

## Proposal for Type Classification for Building Trust in Medical Artificial Intelligence Systems

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## Abstract

In recent years, artificial intelligence (AI) systems including machine learning, are expected to be used to reduce the burden on doctors and healthcare workers. However, there are many challenges in clinical implementation. In order to facilitate discussions on medical AI software systems among healthcare professionals, technology developers, policy makers, and public/patients, this paper proposed a type classification for medical AI systems (MA Type). In addition to technical requirements, we have developed a classification system that includes the perspectives of user interface, institutional design, and the role and impact on health professionals and patients/users. In developing and implementing medical AI systems, we hope that MA types will be used to share awareness among healthcare professionals and technology developers. The following three recommendations are made regarding the use of MA types and their future development.

### **Policy recommendation 1: Utilize MA Types to Promote Shared Awareness among Stakeholders according to Purposes and Applications**

The requirements for medical AI systems vary depending on the clinical purposes and applications. Depending on the magnitude of risk and ripple effects, with the classification, it will become possible to discuss the types that each clinical department and academic society should aim for.

### **Policy recommendation 2: Utilize MA Types to Construct Real-World Data that Can be Used Effectively**

In recent years, there has been a push towards the use of "real-world data" which is data generated in clinical practice. Therefore, from the development stage of AI that supports the input of information, such as electronic medical records, secondary use of data should be promoted to improve the quality of medical care and medical management.

### **Policy recommendation 3: Utilize MA Types to Promote Institutional Reforms toward Patient-Centered Medicine**

Patient-centered medicine is becoming main-stream worldwide as opposed to the medical institutions centered medicine. For patient information control and patient/user benefits, the introduction of the right of patients to handle their own data digitally (the right to data portability) may also be necessary. With these aspects, a system reform including preventive medical care, healthcare, and life in the scope for the patient-centered medicine should take into account the medical systems, responsibility and roles of physicians and AI systems, and benefits of patients/users.

MA Types can be useful to promote discussion regarding the purpose and application of the clinical site. Although MA Types are based on the current technologies and regulations in Japan, but that does not hinder the potential reform of the technologies and regulations. MA Types aims to facilitate discussions among physicians, healthcare workers, engineers, public/patients and policymakers on AI systems in medical practices.