The Present Situation and Challenges of Utilizing Healthcare Data in Japan and Leading Cases in Europe

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Subject for today's session

1. **Healthcare data as a resource and digitization of healthcare**
2. **The great challenge in the EU—EHDS (European Health Data Space)**
3. **The utilization of healthcare data in Japan and the challenges involved**

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Profile

- **Major:** Public Administration, Public Policy / Healthcare Policy, Digital Policy
- Current position: Professor Emeritus, The University of Tokyo / Representative Director, Next Generation Fundamental Policy Research Institute (NFI) / External Director and Chairman of the Board of Directors, Kyowa Kirin Co., Ltd.
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- **Counsils:** Chairperson, Study Group on the Utilization of Health, Medical, and Nursing Care Information, MHLW / Chairperson, Chairperson of the Customs Subcommittee, Council on Customs, Tariff, Foreign Exchange and Other Transactions, MOF / Acting Chairman, Policy Evaluation Council, MIC / Chairperson, Council on the Use of Real Estate, Cabinet Office / Former Chairperson, Central Social Insurance Medical Council (Chuikyo), MHLW, *and all*
- **Author** of "Politics of Government Councils 3 —*The Realities of the Chuikyo*," Jigakusha Publishing Corporation, 2016, *and many others*

1. Healthcare data as an information resource and the digitization of healthcare

- **Utilizing healthcare data, including electronic medical records and health examination results, is crucial and effective for providing high-quality healthcare efficiently.**

① Personalized medicine — delivering optimal healthcare for each patient
② Wearable devices — monitoring of day-to-day health conditions, medication status, and any other relevant medical information
③ Sharing healthcare data between multiple medical institutions where the patient receives treatment
④ Promptly sharing information on health conditions, medications, and other interventions in emergencies such as disasters
⑤ Investigating the causes and treatment methods of diseases by analyzing large numbers of patient data
⑥ Swiftly comprehending the proliferation of infectious diseases and assessing the efficacy and adverse reactions of vaccines
⑦ Promptly identifying and responding to risks such as drug adverse events
⑧ Developing efficient pharmaceuticals and medical devices in a short period
⑨ Adapting to the community's medical needs and allocating medical resources accordingly as the population decreases
⑩ Streamlining medical insurance finances by rationally determining medical fees *etc.*

I Enhancing the quality of treatment and health management for individual citizens and patients <Primary use>	① to ④
II Promoting public health policies, medical research, and drug discovery by analyzing large amounts of medical data <Secondary use>	⑤ to ⑧
III Optimizing the allocation of medical resources	⑨
IV Improving the efficiency of medical insurance finances	⑩

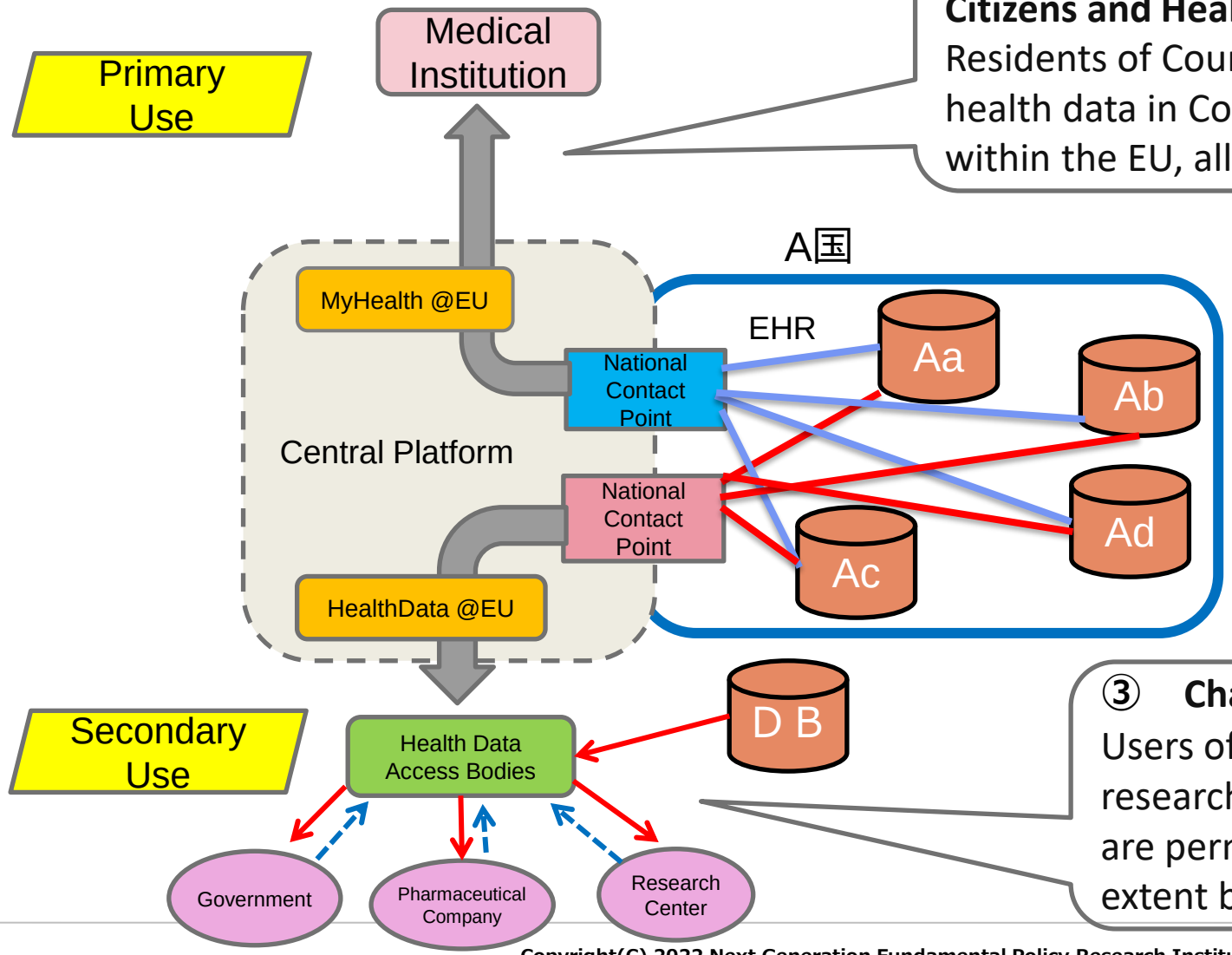
- These medical data, which contribute to improving the quality of medical care, serve as valuable information resources for society.
- The utilization of these information resources enables the improvement of the quality of personalized medicine, the rapid investigation of the causes of diseases, and the efficient development of pharmaceuticals, which, in turn, leads to the prospect of the realization of a new medicine through the application of AI and generative AI.
- Ideally, **health data** should be accumulated and utilized **for all citizens from birth to death**.
- The quality of healthcare is improved by sharing healthcare data under certain restrictions among medical professionals, patients, government officials, pharmaceutical manufacturers, and other stakeholders in the industry.
- However, given the sensitivity of citizens' healthcare data, establishing a reliable system is imperative to guarantee the secure utilization of the information resources.
  1. Secure database with data transfer platform
  2. Standardization to enable interoperability for safe and efficient data sharing and a unique and highly reliable ID system
  3. Governance system for data collection and use to protect privacy
- In light of the experience of the coronavirus pandemic, the European Parliament passed the **European Health Data Space (EHDS)** in April 2024, a regulation (law) aimed at forming a system for the utilization of healthcare data covering the EU region. The regulation serves as a model for enhancing data integrity in Japan.

2. The European Health Data Space (EHDS) initiative in the EU

- The pandemic prompted the EU to acknowledge the necessity of a system for sharing healthcare data across the entire region.
- EU member states will establish a uniform standardized format (Electronic Health Record: **EHR**) to record the health data of their residents following the format.
- Residents of the EU can access their own health data anywhere in the region and provide it to healthcare professionals to receive the best possible treatment. < Primary use >
- Health data of EU residents will be made available for use in health and public health policies, medical research, and the development of pharmaceuticals and other medical treatments, with measures in place to protect rights (the right to opt out). < Secondary use >
- Data will be shared via a platform named **MyHealth@EU** for primary use and **HealthData@EU** for secondary use.
- Forming a system for utilizing health data in this way also aims to promote industry in the medical and health fields.
- Secondary use will enable data from EHRs, administrative data, academic society registries, and other data listed in public metadata catalogs.
- Secondary use is permitted after obtaining approval or notification through an examination by an organization called the Health Data Access Bodies, located in each member state, regarding the purpose of use and the need for data protection.

Primary and Secondary Use in EHDS

Overview of EHDS



② **Chapter 2: <Primary Use> Rights and Obligations of Citizens and Healthcare Professionals**

Residents of Country A within the EU can access their latest health data in Country A even when they are in other countries within the EU, allowing them to receive better treatment.

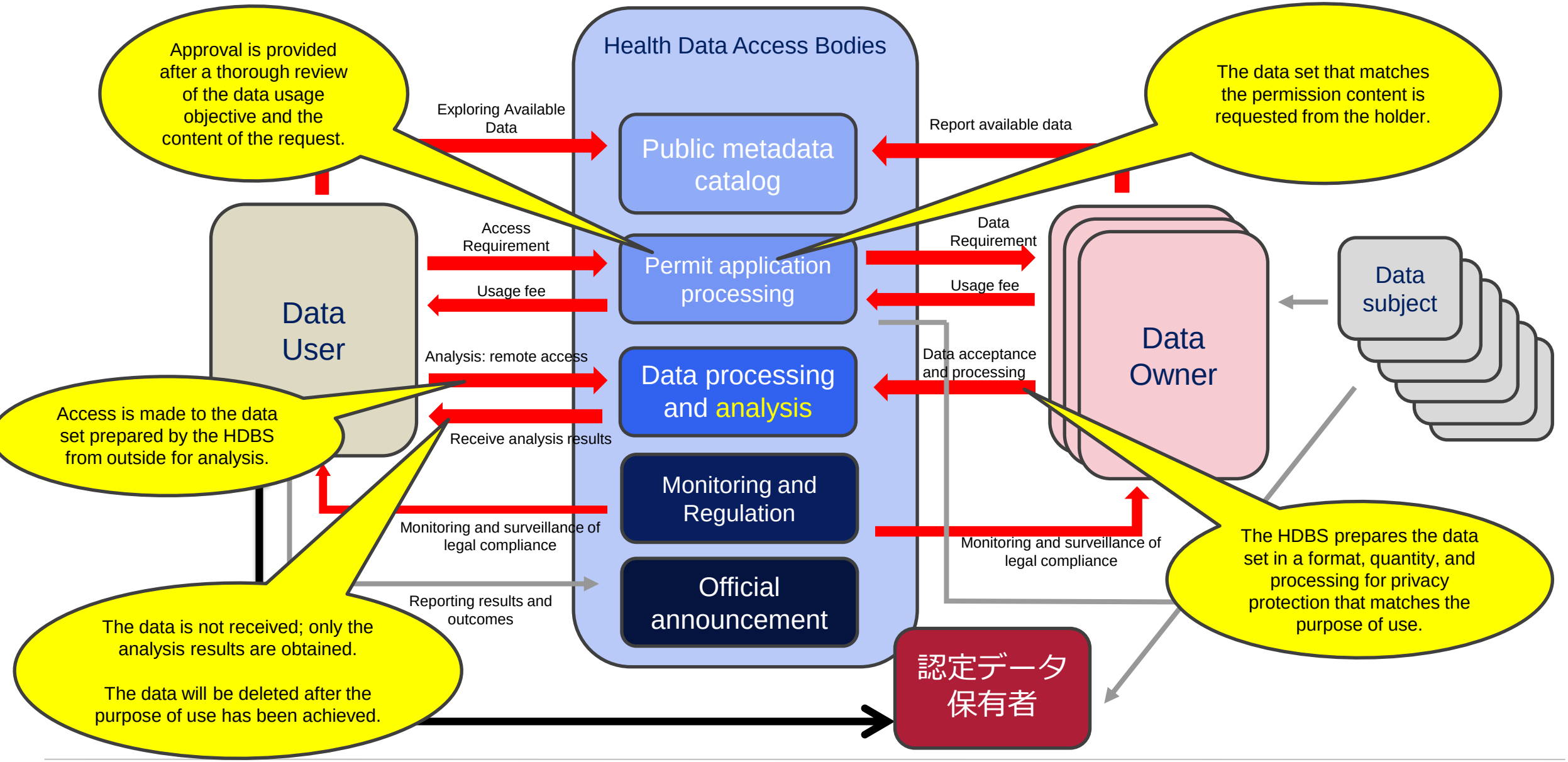
① **Chapter 3: EHR Standards**

Health data of residents is stored in Electronic Health Record (EHR) systems that meet the standards set by the EU.

③ **Chapter 4: <Secondary Use> Governance**

Users of big data, such as government agencies, research institutes, and pharmaceutical companies, are permitted to access data processed to a certain extent by Health Data Access Bodies.

Procedures for Secondary Use



3. The utilization of healthcare data in Japan and the challenges involved

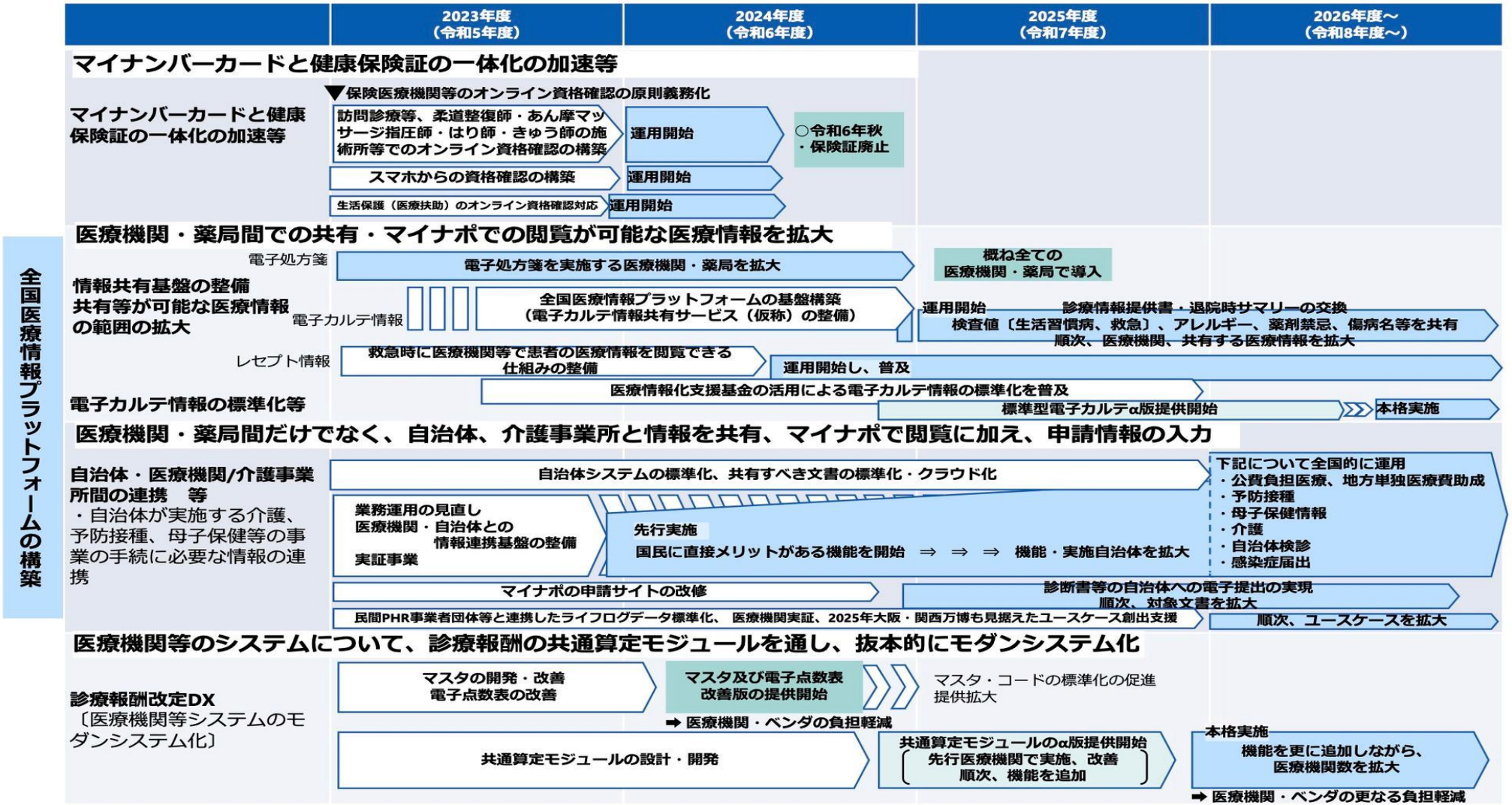
- For information on the current state of medical DX in Japan, refer to the Ministry of Health, Labor and Welfare website:
  https://www.mhlw.go.jp/stf/iryoudx.html#1

- Japan has quickened its healthcare DX improvements after realizing its inadequacy compared to other advanced nations during the coronavirus crisis: For each issue, such as ① online qualification verification, ② electronic medical record information sharing, ③ standardization of electronic medical records, ④ electronic prescriptions, ⑤ vaccination administration, ⑥ nursing care information, ⑦ secondary use of medical information, and ⑧ revision of medical fees, a committee has been established to consider each issue to promote DX.

- The government has also established a Healthcare DX Promotion Headquarters, headed by the prime minister, which was established in 2022 and strives to promote DX per the roadmap it has created.

医療DXの推進に関する工程表〔全体像〕

資料4



- The following **challenges** exist in the system for utilizing healthcare data in Japan.

1. Japan has yet to establish a core infrastructure similar to the **EHR** in the EHDS, MyHealth@EU, and HealthData@EU. The lack of a structure to link systems in each field has resulted in insufficient interoperability between systems, with the overall system still remaining complicated.

2. The emphasis on protecting personal information makes using healthcare data harder. For example, more time is spent debating whether anonymization or pseudonymization is necessary than on the risk of actual infringement of rights, and “consent” and “anonymization” are being overemphasized.

3. The unique and unchanging My Number is not used as an ID to reliably combine the data of each citizen. As a result, there is a cost for identifying the person and a risk of incorrect matching.

From the perspective of pharmaceutical development

Secondary use — Regarding pharmaceutical development

- Drug discovery: High-quality data can be collected from the EHR — Real world data (RWD)
- Post-marketing monitoring: Comprehensive and efficient understanding of drug effects, adverse reactions, and other vital information
- Facilitating the control of the process of distributing pharmaceuticals to healthcare facilities
  — Healthcare traceability
- Providing evidence that serves as the foundation for patient feedback and the opinions of healthcare professionals

Current situation and challenges in Japan

- Lack of an information infrastructure equivalent to the EHR in the EHDS and HealthData@EU
- Restrictions entailed by the collection and utilization of healthcare data that are based on obtaining “consent”
- The diversity of purposes for which healthcare data is employed and the quality of data required
- The ideal form of an organization, corresponding to the Health Data Access Bodies in the EHDS, which handles cataloging, permission for use, data processing, monitoring, and other essential functions to ensure secondary use

Examples of Forms of Secondary Use

Category	A Purpose of use①	A Purpose of use ②	B User	C Forms of information processing	D Number of samples	E Types of data and number of items	F Quality of information	G Time	H Other
				(1) Clear naming (2) Pseudonym (3) Anonymous (4) Statistical Gov	Everyone, Specific Group, Random (Valid Number)	(1) 2 documents and 6 information (2) Specific disease factors, (3) PHR (4) daily behavior	(1) High (2) Middle (3) Low	(1) Immediate (2) Prompt (3) Regardless	
Government	Health care policy		Government Agencies						
	Public health	Understanding the spread of infectious diseases and regulating behavior	Government Agencies						
Research	Basic research	Healthcare solutions that enable effective prevention	Universi… Research Institutes, Research Hospitals						
	Epidemiological research	Effectiveness of barium testing	Universities, research… pharmaceutical companies						
Drug Discovery and Development	Development	Development of new drugs for rare diseases for which there is no cure	Pharmaceutical Companies, Universities						
	Regulatory Affairs		Pharmaceutical companies						
	Post-marketing surveillance	Detection of side effects (carcinogenicity of drugs)	Pharmaceutical companies, government agencies						
	・・・								

B Government Agencies
C Anonymous Information
D Everything is ideal
E Laboratory information on the presence or absence of infection
F ③Low
G ①immediate

B Healthcare companies, research institutes, and academic societies
C Pseudonymously information ?
D Random
E Health Checkup Data, Wearable PHR
F ①Middle or Low
G ③Regardless

B Research Institutes, Government Agencies, Academic Societies
C Pseudonymously information
D Random
E Gastrointestinal treatment data, mortality data, control group
F ①High
G ③Regardless

B Pharmaceutical companies
C Pseudonymously information
D Everything is ideal
E Many（Data on items related to the disease)
F ①High
G ③Regardress

B Pharmaceutical companies
C Clearing name
D All suspicious cases（Specific Groups）
E Many（Long-term treatment data, date of death and outcomes, drug prescriptions, etc., compared to the control group・・・）
F ①Middle
G ②Immediate

Thank you!