Kobe Declaration 2019

For the Continuous Development of Innovative Medical Devices through Collaboration across Industry, Academia, Government, and the Medical Profession

Preamble

Japan is becoming a super-aging society ahead of the rest of the world, and needs to realize "healthy longevity" with people living in good health and remaining socially active long into old age.

For this purpose, it is indispensable to develop innovative medical devices that are useful for maintaining and promoting health, and for providing high-quality medical care. However, Japan is behind when compared to some countries in the globally competitive field of therapeutic medical devices.

In recent years, various attempts have been made in numerous parts of Japan in order to promote the development of domestic medical devices, such as matching seed technology to unmet clinical needs, and introducing the US-style medical device development ecosystem. Various problems have also been identified, notably in regard to the development climate and the availability of human resources. Achievements in the field are limited.

On November 8, 2019, stakeholders and leaders of medical device development in the United States and Japan gathered at the "Japan-US 6th Annual Medtech & Healthtech Innovation Forum Kobe" to discuss various challenges that must be confronted together in medical device development.

This forum DECLARES the outcomes of discussions in Kobe will become the cornerstone of the sustainable advancement of medical device development in Japan.

1. Discussion Outcomes at "Japan-US 6th Annual Medtech & Healthtech Innovation Forum Kobe"

- (1) Response to a Super-Aging Society
- Establish a unique scheme that enables citizens, including the elderly, to actively participate in product development and evaluation, and use the scheme as a demonstration model applicable to super-aged societies across the world.
- Promote preventive medicine, and accelerate the development of services for encouraging senior citizens' social participation and of communication tools based on digital health.
- By combining minimally invasive medical devices with imaging technology and AI, endeavor to develop innovative medical devices that can provide safe and precise treatment with less burden on the elderly.
- (2) Establishment of infrastructure to promote the development of innovative medical devices focusing on therapeutic devices
 - \sim Formation of a "Japanese Ecosystem" for developing medical devices based on industry-academia-government-medical collaboration \sim
- Provide medical device developers with clinical sites that are open as spaces for innovation creation in medical institutions.
- Build recognition across industry, academia, government and the medical profession that a diverse team of experts from different fields is important in initial medical device development, which requires high creativity.
- Develop human resources who are well-versed in the medical device development process and capable
 of overseeing projects and leading the team.
- Through collaboration across industry, academia, government and the medical profession, create an
 environment where trained human resources can immerse themselves in the development of innovative
 medical devices.

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2. Looking ahead to the next 20 years

~New challenges for Kobe Biomedical Innovation Cluster~

The Kobe Biomedical Innovation Cluster reached a milestone of 20 years in October 2018, and it has grown to become one of the leading biomedical clusters in Japan, bringing together industry, academia, and the medical profession.

Kobe Biomedical Innovation Cluster - The Next 20 Years:

- With this forum as a new start, we will continue the discussion between industry, academia, government
 and the medical profession so that Kobe can become a leading model area for innovative medical device
 development based on industry-academia-government-medical cooperation.
- Together, we will strive continuously to create innovative medical devices that contribute to the
 realization of a "healthy longevity society" by respecting the efforts and the will of all parties involved in
 medical device development, and by working together to build partnerships in cities and regions in
 Japan and overseas, in a spirit of productive competition.

November 8th, 2019

Kobe City
Foundation for Biomedical Innovation at Kobe
Kobe University
US-Japan Medtech Frontiers

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About \[Kobe Declaration \]

Kobe City, Foundation for Biomedical Research and Innovation at Kobe (FBRI), Kobe University and US-Japan Medtech Frontiers (USJMF) co-hosted "6th Annual Medtech & Healthtech Innovation Forum", which was held on November 8th, 2019. This forum aimed to support the promotion of medical device development through the lectures and panel discussions by leading experts both from US and Japan. In the forum, various topics in relate to medical device development ecosystem in Japan were discussed, and we have concluded with "Kobe Declaration" by expressing our determination to continuously promote the innovative medical devices development for many years to come.