# What Makes Medical Records Safe in the Cloud?

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One for All, All for One

- Recently, more and more projects have been funded by the Japanese government to accumulate medical records in the cloud and to enable medical practitioners and researchers to share them.

- "One for All, All for One" is the context underlying these projects.

  - The medical record of one patient contributes to saving the life and aiding the health of other patients, while the accumulated records of a number of patients contribute to saving the life and aiding the health of all patients.
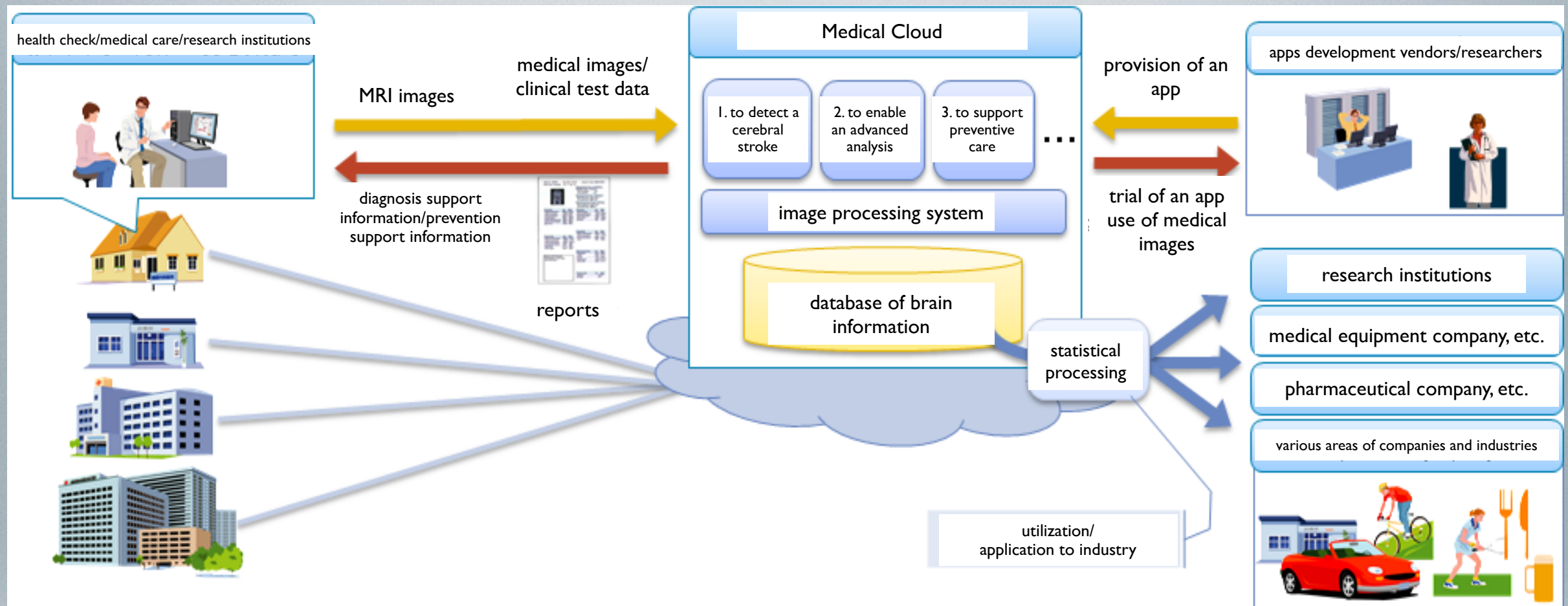
Project to Establish a Platform for the Integrated Diagnosis of Strokes using the Next Generation of Medical Clouds (NTT Data Corporation, NTT Data Institute of Management Consulting, Inc., Iwate Medical University) started in 2013 and is funded by NEDO (New Energy and Industrial Technology Development Organisation).

# My Records for Myself

- The past medical records of a patient contribute to saving their own life and aiding their health.

- Medical clouds can ensure their medical records are available for their current and future attending practitioners.

# The Lesson We Learned from 3.11

- On March 11th, 2011, the Great East Japan Earthquake hit Japan.

- 3.11 reminded us of the importance of the "availability" of medical records.

- 300 or more hospitals and more than 1,200 clinics were damaged due to 3.11.

  ‣ http://www.mhlw.go.jp/stf/shingi/2r9852000001uo3f-att/2r9852000001uo7y.pdf

- Medical records in paper-form or store on hospital servers were destroyed by the TSUNAMI. However, the electronic medical records stored outside of the hospitals were safe.

  ‣ http://www.microsoft.com/ja-jp/casestudies/saiseikan.aspx

# "Break Glass" Policy



IN CASE OF FIRE
BREAK GLASS

- Under usual conditions, only the attending doctor and his/her team are authorized to access the medical records of their patients.

- However, in order to save the patients under disastrous or emergency conditions, such restrictions must be temporarily relaxed and the records made available to medical teams from outside the disaster-affected area (including DMAT = Disaster Medical Assistance Teams).

# "Break Glass" Policy is of no Use when Medical Records are Lost

- "Break Glass" Policy works only when the medical records are safe.

- On 3.11., many medical records stored in local hospitals and clinics were washed away by TSUNAMI.

# Still Hesitant about the Medical Cloud?

- Obviously, medical clouds are essential for realizing the secure storage of medical records, of which information is available to medical practitioners, while protecting the privacy of patients.
- The latest guidelines of the MHLW (Ministry of Health, Labour and Welfare) regarding the security management of medical information systems (ver. 4.1 of February 2010) no longer prohibits the use of cloud computing services for the storage of medical records.
- However, the managements of hospitals and clinics, and conservative lawyers are still hesitating to go forward to employ medical clouds.

# What must be Overcome?

- Lawyers, as well as ordinary but well-educated people, tend to consider that the law is based on the assumption that a person cannot trust others. Moreover, they tend to consider that the law has little relationship with mutual trust between the actors who constitute the social network.
- We must overcome and reform such attitudes, so they understand the laws from the perspective of mutual trust among the social network.

# The Problems

- The assumption of medical regulation - "without mutual trust, no medicine" - is not properly understood by lawyers and citizens.
- The Japanese law provides patients and their attending practitioners no practical means to ensure the availability of their own past medical records.

# Without Mutual Trust, No Medicine

- If the medical practitioners cannot share medical information with their colleagues (or, even with their patients), we cannot expect the healthy provision and development of medicine.
- No doubt, medical records of patients constitute one of the major classes of medical information.
- However, without mutual trust between medical practitioners (and, also, patients), medical records cannot be shared by them.
- Without the sharing of medical information among medical practitioners and patients, no medicine can be administered properly.
- Medicine is based on an information network that enables us to store and share medical information, and such information network is based on mutual trust through the social network.

The Medical Laws and Ethical Practices assume the Sharing of Medical Information

# Diagnosis by a Medical Practitioner is Always Based on Accumulated Knowledge and Cases

- Article 20 of the Medical Practitioners' Act of Japan (Law No. 201 of 1948) provides "No medical practitioner shall provide medical care ... without personally performing an examination ...".
- The Hippocratic Oath states "I will apply dietetic measures for the benefit of the sick according to my ability and judgment ...".
- The law requires that any medical treatment is provided based on a diagnosis conducted by a medical practitioner.
- A medical practitioner can perform his/her own diagnosis because he/she has learned the cases accumulated up until that time.
- The said regulation assumes that accumulated cases are shared by medical practitioners.

Ensure the Availability of My Own Medical Records

# The Lack of Proper Means

- The Act on the Protection of Personal Information (Law No. 57 of 2003), as well as privacy protection under the Civil Code, gives a person the right to stop the use of their personal information by an entity or person that they do not trust.

- However, Japanese law provides a citizen substantially no means to ensure the availability of their own medical records by medical practitioners that they do trust.

- Moreover, Japanese law provides a citizen substantially no means to ensure that their own medical records are maintained and available at the data centers to which they can trust.

Is a New Legal System Necessary to Make Mutual Trust Work?

- Citizens cannot appoint in advance medical teams who may save them in a disaster.
- In order to ensure the availability of past medical records of patients to medical teams in a disaster, we have to assume that patients and their attending doctors "deem" trust to possible medical teams and medical cloud providers in the event of a disaster.
- Such trust would be developed through continuous sharing of information through medical practitioners and patients (including potential patients).
- However, trust can be easily broken by only a few incidents of distrustful activities.
- Moreover, attending doctors and medical cloud providers, as well as medical teams, would demand that they are indemnified if they decide to Break Glass.
- Presumably, we need laws supporting "deemed" trust, assuring a certain degree of indemnity, while regulating the degree of security and moral standards.

# Is a New Right Necessary to Make Mutual Trust Work?

- Mutual trust between parties will be maintained because each party has the power to impose a penalty on the party breaking trust.
- Patients and medical practitioners need rights to ensure the portability of medical records. If a medical cloud provider breaches their trust, they must be able to transfer their records from such provider's data center and store them at a new and trustworthy data center.
- However, portability of medical records of individual patients is not practicable. Such rights demanding portability of medical records should be collectively assigned to a trustee representing the interests of patients and their attending practitioners.
- A new right that ensures portability of medical records, as well as the assignment of such right to a trustee. is necessary.

# We Shall Overcome

- 3.11 has reminded us of the importance of mutual trust among the network of patients, medical practitioners and data center providers storing medical records.
- However, in order to develop mutual trust, so that such trust functions as social capital that promotes the welfare of citizens, we have to continuously create and amend the laws based on the perspective of mutual trust.

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# Thank you