

2019

# ACCELERATING VACCINES CRITICAL TO GLOBAL HEALTH

## 2019 Annual Report

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



**International  
Vaccine  
Institute**



A cistern water canal system for safe water access in Andina, Madagascar featuring Professor Raphael Rakotozandrindrainy, our collaborating Principal Investigator from the University of Antananarivo, and IVI Science Sam. / Credit IVI/Andrea Haselbeck





**“Children  
in Madagascar have  
the best chance of  
preventing typhoid fever  
thanks to IVI  
and the whole  
SETA Plus team.”**

**Professor  
Raphael Rakotozandrindrainy**

Collaborating Principal Investigator  
University of Antananarivo



**International  
Vaccine  
Institute**

# Table of Contents

Reflections on 2019	3
2019 Highlights	4
Advancing the Sustainable Development Goals	10
IVI's strategic development	16
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Typhoid	18
Cholera	24
Accelerating Vaccine #3 iNTS and Shigella	28
MERS-Coronavirus Vaccine Program	29
Aedes-aegypti mosquito-transmitted diseases	30
<hr/>	
New initiatives	
Addressing critical gaps in antimicrobial use and resistance (AMR)	32
Confronting schistosomiasis in Madagascar and Burkina Faso	35
Rallying a global consortium for a Strep A vaccine	37
Adenovirus 55 Vaccine Program	38
SFTS Vaccine Program	38
Protecting more women against cervical cancer with a single-dose HPV vaccine	39
Hepatitis vaccine programs	40
Tuberculosis (TB) vaccine programs	42
Japanese Encephalitis (JE) vaccine program	43
<hr/>	
Quality Management	44
Capacity Building: Promoting vaccine sustainability in low- and middle-income countries	45
Partnerships	50
Executive Leadership Team	52
Board of Trustees	53
Scientific Advisory Group	54
Our Partners	55
2019 financial summary	58
IVI's Global Reach	60

# Reflections on 2019

Dear friends and colleagues,

In the final weeks of the year, we watched as a novel coronavirus made its appearance on the world stage. At the time, we didn't fully appreciate that we were on the brink of a global COVID-19 pandemic, but we've now rolled up our sleeves. One thing was clear from the start: health threats that cross borders require swift, collective action. At IVI, we re-committed to our core beliefs that safe, effective, and affordable vaccines are critical for global health, and the world's most vulnerable people must not be left behind.

In 2019, we began late-stage development of a new typhoid conjugate vaccine to better protect people in endemic regions, worked on simplifying our oral cholera vaccine to increase its accessibility, answered the global call for more data on the universal threat of antimicrobial resistance, began developing a vaccine to protect against *Salmonella* species, formed a global coalition to finally discover a vaccine against Group A Strep, made contributions toward establishing international standards for MERS-CoV vaccine candidates, empowered communities to control and prevent schistosomiasis, fortified our lab practices with globally recognized standards, and much more.

While we expanded and diversified our project portfolio to both respond to emerging global threats and focus research on neglected diseases, we continued to deepen our work in preventing cholera and typhoid in low-income countries. Over 42 million doses of Euvichol/Euvichol-Plus have been released from the WHO stockpile as of November 2019, and continue to protect populations most at risk of epidemic and endemic cholera. This year, we also set out to ensure that critical standard reagents would be available for oral cholera vaccine manufacturers. In March, we joined a consortium of partners to measure the effectiveness of a novel typhoid conjugate vaccine in West Africa, which will help inform delivery of our own TCV, now in the final stage of clinical trials.

It was a milestone year for IVI, and it would not have been possible without the dedication of our teams and collaborators, and the support of our member states and funding partners. As we collectively head into an uncertain future marked by emergent disease, we are especially grateful for your steadfast support. A healthier world is in our reach, and we can—and we must—arrive in it together.

With gratitude,  
Director General **Jerome H. Kim**



# 2019 Highlights



19th International Vaccinology Course hosted by IVI in September 2-6, 2019. / Credit IVI

## • Building capacity through international vaccinology course •

Capacity-building is a vital component in IVI's approach to increasing access to vaccines and health and promoting vaccine sustainability in low- and middle-income countries. This year's 19th Vaccinology Course brought together 175 trainees and faculty members from 49 countries to cover vaccine development, evaluation, production and policy.



IVI-NIBSC-CEPI face to face meeting for MERS-CoV standard material at NIBSC (UK) / Credit IVI

### ● Confronting antimicrobial resistance (AMR) with better data ●

An IVI-led consortium launched the CAPTURA project to confront the challenges of widespread antimicrobial resistance. With a grant from the Fleming Fund, CAPTURA aims to expand the volume of historical and current data on AMR and antimicrobial usage which will ultimately help shape effective policy at the regional and global level and increase our knowledge on the geographical distribution of bacterial pathogens and associated illnesses.

### ● Advancing vaccines for emerging pathogens ●

IVI entered a partnership with the Coalition for Epidemic Preparedness (CEPI) to provide technical services to advance new vaccines against emerging pathogens. This has included providing the UK National Institute for Biological Standards and Control with a significant amount of MERS-CoV-specific neutralizing Ab to begin establishing a MERS-CoV reference standard.





The main team in Nepalgunj, Nepal who will enroll participants for a Phase III trial of IVI's Vi-DT typhoid conjugate vaccine. / Credit IVI

### • Entering final stage for Vi-DT typhoid conjugate vaccine •

IVI began late-stage development of a typhoid conjugate vaccine with Phase III trials in Nepal and the Philippines over the next two years. This partnership with SK Bioscience aims to ensure global supply of the vaccine at an affordable cost for populations in low- and middle-income countries where typhoid is endemic.





A community awareness meeting for schistosomiasis open to the public led by health workers and village officials in Madagascar. / Credit IVI

## ● Tackling schistosomiasis in Africa ●

This year, IVI kicked off the “Vaccine against Schistosomiasis for Africa (VASA)” project, an EU Horizons 2020-funded Phase I clinical study of SchistoShield® anti-schistosomiasis vaccine in healthy adults in Burkina Faso and Madagascar. This project includes disease surveillance and cost-effectiveness studies, and the formation of a global consortium dedicated to advancing research on schistosomiasis vaccines. The Bill & Melinda Gates Foundation has also funded the EPIC group to prepare an Integrated Product Development Plan (IPDP) – a roadmap for the development of the schistosomiasis vaccine.



### Reducing the cost of OCV

IVI is working to simplify the oral cholera vaccine (OCV) which would lower costs and further increase its accessibility. With an award from the Bill & Melinda Gates Foundation, IVI will explore modifications to the existing formula and optimize a single manufacturing process to give higher yields of vaccine and increase production capacity.

### Accelerating Vaccine #3

Following an initial investment of core budget, IVI met all key objectives in a preclinical development plan for a Salmonella vaccine. IVI then received supplemental funding from the Wellcome Trust to identify and select promising vaccine candidates against invasive non-typhoidal Salmonella (iNTS), an enteric disease that affects the world's poorest populations. A proof of concept immunogenicity study in animals is underway.



8th UN Secretary-General Ban-Ki Moon delivering welcoming remarks at the IVI State Forum 2019. / Credit IVI

### ● Engaging diplomatic community for global collaboration on vaccine R&D ●

Ambassadors and senior diplomats from 17 countries attended the IVI State Forum 2019, an annual event that brings together the diplomatic community in South Korea to discuss the importance of vaccine R&D in achieving global goals. The 8th UN Secretary-General Ban Ki-moon attended the event in person and delivered a passionate speech addressing the importance of international support for IVI's work.

### ● Investing in quality management ●

The Korean Ministry of Food and Drug Safety granted IVI a Good Clinical Laboratory Practice certification this year, marking IVI's significant investment in quality management over the past two years, which includes securing related facilities and systems and training personnel. The certification confirms that the IVI GCLP laboratory is aligned with globally recognized standards, as well as regulatory requirements in South Korea.



# Advancing the Sustainable Development Goals



IVI is committed to doing its part to accomplish the Sustainable Development Goals (SDGs). Here's how IVI's work aligns with 11 of the 17 SDGs:



## SDG1 No Poverty

Vaccines alleviate health factors responsible for enduring poverty by enabling workers to avoid lost income from sick days and takes families out of poverty.



## SDG3 Good Health and Well-Being

Vaccines and vaccination decrease deaths and prevent illness, disability and cancer. Vaccination also prevents antimicrobial resistance and ensures healthier, more productive lives.



## SDG4 Quality Education

Vaccines enable students to stay in school and continue their education.



## SDG5 Gender Equality

Gender equality and greater health equity go hand in hand. IVI's research on Human Papilloma Virus (HPV) vaccine, Hepatitis E virus (HEV), and Group A strep (GAS) seeks to expand access to these vaccines for girls and women in low- and middle-income countries.



## SDG6 Clean Water and Sanitation

WASH campaigns integrated within IVI's programs in Madagascar, Malawi, and Mozambique improve access to clean water. Vaccination against water-borne diseases like cholera, schistosomiasis, and typhoid reduces the threat posed by the use of unclean water in resource-poor communities.



## SDG8 Decent Work and Economic Growth

IVI's novel vaccine development model utilizes developing country vaccine manufacturers (DCVMs) to manufacture its vaccines. Vaccine development in these countries accelerates economic growth by creating jobs and export opportunities.



## SDG9 Industry, Innovation and Infrastructure

IVI's support for developing country vaccine manufacturers through technology transfer and technical assistance for licensure and WHO-PQ establishes new scientific capacities and infrastructure in low- and middle-income countries.



## SDG10 Reduced Inequalities

Developing new vaccines and increasing access to existing ones contribute to enhanced health equity.



## SDG11 Sustainable Cities and Communities

Strengthening vaccination in urban environments protects cities and communities against the increased risk of disease outbreaks and contributes to their sustainability.



## SDG 13 Climate Action

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.

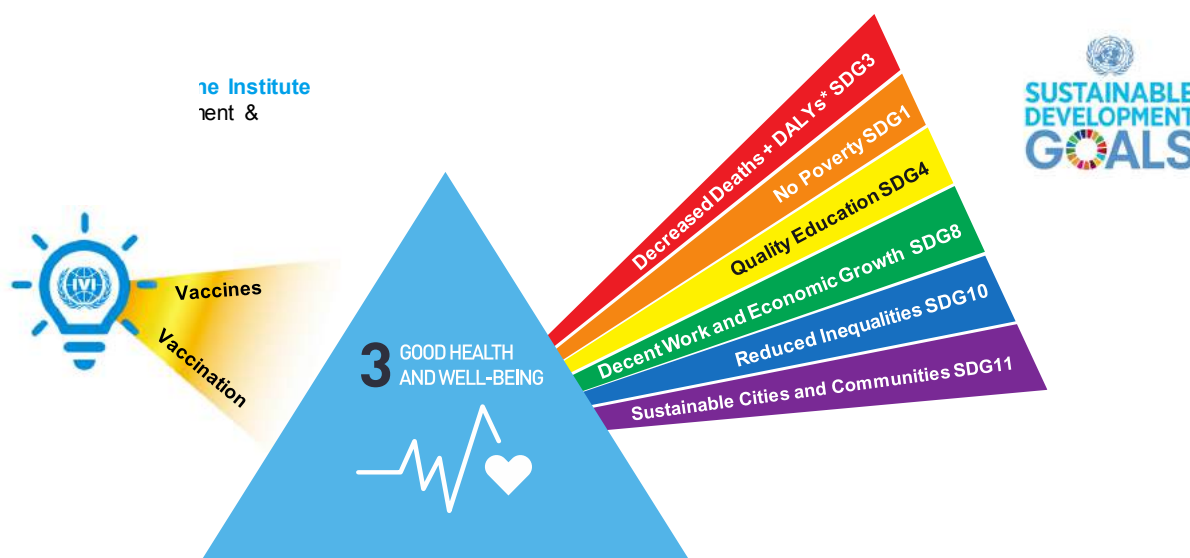


## SDG 17 Partnerships for the Goals

IVI is an integral partner in global health initiatives and coalitions, working closely with CEPI, Gavi, GHSA, JE Alliance, PATH, RIGHT Fund, the WHO, Sida, KOICA, ICMR, US CDC, and more.

## International Vaccine Institute

Discovery, Development & Delivery



“Just as it is important to have scientists with different nationalities, cultural backgrounds and experiences, we need gender-balanced perspectives and work environments to limit bias and achieve scientific advancements. That’s how we’ll enhance the lives of women and men around the globe.”

### Global health depends on gender equality

Gender equality and greater health equity go hand in hand. Developing new vaccines and increasing access to existing ones will significantly impact the health of girls, women, and pregnant people around the world, especially in low- and middle-income countries. We are committed to accelerating vaccine research for HPV, Hepatitis E virus, and Group A Strep to protect women and pregnant people from preventable diseases.

**Catharina Maijgren Steffensson**

Associate Director, Medical Director  
Nordics, Sarepta Therapeutics  
IVI Board of Trustees

## Integrating environmental responsibility into our work

In April 2019, IVI took a concrete step toward adopting an integrated environmental management system by undergoing an environmental impact assessment. The assessment identified IVI activities that cause, or may cause, positive or negative impacts on the environment. Following the results, IVI formed an internal Eco Committee to implement provided recommendations, establish an environmental policy with clear goals, and champion sustainable development.



IVI supports the Sustainable Development Goals

## Innovative vaccine R&D with public-private partnerships for low- and middle-income countries and global health

IVI focuses on vaccine development and studies against infectious diseases such as cholera, typhoid, non-typhoidal Salmonella, schistosomiasis and Group A Strep, which affect the world's most impoverished. We aim to make these vaccines available and accessible for vulnerable populations in low- and middle-income countries. Responding to global public health concerns on biologic risks and new and emerging infectious diseases, IVI also focuses on vaccines against new infectious diseases such as MERS and Antimicrobial resistance (AMR) studies.

Through global public and private partnerships with governments, philanthropies, and vaccine manufacturers worldwide, IVI conducts research, technology transfer, vaccine process development, clinical trials, support for vaccine licensure and WHO-PQ for global use, public health research, and vaccination campaigns together with 160 partners in 24 countries in Asia, Africa and Latin America. Through this collaborative work, we aim to support the achievement of the SDGs and enhance global health security.



## IVI's Impact

### Why Vaccines?



**44 : 1**



#### Vaccines Saves Lives

Full implementation of existing vaccines would save 2.5M lives per year (WHO)

#### Vaccine Return on Investment (VROI)

For every \$1 spent on vaccines, \$16 are saved in future health costs, lost income and lost productivity. If all indirect costs are included, the ROI is 44:1 (Ozawa et al, Health Affairs, 2016).

#### Vaccination has incalculable value for individuals, communities and society

Vaccination improves educational attainment/IQ, childhood survival, parental productivity and prevents AMR & reduces poverty

### IVI's Roles

#### Catalyzing governmental and philanthropic support

South Korea  
KCDC

Sweden SIDA

India ICMR

National and  
International  
philanthropic  
support

Bill & Melinda  
Gates  
Foundation

#### Technology transfer and vaccine development

VaBiotech

Shantha  
Biotechnics  
Ltd

EuBiologics

SK Bioscience

Incepta  
Pharma-  
ceuticals

Biopharma

#### Vaccine licensure and WHO-PQ for global use

National  
regulatory  
authorities

WHO

#### Public health research and vaccination campaigns

Local health  
authorities

Global health  
organizations

### Impact



Supports the  
achievement of the  
SDGs



Enhance global  
health security

Vaccination has incalculable value for individuals, communities, and society as a whole. Full implementation of existing vaccines would save 2.5 million lives per year and protects millions more from illness and disability according to WHO's estimation. For every \$1 spent on vaccines, \$16 are saved in future healthcare costs, lost income, and lost productivity. If all indirect costs are included, the ROI is 44:1 (Health Affairs, 2016).

## IVI vaccines bring affordable innovation to global health

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 with a limited market focused on low- and middle-income countries.

We endeavor to make new discoveries leading to the development of vaccines that are:

**Low-cost**



**Easy to administer in resource-limited settings**



**Easily produced by manufacturers in developing countries**



**Protective against diseases of global public health importance**

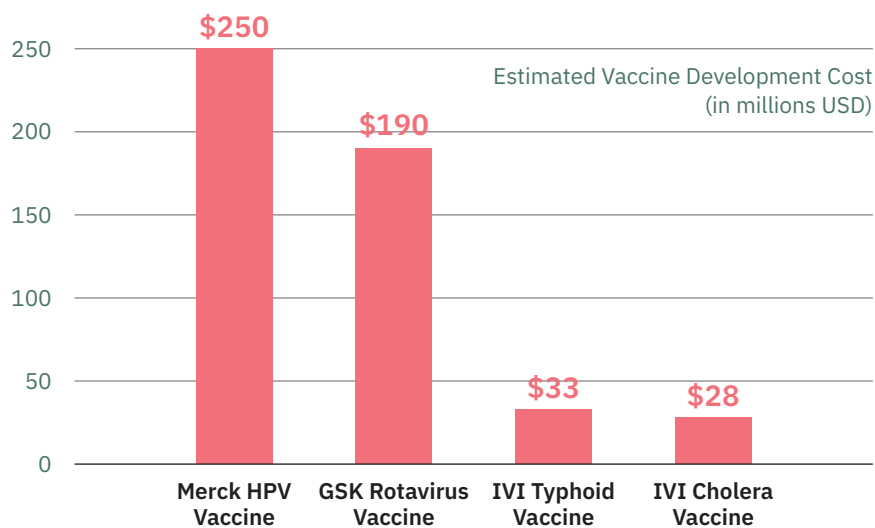


## IVI develops and delivers vaccines against infectious diseases with limited commercial potential, yet high public health importance.

IVI bridges this gap by partnering with vaccine manufacturers, governments, and philanthropies, 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 profit from intellectual property, we partner with multiple companies and transfer the technology to manufacture the vaccines, assist with clinical development,

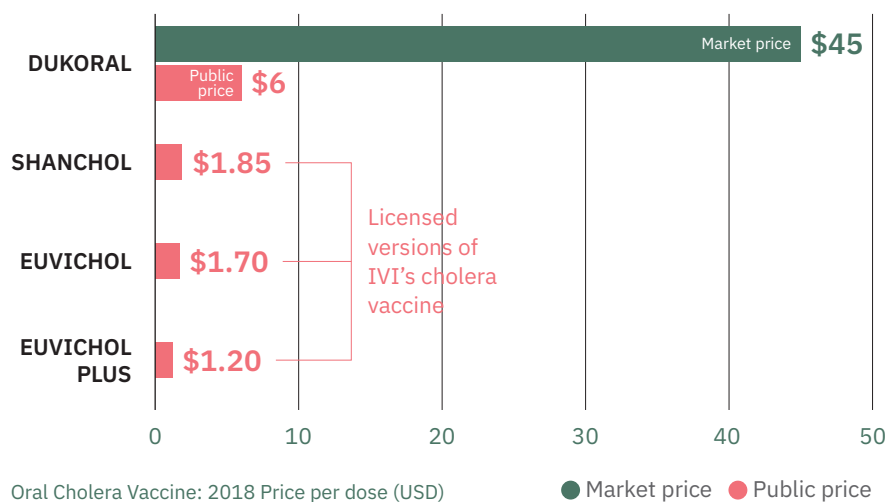
### IVI's vaccine development model Low Cost, High Impact



1. <https://www.the-scientist.com/column/how-much-should-gardasil-cost-46260>

2. Light D, Andrus J, Warburton R. Estimated research and development costs of rotavirus vaccine. Vaccine 27(47), 6627–6633 (2009)

### Affordable vaccines = more lives saved



and help where necessary with WHO prequalification. This, in turn, helps ensure sufficient vaccine supply for the public-sector market.

Through this partnership model, over 42 million doses of the oral cholera vaccine, tech-transferred by IVI, have been deployed in over 20 countries to combat outbreaks (as of November 2019); 80% of Gavi, the Vaccine Alliance's global stock is provided by a South Korean manufacturer, a recipient of technology transfer by IVI. The IVI typhoid conjugate vaccine is also moving closer to WHO-prequalification.



# IVI's Strategic Development

## Our 2018-2021 strategy consists of 3 elements

1. New sites that will allow IVI to better access potential funding and stay relevant in Europe, Africa, India, and the US
2. New vaccine development programs : strengthening the pipeline of new vaccine candidates for global health
3. New people and capabilities : hiring the personnel that IVI needs in order to capitalize on new opportunities and execute existing projects on time and on budget.

### Mission

Discover, develop & deliver safe, effective, and affordable vaccines

IVI accelerates R&D on vaccines critical to global health with our partners around the world to ensure that people everywhere can live healthy and productive lives.

2015-2017

Sustainability

Relevance

Capabilities

2018-2021

New Sites

New sites to fully enable access to new funders

New Vaccines

1-2 new vaccines in clinical development

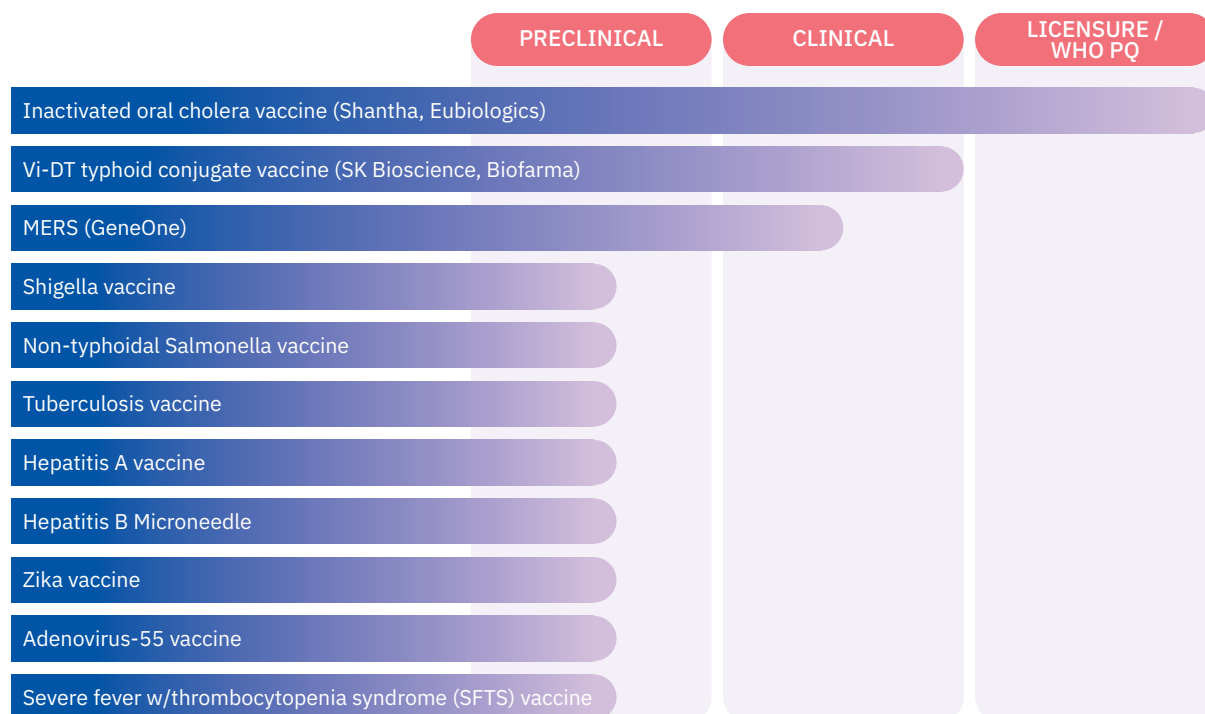
New People

New hires to bring additional capabilities into IVI

## IVI is uniquely present in all steps of the global health value chain

### Vaccine Pipeline- Internal Development

Vaccine candidates under development by IVI



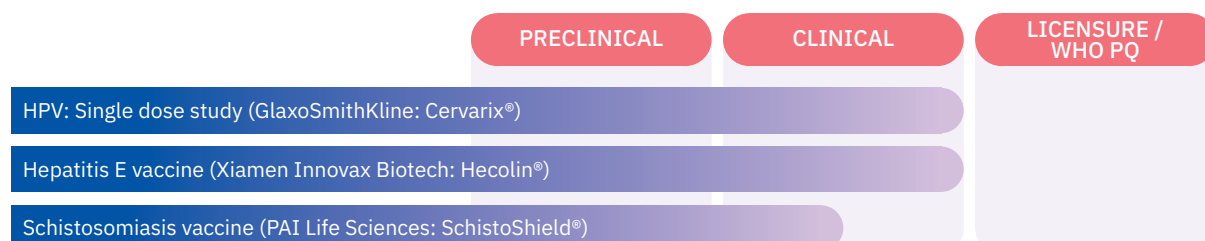
Vaccines under different stages of development.

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).

### Vaccine Pipeline- External Support

IVI collaboration with other vaccine developers



# Typhoid

IVI's Typhoid Program is accelerating the development and introduction of a new-generation typhoid conjugate vaccine (TCV).



## About Typhoid

Globally between 12 million to 22 million cases per year

Between 120,000 to 600,000 deaths per year

Invasive salmonella infections – major cause of global morbidity and mortality with highest burden of disease in South Asia

**2000**

IVI started typhoid disease burden studies through DOMI (Diseases of the Most Impoverished) program

**2007**

Started Vi-based Vaccines for Asia (VIVA) program

**2010-2014**

Conducted the Typhoid Fever Surveillance in Africa Program (TSAP)

IVI developed a typhoid conjugate vaccine (TCV) and transferred the technology to SK Bioscience of South Korea, Biofarma of Indonesia in 2014

**2013-2019**

Conducted Severe Typhoid Surveillance in Africa Program (SETA) to fill gaps on severity, mortality, cost & economic impact of the disease in Africa

**2021**

Aiming at least one additional TCV WHO pre-qualified by 2022

**2020**

SETA + started for continuation of typhoid surveillance in Nigeria and SETA sites

**2019**

Started THECA program to fill the gaps for TCV introduction in Africa

Vi-DT typhoid conjugate vaccine enters phase III in 2019

## Development

IVI developed a typhoid conjugate vaccine (TCV) using initial know-how from the US National Institute of Health, conjugating the Salmonella Typhi Vi polysaccharide to diphtheria toxoid. Unlike other typhoid vaccines, typhoid conjugate vaccine has been shown to protect 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 SK and Biofarma on clinical development for licensure and WHO-prequalification, currently targeted for the end of 2022.



Phase I, II, and III clinical trials for the TCV from SK Bioscience is funded by the Bill & Melinda

Gates Foundation. We completed the phase I study in the Philippines with no safety issues and 100% seroconversion in 144 participants (ages 2 to 45 years) in the Philippines. The phase II study is a dose-schedule study with 285 participants receiving either single dose of Vi-DT, two doses of Vi-DT or placebo. In parallel, we have initiated phase III studies with 1,800 participants: one in Nepal and one in the Philippines.

IVI is currently working with SK and Biofarma on clinical development for licensure and WHO-prequalification, currently targeted for the end of 2022.



The Investigator Meeting held in Kathmandu, Nepal where the IVI team went over protocol, sampling, and electronic data capture with site investigators. / Credit IVI





IVI also received funding from the Gates Foundation to provide technical support to Biofarma with their version of the Vi-DT TCV

technology transfer and clinical trials. IVI works with Biofarma on vaccine process development, as well as clinical, regulatory, and project management. Biofarma has completed the phase I clinical trial at one site in Jakarta, Indonesia in December 2017. The results were similar to the SK phase I study, and there were no safety concerns. IVI and Biofarma teams have been working on the design of the phase III study, and the draft protocol was submitted to BPOM (Indonesian NRA). Biofarma is planning to conduct the phase III study across 3 sites in Indonesia to meet the requirements for WHO PQ.

## Severe Typhoid in Africa Program (SETA and SETA Plus)

In November 2019, after completion of two years of typhoid fever surveillance under the Bill & Melinda Gates Foundation-funded Severe Typhoid in Africa Program (SETA) in 6 countries (Ghana, Burkina Faso, Nigeria, Democratic Republic of Congo (DR Congo), Madagascar and Ethiopia), first incidence estimations were presented at the American Society of Tropical Medicine and Hygiene conference in Washington, DC. At the same time, the study protocol, methodology of monitoring, findings from the previous TSAP study and current study results were published in a supplement of *Clinical Infectious Diseases*. In addition, the Gates Foundation granted further funding to extend typhoid surveillance in five SETA countries: Nigeria, Burkina Faso, Ghana, DR Congo, and Madagascar (SETA Plus), which will commence in the beginning of 2020.



Vi-DT phase III team from Dhulikhel Hospital in Kathmandu, Nepal gives delegates from the Gates Foundation, Enteric and Diarrheal Diseases / Global Health Team, a tour of site preparations for the upcoming trial. / Credit IVI





SETA Plus working group at the Kossodo Hospital in Ouagadougou, Burkina Faso.  
/ Credit IVI/Justin Im



## Typhoid vaccination (THECA)



SETA/SETA Plus surveillance helped close the knowledge gap on disease burden in the African continent. While

typhoid fever is recognized as a public health problem in Asia and Africa, information on its true burden has been lacking, making it difficult to justify vaccination policy and to assess the impact of typhoid vaccination.

The WHO-prequalification of Typbar-TCV® in January 2018 has enabled procurement and supply of TCV through UNICEF and PAHO. While serologic data support the use of Typbar-TCV® (Bharat Biotech, Hyderabad, India) in infants and children as young as 6 months old, studies of clinical protection, including direct and

population-level protection, efficacy, real-world vaccine-effectiveness, and cost-effectiveness are needed from high burden settings to back licensure and guide country decision-makers on the introduction and implementation of Typbar-TCV®. Led by the University of Cambridge, IVI is part of an EDCTP-funded TCV program (THECA) for which co-funding is provided by the Bill & Melinda Gates Foundation. The specific aim of the THECA program is to provide evidence that will be critical to rational decision-making on the introduction of TCVs into public health programs of typhoid endemic countries of Africa. This will be achieved by generating data on the feasibility, acceptability, impact, and cost-effectiveness of the Typbar-TCV® vaccine in field settings.



Typhoid surveillance and vaccine effectiveness teams in Antananarivo, Madagascar in December 2019 to hold a strategic advisory group meeting for the THECA project and to officially kick-off SETA Plus. / Credit IVI

The WHO-prequalification of Typbar-TCV® in January 2018 has enabled procurement and supply of TCV through UNICEF and PAHO.

#### Partners and Collaborators

- SK bioscience (Korea)
- PT Biofarma (Indonesia)
- Incepta vaccines limited
- Bharat Biotech Ltd.
- Biomed
- Zydus Cadila
- Biological E
- Lanzhou Institute of Biological Products
- Finlay Institute
- Walvax
- WHO
- Korean MFDS
- Philippines NRA
- Indonesia BPOM
- Nepal DDA
- Nepal NHRC
- Research Institute for Tropical Medicine, Philippines
- National General Hospital, Indonesia
- Sites in Nepal and Philippines
- University of Cambridge, Dept of Medicine, UK
- Kwame Nkrumah University for Science and Technology, Kumasi, Ghana
- Institute National for Biomedical Research, Kinshasa, DRC
- Institute for Tropical Medicine, Antwerp, Belgium
- Foundation Merieux, Lyon, France
- University of Ouagadougou, Burkina Faso
- University of Antananarivo, Madagascar
- University of Maryland, Baltimore, MA, USA
- International Centre for Diarrhoeal Disease Research, Bangladesh

#### Funders

- Bill & Melinda Gates Foundation
- Second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2)





# Cholera

The Cholera Program ensures adequate supply of high-quality affordable oral cholera vaccines and generates evidence in support of introduction and use in high-risk settings.



## About Cholera

1.3 billion people in 69 endemic countries at risk  
 2.86 million cases 95,000 deaths per year  
 Linked with poverty, poor sanitation and lack of clean drinking water  
 Causes deadly outbreaks in humanitarian crises  
 Children under 5 most affected

**2006**

IVI started reformulating, redeveloping process of mORCVAX(Vietnam) to meet WHO standards

**2011**

WHO prequalified Shanchol™ (India), tech-transferred by IVI in 2008



**2015**

WHO prequalified Euvichol® (Korea), tech-transferred by IVI in 2010~2011



**2023**

BIBCOL (India) tech-transferred by IVI in 2019 and expected registration in 2023 in India

**2020**

Registration of Cholvax in Bangladesh, tech-transferred by IVI in 2014

**2017**

WHO prequalified Euvichol-Plus® in plastic tube, easier to access and more cost effective  
 ~\$1.2/dose



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® and Euvichol-Plus® have been WHO-prequalified and are available for purchase. Cholvax®, manufactured by

Incepta for domestic use in Bangladesh, was registered in early 2020 and we anticipate registration of BIBCOL in India by 2023. To date, over 42 million doses of the oral cholera vaccine, tech-transferred by IVI, have been deployed in over 20 countries to combat outbreaks. It is still quite low in supply according to GAVI's projected demand of OCV which requires an estimated 670M doses for the WHO's Ending Cholera: A Roadmap to 2030.

Company	Trademark	IVI Partnership	Stage of development
<b>Vabiotech (Vietnam)</b>	mORCVAX	IVI re-formulated, redeveloped process to meet WHO standards.	Licensed in Vietnam (mORCVAX™)
<b>Shantha Biotechnics; part of the Sanofi group, India</b>	Shanchol™	Technology transfer May 2008	Licensed in India (Feb 2009). WHO prequalified Sep 2011.
<b>EuBiologics (Korea)</b>	Euvichol® Euvichol-Plus® (plastic tube presentation)	Technology transfer 2010-11	Korean export license 2014 WHO prequalified Dec 2015 Euvichol-Plus prequalified in 2017
<b>Incepta (Bangladesh)</b>	Cholvax®	Technology transfer May 2014	Registered in Bangladesh Jan 2020
<b>Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL) (India)</b>		Technology Transfer 2019	Expected 2023



Meeting on "International Standards for Oral Whole Cell Killed Cholera Vaccines" in Seoul, Korea. / Credit IVI



Health workers from Cuamba, Mozambique, working on MOCA project funded by KOICA's Global Disease Eradication Fund (GDEF) / Credit IVI

In 2019, IVI received a new grant from the Bill & Melinda Gates Foundation to explore a reformulation of OCV that could lower the cost of production by 25% and increase production capacity of Euvichol by 35%. There is strong scientific rationale that only two of the five components in OCV are necessary for efficacy. If successful, this formulation simplification could be shared with all of the manufacturers reducing vaccine cost and further increasing supply.

IVI also received a grant from the Gates Foundation to ensure critical standards and reagents are available to low-cost OCV manufacturers in the global health market. International standardization in the manufacturing and release of OCV will ultimately ensure sufficient supply of low-cost prequalified vaccines in the 39 Gavi countries, where demand currently exceeds the supply.

**If successful,  
this formulation  
simplification could be  
shared with all of the  
manufacturers, reducing  
vaccine cost and further  
increasing supply.**



Targeting the need for both more supply and new vaccination strategies, IVI also launched a partnership with colleagues at Harvard-Mass General Hospital and EuBiologics to complete the pre-clinical development of a novel conjugate cholera vaccine (CCV). With funding from the RIGHT Fund and self-funding by IVI, the collaboration involves the technology transfer of the lab scale manufacturing process developed.

## Delivery

In 2019, IVI completed the healthcare utilization survey (HCUS) for over 500 households in the surveillance catchment as well as data cleaning and WASH activities through the Mozambique Cholera Prevention and Surveillance (MOCA) project funded by the Korea International Cooperation Agency (KOICA). Surveillance and cost-of-illness studies are ongoing and will continue until September 2020.

The Cholera Surveillance in Malawi (CSIMA) Program, which launched in late 2015, is also being continued and additional funding was granted to continue disease surveillance for 8 more months and assess herd immunity in Chikwawa district. Malawi has been a role model for the introduction of OCV and following IVI's CSIMA project, the Ministry of Health forged ahead, developed a national cholera control plan and is vaccinating large parts of the country's populace in 2017/2018. Given the fact that IVI has surveillance ongoing at 40 health centers in two different districts, it provides a unique opportunity to investigate the success of the Malawian vaccination including herd immunity. The team received funding from the Wellcome Trust to continue activities until mid-2020 with a closure workshop.

### Partners and Collaborators

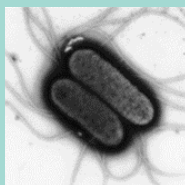
- Harvard-Mass General Hospital
- Vabiotech (Vietnam)
- Shantha Biotechnics (India)
- EuBiologics (Korea)
- Incepta (Bangladesh)
- Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL)
- WHO Global Task Force for Cholera Control (GTFCC)
- Epidemiology and Diseases Control Division (EDCD) of Ministry of Health and Population (MoHP) of Nepal
- Good Neighbors International (GNI)
- National Public Health Laboratory of MoHP of Nepal
- Seti Zonal Hospital, Tikapur Hospital, and Malakheta hospital
- Dept. of Health Services, Nepal
- Department of International Health, Bloomberg School of Public Health at Johns Hopkins University
- WHO and UNICEF country office, Nepal (WaSH programme)
- Instituto Nacional de Saude (INS: National Institute of Health) Mozambique
- Ministry of Health (MOH) Mozambique
- Hospitals and Health Centers in study areas
- Central and regional reference laboratories in target provinces
- Laboratories at selected healthcare facilities if available
- Other Mozambique government ministries and departments for multi-sectoral comprehensive national cholera control and prevention discussions
- WHO and UNICEF country offices in Mozambique for multi-sectoral stakeholder engagements

### Funders

- Bill & Melinda Gates Foundation
- Korea International Cooperation Agency (KOICA)
- Wellcome Trust
- RIGHT Fund

# Accelerating Vaccine #3 iNTS and Shigella

Following the successful development of the oral cholera vaccine and typhoid conjugate vaccine, both of which were developed in-house at IVI laboratories, IVI is investing in the preclinical development of two vaccine candidates: a non-typhoidal Salmonella (iNTS) vaccine and a Shigella vaccine.



## Vaccine #3 Salmonella - Trivalent, injectable NTS vaccine development

### About iNTS

An invasive bacterial disease that causes gastroenteritis, diarrhea, high fever, bacteremia, and focal infection linked with poverty, poor sanitation and lack of clean drinking water.

2.86 million cases 95,000 deaths per year



## Vaccine #3 - Universal Shigella vaccine development

### About Shigella

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. As shigella has the ability to acquire antimicrobial resistance, an effective vaccine is urgently needed.

In 2019, IVI met all key objectives envisaged in the Salmonella vaccine preclinical development plan and received a \$3.3 million grant from the Wellcome Trust to continue the vaccine's development through 2023. A proof of concept immunogenicity study in small animals is ongoing, which will be followed by the development of a scaling-up process, technology transfer to a manufacturer, and a toxicology study.

As a part of the Vaccine #3 effort, we have been trying to develop an oral and/or parenteral Shigella vaccine that will be broadly protective against the 4 species and 50 serotypes of Shigella. In 2019, the IVI lab is focused on recombinant PSSP-1 protein, which confers superior protective immunity across multiple serotypes and Shigella species compared viral vector vaccine candidates. Several versions of genetically modified PSSP-1 are going to be tested for recombinant protein purification and proof-of concept studies.

- IVI
- Wellcome Trust

Funders

- IVI

Funders



# MERS-Coronavirus Vaccine Program



## About MERS-CoV

A viral infection originating in bats and camels that can cause fever, pneumonia, and acute respiratory distress syndrome.

The Middle East Respiratory Syndrome-coronavirus (MERS-CoV) is the MERS-CoV outbreak of 2012 in the Arabian Peninsula led to a global transmission of the disease and highlighted the urgent need for a MERS-CoV vaccine.

## Vaccine development

IVI's MERS-CoV Program was launched in late 2015 with funding from Samsung Life Public Welfare Foundation in order to accelerate the development of two MERS vaccines through phase II trials in South Korea. IVI is partnering with GeneOne Life Science, a Korean biopharmaceutical company, on development of their DNA-based vaccine candidate. In 2019, dosing of the vaccine was completed, and interim samples analysis was initiated. To support the evaluation of MERS-CoV vaccines, IVI is developing ELISA and neutralization assays with funding from the Korean Ministry of Health and Welfare.

## CEPI MERS Project

In 2019, IVI contributed to global efforts to establish international standards for assessing MERS-CoV vaccine candidates. With funding from CEPI, IVI worked with Chungnam National University Hospital and Seoul National University to collect sera from MERS-CoV convalescent patients in Korea. High-titer sera with MERS-CoV-specific neutralizing Ab were collected and then transferred to the UK National Institute for Biological Standards and Control (NIBSC), which is preparing candidate material to establish a MERS-CoV reference standard. The sera collected by IVI and its Korean partners will be used to establish CEPI's interim reference standard as well as the WHO's international reference standard.

### Collaborators

- GeneOne Life Science

- Chungnam National University Hospital
- Seoul National University Hospital

### Collaborators

### Funders

- Samsung Life Public Welfare Foundation

- CEPI

### Funders

# Aedes-aegypti mosquito-transmitted diseases

IVI is the lead agency 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 brings together national regulatory authorities of dengue-endemic countries and vaccine developers to prepare for the next generation of dengue vaccines. IVI was previously the secretariat of GDAC, but in 2019 transferred its role to Duke-NUS Medical School in Singapore.



## Dengue

In 2019, work continued on a safety and effectiveness study in the Philippines on the only licensed dengue vaccine Dengvaxia®. Funded by Sida, the study investigates concerns about potential disease enhancement in dengue naïve vaccine recipients, as well as impact of Japanese encephalitis (JE) and Zika infections on test results.

To support clinical trials of a US NIH-developed dengue vaccine, IVI is developing the centralized vaccine database management system (cVDMS) for sharing data among clinical trial partners. In 2019, IVI continued revisions of cVDMS with vaccine manufacturers and clinical trial partners.

### Collaborators

- U.S. National Institute of Allergy and Infectious Diseases
- Johns Hopkins University
- Instituto Butantan
- Vabiotech
- Indian Immunologicals Ltd.
- Serum Institute of India
- Panacea Biotec Ltd.
- Medigen Vaccine Biotech
- Taiwan CDC

### Funders

- U.S. National Institute of Allergy and Infectious Diseases
- US National Institute of Health
- Swedish International Development Cooperation Agency

## Zika

Zika is a viral infection spread by the Aedes-aegypti mosquito causing mild, dengue-like symptoms. The real danger of Zika lies in disease transmission during pregnancy, which can cause microcephaly in unborn children. Global awareness of Zika rose during an epidemic in 2015-16 across South and Central America, but there is still no vaccine for this virus.

In 2018, the Korean government requested IVI's assistance with the development and evaluation of Zika vaccine candidates. With funding from the Korean Centers for Disease Control and Prevention (KCDC), IVI assessed the immunogenicity of two Zika vaccine platforms, which utilize chimpanzee adenovirus (ChAdOx) and vesicular stomatitis virus (VSV) vectors. Experiments with immunogenicity in mice and protective immunity against Zika virus infection concluded in 2019, with results showing that both Zika vaccine candidates induced protection in a murine challenge model.

In 2019, IVI completed a landscape analysis on Zika burden in Asia with support and final approval from Takeda. The final report described the findings from engagement of various stakeholders with ongoing studies or existing samples for further testing.

### Collaborators

- Takeda

### Funders

- Korea Centers for Disease Control and Prevention
- Takeda

# New initiatives

## Addressing critical gaps in antimicrobial use and resistance (AMR)



### About AMR

Antimicrobial resistance (AMR) is the ability of a microorganism (like bacteria, viruses, and some parasites) to stop an antimicrobial (such as antibiotics) from working against it. As a result, standard treatments become ineffective, infections persist and may spread to others

One of the biggest threats to global health, food security, and development today  
Misuse of antibiotics in humans and animals is accelerating the spread of resistance  
Leads to longer hospital stays, higher medical costs and increased mortality

Vaccines have an important role to play in combatting AMR  
Proper surveillance systems and evidence to prioritize the effort is crucial  
Projects to actively measure the impact on vaccines on AMR in the pipeline

In 2019, the World Health Organization named the spread of antimicrobial resistance (AMR) one of the ten most important global health concerns of the year. IVI has AMR studies embedded in its cholera and typhoid surveillance

programs and is now part of three active Fleming Fund Regional Grants to enhance AMR surveillance and close gaps in confronting the growing challenges of AMR in low- and middle-income countries.



### CAPTURA, Regional Round 1 grant

Collection of historical AMR data Retrospective data mapping(collected and analysed), stakeholder engagement, capacity building



### RADAAR, Regional Round 2 grant

Planning, policy & advocacy Regional bodies are supported for data sharing and policy-relevant analysis



### EQASIA, Regional Round 2 grant

Improving the Quality of Bacteriology Diagnostics for AMR Strengthen External Quality Assurance for AMR Consortium with DTU Food(WHO Collaborating Centre for AMR and FAO and EU Reference Lab for AMR)

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



Many academic, research, and medical institutions in low- and middle-income countries have been

collecting AMR data for years but haven't publicly shared their findings. The IVI-led CAPTURA consortium was awarded two Fleming Fund Regional Grants to work with 12 countries in South and South East Asia to expand the volume of available historical and current data on AMR and antimicrobial use (AMU).

The project began in January 2019 and has been engaging with AMR-coordinating committees within ministries of health to map out current facilities and institutions that hold AMR and AMU data. By partnering alongside these institutions to assess the quality of existing data and digitize them, the project aims to establish an AMR and AMU regional baseline across Fleming Fund priority countries.

IVI leads the CAPTURA consortium, which includes Brigham and Women's Hospital (WHONET), the Public Health Surveillance Group, and Oxford University's Big Data Institute, managing the grant and coordinating in-country work such as stakeholder meetings and in-country and regional trainings and workshops. IVI further supports at-site data collection, including in-country quality monitoring and compilation of datasets, grading and analysis.

Vaccines have  
an important role to  
play in combatting  
AMR



CAPTURA kick-off meeting at the International Vaccine Institute, Seoul, South Korea. / Credit IVI





CAPTURA team in Port Moresby, Papua New Guinea meeting with local stakeholders and representatives from the National Department of Health and the WHO country office. / Credit IVI

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

IVI is also leading the same consortium engaged in CAPTURA 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.

### **EQASIA (Strengthening External Quality Assurance for AMR in Asia)**

In 2020, IVI will partner with the Technical University of Denmark (lead grantee) to strengthen external quality assurance (EQA) in the Asia region, which is vulnerable to the emergence and spread of AMR though holds little high-quality data on the extent of its impact. Through EQASIA, the two institutes will map the coverage, availability and uptake of EQA programs across reference laboratories.

Funding for CAPTURA, RADAAR, and EQASIA are provided by the Fleming Fund, a UK Aid initiative to respond to the global threat of AMR in low- and middle-income countries.

Funders

# Confronting schistosomiasis in Madagascar and Burkina Faso

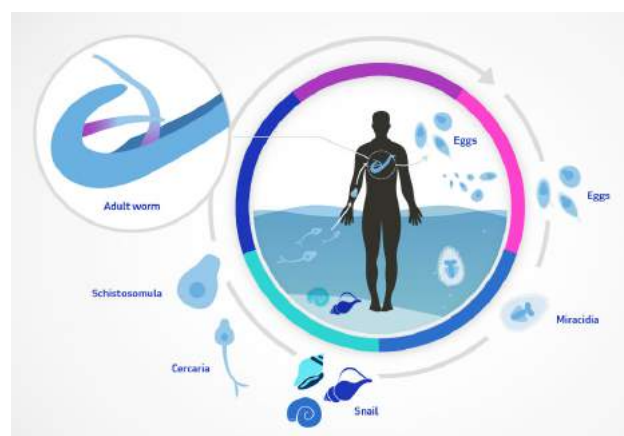


## About schistosomiasis

Schistosomiasis is a neglected tropical disease (NTD) caused by a parasitic infection of schistosome 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.

## Schistosomiasis in Madagascar (SOMA)

IVI launched SOMA, a program aiming to reduce the burden of schistosomiasis infection in at-risk populations in Madagascar, in 2019. SOMA approaches schistosomiasis prevention and control in two ways: 1) mass drug administration campaigns of praziquantel (PZQ) in high-risk populations 2) Water, Sanitation and Hygiene (WASH) education and training programs while constructing new water and sanitation infrastructure.



Credit IVI/Grace Jun

### Collaborators

- Malagasy officials

### Funders

- Yanghyun Foundation of Korea

## Vaccine Against Schistosomiasis for Africa (VASA)

In 2019, IVI and the University of Cambridge formed a consortium to assess the safety and immunogenicity of the SchistoShield® vaccine developed by PAI Life Sciences Inc. VASA will carry out a Phase I clinical study in healthy adults in Burkina Faso and Madagascar, while also developing a human challenge model for the vaccine with the University of Leiden.

### Funders

- EU Horizons 2020

### Collaborators

- University of Leiden
- 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



New toilet & shower facility at a community center in Ambositra, Madagascar. / Credit IVI

# Rallying a global consortium for a Strep A vaccine



## About Strep A

Strep A is one of the deadliest infectious diseases—ranking with TB, HIV, and malaria, but there has been very little investment in Strep A research. Strep A usually begins with a sore throat, but left untreated, may cause heart failure and death. This affects more than 33 million people around the world and claims 500,000 lives every year, with the vast majority of deaths in low- and middle-income countries. A vaccine would be the most effective way to control infection.

In 2019, IVI and the Murdoch Children's Research Institute joined forces to form the Strep A Global Vaccine Consortium (SAVAC), which includes members from the Harvard School of Public Health, Telethon Kids, Imperial College, PATH, University of Cape Town, University of Colorado, Indian Council of Medical Research, and the World Health Organization.



SAVAC aims to put the WHO's 2018 GAS Vaccine Development Technology

Roadmap into action, calling for the development of a GAS vaccine to protect against rheumatic fever and rheumatic heart disease. SAVAC will be the focal point for leadership, advocacy, and organization around GAS vaccine development, and will mobilize and coordinate funding while developing a Full Public Value of Vaccine investment case.

## 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 International
- WHO

## Funders

- Wellcome Trust



# Adenovirus 55 Vaccine Program



## About Adenovirus 55 (AD55)

Adenovirus 55 (AD55) is a viral respiratory-tract infection that causes pneumonia. AD55 infections have a high prevalence in environments where people live in confined, close quarters such as refugee centers and military training facilities. While vaccines for other serotypes of adenovirus have been developed in the past, there are no adenovirus vaccines currently available on the market.



Credit IVI

In 2019, IVI began preclinical development of an Ad55 vaccine in collaboration with the Korea Centers for Disease Control and Prevention (KCDC) and the Republic of Korea Armed Forces Research Institute of Medical Sciences. In 2019, AFMRI provided IVI with Ad55 viruses from infected patients and the viruses were characterized. The Ad55 isolates will be assessed in terms of immunogenicity and prepared as vaccine candidates.

- Republic of Korea Armed Forces Medical Research Institute

Collaborators

- Korea Centers for Disease Control and Prevention

Funders

# SFTS Vaccine Program



## About Severe Fever and Thrombocytopenia Syndrome (SFTS)

Severe Fever Thrombocytopenia Syndrome (SFTS) is an emerging viral infection endemic to Northeast Asia that has the potential to spread with the changing climate. SFTS is transmitted by the *Haemaphysalis longicornis* tick and causes fever, vomiting, diarrhea, multiple organ failure, thrombocytopenia, and leukocytopenia, and has a fatality rate of 30%.

- Catholic University
- Jeju National University
- Seoul National University in Korea

Collaborators

- Samkwang Medical Laboratory

Funders

Working with the Catholic University, Jeju National University, and Seoul National University in Korea, IVI began the early preclinical development of an SFTS vaccine in 2019, preparing several vaccine candidates for future comparative study.



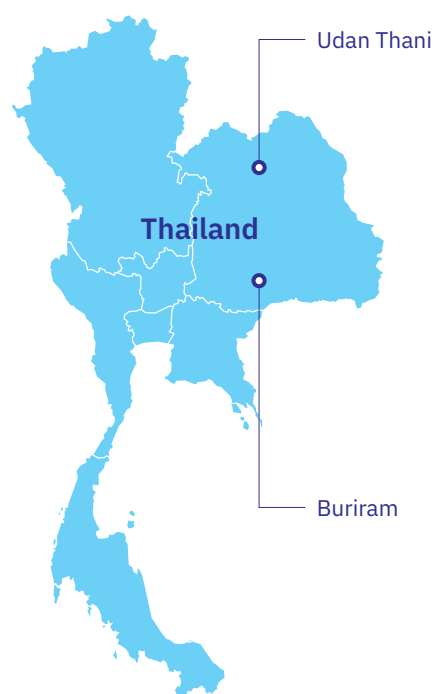
# Protecting more women against cervical cancer with a single-dose HPV vaccine



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 Human Papilloma Virus (HPV) vaccine in 8th grade girls in Thailand. Given the high cost of available vaccines and low uptake, particularly in low- and middle-income countries, a single dose could allow countries to substantially expand coverage.

In the study, over 8,000 grade 8 girls in the provinces of Udan Thani and Buriram, Thailand received either one dose of Cervarix® HPV vaccine or the recommended two doses between December 2018 and March 2019. In addition, a baseline survey of HPV prevalence in single urine samples was conducted among grade 10 and 12 students in the same provinces enrolling 9,000 students.

The initial results indicate higher than expected HPV prevalence in this age group. Preparation is currently underway for the first impact survey, which will launch in November 2020 to evaluate reduction in HPV prevalence associated with vaccination. A health economic study will also launch in 2020 and ultimately evaluate the cost-effectiveness of this approach and inform both Thailand's national program and global public health policy regarding HPV vaccination.



## Funders

- Bill & Melinda Gates Foundation

## Collaborators

- Thailand Ministry of Public Health- Department of Disease Control
- National Vaccine Institute of Thailand
- Center of Excellence in Clinical Virology- Chulalongkorn University
- US Centers for Disease control

# Hepatitis vaccine programs



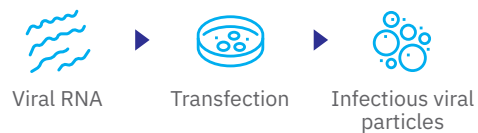
## Hepatitis A Vaccine

### About Hepatitis A

Hepatitis A has a high prevalence in the developing world, with over 1.5 million cases reported annually by the WHO. While three vaccines against Hepatitis A exist, their high price (\$23/dose via Gavi, \$100/dose private market) prevents wider use of the vaccine and places a significant burden on healthcare systems providing the vaccine.

IVI is assisting the Gyeongbuk Institute for Bio Industry (GIB) with the development of a domestically produced low-cost hepatitis A vaccine. As of 2019, work continues on the generation of hepatitis A virus vaccine strain and assessment of its immunogenicity.

### Reverse genetics to produce HAV vaccine strain



• Gyeongbuk Institute for Bio Industry

Collaborators

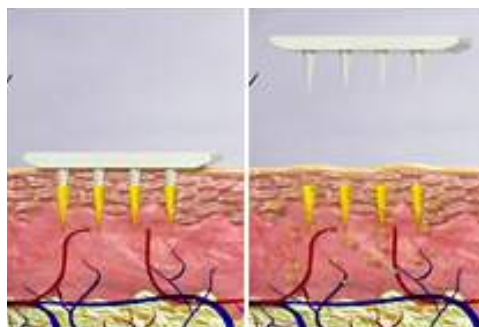
• Andong City, Korea

Funders

## Hepatitis B Vaccine Microneedle Delivery System

IVI's Clinical Research Laboratory is working with the Korean Ministry of Trade, Industry, and Energy (MOTIE), the University of Gachon, and QuadMedicine to develop and evaluate a microneedle delivery system for a Hepatitis B vaccine with adjuvant.

As a method of vaccine delivery, microneedle patches enjoy distinct advantages over traditional syringes, including easy and pain-free administration, thermal stability, light weight and small size, low-cost fabrication, and reduced environmental impact from disposal.



• University of Gachon  
• QuadMedicine

Collaborators

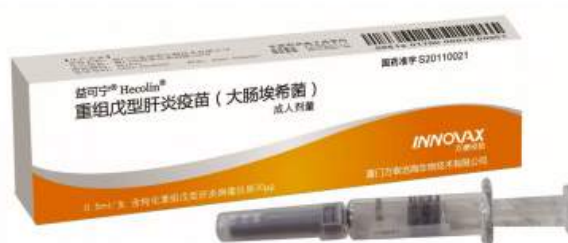
• Korean Ministry of Trade, Industry, and Energy (MOTIE)

Funders

## Hepatitis E Vaccine

### About Hepatitis E virus (HEV)

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 among pregnant women, with mortality rates of 25-40% commonly reported in outbreak settings. The disease places a high burden on displaced populations and refugees and is increasingly recognized as a cause of chronic or fulminant hepatitis in Europe and North America, primarily in individuals with compromised immune systems.



There is no hepatitis E vaccine prequalified by the WHO, but Innovax Biotech's highly effective hepatitis E vaccine Hecolin® is licensed for domestic use in China. In 2019, IVI submitted a research proposal to the Thrasher Research Fund for further study of the Hecolin® vaccine. The project seeks to generate safety and immunogenicity data on the vaccine among pregnant women and their infants in an endemic setting. The study would help inform policies on potential use in endemic settings, and support a stronger SAGE recommendation for use in emergency settings. IVI will seek out additional funders to execute the trial and will remain engaged in advocacy to help bring Hecolin® to WHO prequalification and inform policy on its use in the most needed settings.

### Collaborators

- Johns Hopkins Bloomberg School of Public Health- USA,
- Syracuse University- USA,
- Tribhuvan University- Nepal,
- Kathmandu Model Hospital - Nepal
- Paropakar Maternity & Women's Hospital - Nepal

### Funders

- Thrasher Research Fund (partial)

# Tuberculosis (TB) vaccine programs

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. The currently available TB vaccine, Bacillus Calmette–Guérin (BCG), is used in most countries that have endemic TB, but the efficacy of this vaccine 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.



## U.S.-based Project

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.

- Boston Children's Hospital,
- Harvard School of Public Health
- Tulane University

Collaborators

- U.S. National Institutes of Health

Funders

## Korea-based Project

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 on the optimization and preclinical development of TB polysaccharide-protein conjugate vaccine using TB protein antigens selected by KCDC.

- Division of Vaccine Research at KCDC
- Yonsei University

Collaborators

- Government of Korea

Funders



# Japanese Encephalitis (JE) vaccine program

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



## About Japanese encephalitis (JE)

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 sequelae.

In Bali, Indonesia we are examining the 5-year 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 receive the Chengdu SA14-14-2 JE vaccine (CD-JEV). Through 2022, IVI will evaluate the protective effectiveness of CD-JEV against Japanese Encephalitis through a case-control study embedded within surveillance for acute encephalitis syndrome in all 24 hospitals and health centers in Bali.

This study is important because effectiveness data on the newly manufactured JE vaccine 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.

- WHO Indonesia
- Bali Provincial Health Office
- PATH
- CDC

## Collaborators

- WHO
- PATH

## Funders

# Quality Management

Since the inception of an independent Quality Management (QM) department at IVI in Quarter 1 2018, ongoing efforts have realized significant impacts to IVI quality infrastructure development and systems implementation from a GxP perspective (such as, 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 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 through the conduct of routine quality training and both internal and external audit activities. During 2019, IVI quality management continued to conduct audits of select investigator sites and ensured vendors supporting GxP driven activities were qualified prior to use. In addition, IVI QM performed two (02) mock inspections at the IVI facility to prepare the institute for eventual regulatory and/or stakeholder audits.

In an effort to modernize IVI's infrastructure, the QM department has secured validated electronic systems in 2019 to support document control, laboratory environmental monitoring and Laboratory Information Management System (LIMS) implementation. Three (03) validated cloud-based systems were deployed in support of document control (institute wide), laboratory information system and a laboratory environmental

monitoring system. Additional electronic systems are also being evaluated for implementation in 2020, which will include learning management systems and various clinical research functions (e.g., electronic trial master file and clinical trial management systems).

On the laboratory front, 2019 realized the development of a dedicated biorepository and a Good Clinical Laboratory Practice (GCLP) laboratory became operational, and in October 2019, The Korean Ministry of Food and Drug Safety granted IVI a GCLP certification, marking IVI's significant investment in quality management over the past two years, which includes securing related facilities and systems and training personnel. The certification confirms that the IVI GCLP laboratory is aligned with globally recognized standards, as well as regulatory requirements in South Korea.

Over the course of 2020 and beyond, IVI QM 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

## Promoting vaccine sustainability in low- and middle-income countries

### IVI's International Vaccinology Course

To bolster our vaccine development and delivery programs, we engage in capacity-building within the vaccine industry as well as with governments and universities. Through training, technology transfer, technical assistance, and educational partnerships, IVI provides support to the global vaccine community with particular focus on low- and middle-income countries.

1,544

People have been trained in IVI's International Vaccinology Course

175

Trainees attended the 19th Course

49

Nationalities were represented in the 19th Course



Graduate Students from Yonsei University's Global Health Security program taking part in the 19th International Vaccinology Course. / Credit IVI



# Maternal Immunization IVI Vaccinology Course 2019

Flor M. Munoz, MD  
Associate Professor of Pediatrics and Infectious Diseases  
Baylor College of Medicine  
Texas Children's Hospital  
Houston, Texas

Baylor  
College of  
Medicine



  
Texas Children's Hospital



Dr. Flor Munoz, Associate Professor of Pediatrics and Infectious Diseases at Texas Children's Hospital and Baylor College of Medicine, giving a Topical Lecture of the Day on how to achieve the WHO Sustainable Development Goal of reducing the global maternal mortality ratio. / Credit IVI



Established in 2000, IVI's Vaccinology Course is one of the longest running vaccinology courses in the Asia-Pacific region and has trained more than 1,544 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. IVI grants fellowships to people from LMICs otherwise unable to attend the course. A select number of fellowships are competitively awarded to individuals with financial need, leadership potential, and who have made contributions to public health in their country.

In addition to 134 trainees from 49 countries, the five-day course brought together 41 experts from academia, government, industry, and non-governmental organizations, including Stanford University, Seoul National University, Yonsei University, CEPI, Murdoch Children's Research Institute, the Bill & Melinda Gates Foundation, Merck, and GSK thereby delivering a comprehensive overview of vaccinology with a focus on practicality. Beginning with a refresher in epidemiology and immunology, the course covers the vaccine development spectrum from applied topics in discovery, development, and delivery. The 2019 program was supported by Sky 72 Golf Club, Seoul Metropolitan City, and Community Chest of Korea-Incheon.

### Enhancing Internal Capacity

IVI's Science Unit, supported by Chongkeundang Kochon foundation, held monthly vaccine seminars, in which 10 speakers from South Korea and overseas discussed a vaccine development study of virus and bacteria, an epidemiological study, and a novel vaccine adjuvant.



IVI Vaccine Seminar: Dr. Andrew Lees (Fina Biosolutions LLC), 9th July 2019

**Established  
in 2000, IVI's  
Vaccinology Course is  
one of the longest  
running vaccinology  
courses in the Asia-  
Pacific region.**

### Collaboration between IVI and the University of Cambridge

IVI and the University of Cambridge's Department of Medicine are collaborating on three projects related to typhoid surveillance in Ghana and the DRC, development of a vaccine against schistosomiasis, and accelerating a vaccine for invasive non-typhoidal Salmonella (iNTS). IVI brings to the partnership expertise in conducting clinical trials and epidemiological field research while the University of Cambridge offers high-end laboratory techniques and expertise through the newly established Global Health Center/Biomedical Center. In collaboration with the University of Antananarivo, the team broke ground on a new clinical trial center in Madagascar dedicated to joint projects and to build local capacity.

### The RIGHT Fund

As one of the key founders and supporters, IVI complements the progress of The Research Investment for Global Health Technologies (RIGHT) Fund, a public-private partnership between the Korean government, the Bill & Melinda Gates Foundation, and Korean biopharmaceutical companies. The RIGHT Fund selected 4 projects for support in 2019 – two for vaccines, one for diagnostics, and one for therapeutics. IVI joined the force by building partnerships with Eubiologics and MGH-Harvard for development of a cholera conjugate vaccine with its own funding.

## Vaccine Safety

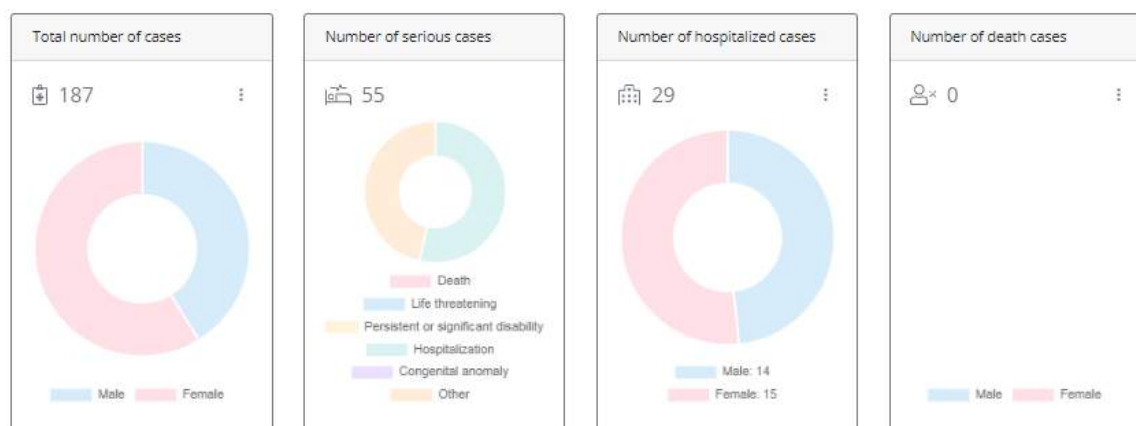
### VAEIMS

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, as well as a global database. This will ultimately guide decision-making at different levels of a country. 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.

### 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 manufacturers through the centralized Dengue Vaccine Data Management System (cDVMS) project. The US National Institute of Health 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.



A screen grab of the VAEIMS app

## Publications

**In 2019, IVI scientists authored or co-authored 55 articles in peer-reviewed scientific journals with 51 articles in the Scientific Citation Index.**

**55**

The number of articles published in peer-reviewed scientific journals

**51**

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

“Typhoid conjugate vaccines: a new tool in the fight against antimicrobial resistance” Andrews JR, Baker S, Marks F, Alsan M, Garrett D, Gellin BG, Saha SK, Qamar FN, Yousafzai MT, Bogoch II, Antillon M, Pitzer VE, Kim JH, John J, Gauld J, Mogasale V, Ryan ET, Luby SP, Lo NC, The Lancet Infectious Diseases, vol. 19, no. 1, pp. e26-e30.

“Deliberations of the Strategic Advisory Group of Experts on Immunization on the use of CYD-TDV dengue vaccine” Wilder-Smith A, Hombach J, Ferguson N, Selgelid M, O'Brien K, Vannice K, Barrett A, Ferdinand E, Flasche S, Guzman M, Novaes HM, Ng LC, Smith PG, Tharmaphornpilas P, Yoon IK, Cravioto A, Farrar J, Nolan TM, The Lancet Infectious Diseases, vol. 19, no. 1, pp. e31-e38.

“First clinical trial of a MERS coronavirus DNA vaccine” Yoon IK, Kim JH, The Lancet Infectious Diseases, vol. 19, no. 9, pp. 924-5.

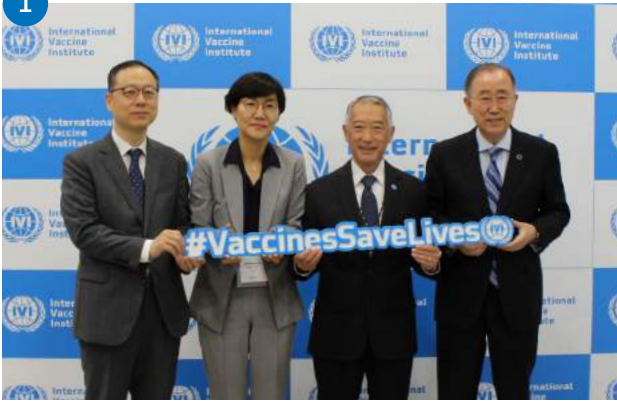
“Parting the Clouds over Typhoid with a New Conjugate Vaccine” Marks F, Kim JH, The New England Journal of Medicine, vol. 381, no. 23, pp. 2262-4.





# Partnerships

1



8th UN Secretary General Ban Ki-moon at the IVI State Forum 2019

“There are still neglected diseases [for which] there is no investment. This is what I call an injustice. Many people still die from vaccine-preventable diseases unnecessarily. It pains me...The dynamic work of the IVI has amplified the essential role of vaccines in achieving the UN’s global goals such as ending extreme poverty, confronting health implications related to climate change, and promoting peace and living with dignity for all people, particularly the world’s most vulnerable group of people....I really thank you all for your support. Moral support, political support, but the most important support would be financial...We really count on your continuing support.”

Ban Ki-moon, 8th UN Secretary General

“IVI, which the Korean government has been supporting, has made achievements in vaccine research collaboration, clinical trials overseas, human resource development, and establishment of a global R&D partnership. Going forward, we hope that IVI continues endeavors to play a key role in global vaccine research, thereby carrying out its mandate as an international organization dedicated to developing vaccines for developing countries and humanity.”

2



Dr. Jeong Eun-kyeong, Director of Korea Center for Disease Control and Prevention, at the ‘IVI Forum for Enhancement of Cooperation’co-hosted by the Korean Parliamentary Forum for Global Health and the KCDC

3



“IVI’s contribution to global health is invaluable considering both the technical support provided to low- and middle-income countries and the focus on diseases disproportionately affecting people living in poverty.”

Dr. Teresa Soop, Senior research advisor at Sida, on IVI and Sida’s renewed partnership



4



H.E. Sripriya Ranganathan, Ambassador of India to the Republic of Korea at the IVI Forum at the Korean National Assembly

“The history of collaboration between IVI and India in research, training, vaccine development, and capacity building is demonstrative of the enduring value of cooperation between IVI, public institutions, and private industry.”

5



“We’re delighted to build this long-term partnership with IVI to reduce the burden of NTS by accelerating the development and implementation of new affordable technologies and interventions.”

Dame Sally Nicholas, Partner, the Wellcome Trust, on IVI’s receipt of a Wellcome Award for accelerating an iNTS vaccine

“As someone who has personally witnessed Korea’s transformation from a foreign aid recipient into a donor country, it’s an honor to be able to personally support IVI’s humanitarian mission for people in developing countries –especially the children. As a biomedical scientist, I understand the value and life-saving potential of vaccines for infectious diseases. I am confident that my donation will enable IVI to accelerate its humanitarian endeavors to discover, develop and deliver safe, effective, and affordable vaccines for global health.”

6



Dr. Richard Hatchett, CEO of The Coalition for Epidemic Preparedness Innovations on signing bilateral ‘Master Implementing Partner Services Agreement.’

“We are delighted to be working with IVI. Our partnership will build on IVI’s existing capabilities in advancing new vaccines for global health, and will complement CEPI’s vaccine portfolio worldwide with an aim to accelerate innovation and increase efficiency in the development of vaccines against emerging pathogens.”

7



Professor Young-Chul Sung of Pohang University of Science and Technology and the Korea Support Committee (KSC) for IVI who donated the largest private donation to IVI through KSC since our founding

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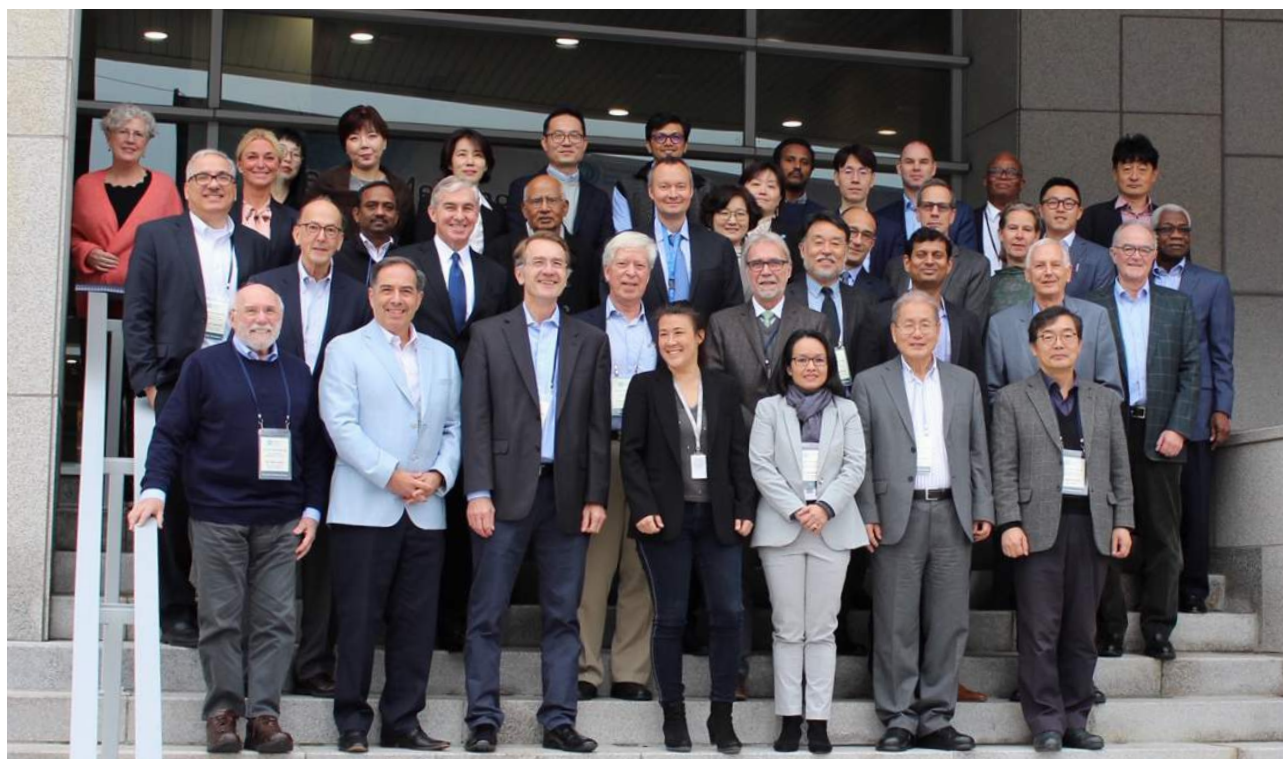
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We thank our donors and partners whose support makes our work possible

Thank you to the governments of the Republic of Korea, Sweden, and India, 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 2019\*



\*Listed in order of level of contribution

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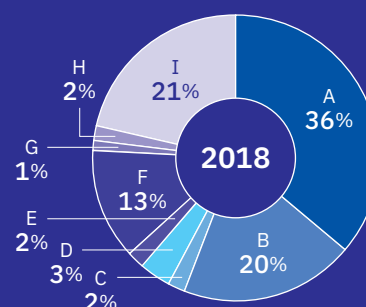
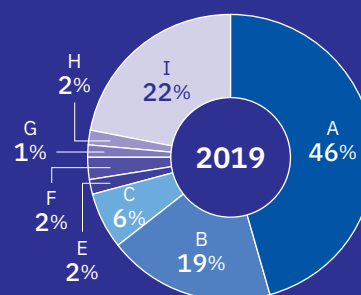
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# 2019 financial summary

## Cash Summary 2019 and 2018

(USD '000)

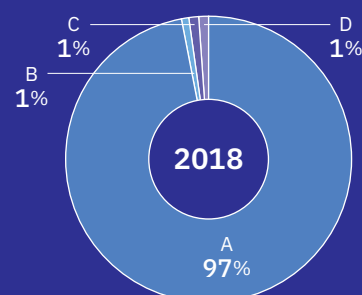
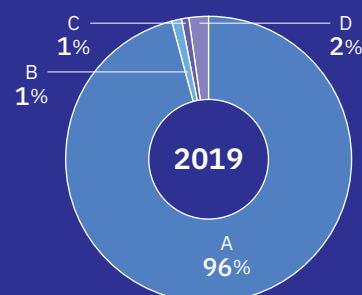
Cash Contribution (in USD)	2019	2018
A. Bill & Melinda Gates Foundation (BMGF)	13,087	10,555
B. Government of the Republic of Korea	5,336	5,733
C. Swedish International Development Cooperation Agency (Sida)	1,831	573
D. Government of India	-	1,000
E. Korea Centers for Disease Control & Prevention	707	606
F. Samsung Life Public Welfare Foundation	529	3,654
G. Korea Support Committee for IVI (KSC)	352	272
H. Interest Income	464	500
I. Corporation & Individuals	6,261	6,180
<b>Total Cash Contribution of the year</b>	<b>28,567</b>	<b>29,072</b>



## Financial Summary 2019 and 2018

(USD '000)

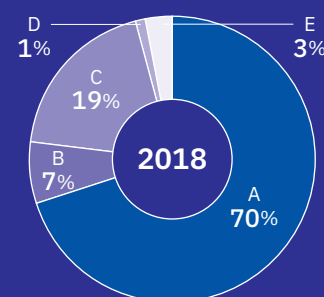
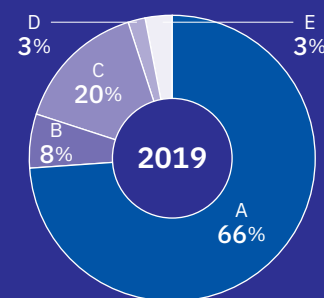
Revenues (in USD)	2019	2018
A. Contribution	30,795	28,180
B. Other Income	379	344
C. Interest Income	370	342
D. Foreign Exchange Gain	718	331
<b>Total Revenue</b>	<b>32,262</b>	<b>29,198</b>





Total Expense (in USD)	2019	2018
A. Program Service	19,024	20,916
B. Laboratory Support	2,263	2,141
C. Management & General	5,754	5,553
D. Communications & Advocacy	706	426
E. Foreign Exchange Loss	944	755
<b>Total Expense</b>	<b>28,692</b>	<b>29,789</b>

<b>Change in Net Assets</b>	<b>3,570</b>	<b>(592)</b>
-----------------------------	--------------	--------------



Assets	2019	2018
Cash and Bank Deposit	19,480	18,507
Current Receivable	5,606	7,009
Other Current Assets	467	305
Non-Current Assets	20,835	16,396
<b>Total Assets</b>	<b>46,389</b>	<b>42,217</b>

Liabilities and Net Assets	2019	2018
Account Payable	1,537	907
Other Current Liabilities	602	626
Non-Current Liabilities	186	190
Net Assets	44,064	40,494
<b>Total Liabilities and Net Assets</b>	<b>46,389</b>	<b>42,217</b>

1. Cash summary table presents donation received for the years, 2019 and 2018

2. Financial Statements are presented with US GAAP from 2019 and statement for 2018 restated accordingly.

# IVI's Global Reach




2019 Annual Report








## IVI PROGRAMS






- C** Cholera
- T** Typhoid
- A** AMR
- D** Dengue
- O** Other

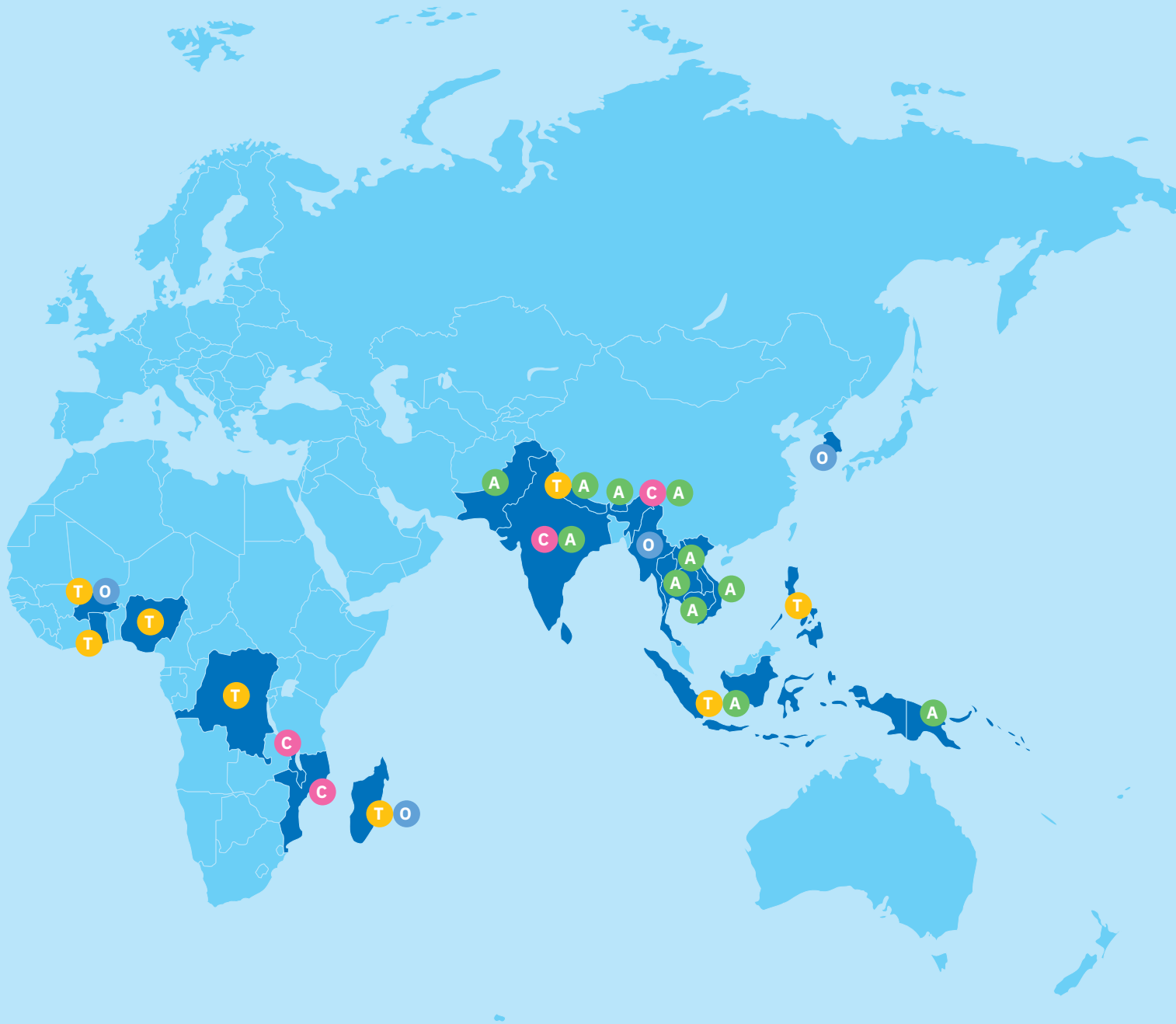
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-  Brazil

-  China
-  Ecuador
-  Egypt

-  India
-  Indonesia
-  Israel
-  Jamaica
-  Kazakhstan

-  Kyrgyzstan
-  Lebanon
-  Liberia
-  Malta
-  Mongolia



Myanmar

Nepal

Netherlands

Oman

Pakistan



Panama

Papua New Guinea

Peru

Philippines

Republic of Korea



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