SUMMARY REPORT ON EU-JAPAN WEBINAR SERIES N06: COVID-19 & Research + Innovation

TOWARDS A MORE INNOVATIVE SOCIETY

BACKGROUND

Since late 2019, a coronavirus disease 2019 (COVID-19) pandemic caused by the coronavirus (SARS-CoV-2) has siginificantly impacted on citizens' lives and livelihoods all over the world. As of mid-September, more than 30 million cases with around 1 million deaths are reported.

To combat against the COVID-19, and seek a real exit strategy from the pandemic, science and innovation comprise a crucial component. The excellent science has guided public policy under the uncertainty, and it will keep providing valuable information for policy makers and citizens. The innovation has been invigorated, as illustrated by the latest diagnostic testing tools, therapeutic drugs and vaccines under development.

To accerelate the research and innovation around COVID-19, international cooperation and effective multilateralism will be pivotal; however, there is a conflict between global solidarity and nationalism, which has been observed in multiple realms including vaccine development and distribution. Moreover, creating an environment where emerging results in scientific reseach are discussed and how the innovation could be incorporated in COVID-19 response.

Both EU and Japan have shared their responsibility to combat against global challenges, and been working as closest and like-minded partners in science, technology and innovation, as illustrated by a signed letter in late May for enhancing synergies between "Horizon Europe," a next EU research and innovation programme, and "Moonshot," a Japan's research and development programme. This will be expected not only for coordinating efforts of EU and Japan towards COVID-19 but also to deepen the cooperation on global challenges including health, climate change, digital transition and ageing societies.

OBJECTIVES

This report summarizes **the 6th Webinar on COVID-19 & Research + Innovation held online on 17th September 2020.**

Research and Innovation is a key area of cooperation between the European Union and Japan, with projects carried out under the EU Research and Innovation Framework Programme with the support of Japanese Ministries and research funding agencies.

Research is key in the fight against COVID-19, where examples of cooperation opportunities can be found in the fields of epidemiology, preparedness, response to outbreaks, the development of diagnostics and treatments as well as vaccines.

The objectives of this webinar is to review the current state of EU Japan cooperation as well as cooperation opportunities including on the acceleration of research and innovation on the prevention and cure of COVID-19.

Webinar Main Statistics

334 REGISTRANTS

242 REGISTRANTS FROM JAPAN

68 REGISTRANTS FROM THE EU & UK

24 REGISTRANTS FROM OTHER COUNTRIES

204 ATTENDEES

PRESENTATIONS

1. Intensive Contribution of European Commission towards COVID-19

Dr. Maria Pilar AGUAR FERNANDEZ
Head of Unit, RTD/E3 "Health Innovations"

The COVID-19 pandemic has severely affected all countries and all activities. Since the COVID-19 pandemic hit Europe, research and innovation has been the first EU policy areas to react. In January 2020, the EU firstly called for research proposals.

The European Commission (EC) within the current Framework Programme (Horizon 2020) has mobilized substantial funds (over € 620 million) to develop diagnostics, treatments, and vaccines, but not only for these topics. We also created opportunities to strengthen our capacity to manufacture and deploy solutions, to understand the behavioural and socio-economic impacts and dedicated to supporting finding innovative Digital Health solutions.

One of the most important activities is the European COVID-19 Data Platform. This research infrastructure provides an open and trusted, environment where researchers can store data, share datasets, and allow scientists to understand some fundamental questions about the virus. This capital can be important for Japanese researchers, as data protection approaches in Japan and EU are aligned, and this resource is open to the world. More than 70,000 researchers have already accessed this platform, and it could be a very good opportunity to share data and bring closer both research communities.

Beyond Europe, the EC has also been a very active global actor, bringing together countries all over the world in the COVID-19 response. We have dynamically cooperated with other research funders (including) in global initiatives like CEPI (Coalition for Epidemic Preparedness Innovations) and GloPID-R (Global Research Collaboration for Infectious Disease Preparedness), ensuring that results would benefit the global citizens, not limited to people in the EU.

In the months and years to come, research and innovation will be a key element at the centre of the transformation of the society of tomorrow. It will be at the centre of achieving normality. Not only health agenda but in digital, socio-economic, and climate-related research and innovation are critical to become a fairer and resilient society and prepare the EU for a future crisis. We are building the new EU Framework Programme for Research and Innovation called “Horizon Europe” for the next 7 years. It will make sure that research and innovation actions become the most impactful and powerful tools to boost the EU economies and competitiveness at a global scale.

The upcoming European Research and Innovation days will give you all the opportunity to have more information on how the future of research and innovation in Europe will look like. Additionally, “Horizon” & “Moonshot” around the same orbit in Tokyo will explore together how to strengthen synergies and enhance cooperation between the EU and Japanese ecosystems, in order to face common challenges such as pandemics, climate change, and ageing societies.

2. International collaboration for vaccine research & development

Prof. Peter PIOT
Special Advisor to the European Commission President on COVID-19
Director, London School of Hygiene & Tropical Medicine

The COVID-19 pandemic is the greatest challenge in peacetime facing the world for more than 100 years. I am a strong believer in the value of scientific collaboration. One of the silver linings in the COVID-19 crisis is the unprecedented scale of international scientific collaboration, from accelerating research and development for COVID-19 health technologies to social science and economics research. The COVID-19 pandemic is not just a public health crisis but a societal crisis. There are many scientific advancements, but today I will focus on vaccines, which could play a critical role in emerging from this crisis, although there are no silver bullets.

There have been intensive efforts for vaccine development. More than 240 COVID-19 vaccine candidates are under development, from classical approaches to innovative approaches, including RNA and DNA vaccines. Massive investments are coming from big companies, small biotechs to start-ups. The EC, Japan, and partners have raised €15.9 billion for vaccines, tests and treatments as part of the Coronavirus Global Response, and US Operation Warp Speed program has announced more than US$10 billion to advance vaccine research and development (R&D). Japan was one of the co-founders of the CEPI, and several vaccine candidates are being advanced under COVAX.

Currently, there are nine candidates in Phase 3 trial, and trials are conducted all over the world. However, in general, it takes 8-10 years or longer from vaccine development to the market, and the success rates are less than 10%. Therefore, it will be a long journey, and accelerating R&D without taking shortcuts will be important. There are many initiatives emerged, such as Access to COVID-19 Tools (ACT) Accelerator. The aim is just not to accelerate the development but also support the manufacturing process. Additionally, these are not just for developing diagnostics, vaccines, and therapeutics but also to ensure the globally equitable access to vaccines, and EC has committed to accelerating international cooperation by cooperating with the African Union and the Africa Centres for Disease Control and Prevention (Africa CDC).

While vaccines will be an important component in ending the pandemic, there are no silver bullets. Five key challenges lie ahead for a safe and effective COVID-19 vaccine. First, whether they will work, to what degree they will truly protect people from COVID-19 is still unknown, as the immunity is still unknown. Whether vaccines will prevent infection or prevent severe disease and mortality is not clear. How long will the immunity continue remains uncertain. Second point is ensuring absolute safety. Third, major international collaboration is essential to scaling up manufacturing capacity to make sure there is not millions but billions of vaccine doses. Fourth, distribution and prioritization of vaccines is a matter of intense debate. We must ensure that everyone, everywhere who needs a vaccine has access, particularly the most vulnerable communities. Finally, whether people will accept the newly developed vaccines is a critical topic. In Europe, there have been several vaccine hesitancy movements, and the vaccine confidence project indicated that Japan ranks lower for vaccine acceptance, which has been affected by issues around human papillomavirus (HPV) vaccine crisis.

Vaccines are essential; at the same time, however, we need to shift our thinking to see ourselves as societies living with COVID-19. We will have flare-ups and outbreaks and, without containing them immediately, we will go again to nationwide lockdowns. Research agenda should not be confined to the development of products. Preparedness for the next epidemic, better governance, and international cooperation are essential. Viruses are not bound by borders, visas, passports. That is why international collaboration is extremely important.

3. Needs of R&D to fight COVID in Japan: Progress and Challenges

Dr. Takaji WAKITA
Director-General, National Institute of Infectious Diseases

National Institute of Infectious Diseases (NIID) is the leading agency of Japan's COVID-19 response and has been working as the representative institute for infectious diseases.

Japan experienced the first wave of COVID-19 in January-May that necessitated the state of emergency, and Japan is in the middle of a second wave. While the second wave became a bigger one compared to the first wave, the effective local governance could avert the declaration of a state of emergency. Cluster detection and containment efforts, the aim of which was to explore the source of infection, have been the center for COVID-19 response. NIID also presented the results of molecular epidemiology to link cases and clusters and inform decision-making for targeted interventions. The haplotype network analysis of viral genomes suggested that the SARS-CoV-2 strains observed in the Diamond Princess operation did not explicitly lead to other infections. Also, the first wave was suggested to be originating mainly from imported cases from Europe, but the second wave was originated only in one strain. Combining epidemiological characteristics with whole genome sequencing will improve the surveillance, clarify detailed transmission dynamics, and help to design the strategy.

In addition, identifying anti-viral drugs are crucial in R&D. NIID has been collaborating with multiple institutions from academia and research institutions in multiple realms, such as biochemistry, in silico informatics, mathematics, and clinics. We looked at 300 approved drugs, and some prominent results that promote synergistic effects have been emerging by combining different modes of actions by Nelfinavir and Cepharanthine. Using the already approved drugs can be beneficial as we can shorten the time for clinical trials, and pharmacokinetics and viral dynamics are well understood. The importance of early intervention is known in influenza, and we have already published a clinical study that indicates the essence of early intervention by Nelfinavir for asymptomatic and mild COVID-19 patients. While Nelfinavir is an oral drug, Cepharanthine needs to be injected; therefore, finding an oral replacement is a next challenge.

Several concerns for SARS-CoV-2 vaccine development must be noted. First, there has been no vaccine for similar coronaviruses such as SARS-CoV or MERS-CoV. Second, BSL3 facility is necessitated to produce inactivated vaccine of SARS-CoV-2. Moreover, a low growth rate of the virus was reported, and it should be finally noted that the disease enhancement by the vaccine was reported during the vaccine research of SARS and MERS.

R&D is most important to fight COVID-19, and viral genome epidemiology of SARS-CoV-2 has supported COVID-19 cluster surveillance in Japan. Novel anti-viral therapeutics can emerge by the combination of compounds with different modes of actions. Finally, vaccine efficacy and safety must be ensured even under the rapid development.

4. The Innovative Medicines Initiative Action on COVID-19

Dr. Pierre MEULIEN
Executive Director, Innovative Medicine Initiative (IMI)

The Innovative Medicines Initiative (IMI) is a public-private partnership based in Europe and represents a long-term commitment from both the public (through the EC) and the European Pharmaceutical industry (through EFPIA). Over the past decade, IMI committed more than €5 billion from public and private sources, financing large scale R&D projects across a wide spectrum of disease settings.

IMI has committed to COVID-19 response in two ways. First, there were many existing programmes, including clinical trial networks that were constructed to combat against antimicrobial resistance in Europe. Also, several data and technological platforms that were launched for previous other unrelated diseases can now be repurposed for COVID-19 related issues. In addition, many learnings from the IMI Ebola programme are also being leveraged. The IMI funded project, ZAPI recently published results in the Nature Communication that a human monoclonal antibody that neutralizes SARS-CoV-2 (and SARS-CoV) in cell culture may offer the potential for prevention and treatment of COVID-19. Other COVID-19 proposals like MANCO or CARE have been recently scheduled for funding.

In late March, the European Health Data & Evidence Network (EHDEN) and the Observational Health Data Sciences and Informatics (OHDSI) community organized a 3-day remote COVID-19 study, with more than 330 researchers, with 37 healthcare databases from 30 different countries to design and execute studies to inform healthcare decision making during the COVID-19 pandemic. There have already been two publications from the network regarding the safety of hydroxychloroquine, and international characteristics of COVID-19 patients.

Furthermore, IMI has been calling for proposals with regard to COVID-19. This was launched in an accelerated manner on March 4th, 2020 as a single stage call and focused on therapeutics and diagnostics. Vaccines were excluded from the main agenda as both EC and industry were already funding R&D through multiple platforms. We received more than 140 submissions.

Selected projects for funding include CARE (Corona Accelerated R&D in Europe), Impentri (Development of Impentri, an intravenous imatinib formulation for COVID-19 acute respiratory distress syndrome), MAD-CoV 2 (Modern approaches for developing anti-virals against SARS-CoV-2), DECISION (A miniaturized disposable molecular diagnostics platform for combatting coronavirus infections) and RAPID COVID (Robust Automation and Point of Care Identification of COVID). Even under the health emergency, IMI reimburses eligible project costs incurred since March 31st, and makes efforts not to delay the research by the internal bureaucracy.

5. Comments

Dr. Kiyoshi KUROKAWA
President, Health and Global Policy Institute

The world is changing rapidly. The cold war ended 30 years ago, and since then, the world has become more flattened. A new paradigm has emerged but OECD member countries, including Japan, could not accelerate their GDP. The Prime Minister of Japan has just changed, but there still remains a significant issue in ageing, the national debt, and other issues.

We knew that influenza pandemic would come, as well as SARS and MERS, but the global preparedness towards pandemic was not enough. The COVID-19 pandemic explicitly exposed issues in policy level, the governmental leadership, and its governance. For example, Japan confronted issues in diagnostics, and lack of testing became a critical matter. We need to analyze the root causes of this issue and present a recommendation. In addition, the national governance regarding the Japan's finance will be pivotal.

While the immediate concerns are in vaccines and therapeutics development, revitalizing the economy will be a long-term agenda during and after the COVID-19 pandemic. But first, the allocation of vaccines will be a critical agenda. The universal, global criteria, even briefly, for how to prioritize vaccines in a specific age or population needs to be carefully considered. Vaccine nationalism will do more harm than good, and Japan, as a developed country, needs to seriously consider the allocation and prioritization of vaccines at the global scale.

Japan has been tested for how to benefit from the results of Global Health Innovative Technology Fund (GHIT) or CEPI. At the same time, the governance and prioritization of Japanese government must be shaken up.

Q & A

Q: What is the scope of resource mobilization in EC's commitment to the COVID-19 response and in increasing the budget?

<Dr. Fernandez>

The number of proposals sent to the commission was much bigger than the final agreement, and each of 27 member states came together, decided the final budget 1.8 trillion, and confirmed whether the funding could achieve a fair agreement.

Additional funds are dedicated specifically to the "recovery package." This is not confined to COVID-19 but other health agendas such as ageing, and other socio-economic agenda at the global level. We try to maximize our commitment to support citizens, companies, economy at the European and global level.

EU recently joined the COVAX, a big promoter and good supporter and facilitator for a global response. Diseases have no boundaries, and Europe is best interested in making sure the global cooperation in COVID-19 response. At the same time, EC will make a commitment for new therapeutic drugs and diagnostics.

Q: Under the limitation of vaccine volumes, and uncertain efficacy by age groups, how can we make prioritizations for vaccines?

<Prof. Piot>

A rigorous debate will occur once vaccines appear, and it can be a mixture of medical hubris and political agendas. We cannot take shortcuts in both efficacy and safety. Also, there is a big difference between the results of a trial (even in a phase 3 trial) and making the vaccine available. It is good to be prepared for the discussion. The WHO has already issued some recommendations and many countries hold their national committee on immunization. In Europe, European CDC (ECDC) leads the discussion of the analysis and recommendations. It will be both a technical and political issue. Healthcare workers and those working in care homes for the elderly will be the firstly prioritized. Europe needs to learn from Japan, a country that has experienced an ultra-ageing population. As vaccines are generally not tested in elderly population during the clinical trials, the efficacy of vaccines in the elderly is still not certain. We may need to change doses or inject different vaccines. Also, serious consideration for ethnic minorities is needed. At least in Europe, a diverse society, a harmonized position will be required. Otherwise, political interference or populist movements will be prevalent. We must not take shortcuts, and high integrity with trust and confidence will be pivotal.

Regarding R&D perspectives, the first generation of vaccines are not going to be an optimal one, and we need to learn from the first implementation. Global cooperation, including COVAX, must not negotiate just for allocating vaccines towards European citizens but for citizens in low-income countries. Japan has also been actively involved in Africa policy, and Japan and Europe can come together for enhancing global solidarity.

Q: Efficacy of vaccines after mutation>

<Dr. Wakita>

We are closely monitoring and analyzing the viral mutation. D614G is a very well-known mutation, and spike mutation also contributes to changing the infectiousness or the nature of the infection. While neutralized antibody is effective, the efficacy of vaccines after these mutations must be looked out for. Also, when the mutation becomes the majority, when the deletion of mutants for spike occurred, or when the mutated strain becomes the dominant strain, should be investigated.

In Japan, vaccination policy has been rigorously discussed in an expert committee, and there is a consensus that the elderly and healthcare workers must be prioritized. To what extent vaccine is effective (i.e. preventing infection? reducing severity? cutting the transmission?) is a very important question. Whether young people will take vaccines can be a huge topic as Japan experienced the HPV crisis. Therefore, if vaccines are deployed, it is assumed that many suspected side effects will be reported. Finally, vaccines must be deployed for developing countries, and not be enclosed by Japan or developed countries. Finally, while there is a task force in the Japanese government, health communication is a significant challenge, and it needs to be strengthened.

Q: Why is Japan left behind in vaccine development?

<Dr. Wakita>

The funding agency called Japan Agency for Medical Research and Development (AMED) holds several research topics for emerging and re-emerging infectious diseases. However, this is different from the system in the United States and there has been limited advancement for developing vaccines for SARS and MERS.

As Japan was not infiltrated of SARS and MERS, and there has been a lack of consciousness in emerging and re-emerging disease, the COVID-19

pandemic highlighted multiple lessons to Japan. However, Japan tries to catch up to the rapid global development. One compound is in Phase 1, and before the end of 2020, it will proceed to the next stage, and there is a cooperation between vaccine manufacturers.

Q: Potential project in IMI

<Dr. Meulien>

ACE-2 has been well focused on COVID-19, and researches can be challenged by many aspects. Therefore, the collaboration with Japanese researchers to bring excellent scientific progress will be important.

Q: Why doesn't Japan use the platform of iDEN, a useful data platform and data protection?

<Dr. Wakita>

There is an initiative of Biobank at Tohoku University for data collection. Scientists can look at data and samples, and but we expand the capacity of the initiative in data platform through the collaboration between University of Tokyo, Tohoku University, National Center for Global health and Medicine.

There is also a COVID-19 patient registry through the Biobank approach, providing open data. It would be wonderful if we could agree on the partnership between EU and Japan for data sharing.

Q: COVID-19 accelerated the collaboration in data synthesis, sharing, and analysis. However, there is limited open data in Japan. How can Japan promote data sharing?

<Dr. Kurokawa>

The pandemic evidently showed the innovative data platform, and global pandemic necessitated the collaboration beyond the national sector. We would like to get input from the European side.

<Dr. Wakita>

At the beginning phase, front-line healthcare workers had to input the data, and who owns the data on what subjects remained unclear. I think it should be opened to the public to accelerate the research.

Q: EU has a strict data protection policy while protecting citizens' privacy. How did the EU leverage the use of IT and protecting privacy?

<Dr. Meulien>

The General Data Protection Regulation (GDPR) registry is very advanced in terms of protecting personal data. But this has not been so neutral in terms of its impact on chemical and biomedical research. Sometimes we struggled with pan-Europe project in how to manage all problems. Registration is a good scheme in terms of research perspective, and during a large scale of projects, jurisdiction in multiple institutions is required.

Q: How to facilitate IT technology to fight against COVID-19 through protecting personal data?

<Dr. Fernandez>

Personal data protection is a significant issue. An open data sharing platform is important in COVID-19 response, and different personal data is included in the platform openly. The GDPR and registration platform in the EU is very close to the system in Japan, and this will be a big advantage for both. Data needs to be shared in complying with the registration. Both sides have overcome some difficulties, and the international cooperation needs to be strengthened not only for COVID-19 but for other multiple agenda. European Health Data Space will be useful to freely circulate the data in a controlled manner. Sharing the data is sometimes challenging but it can be possible if the protocol of data handling is shared enough.

Q: Political influence is a big issue in COVID-19 response. How can we cope with it?

<Prof. Piot>

There is no doubt that the COVID-19 response is political, and I would like to stress that political pressure will be bigger when vaccines appear. Every country must not seek shortcuts in vaccine development as this may damage the entire global progress to vaccine development. That is why a multilateral approach is vital. If we rush into the vaccine nationalism, we, global citizens, will all suffer from it. COVAX, GAVI, CEPI, EU and many other actors will play a vital role in negotiation for achieving the fair distribution of vaccines.

While it is going to be tough in the beginning, likeminded partners like Japan and the EU need to work together for COVAX and other platforms. Considering the landscape of populism and vaccine scepticism, countries sticking to the vaccine nationalism will lose. As there is an enormous potential between the EU and Japan for working together, we need to continue the conversation.

OUTCOME AND WAY FORWARD

Dr. Osamu Kunii
Head of Strategy, Investment and Impact Division, The Global Fund
Moderator

While experts predicted that a serious pandemic by a new pathogen or "Disease X" would occur in near future, many could hardly imagine such a large scale and magnitude of pandemic like COVID-19 would happen in reality. Research and development (R&D) of diagnostics, therapeuics and vaccines is critical for the fight against COVID-19, and in this Webinar we learned various opportunities, progresses and challenges in it. Furthermore, this Webinar informed that there are challenges even after effective vaccines, diagnostics and therapeutics are developed, especially equitable allocation of and access to those products, vaccine hesitancy, long-term effect and safety. At the same time, there are lots of opportunities and progresses not only within R&D of products but also beyond it, especially global and regional collaboration such as ACT-Accelerator, COVAX, EC's and IMI's initiatives and networking in data and information.

This Webinar demonstrated Japan's advanced research and innovation linked to cluster detection and containment efforts, and future measures to end the epidemics.

Yet, it was recognized that Japan could do more and better in research and innovation by participating in and contributing to global efforts, networks and collaboration.

The panelists and audience found many areas for EU and Japan to promote collaboration and coordination in oroder to accelerate research and innovation for fighting and ending the epidemics.

This webinar is not the end of the story but the start to kick off the discussion and connect experts, researchers, funders and policymakers between EU and Japan to tackle and overcome this global crisis.

I hope EU and Japan partnership would also facilitate networking and collaboration in various areas of research and innovation not only to end this epidemic but be prepared for future "Disease X" and improve global health security.

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This webinar can be watched on the following YouTube link:
https://www.youtube.com/watch?v=4zuQpV8sOFw

CONTACT:

Delegation of the European Union to Japan
Europa House, 4-6-28 Minami-Azabu, Minato-ku, Tokyo 106-0047
www.euinjapan.jp
delegation-japan@eeas.europa.eu
+81 3-5422-6001

European Union