

2016 Annual Report

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International Vaccine <u>Ins</u>titute



International Vaccine Institute

#### **Our Mission**

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

# impact

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# Signatories to IVI's **Establishment Agreement**







Indonesia

Liberia

Oman

Thailand



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Israel

Malta

Pakistan

Turkey

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Jamaica

Mongolia

Panama



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Myanmar

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Sri Lanka































Bangladesh









Lebanon











Tajikistan













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Uzbekistan

Vietnam



# IVI's Global Outreach



# **Director General's** Letter

Dear Friends,

The first international organizational exclusively dedicated to making vaccines available for developing countries was established in Seoul, South Korea in October 1997. Twenty years later, IVI continues to hold true to its original mandate.

We brought to market the first affordable oral cholera vaccine and We are among…the few PDPs to successfully develop a vaccine from the bench to licensure and WHO prequalification.

As IVI's third Director General, I'm proud of our past achievements. We brought to market the first affordable oral cholera vaccine and changed the supply-demand dynamics for the vaccine. We also established the product development partnership (PDP) model in Asia and made partnerships with several Asian manufacturers to develop vaccines of public health importance to the region and the world. We are among the few PDPs to successfully develop a vaccine from the bench to licensure and WHO prequalification.

In 2017, we celebrate IVI's twentieth anniversary and reflect on our contributions to global health. I will ensure that we continue to fulfill our mission in the next phase of IVI's evolution. The seeds were set in 2016 when we re-assessed our



"We brought to market the first affordable oral cholera vaccine and we are among the few product development partnerships to successfully develop a vaccine from the bench to licensure and WHO prequalification."

> strategy and capabilities in order to strengthen IVI's sustainability. We increased our scientific leadership capacity through new hires such as a Deputy Director General of Development & Delivery and Program Director of Delivery. Three new members were added to our Board that include a former ambassador from Korea, chief medical officer from the Finnish National Institute for Health and Welfare, and director general from the Korean Centers for Disease Control and Prevention. After a two-year hiatus, our Scientific Advisory Group was re-launched in October 2016.

> We strengthened relations with our stakeholders, Korea and India. IVI began a relationship with the Korean Ministry of Health & Welfare (MOHW), signifying a new turn in the institute's relations with our host country. Formerly under the oversight of Ministry of Education, IVI was transferred to MOHW in 2016 and this transfer is expected to increase cooperation between IVI and Korea on vaccine research and public health initiatives. India recently agreed to become a financially contributing member state and it will be the third member state to provide annual funding to IVI in addition to Korea and Sweden.

> As you will see in the report, we made considerable progress in our cholera, typhoid, dengue and MERS-CoV programs in 2016. New vaccine development projects are in the pipeline such as inactivated rotavirus, human papillomavirus (HPV), hepatitis E, EV71 (hand, foot and mouth disease), and group A Streptococcus vaccines.

In closing, we are excited about IVI's next 20 years and our future direction. None of this would be possible without our friends and supporters. In particularly, I would like to thank the Bill & Melinda Gates Foundation and the governments of Sweden and Republic of Korea for their commitment to IVI. I also would like to thank the Korea Support Committee for IVI (KSC) and our many partners and collaborators.

for 74. Kin

Jerome H. Kim, MD



# Vaccine Development & Delivery

We develop vaccines against infectious diseases that are of global health concern (e.g., MERS, Zika) and that affect developing countries (e.g., cholera, typhoid, dengue). Vaccine development and commercialization can be costly, lengthy and fraught with risk, and there are few incentives for companies to pursue development of a vaccine against a neglected disease and/or with a limited market.

IVI bridges the gap by partnering with vaccine manufacturers, governments and philanthropies, and mobilizing resources and funding to develop and license vaccines for the publicsector market. We also drive innovation by transferring technology we develop in-house to companies, and partner with them on 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. As we do not make a profit from intellectual property, we partner with multiple companies on tech transfer, which helps ensure sufficient vaccine supply for the public-sector market.

We brought to market a low-cost oral cholera vaccine that is WHO-prequalified and stockpiled by WHO for emergency use. More than 4 million doses of the vaccine has been deployed to prevent and control cholera in 13 countries. IVI is currently developing vaccines against typhoid and MERS.



# 4,000,000

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

13

the number of countries the vaccine has been deployed in Making vaccines available and accessible for the world because everyone has the right to good health



UTTINIA (STATE)

# Cholera

We accelerate the development and delivery of oral cholera vaccines against epidemic and endemic cholera.





#### **Euvichol**®

IVI developed the world's first affordable oral cholera vaccine for developing countries. Development

Our cholera story dates back to 2006 when IVI reformulated an oral cholera vaccine (OCV). The technology was transferred to manufacturers and IVI partnered with some of them on development and commercialization. Since then, two oral cholera vaccines, Shanchol<sup>™</sup> and Euvichol<sup>®</sup> are WHOprequalified and available for purchase.

We continue to work on the oral cholera vaccine. A thimerosal-free version of Euvichol® was WHO-prequalified in September 2016. In addition to removing thimerosal from the vaccine, production capacity was scaled up to 25 million doses per year through a new 600-liter fermenter. Even though Euvichol® was prequalified in 2015, these modifications required a second approval by the WHO Prequalification Program.

We also work on optimizing vaccine use. The oral cholera vaccine is administered in two doses over a 14-day interval however a single-dose regimen would be advantageous for outbreaks, refugee camps and other emergency situations. IVI is partnering with icddr,b on a single-dose study in Bangladesh. Subjects were followed up six months after vaccination, showing the single dose is mildly protective for all cholera cases while more protective for severe cholera. Follow-ups will continue to be made at 12 months, 18 months and 24 months.

Product	Status
Shanchol™ Shantha Biotechnics; part of the Sanofi group, India	<ul> <li>Licensed in India in 2009.</li> <li>WHO-prequalified in 2011.</li> <li>Used in vaccination campaigns against endemic and epidemic cholera in Ethiopia, Nepal and Malawi that IVI helped coordinate in 2015.</li> </ul>
Euvichol <sup>®</sup> EuBiologics, South Korea	<ul> <li>Licensed in South Korea in January 2015.</li> <li>WHO-prequalified in December 2015.</li> <li>thimerosol-free version prequalified in September 2016.</li> <li>Additional manufacturer will help double global supply to 6 million doses for 2016.</li> </ul>
Cholvax <sup>®</sup> Incepta Vaccine, Bangladesh	<ul> <li>Under clinical development; clinical trials initiated in 2016.</li> <li>To be licensed in Bangladesh only.</li> <li>country has very high burden of cholera.</li> </ul>

Delivery



#### ©Lorenzo Pezzoli / WHO. 2015

An emergency vaccination campaign was implemented in 2015 in response to cholera outbreaks following flooding in Nsanje district, Malawi. IVI is conducting surveillance to measure vaccine effectiveness. We support delivery efforts of the oral cholera vaccine. In 2016, one million doses of Euvichol was provided by EuBiologics to Haiti as part of public health efforts to control the outbreak in the country. IVI, with Rotary International and Nepalese health authorities conducted a cholera vaccination campaign in Banke, Nepal with Euvichol, vaccinating about 27,000 people.

We also conduct the Cholera Surveillance in Malawi (CSIMA) project, funded by the Bill & Melinda Gates Foundation (BMGF). CSIMA aims to establish a cholera surveillance platform in two districts of Malawi to assess effectiveness of the oral cholera vaccine 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.

Social mobilization campaign in Banke, Nepal



# Typhoid

The Typhoid Program aims to accelerate the development and introduction of newgeneration typhoid vaccines in two ways.

- development of new typhoid conjugate vaccines in collaboration with manufacturers
- generation of evidence on the burden of typhoid in Africa





#### © Justin Im/ IVI

Infants are at high risk for typhoid; current vaccines don't protect them against this disease, which is why IVI is developing a new typhoid vaccine that can. Development

We developed a typhoid conjugate vaccine using technology from U.S. National Institutes of Health, conjugating the Salmonella Typhi Vi polysaccharide to diphtheria toxoid (Vi-DT). The new vaccine has the advantage of conferring protection in infants (a high-risk group) against typhoid. IVI transferred the technology to SK Chemicals of South Korea and Biofarma of Indonesia and is working with them on preclinical and clinical development for vaccine licensure and WHO-prequalification. More recently, IVI started a partnership with Incepta Vaccine of Bangladesh to develop the Vi-DT vaccine. Other typhoid conjugate vaccines are on the market and IVI will work with the manufacturers on getting their vaccines WHO-prequalified to ensure the vaccine is globally available and accessible.

In 2016, work continued on Vi-DT vaccine development. In particular, the phase I trial for SK Chemicals' vaccine candidate was initiated in the Philippines, a major milestone in the vaccine's clinical development pathway.



Delivery

We conduct epidemiologic and socio-economic research of typhoid in Africa in order to close the knowledge gap on disease burden in 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.

From 2011 to 2015, we conducted the Typhoid Fever Surveillance in Africa Program (TSAP), which evaluated the typhoid burden through standardized surveillance at 13 sites in 10 sub-Saharan African countries. One of the major findings of TSAP is confirmation that enteric fever caused by S. *Typhi* and non-typhoidal *Salmonella* is a significant problem in Africa. IVI launched a follow-on study, Severe Typhoid in Africa (SETA) in 2016 to assess severe disease outcomes of invasive *Salmonella* infections and its economic burden at several sites in Africa.

© Justin Im /IVI Blood culture samples collected for the typhoid surveillance program

"One of the major findings is confirmation that enteric fever caused by S. *Typhi* and non-typhoidal *Salmonella* is a significant problem in Africa."





## Dengue

We promote research and development of prevention and control measures against dengue and other Aedestransmitted diseases.





IVI is the lead agency for 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 aims to promote data generation and synthesis, accelerate innovations in research, and support implementation of new and existing tools. Each partner has specific areas of expertise: IVAC focuses on health economics, strategic demand forecasting and vaccine development; Sabin focuses on communications and advocacy; PDC focuses on integration of vaccine and vector control, diagnostics, clinical case management, and pathogenesis. Besides leading the consortium, IVI is responsible for disease burden and epidemiology, laboratory testing, modeling, policy and access, and regulatory issues.

GDAC was created in August 2016 by joining the Dengue Vaccine Initiative (DVI) with the Partnership for Dengue Control, with the intent to expand the mission from dengue vaccines to a broader scope encompassing comprehensive prevention and control measures for Aedes-transmitted diseases including dengue, Zika, yellow fever and chikungunya.

"GDAC aims to promote data generation and synthesis, accelerate innovations in research, and support implementation of new and existing tools… for comprehensive prevention and control measures for Aedes-transmitted diseases including dengue, Zika, yellow fever and chikungunya."

> Specific projects by DVI continue to be conducted with support by the Bill & Melinda Gates Foundation. These projects include dengue burden field studies in Africa, Asia and South America, support for national regulatory authorities (NRAs) reviewing dengue vaccine candidates, and convening of dengue prevention board meetings to address key issues in prevention and control of Aedes-transmitted diseases. Other GDAC activities include the development of a centralized database for clinical trials of the U.S. NIH dengue vaccine candidate conducted by sub-licensees of the NIH dengue vaccine. Efforts are being made to obtain additional funding for proposed GDAC activities, with a focus on integrated vaccine/vector control.

IVI continued to make progress in dengue in 2016, through DVI and subsequently, GDAC, by conducting disease burden field studies in multiple countries, and supporting activities to increase readiness of low- and middle-income countries to introduce dengue vaccines, particularly in light of the recent licensure of Sanofi Pasteur's CYD-TDV vaccine (Dengvaxia®).

IVI launched the MERS Program in late 2015 with funding from Samsung. The five-year grant will accelerate the development of MERS vaccines, with the aim of having two MERS vaccines demonstrated to be safe and immunogenic in Phase II trials conducted in South Korea, and that can be deployed in clinical efficacy trials at possible outbreak sites.

IVI will partner with two vaccine manufacturers on 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 2016, IVI and GeneOne Life Sciences signed a collaboration and access agreement to support GeneOne's MERS DNA vaccine candidate.



### Middle East Respiratory Syndrome (MERS)



We accelerate the development of MERS vaccines.

# Lab Highlights

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

#### **CLINICAL RESEARCH**

In 2016, IVI's Clinical Research Lab started a partnership with the Korean Ministry of Food and Drug Safety (MFDS) on several projects: lead development of a proposal for a MFDS Reference Laboratory based on a WHO Collaborating Centers model; and development of vaccine evaluation systems for typhoid, dengue, respiratory syncytial virus (RSV) and Zika.

IVI is also partnering with the Korean Centers for Disease Control and Prevention (KCDC) to develop a rapid test kit and ELISA for the detection of antigen/antibody of viral hemorrhagic fever viruses including Ebola virus, as well as to develop neutralizing antibodies. Discussions are ongoing with the Korean Ministry of Health & Welfare to support development of a novel mucosal adjuvant.

We help build knowledge in the vaccine spectrum through training, technology transfer, technical assistance, and educational partnerships.

#### **VACCINE DEVELOPMENT**

IVI's Vaccine Process Development (VPD) Lab is developing several vaccine candidates. There was progress in 2016 with the *Salmonella* Typhi / *Salmonella* Paratyphi A bivalent conjugate vaccine. While data from preclinical studies indicate the vaccine is safe, the *S*. Paratyphi A conjugate component is not immunogenic, indicating it may need to be redeveloped. Discussions are ongoing to develop a hepatitis A vaccine in collaboration with the KCDC. Finally, a laboratory information management system (LIMS) was established in VPD in 2016.



# **Capacity-building**

BIOHAZARD

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We help build knowledge in the vaccine spectrum through training, technology transfer, technical assistance, and educational partnerships.

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(lower photo) Dr. Jean William Pape, Cornell University Professor of Medicine and founder of GHESKIO medical clinics in Haiti, was the keynote speaker.

One of the oldest vaccinology courses in Asia, IVI's Vaccinology Course has trained more than 1,000 people. 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 development of collaborative networks and partnerships among LMICs.

The 16th Vaccinology Course had 108 participants of 25 different nationalities. Twenty-six experts from international agencies (e.g., IVI, World Health Organization); research institutions (e.g., U.S. National Institutes of Health); universities (e.g., London School of Hygiene & Tropical Medicine); industry, and non-profit organizations served as faculty members. Course evaluations from the participants found the quality of the course overall to be high. Planning is underway for the 17th Vaccinology Course, scheduled on September 4-8, 2017 at IVI.

Vaccinology Course, September 26-30, 2016



1,000

the number of people trained in IVI's Vaccinology Course

108

the number of participants of the 16th Vaccinology Course

25

the number of nationalities of participants in the 16th Vaccinology Course



IVI developed a new software tool, the Vaccine Adverse Events Information Management System (VAEIMS) for the WHO Global Vaccine Safety Initiative (GVSI), of which IVI is a participating partner. VAEIMS was developed by IVI to efficiently transfer vaccine safety data from periphery health care centers to a central database. This will help improve reporting, monitoring, and management of vaccine safety data by public health authorities, enabling them to respond more quickly to public vaccine safety issues.

Following its pilot launch in Sri Lanka in 2015, the tool was rolled out in Chile and Iran in 2016. Based on positive feedback from the countries, there are plans to expand VAIEMS such as developing an online version.

In December 2016, an IVI branch lab was inaugurated in Andong City, Gyeongbuk Province, South Korea. This is part of a collaboration between IVI and the provincial government to develop an emerging biomedical cluster in the region. The lab will be used for vaccine evaluation and for training Korean scientists.

IVI is partnering with Incheon National University (INU; a public national university based in Incheon, South Korea) to develop a global Master's in vaccinology program in collaboration with University of Siena

IVI is partnering with Yonsei University (among the top three universities in South Korea) for its Global Health Security Agenda (GHSA) Master's Program, which will be launched in 2017. Funded by the Korean International Cooperation Agency (KOICA) and hosted by Yonsei University, this new graduate program will train health professionals from developing countries in global public health. IVI will provide lecturers and project advisors for the program.



# Impact

In 2016, IVI scientists authored or co-authored 93 articles that were published in peer-reviewed scientific journals, among which 84 were in Scientific Citation Index (SCI) journals.

Some articles were published in journals with a high impact factor such as *The New England Journal of Medicine and Nature Medicine*.

# 93

iournals

the number of articles published in peer-reviewed scientific journals

Scientific Citation Index (SCI)

#### Impact of the Oral Cholera Vaccine

A global cholera vaccine stockpile, managed by WHO, was created in 2013 using the oral cholera vaccines developed by IVI. The stockpile created a market for oral cholera vaccines, which did not exist before. It is estimated >4 million doses of the vaccine have been deployed in epidemic and endemic situations in 12 countries so far (India, Bangladesh, Ethiopia, Malawi, Iraq, South Sudan, Haiti, Tanzania, Cameroon, Guinea, Nepal, and Democratic Republic of Congo).

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 in December 2015 when Euvichol<sup>®</sup> was approved by the WHO Prequalification Program. The addition of another cholera vaccine producer is expected to double global supply to 6 million doses for 2016, with potential for further increased production in the future. More importantly, the extra capacity will contribute 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.

While supply has increased, there is room for improvement in 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.

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Core funding is provided by the Governments of the Republic of Korea and Sweden. We welcome India who recently became a financially contributing member state to IVI.

Public- and private-sector organizations and individuals also provide support, both monetary and in-kind, for the Institute's research and programs. Prominent organizations and individuals in Korea also provide support due to efforts of the Korea Support Committee for IVI (KSC). Your generosity is deeply appreciated.

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

Sabin Vaccine Institute USA

Sanofi Pasteur France Secretaria de Salud Medellín, Colombia

Sejong University Republic of Korea

Seoul National University Republic of Korea

Shantha Biotechnics India

SK Chemicals Republic of Korea

Stanford University USA

Takeda Pharmaceutical Company Limited Japan

Technical University of Berlin (TUB) Germany

Transgovernment Enterprise against Pandemic Influenza of Korea (TEPIK)

UNICEF Nepal

United States Centers for Disease Control and Prevention (CDC) USA

University of Alabama at Birmingham, USA

University of Antananarivo Madagascar

University of Antioquia Columbia

University of Florida USA

University of Gezira Sudan

University of Gothenburg Sweden

University of Melbourne Australia University of Ouagadougou Burkina Faso

University of Oxford

University of Queensland Australia

University of Vermont USA

University of Virginia

University of Wisconsin USA

VaBiotech Vietnam

Walter Reed Army Institute of Research (WRAIR) USA

Washington University USA

Wellcome Trust Sanger Institute

WHO Initiative for Vaccine Research  $({\sf IVR})$ 

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

# Leadership



Jerome Kim, MD Director General



Phil Driver Deputy Director General, Finance & Operations



Julia Lynch Deputy Director General, Development & Delivery



In-Kyu Yoon Deputy Director General, Science



**Kyung-taik Han** Deputy Director General, Government Affairs & Governance

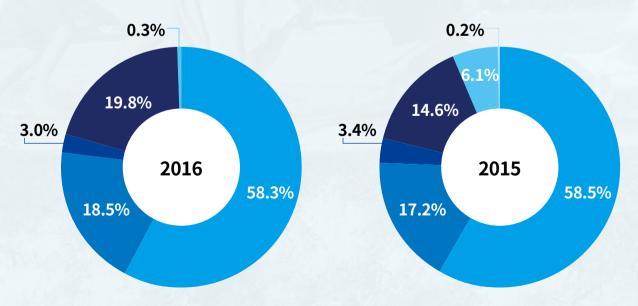


# **Finances**

Revenue	2016	2015
Bill & Melinda Gates Foundation (BMGF)	15,205,867	12,380,328
Government of the Republic of Korea	4,813,476	3,631,659
Swedish International Development Cooperation Agency (Sida)	780,368	720,420
Corporations / Individuals / Others	5,149,713	3,095,397
Korean Government Laboratory Support		1,294,612
Investments (Interest Income)	112,108	35,005
Total Revenue	26,061,531	21,157,421



- Government of the Republic of Korea
- Swedish International Development Cooperation Agency
- Corporations / Individuals / Others
- Korean Government Laboratory Support
- Investments(Interest Income)

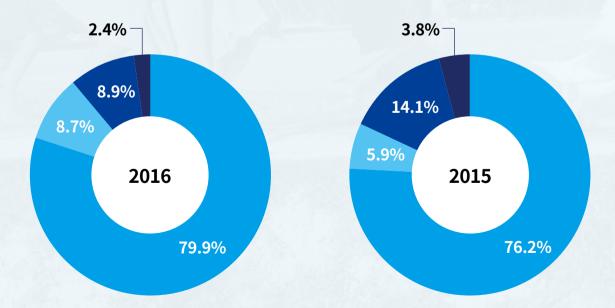


Total Expense	2016	2015
Program Service	20,009,212	16,634,140
Laboratory Support	2,188,346	1,287,420
Management & General	2,223,861	3,081,691
Communications & Advocacy	608,234	831,373
Total Expense	25,029,653	21,834,624
Foreign Exchange Gain(Loss)	179,765	(480,939)
Net Surplus(Deficit)	1,211,643	(1,158,141)

Program Service

Laboratory Support

- Management & General
- Communications & Advocacy



Assets	2016	2015
Cash and Cash Equivalents	5,676,076	5,126,466
Bank Deposits	15,980,280	21,409,144
Other Current Assets	763,775	1,031,521
Other Assets	1,064,298	1,090,148
Total Assets	23,484,429	28,657,279

Liabilities and Net Assets	2016	2015
Grant Funds-Deferred Support	15,803,851	23,079,592
Other Current Liabilities	2,734,583	1,843,335
Other Liabilities		
Net Assets	4,945,995	3,734,352
Total Liabilities and Net Assets	23,484,429	28,657,279



International Vaccine Institute



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