Vaccines for a Healthier Future

Annual Report 2023

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.

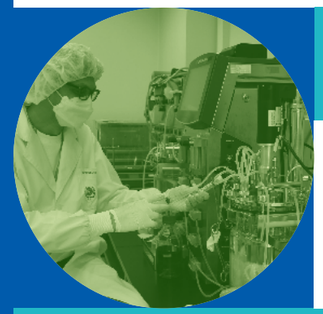
International Vaccine Institute

IVI is an international organization with a mission to discover, develop, and deliver safe, effective, and affordable vaccines for global health. We focus on vaccines for poverty-associated infectious diseases that kill or cause severe illness in millions of people every year, mostly in low- and middle-income countries.

IVI has the skills, knowledge, and resources to work along the entire vaccine value chain: from epidemiological studies establishing the burden of an infectious disease through the discovery of new vaccines in the laboratory, demonstrating efficacy in Phase I-III trials, securing regulatory approval, and demonstrating impact through effectiveness studies in real-world settings.

Discover

Our laboratories are equipped with microbiological, immunological, and genomic containment facilities as well as animal facilities and teams with expertise across molecular biology, microbial genetics, bioinformatics, and immunology. Through our laboratory capacity, IVI improves existing vaccines and identifies new candidates for research and clinical development.



Develop

We lead Phase I-IV clinical trials and partner with qualified manufacturers from low- and middle-income countries to transfer vaccine technology and know-how. Through technology transfer and training, we enable manufacturers to lead the vaccine development process and assist them through regulatory approvals.

Deliver

We facilitate the introduction of newly licensed vaccines in countries where they are needed, through vaccination campaigns and implementation research, generating scientific data on the need for vaccines and the potential impact of vaccination on population health and economies.

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IVI creates public-private partnerships among governments, companies, research institutions, and the philanthropic community that greatly reduce the costs of developing vaccines to tackle neglected and emerging global health threats.

Last updated April 30, 2024

1997
Established in 1997 at the initiative of the UNDP

BSL3+
Biosafety level 3 enhanced (BSL3+) laboratories at headquarters

40 countries
40 countries and WHO as member states

2 vaccines developed for global health
- Oral cholera vaccine
- Vi-DT typhoid conjugate vaccine

50+ countries
Research collaborations in 50+ countries across 6 continents

9 infectious diseases
Vaccines for 9 infectious diseases of global health importance in clinical trials

WHO prequalification
Led clinical development for 5 vaccines with WHO prequalification

1,400+
More than 1,400 published journal articles

830+ professionals trained in-person
Through the Global Training Hub for Biomanufacturing

40+
More than 40 clinical trials sponsored by IVI since 2005

5,000+
Professionals from LMICs trained through IVI's annual International Vaccinology Course

2,100+ professionals trained online
Through the Global Training Hub for Biomanufacturing

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Reflections on 2023

Dear friends and colleagues,

On behalf of the IVI team, thank you for another year of invaluable support and collaboration. In 2023, IVI and our global network of partners were able to advance the discovery of new vaccines, conduct clinical trials and license vaccines for emergent diseases like COVID-19 and highburden endemic diseases like typhoid, organize technical training programs around the world to better prepare for future pandemic threats, and bring together stakeholders from across sectors to rigorously engage in whole-of-society solutions to global health challenges.

2023 was a validation of IVI's 5-year strategy, launched in 2022, which focuses on amplifying IVI's core strengths and capabilities, scaling our global footprint, and future-proofing governance. We proudly share an annual report that highlights IVI's major achievements across these strategic initiatives as well as our growing portfolio of infectious disease research and vaccine R&D. In our laboratories, we are developing an mRNA vaccine platform against Lassa fever alongside a practical effort to boost clinical trial capacity and disease outbreak readiness for Lassa fever and other viral threats in West Africa. In Fiji and Madagascar, we launched a government-supported vaccination campaign and vaccine effectiveness study, respectively, to assess the impact of typhoid vaccination in communities at risk of this deadly enteric disease.

In an effort to incorporate the perspectives of IVI's member states into our governance structure as well as our new initiatives, we formed the Global Council, a representative body composed of IVI's State Parties, and held its first meeting in October 2023. Following the inaugural session, the country delegates aligned around a Joint Statement that calls for global solidarity in preparing against emerging and endemic infectious diseases while welcoming IVI's intention to build up its presence in the African continent and recommending to the IVI Board of Trustees the establishment of an end-to-end ecosystem spanning vaccine research, development, and training with sustainable manufacturing in Africa as its final goal. We now call this concept the Advancing Vaccine End-to-End Capabilities in Africa (AVEC Africa) project. At the encouragement of the Global Council and the Board, we are excited to implement this project on the ground with regional and local partners.

IVI's technology transfer with Biovac is an important and successful proof-of-concept of the AVEC Africa model. In 2023, we completed the technology transfer of simplified oral cholera vaccine (OCV-S) to the South African manufacturer while training and supporting technicians every step of the way. This technology transfer may culminate in the first instance of end-to-end vaccine production on the African continent which is not only a significant step forward for regional vaccine security but for the global cholera vaccine supply, which remains alarmingly low in the face of an unprecedented number of cholera outbreaks around the world. In 2023, we celebrated the 10th anniversary of the creation of the OCV global stockpile during an annual Global Task Force for Cholera Control meeting held at IVI while acknowledging the myriad of present-day challenges related to vaccine supply and delivery. In this regard, IVI continues to advance a comprehensive vaccine and disease control program for cholera and other poverty-associated infectious diseases which includes the development of new vaccines, technology transfer to manufacturers like Biovac for wide-scale vaccine production and working with policymakers and other stakeholders to make sure these vaccines are not only accessible, but also used.

Throughout the year, IVI organized and participated in conferences and stakeholder meetings at the highest levels as well as very local levels, from the World Health Assembly to workshops gathering regional collaborators working at the intersection of infectious disease prevention and climate resilience. We remain steadfast that equity in global health requires the active and integrated participation of government, industry, academia, civil society, and individuals. It is through these public-private partnerships that we are able to celebrate the national licensures of three new vaccines this year (SKYCovion™ COVID-19 vaccine, SK bioscience; Bio-TCV® typhoid conjugate vaccine, Bio Farma; and Euvichol-S, EuBiologics). It is through these partnerships we can make progress on our mission to accelerate vaccines for global health. Thank you.

With gratitude,

Jerome H. Kim, MD
Director General

Vaccines for a Healthier Future
Reflections on 2023

2023 Highlights

01

Launched a typhoid vaccination campaign and study in Fiji and Madagascar

As a component of the Typhoid in Fiji – Vaccination towards Elimination (Ty-FIVE) and Typhoid Conjugate Vaccine Introduction in Madagascar (TyMA) projects, IVI led vaccinations using typhoid conjugate vaccine in the Northern District of Fiji and the Arivonimamo and Antananarivo-Atsimondrano districts of Madagascar in partnership with ministries of health and partner organizations to protect communities and assess the impact of vaccination in controlling typhoid.

The Ty-FIVE consortium hosted a ceremony to mark the launch of a mass vaccination campaign against typhoid in the Northern Division on July 3, 2023. Credit: IVI

02

Three vaccines approved by national regulatory authorities including one on WHO's Emergency Use Listing (EUL)

WHO's Emergency Use Listing adds SKYCovion™ COVID-19 vaccine. Credit: SK bioscience

Based on strong results of an IVI-led global Phase III trial, SK bioscience's COVID-19 vaccine SKYCovione™ has been listed on the WHO EUL following its full marketing authorization in the UK. Another partner of IVI, Bio Farma's Bio-TCV® typhoid conjugate vaccine, initially developed at IVI and transferred to Bio Farma in 2014, was licensed in Indonesia following marketing approval from the national regulatory authority, BPOM. Additionally, EuBiologics' Euvichol-S, a simplified formulation of the oral cholera vaccine, was licensed for export by the Korean Ministry of Food and Drug Safety. The licensure of Euvichol-S is the culmination of a comprehensive Phase III clinical trial conducted by IVI and paves the way for a potential solution to the critical shortage of OCV worldwide.

03

Completed the Phase I clinical trial of a novel cholera conjugate vaccine (CCV)

In partnership with investigators at Massachusetts General Hospital-Harvard University, IVI conducted a Phase I trial of a first-of-kind cholera conjugate vaccine in the Republic of Korea. The promising safety and immunogenicity results have led to proposals for Phase II funding.

04

Began clinical development of DuoChol, a new low-cost oral cholera vaccine in capsule form

With funding support from the Wellcome Trust and the Government of Sweden, IVI is partnering with NorthX Biologics, Sweden and Gotovax AB to conduct a Phase I clinical trial of DuoChol, a capsule oral cholera vaccine, developed by scientists at the University of Gothenburg. With its thermostability and light-weight presentation, DuoChol has the potential to simplify vaccine storage and delivery, contributing to more effective and efficient vaccination campaigns in outbreak and endemic settings.

05

Supported development of microneedle array patch (MAP) for delivery of Measles-Rubella (MR) vaccine

IVI is leading the establishment of animal models for MR vaccine challenge studies, optimization and validation of serological assays, and assessment of immunogenicity and efficacy of MR-MAP candidates in a joint study with QuadMedicine and Yonsei University. The aim is to develop and expand global access to MR vaccine using new-generation MAP technology, an easy-to-use method of vaccine delivery with minimal discomfort.

06

Expanded capacity-building initiatives to strengthen resilience and sustainability of vaccine ecosystems in LMICs

IVI continues to lead professional trainings in partnership with governments, global health agencies, research institutes, and industry, including the 22nd edition of IVI's flagship International Vaccinology Course, 2023 Global Training Hub for Biomanufacturing courses, KOR-IDB Biomanufacturing Training, and Hands-on Training for Upstream Process in Vaccine Manufacturing, to build a skilled and experienced vaccine manufacturing workforce in low- and middle-income countries (LMICs).

Dr. Jerome Kim, Director General of IVI, gives the opening lecture "History of Vaccines" on the first day of the 22nd International Vaccinology Course in Seoul, Korea. Credit: IVI

Witnessed by the Secretary for Health of the HKSAR Government Professor Lo Chung-mau (back row, center); Club Chairman Michael Lee (back row, 2nd right); Pro-Chancellor of HKU and Founding Chairman of the Friends of Cambridge University in Hong Kong Dr the Hon Sir David Li (back row, 1st right); the Chairman of the Council of HKU Priscilla Wong (back row, 2nd left); and the Chairperson of the Board of Trustees of the IVI George Bickerstaff (back row, 1st left), the MOU was signed by Club CEO Winfried Engelbrecht-Bresges (front row, 2nd right); the President and Vice-Chancellor of HKU Professor Xiang Zhang (front row, 2nd left); Regius Professor of Physic and Head of the School of Clinical Medicine of the University of Cambridge Professor Patrick Maxwell (front row, 1st right) and the Director General of the IVI Dr Jerome Kim (front row, 1st left). Credit: HKJC

07

Signed an MOU for the establishment of the Global Health Institute in partnership with the University of Cambridge, University of Hong Kong, and the Hong Kong Jockey Club

IVI is excited to co-found the Hong Kong Jockey Club Global Health Institute, a new hub for vaccine science and education, translational vaccine research, cultivation of cutting-edge technologies to strengthen pandemic preparedness and regional prevention and control of infectious diseases.

Presented the 2023 IVI-SK bioscience Park MahnHoon Award and IVI Founders Medal

Drs. Rino Rappuoli and Mariagrazia Pizza and Profs. Sir Andrew Pollard and Dame Sarah Gilbert received the second Park MahnHoon Award for their extraordinary contributions to the development of crucial vaccines for global health. On the occasion of IVI's 26th anniversary, Dr. Richard Mahoney received the IVI Founders Medal in recognition of his pivotal role in IVI's establishment and growth.

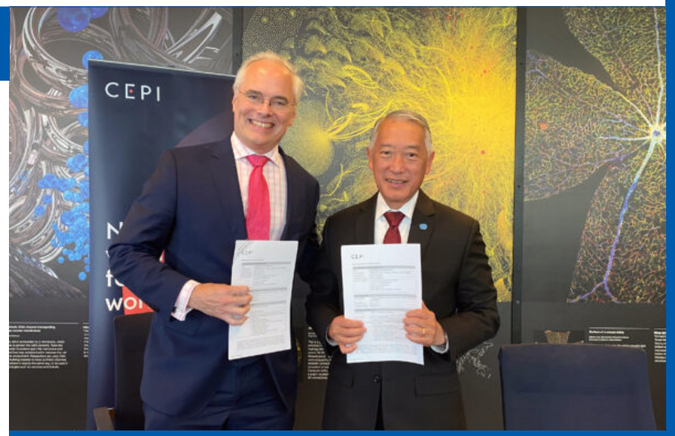
08

Three of the awardees pose for a commemorative photo with key participants during the 2023 IVI – SK bioscience Park MahnHoon Award at IVI headquarters in Seoul, Korea on April 25. From left: SK bioscience CEO Jaeyong Ahn, H.E. Federico Failla, Italian Ambassador to Korea, IVI Director General Dr. Jerome Kim, Dr. Mariagrazia Pizza, Prof. Sarah Gilbert, Dr. Rino Rappuoli, Prof. Hong-lim Ryu, President of Seoul National University, Mr. Gareth Weir, Deputy Head of the UK Mission to Korea. Credit: IVI

09

Renewed partnership with CEPI to accelerate vaccines against emerging infectious diseases

Under the renewed CEPI-IVI Implementing Partnership Agreement, IVI will provide an array of technical services for CEPI-funded projects across the vaccine value chain to help accelerate vaccine development against pathogens with epidemic or pandemic potential in support of the 100 Days Mission.



Dr. Richard Hatchett, CEO of CEPI (left), and Dr. Jerome Kim, Director General of IVI (right), during the partnership signing ceremony. Credit: CEPI

Steered global coalition-building to advance development and availability of safe, effective, and affordable vaccines against Group A Strep *(Streptococcus pyogenes)* and chikungunya

IVI launched SAVAC 2.0, a continuation of the Strep A Vaccine Global Consortium formed to enact the Strep A vaccine R&D roadmap. In Panama, IVI and Gorgas Memorial Institute for Health Studies co-organized the first global stakeholder meeting to identity the current standing of chikungunya vaccines in development, gaps ahead of their availability and accessibility, and ways forward to address these gaps.

10

IVI and Gorgas Institute organized the first Chikungunya Global Meeting in Panama City, Panama from December 12-13, 2023. Credit: IVI

11

Initiated hepatitis E vaccine studies for the health and wellbeing of women and children

IVI secured funding and approval for two studies of Hecolin® hepatitis E vaccine: a safety and immunogenicity study in pregnant women in Pakistan, aiming to enhance available safety information, and a study to evaluate the immunogenicity and safety of this hepatitis E vaccine in children and HIV-positive populations in South Africa. Both studies are co-funded by the Bill & Melinda Gates Foundation and Open Philanthropy.

12

Hosted a side event at the 76th World Health Assembly with the Government of the Republic of Korea

IVI and the Korean Ministry of Health and Welfare hosted an event on the sidelines of WHA76 with co-sponsoring countries Brazil, Ghana, Kenya, Rwanda, Sweden, and Thailand. The event brought together ministers of health, and global health and immunization leaders to discuss needs for a skilled and sustainable global biomanufacturing workforce and infrastructure.

Empowering local biomanufacturing: How to equip countries for current and future infectious disease outbreaks brought together ministers of health and global health and immunization leaders to discuss needs for a global biomanufacturing workforce and infrastructure. Credit: IVI

13

14 representatives of the IVI Global Council attended the inaugural meeting from October 19-20, 2023. Credit: IVI

Launched the IVI Global Council with a joint statement for stronger global vaccine ecosystems and end-to-end vaccine R&D capacity in Africa

IVI convened the inaugural meeting of its Global Council, a new advisory body composed of State Party representatives. In a Joint Statement, the Global Council called for global solidarity in preparing against emerging and endemic infectious diseases and supports the establishment of an end-to-end vaccine R&D and manufacturing model to strengthen vaccine capacity and security across the African continent.

The Ambassador of Panama to the Republic of Korea, H.E. Athanasio Kosmas Sifaki, raises the flag of Panama during the Ratification Ceremony. Credit: IVI

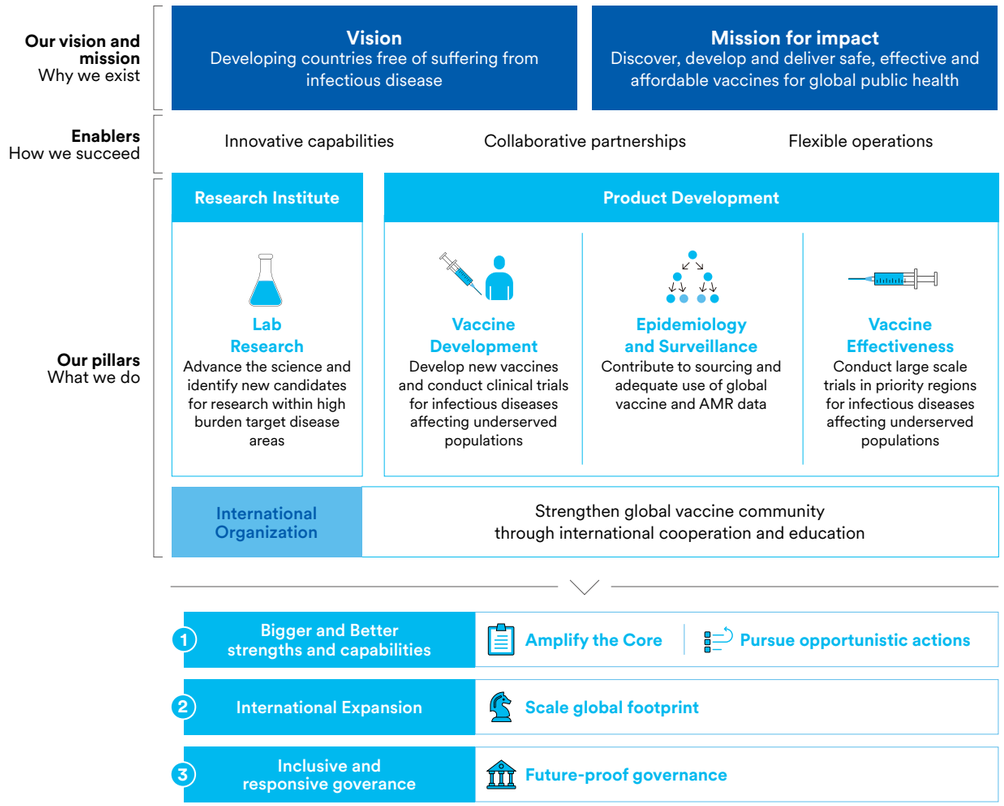
14

Welcomed the Republic of Panama as a State Party of IVI

IVI hosted a ceremony at Headquarters in recognition of Panama ratifying IVI's Establishment Agreement and becoming a State Party. The ceremony brought together diplomats of Latin American and Caribbean countries in celebration of Panama's full membership.

IVI's Strategic Roadmap 2022-2026

Framework for IVI's strategic roadmap 2022-2026



IVI has made significant progress across each strategic pillar in 2023:

Amplify the Core (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. In 2023, IVI achieved notable milestones in various research grants, including the WHO Emergency Use Listing (EUL) for SK Bioscience's COVID-19 vaccine, based on compelling results from an IVI-led global Phase III trial; pending WHO prequalification of two typhoid conjugate vaccines produced by SK bioscience and Bio Farma; a typhoid vaccination campaign and study in Fiji and Madagascar; the HPV Single Dose Impact Study, and the HPV Global Burden Study.

Furthermore, IVI has expanded its grant portfolio to encompass major new research initiatives, including studies on Sanofi's COVID-19 and RSV vaccine candidates, the Global Chikungunya Vaccine Clinical Development Program, safety and immunogenicity evaluations of hepatitis E vaccine in vulnerable populations, the Strep A Vaccine Global Consortium 2.0, and other projects dedicated to advancing global health research and development efforts.

Scale the Global Footprint (International Expansion)

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 regional and country levels. In 2023, the IVI Board of Trustees approved the establishment of two new offices: the Hong Kong Jockey Club Global Health Institute, funded by the Hong Kong Jockey Club, in collaboration with Hong Kong University and the University of Cambridge, and the IVI Africa Regional Office to enhance IVI's global health impact through project-driven end-to-end vaccine programs in Africa. The inauguration of the African Regional Office is planned for 2024, while the IVI Europe Regional Office (IERO) continues to expand through the support of the Swedish Government.

Future-proofing Governance (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. IVI held its first Global Council meeting in October 2023, attended by government representatives from both IVI State Parties and observing countries. At the meeting, the delegates endorsed IVI's role and program to strengthen African vaccine manufacturing capacity and advocated for global solidarity in fortifying the vaccine ecosystem on the continent.

IVI held its inaugural Global Council meeting in October 2023, establishing a new representative body for all of its State Parties. Credit: IVI

Vaccine R&D Portfolio

Research institute

Engaging in the development and testing of vaccines in laboratories and animal models.

Product development partnership

Undertaking process development, technology transfer, human clinical trials, epidemiology studies, and providing support to companies in navigating regulatory pathways. IVI collaborates with other global health agencies such as the WHO and Gavi to secure necessary approvals, recommendations, and ensure equitable access to vaccines.

International organization

Dedicated to supporting countries in formulating policies for vaccine development and implementation, advocating for equity and access, and fostering global capacity-building in vaccine development, testing, manufacturing, and implementation to improve global health.

IVI's current portfolio includes vaccines at all stages of preclinical and clinical development for infectious diseases that disproportionately affect LMICs. These diseases include cholera, typhoid, chikungunya, *Shigella, Salmonella,* schistosomiasis, hepatitis E, group A *Streptococcus,* HPV, COVID-19, and more.

What do we do?

IVI provides translational and support services to accelerate vaccine development

Vaccine Development Services*

Discover	Develop	Deliver	Epi. Surveillance
Preclinical Study & Support · Material production, test & release for toxicology studies · Protocol dev. · CMO/CRO identification	**Assay Validation & Clinical Samples Evaluation** · Critical assay development & optimization · Method validation according to ICH guidelines · Clinical sample evaluation in GCLP lab	**Health Economic Study** · Field-based data collection incl. costing & willingness to pay · Global/country analyses incl. invest., budget impact, cost-effectiveness, demand & disease burden	**Epidemiology/ Observational Study Support** · Protocol dev. incl. definition of endpoint, bio investigation, & database · Prevalence & incidence est. of infection/disease severity · Data for decision on vaccine introduction · Site preparedness for Ph.3 trial & effectiveness study
Process & Analytical Dev. · Scalable & optimized processes for candidate Ag · Analytical methods for qual. testing · In vivo animal studies	**Tech Transfer Support** · Candidates & process transfer to CMOs & stability plan dev.	**Policy & Advocacy Research**	**AMR Monitoring** · AMR assessment & public database creation
	Mfg. Support · Process scale-up & ensuring of commercial-scale mfg. & vaccine candidate supply	**Modeling** · Vaccine impact & disease risk mapping etc.	**Vaccine Impact & Effectiveness Study** · Mass vaccination campaign · Vaccine intro through health authorities · Real-life vaccine performance assessment
	Clinical Dev. & Regulatory Support · IPDP & CDP development · Clinical trial implementation & management in HIC & LMIC · Regulatory affairs consultation		

Diseases

· iNTS · Group A strep · SFTSV · *Shigella* · Hepatitis A, B	· Tuberculosis · HAdV-55 · COVID-19 · Paratyphoid A · Zika	· Hantavirus Pulmonary · Syndrome (HPS) · Lassa fever · MERS	· Invasive Nontyphoidal *Salmonella* (iNTS) · MERS-CoV · Chikungunya · Schistosomiasis	· Typhoid · COVID-19 · Cholera · Micro-needle array (MAP) Hep-B	· Human Papilloma Virus (HPV) · Hepatitis E · Cholera · COVID-19	· Typhoid · Cholera · COVID-19 · RSV	· GAS · *Shigella* · AMR

Cross-Functional Activities

IVI develops and supports: · Translational Hubs · Innovation Vaccine Research Centers · Training and Capacity building · Project Management

Signatories and Parties of the IVI Establishment Agreement

(as of December 31, 2023)

Bangladesh	Bhutan	Brazil	China	Ecuador
Egypt	Finland	India	Indonesia	Israel
Jamaica	Kazakhstan	Kyrgyzstan	Lebanon	Liberia
Malta	Mongolia	Myanmar	Nepal	Netherlands
Oman	Pakistan	Panama	Papua New Guinea	Peru
Philippines	Republic of Korea	Romania	Rwanda	Senegal
Spain	Sri Lanka	Sweden	Tajikistan	Thailand
Türkiye	United Arab Emirates	Uzbekistan	Viet Nam	World Health Organization

Map of Project Host Countries

Vaccines for a Healthier Future
Member States

Europe Regional Office

Vaccines for a Healthier Future

The IVI Europe Regional Office (IERO) is based in Stockholm, Sweden. As IVI's first regional office beyond its headquarters in Seoul, Republic of Korea, IERO aims to bolster the life science and global health networks in Sweden and Europe, engaging stakeholders across research centers, academia, industry, and government to identify and pursue potential areas of collaboration. Due to its regional advantage, IERO also enables more effective engagement with our collaborators in Africa, where IVI has helped build an extensive network of disease surveillance and clinical trial sites.

The establishment of IERO and its activities are made possible through funding support from the Swedish Government. Since the start of operations in September 2022, IERO has launched two vaccine research and development projects with grants from European funders.

Additionally, IVI opened its Austria Country Office in November 2022 through funding support from the Federal Ministry for European and International Affairs of Austria. This country office interfaces with the Austrian Government and life sciences ecosystem, creating opportunities for joint vaccine R&D initiatives while supporting IERO with European outreach.

Strep A Vaccine Global Consortium (SAVAC) 2.0: Paving a Path for Development of a *Streptococcus* A Vaccine

In November 2023, IVI and consortium partners launched SAVAC 2.0 as a continuation of SAVAC, which ran from 2019 to 2023 and successfully developed a group A strep vaccine R&D roadmap, vaccine safety white paper, and Full Value of Vaccine Assessment, health economics studies, and a series of standardized surveillance protocols.

SAVAC 2.0 focuses on three workstreams: 1) Preparing for vaccine clinical trials, which includes the establishment of a sentinel site network and conducting a data linkage study; 2) preparing industry stakeholders by engaging with developers and manufacturers; and 3) preparing non-industry stakeholders such as WHO and country-level policymakers to facilitate eventual vaccine introduction.

Collaborators:

- Telethon Kids Institute, University of Western Australia
- Murdoch Children's Research Institute, Australia
- Shift Health, Canada
- Harvard T.H. Chan School of Public Health, USA
- Johns Hopkins Bloomberg School of Public Health, USA
- London School of Hygiene and Tropical Medicine, UK

Funders:

- Leducq Foundation, USA
- Open Philanthropy, USA
- Wellcome Trust, UK

The cause of strep throat, rheumatic scarlet fever, and rheumatic heart disease, group A *Streptococcus* (GAS) is one of the world's deadliest infectious diseases with an estimated 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.

In November 2023, IVI officially announced SAVAC 2.0, the next chapter of the Strep A Vaccine Global Consortium. Credit: IVI

Science

Vaccines for a Healthier Future

IVI's laboratory science division designs new vaccines, improves the formulation of existing vaccines, conducts preclinical studies, evaluates the safety and performance of promising vaccine candidates, develops technologies to support vaccine clinical testing in human, optimizes production processes in advance of industrial-level scale-up, and transfers vaccine technology to manufacturers. Technology transfer takes place on the condition that selected manufacturers produce high-quality vaccines at low cost in a country with a functional National Regulatory Authority accredited by WHO.

Our laboratories in Seoul are equipped with microbiological, immunological, and genomic containment as well as BSL-3, BSL-2, GCLP labs and animal facilities. Our teams specialize in molecular biology, microbial genetics, bioinformatics, and immunology.

The Science unit consists of eight core functions

- Molecular Immunology
- Animal Facilities
- Clinical Immunology
- Biosafety
- Translational Immunology
- Animal Research Lab
- Vaccine Process Development
- Project Administration

Vaccines in the discovery phase as well as other Science unit programs include

COVID-19

- Immunological analysis in clinical study
- Preclinical studies

Bacterial vaccines

- Trivalent Typhi-iNTS vaccine
- Bivalent Typhi-Paratyphi A vaccine
- *Shigella* vaccine

Virus vaccines

- Ad55 vaccine development
- Microneedle type influenza vaccine
- rVSV-based bivalent SFTS and HFRS vaccine
- Lassa mRNA vaccine

Others

- Systems serology
- Liposome-based adjuvant
- Support for WHO Training Hub for Global Biomanufacturing Workforce

IVI's Assay Portfolio

IVI's assay portfolio assists partners in evaluating vaccine candidates against locally prevalent pathogens, ensuring vaccines are tailored to specific populations and contexts. These assays are used to ensure the quality and consistency of vaccines produced around the world, particularly in LMICs, aligned with international standards.

Finally, these assays aid in disease surveillance by conducting diagnostic tests to monitor infectious disease prevalence across African settings, helping scientists identify emerging threats and prioritize vaccine development.

Validated | Quallfied | Being Qualfied | Established | In Progress

Pathogens		Binding antibody	Neutralizing antibody		Neutralizing antibody using pseudo-virus	Challenge model
SARS_Cov_2	Wu-Hu-1	ELISA	FRNT		Pseudo Neut	Animal challenge
	Alpha variant	ELISA	FRNT		Pseudo Neut	Animal challenge
	Beta variant	ELISA	FRNT		Pseudo Neut	Animal challenge
	Gamma variant	ELISA			Pseudo Neut	Animal challenge
	Delta variant	ELISA	FRNT		Pseudo Neut	Animal challenge
	Omicron variant (BA. 1)	ELISA*	FRNT		Pseudo Neut	Animal challenge
	Omicron variant (BA. 5)	ELISA	FRNT		Pseudo Neut	Animal challenge
Influenza	H1N1 (CA/04/09)	ELISA	MN	HI		Animal challenge
	H1N1 (PR8)		MN	HI		
	H1N1 (07/09)	ELISA	MN	HI		Animal challenge
	H3N2 (2/82/phillipines)	ELISA	MN	HI		Animal challenge
	H5N1 (NIBAG)		MN	HI		Animal challenge
	H5N2	ELISA	PRNT			Animal challenge
Zika virus	Brazil strain/2015	ELISA	PRNT			
	Thailand strain/2014	ELISA	PRNT			
	Philippines/2012	ELISA	PRNT			
MERS_Cov	EMC/2012	ELISA	PRNT			Animal challenge
	KNIH/002	ELISA	PRNT			Animal challenge
Adeno 55		ELISA	PRNT			Animal challenge
HBV		ELISA				
HAV		ELISA				
SFTSV		ELISA	FRNT			Animal challenge
HFRS	Hantaan virus	ELISA	FRNT			
CCHFV		ELISA			Pseudo Neut.	
JEV			PRNT			
RSV		ELISA				Animal challenge
Norovirus		ELISA	HBGA			
Pneumococcal		ELISA				Animal challenge
iNTS (currently only for preclinical)	ST strain	ELISA	SBA			Animal challenge
	SE strain	ELISA	SBA			Animal challenge
Nipah virus					Pseudo Neut.	
Ebola virus					Pseudo Neut.	
Lassa virus					Pseudo Neut.	
Cholera		ELISA	SBA			
Typhoid		ELISA	SBA			
Salmonella Paratyphi A (currently only for preclinical)		ELISA	SBA			

Cholera vaccines international standards and reagents

Since 2019, IVI has been working to ensure that internationally recognized critical standards and reagents are available to manufacturers and developers of low-cost oral cholera vaccine for Gavi markets.

This project involves the development of reference reagents for the coating of microtiter plates, reference reagents for detection use, and the establishment of one reference cholera vaccine. Once completed, these reference materials will be released by the National Institute for Biological Standards and Control (NIBSC), and the project partners will organize a collaborative study to evaluate WHO-developed international standards.

Collaborator
- NIBSC, UK
- EuBiologics, Republic of Korea
- Covance
- icddr,b, Bangladesh

Funder
- Bill & Melinda Gates Foundation, USA

Oral cholera vaccine reformulation

In 2019, IVI launched a project to simplify and reformulate OCV, which could potentially lower the cost of production by up to 20% and increase production capacity by 38%.

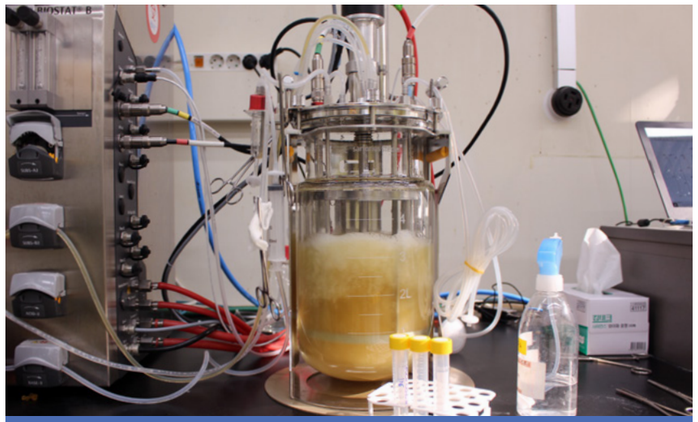
The OCV reformulation involves simplifying the vaccine formulation from five components to two and the inactivation process from two to one. IVI then conducted a Phase III pivotal clinical trial for the vaccine, Euvichol-S. The clinical trial to compare the simplified Euvichol-S to Shanchol™ was completed in October 2022, and the Korean Ministry of Food and Drug Safety licensed the vaccine for export on December 19, 2023. The vaccine is now under review for WHO prequalification.

Affordability and supply remain barriers to full access to OCV in cholera-burdened countries. Gavi considers OCV moderately cost effective at the current price (~$1.85/dose) and called for improved value for money to sustain or expand their investment.

Collaborator
- EuBiologics, Republic of Korea

Funder
- Bill & Melinda Gates Foundation, USA

Packaging of Euvichol-S. Credit: EuBiologics



A batch of OCV-S in the IVI laboratory. Credit: IVI

OCV-S technology transfer

IVI scientist walks through OCV-S technology transfer with colleagues from Biovac. Credit: IVI

In 2022, IVI initiated the technology transfer of simplified oral cholera vaccine (OCV-S) to South Africa's Biovac Institute in a landmark agreement which enables drug substance manufacturing—one of the remaining steps in the vaccine manufacturing value chain across Africa. The partnership aims to not only increase production volumes of OCV during a critical global shortage of vaccines but to establish and demonstrate capacity for Good Manufacturing Process and end-to-end production of vaccines in Africa, for Africa.

In 2023, the team successfully completed Phase I and II of the technology transfer, signing the report in December. The OCV-S manufacturing process technology transfer demonstrated that the process produces a product compliant with the expected quality attributes, paving the way for further development and scale-up.

The global health OCV supply and demand situation remains unstable, with EuBiologics operating as the sole supplier for the immediate future. Gavi's OCV demand forecast remains higher than the current supply. The inability to fulfill country-level requests for the vaccine from the global OCV stockpile is compounded by the climate change crisis, with a growing number of cholera outbreaks emerging alongside increased flooding and other extreme weather events in resource-constrained regions.

Collaborators
- The Biovac Institute, South Africa

Funder
- Bill & Melinda Gates Foundation, USA

Development of human adenovirus type 55 (HadV-55) vaccine

In 2023, IVI successfully completed the establishment of the HAdV-55 vaccine candidate production process, production of the preclinical sample, and the immunogenicity test of the pre-clinical test sample. Before the toxicity study, IVI had a pre-IND meeting with the Korea Ministry of Food and Drug Safety (KMFDS) and revised the toxicity study design based on the comments from KMFDS. Toxicity tests after one-shot immunization in rats and rabbits were completed, and there were no adverse events. After repeated immunization in rats and rabbits, toxicity tests were completed in December 2023.

In July 2023, IVI received a new $1.27 million USD grant from Korea's Ministry of Health and Welfare to assess the protection efficacy of the HAdV-55 vaccine in nonhuman primates and double transgenic mice.

HAdV-55 is a reemerging virus which causes acute respiratory disease with relatively high hospitalization and fatality rates. Outbreaks have occurred via community and household transmission, and in densely populated facilities like military training camps and refugee camps. HAdV-55 could have pandemic potential and no vaccine is currently available.

Collaborators
- Armed Forces Medical Research Institute, Republic of Korea
- Key Prime Research, Republic of Korea

Funders
- Korea National Institute of Health
- Ministry of Health and Welfare, Republic of Korea

Development of rVSV-SFTS/HFRS bivalent vaccine

Since 2022, IVI has been engaged in the preclinical development of a bivalent vaccine against severe fever with thrombocytopenia syndrome (SFTS) and hantavirus hemorrhagic fever with renal syndrome (HFRS).

In 2023, the optimal vaccine candidates for SFTS and HFRS were selected following the evaluation of the immunogenicity of vaccine candidates and the verification of their neutralizing antibody titers. In 2024, preclinical animal studies will begin for this vaccine.

Collaborators

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

Funder

- GyeongBuk and Andong City, Republic of Korea

SFTS is a zoonotic disease spread by ticks. The mortality rate for SFTS is high, with estimates in Korea of 18.4%. Climate change is spreading the global distribution of virus and there is no human vaccine available.

HFRS is a zoonotic disease transmitted from rodents to humans with approximately 150,000 cases every year and a mortality rate of 10%. A commercial vaccine (Hantavax®) is currently available, but it is less effective and requires 4 doses. Climate change is influencing the spread of hantavirus into new regions of the world.

Development and production of microneedle-based influenza vaccine for improving mucosal immunity

As part of IVI's programs to develop vaccines which can be delivered by microneedle array patch, IVI's Vaccine Process Development (VPD) team has undertaken development of a CTA1-based mucosal adjuvant for use with an influenza vaccine. The CTA-1 adjuvant has been evaluated in a mouse-model, with larger scale production of the adjuvant underway.

In addition to the influenza vaccine model, IVI is also developing hepatitis B, measles-rubella, and COVID-19 microneedle vaccines.

Since 2019, IVI and its partners have been developing a novel new vaccine delivery system that uses microscopic needles on a bandage-like patch to administer vaccines. Microneedle patches enjoy distinct advantages over traditional syringes, including easy and pain-free administration, thermal stability, light weight and small size, low-cost fabrication, and reduced environmental impact from disposal.

Collaborators

- Yonsei University, Republic of Korea
- Chungnam University, Republic of Korea
- Korea University, Republic of Korea
- QuadMedicine, Republic of Korea
- Il-Yang Pharmaceutical, Republic of Korea

Funder

- Ministry of Trade, Industry and Energy, Republic of Korea

Development and evaluation of an IVI liposome-based adjuvant

Since 2020, IVI and its partners have worked to develop and establish the basic production processes for the IVI liposomal-based adjuvant (ILA) and evaluate its characteristics. If the development of ILA is successful, this novel adjuvant could be used by IVI in the development of new conjugate vaccine platforms.

Ongoing studies have demonstrated ILA's safety in animal models, its temporal stability, and determined its dose dependent immunogenicity. Additional studies will characterize and optimize various formulations of ILA with other adjuvants.

Collaborators
- University of Helsinki, Finland
- Jeonbuk University, Republic of Korea
- Catholic University of Korea, Republic of Korea
- Korea Research Institute of Chemical Technology, Republic of Korea
- Korea Ginseng Corporation, Republic of Korea

Funders
- Ministry for Social Affairs and Health, Finland
- National Research Foundation of Korea

Development of a *Salmonella* Paratyphi A/Typhi bivalent vaccine through proof-of-concept (POC) in animals

2021, IVI initiated a proof-of-concept study to develop a bivalent S. Typhi/S. Paratyphi A vaccine with funding support from the Wellcome Trust. Through this project, IVI determined an optimal O-specific polysaccharides conjugation chemistry and carrier protein, evaluated the induction of immunogenicity in the bivalent formulation with typhoid conjugate vaccine. As next steps, the project team is seeking to establish an optimal adjuvant for S. Paratyphi A/Typhi bivalent formulation and to launch process development and a toxicology study with additional grants.

Funder
- Wellcome Trust, UK

mRNA vaccine platform against Lassa fever

Since 2022, IVI and its collaborators in Korea have been developing an mRNA vaccine platform against Lassa fever. In addition, this project is seeking to establish a pseudovirus-based neutralization system against Lassa, Nipah, COVID-19, MERS, Ebola and Crimean-Congo haemorrhagic fever viruses using a Lentivirus/Vesicular stomatitis virus (VSV)-platform.

In 2023, IVI completed an immunogenicity assessment (ELISA, PBNA) using sera from an immunogenicity study, SK bioscience established an analytical method and Standard Operating Procedure for the study, completed production, documentation, and analysis of newborn calf serum while also beginning stability tests on the serum.

Collaborators:
- SK bioscience, Republic of Korea
- Gachon University, Republic of Korea

Funder:
- Korea mRNA Vaccine Initiative, Republic of Korea

Lassa fever virus is a neglected zoonotic disease spread by *Mastomys* rodents. It causes hemorrhagic fever with an estimated 100-300 thousand cases each year in West Africa and an estimated 5-10 thousand deaths. There is currently no vaccine available against this virus.

Systems serology platform technology

In 2022, IVI launched an initiative to establish a systems serology platform technology to facilitate the discovery of novel biomarkers for infectious diseases. Once established, this platform technology will be used to identify immune correlates of protection/distinct biomarkers in typhoid, iNTS, and COVID-19 using both animal and human clinical samples.

In 2023, the research team successfully established key assays for systems serology, while assessments began of preclinical and clinical samples for iNTS, TCV, and COVID-19 vaccines to investigate distinct immunological biomarkers. Furthermore, analysis began on clinical samples from the OCV-S Nepal study to characterize the function and biophysical profiling of antibodies induced by cholera vaccines.

Collaborators
- Yonsei University College of Medicine, Republic of Korea
- Dr. Galit Alter, Ragon Institute of MGH, MIT and Harvard, USA

Funder
- Ministry of Science and ICT, Republic of Korea

Systems serology can identify the breadth and depth of antibody responses induced by vaccines, providing insights into their efficacy and durability. It can also help optimize vaccine design to elicit more protective antibody profiles.

Clinical, Assessment, Regulatory, Evaluation (CARE)

Vaccines for a Healthier Future

IVI's Clinical, Assessment, Regulatory, Evaluation (CARE) unit assesses vaccine safety and efficacy in humans, collaborating with partners around the world to plan and implement Phase I-IV clinical trials. We provide training and technical assistance and mobilize funding support while helping to coordinate and monitor trials to ensure adherence to international standards and principles of Good Clinical Practice (GCP). Additionally, we work with manufacturers and sponsors of new vaccine products navigate the regulatory pathway from the preparation of a new Investigational New Drug (IND) application to facility inspections.

With new vaccines, one of our key objectives is supporting manufacturers all the way to WHO prequalification which enables public procurement of vaccines for global health use.

The CARE unit consists of five core functions

- Clinical Development
- Clinical Operations
- Regulatory Affairs
- Trial Management
- Project Administration

Supporting end-to-end vaccine R&D and further clinical studies post licensure

- Phase I
- Phase II
- Phase III
- National licensure and WHO PQ
- Postlicensure clinical studies
- Observational studies

Vaccines for a Healthier Future
Clinical, Assessment, Regulatory, Evaluation(CARE)

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

IVI developed a new-generation typhoid conjugate vaccine (TCV), Vi polysaccharide conjugated with diphtheria toxoid (Vi-DT), which distinguishes itself from other typhoid vaccines with its immunogenicity in young children. IVI then transferred the technology, process, and know-how for this vaccine to SK bioscience in the Republic of Korea (2013) and Bio Farma in Indonesia (2014) with the goal of supporting both manufacturers gain World Health Organization (WHO) prequalification, a designation that would expand global public access to safe, effective, and affordable TCVs.

Alongside the clinical development and licensure of Vi-DT TCV, IVI is working to amplify the global health impact of typhoid vaccines and vaccination through disease surveillance, vaccination campaigns, and effectiveness studies in Africa, Asia, and the Pacific Islands.

Vi-DT with SK bioscience

After the successful completion of two Phase III clinical trials, the 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 was subsequently submitted for WHO prequalification. In the second quarter of 2023, SK bioscience reported 36 months of stability data, and expects final data up to 48 months to meet the WHO Vaccine Vial Monitor requirement to be available by the second quarter of 2024.

Collaborators

- SK bioscience, Republic of Korea
- World Health Organization
- Ministry of Food and Drug Safety, Republic of Korea
- Drug Development Association, Nepal
- National Health Research Council, Nepal
- Research Institute for Tropical Medicine, Philippines
- Sites in Nepal and the Philippines

Funders

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

SK bioscience's typhoid conjugate vaccine SKYTyphoid™ developed with technology transfer from IVI has achieved the World Health Organization prequalification. Credit: SK bioscience

Vi-DT with Bio Farma

Bio-TCV® Vi-DT typhoid conjugate vaccine, developed at IVI and technology-transferred to Bio Farma, was licensed by BPOM, Indonesia's regulatory authority. Credit: Bio Farma

The joint vaccine development program with Bio Farma includes preclinical development and Phase I-III clinical trials followed by technical support through local licensure and submission for WHO prequalification. With the results of a successful Phase III clinical trial in Indonesia which confirmed the safety and immunogenicity of a single dose of Vi-DT and its noninferiority to a control WHO-prequalified TCV, the Indonesian Food and Drug Authority (BPOM) approved the vaccine for national use in individuals aged nine months to 45 years in July 2023. Submission for WHO prequalification is under discussion.

Collaborators
- Bio Farma, Indonesia
- World Health Organization
- Indonesian Food and Drug Authority (BPOM)
- National General Hospital, Indonesia

Funder
- Bill & Melinda Gates Foundation, USA

Clinical development of DuoChol and Uptake Likelihood Assessment

Scientists at the University of Gothenburg developed DuoChol, a dry formulation inactivated bacterial whole cell/cholera toxin B subunit oral cholera vaccine with a similar composition as the world's first WHO-prequalified OCV, DUKORAL®. While DUKORAL® as well as the currently available WHO-prequalified low-cost OCVs, Shanchol™ and Euvichol-Plus®, both developed at IVI, are drinkable vaccines, what sets DuoChol apart is its dry formulation in capsule form. This presentation improves the vaccine's thermostability, meaning the active ingredients remain stable at higher relative temperatures for a longer duration, while also reducing its weight and volume.

Following GMP production and toxicity testing of DuoChol led by Gotovax AB/University of Gothenburg, IVI will complete an IND application for a Phase I clinical trial of DuoChol OCV in Sweden and begin a Phase I clinical trial in accordance with ICH Good Clinical Practice.

Alongside the clinical study of DuoChol, IVI is conducting an Uptake Likelihood Assessment in partnership with the WHO's Immunization, Vaccines and Biologicals unit. The primary objectives are to determine country-specific immunization challenges relevant to the handling, distribution, and storage of cholera vaccine that could potentially be addressed by DuoChol product attributes. Additionally, the assessment will evaluate the feasibility, acceptability, cost implications, and policy/regulatory implications of DuoChol in comparison to current products and practices.

Collaborators
- Gotovax AB, Sweden
- University of Gothenburg. Sweden
- Immunization, Vaccines and Biologics, WHO

Funders
- Wellcome Trust, UK
  (Clinical development of DuoChol)
- Government of Sweden
  (Uptake Likelihood Assessment)

Clinical development of cholera conjugate vaccine

There are an estimated 2.9 million cases of cholera every year with 95,000 deaths worldwide. Approximately half of these cases and deaths are estimated to occur in children five years of age and younger—however, the currently available two-dose oral cholera vaccines (OCVs) have significantly reduced efficacy in children under five, and a single dose has no efficacy. With the intent to encourage the development of new and improved vaccines, the WHO Initiative for Vaccine Research convened a stakeholder consultation for next-generation cholera vaccine with the aim of "supporting a new sustainable implementation paradigm that will maintain cholera control."

In 2023, IVI completedbegan a Phase I clinical trial in Korea to develop a cholera conjugate vaccine (CCV) that offers the possibility of improved efficacy in younger children—a characteristic of conjugate vaccines—and longer duration of protection. The trial demonstrated the safety and immunogenicity of CCV sufficient to support advancing the product to Phase II. Applications for additional funding for Phase II are under review.The preclinical evaluation of CCV was completed and the IND application was approved by the Korean Ministry of Food and Drug Safety in May 2022.

Collaborators
- EuBiologics, Republic of Korea
- Massachusetts General Hospital, USA
- National Institutes of Health, USA

Funders
- Open Philanthropy, USA
- RIGHT Foundation, Republic of Korea

A girl receives a dose of oral cholera vaccine during an IVI vaccination campaign in Nepal in 2022. Credit: IVI

Enhancing cholera control in (ECHO) Nepal and Mozambique

The objective of the ECHO-N and ECHO-M projects is to contribute to cholera prevention and control while building up national programs aligned with the WHO Global Task Force on Cholera Control's Ending Cholera – A Global Roadmap to 2030.

In Nepal, ECHO-N takes a four-pronged approach to enhance Nepal's capacity to detect, respond to, and prevent outbreaks of cholera:

1. **Prevent:** Prevent cholera infections through OCV vaccination campaigns in two identified hotspots, Kathmandu Valley and Kailali District
2. **Detect:** Strengthen laboratory diagnostic and surveillance capacity for cholera in those two same subregions
3. **Respond:** Limit outbreaks and prevent cholera cases through stronger rapid response capacity
4. **Coordinate:** Build the platform for multisectoral stakeholder engagements and development of an evidence-based cholera control plan

Collaborators
- Epidemiology and Diseases Control Division, Ministry of Health and Population, Nepal
- National Public Health Laboratory, Nepal
- Group for Technical Assistance, Nepal
- Seti Zonal Hospital, Nepal
- Nepal Medical College
- New Era, Nepal
- Good Neighbors International
- Johns Hopkins University, USA
- icddr,b, Bangladesh

Funder
- KOICA Global Disease Eradication Fund, Republic of Korea

In Mozambique, cholera remains endemic with periodic outbreaks, calling for stronger cholera outbreak preparedness and response as well as a comprehensive national cholera control and prevention plan. ECHO-M also has four key objectives:

1. **Prevent:** Conduct a pre-emptive OCV vaccination campaign in a hotspot in Nampula province
2. **Detect:** Enhance cholera and diarrheal disease surveillance and conduct a cost-of-illness study associated with cholera in outbreak and endemic settings
3. **Preparedness:** Strengthen the local government's response and preparedness to cholera outbreaks
4. **Policy engagement:** Support the development of the Government of Mozambique's National Cholera Plan

Collaborators
- Instituto Nacional de Saude, Mozambique
- Global Task Force on Cholera Control
- EuBiologics, Republic of Korea

Funder
- KOICA Global Disease Eradication Fund, Republic of Korea

Ethiopia Cholera Control and Prevention (ECCP)

Euvichol-Plus® oral cholera vaccine. Credit: EuBiologics

Cholera remains a significant public health concern in Ethiopia, with recent outbreaks reported across the country since 2019. A series of reactive OCV mass vaccination campaigns have been conducted for cholera outbreak control. The Ethiopian Government has initiated the development of its multiyear and multisectoral national cholera control plan (NCP), which includes the preemptive use of OCV in identified cholera hotspots. IVI initiated the ECCP project in 2020 and launched the following year in support of the Ethiopian NCP and aligned with the WHO Global Task Force on Cholera Control's Ending Cholera – A Global Roadmap to 2030.

Following the preemptive OCV mass vaccination campaign and population-based survey successfully conducted in 2022, prospective systematic cholera surveillance continued in 2023. The team conducted an analysis of OCV vaccination coverage and cholera-associated risk factors and submitted manuscripts to a peer-reviewed journal in 2023. Additionally, the team retrospectively analyzed government data on the use of OCV and national cholera surveillance in recent years in collaboration with the Ethiopian Public Health Institute, Ministry of Health, and Armauer Hansen Research Institute in 2023.

ECCP aims to contribute to evidence-informed public health prioritizations and policy engagement for impactful cholera control and prevention in Ethiopia. Key research and public health policy engagement activities include:

Collaborators

- Armauer Hansen Research Institute, Ethiopia
- Ethiopian Public Health Institute
- Ministry of Health, Ethiopia
- Global Task Force on Cholera Control
- EuBiologics, Republic of Korea

Funders

- Korea Support Committee for IVI
- LG Electronics

01 Preemptive OCV mass vaccination in cholera high priority hotspot areas

- OCV administration in approximately 100,000 people (>1 year)
- OCV vaccination coverage survey to estimate vaccine coverage and barriers

02 Prospective sentinel healthcare facility-based cholera and diarrheal disease surveillance

- Assessment of the impact and effectiveness of preemptive OCV mass vaccination
- Prospective and systematic cholera and diarrheal disease surveillance and analysis

03 Cholera associated site-specific risk factors and healthcare seeking behavior

- Population-based survey in randomly selected household
- Cholera associated WaSH and socio-economic risk factors, healthcare-seeking behavior, and disease perception analysis

04 Policy engagement for Ethiopian NCP

- Local government stakeholder engagements on study objectives, progress, and results
- Evidence-informed public health policy dialogue on cholera control in Ethiopia
- Joint partnership with the Ethiopian Public Health Institute and the Ministry of Health on retrospective analysis of the national cholera data and OCV vaccinations conducted by the Ethiopian Government

Global Chikungunya Vaccine Clinical Development Program (GCCDP)

GCCDP was initiated by IVI in June 2020 in partnership with Bharat Biotech in India to advance Bharat's chikungunya vaccine candidate with the ultimate goal of achieving WHO prequalification and or 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 in five countries across 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.

From November 2022 to February 2023, the team finalized data sets for Parts A and B of the study. Subsequently, the third Data and Safety Monitoring Board meeting concluded in May 2023 with no identified safety issues. The optimal dose for Part C has been selected and supported by the immunogenicity and safety data and results of the nonhuman primate study. Beginning 2024, recruitment for Part C will be initiated and consultations with WHO entities, NRAs, and National Immunization Technical Advisory Groups (NITAGs) will continue.

GCCDP
Global Chikungunya Vaccine Clinical Development Program

There is currently no vaccine or specific drug to protect against or treat chikungunya, and available treatment focuses on relieving symptoms of the disease. IVI is leading the Global Chikungunya Vaccine Clinical Development Program (GCCDP) consortium with the objective of accelerating a vaccine solution to prevent chikungunya worldwide.

IVI is also working to collect disease burden data and advocate for a multistakeholder approach to chikungunya vaccine development through the Uptake and Demand Assessment of a Potential Chikungunya Vaccine (UDAC) project, launched in 2022.

Collaborators

- Bharat Biotech, India
- VaxTRIALS, Latin American expert CRO, Panama
- Zifo
- National Institute for Biological Standards and Control, UK
- Interactive Research School for Health Affairs, Bharati Vidyapeeth, India
- APCER Life Sciences
- Nexelis, a Q² Solutions Company

Funder

- Coalition for Epidemic Preparedness Innovations (CEPI)

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

Initiated jointly by IVI and the London School of Hygiene and Tropical Medicine in 2022, the UDAC 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 rollout; and facilitate multistakeholder encounter through coauthoring an editorial/opinion piece with global partners, including CEPI and the WHO, emphasizing key areas of work and drivers for change.

By September 2023, the team completed review of data and statistical modelling with reference to 61 articles out of 5,300 screened articles. A total of 18 informant interviews were conducted via video call between February and July 2023, in addition to semistructured interviews with vaccine manufacturers, financing institutions, global health agencies, and country stakeholders focusing on models of collaborative partnerships, success factors for chikungunya vaccine development, and roles and responsibilities of global agencies in this effort. Manuscripts of the results of disease burden and risk perception assessments have been completed and await submissions to international journals.

In December 2023, IVI convened the first Chikungunya Global Stakeholder Meeting in Panama in partnership with Gorgas Institute, bringing together stakeholders across government, research and development, and industry to map a comprehensive landscape of the problem of chikungunya and to advocate for the recognition, approval, and support of a global chikungunya vaccine agenda.

Collaborator

- London School of Hygiene and Tropical Medicine, UK

Funder

- Government of Sweden

IVI and Gorgas Institute organized the first Chikungunya Global Meeting in Panama City, Panama from December 12-13, 2023. Dr. Eduardo Ortega-Barria, National Secretary of Panama's National Secretariat for Science and Technology (Senacyt), delivered opening remarks at the meeting. Credit: IVI

Severe COVID-19 patients in Vietnam: Addressing secondary infections and supporting laboratory diagnostics (COVIET)

IVI is conducting a cross-sectional study through collection of clinical and laboratory data on organisms detected from hospitalized COVID-19 patients in Ho Chi Minh City, Vietnam. COVIET aims to estimate the prevalence of secondary infections, compare the clinical outcome of COVID-19 hospitalized patients with and without secondary infections, and determine the shifts in the antimicrobial resistance profile in major bacterial agents of secondary infections.

The study team extracted, curated, and analyzed electronic medical records of a total of 3,789 COVID-19 patients admitted to the Hospital for Tropical Diseases in Ho Chi Minh City, the largest referral hospital for infectious diseases in southern Vietnam, between 2020 and 2021. A key stakeholder meeting and a workshop were conducted in 2023 to present and discuss preliminary results of the study.

Retrospective data analysis, curation, and manuscript development will continue through 2024. The results of this study will be disseminated through publications in peer-reviewed journals and a joint workshop with key stakeholders.

Collaborators

- Oxford University Clinical Research Unit, UK
- Hospital for Tropical Diseases, Vietnam

Funder

- Korea Support Committee for IVI

Ho Chi Minh City had the highest number of COVID-19 cases and COVID-19-associated deaths in Vietnam during the first two years of the COVID-19 pandemic. However, there is no report on risk factors or predictors of secondary infection and high mortality in COVID-19 patients. Data analysis generated from disease surveillance is expected to help improve the treatment and clinical outcome of COVID-19 patients.

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

WHO's Emergency Use Listing adds SKYCovione™ COVID-19 vaccine. Credit: SK bioscience

IVI is collaborating with SK bioscience through the COVID Vaccine Clinical and Operational Alliance (COCOA) consortium to advance the development of SK bioscience's COVID-19 recombinant protein nanoparticle vaccine GBP510 with funding support from CEPI.

In parallel with study sites in Korea overseen by SK bioscience, IVI coordinated the global Phase III clinical trial in five countries (New Zealand, the Philippines, Thailand, Ukraine, and Vietnam) of SK bioscience's GBP50 vaccine, which demonstrated both superiority and noninferiority of the vaccine compared to the comparator vaccine (AstraZeneca's Vaxzevria®). Based on the results, GBP510 (brand name SKYCovione™) was licensed by the Korean Ministry of Food and Drug Safety in June 2022.

In June 2023, SKYCovione™ was listed on the WHO's Emergency Use Listing following its full marketing authorization by the Medicines and Healthcare Products Regulatory Agency in the UK. It is Korea's first homegrown vaccine to receive full marketing authorization in the UK and the 12th COVID-19 vaccine recognized by the WHO.

A booster dose extension stage of the study was launched to assess the immune response and safety of a booster dose of GBP510 adjuvanted with AS03, GSK's pandemic adjuvant. A total of 449 subjects in Korea and Thailand who received two doses of either GBP510 or Vaxzevria® in the initial stage were enrolled in the extension stage and received a booster dose of GBP510. The final safety and immunogenicity readouts will be available in 2024.

Collaborators
- SK bioscience, Republic of Korea
- Institute for Protein Design, University of Washington, USA
- GSK
- Bill & Melinda Gates Foundation, USA
- Government of the Republic of Korea
- CRO and logistics partners: Novotech, SMART Research, EastHORN, Marken, LSK Global Pharma Services

Funder
- Coalition for Epidemic Preparedness Innovations (CEPI)

EdJen BioTech COVID-19 vaccine development

Since 2022, IVI has been working with the Vaccine Research Group at Mayo Clinic to advance the development of an affordable, rapidly produced, temperature stable peptide-based SARS-CoV-2 vaccine that is readily deployable in low- and middle-income countries. A Scientific Advisory Board meeting was held in October 2023 to review all data generated by project partners and define the next steps, including preclinical data publication and additional studies with optimized peptides and selected adjuvant. Finalization of the vaccine candidate and testing in small animal models are planned for Q2 2024. A Go/No Go decision on GMP production and clinical development is expected around Q3 2024.

Collaborators
- Vaccine Research Group, Mayo Clinic, USA
- Amarex, USA
- Vaccine Formulation Institute, Switzerland
- EUROAPI, France

Funders
- EdJen BioTech, USA
- Government of Sweden

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 vaccines.

The subjects enrolled in this study were being followed for safety and immunogenicity assessment. Upon consent, the participants were offered the monovalent booster dose in an open-label extension phase. Subject enrollment for the extension phase was completed in October 2023. Follow-up study activities will continue through 2024 to generate additional data on efficacy, safety, and immunogenicity.

Collaborators
- Sanofi
- Dhulikhel Hospital, Nepal
- Nepalgunj Hospital, Nepal
- Institute of Medicine, Nepal

Funder
- Biomedical Advanced Research and Development Authority, USA

HPV single dose vaccine effectiveness study in Thailand

IVI's human papillomavirus (HPV) vaccine single dose impact study aims to demonstrate the effectiveness and cost-effectiveness of a single-dose versus two-dose regimes of the HPV vaccine Cervarix in girls in eighth grade in Thailand. Given the high cost of HPV vaccines and low uptake, particularly in 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.

Between December 2018 and March 2019, over 8,000 girls in eighth grade in the Udon Thani and Buri Ram provinces of Thailand received either one dose or the currently recommended two doses of Cervarix® HPV vaccine in school-based vaccination campaigns. Following vaccination, participants were enrolled in sequential cross-sectional surveys to track the prevalence and occurrence of HPV infection among the vaccinated girls. In 2022, the data evaluating the two-year effectiveness contributed to the WHO SAGE's updated recommendation that a single-dose vaccine regimen for girls and women aged nine to 20 years old was an acceptable alternative to the two-dose regimen.

A second round of cross-sectional surveys was repeated between November 2022 and January 2023, now four years post vaccination, and provided valuable data on the durability of single-dose vaccine effectiveness. Concurrent evaluation of cost-effectiveness demonstrated the economic viability of HPV vaccine introduction particularly with the single-dose approach.

Globally, HPV-associated cervical cancer kills an estimated 250,000 women every year. A single dose vaccine regimen could allow countries to substantially expand coverage by lowering costs and simplifying delivery.

Collaborators

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

Funder

- Bill & Melinda Gates Foundation, USA

The IVI HPV clinical team leads a training workshop with project collaborators at Chulalongkorn University. Credit: IVI

IVI leads a hands-on training with the Ministry of Public Health of Thailand ahead of the Year 4 Survey. Credit: IVI

Global Burden of HPV

Workshop held in Dar es Salaam, Tanzania to receive input for harmonized study protocol spanning 8 countries. Credit: IVI

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 Government of Sweden through IVI's Europe Regional Office.

This harmonized, multicountry and multisite study will estimate the prevalence of high-risk HPV genotype infections among representative samples of girls and women aged nine to 50 years, and among specific subpopulations, to better understand the incidence of persistent HPV infection in girls and women in three LMICs in Asia and five in 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.

By the end of 2023, enrollment has been initiated in three countries in Asia (Bangladesh, Nepal, and Pakistan) with countries in Africa expected to begin in early 2024 (Democratic Republic of the Congo, Ghana, Sierra Leone, Tanzania, and Zambia). Over the next three years, 33 substudies of four types, including cross-sectional surveys in general populations, longitudinal studies, special population studies, and qualitative studies, will be launched.

The results of this study will enable a more accurate understanding of the HPV disease burden as well as barriers to effective interventions at the country and global level, therefore better inform policymakers and health program designers and encourage prioritization of research and development efforts toward those with the greatest potential public health impact.

Collaborators

- Karolinska Institutet, Sweden
- London School of Hygiene and Tropical Medicine, UK
- Centers for Disease Control and Prevention, USA
- Aga Khan University, Pakistan
- icddr,b, Bangladesh
- Dhulikhel Hospital, Nepal
- B.P. Koirala Institute of Health Sciences, Nepal
- New ERA, Nepal
- College of Medicine and Allied Health Sciences, University of Sierra Leone
- Mwanza Intervention Trials Unit, Tanzania
- National Institute for Medical Research, Tanzania
- University of Health and Allied Sciences, Ghana
- Zambart, Zambia
- Institut National de la Recherche Biomédicale, DRC

Funders

- Bill & Melinda Gates Foundation, USA
- Government of Sweden

Shigella surveillance study in Nepal

Shigella, **an invasive bacterium 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. It has the potential to create pandemics in children under the age of five and the elderly, and both groups face a higher risk of mortality from *Shigella* infections. Currently, 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.

IVI is conducting a study to estimate the proportion of shigellosis, disease severity, antimicrobial resistance, and serotype distribution among children with diarrhea in Nepal. Data generated from this surveillance study will help stakeholders make evidence-based decisions on resource allocation and promotion of vaccine development as well as other effective strategies for shigellosis control.

In 2023, IVI initiated a prospective surveillance study to estimate the burden of medically attended shigellosis in children under five years of age in Nepal. This study is being conducted at three sites across Nepal. Subject enrollment was launched at the end of 2023 following approvals from the Nepal Health Research Council and institutional review boards at IVI and study sites.

The results of this study will help inform decision-making of funders, public health officials, and policymakers to accelerate the development of new vaccines and other effective interventions for shigellosis as well as provide baseline data for future vaccine clinical trials in Nepal.

Collaborators

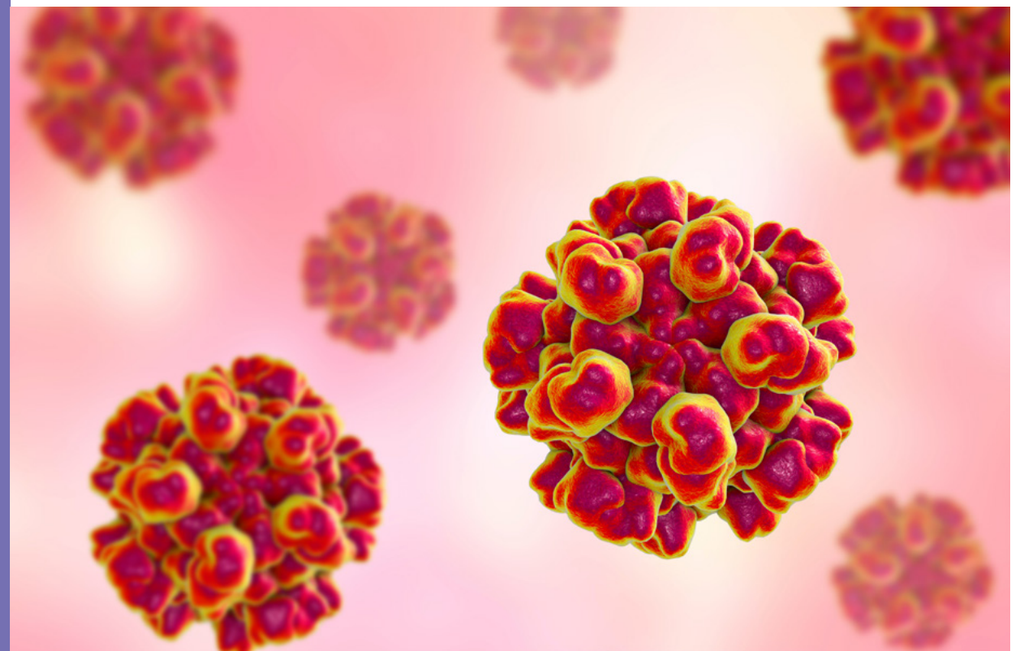
- Kanti Children's Hospital, Nepal
- B.P. Koirala Institute of Health Sciences, Nepal
- Nepalgunj Medical College, Nepal

Funder

- Government of Sweden

Safety and immunogenicity of Hecolin® (HEV vaccine) in pregnant women

Hepatitis E virus (HEV) is one of the most common causes of acute viral hepatitis globally, with an estimated 20 million infections annually and over 70,000 reported deaths. However, the burden is likely underestimated, considering the limited availability of diagnostics and insufficient surveillance. Populations considered to be at a higher risk for severe disease and death include pregnant women, who suffer a 20-40% mortality rate, immunosuppressed individuals, and those with pre-existing chronic liver disease.



In 2022, IVI launched several projects to generate necessary epidemiologic and clinical data to advance the use of Hecolin®, a highly efficacious HEV vaccine registered for domestic use in China and Pakistan, in global endemic settings. As a result of this work, several grants were awarded in 2023 to conduct clinical trials and generate disease burden data to fill evidence gaps.

Additionally, IVI and collaborators received funding from the Bill & Melinda Gates Foundation, Open Philanthropy, and Thrasher Research Fund 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 nonpregnant 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 biobanking study participated by investigators researching maternal and newborn health interventions in South Asia and sub-Saharan Africa, as well as the WHO.

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 recommendation by the Strategic Advisory Group of Experts on Immunization (SAGE) for this critically needed vaccine.

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

Funders
- Bill & Melinda Gates Foundation, USA
- Open Philanthropy, USA
- Thrasher Research Fund, USA

While there is no HEV vaccine available for global use, the Hecolin® vaccine produced by Xiamen Innovax Biotech is licensed for use in China and Pakistan. Efforts are underway to develop the further evidence needed for a stronger WHO SAGE recommendation for use and to secure WHO prequalification for this vaccine. Strengthening surveillance to better understand the epidemiology of this infection will play a key role in clarifying the disease burden and demonstrating the global need for this vaccine.

Hepatitis E vaccine Phase IIb in South Africa

In 2023, IVI launched a project to evaluate the immunogenicity and safety of Hecolin® in HIV positive/negative children and adults from two to 45 years old and to demonstrate the immune non-inferiority of two-dose versus three-dose regimens in younger age groups. This study will generate the evidence needed for inclusion of children within vaccine use policy recommendations and for informing policy on vaccine administration to people living with HIV/AIDS at risk for HEV infection.

By investigating the efficacy of abbreviated dosing regimens aimed at reducing vaccine costs and logistical complexity, the findings of this study could contribute to promoting the coadministration of HEV and HPV vaccines, providing a pathway for the routine introduction of the HEV vaccine in endemic countries. Subject enrollment for the study is set to begin in early 2024.

Collaborators:

- Xiamen Innovax Biotech, China
- Ardent Consulting, South Africa
- Be Part Research, UK
- Medunsa Clinical Research Unit, South Africa
- Newtown Clinical Research Centre, South Africa
- OnQ Research, South Africa
- Cytespace Africa Laboratories, South Africa

Funders:

- Bill & Melinda Gates Foundation, USA
- Open Philanthropy, USA

QuadMedicine hepatitis B microneedle array patch vaccine Phase I study in Korea

In 2021, IVI and partner QuadMedicine successfully completed preclinical assessment of the hepatitis B microneedle patch and signed an agreement to prepare the first in human study. This study is a Phase I, randomized, open-label, active-controlled study designed to evaluate the safety, tolerability, and immunogenicity of a hepatitis B vaccine administered trans-dermally via a microneedle array patch (MAP) compared to the intramuscular hepatitis B vaccine (Euvax B™). IVI is seeking to obtain Investigational New Drug approval from the Korean Ministry of Food and Drug Safety and the study launch is targeted for 2024.

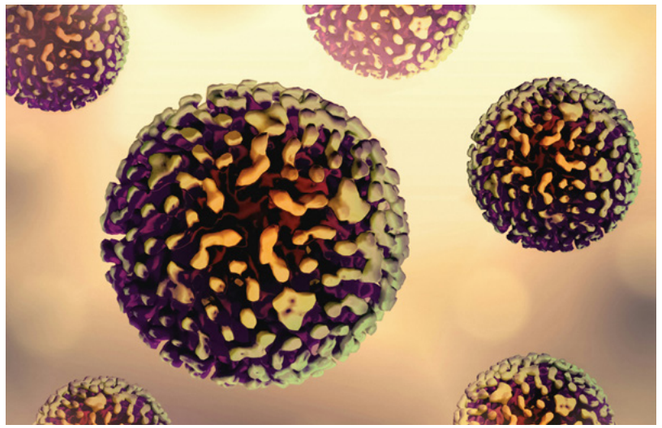
Since 2019, IVI and partners have been developing the MAP vaccine delivery platform which offers distinct advantages over traditional syringes, including easy and pain-free administration, thermal stability, light weight, low-cost fabrication, and reduced environmental impact from disposal. Other microneedle projects at IVI include preclinical studies to assess the immunogenicity and efficacy of microneedle vaccine candidates against influenza, SARS-CoV-2, and measles and rubella (MR).

Collaborators:

- QuadMedicine. Republic of Korea
- LG Chemical, Republic of Korea
- Yonsei Gangnam Severance Hospital, Republic of Korea

Funder:

- QuadMedicine, Republic of Korea



Epidemiology, Public Health, Impact (EPIC)

Vaccines for a Healthier Future

A core component of IVI's work to accelerate safe, effective, and affordable vaccines for global health is ensuring the use of these vaccines in public health programs.

The Epidemiology, Public Health, Impact (EPIC) unit consists of five crosscutting departments focusing on disease and antimicrobial resistance (AMR) surveillance and epidemiologic studies, health economics, biostatistics, data management, and vaccine effectiveness. Researchers in the EPIC unit work closely with in-country collaborators and key decision-makers at national, regional, and global levels to facilitate the introduction of newly licensed vaccines.

2023 Annual Report

The EPIC unit consists of five departments

- Real-world Evidence
- Immunoepidemiology
- Antimicrobial Resistance
- Policy & Economic Research
- Biostatistics & Data Management

Vaccines for a Healthier Future
Epidemiology, Public Health, Impact (EPIC)

Severe Typhoid in Africa Plus / Surveillance for TCV Impact Assessment in Africa (SETA+/STIA)

In 2015, IVI launched a multicountry typhoid burden study in six sub-Saharan African 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 project launched as the Severe Typhoid in Africa (SETA, 2015-2019) project, then transitioned to SETA Plus (2020-2023), and has now evolved into the Surveillance for TCV Impact assessment in Africa (STIA) project until the end of 2025.

Collaborators:

- Cambridge Institute of Therapeutic Immunology and Infectious Disease, University of Cambridge School of Clinical Medicine, UK
- Institut Supérieur des Sciences de la Population, Burkina Faso
- Madagascar Institute for Vaccine Research, University of Antananarivo
- Kwame Nkrumah University of Science and Technology, Ghana
- Institut National de Recherche Biomédicale, DRC
- University of Ibadan, Nigeria
- Institute of Tropical Medicine Antwerp, Belgium

Funder:

- Bill & Melinda Gates Foundation, USA

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 implemented alongside SETA Plus, encompassing a Phase IV cluster-randomized trial of Typbar-TCV® involving children aged nine months to 16 years in Ghana, a Typbar-TCV® massvaccination campaign with a prospective cohort evaluation of vaccine effectiveness in the DRC, a vaccination campaign with effectiveness evaluation of TYPHIBEV® in Madagascar, and advocacy support for the introduction of TCV in Burkina Faso.

Within these studies, postvaccination enhanced surveillance was integrated into the SETA Plus hospital-based surveillance area, enhancing case detection and supporting the calculation of vaccine impact at both individual and population levels.

Collaborators
- Institut National de Recherche Biomédicale, DRC
- Institute of Tropical Medicine Antwerp, Belgium
- Kwame Nkrumah University of Science and Technology, Ghana
- University of Cambridge, UK
- The Mérieux Foundation, France
- 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, USA
- European and Developing Countries Clinical Trials Partnership, EU

Typhoid in Fiji – Vaccination towards Elimination (Ty-FIVE)

Typhoid is a major public health concern in Fiji and a priority disease for the Fijian Ministry of Health and Medical Services. The goal of the Ty-FIVE project is to strengthen the current typhoid surveillance system and subsequently introduce the typhoid conjugate vaccine to the entire population of the Northern Division of Fiji aged between nine months to 65 years (approximately 139,000 people) with the aim to eliminate typhoid locally. From 2021 to 2022, the Ty-FIVE team improved detection of typhoid cases and asymptomatic shedders through blood culture and contact tracing, 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.

In 2023, the team successfully carried out the typhoid mass vaccination campaign for ten weeks from July to September, vaccinating nearly 70,000 individuals in the Northern Division.

A student receives the typhoid conjugate vaccine at St. Mary's Primary School during a mass vaccination campaign in the Northern Division of Fiji. Credit: IVI/Navneel Kumar

"I am hopeful that the impact of this typhoid vaccination campaign will be far-reaching a broad, not only reducing morbidity and mortality but also having economic and social benefits for the North and the nation as a whole."

– Dr. Ratu Atonio Rabici Lalabalavu, Minister of Health and Medical Services, Fiji

Collaborators
- Ministry of Health, Fiji
- Murdoch Children's Research Institute, Australia
- Peter Doherty Institute for Infection and Immunity, Australia

Funders
- Bill & Melinda Gates Foundation, USA
- Prof. Young Chul Sung, Pohang University of Science and Technology through the Korea Support Committee for IVI, Republic of Korea

Typhoid Silent Contamination Surveillance (Ty-SICS)

The Typhoid Silent Contamination Surveillance (Ty-SICS) project began in 2021 to assess environmental prevalence of *Salmonella* Typhi before and after the Ty-FIVE mass vaccination campaign in parallel to symptomatic typhoid surveillance. This study aims to assist the Fijian Government in understanding the distribution of environmental *Salmonella.*

In 2023, the team designed, refurbished, and installed two containers for laboratory space (donated by UNICEF) equipped to perform water filtration and molecular work. Samples are taken monthly from 35 surface water sampling sites across the island of Vanua Levu with the presence of *Salmonella* Typhi and fecal contamination detected by PCR. Preliminary data is under analysis to map clinical and environmental cases of *Salmonella.*

Collaborators
- Imperial College London, UK
- University of Washington, USA

Funder
- Bill & Melinda Gates Foundation, USA

Researchers retrieve samples for environmental surveillance for typhoid in Fiji. Credit: Ty-FIVE

"As a country with endemic typhoid, vaccination is a very important preventative measure for Fiji. We are taking a holistic approach to typhoid control, combining vaccination with more clinical surveillance, and introducing environmental surveillance. I hope to see a decrease in case numbers."

– Orisi Cabenatubua, Microbiology Scientist

A child receives a single dose of TYPHIBEV typhoid conjugate vaccine at a health center in the Imerintsiatosika commune during the Typhoid Conjugate Vaccine Introduction in Madagascar vaccination campaign on August 30, 2023. Credit: IVI

Typhoid Vaccine Introduction in Madagascar (TyMA)

The Typhoid Vaccine Introduction in Madagascar (TyMA) project aims to control the spread of typhoid fever by vaccinating at-risk groups, particularly children nine months to 16 years of age, and supporting the development of a national typhoid fever control plan in Madagascar. The vaccine effectiveness study using TYPHIBEV® typhoid conjugate vaccine involves three main workstreams:

Geographic Information System (GIS) -supported census

Vaccination

Surveillance

The team initiated a baseline census covering a population of approximately 200,000 individuals in six communes in Arivonimamo and Antananarivo-Atsimondrano following extensive training with community health workers on census implementation. In 2023, the team expanded typhoid disease surveillance from three to eight sites and launched the typhoid conjugate vaccine campaign in August in Imerintsiatosika. As of mid-November, a linkage rate to the census database exceeded 65% and the team successfully recruited an age-stratified safety cohort.

"This typhoid conjugate vaccine campaign is the culmination of a 12-year research collaboration between IVI and MIVR to understand the burden of typhoid fever in Madagascar and bolster clinical surveillance. The campaign will not only protect nearly 60,000 children in Arivonimamo and Antananarivo-Atsimondrano districts but help build an evidence-based case to register TCV in Madagascar."

– Prof. Raphael Rakotozandrindrainy, Head of Madagascar Institute for Vaccine Research (MIVR)

Collaborators
- Madagascar Institute for Vaccine Research, University of Antananarivo
- University of Cambridge, UK

Funder
- Prof. Young Chul Sung, Pohang University of Science and Technology through the Korea Support Committee for IVI, Republic of Korea

Mozambique Typhoid Fever Surveillance (MOTiF)

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 typhoid conjugate vaccine into the national immunization program. Typhoid surveillance in Nampula and Pempa started in August 2022 and March 2023, respectively, and the blood culture surveillance period at both sites will extend until mid-2024.

Collaborator
- Instituto Nacional de Saúde, Mozambique

Funders
- Prof. Young Chul Sung, Pohang University of Science and Technology through the Korea Support Committee for IVI, Republic of Korea
- Government of Sweden

Vaccine against Schistosomiasis for Africa (VASA)

IVI's primary activities for the VASA project are: 1) A seroprevalence and disease burden study in Madagascar and Burkina Faso to understand the current disease burden and evaluate the age of exposure to schistosoma. This information will help inform vaccine development and guide control measures; 2) A cost-of-illness study to comprehend the financial burden of schistosomiasis on local populations and estimate the cost-effectiveness of a vaccine; 3) A phase Ib clinical trial to assess the safety and reactogenicity of the SchistoShield® vaccine, one of the leading schistosomiasis vaccine candidates.

In 2023, data analysis suggests a heavy burden of schistosomiasis in rural settings in Madagascar, including in children under five years of age. The disease burden is much lower in Burkina Faso, in line with a successful national helminth control program.

For the Phase Ib trial, the First Participant First Visit took place in November 2023 in Madagascar.

Collaborators
- Department of Medicine, University of Cambridge, UK
- Group 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., USA
- Leiden University Medical Center, Netherlands
- University of Gothenburg, Sweden
- Institute for Tropical Medicine, University of Tübingen, Germany

Funder
- European Union Horizon 2020

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

IVI leads the CAPTURA project, working to expand the volume of historical and current data on antimicrobial resistance (AMR) and antimicrobial use (AMU) 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.

Through its engagement with AMR stakeholders in CAPTURA priority countries, the project collected, digitized, analyzed, and disseminated findings of AMR data from 72 laboratories in seven countries, strengthening countries' capacity in data sharing, analysis, and use. In 2023, the team published a supplement in Clinical Infectious Diseases, highlighting the findings and regional experience of the project.

IVI was invited by the Fleming Fund to the second round of the Fleming Fund Regional Grants call, focusing on improving AMR data quality and use through CAPTURA II. This next phase started in October 2023 and will run until December 2025, aiming to support countries in Asia to improve the quality of AMR data and its use in policymaking.

Collaborators
- University of Heidelberg, Germany
- University of Melbourne, Australia
- Brigham & Women's Hospital, USA
- SwipeRx, Indonesia

Funder
- The Fleming Fund, UK aid, UK

Regional Antimicrobial resistance Data Analysis for Advocacy, Response and policy (RADAAR)

The RADAAR project aims to improve regional data-sharing and analysis for use in AMR planning, policy, and advocacy. IVI (lead grantee), Brigham and Women's Hospital (WHONET), Big Data Institute (University of Oxford), and Public Health Surveillance Group, as well as the Evidence-Informed Policy Network (EVIPNet) of the WHO, have been collaborating across various activities since 2021.

Based on identified need and demand emerging from countries, RADAAR laid the groundwork and embarked on a strategic pathway to strengthen LMIC capacities in translating AMR knowledge (data/evidence) into effective policies. Towards this end, IVI's Policy and Economic Research (PER) department has completed a series of training workshops and disseminated a codeveloped 'step-by-step' AMR Policy Advocacy country guide. In addition, the IVI PER team conducted the RADAAR–EVIPNet country capacity strengthening pilot initiative on AMR knowledge translation, piloted in Bangladesh, Malawi, Nepal, and Uganda.

Collaborators
- Evidence Informed Policy Network, WHO
- Brigham and Women's Hospital, USA
- ReAct Africa
- DataLEADS, India

Funder
- The Fleming Fund, UKAid, UK

Strengthening External Quality Assurance for AMR in Asia (EQASIA)

IVI is part of a consortium led by the Technical University of Denmark (DTU) along with the Veterinary Faculty at Chulalongkorn University in Thailand to strengthen External Quality Assurance (EQA) for AMR in Asia through the EQASIA project.

Phase I of the project identified and mapped the coverage, availability, and uptake of EQA programs in Asia and provided seven rounds of EQA services and relevant training (two virtual and one face-to-face workshop) to National Reference Laboratories and Centers of Excellence across One Health sectors in Asia during 2021-23. The report from the first six rounds of EQA has been published. Similarly, IVI developed the EQAsia costing tool for cost analysis and cost forecasting of the EQA program.

The EQAsia project started in January 2019 and continued until October 2023. The project transitioned into the second phase in November 2023 with a similar scope of work and will continue to run through December 2025. The second phase will provide four rounds of EQAs to 33 National Reference Laboratories/Centers of Excellence in Asia and support two out of 13 countries participating in the EQAsia project to establish a National External Quality Assurance program, provide training in Quality Management Systems, and build up countries' capacity to conduct One Health-focused EQA independently.

Collaborators:
- Technical University of Denmark. Denmark
- Chulalongkorn University, Thailand

Funder:
- The Fleming Fund, UK aid, UK

Impact of vaccination using the Clover SCB-2019 COVID-19 vaccine on household transmission of SARS-CoV-2 infection

The main objective of this study is to assess whether there is a reduction in COVID-19 infections in the households of clinical trial participants who received the Clover SCB-2019 COVID-19 vaccine compared to those who received placebo. The study outcomes, focusing on the occurrence of confirmed COVID-19 infections among households and household contacts of SPECTRA placebo or SCB-2019-infected recipients, were published in Clinical Infectious Diseases in April 2023.

The findings revealed a trend indicating a potential reduction in the risk of secondary SARS-CoV-2 infections in contacts of vaccinated index cases compared to their unvaccinated counterparts.

Concurrently, the team successfully concluded a substudy employing dried blood spots for the quantitative detection of anti-SARS-CoV-2 IgG antibodies through ELISA. The results demonstrated that, in comparison with sera, the DBS method exhibited 100% sensitivity, 99% specificity, a 99% positive predictive value, and 100% negative predictive value. The manuscript detailing this substudy was submitted to the American Journal of Tropical Medicine and Hygiene in July 2023. This innovative approach using dried blood spots may prove valuable in SARS-CoV-2 household or population serosurveys in contexts with limited sample collection, shipment, and storage.

Collaborators
- University of the Philippines, Philippines
- Tropical Disease Foundation, Philippines
- Asian Hospital and Medical Center, Philippines
- Manila Doctor Hospital, Philippines
- Las Piñas Doctors Hospital, Philippines
- UERM Memorial Medical Center-Laguna, Philippines
- FEU-NRMF Clinical Research, Philippines
- UERM Memorial Medical Center-Quezon City, Philippines

Funder
- Clover Biopharmaceuticals, China

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

IVI and Mozambique's Instituto National 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 Johnson & Johnson's Ad26.COV2.S vaccines compared to prime-boost regimens using the same product for homologous prime and boost.

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 Johnson & Johnson.

The project aims to demonstrate the safety and efficacy of a mixed schedule of COVID-19 vaccines, which may have a significant impact on ensuring timely vaccinations and controlling the pandemic in regions most affected by vaccine shortages.

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

Funder:
- Coalition for Epidemic Preparedness Innovations (CEPI)

Enhanced surveillance and vaccine effectiveness for Japanese encephalitis in Bali, Indonesia (JE-Bali)

The objective of this study is to estimate the effectiveness and impact of CD-JEV Japanese encephalitis (JE) vaccine at 3- and 5-years following immunization. Additionally, the study estimates the number of JE-associated hospitalizations and deaths in Bali while characterizing and describing the clinical and epidemiological patterns of JE disease in terms of age, gender, seasonality, and geographical distribution of JE in Bali.

From 2001-2006, IVI conducted JE surveillance, identifying a significant burden of disease in Indonesia with the highest incidence in Bali. A decade later, the World Health Organization called for JE vaccine effectiveness assessment as well as surveillance for impact monitoring in 2016. IVI then led a mass JE vaccination campaign in Bali in collaboration with the Indonesian Ministry of Health and Gavi in 2018. Since the campaign, IVI has been leading a 6-year surveillance study in Bali to evaluate vaccine effectiveness of CD-JEV and its impact.

Collaborators
- Sanglah Hospital, Indonesia
- Indonesia Provincial Health Office
- WHO Indonesia Office

Funders
- PATH (2020-2021)
- Shinhan Bank, Republic of Korea (2021-2022)
- Korea Support Committee for IVI (2022-2023)
- Government of Sweden (2023-2024)

Hepatitis E seroepidemiology in Africa (HEVA)

While hepatitis E (HEV) is an emergent cause of acute viral hepatitis worldwide, with particularly serious adverse consequences for pregnant women and their fetuses, there is little to no HEV data reported in more than half the countries in sub-Saharan Africa despite high HEV seroprevalence found in studies of the general population.

The HEVA study aims to fill critical data gaps on HEV and generate disease burden estimates across 13 countries in sub-Saharan Africa. To date, all laboratory analyses have been completed with serological screenings of over 13,000 samples with additional PCR analyses of anti-HEV IgM positive samples. Analysis of overall seroepidemiology data is now in the final stages.

In April 2023, the team held the second International Hepatitis E Symposium, bringing together 95 participants and speakers.

Collaborators:
- Institut Pasteur Dakar, Senegal
- University of Ibadan, Nigeria
- L'Institut National de Recherche Biomédicale, DRC

Funder:
- Bill & Melinda Gates Foundation, USA

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 (LSHTM). The iNTS FVVA will help stakeholders, investors, and policymakers understand the value of investment in iNTS vaccine development and use.

In 2023, Following discussions with the Research Steering Group (including the Wellcome Trust Representative), it was agreed to shift the scope of project to the development of a trivalent vaccine composed of typhoid conjugate vaccine (S. Typhi) and bivalent iNTS vaccine (S. Typhimurium and S. Enteritidis). The Preferred Product Characteristics (PPC) and R&D roadmap as well as Business Case and Investment Case would reflect this change.

Also in 2023, Shift Health made significant process on the completion of the business case report; IVI and LSHTM completed their respective literature reviews; and the consortium launched their website: https://inovvel.org/.

In 2010, of an estimated 3.4 million global cases of iNTS disease, 1.9 million were estimated to have occurred in sub-Saharan Africa. iNTS is the leading cause of community-acquired bacteremia in adults and the second most common pathogen identified in African children.

Collaborators
- World Health Organization
- Shift Health, Canada
- London School of Hygiene and Tropical Medicine, UK
- Swiss Tropical and Public Health Institute, Switzerland

Funder
- Wellcome Trust, UK

Vaccine Impact Modeling for typhoid fever and cholera (VIM-TyChol)

Established in late 2022, VIM-TyChol works with Vaccine Impact Modelling Consortium (VIMC) partners to develop updated cholera and typhoid vaccine impact estimates to inform Gavi, the Vaccine Alliance, the WHO, and the Bill & Melinda Gates Foundation resource allocation strategies.

In 2024, VIM-TyChol will continue the development of cholera and typhoid vaccine impact models and begin disseminating their findings in peer-reviewed journals.

Collaborators

- Vaccine Impact Modelling Consortium
- Imperial College London, UK
- Gavi, the Vaccine Alliance
- World Health Organization
- Bill & Melinda Gates Foundation, USA
- Yale School of Public Health, USA
- Stanford Medicine, USA
- Institute for Disease Modeling, USA
- Indian Institute of Technology, Kanpur, India

Funders

- Gavi, the Vaccine Alliance
- Bill & Melinda Gates Foundation, USA

Vaccine impact modelling provides vital data on the potential effectiveness, cost-benefit, and optimal deployment strategies for vaccines. This data helps global health officials understand the dynamics of disease transmission and informs the development of vaccination strategies to reduce the incidence and impact of cholera and typhoid fever globally.

Extended analysis of past datasets of cholera, typhoid and rotavirus II (EAD II)

From 2021 to 2023, IVI worked alongside Dr. Firdausi Qadri at Bangladesh's icddr,b to re-examine disease surveillance and vaccination data collected at field sites across Africa and Asia since the 1980s. Datasets from these previous studies have been cleaned, archived, documented, and are available for analysis in a digitized and curated format.

As a result of EAD II's efforts, the now digitalized datasets have yielded new research papers on cholera, typhoid, and rotavirus and demonstrated the usefulness of new methodological approaches, such the fried egg analysis of cluster randomized trials, novel uses of machine learning, and innovative uses of vaccine probe analysis.

EAD II is a successor project to EAD I, which ran from 2017 to 2019. EAD I successfully published eight manuscripts and taught new methodologies to young researchers at icddr,b and IVI.

Collaborator:

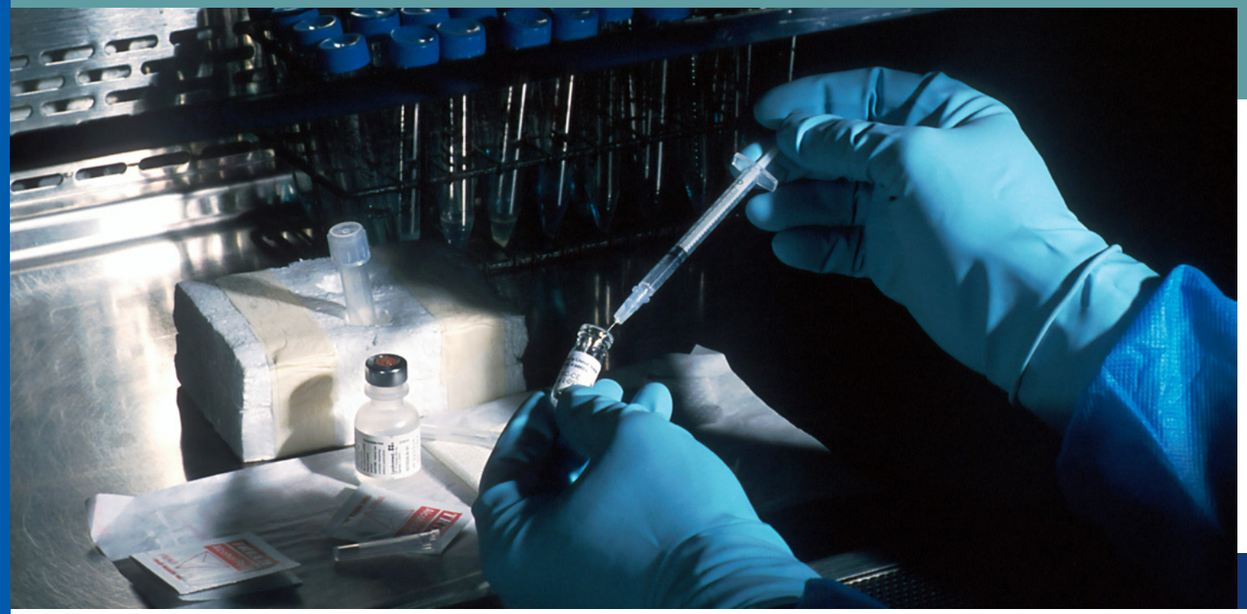
- icddr,b, Bangladesh

Funder:

- Bill & Melinda Gates Foundation, USA

Vaccines for a Healthier Future
Epidemiology, Public Health, Impact (EPIC)

Quality Management



Quality management (QM) and oversight according to Good Practice guidelines are essential to IVI's regulated activities and global infrastructure development. As IVI continues to expand in scope and scale, the importance of quality oversight remains a priority. The QM unit ensures IVI's clinical, observational, and laboratory research activities remain compliant to international regulations while operating in a state of continuous inspection readiness.

The QM team additionally provides training and consulting services on-site at vaccine manufacturing facilities to guide biopharmaceutical production personnel on regulation and quality control.

Training and Capacity-Building

Strengthening and bridging gaps in vaccine capacity for sustainable development is a core component of IVI's mission to accelerate vaccines for global health. IVI's training and capacity-building programs aim to boost capabilities in LMICs to develop and produce vaccines and other biologics locally to enhance regional vaccine security and address inequities in vaccine access.

International Vaccinology Course

Established in 2000, the IVI International Vaccinology Course (IVC) 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 low- and middle-income countries worldwide and certified an additional 1,100 participants through its online course in 2021, fostering meaningful partnerships in research and public health.

The 22nd chapter of the annual IVC took place at two locations, IVI headquarters in Seoul and at Karolinska Institutet in Stockholm, seamlessly connecting in real-time for a dynamic experience accommodating more lecturers and a diverse cohort of trainees. The curriculum included lectures, interactive case studies, and site visits to local vaccine centers with a central theme of "Bouncing back from COVID-19: Lessons for vaccinology."

The 22nd edition of IVI's International Vaccinology Course highlighted lessons for vaccinology in the wake of the COVID-19 pandemic. Credit: IVI

A total of 90 trainees representing 33 different nationalities participated at the course's flagship location at the Seoul National University campus in Korea in addition to a second site at Karolinska Institutet in Stockholm, Sweden. Credit: IVI

A total of 90 trainees representing 33 different nationalities participated at the course's flagship location, including 18 participants who received a Vaccinology Fellowship to attend in Seoul.

In addition to the course sponsors, the Governments of India, the Philippines, and Thailand provided additional scholarships through their core contributions to IVI in support of its mission and values.

Collaborator:
- Karolinska Institutet, Sweden

Funders:
- Bill & Melinda Gates Foundation, USA
- Moderna, USA
- Sanofi, France
- Valneva, Sweden
- SK bioscience, Republic of Korea
- Serum Institute of India, India
- Hilleman Laboratories, India
- Karolinska Institutet, Sweden

Global Training Hub for Biomanufacturing (GTH-B)

The 2023 Introductory Course for Biologics Development and Manufacturing was held in June as the second course of the Global Training Hub for Biomanufacturing initiative to help strengthen LIMIC's capacity in production of vaccines and biological products. Credit: IVI

In 2022, IVI was designated by the Ministry of Health and Welfare of the Republic of Korea to operate the 2022 Global Training Hug for Biomanufacturing (GTH-B) program, providing workforce training in vaccine and biologics R&D and manufacturing for students and professionals from LMICs and Korea.

Following the successful completion of two multiweek courses in its first year, IVI organized the Introductory Course for Biologics Development and Manufacturing as well as the Introductory Course for Standard Practice (GxP) again in 2023, training over 450 professionals from around the world.

The biologics development and manufacturing course covers the full cycle of vaccine research and development, production, and use, including immunology, vaccine technology, product development, preclinical and clinical development, quality control, intellectual property, product licensing, and vaccination, taught by a faculty team of experts across government, international organizations, academia, and funding agencies.

The GxP course is a comprehensive overview of international standards of quality for vaccine and biomedical product development and manufacturing known as Good Clinical, Manufacturing, and Laboratory Practice, and Clinical Laboratory Practice (GCP, GMP, GLP, GCLP).

Collaborators
- Ministry of Health and Welfare, Republic of Korea
- World Health Organization

Funder
- Ministry of Health and Welfare, Republic of Korea

KOR-IDB Biomanufacturing Training

In October 2023, IVI conducted the didactic training component of the KOR-IDB Biomanufacturing Training with 20 bio-R&D and production personnel from Latin American countries. With the COVID-19 pandemic highlighting the need for biomanufacturing in LMICs to improve global vaccine equity, this training was initiated as a pilot project to strengthen biomanufacturing capacity of South and Central American countries. The weeklong didactic training centered on basic theory, basics of cGMP, biosafety, and case studies.

Collaborator
- K-Bio Health, Republic of Korea

Funder
- Inter-American Development Bank

Participants of the KOR-IDB Biomanufacturing Training. Credit: IVI

2023 Hands-on Training for Upstream Process in Vaccine Manufacturing

IVI held an opening ceremony at headquarters in Seoul on October 30, 2023, to kickstart Hands-on Training for Upstream Process in Vaccine Manufacturing in partnership with KEMRI-Wellcome Trust Research Programme and Korea Biopharmaceutical CMO. Credit: IVI

This 6-week course was tailored to train African vaccine manufacturing industry workers on all aspects of the upstream production process. Following the didactic component at IVI, the apprentices spent an additional four weeks for a hands-on segment at K-BIO, a contract manufacturing organization based in Korea. The objective of the course was to prepare the apprentices to transition from the preclinical vaccine R&D phase to small-scale production in their home facilities while prioritizing quality control from inception to product.

Collaborator
- K-BIO CMO Center, Republic of Korea

Funder
- KEMRI-Wellcome Trust Research Programme, Kenya

AHRI-IVI Collaborating Center Seminar Series

In 2023, IVI's clinical development team began hosting the AHRI-IVI Collaborating Center Seminar Series focusing on vaccine R&D and manufacturing capacity-strengthening. The first three seminars focused on experiences from cholera vaccine research and development with perspectives from both researchers and manufacturers:

Collaborators
- Armauer Hansen Research Institute, Ethiopia
- EuBiologics, Republic of Korea

01 Inactivated oral cholera vaccines: from biomedical concept to public health reality

Speaker: Prof. John D. Clemens, Senior Scientific Advisor, IVI (and former Director General), AHRI Scientific Advisory Board

02 Introduction to technology transfer with special emphasis to oral cholera vaccine (OCV)

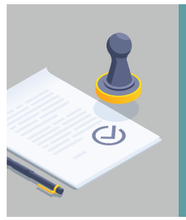
Speaker: Dr. Ruchir Kumar Pansuriya, Research Scientist, IVI

03 Development, production, and innovations of oral cholera vaccine from manufacturer's point of view

Speaker: Rachel Park, Director of Business Development, EuBiologics

Publications

In 2023, IVI scientists authored or co-authored 103 articles in peer-reviewed scientific journals with 94 articles in the Scientific Citation Index Expanded (SCIE).



103 articles published in peer-reviewing scientific journals

94 articles published in SCIE journals

The top 6 most “high impact” articles from 2023

Title / Authors	Authors from IVI	Reference	Edition	Journal Impact Factor
It is time for ambitious, transformational change to the epidemic countermeasures ecosystem. Torreele E, McNab C, Adeyi O, Bonnell R, Dhaliwal M, Hassan F, Kazatchkine M, Kim H, Kim J, Legido-Quigley H, Liu J, Nishtar S, Ruxrungtham K, Terblanche P, Todd E, da Silva Freire M, Velasquez G, Sirleaf EJ, Clark H.	Jerome Kim	Lancet 2023/ Mar/25; 401(10381): 978-982	SCIE	168.9
Evaluation of the safety, immunogenicity, and faecal shedding of novel oral polio vaccine type 2 in healthy newborn infants in Bangladesh: a randomised, controlled, phase 2 clinical trial. Zaman K, Bandyopadhyay AS, Hoque M, Gast C, Yunus M, Jamil KM, Mainou BA, Konopka-Anstadt JL, Hendley WS, Vincent A, Clemens R, Clemens SAC, Ross AG, Clemens JD, Tritama E.	John D. Clemens	Lancet 2023/ Jan/14; 401(10371): 131-139	SCIE	Lancet 2023/ Jan/14; 401(10371): 131-139
The unfinished agenda of communicable diseases among children and adolescents before the COVID-19 pandemic, 1990-2019: a systematic analysis of the Global Burden of Disease Study 2019. GBD 2019 Adolescent Communicable Disease Collaborators	Suneth Agampodi	Lancet 2023/ Jul/22; 402(10398): 313-335		168.9
Defining a research agenda for environmental wastewater surveillance of pathogens. Shaw AG, Troman C, Akello JO, O’Reilly KM, Gauld J, Grow S, Grassly N, Steele D, Blazes D, Kumar S, Environmental Surveillance Working Group	Raphael Zellweger	Nat Med 2023/Sep; 29(9): 2155-2157	SCIE	82.9
Efficacy of a bivalent (D614 + B.1.351) SARS-CoV-2 recombinant protein vaccine with AS03 adjuvant in adults: a phase 3, parallel, randomised, modified double-blind, placebo-controlled trial. Dayan GH, Rouphael N, Walsh SR, Chen A, Grunenberg N, Allen M, Antony J, Asante KP, Bhate AS, Beresnev T, Bonaparte MI, Celle M, Ceregido MA, Corey L, Dobrianskyi D, Fu B, Grillet MH, Keshtkar-Jahromi M, Juraska M, Kee JJ, Kibuuka H, Koutsoukos M, Masotti R, Michael NL, Neuzil KM, Reynales H, Robb ML, Villagomez Martinez SM, Sawe F, Schuerman L, Tong T, Treanor J, Wartel TA, Diazgranados CA, Chicz RM, Gurunathan S, Savarino S, Sridhar S.	Anh Wartel	Lancet Respir Med 2023/Nov; 11(11): 975-990	SCIE	76.2
Population health outcomes in South Korea 1990-2019, and projections up to 2040: a systematic analysis for the Global Burden of Disease Study 2019. GBD 2019 South Korea BoD Collaborators	Suneth Agampodi	Lancet Public Health 2023/ Aug; 8(8): e639-e650	SCIE	50.0

Partnerships and Advocacy

First Lady Kim Keon Hee of the Republic of Korea inaugurated as 5th Honorary President of IVI Support Committee

First Lady Kim Keon Hee of the Republic of Korea was inaugurated as the 5th Honorary President of the Korea Support Committee for IVI on March 9, 2023, and pledged to support vaccine development and delivery efforts during her visit to the IVI Vaccine Diplomacy Day event. As the Committee's Honorary President, the First Lady is expected to urge countries and the international community to join IVI as member states and strengthen partnerships with the Institute going forward.

First Lady Kim Keon Hee (right) of the Republic of Korea receives the plaque of appointment as the 5th Honorary President of the Korea Support Committee for IVI from IVI Director General Dr. Jerome Kim (center), and KSC President Prof. Park Sang-chul at IVI headquarters in Seoul on March 9, 2023. Credit: Presidential Office, Republic of Korea

Ambassador Ma. Theresa Dizon-de Vega announces the Government of the Republic of the Philippines has made a donation to the International Vaccine Institute. She poses for a photo with IVI's Director General Dr. Jerome Kim. Credit: IVI

Government of the Republic of the Philippines makes voluntary contribution to IVI

During IVI's Vaccine Diplomacy Day, H.E. Ma. Theresa Dizon-de Vega, the Philippine Ambassador to the Republic of Korea, announced a $20,000 USD voluntary contribution from the Government of the Republic of the Philippines to IVI, expressing continued support for IVI's efforts in researching and developing vaccines against infectious diseases to protect vulnerable populations worldwide.

Dr. Julia Lynch, Director of IVI's Cholera Program, opens Cholera Vaccine Research Day at IVI headquarters on October 10, 2023. Credit: IVI

IVI hosts a Cholera Vaccine Research Day on the 10th anniversary of the creation of the oral cholera vaccine global stockpile

2023 marks the 10th anniversary of the World Health Organization's establishment of the oral cholera vaccine (OCV) global stockpile managed by the International Coordinating Group (ICG), yet the current supply falls short of meeting the needs of countries at risk amid a surge in cholera outbreaks; to address enduring vaccine research questions and explore the next generation of cholera vaccines, IVI hosted a Cholera Vaccine Research Day attended by stakeholders including researchers, global health funders, manufacturers, and representatives from affected countries, ahead of the Global Task Force on Cholera Control's (GTFCC) annual Working Group Meeting on Oral Cholera Vaccine.

IVI-WHO Consultation on *Salmonella* Combination Vaccines

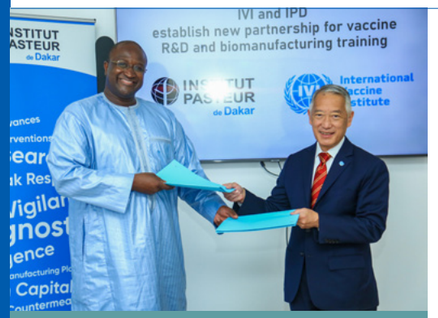
On December 4, 2023, IVI and the World Health Organization jointly hosted a consultation during the 13th International Conference on Typhoid & Other Invasive Salmonelloses in Kigali, Rwanda, aimed at gathering opinions from key stakeholders and subject-matter experts on *Salmonella* combination vaccines to inform developers, policy decision-makers, and donors, with a follow-up consultation planned in 2024 for a more in-depth analysis of the discussed issues.

Key stakeholders gathered at a joint consultation on the sidelines of the 13th International Conference on Typhoid & Other Invasive Salmonelloses in Kigali, Rwanda. Credit: IVI

IVI and CEPI co-host Vaccine Session at the World Bio Summit 2023

IVI and CEPI co-hosted the “Vaccine Session” during the World Bio Summit 2023 in Seoul, focusing on strengthening global preparedness through CEPI’s 100 Days Mission and featuring presentations and discussions on collaboration between IVI and CEPI, vaccine development efforts, and industry-academia partnerships in vaccine research and production, with a focus on South Korea’s role in enhancing bio production and R&D cooperation in Asia.

Dr. Jerome Kim, Director General of IVI, presents on IVI/CEPI collaborations during the World Bio Summit 2023. Credit: IVI



Dr. Amadou Sall, CEO of IPD (left), and Dr. Jerome Kim, Director General of IVI (right), exchange a Memorandum of Understanding establishing a partnership between the IVI and IPD.

IVI and Institut Pasteur de Dakar establish new partnership for vaccine R&D and biomanufacturing training

IVI and Institut Pasteur de Dakar (IPD) have signed an MoU to collaborate on establishing IPD as a regional Center of Training Excellence for Biomanufacturing, supporting vaccine manufacturing and technology transfer in Africa, and conducting end-to-end vaccine development while focusing on capacity-building, particularly for young women, and leveraging IVI’s expertise and network of partners to accelerate research and development efforts.

IVI, Korea Advanced Institute of Science and Technology to collaborate in global vaccine research to accelerate innovations in vaccines and immunology

IVI and the Korea Advanced Institute of Science and Technology (KAIST) exchanged an MoU for global vaccine research collaboration at KAIST headquarters in Daejeon, Korea on November 23, 2023. Under the MoU, the two organizations agreed to work together in four main areas including vaccine immune response analysis using KAIST’s technology.

Key participants including KAIST President Prof. Kwang-Hyung Lee (left from left) and IVI Director General Dr. Jerome Kim (fifth from left) pose for a commemorative photo at the signing ceremony. Credit: KAIST

Memorandum of Understanding for cooperation in vaccine research, global public health between Nankai University and IVI

On May 16, 2023, IVI and Nankai University signed an MoU for cooperation in vaccine research, global public health, and talent development, with the aim of enhancing global health security.

Chen Yulu, President of Nankai University (left), and Jerome H. Kim, Director General of IVI (right), sign an MOU establishing the IVI Nankai Joint Vaccine Center. Photo courtesy of Nankai University

IVI receives grand prize for running exemplary IACUC to ensure protection of laboratory animals

IVI has been awarded for its exemplary care of laboratory animals by the Government of the Republic of Korea, recognizing its commitment to ethical research practices. IVI’s Animal Research Facility Supervisor Seung Yeon Kim (left) and Senior Scientist Dr. Jae-ouk Kim (right), who are serving as Coordinator and Vice Chair of IVI’s IACUC respectively, pose for a photo as they receive the Agriculture, Food and Rural Affairs Minister’s Prize at an award ceremony on April 27, 2023.

IVI’s Animal Research Facility Supervisor Seung Yeon Kim (left) and Senior Scientist Dr. Jae-ouk Kim (right), who are serving as Coordinator and Vice Chair of IVI’s IACUC respectively, pose for a photo as they receive the Agriculture, Food and Rural Affairs Minister’s Prize at an award ceremony on April 27.

Dr. Jae Ouk Kim, Senior Research Scientist at IVI, receives the Health Minister’s Award for her contributions to infectious disease education. Credit: IVI

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Florian Marks, PhD
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As of December 31, 2023

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IVI Board of Trustees at Headquarters in Seoul, Republic of Korea. Credit: IVI

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As of December 31, 2023

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As of December 31, 2023

IVI Scientific Advisory Group at Headquarters in Seoul, Republic of Korea. Credit: IVI

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On October 22, 2022, IVI launched its Global Advisory Group of Experts chaired by Dr. Deborah Birx to advise IVI on matters of global health and diplomacy. Credit: IVI

As of December 31, 2023

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As of October 2023

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Vaccines for a Healthier Future
Korea Support Committee for IVI

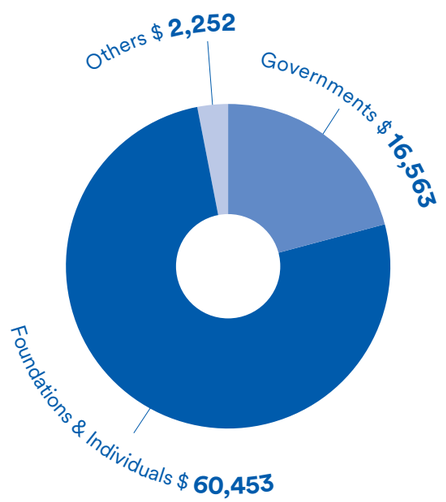
Financial Summary 2022 & 2023

(USD '000)

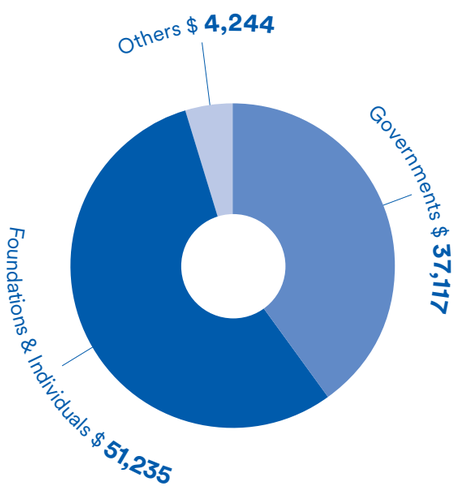
Revenue (Grants and contribution)	2022	2023
Governments	16,563	37,117
Foundations & Individuals	60,453	51,235
Others	2,252	4,244
Total Revenue	**79,267**	**92,595**

Expenses	2022	2023
Program Service	50,359	58,405
Cholera	5,145	5,886
Typhoid	2,892	3,080
COVID19	24,598	18,608
Chikungunya	2,947	1,504
HPV	795	4,212
Others	13,983	25,115
Laboratory Support	1,886	2,495
Administration	8,922	8,905
Fundrasing & Advocacy	1,119	1,306
Others	3,110	2,469
Total Expense	**65,396**	**73,580**

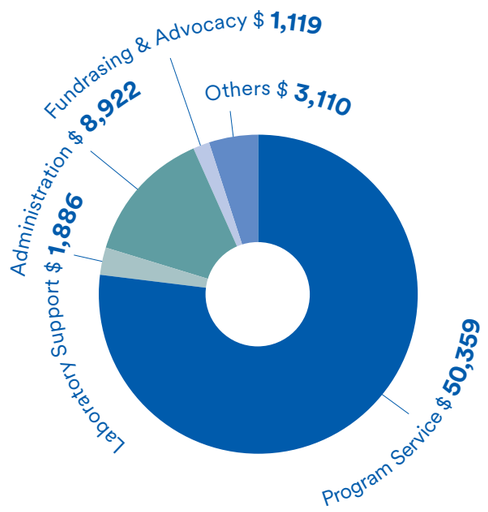
2022



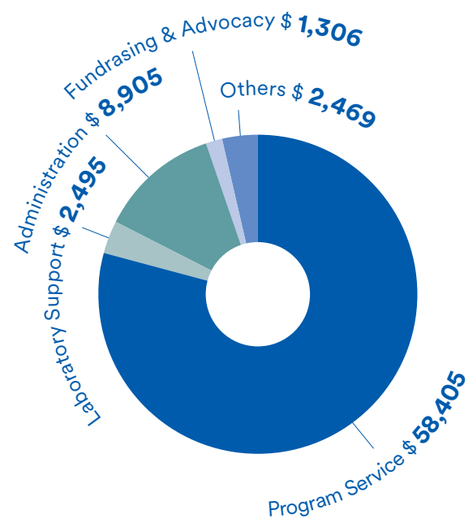
2023



2022



2023



Assets	2022	2023
Cash and Bank Deposit	55,039	57,688
Contribution receivable	11,072	25,007
Fixed Assets	19,301	20,546
Other	1,323	1,549
Total Assets	**86,736**	**104,790**

Liabilities and Net Assets	2022	2023
Liabilities	6,113	5,152
Net Assets	80,623	99,638
Total Liabilities and Net Assets	**86,736**	**104,790**

Vaccines for a Healthier Future
Financial Summary 2022 & 2023

IVI is uniquely present at every step of the vaccine value chain

Vaccines for a Healthier Future

2023 Annual Report

International Vaccine Institute

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