Cross-ministerial Strategic Innovation Promotion Program (SIP)
Innovative Artificial Intelligence (AI) Hospital System

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Cabinet Office
Director - General for Policy Planning

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Overview of the research and development project

1. Purpose and goal

It is aimed to use medical equipment and IoT devices to collect comprehensive patient information and transform that into big data, and is also aimed to utilize AI analysis technology to develop, construct and implement the Innovative Al Hospital System to support the diagnosis, education and communication at medial service sites. These will ensure the effective usage of the vast medical information in the treatment and construction of a system providing advanced, cutting-edge and optimized medical services. In addition, these technologies will reduce the burden on doctors, nurses and other medical staff working in hospitals. These technologies will also improve the cost-effectiveness of medical care, contributing to solving problems faced by the super-aging society and in developing the economy.

2. Research content

This project will provide advanced and cutting-edge medical services through the development, construction and social implementation of the Innovative AI Hospital System that utilizes AI, IoT and big data technology. Moreover, it will reduce the burden on medical staff including doctors and nurses. This project is consists of subthemes A to E and will be implemented through the coordination of the medical information database of universities and research institutes.

Subtheme A: A highly secure medical database and analytical technologies to find medically useful information.

Subtheme A is aimed at creating a database (big data) that comprises information of clinical, imaging, pathological, biochemical examination and wearable device. As such accumulation of patient information includes sensitive personal information, data management based on a secret sharing scheme that considers cyberattacks is necessary. Moreover, analysis based on secret computing technology for an encrypted processing of personal data is imperative for the database information.

① Development and construction of the technology for a secure physical and electronic storage of clinical information, image information, pathological information, information obtained through biochemical examination and information obtained by wearable devices.
② Construction of technology for safe transmission/reception of information from wireless sensor devices.
③ Examination of the security of database and calculation system.
④ Development of technology to extract information useful for medical practice from the database (big data) and construction of a thesaurus.
⑤ Development of technology for safe extraction calculation from the database (big data).
⑥ Construction of corpus that is linked to existing Japanese and international glossaries (compatible with regional dialects) for appropriate documentation of voice inputs (compatible with multiple languages).
⑦ Development of communication protocol that utilizes blockchain technology that includes traceability and smart contracts.

Furthermore, to guard against cyberattacks, blockchain technology with features for the medical field such patient information exchange will be developed and utilized to ensure secure information traceability and information access authority management.

The objectives of this project are to build these features in an automated or semiautomated system utilizing AI technology multilingual (and compatible with regional Japanese dialects). This was intended for examining its coordination with existing glossaries and to develop basic structures permitting a flexible response to differences in glossaries used by the system.

Subtheme B: Development of an AI-assisted automated medical record documentation system, an AI-assisted bilateral communication system used in obtaining informed consents and an AI-assisted diagnosis and treatment support system.

Subtheme B focuses on major issues that have been a significant burden on medical service staff. It aims to build a system for reducing the burden on medical staff through the utilization of sensors (IoT), big data and AI. In addition, it aims to develop a simulation and navigation system for the diagnosis and treatment using AI technology.

The following basic structure will be prepared to implement the voice input system that is required for the simplification of administrative tasks like establishing medical and nursing records and summaries at the time of discharge from the hospital.:

(1) Standardization of terms used in medical services.

(2) Creation of a corpus [※1] structuring the natural language sentences that compiles them in large-scale.

[※1] Corpus: A large collection of structuralized spoken and written languages used for research on language processing or as data for machine learning. This project requires documentation of spoken words.

(3) Creation of a thesaurus [※2] containing glossaries that classify and organize words by their meaning and describing the similarity, contrast and inclusion relationship of related words.

① Development of a system for the electronic documentation from recorded conversations between doctors and patients (related to Subtheme A).
② Development and implementation of a real-time interactive communication system for patient explanations that considers the comprehension level of each patient through the application of sensors and the AI technology.
③ Survey on the changes in the burden on medical staff and the satisfaction of patients and their families through the implementation of various features and the implementation of the received feedback through improvements (related to Subtheme D).
④ Creation of a document preparation system accounting for the characteristics of each patient, including the information collected from medical journals through online research.
⑤ Development of a simulation and navigation system for the diagnosis and treatment that utilizes AI technology.

Subtheme C: AI-assisted highly-sensitive and low-invasive testing of blood or other biological samples to enable the earliest detection of cancer and other severe diseases and.

Subtheme C involves the conduction of ultraprecise examination of blood and other samples utilizing AI technology (including sample transportation and confirmation of the quality of examination results) that is considered effective for the screening of diseases such as cancer and the ultra-early diagnosis of their recurrence and exacerbation and enabling a reduction in the cost and burden of examinations on patients. Moreover, using these technologies as the foundation, a diagnosis and assessment support system including patient vital data, imaging and activities (including exercise, resting and nutrition intake) information and monitoring data will be created. Furthermore, a diagnosis and judgement system based on the characteristics of individuals will be constructed through coordination with the information database (big data) of other patients (including academic information). In addition, a monitoring system that applies and utilizes AI technology and enables the selection of a diagnosis and treatment (including medication) based on a comprehensive analysis of patient information and the database (big data) and medical equipment with improved safety will be produced. Additionally, we aim to create a system that could be used by the "family doctor" as well, through the simplest monitoring, thereby preventing disparity in medical services between regions.

By coordinating the results from this Subtheme with those of Subtheme B, an organization that enables interactive easy explanations for patients and responds to their individual understanding level will be established.

※2 Thesaurus: A dictionary of synonyms classifying words according to their similarities. In medicine, one phenomenon is sometimes described using different terms. Thus, a thesaurus is required in this project for the creation of a language database and its processing.

① Standardization of the transportation method of blood and urine samples and methods to isolate the components for examination.
② Standardization of ultraprecise analyses methods applying AI technology.
③ Establishment of a method utilizing AI for processing from sampling to testing, including monitoring, test quality verification and communication of the test results in an easy way.
④ Development of sensors for collecting vital data, including implementation inside Innovative Al Hospital System that utilize sensors for collecting vital data that are already commercially available.
⑤ Development of a system for understanding the state of an individual and that can be used for a comprehensive analysis of the sensor data and genetic data accomplished using AI.
⑥ Demonstration through AI application analysis as well as its feedback, correction (Subtheme D) and coordination.

Subtheme D: Proof-of-concept study of Al hospital functions in clinical practice settings.

Install technology and devices like the sensors researched and developed in Subthemes A to C to the existing ICT technology for treatment to advance learning of the diagnosis and assessment system using the AI technology system. Moreover, to construct a system that is more practically applicable in medical services.

The obtained results are reintegrated into each Subtheme, reflected in the correction of the AI (analysis algorithm) and used for the analysis of information collection devices and redundant information collection, triggering improvement and adjustment of the system.

① Verification test for ensuring consistency with the existing system.
② Demonstration of the sensor devices at the service frontline.
③ Analysis based on the information acquired from ② and its verification.
④ Development and establishment of a real-time resilient monitoring system.

Subtheme E: Technical standardization of the Al hospital system, management of intellectual property rights, open and closed innovation strategies and government–industry-academia collaboration and.

The technologies developed in Subthemes A to D are incapable of supporting the treatment of patients or reducing the workload of medical staff unless used in medical services. Thus, this Subtheme addresses ways of solving the problems facing the dissemination and adaptation of these research results.

In addition to cost, intellectual property rights are also expected to present an obstacle to dissemination of this technology. Thus, we believe that the management strategy for intellectual

property of the technology is important. Actively making the technology available to the public is equally important, thereby prioritizing its dissemination in society. This will also encourage competition with the emergence of other companies, thereby solving cost issues through the economies of scale and price competition and consequently facilitating wide use in medical services while maintaining precision.

Moreover, for the handling of sensitive personal information, it is important to examine the international standard of information handling if international expansion is being considered. This prevents solely focusing on competition and maintains the collaborative platform construction and its control rights in Japan. Additionally, coordinate with patient associations.

Thus, based on the above, this Subtheme examines social issues that accompany the digitization of medical information and its utilization, with the aim of establishing a common understanding for its handling in future.

In addition, regulations and a framework toward its social implementation, obstacles and planning toward overcoming these obstacles for social implementation will be examined in consultation with relevant governmental organizations like the Ministry of Health, Labor and Welfare and also including the perspectives of patients and medical staff.

① Designing an intellectual property plan based on research and development.
② Examination and development of a standardization strategy and an open or close strategy that will optimize the characteristics of the developed technologies.
③ Realization of public-private partnerships and technology-business matching and its future follow-up.
④ Examination and development of methods necessary for adaptation of the developed technologies by the private sector like PFI.
⑤ Examination and development relative to the legal framework of information usage (including international frameworks) as well as its utilization (including legal protection of personal information).
⑥ Coordination with patient associations.

3. Intellectual property management

To establish an intellectual property committee at the National Institutes of Biomedical Innovation, Health and Nutrition for appropriate intellectual property management to secure incentives for the inventors and those working toward the dissemination and industrialization of the inventions and increase the benefits for the public.

The intellectual property strategy involves active acquisition of patents in fields and technologies that can be patented, with the ownership of the patent being beneficial for their practical application. Regarding medical equipment, those requiring significant involvement of a third party, including the AI analysis program, data format, primary treatment method and In/Out protocol, will be published to establish their international standardization. As the competition in AI algorithm for

analysis of images, pathologic tissues, blood, etc., is especially fierce, intellectual property and standardization strategies will be actively deployed, with their standardization employed as a preventive measure against patent trolls※3.

The IoT devices for measurement will constitute the "cooperation area," with the protocol published and standardized to facilitate entry of Japanese and international companies (naturally, regulations like the Pharmaceutical Affairs Act will be strictly followed), to promote rapid and widespread dissemination and de facto standardization. Regarding the technological aspects of, for instance, the AI analysis algorithm exhibiting technological supremacy, direct publication will be avoided; however, their competitiveness will be ensured through methods including indirect publication, intellectual property protection and concealment.

4. Evaluation

Internal inspections will be conducted by the Research Director, Program Director (PD) and sub PD to establish a system that is capable of self-improvement in addition to the regular evaluation by the Governing Board at the end of each year. In addition to the internal inspection and evaluation by the PD and sub PD, various committees, i.e., a promotion, an evaluation (comprising the third party), an intellectual property, an evaluation from the research and development perspective, an ethics, law and social issues (hereafter referred to as the ELSI committee), will be established alongside a project management office (PJMO) to conduct internal and external evaluations. Furthermore, progress management would be established by implementing the PDCA cycle.

5. Exit strategies

(1) Exit-oriented research promotion

1) Practical applicability of the AI hospital service package

Achieve practical application of the AI hospital package and domestically and internationally expand the same. Establish a diagnostic system that is usable for telemedicine.

2) Practical application of AI medical equipment

Work toward the manufacture and sales of medical equipment equipped with AI functions.

This project will develop medical equipment that utilizes AI, with clinical tests primarily conducted by private companies with support from Cross-ministerial Strategic Innovation Promotion Program (SIP). Private companies will gain the manufacturing and sales approval and certification and will be responsible for sales.

Utilize high-efficiency distributed data processing infrastructure and coordinate with other challenges for developing IoT medical equipment.

※3Patent troll: An organization or individual using owned patent rights to sue large companies and other such organizations for patent infringement to receive a large compensation or license fee. This particularly concerns those who acquire many patent rights from third parties for the purpose of litigation. Patent troll.

(2) Measures for dissemination

- The AI hospital package and the medical equipment using AI will also be disseminated by companies collaborating in this research, through commercialization and marketing.
- The telecommunication standards will be published. An open strategy will be adapted regarding the development environment to enable diverse private companies to join the development.
- Through early partial introduction to other facilities, experiments for utilization of the high-speed communication line crucial for quick domestic expansion of the AI hospital package will be conducted.

1. Purpose and goal

It is essential that efficient collection of imaging, pathological diagnostics and biochemical examination information, as well as the construction of a binding interface database and introduction of data analysis using AI, to guarantee the quality of medical practice, limit the increase in medical cost and improve the international competitiveness of Japanese medicine in our super-aging society. The implementation of these will strengthen industrial competitiveness, improve diagnostic precision, prevent human errors and comprehensively and seamlessly select the best treatment approach in the medical service, enabling the realization of Society 5.0.

The discrepancy in knowledge and information in medical services makes understanding advanced technology difficult for medical staff, thereby hindering them from providing suitable explanations to patients. This is a major obstacle for the dissemination of the cutting-edge diagnostics and treatment to the medical services frontline. Moreover, the application of cutting-edge technology requires utmost care in standardization, evaluation of test result quality and data interpretation. Any error in the test results or interpretation of the same poses a health hazard for patients. Therefore, strict checks during the testing process are paramount. Furthermore, the exhaustion of doctors and other medical staff in medical services is a mounting social problem. Thus, devising a new system that radically changes the health care system is essential to avoid a further increase in the burden on the medical services while ensuring quality is maintained or improved. In other words, the introduction of AI for developing a medical and diagnostic information database for usage in the medical information industry and medical services is indispensable.

High-precision imaging, pathologic tissue and blood diagnosis using AI will achieve prevention, early detection, aggravation prevention, selection of the best medication, avoidance of medications with side effects and produce a major social reform in medicine. Such changes are expected to limit the increase in medical costs, which is an urgent problem for Japan.

As the imaging and pathological tissue diagnoses conducted thus far exhibit discrepancies between individual technicians, a diagnosis supported by AI will improve the diagnosis quality, while maintaining compatibility with remote diagnosis. Moreover, new technologies including ultraprecise tests for blood and other samples utilizing AI technology are currently gaining international standards including examination standardization, data interpretation unification and building of a system to communicate the results to medical staff, patients and families. Thus, it is urgent for Japan to join this process.

Japan is simultaneously facing problems of an increasing dependent population and a decreasing working population due to declining birth rates and the super-aging society. The prevention, early diagnosis and treatment optimization of diseases contribute to the extension of a healthy lifespan and limits medical costs through reduction of treatment duration and protecting the working population.

In Japan, where a universal health insurance system for citizens is the norm, the collection and sharing of diagnosis and treatment information of patients is predicted to be possible at an initial

stage through the introduction of ICT. Thus, providing a service utilizing such information accumulation, constructing its interpretation algorithm and employing the analysis capability and interactive communication capability of AI will encourage international patients to commission analyses (+ treatment) to Japanese medical services. The retention of such knowledge in Japan through this project and international provision of services (or establishment of international bases) will contribute to improving the international industrial competitiveness of Japanese businesses and energize the Japanese economy.

However, awareness of the intellectual property strategy, international standardization and open or close strategy within international competitiveness is important. Furthermore, it is important to acquire as many patents as possible for the intellectual property strategy and use the AI analysis program in the widest possible way. Thus, the data format, the primary treatment approach and the In/Out protocol must be made public, to ensure that these will become international standards. In particular, as the competition in the AI application algorithm for imaging, pathological and blood tests is currently intense, an active intellectual property strategy and de facto standardization will be conducted in tandem.

The Innovative AI Hospital System will not be limited to the project at a single hospital, but will instead create a domestic network of medical facilities. Many governmental agencies will be involved in this project. The medical field will be relevant for the Ministry of Health, Labor and Welfare and the Ministry of Education, Culture, Sports, Science and Technology. Medical equipment, pharmaceutical development and equipment for pharmaceutical preparation of isotopes used in diagnostic and treatment purposes will be relevant to the Ministry of Health, Labor and Welfare and the Ministry of Economy, Trade and Industry. The communication infrastructure for information sharing, remote imaging and pathological analysis and diagnosis is relevant to the Ministry of Internal Affairs and Communications, whereas the distribution of pharmaceutical products, test equipment and test samples is relevant to the Ministry of Land, Infrastructure, Transport and Tourism and the National Police Agency. Furthermore, we believe that imaging, pathological and blood information are important for providing medical services to victims of disasters and the future identification of these victims. Thus, such coordination will facilitate the deployment of the database and AI in disaster response, for instance at the time of a great earthquake disaster.

An example of the latest AI system is Watson, developed by IBM of the United States. It is a "question and answer system and a decision support system using AI," that has been applied in different fields including cancer diagnostic support, finance and human resources matching. In April 2018, "IDx-DR" used in diagnosing diabetic retinopathy in place of a doctor received its first medical equipment certification of FDA in the United States. By analyzing the image of the retina of a patient using the IDx-DR, a diagnosis of diabetic retinopathy can be obtained in less than one minute. Moreover, in the cancer treatment field, it is necessary to include delicate information such as genome information, as is the case with serious hereditary diseases. Currently, many issues must be solved owing to discrepancies in the quality of the diagnosis and treatment data from which AI

must learn and the amount of training data is also insufficient. The common view in this field is that the development of an information analysis tool using AI for the medical field will require many more years.

Today, discussions continue at the United Nations on the impact of AI on domestic economies in different fields including the medical field. However, Japan lags behind the United States and China in the field of AI. However, the domestic interest is at stake in deciding whether to employ foreign systems for the AI used in processing medical information comprising delicate information on our privacy. We believe that the fact that we are lagging in the field of AI is a good reason for this project to move toward the commercialization of AI in Japan.

Therefore, this project will establish a liaison committee of representatives from industry, academia and government agencies, actively publish its achievements and impact (using the Internet), encourage the participation of private companies for the practical application or implementation of its achievements and recruit staff for the application of the basic technology. In addition, the project will arrange to match researchers and private companies through information sharing platforms.

The results of this project will provide optimal and minimally invasive treatments and medications that consider the diverse attributes of each patient including genetics, physical and lifestyle characteristics (the patient would make the final decision). Thus, it will ensure the avoidance of medications and treatments with low curative potential, faster rehabilitation of patients, medical cost reductions and workforce protection. Furthermore, a diagnosis utilizing AI technology like the ultraprecise testing of samples like blood will be applicable for the early detection of diseases including cancer, ultra-early diagnosis of recurrence and ultraprecise comprehension of the effects of the treatment. The economic effects in the field of cancer treatment will involve improvement in the cure rate (10% improvement in the five-year survival rate) and a significant reduction in medical costs (approximately several hundred billions of yen per year).

(1) Background/Japanese and global situations

By 2025, Japan will be a super-aging society with over 30% of its total population aged 65 years or older. This certainly will further increase medical costs through an increase in the ratio of sick people in the population, the advancement and specialization of medical equipment and increase in the cost of treatment and medication. Following the advancement and specialization of medical practice, the regional discrepancy in the standard of medical services is worsening. For instance, the regional discrepancy in cancer mortality is approximately 2.3 times [※4] between the region with the lowest mortality and that with the highest. Currently, it is impossible for everyone to receive medical services of the same quality regardless of the area of their residence. Radical reform of the healthcare system is essential for everyone in Japan to equally receive high-quality and safe medical

※4 Source: Nihon Keizai Shinbun, "Regional discrepancies between the three major causes of death and medical expenses" (Published on 21.05.2017)

services and extend the lifespan of the people. As proposed in the idea of Society 5.0, it will be difficult that constructing a system providing advanced and high-quality medical services to all residents in this super-aging society without digitizing medical information, creating a large-scale database and using cutting-edge technology such as AI to optimize such information.

However, in medical practice, diverse data including changes in patient condition, imaging, pathological and biochemical tests are chronologically obtained for use in making decisions. Thus, "integration of multifaceted and chronological information" is required for the recreation of such data in cyberspace. Moreover, the usage of medical information is characteristically "limited to protect personal information" that is delicate. Therefore, the state of AI in the medical field is still at the research level, where already digitized images, pathological, or biochemical information are externally and only sporadically analyzed, although AI is rapidly expanding as the next generation social infrastructure. This state is far from the Cyber-Physical-System (CPS) that is Society 5.0 being pursued.

(2) Meaning/Policy Significance

This proposal will achieve practical application of the "Innovative AI Hospital System," wherein AI assists with medical practice and it will be established as a package for international expansion or application to other fields. This will result in the radical reform essential for maintaining safe and reliable medical services in a super-aging society. Moreover, it is expected to improve the competitiveness of Japan's pharmaceutical, medical equipment and medical information industries, that lagging in comparison to their international counterparts to a significant degree.

(3) Purpose/Target

① Toward the realization of Society 5.0.

1) The present information society (Society 4.0) displays an inadequate connection between electronic information and the real world, as well as an inability to share knowledge and information in general. One of the most conspicuous manifestations of these problems is in the medical field, where the amount of information is estimated to yearly increase by approximately 30 times[※5]. As the diagnosis of diseases advances with multiple subdivisions and the rapid development of new drugs, not only patients but also medical personnel are unable to keep pace with the information increase in clinical practice. Thus, a large knowledge or information discrepancy exists between cutting-edge researchers and general medical practitioners, in addition to the discrepancy between medical staff and patients or their families.
2) The realization of high-precision diagnosis, prevention of human error and selection of optimal treatment will be comprehensively and seamlessly provided for actual medical site and Society

※5 Source: Peter Densen, "Challenges and Opportunities Facing Medical Education." Am Clin Climatol Assoc. 2011; 122:48–58.

5.0 will be realized, through effective collection of clinical information including imaging, pathological and biochemical information, construction of an extensive database and the introduction of data analysis through AI.

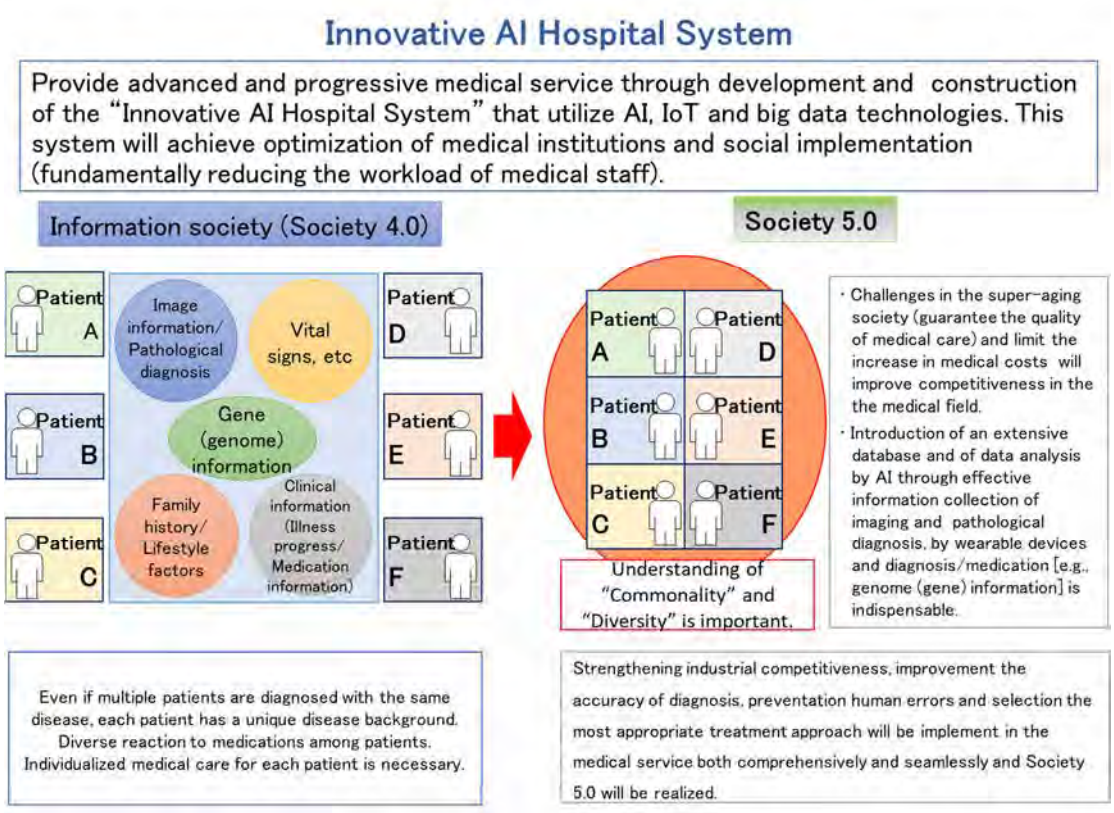


Figure 1　From the information society (Society 4.0) to Society 5.0.

② Social objectives

1) Data or information collection using IoT and sharing of past experiences based on ICT technology, diagnosis and treatment support using AI will not be limited to research and development only but will produce social changes throughout the medical field. Through the development of these, it will be possible to provide more precise medical services. Moreover, through the accumulation of data and effective utilization, information leading to new discoveries and treatments will be easily extracted, thereby revitalizing the medical industry.
2) High-precision imaging, pathologic tissue and blood diagnosis using AI will improve prevention, early detection, aggravation prevention, selection of the most appropriate medication and avoidance of medication with side effects and will certainly reinforce social reform in the medical field. Naturally, these changes are expected to contribute to control the medical cost increase, which is a challenge that requires immediate attention in Japan.

③ Industrial objectives

1) In medicine, with practice based on the empirical knowledge of the past, the sharing of such empirical knowledge is important. However, sharing of medical information is currently insufficient because delicate personal information is involved and therefore sharing of empirical knowledge is currently insufficient. This project will enable highly precise pathogenic diagnosis that considers the background of each patient and select the optimal treatment (including pharmacotherapy) even when symptoms/disease are similar through the collection and utilization of medically relevant big data and the application of AI. This will thus reduce hospital visits and hospitalization durations. For Japan, that is facing the prospect of a super-aging society, this will help to limit medical costs and also protect the workforce. Consequently, it is expected to improve domestic productivity.
2) The social security cost (medical cost) is yearly increasing due to the ongoing aging and population decline. Regarding this challenge, appropriate medication and treatment selection based on highly precise diagnosis will help in control medical costs. Moreover, it will likely elucidate the incidence/aggravation risk of a disease through big data analysis of significant medical information, which will contribute to the effective prevention and aggravation prevention. For cancer, measures like early detection and early treatment will be possible. Consequently, a society of energetic elderly people will emerge, ensuring revitalization of the workforce in society.
3) In Japan, where a universal health insurance system for citizens is the norm, collection and sharing of diagnostic and treatment information of patients will be possible at an early stage through the introduction of ICT. Thus, providing a service utilizing such information collection, constructing its interpretation algorithm and employing the analysis and interactive communication capability of AI will promote the commissioning of analysis (+ treatment) to Japanese medical services by patients of worldwide. The retention of such knowledge in Japan through this project and international provision of its services (or establishing international bases) will contribute in improving the international industrial competitiveness of Japanese businesses and energize the Japanese economy. It will play a leading role as the system for the Innovative AI Hospital System in international collaboration. Regarding individual techniques like liquid biopsy, endoscopy and conversation systems, the project will be expanded through the viewpoint of international competition.

④ Technical objectives

1) It is inferred that the practical application and social implementation of IoT used for recording vital signs and activities will be realized by exploiting its noninvasive characteristics. Specifically, the downsized models of high-precision devices developed for patients can be expanded as devices designed for health management of healthy individual.
2) Expansion of diagnosis supporting business with diagnosis support algorithms (programs)

based on AI will not be limited to Japan; however, it can be internationally expanded. Moreover, it will be connected to a compound diagnosis system that comprehensively utilizes such information, enabling the provision of a wider range of services.

⑤ Institutional objectives

1) A telecommunication standard to unify medical data including test devices and electronic medical records is not yet decided. In this project, a standard acceptable internationally will be designed eventually.
2) Conduct international standardization of the filtering and communication standard when analyzing the unified data in cloud AI.
3) Design an inspection guideline for medical equipment that uses AI in coordination with the Pharmaceuticals and Medical Devices Agency (PMDA).

⑥ Global Benchmark

1) While the development of the smart hospital or digital hospital is being internationally conducted in various ways, the objective of this project is to unify AI analysis by integrating medical services into cyberspace and achieve the practical application of a standardized Innovative Al Hospital System for the first time in the world.
2) Introduce the ultraprecise test system for samples like blood that utilizes the AI technology for medical services and improve the cure rate of diseases including cancer through early detection, early detection of recurrence and comprehension of aggravation. International expansion of this aspect will also be achieved by spearheading its global standardization.
3) It is important to pay attention to intellectual property strategy, international standardization and the open or close strategy for international competitiveness. It is vital to acquire as many patents as possible for the intellectual property strategy and to use the AI analysis program in the widest possible way. Thus, the data format, the primary treatment approach and the In/Out protocol must be disclosed and it must be focused that these will become international standards. As the competition in the application of the AI algorithm for imaging, pathological and blood tests is especially competitive at present, an active intellectual property strategy and de facto standardization will be conducted as two sides of the same coin as dual issues.

⑦ Coordination with local governments

Coordinate with local governments to design a model of remote pathological and imaging diagnosis or a system that is capable of processing dialect of patients during consultation.

⑧ Other types of coordination

1) The Innovative AI Hospital System will not be limited to a single hospital, rather it will coordinate a domestic network of medical facilities.

2) In disasters, imaging, pathological and blood information is important in providing medical services to victims and in their identification. This coordination will facilitate deployment of the database and AI to disaster response, for instance at the time of a major earthquake.

2. Content of research and development

Medical institutions offering frontline medical services will be used as the demonstration fields to digitize multifaceted and chronological patient and medical information including biochemical, pathological and imaging or sensor data, integrate the data into cyberspace and construct a database. Then, to protect privacy, advanced personal information protection technology like a secret sharing scheme will be utilized. Moreover, a secret calculation technology enabling mathematical processing of encrypted personal information without decryption is used for various analyses. Furthermore, the security of information traceability through technologies like blockchain and management of information access authorization to guard against cyberattacks are strictly enforced. In addition, measures to minimize human error in medical services utilizing AI would be implemented. Concurrently, use AI as support for consultation or informed consent to secure a time when medical staff can engage with the patients and their families and to reduce the burden on medical services.

Cancer has been selected as the first disease that has caused the maximum number of deaths in Japan since 1981※6, with an estimated incidence rate of approximately 50%. For Japan, which is facing the prospect of becoming a super-aging society, measures taken against cancer can serve as a model case for the medical field in general. Moreover, many medical and social benefits are involved as it will alleviate, for instance, unemployment, cognitive decline and the rapidly increasing medical costs. Moreover, cancer treatment involves many challenges, such as countermeasures against cancer in elderly people, treatment of pediatric cancer lacking standardization, the emergence of secondary cancer among pediatric cancer patients, or treatment of patients with weakened heart, liver, or kidney functions. The database and its analysis are expected to provide solutions to such challenges. Specifically, the ultraprecise testing of samples like blood utilizing AI technology is expected to directly improve the cancer cure rate through early detection due to the increase in the cancer examination rate, early detection of cancer recurrence and comprehension of aggravation. Since these applications of AI are adaptable to remote medical services, their standardization through advanced and regular medical institutions is vital. Naturally, in regard to AI-based medical equipment for which evaluation guidelines have yet to be established, it is essential to advance the project in coordination with regulators.

Participation will involve not only medical institutions but also the Ministry of Education, Culture, Sports, Science and Technology (universities) and private companies that are

※6 Source: Ministry of Health, Labor and Welfare, Annual report on the vital statistics of population, Main statistics (the latest data, annual changes) https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/suii09/deth7.html

indispensable to this project. As discussed earlier, the medical field is relevant to the Ministry of Health, Labor and Welfare and the Ministry of Education, Culture, Sports, Science and Technology; medical equipment, pharmaceutical development and equipment for pharmaceutical preparation with isotopes used for diagnosis and treatment are relevant to the Ministry of Health, Labor and Welfare and the Ministry of Economy, Trade and Industry; the communication infrastructure for information sharing, remote imaging and pathological analysis and diagnosis are relevant to the Ministry of Internal Affairs and Communications and the distribution of pharmaceutical products, test equipment and test samples are relevant to the Ministry of Land, Infrastructure, Transport and Tourism and the National Police Agency.

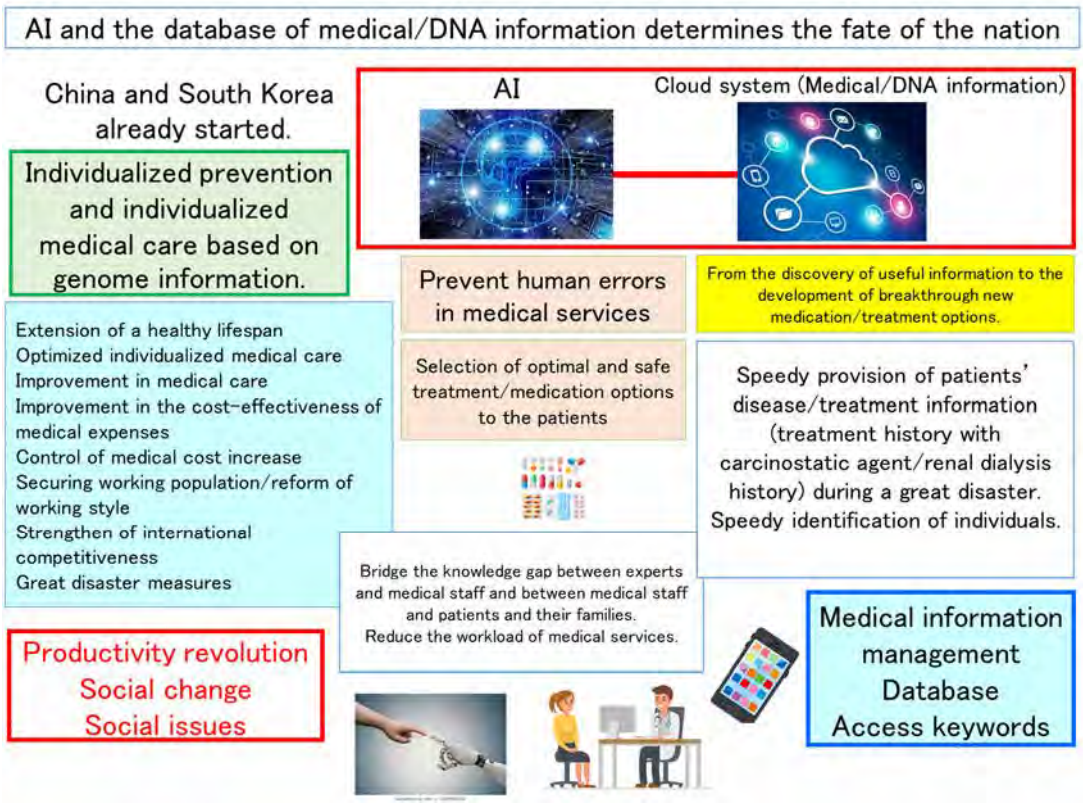


Figure 2-1 Importance of medical and DNA information and their utilization.

This project will provide advanced and progressive medical services through the development, construction and social implementation of the "Innovative AI Hospital System " that employs AI, IoT and big data technologies. Moreover, it will optimize medical institutions to fundamentally reduce the workload of medical staff. Subthemes A to D will be coordinated throughout the development, with corresponding progress managed by the project management committee.

(A) A highly secure medical database and analytical technologies to find medically useful information.

(B) Development of an AI-assisted automated medical record documentation system, an AI-

assisted bilateral communication system used in obtaining informed consents and an AI-assisted diagnosis and treatment support system.

(C) AI-assisted highly-sensitive and low-invasive testing of blood or other biological samples to enable the earliest detection of cancer and other severe diseases.

(D) Proof-of-concept study of AI hospital functions in clinical practice settings.

(E) Technical standardization of the AI hospital system, management of intellectual property rights, open and closed innovation strategies and government–industry-academia collaboration.

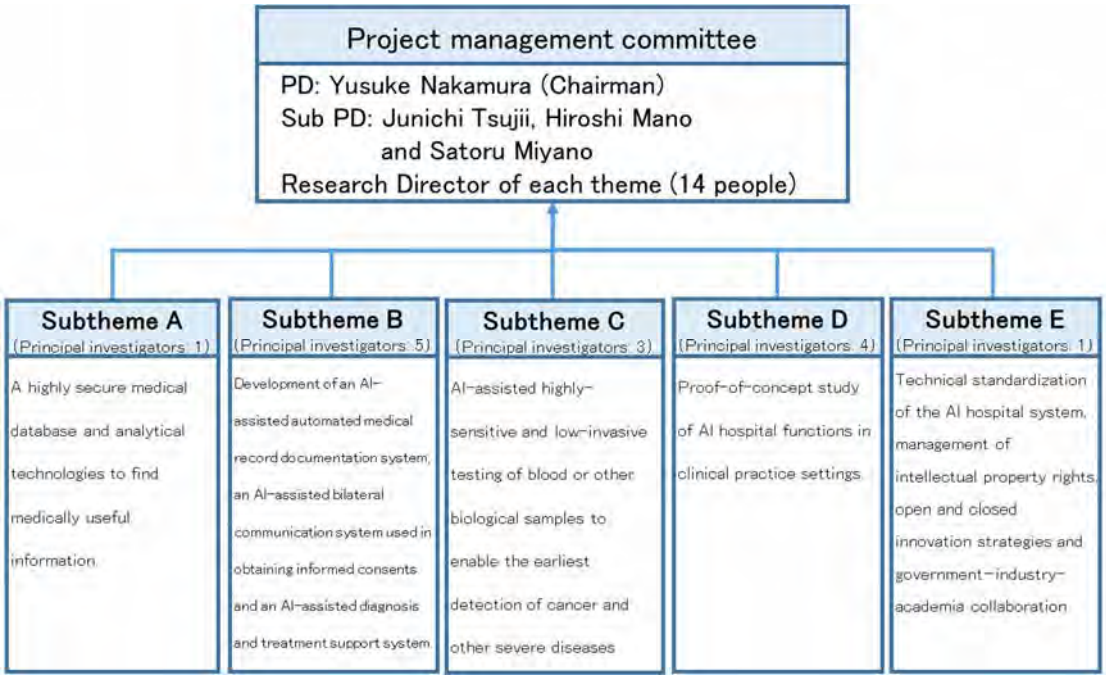


Figure 2-2 Progress framework for each subtheme

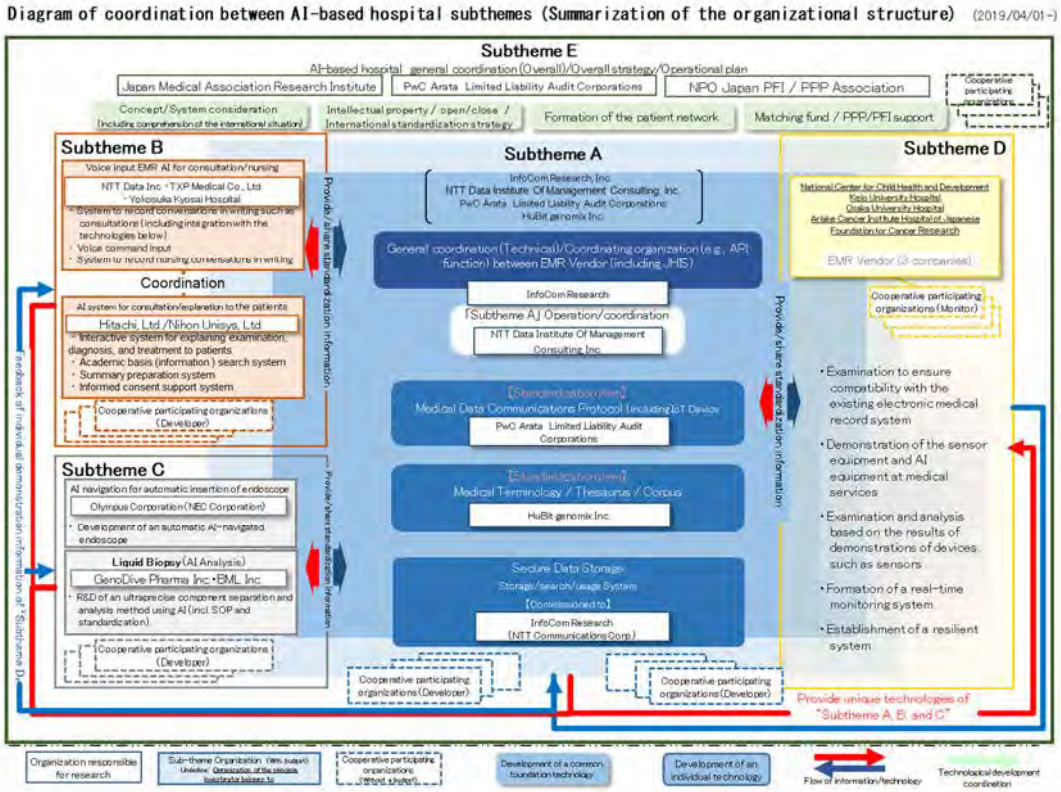


Figure 2-3 Diagram illustrating the inter-relationships among the subthemes. ①

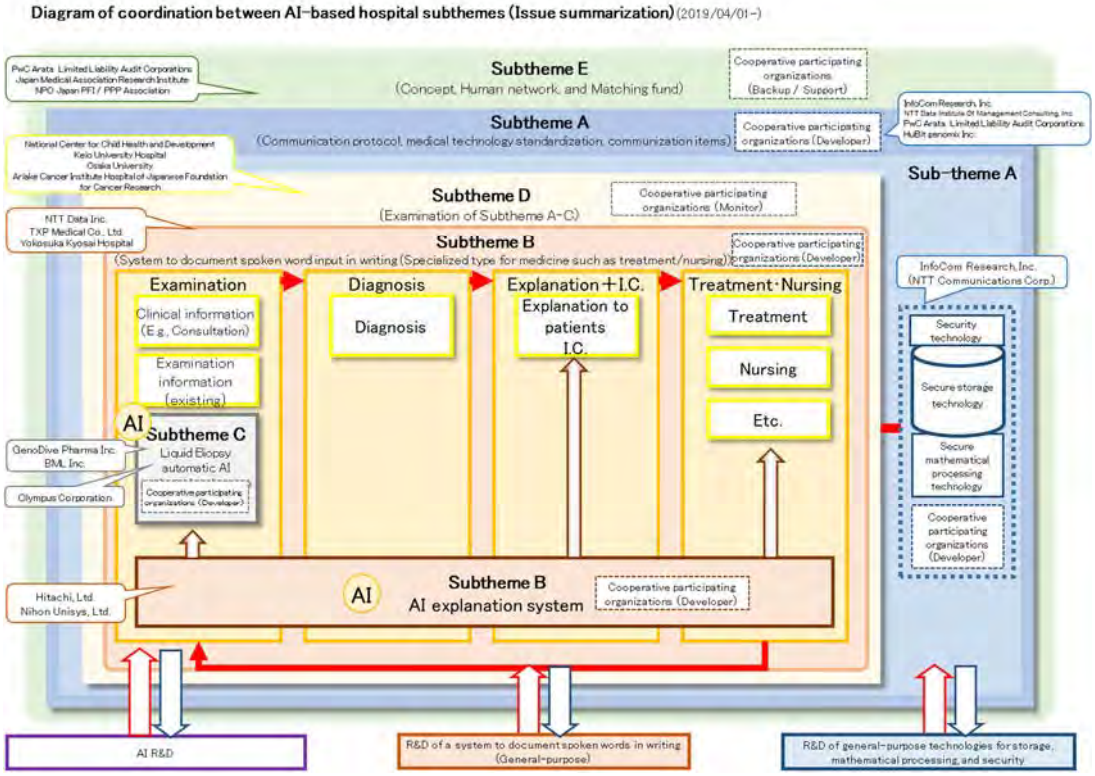


Figure 2-4 Diagram illustrating the relationship among the subthemes ②

【Subtheme A】:

A highly secure medical database and analytical technologies to find medically useful information.

This subtheme involves one research and development project. Its contents are as follows:

1) Objectives

The aim is to construct a database (big data) comprising clinical, imaging and pathological information, as well as information on biochemical examinations and wearable devices. As the accumulated individual patient information is also personal sensitive information, data management based on secret sharing schemes that considers protection from cyber-attacks is necessary. Moreover, analysis based on secret calculation technology that enables mathematical processing of encrypted personal information without decryption must be applied to the analysis using the database. Furthermore, to prepare for cyber-attacks, blockchain technology will be developed and utilized based on the characteristics of the medical field for patient information exchange, enabling securing the information traceability and management of information access authority.

Moreover, it will involve the standardization of terms used in medical practice, which is necessary for implementing the voice input system that is required to simplify administrative tasks such as maintaining medical records, nursing records and summaries at the time of discharge. It also includes the construction of a corpus with a large-scale compilation of structured sentences of languages and the construction of a thesaurus with glossaries that classify and organize words according to their meaning. The thesaurus should also describe the synonyms, antonyms and related words to enable smooth application of AI in medical services.

The objectives of this project are: to build the features as an automated or semiautomated system utilizing AI technology that is compatible with multiple languages, to examine its coordination with the existing glossaries and to develop the basic structures that enable flexible responses to differences in the glossaries used by the system.

Project number: SIPAIH18A01

Research project name: Construction of high-security medical information database and development of technologies for useful medical information extraction and analysis utilizing the database.

Principal Investigator: Hiroshi Ohira (InfoCom Research, Inc.)

Research summary: The project will involve the comprehensive, efficient and secure collection of large amounts of medical information including clinical, imaging, pathological, biochemical test and wearable device information. This will ensure the examination of the operation of the database that enables extraction of useful information for medical services, guiding its structure and development toward the realization of the "Innovative Al Hospital System". In addition, it will standardize medical terms and

structure sentences of languages essential for communication between patients and medical staff as well as between the medical staff and prepare a corpus and a thesaurus based on these.

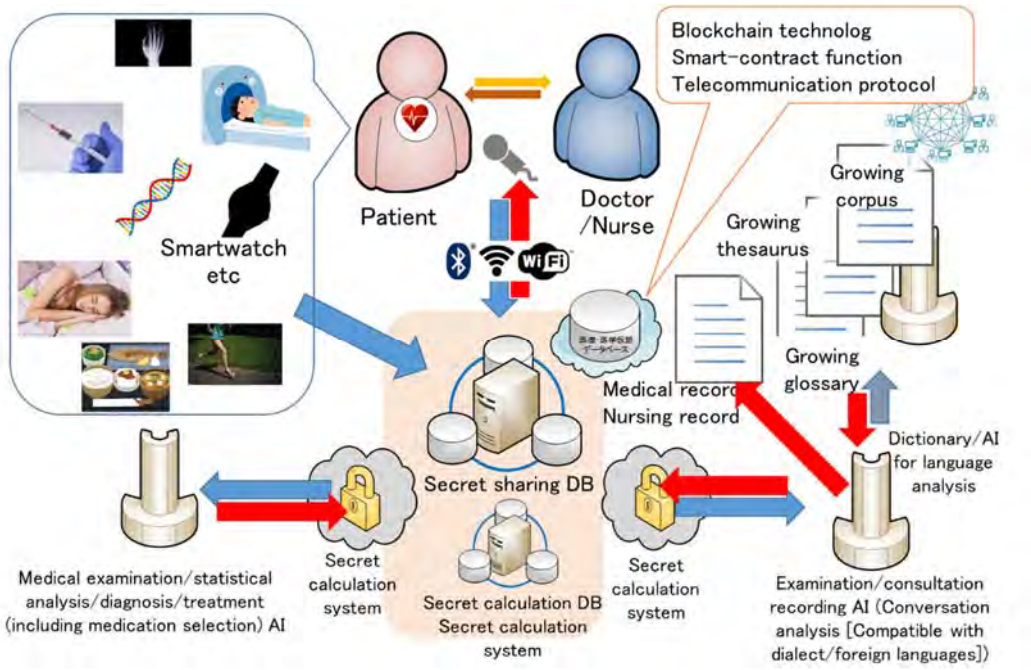


Figure 2-5 Construction of a highly secure medical information database and the development of technology for extracting and analyzing the medically useful content therein.

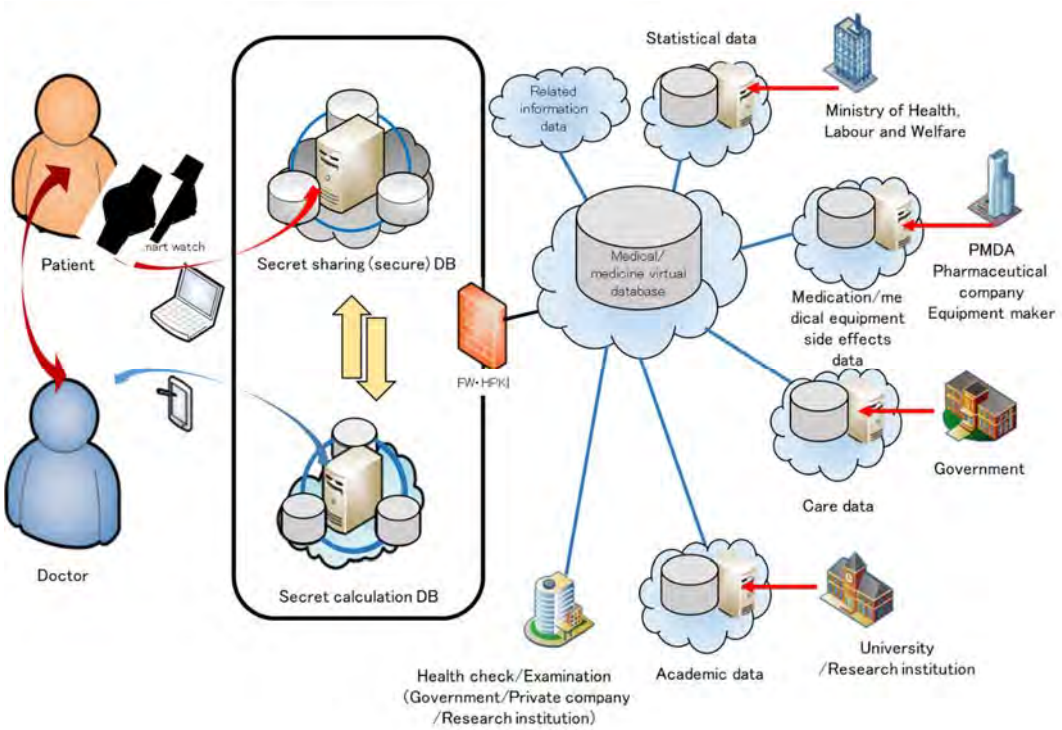


Figure 2-6　Construction of a highly secure medical information database and the development of technology for extracting and analyzing the medically useful content therein. (Database overview)

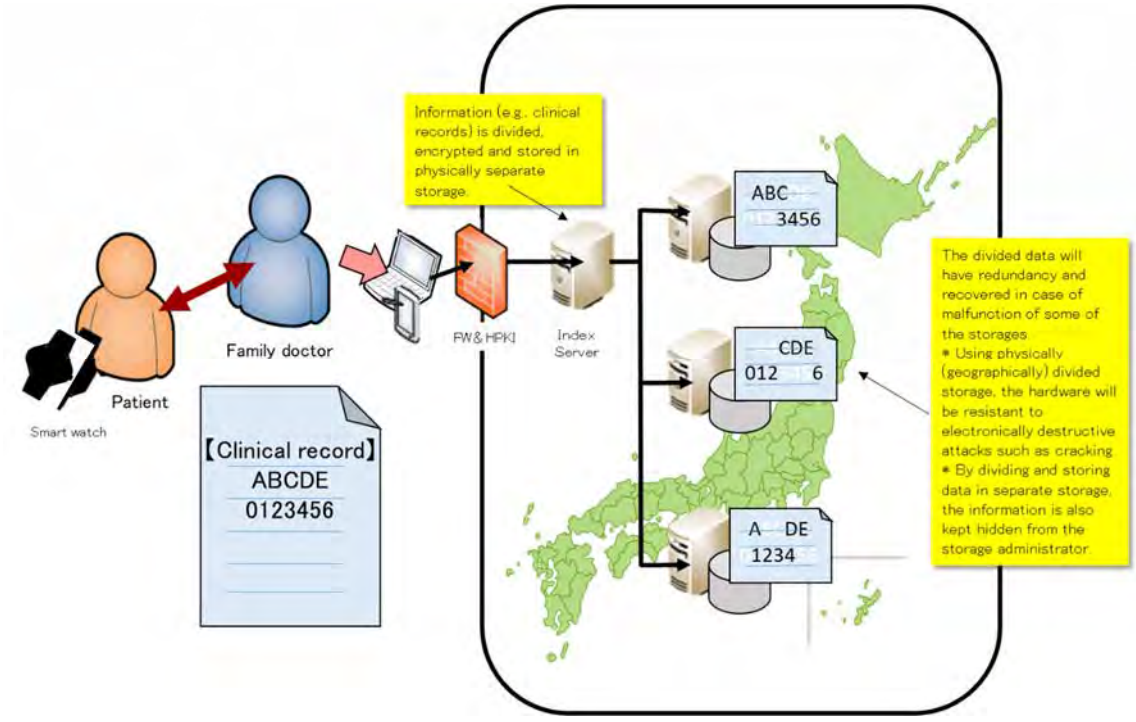


Figure 2-7　Construction of highly secure medical information database and the development of technology to extract/analyze medically useful information from it. (Clinical database overview)

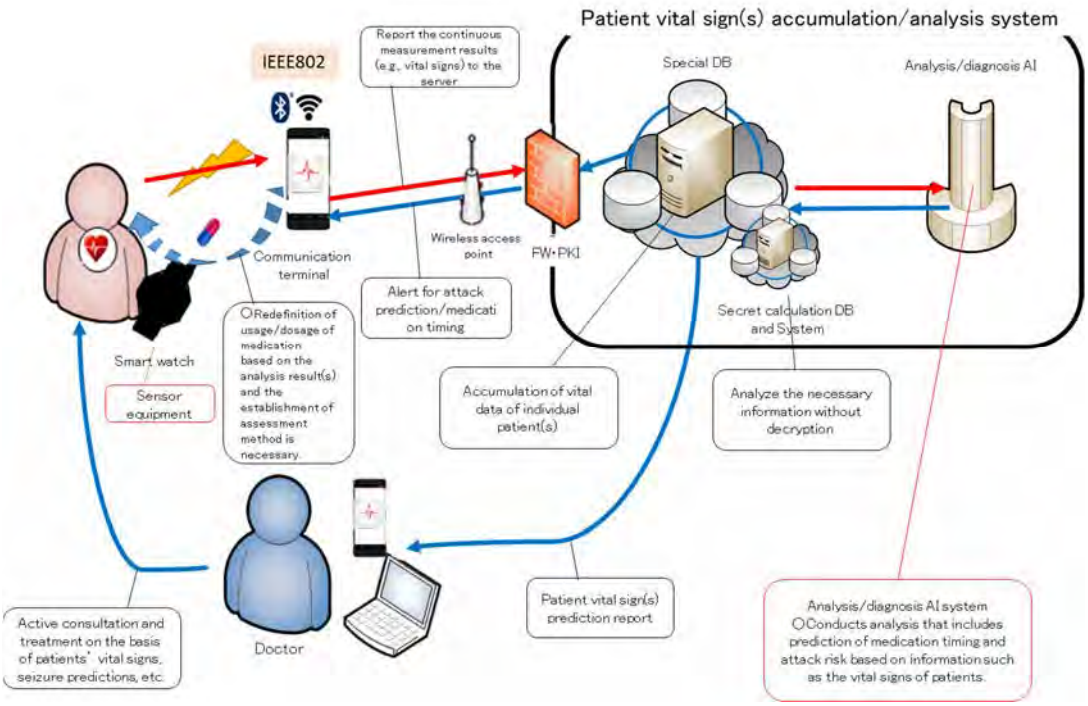


Figure 2-8 Construction of a highly secure medical information database and the development of technology for extracting and analyzing the medically useful content therein. (Possible data usage)

2) Organization:

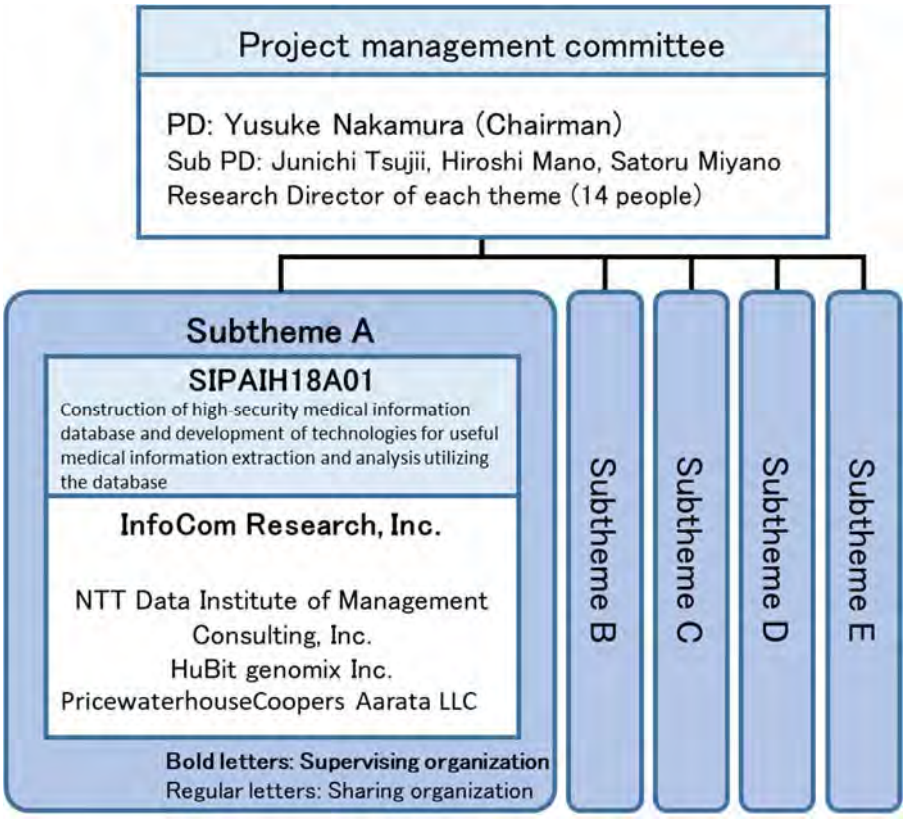


Figure 2-9 Research and development organization of Subtheme A

3) Implementation method:

Implementation based on the information acquired from medical practice.

① Development and construction of the technology for secure physical and electronic storage of clinical information, image information, pathological information, information obtained through biochemical examination and information obtained from wearable devices.

The aim is to create a system that utilizes patient information more securely and easily through electronic programs and responses based on physical measures. The development of a secure processing method utilizing grid computing and guaranteeing security in central processing during analysis will be conducted in coordination with ⑤.

② Construction of technology for secure transmission/reception of information from wireless sensor devices.

Specifications and devices to more securely provide information from sensor equipment with IoT (e.g., a system to provide information only pertaining to a body part that experiences change subsequent to the provision of initial information) will be developed in hardware and software. This involves constructing a device usage environment or specification and developing very more secure devices that can be used by patients without fear.

③ Examination of the security of database and calculation system.

Making the secure system constructed by this project, produce a robot program for security checks and conduct evaluations involving, for instance, security checks by white hackers and return feedback of the results to the system and operating SOP (Standard Operating Procedure) to render the constructed system more secure and ensure it is capable of self-improvement.

④ Development of technology to extract information useful for medical practice from the database (big data) and construction of a thesaurus.

Construct a thesaurus compatible with dialect to enable a wide-ranging search and analysis of patients and academic information. Moreover, construct an automated thesaurus preparation system utilizing AI technology to respond to changes in languages and work toward the construction of a system that allows for more accurate voice input in coordination with ⑥.

⑤ Development of technology for secure extraction calculation from the database (big data).

Work toward the construction of a system that prevents the decryption of encrypted information while extracting and analyzing patient information and creating a system that ensures security of the entire system, instead of individual subsystems in coordination with ⑦.

⑥ Construction of corpus that is linked to existing domestic and worldwide glossaries (compatible with dialect) for appropriate conversation and documentation of voice inputs into written text (compatible with multiple languages).

Produce a corpus enabling comprehension of the usage of words, distinguishing of

homophones, identifying emphasis and expressions like metaphor in the conversation of patients and doctors. This will be created in coordination with the thesaurus in ④, with standardization through a signification code of the terms in usage in view. Furthermore, construct a system that utilizes AI with supervised machine learning, enabling automated construction of a corpus to automatically respond to changes in the meaning or usage of words. This will be accompanied by work to establish a system with specifications designed for usage at the service frontline. Ultimately, the goal is to construct a system with a corpus (including a glossary) capable of continuous growth.

⑦ Development of communication protocol that utilizes a blockchain technology that includes traceability and smart contracts.

Apply the blockchain technology currently used in finance system to store the usage log of patient and associated information. In addition, embed a smart-contract protocol for access management to ensure the security of patient information and construct or establish conceptual specifications and technical specifications encouraging the active usage of the information. This development will start with at the laboratory level, followed by small-scale tests using, for instance, SOHO and tests within the hospital network level. Eventually, work toward its demonstration for a wide area network and internet.

4) Goal:

Utilize AI analysis technology to construct and implement the "Innovative Al Hospital System" to support diagnosis, education and communication in medical institutions. In addition, use medical equipment and IoT devices to comprehensively collect patient information and convert the same into big data. This will enable the effective usage of the vast medical information in treatment and in realistic construction of a system and realize well-maintained providing system of advanced, cutting-edge and optimized medical services. Within three years, the information of 10,000 people will be entered into the integrated database including clinical information, test information, pathological information and, if available, genetic information and information obtained from wearable devices in coordination with the model hospitals, allowing the commencement of their utilization. The objective is to collect and utilize information of 100,000 people by the final year of this project. In addition, these technologies will be applied for reducing the workload of medical staff at these Innovative Al Hospital System and optimizing medical costs, thereby solving challenges faced by the super-aging society and improving the economy.

【Goal accomplished by the end of 2018 and the state their achievements】

1. Definition of data specifications for secure storage. (Achieved)
2. Compilation of challenges faced the technology to extract medically useful information utilizing the sample data. (The challenges faced by hospitals are already extracted, whereas only 50% of vendor challenges have been extracted due to regulatory reasons). This is to be

achieved in 2019.

3. Construction of the coordination relationship with other subthemes. (Achieved)

【Intermediate goal】(By the end of 2020)

1. Development of technology for secure data storage.
2. Development of technology for extracting medically useful information from the database (big data).
3. Development of a communication protocol utilizing technologies like blockchain.

【Goal】(By the end of 2022.)

1. Implementation of technology for secure data storage.
2. Implementation of a simulation and navigation system for diagnosis and treatment utilizing AI technology.
3. Implementation of communication protocol that utilizes technologies like blockchain technology.

【Subtheme B】

Development of an AI-assisted automated medical record documentation system, an AI-assisted bilateral communication system used in obtaining informed consents and an AI-assisted diagnosis and treatment support system.

This subtheme comprises five research and development projects. The common aspects and the individual contents of these projects are as follows:

1) Objectives

A support function needs to be developed based on the roles of patients, doctors and nurses for voice input (including the nonverbal parts), comprehension, searching academic data that forms the basis for the diagnosis and treatment, extraction of key points (reporting) in the scene of consultation, explanation and informed consent. Working toward the construction of a system for workload reduction by focusing on the significant burden on medical staff and applying sensors (IoT), big data and AI technologies.

Due to the rapid development in medicine and the advancement of medical technology, the gaps in knowledge and information in the medical service continue to widen. Therefore, for medical staff, advanced technology is beyond their comprehension and they are facing difficulties of offering explanations to patients and their families by medical staff is challenging. This is a major obstacle to the dissemination of the cutting- edge diagnostics and treatment in medical services.

The deterioration in the quality of medical services due to the excessive burden bridging enormous gaps between insufficient digitization and mechanization of the medical practice placed

on medical staff including doctors and nurses because of is a developing into a social problem. For instance, due to the digitization of clinical information, situations are increasing where the doctor conducts consultation (conversation) while looking at the computer screen without even making eye to eye contact with the patient for diagnosis. Moreover, although manuals for explaining treatment plans exist, treatment, operations, operation results, the effect and side effects of medication and situations are increasing wherein the medical staff are unable to understand the meaning of these explanations due to the advanced specialization of these explanations and medical fields of doctors. Thus, such environments are increasing the frustration among medical staff and patients or their families.

Therefore, to maintain or improve the quality of medical practice while avoiding an increase in the burden on frontline medical services, it is imperative to create a new system enabling seamless coordination between the clinical and information environment (digital environment) that will be established the healthcare system from tis roots. In such a system, the in and out from the information environment automatically occurs and this will radically change the healthcare system. In other words, it is necessary to be able to automatically input medical/diagnostic information to the database and utilize such information in the medical information industry and frontline medical service based on analysis. To achieve this, it is essential to introduce AI technology that is compatible with medical services.

The objective of this subtheme is to develop and implement an interactive communication system using AI, for assessing the understanding of patient explanations, which is a significant burden on medical staff and offering them explanations appropriate for their understanding level on time. Moreover, to enable doctors to talk face-to-face with the patients instead of looking at the computer screen, development of information input for documenting conversation by the medical staff, sensors for information output and AI as well as an automated medical support system for coordinating the utilization of these technologies will be conducted. Reduction of the workload of the medical staff including doctors and nurses at the frontline of medical services will be targeted through implementation of this system. Furthermore, a simulation and navigation system for the diagnosis and treatment utilizing AI technology will be constructed.

Project number: SIPAIH18B01

Research project name: Development of Smart Communication Technologies for Hospital transformation by utilizing Artificial Intelligence.

Principal investigator: Atushi Ugajin (Hitachi, Ltd.)

Research summary: Automate administrative tasks in medical services such as medical record, nursing record, preparing documents for treatments provided to patients through digital technology and AI to reduce the workload of medical staff and developing technologies. This aims for the improvement of the quality of medical services and consequently, the QOL of patients.

Project number: SIPAIH18B02

Research project name: Simultaneous derivation of structured medical information from EHR text data and voice command use in medical recording.

Principal investigator: Tomohiro Sonoo (TXP Medical Co., Ltd.)

Research summary: Although digital data for prescriptions and test values are available, regarding medical record texts, the association between analysis technology and clinical data is minor. Moreover, analysis requires advanced medical knowledge and thus, commercialization of this analysis faces considerable difficulty. This research and development project will produce a technology that collects and analyzes high-quality medical data categorizes and standardizes medical text into a structured field. This will involve providing a medical record documentation support system for hospital emergency department that improves work efficiency and data collection. As an extension, a technology for optimizing medical record preparation through voice commands will be developed.

Project number: SIPAIH18B03

Research project name: Development of an automated voice-input electric medical record and its contribution to reduce working hours of medical staffs.

Principal investigator: Kaoru Nagahori (Yokosuka Kyosai Hospital of the Federation of National Public Service Personnel Mutual Aid Associations)

Research summary: The objective of this research is to shift tasks from humans to AI through the automatic input of electronic medical records, to build a real-time interactive communication system that considers patients, saving both the medical staff from exhaustion due to work overload and patients forced to obey doctors due to gaps in their knowledge. To achieve this, automated document production and automated input systems for diverse situations including advanced voice recognition using AI and a system for checking the comprehension level and follow-up with the patients during informed consent (hereafter referred to as IC) through the parallel utilization of image recognition and emotion analysis will be developed. An early detection and prediction system for changes in the condition of patients through biological data analysis using IoT sensors will be constructed. Develop an AI engine equipped with highly accurate AI technologies such as voice recognition, voice documentation as text, noise reduction and background noise separation, identification of multiple speakers, learning and conversion of specialized terms and abbreviations (preparation of multilingual dictionary), text summary, emotion recognition and analysis, learning and predicting chronological sensing data and is able to process multiple types of data related to voice, image and sensor. The system must be able to assist in diverse ways

such as the simplification of logging and documentation of conversations in the hospital as text, input of electronic medical record into the system and support during IC. By shifting the tasks from humans to AI using this system, reduced workload for medical staff and improved communication with patients will be realized.

Project number: SIPAIH18B04

Research project name: R&D Project for Physician Support AI Using Medical Records.

Research Director: Yasuhide Hatta (Nihon Unisys, Ltd.)

Research summary: Conduct a feasibility study on the performance of the doctor support system that uses a global AI, for instance by IBM or Google and realize practical application of an AI specialized in medicine that will improve patient satisfaction through the realization of "Near zero input time to computers for doctors," thereby radically reducing the workload of medical staff and creating better communication between doctors and patients. Through this, reduction of the medical administrative work duration, preparation of an environment for doctors to examine human's instead of illnesses, creation of an AI environment including the latest medical papers that can support doctors, balancing of optimal medical costs and high-quality medical services will be realized.

Furthermore, a simulation and navigation system for the diagnosis and treatment utilizing the AI technology will be developed.

Project number: SIPAIH18B05

Research project name: Develop auto documentation using AI in diagnosis reporting and interactive communication system using AI in informed consent.

Research Director: Yoichiro Yukawa (NTT Data Corporation)

Research summary: Through this project, an automated documentation of consultation record into for instance, an electronic medical record using AI will be developed. This will also involve a system that enables appropriate communication, designed in accordance with the characteristics and level of understanding of each patient from big data, to reduce the workload of medical staff at the frontline of medical services and the stress of patients caused by insufficient understanding of explanations of symptoms and related information by doctors. Through these, the introduction of AI to the entire hospital, "workstyle reformation" of medical staff and quality improvement in medicine by providing advanced medical services will be achieved.

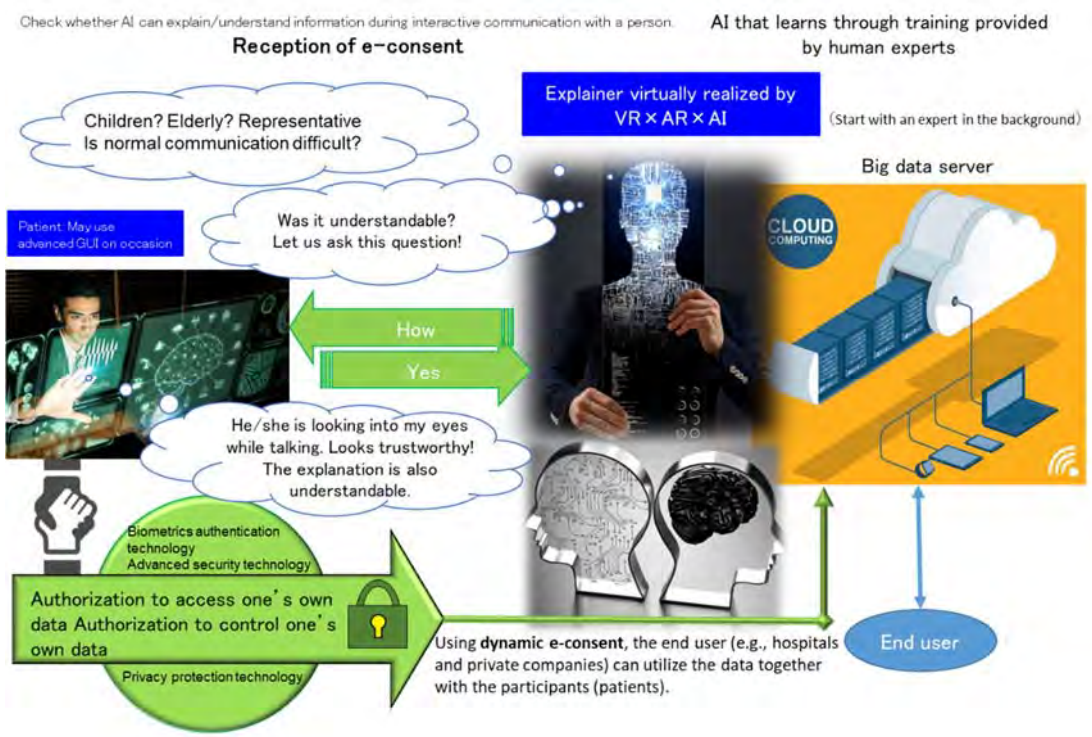


Figure 2-10 Example of using AI to secure sufficient time for the medical staff to conduct consultation and provide explanation to patients or their family through eye contact. (The following figures illustrate its usage in frontline medical services.)

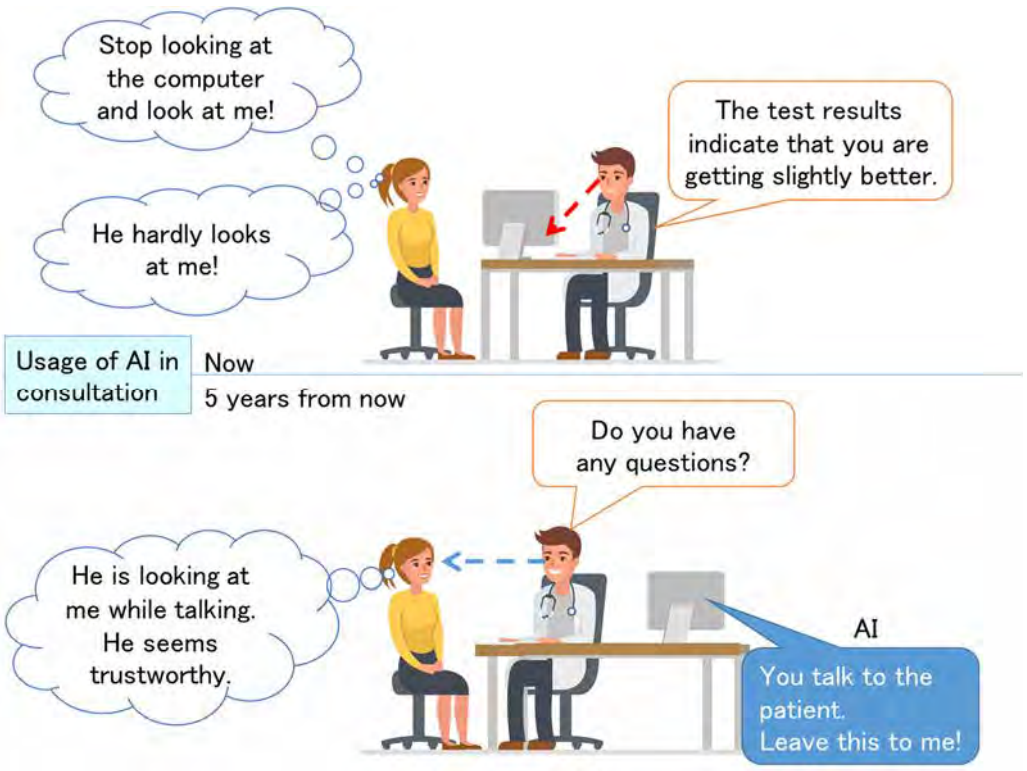


Figure 2-11 Documentation of conversation information from consultation as text using AI

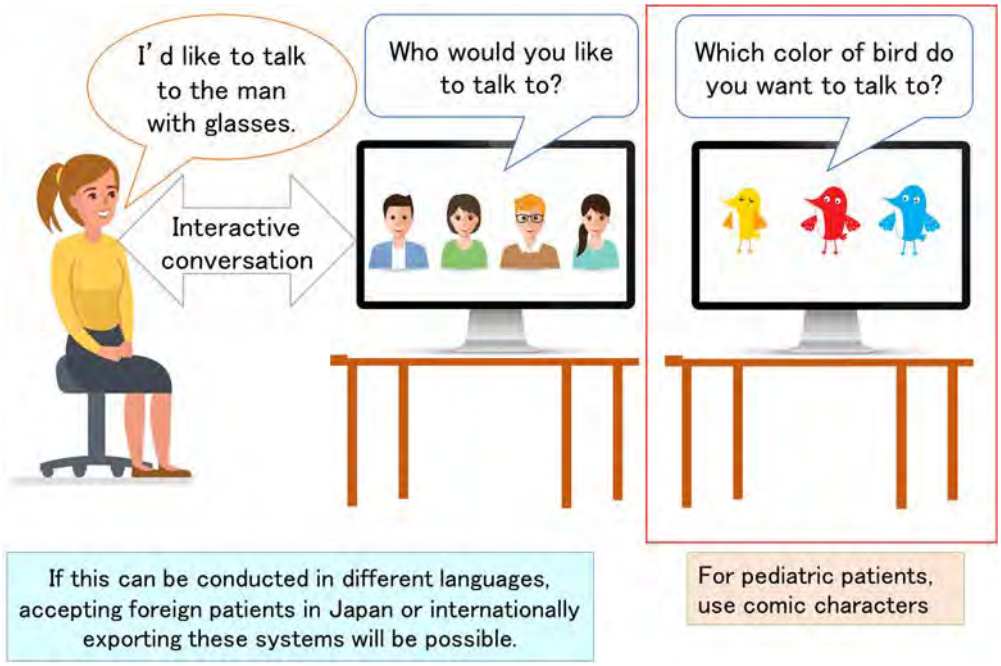


Figure 2-12 Support in providing explanations to patients or their family members through AI

2) Organization:

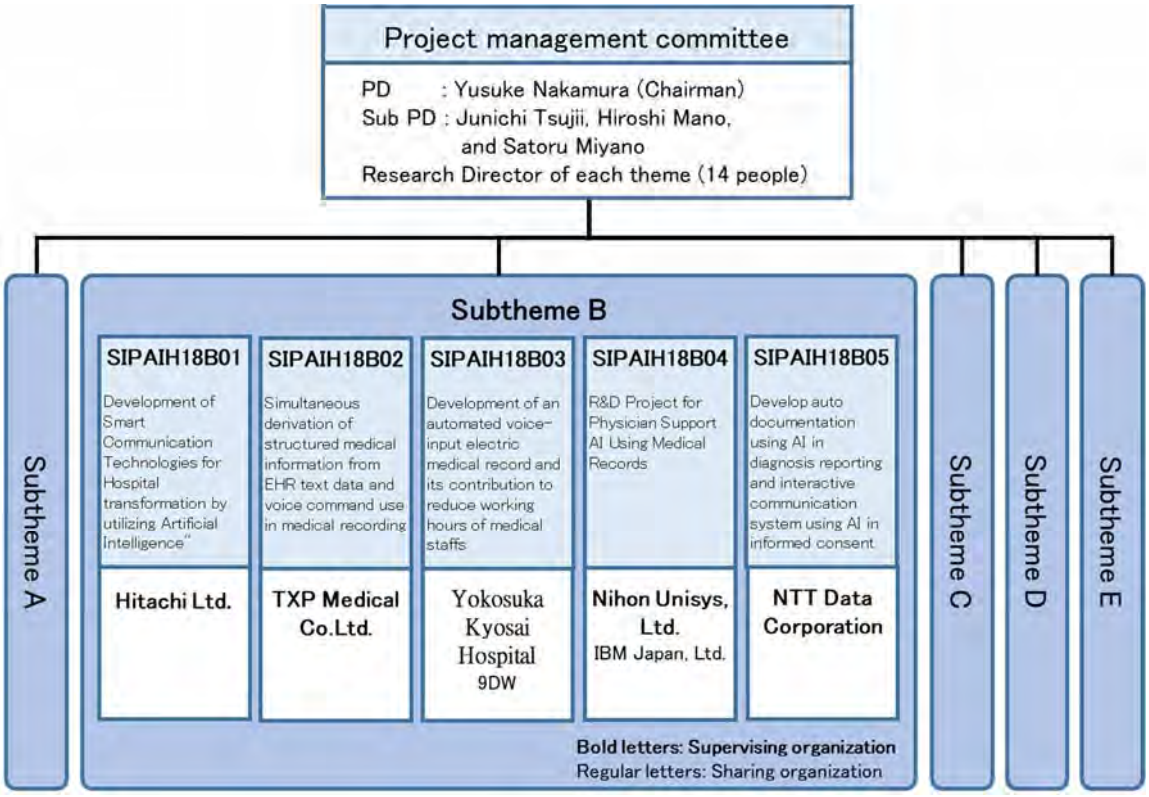


Figure 2-13 Research and development organization of Subtheme B

3) Implementation method:

① Development of a system that is able to make written documents from the conversation between doctors and patients in written text (Related to Subtheme A).

Construct a system utilizing AI technology for automatically preparing medical and nursing records from the conversations with patients during consultations or with hospitalized patients at their bedside (including images and results from blood tests and other examinations). This will be coordinated with Subtheme A, with work toward the construction of a precise and efficient system capable of growth from reliable usage.

② Development and implementation of a real-time interactive communication system for providing explanations to patients that corresponds to the level of understanding of individual patients through the application of sensors and AI technology.

Work toward the construction of a system that offers explanations to patients appropriate for individual understanding, supporting the explanation of treatment policy and other subjects to patients. Work toward the construction of a system that conjectures the levels of understanding of patients from their answers, voice tone and expressions, producing or providing content for individual patients that enables more precise understanding through AI technology.

③ Survey on changes in the workload of medical staff and satisfaction gained by patients and their families through the implementation of various features and feedback in the form of improvement based on the survey results (related to Subtheme D).

To construct a system that coordinates with supervised and unsupervised machine learning, ensuring a system capable of growth, electronic system usage based on implementation in clinical sites and research through, for instance, questionnaires will be conducted. The results will used as inputs to realize a better system.

④ Construction of a document preparation system that corresponds to the characteristics of individual patients, which includes the information collected from academic medical journals through online searches.

Work toward a system that automatically prepares a summary for treatment from information recorded on the treatment environment at the time of the patient's hospitalization like consultation, examination and nutrition to reduce the workload of staff and enable efficient grasping of patients' situations during an emergency, such as a disaster.

⑤ Development of a simulation and navigation system for the diagnosis and treatment that utilizes AI technology.

Develop a system that comprehensively analyzes voice inputs from consultation and nursing, test data from blood and other samples, imaging data, the effect of treatments using AI technology, conducts navigation and simulation of diagnosis, treatment method selection and treatment.

4) Goal:

Utilize AI analysis technology to construct and implement an "AI hospital system" to support diagnosis, education and communication in medical institutions. In addition, use medical equipment and IoT devices to comprehensively collect patient information and convert the same into big data. This will enable the effective usage of the vast medical information in treatment and realistic construction of a system providing advanced, cutting-edge and optimized medical services. In addition, these technologies will be applied for reducing the workload of medical staff at these hospitals and optimizing medical costs, thereby solving challenges faced by the super-aging society and improving the economy. Examples include the objective doubling of the eye contact duration between doctors and patients or their families during medical care and reduction in the time required for providing explanations by 30% in three years. Another objective is to reduce the time required for doctors to type on the keyboard to almost zero and to reduce the time required for providing explanations by 50%, enabling 50% of medical staff to experience workload reduction while patients and their families obtain satisfactory understanding within five years.

A feasibility study will be conducted for this subtheme to identify research and development projects that have achieved results close to practical application, reorganize projects for additional budget allocation and promote research and development.

【Goal accomplished by the end of 2018 and the state these achievements】

1. Compilation of challenges faced in the construction of a system that is capable of documenting conversations between patients and doctors as text. (Achieved)
2. Extraction of challenges faced in the development of a real-time interactive communication system for providing explanations suitable for the understanding level of patients. Development of a system documenting conversations between patients and doctors as text. (Achieved)
3. Construction of the coordination relationship with other subthemes. (Achieved)

【Intermediate goal】(By the end of 2020)

1. Development of a system documenting the conversations between patients and doctors as text.
2. Development of a real-time interactive communication system for providing explanations to patients based on individual comprehension levels through application of the AI technology.
3. Conduct demonstrations in coordination with Subtheme D of this project.
4. Development of a simulation and navigation system for the diagnosis and treatment utilizing the AI technology.

【Goal】(At the end of 2022.)

1. Implementation of a system that documents the conversations between patients and doctors

as text.

2. Implementation of a real-time interactive communication system for providing explanations to patients that considers individual comprehension levels through application of AI technology.
3. Research on the workload of medical staff and satisfaction of patients and families.
4. Development of a simulation and navigation system for the diagnosis and treatment utilizing AI technology.

【Subtheme C】:

AI-assisted highly-sensitive and low-invasive testing of blood or other biological samples to enable the earliest detection of cancer and other severe diseases.

This Subtheme contains three research and development projects. The common aspects and the individual contents of these projects are as follows:

1) Objectives

Subtheme C will allow for the development of an ultraprecise examination system for blood and other samples that utilize AI technology (including sample transportation and confirmation of the quality of the examination results), that is considered effective for the screening of diseases such as cancer and ultra-early diagnosis of recurrence or exacerbation of the same. This is intended to reduce the cost and burden of examinations on patients. Moreover, medical equipment with better safety will be developed as well. By using these technologies as the foundation, a diagnosis or assessment support system including vital data from individual patients, imaging information and activity (exercise, resting, nutrition intake, etc.) monitoring utilizing AI technology will be developed. Furthermore, a more advanced and precise diagnosis or assessment system based on the characteristics of individuals will be constructed through coordination with the information database (big data) of other patients (including academic information). A monitoring system applying AI technology that enables the selection of diagnosis and treatment (including medication) based on the comprehensive analysis of patient information and the database (big data) will be constructed. Additionally, we aim to realize a system that is usable by "family doctors" through simple monitoring to prevent disparity in the available medical services among regions.

By coordinating the results obtained from this subtheme with that of Subtheme B, an organization enabling interactive explanations that are easy for patients to understand and that is capable of responding based on the patient will be established.

Project number: SIPAIH18C01

Research project name: System Development for AI Guided Flexible Endoscope Control.

Principal investigator: Yuichi Ikeda (Olympus Corporation)

Research summary: A colonoscopy, an operation that is rapidly increasing all over the world, is difficult to perform and require advanced skill to guarantee the quality of testing. Thus, it poses a burden on the work and time of doctors. This project will research and develop a technology for estimating the appropriate insertion operation using AI to achieve automatic insertion of colonoscopes. It will lead to reductions in examination time and training period as well as patient pain level during the examination. Concurrently, it will utilize data like test information and thereby contribute to the provision of advanced medical care.

Project number: SIPAIH18C02

Research project name: Development of a minimally invasive super early diagnosis system for cancer recurrence subsequent to an operation based on liquid biopsy and AI.

Principal investigator: Hidetoshi Inoko (GenoDive Pharma, Inc.)

Research summary: The purpose of this research and development project is to use liquid biopsy and AI to develop a prediction model and a monitoring method for cancer recurrence to help improve treatment results. Hepatoma, a refractory cancer, involves a 50% chance of recurrence subsequent to a radical operation. However, an easy method for detecting early recurrence is unavailable. The objective of this project is to employ a minimally invasive liquid biopsy to conduct a recurrence prediction and monitoring for very early intervention and treatment improvement.

Project number: SIPAIH18C03

Research project name: The Standardization and Implementation of Ultra High-Precision Diagnostic System Assisted with AI Technology for Cancer Liquid Biopsy.

Principal investigator: Toshikazu Yamaguchi (BML, Inc.)

Research summary: This research and development project aims toward the standardization and implementation of an ultraprecise cancer diagnosis system with liquid biopsy of blood and other samples using cell-free DNA and cell-free RNA (cfDNA/RNA). The effectiveness of this system in cancer screening, detection of the presence or absence of tumor cells, selection of molecular target drugs, super early diagnosis of the recurrence and assessment of the effectiveness of chemotherapy will be examined for its implementation. Moreover, through the construction of a monitoring system using AI technology, integrated analysis of clinical, pathological and database information using AI, the usage of an AI explanation system for patients and medical staff and the introduction of a diagnosis system available for use by even family doctors will become a reality in the future.

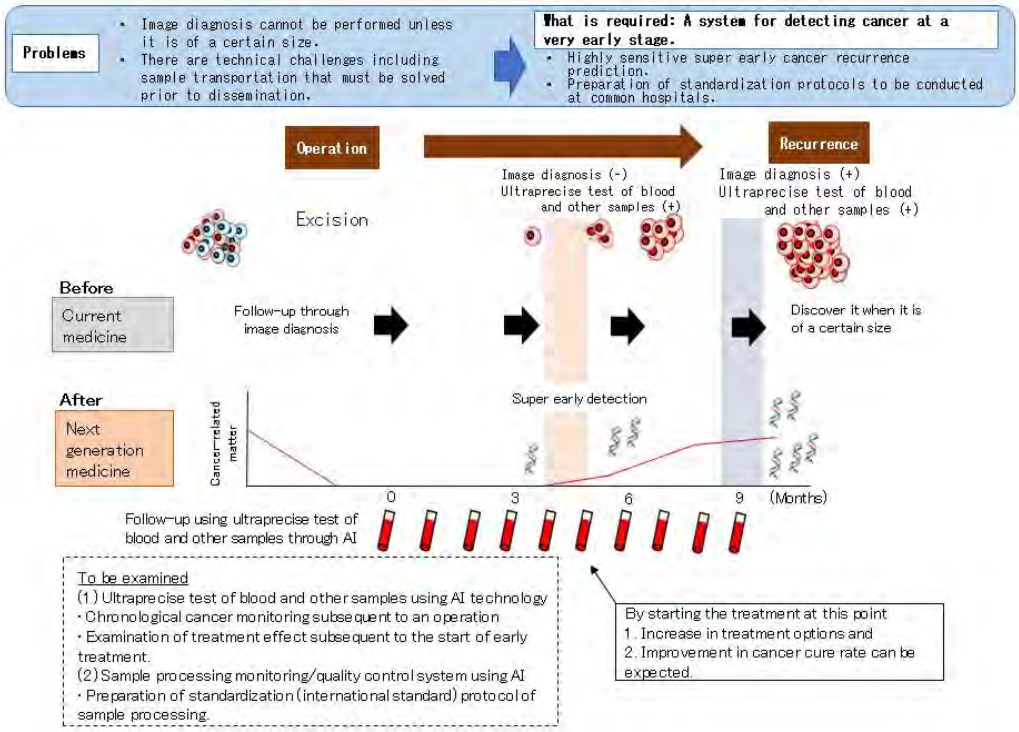


Figure 2-14 Implementation of an ultraprecise test system for blood and associated samples utilizing AI technology.

2) Organization:

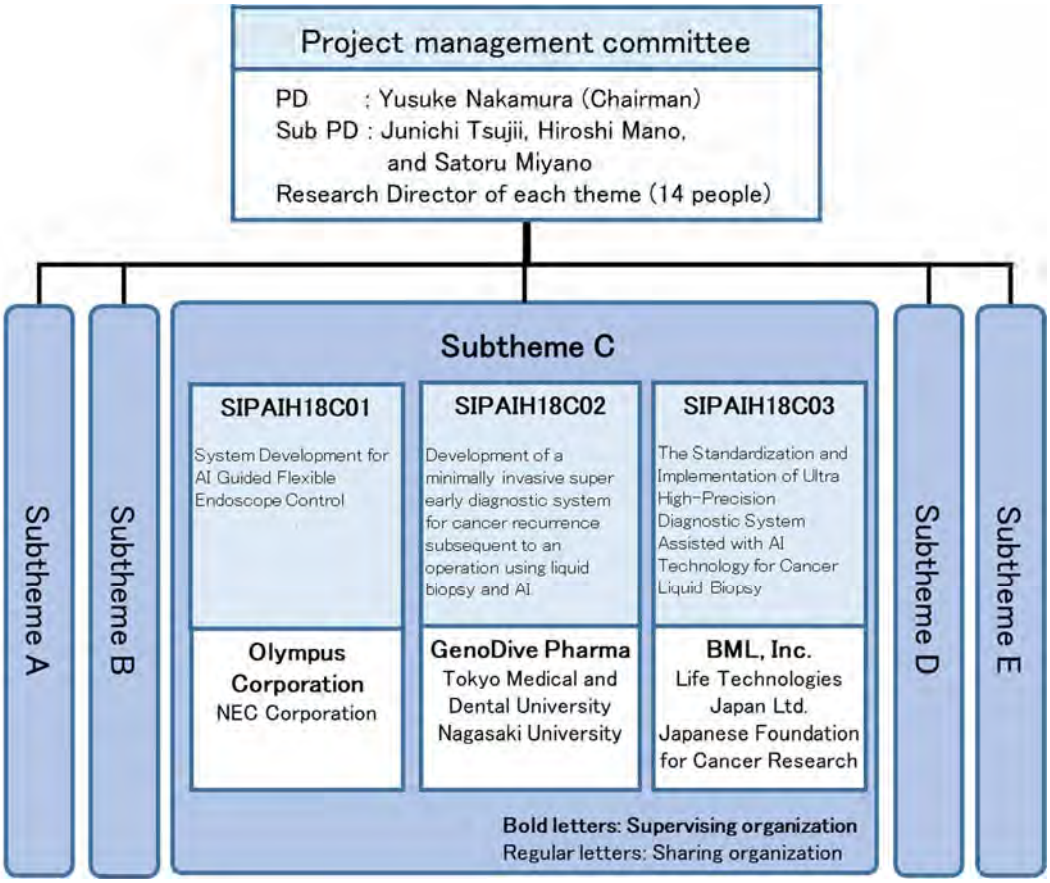


Figure 2-15 Research and development organization of Subtheme C

3) Implementation method:

This Subtheme involves examination of the clinical effectiveness of the ultraprecise examination system for blood and associated samples utilizing AI technology. This is considered effective for the collection of basic information and screening for diseases like cancer and ultra-early diagnosis of their recurrence or exacerbation. It will promote reductions in cost as well as the burden of examinations on patients. The work is envisaged to be completed by the end of 2020 to overcome challenges in the standardization of AI technology. In 2021, clinical tests will be conducted through the diagnosis and assessment support system utilizing AI technology. This will include vital data of individual patients, imaging and activity (exercise, resting, nutrition, etc.) information. The standardization protocol for the ultraprecise test system for blood and associated samples will also be involved. Moreover, a quality control system for sample processing, procedure monitoring and testing and the explanation support system for test results using AI will be developed and implemented.

① Ultraprecise test system for blood and other samples for diseases like cancer.

Recurrence monitoring of cancer after an operation is commonly conducted once every three to four months based on imaging diagnosis. Currently, recurrent cancers detected through imaging diagnosis are extremely difficult to cure, even if several treatment methods are applied. Therefore, a chronological cancer monitoring and super early detection system operating non-invasively through samples like blood will be developed. Moreover, the application of these technologies to other diseases in addition to cancer will also be considered. Furthermore, by using AI to integrate and analyze the clinical information of patients, tumor marker information and imaging diagnosis will accelerate the development of a super early cancer detection system by AI in coordination with the ultraprecise test system for blood and other samples.

② Test sample monitoring and quality control system by AI.

For practical application of the ultraprecise test system for blood and other samples, it is essential to obtain high-quality test samples. Therefore, we will identify the problems associated with each step, from blood sampling, to the storage and transportation of samples, to extraction of the component(s) to be analyzed, that can cause errors in analyses results and prepare a standardization (international standardization) protocol. Develop a quality control system for test samples by performing analysis using AI. In addition, create a system that can be disseminated to general hospitals and family doctors.

③ Create an interactive explanation system based on AI offering explanations that are easy for medical staff and patients to understand, considering the understanding level of individual patients.

Coordinate with Subtheme B, examine the explanation system for test results that utilizes AI for medical staff and the interactive system that enables medical staff to provide understandable explanations to patients in consideration of their understanding levels.

4) Goal:

Work toward the practical application of a super early cancer detection system based on ultraprecise tests of blood and associated samples using AI in five years. Moreover, establish it as a test method accessible from anywhere in Japan, with the capability of examining samples taken at the local core hospitals and at family doctors as well as key hospitals by developing the technology to a level that makes this possible. Establish a diagnosis and assessment support system utilizing AI technology including vital information on individual patients, as well as imaging and activity (such as exercise, resting and nutrition) information, in addition to the standardization protocol for the ultraprecise test system for blood and other samples. The objective is to improve the cancer cure rate by 10% and reduce medical costs by thousands of dollars. Establish a simple information transfer system utilizing AI for disseminating information from the examination agency to the medical staff and then from the medical staff to patients and their families in coordination with Subtheme B. Through this, the workload on medical staff will be reduced while ensuring that the quality of medical services is maintained.

【Goal accomplished by the end of 2018 and the state of their achievement】

1. Compilation of challenges faced in the ultraprecise analysis method utilizing AI technology. (Almost achieved)
2. Compilation of challenges faced in the monitoring system for the process from sampling to examination using AI (One organization has achieved this. The progress at another organization is at 75% due to a longer time taken to prepare the facility and acquire a staff for this project. However, it is already in progress and currently rearranging its system, on track for 2019.)
3. Compilation of challenges faced in sensing devices used for collecting different data types. (Achieved)
4. Construction of a coordination relationship with other subthemes. (Achieved)

【Intermediate goal】(By the end of 2020)

1. Standardization of ultraprecise analysis method using AI technology.
2. Preparation of SOPs for development of the monitoring system for the process from sampling to examination using AI.
3. Development of sensor devices for collecting various data.
4. Collection of supervised data using the model for developing an AI endoscope.

【Goal】(By the end of 2022.)

1. Implementation and evaluation of ultraprecise analysis method using AI technology.
2. Implementation and evaluation of the sensor devices for obtaining various data types.
3. Implementation and evaluation of medical equipment with better safety utilizing AI technology.

【Subtheme D】:

Proof-of-concept study of Al hospital functions in clinical practice settings.

This subtheme comprises four research and development projects. The common aspects and the individual contents of these projects are as follows.

1) Objectives:

Install technologies and devices such as sensors researched and developed in Subthemes A, B and C as well as equipment developed by matching funds to existing ICT technology for treatment. This is to advance learning of the diagnosis and assessment system using the AI technology system and to construct a system that is more practically applicable for medical services.

The obtained results are reintroduced in each subtheme, reflected in correcting the AI (analysis

algorithm) and used for the analysis of information collection devices and redundant information collection to trigger improvement or adjustment of the system.

Moreover, we will develop basic structures that enable flexible responses to be made to differences in the glossaries used by the system. An inspection organization corresponding to the development level will be established through the coordination of the four cooperating and participating organizations to enable appropriate evaluation and usage of the AI technology.

Project number: SIPAIH18D01

Research project name: Development of an automated voice-input electronic medical record and its contribution to reduce working hours of medical staffs

Principal investigator: Takashi Igarashi (National Center for Child Health and Development)

Research summary: Implement technologies and devices such as sensors that were researched and developed in Subthemes A to C to ICT technology used for the treatment of autism spectrum disorder or pediatric cancer. Construct a system that is more practically applicable to frontline medical services through the utilization of wearable devices and enhance learning of the diagnosis and assessment system utilizing AI technology. Conduct empirical research on the AI hospital for pediatrics that appropriately selects data from devices (including imaging, pathological and vital clinical information) and uses data that can assist patient, family and medical staff care.

Project number: SIPAIH18D02

Research project name: AI Hospital Realized: Establishing Foundation for the Next-Gen Medical System.

Principal investigator: Yuko Kitagawa (Keio University Hospital)

Research summary: This hospital has promoted the development of AI technology and its introduction to the hospital system at its medical AI center. In this research, the ICT and AI technologies originating from this group as well as the technologies being developed by external companies will be systematically introduced to construct a model for an AI hospital that will serve as the foundation of future medical systems. Through this provision of safe, reassuring, advanced and progressive medical services to patients, it will be possible to lighten the burden on medical staff and realize advanced support for regional medical services. This model will be introduced in pilot hospitals, with an aim toward promoting coordination with general hospitals, communities and beyond.

Project number: SIPAIH18D03

Research project name: Osaka University Hospital Artificial Intelligence Center for Medical Research and Application.

Principal investigator: Tadashi Kimura (Osaka University Hospital)

Research summary: Establish a base hospital as the foundation for AI, with artificial intelligence comprehensively introduced in Osaka University Hospital (hereafter referred to as Handai Hospital) to achieve safe and reliable medical services with zero medical errors, higher-level patient-centered holistic care and precision medical practice. In this project, confirmatory demonstration of AI seeds diverse fields with completed exploratory phases and their practical applications to medical practice will be conducted by utilizing the optimal resources of Handai Hospital and the connected Osaka Clinical Research Network (OCR-net) to establish a base hospital as the foundation for AI.

Project number: SIPAIH18D04

Research project name: AI-equipped integrated cancer medical support system

Principal investigator: Takeshi Sano (Cancer Institute Hospital of Japanese Foundation for Cancer Research)

Research summary: Develop an "integrated cancer care support system equipped with AI" for advanced practice and progressive cancer treatment based on unique biological tumor and social information from patients, with treatment options presented to the doctor and patient as appropriate. This system will be based on the high-quality clinical and pathological database of specialized cancer organizations. It will contribute to the overall improvement of cancer care in Japan and promote regional medical services through expansion to hospitals that act as bases for cancer treatment coordination.

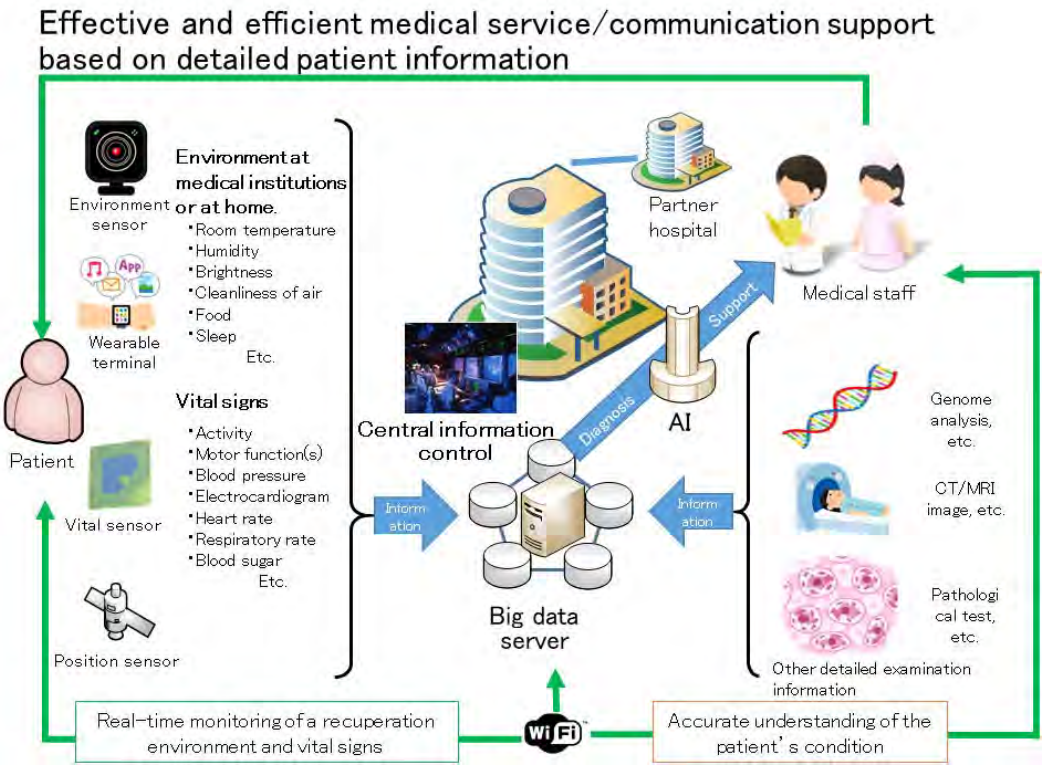


Figure 2-16 AI hospital system of the near future.

2) Organization:

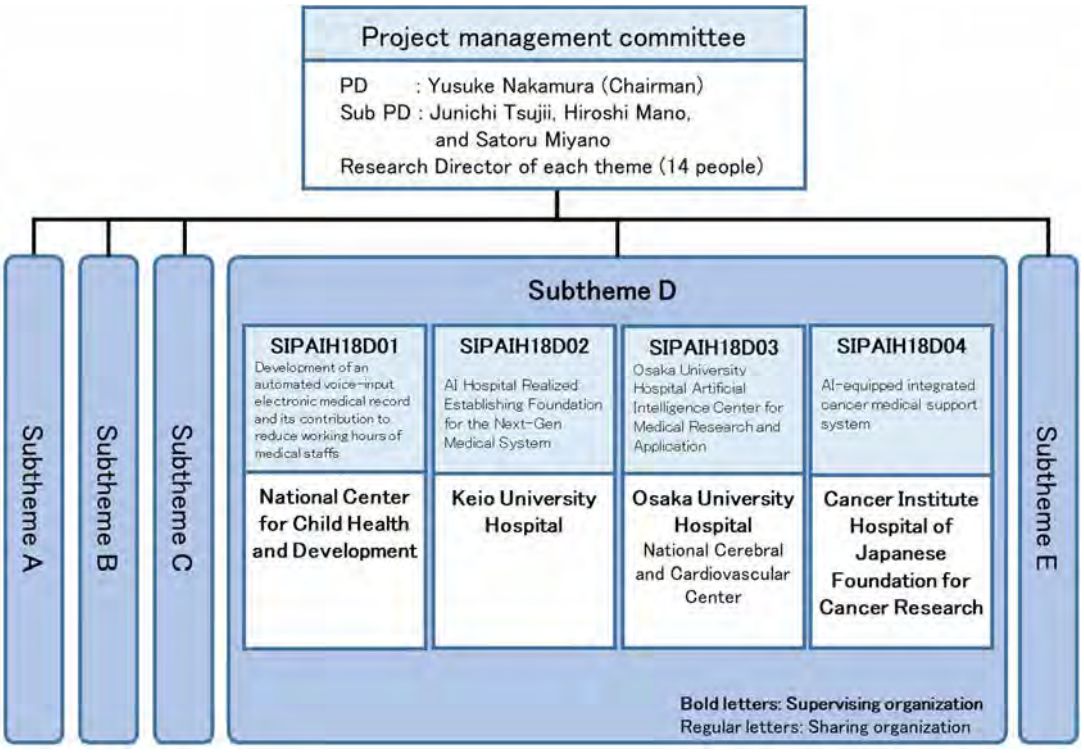


Figure 2-17 Research and development organization of Subtheme D.

3) Implementation method:

Implement based on the factual information from medical practice.

① Verification test for ensuring consistency with existing system(s).

Based on survey of the systems currently in use such as electronic medical records, objectification of the new system and its demonstration based on development and implementation of, for instance, the bridge system between systems, will be conducted subsequent to comprehending the usability of the developed IoT sensors and the stored information.

② Demonstration of the sensor devices at the frontline service.

In addition to demonstration of information collection by developed sensors, development will focus on coordination with other information and will be concurrently conducted while compiling the challenges such as the processing delays of the existing systems.

③ Analysis based on the information of ② and its verification.

Reintroduce the collected information in medical care and examine the same through evaluation to comprehend overall and individual usability in medical, labor, electronic system and economic applications.

④ Construct a real-time monitoring system and establish a resilient system.

Construct a system for instantly collecting the constantly changing patient information in real-time and feedback factors such as the effect of treatment and reduction of the workload of medical staff.

⑤ Development of infrastructure such as emergency power sources that could be used during a disaster.

Research, develop and test a system for ensuring durability and resilience against blackouts or infrastructure damage during disasters from the human, electronic, physical and energy perspectives.

4) Goal:

Utilize AI analysis technology to construct/implement the “Innovative Al Hospital System” to support the diagnosis, education and communication at the sites of medial service. In addition, to take advantage of comprehensively collection patient information and converting into big data through medical equipment and IoT devices. This will enable effective usage of the vast medical information in treatment and realistic construction of a system to provide advanced, cutting-edge and optimized medical services. In addition, these technologies will be applied to the reduction of the workload of the medical staff at these hospitals and optimization of medical costs to solve various challenges the super-aging society is facing and to improve the economy. The milestones for this project are: In three years, the Innovative Al Hospital System will be operational in two or three medical institutions. In five years, it will be implemented in at least 10 medical institutions and its commercialization will be intensified.

Note that a feasibility study will be conducted for this subtheme to identify the research and development projects that have achieved results that are close to practical application, to reorganize these projects so as to allocate a larger budget and promote their research and development.

【Goal accomplished by the end of 2018 and the state of their achievement】

1. Compilation of the challenges faced in modeling the AI system. (Achieved)
2. Compilation of the challenges faced in the introduction of the Innovative Al Hospital System with sensor devices. (Achieved)
3. Construction of the coordination relationship with other subthemes. (Achieved)

【Intermediate goal】(By the end of 2020)

1. Coordination with relevant facilities during the initial, mid and final phases of the development that are compatible with the characteristics of each medical institution to evaluate AI and other technologies.
2. Verification of technical programs of each subtheme of the Innovative Al Hospital System as well as our facilities.

【Goal】(By the end of 2022.)

1. Implementation and evaluation of the Innovative Al Hospital System.
2. Evaluating the contributions of the introduction of the Innovative Al Hospital System made to precision in medical practices such as in the safety of medicine and in effective prediction.

【Subtheme E】:

(E) Technical standardization of the Al hospital system, management of intellectual property rights, open and closed innovation strategies and government–industry-academia collaboration.

1) Objectives:

The technologies developed in Subthemes A to D will be unable to support the treatment of patients or reduce the workload of the medical staff unless used in medical services. Thus, this subtheme take realization of widespread of the technologies by these research results..

In addition to cost, intellectual property rights are also expected to be an obstacle for dissemination of this technology. Thus, we believe that a management strategy for intellectual property in the constructed technology is important. It is also important to actively make such technology available to the public, thereby prioritizing its dissemination in society, encouraging an increase in the entry of new companies to solve the cost issue through economies of scale and price competition and promoting widespread use in medical services while maintaining precision.

In addition, the “General Data Protection Regulation” of the EU that came into effect on May 25, 2018 shows that the attitudes and laws regarding the handling of sensitive private information differ countrywide. Thus, when internationally expanding the system, it is important to consider the international standards for information handling in advance.

When developing systems and technologies, it is important to consider the feelings of patients experiencing the illness and their families to understand their positions and collaborate with the patient associations for these purposes.

Based on the above, this subtheme will examine various social issues that accompany the digitization of medical information and its utilization and it will aim at the establishment of a common understanding of its future handling.

Project number: SIPAIH18E01

Research project name: Building consensus, policies and criteria under the AI (Artificial Intelligence) Hospital Program in relation to IP (Intellectual Property) management, open & closed strategy, and government/industry/academia collaboration

Principal investigator: Koichiro Kimura (PricewaterhouseCoopers Aarata LLC)

Research summary: Examination and development of a sharing or management scheme for the rights and values of patients and medical staff related to medical information and examination and development of the system for handling land utilization laws (including laws of other countries) and regarding the usage of information (including the protective measures for personal information) will be conducted. Simultaneously, an effective wide spreading strategy for technologies or systems developed at the AI hospital will be established. Moreover, support in research and development of the technology or system related to the construction of the network for information and technology including coordination with patient associations will be conducted. In addition, a standardization strategy for maximizing the characteristics of the developed technologies or systems and an intellectual property strategy (open or close strategy) will be considered and developed, as well as a strategy for implementation and sustainable follow-up of private-private or public-private partnerships and needs-technology-company matching. These will be combined with consideration and development of methods that are necessary for the adaptation of the developed technologies or systems by private businesses like PPP/Private Finance Initiative (PFI) to support the research, development, dissemination and deployment of the Innovative Al Hospital System. Technologies or systems and an intellectual property strategy (open or close strategy) will be considered and developed as well as a strategy for the implementation and sustainable follow-up of private-private or public-private partnerships and needs-technology-company matching.

2) Organization:

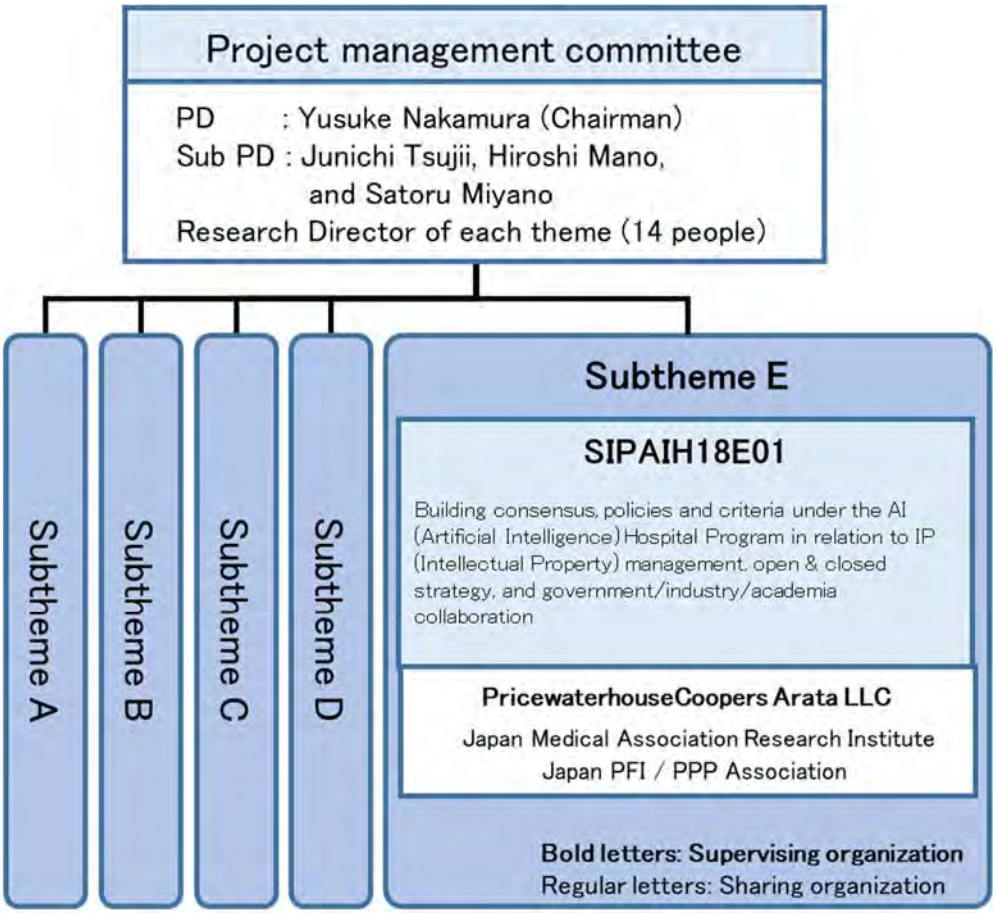


Figure 2-18 Research and development organization of Subtheme E

3) Implementation method:

① Drawing the intellectual property strategy based on research and development.

Through the committee for considering intellectual property strategies, appropriate intellectual property management will be conducted to incentive inventors and those working toward dissemination and industrialization of the inventions, as well as to increase the benefit to Japanese citizens.

The intellectual property strategy includes active acquisition of patents in fields or technology that can be patented and the ownership of the patent will be beneficial for practical application. This should be conducted by taking the open or close strategy into consideration.

② Examination and development of the standardization strategy and open or close strategy to maximize the characteristics of the developed technologies.

Regarding the medical equipment, those that require wide-range involvement of the third party like the AI analysis program, data format, primary treatment method and In/Out protocol, will be actively published to establish their international standards. As the competition in AI algorithms for analysis of images, pathologic tissues, blood, etc., is especially fierce, intellectual property and standardization strategies will be actively deployed, with

standardization also used as a preventive measure against patent trolls.

③ Realization of public-private partnerships and technology-business matching and future follow-up.

The IoT devices for measurement will be set as the “cooperation area” and the protocol will be published and standardized to facilitate entry of Japanese and international companies (regulations like the Pharmaceutical Affairs Act will be strictly followed), enabling quick and widespread dissemination and de facto standardization. Regarding the technological aspects of, for instance, the AI analysis algorithm with technological supremacy, direct publication will be avoided but competitiveness will be ensured through methods like indirect publication, intellectual property protection and concealment.

④ Consideration and development of methods necessary for adaptation of developed technologies by private businesses like the PFI.

Through the increase in third-party companies such as those specializing in sensor devices used for measurement, the usage range, including information collection, could be expanded upon. In particular, for the diagnosis utilizing AI technology, the intensive collection of diverse information will be possible and consequently improve the accuracy of diagnostic support. Therefore, the deployment policy for the database will bring related information, including international information, to Japan.

Moreover, this project will establish a liaison committee with representatives from industry, academia and governmental agencies, regularly publish its achievements and effects (not only providing information through the Internet, but also through means such as forums), encourage participation of private companies for practical application or concrete realization of its achievements and secure staff for technical application of its basic technology to actively promote practical application and adaptation of its technologies. In addition, information will be provided to companies that attended the explanatory meetings, encouraging their participation in the project, to match researchers with private companies. Financial support will be considered as necessary.

⑤ Examination of and the development in relation to, the legal framework of information usage (including international frameworks) as well as its utilization (including the legal protection of personal information).

To improve the accuracy and reliability of the collected information in the future, standardization of terms and concepts in use is vital. However, if original data is just for Japan, it is possible that it will be less internationally compatible. Thus, it is important to clarify the relationship with international organizations and terms. Therefore, the Japanese legislation related to the handling of personal information, as well as international legislation like GDRP and international cultural backgrounds on this issue will be analyzed to support the production of an original corpus (Subtheme A) and construction of a standard thesaurus including international terms (Subtheme A). In addition, the systematic measures necessary

to utilize both Japanese and international information will be considered and a system that closely automates the legal measures related to international information exchange will be developed.

⑥ Coordination with patient associations.

It is important for patients to understand medical technology to provide effective medical care to the Japanese residents. Moreover, the impression of patients on the treatment being received is important information because it could influence the treatment given by the medical staff.

As one can see, the patients and their associations are important factors in treatment. However, these patient associations are separately established for each disease today.

To promote coordination of information among these patient associations and help them to cooperatively deepen the process of treatment and find solutions for everyday problems, social and electronic networks consisting of the patient associations will be constructed. The objective of this network is to become a patient-centered knowledge base for the improvement of medical care offered by medical staff and mutual support between patients, in addition to support for the basic understanding of diseases and their treatments among patients.

⑦ Others

As implementation of this subtheme will involve a wide range of related medical fields, as well as diverse non-medical fields such as ICT and AI, it is expected to involve a large number of researchers. Thus, the management of progress in research and development will be unified to efficiently support the operation in coordination with the National Institute of Biomedical Innovation, Health and Nutrition, which is the fund management organization of this project.

4) Goal:

Utilize AI analysis technology to construct/implement the "Innovative Al Hospital System" to support diagnosis, education and communication at medical service sites. In addition, use medical equipment and IoT devices to comprehensively collect patient information and convert it into big data. This will enable the effective use of a large amount of medical information in treatment and in realistic construction of a system providing advanced, cutting-edge and optimized medical services. In addition, these technologies will be applied to reduce the workload of medical staff at these hospitals and optimize medical costs, thereby solving challenges faced by a super-aging society and improving the economy. A milestone of this project is to work toward transferring the Innovative Al Hospital System technology and equipment developed by the project to private companies within 5 years.

【Goal accomplished by the end of 2018 and the state of achievements】

1. Construction of the basic concept classification of medical information. (Achieved)

2. Feedback of the concept to the system (implementation based on feedback). (Achieved)
3. Preparation of summaries, for instance, of the open/close strategy. (Achieved)
4. Construction of the coordination relationship with other subthemes. (Achieved)

【Intermediate goal】(By the end of 2020)

1. Revaluation based on information feedback from the implemented system of the concept.
2. Reconstruction of the concept based on the implementation result.
3. Feedback to the system.
4. Overall emphasis, concrete products, construction of an open/close strategy for each system, etc.

【Goal】(By the end of 2022.)

1. Brush-up of the concept based on its implementation and feedback.
2. General dissemination and standardization of the concept.
3. Implementation of a concrete open/close strategy (for overall or individual equipment and a system).
4. Construction and deployment of a PPP/PFI strategy for implementation.

3. Implementation system

(1) SIP promotion system

SIP is to be conducted as one of the measures to strengthen the headquarters function of the Council for Science, Technology and Innovation (CSTI). It is financed via the promotion budget allocated by the Cabinet Office. Its promotion system is formulated under the CSTI.

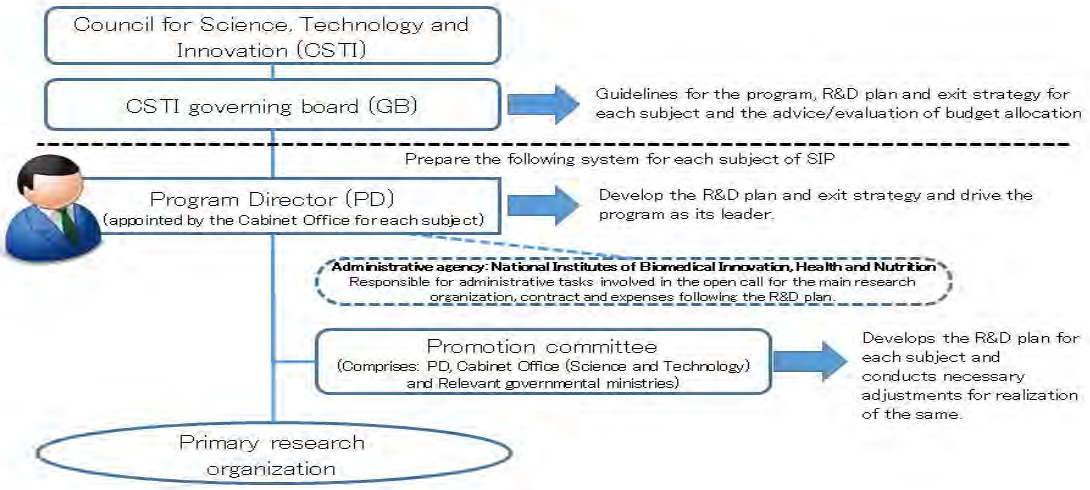


Figure 3-1 Operation system of SIP of the Cabinet Office

(2) Utilization of the National Institute of Biomedical Innovation, Health and Nutrition

This issue will be addressed by utilizing the Management Expenses Grants of the National Institute of Biomedical Innovation, Health and Nutrition and implemented under the following system. The National Institute of Biomedical Innovation, Health and Nutrition will support the public call for the primary research organization, organization of selection/evaluation committees, management of contracts and budgets, operation of the project management committee that will manage the progress of the research, administrative tasks related to self-inspection by the primary research organization and administrative tasks related to the third-party evaluation necessary for the self-inspection by the PD following the instructions from the PD and the Secretariat of the Cabinet Office and according to the decisions of the PD and promotion committee.

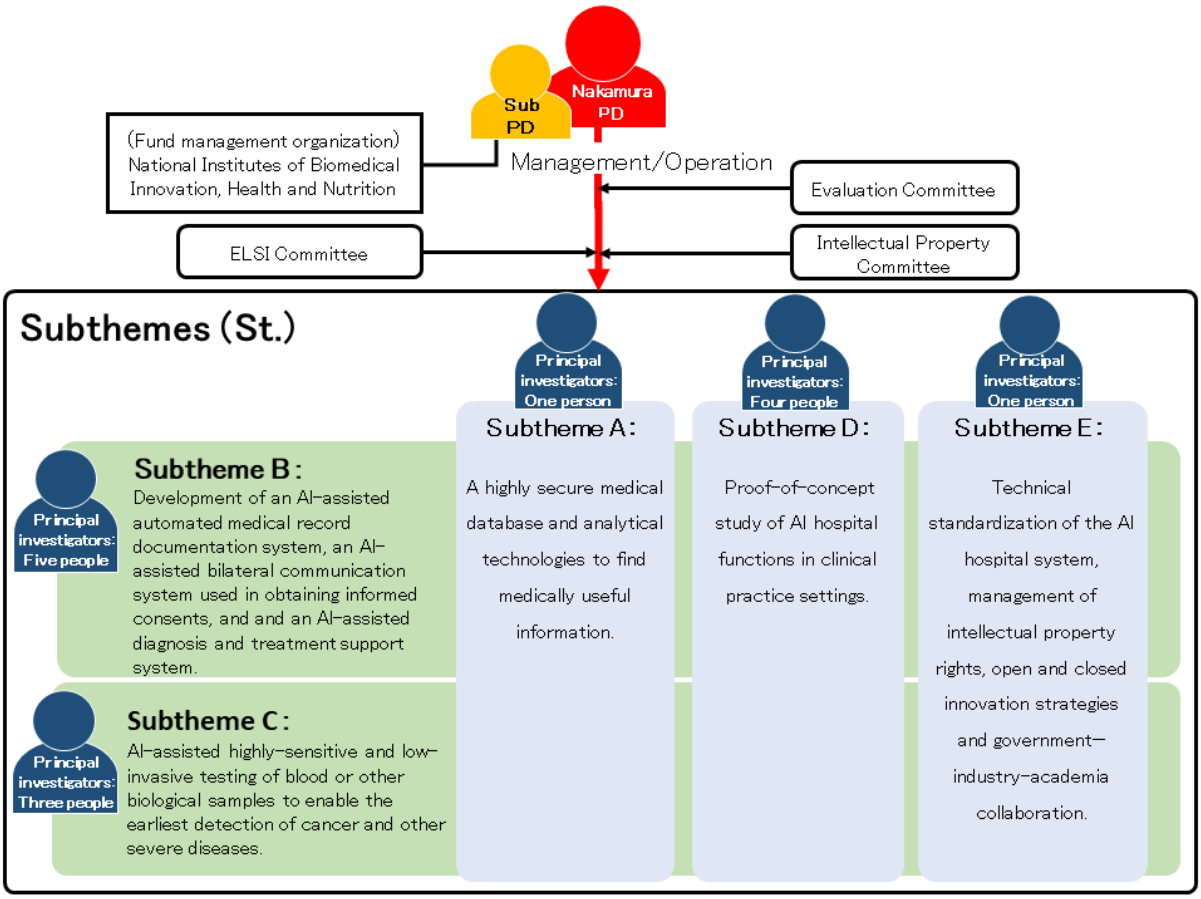


Figure 3-2 Promotion system of the issues

(3) Selection of the principal investigator

Following this plan, the National Institute of Biomedical Innovation, Health and Nutrition will organize a public call for the primary research organization and establish a selection/evaluation committee comprising external experts following an evaluation committee establishment and operation regulations determined by the PD. Based on the examination results, the evaluation committee will select the principal investigator and answer questions from the PD. The National Institute of Biomedical Innovation, Health and Nutrition will be responsible for the administration of the examination. Note that the examination criteria and the members of the selection/evaluation committee will be selected after carefully considering any conflicts of interest and consulting the PD and Cabinet Office. Committee members who have a conflict of interest with the primary research organization developing the proposal to be examined will not participate in the examination.

(4) Measures to optimize the research system

The application to become the primary research body will be conducted either by an individual research institution or by a research group consisting of several research institutions. To build a

system for conducting integrated research from a basic to application as well as promote an intellectual property strategy for the improvement of international competitiveness, a consortium will be formed for each open call, if necessary, to conduct the research.

Each research consortium will work closely under the instruction of the PD or the sub PD to produce a synergistic effect.

(5) Inter-governmental coordination

The medical field will be relevant to the Ministry of Health, Labor and Welfare and the Ministry of Education, Culture, Sports, Science and Technology; medical equipment, pharmaceutical development and equipment for pharmaceutical preparation with isotopes used in diagnosis and treatment will be relevant to the Ministry of Health, Labor and Welfare and the Ministry of Economy, Trade and Industry; communication infrastructure for information sharing, remote image/pathological analysis and diagnosis will be relevant to the Ministry of Internal Affairs and Communications; and distribution of pharmaceutical products, test equipment and test samples will be relevant to the Ministry of Land, Infrastructure, Transport and Tourism and the National Police Agency. An organization that can appropriately adapt to the opinions of the patients and users and consider how to design a system for the optimization of society overall as well as the regulations that will pose as its obstacles to conduct opinion collection from relevant ministries and coordination with them.

(6) Contribution from the industry

Subthemes A to C anticipate contributions from the industry in the form of private investments of 5% in 2018, 20% in 2019 and 2020 and 50% in 2021 and 2022 toward the project. This is not the case for Subthemes D and E.

4. On intellectual properties

The intellectual property strategy includes active acquisition of patents in those fields/technologies that can be patented and wherein the ownership of the patent will be beneficial for their practical application. Regarding medical equipment, those that require wide-range involvement by a third party such as an AI analysis program, data formatting, a primary treatment method and an In/Out protocol will be actively published to establish their international standards. As the competition in AI algorithms for analysis of images, pathologic tissues and blood is especially fierce, intellectual property and standardization strategies will be actively deployed. Standardization will also be used as a preventive measure against patent trolls.

The IoT devices for measurement will be set as the “cooperation area” and the protocols will be published and standardized to facilitate Japanese and international companies to enter (naturally, regulations such as the Pharmaceutical Affairs Act will be strictly followed), enabling rapid and widespread dissemination and de facto standardization. Regarding the technological aspects of, for

instance, the AI analysis algorithm that has technological supremacy, their direct publication will be avoided and their competitiveness ensured through methods such as indirect publication, intellectual property protection and concealment.

Through the increase in third-party companies, the range of use, including information collection, can be expanded. Especially for diagnoses utilizing AI technology, it would be possible to intensively collect diverse types of information and, as a result, improve its accuracy in diagnosis support. Therefore, the deployment policy for the database is to combine related information, including international information, to Japan.

Moreover, this project will establish a liaison committee of representatives from relevant industry, academia and governmental agencies, regularly publish its achievements and effects (not only providing information through the Internet but also through, for instance, forums), encourage the participation of private companies for practical application/concrete realization of its achievements and secure staff for technical application of its basic technology to actively promote practical application and adaptation of its technologies. In addition, information will be provided to the companies that attended the explanatory meetings and their participation in the project will be encouraged to appropriately match researchers with private companies. Financial support will be considered as necessary.

Moreover, to improve the accuracy and reliability of the collected information in the future, it will be essential to standardize the terms and concepts currently in use. However, if we produce original data just for Japan, it is possibility that internationally it will be less compatible. Thus, it is important to clarify the relationship with international organizations and terms. Therefore, an original corpus as well as a standard thesaurus that includes international terms will be produced.

(1) Intellectual property committee

○ An intellectual property committee will be established in the National Institute of Biomedical Innovation, Health and Nutrition to secure the incentive of the investors and those who are responsible for the technologies' dissemination/industrialization as well as to appropriately manage the intellectual properties so as to increase the benefit to Japanese residents.

○ The intellectual property committee will be responsible for determining the policies regarding the publication of papers on research and development achievements and application/retention of the patents (hereafter referred to as an "intellectual property right") of the organization to which it belongs, as well as for the administration of the licensing of the intellectual property right, if necessary.

○ As a rule, the intellectual property committee will consist of the PD or his/her representative and the primary relevant parties and experts.

○ The details on how the intellectual property committee would function will be determined by each organization establishing the committee.

(2) Agreement on the intellectual property rights

○ The administrative entity must develop an agreement in advance with the contractors regarding confidentiality, background intellectual property rights (the intellectual property rights the principal investigator or the organization he/she belongs to as held before participation in the program as well as those acquired outside the funding of the SIP during the participation in the program) and foreground intellectual property rights (the intellectual property rights acquired within the funding of the SIP during the program).

(3) Licensing of background intellectual property rights

○ The licensing of the background intellectual property rights to other participants of the program will follow the conditions outlined by the rights holder (or will follow the agreement between the program participants) and will be licensed by the rights holder.

○ If the position of the intellectual property right holder under these conditions could hinder SIP progress (i.e., research and development as well as the practical application/commercialization of results), the intellectual property committee will mediate to find a reasonable solution.

(4) Handling of foreground intellectual property rights

○ In principle, the foreground intellectual property rights will belong to the organization (contractor) to which the Research Director, who is the investor, belongs following article 19, paragraph 1, of the Industrial Technology Enhancement Act.

○ On a successful invention by a subcontractor, the intellectual property committee must approve its intellectual property right for it to belong to the subcontractor. At this time, the intellectual property committee can set the terms.

○ When the intellectual property right holder is not actively willing to commercialize, the intellectual property committee will promote the right to be held by, or licensed to an organization that will actively engage in its commercialization.

○ When an organization withdraws from the program before its completion, all or parts of the results achieved through the funding of the SIP (if the participation lasted for several years, all the results right from the start), as well as their licensing rights, will be transferred to the administrative entity for free at the point of the withdrawal.

○ As a rule, the costs involved in application/retention of intellectual property rights will be borne by the rights holder. When it is a joint application, the percentage of the share and expenses will be determined by the discussion between the co-applicants.

(5) Licensing of a foreground intellectual property rights

○ The licensing of the foreground intellectual property rights to other participants of the program will follow the conditions outlined by the rights holder (or will follow the agreement between the program participants) and will be licensed by the rights holder.

○ The licensing of the foreground intellectual property rights to the third party will follow the conditions outlined and will be licensed by the rights holder. These conditions must be less favorable than those for other program participants.

○ If the position of the intellectual property rights holder under these conditions could hinder SIP progress (its research and development as well as the practical application/commercialization of results), the intellectual property committee will mediate to find a reasonable solution.

(6) Transfer of foreground intellectual property rights and approval of the setting/transfer of exclusive license

○ Following article 19, paragraph 1 (4), of the Industrial Technology Enhancement Act, transfer of foreground intellectual property rights and setting/transfer of exclusive license will require approval from the administrative entity unless it is a case of transfer as a result of merger, split-up, rights transfer or setting/transfer of exclusive license to a subsidiary or a parent company (hereafter referred to as a "case of intellectual property right transfer such as merger").

○ When it is a case of intellectual property rights transfer such as a merger, it requires approval from the administrative entity based on its contract with the rights holder.

○ Even after a case of intellectual property rights transfer such as a merger, the administrative entity will be able to retain the right to relicense the intellectual property rights. Transfer will not be approved unless these conditions are accepted.

(7) Handling of intellectual property rights after the completion of the program

○ For intellectual property rights that no party wishes to retain at the end of research and development, the intellectual property committee will discuss its handling (renunciation or retention by the administrative entity).

(8) Participation of international organizations (foreign companies, universities, or researchers)

○ If participation of an international organization is necessary for project progress, then its participation will be allowed.

○ In principle, a liaison or a representative of this organization who can conduct administrative tasks involved in the commissioning of research and development must be in Japan to enable appropriate program management.

○ These international organizations must share the intellectual property rights with the administrative entity.

5. On evaluation

(1) Evaluating organization

Evaluation is conducted by external experts invited by the governing board while referring to the reports on self-inspection results by the PD and the National Institute of Biomedical Innovation,

Health and Nutrition. A governing board can also be organized for each subtheme. In addition to the self-inspection and evaluation by the PD and the sub PD, a promotion committee, an evaluation committee comprising third parties, an intellectual property committee, an ELSI committee and a project management office (PJMO) will be established to conduct internal and external evaluations and monitor the progress management of the PDCA cycle.

(2) Evaluation period

○ An evaluation will be conducted during the following periods: prior to the program, at the end of each year and a final evaluation at the end of the program.

○ If necessary, a follow-up evaluation may be conducted subsequent to the completion of the program (3 years in principle).

○ Aside from the aforementioned periods, an evaluation could be conducted during the ongoing year if necessary.

(3) Evaluation item/Evaluation criteria

Following the "National Guidelines for Evaluating Government Funded R&D (approved by the Prime Minister on December 21, 2016)," the evaluation items/criteria that evaluate the necessity, efficiency and effectiveness are as follows. In addition to the determination of successful/unsuccessful completion, the evaluation will also conduct analysis of its cause/factors and proposals for improvement measures.

① Significance of the purpose and compatibility between the system of the SIP and the objective.

② Validity of the objective (especially the outcome to be achieved) and fulfilment level of the work schedule prepared for accomplishing the goal.

③ Whether it is being appropriately managed. In particular, how effective is coordination among government ministries?

④ Strategic value for practical application/commercialization and the level of achievement.

⑤ The final evaluation will also evaluate the expected effects or ripple effects as well as whether the follow-up method subsequent to the completion is appropriately and clearly set.

(4) How to reflect evaluation results

○ An initial evaluation is conducted for the plan for the following year and beyond; it will be reflected in the plan.

○ The evaluation conducted at the end of each year evaluates the achievement accomplished till that year and the plan for the following year and beyond; it is reflected in the plan.

○ The final evaluation evaluates the achievement accomplished till the final year and it is reflected in the follow-up subsequent to the project completion.

○ The follow-up evaluation evaluates the progress of practical application/commercialization of the achievements of each subject and proposes measures for improvement.

(5) Publication of the results

○ As a rule, the evaluation results will be published.

○ As the governing board that conducts the evaluation also handles unpublished research and development information, it will not be made public.

(6) Self-inspection

① Self-inspection by the Research Director

The PD selects the principal investigator who will conduct the self-inspection. (As a rule, the primary researcher/research institute of each research subject is selected.)

The selected Research Director conducts inspections of both the achievements since the last evaluation and the plan for the future by applying the evaluation items/criteria listed in 5 (3) to determine successful/unsuccessful completion and moreover, to analyze its causes/factors and propose improvement measures.

② Self-inspection by the PD

The PD conducts inspection of their achievements and those of the National Institutes of Biomedical Innovation and each Research Director and Health and Nutrition and the plan for the future by applying the evaluation items/criteria listed in 5 (3) while considering the results of the self-inspection by the Research Director and, if necessary, referring to the opinions of third parties and experts, to determine successful/unsuccessful completion and moreover, to analyze its cause/factors and propose improvement measures. Following the results, whether to continue the research by each primary research organization or not will be decided and necessary advice to the Research Director will be provided. This process allows the system to independently improve.

Based on this result, the PD prepares documents for the governing board with support from the National Institute of Biomedical Innovation, Health and Nutrition.

③ Self-inspection by the administrative entity

Self-inspection by the National Institute of Biomedical Innovation, Health and Nutrition is conducted on subjects such as whether the administrative procedure on budget implementation is appropriate.

(7) Feasibility study and re-evaluation of approval

Based on the results of self-evaluation and evaluation by third parties, a feasibility study of the approved subject will be conducted. Subjects whose realization is unlikely, those who are not well coordinated with other subjects and those with low cost-effectiveness are identified. Their approval will be re-evaluated so as to select the issues to be addressed and concentrate the budget to accomplish the goal(s) of the overall project.

6. Exit strategy

(1) Practical application of the Innovative Al Hospital System package

Achieve the practical application of the Innovative Al Hospital System package and deploy it in a manner that is usable not only for large medical institutions such as hospitals but also for family doctors.

Complete the Innovative Al Hospital System package that includes various medical equipment, software/specifications for connection to the electronic medical record and software/specifications for connection to the cloud AI as SIP. The companies that participate in the joint research will be responsible for the commercialization and service provision subsequent to this point.

(2) Practical application of AI-based medical equipment

Obtain the manufacture and sales approval/certification of the AI-based medical equipment whose shared infrastructure is the Innovative Al Hospital System package.

In principle, development of the AI-based medical equipment is conducted through joint research studies and SIP will jointly conduct the process until the completion of their clinical tests. Private companies will obtain the manufacture and sales approval and certification and be responsible for marketing and sales.

Utilize high-efficiency distributed data processing infrastructure and coordinate other challenges in developing IoT medical equipment.

(3) Implementation of AI system for reducing the medical service workload while ensuring that appropriate time is provided for consultation and explanation to patients and their families

Secure time for the medical staff to be in direct contact with patients through documentation of the explanation during consultation in writing and implementation of the interactive AI system for informed consent and explanation of the treatment policy. Needless to say, these systems will be constantly updated/improved by private companies; therefore, they will lead to activation of the medical information industry. Moreover, if they enable explanation in other languages, this will support the treatment of foreign patients in Japan. In addition, this will enable the international export of these systems.

(4) Implementation of an ultraprecise test system for blood and other samples utilizing AI technology in medical service

Establish a SOP (aim to establish it as the international standard as much as possible) for the ultraprecise test system for blood and other samples utilizing AI technology; develop it to a level wherein samples collected by family doctors, not only at the primary regional hospitals, can be examined; and work toward establishing it as a test system that can be accessed from anywhere in Japan. Needless to say, the test will be primarily conducted by private testing companies.

7. Other important issues

(1) Legal basis

This program will be realized by adhering to the following legislations and regulations: article 4, paragraph 3 (7) of the Cabinet Office Establishment Act (Act No. 89 of 1999); Guidelines for the Creation of Science and Technology Innovation budget (May 23, 2014, CSTI); the Implementation Policy for Phase 2 (for the 2017 supplementary budget) of the Cross-ministerial SIP (March 29, 2018, CSTI); and the SIP guidelines (revised on June 27, 2019, by the governing board of the CSTI).

(2) Flexible revision of the plan

This plan will be flexibly revised in response to the changing situation to achieve the optimal result through the fastest process.

(3) Professional history and purview of the PD

① PD Yusuke Nakamura (Director of the Cancer Precision Medicine Center, Japanese Foundation for Cancer Research)

1977 M.D. in Faculty of Medicine, Osaka University
1977 Osaka University Hospital (Second Department of Surgery)
1984 Obtained Ph.D. in medicine (Osaka University)
1994 Professor, Laboratory of Molecular Medicine Institute of Medical Science, The University of Tokyo
1995 Professor, Director, Human Genome Center Institute of Medical Science, The University of Tokyo (～January 2011)
2001 Established OncoTherapy Science, Inc
2005 Director, RIKEN Center for Genomic Medicine (～March 2010)
2010 Special advisor to the RIKEN Center for Genomic Medicine
2010 Director, Research Institute, the National Cancer Center (～2011)
2011 Special Advisor to the Cabinet Secretary General, Office of Medical Innovation, Cabinet Secretariat (Devising a strategy for promoting medical innovation in Japan)
2012 Professor, Department of Medicine, Hematology/ Oncology Dept., Deputy Director, Center for Personalized Therapeutics, The University of Chicago
2018 Professor Emeritus, The University of Tokyo
2018 Professor Emeritus, The University of Chicago
2018 Director, the Cancer Precision Medicine Center, Japanese Foundation for Cancer Research

More than 1,400 original papers in English, including 17 published in Nature, 70 published in Nature Genetics, seven published in The New England Journal of Medicine, 11 published in

Science, 115 published in Cancer Research. These have been cited more than 160,000 times.

② Sub PD

Satoru Miyano
(Professor, Head of
Human Genome Center
Institute of Medical
Science, The University of
Tokyo)

Hiroshi Mano
(CEO, CTO
EverySense,Inc.)

Junichi Tsujii
(Fellow at National Institute of
Advanced Industrial
Science and Technology
Director of the Artificial
Intelligence Research Center of
AIST)

③ Responsible Councilor

Kazunari Asanuma
(April 2018～June 2019)

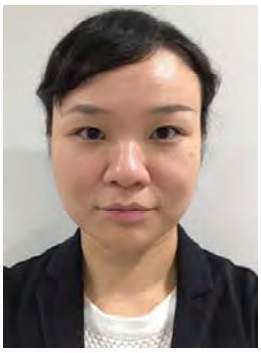
Masahiro Sasaki
(July 2019～)

Kazuhisa Hasebe
(August 2018～)

Yuji Furuta
(April 2018～March 2019)

④ Responsible staff

Isamu Terashima
(April 2018～September 2018)



Etsuko Sudo
(October 2018～)

Attachment　　Financial plan and estimate

2019　　Total Amount: 3,000,000,000 Yen

(Breakdown)

1. Research expense (including general administrative expenses/indirect expenses)
   2,499,340,000 Yen

(Breakdown by research and development items)

(A) A highly secure medical database and analytical technologies to find medically useful information.　　643,795,000 Yen

(B) Development of an Al-assisted automated medical record documentation system, an Al-assisted bilateral communication system used in obtaining informed consents and an Al-assisted diagnosis and treatment support system.
618,895,000 Yen

Construction of the AI system　　300,000,000 Yen

(C) Al-assisted highly-sensitive and low-invasive testing of blood or other biological samples to enable the earliest detection of cancer and other severe diseases. and　　456,650,000 Yen

(D) Proof-of-concept study of Al hospital functions in clinical practice settings.
. 743,500,000 Yen

(E) Technical standardization of the Al hospital system, management of intellectual property rights, open and closed innovation strategies and government－industry-academia collaboration and.
36,500,000 Yen

2. Project promotion expenses (labor, evaluation and meeting costs) *2　　197,290,000 Yen

Total　　197,290,000 Yen

3. Retention money for redistribution during the same year.　　3,370,000 Yen

Total　　3,370,000 Yen

＊　Present the estimate for each subtheme of this research and development program in the budget; it is allocated twice during the 1st and 2nd term. Note that the budget allocation of the 2nd term is based on the results of the 1st term and an allocation appropriate to its level of achievement is made.

＊2　52,712,000 Yen, which is the refund from 2018, will be added to the project promotion expenses.

Toward the exit strategy/social implementation

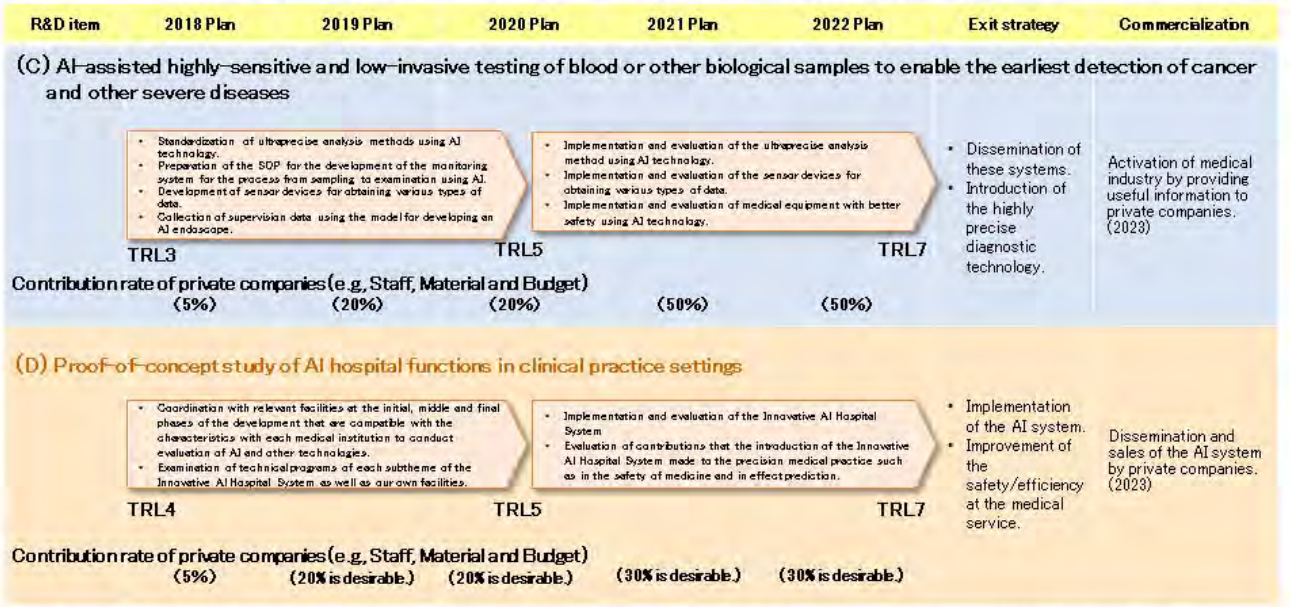
Innovative AI Hospital System Work Schedule

R&D item	2018 Plan	2019 Plan	2020 Plan	2021 Plan	2022 Plan	Exit strategy	Commercialization
(A) A highly secure medical database and analytical technologies to find medically useful information.	• Development of a technology for secure data storage. • Development of a technology to extract medically useful information using the database (big data). • Development of a communication protocol that utilizes blockchain technology. TRL3		TRL5	• Implementation of the technology for secure data storage. • Implementation of the simulation and navigation system for the diagnosis/treatment using AI technology. • Implementation of the communication protocol that utilizes technologies such as the blockchain technology. TRL7		• Formation of a highly secure medical information database and data utilization. • Extraction of medically useful information	Activation of medical industry by providing useful information to private companies. (2023)
Contribution rate of private companies (Staff, Material, Budget, etc.)	(5%)	(20%)	(20%)	(50%)	(50%)		
(B) Development of an AI-assisted automated medical record documentation system, an AI-assisted bilateral communication system used in obtaining informed consents, and and an AI-assisted diagnosis and treatment support system	• Development of a system that documents conversations between patients and doctors in written text. • Development of a real-time interactive communication system for providing explanations to patients that corresponds to the level of comprehension of an individual patient through the application of AI technology. • Conduct demonstrations in coordination with Subtheme D of this system. • Development of the simulation and navigation system for diagnosis/treatment using AI technology. TRL3		TRL5	• Implementation of a system that documents conversations between patients and doctors in written text. • Implementation of a real-time interactive communication system for providing explanations to patients that corresponds to the level of comprehension of an individual patient through the application of AI technology. • patients that corresponds to the level of comprehension of an individual patient through the application of AI technology. • Development of the simulation and navigation system for diagnosis/treatment using AI technology. TRL7		• Dissemination of these systems • Reduction in the workload of the medical staff	Commercialization of the medical staff workload reduction system (2023~)
Contribution rate of private companies (e.g, Staff, Material and Budget)	(5%)	(20%)	(20%)	(50%)	(50%)		

*Contribution rate from TRL and private companies is the expectation at the point of planning. It can change in response to future developments

Toward the exit strategy/social implementation

Innovative AI Hospital System Work Schedule



*Contribution rate from TRL and private companies are the expectation at the point of planning. It may change in response to future developments.

Toward the exit strategy/social implementation

Innovative AI Hospital System Work Schedule

R&D item	2018 Plan	2019 Plan	2020 Plan	2021 Plan	2022 Plan	Exit strategy	Commercialization
(E) Technical standardization of the AI hospital system, management of intellectual property rights, open and closed innovation strategies, and and government–industry–academia collaboration	• Construction of the basic concept, classification of medical information. • Feedback of the concept to the system (implementation based on feedbacks). • Preparation of summaries for the open/close strategy.	• Re-evaluation based on the information feedback from the implemented system of the concept. • Reconstruction of the concept based on the result of implementation. • Feedback to the system. • Overall emphasis, concrete products, and and the formulationconstruction of the open/close strategy for each system.	• Brush-up of the concept based on its implementation and feedback from it. • General dissemination and standardization of the concept. • Implementation of a concrete open/close strategy (overall or individual equipment system). • Construction and deployment of the PPP/PFI strategy for implementation.			• Construction of these concepts and their feedback to the systems. • Evaluation subsequent to their introduction and reconstruction of the concepts based on their revaluation.	Activation of medical service and medical industry by providing useful information to private companies. (2023)
	Construction of the coordination relationship with other subthemes.		Construction of the coordination relationship with other subthemes.				
	TRL3		TRL5		TRL7		
Contribution rate of private companies (e.g, Staff, Material, Budget)	(0%)	(0%)	(0%)	(0%)	(0%)		

*Contribution rate from TRL and private companies are the expectation at the point of planning. It may change in response to future developments.