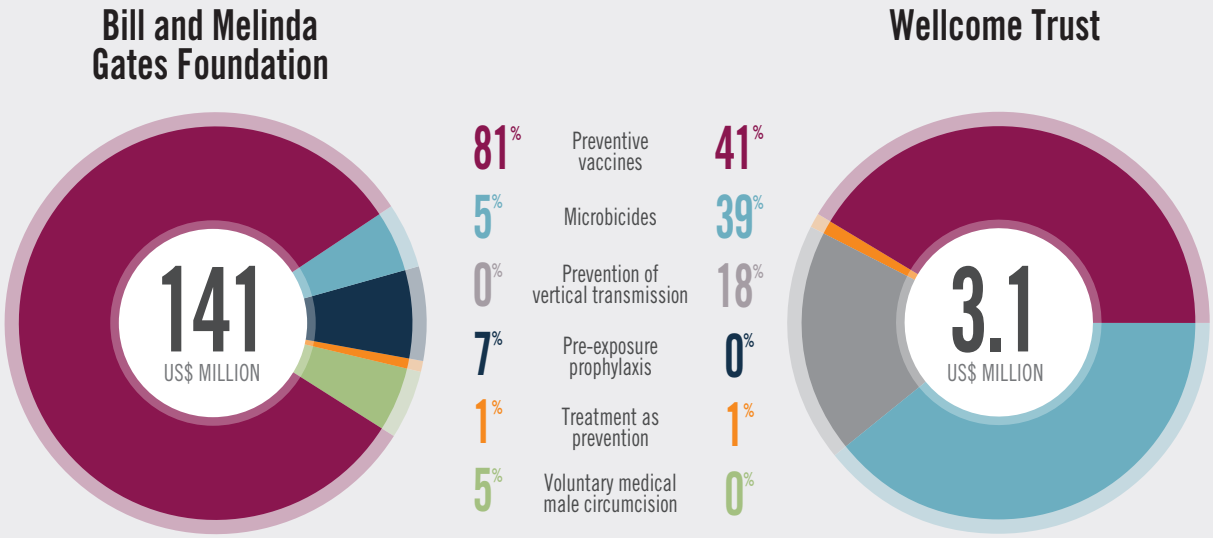
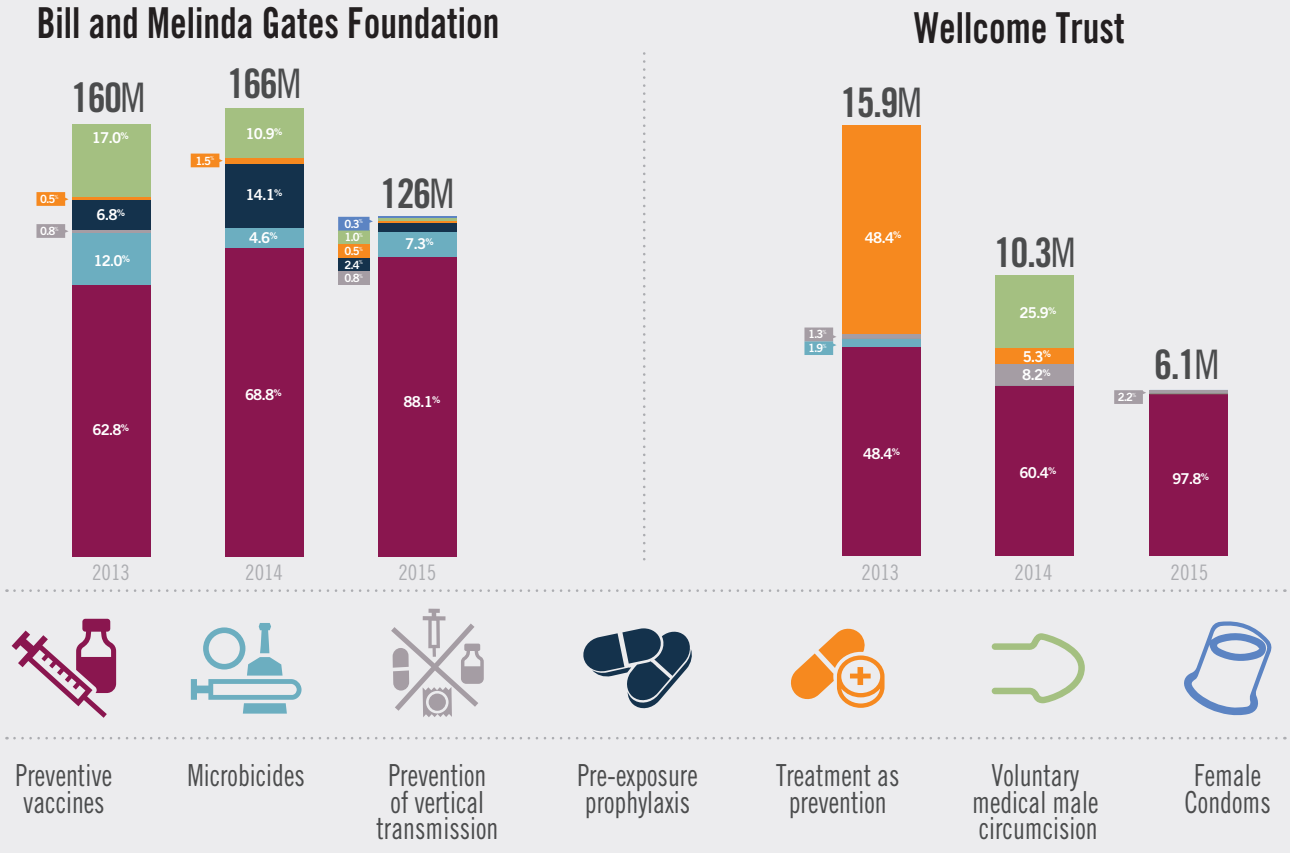


FIGURE 7B **Investment in R&D Prevention by Top Philanthropic Funders, 2013-2015** (US$ millions)

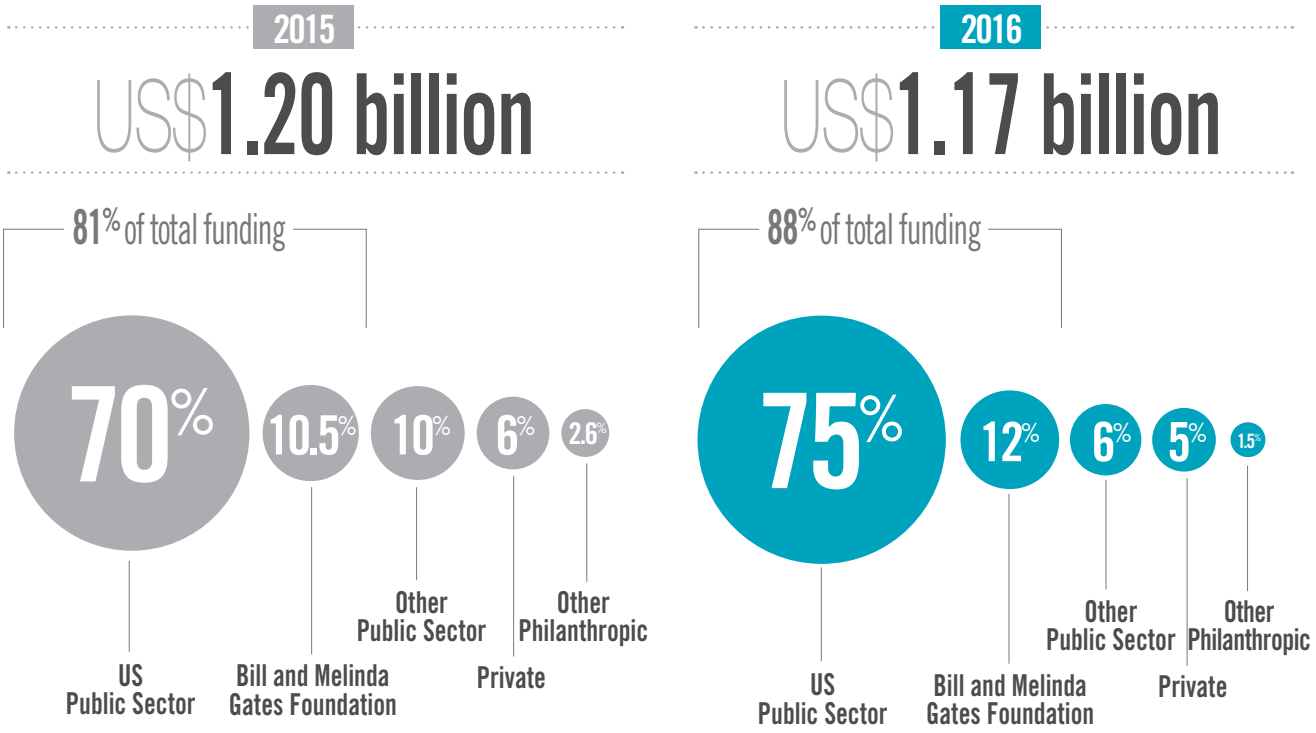


Key Findings

Intensifying trend towards a small number of large investors

The call for a more diverse base of funders in the prevention R&D landscape is not a new one, but recent trends display greater polarization and a more extreme funding imbalance. In 2016, 75 percent of the overall funding (US$881 million out of US$1.17 billion) came from the US public sector- an increase of five percent from 2015 *(Figure 8)*. Moreover, 89 percent of philanthropic funding in 2016 was from one principal donor: The Bill and Melinda Gates Foundation, up notably from 2015 when BMGF contributed roughly 80 percent of overall philanthropic investment. Together, the US public sector and the BMGF represented 88% of the total global investment in 2016, compared to 81% in 2015. Simply put, for every dollar spent on HIV prevention R&D in 2016, 88 cents came from just two donors. This highlights the urgency of expanding the roster of funders to ensure sustainability and consistency of R&D financing, and buffering any reallocation or reduction of investments from principal donors.

FIGURE 8 **Composition of the Global HIV Prevention R&D Investment Base, 2015-2016**



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

Diminished funding beyond the US public sector

In 2015, public sector investments outside the US had amounted to US$119 million, accounting for 10% of total funding for that calendar year *(Figure 9)*. However, this number reduced to US$71 million in 2016, with 16 countries representing only six percent of the overall funding. This is partly attributable to the 47 percent decrease in European Commission funding (down from US$27 million to US$14 million), and partly to the decline in Canadian investment in HIV prevention R&D, from US$26.8 million to US$2.6 million. Compared to 2015 levels, Australia, Brazil, India and Japan reduced funding by 42 percent, 50 percent, 74 percent and 42 percent, respectively *(Figure 10)*; declines that may at least partially reflect changes in grants and funding cycles.

FIGURE 9 **Top Countries Investing in HIV Prevention R&D, 2015-2016** (US$ millions)

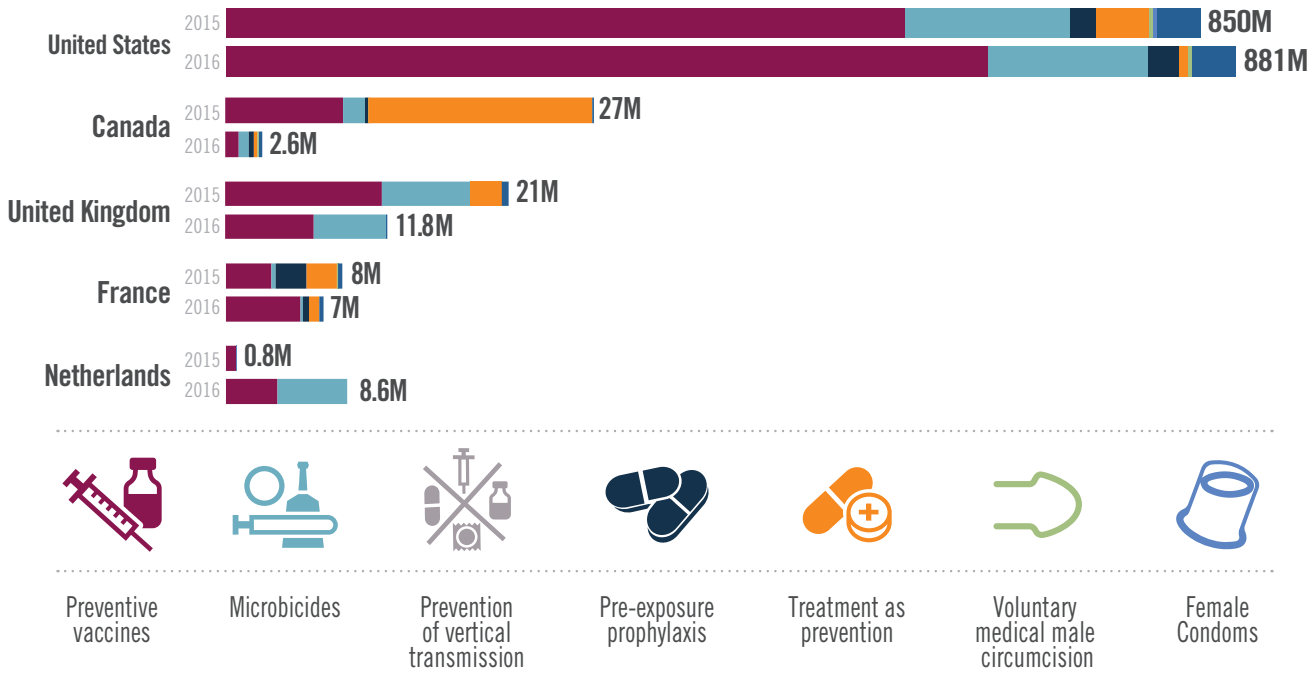
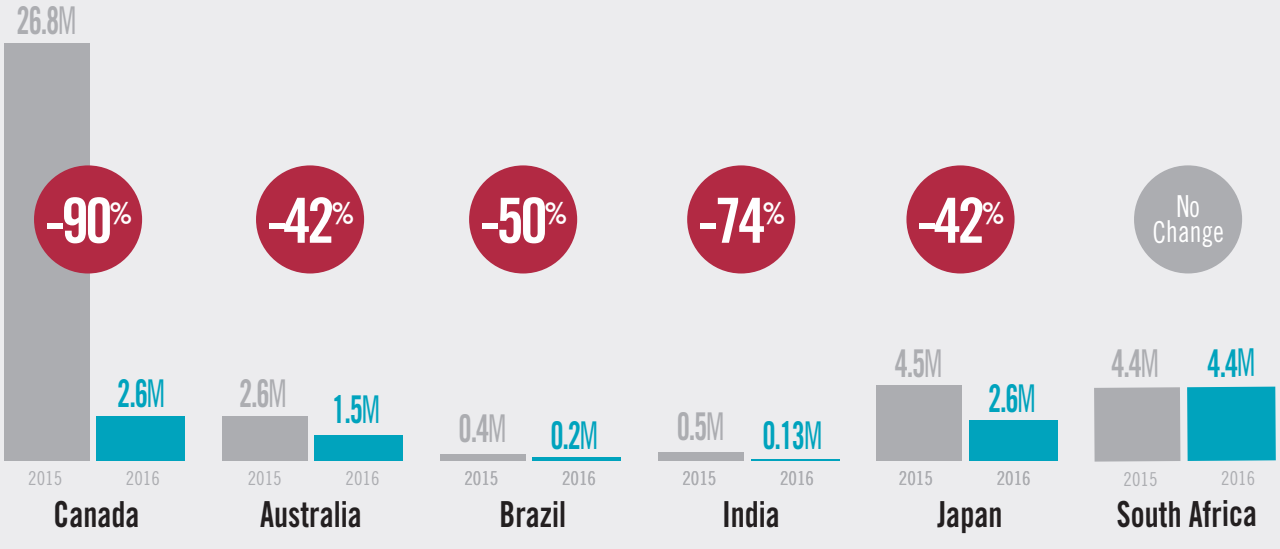


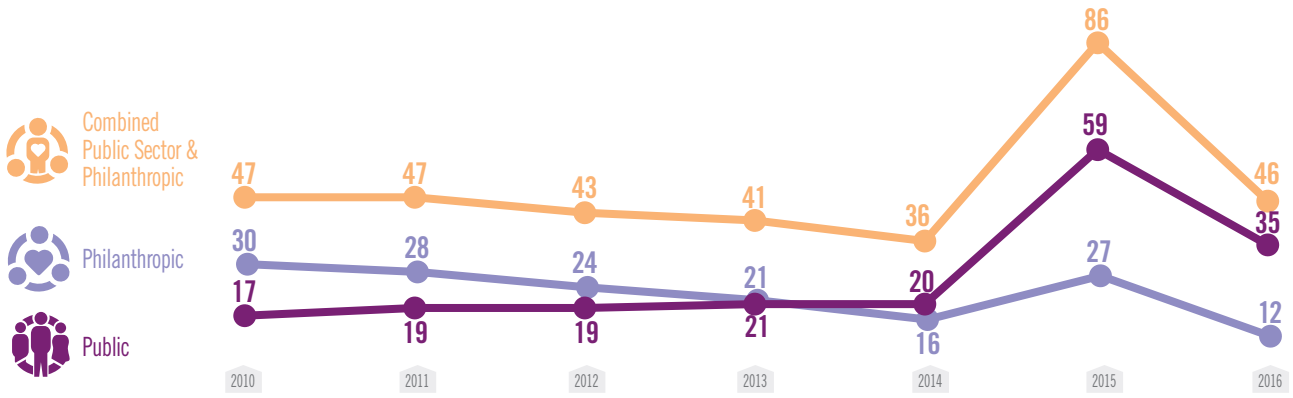
FIGURE 10 **Changes in Public Sector Investments Outside the US and Europe, 2015-2016** (US$ millions)



Decrease in the number of philanthropic funders

The dollar amount of philanthropic funding remained steady between 2015 and 2016, but the number of philanthropies engaged has declined. Only 12 donors from the philanthropic sector invested in HIV prevention research last year, down from 27 in 2015. This is a continuing trend since 2010, which while it reversed briefly in 2015, is on the decline once more *(Figure 11)*.

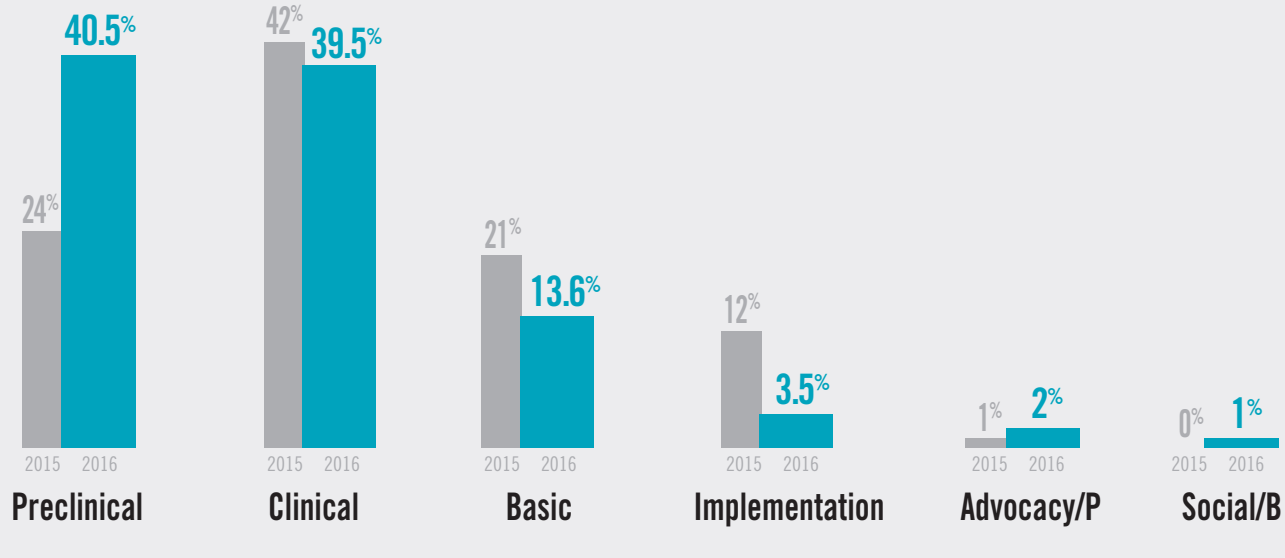
FIGURE 11 **Number of Public Sector and Philanthropic Funders Investing in HIV Prevention R&D, 2010-2016**



Sustained focus on the "science of delivery"

For biomedical options backed by empirical evidence and with proven efficacy, the focus is on moving beyond bench science to rollout in the target populations. Investment in the science of delivery ("implementation science") is central to eventual uptake of products and the understanding of user needs and preferences. This is why, although preclinical and clinical-stage research dominated total funding at 40 percent and 39 percent, respectively, implementation science was the leading priority for the scale-up and rollout of proven interventions like VMMC and PrEP in 2016 *(Figure 12)*. Approximately US$20 million (50 percent) of PrEP funding and US$7 million (70 percent) of VMMC funding was allocated to demonstration projects aimed at the service delivery and scale-up of proven prevention options.

FIGURE 12 **Research to Rollout: Investments by Research Stage, 2015-2016**

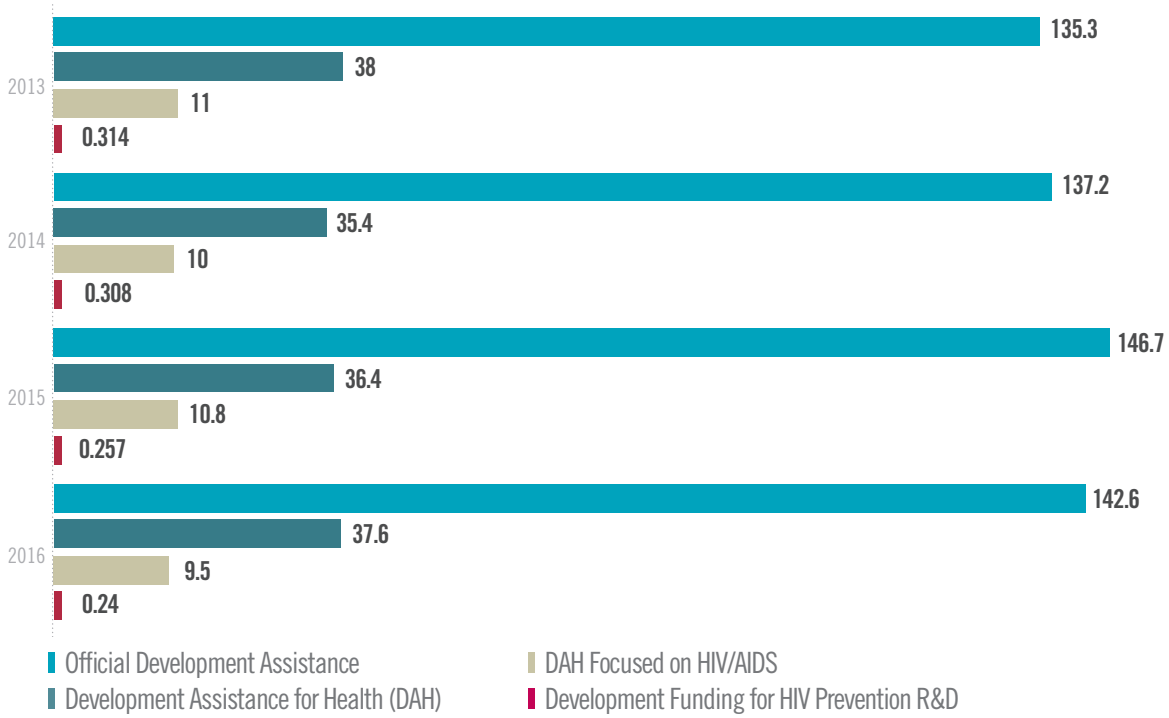


Declining priority in development funding

Development assistance for health (DAH) is the financial and in-kind support from development agencies to low- and middle-income countries in order to maintain or improve health. During the era of the Millennium Development Goals, and spurred on by global momentum, DAH grew by 11 percent between 2000 and 2010[4]. The annualized growth rate remained flat after 2010 at 1.8 percent and the 2016 DAH amount (US$37.6 billion) is congruent with that trend *(Figure 13)*. Assistance for HIV/AIDS dropped from 29.6 percent of total spending (US$10.8 million) in 2015 to 25.4 percent (US$9.5 billion) in 2016. This is in keeping with the trend of decreasing HIV/AIDS investment since 2011 (-1.4 percent annually), a shift from the increase observed in the decade after 2000.

In 2016, development agency support for HIV prevention R&D amounted to US$240 million, decreasing by 6.6 percent from US$257 million in 2015. This finding is notable because ending the AIDS epidemic by 2030 is one of the targets of Goal Three of the Sustainable Development Goals (SDGs), with target 3b exclusively dedicated to supporting health R&D. Effective and innovative prevention strategies are key to reducing disease incidence and achieving epidemic control, which is why HIV prevention R&D must regain its significance in the global SDG agenda.

FIGURE 13 **HIV Prevention R&D in the Context of Development Assistance for Health and Total Official Development Assistance, 2013-2016** (US$ billions)

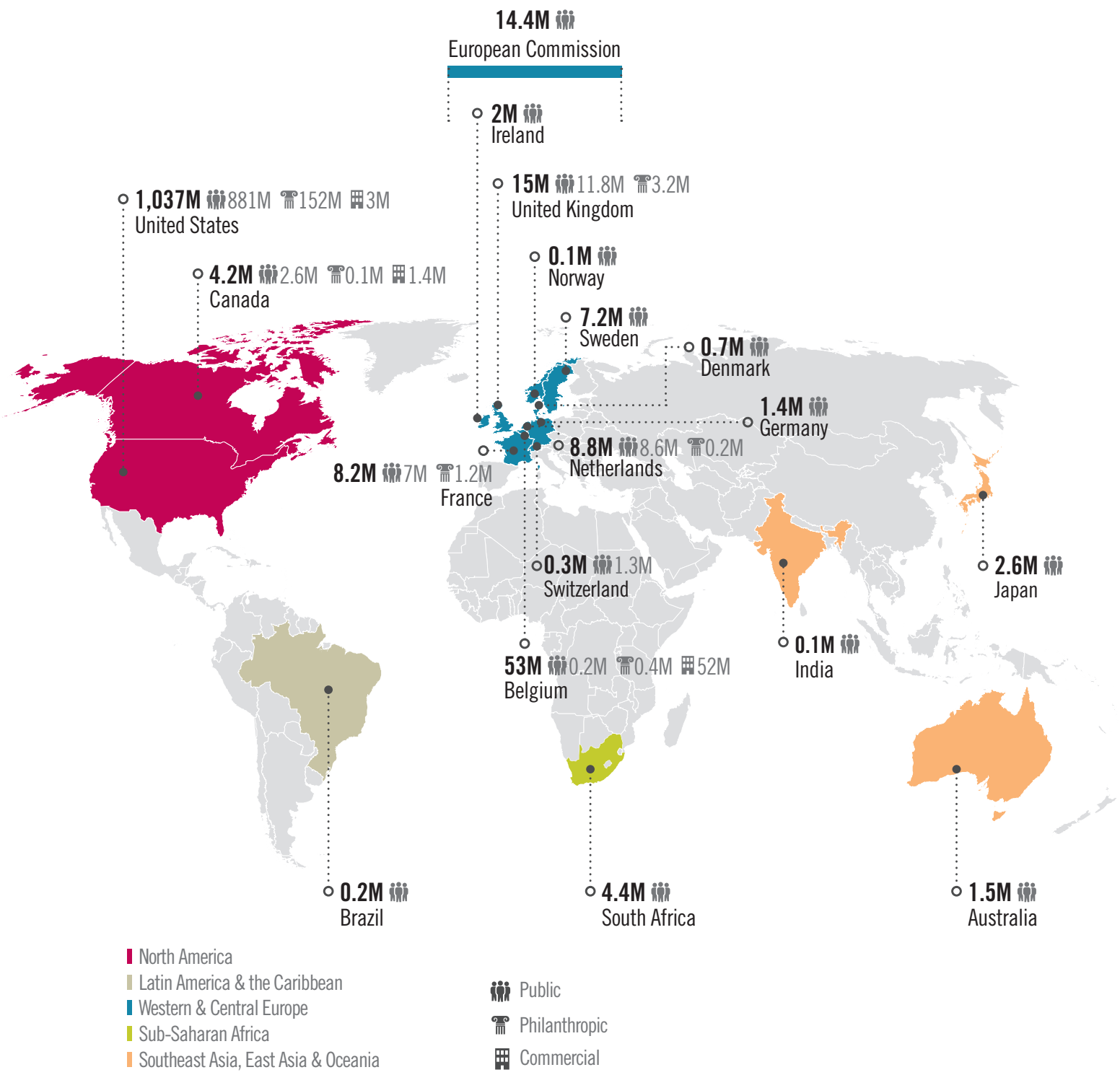


Sources: AVAC: *www.avac.org*; Institute for Health Metrics and Evaluation (IMHE). *www.healthdata.org*; Organization for Economic Co-operation and Development (OECD). *www.oecd.org*; Resource Tracking for HIV Prevention R&D Working Group 2016 data collection.

South-South Collaboration and Co-Financing

The India-Africa Health Services Summit took place in September 2016 and marked a new phase of research collaboration and knowledge exchange[6]. The Summit demonstrated strong resolve for a regional platform and policy agenda to promote innovative solutions specific to the burden of disease in India and Africa. The managerial structure for the South-South partnership is under development by the Indian Council for Medical Research (ICMR) and the African Union, and is expected to be in place by the second half of 2017.

FIGURE 14 **Total Global Investments in HIV Prevention R&D by Country, 2016** (US$)



* 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

HIV prevention research cannot be conducted without those who volunteer to participate in clinical trials or without the engagement of communities in which those trials take place. In 2016, there were almost 700,000 participants in HIV prevention research trials, primarily based in sites with high HIV/AIDS burdens in Africa, Asia, Latin America and the US *(Figure 15)*.

It is important to note the dearth in enrollment of members of key populations (KPs) *(Figure 16)*. While there are trials aimed specifically at men who have sex with men (MSM), transgender individuals and people who inject drugs (PWID), and hence trials which require the participation of these KPs, the preponderance of trials do not specify the need to include members of KPs.

FIGURE 15 **HIV Prevention R&D Trial Participants by Region, 2016**

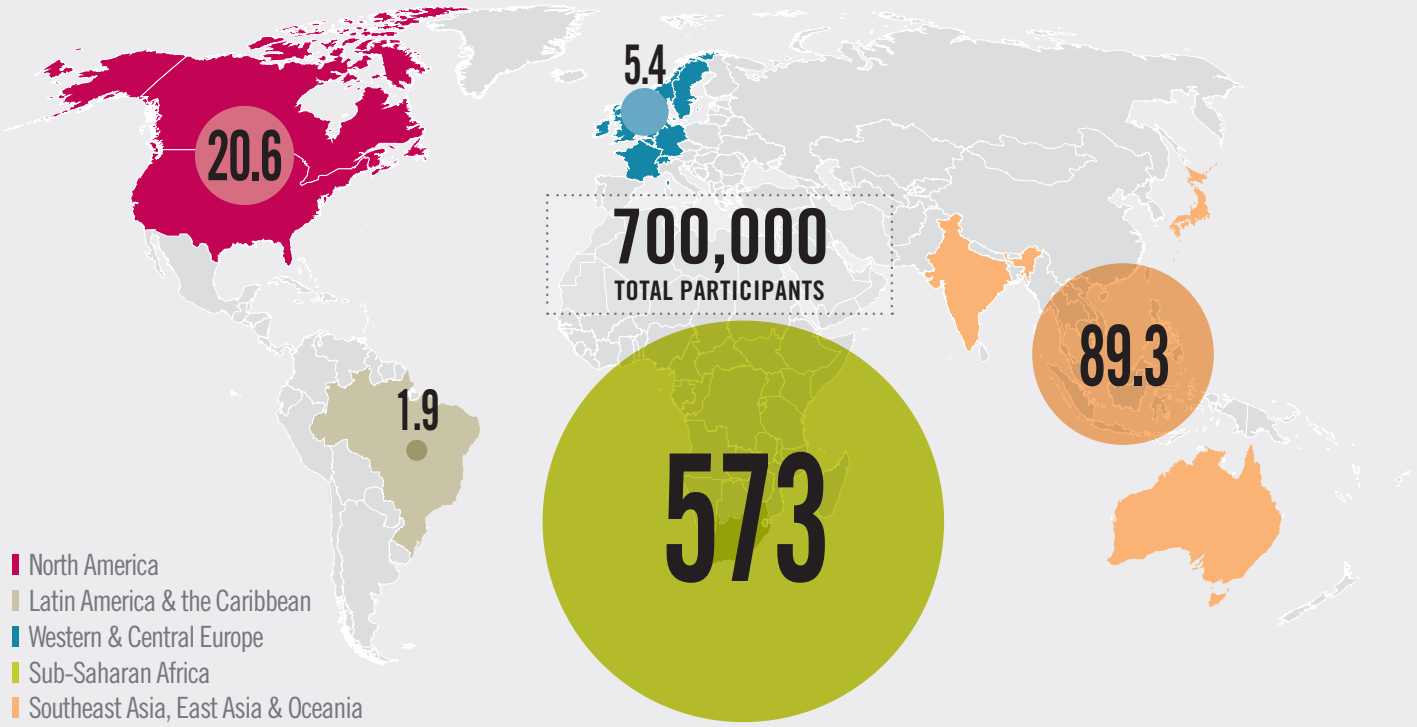
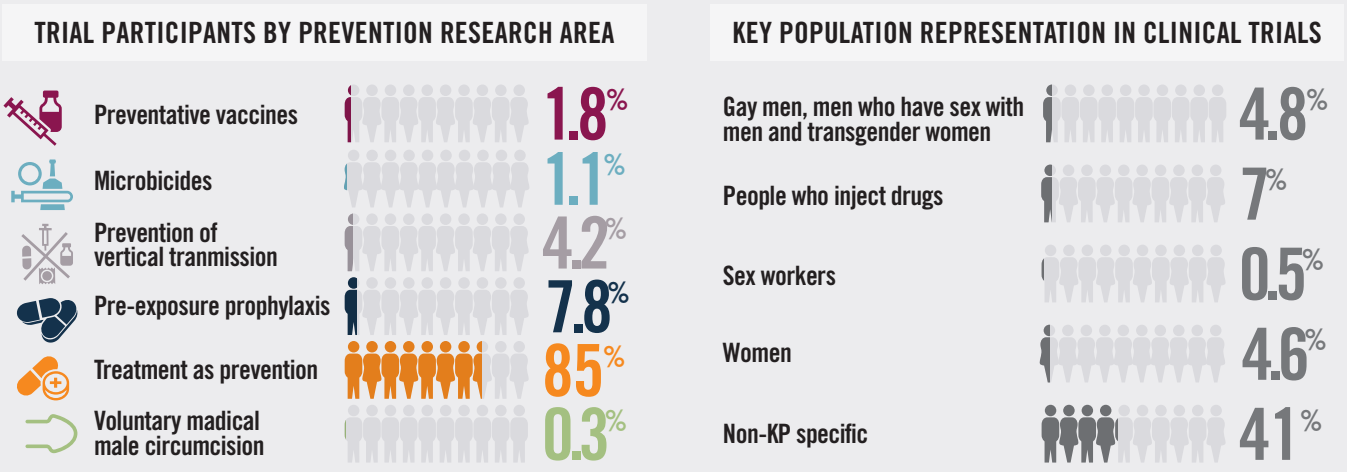


FIGURE 16 **Trial Participantions, 2016**



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, 80 funders reported their investments. A total of 450 grants were allocated to HIV prevention research, with an average grant size of US$2.6 million.

TABLE 1 Global Investments in HIV Prevention R&D: 2016 funding map

Funding type	2015	2016	% Change 2015-2016	Funder	Total 2016	Total 2015	% Change
US Public Sector	**$850 million**	**$881 million**	**3.65%**	NIH	$762.0	$730.0	4.4%
				USAID/PEPFAR	$73.9	$74.7	-1.10%
				CDC	$11.3	$15.7	-28%
				MHRP	$33.0	$26.6	24%
European Public Sector	**$69 million**	**$59 million**	**-14.5%**	Belgium	$0.2	$0.3	-33%
				Denmark	$0.7	$2.2	-68%
				EC	$14.4	$27.3	-47%
				France	$7.0	$8.3	-15.6%
				Germany	$1.4	—	—
				Ireland	$2.0	$2.2	-9%
				Italy	—	—	—
				Netherlands	$8.6	$0.8	975%
				Norway	$0.1	$1.5	-93%
				Spain	—	$1.0	—
				Sweden	$7.2	$3.9	84.6%
				Switzerland	$0.3	$1.3	-77%
				UK	$11.8	$20.7	-43%
Other Countries	**$50 million**	**$12 million**	**-76%**	Australia	$1.5	$2.6	-42.3%
				Brazil	$0.2	$0.4	-50%
				Canada	$2.6	$26.8	-90%
				China	—	$9.4	—
				Cuba	—	$0.4	—
				India	$0.13	$0.5	-74%
				Israel	—	$0.04	—
				Japan	$2.6	$4.5	-42%
				Russia	—	—	—
				South Africa	$4.4	$4.4	0.0%
				Taiwan	—	—	—
				Thailand	—	$0.5	—
Philanthropic	**$157 million**	**$157 million**	**No Change**	BMGF	$141.0	$125.7	12%
				Wellcome Trust	$3.1	$6.1	-49%
				Other	$13.5	$25.4	-47%
Industry	**$75 million**	**$56.4 million**	**-25%**	Commercial Sector	$56.4	$75.0	-25%
Total	**$1.20 billion**	**$1.17 billion**	**-3.00%**	**HIV prevention option totals**	$117 billion	$120 billion	-3%
				% Change 2015–2016	**-3%**		

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

2016 totals in US$ millions *(2015 investments, percent change[a])*

Preventive AIDS vaccines			Microbicides			Prevention of vertical transmission			Pre-exposure prophylaxis			Treatment as prevention			Voluntary medical male circumcision			Female condoms		
2016	2015	Change	2016	2015	Change	2016	2015	Change	2016	2015	Change	2016	2015	Change	2016	2015	Change	2016	2015	Change
$605.0	$538.0	12.4%	$96.9	$106.3	-9%	$37.7	$38.4	-1.8%	$20.6	$16.4	25.6%	—	$28.7	—	$0.8	$1.6	-50%	$0.5	$0.6	-16.6%
$28.7	$28.7	0.0%	$42.8	$35.0	22%	—	$0.7	—	$2.4	$3.9	-38%	—	$6.3	—	—	—	—	—	—	—
—	$15.7	—	$0.4	$1.0	-60%	—	—	—	$2.6	$0.5	420%	$6.2	$10.7	-42%	$2.0	$3.5	-42.8%	—	—	—
$33.0	$26.6	24%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
—	$0.1	—	$0.2	$0.1	100%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
—	$0.7	—	—	$1.4	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
$12.1	$22.8	-47%	$1.7	$3.9	-56%	$0.6	$0.6	0.0%	—	—	—	—	—	—	—	—	—	—	—	—
$5.3	$3.2	65%	$0.2	$0.3	-33%	$0.3	$0.3	0.0%	$0.5	$2.2	-77%	$0.7	$2.2	-68%	—	$0.1	—	—	—	—
$0.01	—	—	$1.4	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
$0.9	$1.1	-18%	$1.1	$1.1	0.0%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
$3.6	$0.7	414%	$5.0	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	$0.03	—
—	$0.7	—	$0.1	$0.8	-87.5%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
—	$1.0	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
$6.0	$0.9	566%	$1.1	$2.9	-62%	—	$0.1	—	—	—	—	—	—	—	—	—	—	—	—	—
$0.3	$1.0	-70%	—	—	—	—	$0.1	—	—	—	—	—	—	—	—	—	—	—	—	—
$6.5	$11.5	-43%	$5.3	$6.4	-17%	$0.1	$0.5	-80%	—	—	—	—	—	—	—	—	—	—	—	—
$1.3	$0.9	44%	—	$0.2	—	—	—	—	—	$0.3	—	$0.2	$0.7	-71%	—	$0.01	—	—	—	—
$0.03	$0.01	66%	—	—	—	—	—	—	$0.1	$0.3	-66.6%	—	—	—	—	—	—	—	—	—
$0.9	$8.5	-89%	$0.7	$1.6	-56%	$0.3	—	—	$0.4	$0.2	100%	$0.2	$16.3	-98.7%	$0.05	$0.02	150%	—	—	—
—	$7.0	—	—	—	—	—	—	—	—	—	—	—	$2.4	—	—	—	—	—	—	—
—	$0.4	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
$0.04	$0.3	-86%	$0.1	$0.1	0.0%	—	—	—	—	—	—	—	—	—	—	—	—	—	$0.1	—
—	$0.04	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
$0.8	$4.5	-82%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
$3.9	$3.9	0.0%	$0.5	$0.5	0.0%	$0.01	$0.01	0.0%	—	—	—	—	—	—	—	—	—	—	—	—
—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
—	$0.03	—	—	—	—	—	—	—		$0.02		—	$0.5	—	—	—	—	—	—	—
$113.8	$110.7	2.8%	$7.6	$9.2	-17.4%	$0.1	$0.4	-75%	$10.3	$3.1	232%	$1.5	$0.7	114%	$7.5	$1.3	477%	—	$0.4	—
$1.3	$6.0	-78.3%	$1.2	—	—	$0.6	$0.1	500%	—	—	—	$0.04	—	—	—	—	—	—	—	—
$11.0	$18.5	-40.5%	$0.4	$0.1	300%	$1.2	$1.8	-33.3%	$0.4	$0.1	300%	$0.5	$4.8	-89.6%	—	$0.2	—	—	—	—
$53.6	$62.2	-13.8%	$0.4	$6.0	-93%	—	$0.5	—	—	$1.6	—	—	$0.03	—	—	—	—	$2.4	$4.4	-45%
$894.0	**$862.0**	**3.7%**	**$167.0**	**$178.0**	**-6%**	**$41.0**	**$44.0**	**-6.8%**	**$40.5**	**$29.0**	**39.6%**	**$10.3**	**$77.0**	**-86.6%**	**$10.4**	**$6.6**	**57.6%**	**$2.8**	**$5.9**	**-52.5%**
3.7%			-6%			-6.8%			39.6%			-86.6%			57.6%			-52.5%		

AIDS Vaccines

1.0 Global investment in preventive AIDS vaccines research and development

In 2016, funding for preventive AIDS vaccine R&D increased by four percent or US$32 million from the previous year, to a total of US$894 million: the highest annual investment since 2007 *(Figure 17)*. At US$714 million, the public sector accounted for 80 percent of the global investment, with the philanthropic and commercial sectors contributing 14 percent and six percent, respectively *(Table 2)*. The United States was the largest global contributor by far, representing 93 percent of all public sector funding and increasing its investments by 12 percent to US$667 million. This marks the highest level of US investment in the past 16 years and is attributed to the 12.4 percent increase in NIH funding for preventive vaccine research *(Figure 18* and *Table 5)*.

FIGURE 17 **AIDS Vaccine Funding from 2000-2016** (US$ millions)

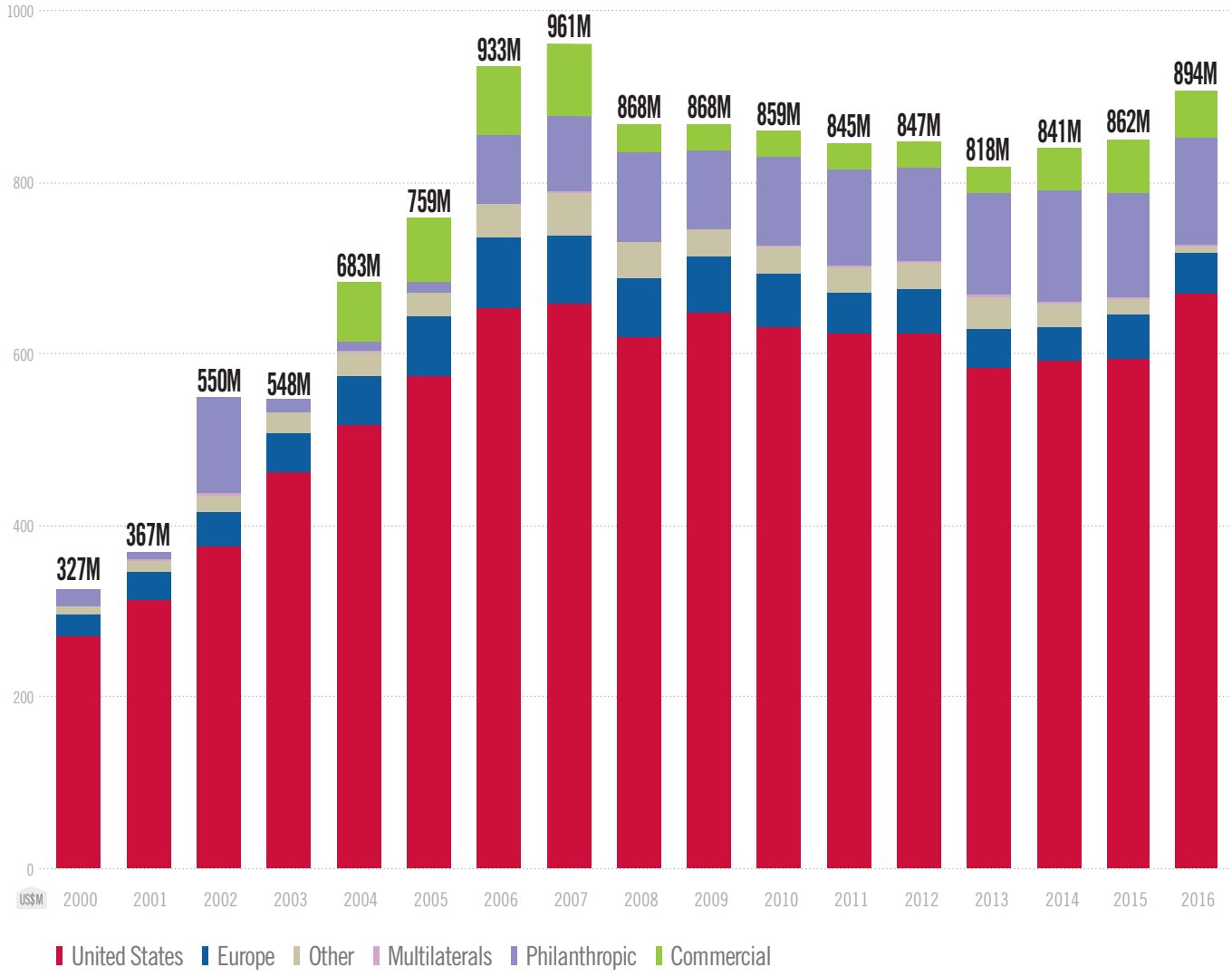
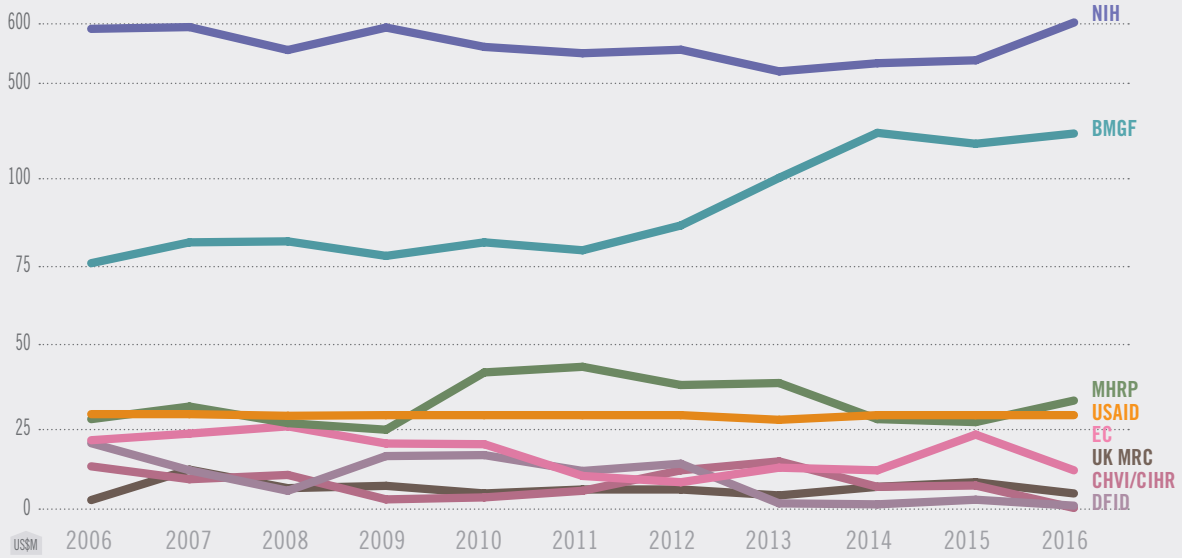


TABLE 2 Annual Investment in AIDS Vaccine R&D, 2000-2016 (US$ millions)

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

FIGURE 18 Top AIDS Vaccine Funder Trends, 2006-2016 (US$ millions)

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
NIH	593.7	596.8	556.1	596	561.6	550.4	556.6	518.2	532.7	537.9	605
BMGF	74.6	80.9	81.2	76.8	80.9	78.5	86	100.4	114	110.7	113.8
USAID	29	29	28.5	28.7	28.7	28.7	28.7	27.3	28.7	28.7	28.7
MHRP	27.5	31.3	26.3	24.3	41.6	43.3	37.8	38.4	27.5	26.6	33.1
EC	21.1	23.1	25.3	20.1	19.9	10.3	8.4	12.8	12	22.8	12
DFID	20.2	12	5.8	16.3	16.6	11.8	14	2	1.7	3.1	1.3
CHVI/CIHR	13.2	9.3	10.6	3.2	3.8	5.8	12	14.7	7	7.4	0.6
UK MRC	3	12.2	6.6	7.3	5	6.2	6.2	4.4	7	8.4	5



European annual investment decreased by 12 percent, from US$44 million to US$38.5 million in 2016. This decline comes at the heels of a 47 percent (US$11 million) decrease in funding from the European Commission. Philanthropic contributions decreased by 4.5 percent to US$126 million, while commercial sector funding also went down by 13 percent (*Tables 2, 3* and *4)*. It is worth mentioning that the decline in commercial funding in 2016 is likely a function of reduced reporting by commercial funders.

Outside of the US, only Australia, France and the Netherlands increased their commitments, which helped offset the decrease in funding from the United Kingdom (UK), Canada, Switzerland, India and Brazil.

TABLE 3 Philanthropic Investment in AIDS Vaccine R&D by Foundations and Commercial Philanthropy in 2016

Amount	Investors
US$114 million	Bill and Melinda Gates Foundation
US$1 million to US$10 million	Wellcome Trust, Ragon Foundation
US$250,000 to <US$1 million	Institut Pasteur, SIDACTION
<US$250,000	Aidsfonds, amfAR, MAC AIDS

TABLE 4 Estimated Commercial Sector Engagement in AIDS Vaccine R&D by Company in 2016

Amount	Investors
US$1 million to US$5 million	Sumagen Canada Inc.

[a] The Working Group provided "Company X" with a confidential disclosure agreement. Investments from Company X are not reflected on Table 4, but are included in the total commercial and global investment figures.

TABLE 5 Top AIDS Vaccine Funder for 2010-2016 (US$ millions)[a,b]

	2010		2011		2012		2013		2014		2015		2016	
Rank	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount
1	NIH	561.6	NIH	550.4	NIH	557	NIH	518.2	NIH	532.7	NIH	538	NIH	605
2	BMGF	80.9	BMGF	78.5	BMGF	86	BMGF	100.4	BMFG	114	BMFG	103	BMGF	114
3	MHRP	41.6	MHRP	43.3	MHRP	37.8	MHRP	38.4	USAID	28.7	USAID	28.7	MHRP	33
4	USAID	28.7	USAID	28.7	USAID	28.7	USAID	27.3	MHRP	27.5	MHRP	26.6	USAID	29
5	EC	19.9	DFID	11.8	DFID	14	CHVI[c]	14.7	EC	12	EC	22.3	EC	12
6	China	18.3	EC	10.3	CHVI[19]	12	EC	12.8	Ragon Institute	10	Ragon Institute	10	Ragon Institute	10
7	DFID	16.6	Ragon Institute	10	Ragon Institute	10	Ragon Institute	10	CHVI	7	UK MRC	8.3	Swedish Research Council	6
8	Ragon Institute	10	ANRS	7.3	EC	8.4	Wellcome Trust	7.7	China[d]	7	CHVI	7.2	ANRS	5.3
9	ANRS	6.6	China	6.9	Wellcome Trust	8.2	China[d]	7	UK MRC	7	China[d]	7	UK MRC	5
10	Wellcome Trust	5.1	Wellcome Trust	6.5	China	7	NHMRC	6.8	Wellcome Trust	6.2	Wellcome Trust	6	Dutch PDP	3.6
11	UK MRC	5	UK MRC	6.2	MRC	6.2	ANRS	5.3	Nether-lands	5.1	Institut Pasteur	5.5	EDCTP	3
12	EDCTP	4.5	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
13	CIDA	3.8	CIDA	4.9	Netherlands	4.8	Institute Pasteur	4.8	Sumagen Canada Inc.	2.8	DFID	3.1	Sumagen Canada Inc.	1.4
14	AECID		NMHRC	3.9	NHMRC	4.4	UK MRC	4.4	ANRS	2.7	Japan AMED	2.4	DFID	1.3
15	NORAD	2.5	The Netherlands	3.8	ANRS	4	DANIDA	2.2	South Africa DST/DOH	2.5	CIHR	2.4	Wellcome Trust	1.3

[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 Developments in the field of preventive AIDS vaccine research and development

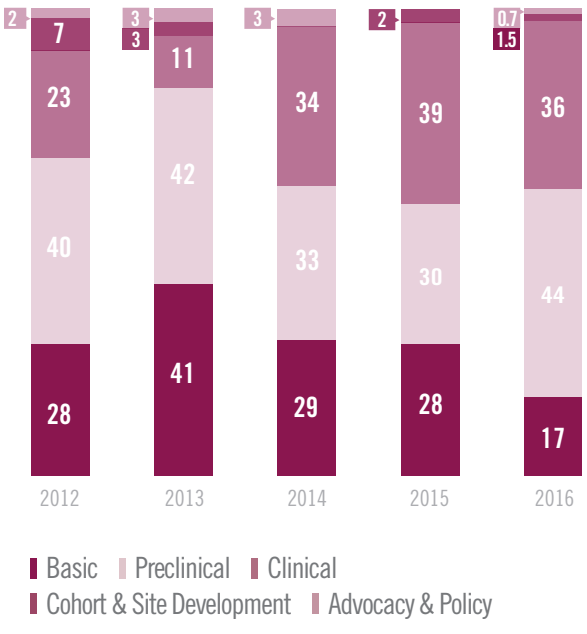
There has been a surge in vaccine efficacy trials in the past two years, and some notable developments in the field include:

- The AMP Study (HVTN 703/HPTN 081[7] and HVTN 704/HPTN 085[8]), which comprises two "sister" Phase II safety and efficacy trials, is currently recruiting participants. 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.
- The Phase IIb/III HVTN 702 study (the most advanced vaccine efficacy trial in the field) has begun recruitment and is currently planning to enroll 5,400 men and women in South Africa[9]. Driven by the Pox-Protein Public Private Partnership, or P5, HVTN 702 is evaluating the efficacy, safety and tolerability of a clade C subtype vaccine candidate.
- Another vaccine efficacy trial launching at the end of 2017 is the Phase IIb HPX2008/HVTN 705 study[10]. Sponsored by Janssen, this large-scale trial is set to test the effectiveness and tolerability of a heterologous prime/boost regimen in 2,600 HIV-negative women in sub-Saharan Africa. The industry sponsorship and involvement in HVTN 705 is a welcome development, as funding for vaccine trials has traditionally come from the public and philanthropic sectors.

1.2 Funding allocations for preventive AIDS vaccine research and development

Funding for vaccine R&D was allocated to the following areas in 2016: basic research (16.7 percent), preclinical research (44.7 percent), clinical trials (36 percent), cohort and site development (1.5 percent) and advocacy and policy (less than one percent). These allocations reflect shifting priorities toward preclinical research from 2015, when the bulk of funding was directed towards clinical trials (39 percent) *(Figure 19)*. This variation could have to do with the cyclical nature of clinical research and the preponderance of preclinical studies in the research-to-rollout pipeline in 2016.

FIGURE 19 **Preventive Vaccine Funding Allocations by Percentage, 2012-2016**



CEPI: An alliance for novel vaccine development

The Coalition of Epidemic Preparedness Innovations, or CEPI, is a partnership of public, private, philanthropic and civil organizations. It was launched in January 2017 to coordinate, fund and accelerate the development and rollout of vaccines against emerging infectious diseases[11]. The recent epidemics of Ebola, Zika and SARS served as the impetus for this cross-sectoral partnership, as they exposed the vulnerability of public health systems to the ravages of previously unknown pathogens. CEPI aims to coordinate the timely development of safe, effective and affordable vaccines to protect against and contain outbreaks. Using a preemptive approach, the coalition will put in place systems to facilitate vaccine development and to move candidates quickly from preclinical studies closer to rollout. The Bill and Melinda Gates Foundation is one of the founding partners of CEPI alongside the Wellcome Trust, Government of India, Government of Norway and the World Economic Forum. The coalition will remain in a start-up phase until late 2017.

Microbicides

2.0 Global investment in microbicide research and development

In 2016, global investment in microbicide R&D amounted to US$167 million. This represented a six percent decrease from the 2015 level (US$178 million), and is the lowest annual funding in more than a decade *(Figure 20)*. Reflecting past trends, the public-sector made up the bulk of funding (94 percent) at US$156 million *(Figure 21)*. Philanthropic contributions were unchanged at US$9 million (5.6 percent), while commercial funding decreased to just US$0.4 million (0.2 percent) in 2016. Commercial sector investments in microbicide research displayed a steep decline: down 93 percent from US$6 million in 2015, although this could also be a function of reduced reporting by commercial funders.

FIGURE 20 **Microbicide Funding, 2000-2016** (US$ millions)

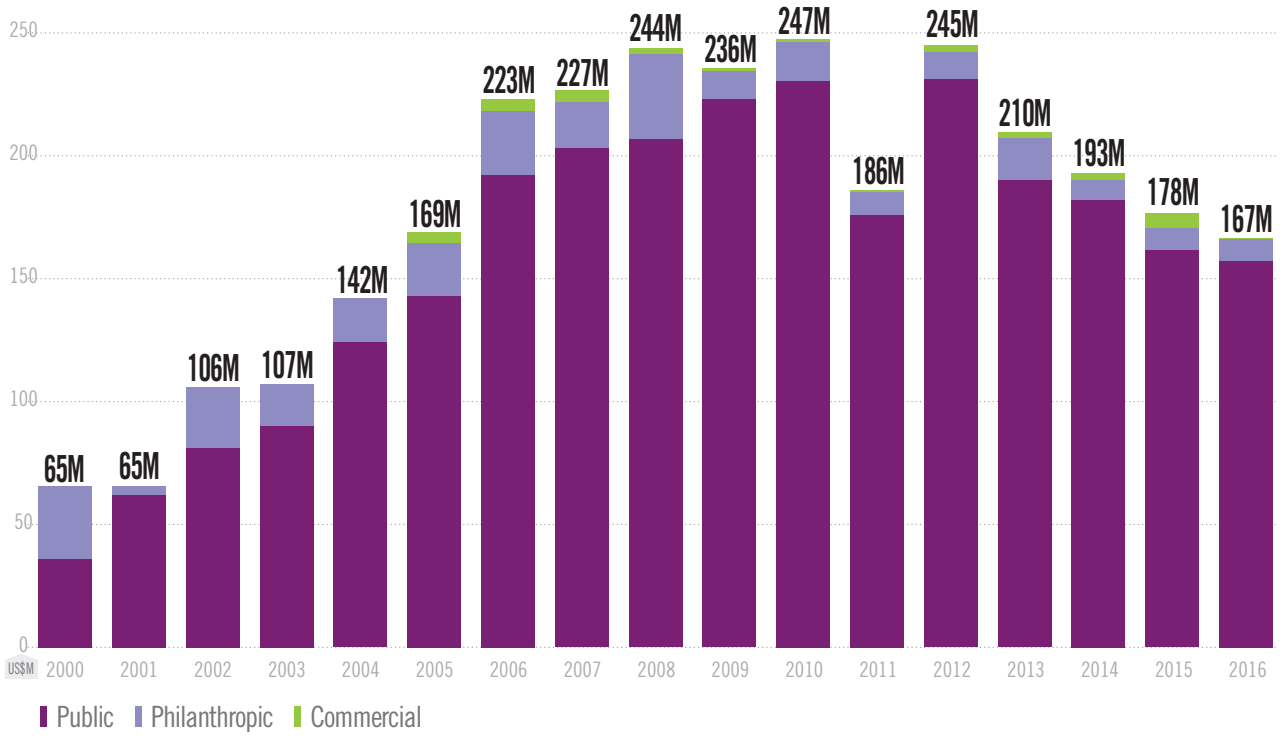


FIGURE 21 **The Funding Base for Microbicide R&D by Percentage, 2016**

US$167 million

84%	9%	5%	1%	0.2%	0.06%
United States	Europe	Philanthropic	Other Countries	Commercial	Multilaterals

At US$140 million, almost 84 percent of the overall funding came from the US, with the European public sector following at a distance at US$16 million or nine percent, a level largely unchanged from last year *(Table 6)*. European Commission funding decreased by 57 percent to US$1.7 million, a drop mirrored by other donors on the continent, such as the Medical Research Council UK (MRC UK, down 33 percent), the Department for International Development (DFID, down 15 percent) and the Norwegian Agency for Development Cooperation (NORAD, down 85 percent) *(Figure 22)*. This decline was somewhat offset by an increase in financing from the Netherlands Ministry of Foreign Affairs and the German Federal Ministry of Education and Research (BMBF), which contributed US$5 million and US$1.4 million, respectively *(Table 7)*.

TABLE 6 **Annual Investment in Microbicide R&D by Sector, 2006-2016** (US$ millions)

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
US	130	140	154	173	182	148	173	155	154	143	140
Europe	56	60	40	44	40	16	27	27	23	17	16
Other Countries	4.7	3.4	12	5.7	8.3	12	17	5	4.5	2.4	1.3
Multilaterals	1.4	0.2	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Public	192	203	207	223	230	176	217	187	182	162	157
Total Philanthropic	26	19	35	12	16	9	25	20	20	9.3	9
Total Commercial	4.5	4.5	2.5	1	1	1	3	3	3	6	0.4
Total Global Investment	**223**	**227**	**244**	**236**	**247**	**186**	**245**	**210**	**193**	**178**	**167**

FIGURE 22 **Top Microbicide R&D Funder Trends, 2006-2016** (US$ millions)

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
NIH	88	99	116	133	147	112	130	111	108	106	97
USAID	40	40	38	39	38	36	43	43	45	35	43
BMGF	21	15	35	7	17	7	23	19	8	9	7.6
DFID	19	21	13	22	16	3	5	8	8	5.2	4.4
EC	13	12	5	7	7	1	14	7	7	4	1.7
UK MRC	3	8	4	4	3	1	2	1	0.5	1.2	0.8

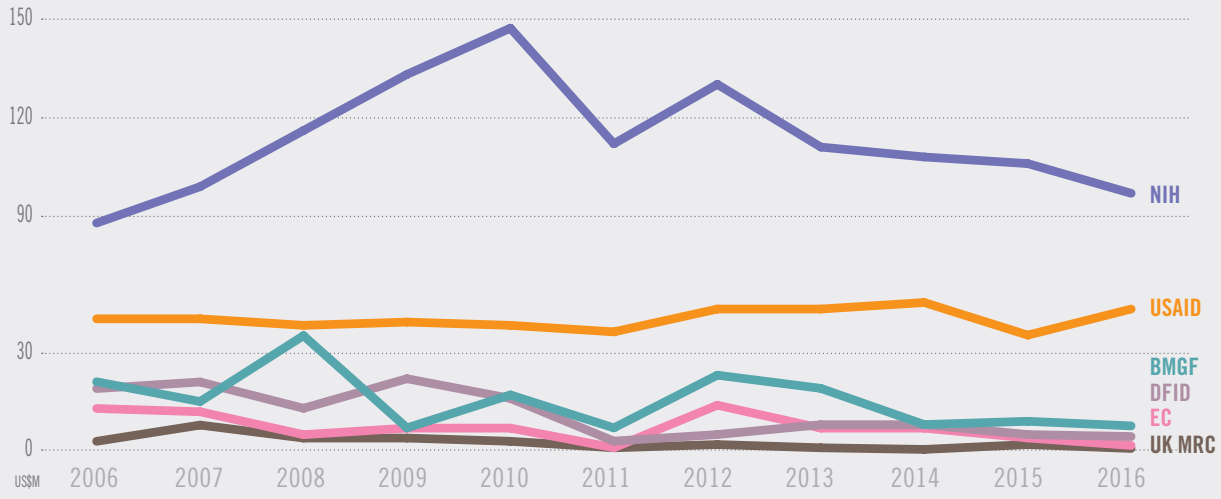


TABLE 7 **Top Microbicide R&D Funders, 2010-2016** (US$ millions)

	2010		2011		2012		2013		2014		2015		2016	
Rank	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount
1	NIH	147	NIH	111.8	NIH	129.9	NIH	111.2	NIH	107.8	NIH	106.3	NIH	97
2	USAID	38	USAID	36	USAID	43.2	USAID	42.8	USAID	45	USAID	45.2	USAID	43
3	DfID	16.5	South African DST/DOH	10	BMGF	22.9	BMGF	19.2	BMGF	7.6	BMGF	8.9	BMGF	7.6
4	BMGF	15.7	BMGF	7	EC	13.6	DFID	8.4	DFID	7.4	DFID	5.2	Netherlands Ministry of Foreign Affairs	5
5	EC	6.7	DfID	3.2	CHVI19	9.2	EC	6.7	EC	5.7	EC	3.9	DFID	4.4
6	China	3.6	Netherlands	2.7	South Africa[1]	7	Netherlands	3.6	Sweden	3.2	Sweden	2.9	EC	1.7
7	UK MRC	3.4	NORAD	2.5	DFID	4. 7	South Africa DST/ DOH	2.3	Nether-lands	3	DANIDA	1.4	BMBF	1.4
8	NORAD	3.3	Wellcome Trust	1.6	UK MRC	2.2	Denmark	2.2	ICMR	2.3	UK MRC	1.2	Wellcome Trust	1.2
9	EDCTP	2	Irish Aid	1.4	Netherlands	1.7	EDCTP	2.2	Ireland	1.3	IrishAid	1.1	Swedish Research Council	1.2
10	Spain	1.9	UK MRC	1.3	Ireland	1.2	Norway	1.5	CDC	1.2	CDC	0.9	IrishAID	1.1
11	Netherlands	1.7	Denmark	0.9	Norway	1	US CDC	1.5	NORAD	1	CIHR	0.8	UK MRC	0.8
12	Denmark	1.7	NHMRC	0.6	OPEC	1	Ireland	1.3	DANIDA	0.8	NORAD	0.8	CIHR	0.7
13	Germany	1.3	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
14	Irish Aid	1.1	Spain	0.4	NHMRC	0.5	NHMRC	0.5	UK MRC	0.5	ANRS	0.2	CDC	0.4
15	CDC	0.7	ARC	0.4	Wellcome Trust	0.5	Wellcome Trust	0.3	South Africa DST/DOH	0.4	NHMRC	0.2	Osel Inc.	0.2

At the same time, the number of philanthropic entities investing in microbicide research increased from one to five in 2016, with funders like the Wellcome Trust renewing investments in the field (US$1.2 million). Last year's sole philanthropic donor, BMGF, decreased its funding for microbicide R&D by 18 percent, from US$9.3 million to US$7.6 million.

Investments totaling US$1.8 million were also made in rectal microbicide research by the CDC, CDC Foundation and the European Commission.

2.1 Developments in the field of microbicide research and development

Following positive results from ASPIRE (MTN 020) and the Ring Study (IPM 027), open-label extensions of these "sister" trials are underway to assess the continuous adherence and safety of the dapivirine-containing vaginal ring as a prevention option[12, 13]. MTN 025, the HOPE trial, is about to roll off participants, as it was a one-year follow-on to assess age group-related factors impacting adherence and efficacy of the vaginal ring[14]. The other open-label trial, DREAM, is ongoing since July 2016 and has enrolled close to 2000 HIV-negative Ring Study participants as

well as a cohort of young women using the ring for the first time[15]. IPM is filing for an extension to DREAM so that prevention continues uninterrupted during application for regulatory approval of the vaginal ring.

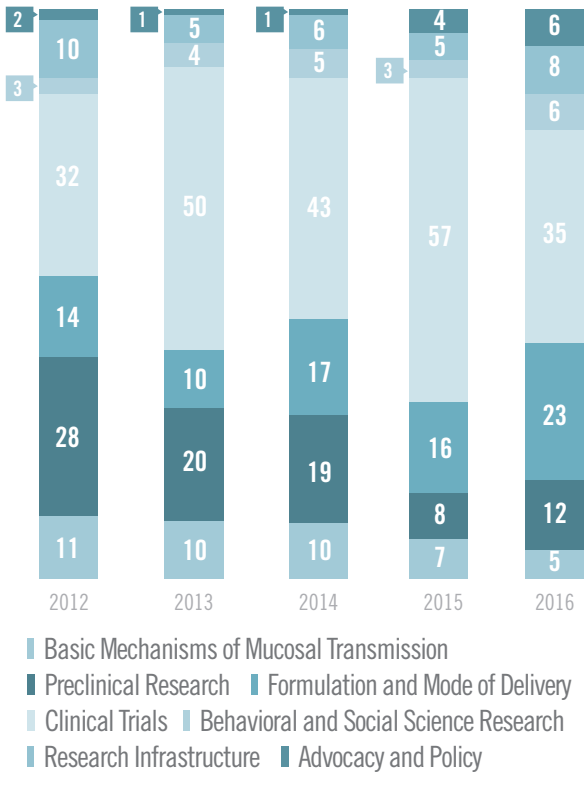
The Phase IIa crossover study, MTN-034/ IPM 035, is also on track to begin in late 2017 in South Africa, Kenya and Zimbabwe. The study will enroll 300 adolescent girls (ages 16 to 21) to assess the safety and acceptability of and adherence to the vaginal ring as compared to oral PrEP[16].

Interesting developments have also taken place in the field of rectal microbicide research. The Phase II study, MTN 017, was successful in demonstrating the safety and effectiveness of a rectal microbicide gel but documented low acceptability for the modality of rectal administration[17]. A new Phase I trial, Adonis, is planned to launch soon and will investigate the pharmacokinetics of a rectally-applied 0.05 percent dapivirine gel. The study will also compare the delivery of the gel in rectal-lubricant form versus delivery via an applicator, as used in the MTN 017 trial[18].

2.2 Funding allocations for microbicide research and development

Allocations to microbicide R&D were as follows: basic mechanisms of mucosal transmission (4.6 percent), preclinical research (11.7 percent), formulations and modes of delivery (22 percent), clinical trials (35 percent), social and behavioral research (6 percent), research infrastructure (8 percent) and advocacy and policy (6 percent) *(Figure 23)*. Although down from 2015 levels (57 percent), allocations for clinical trials continued to make up the bulk of R&D expenditure in microbicide research. Investment in formulations and modes of delivery rose in 2016, and can be attributed to the numerous preclinical studies evaluating long-acting leads and topical microbicides, as well as the various vaginal rings in development e.g., the tenofovir/levonorgestrel multipurpose technology (MPT) ring and the CDC intravaginal ring. Funding allocated to social and behavioral research also increased, to explore the poor adherence observed in some participants in clinical trials and to understand the contributing factors.

FIGURE 23 **Microbicide Funding Allocations by Percentage, 2012-2016**



Non-Antiretroviral Microbicides: The candidates

Non-ARV alternatives, and especially microbicides, are of continued interest to researchers, due to concerns about the widespread use of ARV products and the possible emergence of ARV-resistant HIV strains. Several non-ARV microbicides are in various stages of research and, if found viable and effective, would be a valuable addition to the HIV prevention toolbox. Two significant non-ARV microbicides in development are:

- A cyanobacterium lectin product, Cyanovirin-N, impedes the entry and transmission of HIV by binding to the gp120 receptor. Cyanovirin-N successfully averted the vaginal acquisition of simian-human immunodeficiency virus (SHIV) in preclinical studies and human *ex vivo* tissue[19].
- Griffithsin (GRFT) is a lectin derived from marine red algae that displays cross-clade anti-HIV potency and blocks HIV infection irreversibly by binding to viral particles and preventing their assimilation into target cells. GRFT has shown to be safe in *in vitro* and preclinical studies as a microbicide candidate and the Population Council is evaluating the efficacy of a GRFT-based microbicide gel in preclinical and clinical studies[19].

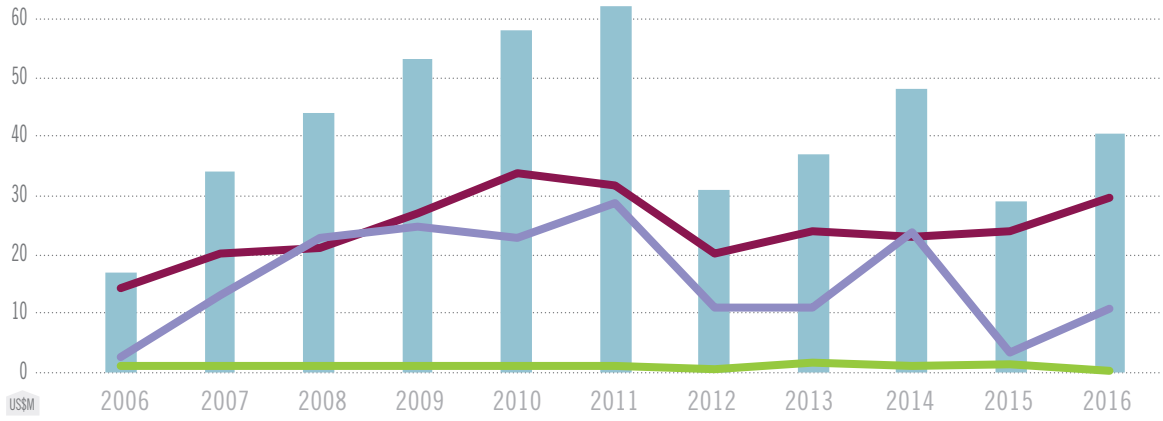
Other HIV Prevention Options

3.0 Global investment in research and development related to pre-exposure prophylaxis

Global funding for PrEP increased by 39 percent to US$40 million in 2016, a surge largely driven by the public and philanthropic sectors. Public investment in PrEP increased by 25 percent to US$30 million—attributable to the 25 percent increase in NIH funding (US$20.6 million) for PrEP R&D *(Figure 24)*. At US$10.3 million, BMGF almost tripled its investment from last year and made up 96 percent of the overall philanthropic funding (US$10.6 million). It is worth mentioning that a large portion of the PrEP funding is focused on aspects such as guidelines development and delivery mechanisms that are outside the R&D scope of this report.

FIGURE 24 **Investment in Pre-Exposure Prophylaxis, 2006-2016** (US$ millions)

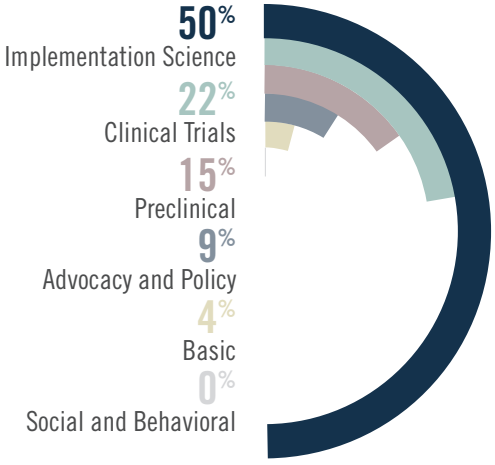
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Public	14	20	21	27	34	32	20	24	23	24	29.8
Philanthropic	2.4	13	23	25	23	29	11	11	24	3.2	10.7
Commercial	1.3	1.3	1.3	1.3	1.3	1.3	0.5	2	1.2	1.6	0
Total Funding	17	34	44	53	58	62	31	37	48	29	40.5



3.1 Funding allocations for pre-exposure prophylaxis research and development

Almost 50 percent of all funding, or US$20 million, was allocated to PrEP implementation studies, research aimed at the science of delivery, adherence support and user needs and preferences. Other investment allocations were in basic research (4 percent), preclinical research (15 percent), clinical trials (22 percent) and advocacy and policy (8.5 percent) *(Figure 25)*.

FIGURE 25 **PrEP R&D Funding Allocations by Percentage in 2016**



3.2 Developments in the field of pre-exposure prophylaxis research and development

Following the 2015 WHO recommendation approving daily, oral PrEP, its uptake as a preventive tool for high-risk populations has varied across the globe[20]. As of 2017, Truvada (FDF/FTC) as PrEP is approved for use in 17 countries, with another five having submitted applications for regulatory approval. Demonstration projects are also ongoing in 21 countries and are enrolling a variety of target audiences on PrEP. Some of these include:

- **Introducing PrEP in Combination Prevention (IPCP):** Led by LVCT Health and the Sex Workers Outreach Program (SWOP), IPCP is currently underway in Kenya, and is enrolling females sex workers, MSM and adolescent girls and young women on PrEP as part of a combination prevention approach. With its 2500 planned enrollees, this implementation study is examining optimal delivery approaches for PrEP as well as adherence strategies and health system requirements. Final results for this demonstration project are expected in December 2017[21].
- **Amsterdam PREP (AMPrEP):** This study is assessing the acceptability, feasibility and usability of daily oral PrEP and intermittent PrEP (before and after anal sex) in a group of 370 MSM and transgender women in the Netherlands. This study is mean to inform the inclusion of PrEP in the national prevention strategy and is slated to end in December 2018[22].
- **PrEP Expanded (The PrEPX Study):** Ongoing in Australia, this multi-site and population-level study is enrolling 2600 high-risk participants to gauge the effectiveness of PrEP in preventing new HIV infections. Results from the study are expected in March 2018[23].

PrEP Implant Studies

Adherence is a recurring issue that dampens the efficacy of PrEP. To address this issue, long-acting drug delivery systems are being explored in the form of injectables and implants to foster adherence and to ensure optimum systemic drug levels. One PrEP product in preclinical development is a biodegradable subcutaneous implant roughly the same size as a contraceptive implant that releases tenofovir alafenimide fumarate (TAF) from a rate-adjustable reservoir[24].

CAPRISA-018 is another PrEP implant trial slated for launch in 2017. Funded by the European and Developing Countries Clinical Trials Partnership (EDCTP), the randomized clinical trial is evaluating the safety, acceptability and effectiveness of a subdermal TAF implant in women[25].

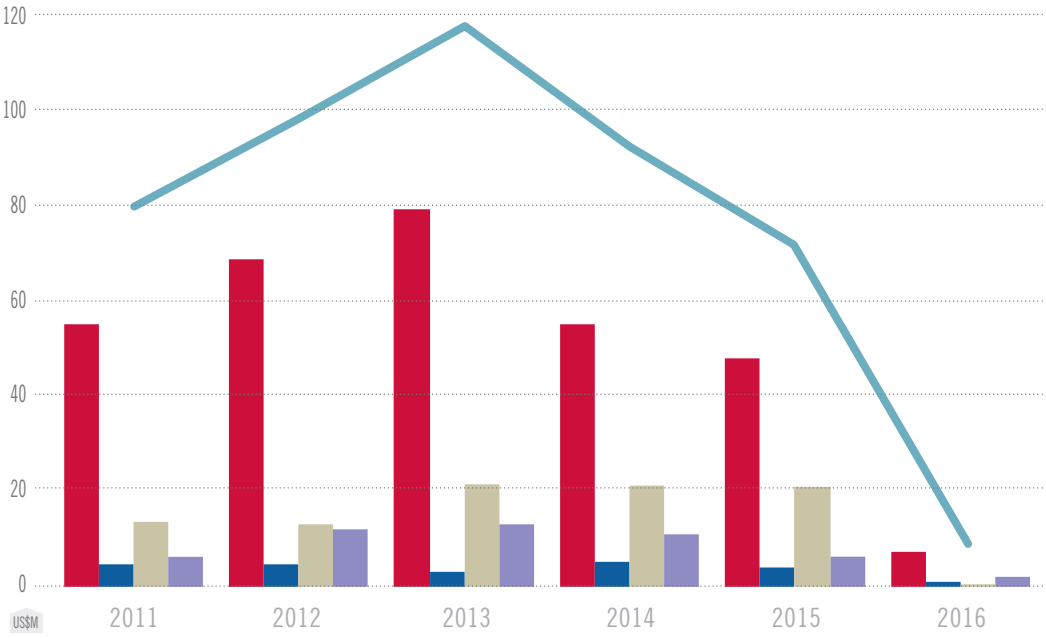
4.0 Global investment in research and development related to treatment as prevention

Global investment in TasP declined dramatically by 87 percent, down from US$77 million in 2015 to US$10 million in 2016. Funding decreased across the board, with all sectors and countries tempering their investment. US public-sector funding decreased by 85 percent (US$40 million) to just US$7 million in 2016, a drop explained by reduced commitments from the NIH (US$0.7 million in 2016, compared to US$28 million in 2015) and the CDC (US$6 million in 2016, compared to US$10.2 million in 2015). European public sector funding also fell by 84 percent, from US$4.6 million to US$0.7 million. Similarly, philanthropic funding decreased from US$5.5 million to US$2 million *(Figure 26)*.

While 68 percent of funding was allocated for TasP clinical research and site development, 28 percent of investments went toward implementation science. This is a reversal from last year, when 90 percent of all funding was designated for implementation research and the science of delivery.

FIGURE 26 **Investment in Treatment as Prevention by Sector, 2011-2016** (US$ millions)

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

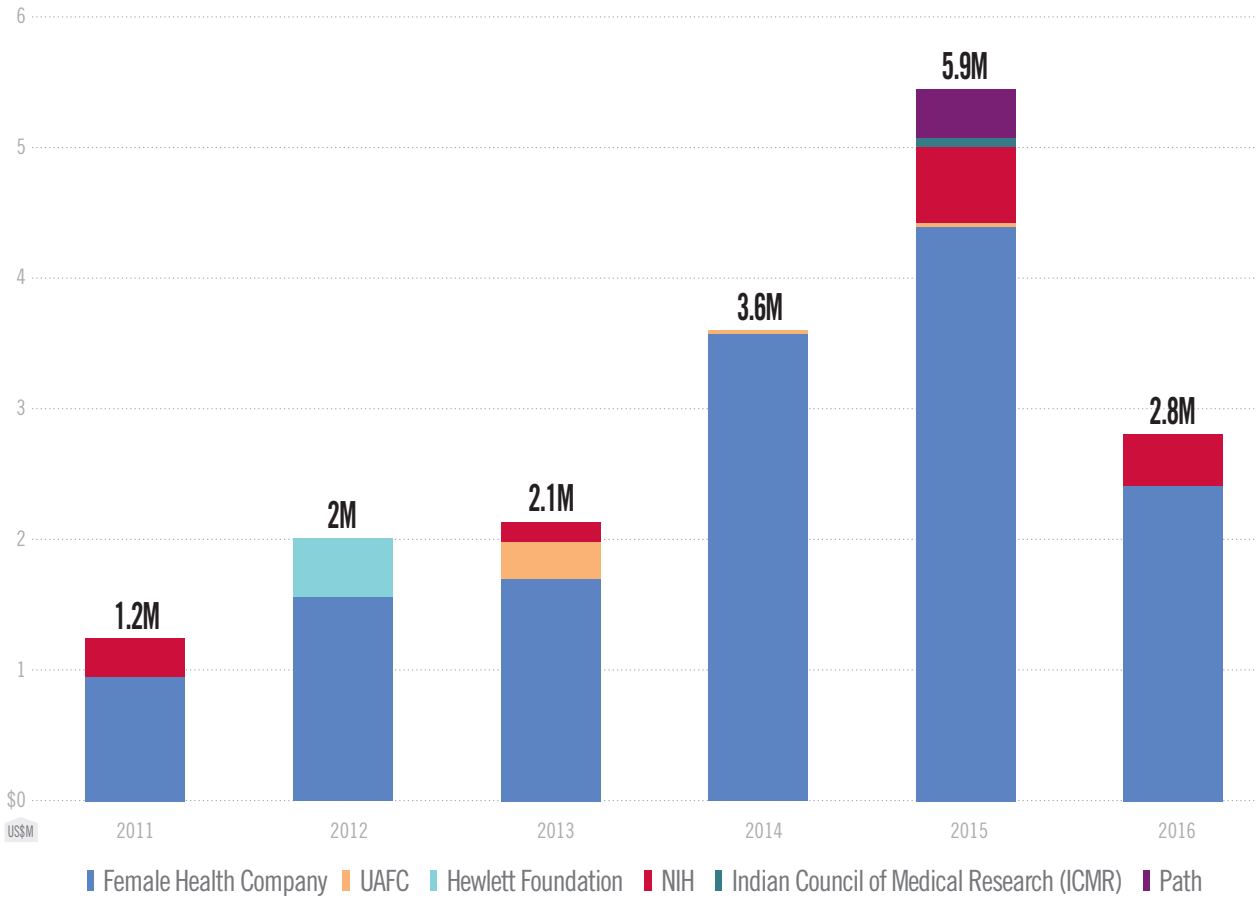


5.0 Global investment in female condom research and development

Funding for research into female condoms dipped in 2016, reversing the five-year trend of increasing global investments. Absolute funding decreased by 52 percent, from US$5.9 million to US$2.8 million, and the number of investors also fell from six to two in 2016 *(Figure 27)*. The Female Health Company, the private US entity at the forefront of female condom research, reduced its investment from US$4.4 million to US$2.4 million. The only public-sector investment came from the NIH (US$0.4 million) and was for implementation science research.

In 2016, 85 percent of funding was allocated to the advocacy and policy development of the FC2 female condom. This signaled a change from last year, when 90 percent of the public and commercial investments were allocated to implementation science and only 6.8 percent went to policy and advocacy.

FIGURE 27 **Investment in the Female Condom, 2011-2016** (US$ millions)



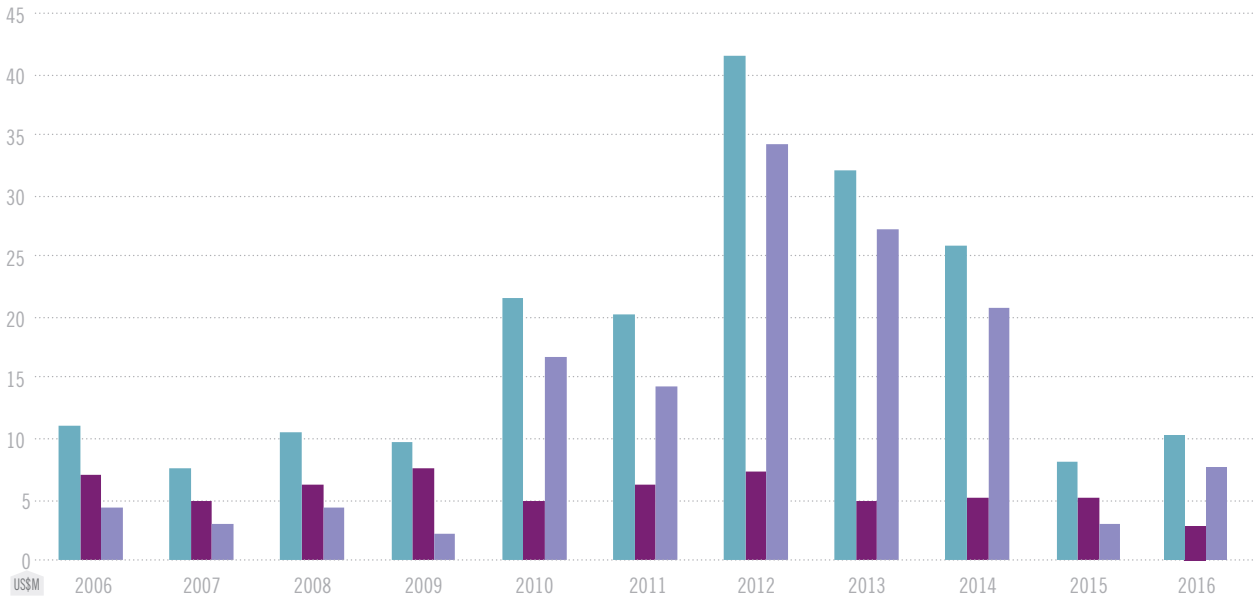
6.0 Global investment in the implementation and expansion of voluntary medical male circumcision

R&D funding related to VMMC increased by 57 percent in 2016, from US$6.6 million to US$10.4 million. This surge was attributed to investment by the sole philanthropic donor, the BMGF, which made up 72 percent of the overall global investment in VMMC R&D. Funding from the BMGF increased from US$1.3 million in 2015 to US$7.5 million in 2016—a dramatic 477 percent increase. The public sector followed with US$2.9 million, with contributions from the CDC (US$2 million), NIH (US$0.7 million) and the Canadian Institutes for Health Research (US$0.05 million) *(Figure 28)*.

Like PrEP, VMMC is now geared toward uptake in research-to-rollout continuum. With strong empirical evidence supporting the efficacy of VMMC, donor priorities have now shifted to the scale-up and service delivery of this prevention option. This is evidenced in the allocations, as implementation science and service delivery comprised 70 percent of the overall investments toward VMMC. Other allocations included clinical trials (20 percent), advocacy (9 percent) and behavioral research (1 percent).

FIGURE 28 **Investment in Voluntary Medical Male Circumcision by Sector, 2006-2016** (US$ millions)

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total Public	6.9	4.8	6.2	7.5	5	6.1	7.2	5	5.2	5.1	2.9
Total Philanthropic	4.3	2.9	4.3	2.1	16.7	14.2	34.4	27.2	20.8	1.4	7.5
Total Global Investment	11.2	7.7	10.5	9.6	21.7	20.3	41.6	32.2	26	6.6	10.4



7.0 Investment in research related to the prevention of vertical transmission

Investments related to the prevention of vertical transmission of HIV from mother to child at birth and during breastfeeding decreased by seven percent from 2015 levels, to US$41 million. The NIH was the largest donor in 2016, and at US$37.7 million, its contribution decreased slightly (by 1.8 percent) from 2015. Philanthropic funding also decreased by 26 percent, from US$2.3 million in 2015 to US$1.7 million in 2016 *(Table 8)*. The largest philanthropic donor was the Wellcome Trust, at US$0.56 million, followed by the Oak Foundation (US$0.5 million) and the King Baudouin Foundation (US$0.44 million).

TABLE 8 **Annual Investment in Prevention of Vertical Transmission by Sector, 2008-2016** (US$ millions)

	2008	2009	2010	2011	2012	2013	2014	2015	2016
US	10.3	44.6	56.9	36.2	34.6	42	44.9	39.1	37.7
Europe	7.3	5.9	1.5	1.1	1.7	0.1	1.2	2.1	0.9
Other Countries	–	–	1.3	5.1	6.7	0.2	–	0.8	–
Total Public	17.6	50.5	59.7	42.6	42.9	42.4	46.6	41.3	39
Total Philanthropic	3.6	0.9	0	0.5	0.8	1.7	2.5	2.3	1.7
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**

8.0 Global investments in multipurpose prevention technology research and development

As part of an ongoing collaboration, the Working Group partnered with CAMI Health, Secretariat to the Initiative for MPTs, in order to collect and analyze data on grants for multipurpose prevention technologies or MPTs for 2016. The goal of MPT research is the development of products that simultaneously offer protection from unintended pregnancy and/or one or more sexually transmitted infections, importantly, though not exclusively, HIV.

In 2016, overall investments totaled US$40 million, a 16 percent decrease from the US$48 million reported in 2015. Approximately 92 percent of all funding or US$37 million was designated for MPTs with HIV prevention as an indication or potential research goal. The US remained the largest funder of MPT R&D accounting for three-fourths of overall funding, and 88 percent of public sector funding at US$27 million. This signals an increase in non-US funding from 2015 levels when 86 percent of total and 99 percent of public sector funding was from the US. In an ongoing trend since 2013, USAID and NIH remain the primary US public sector MPT R&D funders; estimates for European funding signal an increase from 2015 levels to approximately US$3 million. Philanthropic investments totaled US$4 million with BMGF as the predominant funder at US$3.5 million. Moreover, the commercial sector accounted for 13.5% of overall MPT R&D funding at US$5.4 million.

Recipients of public sector support for MPT R&D continue to be nonprofit entities such as CONRAD, the Population Council and the International Partnership for Microbicides; academic research groups, such as the Eastern Virginia Medical School, University of Louisville and University of Pittsburgh; and biotechnology companies such as Auritec and Advanced Bioscience Laboratories, Inc.

FIGURE 29 **Investment by Sector**

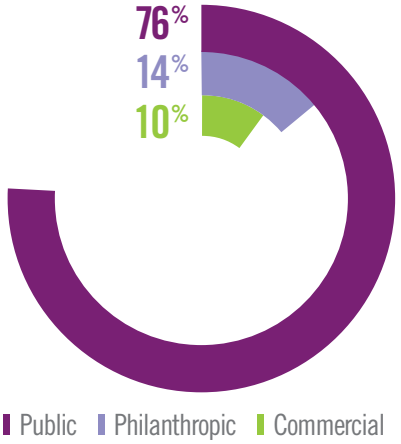
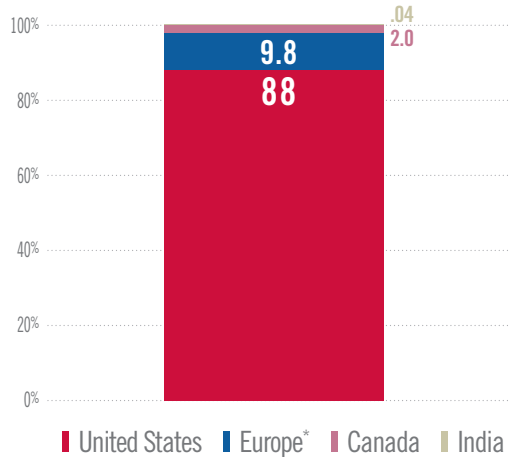


FIGURE 30 **Investment by Funder**



* European public-sector investments represent estimates.

The only prevention technologies available in today's marketplace that can be defined as MPTs are male and female condoms, which provide protection against both STIs and pregnancy. Much of the MPT R&D is taking place in the earliest stages of preclinical testing or in Phase I trials, and includes a wide range of formulations and delivery systems for both sustained-release and on-demand use. These include combinations of antiviral agents, including lectins and monoclonal antibodies; intravaginal rings in various configurations, vaginal gels, vaginal and rectal films and fast-dissolving tablets; and new delivery strategies, such as nanofiber platforms and long-acting PrEP formulations that could form the basis for long-acting injectables.

One example of an MPT trial is the phase 1 MTN 030/IPM 041 study sponsored by the International Partnership for Microbicides currently ongoing to test the safety and effectiveness of a vaginal ring containing both the antiretroviral drug dapivirine and the synthetic contraceptive, levonorgestrel. The study will enroll 36 women from two US trial sites with the goal of developing a long-acting product to prevent both unintended pregnancy and HIV infection.

There are approximately two dozen other potential MPT products in the product development pipeline and more information about specific products can be found on the CAMI health website *(www.theimpt.org)*.

9.0 Investment in cure and therapeutic vaccine research and development

The Working Group estimates that in 2016, US$267.1 million was invested in cure research, representing a substantial increase of 33 percent over the US$201.8 million invested in 2015 and an increase of 203 percent over the US$88.1 million invested in 2012. The majority of investments (US$252.6 million) came from the public sector, with US$13.8 million invested by philanthropies such as amfAR, CANFAR, the Bill and Melinda Gates Foundation and the Wellcome Trust. In 2016, the United States through the NIH contributed the majority of public funding, with the European Commission, Canada, France, the United Kingdom, Australia, Germany, Switzerland, Norway and Japan also serving as contributors to HIV cure research. Active cure initiatives in 2016 include:

- **International AIDS Society 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.

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

  amfAR ramps up 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] The United Kingdom European Union membership referendum or the Brexit referendum, took place in June 2016 and resulted in a majority vote for the UK to leave the European Union. However, this has had no apparent influence or effect on European funding for HIV prevention R&D in 2016.

[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 Emily Donaldson (AVAC), Kevin Fisher (AVAC), Jennifer Garrett (IAVI), Polly Harrison (AVAC), 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 9 Public, Philanthropic and Commercial Sector Primary Funders

Total responders: 80	
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 June 2017 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 multi-year 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, 2016, 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
- HSV-2
- Prevention of vertical transmission
- HIV cure
- Therapeutic AIDS vaccines
- Antiretrovirals (ARVs)
- Immune-based therapies & anti-inflammatory drugs
- Co-infection & opportunistic infection drugs
- Other HIV-associated drugs
- HIV diagnostics

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 that would 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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Resource Tracking for HIV Prevention R&D Working Group

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