То	≗ Person ≗ Person
Сс	≗ Person
Всс	≗ Person
Subject	

Connectathon 36

Track Report Out

Please add your track report out to this document by answering each of these questions:

- What was the track trying to achieve?
- List of participants (with logos if you have time and energy)
- Notable achievements
- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)
- Now what?

Bulk Match

What was the track trying to achieve?

Test and refine the draft Bulk Match Implementation Guide (https://build.fhir.org/ig/HL7/bulk-data/branches/bulk-match/match.html) which extends the single patient FHIR Match Operation (https://build.fhir.org/patient-operation-match.html) into an operation that supports matching multiple patients through an asynchronous request.

Participants

- Boston Children's Hospital
- Helios Software
- Minnesota DOH
- Lantana Consulting Group

Notable achievements

- Demonstrated the use of a bulk-match server and client
- Tested proxying match operations from a bulk match server to the Epic sandbox
- Refactored parts of the reference implementation configuration UI to improve how proprietary options are being specified

Now what?

- Improvements to the reference implementation
- Pilot implementations!

C-CDA to FHIR Mapping Track

- What was the track trying to achieve?
- •PAMPIP gap filling: Compare and align mapping to FHIR resources from the same inbound CCD between multiple vendors
- -Highlight areas of discrepancies for further discussions
- -Create JIRA tickets as needed
- Social history mapping
- •Quality assurance bi-directional mapping exercise
- Document header mapping discussion and gaps
- Presentations

List of participants (with logos if you have time and energy)











Summary: What Was the Track Trying to Achieve

Notable Achievements

PAMPI(P) (Problems/Allergies/Medications/ Procedures/Immunizations/Patient (Chun)

(vendors Availity, Google, MDIX, Smile)

Patient Telecom value (decision) - NO spaces in telecom contact. Do not need to change the format for the original value string

```
telecom value="tel:+1(565)867-5309" use="MC"/>
```

Marital Status:

Additional Race and Ethnicity

Only one field is available (Lantana concatenates text for Race and Ethnicity)

sdtc race: they can either be the category info, or the detailed level. To map, need to check if the sdtc race is at the category level, and if so map to the omb extension; otherwise map to the detailed.

Text: concatenate the text from all the race and sdtc race and separate by comma

```
Additional Race and Ethnicity
                                                                         RACE
                                                                                                                                                                                                                                                                                                     Ethnicity
                                                                                                                                                        Smile
                    Availity
                                                                                                                                                                                                                                                                                                          Smile
"extension": [
                                                                                                                                                                                                                                                                orl": "http://hl7.org/fhir/us/core/StructureDefinition/us-core-ethnicity", extension": [
  {
    "url": "embCategory",
    "walueCoding"; {
        "system": "urn:oid:2.16.840.1.113883.6.238",
        "code": "2166-3",
        "display": "white"
}
                                                                                                "url": "http://hl7.org/fhir/us/core/StructureDefinition/us-core-race", "extension": [
                                                                                                  extension: {
    "url": "ombCategory",
    "valueCoding": {
        "system": "umreid:2.16.848.1.113883.6.238",
        "code": "umreid:2.16.848.1.113883.6.238",
        "display": "maite"
}
}
                                                                                                                                                                                                                                                                   "valueCoding": {
    "system": "urn:oid:2.16.840.1.113883.6.238",
    "code": "2135-2",
    "display": "Hispanic or Latino"
                                                                                                                                                                                                                                                               "url": "text",
"valueString": "Hispanic or Latino"
},
      "url": "detailed",
"valueCoding": {
    "system": "urn:oid:2.16.840.1.113883.6.238",
    "code": "2180-9",
    "display": "European"
                                                                                                     "url": "detailed",
"valueCoding": {
    "system": "urnoid:2.16.840.1.113883.6.238",
    "code": "2188-9",
    "display": "European"
                                                                                                                                                                                                                                                               "urlueCoding": {
    "system": "urn:oid:2.16.840.1.113883.6.238",
    "code": "20146-9",
    "display": "Spanish Basque"
```

Guardian

If it is in the Guardian field (contact party) we need to keep relationships.

Map the relationship to the "contact.relationship": Need to map both the code, and the hard coded classCode of "Guard". If there is an extension under the guardianPerson that specified the relationship further, include that mapping in the coding as well.

Preferred implementation:

```
"relationship": [
    {
        "coding": [
            {
                "system": "urn:oid:2.16.840.1.113883.5.111",
                "code": "POWATT",
                "display": "Power of Attorney"
        ],
        "text": "Power of Attorney"
   } ,
{
        "coding": [
                "system": "http://terminology.hl7.org/CodeSystem/v3-RoleCode",
                 "code": "GUARD",
                "display": "Guardian"
        1,
        "text": "Guardian"
```

Religion and Birthplace

Preferred mapping for Religion (Comment: MDIX should remove the [] brackets the other examples are ok):



Birthplace:

If there is a Name, it can be sent as a text string.

If there are multiple lines for address in CDA, just map to the same line array

Language modeCode and Proficiency level - map to "type" and and "proficiency" extensions, respectively

https://docs.google.com/document/d/1dJQ79zuRpFmWicBaNpsnnw8wXHDid81NXUKKJ12wJCc/edit#heading=h.ytop3leewum6

Header

https://docs.google.com/spreadsheets/d/1S3hnhcrDNnPFhMI1CuIsUADTvivw1A2ZQki3jjpyd E/edit#gid=202855715

https://build.fhir.org/ig/HL7/ccda-on-fhir/branches/2024/

SDOH to consider (one vendor's approach):

Identify a SDOH value set (based on Gravity value set), and tag the identified SDOH items with the us-core-tags as SDOH, and with observation-category of survey.

Recommend vendors to start with a SDOH value set, and the mapping project provide the structure to map to the category

Allergy reaction onset:

If the reason onset from CDA has a low and high and they are different, then calculate the difference and put that value in the <u>intolerance-during extension</u>, in addition to map to the "onset" property; if the time is the same, then just map to "onset"

Different proposal to handle negation of specific allergies:

- Map to the text of the coding
- Map to refuted for "verification", map the original status to "clinicalStatus"
- Follow the current guidance, map to substanceExposureRisk

effectiveTime low and high:

If only effectiveTime.low is present, map to onsetDateTime. If the high time present, map to the abatement extension

Issues/Discussion points/Questions

FHIR limitations regarding observations for various clinical procedure categories like Lab, Xray reports, vital signs, etc.

Patient Race and Ethnicity is an extension.

Reference:

CCDA-FHIR Map Inventory

Recommend against mapping to reaction.substance as that's the substance the allergy is triggered from, not the medication used to treat.

Allergy manifestation

R4-

R5- is an observation

Rection ID and Onset:

Map the reaction id to the FHIR_identifier extension

Immunization

Vaccine manufacturer is a reference to Organization. But if there is only name in the source data without an id for the Organization, should we just populate reference.display with the name? Or create an Organization resource with just the name and reference to it?

Now What?

Chun:

Restart vendor calls;

Review the report-out with vendors

Review Benjamin's draft branch

Add this to the CDA id to FHIR identifier mapping guidance?

Benjamin:

Add value string to social history mapping page.

Revisit allergy negation

Sarah:

Review Provenance

Create mappings of persons (practitioner, practitionerRole, etc.)

Ben:

Create a page of mapping

<u>Jay: Allergy reaction medication and procedure</u>: Ask Patient Care/ Pharmacy group, Where do document the treatment administered for the (Patient care and pharmacy)

Concept maps

Clinical Reasoning

- What was the track trying to achieve?
 - Terminology
 - Testing Artifact Terminology Service capabilities as specified by the CRMI Artifact Terminology Service capability statement
 - Quality Measures
 - Testing quality measure capabilities for eCQMs exported from the MADiE authoring environment.
 - Testing in VSCode and CQFRuler to ensure consistent evaluation of the measure in both the JavaScript and Java engines.
 - CQL Engine Parity
 - Testing CQL engine capability using the cql-tests-runner, a Node application that runs the tests published as part of the CQL specification.
 - Decision Support
 - Testing PlanDefinition/\$apply engine capability using the pd-apply content, a Postman collection of tests based on various content sources
- List of participants (with logos if you have time and energy)
 - 1. Bellese
 - 2. Carrera Group
 - 3. CDC
 - 4. CMS
 - 5. Dynamic Health IT
 - 6. ICF
 - 7. Firely
 - 8. Google
 - 9. Leavitt Partners
 - 10. Mathematica
 - 11. Microsoft
 - 12. NCQA
 - 13. Smile Digital Health
 - 14. The Joint Commission
 - 15. The MITRE Corporation
 - 16. Vermonster
- Notable achievements
 - Terminology Testing
 - Testing against VSAC, gathering details but ~92% passing
 - Testing against OCL, gathering details, but identified some issues with the test content that prevented progress, addressing those issues
 - Quality Measure Testing

- o 60 Measures tested
- o 36 Measures passed
- 18 Measures ran but had some issues with the data, in many cases it found no results for any population
- o 6 Measures had CQL issues
- Detailed results in conman and following up for reproduction and next steps
- CQL Engine Parity Testing
- Decision Support
 - Introduction of interactive CDS
 - Question items are based on on PD.action.input (SDs)
 - Conceptually a process of:
 - For each PD.action.input call \$questionnaire (in a minimal mode)
 - 2. Build a pre-populated QR containing the Questionnaire from (1)
 - 3. Extract the QR and add to context
 - 4. Pass the context to PD \$apply operation
 - 5. Pause for user input to either (a) change QR or (b) select recommendation(s).
 - Wrap up this set of operations into \$apply, based on heuristics -e.g. if there exist PD.action.input then build the dynamic Q and
 QR.
 - Successfully tested new HAPI FHIR StructureDefinition/\$questionnaire operation with Interactive CDS content
 - Successfully tested the following \$apply scenarios on latest JPA Server Starter with HAPI 7.2.0:
 - PD-Apply (All ActivityDefinition and PlanDefinition test cases)
 - LCS-CDS
 - Opioid-CDS-R4 (Partial success, some REC's are failing, working through those issues)
- Screenshots and/or links to further information

Clinical-Decision-Support-using-FHIR-CPG-and-SDC.pdf

C36-CR-Quality Reporting in FHIR.pptx

MITREMeasureRepositoryService.pptx

https://docs.google.com/presentation/d/10KY7RW2MuNjl5pk1KDeQLnRlnW0vmryrxcuZPH50k28/edit#slide=id.p

- Discovered issues / guestions (if there are any)
 - Terminology Testing
 - Issues with valueset-author and valueset-effectiveDate extensions not being returned correctly by systems
 - Quality Measure Testing
 - o AdverseEvent retrieve gives a warning about not resolving, but shouldn't

- CQL Engine Parity Testing
 - FHIR Type Mapping Issues
 - Mapping for open intervals
 - Mapping for Long in R4 systems
 - Multi-statement testing a proposed extension to the test schema to support testing of library content, not just expressions (https://github.com/cgframework/cgl-tests/issues/17)
 - Error codes in the specification (so tests can validate the correct errors)
 (https://github.com/caframework/cgl-tests-runner/issues/21)
 - Adding some test cases for query capability: https://github.com/cgframework/cgl-tests/pull/18
- Decision Support
 - How to distinguish inferred vs asserted extracted resources
 - Extend
 https://build.fhir.org/ig/HL7/fhir-extensions/StructureDefinition-cqf-partOf.ht
 ml to be used on any generated resource to refer back to the PD (or back to the SD) it came from.
 - Figure out a pattern in CQL to simplify this

0

Now what?

Da Vinci Burden Reduction

Our Goal is to test CRD/DTR/PAS interoperability with as many interested parties as possible. e.g. EHR vendors, Providers, Payers, and others. The Da Vinci *Coverage Requirements Discovery (CRD)*, *Documentation Templates and Rules (DTR)*, and *Prior Authorization Support (PAS)* Implementation Guides (IGs) together support an integrated workflow to enable automated submission of required documentation and/or prior authorization from EHR and payer systems respectively. The use of these IGs is likely to be mandated as part of regulation. We have had past Connectathon testing of CRD, DTR, and PAS. This track will ensure that the IGs work appropriately, independently, as well as in concert.

Participants:

































Notable achievements:

Epic:

- prototype native DTR / SDC renderer
 - We implemented a small slice of Structured Data Capture and loaded content from many groups (Edifecs, eviCore, HIKE, MCG, Mettle Solutions, Motive, Onyx) to test rendering.
 - Overall results were pretty good.
 - We need to improve support for multiple nesting levels, enableWhen, dealing with large value sets, and adaptive forms. Testing will be ongoing.
- appointment-book CRD
 - We implemented CRD using the profile where Appointment.basedOn contains the ServiceRequests that need coverage-information.
 - Successfully filed system actions with both HIKE and Onyx.
- order-sign CRD

- Successful system actions with Onyx
- Authentication issues with Aetna. Leading to some discussions with CDS workgroup about using signed JWT and jku.
- We tested a single endpoint with eHealth Exchange that would route to multiple payers (Cambia, Itiliti, and BCBS Palmetto) based on the organization ids
 - This saved provider build time, but we still had issues we're working through with each downstream payer endpoint.
- Third party DTR launch context
 - We started this with Infor but ran into CSP and auth issues.
- Other follow ups
 - We want to add citation/footnote support (a tooltip explaining why a question is being asked) to SDC.
 - Discussions about establishing consistent patterns for signed JWT+jku
 - Some places in the IGs need clarification on the CRD to DTR launch flow, the PAS to DTR flow, and what is actually required.
 - Discussions on NPIs+TINs and prefetch syntax that works.

Evicore/Evernorth:

- Continued DTR (Adaptive) integration testing with Cambia and Mettles (not completed, work will continue after Connectathon)
- Continued DTR (Adaptive) integration testing with Epic (not completed, work will continue after Connectathon)
- Continued PAS submit and inquiry testing with Nucural and Mettles (not completed, work will continue after Connectathon)
- Initiated conversations about integration and testing with BCA and Aetna
- Specification Questions discussed:
 - CRD specification on "Doc needed" and the URL needs to be updated to clarify that URL is optional and DTR is supposed to be invoked based on existence of Doc needed and not URL
 - 2. SNOMED vs CPT code evaluation and mapping needs more clarity and discussion in terms of who will be responsible to maintain the mapping.
 - 3. The Claim response payload for different scenarios of error (data and structure) needs to be clarified and documented.
 - 4. CDex documentation for CommunicationRequest needs more clarity to work with multiple line items and how it will work end to end. It seems we need to account for scenarios where a provider may decide to take the route of CDEX task or PAS Update.

Onyx:

(Testing with Epic)

Appointment-Book Hook:
 Prior Auth Needed - Tested, successful within Epic's workflow
 No Auth needed - Tested, successful within Epic's workflow

Order-Sign Hook:

No Auth Needed - Tested, successful within Epic's workflow Prior Auth Needed - Tested, successful within Epic's workflow Documentation Needed - Tested, successful within Epic's workflow, proper questionnaires delivered in response

Onyx Questionnaires:

Rendering capability / success within Epic's DTR app (currently being development by Epic, not completed)

(Testing with Meditech)

Order-Sign Hook:

Tested, successfully triggered, routed request, and identified rules & cql required to process. Predominantly success, but Meditech FHIR server would need to support _include. Once supported workflow would be fully successful.

(Testing with CorroHealth)

Order-Sign Hook:

Tested Order-Sign with some success. Could not read FHIR server with search parameters

eHealthExchange

- Payor systems we're using for testing aren't very flexible. Data sent in a slightly different format (based on how the EHR/sender creates it) leads to response issues
 - We're testing really constrained use-cases today, which basically means that a
 given test only works if the FHIR request is formatted exactly as defined by the
 payor. This means unique CPT codes, use of a different system string to identify
 NPI, etc. will cause the request to fail
- Use of _include parameter in the prefetch queries causes issues with some EHRs that don't support it
- Requiring the order that triggers an order-sign hook to be a ServiceRequest resource in the EHR isn't well understood and is not how EHRs function today. An order that is being signed is not in the EHR database until after signature is completed
- CRD takes time! We're seeing 20-second to 1-minute response times for CRD in most cases
- We found that Palmetto (Smile CDR) doesn't allow for the crd extension on the CDS hook.

ZeOmega

 initiated CRD testing with Meditech and surfaced some issues in working across STU 1 and STU 2. We'll continue testing after this Connectathon and into the CMS Connectathon. Palmetto and ZeOmega plan to continue testing as well with eHealth Exchange and other payers and providers in the Da Vinci Trebuchet pilot. We also dedicated time to a breakout session on Da Vinci's Standard CQL Discovery project.

Edifecs

- Worked with Epic sandbox to get reliable OIDC authentication leveraging Epic credentials into Edifecs SoF DTR client. Had issues on Saturday with our internal security framework so had to get devs to reset the systems and configs so most of Saturday was spent on this.
- Worked w/ Kyle on his DTR prototype. Provided 11 questionnaire bundles w/ associated prefill CQL. Kyle was able to identify some gaps that he resolved at the event to be able to render the questionnaires successfully. We worked side by side to then cover differences in how our authoring impacted their prototype rendering and he had a few takeaways for improvement.
- Got connected with the Inferno PAS sandbox and plan to continue work post-connectation to vet out our PAS submission / response implementation.

CorroHealth

(Testing with eHealth Exchange)

• Tested order-sign CRD. The basic order-sign hook exchange was successful. Still working through meeting prefetch data needs.

(Testing with Onyx)

 Tested order-sign CRD. The basic order-sign hook exchange was successful. Still working through meeting prefetch data needs.

(Testing with Cambia)

• Attempted order-sign CRD but had authentication issues.

Learnings of CDR deviations from CDS Hooks specification.

 Some CDS Services requiringOAuth Client Credentials for CDS Service requests instead of using the authentication mechanism stated in the CDS Hooks specification.

Now what?

The Burden Reduction track team will incorporate our experiences and discoveries from this FHIR Connectathon as a springboard into preparations for the upcoming CMS Connectathon

HL7 FHIR Connectathon 36: CDEX Vinci Clinical Data Exchange (CDex) Summary



HL7



Connectathon Activities

- Demonstrations
- Break outs
- Testing





CDex Transactions

The CDex guide documents three types of FHIR transactions for requesting and sending information.

- Direct Query
- Task Based
- Attachments for Claims and Prior Authorization
 - Using LOINC Attachment Codes
 - Using FHIR Questionnaires
 - Combined with Da Vinci PAS(Burden Reduction) for "pended" PA Claims





Testing Toolkit



Migrating to HL7 Foundry

CDex Reference Implementation (HealthLX)

- Joel Walker
- Karell Ruiz Rodriguez





CDex Test Scripts (Aegis)

• Carie Hammond



Postman Collection For Testing CDex Scenarios

Eric Haas





CDex Connectathon Scenarios

Scenario	Requirements from Implementation Guide	Implemented in Reference implementation?	TestScripts Available?	Implemented in Postman Collection?
5 USCORE 3.1.1	3 Direct Query	x	V.&	~
6 USCORE 3.1.1	4 Task Based Approach	✓ Æ	√ @	~
9 PROPOSED USCORE 3.1.1	9 Task-Based Approach Using Topic- based Subscriptions	×	×	✓ &
1,2,3,4 USCORE 3.1.1	5.1 Solicited and Unsolicited Attachments	√ &	✓ (see links below)	✓ (see links below)
1 USCORE 3.1.1	5.1.1 Unsolicited Attachments	√ &	√ &	~
2 USCORE 3.1.1	5.3 Requesting Attachments Using Attachment Codes	✓ &	~	~
3 USCORE 3.1.1	5.4 Requesting Attachments Using Questionnaires	! &	~	~
OBSOLETE USCORE 3.1.1	5.4 PAS-CDex Transaction	×	×	~
S PROPOSED USCORE 3.1.1	CDex Bulk Transactions	×	×	~
NOT TESTED	6 Signatures	×	×	×
	7 Security and Privacy	×	x	×



CDex Implementation Cross Reference Table



Breakouts

- Comparison PAS Guide's updated <u>Request for Additional</u> <u>Information Section</u> with CDex Attachments
- Bulk Data Discussion with DaVinci PDex
- Trebuchet Overview Featured Task-Based Transactions and mentioned Cdex Signature
- · Discussion of CQL Library for DTR





Testing

- Christol Green Elevance
 - Testing Scenarios using RI and Testscripts
- Durwin Day. BlueCross BlueShield of Illinois
 - Testing Scenarios using RI and Testscripts
- Scott Rossignol eHealth Exchange
 - (Trebuchet) Tasked based approach





Testing Highlights

- RI Testing*
 - · Identified RI issues with DTR interface
- (Trebuchet) "Tasked Based Pull"
 - Payer POSTs Task to Intermediary with multiple query requests in Task.input
 - Payer Uses member's FHIR_ID for queries or create an initial Task to fetch it
 - Intermediary completes Tasks and prepares an ndjson output file (typically large)
 - · Payer polls Task on Intermediary server and fetches output file





Next Steps

- RI
 - Migrate to Foundry
 - Update/refresh mashup with DTR RI (if available)
 - Improve Documentation (esp when using own server)
- Trackers/Updates on Task-Based Approach Documentation
 - Allow for multiple query requests
 - Update guidance on using/discovery of a member's FHIR_ID (e.g., create an initial Task to fetch it)
 - Clarify that output can be other files types not just Fhir resources (e.g, ndjson)
 - Benefits of Task over Bulk query for large data?







References

See track page for links





Da Vinci PDex

What was the track trying to achieve?

The PDex Track set out to test the Bulk API capabilities that are being added to the PDex STU2.1 IG·

- Provider Access API using \$Davinci-data-export
- Payer-to-Payer Bulk Member Match
- \$Davinci -Data Export Operation for Payer-to-Payer

A stretch goal was to use UDAP to enable registration

List of participants (with logos if you have time and energy)

Availity, Drummond Group, Edifecs, Firely, Infor, MITRE(Inferno), Onyx



Notable achievements

Successful Testing of \$davinci data export by Infor.

Successful Test of Payer-to-Payer Bulk Member Match.

Inferno was tested against Firely for Single Member-Match.

Onyx and Edifecs were able to perform bulk testing of Provider Access API.

Onyx successfully tested with Touchstone performing Bulk Member Match.

Onyx successfully tested against the PDex RI.

Infor successfully tested with Touchstone for Single Member Match and Bulk Member Match.

Screenshots and/or links to further information

N/A

Discovered issues / questions (if there are any)

Data holders are implementing custom solutions to address scoping of system-system connections. For example, a Provider being permitted to access a subset of Members at a Payer. Payers only being granted access to the matched members that Payers identify. PDex is exploring an approach that:

- Users of Payer-to-Payer or Provider Access API will have a closely defined CapabilityStatement that only provides access to the required Operations.
 - o Payers:
 - Bulk Member Match
 - Da Vinci Data Export
 - o Providers:
 - Da Vinci Data Export
- Define a control mechanism to restrict system access to the resources a data requestor is permitted to see. This can be represented in FHIR terms using a "Delegated" Group resource, where the \$davinci-data-export validates that the group id being requested is associated with the data requestor.
 - o Da Vinci Data Export

Single member match is representing a challenge to perform consent authorization during the issuing of an access token. Ticket raised: https://jira.hl7.org/browse/FHIR-45970

Now what?

- Finalize PDex STU2.1 and prepare for a Limited scope ballot in September.
- Expanding the IG to provide more guidance around scoping system credentials for system-to-system bulk interactions
- Incorporate additional capability statements into the IG for the Bulk API use cases.
- Prepare for CMS Connectation with UDAP integrated for registration to the Bulk APIs.

Da Vinci Risk Adjustment

- What was the track trying to achieve?
 - Support implementers/testing partners to test the consumption of the Risk Adjustment Coding Gap Reports based on the updates made to the profile.
 - Hold a breakout session to discuss the use of Remark for condition category gaps and care gaps.
- List of participants (with logos if you have time and energy)
 - Great participation for the breakout session: Optum, Smile Digital Health, ICF, TJC, MITRE, EPIC, etc.
- Notable achievements

- Great discussion at the breakout. The group agreed that the similar Remark structure and workflow would also be useful for the care gaps scenario in the Data Exchange for Quality Measure IG.
- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)
- · Now what?
 - Conduct off-line ad hoc testing with EPIC to test their implementation
 - Work towards wrapping up updates to STU2 based on implementers feedback for publication

Da Vinci Patient Cost Transparency

What was the track trying to achieve?

Test the Da Vinci PCT IG latest balloted version with the the new GFE Coordination Workflow and the updates to the GFE Submit.

Testing with new TestScripts.

• List of participants (with logos if you have time and energy)





AEGIS

Notable achievements

Tested new Coordination Platform Reference Implementation supporting the new STU2 GFE Coordination Workflow supporting the major interactions

Testing the changes to the Client and Payer Server RIs changes to support STU2 Testing Coordination Platform with Aegis Touchstone TestScripts

Discovered issues / questions (if there are any)

It was difficult to identify different type of bundles. That makes it difficult to process and to search for. Will need to look into addressing that for an upcoming version.

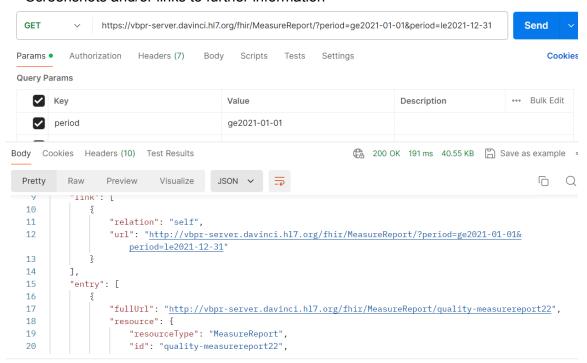
Test Scripts could be updated to support more scenarios.

Now what?

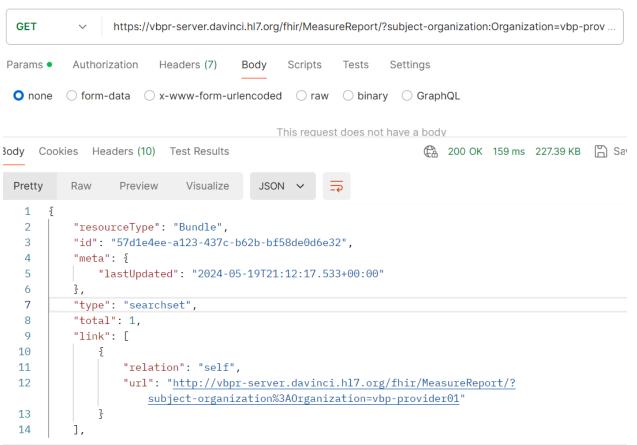
Finding more testers to test the ballot version and the upcoming changes.

Da Vinci Value - Based Performance Reporting

- What was the track trying to achieve?
 - Test the Da Vinci Value-Based Performance Reporting IG using the Da Vinci Reference Implementation in Foundry
- List of participants (with logos if you have time and energy)
 - Cambia Solutions, Optimum eHealth
- Notable achievements
 - In preparation to the Connectathon, successfully moved the Edifecs developed Da Vinci VBPR Reference Implementation (both Server and Client) into HL7 Foundry
 - Successfully retrieved Value-Based Performance Reports using the Da Vinci VBPR RI end point.
 - Tested the IG defined subject-organization search parameter on MeasureReport to get the report back from the RI end point.
- Screenshots and/or links to further information



https://vbpr-server.davinci.hl7.org/fhir/MeasureReport/?subject-organization:Organization=vbp-provider01





Value-based Performance Reporting Demo App

Available Reports

ee, quality incentive payment for the ch	ronic care management incentive program, q	quality incertiive payment for the annual office		
Subject (Provider)		Period	Paid Through Date	Status
, , ,	Reporter (Payer)	01/01/2022 to 12/31/2022	12/31/2022	
Good Health Clinic				
Performance Measu	1100			
eighted average star				
lember months				
iember monus				
verage risk score				

- Discovered issues / questions (if there are any)
- Now what?
 - Set up in Touchstone for testing against the RI
 - Update the RI Client to display the quality measure reports

Enhancing Oncology Model Implementation Guide (EOM IG)

- What was the track trying to achieve?
- List of participants (with logos if you have time and energy)
- Notable achievements
- Screenshots and/or links to further information
- Discovered issues / guestions (if there are any)
- Now what?

Evidence Based Medicine

The Evidence Based Medicine track worked closely with the Vulcan UDP track. The FEVIR platform was used to transfer a Composition resource with the M11Report profile (sub-profile of EvidenceReport) and transfer to the UDP server. (See "Vulcan - UDP" track report out further down in this document) The M11Report and EvidenceReport profiles are part of the Evidence-Based Medicine IG. Other than the Vulcan UDP collaboration, the Evidence-Based Medicine track discussed user interfaces on FEVIR.net and ideas on how to represent data in the Evidence, EvidenceVariable, and Group resources. In particular the Inclusion and Exclusion Criteria using Group.characteristic where it references another Group resources.

Participants

Khalid Shahin

Brian Alper Sophie Klopfenstein Irina Angel

FAST Infrastructure (Security & Identity)

What was the track trying to achieve?

Test end-to-end FAST solutions (Security, Identity)

Verify that the FAST infrastructure supports requirements in the CMS rules for Interoperability and Patient Access as well as Reducing Provider and Patient Burden

Integrate AEGIS Touchstone monitoring of data exchange as a stepping stone to broader future testing capability

List of participants (with logos if you have time and energy)

Lantana Consulting Group AEGIS.net

SureScripts Optum

Evernorth

eCW

Meditech

Aetna

Sequoia Project

Leavitt Partners

eHealth Exchange

Notable achievements

SureScripts was able to complete Scenarios 1-4 using \$match in UDAP workflows

Used AEGIS Touchstone application to capture tests for participants and was able to capture testing across all four Infrastructure scenarios

Evernorth was able to stand up an identity server to test \$match and was set up with Touchstone for testing

Optum was able to plump multi-community support within their implementation and will be able to test via Touchstone's proxy soon after

- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)

Some matching algorithms in Identity Matching RI are not consistent with the IG Patient Match Scoring table

Found several bugs in the Touchstone test scripts, both related to the scripts and the actors, that should be remedied for future testing on the scenarios

Now what?

Testing Next Steps

Multi-community Testing

Use the modularized SureScripts implementation to test UDAP workflows on top of PDex and BR scenarios (payer-to-payer, payer-to-provider, etc.)

Expect to see additional organizations involved with testing and public call involvement (Epic, Firely, Intersystems, eCW)

STU2 Requirements takeaways

Include "purpose of use" during client registration

- Include multiple "purpose of use" values

Scopes

- Review Whitepaper from May2023 breakout session
- Review behaviors of QHINs and determine where there is commonality to see what might be a good idea to pull into the IG

Universal Realm

Makes sense to do but requires review. May need to test with non-US implementers to prove value

Include more detailed error responses in authorization objects

 Overlap with FAST Consent IG, will need to work with them to see whose responsible for capturing this

Multiple Trust Communities

 Difficult requirement to write guidance on, but recognize it is something that comes up frequently

Enhancing Oncology Model (EOM) IG

What was the track trying to achieve?

The purpose of this track was to test the Center for Medicare and Medicaid Innovation (CMMI) Enhancing Oncology Model Implementation Guide (EOM IG) for the collection and reporting of clinical data for specific cancer types as part of the strategic goals of EOM. The model is designed to promote patient-centered care, aligning with President Biden's Unity Agenda and the Cancer Moonshot initiative. EOM supports Cancer Moonshot's priorities, including supporting patients, caregivers, and survivors, learning from all patients, targeting the right treatments for the right patients, and addressing inequities.

In addition to this primary goal, we will also use this session to gather information on whether all or part of the EOM IG data elements can support the USCDI + Cancer trial matching use case.

List of participants



- 1. Christine Q Duong (cqduong@mitre.org) MITRE
- 2. Lisa Deister (Lisa.Deister@McKesson.com) Ontada
- 3. Jimmy Carrington (jcarring@epic.com) EPIC
- 4. Sam Sahakian (ssahakia@epic.com) EPIC
- 5. Kevin McHale (kevin@oncoramedical.com) Oncora Medical
- 6. Liz Turi (liz.turi@hhs.gov) ONC
- 7. Alexa Williams (alexa@nextlevelhealthinnovations.com) Next Level Health Innovations

- 8. Kwekour Quaynor (Kwekour@NextLevelHealthInnovations.com) Next Level Health Innovations
- 9. Bapi Behera (bapi@clinDCast.com) ClinDCast
- 10. Jansi Mohan (Jansi.m@globalalliantinc.com) Global Alliant, Inc.
- 11. Prakash Gadepalli (prakash.g@globalalliantinc.com) Global Alliant, Inc.
- 12. Denise St. Clair (Denise.s@globalalliantinc.com) Global Alliant, Inc.
- 13. Curtis Naumann (CMS/CMMI) (Curtis.Naumann@cms.hhs.gov) CMS

Notable achievements

- o All three of the planned EOM scenarios were successfully tested:
 - Scenario 1: Vendor systems were able to successfully query ISP (the CMS system) to receive a test attribution list for a panel of patients via a Parameters Resource.
 - Scenario 2: Reporting system (vendors) were successfully able to send an EOM bundle for test patients to the receiving system (ISP).
 - Scenario 3: Receiving system (ISP) was able to validate the bundles received.
- We were successfully able to identify next steps for supporting the USCDI + Cancer trial matching use case.
- Discovered issues / questions (if there are any)
 - Through testing the group surfaced several areas for further investigation and/or update specific, including:
 - Including identifiers only in the patient resource and not making MBI mandatory in all other resources (validate as a bundle and leverage sender's reference ID).
 - Investigating the request to remove reference to EOM IG profiles for each resource (Observations/Condition/Patient) that is part of the EOM submission bundle (meta.profile) and impact on validation.
 - Making the FHIR submission request conformant, as the FHIR submission response is conformant with FHIR async operation.
 - Making the OperationOutcome issue.details conformant.
 - Reviewing displays and evaluating setting display mismatches to warnings. Currently, the validator mandates Display issues as errors.
 - There was also discussion around certain data elements and profiles that will be further discussed, specifically related to metastasis and staging.

Now what?

- All questions raised will be discussed with our FHIR technical partners to ensure any updates considered are valuable across systems and scalable across use cases; agreed on updates will then be incorporated into the IG.
- All data questions will be reviewed with the EOM Model team for consideration now or in the future

- Additional information planned for inclusion in the IG will be added prior to the July CMS Connectathon including information related to the query using the Parameters Resource, the expected response, and polling, as well as information related to EOM specific requirements currently included in the EOM CDE Guide to make review of this information easier for implementers.
- Any updates or edits to the IG will be made prior to the July Connectathon. The group will plan to test in July and between July and production deployment in fall informally.
- We'll continue to communicate on all things EOM IG including additional thoughts post-Connecathon, review of findings and questions and decisions on these items, updates, and next steps via the <u>EOM Zulip channel</u>.
- We'll also discuss SDE submission.

Feature Capability Statement

- What was the track trying to achieve?
 - Test the new <u>Feature CapabilityStatement</u> Implementation Guide (formerly CapabilityStatement2), including the Feature CapabilityStatement profile, the Feature extension, and the \$feature-query operation.
- List of participants (with logos if you have time and energy)
 - Rick Geimer, Lantana (nominal track lead)
 - Grahame Grieve, Health Intersections/HL7
 - Gino Canessa, Microsoft (should have been track lead)
 - Reinhard Egelkraut, CGM
- Notable achievements
 - started from draft spec
 - fixed several issues related to implementability and overall workflow
 - o discussions about what constitutes a feature, context, and value
 - discussions about responses and what information clients need
 - discussions about what components are needed in definitions
 - discussions about feature query and its relationship to a capability statement
 - o discussions about single and multi-tenant use
 - discussions about discoverability
 - discussions about implementation burden
 - discussions about use cases and potential implementers
 - created two independent test implementations
 - Started IG updates based on discussions
- Screenshots and/or links to further information
 - https://build.fhir.org/ig/HL7/capstmt/
 - https://chat.fhir.org/#narrow/stream/434649-Feature-Capability-Statement
- Discovered issues / questions (if there are any)
 - Original IG had implementation issues, did not work for GET version of feature-query operation

- Context syntax needs work
- Now what?
 - Finish updating the IG based on Connectathon feedback
 - Review findings and updates during FHIR-I Q2 on Tuesday at the WGM
 - Hopefully go to ballot in Sept

FHIR Clinical Document

- What was the track trying to achieve?
 - Targeted investigation of the IGs compatibility with Versioning and Immutable/Parsable features need for FHIR Clinical Documents
 - Further advancement of the topics covered by the scope of the IG
- List of participants (with logos if you have time and energy)

Giorgio Cangioli IT (HL7-Italy)

Alexander Henket NL (National IT Institute for Healthcare in the Netherlands)

Rob Hausam US (Hausam Consulting)

James Jahns US (EPIC)

Rashid Kolaghassi US (EPIC)

Cooper Thompson US (EPIC)

Stephen Chu AU (Australian Digital Health Agency)

John D' Amore (More Informatics)

Angie Benoit US (Availity)

Sarah Gaunt AU (Lantana Consulting)

Benjamin Flessner US (Availity)

Lisa Nelson US (ADVault Inc)

May Terry US (Mitre)

Bret Heale US (ELIMU/Humanized Health Consulting)

Bob Dolin US (ELIMU)

· Notable achievements

Established lab reporting clinical documents, international patient summary clinical documents and advanced directive clinical documents as vital use cases to demonstrate the importance of immutability/parsability and versioning - both single-set and multi-set.

Discussed guidance with key stakeholders.

Summary of discussions:

Must Support in a Universal IG and Obligations - a lightweight must-support definition in the universal IG is likely best. Downstream IGs can redefine the MS

General guidance would be helpful such as the use of a query by date(created) + business identifier to locate the document. That is, in a scenario where a registry acts as a third party, a recipient pulling the document will know the originating system. However, the Resource.ids and other meta-data are not guaranteed to be the same as within the originating system. To find the document on the originating system (and the correct version), the recipient downstream of the registry would use a query to the originating

system with a date and business identifier to interrogate the original document on the originating system.

DocumentReference guidance will be a helpful addition as the identifiers and status in the DocumentReference should be in alignment with the contained clinical document.

Versioning:

A dynamic, non-static use case such as the International Patient Summary is one in which the clinical document is not meant to be revised or replaced. In CDA terms, every generation of the summary is a unique set ID. Will every generation be version 1? When pulled on demand, what is the sending system's responsibility? Should the Resource IDs in the Clinical Document all be internal to the Document Bundle? A transfer of care clinical document may not have a live signator.

Extensions to support versioning, which also bring R4 into alignment with R5/R6. The clinical document version string is useful. Additionally, to aid version status disambiguation add extension:terminal-status with value set:

deprecated <like superseded>

entered-in-error <oops, please ignore this one>

canceled <no longer valid>

*Multi-set versioning r*equires additional guidance. An example from Advanced Directives is as follows:

The Nursing Home, Temporary Care Facility, and Hospital all have Advanced directives for the same patient, which are sent to a registry. The patient (or caregivers) have also added the Texas DSHS (a fourth Advanced directive clinical document distinct from the others) and have chosen the registry to provide the Texas DSHS as THE Advanced directive clinical document.

For this case of multi-set versions, it would aid the provision of the correct 'version' of the clinical document to use the relatesTo Composition field to indicate that the 3 non-Texas DSHS ones are "replaced" by the Texas DSHS one - similar to suppressing non-current versions of the same document set.

Provenance and signatures define the actual 'final' version of the clinical document. The workflow is as follows: when ready a clinician initiates document finalization, this adds a Provenance Resource instance, with their signature, that points to a specific instance and version of the clinical document Composition. A Document Bundle is then created. This addition of the signature finalizes the clinical document. Because the Provenance Resource instance points to a specific instance and version of Composition, any changes to the Composition (which include narrative changes if referenced material changes) will NOT be connected to the Provenance Resource. This means the incipient clinical document is no longer final. It needs to be discussed how to update the status of the Composition but currently 'amended' is a strong candidate.

Receiver Server Behavior for Parsability

Lab Report Clinical Document

Example where the parse-ability is critical

Document Bundle is typically stored as a complete Immutable work

but in Lab Reporting as an example, there is a need for the receiver to take action and parse

the contents to have Observations populate the appropriate fields

Operations - such as \$Document may need revision, and Receiver Server endpoints for reliable parsing/use of clinical documents should be discussed.

- Screenshots and/or links to further information
- Discovered issues/questions (if there are any)
 General versioning in FHIR
- Now what?

Initiation of Tiger team and further development of the guidance in the IG around versioning. Continue progress to STU September Ballot.

Goal Directed Care Planning

- What was the track trying to achieve?
 - Create and test the interoperability of an <u>MCC CarePlan</u> that includes person-centered goals, action steps, and outcome assessments.
 - Evaluate and test <u>MCC Goal</u> extensions for acceptance and prioritization of a goal by each relevant stakeholder, including the patient or caregiver. Test the ability to capture and share different priorities for a single Goal by each stakeholder.
 - Evaluate and test MCC eCare Plan IG use of resource-pertainsToGoal extension (Must Support) to include relationships with a Goal, e.g. its use in MCC ServiceRequest for interventions and action plans.
 - Discuss and test examples and implementations for person-centered goal outcome assessments, including <u>Goal Attainment Scaling</u> and Patient-Reported Outcome Measures.
 - Discuss and test examples and implementations for Goal assessment by a
 patient for Importance, Confidence, and Readiness (aka, "Readiness Ruler"),
 plus use of these assessments with Goal Attainment Scaling for scoring.
 - Discuss requirements for quality measures to track progress on Person-Centered Goals, Outcomes, and Care Plans for persons with multiple chronic conditions.
 - Explore use of the <u>Standard Personal Health Record (SPHR)</u> format to export and share a person-centered care plan and outcome assessments.
- List of participants (with logos if you have time and energy)















- Notable achievements
 - Discussed operationalizing goal attainment scaling (GAS) within clinical settings through FHIR standards.
 - Demonstrated a POC for patients/caregivers to identify goal domains (as defined by NCQA) and what's important to them (Patient Priorities Care values framework) using FHIR Questionnaire within MyCarePlanner, an open source SMART on FHIR web application for patients and caregivers.
 - Demonstrated a PrioritiesAI, a digital chat app that facilitates a text conversation with a patient to define their goals surrounding surgical procedures. The goals, as articulated by the patient, are shared with the clinicians to inform care.
 - Converted sample patients from PACIO ADI Advanced Care Directives which have CarePlan records. Martha DeLarosa patient also includes an international patient summary.
 - CarePlan + Advanced Directives

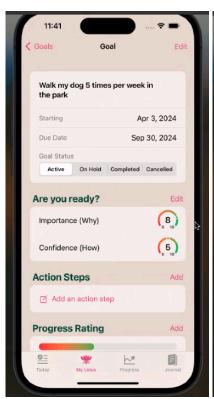
Roger-McBee.phr
Roger-McBee.Bundle.json
Betsy-Smith-Johnson.phr
Betsy-Smith-Johnson.Bundle.json

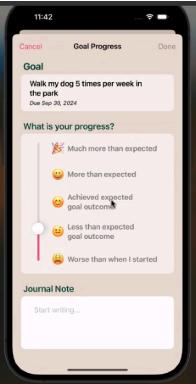
- CarePlan + International Patient Summary

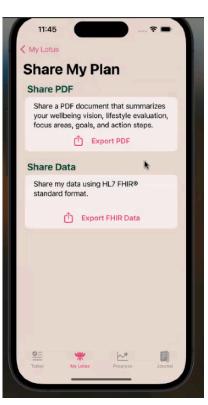
 MarthaDeLarosa-7685713c-e29e-4a75-8a90-45be7ba3be94.phr

 MarthaDeLarosa-7685713c-e29e-4a75-8a90-45be7ba3be94.json
- Screenshots and/or links to further information.

The screenshots demonstrate a series of setting a goal in a health and wellness application (Mountain Lotus WellBeing) using goal attainment scaling

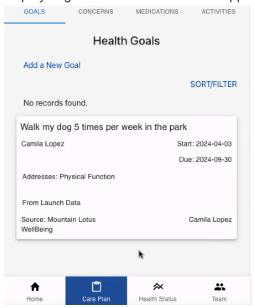




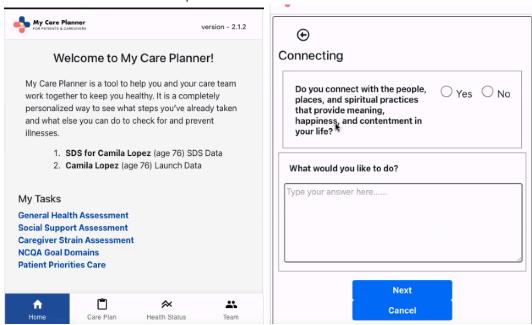


FHIR format of exported data

Display of goals in the eCarePlanner app



Addition of new screeners to represent NCQA Goal Domains and Patient Priorities Care



- Discovered issues / questions (if there are any)
 - Agreement is needed on how GAS and other goal-directed care planning can be incorporated into the clinical workflow. For example, how do patient-authored goals fit into a care plan generated from clinical guidelines for specific conditions such as diabetes management?
 - Time constraints for clinicians to document goal attainment scaling definitions
 - Lack of standardized goal questions for data exchange

- Balancing structured and standardized goal of interoperable goal-directed care planning with free form expression of patient goals in context of their particular circumstance.
- Standardizing a person-centered approach to using goals and care planning by identifying what matters most to the person, i.e., there are many frameworks to describe goal domains, values, and what their priorities are.
- Poor representation of patient-authored goals in EHRs
 - Kaiser prominently displays goals and uses GAS, while in other EHRs like Epic, goals are not easily accessible
 - Where to put goals in an EHR that conforms to clinical guidelines (i.e. ADA)

Now what?

- Integrate technology within EHRs to streamline the goal-setting process.
- Continually refine AI modules to better facilitate the creation of specific and measurable health goals.
- Use Goal Attainment Scaling to measure the success of treatments and procedures against set goals.
- o Standardize and codify questions for exchanging goal data.
- Need to define goal-directed care planning in the context of clinical workflows.

Helios Query and Response

· What was the track trying to achieve?

- Test a generic query and response workflow for use cases applicable to public health investigations with both a public health-to-electronic health record and a facilitated FHIR approach.
- Test the use of USCDI-based FHIR APIs for public health data access.
- Find issues and questions that may arise in real-world applications and discuss with public health subject matter experts.
- To perform patient matching and retrieve additional clinical details for specific patient from electronic health records via health information exchange or direct one to one connections with EHR systems
- List of participants (with logos if you have time and energy)

































• Skylight - CDC contractor

Developed a front end client tool https://dibbs.cloud/tefca-viewer to enter key information for a patient that sends FHIR API query requests to a QHIN (eHealth Exchange for Connectathon) or HIE or EHR directly to obtain related information from EHR servers (MELD test server for Connectathon contains synthetic test patient data FHIR bundles) and returns data that gets translated back to a human readable format or in json format to be ingested with NBS.

• New York City Department of Health & Mental Hygiene

NYC DOHMH receives a HL7v2.5 ELR message for a sexually transmitted infection (STI) reportable condition which is parsed and saved in the ELR database. NYC DOHMH FHIR Query Client monitors for a reportable condition and executes a patient match FHIR search query using demographics from the ELR. The returned patients are passed through an internal matching service that includes the HIE to check for matches. The patient identifier from the matched Patient Resource is used for further clinical queries. Data is received in a FHIR Resource bundle and each Resource is validated, parsed, and written into the ECR database. NYC DOHMH technology department then provides filtered data to the appropriate bureau for the surveillance system as requests are received.

HLN

HLN set up some synthetic test eCR message FHIR Resources in the MELD sandboxes to be used as the trigger to send a FHIR query to a provider EHR through eHealth Exchange or directly to the MELD sandboxes. They are aiming to query for additional patient clinical details related to a particular reported STI condition (e.g. chlamydia, syphilis, ...) to facilitate case investigations.

WA State Department of Health

WA DOH added an interface to their WA Verify+ IPS (International Patient Summary) application to run Q&R testing workflows by receiving patient demographic information, matching that information to a patient either through a QHIN proxy (eHealthExchange), or via an HIE/EHR directly, and finally receiving all data related to the matched patient that the source has. WA

Verify+ then compiles this data into an IPS and packages it as a SMART Health Link for the patient to share.

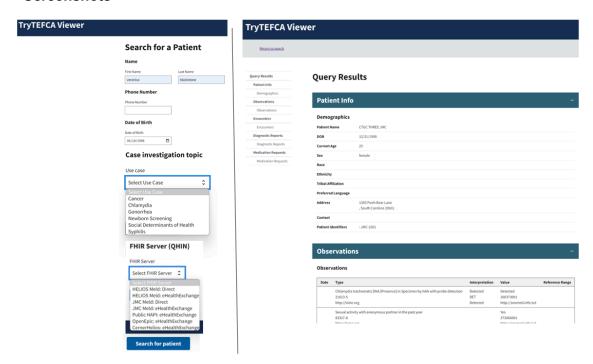
Demo here, under the "TEFCA Query" tab:

https://smart-health-links-ips.cirg.washington.edu/create

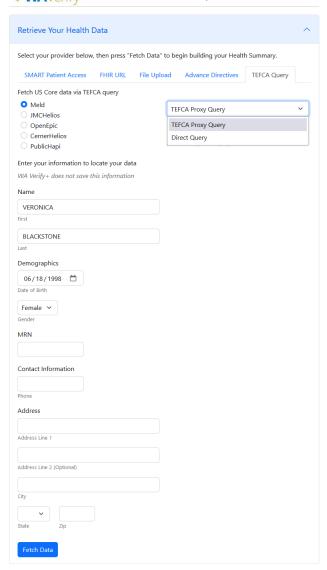
Notable achievements

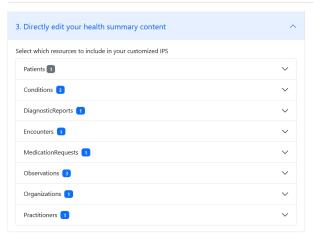
 MELD servers contained synthetic FHIR data. NYC DOH could grab patient information from their synthetic ELR message, auto-send a FHIR query to collect additional related synthetic patient data from the MELD Sandboxes. They could then add records into their SQL server database. Similarly, HLN could send and receive information via eHealth Exchange to one of the MELD servers. Both participants also used the web-based TryTEFCAViewer client developed by Skylight to demonstrate getting patient data and displaying it in a human readable format.

Screenshots











Discovered issues / questions (if there are any)

- All codes for each reportable condition need to be identified in standard value sets that can be called. (e.g. RCKMS/CSTE content repository reporting specifications, eRSD RCTC reportable condition trigger codes).
- Patient Match
 - Demographic data formats US Core standard capability statement
 - FHIR API specification vs. EHR FHIR Server implementation of FHIR API spec.
 Needs standardization across EHRs.
- Query sequence use case specific
 - o Ideal: for a given use case, make no change to application layer source code, but identify what terminology would be used in a pre-defined query for a particular use case. Example, if the use case is for a reportable condition (e.g. STI Chlamydia) we can setup the query for the set of conditions in a generalized way. Example, for Newborn Screening use cases, we can setup a query for the data and resources needed that may be different than a STI use cases.

· Now what?

- Populate the terminology database for the condition specific codes.
- TEFCA Queries fan-out for multiple EHRs to return patient data beyond a single EHR.
- More robust patient matching include additional parameters phone, address, race, ethnicity, MRN, other IDs...
- More realistic production like for EHR FHIR Sandboxes to test against
- Add the use of authentication and data access authorization

Links:

Helios Query & Response Track Page

<u>Helios Query & Response Zulip Stream</u>
Skylight Web Portal Query Tool "<u>TryTEFCA Viewer</u>" (Open Source)
Interoperability Institute <u>MELD Platform</u>

Imaging

- · What was the track trying to achieve?
 - Development and testing of Imaging ServiceRequest Profile IG
 - Further testing of DICOM SR to FHIR Observation IG
- List of participants (with logos if you have time and energy)
 - Array Corporation
 - Canon Medical
 - HL7 Japan
 - Philips
- Notable achievements
 - Imaging ServiceRequest
 - Identified interaction between IG actors
 - Initial draft of FHIR resources
 - Presentation on CloudPDI Image Exchange Using FHIR project in Japan
 - Demonstration of Philips DICOM SR to FHIR implementation and FHIRcast hub-to-hub syncing
- · Screenshots and/or links to further information
 - Cloud PDI presentation

cloudPDI — Image Exchange using FHIR

Department of Health Informatics, Kawasaki University of Medical Welfare
Member of the Science Council of Japan
Chair, HL7 Japan
Vice Chair, IHE-Japan

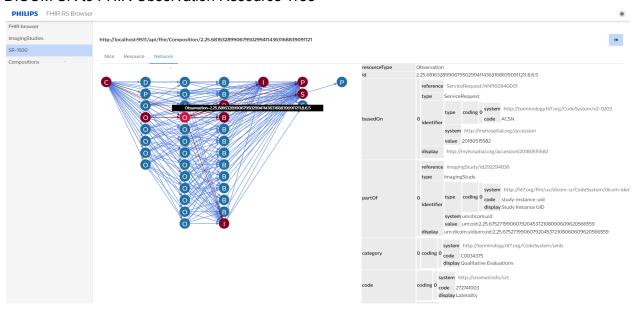
Michio Kimura

May 18, 2024

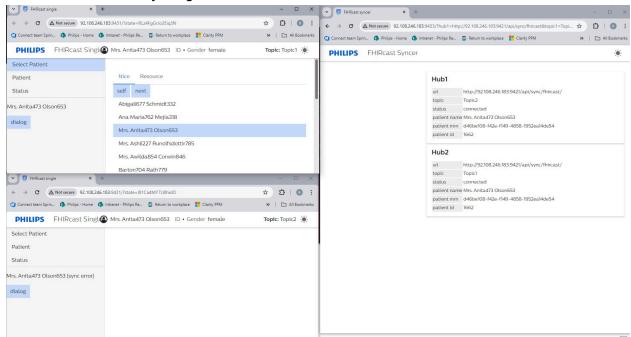
Michio Kimura M.D. Ph.D, FACMI, MSCJ. Kawasaki University of Medical Welfare

https://confluence.hl7.org/display/IMIN/cloudPDI+-+Image+Exchange+using+FHIR

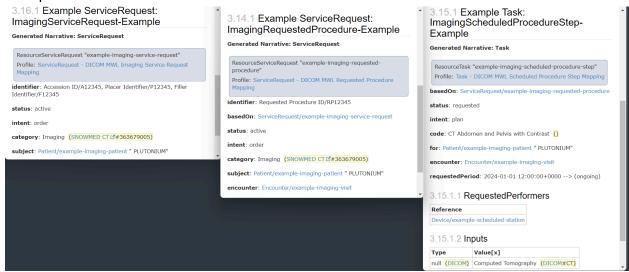
DICOM SR to FHIR Observation Resource Tree



FHIRcast hub-to-hub syncing:



 FHIR ImagingServiceRequest, RequestedProcedure and ScheduledProcedureStep examples:



- Discovered issues / questions (if there are any)
 - Interaction between ordering system and Modality Worklist service is best described by an operation
 - Ordering system may provide only a subset of information needed to support MWL query with MWL service filling in details
 - Once created, resource changes may be constrained by business logic and should not be altered freely. Operations can constrain the updates.
- · Now what?
 - Continue IG development
 - Explore turning cloud-based PDI into IG

Laboratory Report

What was the track trying to achieve?

The Laboratory Report FHIR IG track aims to engage implementers, and other stakeholders, working with FHIR-based representations of Laboratory Reports.

It uses as first reference the HL7 Europe FHIR Laboratory Report IG, but it is open to all implementers of FHIR Laboratory Reports and Laboratory Results wishing to share, discuss and analyze their implementations.

List of participants (with logos if you have time and energy)

Giorgio Cangioli HL7 Europe Alexander Henket HL7 NL Rob Hausam Hausam Consulting LLC Vassil Peytchev Epic Bret Heale Humanized Health Consulting LLC More people 'dropped in' for a quick question or update so their name was not specifically recorded.

Notable achievements

We added a Dutch example to the stack and used that as a basis for discussing the validation output which differs significantly from tool to tool.

We engaged on lifecycle issues. What's the expected behavior upon updated data at document level and below. This should lead us into updating the guide to explain that better We engaged in a discussion DiagnosticReport vs/or Composition. This was a discussion we have had at length before within the writers group, but probably needs more explanation for the broader community

Screenshots and/or links to further information

https://confluence.hl7.org/display/FHIR/2024+-+05+Laboratory+Report

Discovered issues / questions (if there are any)
 We found a bug in the specification for Patient.address and created <u>FHIR-45972</u> for a future fix.

Now what?

We resume work in the regular writers group, applying the feedback we gathered here and elsewhere.

Mental Health Care Team Orchestration

- What was the track trying to achieve?
 Continue implementation of care team orchestration of a Clinical Practice Guideline (CPG) for suicide risk identification and management using a combination of FHIR and Business Process Model and Notation (BPMN) and complementary process modeling standards.
- List of participants (with logos if you have time and energy)
 - BPM+ Health
 - Department of Veterans Affairs
 - Interoperability Institute
 - Smile Digital Health
 - Team of Care
 - Trisotech
- Notable achievements

- Successfully executed a shared process between 3 notional healthcare organizations and settings (ED, Inpatient hospital, outpatient therapy) in accordance with the Clinical Practice Guideline (CPG) for Suicide Risk Identification and Management from the VA.
- Interoperate between CPG on FHIR Implementation Guide and BPMN workflows via shared FHIR server.
- Agreed to develop an Implementation Guide subordinate to the FHIR Clinical Guidelines (CPG-on-FHIR) IG to exchange "state" and orchestrate the execution of a care plan being simultaneously executed using CPG on FHIR and BPMN.

Details of the implementation / execution:

- Developed a version of the Clinical Practice Guideline and scenario in CPG on FHIR.
- Developed two versions of the Clinical Practice Guideline and scenario in two BPMN systems.
- Established subscription-based workflow response and interaction via shared FHIR server access.
- o Developed and published FHIR resources via workflow automation systems.
- Consumed and responded to FHIR resources via workflow automation systems.
- Simulated EHR response and interaction via shared FHIR server access.
- Incorporated the following FHIR resources into a shared process:
 - Encounter
 - ServiceRequests
 - Communications
 - Observations
 - Appointments
 - Conditions
 - Questionnaire
 - QuestionnaireResponse
 - Update process state via FHIR resources
- User Experience / User Interface integration via web applications and SMART on FHIR standards.
- Tracked process status and state at each point in the scenario.
- Screenshots and/or links to further information.
 - https://vimeo.com/919789206?share=copy
 - This link is a talk-through demonstration of the process / scenario execution.
- Discovered issues / questions (if there are any)
 - The primary issue for the track was the need to gain a shared understanding of the respective standards and the capabilities of each: CPG on FHIR and BPMN.
- Now what?

- We are seeking to create a sub-IG to create an interface/API to exchange "state" between to running orchestration of a same care plan.
- A CPG on FHIR execution of the care plan and a BPM execution of the same care plan.
- A sub-IG that maps to BPM+ health notations could be a second phase of that project, but first phase is being able to exchange state status.
- The BPM community / track will review the concepts with the CDS Work Group to obtain input and direction about how to develop this subordinate IG.
- The track will transition from a focus on the specific clinical topic of mental health to a technical focus on "Automating Clinical Practice Guidelines." We expect to perform projects and sprints relating to specific clinical needs as an important step in testing the practical application of important use cases, such as identification and treatment of mental health.

International Patient Summary

IPS Track Report Out

What was the track trying to achieve?

Several goals were associated with the May 2024 IPS Track

- 1. Work on new sections of the IPS and sections needing additional guidance.
- 2. Create and integrated guidance on emptyReason
- 3. Testing of \$summary operation
- 4. Usage of IPS validation
- 5. Testing of FHIR servers
- 6. Coordination with IPA
- 7. Advancement of SMART Health Cards/Links Ballot

List of participants (with logos if you have time and energy)

John D'Amore, US (Co-Lead)
Rob Hausam, US (Co-Lead)
Peter Jordan, NZ (HL7 New Zealand)
John Carter, NZ (HL7 New Zealand)
Nikolai Ryzhikov, PT (Health Samurai)
Pavel Smirnov, PT (Health Samurai)
Bill Lober, US (State of Washington DoH)
Justin McRenyolds, US (State of Washington DoH)
Dan Lorigan, US (State of Washington DoH)
Andrew Liu, CA Canada Health Infoway
James Jahn, US Epic

Isaac Vetter, US Epic Vassil Peytchev, US Epic Rasid US Epic Allana Cameron, CA Health Infoway Martin Kaye, CA VeroSource Pat Kerry, CA VeroSource Ivana Marzura, CA Verto Darren, Liu, CA Verto Samuel Zhou, CA Verto Yifei Yin, CA Verto James Agnew, CA Smile Digital Health Mark Roberts, US Leavitt Partners Ken Sinn, CA Health Infoway Stephen Chu, AU, Australian Institute of Digital Health Agency, Josh Mandel, US, SMART Bret Heale, US Humanized Health Consulting Matt Rahn, US Office of the National Coordinator for Health IT Brett Marquard, US Wave One Associates Blanda Helena de Mello, BR Ministry of Health

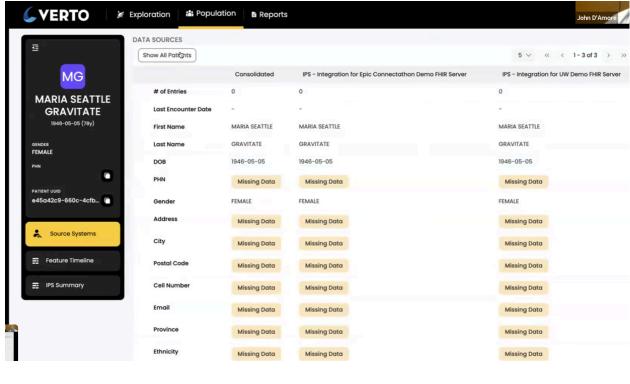
Screenshots and/or links to further information

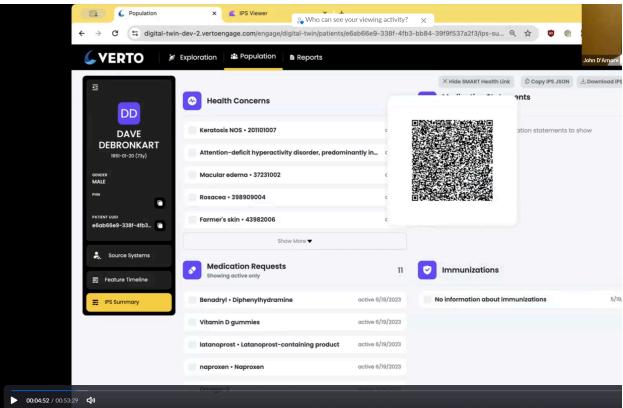
Italo Macedo, BR Ministry of Health

IPS Demonstrations



Verto Demo



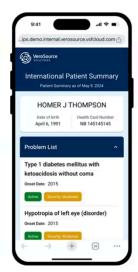


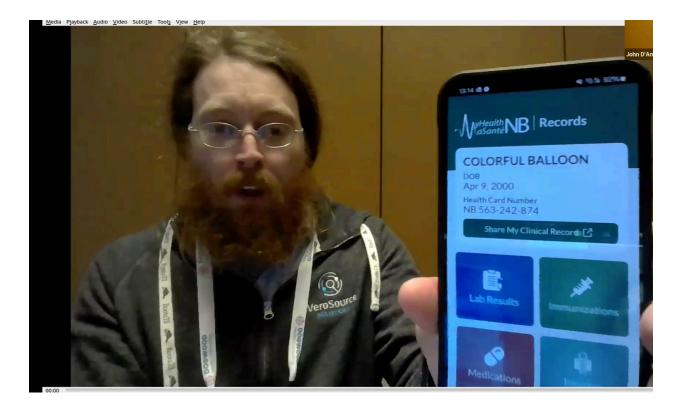
VeroSource Demo

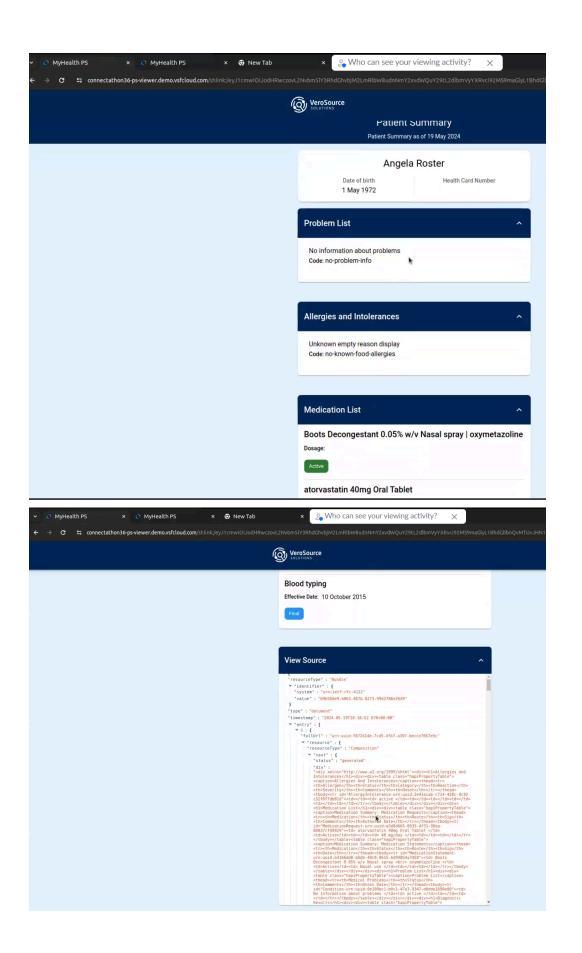
International Patient Summary (IPS)

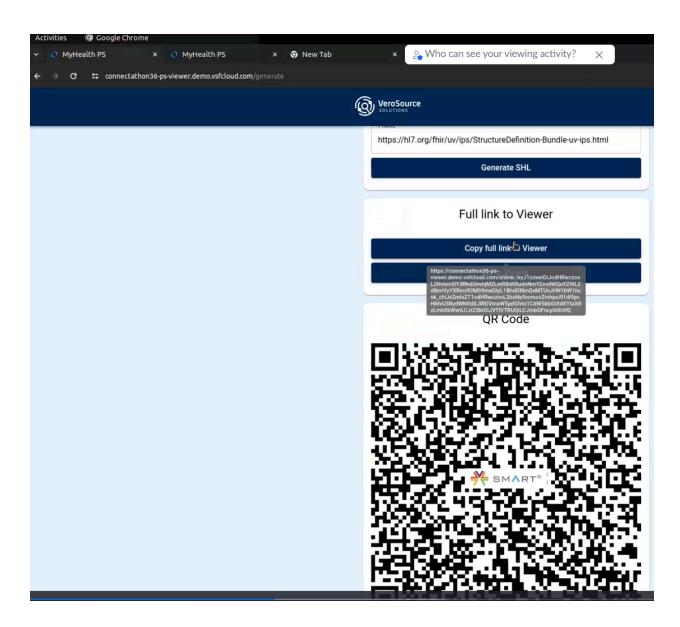
- Focused on patient mediated sharing of personal health data
- Implementing Pan Canadian (PS-CA) specification of IPS
- Adding Patient Summary sharing functionality to our VeroSource MyHealth app
- Includes Patient Summary Generation, Smart Health Links with QR Code, and Patient Summary Viewer



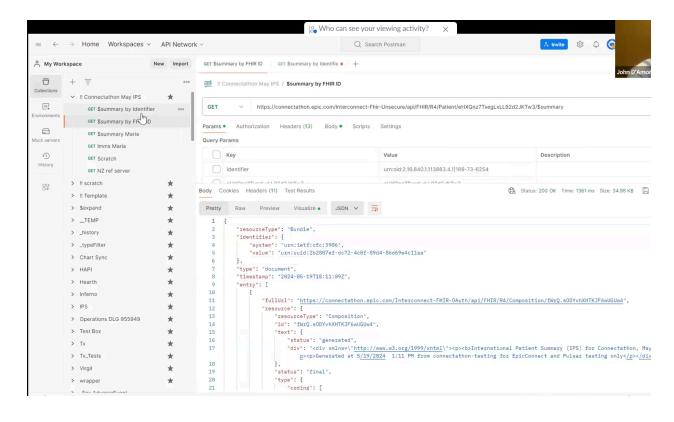


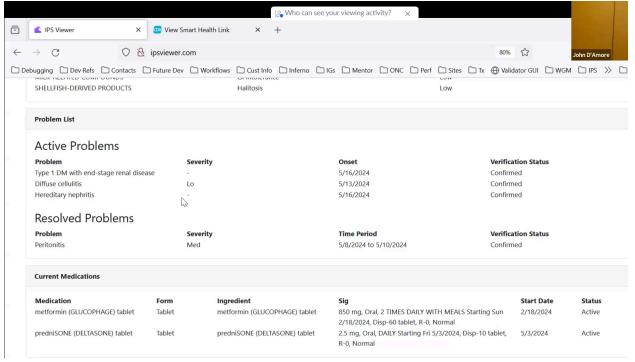






Epic Demo



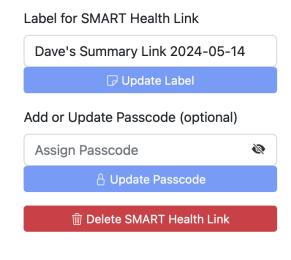


SMART Health Link Discussion



^^ this means the link is "open"
^^ this means the link requires more to view
(such as a password, or user login, etc.





Notable achievements

- 1. Held breakout sessions on:
 - a. SMART Health Links Layout/Template Guidance (impromptu)
 - b. PACIO<>IPS Advance Directive Discussion (impromptu)
 - c. IPS/IPA updates
 - d. Demo IPS Example Generation (HAPI server)
 - e. IPS Demo by Verto, Verosource, Epic and Health Samurai
 - f. SMART Health Links IG Review
- 2. Progress on validation issues
 - a. Fixed errors Verto, Verosource, Epic, Brazil MoH, NZ examples
 - b. Jira FHIR-45979 Fix example bundle reference errors
 - c. New 5+ samples loaded into connectathon folder
 - d. Researched issues around CVX terminology (NZ sample)
 - e. Debug issues around ID usage of UUID reference (narrativeLink)
- 3. Demo
 - a. Verto
 - b. VeroSource
 - c. Epic

Discovered issues / questions (if there are any)

- 1. Inadvertently had constrained out Bundle.link in the IPS Bundle profile
 - a. Jira FHIR-45973 Remove IPS Bundle.link 0..0 constraint
- 2. Slicing potentially can be used on Bundle for Observation type (see chat.fhir.org)

Now what?

- 1. Continue to work on preparing of IPS 2.0 submission for September ballot
 - a. Sending "empty" sections allowed (must use emptyReason)
 - i Add & revised sections to IPS
 - ii. Add Alerts Section
 - iii. Add Patient Story Section
 - iv. Other sections under evaluation
 - b. Revise resources in Advance Directive
 - c. Clarifications on the \$summary operation
 - d. Rework of Observation profiles
 - e. Additional narrative guidance proposed
- 2. Investigating solutions for overlapping Observation profile validation errors/warnings
- 3. Additional sample on emptyReason (not completed during connectathon)
- Additional sample where Consent only used for "who" in advance directive section and also to include DocumentReference

NHSN dQM Reporting

- What was the track trying to achieve?
 - This track will tested the NHSN dQM Reporting implementation guide, including a) extracting relevant data from EHRs, b) evaluating those data against one or more sample NHSN measures, and c) reporting the results to a test NHSN server for further analytics.
- List of participants (with logos if you have time and energy)
 - Rick Geimer, Lantana (track lead)
 - o Adam Philips, Lantana
 - Siranush Abajyan, Lantana
 - o Daniel Vargas, Lantana
 - Heath Dinkins, Leidos (NHSN contractor)
 - Jennifer Watkins, CACI (NHSN contractor)
 - o Cooper Thompson, Epic
- Notable achievements

o Lantana

- Successfully generated an NHSN dQM report against the public HAPI FHIR server
- Successfully generated an NHSN dQM report againt the NHSN connectation FHIR server
- Successfully generated an NHSN dQM report against the Epic connectation FHIR server
- Successfully generated an NHSN dQM report against the public Cerner FHIR server

Epic

- Several test patients were made available on our test server.
- Options for different exchange methods were discussed. The current pilot uses a periodic RESTfull polling approach. We discussed moving to a more event-based model, where we send a notification on discharge, which triggers the RESTful query.

NHSN

- Successfully
 - hosted the NHSN FHIR Server
 - queried NHSN FHIR Server to pull Connectathon Bundle (1442) in ADF
 - passed bundle to Databricks for parsing
 - parsed FHIR bundle using the Python IgniteDB library
 - added bundle to a DataFrame in Databricks
 - added DataFrame Patient data to Delta Lake table
- In-progress
 - flatten patient records into a Delta Lake more cleanly
 - process matching rule to generate an EMPI Global Patient ID
 - update patient Delta Lake records with EMPI Global Patient ID
- Screenshots and/or links to further information
 - https://build.fhir.org/ig/HL7/nhsn-dqm/
 - o https://chat.fhir.org/#narrow/stream/433659-NHSN-dQM-IG
- Discovered issues / questions (if there are any)
 - Noted issues with some profiles in the IG (requiring fields not called out in US Core, thus not typically found in EHRs)
- Now what?
 - Update IG based on Connectathon feedback
 - Discuss during Thursday Q4 CQI/PH joint session
 - Target Sept 2024 ballot

Ophthalmology

- What was the track trying to achieve?
- List of participants (with logos if you have time and energy)
- · Notable achievements
- Screenshots and/or links to further information.
- Discovered issues / guestions (if there are any)
- · Now what?

PACIO Advance Directive Interoperability (ADI)

What was the track trying to achieve?

Seamless create, update, share, query/retrieve, verify current version of ADI, both structured and unstructured documents. Focus was on metadata enhancements to STU1, based on real-world use of the IG, so only the Personal Advance Care Plan was structured, while the Advance Directive, Portable Medical Order (PMO) and Mental Health/Psychiatric Advance Directives (MHADs/PADs) were unstructured so as to meet the industry where they are. The sharing was demonstrated among the patient, healthcare agent, national registry & repository, and provider E.H.R.s which reflect the patient's most recent ADI document versions to ensure that the current expression of care and treatment preferences would inform care, should the patient become incapacitated or unable to interact with the care team to participate in decision-making.

List of participants

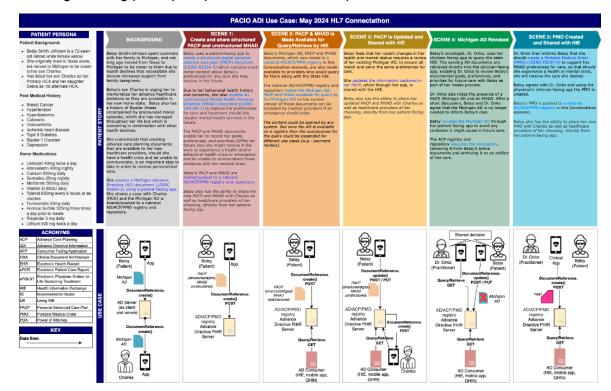
MyDirectives
MyDirectives for Clinicians
ADVault Exchange
Washington State Department of Health
Pie Connect Health
MITRE Corporation

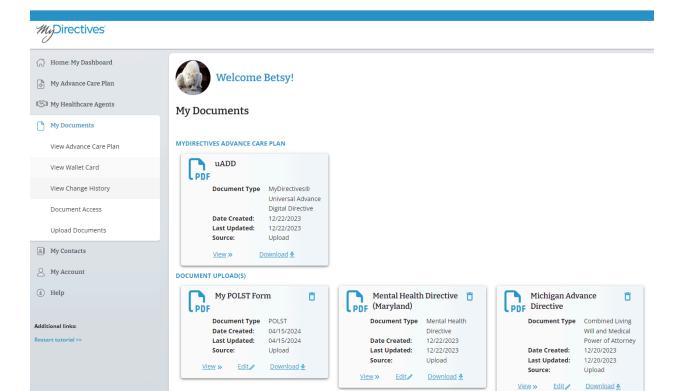


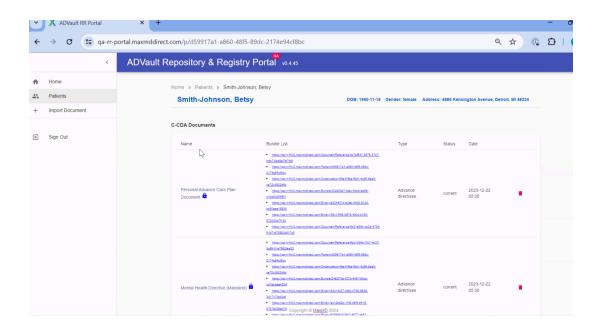
Notable achievements

- •Successfully exchanged advance directive documents of various types between ADI creators, registry, and ADI consumers.
- •Cross-project discussion with Int'l Patient Summary (IPS) team on representing the ADI section.
- · Screenshots and/or links to further information

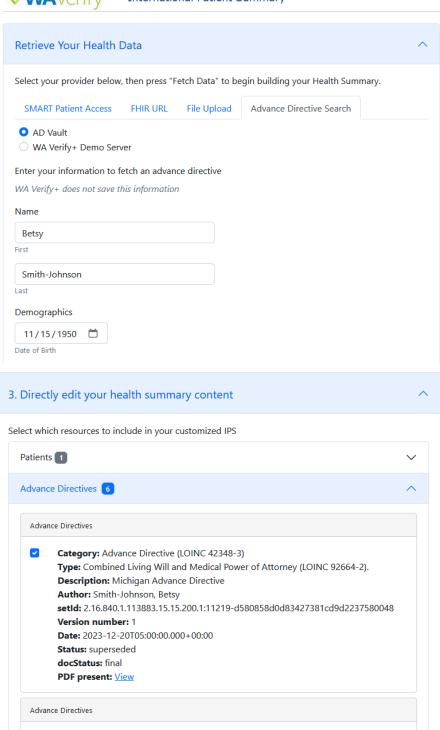
The following use case scenarios were successfully demonstrated with real-time data exchange among participant provided reference implementations:





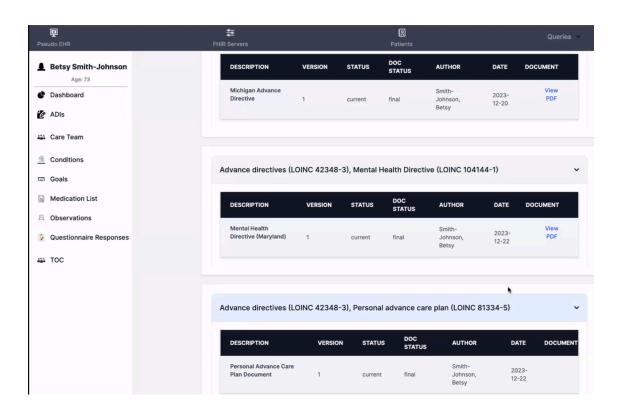


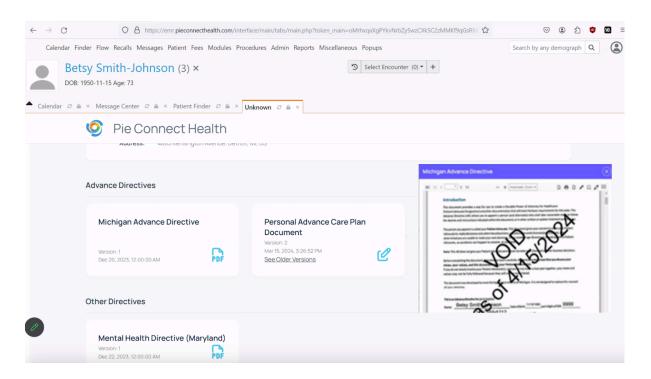


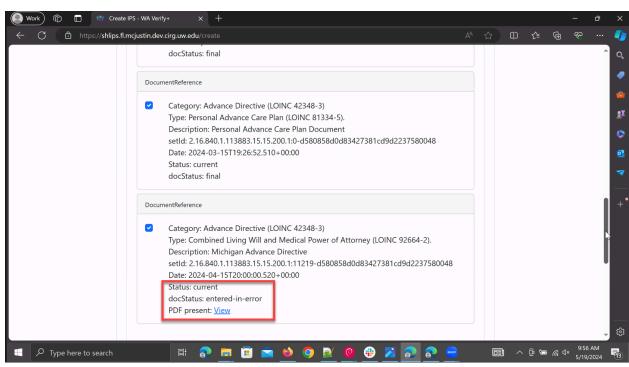


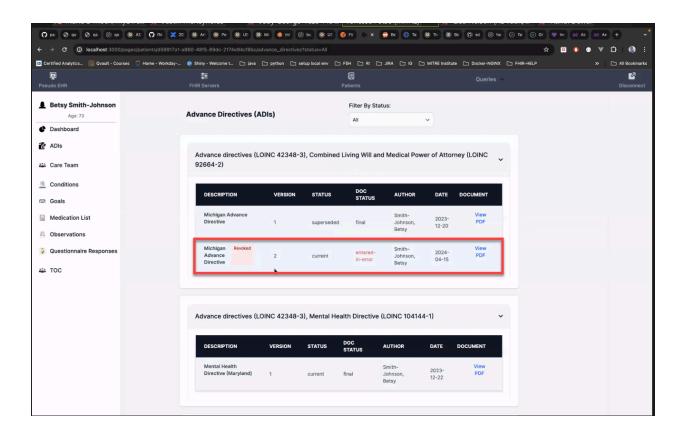
Category: Advance Directive (LOINC 42348-3)

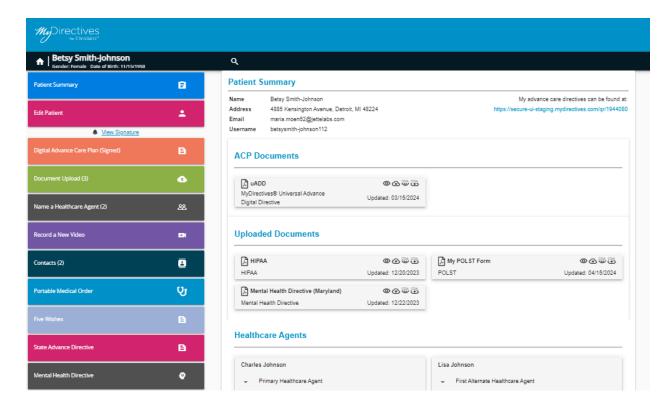












Discovered issues / questions (if there are any)

IG Narrative Change Requests:

- -Explain analogy of DocumentReference like a Dewey decimal system.
- -Clarification on AD document version version is not the FHIR id version in meta.version id but it is a document version that is created by the custodian/registry.

IG Profiling Change Requests:

- DocumentReference for signature pages should have a type and category.
- Constrain DocumentReference type for advance directive.
- Revoke use case:
 - specify DocumentReference replaces to include prior versions
 - may need to explain that revoke actually creates a new "document" that carries the revoke status, with the prior showing superseded.
 - Current CDA and FHIR R4 document status values are not aligned, nor are the FHIR R4 document status values sufficient to support the Revoked Use Case

Other:

 Work with other stakeholders (e.g.: CMS, Da Vinci, HL7 Financial Mgt Working Group) on how ADI can be extended to other FHIR resources and IGs (e.g.: Da Vinci CDex and DTR).

Now What?

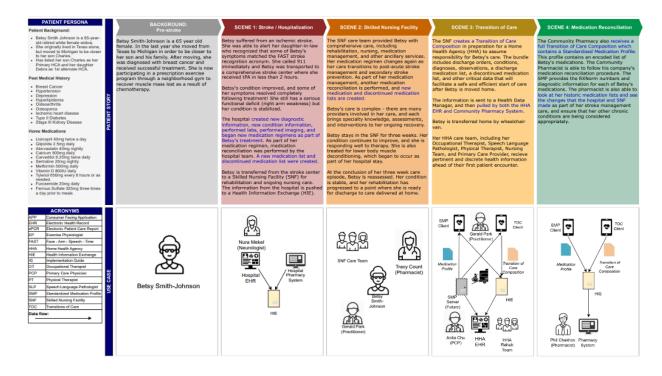
- Enter JIRA tickets for all change requests.
- Modify the ADI STU2 narrative with requested clarifications.
- Follow-up with Structured Documents on handling the DocumentReference docStatus for the Revoke use case.
- Explore extended use of advance directives for sending additional documents to the payer and other providers.
- Planning for CMS Connectathon in July 2024 which will expand the use case to send structured PMO documents.

PACIO Transitions of Care and Standard Medication Profile

What was the track trying to achieve?

Track will test the Transitions of Care (TOC) and Standardized Medication Profile (SMP) IGs through the following scenario in preparation for a STU1 version of the standard: transfer

diagnoses, conditions, medications, orders, and single observation information from a Skilled Nursing Facility (SNF) to a Home Health Agency (HHA) for a post-stroke patient.



List of participants (with logos if you have time and energy)





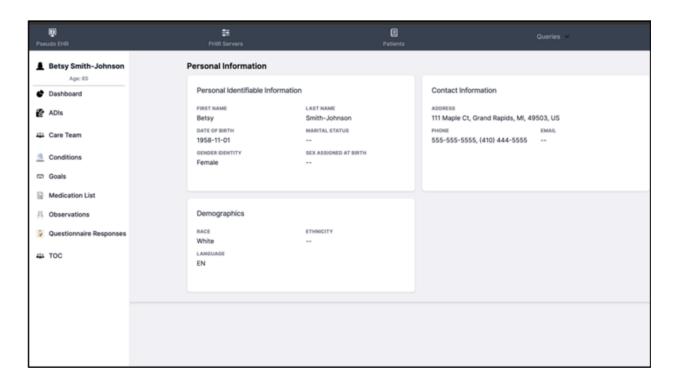


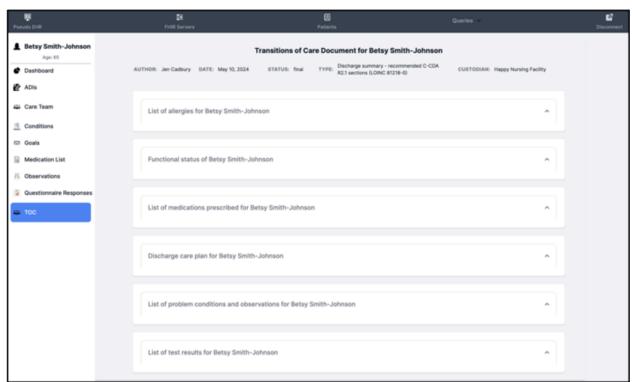
Notable achievements

- Successfully created test data.
- Retrieval and display of created test data is working fine in simple applications.

Screenshots and/or links to further information

MITRE Pseudo EHR





ist of allergies for Betsy Smith-Joh	nson				
Classification: LOINC 48765-2 Allergy Intolerance					
CODE	CATEGORY	CRITICALITY	ASSERTER	LAST OCCURENCE	REACTIONS
Substance with angiotensin- converting enzyme inhibitor mechanism of action (substance) (372733002)	medication	High	Betsy Smith- Johnson	2011-10	Substance: captopril 12.5 MG Oral Tablet (308963) Manifestation: Hyperkalemia caused by angiotensin-converting enzyme inhibitor (disorder) (SNOMED 427195008)

lassification: LOIN	C 54522-8						
Observations							
CODE	EFFECTIVE	CATEGORY	DOMAIN	PERFORMER	VALUE	MEMBERS	EVENT LOCATION
MDS v3.0 - RAI v1.18.11 - Nursing home discharge (ND) item set during assessment period [CMS Assessment] (101107-1)	May 16, 2024	Survey & Functioning	Self-care (blockl2- d51)	Jen Cadbury		Observation/BSJ-MDS-Donning1 Observation/BSJ-MDS-Doffing1	Happy Nursing Facility
Upper body dressing - functional goal during assessment period [CMS Assessment] (89387-5)	May 16, 2024	Survey & Functioning	Taking Off Clothes (d5401)	Jen Cadbury	Dependent - Helper does all of the effort. Resident does none of the effort to complete the activity. Or, the assistance of 2 or more helpers is required for the resident to complete the activity. (I_A27998-6)	No members	Happy Nursing Facility
Lower body dressing - functional goal during assessment period [CMS Assessment] (89406-3)	May 16, 2024	Survey & Functioning	Putting On Clothes (d5400)	Jen Cadbury	Dependent - Helper does all of the effort. Resident does none of the effort to complete the activity. Or, the assistance of 2 or more helpers is required for the resident to complete the activity. (I.A27998-6)	No members	Happy Nursing Facility
MDS v3.0 - RAI v1.18.11 - Nursing home discharge (ND) item set during assessment period [CMS Assessment]	May 16, 2024	Survey & Functioning	Mobility (blockl2- d41)	Jen Cadbury		Observation/BSJ-MDS-ShortWalk1 Observation/BSJ-MDS-SitStand1 Observation/BSJ-MDS-SitUp1	Happy Nursing Facility

Classification: LOINC 74449-0

Care Plan

ntent: plan

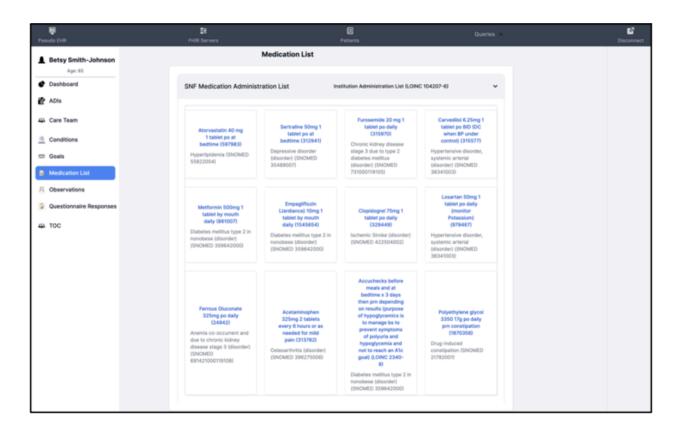
Category: 736055001, Assess Plan

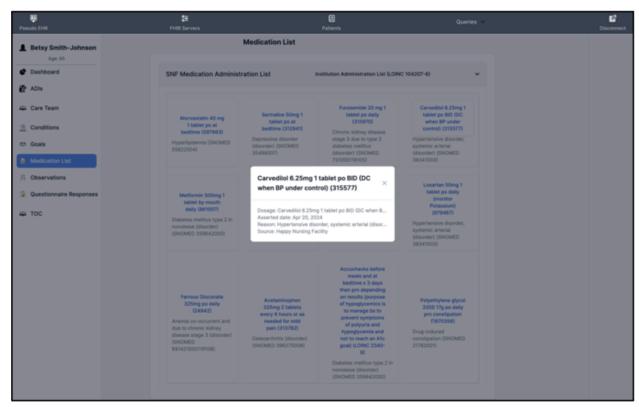
Service Requests

REQUEST	STATUS	INTENT	CATEGORY	PRIORITY	OCCURENCE	AUTHORED ON	REQUESTER
Follow-up visit (procedure) (SNOMED 185389009)	active	order	Evaluation procedure (procedure)	routine	May 28, 2024	May 18, 2024	Gerald Park
Informing doctor (procedure) (SNOMED 304562007)	active	order	Evaluation procedure (procedure)	routine		May 18, 2024	Gerald Park
Occupational therapy assessment (procedure) (SNOMED 410155007)	active	order	Evaluation procedure (procedure)	routine		May 18, 2024	Gerald Park
Speech therapy assessment (procedure) (SNOMED 410161005)	active	order	Evaluation procedure (procedure)	routine		May 18, 2024	Gerald Park
Decreased protein and/or protein derivative diet (regime/therapy) (SNOMED 1055201009)	active	order	Dietary regime (regime/therapy)	routine		May 18, 2024	Gerald Park
Decreased sodium diet (regime/therapy) (SNOMED 437421000124105)	active	order	Dietary regime (regime/therapy)	routine		May 18, 2024	Gerald Park
Blood chemistry (procedure) (SNOMED 166312007)	active	order	Laboratory procedure	routine	May 28, 2024	May 18, 2024	Gerald Park
Complete blood count without differential (procedure) (SNOMED	active	order	Laboratory procedure	routine	May 28, 2024	May 18, 2024	Gerald Park

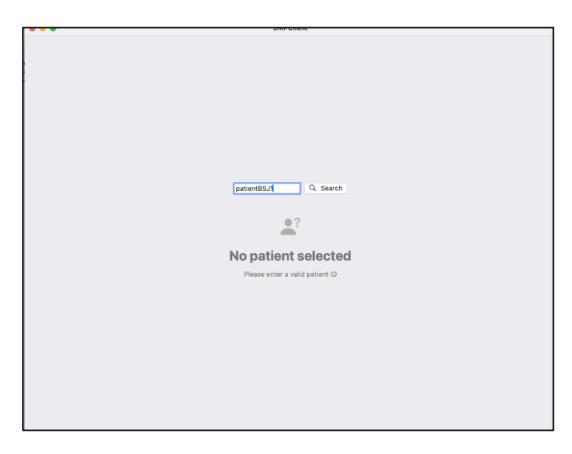
ssification: LOINC 18	3776-5					
conditions						
CODE	CATEGORY	ONSET/RECORDED/ASSERTED DATE	ASSERTER	BODY SITE	NOTE	EVIDENCES
Anemia co- occurrent and due to chronic kidney disease stage 3 (disorder) (691421000119108)	Functions related to the digestive system, other specified and unspecified (b539), Encounter Diagnosis (encounter- diagnosis), encounter- diagnosis	Apr 23, 2024		Structure of cardiovascular system (body structure) (SNOMED 113257007)	See lab	
rug-induced onstipation disorder) 21782001)	Frequency of defecation (b5252), Encounter Diagnosis (encounter- diagnosis), encounter- diagnosis		Dr. Anita Chu	Colon structure (body structure) (SNOMED 71854001)		
Depressive disorder disorder) 35489007)	Emotional functions (b152), Encounter Diagnosis (encounter- diagnosis), encounter- diagnosis		-	Brain structure (body structure) (SNOMED 12738006)		

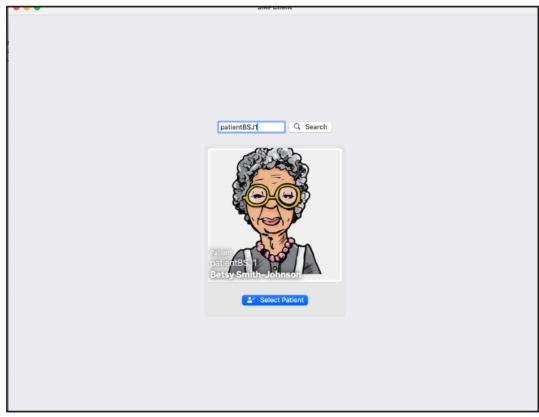
Carbohydrate

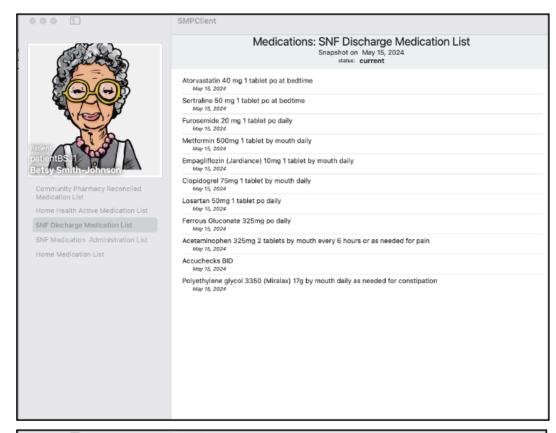


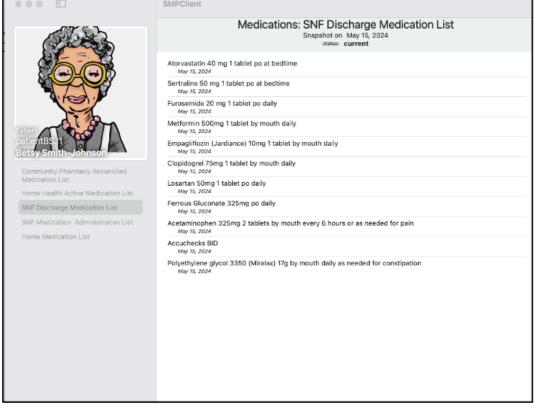


Standardized Medication Profile Reference Implementation









Discovered issues / questions (if there are any)

- Clarify that the TOC and SMP IGs encompass and expand upon the current discharge paperwork shared between providers after a visit.
 - TOC/SMP IGs are the minimum set of codes and data elements a new facility would require to
 - Accept a new patient
 - Prepare for treatment of a new patient
 - Provide treatment to a new patient

Now What?

- Continue testing and validating clinical data requirements.
- Involve multiple servers during a Connectathon to replicate real-world scenarios.
- Incorporate richer, more complex data to replicate real world scenarios.
- Continue updating and refining TOC and SMP IGs as necessary with learnings.

Questionnaires and SDC

- What was the track trying to achieve?
- List of participants (with logos if you have time and energy)
- Notable achievements
- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)
- Now what?

Standard Personal Health Record (SPHR)

What was the track trying to achieve?

We went into this Connectathon with modest expectations, and with a primary intent of supporting the Goal Oriented Care Track and doing another round of testing to prepare the Implementation Guide for a Notification of Intent to Ballot (NIB). We continue to have an open-office style "Bring Your Own Health Record" format, where patients and caregivers can bring medical records and health records to discuss the data they are able to receive, and how things could be improved.

List of participants (with logos if you have time and energy)

James Cummings
Abigail Watson (MITRE)
Dan Gottleib (SMART Health IT)
Josh Mandel
Rashid (Epic)

Goal Oriented CarePlan Participants

- Notable achievements
 - Created a .phr file of the Martha DeLarosa sample patient, using NDJSON format. We wanted to make sure we had a International Patient Summary example in the SPHR implementation guide. Attaching it for anybody who is interested.

MarthaDeLarosa-7685713c-e29e-4a75-8a90-45be7ba3be94.phr

Also created .phr files from the PACIO ADI implementation guides

Roger-McBee.phr Roger-McBee.Bundle.json Betsy-Smith-Johnson.phr Betsy-Smith-Johnson.Bundle.json

- 2. This connectathon, we gave focused attention to a complex rare-disease pediatric case file, with medical records spread across a half-dozen hospitals, totalling 10,000+ pages of PDFs. With the health of SMART Health IT, we deployed a copy of Procure WIP to Cloudflare, registered it with Epic on FHIR, and deployed to production. We fetched 1000+ FHIR resources from 3 hospitals, and then assembled them into a .PHR file. Lastly, we stringified the contents of the resources and put a clinical text normal form copy of the record into the Resource.text.div field; and assembled those stringified representations into a clinical summary. With remaining time, we are looking at the 8192 API token limit, and crafting a copy of the clinical summary that can be used with LLM to query/investigate treatment protocols, clinical trials, careplanning, etc.
- Screenshots and/or links to further information In progress
- Discovered issues / questions (if there are any)
 - Lack of error messages with Epic systems
 - 24 hour deployment with Epic systems
 - Procure-WIP' mechanism for updating Cerner endpoints isn't automated?
 - Procure-WIP' support for R4 on Cerner systems?
 - Procure-WIP doesn't support UDAP (yet)
 - Need to de-duplicate Patient resource records
 - Some Conditions and Procedures may have been double-entered between medical systems

- DocumentReferences point to PDFs, which need to be resolved and fetched; then OCRed?
- 100MBs of data in PDFs vs ~1MB of data via FHIR. Is there simply 99MB of overhead in PDFs? Was data left out? If so, which data?Where to store post-processed files?
- Can we create a data processing pipeline for 21st Century Cures that doesn't require storing PHI along the way?
- 8192 token limit for medical record summaries when querying ChatGPT via API

Now what?

- Procure-WIP does have a TEFCA-style provider directory (good)
- Locate latest list of Cerner endpoints.
- Incorporate PHR artifacts into implementation guide.
- Document IPS and PACIO ADI support in implementation guide.
- Add IPS and PACIO ADI tooling to reference app.
- Document Procure-WIP installation instructures, and add to implementation guide so patients can fetch their own records.
- Create public utility for adding clinical text normal form to FHIR records, and prepping for language model analysis. (Bring Your Own OpenAl API Key)
- Create ChatGPT instance for summarizing medical records?
- Compare/contrast records pulled from Epic vs Cerner (Boton Children's Hospital goes live in June 2024)
- Compare/contrast data in PDFs versus what data was received via FHIR API.
- Upgrade Diamond Blackfan Anemia Registry to be FHIR compliant.
- Send to Health Registry for storage and analysis.
- Add DICOM images to SPHR folder
- FILE NEW RESOURCES FOR R6 Baseline, FinancialReceipt, Environment, Bodylnventory / Dermatogram

Terminology Change Set Exchange

What was the track trying to achieve?

Test the exchange of incremental terminology revisions (change sets), including their underlying semantics, between disparate entities. It utilizes primarily the CodeSystem resource supported by Provenance resources.

List of participants (with logos if you have time and energy)





Name	Organization	
Jess Bota	Apelon	
Andrew Sills	Deloitte Consulting LLP	
Jieun Rim	Deloitte Consulting LLP	
Lauren Cleaver	Deloitte Consulting LLP	
Raja Cholan	Deloitte Consulting LLP	
Russell Ott	Deloitte Consulting LLP	
Keith Campbell	FDA / VA	
Jon Payne	Open Concept Lab	
Sivaram Arabandi	Optum	
Vijay Raj	Optum	
Joe Amlung	Regenstrief	
Jeff Miller	Safe Health Systems, Inc	
Ravinder Singh	Safe Health Systems, Inc	
Rueben Daniels	Saludax	
Marti Velezis	Sonrisa/FDA	
David Rocha	UTHealth Houston	

Notable achievements

We demonstrated the live extension of SNOMED CT concepts and distribution as a Terminology Change Set compliant to with the IG Profiles, and usage of those change sets by a Forms platform to update local terminology references

We held a robust breakout session discussion related to native distribution of Terminologies in a FHIR format with the following decisions:

- 1) Nikolai Ryzhikov and Josh Mandel can start and maintain a community project to address this issue, potentially under FHIR.org, and where IP restrictions prevent directly hosting a FHIR representation of a given terminology, the intent would be to post transform tools that could be used in combination with source files from the appropriate terminology authority to obtain a FHIR representation.
- 2) We discussed the possibility of a "Concept" resource, which would help with performance issues related to distribution of large CodeSystem resources, and more robust Concept modelling/versioning. A resource proposal may be authored and brought to the Terminology Infrastructure Work Group for approval.

Screenshots and/or links to further information

Broader use case involving Change Set Exchange: May 2024 Connectathon Storyboard

Discovered issues / questions (if there are any)

- Unclear if it's reasonable to expect a "Change Set" to apply at the global level to CodeSystem attributes (allowable properties, etc.) or if it can only contain changes to concepts
- 2. Need more clarity on the anticipated usage of a Change Set by a retrieving client. (e.g. is it expected to persist this CodeSystem as a separate object from the source CodeSystem to which it applies, or directly incorporate it in an updated definition for that source CodeSystem)
- 3. Would benefit from more specific intended use cases, including descriptions of what these profiles are not expected to be used for. (e.g., can it include a chance to a CodeSystem's hierarchy?)
- 4. Consider how operations would need to change in the presence of Change Sets would a \$lookup first need to check the Change Set resource for that code, and if it doesn't exist in the Change Set, then check the CodeSystem?
- 5. What is the best way to convey the contents of the change set what differences are reflected in this change set?

Now what?

- 1. Further evolution of the guide anticipating another track at Sep 2024 Connectathon
- 2. Add "breadcrumbs" to authoring policies for various Terminologies
- 3. Guidance for utilizing URIs for identifying localized
- 4. Approach to managing/identifying versions when Change Sets have been applied beyond baseline versions of Terminologies (e.g., How do you identify LOINC 2.77 that has had a Change Set applied to it?)
- 5. Consider use of Task to formalize a request for a Change Set

Testing - Measure the Impact of US Core Version Differences

What was the track trying to achieve?

Discuss process used in testing the US Core 3.1.1 to 6.1.0 intra-version exchange. Answer the "what was tested and how?"

- List of participants (with logos if you have time and energy)
- Notable achievements

While there were a couple discussions at the table there was no targeted focus on intra-version testing.

- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)

IG authors across US realm are evaluating US Core to determine strategy for upgrades to the national IGs. As IGs are not published with US Core 6.1.1 there are no development systems ready for testing.

Now what?

Continue to engage the community, IG authors, implementers to talk through and test handling versioning and measuring impact of systems that expect resources conformant to one version and receive resources conformant to another.

Focus at next track session to identify testers with implemented US Core 3.1.1 and US Core 6.1.0 so that intra-version testing can be facilitated.

Vulcan - UDP

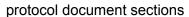
What was the track trying to achieve?

This is the first of a series of Connectathons. This first iteration will look at a document centric approach. Objectives:

1. Transfer of a clinical trial protocol from sponsor to regulator according to the development being done by ICH M11/M2, CDISC and TransCelerate.

2. Look looked at use of profiles of a composition resource to enable transfer of

- Brian Alper, Computable Publishing
- Matt Elrod, ONC
- Hugh Glover, Vulcan TRACK LEAD
- Dave Iberson-Hurst, CDISC
- Dan Newingham, ZS Associates
- Jimita Parekh, Vulcan
- Khalid Shahin, Computable Publishing
- Rik Smithies, HL7 UK
- Kimberly Tableman, Espero
- Panagiotis Telonis, Vulcan, ICH M2 Topic Lead, EMA
- Stacy Tegan, Vulcan, TransCelerate



3. Build experience and test implementation guidance

Participants

Notable achievements

- Exercised tools from participants to create sets of data and load to the server using multiple tools as identified in the drawing below
- Had 6 sample protocols created and in FHIR format
- Identified issues with server configuration
- Extensions made to Vhewer (generic FHIR viewer)

Screenshots and/or links to further information

Discovered issues / questions (if there are any)

- Made changes to the server configuration particularly to allow submission of resources up to 10MB in size. The large size is due to embedded image files.
- Identified subtle issues with server handling of HTML blocks investigation is ongoing
- Issue around how the profile represents sections, particularly where user may add additional subsections, use of optional subsections

Now what?

- Continue to pursue issues identified as a priority (preferably by end of May)
- Public Webinar 11 July 2024 to raise awareness of progress to date (including outcomes of this Connectathon)
- Determine scope/goals for September Connectation. Under consideration:
 - Inclusion/Exclusion











- Structured title page (highest-level protocol metadata)
- Expand vendor participation
- Early thinking on 2025 Connectathon Topics: SoA, Mapping to data capture tools, utilization of ODM

Questionnaire

What was the track trying to achieve?

The goal of the track was to continue testing implementation of the Structured Data Capture (SDC) implementation guide which all provides guidance on how to define and complete questionnaires in healthcare, including the ability to automatically populate forms and the ability to extract resource information from completed forms.

List of participants (with logos if you have time and energy)

- Thomas Debertshäuser (Charite Berlin)
- Paul Lynch (NLM, track co-lead)
- Brian Postlethwaite (Microsoft, track co-lead)
- Lloyd McKenzie (Dogwood; honorary track co-lead)

Notable achievements

- Thomas brought three issues that were blockers for using LHC-Forms, including support for the observation-extract-category extension.
- Paul implemented support for observation-extract-category in LHC-Forms.
- Brian worked on pre-population in his Questionnaire/renderer testing tools in https://fhirpath-lab.com to add in pre-populate testing (Iforms/csiro/forms-lab engines) and enhancements to roundtrip between the CSIRO and NLM forms renderers
- A breakout session was held for demos of Questionnaire tools, including the NLM Questionnaire tools, Health Samurai's Questionnaire tools, and new features in the FHIRPath Lab.

Screenshots and/or links to further information

Discovered issues / questions (if there are any)

• Through Brian's work on the FHIRPath lab, some issues were found in implementations.

Now what?

Implementers will continue to make progress on the features in the Structured Data Capture IG.

Vulcan/ Gravitate Health - ePI/IPS and UNICOM/GIDWG

What was the track trying to achieve?

The aim of this track, the 8th in a sequence of a multiyear effort, is to test the creation, exchange and display of electronic Product information (ePI) in connection to the International Patient Summary (IPS) and IDMP.

This track is part of the HL7 Vulcan Accelerator supported by the Innovative Medicines Initiative (IMI) Gravitate-Health Project, the EU funded UNICOM project, WHO/UMC, EMA, and FDA. Thus, aligns with the European Medicines Agency's ePI pilot project, FDA's SPL-to-FHIR project, EMA's SPOR, and the Global IDMP Working Group (GIDWG) initiative on End-to-End use cases.

Standards development is supported by the HL7 BR&R working group.

Track Objectives are to test and gather feedback on the following:

- 1. ePI Governance: Define joint profiles and governance model between EMA, Gravitate Health and Vulcan
- 2. ePI style sheet: Create and test a final draft of a default style sheet for ePIs
- 3. ePI Capability: Define basic API functionality requirements
- 4. Connectation Roadmap: Define objectives for the next 4 connectations (including IDMP testing)
- 5. PhPID IG: language
- 6. ANVISA: Incorporate Brazilian scenarios and data into ePI and IDMP testing

List of participants





Notable achievements

Topic #1(a): ePI Governance

- 1. Proposal: EMA and Gravitate Health/Vulcan to co-lead governance of the UV ePI IG and profile.
 - a. ePI Type 1 is aligned between Vulcan and EMA.
 - b. Vulcan ePI IG is the parent/global profile. Child implementations or IGs will inherit common aspect from the global IG
 - c. ACTION: Panagiotis and Libby to obtain official endorsement from EMA leadership
- 2. Proposal: clarify roadmap activities to achieve specific goals by June 2026; e.g., focus on developing the capability to convert essential products list to FHIR

Topic #1(b): Define joint ePI profiles between EMA and Vulcan

Profile gap analysis EMA samples vs Vulcan ePI IG

- List Resource identifier is the SetID
- Bundle Document resource identifier is the document version id
- Each language is a separate document
- List tracks all document types, all versions and all languages for a given medicinal product
- Bundle.composition.language mandatory in the profile

Updated ePI Definitions

Collection Bundle: The Bundle of type Collection is used to submit a package of resources to a regulator. The Collection can contain a List and one or more Document Bundles. E.g., a Collection is used to package and submit a List, SmPC and PIL for a given product.

List: The List is used as an index to track the lifecycle of all ePI documents related to a given product. E.g., the List will track all versions and languages for all SmPCs, PILs, and pack labels for a product.

Document Bundle: The Bundle of type Document is used to capture the section headings and narrative text (e.g., paragraphs, tables images) that describes a medicine's regulated and scientifically validated product information that assists healthcare professionals in prescribing and dispensing and informs patients and consumers about their medicine and its safe use.

ePI Type 1 Definition:

Definition was updated to only include the electronic drug label. The scope includes the following resources:

- Bundle (Type=Document)
- Composition
- Binary (i.e., contained within the Composition)

Note

- The document Bundle will only contain a single Composition.
- Composition resource contains Binary
- Organization resource is now excluded from ePI Type 1 and is moved to ePI Type 2
- Composition.subject(s) is a string with the product name and/or identifiers in text
- Composition.Author is a string with the market authorization holder's name and/or identifiers in text (e.g. SPOR identifier)

ePI Type 2 definition:

Definition was updated to include Organizations. The scope includes Type 1 plus the following resources:

- Organization
- Regulated Authorization
- Medicinal Product Definition
- Administrable Product Definition
- Manufactured Item Definition
- Ingredient
- Substance Definition
- Packaged Product Definition

ePI Type 3 definition:

Definition was not changed and remains the same. The scope includes Type 1, Type 2 and the following resources:

Clinical Use Definition

Bundle and Composition Hierarchy

Team agreed to manage document and section hierarchy according to Option #2 (i.e., align with EMA and Felleskatalogen approach).

Option 1 – hierarchy	Option 2 – hierarchy	
Type is the top level document.	Type is the top level document	
Don't repeat the document type	Section 1 repeats the document type	
Level 1 headings are siblings	All level 1 headings are children	
Level 2+ headings are nested children	Level 2+ headings are nested children	
Type = Package Leaflet	Type = Package Leaflet	
1. What X is and what it is used for	1. Package Leaflet	
2. What you need to know before you	a) What X is and what it is used for	
<take> <use> X</use></take>	b) What you need to know before	
a. Do not <take> <use> X</use></take>	you <take> <use> X</use></take>	
b. Warnings and precautions	i. Do not <take></take>	
c. Children <and< td=""><td><use> X</use></td></and<>	<use> X</use>	
adolescents>	ii. Warnings and	
d. Other medicines and X	precautions	
e. X with <food> <and> <,></and></food>	iii. Children <and< td=""></and<>	
<drink> <and> <alcohol></alcohol></and></drink>	adolescents>	
f. Pregnancy <and> <,></and>	iv. Other medicines and	
breast-feeding <and< td=""><td>X</td></and<>	X	
fertility>	v. X with <food> <and></and></food>	
g. Driving and using	<,> <drink> <and></and></drink>	
machines	<alcohol></alcohol>	
h. X contains {name the	vi. Pregnancy <and></and>	
excipient(s)}	<,> breast-feeding	
3. How to <take> <use> X</use></take>	<and fertility=""></and>	
	vii. Driving and using	
	machines	
	viii. X contains {name	
	the excipient(s)}	
	c) How to <take> <use> X</use></take>	

However, the team recommends EMA update the Referentials "Quality Review of Documents Product Information Template" list to include "Package leaflet: Information for the patient" as a new section heading between "PACKAGE LEAFLET" and "1. What X is and what it is used for". See **Figure 1** and **Figure 2**).

Figure 1 Package Leaflet section missing from the QRD Referentials list

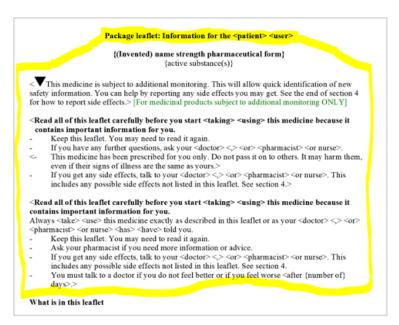


Figure 2 Recommendation to add a missing QRD section heading to SPOR Referentials

		44
Identifier ▲	Term Name ‡	
200000029891	4. BATCH NUMBER<, DONATION AND PRODUCT CODES >	
200000029892	5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT	
200000029893	6. OTHER	
200000029894	PACKAGE LEAFLET	
New code	Package leaflet: Information for the <patient> <user></user></patient>	
200000029895	1. What X is and what it is used for	
200000029896	2. What you need to know before you <take> <use> X</use></take>	
200000029897	Do not <take> <use> X</use></take>	
200000029898	Warnings and precautions	

Composition Profile

Team agrees Composition.section should be 1..1 and the subsections (i.e., Composition.section.section) should be 1..*

Team agrees Composition.section.title should be 1..1 since we should not allow sections without a title.

Move LastUpdateDate and versionId from Bundle to the Composition.

All sections should have an Identifier to facilitate cross-referencing to a section.

Update Composition. Type to remove reference to LOINC

PhPID location in ePI

Team agreed that PhPIDs are placed in the ePI's AdministrableProductDefinition resource as a Classification extension rather than as an identifier.

See below for a JSON example of the system and code:

```
{
  "system": "http://idmp.who-umc.org/fhir/CodeSystem/phpid",
  "code": "91B3CA582581F57E4092F13AAF476215"
}
```

MedicinalProductDefinition.name Jurisdiction

Team agreed to create a new code system for Jurisdiction to account for regions and unions like "Europe", "EU", "African Union", "WHO", "GCC"

Note:

• One valueset with two code systems. Code system #1 is ISO country and code system #2 has custom terms to cover the regions and unions.

List Profile

Each List. Entry should be updated to include the following:

- 1. Document identifier
- 2. version
- 3. last updated date
- 4. Type
- 5. Status

List Resource Lifecycle

Team agreed that the List resource should be versioned according to option #1 (See Figure).

Option #2 is not recommended because a single List has the potential to become unmanageably large if it maintained all versions, all languages, for all documents for the life of a drug product which could be over fifty years.

Option #1 is recommended since it will be akin to a saved search index showing what is current for a given product. The superseded versions can still be made available on a server and made available for use if needed.

Whenever a document in the List changes, the List version and last updated date should change as well.

Figure 3 List lifecycle option #1: generate a new List for each change/version

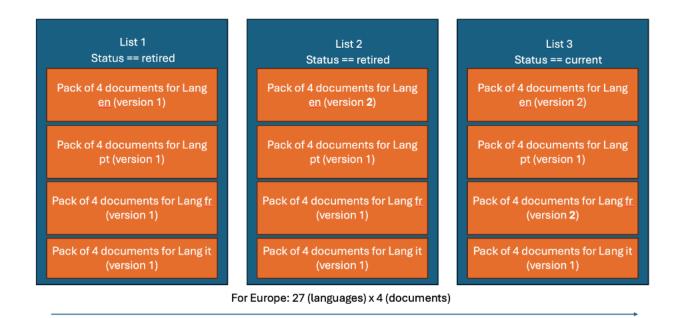


Figure 4 List lifecycle option #2: Maintain one List across all changes



For Europe: 27 (languages) x4 (documents) x n (versions)

time

Accessibility

As per WCAG guidelines, update the Implementation Guide to require all images to have alt text.

Topic #2: ePI style sheet: Create and test a final draft of a default style sheet for ePIs

Style sheet recommendations

Team recommends that regulator's style sheet should not be inline with the FHIR ePI content and should instead be available as a separate and publicly available resource.

Only basic formatting, like the following, will be supported in regulator's style sheets by default:

- Use of **standard HTML elements and attributes**, avoiding the use of browser-specific or deprecated attributes.
- **Don't include heading elements** <h1>-<h6> in ePI document section content, as EPI document headings are mapped to section.title elements.

• Text styles:

- Bold use of element. To indicate text of special importance, use of the element is also supported.
- Underline use style with CSS text-decoration property set to underline.
- Italics use of <i> element
- Superscript use of <sup> element
- Subscript use of <sub> element
- Highlight use of <mark> element
- Represent formulas using MathML. See the following for an example of a formula to be embedded in HTML to generate an equation:

Tables:

- Avoid the use of deprecated or non-standard attributes of the table element, including align, border, cellpadding, cellspacing, frame, height and width. Instead, use the corresponding CSS properties. Additional information in Mozilla HTML developer documentation : The Table element - HTML
- To promote interoperability, we recommend the use of a selected group of elements (and attributes) for the visual layout of table contents, that includes:

- § The <caption> element specifies the title of a table, providing an accessible description.
- § Table rows defined with elements, and columns defined with table header elements and data cell elements.
- § The <thead> element is supported with information about the table's columns.
- § The element is supported and encapsulates a set of table rows.
- § Use of colspan and rowspan attributes to the elements is supported to allocate the correct number of columns and rows.

Below an example, with a selected number of elements:

```
<thead>
 Medicine Name
 Product ID
 Dates
 Quantity (mg)
 Active
 Retired
</thead>
Product X
 427311
 3 June, 2020</time>
 n/a
 0.00
 Product Y
 533175
 13 January, 2021</time>
 8 April, 2022</time>
 37.00
 Product Z
 601942
 23 July, 2020</time>
 n/a
 15.00
```


The following should be defined as classes in an external stylesheet:

- Headings (predefined styling for the headings)
 - font family
 - o font size
 - alignment
 - text decorations
 - text transformation (upper/lower case...)
 - text style
 - text color
- Paragraph level:
 - font family
 - o font size
 - alignment
 - text spacing
 - text color
 - font style
- Bulleted Lists:
 - marker list (multilevel):
 - types of bullets
 - numbered list (single level):
 - Arabic numerals
- Hyperlink style
- Footnotes can be created with the use of CSS properties in elements.

Vulcan ePI Style Sheet

Team agreed to develop an open-source style sheet (e.g., CSS and XSL) that will be included in the next version of the IG.

The style sheet will provide an art of the possible demonstration to show all content included with ePI Type 1, Type 2 and Type 3. This includes narrative text; images; tables; section headings and sub-section headings; and all product details associated with ePI Type 2 and ePI Type 3.

Implementers will be able to use the style sheet as is to present ePI content in a human friendly manner or use it as a starting point to help build their own style sheet.

Lessons learned can be adapted from the Jordan FDA's FHIR ePI viewer which includes accessibility features like Text to Speech; dark and light mode; ability to increase and decrease font size.

Q النشرة الالكترونية - Enbrel العناوين الرئيسية / <u>اللغة العربية</u> الاستطبابات وكيفية الاستخدام Table of Contents. موانع الاستعمال الجرعة وطريقة الاستعمال Clicking the link takes الثفاعلات والاعراض الجانبية you to the section الشكل الصيدلاني وعيارات الدواء E E XE OE E & B I U A- A A+ السوق المرجعية :الاتحاد الأوروبي Text to speech. Click the speaker icon and نشرة العبوة: معلومات للمستخدم a voice over reads محلول إنبريل 25 مجم للحقن معبأ في محقنة مسبقة التعبثة this section يتم تنظيم المعلومات الواردة في هذه النشرة في الأقسام الـ7 التالية: Click header to go 1. ما هو إنبريل وفيم يستخدم 2. ما ينبغي عليك معرفته قبل استخدام إنبريل back to table of طريقة استخدام إنبريل contents. 4. الأثار الجانبية المحتملة 5. كيفية تخزين إنبريل 6. محتويات العبوة ومعلومات أخرى This appears when 7. تعليمات تحضير وإعطاء حقنة من إنبريل (انظر الجانب الخلفي من النا the voice over is playing. Can stop, pause, fastforward.

Figure 5 Screen capture from Jordan FDA FHIR ePI viewers text to speech feature

Note:

There will be no requirement for implementers to use the Vulcan ePI style sheet. They
are still free to use their own.

Topic #3: ePI Capability: Define basic API functionality requirements

Topic #4: Connectathon Roadmap: Define objectives for the next 4 connectathons

Connectathon Roadmap for GIDWG FHIR Sub-Group (in collaboration with Gravitate Health and Vulcan)

Connectathon	Topics	Objectives
21-22 Sep 2024 (Atlanta)	 Test updates to Harmonized Global ePI IG as international standard (API, validation, integrity and style sheet) Nordic+1 Testing: UK:Norway product map Test updates to PhPID IG Define a testing framework for Gen AI to create Type 2 and Type 3 resources from the SmPC, Label and PIL content 	 Define how to leverage Al's ability to automate the conversion of ePIs to FHIR and creation of ePI product details Obtain endorsement of connectathon roadmap from GIDWG plenary Update Harmonized Global ePI IG to draft Edition 2.0 Clarify via poll how many regulators are aware of ePI and how many are ready for it and how many have tools Clarify via poll how many companies are aware of ePI and how many are ready and how many have tools
Jan 2025 (Virtual)	Test updates to Harmonized Global ePI IG as international standard Testing operating model(s): a. EMA:UMC PhPID exchange (Excel to FHIR Tasks) Shortages Essential List of medicines ePI FHIR exchange Pharmacovigilance	1. Finalize and ballot Vulcan ePI IG Edition 2.0 in collaboration with EMA (for May ballot) 2. Clarify what is preventing us from achieving ePI 80% goal for Essential List of medicines list 3. Define KPI's for addressing shortages
May 2025 (Madrid)	Test updates to Harmonized Global ePI IG as international standard Testing operating model(s): a. EMA:UMC PhPID exchange (Excel to FHIR Tasks)	
Sep 2025	Test updates to Harmonized Global ePI IG as international standard Testing operating model(s): a. End to end: Authorization, Lifecycle, Adverse Event Report, withdrawal	
Jan 2026	Test updates to Harmonized Global ePI IG as international standard Testing operating model(s)	
May 2026	Test updates to Harmonized Global ePI IG as international standard Testing operating model(s)	

4 0041 000/ 6/1 5
1. GOAL: 80% of the Essential
Medicines List is converted to ePI
2. GOAL: 50% of the 78 IPRP
regulators endorse ePI IG
3. GOAL: EFPIA and PhRMA endorse
the IG
4. Majority of regulators endorse
Global ePI IG standard
5. End to end Vulcan ePI process is
complete (i.e., API exchange, ePI repo,
validation, profiles, complete)
6. FHIR use cases aligned with IDMP
definitional fields (e.g., minimum
substance requirements)
7. Vulcan ePI IG is ready for handover
to governance body for long term
maintenance

Use ICSR approach as an example. E.g., Part 1 = framework for ePI maintenance

Topic #5: PhPID IG: Test and clarify API capability, profiles and resources to support the end-to-end request process

Figure 6 Simplified presentation of PhPID levels

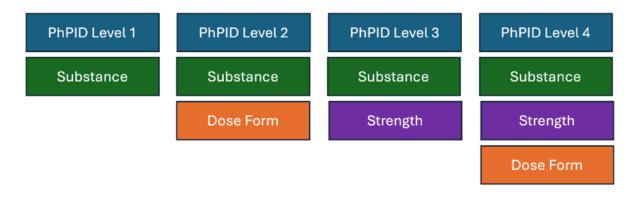
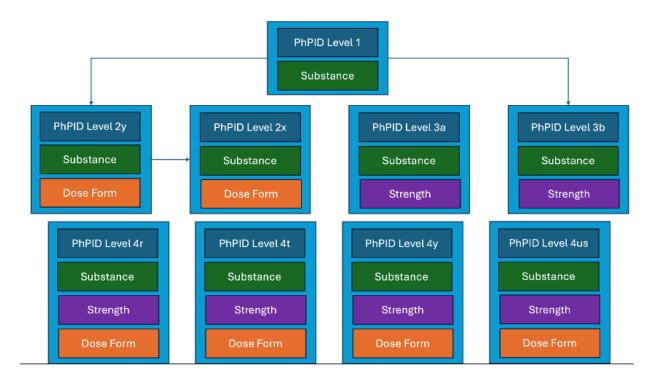


Figure 7 Simplified view of PhPID levels and lifecycle



General comment on URIs for PhPIDs

The uri for the PhPIDs was suggested to change to a URI less connected to the API and resources of the IDMP Service. This was not discussed in the big group but the suggestion was to change from http://idmp.who-umc.org/fhir/CodeSystem/phpid to the less complicated (anf fhir focused) http://www.who-umc.org/idmp/phpid. The suggestion was implemented and is part of the examples that will follow.

For "real" CodeSystems defined as part of the API, like php-level the former structure is kept.

Resource to represent PhPID

After a lengthy discussion originating from the fact that a PhPID on level 1 (especially for single ingredient PhPIDs) is essentially thre same as a Substance, it was decided to keep the AdministrableProductDefinition (APD) for all levels of PhPIDs.

In the APD the level of the specific resource is identified through the identifier using a CodeSystem identifying level as follows.

Referencing PhPID(s) from MedicinalProductDefinitions (MPDs)

We will use the classification on the MPD resource to reference the PhPIDs. In the example below we only reference level 4 but we could reference all applicable levels using the same scheme just replacing the system with the correct level.

The same way of referencing the global PhPID could also be used on the MPD in for example the ePI.

PhPIDs as CodeSystem

Is there a need for PhPIDs to be published as a "real" CodeSystem. It would mean that the PhPIDs would have a dual nature, bothe as APD resources and CodeSystem codes.

Use CodeSystem references and not resourceReferences where applicable

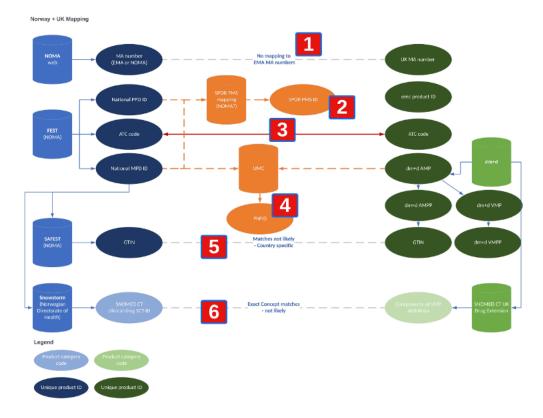
In several places in the examples of the current Implementation Guide, resource references are used like for example:

```
"code": {
    "reference": {
        "reference": "SubstanceDefinition/GSID9XBS2KCF3K1Z1",
        "display": "METHOTREXATE SODIUM"
    }
},
```

Even if the above would work in the context of an APD resource it was agreed that a CodeSystem and code should be used instead, as follows:

Nordic + UK dataset preparation

The Nordic pilot will target a set of medicines covering three disease areas. To match these medicines across the five jurisdictions the following common identifiers were considered. Please note this is a Norwegian example only:



The left hand side of the diagram represents the Norwegian identifiers and the right hand side green identifiers represent the UK identifiers.

The common candidate identifiers to map have been labelled in the diagram above. These are:

- 1. Marketing authorization number number. These are country specific, so no match is possible.
- SPOR PMS ID. This is specific to the EMA, so no match is possible.
- ATC Code. This code has high coverage for both countries so is a useful aid in matching between the jurisdictions. No dose form and strength are in the code, so only useful for a top level match.
- 4. Should PhPIDs be available based on the MPID, then this can provide a match between the country's products.
- 5. THe GTIN codes are assigned to product packs but are organisation specific, so cannot be used.
- The dm+d data is available in the SNOMED CT UK drug extensions but concept matches with SNOMED CT international may have a low success rate.
- 7. The ATC Code and a PhPID have been identified as the preferred common identifiers. The UK represents the MPID with the Actual Medicinal Product (AMP) from the NHS BSA dm+d dataset. The data model for this dataset is available here.

The following UK data will be required to request a UMC PhPID:

- 1. MPID System and identifier: Use dm+d AMP ID for each of the required medicines in the Nordic Pilot pilot dataset.
- Substance English free text (or GSRS)

- 3. Dose Form MPD CombinedPharmaceuticalDoseForm -EDQM preferred. Could be Free Text.
- 4. Strength UCUM
- 5. Classification: ATC Code (if available)
- 6. SmPC document as an ePI Composition or deep link to the full ePI
- 7. Country: GBR from iso:3166 from previous example
- 8. Language: en
- 9. Jurisdiction: Will be based on ISO-3166 (GBR)

Screenshots and/or links to further information

See section 4

Discovered issues / questions (if there are any)

- 1. Regarding PhPID
 - a. Clarify how to handle products that are mixtures or have multiple active ingredients. E.g., does the PhPID cover the fixed dose combination for the finished drug product?
 - b. Does the PhPID cover the administrable form of the drug or the manufactured item?
 - c. How are drug/device combo products handled?
- 2. Regarding EMA's system, https://spor.ema.europa.eu/v1/lists/200000029659/terms/ do we need the highlighted segment or can that be removed?
- Need help from European regulatory experts to explain the differences and lifecycle of Market Authorization Number, Procedure Number, and Product Number. Need to confirm how these concepts work before determining how they should be incorporated into the List and RegulatedAuthorization resources.

Now what?

- 1. Gather feedback on the connectathon roadmap, refine, and finalize for planning.
- 2. Regarding the EMA's QRD template, request breaking the "Marketing Authorisation Holder and Manufacturer" section into two sections. One called "Marketing Authorisation Holder" and the other called "Manufacturer". Breaking this section into two aligns them the Organization resource which in turn helps industry auto-populate this section via automation or generative AI.

- 3. Incorporate Giorgio Cangioli's API search slides and API search model into the next version of the IG
- 4. Add content to the IG to explain upstream and downstream process use cases. E.g., for upstream, clarify how to package (Bundle Collection), exchange (API capability), and search.
- 5. Develop a detailed FHIR ePI governance proposal for EMA leadership's consideration.