Department of Veterans Affairs
Veteran Health Administration
Knowledge Based Systems

Informatics Architecture Support Services

FHIR Resources and Profiles in Relation to CIMI and SOLOR

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Outline

- Review of FHIR resources
- Profiling of FHIR resources
- Limitations of existing approaches to FHIR profiling
- Role of CIMI detailed clinical models in FHIR profiling
- Role(s) of SOLOR in CIMI DCMs and FHIR profiling

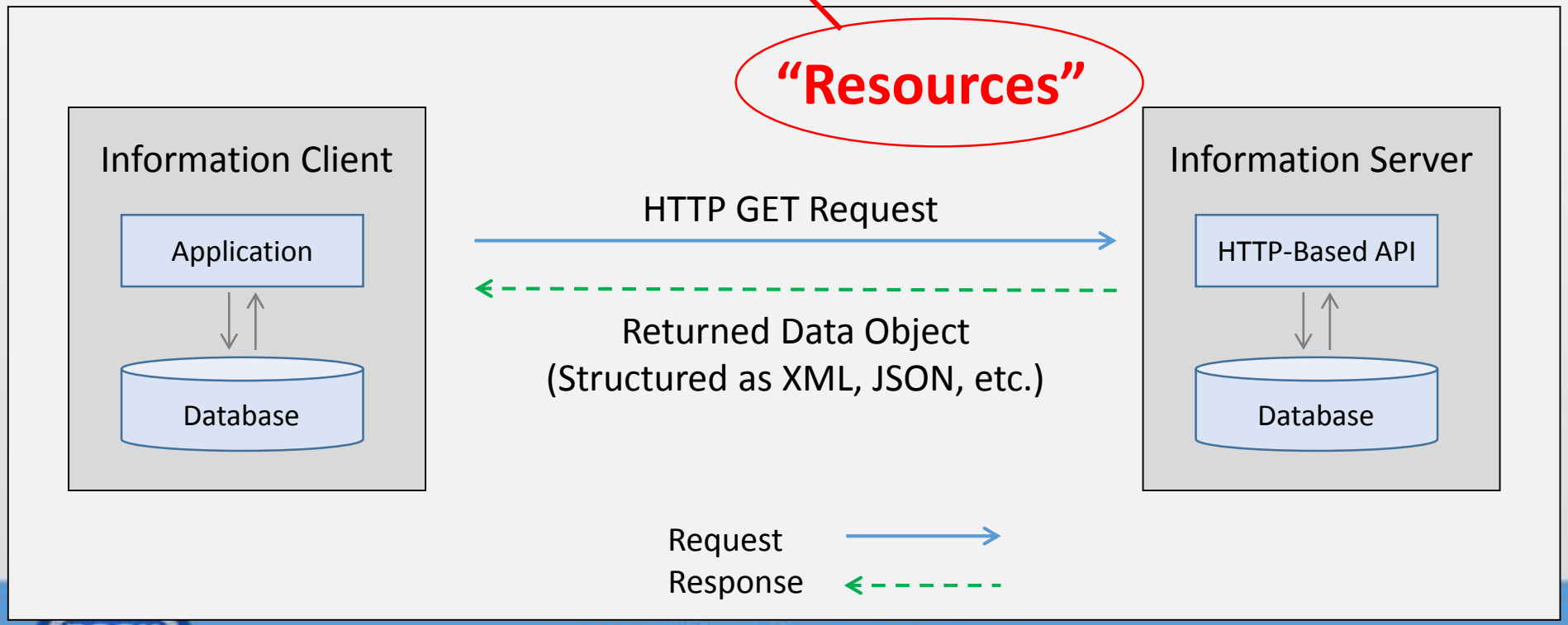
Review of FHIR

An internet-based application programming interface (API) characterized by:

1. "REST" model for requesting/retrieving data
2. "Resources" for standardizing the data content
3. "OAuth" for authorizing access to the data

“REST” Model for Data Access Over the Internet

- GET hospital.com/ehr/Patient?Lname=Cox&Fname=Joe
- GET hospital.com/ehr/Condition?PtID=1234&Status=Active
- GET hospital.com/ehr/Medication? PtID=1234&Date=gt2017



“REST” Model for Data Access Over the Internet

- G
- G
- G

Info

```
{
  "resourceType": "Condition",
  "id": "f202",
  "subject": {
    "reference": "Patient/f201"
  },
  "clinicalStatus": "resolved",
  "verificationStatus": "confirmed",
  "code": {
    "coding": [
      {
        "system": "http://snomed.info/sct",
        "code": "363346000",
        "display": "Malignant neoplastic disease"
      }
    ]
  },
 "bodySite": [
    {
      "coding": [
        {
          "system": "http://snomed.info/sct",
          "code": "361355005",
          "display": "Entire head and neck"
        }
      ]
    }
  ],
}
```

Defining "Resources" to Standardize Data (Content/Optionality/Structure/Coding)

- E.g., Condition resource definition => ("HL7 Core" resource)

Name	Flags	Card.	Type	Description & Constraints
Condition	Σ		DomainResource	Detailed information about conditions, problems or diagnoses
identifier	Σ	0..*	Identifier	External Ids for this condition
patient	Σ	1..1	Reference(Patient)	Who has the condition?
encounter	Σ	0..1	Reference(Encounter)	Encounter when condition first asserted
asserter	Σ	0..1	Reference(Practitioner |	Person who asserts this condition
dateRecorded	Σ			
code	Σ			
category	Σ			
clinicalStatus	?! Σ			
verificationStatus	?! Σ			
severity	Σ			
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age
onsetDateTime			dateTime	
onsetQuantity			Age	
onsetPeriod			Period	
onsetRange			Range	
onsetString			string	

Name	Flags	Card.	Type	Description & Constraints
Identifier	Σ		Element	An identifier intended for computation
use	?! Σ	0..1	code	usual | official | temp | secondary (If known) IdentifierUse (Required)
type	Σ	0..1	CodeableConcept	Description of identifier Identifier Type Codes (Extensible)
system	Σ	0..1	uri	The namespace for the identifier
value	Σ	0..1	string	The value that is unique
period	Σ	0..1	Period	Time period when id is/was valid for use
assigner	Σ	0..1	Reference(Organization)	Organization that issued id (may be just text)

“Resources” for Standardizing Data

~90 resources defined (HL7 FHIR v1.0.2 - DSTU2)

- Condition
- Procedure
- Medication
- Observation
- Immunization
- FamilyMemberHistory
- CarePlan
- NutritionOrder
- Specimen
- …

- Patient
- Practitioner
- Organization
- Location
- Encounter
- Appointment
- Schedule
- Device
- SupplyRequest
- …

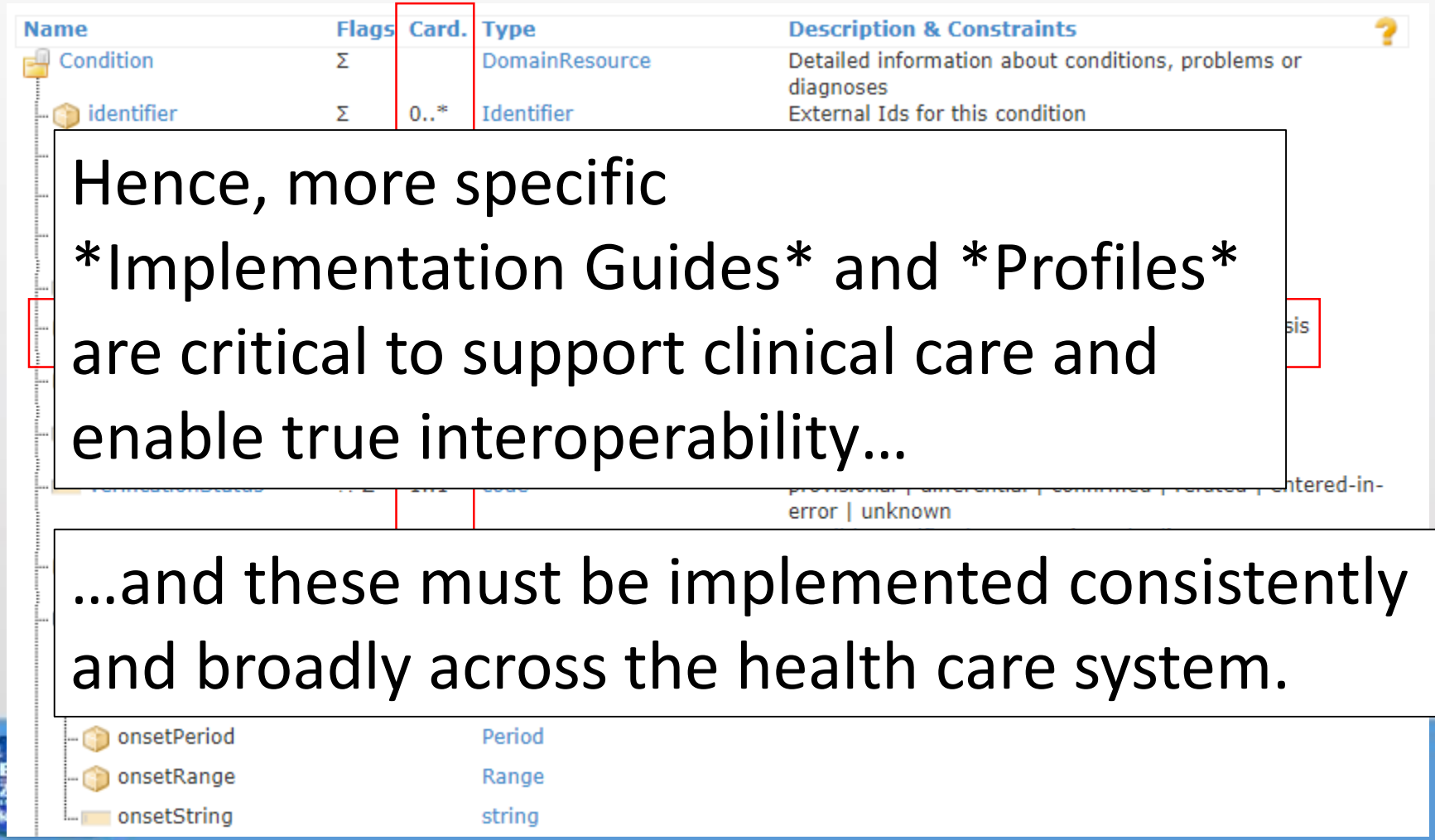
“Resources” for Standardizing Data

- E.g., Condition
  - Resource Definition =>

Name	Flags	Card.	Type	Description & Constraints
Condition	Σ		DomainResource	Detailed information about conditions, problems or diagnoses
identifier	Σ	0..*	Identifier	External Ids for this condition
patient	Σ	1..1	Reference(Patient)	Who has the condition?
encounter	Σ	0..1	Reference(Encounter)	Encounter when condition first asserted
asserter	Σ	0..1	Reference(Practitioner | Patient)	Person who asserts this condition
dateRecorded	Σ	0..1	date	When first entered
code	Σ	1..1	CodeableConcept	Identification of the condition, problem or diagnosis Condition/Problem/Diagnosis Codes (Example)
category	Σ	0..1	CodeableConcept	complaint | symptom | finding | diagnosis Condition Category Codes (Preferred)
clinicalStatus	?! Σ	0..1	code	active | relapse | remission | resolved Condition Clinical Status Codes (Preferred)
verificationStatus	?! Σ	1..1	code	provisional | differential | confirmed | refuted | entered-in-error | unknown ConditionVerificationStatus (Required)
severity	Σ	0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age
onsetDateTime			dateTime	
onsetQuantity			Age	
onsetPeriod			Period	
onsetRange			Range	
onsetString			string	

“Resources” for standardizing the exchanged data

- E.g., Condition
  - Resource Definition =>



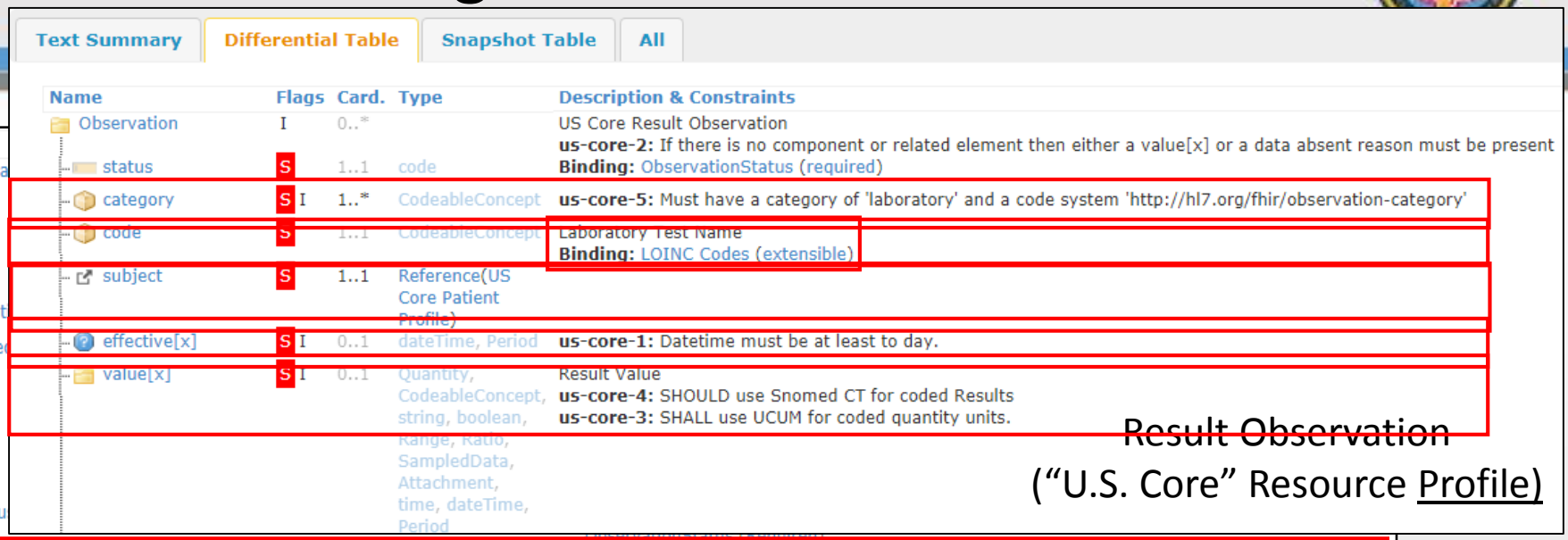
Hence, more specific *Implementation Guides* and *Profiles* are critical to support clinical care and enable true interoperability…

…and these must be implemented consistently and broadly across the health care system.

HL7 FHIR Profiling

- Further constraints on and extensions to “core” HL7 FHIR Resources
  - Structure
    - Required/Optional Data Elements
    - Cardinality of Data-Element Values
    - Datatype(s) of Data-Element Values (atomic and complex)
  - Terminology Bindings
    - Value Sets
    - Binding “Strength” (required vs. suggested)

Profiling FHIR Resources



Result Observation
("U.S. Core" Resource Profile)

category		0..*	CodeableConcept	Classification of type of observation Observation Category Codes (Preferred)
code	Σ	1..1	CodeableConcept	Type of observation (code / type) LOINC Codes (Example)
subject	Σ	0..1	Reference(Patient | Group | Device | Location)	Who and/or what this is about
context		0..1	Reference(Encounter | EpisodeOfCare)	Healthcare event during which this observation is made
effective[x]	Σ	0..1		Clinically relevant time/time-period for observation
effectiveDateTime			dateTime	
effectivePeriod			Period	
issued	Σ	0..1	instant	Date/Time this was made available
performer	Σ	0..*	Reference(Practitioner | Organization | Patient | RelatedPerson)	Who is responsible for the observation
value[x]	Σ I	0..1		Actual result
bodySite		0..1	CodeableConcept	Observed body part SNOMED CT Body Structures (Example)
method		0..1	CodeableConcept	How it was done Observation Methods (Example)
specimen		0..1	Reference(Specimen)	Specimen used for this observation
device		0..1	Reference(Device | DeviceMetric)	(Measurement) Device
referenceRange	I	0..*	BackboneElement	Provides guide for interpretation

Observation
(HL7 Core Resource)

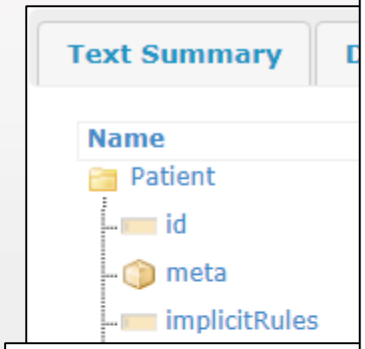
Profiling FHIR Resources

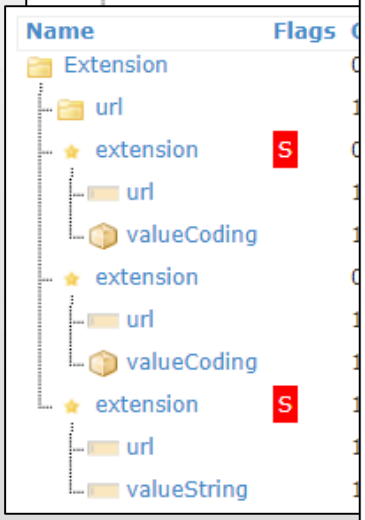
- Terminology Binding "Strength"
  - E.g., "LOINC Codes (Example)" vs. "LOINC Codes (Extensible)"

required	To be conformant, the concept in this element SHALL be from the specified value set
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	Instances are encouraged to draw from the specified codes for interoperability purposes but are not required to do so to be considered conformant.
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.

Profiling FHIR Resources

- Extensior






```
{
  "resourceType" : "Patient",
  "id" : "example",
  "meta" : {
    "profile" : [
      "http://hl7.org/fhir/us/core/StructureDefinition/us-core-patient"
    ]
  },
...
  "extension" : [
    {
      "url" : "http://hl7.org/fhir/us/core/StructureDefinition/us-core-race",
      "extension" : [
        {
          "url" : "ombCategory",
          "valueCoding" : {
            "system" : "urn:oid:2.16.840.1.113883.6.238",
            "code" : "2028-9",
            "display" : "Asian"
          }
        },
         {
          "url" : "detailed",
          "valueCoding" : {
            "system" : "urn:oid:2.16.840.1.113883.6.238",
            "code" : "2036-2",
            "display" : "Filipino"
          }
        },
        {
          "url" : "text",
          "valueString" : "Asian/Filipino"  } ] },
  ],
...
  "name" : [
    {
      "family" : "Shaw",
      "given" : [
        "Amy",
        "V."    ]  } ],
  "gender" : "female",
  "birthDate" : "2007-02-20",
}
```

Profiling FHIR Resources

- Recognizing and requesting instances of specific profiles
  - Recognizing: Identifier(s) of relevant profile(s) must be indicated in the "Meta" data element of each resource instance
  - E.g.:

```
{
  "resourceType" : "Observation",
  "id" : "serum-total-bilirubin",
  "meta" : {
    "versionId" : "1364",
    "lastUpdated" : "2016-03-09T15:29:59.089+00:00",
    "profile" : [
      "http://hl7.org/fhir/us/core/StructureDefinition/us-core-observationresults"
    ]
  },
  ...
  "code" : {
    "coding" : [
      {
        "system" : "http://loinc.org",
        "code" : "1975-2",
        "display" : "Bilirub SerPl-mCnc"
      }
    ],
    "text" : "Bilirub SerPl-mCnc"
  },
  "valueQuantity" : {
    "value" : 8.6,
    "unit" : "mg/dL",
    "system" : "http://UCUM.org"
  },
 ...
}
```

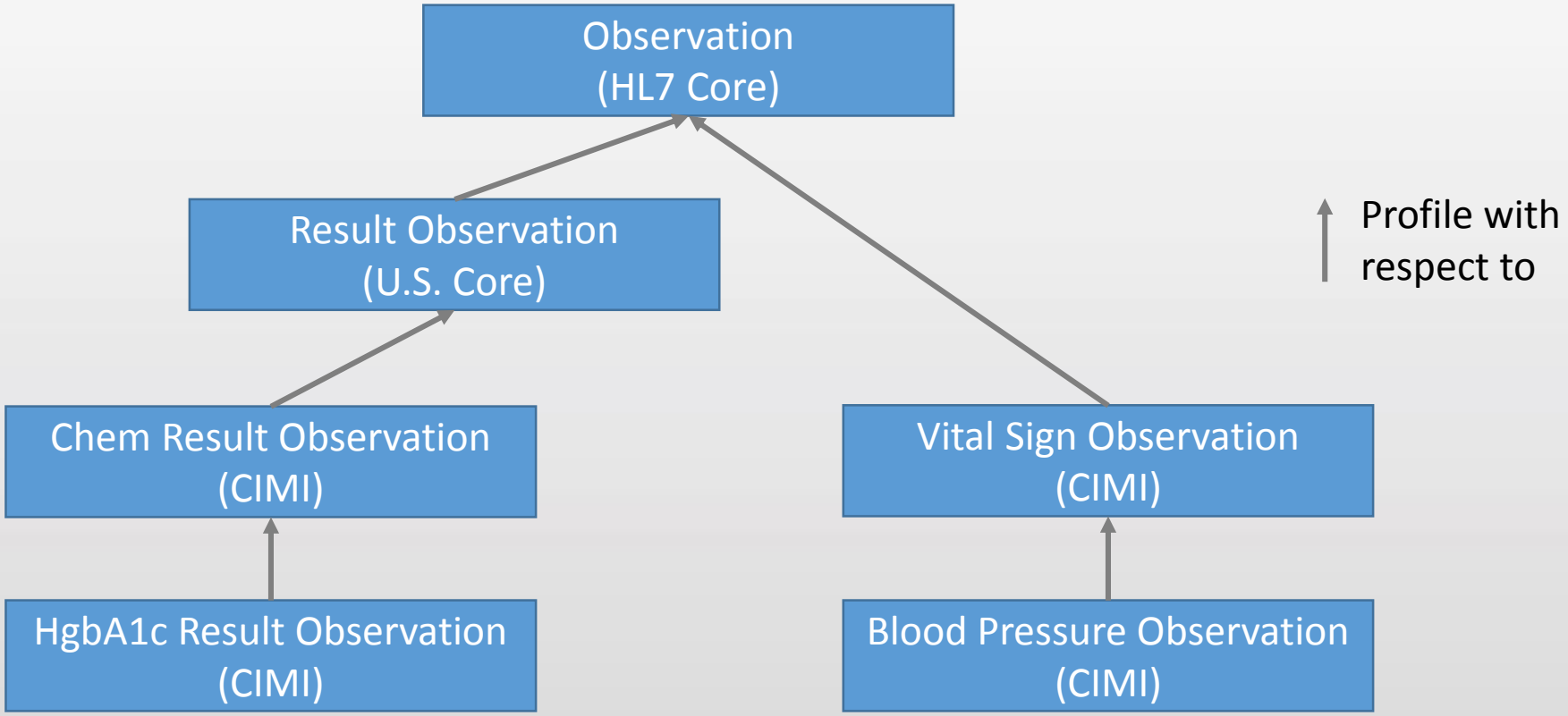
Profiling FHIR Resources

- Recognizing and requesting instances of specific profiles
  - Recognizing: Identifier(s) of relevant profile(s) must be indicated in the "Meta" data element of each resource instance
  - Requesting: "_profile" parameter may be specified in any RESTful GET query
  - E.g.:

```
GET https://fhir-db/Observation?patient=1032702&
effectiveDateTime=ge2017-10-01&effectiveDateTime=le2017-10-23&
_profile=http://hl7.org/fhir/us/core/StructureDefinition/us-core-observationresults
```

FHIR Profiling Rules

- Profiles may be created with respect to HL7 Core Resources or with respect to other profiles



FHIR Profiling Rules

- Profiles may be created with respect to HL7 Core Resources or with respect to other profiles
- Profiles cannot break the rules established in the base specification
  - Optionality, cardinality, data types, value sets
  - *Valid instance of profile must be a valid instances of base specification*
  - E.g., Base cardinality: 0..1, Profile Cardinality: 1..1 => OK
    Base cardinality: 0..1, Profile Cardinality: 1..* => NOT OK
  - E.g., Base value set: SCT, Profile value set: SCT Finding Hierarchy => OK
    Base value set: SCT, Profile value set: SCT and ICD-10 => NOT OK

FHIR Profiling Rules

- Profiles may be created with respect to HL7 Core Resources or with respect to other profiles
- Profiles cannot break the rules established in the base specification
- It must be safe to process a resource without knowing the profile
  - "Safe" not defined.
  - (?) Any application that can parse, persist, and process valid instances of the HL7 Core resource can parse, persist, and process valid instances of the profile
  - Does not guarantee *patient* safety, however…

FHIR Profiling Rules

- Profiles may be created with respect to HL7 Core Resources or with respect to other profiles
- Profiles cannot break the rules established in the base specification
- It must be safe to process a resource without knowing the profile
- Any extension element that can change the meaning of the base resource must be a *modifier extension* (cannot be ignored)
  - E.g., the extension element “negated (Boolean)” in a profile on the Observation resource
  - The value of “negated (Boolean)” in any instance of this profile must be processed and correctly handled by the receiving system
  - E.g., { "resourceType" : "Observation",
    “meta” : { “profile” : [“http://hl7.org/fhir/profile/NegatableObservation”] },
    “code” : { “system” : “http://snomed.org”, “code” : “759375”, “display” : “Headache” },
    “negated” : “true” } → Changes meaning

Limitations of FHIR Profiles: Lack of Granularity

- Because most existing FHIR profiles attempts to accommodate broad use cases, they rarely require all the data elements that may be needed for a clinician to fully interpret a particular value or observation
  - Important data elements may be NULL in even fully compliant instances of FHIR profiles, diminishing the data's usefulness
  - Example: A reference range for a chemistry lab result may be NULL because the U.S. Core "Result Observation" profile must also represent culture results, blood-typing results, etc., which have no reference ranges
- Furthermore, profiles for specific use cases must include many extension data elements to represent the 20% of clinical content that the HL7 Core FHIR specification lacks by design ("80/20 rule")

(Courtesy of Julia Skapik, Cognitive Medicine, AMIA 2017)

Limitations of FHIR: Extension Salad

- There exist a great number of profiles that include extensions

Limitations of FHIR: Extension Salad

1.3 Profiles defined as part of FHIR

This specification is a common platform standard that must be adapted to particular use cases. Some particular use cases are common or important enough to be described as a part of the specification itself. These are published as a "Profile" - a group of Structure Definitions (Constraints or Extensions), Value Sets, and examples that are all defined with a common purpose. Additional profiles may be registered on the HL7 FHIR registry at http://hl7.org/fhir/registry

Name	Description	Kind	FMM
General			
EHRS FM Record Lifecycle Event - Audit Event	Defines the elements to be supported within the AuditEvent resource in order to conform with the Electronic Health Record System Functional Model Record Lifecycle Event standard	profiles	
Common extensions for Coding data type	Defines "common" extensions for use with the DataElement data type	extensions	
CQIF Extensions	Defines common extensions used by the Clinical Reasoning Module.	extensions	
CQIF Guidance Extensions	Defines common extensions used by the Decision Support-Specific Clinical Quality Improvement Framework.	extensions	
Element-definition Extensions for use by FHIR Implementers	A set of extensions that constrain data elements, whether used in DataElements, StructureDefinitions or Questionnaires	extensions	
ISO 11179 Element Definition Profile	A profile showing how to use ElementDefinition to express 11179 Data_Element and Concept_Elements. At present, the profile is a partially-complete place-holder	extensions, search parameters	
DataElement constraint on ElementDefinition data type	Identifies how the ElementDefinition data type is used when it appears within a data element	profiles	

80 sets just on HL7 FHIR web site!

Specimen			
Specimen HL7 Extensions	Defines common extensions used with or related to the Specimen resource	extensions	
StructureDefinition			
Standard Structure Definition Extensions	This profile describes common extensions that are used with Structure Definitions	extensions	
Task			
Task HL7 Extensions	Defines common extensions used with or related to the Task resource	extensions	
ValueSet			
ValueSet HL7 Extensions	Defines common extensions used with or related to the ValueSet resource	extensions, search parameters	
Shareable ValueSet	Enforces the minimum information set for the value set metadata required by HL7 and other organisations that share and publish value sets	profiles	

Limitations of FHIR: Extension Salad

- There exist a great number of profiles that include extensions
- Because FHIR is not built against a logical model the development of extensions is largely free-form
- There is not currently any tooling or method to cross-check extensions across use cases to determine conformance for multiple purposes; in fact, it is known that many sets of extensions directly conflict one another

(Courtesy of Julia Skapik, Cognitive Medicine, AMIA 2017)

Limitations of FHIR: Content

- While it is easy to develop applications using FHIR, developers rely on others to define and populate clinical concepts
- Plug-and-play interoperability requires that clinical concepts:
  - Can be retrieved via APIs
  - Have a clearly defined meaning that is clinically useful to users
  - Are structed/coded in a standard way across many HIT systems
- Any single FHIR profile provides *just one possible* representation of a clinical concept

(Courtesy of Julia Skapik, Cognitive Medicine, AMIA 2017)

Limitations of FHIR: Example

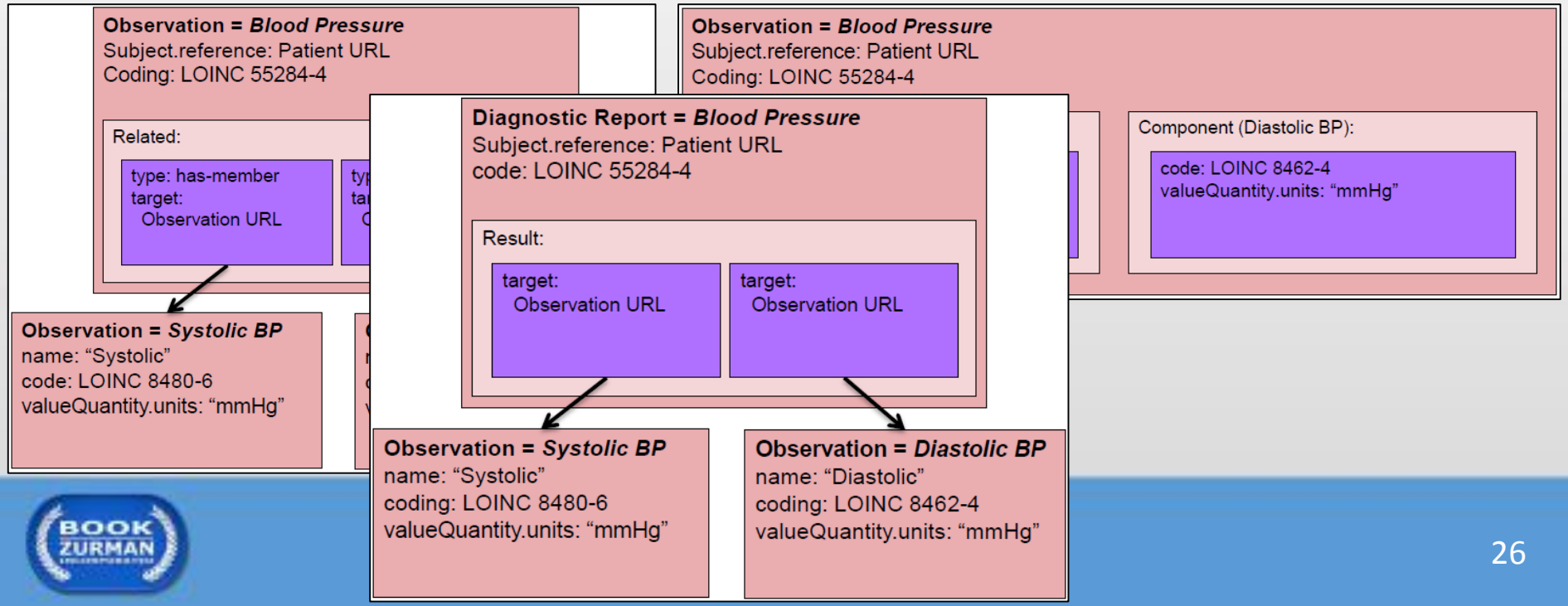
- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified
- Existing FHIR profiles may lack needed clinical detail
- Example: Blood Pressure measurement (systolic/diastolic) using Observation and/or Diagnostic Report resources

Name	Flags	Card.	Type
Observation	I		DomainResource
code	Σ	1..1	CodeableConcept
subject	Σ	0..1	Reference(Patient | Group | Device | Location)
value[x]	Σ I	0..1	
related	Σ	0..*	BackboneElement
type		0..1	code
target		1..1	Reference(Observation | QuestionnaireResponse | Sequence)
component	Σ	0..*	BackboneElement
code	Σ	1..1	CodeableConcept
value[x]	Σ	0..1	

Name	Flags	Card.	Type
DiagnosticReport			DomainResource
code	Σ	1..1	CodeableConcept
subject	Σ	0..1	Reference(Patient | Group | Device | Location)
result		0..*	Reference(Observation)

Limitations of FHIR: Example

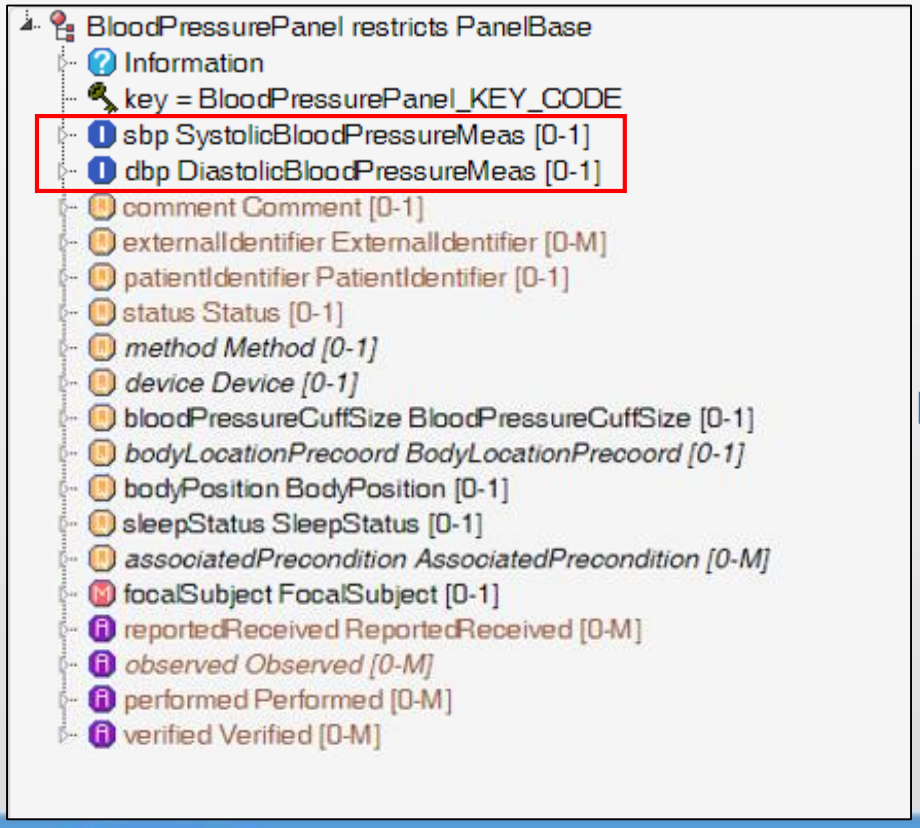
- Existing FHIR profiles still allow too much variability in the way that clinical data may be specified
- Existing FHIR profiles may lack needed clinical detail
- Example: Blood Pressure measurement using Observation and/or Diagnostic Report resources



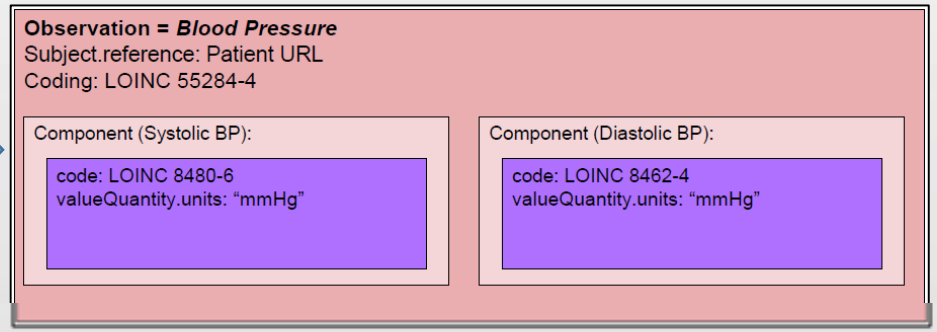
CIMI Addresses FHIR Profile Limitations

- CIMI defines a *Detailed Clinical Model* for Blood Pressure, and then a corresponding *standard* FHIR profile

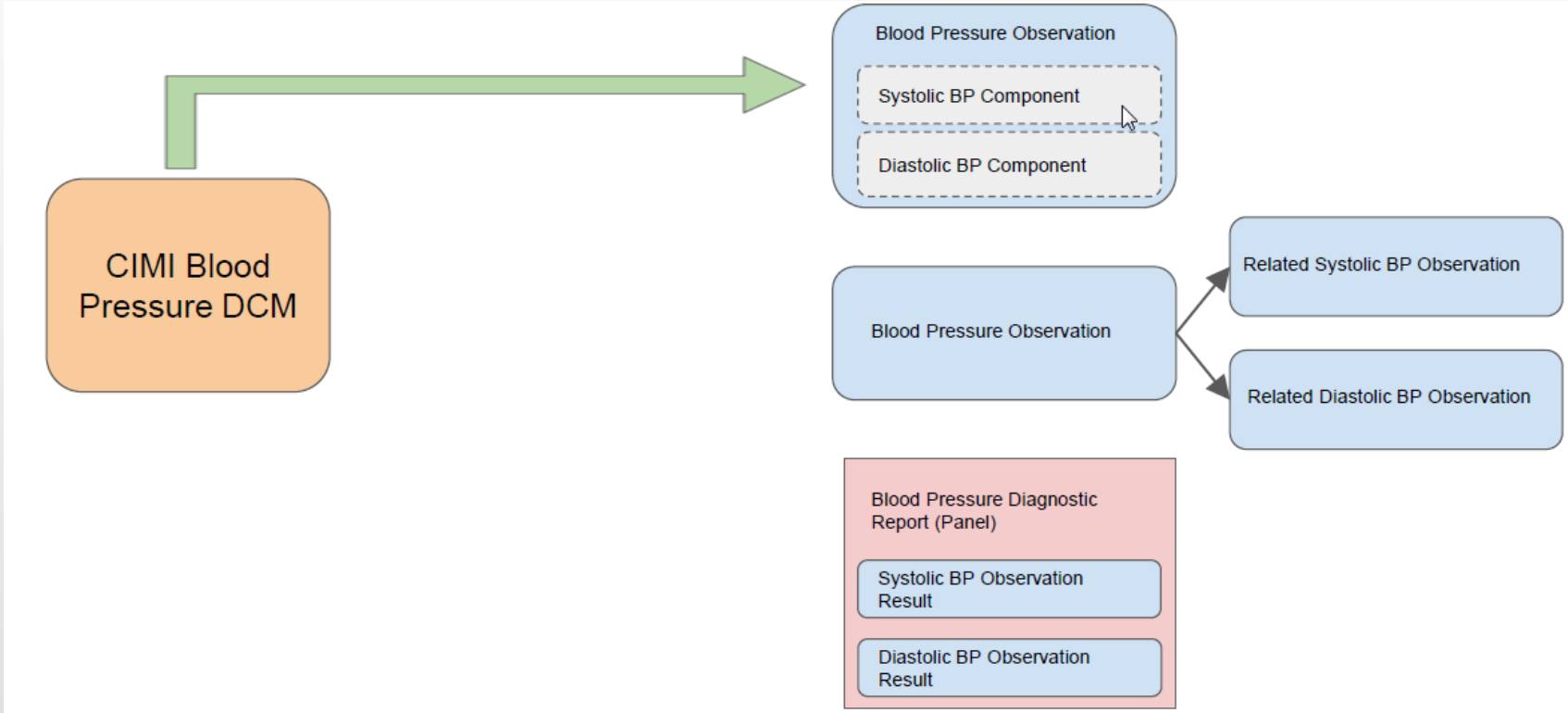
CIMI Detailed Clinical Model



FHIR Profile



CIMI Addresses FHIR Profile Limitations

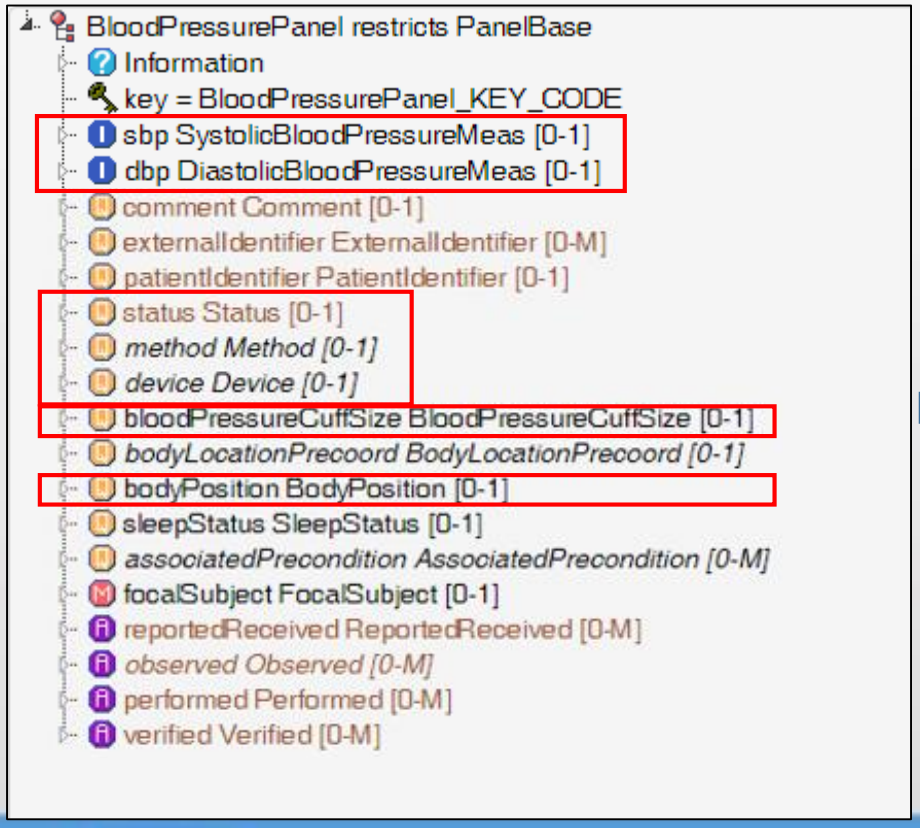


(Diagram courtesy of Claude Nanjo, Cognitive Medicine, AMIA 2017)

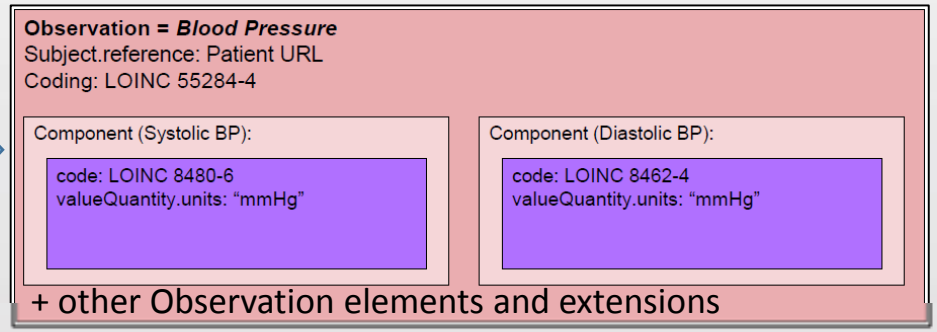
CIMI Addresses FHIR Profile Limitations

- CIMI defines a *Detailed Clinical Model* for Blood pressure, and then a corresponding FHIR profile

CIMI Detailed Clinical Model

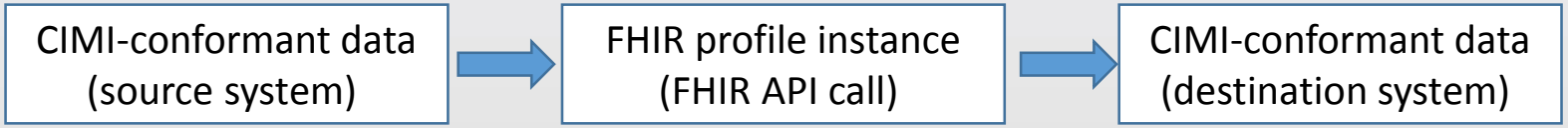


FHIR Profile



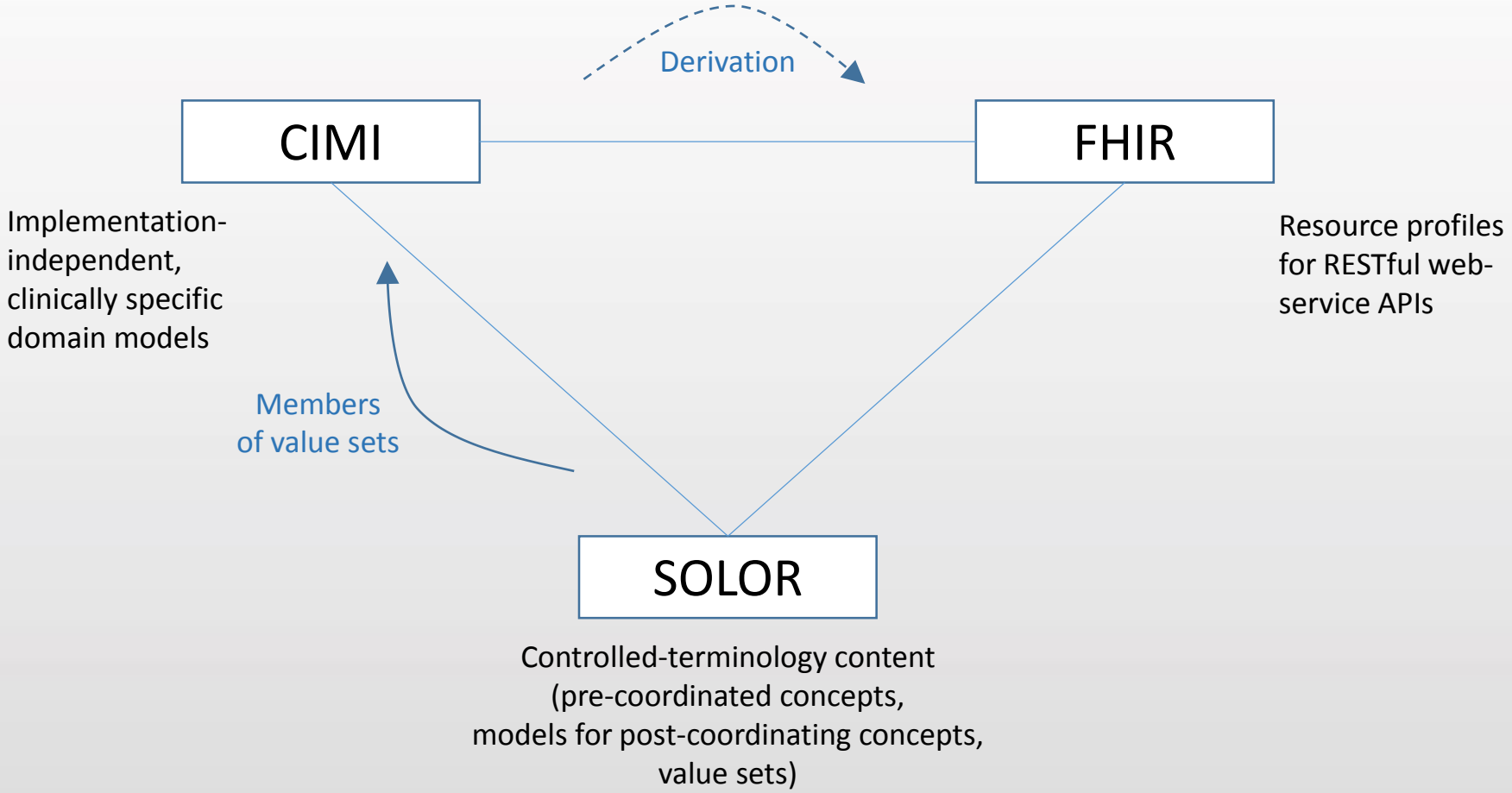
CIMI DCMs and FHIR Profiles: Challenges

- Scope
  - To provide the needed level of granularity for clinical concepts, potentially 1,000's of CIMI DCMs and corresponding FHIR profiles must be defined
- Model mismatches
  - Differences between the modeling of CIMI base classes and FHIR Core Resources
    - E.g., "status" element
- Bi-directional data mapping



  - Without loss of information
- Adoption
  - CIMI-based FHIR profiles versus any others that do/will exist

Role(s) of SOLOR

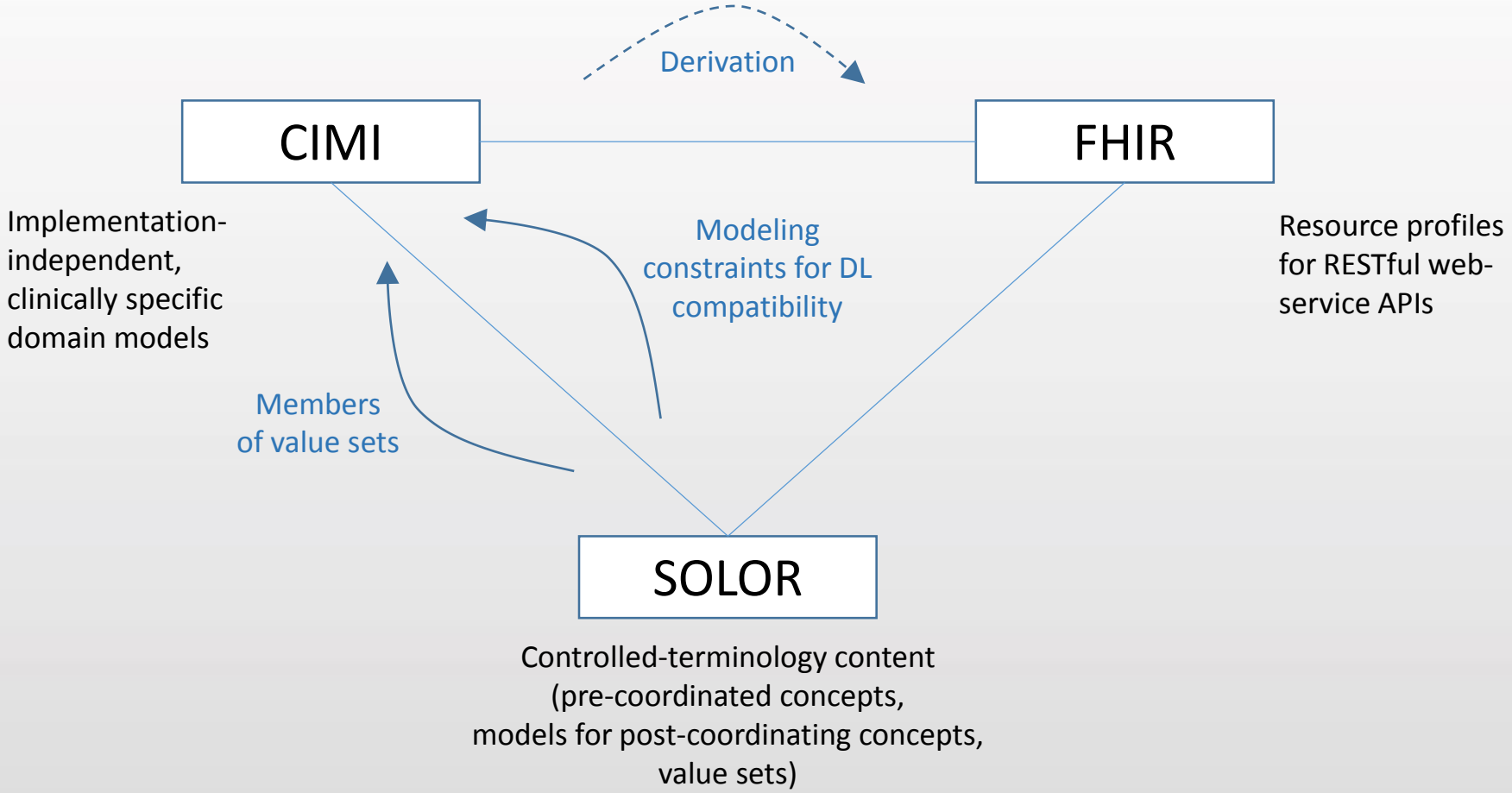


SOLOR in CIMI DCM Value Sets

A DCM for recording pain symptoms (actually from CEM, but similar to CIMI)

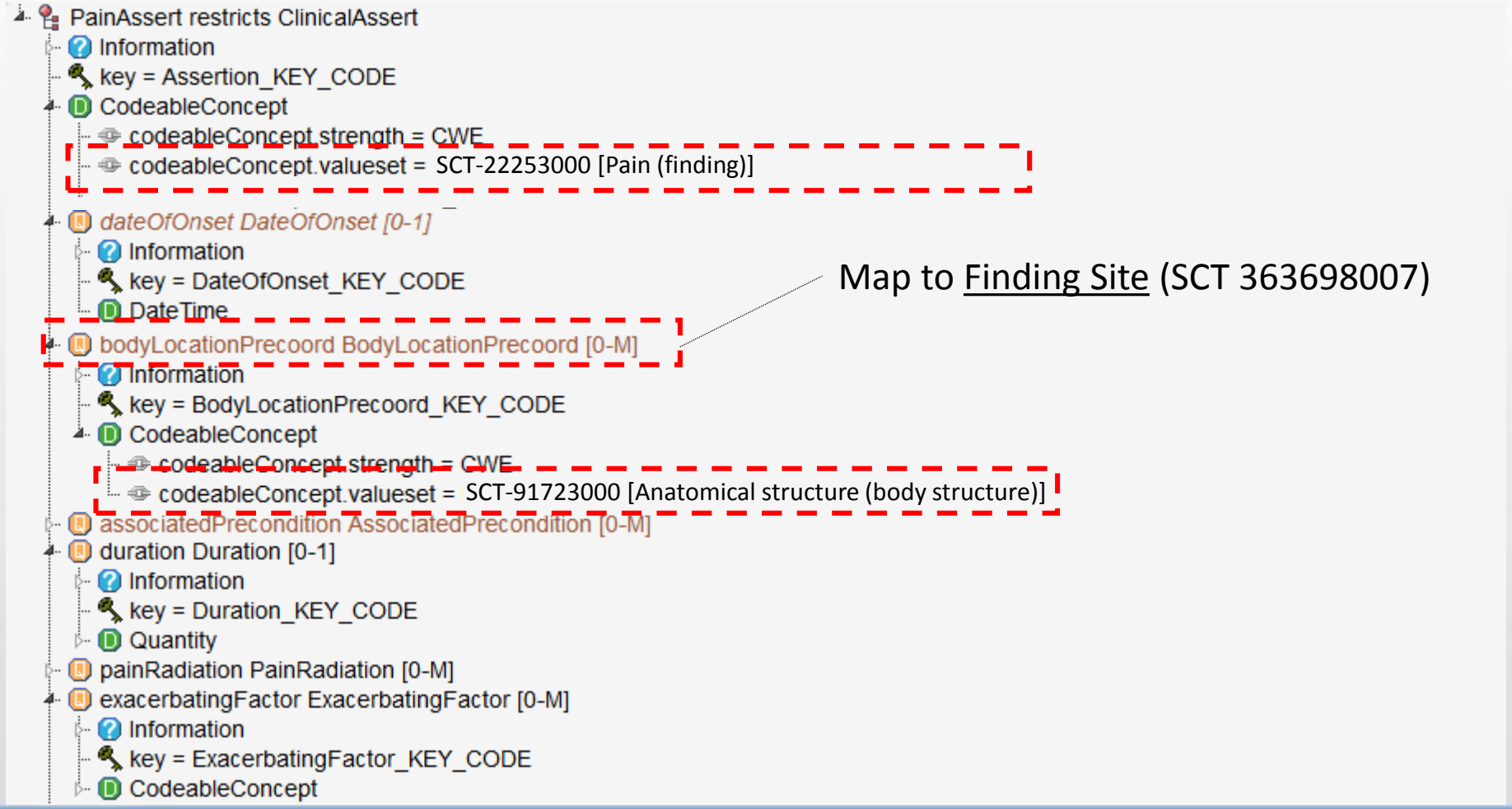
- PainAssert restricts ClinicalAssert
  - Information
  - key = Assertion_KEY_CODE
  - CodeableConcept
    - codeableConcept.strength = CWE
    - codeableConcept.valueset = SCT-22253000 [Pain (finding)]
  - *dateOfOnset DateOfOnset [0-1]*
    - Information
    - key = DateOfOnset_KEY_CODE
    - DateTime
  - bodyLocationPrecoord BodyLocationPrecoord [0-M]
    - Information
    - key = BodyLocationPrecoord_KEY_CODE
    - CodeableConcept
      - codeableConcept.strength = CWE
      - codeableConcept.valueset = SCT-91723000 [Anatomical structure (body structure)]
  - associatedPrecondition AssociatedPrecondition [0-M]
  - duration Duration [0-1]
    - Information
    - key = Duration_KEY_CODE
    - Quantity
  - painRadiation PainRadiation [0-M]
  - exacerbatingFactor ExacerbatingFactor [0-M]
    - Information
    - key = ExacerbatingFactor_KEY_CODE
    - CodeableConcept

Role(s) of SOLOR



SOLOR in CIMI DCM Modeling/Mapping

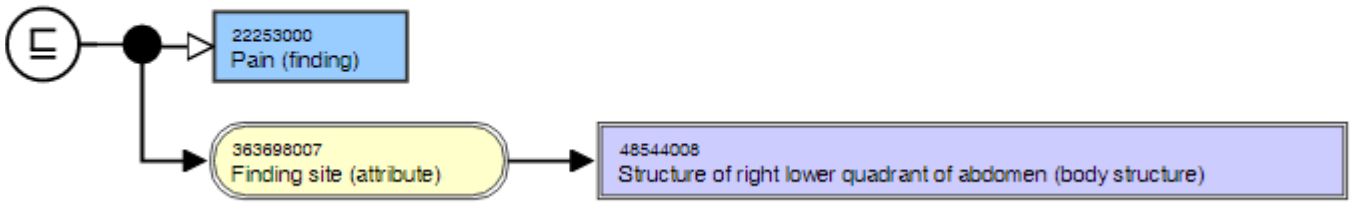
A DCM for recording pain symptoms (actually from CEM, but similar to CIMI)



Map to Finding Site (SCT 363698007)

SOLOR in CIMI DCM Modeling/Mapping

Description Logic Representation of “Pain RLQ” Data Instance (KRSS/SOLOR)




```
SubClassOf:
Pain and
  ( Finding site some Structure of right lower quadrant of abdomen)
```

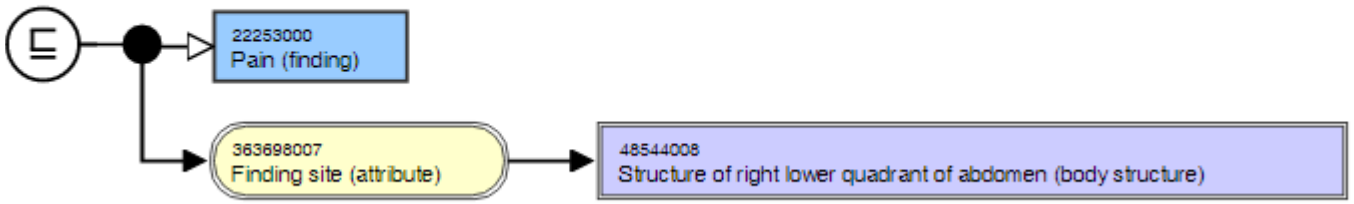
SOLOR in CIMI DCM Modeling/Mapping

Object-oriented (CIMI) representation of “Pain RLQ” Data Instance

```
<?xml version="1.0" encoding="UTF-8"?>
<PainAssert>
  <Archetype archetypeId="4784894573"/>
  <CodeableConcept>
    <Code codingSystem="SCT" code="22253000" text="Pain"/>
  </CodeableConcept>
  <DateOfOnset dateTime="2017-04-21 00:00:00"/>
  <BodyLocationPrecoord>
    <CodeableConcept>
      <Code codingSystem="SCT" code="48544008" text="Right lower quadrant of abdomen"/>
    </CodeableConcept>
  </BodyLocationPrecoord>
  <Duration>
    <Quantity value="2" units="days"/>
  </Duration>
  <ExacerbatingFactor>
    <CodeableConcept>
      <Code codingSystem="LN" code="83184-2 " text="Eating"/>
    </CodeableConcept>
  </ExacerbatingFactor>
</PainAssert>
```

SOLOR in CIMI DCM Modeling/Mapping

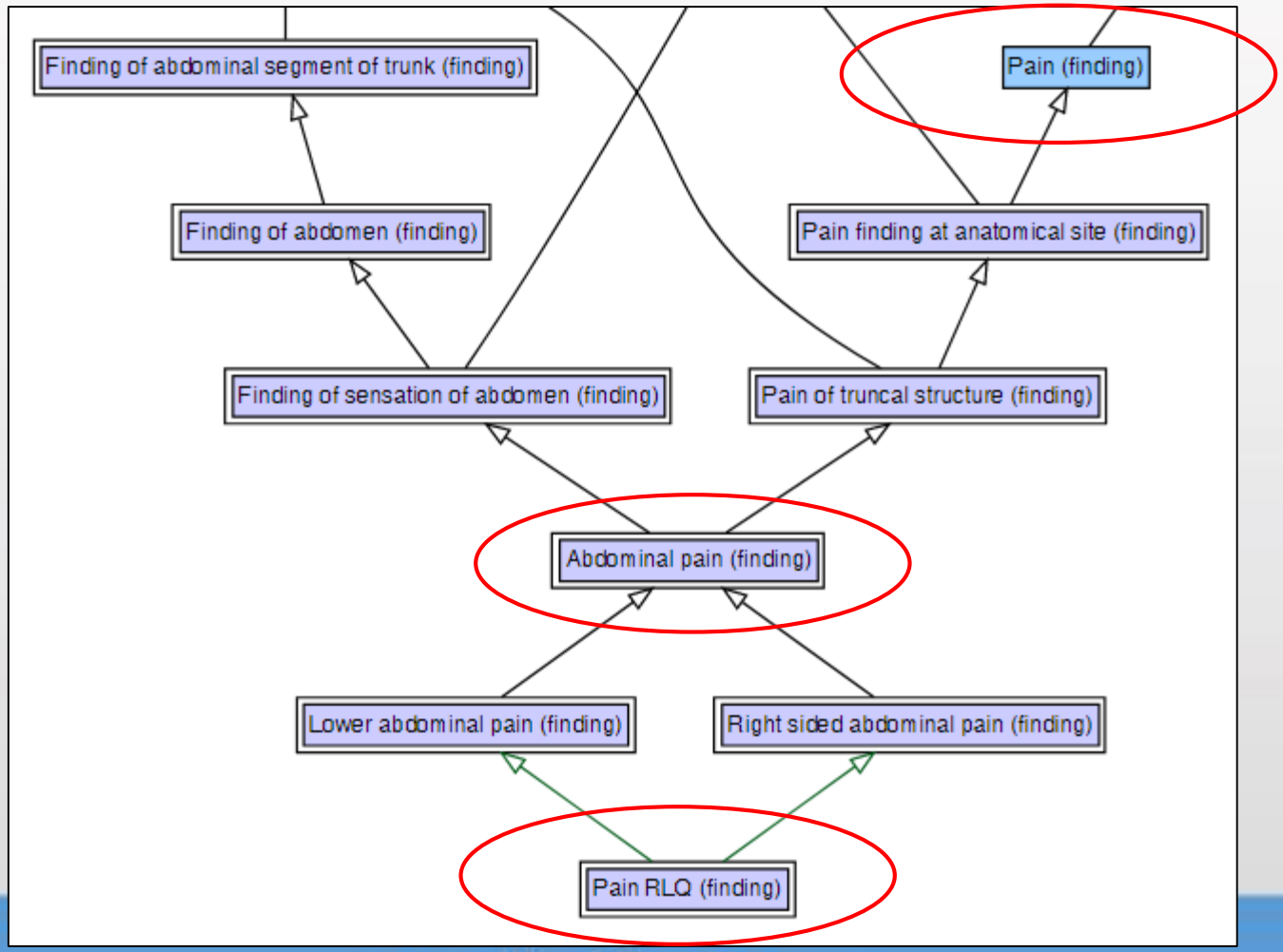
Description Logic Representation of “Pain RLQ” Data Instance (KRSS/SOLOR)



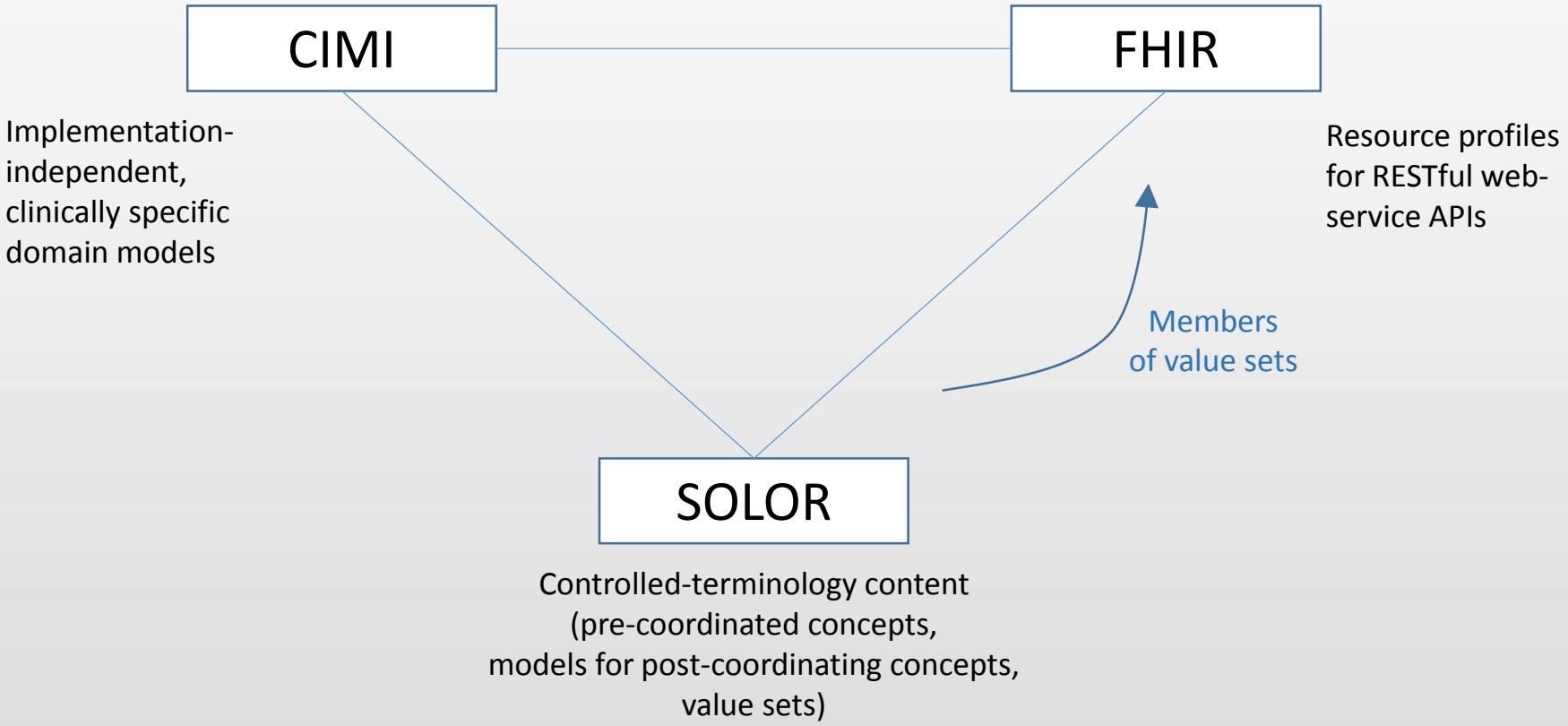

```
SubClassOf:
Pain and
  ( Finding site some Structure of right lower quadrant of abdomen)
```

SOLOR in CIMI DCM Modeling/Mapping

Description Logic Classification of “Pain RLQ” Data Instance



Role(s) of SOLOR



SOLOR in FHIR Profile Value Sets

Name	Flags	Card.	Type	Description & Constraints
Observation	I		DomainResource	Measurements and simple assertions *+ If code is the same as a component code then the value element associated with the code SHALL NOT be present* *+ dataAbsentReason SHALL only be present if Observation.value[x] is not present* Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	Business Identifier for observation
basedOn	Σ	0..*	Reference(CarePlan | DeviceRequest | ImmunizationRecommendation | MedicationRequest | NutritionOrder | ProcedureRequest | ReferralRequest)	Fulfills plan, proposal or order
status	?! Σ	1..1	code	registered | preliminary | final | amended + ObservationStatus (Required)
category		0..*	CodeableConcept	Classification of type of observation Observation Category Codes (Preferred)
code	Σ	1..1	CodeableConcept	Type of observation (code / type) LOINC Codes (Example)
subject	Σ	0..1	Reference(Patient | Group | Device | Location)	Who and/or what this is about
context		0..1	Reference(Encounter | EpisodeOfCare)	Healthcare event during which this observation is made
effective[x]	Σ	0..1		Clinically relevant time/time-period for observation
effectiveDateTime			dateTime	
effectivePeriod			Period	
issued	Σ	0..1	instant	Date/Time this was made available
performer	Σ	0..*	Reference(Practitioner | Organization | Patient | RelatedPerson)	Who is responsible for the observation
value[x]	Σ I	0..1		Actual result
bodySite		0..1	CodeableConcept	Observed body part SNOMED CT Body Structures (Example)
method		0..1	CodeableConcept	How it was done Observation Methods (Example)
specimen		0..1	Reference(Specimen)	Specimen used for this observation
device		0..1	Reference(Device | DeviceMetric)	(Measurement) Device
referenceRange	I	0..*	BackboneElement	Provides guide for interpretation

Observation
(HL7 Core Resource)

Thank you

Questions?