



Translating **science**
into **global** health impact

IAVI

Annual Report

2019



Dear Friends of IAVI,

Writing this letter near the end of 2020 to reflect on 2019 is challenging: we're now several months into the COVID-19 pandemic, and memories of last year are shaded by the widespread uncertainty and suffering we currently face. This tenuous position makes me even more aware of the need to connect with IAVI friends

and renew our commitment to fulfilling IAVI's mission of translating scientific discoveries into affordable, accessible public health solutions. We have been actively engaged in developing a vaccine and monoclonal antibodies for COVID-19 and look forward to sharing that progress with you in our next annual report.

In 2019, IAVI made significant progress across our core HIV work and completed our strategic evolution to expand our global health impact by building on IAVI's established areas of scientific expertise, technology platforms, partnerships and community connections. To reflect this mandate, we began a shift to being known simply as IAVI, a name more inclusive of our broadened scientific strategy.

In 2019 IAVI's Phase I clinical trial ([IAVI G001](#)) of a novel germline-targeting HIV vaccine candidate continued. This candidate is designed to stimulate the immune system to initiate a key first step in generating potent broadly neutralizing antibodies (bnAbs) against HIV. Results will be presented in 2020.

Another major 2019 achievement was the initiation of the Phase I trial ([IAVI W001](#)) of a native-like HIV trimer envelope vaccine candidate. IAVI W001 is unique because it is one of the first clinical trials to employ the complete, structurally relevant HIV outer envelope protein. Both IAVI G001 and IAVI W001 could provide critical information about how vaccine immunogens can be given in a logical sequence to achieve the goal of inducing protective bnAbs.

Work to develop antibodies as products for HIV prevention advanced the selection of several potent HIV bnAbs for further development. Selected antibodies generated by IAVI and Scripps Research are being engineered to increase their neutralization breadth and

potency. The program receives support from the United States Agency for International Development (USAID) and [Global Health Vaccination and Research](#) (GlobVac, Norway), and involves an innovative partnership between IAVI, the Serum Institute of India Pvt. Ltd. and the National Institutes of Health, with the goal of expediting the development of affordable, globally available bnAbs as a promising tool for HIV prevention.

In October 2019 IAVI and GSK published final results of the M72/AS01_E Phase IIb tuberculosis (TB) vaccine candidate trial in the [New England Journal of Medicine](#). Those results were the first ever to demonstrate protection in adults already infected with the bacteria that cause TB. While the findings need to be confirmed in other populations, they were an encouraging sign that an effective TB vaccine is within our reach. IAVI is sponsoring several ongoing TB vaccine clinical trials.

IAVI and the Liverpool School of Tropical Medicine announced in May 2019 a new [global research consortium](#), the Scientific Research Partnership for Neglected Tropical Snakebite (SRPNTS). Funded by the U.K. government through the Department for International Development, this consortium aims to develop novel antibody therapies to improve the efficacy, safety, and affordability of snakebite treatment in India and Africa.

Building on its work on HIV vaccine design, IAVI's Vaccine Design and Development Laboratory (DDL) has become one of the world's leading viral vector vaccine research and development labs, and researchers there are applying their expertise to emerging infectious diseases. IAVI's Lassa fever vaccine candidate, supported by CEPI, is moving to clinical testing, and will be supported by a network of clinical partners in West Africa. IAVI established a new vaccine development program to combat [Marburg virus](#), in partnership with the U.S. Defense Threat Reduction Agency.

The progress I've described would not have been possible without your tremendous support and partnership. We are deeply grateful for your contributions and passion for improving global public health, and we look forward connecting with you throughout 2020.

Best regards,

A handwritten signature in blue ink that reads "Mark Feinberg". The signature is fluid and cursive, with a large loop at the end.

Mark Feinberg, M.D., Ph.D.
President and CEO

About IAVI

IAVI is a nonprofit organization dedicated to developing vaccines and antibodies for HIV, tuberculosis (TB), emerging infectious diseases, and neglected diseases. For more than 20 years, we have been a leading force in HIV vaccine research. That mission continues unabated, and now we're also leveraging this expertise to generate innovative solutions to the world's most intractable infectious and neglected diseases by building new partnerships and coalitions.

An important part of our expertise is in convening public and private partners to accelerate development of new candidates in areas where the need is greatest and there is no traditional market incentive. Together, we're advancing the next generation of vaccines and long-lasting injectable antibodies to prevent HIV infection and conducting clinical trials of promising TB vaccine candidates in partnership with high-burden communities. We apply our decades of experience in HIV to develop cheaper, safer, more potent antibody products that target venoms of medically important snakes in India and Africa as well as vaccines for emerging infectious diseases that pose bioterror threats. And we help product developers avert the "valley of death" so today's laboratory concepts become tomorrow's public health solutions.

IAVI is headquartered in New York City, with offices in six countries and four laboratories across the world. Supported by a longstanding partnership with the U.S. Agency for International Development through the U.S. President's Emergency Plan for AIDS Relief, we also collaborate with a robust network of clinical research center partners at leading academic institutions in sub-Saharan Africa.

Whether studying epidemics on the ground, understanding local barriers to effective treatment, or working with governments to support optimal health policies and access, we foster lasting partnerships to transform lives and communities.

Our mission

To translate scientific discoveries into affordable, globally accessible public health solutions

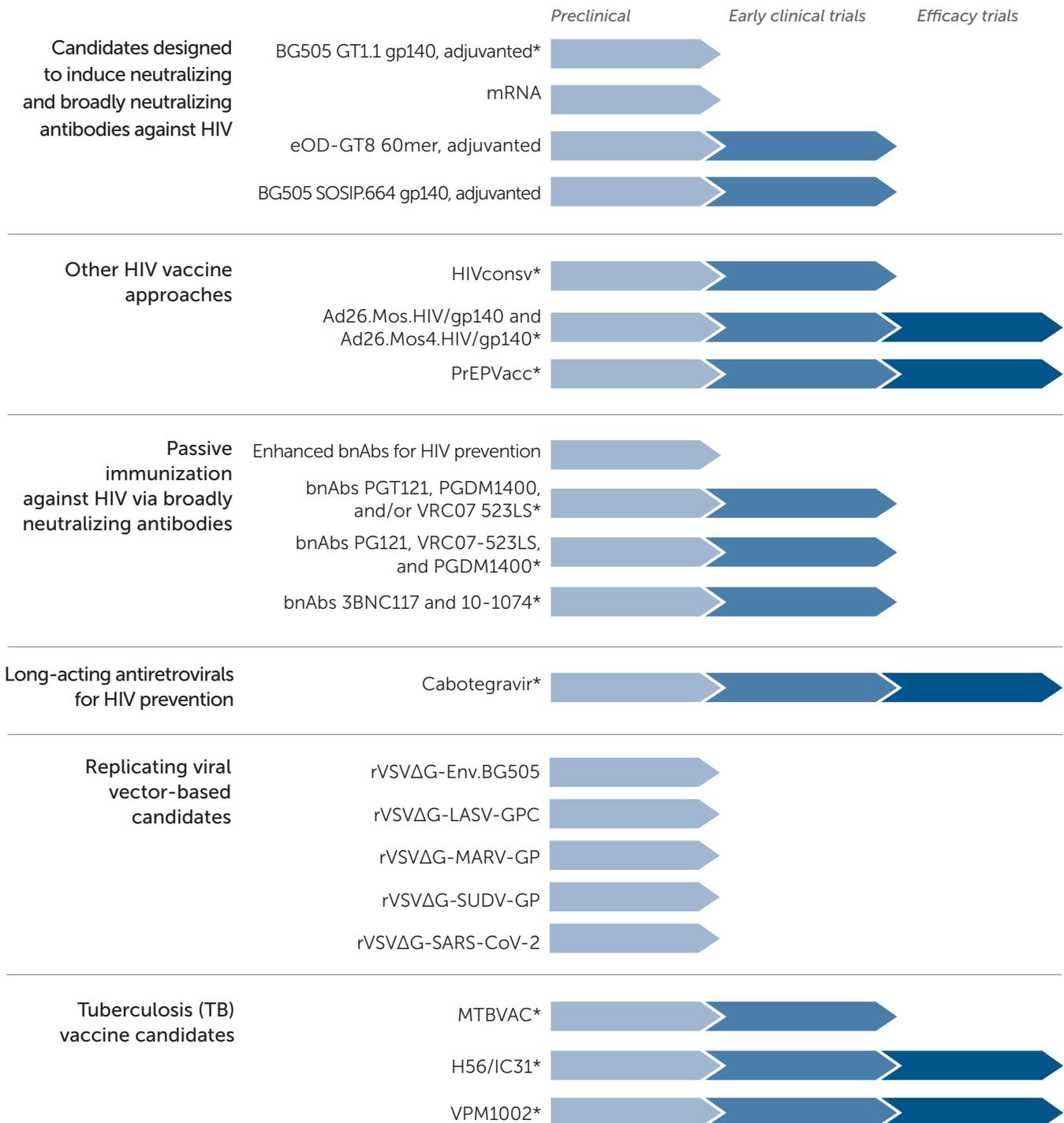
Our vision

A world where all people have equitable access to innovative vaccines and therapeutics



Pipeline

IAVI, in collaboration with partners in the public, private, and philanthropic sectors, develops vaccines and antibodies to address urgent, unmet global health challenges including HIV and tuberculosis. IAVI and its partners conduct and support preclinical work and clinical trials for vaccine and antibody candidates, as well as a long-acting antiretroviral for HIV prevention. Below is the pipeline as of October 2020. For the most updated version, go to www.iavi.org/our-science/pipeline.



* Includes third party candidates under development where IAVI is providing translational and/or clinical development support.

Our track record



Accelerate vaccine research with a pipeline of novel vaccine approaches and the development of new tools and technologies

29

HIV vaccine candidates advanced to clinical trials across 11 countries, with first ever Phase I trials in Kenya, Rwanda, Zambia, India, and Germany.

51

Epidemiology studies conducted that informed the design of HIV vaccine efficacy trials, improving future accessibility and acceptability of final product.

24

Potent and broad HIV neutralizing antibodies, identified from 2,300 samples collected from people living with HIV, are currently being used in research for vaccine design and other prevention treatment. Three IAVI isolated antibodies are being used in clinical studies.

3

IAVI-sponsored replicating VSV vector candidates advanced in novel portfolio toward clinical development (rVSV-HIV, rVSV-Marburg, rVSV-Lassa).

1,222

Vaccine and epidemiology samples stored in an open access data warehouse maximize scientific advances.



Strengthen scientific leadership and collaboration for vaccine research and development and future access

29

Clinical research partners in Africa and India, including 11 state-of-the-art clinical research center partners with 12 GCLP-accredited laboratories capable of conducting clinical research at international standards.

742

Scientists in LMICs trained in GCP and GCLP to international standards for conducting clinical trials (2018 + 2019).

90%

Overall retention rate of HIV vaccine trial participants with an average of 50% participation by women, improving gender balance to garner research insights in communities most at risk.

107

Community and health workers trained on integrating gender issues into HIV vaccine clinical research, based on IAVI's past experience and training manuals.

52

Students and researchers furthered their HIV-related work: 20 early stage scientists supported with research grants; 32 students supported by the International Training Program. In 2019, 14 students were ongoing (5PhD/9MSc); 4 completed adolescent research fellowships.



Work in partnership for continued support for HIV research and development

184

Partners from academia, biotechnology, and pharmaceutical sector, as well as civil society and global health initiatives.

34

Governments, foundations, and other donors, with work from across the globe on four continents.

42

Projects managed by the IAVI Product Development Center since its establishment in 2013, as an integrated platform to advance promising concepts from bench to clinic; 23 external investigators supported to date.

22

Phase I/II trials supported by IAVI's Product Development Center to assess external vaccine candidates and biologics.



Provide benefits for communities most impacted by HIV/AIDS

837,545

People in Africa received counseling services and health care referrals for treatment and care.

12

National and regional policies included HIV vaccine research, resulting in enhanced local ownership and an improved environment for research with at-risk populations.

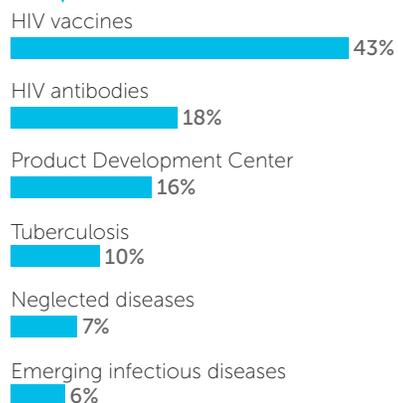
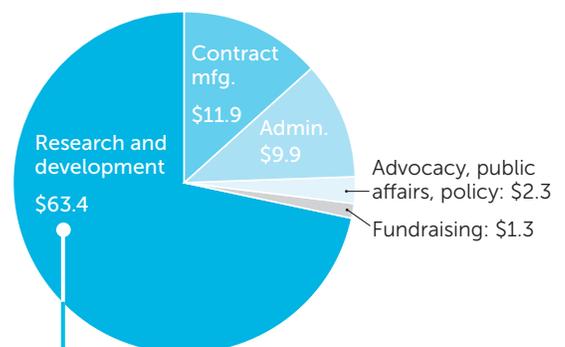
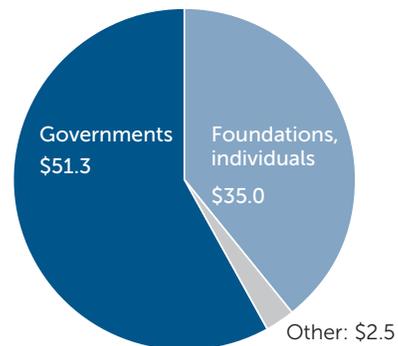
2,400+

Volunteers enrolled in IAVI-sponsored HIV vaccine trials in Africa; more than 50,000 participants enrolled into epidemiology studies that not only helped HIV research, but also informed about other problems and health care issues relevant for each respective community.

2019 financials

All figures in millions of U.S. dollars

	2018	2019
REVENUE		
<i>Grants and contributions</i>		
Governments	43.3	51.3
Foundations	35.5	35.0
Investment income and other	1.2	2.5
Total	80.0	88.8
EXPENSES		
<i>Programs</i>		
Research and development	60.6	63.4
Contract manufacturing-related activities	10.1	11.9
Vaccine advocacy, public affairs, and policy	2.8	2.3
Administration	8.5	9.9
Fundraising	1.7	1.3
Total	83.7	88.8
ASSETS		
Cash and investments	60.2	49.2
Grants receivables	21.3	23.8
Fixed assets	6.5	5.2
Other	0.4	0.5
Total Assets	88.4	78.7
Liabilities	46.4	37.3
Net assets	42.0	41.4
Total liabilities and net assets	88.4	78.7



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Donor acknowledgment

Thank you to all of our generous donors, whose support makes possible the advancement of research and clinical trials toward affordable, globally accessible public health solutions.

IAVI gratefully acknowledges the generous support provided by the following major donors



Foundation for the National Institutes of Health | National Institute of Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research | The Buimerc Group | Broadway Cares/Equity Fights AIDS | Cancer Research UK | The City of New York, Economic Development Corporation | Congressionally Directed Medical Research Program (DoD) | GSK | The Hearst Foundations | Keith Haring Foundation | Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the USA and Canada)

And many other generous individuals and partners around the world

As of September 2020

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