

Vaccines for a Safer Future

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.

2020 ANNUAL REPORT



"With significant capacity-building followed by the successful completion of the Vi-DT Phase 3 clinical trial in Nepal, Dhulikhel Hospital and IVI have significantly contributed to meeting the public health needs of typhoid endemic countries and paved a way for fostering the research culture in Nepal."

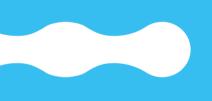
















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Reflections on 2020

Dear friends and colleagues,

2020 was a historic year, bookended by the emergence of a novel virus that has wreaked tragedy around the world and the start of public vaccinations following the largest and fastest ever effort to develop and deliver new vaccines. The consequences of the COVID-19 pandemic on every aspect of our lives may come to define 2020 for most, but our collective response to the crisis, from the setbacks to the successes, is a significant part of the story—one that will guide the future of global health and vaccine equity.

Like other R&D institutions around the world, IVI quickly mobilized resources and project teams to accelerate vaccine solutions to end the pandemic. Our approach was to leverage our lab and clinical trial expertise to support clinical and pre-clinical development of 10 different vaccine candidates, which has included vaccine clinical trials, supporting the establishment of the WHO's international standard for anti-SARS-CoV-2 antibody, as well as epidemiological studies to expand transmission data in sub-Saharan Africa.

IVI applauds the tireless work of other researchers who have achieved extraordinary scientific achievements to bring the finish line in sight; the health workers who responded to the pandemic at the frontline; the leaders and policymakers who created global mechanisms like the COVAX Facility to ensure equity is a priority for global vaccine roll-out; and the essential workers, organizers, and volunteers who supported their communities every step of the way at great personal cost.

Of course, as an international organization with the mission to discover, develop and deliver safe, effective and affordable vaccines for global health, preventing and eliminating widespread diseases has been our modus operandi for the past nearly 24 years. In 2020, IVI took a meaningful step closer to licensing a new typhoid conjugate vaccine to protect more people against a deadly endemic disease, launched a new global program to advance the world's first Chikungunya vaccine, and secured new partnerships to prevent and control cholera outbreaks in atrisk populations using IVI's oral cholera vaccine. All the while, we made steady progress on our existing R&D portfolio, which includes various stages of vaccine clinical development and epidemiological studies for diseases such as non-typhoidal Salmonella, shigella, schistosomiasis, Group A Strep, hepatitis A, HPV, tuberculosis, and Japanese encephalitis.

Beyond vaccine research and development projects, IVI additionally kicked off two new projects to build global capacity in effectively responding to the threat of antimicrobial resistance, an urgent and growing threat to global health that is often referred to as the "silent pandemic." In 2020, IVI was also pleased to welcome Finland as IVI's 36th member state and the First Lady of the Republic of Korea as the Honorary President of IVI's Support Committee.

The COVID-19 pandemic continues to be (at time of writing) a global public health emergency that transcends borders, demanding a truly global solution that leaves no country or person behind. This historic moment is an opportunity to unite, collaborate, innovate, and build a healthier future. The work continues, and we are grateful to do it with you.

With gratitude,

Director General **Jerome H. Kim**, M.D.

Jecom H. Kum

2020 Highlights

01

Finland joins IVI

IVI welcomed Finland as IVI's 36th member state and fourth funding state, committing core support as well as additional funding to advance IVI's COVID-19 vaccine research and development.



Ambassador Eero Suominen hoists the flag of Finland at IVI following Finland's accession to IVI, becoming the organization's 36th member state. Credit IVI

02

Supporting the establishment of WHO international standard for anti-SARS-CoV-2 antibody

IVI partnered with vaccine developers and global regulatory agencies to establish vaccine evaluation systems such as ELISA and standard sera for COVID-19 to assess the binding and neutralizing Ab titers. Our support led to the establishment of the World Health Organization's international standard as well as the Republic of Korea's standard. Our lab has additionally partnered with vaccine developers in Korea—Celltrion, Sumagen, GI Innovation, and Genofocus—to evaluate the immunogenicity and protective efficacy of each of their vaccine candidates in an animal infection model.

03

Advancing clinical development of **COVID-19 vaccines**

IVI partnered with INOVIO, an American biotech company; the Korea National Institute of Health: and the Coalition for Epidemic Preparedness Innovations (CEPI) to conduct a Phase 1/2 clinical trial of INOVIO's COVID-19 vaccine candidate at four sites in South Korea. IVI also partnered with Clover Biopharmaceuticals as a co-sponsor to conduct a Phase II/ III study in Nepal,. and is additionally supporting Genexine, CELLID, and EuBiologics with the immunological assessment of their respective COVID-19 vaccine candidates.

04

Conducting epidemiological studies of **COVID-19 in Madagascar and Burkina** Faso to determine disease burden and support case reporting

IVI received support from Sweden's Sida to partner with local institutions in Madagascar and Burkina Faso to detect COVID-19 by putting into place surveillance measures across health care centers. Additional efforts include tracing and testing household contacts of confirmed cases to improve household transmission data.

05

Improving surveillance and data collection to create sustainable solutions for AMR

Through three separate Fleming Fund Regional Grants, funding provided by the UK government, IVI and consortium partners are working with low- and middle-income countries across Asia and sub-Saharan Africa to identify, evaluate, and create a demand for quality data to inform effective AMR policy.

06

Developing the world's first Chikungunya vaccine

IVI and Bharat Biotech, an Indian biotech company, formed a consortium with support from CEPI to conduct a multi-country Phase 2/3 adaptive clinical trial in Asia and Latin America and accelerate vaccine manufacturing to advance a globally needed Chikungunya vaccine.

07

Protecting more people from typhoid

A study from IVI in collaboration with SK bioscience, a Korean biopharma company, confirmed that single- and two-dose regimens of Vi-DT, a new typhoid conjugate vaccine developed by IVI, are safe and immunogenic in children 6-23 months of age. Phase III studies are nearing completion in Nepal, the Philippines, and Indonesia.



Investigators Meeting for Vi-DT Typhoid Conjugate Vaccine Phase III study in Kathmandu, Nepal. Credit IVI

08

Reducing the burden of Schistosomiasis in **Madagascar and Burkina Faso**

In 2020, IVI wrapped its Schistosomiasis in Madagascar (SOMA) project, an effort in collaboration with the University of Antananarivo. IVI keeps working with key collaborators in Madagascar and Burkina Faso (two Schistosomiasis-endemic countries) through the VASA project to address the gap between pre-clinical and early clinical development of vaccines against Schistosomiasis.

09

Advocating for vaccine diplomacy

IVI's annual State Forum focused on building multilateral cooperation through vaccine diplomacy to develop sustainable. equitable, and cooperative vaccine solutions to end the COVID-19 pandemic.



10

Preventing cholera outbreaks with OCV

IVI and South Korea's Global Disease Eradication Fund joined forces to protect people at risk of cholera in Nepal and Mozambique through vaccination; water, sanitation, and hygiene (WASH) activities; and disease surveillance.

11

Developing a novel vaccine platform

IVI and Sumagen, a Korean biopharma company, started to develop a new viral vaccine platform funded by VITAL KOREA. IVI and Sumagen will evaluate the viral vaccine platform using two disease models: Middle East respiratory syndrome coronavirus (MERS) and Crimean-Congo hemorrhagic fever, two priority diseases included in the WHO's R&D Blueprint.

In 2020, IVI made significant progress on incorporating gender equality into our operations, the way we conduct research, and how we work with each other and our partners.

Following an internal workshop on gender mainstreaming, IVI created its first standalone Gender Policy that was approved by the Board of Trustees in early 2021.

Through a comprehensive approach to achieving gender equality through our work and how we do it, we aim to remove gender-related barriers to essential health services including vaccination as well as to leadership positions within our organization and beyond.



Credit IV

Vornoing the SDGs: Gender Equality

Advancing the SDGs: Gender Equality

healthy society

Gender equality is

a precondition of a

Gender mainstreaming at IVI

International Vaccine Institute

Incorporating a gender analysis in project lesigns, beginning in the grant-writing phase

Conducting equitable epidemiological studies and clinical trials with gender-sensitive communications between research staff and targeted populations

Ensuring IVI's research programs consider expanding access to vaccines for girls and women in low- and middle-income countries

Designing and implementing vaccination programs with a gender-sensitive approach to the role of caregivers

Ensuring genderinclusive participation in policy-making decisions and valuing diverse representation in study teams

Applying a gender
equality perspective
across organizational
rules, procedures,
systems, mechanisms,
projects, and
programming within

8

Bringing environmental sustainability to vaccine research, development, and delivery



Vaccines and climate change

In an increasingly globalized world, new and emerging infectious diseases have become threats of major global health concern while endemic diseases like cholera continue to devastate livelihoods, economies, and social structures.

Vaccination, reinforced by other public health measures such as Water, Sanitation, and Hygiene (WASH) campaigns, saves lives and serves an integral part of holistic action against climate change, most evidently by protecting against diseases potentially made worse by warmer temperatures and altered rainfall patterns.

The distribution and prevalence of water-borne diseases like schistosomiasis, and viral infections transmitted by mosquitos like chikungunya, may be shifted or exacerbated by changing climates and precipitation patterns. Our epidemiology and clinical research teams are conducting clinical trials for vaccine candidates with the ultimate goal of developing and delivering long-term protection against these debilitating diseases.

Greening IVI's operations

In 2020, IVI took steps to integrate environmental responsibility into the way we work, such as adopting an environmental management system to reduce our carbon footprint and negative environmental impacts.

Increasing efficiency, saving energy

By replacing old boilers with higher efficiency ones, IVI educed LNG gas consumption by 16.3% and energy costs by 12% for an annual cost saving of approximately \$33,000 USD

Reducing our carbon footprint

IVI enhanced its bid guidelines for procurement of energy-efficient goods and developed a new Traveler's Checklist to reduce travel-related carbon emissions

Communicating our committment

IVI made available a publi statement committing to environmental sustainability in our work and how we operate





IVI team members on World Environment Day 2020. **Credit** IVI IVI's role in the global health landscape

From the lab to the field

Making available safe, effective and affordable vaccines for use in resource-limited settings

IVI conducts vaccine research and development from epidemiological studies to clinical trials and licensure with a range of public-private partnerships and industry partners to make vaccines available for public use.

By executing upstream vaccine R&D, IVI makes it possible for organizations like national regulatory agencies and the WHO to approve vaccines; CEPI to complete their mission to accelerate the development of vaccines against emerging diseases, Gavi, the Vaccine Alliance to purchase affordable vaccines for use in low- and middle-income countries; and UNICEF to deliver vaccines where they're needed most.

Through this ecosystem of global health partners, we can make life-saving vaccines available for those most vulnerable to the threat of infectious diseases and take steps toward achieving global health equity.

IVI's vaccine R&D capabilities

Field surveillance and Laboratory research Policy, Delivery, Product development Licensure and and clinical trials vidence generation and discovery registration Effectiveness Vaccine technology · WHO pre- Epidemiology · Proof-of- concept Vaccination qualification transfers vaccine prototypes campaigns · Health economics · Pre-clinical, animal, Trial site preparation · Capacity-building Effectiveness · Post-vaccineand toxicology demonstration introduction studies Project management · Technical support to studies Uptake and access vaccine developers · Field site capacity-· Clinical trial Process building execution Coordination with development national regulatory Policy studies · Data management agencies Economic analysis · Full Value of Vaccine and Investment **Analysis** cases · Control strategies

IVI's model

Developing unincentivized vaccines for equitable global health

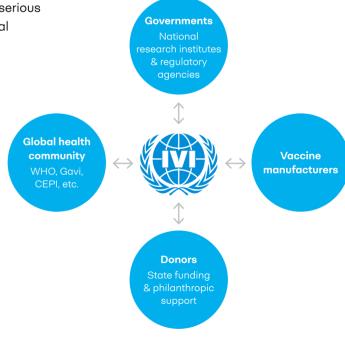
Unincentivized vaccines are vaccines that protect against infectious diseases that predominantly affect low- and middle-income countries. These vaccines have the potential to save lives and improve the livelihoods of billions of people, but the high investment for limited return provides little financial incentive for major vaccine makers to pursue vaccine development.

The product development partnership (PDP) model

PDPs mobilize partnerships between the public, private, and philanthropic sectors to develop new products urgently needed by people suffering from, or at risk of, serious diseases that are often neglected by traditional markets.

The development of IVI's oral cholera vaccine (OCV)—the first affordable OCV available for global public use—was a product of PDPs made possible by publicly funded research, partnerships with private biotech companies and vaccine manufacturers, and coordination with government bodies and other global health organizations.

IVI continues to work with product development partners to accelerate vaccine development for other diseases such as typhoid, MERS, shigella, non-typhoidal Salmonella, chikungunya, COVID-19, and more. The PDP model was critical to the global COVID-19 response, enabling the largest and fastest vaccine development effort to end the pandemic.



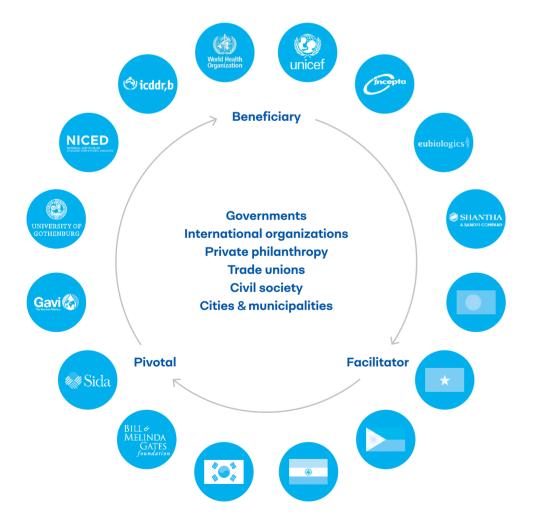
The PDP model fills critical gaps in global health by mobilizing the necessary resources, capabilities, and political will to develop vaccines and other essential health innovations for the public market.

IVI additionally employs the SSTC model to advance sustainable vaccine development and delivery with multiple state beneficiaries. As part of our mandate to build in-country capacity everywhere we work, IVI facilitates multilateral collaboration to exchange knowledge, expertise and resources to meet shared health and development goals.

IVI's pivotal role in facilitating the development and production of affordable, WHOprequalified OCVs led to the creation of a global stockpile for public use.







The development of affordable oral cholera vaccines (Shanchol, Euvichol® and Euvichol-Plus®) relied on a triangular cooperation model with multiple partners in each role:

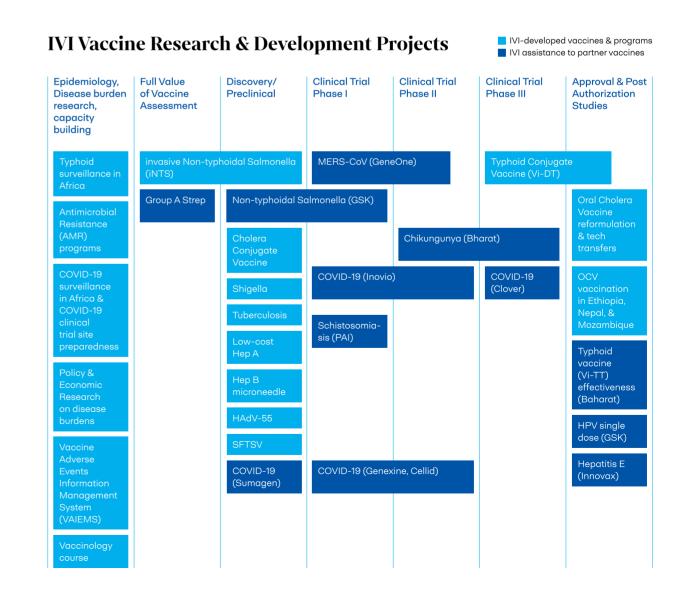
Beneficiary partner: Requests assistance for a specific health intervention Pivotal partner: Shares expertise resources and assistance Facilitator: Provides financial and technical support

IVI Vaccine R&D Programs

Vaccine Research and **Development at IVI**

IVI's capabilities span epidemiology and health economics research to vaccine discovery in the lab, clinical trials through licensure and WHO pregualification, technology transfer to manufacturers, and post-introduction impact studies.

We focus on infectious diseases of global health importance such as cholera, typhoid, shigella, non-typhoidal Salmonella, schistosomiasis, chikungunya, group A strep, Hepatitis A, HPV, TB, HIV, MERS, and COVID-19, as well as solutions to combat the global spread of antimicrobial resistance.



On January 30, 2020, the WHO declared the novel coronavirus outbreaka Public Health Emergencyof

International Concern. By March, the spread of COVID-19 was characterized as a pandemic.

COVID-19

Accelerating vaccines to end the COVID-19

pandemic





In 2020, IVI began working with multiple international and Korean partners to help develop several COVID-19 vaccine candidates, conduct early-stage clinical trials and epidemiological studies, establish vaccine evaluation systems, and develop COVID-19 vaccine adjuvants.

COVID-19 is a respiratory illness caused by a novel coronavirus first identified at the end of 2019. The most common symptoms of COVID-19 are fever, dry cough, and fatigue with severe symptoms of the disease including shortness of breath, loss of appetite, pressure in the chest and high temperature.

Vaccine research & development

Conducting a Phase I/II clinical trial at four sites in the Republic of Korea

IVI is supporting clinical development of INOVIO's COVID-19 vaccine candidate(DNA vaccine with electroporation) by conducting a Phase I/IIa clinical trial at four sites in the Republic of Korea to demonstrate tolerability, safety, and immunogenicity.

Collaborators

INOVIO Pharmaceuticals Korea National Institute of Health

Funder

Coalition for Epidemic Preparedness Innovations (CEPI)



With clinical supplies in high demand al over the world, IVI worked with a local supply partner to produce and receive necessary supplies at staggered intervals.

Clinical studies to develop **COVID-19 vaccines**

/accine	IVI's role
NOVIO (INO-4800)	Conducting clinical trial Assessing the immunogenicity of the vaccine by conducting ELISA and FRNT of Phase I/IIa clinical trial samples
Genexine (GX-19, GX-19N)	 Assessing neutralizing Ab titer for the Phase I/IIa clinical trial in Korea
CELLID (AdCLD-CoV19)	Assessing the immunogenicity of the vaccine in Phase I/IIa clinical trial
EuBiologics (EuCorVac-19)	Assessing the immunogenicity of the vaccine in Phase I/IIa clinical trial
Clover Biopharmaceuticals (S-Trimer)	Co-sponsoring Phase III clinical trial in Nepal

Pre-clinical studies to develop **COVID-19 vaccines and** therapeutics

Vaccine	Features	IVI's role
Celltrion	Monoclonal Ab	 Evaluating efficacy in animal infection model
Sumagen	Recombinant Vesicular Stomatitis Virus vector- based COVID-19 vaccine	Assessing immunogenicity and protective efficacy in animal model Immunological assessment in clinical trial (ELISA/Neut)
GI Innovation	Vaccine adjuvant	 Assessing immunogenicity and protective efficacy in animal model
Genofocus	Bacterial spore displayed COVID-19 vaccine	Assessing immunogenicity and protective efficacy in animal model

IVI tested international standard candidates in terms of binding antibody titer and neutralizing antibody titer, and transferred the results to the UK's National Institute for Biological Standards and Control, ultimately supporting the establishment of the WHO international standard for anti-SARS-CoV-2 antibody.

IVI additionally supported the Korea Disease Control and Prevention Agency to establish the Korean standard for anti-SARS-CoV-2 antibody.

Epidemiological studies and capacity-building

Building COVID-19 testing capacity in Madagascar and Burkina Faso

COVID-19 Research in African Settings (COVIA)

In response to the disproportionate lack of disease burden data in low- and middle-income countries, COVIA aims to support local institutions in Madagascar and Burkina Faso to detect COVID-19 cases by implementing health care center-based disease surveillance. The COVIA project also includes case finding through tracing and testing household contacts of confirmed cases to broaden understanding of household transmission.

Funder

Swedish International Development Cooperation Agency (Sida)



Inside IVI's BSL 3 labs. Credit IVI

Chikungunya

Advancing the world's first Chikungunya vaccine















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

Global Chikungunya vaccine Clinical Development Program (GCCDP) Conducting a phase II/III adaptive seamless design of BBV87 chikungunya vaccine candidate in Latin America and Asia



In June of 2020, IVI kicked off the GCCDP in partnership with Bharat Biotech to advance clinical development of Bharat's

Chikungunya vaccine candidate. The program involves an adaptive Phase II/III vaccine clinical trial across countries in Asia and Latin America with the ultimate goal of achieving WHO pre-qualification.

The study is a Phase II/III randomized, controlled trial with an adaptive and seamless design to evaluate the safety and immunogenicity of a 2-dose regimen of BBV87 Chikungunya vaccine in healthy subjects aged 12-65 years in Costa Rica, Guatemala, Dominican Republic, Panama, Colombia, 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.

Collaborators

Coalition for Epidemic Preparedness Innovations (CEPI) National Institute for Biological Standards and Control, UK

Funder

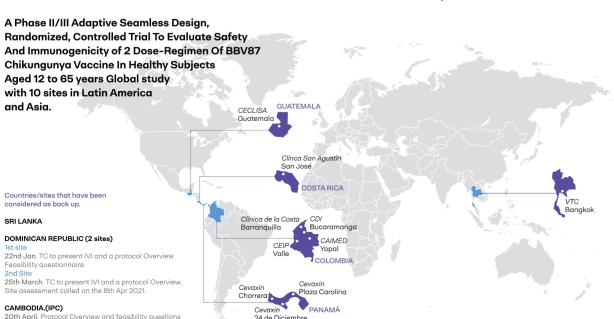
CEPI



GCCDP kick-off meeting at IVI headquarters. Credit IVI

Although the virus was first identified in 1952. Chikungunya began to spread quickly in 2004, causing large-scale outbreaks around the world. Since its re-emergence, the total number of cases has been estimated at over 3.4 million in 43 countries.

The name "Chikungunya" comes from the Kimakonde language of the Makonde people meaning "that which bends up," referring to the hunched posture of those who suffer from the joint pain caused by the disease.



Controlling Typhoid Fever

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













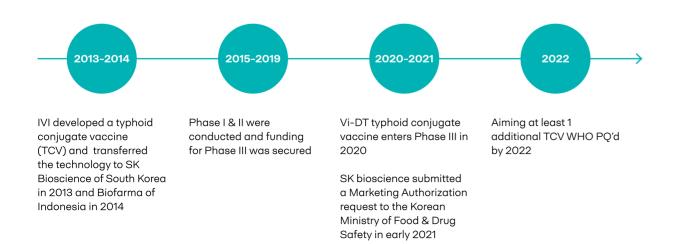
Typhoid fever is a bacterial disease caused by Salmonella enterica serovar Typhi spread through the ingestion of food or drink contaminated by the feces or urine of infected people. It is usually characterized by fever, headache, constipation, and malaise, but it has few symptoms that reliably distinguish it from other infectious diseases, making it difficult to diagnose and treat. Invasive Salmonella infections are a major cause of global morbidity and mortality with the highest burden of disease in South Asia, and account for 12 million to 22 million cases globally every year.

2020 Annual Report

The Gates Foundation shared a global strategy for typhoid fever control that consists of seven pillars. Here's how IVI upholds each of them:

The Gates Foundation's Seven Pillars for Typhoid Fever Control	IVI Programs
Supporting at least two effective typhoid conjugate vaccines that are targeted for achieving World Health Organization prequalification by 2020	Vi-DT typhoid conjugate vaccine development program with SK bioscience and Bio Farma
Starting work on a proof-of-concept for the development of combined pan-Salmonella vaccine	IVI's iNTS vaccine development program
Improving surveillance by developing new and low-cost surveillance methods that can be used for introduction decisions or TCV effectiveness assessment	IVI's epidemiological and vaccine introduction and effectiveness studies: • Severe Typhoid in Africa Program (SETA) • Effect of a novel typhoid conjugate vaccine in
Ensuring introduction of TCVs in at least 10 Gavieligible countries	Africa: a multi-center study in Ghana and the Democratic Republic of the Congo (THECA) • Economic evaluation of TCV introduction in
Generating new TCV performance and operational research data to expand TCV use in endemic and outbreak settings	Navi Mumbai, India TCV introduction in Madagascar (TyMA) Typhoid Fever Fiji Intervention and Elimination Program (Ty-FIVE)
Working towards adoption of a global control strategy	Mozambique Typhoid Fever Surveillance Program (MOTIF)
Assessing the feasibility of the elimination of typhoid fever	

Developing a new-generation typhoid conjugate vaccine (TCV)



IVI developed a TCV—Vi-DT—conjugating the Salmonella Typhi Vi polysaccharide to diphtheria toxoid. Unlike other typhoid vaccines, TCV has been shown to protect infants (a high-risk group) against typhoid. IVI transferred the technology to SK bioscience of South Korea, Bio Farma of Indonesia, and Incepta of Bangladesh and is currently working with SK bioscience and Bio Farma on clinical development for licensure and WHO-prequalification, currently targeted for the end of 2022.



IVI transferred Vi-DT technology in 2013 to SK bioscience for manufacturing and commercialization. A Phase I safety trial of Vi-DT was first conducted in the Philippines in volunteers aged

2-45 years and showed that the vaccine was safe and immunogenic four weeks after the first dose.

Following the successful completion of a Phase II trial with infants under 2 years, large-scale Phase III studies with a single-dose of Vi-DT started in the Philippines and Nepal in 2020. Despite delays with enrollement and participant follow-up visits due to COVID-19 restrictions, Vi-DT was shown to be safe in all trial participants and met its primary endpoints in the Nepal study at the end of 2020, a significant milestone in the effort to license another safe and effective TCV.

The Phase III study in the Philippines is nearing completion and, with IVI's technical support, SK bioscience submitted a Marketing Authorization request to the Korean Ministry of Food & Drug Safety in early 2021. After the MFDS approves the vaccine, it will be submitted to the WHO for pre-qualification review.



IVI also received funding from the Gates Foundation to provide clinical, regulatory, and management support to Bio Farma following Vi-DT technology transfer.

Bio Farma completed a Phase I clinical trial at one site in Jakarta, Indonesia in December 2017. The results were similar to the SK bioscience Phase I study, and there were no safety concerns. Bio Farma's Phase II study with 600 participants was also completed with 12 months of follow up. The Phase III study with a target enrollment of 3,071 volunteers was initiated in January 2020, but due to the high number of COVID-19 infections in Indonesia, enrollment was stopped in March. The enrollment has started again and is tentatively planned to be completed by April 2021.

Collaborators

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

Funder

Bill & Melinda Gates Foundation

Surveillance and Effectiveness Studies

TSAP 2010-2014

SETA 2015-2019 SETA Plus

2019-2023

Invasive Salmonella burden evidence from 10 African countries

Data supported SAGE, Gavi, WHO to introduce TCV into the Gavi portfolio

Filling the gaps on severity, mortality and cost of invasive Salmonella in Africa

Data will support decision-makers and partners on TCV introduction

Surveillance before, during and after TCV vaccination in Ghana, DRC, Madagascar & Burkina Faso

Data will provide evidence of TCV protection at the population level

Filling the gaps for TCV introduction in Africa

Data will provide evidence of TCV clinical efficacy, safety, immunogenicity and costs

Severe Typhoid in Africa Program (SETA) Plus

IVI has conducted the SETA project since 2015, successfully completing it at the end of 2019 and transitioning to SETA Plus in 2020 following further funding. Our "SETA countries" are Nigeria, Burkina Faso, Ghana, the Democratic Republic of the Congo (DRC), and Madagascar, where we collect standardized data on typhoid fever disease incidence, severity, sequelae, and economic burden in addition to invasive salmonellosis incidence and severity.

In response to the COVID-19 outbreak, the SETA Plus team provided the Nigeria site with personal protective equipment (PPE) to ensure the safety of team members and study participants, and co-developed risk mitigation plans. Safety trainings were also implemented in Burkina Faso and Ghana. With additional funding from the Cambridge-Africa ALBORADA

Research Fund and Sida, diagnostics for COVID-19 were expanded in DRC, Burkina Faso, and Madagascar, and surveillance platforms in Burkina Faso and Madagascar were leveraged to track COVID-19 in the regions.

Collaborators

Kwame Nkrumah University for Science and Technology, Ghana Institute National for Biomedical Research, DRC Institute for Tropical Medicine, Belgium University of Ouagadougou, Burkina Faso

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Bill & Melinda Gates Foundation



SETA Plus team provided the Nigeria site with personal protective equipment (PPE) to ensure the safety of team members and study participants.

and this was a cause for concern as four individuals from the same compound tested positive for Salmonella typhi. Their results were handed over to the physician and they were given the necessary medical attention. This would not have been possible if the SETA study team had not visited the home of the initial enrollee from OLACH." Halimat Babalola, Phlebotomist at General Out-Patients' Department, Our Lady of Apostles' Catholic Hospital (OLACH)

"A pediatric patient recruited at OLACH in 2018 tested

positive for Salmonella typhi. This led to the recruitment of two household and four neighborhood controls. After the first follow-up, three days after recruitment, one of the

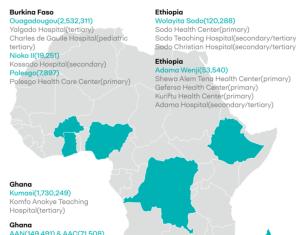
recruited household members and two individuals from

the neighborhood controls became febrile: they visited OLACH and were recruited into the SETA study. Their

blood culture results were positive for Salmonella typhi,

SETA(2015-2019)

Severe Typhoid Surveillance in Africa Program



Ghana AAN(149,491) & AAC(71,508)

Nigeria Ibadan(1,343,147) Our Lady of Apostles Catholic Hosp Adeoyo Maternity Teaching

Kola Daisi Founda Democratic Republic of the Congo

Kayuaya Health Center(primary)

d'Antananarivo-Hospital

Raseta Befelatanana(secondary/tertiary saralalana(pediatric secondary/tertiary)

SETA+(2020-2022)

Severe Typhoid Surveillance in Africa Program+



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



The THECA project was initiated in 2019, planned in parallel to the SETA program. THECA includes a cluster-randomized vaccine effectiveness trial in Ghana and a mass vaccination campaign in

DRC using the recently licensed typhoid conjugate vaccine Typbar-TCV® (also referred to as Vi-TT). An embedded health economics study will also assess the feasibility and cost-effectiveness of TCV when administered through a mass vaccination campaign. These studies will additionally generate data on the safety and immunogenicity of Vi-TT and measure the impact of vaccination in limiting the spread of antimicrobial resistance.

Collaborators

Kwame Nkrumah University for Science and Technology, Ghana Institute National for Biomedical Research, DRC Institute for Tropical Medicine, Belgium Foundation Merieux, France University of Ouagadougou, Burkina Faso

Funders

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

THECA(2019 - 2023)

Typhoid conjugate vaccine effectiveness



Economic Evaluation of TCV introduction in Navi Mumbai, India

IVI partnered with the Navi Mumbai Municipal Corporation to introduce TCV in its public immunization program to help control typhoid fever with a two-phase vaccination activity targeting a population of approximately 400,000 children aged 9 months to 14 vears.



IVI is leading the economic analysis which has three components: 1) estimation of TCV delivery costs and development of a global TCV delivery costing tool, 2) estimation of cost-of-illness, and 3) estimation of cost-effectiveness of TCV introduction in Navi Mumbai.

The result of this economic evaluation study will serve as a comprehensive set of evidence to inform decision making around TCV introduction in India as well as at regional and global levels. The generated data will be also helpful in budgeting and planning for future introduction activities as well as to understand the economic burden resulting from typhoid fever in India.

Collaborators

Navi Mumbai Municipality Corporation, India Centers for Disease Control and Prevention, USA World Health Organization National Institute of Cholera and Enteric Diseases

Funders

World Health Organization **CDC** Foundation

New typhoid surveillance and **TCV introduction programs**

In 2020, IVI initiated three new typhoid programs across Mozambique, Madagascar and Fiji

The Mozambique Typhoid Fever Surveillance Program (MOTIF) aims to support the government of Mozambique in generating typhoid fever burden data, enabling the country to apply for Gavi subsidies and introduce TCV into their national immunization program.

TCV introduction in Madagascar (TyMA) aims to control the spread of typhoid fever by vaccinating at-risk groups (namely, children) and supporting the development of a national typhoid fever control plan.

Typhoid in Fiji - Vaccination & Elimination (Ty-FIVE), in partnership with the Fijian EPI program, aims to vaccinate the entire population (over the age of 9 months) of Vanua Levu to protect the island against typhoid fever and assess the preventive impact and feasibility of a single-dose regimen of Vi-TT.

Instituto Nacional de Saúde, Mozambique (MOTIF) University of Cambridge, Dept of Medicine, UK (TyMA) University of Antananarivo, Madagascar (TyMA) Ministry of Health, Madagascar (TyMA) Ministry of Health, Fiji (Ty-FIVE)

Murdoch Children's Research Institute, Australia (Ty-FIVE) Peter Doherty Institute for Infection and Immunity, Australia (Ty-FIVE)

Funder

Prof. Young Chul Sung, POSTECH, Republic of Korea

Ending Cholera

IVI's Cholera Program makes available highquality and affordable oral cholera vaccines (OCV) to protect people in cholera-epidemic and endemic countries while generating evidence to support decision-makers in using OCV in highrisk settings.





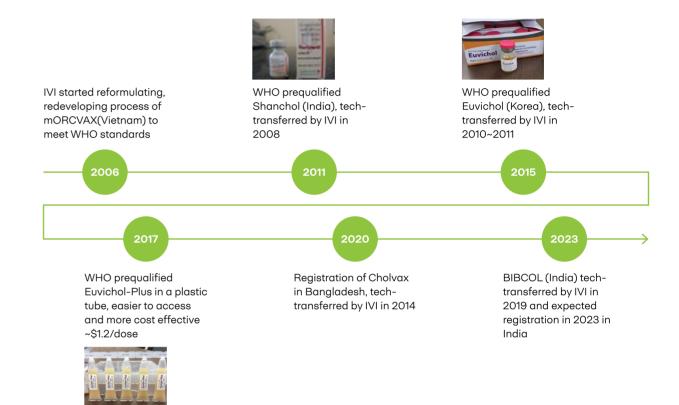






Cholera is a poverty-associated diarrheal infection that strikes in overly crowded settings with limited access to safe water and sanitation. Deadly outbreaks also occur following natural disasters and other humanitarian crises such as forced displacement, making disease prevention for vulnerable populations a global health priority. Cholera affects both adults and children, causing disease in more than 2.5 million people every year and killing nearly 100,000.

Oral Cholera Vaccine development at IVI



IVI has been committed to making safe, effective, and affordable OCV available to communities made vulnerable by poverty, lack of resources, and conflict since 2006. The creation of a global public stockpile of OCV in 2013 continues to save countless lives and helped map a pathway to a world free of this devastating disease, an undertaking made possible by close partnerships between the public and private sectors.

As of 2020, an estimated 60 million doses of OCV

developed by IVI have been

deployed in more than 20

countries from the global

stockpile.



Yemen 201



Mozambique 2018



Nepal 2015

Looking ahead, IVI is working toward 3 goals to increase OCV use and accessibility:

Goal 1: Support current OCV manufacturers to maintain or increase supply

Technology transfer and capacity-building

In 2020, Bangladesh licensed Cholvax, the OCV made possible by IVI's technology transfer to Incepta Vaccine Ltd., a vaccine manufacturer in Bangladesh. Cholvax is Bangladesh's first domestically produced cholera vaccine, a huge step forward for cholera control in one of the most cholera-endemic countries.

IVI's OCV technology transfer with BIBCOL, an Indian vaccine manufacturer, is also underway, though COVID-19-related obstacles slowed down progress in 2020.

International standardization

With no current international standards or reference reagents available to low-cost OCV manufacturers, IVI is working with EuBiologics and the UK's National Institute for Biological Standards and Control to help ensure uniform efficacy and scale up production. Increasing supply of OCV is critical to global health, as supply continues to fall short of global demand.

OCV reformulation

IVI is pursuing a reformulation of OCV that could potentially lower the cost of production by 20% and increase production capacity of Euvichol® by 30%. Consultations with the Korean regulatory authority as well as the WHO PQ Team found the proposed change and clinical development plan satisfactory.

EuBiologics is advancing with cGMP production of the new simplified formulation (Euvichol-S) and clinical trial preparation is underway for a phase III trial in Nepal to begin in late 2021.



Additional OCV-related studies

Project name	Scope	Outcomes
OCV Critical Standards and Reagents	Ensure material availability and supply to development labs for methods development & standards preparation	Development of international standards and reagents for OCV manufacturers
Euvichol-S Controlled Temperature Chain label	Develop the data package to support application for a CTC label for Euvichol-S	A CTC label for Euvichol-S that allows use at 40 degrees for 14 days to support out-of-cold-chain use and self-administration of the second dose

Partners and Collaborators

Vabiotech, Vietnam Shantha Biotechnics, India EuBiologics, Republic of Korea Incepta Vaccine Ltd, Bangladesh Bharat Immunologicals and Biologicals Corporation Limited, India UK's National Institute for Biological Standards and Control

Funder

Bill & Melinda Gates Foundation

Goal 2: Develop improved cholera vaccines, particularly to enhance efficacy for children under 5 years

IVI partnered with colleagues at Harvard University and EuBiologics to co-develop a cholera conjugate vaccine (CCV) that offers the possibility of improved efficacy in younger children and longer duration of protection.

The team successfully technology transferred the pilot production process to EuBiologics. In 2020, IVI initiated the GLP toxicology study with an additional grant from the Wellcome Trust. The team anticipates IND filing in Korea in late 2021 and will seek additional funding for a Phase 1 clinical trial in 2021.

Partners and Collaborators

Harvard-Mass General Hospital, USA EuBiologics, Republic of Korea

Funders

Wellcome Trust, UK RIGHT Fund, Republic of Korea

Goal 3:

Generate evidence to support use of **OCV** in endemic countries

In 2020, IVI launched two new major cholera control and prevention projects in Nepal and Mozambique which include OCV vaccination campaigns combined with Water, Sanitation and Hygiene (WASH) activities, disease surveillance, and other interventions.

IVI also initiated a cholera vaccine effectiveness project in Ethiopia evaluating the effectiveness and impact of OCV after vaccination and collecting epidemiological data of cholera and other diarrhea diseases with follow-up monitoring for several years.

Project name	Scope	Outcomes
Enhancing Cholera Control (ECHO) – Nepal	OCV vaccination campaigns with case area-targeted intervention Rapid WASH response and outbreak investigation Enhanced disease surveillance including lab diagnostics Cost of illness study and economic evaluation	Enhanced approaches to cholera control, prevention, and response in Nepal Nationally representative cholera serosurvey Data generation and development of evidence toward a National Cholera Control Plan
Enhancing Cholera Control (ECHO) -Mozambique	Preemptive OCV introduction in cholera hotspots Strengthen and implement enhanced systematic cholera and diarrheal disease surveillance Assess site-specific cholera risk factors and health-seeking behavior Cost of illness study of cholera outbreaks and economic evaluation	Enhanced cholera surveillance in hotspots Mass vaccination campaign Enhanced national rapid response and preparedness for cholera outbreaks Development and approval of a National Cholera Control Plan
Ethiopia Cholera vaccine effectiveness Control and Prevention (ECCP)	Preemptive OCV vaccination in cholera hotspots Establishment of a disease monitoring system to strengthen local public health capabilities	Evaluation of OCV effectiveness

Creation of a global stockpile of OCV enabled massscale cholera prevention campaigns with 60 million doses deployed in over 20 countries.

Partners and Collaborators

WHO Global Task Force for Cholera Control (GTFCC)

Ministry of Health and Population, Epidemiology and Diseases Control Division, Nepal

Good Neighbors International

National Public Health Laboratory, Nepal

Seti Zonal Hospital, Tikapur Hospital, and Malakheti Hospital

Department of Health Services, Nepal

Department of International Health, Bloomberg School of Public Health, Johns Hopkins University

WHO and UNICEF country office, Nepal (WASH program)

National Institute of Health, Mozambique

Ministry of Health, Mozambique

Ministry of Health, Ethiopia

Ethiopian Public Health Institute, Ethiopia

Funders

Global Disease Eradication Fund (MOFA/KOICA), Republic of Korea

Korea Support Committee for IVI



Accelerating Vaccine #3: iNTS and Shigella

Vaccine #3 (iNTS, Shigella)



Following IVI's successful "in-house" development of the oral cholera vaccine and typhoid conjugate vaccine, IVI is investing in the pre-clinical development of two vaccine candidates: an invasive non-typhoidal Salmonella (iNTS) vaccine and a Shigella vaccine, one of which may become IVI's Vaccine #3.

Trivalent Vi-iNTS conjugate vaccine

An invasive infection of the bacteria Salmonella enterica and S. typhimurium, iNTS causes gastroenteritis, high fever, bloodstream infections, sepsis, and potentially even death. iNTS is linked with poverty, malnutrition, poor sanitation, and lack of safe drinking water. Sub-Saharan Africa and Eastern Europe have the highest incidence rates of iNTS, and infants, young adults, and immunocompromised individuals including those infected with HIV and malaria—are particularly at risk of infection. The disease is often fatal if untreated and there are no licensed vaccines available.

In 2020, IVI successfully established the proof of concept for the iNTS vaccine after it demonstrated safety and efficacy in small animals. In addition, IVI established the methods to produce the vaccine at scale and will transfer the vaccine technology to SK bioscience, who will manufacture doses of the vaccine for use in IVI's pre-clinical toxicology studies.

IVI began work on the iNTS vaccine in 2018 with funding from its core budget. In 2019, the Wellcome Trust provided IVI a \$3.3 million grant to continue the vaccine's development through 2023.

Collaborators

Funders

IVI core budget Wellcome Trust

SK bioscience

3.4 million cases and over 680,000 deaths every year with two-thirds of all cases occurring in children under 5.

Antimicrobial resistance (AMR) is a serious obstacle to treating iNTS and Shigella, which are becoming increasingly resistant to all antibiotics. In the near future, vaccines may be the only tools available to prevent iNTS and Shigella mortality.



Universal Shigella Vaccine

An invasive bacterium that causes severe dysentery, long-term health and cognitive defects, bloodstream infections, and potentially even death. Shigella is linked with poverty, malnutrition, poor sanitation, and lack of safe drinking water. Sub-Saharan Africa and South Asia have the highest Shigella incidence rates. With 165 million cases and 270,000 deaths every year with over a quarter of all cases occurring in children under 5, Shigella has the potential to create pandemics in small children and the elderly–two groups facing a higher risk of mortality from infection. There are no licensed Shigella vaccines available for global use.

In 2020, IVI engaged in three shigella vaccine projects: 1) preclinical development of a universal Shigella vaccine 2) optimization of a Shigella Truncated Mutant (STM) vaccine platform, and 3) establishment of Shigella vaccine evaluation methods and reference antigens.

PSSP-1-based Universal Shigella Vaccine

In 2015, IVI made the important discovery that pan-Shigella Surface Protein 1 (PSSP-1) induces cross-protective immunity against Shigella infections, meaning PSSP-1 can serve as the fundamental building block for a universal Shigella vaccine. In 2020, IVI worked to improve the solubility of PSSP-1 for use in a vaccine, testing the fusion of PSSP-1 with proteins like Flagellin-B (FlaB). Once the optimal protein combination is identified, IVI will evaluate its immunogenicity and cross-protective efficacy against Shigella.

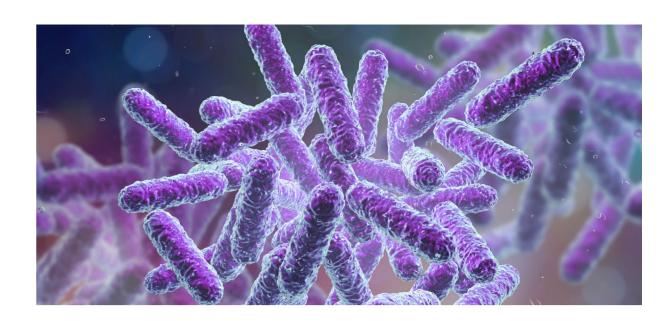
Collaborators

Prof. Byung Woo Hahn, Seoul National University
Prof. Jun Haeng Lee, Chonnam National University
Prof. Baik Lin Seong, Yonsei University

Funder

IVI core budget





Optimization of a STM Vaccine Platform

The STM vaccine platform, which uses the Shigella PSSP-1 antigen technology developed by IVI, could be used as an effective vaccine platform against a number of enteric diseases. In 2020, IVI began the optimization and analysis of STM technology with the intent to transfer the technology to its global health partner PATH and test its efficacy with the Walter Reed Army Institute of Research and the University of Georgia in the US.

Collaborators

Dr. Rob Kaminsky, Walter Reed Army Institute of Research, USA Dr. Lou Bourgeois, PATH, USA Dr. Christine Szymanski, University of Georgia, USA

Funders

PATH / Wellcome Trust Discretionary Award

Shigella Vaccine Evaluation Methods and Reference Antigens

With multiple Shigella vaccines under development globally, it is important to establish standardized evaluation methods and reference antigens to assess the vaccines. In 2020, IVI began assembling and characterizing a cell bank and a reference catalogue of Shigella proteins and established protocols for immunogenicity testing. Shipping delays caused by the COVID-19 pandemic have partially slowed progress, but work will continue through 2021.

Collaborators

Dr. Rob Kaminsky, Walter Reed Army Institute of Research Prof. Dong-Chan Oh, Seoul National University

Funde

Korea Ministry of Food & Drug Safety

Confronting the "silent pandemic" of antimicrobial resistance



Antimicrobials, or, agents that prevent the spread and growth of unwanted microbes, are an extraordinary medical advancement that have treated people against deadly infections since the early 20th century. However, an overdependence on them coupled with widespread misuse have led to an urgent global health crisis: antimicrobial resistance, when bacteria, viruses, fungi, and parasites no longer respond to antimicrobial medications (such as antibiotics).

- Misuse of antibiotics in humans, animals, and agriculture are accelerating AMR
- \cdot AMR is one of the biggest threats to global health, food security, and development today
- AMR leads to longer hospital stays, higher medical costs, and more deaths due to ineffective treatment for certain diseases

IVI's AMR Fleming Fund program

CAPTURA	RADAAR	EQASIA
Regional Round 1	Regional Round 2	Regional Round 2
Collation and mapping of historical AMR data Building in country data management capacity	 Planning, policy and advocacy Systemized data-sharing, visualization, and use Increased demand for AMR data for policy use 	 Strengthened External Quality Assurance (EQA) for AMR in Asia Costing EQA and surveillance for sustainability



Lab training during the EQASIA kick-off meeting in Kgs. Lyngby, Denmark with the IVI and DTU teams. Credit National Food Institute

Capturing data on Antimicrobial resistance Patterns and Trends in Use in Regions of Asia (CAPTURA)

The IVI-led CAPTURA consortium was awarded two out of four Fleming Fund Regional Grants to work with 12 countries in South and South East Asia to collect and analyze historical and current data on AMR and antimicrobial use (AMU) in the human health sector.

Since January 2019, the project has been actively working within the participating countries to identify, assess, collect and analyze existing data. In addition to improving local surveillance capacity, the activities can also help identify opportunities for and streamline research on "Vaccines and AMR" including prioritization of pathogens to be targeted by vaccines.

Collaborators

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

CAPTURA countries

Bangladesh Indonesia Ner Bhutan Laos Pak India Myanmar Par

Nepal Sri Lanka
Pakistan Timor Leste
Papua New Guinea Vietnam

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

The IVI-led RADAAR consortium aims to develop a framework for regional data sharing and analysis that will ultimately influence regional and global policies for sustained commitment to AMR control. The RADAAR project seeks to catalyze sustained demand for high-quality information-sharing and its use in policymaking among decision-makers.

Collaborators

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

Strengthening External Quality Assurance for AMR in Asia (EQASIA)

In partnership with IVI, the Technical University of Denmark's National Food Institute is leading an effort to improve the quality of bacteriology diagnostics in the Asia region. Starting in 2020, IVI mapped the coverage, availability, and uptake of external quality assurance (EQA) programs across all One Health sector national reference labs in Asia and submitted the final report and recommendations in September. The second phase of the project kicked off the following month to proceed with EQA services, relevant training to National Reference Laboratories and Centers of Excellence across One Health sectors, and costing for sustainability exercises.

Collaborators

Technical University of Denmark (Lead grantee)
National Institute of Health, Thailand
Veterinary Faculty, Chulalongkorn University, Thailand

Funder

CAPTURA, RADAAR, and EQASIA are funded by the Fleming Fund

The Fleming Fund is a £265 million UK aid investment to tackle antimicrobial resistance in low- and middle-income countries around the world. The programme is managed by the UK Department of Health and Social Care, in partnership with Mott MacDonald, the Fleming Fund Grants Management Agent.

Real-time Tracking of Neglected Bacterial Diseases and Resistance Patterns in Asia (TuNDRA) Plus

For the past 3 years the TuNDRA and subsequent TuNDRA Plus projects established standardized, real-time and on-site pathogen surveillance that characterizes pathogen resistance patterns phenotypically and genotypically and estimated economic burden in hospitalized children across Bangladesh, Cambodia, and Vietnam.

The TuNDRA Plus project has identified the bacterial and viral etiology of febrile and respiratory illnesses in hospitalized children and examined trends in bacterial AMR. The high proportion of viral respiratory infections indicate the importance of point-of-care PCR viral diagnostics, without which infections would typically be (mis)treated with antibiotics and contribute to the emergence and spread of AMR.

Through the TuNDRA Plus project, whole genome sequencing (WGS) capacity was introduced in Bangladesh and Cambodia sites where it did not previously exist, and proof-of-concept of using molecular diagnostics for clinical care was demonstrated when WGS was used to serotype Dengue virus isolates in a recent large outbreak of in Dhaka, Bangladesh.

Collaborators:

Robert Koch Institute, Germany
Cambodia-Oxford Medical Research Unit
Child Health Research Foundation, Bangladesh
Vietnam-Oxford Clinical Research Unit

Funder

Federal Ministry of Health, Germany



Science Unit

Vaccine R&D for emerging global threats





We design, formulate and evaluate promising vaccine candidates at the preclinical stage, and develop technologies to support vaccine development and evaluation.

Adenovirus 55 Vaccine Program

HAdV-55 is a viral respiratory-tract infection that can cause pneumonia and potentially fatal Acute Respiratory Distress syndrome. HAdV-55 infections occur in environments where people live in close quarters, such as refugee camps, schools, hospitals, and military bases. In recent years, isolated outbreaks have been reported in Argentina, China, Egypt, Israel, Japan, Korea, Singapore, Turkey, and the United

The HAdV-55 strains evolving in China and Korea are persistent, severe, and highly contagious, and may have the potential to cause future epidemics. While vaccines for other serotypes of adenovirus have been developed in the past, there are no adenovirus vaccines currently available on the global market.

In 2020, IVI successfully discovered and selected an HAdV-55 vaccine candidate, following the establishment of a vaccine evaluation system and assessment of strain and adjuvant combinations. In 2021, IVI will continue to assess the long-term immune response and dosing schedule of the HAdV-55 vaccine, while also preparing for eventual clinical trials of the vaccine.

The HAdV-55 Vaccine Program began in 2019, in collaboration with the Republic of Korea Armed Forces Research Institute of Medical Sciences, which provided IVI with HAdV-55 virus samples.

Collaborators

Republic of Korea Armed Forces Research Institute of **Medical Sciences**

Funders

Korea Disease Control and Prevention Agency

The HAdV-55 strains evolving in China and Korea are persistent, severe, and highly contagious, and may have the potential to cause future epidemics.



Hemorrhagic Fevers (SFTS/HFRS) **Vaccine Program**



About Severe Fever and Thrombocytopenia Syndrome (SFTS)

SFTS is caused by Dabie bandavirus, a newly discovered virus spread by the Haemaphysalis longicornis tick. SFTS causes vomiting, diarrhea, hemorrhagic fever, and multiple organ failure, and has a fatality rate of up to 30%.

As a result of climate change and increased global connectivity, the H. longicornis tick is now spreading in Australia, China, Fiji, Japan, Korea, New Zealand, Taiwan, the United States, and Vietnam, and SFTS could spread with its tick host. SFTS first emerged in China in 2009 and there are no vaccines currently available.

About Hemorrhagic Fever with Renal Syndrome (HFRS)

Commonly known as Hantavirus, HFRS is spread by infected rodents and causes fever, headache, nausea, hemorrhagic fever, and renal failure with a fatality rate of up to 15%. HFTS occurs globally, with roughly 150,000 estimated cases each year. Climate change is accelerating the spread of HFTS as rising global temperatures facilitate the population growth of HFTS carrier rodents. While there are licensed vaccines available in China and Korea, there is no vaccine available for global use.

IVI is undertaking the pre-clinical development of a bivalent vaccine to protect against both SFTS and HFRS. The vaccine is based on the innovative recombinant Vesicular Stomatitis Virus (VSV) vector platform technology. In 2020, IVI completed the bivalent vaccine design and secured the virus samples needed to develop the vaccine. In 2021, IVI will establish a vaccine evaluation system using ELISA and neutralization assays to assess the vaccine's effectiveness.

Collaborators

Gyeongbuk Institute for Bioindustry Sumagen

Gyeongbuk Province and Andong City

Climate change is accelerating the global dispersion of the tick and rodent hosts of hemorrhagic fever.

Other Lab Projects

Project	Description	Collaborators	Funders
Novel protein adjuvant	Development and evaluation of a protein adjuvant (GI-101 & 102) targeting humoral as well as cellular immunity.	-	GI Innovation
Noro vaccine evaluation system	Establishment of norovirus virus- like particle vaccine evaluation system using human enteroid.	Yonsei University	Ministry of Food and Drug Safety, Korea
Tuberculosis Vaccine Programs	IVI is supporting two vaccine development projects, one in the United States and the other in South Korea.	 Boston Children's Hospital Harvard School of Public Health Tulane University Vaccine Research Division, KDCA Yonsei University 	 U.S. National Institutes of Health R01 grant Korea Disease Control and Prevention Agency
Low-Cost Hepatitis A Vaccine	The HAV project was started in 2015 by a suggestion from the Korea Ministry of Health and Welfare. In 2020, IVI completed early pre-clinical work on a Hepatitis A vaccine candidate following the successful generation and adaptation of the vaccine strain in Vero cells. Moving forward, IVI will develop the vaccine production scale-up process and continue negotiations for transferring the vaccine technology to a biotech company.	Gyeongbuk Institute for Bio Industry	Gyeonbuk Province and Andong City, Republic of Korea
Hepatitis B Vaccine Microneedle Delivery System	IVI's Clinical Research Laboratory is working with Gachon University and QuadMedicine to develop and evaluate a microneedle delivery system for a Hepatitis B vaccine with adjuvant. In 2020, IVI completed the assessment of the vaccine's immunogenicity and selected an optimal adjuvant.	Gachon University, Republic of Korea QuadMedicine, Republic of Korea	Ministry of Trade, Industry, and Energy, Republic of Korea

As a method of vaccine delivery, microneedle patches enjoy distinct advantages over traditional syringes, including easy and pain-free administration, light weight and small size, low-cost fabrication, and reduced environmental impact from disposal. Most importantly, microneedle systems are thermostable, reducing or eliminating the need for cold chain infrastructure.

Group A Strep

The world needs a Group A Strep Vaccine



The cause of strep throat, Rheumatic Fever, and Rheumatic Heart Disease, Group A Streptococcus (GAS) is one of the world's deadliest infectious diseases with 33 million infections and half a million deaths each year in LMICs. However, little funding has been invested in GAS vaccine development and no vaccine is currently available. While GAS infections are typically treated with antibiotics, the acceleration of antimicrobial resistance (AMR) may render GAS infections untreatable in the near future, making the development of GAS vaccines a matter of critical importance to global health.

Strep A Global Vaccine Consortium (SAVAC)



Launched in 2019 by IVI and Australia's Murdoch Children's Research Institute, SAVAC brings together a broad consortium of global health partners to accelerate the development of GAS

vaccines and implement the WHO's 2018 GAS Vaccine Development Technology Roadmap.

In 2020, SAVAC began work on the Full Value of Vaccine Assessment (FVVA) of GAS vaccines. FVVAs are critical tools for advancing the development of neglected vaccines because they quantify the social, economic, and health value of vaccines, providing policy makers with the information they need to justify the allocation of resources towards vaccine development.

Collaborators

Murdoch Children's Research Institute
Telethon Kids Institute, University of Western Australia
Harvard School of Public Health
PATH

Imperial College

Indian Council of Medical Research

India's National Technical Advisory Group on Immunization

University of Cape Town

University of Colorado

Shift Health

World Health Organization

Funder

Wellcome Trust

GAS is one of the world's deadliest infectious diseases with 33 million infections and half a million deaths each year in low- and middle-income countries.



Schistosomiasis

A comprehensive approach to Schistosomiasis control in Burkina Faso and Madagascar













Schistosomiasis is a neglected tropical disease (NTD) caused by a parasitic infection of schistosoma flatworms. It is a major global public health problem in 79 countries with the highest disease burden in sub-Saharan Africa. Schistosomiasis is a significant cause of morbidity for an estimated 200 million people, with an additional 779 million individuals at risk for infection.

Vaccine Against Schistosomiasis for Africa (VASA)

The VASA project aims to address the gap between pre-clinical and early clinical development of vaccines against Schistosomiasis. The project's key objectives include understanding the current disease burden in Madagascar and Burkina Faso (two Schistosomiasis-endemic countries), assessing the financial burden of Schistosomiasis on local populations with cost-of-illness and vaccine costeffectiveness studies, and conducting a Phase I clinical trial to assess the safety and immunogenicity of one of the currently leading Schistosomiasis vaccine candidates.

Collaborators

University of Cambridge. Dept of Medicine. UK Groupe de Recherche Action en Santé and 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 at University Tübingen, Germany

Funder

EU Horizons 2020

Schistosomiasis in Madagascar (SOMA)

In 2018, IVI and the University of Antananarivo launched the SOMA project with the aim of reducing the intensity and prevalence of Schistosomiasis infection for at-risk populations in the Ambositra District of Madagascar.

At the project's conclusion at the end of 2020, over 100,000 people were treated with praziquantel (PZQ) through a mass drug administration campaign, and Water, Sanitation, and Hygiene (WASH) education and training programs were held in schools and at community gatherings. The SOMA project oversaw the construction of two cisterns, 20 new toilets and two shower facilities across schools. public markets and healthcare centers to increase access to sanitation and hygiene practices.

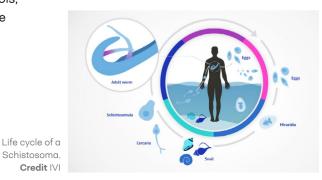
Collaborators

Malagasy officials, Madagascar

Funder

Yanghyun Foundation of Korea

Schistosomiasis is considered one of the neglected tropical diseases (NTDs) and second only to malaria as the most devastating parasitic disease.



Expanding HPV vaccine coverage to eliminate cervical cancer



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

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

Between December 2018 and March 2019, over 8,000 grade 8 girls in the Udan Thani and Buriram provinces of Thailand received either one dose of Cervarix® HPV vaccine or the currently recommended two doses in school-based vaccination campaigns. Following vaccination, participants were enrolled in surveys to track the prevalence and occurrence of HPV infection.

In 2020, IVI and collaborators completed review of first year data on baseline HPV prevalence and worked with Thai MoPH staff to complete the Year 2 survey in December 2020.

The Gates Foundation provided an additional grant to study the impact of these school closures on HPV transmission. In 2020, the team initiated a health economics study to evaluate the cost effectiveness of this approach and inform both Thailand's national program and global public health policy regarding HPV vaccination.

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

Funder

Bill & Melinda Gates Foundation



A single dose of HPV vaccine could allow countries to substantially expand coverage by lowering costs and simplifying delivery.



Other Epidemiology and Public Health Projects

Project

Description

Funders

Policy and Economic Research

Health economics to support vaccine development and use, and policy action





IVI's Policy and Economic Research (PER) department collaborates extensively with IVI research teams and external partners to collect and disseminate health economics evidence to support vaccine development, deployment, and policy actions. The PER team currently conducts field activities across 30 LMICs. In 2020, the PER department made the following contributions to IVI programs:



AMR (RADAAR)

As the lead-grantee, the PER Department launched a Fleming Fund Regional Grant Round 2 project supported by the UK Aid, titled 'Regional AMR Data Analysis for Advocacy, Response, and Policy' (RADAAR). Working in 22 Fleming Fund priority countries across Asia and Africa, the RADAAR consortium completed scoping and literature reviews on the AMR policy landscape and conducted nearly 90 key informant interviews with regional and global stakeholders in 6 countries. Learn more on page 42.



AMR (EQASIA)

Cost estimation of AMR surveillance and external quality assessment in East Asia. Learn more on page 42.



Measles and Rubella

Delivery cost estimation on a Measles-Rubella vaccination campaign in India.



Respiratory syncytial virus (TuNDRA)

Cost-of-illness studies linked to surveillance of respiratory syncytial virus in Bangladesh, Cambodia, and Vietnam. Learn more on page 43.



Cholera Programs

Field-based health economics activities such as vaccine delivery costing, cost of illness and cost-effectiveness analyses around oral cholera vaccine use in Malawi, Mozambique, and Nepal. Additionally, a project on estimating the impact and cost-effectiveness of a global cholera elimination plan. Learn more on page 30.



Schistosomiasis Program

Cost-of-illness studies linked to surveillance activities and cost-effectiveness analysis of vaccine against Schistosomiasis in Burkina Faso and Madagascar. Learn more on page 50.



Typhoid Programs

Health economics activities around typhoid conjugate vaccine in India, Ghana, and the Democratic Republic of Congo. Learn more on page 28.

Cost of illness studies and risk-mapping linked to surveillance activities in Burkina Faso, Ethiopia, Ghana, Madagascar, and Nigeria. Learn more on page 26.



iNTS (Vaccine #3)

Cost-of-illness studies and risk-mapping linked to surveillance activities in Burkina Faso, Ghana, and Malawi. Learn more on page 37.



HPV Program

Vaccine delivery costing, cost of illness, and cost-effectiveness analyses for single-dose HPV vaccine use in Thailand. Learn more on page 52.



Group A Strep Program

Quantifying GAS's disease and economic burden in endemic countries and investigating the cost-effectiveness of potential vaccination strategies for future GAS vaccines. Learn more on page 48.



Vaccine Impact

PER conducts global vaccine impact modeling in close cooperation with the Vaccine Impact Modeling Consortium.

Quality Management



Quality Management (QM) has been successfully integrated at IVI in support of both clinical trials and laboratory infrastructure development and is recognized as an integral part of IVI's continued efforts to align quality process with industry peers, donor and stakeholder expectations.





Support for Antimicrobial Resistance (AMR) Programs

As part of the 2020 EQASIA grant, QM identified and characterized regional laboratories for participation in AMR testing. The goal of EQASIA and AMR testing is to avert the human and economic burden of AMR and improve and create sustainable lab capacity and diagnosis, as well as data and surveillance of AMR.

IVI and the Technical University of Denmark's National Food Institute are preparing the second phase of activities which include the development and implementation of laboratory QM training and the distribution of AMR test panels to regional laboratories. Learn more on page 42.

Biostatistics and Data Management



BDM provides consulting, services, platforms, and solutions addressing institutional business developments and scientific and global public health needs in 4 broad areas: biostatistics, data management, systems development, and innovative technology.

Clinical trials and observational studies require EDC systems to manage and store patient data. In 2020, the BDM team developed the Bella EDC System, which was successfully validated as in compliance with FDA 21 CFR Part 11 regulatory requirements. Following validation, IVI's Vi-DT Phase 2 clinical trial and the HPV cross-sectional began using the Bella EDC system for electronic case reporting.

Vaccine Adverse Events Information Management System (VAEIMS)

IVI developed VAEIMS in collaboration with the WHO to facilitate the transfer of Adverse Events Following Immunization (AEFI) data from the periphery of healthcare systems into centralized national databases and a global database for processing and analysis. Customized VAEIMS suites has been deployed at the national level in several countries. IVI has continuously participated in global vaccine initiatives and regional workshops of AEFI surveillance and strengthening regulations organized by WHO and provided VAEIMS training courses and technical supports in several countries

VAEIMS Advancing the global integration of vaccine safety

Year	Countries	WHO Region
2021	Planning VAEIMS deployment in the Philippines, Fiji, Solomon Islands, and more	WPRO
2020	Participated in regional training on vaccine and immunization safety Invited to Regional training on AEFI surveillance (canceled due to travel restrictions)	WPRO WHO/Europe
2019	Provided refresher training to Vietnam	WPRO
2018	Held training course and invited Cambodia, Lao PDR, Mongolia, and Vietnam	WPRO
2017	Deployed VAEIMS in Cambodia, Lao PDR, Mongolia, and Vietnam	WPRO
2016	Deployed VAEIMS bridging tool in Chile	PAHO
2013	Deployed VAEIMS in Sri Lanka and Iran	WHO/HQ
Annual	Participating in Global Vaccine Initiative	WHO/HQ
Annual	Participating in NRA Workshop in Western Pacific Region	WPRO

WHO/Europe

World Health Organization Western Pacific Regional Office





Publications

In 2020, IVI scientists authored or co-authored 60 articles in peer-reviewed scientific journals with 57 articles in the Scientific Citation Index.

THE LANCET Volume 395, Issue 10221, 1–7 February 2020, Pages 384-388



The complex challenges of HIV vaccine development require renewed and expanded global commitment

Prof Linda-Gail Bekker MD, Roger Tatoud PhD, Prof Francois Dabis PhD, Mark Feinberg PhD, Prof Pontiano Kaleebu PhD, Mary Marovich MD, Prof Thumbi Ndung'u PhD, Nina Russell MD, Jeremiah Johnson MPH, Maureen Luba BPA, Anthony S Fauci MD, Prof Lynn Morris PhD, Prof Giuseppe Pantaleo MD, Prof Susan Buchbinder MD, Prof Glenda Gray MD, Johan Vekemans PhD, Prof Jerome H Kim MD, Prof Yves Levy PhD, Prof Lawrence Corey MD, Prof Robin Shattock PhD, Michael Makanga PhD, Prof Carolyn Williamson PhD, Carl Dieffenbach PhD, Prof Maureen M Goodenow PhD, Yiming Shao PhD, Silvija Staprans PhD, Mitchell Warren BA, Margaret I Johnston PhD

THE LANCET Infectious Diseases Volume 20, Issue 7, July 2020, Pages 816-826



Safety and immunogenicity of a candidate Middle East respiratory syndrome coronavirus viral-vectored vaccine: a dose-escalation, open-label, non-randomised, uncontrolled, phase 1 trial

Pedro M Folegatti MSc, Mustapha Bittaye PhD, Amy Flaxman DPhil, Fernando Ramos Lopez MSc, Duncan Bellamy MSc, Alexandra Kupke Dr, Catherine Mair MSc, Rebecca Makinson MBiol, Jonathan Sheridan MSc, Cornelius Rohde PhD, Sandro Halwe PhD, Yuji Jeong MSc, Young-Shin Park MSc, Jae-Ouk Kim PhD, Manki Song PhD, Amy Boyd PhD, Nguyen Tran PhD, Daniel Silman MSc, Ian Poulton DipHE, Mehreen Datoo MRCP, Julia Marshall MBBS, Yrene Themistocleous MBChB, Alison Lawrie PhD, Rachel Roberts MSc, Eleanor Berrie PhD, Prof Stephan Becker PhD, Teresa Lambe PhD, Adrian Hill FMedSci, Katie Ewer PhD, Prof Sarah Gilbert PhD

THE LANCET Infectious Diseases Volume 20, Issue 7, July 2020, Pages 760-761



Two Middle East respiratory syndrome vaccines: first step for other coronavirus vaccines?

Kayvon Modjarrad, Jerome H Kim

Partnerships

IVI and Sweden renewed their partnership to accelerate vaccines for global public health

In 2020, the Swedish International Development Cooperation Agency (Sida) renewed its contract with IVI to support our mission to accelerate vaccine research and development for global health with a total contribution of SEK 50 million (approximately 5.24 million USD) over the next five years as part of a longstanding partnership between the Swedish government and IVI. Sida also provided additional funds to IVI to strengthen COVID-19 surveillance in sub-Saharan Africa.







IVI welcomed the First Lady of the Republic of Korea to a solidarity event for global health and vaccine equity

On July 8, 2020, IVI welcomed the First Lady of South Korea, Madame Kim Jungsook, to our "Shared Future, Global Solidarity: Vaccines Save Lives," event. First Lady Kim Jungsook urged the diplomatic community in South Korea to garner support for IVI in their home countries, emphasizing the need for multilateral cooperation and partnership in a global pandemic that affects every country in the world.



IVI Virtual State Forum 2020: Building Vaccine Diplomacy & Advocacy

IVI hosted a virtual State Forum on October 13, 2020 to advocate for multilateral cooperation through vaccine diplomacy. The forum was livestreamed online from IVI headquarters in Seoul, Korea and featured remarks from First Lady Kim Jung-sook of the Republic of Korea and Queen Sylvia of Sweden, as well as ambassadors from the Republic of Korea, Sweden, India, Finland, Mexico, and Pakistan.

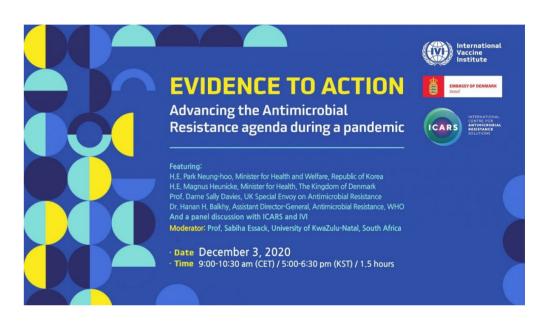
A panel of leaders in global health urged support for stronger partnership, including Dr. Soumya Swaminathan, Chief Scientist of the World Health Organization; Dr. Seth Berkley, CEO of Gavi, the Vaccine Alliance; Dr. Richard J. Hatchett, CEO of CEPI; Ms. Etleva Kadilli, Director of the Supply Division at UNICEF; and Dr. Peter Hotez, Dean of the National School of Tropical Medicine at Baylor College of Medicine.





Taking action on AMR during the COVID-19 pandemic

IVI, the International Centre for Antimicrobial Resistance Solutions (ICARS), and the Embassy of Denmark in Korea co-hosted a webinar on December 3, 2020 to share strategic reflections and insights for advancing national prevention/control policies and plans against antimicrobial resistance (AMR). Prof. Sabiha Essack from the University of KwaZulu-Natal moderated the webinar with talks by Prof. Dame Sally Davies (UK Special Envoy on AMR), Dr. Hanan H. Balkhy (Assistant Director-General for AMR, WHO) and a panel of experts including Dr. Marianne Holm, Head of Epidemiology and Public Health Research at IVI.



IVI and LINE teamed up to promote the importance of vaccination

LINE Plus Corporation, the Korea-based subsidiary of LINE Corporation, signed an MOU with IVI to promote the importance of vaccines and vaccination. LINE provided three Official Accounts to IVI as well as a customized sticker set for the LINE app called "BT21: Protect You by LINE × IVI." LINE donated the funds raised from the sticker sales to IVI for child immunization initiatives.



LG Chairman Koo Kwang-Mo personally donates 1 billion KRW to IVI to support COVID-19 vaccine development

IVI will use the donation to support research into ways to understand how the immune system protects against COVID-19, improve the response to COVID-19 vaccines (as well as other vaccines), increase IVI's capacity to measure important protective (immune) responses generated by COVID-19 vaccines, and prepare sites around the world where COVID-19 vaccine trials might be conducted.



IVI and the Vaccine Innovative Technology Alliance – Korea partner up for innovative vaccine research and development

IVI and VITAL-Korea signed a Memorandum of Understanding to commit to cooperation on vaccine R&D at IVI headquarters on November 17. In attendance at the MOU signing ceremony were Director General Dr. Jerome Kim and Deputy Director General Dr. Manki Song from IVI, and Director General Prof. Baik Lin Seong (Professor at Yonsei University) and Director Mr. Sung-Ho Park from VITAL-Korea. Under the MOU, the two sides are to establish a collaborative relationship to (1) promote innovative vaccine research & development in Korea, (2) exchange information on global vaccine research & business development networks, and (3) co-host vaccine-related events.





Clinical Research Building at the University of Antananarivo in Madagascar

IVI Office and Collaborating Centers in Madagascar and Ghana

In 2020, IVI made good progress on establishing IVI offices and Collaborating Centers in Africa. In Madagascar, a new Clinical Research Building at the University of Antananarivo is now complete; the building will host an IVI office and Collaborating Center. In Ghana, IVI and the Kwame Nkrumah University of Science and Technology (KNUST) signed an MOU to establish a Collaborating Center.

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

Thank you to the governments of the Republic of Korea, Sweden, India, and Finland as well as the Korea Support Committee for IVI, for continuing to provide core program support.











Thank you to our generous donors who supported specific projects at IVI in 2020*

*Listed in order of level of **Annual Report**

























And also.

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Boston Children's Hospital

Ministry of Food and Drug Safety, Korea

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GI Innovation

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as of February 2021

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74

Total Revenue

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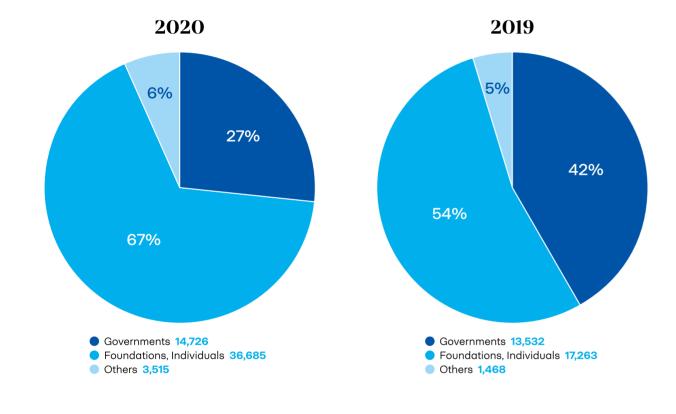
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Financial Summary 2020 & 2019

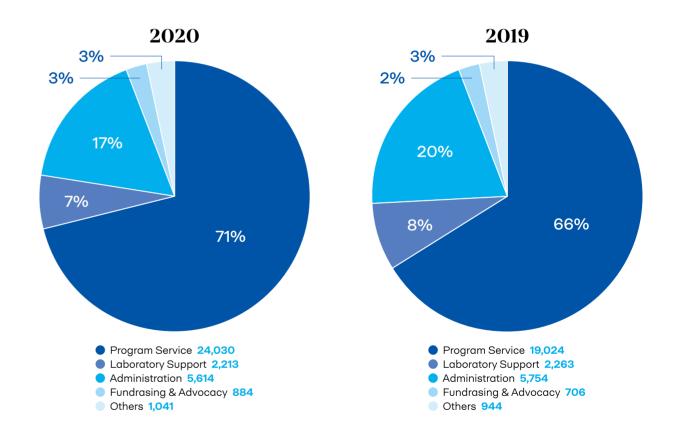


54,926

32,263



Expenses	2020	2019	(USD '000)
Program Service	24,030	19,024	
Cholera	2,250	1,293	
Typhoid	7,535	7,228	
COVID19	2,546	-	
Chikungunya	1,959	-	
HPV	1,692	843	
Others	8,047	9,659	
Laboratory Support	2,213	2,263	
Administration	5,614	5,754	
Fundrasing & Advocacy	884	706	
Others	1,041	944	
Total Expense	33,783	28,692	



Assets	2020	2019	(USD '00
Cash and Bank Deposit	36,894	19,480	
Contribution receivable	13,489	9,860	
Fixed Assets	16,513	16,198	
Other	829	852	
Total Assets	67,725	46,389	

Liabilities and Net Assets	2020	2019	(USD '000)
Liabilities	2,518	2,325	
Net Assets	65,208	44,064	
Total Liabilities and Net Assets	67,725	46,389	

