# Annual Report 2024

## Letter from the CEO



Dear colleagues and friends,

With the support of partners, funders, and communities, IAVI made significant progress in 2024 across our portfolio of products designed to translate scientific innovation into public health solutions.

I'm pleased to share this Annual Report with you describing the state of the organization.

As IAVI navigates the uncertainties of 2025 — including the U.S. government's withdrawal of funding for many global health programs — we remain confident that those who recognize the value of global cooperation will reaffirm their commitment. Advancing solutions for infectious diseases that disproportionately affect low-income countries will require renewed dedication. In this evolving landscape, collaboration across sectors and governments is more vital than ever.

A key accomplishment for IAVI in 2024 was the launch of the first-ever Phase 2 Lassa fever vaccine clinical trial at sites in Nigeria, Liberia, and Ghana. The CEPI-funded, IAVI-sponsored study is evaluating the safety, tolerability, and immunogenicity of IAVI's single-dose vaccine candidate in people aged two years and older. This trial marks a significant expansion of IAVI's work in West Africa, where Lassa fever is endemic. The Lassa vaccine candidate is one of a suite of IAVI vaccine candidates for emerging infectious diseases (EIDs), in addition to candidates for Sudan and Marburg viruses.

Our work in EID vaccine development continues to support global efforts to address gaps in pandemic preparedness and response. In particular, IAVI's agenda aligns closely with initiatives such as the Pandemic Fund to strengthen readiness capacity in low- and middle-income countries for neglected and future epidemics, and to improve global health security and spur health innovation.

In 2024, IAVI completed preparations for the IMAGINE trial, a Phase 2b efficacy trial of the promising TB vaccine candidate MTBVAC, developed by the Spanish biopharmaceutical company Biofabri, scheduled to begin in early 2025. IAVI continued to build its reputation as a convener for the TB vaccine research field by co-organizing the 7th Global Forum on TB Vaccines, sponsored with the Brazilian Ministry of Health and held in Rio de Janeiro in October. Through our role in the stakeholder group of the WHO-hosted TB Vaccine Accelerator Council, IAVI hosted a roundtable at the World Health Summit to identify innovative financing mechanisms to support latestage TB vaccine R&D, with further activities planned in 2025.

Development of IAVI's promising germline-targeting (GT) HIV vaccine approach continued, with four preclinical papers published in high-impact journals. These study results provided further evidence to support our strategy to design HIV antigens to induce antibodies capable of developing into broadly neutralizing ones (bnAbs). Results from the IAVI G002 and

IAVI G003 trials (<u>published</u> in Science in May 2025) show that mRNA-delivered GT vaccines are as immunogenic as or more immunogenic than protein-delivered ones. Next studies of GT antigens in humans will launch in 2025 via a consortium of partners led by IAVI and funded by the Gates Foundation. While this clinical work was being planned, investigators, led by IAVI's Netherlands-based legal entity IAVI Stichting, continued through 2024 to research end-user perspectives on HIV prevention from adolescent girls and young women in African countries.

IAVI and partners continued to advance development of bnAbs to protect babies from acquiring HIV. At the AIDS 2024 conference in Munich, an IAVI-led task force published an action plan to accelerate clinical development, regulatory approval, and broad access to bnAbs for peri- and post-natal HIV prophylaxis. Adding to the evidence base, IAVI and Impact Global Health published a <u>report</u> evaluating the current state of R&D and access for monoclonal antibodies (mAbs) and related products, with new insights into the Africa region.

IAVI Africa, with registered legal entities in Kenya and South Africa, continued to strengthen its presence in the region. The program expanded its capabilities in lab operations, regulatory science, clinical development, pharmacovigilance, and fundraising, with an increased focus on the West Africa region. An updated IAVI Africa strategy includes plans to ensure regional capacity strengthening and capacity utilization, with a focus on supporting African R&D efforts with adequate resources.

To support the IAVI Africa strategy and vaccine equity, IAVI formed partnerships with two key African organizations. By signing an <u>agreement</u> with Africa CDC, IAVI aims to advance vaccine development, manufacturing, and access in Africa by harnessing complementary strengths to advance our shared mission of creating an innovative, end-to-end model for sustainable vaccine access in Africa. Additionally, IAVI and Institut Pasteur de Dakar established a <u>collaboration</u> to research, develop, manufacture, and commercialize a range of vaccine candidates for endemic and EID threats – including Lassa fever – all produced using a common vaccine platform.

IAVI gratefully acknowledges contributions from our funders, partners, staff, and committed colleagues in global health, along with study volunteers. Together, we are paving the way for the development of safe and effective vaccines and antibody products that will benefit people globally. In 2025, despite political headwinds, we look forward to developing global health tools and strengthening sustainable capacity for health research in Africa and India.

Best regards,

Mark Feinberg, M.D., Ph.D. IAVI President and C.F.O.

# 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. Our vision is a world where everyone has equitable access to innovative vaccines and therapeutics. 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.

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 infectious disease burdens globally.

Together with our partners, IAVI conducts research and development and strengthens capacity to:

- Design and test the next generation of HIV vaccine candidates.
- Optimize antibodies for HIV prevention and treatment and enable future access.
- Conduct TB vaccine development and advocate for funding for TB R&D.
- Prepare for future outbreaks of EIDs that repeatedly spill over from animals to humans.
- Enhance local manufacturing capacity for vaccines and monoclonal antibodies in Africa.
- Support our partners to 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

# IAVI and partners convene the 7th Global Forum on TB Vaccines



More than 300 stakeholders from around the world and across all areas of TB vaccine research, development, and implementation gathered in Rio de Janeiro, Brazil from 8-10 October 2024 for the 7th Global Forum on TB Vaccines. The 7th Global Forum, convened by the Stop TB Partnership Working Group on New TB Vaccines in collaboration with IAVI and the TuBerculosis Vaccine Initiative, and hosted by the Ministry of Health of Brazil and the Brazilian TB Research Network, was the first time this important conference took place in the Americas.

Under an overarching theme of "Driving innovation from discovery to access," the program covered the full spectrum of TB vaccine development. Presentations covered everything from discovery research to diversifying the TB vaccine pipeline through clinical research, as well as strategies to ensure new TB vaccines reach the populations that most need them to maximize public health impact.

With multiple promising vaccine candidates in late-stage efficacy testing and work underway to ensure new TB vaccines will be affordably and equitably accessible to all who need them, the 7th Global Forum stoked optimism but raised questions about how the field can optimize efforts to introduce new vaccines this decade. Learn more about the key takeaways in the IAVI Report article, "TB vaccines: achievable not aspirational."

IAVI was proud to lead the Forum's first-ever Community Engagement Committee, who developed a <u>Community Declaration</u> via public consultation. The declaration outlined community demands for the development and implementation of new TB vaccines and was endorsed by 1,410 individuals and organizations from 81 countries.

Read the <u>official meeting report</u> for a comprehensive overview of this milestone event. A selection of presentations and posters are also available on the <u>Global Forum website</u>, including a number of interventions delivered by IAVI.

# Pipeline 2025-2027

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 2025. For the most updated list of current candidates, go to <a href="mailto:iavi.org/iavi-pipeline">iavi.org/iavi-pipeline</a>.

IAVI products in development														
	Candidate		2025				2026				2027			
			Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
	Germline targeting preclinical antigen research	Preclinical												
HIV vaccine candidates	rVSVΔG-Env-HIV	Preclinical												
	eOD-GT8 60mer mRNA + coreg28v2 60mer mRNA; N332 GT5 mRNA		Phase 1 (IAVI G004/DESIIGN 001)											
Passive immunization against HIV via bnAbs	Triple antibody combination product	Preclinical Phase 1 (HVTN 141/HPTN 105)												
Emerging infectious diseases vaccine candidates	rVSVΔG-LASV-GPC	Phase 1 (IAVI C102) / 2 (IAVI C105)												
	rVSVΔG-SEBOV-GP	Phase 3 (Tokemeza)												
	rVSVΔG-SUDV-GP	Preclinical Phase 1 (IAVI C109)												
	rVSVΔG-MARV-GP	Precli	nical		Phase 1 (IAVI C104)									
	rVSVΔG-CCHFV-GPC	Preclinical												
Tuberculosis (TB) vaccine candidates	MTBVAC*	Phase 2b (IAVI C113 IMAGINE)												
	mRNA-encoded TB antigens	Preclinical												

<sup>\*</sup> Trial in adults and adolescents. Biofabri industrially developed and in-licensed MTBVAC and is leading clinical development of the candidate in infants (currently in a Phase 3 trial).

IAVI-supported candidates													
	Candidate	2025				2026				2027			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
HIV vaccine candidates	BG505 SOSIP gp140, adjuvanted (3M-052 AF + alum)	Ph 1	← IAV	C107									
	BG505 SOSIP gp140, adjuvanted (3M-052 AF + alum)	Ph 1	← IAV	C110									
	GRAd networked T-cell epitope*		Phase 1 (IAVI C114)										
Tuberculosis (TB) vaccine candidates	MTBVAC**	Phase 2a (HVTN 605)											
Mini-protein for COVID-19 prophylaxis	IPD-52520	Precl	nical			Phase	1 (IAVI	C106)					

<sup>\*</sup> 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. Mutula Trust is the clinical lead.

<sup>\*\*</sup> Trial in adults and adolescents living with and without HIV. Biofabri industrially developed and in-licensed MTBVAC and is leading clinical development of the candidate in infants (currently in a Phase 3 trial).

# IAVI's impact



IAVI formed partnerships with the Africa Centres for Disease Control and Prevention and Insitut Pasteur de Dakar to harness complementary strengths to advance vaccine development, manufacturing, and sustainable access in Africa, including work on Lassa fever.



IAVI launched a **Phase 2a trial of our Lassa fever vaccine candidate** in Ghana, Liberia, and Nigeria, bringing the world closer to a vaccine that could prevent this disease that sickens at least 300,000 people a year in West Africa.



A **Phase 2a study** launched in January 2024 of Biofabri's **TB vaccine candidate MTBVAC** in South African adolescents and adults living with HIV (PLWH) and well-controlled on antiretroviral drug treatment, as well as those without HIV. IAVI helped facilitate the partnership between Biofabri, the National Institutes of Health, and the HIV Vaccine Trials Network that made this trial possible. The safety and immunogenicity data gathered in this trial 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.



Preparations were made for the IAVI-sponsored **Phase 2b trial of MTBVAC** in adults and adolescents in three African countries to begin in early 2025.



IAVI continued to spearhead advances in the development and eventual uptake of **broadly neutralizing antibodies to prevent HIV acquisition by infants**. A task force established by IAVI worked to accelerate the clinical development, licensure, and availability of bnAbs for peri- and post-natal HIV prevention. The task force launched an action plan in mid-2024 to mobilize and guide partners.



IAVI's **socio-behavioral research and global access initiatives** continued to support product development 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 center partners in Africa and India.

# Impact by the numbers



219

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



31

Community and stakeholder engagement workshops and trainings held, reaching 634 participants.



43

Peer-reviewed publications published by IAVI and partners: 15 LMIC authorship; 23 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 for our scientific work.

During 2024, 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.

## IAVI will partner, strengthen capacity, and lead programs to:



# Build the next generation of HIV vaccines

for clinical testing

Support advancement of next-generation HIV vaccine candidates.



# Conduct HIV antibody development and enable access

Deliver proof-ofconcept data and create a viable pathway to enable affordable, accessible HIV antibodies for prevention.



# Facilitate TB vaccine development to prevent disease

Catalyze and support leading TB programs and generate promising nextgeneration candidates.



# Advance a flexible platform for emerging infectious diseases (EIDs)

Deliver efficacy data and plan for access for one EID product.



mpact Goals

## Novel technologies and platforms

Pioneer the application and validation of novel technologies to address unmet global health needs.



## Enable global health innovation and impact

Enable product development of our partners through our internal expertise and assets.



### Sustainable resourcing

Building innovative financial models and sustainable resourcing to enable innovative seed funding and ensure our scientific programs are well supported and funded.



# Empowered, diverse, and engaged talent

Attracting and retaining the best talent.



# **Enabling policies** and partnerships

Bringing partners together and shaping policies to ensure clear regulatory and public health pathways to drive global access.



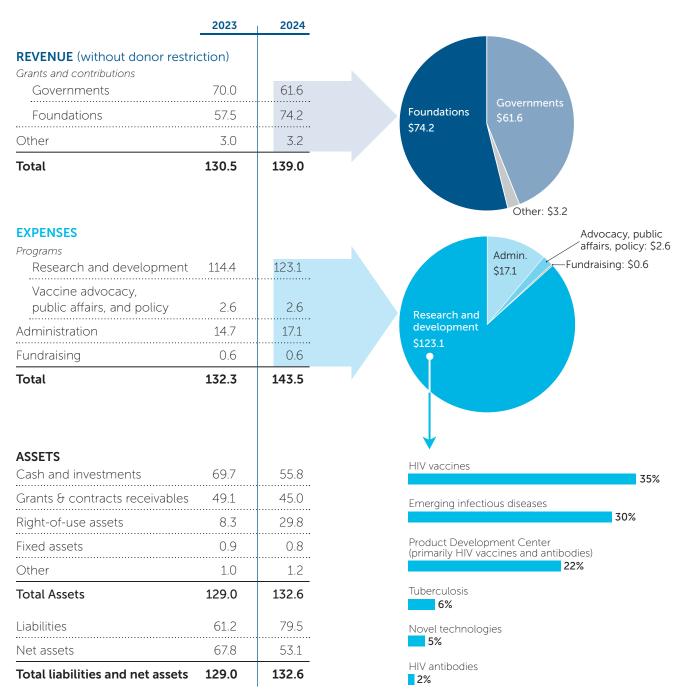
# Integrated communications

Sharing our impact to recognize the contributions from our funders and provide scientific and thought leadership to advocate for action.

Enablers

# 2024 financials

All figures in millions of U.S. dollars



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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 |
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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 January 2025



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LONDON

NAIROBI

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NEW YORK

MAILING ADDRESS 125 Broad Street New York, NY 10004 U.S.

