

Research and Development on COVID-19

<Establishment of the Government Response Headquarters>

On March 26, 2020, Japan established the Government Response Headquarters pursuant to Article 15, paragraph (1) of the Special Measures Act, as applied *mutatis mutandis* pursuant to Article 1-2, paragraphs (1) and (2) of the Supplementary Provisions of the Special Measures Act. Based on the Basic Policies for Novel Coronavirus Disease Control decided by the Headquarters on March 28 (subsequently amended), the government has been steadily taking measures against COVID-19.

Among COVID-19 measures taken under the Basic Policies for Novel Coronavirus Disease Control, R&D on COVID-19 and other emerging infectious diseases is one of the most important initiatives to end the pandemic.

<Promotion of R&D >

The Headquarters for Healthcare Policy announced a government-wide policy on R&D on COVID-19 on February 13, 2020. Based on the findings of Japanese researchers on SARS,¹ MERS,² etc., the Headquarters developed COVID-19 measures including the development of diagnostic and therapeutic methods and vaccines. More specifically, it has decided to provide a total of about 2 billion yen for R&D of rapid diagnostic kits, physician-led clinical trials using existing drugs, and R&D of new mRNA vaccines.

Another budget of approximately 3.1 billion yen was provided for the Measures for COVID-19 and Other Emerging Infectious Diseases (2nd Phase) announced on March 10, 2020, which included the establishment of a platform for immediate response to new infectious disease epidemics, verification of the effectiveness of existing therapeutic agents, and development of rapid testing equipment. Specifically, the measures included accelerating the renovation and maintenance of the existing BSL3 units (biosafety level³ 3 containment laboratories), studying the efficacy and safety of anti-influenza drugs such as favipiravir (Avigan), and developing simple testing equipment that can rapidly detect novel coronaviruses.

Furthermore, the Emergency Economic Measures to Cope with COVID-19, approved by the Cabinet on April 7, 2020, also included measures totaling 75.1 billion yen to fundamentally resolve the spread of COVID-19. These measures aim to mobilize the world's wisdom to accelerate the development and dissemination of effective drugs and vaccines, which are the highest priority issues, while also ensuring the early use of drugs and vaccines that have been shown to be effective and safe. Specifically, Japan plans to develop facilities to produce favipiravir (Avigan), promote observational studies of existing drugs such as nafamostat mesylate (Futhan), which is used for the treatment of pancreatitis, accelerate the development of vaccines, and contribute to the global community through contributions to international organizations (see also Part 2, Chapter 3 for more information on R&D on infectious diseases).

¹ Severe Acute Respiratory Syndrome

² Middle East Respiratory Syndrome

³ The biosafety level (BSL) is a rating for laboratories and facilities that handle microorganisms and pathogens. The level of precautions required is determined according to the risk of pathogens used in the laboratory or facility. The novel coronavirus is to be handled at BSL3.

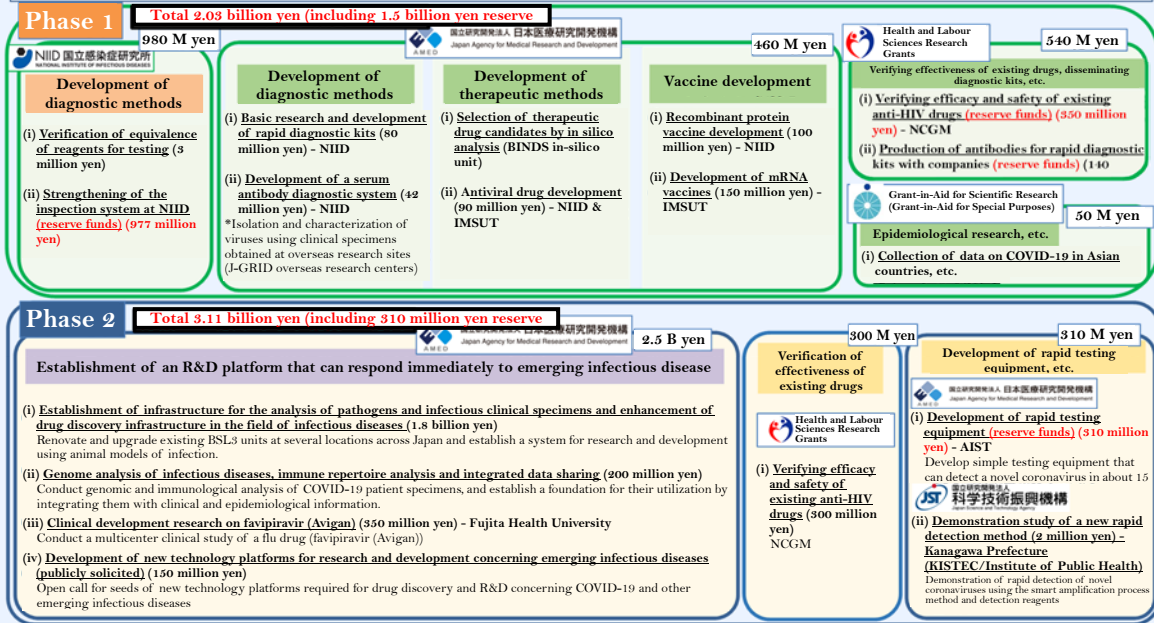
Figure: Research and development concerning COVID-19

R&D on COVID-19 and other emerging infectious diseases

March 10, 2020
Office of Healthcare Policy
MEXT
MHLW
METI

○ COVID-19 Measures Phase 1 (February 13, 2020): Develop diagnostic and therapeutic methods and vaccines using the AMED's remaining budget and reserve funds for FY2019; Phase 2 (March 10, 2020): Accelerate clinical research to utilize existing drugs for COVID-19 and the development of rapid testing equipment using adjustment funds for medical research and development and reserve funds for FY2019.

○ Based on the knowledge on SARS and MERS, etc. that has been gained by Japanese researchers, promptly start research and development on the following topics.



Research and Development of COVID-19 Measures (Healthcare policy-related) 75.1 billion yen

April 7, 2020
Office of Healthcare Policy
Cabinet Office
MOFA
MEXT
MHLW

○ The government has promoted the development of diagnostic and therapeutic methods and vaccines for emerging infectious diseases including COVID-19 using the AMED's remaining budget for FY2019, as well as R&D-related adjustment funds in the medical field and reserve funds in 2019.

○ The spread of COVID-19 is having an adverse effect on Japan's economic activities. In order to overcome the pandemic and get the economy back on track for growth, Japan will add initiatives to further accelerate the development of devices, systems, treatments and vaccines for infectious diseases.

R&D

Treatment and vaccine development

- **Study of the efficacy and safety of existing drugs:** 600 million yen (MHLW)
Conduct studies of the efficacy and safety of nafamostat mesylate (Futhan) and other products
- **Support for vaccine development:** 10 billion yen (MHLW)
Support vaccine development from basic research, such as the generation of vaccine candidates, investigations using animals, and the development of adjuvants and other related technologies, to non-clinical studies (pharmacology and toxicity studies) and clinical studies (phase 1 studies).
- **Cyclic Innovation for Clinical Empowerment (CiCLE):** 20 billion yen (Cabinet Office)
Promote R&D of innovative pharmaceuticals and medical devices, including COVID-19 measures, through industry-academic-government collaboration

Equipment and system development

- **Development of technology to combat viral and other infectious diseases:** 11 billion yen (METI)
Support the development and demonstration of simple, rapid and decentralized virus testing methods, systems to prevent the spread of infection, and medical devices for critically ill patients.
- **Emergency response to infectious diseases and other emergencies using AI and data bases:** 700 million yen (Cabinet Office)
Develop a system that contributes to emergency response (such as COVID-19 and other future infectious diseases) based on the findings from the SIP (Cross-Ministerial Strategic Innovation Promotion Program).

Environmental improvements

- **Strengthening and enriching the research base for combating COVID-19:** 6.2 billion yen (MEXT)
Strengthen support for drug discovery research and conduct basic research at overseas research centers for infectious diseases
- **Project for the rapid development of a new COVID-19 treatment, etc.:** 1.4 billion yen (MHLW)
- **Project for development of a system to prevent the spread of COVID-19 through genome analysis, etc.:** 700 million yen (MHLW)

International

- **Project to establish a clinical research and clinical trial network in the Asian region:** 3 billion yen (MHLW)
- **Contributions to international organizations:** 10.6 billion yen to CEPI (MHLW), 11 billion yen to Gavi (MOFA, MHLW)

(Reference)

Phase 1 (February 13, 2020) 2.03 billion yen in total
Promptly start the development of diagnostic and therapeutic methods and vaccines based on the knowledge of SARS and MERS, etc.

Phase 2 (March 10, 2020) 3.11 billion yen in total
Accelerate clinical research and development of rapid testing equipment to utilize existing drugs for COVID-19, and build an R&D platform to respond immediately to emerging infectious disease epidemics

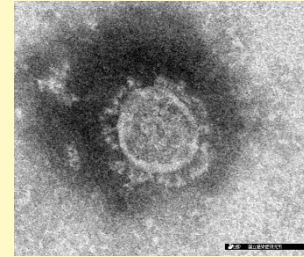
Source: Prepared by the Cabinet Secretariat

Column
1-1**What is a novel coronavirus?**

A novel coronavirus (SARS-CoV₂) is a kind of coronavirus. Coronaviruses include the viruses that cause the common cold, the severe acute respiratory syndrome (SARS) and the Middle East respiratory syndrome (MERS), which has been reported since 2012.

There are several types of viruses; coronaviruses are a type of RNA virus (single-stranded RNA virus) that carry RNA as genetic information and have a double-layered membrane made of a lipid called an "envelope" on the outermost side of the particle. While it cannot reproduce on its own, it can attach to mucous membranes and other host cells and spread.

It is said that the virus can get into mucous membranes, but it is incapable of penetrating healthy skin and only sticks to surfaces instead. It is also said that the virus on the surface of an object will break down after some time. Depending on the type of object, it stays infectious for 24 to 72 hours.



Electron micrograph of a novel coronavirus
Courtesy of the National Institute of Infectious
Diseases (NIID)

<Reference URL> For the latest information on COVID-19, please visit the MHLW website.
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/dengue_fever_qa_00001.html#Q2-1