



IAVI

Annual Report

2018



Dear Friends of IAVI,

As I reflect on IAVI's accomplishments in 2018, I'm pleased to share the significant progress we and our partners made as we continued to work toward an HIV vaccine and applied our strengths to other unmet public health needs. We are more committed than ever to translating scientific discoveries into affordable, accessible public health solutions for the people who need them most.

We advanced an innovative HIV vaccine concept into a Phase I clinical trial known as IAVI G001. The vaccine candidate eOD-GT8 60mer is the first HIV immunogen to be tested in humans that was designed using a structure-based approach based on highly sophisticated and elegant vaccine science. Another promising candidate, BG505 SOSIP.664 gp140, a native-like HIV Envelope trimer, received "safe-to-proceed" designation from the FDA, and screening for a Phase I clinical trial began for volunteer vaccinations in 2019. These vaccine candidates represent an important step forward in the quest to develop an HIV vaccine. If the trial results are encouraging, we may be closer to elucidating the pathway to the production of broadly neutralizing antibodies (bNAbs), proteins that most HIV vaccine researchers think will be a necessary component of immunization against HIV.

In October, IAVI acquired tuberculosis (TB) vaccine clinical research programs and assets, including clinical staff, from Aeras, the product development nonprofit focused on TB vaccines. We have already benefited from the expertise of their TB clinical operations group and South African network. Our organizational expansion closely followed the publication of results from two encouraging TB vaccine efficacy trials to which Aeras was a key contributor. The findings of these trials, if confirmed in follow-up studies, could represent a breakthrough in the decades-long quest to develop an effective TB vaccine. We look forward to working as a team to advance solutions for HIV, TB, and other global health challenges.

Toward our mission of developing affordable, accessible public health solutions, we have successfully built upon our strong work in monoclonal antibodies. We launched an

ambitious new initiative to work toward global access to monoclonal antibodies for a range of disease indications, and we established a promising partnership with Serum Institute of India to help achieve this goal. We also signed a memorandum of understanding with the National Institutes of Health to select and advance antibody combinations for HIV prevention and treatment.

We received support from the U.K. Department for International Development to form a consortium to develop monoclonal antibodies to reduce deaths and injury from snakebite envenoming in Africa and India. Additionally, in August 2018, IAVI signed an agreement with CEPI to use our promising vesicular stomatitis virus (VSV) vector platform to advance a vaccine candidate against Lassa fever, a viral hemorrhagic fever illness with a high case-fatality rate.

With the generous support of USAID and other donors, we have continued to cultivate HIV and TB research and development by and with African scientists, with support from scientists in India. In 2018, through the ADVANCE (Accelerate the Development of Vaccines and New Technologies to Combat the AIDS Epidemic) program, researchers provided clinical support for IAVI G001 and contributed to the advancement of several other innovative HIV vaccine candidates toward efficacy trials. The Serum Institute of India partnership will give ADVANCE researchers a unique opportunity to take the most promising bNAbs from bench to field for clinical evaluation. Many of our labs and clinical research center partners are expanding their research capacity so that they can lead humoral immune response evaluation in clinical trials. Moreover, the recently launched online IAVI DataSpace will offer researchers all over the world access to more than 150,000 samples and integrated data from at-risk populations at the center of the epidemic in Africa.

Our achievements rely on the support of our donors, staff, partners, and committed colleagues in global health. We are grateful for your contributions and your passion for solving the world's most urgent public health challenges, and we look forward to making more progress in 2019.

Best regards,

A handwritten signature in blue ink, reading "Mark Feinberg". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

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

About IAVI

IAVI is a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges including HIV and tuberculosis. Our mission is to translate scientific discoveries into affordable, globally accessible public health solutions.

Through scientific and clinical research in Africa, India, Europe, and the U.S., IAVI is pioneering the development of biomedical innovations designed for broad global access. We develop vaccines and antibodies in and for the developing world and seek to accelerate their introduction in low-income countries.

IAVI programs and partnerships are grounded in the regions of the world where the disease burden is the greatest, and our approach emphasizes sustainability. Our network of clinical research center partners in Africa and India helps strengthen in-country research capacity and supports the training and education of the next generation of scientists. The global impact of our science includes fundamental contributions to understanding the biology of HIV infection, which IAVI and others are applying toward advancing vaccine science and immunology.

IAVI accelerates scientific discovery and development by fostering unique collaborations among academia, industry, local communities, governments, and funders to explore new and better ways to address public health threats that disproportionately affect people living in poverty.

Our global reach, including a clinical research network in five countries in sub-Saharan Africa and in India, has allowed us to make fundamental contributions to understanding the epidemiology, transmission, virology, and immunology of HIV. This work played a key role in facilitating the design of promising HIV vaccine candidates, as well as the discovery of broadly neutralizing antibodies that are now being advanced as promising approaches for HIV prevention. Our integrated capabilities in vaccine and antibody discovery, development, and clinical research take advantage of biopharmaceutical industry expertise to accelerate the development and testing of prevention methods for HIV and other diseases. Through the Product Development Center, we support external researchers with technical and scientific expertise to accelerate the development of their own products.

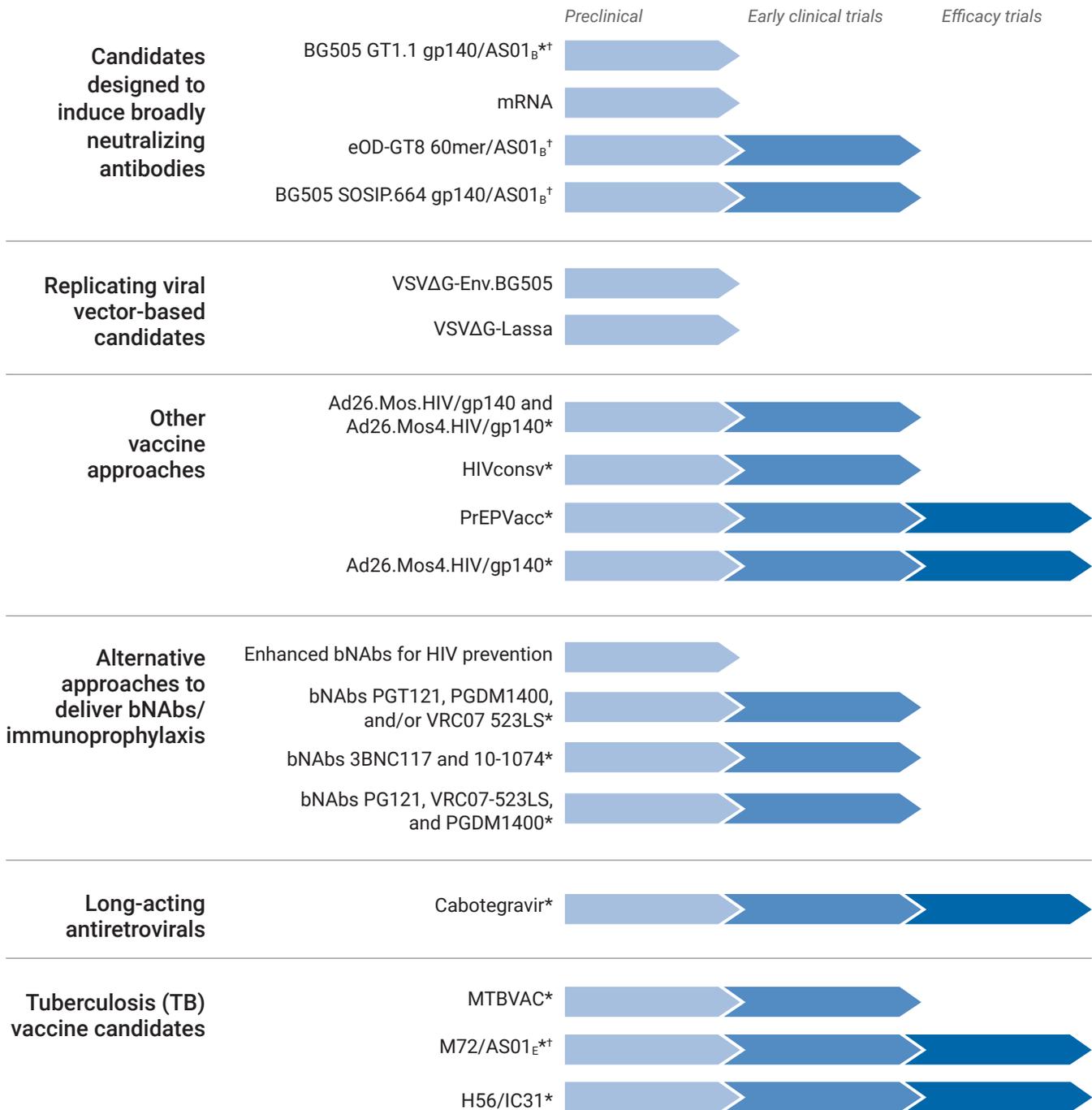
Our mission

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



2019 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 June 2019. 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.

† The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon® adjuvant licensed from Antigenics LLC, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes.

Our track record



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

33

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

47

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

81

Potent and broad HIV neutralizing antibodies identified and used in research for vaccine design and other prevention and treatment modalities. Since 2009, 2,200 samples have been collected from people living with HIV, bringing new hope for a protective HIV vaccine; 3 of IAVI's isolated antibodies being used in clinical studies

3

IAVI-sponsored replicating viral vector candidates advanced in novel portfolio toward clinical development

1 million

Vaccine and epidemiology samples stored in a data warehouse, maximizing scientific advances by sharing all of these materials, promising technologies and technical expertise



Strengthen a new model of African scientific collaboration for vaccine research and development and future access

11

State-of-the-art partner network CRCs in Africa and India with 12 GCLP-accredited laboratories capable of conducting clinical research at international standards

500+

Scientists in the developing world trained in Good Clinical Practices and GCLP to international standards for conducting clinical trials

90%

Overall retention rate of HIV vaccine trial participants with an average of 44% participation by females; bringing better gender balance to trial data for more accurate vaccine design

107

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

20

Early stage scientists supported with research grants

31

Advanced degree candidates supported by ITP; 15 students ongoing; 8 PhD/23 MSc; 10 adolescent research fellowships



Work in partnership for continued support for AIDS vaccine research and development

100+

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

25+

Governments, foundations and other donors; with work in 22 countries over 4 regions

35

Projects managed by the Vaccine Product Development Center since its establishment in 2013, as an integrated platform to advance promising concepts from bench to clinic; 20 external investigators supported to date

20

Phase I/II trials supported by IAVI's Product Development Center assessing external vaccine candidates and biologicals

15

Biotechnology partners engaged in HIV vaccine research and development through the Innovation Fund, yielding new technologies such as advanced screening tools, a manufacturing platform, and novel vaccine delivery



Provide benefits for communities

790,000+

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

8

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

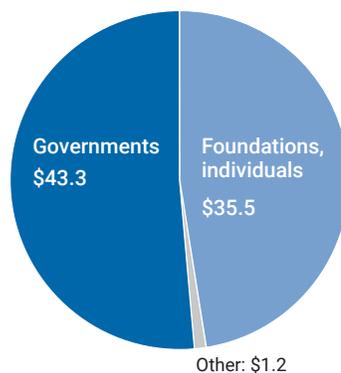
900

Volunteers enrolled in IAVI-sponsored HIV vaccine trials in Africa; more than 48,000 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

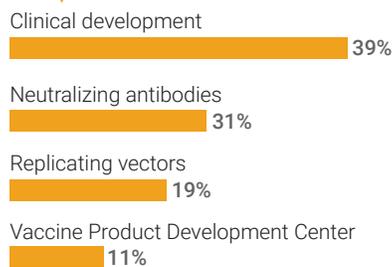
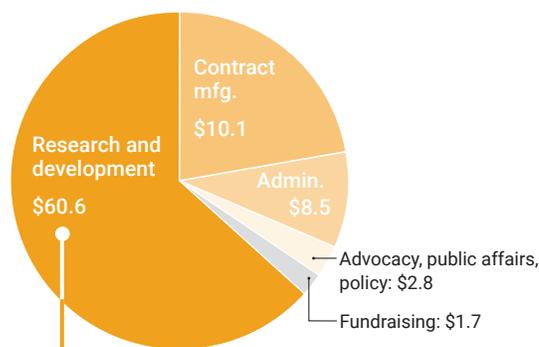
2018 financials

All figures in millions of U.S. dollars

	2017	2018
REVENUE		
<i>Grants and contributions</i>		
Governments	39.5	43.3
Foundations	42.7	35.5
Investment income and other	0.7	1.2
Total	82.9	80.0



EXPENSES		
<i>Programs</i>		
Research and development	54.2	60.6
Contract manufacturing-related activities	19.0	10.1
Vaccine advocacy, public affairs, and policy	2.6	2.8
Administration	8.0	8.5
Fundraising	1.7	1.7
Total	85.5	83.7



ASSETS		
Cash and investments	55.1	60.2
Grants receivables	19.4	21.3
Fixed assets	7.6	6.5
Other	0.5	0.4
Total Assets	82.6	88.4
Liabilities	38.2	46.4
Net assets	44.4	42.0
Total liabilities and net assets	82.6	88.4

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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



USAID
FROM THE AMERICAN PEOPLE



PEPFAR
U.S. President's Emergency Plan for AIDS Relief

**BILL & MELINDA
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THE WORLD BANK



UKaid
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EDCTP



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सत्यमेव जयते
Ministry of Science & Technology
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amfAR, The Foundation for AIDS Research | Bill & Melinda Gates Foundation | The Buimerc Group | Broadway Cares/Equity Fights AIDS | Cancer Research UK | The City of New York, Economic Development Corporation | Coalition for Epidemic Preparedness Innovations | European & Developing Countries Clinical Trials Partnership | European Union | Foundation for the National Institutes of Health | GlaxoSmithKline | Government of Japan | The Hearst Foundations | Irish Aid, Department of Foreign Affairs and Trade | Ministry of Foreign Affairs of Denmark | Ministry of Foreign Affairs of The Netherlands | Ministry of Science & Technology, Government of India | National Institute of Allergy and Infectious Diseases | The Research Council of Norway | U.K. Department for International Development | The U.S. President's Emergency Plan for AIDS Relief through the U.S. Agency for International Development | The World Bank

And many other generous individuals
and partners around the world

As of June 2019

iavi.org

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