



Translating **science** into
global health impact

IAVI

Annual Report

2022



Dear colleagues and friends,

I'm pleased to introduce IAVI's 2022 Annual Report and to share with you what IAVI and our valued partners achieved during the year. I feel truly fortunate to lead this organization of dedicated, mission-driven colleagues and to work

with our committed global health partners as we strive to achieve our mission to translate scientific discoveries into affordable, globally accessible public health solutions.

This year saw the publication in *Science* of data from IAVI G001, a proof-of-concept study of the germline-targeting HIV vaccine strategy. This innovative approach seeks to elicit HIV broadly neutralizing antibodies with a specific sequence of rigorously defined HIV immunogens. The exciting results of the study provided critically important validation of the initial stages of this approach. Building upon these encouraging data, and with the hope of further accelerating the translation of promising immunogen concepts from the lab into clinical evaluation, IAVI and Scripps Research have partnered with Moderna on mRNA-based delivery of IAVI/Scripps-developed HIV immunogens. The IAVI team and our partners launched two Phase I trials in 2022, IAVI G002 and G003, both of which are testing the ability of RNA-delivered germline-targeting immunogens to replicate and extend the results of IAVI G001 (which employed a recombinant protein-based immunogen plus an adjuvant). Importantly, the IAVI G003 study, and associated immunologic analyses, are being conducted in sites in Africa and made possible with support from the USAID-supported ADVANCE program.

We completed a Phase II trial of MTBVAC, the novel tuberculosis vaccine candidate, and our partner Biofabri launched a Phase III trial of the vaccine candidate in infants in three African countries. A study of MTBVAC among people living with HIV is slated for 2023, and we also are planning an efficacy study in adults and adolescents.

When an outbreak of Ebola Sudan virus disease was reported in Uganda in September, the IAVI team and our collaborators at Merck & Co., Inc., (known as MSD outside the United States and Canada), were able to provide vaccine doses to the World Health Organization and the Uganda Ministry of Health for use in a ring vaccination clinical trial. Fortunately, public health measures were able to quickly bring the outbreak under control prior to starting the ring trial. Though the ring trial could not be conducted as planned, IAVI continues to move our Ebola Sudan vaccine program forward as expeditiously as possible. This experience yet again reinforces the importance of

preparing for, rather than simply responding to, emerging infectious disease (EID) outbreaks. IAVI remains committed to bringing our Ebola Sudan vaccine candidate to licensure and to have it be available to help contain future outbreaks of this deadly pathogen. Similar product development work is being conducted for our Marburg vaccine program, another filovirus that has caused outbreaks over the last year and in the past.

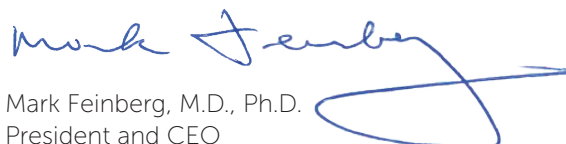
We had additional success in advancing our vaccine candidates for Lassa fever and COVID-19, other key products in our EID vaccine portfolio. Our Lassa fever vaccine program has generated encouraging results in a Phase I trial and will be advanced into later stage clinical development in 2023, with support from the Coalition for Epidemic Preparedness Innovations and the European and Developing Countries Clinical Trials Partnership.

Throughout 2022, IAVI continued to forge new and build on existing partnerships with governments, academia, industry, and other scientific consortia globally that advance vaccine and antibody candidates from concept to clinic. Our socio-behavioral research and global access initiatives support product development that is rooted in and informed by the realities of communities where disease burden is the greatest. Together with our network of clinical research center partners in Africa and India, we conducted clinical trials, strengthened in-country research capacity, and supported the training and education of the next generation of scientists and advocates.

To conclude IAVI's 25th anniversary year — delayed slightly by the COVID-19 pandemic — IAVI and our founding donor, The Rockefeller Foundation, convened a unique in-person summit of partners working across the globe and across public and private spheres. Together, we examined what recent EID outbreaks have taught us, and how we can meet future challenges with more effective partnerships for EID vaccine development. We have since continued to advance this agenda with further pivotal meetings and publications.

The progress I've described would not have been possible without your tremendous support and partnership. We are deeply grateful for your contributions to and passion for global public health, and we look forward to further advances in 2023.

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, tuberculosis (TB), and emerging infectious diseases (EIDs). Our mission is to translate scientific discoveries into affordable, globally accessible public health solutions. We do this in collaboration with public, private, and community partners to accelerate the development of new biomedical prevention candidates in areas where the need is greatest and there is no traditional market incentive.

Together with our partners, IAVI strengthens capacity and leads programs to:

- Build the next generation of HIV vaccines for clinical testing;
- Conduct HIV antibody development and enable access;
- Facilitate TB vaccine development to prevent disease;
- Advance a flexible platform for EID vaccines;
- Pioneer the application and validation of novel technologies to address unmet global health needs; and
- Enable product development of our partners through our internal expertise and assets.

IAVI has offices and laboratories across five countries and collaborates with a network of clinical research center partners on four continents. This includes leading academic and research institutions in sub-Saharan Africa – where the HIV/AIDS burden is greatest – supported by a longstanding partnership with the U.S. Agency for International Development through the U.S. President’s Emergency Plan for AIDS Relief.

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

Vaccine Literacy Library

In 2022, we launched the [IAVI Vaccine Literacy Library \(VaxLit\)](#). This library contains basic information about HIV, tuberculosis (TB), and Lassa virus vaccines, explained in simple language and in a user-friendly format. It's targeted to a broad range of stakeholders involved in HIV, TB, and Lassa virus vaccine-related work. The text is divided into eight modules covering a range of topics, from basic science and clinical trials to social and ethical issues related to vaccine development and testing, as well as future access to and use of vaccines. While all the modules can be adapted for use at the local community level, they are generally written for individuals who provide education and information related to HIV, TB, and Lassa virus, including: clinical vaccine trial site staff; non-governmental organization staff, to incorporate vaccine messages into their existing work; medical professionals or institutions, to provide vaccine information to patients or to incorporate into advocacy efforts; health centers, to provide clients with vaccine information; academic or religious leaders, to provide information and/or informed advice; and Community Advisory Boards.



Implementation:

- IAVI will conduct community engagement training on the IAVI G003-specific concepts in the VaxLit toolkit and roll out VaxLit materials to the ADVANCE clinical research center partner network.
- IAVI will conduct VaxLit training on 50% of the modules for 100% (7/7) of our clinical research center partners by mid 2023.



Sharon Owuor testing samples at the KEMRI Wellcome Trust Research Programme in Kilifi, Kenya in August 2022



Pretty Khathi of University of KwaZulu-Natal Mandela School of Medicine in Durban, South Africa in August 2022

Pipeline 2023–2025

IAVI, in collaboration with partners in the public, private, and philanthropic sectors, develops vaccines and antibodies to address urgent, unmet global health challenges. Below is the pipeline as of July 2023. For the most updated list of current candidates, go to iavi.org.

IAVI products in development													
Candidate	2023				2024				2025				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
HIV vaccine candidates	eOD-GT8 60mer + Core-g28v2 60mer mRNA				Phase I (IAVI G002)								
	eOD-GT8 60mer mRNA				← Phase I (IAVI G003)								
	BG505 SOSIP gp140, adjuvanted (AS01B)				← Phase I (IAVI W001)								
	rVSVΔG-Env-HIV				Preclinical								
Passive immunization against HIV via bnAbs	bnAbs ePGT121v1, ePGDM1400v9, VRC01.23LS				Preclinical				Phase I				
	rVSVΔG-MARV-GP				Preclinical				Phase I (IAVI C104)				
Emerging infectious diseases vaccine candidates	rVSVΔG-LASV-GPC				Phase I (IAVI C102) / IIa (IAVI C105) / IIb (IAVI C111)								
	rVSVΔG-SUDV-GP				Preclinical →				Phase I (IAVI C108, C109)				
	rVSVΔG-SARS-CoV-2				Preclinical				Phase I				
Tuberculosis (TB) vaccine candidates	MTBVAC*				Phase Ib / IIa (A-050) →				Phase IIa (PLWHIV) / IIb				
	mRNA-encoded TB antigens				Preclinical								

* Trials in adults and adolescents. Biofabri is leading clinical development of the candidate in infants (currently in a Phase III trial).

IAVI-supported candidates													
Candidate	2023				2024				2025				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
HIV vaccine candidates	BG505 GT1.1 gp140, adjuvanted				Phase I (IAVI C101)								
	BG505 SOSIP gp140, adjuvanted (3M-052-AF + Alum)				Phase I (IAVI C107)								
	BG505 SOSIP gp140, adjuvanted (3M-052-AF + Alum)				Phase I (IAVI C110)								
Passive immunization against HIV via bnAbs	DNA-HIV-PT123, AIDSVAX®B/E; DNA-HIV-PT123, CN54gp140, MVA CMDR,CN54gp140; TAF/FTC; TDF/FTC				Phase III (PrEPVacc)								
	bnAbs 3BNC117-LS-J and 10-1074-LS-J				Phase I / II (IAVI C100)								
TB vaccine candidates	H56/IC31®				Phase II (A-055) →								
Mini-protein for COVID-19 prophylaxis	IPD-52520				Preclinical				Phase I (IAVI C106)				

IAVI's impact



Data from IAVI G001, a proof-of-concept study of the germline-targeting HIV vaccine strategy, was published in Science. The exciting results of the study provided critically important validation of the initial stages of this approach.



With partners we launched two Phase I trials, IAVI G002 and G003, both of which are testing the ability of RNA-delivered germline-targeting immunogens to replicate and extend the results of IAVI G001.

We **completed a Phase II trial of MTBVAC**, the novel tuberculosis vaccine candidate.



IAVI **had additional success in advancing product development for our EID portfolio**, which includes vaccine candidates for Lassa fever, Marburg virus disease, Sudan virus disease, and COVID-19.



We continued to **forge new and build on existing partnerships** with governments, academia, industry, and other scientific consortia globally that advance vaccine and antibody candidates from concept to clinic.



Our socio-behavioral research and global access initiatives support product development that is rooted in and **informed by the realities of communities where disease burden is the greatest**.

We **conducted clinical trials, strengthened in-country research capacity, and supported the training and education of the next generation of scientists and advocates** with our network of clinical research centers in Africa and India.

Impact by the numbers



110

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



8

Community and stakeholder engagement workshops and trainings held, reaching **341** participants.



45

Peer-reviewed publications published by IAVI and partners: **21** LMIC authorship; **20** female authorship.



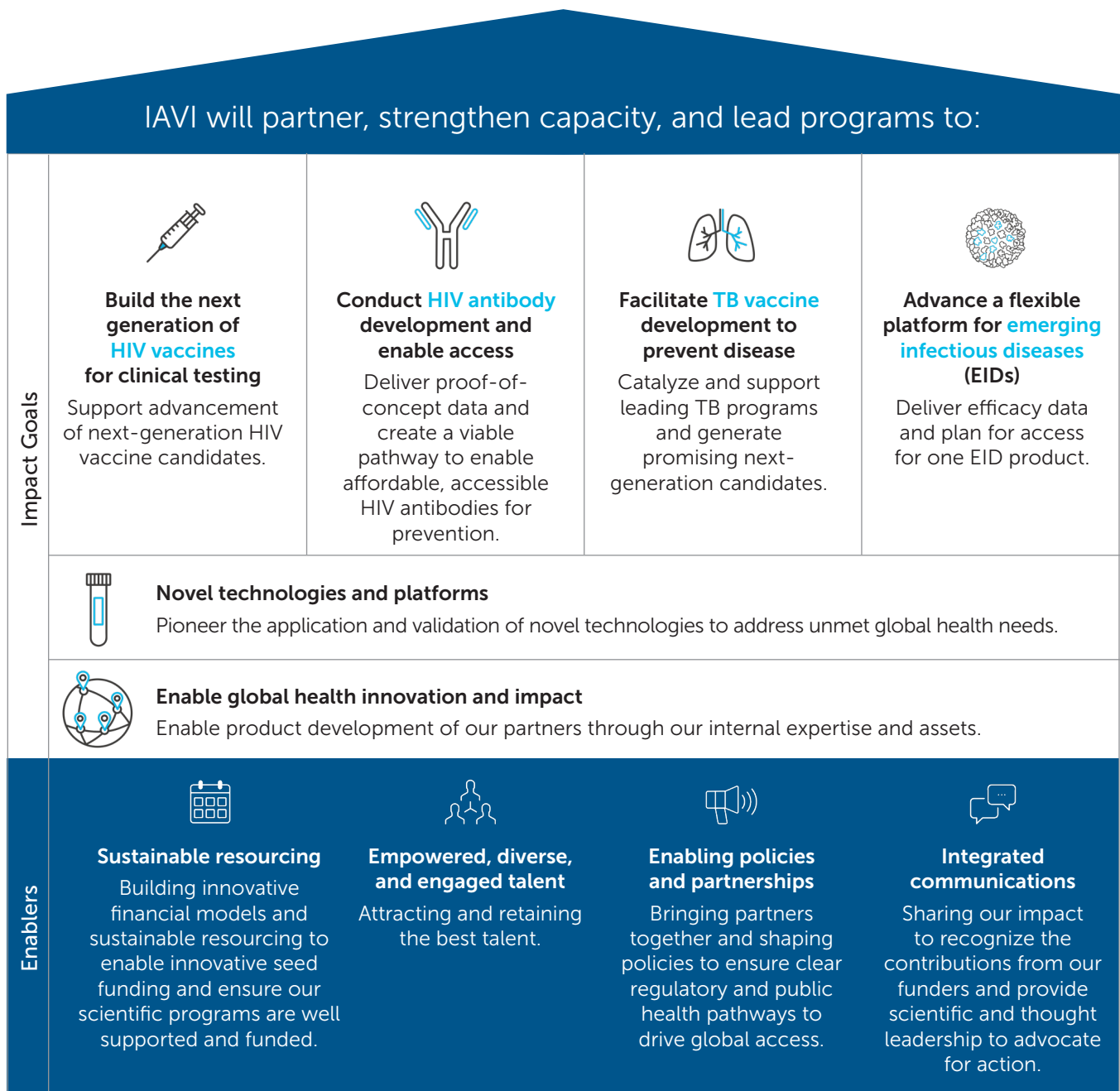
11

National and regional policies, plans, official strategies, roadmaps, guidelines or other official/government documents published with support and/or participation of IAVI.

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 with goals 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.

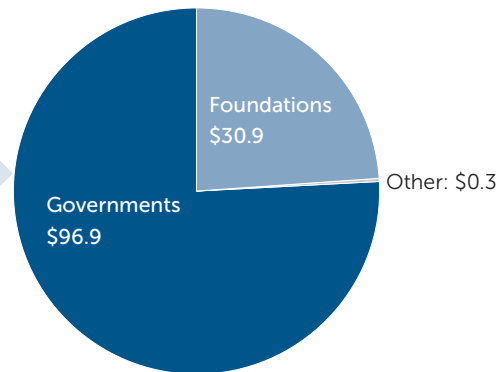
During 2022 we made significant progress across our portfolio. While doing so, we accelerated scientific discovery and development by fostering unique collaborations among academia, industry, local communities, governments, and funders to explore new and better ways to address public health threats that disproportionately affect people living in poverty.



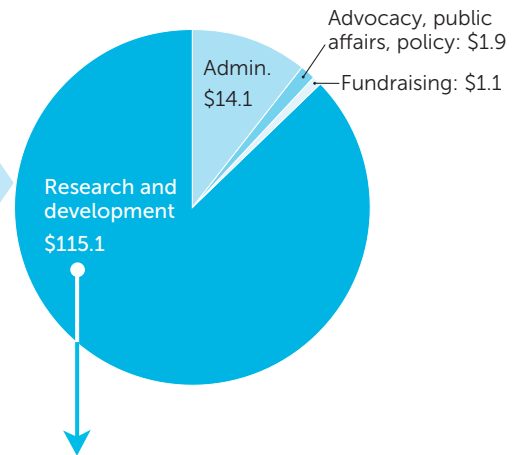
2022 financials

All figures in millions of U.S. dollars

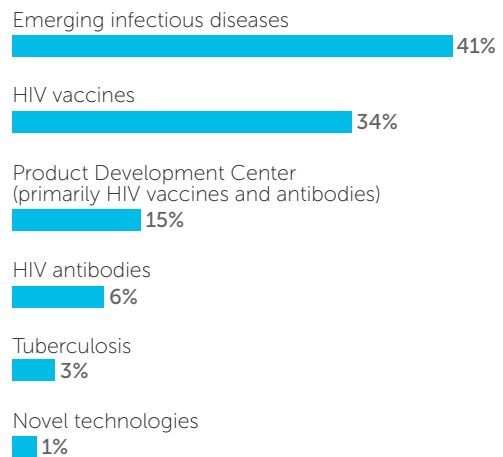
	2021	2022
REVENUE		
<i>Grants and contributions</i>		
Governments	89.6	96.9
Foundations	27.9	30.9
Other	3.6	0.3
Total	121.1	128.1



EXPENSES		
<i>Programs</i>		
Research and development	101.0	115.1
Vaccine advocacy, public affairs, and policy	1.8	1.9
Administration	11.4	14.1
Fundraising	1.1	1.1
Total	115.3	132.2



ASSETS		
Cash and investments	70.6	61.7
Grants & contracts receivables	37.4	56.1
Right-of-use assets	N/A	11.2
Fixed assets	3.9	2.3
Other	0.6	1.3
Total Assets	112.5	132.6
Liabilities	56.7	63.1
Net assets	55.8	69.5
Total liabilities and net assets	112.5	132.6



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Funder acknowledgment

Thank you to all of our generous funders, 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 funders



Biomedical Advanced Research and Development Authority (BARDA) | 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 July 2023

iavi.org

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