Survey on HL7 FHIR

Final Report

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Fujitsu Research Institute

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Background and objectives of the survey

(1) Background of the survey

- Currently, in the field of health information in Japan, the standards for health information exchange established by the Ministry of Health, Labour and Welfare (MHLW) are based on international standards such as HL7 version 2.5 and HL7 CDA release 2. By utilizing these standards, health information is exchanged in a variety of ways, such as intra-institutional medical examinations, ordering of prescriptions, tests, accounting, etc., and regional medical cooperation among medical institutions.
- HL7 version 2.5, which is the basis of the existing standard in Japan, was established 16 years ago. HL7 version 3, was established as a successor standard in 2005, but it has become too complex to implement, which makes it difficult to implement with modern web technologies.
- In other countries, HL7 FHIR (Fast Healthcare Interoperability Resource) as a new standard has attracted attention as a quickly implementable resource model that is structurally generally compatible and can be coordinated using popular information technologies.

(2) Objectives

The objectives of this survey were to identify challenges that would arise if the standard were to be applied in Japan, and action items need to be taken in the future when considering HL7 FHIR as a next-generation standard for health information exchange by surveying the current status of development of HL7 FHIR standard specification and advanced cases of HL7 FHIR in other countries.

1. What is HL7 FHIR?

Overview of the HL7 FHIR features

- The next generation standard framework for health information exchange which was created by HL7 International.
- Based on the HL7 International standards, HL7 version 2 and HL7 version 3, and the excellent features of the Clinical Document Architecture (CDA), the new document was developed based on the modern web technologies and focused on ease of implementation.
- It is designed to enable the exchange of healthcare-related information, including medical records and other data, as well as data on healthcare-related administrative tasks, public health, and research data.
- It covers both human medicine and veterinary medicine and is intended to be used worldwide in a wide variety of settings including inpatient and outpatient care, acute care, convalescent care, and community medicine.

FHIR: Fast Healthcare Interoperability Resources

- **By adopting popular web technologies and using standards that emphasize implementation, services can be launched in a short time**
  - **Interoperability can be ensured by using information from existing health information systems (the core of digital health policy in the U.S. is to "promote interoperability")**
    - **It defines a small logically independent unit of data exchange called a "Resource" and its API specifications**

Source: Compiled by Fujitsu Research Institute from HL7 Japan materials

Why FHIR is better?

Easy to implement

- Concise and understandable specifications, human-readable data format, fast and easy to implement.
- Presently, HL7 International has published the specification and its free of charge to use.
- Adopted RESTful API method, which is widely used in web applications for PCs and smartphones.
- Support for RESTful architecture, seamless information exchange using messages or documents, and service-based architecture
- Adopted or recommended XML, JSON, HTTP, OAuth, etc.
- Basic resources can be used as they are, and can be tailored to meet local requirements with profiles, extensions, glossaries, etc.

Active implementation community

- Many implementation libraries and examples are available to start development immediately.
- In addition to the extended specifications, various documents, development frameworks, implementation libraries, etc. are available to support implementers.

Only necessary data can be extracted and used from accumulated data in existing formats

- It has been evolved from HL7 version 2.x and CDA, and the mapping and implementation strategies are presented so that it can coexist with the older standards and can be used mutually. (However, each case has its own challenges.

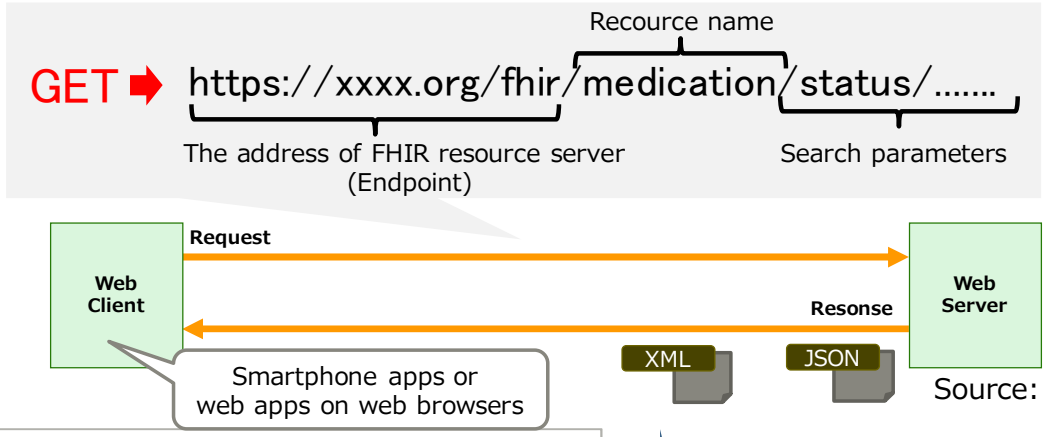
FHIR's features based on modern web technology are actively used in other countries.

Benefits of RESTful API based FHIR API

(1) Benefits of RESTful API

It is expected to contribute to the expansion of applicability from health information exchange based on "document exchange" (document-centric) to use-cases where health data are used for secondary purposes as needed.

- HL7 FHIR's core technology is based on RESTful API, which is easier to develop and allows for more flexible data retrieval than APIs based on SOAP technologies.
- It takes the traditional methods (called "paradigms" in FHIR) such as Messages, Documents, and Services and makes them available in a resource REST-style API. (in FHIR, it's called the paradigm) can be expressed as an API in the resource and REST format.



Source: HL7 International、HL7 Japan

RESTful is the architectural style for distributed hypermedia systems with the following characteristics:

- ✓ Uniformed Interface (Use HTTP methods: POST/GET/PUT/DELETE, etc.)
- ✓ Addressability (Utilize resource data on Web servers at its URI)
- ✓ Stateless (No need for servers to manage the status of the connected clients) suitable for distributed processing with multiple servers, mobile access.)
- ✓ Mainly, data format of resources are JSON or XML.

REST APIs are:

- ✓ Mainstream architecture of modern web services
- ✓ Accessible by Web browser (complex middleware or configuration are not required)
- ✓ Flexible to specifying and retrieve necessary data (elements of resource data).(no need to obtain the entire document or the entire data structure in the format specified by the originator.)

Benefits of the FHIR API based on RESTful API technology

(2) Comparison with the conventional cooperation method

■ The RESTful API (FHIR) has advantages over messaging or document-based collaboration methods in terms of ease of implementation and, ability to deploy resources for multiple purposes.

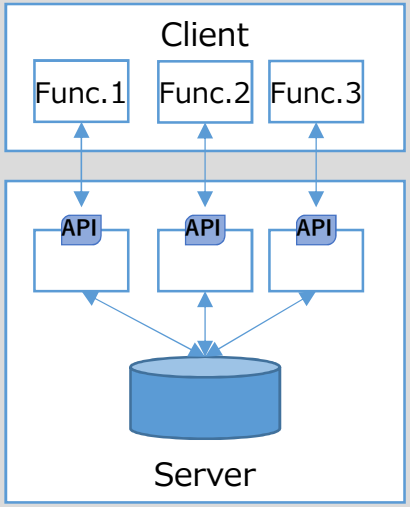
Conventional linkage methods

Document-Centric Approach

Some existing paper-based documents are defined as digital formats and exchange them by file-transferring or attaching to messages.
(A document may be utilized for multi purposes, however, it is mostly used for one purpose and many documents containing duplicate content have been produced for different purposes.)

Implementation with conventional linkage methods

- Data access needs to be built while checking the API specification of the server to which data is accessed with a test application.
- Both client side and server side need to implement APIs for different purposes.
- HL7 v3 is relatively complex and difficult to implement.



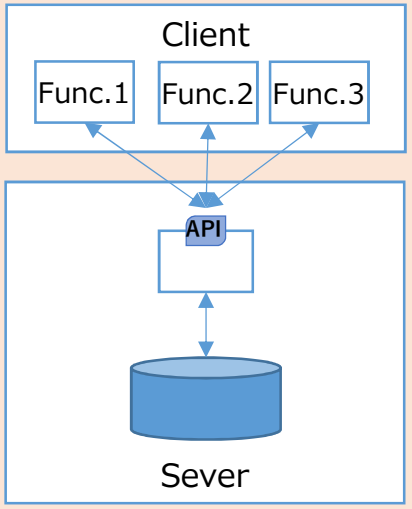
RESTful API(FHIR)

Transaction/API-Centric Approach

Instead of defining and sharing data as a document, information is defined as a module and shared by specifying only the information items necessary for business context.
The shared items can be utilized and displayed at client side.
(The side that shares the data only manages it according to the shared specifications, and the side that uses the data, regardless of the circumstances of the side that shares the data, simplifies the coordination specifications and testing methods, and secures the degree of freedom).

Implementation with FHIR (RESTful API)

- ✓ Development of client apps are relatively easy because the specifications of the API can be easily confirmed with web browsers and sandbox environment can be utilized.
- ✓ By preparing “resources” based on general implementation guide, API structure can be designed simply (A “resource” can be utilized multi-purpose.)
- ✓ Since RESTful API is more flexible than SOAP, unifying the specifications and implementation rules is a challenge.
  FHIR meets this challenge by defining clear specifications and rules related to collaboration in medical scenario with flexibility.



Source: Fujitsu Research Institute

Overview of the HL7 FHIR Specifications

(1) Basic components

■ The FHIR defines “resources” as “small, logically independent units of data exchange” and APIs as key components in the basic specification.
The basic frame, including the specific methods required for implementation, is presented and easy to implement.

Resource:

- All exchangeable content is defined as resources
- Expressing an abstract concept about healthcare
  (The entities involved (patient, physician, care team, device, etc.) and the information to be recorded and managed (clinical information, diagnostic information, medications, etc.)
- Behaviour and meaning of the resources are defined.
- Uniquely identifiable by the Uniform Resource Identifier (URI)
- Defined in general web technologies such as XML and JSON (JavaScript Object Notation)
- Developed under the 80/20 rule, meaning resources that exist in FHIR cover 80 percent of needs and the remaining 20 percent are specific use cases that can be dealt with as FHIR extensions.
- Actively referring to and reusing other general specifications, glossaries, etc.

API (Application Programming Interface):

- Accepting requests for processing of information coordination between medical information systems or other systems
- Positioning REST (Representational State Transfer) API as the core technology
  (It is possible to retrieve, update, create and delete resources, retrieve resource metadata and get the methods supported by the resource.

Source：HL7 International

Overview of the HL7 FHIR Specifications

(2) Process and level of FHIR specification development (1/2: The standard Level)

Standard Level	Description
Draft	This portion of the specification is not considered to be complete enough or sufficiently reviewed to be safe for implementation. It may have known issues or still be in the "in development" stage. It is included in the publication as a place-holder, to solicit feedback from the implementation community and/or to give implementers some insight as to functionality likely to be included in future versions of the specification. Content at this level should only be implemented by the brave or desperate and is very much "use at your own risk". The content that is Draft that will usually be elevated to Trial Use once review and correction is complete after it has been subjected to ballot.
Trial Use	This content has been well reviewed and is considered by the authors to be ready for use in production systems. It has been subjected to ballot and approved as an official standard. However, it has not yet seen widespread use in production across the full spectrum of environments it is intended to be used in. In some cases, there may be documented known issues that require implementation experience to determine appropriate resolutions for. Future versions of FHIR may make significant changes to *Trial Use* content that are not compatible with previously published content. The content is managed with FHIR Maturity Model (FMM).
Normative	This content has been subject to review and production implementation in a wide variety of environments. The content is considered to be stable and has been 'locked', subjecting it to FHIR Inter-version Compatibility Rules. While changes are possible, they are expected to be infrequent and are tightly constrained.
Informative	This portion of the specification is provided for implementer assistance and does not make rules that implementers are required to follow. Typical examples of this content in the FHIR specification are tables of contents, registries, examples, and implementer advice.
Deprecated	This portion of the specification is outdated and may be withdrawn in a future version. Implementers who already support it should continue to do so for backward compatibility. Implementers should avoid adding new uses of this portion of the specification. The specification should include guidance on what implementers should use instead of the deprecated portion.

Source：HL7 International http://hl7.org/fhir/versions.html#std-process

Overview of the HL7 FHIR Specifications

(2) Process and level of FHIR specification development (2/2: FHIR Maturity Model/FMM)

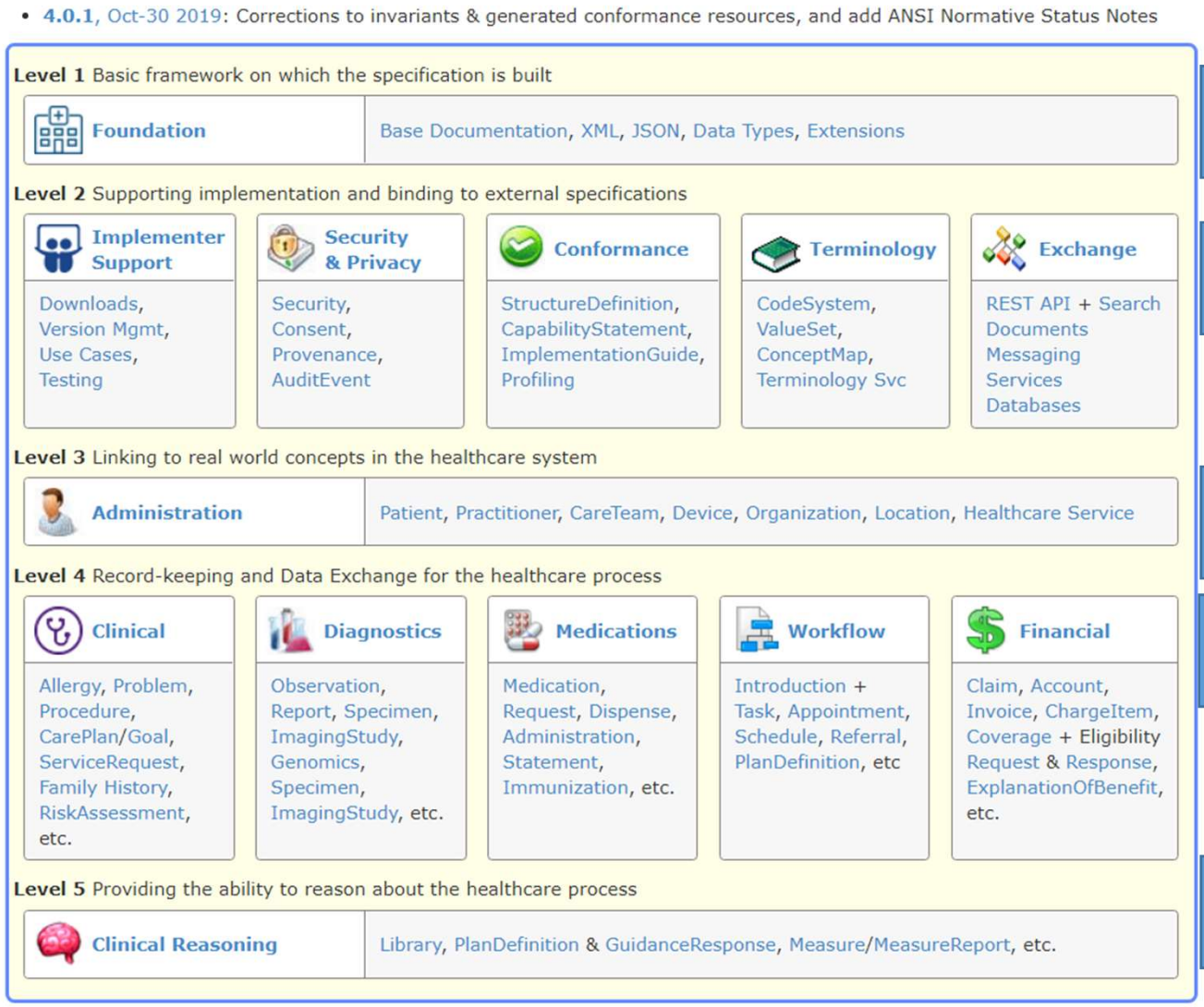
Level	Description
Draft (0)	the resource or profile (artifact) has been published on the current build. This level is synonymous with Draft
FMM 1	PLUS the artifact produces no warnings during the build process and the responsible WG has indicated that they consider the artifact substantially complete and ready for implementation. For resources, profiles and implementation guides, the FHIR Management Group has approved the underlying resource/profile/IG proposal
FMM 2	PLUS the artifact has been tested and successfully supports interoperability among at least three independently developed systems leveraging most of the scope (e.g. at least 80% of the core data elements) using semi-realistic data and scenarios based on at least one of the declared scopes of the artifact (e.g. at a connectathon). These interoperability results must have been reported to and accepted by the FMG
FMM 3	PLUS + the artifact has been verified by the work group as meeting the Conformance Resource Quality Guidelines ; has been subject to a round of formal balloting; has at least 10 distinct implementer comments recorded in the tracker drawn from at least 3 organizations resulting in at least one substantive change
FMM 4	PLUS the artifact has been tested across its scope (see below), published in a formal publication (e.g. Trial-Use), and implemented in multiple prototype projects. As well, the responsible work group agrees the artifact is sufficiently stable to require implementer consultation for subsequent non-backward compatible changes
FMM 5	the artifact has been published in two formal publication release cycles at FMM1+ (i.e. Trial-Use level) and has been implemented in at least 5 independent production systems in more than one country
Normative	the artifact is now considered stable

Source: HL7 International http://hl7.org/fhir/versions.html#std-process

Overview of the HL7 FHIR Specifications

(3) The hierarchy and modules of FHIR specification

- HL7 FHIR specification defines various resources and APIs, etc. as necessary for implementation. (The specification system is organized by hierarchy and each module (classification unit), and necessary resources and related materials are developed and organized)



Level 1
Basic Framework on which the FHIR specification is built

Level 2
Supporting implementation and binding to external specifications

Level 3
Linking Medical Information Systems and Real World Concepts

Level 4
Record-keeping and Data Exchange for the healthcare processes

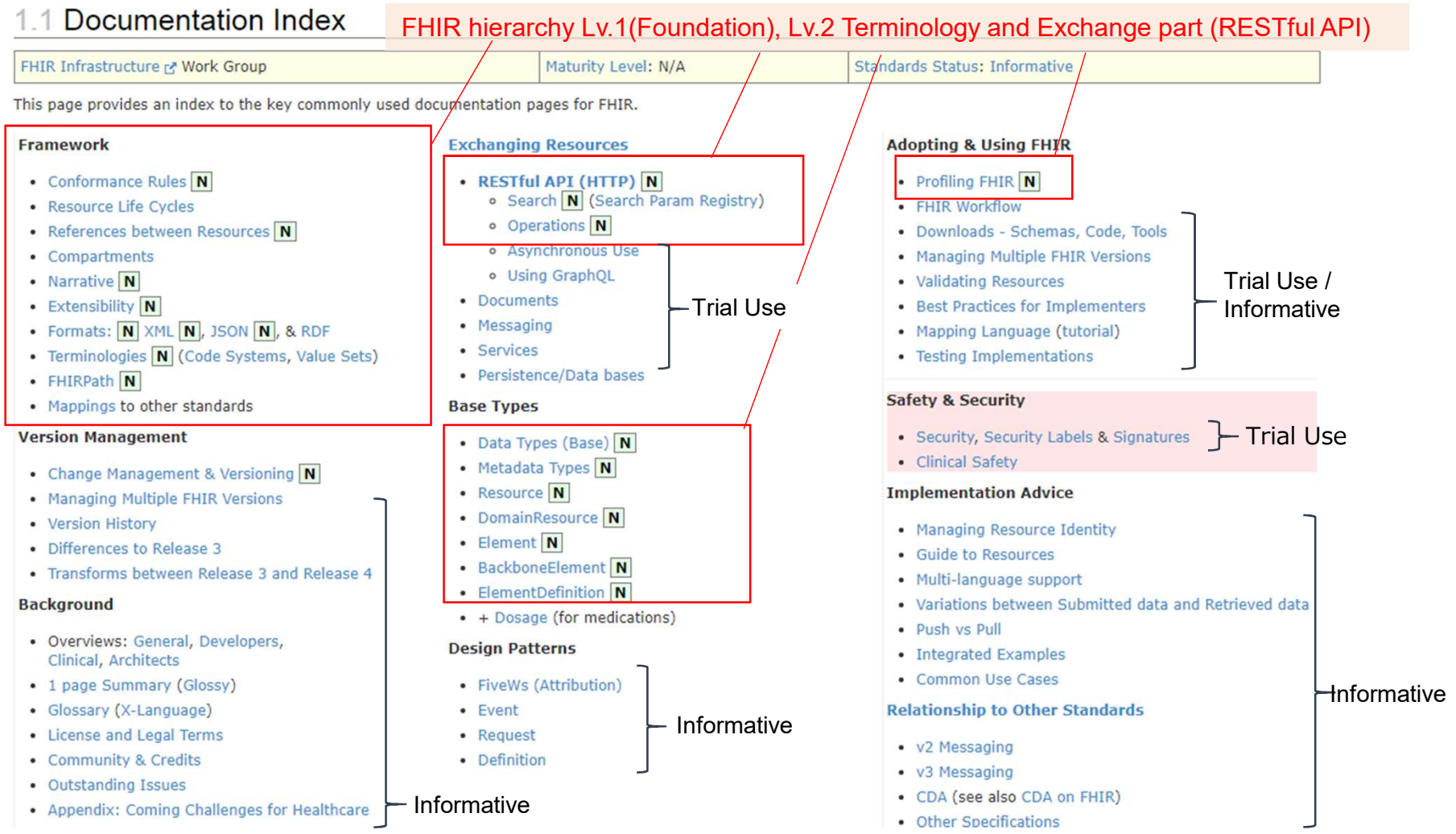
Level 5
Providing the ability to reason about the healthcare process

Source: HL7 International http://hl7.org/fhir/

Overview of the HL7 FHIR Specifications

(4) FHIR documentation system and standardization levels

- Current version is Release 4 (the first release with normative content)
- The standardization level of the specifications regarding REST API development and the basic data types used for exchanging health information (in red boxes) is **N** normative.

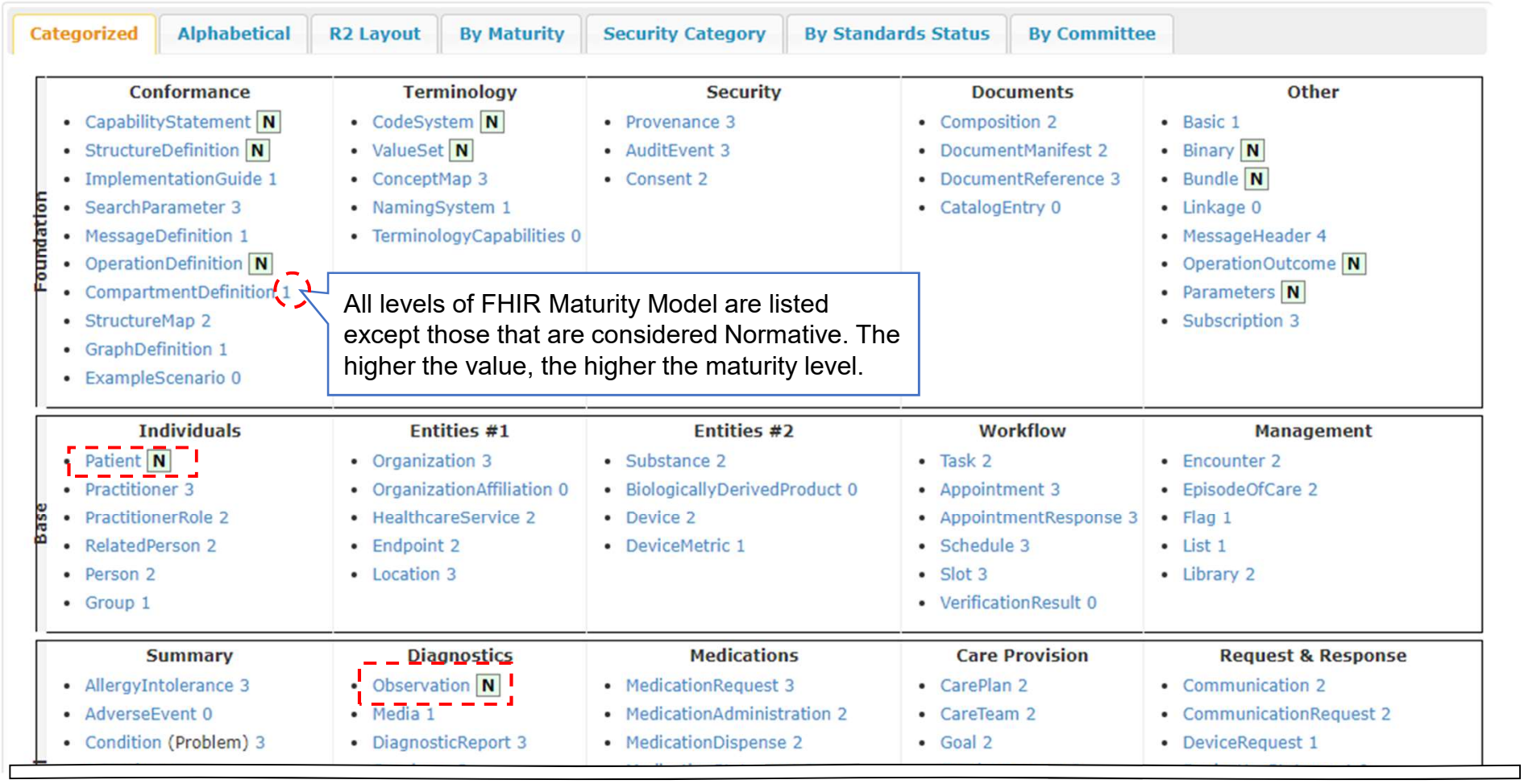


Source: HL7 International http://hl7.org/fhir/documentation.html

Overview of the HL7 FHIR Specifications

(5) Status of Resource Specification Development in FHIR

- Only “Patient” and “Observation” are Normative status and other resources are still in Trial Use status.



Source: HL7 International https://www.hl7.org/fhir/resourcelist.html

Overview of the HL7 FHIR Specifications

(6) Elements of Resource (Example from Patient Resources)

- Defines the elements of each resource. Each element specifies the composition by Flags and Cardinality.
- In order to be Normative, it is assumed that each item of data type and external reference code system in FHIR specification Lv.1 and Lv.2 used should be also stable status

Defined in various formats

Data structure

Flags: Key flag
N:Normative (TU: Trial Use/ D: Draft)、Σ: elements that are part of the set, S: elements that must be supported, ?!: a qualifier with a Boolean value (0 or 1), I: an element that defines or is affected by a constraint

Card.: Cardinality
(0...1: none or one, 0...*: none to any number, 1...1: required and one only) *: none to any number of, 1...1: mandatory and only one)

1.2 Resource Content

Structure | UML | XML | JSON

Structure

Name	Flags	Card.	Type	Description & Constraints
Patient	N		DomainResource	Information about an individual or animal receiving health care services Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	An identifier for this patient
active	?! Σ	0..1	boolean	Whether this patient's record is in active use
name	Σ	0..*	HumanName	A name associated with the patient
telecom	Σ	0..*	ContactPoint	A contact detail for the individual
gender	Σ	0..1	code	male | female | other | unknown AdministrativeGender (Required)
birthDate	Σ	0..1	date	The date of birth for the individual
deceased[x]	?! Σ	0..1		Indicates if the individual is deceased or not
deceasedBoolean			boolean	
deceasedDateTime			dateTime	
address	Σ	0..*	Address	An address for the individual
maritalStatus		0..1	CodeableConcept	Marital (civil) status of a patient MaritalStatus (Extensible)
multipleBirth[x]		0..1		Whether patient is part of a multiple birth
multipleBirthBoolean			boolean	
multipleBirthInteger			integer	
photo		0..*	Attachment	Image of the patient
contact	I	0..*	BackboneElement	A contact party (e.g. guardian, partner, friend) for the patient *+ Rule: SHALL at least contain a contact's details or a reference to an organization*
relationship		0..*	CodeableConcept	The kind of relationship Patient Contact Relationship (Extensible)
name		0..1	HumanName	A name associated with the contact person
telecom		0..*	ContactPoint	A contact detail for the person
address		0..1	Address	Address for the contact person
gender		0..1	code	male | female | other | unknown

The Gender Code needs to be based on the FHIR's AdministrativeGender. (Required)
*Elements such as biological sex and sex at birth can be added as extension of basic specification referring to healthcare glossary / codes such as the SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms) and LOINC (Logical Observation Identifier Names and Codes)

Source： HL7 International https://www.hl7.org/fhir/patient.html

Overview of the HL7 FHIR Specifications

(7) Resource definition (Example from Medication Resource)

■ On HL7 International's FHIR website, each resource is finely and logically defined with the following structure.

Summary: Resource name, maturity level, etc.

11.5 Resource Medication - Content

Pharmacy Work Group	Maturity Level: 3	Trial Use	Security Category: Business	Compartments: Not linked to any defined compartments

This resource is primarily used for the identification and definition of a medication for the purposes of prescribing, dispensing, and administering a medication as well as for making statements about medication use.

Scope and Usage

11.5.1 Scope and Usage

Representing medications in the majority of healthcare settings is a matter of identifying an item from a list and then conveying a reference for the item selected either into a patient-related resource or to other applications. Additional information about the medication is frequently provided for human verification, but a full representation of the details of composition and efficacy of the medicine is conveyed by referring to drug dictionaries by means of the codes they define. There are some occasions where it is necessary to identify slightly more detail, such as when dispensing a package containing a particular medication requires identification both of the medicine and the package at once. There are also some occasions (e.g. custom formulations) where the composition of a medicine must be represented. In these cases, the ingredients of the medicine have to be specified together with the amount contained, though the Medication resource does not provide full details.

The Medication resource allows for medications to be characterized by the form of the drug and the ingredient (or ingredients), as well as how it is packaged. The medication will include the ingredient(s) and their strength(s) and the package can include the amount (for example, number of tablets, volume, etc.) that is contained in a particular container (for example, 100 capsules of Amoxicillin 500mg per bottle).

The Medication resource can be used to describe a compounded (aka extemporaneous or magistral) product that is manufactured by the pharmacy at the time of dispensing. In this case there will be multiple ingredients which are typically base chemicals (for example, hydrocortisone powder) and there may be other ingredients that are manufactured products (for example, Glaxal Base).

When a medication includes a package, further details about the composition can be provided. A package has a container (vacuum packed box, jar, etc.) and a list of the products or other packages that are in the package.

This resource is referenced by ActivityDefinition, AdverseEvent, CarePlan, CatalogEntry, ChargeItem, ChargeItemDefinition, Flag, Group, itself, MedicationAdministration, MedicationDispense, MedicationKnowledge, MedicationRequest, MedicationStatement, MedicinalProductContraindication, MedicinalProductIndication, MedicinalProductInteraction, MedicinalProductUndesirableEffect, Procedure, SupplyDelivery and SupplyRequest

Resource content: detailed data structures

11.5.2 Resource Content

Structure | UML | XML | JSON | Turtle | R3 Diff | All

Structure

Name	Flags	Card.	Type	Description & Constraints
Medication	TU		DomainResource	Definition of a Medication Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	Business identifier for this medication
code	Σ	0..1	CodeableConcept	Codes that identify this medication SNOMED CT Medication Codes (Example)
status	?! Σ	0..1	code	active | inactive | entered-in-error Medication status codes (Required)
manufacturer	Σ	0..1	Reference(Organization)	Manufacturer of the item
form		0..1	CodeableConcept	powder | tablets | capsule + SNOMED CT Form Codes (Example)
amount	Σ	0..1	Ratio	Amount of drug in package
ingredient		0..*	BackboneElement	Active or inactive ingredient
item[x]		1..1		The actual ingredient or content
itemCodeableConcept			CodeableConcept	
itemReference			Reference(Substance | Medication)	
isActive		0..1	boolean	Active ingredient indicator
strength		0..1	Ratio	Quantity of ingredient present
batch		0..1	BackboneElement	Details about packaged medications
lotNumber		0..1	string	Identifier assigned to batch
expirationDate		0..1	dateTime	When batch will expire

Documentation for this format

Terminology: definition of the terms and vocabulary used

11.5.2.1 Terminology Bindings

Path	Definition	Type	Reference
Medication.code	A coded concept that defines the type of a medication.	Example	SNOMEDCTMedicationCodes
Medication.status	A coded concept defining if the medication is in active use.	Required	Medication Status Codes
Medication.form	A coded concept defining the form of a medication.	Example	SNOMEDCTFormCodes

Best practices: scenario examples of using this resource

11.5.3 Best practices for using 'Medication'

Medication does not have a status. If Medication was used to support a formulary use case, then an extension can be used to convey formulary statuses, such as active (e.g. the medication can be ordered) or inactive (e.g. the medication can be documented, but not ordered). Pharmacy is evaluating formulary use cases. Feedback is encouraged to the Pharmacy working group.

Search Parameters: Searching with the RESTful API parameter

11.5.4 Search Parameters

Search parameters for this resource. The common parameters also apply. See Searching for more information about searching in REST, messaging, and services.

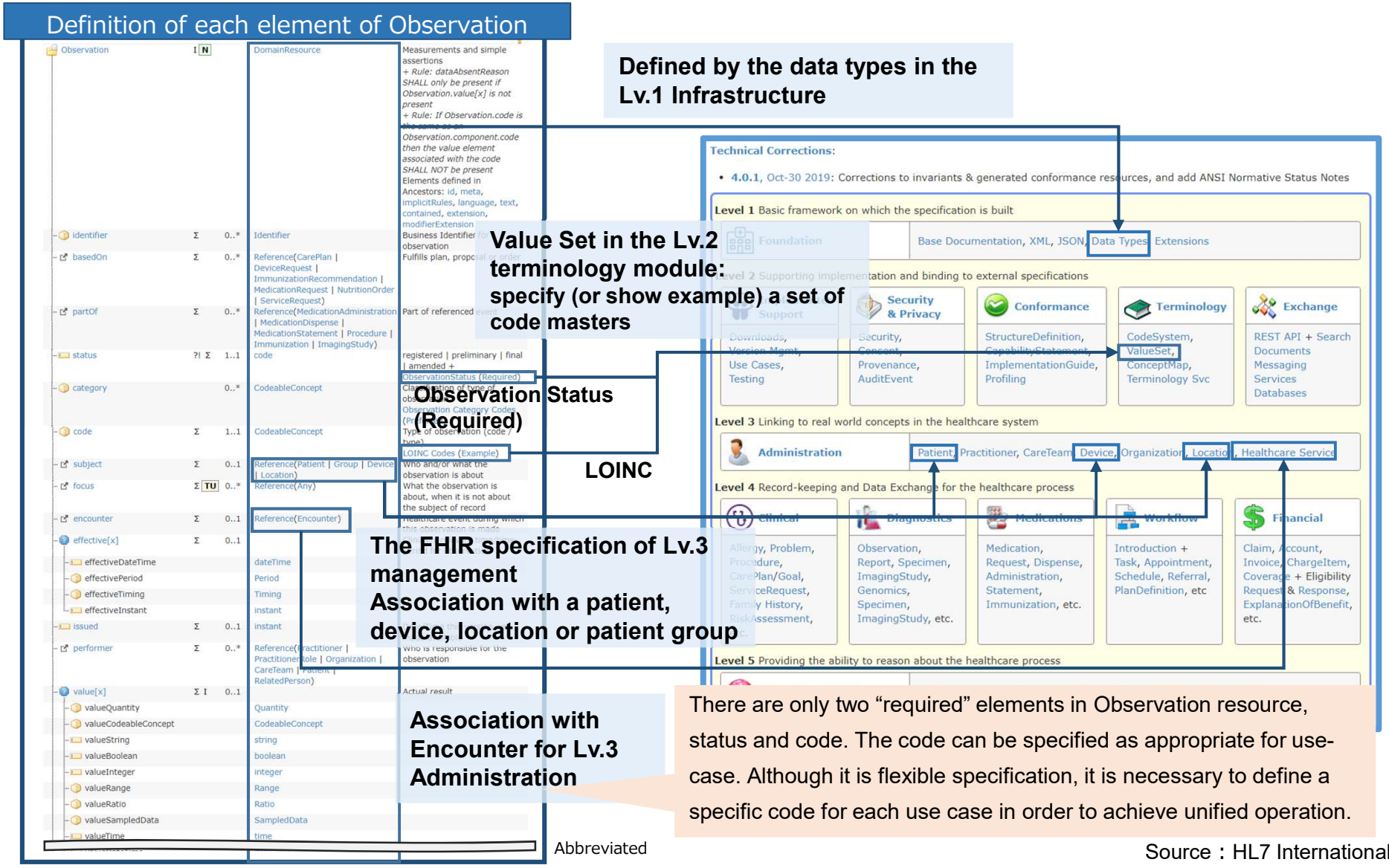
Name	Type	Description	Expression	In Common
code	token	Returns medications for a specific code	Medication.code	13 Resources
expiration-date	date	Returns medications in a batch with this expiration date	Medication.batch.expirationDate	
form	token	Returns medications for a specific dose form	Medication.form	
identifier	token	Returns medications with this external identifier	Medication.identifier	
ingredient	reference	Returns medications for this ingredient reference	(Medication.ingredient.item as Reference) (Medication, Substance)	
ingredient-code	token	Returns medications for this ingredient code	(Medication.ingredient.item as CodeableConcept)	
lot-number	token	Returns medications in a batch with this lot number	Medication.batch.lotNumber	
manufacturer	reference	Returns medications made or sold for this manufacturer	Medication.manufacturer (Organization)	
status	token	Returns medications for this status	Medication.status	

Source： HL7 International http://hl7.org/fhir/medication.html

Overview of the HL7 FHIR Specifications

(8) Relationship between Lv.4 resources and Lv.1-3 resources (Observation) (1/2)

- The specification of each element of Observation, which is hierarchy Lv.4 of the Lv.4 of the FHIR specification, consists of resources from Lv.1 to Lv.3 resources.

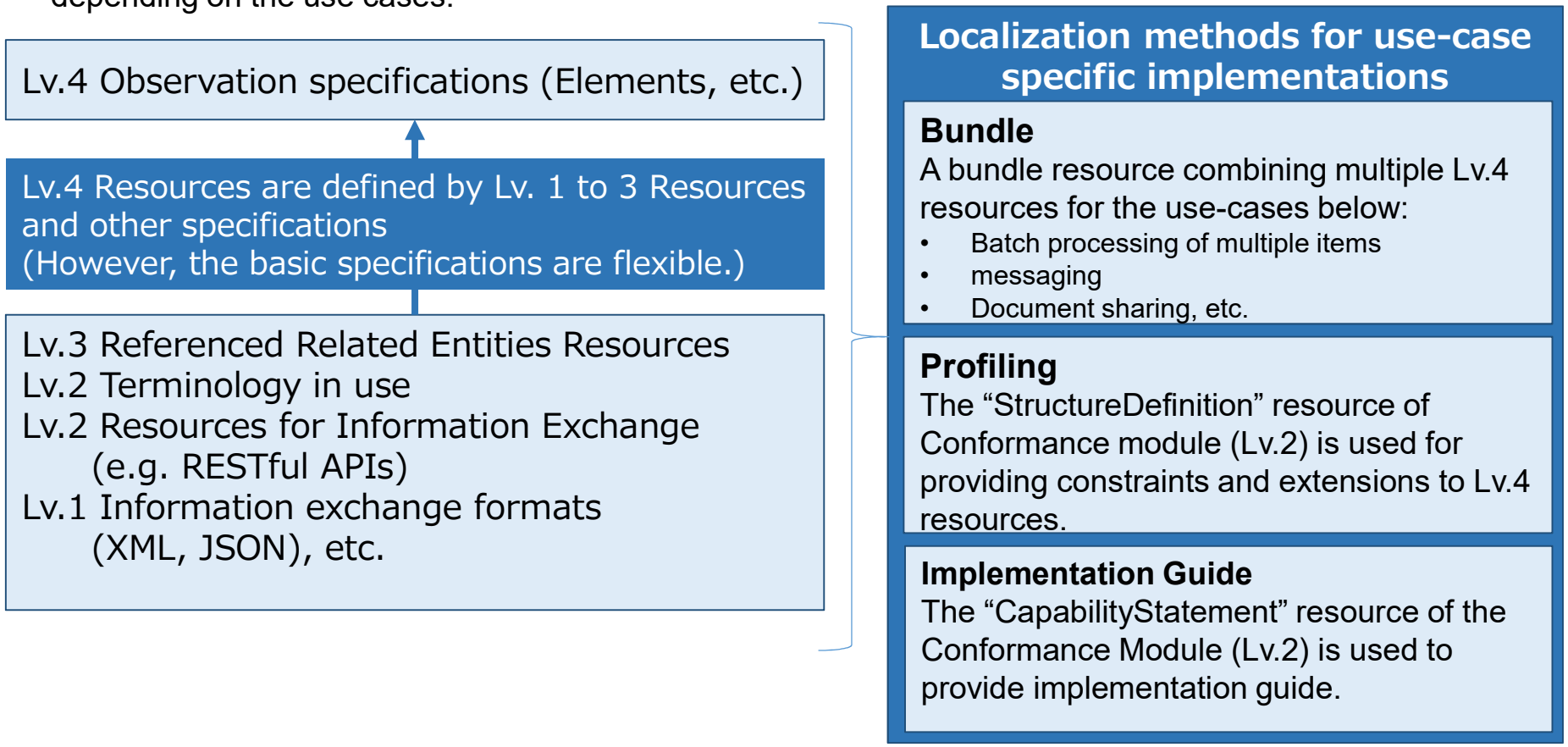


Source：HL7 International

Overview of the HL7 FHIR Specifications

(8) Relationship between Lv.4 resources and Lv.1-3 resources (Observation) (2/2)

- FHIR defines generic specification, and much of the content of Lv.4, as defined by each resource and others in Lv.1-3, is less restrictive.
- To the extent that it is used in cooperation within individual medical institutions or between specific medical institutions, it is easy to implement by deciding on and operating rules from basic specifications.
- When unspecified number of users access open APIs, etc., it is necessary to specify the content of Lv.1-3 specifically for each user, and to further define and publish restrictions such as making them mandatory and extensions to specify additional items. (e.g., profiles, implementation guides, etc.) Note that there may be issues to be considered, such as taking into account existing efforts, existing standards, and legal systems, depending on the use cases.



Overview of the HL7 FHIR Specifications

(9) Bundle, Profile, and Implementation Guide (1/2)

- Since the FHIR specification is a general-purpose specification and is developed under the “80/20 rule”, profiles or implementation guide needs to be defined as a means of localization in order to be used in specific use cases and to properly share health information.

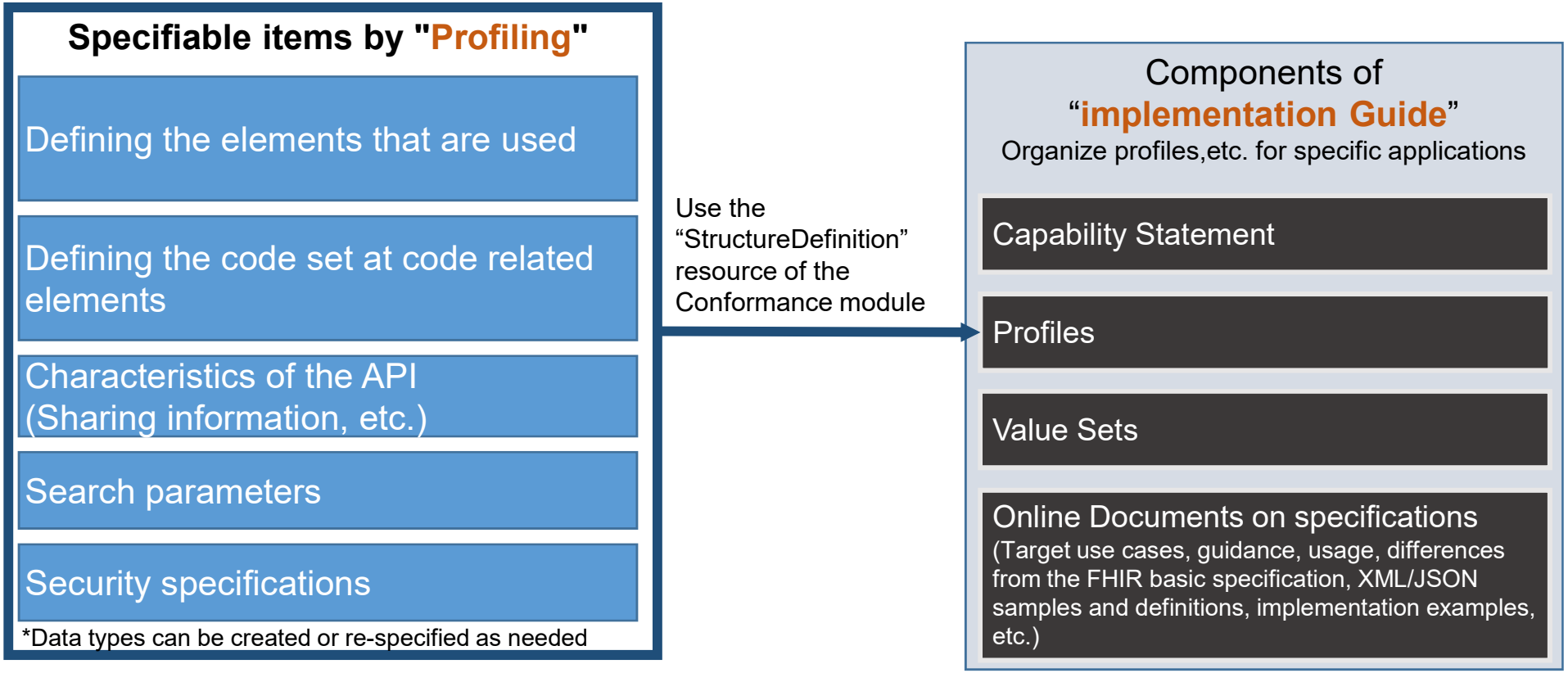
Resource	Bundle	Profile	Implementation Guide
• The smallest unit of information for the exchange of health information • Extension elements can be defined and implemented in addition to standard data elements by profiling	• Used for processing health information using a collection of multiple resources in a single exchange Example of use: • To request a set of resources for processing • To provide information based on old standards such as Document and Message, etc.	• To apply restrictions and extensions to the basic FHIR specification (e.g., resources), which is a general-purpose specification, in order to adapt it to the specific requirements of a particular country/region or use case. • You can extend the elements in individual resources. • In addition, constraints such as values and multiplicity specification of individual elements can be strengthened, and prerequisite codes and glossaries can also be specified.	• A compilation of a series of related profiles. • A collection of documentation describing how the FHIR API provides functionality to support a specific use case. (equivalent to an API specification)

Source: Fujitsu Research Institute based on HL7 International website

Overview of HL7 FHIR Specifications

(9) Bundle, Profile, and Implementation Guide (2/2)

- The restrictions and extensions to individual resources are defined as profiles.
- In the implementation guide, descriptions related to the terminology, such as the collection of profiles and the code system used, will be organized as a “Capability Statement” for localization such as the specification of the most appropriate one in each country.
  A set of documents to be published on the Web will also be prepared.



Source: Fujitsu Research Institute based on HL7 International website

(10) FHIR security and access control

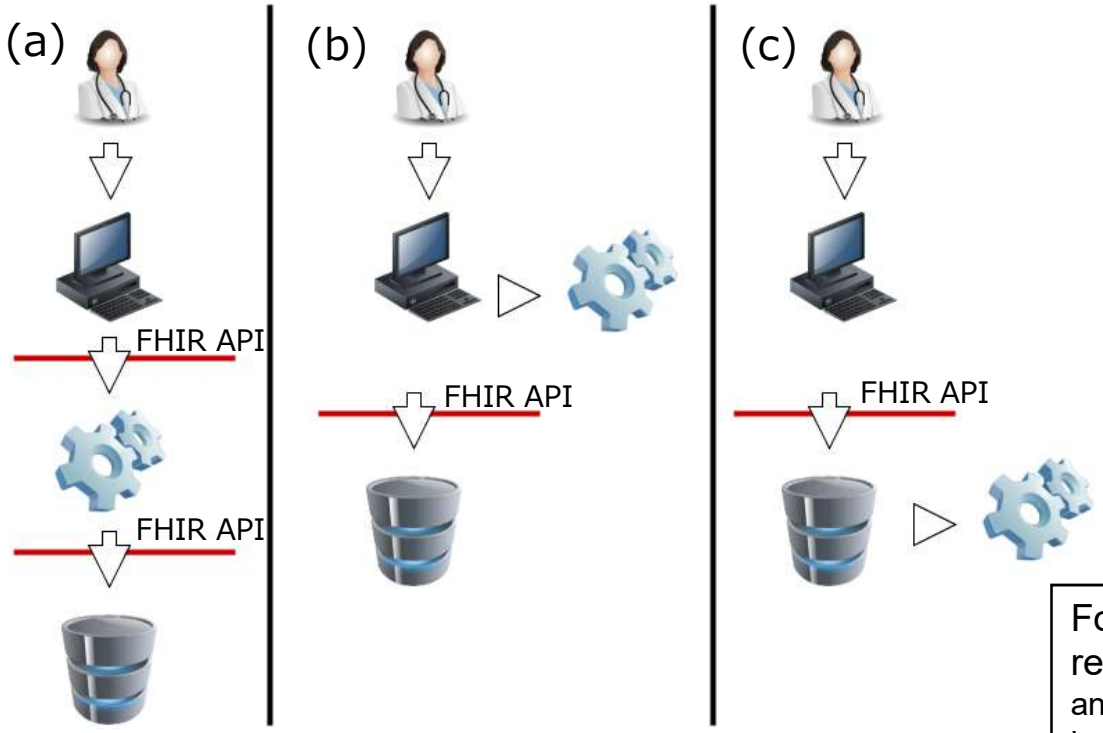
- Adoption of external standards is recommended, except for security labels and audits.

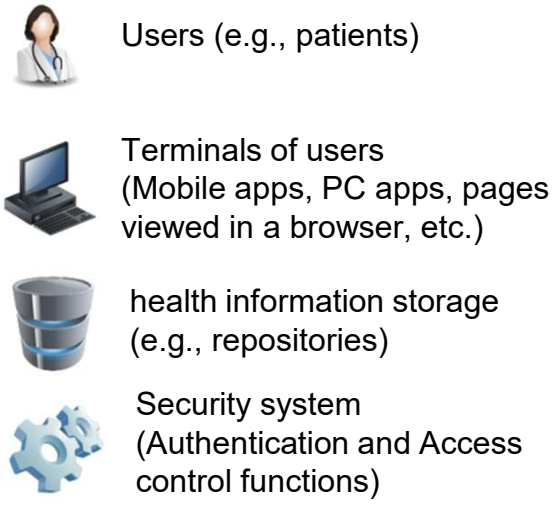
Items	Summary of FHIR Security Policy Content
Time Keeping	all clocks should be synchronized using NTP/SNTP, and the design of the system should be robust against a system clock with the wrong value
Communications Security	all exchange of production data should be secured using TLS (e.g., https).
Authentication	Users/Clients must be authenticated. **For web-centric, Oauth + OpenID Connect is recommended**. When using OAuth, a profile of OAuth will be needed. **Consider use of Smart-On-FHIR where appropriate**.
Authorization/Access Control	FHIR defines a **Security Label infrastructure** **to support access control management**.
Audit	**FHIR defines provenance and audit event resources suitable for tracking the origins, authorship, history, status, and access of resources**
Digital Signatures	FHIR includes several specifically reserved locations for digital signatures
Attachments	FHIR allows for binary resources and attachments. These have their own concerns
Labels	FHIR allows for set of security related tags that affect the way resources are handled (**In the meta element of each resource, access control is realized on a per-resource basis**)
Data Management Policies	FHIR defines a set of capabilities to support data exchange. Not all the capabilities that FHIR enables may be appropriate or legal for use in some combinations of context and jurisdiction (e.g., HIPAA, GDPR). It is the responsibility of implementers to ensure that relevant regulations and other requirements are met
Narrative	Care must be taken when displaying the narrative from FHIR resources
Input Validation	Validate all input received from other actors to assure the data is well formed and does not contain content that would cause unwanted system behaviour. Testing ensures that the input is not susceptible to data input validation errors by using techniques such as fuzzing, invalid input attacks, and injection attacks.

Source: HL7 International https://www.hl7.org/fhir/security.html

(11) User authentication and app authorization/access control in FHIR

- As with many other Web API specifications, FHIR recommends the adoption of external standards for patient access (viewing, updating, etc.) to health information, etc.





Pattern	Process flow
Pattern(a)	The security system also functions as an API server and mediates between the actual location of the health information data storage sites.
Pattern(b)	Authentication and authorization are completed by a separately installed security system, and access to the location where health information is stored.
Pattern(c)	The site where health information is stored redirectes to the internal security system and performs authentication and authorization processes before granting access.

For FHIR-based systems, the security system requires the following (The timing of installation and use varies depending on the system configuration, but the logic is the same.):

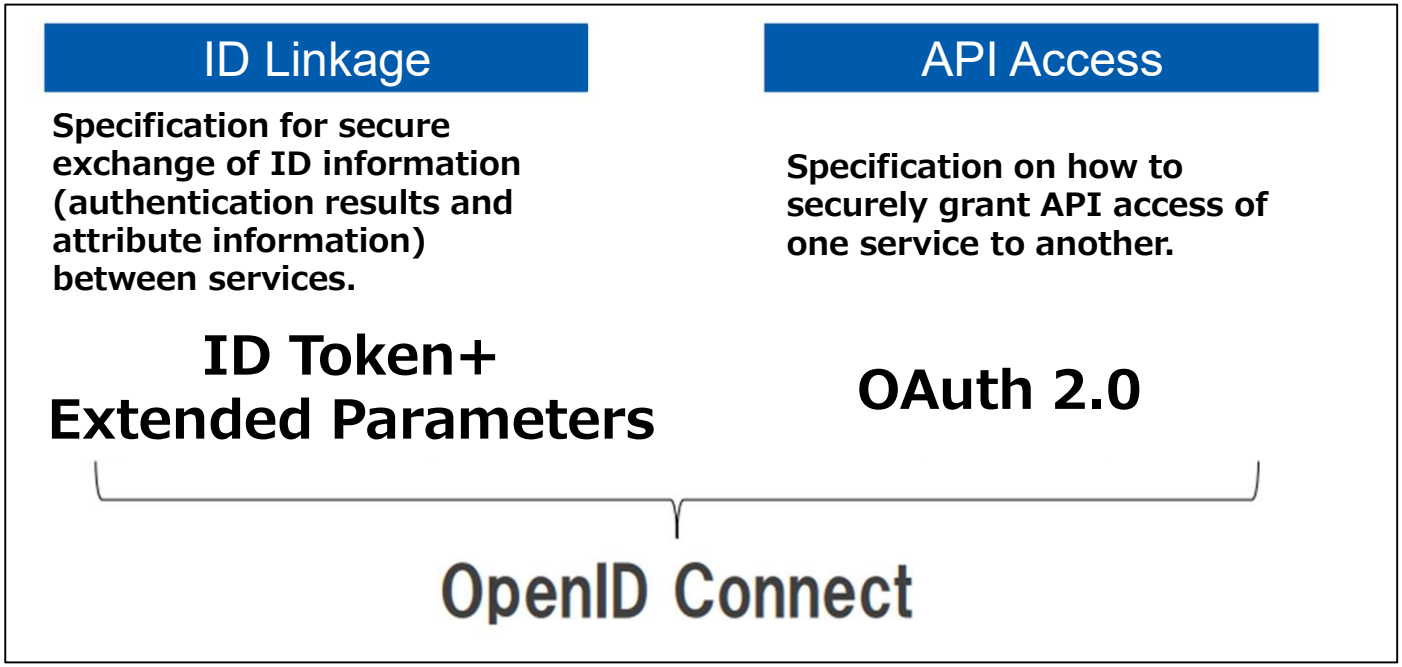
- ✓ User authentication
- ✓ App authorization (Access Control)
- ✓ Audit log management

*It is assumed that if a healthcare professional is a user, his or her qualifications must also be a factor in the authorization process.

(Reference) Access control (authentication and authorization)

(1) FHIR Security and OpenID Connect

- FHIR Security **recommends** OAuth as the technology for app authorization and **OpenID Connect** as the technology for user authentication, an **open standard,** especially for **web-centric systems**.
- Access control of individual resources is specified on a behavioral basis (e.g., updating, referencing, etc.) and on a target information unit (individual resources and their elements).
- **OpenID Connect** is based on **OAuth2.0, which is a standard for "authorization and API integration"** and user and device authentication, considering the cases where the terminal applications (web, mobile, etc.) and APIs work together. **ID Token and extended parameters are adopted as specifications for "ID linkage"**.

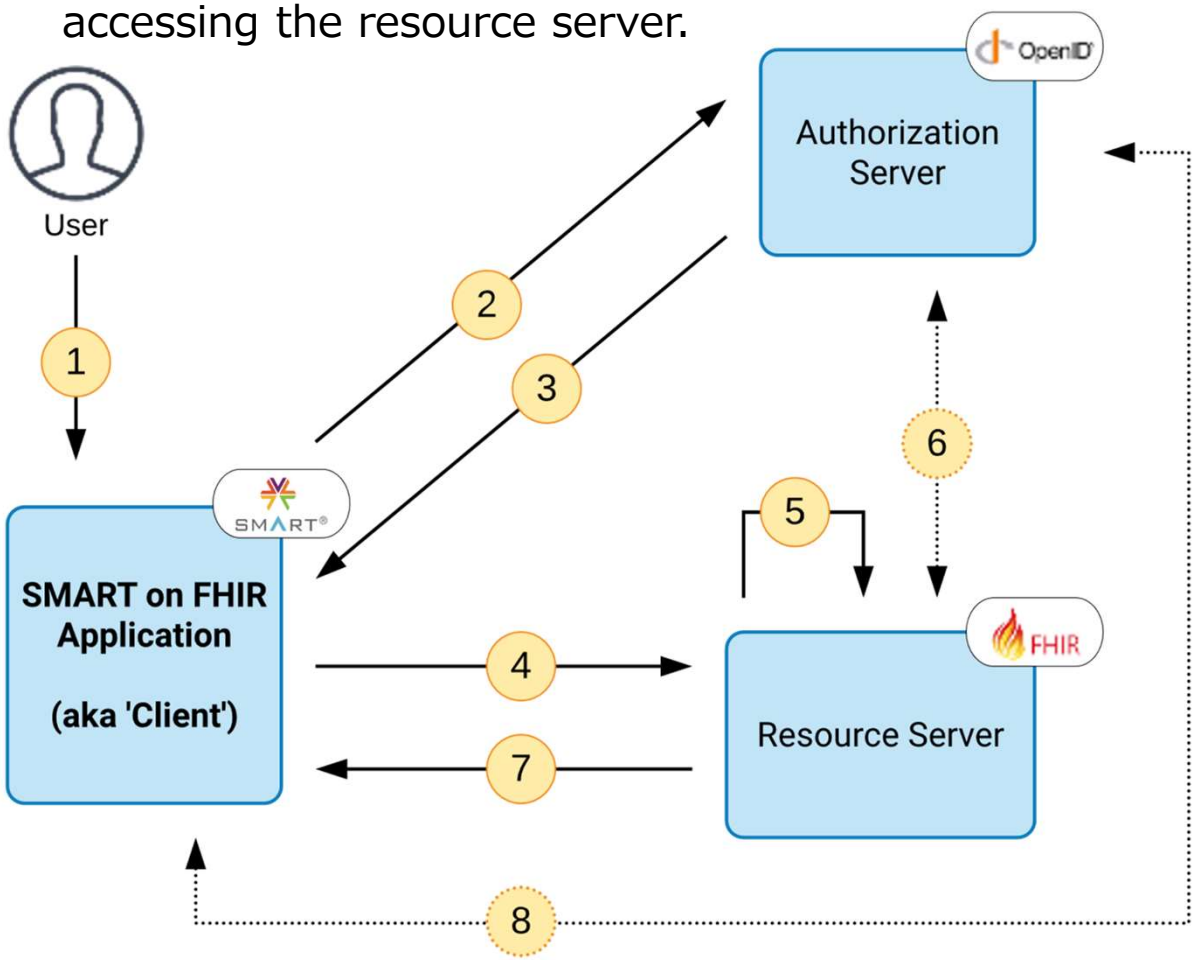


Source : Ministry of Health, Labour and Welfare of Japan, “Final Report - Survey and Research on User Authentication”
Reference Material: “Overview of OpenID” https://www.mhlw.go.jp/content/10800000/000537444.pdf

(Reference) Access control (authentication and authorization)

(2) Image of Access Control at SMART on FHIR

- The use of OAuth requires a profile, and the FHIR Basic Specification **recommends SMART on FHIR's OAuth profile**.
- Based on OpenID Connect/OAuth 2.0, the SMART on FHIR app accepts access privileges after authentication and tokenized access to the resource server prior to accessing the resource server.



Step 1 :Application Launch
Step 2: Request Access
Step 3: Receive Token
Step 4: Client Request to Access or Modify Clinical Data
Step 5: Validate Token
Step 6 (optional): Introspect Token and Request
Step 7: Server Response to Access or Modify Clinical Data
Step 8 (optional): Refresh Token

Source: Smile CDR "SMART on FHIR: Introduction"
https://smilecdr.com/docs/security/smart_on_fhir_introduction.html

2. Trend of policies and other issues related to HL7 FHIR in other countries

Summary of foreign policy trends

[Promotion of information sharing with FHIR through policy guidance]

- The Office of National Health IT Coordination (ONC) of the U.S. Department of Health and Human Services contributed to the modernization of the healthcare IT field by encouraging the participation of EHR development vendors and the **implementation of open APIs** through **incentive measures in the public health insurance system and a substantial penalty of reduced remuneration**.
- NHS Digital in England's Health and Social Care Information Centre included the implementation of APIs predicated on, for example, collaboration between GPs as an accreditation criterion in its procurement plan, resulting in a consequential force on the **vendor side to implement FHIR APIs**, thus contributing to their spread.
- In the Netherlands, the Client Rights Protection Act (2016) was enacted to promote the use of health care data including preventive health care of healthy people. This triggered the need to build a PHR infrastructure. While the patient-focused EHR had already been built with HL7 v3, since PHR was a new infrastructure, FHIR was adopted for ease of implementation and to encourage participation of many companies.

[Operation of existing standards]

- Although there are differences in the medical systems and insurance systems, and the purpose of establishing the infrastructure for sharing health information in other countries, the development of networks in other countries is progressing gradually. However, the standards used in each country have been based on HL7 v2/v3/CDA due to the past history, and it cannot be said that there is a situation in which the existing system is converted to FHIR standards. On the other hand, it is actively being used in new fields.
- As an example, Gematik, the governing body in Germany, developed standards for health information exchange in 2018 based on HL7 v3 as EHR Guideline, which makes it difficult to promote the transition to FHIR as soon as possible.

Dissemination promotion strategies in other countries (1/2)

- US, UK (England): FHIR-based APIs are being used in government-run information systems and they are building and deploying implementation guides, sandboxes, etc., contributing to the promotion of HL7 FHIR.
- US and Netherlands: The Public-Private Partnership Initiative has built and deployed implementation guides, sandboxes*, etc., contributing to the promotion of HL7 FHIR dissemination.
- Incentive measures are taken in the US and Netherlands. And mandatory measures are taken in the US and UK (England) . These measures have contributed to the spread of HL7 FHIR.
- HL7 FHIR seems to have been encouraged to spread through the government's development of implementation guides as well as policy guidance.

Development of standards and Implementation Examples As Promotional measures

Implementation of FHIR-based APIs for Gov't-run information systems and implementation guides, sandboxes*, etc.

E.g., CMS in the United States (Blue Button 2.0), NHS Digital in the UK

or

Coordination of the Public-Private Partnership Initiative and development of implementation guides, sandboxes*, etc.

E.g. MedMij in the Netherlands. CARIN Blue Button in the United States

*The sandbox here refers to an environment in which API integration can be tested. The sandbox is a virtual API service integration partner with which products that want to comply with the standards can integrate their APIs on a trial basis.

×

Dissemination measures by encouraging medical institutions, etc.

Incentive Measures

Subsidies for certified EHRs (electronic health records), etc.

E.g., Meaningful Use Policies in US, the Dutch Acceleration Program (VIPP), the Subsidy for PHR businesses, SME investment, etc.

and/or

Mandatory measures

Contracts with only certified EHRs, and other penalty measures, etc.

E.g., Electronic Medical Records Standard Agreement for the UK (England) Requirement Guidelines, Meaningful Use policies in US.

⇨ **HL7 FHIR's implementation guide development and deliberate policy guidance have encouraged widespread adoption of FHIR.**

Source: Fujitsu Research Institute

Dissemination promotion strategies in other countries (2/2)

Gov't owned Information Systems

US：CMS（Blue Button2.0）
APIs that provide information on prescriptions, primary care, etc. to patient-oriented apps

England： NHS Digital implements the FHIR API in its health information exchange platform Spine operation. The company is currently developing patient information location identification, opt-out management, and medical services for immigrants, etc.

X

Incentive or Mandatory Measures

Incentive Measures
US: Meaningful Use (incentives for implementation conditional on achievement. On the other hand, if the criteria for Meaningful Use are not met, reimbursement will be reduced.)

X

Mandatory Measures
England: Developed accreditation criteria for procurement contracts for EHRs including implementation of the "Transfer of Care API".

Public-Private Partnership Initiative

Netherlands: MedMij (PHR/MedMij: My Health)
Healthcare Provider Communication Association
VZVZ's HIE offers API for PHRs

England: Specification developed by INTEROpen, together with NHS Digital, based on "Care Connect".

X

Incentive or Mandatory Measures

Incentive Measures
The Netherlands: the Acceleration Programme for Patient-Healthcare Worker Collaboration (VIPP) with subsidies for healthcare organizations for HIE infrastructure connectivity (€75 million over 5 years in total) and grants for PHR vendors (€160,000 for 25 companies) and investment in SMEs to promote investment and participation (€20 million over 4 years).

X

Mandatory Measures
England: NHS England has effectively implemented "discharge summary" API (Transfer of Care API) as mandatory.

Examples and status of the use of existing standards in other countries

- Since EHR network in some countries has already been established using existing standards, government-operating entities did not have to lead the adoption of FHIR.

Country	Law	operating entity	Status of EHR development and operation	Standards
US	HITECH Act	ONC、CMS	Developed Consolidated-Clinical Document Architecture (C-CDA) and promote its dissemination by including it in the Incentive Measures 2014 Standards. (e.g., consultation notes for second opinions, continuing care documentation, discharge summaries, etc.)	HL7 CDA r2
Netherlands	Act on EHR	Healthcare Provider Communication Association: VZVZ	VZVZ operates LSP, a platform for healthcare data exchange between medical institutions (a platform that does not store information, but only exchanges it)	HL7 v3
Germany	Act on Modernization of Public Insurance: 2003 *Enacted Act on e-Health in 2016 and Digital Health Act in 2019 to strengthening data exchange further	Gematik mbH (Established under the direction of the German Federal Ministry of Health)	Networking of public health insurance subscribers (70 million people) using the electronic health card (eGK) as the key. New law of 2019 covers e-prescribing to apps, telemedicine, patient data access for research, patient data access to public insurance, mandatory connection of health care institutions to national networks, health insurance online registration, and €200 million in subsidies for innovative projects, etc .	HL7 v3
France	DMP(Dossier Médical Personnel->2016 Dossier Médical Partagé) (National Healthcare Data Exchange project from 2014)	ASIP Santé ： Public organization established in 2009 for development of DMP	Preceded in 2011; re-launched as DMP2 in 2016; expanded to 6 million users as of 2019. Promoted the adoption of opt-in methods, strict authentication and DMP-compatible EHRs.	HL7 CDA r2
Finland	The Electronic Processing of Client Data in Social Health and Care Services Act: 2007	Social Insurance Agency (KELA) of Finland	National Electronic Medical Record Network (Centralized Health Information Archive)	HL7 v3

Source: Fujitsu Research Institute from various sources

New use cases in private sector and their benefits (PHR, IoT)

- Major IT vendors that are not specialized in healthcare have entered the market for use cases such as PHR and IoT, and the use of FHIR is expanding. This has the advantage of making it easier for patients to manage their own health.

Field in Healthcare	Use Cases (Function)	Company	Product, Service or Research
Diagnosis and Treatment	Biometric information collection and monitoring	Google (including companies under Alphabet)	•Study watch (ECG and heart rate): For research purposes only •Passive heart monitor with optical sensors (patent pending)
	Biometric information collection and monitoring	Apple	•Apple Watch 4 (ECG) •Collecting biometric data using air pod-like earphones (patent pending) •Biometric information collection using a camera on the device or a light sensor (patented)
	Detecting the disease and its symptoms	Google (including companies under Alphabet)	Conduct research and development and clinical trials for the detection of eye disease, diabetes, Parkinson's disease, heart disease, etc. using AI technology
	Detecting the disease and its symptoms	Apple	Conducting a clinical trial to diagnose autism and developmental disorders in children using iPhone FaceTime for facial recognition
	Disease management and monitoring	Google (including companies under Alphabet)	Diabetes (virtual clinic, smart syringes for insulin administration to help manage the condition)
	Disease management and monitoring	IBM	•Sugar.IQ, an iOS app to help manage diabetes conditions (in collaboration with medical device giant Medtronic) •Disease monitor: Small AI sensor under development for fingertip attachment (Parkinson's disease, schizophrenia)
	Disease management and monitoring	Apple	•Research Kit" app for clinical research: continuous and efficient remote monitoring •Care Kit, an app for chronic disease management and pre- and post-operative management
Insurance and Pharmacy	Health insurance	Amazon	Healthcare venture with investment holding company Berkshire Hathaway and financial institution JP Morgan Chase
	Online pharmacy	Amazon	Acquired an online pharmacy startup in 2018. This secured a source of drugs and a pharmacy license to operate in 50 states.
Information management/ operation	PHR	Apple	Personal Health Record iOS app: Consolidates personal health care information on the app, allowing iPhone users to view and manage it.
	Building a business processing system in the hospital	Microsoft	Announced FHIR Server for Azure, a FHIR compliant healthcare platform based on our cloud system.

Source: Mihoko Tanaka, "Tech Industry's Continued Entry into Health Care Field, Regional & Analytical Report, U.S. - Overseas Business Information," Japan External Trade Organization, San Francisco Office

(Reference) Trends in IoT devices (1/2)

- FHIR has been used in the development of products such as PHR apps for Apple's iOS devices and integration with IoT devices, and these efforts are attracting considerable attention.
- For smaller devices with limited communication functions, standardization efforts are underway in IEEE 11073, Continua, etc., and recently, the implementation of FHIR has been studied.

Action items	Details of FHIR's device related activities
Device resources in the basic FHIR specification	• Defines resources that track individual instances of devices and their locations. Referred to by other resources to record which devices have performed actions such as procedures and observations, which are referenced when prescribing and dispensing devices for patients or for ordering supplies, and which are used to record and transmit unique device identifier (UDI) information. • Compatible with medical or non-medical devices.
Efforts to standardize the coordination of medical devices to date	• "ISO/IEEE 11073 Health informatics - Medical / health device communication standards” Communication protocol for data collected by personal health devices (PHD) that are also intended for use by individuals • Continua DESIGN GUIDELINES The Continua Health Alliance (NPO) developed a design guide for communication between devices and gateway devices (PCs, personal health systems, smart phones, and other data-intensive devices) and for access by providers of medical and other services.
Maintenance of Implementation Guide	The implementation guide for point-of-care devices in medical institutions was developed in the Device WG of HL7 International. In addition, a new Continua design guide for personal health devices (FHIR) for home and personal use was updated to cover not the devices themselves, but the linkage between gateway devices. Both are based on the IEEE 11073 specification.

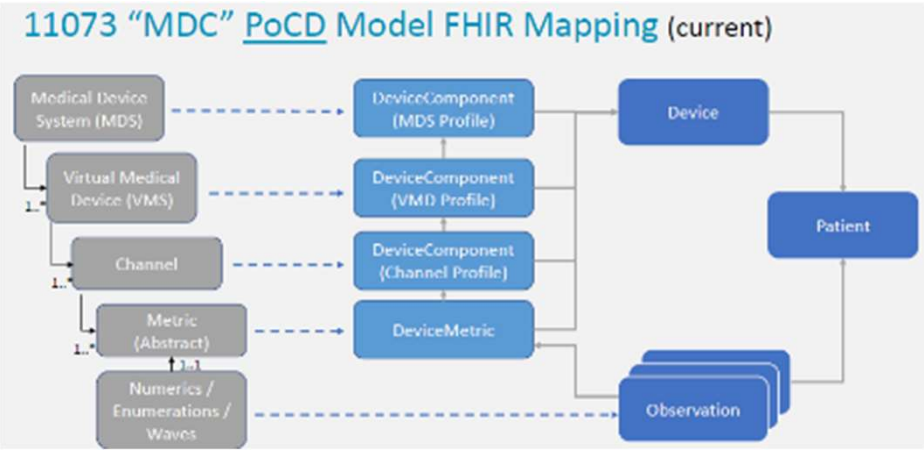
Source: Fujitsu Research Institute from various sources

(Reference) Trends in IoT devices (2/2)

Device on FHIR

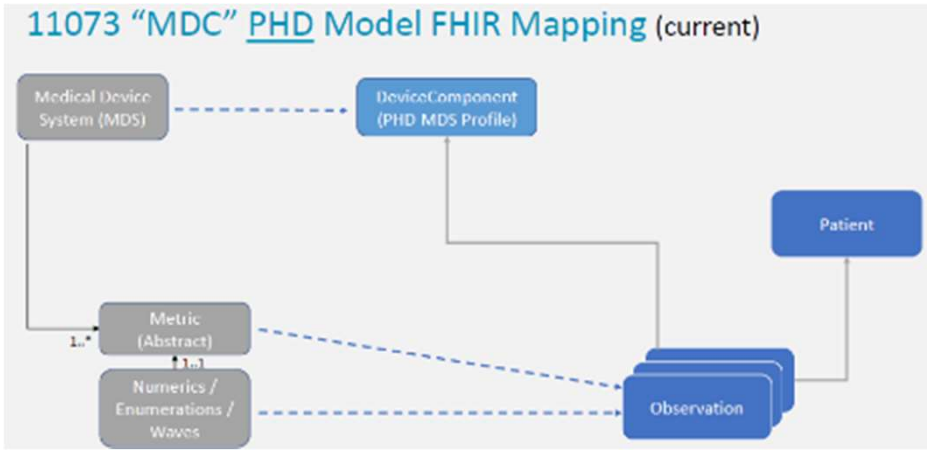
- Device resources in the FHIR specification are envisioned for both use cases of devices for healthcare professionals and devices that are also expected to be used by patients.
- An implementation guide for each use case is being considered.

Mapping to IEEE 11073 Point-of-Care Devices (PoCD) device standards



Point-of-Care Device General Implementation Guide v0.1.0 (STU1)
HL7 Health Care Devices Work Group (DEV WG)

Mapping to IEEE 11073 Personal Health Devices (PHD patient/healthcare worker) device standards



Continua Personal Health Device Data Implementation Guide (v0.1.0)
The Personal Connected Health Alliance (PCHA)

Source: Todd Cooper, Chief Instigator, Devices on FHIR (DoF) Initiative"Using FHIR to Connect Devices & Apps: How hard can it be?!" (HL7 FHIR DevDays 2017)
https://www.slideshare.net/DevDays/furore-devdays-2017-fhir-and-devices-cooper-thc2

(Reference) Policy trends that led to the attention of HL7 FHIR (1/3)

(1) Policy initiatives in other countries

■ Promote interoperability of health information (PHR) and develop a legal system for individuals to self-control their health information, incentive measures and mandatory measures to adopt FHIR API.

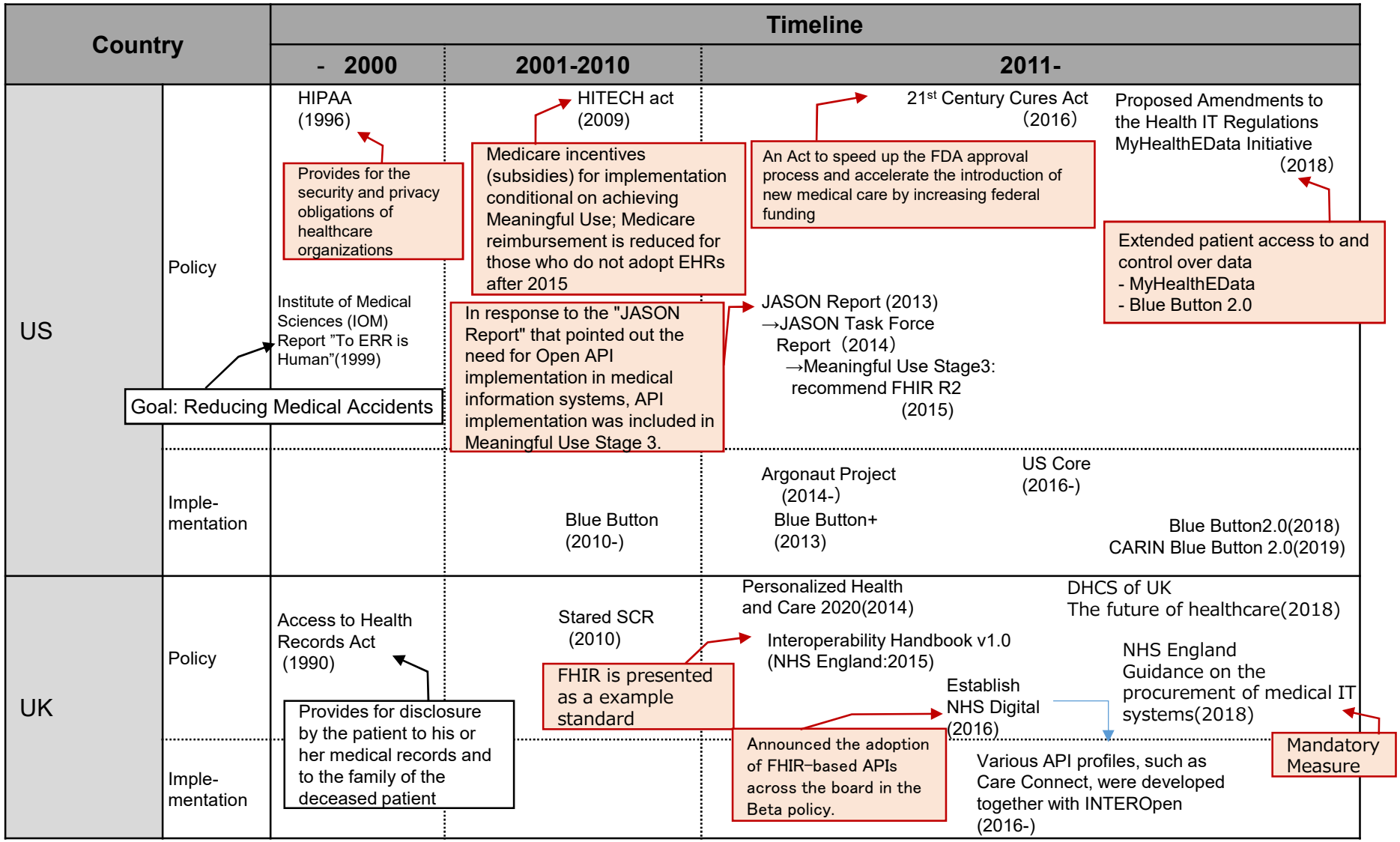
	Overview
US	• The HIPAA Act establishes security and privacy obligations for healthcare organizations. • In accordance with the HITECH Act, incentives (subsidies) for implementation are conditional on the achievement of "Meaningful Use". On the other hand, reimbursement is reduced in case of failure to achieve the "Meaningful Use" requirement. • The 21st Century Cures Act accelerated the FDA approval process and accelerated the introduction of new health care by increasing federal funding.
UK	• The UK Department of Health and Welfare (DOH) and NHS Digital operate Spine, a health information exchange platform, and provide various services such as SCR, e-Prescription and e-Referral. FHIR will be actively adopted and APIs such as Care Connect will be developed with INTEROpen (Public-Private Partnership Initiative). • NHS England developed 'Personalised Health and Care 2020' in 2014, which outlines measures to promote interoperability; developed accreditation criteria for contracting for electronic health record (EHR) procurement, subject to the implementation of Transfer of Care APIs and other Procurement (enforcement). Meanwhile, promoting the transition from paper to electronic databases and presenting and funding inter-system collaboration schemes for localities.
Netherlands	• The Client Rights Protection Act (2016), a law that promotes the use of health care data (PHR) from a preventive perspective, which covers not only patients but also healthy people *including those who were not clients = patients before they became patients. • Developed guidelines and standards for eHealth, led by the Ministry of Health, Welfare and Sports, VWS, and the National Institute for Health Care ICT, Nictiz. The actual development of the system and provision of services is promoted by private organizations. • Implemented a grant program to promote investment and participation by healthcare organizations in API implementation and PHR app development SMEs.
Finland	• In accordance with the 2007 Act on Electronic Processing of Client Data in Social and Health Care Services, the Finnish Social Insurance Agency (KELA) established the National Electronic Medical Records Network (Centralized Medical Information Archive: Kanta) (2015).
Switzerland	• The Computerized Patient Record/Electronic Patient Dossier (EPD) Federal Act was passed (to be implemented after 2020) to enable patient data to be shared among designated health care providers. • eHealth Swiss (WG of the Federal Ministry of the Interior, Department of Health and other relevant ministries and agencies) issued the 2018 "Strategy eHealth Switzerland 2.0 2018-2022", which updates the 2007 Strategy “e-Health Switzerland”. It also made use of standards such as FHIR, HL7, IHE, LOINC, and SNOMED CT (in order of enumeration of sources) for medical information coordination a mandatory goal.
Lithuania	• The Lithuanian Health Strategy 2014-2025 in 2014, the eHealth System Building Program 2017-2025 in 2017 and the Program's Action Plan 2018-2025 in 2018, and the national EHR/PHR (No mention of interoperability, etc.) (No mention of interoperability, etc.)

Source: Compiled by Fujitsu Research Institute from each websites of the government or public-private sector initiative

(Reference) Policy trends that led to the attention of HL7 FHIR (2/3)

(2) Timeline of policy trends by country (1/2)

- US has continued to implement incentive measures since 2009, with an emphasis on promoting APIs from 2015.
- UK has a policy of adopting FHIR from 2016, with an emphasis on API dissemination. API enforcement measures partially implemented.



Source: Fujitsu Research Institute from various sources

(2) Timeline of policy trends by country (2/2)

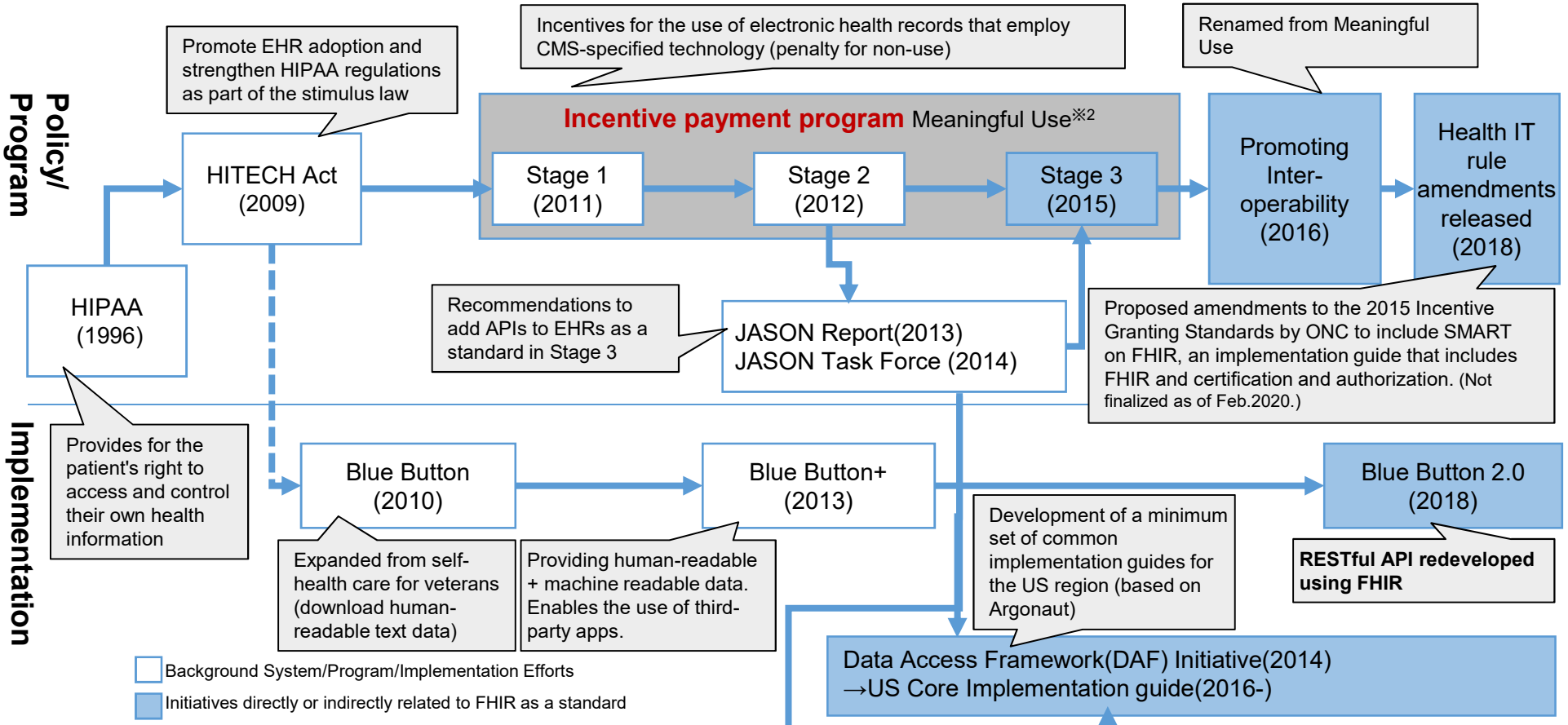
- European countries have been promoting the implementation of FHIR-based APIs in their efforts for patient access to health information. In addition, in accordance with the EU Directive on Cross-Border Healthcare (2011), Member States are required to enact legislation to implement the Directive by 2013/10. An evaluation report was published in 2015.

Country		Timeline		
		- 2000	2001-2010	2011-
The Netherlands	Policy		Legislation to promote the use of healthcare data (PHR)	Client Rights Protection Act (2016) Developed guidelines, standards, etc. for eHealth, led by VWS, Ministry of Health, Welfare and Sports, and Nictiz, National Institute of Medical ICT
	Imple-mentation			MedMij project Launched (2016)
Finland	Policy		National health project launched (2003) The Electronic Processing of Client Data in Social Health Care Services Act (2007)	Preparing revisions to Act on electronic processing of client data in social health care services(2019)
	Imple-mentation		Public health authorities must record patients in a centralized Finnish archive	Kanta launched (2015) Finnish PHR Implementation Guide (2017) implemented in Kanta PHR
Switzerland	Policy		Mandatory EHR adoption of standards in healthcare organizations (Since 2017.)	Federal legislation passed regarding computerized patient records(2015) Strategy eHealth Switzerland 2.0 2018–2022 (2018)
	Imple-mentation			CH Core etc. Implementation guide development started (2018)
Lithuania	Policy			Lithuania's Health Strategy 2014-2025(2014)
	Imple-mentation			ESPBI IS launched(2014-)

Source: Fujitsu Research Institute from various sources

(Reference) Policy trends that led to the attention of HL7 FHIR in the United States

- Promoted the HITECH incentive payment program based on the patients' right to access their own health information under HIPAA. In the process, the JASON Report led to a shift in emphasis on the implementation of APIs in health information systems, which brought FHIR into the spotlight. In response to this, the US government promoted the development of implementation guides for the Argonaut project and other projects. Currently, the implementation of FHIR APIs for patient access to health information in EHRs (electronic health records) is expanding in the United States*1
- From the trends of the HITECH Act, the Blue Button initiative was born and later re-implemented by the FHIR API.



*1 According to the ONC survey, FHIR API use is 82% among hospitals and 64% among health care providers. (Source:ONC "Heat Wave: The U.S. is Poised to Catch FHIR in 2019")

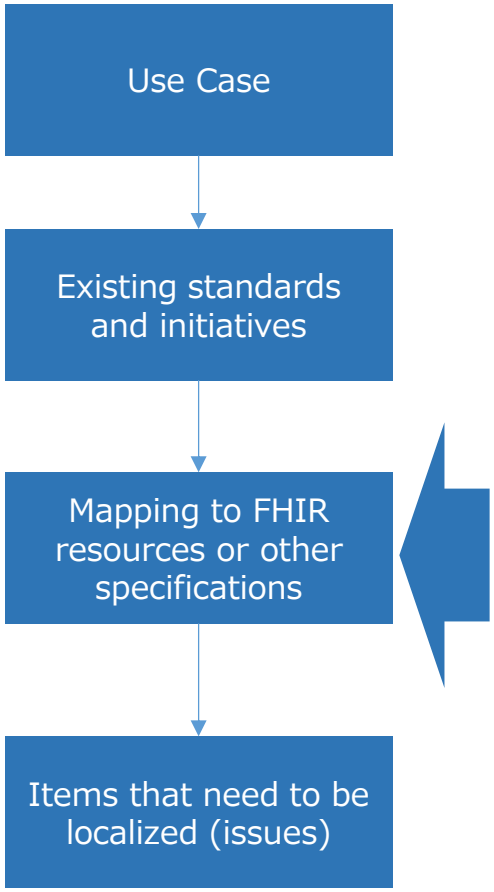
*2 The year of each stage of Meaningful Use is the year of publication of the standard (note that the year of the start of the incentive payment program that actually applied the standard is not the year of the start of the incentive payment program).

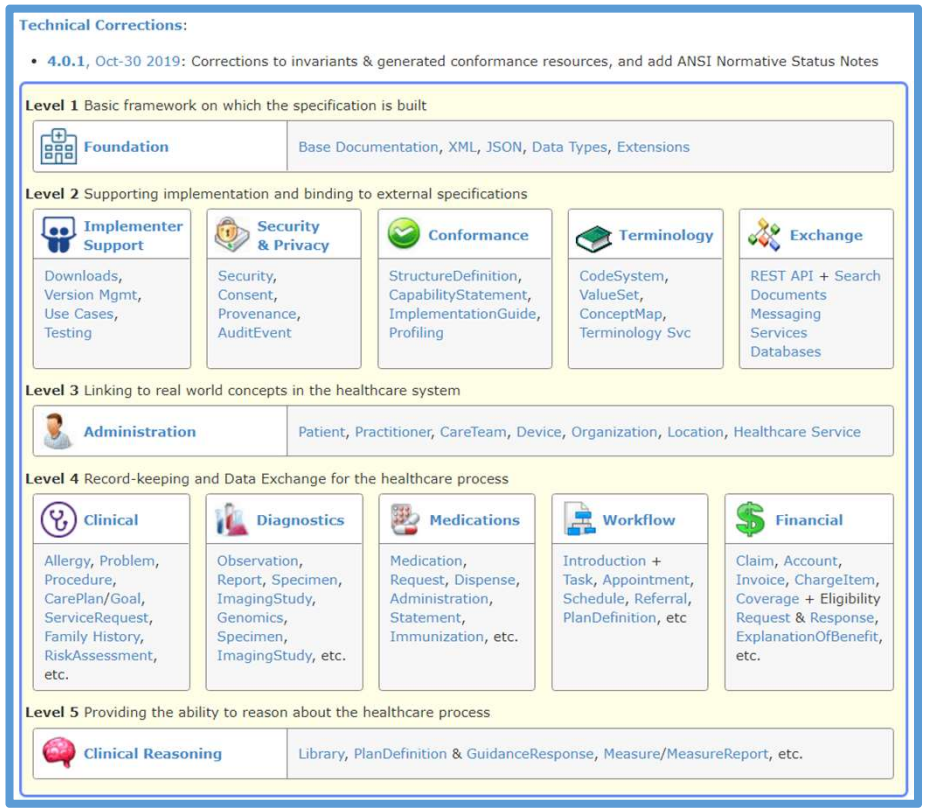
Source: Fujitsu Research Institute from various sources

3. Procedures for utilizing HL7 FHIR

Image of the general procedure for utilizing FHIR

- Easy to implement within or among specific medical institutions.
- Since there are existing efforts and standards related to each use case, various issues such as the extension of the FHIR standard and incorporation into national standards should be considered, to spread spread the open APIs that are accessed by an unspecified number of medical institutions, patients, and other applications and to ensure interoperability among a large number of medical institutions. This work must be done for each use case.
- In other countries, there is a movement to develop a "core implementation guide" or “collection of core profiles" that does not limit the use cases but complies with local rules in each country, and "implementation guides for each use case" to ensure the consistency based on the core implementation guide.





Source: HL7 International

Summary of the resource structure and considerations and developments in the FHIR basic specifications (1/2)

The following is a list of items that need to be considered in the modules of the basic FHIR specification

Hierarchical level	Module	Resources	Items to be considered for implementation
Lv.1 The basic framework of FHIR specification	Foundation	**Basic resource formats are defined** such as Resource, Binary, Bundle, etc., **and a group of resources corresponding to their constituent elements.** FHIR specification documentation system also organized.	Since each resource is the basis of the FHIR specification and is Normative, it is unlikely to change. The use of **Bundle** is recommended for use cases where Lv.3-4 resources are to be processed together, and the use of **Binary** is recommended for use cases where existing formats (CDA, PDF, images, etc.) are to be handled as resources.
Lv.2 Implementation support and assignment of external specification use	Implementation Support	Organizes useful information for implementation, such as FHIR API testing methods (TestScript resources), validation, mapping to existing standards, compatibility with existing systems, links to development resources, etc.	Although not the specification itself, the documentation that has been enriched through the community should be followed as a basis for specific consideration of the implementation guide and its inclusion in the documentation.
	Security and Privacy	Resources such as Consent, Provenance, and Audit Events for **security and privacy implementations** are defined. Basic security and privacy guidelines are also defined.	The basic guidelines have a maturity level of Lv. 4, while the others have a maturity level of Lv. 2 or Lv. 3. Therefore, **it is necessary to study the implementation method and conduct implementation tests based on trends in HL7 International (e.g., connectathons) and individual overseas implementations.**
	Conformance	Resources for overall structure of the API implementation, to which the app must conform to in order to access the API are defined, such as CapabilityStatement, StructureDefinition, OperationDefinition, SearchParameter, etc.	The **main resources in this module is the foundation of the FHIR specification and must be used in profile definitions and implementation guide definitions**. Since the maturity level is Normative and it is basically used as is, it is assumed that there is little room for consideration in each country, based on implementation examples in other countries.
	Terminology	**Resources for handling terminologies** are defined, such as CodeSystem, ValueSet, ConceptMap (mapping of concepts between each terminologies (e.g. SNOMED/LOINC)), etc.	**The specifications of CodeSystem and ValueSet of this module must be reviewed when used in each country**. They are Normative, and each country must have its unique terminology representation method. In addition, although it is assumed that the mapping method of ConceptMap needs to be considered for overseas codes, the maturity level of ConceptMap is Lv. 3 and it is necessary to understand overseas examples and trends.
	FHIR Exchange	RESTful APIs, messaging, document and other information sharing methods are defined.	Basically, RESTful FHIR is assumed to be the way to go, as it is assumed that the benefits of FHIR will be considered for implementation, but other methods will need to be considered for adoption depending on the use case.

Source: HL7 International

Continued to next page

Summary of the Resource Structure and Considerations and Developments in the FHIR Basic Specifications (2/2)

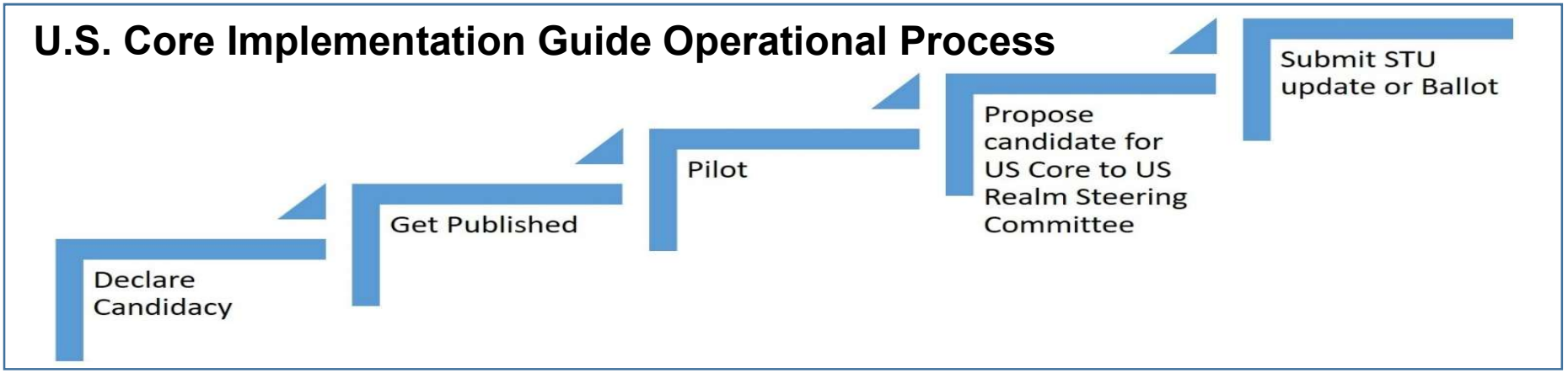
Continued from previous page

Hierarchical level	Module	Resources	Items to be considered for implementation
Lv.3 Linking to real world concepts in the healthcare system	Administration	**Resources of related entities** are defined, such as Patient, Practitioner, Device, etc.	The patient is Normative, but the rest of the patients have a maturity level of Lv.2-3. Based on the use case, it is necessary to **identify each resource that needs to be defined to be used for information sharing because it is referenced by each resource in the specification hierarchy Lv.4, and then consider the profiling of individual resources (e.g., constraints on items, extensions, etc.).**
Lv.4 Record-keeping and Data Exchange for the healthcare process	Clinical	**Resources in the clinical process** are defined such as, AllergyIntolerance, Condition, Procedure, and FamiliyHistory.	Observation is Normative, but the rest are at the level of maturity of Lv. 2~3. Based on **the use cases, it** is **necessary to consider the selection of necessary resources and the profiling of individual resources (e.g., constraints on items and extensions).**
	Diagnostics	**Resources related to testing and diagnosis** are defined, such as DiagnosticReport, Observation, ImagingStudy, and Specimen.	
	Medication	**Resources related to information definition and processes** of drugs are defined, such as Medication, MedicationRequest, MedicationDispense, and Immunization.	
	Workflow	**Requirements and resources for each business process that collaborates with the hospital and external agencies are defined.** This includes those pertaining to scheduling and clinical processes (referral, ordering, etc.).	
	Financial	Resources such as Claim, Coverage, ExplanationOfBenefit are defined.	

Source: HL7 International

Document maintenance and operation processes

- The process to develop implementation guide in US Core in the United States is shown below. Even it is a minimal set of “core implementation guides”, implementation issues are analyzed through connectathons in actual systems.
- Decisions are made by the U.S. Territorial Steering Committee within the U.S. HL7 Association, which includes U.S. government agencies as members, and it is essential that the operational organizations make decisions on updating international standards (updates) and dealing with localization in each country.



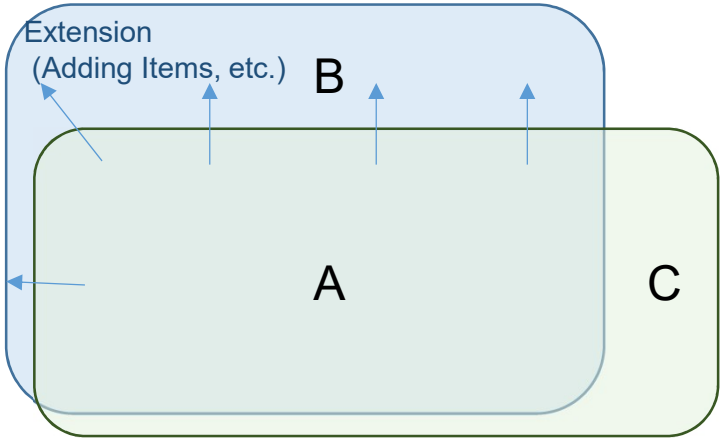
Need to develop implementation guides and operational processes for adoption of FHIR

Decision-making process on FHIR artifacts development by appropriate entities and **community ballot system** are needed.
In addition to responding to the needs and requests for the implementation guide, the **operational process should be designed considering update process and status of the FHIR basic specification.**

Source: HL7 International

Definition target in the implementation guide / profiles

- In considering the subject of an implementation guide or profiles, even if it is a core one, it is necessary to synthesize what is necessary in each use case, and to assume a minimal set.
- When considering maintaining interoperability with foreign countries, even for unnecessary items that are not used within each country, consideration should be given to their treatment.



Resources in the FHIR specification hierarchy Lv.3 and Lv.4

Legend:

Elements of the resource in the **FHIR basic specification**

Items of resources required by the expected **use cases within each country**

A	Target items that can be represented by mapping with local masters, etc. assuming a specific use case from the FHIR specification.
B	Items that are not in the FHIR basic specification, but implementation is needed additionally. It is needed to decide whether to specify this in a core implementation guide/profile or in an individual implementation guide/profile.
C	Items that are not expected to be used in the expected use cases. Treatment in a core implementation guide for these items. (Should consider the treatment in core implementation guides/profiles overseas.)

Source: Fujitsu Research Institute

Anticipated tasks need to prepare an implementation guide (1/2)

■ One of the main tasks is the maintenance of an implementation guide (IG). The tasks anticipated to develop and maintain an IG are shown below and a vast amount of work is required to complete them.

Items for consideration		Issues	Artifacts
1 Use case	1.1 Assumed actors	Stakeholders, systems (Data sources), new systems to be developed	Compile in "Guidance" for the relevant implementation guide for API implementers and app implementers who use the API
	1.2 Context	Business needs, key success factors, etc.	
	1.3 Relevant legislation/ rules	Systems and rules that serve as conditions for information sharing, formats, etc.	
	1.4 Shared health information, etc.	Information stored in existing systems and information to be added	
	1.5 Other requirements	Collaboration method (RESTful API, etc.), file format (JSON, XML, etc.), security requirements, authentication and authorization, etc.	
2 Information for sharing	2.1 Resources to be shared in the basic FHIR specification	Lv. 4 resources: medical information etc. and Lv. 3 resources: identification of relevant entities.It is also necessary to organize issues and points to keep in mind for each use case based on the maturity level of the Lv.1 Foundation (FMM Lv.), standard status (Normative, Trial Use, etc.), and implementation guide examples from other countries.	A collection of profiles (including specification of extended items).
	2.2 Information to be set for elements and terminology to be used in sharing resources	Consideration of what to set for each specific item in line with the use case (e.g., Observation→Vital Signs (measurement of weight, blood pressure, body temperature, etc.), blood tests, etc., will be considered for use based on the type of test. In addition, the standard codes used for items expressed in codes are discussed based on the Code System of Lv.2 Terminology. Translations, extensions, and mappings for use in domestic and international terminology must be considered separately.	
	2.3 Relationships and dependencies of each shared resource	Identify related/dependent resources, particularly other resources specified in the reference type of each item, and check for excess or deficiency. (e.g., in the case of Observation, see the resources for the subject (e.g., Patient) to be covered by the Subject element and the consultation (Encounter) to be covered by the Encounter element).	
	2.4 Basic scenarios and search parameters for each shared resource	Basic use cases and individual search criteria (parameters) (e.g., Patient ID to be targeted, etc.)	
	2.5 Required items for each shared resource and items that need to be expanded	Necessity of extending the target resource for insufficient items, structure of the items when extending them, consideration and organization of the data format (required elements, code that must be supported, other constraints, specification of extended items)	
	2.6 Organizing the Data Format	Lv.1 Foundation's basic specification for XML, JSON, etc. and each resource, including error conditions, should be included in the Implementation Guide. Note that MustSupport constraints are currently too difficult to implement as a function of FHIR Server.	
	2.7 Define the structure of a profile	Lv.2 conforming Conformance structure definition organized as a StructureDefinition resource (document XML and JSON types). (Document XML and JSON formats)	

Note: Lv.1-Lv.4: Hierarchical Levels of resources and other information in the FHIR Basic Specification System

Continued in next page.

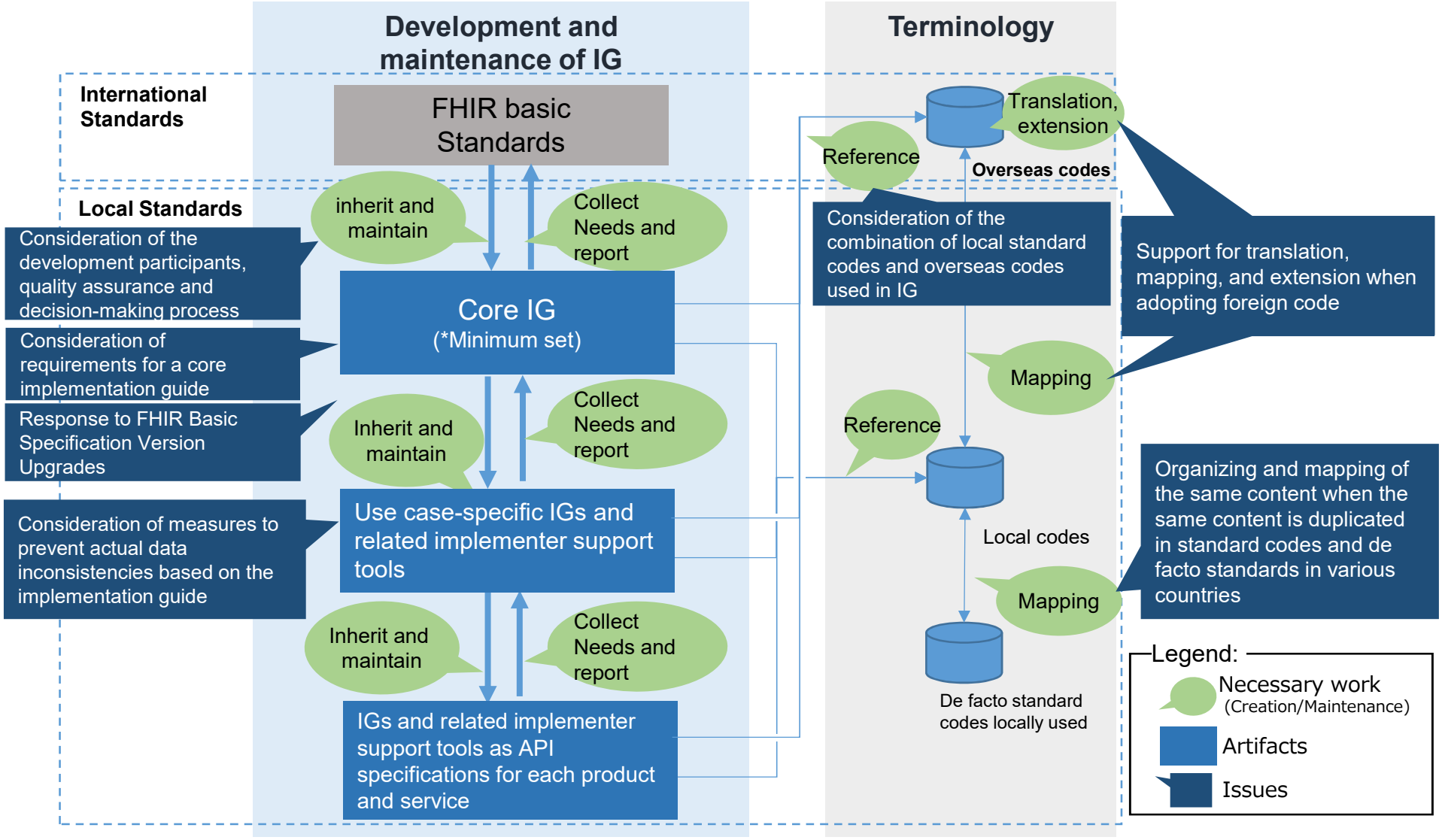
Anticipated tasks need to prepare an implementation guide (2/2)

Items for consideration		Issues	Artifacts
3 Overall shared specifications for use case realization	3.1 Operations	Consideration of how to specify the expression in bundles when processing all the resources needed for a use case.	Search parameters and processing methods and Capability Statements
	3.2 Search Parameters	Compilation of the search parameters considered in 2.4, and arrangement of the basic ideas for processing them together	
	3.3 Terminology	Arrangement of The terms (terminology) considered in 2.2 as a list of Value Sets in Lv.2 based on the upper-level implementation guide and other implementation guides.	
	3.4 Capability Statements	Organization of the system (responder) that implements the APIs based on 2 and 3.1 to 3.3 and the functions of the app side (requestor) that accesses the APIs as a functional definition (CapabilityStatement) resource of Lv.2 Conformance (HTML document, XML, and Each type of JSON),	
4 Security	4.1 Necessary actions based on the security category of each resource	Deeply summarize the necessary security requirements based on the security categories of FHIR security (e.g. Patient Sensitive) in Lv.2 specified for each resource.	Security requirements
	4.2 Security Requirements for the API	Specific elements to be considered for FHIR security in Lv.2 ・Authentication (OAuth, etc.), ・Authorization/access control (FHIR does not specify specific examples), ・Audit (Lv.2 Authenticity management method Provenance profile development, Lv.2 AuditEvent resources and audit logs, and ・Electronic signature etc.	
5 Other support for implementers	5.1 Publication of Implementation Guides and Profiles	Publication and maintenance of documents and resources from 5.2 to 5.6 that have gone through development, testing (e.g., connectathons / projectathons), decision-making, etc.	
	5.2 Sample data and data for validation	Based on the results of 2~4, prepare data, etc. that can be utilized to check (validate) the contents of sample data, the time of API access and the format of provided data, etc.	Download resources and various servers to support implementers
	5.3 Test Servers, Sandboxes, etc.	Create an environment for app implementers to test	
	5.4 Sample Programs	Preparation of sample programs based on the implementation guide	
	5.5 Case studies, etc.	Organize specific API implementation examples and app-side implementation examples through the development and testing of profiles and implementation guides.	
	5.6 Development Community Management	Management of community sites and sample programs, holding events to discuss examples of implementations and the future of implementation guides, holding a connectathon, etc.	

Note: Lv.1-Lv.4: Hierarchical Levels of resources and other information in the FHIR Basic Specification System

Issues regarding the development of the document system

■ If FHIR is to going to be used in Japan for interoperable coordination, various studies and actions related to developing implementation guides (IGs), etc. based on the FHIR basic specifications and developing a terminology system to be used, are assumed necessary.



Source: Fujitsu Research Institute

Terminology used in implementation guides in US/Europe

■ Basically SNOMED-CT and LOINC are shown as terminology examples in the FHIR. Many countries adopt local codes as well in their IGs.

Source: Fujitsu Research Institute

Category	Key Terminology-Related Standards in FHIR		Note	Examples of existing Japanese terminology-related standards
	FHIR Basic Specifications	Examples of core implementation guide profiles from other countries		
Disease name	SNOMED CT *In Claims diagnosis code is ICD-10.	**US:** ICD-10 or ICD- 9 (including SNOMED CT) **UK:** SNOMED CT UK **AU:** country-local code (recommended) **NL:** SNOMED CT, ICD-10, Dutch National Standard V&VN, NANDA-I, Omaha Systems, ICF, ICPC-1 EN, Dutch proprietary (G-Standaard Contra Indications (Table 40)), DSM-IV, DSM-IV V	ICD-11 is approved in WHO General Assembly (May 2019)	ICD-10 compliant Standard Name Master (HS005) and Standard Dental Name Master (HS013)
Medicine	SNOMED CT	**US:** RxNorm **UK:** SNOMED CT UK **AU:** PBS Medicines Item Codes, GTIN for Medicines, Australian Medication, and MIMS Package. (All are recommended.) **NL:** SNOMED CT(example)		HOT code (HS001), code for the receipt computer processing system, YJ code, etc.
Observation	LOINC	**US:** LOINC **UK:** SNOMED CT UK **AU:** N/A (Resources not covered) **NL:** Same as FHIR Standards(LOINC)(Recommended)	JLAC11, based on JLAC10, is also in operation	Clinical Laboratory Master(JLAC10+Clinical Practice Code) (HS014)
Image	DICOM	**US, UK, AU, NL:** N/A (Resources not covered)		Imaging test item code JJ1017 (HS017)
Allergy	SNOMED CT	**US:** SNOMED CT、RxNorm(Medicine) **UK:** SNOMED CT UK (Example) **AU:** Local code **NL:** SNOMED-CT, Local code(G-Standaard, etc.)		SS-MIX2 code table (allergen), clinical laboratory master (JLAC10) identification code, etc.
Operation	SNOMED CT	**US:** CPT(Current Procedure Terminology), SNOMED CT or HCPCS Level II Alphanumeric Codes **UK:** SNOMED-CT **AU:** N/A (Resources not covered) **NL:** SNOMED CT		Code for the receipt computer processing system From the MID-NET

Image of the review process for individual use cases (1/2: PHR)

Since the FHIR basic specification is a general-purpose specification, there is significant flexibility, especially in the resources of hierarchies Lv. 3 and 4, which define the health information to be exchanged, it is necessary to consider extensions and restrictions. On the other hand, since Lv. 1 and Lv. 2 are the foundation, most of the resources other than those related to implementation guides/profiles and terminology should be considered for use. The following is an image of the procedure for developing PHRs for data held by healthcare organizations.

1 Use Case		e.g., PHR (a PHR is an application that helps patients with chronic diseases (lifestyle-related diseases, etc.) to voluntarily work on improvement by obtaining health information maintained by medical institutions, etc., and the patients utilize it themselves or show it to health services, etc. at their own will)
2 Existing standards and initiatives		e.g., for dispensing data, standards and mechanisms for electronic medication notebooks exist. Although there are no standards for PHRs related to health information held by medical institutions, six clinical societies have jointly created "PHR Recommended Settings". In addition, there are standards related to medical information systems that manage the necessary resources and standards for cooperation with other systems (e.g., SS-MIX). It should be noted that many existing medical information systems perform their own code management and other functions on their own.
3 Mapping to FHIR resources	**a. Identify key resources needed**	Review FHIR Basic Specification Hierarchy **Lv.4**, "Record Management and Data Exchange for Health Care Processes," for data obtained from health care organizations that patients refer to in the app, identify the resources needed, and analyze for excesses and deficiencies in the components. Example: **Blood Test Results** -> (Diagnostic) **Observation** **Allergy Information**-> (Clinical) **AllergyIntolerance** **Prescription history** -> (drug) **prescription** (MedicationRequest) (in-hospital prescriptions can be assumed to include dispensing and medication information), etc. Relevant resources to which key resources refer are identified within the FHIR Basic Specification Hierarchy **Lv.4** and from **Lv.3**, "Linking Health Care Information Systems and Real World Concepts," and analyzed for excesses and deficiencies in the components. For example: Patient and Organization resources referenced by Observation resources If you want to get them all together, consider defining a bundle resource in the FHIR Basic Specification Hierarchy **Lv.** 1.
	b. Resources, components of arrangement	In each of the identified resources, the following elements and their conditions shall be considered and defined in the StructureDefinition resource in the conformance of the FHIR Basic Specification Hierarchy **Lv.2** "Support for Implementation and Association with External Specifications". In that case, new consideration is also required for data types that do not match the data types in the FHIR Basic Specification Hierarchy **Lv.1**, "Framework as a basis for FHIR specification development". Ex.) -Specifies the minimum number of components that must be maintained in each resource. -Determine and specify the terminology to be used (definition of CodeSystem etc. of FHIR Basic Specification Hierarchy **Lv.2**) - Expansion of the number of components that need to be added, etc. (e.g., adding kana names, etc.)
4 Localization (Development of API specification)		Define the API specifications (functions, etc.) of the FHIR API that are assumed in the implementation guide, etc. other than the health information to be exchanged such as. - Compilation of profiles to be used - Consideration of API methods: RESTful API of FHIR Basic Specification Hierarchy **Lv. 2**, persistent storage (stored in FHIR format), etc. - Scope of the data format to be exchanged: Refer to XML and JSON of FHIR Basic Specification Hierarchy **Lv.1** to study the range of restrictions. - Confirmation of the terminology used: Consolidation and consistency check of CodeSystem and ValueSet of FHIR Basic Specification Hierarchy **Lv. 2** for each resource code etc. -The functions of the FHIR API:Define "CapabilityStatement" resource in FHIR Basic Specification Hierarchy **Lv.2** "Support for Implementation and External Specification" based on the results of the above discussion. - Examination of security measures: Examination of authorization of OpenID Connect/OAuth2.0 of FHIR Basic Specification Layer **Lv.2,** etc.

Image of the review process for individual use cases (2/2: Discharge summary)

Since the FHIR basic specification is a general-purpose specification, there is significant flexibility, especially in the resources of hierarchies Lv. 3 and 4, which define the health information to be exchanged, it is necessary to consider extensions and restrictions. Conversely, since Lv. 1 and Lv. 2 are the foundation, most of the resources, except for those related to implementation guides/profiles and terminology, should be considered to be utilized. The following is an image of the development procedure in the discharge summary (document).

1 Use Case		In a use case where a hospitalized patient is discharged from a hospital and provides summary data at the time of discharge to other departments and other medical institutions, we will study the exchange of data via the FHIR API. (Assuming cooperation between medical institutions.)
2 Existing standards and initiatives		E.g., the Ministry of Health, Labour and Welfare (MHLW) has developed the "Summary Rules for Hospital Discharge Based on HL7 CDA" (HS032), which has become a MHLW standard, so the structure of the information to be handled, terminology, etc. will be confirmed.
3 Mapping to FHIR resources	**a. Identify key resources needed**	If the format defined in the "HL7 CDA Based Discharge Summary Agreement" is used as it is, and it is to be exchanged via the FHIR API (RESTful API), it is to be attached as a binary resource in the FHIR Basic Specification Hierarchy **Lv.1** "Framework as a Basis for FHIR Specification Development". Consider the Bundle resources of the **same Lv.1,** such as messages, etc. On the other hand, if the resources are represented by FHIR resources rather than HL7 CDA, then for documentation purposes, the resources comprising Bundle will be mapped and organized according to the "Summary Rules for Discharge Under HL7 CDA". - Patient information: Patient of FHIR Basic Specification Hierarchy **Lv 3** "Linking Medical Information Systems and Real World Concepts". - The person listed, the original custodian, the insurer, the approver, the person in charge, the attending physician, etc.: Practitioner, Organization, etc. of **Lv. 3** - Information on admission and discharge: Encounter for **Lv.3** - FHIR Basic Specification Hierarchy **Lv. 4** "Record Management and Data Exchange for Medical Processes", **test results, allergies, diagnosis on admission, family history, discharge medication instructions, surgery and treatment** (Observation, AllegeryIntolerance, Condition, **etc.)** FamiliyHistory, Medication, Procedure, etc.)
	b. Resources. The components of arrangement	As in the PHR, the following elements and their conditions are defined in each of the identified resources, and the profile is defined in the StructureDefinition resource in the FHIR Basic Specification Hierarchy Lv.**2.** At that time, a new study is also required for data types that do not match the FHIR Basic Specification Hierarchy Lv.**1.** - Specifies the minimum number of components that must be maintained in each resource. - Determine and specify the terminology to be used (definition of CodeSystem etc. of FHIR Basic Specification Hierarchy **Lv.2**) - Expansion of the number of components that need to be added, etc. (e.g., adding kana names, etc.)
4 Localization (Development of API specification)		Define the API specifications (functions, etc.) of the FHIR API that are assumed in the implementation guide, etc. other than the health information to be exchanged. Examples are shown below. - Compilation of profiles to be used - Consideration of API methods: RESTful API of FHIR Basic Specification Hierarchy **Lv. 2**, persistent storage (stored in FHIR format), etc. Scope of data format to be exchanged: Refer to XML, JSON, and Binary resources in FHIR Basic Specification Hierarchy **Lv.1** to study the range of restrictions. - Confirmation of terminology used: Compilation and consistency check of CodeSystem and ValueSet of the FHIR Basic Specification Hierarchy **Lv. 2** for each resource code, etc., based on the "HL7 CDA based discharge summary agreement". - Based on the results of the above discussion, we will define the functions of the FHIR API: Hierarchy **Lv.2** "Support for Implementation and External Specification" of FHIR Basic Specification.CapabilityStatement resource definition of "association". - Examination of security measures: Examination of authorization of OpenID Connect/OAuth2.0 of FHIR Basic Specification Layer **Lv.2,** etc.

(Reference) Efforts to develop core Implementation guides and profiles in US/Europe

There is variation in scope, components, and based FHIR versions of the core IG/profile in each country.

Country	Name	Operator	Overview	Components	FHIR ver.
US	US Core	US Realm Steering Committee of HL7 US, Argonaut PJ Team Sponsored by ONC	• A set of requirements for minimum compliance with the **use case for access to patient data.** • Pilot implementation of the Argonaut project, addressing the CCDS and USCDI (Designated Data Set) requirements that ONC assumed for incentives in Meaningful Use.	• Guidance (general guidance, use case specific guidance, FHIR DSTU2 to R4 conversion, future of US Core) • Profiles and extensions • Search parameters and processing methods • terminology • Capability Statements • General Security Requirements • Implementation Example (Data Sample) • Packages for data checking (validation) during implementation, profile definitions in JSON and XML formats, schematrons, and sample data	R4
UK	CareConnect (FHIR UK Core)	NHS Digital (England) and INTEROpen Community	A list of requirements for use cases with the primary purpose of disclosing information and data related to treatment.	• In addition to profiles, CareConnect provides case studies (case studies), samples of each implementation process, and reference information such as the flow of API implementation utilizing CareConnect. • The full UK Core (2019/12) provides guidance, functional definitions, profiles, terminology relationships, search parameters, samples, etc.	**DSTU2a nd STU3** **Preparing for R4**
AU	AU Base 2	Each working group in HL7 Australia	It does not **impose restrictions on individual use cases,** but rather responds to general needs in Australia.	• Guidance • Profiles and extensions • terminology • Validator packs (data checking tool for implementation), profile definitions and sample data in JSON, XML and ttl formats	**STU3** and R4
NL	HL7 FHIR-NL profiles	National Institute for Health Care ICT (NICTIZ) of the Netherlands	Profile to be followed by the FHIR Implementation Guide, including the Implementation Guide Medmij for PHRs in the Netherlands, defined **only for relevant data types and the entities involved, such as Patient, Organization, and Practitioner.**	• Profile • It has a verification tool (validator) and accreditation mechanism to ensure that the architecture system is compliant with the profile.	**STU3**
CH	CH Core	HL7 Swiss Technical Committee,. eHealth Switzerland	Defines **only** the **basic resources such as Bundle of Documents (Bundle), Patient, Organization, Encounter, etc.** for the Electronic Patient Record (EPR) to be shared under the law.	• Profiles, Extensions • terminology	R4

Source: Fujitsu Research Institute

(Reference) Efforts in US/Europe to develop Implementation guides and profiles

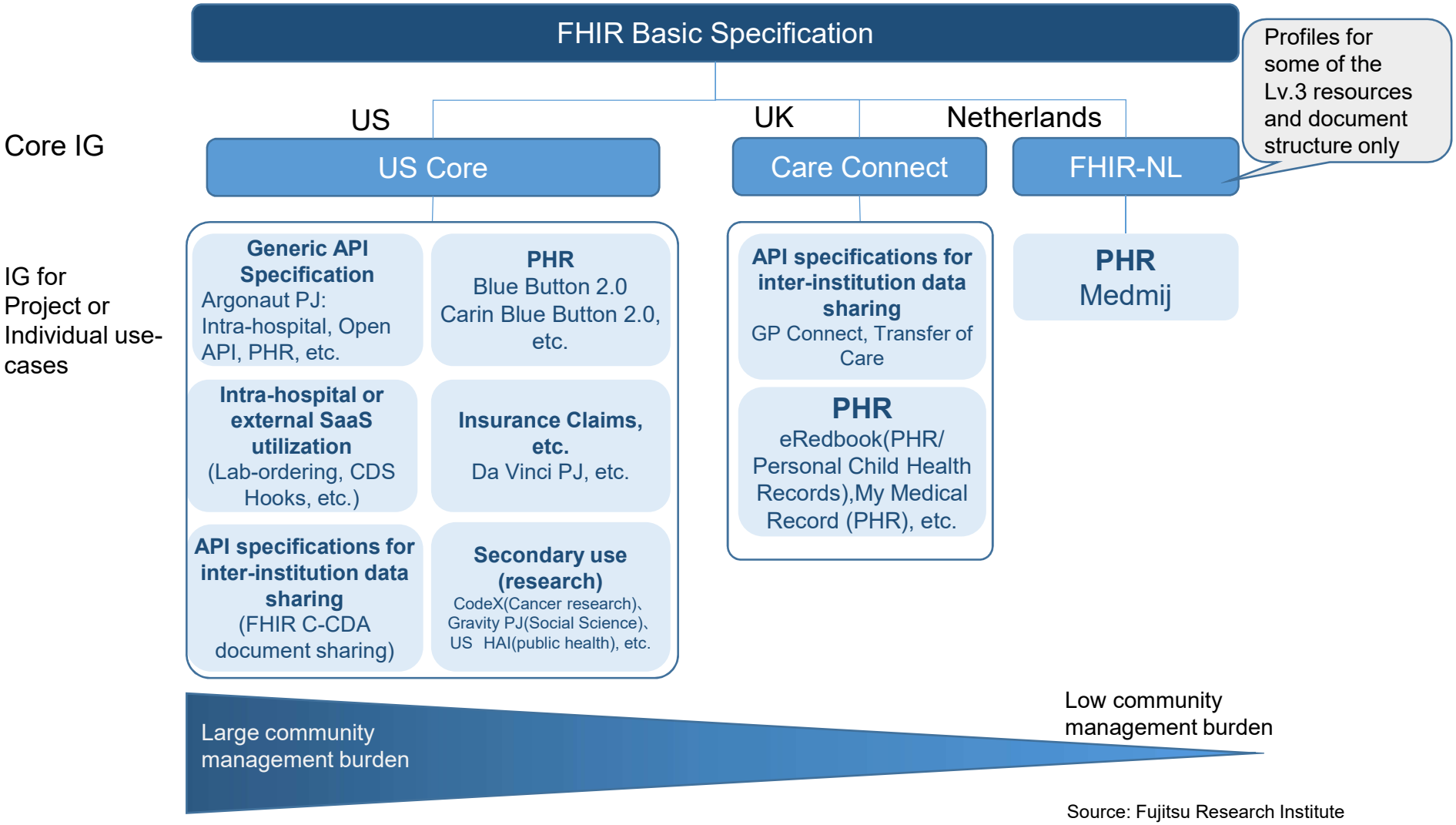
Many of the use case-specific IGs have been developed through public-private partnership initiatives.
(In some cases, public subsidies are included in development funding.)

Source: Fujitsu Research Institute

	Intra-/Inter-institution	For Patient	Institution and Insurers	Others
US	CDS Hooks (Clinical Decision Support)	Blue Button 2.0、CARIN Blue Button 2.0 (PHR)		Gravity Project (Analysis of Social determinants on health)
				mCode and Code X Project (cancer research)
	Da Vince Project (Appointment, Insurance Verification, prescription confirmation, etc.)			Modernizing Mortality Systems Project (Mortality data reporting)
	PoCD General IG (Medical Devices)	Continua Design Guide (PHD/Personal Devices)		Agile Genomics consortium (Genomics)
UK	Transfer of Care (Discharge Summary, etc.)	11 services, such as eRedbook(PHR/Personal Child Health Records)、My Medical Record (PHR), etc. *Fund Supported by NHS England	N/A in NHS activities	
	GP Connect (Inter-GP and Emergency call)			
Australia	Developed with HL7 v.3	My Health Records (PHR)	N/A in HL7 Australia activities	RCPA Cancer Reports FHIR (Cancer registry)
		Child Digital Health Record(PHR)		
Nether-lands		MedMij (PHR)	N/A in HL7 Netherlands activities	
Finland		KANTA PHR (PHR)	N/A in HL7 Finland activities	
Swiss	CH-EPR(Eletronic Patient Records)		N/A in HL7 Swiss activities	Swiss CR (Cancer registry)
	CH-ORF(Ordering/Letter of Refference)、CHMED16AF(e-prescribing), etc.			
Lithania	ESPBI IS(Patient portals, Health information sharing and e-prescribing)		N/A	

(Reference) Efforts in US/Europe to develop Implementation guides and profiles

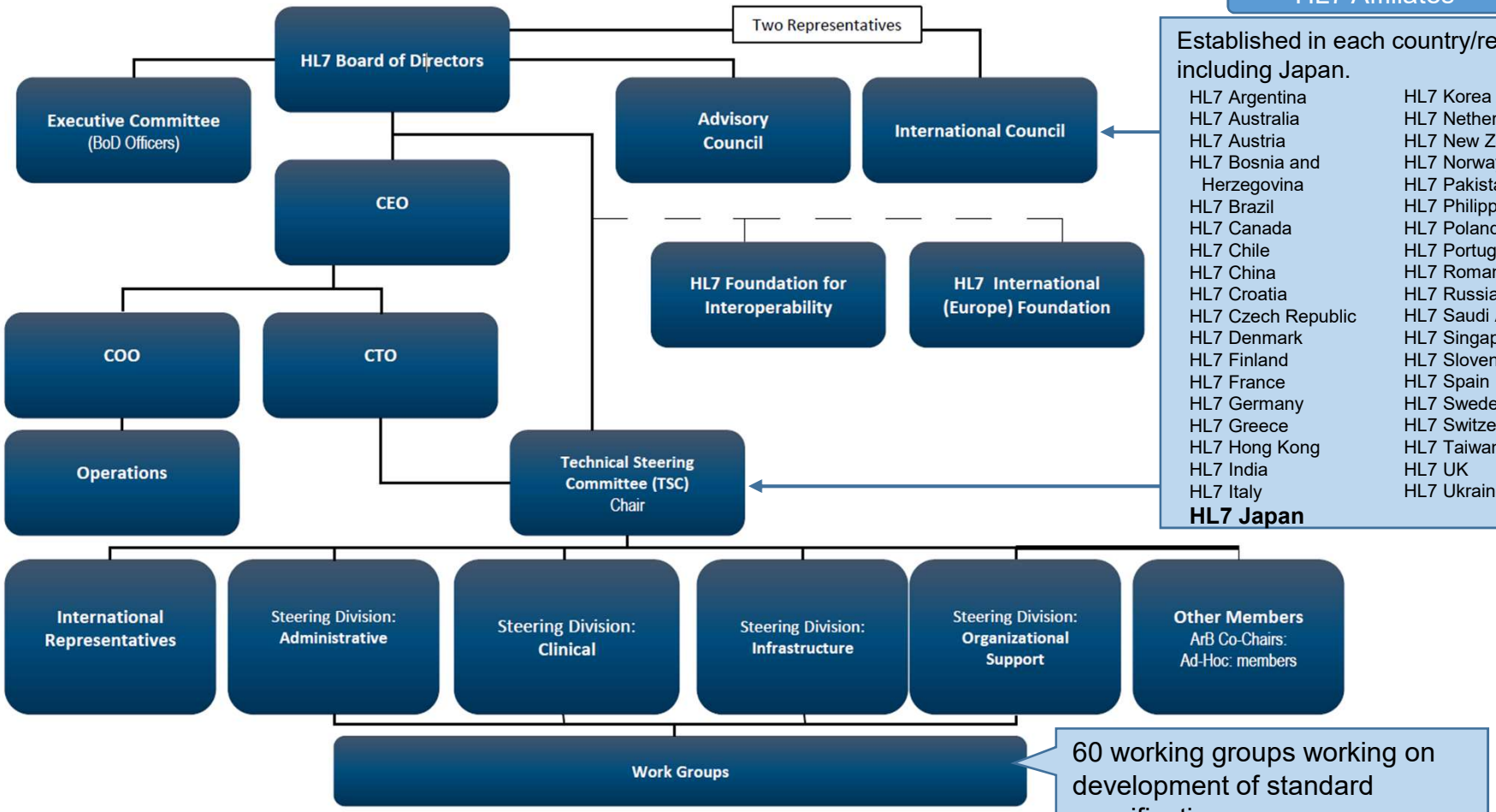
- The scope of the core implementation guide in each country varies.
- If a government focuses on developing implementation guides for use cases that it wants to guide as policy, the number of projects to be operated and managed is also limited. When working on a large number of areas at the same time, the burden of community management is likely to be greater, including the coordination of the overall project, support for each project, and confirmation of interoperability between projects.



Source: Fujitsu Research Institute

(Reference) HL7 International and HL7 associations around the world

- HL7 International recognizes organizations that have signed an Affiliate Agreement as HL7 Affiliates.
- Each nation's HL7 Affiliates has the right to license the works of the international standard specifications (HL7 v2.x, v.3, FHIR, etc.) as developed in HL7 International, as well as to vote on the Technical Steering Committee (TSC), which makes decisions on updates, etc.
- HL7 International has been actively collaborating with other organizations such as IHE International, and it is important for Japan to collaborate and interact with them.



Source: HL7 International

(Reference) HL7 and IHE

■ IHE (Integrating the Healthcare Enterprise) International has been working with HL7 International on the FHIR specification since 2018.

Differences between the missions and roles of HL7 and IHE

HL7: To provide standards that empower global health data interoperability

IHE: To improve healthcare by providing specifications, tools and services for interoperability.
To improve healthcare by providing specifications, tools and services for interoperability. IHE engages clinicians, health authorities, industry, and users to develop, test, and implement standards based solutions to vital health information needs

Joint Project: Project GEMINI

The following five areas regarding FHIR were jointly implemented

(1) Development of FHIR-based IHE profiles and tooling
(2) Publication of FHIR-based IHE profiles
(3) Testing (FHIR DevDays, FHIR Connectathon, and (IHE Connectathon)
(4) Identification and implementation of pilot projects.
(5) Management of joint information dissemination and marketing

FHIR-based IHE profiles have been created; the following FHIR r4 version of the profile was developed at Project GEMINI.
- Mobile Access to Health Documents(MHD)
- Mobile Care Services Discovery(mCSD)
- Patient Demographics Query for Mobile(PDQm)
- Query for Existing Data for Mobile(QEDm)

The following pilot project was implemented by Project GEMINI
✓Imaging for Cancer Care
(Use of medical imaging and other diagnostic data for cancer treatment)
✓Computable Care Guidelines (A WHO, CDC, HHSC, IHE, HL7 FHIR collaboration regarding computable care guidelines (CCG)
(CCG: Machine readable guidelines for computer processing)
✓e-Immunization (electronic vaccination information management)

Source: Gregorio Canal (Consorzio Arsenàl.IT) "XDS on FHIR" Nov 14, 2018
https://www.devdays.com/wp-content/uploads/2019/03/DD18-EU-Gregorio-Canal-XDS-on-FHIR-DevDays-2018-11-14.pdf
HL7 International Project GEMINI Confluence page
https://confluence.hl7.org/display/GP/Project+Gemini

(Reference) Activities of the Working Group in HL7 International

- Of the 60 working groups in HL7 International, the FHIR Management Group and the FHIR Infrastructure WG led the development and review of the FHIR Basic Specification and major implementation guides in cooperation with the following working groups
- Many of the WGs have weekly activities and operate with a number of members who participate almost exclusively in them.

WG	Frequency of meetings	Number of Attendance	Responsibilities
FHIR Management Group	Almost weekly	6 to 10 + 2-13 observers / guests	Lv.1 HL7, ANSI and the FHIR Standard
FHIR Infrastructure	Almost weekly	8 to 10	Lv.1 Foundation Module Lv.2 Implementor Support Module Lv. 2 Security Module Lv. 2 Conformance Module etc. and DAF / US Core / SMART related IG development
Implementable Technology Specifications	Every few months.	3 to 5	Lv.1 XML, JSON, FHIR Ontology, RDF, etc. Developing a vendor-independent marketplace, etc.
Community-Based Care and Privacy (CBCP)	Almost weekly	6 to 15	Lv.2 Consent Resources
Security Work Group	Almost weekly FHIR Security only meetings are held about 1-3 times a month out of these meetings.	6 to 16 (FHIR Security meetings are 3-6)	Lv.2 Provenance Resources etc.
Patient Administration	Almost weekly	4-6	Lv.3 Administration Module Review of the Da Vinci Project
Patient Care	Almost weekly	8 to 15	Many resources in the Lv.4 Clinical module (except RiskAssessment). Review of the Gravity project, etc.
Clinical Quality Information	Almost weekly	21 to 30	Lv.5 Clinical Reasoning Implementation Guide QI-Core, FHIR Quality Measure IG
Clinical Decision Support	Almost weekly	14 to 16	Lv.5 Clinical Reasoning Module HL7 CDS Hooks IG etc.
Pharmacy	Intensive discussion once every few months for a few days	5 to 14	Lv.4 Medication Module
Vocabulary	Intensive discussion once every few months for a few days	10 to 16	Lv.2 Terminology Module
Orders and Observations	Intensive discussion once every few months for a few days	14 to 40	Lv.3 Device Lv.4 Diagnostics Module
Clinical Genomics	Intensive discussion once every few months for a few days	10 to 14	Lv.4 Diagnostics Module
Financial Management	almost weekly	7 to 15	Lv. 5 Financial Module

(Reference) Operational system of the Implementation Guide

(1)US Core Implementation Guide

Operating organization	HL7 International
Screening system	The US Realm Steering Committee (US-RSC) • Chair: Deputy Director, Office of National Health IT Coordination (ONC), U.S. Department of Health and Human Services (HHS) • Chair Emeritus: Duke University Clinical and Translational Science Institute (Academician) • CTO(Chief Technology Officer): HL7 International • Co-chair: Experts and technicians • Members: the person from Mayo Clinic, Cerner, HL7 Canada, Epic, Anthem, Leidos, Dynamic Content Group, Department of Veterans Affairs (Architect), Kaiser Permanente (health insurance organization)
Operational body of testing (connectathon)	the Argonaut Project Team
Test server	Inferno of ONC (A service that can verify 21st Century Cures interoperability, information blocking, and compliance with the rules presented by the ONC Medical IT Accreditation Program. By using inferno, conformance to the Argonaut Implementation Guide, SMART Application Launch Framework and OpenID Connect as described in the rules can be verified. From the client's perspective, testing program access to the server and verity.).
Support system	
Funds	ONC grants (ballot process, connectathon operations, etc.)

(Reference) Operational system of the Implementation Guide

(2)CareConnect of UK

Operating organization	NHS Digital / INTEROpen
Screening system	INTEROpen Board of Representatives Co-Chair: INTEROpen, Members: NHS Digital, NHS, PRSB (Standards body for healthcare), British Computer Society, IHE, CCIO Network, Key Vendors
Operational body of testing (connectathon)	INTEROpen
Test server	None. The resources required by the use case are mapped and evaluated in CareConnect using an Excel tool called Design Decision Matrices (DDMs).
Support system	INTEROpen Participating Companies
Funds	Undisclosed (the operation of the INTEROpen is likely to be supported by NHS Digital)

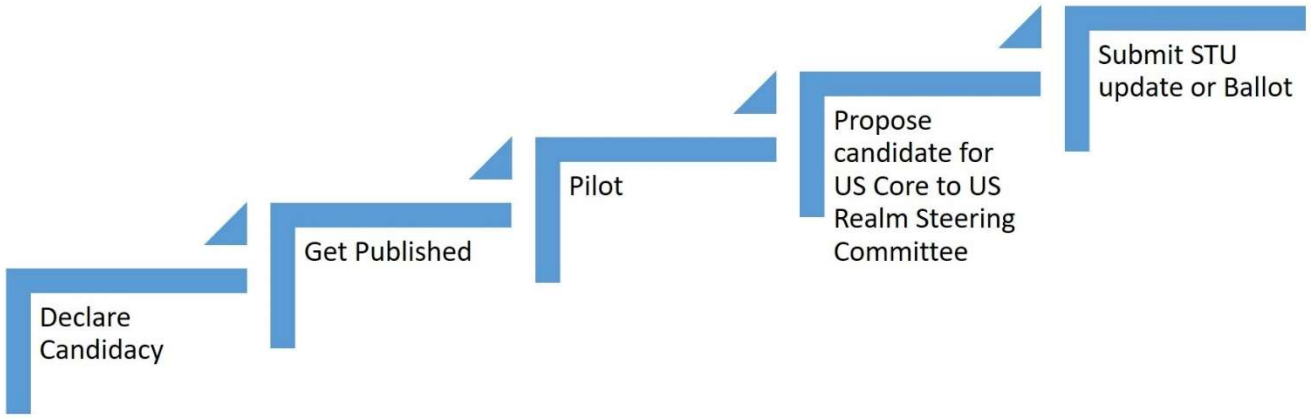
(Reference) Operational system of the Implementation Guide

(3)AU Base 2 of Australia

Operating organization	• HL7 Australia working groups • Australian FHIR Implementers Community • HL7 Australia Working Groups • Australian Digital Health Agency • Secure Messaging Technical Working Group • HL7 Argonaut Australia Project
Screening system	Individual assessment with HL7 Australia Working Groups
Operational body of testing (connectathon)	None *Installed and implemented IG of individual use case
Test server	None *Installed and implemented IG of individual use case
Support system	• Australian FHIR Implementers Community • HL7 Australia Working Groups • Australian Digital Health Agency • Secure Messaging Technical Working Group
Funds	Undisclosed

(Reference) Process for updating the US Core Implementation Guide

- The core implementation guide is considered a minimal set, but it is analyzed for implementation problems through connectathons with actual systems.
- Decisions are made by the U.S. Realm Steering Committee of HL7 International, which includes members from U.S. government agencies.

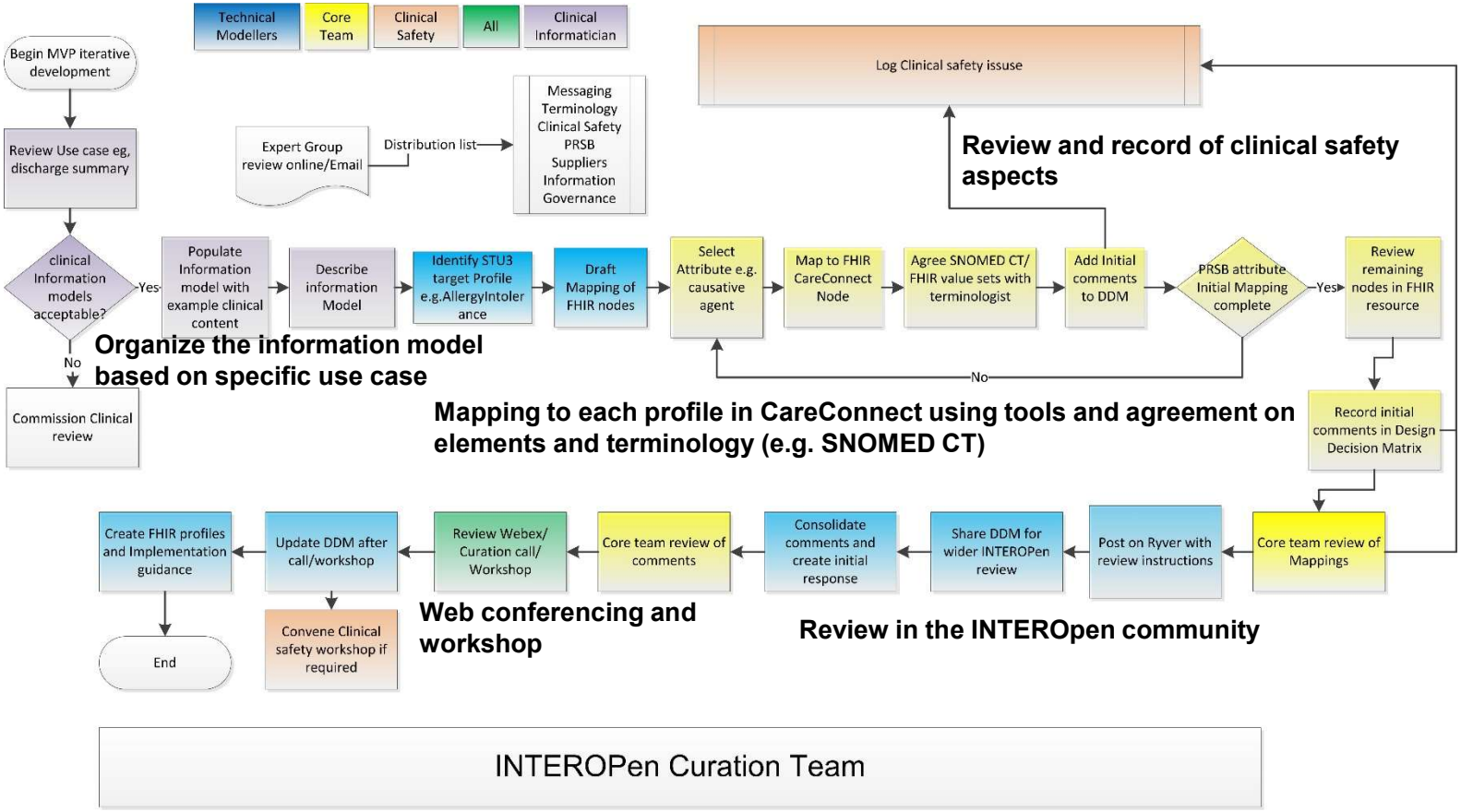


Process	Description
Declare candidacy	This step can be completed by presenting to **the US Realm Steering Committee (USR-SC)** through a Project Scope Statement.
Get Published	Development a formal profile, implementation guide, or get requirements directly published in FHIR Core. The initial publication could be an outside consortium, or vendor publication.
Pilot	Coordinate with 3 or more implementers an in-person or virtual connectathon. This is the time to identify issues with the new proposal.
Propose candidate for US Core to US Realm Steering Committee	Receive formal approval from the US Realm SC to add.
Submit STU update or Ballot	Receive **(public) comments** or seek a **ballot** for an update of the formal Standard for Trial Use.

Source: US Core https://www.hl7.org/fhir/us/core/future-of-us-core.html

(Reference) Curation process for NHS CareConnect profiles in England

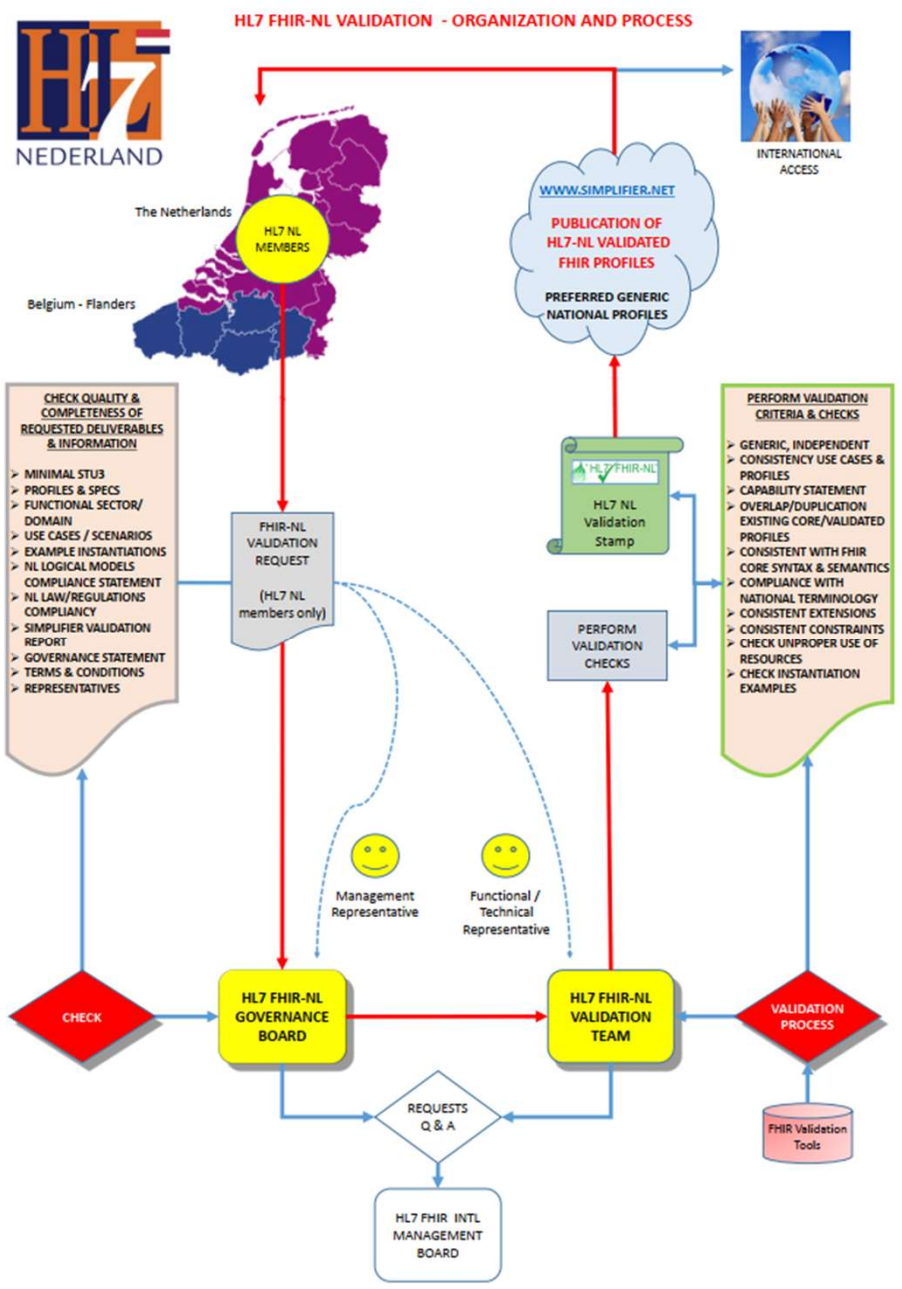
- INTEROpen uses a curatorial process to develop profiles in specific use cases, based on the core UK FHIR profile, CareConnect. Through this process, the new profile will be mapped to CareConnect and validated for both clinical and technical aspects in the community.
- Requirements for each use case are placed in profiles using an Excel tool called Design Decision Matrices (DDMs), which are also reviewed and validated by professional organizations in the clinical field.
- This process took about five months to implement.
- Conducted in the INTEROpen community via web conferencing.



Source：INTEROPen FHIR Curation Guide
http://www.interopen.org/2018/07/05/fhir-curation-guide/

(Reference) Update process of core profiles and service conformity certification system in HL7 Netherlands

- The HL7 Netherlands has developed a validation tools and certification process for the Netherlands national core profiles, HL7 FHIR-NL, and provides a stamp for profiles that have been certified as conformant.
- The profiles are checked for the validation readiness by the HL7 FHIR-NL Governance Board, and validation checks for them are conducted by the HL7 FHIR-NL Validation Team.
- If there are requests or questions concerning improvement in HL7 FHIR-NL itself as a result of the validation, the "HL7 FHIR-NL Management Board" will consider them.



Source: HL7 Netherlands
https://www.hl7.nl/downloads/category/21-whitepaper.html

(Reference) IHE's Connectathons for interoperability verification

- IHE International has been conducted connection testing for conformance to the Integrated Profiles and Technical Framework, as shown in the table below.
- IHE International provides Gazelle and CAsC (Conformity Assessment Coordination) testing tools, which are used for free testing by companies such as connectathons, and also provides companies with support for individual testing on a fee basis.

	Plugathon	**Connectathon**	**Conformity Assessment**	**Projectathon**
Objectives	Improvement of conformance to technical frameworks and other specifications	Interoperability testing of our products based on standard rules in a country or region.	Certification by an ISO 17025-accredited testing organization for interoperability of the products	IHE-supported product conformance testing for implementation in specific projects
Prerequisites for participation	None in particular.	Completion of pre-testing with tools	Passing on the Connectathon	Passing the Connectathon *Subject to the criteria for specific projects.
Participating Products	Prototype, unfinished product	Prototypes, unfinished products and finished products	Finished product	Finished product
Deliverables	Knowledge of participating vendors, product proficiency	Self-Declaration of conformity of the product by the company based on the assessment by the jury and the results and evaluation of the connectathon	Conformity Assessment (CA) mark from IHE *Unlike the deliverables of the connectathon, it is valid internationally	Implementation of specific projects, etc.
Prerequisites for participation	Device on FHIR was also developed at Plug-a-thon.			Conducted for CH-EPR (Swiss Electronic Patient Record) *The organization which has the lead of the project has the responsibility for the projectathon

Source： Yasunari Shiokawa "CAsC：Conformity Assessment(IHE Japan) https://www.ihe-j.org/file2/ws-connectathon-2019/03-IHE-WS-CAsC.pdf
Alexander Berler "Strategic Vision on the Information Exchange Testing Continuum" (IHE Europe) https://www.ihe-europe.net/sites/default/files/2018-05/IHE%20Symposium_Berler.pdf

4. Implementers Support of HL7 FHIR

Support tools for implementers

- The FHIR specification adopts modern web technologies and is based on RESTful APIs for the services that implement open APIs or services that mediate system's interface.
- In other countries, the following tools are available to support implementers of APIs based on modern web technologies.

Reference Implementation	A reference implementation is software for server or client app development that is based on the FHIR basic specification or implementation guides, intended to help implementers. **Many of reference implementations are published in open source in order to enhance the quality of the FHIR specification or implementation guides, and to enhance the interoperability of products based on them.**
Validator	Validator checks whether the data issued by the API is consistent with the format, structure, cardinality, value format, etc. of the resource as defined in the FHIR Basic Specification or Implementation Guides (Profiles).
Test sever	Services provided as a test connection for developing client applications and API services
Sandbox	The sandbox is an environment for developing and testing APIs. On a trial basis, a virtual API service/application can be used as a partner for API connections to test the impact of code changes and other factors for various products that want to comply with standard specifications. Validators and test server functions are also included, and a sandbox is usually maintained with reference implementations.
Community Tool	Tools that enables sharing of information for implementers, sharing and reviewing of development resources, documents, etc.

Source: Fujitsu Research Institute

Support tools for implementers

(1) Reference Implementation

- There are a variety of reference implementations for free and paid service, including those based on the FHIR basic specification, support for authentication/authorization, and support for implementation guides.

Products	Provider	Key feature
HAPI FHIR	The University Health Network (UHN), etc.	Developed in Java. This reference implementation based on the FHIR basic specification, which is up to date with the latest FHIR R5 candidates and contributes to FHIR maturity. Validation tools and test servers are available.
SMART on FHIR	SMART Health IT Project	• A reference implementation including authentication and authorization server for OpenID Connect based on HAPI FHIR and MITREid Connect. • It has been implemented in Apple's app products, Microsoft's cloud services, and various EHR (electronic health record) products in US. • Published a library of trusted apps implemented with SMART on FHIR. • Sandbox is available.
CCRI (Care Connect Reference Implementation)	NHS Digital / INTEROpen	The reference implementation that comforms with the CareConnect API profiles, etc.
Firely Vonk	Firely	Paid reference implementation based on .NET developed by Firely. Firely develops various tools to support FHIR implementers and runs the event DevDays. Test server, etc. are available. (A free HL7 official .net reference implementation is also available)

Source: Website of each service

Support tools for implementers

(2) Validator, Test Server, Sandbox, etc.

- Test servers and sandboxes are provided for each implementation guide or product-specific. For Smart on FHIR, test sever environment support registration to the library of created apps.

Category	Typical Services	Key Features
Validator	HAPI Public Server	Provides a form that allows you to paste resources for online validation.
	AEGIS WildFHIR public server	Support for each version of the FHIR Basic Specification and additional FHIR Implementation Guides (including the Da Vinci Project, MedMij/FHIR-NL, etc.).
Test Server, Sandbox	HAPI FHIR Reference Server	A virtual environment with HAPI FHIR. Each version of FHIR is supported.
	HSPC Sandbox	Smart on FHIR-based sandbox environment. (OAuth2 is also supported.) Smart on FHIR registration is also supported.
	Vonk Demo Server	.NET-based virtual environment for FHIR servers. Each version of FHIR is supported.
	Cerner, EPIC, etc.	Smart on FHIR-based sandbox environment. (OAuth2 is also supported.) Smart on FHIR registration is also supported.
	HealthIT.gov FHIR Sandbox	It contains resources and tools that can be used by implementers of the FHIR standard in the Standards Implementation & Testing Environment (SITE) provided by ONC. These resources are complementary to those already available and published by HL7.
IHE Test Management Tool	IHE Gazelle	A comprehensive management tool for testing that has been used in the IHE Connectathon since 2012. It also has a pre-connectathon function (a test tool equivalent to the test server above).
	NIST FHIR Toolkit	NIST developed a test tool for FHIR verification. Used for IHE connectors and pre-testing in North America and Europe. (For Mobile access to Health Document: MHD)

Source: HL7 international Confluence and IHE international, IHE Japan's Material
- HL7：https://confluence.hl7.org/display/FHIR/Public+FHIR+Validation+Services and https://confluence.hl7.org/display/FHIR/Public+Test+Servers
- IHE Gazelle: http://www.ihe-j.org/file2/n84/material-dl/IHEJVWS20130529A3_Gazelle.pdf and https://gazelle.ihe.net/content/fhirtoolkittestsperactor

Support tools for implementers

(3) Community Tool

■ Tools such as GitHub are used to support implementers, as well as general modern web development.

Tools	Key Features	Providers	Fee
GitHub	A general platform for software development that allows programs and documentation to be managed in an open way. It is widely used in the FHIR community for various reference implementations based on the FHIR Basic Specification and Implementation Guide, etc.	GitHub	For each user 9 USD per month, 108 USD per year (Team license)
Simplifier	A service that enables management and publication of implementation guides, profiles, etc. (For FHIR development only)	Firely	Enterprise license: 25,000 EUR/year (10 projects/100 members) Team license: 7,500 EUR/year (5 projects/10 members)
Forge	An editing tool to create an HL7 FHIR profile (For FHIR development only)	Firely	Included in the Simplifier license.
JIRA	Project and Program Management Tool	Atlassian	For 50-100 project members: $831,000 per year
Confluence	This is the business version of Wiki used in HL7 International. Confluence can be used to create usufuldocuments that are not part of the FHIR specification.	Atlassian	Premium license: 1,190 JPY per user per year
Stack Overflow	A knowledge community on programming technology, etc. It is used to manage questions about FHIR.	Stack Exchange	12 USD per user per month, 144 USD per year

Source: HL7 International and website of each products

Cloud services for the implementation of FHIR API

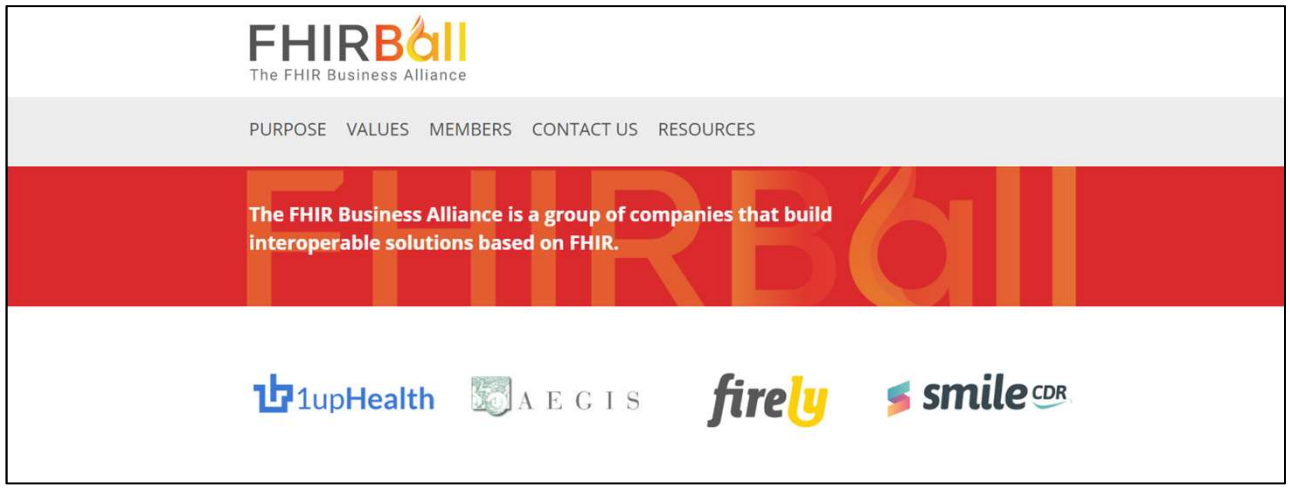
■ Since FHIR fundamentally assumes the adoption of modern web technologies and a loosely-coupled architecture, the use case for adopting FHIR is assumed to be cloud utilization.

Company/Service	Features
Amazon Web Services (AWS) : Amazon Comprehend Medical	• Users can extract clinical entities from unstructured text, such as medical notes • The service can be used for several use cases, such as using medical conditions extracted from memos to identify patients for clinical trials and evaluate the effectiveness of drugs based on drug information extracted from the memos. The NLP engine is available to developers using a simple API. • All services used as part of the solution are HIPAA-eligible services and can be used to transmit and process PHI (protected health information). • The credentials to invoke the FHIR APIs are maintained in AWS Secrets Manager, and the self-management capabilities of AWS Lambda and AWS Step Functions allow for scalability and high availability.
Google : Cloud Healthcare API	• Google Cloud simplifies the ingestion of data by converting data in other formats to and from FHIR resources, making it available to analytics and machine learning tools • FHIR API fully supports STU3 resources • The product has an interface that allows data to be read into Native, and the data is stored in auto-scale storage. • Data is encrypted and can be made available for de-identification, search and retrieval, and Rest APIs for machine learning, analysis, devices and applications • This API supports not only FHIR, but also HL7v2 and DICOM.
Microsoft : Azure API for FHIR	• The Azure API for FHIR allows you to connect to existing data sources such as electronic health record systems and research databases. • Simplify data management with a single, consistent solution for protected health information • The Azure API for FHIR enables medical data from multiple disparate systems to be brought together using the industry standard HL7 FHIR. • The Azure API for FHIR meets HIPAA regulatory requirements and is ISO 27001 certified. • Securely connect multiple systems using FHIR API. • Use role-based access control to manage storage and access. (Expected to be available in the East Japan region in Q2 2020.)
SalesForce : Salesforce Health Cloud	• The latest version of the FHIR open standard for the electronic exchange of health information provides an essential and appropriate target for continued investment in interoperability. • Interoperability efforts with EHRs are possible by maturing the FHIR function and expanding the data model to cover US Core data standards.
AEGIS Touchstone	• A cloud IaaS or TaaS (Test as a Service) platform for managing and testing paid development assets. • Enables automation of testing and other activities in the conformance testing community at HL7 International. ($40,000 per year)

Source: Website of each service

(Reference) Trends in Business Alliances for Community Tools

■ 1upHealth, AEGIS, Firely, and Smile CDR, providers of tools for FHIR-based services and connectathons, have announced an alliance called the FHIR Ball; the market for the provision of related tools specifically for FHIR is also growing.

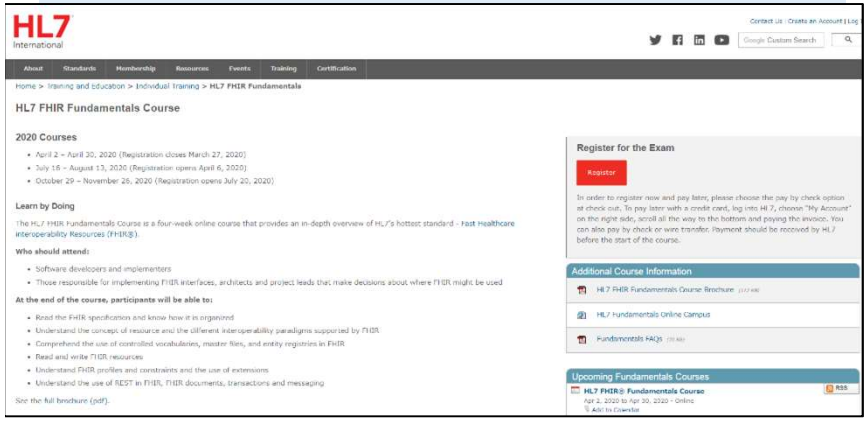


Company name	overview	Pricing
1upHealth, Inc.	Integrated FHIR-based cloud API platform providing a variety of services for patients, users, medical institutions, insurance companies, etc.	Pay-as-you-go: 0.0049USD to 0.0029USD per call, depending on API call volume (about 1-2USD per patient per year)
AEGIS, Inc.	Providing WildFHIR as a reference implementation and Touchstone as a testing tool from the very beginning of the development of the FHIR base specification.	Touchstone: 40,000 per year for Enterprise (100 users)
Firely Inc.	Simplifier, forge and more. He also runs HL7 International accredited educational courses and FHIR related events such as DevDays.	Simplifier: Enterprise license: 25,000 EUR/year (10 projects/100 members) (Reprinted.)
Smile CDR, Inc.	Provides platform services such as paid repositories and data linkage intermediaries by the members who developed and maintained the HAPI FHIR.	Undisclosed

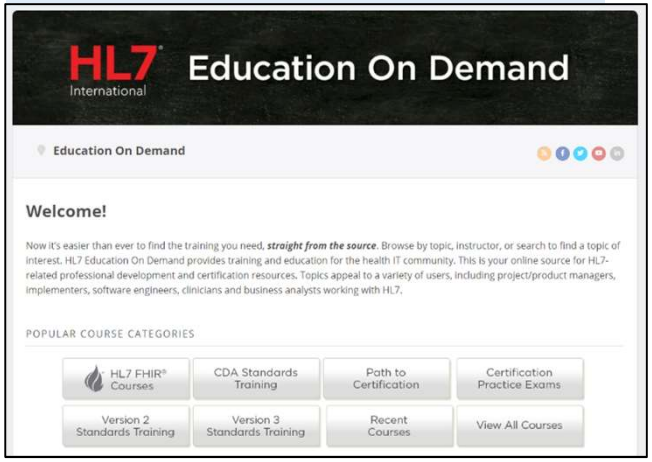
(Reference) Official educational content and qualifications for FHIR

- HL7 International, in collaboration with Firely and others, has developed educational content/educational courses/workshops on FHIR in addition to HL7 v.2 and CDA.
- The certification system includes HL7® FHIR® Certification as part of the HL7 International certification system.

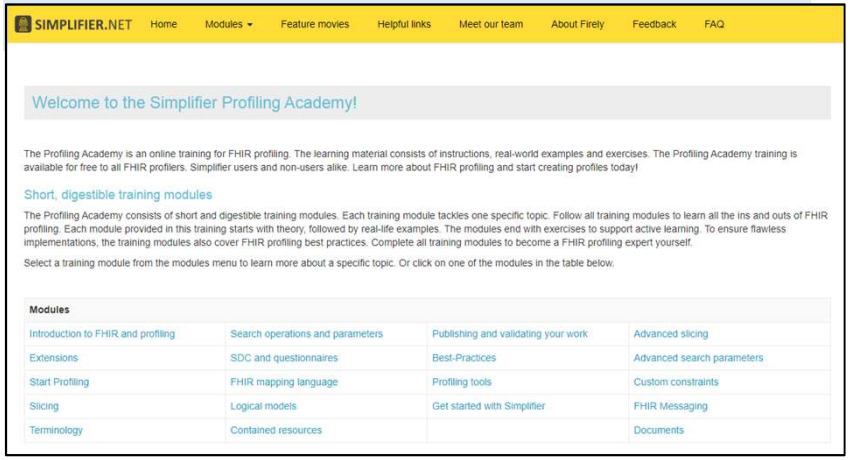
HL7 FHIR Fundamentals
https://www.hl7.org/training/fhir-fundamentals.cfm



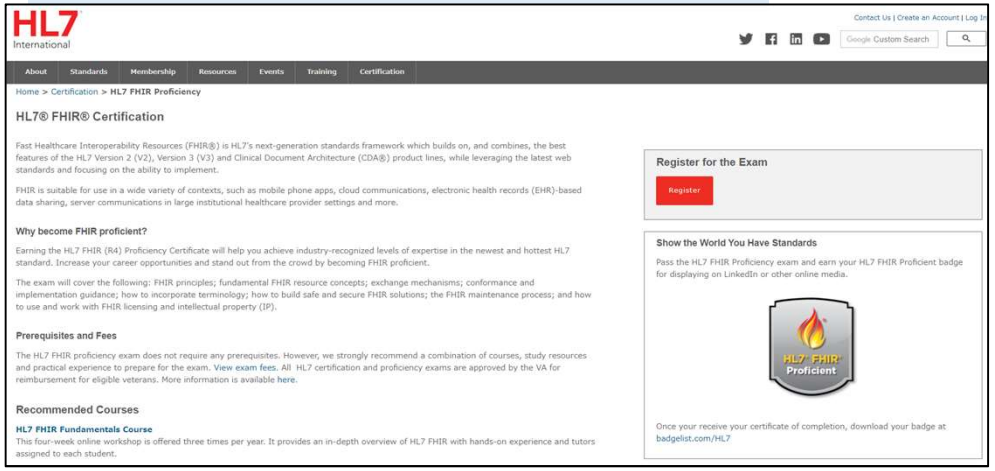
HL7 Education on Demand
https://www.pathlms.com/hl7



Simplifier Profiling Academy
https://simplifier.net/guide/profilingacademy/home



HL7 FHIR Certification
https://www.hl7.org/certification/index.cfm



5. Challenges in the case of utilizing FHIR in Japan

Challenges in the case of utilizing FHIR in Japan (Overview)

- In the health-information exchange scenario in Japan where the benefits of modernization are expected, there will be a great demand for implementation of open APIs with modern web technologies such as FHIR.
- Assuming that FHIR is to be adopted in use cases with high demand, it is **necessary to consider what should be commonly maintained and how the operation system and processes should be,** including the standard specifications of APIs that are accessed by many users (e.g., implementation guides). When there are **many target use cases, the tasks will be extensive and enormous.**
- In the case of other countries, the use cases and the scope of application of FHIR vary. When considering the case in Japan, it is necessary to consider the implementation method and scope in the process of transition while envisioning the ideal state.

To identify the tasks that need to be addressed for promotion, based on examples from FHIR ready countries.
To summarize the challenges from the tasks assuming if FHIR were to be utilized in Japan.

The assets should be maintained commonly

Consideration of the scope and method of maintenance is needed

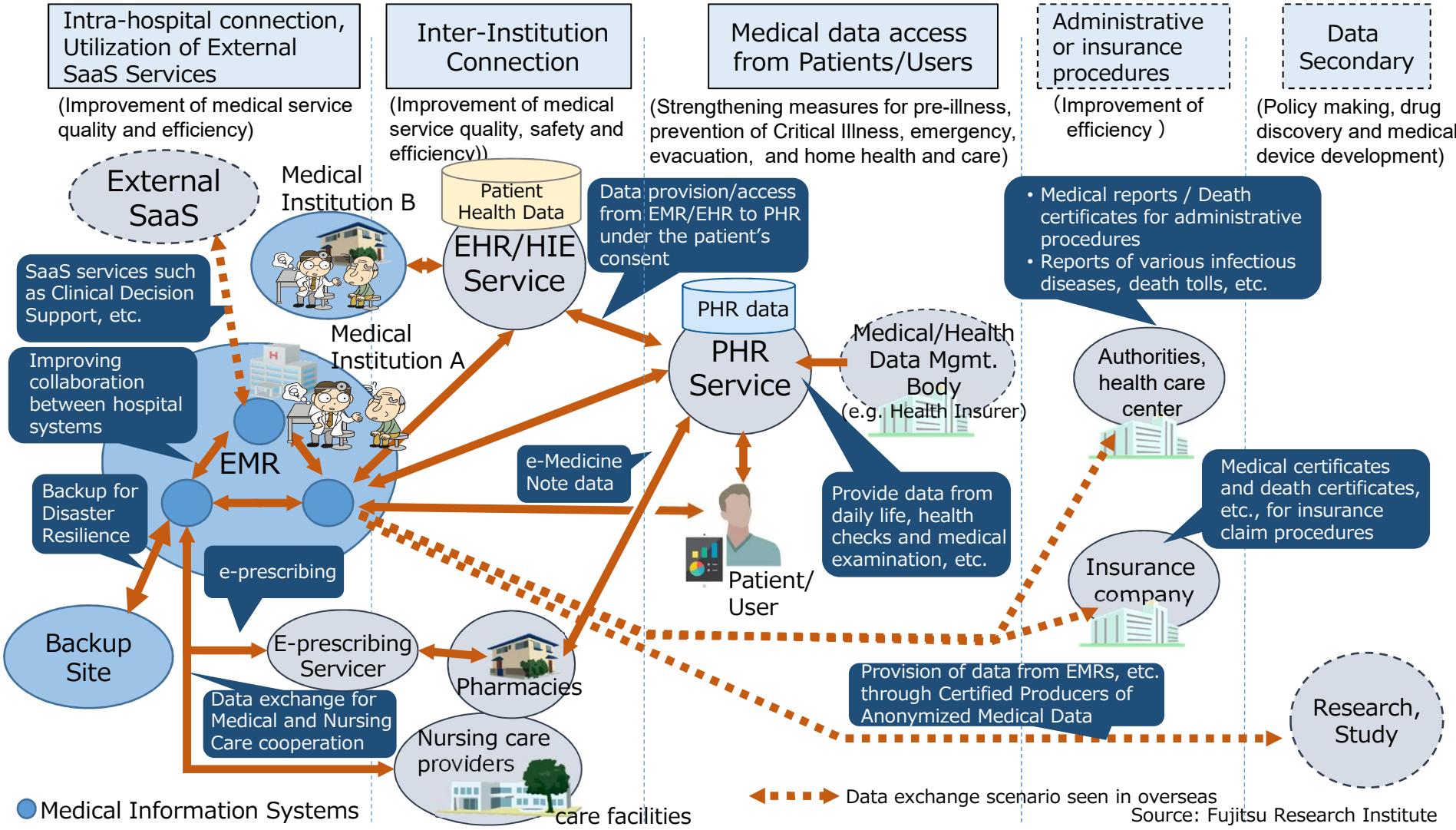
Localization	Implementation Guide, Profiles
	Terminology
	Reference Implementation
Software Infrastructure, Implementers Support Tools, etc.	Validator, Test Server, Sandbox
	Community Tools
	Certification Program of Software, etc.
	Educational contents and certification program for human skills
	Common Infrastructure for Authentication/Authorization

Operational structure and processes

- Formulation and management of policies and plans for overall asset development
- The role of the operation and management body of developed assets for common use.
- The cycle of development / maintenance of Japan's common asset including implementation and testing
- Community Building
- Establishment and maintenance of the management system for the assets, including financial aspects

Current status of health information exchange in Japan

- Example scenarios of health information exchange are illustrated below, including including the paper documents currently being exchanged.
- Considering the foreign cases and the future development of domestic medical information systems, the application of modern web technologies is likely to be beneficial in fields where existing initiatives are few, such as creating new services or connection between those services.



Source: Fujitsu Research Institute

Laws and rules regarding the handling and sharing of health information

- To build services using HL7 FHIR, it is necessary to identify issues based on the relevant laws and guidelines. Issues based on legislation and rules are envisaged depending on the use case, such as authentication and authorization mechanisms, management of FHIR resources, and the need for electronic signatures.
- An expert commented that, depending on the use cases to which FHIR is applied, the legal system should be developed such as PHR. Another expert suggested that the content of agreements (contractual content) should be common in the industry when actually promoting the services.

Category	Relevant laws and rules, etc.
Laws and rules regarding the overall handling of personal information, including consent management	• Act on the Protection of Personal Information • Guideline regarding Appropriate Handling of Personal Information for Medical and Nursing-Care Service Providers • Guidelines on the provision of health information
Laws and rules pertaining to the sharing of individual medical information	• Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (Next Generation Medical Care Platform Act) • Ordinance for Enforcement of the Act on the Use of Information and Communication Technology in the Preservation of Documents by Private Business Operators, Pertaining to the Provisions of the legal system under the jurisdiction of the Ministry of Health, Labour and Welfare • Operational Guidelines on Electronic Prescription
Legislation and rules when using the cloud	• Guidelines for Safety control of Medical Information Systems • Guidelines Relating to Safety Management When Cloud Service Businesses are Handling Healthcare Information • Safety Control Guidelines for Information Processing Businesses Handling Healthcare Information on Behalf of Others
Legislation and rules for handling data from IoT devices	• Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices • IoT Security Guidelines • Guidelines for Safety control of Medical Information Systems
Rules for Cooperation with Other Countries	Requirements of privacy legislation in each country and region • Europe: GDPR (General Data Protection Regulation), etc. • U.S.: HIPAA, etc.

Issues to be examined for localization (Draft)

(1) Issues to be examined for implementation guide and profile

Challenges to the development of core implementation guides and use case-specific implementation guides, while keeping the relationship consistent are discussed among various experts as below.

Expert opinions

- For the time being, it is necessary to have a policy of applying FHIR to undeveloped areas where there are no existing standards.
- It is not necessary to specify use cases. (There are examples of efforts to localize without limiting use cases such as patient profiles.)
- Based on the principle of Meaningful Use, priority use cases should be selected and implemented in Japan as well.
- It is necessary for the clinical side to urgently examine the future use cases for disease-specific (clinical field specific) PHR, for which digitization of the recording notes are gradually proceeding in the private sector.
- There is a need for a business model/social environment in which FHIR interoperability will benefit healthcare institutions, IT vendors and insurers.
- Profiles or Implementation Guides for FHIR users such as hospitals, clinics, other healthcare providers, and individual app developers would be helpful.

Drafted Policy

Items to be examined on development of core implementation guides/profiles

The core implementation guide should meet the following requirements, but also consider the relationship to the scope of content defined in the use case-specific implementation guide and determine the scope of profiling collection and the scope of maintenance.

- In order to ensure interoperability, it is necessary to specify terminology and resources and elements of them which API should support. (Need to examine whether security-related measures such as authentication, authorization, consent management, etc.)
- It is also necessary not to inhibit the spread of use cases and the creation of open innovation, which have not been achieved in the past.

Issues to be Examined	Basic Policy	The target use cases are basically not limited at this moment. Considering efforts in other countries, the abstract use cases shown below were seemed to targeted. ✓ Referencing, updating, and registering patient health information maintained by medical institutions through APIs, etc. ✓ Provide health information attached to insurance claim information obtained by the insurer
	The scope of profiling	After examining the relationship with the core implementation guides/profiles of other countries, individual cases, and the contents of the use case-specific implementation guides, the minimum necessary resources and their elements were selected.
	The scope of maintenance	When the implementation guide for each specific use case is in progress, there are cases in which the core implementation guide is a simple guidance, a collection of profiles, codes and terms used (value set), and references. A decision needs to be made.

Items to be examined on development of use case-specific implementation guides/profiles

It is necessary to encourage the development of the project in areas where there is a high need and significance of modernization.
The burden of operation and management will vary depending on the scope of the project.

Issues to be examined for localization (Draft)

(2) Issues to be examined for terminology

For codes and masters specified in the implementation guide, etc., it is expected that mapping information between domestic standard codes and other masters will be maintained, as well as a Japanese glossary and an extended glossary of terms when using codes that are used in other countries.

Expert opinions

- In order to use an API in a more flexible manner, it is necessary to use both Japanese domestic standard codes and international standard codes.
- Only the Japanese standard terminology should be adopted in the Japanese implementation guide to avoid confusion in the field.
- In Japan, it is desirable to adopt ICD11 (Classification of Diseases) as a terminology in FHIR.
- The MEDIS standard master* could be ported to FHIR (in the core implementation guide, etc.).

Drafted Policy

Items to be examined on terminology

Code masters with high interoperability and usefulness must be specified in the core implementation guide or the implementation guide for each use case. In addition, when using overseas codes in Japan, "translation" for accurate Japanese notation and "enhancement" for Japanese needs and mapping with existing standard masters are necessary.

Issues to be Examined	Code system selection	It is necessary to identify which domestic or international standard codes/masters are required to be used commonly and which should be used separately for each use case. Then, to study the appropriate way to specify them in the implementation guides is needed.
	Mapping to de facto standards other than standard masters	If there is a code/master that is not fully mapped to the standard master/code, the challenge is to maintain the mapping information. *For vendor-specific proprietary code, the vendor should individually map to the standard master and apply it to FHIR.
	Selection of codes that are used in other countries	Based on the trends of the standard codes specified in the FHIR Basic Specification and the core implementation guides of each country, the codes of other countries with interoperability that could be circulated in our country need to be maintained so that they can be used in Japan.

Existing standard masters

*MEDIS Standard Masters: Standard masters for 10 fields provided by the Medical Information System Development Center (MEDIS-DC).

Issues to be examined for localization (Draft)

(3) Issues to be examined for reference implementation

The reference implementations should be developed commonly, because those are expected to be widely utilized for implementation testing (projectathons and connectathons) and distributed as open-source software of FHIR server or client apps, and to contribute to the widespread use of implementation guides.

Expert opinions

- The development of open-source server or client applications is useful for the spread of standards in Japan.
- Reference implementations should be formed in the community so that developers can easily work on them.
- It is necessary to consider how to develop human resources who can develop the Japanese reference implementation and who are familiar with the FHIR specification.
- There are three groups of implementers: "corporate engineers," "staff in hospital or university hospital," and "standardization and technology alignment actors“, and their different needs and positions should be considered.

Drafted Policy

Items to be examined for the development of reference implementations

For development of common implementation guides and their implementation tests on the actual system, there should be an operational structure and process in which implementers can jointly develop open-source reference implementations to test it in specific scenarios.
In addition, quality control and maintenance of the reference implementation itself is also necessary because each vendor develops its own products based on the reference implementation, which helps to ensure interoperability and disseminate the implementation guide, rather than just for testing.

Issues to be Examined	Targe Implementation guides/profiles	It is necessary to examine whether to build based on the core implementation guide/profiles or on the implementation guides/profiles for each individual use case.
	Necessity of covering authentication and authorization function etc.	It is necessary to examine the scope of coverage, such as whether to cover promoting the spread of standard methods such as “SMART on FHIR”, which includes authentication and authorization server components.
	Ensuring the formation of a community (operational systems of reference implementation)	In order to encourage the implementation of actual server and client application products, it is necessary to develop human resources and build a community that can develop reference implementations for the Japanese version of the Implementation Guide with reference to the reference implementations of the FHIR basic specification such as "HAPI FHIR" and "SMART on FHIR".

Issues to be examined for infrastructure and implementer support tools (Draft)

(1) Issues to be examined for validators, test servers, sandboxes, and community tools

Validators, test servers, sandboxes are considered to be common objects to be developed and maintained. This is because they can be used for testing and evaluation of implementation guides/profiles, verification and testing of products developed based on implementation guides and reference implementations, and as an environment for supporting implementers to encourage their development.
In addition, it is expected that implementation guides will be created, reviewed, modified, and released by experts and engineers in the FHIR community, and therefore community tools are assumed to be a common target for maintenance.

Expert opinions

- FHIR's test tools for overseas connectathons are considered expensive. However, the IHE's connectathon tools are developed jointly and are available free of charge, and the IHE's approach should be used as a reference.
- It would be good if they are developed in the community to make it easier for developers.
- There should be some sort of CI/CD tool. It is also important to include negative testing in the testing.

Drafted Policy

Issues to be examined for validators, test servers, sandboxes, and community tools

As with the reference implementation, the following items are expected.
It is expected that Japan will not develop new tools, but will introduce tools made overseas, but it is also necessary to examine the cost burden.

Issues to be Examined	Target Implementation guides/profiles	The scope of each implementation guide for commonly operated validators, test servers, sandboxes, and community tools
	Target tools selection	It is necessary to examine whether the tools should be developed in Japan (proprietary tools based on the core implementation guide and use case specific implementation guides of Japan, or the tools based on the FHIR basic specification) or whether to utilize tools made overseas.

Issues to be examined for infrastructure and implementer support tools (Draft)

(2) Issues to be examined for certification of systems to implementation guides

It is envisioned that FHIR basic specifications, use case-specific implementation guides that conform to the core implementation guide, or products that conform to the use case-specific implementation guide will be published to ensure interoperability and promote dissemination.

Expert opinions

- FHIR is only doing its own testing by providing connectathons and tools in the sense of improving the basic specifications. Challenges were found that there was a burden to ensure interoperability in MID-NET. In addition, even with DICOM that have testing tools, the medical community has been confused by the manufacturer's self-proclaimed DICOM-compliant products; In light of these factors, the IHE process should be taken as a guide. (Phase 1: Product Functionality Test (In-house Test/Connectathon), Phase 1+1: Product Functionality Qualification Test, and Phase 3: Comprehensive Test on the Usage Environment (Projectathon)
- With a connectathon, we can verify not only the whole application but also each algorithm (each module). Therefore, I believe that incentives such as simplifying the connectathon verification are also effective for applications that consist of only verified modules.

Drafted Policy

Issues to be examined in the certification of systems to implementation guides

To development of the core implementation guide and use case specified implementation guides, the process and structure of the IHE certification (including product certification and comprehensive testing on the usage environment) and its support system will need to be considered.
In addition, the formation of a marketplace for certified apps, like SMART apps, also needs to be examined.

(3) Issues to be examined for educational content and qualification system

HL7 International and Affiliates in Europe have published the results of discussions on various topics through community tools (e.g. wikis and Confluence) and have established qualification systems for FHIR together with HL7 v.2.x and v.3. In addition, educational content (tutorials) and educational services (training courses and workshops) related to the examination content of the qualification system have been developed. These efforts should be examined as targets to develop commonly if necessary.

Issues to be examined for educational content and qualification system

The following tasks are expected to be undertaken in the development of educational content.
- Purchase and translation of foreign content
- Content development in line with the Japanese legal system, rules, implementation guides and tools

It is also expected that coordination with HL7 International on the qualification system will be necessary.

Issues to be examined for infrastructure and implementer support tools (Draft)

(4) Issues to be examined for user authentication and apps authorization (Access Control)

The FHIR specification recommends OpenID Connect / OAuth2.0 for authentication and authorization when implementing a web-centric API. Although various patterns of security systems such as authentication and authorization servers are expected to be used, it is also expected that they will be developed as a common infrastructure if necessary.

Expert opinions

- This issue is a general discussion of all open information systems with REST API, and not the matters specific to healthcare or to FHIR. This topic should be properly discussed as an issue for e-government of Japan.

Drafted Policy

Issues to be examined for authentication, authorization server

In the financial sector in Japan, financial companies use individual or joint services of authentication/authorization server. In many other fields, common infrastructure has not necessarily been developed.
In the medical sector, it is necessary to examined based on the trends in other sector whether a common infrastructure should be developed, to what extent it should be covered, what technologies to base it on, and the necessity of cooperation with existing certification infrastructure.

Issues to be examined for operational system and process (Draft)

As in other countries, it is expected that an FHIR community of implementers in Japan should be formed and the operational process should be spun around.

Expert opinions

- We should hold a kind of core meeting in the near future and consolidate the policies that will become the main premise of the project at first. The discussion should be developed in a scheme that can summarize the entire issues. A core meeting body should be set up as a starting point for future projects.
- Since implementation guides and other documents need to be improved and revised periodically, it is one of the requirements that an organization that can guarantee some degree of continuity issue them.
- The FHIR specifications and products are being developed on an implementation basis in open communities, which makes them different from the standards developed by experts in small meetings.
- Independent test management organizations are needed for connectathons.
- The implementation guide should not deviate from medical guidelines and should be clinical society-centered. It is necessary to objectively evaluate the elements.

Drafted Policy

Issues to be examined for operational system and process of Implementation Guides

Unlike the existing standardization regime and process, issues concerning development process and improvement cycle designed to be implemented in the community for the implementation guides/profiles need to be examined, particularly with respect to the following

Issues to be Examined	Formulation and management of over-all policies and plans	In identifying the needs to be covered by each implementation guides/profiles, it is necessary to conduct surveys and develop policies. In addition, it is also necessary to examine policies based on trends such as updates in the FHIR basic specification.
	Development and decision-making process for the core implementation guide	A process and structure for decision-making is needed. In this case, the community and the ballot must be conducted.
	Translation/Expansion process of overseas masters	In case the implementation guide shows how to implement not only domestic standard codes but foreign codes, foreign codes need to be maintained for use in Japan, such as translation and expansion. (Response to annual update, etc.)
	Process for certification of apps and services	Apart from the implementation guide development process, there should be a certification process for products, services, etc., through connectathons , etc. continuously, that is separate from the implementation guide development process. It is also expected that the process will utilize validators, test servers, and sandbox testing tools.

Issues to be examined for operational system and process (Draft)

Since various tasks such as localization, infrastructure, and implementer support tools will be required, it is assumed that the operational system will be difficult for a single organization. In addition, it will be necessary to coordinate the work of the community of implementers, including vendors and engineers, more than ever before.
Based on the opinions of the experts, etc., the assumed image of the classification of the organizational body is presented according to the required functions.

Organizational unit classification	Main Position
Core meeting body	Conduct surveys of needs and issues, etc., and develop overall policies and plans.
Core operational Organization	• Develop, operate and manage the core implementation guide and be responsible for its dissemination and promotion measures. • It is also expected that the organization will work with each of the following operational organizations for each use case, project to also manage the whole community for the implementation, testing and evaluation process of the core implementation guide. • If the core implementation guide is based on some specific use cases, and connectathons of the core implementation guide on those use cases are conductible, the organization could also be responsible for apps/services certification, etc.
Operational organizations for each use case or project	• Develop profiles/implementation guides for specific use cases and scenarios. • Manage the community for the project. • Responsible for app and service certification, if connectathons are conductible.
Independent Test management body	• Prepare test cases and test tools based on the implementation guide etc. • Conduct independent connectathons, conformity testing and certification, and other support.
Terminology management body	• Conduct tasks including translation of the foreign masters referenced by FHIR apart from the FHIR specification.
Authorization/Authorization Infrastructure Management Body	• Operate the infrastructure system if a common infrastructure system for certification, approval, etc. is to be developed

Issues to be examined for operational system and process (Draft)

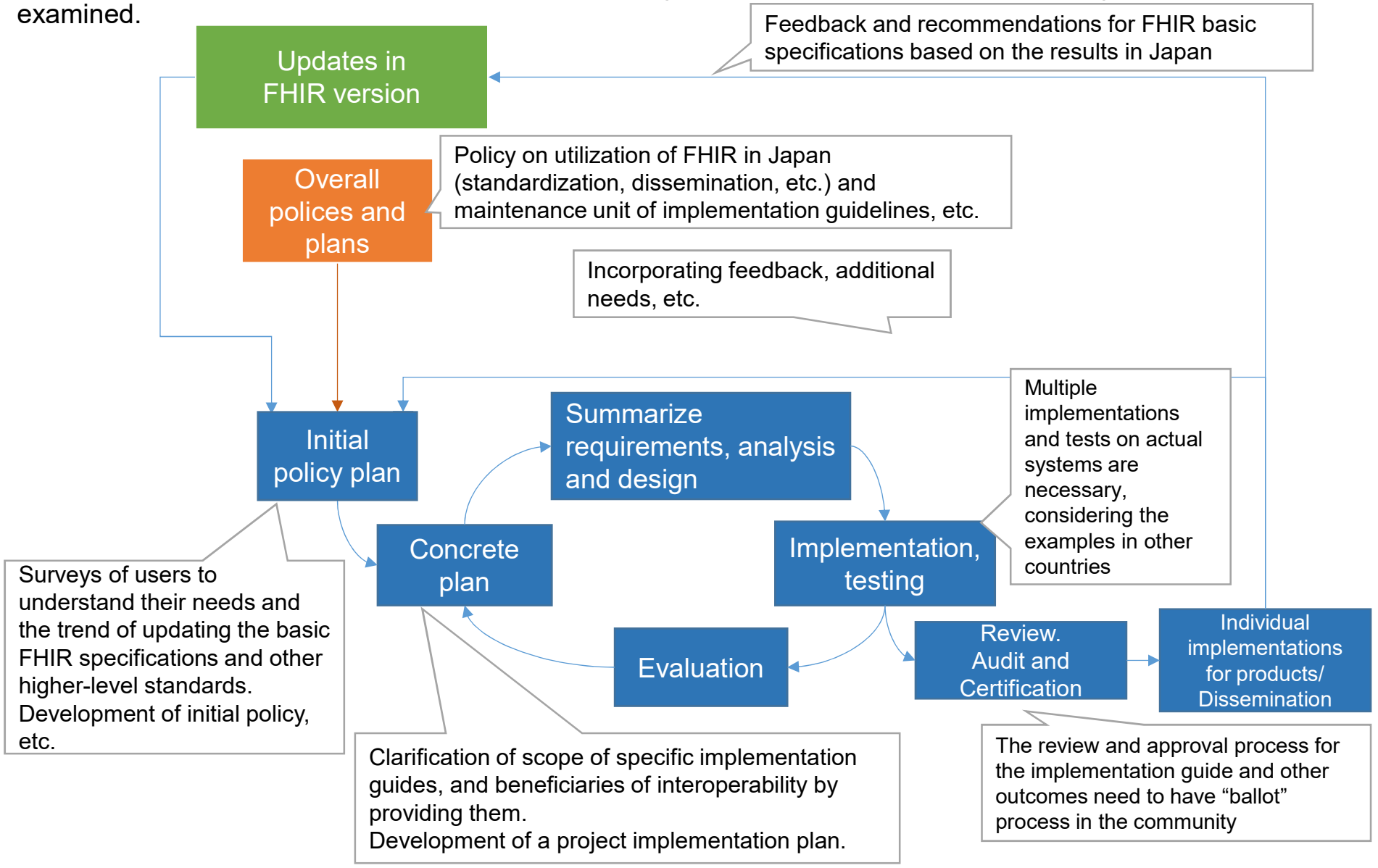
The following table presents the assumed role of the each operational organization.

Source: Fujitsu Research Institute

Items to be worked on in common		Core Meeting body	Core operational organization	Operational organization for specific use cases / projects	Independent Test Operator	Terminology management body	Authorization/ Authorization Infrastructure Management Body
Overall policy and plan		Formulation					
Localization	Implementation Guides/Profiles		Develop the Core Implementation Guide	Participation in development of the Core Implementation Guide Develop implementation guides for each use cases		Participation in or support of development	
	Terminology					Translation and expansion	
	Reference Implementation		Develop for the core implementation guide	Develop for the implementation guides for each use cases		Participation in or support of development	
Infrastructure, Implementers support	Validators, Test servers, Sandboxes		Develop tools for the core implementation guide	Develop tools for the implementation guides for each use cases	Develop tools, etc.	Participation in or support of development	
	Community tools		Maintenance and operation	Maintenance and operation			
	Certification program for products/services			Establishment of a certification program	Support for operation, certification and verification in connectathons		
	Educational Contents/qualification program		Translation of FHIR's own educational content Operate qualification program for FHIR basic specification				
	Infrastructure for authentication / authorization						Develop and operate infrastructure

Issues to be examined for operational system and process (Draft)

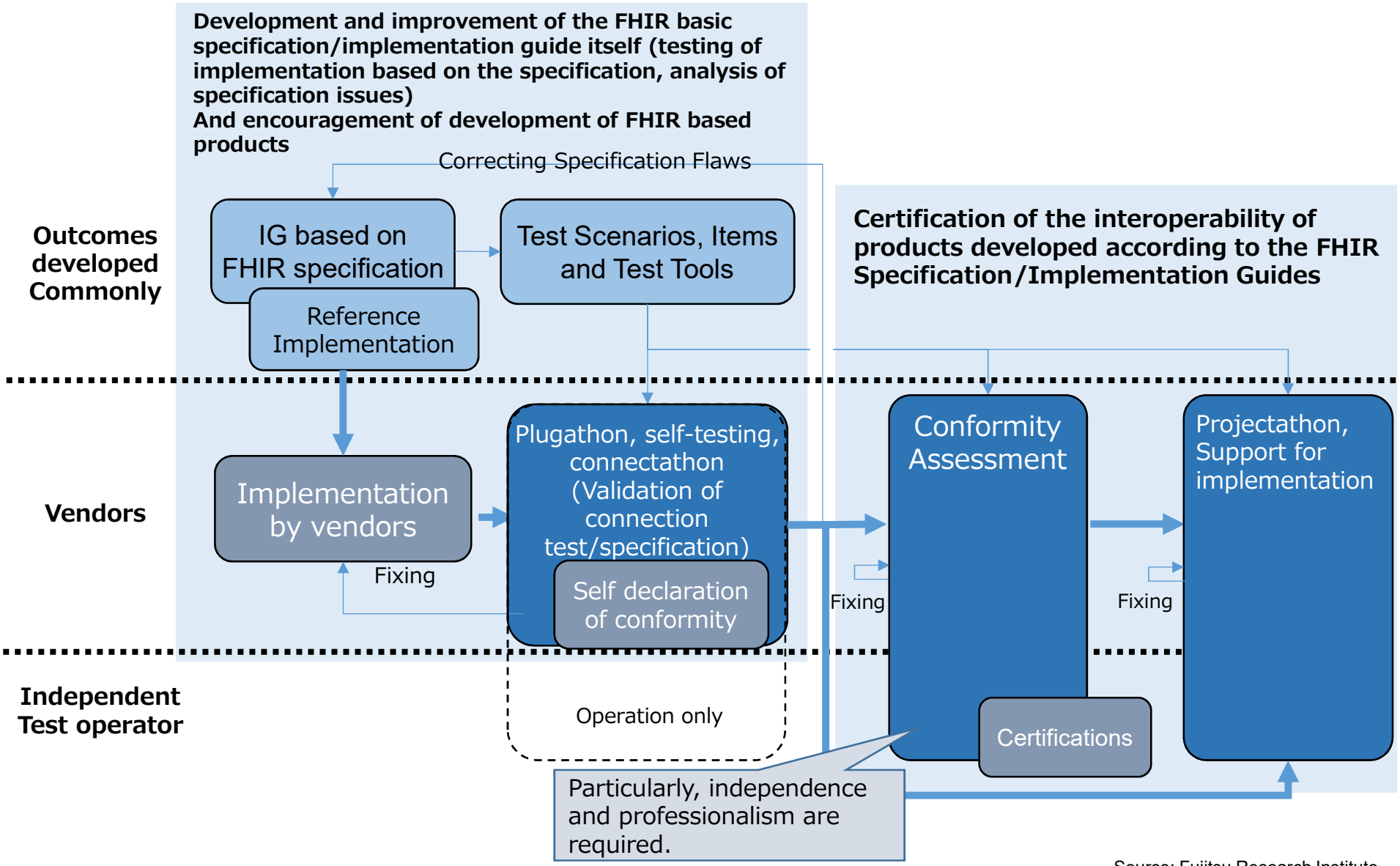
In terms of the operational process of implementation guide development, etc., the following flow should be examined.



Source: Fujitsu Research Institute

An image of connectathons, etc.

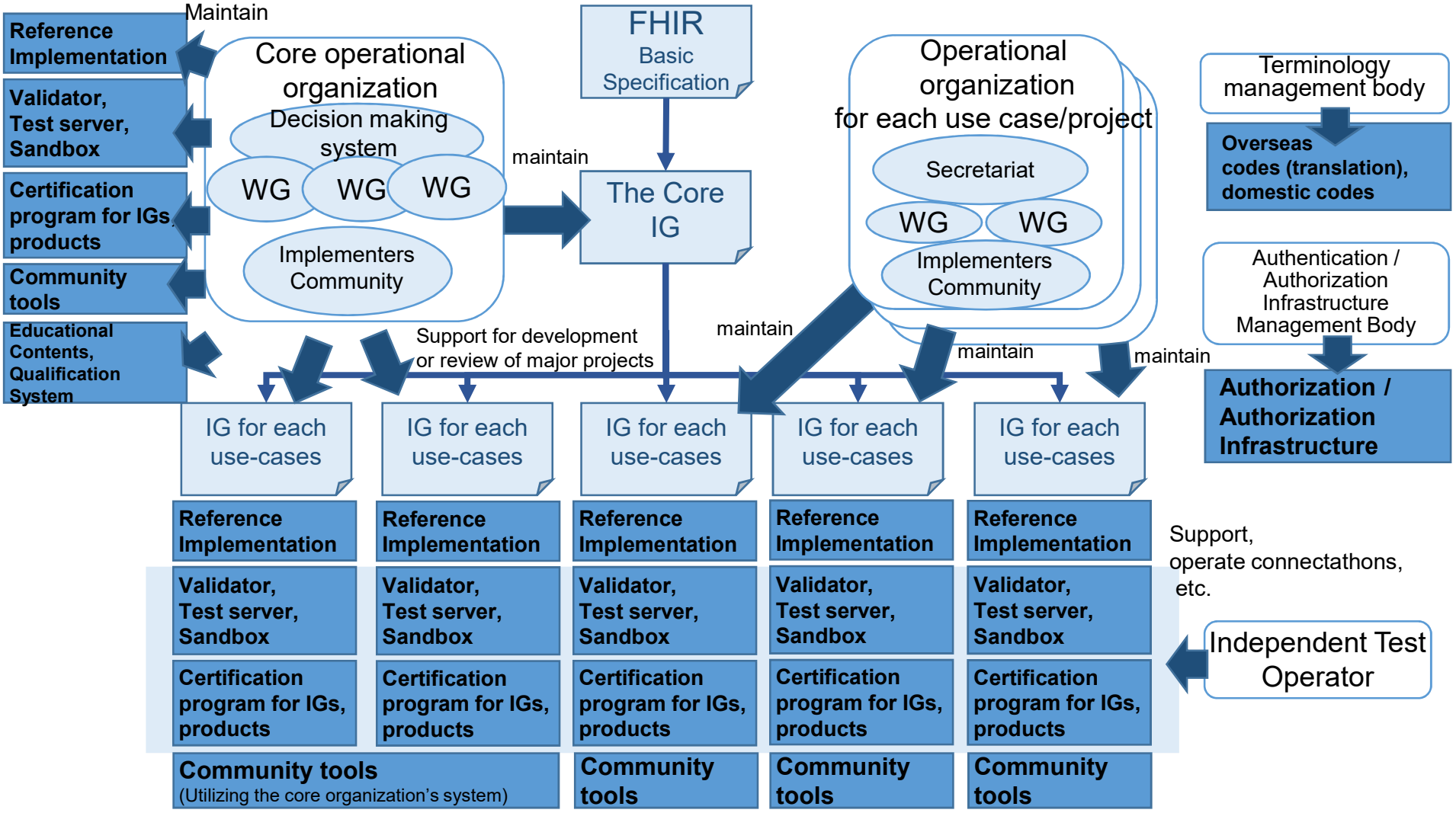
Based on examples from other countries and IHE International's efforts, the following process and structure of connectivity testing environment (test tools) and certification testing is proposed.



Source: Fujitsu Research Institute

An overall image of artifacts that should be developed commonly and operational bodies of them (Draft)

It is assumed that FHIR is to be used in various use cases in Japan, there is a wide range of items that need to be commonly maintained, and it is expected that the amount of work, such as coordination among operational entities (especially core operational organization), will increase as the number of implementation guides for each use case increases. It is necessary to examine a system that can handle the amount of work and the scope of application of the implementation guides.



Source: Fujitsu Research Institute

(Reference) FHIR Basic Specifications and cost estimates for translation

- There are 17,120 files (HTML files only) covering all FHIR basic specifications.
- 10,500 JPY per page, assuming an average of 300 words per page, about 1 to 2 A4 pages (Source: JTF (Japan Translation Federation) quotations for the fields of "Medicine, Medical and Pharmaceutical Sciences")
- If all the pages were translated at the average price above, the cost would be 180 million yen.