Digital Health in Japan

2024/7/19

Takanori FUJITA, MD, JD

Senior Research Fellow, Tokyo Foundation for Policy Research

Project Associate Professor, Keio University School of Medicine

Project Associate Professor, Information & Communications of Nagoya University

Takanori FUJITA

2006 Graduated from the University of Tokyo, School of Medicine

Medical Research Student, Department of Molecular Medicine, Graduate School of Medicine, Kyoto University

2007 Researcher, Health and Global Policy Institute

2008 Graduate School of Law and Politics, University of Tokyo, Law School (completed in 2011)

2011 Project Researcher, (2012 -) Project Assistant Professor, Faculty of Medicine, Keio University

2015 Endowed Associate Professor on CBM Healthcare Innovation, Graduate School of Economics, Nagoya University, Aika Industries

2017 Research Fellow, Center for Global Health Policy, National Center for International Medical Research

2018 Project Lead, World Economic Forum C4IRJ

2021 Project Associate Professor, Keio University School of Medicine

2023 Project Associate Professor, Kanagawa University of Human Services

Project Associate Professor, Nagoya University

2024 Senior Research Fellow, Tokyo Foundation for Policy Research

Member of the Advisory Committee on Contact Confirmation App for the Cabinet Secretariat
Member of the Trusted Web Promotion Council, Cabinet Secretariat

State of Digital Health in Japan

- Efforts to digitize healthcare began in the late 20th century
- The adoption of electronic medical records lags behind global standards
- Tele-medicine has progressed since COVID-19
- The government is currently promoting medical digital transformation (DX)
- The vision and grand design are not well explained, leading to insufficient public understanding
- Numerous issues exist, including legal arrangements for the secondary use of data and AI implementation
- Digitization efforts in other fields are more advanced than in healthcare

Related regulations in Japan

- Medical Regulations

  Medical Practitioners Act, Medical Service Act,

  Pharmaceutical and Medical Device Law

Many laws are
Not Digital-based

- Data and Business Regulations

  Personal Information Protection Law,

  Intellectual Property Rights Law, and AI Regulations

- Rules Where Both Intersect

  Various Guidelines,

  Next-Generation Medical Infrastructure Act

APPA: Authorized Public Purpose Access

https://www.weforum.org/whitepapers/appa-authorized-public-purpose-access-building-trust-into-data-flows-for-well-being-and-innovation

APPA is a model that achieves the desired value by allowing access to data for specific, agreed-upon public purposes, such as the development of medical care or the improvement of public health, without necessarily requiring explicit individual consent, and by guaranteeing individual human rights in other ways.

Existing examples

◆Natural disaster

Using a person's medical data to care for victims of a natural disaster

◆Disease pandemic

When data on infectious disease patients are used to prevent an epidemic

◆Cancer registration

For the development of Precision Medicine therapies for rare diseases and rare cancers

Value created by APPA (provisional)

◆Expanding disease registry to illnesses other than cancer

- Government: Monitor trends in morbidity and mortality and develop countermeasures
- Pharmaceutical companies: use as candidate list for clinical trials
- Patients: access to public services, participation in clinical trials

◆Efficient Post Marketing Surveillance (PMS) in medicine

- Pharmaceutical companies: used to study side effects and efficacy after launch

◆Prevention of child abuse

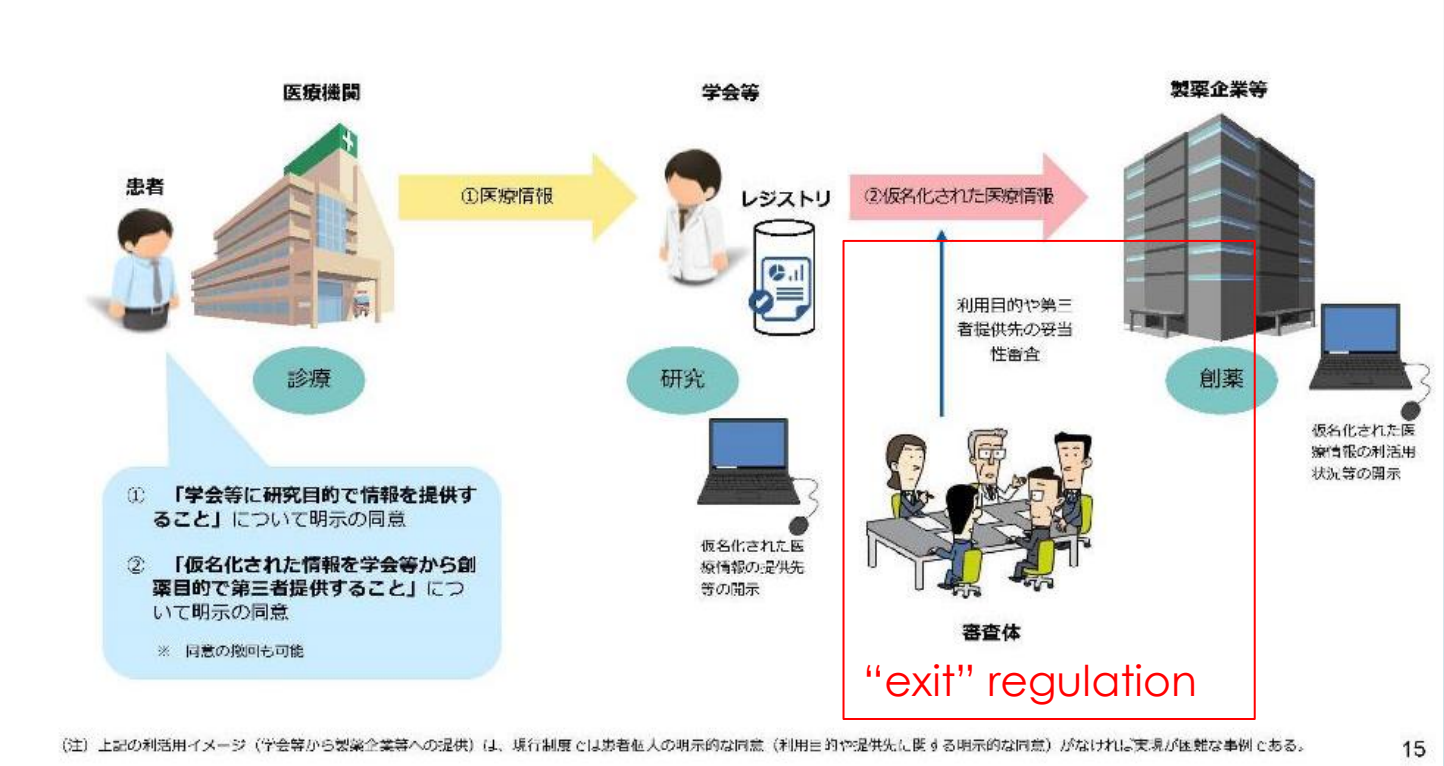
- Children: When a doctor or teacher obtains information about a child suspected of being abused, the information is shared with the local government and other organizations for abuse prevention

◆Combining medical data and daily life logs (walking, eating, purchasing information, etc.) for the development of healthcare services

- Individuals : Use of advanced healthcare services

Promoting the usage of Pseudonymized personal information

From the materials of the 7th Review Committee on the Protection and Utilization of pseudonymised Information in the Medical Field

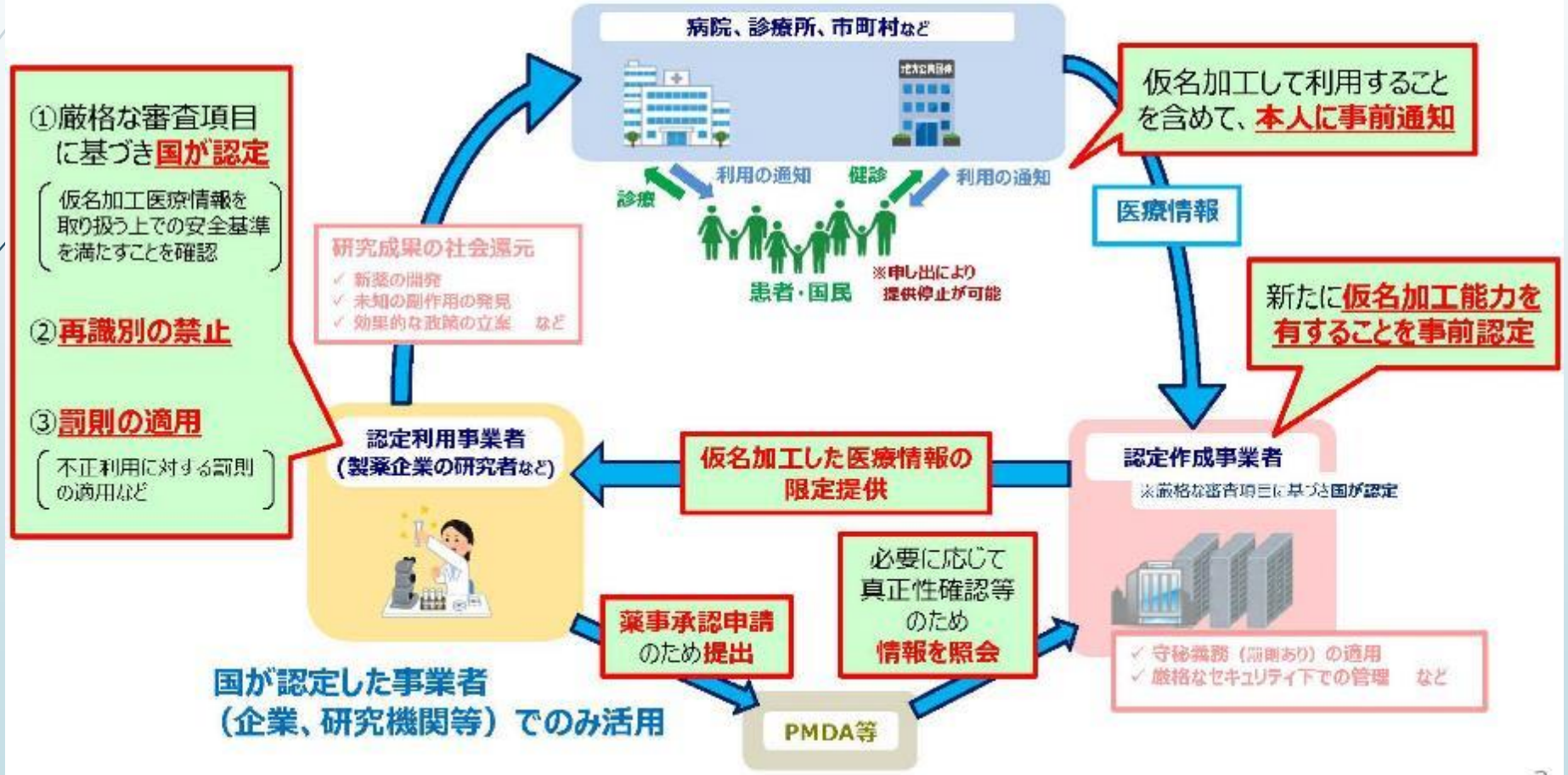


- Use by certified providers based on the Next-Generation Medical Infrastructure Act (revised in 2023)
- Discussion for the 2025 revision of the Personal Information Protection Act

"Working Group on Secondary Use of Medical Information" of the Ministry of Health, Labour and Welfare

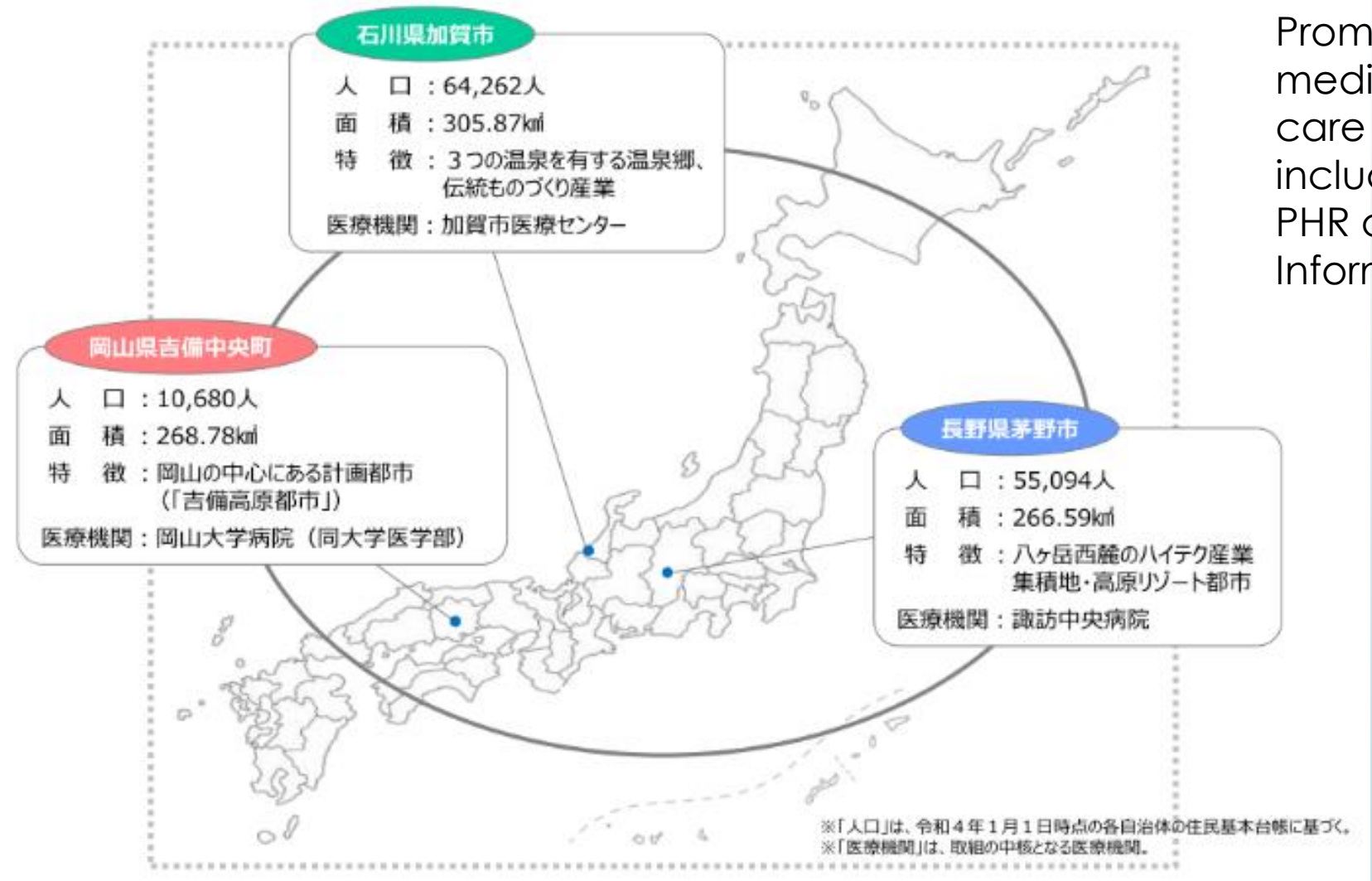
仮名加工医療情報の利活用イメージ

- 医療情報の研究ニーズ、社会的便益の観点から、**新たに「仮名加工医療情報」の作成・提供を可能とする**
- その際、個人情報の保護の観点から、**仮名加工医療情報の提供は国が認定した利活用者に限定**



内閣府 健康・医療戦略推進事務局2022年12月27日資料より

Digital Garden Health Special Zone



(Source: Cabinet Office)

Promotion of DX for medical and nursing care in the region, including initiatives by PHR and the Medical Information Bank

⇩

Guidelines for spreading to other local governments

PHR/Healthcare Data Utilization Principle Toolkit for Local Governments

Based on WS with local governments such as Kobe City, Chino City, Kibichuo-cho, Kaga City, Fukuoka City, Maebashi City, Niigata Prefecture, Kanagawa Prefecture and Tokyo
2023/4/8"**Toolkit for Personal Health Records and Data Use by Municipalities: Proposal for Healthcare Data Management through Public-Private Partnerships**" (Toolkit ver0) Open to the public

↓

Reflected in the **guidelines of the PHR Promotion Council**
https://phr.or.jp/archives/2211 (in Japanese)

Contents:
1. **Basic Principles** (Individual autonomy/benefits to the individual, transparency/privacy, interoperability/openness, fairness/inclusion, value realization/social justice, sustainability)
2. **Checklist** for Benchmarks
3. **Tips** by Item: Advanced Case Studies, Q & A Introduction
   In particular, regarding secondary use of data, handling of information related to COVID-19, such as vaccines, etc.

Appendix: Guidelines and articles to be referred to, excerpts from white papers such as APPA, etc.

https://www3.weforum.org/docs/WEF_Toolkit_for_Personal_Health_Records_and_Data_Use_by_Municipalities_2022.pdf

About Toolkit Ver0 ⇒https://note.com/c4irj/n/n6e0bc17e217d

Generative AI such as ChatGPT and medical treatment

- Report that ChatGPT can pass national medical examination
- Amazon's HealthScribe: A summary of medical care
- Nvidia: Generative AI services for drug discovery
- Images can be used for educational purposes
- Individuals can use them for health and medical consultation

etc.

On the other hand,

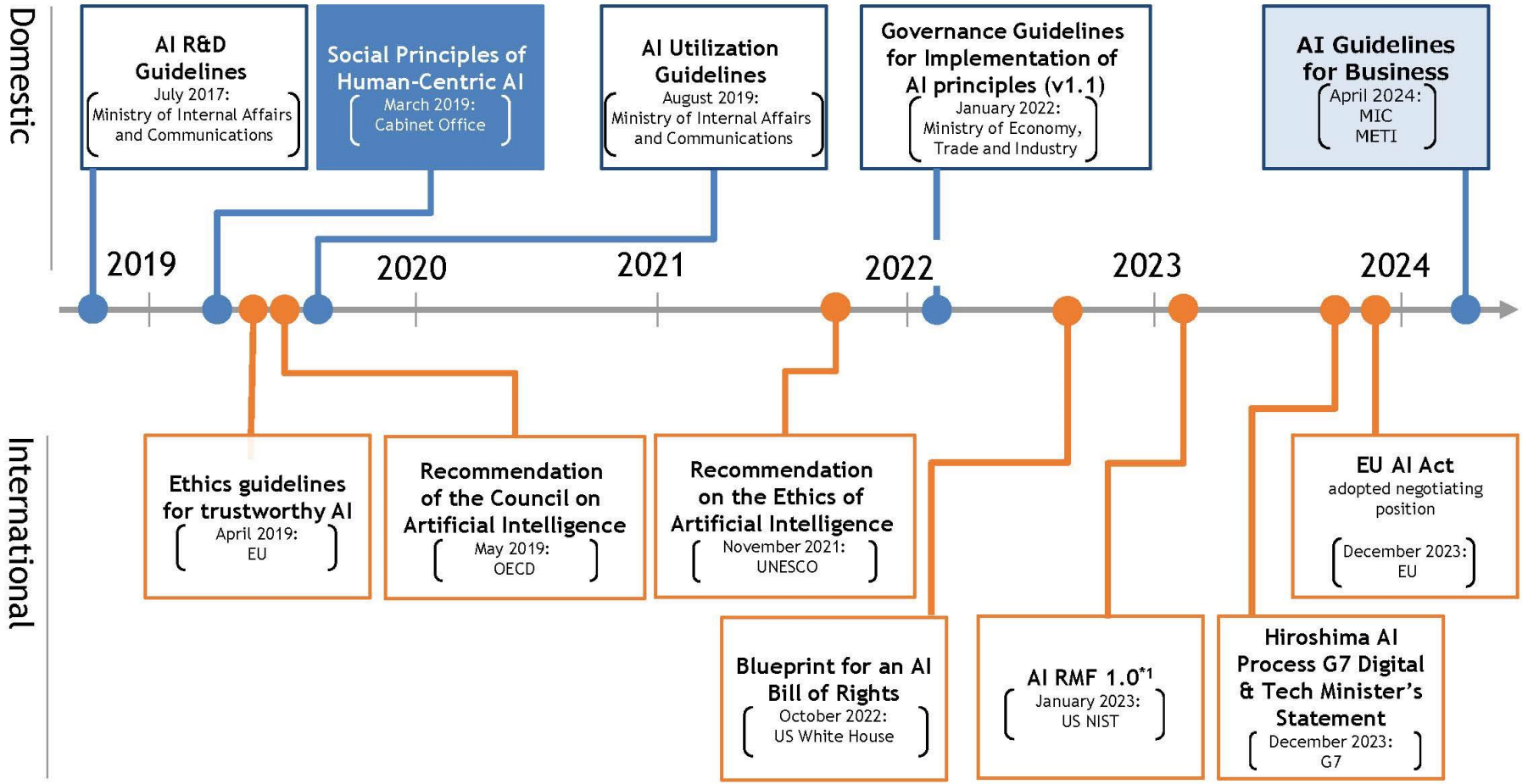
the accuracy of the content, the positioning by medical practice, the responsibility for judgment, and the copyright treatment

and other issues

EU AI Act, US Presidential Decree, etc.
As rules are increasingly being made, rules for their use in the medical field are needed

Reference) Major Principles Related to AI, etc.

- As the formulation of various regulations and guidelines is actively discussed in other countries, "AI Guidelines for Business" will also be closely aligned with various principles and regulatory trends.



*1: AI Risk Management Framework 1.0

https://www.meti.go.jp/shingikai/mono_info_service/ai_shakai_jisso/20240419_report.html

Main | Appx. | Preface

Structure of "AI Guidelines for Business"

- The descriptions in the Appendix correspond to those in the main part and serve as a supporting document for the reading of the main part and considerations and actions based on the main part.

	Main part (why, what)			Appendix (how)	
For all AI business actors	Part 1	Definitions		1. Relevant to Part 1 [About AI]	A. Preconditions for AI B. AI's benefits and risks
	Part 2	Society to aim for with AI, and matters each AI business actor works on	A. Basic philosophies B. Principles C. Common Guiding Principles D. Common Guiding Principles for AI business actors involved in advanced AI systems E. Building AI governance	2. Relevant to Part 2 [E.Building AI Governance]	A. Building of AI governance and monitoring by management B. Examples of business operator's efforts at AI governance
For each AI business actor	Part 3	Matters Related to AI Developers	* Includes additional matters described in "Hiroshima Process International Code of Conduct for Organizations Developing Advanced AI Systems" as well	3. Relevant to Part 3 [For AI Developers]	A. Descriptions of Part 3 "Matters Related to AI Developers" B. Descriptions of "Common Guiding Principles" in Part 2 C. Matters to be observed in developing advanced AI systems
	Part 4	Matters Related to AI Providers		4. Relevant to Part 4 [For AI Providers]	A. Descriptions of Part 4 "Matters Related to AI Providers" B. Descriptions of "Common guiding principles" in Part 2
	Part 5	Matters Related to AI Business Users		5. Relevant to Part 5 [For AI Business users]	A. Descriptions of Part 5 "Matters Related to AI Business Users" B. Descriptions of "Common Guiding Principles" in Part 2
Other references				6. Major precautions for referring to "Contract Guidelines on Utilization of AI and Data" 7. Checklist 8. Cross-actor virtual cases 9. References for overseas guidelines, etc.	

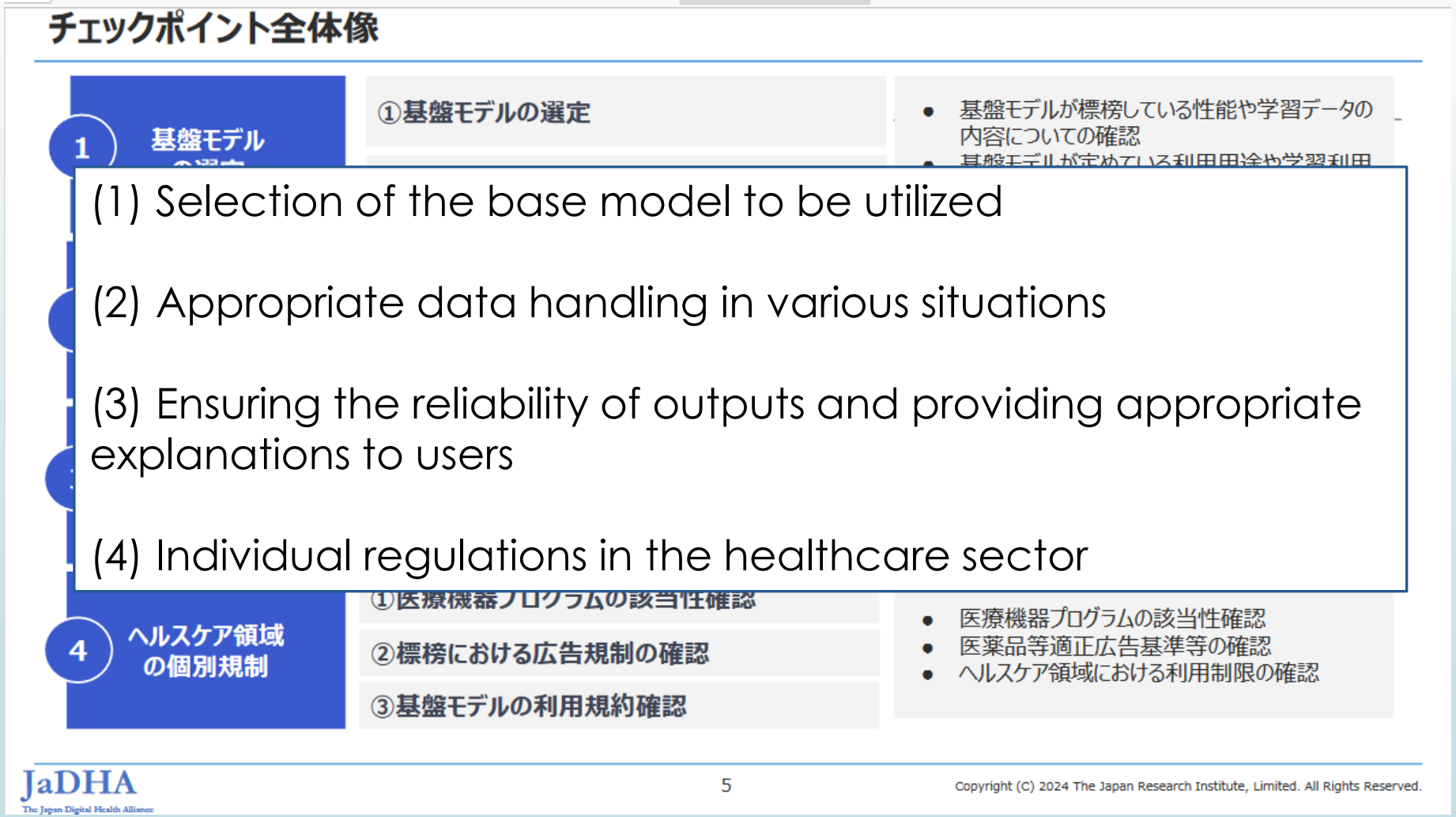
The appendixes 7, 8, and 9 are Japanese only.

https://www.meti.go.jp/shingikai/mono_info_service/ai_shakai_jisso/20240419_report.html

Voluntary Guidelines for Providers of Services Utilizing Generated AI in the Healthcare Sector

(The Japan Digital Health Alliance (JaDHA), January 18, 2024)

https://jadha.jp/news/news20240118.html



Trusted Web for "Data Free Flow with Trust (DFFT)

https://www.weforum.org/agenda/2023/01/how-japan-trusted-web-improve-digital-governance-davos2023/

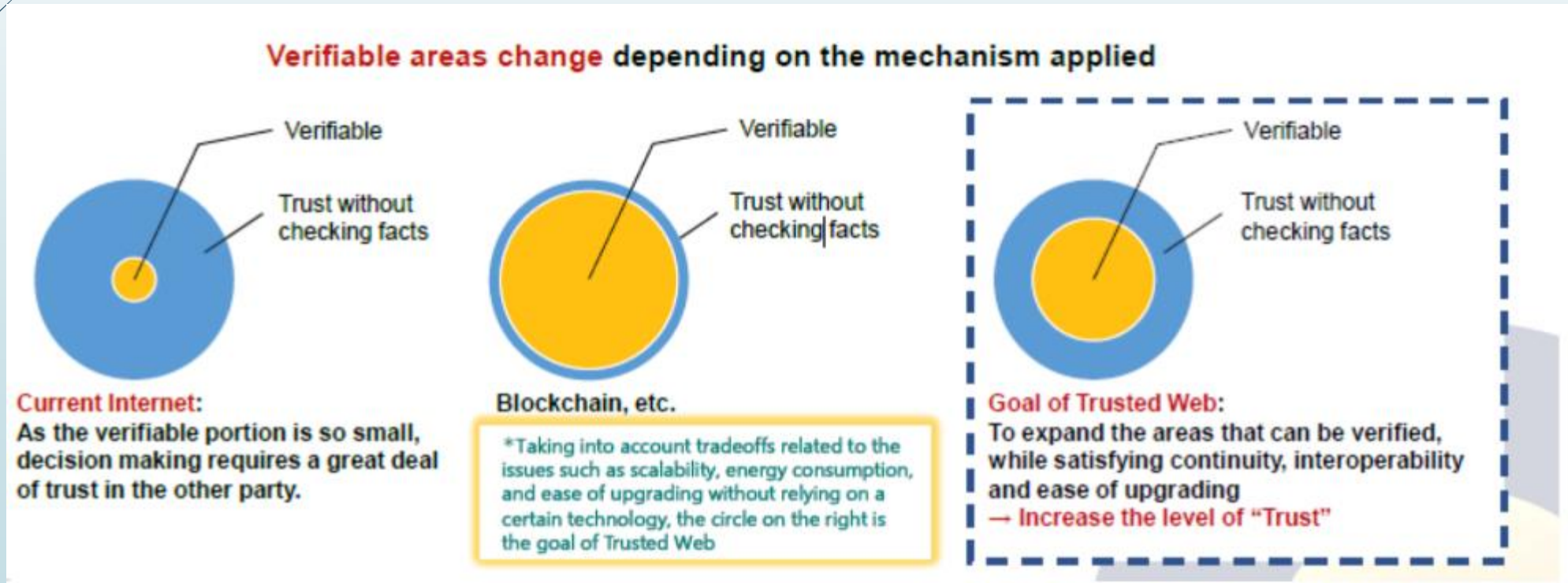
https://trustedweb.go.jp/en/

Concept (Principle):

Creating a **Trust System** in a Digital Society to Create New Value by Diverse Entities

The Trust System does not rely too heavily on specific services

- allowing the user (natural or legal person) to control the data related to them
- incorporating consensus-building mechanisms in the exchange of data and tracing the implementation of that agreement
- aim to improve trust by expanding the scope of verification



Reliable and applicable information circulation system in clinical trials and healthcare settings (CMIC Co., Ltd.) (1/2)

Current Issues (Pain Points) (As-Is)

1. **Obtaining Personal Identification and Consent (eConsent)**
   - In current online medical consultations and remote participation in clinical trials, eConsent is used to verify the identity of the individual by displaying identification documents such as a driver's license and the person's face on a web screen. However, it is difficult to argue that this method is appropriate.
   - In face-to-face environments, as opposed to remote environments mentioned above, verification of the individual and obtaining consent for various scenarios such as medical treatment, hospitalization, surgery, and participation in clinical trials are done through signatures on paper documents. However, due to the nature of paper media, seamless integration and coordination with other actions are not possible.

2. **Utilizing PHR (wearable devices, etc.)**
   - In general medical care and clinical trials (DCTs), there are difficulties in utilizing data from patients (subjects) on wearable devices. One of the reasons for this is the lack of a trusted environment and control mechanism on existing networks and devices, where patients give consent on the range of data and who to provide it to.
   - Regarding the above, implementing individual technologies for each wearable device would increase operational costs and impose burdens on users (patients, subjects, and on-site staff) understanding, making it impractical.
   - From the perspective of data integrity, since the wearable device is a source of data, it is necessary to consider security, personal authentication, and other factors with the wearable device as a starting point. However, there is insufficient technical verification and investigation regarding the practicality of utilizing these aspects in real clinical settings and clinical trials.

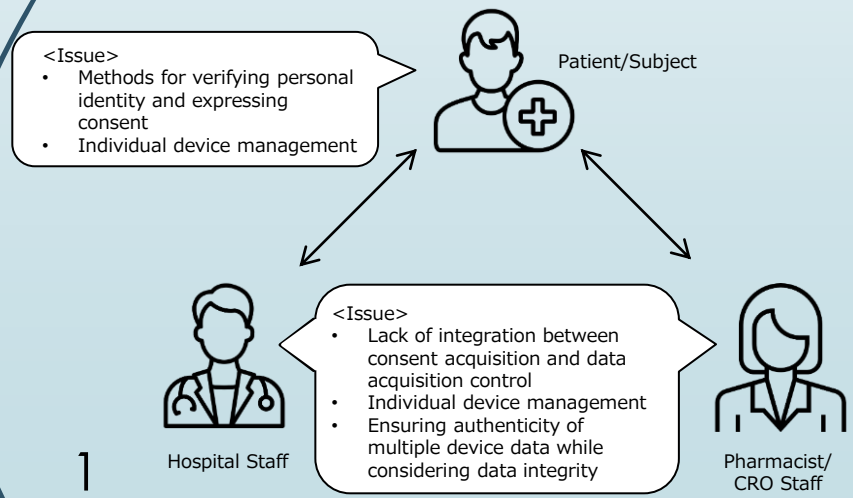
What Trusted Web Will Solve (To-Be)

1. **Obtaining Personal Identification and Consent (eConsent)**
   - Creating personas, implementing DID, and using pairing to build a trust relationship with hospital staff (as well as pharmaceutical company/CRO staff) through smartphone applications.
   - The process of identity verification and consent acquisition is considered complete after pairing with hospital staff (as well as pharmaceutical company/CRO staff) is performed. This is achieved by displaying an eDocument on the medical institution's device, which includes an eSignature linked to personal information through a DID, thereby making the consent acquisition process visible (= eConsent).

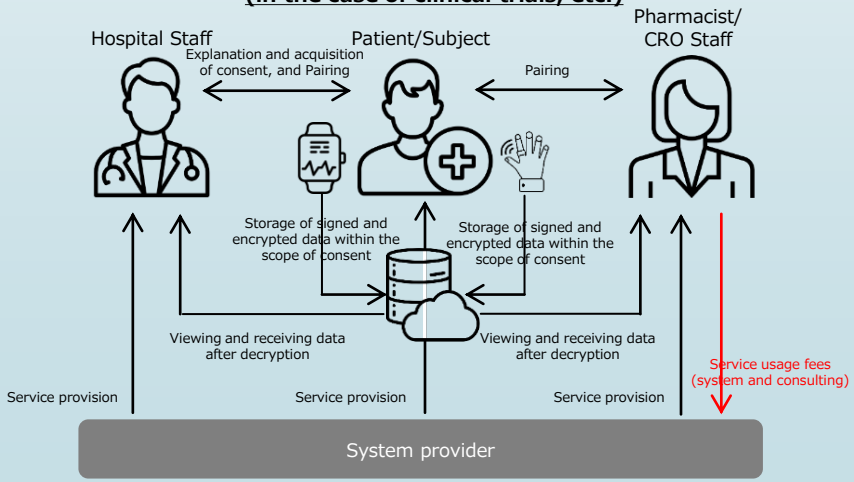
2. **Utilizing PHR (wearable devices, etc.)**
   - During the pairing process (step 1), using DID mapping, multiple wearable devices that are identified as being owned by the same entity are seamlessly paired with the smartphone, which serves as a hub and implements a DID. After pairing, each wearable device can share data within the scope of the consent given in step 1 (data is encrypted and can only be accessed by paired users). Additional coding is done to specify the range of data sharing and provide consent control, in accordance with general medical care or the clinical trial protocol.
   - On the smartphone application from step 1, it is also possible to revoke consent (terminate the pairing), and data sharing is halted after consent revocation.

The above steps 1 and 2 are seamlessly implemented, using the initial pairing as the touchpoint.

Scheme diagram before problem-solving (As-Is)



Business scheme diagram of the generated use case (To-Be) (in the case of clinical trials, etc.)



Trustworthy gait data authentication and distribution system connecting doctors, researchers and patients with lower limb musculoskeletal diseases (ORPHE Inc.) (1/2)

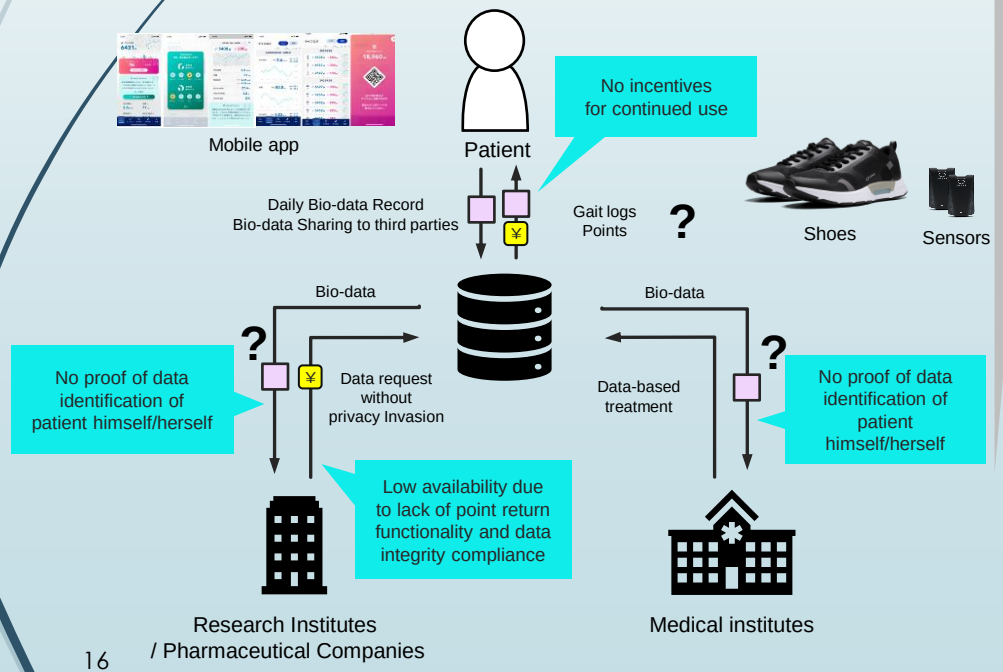
Current issues (Pain points)

- While the mobile application is assigned a DID, there is **no proof that the sensor data is the patient's own**.
- **No balance between patients' proactive data control and an attractive token economy** for research/pharmaceutical institutions. (No functionality to return points upon data revoke, etc.)
- **No incentive design** to encourage users to continue to use the application and share data with third parties.

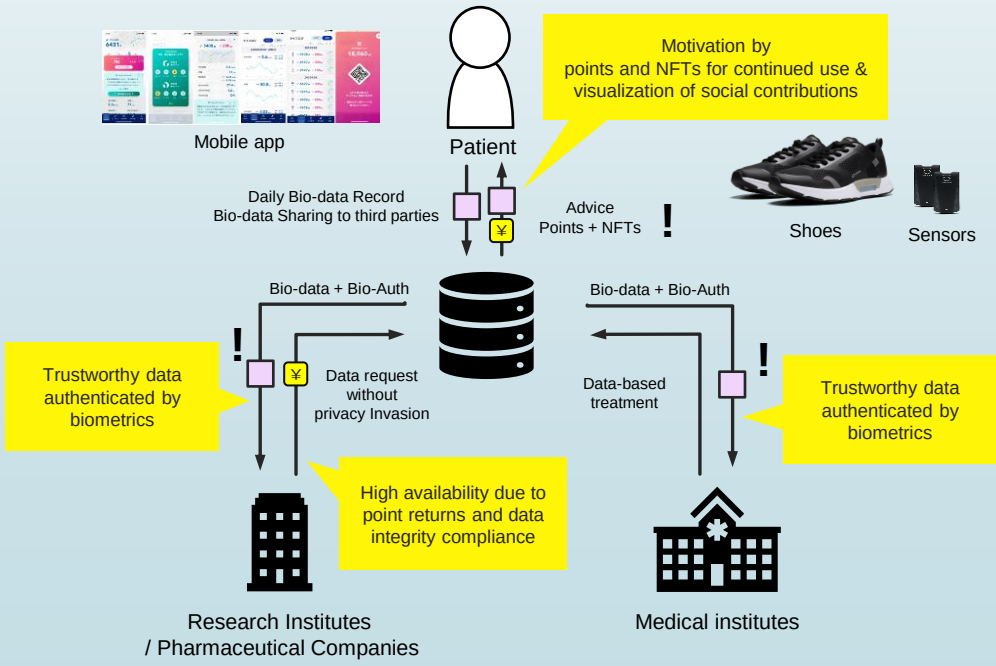
What Trusted Web Solves

- Verify several authentication methods using biometric methods like **facial identification or gait identification**, and implement an **identification system for data itself**.
- **Establish a scalable ecosystem** by implementing a **point return function** and guaranteeing the **data integrity required for DCT** (Distributed Clinical Trials).
- **Design incentives to encourage continued use** by granting tokens and NFTs that make visible the social contributions of patient users.

Scheme of the Previous Project (As-Is)



Future Scheme (To-Be)

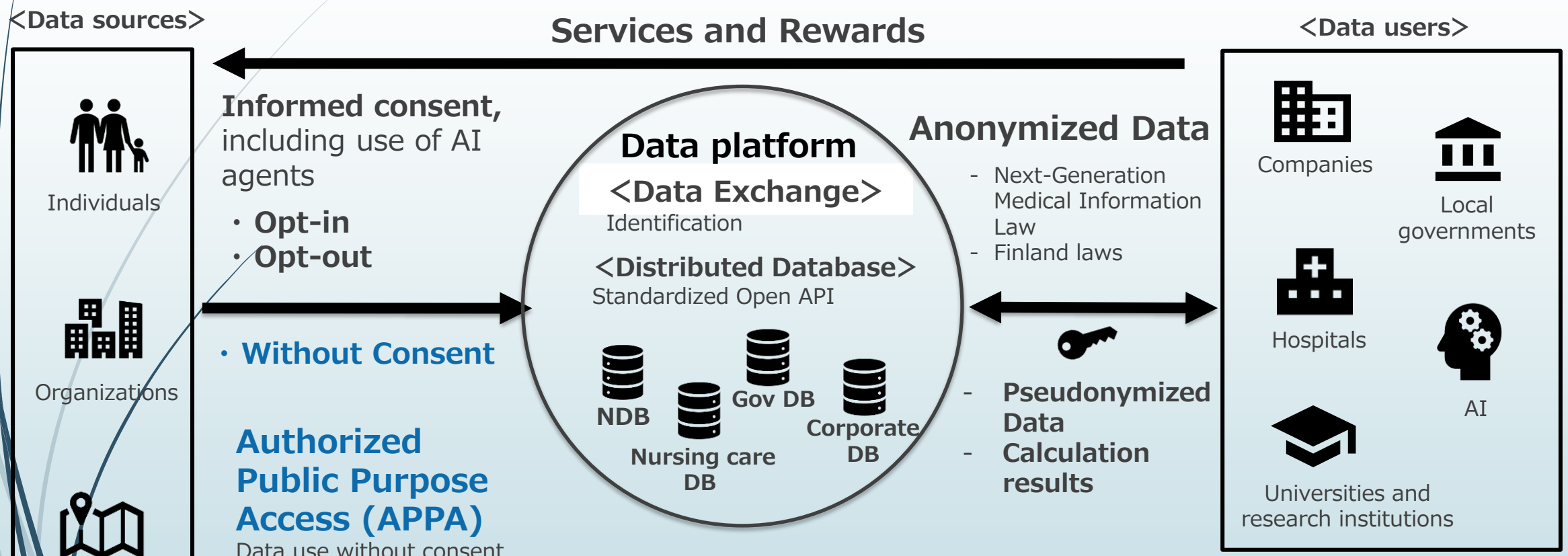


Thank You !

Major Works

Mainly on legal and political issues for
The Use of AI for dementia prevention

Healthcare Data Governance framework



<Trust> **Trust & Willingness**

Secure trust by eliminating fake data, obtaining effective consent, satisfying APPA requirements & traceability, building self-governance system, obtaining trust through communication with society etc. Includes ethics review committee function