Connectathon 39 Track Report

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

Table of Contents

Clinical Reasoning (including CDS Hooks)

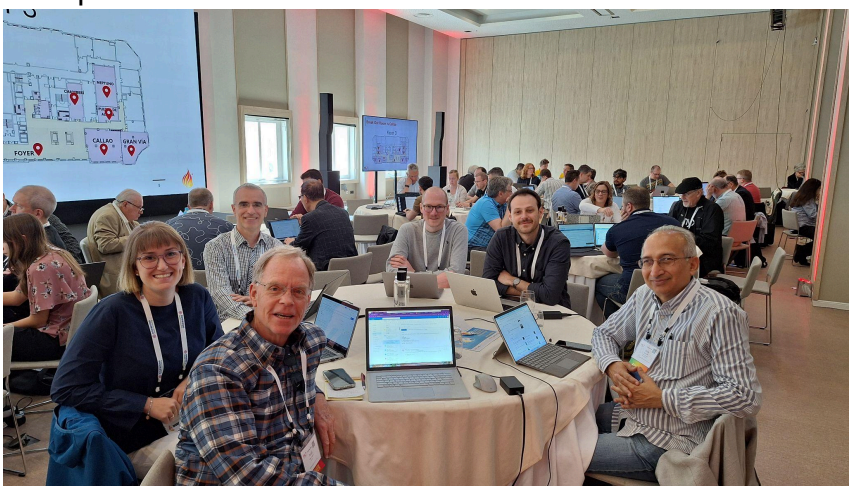
- What was the track trying to achieve?
  - Quality Reporting - Testing parity of FHIR Measures
  - CRMI Manifest - Testing $release and $package operations
  - CQL Engine - Testing parity of engines using $cql and cql-tests
  - Prior Authorization Questionnaires - Testing pre-population w/ CQL
- List of participants (with logos if you have time and energy)
  - CMS
  - Firely
  - Fyrstain
  - ICF
  - Microsoft
  - NCQA
  - Optum
  - Qualitype Gmbh
  - Reason Healthcare
  - Smile Digital Health
- Notable achievements
  - Successfully used Manifest release to obtain versioned expansions for AU FHIR measures

    - Successfully packaged 27 AU FHIR measures exported from MADiE authoring environment
    - Successfully ran cql-tests suite against Firely .NET CQL Engine
- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)
    - Quality Measure Testing
        - Discussion on how structured information is captured as part of clinical workflow. For example, how are the components of a diabetic foot exam captured in the record. The answer is that it varies based on configuration settings in systems. Some systems it will be captured in notes, some systems will have configured documentation templates.
        - Discussion on claim-related elements (present-on-admission, principal-procedure, etc.) http://jira.hl7.org/browse/FHIR-50824
        - Dx Anomaly in CMS69 resolved by refactoring union: https://chat.fhir.org/#narrow/channel/179220-cql/topic/DX.20Anomaly.20in.20CMS69-bmi.20Resolved.20by.20Refactoring.20union.20clause
        - Successfully loaded Measure bundles in Value Set Manager to perform $release processing
        - Successfully loaded Measure bundles
            - EXM2, EXM22, EXM50, EXM56, EXM68
    - Prior Authorization Questionnaire Testing
        - Issues in MDOBA questionnaire: https://jira.hl7.org/browse/FHIR-50835
        - Issues in GMTP Questionnaire: https://jira.hl7.org/browse/FHIR-50826 https://jira.hl7.org/browse/FHIR-50823
    - CQL Engine Testing
        - Proposal to add inline Library parameter in $cql https://jira.hl7.org/browse/FHIR-50821
        - .NET Firely Engine successfully ran cql-tests SUITE!!!!!!!!
            - 1000+ tests passing
        - Add conformance around context declaration usage: https://jira.hl7.org/browse/FHIR-50831
        -
    - Manifest Release/Package Processing
        - Technical correction proposed to fix the type of the url parameter to ValueSet/$expand to canonical https://jira.hl7.org/browse/FHIR-50825
        - Testing batch process w/ terminology servers, identified an issue with order of results in the batch response (implementation issue)
        - Fix for recursive dependencies in cqf-tooling package: https://github.com/cqframework/cqf-tooling/pull/546
    - Terminology Testing:
        - 651 Passed, 64 failed

    - CRMI Representation of NPM Packages
        - https://jira.hl7.org/browse/FHIR-50820
    - CRMI Representation of Chat Prompt Templates
        - https://jira.hl7.org/browse/FHIR-50819
    - CRMI Canonical Resolution
    - CRMI Non-canonical Artifact Search
        - PR
        - https://jira.hl7.org/browse/UP-679 (canonical identifier type code)
    - CPG Testing
        - Consider a $feedback operation: https://jira.hl7.org/browse/FHIR-50830
    - PQCMC Manufacturing
        - https://jira.hl7.org/browse/FHIR-50828
        - https://jira.hl7.org/browse/FHIR-50829
- Now what?

Devices

- What was the track trying to achieve?
    - Primarily, testing of the new DeviceAlert resource. Secondarily, testing the PoCD FHIR IG, with focus on DeviceMetric and its IG profiles.
    - Support track participants who were working to advance device-interoperability projects (e.g., implementation guides)
    - Understand R6 server requirements for device interoperability (discussion with Health Samurai re. AidBox)
- List of participants



        - Participants (6) including representation from Charité / Berlin, Dräger, Philips

    - ***Kudos to Health Samurai*** for providing their Aidbox that was R6 device resource ready - a FIRST!!! for FHIR CAT use in the Devices Tracks.
- Notable achievements
    - Achieved > 80% (of elements exercised) DeviceAlert testing with 3 implementations!
    - Findings (captured in Jira) for discovered issues
    - Tested PoCD FHIR IG (for first time)
    - Advanced DeviceMetric testing, 80% (of elements exercised) for two systems, less for a 3rd system
- Screenshots and/or links to further information
    - Detailed notes captured on: 2025-05-10 to 11 FHIR CAT - DEV Track
- Discovered issues / questions
    - During preparation for testing (pre-event): FHIR-50656
    - FHIR-50818
    - FHIR-50822
    - Additional discussions:
        - Charité / Berlin two projects reviewed (one teleconsultation & one ventilator capture)
        - Server Requirements for Device Informatics - focused breakout discussion with Health Samurai and Dev Track Participants
- Now what?
    - For the September FHIR CAT in Pittsburgh …
    - Need to get DeviceMetric 80% @ 3+ systems (in Pittsburgh) - i.e. at least 1 more system more
    - DeviceAlert testing with Device and DeviceMetric "activation state" extensions
    - Need to complete testing of the PoCD FHIR IG
    - Test SDPi (SDC-to-FHIR) Gateway using PoCD FHIR IG

EHDS (European Health Data Space)

- What was the track trying to achieve?

Progress with and Improve specifications that have been or are being developed to support the European Health Data Space. This includes the HL7 FHIR Implementation

Guides (IGs) for the EU Base/Core Profiles, EU Laboratory Report, EU Hospital Discharge Report (HDR), EU Medication Prescription and Dispense (MPD), EU Patient Summary (EPS), and EU Imaging Report (IMG). These IGs are expected to serve as the foundation for the future European Electronic Health Record Exchange Format (EEHRxF).

Support participants in enhancing their knowledge of these guides and provide clarification on any questions or uncertainties.

Collect real-world examples shared by participants and validate them against the relevant Implementation Guides.

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

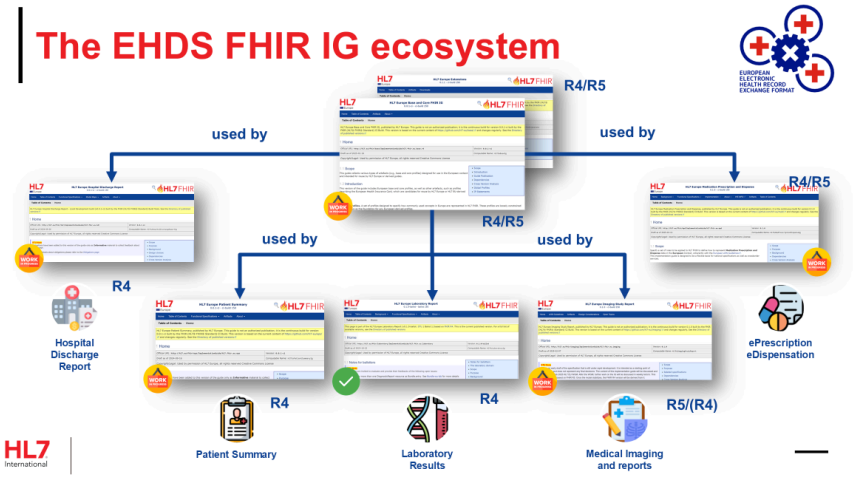
Alexander Henket	Nictiz
Bas van den Heuvel	Philips
Ben McAlister	Oracle / HL7 UK
David Wattien	Nictiz
Eduard de Rijcke	Nictiz
Francisco Novillo (Paco)	Orion Health
Gabriel Kleinoscheg	HL7 Austria, ELGA GmbH
Gert Koelewijn	Nictiz / HL7 Netherlands
Giorgio Cangioli	Hl7 Italy/Europe
Ignacio Jauregui	Philips
Jonas Schön	HL7 Germany, gefyra GmbH
José Costa Teixeira	HL7 Belgium
Julian Saß	Berlin Institute of Health at Charité
Marc de Graauw	Nictiz / HL7 Netherlands
Margaux Gatrio	Berlin Institute of Health at Charité
Marti Pamies	Vico
Mattias Colliander	HL7 Sweden
Oliver Egger	HL7 Switzerland / ahdis
Patrick Werner	HL7 Germany, gefyra GmbH
Reinhard Egelkraut	HL7 Austria, CGM
Rutt Lindström	HL7 Europe / TEHIK

Sarah Leroy	Kereval
Vania Manzelli	Nuvyta
Ward Weistra	Firely
Yacine Tamoudi	Kereval / IHE-Europe

- Notable achievements
  - a hapi-fhir server was set-up with all EPS dependencies as a validation endpoint
  - collected examples for MPD, HDR, EPS and validated against the guides
  - Identified issues in the guides (dependencies, technical errors) and in the examples. Most of them have been fixed.
  - Improved the general knowledge on the treated guides.
  - Identified open issues to be discussed in future meetings (e.g. validation of obligations; hdr structure)
  - Creation of a profile comparing gh action to compare german ISIK spec with eu EPS & HDR (https://github.com/Gefyra/ISiK-EU-Compare)
  - Joint MPD meets ePI session to compare clinical and regulatory medication resources, and initiate a proposal for clearer recommendation for use.
  - Kereval ran their AI quality validation tool on all our IGs, and created a report for each - testing the IG quality as well as the AI tool performance.
  -

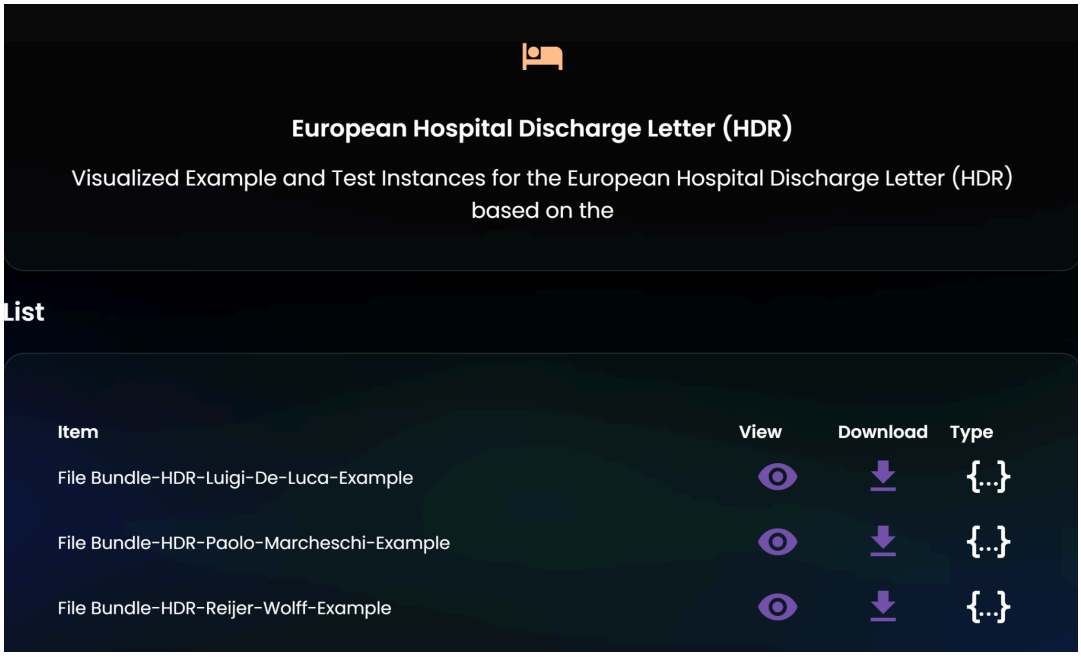
- Screenshots and/or links to further information

… work in progress…

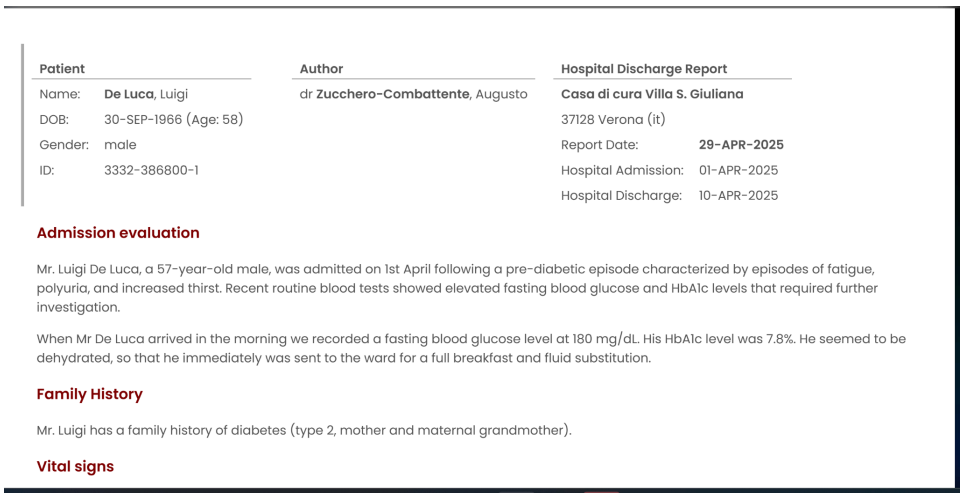


o

the EHDS-related HL7 FHIR IG overview



some examples have been collected in https://vi7eti.net/ and in the https://drive.google.com/drive/folders/1mkT5gfVaUtsIuYz_G1DseKG8I5bcMRzO?ths=true drive



Patient

Name: **De Luca**, Luigi
DOB: 30-SEP-1966 (Age: 58)
Gender: male
ID: 3332-386800-1

Author

dr **Zucchero-Combattente**, Augusto

Hospital Discharge Report

Casa di cura Villa S. Giuliana
37128 Verona (it)
Report Date: **29-APR-2025**
Hospital Admission: 01-APR-2025
Hospital Discharge: 10-APR-2025

Admission evaluation

Mr. Luigi De Luca, a 57-year-old male, was admitted on 1st April following a pre-diabetic episode characterized by episodes of fatigue, polyuria, and increased thirst. Recent routine blood tests showed elevated fasting blood glucose and HbA1c levels that required further investigation.

When Mr De Luca arrived in the morning we recorded a fasting blood glucose level at 180 mg/dL. His HbA1c level was 7.8%. He seemed to be dehydrated, so that he immediately was sent to the ward for a full breakfast and fluid substitution.

Family History

Mr. Luigi has a family history of diabetes (type 2, mother and maternal grandmother).

Vital signs

Small excerpt from MPD IG R4 validation results:

Writing and narrative	Presence an explanation of what "mustSupport" means for different types of implementations of the IG	False	
Writing and narrative	Presence of information on how to engage with the community	True	• Extract (page authors.html): The HL7 Europ project, cross-SDO and volunteer communit data exchange regulators, implementers, ar • Extract (page downloads.html): Propose a c
Writing and narrative	Presence of an explanation of the relationship of the IG to any other guides	True	• Extract (page index.html): This project is th several other European and national organiz • Extract (page background.html): This imple national use cases. Also, more restricted sp

visualization capability offered by https://vi7eti.net/

Breakout session: Advancing EHDS FHIR IGs with generative AI: from automated IG review to test case generation FHIRxAI_Madrid.pdf

Worked on DICOM KOS ImagingStudy mapping and created examples of imaging manifest and reports.

- Discovered issues / questions (if there are any)
  - The lack of published eu profiles package in the fhir package registry prevents easy local or online validation of test instances.
  - several improvements have been identified in all the guides and most of them applied.
  - How to take advantage of the obligations for testing and data quality.
  - harmonize the different guides and improve the packages organization.
  - Medication / MedicationKnowledge / Medication Definition module mapping (starting from Medication Knowledge) highlights the need for further revision of the medication domain in FHIR.

- Now what?

Specifically to imaging we created a set of examples based on sample radiology reports. This resulted in discovering some minor omissions in the specification. The editorial ones will be fixed in the ballot response, the others are or will be filed as ballot comments.

```
Instance: Example1-ImagingStudy
InstanceOf: ImImagingStudy
Usage: #inline
* id = "1"
* identifier
  * type = MissingDicomTerminology#0020000D "Study Instance UID"
  * system = "urn:dicom:uid"
  * value  =  "1.2.840.113674.1115.261.200.20240111.163748.100" // (0020,000D)
* status = #available
* subject = Reference( Example1-Patient )
* started = 2024-01-11T16:37:48+01:00 //(0008,0020)+(0008,0030)
* basedOn.identifier
  * type = http://terminology.hl7.org/CodeSystem/v2-0203#ACSN
  * system = "1.2.840.10008.2.16.4.999" // example
  * value = "123445678" //(0008,0050)
* referrer = Reference( Example1-referrer )
* endpoint = Reference( Example1-WadoEndpoint )
* series[+]
  * uid = "1.3.6.1.4.1.40771.779024114571172598156790703413549454 27" //(0020,000E)
  * number = 1 //(0020,0011)
  * modality = http://dicom.nema.org/resources/ontology/DCM#KO "Key Object Selection" // (0008,0060)
  * instance[+] // further mapping depends on resolution of https://github.com/hl7-eu/imaging/issues/49
    * uid = "999.999.133.1996.1.1800.1.6.9"
    * sopClass = urn:ietf:rfc:3986#1.2.840.10008.5.1.4.1.1.6.1
    * number = 8
```

The examples will be included in the build version of the specification.

Another noticeable achievement is that we manifest examples that are based on the DICOM KOS objects. Bases on this work, a first version of a KOS FHIR mapping has been defined!.

KOS Definition based on "Xt-EHR EHDS Imaging Study Manifest - DICOM KOS Specification_V7e"

Excerpt from **DICOM PS3.3 Table C.7-1 Patient Module** © NEMA					EHDS Patient (EU Core), FHIR R5
Attribute Name	**Tag**	**Value Type**	**Attribute Description**		**Elements**
Patient's Name	(0010,0010)	2	Patient's full name.		Patient.name
Patient ID	(0010,0020)	2 1 (EHDS)	Primary identifier for the patient. Value: National Patient Id.		Patient.identifier.value
Issuer of Patient ID	(0010,0021)	3	Identifier of the Assigning Authority (system, organization, agency, or department) that issued the Patient ID. If present should contain a label that corresponds to the authority identified by the Universal Entity ID (0010,0032) in the Issuer of Patient ID Qualifiers Sequence (0010,0024).		Patient.identifier.assigner
Issuer of Patient ID Qualifiers Sequence	(0010,0024)	3 1 (EHDS)	Attributes specifying or qualifying the identity of the Issuer of the Patient ID (0010,0021), or scoping the Patient ID (0010,0020). Only a single Item shall be included in this Sequence.		
> Universal Entity ID	(0010,0032)	3 1 (EHDS)	Globally unique identifier (OID) for the Patient ID Assigning Authority. The authority identified by this attribute shall be the same as that labelled by the Issuer of Patient ID (0010,0021).		Patient.identifier.system
> Universal Entity ID Type	(0010,0033)	1C	Standard defining the format of the Universal Entity ID. Required if Universal Entity ID (0040,0032) is present. Fixed value: "ISO"		if necessary part of Patient.identifier.system
> Type of Patient ID	(0010,0022)	3	The type of identifier in the Patient ID (0010,0020). Fixed value (if present): "TEXT"		Patient.identifier.type
Patient's Birth Date	(0010,0030)	2	Birth date of the patient.		Patient.birthDate
Patient's Sex	(0010,0040)	2	Sex of the named patient. Enumerated Values: • "M" - male • "F" - female • "O" - other		Patient.gender "male" "female" "other"

This a great first step in harmonizing these specifications and removing any interoperability hurdles between these alternatives.

Discuss and apply improvements identified in the Implementation Guides (IGs).

Gather additional examples that reflect the different national implementations (“flavors”).

Continue this work during the next IHE Europe Plugathon event in June, in Vienna.

Work for making available **more sandboxes and validation tools** for supporting the EHDS specifications.

Evidence Based Medicine

- What was the track trying to achieve?
    - 1. Demonstrate that a EU CTIS record can be represented in a FHIR ResearchStudy Resource (with EBMonFHIR IG Profile)
    - 2. Demonstrate that a EU CTIS record in FHIR can be transmitted for data exchange in the cloud
    - 3. Demonstrate that an M11 report can be represented in a FHIR ResearchStudy Resource (with EBMonFHIR IG Profile)
    - 4. Demonstrate added value for using FHIR to represent data for a research study covering EU CTIS and M11 report data
- List of participants
    - Brian S. Alper, Computable Publishing LLC and EMA, Track Lead
    - Khalid Shahin, Computable Publishing LLC, Track Lead
    - Panagiotis Telonis, European Medicines Agency (EMA)
    - Jimita Parekh, EMA
    - Raju Rayavarapu, DNAnexus
    - Martin Lucht, Roche
    - Filippo Napoli, HL7 Vulcan Accelerator
- Notable achievements
    - 1. EU CTIS records (public data available from https://euclinicaltrials.eu/) successfully represented in FHIR with https://fevir.net/resources/ResearchStudy/367122 and https://fevir.net/resources/ResearchStudy/367203 (the DEUCRALIP trial) and confirmed by EMA
        - including StudyEligibilityCriteria Profiles at https://fevir.net/resources/Group/367123 and https://fevir.net/resources/Group/367204
    - 2. JSON files for EU CTIS records (e.g. https://fevir.net/resources/ResearchStudy/367122#json) successfully transmitted in a Cloud technology that simulated spaces for regulatory use
    - 3. M11 report (created from a prior Vulcan UDP Connectathon) successfully represented in M11ResearchStudy Profile at https://fevir.net/resources/ResearchStudy/367214 (the DEUCRALIP trial) including reference to StudyEligibilityCriteria Profile at https://fevir.net/resources/Group/367215
    - 4. Showing the DEUCRALIP trial in FHIR with data derived from CTIS (https://fevir.net/resources/ResearchStudy/367122, #1 above) and M11 report (https://fevir.net/resources/ResearchStudy/367214, #3 above) successfully identified areas for improvements in data structure or data quality, including:
        - Study acronym encoded as public title in CTIS
        - sponsor protocol identifier encoded as short title in CTIS

        - 28 inclusion/exclusion criteria vs. 27 inclusion/exclusion criteria ("Subjects who neither received a COVID-vaccination following EU regulations nor experienced a COVID-19 infection" handled as 2 criteria vs. 1 criterion)
- Screenshots and/or links to further information
    - Screenshots for Part 1 (20+ screenshots) in EBM Track Screenshots PPT
    - Ongoing effort (working group meetings) at https://fevir.net/HEvKA
- Discovered issues / questions (if there are any)
    - Coordination of M11 data elements and CTIS data elements may show data quality issues more often than data model issues
- Now what?
    - 1. Change CTISRecord Profile to StudyRegistryRecord Profile in the EBMonFHIR IG
    - 2. Identify the full list of CTIS data elements and map those to the StudyRegistryRecord Profile (if not captured in the sample set shown in the Connectathon 39)
    - 3. for Connectathon 40 Evidence Based Medicine Track - Test the full CTIS record representation in FHIR

FAST Infrastructure (Security & Identity)

- What was the track trying to achieve?
    - ➢ Testing of the FAST Security IG STU2 draft including:
        - Scope negotiation
        - Multiple communities
- List of participants (with logos if you have time and energy)

MEDITECH

onyx

- Notable achievements
    - ➢ Review of potential for Buyer Adoption for trust communities
    - ➢ Review of differences from STU 1/1.2 and STU2
    - ➢ Potential for EHDS adoption

        - ➢ Mapping of Onyx portal to use FAST Security

- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)
- Now what?
    - ❖ Continue to review ballot tickets and push for publication.

International Patient Access (IPA)

- 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?

International Patient Summary

- What was the track trying to achieve?

This track will test the guidance, creation, exchange, editing and visualization of International Patient Summary (IPS) documents. It will specifically test many of the changes in the IPS 2.0 ballot (September 2024)
Specific Agenda:

1. Work on examples for Ballot Reconciliation
2. Look at PSS-2566 Profile and Implementation Guide for Advancing Collection of Standardized Symptoms Data and consider "symptom" intersection with IPS
3. Narrative linking within IPS (FHIR-I discussion on May 5)
4. Have a discussion around NUVA (May 2025 Bordeaux meeting)
5. Joint IPA-IPS Discussion
6. Exchange of IPS documents (instances) among vendors
7. Demonstration of Visualization Tools for IPS

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

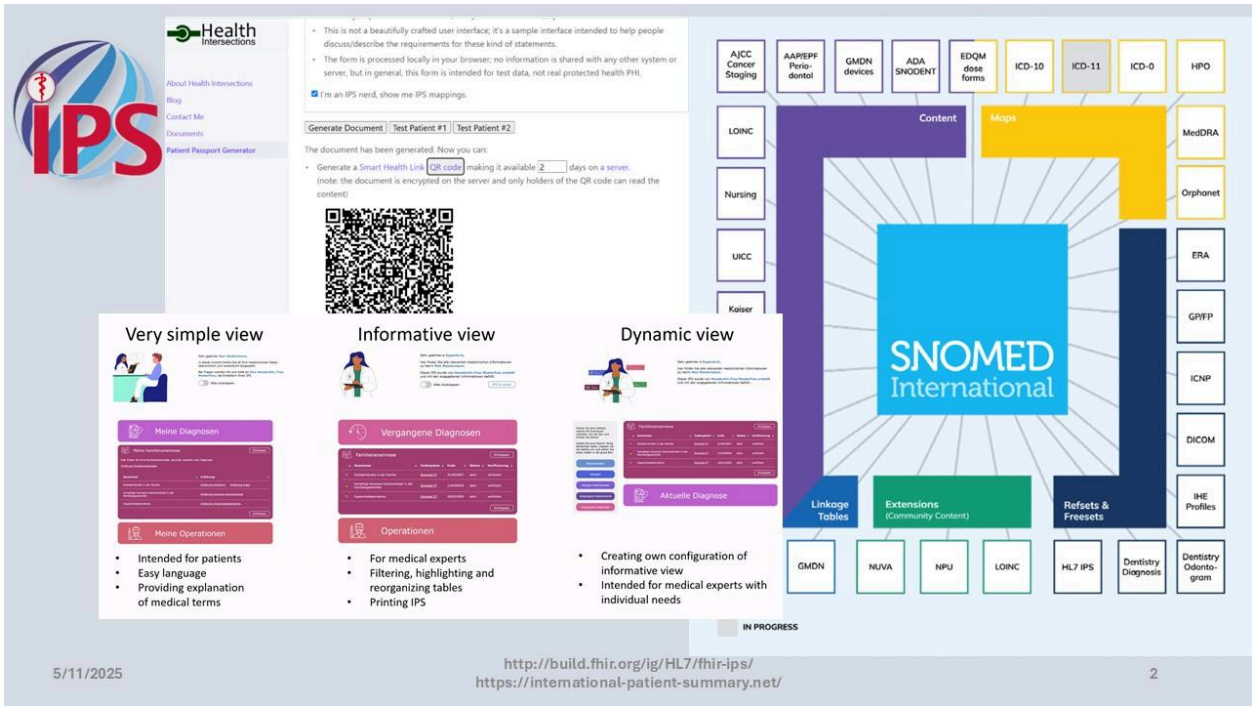
Danielle Tavares-Rixon (AU) Digital Health Australia
Dave DeBronkart (US)
Gabriel Kleinschog (AT)
Grahame Grieve (AU)
Jason Vogt (US) MEDITECH

John Carter (NZ) HL7 New Zealand
John D'Amore (US) More Informatics
John Smolic (US) MEDITECH
John Waldron (US)
Jose Costa Teixeira (BE)
Justin McReynolds (US) University of Washington
Katie Reynolds (UK) Epic
Nik Tanjga (AT)
Oliver Eggers (CH)
Peter Groves Williams (UK) SNOMED International
Peter Jordan (NZ)
Rob Hausam (US) Hausam Consulting
Russ Leftwich (US) InterSystems
Stephen Chun (AU) Digital Health Australia

- Notable achievements

- Status: 2.0 version in ballot reconciliation
- Multiple connections tested among participants:
    - Epic (now live!!), MEDITECH, New Zealand, Washington State, Australia, Austria
    - Testing of exchange and viewing of IPS document
    - Demonstration of 2 Viewers and debugging of SMART Health Links
- Two in-depth discussions on NUVA (FHIR-49146) and Signs & Symptoms (PSS-2566)
- Examples! Particularly on textLink extension
- Comments on FHIR-49146, 47263,
- Active discussion on narrative sections of IPS
    - New content in General Principles and Design that IPS does not contain actionable orders (FHIR-50832)
    - New General Principles and Design section on patient safety drafted (FHIR-50833)

- Screenshots and/or links to further information



- Discovered issues / questions (if there are any)

Multiple new issues documented

    - New content in General Principles and Design that IPS does not contain actionable orders (FHIR-50832)
    - New General Principles and Design section on patient safety drafted (FHIR-50833)

Technical correction identified on display on datatypes (Danielle Tavares-Rixon)

Encoding of SHL for JWE and base64 encoding

Licensing discussion around IPS Viewers

- Now what?

1. Block-Vote-9 Going to Patient Care on Monday May 12, Q2
2. Consideration on contributing Austrian IPS Viewer to HL7 Foundry
3. Move textLink extension forward to extension registry
4. Working to publish 2.0 version as soon as possible!

MolecularDefinition Logical Model and CDS

- What was the track trying to achieve?

Implement a CDS application that leverages MolecularDefinition in order to adjust medication dosing guidance based on the patient's genetic profile.

- List of participants (with logos if you have time and energy)
    - Nathan Davis - Graphite Health
    - Claude Nanjo - University of Utah
    - Ben Mccalister - Oracle
- Notable achievements
    - Implemented CDS service architecture
    - Implemented an R5 MolecularDefinition resource in HAPI FHIR
    - Currently discussing potential representation of phenotype as a FHIR observation
    - Modeling haplotype using Molecular Definition
- Screenshots and/or links to further information
    - Not available at this time
- Discovered issues / questions (if there are any)
    - Unclear at this point how to represent a poor/intermediate metabolizer of a drug as an observation
- Now what?
    - Define more concrete MolecularDefinition instances to support CDS use case (thiopurine)
    - Fully define CDS rule

    - Implement CDS rule and supporting tests
    - Implement/integrate knowledge layer that converts a molecular definition instance for a given patient obtained via genetic testing into a set of observations that describe patient phenotype for use by the CDS rule.

Questionnaires

What was the track trying to achieve?

Looking to test additional features in the SDC IG

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

- Brian Postlethwaite (Microsoft)
- Lloyd McKenzie (Dogwood)
- Maria Ryzhikova (Health Samurai)
- Thomas Debertshäuser (BIH / Charite)

A few additional “first time attendees” hung out with us to get up to speed on FHIR

Notable achievements

Using CQL with Questionnaires (Brian)

- POC work to put the updated Firely CQL engine into my hist pre-pop code
    - Worked with Alexander Zautke to do the changes
    - Uploaded the content using UploadFIG
    - Discovered that not all libraries reference the required content (specifically the CQL helpers - they assume they're available)
    - mis-matched versioning between CQL lib and it's fhir library wrapper (in published content)
    - some issues with dotnet engine - need to send feedback to Ewout
- Links
  https://build.fhir.org/ig/HL7/us-cql-ig/Questionnaire-ExamplePatientAndCoverageQuestionnaire.json.html
  https://build.fhir.org/ig/HL7/us-cql-ig/Library-ExamplePatientAndCoverageInitialExpressions.json.html
  https://build.fhir.org/ig/HL7/us-cql-ig/Library-USCoreElements.html
  https://build.fhir.org/ig/HL7/us-cql-ig/Library-USCoreCommon.html

Worked with Thomas Debertshauser on a possible way to tweak item weights in codings using supplements for localised weights used in scoring, using the questionnaire valueset parameter extension

Now what?

Will incorporate CQL learnings in the SDC IG and continue to work on validating SDC functionality in Pittsburgh.

Vulcan/Gravitate Health - ePI and GIDWG/IDMP

- **What was the track trying to achieve?**

The aim of this track is to test the creation, exchange and display of electronic Product information (ePI) in connection to ISO IDMP.

This track is part of the HL7 Vulcan Accelerator supported by the Innovative Medicines Initiative (IMI) Gravitate-Health Project, WHO/UMC, and EMA. Thus, aligns with the European Medicines Agency's ePI 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 Objective is to test and gather feedback on the following:

- ☐ PhPID workflow
- ☐ ePI Style sheet
- ☐ ePI version control
- ☐ ePI Type 4

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

- ☐ João Almeida (HL7EU/HL7PT)
- ☐ Mattias Colliander (HL7 Sweden, Fass, Sweden)
- ☐ Ádám Z. Kövér (Felleskatalogen, Norway)
- ☐ Alejandro Medrano Gil(UPM)
- ☐ Philippe Michiels (Datapharm)
- ☐ Bernd Moeske (NOMA / DMP, Norway)
- ☐ Åsa Pärnaste (UMC)
- ☐ Raphael Sergent (Accurids / ISO)
- ☐ Kim Sherwood (Sweden)
- ☐ Panagiotis Telonis (EMA)
- ☐ Magnus Wallberg (UMC)

- **Notable achievements**

1. discussed and reached a formal definition of epi type 4, being: **The difference between the type 3 and 4 could be the linking of the content in structured format and the actual concepts.**
2. Reached a consensus around how to link narrative content to structured information, being first step the narrative link with more flexible link and to aim to only link to resources or elements inside resources.
3. The group reached consensus that MedicationKnowledge/ Medication needs a change in order to be less redundant and best serve the community. Data was created to show elements in both medication and MedicationKnowledge, only missing 4 elements.
4. Proposed the first version of what a variation workflow would look like in FHIR for epi type 1 and 4.
5. Validation of the PhPID request process (operating model) with recent changes and feedback from NOMA using the request API in production
6. Looking at the AdministrableProductDefinition (APD) resource as the carrier for the PhPID. We noted that we really would have preferred a separate resource for this since we have a lot of extensions and things that we do not use but for the foreseeable future we will probably need to use the APD.
7. We are so far happy with the SubstanceDefinition (SD) resource when publishing Global Substance Identifiers (GSIDs).
8. We demonstrated how the APD and SD resources can be imported in a knowledge graph building an IDMP ontology.
9. We discussed in length the usage of Globally Unique, Persistent, Global Identifiers (GUPRIS) to provide a long-term stable identifier, currently pointing to the published APD and SD resources. The GUPRIs are added as Identifiers in the FHIR resources - it seems to work satisfactorily.

• Screenshots and/or links to further information

Example: side effects of constructing a narrative from structured content.

1. Template of the composition:
Aware of the required first-level headings, calls generation of each in sequence:

2. Template of section 4:
Creates the section element for QRD section 4 and calls templates for subsections (only 4.8 is in the example):

```
<xsl:template name="qrdSection4"> template for section 4
  <xsl:param name="mpdNodes"/>
  <section xmlns="http://hl7.org/fhir">
    <title value="4. CLINICAL PARTICULARS"/>
    <code>... SPOR ...</code>
    <text>
      <status value="additional"/>
      <div xmlns="http://www.w3.org/1999/xhtml">
        <h2>4. CLINICAL PARTICULARS</h2>
```

```
    </div>
  </text>
  ...
  <xsl:call-template name="qrdSection48"> sub-template for section 4.8 side effects
        <xsl:with-param name="mpdNodes" select="$mpdNodes"/>
        </xsl:call-template>
```

3. Template of the side effects section:
Queries structured FHIR data and renders results as text

```
<xsl:template name="qrdSection48">
...
 <div xmlns="http://www.w3.org/1999/xhtml">
  <h3>4.8 Undesirable effects</h3>
  <xsl:call-template name="sideEffectFrequencyDescription"/> static text in own template
  <xsl:variable name="sideEffects" select="doc(concat( look up data based on MPD ID
     $fhirBaseUrl, '/ClinicalUseDefinition', constructing a FHIR REST API search
     '?subject=', 'MedicinalProductDefinition/', $mpdIds,
     '&amp;type=', 'undesirable-effect',
     '&amp;_format=xml'))"/>
  <xsl:apply-templates select="$sideEffects" mode="qrdSection48"/> generate text from data
 </div>
```

4. Template for rendering the result (search result Bundle), groups side effects by SOC and frequency:

```
<xsl:template match="fhir:Bundle" mode="qrdSection48">
 <div xmlns="http://www.w3.org/1999/xhtml" class="resource-data side-effect-list">
  <xsl:for-each-group select="... fhir:ClinicalUseDefinition"
   group-by="... fhir:coding[fhir:system/@value = 'https://gravitatehealth.eu/meddra/soc'] ...">
   <div>
    <xsl:for-each-group select="current-group()"
     group-by="fhir:coding[fhir:system/@value = 'https://gravitatehealth.eu/meddra/frequency']">
    <xsl:apply-templates select="current-group()" mode="qrdSection48"/>
```

5. Display a single side effect:

```
<xsl:template match="fhir:ClinicalUseDefinition" mode="qrdSection48">
 (display information from the text narrative or
undesirableEffect/symptomConditionEffect/concept)
```

Mapping for content in narrative and resources:

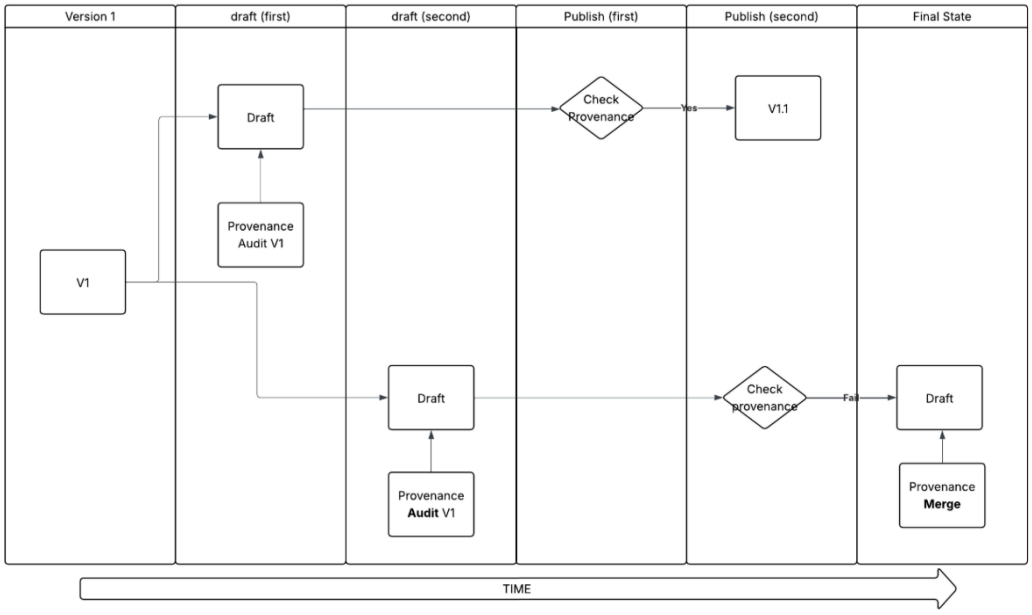
Tag/ Objective	Resource
Indication	ClinicalUseDefinition
Interaction	ClinicalUseDefinition
Warning	ClinicalUseDefinition
undesirable-effect	ClinicalUseDefinition
contraindication	ClinicalUseDefinition
Image	Binary / DocumentReference
Video	Binary / DocumentReference
URL	DocumentReference
Text	DocumentReference
PDF / Document	DocumentReference

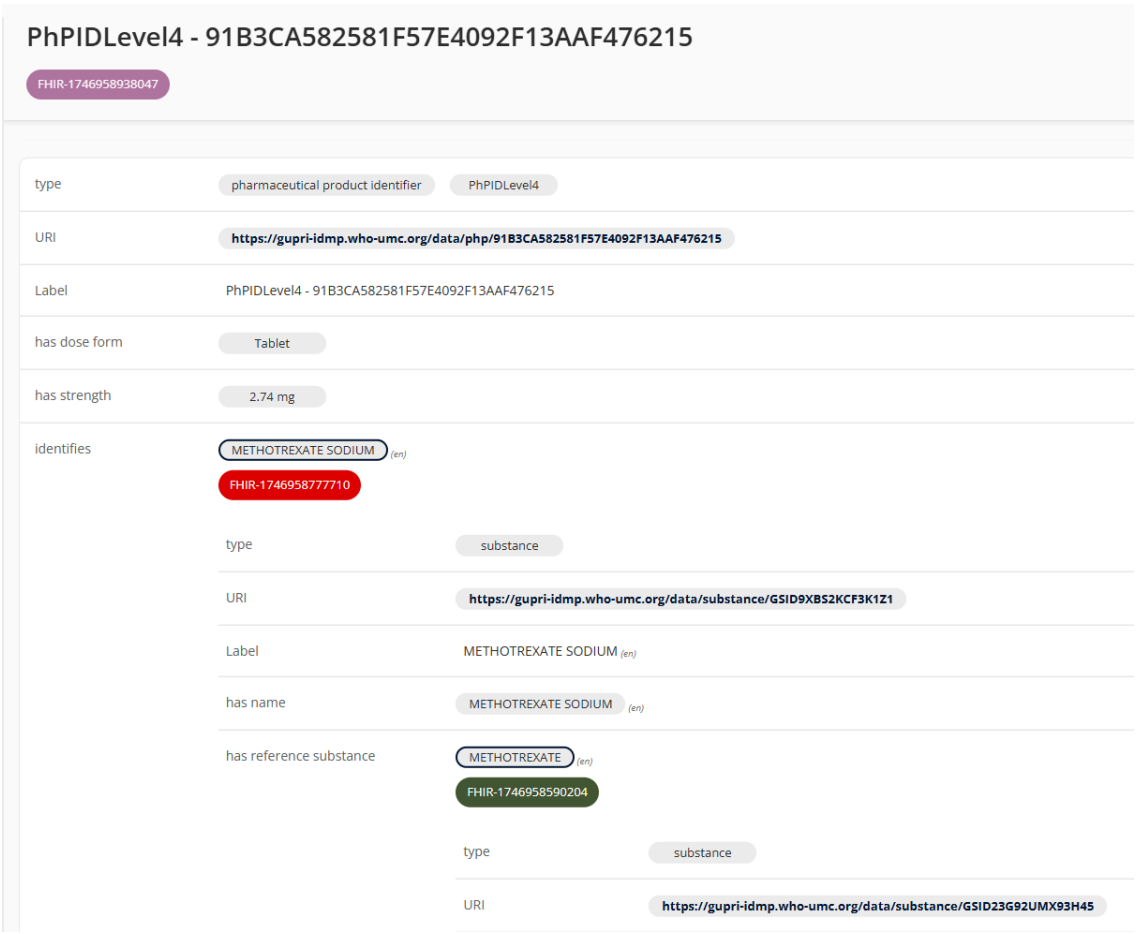
Analysis of Medication and MedicationKnowledge

Medication	MedicationKnowledge
Medication.identifier	MedicationKnowledge.identifier
Medication.code	MedicationKnowledge.code
Medication.status	MedicationKnowledge.status
Medication.marketingAuthorization Holder	RegulatedAuthorization.holder (ref. Organization)
Medication.doseForm	MedicationKnowledge.definitional.doseForm
Medication.totalVolume	PackagedProductDefinition.containedItemQuantity
Medication.ingredient.item	MedicationKnowledge.definitional.ingredient.item
Medication.ingredient.isActive	MedicationKnowledge.definitional.ingredient.type
Medication.ingredient.strength[x]	MedicationKnowledge.definitional.ingredient.strength[x]

Medication.batch.lotNumber	PackagedProductDefinition.identifier
Medication.batch.expirationDate	PackagedProductDefinition.property, type & valueDate
Medication.definition	MedicationKnowledge.definitional.definition

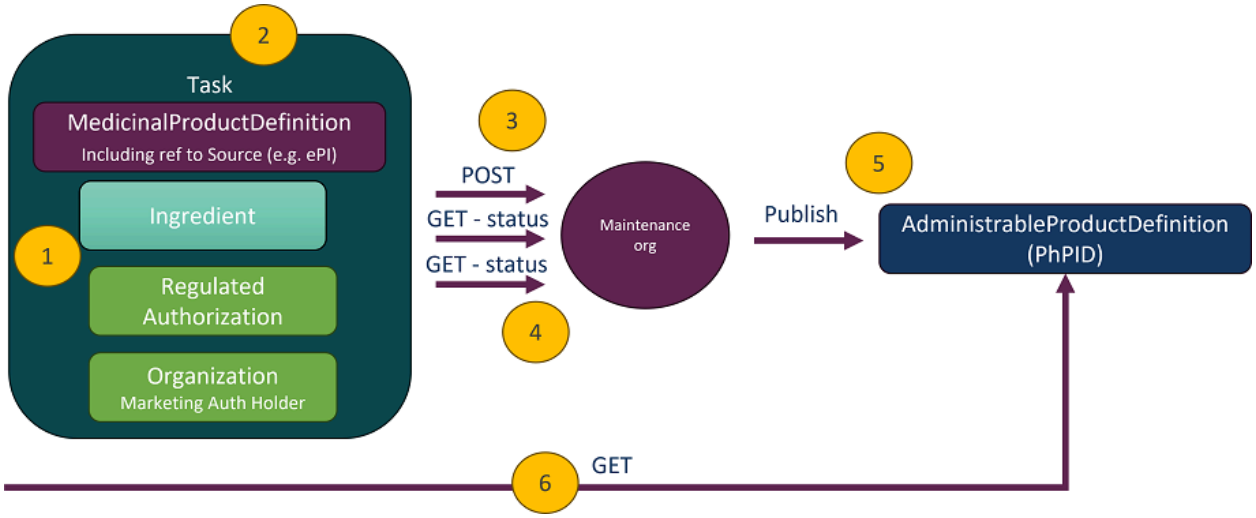
Graph for versioning / variation workflow of epi.



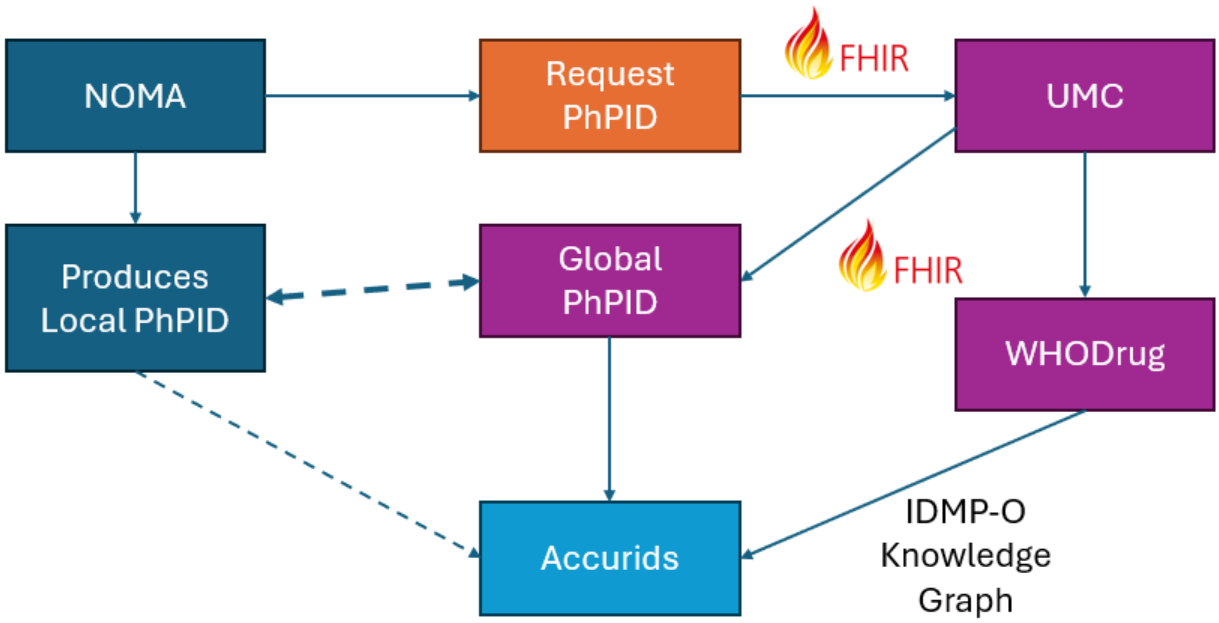


Calling the URI as a resource will link the different datasets together, enabling interoperability, unique naming convention and simplified maintenance of data assets (maintained only in one place).

Capturing the changes made to PhPID operating model



Data exchange schema - Proposal:



- **Discovered issues / questions (if there are any)**

packagedMedicinalProduct	Σ	0..*	CodeableConcept	Package type for the product Binding: Medicinal Product Package Type (Example)

- MPD.packagedMedicinalProduct. Why does it not contain type in it?

ingredient	Σ	0..*	CodeableConcept	The ingredients of this medicinal product - when not detailed in other resources Binding: SNOMED CT Substance Codes (Example)

- MPD.ingredient, seems weird to be able to reference ingredient to codeable concept and have ingredient refer to it as well?

- MPD.name is a complex element, PPD.name is a simple element.

- AdministrableProductDefinition in R6 still doesn't have the very needed change agreed in https://jira.hl7.org/browse/FHIR-42068 APD right now only has a primary identifier, but it needs to have a code to make it possible for create a local instance of APD using PhPID as a classification.

- MedicationKnowledge.relatedMedicationKnowledge vs MedicationKnowledge.associatedMedication?

- MedicationKnowledge.ingredient.role vs Medication.ingredient.isActive
- Need to map all the epi information categories (titles and subtitles) to FHIR resources
  - Agree to changes in the request process
    - New resource has been added, to be used for adding the MAH to the product in the task: Regulated Authorization.
    - Package information is not included in the request, but the Market Authorization can be assigned on a package level (in the national data).
    - Allow for several RegulatedAuthorization resources and corresponding Organization resources linked to one MPD resource in one request.
  - Other issues from NOMA testing
    - Requester adds an Id to the task, but the call back url responds with a different taskID (the one generated by the IDMP API). Needs to be made clear in the IG.
    - The requester taskID should be possible to use when searching for tasks by adding the requester taskID as an identifier.
  - More examples should be added to the IG, for example to illustrate what way to present the strength (e.g. to use strength.presentationQuantity instead of strength.presentationRatio for medicinal gas.) and requesting PhPID for e.g. combination packs

Vulcan Utilizing the Digital Protocol (UDP)

- What was the track trying to achieve?

All aspects of a clinical trial are governed by the protocol agreed between sponsor and regulator. Vulcan, ICH M11/M2, CDISC and TransCelerate are working toward a digital form of this protocol. The Vulcan UDP project will express this digital form in FHIR, integrating work products of ICH M11 (i.e., M11 template, technical specification, models, terminology) and CDISC/TransCelerate (Unified Study Definition Model or USDM) and explore the ways in which it enables more efficient definition and execution of clinical trials and better integration with regular clinical care. The first use case is focused on protocol exchange between sponsor and regulators; however, additional use cases based on the foundational work of Vulcan UDP and Vulcan SoA are planned.

By integrating work from previous Connectathons, the goal is to establish a standardized and joined-up approach to protocol representation. This is the third of a series of Connectathons which aims to further the structured digitization of clinical trial protocols by testing and refining key aspects of data exchange and interoperability. There are three levels of document structuring, 1) a PDF document, 2) a FHIR document, structured but still treated as a single entity and 3) a FHIR database, where elements are modular and reusable outside of the document.

The event will focus on three core topics:

1. Defining and Structuring Eligibility (Inclusion/Exclusion) Criteria - This Connectathon will explore how inclusion and exclusion criteria can be digitally represented in a structured and machine-readable format, ensuring they are consistently applied across different regulatory and clinical contexts. As part of this, clear and precise mapping between USDM, ICH M11 and FHIR elements will be tested to enable seamless data translation. This will help establish best practices for structuring protocol data within digital ecosystems, ensuring eligibility criteria are accurately represented and aligned with regulatory expectations and clinical workflows.

2. Exploring the use of FHIR Extensions – We will also explore how FHIR extensions can be used to address specific protocol representation needs which were not currently covered by the FHIR specifications. This will allow for more detailed and flexible representations without altering core standards. Given that extensions are a tool rather than a functional goal in themselves., this work will focus on practical use cases where extensions may be necessary.

3. Terminology Standardization - Review the Implementation Guide for alignment of terminology across ICH M11, USDM, and FHIR. Ensure consistent use of terminology across standards. The Connectathon will serve as a forum to discuss and validate whether terminology mapping is working as expected.

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

- Stacy Tegan, TransCelerate – **Track Lead**
- Hugh Glover, Vulcan – **Track Lead (Remote)**
- Brian Alper, Computable Publishing
- Rhonda Facile, HL7 Europe
- Smita Hatak, Samvit Solutions LLC
- Dave Iberson-Hurst, CDISC
- Sophie Klopfenstein, Berlin Institute of Health at Charité
- Mark Kramer, MITRE
- Martin Lucht, Roche
- Jimita Parekh, EMA
- Shani Sampson, TransCelerate
- Khalid Shahin, Computable Publishing
- Rik Smithies, HL7 UK
- Panagiotis Telonis, EMA
- Raju Rayavarapu, DNAnexus

- **Observers:** ICH M11 Technical Subteam: Mitzi Allred, Guillaume Schoch, Tanya Fleege

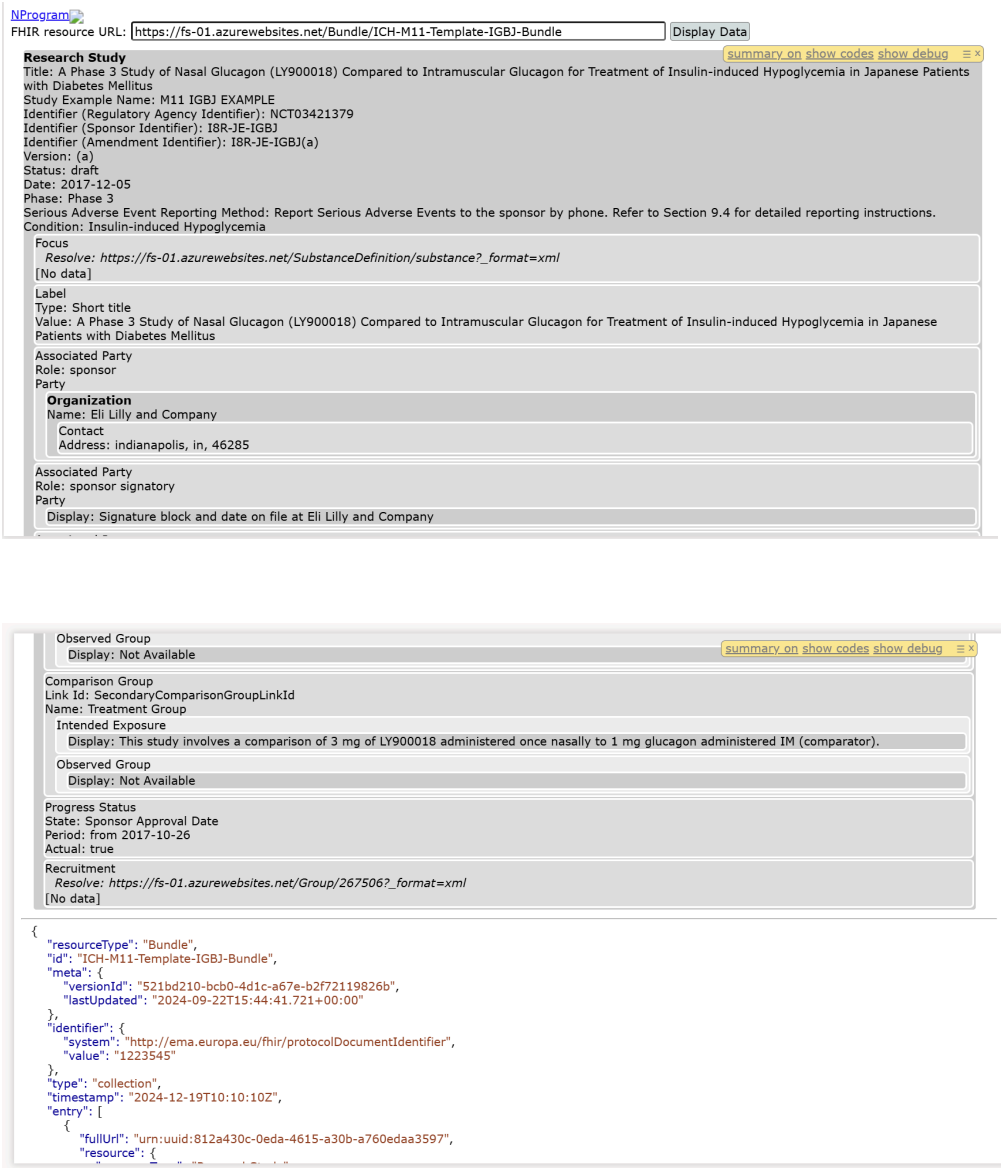
- Notable achievements

Objective	Outcome
(1) Defining and Structuring Eligibility (Inclusion/Exclusion) Criteria	Generated a protocol with structured information that can be displayed as a document a. Varying degrees of granularity of structured information b. Code visible from document view when hover over text
(2) Exploring the use of FHIR Extensions	**Summary of Outcomes** •Principle: the skeleton is separate from the data •Create a profile of Composition that represents the full structure of

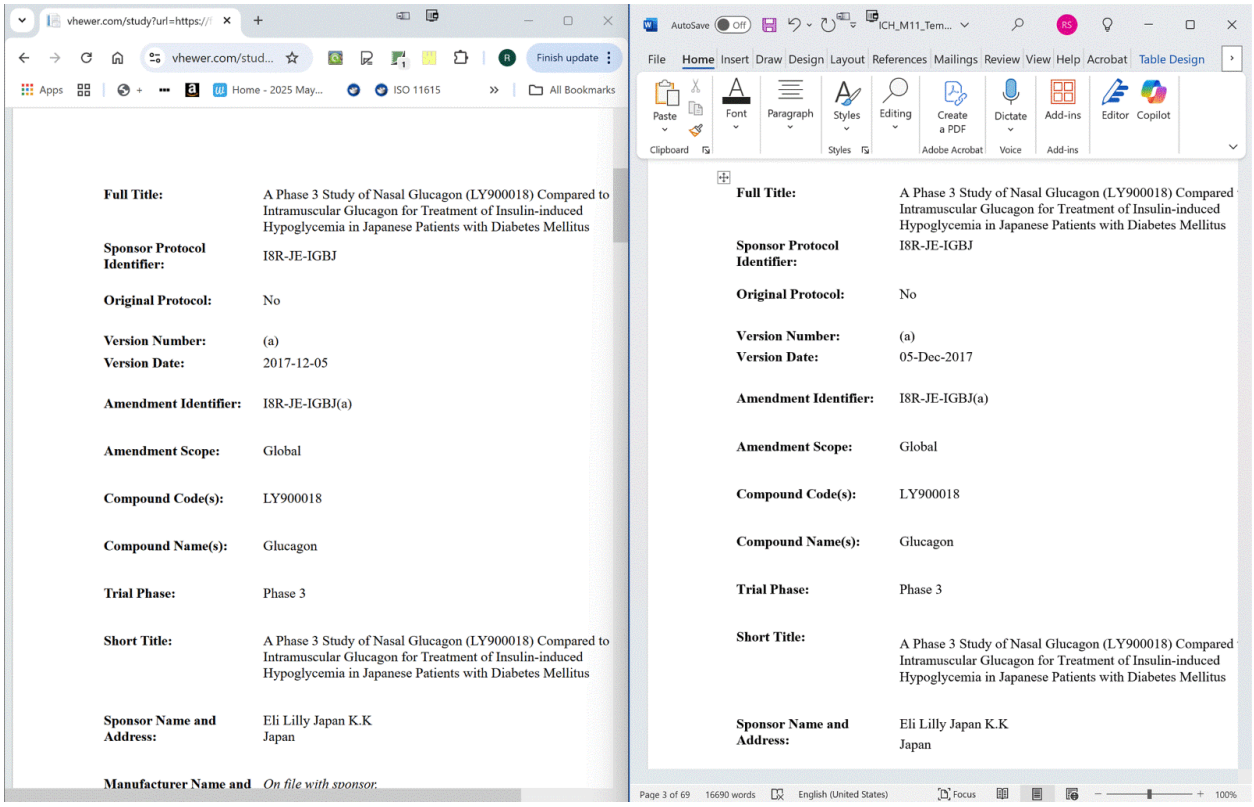
	M11 document •The profile will constrain what goes into each leaf-node of the M11 outline •Leaf nodes will reference appropriate FHIR resources for the content •Ex Title Page will point to a Research Study resource. I/E will point to a Group resource appropriately FHIR-profiled •The majority of sections will point to profile of Composition that might be called “M11 Narrative Element” – a profile of Composition, identified by an appropriate code from the M11 section name
(3) Terminology Standardization	• Decision: Will utilize NCI EVS for controlled terminology. Aligns with current practice in another HL7 project (PQ/CMC). Target to include NCI Thesaurus C codes on the IG. • Team interaction with ICH to establish requirement for M11 terminology and NCI Thesaurus C Codes for inclusion into the UDP IG.

- Screenshots and/or links to further information

1) Objective 1: An MS Word, M11 structured clinical research protocol was converted to FHIR. The following illustrates the now structured protocol (FHIR USDM, HTML) that was then utilized to (re)construct a protocol document.



Screen shot comparison of FHIR data on the left and original MS Word protocol on the right.



Screenshot of the "popup" feature, showing where the Sponsor Approval Date comes from in the FHIR JSON (not just in theory, the screen text is derived from that data).

Manufacturer Name and Address: *On file with sponsor.*

Regulatory Agency Identifier Number(s): NCT03421379

Sponsor Approval Date: 26-Oct-2017

ResearchStudy.progressStatus[state/coding/code/@value='sponsor-approved'].period.start

Sponsor Signatory: Signature block and date on file at Eli Lilly and Company

Medical Expert Contact: Medical Expert details on file at Eli Lilly and Company

SAE Reporting Method: Report Serious Adverse Events to the sponsor by phone. Refer to Section 9.4 for detailed reporting instructions.

Amendment Details: This protocol has not been amended previously. (expected string extension with url http://example.org/fhir/extension/studyAmendment or http://hl7.org/fhir/uv/ebm/StructureDefinition/studyAmendment)

Overall Rationale for the Amendment:
Updates to address safety concern & align with product guidelines.

3 TRIAL OBJECTIVES AND ESTIMANDS

3.1 Primary Objective(s) and Associated Estimand(s)

To demonstrate that 3 mg LY900018 is non-inferior to 1 mg IMG for the proportion of patients achieving treatment success from insulin-induced hypoglycemia using a non-inferiority margin of 10%

Screenshot of generated eligibility criteria.

analog (insulin lispro, insulin aspart, or insulin glulisine), or

ii. continuous subcutaneous insulin infusion (CSII)

Or

b. T2DM based on the WHO diagnostic criteria, and have received the following daily insulin therapy with or without oral anti-hyperglycemic medications (OAMs) for at least 1 year

i. insulin: long-acting insulin analog (either insulin glargine [U-100 or U-300] or insulin degludec [U-100]) alone, or in combination with rapid-acting insulin analog (insulin lispro, insulin aspart, or insulin glulisine) or CSII

ii. OAM: up to 3 of the following OAMs in accordance with local regulations: metformin, di… inhibitor, sulf… doses), glinid…

characteristic.extension[@url='http://hl7.org/fhir/6.0/StructureDefinition/extension-Group.characteristic.description'].valueString.extension[@url='http://hl7.org/fhir/StructureDefinition/rendering-markdown'].valueMarkdown

2. male patients: agree to use an effective method of contraception for the duration of the study and for 28 days following the last study treatment

5.2 Inclusion Criteria

Patients are eligible for inclusion in the study only if they meet all of the following criteria at screening and/or enrollment:

1. have had a diagnosis of either:

    a. T1DM based on the World Health Organization (WHO) diagnostic criteria, and have been on the following daily insulin therapy for at least 1 year

        i. multiple daily injection of long-acting insulin analog (either insulin glargine [U-100 or U-300] or insulin degludec [U-100]) and rapid-acting insulin analog (insulin lispro, insulin aspart, or insulin glulisine), or

        ii. continuous subcutaneous insulin infusion (CSII)

Or

    b. T2DM based on the WHO diagnostic criteria, and have received the following daily insulin therapy with or without oral anti-hyperglycemic medications (OAMs) for at least 1 year

        i. insulin: long-acting insulin analog (either insulin glargine [U-100 or U-300] or insulin degludec [U-100]) alone, or in combination with rapid-acting insulin analog (insulin lispro, insulin aspart, or insulin glulisine) or CSII

        ii. OAM: up to 3 of the following OAMs in accordance with local regulations: metformin, dipeptidyl peptidase-4 inhibitor, sodium glucose cotransporter 2 inhibitor, sulfonylurea (should not be more than half of maximum approved doses), glinides, alpha-glucosidase inhibitor, or thiazolidine

(NOTE: Expression of eligibility criteria is also possible per this example): https://fevir.net/resources/Group/279340 shows this eligibility criterion in a ConceptualCohortDefinition Profile from the Evidence Based Medicine on FHIR IG

- Discovered issues / questions (if there are any)/ Now what?
    - Need to validate a concern around using the document approach to nest structured content.
    - Consideration of “user personas”/ “user types” - need to map
    - Need to organize team input into M11 to FHIR mapping
        - Consider FSH (consult with Mark Kramer)
    - Confirm timing of availability of NCI Thesaurus C Codes and impact on IG development.
    - Continue to explore dependencies and synergies with EBM IG and working group.