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Meeting Info

Meeting Location

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<thead>
<tr>
<th>US Eastern</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
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<tbody>
<tr>
<td>Q1</td>
<td>9:00 am</td>
<td>Plenary</td>
<td>Parlor 9029</td>
<td>Watertable A</td>
<td>Pride of Baltimore</td>
</tr>
<tr>
<td>Q2</td>
<td>11:00 am</td>
<td>Plenary</td>
<td>Parlor 9029</td>
<td>Watertable A</td>
<td>Pride of Baltimore</td>
</tr>
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<td>Q3</td>
<td>1:30 pm</td>
<td>Parlor 10029</td>
<td>Parlor 9029</td>
<td>Baltimore Ballroom B</td>
<td>Pride of Baltimore</td>
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<tr>
<td>Q4</td>
<td>3:30 pm</td>
<td>Maryland Ballroom A</td>
<td>Parlor 9029</td>
<td>Homeland</td>
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Reference Links

- Meeting Agenda
- Meeting Attendance

Monday, September 19, 2022

Q3

Chair: Hans Buitendijk
Scribe: Riki Merrick

Agenda Topics:
- Administrivia
- Mission Charter Review
- Decision Making Process (any exceptions needed)

Monday-Q3: Meeting Notes

- Introductions
- Agenda review
- Administrivia:
  - Project insight:
    - 1095 – LRI Functional Model
      - STU extension (need to check that went through) and then adjust based on LRI publishing
      - Plan for an informative ballot?
      - Set milestone to May 2023
    - 1700 – IHE SDC
      - in ballot reconciliation
      - next milestone Jan 2023
    - 1742 – At Home
      - in ballot reconciliation
      - next milestone Jan 2023
      - remove the ‘??’ in the beginning of the description;
      - PSS-1892 has none, but the description is different
      - Can’t seem to find the project insight access to this – Hans Buitendijk to ask Dave Hamill
    - 1068 -
      - no change
    - 1115 -
      - no change
    - 1756 – RBC Phenotype
      - John Spinosa PSS-1942
      - Motion to put this on hold due to lack of resources: Lorraine, Patrick, no further discussion, against: 0, abstain: 0, in favor: 8
      - Question to Dave: how does a project placed on hold show up in the jira approval process
    - 972 – LOI
      - Publication Request is on TSC desk
      - Milestone date Jan 2023
      - Project end: May 2025
      - Then we need to deal with Gender Harmony
      - Discussion around gender harmony data via lab flows (what if the patient walks in there)
    - 973 – eDOS
      - Requirements form this went into FHIR catalog
      - In the near future we should withdraw this
      - This STU expires in Oct 2022 - so we need to submit an extension request
    - 1010 – Catalog
      - Waiting for R5 to publish so it can be published
      - Milestone date May 2023
    - 1067 – laborder Conceptual Model
In ballot reconciliation
Next milestone: Jan 2023

1292 – SpecimenDAM
Next milestone: May 2023
Want to keep it open till we have FHIR resources

1294 – LRI
Publication Request is on TSC desk
Milestone date Jan 2023
Project end: May 2025
Then we need to deal with Gender Harmony
Discussion around gender harmony data via lab flows (what if the patient walks in there)

1335 – LIVD
Milestone date Jan 2023
Working on getting this published
Project end: May 2025

1370 – Transfusion
No answer from Bob Milius
Motion to put this on hold due to lack of resources: JD, Patrick, no further discussion, against: 0, abstain: 0, in favor: 8

1481 – V2-FHIR
Making slow progress
This is getting use, since we are getting questions?
Still a red PBS metric, but nothing much we can do about it
Milestone date Jan 2023
Using the latest version of FHIR
Project end: May 2025

1496 – DME
Still in ballot reconciliation
Milestone date Jan 2023

1539 – Lab Model
Milestone date Jan 2023
Put this on Thursday Q4

1614 – nutrition DAM and FHIR
Milestone date May 2023
Resource updates are in R5
Completing the DAM reconciliation comments

1634 – AOE Crossparadigm
Preparing for ballot
Milestone date May 2023
Add to Friday lab call topics
End date Sept 2024

1686 – Cancer Pathology
In publication request
Milestone date May 2023
End date Sep 2025

1541 – Vital Signs
Need to check if the must support changes were done in R5
Approved for publication
Check with CIMI

Q4
Chair: Hans Buitendijk
Scribe: Riki Merrick

Agenda Topics:

**OO + CDS + CIMI / CQI**
- ADI-on-FHIR Report Out
- Project 1359 Status
- Project 1541
- ISA Suggestions (time permitting)
- USCDI v4 Proposals (time permitting)
- JIRAs
  - **OO Dashboard**

**Note:** Reps to Patient Empowerment

**Monday-Q4: Meeting Notes**

With CQI (not present), CIMI, CDS (not present)

- Agenda review
- ADI on FHIR report out – not discussed
- CIMI project 1359 and 1541 updates
  - 1359 Lab Model Profiles
    - Work delayed, but still interested
    - Working on high level patterns (titer / coded / ) – worked with Graham on a library to create the subtypes for more specific LOINCs
  - Next Milestone date: Jan 2023 – to be updated Ulrike Merrick
- 1541 Vital Signs
  - Next published as STU1 for US
  - Now working on the universal realm with goal of ballot in Sep 2023
  - Next milestone Sep 2023 – to be updated Ulrike Merrick
  - No topics for Thu Q4 – so update agenda to jira review
- ISA review
  - Review for OO content to comment on:
- TERMINOLOGY SECTION:
  - Biologics = Biological Derived Product
    - Is there any other vocabulary we should propose?
    - Looking at the FHIR resource the product codes look like these are HL7 curated, but this needs to get updated to indicate that this is ICCBBA
    - Make a ballot comment in R5 to get this fixed
• No comment to make

• Clinical Tests (non-images / non-lab)
  • LOINC sounds good for the test identification
  • MAKE THIS COMMENT: For the values they should create a separate descriptions similar as they have done for “Performed test” -- for coded results could propose use of SNOMED CT
  • Review again after we discuss use of CPT4 for lab as indicated by AMA

• COVID-19
  • Why is SANER listed – check with Keith and Bryn @Riki
    • This IG does define a few code system (ADD LINK to supporting vocabulary code system)
      • Measure group system
      • Situational Awareness Measure population
      • Measured values system (CHECK ON THE NAME!!!)
    • Logica COVID-19 IG also defines one code system
    • COMMENT: ISA should update to link to the vocabulary in this space rather than just the full IG – same applies to the Immunization IG
    • Give the PH WG a heads up to look at this @Riki

• Dietary + Nutritional Needs
  • COMMENT: ISA should update to link to the vocabulary in this space rather than just the full IG; the full IG should be listed under content/structure

• Laboratory
  • Ordered test
    • CPT has been added at request of AMA
      • In 2021 request to include CPT
        • in LOI under ORC-16 – trying to catch up with Nancy Specter to find out what is meant there
        • why is this included here, since it is used for billing and not for ordering
    • Performed Test
      • No comment
    • COMMENT: ADD as separate category specimen and point to SNOMED CT

• Vital Signs
  • Listing IEEE11073 under vocabulary
    • COMMENT: ISA should update to link to the vocabulary in this space rather than just the full IG; the full IG should be listed under content/structure or Services/Exchange – make this a general comment and use these as examples

• CONTENT AND STRUCTURE
  • Diet and Nutrition
    • No comment needed
  • Lab
    • IVD data exchange
      • LIVD IICC – is there a cost? @Riki to check with Serge
    • Ordering
      • COMMENT: To update to the latest version of LOI
      • COMMENT: Add the AOE document here
    • Resulting
      • COMMENT: To update to the latest version of LRI
    • Catalog
      • COMMENT: Double-check which one was put into production and then suggest to drop the ones that are not
      • COMMENT: Second one is not really in production
  • Unique Device Identification
    • COMMENT – applicable to ALL sub points: Update UDI Pattern to list release 2 and probably update the production level, since this is being used as building blocks for implementation of other IGs in certified systems that refer to Service/Exchange
    • Both Unsolicited push
      • COMMENT: add V2 as the base standard – no specific version or IG

• USCDI V4:
  • USCDI V1 and V2 published and enabled in CCD and FHIR USCore
  • USCDI V3 – published; will be enabled early 2023
  • Reviewing attributes if they have value and enough implementation that it should be added into V4
    • Level 2:
      • Biological Derived Product
      • Product Code
      • Have specification
Unique Identifier
- Have specification
Source Identifier
- Maybe this is the same as biologicalSourceEvent? – need to double-check – David Barlin – @Marti??
Division
- Have specification
Processing Facility
- Have specification
- Not every HIT system has interest in this, so may not be applicable to many
Laboratory
- Dates
- This needs to be more specific
  - For sure would need the
  - COMMENT: put in ALL the attributes that are included in the LRI – OR AT MINIMUM ALL the CLIA elements
Specimen
  - COMMENT: at minimum need type and collection date/time; CLIA says also source site, when appropriate
Nutrition
- Check with Becky
Observation
- How does this relate to lab and clinical tests and vital signs?
- Comments on V3 – see if there are any errors – Riki to review, think there may be something

FHIR-38635 – DocRef operation into base spec
- Who owns this?
  - OO owns docRef, but who defines the operations
- Looking at USCore Fetch Document Reference (ADD LINK)
- For the Operation$ - on the patient ID that would return every resource available for a specific patient – that text is written on the patient resource page – need to talk with PA about that

Tuesday, September 20, 2022

Q1
Chair: Hans Buitendijk
Scribe: Lorraine Constable
Agenda Topics:

- Lab Conceptual Model Reconciliation
- State Definitions 20220920.docx
- Continued review of affirmative comments HL7_DAM_LABORD_R2_I1_2020FEB_consolidated 20220920.xls

Tuesday-Q1: Meeting Notes

- Introductions
- Lab Conceptual Model Reconciliation
- Reviewed proposed State definitions State Definitions 20220920.docx
- Continued review of affirmative comments HL7_DAM_LABORD_R2_I1_2020FEB_consolidated 20220920.xls

Q2
Chair: Lorraine Constable
Scribe: Riki Merrick
Agenda Topics:

- Order Logical Model in FHIR
- Table 0301 – Universal Identifier Type - similar to HL70203 (both owned by InM)
- We do not have GTIN, GS1 in either of these tables
- We need to make sure we align with FHIR handling of identifiers https://hl7.org/fhir/datatypes.html#Identifier
  - identifier.type uses the identifiertype code system (owned by Vocab) = https://hl7.org/fhir/valueset-identifier-type.html
  - this is also referencing identifier registry = https://hl7.org/fhir/identifier-registry.html
  - Ralf Herzog will make a change request against V2
  - This is really one of the tables used across all product families, so maybe we can work on that with QDA
  - Could we get this cleaned up as a R5 ballot comment - Ulrike Merrick to submit
- X-eHealth IG on Lab Reporting (Rob)
  - https://build.fhir.org/ig/hl7-eu/x-ehealth/StructureDefinition-Bundle-lab-xeh.html
  - In Europe many countries are using CDA (IHE XD-Lab) for result reporting, but many governments wanted to migrate to FHIR
    - In EU they are working on exchanging lab results between countries
    - They are making updates to the XD-Lab specification as part of this project
Migration to FHIR – open question

- Specification – FHIR Profiles
- Bundle Laboratory Report (snapshot view)

- They want to use the composition for this as the main entry, while OO previously has proposed to use composition only when structuring is needed inside the diagnosticReport
- DiagnosticReport with cardinality 1..*  
- The bundle then also includes all the referenced resources separately (or discuss if we want these as contained resources, so that the diagnosticReport can be signed off – this is how Labcorp does this
- Report as a whole needs to be signed, which is why this group decided to use composition, as that handles the signature
- One option was discussed a while ago to create diagnosticReport as a profile on composition
- In V2 we have the group of OBX segments – these don’t have to be used in order, but most often is – but we should not perpetuate

- imagingStudy (covers DICOM metadata) and genomicsStudy (covers the pipeline info) but that does not cover the results
- Use composition for structuring
- Proposal: remove reference to observation in DiagnosticReport.result and allow only reference to composition

- This is a breaking change, but we have not that many implemented AND all would benefit the approach
- This needs more discussion with FHIR-I (and maybe Structured Doc)
- Or do we just create a NEW resource or a profile on the resource
- Option would be to make DiagnosticReport.result and backbone element (Dan + Rob H to write this up (maybe draft in CU build for discussion in FHIR-I for Thu Q2)

- To add name (to allow giving it a section name) AND result.sequence (for grouping) which both are optional
- Signature for the DiagnosticReport is needed (the report is the one that is being signed)
- Suggestion was around using provenance in addition the DiagnosticReport
- Composition has authenticator
- Move this to FHIR-I discussion on Thu Q2
- An IG can limit the performer to the releasing person (legal requirement to track back the)

- Rob need to have some idea where we need to go ASAP, so we may need the long-term approach, but may also identify a short-term solution

- Xehealth does not want to break the Belgium implementation: http://build.fhir.org/ig/hl7-be/lab/StructureDefinition-be-laboratory-report-composition.html
  Bundle contains section as 1..1 which an entry 1..1 reference to the laboratory report profile
  A section can have another section 0..*

- Create a list of the functional requirements:
  - Sequencing the observations in a diagnostic report is important
  - Signing of a diagnostic report (what is the reason for this signature – is this a legal construct
  - Break as few of the in-process or existing implementations if possible
  - If we break a solution we need to identify what the rationale is for that
  - The X-ehealth is an implementation on top of national profiles

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**Q3**

Chair: Ralf  
Scribe: Marti

**Tuesday-Q3: Meeting Notes**

Discussed Lab Workflow

Reference Links to content reviewed:

- [https://build.fhir.org/workflow-management.html](https://build.fhir.org/workflow-management.html)
- [https://build.fhir.org/examplescenario-example-laborder.html](https://build.fhir.org/examplescenario-example-laborder.html)
• Create Order Sequence Diagram – provide the options in the Implementation Guide and the conditions for the scenarios/use cases
• Accept Order
  • Need order acknowledgement (similar to v2)
  • Initiate procedure (discussed as out of scope of the lab workflow)

Reviewing other Implementation Guides to assess how the lab workflow information is being done currently:

• E.g., DME IG

Need to handle “How to issue someone else a "Task" should be in a separate IG

Discussed that there are many variations to the order workflow across jurisdictions and the general flow should be described. The Implementation Guides can give additional options/details for the variations as necessary.

Additional Use Cases/Examples (Add Jose’s List - below in general capture)

• Order to a Specific lab, but change by patient
• Change to the Order Requested
• Tasks across Order
• Billing Tasks - sub-workflow

Will discuss high-level with II – Q2 Thursday-- the general approach for workflow; would like the examples of core to be generated from IG publisher.

Tuesday-Q4: Meeting Notes

Mission / Charter Review

Draft:

Mission - No change

The mission of the Orders and Observation work group is to define information exchange capabilities to support the order/scheduling and clinical event management/reporting requirements between the stakeholders in the healthcare organization regarding patients, non-patients, people, other species, or inanimate objects. These information exchanges are not limited to intra-organizational transactions, but may cross organizational boundaries. These information exchanges may involve messages, documents, services, and other HL7 constructs.

Charter - Updated

The basic charter of the Orders and Observation work group is to continue to support the ongoing development of Version 2.x supporting critical regulatory and implementer requirements, support V3 artifacts owned by OO, and expanding the capabilities of FHIR, including current capabilities in v2.

Formal Relationships With Other HL7 Groups - Updated

The Orders and Observations work group has formal relationships with the following HL7 groups, in many cases as a result of V2.x and V3 content overlaps.

• Clinical Genomics
• Devices
• Imaging Integration
• Patient Administration
• Patient Care
• Patient Safety
• Pharmacy
• Public Health
• BR&R
• Structured Documents
• Management Groups

Wednesday-Q1: Meeting Notes

Chair: Patient Care
Scribe:

Agenda Topics:

**FHIR-33394**, which deals with Specimen* and Procedure resources (*note JIRA does not show up in OO Specimen dashboard*).

Specimen Dashboard

BPM+Health

- Meeting is happening in parallel - 21st to 23
- Initial information orientation - may want to see where this might overlap with our workflow

Q2 - Joint: **OO / II**

Chair:

Scribe:

Agenda Topics:

- Specimen stuff
  - TerminologyCapabilities resource proposal
  - eCC on FHIR update - how to handle specimens (children), SNOMED pre-coordination ask Alex G for his schedule
  - Example Specimens
    - How to handle Grouping Specimens Parent-Child Relations
- Specimen JIRA
- Specimen Dashboard
- JIRA Tickets - with II
  - FHIR-38673

Wednesday-Q2: Meeting Notes

- **FHIR-33394** - Need to get with Ricardo in Specimen
- **FHIR-13047** - Need a call with Ricardo, John Hatem, Michelle/PC, (Paul Ashford), David Barwin, Karen Moniz. HCP call.
  - General pattern for product ordering, "administering" for BCP and other non-medication use cases.
  - Consider dosage instructions on ServiceRequest further.
  - Included NutritionIntake, MedicationAdministration, "BDP Procedure", etc.
- **FHIR-33326** - Suggest to use Device for the use case at hand, with limited/no identifying information. Also, add an example in Device to indicate why you would one or more Device instances even though you only know "type" information.
- **FHIR-37975** - Hard to pre-adopt R5 resource as that is not permitted, but could build one on Basic that looks alike.
- **FHIR-33389** - Seems to need to be on Procedure more so than Device, definitely not DeviceDefinition as it is about data in context of the procedure being performed. Specimen
- **FHIR-38161**
- **FHIR-38657**
- **FHIR-32889**
- **FHIR-29793** - Needs follow-up

Q3 - Joint: **OO / CG**

Chair:

Scribe:

Agenda Topics:

- Glance at ImagingSelection resource ([https://build.fhir.org/imagingselection.html](https://build.fhir.org/imagingselection.html))
- Review where we landed with GenomicStudy (and Molseq).
  1. Review pattern for reference options for "subject" in both R5

Wednesday-Q3: Meeting Notes

- ImagingSelection
  - Check how to approach genomic selection and possibly combine into one resource
- MolecularSequence
  - Check out subject - may need to be elsewhere
  - Check out device
- GenomicStudy
  - Check out subject (similar to MolecularSequence)
  - Output is used to then perform analysis that yield DiagnosticReport | Observation
  - Do we need to model Observation.method and DiagnosticReport.study and DiagnosticStudy.SupportingInfo(Procedure) the same to reference the study/procedure that yielded the observation, diagnostic report. Start in OO Main. Invite CG and II.
  - Consider changing .analysis.subject 0..1 to .analysis.focus 0..* and adjust choices and include RelatedPerson
1. Multiple subject studies - Group / RelatedPerson instead of Patient for certain use cases - confirm usage is consistent. Bring examples and questions/suggested guidance
   a. https://build.fhir.org/genomicstudy.html#10.4.4.1

• DiagnosticReport update
  1. supportingInfo
  2. Revisit DiagnosticReport + Composition guidance
  3. Do we need an IG?
• Perhaps add 'valueCodeableReference()' to Obs.value and Obs. component.value
• New release of LRI? We have some questions about codes (allelic phase / sequence phase relationship)
• TumorMarkers: https://jira.hl7.org/browse/FHIR-28943

Q4 - Joint:

Chair:
Scribe:
Agenda Topics:

• JIRAs with whomever is available

Note: Gender Harmony IG - Send Reps!

Wednesday-Q4: Meeting Notes

Thursday, September 22, 2022

Q1 - Joint: OO / BR&R / DEV

Chair:
Scribe:
Agenda Topics:

• Device Scope Whitepaper
• Gemini Safe, Effective & Secure Medical Device Interoperability (SES+MDI)
• Resource topics:
  • Device
    • specialization
      • systemType and specialization.category
    • Mappings - PHD, PoCD
    • Identify stable

• Is a study a kind of procedure? Is a study the more analytical/intellectual analysis vs. procedure interventional/invasive (surgery, therapy)? But what about an interventional study where one must have a cath lab procedure or study? Need a boundary discussion between CG, Pt Care, and OO so it is clearer when to use when another. Also note that certain procedures are very granular (e.g., robotic surgeries) or more general.
• There is discussion to consider analysis to become a separate resource. Compare analysis with procedure and observation to help inform whether to keep it, create a new resource, or use either procedure or observation.
• DiagnosticReport
  • SupportingInfo as added. Need to consider GenomicStudy. It also has typing available.
  • Some concerns with naming of supporting information, but no clear suggestion
  • Revisiting whether to reference Composition, or whether the direction needs to be reversed.
  • OO will be working on implementation guidance to ensure structures are used as intended.
• Observation
  • Perhaps add valueReference, but concerned with which resources to include as a choice.

Thursday-Q1: Meeting Notes

• Device Scope
• Gemini
  • Link to Confluence: Project Gemini
  • Plug-and-Trust
• Device
elements, those that have changed and need further testing
- Examples (review /clean-up based on R5)
- FMM 3 or 4?
- Device Definition
- Scope /Boundary
- Mappings to EUDAMED, GUDID (Catalog)

Q2 - Joint: **OO + FHIR-I**

Chair: Hans
Scribe: Marti

Agenda Topics:

- Planning
- DocumentReference Operation Ownership
  - FHIR-38635
- Workflow update
  - Task FMM 3 or 4?
- FHIR-33389 Device Used Parameters
- DiagnosticReport/Composition
- Catalog
- FHIR-37966 - Clarifying groupIdentifier (RE: CommunicationRequest, DeviceRequest (was DeviceUseRequest), MedicationRequest, RequestGroup)

Thursday-Q2: Meeting Notes

- Planning
- FHIR-38635 - See vote and approval.
- Workflow Update
  - Guidance document (not IG) on how to use ServiceRequest and Task more consistently as currently there is variations in how different IGs are approaching this.
  - II is working on an IG on how FHIR workflow approach impacts DICOM. Should be added to the list.
  - Also need to look at service model.
  - Need to resolve how to publish this guidance. Special page? Project Team to review with Publishing, FHIR-I and OO.
- Task - Aim for FMM3 as 4 seems a stretch.
- Device Used Parameters
- DiagnosticReport/Composition

Q3 - Joint: **OO + PA**

Chair:
Scribe:

Agenda Topics:

- Transport resource
- various R5 PA updates
- v2-FHIR Extensions
  - 36650
  - 32997
- Updating bodySite element to use BodyStructure resource along with updated codes for BodyStructure
- Specimen JIRA

Thursday-Q3: Meeting Notes

32997 to be reviewed by v2-FHIR

Q4 - Joint: **OO + CIMI**

- No CIMI Topics
- DMP Review
- JIRA Progress

Thursday-Q4: Meeting Notes

- DMP Review
  - We have updated in Jan18, 2022, so not sure this needs to be done again already
  - We kept the track changes since we made some changes outside the colored highlights
- Jira review
V2-25376

- For V2:
  - How would you handle the added interpretation in OBR when there are OBX(es) with interpretations available - is it a summary or only used, if no OBX?
    - probably would role up - if any of the interpretations is abnormal of some form, then the code rolls up = would need to provide rules on how to map from the OBX-8 or is this more of a flag for physician review?
    - Epic has concept of "unsuccessful event" - exam was performed, but it did not be satisfactory for the requirement - example here is a colonoscopy that was done, but cannot be counted against the preventative screening requirement for example - so maybe we need a clinical assertion flag - maybe that could be combined into this new field? if we do that could we also use that in FHIR - Daniel Rutz to create a new Jira and link to this one, so that we can discuss together
  - you have a result, even though if it just a paper or scan of a paper - would create an OBX with datatype either ED or
  - For FHIR:
    - Create a ServiceRequest and a DiagnosticReport with a pointer to the image of the paper scan in .presentedForm, so there is no creation of an observation for this report

- Update on the DiagnosticReport changes around result
  - what do we really need: hard requirements what is permissible / not permissible for CLIA requirement acceptance from Freida Hall and Kathy Walsh (with some good examples from the different domains in the lab) - so that the presentation in the EMR is matching what is in the report on the lab side to help us decide what we need for grouping / ordering. Also need to understand if the report signature is part of the report, or is the addition of the signature added AFTER review of the report (stamped later) even though the precedent in V2 is to just reference it to the Medical director
  - presentedForm: the laboratories canonical representation needs to be presented in the EMR (use a pointer to the composition into presentedForm (rather than pdf - or in addition) to create the "report of record"
  - Having DiagnosticReport and composition exist in parallel should not be an issue, we may need to create an invariant
  - what type of signature do we need to have - electronic or digital (assume we will have to have digital for European rules sooner or later
  - in order to ensure the full report is always signed and available - maybe put this into the structural version of the .presentedForm?
    - this is supporting the 3 actions rule for this data as described in the
    - can we live with the situation where we have a data in the structured data that is not in the presentedForm, and vice versa?
    - this might make presentedForm the source of truth
  - we can have more than one presentedForm, how do we make clear which of those is the source of truth is the one of these that is signed
  - at the moment we only support attachment as datatype
  - do we need a backbone element
    - indicating which one is the "Report of Record" or do we need a presentedForm.type
    - also do we need a different element for referencing the composition (not sure that we want to do that - reason to do that would be we could sign this in a special place and can then work with the other elements - but presentedForm is really meant ONLY to be visually consumed?
    - who is the signer of presentedForm - in the lab case it is the producer, but that is not clearly defined in the resource attribute = we also should make sure that the presentedForm is clearly identified that this should be a SINGLE report, not individual pages of a report
  - John Moehrke how can we ensure an attachment is digitally signed - is there a reference you can share?
    - for ordering: in the element definition for any cardinality n ..*, which is defined as an array, you can indicate that order matters - it has the attribute of OrderMeaning (which is a string) if the element is not populated, then there is no rule around ordering; if populated, then the string describes what the order means - example would be preferred telephone numbers
  - what makes something a diagnosticReport over a SurgicalNote, which is a profile on composition?
    - we could make DiagnosticReport a profile on composition
    - we would need to decide if we want a single solution for simple and "regular" and very complex reports vs. having different solutions for each of the different places
      - user suggests the profile on composition

Friday, September 23, 2022
Q1 - Joint: OO / DEV

Agenda Topics:

- Device
  - Mappings - PHD, PoCD
  - Identify stable elements, those that have changed and need further testing
  - Examples (review /clean-up based on R5)
- Device Definition
  - Scope/Boundary
  - Mappings to EUDAMED, GUDID (Catalog)
- HCP Dashboard
- Administra - time permitting (else co-chairs can do that offline?)
  - PBS Reports

Friday-Q1: Meeting Notes

Devices

- Review Mappings
  - PHD - Brian Reinhold
  - POCD - John Rhoads
  - Need to review others as well.
  - Any data elements that need attention in the standard should get ballot submissions.
- Examples/Stable Elements
  - Need to review.
  - Prefer to have any suggested updates done as part of Ballot submissions.
  - Include a Catalog boundary line to clarify purpose vs. Catalog and point to Catalog for more information.

DeviceDefinition

- Scope/Boundary
  - Clean up language so it does not duplicate Device language that already clarifies that. Hans to prep proposed disposition FHIR-38711
  - Include a Catalog boundary line to clarify purpose vs. Catalog and point to Catalog for more information.
- Mappings
  - Marti and Francois are updating the mappings to EUDAMED and GUDID and as needed record JIRAs to DevDef

Device and DeviceDefinition Other Text

- There is other text where the difference between the context of device and device definition needs to come through clearly. We need to review this across all text.

Use Case Reviews

- We need to create use cases that cross resources that further help clarify use and boundaries.
- Jose is going to create some example drafts and Lloyd is going to find a place to put it.

Device Association Discussion

- need to review any change for backwards compatibility - maybe keep the association in the device resource ONLY for implantables and make that 0..1 and then create a variant to enforce that Jose Costa-Teixeira to create example scenarios Elliot Silver to add the JIRA here
- Lloyd like moving the association out, but may need more discussions
  - scope for just device - document the association that change over time that need tracking beyond history - patient, what else?
  - some of these may influence access controls
  - once we have the list look for other things that we may need to do this to as well and then reach out the their owning WG
  - we want something stable for R6 for sure, but if you delay pull this out by R5, so bring this to FHIR-I as well
  - zulip chat about associations on patient for preferred pharmacy (only need current really, so does not define characteristic is ??)
  - use case: who has this device been used on (e.g. endoscopes in infectious situations, exposure of physicians)
- Existence of DeviceDispense implies a DeviceAssociation
- why is Auditevent not good enough?
  - this is often only accessible to security (it tracks the information about the item), but that also applies to the resource provenance
  - these also don’t move from system to system
  - we are not necessarily looking for event log, but rather a timeframe
  - you also don’t want the whole history in 1 resource
  - could we use https://build.fhir.org/episodeofcare.html for that?
- that may work for patient, but how do we do that for other things
  - a device may be assigned to a patient - DeviceDispense, which is the start of the association period, but we may only know about the association period, but not have information about the dispense
- More generic aspect of tracking what devices (or other resources) are associated with - start just with patient, but may need to also to look at practitioner, ward etc - and how to create logs for this as well - getting into inventory handling a bit
- does this include who operated the device?
  - may need the log for a particular timerange (during a procedure) - probably need complex search parameters
  - DeviceUsage is a patient reported element
  - there is also a clinician assertion (if device was assigned during encounter
• there is the system assertion of the association to the device (label was printed with patient name)
• Need to be clear if we want to track the giving out/association to or the having of
  • we need to ensure we have good documentation what this new resource is expected to be used for (making lists vs including in operational workflow, where we have overlap with existing resources)
  • we can draw an analogy from medication world (where we use the list of medications, when checking for contra-indications, not dispense or administration events
• do we need the distinction between single use (expected anyways) devices vs reusable devices
• do we need to track associations between 2 devices / products (centrifuge vs blood in container)
  • need to review against genomicStudy, where the consecutive use
  • tracking AI algorithm as devices

How do we model software in a device resource?
• there is a software as a medical device (dealing with this as component of the device) vs dealing in FHIR resource
• and there is also software embedded in devices (software releases - are those individual devices (when installed on a specific machine) or deviceDefinitions) - need to set up a call between devices, OO and mobile health Marti Velezis and John Rhoads to plan this out
• when we are dealing with AI, include II, as they are most advanced in that discussion - how do you track the changes in AI algorithms

Friday-Q2: Meeting Notes

Chair:
Scribe:
Agenda Topics: