In search of Medical innovations: Japan’s new Agency for Medical Research and Development (AMED)

Japan wil meer medische innovatie met AMED

Dutch summary


Summary

The Japan Agency for Medical Research and Development (AMED) was established in April 2015. Japan is projected to become the world's first ultra-aging society. The goal of this new national organization is to achieve the world's highest level of medical care and services by enhancing and accelerating the speed of R&D projects from the basic research to practical application.

AMED has named new challenges and announced various research projects such as Regenerative Medicine, Rare Diseases and Infectious Diseases, that are open to international collaborations. (1) AMED established a website in English that has all the information on calls for proposals and R&D programs readily available. (http://www.amed.go.jp/en/)

The Japanese government has announced it will spend JPY25.6 Billion (EUR188 Million) in FY2015. It is the kick-off year for the Japanese government to promote medical research and development as one. AMED consolidates the medical R&D budgets of the relevant government ministries.

Bridging the Gap between research and application

Since Professor Shinya Yamanaka of Kyoto University won the Nobel Prize for iPS stem-cell research in 2012, the government has intensified its commitment to support research and development projects for new drugs and technologies that should propel Japan as a pioneer in the field of lifesciences. However, one of the development hurdles is a lack of realization of
projects aimed at commercial applications - basic research at universities/institutions is not well connected to the product development in Japan.

As a result, the number of new drugs created in Japan has actually been declining due to the slow progress of the clinical trials. The administration traditionally spends more resources on the safety evaluation for approval rather than promoting R&D for innovative drugs or device/technology that meet medical needs of Japan. Some experts have called the gap between the research and its practical application as "Death valley". Bureaucratic sectionalism, including Ministries and agencies that separately funded R&D projects, has been said to be one of the causes (2).

**AMED’s role**

AMED aims to act as a "Control Tower" that directs integrated research and development. Its aim is to spend available R&D funds more efficiently and effectively, providing funds to promote integrated medical R&D from basic research to practical application and managing R&D projects.

The organizational structure was established with purpose in mind for cross-sectional collaboration for accelerating medical R&D. The total number of staff is 330. There are six departments; Research Promotion, Industrial Academic Collaboration, International Affairs and Research Infrastructure, Clinical Research and Trials, Innovative Drug Discovery and Development. In the Research Promotion, they are 7 main research projects; Drug Research, Regenerative Medicine, Cancer, Neurological Psychiatric and Brain, Rare/Intractable Disease, Infectious Disease, and Emerging. (3)(5)

Chart1: Cross-sectional collaboration “Department of Research Promotion” – Source (5)
Research Funding

A new challenge for AMED is that the organization consolidates the budgets for medical research that had previously been spread across three different ministries – the Ministry of Science (MEXT), Ministry of Health, Labor and Welfare (MHLW), and the Ministry of Economy, Trade and Industry Economy (METI).

The consolidated budget for 2015 is JPY124.8 Billion (EUR 917 Million), of which MEXT oversees 48%, MHLW 38%, and METI 14%. This is an increase by 2.7% (+JPY3.3 Billion, EUR 24 Million) compared to last year (4). In addition, AMED is entitled to spend 35% of the government’s “Science and Technology Innovation promotion” budget of JPY50 Billion (EUR 367 Million). The first budget allocation took place in June this year. The government will spend 32% of the budget to create “Japan Brand” drug and medical equipment, promoting cooperation between academic, government and private sector partners. Cutting edge technologies such as Regenerative Medicine (JPY14.3 Billion, EUR 1 Million) and Genome projects (JPY7.4 Billion, EUR 0.5 Million) including “Bio Bank Japan” are also pushed by the government and obtained budgets to promote joint research and international collaboration.

Dynamic Leadership

Dr. Makoto Suematsu, the President of AMED is a dynamic leader and has been actively carrying out the agenda for changing the system since assigned in April this year. Having worked for 8 years as a gastroenterology physician, and later involved in basic research, he has seen the problems of lacking a system that adequately provides sufficient funding from basic research to implement practical applications. Dr. Suematsu thinks that in general, researchers tend to focus only on their own research based on their interest. On another issue, there are many discerning researchers but most of them are seniors due to seniority system in Japan. He says “I want young researchers to have more freedom, flexibility, and broaden their view about their studies. More young researchers should be involved in a “referee role”. Suematsu thinks that number and quality of these referees should be improved and proposes to revise the old system in which it is mostly older researchers taking up the referee roles. AMED should be triggering these changes”. (3)

Dr. Suematsu believes that fostering a more data-driven mindset in development is also necessary in Japan. As the two Ministries have good data for application – MHLW has data on health/diseases and MEXT has data on clinical application – he feels it is very important for medical R&D field to combine the two. In addition, the cooperation between the physicians and patients/family largely contribute in developing new treatment. The role of the AMED is to stand like the “Control Tower” for effective uses of all valuable resources. (6)

Intellectual Property and the Prevention of Research misconduct

In order to maximize research outcomes, AMED provides a variety of support, for example, research institutes working to secure intellectual property, corporate alliances targeting practical application, and international joint research. The initiatives for better prevention of research misconduct were established after the scandals of RIKEN for STAP cell (7) and the
data manipulation of Novartis pharmaceutical in Japan (8), had raised concerns about credibility of research conducted at Japanese institutions.

**Conclusion**

The Japanese government is pushing the medical field as a new growth industry. To improve Japanese competitiveness AMED is expected to play a very important role. **The revised approval system of the pharmaceutical and medical device law enforced last fall enables priority review and approval for innovative products.** The projects that AMED leads such as the regenerative medicine, rare diseases and infectious diseases receive high expectations for practical application. They will be considered as innovative projects and expected to get approval for commercialisation much quicker than before - three to four years including development – after meeting the safety requirements.


(2) "Health Care Policies in Japan and the U.S." Yomiuri International Economic Society Lecture Meeting in Tokyo by Prof. Yusuke Nakamura, M.D., Ph.D., Department of Medicine and Surgery, The University of Chicago, on June 24, 2015

(3) "AMED" Brochure April 2015

(4) 1Euro = JPY136. (August 6 2015)

(5) From the presentation “AMED Missions and Challenges” at EU Delegation in Tokyo, Japan on July 10, 2015

(6) Interview Article of Dr. Makoto Suematsu on AMED (M3 com article on April 8 2015)
