FHIR Overview

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A bit of Standards history

- At the beginning (1987) there was V2
  - A delimiter based message system exemplified with part of complete blood count message below …..

```
OBX|2|NM||789-8^RBC^LN||4.9|10*6/uL|4.0-5.4|N
OBX|3|NM||718-7^HGB^LN||12.4|g/dL|12.0 5.0|N
OBX|4|NM||20570-8^HCT^LN||50|%|35-49|H
OBX|5|NM||30428-7^MCV^LN||81|fL|80-94|N|
```

  V2 to continues to dominate

  - Then there was V3 – an XML based message/document system –which was never successful
  - Then CDA, based on V3 as a document system, which is in use but challenging
  - V2 continues to be mainstay (20-40 billion messages/year)

History more

- Now we have FHIR –which is the future
  - It parallels much of V2's organization. V2 has separate segments for the patient, orders, medications, and observations
  - FHIR does too, but has more
  - V2 had data types, like structured names (last^First^middle^Suffix^title, etc) coded data
  - FHIR does too, but goes further and with more precision
  - FHIR is an API, but can implement a message paradigm like V2 AND a document paradigm like V3

Overview – of FHIR

What is it?

- A set of data structured and designed to store and deliver everything of interest to clinical care and associated activities - billing, research, etc.
- Foundation is a set of more than a 100 "tables" (objects) called resources
- Each table contains multiple fields/attributes
- Fields have an associated data types – like decimal, text, range, address, coded entry, person name
- Some data types are complicated and made up of other smaller data types (e.g. names, addresses, code entry)
- It also has profiles and extensions which I will leave to Lloyd to define

What makes it attractive

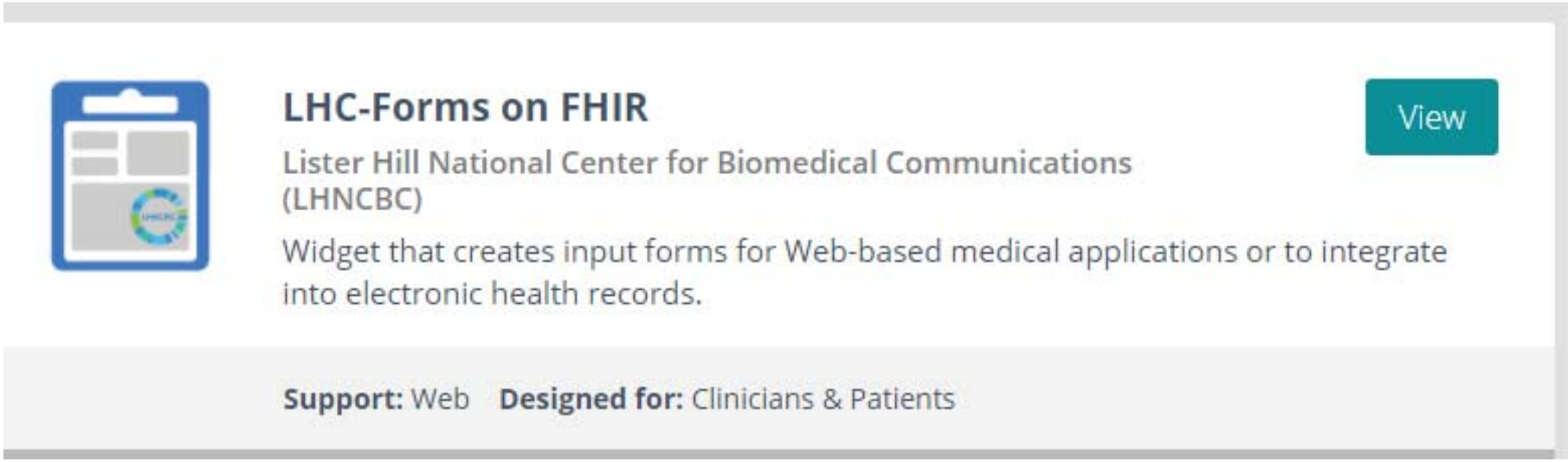
- It is very malleable
  - It does not specify any particular database technology. Just defines how it should behave
  - The structured (resources) can be represented in XML, JSON, or RDF triples (maybe even CSV)
- It dodges the effort of defining *one standard* enterprise model (can't be done) by limiting attention to the key elements (80:20) and allowing users to add things of their choosing as extensions but in a formal and controlled way
- Encourages the use of specific coding systems like LOINC and UCUM but does not require them

Why attractive more

- Available FHIR servers also include hordes of relevant coding systems built in.
- Has strong buy in from industry and growing support from Federal agencies. ONC is on board. CMS and FDA are feeling the pull
- It is accumulating the functions of a full-fledged health system
- Provides a great ecosystem for developing special tools and applications without having to do it yourself
- Apple Health is built on FHIR (as well as the Meaningful Use coding systems – LOINC, RxNorm and SNOMED CT) and so is the emerging Sync For Science and All of Us research projects

Still more

- Free, test servers (For those who want to play) http://hapifhir.io/docindex.html
- SMART on FHIR – an set of FHIR tools and application designed to pull data out of commercial EMRs and do interesting things https://apps.smarthealthit.org/apps/featured/page/2
  - Including one of our own tools



Even more

- Balloted under ANSI rules as a formal HL7 standard
- All available at no cost
- Emerged on a relative shoestring
- Gorgeous and consistent documentation immediately available online
- Will explain it further through that documentation

A walk through the FHIR documentation garden

If you want to walk it yourself here is the URL for the active development version (https://build.fhir.org/index.html)

L will take you
page. It has
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tion but too
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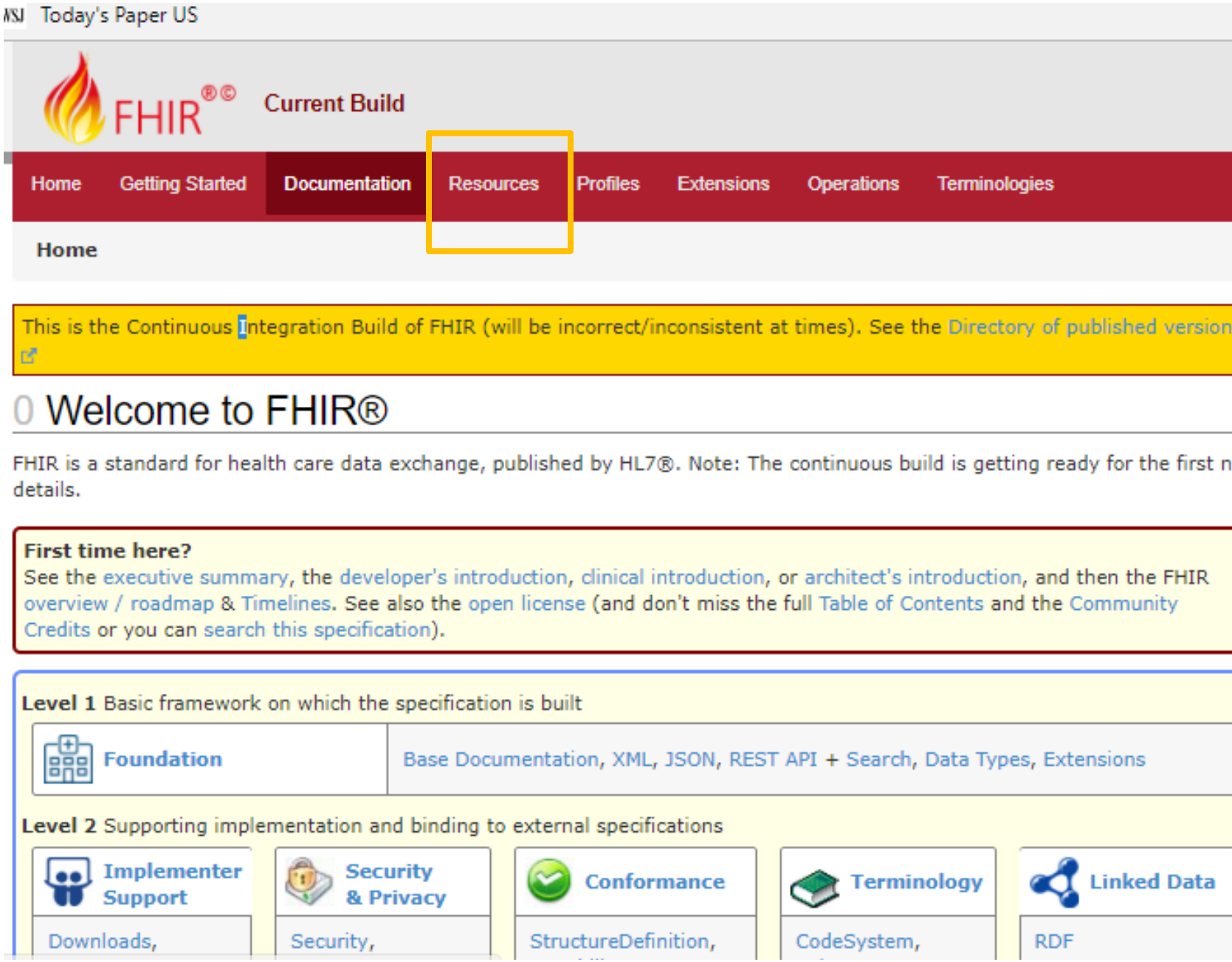

There are more than 100 resources (think of them as tables with special powers) Check out the terminology resources. https://build.fhir.org/resourcelist.html

the digits
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resources
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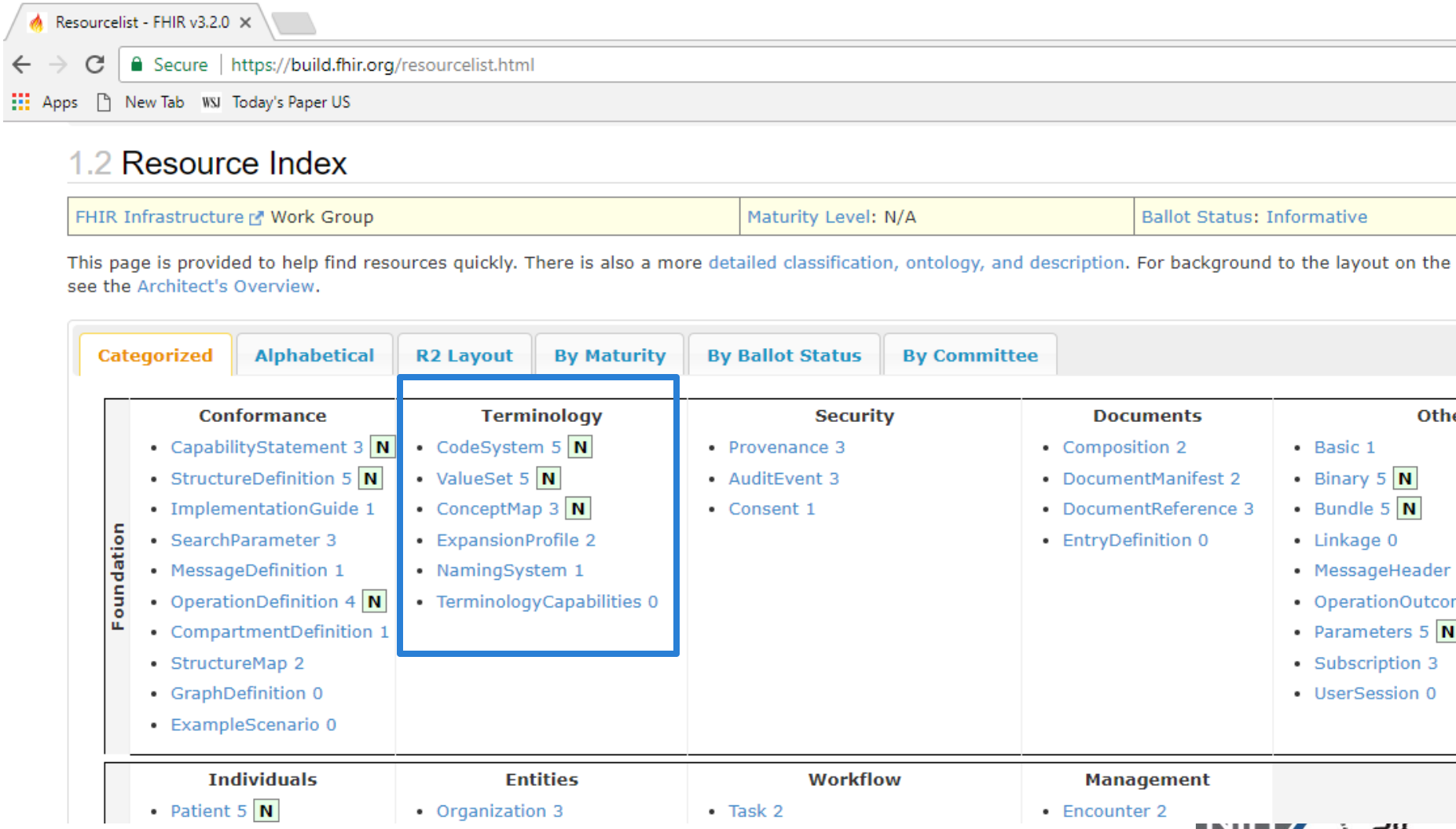


Further down the same page we see other resources – note especially those in the Left most column

Individuals	Entities	Workflow	Management
ient 5 N	• Organization 3	• Task 2	• Encounter 2
ctitioner 3	• OrganizationRole 0	• Appointment 3	• EpisodeOfCare 2
ctitionerRole 2	• HealthcareService 2	• AppointmentResponse 3	• Flag 1
atedPerson 2	• Endpoint 2	• Schedule 3	• List 1
son 2	• Location 3	• Slot 3	• Library 2
up 1	• Substance 2	• ProcessRequest 2	
	• BiologicallyDerivedProduct 0	• ProcessResponse 2	
	• Device 2		
	• DeviceComponent 1		
	• DeviceMetric 1		

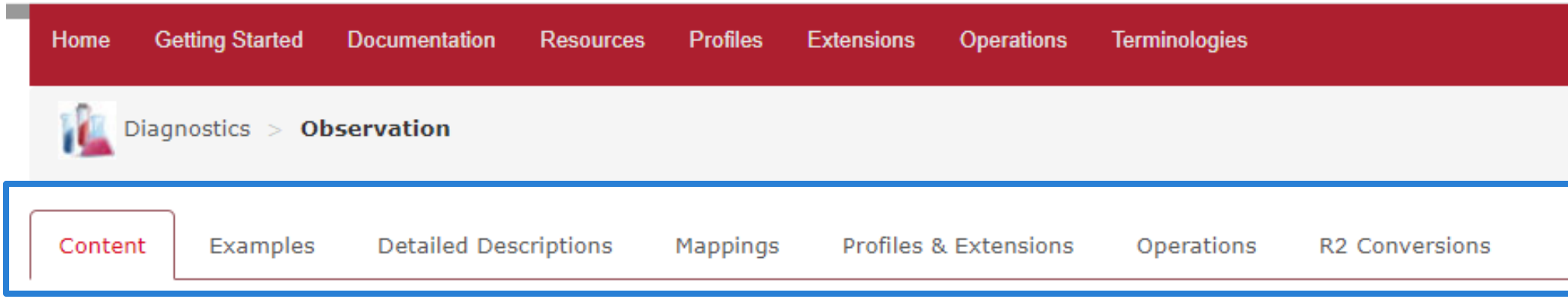
Finally the resources that constitute the guts of the clinical record (I highlighted a few- note that observation is the most mature)

Summary	Diagnostics	Medications	Care Pr
gyIntolerance 3	p Observation 5 N	• MedicationRequest 3	• CarePlan 2
erseEvent 0	• Media 1	• MedicationAdministration 2	• CareTeam
dition (Problem) 3	• DiagnosticReport 3	• MedicationDispense 2	• Goal 2
edure 3	• Specimen 2	• MedicationStatement 3	• ServiceRe
lyMemberHistory 2	• BodyStructure 1	• Medication 3	• NutritionO
calImpression 0	• ImagingStudy 3	• Immunization 3	• VisionPres
upationalData 0	• QuestionnaireResponse 3	• ImmunizationEvaluation 0	• RiskAsses
ctedIssue 1	• Sequence 1	• ImmunizationRecommendation 1	• RequestGr

What you will see in diagnostic report and observations are test and measurements such as the following https://build.fhir.org/resourcelist.html

Concept	Example	Where to find
Clinical Findings		
Laboratory Results	Blood panels such as CBC with Differential, Liver Panel, etc.	DiagnosticReport with Observations
Imaging Study Findings	CT Scans, MRI, Plain Radiographs, Ultrasounds)	DiagnosticReport (some with Observations)
Diagnostic Test Results	EKG, pulmonary function test, EEG	Observations (and maybe a DiagnosticReport)
Vital Signs	Temperature, Blood Pressure, Heart Rate, Respiratory Rate	Observation
Other Physical Exam Findings	Auscultation findings	Observation
Pulmonary Artery Catheter readings	Pulmonary artery pressure	Observation

Click on Observations to learn how to explore any resource. Note the five tabs. (https://build.fhir.org/observation.html)



10.1 Resource Observation - Content

Orders and Observations Work Group	Maturity Level: 5	Normative	Compartments: Device, Encounter, Patient, Pr

Normative Candidate Note: This page is candidate normative content for R4 in the Observation Package. Once normative, it will lose it's I no longer be made.

Measurements and simple assertions made about a patient, device or other subject.

Note to balloters The Orders and Observations work-group wants to draw the attention of reviewers and implementers to the fo resource:

1. The guidance on using code value pairs to represent observations in FHIR

Content tab – a good one

- This one includes lots of narrative descriptions and a structured hierarchy of the fields (attributes) of in the file. Read the text but don't wrestle with the hierarchy on the first pass.
- The example tab shows JASON and XML examples of real observations. Depending on the resource examples and the examples may rich in number and variety or not. Don't start there

Observation-example-f001-glucose

Orders and Observations Work Group	Maturity Level: N/A	Ballot Status: Informative	Compartments: Device, Encounter, Patient, Practitioner, RelatedPerson

This is the narrative for the resource. See also the XML or JSON format. This example conforms to the profile Observation.

Generated Narrative with Details

id: f001

identifier: 6323 (OFFICIAL)

status: final

code: Glucose [Moles/volume] in Blood (Details : {LOINC code '15074-8' = 'Glucose [Moles/volume] in Blood', given as 'Glucose [Moles/volume] in Blood'})

subject: P. van de Heuvel

effective: Apr 2, 2013 9:30:10 AM --> (ongoing)

Resource – Observation
http://hl7.org/fhir/observation.html

esource Observation - Content

Observations Work Group	Maturity Level: 5	Trial Use	Compartments: Device, Encounter, Patient, Practitioner, RelatedPerson

ts and simple assertions made about a patient, device or other subject.

Scope and Usage

e is an *event resource* from a FHIR workflow perspective - see Workflow.

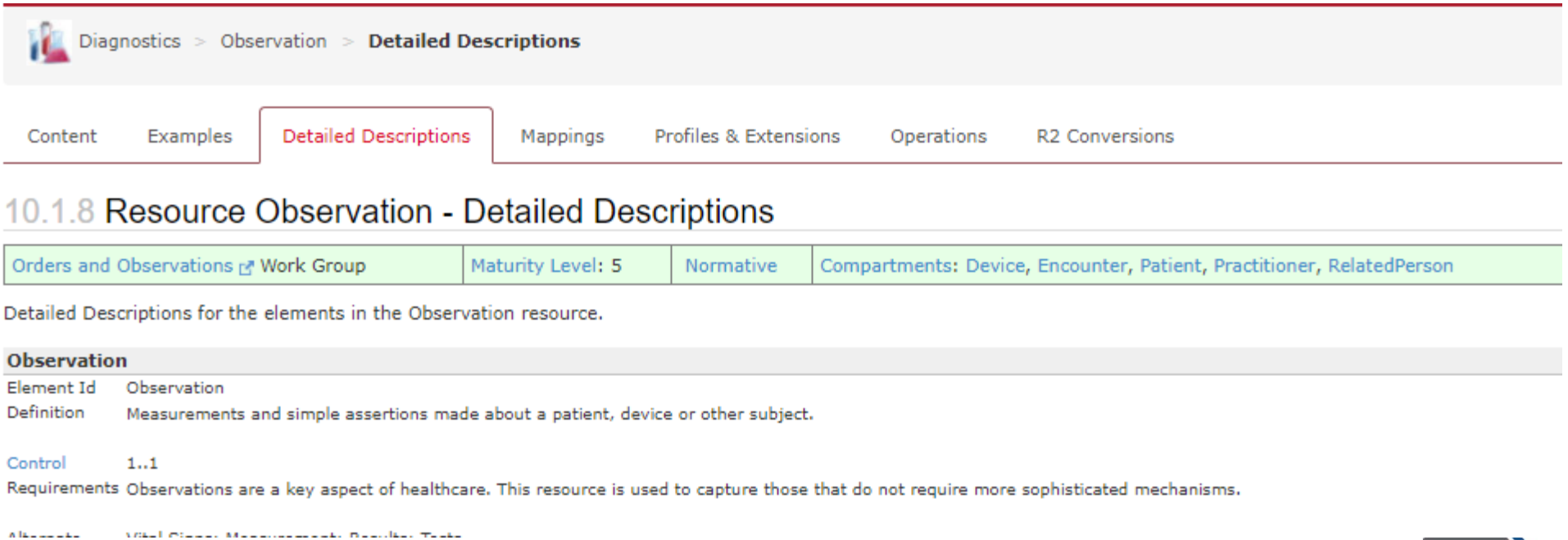
s are a central element in healthcare, used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic chara
ations are simple name/value pair assertions with some metadata, but some observations group other observations together logically, or even are multi-co
. Note that the DiagnosticReport resource provides a clinical or workflow context for a set of observations and the Observation resource is referenced by
eport to represent lab, imaging, and other clinical and diagnostic data to form a complete report.

Observation resource include:

ns such as body weight, blood pressure, and temperature
ory Data like blood glucose, or an estimated GFR
results like bone density or fetal measurements
Measurements such as EKG data or Pulse Oximetry data
assessment tools such as APGAR or a Glasgow Coma Score
characteristics: such as eye-color
story like tobacco use, family support, or cognitive status
aracteristics like pregnancy status, or a death assertion

Detailed descriptions tab (https://build.fhir.org/observation-definitions.html)

- For learning about a given observation, this is the best tab to dwell on
- It lists each field by name, gives its data type and explains what it contains. Once you have negotiated a given resource, the pattern will be the same for all other resources – Nice thing about FHIR



Some observation fields

servation.code

nent Id	Observation.code
nition	Describes what was observed. Sometimes this is called the observation "name".
trol	1..1
ninology ling	LOINC Codes (Example)
e	CodeableConcept
uirements	Knowing what kind of observation is being made is essential to understanding the observation.
rnate nes	Name
mary	true
nments	*All* code-value and, if present, component.code-component.value pairs need to be taken into account to correctly understand the meaning of the observation.

Identifies the observation

servation.subject

nent Id	Observation.subject
nition	The patient, or group of patients, location, or device whose characteristics (direct or indirect) are described by the observation and into whose record the observation is placed. Comments: Indirect characteristics may be those of a specimen, fetus, donor, other observer (for example a relative or EMT), or any observation made about the subject.
trol	0..1
e	Reference(Patient | Group | Device | Location)
uirements	Observations have no value if you don't know who or what they're about.
mary	true
nments	One would expect this element to be a cardinality of 1..1. The only circumstance in which the subject can be missing is when the observation is made by a device that does not know the patient. In this case, the observation SHALL be matched to a patient through some context/channel matching technique, and at this point, the observation should be updated If theactual focus of the observation is different than the subject, the `focus` element may be used. However, the distinction between the patient's own value for an observation versus that of the fetus, or the donor or blood product unit, etc., are often specified in the observation code.

Subject usually the patient

servation.focus

ndards us	This element has a standards status of "Trial Use" which is different to the status of the whole resource

rue

value[x]

bservation.value[x]

he information determined as a result of making the observation, if the information has a simple value.

..1

uantity|CodeableConcept|string|boolean|integer|Range|Ratio|SampledData|time|dateTime|Period

ee Choice of Data Types for further information about how to use [x]

n observation exists to have a value, though it might not if it is in error, or if it represents a group of observations.

rue

n observation may have; 1) a single value here, 2) both a value and a set of related or component values, or 3) only a set of related or component valu
atatype for this element should be determined by Observation.code. A CodeableConcept with just a text would be used instead of a string if the field wa
ype associated with the Observation.code defines a coded value. For additional guidance, see the Notes section below.

ffect this element

bs-7: If Observation.code is the same as a Observation.component.code then the value element associated with the code SHALL NOT be present (expr
omponent.code.where((coding.code = %resource.code.coding.code) and (coding.system = %resource.code.coding.system)).empty(), xpath: not(f:*[s
value')] and (for $coding in f:code/f:coding return f:component/f:code/f:coding[f:code/@value=$coding/f:code/@value] [f:system/@value=$coding/f:s

dataAbsentReason

bservation.dataAbsentReason

rovides a reason why the expected value in the element Observation.value[x] is missing.

..1

ataAbsentReason (Extensible)

odeableConcept

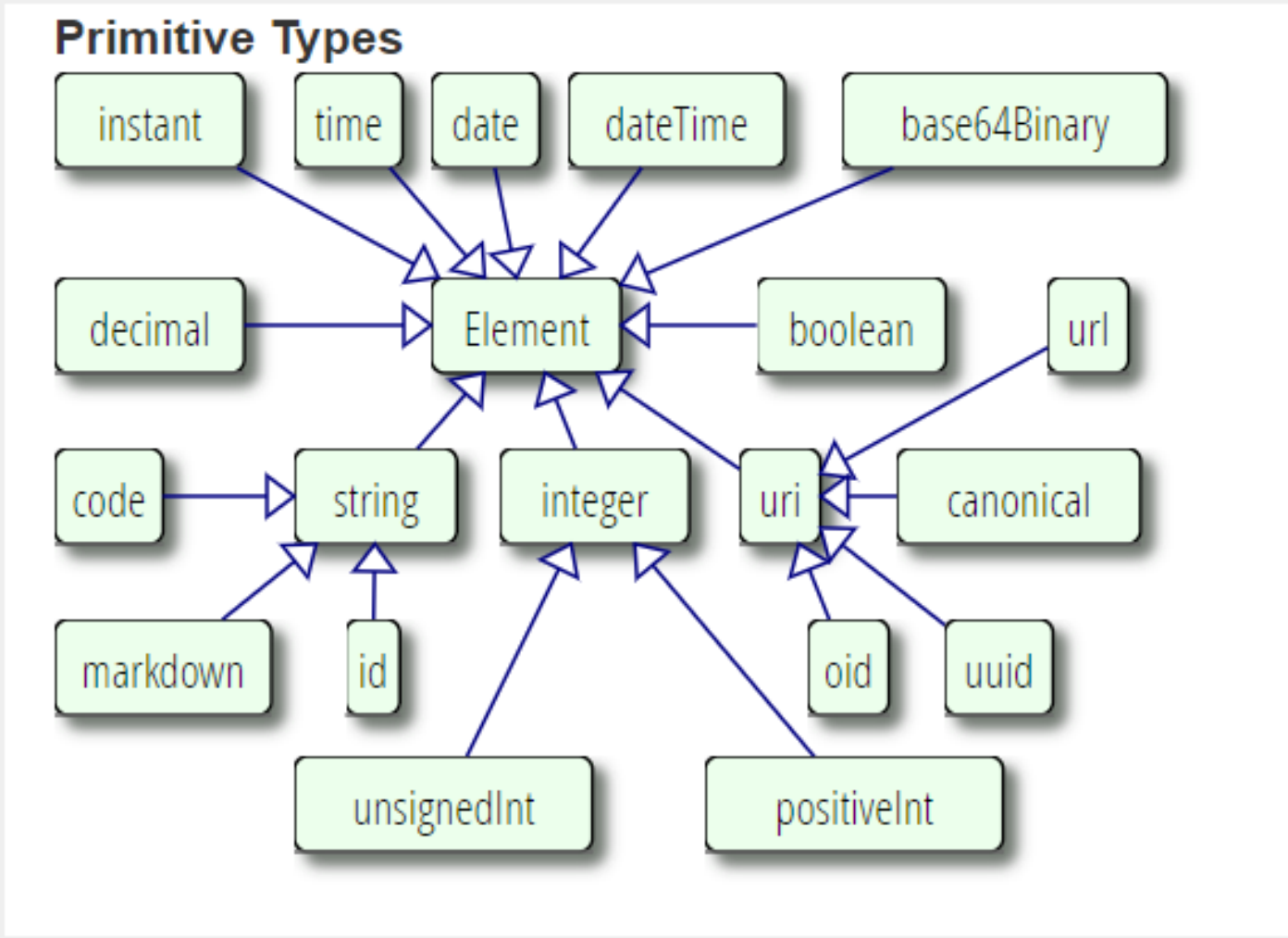
or many results it is necessary to handle exceptional values in measurements.

The value of the observation – the data of the observation. Se possibilities in list.

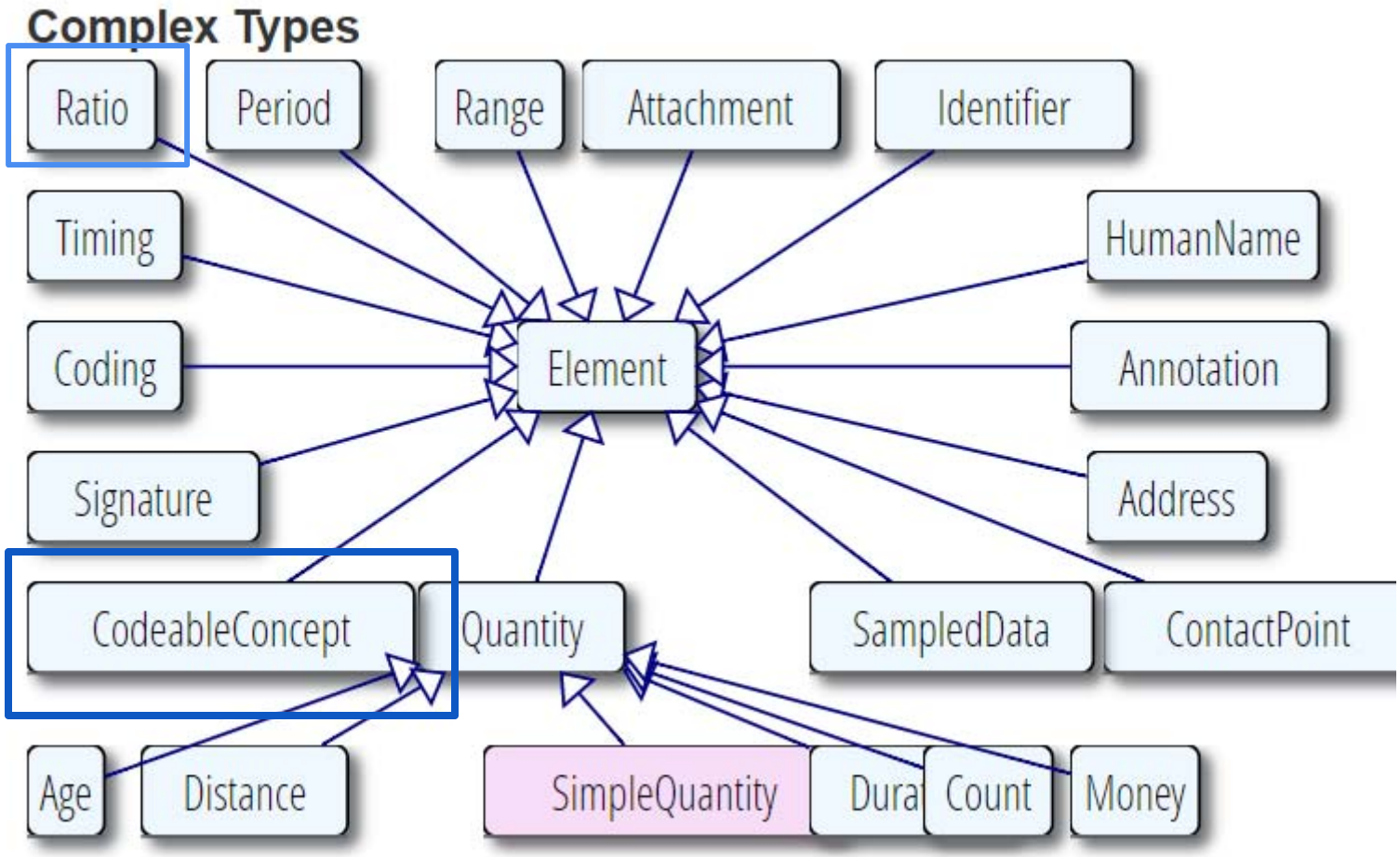
Reason why a value might be missing

FHIR Data types (https://build.fhir.org/datatypes.html)

- Primitive data types

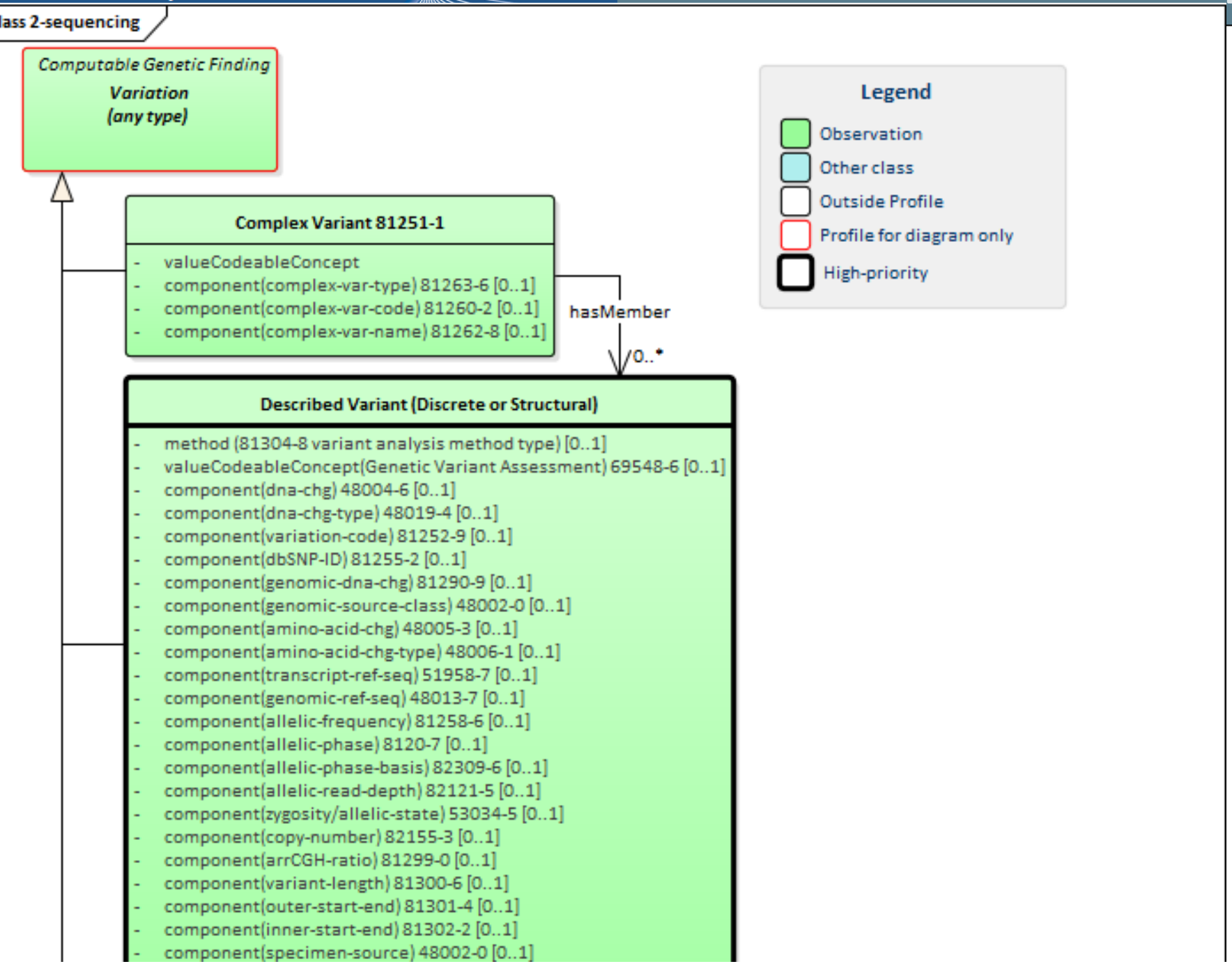


Complex FHIR data types



Specialized connected sets of observations

- We (LHNCBC) have been developing specifications for reporting genetic test results in a structured fashion. The first was for V2 and approved by ballot late 2017 as part of the general Laboratory Result Interface – along with Newborn screening, also born in LHNCBC
- Now we are working in the FHIR workgroup to create a parallel specification in FHIR.
- Lloyd, who is the lead on this project, has created UML diagrams to show the relationships between specific observations needed to support FHIR reporting of structured genetic reports. These distinct observations are all defined by LOINC terms. This UML diagram is a nice way to see the relationships, and you may see them associated with other resources. Will show just one of the pages of the UML diagram (https://docs.google.com/document/d/1juWEnjyXV34yYmPq3FDpLAiJlM0Hiv0FyNBfvPD6enM/edit#heading=h.fk5kmv4ghxne)


lass 2-sequencing
Computable Genetic Finding
Variation
(any type)
Legend
Observation
Other class
Outside Profile
Profile for diagram only
High-priority
Complex Variant 81251-1
- valueCodeableConcept
- component(complex-var-type) 81263-6 [0..1]
- component(complex-var-code) 81260-2 [0..1]
- component(complex-var-name) 81262-8 [0..1]
hasMember
0..*
Described Variant (Discrete or Structural)
- method (81304-8 variant analysis method type) [0..1]
- valueCodeableConcept(Genetic Variant Assessment) 69548-6 [0..1]
- component(dna-chg) 48004-6 [0..1]
- component(dna-chg-type) 48019-4 [0..1]
- component(variation-code) 81252-9 [0..1]
- component(dbSNP-ID) 81255-2 [0..1]
- component(genomic-dna-chg) 81290-9 [0..1]
- component(genomic-source-class) 48002-0 [0..1]
- component(amino-acid-chg) 48005-3 [0..1]
- component(amino-acid-chg-type) 48006-1 [0..1]
- component(transcript-ref-seq) 51958-7 [0..1]
- component(genomic-ref-seq) 48013-7 [0..1]
- component(allelic-frequency) 81258-6 [0..1]
- component(allelic-phase) 8120-7 [0..1]
- component(allelic-phase-basis) 82309-6 [0..1]
- component(allelic-read-depth) 82121-5 [0..1]
- component(zygosity/allelic-state) 53034-5 [0..1]
- component(copy-number) 82155-3 [0..1]
- component(arrCGH-ratio) 81299-0 [0..1]
- component(variant-length) 81300-6 [0..1]
- component(outer-start-end) 81301-4 [0..1]
- component(inner-start-end) 81302-2 [0..1]
- component(specimen-source) 48002-0 [0..1]

Why I like FHIR – a Contrast

cda Obligation Policy Security Observation

[Observation: templateId 2.16.840.1.113883.3.445.14]

This template is constrains the Security Observation to specify a "obligation policy code". This template reuses the SecurityObservation implementing the HL7 Healthcare Security Classification (HCS) standard.

1. **SHALL** contain exactly one [1..1] templateId (CONF-CD-14) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.445.14"
2. **SHALL** conform to *cda Security Observation* template (templateId: 2.16.840.1.113883.3.445.21) (CONF:16828)
3. **SHALL** contain exactly one [1..1] **code** (CONF:14841)**/@code**="SECCONOBS" *Security Control* (CodeSystem: 2.16.840.1.113883.1.11.20457 SecurityObservationTypeCodeSystem) (CONF:14886)
4. **SHALL** contain exactly one [1..1] **value** (CONF:9136), where the @code **SHOULD** be selected from ValueSet HL7 ObligationPolicyCode 2.16.840.1.113883.1.11.20445 **STATIC** (CONF:9137)
   - *This attribute specifies a type of obligation policy, specifically.*

cda Obligation Policy Security Observation example

```
<observation classCode="OBS" moodCode="EVN">
                <!-- Security Observation -->
                <templateId root="2.16.840.1.113883.3.445.21"
                    assigningAuthorityName="HL7 CBCC"/>
                <!--  Obligation Policy Code template -->
                <templateId root="2.16.840.1.113883.3.445.14"
                    assigningAuthorityName="HL7 CBCC"/>
                <code code="SECCONOBS"
 codeSystem="2.16.840.1.113883.1.11.20457"
                    displayName="Security Classification"
                    codeSystemName="HL7 SecurityObservationTypeCodeSystem"/>
                <!-- Value set constraint "2.16.840.1.113883.1.11.20445" -->
                <value xsi:type="CE" code="ENCRYPT"
                    codeSystem="2.16.840.1.113883.5.1063"
                    codeSystemName="SecurityObservationValueCodeSystem"
                    displayName="Encrypt information">
                    <originalText>Information must be encrypted</
originalText>
                </value>
            </observation>
```

Summary

- In theory, FHIR could be used for any application, but it is tuned for healthcare and research applications. And there are miles to go to finish the healthcare side before the FHIR leaders sleep.
- I have emphasized a relatively static data storage and retrieval but FHIR extends to many dynamic features from real time data collection to Structured Data Capture (SDC). (Another area where LHNCBC scientists are active in the development of the SDC specification and a variety of tools for providing support for data capture, including the generation of live SDC forms from the form definition, and autocomplete entry of data from external coding systems). (https://lhc-forms.lhc.nlm.nih.gov)

LHC-Forms Example