



Translating **science** into
global health impact

IAVI

Annual Report

2023



Dear colleagues and friends,

I'm pleased to share with you IAVI's 2023 Annual Report, which reflects the progress that we and our partners have made toward IAVI's mission to translate scientific discoveries into affordable, globally accessible public health solutions.

In 2023, IAVI continued, with the support of partners, funders, and communities, to make advances across our portfolio. After IAVI's mission expanded several years ago to include development not only of an HIV vaccine but also of vaccines for emerging infectious diseases (EIDs) and tuberculosis (TB), we are poised to launch two critical trials in Western and Southern Africa — an efficacy trial for the TB vaccine candidate MTBVAC, and a Phase 2b trial to prepare for an efficacy study of IAVI's Lassa virus (LASV) vaccine. The rapid evolution of our R&D portfolio is nothing short of remarkable and due in large part to the dedication and support of our esteemed funders, partners, and collaborators around the world.

The development of an HIV vaccine continues to be an urgent global health need. IAVI is optimistic that the approach we're advancing to induce broadly neutralizing antibodies (bnAbs) offers the most promising path to an efficacious HIV vaccine. Progress continued in 2023 on two clinical trials of mRNA-delivered novel vaccine candidates, with exciting results to be published in 2024. We and our partners at Scripps Research, and funders the Bill & Melinda Gates Foundation and USAID, and our industry collaborator Moderna, continue to work together to maximize resources and accelerate our program to test additional vaccines in a rapid, iterative fashion. Given the complexities of HIV vaccine development, we are also pleased that other organizations, including the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) and the NIAID-funded HIV Vaccine Trials Network (HVTN), have come together with IAVI and our partners to ensure that our collective efforts are as efficient, effective, and expeditious as possible. In all, with exciting scientific advances and new models for collaboration across investigators and organizations, I believe that the field of HIV vaccine research is more promising than it has ever been.

In 2023 IAVI made key progress to advance the development and eventual uptake of bnAbs to prevent HIV acquisition by infants born to mothers with HIV. Planning is underway for a clinical trial to evaluate antibody combinations and next-generation bnAbs in adults in 2024, with infant trials to follow. To generate support for the infant HIV prevention indication, IAVI and partners established a task force with stakeholders from 45 organizations to accelerate the clinical development, licensure, and availability of bnAbs for peri- and post-natal HIV prevention.

The world urgently needs a new TB vaccine, and we're hopeful that MTBVAC, which IAVI is developing with the Spanish human R&D company Biofabri, will be part of the solution to end the TB epidemic. Building on support from the German Federal Ministry of Education and Research through the KfW Development Bank, IAVI [announced](#) a \$55 million award from the Gates Foundation and Open Philanthropy to conduct a Phase 2b trial assessing the safety and efficacy of MTBVAC in adults and adolescents in several sub-Saharan African countries. This trial is slated to begin in the second half of 2024. As part of a comprehensive product development plan, IAVI facilitated a partnership between Biofabri, NIH, and HVTN to fund, design, and conduct a Phase 2a safety and immunogenicity study of MTBVAC in adolescents and adults living with and without HIV in South Africa.

The need to address local outbreaks of EIDs and contain their spread has been a prominent focus for IAVI. Through IAVI's EID vaccine platform and epidemiological research, we are making great strides in this area and mapping out the factors to enable eventual vaccine commercialization and uptake. We shared promising data from a Phase 1 trial of our LASV vaccine candidate, and a Phase 2a trial — the most advanced LASV vaccine trial to date and funded by CEPI — will begin in three West African countries in 2024. We also launched a first-in-human trial of our Sudan virus vaccine candidate in June 2023. As these achievements and continued development of our Marburg virus vaccine candidate indicate, our [EID vaccine platform](#) is a promising, versatile tool to respond to future outbreaks.

IAVI promoted global vaccine equity via several avenues in 2023. Through advocacy and political efforts, we helped shape the commitments in the [Political Declaration](#) for the UN High-Level Meeting on TB. We are [advocating](#) that the E.U. adopt legislation to introduce a Priority Review Voucher, similar to the U.S. FDA program, to incentivize product development of global health vaccines. Additionally, we have engaged in discussions about strategies to increase local vaccine manufacturing, particularly in African countries.

We remain as committed as ever to working with local scientific leadership to strengthen scientific and research capacity in Africa and India, while centering communities and end users in our product development efforts from discovery through eventual access and uptake.

This progress I've described here would not have been possible without your support, partnership, and passion for global health. Thank you so very much.

Best regards,

A handwritten signature in blue ink that reads "Mark Feinberg". The signature is fluid and cursive, with a large, sweeping flourish 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. 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. As we've seen with COVID-19, persistent gaps in incentive and access can have disastrous outcomes during an outbreak.

IAVI's vision is a world where everyone has equitable access to innovative vaccines and therapeutics. Globally, we have offices and laboratories across five countries and collaborate with a network of clinical research center partners on four continents. This includes leading academic and research institutions in India and sub-Saharan Africa – which have the highest HIV and TB burdens – supported by a longstanding partnership with the U.S. Agency for International Development through the U.S. President's Emergency Plan for AIDS Relief.

- Together with our partners, IAVI strengthens capacity and leads programs to:
- Develop the next generation of HIV vaccines to test in the clinic.
- Conduct HIV antibody development and enable future access.
- Facilitate TB vaccine development to prevent disease.
- Advance a proven vaccine platform for EIDs likely to cause global public health emergencies.
- Apply novel technologies that can make vaccines and antibodies more affordable and easier to administer.
- Deploy our internal expertise and assets to help our partners develop their own global health products.

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

Diversity, equity, and inclusion at IAVI



IAVI was founded with the goal of developing an HIV vaccine for use among communities most impacted by its spread. Our global health mission has always prioritized populations left behind by traditional health care models. As we embark on later-stage clinical research, we have an ongoing responsibility to prioritize diversity, equity, and inclusion (DEI) across our global hubs and research programs.

In 2020, colleagues from across IAVI convened the Global Diversity & Inclusion Committee (GDIC) in recognition of this need, starting with a landscape analysis. This occurred at a moment of global reckoning marked by heightened civil justice engagement and attention to COVID-related inequities in health care, social services, and economic security.

In 2023, the GDIC synthesized that analysis into a strategy designed to better integrate diversity, equity, and inclusion into our work culture. It has three pillars:

1. **Build awareness and learning:** The GDIC curates staff resources and sponsors staff town halls and dialogues, sensitivity training sessions, and other interactive forums on DEI topics relevant to IAVI staff and our impact areas.
2. **Explore and adapt promising initiatives from others:** We seek out existing DEI tools, frameworks, and best practices that IAVI colleagues can adapt to our own contexts. One example is the implementation of a research fairness initiative in 2023 to strengthen research and innovation systems among our clinical research center partners in Africa and India.
3. **Support responsive processes:** Based on our landscaping findings, we support the integration of locally tailored DEI initiatives into our organizational practices.

We are gratified by the opportunity to share this strategy with IAVI's stakeholders and are proud of our organizational commitment to fostering an inclusive environment where IAVI employees, research collaborators, and study volunteers alike feel valued and respected.

Pipeline 2024–2026

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 2024. For the most updated list of current candidates, go to iavi.org/iavi-pipeline.

IAVI products in development													
Candidate	2024				2025				2026				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
HIV vaccine candidates	Germline targeting preclinical antigen research	Preclinical											
	eOD-GT8 60mer + Core-g28v2 60mer mRNA*	Phase 1 (IAVI G002)											
	eOD-GT8 60mer mRNA*	Phase 1 (IAVI G003)											
	rVSVΔG-Env-HIV	Preclinical											
Passive immunization against HIV via bnAbs	Triple antibody combination product	Preclinical				Phase 1							
	rVSVΔG-LASV-GPC	Phase 1 (IAVI C102) / 2a (IAVI C105) / 2b (IAVI C111)											
Emerging infectious diseases vaccine candidates	rVSVΔG-SUDV-GP	Phase 1 (IAVI C108, C109)											
	rVSVΔG-MARV-GP	Preclinical				Phase 1 (IAVI C104)							
	rVSVΔG-SARS-CoV-2	Preclinical											
	Tuberculosis (TB) vaccine candidates	MTBVAC**	Phase 2a (HVTN605) / 2b (IAVI C113)										
	mRNA-encoded TB antigens	Preclinical											

* Germline targeting program.

** Trials in adults and adolescents. Biofabri is leading clinical development of the candidate in infants (currently in a Phase 3 trial).

IAVI-supported candidates													
Candidate	2024				2025				2026				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
HIV vaccine candidates	BG505 GT1.1 gp140, adjuvanted (AS01B)	Ph 1 ← IAVI C101											
	BG505 SOSIP gp140, adjuvanted (3M-052 AF + alum)	Phase 1 (IAVI C107)											
	BG505 SOSIP gp140, adjuvanted (3M-052 AF + alum)	Phase 1 (IAVI C110)											
	DNA-HIV-PT123, AIDSVAX®B/E; DNA-HIV-PT123, CN54gp140, MVA CMDR,CN54gp140; TAF/FTC; TDF/FTC	Phase 3				← PrEPVacc							
	GRAd networked T-cell epitope*	Preclinical				Phase 1 (IAVI C114)							
	MosM3.1, MosM3.2, MosM3.3, adjuvanted	Phase 1 (IAVI C112)											
Mini-protein for COVID-19 prophylaxis	IPD-52520	Preclinical				Phase 1 (IAVI C106)							

* Trial in people living with HIV and people living without HIV in Zimbabwe and South Africa. ReiThera is the vaccine contract development and manufacturing organization. Ragon Institute developed the networked epitope vaccine insert.

IAVI's impact



In June 2023 we launched a **first-in-human Phase 1 trial** of our Sudan ebolavirus vaccine candidate. The vesicular stomatitis virus platform, based on these achievements, is a **promising, versatile tool to respond to future outbreaks of emerging infectious diseases**.



As part of a comprehensive product development plan, IAVI facilitated an important partnership between the National Institutes of Health, the HIV Vaccine Trials Network, and the vaccine's manufacturer, Spanish human R&D company Biofabri, to **fund, design, and conduct a Phase 2a safety and immunogenicity study of MTBVAC** in South African adolescents and adults living with HIV (PLWH) and well-controlled on antiretroviral drug treatment (ART), as well as those without HIV. These safety and immunogenicity data **will be a crucial part of assessing whether the vaccine can be used in PLWH well-controlled on ART, who are highly vulnerable to TB**.



IAVI continued to **spearhead advances in the development and eventual uptake of bnAbs** including innovative work using them to prevent HIV acquisition by infants. IAVI, along with 45 organizations, **established the HIV infant post-natal prophylaxis task force** to accelerate the clinical development, licensure, and availability of bnAbs for peri- and post-natal HIV prevention.



Through advocacy and political efforts, we **helped shape the commitments in the Political Declaration** for the UN High-Level Meeting on Tuberculosis.

Impact by the numbers



161

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



9

Community and stakeholder engagement workshops and trainings held, reaching **214** participants.



39

Peer-reviewed publications published by IAVI and partners: **18** LMIC authorship; **21** female authorship.



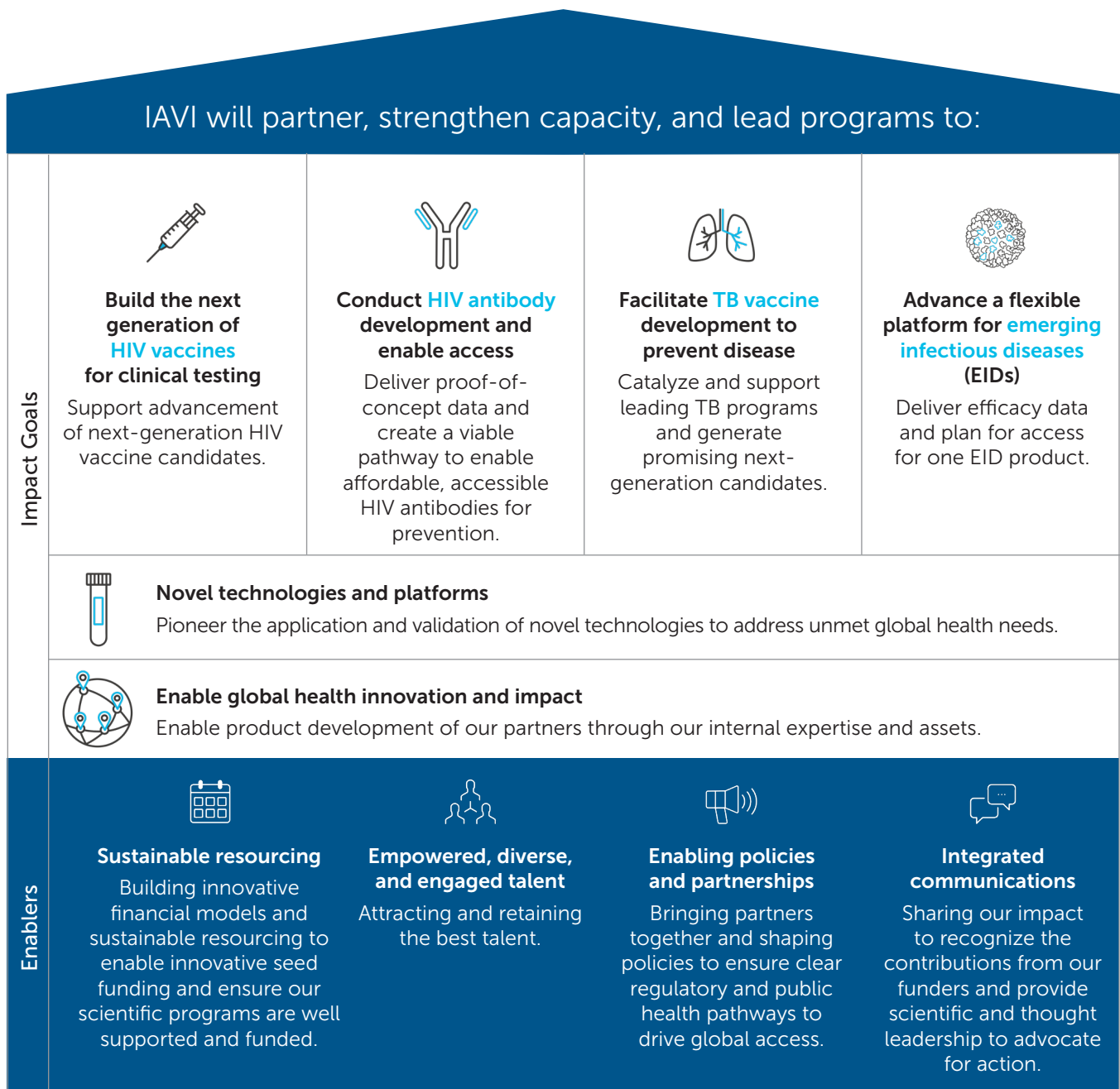
19

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 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.

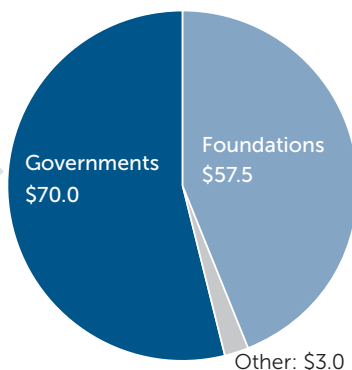
During 2023 we made significant progress across our impact areas. While doing so, we accelerated scientific discovery and development by fostering unique collaborations among academia, industry, local communities, governments, and funders to explore new and better ways to address public health threats that disproportionately affect people living in poverty



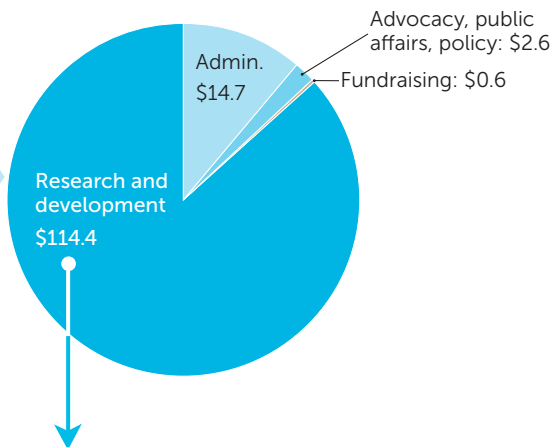
2023 financials

All figures in millions of U.S. dollars

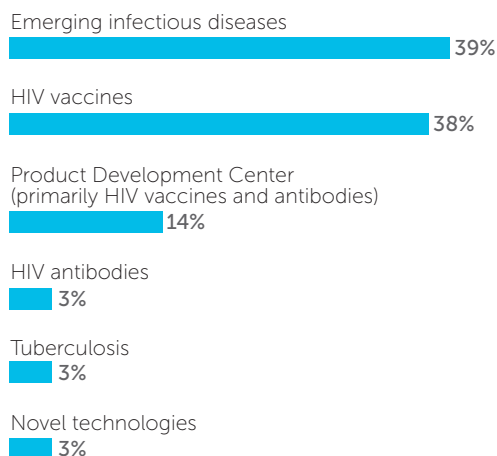
	2022	2023
REVENUE (without donor restriction)		
<i>Grants and contributions</i>		
Governments	96.9	70.0
Foundations	30.9	57.5
Other	0.3	3.0
Total	128.1	130.5



EXPENSES		
<i>Programs</i>		
Research and development	115.1	114.4
Vaccine advocacy, public affairs, and policy	1.9	2.6
Administration	14.1	14.7
Fundraising	1.1	0.6
Total	132.2	132.3



ASSETS		
Cash and investments	61.7	69.7
Grants & contracts receivables	56.1	49.1
Right-of-use assets	11.2	8.3
Fixed assets	2.3	0.9
Other	1.3	1.0
Total Assets	132.6	129.0
Liabilities	63.1	61.2
Net assets	69.5	67.8
Total liabilities and net assets	132.6	129.0



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Funder acknowledgment

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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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