

RESOURCE TRACKING

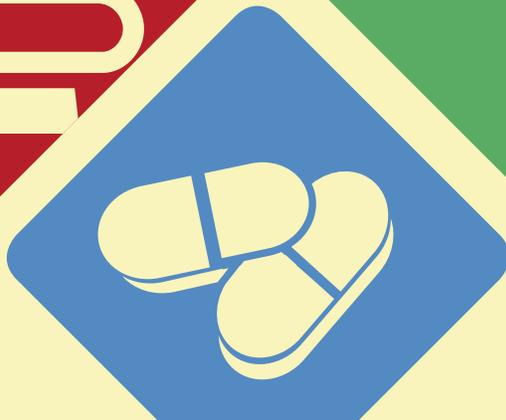
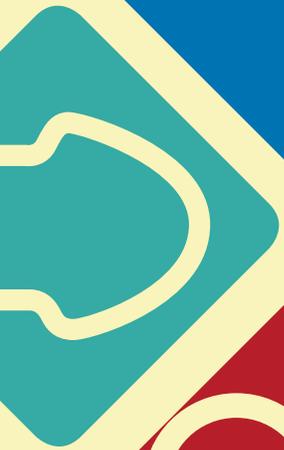
FOR HIV PREVENTION

RESEARCH & DEVELOPMENT

2018

HIV Prevention Research & Development Investments

INVESTING TO END THE EPIDEMIC



HIV Prevention Research & Development Investments, 2018

INVESTING TO END THE EPIDEMIC



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Introduction

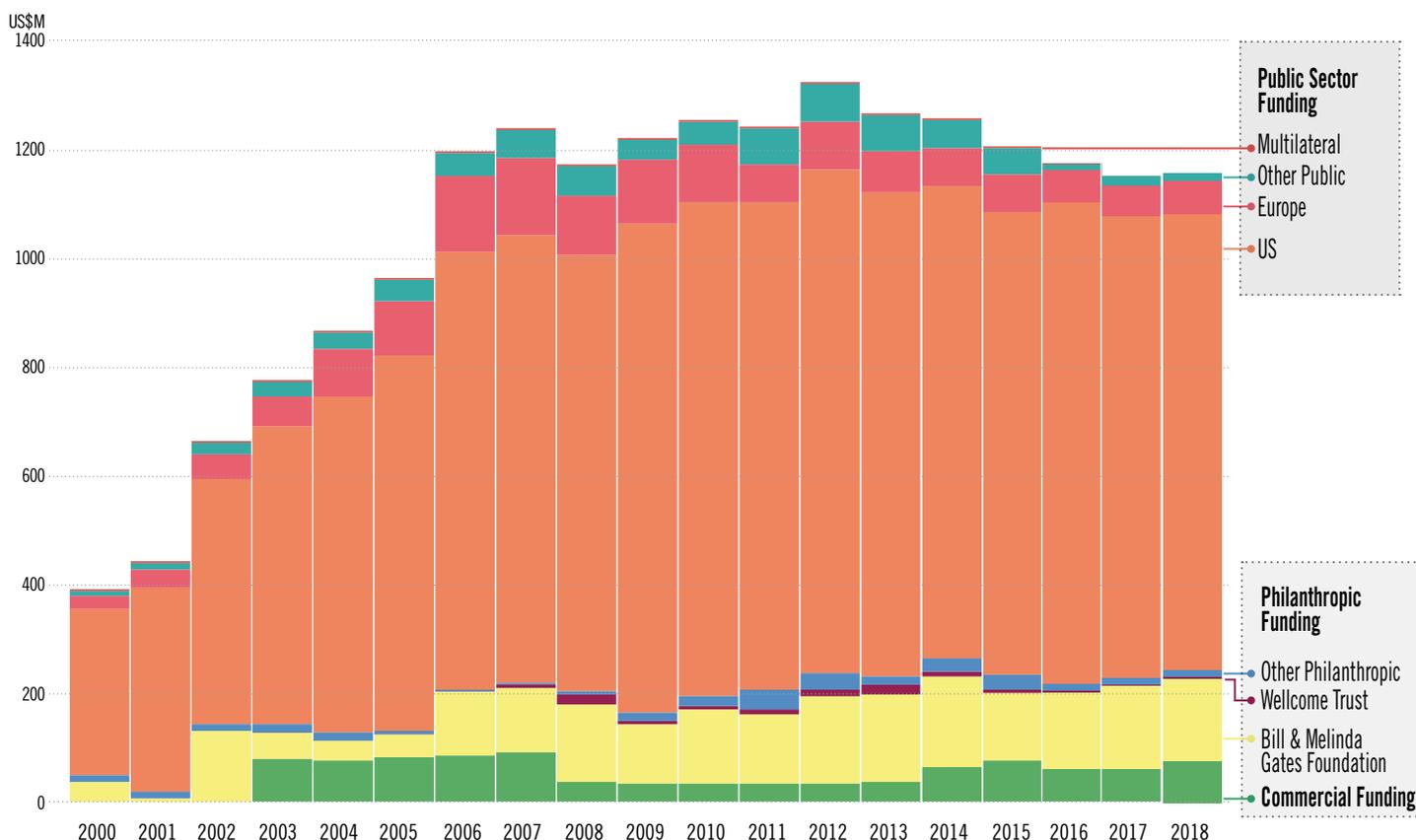
In its 15th annual report, the Resource Tracking for HIV Prevention Research & Development Working Group (“Working Group”) documents research and development spending for the calendar year 2018 and analyzes funding trends spanning eighteen years.

The Working Group has employed a standardized methodology since 2004 to generate comprehensive statistics on investment in HIV prevention research and development (R&D¹), including disaggregated trends for the following biomedical HIV prevention options: preventive 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. As part of an ongoing collaboration with the International AIDS Society, the Working Group also tracks expenditures in HIV cure and therapeutic AIDS vaccine research².

The 2018 Resource Tracking report depicts the most up-to-date and comprehensive field-wide estimates for the *who’s who* in financing HIV prevention research globally. Investment estimates that allow comparison across years, prevention options, sectors and countries engender greater transparency for funders and advocates alike, and help to assess the trajectory and impact of policies. These trends not only furnish vital facts for advocacy but also predict future funding scenarios that can impact the progress of this historic scientific agenda.

The Working Group’s analysis for 2018 builds on the US\$18 billion in funding tracked between 2000 and 2017 and underscores the importance of continued innovation in HIV prevention to bring a lasting end to the HIV/AIDS epidemic (Figure 1).

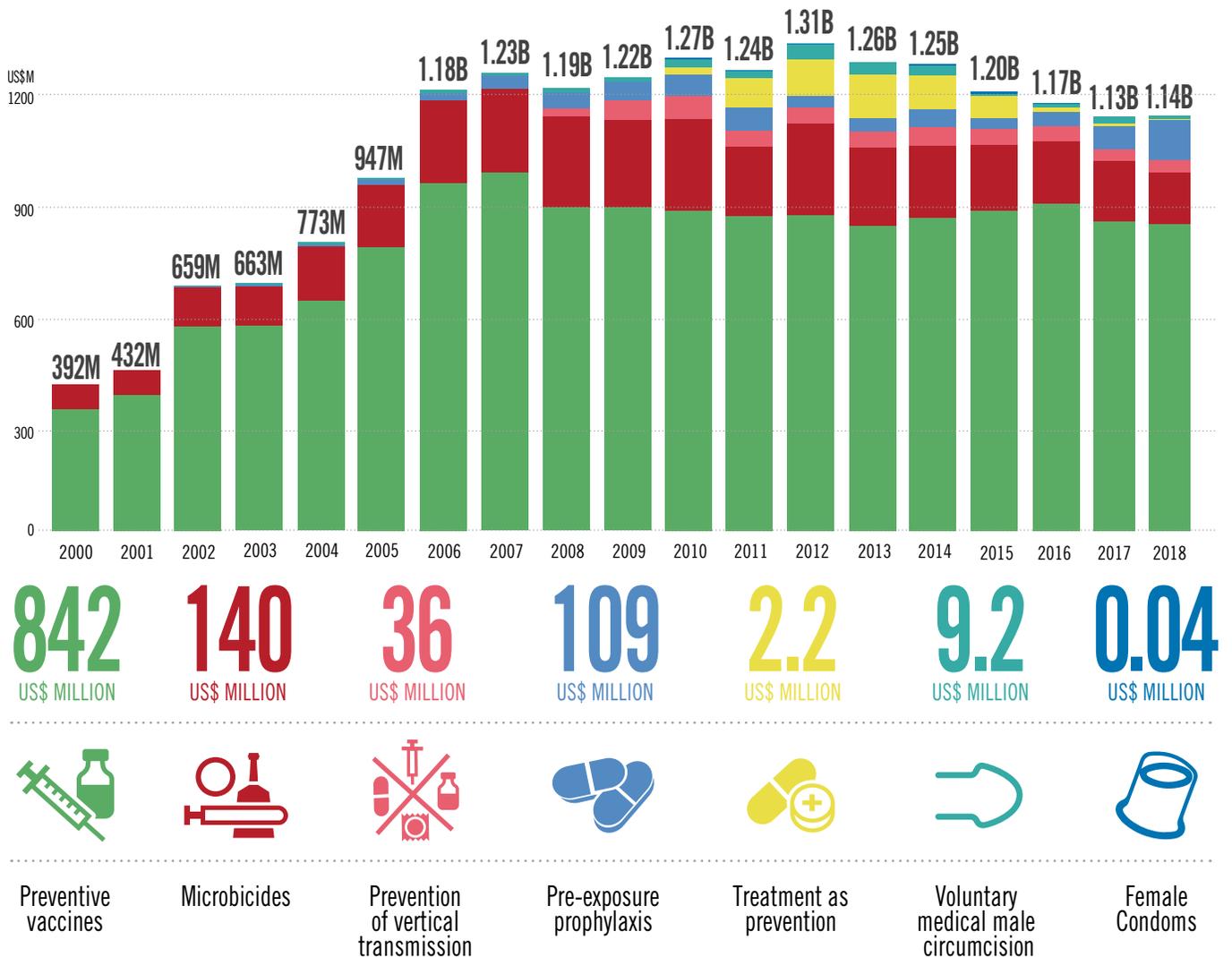
FIGURE 1 Global Funding Sources for HIV Prevention R&D, 2000-2018 (US\$ millions)



Trends in HIV Prevention R&D

In 2018, reported funding for HIV prevention R&D increased by 1.2 percent (US\$13 million) from the previous year, rising to US\$1.14 billion. According to Working Group estimates, this is the first time in five years that the trend of declining funding has reversed. Significant variation existed in investment by technology category: R&D funding increased for PrEP, PMTCT and female condoms, while funding for preventive vaccines, microbicides, VMMC and TasP saw a decline from the previous year (Figure 2). As the focus of three-fourths of total funding, preventive vaccines continued to make up the lion's share of overall HIV prevention funding, followed by microbicides and PrEP. The relative proportion of PrEP funding has been rising since 2016 and peaked at 9.6 percent, according to the most recent estimates (Figure 3).

FIGURE 2 Global HIV Prevention R&D Investment by Technology Category, 2000-2018



^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, 2017-2018

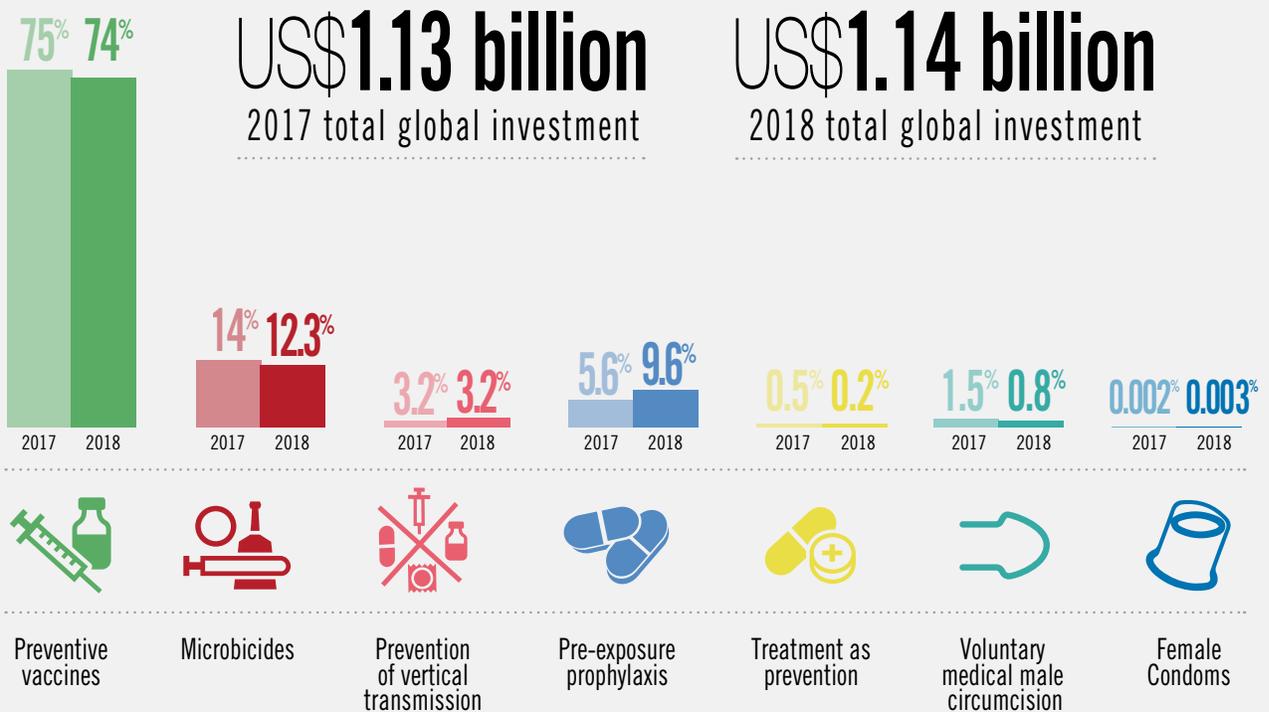
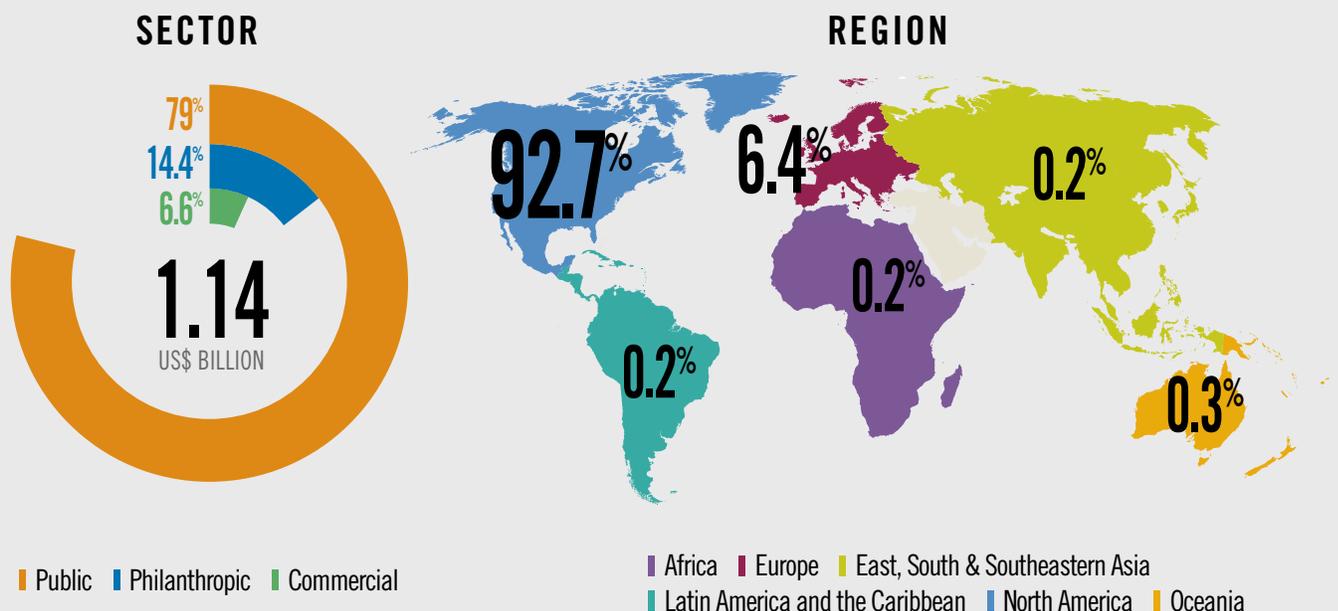


FIGURE 4 Total Global HIV Prevention R&D Investment by Sector & Region, 2018



■ Compared to 2017 levels, a slight decrease in investment was observed in the public sector (0.5 percent), while philanthropic investment remained unchanged. Global private sector investment increased by 30.8 percent to US\$74.7 million; however, this increase could be a factor of improved sector-wide reporting. The public sector continued to dominate, accounting for 79 percent of global investment (US\$900 million), and the philanthropic and private sectors followed with 14.4 percent and 6.6 percent, respectively. North America, and specifically the US, made up the bulk of public sector funding at US\$835 million (93 percent), while the European region came in second at US\$57 million (6.4 percent). Other regions contributed US\$8 million which constituted one percent of the cumulative public sector funding (Figure 4).

FIGURE 5a US Public Sector Investments in HIV Prevention R&D Compared to All Other Funding, 2013-2018 (US\$ billions)

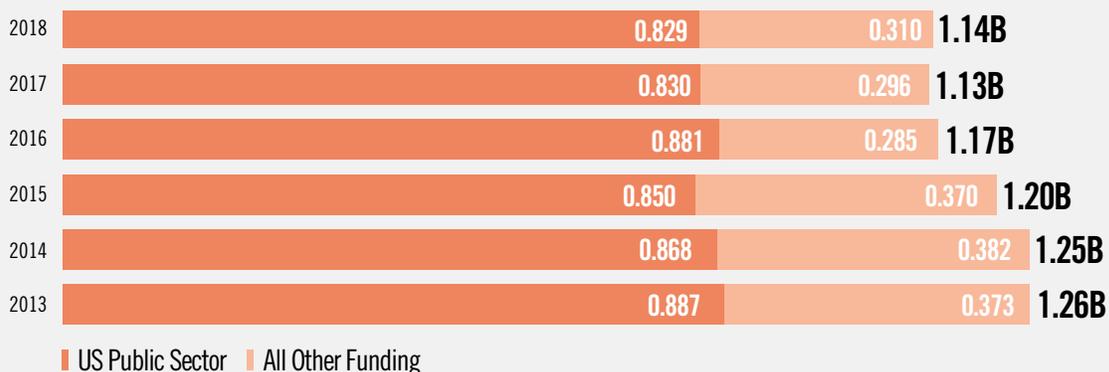
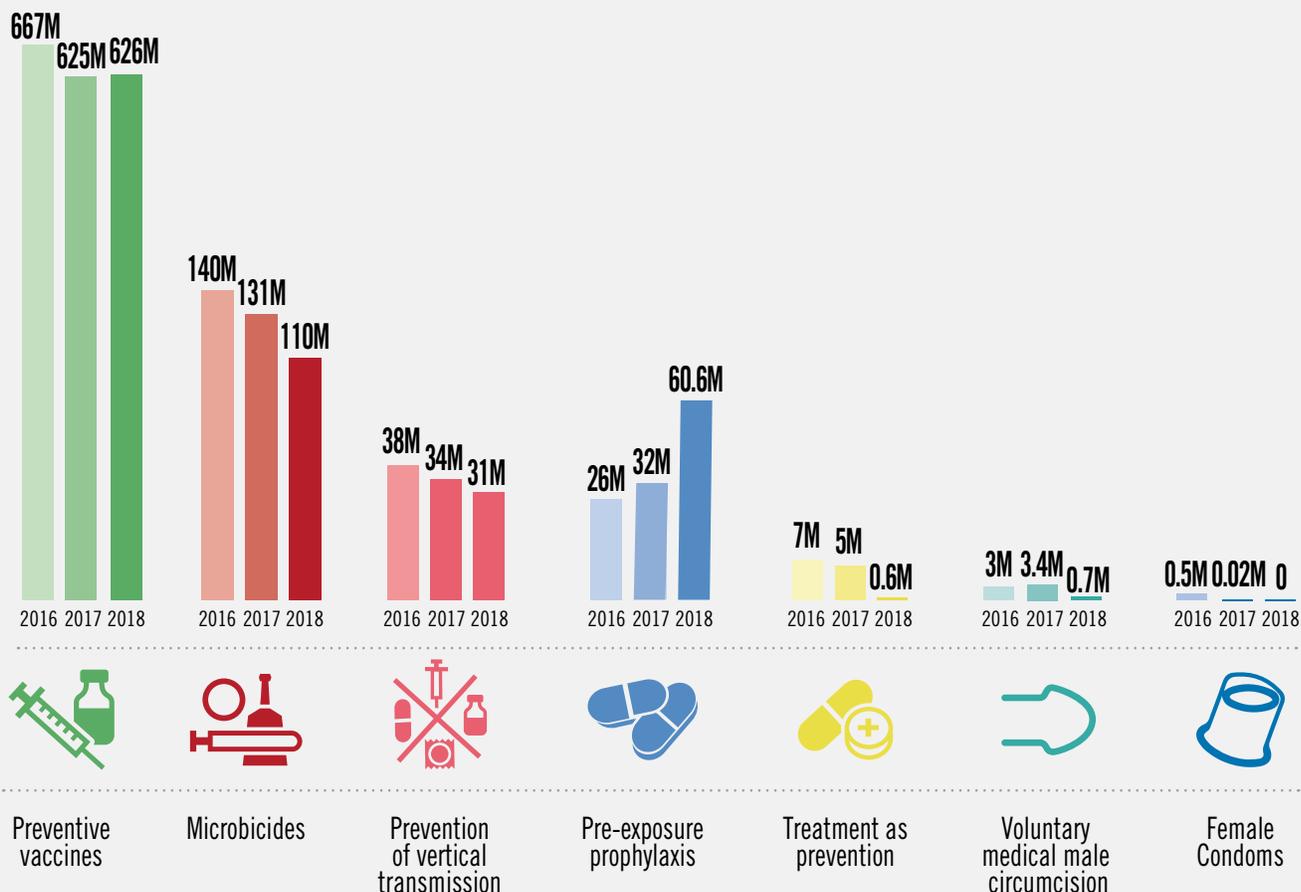


FIGURE 5b US Public Sector Investments in HIV Prevention R&D by Technology, 2016-2018 (US\$ millions)



■ US public sector investment remained unchanged in 2018, decreasing marginally from US\$830 million in 2017 to US\$829 million in 2018 (Figure 5a). This negligible shift masked significant variation in donor trends. The Centers for Disease Control and Prevention (CDC) had a notable 84 percent decrease in investment, from US\$9.9 million in 2017 to US\$1.5 million in 2018. The Military HIV Research Program (MHRP) and the National Institutes of Health (NIH) were the two US public donors with increases of eight percent (US\$35.6 million) and one percent (US\$720 million), respectively.

While US investment for PrEP and preventive vaccines increased by 91.7 percent and 0.2 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, 2013-2018 (US\$ billions)

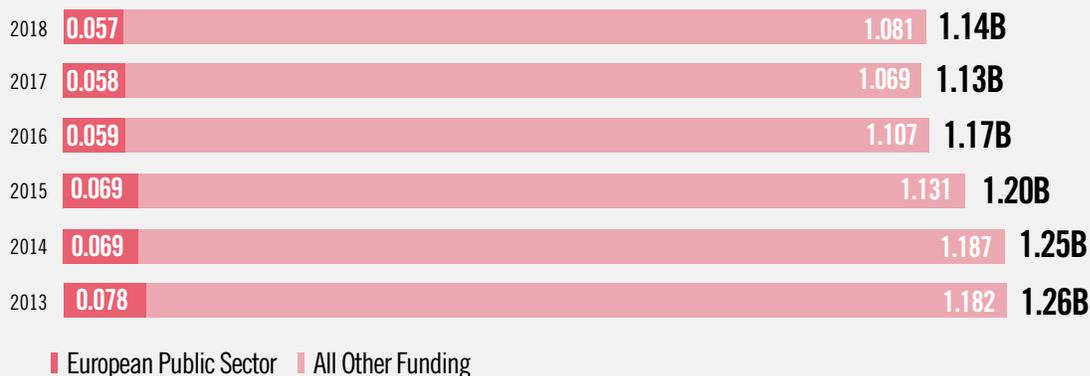
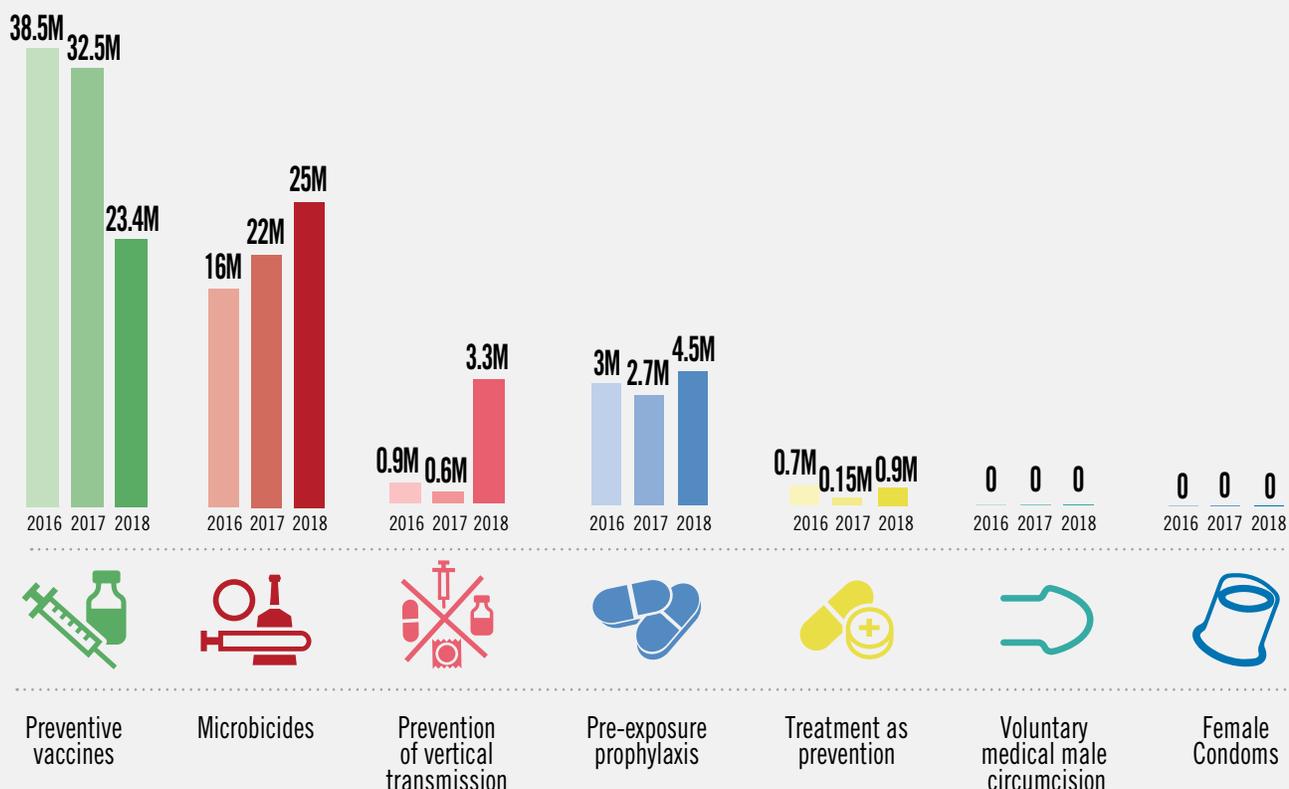


FIGURE 6b European Public Sector Investments in HIV Prevention R&D by Technology, 2016-2018 (US\$ millions)



- European public sector funding was also mostly unchanged at US\$57.5 million, with a 0.7 percent dip from 2017 levels. Regardless, this is the lowest funding observed in over a decade for the region (Figure 6a). Excluding preventive vaccines, European investment in all other prevention options increased in 2018 (Figure 6b).
- Global philanthropic funding levels saw no change in 2018 and remained at US\$164 million, or 14.4 percent of overall funding (Figure 7a). The Bill and Melinda Gates Foundation remained the largest funder and decreased its contribution slightly by 0.3 percent to US\$149.7 million. Wellcome Trust investment rose for the first time in five years to a total US\$2.4 million (Figure 7b). The majority of Gates Foundation investment was directed towards preventive vaccines (79 percent) and PrEP (14 percent), while Wellcome Trust funding was concentrated in preventive vaccine (44.8 percent) and microbicide (24.6 percent) research.

FIGURE 7a Investment in HIV Prevention R&D by Top Philanthropic Funders, 2018 (US\$ millions)

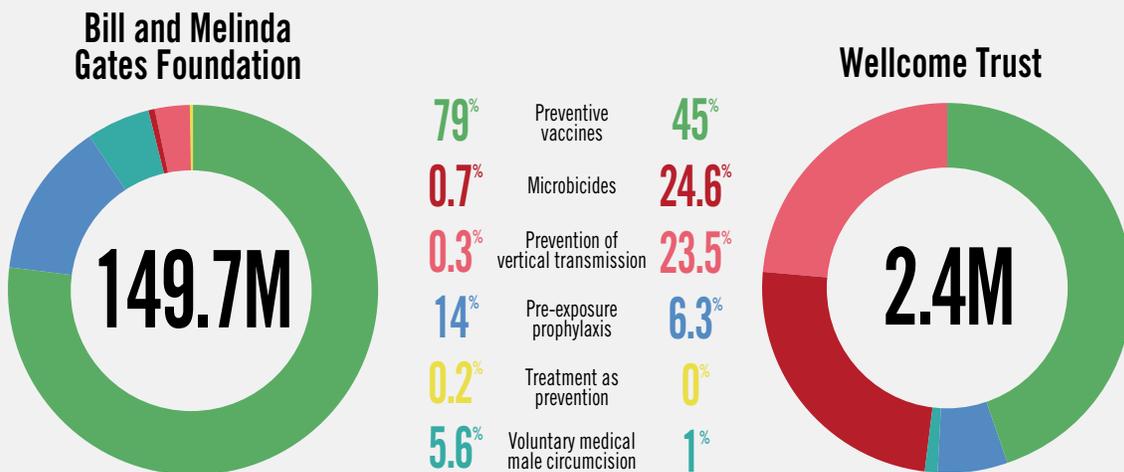
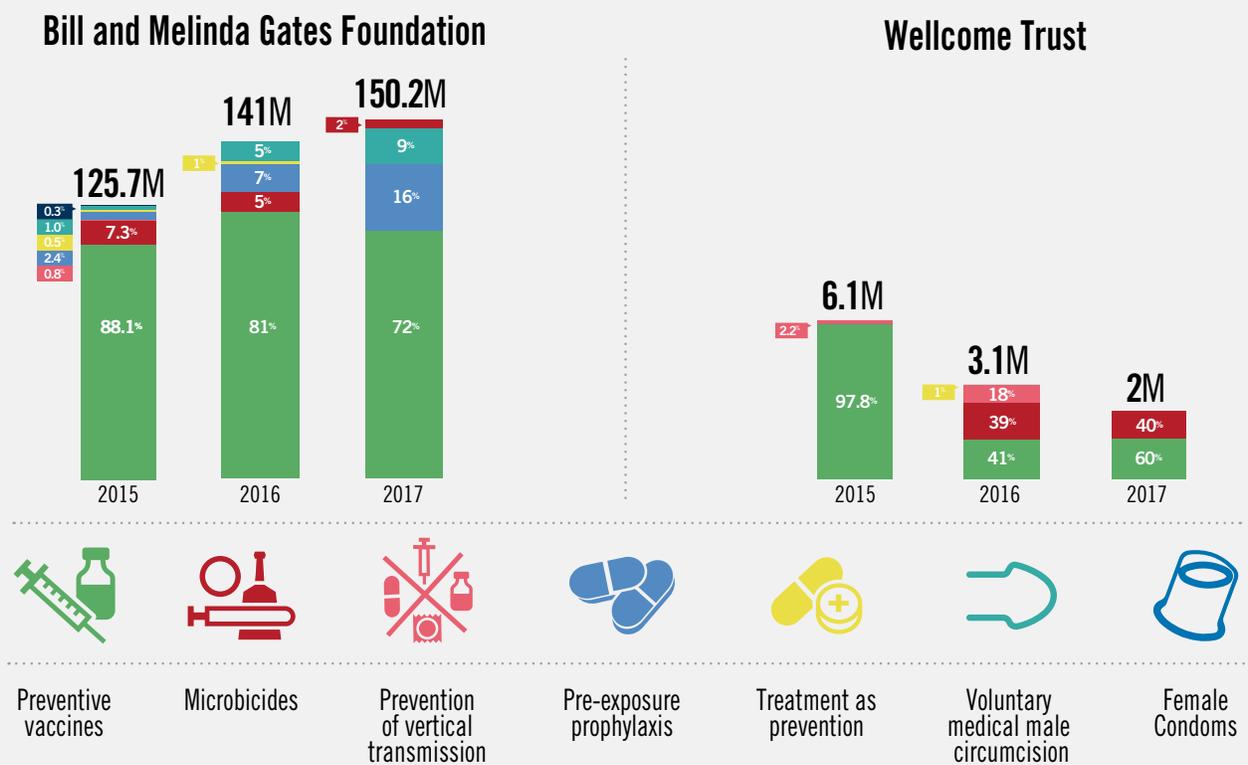


FIGURE 7b Investments in HIV Prevention R&D by Top Philanthropic Funders, 2015-2017 (US\$ millions)



Key Findings

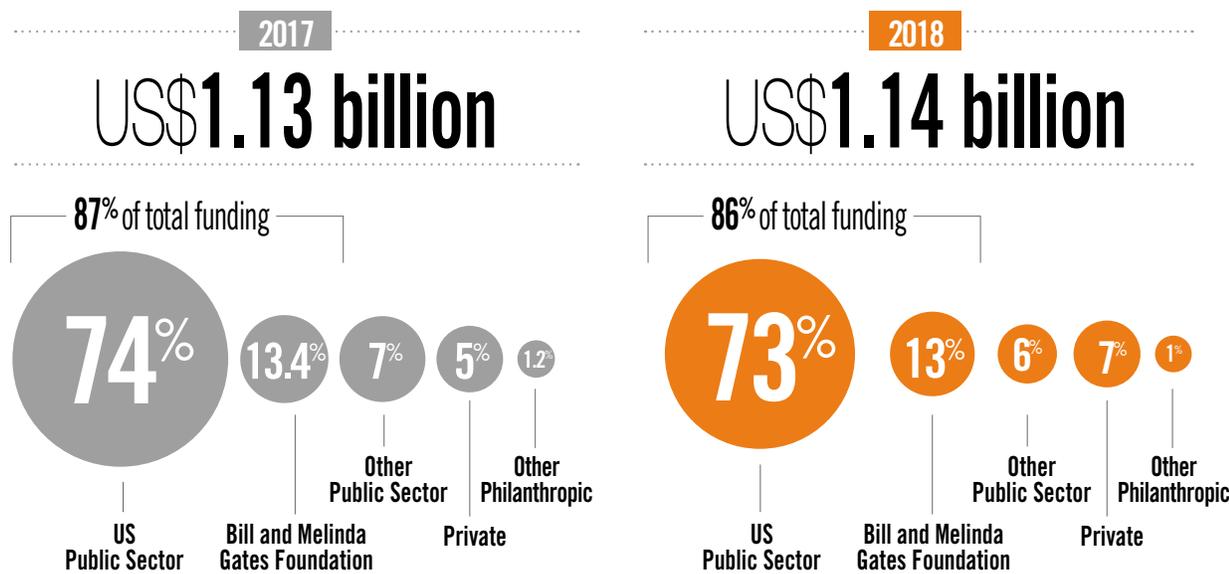
Dominant funders and their field-wide influence

Although past years' trend of a small number of large investors continued in 2018, the degree of funding imbalance has lessened slightly. The US public sector contributed almost three-fourths of all global funding (US\$829 million out of US\$1.14 billion), while the Bill and Melinda Gates Foundation remained the principal philanthropic donor, accounting for 91 percent (US\$149.7 million out of US\$164 million) of all sector investment. Investments by the two leading donors combined accounted for 86 percent of overall funding (Figure 8a), or 86 cents of every dollar spent.

While the slight improvements in the funding imbalance are to be lauded, innovations in HIV prevention R&D are still vulnerable to shifting donor priorities and fluctuations in investment. Predictably, 68 percent of the US\$8.2 million decrease in VMMC R&D in 2018 can be traced back to a reduction in investment from BMGF. Similarly, the 73 percent increase in PrEP funding in 2018 is due largely to enhanced investment from the US public sector, which increased PrEP investment by 91.7 percent, to US\$60.6 million.

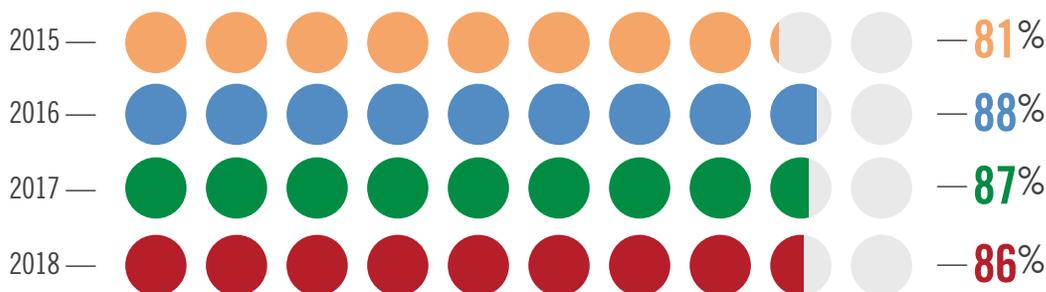
Diversifying the funding base is vital not only for the long-term sustainability of the field, but also to ensure that decades (and accompanying billions of dollars) of gains made in scientific innovation are not lost to mercurial policy shifts. The field has been moving toward greater proportionality for two years now but there is still much to be done to achieve parity in the funding landscape (Figure 8b).

FIGURE 8a Composition of the Global HIV Prevention R&D Investment Base, 2017-2018



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

FIGURE 8b Contributions from the Two Largest Donors, 2015-2018 (Percentage of overall funding)*



* Refers to the US public sector and the Bill and Melinda Gates Foundation

Emerging players outside of the US public sector

Funding outside the US public sector totaled US\$74 million in 2017, with 15 countries accounting for seven percent of the overall funding for that calendar year. This number decreased slightly to US\$71 million in 2018, and the 15 contributing countries represented six percent of overall funding. Prominent increases came from the UK (from US\$11.2M to US\$17.2M), Germany (from US\$3.2M to US\$7M), Canada (from US\$5M to US\$5.4M) and Australia (from US\$1.5 million to US\$1.6 million) (Figure 9). The European Commission showed a 25 percent increase in funding, with levels rising from US\$7.6 million in 2017 to US\$9.5 million in 2018. Investment by Australia and Canada increased by 73.4 percent and 9 percent, respectively, in 2018, while funding from France decreased by 17 percent (Figure 10).

FIGURE 9 Top Countries Investing in HIV Prevention R&D, 2017-2018 (US\$ millions)

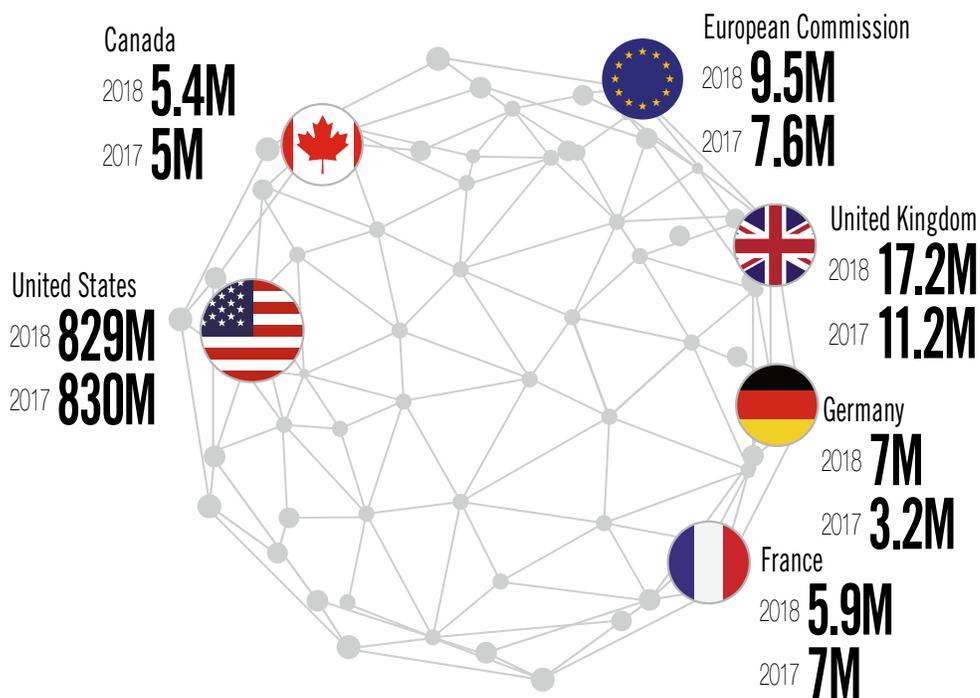
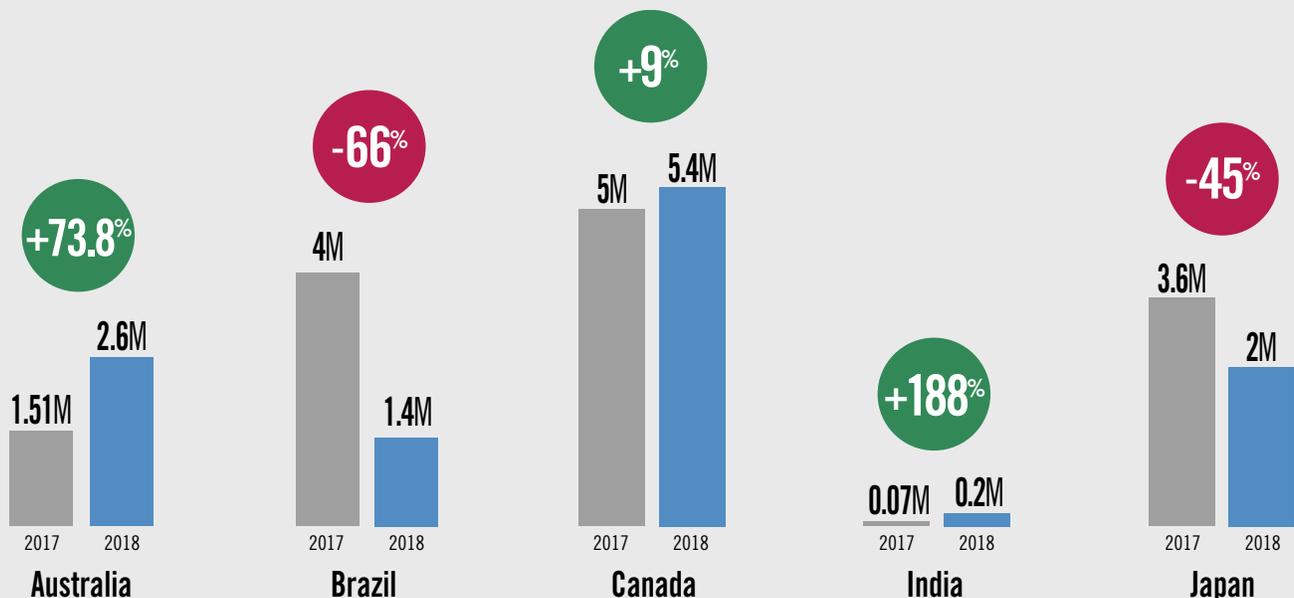


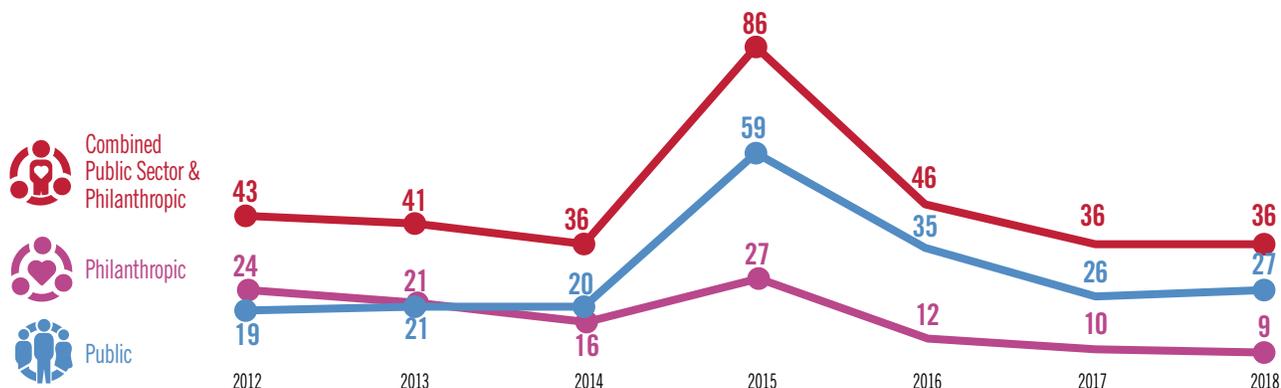
FIGURE 10 Changes in Public Sector Investment Outside the US and Europe, 2017-2018 (US\$ millions)



■ Decrease in the number of philanthropic funders engaged

Despite philanthropic funding levels remaining constant in 2018, the decline in the number of donors continued. In line with a trend observed since 2010 (which reversed briefly in 2015), the number of philanthropies engaged in HIV prevention research decreased to nine in 2018 (Figure 11). For philanthropies that report funding to the Working Group, three reported no longer supporting HIV prevention research in 2018. Independent philanthropic donors are essential to a vibrant funding base and they would also improve the funding imbalance that currently afflicts the investment landscape

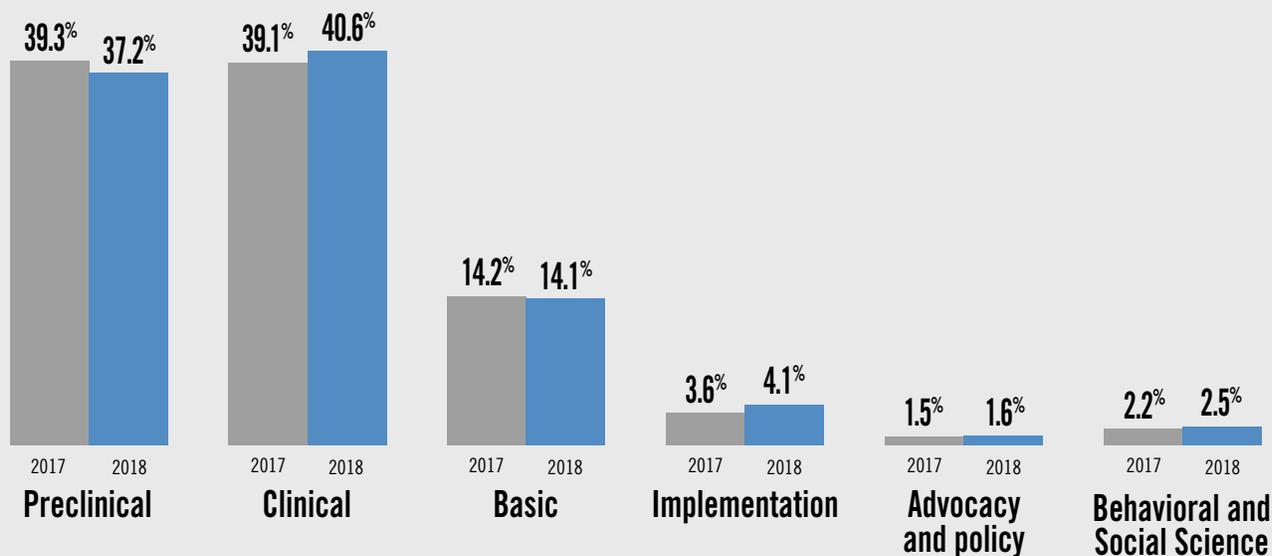
FIGURE 11 Number of Public Sector and Philanthropic Funders Investing in HIV Prevention R&D, 2012-2018



■ The unfinished agenda for social and behavioral research

As observed in previous years—and as is typical for R&D—clinical (40.6 percent) and preclinical research (37.2 percent) received more than three-fourths of overall funding in 2018. As for biomedical options with proven efficacy like VMMC and PMTCT, the emphasis remained on the “science of delivery” or implementation science. Approximately US\$28 million (50 percent) of PMTCT funding and US\$16 million (47 percent) of VMMC funding was allocated to projects aimed at service delivery and roll-out. The trend of increased funding for behavioral and social science research endured in 2018: levels rose from US\$25 million in 2017 to US\$28 million in 2018. These are encouraging—albeit modest—findings when considering the US\$1.14 billion invested in HIV prevention R&D overall (Figure 12).

FIGURE 12 Research to Rollout: Investment by Research Stage, 2017-2018

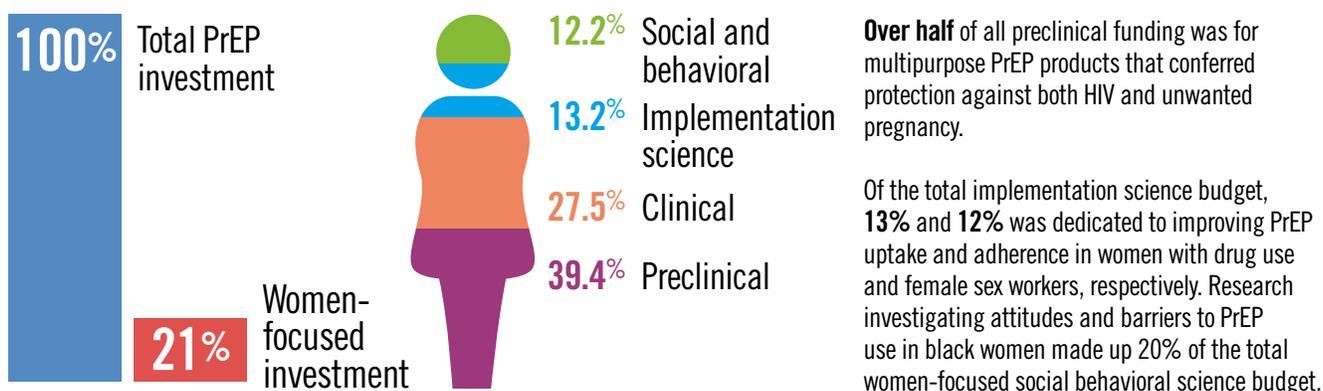


■ Women-focused PrEP research

The intersection of biological and structural factors confers a heightened risk of HIV acquisition in women and girls, and this is reflected in the disease’s epidemiology: 7,000 new HIV infections are recorded weekly in adolescent girls and young women, and girls aged 15-19 years make up three out of every four new HIV cases in sub-Saharan Africa³. This disproportionate burden calls for the development of women-controlled and initiated HIV prevention products that have proven efficacy and are designed from bench to bedside with the unique intersecting needs of women in mind.

One such option is PrEP, both in oral form and in other long-acting delivery systems that would circumvent issues around daily adherence. Out of the US\$109 million invested in PrEP overall, US\$23 million, or 21 percent, was for research explicitly focused on women. Most of this research was preclinical, with an emphasis on long-acting products that conferred multipurpose protection against HIV and unintended pregnancy. Almost half (44 percent) of the implementation science budget focused on the uptake and adherence of oral PrEP in marginalized women, women with injecting drug use, and female sex workers (Figure 13).

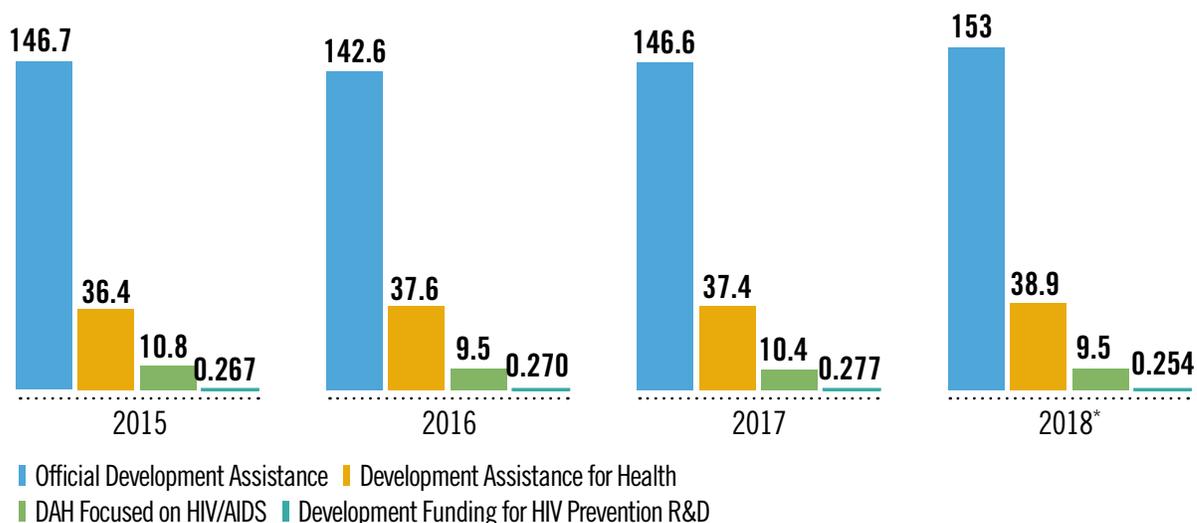
FIGURE 13 Investment in Women-focused PrEP R&D, 2018



■ Spending on HIV/AIDS in the global context

Initiatives to end the HIV/AIDS epidemic have great support in the global health discourse and have been featured prominently in the Millennium Development Goals (MDG 6) and more recently, the Sustainable Development Agenda (SDG 3). Following an upswing in funding worth US\$562 billion between 2000 and 2015, Development

FIGURE 14 HIV Prevention R&D in the Context of Development Assistance for Health and Total Official Development Assistance, 2015-2018 (US\$ billions)

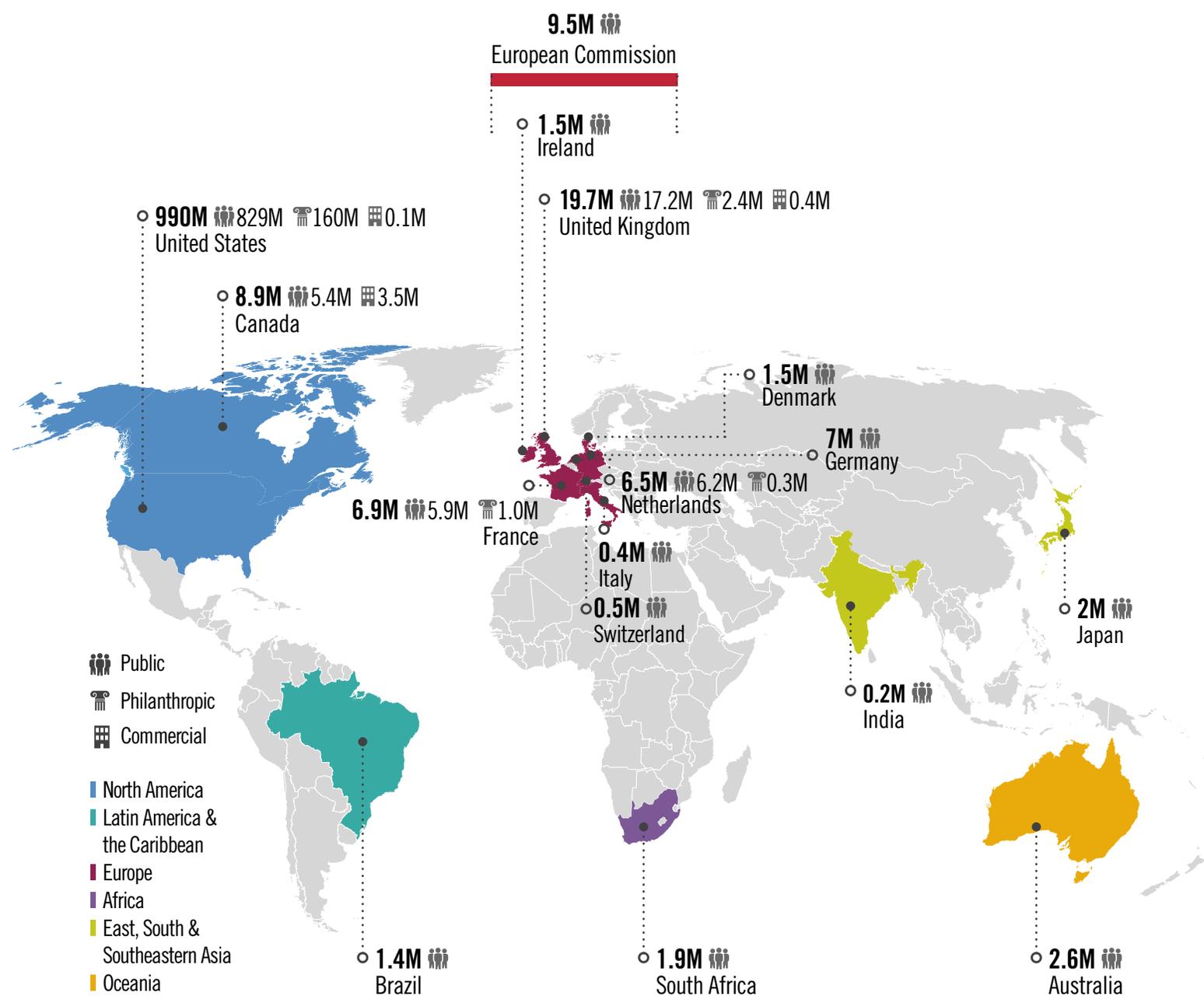


Assistance for Health (DAH) for HIV/AIDS has been declining annually at a rate of 1.4 percent since 2011⁴. DAH is defined as the financial or in-kind support from development agencies to low and middle-income countries in order to maintain or improve health.

In 2018, DAH focused on HIV/AIDS decreased from US\$10.4 billion to US\$9.5 billion. Development agency support for HIV prevention R&D amounted to US\$254 million, or 2.7 percent of total DAH, decreasing from the 2017 level of US\$277 million (Figure 14).

* 2018 estimates are preliminary and subject to change

FIGURE 14 Total Global Investment in HIV Prevention R&D by Country, 2018 (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 2018, there were nearly 630,000 participants in HIV prevention research trials globally, mostly originating from sub-Saharan Africa, Asia, Europe and North America (Figure 16a).

A majority of participants were enrolled in research investigating TasP and PrEP, and while there were trials enrolling groups like MSM, transgender people and PWID, most of the studies did not specify the inclusion of key populations (KPs) (Figure 16b).

FIGURE 16a HIV Prevention R&D Trial Participants by Region in 2018 (thousands)

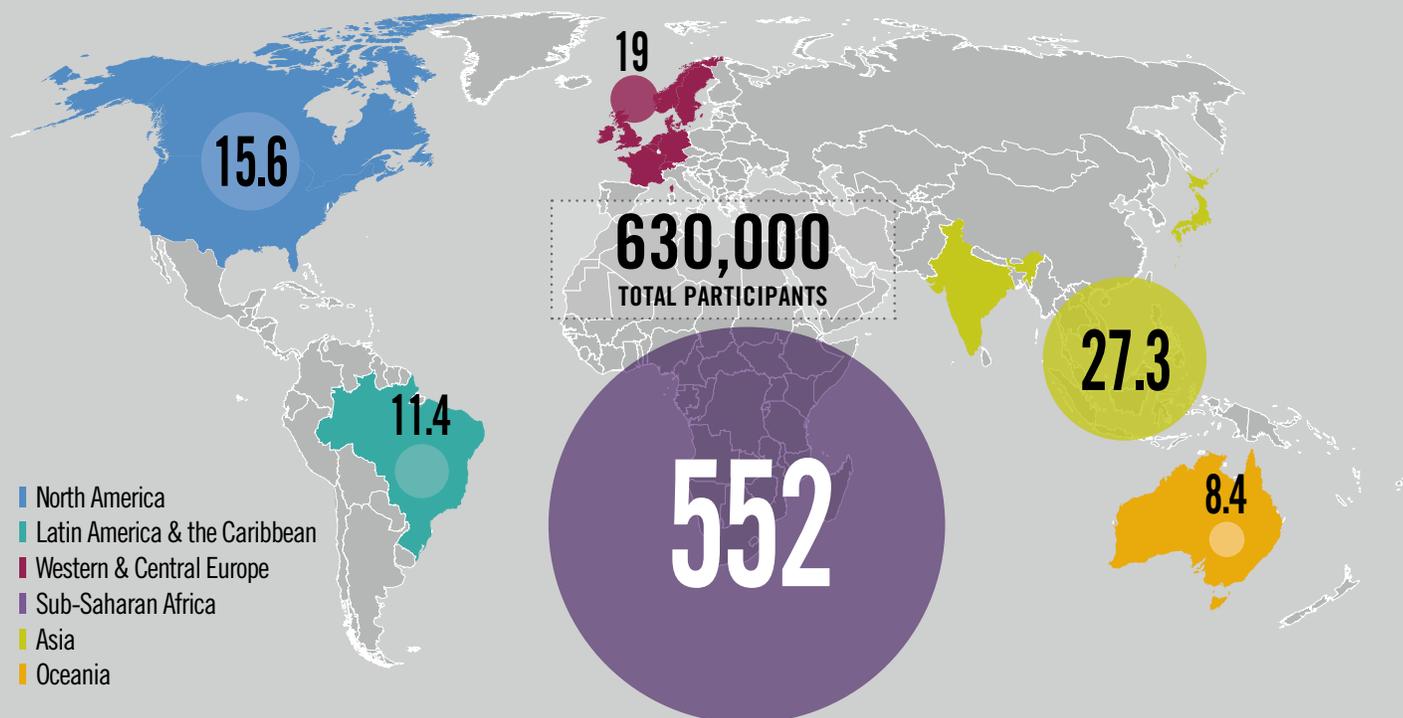
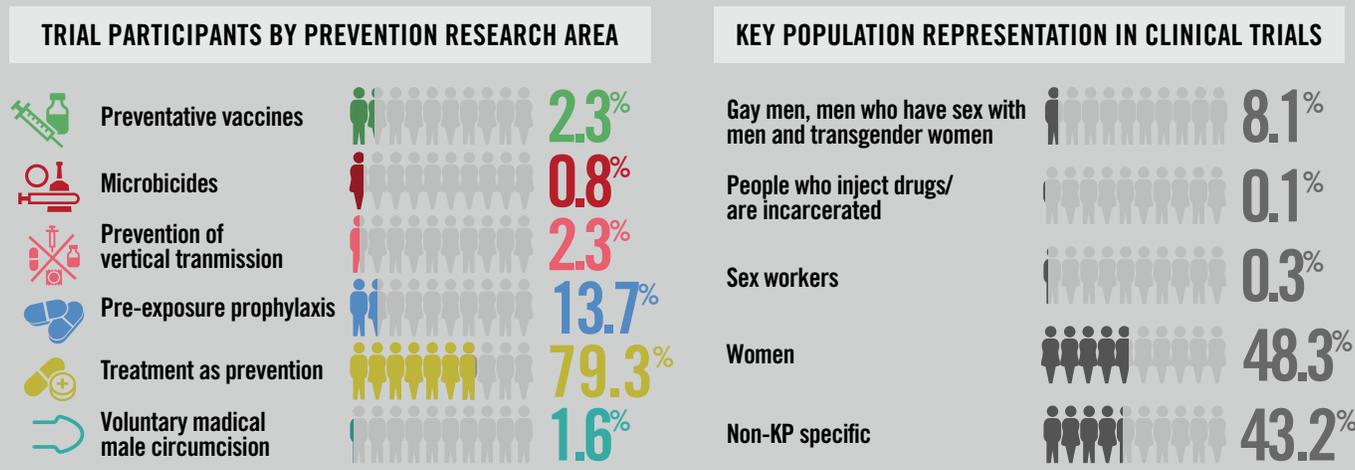


FIGURE 16b Trial Participants, 2018



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 research, trial preparation, behavioral research 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, 65 funders reported their investments. A total of 454 grants were allocated to HIV prevention research, with an average grant size of US\$2.5 million.

TABLE 1 Global Investments in HIV Prevention R&D: 2018 Funding Map

Funding type	2017	2018	% Change 2017-2018	Funder	2018 totals in US\$ millions (2017 investments, percent change ^a)																									
					Total 2018	Total 2017	% Change	Preventive AIDS vaccines			Microbicides			Prevention of vertical transmission			Pre-exposure prophylaxis			Treatment as prevention			Voluntary medical male circumcision			Female condoms				
								2018	2017	Change	2018	2017	Change	2018	2017	Change	2018	2017	Change	2018	2017	Change	2018	2017	Change	2018	2017	Change	2018	2017
US Public Sector	\$830 million	\$829 million	-0.1%	NIH	\$720	\$713	1%	\$561.7	\$561.8	-0.02%	\$88.9	\$95	-6.3%	\$31.3	\$34.3	-9%	\$36.6	\$20.1	82%	\$0.6	—	—	\$0.7	\$1.7	-59.6%	—	\$0.02	—		
				USAID/PEPFAR*	\$72.5	\$74.7	-3%	\$28.7	\$28.7	—	\$19.9	\$34.9	-42.8%	—	—	—	\$23.8	\$10	140%	—	—	—	—	—	—	—	—	—	—	—
				CDC	\$1.5	\$9.9	-84.2%	—	—	—	—	—	—	—	—	—	—	—	\$0.2	\$1.7	-86.4%	—	\$4.9	—	—	\$1.6	—	—	—	—
				MHRP	\$35.6	\$33	8%	\$35.6	\$33	8%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
European Public Sector	\$58 million	\$57.5 million	-0.7%	Belgium	\$0.2	—	—	—	—	—	—	\$0.2	—	—	—	—	—	\$0.06	—	—	—	—	—	—	—	—	—	—		
				Denmark	\$1.5	\$1.5	2%	\$0.7	\$0.7	7.8%	\$0.75	\$0.77	-3.3%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
				EC	\$9.5	\$7.6	25%	\$9.4	\$7.5	26%	—	\$0.01	—	\$0.1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
				France	\$5.9	\$7.1	-17%	\$2.5	\$5.8	-57%	\$0.05	\$0.2	-96.8%	\$0.27	\$0.55	-51%	\$2.4	\$2.7	-12%	\$0.73	\$0.14	416%	—	—	—	—	—	—	—	—
				Germany	\$7.1	\$3.2	122%	\$0.01	—	—	\$6.9	\$3.2	114%	\$0.2	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Ireland	\$1.5	\$2.1	-31%	—	\$0.6	—	\$1.5	\$1.6	-6.4%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Italy	\$0.4	\$1.6	-73%	\$0.14	\$1.6	-91%	—	—	—	\$0.3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Netherlands	\$6.2	\$11.2	-45%	\$4.1	\$3.7	10.2%	\$2.1	\$7.5	-72%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Norway	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Spain	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Sweden	—	\$7.2	—	—	\$6.0	—	—	\$1.1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Switzerland	\$0.5	\$0.31	53.6%	\$0.32	\$0.31	1%	—	—	—	—	—	—	—	—	—	—	—	\$0.16	—	—	—	—	—	—	—	—
UK	\$17.2	\$11.2	53.5%	\$3.1	\$4.5	-30%	\$13.5	\$6.7	102%	\$0.26	\$0.02	1414%	\$0.29	—	—	—	—	—	—	—	—	—	—	—	—	—				
Other Countries	\$16.4 million	\$13.5 million	-17.5%	Australia	\$2.6	\$1.51	74%	\$1.9	\$0.8	132%	—	\$0.2	—	\$0.07	\$0.06	26%	\$0.3	\$0.03	998%	\$0.1	\$0.2	-42%	\$0.19	\$0.21	-5%	—	—	—		
				Brazil	\$1.4	\$4.1	-66%	—	\$0.06	—	—	—	—	—	—	\$0.4	—	\$1.4	\$4	-66%	\$0.03	—	—	—	—	—	—	—	—	
				Canada	\$5.4	\$5	9%	\$2.3	\$3.8	-41%	\$2.2	\$0.8	174%	\$0.3	\$0.2	41%	\$0.5	—	—	\$0.086	\$0.087	-1.7%	\$0.01	—	—	—	—	—	—	
				China	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
				Cuba	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
				India	\$0.2	\$0.07	188%	\$0.2	\$0.07	188%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
				Israel	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
				Japan	\$2	\$3.6	-44%	\$2	\$3.6	-45%	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Russia	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				South Africa	—	\$2.1	—	—	\$1.6	—	—	\$0.2	—	—	—	—	—	—	\$0.2	—	—	—	—	—	—	—	—	—	—	—
				Taiwan	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
				Thailand	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Philanthropic	\$164 million	\$164 million	No change	BMGF	\$149.7	\$150.2	-0.3%	\$118	\$108	9.5%	\$1.1	\$3.3	-67%	\$0.42	\$0.44	-4.5%	\$21	\$24	-12.5%	\$0.23	\$0.20	13%	\$8.3	\$13.9	-40%	—	—			
				Wellcome Trust	\$2.4	\$2.1	18%	\$1.1	\$1.2	-12%	\$0.6	\$0.8	-26.8%	\$0.6	—	—	\$0.15	\$0.005	2669%	—	—	—	\$0.02	—	—	—	—	—		
				Other	\$11.9	\$11.8	1%	\$11.1	\$11.2	-0.7%	\$0.11	\$0.14	-23%	\$0.4	—	—	\$0.41	\$0.40	0.4%	\$0.2	\$0.1	107%	—	—	—	—	—	—		
Industry	\$57 million	\$74.7 million	30.8%	Commercial Sector	\$74.7 million	\$57 million	30.8%	\$53.7	\$57	-6%	\$0.8	\$0.2	303%	—	—	—	\$20.2	—	—	—	—	—	—	—	0.04	—				
Total	\$1.13 billion	\$1.14 billion	1.2%	HIV prevention option totals	\$1.14 billion	\$1.13 billion	1.2%	\$842	\$845	-0.3%	\$140	\$159	-12%	\$36	\$35.7	1%	\$109	\$63	73.4%	\$2.2	\$5.6	-61.5%	\$9.2	\$17.5	-47%	\$0.04	\$0.02	79%		
				% Change 2017–2018																										

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

* The USAID Microbicide Program funding covers topical microbicide products as well as systemic and sustained-release HIV pre-exposure prophylaxes.

AIDS Vaccines

1.0 Global investment in preventive AIDS vaccines R&D

In 2018, funding for preventive AIDS vaccines R&D decreased by a marginal 0.3 percent or US\$2.7 million from the previous year, to a total of US\$842 million. The public sector made up 78 percent of overall investment, at US\$657.8 million, with the philanthropic and commercial sectors contributing 15.5 percent and 6.4 percent, respectively. At US\$626 million or 95 percent of all public sector funding, the US remained the largest donor of preventive vaccine research globally. US public sector funding increased by 0.2 percent from 2017 levels, to US\$626 million, an uptick bolstered by the eight percent increase in funding from the MHRP (Figure 17).

FIGURE 17 AIDS Vaccine Funding, 2000 - 2018 (US\$ millions)

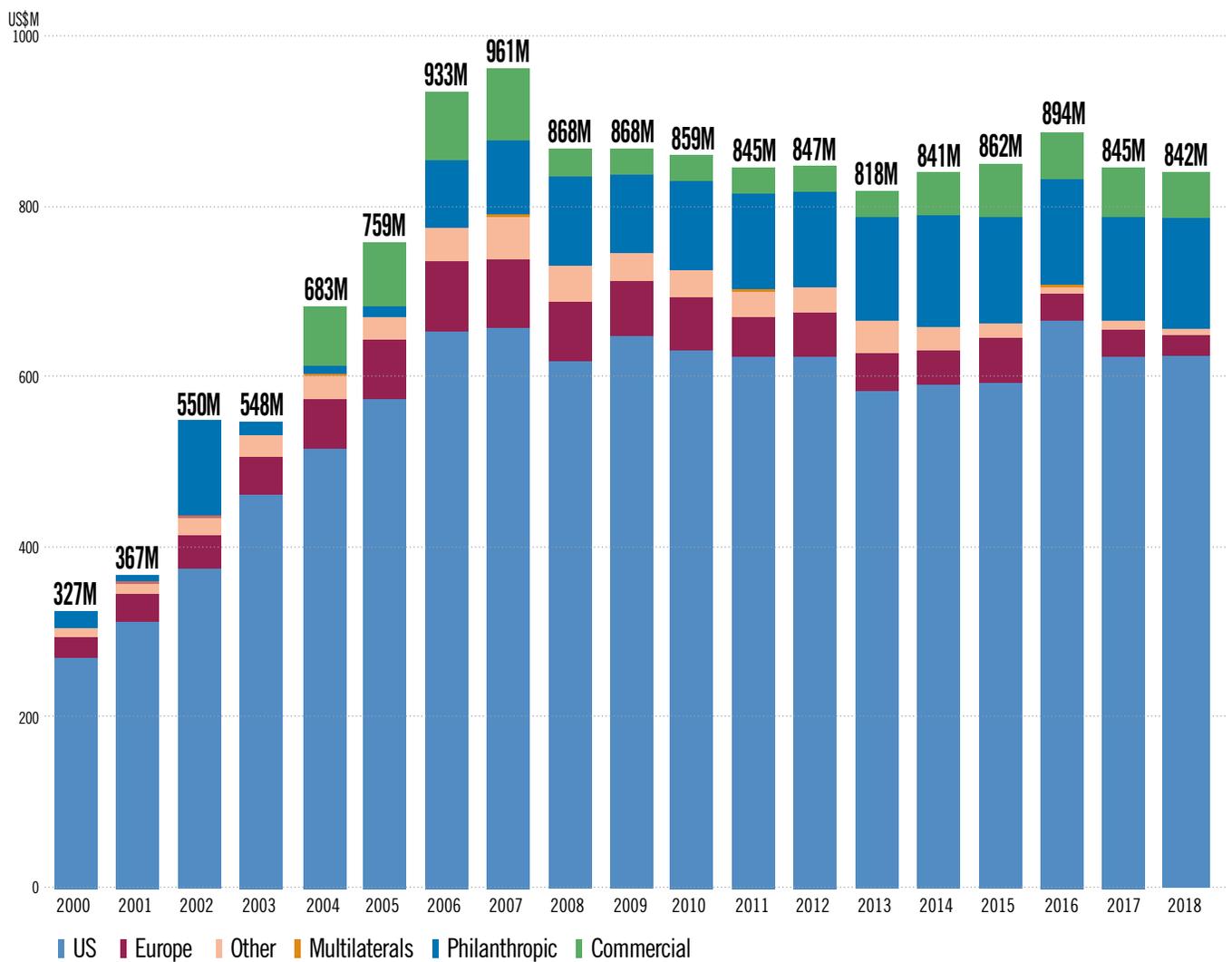
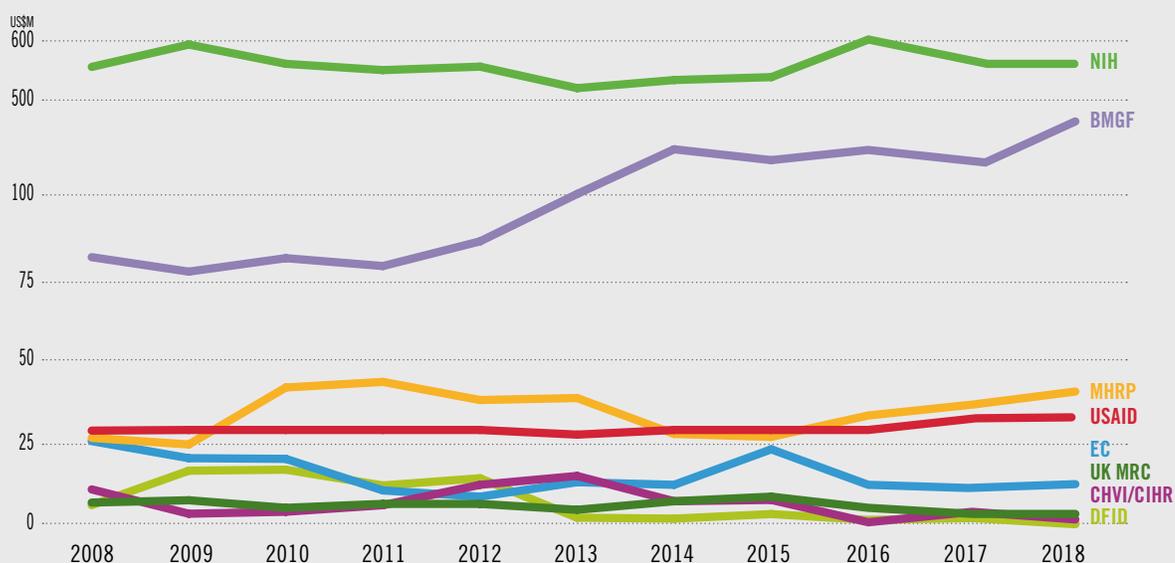


TABLE 2 Annual Investment in AIDS vaccine R&D, 2000 – 2018 (US\$ millions)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
US	272	314	376	463	516	574	654	659	620	649	632	615	623	584	591	595	667	624.7	626
Europe	23	32	39	44	57	69	82	79	69	65	61	48.5	52	44	40	44	38.5	32.5	23.8
Other Countries	10	12	21	24	28	27	38	49	41	31	32	30	31	38	27	26	7.8	10.1	7.9
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	0
Total Public	307	359	436	532	602	672	776	789	731	746	726	702	707	667	653	655	714	667	657.8
Total Philanthropic	20	7	112	15	12	12	78	88	104	92	103	113	110	120.5	131	132	126	120.7	130.7
Total Commercial	–	–	–	–	68	75	79	84	33	30	30	30	30	31	51	62	54	57	53.7
Total Global Investment	327	366	548	547	682	759	933	961	868	868	859	845	847	818	840	859	894	845	842

FIGURE 18 Top AIDS Vaccine Funder Trends, 2008-2018 (US\$ millions)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
NIH	556.1	596	561.6	550.4	556.6	518.2	532.7	537.9	605	561.8	561.7
BMGF	81.2	76.8	80.9	78.5	86	100.4	114	110.7	113.8	108	118.6
USAID	28.5	28.7	28.7	28.7	28.7	27.3	28.7	28.7	28.7	28.7	28.7
MHRP	26.3	24.3	41.6	43.3	37.8	38.4	27.5	26.6	33.1	33	35.6
EC	25.3	20.1	19.9	10.3	8.4	12.8	12	22.8	12	7.5	9.4
DFID	5.8	16.3	16.6	11.8	14	2	1.7	3.1	1.3	1.3	0
CHVI/CIHR	10.6	3.2	3.8	5.8	12	14.7	7	7.4	0.6	3.8	2.3
UK MRC	6.6	7.3	5	6.2	6.2	4.4	7	8.4	5	3.2	3.1



Overall European investment in preventive vaccine R&D decreased by 27 percent and amounted to US\$23.8 million, the lowest levels observed since 2001. Philanthropic contributions increased by US\$10 million, to US\$130.7 million, in 2018. The aforementioned boost is due mostly to the 9.5 percent increase in BMGF funding, and BMGF remains the largest philanthropic funder of vaccine research, at US\$118 million.

The commercial sector contributed US\$53.7 million, representing a six percent decrease from the previous year.

Australia, Denmark, India, the Netherlands and Switzerland all increased their commitments in 2018, which helped cushion against the decrease in funding from Canada, France, Italy, Japan and the UK. The European Commission also stood out with an increase in investment from US\$7.5 million to US\$9.4 million in 2018.

TABLE 3 Philanthropic Investment in AIDS Vaccine R&D by Foundations and Commercial Philanthropy, 2018

Amount	Investors
US\$118.6 million	Bill and Melinda Gates Foundation
US\$1 million to US\$10 million	Ragon Institute
US\$250,000 to <US\$1 million	Wellcome Trust, Institut Pasteur, Sidaction
<US\$250,000	amfAR, Campbell Foundation

TABLE 4 Top AIDS Vaccine Funders for 2012 - 2018 (US\$ millions)^{a,b}

Rank	2012		2013		2014		2015		2016		2017		2018	
	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount
1	NIH	557	NIH	518.2	NIH	532.7	NIH	538	NIH	605	NIH	561.8	NIH	561.7
2	BMGF	86	BMGF	100.4	BMFG	114	BMFG	103	BMGF	114	BMGF	108	BMGF	118.6
3	MHRP	37.8	MHRP	38.4	USAID	28.7	USAID	28.7	MHRP	33	MHRP	33	MHRP	35.6
4	USAID	28.7	USAID	27.3	MHRP	27.5	MHRP	26.6	USAID	29	USAID	28.7	USAID	28.7
5	DFID	14	CHVI ^c	14.7	EC	12	EC	22.3	EC	12	Ragon Institute	10	Ragon Institute	10
6	CHVI	12	EC	12.8	Ragon Institute	10	Ragon Institute	10	Ragon Institute	10	EC	7.5	EC	9.4
7	Ragon Institute	10	Ragon Institute	10	CHVI	7	UK MRC	8.3	Swedish Research Council	6	EDCTP	5	Dutch PDP	4
8	EC	8.4	Wellcome Trust	7.7	China ^d	7	CHVI	7.2	ANRS	5.3	ANRS	4.3	UK MRC	3.1
9	Wellcome Trust	8.2	China ^d	7	UK MRC	7	China ^d	7	UK MRC	5	CIHR	3.8	Sumagen Canada, Inc.	3.5
10	China	7	NHMRC	6.8	Wellcome Trust	6.2	Wellcome Trust	6	Dutch PDP	3.6	Dutch PDP	3.7	EDCTP	3.4
11	MRC	6.2	ANRS	5.3	Netherlands	5.1	Institut Pasteur	5.5	EDCTP	3	Sumagen Canada, Inc.	3.5	ANRS	2.5
12	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 Biotechnology	3.4	CIHR	2.3
13	Netherlands	4.8	Institute Pasteur	4.8	Sumagen Canada Inc.	2.8	DFID	3.1	Sumagen Canada Inc.	1.4	UK MRC	3.2	World Bank (Japan)	2
14	NHMRC	4.4	UK MRC	4.4	ANRS	2.7	Japan AMED	2.4	DFID	1.3	World Bank (Japan)	2	NHMRC	1.8
15	ANRS	4	DANIDA	2.2	South Africa DST/DOH	2.5	CIHR	2.4	Wellcome Trust	1.3	SAMRC	1.6	Wellcome Trust	1

^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 due 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*, regarding a Phase II preventive AIDS vaccine trial started in August 2012, as well as other basic research underway.

1.1 Developments in the field of preventive AIDS vaccine research

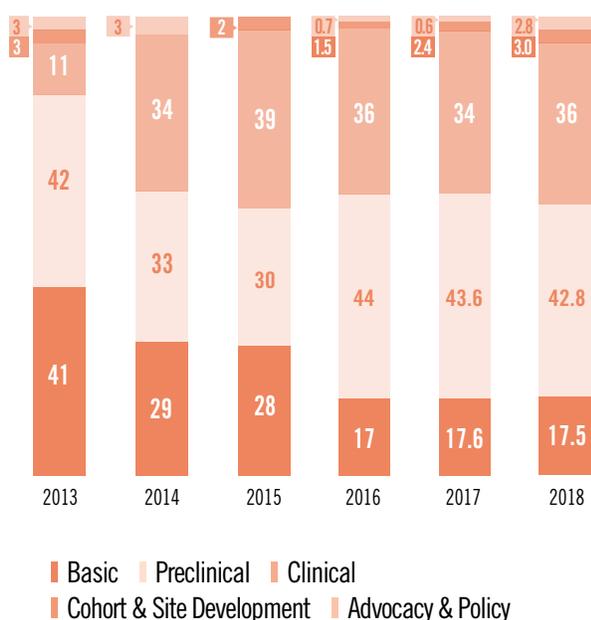
It is an unprecedented time for vaccine research with multiple late-stage vaccine efficacy trials underway. Some of these include:

- The AMP Study (HVTN 703/HPTN 081 and HVTN 704/HPTN 085)—which comprises two “sister” Phase II safety and efficacy trials—is currently active but no longer recruiting participants. These proof-of-concept trials are testing the administration of the VRC01 monoclonal antibody in HIV-negative women in several African countries⁵, and in MSM and transgender men and women in North and South America⁶. Study results are expected in the latter half of 2020.
- The Phase IIb/III HVTN 702 study is ongoing and recruiting the target number of 5,400 men and women in South Africa. 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 May 2022⁷.
- HPX2008/HVTN 705 is the Phase IIb proof-of-concept study currently recruiting participants in five countries across sub-Saharan Africa. 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 in the second quarter of 2022⁸.

1.2 Funding allocations for preventive AIDS vaccine R&D

Funding for HIV vaccine R&D was allocated to the following areas in 2018: basic research (17.5 percent), preclinical (42.9 percent), clinical (36 percent), cohort and site development (2.8 percent) and advocacy and policy (2.8 percent). In an enduring trend since 2016, preclinical strategies out-funded clinical trials, which tend to be much more cyclical in nature. Further information about the categories used to define R&D can be found in Table 13 of the Methodology section of the Appendix.

FIGURE 19 AIDS Vaccine Funding Allocations, 2013-2018



BOX 1

Phase III Trial of the Mosaic Vaccine

Mosaico (HPX3002/HVTN 706) is the Phase III efficacy trial starting in 2019 among 3,800 MSM and transgender people across 55 trial sites in the following countries: Argentina, Brazil, Italy, Mexico, Peru, Poland, Spain and the US⁹. Under investigation is the heterologous vaccine regimen using Ad26. Mos4.HIV and Clade C and Mosaic gp140. This is a slightly revised regimen—in that it has the added Mosaic gp140 to the boost doses—from the one being tested in the Phase IIb Imbokodo (HPX2008/HVTN 705) proof of concept trial in sub-Saharan Africa.

A mosaic-based vaccine regimen is designed to create immune responses to multiple clades and may offer one strategy for overcoming the constantly mutating HIV genes, as well as conferring broader geographic immunity. Mosaico is sponsored by Janssen Vaccines & Prevention B.V. and is estimated to end in June 2023⁹.

Microbicides

2.0 Global investment in microbicide R&D

Investment in microbicide R&D totaled US\$140 million in 2018, a 12 percent (US\$19 million) decrease from 2017 funding levels. This is the sixth consecutive year of declining microbicide funding and the lowest investment levels recorded since 2003 (Figure 19). The majority of funding originated from the public sector (98 percent), while philanthropic and commercial funding trailed at 1.3 percent and 0.6 percent, respectively. Public and philanthropic sector funding decreased by 11 and 57.8 percent, with a US\$0.6 million increase in private funding.

FIGURE 20 Microbicide Funding, 2000-2018 (US\$ millions)

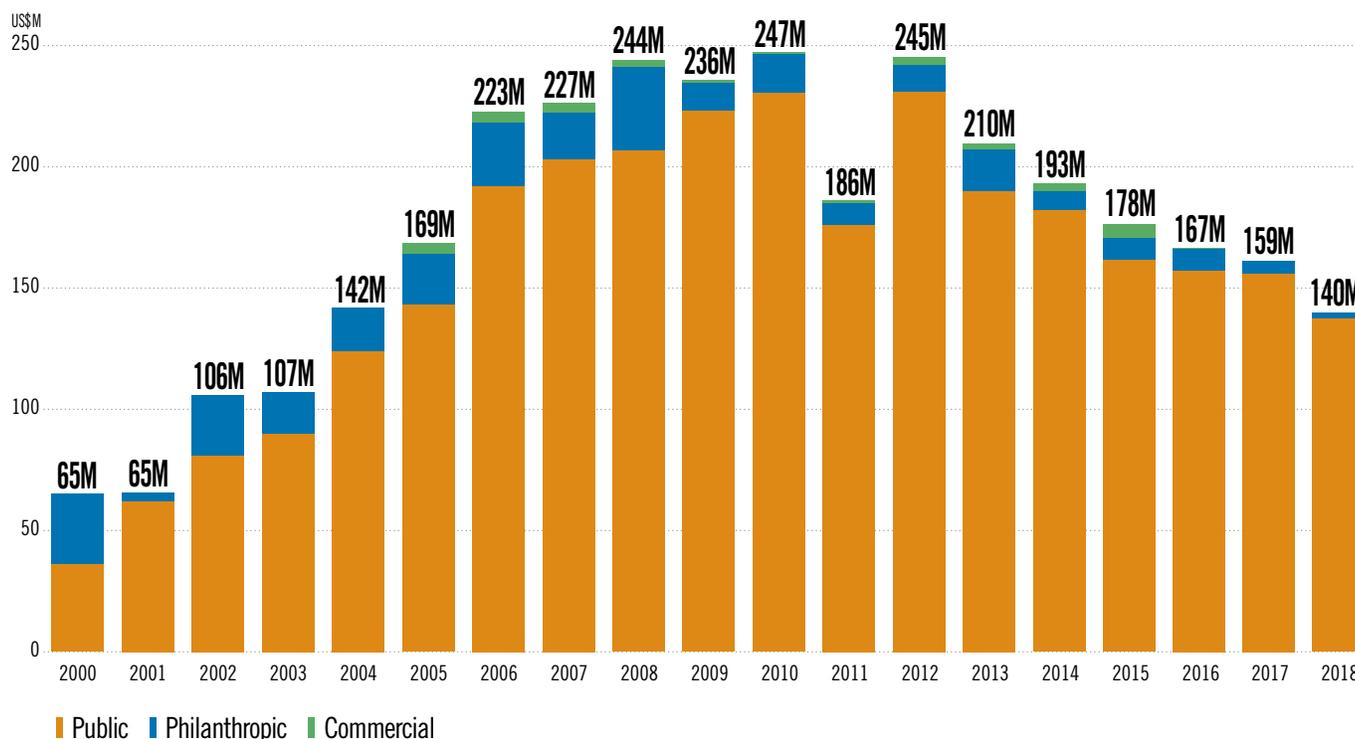
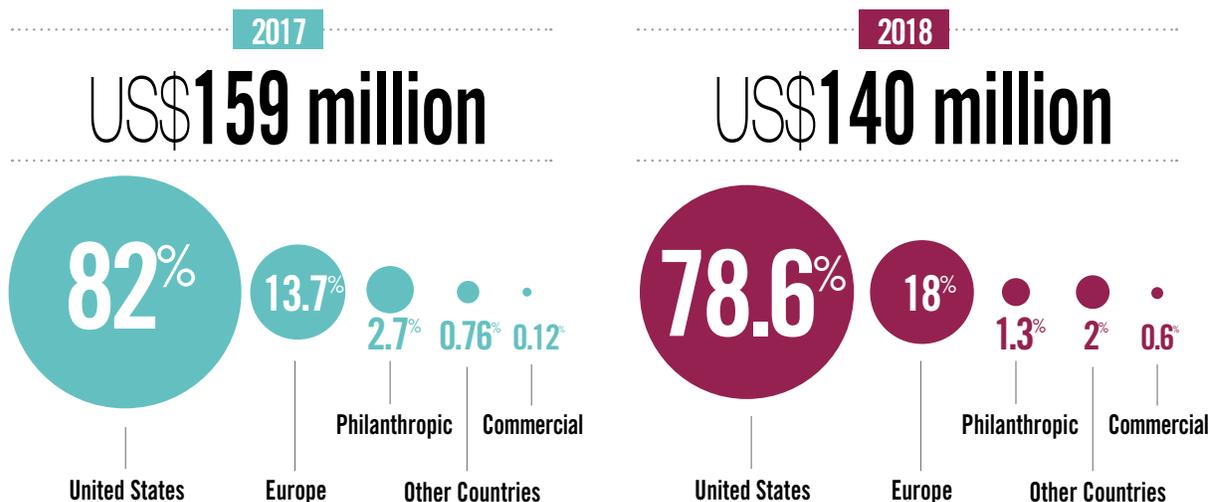


FIGURE 21 The Funding Base for Microbicide R&D by Percentage, 2017-2018 (US\$ millions)



Despite an 18 percent decrease in investment, the US public sector remained the predominant funder at US\$110 million. European funding grew by nine percent, to US\$25 million, boosted mostly by increased investments from the German Federal Ministry of Education and Research (BMBF, up 114 percent) and the UK Department of International Development (DFID, up 98 percent) (Figure 21).

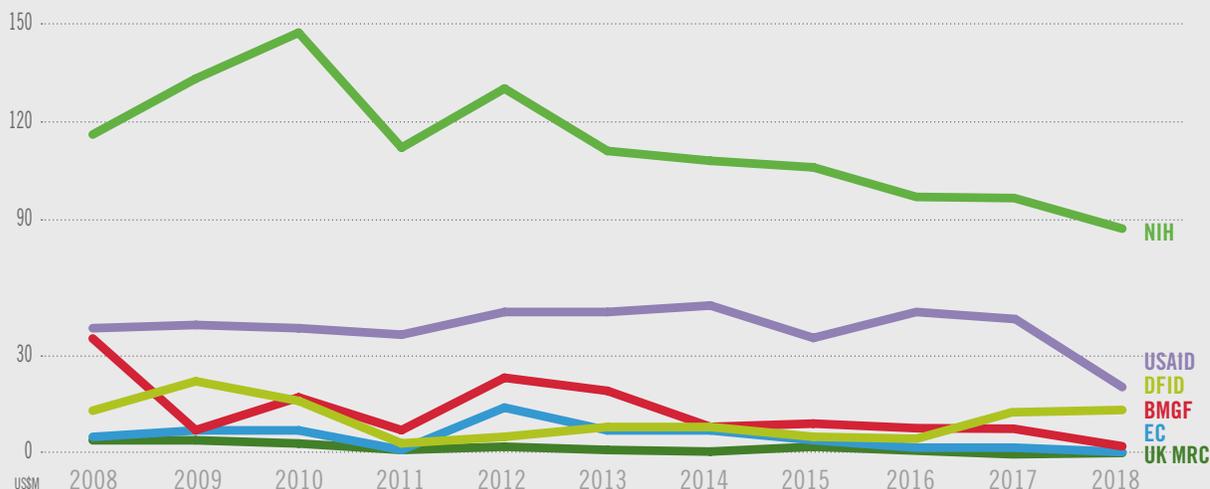
Investment from philanthropies decreased across the board, with the one exception of Sidaction (up 53 percent). The largest decline came from BMGF, with funding for microbicide R&D falling by 67 percent, from US\$3.3 million to US\$1.1 million. Investments totaling US\$2.7 million were also made towards rectal microbicide research by the NIH, Wellcome Trust and Sidaction.

TABLE 5 Annual Investment in Microbicide R&D by Sector, 2008-2018 (US\$ millions)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
US	154	173	182	148	173	155	154	143	140	131	110
Europe	40	44	40	16	27	27	23	17	16	22	25
Other Countries	12	5.7	8.3	12	17	5	4.5	2.4	1.3	1.2	2.4
Multilaterals	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0	0
Total Public	207	223	230	176	217	187	182	162	157	154.7	137
Total Philanthropic	35	12	16	9	25	20	20	9.3	9	4.3	1.8
Total Commercial	2.5	1	1	1	3	3	3	6	0.4	0.2	0.8
Total Global Investment	244	236	247	186	245	210	193	178	167	159	140

FIGURE 22 Top Microbicide Funder Trends, 2008-2018 (US\$ millions)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
NIH	116	133	147	112	130	111	108	106	97	95	89
USAID*	38	39	38	36	43	43	45	35	43	34.9	20
BMGF	35	7	17	7	23	19	8	9	7.6	3.3	1.1
DFID	13	22	16	3	5	8	8	5.2	4.4	6.7	13.2
EC	5	7	7	1	14	7	7	4	1.7	0.12	0
UK MRC	4	4	3	1	2	1	0.5	1.2	0.8	0	0.3



* The USAID Microbicide Program funding covers topical microbicide products as well as systemic and sustained-release HIV pre-exposure prophylaxes.

TABLE 6 Top Microbicide R&D Funders, 2012 - 2018 (US\$ millions)

Rank	2012		2013		2014		2015		2016		2017		2018	
	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount	Funder	Amount
1	NIH	129.9	NIH	111.2	NIH	107.8	NIH	106.3	NIH	97	NIH	95	NIH	89
2	USAID	43.2	USAID	42.8	USAID	45	USAID	45.2	USAID	43	USAID	34.9	USAID*	20
3	BMGF	22.9	BMGF	19.2	BMGF	7.6	BMGF	8.9	BMGF	7.6	Netherlands Ministry of Foreign Affairs	7.5	DFID	13.2
4	EC	13.6	DFID	8.4	DFID	7.4	DFID	5.2	Netherlands Ministry of Foreign Affairs	5	DFID	6.7	BMBF	6.9
5	CHVI ¹⁹	9.2	EC	6.7	EC	5.7	EC	3.9	DFID	4.4	BMGF	3.3	Netherlands Ministry of Foreign Affairs	2.1
6	South Africa	7	Netherlands	3.6	Sweden	3.2	Sweden	2.9	EC	1.7	BMBF	3.2	IrishAid	1.5
7	DFID	4.7	South Africa DST/DOH	2.3	Netherlands	3	DANIDA	1.4	BMBF	1.4	CDC	1.6	CDC	1.3
8	UK MRC	2.2	Denmark	2.2	ICMR	2.3	UK MRC	1.2	Wellcome Trust	1.2	Irish Aid	1.6	Public Health Agency of Canada	1.2
9	Netherlands	1.7	EDCTP	2.2	Ireland	1.3	IrishAid	1.1	Swedish Research Council	1.2	Wellcome Trust	0.8	BMGF	1.1
10	Ireland	1.2	Norway	1.5	CDC	1.2	CDC	0.9	IrishAID	1.1	CIHR	0.8	CIHR	0.9
11	Norway	1	US CDC	1.5	NORAD	1	CIHR	0.8	UK MRC	0.8	DANIDA	0.8	DANIDA	0.7
12	OPEC	1	Ireland	1.3	DANIDA	0.8	NORAD	0.8	CIHR	0.7	SAMRC	0.2	Wellcome Trust	0.6
13	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	UK MRC	0.3
14	NHMRC	0.5	NHMRC	0.5	UK MRC	0.5	ANRS	0.2	CDC	0.4	MAPP Biopharmaceutical	0.2	Government of Flanders	0.2
15	Wellcome Trust	0.5	Wellcome Trust	0.3	South Africa DST/DOH	0.4	NHMRC	0.2	Osel Inc.	0.2	ANRS	0.2	EDCTP	0.1

* The USAID Microbicide Program funding covers topical microbicide products as well as systemic and sustained-release HIV pre-exposure prophylaxes.

2.1 Developments in the field of microbicide research

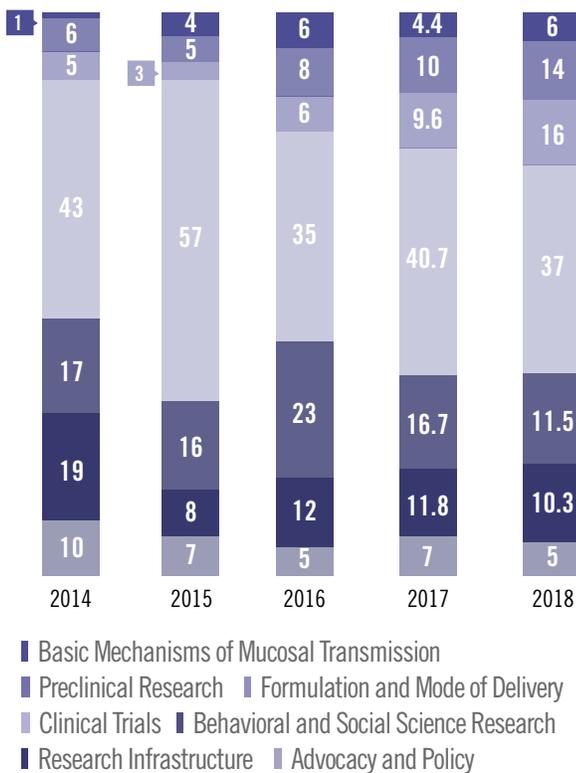
- While an opinion by the European Medicines Agency (EMA) on the dapivirine vaginal ring is expected in the latter half of 2019, the International Partnership for Microbicides (IPM) is moving forward with submissions to the US Food and Drug Administration (FDA) and the South African Health Products Regulatory Authority (SAHPRA). The intravaginal silicone ring is the first microbicide to be submitted for regulatory approval¹⁰.
- A new Phase I study (MTN-038) launched in December 2018 is testing the pharmacokinetics and safety of a 90-day intravaginal ring containing tenofovir. The study is currently recruiting participants in three US trial sites and is designed to provide women with protection from both HIV and herpes simplex virus type 2 (HSV-2). MTN-038 is the first trial of its kind to recruit participants, and results are expected in the first quarter of 2020¹¹.

- The MTN-035 study, or DESIRE (Developing and Evaluating Short-acting Innovations for Rectal Use), began to enroll participants in April 2019 across sites in the US, Peru, Malawi, South Africa and Thailand. The study is the first to investigate the preferences of cis- and transgender men and transgender women regarding drug delivery methods to prevent HIV during receptive anal intercourse. The trial is employing three placebos in the form of a douche, a suppository and an insert for on-demand use. Results are expected in July 2020¹².

2.2 Funding allocations for microbicide R&D

Allocations for microbicide R&D in 2018 were as follows: basic mechanisms of mucosal transmission (six percent), preclinical research (14 percent), formulations and modes of delivery (16 percent), clinical trials (37 percent), behavioral and social science research (11.5 percent), research infrastructure (10 percent) and advocacy and policy (five percent) (Figure 23). Investment in clinical trials decreased from 2017 levels but still made up the bulk of microbicide R&D at 40.7 percent. This is largely attributed to the topical microbicides, intravaginal rings (with active drugs tenofovir and tenofovir/levonorgestrel) and inserts that are currently in clinical testing. Investment in social and behavioral research also rose in 2018 (11.5 percent versus nine percent in 2017), and this may account for the improved acceptability and attitudes surrounding the dapivirine vaginal ring.

FIGURE 23 Microbicide R&D Funding Allocations by Percentage, 2014-2018



BOX 2

Results of the ECHO Study

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) study assessed the impact on women’s HIV risk of three different contraceptive options, specifically, depot medroxyprogesterone acetate-intramuscular (DMPA-IM), or Depo-Provera, the copper intrauterine device and the levonorgestrel implant¹³. The results, released on June 13, 2019, are of major significance to women and girls—especially in East and Southern Africa—providers, policy makers, funders and advocates¹². The ECHO study did not find any substantial difference in HIV risk among women using the aforementioned methods. All three contraceptive methods tested were safe, effective and acceptable. The majority of women stayed on the method that they were assigned to use and very few had unwanted pregnancies. High HIV incidence rates in all three arms of the trial highlight the importance of women-centered programs that offer a full range of contraceptive choices and HIV prevention strategies at the same site, and with an approach that is centered on women’s informed choice.

Adapted from AVAC. *Understanding the Results of the ECHO Study*. June 2019¹⁴.

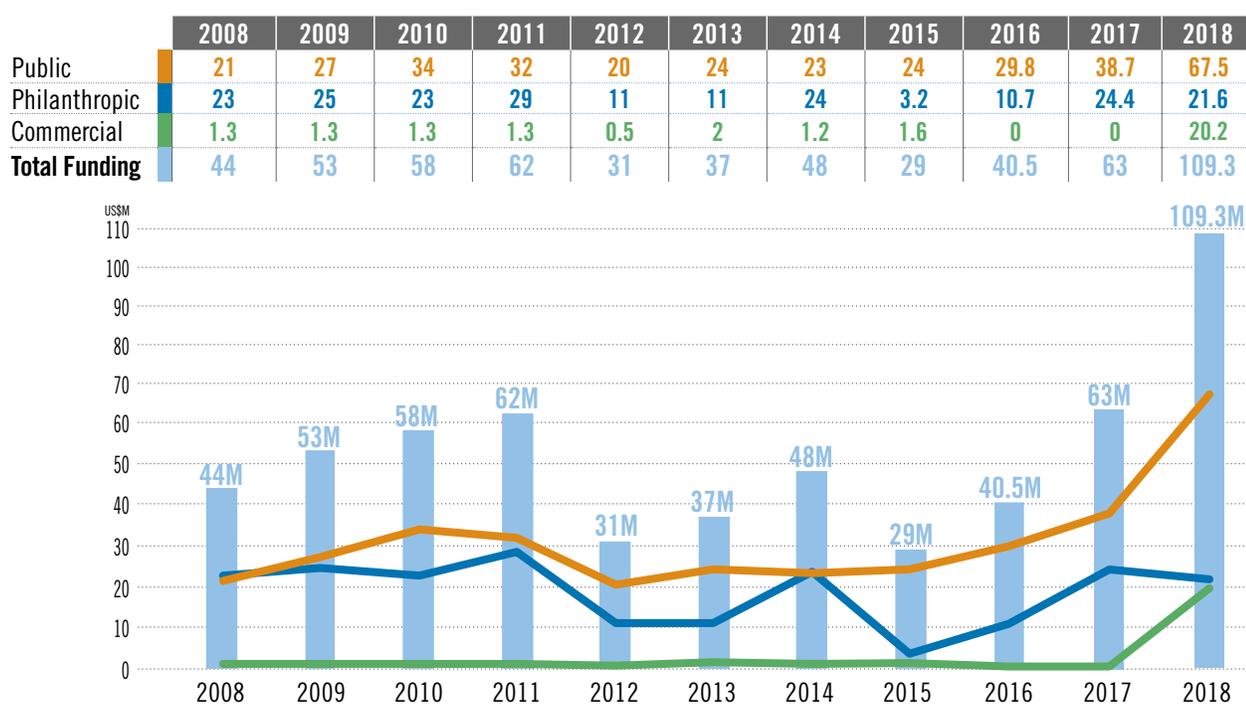
Other HIV Prevention Options

3.0 Global investment in R&D related to PrEP

In 2018, global investment in PrEP R&D amounted to US\$109 million. This is a 73 percent increase from 2017 and the highest funding recorded in more than a decade (*Figure 23*). The impetus behind this surge is the 75 percent increase in investment from the public sector, rising from US\$38.6 million to US\$67.5 million. The US NIH and USAID⁶ were the two leading donors at US\$36.6 million and US\$23.8 million, respectively.

Commercial sector investment in PrEP totaled US\$20.2 million; it must be noted, however, that a lack of reporting from the commercial sector explains the absence of investment in past years. Philanthropic investment decreased by 12 percent in 2018, a trend that is linked directly to the decline in BMGF funding from US\$24 million to US\$21 million.

FIGURE 24 Investments in Pre-Exposure Prophylaxis by Sector, 2008-2018 (US\$ millions)



⁶ The Working Group methodology defines systemic ARV prevention as PrEP, and accordingly, allocates microbicide funding in programs at USAID to PrEP notwithstanding their official designation as microbicide research funds by USAID.

3.1 Developments in the field of PrEP research

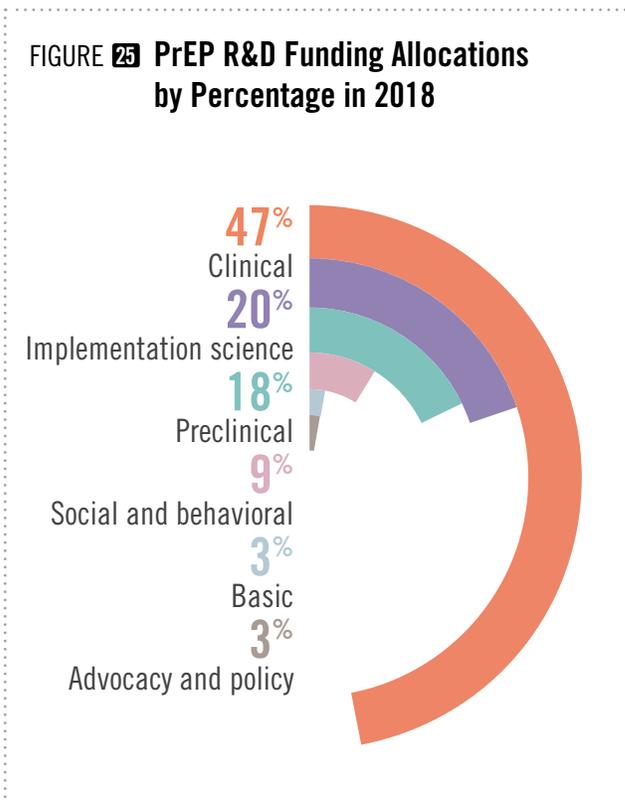
The global demand for oral PrEP is growing: Truvada and generic TDF/FTC have been approved for HIV prevention in 44 countries, while another nine have submitted applications for regulatory approval¹⁵. As PrEP rollout continues, the focus shifts towards improving uptake and adherence, as well as investigating alternative active drugs and delivery methods, e.g., long-acting injectables, implants etc. Relevant PrEP research that is currently underway includes:

- Two Phase III trials investigating the safety and efficacy of the long-acting injectable drug cabotegravir as a PrEP agent are currently recruiting participants. HPTN 083 is ongoing in 4,500 HIV-negative cisgender men and transgender women who have sex with men (MSM and TGW) in the Americas, Asia and South Africa¹⁶. HPTN 084 is recruiting 3,200 women at high risk in sub-Saharan Africa¹⁷.

- ImPrEP is a demonstration project sponsored by UNITAID and the Ministries of Peru, Mexico and Brazil for implementation across the three countries. Almost 7,500 high-risk MSM and transgender individuals will be enrolled and the impact of sociodemographic status on the uptake and adherence of oral PrEP will be assessed¹⁸.
- NZ PrEP is sponsored by the New Zealand AIDS Foundation and other donors, and aims to assess the impact of providing PrEP at clinics in Auckland to individuals at high-risk of HIV (MSM, TGW and others). The demonstration project is also looking to assess any difference in risk behaviors while on PrEP and the sociodemographic factors impacting the acceptability and retention of PrEP¹⁸.

3.2 Funding allocations for PrEP R&D

In 2018, PrEP R&D was allocated across the following six categories: basic (three percent), preclinical (18 percent), clinical (47 percent), implementation science (20 percent), behavioral and social science (nine percent) and advocacy and policy (three percent). Investments allocated for clinical research increased in 2018 and could be a result of the clinical studies investigating novel long-acting PrEP formulations and alternative active drugs for PrEP (Figure 24).

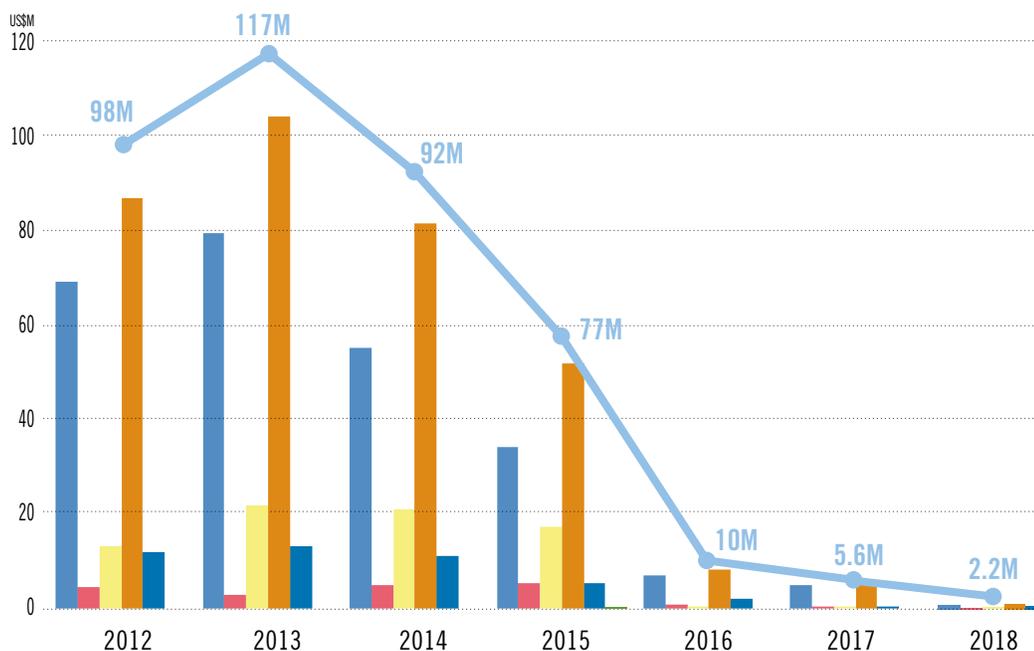


4.0 Global investment in R&D related to TasP

Following a 61 percent decrease from 2017 levels, funding for TasP totaled US\$2.2 million in 2018. Philanthropic funding increased slightly but public sector investment decreased by 68 percent, from US\$5.3 million in 2017 to US\$1.7 million in 2018. This decrease is linked directly to the completion of the CDC-funded Botswana Combination Prevention project, which had been ongoing since 2013¹⁹ (Figure 25). 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 2²⁰. This likely explains the sharp decline in R&D investment for TasP since 2015.

FIGURE 25 Investment in Treatment as Prevention by Sector, 2012-2018 (US\$ millions)

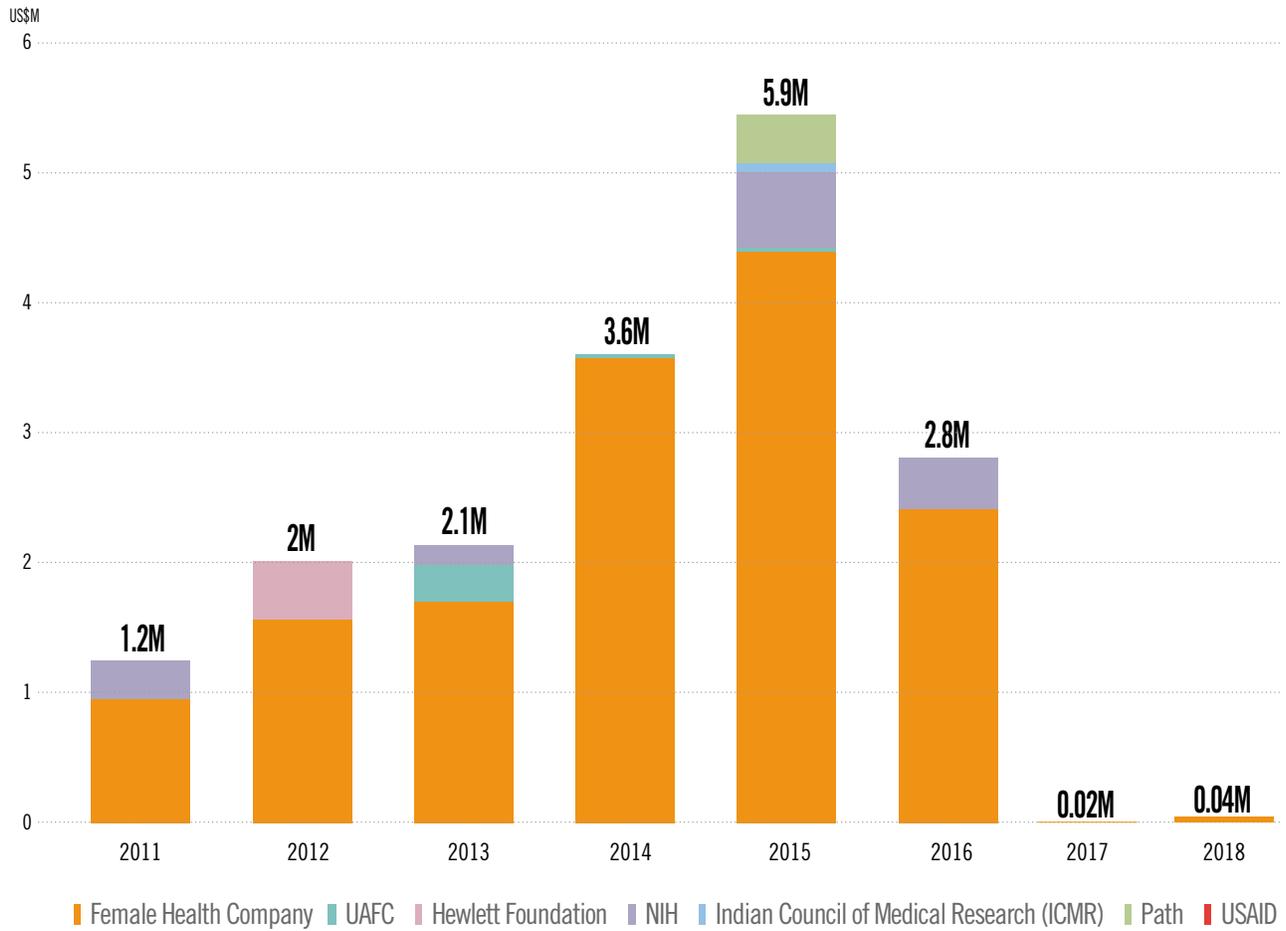
	2012	2013	2014	2015	2016	2017	2018
US	68.6	79	55	47	7	4.9	0.5
Europe	4.6	3	5	4.6	0.7	0.1	0.9
Other Countries	13	21.5	21	20	0.4	0.3	0.2
Total Public	86.2	103.5	81	71	8	5.3	1.7
Total Philanthropic	11.8	13.1	11	5.5	2	0.3	0.5
Total Commercial	–	–	–	<0.1	–	–	–
Total Global Investment	98	117	92	77	10	5.6	2.2



5.0 Global investment in female condom R&D

Investment in female condom research increased by 79 percent to US\$0.004 million. Although an uptick from 2017, these levels are still a far cry from the millions invested between 2011 and 2016 (Figure 26). The Female Health Company, traditionally the preeminent sponsor of female condom research, was the only donor internationally.

FIGURE 27 Investments in the Female Condom, 2011-2018 (US\$ millions)



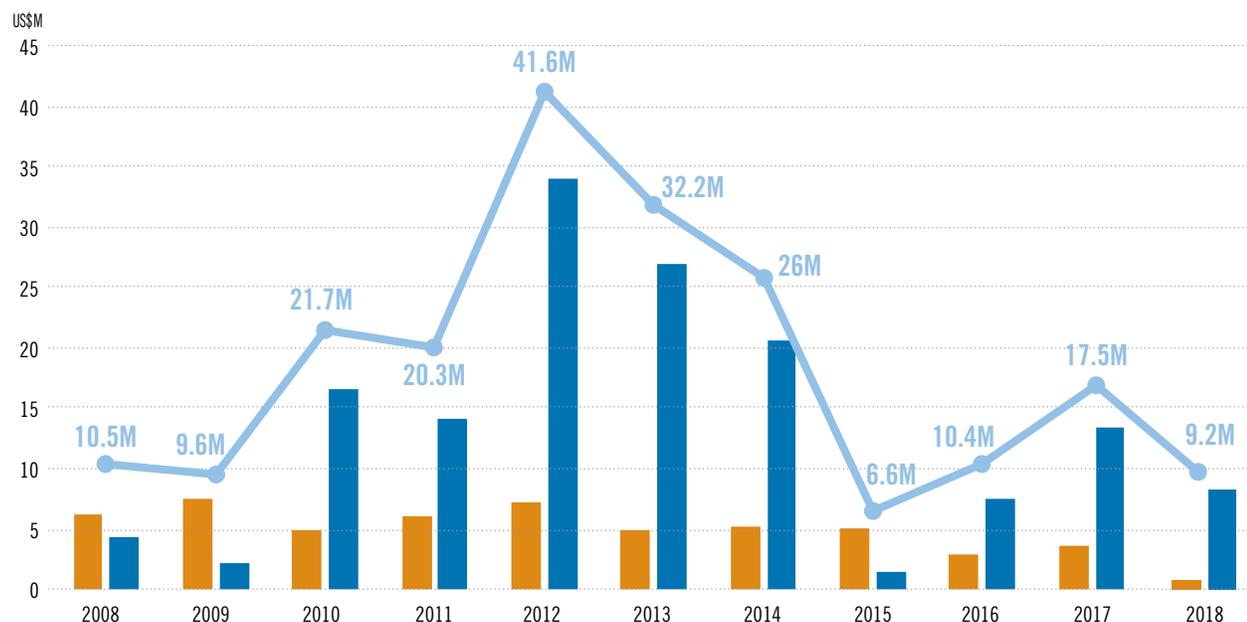
6.0 Global investment in the implementation of VMMC

The sharp 64 percent increase in VMMC observed last year reversed course in 2018. Overall funding decreased by 47 percent falling to US\$9.2 million. This drop can be traced back to a 40 percent decline in investment from BMGF, the largest technology-specific donor. BMGF funding fell to US\$8.3 million in 2018 but still constituted 90 percent of all investment. US public sector investment also declined from US\$3.4 million to US\$0.7 million, with the only contribution coming from the NIH.

Sufficient empirical studies have already affirmed the efficacy of VMMC as a prevention option, which is likely why 66 percent of the research is allocated to implementation science and the large-scale rollout of services in underserved populations. Other areas of focus include behavioral and social science research (19 percent), basic (2 percent) and advocacy and policy development (12 percent).

FIGURE 28 Investment in Voluntary Medical Male Circumcision by Sector, 2008-2018 (US\$ millions)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total Public	6.2	7.5	5	6.1	7.2	5	5.2	5.1	2.9	3.6	0.9
Total Philanthropic	4.3	2.1	16.7	14.2	34.4	27.2	20.8	1.4	7.5	13.9	8.3
Total Global Investment	10.5	9.6	21.7	20.3	41.6	32.2	26	6.6	10.4	17.5	9.2



7.0 Investments in research related to PMTCT

Funding for PMTCT increased by one percent, with levels rising from US\$35.7 million to US\$36 million in 2018 (*Table 7*). The number of donors financing PMTCT research also increased from seven to 12 in 2018. Most PMTCT research (almost 97 percent) was funded by the public sector, with the US NIH remaining the largest donor, at US\$31 million. European funding increased by 477%, which can be attributed largely to commitments from the EDCTP (US\$2.1 million) and the European Commission (US\$0.1 million). Philanthropic funding levels also rose to US\$1.03 million, bolstered by funding from BMGF, Wellcome Trust and Aidsfonds.

TABLE 7 Annual Investment in Prevention of Vertical Transmission by Sector, 2010-2018 (US\$ millions)

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
US	44.6	56.9	36.2	34.6	42	44.9	39.1	37.7	34.3	31.3
Europe	5.9	1.5	1.1	1.7	0.1	1.2	2.1	0.9	0.5	2.9
Other Countries	–	1.3	5.1	6.7	0.2	–	0.8	–	0.3	0.4
Total Public	50.5	59.7	42.6	42.9	42.4	46.6	41.3	39	35.3	34.6
Total Philanthropic	0.9	0	0.5	0.8	1.7	2.5	2.3	1.7	0.4	1
Total Commercial	0	0	0	0	0	0.5	0.5	–	–	–
Total Global Investment	51.4	59.7	43.1	43.7	44.1	49	44.1	41	35.7	35.7

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.
- ⁴ Institute of Health Metrics and Evaluation. *Financing Global Health 2018: Countries and Programs in Transition*. Seattle, WA; 2019.
- ⁵ Evaluating the Safety and Efficacy of the VRC01 Antibody in Reducing Acquisition of HIV-1 Infection in Women - Full Text View - ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT02568215>. Published 2018. Accessed June 10, 2019.
- ⁶ Evaluating the Safety and Efficacy of the VRC01 Antibody in Reducing Acquisition of HIV-1 Infection Among Men and Transgender Persons Who Have Sex With Men - Full Text View - ClinicalTrials.gov. [ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT02716675](https://clinicaltrials.gov/ct2/show/NCT02716675). Published 2018. Accessed June 10, 2019.
- ⁷ Pivotal Phase 2b/3 ALVAC/Bivalent gp120/MF59 HIV Vaccine Prevention Safety and Efficacy Study in South Africa - Full Text View - ClinicalTrials.gov. [ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT02968849](https://clinicaltrials.gov/ct2/show/NCT02968849). Published 2018. Accessed June 10, 2019.
- ⁸ A Study to Assess the Efficacy of a Heterologous Prime/Boost Vaccine Regimen of Ad26.Mos4.HIV and Aluminum Phosphate-Adjuvanted Clade C gp140 in Preventing Human Immunodeficiency Virus (HIV) -1 Infection in Women in Sub-Saharan Africa - Full Text View - ClinicalTrials.gov. [ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03060629](https://clinicaltrials.gov/ct2/show/NCT03060629). Published 2018. Accessed June 25, 2019.
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- ¹⁰ (2018). Retrieved from https://mtnstopshiv.org/sites/default/files/rosenberg-mtn_regional_meeting_zeda_regulatory_update_final3.pdf
- ¹¹ Pharmacokinetic and Safety Study of a 90 Day Intravaginal Ring Containing Tenofovir - Full Text View - ClinicalTrials.gov. (2019). Retrieved from <https://clinicaltrials.gov/ct2/show/NCT03670355>
- ¹² Rectal Microbicide Acceptability, Tolerability and Adherence - Full Text View - ClinicalTrials.gov. (2018). Retrieved from <https://clinicaltrials.gov/ct2/show/NCT03671239>
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- ¹⁴ Understanding the Results of the ECHO Study. (2019). Retrieved from <https://www.avac.org/resource/understanding-results-echo-study>
- ¹⁵ Regulatory Status of TDF/FTC for PrEP. AVAC. <https://www.avac.org/infographic/regulatory-status-tdftc-prep>. Published 2019. Accessed June 25, 2019.
- ¹⁶ HPTN 083. AVAC. <https://www.avac.org/trial/hptn-083>. Published 2018. Accessed June 25, 2019.
- ¹⁷ HPTN 084. AVAC. <https://www.avac.org/trial/hptn-084>. Published 2018. Accessed June 25, 2019.
- ¹⁸ Ongoing and Planned PrEP Demonstration and Implementation Studies. AVAC. <https://www.avac.org/resource/ongoing-and-planned-prep-demonstration-and-implementation-studies>. Published 2018. Accessed June 25, 2019.
- ¹⁹ Botswana Combination Prevention Project - Full Text View - ClinicalTrials.gov. (2013). Retrieved from <https://clinicaltrials.gov/ct2/show/NCT01965470>
- ²⁰ Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV. Cdc.gov. <https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf>. Published 2018. Accessed June 27, 2019.

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 microbicide—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: 65	
Sector	Type of Responders
Public	<ul style="list-style-type: none"> • National governments (including government research bodies, international development assistance agencies and other government funding agencies) • European Commission • Multilateral agencies
Philanthropic	<ul style="list-style-type: none"> • Private, not-for-profit organizations (e.g., foundations, trusts and non-governmental organizations) • Charities • Corporate donations
Commercial	<ul style="list-style-type: none"> • 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 2019 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, 2018, 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 research	Medical research involving human volunteers and encompassing clinical trials (Phases I, II, III and IV) as well as observational studies.
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 research	Medical research involving human volunteers and encompassing clinical trials (Phases I, II, III and IV) as well as observational studies.
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).
Behavioral and social science research	Conduct applied behavioral and social science research to inform and optimize product development, acceptability and use.
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 \geq 350 cells/mm ³ 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: <ul style="list-style-type: none"> • 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	LAI	Long-acting injectable
ANRS	National Agency for Research on AIDS and Viral Hepatitis (France)	LMIC	Lower-middle-income country
ARC	Australian Research Council	MDG	Millennium Development Goal
ART	Anti-retroviral therapy	MHRP	US Military HIV Research Program
ARV	Anti-retroviral	MPT	Multipurpose prevention technology
ASPIRE	A Study to Prevent Infection with a Ring for Extended Use	MRC	UK Medical Research Council
BMGF	Bill & Melinda Gates Foundation	MSM	Men who have sex with men
BMS	Bristol-Meyers Squibb	MTN	Microbicide Trials Network
bNAB	Broadly neutralizing antibody	NEMAPP	National Evaluation of Malawi's PMTCT programme
BV	Bacterial vaginosis	NHMRC	Australian National Health & Medical Research Council
CANFAR	Canadian Foundation for AIDS Research	NIAID	US National Institute of Allergy and Infectious Diseases
CDC	US Centers for Disease Control and Prevention	NIH	US National Institutes of Health
CEPI	Coalition for Epidemic Preparedness	Norad	Norwegian Agency for Development Cooperation
CHVI	Canadian HIV Vaccine Initiative	OAR	US NIH Office of AIDS Research
CIDA	Canadian International Development Agency	ODA	Official Development Assistance
CIHR	Canadian Institutes of Health Research	OECD	Organisation for Economic Co-operation and Development
COP	Country Operational Plan	OFID	OPEC Fund for International Development
CROI	Conference on Retroviruses and Opportunistic Infections	OHTN	Ontario HIV Treatment Network
DAH	Development assistance for health	OPEC	Organization of the Petroleum Exporting Countries
DANIDA	Danish International Development Agency	P5	Pox-Protein Public-Private Partnership
DBT	Department of Biotechnology at India's Ministry of Science and Technology	PDP	Product development partnership
DFID	UK Department for International Development	PEPFAR	US President's Emergency Plan for AIDS Relief
DIB	Development Impact Bond	PHAC	Public Health Agency of Canada
DOH	Department of Health	PMTCT	Prevention of vertical transmission
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women	POWER	Prevention Options for Women's Evaluation Research
DST	Department of Science and Technology, South Africa	PrEP	Pre-exposure prophylaxis
EAVI2020	European AIDS Vaccine Initiative	R&D	Research & development
EC	European Commission	SA DOH	South African Department of Health
ECHO	Evidence for Contraceptive Options and HIV Outcomes	SDG	Sustainable Development Goal
EDCTP	European and Developing Countries Clinical Trials Partnership	SIDA	Swedish Agency for International Cooperation Development
EHVA	European HIV Vaccine Alliance	SIDACTION	Association de lutte contre le sida
EIMC	Early infant male circumcision	SNSF	Swiss National Science Foundation
FDA	US Food and Drug Administration	START	Strategic Timing of AntiRetroviral Treatment study
FRESH	Females Rising through Education, Support, and Health	TasP	Treatment as prevention
FSW	Female sex workers	TDF	Tenofovir
GIS	Geographic information systems	TDF/FTC	Tenofovir/Emtricitabine
GSK	Glaxo SmithKline	TEMPRANO	A Trial of Early Antiretrovirals and Isoniazid Preventive Therapy in Africa
HOPE	HIV Open-label Prevention extension trial	TPP	Target Product Profiles
HPTN	HIV Prevention Trials Network	UAFC	Universal Access to Female Condoms Joint Programme
HPV	Human papillomavirus	UK	United Kingdom
HSV	Herpes simplex virus	UMIC	Upper-middle-income country
HVTN	HIV Vaccine Trials Network	UNAIDS	Joint United Nations Programme on HIV/AIDS
IAS	International AIDS Society	US	United States
IAVI	International AIDS Vaccine Initiative	USAID	US Agency for International Development
ICMR	Indian Council of Medical Research	USD	United States dollar
IHME	Institute for Health Metrics and Evaluation	UTI	Urinary tract infections
IMF	International Monetary Fund	VMMC	Voluntary Medical Male Circumcision
IMPT	Initiative for Multipurpose Prevention Technologies	VOICE	Vaginal and Oral Interventions to Control the Epidemic
IPM	International Partnership for Microbicides	VRC	US Vaccine Research Center
KP	Key population	WHO	World Health Organization

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Resource Tracking for HIV Prevention R&D Working Group

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