

New Solutions Using ICT in Clinical Trials and Clinical Research

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Fujitsu has been providing electronic medical record (EMR) solutions to medical institutions for many years. Now, with the increasing penetration of EMR systems, there is a growing desire to apply the data accumulated from medical consultations and examinations to diagnosis support and to link EMR data with tasks performed in clinical trials and clinical research. Specifically, there are expectations of using information and communications technology (ICT) in trials and research centered about large medical institutions such as university hospitals, of incorporating genome information management in research conducted by faculties of medicine in universities, and of feeding back knowledge so gained to medical practitioners. To enable the practical application of EMR data accumulated over many years, Fujitsu is offering new solutions and working to create new lines of business based on those solutions. This paper describes Fujitsu's approach to next-generation EMR solutions and the use of ICT in linking them with clinical trials and clinical research. It also touches upon Fujitsu's approach to the future with a view to creating a personal health record (PHR) system.

1. Introduction

In line with the worldwide trend toward an aging population and low birth rate, Japan's national medical expenditure for fiscal year 2012 topped 39 trillion yen, signaling an urgent need for reforming the country's public health insurance system. This can be accomplished by revising the healthcare system for the elderly, shifting to in-home medical and nursing care, and setting appropriate fees for medical care to ensure the sustainability of the national health insurance system.

At the same time, Japan, faced with becoming the world's first "super-aging society," has begun looking at disease prevention as one means of raising national health consciousness and has begun studies on technology and systems for watching over the elderly (in 2013, the elderly made up 25.1% of the population).¹⁾ In June 2013, the government formulated the "Japan Revitalization Strategy—Japan is Back" (revised in June 2014 as the "Japan Revitalization Strategy—Japan's challenge for the future") and set "extending the nation's healthy life expectancy" as a next-generation policy objective for medical care.²⁾

The government subsequently formulated a healthcare strategy called the "Healthcare Policy" based on the "Act on Promotion of Healthcare Policy." At present, a variety of specific policies are being planned or executed, all of which relate to electronic medical record (EMR) systems, which constitute the core of information and communications technology (ICT) supporting the information infrastructure in healthcare institutions.

Fujitsu has been expanding its healthcare solutions business based on EMR systems for many years. Today, as a result of these efforts, the company has the largest share (37%) of the healthcare market in Japan.

In this paper, we first take a look at government healthcare-related policies and guidelines and describe how they are making it necessary to incorporate new elements in healthcare information systems centered about EMR systems. Next, we describe Fujitsu's approach to expanding its healthcare business centered about EMR solutions based on new needs and introduce new Fujitsu solutions. Finally, we touch upon Fujitsu's approach to the future, which includes the roll out of a personal health record (PHR) system for individual use

of EMR information for personal health management over HumanBridge, a health information exchange (HIE) network provided by Fujitsu to expand the use of EMR systems. This endeavor reflects Fujitsu's vision of innovative information services centered about the individual user.

2. Japanese healthcare-related strategies and Fujitsu solutions

The correlation between healthcare-related strategies in Japan and Fujitsu's healthcare solutions are shown in **Figure 1**.

2.1 Government's IT national strategies

The Japanese government announced the e-Japan Strategy in 2001 followed by the e-Japan Strategy II in 2003 and New IT Reform Strategy in 2006 as a series of IT strategies incorporating a variety of reform-oriented policies. These included "promotion of EMR systems," "further promotion of IT in healthcare through a treatment remuneration system," and "promotion of collaborative use of healthcare information."

Next, the government announced plans for a

Japanese Electronic Health Record (EHR) system as part of its "i-Japan Strategy 2015" drawn up in 2009 with the aim of "reducing medical errors and providing ongoing healthcare throughout a person's life," "issuing prescriptions electronically," and "collecting anonymous health-related information on a nationwide basis and using that information for immunological purposes."

Moving to the present, the government envisions a society with the following characteristics as a goal to be realized by 2030, as described under the theme "extending the nation's healthy life expectancy" in the "Japan Revitalization Strategy (2013)."

- 1) A society in which people can lead a healthy life even in their later years through effective disease-prevention services and thorough health management
- 2) A society in which people can receive the world's most advanced medical care through stimulation of healthcare-related industries
- 3) A society in which people incapacitated by illness or injury can return to their social roles quickly by giving them access to high-quality medical and nursing care.

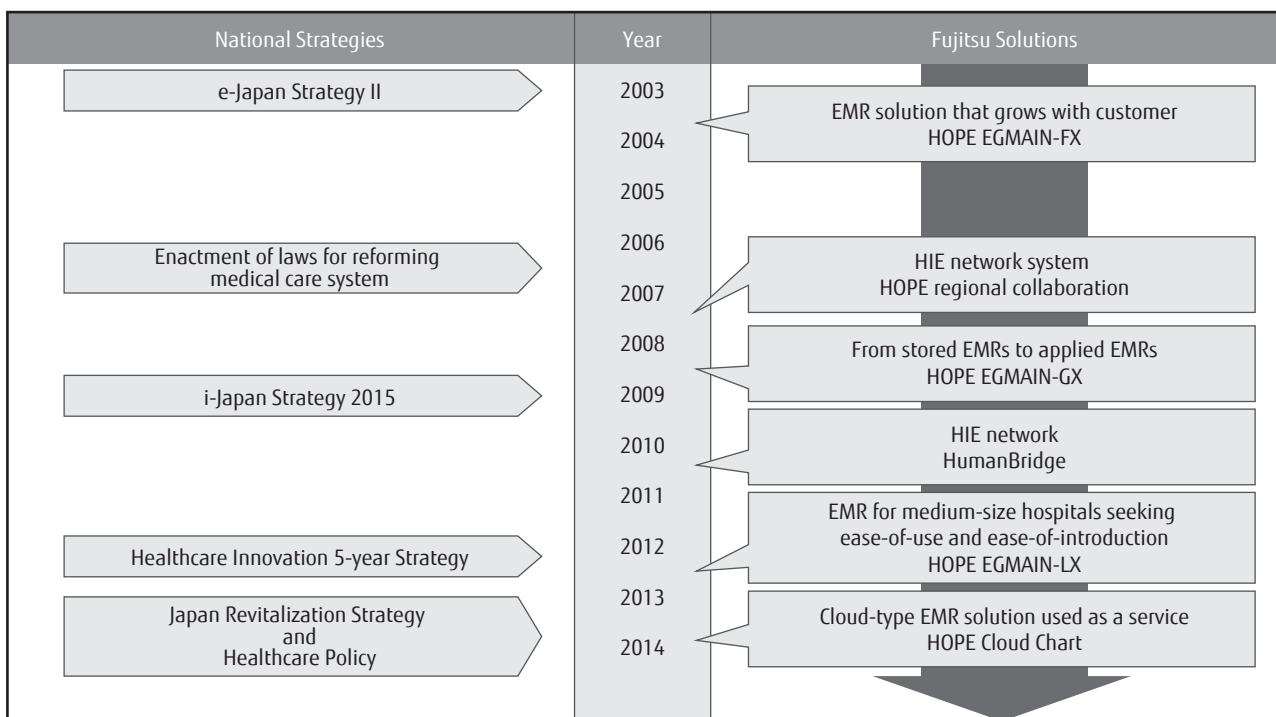


Figure 1
Japanese healthcare-related strategies and Fujitsu solutions.

In addition to the above, “Measures related to digitization and ICT use associated with medical, nursing, and health care required to achieve the world’s most advanced medical care” are compiled in the “Healthcare Policy” approved by the Cabinet in July 2014.³⁾

2.2 Fujitsu’s approach in line with national strategies

In 1999, Fujitsu put Japan’s first EMR system into operation at Shimane Prefectural Central Hospital. Then, in 2000, with an eye to promoting the adoption of EMR systems, Fujitsu began to offer its “FUJITSU EMR Healthcare Solution HOPE EGMAIN-EX (HOPE EGMAIN-EX).”

Next, to further promote the use of EMR, Fujitsu placed its “FUJITSU Healthcare Solution HOPE EGMAIN-FX (HOPE EGMAIN-FX)” on the market as a low-cost, non-customized one-stop solution that provides EMR, medical accounting, and various departmental packages as a set of services.

Then, in 2008, in view of the “New IT Reform Strategy (2006)” and the incorporation of Japanese national universities in 2004, Fujitsu placed a new product on the market in the form of “FUJITSU Healthcare Solution HOPE EGMAIN-GX (HOPE EGMAIN-GX),” integrating HOPE EGMAIN-EX and HOPE EGMAIN-FX. Additionally, as the need for introducing EMR systems in medium-size hospitals began to grow, Fujitsu added “FUJITSU Healthcare Solution HOPE EGMAIN-LX (HOPE EGMAIN-LX)” to its lineup as a package oriented to hospitals of this size. Next, to help reduce customer workloads at small hospitals as well, Fujitsu placed its cloud-type “FUJITSU EMR Healthcare Solution HOPE Cloud Chart (HOPE Cloud Chart)” on the market in April 2014.

As a leading company in the field of healthcare ICT, Fujitsu has always endeavored to be one step ahead of national policies and market trends and to be an early provider of necessary solutions for medical care institutions and patients.

Today, as the use of EMR systems progresses, the accumulation of medical examination data in digital form is generating new needs:

- discovery of new knowledge through the analysis of EMR data,
- application of EMR data to clinical decision support systems,

- data linking between clinical trials and clinical research departments, and
- development of genomic personalized medicine by managing genetic information and data from medical examinations, noting that genome-related data is increasingly being used in medical practices.

3. Activities toward new business

In response to the needs described above arising out of Japan’s Healthcare Policy, Fujitsu is involved in a wide variety of healthcare-related activities. These include the enhancement of clinical trials and clinical research systems in relation to rare disorders, incurable diseases, etc. at large medical institutions such as university hospitals, strengthening of clinical-trials coordination systems at designated regional cancer centers and hospitals, and establishment of clinical study core hospitals. Fujitsu is also involved in the genome cohort studies (long-term health studies) being held as part of the Tohoku Medical Megabank Project.

Specifically, Fujitsu has launched business package solutions for trials and clinical research to facilitate the linking and use of EMR information in an efficient, accurate, and high-speed manner.

Fujitsu has also begun work on a next-generation EMR system that will convert genome data and other types of omics information and personal health and medical examination data into an anonymous form, integrate and store that information in a database, and feed back search results from big data such as similar medical cases to medical care facilities (Figure 2).

Additionally, from the viewpoint of connecting with the outside via a network, Fujitsu has also been involved in efforts at regional coordination among different institutions as in enabling medical personnel at the scene of an emergency to access information on available hospital beds in that region.

4. New solutions

In this section, we introduce new solutions born of Fujitsu’s ongoing efforts in healthcare. These solutions will become the core of new Fujitsu businesses.

4.1 Specific solutions now being provided

- 1) Investigator-led clinical trial support solution: FUJITSU Healthcare Solution HOPE Cloud

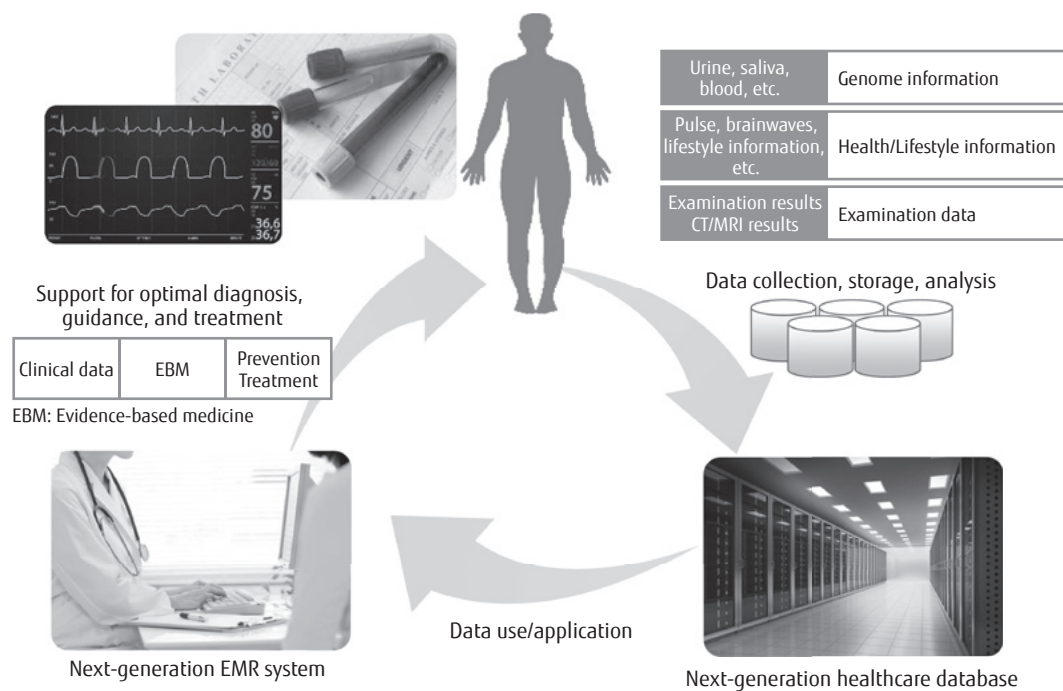


Figure 2
Efforts toward genomic personalized medicine.

DDworks21 HC

This is a cloud-type solution supporting investigator-led clinical trials, which is one of several types of clinical trials conducted at university hospitals and elsewhere. The Ministry of Health, Labour and Welfare (MHLW) is promoting the provision of an infrastructure for clinical research and trials in line with its "2012 Action Plan of 5-year Plan for Revitalization of Clinical Trials" formulated in 2012. It is also selecting clinical study core hospitals and promoting investigator-led clinical trials.

Fujitsu has repackaged for medical care institutions the experience and know-how built up in industry-sponsored clinical trials centered about pharmaceutical companies and has begun to provide the "FUJITSU Healthcare Solution HOPE Cloud DDworks21 HC (DDworks21 HC solution)," which provides total support for investigator-led clinical trials. This solution provides the business flow for clinical trial processes in conformance with good clinical practice (GCP) together with real-time checking for procedural omissions and violations. It also supports an electronic data capture (EDC) function and a "Notice System for Adverse Drug Reaction (NSADR)."

The DDworks21 HC solution significantly reduces

the doctor's data-input load in doctor-led clinical trials by linking with an EMR system (HOPE EGMAIN-GX) to input necessary data. It also allows the input screen to be configured on the basis of Clinical Data Interchange Standards Consortium (CDISC) standards.

2) Clinical research support solution: HOPE eACReSS

This solution supports clinical research tasks performed in accordance with ethical guidelines for clinical research. It covers a wide range of tasks from project planning to data collection, including centralized management of clinical research data to reduce workload and the securing of evidence.

This system has been provided in product form since April 2014 and is based on the results and know-how obtained in the "University Hospital Clinical Trial Alliance Promotion Project." It has several attractive features.

- Its case report preparation function conforms to the International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) standards for performing clinical trials of drugs as determined by an international conference of drug regulatory authorities and pharmaceutical companies in Japan, the United States, and Europe.
- It has functions for examinee allocation, scheduling, results management, and appointment reminders.

- It provides electronic case report form (eCRF) check/test functions.
- It supports multi-facility joint operations.

Fujitsu plans to provide this system in a software as a service (SaaS) format implemented on servers in a Fujitsu data center and to link the system with information on EMR systems operating inside medical care institutions.

3) Clinical trials management system: NMGCP

“New Medical Good Clinical Practice (NMGCP)” is a clinical trials management system supporting a variety of tasks normally performed in a clinical trial management office in a medical care institution. It can seamlessly link these tasks with Fujitsu EMR systems.

By linking with an EMR system, NMGCP enables a doctor to display and check trial-related information with the patient at the time of a consultation or examination, thereby preventing protocol or GCP violations and reducing doctor workload.

The NMGCP system also provides separate management of examinees, hospital visits, and monitoring results, thereby reducing the workload of the clinical research coordinator (CRC). It also promotes more efficient secretarial work through auditing/review management and document management functions.

4.2 Present efforts toward new solutions

Several solutions are scheduled for commercialization and rollout.

1) Anonymization (encryption, data masking)

Personal information generated in the course of clinical practice or research may consist of data from medical examinations stored in EMR systems, health-related information, genetic information, and cohort information. This information is normally subject to privacy management and anti-leaking measures. For this information to be used for further research, such as acquiring genetic information from biological specimens, it also needs to be anonymized. The need for such anonymization is growing due to technical innovations in next-generation genome sequencers, which are expected to drastically reduce the cost of genome analysis and democratize genomic analysis.

Privacy protection is being addressed mainly by using k-anonymity techniques, which enable data analysis to be performed with anonymized information, and by using linkable and unlinkable encryption methods,

which enable management of anonymized information related to biological specimens. It is also necessary to obtain a patient's consent for using personal data, which entails the management of information on general consent and other types of patient consent.

Fujitsu is achieving anonymization and encryption of personal information at a high level of security by incorporating “k-anonymity technology” and “homomorphic encryption technology” developed by Fujitsu Laboratories.

2) Integrated database management

Fujitsu is working on technology for collecting, storing, and integrating data related to individuals who may be patients or people in good health. This data may include information from medical examinations stored in EMR systems, information from health check-ups (based on interviews, tests, images, etc.), genome data and other types of omics information, and lifestyle information obtained from questionnaires in regional cohort studies. Fujitsu is also involved in the development of an integrated database that will enable anonymized big data to be analyzed, new discoveries to be made and knowledge to be accumulated, searches for patients with similar conditions to be executed, and statistical tabulations to be performed.

The plan is to incorporate this know-how on similar-condition searching in next-generation EMR systems as a diagnostic support function. Fujitsu is also studying a solution for presenting a doctor making an on-site diagnosis with related information pulled from a huge amount of stored EMR data.

3) Source data management

Fujitsu's Source Data Management System (SDMS) provides support for securing and guaranteeing source materials in clinical trials in accordance with a variety of domestic and overseas regulations. It manages, in particular, the collection of clinical data as information sources in trials performed mainly by pharmaceutical companies.

SDMS enables case data from the results of clinical trials to be tracked and checked and to be protected from tampering. Moreover, by combining past clinical-trial source materials used and saved in a paper-based form with EMR, the system can facilitate the digital management of source data, reduce doctor workload, and make the sharing of trial data a quick and efficient process.

SDMS also enables source data verification (SDV) tasks for reviewing source materials from the client (pharmaceutical company) side to be performed remotely (**Figure 3**).

4) Emergency medical information matching system

Fujitsu's medical information matching system supports emergency transport services for persons in need of emergency medical care by enabling an emergency response team and medical institutions to share information on the state of the person and on patient-acceptance conditions in real time.⁴⁾

For example, information on the state of the person can be input by the emergency response team on a tablet and then be matched up in real time with patient-acceptance conditions input by medical institutions on a tablet or computer. A list of institutions that can accept the patient can then be listed on the emergency response team's tablet, thereby enabling wide-area information sharing and medical care coordination.

This system can be implemented in a high-reliability, high-performance Fujitsu data center,

enabling safe and secure information sharing.

In this way, efficient and accurate information sharing can be performed between an emergency response team and medical institutions, and emergency medical care can be efficiently provided. In short, a situation in which emergency transport is delayed due to the inability to find an available medical institution can be avoided.

5. Fujitsu's approach to the future

The widespread use of EMR systems in medical institutions is helping to drive the sharing of patient information as part of regional coordination among medical institutions. There will be an even greater need for information sharing as the population continues to age.

Furthermore, in addition to the sharing of information on patients with particular diseases (diabetes, cerebral embolism, etc.), the development of integrated community care systems linking medical and nursing care and centered about the elderly is anticipated. Additionally, from the viewpoint of

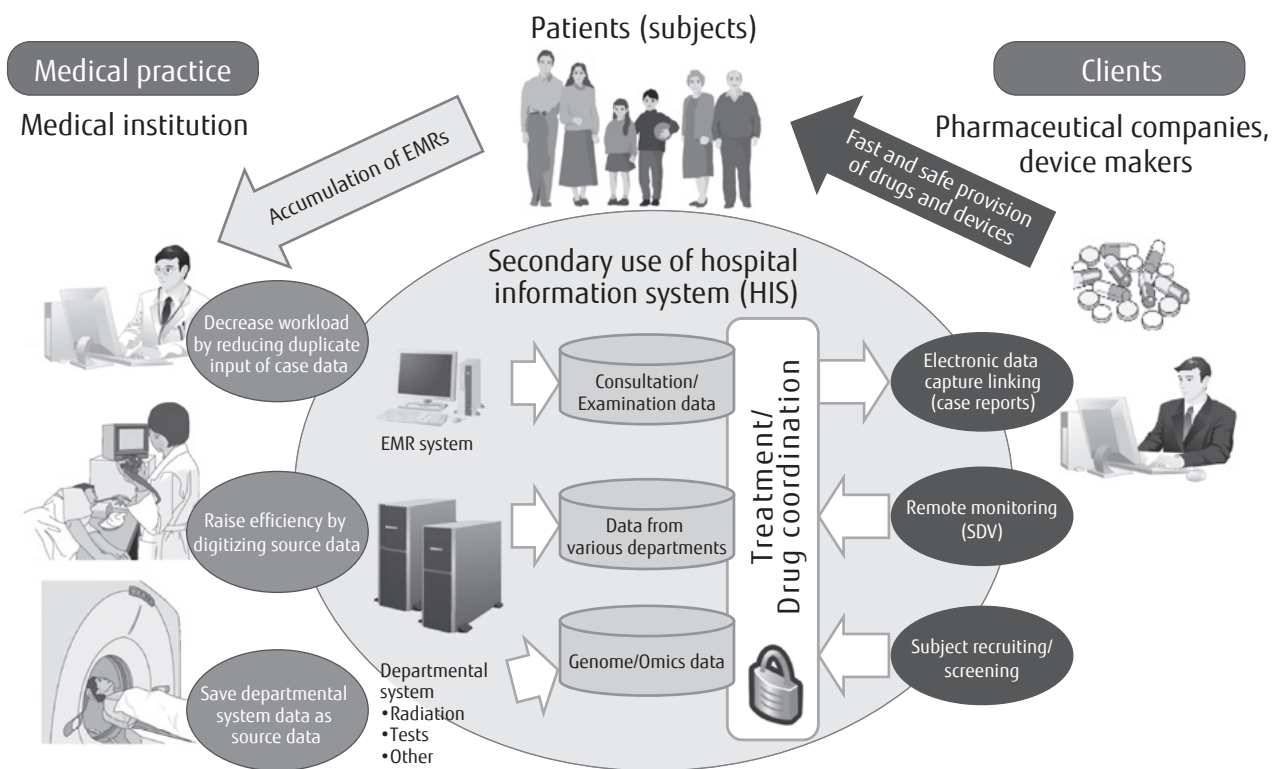


Figure 3
Linking between EMRs and clinical trial data.

preventing disease in the first place, we can expect health-related information even on healthy individuals to be made available for applications including personal health management. Such information will be collected and stored for use in big data analysis.

Fujitsu has developed and provided the "HumanBridge" regional health information exchange network for sharing EMR patient information among medical institutions. HumanBridge enables medical institutions to cross-reference EMR data with an eye to achieving a "one-region, one-patient, one-EMR" system. Fujitsu is also involved in the construction of an ICT coordination infrastructure that would include facilities other than medical institutions to support integrated community care systems. Particular efforts include information sharing with nursing care facilities (nursing care systems) and verification testing and demonstrations of an electronic prescription system toward the sharing of drug-dispensing histories among pharmacies and medical institutions.

Looking to the future, Fujitsu aims to achieve a PHR system that integrates medical care information, health-related information, and nursing care information centered about the individual by adding personal health information as mentioned above. Fujitsu also aims to construct an ICT infrastructure for genomic personalized medicine and to provide cloud-type services that would include personalized health management

services.

Moreover, with the aim of extending the nation's healthy life expectancy, Fujitsu aims to provide health-care, medical care, and nursing care services that can contribute to the realization of a healthy, long-life society (Figure 4). This will be made possible through personalized lifestyle information management of everyday health-related data such as vital signs obtained from sensors so that a person's good health can be maintained and diseases can be prevented in the first place.

6. Conclusion

This paper described new Fujitsu solutions centered about health and medical care policies in Japan and the electronic medical records at the core of medical information systems that support those policies. These solutions are expected to spread through the enhanced use of ICT.

Japan will be the first country in the world to become a super-aging society, and China and other countries in East Asia are coming to view Japan's predicament as a problem that affects them as well. These countries are taking careful notice of the way in which ICT is being used in Japan's medical care industry.

At the same time, Japan is entering a period of transformation into a human-centric society in which various types of data related to individual health, such

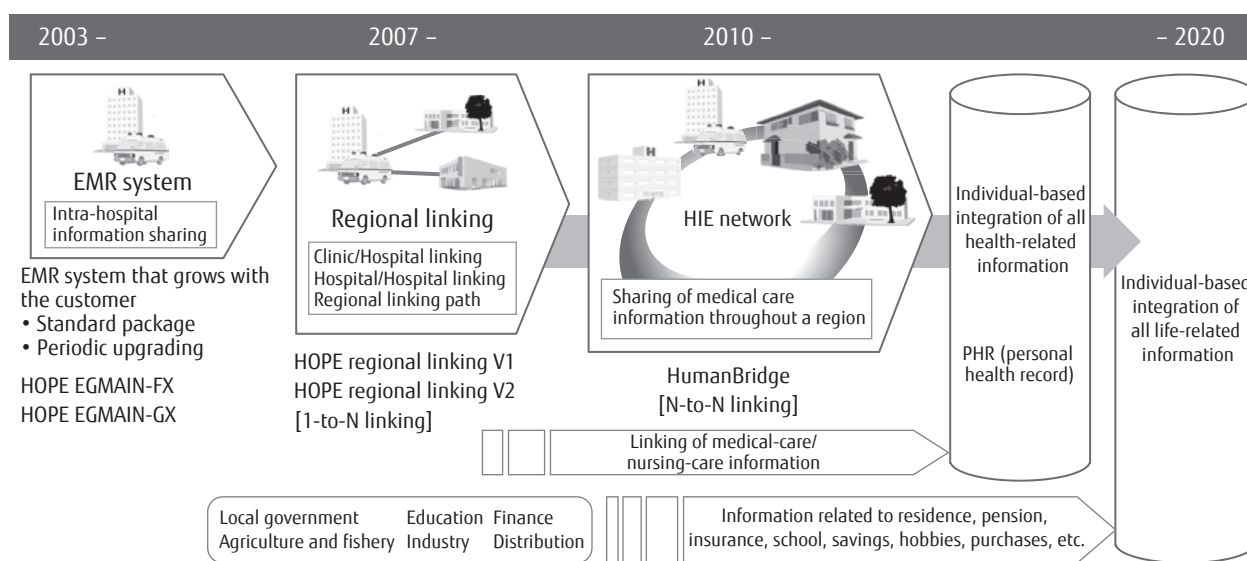


Figure 4
Fujitsu's approach to the future.

as medical-examination data in electronic medical records, general health data, lifestyle information, and genome information, are accumulated and integrated and made accessible over the network. The aim is to achieve healthy long lives and prevent diseases from occurring in the first place with a focus on the user (healthy person, patient, family).

Given the experience and know-how incorporated in the EMR solutions and HIE networks it has developed and implemented, Fujitsu is committed to promoting and providing safe and secure systems through its HOPE brand of solutions and high-quality business services in SaaS and cloud form. By rolling out user-centric services that make use of health, medical care, nursing care, and lifestyle information as well as information from other industries, Fujitsu seeks to create a fruitful and enriching future together with its customers toward the realization of a Human Centric Intelligent Society.



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Mr. Yamaguchi is engaged in new business planning and development in relation to *life innovation* in the healthcare market.

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