



International
Vaccine
Institute

Vaccines for a Healthier Future

Annual Report

2022



The International Vaccine Institute (IVI) is a nonprofit International Organization established in 1997 as an initiative of the United Nations Development Programme (UNDP). We are among the few organizations in the world dedicated to vaccines and vaccination for global health.

Congratulatory messages from IVI's 25th anniversary celebration

“We believe that together we can come up with various vaccines that would save the lives of millions around the globe.”

Prof. Ellis Owusu-Dabo
Pro Vice-Chancellor, Kwame Nkrumah
University of Science and Technology

“It has been 25 years of restless achievements befitting for the global status of IVI...I hope that IVI, which has been protecting the healthy life of mankind by reaching out to alienated parts of the world, will continue to grow and prosper while further expanding the global cooperation for global health.”

Jaeyong Anh
Chief Executive Officer,
SK bioscience

“IVI has been making significant contributions to global health by developing and delivering affordable vaccines against cholera and typhoid to low- and middle-income countries...I convey my sincere gratitude and respect for IVI's tireless efforts and strides for improving global health.”

Minseok Kim
Member of Health and Welfare
Committee, National Assembly, Republic
of Korea

“Since 1997, IVI has made a significant impact on the health of people around the world through the discovery, development and delivery of vaccines for global public health.”

Dr. Mekonnen Teferi
Clinical Researcher/Director for Clinical
Trials Directorate, Armauer Hansen Research
Institute

“During the COVID-19 pandemic, IVI has been the key facilitator on vaccine development and vaccine access.”

Dr. Nakorn Prem Sri
Director, National Vaccine Institute,
Thailand

“IVI was ahead of its time in 1997 when work commenced to discover, develop and deliver safe, effective and affordable vaccines for global public health in every corner of the world.”

Helen Eduards
Director-General, International
Development Cooperation,
Ministry for Foreign Affairs, Sweden



“ This is a wonderful moment to reflect on and take pride in all that IVI has accomplished in its short lifespan; the global networks that you have established, the capacity-building and collaborating centers that you have supported, and the tremendous public health impact IVI’s oral cholera vaccines had and will continue to deliver long into the future. ”

Dr. Richard Hatchett
Chief Executive Officer, Coalition for Epidemic Preparedness Innovations

“ We are pleased to have been a key strategic and funding partner of IVI, from its nascent stages to the mature global health partner that is leading the way in many neglected disease areas. ”

Trevor Mundel
President of Global Health, Bill & Melinda Gates Foundation

“ I believe that IVI will continue to serve the passion and dedication needed to fulfill its mission, tremendously contributing to global public health, and we are happy to be part of it. ”

Yeong-Ok Baik
Chief Executive Officer, EuBiologics

“ Finland commends the work of the International Vaccine Institute in the research and development of critical vaccines for global public health. ”

Veli-Mikko Niemi
Director General, Ministry of Social Affairs and Health, Finland

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Reflections on 2022



Dear friends and colleagues,

In years prior, the world celebrated the landmark achievement of developing and producing new, safe and efficacious vaccines at unprecedented speed in response to a pandemic. In 2022, it is clear that having an available vaccine is vastly different from ensuring communities are protected from a spreading and evolving virus—especially in under resourced settings. While new technologies and innovation drive human ingenuity, a commitment to equity in impact highlights our resolve to facilitate equal access to health technology and our belief that IVI's mission begins with a need (e.g. cholera) and is measured in impact.

This commitment is embedded into IVI's founding mission to discover, develop, and deliver safe, effective, and affordable vaccines for global health. 25 years later, IVI continues to prioritize low-cost, accessible vaccines that prevent diseases found in the most impoverished regions in the world—diseases such as cholera, typhoid, shigella, chikungunya, and other high burden infectious diseases that trap individuals, families, and communities in a cycle of poverty.

This year, IVI set in motion a five-year strategy to further its reach and multiply impact, grounded in three initiatives: first, to amplify IVI's core capabilities across laboratory research, vaccine development, epidemiology and surveillance, and vaccine effectiveness; second, to expand its international presence; and third, to establish a more inclusive and responsive governance structure.

We've already made significant headway. From our science and clinical development units, we have new vaccine candidates in our pipeline in addition to technology transfers and clinical trials underway for vaccines against 8 different infectious diseases. In 2022, IVI's typhoid conjugate vaccine (Vi-DT) produced in partnership with SK bioscience was approved in Korea followed by the approval of SK bioscience's COVID-19 vaccine, for which IVI conducted a global Phase III pivotal clinical trial. Both vaccines are now on their way to the global public market.

A key component of IVI's approach to research and development is skills training and knowledge transfer; capacity-building is both the process and the aim. As the operator of the WHO's Global Training Hub for Biomanufacturing program in partnership with the Korean Ministry of Health and Welfare and the World Health Organization (WHO), IVI is leading training

courses and consultation meetings to ultimately boost vaccine manufacturing capacity in low- and middle-income countries.

In September, IVI launched its Europe Regional Office in Stockholm, the first office beyond IVI's headquarters in Seoul, made possible by the longstanding partnership of the Swedish government. Additionally, IVI opened a Country Office in Austria with the support of the Austrian government. These two sites will enable closer and more efficient collaboration with IVI's existing partners across Europe and Africa, and open doors to new opportunities.

This expansion is also reflected in IVI's updated governance structure. In 2022, IVI added two seats to its Board of Trustees to represent non-funding State Parties and announced the formation of a Global Council during IVI's annual State Forum to encourage more active dialogue and participation with and among its member states. Together, we celebrated IVI's 25th anniversary.

We remain steadfast to our mandate to prevent and eliminate infectious diseases while strengthening agility, scalability, and innovation to more effectively counter future threats to global health. IVI's vision and mission are motivated, not by the Global Health statistics, but by our knowledge that each number is a face, a family, and a community.

With gratitude,

Jerome H. Kim, MD
Director General

2022 Highlights

Highlight 1

Two new vaccines approved by the Korean Regulatory Authority

IVI's Vi-DT typhoid conjugate vaccine, the product of a decade-long partnership with the Bill & Melinda Gates Foundation and SK bioscience, was approved for export by the Korean Ministry of Food and Drug Safety (MFDS) and is under review for WHO prequalification. Additionally, IVI led a Phase III pivotal trial of SK bioscience's SKYCovione™, Korea's first homegrown COVID-19 vaccine licensed by MFDS, supported by CEPI.



SK bioscience's COVID-19 vaccine SKYCovione™

Highlight 2

Launched a Europe Regional Office, a new Country Office and three Collaborating Centers

IVI's Europe Regional Office in Sweden, Country Office in Austria, and Collaborating Centers in Ethiopia, Ghana, and Madagascar represent IVI's international expansion and closer collaboration with partners in Europe and Africa on vaccine research, innovation, and capacity-building for global health.

Highlight 3

Presented evidence to WHO SAGE on the effectiveness of a single dose of Human papillomavirus (HPV) vaccine

Results from IVI's HPV single-dose impact study in Thailand were sent to the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) as part of a data package that informed a new recommendation to update the current dose schedule with the aim of expanding vaccine coverage for HPV in low- and middle-income countries through facilitating new options for current national immunization programs and lowering their costs.

Highlight 4

Collaborated with governments and regional stakeholder groups to inform policy around AMR and typhoid vaccine introduction

In May 2022, IVI organized a workshop in partnership with the Ministry of Health and Family Welfare of Bangladesh to review key research findings and inform evidence-based policy to contain antimicrobial resistance (AMR). In December, IVI hosted the first Africa Regional Meeting on Typhoid and Typhoid Conjugate Vaccine in Cape Town to accelerate vaccine introduction in typhoid-endemic countries.



IVI and the Ministry of Health and Family Welfare of Bangladesh shared key findings from the IVI-led CAPTURA project at a joint workshop on May 18, 2022.

Highlight 5

Award for Best Partnership of the Year in Fiji and Received the Industry Minister's Prize for Biosecurity Management in Korea

IVI's Typhoid Fever in Fiji – Vaccination towards Elimination (Ty-FIVE) project received a distinction from the Northern Health Division of Fiji for its work to strengthen typhoid surveillance and eliminate typhoid fever from the island of Vanua Levu. In Korea, IVI was awarded the Trade, Industry, and Energy Minister's Prize for Biosecurity Management in recognition of its efforts to uphold high standards of biosafety and biosecurity.



Dr. Manki Song, Deputy Director General of Science of IVI, received the Trade, Industry and Energy Minister's Prize during the K-Bio Leaders' Day Conference 2022 on December 7, 2022.

Highlight 6

Launched the Global Advisory Group of Experts (GAGE) to advance global health diplomacy

As a new advisory body chaired by Dr. Deborah Birx and joined by subject matter experts across international relations, global corporations and nonprofits, government affairs, and public policy, GAGE will guide IVI in fulfilling its role as an effective and sustainable international organization as well as a facilitator for strategic partnerships, program delivery, and multilateral cooperation in global health.



On October 20, 2022, IVI launched its Global Advisory Group of Experts to advise IVI on matters of global health and diplomacy. Credit: IVI

Highlight 7

Constructed two mRNA vaccine candidates for Lassa fever

IVI initiated a new laboratory project to establish an mRNA vaccine platform targeting Lassa virus glycoprotein and to prepare for rapid vaccine production against emerging infectious diseases. A final candidate will be selected based on binding and neutralizing Ab results.

Highlight 8

Presented the inaugural IVI-SK bioscience Park MahnHoon Award and IVI Founders Medals

Dr. Tore Godal, Prof. Drew Weissman, and Prof. Katalin Karikó received the first ever IVI-SK bioscience Park MahnHoon Award for their remarkable contributions to global health and vaccine innovation. In commemoration of its 25th anniversary, IVI additionally honored four leaders instrumental to its founding with the IVI Founders Medal: Prof. Seung Il Shin, Prof. Barry Bloom, Prof. Wan Kyoo Cho, and Prof. Sang-Dai Park.



Dr. Tore Godal attended the ceremony in person, accepting the Park MahnHoon Award. From left to right: H.E. Frode Solberg, Norwegian Ambassador to Korea; H.E. Ban Ki-moon, 8th UN Secretary-General; Dr. Tore Godal; Dr. Jerome Kim, Director General of IVI; Dr. Hun Kim, Chief Technology Officer of SK bioscience.



During the 25th Anniversary Celebration, IVI honored four key figures in IVI's establishment with the IVI Founders Medal. From left to right: Mr. George Bickerstaff, Chairperson of IVI's Board of Trustees; Prof. Seung Il Shin; Prof. Barry Bloom; Prof. Wan Kyoo Cho; Prof. Sang-Dai Park; Dr. Jerome Kim, Director General of IVI.

Highlight 9

Led professional trainings to build capacity in vaccinology and vaccine manufacturing in LMICs

As the operator of the WHO's Global Training Hub for Biomanufacturing program in partnership with the Korean Ministry of Health and Welfare, IVI is training a global workforce in vaccine- and bio-manufacturing through on-site and online courses. The 21st edition of IVI's flagship International Vaccinology Course, hosted by IVI Headquarters in Seoul and Karolinska Institutet in Stockholm, brought together 220 trainees for five days of lectures, interactive case studies, and site visits, with a focus on breakthroughs in vaccine science and technology.



138 trainees from 25 countries completed the 2022 Introductory Course for Biologics Development and Manufacturing, the first course of the Global Training Hub for Biomanufacturing initiative.



IVI's 21st International Vaccinology Course was held at two locations: IVI Headquarters in Seoul and Karolinska Institutet in Stockholm.

Highlight 10

Partnered with Biovac to transfer oral cholera vaccine (OCV) technology and establish end-to-end vaccine production in Africa

IVI signed a new agreement with Biovac of South Africa to transfer OCV technology with support from the Wellcome Trust and Bill & Melinda Gates Foundation. This agreement is a critical step forward for vaccine manufacturing in Africa, for use in Africa and beyond, and will increase

the supply of OCV in the face of a growing number of cholera outbreaks and critical shortage of vaccines.



Highlight 11

Welcomed the UAE, Rwanda, Spain, and Thailand as new State Parties

With a community of 39 member states and the WHO, IVI remains committed to the discovery, development, and delivery of safe, effective, and affordable vaccines for global health. In 2023, IVI will launch its Global Council as a representative body of its State Parties.



UAE Accession March 2022



Rwanda Accession June 2022



Spain Accession June 2022



Thailand Ratification October 2022

Our impact over the past 25 years

39
countries and WHO as member states.

Research collaborations in
44
countries across six continents

Biosafety level 3 enhanced (BSL3+) lab at IVI headquarters.



IVI state parties and signatories: ■

2 VACCINES DEVELOPED:

Oral Cholera Vaccine
\$28M



Lower vaccine development costs
LAB TO LICENSURE

Vi-DT typhoid conjugate vaccine
\$29M



Developing COVID-19 vaccines in partnership with over 20 companies that have committed a combined 1 billion doses to COVAX.

VACCINES FOR 9 INFECTIOUS DISEASES
of global health importance in clinical trials.

MORE THAN

1 MILLION

people vaccinated through IVI campaigns across Africa and Asia.

MORE THAN

1,300

journal articles published.

MORE THAN

40

clinical trials sponsored by IVI since 2005.



3,000+

vaccine professionals from LMICs trained through IVI's annual International Vaccinology Course.

Gender Equality

The 2022 Global Health 50/50 report ranked IVI a Good Performer with a “G5+” score, which indicates that IVI commits to gender equality/equity with gender referring to men and women, gender justice, or gender mainstreaming in policy and planning. IVI will continue to adopt gender equality, diversity, and inclusion affirmative policy with specific measures to improve workplace gender equality and balance of power, as well as to promote the position of women and support their careers across IVI’s programs and divisions.

Vaccine R&D Programs for the Health and Well-being of Women and Girls

IVI has several vaccine programs of significant relevance to gender equality and its impact on global health, including increasing access to safe, effective, and affordable vaccines for women and girls.

Group A Streptococcus (GAS)

GAS is a bacterial pathogen that causes a broad spectrum of diseases, including strep throat, scarlet fever, rheumatic fever, and other rare but severe health conditions. Globally over 400,000 people die every year from complications of infection which is twice as common in women, disproportionately affecting women of reproductive age due to increased risks of cardiovascular complications and death during pregnancy and childbirth.

Strep A Vaccine Global Consortium (SAVAC), formed by IVI and its global partners in 2019, strives to accelerate advocacy, disease burden research, vaccine development and safety, and a Full Value of Vaccine Assessment (FVVA) for GAS. IVI remains in close collaboration with its partners to develop a safe, effective, and affordable GAS vaccine for global public use.

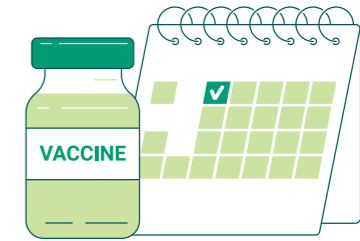


Human Papillomavirus (HPV)

HPV is the leading cause of cervical cancer, causing over 300,000 deaths annually. Although several vaccines against HPV are available, vaccination has become increasingly inaccessible in lower-income countries due to the need for multiple doses of vaccine and their cost. IVI is leading a study to generate evidence on the effectiveness of a single dose to reduce costs while increasing uptake in resource-limited countries.

Hepatitis E Virus (HEV)

Every year, 20 million people are infected with HEV with a disproportionately high mortality rate in pregnant women, especially among displaced peoples and conflict areas. IVI is working to establish the safety and immunogenicity of an approved vaccine in pregnant women to facilitate its use in the highest-risk population.



Female Genital Schistosomiasis (FGS)

Schistosomiasis can develop into a genital variant, estimated to affect 75% of women infected with schistosomiasis—around 56 million women and girls in sub-Saharan Africa. FGS increases the risk of infertility, miscarriages and contracting HIV. IVI is leading a global consortium aimed at advancing the development of a vaccine candidate for schistosomiasis through clinical trials and WHO prequalification.

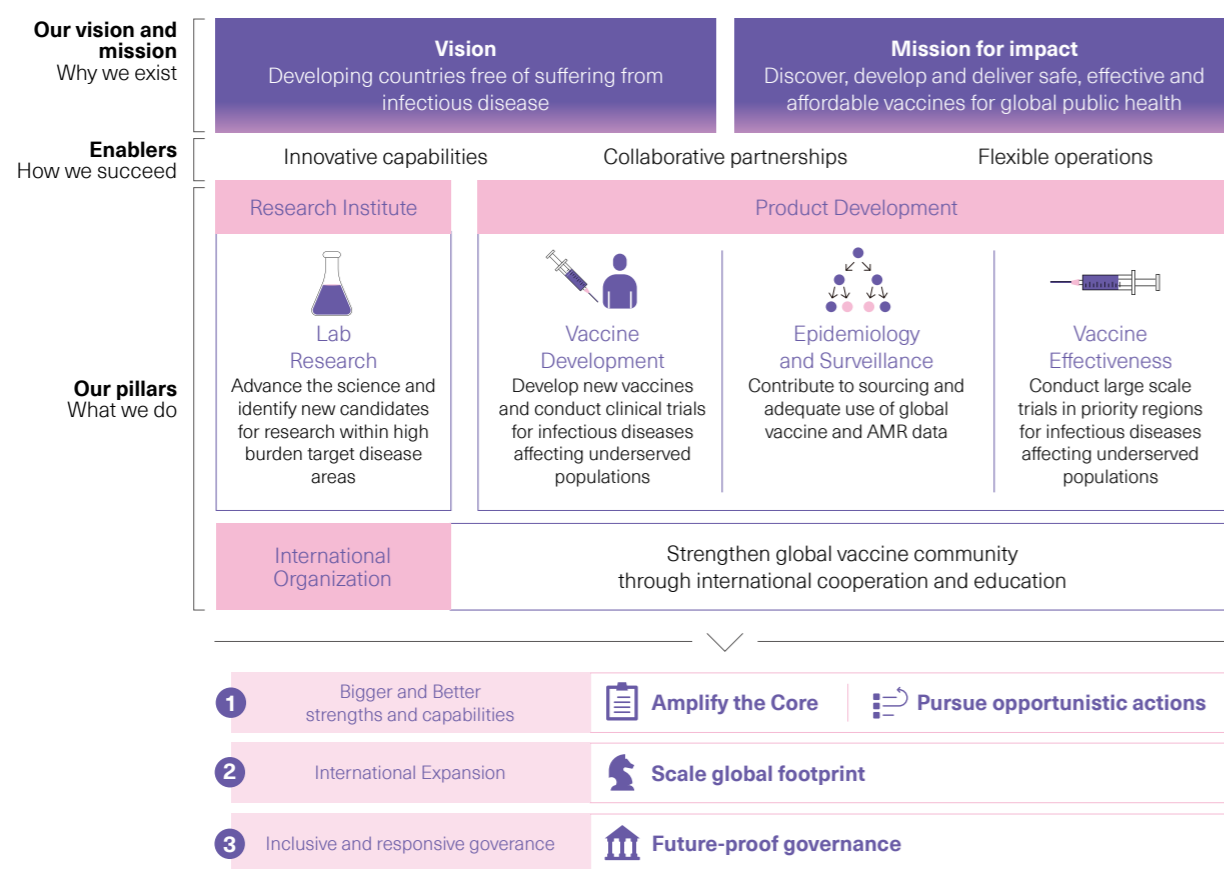
Championing Women and Girls in Science

Every year on February 11, the global science and health communities come together to celebrate International Day of Women and Girls in Science, a UN observance day to promote the full access and participation of women in science, technology, engineering and mathematics (STEM) fields. As an international organization committed to the inclusion of women in research science and global health, IVI joins this annual celebration of the empowerment of women and girls in science.

In 2022, IVI’s Women in Science campaign highlighted the bright minds in our science departments to commemorate the contribution of women’s work for the improvement of global health and gender equality. Here are some of our scientists’ thoughts on working in vaccine science and the importance of gender equality in furthering global health for all.

Strategic Roadmap 2022-2026

Framework for IVI's strategic roadmap 2022-2026



Bigger and Better

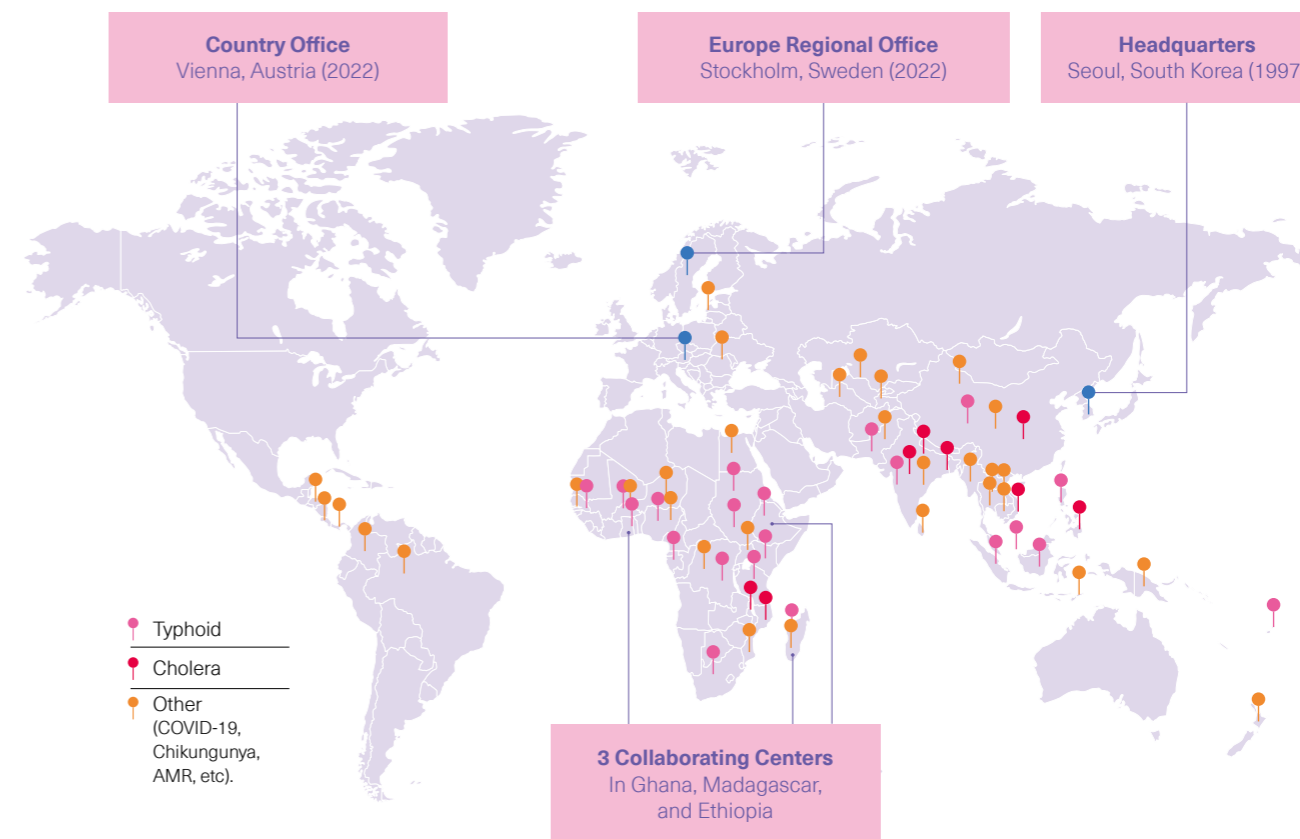
By amplifying its core strengths and capabilities and taking advantage of new opportunities, IVI ensures the success of vaccine candidates or vaccines at any point in the vaccine life cycle. IVI functions as a:

- 1 **research institute** – developing and testing vaccines in the laboratory and in animals;
- 2 **product development partnership** – conducting process development, technology transfer, human clinical trials, epidemiology studies and assisting companies with regulatory pathways, working with

the WHO and Gavi to ensure necessary approvals, recommendations and equitable access to vaccine; and

- 3 **international organization** to develop sound policy around vaccine development and implementation, to advocate for equity and access, and to build capacity around the world to develop, test, manufacture and implement vaccines for global health.

International Expansion



Headquartered in Seoul, Republic of Korea, IVI has built a strong and sustainable network of research partners across Asia, Oceania, Africa, Europe, and Latin America working in tandem in all aspects of vaccine discovery, development, and delivery. Through its international expansion strategy with

the opening of regional and country offices as well as collaborating centers, IVI aims to bring new opportunities for collaborative partnership; facilitate effective engagement with stakeholders; and increase access to talent, funding sources, and key impact at the regional and country levels.

Inclusive and Responsive Governance

Balancing a technical, innovation-driven agenda with a strong commitment to inclusivity, consideration, and sensitivity to the complex issues around equity and access, IVI is putting into place a more inclusive and responsive governance structure to accommodate the needs of IVI's stakeholders. In 2022, IVI added the Global Advisory Group of Experts (GAGE) to its governance and in 2023, IVI will launch the Global Council (GC) with State Parties as members. GC is expected to serve as a platform for IVI's member states to discuss needs and solutions for vaccine development and implementation, vaccine equity and access, and vaccine R&D capacity-building at the global, regional, and national levels.

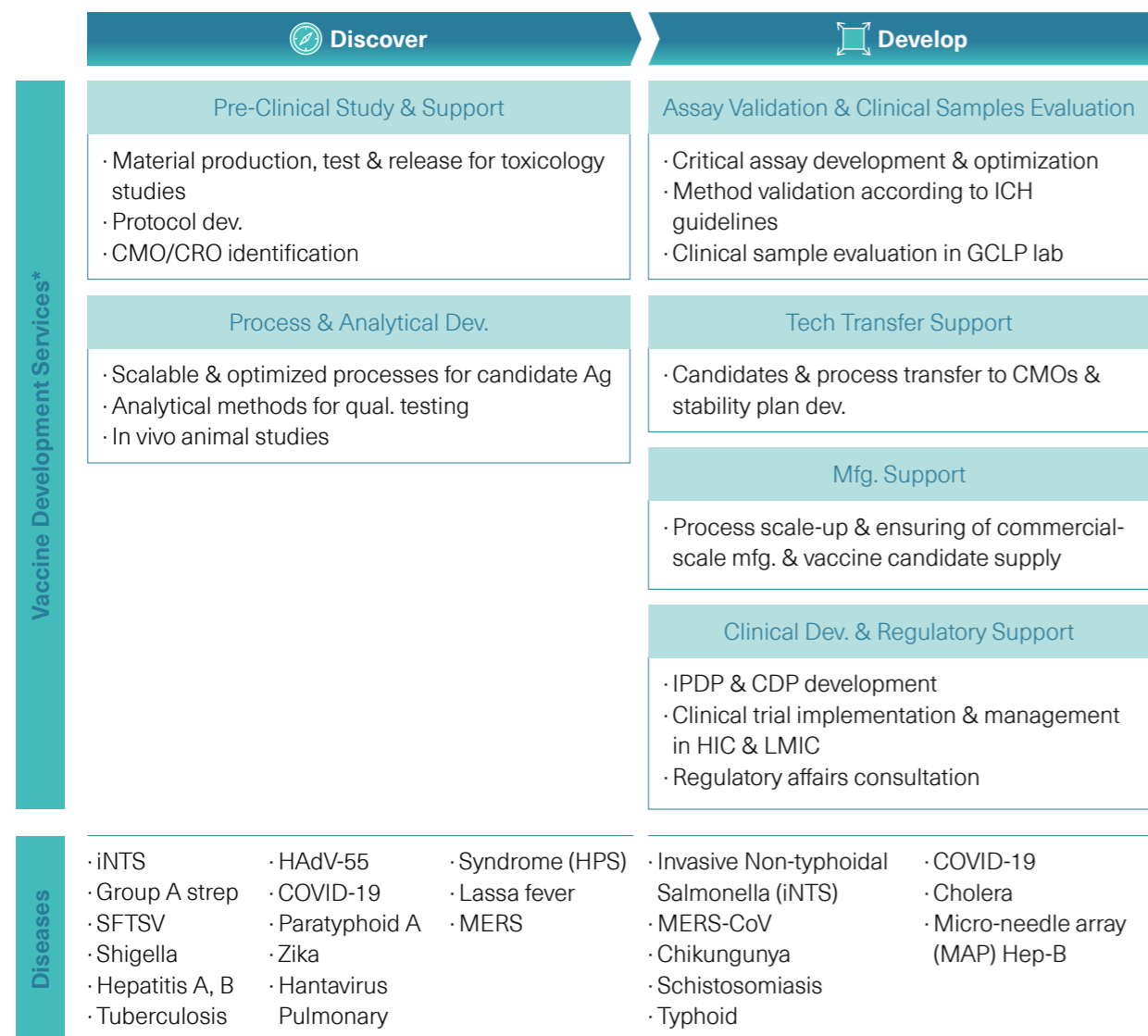


2022 IVI State Forum held in Seoul, Republic of Korea on October 20, 2022

Vaccine R&D Portfolio

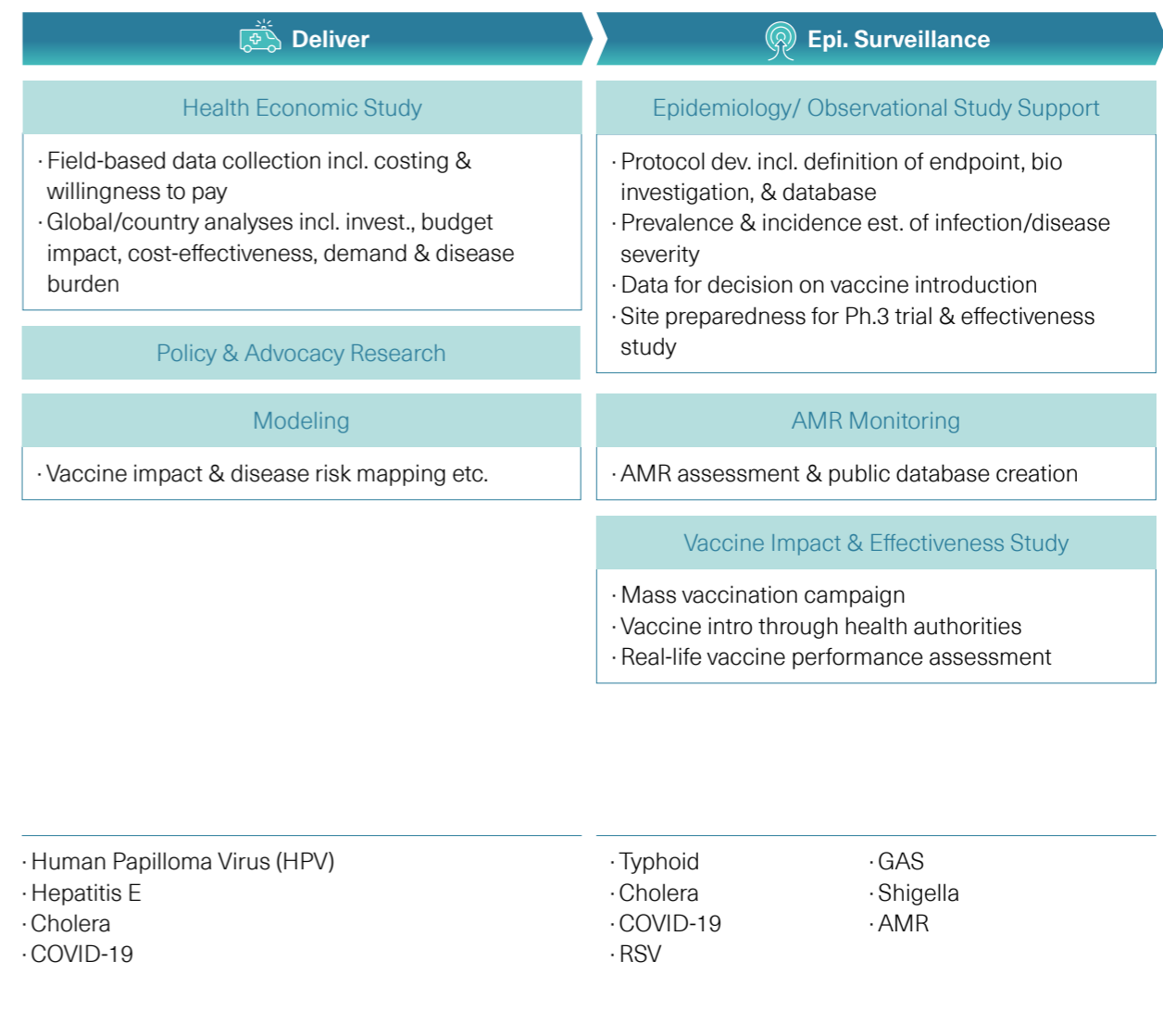
IVI's current portfolio includes vaccines at all stages of pre-clinical and clinical development for infectious diseases that disproportionately affect low- and middle-income countries, such as cholera, typhoid, chikungunya, shigella, salmonella, schistosomiasis, hepatitis E, HPV, COVID-19, and more.

IVI provides translational and support services to accelerate vaccine development



Cross-Functional Activities

IVI develops and supports: · Translational Hubs



· Innovation Vaccine Research Centers

· Training and Capacity building

* IVI also provides **Project Management** service tailored to the needs across the value chain.



Cholera

Developing vaccines against cholera and putting them to use













Cholera is a diarrheal infection that strikes in poor and overly crowded settings. With climate change spurring extreme weather events such as hurricanes, flooding, and droughts, forcing migration and obstructing access to safe water and sanitation, outbreaks of cholera and other waterborne diseases have been on an alarming rise around the world.

Once detected, cholera is easily treatable with proper hydration and antibiotics, but lack of access to such healthcare can turn deadly. Cholera affects people of all ages, causing disease in more than 2.5

million people and killing nearly 100,000 every year.

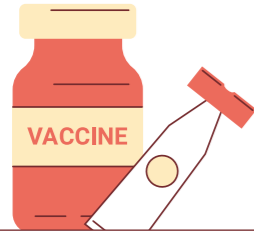
Prevention is key to reducing deaths and controlling outbreaks, requiring a concerted effort to eliminate the stigma of poverty-associated infectious diseases; strengthen surveillance systems to accurately determine its burden; improve access to safe water, sanitation, and routine healthcare; develop new and improved vaccines; ensure an adequate global supply of low-cost vaccines; and vaccinate communities vulnerable to endemic and epidemic cholera.

IVI's technology transfers to bring more low-cost oral cholera vaccines to market

Vaccine manufacturer	Vaccine	Partnership	Stage of development
 VaBiotech Vietnam	 mORCVAX™	Reformulation of VaBiotech's existing OCV licensed in Vietnam to meet WHO standards	Licensed in Vietnam for domestic use in 2009
 Shantha, a Sanofi company India	 Shanchol®	Technology transfer in 2008	Licensed in India in 2009 and WHO pre-qualified in 2011
 EuBiologics Republic of Korea	 Euvichol® Euvichol-Plus®	Technology transfer 2010-2011	Licensed in Korea for export in 2014, and WHO pre-qualified in 2015 and 2017, respectively
 Incepta Bangladesh	 Cholvax™	Technology transfer in 2014	Licensed in Bangladesh for domestic use in 2020
 Bharat Immunologicals and Biologicals India		Technology transfer since 2019	Ongoing
 Biovac South Africa		Technology transfer in 2023	Started in January 2023

Goal 1: Ensure supply of OCV

Simplifying OCV



In 2019, IVI began simplifying OCV through a reformulation of the vaccine to lower the cost of production by 20% while increasing production capacity of Euvichol® by 35%. In October 2022, IVI completed the clinical trial comparing the lower-cost formulation (Euvichol-S) to Shanchol®. A final study report is forthcoming in early 2023.

Technology transfer

Demand for OCV remains higher than the current supply. Additional manufacturers with lower-cost products would help maintain a sustainable global stockpile.

IVI and BIBCOL completed the Phase I technology transfer visit at IVI headquarters for training in production and QC assay performance. The intended outcome is full-scale production of OCV and registration in India.



To help establish another OCV manufacturer, IVI entered a new technology transfer and licensing agreement with Biovac, a bi-pharmaceutical company based in South Africa. This agreement may result in the first instance of end-to-end manufacturing of vaccines in Africa for use in Africa—a long-awaited step forward for vaccine self-reliance on the continent.



IVI Vaccine Process Development scientist during a technology transfer demonstration
Credit: IVI

International standards and reagents

Reference preparations of lipopolysaccharides and vaccine have been made and ready for fit-for-purpose evaluation for monoclonal antibodies as reagents is under planning.



Collaborators

- Shantha Biotechnics
- EuBiologics
- Bharat Immunologicals and Biologicals Corporation Limited
- National Institute for Biological Standards and Control, UK
- Biovac

Funders

- Government of India
- Bill & Melinda Gates Foundation
- Wellcome Trust

#IVI25YEARS

25 years of accelerating vaccines for global health



IVI is the world's only international organization dedicated to research on vaccines of priority for developing countries.

#IVI25



25 years of accelerating vaccines for global health



IVI has led the fight against cholera in LMICs for 20 years, developing the world's first affordable oral cholera vaccine.

#IVI25



Goal 2: Improve cholera vaccine

Project 1

Cholera conjugate vaccine

The second goal of IVI's Cholera Strategy is developing improved cholera vaccines, particularly to enhance efficacy for children under five years. IVI has partnered with collaborators at Harvard and EuBiologics to develop a cholera conjugate vaccine (CCV) that offers the possibility of improved efficacy in younger children and longer duration of protection.

The pre-clinical evaluation of CCV was completed and an investigational new drug application was approved by the Korean Ministry of Food and Drug Safety in May 2022. The Phase I clinical trial will take place in 2023.

Collaborators

- EuBiologics
- Massachusetts General Hospital, USA
- National Institutes of Health, USA

Funders

- Open Philanthropy
- Research Investment for Global Health Technology Foundation (RIGHT Foundation)

Project 2

Thermostable oral cholera vaccine capsules

In 2022, IVI launched a collaboration with colleagues at the University of Gothenburg to develop a new low-cost oral cholera vaccine, DuoChol. This highly thermostable capsule vaccine has the potential to increase efficacy and lower delivery costs. The project will span GMP production of clinical trial material, a Phase I trial, and a clinical development plan to bring DuoChol through to registration.

Collaborators

- University of Gothenburg, Sweden

Funders

- Wellcome Trust
- Government of Sweden (through IVI Europe Regional Office)

Goal 3: Support OCV use and introduction

The third goal in IVI's strategy is generating evidence to support use of OCV in endemic countries. IVI's Enhancing Cholera Control (ECHO) project in Nepal and Mozambique both made substantial progress with both sites advancing to launch surveillance in targeted areas.

Notably, the surveillance system established by the project in partnership with the Government of Nepal was able to identify a cholera outbreak in

Kathmandu. In another region of Nepal, Rupani, IVI also assisted with a mass vaccination campaign using OCV in partnership with the Ministry of Health and Population.

In 2022, the Ethiopia Cholera Control and Prevention (ECCP) project also conducted an OCV vaccination campaign in Shashemene, an area at high-risk of cholera outbreaks.



An IVI researcher delivers oral cholera vaccine to a woman in Rupani, Nepal. Credit: IVI

Collaborators:

- WHO Global Task Force for Cholera Control
- Epidemiology and Diseases Control Division, Ministry of Health and Population, Nepal
- Good Neighbors International
- National Public Health Laboratory, Nepal
- Seti Zonal Hospital, Nepal
- Tikapur Hospital, Nepal
- Malakheta Hospital, Nepal
- Department of Health Services, Nepal
- Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, USA
- WHO Nepal
- UNICEF Nepal
- National Institute of Health, Mozambique
- Ministry of Health, Mozambique
- Ministry of Health, Ethiopia
- Ethiopian Public Health Institute

Funders:

- Global Disease Eradication Fund, Republic of Korea
- LG Electronics
- Korea Support Committee for IVI

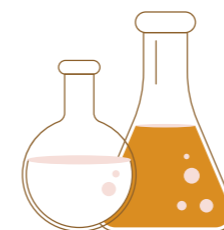
Typhoid Controlling typhoid fever



Typhoid fever is a bacterial disease spread through the ingestion of food or drink contaminated by the feces or urine of infected people. It is usually characterized by fever, headache, constipation, and malaise, but it has few symptoms that reliably distinguish it from other infectious diseases, making it difficult to diagnose and treat. Invasive Salmonella infections are a major cause of global morbidity and mortality with the highest burden of disease in South Asia, and account for 12 to 21 million cases every year.





IVI's Typhoid Program encompasses the development of a typhoid conjugate vaccine (Vi-DT), typhoid fever disease surveillance, and vaccine introduction with effectiveness studies across several countries in Africa, Asia, and the Pacific Islands.

Developing a new-generation typhoid conjugate vaccine (Vi-DT)



IVI developed Vi polysaccharide conjugated with diphtheria toxoid (Vi-DT), a new-generation typhoid conjugate vaccine (TCV) that distinguishes itself from other typhoid vaccines with its immunogenicity in young children. IVI transferred the technology to SK bioscience of the Republic of Korea, Bio Farma of Indonesia, and Incepta of Bangladesh. We are now working with SK bioscience and Bio Farma on clinical development for licensure and WHO prequalification.

Typhoid vaccine technology transfers

Vaccine manufacturer	Vaccine	Partnership	Stage of development
 SK bioscience South Korea	SKYTyphoid (TCV)	Technology transfer 2014	Licensed for export by Korean Ministry of Food and Drug Safety. Undergoing WHO PQ certification process
 PT Bio Farma Indonesia	TCV	Technology transfer 2014	BLA submitted to BPOM (National Agency of Drug and Food Control of Indonesia)
 AMSON Vaccines & Pharma Pvt Ltd Pakistan	 typbar	IVI-facilitated technology transfer 2008 Vi-PS from Bharat Biotech	Licensed for domestic use by Drug Regulatory Authority of Pakistan

Project 1

SK bioscience Vi-DT



IVI transferred Vi-DT technology in 2013 to SK bioscience for manufacturing and commercialization. Phase I-III clinical trials for SK bioscience Vi-DT were funded by the Bill & Melinda Gates Foundation. After successful completion of two Phase III clinical trials, the Vi-DT dossier was submitted to the Korean Ministry of Food and Drug Safety (MFDS) for export-only licensure in June 2021. The vaccine received final Biological License Approval from MFDS in May 2022 and has been submitted for WHO prequalification, targeted for April 2023.

Project 2

Bio Farma Vi-DT



IVI also received funding from the Bill & Melinda Gates Foundation to provide clinical, regulatory, and management support to Bio Farma following Vi-DT technology transfer in 2014. Phase I-III clinical trials have been completed, and the TCV dossier was submitted to the Indonesian Food and Drug Authority (BPOM) in April 2022 for local licensure, targeted for early 2023. Submission for WHO prequalification is

Collaborators:

- SK bioscience
- PT Bio Farma
- World Health Organization
- Ministry of Food and Drug Safety, Republic of Korea
- Philippines Food and Drug Administration
- National Agency of Drug and Food Control, Indonesia
- Drug Development Association, Nepal
- National Health Research Council, Nepal
- Research Institute for Tropical Medicine, Philippines
- National General Hospital, Indonesia
- Sites in Nepal and Philippines

Funders:

- Bill & Melinda Gates Foundation
- Government of the Republic of Korea

#IVI25YEARS

25 years of accelerating vaccines for global health



11-20 million people get sick from typhoid every year. We're working to make sure safe and effective vaccines are readily available to keep communities safe and healthy from a preventable disease.

#IVI25



Surveillance and effectiveness studies

Project 3

Severe Typhoid in Africa (SETA/SETA+)

IVI launched the SETA program in 2015 in six countries: Burkina Faso, the Democratic Republic of the Congo (DRC), Ethiopia, Ghana, Madagascar, and Nigeria to collect standardized data on typhoid fever disease incidence, severity, sequelae, and economic burden in addition to invasive salmonellosis incidence and severity. The program was successfully completed at the end of 2019 and transitioned to SETA Plus (except Ethiopia) in 2020 following further funding. Surveillance was completed at the end of 2022.

introduce typhoid vaccination, and Malagasy officials from the newly established National Immunization Technical Advisory Group (NITAG) are reviewing typhoid burden data in the country. In December 2022, IVI hosted the first Africa Regional Meeting on Typhoid and Typhoid Conjugate Vaccine in Cape Town, South Africa to accelerate vaccine introduction in typhoid-endemic countries.

To date, the largest case numbers have been identified in the DRC and Nigeria, including severe typhoid and intestinal perforation cases. Further characterization of disease severity, the extent of carriage of pathogens in stool, patterns of antibiotic consumption, prevalence of resistance, and cost-of-illness data are underway.

SETA Plus surveillance has provided valuable evidence to support national decision-making processes for TCV roll-out. In Burkina Faso, a typhoid stakeholder meeting concluded with the decision to

Collaborators:

- Institut National de Recherche Biomédicale, Democratic Republic of the Congo
- Institute of Tropical Medicine Antwerp, Belgium
- University of Ibadan, Nigeria
- Kwame Nkrumah University of Science and Technology, Ghana
- University of Ouagadougou, Burkina Faso
- Madagascar Institute for Vaccine Research (MIVR), Université d'Antananarivo, Madagascar
- Armauer Hansen Research Institute, Ethiopia

Funders:

- Bill & Melinda Gates Foundation



SETA Plus investigators Prof. Raphael Rakotozandrindrainy (far right) and Dr. Florian Marks (third from left) with hospital personnel at a healthcare facility in Madagascar.

Project 4

Effect of a novel typhoid vaccine in Africa: A multicenter study in Ghana and the Democratic Republic of the Congo (THECA)

The THECA project was established in 2019 in parallel to the SETA program. THECA includes a Phase IV cluster-randomized, controlled vaccine effectiveness trial in Ghana (TyVEGHA) and a mass vaccination campaign in the DRC using Bharat Biotech's Vi-TT conjugate vaccine Tybbar-TCV® (TyVECO). An embedded health economics study also assesses the feasibility and cost-effectiveness of TCV when administered through a mass vaccination campaign. These studies additionally generate data on the safety and immunogenicity of Vi-TT and measure the impact of vaccination in limiting the spread of antimicrobial resistance.

In the DRC, 30,000 children and adolescents between nine months and 15 years have been vaccinated against typhoid at 17 vaccination centers in Kisantu Health Zone. The TyVECO project aims to vaccinate an additional 48,000 people by early

2023. Typhoid fever surveillance began in August 2021 and continued through 2022 at eight health centers and one hospital, where a significant burden of both typhoid fever and non-typhoidal Salmonella infections as well as high prevalence of suspected typhoid intestinal perforations have been observed.

Hosted by the KNUST-IVI Collaborating Center, TyVEGHA aims to generate evidence to support critical decision-making for introduction of TCV into routine immunization programs in typhoid-endemic African countries. In Asante Akim, Ghana, TyVEGHA has vaccinated a total of 20,120 children and adolescents between nine months and 16 years. Moving forward, the project will strengthen disease surveillance for typhoid fever in the catchment area and initiate vaccine cost effectiveness analysis based on the mass vaccination activities and cost-of-illness data.

As part of the THECA Program, several engagement activities were performed to support countries for decisions in TCV introduction in their immunization programs.



1 Support regulatory affairs for TCV introduction in African early-adopter countries (Ghana, DRC, Madagascar, Burkina Faso): The Africa Regional Typhoid Meeting was held in Cape Town, South Africa from December 7-9, 2022, to create a platform for national stakeholders and international partners to connect with each other and share updates on typhoid burden, typhoid conjugate vaccine (TCV) evidence, and operational research. A total of 99 participants attended the meeting including EPI/NITAG members from 15 African countries and international stakeholders and collaborators such as representatives from the WHO, Bill & Melinda Gates Foundation



2 Stakeholder consultation for TCV introduction in Ghana: a high-level workshop with national stakeholders in typhoid disease and decision-making for TCV introduction. This meeting brought together key experts from Ghana's Ministry of Health, Food and Drugs Authority, and the WHO and other public health scientists to share findings on typhoid disease burden and the potential introduction of typhoid vaccines in Ghana.

3 Consultative meeting for TCV introduction in Madagascar: Findings from typhoid fever surveillance projects at the University of Antananarivo/Madagascar Institute of Vaccine Research were presented to decision-makers from the Ministry of Health of Madagascar. Key stakeholders discussed the possible use of TCV in future projects and re-convened later in the year for a national TCV meeting.

4 Consultative meeting in Burkina Faso: Following an initial national stakeholders meeting supported by IVI and PATH, the NITAG issued favorable recommendations for 1) the introduction of TCVs in the expanded immunization program and 2) a mass national vaccination campaign with children 1-15 years.



Collaborators:

- Institut National de Recherche Biomédicale, Democratic Republic of the Congo
- Institute of Tropical Medicine Antwerp, Belgium
- Kwame Nkrumah University of Science and Technology, Ghana
- University of Cambridge, UK
- The Mérieux Foundation
- University of Ouagadougou, Burkina Faso
- International Centre for Diarrhoeal Disease Research, Bangladesh
- University of Maryland, USA
- Université d'Antananarivo, Madagascar

Funders:

- Bill & Melinda Gates Foundation
- European and Developing Countries Clinical Trials Partnership

Project 5

Typhoid in Fiji – Vaccination towards Elimination & Typhoid Silent Contamination Surveillance

Typhoid in Fiji – Vaccination towards Elimination (Ty-FIVE), in partnership with the Fijian Expanded Program on Immunization (EPI) program, aims to vaccinate the entire population (over the age of nine months) of Vanua Levu to protect the island against typhoid fever and assess the preventive impact and feasibility of a single-dose regimen of Vi-TT typhoid conjugate vaccine. In 2021 and 2022, the Ty-FIVE project team strengthened surveillance including case investigation and stool sampling in contacts of cases, trained all health facility personnel to ensure standardized processes, and began preparations for a mass vaccination campaign in collaboration with the Fijian Ministry of Health, planned for 2023.

As an add-on to the Ty-FIVE project, Typhoid Silent Contamination Surveillance (Ty-SICS) started in the third quarter of 2021 to assess environmental prevalence of typhoid before and after the Ty-FIVE vaccination campaign, helping the Fijian government understand the distribution of environmental Salmonella. In 2022, the project team successfully designed and installed two 40-foot containers donated by UNICEF as laboratory space and completed technology transfer for all standard operating procedures.

Collaborators:

- Ministry of Health, Fiji (Ty-FIVE)
- Murdoch Children's Research Institute, Australia (Ty-FIVE)
- Peter Doherty Institute for Infection and Immunity, Australia (Ty-FIVE)
- Imperial College London, UK (Ty-SICS)
- University of Washington, USA (Ty-SICS)

Funders:

- Bill & Melinda Gates Foundation
- Prof. Young Chul Sung

Project 6

Mozambique Typhoid Fever Surveillance & Typhoid Vaccine Introduction in Madagascar

Mozambique Typhoid Fever Surveillance (MOTIF) aims to support the government of Mozambique in generating typhoid fever burden data, enabling the country to apply for Gavi subsidies and introduce TCV into their national immunization program. Typhoid surveillance in Nampula and Pempa, Mozambique began in August 2022 and will continue for one year. Several typhoid cases have been identified to date.

Typhoid Vaccine Introduction in Madagascar (TyMA) aims to control the spread of typhoid fever by vaccinating at-risk groups, particularly children, and supporting the development of a national typhoid fever control plan in Madagascar. A baseline census covering a population of approximately 200,000 individuals in six communes in Arivonimamo and Antananarivo Atsimondrano was initiated in July 2022 after community health workers received thorough training in census implementation. Typhoid surveillance is ongoing in rural and urban communities in six healthcare centers (one in each commune), and a plan to expand surveillance sites is being finalized. Mass vaccination of all eligible, consenting participants using Vi-CRM₁₉₇ TCV is planned for the first quarter of 2023.

Collaborators:

- Instituto Nacional de Saúde, Mozambique (MOTIF)
- University of Antananarivo, Madagascar (TyMA)

Funders:

- Bill & Melinda Gates Foundation
- Korea Support Committee for IVI
- Prof. Young Chul Sung



The Northern Health Services of Fiji awarded IVI's Typhoid in Fiji–Vaccination towards Elimination (Ty-FIVE) team with Best Partnership of the Year 2022



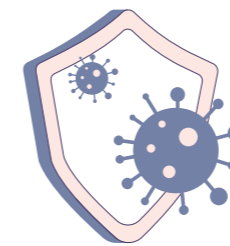
COVID-19 Accelerating vaccines to end the pandemic



COVID-19 is a respiratory illness caused by a novel coronavirus (SARS-Cov-2). The most common symptoms of COVID-19 are fever, dry cough, and fatigue with severe symptoms of the disease including shortness of breath, loss of appetite, pressure in the chest and high temperature.

The world has seen a light at the end of the long COVID-19 pandemic tunnel. However, variants and subvariants of the virus continue to emerge, posing a lingering threat to global health. To tackle variants, the world needs stronger and coordinated capabilities to develop safer and more efficacious vaccines.

IVI's COVID-19 response



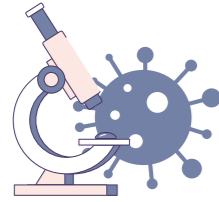
Throughout 2022, IVI continued working with multiple international and Korean partners to help develop several COVID-19 vaccine candidates, conduct pre-clinical and early- to late-stage clinical trials, epidemiological studies and capacity-building activities, establish vaccine evaluation systems, and develop COVID-19 vaccine adjuvants.

IVI works throughout the value chain to enable our global partners in COVID-19 vaccine development

Pre-clinical and International Standard Serum & Assay Development	Clinical Development Laboratory: EIA, PRNT, PsVNa Phase I-III / effectiveness	Capacity Building Support for Epi. and Phase III site development, manufacturing workforce training

IVI is testing COVID-19 vaccines from companies that have committed ~1 billion doses of COVID-19 vaccines to COVAX (~20% of the total)

Pre-clinical studies for COVID-19



In 2022, IVI conducted immunogenicity tests and other tests for pre-clinical studies of a number of COVID-19 vaccine candidates and therapeutics using established vaccine evaluation systems such as ELISA, wildtype virus neutralization (focus reduction neutralizing test, FRNT), and animal infection model.

Partner	Vaccine/therapeutics platform
QuadMedicine	Microneedle patch, Nanoparticle protein vaccine
Sumagen	rVSV-based vaccine
Eyegene	mRNA vaccine
Bioapp	Plant-derived recombinant protein vaccine
LG Chemical	Recombinant protein vaccine
SL Vaxigen and Genexine	DNA vaccine
Celltrion	Monoclonal Ab (Regkirona)
NeolImmuneTech	Interleukin-7

Clinical trial sample assessment for COVID-19

Project 1

Establishing a validated neutralization assay for SARS-CoV-2

IVI supported the establishment of the WHO international standard and reference panel for anti-SARS-CoV-2 antibodies, which is essential for clinical sample analysis. Through 2022, IVI assessed neutralizing antibody titers for over 6,000 samples using the validated Focus Reduction Neutralization Test (FRNT) assay from seven clinical trials conducted by four vaccine developers (INOVIO,

Cellid, Eubiologics, and SK bioscience). Importantly, IVI transferred FRNT assay technology to the Korea Disease Control and Prevention Agency (KDCA), and IVI and KDCA jointly analyzed 4,400 clinical samples from the Phase III trial of SK bioscience's GBP510 vaccine, leading to the vaccine's approval by the Korean Ministry of Food and Drug Safety in June 2022.

Project 2

Assessment of binding antibodies induced by COVID-19 vaccines

IVI also supported the establishment of the 2nd WHO international standard and reference panel for anti-SARS-CoV-2 immunoglobulins, to assess binding antibodies induced by COVID-19 vaccines.

IVI evaluated SARS-CoV-2 Spike-binding IgG titers using the established ELISA SOP in sera from clinical trials by four vaccine developers (INOVIO, Cellid, EuBiologics, and Quratis).

Partner	Platform
Inovio	DNA vaccine
Cellid	Adenoviral vector
EuBiologics	Recombinant protein
SK bioscience	Recombinant protein
Quratis	Self-replicating mRNA
ST Pharm	mRNA

COVID-19 vaccine clinical development



IVI is conducting early- to late-stage clinical trials of several vaccines to accelerate the development of vaccines for variants and the introduction of vaccines in low-income countries to help ensure vaccine equity for all.

Project 1

Phase III clinical trials of SK bioscience's licensed recombinant protein vaccine candidate (GBP510)



IVI coordinated the global Phase III clinical trial in five countries of SK bioscience's GBP50 vaccine, which demonstrated both superiority and non-inferiority of the vaccine compared to the comparator vaccine (AstraZeneca's Vaxzevria®). Based on the results, the GBP510 (brand name SKYCovione™) was licensed by the Korean Ministry of Food and Drug Safety in June 2022. Additional studies are ongoing.

Collaborators:

- SK bioscience
- Korea National Institute of Health
- Clinical trial sites across six countries (New Zealand, the Philippines, Republic of Korea, Thailand, Ukraine, and Vietnam), and Colombia
- CRO partners: Novotech, SMART, East Horn, LSK
- Logistics partner: Marken

Funders:

- Coalition for Epidemic Preparedness Innovations

SK bioscience's COVID-19 vaccine SKYCovione™



Project 2

Phase III clinical trial of Sanofi and GSK’s adjuvanted recombinant-protein COVID-19 vaccine candidate in Nepal

IVI is supporting a Phase III study to assess the efficacy, safety, and immunogenicity of Sanofi’s two SARS-CoV-2 vaccines (monovalent and bivalent) adjuvanted with AS03 recombinant protein. In 2022, IVI supported stage 1 and 2 of a Phase III study in Nepal with 2,300 enrolled subjects. The study of the bivalent COVID-19 vaccine containing both parental and Beta strains was the first ever to report efficacy data in an Omicron environment. Additional safety and immunogenicity studies were conducted with the booster formulation modeled on the Beta variant adjuvanted with the AS03 GSK-adjuvant, and these data led to the European Commission’s approval of the next generation of COVID-19 booster vaccine Beta.

Collaborators:

- Sanofi
- Clinical trial sites in Nepal
- CRO with CCR

Funders:

- BARDA
- SANOFI

Project 3

J&J heterologous prime booster study in Thailand

IVI is conducting a Phase I/II study of the Johnson & Johnson (J&J) vaccine to evaluate the safety, reactogenicity and immunogenicity of a heterologous boost of a single dose of the Ad26.COVS.2 vaccine in Thailand.

Collaborators:

- Mahidol University, Thailand (sponsor)
- National Vaccine Institute, Thailand
- Janssen Asia Pacific
- Biophics in Thailand

Funders:

- Janssen Asia Pacific

Project 4

Expanding Access and Delivery of COVID-19 Vaccines in Africa (ECOVA)

IVI and Mozambique’s Instituto Nacional de Saúde (INS) are conducting a Phase II mix-and-match trial in Mozambique to investigate a (heterologous) prime-boost regimen using Sinopharm’s BBIBP-CorV and J&J’s Ad26.COVS.2 vaccines compared to prime-boost regimens using the same product for prime and boost (homologous). The ECOVA team conducted a COVID-19 vaccination campaign in Beira with the Sinopharm vaccine where 55,051 people were vaccinated with the first dose and 43,681 with the second dose in a phase II mix-and-match trial of two Covid-19 vaccines from Sinopharm and J&J.

which will have a significant impact on ensuring timely vaccinations and controlling the pandemic in the regions most affected by vaccine shortages.

Collaborators:

- Instituto Nacional de Saúde, Mozambique
- University of Antananarivo, Madagascar
- Harvard University, USA
- icddr,b, Bangladesh

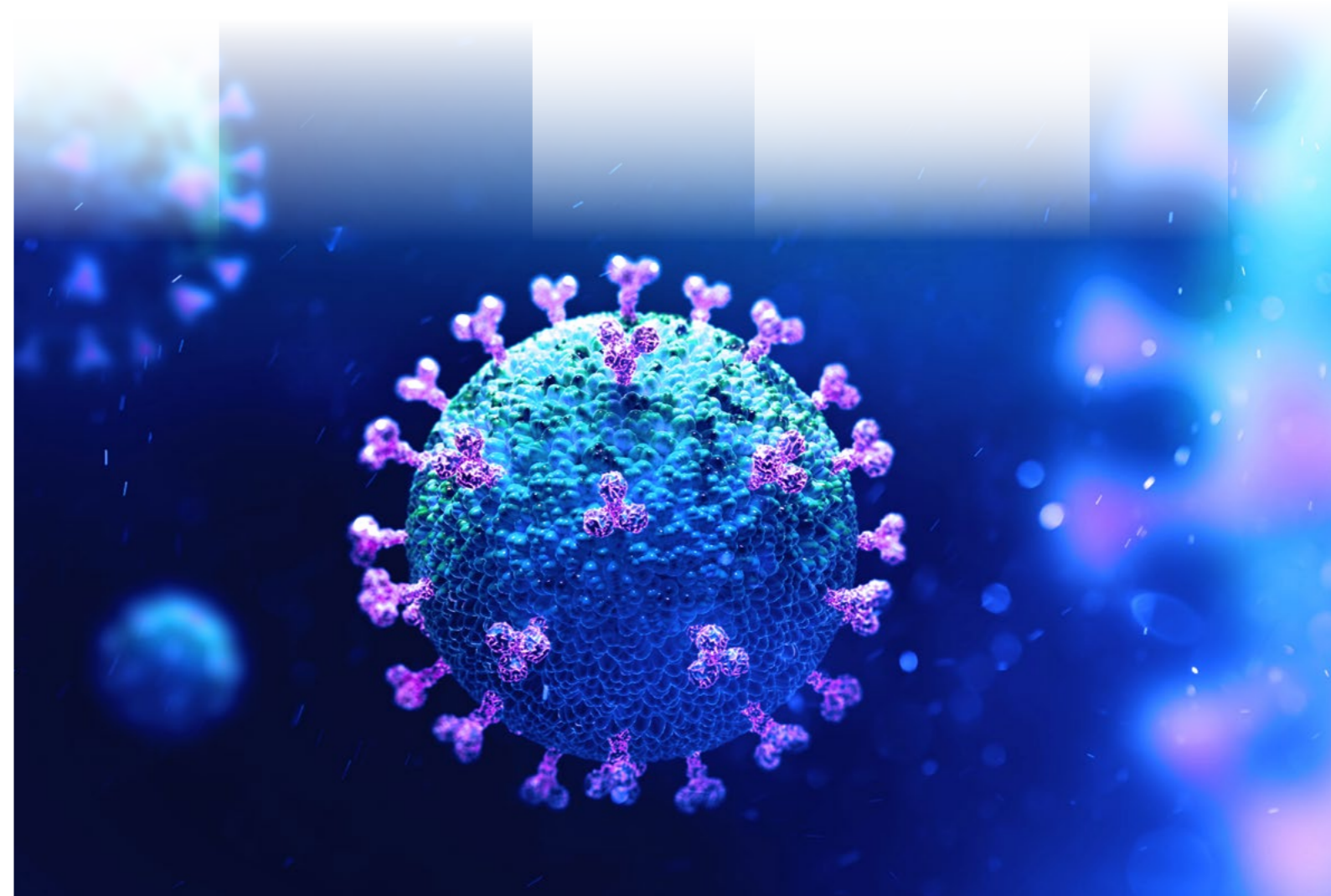
Funders:

- Coalition for Epidemic Preparedness Innovations

The project aims to demonstrate the safety and efficacy of a mixed schedule of COVID-19 vaccines,

Other COVID-19 vaccine clinical studies at IVI

Vaccine	Platform / Phase	IVI’s role	Funder
EdJen BioTech	Peptide-based vaccine Phase I/II	Pre-clinical development Clinical trials in Korea and Brazil	ICW Ventures
EuBiologics (EuCorVac-19)	Recombinant nanoparticle protein-based vaccine Phase I/IIa	Assessing the immunogenicity of the vaccine	KDDF
Everest	A Phase III, Randomized, Observer-Blind Pivotal Study	To evaluate the safety and non-inferiority in immunogenicity of PTX-COVID19-B administered as booster vaccination compared to AZ or Pfizer-BNT	Everest
Clover Biopharmaceuticals (SCB-2019)	Protein-based S-Trimer	Evaluate the impact of the vaccine in preventing household transmission of SARS-CoV-2 in the Philippines	Clover/CEPI
INOVIO (INO-4800)	DNA Phase I/IIa	Conduct Phase I/IIa clinical study of COVID-19 vaccine candidate in Korea	Inovio/CEPI
Quratis	Self-replicating mRNA Phase 1	Phase I (ELISA analysis)	



Chikungunya Advancing the world's first Chikungunya vaccine



Chikungunya is a viral disease spread to humans by infected *Aedes* mosquitoes and causes fever, severe joint pain, muscle pain, headache, nausea, fatigue, and rash. Although not a usually fatal disease, the resulting joint pain is often debilitating and can persist for weeks to years. There is currently no vaccine or specific drug to protect against or treat the virus, and available treatment is focused on relieving symptoms of the disease.

Although the virus was first identified in 1952, chikungunya began to spread

quickly in 2004, causing large-scale outbreaks around the world. Since its re-emergence, the total number of cases has been estimated at over 3.4 million in 43 countries.

The name “chikungunya” comes from the Kimakonde language of the Makonde people (an ethnic group living in southeast Tanzania, northern Mozambique, and Kenya) meaning “that which bends up,” referring to the hunched posture of those who suffer from the joint pain caused by the disease.

Project 1

Global Chikungunya Vaccine Clinical Development Program (GCCDP)

GCCDP was initiated by IVI in June 2020 in partnership with Bharat Biotech to advance Bharat's chikungunya vaccine candidate with the ultimate goal of achieving WHO prequalification and emergency use listing. This program involves a Phase II/III randomized, controlled vaccine clinical trial with an adaptive and seamless design to evaluate the safety and immunogenicity of a two-dose regimen of BBV87 chikungunya vaccine in healthy subjects aged 12-65 years Colombia countries in Asia and Latin America, including Colombia, Costa Rica, Guatemala, Panama, and Thailand. These studies are running in parallel to Bharat Biotech's clinical trials in India as part of the global clinical development plan of BBV87 vaccine.

In the first half of 2022, the GCCDP team completed quality audits in Costa Rica and Panama and two quality control visits were performed by the Study Medical Monitor/Project Technical Lead. In June, the second Data and Safety Monitoring Board meeting was held and concluded with a “Go” safety decision to initiate Part C of the study. Follow-up monitoring of trial participants will continue for 12 months. No serious unexpected adverse reactions have been observed.

The British National Institute for Biological Standards and Control, GCCDP's partner laboratory for the non-human primate (NHP) study, completed the active immunization study and the final report is now available. Study data demonstrated potent

protection with Bharat Biotech's BBV87 chikungunya vaccine by both the impact on virus replication and host response to infection. The interim clinical study report was finalized in July 2022, and unblinded immunogenicity results are now available. Together with the NHP study findings, these results will support the selection of the optimal dose for Part C. Meanwhile, IVI is working closely with the project's funder, CEPI, and the WHO on vaccine value profile development for chikungunya.



Collaborators:

- APCER Life Sciences
- Bharat Biotech
- Interactive Research School for Health Affairs, Bharati Vidyapeeth, India
- National Institute for Biological Standards and Control, UK
- VaxTRIALS
- Zifo

Funders:

- Coalition for Epidemic Preparedness Innovations

Project 2

Uptake and Demand Assessment of a Potential Chikungunya Vaccine (UDAC)

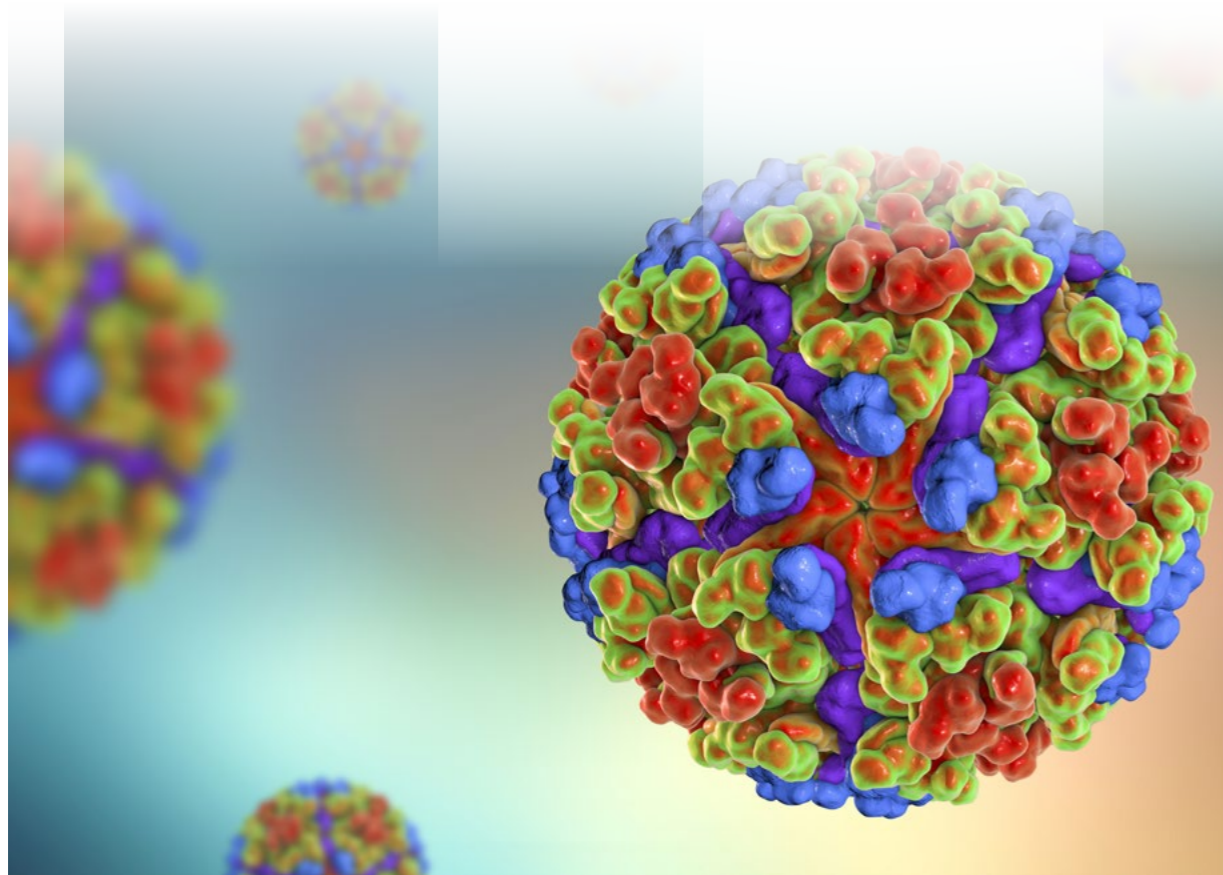
IVI initiated the UDAC project in collaboration with the London School of Hygiene and Tropical Medicine in the last quarter of 2022. This project aims to estimate the disease burden of chikungunya at global, regional, and national levels through statistical modelling and a systematic review of age-stratified data on seroprevalence, incidence of cases, and mortality rates; conduct a qualitative assessment of stakeholders' perceptions of risk of chikungunya outbreaks and feasibility of vaccine roll-out; and facilitate multi-stakeholder encounter through co-authoring an editorial/opinion piece with global partners, including CEPI and the WHO, emphasizing key areas of work and drivers for change. The formation of a partner consortium to gather efforts around chikungunya vaccine development and introduction is targeted for the first half of 2023.

Collaborators:

- London School of Hygiene and Tropical Medicine, UK

Funders:

- IVI Europe Regional Office



Vaccine R&D Programs

iINTS

Invasive non-typhoidal *Salmonella* vaccine program



WHO identifies iNTS disease as one of the top four global causes of diarrheal diseases. iNTS causes gastroenteritis, high fever, bloodstream infections, sepsis, and death, and is linked with poverty, malnutrition, poor sanitation, and the lack of safe drinking water. Sub-Saharan Africa and Eastern Europe have the highest incidence rates of iNTS disease. Infants, young adults, and immunocompromised individuals, including those infected with HIV and malaria, are particularly at risk of acquiring iNTS. The disease is often fatal if untreated and there are no licensed vaccines available.

iNTS causes approximately 3.4 million cases and 70,000-680,000 deaths per year. Two-thirds of all cases occur in children under five years-old. Additionally, antimicrobial resistance is a serious obstacle in treating iNTS, which is increasingly becoming resistant to all antibiotics. In the near future, vaccines may be the only tools available to prevent iNTS mortality.

Project 1

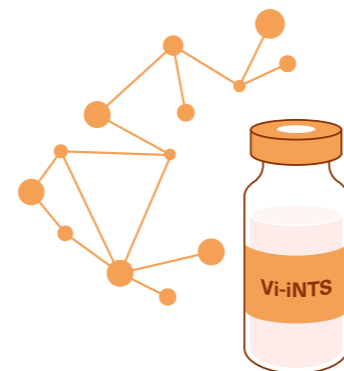
Trivalent Vi-iNTS conjugate vaccine development

Since 2018, the IVI laboratory has been developing a trivalent iNTS vaccine. In 2022, IVI completed significant objectives in the iNTS vaccine development plan, including the optimization of a trivalent, multi-dose drug product formulation, an immunogenicity study in mice, and the completion of the technology transfer process to manufacturing partner SK bioscience.

Collaborators:
• SK bioscience

Funders:
• IVI core budget
• Wellcome Trust

In 2023, work will continue on toxicology studies for the vaccine, alongside discussions with the Korean Ministry for Food and Drug Safety for eventual Investigational New Drug (IND) authorization, and the submission of plans for a Phase I clinical trial.



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25 years of accelerating vaccines for global health

IVI campaigns have Vaccinated over one million people Africa and Asia, delivering long-term protection against preventable infectious diseases.



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Project 2

Full Value of Vaccines Assessment (FVVA) for iNTS vaccines

In 2021, IVI began work on a FVVA for iNTS vaccines in collaboration with the WHO, Shift Health, and the London School of Hygiene and Tropical Medicine. The iNTS FVVA will help stakeholders, investors, and policymakers understand the value of investment in iNTS vaccine development and use.

Collaborators:

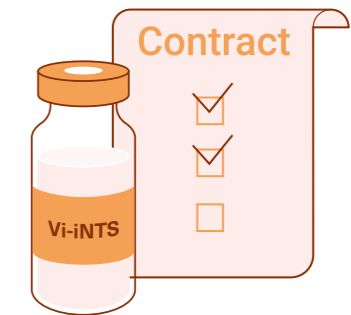
- World Health Organization
- Shift Health
- London School of Hygiene and Tropical Medicine, UK

Funders:

- IVI core budget
- Wellcome Trust

In 2022, the Research Steering Group made the significant decision to broaden the scope of the FVVA by focusing on the development of a trivalent vaccine that would consist of both typhoid conjugate vaccine (TCV) and bivalent iNTS vaccine.

In addition, the WHO Product Development for Vaccines Advisory Committee announced support for a trivalent iNTS vaccine approach and the WHO agreed to develop a modular Preferred Product Characteristics and R&D roadmap. IVI's Policy & Economic Research department completed a systematic literature review on the economic burden of iNTS and Shift Health completed the iNTS vaccine landscape analysis.



Shigella Vaccines against Shigella



Shigella, an invasive bacteria that can cause severe dysentery, long-term health and cognitive disability, bloodstream infections, and death, is often associated with poverty, malnutrition, poor sanitation, and lack of safe drinking water. Sub-Saharan Africa and South Asia have the highest shigella incidence rates. Shigella has the potential to create pandemics in children under five years and the elderly, and both groups face a higher risk of mortality from shigella infections. There are no licensed vaccines available for global use.

There are approximately 165 million cases and 270,000 deaths related to shigella every year. 27% of all cases occur in children under five years-old. Antimicrobial resistance is a serious obstacle to treating shigella, which is becoming increasingly resistant to all antibiotics. In the near future, vaccines may be the only tools available to prevent shigella mortality.

Project 1

Optimization of a STM Vaccine Platform

The Shigella Truncated Mutant (STM) vaccine platform, which uses the shigella PSSP-1 antigen technology developed by IVI, could be used as an effective vaccine platform against a number of enteric diseases.

In 2022, IVI prepared an STM platform using fermentor culture and formalin inactivation provided by the Walter Reed Army Institute of Research (WRAIR) which showed protection against homologous and heterologous shigella challenges in a mouse lung model. In 2023, IVI will conduct a proof-of-concept in animal models trial using the STM platform.

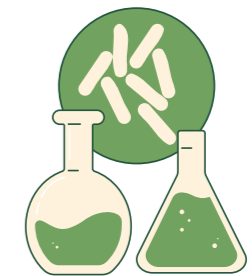
Additionally, IVI received a small grant from BactiVac to conduct a proof-of-concept in animal models trial of PGTx's PAL (peptidoglycan-associated lipoprotein) vaccine candidate, which will begin in 2023.

Collaborators:

- Dr. Rob Kaminsky, Walter Reed Army Institute of Research
- Dr. Christine Szymanski, University of Georgia
- PGTx (Pacific GeneTech subsidiary)

Funders:

- PATH / Wellcome Trust Discretionary Award
- BactiVac



HPV

Expanding HPV vaccine coverage to protect girls and women from cervical cancer



IVI's Thailand HPV Single Dose Impact Study aims to demonstrate the effectiveness and cost effectiveness of single-dose versus two-dose regimens of HPV vaccine in 8th grade girls in Thailand. Given the high cost of HPV vaccines and low uptake, particularly in low- and middle-income countries (LMICs), a single-dose option could substantially expand coverage by lowering costs and simplifying delivery.

Cervical cancer is the fourth most common cancer in women around the world, and nearly all cases are due to HPV infection. While there are several vaccines available to prevent HPV, less than 15% of women are fully vaccinated and coverage is even lower in LMICs.

Project 1

A community intervention effectiveness study of a single dose or two doses of bivalent HPV vaccine (CERVARIX) in female school students in Thailand

Between December 2018 and March 2019, over 8,000 8th grade girls in the Udon Thani and Buri Ram provinces of Thailand received either one dose of Cervarix® HPV vaccine or the currently recommended two doses in school-based vaccination campaigns. Following vaccination, participants were enrolled in surveys to track the prevalence and occurrence of HPV infection, and the data was provided to the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) in 2021 as part of a larger data package with results from similar studies. In 2022, this data package led to the WHO SAGE's updated recommendation of a single-dose vaccine regimen for girls and women aged 9-20 years old.

In 2022, Year 4 cross-sectional surveys and health economic assessments continued and will conclude in 2023. The results of these studies will provide valuable data on longer-term vaccine effectiveness and the economic viability of HPV vaccine introduction.

Collaborators:

- Department of Disease Control, Ministry of Public Health, Thailand
- National Vaccine Institute, Thailand
- Center of Excellence in Clinical Virology, Chulalongkorn University, Thailand
- Centers for Disease Control and Prevention, USA
- Health Intervention and Technology Assessment Program, Thailand
- Mahidol University, Thailand

Funders:

- Bill & Melinda Gates Foundation



IVI's HPV Single Dose team with collaborators in Thailand. Credit: IVI

Project 2

Global HPV Burden Study

In late 2022, the Bill & Melinda Gates Foundation granted \$14.99 million USD to an IVI-proposed HPV global disease burden study with \$1 million in co-funding from the Swedish government through IVI's European Regional Office.

This harmonized, multi-country and multi-site study will estimate the prevalence of high-risk HPV genotype infections among representative samples of girls and women aged 9-50 years, and among specific sub-populations, to better understand the incidence of persistent HPV infection in girls and women in low- and lower middle-income countries in Asia and sub-Saharan Africa.

Data will also be collected on girls' and women's knowledge, attitudes, and beliefs about HPV and vaccination, and on risk factors for HPV infection and explore barriers to prevention, screening and treatment access for girls and women. The results of this study will enable a more accurate understanding of the HPV disease burden at the country and global level, and the development of effective intervention strategies.

Collaborators:

- Centers for Disease Control and Prevention, USA
- Karolinska Institutet, Sweden
- London School of Health and Tropical Medicine, UK
- Aga Khan University, Pakistan
- iccdr,b, Bangladesh
- New Era, Nepal
- Dhulikhel Hospital, Nepal
- B.P. Koirala Institute of Health Sciences, Nepal
- College of Medicine and Allied Health Sciences (COMAHS), Sierra Leone
- Mwanza Intervention Trials Unit, Tanzania
- National Institute for Medical Research, Tanzania
- University of Health and Allied Sciences, Ghana
- Institut National de Recherche Biomédicale, Democratic Republic of the Congo
- Zambart, Zambia

Funders:

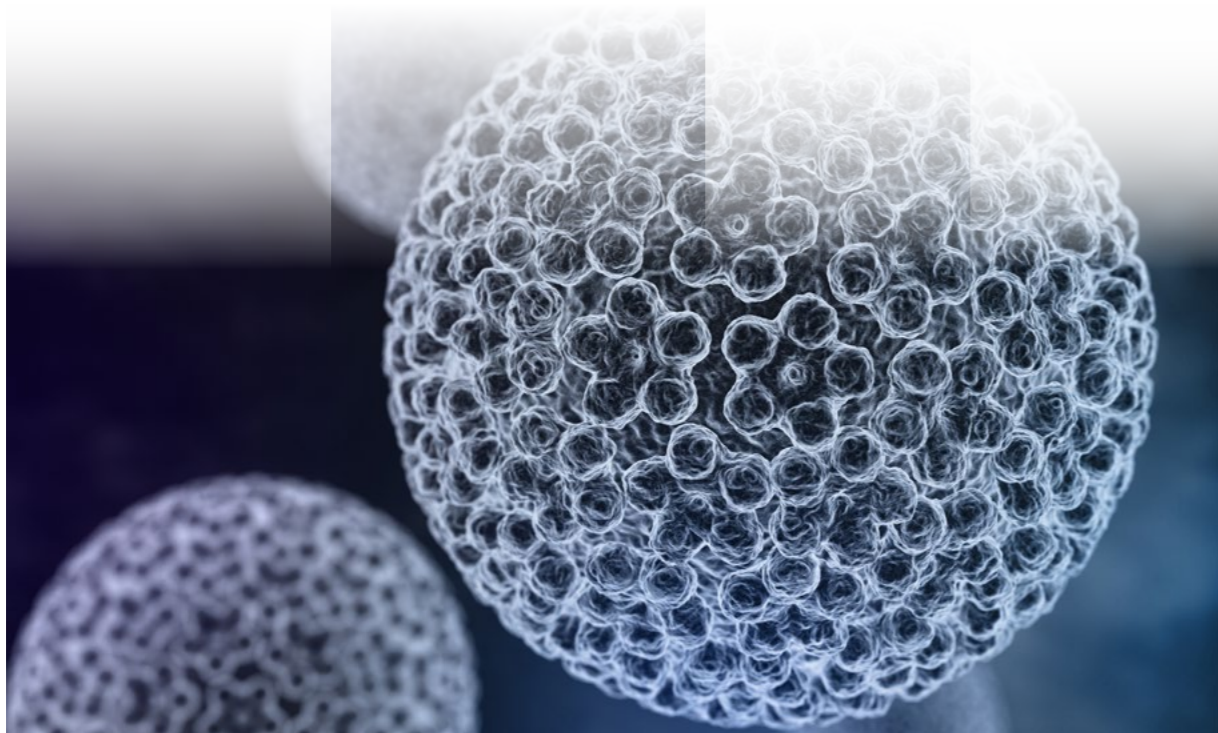
- Bill & Melinda Gates Foundation
- Government of Sweden (through IVI Europe Regional Office)

Vaccine R&D Programs

Hepatitis E

Hepatitis E Virus

program



HEV is one of the most common causes of acute viral hepatitis globally with 20 million infections estimated annually and over 70,000 reported deaths, including 3,000 stillbirths. However, the burden is likely underestimated considering the limited availability of diagnostics and insufficient surveillance. Pregnant women, immunosuppressed individuals, and individuals with preexisting chronic liver disease are at a higher risk for severe disease and suffer a 20-40% mortality rate.

HEV is primarily spread through contaminated water, however it can also be transmitted at birth from mother to

child, from infected blood transfusions, and through the consumption of infected animal products. Outbreaks have been documented in Asia and eastern Africa, often taking place in refugee settings with limited access to safe water and sanitation.

There is a highly efficacious vaccine, Hecolin®, registered for domestic use in China and Pakistan, however, despite endemic disease in South Asia and large outbreaks of HEV in Africa, the vaccine has rarely been used.

Project 2

Phase II Trial of Hecolin® in Pregnant Women in Pakistan

In 2022, IVI and collaborators received funding to conduct a Phase II clinical trial of Hecolin® in Pakistan. This trial will evaluate the safety and immunogenicity of the vaccine in both pregnant and non-pregnant women. Under the supervision of Aga Khan University, over 2,300 participants will be enrolled in Karachi across four sites which previously hosted the Alliance for Maternal and Newborn Health Improvement study. By demonstrating the safety and immunogenicity of Hecolin® in pregnant women, IVI and its partners aim to facilitate use of the vaccine in pregnant women at highest risk for severe disease and advance WHO prequalification and potential SAGE recommendation for this critically needed vaccine.

Collaborators:

- The Aga Khan University, Pakistan
- Johns Hopkins University, USA
- Syracuse University, USA

Funders:

- Bill & Melinda Gates Foundation
- Open Philanthropy
- Thrasher Foundation



Project 1

Hepatitis E Epidemiology in Africa (HEVA)

In 2021, the HEVA project brought together three partner institutions in the Democratic Republic of the Congo, Nigeria, and Senegal to assess the burden of HEV by analyzing samples collected over 10 years in 13 central and west African countries.

In 2022, the HEVA team completed serologic screening for anti-HEV IgG and IgM antibodies in all study samples. In total, 13,960 serum samples collected between 2010 and 2021 were analyzed with ELISA. In 2023, the HEVA team will continue its depth analyses of the serology data, including sero-epidemiology, spatial distributions, and seasonality within each country.

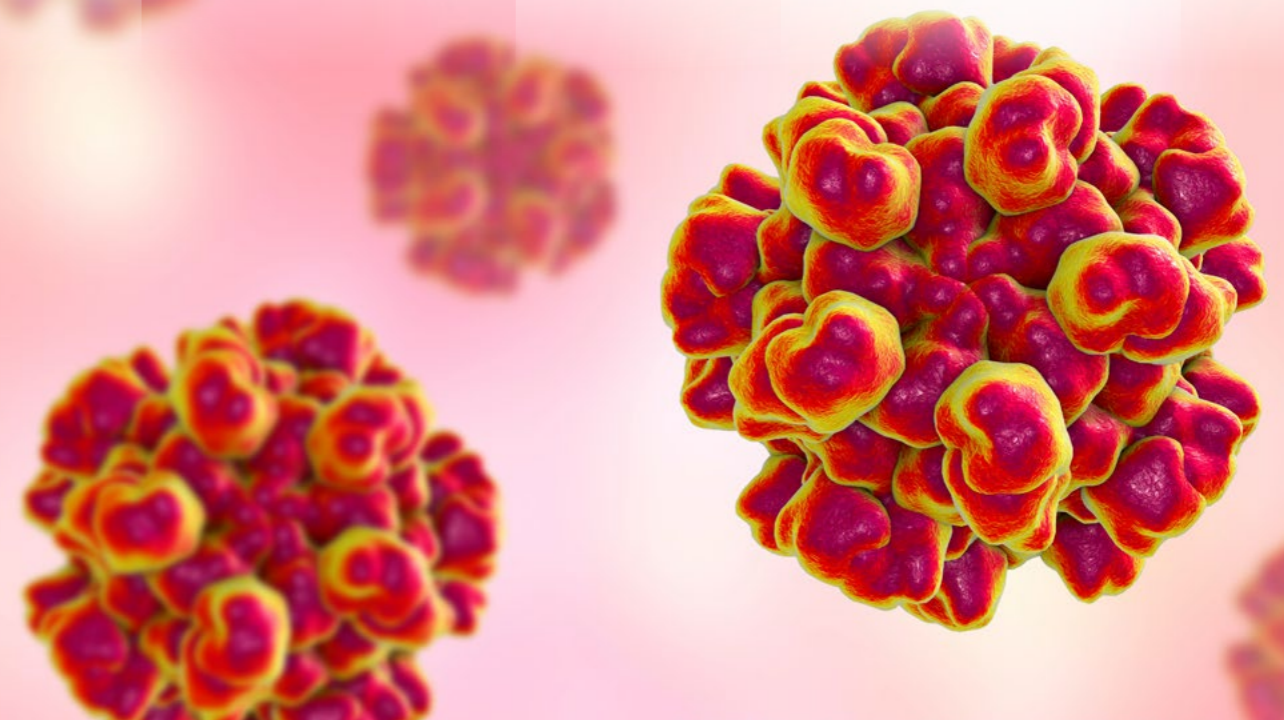
In addition, the IVI team will host the 2nd International HEV Symposium in 2023, bringing together the research community to present the latest research on the epidemiology, diagnostics, and vaccines/ vaccination for hepatitis E.

Collaborators:

- Institut Pasteur de Dakar, Senegal
- University of Ibadan, Nigeria
- Institut National de Recherche Biomédicale, Democratic Republic of the Congo

Funders:

- Bill & Melinda Gates Foundation



Schistosomiasis Understanding and eliminating Schistosomiasis



Schistosomiasis is a poverty-associated disease and classified as a Neglected Tropical Disease caused by parasitic worms. The disease is spread when people come into contact with infested waters during work-related and recreational activities. It is a major global public health problem with the highest disease burden in sub-Saharan Africa.

Schistosomiasis is a significant cause of morbidity for an estimated 200 million people, with an additional 779 million individuals at risk of infection. Of deaths caused by parasites, schistosomiasis ranks second only to malaria, killing more than 200,000 people annually in sub-Saharan Africa alone.

Project 1

Vaccine Against Schistosomiasis for Africa (VASA)

IVI's VASA project in collaboration with the University of Cambridge has three main activities:

1. Seroprevalence and disease burden study in Madagascar and Burkina Faso to understand the current disease burden and evaluate the age of exposure to *Schistosoma* to inform vaccine development and roll-out policies
2. Cost-of-illness study to understand the financial burden of Schistosomiasis on local populations and to estimate the cost-effectiveness of a vaccine
3. Phase I clinical trial to assess the safety and immunogenicity of SchistoShield®, one of the leading Schistosomiasis vaccine candidates

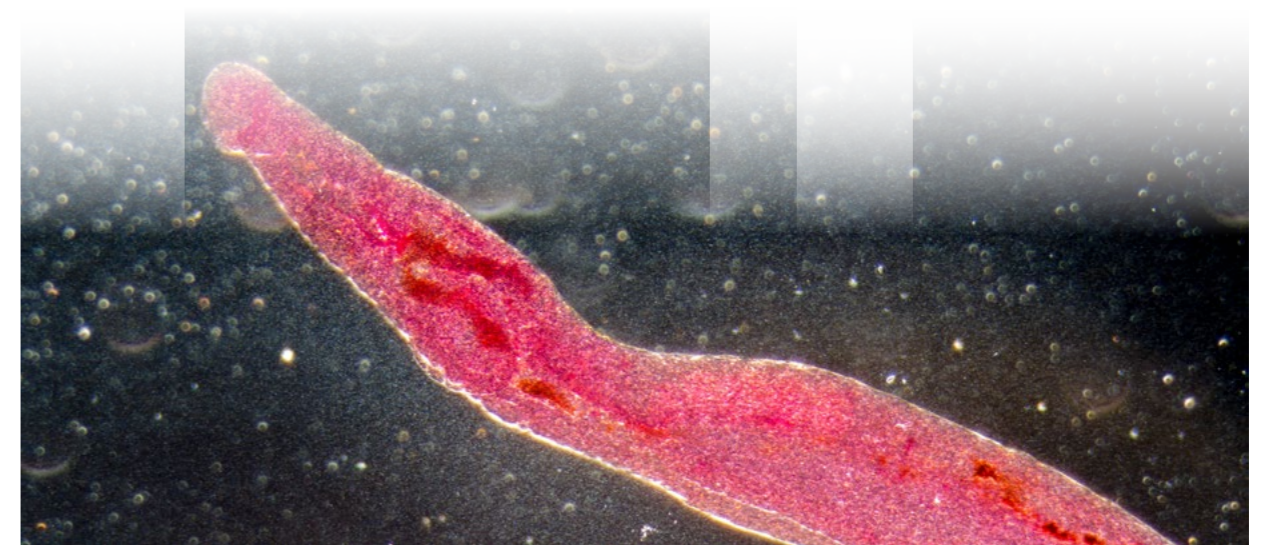
In 2022, the VASA team completed recruitment for the seroprevalence and disease burden studies in Madagascar and Burkina Faso in addition to the cost-of-illness study for asymptomatic/non-severe cases. The clinical trial site in Burkina Faso completed its site assessment visit.

Collaborators:

- Department of Medicine, University of Cambridge, UK
- Groupe de Recherche Action en Santé, Burkina Faso
- University of Ouagadougou, Burkina Faso
- University of Antananarivo, Madagascar
- Texas Tech University Health Sciences Center, USA
- PAI Life Sciences Inc.
- Leiden University Medical Center, Netherlands
- University of Gothenburg, Sweden
- Institute for Tropical Medicine, University Tübingen, Germany

Funders:

- European Union Horizon 2020 program



Antimicrobial resistance Unifying countries against AMR



AMR is caused by the overuse of antimicrobial medicines, such as antibiotics, antivirals, and antifungals. When used correctly, these medicines prevent and treat infection in human, animals, and plants, but the pathogens that cause infections (bacteria, viruses, parasites) can evolve over time and become resistant to medicines. These resistant pathogens spread from infected individuals to other members of their community. Consequently, infections and illnesses can become untreatable and risk of disease increases.

AMR is a health and development threat to all people, regardless of who they are or where they live, as well as to animals and the environment. That's why One Health solutions are the path forward, bridging the health of

humans, animals, and the environment to preserve the effectiveness of medicines and protect our food, our planet, and each other.

In 2022, IVI created an AMR department nested in the Epidemiology, Public Health, and Impact unit in recognition of AMR's incredible threat to global health and the role of vaccines in mitigating its spread and impact. This department launched a new project, AMR and Vaccines, to analyze AMR markers during vaccination campaigns.

IVI also currently has three active projects supported by the Fleming Fund, a £265 million UK aid investment to tackle antimicrobial resistance in low- and middle-income countries (LMICs) around the world.

Project 1

Capturing Data on Antimicrobial Resistance Patterns and Trends in Use in Regions of Asia (CAPTURA)

In many LMICs, all kinds of agencies and academic, research, and medical institutions have been generating data on antimicrobial resistance (AMR), use (AMU), and consumption (AMC), but without sharing their information publicly. IVI leads the CAPTURA project, working to expand the volume of historical and current data on AMR and antimicrobial use in 12 countries across South and Southeast Asia. By building a network of laboratories and pharmacies for data sharing and identifying human health facilities that are generating AMU and AMR data, CAPTURA is helping to both establish and expand surveillance in Asian countries while unifying their efforts.

The team has completed the collection, digitization, and analysis of existing data, and disseminated their findings through a three-day regional workshop in 2022. These data will be used to inform regional and national efforts in improving AMR surveillance, AMR stewardship, and evidence-based policy and planning. Capacity-building was also a critical factor in the sustainability of CAPTURA's goals, with the team helping to strengthen data interpretation and analysis methods and digital surveillance systems.



Members of the Ministry of Health of Bhutan attending the CAPTURA regional workshop virtually.

Collaborators:

- Brigham & Women's Hospital (WHONET), USA
- Public Health Surveillance Group, USA
- Big Data Institute, Oxford University, UK

CAPTURA countries

- Bangladesh
- Bhutan
- India
- Indonesia
- Laos
- Myanmar
- Nepal
- Pakistan
- Papua New Guinea
- Sri Lanka
- Timor-Leste
- Vietnam

Funders

- Fleming Fund, UK Aid

Project 2

Regional Antimicrobial Resistance Data Analysis for Advocacy, Response, and Policy (RADAAR)

The RADAAR project focuses on regional data sharing and analysis to influence and facilitate evidence-based policymaking, advocacy, and response. Activities include bringing together partners generating AMR, AMU, and AMC data to share their experiences through a participatory approach, establishing a regional data-sharing framework and platform for analysis and visualization, and providing Fleming Fund priority countries with relevant information for planning, policy, and interventions.

In 2022, the RADAAR team hosted a series of workshops across AMR policy and data. The three-day AMR Policy Workshop had the goal of strengthening capacities for evidence-informed AMR policymaking to support the implementation of National Action Plans. AMR and policy experts shared experiences and current thinking on issues impacting AMR policymaking.

Three workshops on AMR data-sharing and analysis were organized by region: South Asia, Africa, and Southeast Asia, with the aim of informing the creation of a regional framework for AMR data-sharing and analysis as well as guidance to help LMICs translate data and evidence into compelling policy pitches.

Collaborators:

- Brigham & Women's Hospital (WHONET), USA
- Public Health Surveillance Group, USA
- Big Data Institute, Oxford University, UK

Funders

- Fleming Fund, UK Aid

Project 3

Strengthening External Quality Assurance for AMR in Asia (EQASIA)

IVI is part of the EQASIA consortium led by the Technical University of Denmark (DTU) to improve the quality of AMR surveillance in Asia. After mapping the coverage, availability, and uptake of external quality assurance (EQA) programs in Asia, the consortium proceeded with five rounds of EQA services and relevant training to National Reference Laboratories (NRLs) across One Health sectors in Asia from 2021 to 2022. At the same time, IVI developed the EQASIA costing tool for cost analysis and cost forecasting of the EQA program.

The project aims to support four participating countries in establishing national EQA programs. Additionally, EQASIA will provide trainings in Quality Management Systems to NRLs and implement the EQA costing tool for country-specific understandings of budget implications and financial sustainability in conducting EQA.

Collaborators:

- Technical University of Denmark (lead grantee)
- National Institute of Health, Thailand
- Chulalongkorn University, Thailand

Funders

- Fleming Fund, UK Aid

Group A Strep

The world needs a Group A Strep vaccine



The cause of strep throat, rheumatic scarlet fever, and rheumatic heart disease, GAS is one of the world's deadliest infectious diseases with 33 million infections and over half a million deaths each year in LMICs. However, little funding has been invested in GAS vaccine development and no vaccine is currently available.

While GAS infections are typically treated with antibiotics, antimicrobial resistance may render GAS infections untreatable in

the near future, making the development of GAS vaccines a matter of critical importance to global health.

In 2022, Europe and North America experienced a surge of invasive GAS infections in children, resulting in numerous hospitalizations and deaths. The concurrent shortage in amoxicillin, the antibiotic used to treat GAS infections, further underlined the urgent global need for GAS vaccines.

Project 1

Strep A Global Vaccine Consortium (SAVAC)

IVI and global partners formed SAVAC in 2019, following a global resolution by the 71st World Health Assembly which recognized rheumatic heart disease and acute rheumatic fever as major global health issues and called for the development of GAS vaccines. SAVAC is a diverse consortium bringing together 45 experts from 25 institutions spanning 12 countries, dedicated to accelerating the development of GAS vaccines.

In 2022, SAVAC successfully completed the Full Value of Vaccine Assessment (FVVA), vaccine landscape analysis, and a vaccine safety white paper while making significant progress on GAS disease burden and correlates of protection research. SAVAC held its 2nd annual stakeholder meeting in Stockholm, where the consortium also presented its progress at the Lancefield International Symposium on Streptococci and Streptococcal Diseases.

Collaborators

- Murdoch Children's Research Institute, Australia
- Telethon Kids Institute, Australia
- Harvard T.H. Chan School of Public Health, USA
- PATH
- Imperial College London, UK
- Indian Council of Medical Research
- National Technical Advisory Group on Immunization, India
- University of Cape Town, South Africa
- University of Colorado, USA
- Shift Health
- World Health Organization

Funders

- Wellcome Trust
- Open Philanthropy
- Leducq Foundation



The Strep A Vaccine Global Consortium (SAVAC), co-chaired by Dr. Jerome Kim, Director General of IVI, and Prof. Andrew Steer of Murdoch Children's Research Institute - MCRI, shared work progress and achievements at a Second Stakeholders Meeting gathering participants across academia, industry, non-profit organizations, and funding agencies. Credit: IVI

Other Lab Programs



Project 1

Development of new liposome-based adjuvant

IVI is working to develop basic production/testing processes for an IVI liposomal-based adjuvant system (ILA) to be used in conjunction with alum-adjuvanted formulations (ILAA) and/or QS-21 (ILAQ), compare the system with commercial adjuvants such as ALFQ (from the Walter Reed Army Institute of Research) or AS01b (GSK), and evaluate this adjuvant system in formulations with COVID-19 antigens with the others in order to establish a proof of concept. IVI is also exploring adjuvant efficacy of ILA by combining it with other toll-like receptor (TLR) agonists.

In 2022, IVI established key laboratory infrastructure to support process development, adoption, and fine tuning in its vaccine process development laboratory. The first animal study was completed, finding ILA and ILAG to be safe in mice and well tolerated.

Collaborators

- University of Helsinki, Finland
- Jeonbuk National University, Republic of Korea
- Chungnam National University, Republic of Korea
- The Catholic University of Korea, Republic of Korea
- Korea Research Institute of Chemical Technology
- KGC

Funders

- Ministry for Social Affairs and Health, Finland
- National Research Foundation of Korea
- Government of the Republic of Korea

Project 2

Lassa mRNA vaccine and Pseudovirus neutralization system

IVI is working to establish an mRNA vaccine platform targeting Lassa virus glycoprotein, which will be prepared for the future rapid production of mRNA vaccines against emerging infectious diseases using mRNA platform technology. The Pseudovirus-based neutralization assay has been established for Lassa vaccine evaluation and other highly pathogenic emerging virus vaccines. These pseudovirus-based neutralization systems will be utilized in various vaccine evaluations.

Collaborators

- SK bioscience
- Gachon University, Republic of Korea

Funders

- Korea mRNA Vaccine Initiative

Project 3

Development of S. Paratyphi A / S. Typhi bivalent vaccine through proof-of-concept in animals

IVI initiated corrective actions in 2021 to rectify probable cause of previously unsuccessful projects, and continued efforts to develop bivalent S. Typhi/ Paratyphi A vaccine. IVI produced a number of S. Paratyphi A OSP conjugates and selected an optimal S. Paratyphi A OSP conjugate batch through immunogenicity testing in mice in 2022, and is currently working to develop an optimal bivalent Typhi/Paratyphi vaccine formulation in 2023.

Funders

- Wellcome Trust

Project 4

Preclinical study of adenovirus type 55 vaccine

IVI, in collaboration with the Korean Armed Forces Medical Research Institute, selected HadV-55 vaccine candidate strain in a previous project. Now, IVI is working to establish vaccine production process and standard sera and conduct a toxicological study to prepare for IND application. The establishment and characterization of master cell bank (Vero cell) and master virus bank of the HAdV-55 vaccine strain started in 2022. To establish standard sera, the collection of convalescent sera was completed. For assessment of the protective efficacy, transgenic mice expressing HAdV-55 receptors (desmoglein 2 and CD46) have been established.

Collaborators

- K-Bio CMO Center
- Armed Forces Medical Research Institute, Republic of Korea

Funders

- Korea mRNA Vaccine Initiative

Project 5

Systems serology

IVI received a new grant for systems serology from the Korean government in 2022. IVI aims to establish systems serology at the institute to find novel biomarkers for infectious diseases through this project, which will receive technical support from Dr. Galit Alter, a leading expert in this field at Harvard University. This platform technology will be used to identify immune correlates of protection/distinct biomarkers in typhoid, iNTS, Covid-19 using animal and human clinical samples.

Collaborators

- College of Medicine, Yonsei University, Republic of Korea

Funders

- Ministry of Science and ICT, Republic of Korea

Project 6

Development of rVSV-SFTS/HFRS bivalent vaccine

In 2022, IVI started animal studies to evaluate the immunogenicity of vaccine candidates. As a result, rVSV-HFRS-GP and rVSV-HFRS-msp-GP-Gtc have been selected for Hemorrhagic fever with renal syndrome (HFRS) vaccine candidates. For rVSV-SFTS vaccine, immunogenicity evaluation is ongoing for candidate selection. The establishment of a vaccine evaluation system is ongoing, and the development of neutralization assay for SFTS and HFRS is in progress. Also, IVI and NIBSC are in discussion to establish the international standard for SFTS virus vaccines for assessment of SFTS vaccine efficacy.

Collaborators

- Sumagen
- Gyeongbuk Institute for Bio Industry
- Armed Forces Medical Research Institute, Republic of Korea

Funders

- Andong City, Republic of Korea

Technology transfers by the Lab Science Unit in 2022

Activities	Details
IVI conducted technology transfer of trivalent iNTS/ Typhoid vaccine drug product (DP) process and related assays to SK bioscience.	Transfer of procedures (DP formulation and analytical methods) were successful and SK bioscience was able to use the processes to formulate trivalent DP. Through the DP technology transfer, materials produced therefrom at SK for use in pre-clinical toxicology testing was successfully delivered to CRO.
IVI conducted on-site training and consultation at Incepta Pharmaceuticals Ltd as part of Global Training Hub for Biomanufacturing (GTH-B) activities, established by the Korean Ministry of Health and Welfare with support from the WHO including the WHO Academy.	Through on-site training, batch production of pneumococcal conjugate was performed at the facility, providing technical consultation on process and analytical method improvement.
IVI conducted technology transfer of oral cholera vaccine production processes (DS & DP) and quality control testing to BIBCOL.	Stage 1 transfer has been completed successfully. The IVI team will visit BIBCOL facility for stage 2 technology transfer in 2023.



Lab scientists in IVI's BSL-3 lab. Credit: IVI

Other Public Health Programs



Project 1

Establishing a health and demographic surveillance system in Madagascar and the Democratic Republic of the Congo

In 2022, IVI's Europe Regional Office launched the Health Demographics Surveillance Study to establish a health and demographic surveillance system (HDSS) in Imerintsiasika, Madagascar and Kisantu, Democratic Republic of the Congo. With an HDSS in place, the project aims to empower these two sites with the tools and training to monitor their populations and their health. Ultimately, this study will lead to sustainable census activities led by trained site staff.

Collaborators

- Madagascar Institute for Vaccine Research, University of Antananarivo, Madagascar
- Institut National de Recherche Biomédicale, DRC

Funders

- Government of Sweden (through IVI Europe Regional Office)

Project 2

Investigating the impact of Respiratory syncytial virus (RSV)

RSV causes significant morbidity globally, however, an effective vaccine is not yet available. In 2022, IVI received a grant from the Federal Government of Germany (via Robert Koch Institute) to investigate the clinical and genomic epidemiology of RSV infections in children from both urban and rural settings in Bangladesh. RSV cases will also be included in a health economics study that estimates the cost-of-illness of RSV.

Collaborators

- Child Health Research Foundation, Bangladesh

Funders

- Federal Government of Germany (through Robert Koch Institute)



Participants of the Global Training for Biomanufacturing program engage in a breakout session at IVI HQ.
Credit: IVI

Policy & Economic Research



IVI's Department of Policy and Economic Research (PER) collaborates extensively with IVI teams and external partners including the WHO in multiple projects,

generating evidence for decision-makers to better underpin public health interventions and policies in fighting vaccine-preventable diseases.

In 2022, PER's portfolio of activities included:

<p>iNTS</p> <p>Full Public Value of Vaccines, cost-of-illness and cost-effectiveness analysis</p>	<p>Typhoid</p> <p>Cost-of-illness/cost-effectiveness for SETA Plus, economic evaluation of TCV introduction</p>
<p>AMR</p> <p>Fleming Fund policy, planning and advocacy: RADAAR</p>	<p>HPV</p> <p>Economic evaluation of HPV Single-Dose study (Thailand)</p>
<p>Schistosomiasis</p> <p>Cost-of-illness and value of schistosomiasis vaccines (Burkina Faso and Madagascar)</p>	<p>RSV</p> <p>Economic evaluation of a hypothetical RSV vaccine (Bangladesh)</p>
<p>Modeling</p> <p>Estimate impact of typhoid and cholera vaccine introductions in LMICs</p>	<p>Cholera</p> <p>Economic evaluation of oral cholera vaccine use (Nepal and Mozambique)</p>



Quality Management



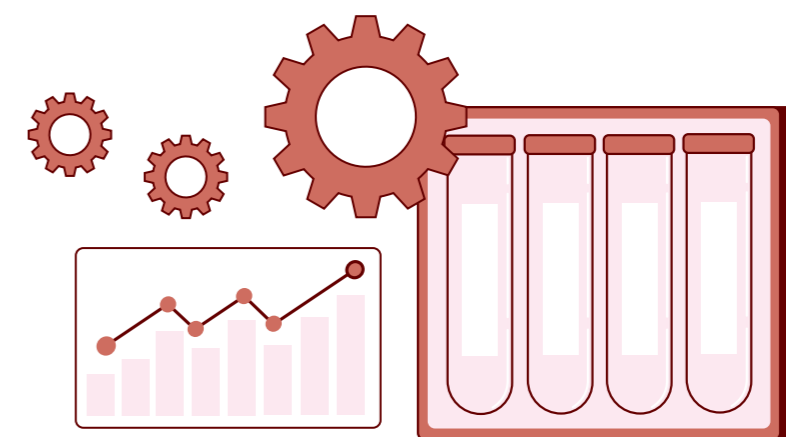
Quality Management (QM) and objective quality oversight are essential to GxP compliance in support of IVI's regulated activities and global infrastructure development.

IVI QM efforts continue to focus on alignment with global expectations defined by regulatory requirements, guidance and industry standards which ensure successful outcomes to IVI's clinical, observational and laboratory research conducted within respective regulated environments.

As IVI continues to expand globally, the importance of quality oversight remains a priority which has further bolstered QM's role of ensuring IVI's clinical research activities (as an example) remain compliant to international regulations, and that IVI operate in a state of continuous inspection readiness.

Over the course of 2022, IVI QM continued to make inroads into quality process and infrastructure development including implementation of a validated instance of Box (a cloud-based content management system), development of an institutional archiving room and compliance to Personal Protected Information (PPI) requirements (e.g., GDPR). In addition QM provided support to IVI collaborators and stakeholders (e.g. regulatory inspection support), which ensured continued and sustainable quality improvement and compliance to international regulations, guidelines, and best practice.

IVI's quality assurance efforts realized in previous years will be sustained through the conduct of mock regulatory inspections, routine quality training and lectures, and both internal and external audit activities. These activities will ensure IVI as an organization remains relevant and accountable to our research subjects, regulators, and stakeholders.



Capacity Building Programs

Building and bridging gaps in vaccine capacity for sustainable development is a core component of IVI's mission. IVI's capacity-building programs aim to boost capabilities in low- and middle-countries

to develop and produce vaccines and other biologics locally to help address vaccine inequity and enhance global pandemic preparedness.



Project 1

IVI International Vaccinology Course

Established in 2000, IVI's International Vaccinology Course is one of the longest-running vaccinology courses in the Asia-Pacific region. For more than 20 years, the course has trained nearly 5,000 vaccine professionals from LMICs worldwide, fostering collaborative partnerships in research and public health.

In September 2022, IVI's 21st International Vaccinology Course hosted 200 international trainees at IVI headquarters in Seoul and 20 trainees at Karolinska Institutet in Stockholm with the two sites connected through live streaming. The course included five days of lectures, interactive case studies, and site visits to local vaccine centers. IVI awarded Vaccinology Fellowships to 11 trainees to attend the course at IVI free of charge.

Collaborators

- Karolinska Institutet, Sweden

Funders

- IVI Europe Regional Office
- Genexine
- Hilleman Laboratories
- Moderna
- Sanofi
- SK bioscience
- Valneva
- Vaccine Innovative Technology Alliance Korea (VITAL)-Korea



International Vaccinology Course participants at Karolinska Institutet in Stockholm, Sweden.



The 21st International Vaccinology Course in session in Seoul, Republic of Korea.

Project 2

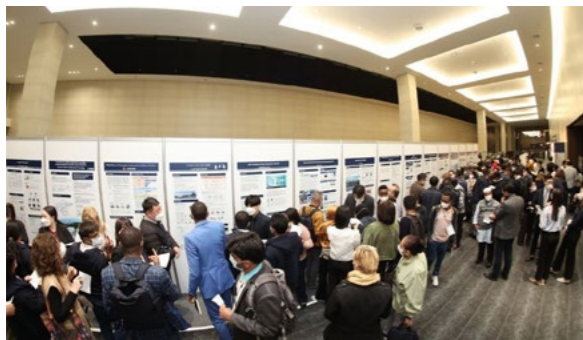
Global Training Hub for Biomanufacturing (GTH-B) program

In February 2022, IVI was designated by the Ministry of Health and Welfare, Republic of Korea as the operator of the 2022 Global Training Hub for Biomanufacturing (GTH-B) program to provide workforce training in vaccine and biologics R&D and manufacturing for students and professionals from low- and middle-income countries and Korea.

Funders

- Ministry of Health and Welfare, Republic of Korea

IVI successfully completed the 2022 Introductory Course for Biologics Development and Manufacturing in July to train 106 participants from 24 LMICs and 32 from Korea, and the Introductory Course for Standard Practice (GxP Course) in November to train 200 trainees from 33 LMICs and 42 from Korea. On-site consultation meetings were also provided to Incepta of Bangladesh in July and Afrigen (mRNA Tech Transfer hub) of South Africa in November.



Trainees participate at the poster presentation in the Mini Convention that brought together leading biotech companies in Korea during the 2022 Introductory Course for Standard Practice in November.



IVI conducted on-site consultation for Afrigen Biologics & Vaccines (Afrigen) at the company's headquarters in Cape Town, South Africa on December 7 – 8. Credit: IVI



The 2022 Introductory Course for Biologics Development and Manufacturing was held in July as the first course of the Global Training Hub for Biomanufacturing initiative to help strengthen LMIC's capacity in production of vaccines and biological products. Credit: IVI

Project 3

Fellowship programs with partner institutes

IVI provides fellowships to strengthen vaccine workforces around the world.

In January 2022, IVI and Thailand's National Vaccine Institute (NVI) signed a Definitive Agreement to strengthen our partnership. As part of this agreement, a fellowship program was launched and two vaccine technical officers from NVI were seconded to IVI for a fellowship from September to December for training and collaboration.

In July 2021, Ghana's Kwame Nkrumah University of Science and Technology (KNUST)-IVI Collaborating Center opened to expand collaboration and introduced a fellowship program. In 2022, a PhD candidate received support for his research in clinical microbiology at KNUST.

Collaborators

- National Vaccine Institute, Thailand
- Kwame Nkrumah University of Science and Technology, Ghana

#IVI25YEARS

25 years of accelerating vaccines for global health

IVI trains and collaborates with talented investigators around the world to conduct vaccine research and development, building sustainable local capabilities, capacity, and infrastructure.

#IVI25 International Vaccine Institute 25

25 years of accelerating vaccines for global health

"IVI mobilizes cooperation between the public and private sectors to make progress on global goals, and to make available safe, effective, and affordable vaccines to protect against vaccine-preventable diseases in low- and middle-income countries."

Jerome Kim, M.D.
Director General, IVI

#IVI25 International Vaccine Institute 25

Publications

In 2022, IVI scientists authored or co-authored 71 articles in peer-reviewed scientific journals with 63 articles in the Scientific Citation Index Expanded.



71
articles

published in peer-reviewing scientific journals



63
articles

published in SCIE journals



Title	Authors from IVI	Journal
Progress in health among regions of Ethiopia, 1990-2019: a subnational country analysis for the Global Burden of Disease Study 2019	Tadesse BT	Lancet 2022/Apr. Pages 1322-1335
Heterologous versus homologous COVID-19 booster vaccination in previous recipients of two doses of CoronaVac COVID-19 vaccine in Brazil (RHH-001): a phase 4, non-inferiority, single blind, randomised study	Clemens R	Lancet 2022/Feb. Pages 521-9
Safety and immunogenicity of two recombinant DNA COVID-19 vaccines containing the coding regions of the spike or spike and nucleocapsid proteins: an interim analysis of two open-label, non-randomised, phase 1 trials in healthy adults	Seo SH, Song M	Lancet Microbe 2022/Feb
Estimating typhoid incidence from community-based serosurveys: a multicohort study	Jeon HJ, Haselbeck A, Park SE, Zellweger RM, Marks F	Lancet Microbe 2022/Aug. Pages e578-e587

Partnerships and Advocacy

Partnerships with the Korean Government



IVI and the Ministry of Health and Welfare of the Republic of Korea exchanged an MOU on April 1, 2022 to strengthen their partnership in promoting vaccine R&D and biomanufacturing training for low- and middle-income countries and Korea.



IVI and the Korea Disease Control and Prevention Agency exchanged an MOU on the Republic of Korea's state funding, strengthened cooperation on May 13, 2022.

AHRI-IVI Collaborating Center in Ethiopia

Left to right: Dr. Se Eun Park, H.E. Kang Seok-hee, H.E. Dereje Duguma, Mr. Seunghwan Yang, and Dr. Shallo Dhaba cut the ribbon to officially open the AHRI-IVI Collaborating Center in Addis Ababa, Ethiopia on May 23, 2022. IVI and AHRI also conducted a mass vaccination campaign in May to provide 100,000 Ethiopians with oral cholera vaccine, aligned with Ethiopia's health policy of 'Ending Cholera – A Global Roadmap to 2030'.



IVI's collaboration with Smilegate to vaccinate against cholera in Nepal

In May 2022, IVI launched a campaign with support from the global mobile gaming company SmileGate in Korea and Nepalese partners to vaccinate 28,000 people against cholera in the Rupani Rural Municipality of Nepal. The campaign aimed to prevent and control outbreaks that have worsened since October 2021, contributing to great pressure on a health care system already impacted by the COVID-19 pandemic.

By using Euvichol-Plus® developed by IVI and produced by the Korean vaccine manufacturer EuBiologics, the campaign also assessed the potential of a self-administration strategy for the second dose of oral cholera vaccine.



A child receives oral cholera vaccine during a vaccination campaign in Rupani, Nepal.



Workshop to advance multisectoral and multidisciplinary collaboration for vaccine research in Africa



In July 2022, long-time collaborators of IVI's Epidemiology, Public Health, and Impact (EPIC) projects had the opportunity to gather at IVI headquarters for the first time, reflecting on past achievements and strategizing the way forward for multisectoral and multidisciplinary collaboration for vaccine research in Africa.

Participating partners

- Kwame Nkrumah University of Science and Technology
- Institut National de Recherche Biomédical
- University of Antananarivo
- Instituto Nacional de Saúde
- Institut Supérieur des Sciences de la Population
- Heidelberg Institute of Global Health
- University of Cambridge
- Coalition for Epidemic Preparedness Innovations

Denmark's core contribution to IVI



The Danish Minister for Health, H.E. Magnus Heunicke, visited IVI on August 30, 2022 and announced Denmark's contribution of four million DKK to IVI for 2022. As part of the Health Minister's visit, the Embassy of Denmark in Korea and IVI organized a seminar around vaccine solutions for pandemic preparedness and antimicrobial resistance.

IVI's State Forum 2022: 25th anniversary and Global Council introduction



IVI hosted its annual State Forum on October 21, 2022, gathering collaborators and State Parties in Seoul. This year's forum focused on the creation of IVI's Global Council, launching in 2023 as a representative body of State Parties and other key stakeholders to discuss needs and solutions for vaccine R&D and implementation, vaccine equity and access, and capacity-building at global, regional, and national levels. During the State Forum, IVI's Director General, Dr. Jerome Kim, also advocated for the addition of leptospirosis to the World Health Organization's list of Neglected Tropical Diseases.

World Vaccine Congress Europe

IVI had a booth at the World Vaccine Congress Europe held in October 2022 in Barcelona, promoting the recently launched IVI Europe Regional Office in Sweden and Global Training Hub for Biomanufacturing program.



Signed agreement to open IVI Country Office in Austria

Dr. Jerome Kim, IVI's Director General and H.E. Wolfgang Angerholzer, Ambassador of the Republic of Austria to the Republic of Korea, signed a Seat Agreement to host an IVI Country Office in Vienna. The office began operations in November 2022 and will work together with the Austrian government and partners in industry, academia, and research institutes to develop and execute vaccine R&D and capacity-building projects.

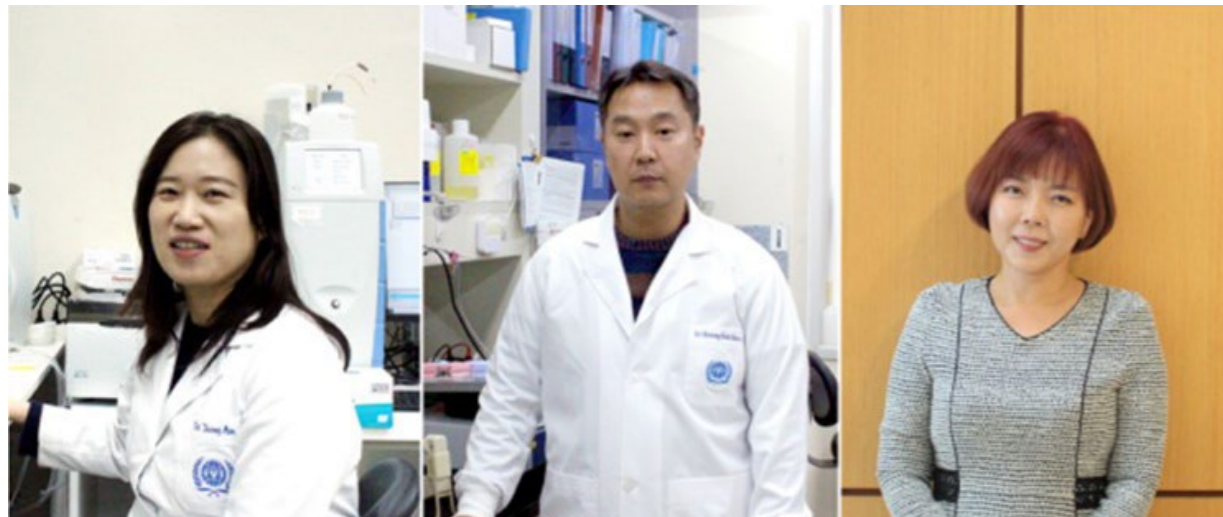


SK bioscience's donation to IVI to support global R&D

SK bioscience made a philanthropic grant for R&D to IVI on November 16. From left: SK Discovery Vice Chairman Chang-won Chey; SK bioscience President Jae-yong Ahn; Dr. B.G. Rhee, Chairman of the Korea Support Committee for IVI; and IVI Director General Dr. Jerome Kim.



IVI scientists awarded by the Korean Government



Dr. So Jung An, Research Scientist in the Vaccine Process Development department of IVI's Science Unit, Dr. Byoung Shik Shim, Research Scientist in Science, and Ms. Alice Lee, IVI's Business Development Director, received the Korean Health and Welfare Minister's Prize for their contributions to the Korea Global Vaccine Hub initiative in December 2022.

IVI also received the Korean Trade, Industry and Energy Minister's Prize in recognition of its efforts to strengthen biosecurity management in December 2022. This prize honors companies and organizations that have demonstrated an outstanding contribution to security management of biological agents over the past three years. This came after IVI's received the Korean Health and Welfare Minister's Prize for excellence in biosafety in 2020.

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Director General



Francois Belin, M.Sc.
Chief Operating Officer



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Deputy Director General
Government & Public Relations



Florian Marks, Ph.D.
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Manki Song, Ph.D.
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Science



Anh Wartel, M.D.
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In 2022, IVI launched its Global Advisory Group of Experts (GAGE) chaired by Dr. Deborah Birx to advise IVI on matters of global health and diplomacy. Other founding GAGE members include Dr. Anders Nordström (Vice Chairperson), Dr. Agnès Buzyn, Dr. Carla Vizzotti, Dr. Kyung-wha Kang, Dr. Samba Sow, and Dr. Yasuhiro Suzuki.
Credit: IVI



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We thank our donors and partners whose support makes our work possible



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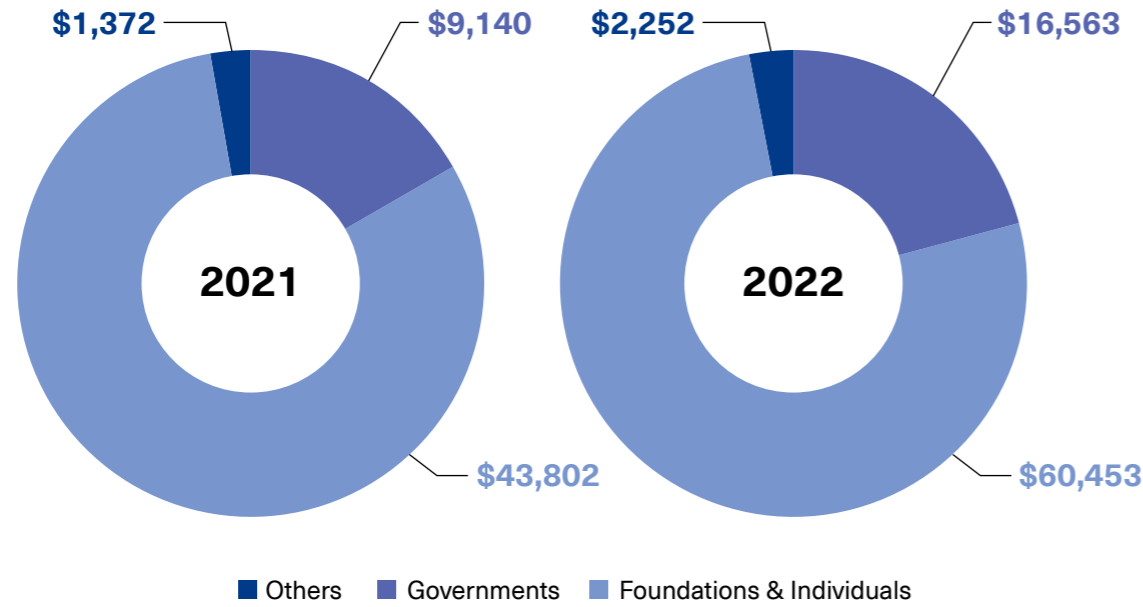
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Professor, Seoul National University

2022 Financial Summary

Revenue (Grants and contribution)

	2021	2022
Governments	9,140	16,563
Foundations & Individuals	43,802	60,453
Others	1,372	2,252
Total Revenue	54,314	79,267



Assets

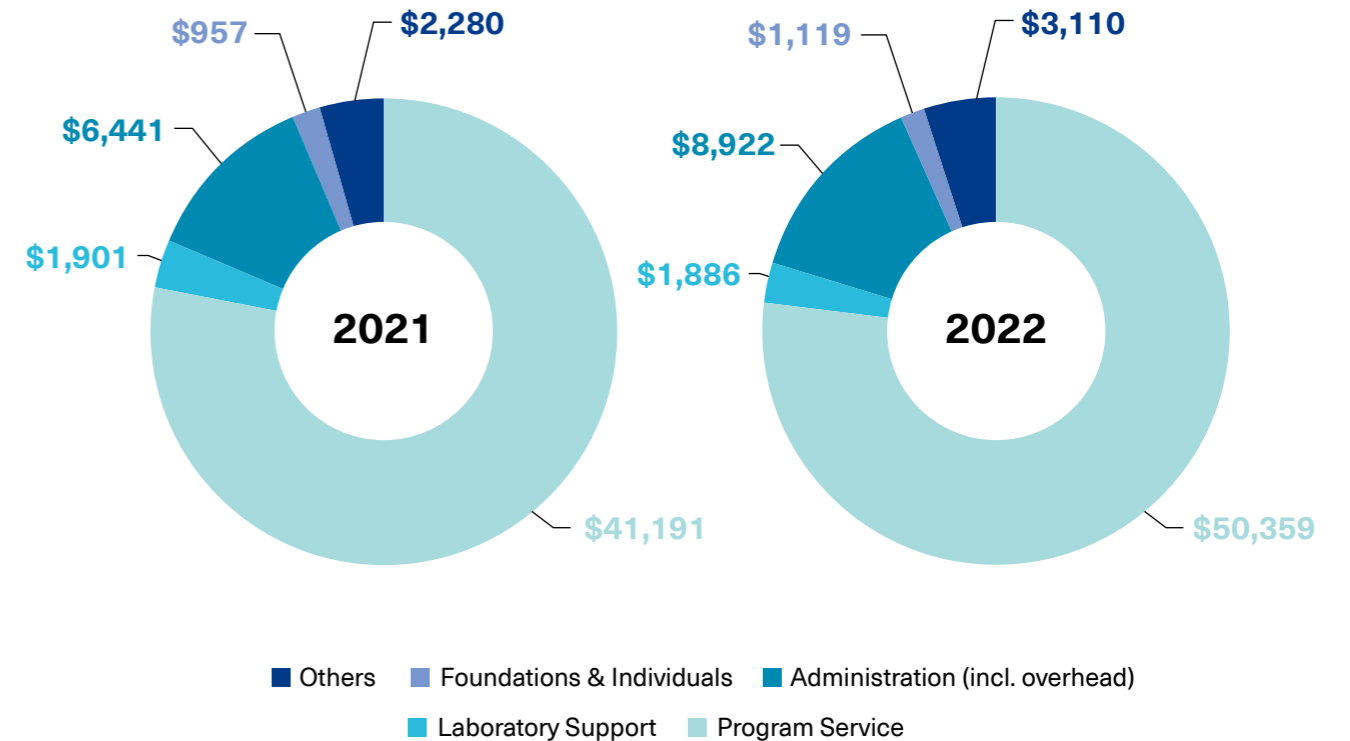
	2021	2022
Cash and Bank Deposit	40,627	55,039
Contribution receivable	11,705	11,072
Fixed Assets	18,403	19,301
Other	877	1,323
Total Assets	71,612	86,736

Liabilities and Net Assets

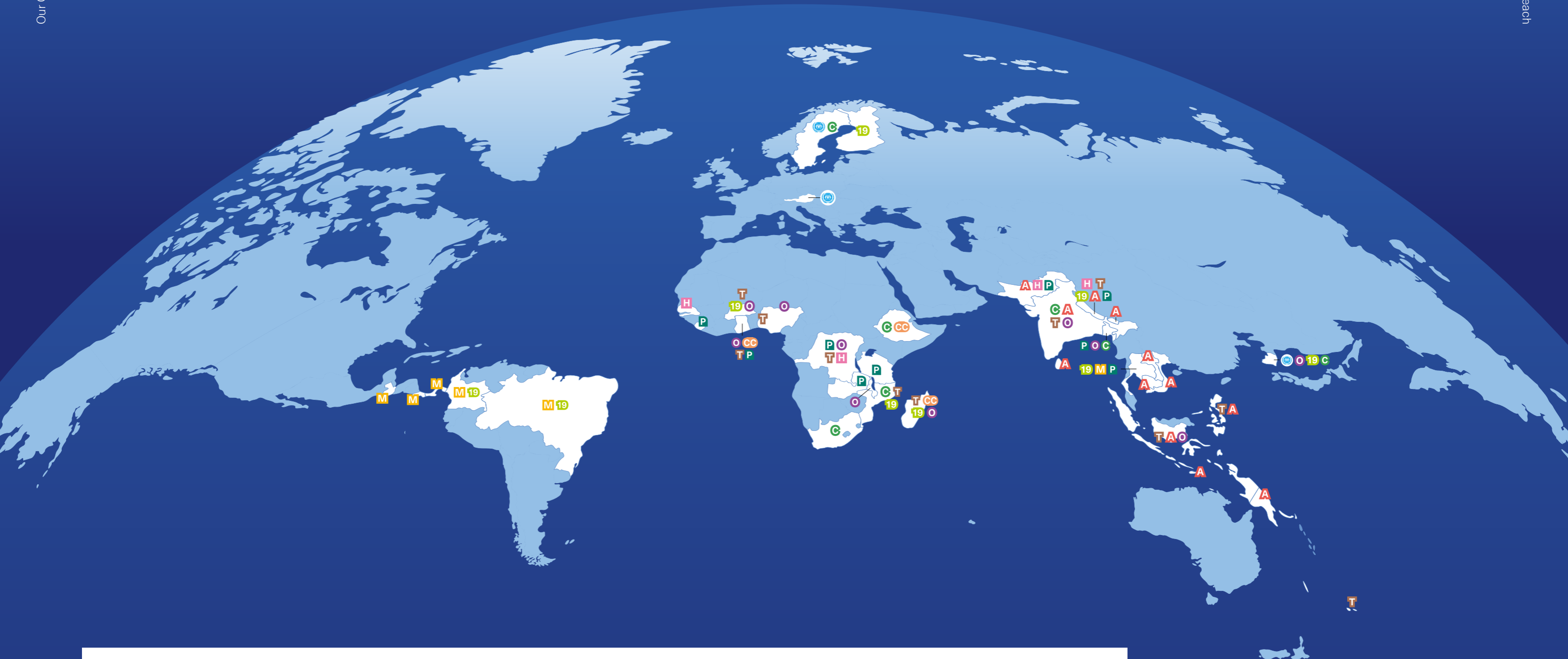
	2021	2022
Liabilities	4,860	6,113
Net Assets	66,751	80,623
Total Liabilities and Net Assets	71,612	86,736

Expenses

	2021	2022
Program Service	41,191	50,359
COVID19	17,259	24,598
Cholera	4,161	5,145
Chikungunya	4,018	2,947
Typhoid	3,748	2,892
HPV	799	795
Others	11,207	13,983
Laboratory Support	1,901	1,886
Administration (incl. overhead)	6,441	8,922
Fundrasing & Advocacy	957	1,119
Others	2,280	3,110
Total Expense	52,770	65,396



Our Global Reach



40 State Parties/Signatory Countries				IVI Programs
Bangladesh	Jamaica	Oman	Spain	Cholera
Bhutan	Kazakhstan	Pakistan	Sri Lanka	Typhoid
Brazil	Kyrgyzstan	Panama	Sweden	AMR
China	Lebanon	Papua New Guinea	Tajikistan	Mosquito: Dengue, Chikungunya
Ecuador	Liberia	Peru	Thailand	Hepatitis E
Egypt	Malta	Philippines	Turkey	Other
Finland	Mongolia	Republic of Korea	UAE	COVID-19
India	Myanmar	Romania	Uzbekistan	Collaborating Center
Indonesia	Nepal	Rwanda	Vietnam	HPV
Israel	Netherlands	Senegal	World Health Organization	

Vaccines for a Healthier Future

2022 Annual Report



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