

Medical Device Strategy Institute  
Japan Association for the Advancement of Medical Equipment  
Research Paper No.43

## The Role and Future of Medical Devices in Modernizing Healthcare:

Evidence-Based Practice, Enhancing Patient QOL and Productivity, and Treatment Beyond Time and Space

(Executive Summary)

Huimin Wang, M.D.

Senior Advisor, Healthcare System Planning Institute (HSPI)

Makoto Tamura, Ph.D.

Senior Research Fellow, Medical Device Strategy Institute (MDSI)

Director, Medical Technology Policy Research Institute

American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

One of the challenges in policy discussions related to medical devices is the lack of understanding among stakeholders about the devices themselves. The authors have consistently felt this being an issue while engaging in policy discussions and have made an effort to address it. We have compiled our learnings into a trilogy of research papers, which we believe will be useful for the future of the medical device industry. The first part serves as the "General Introduction" of the trilogy. This paper discusses the following four points:

### 1. Representative Medical Devices and Technologies that Have Greatly Changed Healthcare

The development of medical devices has revolutionized diagnosis, treatment, and the quality of life for patients. These technologies have enabled treatments that were previously impossible, facilitated minimally invasive surgeries, standardized the skills of healthcare professionals, and significantly improved the quality of healthcare.

### 2. How Breakthrough Medical Devices are Developed and Introduced into Clinical Practice

The development is driven by innovative ideas and collaboration between clinicians and engineers. It progresses through non-clinical trials, First In Human (FIH) trials, and clinical trials to confirm safety and efficacy. Other steps include patent applications, approvals, and insurance reimbursement. Development projects emphasize risk management, milestone setting, and progress management to pave the way for new technologies to be used in clinical practice and widely accepted.

### 3. How Medical Devices Have Changed Clinical Practice

Innovative medical devices have brought standardization and efficiency to day-to-day clinical operations. These advancements have improved diagnostic and treatment accuracy, popularized minimally invasive surgeries, shortened hospital stays, reduced the burden on healthcare workers, and improved the efficiency of in-hospital operations. While they have made cost reduction and improved medical provision possible, it is important to note that their efficiency varies depending on the patient, necessitating careful evaluation.

### 4. The Essence of Digital Health Technology

The evolution of digital health technology, particularly AI, has the potential to fundamentally transform future healthcare. Digital health technologies support healthcare professionals' decision-making, enhancing everything from diagnosis to treatment selection. The use of AI in medical image analysis improves diagnostic accuracy and healthcare quality. In the future, generative AI is expected to contribute across the entire medical process, from diagnostic support to the planning and execution of surgical procedures. The essence of digital health technology lies in its ability to transcend time and space, expanding the limits of healthcare and providing optimal treatments for individual patients.

---

This research paper is intended to be a material for research and discussion. It may be cited and discussed for research purposes, but any damage or loss caused by citing and/or discussing and/or referencing it is not compensated by the author, Japan Association for the Advancement of Medical Equipment, and/or the Medical Device Strategy Institute.

The opinions and/or ideas described in this research paper are the author's and do not represent the official views of the Japan Association for the Advancement of Medical Equipment and/or Medical Device Strategy Institute.

This is an Executive Summary. The full text is distributed to supporting members of the Medical Device Strategy Institute.

[Contact information]

Medical Device Strategy Institute,  
Japan Association for the Advancement of Medical Equipment  
E-mail: [mdsi@jaame.or.jp](mailto:mdsi@jaame.or.jp) TEL: +81-3-3813-8553