Accelerating Vaccines Critical to Global Health

2018 Annual Report

International Vaccine Institute

2018

Signatories to the IVI Establishment Agreement


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Peru


Philippines


Republic of Korea


Romania


Senegal


Sri Lanka


Sweden


Tajikistan


Thailand


Turkey


Uzbekistan


Vietnam


World Health Organization

IVI's Global Outreach

International Vaccine Institute

Vision

Developing countries free of suffering from infectious disease

Mission

Discover, develop and deliver safe, effective and affordable vaccines for global public health

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IVI and UN Sustainable Development Goals (SDGs)

IVI is committed to doing its part to accomplish the Sustainable Development Goals (SDGs). IVI's work is aligned with the following SDGs:

Vaccines alleviate the health factors responsible for poverty by enabling workers to avoid lost income from sick days, and students to stay in school and continue their education. The low cost of IVI-developed vaccines saves a considerable amount of money for low-income families.

Vaccines are a critical component of ensuring good health and well-being, preventing antimicrobial resistance, and ensuring healthier, more productive lives.

Young girls face a heavy risk of developing cervical cancer if infected with HPV. IVI's HPV vaccine trial seeks to expand access to the HPV vaccine for girls and women in developing countries.

WASH campaigns are integrated within IVI's programs in Madagascar, Malawi, and Mozambique. Vaccination against waterborne diseases like cholera, schistosomiasis, and typhoid reduces the threat posed by the use of unclean water in developing communities.

IVI's novel vaccine development model utilizes developing country vaccine manufacturers (DCVMs) to manufacture its vaccines. IVI's support for DCVMs provides technical assistance, creates jobs, and establishes new scientific capacities in developing countries.

The rising temperatures caused by climate change have resulted in storms and flooding that can quickly spread epidemic diseases. Vaccination against water-borne diseases helps reduce the negative health consequences of climate change. IVI is also committed to achieving the goals of the 2015 Paris Agreement, and is doing its part by developing and implementing an environmental management plan.

IVI strengthens health institutions in developing countries by providing epidemiological and cost of illness data along with vaccinology training, and by supporting the establishment of national immunization advisory committees.

IVI is an integral partner in global health initiatives, working closely with CEPI, GAVI, GHSA, JEE Alliance, PATH, RIGHT, WHO, Sida, KOICA, ICMR, US CDC, and more.

Annual Letter

Dear Friends,

It gives me great pleasure to report the progress and achievements that IVI made in 2018, as we continue to build upon our 21 years of success in advancing global health. IVI remains the world's only international organization devoted exclusively to the discovery, development and delivery of vaccines for use in developing countries.

In 2018, we continued to advance important work in cholera, typhoid fever, MERS, and other programs, while launching new initiatives and projects. The world's first low-cost oral cholera vaccine, brought to the global health market by IVI, continues to play a pivotal role in the fight against the disease. Since 2013, more than 36 million doses of the vaccine have been deployed in 22 countries worldwide through the WHO stockpile and other channels, and demand for OCV has been increasing steadily. In order to accelerate the use of OCV where it is most needed, IVI, in collaboration with KOICA and the Mozambican Ministry of Health, vaccinated more than 190,000 people at risk of cholera, and implemented a water quality, sanitation and hygiene (WASH) campaign in

Mozambique in 2018, as we continued to contribute to the WHO target for cholera control articulated in the Ending Cholera – A Global Roadmap to 2030.

The IVI Typhoid Program continues to execute the clinical development of Vi-DT typhoid conjugate vaccine in an exemplary manner, namely the Phase II clinical trials of Vi-DT with SK bioscience of Korea and BioFarma of Indonesia. These efforts are aimed at completing clinical development, licensure, and ultimately WHO prequalification of the vaccine by 2022, bringing additional TCV to the global health market. We also continued to conduct the Severe Typhoid in Africa (SETA) program to estimate disease burden, assess severe disease outcomes, long-term health impacts, and economic costs of typhoid in Africa.

The Phase I/IIa clinical trial of GeneOne Life Science's MERS DNA vaccine in South Korea was started and is ongoing. Work on a novel TB conjugate vaccine with Prof. Rick Malley and his team at Harvard Medical School continues on track. With our core and project-funding pipeline diversifying, IVI has initiated projects on several new global health disease targets, including Schistosomiasis, HPV, bivalent non-typhoidal Salmonella, Shigella, Adeno 55 and hepatitis A vaccine. IVI scientists, working with the Thai Ministry of Public Health, are now conducting a study to compare a single dose versus two doses of HPV vaccine. If successful, this trial will simplify the delivery and lower the cost of a highly effective vaccine that prevents cervical cancer, making the vaccine more available to "middle income" countries, which currently have the largest burden of vaccine-preventable disease. The annual IVI Vaccinology Course, which marked its 18th event in 2018, has trained more than 1,350 professionals from around the world, strengthening developing country capacity in vaccines and immunization.

In 2018, we also further expanded cooperation with key stakeholders and formed new partnerships. At the request of the Korean Ministry of Health & Welfare, IVI was critical in the organization and establishment of the RIGHT (Research Investment for Global Health Technology) Fund. This public-private partnership, involving the Bill & Melinda Gates Foundation and the Korean government and industry, has already started financing the development of vaccines, drugs, and diagnostics for global health. We have also initiated a collaboration with the Translational Health Science and Technology Institute (THSTI) of India, which followed the exchange of an MOU in 2017 between the government of India and IVI. Government and Global Affairs continues its outreach activities, organizing a Member State Meeting for local embassy delegations during the IVI Vaccinology Course.

Mr. George Bickerstaff assumed the role of Chair of the Board of Trustees, succeeding Prof. Adel Mahmoud, who passed away later in 2018. Prof. Mahmoud's took over as the Chairman of the BOT during a critical phase in IVI's history and much of the success we enjoy today is a result of his vision and devotion to the Institute. We wish Mr. Bickerstaff similar success in his time as Chairman and welcome Dr. Hannah Nohynek as incoming Vice Chair. Mr. Bickerstaff is a leader in business and philanthropy, with over 35 years of experience in healthcare and finance; while Dr. Nohynek is currently the Chief Medical Officer at the National Institute for Health and Welfare in Finland. Together, they bring decades of experience and expertise within their respective fields to IVI's Board.

IVI's financial outlook improved significantly in 2018, building on growth in 2016 and 2017. Our revenue surpassed $30 million for the first time, with record-breaking success in the generation of new projects. However, this success and its growth remain dependent upon the efforts of IVI scientists and staff and the support they receive from our state funders, partners, and donors. IVI is profoundly grateful to the Bill & Melinda Gates Foundation; the governments of Korea, Sweden, and India; and the Korea Support Committee for their continued commitment, generosity and friendship.

Sincerely,

Jerome H. Kim, MD

The Year in Review

Girl vaccinated during an OCV vaccination campaign conducted jointly by IVI, KOICA and Mozambican MOH

18th IVI International Vaccinology Course

IVI Board of Trustees and senior IVI staff visiting the Korea Center for Disease Control and Prevention

IVI's annual Member State Meeting on September 4

WHO-IVI joint MERS-CoV Vaccine Development symposium

Swedish Ambassador to Korea Jakob Hallgren (left) shaking hands with IVI Director General Dr. Jerome Kim during the ambassador's visit to IVI

Members of KSC and other key participants pose for a comemmorative photo at the 20th anniversary celebration of the Korea Support Committee for IVI

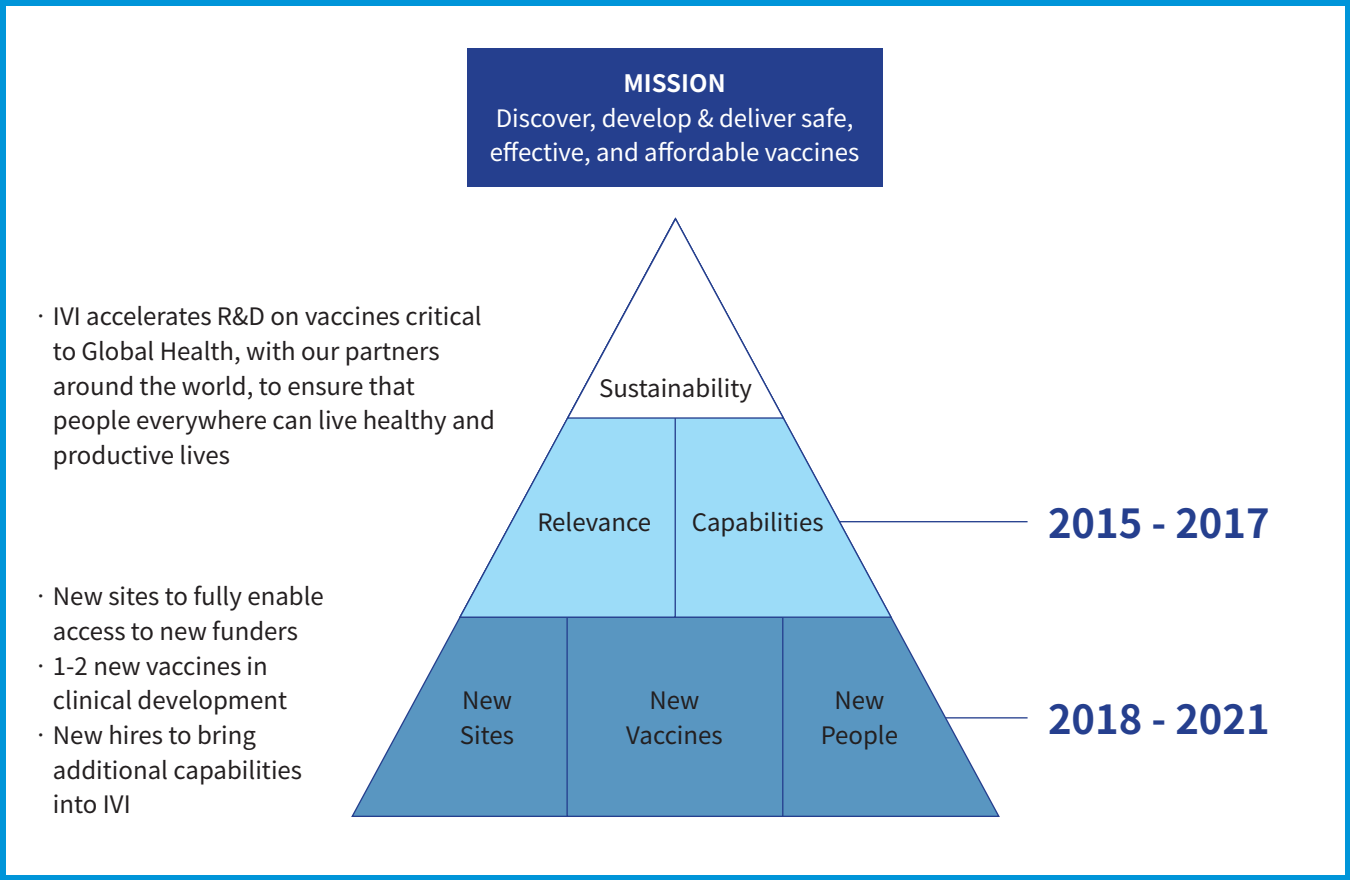
Students in Bali, Indonesia, where IVI is conducting Japanese Encephalitis Diagnosis and Vaccine Effectiveness Study

IVI Mission and Strategy

In 2018, the Board of Trustees approved a 3 year strategic plan towards 2021, which consists of 3 elements:

- New sites that will allow IVI to better access and utilize funding from entities in Europe, India, and the US;
- New vaccines development programs – strengthening the pipeline of new vaccine candidates for global health;
- New capabilities – hiring the personnel that IVI needs in order to capitalize on new opportunities and execute existing projects on time and on budget.

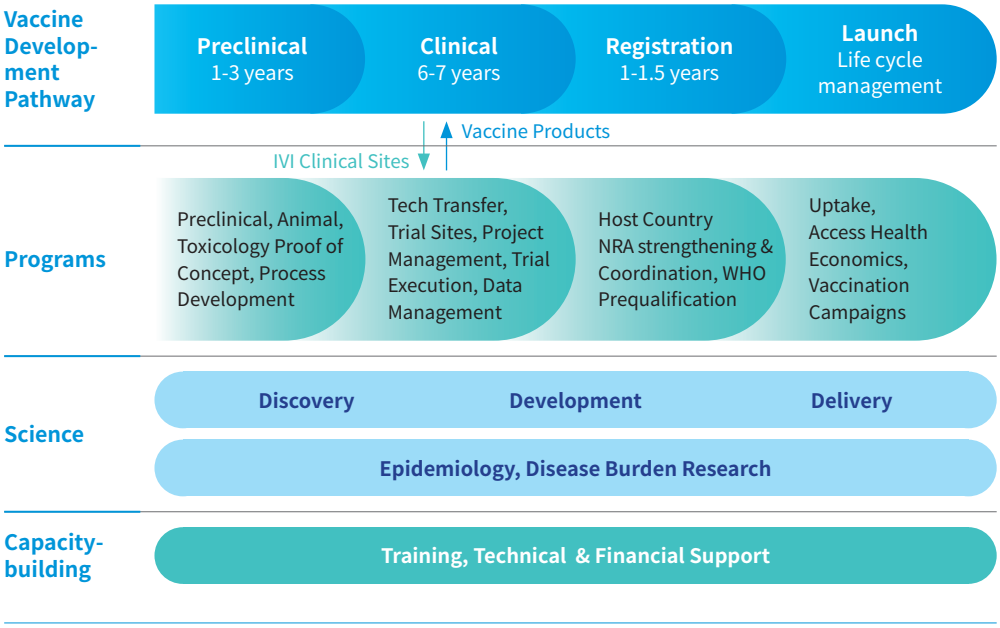
In this light, IVI has started proactive investment in the development of two critical vaccines for global health: one against Shigella and the other for non-typhoidal Salmonella (NTS). We hope that one or both of these vaccines will follow the same path of success as our cholera vaccine and our typhoid vaccine.



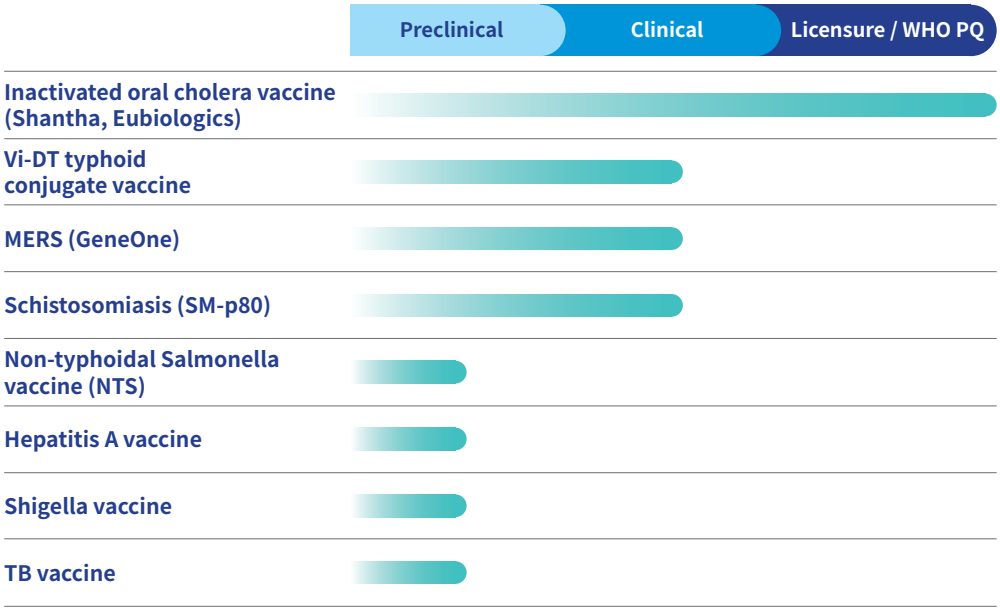
IVI Mission & Strategy

IVI's Approach

IVI develops and delivers vaccines against infectious diseases with limited commercial potential, yet high public health importance.



IVI's Vaccine Pipeline



- *Vaccines under different stages of development.*
- *Bivalent inactivated oral cholera vaccine is first product licensed and approved by WHO.*
- *Vi-DT typhoid conjugate vaccine is next vaccine out of pipeline (year 2020).*

Several vaccine candidates under development by IVI

Vaccine Development & Delivery

Accelerating research and development on vaccines critical for Global Health

36,000,000

the number of doses of vaccine deployed to prevent and control cholera

22

the number of countries the vaccine has been deployed in

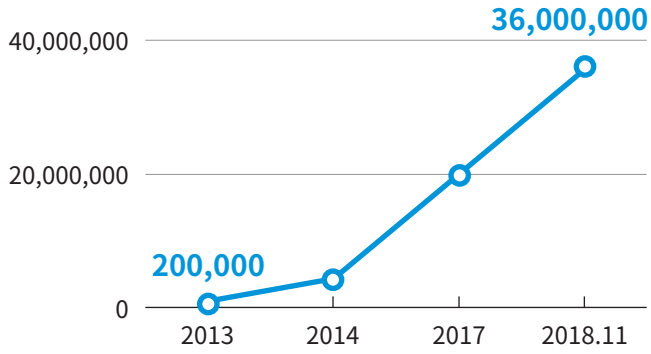
Cholera vaccination in Mozambique using Euvichol-Plus®

Vaccine development and commercialization can be costly, lengthy and fraught with risk; and there are few incentives for companies to pursue development of vaccines against neglected diseases and/or within a limited market.

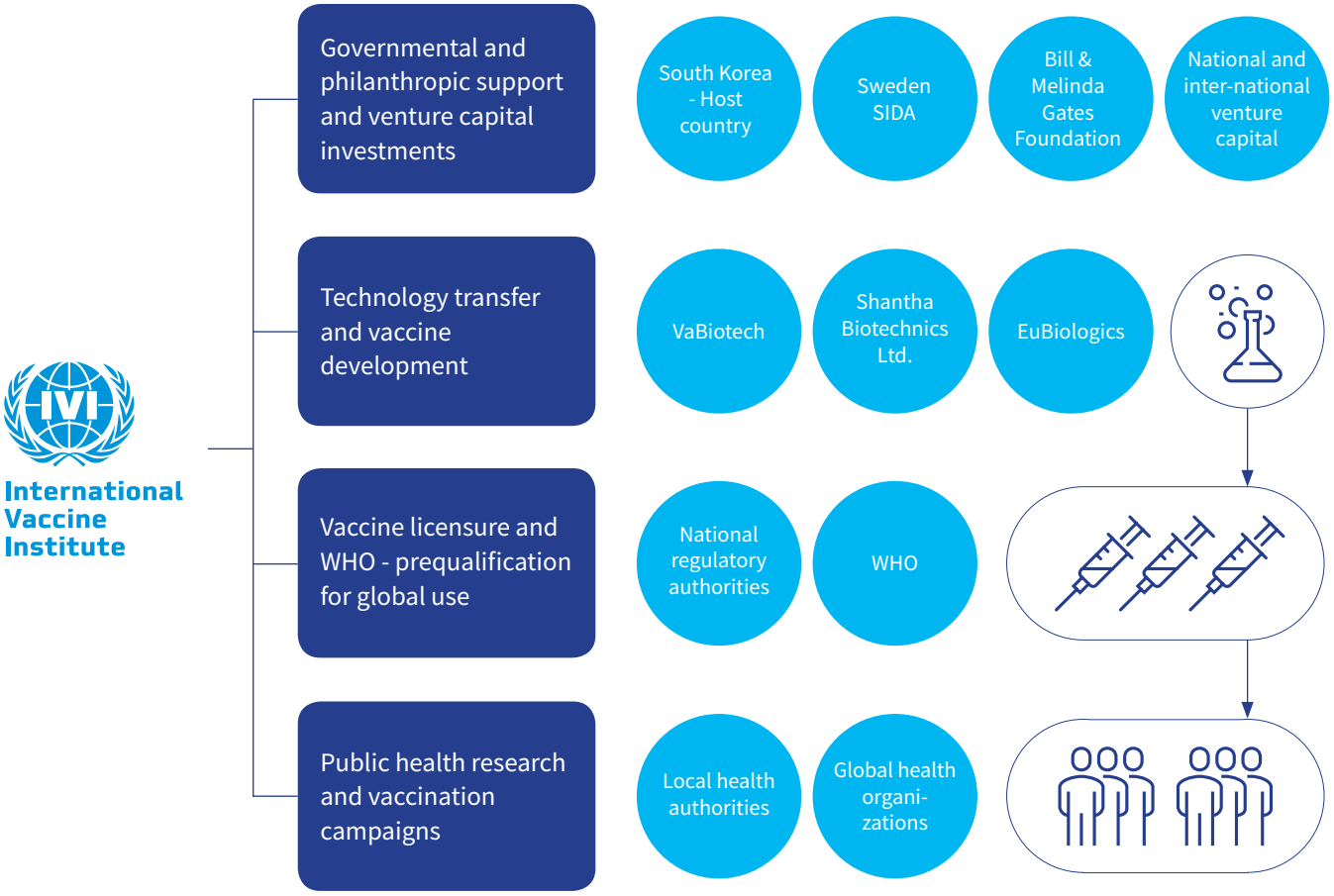
IVI develops and delivers vaccines against infectious diseases with limited commercial potential, yet high public health importance. IVI bridges this gap by partnering with vaccine manufacturers, governments, and philanthropists, and by mobilizing resources and funding to develop and license vaccines for the public-sector market. We drive vaccine innovation by transferring our in-house technology innovations to vaccine manufacturers and partnering with them on training, clinical testing, and production.

In exchange for technology and support, manufacturers make a proportion of their product accessible to the public sector at a low price via an “access agreement”. Because we do not make a profit from intellectual property, we partner with multiple companies and transfer the technology to manufacture the vaccines, assist with clinical development, and help where necessary with WHO prequalification. This, in turn, helps ensure sufficient vaccine supply for the public-sector market.

Number of OCV Doses Deployed through WHO Stockpile



Source https://www.fondation-merieux.org/en/events/5th-gtfcc-working-group-on-oral-cholera-vaccine/



Through partnership with funders, the private sector, NGOs and the public-sector IVI can catalyze the development, production and licensure of affordable oral cholera vaccines and accelerate the introduction of these vaccines to the global market.

Cholera

The Cholera Program aims to ensure adequate supply of high-quality affordable oral cholera vaccines and to generate evidence in support of introduction and use in high-risk settings.

Development

IVI's work with oral cholera vaccine (OCV) dates back to 2006 when IVI reformulated an existing OCV from VaBiotech in Vietnam. The technology was transferred to several manufacturers, and IVI partnered with some of them in development and commercialization. Since then, two oral cholera vaccines, Shanchol™ and Euvichol® & Euvichol-Plus® have been WHO-prequalified and are available for purchase. To date, over 36 million doses of Shanchol™ and Euvichol® have been shipped from the GAVI stockpile to countries in need.

Product	Status
Shanchol™ Shantha Biotechnics; part of the Sanofi group, **India**	• Licensed in India in 2009; WHO-prequalified in 2011 • Used in vaccination campaigns (co-coordinated by IVI in 2015) against endemic and epidemic cholera in Ethiopia, Malawi and Nepal; tested in Bangladesh in a single dose regimen trial sponsored by IVI from 2014-2017
Euvichol® **Euvichol-Plus®** plastic tube presentation (EuBiologics), **South Korea**	• Licensed in South Korea in January 2015 • WHO-prequalified in December 2015; thimerosal-free version prequalified in September 2016; Euvichol-Plus® was WHO-prequalified in August 2017, enabled supply up to 25M doses per year • Used in a vaccination campaign coordinated by IVI (197,874 persons) in Mozambique in 2018 • More than 20M doses used globally through the GAVI OCV Stockpile • Working on obtaining a Controlled Temperature Chain (CTC) label
Cholvax® Incepta Vaccine, **Bangladesh**	• OCV technology transferred in 2014, clinical trials initiated in 2016 • Provided technical support to Incepta Vaccine for remediation of manufacturing issues and subsequent licensure of Cholvax® • To be licensed in Bangladesh only; country has very high cholera burden
BIBCOL **India**	• OCV technology transfer requested by the Government of India in 2018 partnering with Translational Health Science and Technology Institute (THSTI) to build a national stockpile of vaccine • Finalized the licensing and technology transfer agreements to commence projects in 2019

We continue to support all of the manufacturers of IVI's OCV with reagents critical for quality control in manufacturing. In May 2018, IVI convened a meeting to initiate development of international standards for quality control testing. Currently IVI is seeking funding to develop the international standards in collaboration with the National Institute for Biological Standards and Control (NIBSC).

We are also working on optimizing vaccine use in a collaboration with Eubiologics by demonstrating the stability of the vaccine out of cold chain. Obtaining a Controlled Temperature Chain (CTC) label would be advantageous in many situations where OCV is needed -such as outbreaks, refugee camps, and other emergency situations where maintenance of the cold chain for vaccines is quite difficult.

Shanchol™

Euvichol-Plus® with its plastic tube presentation increased global annual supply of OCV to 25 million doses.

Delivery

We continue to support delivery efforts of OCV. IVI, with international partners and national health authorities, have conducted OCV vaccinations in Ethiopia, Malawi, and Nepal throughout 2015-2017. IVI, KOICA, and other partners conducted a cholera vaccination campaign in Mozambique in 2018 with Euvichol-Plus®, vaccinating 197,874 people. Surveillance for cholera was also established in the area of the vaccination campaign and a cost effectiveness study of the vaccine is now underway in this same setting.

We are in the process of completing the Cholera Surveillance in Malawi (CSIMA) project, funded by the Bill & Melinda Gates Foundation (BMGF). Through CSIMA a cholera surveillance platform was established in two districts of Malawi to assess the effectiveness of OCV following an emergency vaccination campaign in early 2015. This evidence will be useful to funders, policymakers, and countries who have cited the need for more data on use of the vaccine in real-life situations to support decision-making on vaccine introduction.

The Swedish International Development Cooperation Agency (Sida) supported a project called Modeling Impact and Cost-Effectiveness of the Ending Cholera Global Roadmap, launched by the WHO in 2018. The research plan and updates were presented at WHO GTFCC meetings in June and December 2018. An advisory committee was formed and is actively supporting the research. Modelling results will be presented at the WHO GTFCC meeting in June 2019 and overall results will be out in December 2019.

Snapshots from OCV & WASH Campaigns conducted in the Cuamba District, Mozambique in August 2018

Photo: Youngmi Cho, IVI

Mobile vaccinators were sent to each designated location

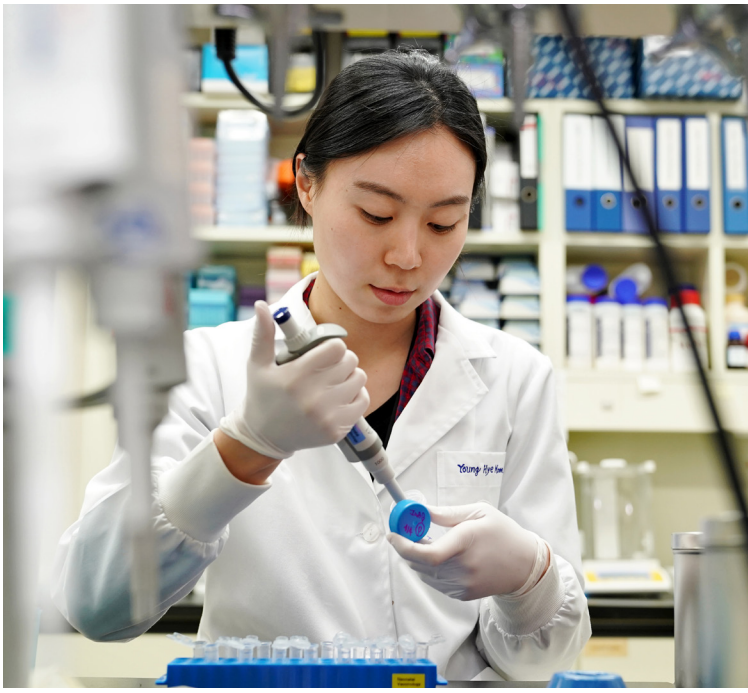
Vaccinating at one of the fixed vaccination posts: Adine III

Demonstration of handwashing at the Heath Center Tererane

Ms. Kyungsoo Woo from KOICA, Mr. José Paulo Langa from INS (NIH) of Mozambique, and Dr. Florian Marks from IVI beside the Lab signboard

Typhoid

The Typhoid Program aims to accelerate the development and introduction of a new-generation typhoid conjugate vaccine (TCV).



Development

Similar to the Cholera Program, TCV development is done through a public-private partnership. IVI originally developed a typhoid conjugate vaccine (TCV) using initial know-how from the U.S. National Institutes of Health, conjugating the Salmonella Typhi Vi polysaccharide to diphtheria toxoid. Unlike other typhoid vaccines, the typhoid conjugate vaccine protects infants (a high-risk group) against typhoid. IVI transferred the technology to SK bioscience of South Korea, BioFarma of Indonesia, and Incepta of Bangladesh and is currently working with two of them (SK and BioFarma) on clinical development for licensure and WHO-prequalification, currently targeted for the end of 2021.

In 2018 a manuscript was published in the journal Vaccine describing the results of a phase I study for SK Vi-DT in the Philippines. The phase I results are encouraging, with no safety issues and 100% seroconversion in 144 participants (ages 2 to 45 years). Based on these promising results, BMGF funded a phase II study in the target population (children younger than 2 years of age). The phase II study compares a single dose of Vi-DT to two doses or placebo.

We have finalized plans for the phase III study of SK Vi-DT after multiple discussions with the key stakeholders. We will conduct 2 phase III studies: an immune non-inferiority study with prequalified TCV (Bharat Biotech) in Nepal , and an immune equivalence study in the Philippines.

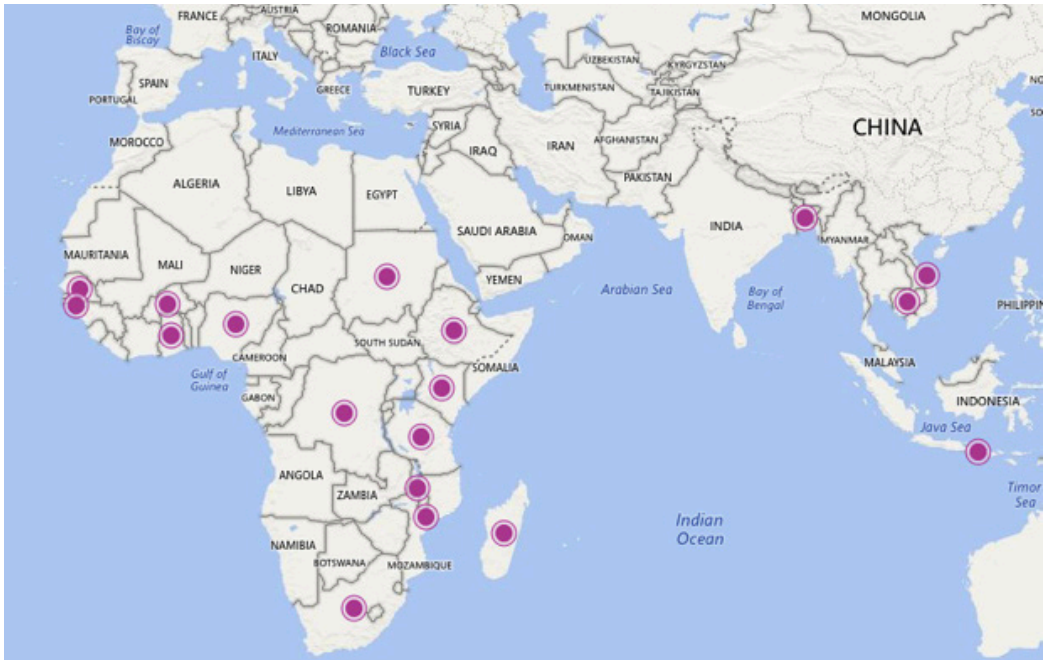
BioFarma also completed the phase I clinical trial in Jakarta, Indonesia in December 2017. The results were similar to the SK phase I study results, and there were no safety concerns. With these encouraging results, the phase II study started in 2 sites in Jakarta, Indonesia. BioFarma has also started working with IVI on phase III study design.

Epidemiology | PAVE: Public Health, Access and Vaccine Epidemiology

IVI conducts typhoid surveillance in Africa to close the knowledge gap on disease burden throughout the continent. While typhoid is recognized as a public health problem in Asia and Africa, information on its true burden is lacking, making it difficult to justify vaccination policy and to assess the impact of typhoid vaccination. In 2016, IVI launched the Severe Typhoid in Africa (SETA) Program that will, in addition to further estimating disease incidence, assess severe disease outcomes, long-term health impact, and economic burden of typhoid in 6 African countries (Ghana, Burkina Faso, Nigeria, Democratic Republic of the Congo, Madagascar and Ethiopia). First year data were submitted to the WHO typhoid working group to support the recommendations by the WHO Strategic Advisory Group of Experts (SAGE). The SETA Program includes a two-component health economics study conducted in four African countries. The initial results from the cost of illness (COI) study and the long-term socioeconomic follow-up study (LT-SES) from SETA were presented at an international meeting in Geneva in 2018.

In 2018, IVI initiated a study on the economic evaluation of typhoid conjugate vaccine (Typbar TCV) introduction in Navi Mumbai, India with funding support from the WHO and the US Centers for Disease Control and Prevention (CDC). The TCV campaign was conducted by the Navi Mumbai Municipality Corporation (NMMC) from June to August 2018. A Sida-funded project that estimates global economic burden of typhoid antimicrobial resistance (AMR) also started in 2018. This builds on the Policy and Economic Research (PER) team's economic modeling performed as part of a typhoid fever vaccine investment case study.

Epidemiology continued its success in securing important anticipatory project funding for antimicrobial resistance and beginning an exciting new collaboration with Cambridge University in the UK. In early 2019 Epidemiology became "PAVE (Public Health, Access and Vaccine Epidemiology)" and the 2019 Annual Report will no doubt contain exciting reports of their newest efforts.



IVI's epidemiology field site network

Dengue

IVI is the secretariat of the Global Dengue & Aedes-Transmitted Diseases Consortium (GDAC), a consortium of four partners – IVI, the International Vaccine Access Center (IVAC) at Johns Hopkins University, Sabin Vaccine Institute, and the Partnership for Dengue Control (PDC) at Fondation Merieux.

GDAC's mission is to promote the development and implementation of innovative and synergistic approaches for the prevention and control of dengue and Aedes-transmitted diseases. It does this through accelerating innovations, promoting data generation and synthesis, supporting implementation of evidence-based strategies, strengthening advocacy, and supporting WHO global strategy for prevention and control of dengue and other Aedes-transmitted diseases.

Each partner has specific areas of expertise: IVAC focuses on health economics, strategic demand forecasting and vaccine development; Sabin focuses on communications and advocacy; and PDC focuses on integration of vaccine and vector control, diagnostics, clinical case management, and pathogenesis. In addition to serving as the Secretariat of the consortium, IVI is responsible for disease burden and epidemiology, laboratory testing, modeling, policy and access, and regulatory issues.

Working together, GDAC aims to promote data generation and synthesis, accelerate innovations in research, and support implementation of new and existing tools in the fight against dengue and Aedes-transmitted diseases.

As part of BMGF-funded projects, GDAC completed dengue burden studies in Burkina Faso, Gabon, Kenya, Cambodia, Thailand and Vietnam. GDAC successfully convened the Global Dengue and Aedes-Transmitted Diseases symposium on November 1-2, 2018 in New Orleans after ASTMH. GDAC also continues to interface with dengue-endemic country national regulatory authorities (NRAs) to prepare for regulatory strategies for next-generation dengue vaccines.

A safety and effectiveness study of Dengvaxia® introduction in the Philippines was initiated in 2018 with funding from Sida. Sanofi Pasteur's Dengvaxia®, the only licensed dengue vaccine, has been introduced in only two countries: the Philippines and Brazil, as part of sub-national public health programs, due to concerns about potential disease enhancement in dengue naïve vaccine recipients. A total of 2,996 samples were collected from the cohort in Cebu, prior to Dengvaxia® introduction, and were tested with neutralization assay. Of 302 samples with both IgG ELISA and neutralization assay results available,

Participants at the Global Dengue and Aedes-Transmitted Diseases symposium on November 1-2, 2018 in New Orleans, USA after ASTMH

274 were shown to have neutralizing antibodies to at least one of 4 dengue viruses. Screening of all samples with single dilution neutralization assay (1:40 dilution) is ongoing and full-titration neutralization on all primary dengue cases is also underway.

Landscape analysis on Zika burden in Asia was initiated with support from Takeda in October 2018. As part of the project, engagement with various stakeholders with ongoing studies or existing samples for further testing began in November 2018. Also, development and maintenance of a centralized database for clinical trials of the NIH-developed dengue vaccine continued into its second year of the project.

MERS Program & CEPI Program

CEPI

IVI's Middle East Respiratory Syndrome (MERS) Program was launched in late 2015 with funding from Samsung Life Public Welfare Foundation in order to accelerate the development of MERS vaccines, with the specific objective of supporting two MERS vaccines through phase II trials in South Korea. These phase II trials are intended to demonstrate sufficient safety and immunogenicity for the vaccine to be available for potential emergency use in Korea. IVI would partner with two vaccine manufacturers in early stage clinical development of their MERS vaccine candidates by providing technical and financial support, as well as support in project management and coordination.

In December of 2016, IVI formally initiated a partnership with GeneOne Life Science, a biopharmaceutical company based in Korea, on the development of their DNA-based MERS-CoV vaccine candidate. In 2017, the investigational new drug (IND) application for GeneOne's MERS-CoV vaccine (GLS-5300) was approved by the Korean Ministry of Food and Drug Safety. In 2018, a toxicology study was successfully conducted in Korea, showing no safety issues in rabbits, paving the way for the initiation of a phase I/IIa trial of GeneOne's MERS-CoV vaccine at Seoul National University Hospital. The enrollment started in September 2018 and was completed in February 2019. Selection of a second MERS vaccine candidate is currently under discussion with Samsung.

IVI's partnership with the Coalition for Epidemic Preparedness Innovations (CEPI) was formalized with the signing of a master services agreement between IVI and CEPI in November of 2018, allowing IVI to undertake cross-cutting projects to support CEPI-funded initiatives under specifically-negotiated service orders for each project. Under the terms of the CEPI–IVI Master Implementing Partner Services Agreement, IVI will provide technical services for CEPI-funded projects, executing specific activities as needs arise on behalf of CEPI in the course of advancing new vaccines against emerging pathogens.

This particular agreement was possible due to IVI's status as a not-for-profit international organization. To this end, IVI will receive funding and support from CEPI to implement the necessary technical services per service orders for vaccine development by engaging local scientists in Korea and by mobilizing IVI's expertise and capabilities, which includes: laboratory and vaccine process development, epidemiological studies, and clinical trial and regulatory support. Potential projects under consideration include: emergency preparedness and response coordination, MERS reference laboratory functions, Lassa epidemiology studies, clinical trial support, manufacturing interfaces, etc.

The WHO-IVI Joint Symposium for MERS-CoV Vaccine Development was held in Seoul on June 26 and 27, 2018. It brought together more than 120 experts and professionals from industry, academia, international organizations and government agencies around the world. The symposium provided a forum to update the status of animal and human MERS-CoV vaccine development, and identified and prioritized activities to accelerate vaccine R&D.

Other Programs & New Initiatives

HPV Vaccine

The IVI HPV Vaccine Study Program aims to demonstrate the effectiveness and affordability of a single-dose of Human Papilloma Virus (HPV) vaccine. In this study, over 15,000 grade 8 girls in two provinces of Thailand will receive either one or two doses of the HPV vaccine Cervarix®. These students will then be followed with periodic cross-sectional surveys every two years to assess HPV prevalence as they advance through school. The cost-effectiveness data from this study is expected to inform Thailand's national program and, more broadly, global public health policy regarding HPV vaccines.

In 2018, we began laying the groundwork for the vaccine trial, completing agreements and laboratory preparations with the Thai Ministry of Public Health, Department of Disease Control, Chulalongkorn University in Bangkok, and the US CDC. IVI participated in the Consortium meeting at the International Papilloma Virus Meeting in Sydney, Australia and established links with the HPV Consortium led by PATH and funded by the Bill & Melinda Gates Foundation.

The HPV study is funded by a 5-year, $6.4 million grant from the Bill & Melinda Gates Foundation.

Hepatitis E Vaccine

The Hepatitis E virus (HEV) is a global pathogen that kills roughly 70,000 people per year. Its true burden is not known, but mortality is particularly high amongst pregnant women, with mortality rates of 25-40% commonly reported in outbreak settings. The disease has been a problem among displaced populations/refugees and is increasingly recognized as a cause of chronic or fulminant hepatitis in Europe and North America, primarily in immunocompromised individuals. A hepatitis E vaccine (Hecolin®) has been licensed for several years in China but is not WHO prequalified. Hecolin's® efficacy is over 90% at both 1 and 5 years.

In 2018, we assisted GAVI with its vaccine investment strategy (VIS) investment case review for an HEV vaccine. We also hosted a symposium with Médecins Sans Frontières at the American Society of Tropical Medicine and Hygiene (ASTMH) meeting to increase awareness of this disease and the lack of access to an effective vaccine. We are discussing proposals with multiple donors to support prequalification of the Hecolin® vaccine and the generation of evidence to develop policy for use in at-risk settings.

TB Vaccine

There is an urgent need for a more effective tuberculosis (TB) vaccine. TB has superseded AIDS as the leading cause of death by infectious diseases worldwide, with the WHO estimating that in 2014, 9.6 million people fell ill and 1.5 million people died from TB. The currently available TB vaccine, Bacillus Calmette–Guérin (BCG), is used in most countries that have endemic TB, and appears mostly to reduce the risk in children under the age of 5. To date, there is no effective vaccine to prevent pulmonary disease (the most important source of transmission) or to protect adults. In order to develop an effective TB vaccine we are supporting two vaccine development projects, one in the United States and the other in South Korea.

In the American project, we are collaborating with Boston Children's Hospital (BCH), the Harvard School of Public Health, and Tulane University on the development of a vaccine directed against Mycobacterium tuberculosis (Mtb). This new vaccine will use a novel platform, the Multiple Antigen Presentation System (MAPS) developed by Dr. Rick Malley and colleagues at BCH. MAPS will be evaluated alone and in combination with the BCG tuberculosis vaccine in a non-human primate model of tuberculosis infection. This project is funded by a R01 US NIH grant.

In South Korea, we are working with the Korea Center for Disease Control and Prevention (KCDC) Division of Vaccine Research and Dr. Ray Cho of Yonsei University (YU) on the optimization and preclinical development of TB Polysaccharide-protein conjugate vaccine using TB protein antigens selected by KCDC. These projects are funded by the Korean government.

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

In many low and middle-income countries, infections caused by agents such as Streptococcus pneumoniae and Salmonella Typhi still constitute a considerable public health problem despite the availability of therapeutic antibiotics. Vaccines, while also available, are often limited in supply and effectiveness, and face challenges in securing funding and infrastructure for continued administration. Therefore, the reliance on antibiotics to treat infection has increased throughout Asia. This trend has been rapidly followed by the emergence of antimicrobial-resistant (AMR) strains of bacteria and viruses, and many once-effective therapies now frequently fail to clear infection. The emergence of these bacteria, the evolutionary origins, and the additional threats posed to global health security must be further examined through robust surveillance. Data from surveillance networks uploaded to global, open access, pathogen sequencing databases currently enables researchers to follow the evolution of drug-resistant pathogens and determine high-risk areas at an unprecedented level of granularity.

The TUNDRA project began in late 2017 and has implemented a febrile and respiratory disease surveillance system in 3 Asian sites (Cambodia, Vietnam, and Bangladesh). This program will serve as a prototype project to demonstrate the importance of identifying and tracking human disease-causing pathogens, with a focus on resistant pathogen strains. Cutting-edge technology, including whole-genome sequencing capacity, has been provided to collaborating sites in Asia to optimize laboratory analyses and performance, and ongoing training and technical support is being provided. This will further strengthen the research capacity for AMR in Asia and ensure that the infrastructure being created is sustainable. Ultimately, findings from TUNDRA will contribute to shaping public health strategies regarding not only the prudent use of antimicrobials, but also vaccine policies.

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

Japanese encephalitis (JE) is a mosquito-borne virus. Culex species mosquitos thrive in rice fields and transmit the virus from their natural hosts, primarily pigs, to humans. Children less than 15 years of age are particularly at risk. JE virus infections causing symptomatic disease are relatively rare. However, when clinical manifestations do occur, the prognosis is often dire, with 1/3 succumbing to infection and of the survivors, an additional 1/3 retaining neurologic sequalae.

In Bali, Indonesia we are examining the effectiveness of a JE vaccine used in a March 2018 vaccination campaign. Funded and coordinated by the Indonesian Ministry of Health (MOH) and Gavi, the Vaccine Alliance, the two-phase, school- and community-based mass campaign saw over 890,000 Balinese children between the ages of 9 months and 15 years old receive the Chengdu SA14-14-2 JE vaccine (CD-JEV).

For a period of 5 years following vaccination, IVI will track the effectiveness of CD-JEV via surveillance for acute encephalitis syndrome in all 24 hospitals and health centers in Bali. Vaccine effectiveness will be measured using a case-control design, where vaccine status of confirmed JE cases will be compared to that of healthy, age-matched controls. This study is important because effectiveness data on the CD-JEV, now manufactured at a GMP-compliant facility, do not yet exist, and the WHO needs additional data on the impact and effectiveness of JE vaccines to inform its broader policies. In addition, the feasibility and impact results of vaccination analyses will serve to inform other endemic countries and the effectiveness data from this study will help Gavi rationalize its JE vaccine subsidies.

The Bali JE vaccine campaign and effectiveness study are a direct result of IVI's Bali JE surveillance from 2002 to 2008, which identified a high prevalence of JE in Bali and prompted the Indonesian MOH to include JE vaccines in the Balinese routine immunization program and to conduct the mass JE vaccination program.

Lab Science Highlights

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

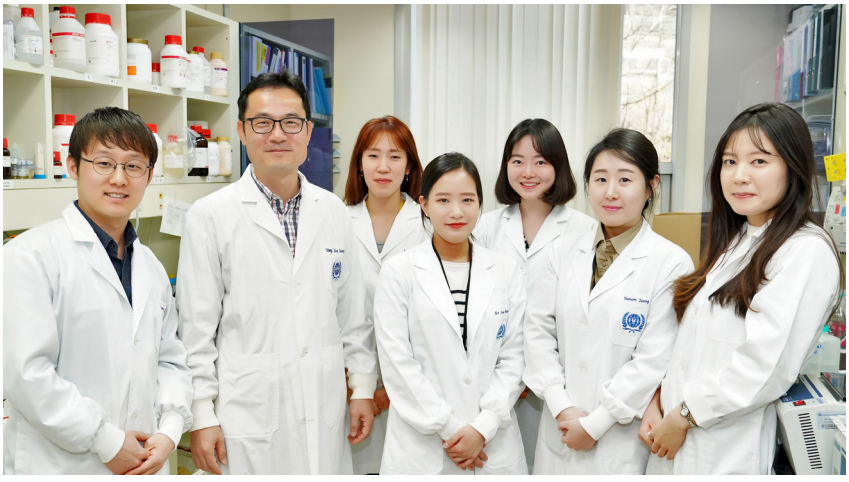
LABORATORY SCIENCE

The IVI lab has been working on the development of vaccine evaluation systems for typhoid, Zika, and MERS-CoV with support from the Korea Ministry of Health and Welfare (MOHW). Through the project for the development of a Zika vaccine evaluation system, assay systems to detect Zika-specific antibody and neutralizing antibody were successfully established.

In collaboration with Gyeongbuk Institute for Bio-industry in Andong, Korea, the IVI lab has been conducting a project for the development of a vaccine against Hepatitis A virus (HAV).

Additionally, the IVI lab has been developing detection kits (rapid kits and ELISA kits) for hemorrhagic fever viruses, including the Ebola virus and a neutralizing antibody against hemorrhagic fever virus, funded by KCDC. As a next-generation technology for vaccine formulation, the IVI lab has been studying the microneedle-type HBV vaccine in collaboration with professor Jung Hwan Park (Gachon University, Korea) with funding from the Korean Ministry of Trade, Industry and Energy.

As a new project, the IVI lab will initiate a study to develop vaccines for severe fever with thrombocytopenia syndrome virus, an endemic virus in the Northeast Asian region. For the launch of this project, the IVI lab has been involved in discussions with external funders and collaborators (Seoul National University, Catholic University, and Jeju National University). In addition, the IVI lab has been discussing the development of standard materials for evaluation of MERS-CoV vaccine candidates with CEPI and NIBSC.



Vaccine #3

The vaccine #3 effort is aptly-named to follow the success of vaccines #1 (OCV) and #2 (Vi-DT typhoid conjugate vaccine). The Board of Trustees approved the use of IVI funding to support initial preclinical efforts in non-typhoidal Salmonella (NTS) and Shigella vaccine development with the hope that one of these would progress to be the third IVI vaccine.

Vaccine #3 Salmonella
Trivalent NTS vaccine development

The Salmonella Vaccine Program aims to accelerate development of an injectable, trivalent vaccine for typhoid and invasive non-typhoidal salmonella (NTS). NTS is an invasive bacterial disease that causes gastroenteritis, diarrhea, high fever, bacteremia, and focal infection. NTS is estimated to cause over 600,000 deaths every year, primarily in Africa and south Asia.

In September 2018 we initiated preclinical work on the NTS vaccine. Cell banks were generated for NTS clinical isolates from IVI's TSAP surveillance program that had been stored at the Bernhard Nocht Institute. *Salmonella* Typhimurium (ST) and S. Enteritidis (SE) strains were screened using predefined selection criteria. Currently we are working on various purification techniques to obtain high purity OSP as a prelude to conjugation with diphtheria and tetanus toxoids.

Vaccine #3
Shigella vaccine development

Shigella is an invasive bacterium that causes severe diarrhea and dysentery. The WHO estimates that shigella infects 165 million people each year and causes 164,000 deaths annually. In addition to mortality, evidence suggests that Shigella-associated environmental enteropathy may play a major role in malnutrition, developmental delay, and stunting, which has dramatic implications for global health and sustainable development. The burden of Shigella infection falls predominantly on children under 5 years of age in impoverished areas with unsafe drinking water sources, poor sanitation, and rapid population expansion. As Shigella has the ability to acquire antimicrobial resistance, an effective vaccine is urgently needed.

As a part of the Vaccine #3 effort, we are developing an oral and/or parenteral Shigella vaccine that will be broadly protective against the 4 species and 50 serotypes of Shigella. In 2018, preclinical development began on a universal Shigella vaccine using a replication-defective adenoviral vector platform. IVI collaborated with the Jenner Institute for a chimpanzee adenoviral vector possessing Shigella genes. A proof-of-concept study is ongoing in a mouse pneumonia model.

While IVI is funding the shigella vaccine development with in-house funding, we have joined PATH, the University of Georgia, and the Walter Reed Army Institute of Research (WRAIR) in submitting a discretionary award proposal to the Wellcome Trust, "Development of a Combined Shigella-Campylobacter Vaccine for Oral Delivery."

Our shigella vaccine development program is a follow-up to IVI's 2001-2005 Diseases of the Most Impoverished (DOMI) Shigella Program, in which over 600,000 individuals were followed to determine the shigella disease burden in Bangladesh, China, Indonesia, Pakistan, Thailand, and Vietnam.

VACCINE PROCESS DEVELOPMENT

IVI's Vaccine Process Development (VPD) Lab is developing several vaccine candidates and transferring vaccine technologies developed at IVI.

In addition to the previously-described Vaccine #3 NTS, the VPD Lab launched two new tuberculosis (TB) vaccine development projects in late 2017 which aim to overcome the limitations of existing BCG vaccine (also previously-described).

For Cholera projects, IVI worked with Incepta Vaccine (Bangladesh) on the technology transfer of an LPS ELISA assay, and validation work was executed by Incepta Vaccine with the VPD Lab's oversight. A validation report for a redeveloped LPS ELISA potency assay was issued to support release of new Cholvax (OCV vaccine by Incepta) lots in 2018. A due diligence inspection to assess the BIBCOL facility in India for OCV technology transfer suitability and production of OCV was also conducted by the VPD Lab.

The VPD Lab has also worked on technology transfer of pneumococcal conjugate vaccine processes and is supporting the release of assays developed by the VPD Lab for serotype 6B and 19F to Celltrion, a Korean biotech company.

QUALITY MANAGEMENT

Since the inception of an independent Quality Management (QM) department at IVI in the 1st quarter of 2018, ongoing efforts have had significant impact upon IVI's quality infrastructure development and systems implementation from a GxP perspective (i.e., Good Clinical Practice, Good Laboratory Practice and Good Manufacturing Practice).

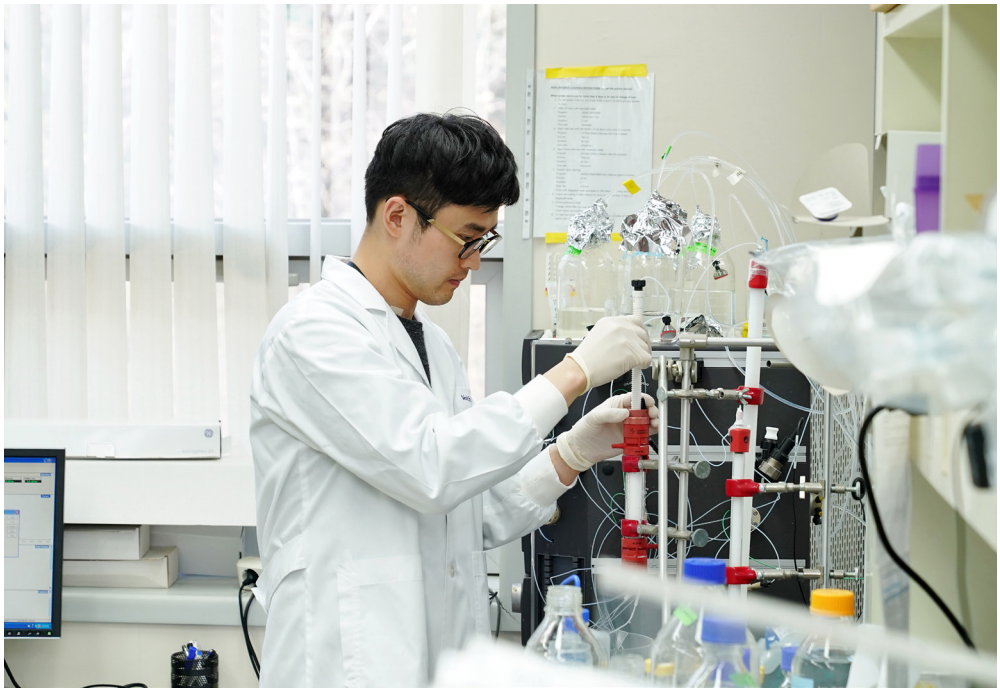
QM has been successfully integrated in support of both clinical trials and laboratory infrastructure development and has been accepted as an important part of IVI's continued efforts to align our quality process with industry peers and stakeholder expectations.

An integral part of IVI's QM process is to ensure the institute is inspection-ready at all times by conducting routine quality training and both internal and external audit activities. This work has been accomplished from a global perspective, with activities performed in four supported countries (China, India, the Philippines and Thailand), as well as IVI's Korean base, during 2018.

In an effort to modernize IVI's infrastructure, the QM department has introduced electronic systems to support document control, laboratory environmental monitoring, and Laboratory Information Management System (LIMS) implementation. Additional electronic systems are also being evaluated for implementation in 2019, which may include learning management systems and various clinical research functions (e.g., clinical trial and data management systems).

On the laboratory front, the QM department has begun the process of Good Clinical Laboratory Practice (GCLP) infrastructure development with a timeline for accreditation by the end of 2019, and (with close laboratory interaction) has created a dedicated biorepository meeting international standards for sample management and chain of custody.

Over the course of 2019 and beyond, the IVI QM department will continue to make inroads into quality process and infrastructure development, as well as provide support to IVI collaborators and stakeholders, to ensure continued and sustainable quality improvement and compliance to international regulations, guidelines, and best practice.



Capacity Building

To bolster our vaccine development and delivery programs, we engage in capacity-building within the vaccine industry, governments, and universities. Through training, technology transfer, technical assistance, and educational partnerships IVI provides support to the global vaccine community. While our focus is on developing countries, we support vaccine professionals and organizations around the world.

One of the longest-running vaccinology courses in Asia, IVI's International Vaccinology Course has trained more than 1,350 people to date. The week-long course promotes vaccine sustainability in developing countries by training early- to mid-career vaccine professionals from low- and middle-income countries (LMICs), and fosters the development of collaborative networks and partnerships among LMICs.

The 18th Vaccinology Course brought together 178 participants from 31 countries. More than 38 experts from international agencies, including IVI and the World Health Organization; research organizations, including the U.S. National Institutes of Health; industry; universities; and non-profit organizations served as faculty members. Course evaluations from the participants found the quality of the course overall to be high. The 2018 program was supported by GlaxoSmithKlein, EuBiologics, Sky 72 Golf Club, Seoul Metropolitan City, and Community Chest of Korea-Incheon. The trainees included 12 students from developing countries who were awarded fellowships. IVI's 19th International Vaccinology Course is scheduled for September 02-06, 2019.

Vaccinology Course
September 3-7, 2018

1,350

the number of people trained in IVI's Vaccinology Course to date

178

the number of participants in the 18th Vaccinology Course

31

the number of nationalities of participants in the 18th Vaccinology Course

Group Activities: Case Study

Vaccine Safety

VAEIMS

IVI developed a software tool, the Vaccine Adverse Events Information Management System (VAEIMS) in collaboration with the WHO, to facilitate the transfer of AEFI data from the periphery of a healthcare system into a central database for processing and analysis to guide decision-making at different levels of a country; as well as transferring it into a global database. In 2018, two more NRAs (Chile and Vietnam) successfully transferred national AEFI data into the global database in the UMC system through the VAEIMS tool. The customized and upgraded version of VAEIMS has been deployed at a national level in four priority countries in the WHO Western Pacific Region – Cambodia, Lao PDR, Mongolia and Vietnam. The new features of the upgraded version include a multilingual interface (in addition to English) to support district-level AEFI data collection, as well as the capacity to automatically generate an AEFI bulletin in order to share AEFI data with other stakeholders.

The lack of knowledge of standard terminology of adverse events is a critical barrier to harmonization among global databases. A training course was developed for national focal points with responsibility for pharmacovigilance to enhance their use of VAEIMS and to improve their knowledge of standard adverse events terminology (the Medical Dictionary for Regulatory Activities, MedDRA). This first VAEIMS training course was held in September 2018. It was hosted by IVI in collaboration with the WHO Regional Office of the Western Pacific Region. The sessions provided an opportunity to discuss and exchange information about AEFI collection, reporting and information management across countries, and to gain practical experience through hands-on workshops as well as training on pharmacovigilance concepts and MedDRA coding.

Participants at the first VAEIMS training course held in September 2018

cDVMS project

IVI has also been developing a dengue vaccine safety data monitoring system. IVI's effort in the vaccine safety area has been extended to help low- to middle- income country manufactures through the centralized Dengue Vaccine Data Management System (cDVMS) project. The US National Institutes of Health (US NIH) developed tetravalent live recombinant dengue vaccine candidates, TV003/TV005, and subsequently licensed these to several developing country manufacturers located in Brazil, India and Vietnam, and to Merck (exclusive rights only in the US, Canada, Europe, and China).

While various tools and formats for managing vaccine safety data are utilized by different manufacturers at different phases of vaccine development in different countries, these are not harmonized, and no standard procedures exist to share such data among manufacturers. As part of the efforts to support developing country manufacturers of dengue vaccines, IVI proposes to establish a data sharing paradigm in collaboration with developing country licensees of TV003/TV005, in which a centralized safety database for clinical trials will be shared.

Once IVI has developed and proceeds to manage a centralized safety database, the data format among different manufacturers will be integrated in order to enter uniform data into a single harmonized database. These efforts will ensure that the safety of the vaccine is evaluated in a comprehensive, consistent manner. A centralized safety database will be shared among licensees for their pharmacovigilance activities, regulatory submissions, and future collaborations of interest.

Partnerships

The Research Investment for Global Health Technology (RIGHT) Fund, a public-private partnership between the Korean government, the BMGF, and Korean biopharmaceutical companies to fund the development of vaccines, drugs, diagnostics, and other selected technologies for global health, was established as a non-profit foundation in July 2018, with its office located within the IVI headquarters building. IVI has played a pivotal role in the establishment of the fund.

Following the exchange of a trilateral memorandum of understanding between IVI, the Indian Council of Medical Research, and the Department of Health and Family Welfare of India in 2017, cooperative programs between IVI and the Indian government institutes such as the Translational Health Science and Technology Institute (THSTI) are being actively established to help accelerate research cooperation and broaden partnership between IVI and India, one of the world's biggest producers and exporters of vaccines.

In an effort to diversify state funding resources, IVI initiated country engagement activities in 2018 to establish relationships with the embassies of Australia, China, Denmark, the EU, Finland, the Netherlands, Norway, Switzerland, and the USA. IVI invited these countries to become funders and signatory member states of IVI and to participate in the envisioned IVI State Council. IVI also organized the 1st annual IVI Member State Meeting, which saw embassy representatives from 14 signatory countries attend a forum on IVI's global accomplishments and ongoing projects.

In 2018, IVI continued its role as an advisor to the Global Health Security Agenda (GHSA) Steering Group and a member of the JEE Alliance. In August 2018, IVI completed

Members of KSC and dignitaries pose for a commemorative photo at KSC's 20th anniversary celebration on June 19, 2018

IVI appointed violinist Lee Sang Hee as the first Giving Ambassador to acknowledge her tremendous generosity and continuous dedication to IVI as she has donated the entire proceeds from 15 concerts.

Prof. Gagandeep Kang, Executive Director of the Translational Health Science and Technology Institute (THSTI) of India takes questions after introducing her organization at a joint symposium on November 22, 2018.

its joint effort with the GHSA, welcoming participants of the Infectious Disease Field Management Training (IDFMT) program, which is supported by the Korea International Cooperation Agency (KOICA) as part of the GHSA; as well as students from Yonsei University School of Public Health's 2018 Master's Degree Program in Global Health Security Capacity Building. The participants included government officials from Ethiopia, Cameroon, Congo, East Timor, Ethiopia, Indonesia, Kenya, Mongolia, Rwanda, Tanzania, and Vietnam.

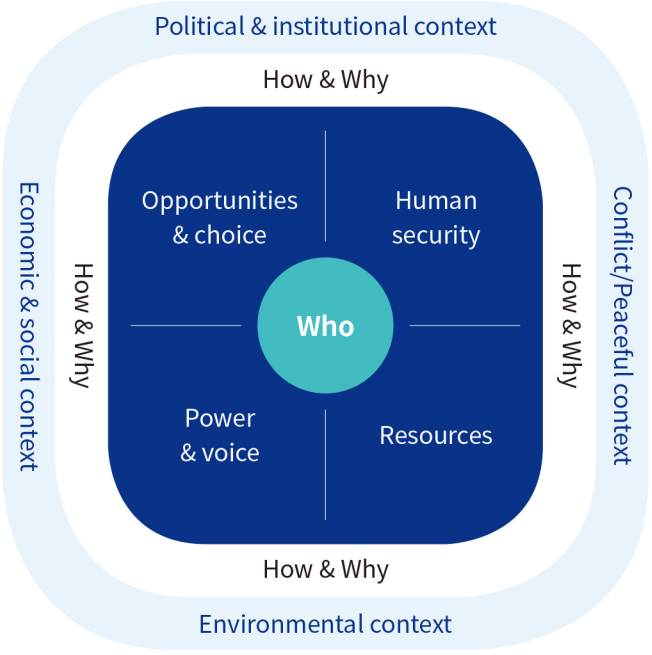
While continuing to increase our interaction and cooperation with vaccine companies, organizations, and universities in Korea, IVI formed partnerships with the Public CMO for Microbial-based Vaccines (PCMO) in Hwasun, and the Animal Cell Culture Substantiation Center (ACCSC) in Andong, which are dedicated to bacterial vaccines and viral vaccines, respectively, for Korea's two vaccine clusters.

IVI's Impact on Environment

Sida, the Swedish International Development Agency, a core funder of IVI, requires that partner organizations integrate environmental and climate change considerations into their operational policies. To that end, IVI is now analyzing and addressing its own impact on the environment and taking a clear position on our ecological footprint and behavior.

In 2018, Sida's Helpdesk for Environment and Climate Change reviewed IVI's environmental policies and practices, including IVI safety guidelines, SOPs for waste disposal, and general procurement policy and procedures in order to provide IVI with guidelines for an environmental impact assessment and the eventual establishment of an integrated environmental management system.

With Sida Helpdesk's support, IVI has undertaken an environmental impact assessment of its work with a target completion timeline of mid-2019. Through this process, IVI aims to develop an integrated environmental management system which will enable IVI to: 1) proactively enhance opportunities for positive environmental impact; 2) identify and manage environmental risks arising from IVI's operations; and 3) identify and manage vulnerability to environmental change, including climate change.



Sida's Poverty Toolbox with environmental context as one key component

Impact

In 2018, IVI scientists authored or co-authored 66 articles that were published in peer-reviewed scientific journals. Fifty-eight were in the Scientific Citation Index (SCI) including high-profile journals such as The Lancet, The Lancet Infectious Diseases, Nature Medicine, and Nature.

Photo: Se Eun Park, IVI

Impact of the Oral Cholera Vaccine

A global cholera vaccine stockpile, managed by the WHO, was created in 2013 using the oral cholera vaccines developed by IVI. The stockpile created a previously non-existent market for oral cholera vaccines. More than 36 million doses of the vaccine were deployed in epidemic and endemic situations in more than 20 countries through 2018 (including India, Bangladesh, Ethiopia, Malawi, Iraq, South Sudan, Haiti, Tanzania, Cameroon, Guinea, Nepal, Democratic Republic of Congo, and Mozambique).

Globally, OCV production was low, with demand exceeding supply. The WHO had to turn down requests from countries for supplies of vaccines that could not be filled because of the shortage.

That all changed when Euvichol® was approved in December 2015, followed by Euvichol-Plus® employing a user-friendly plastic container approved by the WHO Prequalification Program in December 2017. The addition of Euvichol-Plus® has increased annual global supply to more than 25 million doses since 2017, with the potential for further increased production to over 50 million doses per year. More importantly, the extra capacity has contributed to reversing the cycle of low demand, low production, high price and inequitable distribution to one of increased demand, increased production, reduced price and increased access. Euvichol-Plus®, priced at about $1.30 per dose, is 25 percent cheaper than Euvichol®, and it will therefore enable aid and vaccine delivery organizations to procure more doses of OCV at the same cost. Its producer EuBiologics is capable of further increasing supply. IVI also transferred OCV technology to Incepta in Bangladesh to support local supply of the vaccine, and is taking steps to transfer it to BIBCOL of India through THSTI.

With the vaccines and other tools now available to combat cholera, in 2017 the WHO launched 'Ending Cholera—A Global Roadmap to 2030,' a strategy aimed at reducing cholera deaths by 90 percent by 2030. OCV is a key tool in this ambitious strategy. The stage has been set for the vaccine to make bigger contributions to combating cholera worldwide. For its part, IVI, in collaboration with KOICA and the Mozambican Ministry of Health, conducted a mass OCV vaccination in over 190,000 people at risk of the disease in the Cuamba District near the Malawi border in 2018, and the institute plans to conduct additional vaccination campaigns in collaboration with partners worldwide.

While supply has increased, there is room for further improvement in the uptake of the vaccine. Funders, policymakers and countries have cited the need for more advocacy and evidence on use of the vaccine in real-life situations to support decision-making on vaccine introduction. IVI is committed to continuing efforts to meet programmatic needs and ensure the vaccine is available and accessible to those who need it the most.

66

the number of articles published in peer-reviewed scientific journals

58

the number of articles published in Scientific Citation Index (SCI) journals

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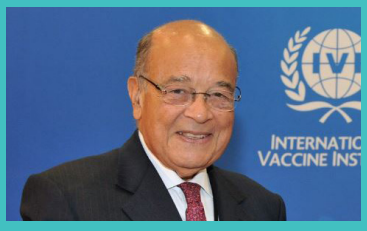
In Memoriam: Prof. Adel Mahmoud (1941-2018)



The late Prof. Adel Mahmoud, former Chairman of the IVI Board of Trustees

IVI pays respect to the late Prof. Adel Mahmoud, former Chairman of the IVI Board of Trustees and a global pioneer in the treatment and prevention of infectious diseases, who passed away on June 13, 2018. Prof. Mahmoud joined the IVI BOT in 2010 and served as its Chairman from 2013 when IVI was going through a difficult period, before resigning due to health reasons in February 2018. He came to the IVI Board after a remarkable career in academia and industry, culminating as the President of Merck Vaccines. Before passing away, he was a Professor of the Department of Molecular Biology and the Woodrow Wilson School of Public and International Affairs at Princeton University, USA. IVI is a stronger and more vital institution because of Prof. Mahmoud's vision and leadership, and IVI is eternally grateful to him. He will be remembered by IVI and the broader international community for his contributions to global health.

Former BOT member Kyu-hyung Lee acknowledged

IVI presented an appreciation plaque to Mr. Kyu Hyung Lee, advisor to the Korea Support Committee for IVI and former Korean Vice Minister of Foreign Affairs, to acknowledge his dedicated service on the IVI BOT.

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SAG members with IVI's senior scientists

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Bharat Biotech
India

Big Data Institute, University of Oxford
UK

BioFarma
Indonesia

Bio-Korea
Republic of Korea

BOSTON CONSULTING GROUP

B.P. Koirala Institute of Health Sciences
Nepal

Brigham and Women's Hospital
USA

Catholic University
Republic of Korea

Celltrion
Republic of Korea

Centers for Disease Control, R.O.C.
Taiwan

Central Diagnostic Laboratory
Nepal

Centre de Recherch?s Mdicales de Lambarn
Gabon

Centre MURAZ / AGIR
Burkina Faso

Chonbuk National University
Republic of Korea

Chonnam University
Republic of Korea

Christian Medical College
India

Chungnam National University
Republic of Korea

Coalition against Typhoid
USA

Coalition for Epidemic Preparedness Innovations

Department of Drug Administration
Nepal

Developing Countries Vaccine Manufacturers Network (DCVMN)
Switzerland

Dhulikhel Hospital
Nepal

Duke University Medical Center
USA

Embassy of the United States to the Republic of Korea

Emory University
USA

Ethiopian Health and Nutrition Research Institute
Ethiopia

EuBiologics
Republic of Korea

Ewha University
Republic of Korea

Food and Drug Administration Philippines
Philippines

Fred Hutchinson Cancer Research Center

Gavi, the Vaccine Alliance Switzerland

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USA

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Global Health Security Agenda

Global Health Technology Coalition
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Republic of Korea

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Republic of Korea

Hanyang University
Republic of Korea

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Bangladesh

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Bangladesh

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Senegal

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Burkina Faso

Instituto Butantan
Brazil

International Society for Vaccines (ISV)
USA

JEE Alliance

Johns Hopkins University International Vaccine Access Center (IVAC)
USA

John Snow, Inc.
USA

Kangwon National University
Republic of Korea

Kanti Children's Hospital
Nepal

Kenya Medical Research Institute
Kenya

Kilimanjaro Christian Medical Centre
Tanzania

Konkuk University
Republic of Korea

Korea Center for Disease Control and Prevention
Republic of Korea

Korea Institute of Tuberculosis
Republic of Korea

Korea National Institute of Health (KNIH)
Republic of Korea

Korea Research Institute of Bioscience and Biotechnology (KRIBB)
Republic of Korea

Korea University
Republic of Korea

Kumasi Centre for Collaborative Research in Tropical Medicine
Ghana

Kyunghee University
Republic of Korea

LG Chem
Republic of Korea

Mahidol University
Thailand

Medigen Vaccine Biologics Corp.
Taiwan

Metrosalud ESE / Unidad Hospitalaria communa Santa Cruz
Medellín, Colombia

Ministry of Food and Drug Safety
Republic of Korea

Ministry of Health and Population
Nepal

Ministries of Health
Ethiopia, Malawi Sudan

Ministries of Public Health
Brazil, Colombia, Thailand

Ministry of Health and Population
Nepal

Murdoch Children's Research Institute, University of Melbourne
Austrlaia

National Institute for Biological Standards and Control (NIBSC)
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South Africa

National Institute of Cholera & Enteric Diseases (NICED)
India

National Institute of Hygiene and Epidemiology (NIHE)
Vietnam

National Institutes of Health (NIH)
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Nepalgunj Medical College
Nepal

Nepal Research Health Council
Nepal

Oromia Regional Health Bureau
Ethiopia

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United Kingdom

Panacea Biotec Ltd.
India

Pan American Health Organization (PAHO)

Patan Hospital
Nepal

PATH
USA

Pohang University of Science and Technology (POSTECH)
Republic of Korea

Programa de Estudio y Control de Enfermedades Tropicales (PECET), Universidad de Antioquia
Medellín, Colombia

Public CMO for Microbial-based Vaccine
Hwasun, Republic of Korea

Public Health Surveillance Group (PHSG)

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Korea

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India

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Republic of Korea

SK Chemicals
Republic of Korea

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Takeda Pharmaceuticals International AG
Switzerland

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Germany

Telethon Kid's Institute, University of Western Australia

Transgovernment Enterprise against Pandemic Influenza of Korea (TEPIK)
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Madagascar

Tropical Disease Foundation
Philippines

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UNICEF
Nepal

United States Centers for Disease Control and Prevention (CDC)
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Universidad Industrial de Santander
Colombia

University of Alabama at Birmingham
USA

University of Antioquia
Columbia

University of Florida
USA

University of Gezira
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University of Oxford
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Australia

University of Sienna

University of Vermont
USA

University of Virginia
USA

University of Wisconsin
USA

VaBiotech
Vietnam

Vaccine and Biological Production No1 (VABIOTECH)
Vietnam

Vaccine and Biological Production No1 (VABIOTECH)
Vietnam

Vaccine Research Initiative, WHO
Geneva

Walter Reed Army Institute of Research (WRAIR)
USA

Washington University
USA

Wellcome Trust Sanger Institute
UK

WHO Initiative for Vaccine Research (IVR)

WHO Programme for Immunization Preventable Diseases (IPD)
Nepal

WHO Regional Office for Europe (EURO)

WHO Regional Office for South-East Asia (SEARO)

WHO Regional Office for the Western Pacifi (WPRO)

World Health Organization (WHO)

Yonsei University
Republic of Korea

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Established in 1998, the Korea Support Committee for IVI (KSC) is a nonprofit organization based in Seoul, Korea that mobilizes local support for IVI. KSC consists of prominent leaders from government, industry and academia in Korea who contribute their time and expertise to support IVI.

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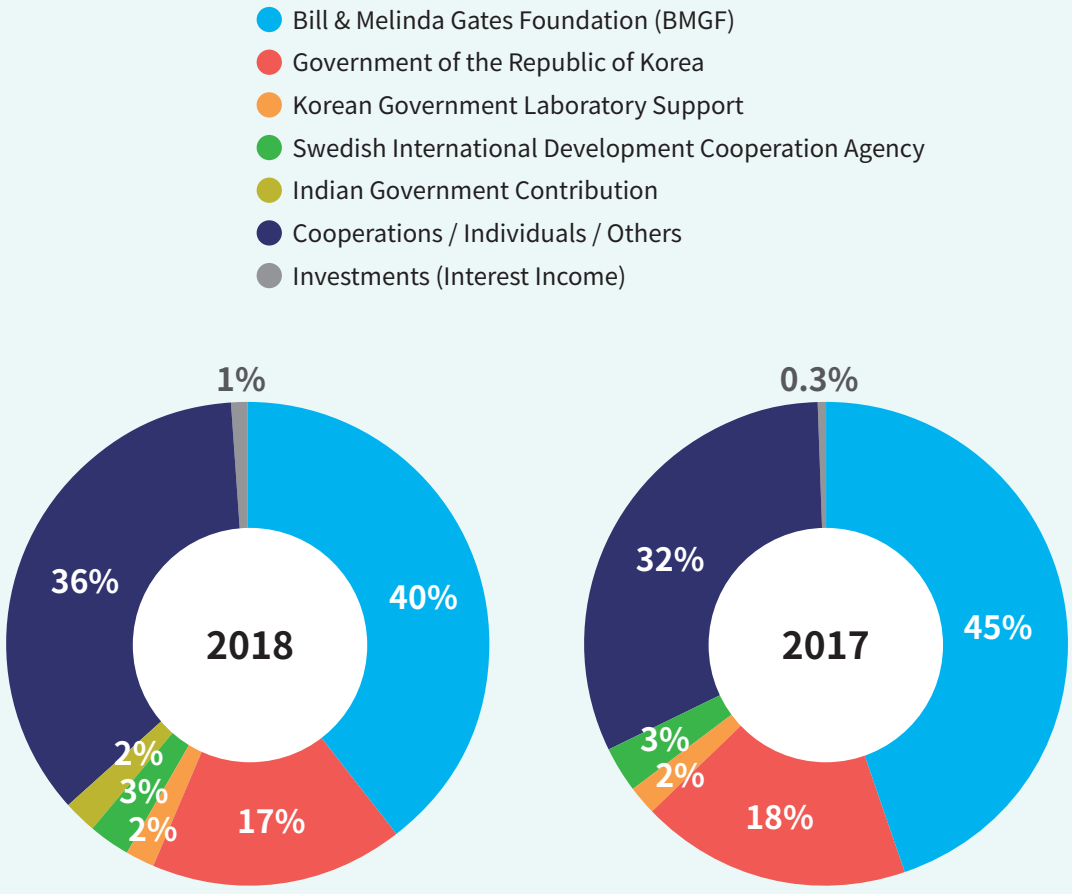
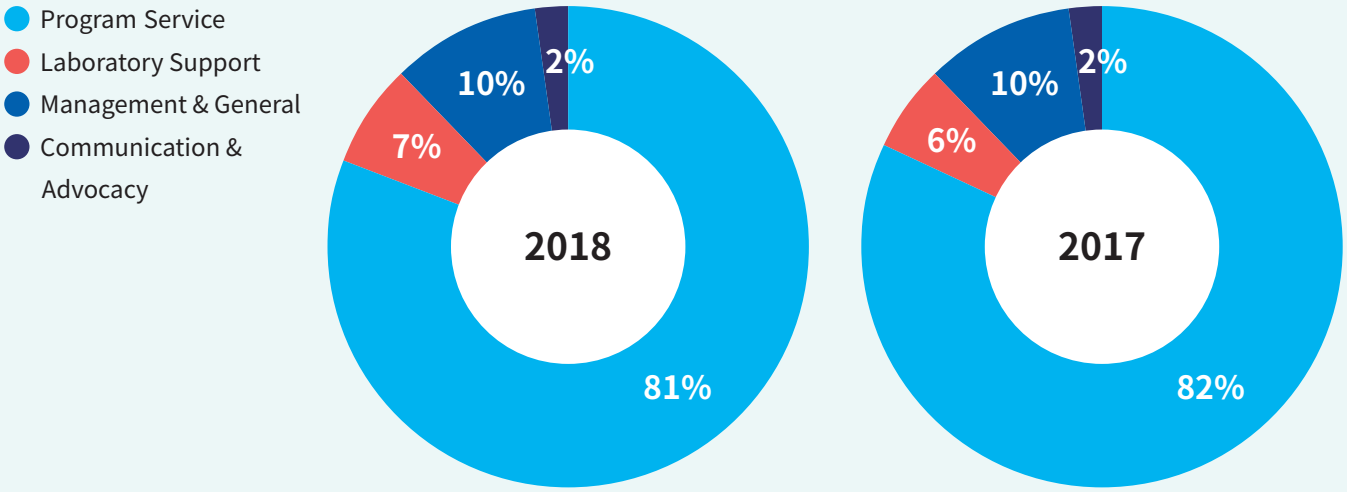
Finances

(in US dollars)

Revenue	2018	2017
Bill & Melinda Gates Foundation (BMGF)	12,007,442	12,378,492
Government of the Republic of Korea	5,277,286	5,022,300
Korean Government Laboratory Support	452,163	446,978
Swedish International Development Cooperation Agency (Sida)	885,196	793,596
Indian Government Contribution	500,000	-
Corporations / Individuals / Others	10,827,948	9,039,548
Investments (Interest Income)	317,307	115,729
Total Revenue	**30,267,343**	**27,796,643**



Expense	2018	2017
Program Service	23,261,363	21,409,516
Laboratory Support	2,140,763	1,514,689
Management & General	2,758,661	2,496,354
Communications & Advocacy	425,818	521,743
Total Expense	**28,586,605**	**25,942,303**
Foreign Exchange Gain (Loss)	**(142,604)**	**72,316**
Net Surplus (Deficit)	**1,538,134**	**1,926,656**



Assets	2018	2017
Cash and Cash Equivalents	4,154,291	3,389,308
Bank Deposits	14,352,428	15,696,083
Other Current Assets	751,579	555,329
Other Assets	1,950,532	1,275,619
Total Assets	**21,208,830**	**20,916,339**

Liabilities and Net Assets	2018	2017
Grant Funds-Deferred Support	10,576,991	11,557,615
Other Current Liabilities	2,030,813	2,354,718
Other Liabilities	190,241	131,355
Net Assets	8,410,785	6,872,651
Total Liabilities and Net Assets	**21,208,830**	**20,916,339**

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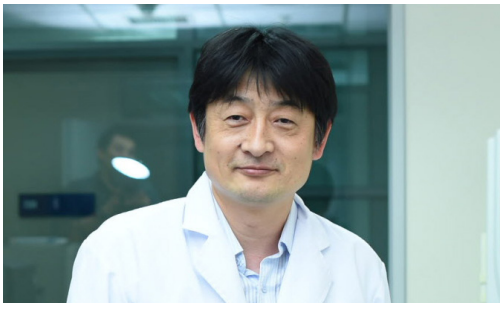
Director General

Francois Belin, MSc Management
Chief Operating Officer

Julia Lynch, M.D.
Deputy Director General, Development & Delivery

Kyung-taik Han, Ph.D.
Deputy Director General, Government & Global Affairs



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Acting Deputy Director General, Science

Florian Marks, Ph.D.
Deputy Director General, Public Health, Access and Vaccine Epidemiology

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