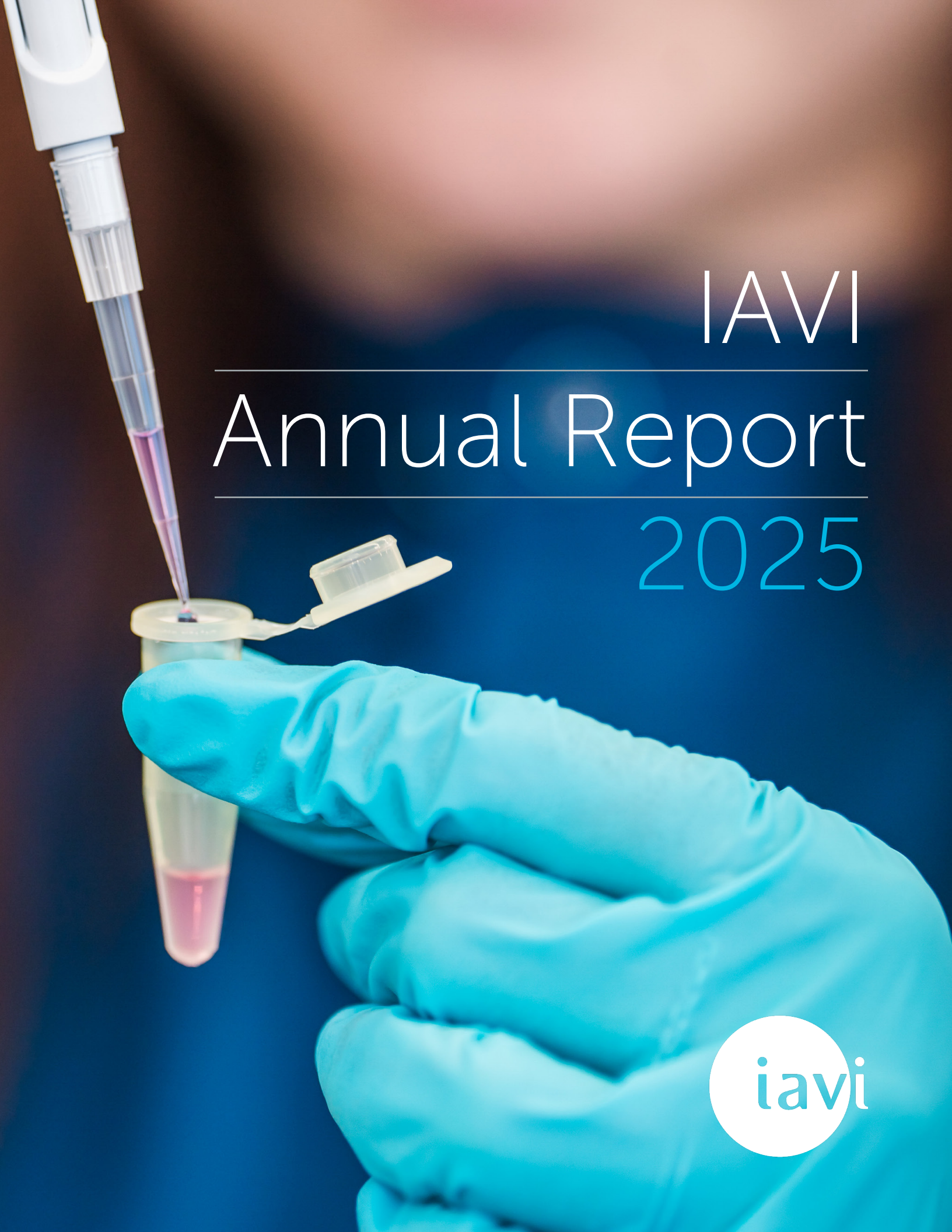


IAVI

Annual Report

2025

iavi

Dear colleagues and friends,

I am pleased to share IAVI's 2025 Annual Report, which highlights the achievements of our teams and collaborators during a year of both significant progress and considerable disruption.

We will all remember how dramatically the global health landscape changed in 2025. Reductions in U.S. government support for global health research and development, combined with broader declines in investment in global health, created challenges for IAVI and many other organizations. These pressures had a direct effect on our revenue for the year, requiring us to make difficult programmatic and operational decisions and sharpen our focus, especially in our HIV program, on approaches with the greatest potential impact. At the same time, renewed support from longstanding partners and investments from new collaborators reaffirmed confidence in our scientific strategy.

Throughout these changes, our aim has remained constant: to advance biomedical innovations that address urgent infectious disease threats while ensuring that the products we develop are accessible to all who need them.

One of the year's most significant scientific accomplishments came from our HIV vaccine program. Results published in Science from the IAVI G002 and G003 trials demonstrated proof of concept for a pathway toward inducing broadly neutralizing antibodies (bnAbs)—an important scientific achievement that we and many others think will be a critical component of an effective HIV vaccine. These findings represent the culmination of years of collaborative work across a global network of scientists, clinical researchers, and study participants.

Even as the HIV vaccine field faces a period of reduced investment and shifting priorities, we remain committed to pursuing bold science that could ultimately change the trajectory of the HIV epidemic. To get us closer to that goal, we and six partner clinical research centers in South Africa launched IAVI G004, a follow-on study to IAVI G002 and G003, in late 2025. Additionally, enrollment opened in IAVI C114, an IAVI-sponsored trial of Ragon Institute and Reithera's novel HIV T cell vaccine led by investigators in Zimbabwe and South Africa.

Our HIV antibody portfolio also made substantial progress. Preparations continued for clinical evaluation of a bnAb intended to help prevent HIV acquisition in infants, an area where unmet need remains significant. Through collaborations with partners across Africa, North America, and Europe, we are helping build the scientific, regulatory, and access pathways needed to ensure these innovations can benefit the populations that need them most.

To address tuberculosis, we continued to support one of the most promising vaccine candidates currently in development, Biofabri's MTBVAC. In 2025, IAVI launched the IMAGINE trial, a Phase 2b study evaluating MTBVAC in adolescents and adults in three African countries. Beyond clinical development, IAVI continues to bring together researchers, policymakers, funders, and community advocates to help prepare for equitable access to future TB vaccines, including MTBVAC, should it prove to be safe and effective.

Our work in emerging infectious diseases (EIDs) continued to demonstrate the value of IAVI's vaccine portfolio in outbreak preparedness and response. Notably, we were able to provide doses of our investigational Sudan virus vaccine to Ugandan authorities within four days of an outbreak being declared in late January 2025. Our vision of having regional stockpiles of investigational outbreak vaccines available for clinical evaluation during public health emergencies has never been more relevant as EID outbreaks are occurring with more frequency.

Our EID vaccine platform technology and efforts to strengthen outbreak preparedness in Africa were furthered by innovative regional partnerships and coalitions launched during the year to build more resilient research, development, and manufacturing ecosystems. In particular, we laud the support that West African health ministers have expressed in a call to action for Lassa fever vaccine development in conjunction with the West African Health Organization, CEPI, and IAVI. It is an example of bringing together stakeholders to ensure that affected regions can respond quickly to endemic and outbreak infectious diseases.

Our commitment to partnership and local leadership remains central to our approach. Throughout 2025 and in spite of the dissolution of USAID, IAVI and our partners continued to support clinical research infrastructure, laboratory capabilities, regulatory science, stakeholder engagement, and biomedical manufacturing initiatives across Africa and India. We continue to believe that lasting solutions to global health challenges cannot be developed in isolation. They require collaboration across governments, academia, industry, philanthropy, communities, and international organizations. They also require ensuring that countries most affected by infectious diseases play a leading role in shaping research priorities and delivering solutions.

As we look ahead, I am optimistic about the future despite the gaps left by declines in global health research funding. The advances achieved this year, the promise of further progress in 2026, the strength of our partnerships, and the dedication of our colleagues around the world reinforce my confidence that progress will continue.

I extend my sincere gratitude to our funders, partners, collaborators, community representatives, researchers, and study volunteers. Your commitment makes this work possible. Together, we are helping build a future in which scientific innovation delivers meaningful health impact for people everywhere.

Best regards,

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

About IAVI

IAVI is a global nonprofit biomedical 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 six 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

Racing against an outbreak

A health worker prepares to administer the first dose of IAVI's Sudan virus vaccine as part of a ring vaccination trial launched in response to an outbreak of Sudan virus disease in Uganda. Credit: WHO

On January 30, 2025, a health worker in Kampala, Uganda, died from confirmed Sudan virus disease, marking Uganda's sixth outbreak of the deadly virus. Within days, 45 close contacts were identified, each at heightened risk of transmission. Sudan virus disease has a case fatality rate of up to 50% and, unlike the related Ebola Zaire virus, has no licensed vaccine or treatment. For such a high-priority pathogen, every day without a response tool increases risk.

This time, Uganda had a head start: IAVI had prepositioned its investigational Sudan virus vaccine candidate in the country as part of global outbreak preparedness. Doses were ready before they were needed, helping shift the response from months to days.

A trial mobilized in days

The World Health Organization (WHO) prioritized IAVI's candidate in Uganda's outbreak response, and the first participants were vaccinated in a WHO-led ring vaccination trial at Makerere University Lung Institute in Kampala. Ring vaccination immunizes contacts and contacts-of-contacts to contain transmission, with Uganda's index case contacts prioritized first.

The strategy had a strong precedent. A *New England Journal of Medicine* study confirmed ring vaccination's effectiveness in containing Ebola outbreaks in the Democratic Republic of the Congo using Merck's licensed Ebola Zaire vaccine. This vaccine uses the same rVSV platform as IAVI's Sudan virus candidate, extending a proven approach to a virus with no licensed tool.

From bench to outbreak response

IAVI had previously conducted a Phase 1 trial of its rVSV-based Sudan virus vaccine candidate in 2023, testing three dose levels in healthy U.S. adults. Initial results shared in November 2024 showed that it was well tolerated across all groups and generated immune responses. IAVI and partners are now planning a follow-up Phase 1 study in Africa, alongside the evaluation of results from the ring vaccination trial.

This dual track clinical development reflects both urgency and scientific rigor. The Uganda ring vaccination trial is an important step toward assessing the candidate's potential to protect exposed individuals and support future outbreak responses.

A platform built for what comes next

The Sudan virus candidate is part of IAVI's broader emerging infectious diseases vaccine portfolio. Its rVSV platform also supports a Lassa virus vaccine candidate in a Phase 2 trial in West Africa that is backed by the Coalition for Epidemic Preparedness Innovations (CEPI) and the European and Developing Countries Clinical Trials Partnership (EDCTP), as well as a Marburg virus vaccine candidate that is backed by the Biomedical Advanced Research and Development Authority (BARDA). Together, these programs show the value of adaptable platforms that can be readied before outbreaks begin.

Uganda's sixth Ebola outbreak caused by Sudan virus thankfully resolved quickly, with only 14 confirmed cases and four deaths. However, the outbreak underscores that the disease will return. IAVI's rapid mobilization enabled by prepositioned doses, alignment with global and regional health authorities, and prior clinical work shows how preparedness can turn readiness into action within days.

Inside the partnership advancing an urgently needed TB vaccine

IMAGINE

The **"Investigation of MTBVAC toward Accelerating Global Immunization for a Neglected Epidemic" (IMAGINE) trial** announced first vaccinations in February 2025 with the trial's first participants vaccinated at Be Part Research (Pty) Limited in Paarl, South Africa. This milestone reflects what a disciplined, science-driven partnership between a global nonprofit and a biopharmaceutical innovator can achieve against the world's deadliest infectious disease.

Tuberculosis (TB) is the world's most lethal infectious disease, and in 2024 alone it claimed an estimated 1.23 million lives. The only licensed vaccine against TB, BCG, is more than a century old: it helps protect young children but offers little defense for the adolescents and adults who drive most transmission. Closing that gap has long been one of global health's most stubborn challenges, which is why the start of this large-scale efficacy trial of MTBVAC marks such a consequential moment for IAVI, our partners, and the millions of people who live with the daily risk of TB.

The IMAGINE trial will assess the safety and efficacy of MTBVAC, a single-dose, live-attenuated vaccine candidate developed by Biofabri to prevent active TB lung disease in 4,300 adolescents and adults with latent TB infection across 16 sites in South Africa, Kenya, and Tanzania. An additional cohort of 1,200 participants who have never been exposed to TB infection was added to strengthen data collection. It is a scientific and logistical achievement built on years of shared investment between IAVI and Biofabri, and on the trust of thousands of study volunteers and their communities.

Shared strengths behind the trial

MTBVAC's progress from laboratory research to late-stage efficacy trials shows how complementary partnerships can advance vaccines for key global health emergencies. Each partner contributes distinct expertise, resources, and capacity:

>>> Scientific discovery and development

MTBVAC was designed by Carlos Martin of the University of Zaragoza and Brigitte Gicquel of Institut Pasteur, then in-licensed and industrially developed by Biofabri, part of the Zendal Group. It is the only live-attenuated TB vaccine candidate derived directly from *M.tuberculosis* currently in clinical trials.

>>> Trial sponsorship and global coordination

IAVI sponsors the IMAGINE trial and contributes decades of experience leading clinical trials in countries and communities heavily affected by infectious diseases. It also helps convene partners across the broader TB vaccine field.

>>> Diversified funding

The trial is supported by a broad coalition, including Coefficient Giving, the Gates Foundation, Germany's Federal Ministry of Research, Technology and Space through KfW Development Bank, Wellcome, and Global Health EDCTP3. This diversified support reinforces confidence in the program.

>>> Delivery in affected communities

Sixteen clinical research centers across South Africa, Kenya, and Tanzania enrolled and are following 5,500 participants. Many of these centers have been strengthened through IAVI's long-term support for local research capacity.

Momentum across the MTBVAC program

IMAGINE began in February 2025, when the first participant was enrolled in the Phase 2b efficacy study, following IAVI's completion of trial preparations in 2024. That launch did not happen in isolation: it built directly on earlier evidence that had de-risked the program and strengthened confidence in moving forward at scale. Results from the preceding Phase 1b/2a A-050 trial, published in *Lancet Global Health*, showed that MTBVAC had a safety profile comparable to BCG at selected doses and induced immune responses in adults similar to or stronger than those generated by BCG revaccination.

The momentum behind MTBVAC also extends to Biofabri's ongoing Phase 3 efficacy trial evaluating MTBVAC in infants in Madagascar, Senegal, and South Africa. These efficacy studies are generating critical evidence on whether a new vaccine can finally offer meaningful protection against TB disease across the lifespan.

IAVI's pipeline

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 our pipeline as of June 2026. For the most updated list of current candidates, go to iavi.org/iavi-pipeline.

IAVI products in development

	Candidate	2026 Q1	2026 Q2	2026 Q3	2026 Q4	2027 Q1	2027 Q2	2027 Q3	2027 Q4	2028 Q1	2028 Q2	2028 Q3	2028 Q4
HIV vaccine candidates	Germline targeting preclinical antigen research	Preclinical											
	rVSVΔG-Env-HIV	Preclinical											
	eOD-GT8 60mer mRNA + coreg28v2 60mer mRNA; N332 GT5 mRNA	Phase 1 (IAVI G004)											
Emerging infectious diseases vaccine candidates	rVSVΔG-LASV-GPC	Phase 2 (IAVI C105)											
	rVSVΔG-SEBOV-GP	Phase 1 (Tokemeza)											
	rVSVΔG-SUDV-GP	Precl.	Phase 1 (IAVI C109)										
	rVSVΔG-MARV-GP	Phase 1 (IAVI C104)											
	rVSVΔG-CCHFV-GPC	Preclinical											
	rVSVΔG-BDBV-GP		Preclinical										
Tuberculosis (TB) vaccine candidates	MTBVAC*	Phase 2b (IAVI C113 IMAGINE)											
	mRNA-encoded TB antigens	Preclinical											

* 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	2026 Q1	2026 Q2	2026 Q3	2026 Q4	2027 Q1	2027 Q2	2027 Q3	2027 Q4	2028 Q1	2028 Q2	2028 Q3	2028 Q4
HIV vaccine candidates	GRAd networked T-cell epitope*	Phase 1 (IAVI C114)											
HIV bnAbs candidates	ePGT121v1-LS		Phase 1 (HVTN 141 & PedMab1-Ex)										
Tuberculosis (TB) vaccine candidates	MTBVAC**	Phase 2a (HVTN 605)											

* 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.
** 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

Highly anticipated results from IAVI's **HIV vaccine program** were published, demonstrating proof of concept for a pathway toward inducing broadly neutralizing antibodies — a potentially critical component of a future HIV vaccine. IAVI and our partners are further investigating this sequential immunization strategy in the IAVI G004 clinical trial that began at the end of 2025. Another IAVI-supported trial, IAVI C114, launched in mid-2025 to examine a novel HIV T cell vaccine candidate.

Early in the year, IAVI kicked off the **Phase 2b IMAGINE trial** of Biofabri's promising tuberculosis vaccine candidate MTBVAC in South Africa, Kenya, and Tanzania. Following favorable results from the preceding Phase 1b/2a trial, this large-scale safety and efficacy study is a major milestone that brings us closer to addressing the world's deadliest infectious disease.

Just four days after an outbreak was declared in Uganda, IAVI made available prepositioned and WHO-prioritized doses of our investigational **Sudan virus vaccine candidate** for use in a ring vaccination trial in February 2025 by collaborating with a global response team.

IAVI remained a leader in **Lassa fever vaccine** development, gaining support from West African ministers of health with a joint commitment and sharing positive results from our first-in-human Phase 1 clinical trial.

IAVI continued to spearhead advances in the development and eventual uptake of broadly neutralizing antibodies to prevent **HIV acquisition by infants**, including preparing for multiple clinical trials of IAVI bnAbs set to begin in 2026.

IAVI's **global access initiatives** supported 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.

Together with our partners, IAVI researchers authored **36 peer-reviewed publications** contributing to the global knowledge base spanning clinical research, epidemiology, manufacturing, access, community engagement, and more.

IAVI continued forming **strategic partnerships to accelerate global health innovation**. In 2025, this included a memorandum of understanding with Minapharm and ProBioGen to prioritize end-to-end development and manufacturing of vaccines and biologics in Africa.

IAVI fast facts

260+
Staff at hubs across **6 countries**

3
Global laboratories

25+
Years of breakthrough vaccine and antibody research

Building lasting impact in Africa

40+
IAVI-sponsored/supported clinical trials

60,000+
Adult and adolescent participants enrolled in clinical trials and epidemiology studies

3,000+
People trained in Good Clinical Practices and/or Good Clinical Laboratory Practices to international standards for conducting clinical trials

Our 2030 strategy

Our IAVI 2030 strategy launched in mid-2025. It guides us in delivering on our mission to translate scientific discoveries into affordable, globally accessible public health solutions. The framework includes six strategic priorities that encompass the scientific scope of our programs and two cross-cutting enablers to ensure a solid foundation and support mechanisms for our scientific work.

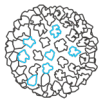
During 2025, we made significant progress across all of our strategic goals. While doing so, we accelerated scientific discovery and development by fostering unique collaborations among academia, industry, local communities, governments, and funders to explore new and better ways to address public health threats that disproportionately affect people living in poverty.

IAVI will partner, strengthen capacity, and lead programs by:

Strategic Priorities

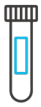
Accelerating TB vaccine development

Bring the world closer to a new, accessible TB vaccine.



Paving the way for regulatory approval of a VSV Sudan vaccine

Achieve readiness for regulatory submission of a safe and effective VSV Sudan vaccine.



Leading the charge in Lassa fever vaccine development

Be at the forefront of delivering a much-needed Lassa fever vaccine.

Uniting the HIV vaccine field to advance germline targeting

Drive progress in HIV vaccine development through the innovative GT strategy.

Protecting infants from HIV with antibodies

Establish proof of concept that bnAbs can contribute to the prevention of vertical HIV transmission.

Fueling the future pipeline

Accelerate translation of candidates from bench to clinical testing in key disease areas.

Cross-cutting Enablers

Maximizing impact through innovative science and product development

By applying IAVI's unique scientific and product development capabilities, we can accelerate programs and proactively identify and pursue opportunities beyond core areas where we are uniquely positioned, maximizing our impact in the evolving global health landscape.

Building a sustainable future through collaboration and revenue generation

By forging innovative and impactful partnerships, developing novel business models, and significantly increasing sustainable funding streams, we will generate the resources that enable successful execution of our key objectives and position IAVI as a resilient and relevant partner capable of delivering critical global health solutions in a shifting ecosystem.

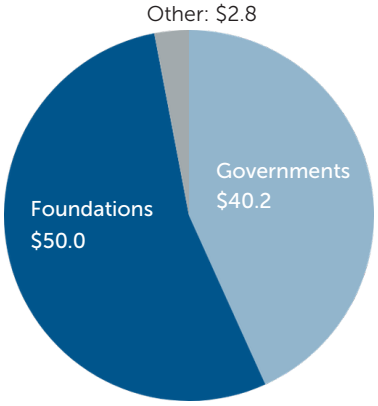
2025 financials

All figures in millions of U.S. dollars

REVENUE (without donor restriction)

Grants and contributions

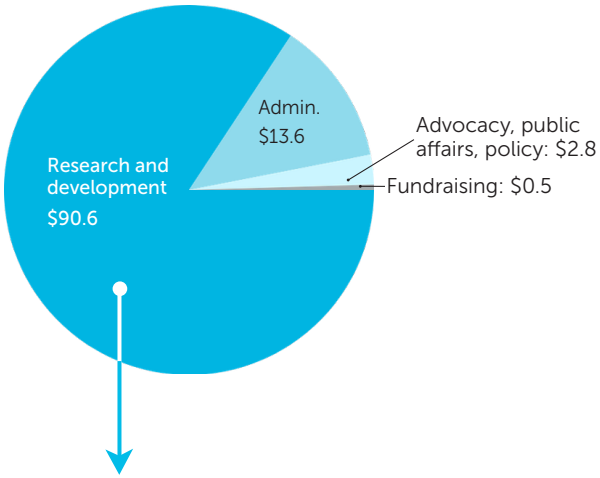
Governments	40.2
Foundations	50.0
Other	2.8
Total	**93.0**



EXPENSES

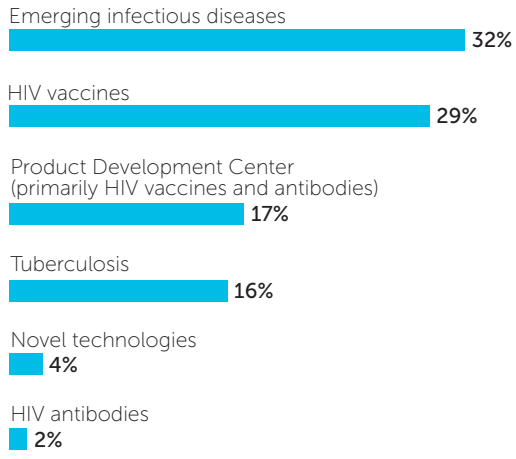
Programs

Research and development	90.6
Vaccine advocacy, public affairs, and policy	2.8
Administration	13.6
Fundraising	0.5
Total	**107.5**



ASSETS

Cash and investments	54.9
Grants and contracts receivables	56.7
Right-of-use assets	29.4
Fixed assets	0.5
Other	1.0
Total assets	**142.5**
Liabilities	92.4
Net assets	50.1
Total liabilities and net assets	**142.5**



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Funder acknowledgment

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Gates Foundation | Coefficient Giving | CEPI | Ministry of Foreign Affairs of the Netherlands | सत्यमेव जयते Ministry of Science & Technology Government of India | From the People of Japan | THE WORLD BANK | wellcome | MINISTRY OF FOREIGN AFFAIRS OF DENMARK Danida | With funding from the: Federal Ministry of Research, Technology and Space | KFW | EDCTP | Funded by the European Union | The Research Council of Norway

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And many other generous individuals and partners around the world

As of January 2026

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