Launch of the Medical & Health Informatics Laboratories

Hitonobu Tomoike

Abstract

NTT Research, Inc. has launched the Medical & Health Informatics Laboratories (MEI Labs) as a basic research institute for information technology in the medical and healthcare fields. This article gives a summary of environmental changes in clinical research in Japan and the prospects for MEI Labs in the globalization of medical and health informatics research.

Keywords: precision medicine, regulatory science, data science

1. Targets of biological information research

On November 28, 2018, NTT announced the establishment of three new research facilities responsible for basic research into next-generation technologies. Our stated policy is to focus on techniques such as artificial intelligence (AI) for analyzing biological information for precision medicine. The Medical & Health Informatics Laboratories (MEI Labs) was then launched on July 1, 2019.

The history of bioinformatics research dates back to the establishment of the Japan ME Society (currently, Japanese Society for Medical and Biological Engineering) in 1962. An increasingly broad range of biological information has recently become available due to the increased use of information and communication technology (ICT) in medicine. The fact that the scientific discipline known as *Translational Medicine* was renamed *Translational Bioinformatics* after just a few years is a testament to advancements in this field [1]. The explanation offered by the American Medical Informatics Association (AMIA) regarding what constitutes Translational Bioinformatics is perhaps the most canonical definition: "… *the development of storage, analytic, and interpretive methods to optimize the transformation of increasingly voluminous biomedical data and genomic data, into proactive, predictive, preventative, and participatory health. Translational bioinformatics includes research on the development of novel techniques for the integration of biological and clinical data and the evolution of clinical informatics methodology to encompass biological observations*."

There has been extensive research in this field, and the desired outcomes from such research are also being clarified. It could be argued that this definition is similar to that of *Smart World* advocated by NTT [2]. Therefore, the range of biological information that MEI Labs focuses on includes not only biological phenomena but also medical records, genome data, and information processing technology.

2. Approaches of bioinformatics in medicine and healthcare

Medical research has been conducted in three different areas: laboratory (experimental) studies, clinical research (non-invasive/invasive, observation/intervention), and epidemiological studies. Bioinformatics and recently advanced data science play key roles in these three areas as analysis tools. Apart from the MEI Labs, there are perhaps no other research institutes conceptualized as a center for basic research in information technology across multiple research fields.

2.1 Characteristics of data in medicine and healthcare

The diagnosis, treatment, and prevention of medical conditions are documented in medical records.

Since Japan provides universal health insurance, medical records can be regarded as official records. The use of this information for research and development has been prohibited since it was not intended to be used in this manner. Before collecting and using information in clinical research, researchers must obtain patients' written consent after they have been given a full explanation of how this information will be used. Researchers must also ensure that their research will be carried out honestly while complying with the obligation to correctly manage the collected information. Although health monitoring information can be provided through apps running on smartphones and other mobile devices, the collection and use of this information in research is governed by personal data protection rules and must therefore be handled with similar procedures as in clinical studies. When MEI Labs conducts basic clinical research, it will comply with the personal data protection laws of each country. In the United States, it is necessary to abide by the conditions of the Health Insurance Portability and Accountability Act (HIPAA), and in Europe, by the conditions of the General Data Protection Regulation (GDPR), which was revised and enforced on May 25, 2018.

The importance of innovation in medical and healthcare has also recently been emphasized. The patent application and associated intellectual property, which are regarded as important in business and industry, are also the primary responsibility of biological researchers. Carefully following procedures is necessary when dealing with intellectual property in matters such as device development and the discovery of new biological functions. Therefore, the broad understanding of norms and regulations regarding basic research at MEI Labs is necessary in planning and managing clinical or population research.

Regarding clinical data usage in Japan, we can see the steps in how the concept of personal information protection has been established in various directions. Discussions on how to go about digitizing medical and healthcare information began in 2001 by the Ministry of Health, Labor and Welfare, which published its grand design for the computerization of the healthcare field [3]. The Act on the Protection of Personal Information was fully enforced in 2005 [4] and revised in 2015. The Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development (Next Generation Medical Infrastructure Act) came into effect in May 2018. This act relates to processes such as anonymizing data that will be shared [5]. Therefore, progress is being made in achieving a broad consensus on how to protect personal information when sharing medical data, conducting experiments, establishing laws, and allocating time for discussions and improvements.

A need has arisen for inter-regional healthcare cooperation and occasional mutual disclosure of information among different medical institutions by way of electronic health records (EHRs). To this end, the government has enacted the Health and Medical Strategy Promotion Act (Act No. 48 of 2014) to construct a digital infrastructure for the medical and healthcare field [6].

Basic research on biological information can thus be considered closely related to ethics, laws, and social implications (ELSI) [7]. Since these efforts are aimed at providing better health and medical care, it is important to approach the problem with ingenuity and from a social implementation perspective.

2.2 Data-driven era

Various concepts have been proposed as technical models of how industry and society should function in the future, e.g., Internet of Things (IoT), Society 5.0, and Industry 4.0. The basic principle is to increase productivity based on digital data, but there should also be a mechanism for sustainable development based on circulation, whereby information technology drives change through the gathering of new knowledge and evidence. This concept is having a major impact on healthcare reform. For example, it can be applied to data-driven circulation systems that automatically collect data generated during consultations, use ICT to extract new medical knowledge from these data, and use this knowledge to implement better medical care. In 2007, the Institute of Medicine, now the National Academy of Medicine, proposed the Learning Health System [8].

The importance of data gathering and information technology in the medical and healthcare fields is increasing yearly. Image diagnosis using AI and clinical applications of the human genome are regarded as major achievements. For this reason, big data and information technology have started to experience competition on a global scale. This sense of urgency is expressed in the strategic plan issued by the National Institutes of Health (NIH) in the United States in June 2018 ("Strategic Plan for Data Science"), whereby a specific plan was formulated at the national level [9]. This plan opens with the following sentence: "*As articulated in the National Institutes of Health (NIH)-Wide Strategic Plan and the Department of Health and Human Services (HHS) Strategic*

Plan, our nation and the world stand at a unique moment of opportunity in biomedical research, and data science is an integral contributor." This declaration is thought to originate from the precision medicine initiative set out by President Obama in his 2015 State of the Union address. Precision medicine is spreading from cancer treatment to medical treatment in general. Again, data science is essential for the creation of new concepts.

The quantity of information worldwide is growing exponentially in response to changes in the social environment of ICT. This amount is expected to increase by about 1.9 times between 2017 and 2020, and at a rate of 228 exabytes per month [10]. The number of IoT devices is expected to increase in the healthcare field (3 times more in 2020 compared with 2014), and a variety of information, such as genome information and medical images, are being digitized in the medical field. With the rapid expansion of medical IoT, it is expected that the amount of such information will increase even more in the future. A large medical institution has a large server for each modality for diagnostic imaging, but there are fears that this could result in the creation of information silos and memory depletion. Technological development, such as the application of *Innovative Optical and Wireless Networks (IOWN)*—on which NTT is actively working [2]—will be necessary to cope with this information explosion. At MEI Labs, we are constantly working on new ways to analyze, summarize, and use information.

2.3 Standardization in data science

Terminology can sometimes vary from one specialization to the next, with the same word having more than one definition. Furthermore, biological signals from different sources may have been gathered using equipment with different calibrations or subject to processing with different machines of undefined characteristics. Such differences can make it almost impossible to acquire new knowledge from the collected data. Therefore, data standardization is important for promoting data science in the medical field. Well-known examples include DICOM® (Digital Imaging and Communications in Medicine; a standard format for images) and SNOMED-CT (Systematized Nomenclature of Medicine Clinical Terms; a standard nomenclature for technical terms). Japan is promoting DPC (Diagnosis Procedure Combination), which standardizes the names of diagnosed illnesses according to International Classification of Diseases (ICD)-10. Information such as NDB (National Database) medical fee receipt information and the results of special health checks are maintained as big data, and there are high expectations from research using such data.

ICT has been used in the medical field for maintaining EHRs and personal health records (PHRs) and providing cooperative medical care. However, with the emergence of AI and big data, ICT is expected to play an increasingly important role. Again, the standardization of ICT must take place first. Legislation (HITEC Act: Health Information Technology for Economic and Clinical Health Act) and federal entities (ONC: Office of the National Coordinator for Health Information Technology) play an important role in the United States, where ICT has been rapidly deployed in clinical practice throughout the country.

The abovementioned US strategic plan states that medical research data should be findable, accessible, interoperable, and reusable (FAIR) [9]. This principle regarding the use and sharing of data is considered the basic attitude that should apply to all research involving the use of medical and healthcare data, where it is necessary to protect personal information and respect confidentiality.

3. MEI Labs initiatives

A principal concept of assessing variables in medical research is expanding from evidence-based medicine toward data-driven medicine that involves using large volumes of multidimensional data [11]. MEI Labs will be operated based on informatics, and we hope to generate knowledge and proposals that can contribute to the medical and healthcare fields. To carry out high-impact scientific research, we are conscious of the appropriateness of problem setting, quality of data (in terms of correctness, precision, and quantity), and highly sophisticated analysis. Our goals and the perspectives accord well with *IOWN* for *Smart World* and *Natural Technology* solutions [2].

There are at least three areas in medical and health informatics. These are: 1) sensor technology to measure the structure or function of a subject at rest during daily activity or under loaded conditions, 2) the accumulation and analysis of data for diagnosis, prevention, or treatment, and 3) EHRs or PHRs for lifelong care. As an extension of continued studies at NTT Basic Research Laboratories, MEI Labs in collaboration with Technical University of Munich will add a new research area focusing on nano- and/or micro-devices to efficiently sense biometric signals on the minute level and function as treatment modalities.

We will take advantage of our location in North America and quickly adapt to global standards while fostering a productive research environment for young researchers in Japan, the United States, and around the world. MEI Labs contributed to the proposal and implementation of at least seven of the eleven technical innovations advocated for NTT's *Smart World* vision [2]. The realization of *Bio Digital Twins* [12] would be ideal for accurate real-time diagnosis and high-quality treatment, and we hope to pursue this as one of our research targets.

References

[1] Translational Bioinformatics, AMIA (American Medical Informatics Association), https://www.amia.org/applications-informatics/translational-bioinformatics

[2] NTT Technology Report for Smart World, https://www.ntt.co.jp/RD/e/techtrend/index.html

[3] Press release issued by the Ministry of Health, Labour and Welfare on Dec. 26, 2001 (in Japanese). https://www.mhlw.go.jp/shingi/0112/s1226-1.html

[4] The Act on the Protection of Personal Information (in Japanese), https://www.ppc.go.jp/files/pdf/290530_personal_law.pdf

[5] The Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development (in Japanese), https://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=429AC0000000028

[6] Health and Medical Strategy Promotion Act (in Japanese), https://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=426AC0000000048

[7] T. Kamisato, "The Possibility of Applying Ethical, Legal and Social Implications (ELSI) to Information Technology—A Historical Background," Journal of Information Processing and Management, Vol. 58, No. 12, pp. 875–886, Mar. 2016.

[8] The Learning Health System, National Academy of Medicine, https://nam.edu/programs/value-science-driven-health-care/learning-health-system-series/

[9] NIH Strategic Plan for Data Science, https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf

[10] Ministry of Internal Affairs and Communications, Japan, "White Paper on Information and Communications in Japan," http://www.soumu.go.jp/johotsusintokei/wp_eng.html

[11] N. H. Shah and J. D. Tenenbaum, "The Coming Age of Data-driven Medicine: Translational Bioinformatics' Next Frontier," J. Am. Med. Inform. Assoc., Vol. 19, pp. e2–e4, 2012.

[12] Press release issued by NTT Research, Inc., "World-class Research Center Opens in Palo Alto," July 8, 2019. https://www.ntt-research.com/2019/07/08/world-class-research-center-opens-in-palo-alto/

Hitonobu Tomoike

Director & Senior Vice President, Medical & Health Informatics Laboratories, NTT Research, Inc.; Research Professor, Bio-Medical Informatics Research Center, NTT Basic Research Laboratories.

He received a Bachelor of Medicine from Kyushu University, Fukuoka in 1969. Before taking on his current positions, he held several senior positions at universities and research institutes, including serving as associate professor at the Research Institute of Angiocardiology and Cardiovascular Clinic in the medical department of Kyushu University; professor in the First Department of Internal Medicine of Yamagata University; hospital director (Director General) at the National Cerebral and Cardiovascular Center; director emeritus at the National Cerebral and Cardiovascular Center; and hospital director at the Sakakibara Heart Institute.