HIV Prevention Research & 2000–2016 Development Investments

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

Bill and Melinda Gates Foundation **Development** Basic research Medical Research Council **Prevention** Philanthropic **Implementation Research** Medical Passive immunity

Microbicideș

Vaccines ARV-based prevention Africa Treatment as Prevention Preclinical Development PrEP Medical Research Council Option B+ Bill and Melinda

> sive immunity Concern Prevention **Transmission** R&D <u>circumcision</u> devices Vaccines Wellcome Trust

Policy & Advocacy ARV-based prevention PrEP Option B+ Vaginal Rings

Vaccines

ANRS National Institutes of Health Development Medical Research Council Preclinical

Epidemic Advocacy

nical trials

Bill and Melinda Gates Foundation ARV-based prevention Microbicides Trends Development Philanthropic

Female Condom

North America Clinical trials Advocacy circumcision devices Africa Treatment as Prevention Option B+ circumcision devices

Passive immunity

Resource Tracking for HIV Prevention Research & Development JULY 2017

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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&D¹) *(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 landscape².

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 II 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 I Global HIV Prevention R&D Investment by Technology Category, 2000-2016 (US\$ millions)

^a Tracking funding for female condom and treatment as prevention research began in 2010 ^b Tracking funding for prevention of vertical transmission began in 2008 ^c Tracking funding for pre-exposure prophylaxis began in 2002 ^d Tracking funding for medical male circumcision began in 2001



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



FIGURE **33** 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 investment³. 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 CALE European Public Sector Investment in HIV Prevention R&D, Compared to All Other Funding, 2012-2016 (US\$ billions)



FIGURE DE 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 11 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 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 I Top Countries Investing in HIV Prevention R&D, 2015-2016 (US\$ millions)



FIGURE TO 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 III 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.



Declining priority in development funding

Development assistance for health (DAH) is the financial and in-kind support from development agencies to lowand 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 2010⁴. 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 III 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.

obicides

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 exchange⁶. 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 III 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 II HIV Prevention R&D Trial Participants by Region, 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 EL Clobal Invoctments in UIV Provention DVD. 2016 fundi

TABLE Global investments in hiv Prevention R&D: 2016 funding map					2016 totals in US\$ millions (2015 investments, percent change ^a)																							
Funding type	2015	2016	% Change 2015-2016	Funder	Total 2016	Total 2015	% Change	Pre	ventive vaccine	AIDS s	Mi	crobici	des	Preven tra	tion of v Insmissi	ertical on	Pre	e-exposu ophylaxi	re s	Tre pi	atment reventio	as on	Volun male	tary me circumo	dical cision	Fema	ale conc	doms
				NIH	\$762.0	\$730.0	1 1%	2016 \$605.0	2015 \$538.0	Change	2016 \$96.9	2015 \$106.3	Change	2016	2015 \$38.4	Change	2016	2015	Change 25.6%	2016	2015 \$28.7	Change	2016	2015	Change	2016 \$0.5	2015	Change
IIS Public Sector	\$850 million	¢991 million	2 65%		\$702.0 \$72.0	\$730.0 \$71.7	4.4 %	¢005.0	¢20.0	12.4%	\$30.3 \$42.8	\$100.5 \$25.0	-370	φ37.7	\$30.4 \$0.7	-1.0 /0	\$20.0	¢2.0	20.0%		\$20.7		φυ.ο	φ1.0	-JU /0	φ0.5	φυ.υ	-10.076
03 F unic 360101	\$0 00 IIIIII0II	add i iiiiiidii	J.UJ /0		\$73.5 \$11.2	φ/4./ ¢15.7	-1.10%	φ20.7	\$20.7	0.076	\$42.0	\$33.0 \$1.0	-60%		φ0.7		\$2.4	\$0.5	-30%	\$6.2	\$0.5		\$20	\$3.5				
				MHRP	\$11.5	\$15.7	-20%	\$33.0	\$26.6	24%	φ0.4	φ1.0	-0078				φ2.0	φυ.σ	42076	φ0.2	φ10.7	-42 /0	φ2.0	φυ.υ	-42.070			
				Belgium	\$0.2	\$0.3	-33%	<i>\u00000</i>	\$0.1		\$0.2	\$0.1	100%												_			_
				Denmark	\$0.7	\$2.2	-68%		\$0.7			\$1.4													_	_		_
				EC	\$14.4	\$27.3	-47%	\$12.1	\$22.8	-47%	\$1.7	\$3.9	-56%	\$0.6	\$0.6	0.0%				_					_			_
				France	\$7.0	\$8.3	-15.6%	\$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	_			
				Germany	\$1.4			\$0.01			\$1.4	_		_	_						· 	_			_			_
				Ireland	\$2.0	\$2.2	-9%	\$0.9	\$1.1	-18%	\$1.1	\$1.1	0.0%		_					_		_			_	_		_
European Public Sector	\$69 million	\$59 million	-14.5%	Italy																		_			_	_		
				Netherlands	\$8.6	\$0.8	975%	\$3.6	\$0.7	414%	\$5.0									_	_	_	_		_	_	\$0.03	_
				Norway	\$0.1	\$1.5	-93%		\$0.7		\$0.1	\$0.8	-87.5%		_					_	_	_	_		_	_		_
				Spain		\$1.0		_	\$1.0		_				_					_	_	_	_		_	_	_	_
				Sweden	\$7.2	\$3.9	84.6%	\$6.0	\$0.9	566%	\$1.1	\$2.9	-62%		\$0.1	_				_	_	_				_		_
				Switzerland	\$0.3	\$1.3	-77%	\$0.3	\$1.0	-70%	_				\$0.1	_			_	_	_	_	_		_	_	_	_
			UK	\$11.8	\$20.7	-43%	\$6.5	\$11.5	-43%	\$5.3	\$6.4	-17%	\$0.1	\$0.5	-80%				_	_	_	_			_		_	
			Australia	\$1.5	\$2.6	-42.3%	\$1.3	\$0.9	44%	_	\$0.2	_	_	_		_	\$0.3	_	\$0.2	\$0.7	-71%	_	\$0.01	_	_	_	_	
				Brazil	\$0.2	\$0.4	-50%	\$0.03	\$0.01	66%	_	_	_	_	_	_	\$0.1	\$0.3	-66.6%	_	—	_	_		—	_	_	_
				Canada	\$2.6	\$26.8	-90%	\$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%	_	_	_
				China		\$9.4	_		\$7.0		_	_		_		_				_	\$2.4	_	—		—	—	_	_
				Cuba		\$0.4	_	_	\$0.4	_	_	_	_	_		_				_	—	—	—		—	—	_	_
Ather Countries	\$50 million	\$12 million	-76%	India	\$0.13	\$0.5	-74%	\$0.04	\$0.3	-86%	\$0.1	\$0.1	0.0%	_	—	—			—	—	—	_	—		—	_	\$0.1	_
	φJU IIIIIIUII	φιζ πποπ	-70%	Israel		\$0.04	—	_	\$0.04				_	_	_					—	—	—	—		—	—		_
				Japan	\$2.6	\$4.5	-42%	\$0.8	\$4.5	-82%					_					_	—	_	_			—		
				Russia										_	_	_			_	_						—		
				South Africa	\$4.4	\$4.4	0.0%	\$3.9	\$3.9	0.0%	\$0.5	\$0.5	0.0%	\$0.01	\$0.01	0.0%			_	_			_			_		
				Taiwan											_	_			_	_						_		
				Thailand		\$0.5			\$0.03							_		\$0.02		_	\$0.5		_			—		
				BMGF	\$141.0	\$125.7	12%	\$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	
Philanthropic	\$157 million	\$157 million	No Change	Wellcome Trust	\$3.1	\$6.1	-49%	\$1.3	\$6.0	-78.3%	\$1.2			\$0.6	\$0.1	500%				\$0.04						_		
				Other	\$13.5	\$25.4	-47%	\$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		—		
Industry	\$75 million	\$56.4 million	-25%	Commercial Sector	\$56.4	\$75.0	-25%	\$53.6	\$62.2	-13.8%	\$0.4	\$6.0	-93%	—	\$0.5	-	—	\$1.6	—	—	\$0.03	—	—	—	—	\$2.4	\$4.4	-45%
Total	\$1.20 billion	\$1.17 billion	-3.00%	HIV prevention option totals	\$117 billion	\$120 billion	-3%	\$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%
% Change 2015–2016					-3%			3.7%			-6%			-6.8%			39.6%			-86.6%			57.6%			-52.5%		

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

AIDS Vaccines

1.0 Global investment in preventive AIDS vaccines 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 D AIDS Vaccine Funding from 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

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

FIGURE 10 Top AIDS Vaccine Funder Trends, 2006-2016 (US\$ millions)



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 IPhilanthropic 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<="" td=""><td>Institut Pasteur, SIDACTION</td></us\$1>	Institut Pasteur, SIDACTION
<us\$250,000< td=""><td>Aidsfonds, amfAR, MAC AIDS</td></us\$250,000<>	Aidsfonds, amfAR, MAC AIDS

TABLE 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.

2010 2011 2012 2013 2014 2015 2016 Rank Amount NIH 561.6 518.2 NIH 532.7 NIH 550.4 NIH 557 NIH NIH 538 NIH 605 BMGF 80.9 BMGF 78.5 BMGF 86 BMGF 100.4 BMFG 114 BMFG 103 BMGF 114 MHRP 41.6 MHRP MHRP 37.8 MHRP 38.4 USAID 28.7 USAID 28.7 MHRP 33 43.3 USAID 28.7 USAID 28.7 USAID 28.7 USAID 27.3 MHRP 27.5 MHRP 26.6 USAID 29 EC 19.9 DFID 11.8 DFID 14 **CHVI**° 14.7 EC 12 EC 22.3 EC 12 Ragon Ragon Ragon EC CHVI¹⁹ 10 China 18.3 10.3 12 EC 12.8 10 10 Institute Institute Institute Swedish Ragon Ragon Ragon DFID 10 10 10 CHVI 7 UK MRC 8.3 16.6 Research 6 Institute Institute Institute Council Wellcome Ragon EC 7.7 7 10 ANRS 7.3 8.4 Chinad CHVI 7.2 ANRS 5.3 Institute Trust Wellcome ANRS 6.6 China 6.9 8.2 **China**^d 7 UK MRC 7 **China**^d 7 UK MRC 5 Trust Wellcome Wellcome Wellcome Wellcome Dutch 5.1 6.5 China 7 NHMRC 6.8 6.2 6 3.6 Trust Trust Trust Trust PDP Nether-Institut 5 UK MRC UK MRC 6.2 MRC 6.2 ANRS 5.3 5.1 5.5 EDCTP 3 lands Pasteur South South Institute The Institute Africa Africa EDCTP 4.5 CHVI 5.8 4.8 4.9 3.9 3.9 3.9 Netherlands DST/ Pasteur Pasteur DST/ SAMRC SAMRC Sumagen Sumagen Institute CIDA CIDA 4.9 4.8 4.8 2.8 DFID 3.8 Netherlands Canada 3.1 Canada Inc. 1.4 Pasteur Inc. Japan AECID NMHRC 3.9 NHMRC **UK MRC** 4.4 ANRS 2.7 DFID 4.4 2.4 1.3 AMED South The Wellcome NORAD 2.5 3.8 ANRS DANIDA 2.2 2.5 CIHR 2.4 1.3 4 Africa Netherlands Trust DST/DOH

TABLE **5** Top AIDS Vaccine Funder for 2010-2016 (US\$ millions)^{a,b}

^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 081⁷ and HVTN 704/HPTN 085⁸), 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 VRCO1 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 Africa⁹. 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 study¹⁰. 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 D 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 diseases¹¹. The recent epidemics of Ebola, Zika and SARS served as the impetus for this crosssectoral 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)



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*).

	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

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

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



	201	0	201	1	201	2	201	3	20	14	20	2015		6
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

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

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 ring¹⁴. 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 time¹⁵. 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 PrEP¹⁶.

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 administration¹⁷. 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 trial¹⁸.

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.



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* tissue¹⁹.
- 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 studies¹⁹.

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 22 Investment in Pre-Exposure Prophylaxis, 2006-2016 (US\$ millions)

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 **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 globe²⁰. 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 2017²¹.
- 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 2018²².
- 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 2018²³.

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 reservoir²⁴.

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 women²⁵.

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.

	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

FIGURE 20 Investment in Treatment as Prevention by Sector, 2011-2016 (US\$ millions)



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 22 Investment in Voluntary Medical Male Circumcision by Sector, 2006-2016 (US\$ millions)

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).

	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

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

8.0 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.
- ⁵ Institute for Health Metrics and Evaluation. 2017. Financing Global Health 2016: Development Assistance, Public and Private Health Spending for the Pursuit of Universal Health Coverage. *http://www.healthdata.org/sites/default/files/files/policy_report/FGH/2017/IHME_FGH2016_Technical-Report.pdf.*
- ⁶ "India, Africa To Boost Collaborations in Medical Research". *The Indian Express.* N.p., 2017. Web. 6 July 2017.
- ⁷ "Evaluating the Safety and Efficacy of The VRC01 Antibody in Reducing Acquisition Of HIV-1 Infection In Women Full Text View Clinicaltrials. Gov". *Clinicaltrials.gov*. N.p., 2017. Web. 6 July 2017.
- ⁸ "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*. N.p., 2017. Web. 6 July 2017.
- ⁹ "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. N.p., 2017. Web. 6 July 2017.
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- ¹⁴ "Trial to Assess the Continued Safety of and Adherence to a Vaginal Ring Containing Dapivirine in Women Full Text View *Clinicaltrials.Gov*". Clinicaltrials.gov. N.p., 2017. Web. 6 July 2017.
- ¹⁵ "Dapivirine Ring Open-Label Studies". *Ipmglobal.org.* N.p., 2017. Web. 6 July 2017.
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- ¹⁷ Cranston, Ross D. et al. "MTN-017: A Rectal Phase 2 Extended Safety and Acceptability Study of Tenofovir Reduced-Glycerin 1% Gel". *Clinical Infectious Diseases* (2016): ciw832. Web.
- ¹⁸ "The Basics". *AVAC*. N.p., 2017. Web. 6 July 2017.
- ¹⁹ Scott, Yanille, and Charlene S. Dezzutti. "Non-Antiretroviral Microbicides for HIV Prevention". AIDS Reviews 18.3 (2016): 145-150. Print.
- ²⁰ World Health Organization. WHO Expands Recommendation on Oral Pre-exposure Prophylaxis of HIV Infection (Prep). 2015. Print.
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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.

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

TABLE Public, Philanthropic and Commercial Sector Primary Funders

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	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 \geq 350 cells/mm3 on HIV and/or TB-related morbidity and mortality or HIV transmission.			
	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:			
Multipurpose Prevention Technologies (MPTs)	• HIV	• Hepatitis		
	HSV	• HPV		
	Pregnancy Bacterial Vaginosis (BV)	• Syphills • Trichomoniasis		
	Chlamydia	Illinary Tract Infections (IITI)		
	• Gonorrhea	• 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	LMIC	Lower-middle-income country
	AIDS and Viral Hepatitis (France)	MDG	Millennium Development Goal
ARC	Australian Research Council	MHRP	US Military HIV Research Program
ART	Anti-retroviral therapy	MPT	Multipurpose prevention technology
ARV	Anti-retroviral	MRC	UK Medical Research Council
ASPIRE	A Study to Prevent Infection with	MSM	Men who have sex with men
	a Ring for Extended Use	MTN	Microbicide Trials Network
BMGF	Bill & Melinda Gates Foundation	NEMAPP	National Evaluation of Malawi's
BMS	Bristol-Meyers Squibb		PMTCT programme
bNAB	Broadly neutralizing antibody	NHMRC	Australian National Health & Medical
BV	Bacterial vaginosis		Research Council
CANFAR	Canadian Foundation for AIDS Research	NIAID	US National Institute of Allergy and
CDC	US Centers for Disease Control and Prevention		Infectious Diseases
CEPI	Coalition for Epidemic Preparedness	NIH	US National Institutes of Health
CHVI	Canadian HIV Vaccine Initiative	Norad	Norwegian Agency for Development Cooperation
CIDA	Canadian International	UAR	US NIH Office of AIDS Research
	Development Agency	UDA	Official Development Assistance
CIHR	Canadian Institutes of Health Research	UECD	Organisation for Economic Co-operation
COP	Country Operational Plan	0.515	and Development
CRUI	Conference on Retroviruses and	UFID	OPEC Fund for International Development
	Opportunistic Infections	UHIN	Ontario HIV Treatment Network
DAH	Development assistance for health	UPEC	Organization of the Petroleum Exporting Countries
DANIDA	Danish International Development Agency	P5	Pox-Protein Public-Private Partnership
DRI	Department of Biotechnology at India's Ministry of	PUP	Product development partnership
DEID	Science and Technology	PEPFAR	US President's Emergency Plan
	UK Department for International Development	DUAG	for AIDS Relief
DIR	Development Impact Bond	PHAC	Public Health Agency of Canada
DOH	Department of Health	PMICI	Prevention of vertical transmission
DREAMS	Determined, Resilient, Empowered, AIDS-free,	POWER	Prevention Options for Women's Evaluation Research
DOT	Mentored, and Safe women	Prep	Pre-exposure prophylaxis
DSI	Department of Science and Technology,	R&U	Research & development
E MU0000	South Africa	SA DOH	South African Department of Health
EAVIZUZU	European AIDS Vaccine Initiative	SDG	Sustainable Development Goal
EU FOUO	European Commission	SIDA	Swedish Agency for International
EGHU	Evidence for Contraceptive Options and	CIDAOTION	Cooperation Development
CDOTD	HIV Outcomes	SIDACTION	Association de lutte contre le sida
EDGIP	European and Developing Countries Clinical Trials	SN9L	Swiss National Science Foundation
EUVA	Partnership	START	Strategic Timing of AntiRetroviral
ERVA	European HIV Vaccine Alliance	TeeD	Treatment study
	Early Infant male circumcision		Treatment as prevention
	US Food and Drug Administration	IUF TDE/ETC	Tenotovir
гкезп	Females Rising through Education,		Tenotovir/Emtricitabine
ECW	Support, and Health	TEMPKANU	A Trial of Early Antifetrovirals and Isoniazio
L 2 M	Fernale sex workers	TDD	Preventive Therapy in Arrica
	Geographic information systems		Idrget Product Promes
	UID/Open Jabel Drevention extension trial	UAFG	Universal Access to Female Condoms
HDTN	HIV Drevention Trials Network	шк	Joint Programme
HDV			Upper middle income country
HCV			loipt United Nations Programme on HIV/AIDS
HVTN	Helpes simplex virus	IIC	Joint Onited Nations Flogramme on Hiv/AIDS
1010	International AIDS Society		United States
ΙΔ	International AIDS Vaccing Initiative		United States dollar
	Indian Council of Modical Possarch	IITI	United States dollar
IHMF	Institute for Health Matrice and Evaluation	VMMC	Voluntary Medical Male Circumcision
IMF	Institute for meditin Metrics drid Evaluation	VOICE	Varinal and Oral Interventions to Control
IMPT	Initiative for Multipurpose Provention Technologies	TOTOL	the Enidemic
IPM	International Partnershin for Microbicides	VRC	LIS Vaccing Research Conter
KP	Key nonulation	WHO	World Health Organization

Appendix: Acknowledgements

Daniela Aceska, Australian Research Council Donna D. Adderly, Office of AIDS Research Susanne Amsler, Swiss Agency for Development and Cooperation Bobbie Annonson, The Female Health Company Anne Aslett, Elton John AIDS Foundation Raphael Banz, Swiss National Science Foundation Niki Baxter, National Health & Medical Research Council Maria Teresa Bejarano, Swedish International Development Cooperation Agency (SIDA) Adele Schwartz Benzaken, Brazilian Department of STD, AIDS and Viral Hepatitis Detlef Boecking, German Federal Ministry of Education and Research (BMBF) Christian Brander, Esteve Doris Brauer, German Federal Ministry for Economic Cooperation and Development Kim Brehm, William and Flora Hewlett Foundation Gabrielle Breugelmans, European & Developing Countries Clinical Trials Partnership Serwait Bruck-Landais, SIDACTION Christopher Bunting, Canadian Foundation for AIDS Research Swandi Chan, Bill & Melinda Gates Foundation Eunsil Choi, Sumagen Canada Inc. Monika Ciesielczyk, U.S. Military HIV Research Program Lee Claypool, US Agency for International Development Doug Colvard, CONRAD Kent Cozad, amfAR, The Foundation for AIDS Research Stephanie Ecker, International Partnership for Microbicides Inger Florin, The Swedish Foundation for Strategic Research Anders Fomsgaard, Statens Serum Institut Marc-Andre Gaudreau, Public Health Agency of Canada Andrew Goumas, US Agency for International Development Mari Grepstad, Norwegian Agency for Development Cooperation Gerardo Guillén, Center for Genetic Engineering & Biotechnology Emilia Hellqvist, Swedish Postcode Foundation Marein de Jong, Aids Fonds Ramu Kaladi, US Centers for Disease Control and Prevention Dietmar Katinger, Polymun Scientific Maggie Kilbourne-Brook, PATH

Robert Kirshner, Gordon and Betty Moore Foundation Wiebke Kobel, Deutsche Gesellschaft für Internationale Zusammenarbeit Surangchit Koottathep, Chiang Mai University Ciska Kuijper, Universal Access to Female Condoms Joint Programme, Oxfam Novib Laurel Lagenaur, Osel, Inc. Pierre Legrain, Institut Pasteur Franco Lori, ViroStatics Lori Lyons, Ontario HIV Treatment Network Diana Macauley, Regional HIV & AIDS Team for Africa, Embassy of Sweden Vincent Maher, Irish Aid Samia Majid, Medical Research Council Alessandra Martini, European Commission Tetsuro Matano, National Institute of Infectious Diseases Japan Jay McAuliffe, US Centers for Diseases Control and Prevention Margaret McCluskey, US Agency for International Development Kevin McCormack, California Institute of Regenerative Medicine Ryan McKeel, Gilead Toon Monbaliu, Research Foundation Flanders Ayah Nayfeh, International Development Research Center Robert Oelrichs, World Bank Nittaya Phanuphak, National Research Council Thailand Ken Rapkin, Campbell Foundation Mark Reynolds, GeoVax Labs, Inc. Thibault Robert, National Agency for Research on AIDS and Viral Hepatitis (France) Anna Laura Ross, Agence Nationale de Recherche sur le Sida Virginia Ruan, Oak Foundation Sundeep Sarin, Indian Department of Biotechnology Gabriella Scarlatti, San Raffaele Scientific Institute Sarjan Shah, Auritec Martin Smith, Department for International Development Kathryn Stewart, CAMI Health Liz Stirling, Canadian Institutes of Health Research Karin Tegerstedt, Swedish Research Council Matt Thakur, Wellcome Trust Annemie T'Seyen, King Baudouin Foundation Kevin Whaley, Mapp Biopharmaceutical Dianne Young, Roche

Financial support for this project was provided by AVAC. In past years, support was also provided by the International AIDS Vaccine Initiative (IAVI), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the International Partnership for Microbicides (IPM) and the Alliance for Microbicide Development (AMD).

Resource Tracking for HIV Prevention R&D Working Group

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International AIDS Vaccine Initiative (IAVI)

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This report is made possible by the generous support of several donors, including the Bill and Melinda Gates Foundation, and the American people through the US President's Emergency Plan for AIDS Relief (PEPFAR) and the US Agency for International Development (USAID). The contents are the responsibility of AVAC and do not necessarily reflect the views of PEPFAR, USAID or the United States Government. AVAC does not accept funding from the pharmaceutical industry.

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