



**KIT**

# Sustainability of the activities of the International Vaccine Institute in Seoul

**2010-2016**

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## List of Acronyms

BCG	Boston Consulting Group
BMGF	Bill & Melinda Gates Foundation
CEPI	Coalition for Epidemic Preparedness Innovations
CDC	Centers for Disease Prevention and Control
DVI	Dengue Vaccine Initiative
IVI	International Vaccine Institute
KOICA	Korea International Cooperation Agency
KSC	Korea Support Committee for IVI
LMIC	Low and/or Middle Income Countries
MERS-CoV	Middle East Respiratory Syndrome- Coronavirus
MoH	Ministry of Health and Welfare
MOFA	Ministry of Foreign Affairs
OCV	Oral Cholera Vaccine
ODA	Official Development Assistance
PDP	Product Development Partnership
PPP	Public Private Partnership
ROK	Republic of Korea
Sida	Swedish International Development Cooperation Agency
SDG	Sustainable Development Goal
UNDP	United Nations Development Program
UNICEF	United Nations Children's Fund
SAG	Scientific Advisory Group
SEARO	WHO Regional Office for South-East Asia
TSAP	Typhoid Surveillance in Africa Program
WHO	World Health Organization
WPRO	WHO Regional Office for Western Pacific Region

## Executive summary

The International Vaccine Institute (IVI) is a nonprofit international organization established in 1997 through the initiative of the United Nations Development Programme. IVI is hosted by the Republic of Korea and headquartered in Seoul. The mandate of IVI is to make vaccines available and accessible for the world's most vulnerable people. IVI is exclusively dedicated to vaccines for diseases of global health importance like cholera, enteric fever (typhoid) and dengue. Vaccination is crucial to reach Sustainable Development Goals which include supporting research and development of vaccines that primarily affect developing countries and providing access to affordable vaccines. Vaccination is considered the most successful and cost-effective medical intervention ever introduced. According to WHO's estimates vaccinations save two to three million lives every year. The Strategic Advisory Group of Experts on Immunization have expressed their concerns that progress toward increasing equitable access to lifesaving vaccines is too slow.

IVI's programs include a broad range of in-house technical activities from vaccine discovery and preclinical to clinical development to generation of evidence for policy. IVI is unique in not only developing vaccines for the poor, but also actively pursue to ensure the vaccines reach those who need them the most. The Bill & Melinda Gates Foundation, Republic of Korea, the Korea Support Committee for IVI and Sweden are IVI's key funders.

The Swedish International Development Cooperation Agency (Sida) commissioned the knowledge institute KIT in Amsterdam, the Netherlands, to perform a study to assess the sustainability, in terms of funding as well as IVI's external communication and visibility. The current report is based on desk research of IVI's annual and financial reports and strategy updates in combination with interviews of IVI's main stakeholders.

Using a public-private partnership approach, IVI aims to accelerate the development and introduction of vaccines. Many vaccines are too costly for low income countries. Having multiple manufacturers will help ensure a sufficient and cost-competitive supply for the global market. IVI has thus assured that low cost oral cholera vaccines are now available for high burden countries like Bangladesh as well as for outbreaks such as those which have occurred in South Sudan and Haiti. These partnerships involve technology transfer, process development and studies needed for regulatory approval.

IVI has successful partnerships with international organizations such as the World Health Organization and the Global Alliance for Vaccines and Immunization. These partnerships are used to ensure adequate production of vaccines, stockpiling, and prequalification of vaccines. New international partnerships are being explored, for example with the Coalition for Epidemic Preparedness Innovations Collaborations while Indian partners are likely to open up with the help of the Indian Government. Relations with the Government of the Republic of Korea have priority for IVI as global health is high on the agenda of the government and collaboration with IVI is valued.

All interviewees agreed that IVI is very much needed. IVI is clearly the partner of choice in their areas of expertise. No other parties operate in the same field as IVI, which is to develop vaccines that the commercial market is not working on, and to address preparedness for diseases which hit low and middle income countries the hardest. The fact that IVI has been so successful in the development of a cholera vaccine may pose a strategic threat ("victim of their own success") in the sense that there is now less work to do in the field for which IVI is most well-known. The strategic direction of IVI in terms

of disease areas seems well chosen, though there has not been a clear preference on geographic investments, i.e. in either Asia or more worldwide. When IVI's leadership changed in March 2015, the ensuing transition period posed difficulties for the institute, which, according to major stakeholders, were adequately addressed. The IVI staff likely have been affected by the leadership changes, and therefore, internal communication is a top priority for IVI.

None of the key funders see a reason to discontinue their funding of IVI in the near future as they are pleased with the results of IVI and are content with its communication. Worries about the dependence on a limited number of key donors have been expressed. All interviewees agree that new key donors and consequently diversification of funding would be important for the sustainability of IVI. Some funders provide core funding, whilst others provide funding which is earmarked for specific projects. Core funding is important for IVI as it can help to sustain the laboratory, drive innovations forward, or provide funding to important areas of work which no donor is currently willing to fund. Core funding may also help to ensure job security for talented staff. Recently India became a signatory country and committed to provide annual core funding to IVI, yet the number of paying signatory countries should still increase. It is recommended to select a number of (high income) countries that might potentially fund IVI, based on their Official Development Assistance priorities and existing collaborations, and to intensify communication with these countries. Clarification IVI's role in collaborations with the private sector could be helpful to show potential donors that IVI is using industry to serve the needs for the world's poor and that it's not merely being used by the private sector to obtain free technology. Short business cases on important new or existing programs that need funding can be developed for potential new funders.

While the level and content of communication with current stakeholders is working well, communication to potential new funders is a priority for IVI. Website upgrades are planned, including integration with social media. The website currently does not highlight the positive, unique qualities and impact of IVI. The staff involved in communication are limited, so clear priorities should be set on ways to increase general visibility and to target communication to potential funders. IVI identified its 20<sup>th</sup> anniversary as an opportunity to increase its visibility.

The uptake of vaccines is essential to IVI's mission to contribute to the reduction of diseases in developing countries and to show impact. IVI has many broad activities that contribute to its increase. Participation in immunization campaigns is one step beyond the usual scope of work of IVI, and there has been no decision yet on whether IVI should focus on this more or use partnerships to increase vaccine delivery.

The general conclusion of the external assessment conducted by KIT is that IVI is an important relevant institute with impressive achievements. There are no immediate threats to the sustainability of the institute, though efforts are needed to remain in this same position in the coming years. These efforts should focus on three main areas: 1) increasing the number of key funders; 2) selection of strategic choices on the focus of IVI's activities; and 3) increasing IVI's visibility and claiming its successes in the most strategically important areas of work. Key initiatives for these areas have been identified by the current leadership and are being integrated into the strategy of the institute, while others are outlined in this report.

# 1. Background

The International Vaccine Institute (IVI) is a nonprofit international organization established in 1997 through the initiative of the United Nations Development Program (UNDP). Headquartered in Seoul, Republic of Korea (ROK), IVI was the first international organization hosted by ROK. The mandate of IVI is to make vaccines available and accessible to the world’s most vulnerable people in developing countries. IVI is exclusively dedicated to vaccines and vaccination for global public health. IVI’s disease programs are focused on infectious diseases of global health importance: cholera, enteric fever (typhoid), dengue, MERS-CoV (Middle East Respiratory Syndrome-coronavirus), and Hepatitis E. Vaccination is crucial to reach Sustainable Development Goals which include supporting research and development of vaccines that primarily affect developing countries and providing access to affordable vaccines. Vaccination is considered the most successful and cost-effective medical intervention ever introduced. According to WHO’s estimates vaccinations save two to three million lives every year. At the midpoint of the Global Vaccine Action Plan (2012-2020), the Strategic Advisory Group of Experts on Immunization (SAGE) remains gravely concerned that progress toward the goal to increase equitable access to lifesaving vaccines is too slow.

IVI’s program’s include the broad range of in-house technical activities from vaccine discovery & design to vaccine development and research to generate evidence for policy (Figure 1). IVI is thus unique in not only developing vaccines for the poor, but also actively pursue to ensure the vaccines reach those who need them the most.

## IVI's Approach

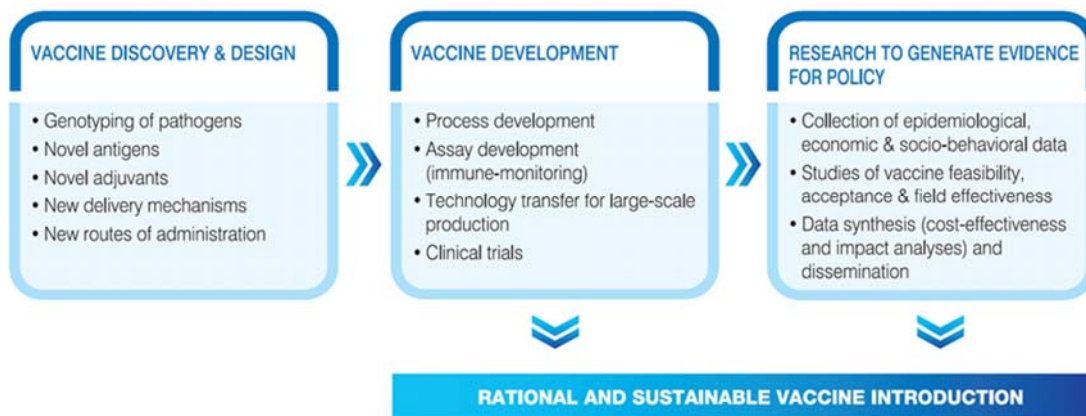


Figure 1 IVI's approach

IVI has approximately 131 staff members from more than 10 nationalities. While discovery and early development research mainly takes place at IVI’s own laboratory facilities in Seoul, clinical and epidemiological research is conducted in field sites in more than 20 countries in Asia, Africa and South America. In addition to ROK, IVI has 35 signatory countries and the World Health Organization (WHO) on its treaty. A signatory country can be seen as country (or state party) providing moral support to the existence of IVI. To date ROK and Sweden are the only two signatory countries of IVI; while India has also committed to fund IVI in 2017.

Since 2015, IVI has been going through several organizational and leadership changes including contracting Dr. Jerome Kim as the new Director General of IVI, as well as other new members of the Executive Leadership Team. With support from the Boston Consulting Group (BCG), IVI is currently assessing its strategy, with a particular focus on advancing key grant opportunities; assessing capabilities and identifying the right investments and organizational structure to position IVI for sustained success and to reduce costs in ways that do not impact IVI's ability to carry out its mission. This process is expected to result in strategic changes for the organization and possibly in the formulation of a new mission. Since 2017, IVI's mission is to discover, develop, and deliver safe, effective and affordable vaccines for global public health. Global public health was added to IVI's mission in 2017 to reflect the expanded focus on new and emerging diseases of global health importance such as MERS-CoV.

The Swedish International Development Cooperation Agency (Sida), one of IVI's core funders, commissioned an external evaluation (Sida Evaluation 07/09) to study the relevance and future role of IVI over the period of 2000-2006. Sida's report emphasized the impressive growth of IVI and its major impact on policy decisions related to vaccine development and the introduction of vaccines against a number of diseases, especially in Asia, was highlighted. The evaluation team was positive about IVI's vaccine portfolio but recommended increasing the number of collaborating partners and to expand activities in Africa. The role of IVI was seen to complement other activities in this area carried out by the public and private sector and the team recommended increasing partnerships, particular with WHO and Gavi, The Vaccine Alliance. To ensure financial sustainability, the evaluation team stressed increasing the number of donors and the proportion of core funding. In 2016, Sida commissioned the knowledge institute KIT Amsterdam (the Netherlands) to perform a study assessing IVI's sustainability in terms of funding as well as IVI's external communication and visibility. This report describes the results of this assessment in which KIT interviewed several members of IVI's executive leadership team, key donors, and stakeholders within the government of ROK (Annex 1).

## 2. Main achievements of IVI

The development of new vaccines, getting them WHO-prequalified and produced is a long term process that may take up to 20 years per vaccine. Though many achievements were mentioned, four main achievements of IVI since its establishment have been put forward during interviews by different stakeholders and were highlighted in IVI's annual reports. IVI has contributed to making vaccines for important neglected diseases such as cholera, typhoid fever and dengue available to those who need them. For cholera, IVI's work now mainly focuses on supporting vaccine introduction while for typhoid and dengue, work has not yet reached that stage. Emphasis still lies more in creating evidence regarding the use of the recently developed vaccines.

### 2.1 Development and prequalification of world's first low-cost cholera vaccine

A unique achievement for IVI is the development and WHO prequalification of two oral cholera (OCV) vaccines: Shanchol™ and Euvichol®. WHO prequalification means that the vaccine is approved for purchase by UN organizations (e.g. United Nations Children's Fund (UNICEF)) and global health partnerships (e.g. Gavi, the vaccine alliance). The third OCV Cholvax® is in the pipeline and intended for licensure and use in Bangladesh, which has a high burden of cholera. The OCVs have been deployed in Asia (Nepal, India, Bangladesh, Thailand and Vietnam), in Africa (Malawi, Guinea, Ethiopia and South

Sudan), Central America (Haiti) and the Middle East (Iraq). Worldwide, an estimated more than two million people are now protected through IVI developed cholera vaccines. A stockpile for OCV was established in 2013, supported by Gavi, and managed as a rotating fund by the International Coordinating Group including the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières, UNICEF and WHO, as an additional mechanism to help control cholera epidemics. The stockpile was used for the first time in 2014 to combat a cholera outbreak in South Sudan and was also used in 2016 in Haiti which was struck by epidemics since the hurricane. IVI currently focuses on optimizing the use of the OCVs, supporting vaccine introduction in countries, and providing support to manufacturers.

## 2.2 Developing typhoid vaccine suitable for infants and young children

IVI has been conducting studies such as the Diseases of the Most Impoverished and Typhoid Surveillance in Africa Program (TSAP) that demonstrate typhoid fever is a serious problem in sub-Saharan Africa and South Asia, affecting mainly children. TSAP, which started in 2011, was the first multi-country study to show that typhoid and invasive Salmonella infections had significant burden in African countries and warranting public health action including vaccination for disease prevention and control. Several vaccines are available but they are not very suitable for use in young children and infants (a high-risk group). One live oral vaccine (Ty21a) is mainly used as a traveler's vaccine while two injectable polysaccharide typhoid vaccines, Vi vaccine and Typbar, can be used in children, although they protect for a limited time period. IVI is currently developing a typhoid conjugate vaccine (Vi-DT) which is suitable for children and provides a longer duration of protection. Moreover IVI is working on a combination vaccine with paratyphoid, another type of disease in low and middle income countries (LMICs). IVI transferred technology for the Vi-DT to manufacturing partners in ROK, Indonesia and Bangladesh. IVI is working with these partners on preclinical and clinical development for vaccine licensure and WHO prequalification. Having three manufacturers of the typhoid vaccine will help to ensure a sufficient and cost-competitive supply for the global market. The vaccine is expected to be licensed and WHO prequalified in anticipation of global use as early as 2019.

## 2.3 Dengue: accelerating introduction of vaccines to the poor

Dengue mostly causes flu-like illness but occasionally takes on a severe form which can cause death. It is transmitted via mosquitoes and its prevalence is increasing, such that about half of the world's population is at risk of infection. IVI is the lead agency for the Dengue Vaccine Initiative (DVI), a consortium of four organizations: IVI, WHO, Johns Hopkins University, and Sabin Vaccine Institute. This consortium aims to accelerate the introduction of dengue vaccines to the poor in dengue-endemic countries through policy and advocacy. IVI is responsible for generation of evidence for decision-making, developing a case for country vaccine introduction, as well as a global investment case. DVI is currently transitioning to the Global Dengue and Aedes-transmitted Diseases Consortium and will expand its expertise to other diseases including Zika, chikungunya and yellow fever. IVI will remain the lead agency of this consortium. In December 2015, the first approvals ever granted to a dengue vaccine manufacturer for use of its candidate vaccine in-country were granted. Mexico registered Dengvaxia® on December 10, followed a few weeks later by the Philippines, then by Brazil and, in February 2016, by El Salvador. These registrations are followed up with close consideration of how these vaccines can be applied in the field. Though the work is ongoing, important steps towards the introduction of dengue vaccines to the poor in dengue-endemic countries have been taken by this IVI led consortium.



## 2.4 IVI Vaccinology Course

IVI established its Vaccinology Course in 2000 specifically in order to provide a comprehensive overview of vaccinology to vaccine professionals from developing countries, for which a five day course has been held at the IVI headquarters in Seoul for the past 16 years. IVI also awards fellowships to participants from LMICs whom IVI has trained to more than 1,000 developing country vaccine professionals. More than 30 experts from international agencies (e.g. IVI, WHO), research institutions (e.g. United States National Institutes of Health), universities (e.g. London School of Hygiene & Tropical Medicine, Oxford), industry, and non-profit organizations serve as faculty members. Several interviewees have participated in or contributed to the course and mentioned it as an important achievement.

## 3. Collaboration

IVI's international legal status allows it to establish collaborations with many bodies, including those in the private sector. IVI has over 100 partnerships with stakeholders from the government, public sector, private sector, civil society and global health sectors; these collaborations are essential to accomplish IVI's mission. Collaborations with research institutes are frequent and no difficulty was identified in this respect. Good collaborations with the government of ROK are essential to the position and functioning of IVI.

### 3.1 Public-Private Partnerships

Using a public-private partnership (PPP) approach, IVI aims to accelerate the development and introduction of vaccines. Collaboration of IVI with vaccine manufacturers and biotechnological industry is frequent, especially in Asia, and these collaborations contributed to important outcomes, for example in the fields of cholera and typhoid vaccines (chapter 2). These PPPs typically involve technology transfer, process development, (pre)clinical studies and the regulatory approval process in order to register and prequalify the vaccines by WHO. Having multiple manufacturers of a vaccine will help to ensure a sufficient and cost-competitive supply for the global market.

*Box 1 Overview of IVI's main public private partnerships*

Vaccine	Manufacturer	Country	Year of start of collaboration
mORC-VAX	VaBiotech	Vietnam	2007
Shanchol™	Shantha Biotechnics	India	2009
Euvichol®	EuBiologics	Republic of Korea	2015
Cholvax®, Vi-DT	Incepta Vaccine Ltd.	Bangladesh	2015
Typhoid vaccine (Vi-DT)	SK Chemicals	Republic of Korea	2014
Typhoid vaccine (Vi-DT)	PT Biofarma	Indonesia	2014

Because of IVI's collaboration with the private sector, some interviewees have expressed concerns regarding the use of public money to produce and sell vaccines for profit purposes by the private companies. Therefore it may be advisable for IVI to develop a 'code of conduct' to which they adhere

to, and which they can show to public funders. The ROK Ministry of Foreign Affairs (MOFA) is taking several initial steps to further enable the facilitation of PPPs including: i) clarifying who will receive the intellectual property rights; ii) confirming that there are no constraints in the governmental regulations allowing private manufacturers to receive intellectual property rights; iii) confirming with the World Trade Organization that technology transfer is not being perceived as a subsidy to pharmaceutical companies. No legal obstacles have been identified so far, but an open discussion on these issues is needed so that ROK ministries are able to actively facilitate PPPs.

For IVI the number of yearly acquisitions of patents is one of its major outcomes. Once a patent is obtained, it is preferably transferred as there is no funding to maintain patents. To manage intellectual property rights IVI is assisted by ROK specialists in intellectual property rights. IVI as an organization will not support infringement on patents. IVI indicated that technology transfer and intellectual property rights are practiced within regulations of specific donors. For example, BMGF negotiates global access agreements to ensure that a sufficient quantity of vaccines and/or a sufficiently low price for vaccines will be made available for developing countries as part of their investment in the program. Making a profit is not an objective for IVI. PPPs are fundamental in reaching IVI's mission but IVI's communication to funders could be more explicit when it comes to its code of conduct with regards to PPPs. PPPs occur also in the field of vaccine research. In 2015, IVI established a partnership with the Gyeongbuk Institute of Bio Industry of ROK to collaborate on adjuvants, immune-monitoring platform technology, and preclinical vaccine research.

### 3.2 International organizations

Next to collaboration with its manufacturing partners, it is essential for IVI to collaborate with international organizations on vaccine stockpiling, prequalification and vaccine delivery. Interviewees, including IVI itself, have been asked to provide their perspective on the collaborations between IVI and international organizations such as WHO, Gavi and UNICEF.

Collaboration with WHO headquarters in Geneva has resulted in fast and successful prequalification of oral cholera vaccines, an essential step before the vaccine stockpile took place. IVI also collaborates with WHO on specific initiatives such as the Global Taskforce for Cholera Control and the Global Vaccine Safety Initiative. Through the Vaccine Safety Initiative, IVI developed software for vaccine safety monitoring and reporting, which has been adopted by Sri Lanka, Iran and Chile to date. Apart from this well-functioning collaboration, it was suggested that IVI further explores collaboration with WHO regional offices including WHO Regional Office for Western Pacific Region (WPRO) and WHO Regional Office for South-East Asia (SEARO), especially related to the implementation of country programs.

Gavi is also seen by interviewees as an important international partner. At the end of 2011 the leaders of Gavi and IVI agreed to expand collaborations between these two organizations in light of their complementary mandates dedicated to delivering vaccines to the world's poorest countries. Gavi's focus is on uptake of vaccines, and Expanded Program on Immunization in national health systems, while IVI's main focus is currently on research and development of vaccines. As such, the two organizations complement each other. Current engagement and collaboration between IVI and Gavi is mainly on vaccine advocacy, access and policy issues, particularly for cholera, typhoid and dengue vaccines. In late 2013, a global vaccine stockpile for the oral cholera vaccine managed by WHO and

other partners was financed by Gavi for five years. Gavi has a position on the IVI's Board of Trustees that has not been filled by Gavi in the past years, but recently Gavi indicated interest in filling the seat.

There has been little collaboration between IVI and UNICEF in the past years; therefore, the ROK MOFA aims to stimulate this by exploring opportunities for potential partnership between IVI and UNICEF for example during the annual dialogue between UNICEF and MOFA. Current collaboration with UNICEF consists of one proposal to improve cholera vaccine uptake in Mozambique, which might be funded by ROK after the final version of the proposal has been approved. The interviewees expressed different opinions regarding whether IVI should focus more on delivery instead of vaccine development, and it has been recommended that if IVI chooses the strategic direction to focus more on delivery and uptake of vaccines, an intensified collaboration and/or outsourcing to experienced international partners as Gavi and UNICEF will remain important.

An interesting new international initiative aiming to stop future epidemics by developing new vaccines for a safer world is the Coalition for Epidemic Preparedness Innovations (CEPI). CEPI will be a partnership of public, private, philanthropic and civil organizations to stimulate, finance and coordinate vaccine development against priority threats. IVI has submitted three proposals to CEPI together with Jenner Institute (UK) and two with Inovio Pharmaceuticals on development of Lassa, Nipah and MERS-CoV vaccines.

### 3.3 Collaborations with the host country

Health is, and was for a long time, a major priority both in foreign policy and Official Development Assistance (ODA) for ROK. The government endeavors to contribute to discussion and programs in health issues among others via WHO. This year (2017) ROK is chairing the steering group of the Global Health Security Agenda. After the Korean War, ROK received much contribution from the international world, and therefore would like to pay back the international community. As such the Government of ROK successfully applied in a bid to be the host country of IVI. Collaboration with IVI still fits the ambitions of the Government of ROK. Good collaboration with the host country is considered important for IVI; which accordingly has hired a Deputy Director General in 2016 to assist in managing government relations. Current important collaborations exist with the Ministry of Health & Welfare (MoH) and the ROK Centers for Disease Prevention and Control, the MOFA and KOICA as well as universities. The Korea Support Committee for IVI (KSC) plays an important role in seeking and strengthening collaborations and partnerships with parties in ROK. Interviewees stressed the importance of linking with the host country needs. Current relations with the host country seem to be satisfactory, but opportunities exist to strengthen them even further. An example is the plan to have a ROK CDC staff member seconded at IVI.

## 4. Sustainability

In order to prepare for the future, it is essential that IVI identifies its strategic direction. Moreover the institute should ensure financial sustainability and operational efficiency. Points of attention have been the core cost structure and overhead, relationships with key funders and stakeholders, and the identification and engagement of new funders.

### 4.1 Sustainability with regards to the strategic direction/niche of the institute

When IVI was created, a clear niche for the institute was perceived by various organizations including UNDP, WHO as well as Gavi. Commercial companies in the vaccine industry did not regard the

developments of vaccines for developing countries as a priority. The localization of the institute in ROK was seen as an advantage because of the proximity of the target countries, as well as many relevant industrial/research partners in the region. This section explores whether this niche still exists and if no other parties work on similar initiatives.

All interviewees agreed that IVI is still very much needed. IVI is clearly the partner of choice in their areas of expertise. No other parties operate in the same disease areas as the IVI. A future risk for IVI may be that as LMICs increase their own capacities, the intermediate role of IVI may then be less needed.

The fact that IVI has been so effective in the development of a cholera vaccine may pose a strategic threat in the sense that there is now less work to do in the field for which they are most well-known (i.e. becoming a “victim of their own success”). It is therefore important that IVI diversifies its activities in several disease areas. This may also attract a wider range of funders. The focus areas of work seem to be well-chosen, considering that the landscape of vaccine developers is strongly stratified per disease group. For instance, there are other initiatives on vaccines like Respiratory Syncytial Virus and pneumonia (PATH, Program for Appropriate Technology in Health) and for Tuberculosis / Malaria; however, in the current focus areas of enteric vaccines, IVI is the main player. IVI’s new focus on global health is seen as a positive addition. It is aligned with the ambitions of the ROK government, and there is donor interest in diseases like MERS Co-V using expertise within the institute to develop vaccines.

The Scientific Advisory Group (SAG) provides advice to IVI on scientific strategy. After a short hiatus the SAG was re-activated in 2016 with new members. The new SAG is perceived as highly competent, and interviewees indicate that IVI is receptive to SAG’s advice. IVI has undergone several leadership and management changes since the first Director General departed in 2011. This resulted in the loss of several senior staff members and key scientists, as well as decreased confidence in IVI by funders such as BMGF and ROK, marking a difficult period for IVI. The impression by the interviewees was that IVI has successfully dealt with these difficulties, with several stakeholders expressing a high degree of confidence in the current strategic direction and new leadership of the institute.

Moving forward, IVI plans to engage in vaccines for Hepatitis E, Group A Streptococcus, and the inactivated rotavirus vaccine. There is a need for these vaccines in LMICs because of the high burden of disease, the lack of good treatment (e.g. timely antibiotics) and the lack of suitable vaccines (e.g. current vaccines do not seem to work well in LMICs). It is, however, not easy to obtain earmarked funding for these initiatives since funding for global health research and development has become more limited. Currently, only small steps can be undertaken. The whole process of developing a vaccine may cost 40-60 million USD. Although funding is a challenge, there are interested parties such as the Wellcome Trust. For other diseases which IVI would like to work on there is a need to conduct sound epidemiological studies before the priority of vaccine development can be established (e.g. Schistosomiasis). Such burden of disease studies, particularly for neglected diseases, are also hard to fund.

IVI has not made a clear choice on what to emphasize in its broad range of in-house technical activities. In order to reach impact of these activities it is not only important that vaccines are developed, they also need to be produced, prequalified, and safety, impact and cost-effectiveness studies in the field need to be undertaken before a vaccine can be introduced in national immunization programs. The responsibility for appropriate utilization of vaccines lies primarily with governments whereas WHO

takes a role in policy and recommendations. Besides IVI, there are also other organizations active in implementation/vaccine delivery (e.g. Gavi, UNICEF). Opinions about IVI's role in vaccine delivery vary among interviewees. The delivery and advocacy was not a core priority of IVI in the past (see chapter 6 for further discussion on this point). Some stakeholders believe that IVI should nevertheless be more active in these final phases of the vaccine chain in order to make demonstrable impact. Others believe that IVI should not go in this direction because its main strength lies elsewhere. Maintaining a high level of expertise in a broad range of activities can be a challenge for a relatively small organization and can also make it difficult for the organization to differentiate and position itself.

IVI has a strategically favorable location in Asia. Most product development partnerships (PDP) for vaccines are in the US, while IVI is the only one in Asia. IVI is more readily accessible to manufacturers in Asia than US PDPs. In IVI's initial years, the opportunities of being in Seoul were not fully taken advantage of. Currently, stakeholders feel that this advantage is much better used (see section 3.1 on collaborations).

#### 4.2 Sustainability in resources from key funders IVI

IVI's key funders are BMGF, ROK, Sweden and KSC. Around 50 other public and private sector organizations provide monetary and in-kind support for the Institute's operations and programs. There are no other sources of income apart from donor funding, interest income, and fundraising. The institute currently does not sell services, products or intellectual property rights for profit margins as it does not see this as fitting its mission. BMGF has been the main funder of IVI for many years. Reviewing the financial and annual reports from 2012 onwards showed that BMGF funding varied from 51% of total revenues in 2012 to 59% in 2015. (Figure 1, Annex 2 and Annex 3) The Government of ROK is the second key funder with increasing percentage of overall revenues from 12% in 2012 to 17% in 2015, and it also supports IVI's laboratories (6% in 2015). In addition to ROK, until 2017 Sida has been the only other country providing funding (3% in 2015). Annex 2 shows the funding patterns and expenses from 2012-2016 and Annex 3 the sources of revenues from 2012-2014.

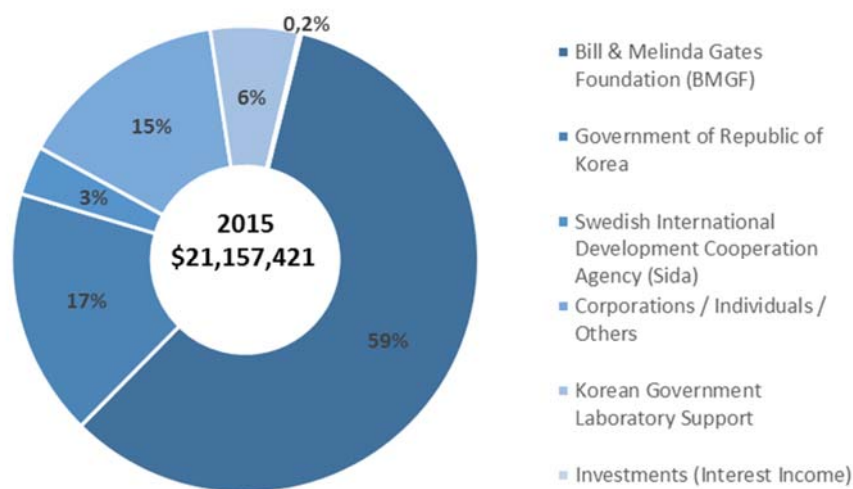


Figure 2 IVI's source of revenues 2015.

The revenue from IVI shows an increasing trend from around 18 million USD in 2012 to 21.2 million USD in 2015. The estimate for 2016 is 26.1 million USD (Annex 2) while the forecast until 2018 (26.2 million USD) looks favorable with a peak revenue forecast in 2017 of 37.7 million USD. The latter is mainly due to the Samsung-funded MERS-CoV program to accelerate the development of MERS-CoV vaccines with two candidate vaccines, of which one has started and the second project will hopefully start around mid-year 2017.

### 4.3 Balance between restricted and unrestricted funding

More than 75% of the total revenues of IVI (excluding interest income and miscellaneous) are from restricted grants (Annex 3). Unrestricted core funding has so far been provided by Sweden, the Government of ROK and the KSC while in 2017 the government of India is expected to sign an agreement to support IVI with 0.5 million USD of annual core funding. Although individual donors policies on earmarked funding and core funding vary, interviewees saw sustaining and increasing of core funding as important for IVI because of the following potential benefits: i) increased retention of staff/talent in the organization on long term contracts rather than insecure positions funded by projects; ii) ability to set and plan own research agenda; iii) ability to finance innovations in new disease areas which may be more difficult to finance with earmarked funding and innovations which require creative open thinking; iv) ability to sustain IVI's laboratory which is considered crucial for IVI's existence but this requires core-funding and v) ability to fund essential epidemiology projects to assess the burden of diseases essential to prioritize diseases for vaccine development (for example schistosomiasis).

Despite the clear advantages of core-funding, currently all stakeholders regarded a mix with earmarked funding as necessary for IVI's financial sustainability. Several donors have policies that prevent them from giving core funding; they are output driven (e.g. BMGF). Core funders in some instances have reservations on the effect of too much earmarked funding. The IVI may be tempted to engage in work that has lower priority because of financial benefits. Currently IVI obtains funding through proposals that the institute develops and submits to funders, solicited and unsolicited, so IVI has freedom to pick and choose its projects. Still there are areas of work for which no earmarked funding is yet available so that the institute cannot work on it at present (see section 4.1).

### 4.4 Increasing number of country governments support

Core funding will most probably come from governments. There are no signs that the current core funders have any intentions to stop funding IVI. The Government of ROK even wants to increase ODA and IVI could potentially benefit. A problem is that ODA is often very output-driven and results-based; while it may take more than 10 years to develop a vaccine, consequently results from IVI seem to be mainly long term. Very few high income countries and none of the G7 countries are signatory countries of IVI. Current signatory countries thus provide little opportunities to build relationships with potential new donor countries. The ambassadors in ROK are working in a high income country (ROK) and may have limited experience with ODA and limited communications with their own national development cooperation agencies. They may not think of recommending to fund IVI via ODA. High income countries would need to identify IVI as ODA-eligible international organization via other routes.

It takes time to build relationships with countries. There is no designated person in IVI for this apart from the Director General. Currently, the research collaborations with high income countries (like

Canada, Ireland, Netherlands or Kuwait) are minimal, making it harder to build a relationship on that basis. This is different for high/middle income countries in Asia as collaboration is clearly possible on diseases that are of regional interest (e.g. both ROK and China have outbreaks of hand, foot, and mouth disease). ROK, Sweden and India have indicated to be willing to advocate and engage towards other states on behalf of IVI. Clarifying the collaborations with the industrial partners and the policy with regards to intellectual property rights may be useful in helping them make the case to other states for IVI support. Increasing visibility of IVI and use of communication channels can further assist in increasing the number of state funders (see further Chapter 5).

#### 4.5 Diversification of restricted funding

Financial sustainability of IVI might be considered vulnerable as more than 50% of income is received through one donor (BMGF). However, BMGF indicated that they are used to working with non-commercial partners for whom they are the main funder. They only have few other partners for PDP in this field and are as such also relying heavily on IVI to reach their targets. BMGF does not see any reason as to why IVI could not continue to receive funding in the coming years, provided that IVI keeps delivering outcomes according to the high quality standard as they currently do. A shift in funding within BMGF may take place from funding for cholera to other diseases like typhoid. Although there is no immediate threat in losing BMGF funding, all interviewees agreed that diversification of funding is important for the financial sustainability of IVI.

Under the new leadership, IVI is continuously taking efforts to actively seek for new funding opportunities and is approaching potential donors on specific disease areas. For example, the Wellcome Trust has been approached to fund projects on the diseases Hepatitis E and group A Streptococcus, diseases which are not on the priority agenda of BMGF but on IVI's. Funding opportunities via global initiatives are also explored like via CEPI (see section 3.2).

One important barrier as indicated by IVI is that proposal writing for international grants is mainly done by management level staff including the Director General. Although management level staff is fluent in English it has been mentioned by some interviewees that other (junior) staff may have limited experience in writing English proposals. Current donors indicated that if IVI wants to achieve more and/or continued funding it is seen as a requirement that project proposals should be presented in a plausible and convincing way according to funders specific requirements.

#### 4.6 Reducing overhead

To increase the financial sustainability, IVI is in the process of reducing or offsetting overhead costs. Currently, core costs have been reduced by 1 million USD but IVI aims to further reduce core costs by 2 million USD by the end of 2018. Reductions have been made by alleviating the costs of IVI's building by subleasing part of the building and laboratory to a biotech company. This also offers advantages in collaborative research and sharing of resources. Furthermore, improved efficiency has been reached by reducing staff numbers in some projects as the staff members were not fully occupied. Use of subcontracting will likely be used for positions that do not need full term contracts.

## 5. Communication

### 5.1 Communication strategy

A renewed focus on strengthening relationships with key funders and stakeholders is part of the strategic priorities since the appointment of the current Director General in 2015. At the moment of KITs assessment (January-March 2017) the BCG is developing a communication strategy to improve IVI's internal and external communication while ensuring the communication strategy will be aligned with IVI's overall strategy. This is part of IVI's and BCG's joint work on assessing capabilities and identifying the right organizational structure to position IVI for sustained success.

While the plans for a redefined communication strategy are being shaped, IVI's communication team has set three goals for 2017: 1) To strengthen IVI's reputation among stakeholders by i) improving digital communication platforms and structure. At the end of 2016 a new website was launched, but there are already plans to further develop the website by improving the publication library, and integrate the website more closely with social media platforms; IVI is currently seeking advice how to increase the number of followers on Facebook and Twitter; ii) continue to work on engagement with ROK (through media relationships and developing relationships with private sector; iii) supporting management involved in business development work on communication and relationships building with selected donors; 2) To develop platforms for improved internal communication (see also section 5.3); 3) Event management: organizing the annually Vaccinology Course, scientific symposia, celebration of IVI's 20<sup>th</sup> anniversary and hosting visitors.

Communication is essential to improve IVI's visibility. Interviewees, including IVI, agreed that there is room for improving IVI's visibility internationally and in ROK. Although IVI is taking several steps to improve visibility (e.g. working with a multinational Public Relationships agency and broadcasting on Korean media; approaching international bloggers, editors and reporters, presenting at the National Assembly), barriers include the low number of communication staff experts on-staff and staff members being able to dedicate sufficient time to public outreach relationships and communication and difficulties engaging US-based reporters due to physical distance, time difference and limited relevant news hooks and story angles. In addition, Seoul is not the news hub for Asia and there are relatively few foreign correspondents (compared with Bangkok and Manila).

Increasing presence in at national and international meetings has been mentioned by interviewees as a means to increase visibility. IVI keeps an event calendar of important conferences but funding to attend these meetings should come from the specific project funding, not core funding. Another opportunity to increase visibility is to exploit the network of alumni of the Vaccinology Course. The course has been running since the year 2000 and alumni are spread all over the world. Currently they receive IVI's newsletter but they could also be invited to a specific alumni group on Facebook or LinkedIn to support network opportunities. In general we suggest that communication with alumni could be explored in more detail when developing the new communication strategy although this would also require dedicated staff or active volunteers among the alumni.

### 5.2 External communication to key funders

Communication channels with key funders consist of monthly strategic meetings, video conferences, email, and personal contact. Project specific communication takes place frequently between IVI's project leaders and donors of earmarked grants. Current key funders interviewed (BMGF, Sida,



Government of ROK and KSC all expressed the opinion that communication is adequate and informative. IVI shares updates with the funders and responds quickly, which is appreciated. Those interviewees who are also member of IVI's Board of Trustees further indicated that through regular board meetings IVI provides relevant updates on its activities.

To improve in country communication IVI hired a Deputy Director General for Government Affairs & Governance, who has worked for 30 years at the ROK Government and is a ROK citizen. This person is highly involved in facilitating the communication and process within the different departments of the ROK Government involved in funding IVI (Ministry of Health (MoH) and ROK CDC, MOFA, and Ministry of Finance). Both understanding of the government's interest and needs by IVI, and understanding of IVI's activities by the government has improved since then. The contact persons interviewed at the MoH and MOFA indicated that IVI is responsive and receptive.

### 5.3 Internal communication

IVI's executive leadership team is very well aware that the changes in past few years regarding strategic direction, new leaderships and waiting for a new strategy to be rolled out may have caused some resistance, stress, cynicism and fatigue among its staff. To improve internal communication different platforms are being rolled out. Quarterly 'all hands meetings' take place in which high level institutional updates are being shared with the staff. Language barriers exist because most management staff does not speak the Korean language while the majority of staff members may not feel comfortable speaking in English during these meetings. To overcome this language barrier, monthly 'staff engagement meetings' are planned in which a member of the leadership team meets with a small number of staff members as a platform to re-iterate similar messages while giving all staff throughout the year the chance to express concerns in smaller intimate settings. Monthly 'senior meetings' with department heads and principal investigators take place to discuss management and operational issues. These new communication platforms aim to contribute to improved internal communication from managerial level to staff level, which has been mentioned during the interviews to be essential.

### 5.4 Opportunities for communication to attract new funders

To be able to attract new funders existing funders have highlighted some aspects of importance that IVI could take into consideration for their communication strategy. To approach country funders it had been suggested that IVI should emphasize the uniqueness of the institute and focus on outputs accomplished while avoiding technical terms. Vaccine development can take up to 20 years but the importance and status of several in between steps to be funded should be emphasized and explained in plain language. The annual report will not suit this purpose because it is too long and may contain too technical terms. Additionally IVI should link to the potential donor countries funding priorities and SDGs. As indicated western ambassadors in ROK do not have clear links to national development funds as ROK does not receive ODA. They may not be the most logical entry point to access country level funding, however they could serve as intermediate point of contact between IVI and those responsible for ODA allocation. IVI identified it's 20 year anniversary as an opportunity to invite new funders. When approaching new funders it would be helpful to have policy briefs and or short business cases for new products or products to be improved including the funding needs. These are currently not available.

IVI's website can play an important role to attract new funders. A brief overview of our observations from the current website that IVI could take into consideration in the planned revision of the website are summarized in Box 2.

Box 2 Brief overview of observations and suggestions after scanning IVI's website

<b>Observations</b>	<b>Suggestions</b>
Website includes relevant information but some information is outdated (no strategy beyond 2012). Search function does not work well	Highlight IVI's uniqueness and IVI's impact by providing examples instead of linkage to journal publications
Overview of donors is available which may convince potential donors that IVI is reliable. This list is outdated (from 2014).	Increase transparency by enabling easier access to financial reports and reports independent evaluations Obtain 'testimonies' of current key donor(s) quoting the importance of/experience with IVI
Important information on eligibility ODA funding is available	Review text which shows up when clicking on 'Donate button' and consider replacing to landing page to explain potential donors why additional funding is necessary highlighting unfunded priority areas.
Website contains empty pages, little use of pictures and it is not always clear what information to expect under specific heading. (under impact you get publications)	Identify key objectives of the website for different target audience and adjust structure website accordingly. Aim to receive information in 3 clicks.
IVI Facebook page has a good 'look and feel' but a link to the webpage is lacking	IVI already indicated to better integrate social media and website (5.1)

## 6. Uptake of vaccines

The uptake of IVI's two most important new vaccines (oral cholera and typhoid fever) has been lagging behind. Reasons for low uptake included the inadequate production of vaccines and possibly also the costs and user-friendliness of the vaccines. For cholera, IVI increased supply of affordable and user friendly cholera vaccines, which in turn supported the creation of a global stockpile and thus created demand for these vaccines. There is a need for more studies on the effectiveness of the cholera vaccine. IVI conducts policy analysis and economic research to synthesize evidence, generate health economics data and developing transmission models to help with forecasting and estimations of vaccination impact. IVI has been collaborating with local health authorities and partners on the introduction of the oral cholera vaccine in among others Malawi, Ethiopia, India and Bangladesh to provide practical evidence that cholera vaccination works, is feasible, and is well-accepted by the community. IVI has made these results available to WHO and Gavi, and some of the data have been used in Gavi's decision making and in WHO recommendations (e.g. 2010 position paper on oral cholera vaccines). However, there is a need for more vaccine effectiveness studies to demonstrate real-life impact of the vaccine. High burden countries have not all adopted the new vaccines. A mass immunization campaign in for example on the islands of Haiti and Dominican Republic where cholera was introduced after the earthquake could show the potential of the vaccine to eliminate cholera. These kinds of intervention studies are however very costly. IVI is still debating internally to which extent it can or should go in increasing uptake of vaccines. As indicated the opinions of stakeholders differ on this point. This is an issue to be discussed further within the Board of Trustees as it is important for the long-term sustainability of IVI.

## 7. Conclusions

The general impression is that IVI is a relevant institute with good achievements to date. There are no immediate threats to the sustainability of the institute, though efforts are needed to maintain a good position for the coming years. These efforts lie mostly in increasing the number of key funders and in making strategic choices on the focus of IVI's activities. Increasing visibility of the institute and claiming its successes strategically needs attention, which IVI is aware of.

IVI's mission is in line with the global health agenda. Including the Global Vaccine Action Plan (2012-2020) and the SDG's. There is a clear niche for IVI seen by all interviewed funders. IVI is unique and no other organization operates in the same disease specific field as IVI. Through capacity building, local partners and countries may need less assistance of IVI as an intermediate partner in the future. The achievements in the field of cholera have been so successful that work in this field, especially in vaccine development is less needed now. IVI's current disease focus is much broader than cholera and this focus is seen as relevant. Several interviewees view the newly-re-established SAG as highly competent and see that IVI is receptive to SAG's advice. IVI is putting efforts on both regional expansion as well as increasing its global focus. No clear choice has been made on where to focus on most and funding opportunities are likely to influence IVI's strategic direction. The location in Seoul is used well in public private partnerships but not yet fully in the identification of potential Asian funders. There is discussion on whether IVI's focus should shift more towards vaccine delivery and uptake. A broad range of in-house activities has an advantage and is part of the uniqueness of IVI. However for a small institute like IVI it may be a challenge to keep high level staff in-house in all areas of work and creates challenges in competitively positioning itself. A clearer focus on some activities will facilitate strategic decisions. Current interviewed funders are content with IVI's work; they will likely continue funding and the forecasts for 2018 are viewed as positive. Core funding is regarded as essential for IVI's financial stability. It is used for innovation, staff retention, maintaining the laboratory, financing epidemiological studies, and freedom to set own research agenda. A mix of core with restricted funding seems preferable. New core funders are desirable and could potentially consist of country governments, e.g. of signatory countries. Potential barriers may exist in IVI's low visibility and lack of clarity of the nature of public private partnerships. In addition the signatory countries are mostly in low income countries and generally do not seem to be able/willing to fund IVI.

The most important threat to financial sustainability is IVI's dependence on a few major donors. BMGF brings in >50% of IVI's revenues. Also a limited number of key funders may reduce the scope of work that IVI can embark on as each funder has its own priorities (at least those offering restricted funding). To address these issues, IVI has made important efforts to find new funders, e.g. through contracts with Samsung and the government of India. At the same time overhead has been reduced, amongst other via subletting parts of the building and laboratory, in order to increase financial sustainability. The most important collaborations for IVI are in the form of PPPs with vaccine manufacturers, primarily in Asia. These collaborations include technology/patent transfer. These collaborations have been successful in ensuring adequate production of vaccines for cholera. Collaboration with international organizations like WHO and Gavi on prequalification and stockpiling is successful for cholera and will remain important also for the new typhoid vaccine. Collaboration with ROK is good and is increasing. A ROK CDC employee will be seconded to work at IVI. The MOFA and IVI and KOICA are willing to assist in establishing more PPPs or other collaborations and are currently clarifying that

there are no legal obstacles. New collaborations are explored with CEPI. Collaborations with other product developers like PATH may bring additional benefits.

Communication with the Board of Trustees and SAG is good. IVI seems receptive to their inputs. Communication with current funders is good in both quality and quantity, and appreciated on at the management level. Still some core funders might appreciate more feedback on the successes of IVI to also share within their organization. This may be information on important milestones or on how the vaccines developed through IVI are now being used. Communication with the ROK Government has been facilitated through the appointment of a Deputy Director General, Government Affairs & Governance. Current contact persons at both the Ministry of Health and Ministry of Foreign Affairs indicate that they are content with the communication. Although at the level of the government more information on intermediate outcomes would be appreciated as a new vaccine may take 20 years to be developed.

After the most recent reorganization, more emphasis is now being placed on internal communication within IVI. This is important to ensure that all staff members are on board and understand the importance of immediate responses to information requests from (potential) funders. In the new communication plan, there is attention to visibility to potential new funders, but since IVI is a relatively small organization the communication team is of modest size. The website has high importance. It does not seem fit for all audiences, can show impact better and can even strongly reflect that IVI is a unique not-for profit organization. Trustworthiness and transparency can be underlined by accessible information about finances, collaborations and evaluations, and use of testimonials. The use of social media is currently still limited. More news items on successes can be added. IVI is often not visible on websites of partners. Visibility in national and international meetings can be increased, although this is more labor intensive and clear prioritization on where to go is necessary. MoH and MOFA may be able to advise. There are no short business cases for new products or improvements in existing products to be shared with potential new funders.

IVI is very active in reducing barriers for uptake via ensuring a stockpile through the International Coordinating Group, reducing costs via manufacturers, ensuring user-friendliness via manufacturers. Although studies on impact and (cost) effectiveness are part of IVI's work, it has been indicated that more effectiveness studies are needed to show impact and consequently help increasing the uptake of vaccines. IVI informs policy/guideline makers (WHO). Participation in immunization campaigns is one step beyond the usual scope of work of IVI and there has been no clear decision on whether IVI should focus on this. Some interviewees indicate that is highly important for advocacy purposes that IVI is involved.

## 8. Recommendations

Based on our conclusions we have postulated the following recommendations of which several are already under the attention of IVI.

- IVI should further increase the diversity in 'key' funders, especially in Asia. The Government of India as a new funder can be instrumental in this respect.

- IVI should aim to find new core funders. National ODA priorities should be considered to identify those countries that might be willing to contribute. Continued efforts can be made to get more signatory countries in High Income Countries though this requires considerable resources and will not lead to new funders on short term.
- IVI could aim to include overhead/core support in fees and applications for funding, although funders like BMGF have limitations on the level of indirect costs that can be included in grants budgets.
- To reach new funders, work on visibility especially for high income countries is needed. IVI can seek collaboration of the MoH and MOFA in this respect. They can propose IVI to be speaker in key-events. The 20th year anniversary has already been identified as an opportunity to increase visibility. Organization of parallel sessions in important conferences can also increase visibility.
- IVI could consider to specify one or two main area of expertise within the broad range of in house activities in order to assist strategic decisions on human resource investments. This area of expertise needs to be selected after discussing the niche with the Board of Trustees.
- IVI is recommended to continue efforts to make more use of IVI's location and collaborations with the government of ROK and also academic societies related to the vaccines or infectious diseases. IVI could attend high level meetings in ROK (such as the National Assembly) or related major academic meetings more frequently.
- IVI could investigate if the niche in Asia can be optimized considering the good regional contacts. This niche can be used to strengthen collaboration with other organizations like PATH who may have less contacts in the region.
- It seems important to clarify the role of IVI in public private partnerships for example in a "code of conduct" of how to transfer patents and how to select manufacturers.
- Improve communication to (country) funders by focusing more on output accomplished; language should be kept concise and in less technical terms (e.g. annual reports are too long);
- The internet presence of IVI can improve. An update of the website is planned. This update should, integrate the website better with the social media and assure that successes are claimed more strongly. Partners can be asked to show collaboration with IVI and joint successes on the web and social media.
- Consider engaging the alumni network via LinkedIn or Facebook. Alumni can be used to provide testimonials and to be ambassadors for IVI. The IVI communication department can thus easily keep track of their careers. When IVI staff travel they can visit alumni, and possibly get into contact with potential funders through them.
- Increase collaboration not only with WHO headquarters but also regional offices (WPRO, SEARO)
- Discuss with IVI's Board of Trustees whether involvement in vaccine delivery should be increased. In relation to this it is important to increase collaboration with GAVI, UNICEF especially on vaccine delivery. It would be good to explicitly invite them to the Board of Trustees again.
- Business cases for new products or improvements in existing products can be developed. These should be short, max 4 pages. These 4 pagers can be used when visiting potential donors.
- While involvement of IVI in small scale impact studies provides a clear opportunity to highlight success, a stronger claim on the impact of IVI can be made larger impact studies are conducted and end-users of the vaccinations are approached to share their experiences.

## Annex 1 Methodology

A mixed method approach was used with a desk review as well as qualitative research and a site visit.

For the desk review documents were reviewed (annual and financial reports of IVI from 2010-15). Financial reports were compared and combined (see Annex 3) to see trends over the 5 year period. The IVI website was analyzed as well as other presence of IVI on the internet and social media.

Semi structured Interviews were held with key stakeholders of IVI (see table below). Interviewees were sent a list of topics for discussion before the interview. Interviews were mostly held via phone, with the exception of some of the stakeholders in ROK which were interviewed face to face.

In the analysis results from the various methods were compared for triangulation purposes.

<b>IVI</b>	<b>Function workplace</b>
Mr. Jerome Kim	Director
Mr. Phil Driver	Deputy Director General, Finance & Administration
Mrs. Deborah Hung	Head PR & Communication
Mr. Kyung-Taik Han	Deputy Director General, Government Affairs & Governance
<b>Funders</b>	
Mrs Becky Frank	Deputy director, Strategy Planning & Management for the Enteric & Diarrheal Disease (EDD) and Pneumonia teams. Bill and Melinda Gates Foundation
Mr Duncan Steele	deputy director and strategic lead for enteric vaccines in the Enteric and Diarrheal Diseases team
Mr Park	Korea Support Committee
Mr Cho	Korea Support Committee
Mrs Ros-Mari Balow	Senior Policy Specialist, Research, Sida
<b>Others</b>	
Mr A Embrechts	the Netherlands's Ambassador to the Republic of Korea
Mrs Anne Höglund	Sweden's Ambassador to the Republic of Korea
Mr Choi Won Seok	Ministry of Foreign Affairs
Mrs Youngmee Jee	Director, Center for Immunology and Pathology; National Institute of Health, ROK Center for Disease Control and Prevention

## Annex 2 Funding patterns and expenses 2012-2016

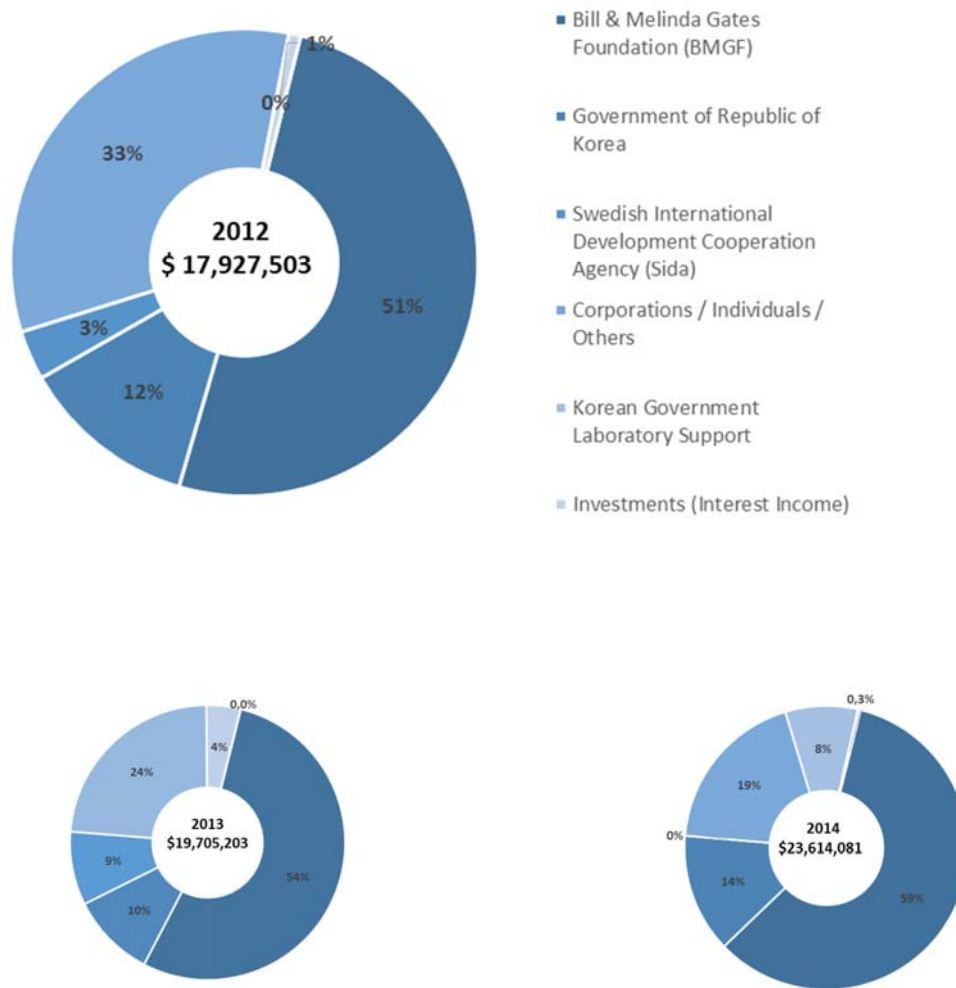
Income (in USD)	2016	2015	2014	2013	2012				
	<i>Estimate</i>								
Bill & Melinda Gates Foundation (BMGF)	12,380,328	59%	13,915,719	59%	10,591,248	54%	9,076,267	51%	
Government of Republic of Korea	3,631,659	17%	3,192,405	14%	1,967,362	10%	2,193,155	12%	
Swedish International Development Cooperation Agency (Sida)	720,420	3%	0	0%	1,705,861	9%	616,313	3%	
Corporations / Individuals / Others	3,095,397	15%	4,485,623	19%	4,647,797	24%	5,897,021	33%	
Korean Government Laboratory Support	1,294,612	6%	1,947,422	8%	785,428	4%	0	0%	
Investments (Interest Income)	35,005	0%	72,912	0%	7,507	0%	144,747	1%	
<b>Total Revenue</b>	<b>26,100,000</b>	<b>21,157,421</b>	<b>100%</b>	<b>23,614,081</b>	<b>100%</b>	<b>19,705,203</b>	<b>100%</b>	<b>17,927,503</b>	<b>100%</b>

Expenditure (in USD)	2016	2015	2014	2013	2012				
	<i>Estimate</i>								
Salary & Benefits	9,053,946	41%	9,598,353	38%	10,112,423	48%	9,364,796	42%	
Travel Expenses	1,389,379	6%	1,602,546	6%	1,886,246	9%	1,904,705	8%	
Service Expenses	3,095,570	14%	1,516,123	6%	1,659,556	8%	2,384,249	11%	
Sub-Awards	4,455,317	20%	7,574,634	30%	4,118,507	19%	5,021,951	22%	
Supplies	1,792,696	8%	2,657,627	11%	1,395,786	7%	1,358,633	6%	
Building Expenses	1,560,228	7%	1,663,046	7%	1,589,226	7%	1,721,169	8%	
Deprecation Expenses	237,282	1%	258,110	1%	360,171	2%	460,413	2%	
Other Costs	250,208	1%	199,954	1%	103,265	0%	211,034	1%	
<b>Total</b>	<b>25,200,000</b>	<b>21,834,624</b>	<b>100%</b>	<b>25,070,394</b>	<b>100%</b>	<b>21,225,180</b>	<b>100%</b>	<b>22,426,950</b>	<b>100%</b>
Net foreign exchange gain	200,000	-480,939	-778,584	-52,373	78,360				
<b>Net surplus</b>	<b>1,100,000</b>	<b>-1,158,141</b>	<b>-2,234,896</b>	<b>-1,572,350</b>	<b>-4,421,087</b>				

Unrestricted Revenue	2016	2015	2014	2013	2012				
	<i>Estimate</i>								
Government of the Republic of Korea	3,631,659	80%	3,192,405	93%	1,967,362	48%	2,193,155	64%	
Sida	720,420	16%	0	0%	1,705,861	41%	616,313	18%	
Korean Support Committee for IVI	115,437	3%	140,805	4%	250,173	6%	349,361	10%	
Government of the Republic of Korea: Laboratory equipment support	18,669	0%	51,071	1%	106,829	3%	165,742	5%	
Donation from Fund Raising	44,483	1%	30,653	1%	91,259	2%	81,246	2%	
IVI Shop	2,067	0%	3,594	0%	2,770	0%	0	0%	
<b>Total unrestricted</b>	<b>6,200,000</b>	<b>4,532,735</b>	<b>21%</b>	<b>3,418,528</b>	<b>15%</b>	<b>4,124,254</b>	<b>27%</b>	<b>3,405,817</b>	<b>24%</b>
<b>Restricted Revenue</b>									
multiple projects	19,800,000	16,573,823	79%	20,094,062	85%	15,559,664	79%	14,287,249	81%
<b>Total revenues (excluding interest income and miscellaneous)</b>	<b>26,000,000</b>	<b>21,106,558</b>		<b>23,512,590</b>		<b>19,683,918</b>		<b>17,693,066</b>	

Note: Unrestricted funding from KSC is decreasing over the years, but restricted funding has been increasing resulting in similar total revenues in the past few years.

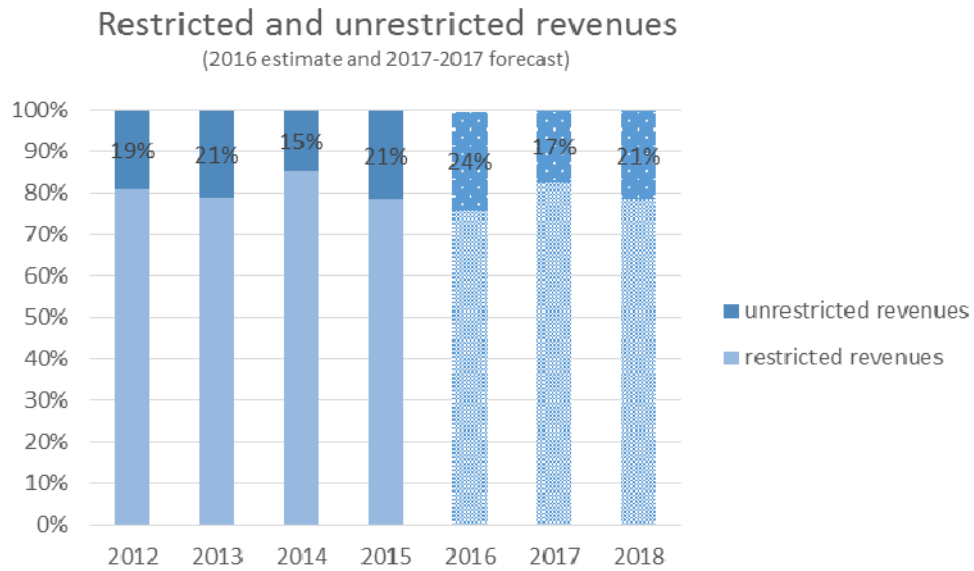
## Annex 3 Sources of revenues 2012 to 2014



Source: The International Vaccine Institute. Financial Statements 2011-2015; Finance update (Board of Trustees, February 2017). The distribution is based on sum restricted and unrestricted revenues as defined in financial reports and does NOT include revenues from categories interest and miscellaneous.



## Annex 4 Trend IVI's restricted and unrestricted revenues since 2012



## Annex 5 Terms of Reference for a study on sustainability of the activities of International Vaccine Institute, Seoul

Date: September 13, 2016

Case number: 14/000465

PLANit: 5410047

### Background

The establishment of the International Vaccine Institute (IVI) in Seoul, Republic of Korea in 1997 was preceded by an extensive process initiated by the United Nations Development Programme (UNDP). The preamble to the constitution of IVI states that the institute is founded “on the belief that the health of children in developing countries can be dramatically improved by the development, introduction and use of new and improved vaccines, and that these vaccines should be developed through a dynamic interaction among science, public health, and business.”

The institute has a unique mandate to work exclusively on vaccine development and introduction specifically for people in developing countries, with a focus on neglected diseases affecting these regions. IVI is unique also because of its involvement in several parts of the vaccine development spectrum – from preclinical development of existing vaccine candidates to vaccine development and evaluation in the field to facilitating sustainable vaccine introduction in countries where vaccines are needed the most.

Signatories to IVI’s Establishment Agreement today include the World Health Organization (WHO) and 35 countries - including Sweden, a signatory country since IVI’s inception. The main financial contributor to the running costs is the Government of the Republic of Korea, which funded building of the institute premises and today contributes with some 17 per cent of the total budget.

Financial contribution from Sweden, channelled by Sida was initiated in 2002. So far, the total amount agreed by Sida is 90 million SEK (2002 – 2019). In line with Sida’s preferred mode of support, the support to IVI is provided as core funding, based on the assumption that core support enables organizations to better develop their strengths and to direct resources in line with the their own strategies.

The main funder in terms of project support is currently the Bill and Melinda Gates Foundation and, very recently Samsung (earmarked for MERS vaccine development).

IVI was evaluated in 2006 by a team assigned by Sida (Sida Evaluation 07/09, The Relevance and Future Role of the International Vaccine Institute (IVI) 2000 - 2006). The scope of this evaluation was to “focus on future direction and management of the programs resulting in concrete and realistic recommendations, especially regarding program activities, interaction/collaboration with other key stakeholders in the area of vaccine research.”<sup>1</sup> One of the main conclusions from the evaluation was that “IVI has shown impressive growth and is well on track in relation to its stated mission and aims.”

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<sup>1</sup> Terms of Reference for the evaluation of the International Vaccine Institute (IVI) to be done 2006

To this was added a number of recommendations regarding the orientation of IVI's work. Most of the recommendations from the evaluation as regards the scope of the IVI activities have been acted upon by IVI.

From 2011 to 2015, the Institute went through a dramatic transition period with changes in its leadership, governance, strategy, and structure. This was in response to stakeholders' concerns about the organization's governance, systems, transparency, strategic prioritization and project management. At the same time, financial sustainability became more of a priority for the organization due to changes in relationship dynamics with its stakeholders and in the funding landscape overall.

In 2015, with the appointment of the third Director General of IVI, Dr Jerome Kim, IVI started a process to develop a new organizational strategy. This major overhaul resulted in a new organizational structure (effectuated by a new executive leadership), an expectation for a better alignment between IVI's future project activities and the overall strategy, and that resource levels are set to match strategic needs.

The new strategy, implemented from 2016 articulates the mission statement of IVI as: "Discover, develop, and deliver safe, effective and affordable vaccines for global public health". The renewed focus of IVI is on diseases where the institute has over the years gathered expertise and broad knowledge: cholera, typhoid, dengue, hepatitis E and more recently MERS.

Against this background combined with that the implementation of the new strategy started only in 2016 it appears less appropriate to evaluate the outcomes of these parts of the work by IVI. There might however be a need to carry out a study on how to enhance the sustainability and visibility of the IVI work is by Sida assessed as justified in its own right and would be valuable for the planning of possible future support from Sweden.

### **Purpose of the study**

The overall aims of the current study is to take stock of IVI's achievements, to identify possible means to augment the impact of these achievements, as well as to provide an objective measure for potential funders to inform their future investment decisions.

This implies that the study should focus on issues related to enhanced sustainability in terms of funding, the effectiveness of the external communication and dissemination of results and possible ways to increase the demand for the IVI services.

### **Aspects to be addressed**

**The following issues and questions should be addressed by the team:**

#### Achievements

1. Summarize main achievements (three to five examples) from any of the areas of activities of IVI (Vaccine Discovery and Design; Vaccine Development; Research to Generate Evidence for Policy) from the start of the institute to 2016 (Output level). To each example should be

added a brief description on how the achievement has been made use of (Outcome level) and contributed to the overall goal of IVI (Impact level);

2. Give a brief overview of IVI's Public-Private-Partnerships that include EuBiologics, SK Chemicals, and Incepta Vaccine and are financed by the core funders (Sida and Republic of Korea) and the Bill and Melinda Gates Foundation.

#### Funding

3. Summarize the funding patterns for IVI over the period 2012 – 2016 in terms of source of funding and type of support (earmarked project support versus core funding);
4. Interview the main funders (Bill and Melinda Gates Foundation, Government of the Republic of Korea (Ministry of Health, Ministry of Foreign Affairs) and Sweden/Sida) with the aim to understand their policies as regards earmark funds versus core funding;
5. Interview representatives of the Government of the Republic of Korea about their view on its role as the host country of IVI in terms of obligations and expectations.
6. What is IVI's and the current funders' view on the reluctance by countries and funding organisations to support IVI?
7. Possible conflict between increased project funds (earmarked for a particular disease) and the research agenda if funders were not earmarking funds: Discuss the pros and cons for these two types of funding, taking into consideration the overheads paid by core funders versus project funding.

#### Uptake of research findings/products

8. EuBiologics is the second world producer of the low-cost cholera vaccine and has capacity to further increase the production. Still the demand from cholera endemic countries for the vaccine is much below the actual needs. Discuss what should be done by IVI, the funding agencies and other actors to raise the demand by cholera endemic countries.

#### Collaboration with other actors

9. IVI works close to the private sector for the large-scale production of vaccines for global health. In which way can this be utilized to enhance funding to the institute?
10. International organizations like UNICEF, GAVI, International Coordination Group (ICG) on Vaccine Provision: How will opportunities for collaboration be exploited?
11. Relation to Global Vaccine Action Plan 2011 – 2020 (GVAP): Is IVI involved in the GVAP activities and if so, in what way?

#### Communication

12. Communication strategy: Are there plans to produce a communication strategy align with the new strategy? If so, which target groups are prioritized?
13. Given the risk that IVI's reputation has been tarnished due to the recent leadership turnover, how is or will the communication from IVI addressing this issue?
14. Information available from the website: Are there plans to improve the website, and if so with what kind of information? If found necessary, give suggestions on further improvements of the website, as well as other communication tools (for instance social media).

#### Intellectual Property Rights

15. How are issues around intellectual property handled?
16. What kind of training would IVI staff need to get a deeper understanding of these issues?

### Other issues

17. Any other issue, identified by the consultancy team as relevant to the overall purpose of this study.

### **Delimitations**

As indicated in section 3. Aspects to be addressed, it is envisaged that the main focus of this assessment should be on sustainability issues and less on the IVI portfolio or the institute's internal management and structure. In case that these latter issues contribute to or counteracts the sustainability of the results produced by the institute such considerations should be made.

### **Approach and Method**

The study is envisaged to be carried out by:

- Analysis of annual reports issued by IVI for the period 2011 – 2015;
- Analysis of financial reports issued by IVI for the period 2011 – 2015;
- Analysis of other relevant reports such as Strategic Reviews by BCG (2015) and Applied Strategies (2012);
- Interviews with representatives of Bill and Melinda Gates Foundation, Sida, and Korean Support Committee for IVI;
- Interviews with representatives of Ministry of Health and Welfare, Republic of Korea and Ministry of Foreign Affairs, Republic of Korea;
- Interview with Sweden's Ambassador to the Republic of Korea, Embassy of Sweden, Seoul.
- Any other organization or person deemed relevant to achieve the objectives of this study.

Interviews may be arranged for by video conference to limit travel time and costs, as well as environmental impact.

### **Time Schedule, Reporting and Communication**

#### Time schedule

The assignment shall be carried out during the first quarter of 2017. It is expected that the assignment will require four weeks to be completed (not including possible participation in an IVI board meeting to present main findings).

The assignment shall be initiated by a face-to-face meeting with Sida in Stockholm in order to further discuss in detail the objective and methods of the evaluation and to reach a common understanding of the scope of the study.

#### Reporting

A draft report shall be submitted to Sida after three weeks of work after which Sida will provide comments within two working days. The final report shall be submitted within one week after the comments by Sida have been received.

The final report, not exceeding 25 pages (excluding annexes), written in the English language, shall be provided as a Word file.

### Communication

The evaluation team should discuss with the management of IVI if a presentation to the IVI Board of Trustees of the findings and recommendations in the study should be made.

### **Resources**

The evaluation team shall consist of a minimum of two people. Ceiling amount for fees and reimbursable costs is SEK 450 000, excluding VAT.

### **Team Qualification**

The team should, apart from general competence to conduct evaluations also include documented basic knowledge on vaccinology and general knowledge about the main actors in the global vaccine landscape. Basic knowledge about Intellectual Property Rights is desirable.

The evaluators must be independent of the activities of IVI and have no stake in the outcome of the study.

### **Appendices**

1. Evaluation report "Sida Evaluation 07/09 - The relevance and future role of the International Vaccine Institute (IVI)"
2. Applied Strategies (2012)
3. Strategic Review by BCG (2015)