## Accelerating Innovation and Access in Global Health Technologies ~The Latest Progress in the Fight against Infectious Diseases~

Date: 25<sup>th</sup> February 2019, 9:00~17:15 Venue: Mitsubishi UFJ Research and Consulting

## **Executive Summary**

"It's not just the product innovation that's taking place, it's the partnership innovation that I think is especially promising." —Mark Feinberg, President and CEO, IAVI

#### Co-organized by

Mitsubishi UFJ Research and Consulting (MURC) Foundation for Innovative New Diagnostics (FIND) Global Health Innovative Technology Fund (GHIT) International AIDS Vaccine Initiative (IAVI) Coalition for Epidemic Preparedness Innovation (CEPI)







Global Health Innovative Technology Fund





#### **Opening Remarks**

The symposium began with opening remarks from David Heymann, Professor of Infectious Disease Epidemiology at the London School of Hygiene and Tropical Medicine and the Head of the Centre on Global Health Security at Chatham House. With the introduction of a newly published report by the G20 Health and Development Partnership called "Healthy Nations, Sustainable Economics: How Innovation can Better Ensure Health for All", Prof. Heymann spoke about the history and current situation of innovations in global health. Beginning with the immunization-related technologies of smallpox-eradication programs, more and more innovations have been realized since the 1980s. Now efforts are under way to create innovations in the diverse fields of global health preventive technology such as diagnostics, surveillance, and vaccines, and health care access and delivery in developing countries. In his speech, Prof. Heymann emphasized that investing in global health activities and promoting innovations are critical not only for developing countries but also for developed countries to achieve sustainable economic growth around the world.

#### Health is Imperative for Economic Growth

In 2001, a report was published from WHO Commission on Macroeconomics and Health that was set up by Gro Harlem Brundtland, former Prime Minister of Norway and then Director General of the WHO. The health economist Jeffrey Sachs, who headed the commission, clearly demonstrated in the report that "healthy populations promote economic growth more rapidly." At the same time, the report disproved the idea that good health could be achieved automatically through economic development—as was the case in many industrialized countries. Therefore, governments and donor organizations should implement specialized policies to improve the health conditions of people in developing countries.

#### Top 3 Priorities to Promote Innovations in Preventive Technologies

The following are often mentioned as the most important priorities to promote innovations in preventive technologies: first, getting available and effective preventive technologies to those in need through creative financing mechanisms; second, developing commercial and other incentives to expand the development pipelines for these technologies; and third, creating an environment conducive to the maximum uptake of newer technologies where they are needed.

#### **Toward Well-balanced Aid: Finance and Health Impact**

Donor countries, including those in the G20, must maintain a proper balance between financial costs and health impacts when providing health-related aid to developing countries. Moreover, recipient countries should not become dependent on that aid. Put another way, aid that helps recipient countries solve their health issues, with an attempt by recipient countries to match that aid with national funding and in kind support, will lead to more sustainable economic growth that benefits both recipient and donor countries.



Prof. David Heymann

# Session1 The Latest Diagnostics Technologies: Point-of-Care/Rapid Testing

Session 1 featured a panel of experts who made brief presentations on the organizations they represent, followed by a discussion on the latest trends and challenges in diagnostics development in the context of Global Health. The main themes that emerged from the discussion are summarized below.

#### **Need for Comprehensive Diagnostic Solutions**

In the case of infectious diseases, diagnostic testing is the first step, but there are many challenges around a testing strategy which is based on laboratory testing using instrumentation-based testing. For example, a survey conducted by the Global Fund found, among other problems, that much purchased diagnostic equipment remains uninstalled, maintenance is lacking or of poor quality, and there is lack of training. Point-of-care (POC) diagnostics with a minimal requirement for laboratory instrumentation, and rapid testing technologies which are more or less instrument-"free", however, can address some of these challenges and help enable access in remote (i.e. non-laboratory based) areas.



Prof. Osamu Kunii



Prof. Etsuro Ito

One example of a novel technology presented by TAUNS, in diagnostics of TB is testing using serum and ultrasensitive ELISA for a biomarker. This method is designed to overcome many of the drawbacks of culture testing, which is considered the gold standard but takes significant time and requires high level facilities to control contamination and highly trained technical staff. Furthermore, with the emergence of new infectious agents and co-infections, there is also an increasing need for multiplex testing for differential diagnosis and selection of the appropriate therapeutic response.

With the advancements in POC and rapid testing, however, it is no longer sufficient to focus just on the development of new and easier-to-use technologies. In addition, we must address all aspects of not only development, but also of implementation into the settings of intended use, including all aspects of; financing, supply chain, quality assurance, training, policy and regulatory guidance, and impact measurement. For example, the lack of clear regulatory paths for multiplex testing was noted as a new challenge to the implementation of such products.

#### **Pre-Market Commitments and Market-Shaping**

Participants pointed out that market shaping is critical. A suggestion was made that a Gavi-like mechanism for diagnostics could be established to guarantee a pre-market commitment for needed diagnostics. There is a perception that diagnostics should be available at a low price, commonly considered less than \$1 in the case of a POC/RDT technology. However, as further discussed, the manufacturing cost is inevitably one piece and not necessarily the main piece of the end-user cost. Manufacturing is but one part of the equation which has to include also, distribution, training service and support, even if the technology is simple to use at the end-user level, these costs are still there. Another misconception is that the technological challenge in the development phases for an NTD should be simpler than for any of the major prevalence

diseases like TB and HIV. In reality, dependent on the market maturity of the IVD technology in question, the fundamental scientific and technical work to develop a HIV test and a Sleeping Sickness test is the same. This in turn result in a required R&D investment, which, without donor funding is a very difficult proposition for a commercial company, where the potential market is not of the order of HIV/TB, so is unattractive as an investment.



In addition, in order to create a market, people must "need" the product, not merely "want" it. In order to ensure "need," however, the product has to suit the patient's experience. This is why the Global Health community

Mr. Javan Esfandiari

has recently spent considerable resources in the development of the Target Product Profiles (TPPs) to guide the development investments of commercial companies and donor investments.

Furthermore, it is also important to improve existing infrastructure instead of continually bringing out new products and technology. Capacity building at all levels, including ability to project local market needs, should be part of a comprehensive solution.

#### **Overcoming Challenges in Going the Extra Mile**

Panelists shared common obstacles in reaching people in developing countries and going the "extra mile." A key requirement is to establish local incountry partners who are trained properly and to put in place a comprehensive maintenance solution that suits local conditions. Building resilient and sustainable systems for health is the approach the Global Fund takes to ensure delivery of diagnostics to people who need them.

Post endorsement by agencies like the WHO, local regulatory requirements and country approval and registration are also bottlenecks when a country



Dr. Ranald Sutherland (left) and Mr. Christian Becker (right)

requires additional testing for its approval of a novel product. Such costs can be prohibitively high especially in the light of addressing the needs of the LMICs. As such, small players who may have innovative and useful IVD solutions do not have the capacity to address more than local/regional activities, unless they can partner with a major commercial and global partner which again begs the question of the commercial attractiveness of such a venture. To overcome these obstacles, at a local level, countries must make political commitments to ensure product availability, and donors must make funding commitments to contribute not only to R&D costs but also to help countries access and implement new products.

#### Session 2

## The Advent of New Technologies and their Contribution to Global Health Surveillance

In Session 2, panelists from startups that utilize AI and other digital technologies in healthcare solutions such as surveillance and early detection, along with panelists from government, NPOs, and academia, introduced the latest solutions in their respective fields. Next, the panelists shared some of the challenges they faced while introducing these preventive technologies and how they overcame (or are working to overcome) these difficulties.

#### **Digital Technologies for the Effective Allocation of Limited Resources**

The limited human and material resources of developing countries must be taken into account when considering how to solve their health issues Digital technologies have the potential to allocate these limited resources more effectively by collecting and analyzing various types of information. For example, AIME's AI system analyzes the current status of the dengue outbreak in a particular area along with other related data, such as meteorological conditions, to predict how the outbreak will expand over the following 3 months at the street level. The results are used when deciding where to allocate resources



Mr. Guido Geerts

to minimize the harm. Also, Delft Imaging Systems has an early diagnostic solution called "CAD4TB" that uses Al to analyze a chest X-ray image to calculate the probability of tuberculosis infection on a scale from 0 to 100. If the score is relatively high, the patient proceeds to a more detailed examination. By functioning as a kind of triage, CAD4TB helps reduce the overall time and cost needed to diagnose tuberculosis. In addition, AfriMedico, which introduced the Japanese *okigusuri* system to Tanzania, uses Al-driven image authentication to calculate medicine stocks in each household; this resulted in a drastic reduction in the time needed to manage medicine stocks compared with the traditional method of visual checks.

#### **Data Availability and Publication**

One of the biggest difficulties in developing and introducing digital technologies is ensuring access to data. Health records are often difficult to access due to privacy concerns. Data stored on government systems cannot be used by solution providers in many cases. Dialogue is essential in such cases to convince the government of the effectiveness of digital solutions. At the same time, it is important to improve the availability of non-personal data that are necessary for controlling infectious diseases, such as meteorological and environmental data.



Dr. Helmi Zakariah

Those involved with public health management often face

a lack of data on diseases that are common in developing countries. In such cases, data may be collected through pilot projects to improve the quality of the digital solutions.

In addition, we must determine the best way to publish information obtained through these solutions in order to

promote health awareness and change people's behavior. For instance, the state of Penang in Malaysia introduced a smartphone app called "The Big Dengue App" to disseminate information about the outbreak of dengue to the public. Users receive a notification if they enter an outbreak zone to raise their awareness of the risk.

#### A Multidisciplinary Approach Is Necessary for Expanding Digital Technologies

To utilize digital technologies effectively, society must accelerate its adoption of these technologies through constant communication between various actors, as well as scale up the impact of technology through collective learning across different sectors. As an academic institution that plays a role in bringing together various stakeholders, Institut Pasteur has established an "all-in" consortium for dialogue that includes the private sector. It has become clear through this dialogue that technology providers from the private sector often underestimate the problem of limited resources in developing countries. In order to close these gaps in recognition, the institute believes that a broader societal approach should be taken in addition to the direct approach aimed at specific stakeholders.

On the policy side, government officials must become accustomed to new technologies and patiently wait for these technologies to produce positive results. At the same time, it is important to design technological solutions that are simple and easy to implement at the community level.

In addition to deepening the mutual understanding between stakeholders, a mechanism with a funding system must be established to accelerate innovations in the relatively new area of digital health. Resources such as medicine, vaccines, and IVDs (in vitro diagnostics) already have the PDPs (product development partnerships) and other support systems in place which have yet to be seen in the field of digital health. These schemes are also critical for cultivating the seeds of future innovations.



Discussion with the audience

### Session 3 The Latest Innovations in Vaccine Research and Development

Session 3 featured panelists from global partnerships on product development, a major private sector player, and a clinical researcher on the ground in Africa. The experts shared their insights from their varied perspectives working in vaccine research and development. The main topics that emerged from the panel discussion as well as in the exchanges with the participants are summarized below.

#### **Beyond Single-Disease R&D**

One common thread in the discussion was how the various fields of vaccine development are increasingly merged. IAVI, which was established decades ago specifically to advance research in HIV vaccines, has recently expanded its mission to leverage their capabilities in other disease areas and biomedical interventions. For example, IAVI has entered the tuberculosis vaccine sphere and is pursuing programs to make monoclonal antibody technology more accessible in low-income countries. This expansion is built on the expertise and capabilities that IAVI has developed over the years working



Dr. Mark Feinberg

on HIV. Similarly, KAVI, which has built impressive clinical trial sites in Kenya for HIV vaccine candidates, has begun offering their services to studies and trials for other diseases, most recently Ebola. CEPI, a global public-private partnership that emerged from the Ebola crisis, pursues as one of their strategies the development of vaccine platform technology on which a vaccine for even a new pathogen - known as "pathogen X" by WHO - can be built.

#### Partnership, Partnership, Partnership

Panelists unanimously agreed that collaborative partnerships between public- and private-sector actors are the only path to advance global health R&D. For partnerships to be fruitful, however, it is critical that partners have a clear understanding of each other - their strengths as well as limitations. Development of a vaccine is such a complex enterprise that private sector expertise is essential. Yet, there is a lack of understanding about the opportunity cost for a private company to take on the development of a vaccine for which there is no commercial market. Companies have demonstrated their willingness to contribute to Dr. Gaudensia Mutua (left) and Dr. Rajeev Venkayya global health crises, such as the recent Ebola outbreak, but external



(right)

assistance quickly disappears once the outbreak dissipates. Companies need public-sector partners to "de-risk" the program so that they can allocate resources to global health R&D. For example, Takeda's program on Zika virus cannot happen without public funding, and CEPI is built on lessons from Ebola to ensure "de-risking" for private companies. Partnerships may expand beyond just government and private companies to communities and community organizations. KAVI's enlistment of community involvement to advance Ebola virus vaccine clinical trials provides a helpful example of such a partnership.

#### **Rebuilding Trust in Vaccines**

A concern was raised about persistent misconceptions of vaccine safety and growing resistance to vaccination. The recent incident in the Philippines around dengue vaccine and the subsequent drop in the vaccination rate for routine pediatric immunization was cited as an example of how quickly trust in vaccines can erode with serious consequences. It was suggested that one way to combat such mistrust is to be completely transparent about the data from clinical trials as well as post-market surveillance. And as global organizations like CEPI and IAVI take on more programs, robust oversight function within organizations is critical.

#### **Ensuring Access**

The panelists devoted some time to discussing ways to ensure access to new vaccines and other medical interventions. An effective model that has been in place for many global public-private partnerships is to offer the product to developing countries at an appropriate cost, while commercializing it in more resource-rich countries. Such tiered pricing may work well, and companies should not be afraid to make such pricing transparent. The challenge of access is not limited to pricing but is also about acceptability by end-users. People would not adopt a product if it did not meet their needs, even if it were affordable. An example of the first generation of pre-exposure prophylaxis (PrEP) was cited as a lesson. To this end, it is important to understand end-users' needs and incorporate them in the process from the very early stages of R&D. KAVI said they now use social-behavioral research to build knowledge about end-users, and IAVI and CEPI are also maintaining "line of sight" on what end-users ultimately want.

#### Linkage between Diagnostics and Vaccine Development



Ms. Anita Kawatra (left) and Dr. Frederik Kristensen (right)

In line with the overall theme of the symposium, the potential of creating synergy between diagnostics and vaccine research was discussed. Development of assays for vaccine research could have application in developing diagnostics. In pursuing its mission to develop vaccines, CEPI realized that better diagnostics and assays are critical, and the development of those technologies cannot be done in isolation. A similar example was found in the TB space where diagnostics for latent TB were necessary for a TB vaccine trial. There is a growing recognition of the benefit and potential for R&D for diagnostics and vaccines to merge, and this could become a reality as the field of global health continues to mature. It was suggested that advancing better diagnostics

also contributes to better surveillance, which is critical in policy decisions around introduction of new vaccines and therapeutic interventions.

#### **Untapped Potential**

The concluding remarks included appreciation for the leadership of the Japanese government in global health and the call for Japanese stakeholders to engage in the "new era" of global health. KAVI invited the Japanese partners to explore the untapped potential of the research community in Africa. An anecdote was shared that highlighted how young people are much more comfortable working across sectors, and with fewer biases. In short, there is a great hope for the new generation of future leaders to continue to advance the field.

### Session 4 Ensuring Access and Delivery in Low- and Middle-Income Countries

Session 4 featured a panel of experts who discussed improving access and delivery in global health from a variety of viewpoints from the policy level, which includes international organizations and research institutions, to the ground level, where work is being done to develop and deliver necessary products and services. At the beginning of the session, Prof. Rosanna Peeling from the London School of Hygiene and Tropical Medicine (LSHTM) highlighted the 5 A's of access and delivery in global health—affordability, accuracy, accessibility, availability, and architecture—and the panelists shared their insights related to these key words. The main message from this session was that both innovators and those involved with access and delivery must work together to move the innovation process forward.

#### Promote Private Sector Development to Improve Access and Delivery



Panel discussion

These days, utilization of private sector innovations and product development capabilities is becoming increasingly widespread in the global health community to improve access and delivery. Prof. Peeling has established an International Diagnostics Centre at LSHTM to provide a neutral platform for public and private interactions and promote dialogue between stakeholders, including private companies, on diagnostic technologies and related policies. GHIT invests in product development for global health solutions through public-private partnerships. Fujifilm developed a urine-based

tuberculosis diagnostic kit under this scheme and is in the process of applying for a WHO endorsement. Another example is Gavi, which started a 5-year strategic plan in 2016 to collaborate with the private sector. They are working together with large companies on the logistics, cold chain management, and ICT necessary for the delivery of vaccines, as well as with small and medium-sized enterprises operating in developing countries.

#### **Deliver to Those Truly in Need**

In order to get resources to those who truly need them, reforms in the legal system and social infrastructure may be required in addition to technological innovations. Based on his experience with public procurement reform in Ukraine, Mr. Bryan Richmond from Crown Agents emphasized the importance of designing a transparent procurement system that takes the local social, political, and economic context into account for effective delivery. It is important to develop a logistics network within target countries that involves customs, transportation, and stock management.



Mr. Bryan Richmond

Furthermore, stakeholders must clarify in advance what kind of products are needed and how they should be

tested by establishing target product profiles or standardized protocols. Doing so makes it possible to simplify the process of approving new medical technologies and would be a great incentive for the private sector. The idea of "regulatory harmonization" is so critical that the National Center for Global Health and Medicine (NCGM) in Japan has held seminars on Japanese regulations and systems of medical devices in collaboration with the Pharmaceuticals and Medical Devices Agency (PMDA) for stakeholders from the African authorities related to medical devices. NCGM also provides trainings for the stakeholders to maintain integrity in this field between WHO and Japan. By harmonizing regulations between Japan and Africa, NCGM is striving to create an environment in which Japanese companies can more easily enter the African health care market.

To effectively use new technologies in the healthcare operations of developing countries, it is important to get the local community involved, adjust technologies for the local market, obtain the understanding of CSOs and community leaders, and train healthcare workers how to use the technology.

#### **Innovation for Financing Mechanisms**

Innovations are required not only in the development of new products and information systems but also in the financing mechanisms that support innovations. Generally, government agencies in many developing countries have limited budgets, which often makes it difficult for them to invest in the health care sector.

As a driver of innovation, the private sector is also faced with a dilemma. While aiming to offer affordable prices to developing countries by minimizing the per-unit cost through mass production, these companies often struggle to set up the sales channels for their products that are necessary for a sustainable business model.



Mr. Teruo Takahashi (Second from the right)

Under these circumstances, Gavi is concerned that innovations tend to stop along with the end of initial aid from a donor. They determined that investing at the scaleup stage is key for innovators, particularly small-scale innovators, to continue their work from the idea, through the pilot, and ultimately to scale-up. As a result, Gavi launched a unique program called "INFUSE" that aims to create an eco-system of continuous support from various stakeholders to nurture the seeds of innovation until they successfully bear fruit.

#### **Closing Remarks**

As the closing of this one-day symposium, Dr. Yasuhiro Suzuki, Chief Medical & Global Health Officer and Vice-Minister for Health at the Ministry of Health, Labour and Welfare (MHLW) of Japan, delivered comments on the sessions. He observed that the symposium had been a valuable experience, driven by meaningful discussions between panelists and participants, and he expressed his appreciation to the five host organizations – MURC, FIND, GHIT, IAVI, and CEPI. Furthermore, he promised that the Japanese government would continue to support efforts to deliver the benefits of preventive technologies and other innovations to those most threatened by infectious diseases in developing countries.

#### Infectious Diseases Cannot Be Overcome by Individual Efforts

For example, CEPI, one of the host organizations, was jointly launched by Norway, Germany, the Bill & Melinda Gates Foundation, and Wellcome Trust, and Japan has just announced its partnership with the University of Tokyo to develop a vaccine against the Nipah virus. CEPI is also supporting the development of a Lassa vaccine by IAVI, another host organization, as well as the expansion of FIND's Lassa fever response program. In addition, FIND and Fujifilm Corporation are collaboratively developing a highly sensitive rapid tuberculosis diagnosis kit with support from GHIT.

#### Japan Continues to Support Global Health Activities



Dr. Yasuhiro Suzuki

Japan continues to actively support these invaluable efforts toward developing preventive technologies and innovations to overcome infectious diseases. To make the world safer for everyone as quickly as possible, I would like to enhance our participation in these efforts by utilizing the ideas and networks developed through this symposium.

#### **Program and Speakers**

#### 9:00-9:25

#### **OPENING SESSION**



## Satoshi Murabayashi

President, Mitsubishi UFJ Research and Consulting

Satoshi Murabayashi started his career as a banker at the Sanwa Bank. Under the period of financial reconstruction, he devoted his effort to digitalization of the Mitsubishi UFJ Financial Group mainly at the system department. After serving as Senior Managing and Executive Officer and Group CIO, he has been appointed to the President of Mitsubishi UFJ Research and Consulting since June 2017. Currently in his position, he engages in the management of a think-tank/ consulting firm especially to provide various solutions toward the transformation to a digital society which utilizes technologies

such as AI and IoT. He made an MOU with Stop TB Partnership to support development of innovation to deal with tuberculosis including the issue of antimicrobial resistance (AMR).

He is also a member of Digital Government Sub-Committee by the Cabinet Office.



#### David Heymann

#### Head and Senior Fellow, Center on Global Health Security, Chatham House

David L. Heymann is Professor of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine and Head of the Centre on Global Health Security at Chatham House in London. Previously, he was WHO's Assistant Director-General for Health Security and Environment and Executive Director of the WHO Communicable Diseases Cluster where he led the global response

to SARS. Before WHO, Prof Heymann was a medical epidemiologist in sub-Saharan Africa, on assignment from the US CDC. Here he participated in the first and second outbreaks of Ebola.

He is the recipient of a number of public health awards, including the Heinz Award on the Human Condition. He has over 200 peer reviewed publications, commentaries and book chapters and is the editor of the Control of Communicable Diseases Manual. In 2009, Prof Heymann was appointed an honorary Commander of the Most Excellent Order of the British Empire (CBE) for service to global public health.

#### 9:25- 11:05 SESSION 1: The Latest Diagnostics Technologies: Point-of-Care/Rapid Testing



#### Christian Becker

#### Vice President Sales, HUMAN

Christian Becker is Vice President Sales and Member of the Management Board of HUMAN Diagnostics in Wiesbaden, Germany. Joining HUMAN in 2011, he is managing and controlling the operations of the International Sales Department and monitoring the global distribution network comprising of 220 distributors in 160 countries.

For more than 20 years, his work has focused on establishing and supporting international sales and distribution channels and implementing ODA projects in LIMCs for medical devices. Based on

his expertise, HUMAN successfully administered ODA projects and became LTA holder for different NGOs and UN entities.



#### Osamu Kunii

Head, Strategy, Investment and Impact Division, The Global Fund to Fight AIDS, Tuberculosis and Malaria

Osamu Kunii (M.D., M.P.H., Ph.D.) serves the Head of Strategy, Investment and Impact Division of The Global Fund to fight AIDS, Tuberculosis and Malaria, which has 5 departments including Strategic Information; Technical Advice and Partnership; Technical Evaluation Reference Group Secretariat.

He has worked more than 25 years of experience in global health, especially emergency response, maternal and child health, infectious diseases control, health systems, health policy and diplomacy. He also served as Deputy Director of Aid Planning Division in the Japan Ministry of Foreign Affairs; a professor of global health at Nagasaki University, Research Institute of Tropical Medicine; Senior Advisor at UNICEF headquarters and a chief of health programme in UNICEF Myanmar and Somalia.



#### Javan Esfandiari

Executive Vice President and Chief Science and Technology Officer, Chembio Javan Esfandiari has 27+ years-experience in point-of-care testing, including 20 years at Chembio. Previously, he co-founded Sinovus Biotech AB a Swedish Biotech Company 1993 and joint venture On-Site Biotech with Swedish National Veterinary Institute.

In Chembio, he developed its infectious disease products, including 3 FDA-approved HIV tests, and invented DPP technology platform, including 15 issued U.S and corresponding international patents.

He also established multiple technology collaborations, including Brazil, Germany, Malaysia, and serves as principle investigator of multiple programs (e.g., BARDA, BMGF, FIND).

Author and co-author of 30+ scientific publications. B.Sc. in Clinical Chemistry and studied to M. Sc. Level in Molecular Biology from Lund University, Sweden.



#### Etsuro Ito

Professor, Department of Biology, Waseda University Advisor, TAUNS Laboratories Inc.

Etsuro Ito, Professor of Department of Biology, Waseda University, has developed an ultrasensitive ELISA that can be used for an early diagnosis for infectious diseases in collaboration with TAUNS

Laboratories. In particular, a culture-free and same-day test for tuberculosis using this ultrasensitive ELISA is now being established. In this system, the results can be obtained from only active tubercle bacilli within 4 hours at the same sensitivity as a culture test. Further, we are expanding our system to non-amplification nucleic acid detection system to overcome the drawbacks of PCR.

#### Moderator



#### Ranald Sutherland

Consultant for Technology and Business Development, Foundation for Innovative New Diagnostics Internationally experienced manager with a track record in operational process design and implementation, product and technology development and commercialisation; contract development, IP analysis and licensing agreements; alliance management and consulting with market-leading, market quoted, global healthcare corporations; and advisor to VC funds and specialist consultant to

biotechnology start-ups. Business focus on life sciences and in particular in vitro diagnostics. The past 10+ years working in the field of Global Health with FIND, with a focus on LMICs, the major public sector Donors and NGO's, for diagnostics projects in the fields of NTDs, malaria, TB and HIV, and HCV. Executed development and commercialisation projects for IVDs targeted to both HICs and LMICs.

#### 11:05-12:45

# SESSION 2: The Advent of New Technologies and Their Contribution to Global Health Surveillance



#### Helmi Zakariah

CEO, AIME

Dr. Helmi Zakariah was appointed as the Chief Executive Officer for AIME INC operation in Malaysia and Asia-Pacific region effective from January 2nd, 2018. With an extensive background and experience in the field of Public Health, Dr. Helmi was previously with Ministry of Health Malaysia. He

co-pioneered the establishment of Global Health Division which strategizes, coordinate, and oversees Malaysia engagement with global health entity such as the World Health Organization, ASEAN Health Secretariat, OIC, and others.

Dr. Helmi started off his career as a clinician in Seremban General Hospital and subsequently a community clinic in Selangor, before he embarked into Public Health as a program manager for National Tuberculosis Control Programme, where he established a new TB screening algorithm to increase screening uptake that is still being used state-wide. After completing his post-graduate training, he was tasked to form and oversee the Ministry global health policy and governance. In his capacity, he also pioneered and managed the Ministry strategic partnership with international NGO such as Medecins Sans Frontiers, Union of International Cancer Control, and the International Committee of Red Cross. He also has a special interest in Trade & Public Health, and was regularly consulted to analyze multilateral trade agreements and its impact on national health policy space. In 2014, he participated in the Joint United-Nations Initiative for Migration in Asia Steering Committee, for his academic and advocacy works in the area of migrant health. Dr. Helmi Zakariah holds a Medical Degree from Russian Federation, and a Master's degree in International Public Health from Liverpool, United Kingdom.



#### Afif Bahardin

#### State Health Minister, Penang State Government, Malaysia

Dr. Afif bin Bahardin is a Malaysian politician and currently serves as the state minister in Penang State Government as Executive Councilor for Agriculture & Agro-Based Industries, Rural Development and Health. He is also the elected state assemblymen for Seberang Jaya one of the state constituency in Penang. Fondly known as Dr Afif among his peers and party members, he

started as his career as medical doctor at Penang Hospital after completing his studies at University Teknologi Mara (UiTM). He also served as a medical officer in Otolaryngology Department at Hospital Sungai Buloh. Entering his second term as the state constituency assemblymen, the young politician is a progressive leader that emphasized youth empowerment in the country.



tuberculosis.

#### **Guido Geerts**

#### CEO, Delft Imaging Systems

Guido Geerts has 20+ years of experience in running multinational companies that deliver diagnostic imaging equipment and related software & services. Currently, Mr. Geerts is the President & CEO of Delft Imaging Systems, a company that provides diagnostic imaging devices & artificial intelligence solutions (CAD4TB) to National Tuberculosis Programs globally. Active in 35 countries and with offices in South Africa and Ghana, Delft's solutions have helped to screen over 3 million people for

Mr. Geerts is also CEO of Thirona, a company focusing on artificial intelligence in the field of the analysis of thoracic CT scans, chest X-rays and retinal images.

In addition, Mr. Geerts is the Co-Chair of the Data & Diagnostic workgroup of the Stop TB Private Sector Consortium and an active member of the Dutch Task Force Health Care.



#### Junna Kiriyama

#### Health Education Group, AfriMedico

Junna Kiriyama got interested in global health, particularly access to medicine during her student days. After graduating university, she works for the pharmaceutical company to engage in the unmet medical needs in Japan. In 2017, she joined AfriMedico as pro-bono, where her main role is health education. In September 2018, she visited the site in Tanzania to observe how the *okigusuri* system works there and discussed its business and operations with the site members and clinic doctors.

She is currently studying master's course at the School of Tropical Medicine and Global Health at Nagasaki University.



#### Mai Ban

Business Development Manager, Technology Transfer and Entrepreneurship Office, Institut Pasteur Dr. Ban (Ph. D.) has nearly 25 years of experience in the research of biotechnology (molecular biology, cancer metastasis) and in business (R&D strategy consulting, technology transfer) in Asia and Europe. In Institut Pasteur, she has become a first business development manager from non-French speaking country at Technology Transfer and Entrepreneurship Office, and is engaging in collaboration with external stakeholder to achieve the mission of the institute (Research, Health, Education and

Innovation).

#### Moderator



#### Michikazu Koshiba

Head, Center on Global Health Architecture, Mitsubishi UFJ Research & Consulting Around 15 years ago, he started his career in International Development and Humanitarian Relief fields as an INGO worker. Serving as a staff for disaster-affected community, the concept of "sustainability" and multi-stakeholder approach became the essential value for his career. Shaping his career as a consultant to dedicate his life to CSV(Creating Shared Values)-related business, especially on global health from the mid-2000s, he has worked with scores of established corporations and startups in Japan, as well as with the financial community, industry bodies, government, the media, NGOs, academia. His favorite description of his role: "nexus between conventional politics and one of the future"

Since 2016, He established an action-oriented P3 consortium called "Access to Health" where the members are focusing on how to make contribution to global health including Infectious Diseases, Nutrition, NCDs, Maternal and Child Health to build new partnerships, create new innovative projects/businesses/products, and mobilize resources and advocate policy changes for individual and global progress. Especially, the development and promotion of digital health technologies and access and delivery such as reform on public procurement mechanism are currently key projects.

Now he is playing a role as a facilitator and coordinator for various stakeholders, working as the HEAD, Center on Global Health Architecture, MITSUBISHI UFJ Research and Consulting Co., Ltd. He is also serving an advisory council member for Global Digital He@lth Initiative2030.

#### 13:45-15:25 SESSION 3: The Latest Innovations in Vaccine Research and Development



#### Frederik Kristensen

#### Deputy CEO, Coalition for Epidemic Preparedness Innovation

Dr. Kristensen, MD has been the Deputy CEO of CEPI since January 2017 and took on a dual role as Director for People, Planning and Policy from January 2019. Before joining CEPI he was a senior advisor on innovation at the World Health Organization in Geneva, in the Family, Women's and Children's Health Cluster. In that role he focused on projects to promote access to life-saving commodities, supporting projects in 20 African and three Asian countries in collaboration with UNICEF

and UNFPA and over 100 implementing partners. His previous experiences include the Norwegian Development Agency, hospital management and the pharmaceutical industry. He is an MD from the Universities of Newcastle-upon-Tyne, UK, and Oslo, Norway and with a MPH/MBA degree from the University of California, Berkeley.



#### Mark Feinberg

#### President & CEO, International AIDS Vaccine Initiative

Dr. Feinberg, M.D., Ph.D., is president and CEO of the International AIDS Vaccine Initiative (IAVI) where he leads a global team working to advance the development of vaccines and other biomedical innovations to protect against infection with HIV, TB, and other infectious diseases that

disproportionately impact low-income countries.

Prior to joining IAVI, he served as chief public health and science officer with Merck Vaccines where he helped advance the development and global availability of vaccines against rotavirus, human papillomavirus among others, and also led the coordination of a private-public partnership to expedite Ebola vaccine development.

He served as the chair of the Interim Scientific Advisory Committee of the Collaboration for Epidemic Preparedness Innovations (CEPI) and currently serves as a member of the CEPI Joint Coordinating Group and as a member of the Council of the Coordinating Group and as a member of the Council of the National Institute of Allergy and Infectious Diseases. He holds an M.D. and a Ph.D. from Stanford University, and B.A. degree from the University of Pennsylvania.



#### Gaudensia Mutua

#### Clinical Trials Team Leader, KAVI-Institute of Clinical Research, University of Nairobi

Dr Mutua had worked at the KAVI-Institute of Clinical Research (University of Nairobi) since 2004 as a senior research physician. During that time, she supervised and conducted more than 30 HIV related epidemiological studies involving more than 3000 volunteers, plus three HIV and two Ebola vaccine trials, as well as three drug trials. She also developed and implemented a research literacy training

program targeting clinical research staff in the East African region. She has received MBChB and MPH both from University of Nairobi.



#### Rajeev Venkayya

President, Global Vaccine Business Unit, Takeda Pharmaceutical

Dr. Venkayya, M.D. manages a vertically integrated business with all functions necessary for the development, manufacturing, and commercialization of Takeda's vaccines. Takeda's development pipeline includes vaccine candidates for dengue, norovirus, Zika (funded by the U.S. government),

and Sabin-strain inactivated polio vaccine (funded by the Bill & Melinda Gates Foundation). Prior to joining Takeda, he has served as director of Vaccine Delivery at the Bill & Melinda Gates Foundation, and the special assistant to the president and senior director for biodefense at the White House. He is a member of the Council on Foreign Relations and an independent board member of the Coalition for Epidemic Preparedness Innovations (CEPI). He completed the six-year B.S./M.D. program at the Northeastern Ohio Universities College of Medicine and was chief medical resident in internal medicine at the University of Michigan.

#### Moderator



#### Anita Kawatra

Vice President, Communications, International AIDS Vaccine Initiative Anita Kawatra is the chief architect of IAVI's global communications activities. Prior to joining IAVI, Kawatra had a 20-year career in life sciences and pharmaceuticals. She was executive vice president at Edelman; headed scientific relations, public affairs, and corporate marketing and communications

at Elan Pharmaceuticals; served as head of external affairs and adviser to the CEO of Prothena Biosciences. Prior to that, she oversaw corporate and executive communications at Merck and media relations and crisis management at Merck-Medco.

Kawatra served in the administrations of New York City Mayor David Dinkins and New York Governor Mario Cuomo. She is a board member of the New York City Health and Hospitals Corporation, Sanctuary for Families, and GrowNYC. She has served as an adjunct professor at New York University.

Kawatra holds a B.A. from Yale University and an M.A. from Columbia University.

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#### 15:25-17:05 SESSION 4: Ensuring access and delivery in low- and middle-income countries



Professor & Chair of Diagnostics Research, Director of the International Diagnostics Centre (IDC), London School of Hygiene and Tropical Medicine

Trained as a medical microbiologist, Prof. Peeling was the Research Coordinator and Head of Diagnostics Research at the UNICEF/UNDP/World Bank/WHO Special Program on Research and Training in Tropical Diseases (WHO/TDR), and the Chief of the Canadian National Laboratory for Sexually Transmitted Diseases before assuming her current position.

Her work focuses on facilitating test development and evaluation to inform policy and procurement decisions in developing countries. She established the IDC to advocate the value of diagnostics, foster innovation, and accelerate evaluation, regulatory approval and policy development for sustainable adoption of quality-assured diagnostics.

Prof. Peeling has served as a member of WHO guideline working groups, WHO Strategic Advisory Group of Experts for invitro Diagnostics, the Global Validation Advisory Committee for the Elimination of Mother-to-Child Transmission of HIV-Syphilis; the Global Antimicrobial Resistance Innovation Fund (GAMRIF), and the UK Longitude Prize to combat antimicrobial resistance. She was awarded the George MacDonald Medal for outstanding contribution to tropical medicine by the Royal Society of Tropical Medicine and Hygiene, becoming the first woman to receive this honour.



#### Naofumi Hashimoto

**Rosanna Peeling** 

Medical Laboratory Technologist, Division of Partnership Development, Department of Global Network and Partnership, Bureau of International Health Cooperation, National Center on Global Health and Medicine (NCGM)

Naofumi Hashimoto is a medical laboratory technologist and is playing multi roles as a giver, connector, catalyst and ventriloquist in order to realize Universal Health Coverage and achieving SDG goals in health-related sectors by combining new technologies or products or organizations.

Before joining NCGM, he worked for total over 12 years in Africa in health sector as an expert of Japan International Cooperation Agency (JICA) in Zambia and Zimbabwe, as a member of Médecins Sans Frontières (MSF) in Uganda and Japan Overseas Cooperation Volunteers of JICA in Kenya and Malawi.

He received his degree on medical laboratory technology from Kitasato Junior College of Hygienic Science and MSc in Public Health in Developing Countries from London School of Hygiene and Tropical Medicine. He is a member of WHO Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) 2019.



#### **Bryan Richmond**

#### Regional Director for East & South Africa, Crown Agents Limited

Bryan is celebrating his 40th year with Crown Agents and has worked on a plethora of programmes. He has spent 16 years living in client countries including the Caribbean, USA and the Middle East but his expertise is Africa where he has lived for over a decade and gained a deep appreciation for Africa's

development and political economy environments.

Among his career highlights, Bryan led the team running the complete supply chain for the UK Government Ebola response in Sierra Leone in 2014/15. He also led the conception of the current health supply chain contract with the Government of Ukraine which is fighting corruption, returning 30% savings on the health budget and saving many lives in the process. Bryan creates rapport and empathy naturally with clients and leads our sales efforts across East & Southern Africa. He is regularly asked to share his experiences by contributing to high level international panels on a range of development issues and is a polished presenter.



#### Li Zhang

Director, Innovation Hub, Resource Mobilisation and Private Sector Partnerships, Gavi, the Vaccine Alliance

Li Zhang joined Gavi, the Vaccine Alliance in July 2012. In her role as the acting director for strategic innovation and new investors, she leads the team in developing Gavi's strategic innovation agenda, engagement with the private sector and resource mobilisation from sovereign donors in Asia, the

Middle East and Africa.

Prior to joining Gavi, Li worked at the World Economic Forum for eight years. During her time at the Forum, Li led WEF's strategic development in the Greater China region including the setting up of the World Economic Forum's first overseas' office in China in 2005; the establishment of the Forum's "Summer Davos" annual conference in 2007 and a tripled increase in Forum's membership and partnership base in the region.

Previously, Li worked for the European Commission's delegation in Beijing on economic and development cooperation programmes.

Li holds a Master of Public Administration from Columbia University, New York.



#### Teruo Takahashi

Manager, In Vitro Diagnostics Division, Medical Systems Business Division, FUJIFILM Corporation Mr. Takahashi serves as Business Development Manager at FUJIFILM Corporation (2010-). At FUJIFILM, he is engaged in expanding overseas sales channels for in vitro diagnostic products and developing new businesses. He has also been worked on the "Immuno AG1", a rapid infection inspection system, since it was first introduced into the Japanese market and has been working on

its diversion to the Global Health field. Prior to his current position, Mr. Takahashi has been posted at the International Marketing, FUJIFILM Holdings America Corporation (2007-2009), OEM Sales and Business Development, Recording Media Division Data Storage Media & Optical Discs (2002 - 2007) and, Domestic Marketing, Consumer Photo Products Division (1997 - 2002). Mr. Takahashi joined FUJIFILM (previously Fuji Photo Film Co., Ltd.) in 1997.

Moderator



#### Hayato Urabe

Director, Investment Strategy, Planning & Management, Global Health Innovative Technology Fund Hayato Urabe is Director of Investment Strategy and Management at the GHIT Fund, where he oversees all portfolio management activities. Previously, Dr. Urabe held several positions across the energy, life sciences, and water treatment sectors, focusing on strategy planning, start-up due diligence, and project management in Silicon Valley. He was also a consultant at Synthetic Genomics for technologies ranging from nutrigenomics to biofuels.

Dr. Urabe completed his Bachelor of Science in Molecular Biology, Master of Science in Innovation Management and Entrepreneurship Engineering, and Doctor of Philosophy in Biomedical Engineering from Brown University. In addition, Dr.

Urabe earned as Master's degree from the School of Global Policy and Strategy at University of California, San Diego.

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#### 17:05-17:15



#### Yasuhiro Suzuki

**CLOSING REMARKS** 

Chief Medical & Global Health Officer/Vice-Minister for Health, Ministry of Health, Labour and Welfare Dr. Suzuki graduated from the School of Medicine, Keio University (MD) in 1984 and trained as neurologist. He received his PhD in public health from Keio University in 1996, and two Master's degrees from the Harvard School of Public Health (MPH in 1989 and MSc in 1990).

Dr. Suzuki has a professional career at the Ministry of Health, Labour and Welfare (MHLW), Japan

for 30 years covering infectious diseases, mental health, environmental health, food safety, international health, aging and health, and health research policy. He served as Executive Director for Social Change and Mental Health, and for Health Technology and Pharmaceuticals (covering vaccines, immunization and biologicals), at the World Health Organization from 1998 to 2002.

Dr. Suzuki currently is the Chief Medical and Global Health Officer, and Vice-Minister for Health in MHLW since July 2017.