Data Standardization within APEC: Focusing on Health Data

APEC Digital Economy Steering Group

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Asia-Pacific Economic Cooperation

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Economic Cooperation

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Part I. Research Paper

1. Introduction

Asia-Pacific Economic Cooperation (APEC) aims to realize trade and investment liberalization within the Asia-Pacific region through the promotion of economic and technical cooperation and the facilitation of trade. Considering the rapid growth in digital products and services, APEC member economies should work to promote cooperation in digital fields.

APEC member economies have recognized the growing importance of the digital economy in the APEC Internet and Digital Economy Roadmap (AIDER) which features 11 Key Focus Areas (KFAs). In this report, we address the issue of data standardization. Data standardization is closely related to multiple KFAs in AIDER, including the promotion of interoperability and facilitating the free flow of information and data for the development of the internet and digital economy.

Since data standardization is a broad topic, this report aims to provide an overview of the general state of data standardization while specifically examining data standardization in the field of health care and related policies. It is noteworthy that APEC members have recognized the importance of health data standardization, especially in the wake of the COVID-19 pandemic.

Despite the importance of collaboration in data standardization, there has been relatively limited research on this topic within APEC. This report aims to fill that gap by exploring directions for cooperation in data standardization cooperation within APEC member economies.

1.1. Background and Necessity

1) The Status of Digital Transformation of the Global Economy

Recently, it has become impossible to discuss the global economy without mentioning digital transformation. Since many economic activities are being digitized, the utilization of digital technology has become a key survival factor in the changing global economy. In fact, many

digital companies are now among the biggest firms in the world. Just over a decade ago, in 2010, most of the world's largest companies were in traditional sectors such as oil and gas, banking, and manufacturing. In 2022, four of the top five largest companies on Earth were major leaders in digital technology.

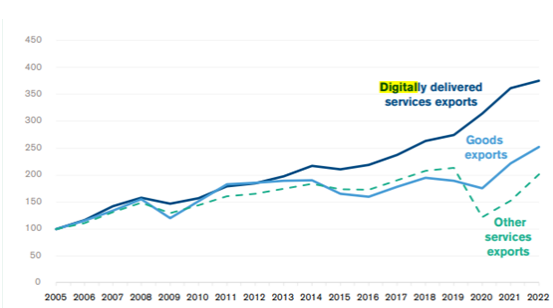
Table 1. Top 10 Global Companies in revenue, 2010 vs. 2022

Rank	2010	2022
1	Walmart	Apple
2	Exxon Mobil	Aramco
3	Chevron	Microsoft
4	GE	Google
5	Bank of America	Amazon
6	ConocoPhillips	Tesla
7	AT&T	Berkshire Hathaway
8	Ford	NVIDIA
9	JP Morgan	FACEBOOK
10	HP	TSMC

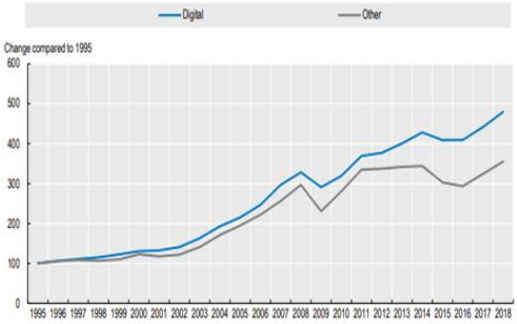
Source: Fortune 500 (2010), https://companiesmarketcap.com/ (2022)

According to a 2020 report by the International Data Corporation (IDC), the value of direct investment related to digital transformation is projected to grow at an average annual rate of 18% between 2020 and 2023, eventually reaching USD 6.8 trillion. Other institutions have collected survey data on the matter as well; most of them expect a rapid increase in investment in digital transformation-related markets.

The growth of the digital economy is driven by the expansion of digital trade, and recently digital trade has emerged as a key growth engine of global trade. The growth of digitally delivered services exports has greatly outpaced traditional trade, and growth in overall digital trade has also greatly exceeded traditional trade. In particular, digital trade during the COVID-19 era is characterized by a steep upward trajectory, as seen in Figure 1 below.



Digitally Delivered Services Exports



Digital Trade

Figure 1. Exports of Digitally Delivered Services and Digital Trade

Source: WTO (2023), OECD Trade Policy Paper (2023)

2) Building a Digital Economy Based on Data

Data is at the heart of digital transformation and the growth of the digital economy. Recent growth in the use of data shows this trend in figure 2. It is difficult to create or strengthen a digital industrial ecosystem without utilizing data.

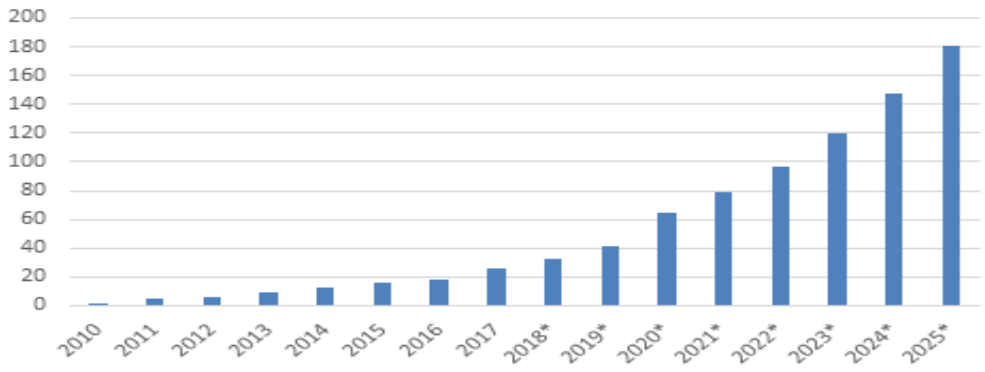


Figure 2. Trends in Global Data Volumes (Unit: zettabyte [ZB])

Source: Statista

Each region generates different volumes of data, and the rate at which data is generated also differs regionally. The rate of data growth in the Asia-Pacific region, including China, is increasing at a rapid rate. This highlights the importance of cooperation in data standardization, which serves as the foundation for harnessing the increasing volumes of data being created within APEC.

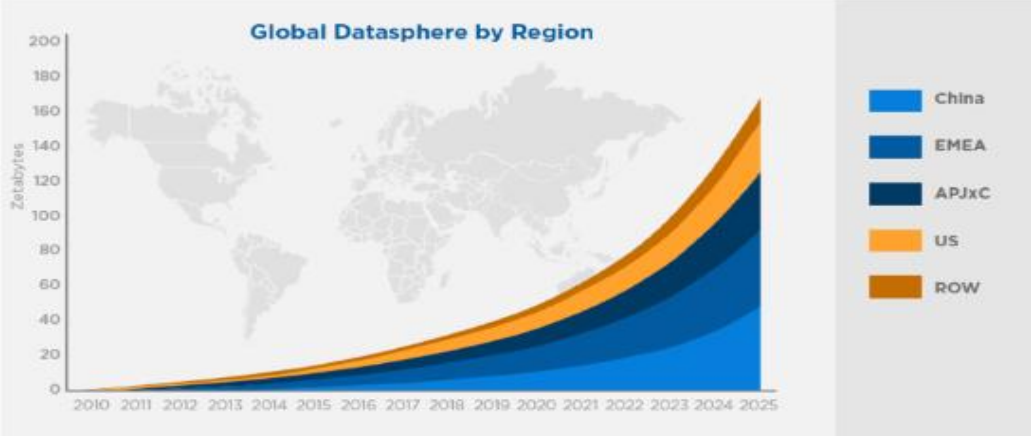


Figure 3. Data by Region

Source: IDC (2018)

In addition, as with regional growth in data, data growth by industry also varies. For this report, we are particularly interested in the growth of data in the health care sector. As shown in Figure 4 below, we can see data growth in health care outpaces other sectors by a fair margin.

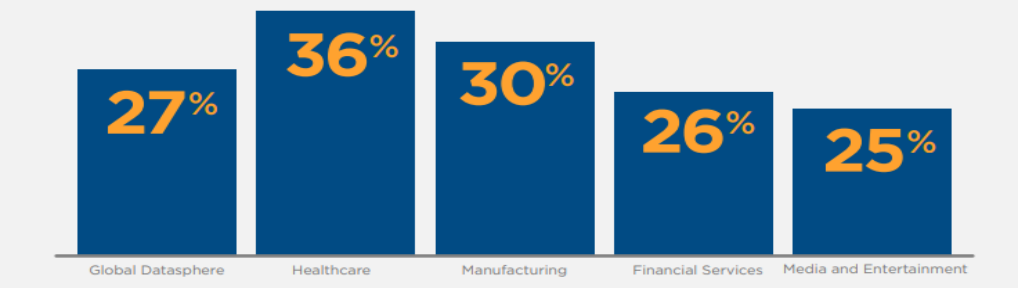


Figure 4. Data Growth Forecast, Major Sectors (2018-2025)

Source: IDC (2017)

The use of data is a key factor in the growth of the digital economy. More health data is being generated now more than ever before, and how to utilize this health data is becoming a critical issue. While Figure 4 illustrates the growth of data in the health care sector, an increase in the generation of data does not guarantee its utilization.

In general, enabling data utilization requires improvements to regulations, infrastructure, and awareness, among other factors. In particular, data standardization, which helps secure data interoperability, is a prerequisite for data utilization of data.

There are challenges in utilizing health care data on many fronts. Above all, health care data contains a lot of sensitive personal information. This is an essential feature of health data. The existence of personal information in health care data inevitably emerges as a barrier to utilization, due to strong regulations and laws related to both intra-economy and cross-border movement of data as well as its utilization.

In addition, the diversity of health data leads to other difficulties in its utilization. Since health care data often take various forms, such as images, documents, recorded audio, and bio-signal data, it is challenging to properly integrate these diverse pieces of information. This necessitates the use of standards suitable to each type of data. Differences in systems and data formats used in the health sector also function as technical barriers to the utilization of health data.

Nevertheless, the acceleration of the digital transformation will serve to magnify the importance of data utilization, especially in the health sector going forward. Various measures can be pursued to expand the utilization of health data. Securing technical and institutional interoperability is a particularly vital consideration.

Data standardization is a fundamental prerequisite to health data utilization. To ensure data interoperability, technical requirements, norms, and regulations must be congruent. However, meeting this requirement does not guarantee efficient data utilization. For this, data standardization is a prerequisite. This is because unstandardized data needs to be rebuilt to be usable. In the end, standardization of health data can be said to be the basis for its stable and efficient utilization. While in this report we focus on health data, we once more reiterate that data standardization is fundamental requirement to data utilization in any field.

1.2 Purpose of the Study

This study was conducted to promote intra-APEC cooperation and efficient utilization in the field of data, a key component of the digital economy. Specifically, we examine the status of data standardization and relevant data standardization policies, which serve as a foundation for

data collaboration. We also formulate approaches to expand data standardization cooperation among APEC member economies.

We first analyze an array of data standardization policies and use cases in APEC and the individual member economies. Second, we explore some policies at global data standardization organizations. Finally, based on the results of the above analyses, we propose a set of policy suggestions designed to promote cooperation intra-APEC cooperation on data standardization. It is worth noting that this report reflects the outcomes of the forum held in Seattle in August 2023.

2. Trends in Data Standardization

2.1 The Definition and Necessity of Data Standardization

Data standardization is the process by which information is converted into a consistent format that computers can read and understand. Data standards refer to documented agreements on the representation, format, definition, structuring, tagging, transmission, manipulation, use, and management of common data.

As the digital transformation accelerates, the use of digital devices around the world is increasing exponentially. Accompanying the rapid spread of digital devices is the creation of enormous reams of data. The economic, social, and cultural data produced can be utilized to enrich human life.

However, data utilization — which has a significant impact on human life — is not automatic. There needs to be a coordinated effort to promote more efficient data utilization, as the data being created is largely heterogeneous, differing by region, language, system, and other variables. Without the standardization of these heterogeneous data, we cannot expect social benefits to follow.

Table 2. Examples of Data Heterogeneity

Heterogeneity factor	Examples
Source	Databases, surveys, questionnaires, interviews, etc.
Characteristics	Location data, personal profiles, institutional affiliations, semantic and lexical Units, language, etc.
Structure	Software, collection method, etc.

Source: The authors

In addition to the factors described in the above table, there are other factors that impede data utilization. Standardization can serve as a solid foundation for addressing these obstacles.

Table 3. Economic Impacts of Standardization

Economy	Publisher	Time Frame	Growth rate of GDP	Contribution of Standards
Australia	Standards Australia(2006)	1962~2003	3.6%	0.8%
Canada	Standards Council of Canada (2007)	1981~2004	2.7%	0.2%
France	AFNOR(2009)	1950~2007	3.4%	0.8%
Germany	DIN(2000)	1960~1996	3.3%	0.9%
UK	DTI(2005)	1948~2002	2.5%	0.3%

Source: Blind et al. (2012)

Standardization has various effects on society and among these a major effect is its economic impact. The literature features various studies on the economic effects of standardization, including data standardization. Miotti (2009) found that standardization in France would increase GDP 0.8%, which corresponded to 25% of the annual French growth rate at the time. Blind et al. (2012) conducted a comprehensive analysis by synthesizing previous research findings on the impact of standardization on economies.

Standardization can contribute to economic growth through various channels. It can lead to cost reductions, increased flexibility, improved responsiveness and quality, and more innovation. In addition to economic effects, standardization can also enhance the quality of human life. In the healthcare sector data standardization can improve human lives through developments such as telemedicine and the creation of therapies using large volumes of medical data. We observed firsthand such possibilities becoming reality during COVID-19 pandemic.

2.2 Global Data Standardization Trends

1) The History of Data Standardization

It was after the introduction and widespread adoption of computers that various organizations, governments, and firms began promoting data standardization in earnest. In the early days, standardization was promoted within individual companies to improve workflows. With the advent of relational databases in the 1970s, interest in data organization and structure increased, and there emerged a growing chorus of voices calling for data standardization. As the importance of data integration and data sharing increased in the 1980s, various industries and companies began to develop their own data standards. For example, standardized message formats such as ISO 8583 in the financial sector emerged in this period.

In the 1990s, there was a growing need to exchange increasingly large volumes of data as the Internet grew in popularity. During this time, standardization bodies were established to integrate data from various companies and industries. An EDI (Electronic Data Interchange) standard was developed to facilitate data exchange. In the period following the turn of the millennium, standards rules were developed and enforced according to technological advancements. In particular, data formats such as XML and JSON have become widely used, facilitating the exchange of data. And as new technologies such as big data, cloud computing, and artificial intelligence (AI) develop, the need for data standardization continues to grow in importance.

2) Global Standards and Data Organization

① International Organization for Standardization (ISO)

The organization now known as the International Organization for Standardization (ISO) is the world's permanent standardization body today. It was first constituted in 1926 as the International Federation of the National Standardizing Association (ISA). In October 1946, representatives from 25 members of the ISA and the United Nations Standards Coordinating

Committee (UNSCC) came together and agreed to merge to establish a new standardization organization, giving birth to the present-day ISO. The ISO is a non-governmental private organization and takes various measures to promote the global harmonization of standards. It develops and publishing international standards, and takes measures to ensure their worldwide adoption, facilitating the exchange of information concerning the work of member bodies and technical committees, collaborating with other international organizations.

ISO maintains a mutually complementary collaborative relationship with the International Electrotechnical Commission (IEC). They formulate and implement joint ISO/IEC Directives, which serve as guidelines for standard development.

Currently, the ISO has developed 24,948 international standards. Standards can be classified under one of two schemes: the International Classification for Standards (ICS) or Technical Committees (TC). Since the scope and use of data are extensive, there are no standalone ICS or TC standards solely dedicated to data. Instead, provisions related to data standardization are specified within individual ICS and TC. Recently, however, the importance of data standardization has received more attention, and now every TC is actively promoting standardization.

For instance, in 2014, the ISO/IEC-Joint Technical Committee (JCT) 1 formed a Working Group (WG) on big data standardization and laid the foundation for standardization to secure interoperability. JTC1 is committed to developing, maintaining, promoting and facilitating information technology (IT) standards required by global markets to meet business and user requirements. It has various Sub-Committees (SC) and Sub-Working Groups (WG) operating under its umbrella.

Sub-Committee (SC) 32 in particular has several essential functions with regards to the standardization of data, including:

Developing reference models and frameworks for the coordination of existing and emerging standards; defining data domains, data types, and data structures, and their associated semantics; coordinating languages, services, and protocols for persistent storage, concurrent access, concurrent update, and data interchange; and developing methods, languages, services, and protocols to structure, organize, and register metadata and other information resources

associated with sharing and interoperability, including electronic commerce.

Table 4. Subcommittees and Working Groups under ISO/IEC JTC1

ISO/IEC JTC 1/SC 2	Coded character sets
ISO/IEC JTC 1/SC 6	Telecommunications and information exchange between systems
ISO/IEC JTC 1/SC 7	Software and systems engineering
ISO/IEC JTC 1/SC 17	Cards and security devices for personal identification
ISO/IEC JTC 1/SC 22	Programming languages, their environments and system software interfaces
ISO/IEC JTC 1/SC 23	Digitally recorded media for information interchange and storage
ISO/IEC JTC 1/SC 24	Computer graphics, image processing and envirnmental data representation
ISO/IEC JTC 1/SC 25	Interconnection of information technology equipment
ISO/IEC JTC 1/SC 27	Information security, cybersecurity and privacy protection
ISO/IEC JTC 1/SC 28	Office equipment
ISO/IEC JTC 1/SC 29	Coding of audio, picture, multimedia and hypermedia information
ISO/IEC JTC 1/SC 31	Automatic identification and data capture technologies
ISO/IEC JTC 1/SC 32	Data management and interchange
ISO/IEC JTC 1/SC 34	Document description and processing languages
ISO/IEC JTC 1/SC 35	User interfaces
ISO/IEC JTC 1/SC 36	Information technology for learning, education and training
ISO/IEC JTC 1/SC 37	Biometrics
ISO/IEC JTC 1/SC 38	Cloud computing and distributed platforms
ISO/IEC JTC 1/SC 39	Sustainability, IT and data centres
ISO/IEC JTC 1/SC 40	IT service management and IT governance
ISO/IEC JTC 1/SC 41	Internet of things and digital twin
ISO/IEC JTC 1/SC 42	Artificial intelligence
ISO/IEC JTC 1/SC 43	Brain-Computer interfaces
ISO/IEC JTC 1/WG 11	Smart cities
ISO/IEC JTC 1/WG 12	3D printing and scanning
ISO/IEC JTC 1/WG 13	Trustworthiness
ISO/IEC JTC 1/WG 14	Quantum information technology
ISO/IEC JTC 1/WG 15	JTC 1 vocabulary

Source: jtc1infor.org

② International Electrotechnical Commission (IEC)

The IEC, established in 1906, promotes international cooperation on matters related to standards compliance, among other issues, in the field of electrical and electronic technology, with the goal of enhancing international understanding. The IEC publishes around 10,000 IEC international standards, which together with conformity assessments provide the technical framework that allows governments to build national quality infrastructure and companies of all sizes to buy and sell consistently safe and reliable products across the world. As of 2023, the IEC has 62 full member economies and 27 associate members.

The IEC has three strategic goals: producing standards and conformity assessment solutions for a safe and secure digital society, developing and deploying SMART Standards and Conformity Assessments that meet evolving market and member needs, strengthening the role of IEC Standards and Conformity Assessments to deliver an all-electric and connected society.

The IEC, like the ISO, primarily focuses on developing standards that ensure the safety, interoperability, and efficiency of systems in the field of electrical and electronic equipment. IEC Standards reflect the global consensus and distilled wisdom of thousands of technical experts delegated by their economies to participate in the IEC. They provide instructions, guidelines, rules, and definitions that are then used to design, manufacture, install, test, certify, maintain, and repair electrical and electronic devices and systems. The IEC continuously develops standards in various fields through its 112 Technical Committees and 102 Subcommittees, with a total of over 700 active working groups.

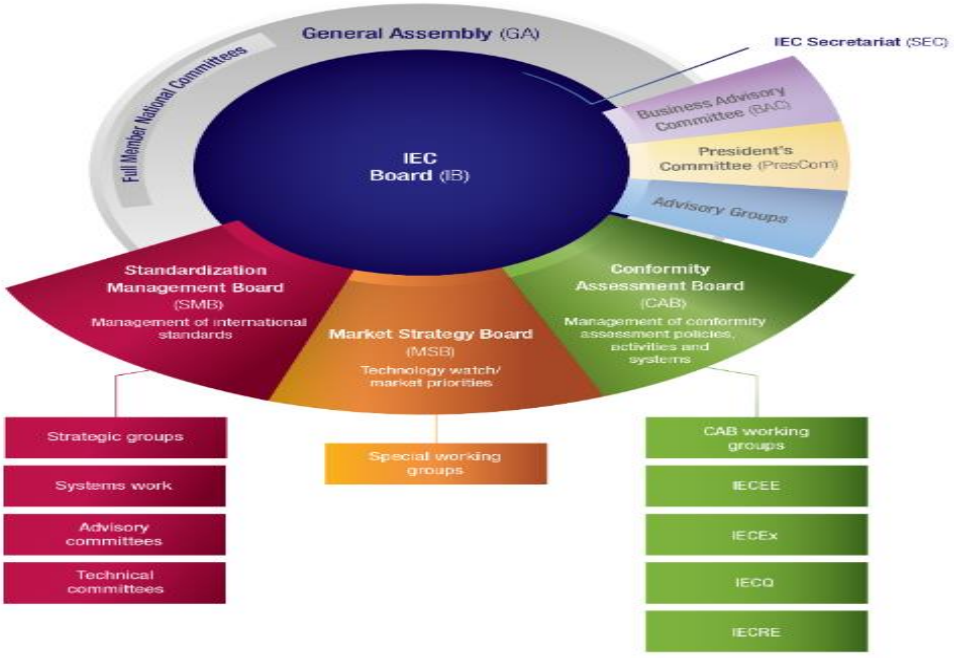


Figure 5. IEC Management Structure

Source: IEC homepage

The IEC is structured around its supreme governing body, the General Assembly. Other key organs include the IEC Board, Standardization Management Board, Market Strategy Board,

Conformity Assessment Board, as well as advisory bodies like the Business Advisory Committee, President's Committee, and Advisory Group.

③ APEC/SCSC (Sub-Committee on Standards and Conformance)

Standardization activities occur not only at the global level but also at the regional level, and one prominent example is the SCSC (Sub-Committee on Standards and Conformance) within APEC. It was established in 1994 to help mitigate the negative effects that divergent standards and conformance arrangements have on trade and investment flows in the Asia-Pacific Region.

Despite the existence of the SCSC, there is a lack of active discussion on data standardization within APEC. Discussions on data standardization do occur periodically, for instance discussions related to Global Data Standards (GDS) occurred at a 2014 workshop in Qingdao, China focused on promoting the adoption and use of GDS in supply chain management.

There is a dearth of active research on data standardization among APEC member economies. Some individual studies exist, such a 2017 paper on the application of GDS in supply chains and a 2020 report called APEC Guidelines and Best Practices for the Adoption of Global Data Standards. But as of yet, there are no established data standardization subgroups or working groups operating in the APEC framework.

④ Private Organizations

Some private organizations are also working to establish global standards. The World Wide Web Consortium (W3C) has organized various working groups to promote global standards. These include groups on Resource Description Framework (RDF), Linked Data Platform (LDP), Government Linked Data (GDL), and Comma Separated Values (CSV). Participants at these fora discuss semantic interoperability and data structures in the web environment.

The Organization for the Advancement of Structured Information Standards (OASIS) is another distinguished non-profit global standards body. It operates various TC. These include the Computing Ecosystem Supply-Chain TC, which seeks to develop use cases, standards for

data schemas, ontologies, and APIs that enable end-to-end visibility on computing supply chains, and the Open Data Protocol TC, which aims to simplify data sharing across disparate applications in enterprise, cloud, and mobile devices.

2.3. Global Health Data Standardization Trends

Data standardization is very broad topic, and so it is necessary to examine specific issues within data standardization to identify implications for policy. In this section, we focus on the standardization of health data. The COVID-19 pandemic led to a growing appreciation and recognition of the importance of utilizing health data in many member economies.

Standardization of global health data began in the 1970s. In the 1970s, the Medical Literature Analysis and Retrieval System Online (MEDLINE) system was developed in the United States. Described as a medical informatics system, it was used as a database of medical literature. In 1973, the first medical information system (MIS) was developed.

By the 1980s, many in the health field had begun to recognize the need for standardized health data. Many reports on the standardization of medical data were published in this period, and in 1988, development on the Health Level 7 (HL7) standard, which remains widely used today, began. Entering the 1990s, the need to exchange standardized health data grew, and in response the European Committee for Standardization (CEN) developed a medical information exchanged standard called ENV 13606. Around the same time, version three of the HL7 standard came out, designed to better integrate medical information. Efforts were made to provide flexibility.

In the 2000s, with the development of digital technology, the standardization of Electronic Health Records (EHR) was actively promoted, and in 2003, a consortium of experts in the health industry founded Integrating the Healthcare Enterprise (IHE). IHE was established to provide a framework for exchanging standard-based medical information and improve interoperability. HL7 also released a markup standard for categorizing medical records called Clinical Document Architecture (CDA), and made efforts to enhance the ease of data exchange between EHR systems.

Throughout the 2010s, many new standards related to diverse types of medical data were developed and promulgated. Notable standards include the Fast Healthcare Interoperability Resources (FHIR) standard for electronic health care data and the Digital Imaging and Communications in Medicine (DICOM) standard for medical imaging information.

Table 5. Examples of Global Health Standards

Organizations	Scope of Work
FHIR	Provide standardized API to facilitate the exchange and interoperability of health data. Enhance structural consistency and free exchange of data. Recently growing in popularity
DICOM	As an international standardization protocol that defines standards for health image data, it provides formats and protocols for exchanging and sharing image data, such as X-rays, CT scans, and MRI images.
CDA	Defines a standardized XML format for medical documents and sets the standard markup and structure of related documents
SNOMED CT	An international standard for medical terminology. Has increased the interoperability of medical terminology

Source: The authors

In the field of healthcare, there are three major types of standards: terminology, formats, and technical methods. Terminology encompasses a wide range of terms in many healthcare fields. These include terms for describing patient symptoms, procedures (such as surgeries or treatments), and more. Internationally recognized standard terminology systems include SNOMED CT for clinical terminology, LOINC for coding diagnostic tests, measurements, and document identification, and the International Classification of Diseases (ICD) — developed by the World Health Organization — for classifying diseases and health issues.

Formatting standards refer to the forms, elements, and content of patient medical records.

Internationally recognized standardized formats include CDA templates and FHIR standard resources, which are widely utilized in healthcare. Lastly, technical methods standards encompass data structures, transmission protocols, information security conventions, and technical requirements that enable the exchange of diverse medical information through computers. Standardized file formats include the XML and JSON formats. Standardized data transmission protocols include IHE XDS.b, HTTP, and API standards. DICOM is a major standard in medical image exchange. All of these standards help facilitate the seamless exchange and interoperability of healthcare data.

1) Fast Healthcare Interoperability Resource (FHIR)

The FHIR is an interoperability standard developed by HL7 designed to enable the electronic exchange of medical data between disparate systems across the healthcare industry. HL7 has been actively involved in the development and dissemination of various standards related to healthcare data over the years. FHIR is the most recent specification, following V2, V3, and CDA.

The V2 messaging standard was the first electronic data exchange standard used in the health care domain and is still widely used as a standard. It is designed to organize information in a predefined format, typically structured on segments, fields, and components. Specific information goes into designated slots. The V2 standard is limited in terms of scalability, however, as it can only accommodate a predetermined number of slots.

Table 6. Comparison: V2 and V3 Messages

V2 Message	MSH|^~\&|LABGL1||DMCRES||199812300100||ORU^R01|LABGL1199510221838581|P|2.3 |||NE|NE PID|||6910828^Y^C8||Newman^Alfred^E||19720812|M||W|25 Centscheap Ave^^ Whatmeworry^UT^85201^^P||(555)777-6666|(444)677-7777||M||773789090 OBR||110801^LABGL|387209373^DMCRES|18768-2^CELL COUNTS+DIFFERENTIAL TESTS (COMPOSITE)^LN|||199812292128||35^ML|||||| IN2973^Schadow^Gunther^^^^MD^UPIN ||||||||||^Once|||||CA20837^Spinosa^John^^^^MD^UPIN OBX||NM|4544-3^HEMATOCRIT (AUTOMATED)^LN||45||39-49 ||||F|||199812292128||CA20837 OBX||NM|789-8^ERYTHROCYTES COUNT (AUTOMATED)^LN||4.94|10*12/mm3 |4.30-5.90||||F|||199812292128||CA20837

V3 Message	<author> <assignedEntity> <id root="2.16.840.1.113883.9876.210.3" extension="5332443" /> <telecom value="tel:+1(317)630-7960" /> <assigneePerson> <name> <given>Keiko</given> <family>Jones</family> <suffix>MD</suffix> </name> </assigneePerson> </assignedEntity> </author> <!-- Removed consumable --> <patientSubject> <patient>

V3, the successor to V2, was designed to address some of the shortcomings of V2. In V3, data is structured in the XML file format, and the use of the Reference Information Model (RIM). RIM allows for the granular representation of healthcare information, enabling the expression of concepts and relationships.

Figure 6. Role of FHIR

Source: Health Information Standard of Korea

FHIR uses application programming interfaces (APIs) to allow various apps to "plug in" into the underlying operating system, allowing health care providers to incorporate any and all relevant data stored in an accessible format to their workflow. FHIR supports data sharing in a variety of formats, including documents, messages, services, and RESTful interfaces. It is

designed to accommodate the growing complexity of healthcare data, user expectations, and the needs of modern, internet-based approaches to communication between disparate components.

FHIR consists of five levels: basic infrastructure, implementation support and binding to external specifications, real-world linkages, data exchange recording and storage, and the ability to reason about the healthcare process.

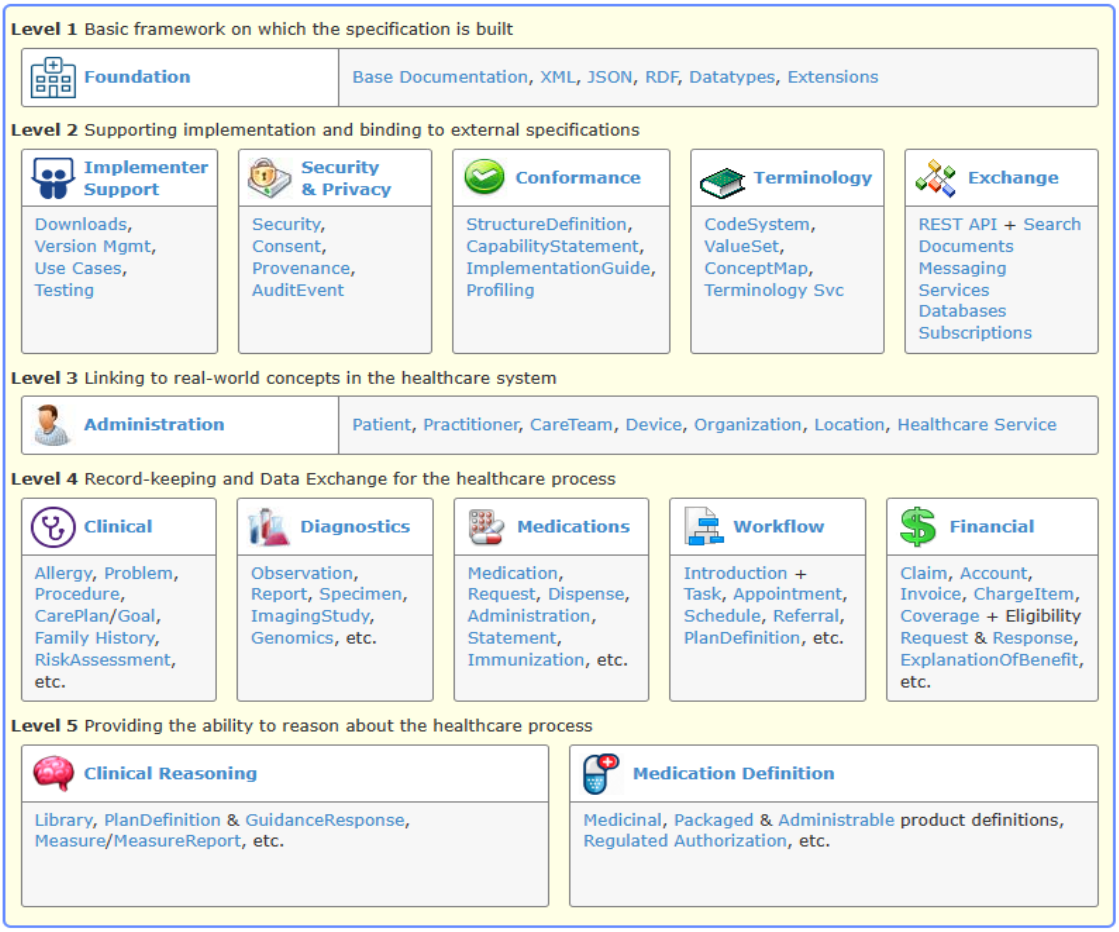


Figure 7. Five Levels of FHIR

Source: Health Information Standard of Korea

2) Digital Imaging and Communication in Medicine (DICOM)

The format of medical data is highly diverse, and this is especially true in the case of image data, which can be extremely challenging to standardize. In the field of medical imaging, the

DICOM standard functions as the international standard for health imaging data. DICOM supports interoperability between health imaging devices and systems by through standardized data formats protocols and the use of standardized file formats for creating, storing, retrieving and transmitting health images.

The DICOM Standards Committee (DSC) features to chairpersons: one chair representing producers and another representing users. The DSC also has an executive committee that addresses issues requiring attention. DSC also forms working groups to develop and maintain standards.

The DICOM standard is characterized by the following key elements. First, DICOM defines standardized data formats and file formats for storing imaging data. This ensures interoperability by standardizing the structure and characteristics of health image data. Second, it defines which metadata is to be transmitted along with the image data. Metadata describes the characteristics and meaning of health image data, and typically includes patient information, image acquisition conditions, and image processing information. Finally, the DICOM standard, widely used in the field of medical imaging, contributes to better medical diagnosis, treatment and management through the standardization and interoperability of health imaging data.

Figure 8 visually illustrates how the DICOM system is applied. Individual images such as X-ray, CT, and MRI scans are stored on servers called Picture Archiving and Communication Systems (PACS). DICOM standards and systems are used to store, process, and transmit data to and from these servers in accordance with standard protocols. The figure simply shows when DICOM is applied. A survey of the technical details of DICOM is beyond the scope of this report.

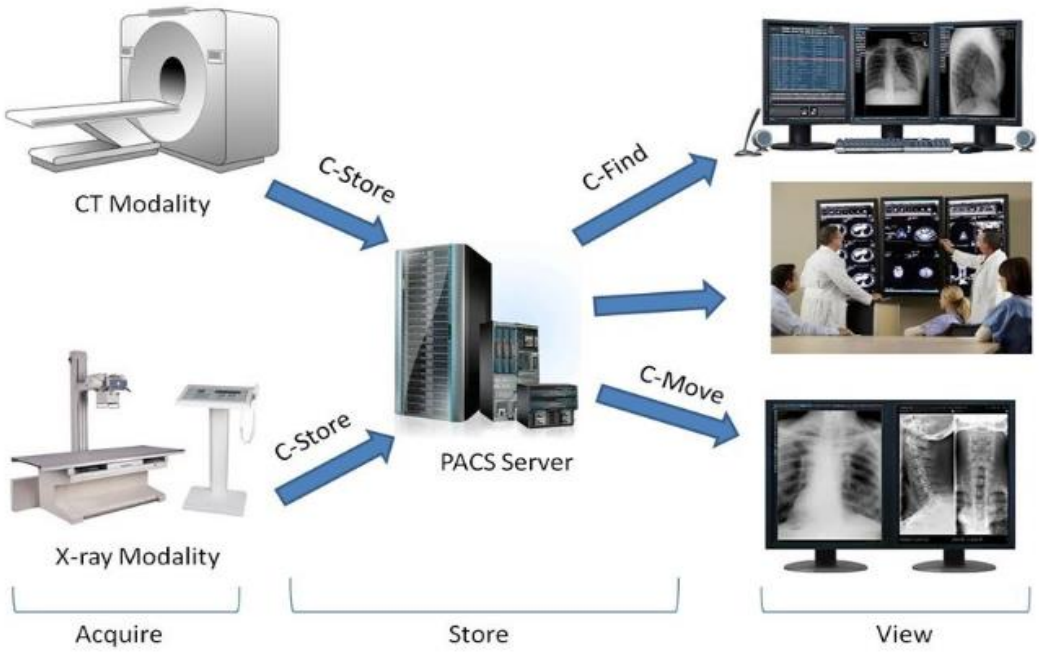


Figure 8. DICOM system

Source: Extracted from Ma and Sartipi (2014), "An Agent-Based Infrastructure for Secure Medical Imaging System Integration," page 3, Figure 1. Conference paper: 2014 IEEE 27th International Symposium on Computer-Based Medical Systems (CBMS).

DICOM operates under the DICOM Standard Committee and 34 specialized Working Groups that develop and disseminate standards in the field of medical imaging. Working Groups design standards for a particular modality, clinical domain, or technical area. In addition, DICOM itself is updated five times a year, implementing enhancements to meet evolving requirements. Importantly, any DICOM user can propose updates or improvements related to the DICOM standards.

3) Clinical Document Architecture (CDA)

CDA, developed by HL7, is a method for expressing and exchanging clinical documents in a standardized format. CDA is a structured representation of an electronic health record or other medical document in an XML-based format.

CDA templates define the structure and content of documents and ensure consistency and interoperability when exchanging documents between health information systems. In general, CDA documents are used to record and share patient health data. Patient health records, diagnoses, reports, surgical reports, prescriptions, and test results can all be expressed in CDA format. CDA also supports integration with other standards and can be used alongside standards such as Logical Observation Identifiers Names and Codes (LOINC).

CDA, based on XML and utilizing RIM, leverages the advantages of SNOMED CT and LOINC coding systems to make EHRs and other healthcare IT systems easily readable by individuals through web browsers and portable devices.

Table 7 Characteristics of CDA

Characteristic	Contents
Persistence	Remaining in use for a long time
Stewardship	Maintained by trusted organizations such as hospitals
Potential for authentication	Legal attestation that the clinical information is accurate
Context	A default context for records, such as patient identity and document creator
Wholeness	The full document, not just parts of it, can be authenticated
Human readable	A person can read the material on a browser or mobile device

4) Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT)

Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) was developed to meet the diverse needs and expectations of healthcare professionals worldwide, and it serves as an international standard terminology system used in over 80 economies. SNOMED CT is a systematized glossary of terms used in the medical field. It was developed to standardize

medical terms and facilitate the semantic interoperability of medical terminology. SNOMED CT terms are organized in a hierarchical structure and use relational representations to define relationships between concepts. This allows more accurate representations of medical information and enables semantic interoperability. It is an internationally standardized terminology and is maintained by the International Health Terminology Standards Development Organization (IHTSDO). Hence, it is continuously maintained and updated.

Table 8. SNOMED CT 19 Hierarchies

- SNOMED CT
  - Body structure (body structure)
  - Clinical Finding (finding)
  - Environment or geographical location (environment / location)
  - Event (event)
  - Observable entity (observable entity)
  - Organism (organism)
  - Pharmaceutical / biologic product (product)
  - Physical force (physical force)
  - Physical object (physical object)
  - Procedure (procedure)
  - Qualifier value (qualifier value)
  - Record artifact (record artifact)
  - Situation with explicit context (situation)
  - SNOMEN CT Model Component (metadata)
  - Social context (social concept)
  - Special concept (special concept)
  - Specimen (specimen)
  - Staging and scales (staging scale)
  - Substance (substance)

Source: SNOMED CT Hierarchies (2022)

SNOMED CT organizes terms into 19 distinct hierarchies, each of which cover distinct aspects of healthcare. Each concept has a number of subhierarchies. For instance, clinical finding (finding) contains both (finding) for symptoms and (disorder) for clinical diagnosis. Body structure (body structure) contains (body structure), (cell structure) and (morphologic abnormality)

3. Data Standardization Policies and Practices

- Focusing on Health Data

3.1 Data Standardization Policies

1) Global Organization

A standard is a documented agreement that includes technical specifications or precise rules, guidelines, or definitions of various characteristics. Standardization refers to the benefits derived from setting these rules, guidelines, and definitions, and by having a large number of people abide by them.

According to this definition, the standardization of health data can be defined as the expression of terms representing medical practices, forms and formats of medical records, technical methods for exchanging medical information through computers, and programs or facilities necessary enabling all the above. Standardization of health data makes it possible to spread domestic and international standards and encourage their use, minimize redundant investments and reduce associated incurred by medical providers and institutions, and contribute to improving the quality of medical services through expanded interoperability.

Economies around the world are implementing medical data standardization policies in numerous ways to promote the efficient use of domestic medical data, and global organizations are working to establish global standards that improve the interoperability of health data used in the economy.

Despite the need for standardization of medical data, there are several barriers to standardization. The first thing to consider is the complexity and diversity of medical data. Health care is a large field with many sub-fields, such as diagnosis, treatment, drug, and bio-signals. Moreover, some medical data are structured while other data are unstructured, which can hamstring standardization efforts. For this reason, global systems and organizations have devised various medical standards such as HL7, DICOM, and SNOMED CT, which have come into popular use. But integrating and standardizing these standards into institutional processes

requires additional work. In addition, medical data often contains sensitive personal information, and so most APEC member economies monitor and regulate the collection, use, and transfer of medical data.

Despite the difficulties of standardizing medical data, both individual APEC member economies as well as global organizations are making efforts to do so. Here we will examine the progress of health data standardization policy efforts at relevant global organizations.

① International Organization for Standardization (ISO)

The ISO is an independent, non-governmental international organization. Its members comprise domestic standards bodies. Its members share knowledge and develop voluntary, consensus-based, and market-relevant international standards that fuel innovation and provide solutions to global challenges.

The ISO committee responsible for medical device standardization is TC 215. TC 215 is a technical committee that works on standardization in health care. It aims to facilitate the capture, interchange, and use of health-related data, information, and knowledge to support and enable all aspects of the health system. To date, TC215 has published 232 ISO standards, and 58 standards are under development.

There are 34 participants in TC215, and these include several APEC member economies, such as Australia; Canada; China; Japan; Korea; Malaysia; New Zealand; The Russian Federation; and the US.

For the development of standards, ISO oversees various development teams.

Table 9. Standard Development Teams

Team	Role
Technical Committee (TC)	Manage technical work within its scope
Sub-Committee (SC)	Similar to a TC, but with an extended sub-scope
Working Group (WG)	Develop approved projects

Task Force (TF)	Deliberate & report on specific subject areas
Ad Hoc Group (AHG)	Conduct short-term investigations & report on single topics

Under TC215-SC1, there are working groups (WG) and joint working groups (JWG) that study standards in various fields. Each working group promotes the development of standards, including structures and models, as well as personalized digital health.

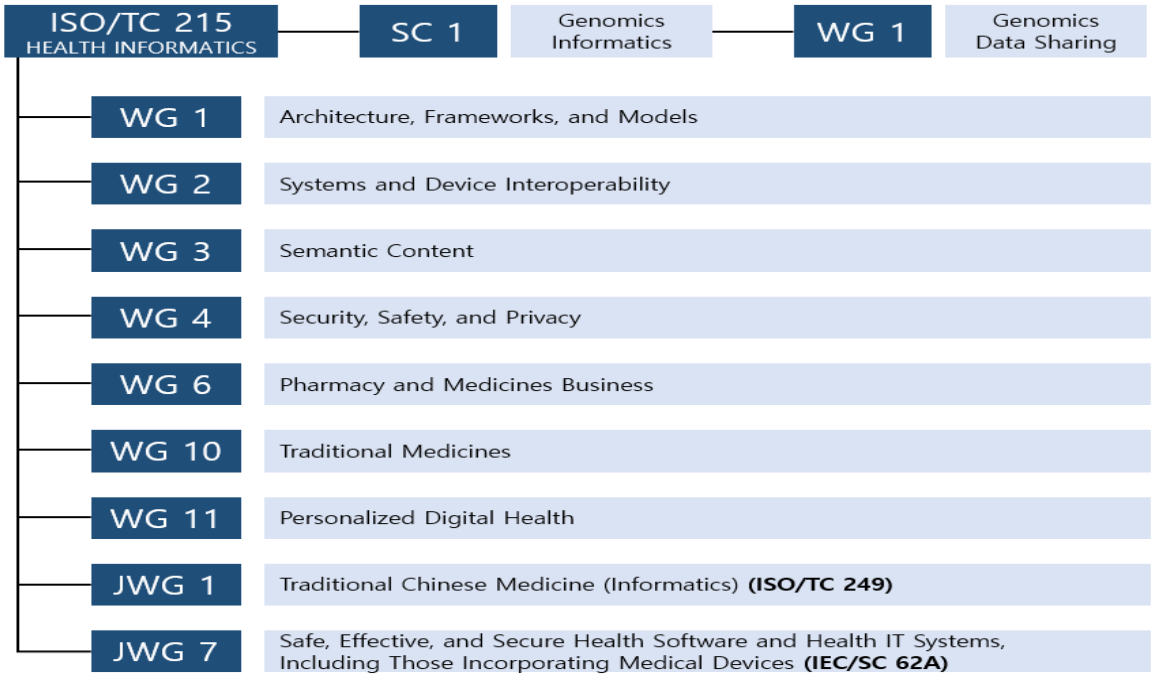


Figure 9. WG and JWG under TC215-SC1

Source: APEC Data Standardization Forum Presentation (7 August 2023)

It is worth mentioning here how the use of digital technology, and especially the use of AI and big data in healthcare settings has rapidly expanded. ISO has worked to orient its discussions and standards development to reflect this. For instance, in November 2019, at the ISO/TC 215 plenary meeting held in Daegu, Korea, a three-year plan was drawn up that included artificial intelligence (AI). As part of the practical work, Ad Hoc Group 2 (AHG 2) on the Application of AI Technologies in Health Informatics was established. ISO/TC 215/AHG 2 focused on exploring and analyzing the overall scope of AI technology applications in health informatics, classifying key items, and conducting investigations into relevant standards. Work was also carried out to create a roadmap for future needs. In addition, the ISO/TS 22756:2020 standard

on Requirements for a Knowledge Base for Clinical Decision Support Systems to be Used in Medication-Related Processes was developed in September 2020, and is one of the first standards related to medical AI. There is also ongoing work on listing and classifying medical AI. Technical report titled ISO/PWI TR 24291 Health Informatics – Applications of Machine Learning Technologies for AI in Medicine is in development.

② Health Level 7 (HL7)

Founded in 1987 Health Level 7, is a non-profit, American National Standards Institute (ANSI)-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice, as well as the management, delivery and evaluation of health services. It aims to provide standards that empower global health data interoperability between different healthcare applications

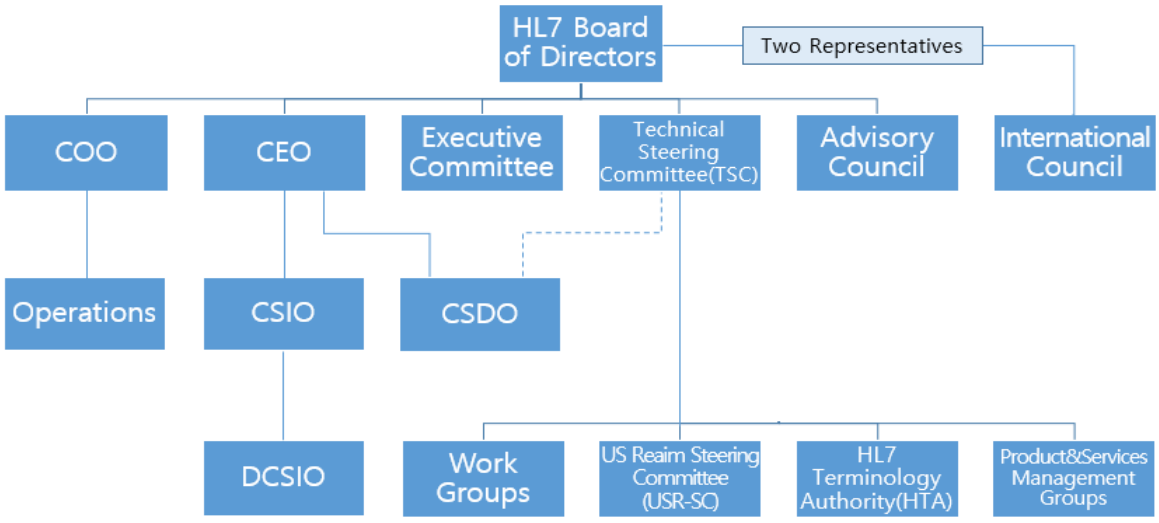


Figure 10. HL7 Organizational Chart

Source: HL7 homepage

According to IQVIA, in 2020, more than 90,000 new healthcare apps hit the market, bringing the total number of such apps to 350,000 globally. HL7 consists of the Technical Steering Committee (TSC) and various councils under the Board of Directors, as well as working groups

under the TSC that study standards related to health data.

As HL7 standards are the most widely used health data standards, almost all HL7 data are transferrable over various communication protocols, such as TCP/IP and HTTP, and can be represented in structured formats such as eXtensible Markup Language (XML) or JavaScript Object Notation (JSON). HL7 continues to develop updated versions of health data standards and has recently released FHIR, which aims to simplify and improve interoperability by using Representational State Transfer (RESTful) web services and a resource-oriented approach.

FHIR refers to both the technology and the agreement on the meaning of the data. Hence, any system, in any programing language, can read and exchange a FHIR resource and retain its meaning. Another advantage of FHIR is that it allows data to be encoded for compliance with standards, such as FHIR or ISO standards. This is known as the 80/20 rule: FHIR resources have data elements representing 80% of existing system requirements. The above are major advantages of the FHIR system and many US federal government agencies, including the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Department of Defense (DoD), and the Veterans Health Administration (VHA) have active FHIR integration programs.

In addition, many Asia-Pacific governments have worked to incorporate HL7 FHIR as follows. See Table 10 below.

Table 10. Examples of HL7 FHIR Implementation in the Asia-Pacific Region

Economy	Implementation
Australia	FHIR is the base for the National Healthcare Interoperability Plan, released July 2023
China	FHIR Connectathon held April 2023. China has its own HL7 affiliate
Japan	Japan FHIR core implementation guide published Nov. 2022. Japan has its own HL7 affiliate
Malaysia	FHIR is the base for the Malaysian Health Information Exchange (MYHiX)

Singapore	Singapore's FHIR-based Healthcert was created for Cross Border Travel. Singapore has its own HL7 affiliate

Source: APEC Data Standardization Forum Presentation (7 August 2023)

2) APEC and APEC Member Economies

①Asia-Pacific Economic Cooperation (APEC)

In this section, we will survey the progress of discussions related to data standardization occurring within the APEC context. Within APEC, the Digital Economy Steering Group (DESG) is best suited to address data standardization. But standardization is a cross-cutting issue, and the need for data standardization is growing in many areas covered by APEC. The Health Working Group (HWG) is a good place.

The APEC Internet and Digital Economy Roadmap (AIDER) adopted by APEC member economies in 2017 also recognizes the importance of data standardization.

Many of AIDER's 11 KFA are directly or indirectly related to data standardization. For example, promoting interoperability and facilitating the free flow of information and data for the development of the internet and digital economy are directly related, while promoting innovation and enhancing trust are indirectly related.

Despite importance of data standardization, intra-APEC talks on data standardization are inactive. A 2020 report titled APEC Connectivity Blueprint: The 2020 Mid-Term Review mentioned Global Data Standards (GDS) as being an important connectivity factor. Hong Kong, China conducted a project in 2019 on promoting GDS to enhance supply chain connectivity. However, the rare APEC reports that do exist are not focused on medical data standardization, but rather on GVC-related standardization. Other than that, the discourse on data standardization is largely inactive.

An overall system for talks on data standardization within APEC is in place. There are some digital related working groups such as DESG and Telecommunication and Information working group. Despite this, there is no group or research task force dedicated to the discussion and study of data standardization. This contrasts with the existence of the Data Privacy Subgroup

(DPS) under the DESG.

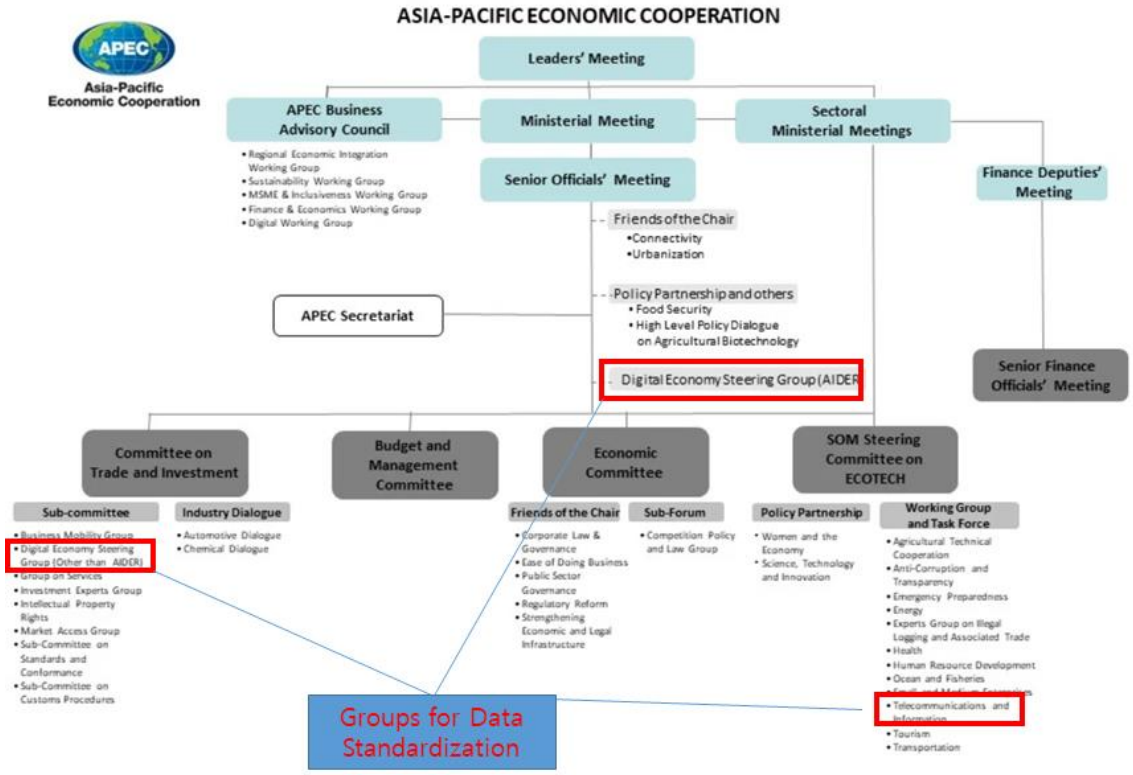


Figure 11. Structure of APEC

Source: apec.org

The APEC organizational chart above makes it clear that APEC recognizes the importance of the data economy. But substantial efforts are needed to strengthen data cooperation among APEC member economies.

Cooperation should go in two directions. First, APEC could seek ways to promote data standardization among APEC member economies. And second, APEC needs to come up with a plan to narrow the gap in digital and data related capabilities among members.

② APEC member economies

In this section, we will identify the government authorities tasked with health data standardization in the APEC member economies and survey the general state of health data standardization in each member economy.

Table 11. Health Data Standardization Authorities, APEC Member Economies

Economy	Health Data Standardization Authority
Australia	The Department of Health & Human Services Australian Digital Health Agency
Canada	Canada Health Infoway
Indonesia	Ministry of Health
Japan	Medical Information System Development Center
Korea	Ministry of Health and Welfare Korea Health Information Service

A) China

Over the past several years, China has developed a Connectivity Standard for its healthcare information system. This standard, which boasts independent intellectual property rights of its own, has been widely applied domestically, and has begun a new chapter in the development digital healthcare in China, driving expanded interoperability and facilitating innovation in service capacity, quality, and delivery.

First, China has established a standard system for healthcare information connectivity. The newly-developed Connectivity Standard consists of three integral parts: data standards, technical standards and management standards. The ultimate goal is to promote the internationalization of China's healthcare information standards.

Second, a technology development pathway which is supported by regional health information platforms and hospital information systems has been generated. The pillars undergirding this technical architecture are a regional health information platform based on residents' health records and a hospital informational platform supported by electronic medical records. The

content of the interactive service is designed to support interoperability and data sharing.

Third, a complete set of multi-dimensional technical assessment plans has been established. A four-dimensional indicator system, which includes a grading rubric consisting of five levels and seven types, is used to evaluate the maturity of interoperability between regional health data and hospital information is established. Thus, to stay up to date with technological advances and business growth, China has produced an iterative mechanism that keeps assessment indicators updated.

Fourth, China has developed automatic testing technologies, including network testing tools. These techs include automated test case generation, automated data dictionary standardization, automated testing for the standard compliance of data sets and shared documents, and interoperable methods to facilitate the exchange of hospital information. This are in addition to an assessment management platform.

Finally, health authorities have established a new paradigm for man-machine interaction in connectivity assessments. This new paradigm includes a quantitative and qualitative homogeneous assessment model. The testing procedure includes preparation, declaration, preliminary examination, document examination, quantitative text, and on-site inspection and results distribution processes. An assessment pathway that is administered level by level has also been developed.

B) Korea

In Korea, the Ministry of Health and Welfare (MOHW) is tasked with establishing directions for standardizing health data and laying the administrative and legal foundations to do so. In particular, MOHW is working to prepare policies and measures that reflect both the on-the-ground situation in Korea and global trends in health data standardization. As part of these recent efforts, in 2021 Korea announced a roadmap for health data standardization. The following year it appointed a task force to promote the dissemination of an international standards system that enhances the interoperability of health data, including terminology and transmission methods. In September 2023, Korea promulgated a comprehensive revision of the

Healthcare Data Standard Terminology and Transmission Standard directives. A roadmap was presented to address the inadequacy of medical data utilization despite the mature level of domestic infrastructure. It also describes a new range of standardization that covers not only clinical data but also patient-generated data, such as genome information and life logs.

The Health Data Standardization task force has three key working groups: CDI, Next-Tech, and Governance. These working groups focus on the on development of Korean CDI, the preparation of next-generation transfer standards (FHIR), and patient-generated health data (PGHD), the preparation of a domestic plan for incorporating the international classification of diseases (ICD-11) standards, and the establishment of efficient governance for health data standardization.

Figure 12. Structure of Health Data Standardization TF

Source: MOHW and KHIS

In Korea, the Korea Health Information Service (KHIS) supports health data standardization as an implementing agency. KHIS aims to set the standards for an EMR system and provide certification for health information standard applications and support programs, such as assistance for the safe and continued treatment of patients by improving the quality of the EMR system. In addition, many medical institutions and university research institutes are engaged in collaborative efforts to standardize Korean health data.

The overall direction of Korea's health data standardization policy can be summarized as follows. The vision for health data standardization is improvement through standards-based digital innovation. To realize this vision, it is necessary to create a digital health environment where people can access and share health information when needed.

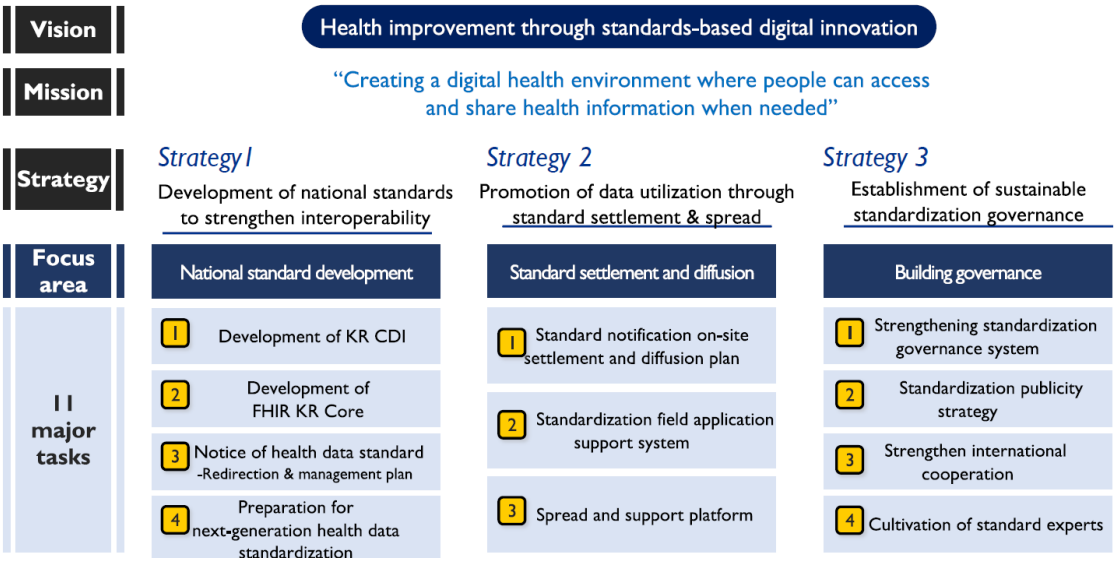


Figure 13. Vision of Health Data Standardization in Korea

Source: MOHW and KHIS

In pursuit of its objectives, Korea has the following strategies in place. First, it is working to develop domestic standards to strengthen interoperability. Second, it is promoting data utilization through standards settlement and expansion. Third, it is in the process of establishing sustainable standardization governance.

According to the government's health data standardization vision, each strategy features multiple sub-strategies for implementation. For the National Standard Development Strategy, there are four implementation action plans: the development of Korea CDI, the development of FHIR Korea Core, the health data standard notification, and the preparation of next generation health data standardization.

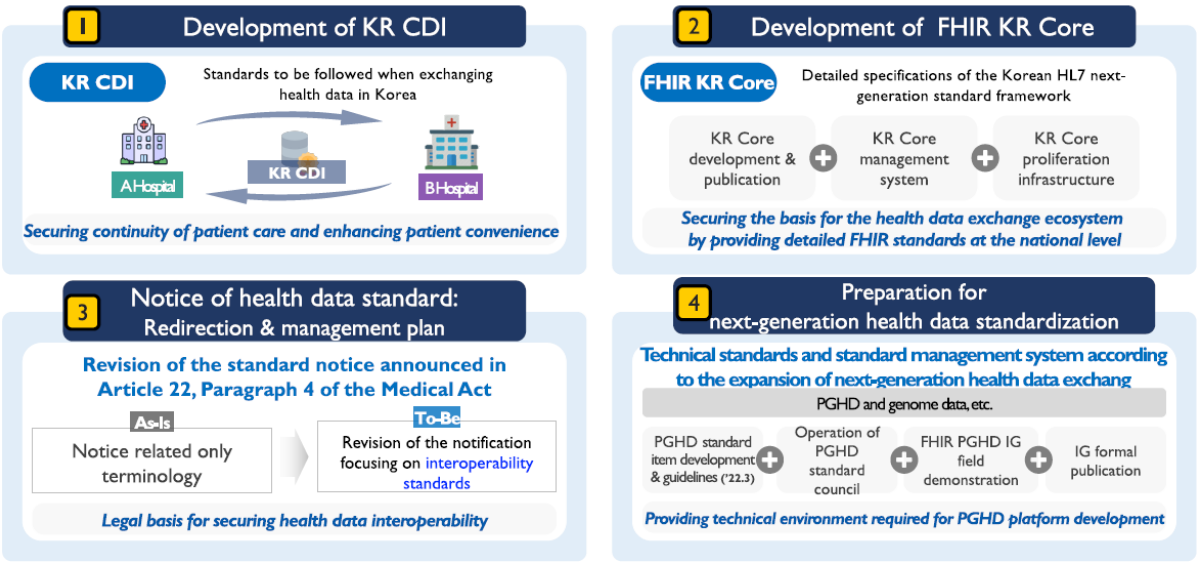


Figure 14. Strategy I: Domestic Standard Development

Source: APEC Data Standardization Forum Presentation (7 August 2023)

The second strategy, Standards Settlement and Diffusion, presents three action plans: the standards notification, on-site settlement, and diffusion plan, the standardization field application support system, and the spread and support platform.

For the standards notification on-site settlement and diffusion plan, it is important to create linkages with domestic projects. This makes realizing domestic standards in connection with projects related to health and medical information and data promoted by the government possible. In addition, it also makes it possible to verify standards at leading hospitals and pursue step-by-step expansion.

The standardization field application support system can be divided into direct and indirect support. In terms of direct support, there is a direct financial support pilot project based on consensus with medical institutions being run. For indirect support, the government has established evaluation indicators for evaluation and certification standards for medical institutions. Building-up a dedicated system through the establishment of a domestic health data standard integrated support system and expanding services such as health data standards application and activation to all medical fields could help establish the spread and support platform.

The last strategy, building governance, lays out the following action plans: strengthening the standardization governance system, publicizing the standardization strategy, strengthening international cooperation, and the cultivation of standards experts.

Despite the efforts described above, it remains difficult to say that medical data standardization in Korea has made much progress. One major stumbling block is lack of participation by the health care institutions that actually hold the data, and finding a way to incentivize their participation is a key task going forward

C) Singapore

Singapore's health care system consists of preventive care, primary care, acute care and care for the elderly. Regarding preventive care, Singaporeans are encouraged to pursue health lifestyles and to take responsibility for their health. The Health Promotion Board (HPB) was formed in 2001 to drive domestic health promotion and disease prevention programs. Primary care is provided through a network of public sector polyclinics and clinics run by private general practitioners (GPs). There are currently 23 polyclinics that together meet 20% of total primary care demand and about 1,800 GP clinics that satisfy the remaining 80% of total primary care demand.

Most (80%) of acute care is delivered through the public sector which includes six general hospitals, one hospital for women and children, one mental health hospital, and six domestic specialty centers providing cancer, cardiac, skin, eye, neuroscience and dental care. Regarding intermediate and long-term care (ILTC), continuing care facilities exist for patients that no longer require acute care but do require continued care. Voluntary Welfare Organizations (VWOs) provide 60% of ILTC services. These services range from residential to community-based care, several of which receive government subsidies for needy patients.

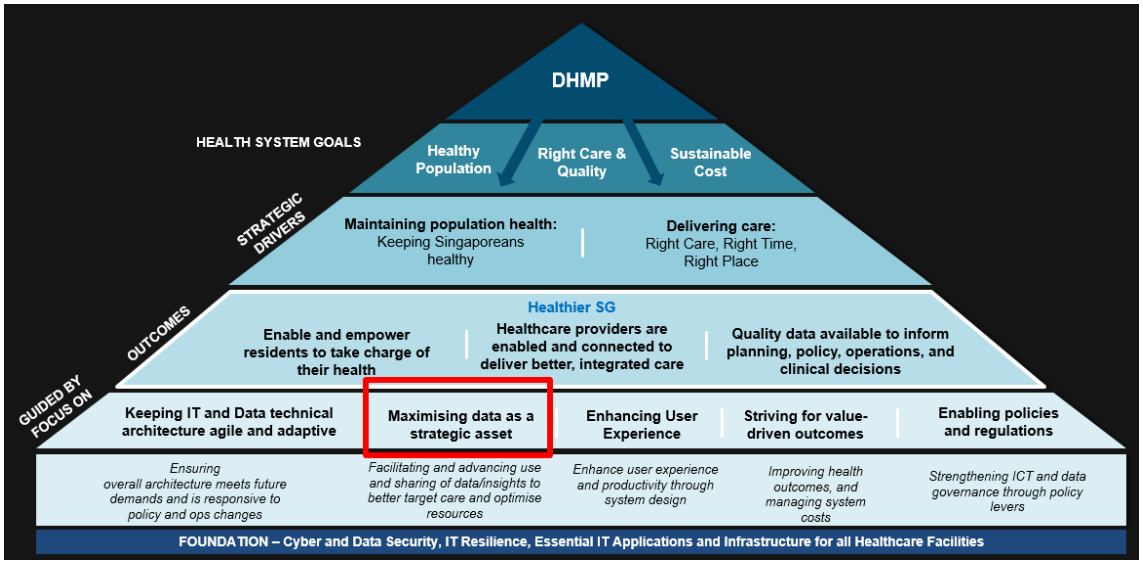


Figure 15. Digital Health Master Plan in Singapore

Source: APEC Data Standardization Forum Presentation (7 August 2023)

In Singapore, healthcare data standards are considered in the context of maximizing data as strategic asset. Its objectives are twofold. First, the government aims to derive and standardize definitions of core data standards and identify policy implications for the public sector health care system. Second, the government looks to promote and ensure compliance with and adoption of data standards adoption through the healthcare system.

The data standardization plan, promulgated by the Ministry of Health (MOH), aligns with the Digital Health Master Plan (DHMP) to achieve two key strategic outcomes: facilitate the seamless exchange of data and maximize data as a strategic asset.

To achieve healthcare data standardization, the Singaporean government has staffed a Healthcare Data Standards Committee under the Chief Data Officer Council. The Healthcare Data Standards Committee classifies activities designated for healthcare data standardization into three levels: Policy Level, Operation Policy Level, and Operation Level, and further defines role as follows in Figure 16 below.

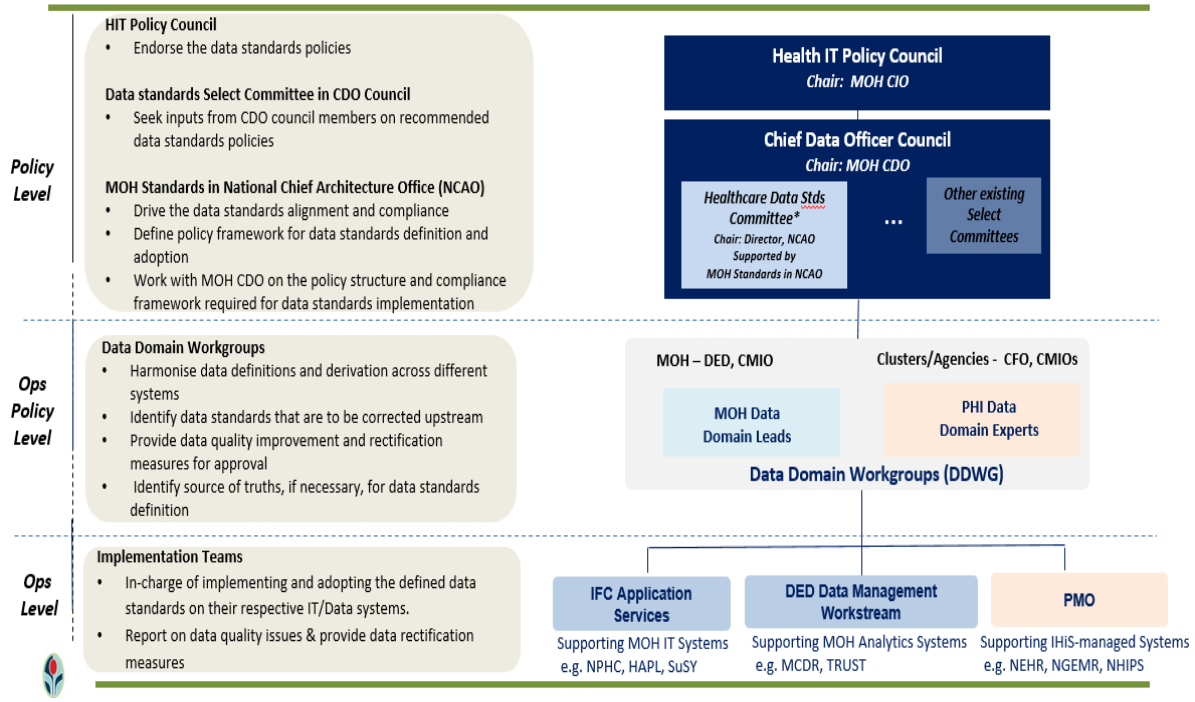


Figure 16. Role of Healthcare Data Standards Committee

Source: APEC Data Standardization Forum Presentation (7 August 2023)

This committee lays the groundwork for healthcare data standardization. It consists of identification, prioritization, monitoring, and development. It identifies use cases, existing gaps in data standards, compliance, and policy, and evaluates current and upcoming MOH strategies and requirements to identify relevant drivers and levers for closing gaps. The framework shows criteria to prioritize use cases and key standards to develop and drive adoption in required domains and sectors.

D) United States

Various organizations and agencies in the US are pursuing policies related to healthcare digitalization. The U.S. Department of Health and Human Services (HHS) takes the lead in healthcare digitalization-related policy initiatives. The Office of the National Coordinator for Health IT (ONC) is tasked with establishing interoperable healthcare IT infrastructure and building common clinical data sets. ONC sets standards for healthcare IT certification and coordinates public-private partnerships in healthcare IT. And Centers for Medicare & Medicaid Services (CMS) promotes healthcare improvement through the statistical processing,

investigation, and analysis of various healthcare-related data. It builds insurance reimbursement systems by aggregating and analyzing data from Medicare and Medicaid. Additionally, CMS effectively utilizes the "Blue Button" Personal Health Record (PHR) platform API and manages related databases and PHR platforms.

During the administration of Barack Obama (2009-2017), there was significant focus on healthcare data standardization and the promotion of Health Information Technology (Health IT) and Electronic Health Records (EHR) adoption. Several key policies and initiatives were introduced to advance these goals, including:

First, the Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted in 2009 to promote the adoption of Electronic Health Records (EHRs) through the provision of federal financial incentives. This law emphasizes healthcare data standardization and interoperability and offers incentives to healthcare providers who adopted EHR systems.

Second, the ONC was established as a key agency to promote Health IT and healthcare data standardization. ONC developed standards and certification programs for EHR systems and provided a standardized EHR model to enhance interoperability. It contributed to improved interoperability of healthcare data.

Third, the government introduced the Meaningful Use program. It encouraged healthcare providers to use EHR systems in a "meaningful" way, focusing on healthcare data standardization and quality improvement.

Progress toward healthcare data standardization continued under the administration of Donald Trump (2017-2021) The Trump administration emphasized deregulation as a core value and sought to ease regulations in the healthcare industry. This regulatory relief was seen as a means to encourage more active data exchange and innovation within the healthcare sector.

Taking advantage the deregulated environment, the healthcare industry was able to engage in more active business activities, including data exchange and innovative solutions. This approach aimed to foster a more dynamic and competitive healthcare environment, encouraging the adoption of modern technologies and practices.

Overall, the emphasis on regulatory relief in the healthcare sector had an impact on the

healthcare data standardization landscape by promoting greater flexibility and innovation in data exchange and utilization.

In addition, the Trump administration introduced interoperability rules through CMS and ONC. These rules were implemented to improve healthcare information exchange and data accessibility, with a strong emphasis on healthcare data standardization and interoperability. Interoperability rules were designed to ensure that healthcare data could be exchanged seamlessly between different healthcare providers and systems, promoting a more connected and interoperable healthcare ecosystem. By emphasizing healthcare data standardization, these rules sought to improve the consistency and compatibility of healthcare data, making it easier for healthcare organizations to share and use patient information effectively.

3.2 Data Standardization Use Cases

In this section we will survey use cases of health data standardization, highlight a few examples at both public and private organizations.

Companies leveraging health data standardization are active in various fields, such as medical information systems, medical research, and medical device development. Here, we examine how major global companies are using health data standardization and identify the implications for policy carried by the findings. We will include use cases presented during the forum on data standardization.

① Seoul Medical Informatics Intelligence Lab

The Seoul Medical Informatics Intelligence Lab uses mCode to create solutions tailored to individual clients. For example, the firm has helped customers obtain critical patient health information from unstructured data in clinical documents. In reality, many healthcare records are stored as unstructured data and extracting meaningful insights from these data can be challenging.

The information that can be extracted from Electronic Medical Records (EMR) is highly diverse. EMRs can include data on patient identity, diagnoses, treatment history, results, genomics, assessments, and more. The following diagram illustrates what kinds of information are included within each category EMR category.

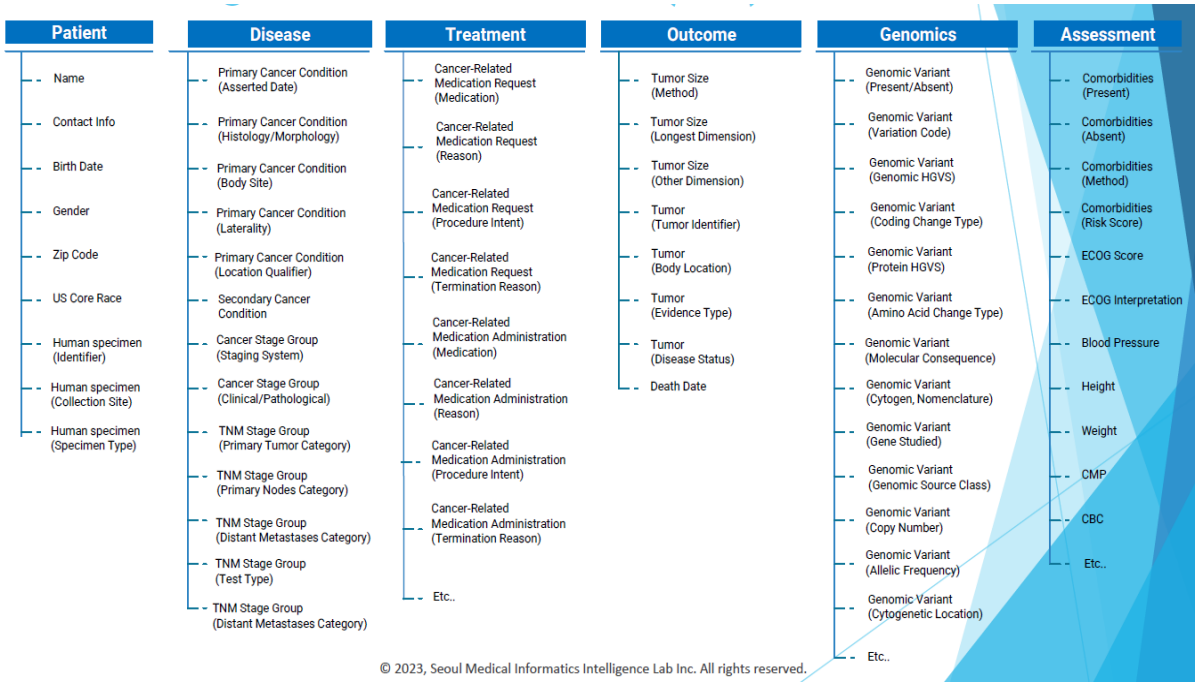


Figure 17. Extracting Fields of Interest in EMR

Source: APEC Data Standardization Forum Presentation (7 August 2023)

Seoul Medical Informatics developed a model for diagnosing patient conditions from health data using mCode and deep learning techniques.

The figure 18 illustrates a simple example of how structured data can be extracted from unstructured data using mCode. The left side in figure 18 shows unstructured data, and from the raw data, structured data is created by separating it into entities, as seen on the right side.

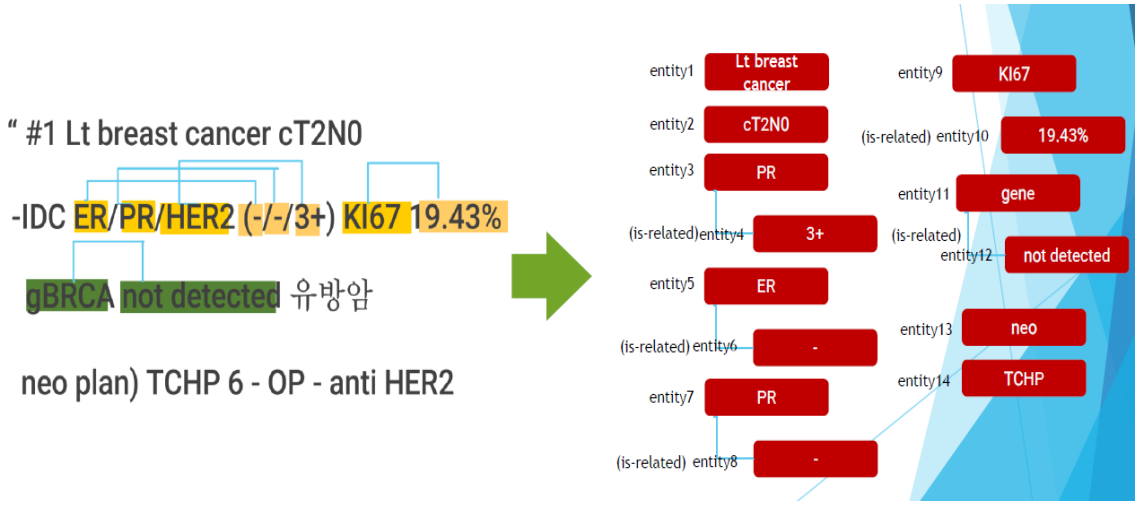


Figure 18. Example: Extracting Structured Data from EMR

Source: APEC Data Standardization Forum Presentation (7 August 2023)

② PRiME Research Institute for Medical RWD Inc.

In Japan, almost all administrative claims are processed online. This means every prescription, measurement, and procedure are recorded using a domestic standard code, along with the date they were performed. Diagnoses are also recorded using the domestic standard code alongside the claims, but for medical research purposes this is considered to inaccurate, as the data are recorded merely to justify the content of claims. As a result, administrative claims data in Japan can be integrated into a single database. This economy-wide database is provided by the government and is known as the National Database (NDB) and can be utilized by academia or various industries.

However, all codes are domestically used, and no concept hierarchy or structure is provided. Consequently, every medical institution must individually select each code to analyze content from the database. A new claims scheme, the Diagnosis Procedure Combination (DPC), has been introduced at approximately 35% of all hospitals.

Consequently, merging EMR data across different hospitals remains a significant challenge in Japan. A combination of diagnosis data from EMR and drugs and procedure data from administrative claims could offer a better data source. However, due to the incompatibility of codes and formats, collecting measurements and/or test results from Japanese hospitals poses significant challenges.

To address this, Japan has implemented a domestic standard for EMR archive data storage called SS-MIX2. SS-MIX2 is an archive of HL7 (v2) messages transferred within hospital information systems and stored in file system folders labeled by patient ID and date. As a result, SS-MIX2 could function as a simple API for accessing the data in EMR via HL7v2 messages. In implementing FHIR endpoints, the existing SS-MIX2 standard could be utilized as a common data source, independent of any one hospital's individual database. However, given that the data within SS-MIX2 consists solely of HL7v2 messages, there is a substantial variety in the codes used and the types of messages used to store information.

As the Japanese regulatory agency (PMDA) has been accepting clinical trial data in CDISC standard format since 2016, pharmaceutical industries are now equipped to maintain their clinical trial data sets in this standard format. While standardization of source data (recorded in the case report form) is not mandated, analysis-ready datasets are typically available in the CDISC SDTM and ADAM formats for industrial trials. For academic trials, the majority of data are not standardized, especially protocols not intended for PMDA submission. Therefore, while integrating data from multiple clinical trials would be straightforward due to the elevated level of standardization, these data are typically proprietary assets of pharmaceutical companies, and are not disclosed to the public.

③ Digital Imaging and Communication in Medicine (DICOM)

DICOM is an international standard protocol and file format for storing, transmitting, and sharing medical imaging data. DICOM was developed to define a standardized format for medical imaging data and to ensure interoperability among various medical imaging devices and systems.

Table 12. Key Features of DICOM

Key Features	Contents
Medical Imaging Data Format	DICOM stores medical imaging data in a standardized format. This format can include images, videos, audio, and text data and is primarily used for storing and transmitting various medical imaging modalities, such as CT scans, MRI, X-rays, ultrasounds, and more.

Multimodality	DICOM can handle diverse types of medical imaging data. It can include various formats of images and related information within a single DICOM file, supporting various medical imaging modalities
Metadata	DICOM files include not only image data but also metadata such as patient information, acquisition conditions, device settings, and more. This metadata provides crucial information for interpreting and managing the images.
Interoperability	DICOM ensures interoperability among medical imaging devices and systems from different manufacturers. This is essential when different devices and systems need to work together and share medical imaging data in healthcare settings.
Data Transmission	DICOM also provides a protocol for securely transmitting medical imaging data. It allows medical imaging data to be transmitted to healthcare information systems such as PACS (Picture Archiving and Communication System) or RIS (Radiology Information System).

Source: The authors

DICOM is a critical tool for managing and sharing medical imaging data in a standardized format. It plays a vital role in the field of healthcare, particularly in medical diagnosis and treatment.

The DICOM standard for medical imaging data is already widely used in various fields. In the following table, we show how DICOM is utilized through a case involving a patient with an arm injury.

Table 13. How to Use DICOM Data

Step	Actions
Injury Assessment	A technical takes a scan of the patient using an X-ray or MRI machine which produces DICOM-formatted images. These images provide detailed information about the injury, allowing healthcare providers to assess the extent and nature of the damage
Image Storage	The DICOM images captured during the examination are stored on a Picture Archiving and Communication System (PACS)

Radiologist Review	A radiologist accesses the PACS system and reviews the DICOM images to assess the injury
Specialist Consultation	If the injury is complicated, the radiologist sends the image to a specialist for review. DICOM's interoperability ensures that the images can be easily shared with other healthcare professionals.
Patient Access	The patient requests a copy of their scan, so the physician sends a link to the patient via the patient portal.

Source: APEC Data Standardization Forum Presentation (7 August 2023)

4. Health Data Standardization Cooperation within APEC

In this chapter, we present a set of policy proposals designed to improve the standardization and utilization of health data in APEC member economies. A variety of options exist in the policy space to achieve this goal and describing them all here would be impossible. Instead, here we describe a plan that would help close the gap in health data standardization among APEC member economies. The narrowing of this gap will ultimately accelerate the standardization of health data and encourage high-level intra-APEC cooperation.

We analyzed contemporary trends, policies, and use cases related to data standardization and health data standardization. We confirmed increasing levels of interest in data standardization among APEC member economies, and that many individual APEC members have policies in place related to data standardization.

In addition, regarding health data standardization, it is clear that international standardization organizations are promoting diverse and dynamic activities. Some standards, such as FHIR, have been adopted in many APEC member economies. But standardization is not compulsory; adoption relies on the will and capacities of individual economies.

We know that standards are most effective and convey the most benefit when they are adopted and used on a large scale. To promote the adoption and proliferation of standards, international organizations and economies that have already established developmental data standardization systems need to continuously develop systems that are easier to use. At the same time, they should prepare measures to promote the participation of more economies.

Enhancing data standardization cooperation within APEC is an urgent matter, given that digital economies based on data are expected to rapidly develop and proliferate in the future. Considering that most economic activities are now data-driven, ensuring data interoperability among APEC member economies can make economies more efficient and innovative.

However, promoting data standardization within APEC is a challenging process, as each member economy has different circumstances, and there is no one-size-fits-all solution to address these differences. This makes intra-APEC cooperation on data standardization a matter of the utmost urgency, but we must take into account the perspectives of individual member

economies and proceed step-by-step. To achieve this, we need to see more effort at both the APEC level and in the governments of the individual member economies in parallel.

At the APEC level, there is a need to create opportunities for member economies to collaborate on data standardization and establish the necessary infrastructure and systems for practical cooperation.

Given the ongoing and rapid growth of the digital economy across APEC, several committees and WGs in digital fields have been formed. APEC established the DESG and the Sub-Committee on Standards and Conformance within the Committee on Trade and Investment to continue its efforts in digital economy and trade regional cooperation. Additionally, under the SOM Steering Committee on Economic and Technical Cooperation, the Telecommunications and Information group is consistently working to address technical issues related to the digital economy and trade.

Figure 19. Groups within APEC

Despite these efforts, discourse and action on data standardization is inactive, especially in comparison to the work being done on other data-related issues such as data protection, cross border data flows, and so on. This relative lack of activity in the data standardization arena may

be attributed to two primary factors. Firstly, rather than pursuing data standardization cooperation as a standalone item on the agenda, it often occurs within sector-specific activities and in the context of a need for data standardization in separate fields such as healthcare or industrial data. Second, it could very well be that APEC members do not consider data standardization to be an emergent issue demanding immediate attention.

Considering these realities, there is a need to raise awareness on the immediate need for active discourse on data standardization and to establish a stable and persistent discussion group that can actively drive these talks forward. We suggest the following plans of action to facilitate intra-APEC cooperation on data standardization.

First, we need to run dissemination and awareness campaigns on the importance of data standardization. These efforts could include regular seminars and conferences attended by experts and policy makers from member economies and global organizations.

Second, it is necessary to grasp the status of data standardization and identify of areas of need in each member economy. The most crucial task for deriving collaboration strategies is to understand the on-the-ground situations and capacities in individual member economies.

The third plan involves capacity building and technical support. The more advanced APEC economies can play a pivotal role in providing technical assistance, facilitating knowledge transfers, and running capacity-building programs. APEC should build a system that can enable this kind of collaboration.

The fourth plan is the establishment of a WG tasked with discussing data standardization within APEC. To pursue sustainable collaboration, it is critical that a stable, long-term discussion group be established. A WG on data standardization can provide a platform for continued activity going forward.

Fifth, APEC should promote collaboration with global standards.

Sixth, we should begin running pilot projects. The feasibility of data standardization policy proposals can be evaluated through the active participation of real business. Expanding private sector involvement is especially necessary, and pilot projects are the best way to stoke private sector participation.

To expand APEC cooperation on data standardization, efforts must be made both at the APEC level and within individual member economies. One priority should be to ensure that individual member economies have the systems and capabilities in place to pursue data standardization. With the recent proliferation of the digital economy, many member economies have established government departments or institutions dedicated to enhancing digital capabilities. These entities are augmenting the digital capacity of APEC members, which in turn contributes to economic development.

Independent new institutions or existing digital-related agencies should be given specific mandates to drive data standardization efforts. While the need for data standards is essential within specific sectors' development processes, it's equally important to set a top-level policy directions for data standardization. This involves analyzing the current status and needs of individual member economies concerning data standardization and formulating strategies to secure necessary areas and functions.

An important consideration in pursuing such policies is the need to ensure complementarity with APEC and other international organizations focused on data standardization. While individual, economy-level data standardization is an objective in itself, ultimately, for the economic development of member economies through the utilization of data on a global scale, interoperability with other systems and economies is essential. To achieve this, the direction of data standardization policies, from their inception and system development phases, should be oriented toward the adoption of internationally recognized systems.

APEC member economies exhibit a significant diversity in their digital capabilities. Some economies have already embarked on or implemented data standardization as part of their strategies, while others recognize the importance of digital transformation including data standardization, but face challenges due to limited capacity and resources. Considering the nature of the digital economy, where more connectivity and greater data utilization lead to more efficient systems, it is crucial to align with the founding goals of APEC. In this context, economies with advanced technology, capabilities, and resources should actively support and collaborate with those economies facing difficulties. This mutual assistance can contribute to the overall development and success of the digital economy within APEC.

Part II. Summary of the Dialogue

1. Executive Summary

1.1 Overview

The data standardization forum was held on 7 August 2023, in Seattle. Two main points were discussed: (1) the data standardization policies of APEC member economies and international standardization organizations, and (2) data standardization use cases. The Dialogue featured experts from the public and private sectors of member economies as well as international organizations such as ISO, HL7 and DICOM. The speakers shared policies and actively discussed practical use cases related to data standardization alongside their potential applications. APEC member economies' officials and experts in the field of data standardization were encouraged to actively participate and exchange views and experiences on government policies and measures.

The event was designed with three primary objectives in mind. First, it sought to emphasize the importance of data standardization in APEC member economies and garner momentum for data standardization initiatives within APEC by sharing policies and use cases. Second, it aimed to understand trends in data standardization within international organizations and explore ways to enhance collaboration among member economies and international organizations. The final objective of the forum was to formulate approaches for activating data standardization within APEC. The event was a success, and featured lively and productive Q&A sessions between the presenters and the participants.

1.2 Event Details

The event was organized as follows:

1) Opening Remarks
2) Keynote Speech
3) Session 1: Policies of Health Data Standardization
4) Session 2: Use Cases of Health Data Standardization

The forum was attended by 49 people from 14 APEC member economies and 3 international organizations. The following esteemed individuals spoke at the forum:

- Hong Su KIM, Senior Deputy Director, Multilateral Trade Cooperation Division, Ministry of Trade, Industry and Energy(MOTIE), Republic of Korea
- Byeong Kee YI, Professor, Department of Artificial Intelligence Convergence, Kangwon National University, Republic of Korea
- Jae Ho LEE, Associate Professor, Department of Emergency Medicine, Seoul Asan Medical Center
- Jorge PACHECO, Head, Department of Health Statistics and Information, Planning Division, Ministry of Public Health, Chile
- Priscilla Phileon CHUA, Deputy Director, National Chief Architect Office, Infocomm, Technology and Data Group, Ministry of Health, Singapore
- Charles JAFFE, Chief Executive Officer, HL7
- Todd COOPER, Chair, ISO TC 215
- Sihyun SUNG, CEO, Seoul Medical Informatics Intelligence Lab
- Masafumi OKADA, Director of Data Science, Prime Research Institute for Medical RWD
- Carolyn HULL, General Secretary, DICOM
- Markus KALLIOLA, Project Director, Health Data 2030, Sitra
- Hyeokki MIN, Research Fellow, Korea Institute for Industrial Economics & Trade

2. Background

Amidst the rapidly-evolving digital economy, adapting to the digital transformation can be a game-changer for both businesses and domestic economies. The digital economy is also increasingly referred to as the data economy, which highlights the growing importance of data. With the proliferation of digital technologies, the generation of data from digital devices has grown exponentially. Such data is being utilized as a valuable resource across various sectors of the economy, society, welfare, culture and more.

However, emphasis must be placed on the need to efficiently harness the rapid expansion of data through standardization. Data is being generated in various fields and in a diverse array of formats. Even if we possess a vast amount of data, we may lose any advantage gained from such possession if it cannot be used effectively due to its disparate formats and characteristics. Moreover, cross-border data is even more heterogeneous, underscoring the risk that data utilization may lag significantly behind its growth if such differences are not addressed.

This project recognizes this reality and explores ways within APEC to reduce inefficiencies caused by differences in data. Addressing these issues through data standardization can contribute to achieving the various objectives AIDER aims to achieve.

3. Event Summary

3.1 Opening Remark

Hong Su KIM, Senior Deputy Director, Multilateral Trade Cooperation Division, Ministry of Trade, Industry and Energy, Republic of Korea

In his opening remarks, Mr. KIM described the rapid progression of the digital transformation across the globe in the wake of COVID-19, with major economic players striving to spearhead this ongoing transformation. He emphasized the importance of both innovative competition and cooperation for the efficient utilization of data.

Mr. KIM also highlighted the importance of this dialogue when it comes to health data standardization and the public health crisis, and emphasized that applying the diverse lessons learned during the COVID-19 pandemic is crucial. Mr. KIM concluded that this dialogue serves to enable a better understanding of the importance of data standardization, and paves the way for future cooperation in health data by spurring enriched discourse on the digital economy and turning our commitments into concrete action.

3.2 Keynote Speech

Byeong Kee YI, Professor, Department of Artificial Intelligence Convergence, Kangwon National University, Korea

Professor YI is a programmer-turned academic and a standards expert with extensive experience with HL7 and ISO TC. His experience bridges theory and practice, and he addressed topics related to standardization and interoperability in healthcare data in his keynote speech.

In his keynote speech, Professor YI first addressed the absence of a standard encoding terminology, which is a critical issue in healthcare data standardization. Although the ISO is working on standards related to this issue, adoption rates are low due to the complexity of implementation. To remedy this, he emphasized the need for enhancing both technical and semantic interoperability.

Here, interoperability refers to the ability to utilize data through various systems. Professor YI explained that facilitating interoperability requires a model that integrates the technical and semantic aspects necessary for encoding data.

The technical mobility of data is related to transmission protocols, which include VIP, HTTP and HTTPS, among many others. He stressed the significant differences in the ability to interpret data transmitted and exchanged by domain, which is why efforts are underway to address this issue. In terms of terminology, the ISO has developed the ICM IDMP standard framework for drug identification. However, the complexity of this framework poses challenges to its universal adoption. HL7 introduced the FHIR standard as part of the efforts to mitigate this problem.

Finally, to improve interoperability, Professor YI emphasized the need for laws, regulations, policies, infrastructure and incentives that facilitate the safe use of data. He explained that achieving these requires active global participation.

3.3 Session 1: Policies of Health Data Standardization

Session 1 Moderator: Hyeokki MIN, Research Fellow, Korea Institute for Industrial Economics & Trade, Korea

In the first session, APEC member economies and international organizations shared data standardization policies. Participants included representatives from Chile; Korea; Singapore, HL7 and the ISO. The five presenters were:

- Mr. Jae Ho LEE, Associate Professor, Department of Emergency Medicine, Seoul Asan Medical Center
- Mr. Jorge PACHECO, Head, Department of Health Statistics and Information, Planning Division, Ministry of Public Health
- Ms. Priscilla Phileon CHUA, Deputy Director, National Chief Architect Office, Infocomm, Technology and Data Group, Ministry of Health, Singapore
- Mr. Charles JAFFE, Chief Executive Officer, HL7
- Mr. Todd COOPER, Chair, ISO TC 215

3.3.1 Presentation 1: Jae Ho LEE, Associate Professor, Department of Emergency Medicine, Seoul Asan Medical Center

Mr. LEE discussed Korea's policies related to data standardization. In his presentation, he described the rapid digital transformation occurring in the global healthcare sector, and how advancements in technologies such as big data, cloud computing and AI are improving the environment for healthcare data utilization. In Korea, there have been changes in laws and regulations related to healthcare data. Notably, the Personal Information Protection Act and the Information & Communication Network Act were amended in 2020, and the Digital Healthcare Act was proposed in 2022. Guidelines have also been established for the processing of pseudonymous information. Furthermore, as the government department responsible for health care data, the Ministry of Health and Welfare is actively undertaking projects related to healthcare data standardization. Such projects include an EMR certification project, the HIE Health Information Exchange (HIE) project and the My Healthway project.

The Korean government released its Health Data Standardization Roadmap in 2021 with a focus on healthcare data standardization. The roadmap includes initiatives such as the adoption and utilization of international terminology standards such as SNOMED-CT, the introduction and expansion of FHIR (Fast Healthcare Interoperability Resources), the dissemination of use cases and the establishment of an incentive system. Additionally, in 2022, Korea established a task force (TF) for improving interoperability through the adoption of interoperable standards, the development of a Korea-specific Clinical Document Infrastructure (CDI) and the promotion of government projects and research. Experts from academia, hospitals, industry and the government are participating in the TF.

Mr. LEE also described the following three strategies pursued by the Korean government related to healthcare data standardization: 1) the development of domestic standards to strengthen interoperability, 2) the promotion of data utilization through standards settlement & spread and 3) the establishment of sustainable standardization governance.

Despite these efforts, there remain challenges to overcome. These include deficiencies in the reward system for data utilization, limitations to the scope of what the Ministry of Health & Welfare can address and the fact that many policies are recommendations, rather than

obligations. These limitations should be addressed to further advance healthcare data utilization.

3.3.2 Presentation 2: Jorge PACHECO, Head, Department of Health Statistics and Information, Planning Division, Ministry of Public Health, Chile

Mr. PACHECO described ongoing processes and efforts in Chile to efficiently manage the vast amount of data being generated. The Ministry of Public Health in Chile manages the entire domestic healthcare system and has sought to establish a foundation for standardization, norms and the enforcement of data systems. In addition, Chile's domestic statistics agency is working on establishing an information standard system as part of the formation of a Health Information Standard Data Classification System under the auspices of the World Health Organization.

Mr. PACHECO explained how Chile's Health Information Standards Regulation, introduced in 2011, has established standards for data content. This data content includes information related to personal data, healthcare practitioner IDs and information about healthcare facilities. The regulation was revised in 2016 to define mandatory and optional sections within the standards and requires that all standards be coded. The most recent revision to the law was in 2023, when standards related to gender and race were introduced and geospatial standards incorporated.

One noteworthy point is that data standardization, which was previously pursued for statistical purposes, is evolving to contribute to interoperability amidst the accelerating digital transformation. To achieve this, there are operational departments responsible for determining process flows and business rules, statistical information departments responsible for maintaining semantic standards and data quality and IT departments responsible for building the structure and infrastructure of data, as explained.

Against this backdrop, efforts are underway to transform standards designed for statistical purposes into a comprehensive framework that enhances patient information exchange facilitation and promotes secondary data utilization.

3.3.3 Presentation 3: Priscilla Phileon CHUA, Deputy Director, National Chief Architect Office, Infocomm, Technology and Data Group, Ministry of Health, Singapore

Ms. CHUA explained that Singapore's healthcare system places a strong emphasis on preventive care and health promotion, with elderly care becoming increasingly important due to an aging population. The challenges posed by aging and the resulting increase in patients have prompted Singapore's healthcare system to pursue improvements through the utilization of data. According to the Digital Health Masterplan (DHM), the Ministry of Health's IT and Data Group underscores the strategic importance of data and prioritizes digital support. Recognizing the significance of healthcare data, they have established the Healthcare Data Standards Committee to facilitate the successful implementation of policies in this area.

The DHM has two main objectives: empowering seamless data exchanges and maximizing data as a strategic asset. The Healthcare Data Standards Committee performs four key roles pertaining to the identification, prioritization, monitoring and development of health standards. The Committee established a system that divides data standardization roles into three levels: policy, operational (ops) policy and operations. For instance, at the ops policy level, data domain working groups are formed, efforts are made to harmonize data definitions and initiatives are pursued to improve data quality and related aspects.

Singapore has established four key principles for data standardization: securing strong business driver support, scoping according to business context, prospective data standardization and facilitating adoption through source mapping. Singapore is also striving to promote data standardization as obligatory, rather than as optional, and is expanding standards beyond healthcare data to encompass various fields such as lifestyle data and long-term care.

3.3.4 Presentation 4: Charles JAFFE, Chief Executive Officer, HL7

Mr. JAFFE described some of HL7's policies and the current status of the organization. He emphasized the importance of enabling the seamless sharing of medical data among healthcare systems, research institutions and stakeholders to achieve better healthcare outcomes. He

pointed out that a lack of data-sharing systems has led to delays in diagnoses and timely treatment, highlighting the need for an environment where healthcare providers and researchers can utilize the necessary health data to facilitate patient-centered care.

Mr. JAFFE explained how HL7's FHIR standards are developed to facilitate the exchange of medical data and stressed how FHIR can address issues like data sharing, terminology, customization and version management. He underscored the importance of collaboration and partnerships between various stakeholders for the continued improvement and implementation of the FHIR standards, emphasizing the importance of collaboration with organizations such Argonaut, Da Vinci, Codex and others.

Mr. JAFFE also discussed FHIR adoption cases in Asia-Pacific economies, including the Australia; United States; and India, and explained how global healthcare systems are integrating with FHIR. He provided examples of FHIR use cases in various fields such as genomics data integration, clinical trials and AI applications. He also pointed to the need for improvements to FHIR security, and called for continued efforts to address ethical concerns related to AI in healthcare and to enhance interoperability in the medical field.

3.3.5 Presentation 5: Todd COOPER, Chair, ISO TC 215

In his remarks, Mr. COOPER also emphasized the importance of collaboration among various stakeholders for the ongoing development and implementation of healthcare standards, alongside ISO and HL7. He explained that the strategic decision to make HL7's FHIR freely available has contributed to the advancement of the global healthcare system, positively impacting patient safety, treatment quality, operational efficiency and more.

He went on to describe some ISO policies and how the ISO operates through technical committees, subcommittees, working groups, task forces and ad hoc groups to propose, develop, approve, review and revise standards. He also explained how ISO subcommittees and working groups in areas such as genomics informatics, system interoperability, semantics, security and privacy and personalized digital health collaborate with other organizations to advance standards in their respective domains.

Mr. COOPER also introduced the current status of initiatives aimed at promoting effective and safe user-centered medical technology solutions, including digital therapeutics, medical regulation apps and personalized health navigation standardization, all of which are necessary for better integrating technology into healthcare services.

3.4 Session 2: Use Cases of Health Data Standardization

Session 2 moderator: Todd COOPER, Todd Chair, ISO TC 215

In Session 2, experts shared data standardization cases and discussed ways to enhance data standardization cooperation within APEC. Representatives of APEC member economies, non-APEC economies and international organizations were present. The expert presenters were:

- Sihyun SUNG, CEO, Seoul Medical Informatics Intelligence Lab
- Masafumi OKADA, Director, Data Science, Prime Research Institute for Medical RWD
- Carolyn HULL, General Secretary, DICOM
- Markus KALLIOLA, Project Director, Health Data 2030, Sitra
- Hyeokki MIN, Research Fellow, Korea Institute for Industrial Economics & Trade

3.4.1 Presentation 1: Sihyun SUNG, CEO, Seoul Medical Informatics Intelligence Lab

Mr. SUNG presented various data utilization use cases from his research institute. He emphasized the importance of digitizing various data, including electronic medical records (EMR), and aggregating them digitally for their provision to relevant sectors. He explained that effective communication between various computer systems in healthcare institutions is necessary for this purpose.

Mr. Sung described how HL7 has introduced FHIR as guidelines to enhance this kind of communication, and highlighted that it has improved flexibility and adaptability between

various systems. The more efficient operation of FHIR can be achieved through standardization of data formats, elements and APIs.

His outfit, Seoul Medical Informatics Intelligence Lab (SMIL), introduced an approach that utilizes deep learning technology for structuring unstructured data contained in medical records. Mr. SUNG then presented an EMR localization framework used in this context. Through this structuring process, medical texts can be accurately interpreted, providing valuable insights to clinical professionals.

The EMR localization framework used by SMIL can recognize data instances, entities, locations, dates and values, and categorize them according to FHIR standards. This approach improves the scalability and accuracy of medical data labeling through deep learning techniques.

3.4.2 Presentation 2: Masafumi OKADA, Director, Data Science, Prime Research Institute for Medical RWD

Mr. OKADA described rapid improvements to the computerization of medical records, diagnoses, procedures and more in Japan. He said that in the process of this computerization, the use of standard codes based on virtual predictive coding is important for standardization, which reduces format variations between data sets.

Medical records in Japan are categorized into administrative claim data, EMR and clinical trial data. Administrative claim data is currently being standardized using domestic codes. Diagnosis, prescription and injection-related data have been standardized in EMR (primarily at large hospitals), but standardization in other areas has not made significant progress. Clinical trial data collected from various formats is converted into CDISC tables for submission to Japan's medical regulator, the Pharmaceuticals and Medical Devices Agency (PMDA). The original data from case report forms is collected in various formats and manually converted to the standard CDISC format by data managers.

Recently, some hospitals have implemented the Diagnosis Procedure Combination (DPC) system for administrative claims. Hospitals participating in the DPC system are required to

report diagnoses based on domestic standard classifications. The new system provides more detailed and standardized information compared to the old one, but it still emphasizes the use of domestic standard formats for reporting diagnoses.

The challenges related to health data standardization in Japan include the use of domestic standard codes and the lack of EMR standardization. To address these issues, there is a need to establish a mapping system between domestic codes and international standards. This would allow for the integration of Japanese health data with global standards, providing a more interoperable and standardized approach to healthcare data management.

3.4.3 Presentation 3: Carolyn HULL, General Secretary, DICOM

Ms. HULL described the current status of DICOM, the standardization body for medical imaging, transmission, storage and printing. DICOM plays a crucial role in standardizing images generated from X-rays, MRIs, ultrasounds and more, as well as providing context-based interpretation through metadata associated with these image data. DICOM also offers network communication protocols to ensure interoperability between systems and facilitates the frictionless exchange of data among public institutions, healthcare professionals and patients themselves.

DICOM undergoes an update process five times a year to incorporate new technologies into its standard regime. It actively collaborates with manufacturers, software developers, users and other stakeholders to conduct these updates openly and transparently. DICOM also works in collaboration with international standardization bodies such as HL7 and ISO as well as government agencies to ensure the universality and openness of the generated data, making it seamlessly integrable with other EMR systems.

With the explosive growth of data and the introduction of AI into healthcare, the future of digital standardization in the medical system is expected to evolve significantly. DICOM is actively focusing on compression technologies to adapt to the changing landscape and aims to establish a sustainable data standardization regime while maintaining consistency with existing systems.

3.4.4 Presentation 4: Markus KALLIOLA, Project Director, Health Data 2030, Sitra

Mr. KALLIOLA outlined the key concepts of the European Health Data Space (EHDS). EHDS is a comprehensive effort within the EU to establish a standardized foundation for the exchange and sharing of health data, with the goal of improving accessibility to personal health records and various medical data while enhancing interoperability. EHDS aims to develop and implement technologies and standards that enable the effective sharing and linking of medical data across the EU, including various healthcare systems and health information records.

EHDS is proposed within the framework of the European Health Data Space Regulation (EHDSPR), which aims to facilitate utilization of the cross-border health data, including the enforcement of standardized data formats for cross-border healthcare services, such as patient summaries, prescription data and imaging data, etc. Electronic Health Record (EHR) systems should adopt common exchange formats, and there is a need to establish standardized processes for accessing data for secondary research purposes, such as the development of AI algorithms.

Mr. KALLIOLA also described the decentralized system adopted in Finland that aligns with individualized healthcare data, and how Finland is standardizing the data access process for research purposes, including the use of secondary health data. The economy operates a one-stop shop called FinData to manage permissions for accessing all healthcare and social data. Researchers who obtain permission can collect and process data remotely, eliminating the need for individual data management. This streamlines and simplifies procedures and ensures transparency in determining fee pricing.

3.4.5 Presentation 5: Hyeokki MIN, Research Fellow, Korea Institute for Industrial Economics & Trade

Mr. MIN described the importance of the data economy and pointed out that within APEC, standardization activities related to data seem to be lagging compared to other fields. While it may be challenging to establish a single system due to the digital disparity within APEC, he argued that we should start now to achieve enhanced data utilization through data

standardization.

To enhance data standardization cooperation within APEC, Mr. MIN proposed the following: 1) the establishment of a Working Group specialized in data standardization, 2) collaboration between global organizations specializing in data standardization and 3) the implementation of pilot projects related to data standardization.

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