



IAVI

Annual Report

2021

Letter from the CEO



Dear friends of IAVI,

In 2021, 40 years after the first reports of what we now know as AIDS, 25 years after IAVI's founding, and thanks to two important milestones this year, we have greater clarity today than ever on what it will take to develop an effective HIV vaccine. We are excited to have made significant progress toward that goal in 2021, while we've advanced the development of vaccines and antibodies to combat other infectious and neglected diseases.

The first HIV-related milestone in 2021 was proof-of-concept demonstrated by the Antibody-Mediated Prevention studies that receipt of HIV broadly neutralizing antibodies (bnAbs) can prevent HIV acquisition under certain circumstances. This finding gave hope to the field and reinforced the validity of IAVI's R&D focus on bnAbs both as targets for HIV vaccine design and as a tool for passive immunization.

Second was a milestone reached in our trial IAVI G001 demonstrating that we have defined a pathway to elicit bnAbs through sequential vaccination and "education" of B cells to produce bnAbs. We are now building on IAVI G001 results in a partnership with biopharmaceutical company Moderna in IAVI G002, a first-in-human trial of mRNA technology applied to deliver our novel HIV proteins. A companion trial will launch in 2022 in Rwanda and South Africa of one of these mRNA-encoded proteins, with immunological assays being performed by our African clinical research center partners. If these trials tell us that results of mRNA-mediated vaccine delivery matches that of recombinant protein delivery, then we will be able to expedite translation of promising ideas from the lab into the clinic and accelerate iteration to hasten the development of an efficacious HIV vaccine.

With the National Institutes of Health's Vaccine Research Center and with significant support from the U.S. Agency for International Development/President's Emergency Plan for AIDS Relief, we have optimized and advanced to development a portfolio of highly potent bnAbs targeting the three most conserved regions on the HIV Envelope. Our partnership with Moderna to research mRNA delivery of HIV bnAbs could bring that platform's speed of production to our program. We plan to begin clinical evaluation of a bnAb combination in 2023.

Under the aegis of the World Health Organization (WHO), IAVI led a technical secretariat that produced a Preferred Product Characteristics document to provide product developers with guidance to ensure future HIV bnAb products are developed to meet the needs of communities, implementers, procurers, and policymakers. The WHO will publish the document in 2022. IAVI also advanced three

research projects on end-user preferences and needs of health care providers and policymakers to inform the development of antibody products with the greatest potential for uptake, especially by adolescent girls and young women.

New tuberculosis (TB) vaccines remain an urgent global health priority, especially given that annual TB deaths have risen for the first time in more than a decade. To address this critical need, IAVI and Biofabri announced a partnership in 2021 to advance late-stage development of MTBVAC, one of the most promising TB vaccine candidates and the only live-attenuated vaccine candidate derived from *M. tuberculosis* (the form of TB that infects humans). In this partnership, IAVI will ensure that people living with HIV, who are especially vulnerable to TB, and adults and adolescents — those who are most likely to transmit TB — are prioritized in clinical research. Biofabri will launch an efficacy trial of MTBVAC in infants in 2022.

The need for more effective and more accessible COVID-19 vaccines remained clear through the second year of the pandemic. IAVI advanced preclinical work on our vesicular stomatitis virus vectored COVID-19 vaccine candidate, including investigation of intranasal administration, which could prevent SARS-CoV-2 infection and lead to a vaccine that is easier to administer. IAVI also entered into a partnership to provide clinical trial support for the mRNA-delivered COVID-19 vaccine candidate developed by Greenlight Biosciences. We share Greenlight's vision of evaluating mRNA COVID-19 vaccines in African populations and enabling low-cost mRNA vaccine manufacturing.

We made progress on other aspects of our rVSV platform with the launch of a Phase I trial of our Lassa fever vaccine candidate, and preclinical work continued on our Marburg virus and Ebola Sudan virus vaccine candidates.

We are proud of what we accomplished in 2021 with key global health organizations and other partners toward our mission of developing affordable, globally accessible public health solutions. And we embrace the opportunities ahead of us to achieve critical global public health goals. Reaching these goals will be challenging, but COVID-19 has shown us that almost anything is possible when science, partners, and political will come together for the common good.

We are grateful to all of our funders and partners for their support and look forward to working with you throughout 2022.

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 scientific research organization dedicated to addressing urgent, unmet global health challenges including HIV, tuberculosis (TB), and emerging infectious diseases (EIDs). Our mission is to translate scientific discoveries into affordable, globally accessible public health solutions. 2021 was a milestone year for IAVI as we marked 25 years of innovation, partnerships, and commitment to access.

At the heart of IAVI's working model is deep expertise in convening public, private, and community partners to accelerate development of new candidates in areas where the need is greatest and there is no traditional market incentive. Our solid portfolio of bnAbs as HIV prevention continue toward a Phase I clinical trial in partnership with other research networks in sub-Saharan Africa. We're also advancing the promising tuberculosis TB vaccine candidate MTBVAC into an efficacy trial in adults in South Africa. And as the COVID-19 pandemic continues, IAVI is applying our extensive clinical trial experience to advance clinical trials of mRNA-based COVID-19 vaccines in Africa. Other multi-country partnerships are facilitating the advancement of IAVI's suite of EID vaccine candidates into clinical trials in West Africa.

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 at the community level, innovating against new outbreaks, understanding local barriers to uptake of novel prevention technologies, 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



IAVI's 25th anniversary

25 years of innovation, partnerships, access

In 2021, to mark IAVI's 25th anniversary, we took the opportunity to celebrate and explore our history and our future.

IAVI was conceived at a 1994 meeting convened by the Rockefeller Foundation and launched in 1996 as a nonprofit, public-private, product development partnership (PDP) with a mission to ensure the development of safe, effective, and accessible HIV vaccines. Since then we, our partners, and the field have made tremendous strides toward this goal, mobilizing a global community of researchers, advocates, communities, and funders to advance HIV vaccine development, nurturing a network of clinical research institutions in sub-Saharan Africa and India, and advancing groundbreaking science and discoveries through innovative partnerships with academic, industry, and other private- and public-sector groups.

More than an opportunity to look back, IAVI 25 has been a moment to focus on future directions for the organization and global health. The COVID-19 pandemic has crystallized our thinking about epidemics and response, and about the gaps that need to be addressed to ensure that people everywhere have access to life-saving disease prevention and treatment tools. Investments in decades of R&D for HIV led directly to tools and capacity to fight COVID-19. The pandemic has underscored that infectious diseases don't live in separate spheres, and they don't require that we focus on them individually. The progress we've made in the fight against COVID-19 – whether that's the science, the partnerships, or the focus on access and equity – should galvanize progress in response to other diseases, especially those that primarily affect people living in poverty. Now is the time to think ahead, and band together.

Explore this [multimedia timeline](#) of IAVI's history and the people and partners who have helped us get where we are today.



Watch

IAVI at 25: Reflecting and looking forward

To celebrate IAVI turning 25, we spoke with Mark Feinberg, president and CEO, Ana Céspedes, COO, and Kundai Chinyenze, executive medical director as they reflected on all we and our partners have accomplished and what the future holds for IAVI and global health research. Click [here](#) to watch the video.

Listen

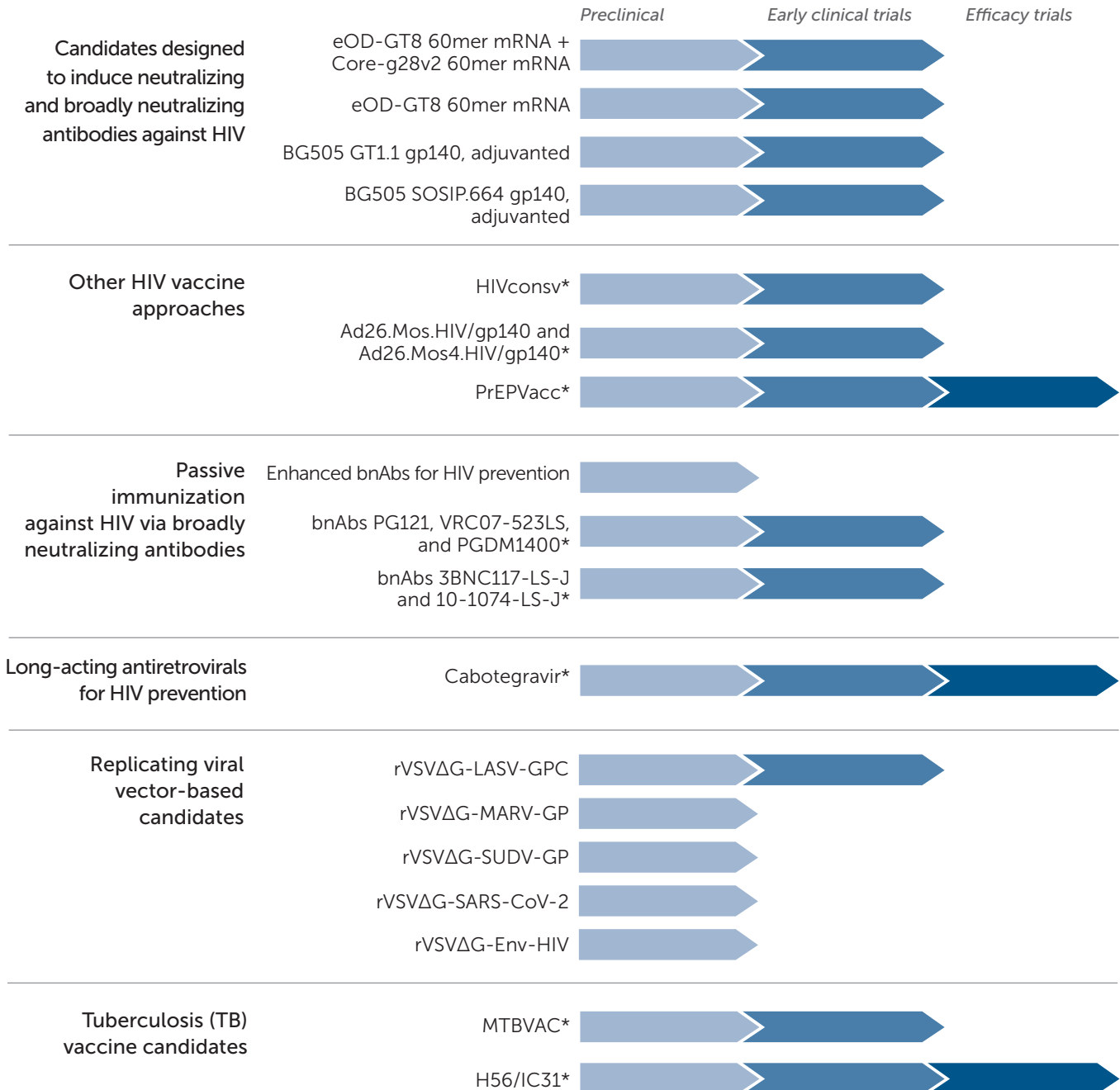
Inside IAVI: Special Edition – In conversation with Seth Berkley & Mark Feinberg

In our special anniversary edition of the Inside IAVI podcast, we were joined by Mark Feinberg, IAVI president and CEO, and Seth Berkley, IAVI's founding CEO who is now leading Gavi, The Vaccine Alliance, as they looked back on IAVI's accomplishments and the current global health landscape. Click [here](#) to listen.



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 May 2022. 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.

2021 by the numbers



76

HIV neutralizing **antibodies discovered**.



248

Scientists in LMICs **trained in Good Clinical Practices and GCLP** to international standards for conducting clinical trials.



13

Active **observational epidemiology studies conducted** that informed the design of HIV vaccine efficacy trials — plus one for Lassa fever — improving future accessibility and acceptability of final product.



90%

Overall **retention rate of HIV vaccine trial participants** with an average of **62.4%** participation by **females**; bringing better gender balance to trial data for more accurate vaccine design.



53

Scientific **papers** published by IAVI and partners: **19** LMIC-led; **23** female-led; **44** open access.



255

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



36

Governments, foundations, and other donors as **funders**.



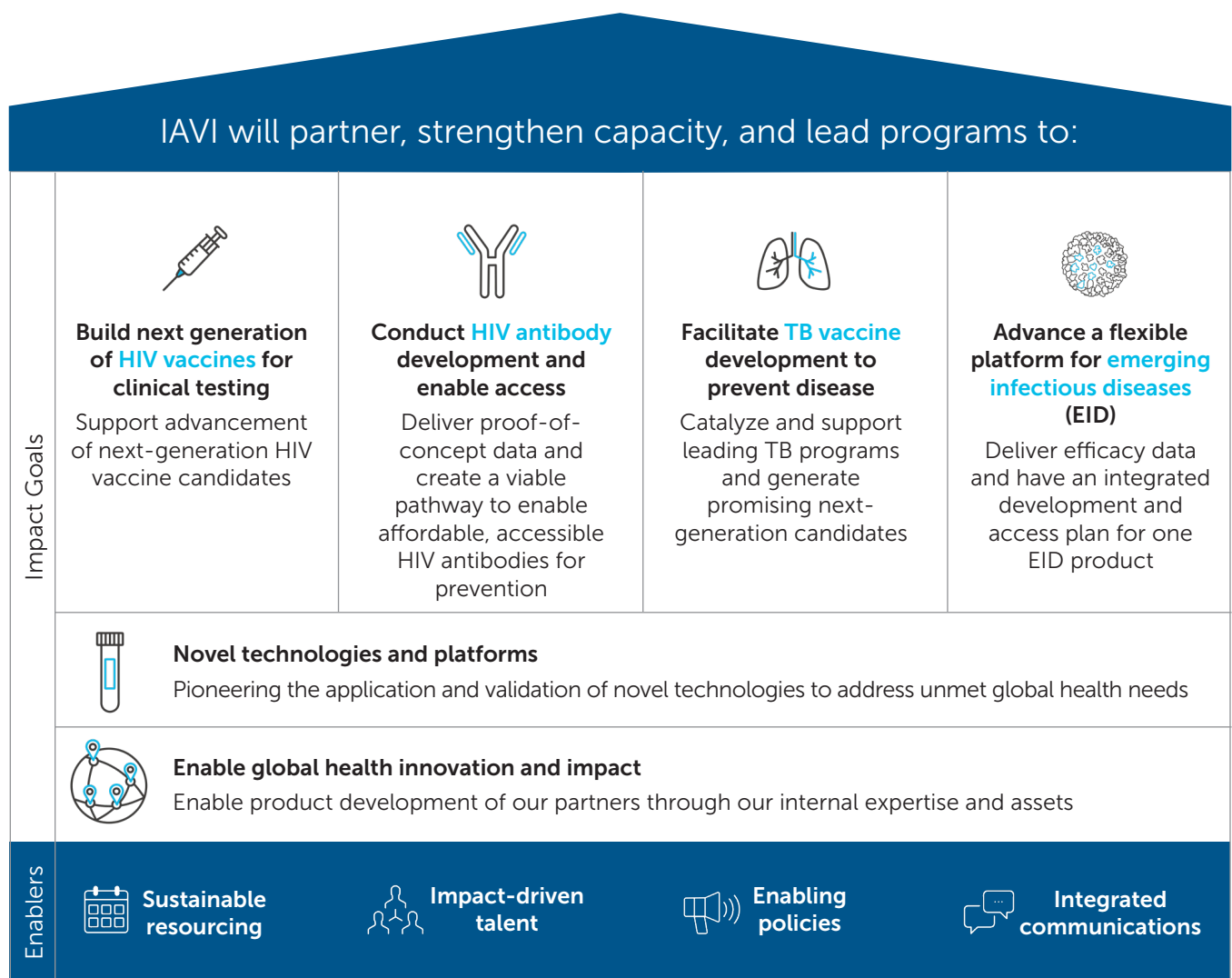
79%

Success rate on **proposals submitted**.

Our impact plan 2025

IAVI's 2020-2025 strategy guides us forward in delivering on our mission to translate scientific discoveries into affordable, globally accessible public health solutions. The strategic framework includes six Impact Areas that encompass the scientific scope of our programs and four strategic enablers to ensure a solid foundation and support mechanisms that will fully enable our scientific work.

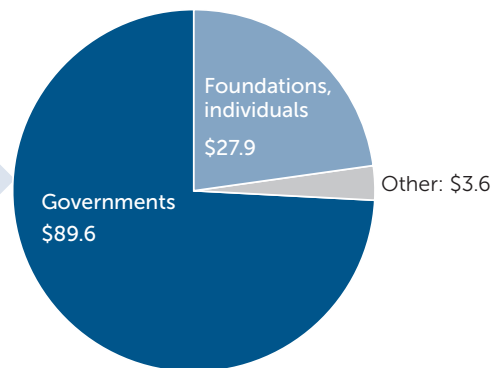
Over 2020 and 2021, we have made significant progress across its portfolio, while the COVID-19 pandemic has brought to the forefront the importance of accessible vaccines and agile product development. IAVI leadership reviewed and refreshed our scientific strategy in 2021 to ensure its continued relevance and focus in ensuring that we achieve our mission.



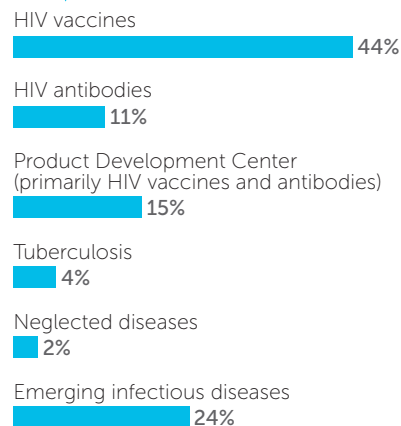
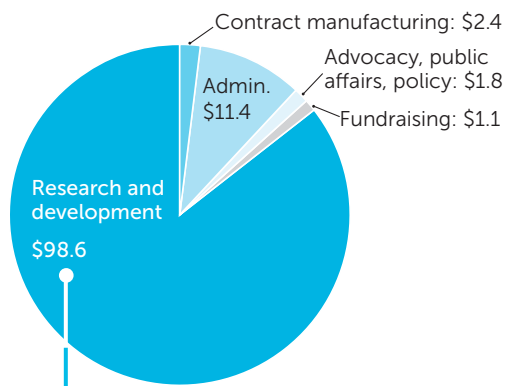
2021 financials

All figures in millions of U.S. dollars

	2020	2021
REVENUE		
<i>Grants and contributions</i>		
Governments	67.4	89.6
Foundations/individuals	28.5	27.9
Investment income and other	7.4	3.6
Total	103.3	121.1



EXPENSES		
<i>Programs</i>		
Research and development	75.6	98.6
Contract manufacturing – related activities	7.3	2.4
Vaccine advocacy, public affairs, and policy	1.8	1.8
Administration	11.4	11.4
Fundraising	1.0	1.1
Total	97.1	115.3



ASSETS		
Cash and investments	54.6	70.6
Grants & contracts receivables	27.0	37.4
Fixed assets	4.0	3.9
Other	0.7	0.6
Total Assets	86.3	112.5
Liabilities	44.1	56.7
Net assets	42.2	55.8
Total liabilities and net assets	86.3	112.5

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Funder acknowledgment

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Foundation for the National Institutes of Health | National Institute of
Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research
| 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 April 2022

iavi.org

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