

「FHIR」相互運用性の為の Profileの紹介

木村映善

国立保健医療科学院 統括研究官

愛媛大学医学部附属病院医療情報部 客員教授

自己紹介

- 北海道大学医学部卒
- 愛媛大学大学院医学系研究科博士
課程医学専攻 社会・健康領域医療
情報学講座
 - 大学時代は電子カルテシステムの導
入・運用に寄与
 - 機械学習, 秘密分散, データマイニン
グ, 情報処理, 匿名加工
 - リアルワールドデータの活用0
- **国立保健医療科学院・統括研究官
(保健医療情報管理分野)**
 - 標準医療情報規格に関する研究
 - 医療情報の匿名加工



国立保健医療科学院は、保健、医療、福祉に関係する職員などの教育訓練や、それらに関連する調査及び研究を行う機関として設置されています。



データ匿名化手法
—ヘルスデータ事例に学ぶ個人情報保護

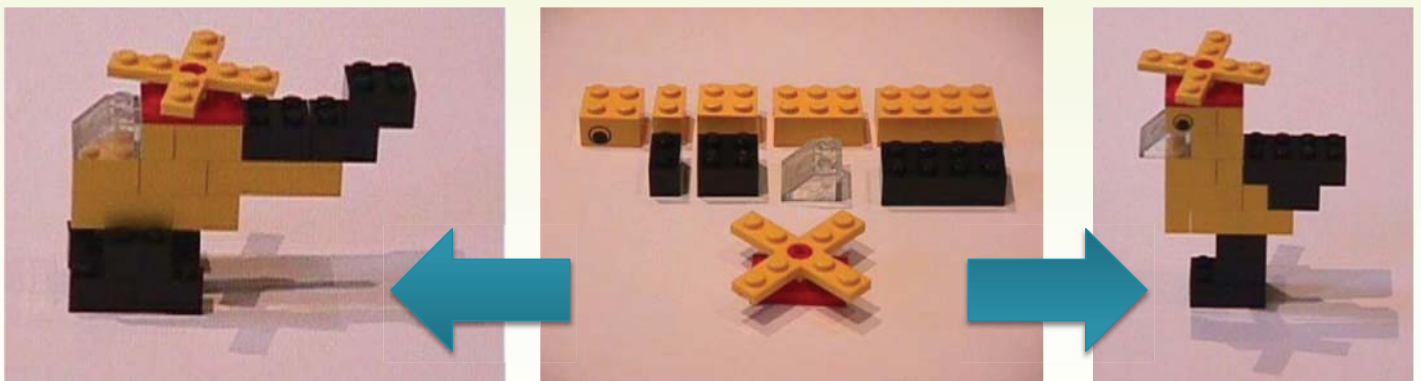
Agenda

- Profileの必要性
 - FHIRにおけるConformanceとは
 - Profileの事例
 - ProfileとProfileにおける記述の解説
 - Profile
 - Extension
 - Package
 - Implementation Guides
 - Registry etc...
 - Profileの編集
-

Clinical Data Model

情報モデルの意義

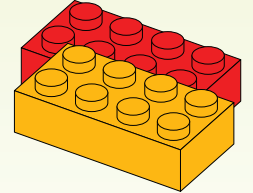
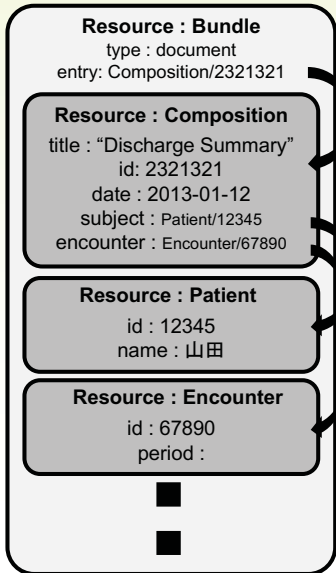
特定のコンピュータに
依存しない仕組みを提供



**“データの持ち方”と“データ構造”
を論理的に分離**

FHIRの情報モデルの特徴

- FHIRでは“Resource”を構成要素として組み合わせることで、医療情報を表現する。



• 退院サマリ文書の例

- リソースを束ねる Bundle
- 文書構造を定義するComposition
- 構成要素: Patient, Encounter...

Resourceにおける既定のカーディナリティは殆ど"0..1"か"0..*"

Patient Resourceの例

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 An identifier for this patient
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

Validationに合格する Patient Resource

```
<Patient xmlns="http://hl7.org/fhir">
  <contact>
    <telecom>
      <system value="phone" />
      <value value="011-111-1111" />
      <use value="home" />
    </telecom>
  </contact>
</Patient>
```



名前すら入っていない
患者情報・・・

FHIR R4 Patient Resourceでの制約情報

8.1.2.2 Constraints

id	Level	Location	Description	Expression
pat-1	Rule	Patient.contact	SHALL at least contain a contact's details or a reference to an organization	name.exists() or telecom.exists() or address.exists() or organization.exists()

参考: FHIR .Net APIでの Validation

```
var ctx = new ValidationSettings() {
  ResourceResolver = new ZipSource(pathSpecification),
  GenerateSnapshot = true,
  Trace = false,
  EnableXsdValidation = true,
  ResolveExternalReferences = false
};

var validator = new Validator(ctx);

Patient pat = new Patient();
var contact = new Patient.ContactComponent();

contact.Telecom.Add(new ContactPoint(ContactPoint.ContactPointSystem.Phone, ContactPoint.ContactPointUse.Home, "011-111-1111"));
pat.Contact.Add(contact);

Console.WriteLine(XmlUtil.tidyXMLString(XmlUtil.generateXML(pat)));

var oc = validator.Validate(pat);

foreach(var issue in oc.Issue) {
  Console.WriteLine(oc);
}
```

- 名前の記載でも様々なバリエーションが考えられる

```

"name": [
  {
    "family": "ヤマダ",
    "given": [
      "タロウ"
    ],
    "text": "タロウ ヤマダ"
  },
  {
    "family": "山田",
    "given": [
      "太郎"
    ],
    "text": "太郎 山田",
    "use": "official"
  }
]

```

```

"name": [
  {
    "use": "usual",
    "family": "カンジャ",
    "given": [
      "タロウ"
    ]
  },
  {
    "use": "official",
    "family": "患者",
    "given": [
      "太郎"
    ]
  }
]

```

```

"name": [
  {
    "extension": [
      {
        "url": "http://hl7.org/fhir/StructureDefinition/iso21090-EN-representation",
        "valueCode": "SYL"
      }
    ],
    "family": "ヤマダ",
    "given": "タロウ",
    "use": "official"
  },
  {
    "extension": [
      {
        "url": "http://hl7.org/fhir/StructureDefinition/iso21090-EN-representation",
        "valueCode": "IDE"
      }
    ],
    "family": "山田",
    "given": "太郎",
    "use": "official"
  }
]

```

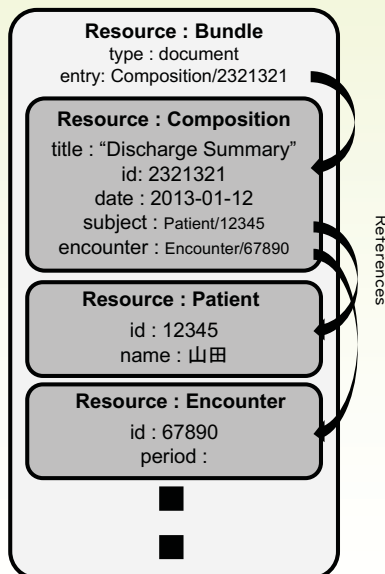


項目の使用の有無のみならず、記述方法にもバリエーションが発生しうることを理解する。

InterSystems Corporationの上中氏より提供

制約は複数のResourceにわたる

- 退院サマリーを記述するResourceを定義したい
 - 何のResourceを使う？
 - それぞれのResourceの中では何の項目を使う？
 - 用語集は何を使う？
 - etc...





Profileの必要性

- 情報を利用する場面は多様
- Resource内で記述可能な内容も多様
 - Resource内に記述する内容に関する「制約」について、当事者間で合意する必要がある
- 「制約」をコンピュータに理解できるDSLで記述することにより、解釈違い・誤解による実装のずれを減少させることを狙う
 - DSL: Domain Specific Language

FHIRとは”platform specification”

- 5.0.1 Introduction
- The core FHIR specification describes a set of resources, frameworks and APIs that are used in many different contexts in healthcare. However, there is **wide variability between jurisdictions and across the healthcare ecosystem** around practices, requirements, regulations, education and what actions are feasible and/or beneficial.
- For this reason, the FHIR specification is a **”platform specification”** - it creates a common platform or foundation on which a variety of different solutions are implemented. As a consequence, **this specification usually requires further adaptation to particular contexts of use.**
- Typically, these adaptations specify:
 - Rules about **which resource elements are or are not used, and what additional elements** are added that are not part of the base specification
 - Rules about which of FHIR's RESTful API, messaging and document **features are used, and how**
 - Rules about **which terminologies are used** in particular elements
 - Descriptions of how the Resource elements and API features map to local requirements and/or implementations

<https://www.hl7.org/fhir/conformance-module.html>

FHIR自体は相互運用性のある規格を記述するための”プラットフォーム”であり、それ自体では相互運用性は担保されない。

相互運用性は、このプラットフォーム上で定義されているResourceに関する利用方法、制約についてProfileを定義し、それに準拠した実装、コネクタソンの検証を通して実現される。

プロファイルの例 (1)

Bundle: MedicationPlan

Entry: Composition

- Parameters like, Date, Identifier
- Patient (Reference)
- ...
- MedicationPlan (Section)
- MedicationStatement (Reference)
- Health Concerns (Section)
- Remarks (Section)

Entry: Patient

Entry: MedicationStatement

Entry: ...

Parameter	Description	Resource/Datatype	CHMEDI5A4	CHMEDI5A4Q
subject	Reference to the Patient	Patient	<P>	
identifier	Logical identifier for document (GUID)	Identifier	ID	ID
date	Date of creation	dateTime	DK	DK
author	Author (or, if available, otherwise name) Practitioner	Practitioner	Auth	<Pr>
authTime	Date of validation	Practitioner	Valid	ID
authParty	Validated by GLN of practitioner	Practitioner	Valid	ID

スイスにおける
電子処方箋プロファイル

ITK3 eDischarge FHIR Document Profile

For a complete definition of the eDischarge document see...

The diagram shows the referencing between the profiles in the ITK3 eDischarge FHIR Document Profile. When using ITK3 there is an outer bundle structure which is called the ITK3 eDischarge FHIR Document Profile. Below is the key to the diagram.

This diagram only goes to one level due to the complexity and size of the document Profile. Below is the key to the diagram.

Key

- Resource
- Profile
- Reference
- Reference type
- Extension
- Extension profile
- Not used in eDischarge

ITK3 eDischarge Bundle Example

```

1 <?xml version="1.0" encoding="UTF-8"?>
2 <bundle xmlns="http://hl7.org/fhir/">
3 <id value="c86e13aa-6c3b-4e67-999-6e7b399e7417"/>
4 <meta>
5 <lastUpdated value="2013-02-17T12:00:00+08:00"/>
6 <profile value="https://fhir.nhs.uk/STU3/StructureDefinition/ITK-Document-Bundle-1"/>
7 </meta>
8 <identifier>
9 <system value="http://snomed.info/sct/rf4422"/>
10 <value value="11737866-fc5b-48d3-9721-2a942e381f65"/>
11 </identifier>
12 <type value="document"/>
13 <entry>
14 <fullUrl value="urn:uuid:fa2a75a7-4257-4226-82a4-cf537f813137"/>
15 <resource>
16 <!-- A resource carrying a set of healthcare-related information about the patient -->
17 <composition>
18 <id value="fa2a75a7-4257-4226-82a4-cf537f813137"/>
19 </id>
20 </composition>
21 </resource>
22 </entry>
23 </bundle>

```

プロフィールの例 (2)

英国NHS eDigitalにおける
退院サマリープロフィール

日本でPatient Resourceを使うには？ (共通編)

Name	Flags	Card.	Type	Description & Constraints
Patient	N		DomainResource	Information about an individual or animal receiving health care services. This resource is defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier		Σ 0..*	Identifier	Identifier for this patient
active	?! Σ	0..1	boolean	The 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	Address of the individual
maritalStatus		0..1	CodeableConcept	Marital (civil) status of a patient

保険証の被保険者番号を使うべき

姓名(漢字)、振り仮名に対応

既婚の女性に関しては旧姓の情報も欲しい?

日本でPatient Resourceを使うには？（調査票等）

deceased[x]	?! Σ 0..1	date	The date of birth for the individual
deceasedBoolean		boolean	Indicates if the individual is deceased or not
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	boolean	Indicates if the individual has multiple births
multipleBirthBoolean		boolean	
multipleBirthInteger		integer	
photo	0..*	Attachment	Image of the patient
contact	I 0..*	BackboneElement	A contact party (e.g. guardian, parent, caregiver, etc.) + Rule: SHALL have at least one contact
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 AdministrativeGender (Required)
organization	I 0..1	Reference(Organization)	Organization that is associated with the contact
period	0..1	Period	The period during which this contact person or organization is valid to be contacted

死亡状況の調査には
死亡日の記載は必須としたい

患者が未成年ならば、保護者の
連絡先も必須としたい

Profile Resource

- Resourceの使い方を制御するDSLは、Profile Resourceによって記述される
 - FHIRは、これに限らず全ての領域でResourceを使うエコシステムを構築している
- FHIRサーバはProfileに関する情報をProfile Resourceとして保有する
 - FHIRサーバはProfileリポジトリとしても機能
 - ProfileについてREST APIを用いて照会できる
 - 指定したProfileに対して提出したResourceのValidationを依頼することもできる。

Conformanceにかかわる Resource群



Home Getting Started Documentation Resources Profiles Extensions Operations Terminologies



This is the current officially released version of FHIR, which is R4 (v4.0.0). For a full list of all versions, see the [Directory of published versions](#).

Work Group [FHIR Infrastructure](#)

Standards Status: Informative

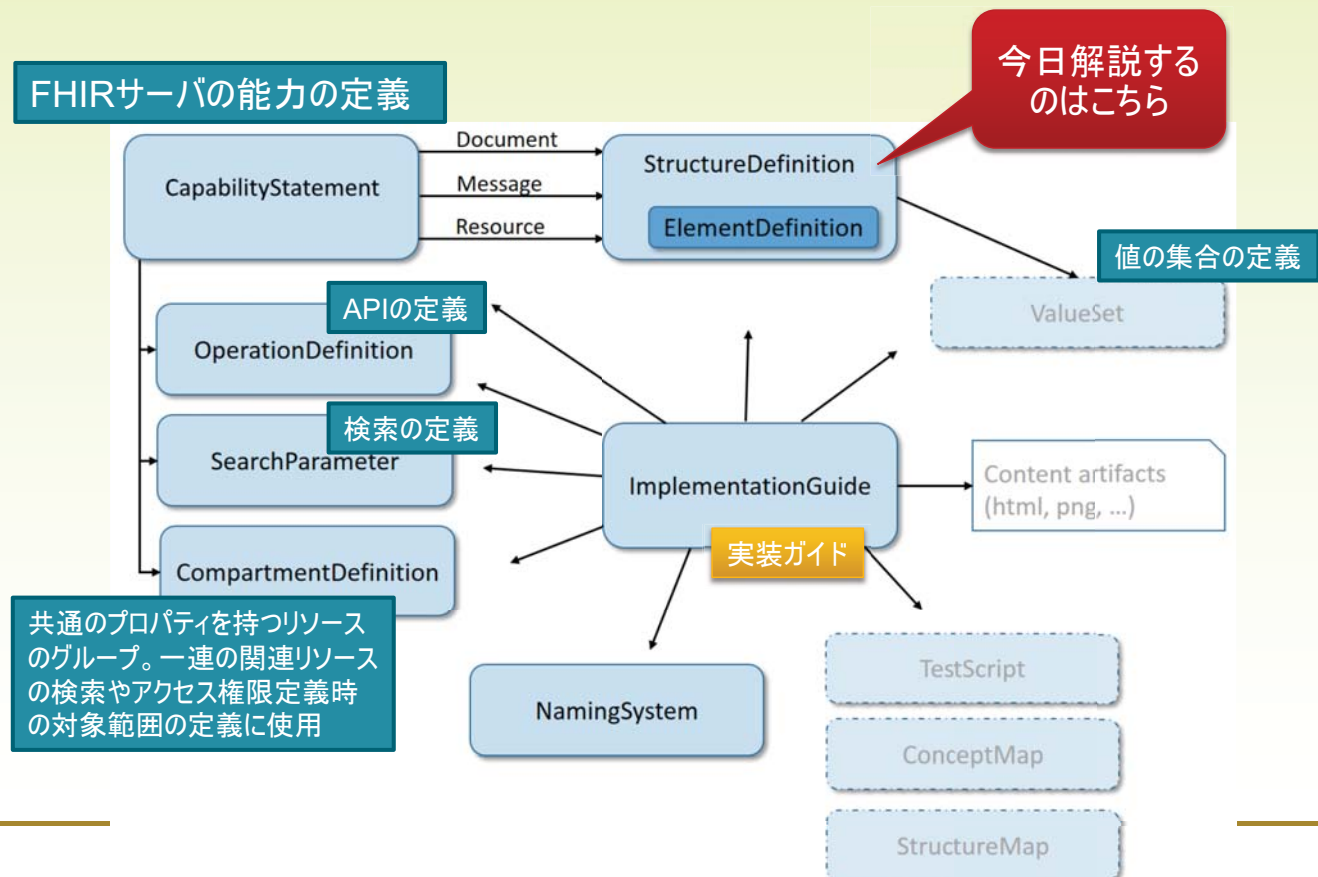
5.0 Conformance Module

The Conformance Module represents metadata about the datatypes, resources and API features of the FHIR specification and can be used to create derived specifications.

- [CapabilityStatement](#)
- [StructureDefinition](#)
- [OperationDefinition](#)
- [SearchParameter](#)
- [CompartmentDefinition](#)
- [ImplementationGuide](#)
- [ElementDefinition \(datatype\)](#)
- [Full profiling details](#)
- [Detailed conformance rules](#)

<https://www.hl7.org/fhir/conformance-module.html>

Profileの定義にもResourceを使う



StructureDefinition

- FHIRのリソースの構造を定義するResource

snapshot	I	0..1	BackboneElement	TypeDerivationRule (Required) Snapshot view of the structure + Rule: Each element definition in a snapshot must have a formal definition and cardinalities + Rule: All snapshot elements must start with the StructureDefinition's specified type for non-logical models, or with the same type name for logical models + Rule: All snapshot elements must have a base definition
element	I	1..*	ElementDefinition	Definition of elements in the resource (if no StructureDefinition) + Rule: provide either a binding reference or a description (or both)
differential	I	0..1	BackboneElement	Differential view of the structure + Rule: No slicing on the root element + Rule: In any differential, all the elements must start with the StructureDefinition's specified type for non-logical models, or with the same type name for logical models
element		1..*	ElementDefinition	Definition of elements in the resource (if no StructureDefinition)

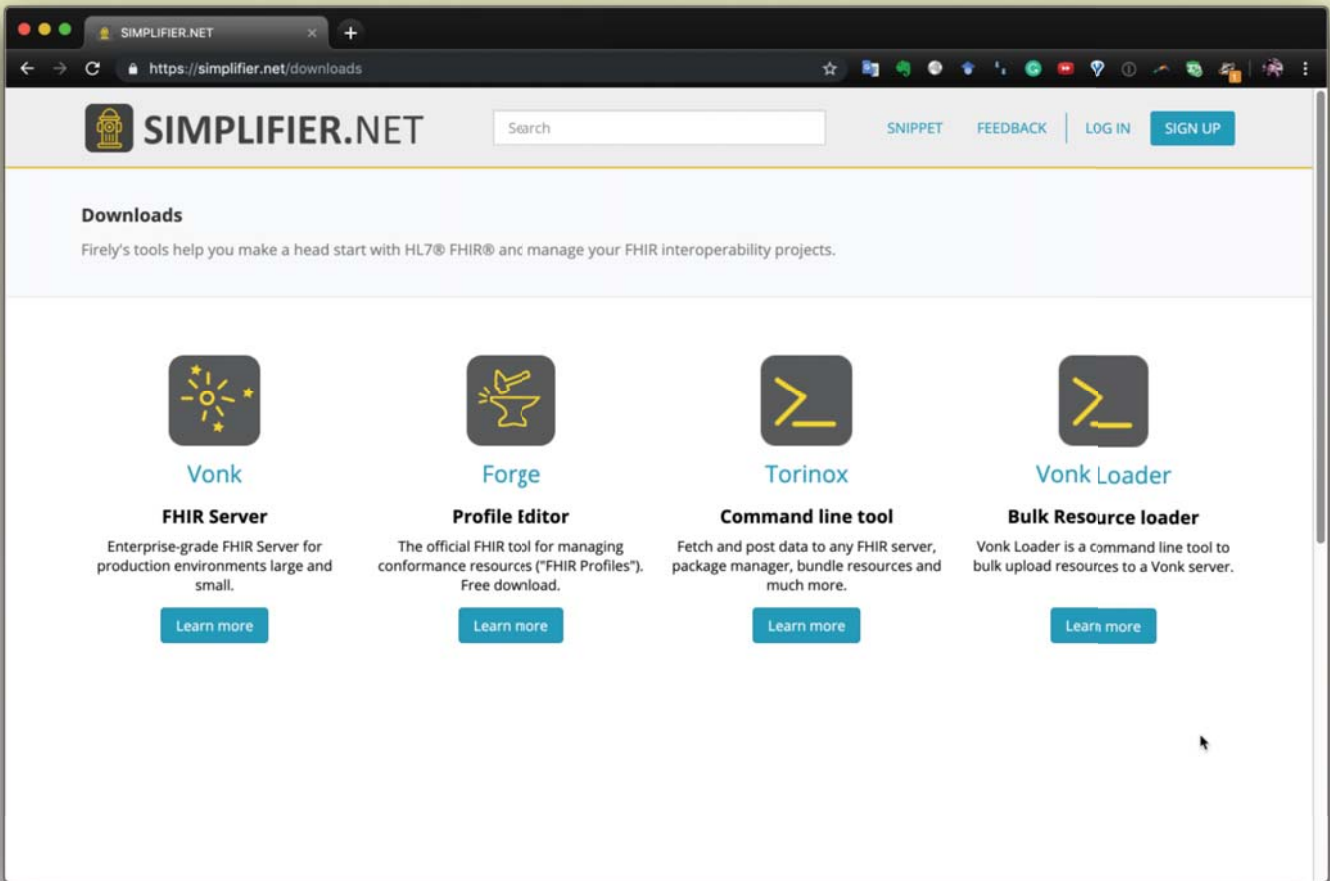
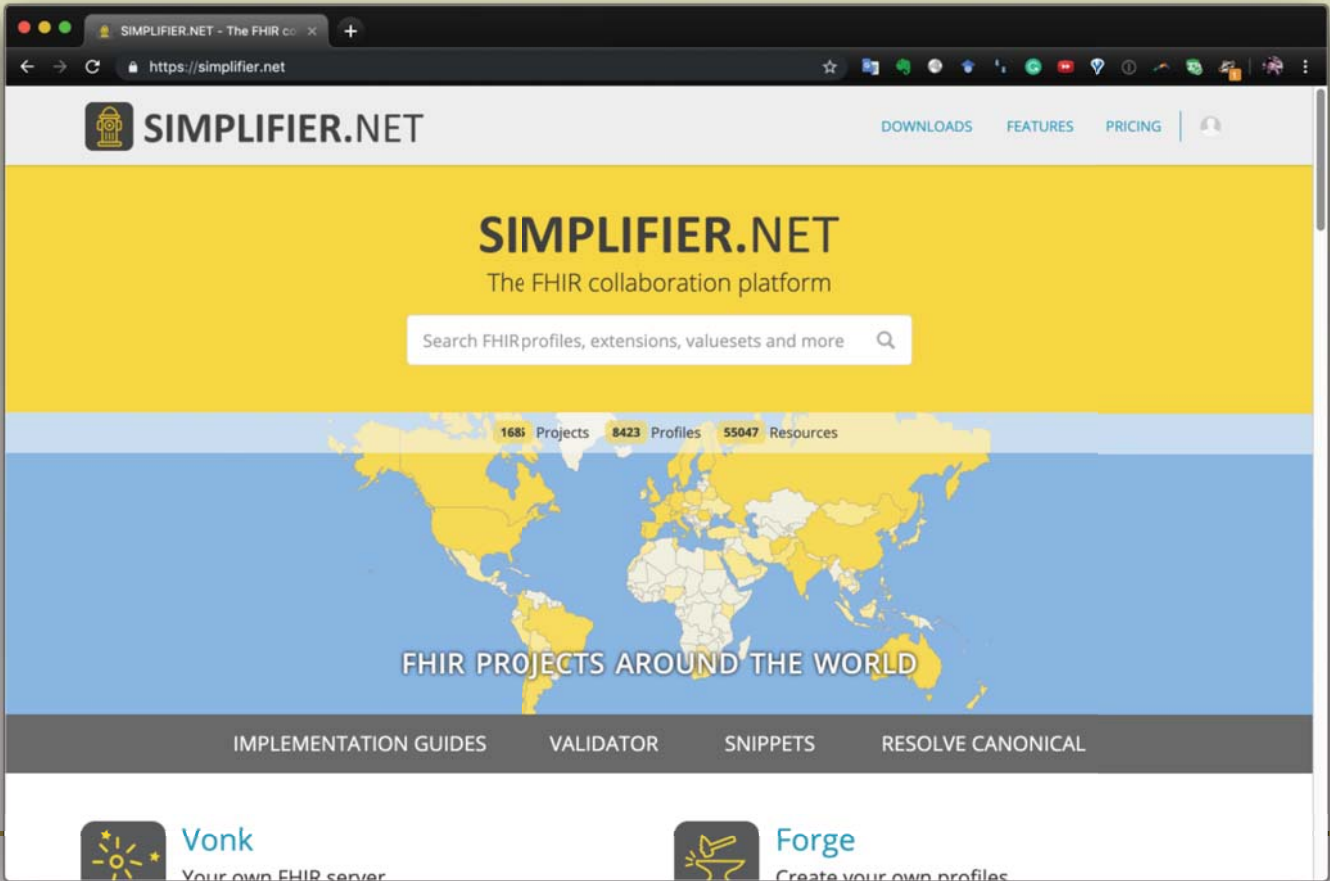
<https://www.hl7.org/fhir/structuredefinition.html>

Patient リソースの定義

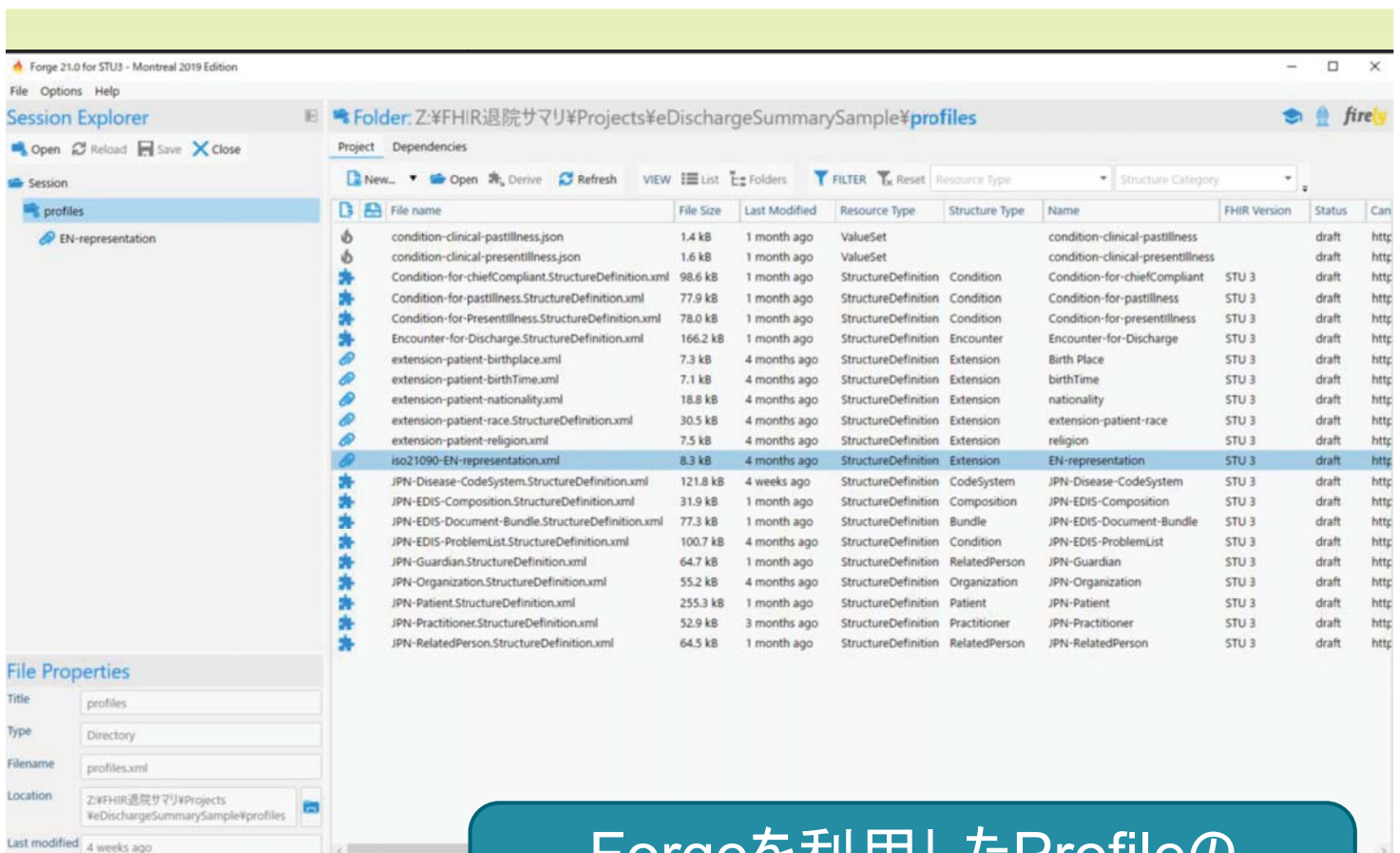
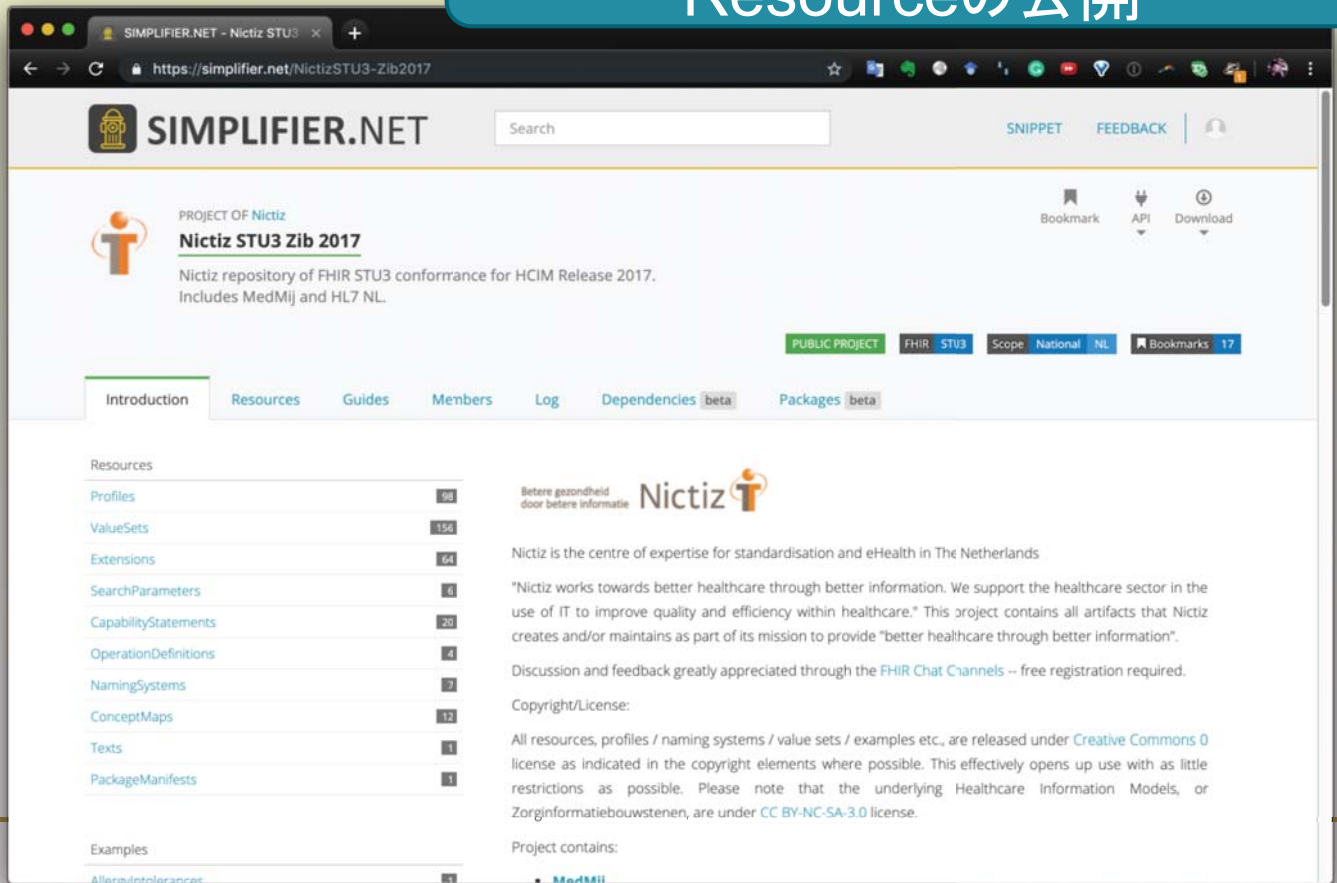
```
<?xml version="1.0" encoding="UTF-8"?>
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="Patient"/>
  <meta>
    <lastUpdated value="2018-12-27T22:37:54.724+11:00"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <table border="0" cellpadding="0" cellspacing="0" style="border: 0px #
        <tr style="border: 1px #F0F0F0 solid; font-size: 11px; font-family:
          <th style="vertical-align: top; text-align: left; background-color
            <a href="formats.html#table" title="The logical name of the elen
          </th>
          <th style="vertical-align: top; text-align: left; background-color
```

XMLを手動で編集するのは
大変...

プロフィール作成の公式ツール



コミュニティによるProfile, Resourceの公開



Forgeを利用したProfileの
視覚的編集が可能

本日扱うProfile関連の話題

- 既存のResourceに拡張、制約
 - Extension 拡張
 - Restriction 制約
 - Cardinality
 - Value Domain
 - Binding ValueSets / CodeSystem統制用語の指定
 - Formal Constraints 評価式による制約記述
 - Slicing 項目の指定
 - 上記の手法を組み合わせて
 - 文書等を定義していく
-

本日扱うProfile関連の話題

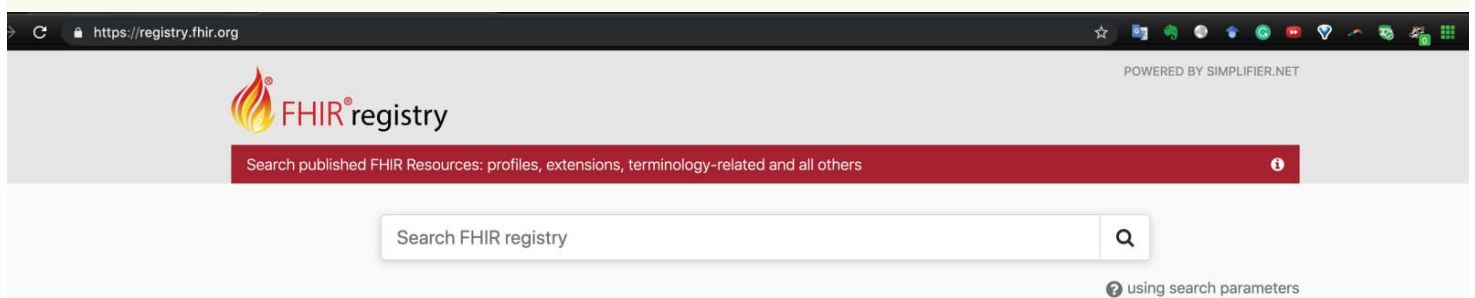
- 既存のResourceに拡張、制約
 - **Extension 拡張**
 - Restriction 制約
 - Cardinality
 - Value Domain
 - Binding ValueSets / CodeSystem統制用語の指定
 - Formal Constraints 評価式による制約記述
 - Slicing 項目の指定
 - 上記の手法を組み合わせて
 - 文書等を定義していく
-

Extension

- FHIRは80%のケースで使われているものを中心に実装。残りの20%はExtensionを利用した拡張で対応させる、という方針
- FHIR公式Webサイト等でextensionの事例公開（後述）
- Extensionを作成するのは上記のWebサイトやSimplifer.netで既に定義されているextensionがないかを確認してから

Profile/Extensionを作成する前に

- Profile、Extension等の必要性を感じたら、まず先行事例がないかを探す
- FHIR profile registry(HL7公式)
<https://registry.fhir.org>



The screenshot shows the top portion of the FHIR registry website. At the top, there is a navigation bar with the FHIR logo and the text "FHIR registry". Below this is a search bar with the placeholder text "Search FHIR registry" and a magnifying glass icon. To the right of the search bar, there is a link that says "using search parameters". The browser's address bar shows the URL "https://registry.fhir.org".

FHIR Core-defined Extension Registry (HL7公式)

<https://www.hl7.org/fhir/extensibility-registry.html>

1.4 FHIR Core-defined Extension Registry

FHIR Infrastructure Work Group	Maturity Level: N/A	Standards Status: Informative
--	---------------------	-------------------------------

All extensions in this list are defined in this specification and have a base URI of <http://hl7.org/fhir/StructureDefinition/>. Additional exten HL7 FHIR registry at <http://hl7.org/fhir/registry>.

Identity	Conf.	Type	Context	FMM
capabilities	0..*	code	CapabilityStatement.rest.security	1
oauth-uris	0..1	(complex)	CapabilityStatement.rest.security	1
11179-objectClass	0..1	Coding	ElementDefinition.mapping	1
11179-objectClassProperty	0..1	Coding	ElementDefinition.mapping	1
11179-permitted-value-conceptmap	0..1	canonical	StructureDefinition.snapshot.element.binding.valueSet, StructureDefinition.differential.element.binding.valueSet, Questionnaire.item.answerValueSet	1
11179-permitted-value-valueset	0..1	canonical	StructureDefinition.snapshot.element.binding.valueSet, StructureDefinition.differential.element.binding.valueSet, Questionnaire.item.answerValueSet	1
DiagnosticReport-geneticsAnalysis	0..*	(complex)	DiagnosticReport	1
DiagnosticReport-geneticsAssessedCondition	0..*	Reference	DiagnosticReport	1
DiagnosticReport-geneticsFamilyMemberHistory	0..*	Reference	DiagnosticReport	1
DiagnosticReport-geneticsReferences	0..*	(complex)	DiagnosticReport	1
allergyintolerance-assertedDate	0..1	dateTime	AllergyIntolerance	1

Simplifier.net (コミュニティ)



SIMPLIFIER.NET

Search

SNIPPET

FEEDBACK

LOG IN

SIGN UP

discharge summary ✕

Search Type

- Resources
- Projects
- Organizations

Resource Categories

or not

- Profiles
- ValueSets
- CodeSystems
- Extensions
- SearchParameters
- CompartmentDefinitions
- CapabilityStatements
- OperationDefinitions
- NamingSystems
- ConceptMaps
- StructureMaps
- ImplementationGuides
- TestScripts
- DataElements
- GraphDefinitions
- ExpansionProfiles
- Examples
- LogicalModels
- Texts
- Images

Document Type Value Set

ValueSet

Project: [Core ValueSets - DSTU2](#)

This is the code specifying the precise type of document (e.g. Pulmonary History and Physical, Discharge Summary, Ultrasound Report, etc.). The Document Type value set includes all LOINC values listed in HITSP...

Active

2015/10/1

Document Class Value Set

ValueSet

Project: [Core ValueSets - DSTU2](#)

This is the code specifying the high-level kind of document (e.g. Prescription, Discharge Summary, Report, etc.). The Document Class value set is reproduced from HITSP C80 Table 2-144 Document Class Value S...

Active

2015/10/1

Document Type Value Set

ValueSet

Project: [Core ValueSets - STU3](#)

This is the code specifying the precise type of document (e.g. Pulmonary History and Physical, Discharge Summary, Ultrasound Report, etc.). The Document Type value set includes all LOINC values listed in HITSP...

Draft

2017/7/18

Document Class Value Set

ValueSet

Project: [Core ValueSets - STU3](#)

This is the code specifying the high-level kind of document (e.g. Prescription, Discharge Summary, Report, etc.). The Document Class value set is reproduced from HITSP C80 Table 2-144 Document Class Value S...

Draft

2017/7/18

Discharge Summary

Project

Discharge Summary







Test SE

2019/3/22








Page Size: 25

Extensionを導入する事例

--Patient での「名前」の扱い --

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

HumanNameの構造

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

Extensionなしの素の状態での運用？

```
"name": [
  {
    "family": "ヤマダ",
    "given": [
      "タロウ"
    ],
    "text": "タロウ ヤマダ"
  },
  {
    "family": "山田",
    "given": [
      "太郎"
    ],
    "text": "太郎 山田",
    "use": "official"
  }
],
```

- HumanResourceの定義に準拠している。
- しかし、「漢字」「ふりがな」の表記を区別するSemanticがない
- 結果、実装者によって記載が様々となる原因に。

Extension導入: EN-representation

<https://www.hl7.org/fhir/extension-iso21090-en-representation.html>

Name	Flags	Card.	Type	Description & Constraints
★ EN-representation		0..1	code	URL = http://hl7.org/fhir/StructureDefinition/iso21090-EN-representation EN-representation: Name Representation.

Binding: NameRepresentationUse (required)
Use on Element ID HumanName

Code Display <https://www.hl7.org/fhir/valueset-name-v3-representation.html>

ABC Alphabetic Alphabetic transcription of name (Japanese: romaji)

IDE Ideographic Ideographic representation of name (e.g., Japanese kanji, Chinese characters)

SYL Syllabic Syllabic transcription of name (e.g., Japanese kana, Korean hangul)

name要素に
extensionを差し込むこ
とを宣言

```
"name": [  
  {  
    "extension": [  
      {  
        "url": "http://hl7.org/fhir/StructureDefinition/iso21090-EN-representation",  
        "valueCode": "SYL"  
      }  
    ],  
    "family": "ヤマダ",  
    "given": "タロウ",  
    "use": "official"  
  },  
  {  
    "extension": [  
      {  
        "url": "http://hl7.org/fhir/StructureDefinition/iso21090-EN-representation",  
        "valueCode": "IDE"  
      }  
    ],  
    "family": "山田",  
    "given": "太郎",  
    "use": "official"  
  }  
]
```

“SYL”で Syllabic、す
なわち音節表記である
ことを指定

使用するextensionは
canonical URLで指定

“IDE”で Ideographic
representationである
ことを指定

これだけでは不完全

- Extensionで拡張内容を定義
- しかし、その拡張内容を「必ず使うよう」に強制しなければならない（そのままだと使わない「自由」が残されている。）
- PatientがHumanName ResourceでEN-representationを使うことを「強制」する
- 適用範囲の検討
 - Patientへの設定
 - 患者の名前のみに適用され、医療従事者等の他の人物エンティティには適用されない
 - HumanResourceへの設定
 - 全ての人物エンティティに適用される。

PatientのProfile作成

- PatientのNameにextensionを強制する例

The screenshot shows the FHIR Profile Editor interface. On the left, the 'Session Explorer' shows the profile 'JPN-Patient'. The main area displays the 'Element Tree' for 'Patient', with the 'transcription' element under 'name' selected. A callout bubble points to the 'transcription' element, stating: 'Transcriptionノードを追加してcardinalityを1にすることで、「必須」項目として指定'. On the right, the 'Element Properties' panel for 'extension' is visible. A callout bubble points to the 'Extension' field, stating: '対象extensionを iso21090-EN-representationとして指定'. The 'Cardinality' field is set to '1'.

本日扱うProfile関連の話題

- 既存のResourceに拡張、制約
 - Extension 拡張
 - **Restriction** 制約
 - Cardinality
 - Value Domain
 - Binding ValueSets / CodeSystem 統制用語の指定
 - Formal Constraints 評価式による制約記述
 - Slicing 項目の指定
- 上記の手法を組み合わせる
 - 文書等を定義していく

Cardinalityの制限

Cardinalityを0..0にすることで「使わない」ことを指定

Element ID: Patient.multipleBirth[x]

Cardinality: 0 .. 0 (Selected: 0..0, 0..1, 0..*, 1..1, 1..*)

Type(s): boolean integer

Short description: Whether patient is part of a multiple birth

Definition: Indicates whether the patient is part of a multiple (bool) or indicates the act

Label:

Code: +

Alias: +

本日扱うProfile関連の話題

- 既存のResourceに拡張、制約
 - Extension 拡張
 - Restriction 制約
 - Cardinality
 - Value Domain
 - Binding ValueSets / CodeSystem統制用語の指定
 - Formal Constraints 評価式による制約記述
 - Slicing 項目の指定
- 上記の手法を組み合わせて
 - 文書等を定義していく

Value Domainの制約(1)

active

- name (*)
- telecom (*)
- gender
- birthDate
- deceased[x]
- address (1+)
- maritalStatus

Cardinality: 0 ... 1 0..0 0..1 0..* 1..1 1..*

Type(s): boolean dateTime

Profile: []

デフォルトでは、死亡に対して、有無(Boolean)か、日付(dateTime)を選ぶ

telecom (*)

- gender
- birthDate
- deceasedBoolean
- address (1+)
- maritalStatus
- multipleBirth[x] (0)
- photo (0)
- contact (*)
- animal (0)

Cardinality: 0 ... 1 0..0 0..1 0..* 1..1 1..*

Type(s): boolean dateTime

Profile: []

Fixed value:

死亡に対して、有無(Boolean)のみにするように制約

Value Domainの制約(2)

Profile on Condition⁽³⁾: Condition-for-chiefCompliant

Properties Narrative Element Tree Element Grid XML

Extend Slice Add Slice Edit the nested elements tree of the selected StructureDefinition resource.

Condition

- id
- meta
- implicitRules
- language
- text
- contained (*)
- identifier (*)
- clinicalStatus
- verificationStatus
- category (*)
- severity
- code
- bodySite (*)
- subject (1)
- context
- onset[x]
- abatement[x]
- assertedDate
- asserter
- stage
- evidence (*)
- note (*)

Element ID: Condition.asserter

Cardinality: 0 ... 1 0..0 0..1 0..* 1..1 1..*

Type(s): Reference(Practitioner) Reference(Patient) Reference(RelatedPerson) Reference(JPN-Patient) Reference(JPN-RelatedPerson) Reference(JPN-Practitioner)

Profile: [] [] [] [] [] []

Target profile: http://hl7.org/fhir/StructureDefinition/Practitioner http://hl7.org/fhir/StructureDefinition/Patient http://hl7.org/fhir/StructureDefinition/RelatedPerson http://niph.go.jp/fhir/StructureDefinition/JPN-Patient http://niph.go.jp/fhir/StructureDefinition/JPN-RelatedPerson http://niph.go.jp/fhir/StructureDefinition/JPN-Practitioner

Fixed value

Short description: Person who asserts this condition

Definition: Individual who is making the condition statement.

Practitioner, Patient, Related Personを、それぞれ日本向けにカスタマイズしたResourceを利用するように指定

Value Domainの制約 (3)

Profile on Composition⁽²⁾: JPN-EDIS-Composition

Element Properties: code

Element ID: Composition.section:allergiesAndAdverseReactionsSection.code

Cardinality: 0 ... 1 0..0 0..1 0..* 1..1 1..*

Type(s) + Profile

CodeableConcept

Valueset binding

Fixed value

Short description: Classification of section (recommended)

Definition

id

title (1)

code code http://loinc.org 48765-2

text

mode

orderedBy (0)

entry (*)

emptyReason (0)

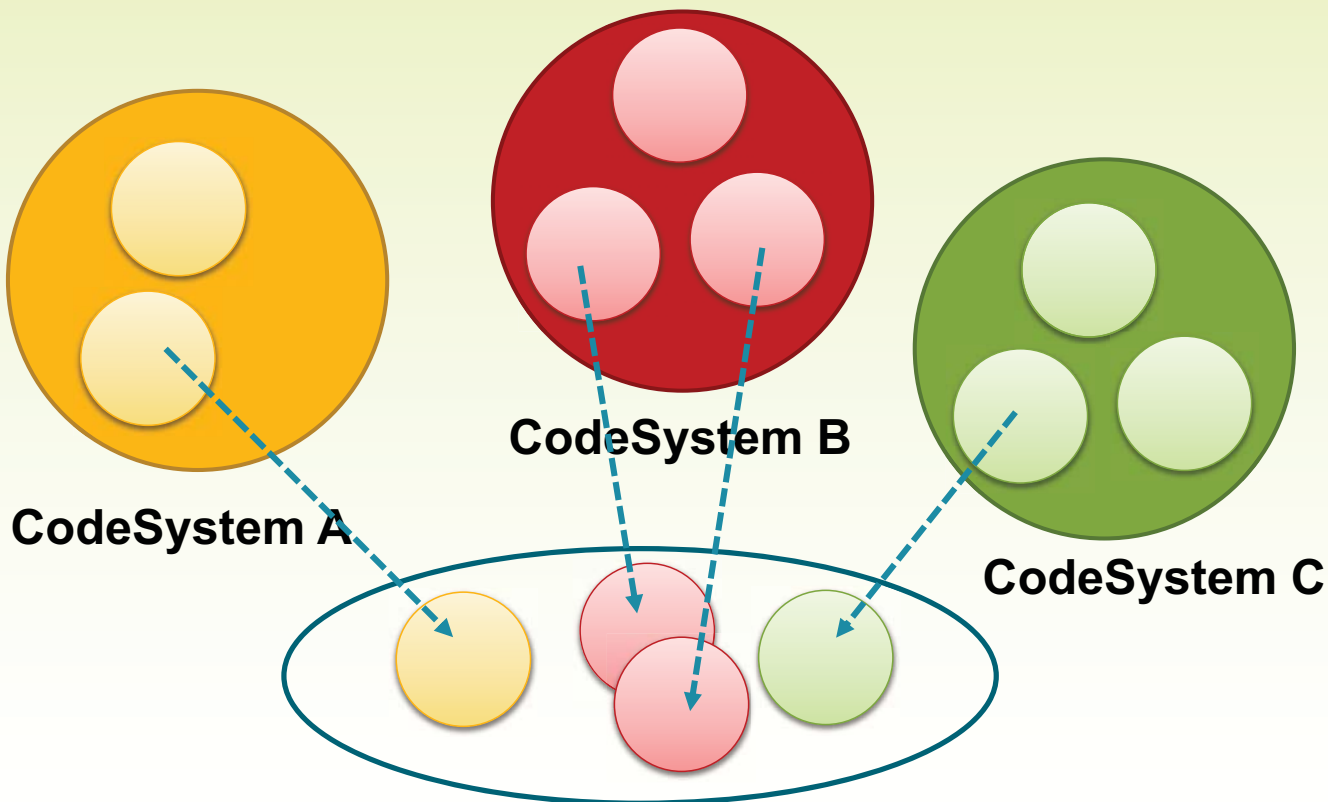
section (0)

アレルギーに関するセクションを指定するcodeは LOINC “48765-2 Allergies and adverse reactions Document”のみである。(固定)

本日扱うProfile関連の話題

- 既存のResourceに拡張、制約
 - Extension 拡張
 - Restriction 制約
 - Cardinality
 - Value Domain
 - **Binding ValueSets / CodeSystem統制用語の指定**
 - Formal Constraints 評価式による制約記述
 - Slicing 項目の指定
- 上記の手法を組み合わせて
 - 文書等を定義していく

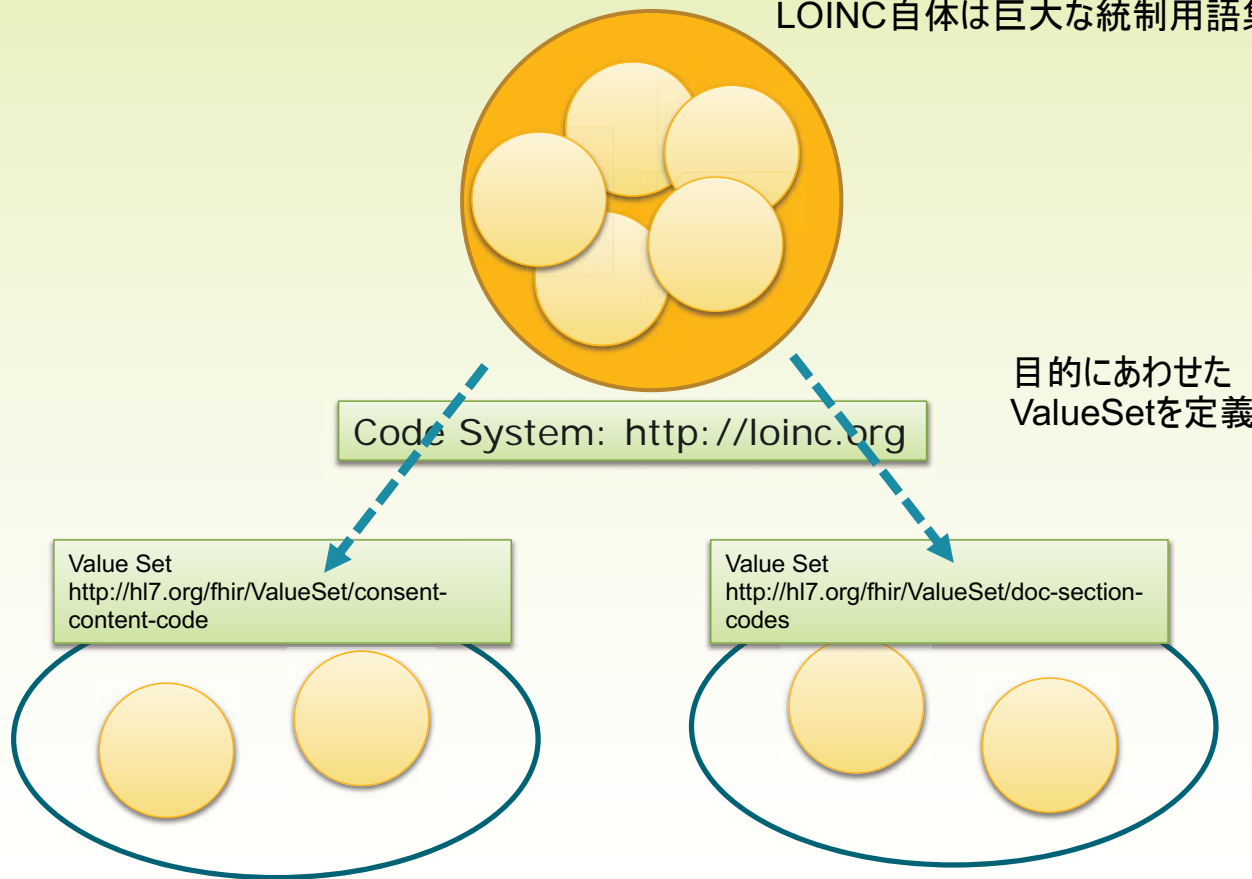
CodeSystemとValueSet



複数のCodeSystemからCodeを採用してValueSetにまとめられる

ValueSet

LOINC自体は巨大な統制用語集



インフォームドコンセントに関するコードをあつめたValueSet

文書のセクションに関するコードを集めたValueSet

Name	Flags	Card.	Type	Description & Constraints
Condition	I TU		DomainResource	Detailed information about conditions, problems or diagnoses + <i>Guideline</i> : Condition.clinicalStatus SHALL be present if verificationStatus is not entered-in-error and category is problem-list-item + <i>Rule</i> : If condition is abated, then clinicalStatus must be either inactive, resolved, or remission + <i>Rule</i> : Condition.clinicalStatus SHALL NOT be present if verificationStatus is entered-in-error Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension External Ids for this condition
identifier	Σ	0..*	Identifier	
clinicalStatus	? Σ I	0..1	CodeableConcept	active recurrence relapse inactive remission resolved Condition Clinical Status Codes (Required)
verificationStatus	? Σ I	0..1	CodeableConcept	unconfirmed provisional differential confirmed refuted entered-in-error ConditionVerificationStatus (Required)
category		0..*	CodeableConcept	problem-list-item encounter-diagnosis Condition Category Codes (Extensible)
severity		0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis Condition/Problem/Diagnosis Codes (Example)
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant SNOMED CT Body Structures (Example)
subject	Σ	1..1	Reference(Patient Group)	Who has the condition?
encounter	Σ	0..1	Reference(Encounter)	Encounter created as part of
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age
onsetDateTime				

4.4.1.118 Value Set <http://hl7.org/fhir/ValueSet/condition-code>

Patient Care	Work Group	Maturity Level: 1	Draft	Use Context: Any
This is a value set defined by the FHIR project.				
Summary				
Defining URL:	http://hl7.org/fhir/ValueSet/condition-code			
Version:	4.0.0			
Name:	Condition/Problem/DiagnosisCodes			
Title:	Condition/Problem/Diagnosis Codes			
Definition:	Example value set for Condition/Problem/Diagnosis codes.			
Committee:	Patient Care Work Group			
OID:	2.16.840.1.113883.4.642.3.161 (for OID based terminology systems)			
Copyright:	This resource includes content from SNOMED Clinical Terms® (SNOMED CT®) which is copyright of the International Health Terminology Standards Development Organisation (IHTSDO). Implementers of these specifications must have the appropriate SNOMED CT Affiliate license - for more information contact http://www.snomed.org/snomed-ct/get-snomed-ct-or-info@snomed.org			
Source Resource	XML / JSON			

Profile on Condition⁽³⁾: Condition-for-presentIllness

Properties Narrative Element Tree Element Grid XML

Extend Slice Add Slice Remove ↑ ↓ ?

- Condition
 - id
 - meta
 - implicitRules
 - language
 - text
 - contained (*)
 - identifier (*)
 - clinicalStatus
 - verificationStatus
 - category (*)
 - severity
 - code
 - id
 - coding (*)
 - id
 - system
 - version
 - code
 - display
 - userSelected
 - text
 - bodySite (*)

Element Properties: code

Element ID:

Cardinality: ...

Type(s)

Valueset binding

Strength:

Description:

Value set reference:

Is a ResourceReference

Fixed value:

required	Required	To be conformant, the concept in this element SHALL be from the specified value set.
extensible	Extensible	To be conformant, the concept in this element SHALL be from the specified value set if any of the codes within the value set can apply to the concept being communicated. If the value set does not cover the concept (based on human review), alternate codings (or, data type allowing, text) may be included instead.
preferred	Preferred	Instances are encouraged to draw from the specified codes for interoperability purposes but are not required to do so to be considered conformant.
example	Example	Instances are not expected or even encouraged to draw from the specified value set. The value set merely provides examples of the types of concepts intended to be included.

現病歴プロファイルの実装例

<https://www.hl7.org/fhir/valueset-binding-strength.html>

本日扱うProfile関連の話題

- 既存のResourceに拡張、制約
 - Extension 拡張
 - Restriction 制約
 - Cardinality
 - Value Domain
 - Binding ValueSets / CodeSystem統制用語の指定
 - **Formal Constraints 評価式による制約記述**
 - Slicing 項目の指定
 - 上記の手法を組み合わせて
 - 文書等を定義していく
-

Formal Constraints

- 形式的な制約(条件) の記述
 - フリーテキストによる定義 (人間)
 - XPATH/Flare Pathを利用した定義 (機械処理)
- 深刻度(severity) "error" "warning" "guideline"

Constraints have a severity level:

- | | |
|---------------------|---|
| Error (rule) | A rule that all resources must conform to. Validators should report it as an error if the rule is violated, and applications processing the content can reject it as an invalid resource |
| Warning | Report this as a warning that there may be a problem with the resource, but it is considered valid and can be processed normally |
| Guideline | A warning marked with an extension (http://hl7.org/fhir/StructureDefinition/elementdefinition-bestpractice) that indicates that it should be treated as an error if the implementation context asks a validator to enforce best practice rules. See Best Practices for a full list |

PatientでのConstraintの例

id	Level	Location	Description	Expression
pat-1	Rule	Patient.contact	SHALL at least contain a contact's details or a reference to an organization	name.exists() or telecom.exists() or address.exists() or organization.exists()

- 名前、電話、住所、組織の何れかは必須
- Cardinalityのみでは、どれも0..1で選択的だが、全体で見れば最低一つは要求

```
<constraint>  
  <key value="pat-1"/>  
  <severity value="error"/>  
  <human value="SHALL at least contain a contact's details or a reference to an organization"/>  
  <expression value="name.exists() or telecom.exists() or address.exists() or organization.exists()"/>  
  <xpath value="exists(f:name) or exists(f:telecom) or exists(f:address) or exists(f:organization)"/>  
</constraint>
```

expressionはFHIRインスタンス評価時に実行、xpathはXML形式で記述された時に評価される式

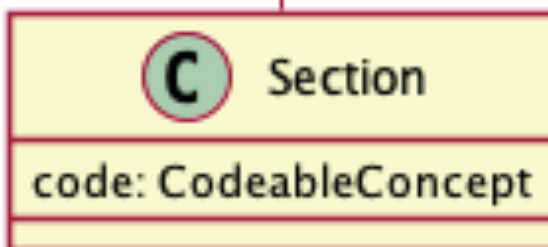
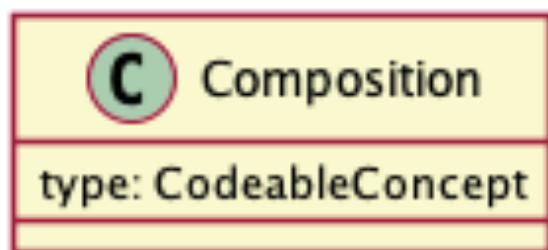
本日扱うProfile関連の話題

- 既存のResourceに拡張、制約
 - Extension 拡張
 - Restriction 制約
 - Cardinality
 - Value Domain
 - Binding ValueSets / CodeSystem統制用語の指定
 - Formal Constraints 評価式による制約記述
 - **Slicing 項目の指定**
- 上記の手法を組み合わせて
 - 文書等を定義していく

Slicing

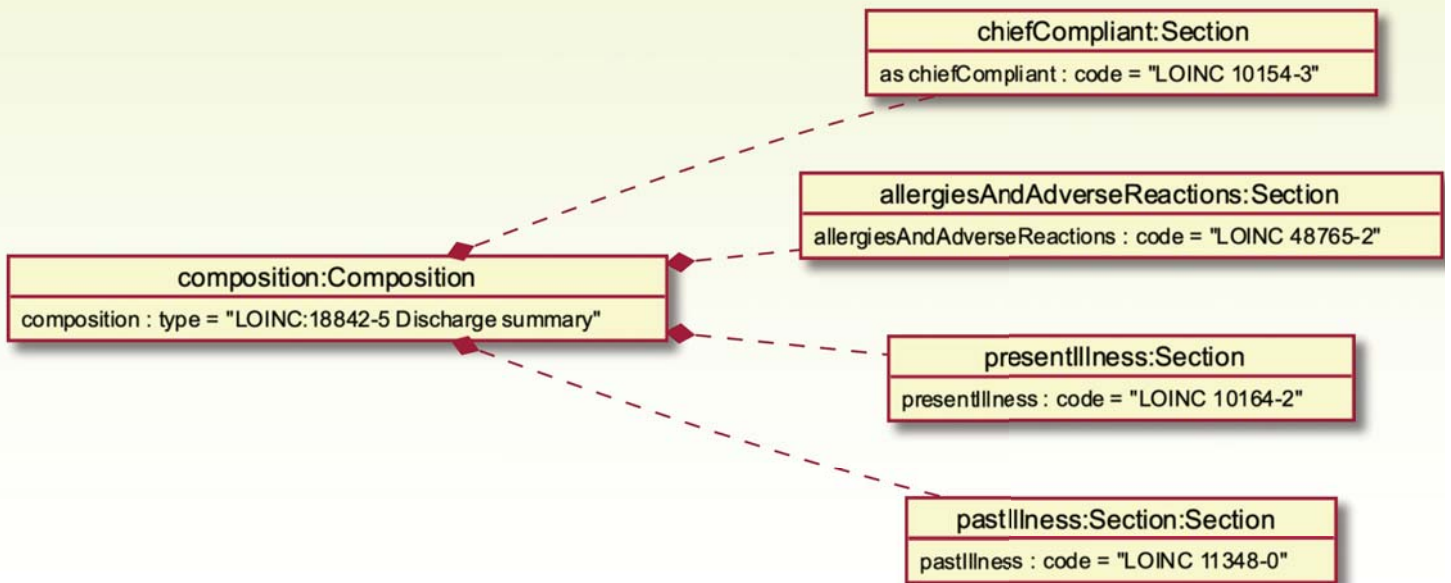
- 繰り返し項目に対して、個別の制約を課する
 - 項目を区別するためのユニークな属性 (discriminator) の定義
 - 項目ごとの制約等の定義
- 主に
 - Composition-Section
 - Observation-component
 - 等において利用

CompositionにおけるSlicingの例



Name	Flags	Card.	Type	Descriptio
Composition	TU		DomainResource	A set of res Elements d Version-inc
identifier	Σ	0..1	Identifier	
status	?! Σ	1..1	code	preliminary Compositio
type	Σ	1..1	CodeableConcept	Kind of cor FHIR Docu
category	Σ	0..*	CodeableConcept	Categoriza Document
subject	Σ	0..1	Reference(Any)	Who and/o
encounter	Σ	0..1	Reference(Encounter)	Context of
date	Σ	1..1	dateTime	Compositio
author	Σ	1..*	Reference(Practitioner PractitionerRole Device Patient RelatedPerson RelatedPerson)	Who and/o
section	I	0..*	BackboneElement	Composition + Rule: A se + Rule: A se Label for sec
title		0..1	string	
code		0..1	CodeableConcept	Classificati Document S
author		0..*	Reference(Practitioner PractitionerRole Device Patient Organization)	Who and/or
focus		0..1	Reference(Any)	Who/what th

CompositionのSectionに対する Slicing例



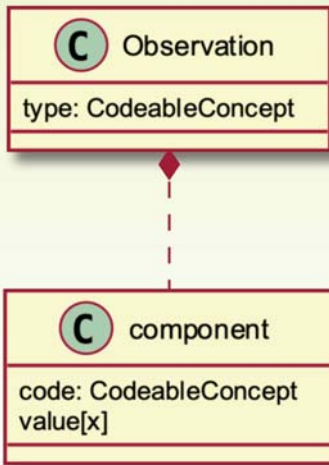
Profile on Composition⁽²⁾: JPN-EDIS-Composition

Properties Narrative Element Tree Element Grid XML

Extend Slice Add Slice Remove ↑ ↓ ?

- ▶ custodian
- ▶ relatesTo (*)
- ▶ event (*)
- ▼ section (*)
 - ▶ guardian (*)
 - ▶ problemList (1)
 - ▶ payer (*)
 - ▶ informant (*)
 - ▶ careteam (*)
 - ▶ clinicalSummary (*)
 - ▶ clinicalStatements (*)
 - ▶ medicalImages (*)
 - ▶ dischargeDiagnosis (*)
 - ▼ allergiesAndAdverseReactionsSection (1)
 - id
 - title (1)
 - ▶ code code http://loinc.org 48765-2 is pattern
 - ▶ text
 - mode
 - ▶ orderBy (0)
 - ▶ entry (*)
 - ▶ emptyReason (0)
 - ▶ section (0)
 - ▶ chiefCompliant (*)
 - ▶ presentIllness (*)
 - ▶ pastIllness (*)

ObservationにおけるSlicingの例



Name	Flags	Card.	Type	Description & Cons
Observation	I N		DomainResource	Measurements and si + Rule: dataAbsentR + Rule: If Observati element associated w Elements defined in / modifierExtension Business Identifier
identifier		Σ 0..*	Identifier	
basedOn		Σ 0..*	Reference(CarePlan DeviceRequest	Fulfills plan, proposa
component		Σ 0..*	Observation MolecularSequence) BackboneElement	
code		Σ 1..1	CodeableConcept	
value[x]		Σ 0..1		
valueQuantity			Quantity	
valueCodeableConcept			CodeableConcept	
valueString			string	
valueBoolean			boolean	
valueInteger			integer	
valueRange			Range	
valueRatio			Ratio	
valueSampledData			SampledData	
valueTime			time	
valueDateTime			dateTime	
valuePeriod			Period	

Blood Pressure Example

```

<Observation>
  ...
  <component>
    <code>
      <coding>
        <system value="http://loinc.org" />
        <code value="8480-6" />
        <display value="Systolic blood pressure" />
      </coding>
    </code>
    <valueQuantity ... />
  </component>
  <component>
    <code>
      <coding>
        <system value="http://loinc.org" />
        <code value="8462-4" />
        <display value="Diastolic blood pressure" />
      </coding>
    </code>
    <valueQuantity .../>
  </component>
</Patient>
  
```

<https://www.hl7.org/fhir/profiling-examples.html>

Componentの中に
拡張期と収縮期の値を
入れさせたい

<https://www.hl7.org/fhir/profiling-examples.html>

```
<!-- setting up the slicing -->
<element>
  <path value="Observation.component"/>
  <slicing>
    <discriminator value="system"/>
    <type value="value"/>
    <path value="code"/>
  </discriminator/>
</slicing>
<!-- net cardinality rules -->
<min value="2"/>
<max value="*" />
</element>
```

Componentの中の各要素を区別する属性(discriminator)は、“System”要素のCode値である。

```
<!-- first slice: systolic -->
```

```
<element>
  <path value="Observation.component"/>
  <name value="systolic"/> <!-- mandatory - gives the slice a name -->
  <min value="1"/>
  <max value="1"/>
</element>
```

Cardinality 1..1 として必須の要素であるとする

```
<element>
  <path value="Observation.component.code"/>
  <min value="1"/>
  <fixedCodeableConcept>
    <coding>
      <system value="http://loinc.org" />
      <code value="8480-6" />
      <display value="Systolic blood pressure" />
    </coding>
  </fixedCodeableConcept>
```

LOINC 8480-6固定 (Systolic BP)とする

Blood Pressure Example

```
<Observation>
  ...
  <component>
    <code>
      <coding>
        <system value="http://loinc.org" />
        <code value="8480-6" />
        <display value="Systolic blood pressure" />
      </coding>
    </code>
    <valueQuantity ... />
  </component>
  <component>
    <code>
      <coding>
        <system value="http://loinc.org" />
        <code value="8462-4" />
        <display value="Diastolic blood pressure" />
      </coding>
    </code>
    <valueQuantity ... />
  </component>
</Patient>
```

<https://www.hl7.org/fhir/profiling-examples.html>

Component内の各要素は、このパスを discriminator としている。

Componentの中に拡張期と収縮期の値を必須として入れさせることをProfileで要求している

Take Home Message

- FHIR自体は“Platform Specification”であり、相互運用性をただちに保障するものではない
- 当事者同士の合意としてのProfileを作成する必要がある。
- FHIRの文書はComposition Resourceに何を追加・制約・削除するかをProfileで定義していく
- Profile作成ツールは公開され、成果物もコミュニティで共有されており、事例が豊富にあります。
 - Forgeを利用してProfileをGUIで編集できるのでなんとなく出来てしまいが、FHIRの規格書は目を通しましょう。
 - Profilingの自習には、下記のWebサイトが参考になります。
 - <https://simplifier.net/guide/profilingacademy/modules>

One more thing...

HAPI FHIR Server R4版をDockerでパッケージングしました。数十秒で検証環境ができます！

📖 README.md

HAPI-FHIR
fhir made simple.

hapi-fhir-r4

Setup experimental environment for learning FHIR R4 Server

HAPI FHIR Serverを開発、検証用に迅速に立ち上げられるようにDockerにパッケージングしました。今後要望に応じてMySQL等の外部データベースサーバの永続化などの機能を追加していきます。

デモ、開発環境として使いたい方は、下記のコマンドのみで稼働可能です。

前提環境

- Docker 18.06以降
- メモリ 4GB以上

Dockerが入っている環境で下記のコマンドを実行します。Docker Imageがダウンロードされ、起動します。

```
docker run -p 8080:8080 kandalva/hapi-fhir-r4
```