Connectathon 37

Track Report Out

This Track Report has been locked for final edits. If you have an update, please email Sandy Vance at sandy@counterpointsol.com.

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?

Accelerating Care Transformation (ACT) Initiative: Improving Care Delivery by Accelerating Evidence into Practice

- 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?

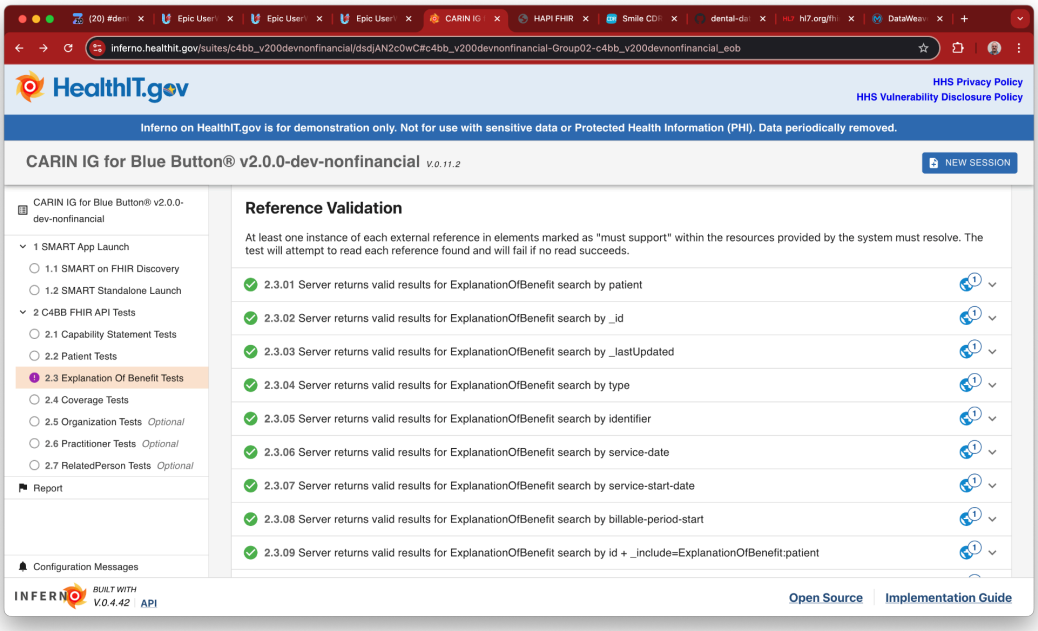
C-CDA to FHIR Mapping

- What was the track trying to achieve?

        - Advance mapping work by comparing implemented maps and developing consensus
- List of participants (with logos if you have time and energy)
    - Veterans Administration, Availity, Lantana, NCQA, ASTP, PSI, APHL
- Notable achievements
    - Completed addressing gaps in PAMPI domains in USCDI
        - Deferred many non-USCDI items for WorkGroup review
    - Identified approach to text transmission for WG review
- Updated IG Content
    - Added several fields to C-CD->FHIR Medications
    - Cleaned TODOs and added BP & PulseOx recommendations to Vital Signs
    - Addressed some TODOs on Encounters
- Now what?
    - Prepare January ballot
    - Plan for completion of USCDI

CARIN IG for Blue Button

- What was the track trying to achieve?
    - Real world testing of the CARIN IG for Blue Button® oral EOB profiles.
- List of participants (with logos if you have time and energy)
    - Monarch
    - Department of Veterans Affairs
    - American Dental Association
    - ASTP/ONC
- Notable achievements
    - Monarch used Inferno to test EOB with Arabica Blue FHIR server. They were able to pass 15 of 38 CARIN 2.0.0 non-financial EOB tests with a new record we entered today.
- Screenshots and/or links to further information



- Discovered issues / questions (if there are any)
    - None that were notable.
- Now what?
    - Monarch believes many or all of these will pass after they complete data cleanup on the new EOB.
    - CARIN will plan to hold ongoing discussions with implementers to prepare for the January 2025 virtual Connectathon and invite any interested participants to reach out to mark.roberts@leavittpartners.com to join the conversation.

CDS Hooks

- Our main goal was to implement and test an enhanced prefetch syntax (refer to the link below) to support search parameters that use dates and references to context resources. The success criteria was for a client to ingest and fulfill prefetch queries from a service using the enhanced syntax.
- Participants
    - Christopher Schuler (Smile Digital Health)
    - Dan Gottlieb (Central Square Solutions)
    - Isaac Vetter (Epic)
    - Steve Millard (FDB Health)
    - Xavier Sevcik (Epic)
- Notable achievements

    - Successfully executed enhanced prefetch queries within Epic.
    - Generated the enhanced prefetch template from a FHIR Library data requirements
    - Evaluated the order-sign hook within the CDS Hooks Sandbox using the enhanced prefetch
- Screenshots and/or links to further information
    - https://build.fhir.org/ig/HL7/cds-hooks/branches/prefetch-enhancements/#prefetch-tokens-containing-simpler-fhirpath
    - https://cds-hooks.org/hooks/order-sign/
    - https://sandbox.cds-hooks.org
- Discovered issues / questions (if there are any)
    - May need to revisit some possible issues discovered in the enhanced prefetch FHIRPath query patterns, especially when determining the type a Reference refers to. What is the ideal method to define the prefetch templates? Is it possible to automate the generation?
- Now what?
    - Continue to test enhanced prefetch scenarios and reach out to possible implementers to ensure support for the majority of their use cases.

Clinical Reasoning

- Our goals were to
    - Test FHIR and CQL-based Measures exported from the MADiE tool
    - Test Measure content from the Goal-directed care planning track
    - Test CQL Engine Parity among different CQL engines
    - Test sample HEDIS measure content
    - Test CQL Prepopulation of Prior Authorization Questionnaires
    - Review USCDI+ Quality Data Elements for Measures
    - Test latest narrative measure output
    - Test CRMI Artifact Terminology Service
    - Test CRMI Artifact Repository Service
    - Test CRMI Packaging capabilities
- List of participants (with logos if you have time and energy)
    - Bellese
    - CDC
    - CMS
    - Dynamic Health IT
    - ICF
    - Firely
    - Leavitt Partners
    - Mathematica
    - NCQA

    - Smile Digital Health
    - The Joint Commission
    - The MITRE Corporation
    - Vermonster
- Notable achievements
    - Due to improvements in the reporting client this round, we were able to test groups of measure test cases all at once
        - Summary: 156 pass, 379 fail across 21 measures
        - Issues with the way test data is exported for the other 40+ measures prevented us from loading the test data completely into the FHIR server
        - Currently investigating the 379 failures with the 21 measures we tested
    - DQIC CQL Engine Parity Testing
        - Pass count went down due to changes in the test runner, working on this issue
    - DQIC Sample HEDIS Measure Testing
        - Several fixes to the Java engine (based on parity testing finds) result in LSC running, working on getting test deck comparison logic to get to pass/fail counts
    - Coordination with the SDC Questionnaire track on testing CQL population and definition-based extraction resulted in agreement on an SDC proposed extension to better support definition-based extraction
    - Coordination with the Provider Burden Reduction track on testing CQL population resulted in several trackers to the SDC and CRD specifications
    - Measure Repository service testing resulted in several trackers to the CRMI specification to clarify artifact repository capabilities
    - Discussion on artifact search capability led to proposed changes in CRMI non-canonical artifact approach
- Screenshots and/or links to further information
    - Detailed measure testing results:
        - https://docs.google.com/spreadsheets/d/1DocNOIX3ZYWCzOxSHw00sl21WHWx5SeazrlSCUcjqqs/edit?gid=1588622835#gid=1588622835
    - Breakout slides
        - DQIC/HEDIS Measure Testing Breakout: Clinical Reasoning Track DQIC Breakout 9-21-24.pptx
        - Terminology/Measure Repository Breakout:
            - [ ] Clinical Reasoning Track Manifest Breakout 9-21-24.pptx
            - [ ] SeptConnectathonMRSDemo-Final.pptx
        - DaVinci CQL Questionnaire Support Breakout: Clinical Reasoning Track DaVinci CQL Questionnaire Support.pptx
- Discovered issues / questions (if there are any)
    - Gathering links to trackers submitted…
- Now what?
    - Provide feedback on measure export/import issues back to test case packaging specification
    - Continue improving engine parity testing and test results display
    - Update CRMI non-canonical artifact specifications (especially for searching)
    - Continue testing sample HEDIS measure content

    - Update DEQM bulk processing approach to make use of updated bulk data specifications
    - Provide feedback on sample HEDIS measure testing back to measure authors

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CodeX/GenomeX Data Exchange

- What was the track trying to achieve?
    - Confirm genomic report transmission and ingest by EHR / EMR.
- List of participants:
    - Tempus AI
    - Myriad Genetics
    - Epic
    - Philips Healthcare
    - Oracle
    - CHLA
    - MITRE Corporation
    - Dogwood Health Consulting
    - NMDP
- Notable achievements:
    - Tempus confirmed 100% data ingest by Epic for germline and somatic test results
    - Myriad created a wide array of test result samples that cover oncology (somatic, germline, and biomarkers) and prenatal testing (single and partnered reports). Focused testing on oncology samples was largely successful.
    - Epic confirmed the successful ingest of the Tempus xG and xF test reports and the MyRisk positive and negative test reports.
    - Philips downloaded Tempus test report examples (from Tempus) and validated data accessibility for use in their clinical application.
    - Philips downloaded and validated the utility of the Tempus data from Epic EHR, showing that there is no loss of fidelity once the EHR has processed the data.
- Screenshots and/or links to further information
- Discovered issues / questions (if there are any):
    - Outstanding Issues - Myriad is sending Epic a PDF in the Foresight bundle, but it errored on a data size limit and failed. Epic typically gets a link to documents, then retrieves the document.
        - Potential Issue Resolution – propose a way forward for resource limits and the inclusion of embedded files vs. document links.
    - Outstanding Issues - Tempus highlighted the fusion error.
    - Outstanding Issue - Negative variants are not described in enough detail in the GRIG for common representation and ingest into the EHR.
        - Potential Issue Resolution – propose a model of negative variants plus when and how they will be included in reports.
    - Outstanding Issue - List of positive / negative / etc. and the associated mapping to present / absent / etc. under gene variant means there are mappings that have the potential to cause misunderstandings.

        - Potential Issue Resolution – submit for a set of LOINC codes specific to gene variation.
- Now what?
    - GenomeX will continue to meet with our use case team in preparation for the January 2025 virtual Connectathon. Please reach out to jpatterson@mitre.org if you are interested in participating.
    - Develop plans for how biomarkers will be represented for genomic reports.
    - Engage with the Clinical Genomics Working Group as appropriate.
    - Work to expand code systems such as LOINC as appropriate.
    - Individual vendors will address implementation issues as appropriate.

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.

- **Notable achievements**

Epic testing:

- Successful testing of
  MITRE/ONC CRD + DTR
  HIKE CRD + DTR
  Smile DTR
  Mettle/CMS DTR
  Itiliti CDex submit-attachment
  Onyx CRD + DTR

- Still working through / partial testing
  HIKE DTR + PAS still working through issues
  Infor PAS working through issues
  Intersystems+Cambia PAS working through issues

And about a dozen jira tickets to write up in various areas

Infor Testing Summary

MITRE/ Inferno Testing

- Tested DTR SMART App launch.
  - Mostly working
    - Some test failures of my QuestionnaireResponse due to missing fhirUser which is used for the QR author.
    - Need more information in the ID Token from Inferno so DTR can populate author fields in the QuestionnaireResponse.

Meditech – DTR Launch

- DTR app successfully authenticated, launched and passed the FHIR context

- Infor had trouble with the Reference Implementation finding the questionnaire we asked for

Epic – PAS

- Converted from X12 to FHIR okay
- We were not able to route the message due to missing payer Organization.name

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Onyx Testing Summary

- EPIC
  - Successfully Tested order-sign
    - Doc needed & Auth needed
    - Proper Questionnaire Package Returned (with required resources)
    - Rendered Questionnaire in Epic Questionnaire App
    - Successfully Tested Appointment Book
    - Auth-needed & doc-needed
    - Successfully scheduled an appointment in Epic's system
- Meditech / EPIC
  - Successfully Tested order-sign
    - Doc needed & Auth needed
    - Proper Questionnaire Package Returned (with required resources)
    - Launch URL generated + present
- MITRE:
  - Successfully Tested/Used Inferno Test Suites for CRD + DTR,
  - Delivered feedback to Mitre for some improvements
  - Onyx Passed over 90% of CRD / DTR Inferno test cases
    - For Order-Sign, Appointment-Book, & $questionnaire-package

Intersystems

- Ran 3 test scenarios of the end-to-end PAS workflow:
  1. Epic → InterSystems PAS → Cambia
  2. Nucural → InterSystems PAS → Cambia
  3. Globex|PIE → InterSystems PAS → Cambia

- 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

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

Track Scenarios

Attachments Scenarios

- **Scenario 1: Unsolicited Attachments of CCDA Documents**
  - CDex Documentation: **Unsolicited Attachments of CCDA Documents Using LOINC Attachment Codes**
- **Scenario 2: Solicited Attachments of CCDA Documents Using LOINC Attachment Codes**
  - CDex Documentation: **Solicited Attachments of CCDA Documents Using LOINC Attachment Codes**
- **Scenario 3: Solicited Attachments Using Static Questionnaire**
  - CDex Documentation: **Requesting Attachments Using Questionnaires**
- **Scenario 4: Solicited Attachments Using Adaptive Questionnaire**
  - Documentation: **Requesting Attachments Using Questionnaires**
- **Scenario 5:** PAS 1.2.0 R **PAS-CDex Transaction - Solicited Attachments of CCDA Documents Using LOINC Attachment Codes in Response to a "Pended"**
  - CDex Documentation: **Requesting Attachments Using Questionnaires**

Task-Based Scenarios

- **Scenario 6: Task-Based Transactions : Polling - Payer Seeks Insured Person's Active Conditions from Provider to support a claims audit.**
  - CDex Documentation: **4 Task Based Approach**
- **Scenario 7: Task-Based Transactions Using Questionnaires**
  - CDex Documentation: **4.9 Task Based Approach:Using Questionnaire as Task Input**
- **Scenario 8: Task-Based Transactions: Subscriptions - Payer Seeks Insured Person's Active Conditions from Provider to support a claims audit.**
  - CDex Documentation: **4.11.2 Task Based Approach:Subscription**

Direct Query Scenarios

- **Scenario 9: Direct Query Transaction - Payer Seeks Insured Person's Active Conditions from Provider to support a claims audit.**
  - CDex Documentation: **Direct Query**

Bulk Transactions PROPOSED

- Scenario 10: Bulk Transaction - **Payer Seeks Clinical Data for Members for HEDIS Measures**
  - No CDex Documentation see the Bulk Data Access IG

HL7 International

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CDex Connectathon Scenario Cross Tabs

CDex Implementation Cross Reference Table

- (Click ✔ to link to the source)
- (Click 🎥 to see video demonstration)

Scenario	Requirements from the Implementation Guide	Implemented in Reference Implementation?	TestScripts Available?	Implemented in Postman ?
1	5.1.1 Unsolicited Attachments	✔ CDEX 2.0.0	✔🎥 CDEX 2.0.0	✔ CDEX 2.0.0
2	5.3 Requesting Attachments Using Attachment Codes	✔ CDEX 2.0.0	✔ CDEX 2.0.0	✔ CDEX 2.0.0
3	5.4 Requesting Attachments Using Questionnaires	✔ CDEX 2.0.0	✔ CDEX 2.0.0	✔ CDEX 2.0.0
4	5.4 Requesting Attachments Using Questionnaires (Adaptive Questionnaires)	✘	✘	✘
5	5.4 PAS-CDex Transaction	✔ CDEX 2.0.0 PAS 1.2.0 R	✘	✔ CDEX 2.0.0
6	4 Task Based Approach	✔ CDEX 2.0.0	✔🎥 CDEX 2.0.0	✔ CDEX 2.0.0
7	4.9 Task Based Approach: Using Questionnaire as Task Input	✘	✘	✘
8 CDEX 2.1.0 P	4.11.2 Task Based Approach: Subscription	✘	✘	✔
9	3 Direct Query	✔ HAPI FHIR server UI CDEX 2.0.0 CDEX 2.1.0 P	✔🎥 CDEX 2.0.0 CDEX 2.1.0 P	✔ CDEX 2.0.0 CDEX 2.1.0 P
10 PROPOSED	CDex Bulk Transactions	✘	✘	✔ PROPOSED
6,7,8	4 Task Based Approach	(see links below)	(see links below)	(see links below)
1,2,3,4,5	5.1 Solicited and Unsolicited Attachments	✔ (see links below)	✔ (see links below)	✔ (see links below)
-	7 Security and Privacy	✘	✘	✘
- NOT TESTED	6 Signatures	✘	✘	✘

CDex Implementation Cross Reference Table

HL7 International

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Testing Highlights

1. RI Testing
   - Identified RI issues
2. Updates to Testscripts
3. Updates to Collection

Next Steps

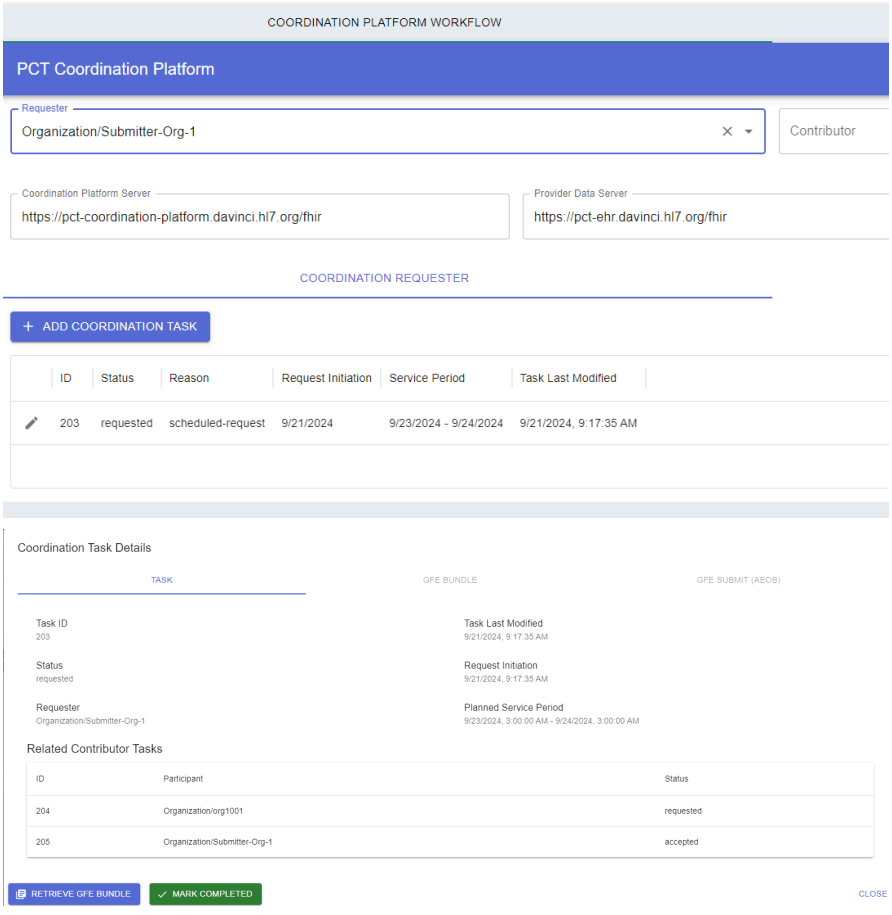
1. RI
   Integration with a form filler on Foundry
   Update to Cdex Version 2.1.0
2. Testscript: Update to Cdex Version 2.1.0
3. Collection
   Update to Cdex Version 2.1.0
   Add more test data

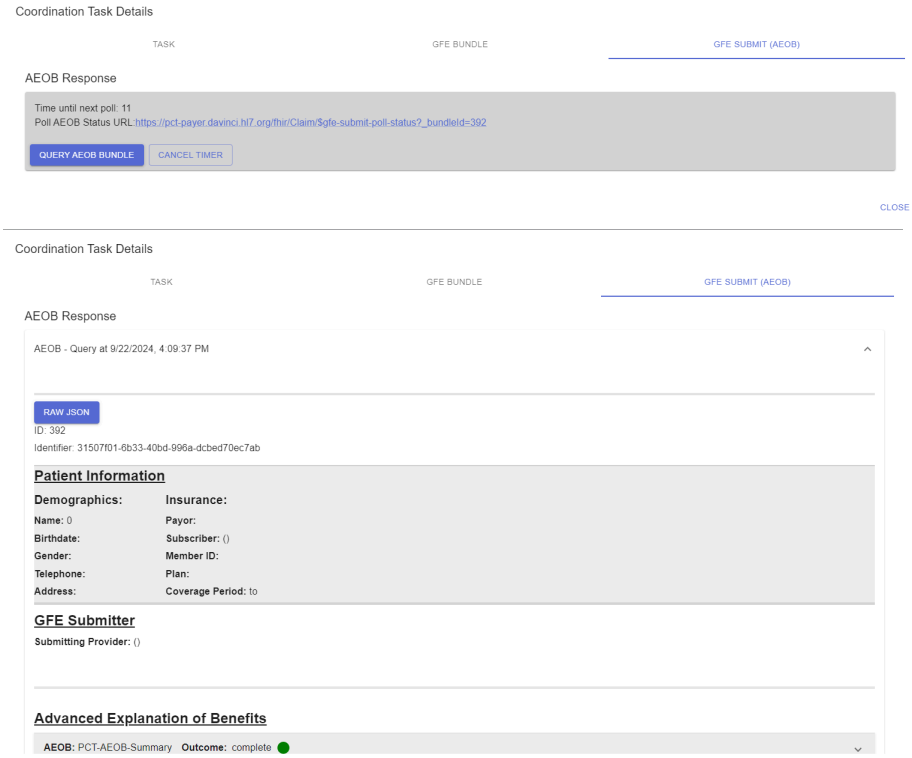
Da Vinci Patient Cost Transparency (PCT)

- What was the track trying to achieve?
  - Testing GFE Submit and retrieval of AEOB Bundle
  - Testing GFE submit with multiple GFE Bundles and retrieval of AEOB Bundle

    - Testing of Coordination Workflow (GFE Coordination Tasks and submissions)
- List of participants (with logos if you have time and energy)

- Notable achievements
    - Able to test new Client RI functionality for GFE Coordination Workflow
        - Successfully created Coordination and Contributor tasks
        - Successfully accepted and rejected tasks as a contributor
        - Successfully attached GFE bundles as a Contributor
        - Successfully retrieved all GFE bundles as the coordination requester
        - Successfully submitted GFE Collection Bundle and retrieved AEOB Bundle
    - Ran some tests with Aegis Touchstone
- Screenshots and/or links to further information





- Discovered issues / questions (if there are any)
    - While running tests with Aegis, it was identified that the gre-retrieve operation is run on the base, but the preferred design pattern for operations with the context of a specific resource should be run against the instance. (e.g. {FHIR Server Base URL}/Task/{Coordination Task ID}/$gfe-retrieve)
      Created a Jira ticket: FHIR-48357 - Change Retrieve GFE Collection Bundle Operation from a global operation to a Task instance operation
- Now what?
    - Continue ballot reconciliation
    - Develop RI to support subscriptions

Da Vinci Payer Data Exchange / Formulary (PDex)

- What was the track trying to achieve?
    - Testing of: PDex STU2.1 APIs:
        - Payer-to-Payer Single Member Match
        - Payer-to-Payer Bulk Member Match
        - Provider Access Bulk API
        - Formulary Bulk Export
- List of participants (with logos if you have time and energy)

- Notable achievements

Successful testing of:

- Formulary Bulk Export was test by Lantana against the RI
- PDex Payer-to-Payer Single Member Match
    - Onyx, Firely and Lantana provided Servers
    - Aveneer, Infor, Inferno and Humana tested successfully with Onyx
    - Infor tested with Firely
    - Inferno tested with Lantana
- PDex Payer-to-Payer Bulk Member Match
    - Onyx provided a Server
    - Aveneer, Humana and Infor tested successfully with Onyx
    - Screenshots and/or links to further information

    - Discovered issues / questions (if there are any)
        - Formulary RI to be updated to support:
            - GraphDefinition parameter
            - Export specific InsurancePlan with an id
    - Now what?
        - PDex STU2.1 was in the September ballot. The focus will be on Ballot reconciliation and publication of the IG with support for Provider Bulk Access, Payer-to-Payer Bulk API and support for US Core 6.1.0

Da Vinci Postable Remittance

We were testing our FHIR IG with a client and server to ensure that the Reference Implementation worked as expected and to answer some questions we had going into the connectathon.

Participants:

Jean Duteau

Naomi Miao

Anoush Mouradian

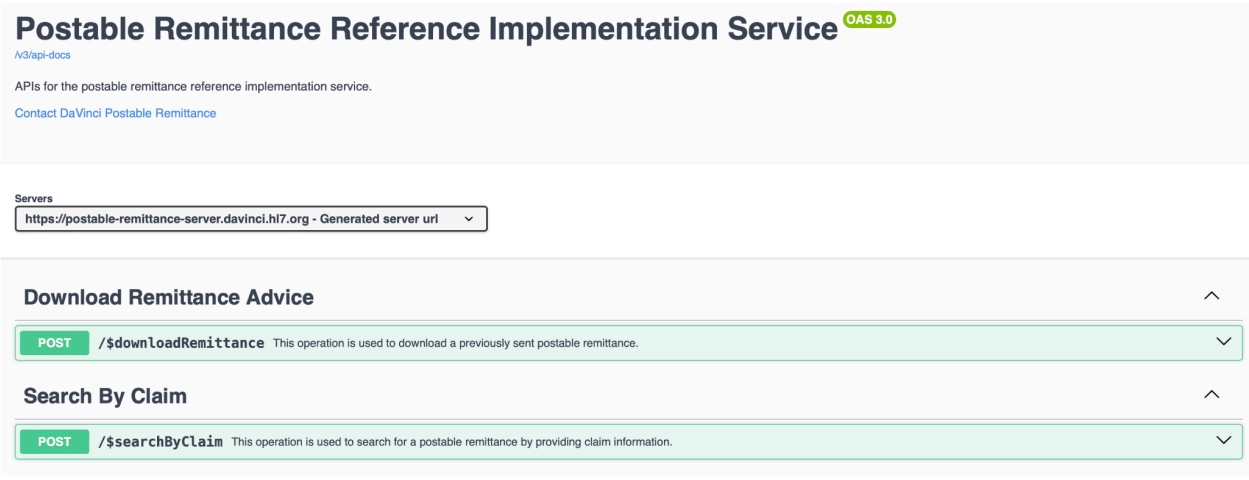
Christina Love

Jessica Kreider

Kevin Prince

We proved that the Reference Implementation works and updated it based on the questions we had. We had a successful client communicate with the RI server. We answered most of the questions that we had.

Foundry Server - https://foundry.hl7.org/products/db125eeb-eeae-4467-9012-cbce6b13c045



Client requesting an 835 remittance

REMITTANCE ID

A123456BCD | X12 835

RETURNED REMITTANCE:

Resource Id: remittance-document-03473f2c-9e4f-476a-93a7-3fe0b8e5f0a3

Remittance Identifier: A123456BCD

Content Type: application/txt+gzip

ISA*00* *00* *ZZ*200787505 *ZZ*450525148 *240826*0912*^*00501*101925142*0*P*:~ GS*HP*200787505*450525148*20240826*0912*101777856*X*005010X221A1~ ST*835*0001~
BPR*I*20.00*C*ACH*CCP*01*123000848*DA*1700020064*12345**01*123000848*DA*153911610365*20240816~ TRN*1*9155284235*12345~ REF*EV*450525148~ DTM*405*20230811~ N1*PR*ABCDE~ N3*PO
BOX 1106~ N4*LEXINGTON*KY*405120000~ REF*2U*TP021~ REF*EO*363917295~ PER*CX*ABCDE*TE*8008007885~ PER*BL*ABCDE*TE*8008007885~ N1*PE*Local clinic LLC*XX*PB654~ N3*PO BOX
18001~ N4*BELFAST*ME*049150000~ REF*TJ*123456789~ REF*0B*OS12165~ LX*1~ CLP*12345V12345*1*20.00*20.00**WC*4567891236*11*1~ NM1*QC*1*ZXCVB*QWERT****34*999999999~
NM1*82*1*Local clinic LLC*Local clinic LLC****XX*PB654~ REF*F8*100184984695~ REF*CE*FL~ DTM*232*20230811~ DTM*050*20230902~ AMT*AU*0.00~ SVC*HC:99214*20.00*20.00~ DTM*472*20230811~
CAS*CO*45*0.00**P24*0.00~ REF*6R*2196311P13648B62477~ AMT*B6*20.00~ SE*32*0001~ GE*1*101777856~ IEA*1*101925142~

Client requesting a PDF remittance

REMITTANCE ID

A123456BCD | PDF

RETURNED REMITTANCE:

Resource Id: remittance-document-4ddfa242-14b5-4683-a181-3d684c6ae09c

Remittance Identifier: A123456BCD

Content Type: application/pdf+gzip

Payer
ABCDE
PO BOX 1106
LEXINGTON KY, 405120000

Payee
Local clinic - (PB654)
PO BOX 15262
BELFAST ME, 049154047
Group Number: Unknown
Check Number: A123456

SUMMARY OF BENEFITS

Patient: ZXCVB, QWERT	**Billed:** $20.00	**Paid:** $20.00
Patient ID: M12345678901		
Provider: Local clinic - (PB654)	**Other Provider #:** Not Available	
Provider NPI: PB654		
Patient Account #: 12345V12345	**Payer Claim #:** 4567891236	**Pay Date:** 2023-10-02

The relationship between remittances and payments was discussed and we determined that it was a one-to-one so the IG and the RI were updated.
We discussed the error responses and agreed that the RI was correct.
We changed the compression algorithm from ZIP to GZIP so that we could use appropriate content MIME types.
We switched from DocumentReference to Binary.
We added the remittance identifier to the outgoing remittance resource.
We discussed a new use case for a bulk download of remittances. This will require more discussion with the group to ensure that it is a valid use case.

We believe the guide is ready to ballot so we will finalize the guide content and start on the HL7 administrative work to begin the ballot process.

Da Vinci Risk Adjustment / Value-Based Performance Report

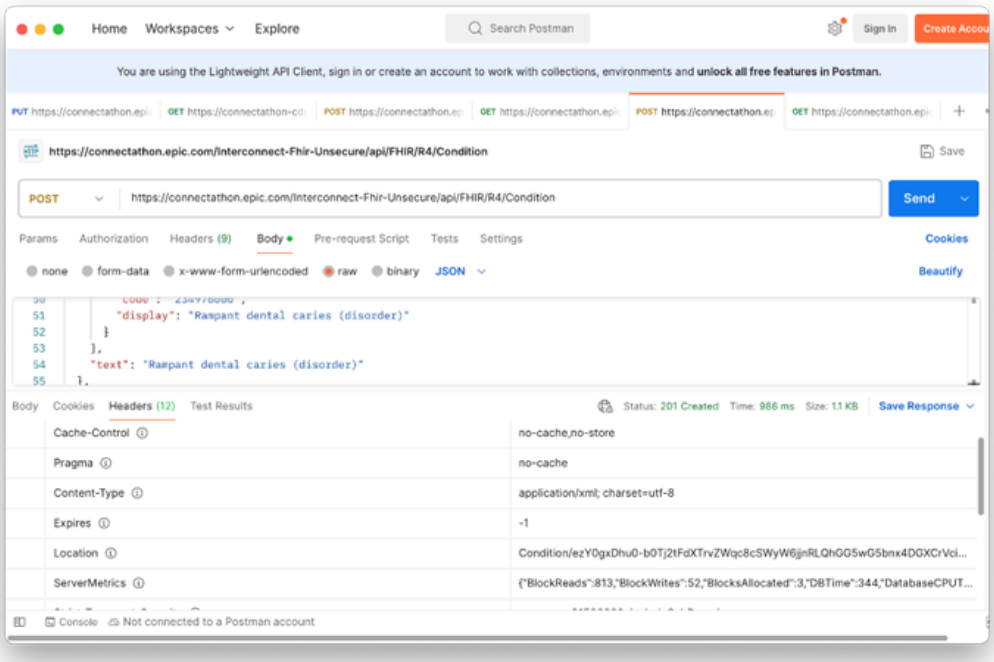
- What was the track trying to achieve?
  - Testing the Da Vinci Risk Adjustment and Da Vinci Value-Based Performance Reporting IG
- List of participants (with logos if you have time and energy)
  - Optum
  - Smile Digital Health
  - Optimum eHealth
- Notable achievements
  - Activities were light for the track this Connectathon because the applied changes for the Risk Adjustment IG STU2 reconciliations were tested in the last Connectathon and the VBPR IG STU1 was published in June, 2024.
- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)
  - Identified the need to document the processes/steps of posting an updated IG package to HL7 foundry.
- Now what?
  - Preparing and taking the Risk Adjustment IG STU2 for publication.
  - Prepare an STU1.1 update for VBPR to support USCore 6.1.0

Dental Data Exchange

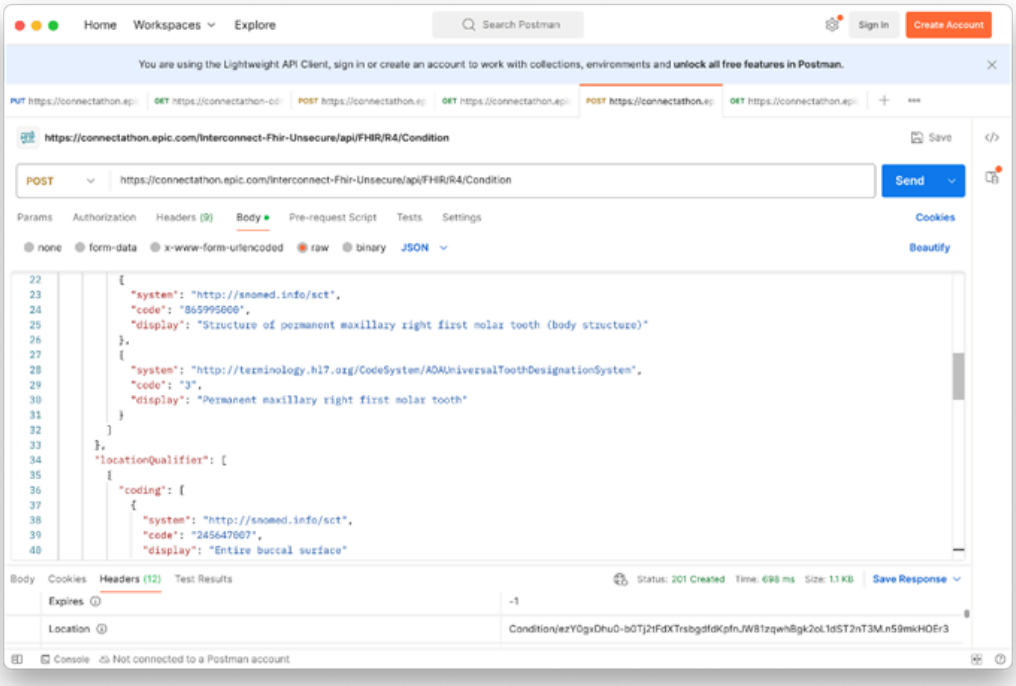
- What was the track trying to achieve?
  - Test vendor implementations of the Dental Condition, Dental Finding (Observation), and Dental Procedure profiles, intended to support

computable exchange of patient data with and among dental providers, including support for the SNODENT code system frequently used by dental systems.

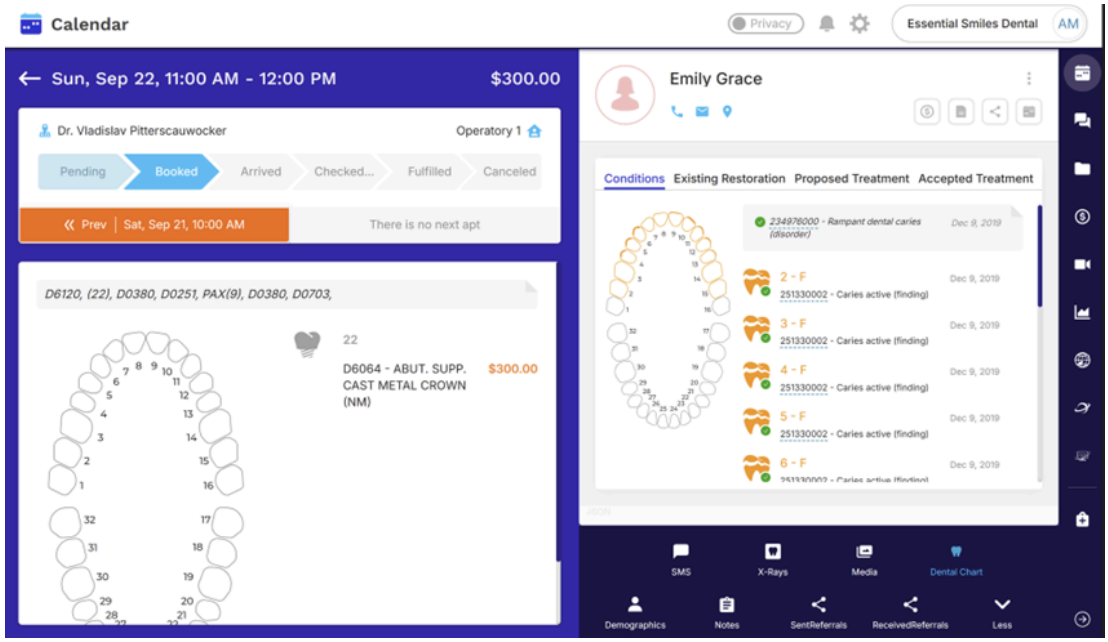
- List of participants (with logos if you have time and energy)
    - American Dental Association
    - Tooth Apps
    - Monarch
    - Veterans Affairs
    - FEHRM
    - EPIC
    - NexGen
- Notable achievements
    - Support real-time calls for conditions (rampant caries) and existing restorations (ToothApps via SmileServer) and display.
    - Connect to Epic Servers (testing and production) to retrieve
    - medical conditions and allergies and read back dental conditions and treatment plans.
    - Read/write to test server (Monarch to Epic and Smile) all data for a patient mobile application.
- Screenshots and/or links to further information
    - Read/write patient data from Smile server to Epic server using Monarch

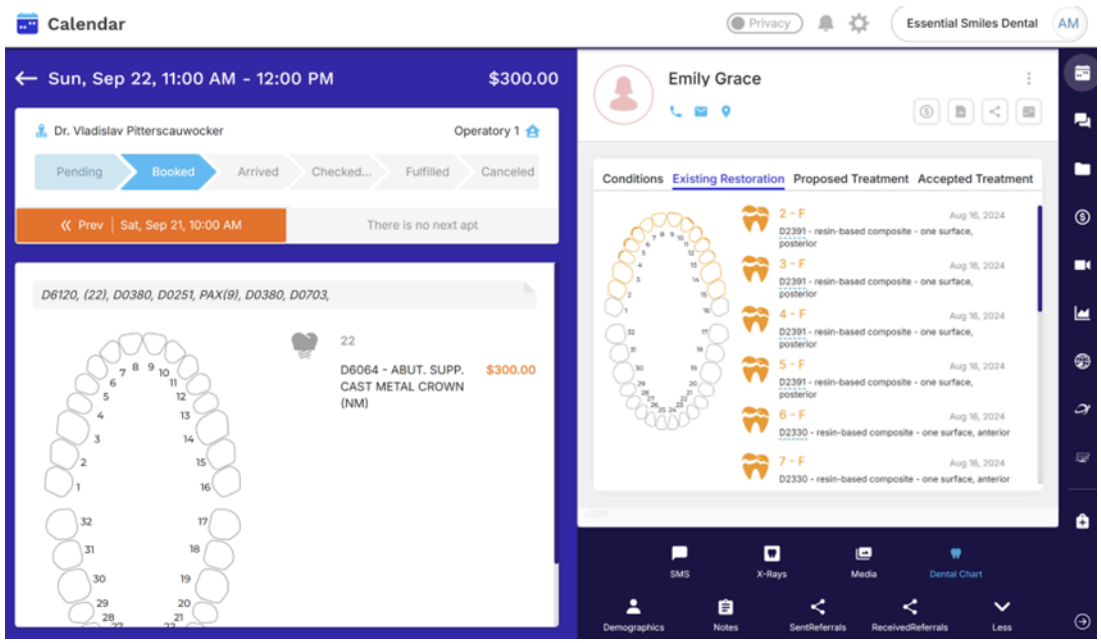


    - Monarch pulled a dental condition (SNOMED 234976000) from the Smile Digital Health server and posted it to the same patient record in the Epic Connectathon server.



- We have posted a condition to Epic without error, and it includes appropriate dental terminology for bodysite/location:
  - "system": "http://terminology.hl7.org/CodeSystem/ADAUniversalToothDesignationSystem",
  - "code": "3",
  - "display": "Permanent maxillary right first molar tooth".

- 

- 

- Discovered issues / questions (if there are any)
  - Lack of synthetic data specific to dental.
- Now what?
  - Expand testing for complex scenarios.
  - Revisit FHIR modeling for dental to remove barriers for wider use by other IGs.

Evidence Based Medicine

- What was the track trying to achieve?
    - introduction to new participants
    - modeling for EBMonFHIR Implementation Guide
    - tooling revisions for FEvIR Platform
- List of participants (with logos if you have time and energy)
    - Brian S. Alper, Computable Publishing LLC
    - Khalid Shahin, Computable Publishing LLC
    - Esmeralda Bolanos, Oracle
    - Zameer Sura, Oracle
    - Kota Torikai, University Hospital in Maebashi Japan
    - Sophie Klopfenstein, Berlin Institute of Health at Charite
- Notable achievements
    - introduction of EBMonFHIR to 3 new participants
    - Modeling of new DataDictionary Resource to use for a data dictionary (the keys for sharing research datasets)
    - FEvIR Platform refactoring to support section-level navigation, viewing and editing for Composition Resources
- Screenshots and/or links to further information
    - https://build.fhir.org/ig/HL7/ebm/StructureDefinition-data-dictionary.html
    - https://fevir.net

FAST Infrastructure (Security & Identity)

Track Goals:

Our overarching goal was to verify that the FAST infrastructure supports requirements in the CMS rules for Interoperability and Patient Access as well as Reducing Provider and Patient Burden. For this, the following track goals were established:

- Conduct end-to-end testing of FAST solutions, including:
    - Security
    - Identity
    - Directory
    - Exchange
- Integration with AEGIS Touchstone testing platform for monitoring of data exchange
- Test new IG functionality (PKCE, scopes, $idi-Match).

Participants: Amongst the organizations helping with our multiple test use cases and bonus points we had:






Notable Achievements and Takeaways

During the Connectathon, all case scenarios established were tested by participants, and all scripts and outcomes were conducted as expected, without any major issues.

Notable Achievements

- Successfully completed testing using the RIs and Touchstone
- Increased engagement from organizations who haven't participated at the FAST Infrastructure track
- Continued validation and interrogation of the Lantana RI from the AEGIS Touchstone application
- Increased engagement from organizations who haven't participated at the FAST Infrastructure track
- Continued validation and interrogation of the Lantana RI from the AEGIS Touchstone application

Security Breakout Session Takeaways

- Review of RFC 6749 - more predictable server behavior when clients ask for scopes that can't be granted or are not supported
- CDS Hooks harmonization
- Engagement with non-US vendors to support universal realm

Technical Takeaways

Complete report can be found here:
2024 - 09 FAST Infrastructure (Security & Identity) - FHIR - Confluence (hl7.org)

Overall analysis from Touchstone:

- The overall status in the middle column (Pass, Fail, Warn) for each TestScript is not very meaningful right now because of three reasons:
    - There are two validator errors on every response from the RI that returns a match (see next bullet).
    - These Connectathon TestScripts are designed for both the client and server to be Systems Under Test (SUTs), so some test runs cause the client to fail, by intention. This can mask the server's results.

    - Long story short, following the links to the test executions will tell the whole story.
- Lantana action: All results with a match returned have failures in the RI's response. These are base FHIR failures caught by the validator:
    - Validation of response body against profile 'http://hl7.org/fhir/StructureDefinition/Bundle' by FHIR specification's Validation Engine produced the following results:
    - ERROR: bdl-8: 'fullUrl cannot be a version specific reference' Rule 'fullUrl cannot be a version specific reference' Failed. Location: Bundle.entry[0] (line 5, col 15).
    - WARNING: Resource has a language, but the XHTML does not have an xml:lang tag (needs both lang and xml:lang - see https://www.w3.org/TR/i18n-html-tech-lang/#langvalues). Location: Bundle.entry[0].resource.ofType(Patient) (line 20, col 8).
    - WARNING: SearchSet Bundles should have a self link that specifies what the search was. Location: Bundle (line 1, col 2).
- Because there are no normative match criteria, we didn't add an error or even a warning if there wasn't a match. Lantana action: Should we add one to the TestScripts? You can still see if there was a match by looking at the test execution of course.

Issues and Questions:

- RFC 6749 for OAuth 2.0 Authorization Framework: This calls for making more predictable server behavior when clients ask for scopes that can't be granted or are not supported.
- $idi-match: Questions about whether or not this operation's results could have accomplished the by $match with the same results.
- CDS-Hooks use of FAST Security IG: Future collaboration between FAST Security and CDS-Hooks teams to integrate FAST security standards.

Next Steps:

- Gather feedback and determine if any changes to the IG are deemed necessary
- Prepare for our STU2 Ballot Cycle in January 2025
- Continue to gather requirements for our IG post STU2
- Expand international participation during our public calls
- Expand UDAP Security beyond the US Realm
- CDS-Hooks use of FAST Security IG: Future collaboration between FAST Security and CDS-Hooks teams to integrate FAST security standards.
- Security IG to conduct a "Testing Day" in collaboration with Sequoia prior to the next Connectathon

FAST National Directory of Healthcare Provider & Services (NDH) & Da Vinci Plan Net

FAST National Directory of Healthcare Provider & Services (NDH) & Da Vinci Plan Net

- Break out meeting , give the NDH IG and RI update; delivered two demonstrations

Participants:

Durwin Day – HCSC

Joel Walker – Health LX

Joe Shook – Surescripts LLC

Brandan Stewart - Lantana

Ming Dunajick - Lantana

Alex Kontur - ASTP

Keith Carlson – ASTP

Tushar Nair – EDEFECS Inc

Rick Lisseveld – AEGIS

Mazk Neumuth – Aetna/Cvsh

Karthik Suresh – AWS

Shaila Mandke – Self

· NDH feature demo:

Demo postman collection for attesting practitioner, verify practitioner, restrict practitioner home address and home phone number, topic subscription for practitioner qualification status change.

national-directory/ndh.postman_collection.json at hapi · HL7-FAST/national-directory (github.com)

· Discovery Endpoint security attribute from NDH RI Demo

Fhirlabs Client

- Touchestone NDH Testing script and results

Testing Scenario 1: Query National Directory for a specific endpoint based on the name or ID of a payer organization.

Query:
https://national-directory.fast.hl7.org/fhir/Organization?name=National%20Rehabilitation%20Hospital%20Inc&_include=Organization%3Aendpoint

Touchstone Test Execution:
https://touchstone.aegis.net/touchstone/execution?exec=20240922102644184907282 4

Result: Pass with Warnings: Conformance Errors in Endpoint Resources

Step 1 Query National Directory API endpoint.

- Action: Query National Directory API
- https://national-directory.fast.hl7.org/
- Success Criteria: ability to access National Directory API

Step 2 Query for endpoint information for a specific Organization -

Action: RESTful GET of endpoint information for a specific organization

https://national-directory.fast.hl7.org/Organization?name=ABC&_include=Organization:endpoint

https://national-directory.fast.hl7.org/Organization?address-state=FL&_include=Organization:endpoint

Success Criteria: ability to return endpoint information for a specific organization.

Testing Scenario 2: Extract bulk data from National Directory

Not Tested - Reviewed Scenario for any issues. Will open JIRA Issue for missing Instantiates in CapabilityStatement and profiling of $export to require _typeFilter

Bonus point:

Testing Scenario 3: Relationship between Practitioner and Networks

Not Tested -Reviewed Possible Issue with the Use Case of modeling a prior relationship of references from the scenario. I will continue to research and will open a ticket for any issue.

Touchstone (aegis.net)

- Findings:

For restricted resource elements response, did not reveal the practitioner's private information, but the response extension indicated the private information should be restricted. Should the NDH IG put requirements to remove the extension which indicate the restricted information? The further discussion is needed for the IG.

-

FDA PQ/CMC - Pharmaceutical Quality - Chemistry, Manufacturing and Controls

Pharmaceutical Quality - Chemistry, Manufacturing and Controls (PQ-CMC) Submissions to FDA Implementation Guide

Participants/Attendees

Participant Name	Role	Affiliation
Scott Gordon	Track Leader	US FDA
Catherine Hosage-Norman	Track Leader	Module3Solutions
Smita Hastak	Track Leader	Samvit Solutions
Lisa Schick	Participant	Samvit Solutions
Bill Friggle	Participant	Samvit Solutions
Vikas Sinha	Participant	IBM
Josiah Tindor	Participant	IBM
Louise Dowling	Participant	Pfizer
Sean Mikeworth	Participant	Lilly

Ryan Adamson	Participant	Glemser

Track Information
Connectathon 37 Track Confluence Page:
https://confluence.hl7.org/pages/viewpage.action?pageId=248877671

PQ/CMC Implementation Guide: https://build.fhir.org/ig/HL7/FHIR-us-pq-cmc-fda/

There were several different planned test implementations for this PQ/CMC Connectathon:

1. Scenario 1, 2 & 3 -- The FDA PQ/CMC Team has developed a Reference Implementation to support Scenario 1, 2, and 3 for the Connectathon. Each Scenario supported different sections of ICH CTD. The Reference Implementation supports FHIR XML file submission, validation against the PQ/CMC FHIR IG, Parsing, Storing and generating reports.
2. Scenario 4 -- Another Implementation application transforms the human readable section of every FHIR message to a nicely formatted human readable output relevant to each message type's information (with tables and images presented comprehensively).
3. Vendor Tool - A third implementation provided by software vendor - Module 3 Solutions, as in January 2024 connectathon, demonstrated the ability to author FHIR files using a forms-based user interface that outputs valid FHIR files for the PQ/CMC IG for ICH CTD sections that were being tested in this Connectathon. These files created by the Module3Solutions tool were then used for the data pipeline of Scenario 1, 2 & 3 above. Thus vendor tool created files were validated, parsed, stored and report generated.

Background

PQ/CMC Initiative and Information Links
A US FDA initiative to establish electronic exchange and content standards for submitting Product Quality (PQ) and Chemistry & Manufacturing Controls (CMC) data, predicated on eSubmission requirements of FDASIA 745A(a). FDA PQ/CMC Homepage for more information: Pharmaceutical Quality - Chemistry, Manufacturing & Controls | PQ/CMC | FDA

Goal:
Establish electronic standards for submitting Pharmaceutical Quality (PQ) and Chemistry & Manufacturing Controls (CMC) data to the FDA

Objective:
Develop structured data standards for PQ/CMC
Implement a data exchange standard for submitting PQ/CMC data

HL7 FHIR is the data exchange standard

•FDA has published three FRNs to date soliciting industry feedback on several areas of PQ domain. To see the past FRNs, visit FDA PQ/CMC: PQ/CMC Federal Register Notices | FDA

•PQ/CMC is a HL7 Project sponsored by the HL7 Biomedical Research & Regulation Work Group (BR&R):
https://confluence.hl7.org/display/BRR/Pharmaceutical+Quality+%28PQ%29+-+Regulatory+Use+Case

•Discussions related to Medication Definition resources and other CMC topics are typically covered during the BR&R WG calls:
https://confluence.hl7.org/display/BRR/Biomedical+Research+and+Regulation

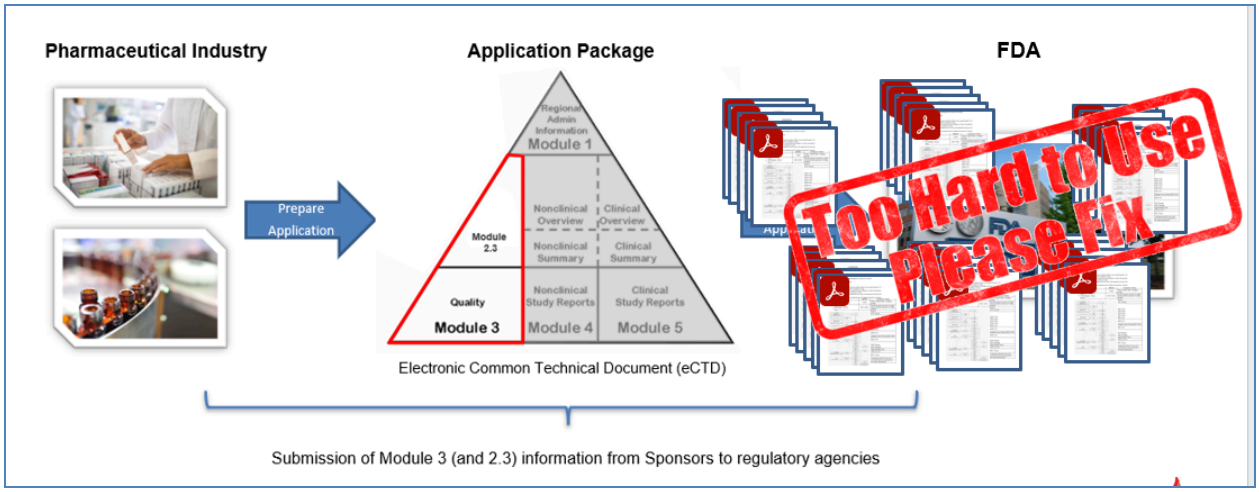
– These are scheduled as needed and agenda is published
– Wednesday calls are typically dedicated to Medication/CMC related discussions
– These WG calls are free

PQ/CMC Use Case and Scope

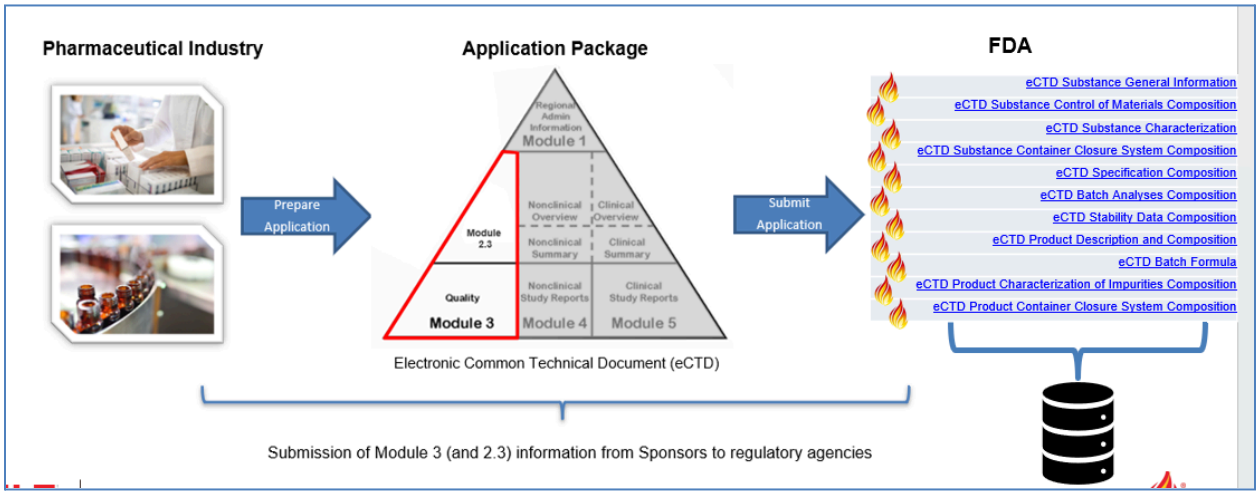
What ***is*** PQ/CMC information?

- Comprehensive definition of every drug product and every substance within a product
- Recipes for making batches of the drug product
- Quality control tests, and acceptance criteria, and results for products and ingredients and batches
- Details on packaging/containers
- Description of manufacturing processes for drug substances and drug products. How a manufacturer:
- Puts everything together to create the products
- Every step, every mechanism, machine, process, etc.
- What steps takes place at which facility, of which there are many for one product

Current State of submissions to Regulators like FDA:



Future State of submissions:



Track Goal (What was the track trying to achieve?)

In January 2024 track we tested several sections of ICH CTD Module 3 (termed Stage 1) use of FHIR xml file to simulate submitting the sections of the eCTD Module 3 of the electronic Common Technical Document (eCTD) to the US Food and Drug Administration (FDA), comprising Stage 1 of the PQ/CMC project:

- Description and Composition of the Drug Product (eCTD 3.2.P.1)
- General Substance Information (eCTD 3.2.S.1)
- Control of Materials (eCTD 3.2.S.2.3)
- Specification (eCTD 3.2.S.4.1; 3.2.P.4.1; 3.2.P.5.1)

In this September 2024 track we tested three additional sections of ICH CTD Module 3 (termed Stage 2):

- Substance Characterisation (3.2.S.3)
- Product Batch Formula (3.2.P.3.2)
- Product Characterisation of Impurities (3.2.P.5.5)

.

The scenarios supported use cases for the submission of FHIR xml files for these sections to FDA using 2 discrete implementations: (1) a reference implementation supporting submission, validation, parsing to database, and report output for FHIR messages, and (2) to allow confirmation of file content for human review, a utility that actively transforms the human readable section of the FHIR message to a comprehensive report view, complete with tables and images, appropriate for each message type. Further, a number of vendors participated and one, as in January, demonstrated a utility to directly create FHIR messages compliant with our PQ/CMC IG. Others learned the nature of the FHIR format and agreed to attempt message creation and testing with our reference implementation over the next few months.

- Implementations:
    - Reference Implementation for Validation, Parsing to DB, and report outputs
    - Implementation to Transform FHIR to human readable HTML output
    - FHIR Message Builder: ModuleSolutions3 -- Compose Tool

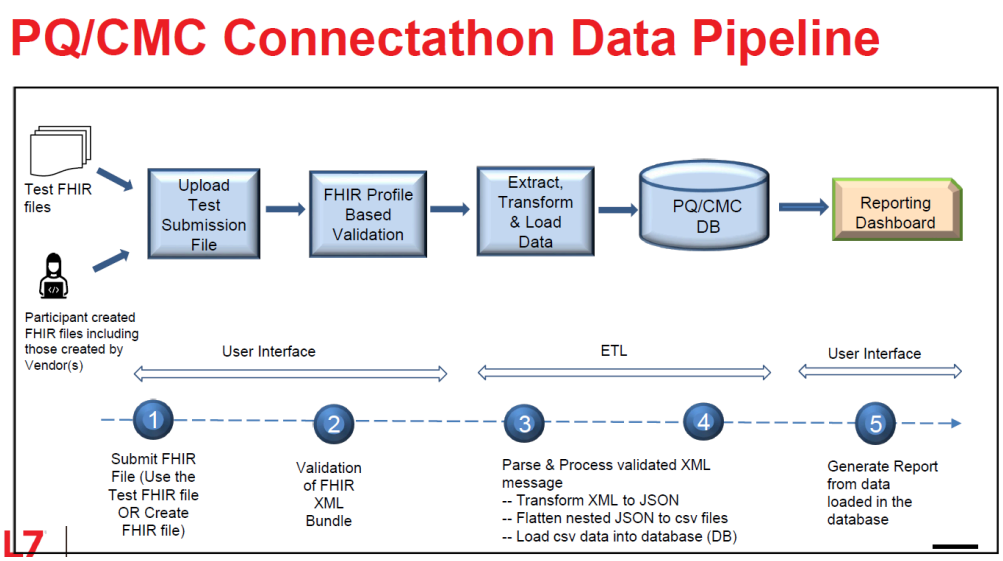
Notable achievements

1. Connectathon on Day 1 had two discrete implementations that tested the PQ/CMC FHIR IG. Attendees tested all Stage 2 message types using these 2 implementations:
    a. The FDA PQ/CMC Reference Implementation to enter, validate, parse, store in database and generate output reports from the data in the database. Messages to test the 3 folders covered in Stage 2 were tested in this way.
    b. Messages of all Stage 2 types were tested with the Transformer utility which allows a user to transform the FHIR xml file into a human readable format (xhtml).
2. Connectathon on Day 2 focused on an independent third implementation of the PQ/CMC FHIR IG developed by a Software vendor. This implementation was for all Stages (covering all the Stage 2 eCTD sections). The tool is developed by Module3Solutions and called the Compose Tool. The Compose Tool has the capability to create eCTD Module 3 FHIR XML files. Attendees on Day 2 used the Compose tool to create their own Stage 2 FHIR XML messages, which were then tested with both the Reference Implementation and with the human-readability Transformation tool.

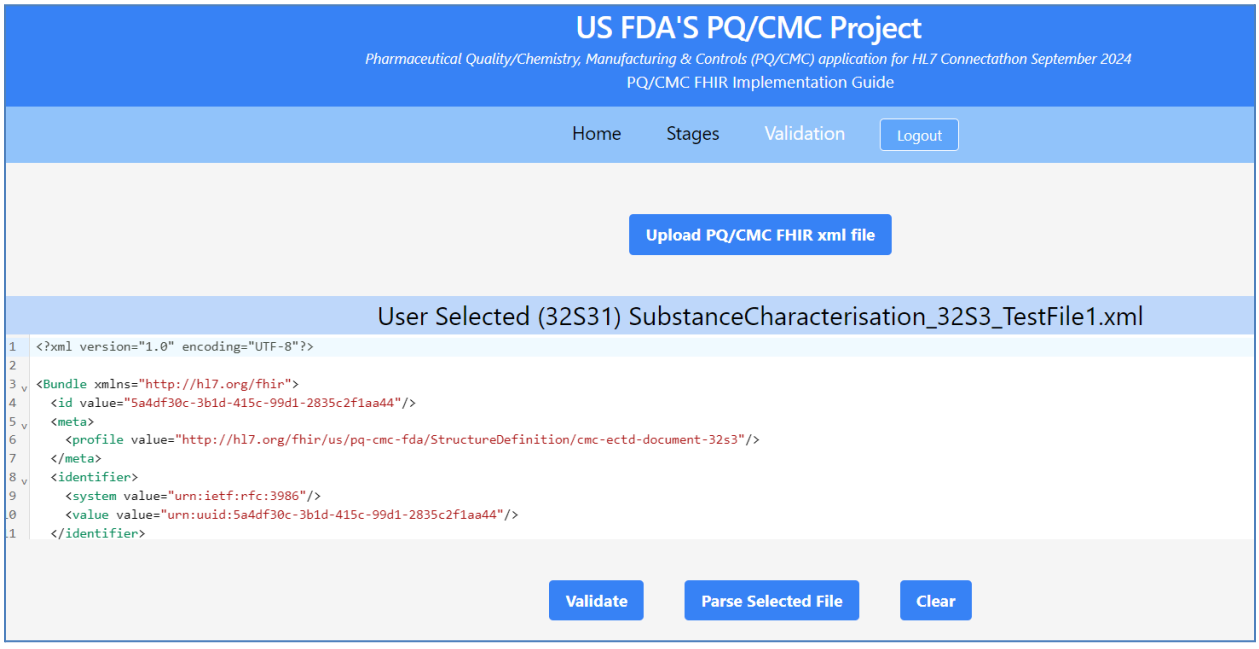
3. The 3 scenarios together supported testing of 100% of the FHIR bundles for Stage 2 that are planned for the January 2025 HL7 ballot.
4. Participants liked the Transformer capability that allowed them to see the content of the xml file in human readable format. Being able to see the content of the FHIR xml file in the human readable format is critical to verify that the content is accurate and presented in a clear and nice format. See examples below.
5. Participants also appreciated the Reference Implementation capabilities to create reports from the final database data, as this fits the intended use case for ingestion and use of Module 3 data at FDA: extraction from the FHIR message and ETL'd into a database for subsequent analysis.
6. Active participation by the attendees in testing the UI application in validating and parsing the FHIR xml files. All attendees participated in the testing during the Connectathon. Attendees also actively used the Vendor provided Compose Tool.

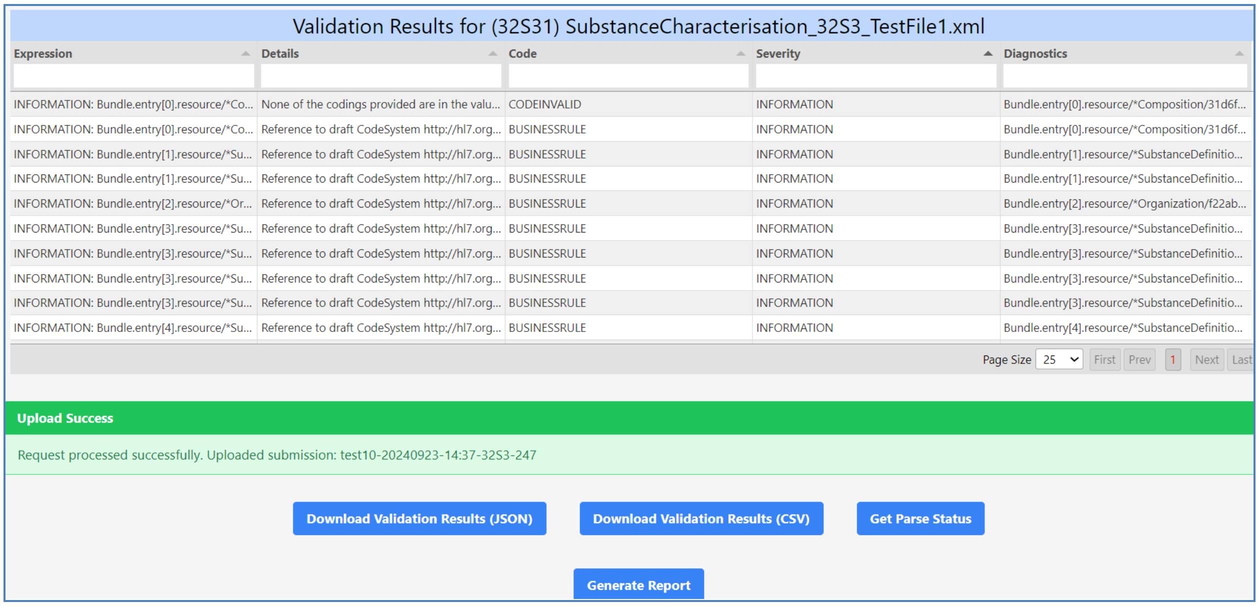
Screenshots and/or links to further information

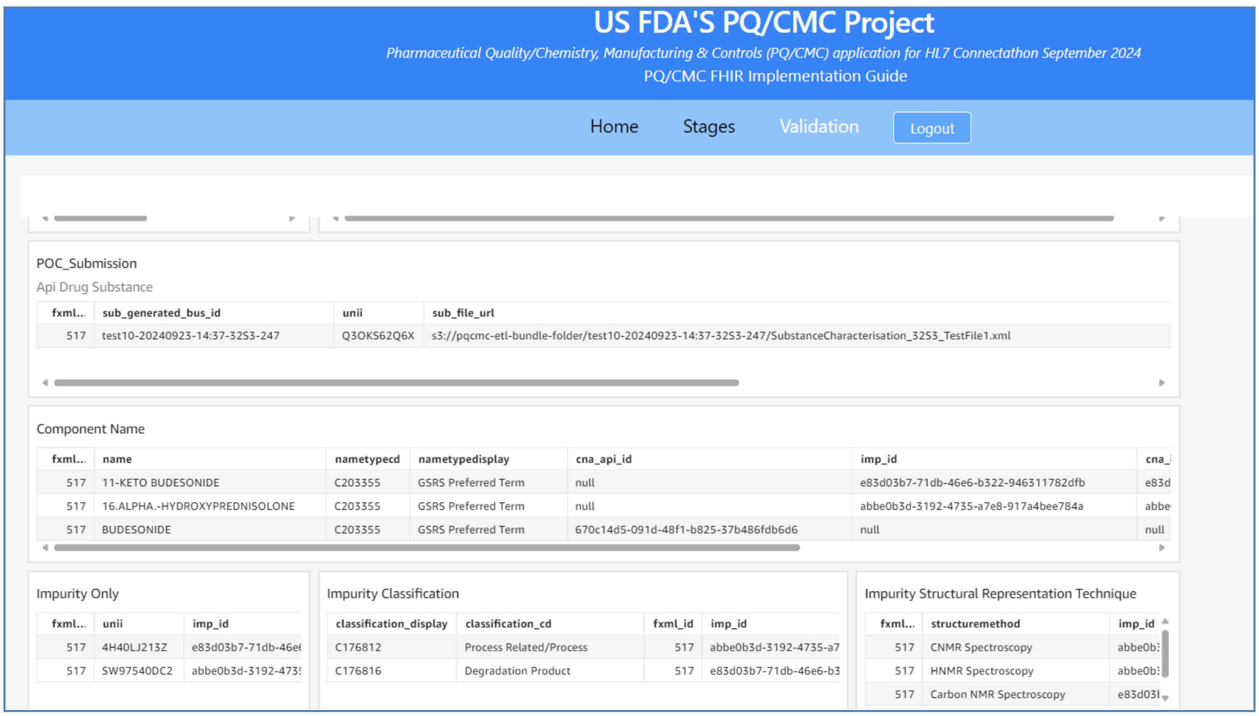
Implementation 1: “Receiver” Reference Implementation made by FDA IBM PQ/CMC Team
Figure of PQ/CMC UI Implementation data flow for Stage 2 messages:

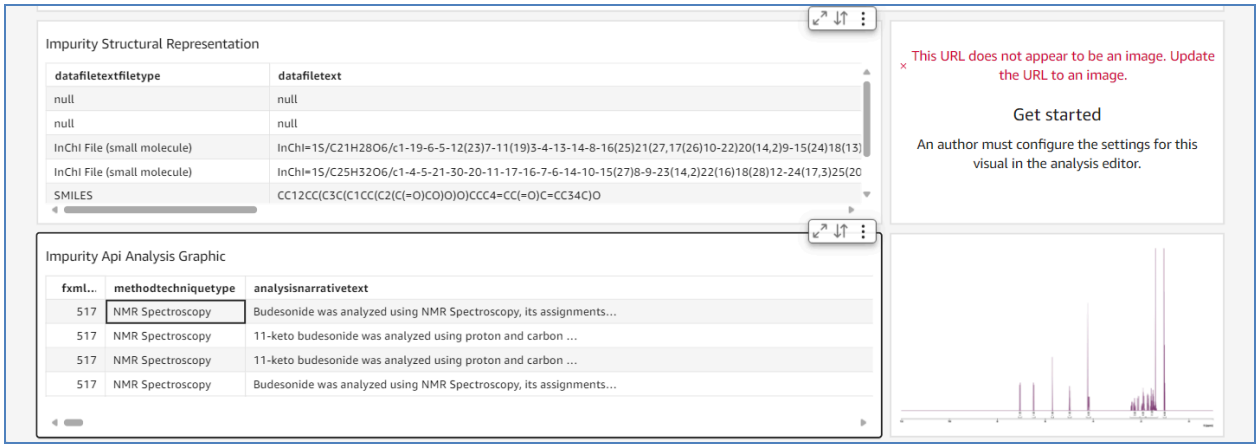


Screen shot of active UI implementation:




Validation Results for (32S31) SubstanceCharacterisation_32S3_TestFile1.xml
Expression
Details
Code
Severity
Diagnostics
INFORMATION: Bundle.entry[0].resource/*Co... | None of the codings provided are in the valu... | CODEINVALID | INFORMATION | Bundle.entry[0].resource/*Composition/31d6f...
INFORMATION: Bundle.entry[0].resource/*Co... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[0].resource/*Composition/31d6f...
INFORMATION: Bundle.entry[1].resource/*Su... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[1].resource/*SubstanceDefinitio...
INFORMATION: Bundle.entry[1].resource/*Su... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[1].resource/*SubstanceDefinitio...
INFORMATION: Bundle.entry[2].resource/*Or... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[2].resource/*Organization/f22ab...
INFORMATION: Bundle.entry[3].resource/*Su... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[3].resource/*SubstanceDefinitio...
INFORMATION: Bundle.entry[3].resource/*Su... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[3].resource/*SubstanceDefinitio...
INFORMATION: Bundle.entry[3].resource/*Su... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[3].resource/*SubstanceDefinitio...
INFORMATION: Bundle.entry[3].resource/*Su... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[3].resource/*SubstanceDefinitio...
INFORMATION: Bundle.entry[4].resource/*Su... | Reference to draft CodeSystem http://hl7.org... | BUSINESSRULE | INFORMATION | Bundle.entry[4].resource/*SubstanceDefinitio...
Page Size 25 First Prev 1 Next Last
Upload Success
Request processed successfully. Uploaded submission: test10-20240923-14:37-32S3-247
Download Validation Results (JSON)
Download Validation Results (CSV)
Get Parse Status
Generate Report


US FDA'S PQ/CMC Project
Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC) application for HL7 Connectathon September 2024
PQ/CMC FHIR Implementation Guide
Home
Stages
Validation
Logout
POC_Submission
Api Drug Substance
fxml... | sub_generated_bus_id | unii | sub_file_url
517 | test10-20240923-14:37-32S3-247 | Q3OKS62Q6X | s3://pqcmc-etl-bundle-folder/test10-20240923-14:37-32S3-247/SubstanceCharacterisation_32S3_TestFile1.xml
Component Name
fxml... | name | nametypecd | nametypedisplay | cna_api_id | imp_id | cna_
517 | 11-KETO BUDESONIDE | C203355 | GSRS Preferred Term | null | e83d03b7-71db-46e6-b322-946311782dfb | e83d
517 | 16.ALPHA.-HYDROXYPREDNISOLONE | C203355 | GSRS Preferred Term | null | abbe0b3d-3192-4735-a7e8-917a4bee784a | abbe
517 | BUDESONIDE | C203355 | GSRS Preferred Term | 670c14d5-091d-48f1-b825-37b486fdb6d6 | null | null
Impurity Only
fxml... | unii | imp_id
517 | 4H40LJ213Z | e83d03b7-71db-46e
517 | SW97540DC2 | abbe0b3d-3192-473
Impurity Classification
classification_display | classification_cd | fxml_id | imp_id
C176812 | Process Related/Process | 517 | abbe0b3d-3192-4735-a7
C176816 | Degradation Product | 517 | e83d03b7-71db-46e6-b3
Impurity Structural Representation Technique
fxml... | structuremethod | imp_id
517 | CNMR Spectroscopy | abbe0b
517 | HNMR Spectroscopy | abbe0b
517 | Carbon NMR Spectroscopy | e83d03



Implementation 2: App to *transform* FHIR XML of all Stage 2 eCTD files to include an HTLM section for easy human readability

Narrative transformation app (keyed to support IG v1.1.6): ZIP FILE LINK
Substance Characterisation (3.2.S.3) files:

- Original XML file
- Transformed XML (can also view human readable layout by loading in web browser):

Product Batch Formula (3.2.P.3.2)

- Original XML file
- Transformed XML (can also view human readable layout by loading in web browser):

Product Characterisation of Impurities (3.2.P.5.5)

- Original XML file
- Transformed XML (can also view human readable layout by loading in web browser):

Screenshot of NarrativeTransform app transforming human readable section into proper HTLM, based on PQ/CMC IG rules and intended output. App has option to update any FHIR message to include the improved human readable section.

PQ/CMC Bundle Narrative Generator

This is version 2 of a Bundle styler for PQ/CMC eCTD Documents for IG version 1.1.6. It currently supports:

- 32S10
- 32P10
- SP4151
- 32S23
- 32P32
- 32P55
- 32S3

Choose a file from your file system and the styler will write a narrative and provide a download button for the document it styled.

Note: files other than images cannot be embedded into narratives. They will appear as download links when viewed in this tool, but will only be text in the actual narrative.

Choose File SubstanceC...estFile1.xml

Narrative preview:

Sponsor: WunderChem GmbH, Munich, GER

Substance Characterization for Budesonide

3.2.S.3.1 Substance Characterization

GSRS Preferred Term BUDESONIDE
UNII Code: Q3OKS62Q6X

Characterization

Technique NMR Spectroscopy

Budesonide was analyzed using NMR Spectroscopy, its assignmentsfor proton and carbon NMR spectroscopy are described in thesubsequent tables

Table 1: Proton NMR Assignments for Budesonide

Hydrogen No.	Delta (ppm)	Multiplicity	No. of Protons	Coupling (Hz)
H1,H2,H3	1.02	t	3	7.43
H4,H5,H6	1.041	s	3	--
H7,H8,H9	1.396	s	3	--
H10	1.402	dtd	1	13.72, 10.23, 3.35
H11	1.482	qd	1	10.23, 2.52
H12,H13	1.502	h	2	7.42
H14,H15	1.583	td	2	7.40, 5.78
H16	1.711	dd	1	13.20, 2.93
H17	1.721	ddd	1	10.21, 9.75, 4.81
H18	1.85	dd	1	10.23, 3.48
H19	1.892	ddd	1	10.55, 9.75, 4.81
H20	1.904	ddd	1	10.55,4.81,1.51
H21	1.95	dddd	1	13.70, 3.26, 2.52, 2.41
H22	2.122	dd	1	13.20, 2.54
H23,H24	2.327	ddd	2	13.15, 6.78, 2.79
H25	4.169	dd	1	6.34, 1.51
H26	4.187	ddd	1	3.48, 2.93, 2.54
H27,H28	4.224	s	2	--
H29	4.976	t	1	5.78
H30	5.693	s	1	--
H31	6.479	d	1	9.54
H32	7.049	d	1	9.54

Description

Table 2: Carbon NMR Assignments for Budesonide

Carbon No.	Delta (ppm)
C1	13.90
C2	18.10
C3	18.69
C4	18.90
C5	31.14
C6,C7	32.20
C8	33.00
C9	38.30
C10	43.41
C11	44.40
C12	46.00
C13	48.40
C14	60.00
C15	65.99
C16	69.13
C17	83.40
C18	103.10
C19	124.07
C20	130.10
C21	151.10
C22	155.70
C23	168.30
C24	185.00
C25	195.10

3.2.S.3.2 Substance Impurities

Impurity: 11-KETO BUDESONIDE

GSRS Preferred Term 11-KETO BUDESONIDE

UNII Code: 4H40LJ213Z

Characterization

Technique NMR Spectroscopy

Description

11-keto budesonide was analyzed using proton and carbon nuclear magnetic resonance. The assignments are describedin the tables below. 11-keto budesonide is very similarto budesonide, but with one ketone in place of a secondaryalcohol.

Table 1: Proton NMR for 11-Keto Budesonide

Hydrogen No.	Delta (ppm)	Multiplicity	No. of Protons	Coupling (Hz)
60,61,62	1.020	t	3	7.429
41	1.138	s	1	--
42,43	1.138	s	2	--
47,48,49	1.441	s	3	--
31	1.502	h	1	7.417
57	1.502	h	1	7.417
39	1.554	dtd	1	14.060, 10.200, 3.410
51,52	1.583	td	2	7.400, 5.778
58	1.739	ddd	1	10.120, 9.720, 4.850
54	1.893	qd	1	10.167, 2.390
35	1.905	ddd	1	10.636, 9.720, 6.350
45	1.970	ddd	1	10.636, 4.850, 1.510
40	2.130	dddd	1	14.060, 3.370, 2.390, 2.240
34,44	2.367	ddd	2	13.136, 6.800, 2.805
36,37	2.504	d	2	16.960
38	2.885	d	1	10.170
32	4.225	s	1	--
53	4.225	s	1	--
46	4.259	dd	1	6.350, 1.510
33	4.969	t	1	5.778
55	5.689	s	1	--
56	6.479	d	1	9.535
50	7.129	d	1	9.535

Table 2: Carbon-14 NMR for 11-Keto Budesonide

Delta (ppm)	No. of Atoms
46	1
48.4	1
151.1	1
35.52	1
83.4	1
38.3	1
58.82	1
49.73	1
41.86	1
210.1	1
18.1	1
195.1	1
31.14	1
103.1	1
168.3	1
18.69	1
155.7	1
32.2	2
65.99	1
124.07	1
130.1	1
185	1
18.9	1
13.9	1

Attached

3.2.S.3.2 Substance Impurities

Impurity: 11-KETO BUDESONIDE

GSRS Preferred Term 11-KETO BUDESONIDE

UNII Code: 4H40LJ213Z

Characterization

Technique: NMR Spectroscopy

Description:

11-keto budesonide was analyzed using proton and carbon nuclear magnetic resonance. The assignments are describedin the tables below. 11-keto budesonide is very similarto budesonide, but with one ketone in place of a secondaryalcohol.

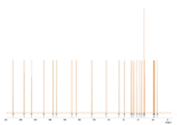
Table 1: Proton NMR for 11-Keto Budesonide

Hydrogen No.	Delta (ppm)	Multiplicity	No. of Protons	Coupling (Hz)
60,61,62	1.020	t	3	7.429
41	1.138	s	1	--
42,43	1.138	s	2	--
47,48,49	1.441	s	3	--
31	1.502	h	1	7.417
57	1.502	h	1	7.417
39	1.554	dtd	1	14.060, 10.200, 3.410
51,52	1.583	td	2	7.400, 5.778
58	1.739	ddd	1	10.120, 9.720, 4.850
54	1.893	qd	1	10.167, 2.390
35	1.905	ddd	1	10.636, 9.720, 6.350
45	1.970	ddd	1	10.636, 4.850, 1.510
40	2.130	dddd	1	14.060, 3.370, 2.390, 2.240
34,44	2.367	ddd	2	13.136, 6.800, 2.805
36,37	2.504	d	2	16.960
38	2.885	d	1	10.170
32	4.225	s	1	--
53	4.225	s	1	--
46	4.259	dd	1	6.350, 1.510
33	4.969	t	1	5.778
55	5.689	s	1	--
56	6.479	d	1	9.535
50	7.129	d	1	9.535

Table 2: Carbon-14 NMR for 11-Keto Budesonide

Delta (ppm)	No. of Atoms
46	1
48.4	1
151.1	1
35.52	1
83.4	1
38.3	1
58.82	1
49.73	1
41.86	1
210.1	1
18.1	1
195.1	1
31.14	1
103.1	1
168.3	1
18.69	1
155.7	1
32.2	2
65.99	1
124.07	1
130.1	1
185	1
18.9	1
13.9	1

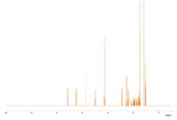
Attached Image:



Attached File: 11keto-budesonide-CNMR.jdx

Attached File: 11keto-budesonide-HNMR.jdx

Attached Image:

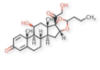


Structure information

InChI File (small molecule): InChI=1S/C25H32O6/c1-4-5-21-30-20-11-17-16-7-6-14-10-15(27)8-9-23(14,2)22(16)18(28)12-24(17,3)25(20,31-21)19(29)13-26/h8-10,16-17,20-22,26H,4-7,11-13H2,1-3H3/t16-,17-,20+,21?,22+,23-,24-,25+/m0/s1

Attached File: 11-keto-budesonide.sdf

Attached Image:



Impurity: 16.ALPHA.-HYDROXYPREDNISOLONE

GSRS Preferred Term 16.ALPHA.-HYDROXYPREDNISOLONE

UNII Code: SW97540DC2

Characterization

Technique: NMR Spectroscopy

Description:

16-alpha hydroxyprednisolone was analyzed using carbon andhydrogen NMR Spectroscopy. The assignments are described inthe tables below

Table 1: HNMR Assignments for 16-alpha Hydroxyprednisolone

Hydrogen No.	Delta (ppm)	Multiplicity	No. of Protons	Coupling (Hz)
38	1.021	s	1	--
39,40	1.022	s	2	--
43,44,45	1.395	s	3	--
36	1.399	dtd	1	13.695, 10.225, 3.350
28	1.490	qd	1	10.223, 2.520
41,52	1.770	dd	2	13.212, 2.735
32	1.812	ddd	1	12.003, 9.750, 6.790
35	1.812	ddd	1	12.003, 4.820, 1.730
27	1.824	ddd	1	10.200, 9.750, 4.820
29	1.887	dd	1	10.230, 3.480
37	1.946	dddd	1	13.695, 3.260, 2.520, 2.310
42	2.281	ddd	1	13.151, 10.210, 3.260
31	2.386	ddd	1	13.151, 3.350, 2.310
33	4.027	dd	1	6.790, 1.730
30	4.202	s	1	--
51	4.202	s	1	--
34	4.261	ddd	1	3.480, 2.940, 2.530
50	5.692	s	1	--
53	6.479	d	1	9.535
46	7.048	d	1	9.535

Table 2: CNMR Assignments for 16-alpha Hydroxyprednisolone

Delta (ppm)	No. of Atoms
151.1	2
71.1	1
73.22	2
48.5	1
35.1	1
38.5	1
71.2	1
44.4	1
28.45	1
23.02	1
31.14	1
168.3	1
195.1	1
18.69	1
126.8	1
124.07	1
65.99	1
130.1	1
185.0	1

Attached File: Hydroxyprednisolone-HNMR.jdx

Attached File: Hydroxyprednisolone-CNMR.jdx

Structure information

InChI File (small molecule): InChI=1S/C21H28O6/c1-19-6-5-12(23)7-11(19)3-4-13-14-8-16(25)21(27,17(26)10-22)20(14,2)9-15(24)18(13)19/h5-7,13-16,18,22,24-25,27H,3-4,8-10H2,1-2H3/t13-,14-,15-,16+,18+,19-,20-,21-/m0/s1

SMILES: CC12CC(C3C(C1CCC(C2)(C(=O)CO)O)O)CCC4=CC(=O)C=CC34C)O

Attached File: Hydroxyprednisolone.sdf

Attached Image:

File preview:

```
<?xml version="1.0" encoding="UTF-8"?>
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  <meta>
    <profile value="http://hl7.org/fhir/us/pq-cmc-fda/StructureDefinition/cmc-ectd-document-32s3"/>
  </meta>
  <identifier>
    <system value="urn:ietf:rfc:3986"/>
    <value value="urn:uuid:5a4df30c-3b1d-415c-99d1-2835c2f1aa44"/>
  </identifier>
  <type value="document"/>
  <timestamp value="2024-07-23T14:30:00.000Z"/>
  <entry>
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    <resource>
      <Composition>
        <id value="31d6f9c5-d41c-4549-8bb3-e8b99d36c276"/>
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          <profile value="http://hl7.org/fhir/us/pq-cmc-fda/StructureDefinition/ectd-composition-32s3"/>
        </meta>
        <text>
          <status value="generated"/>
          <div id="narrative" xmlns="http://www.w3.org/1999/xhtml">
            <p>Sponsor: WunderChem GmbH, Munich, GER</p>
            <hr/>
            <h1>Substance Characterization for Budesonide</h1>
            <h2>3.2.S.3.1 Substance Characterization</h2>
            <table>
              <tr>
                <td>GSRS Preferred Term</td>
                <td>BUDESONIDE</td>
              </tr>
              <tr>
```
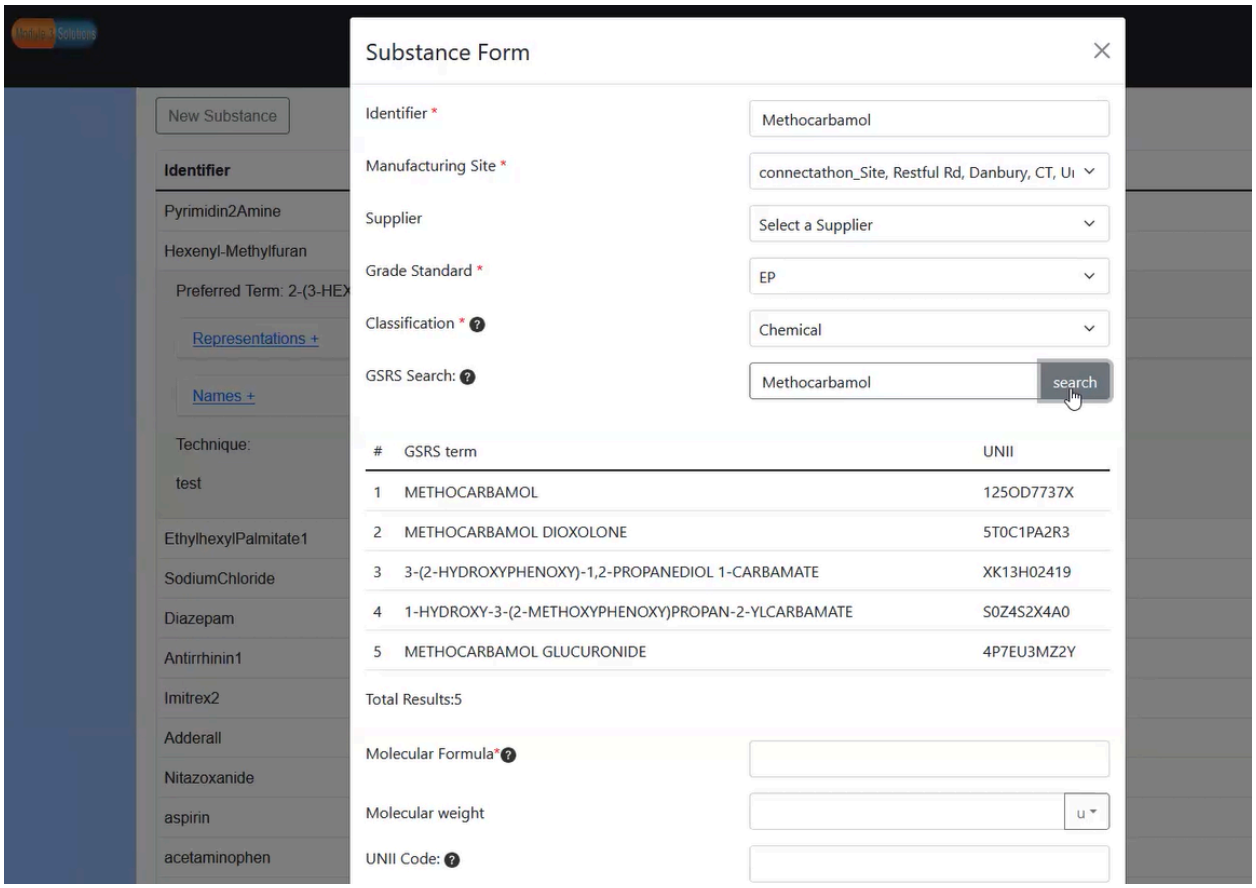
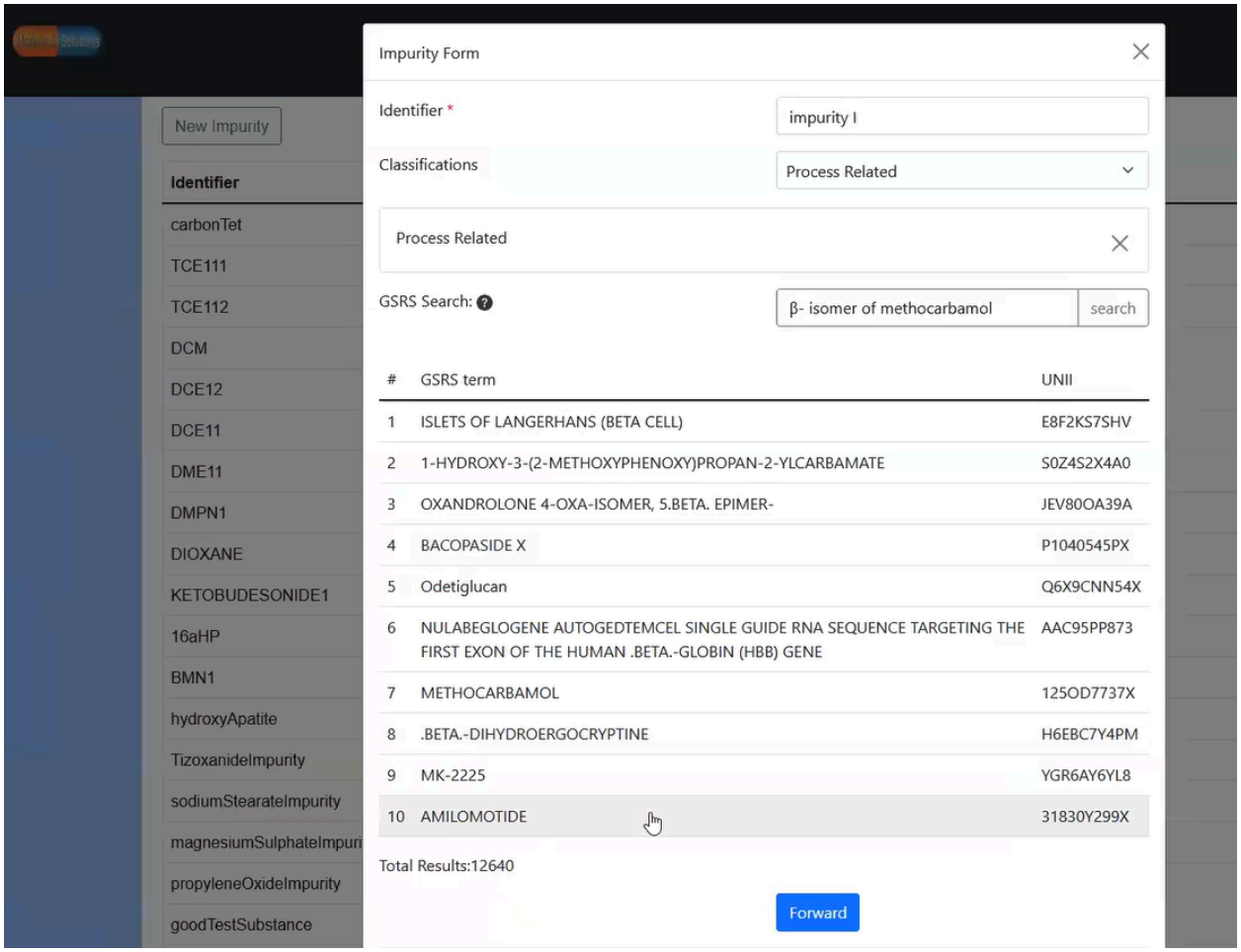

Save File: Save XML to file

Implementation 3: “Compose” PQ/CMC message authoring tool, created by Module 3 Solutions, to create FHIR XML output of all Stage 1 eCTD messages

Screenshot of Compose PQCMC message authoring tool





Screenshots from the testing of the FHIR xml files for the various Stage 1 Bundles

Discovered Issues/Questions

1. No major problems were reported for this Connectathon
2. Discussions about potential implementation strategies for Industry Sponsor and vendors

Next Steps

1. Revise IG based on any comments (minimal)
2. Take the FHIR IG to January 2025 ballot for Stage 2PQ/CMC Bundles of the FHIR IG.

FHIRcast and Imaging

- What was the track trying to achieve?
    - Test FHIRcast context synchronization and associated FHIR imaging use cases
    - Discuss how to fulfill "**content** sharing" use cases in FHIRcast using **context** sharing only
- List of participants (with logos if you have time and energy)
    - Array Corporation
    - Canon Medical
    - Epic
        - Brought FHIRcast Context / Content Hub
    - HL7 Japan
    - Philips
        - Brought FHIRcast Context / Content Hub
- Notable achievements
    - Further testing of Epic FHIRcast hub
        - Philips client connected to Epic hub
        - Context exchange tested
        - Content sharing **not** tested
    - Proposed solution to solve content sharing use cases without needing content sharing extension
    - Discussion and resolution of Jira issues for DICOM SR to FHIR Observation IG
    - Array / HL7 Japan drafted IG proposal for Cloud Portable Document for Imaging
- Screenshots and/or links to further information
    - Pending
- Discovered issues / questions (if there are any)
    - Hubs must allow for a DiagnosticReport session to be initiated without the report previously existing in their system
- Now what?
    - Explore adding temporary FHIR resource storage role to FHIRcast context sharing
    - Review IG proposal during upcoming WGM

Goal-Directed Care Planning

- **What was the track trying to achieve?**
    - Discuss and test examples and implementations for person-centered goal outcome assessments, including Goal Attainment Scaling (GAS) and Patient-Reported Outcome Measures (PROMs).
    - Discuss requirements and prototype implementations for quality measures that track and report progress on Person-Centered Goals, Outcomes, and Care Plans for persons with multiple chronic conditions.
    - Review scope, content, and draft for a Person-Centered Outcomes (PCO) FHIR IG that includes profiles for interoperable GAS Goals, support for GAS Goal editing tools, and PCO measures.

- **List of participants**

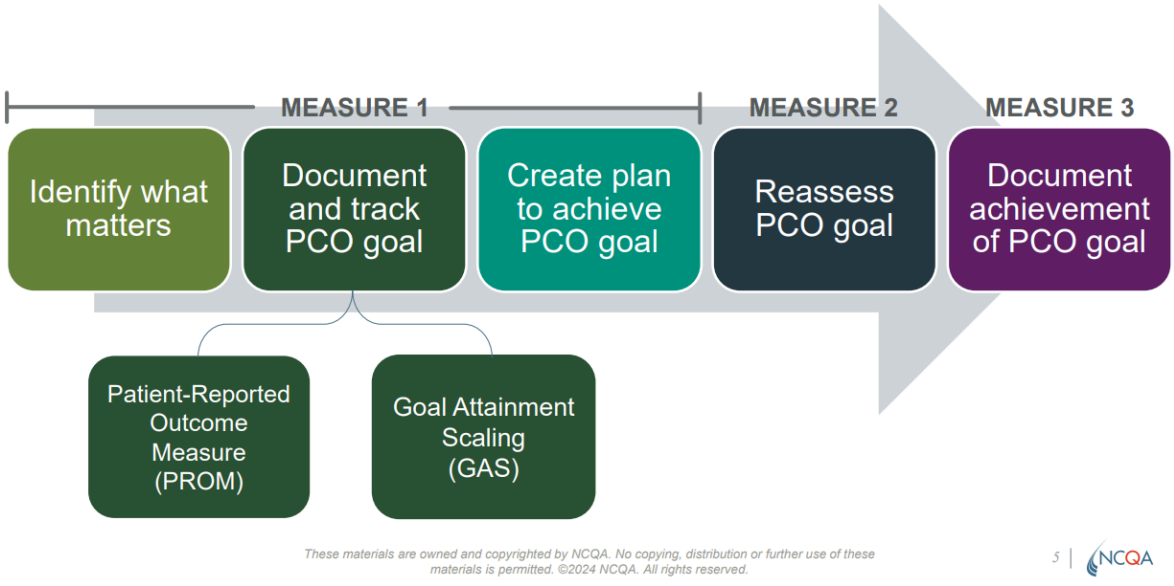
Name	Organization	Logo
Dave Carlson	Mountain Lotus WellBeing, LLC	
Daniela Lawton Anne Smith Amanda Grant Jasmin Smith Torri Weathers Kat Sobel	NCQA	
Karen Bertodatti	EMI Advisors	

- **Notable achievements**
    - Completed changes to the PCO IG
        - Profiles
            - PCOProgressScoreObservation
                - relax focus 1..1 to 0..1
            - PCOPatientReportedOutcomeScore
                - PROM score value change to choice of Quantity **or** integer
        - Terminology

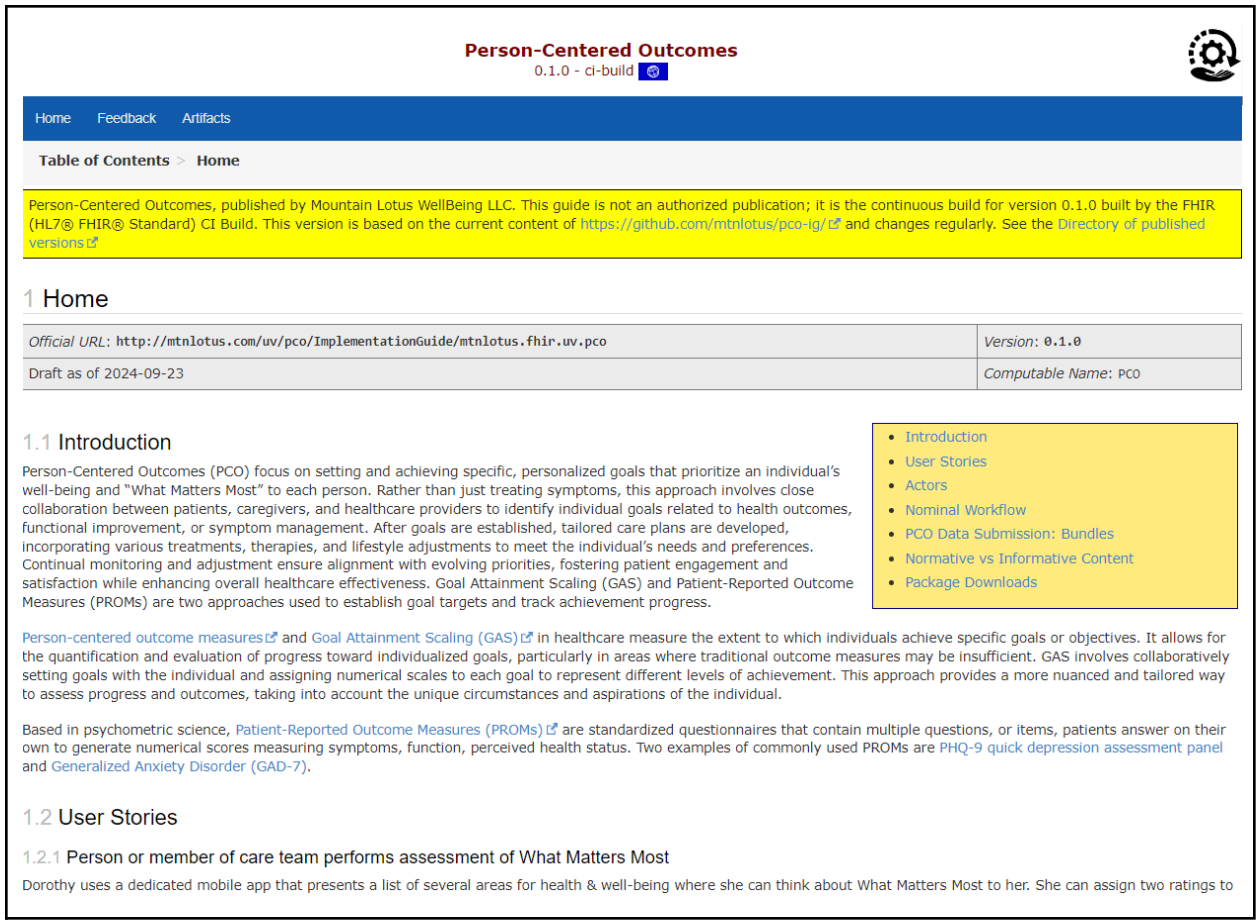
        - GAS Answers, use 3 LOINC codes (need 2 more - to be released in February 2025)
    - Pending changes to the PCO IG
        - Profiles
            - Add extension for Goal.enteredby
        - Terminology
            - PROM code value set
                - Use list of LOINC codes from NCQA
            - PCO Category value set
                - Use SNOMED codes

- **Screenshots and/or links to further information**

NCQA's Person-Centered Outcomes Approach: https://www.ncqa.org/wp-content/uploads/Person-Centered-Outcome-Measures-Measuring-What-Matters-Most_03.28.2024_slides.pdf



Draft PCO FHIR IG home page: https://build.fhir.org/ig/mtnlotus/pco-ig/index.html



Person-Centered Outcomes
0.1.0 - ci-build

Home Feedback Artifacts

Table of Contents > Home

Person-Centered Outcomes, published by Mountain Lotus WellBeing LLC. This guide is not an authorized publication; it is the continuous build for version 0.1.0 built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of https://github.com/mtnlotus/pco-ig/ and changes regularly. See the Directory of published versions

1 Home

Official URL: http://mtnlotus.com/uv/pco/ImplementationGuide/mtnlotus.fhir.uv.pco	*Version*: 0.1.0
Draft as of 2024-09-23	*Computable Name*: PCO

1.1 Introduction

Person-Centered Outcomes (PCO) focus on setting and achieving specific, personalized goals that prioritize an individual's well-being and "What Matters Most" to each person. Rather than just treating symptoms, this approach involves close collaboration between patients, caregivers, and healthcare providers to identify individual goals related to health outcomes, functional improvement, or symptom management. After goals are established, tailored care plans are developed, incorporating various treatments, therapies, and lifestyle adjustments to meet the individual's needs and preferences. Continual monitoring and adjustment ensure alignment with evolving priorities, fostering patient engagement and satisfaction while enhancing overall healthcare effectiveness. Goal Attainment Scaling (GAS) and Patient-Reported Outcome Measures (PROMs) are two approaches used to establish goal targets and track achievement progress.

- Introduction
- User Stories
- Actors
- Nominal Workflow
- PCO Data Submission: Bundles
- Normative vs Informative Content
- Package Downloads

Person-centered outcome measures and Goal Attainment Scaling (GAS) in healthcare measure the extent to which individuals achieve specific goals or objectives. It allows for the quantification and evaluation of progress toward individualized goals, particularly in areas where traditional outcome measures may be insufficient. GAS involves collaboratively setting goals with the individual and assigning numerical scales to each goal to represent different levels of achievement. This approach provides a more nuanced and tailored way to assess progress and outcomes, taking into account the unique circumstances and aspirations of the individual.

Based in psychometric science, Patient-Reported Outcome Measures (PROMs) are standardized questionnaires that contain multiple questions, or items, patients answer on their own to generate numerical scores measuring symptoms, function, perceived health status. Two examples of commonly used PROMs are PHQ-9 quick depression assessment panel and Generalized Anxiety Disorder (GAD-7).

1.2 User Stories

1.2.1 Person or member of care team performs assessment of What Matters Most

Dorothy uses a dedicated mobile app that presents a list of several areas for health & well-being where she can think about What Matters Most to her. She can assign two ratings to

PCO IG Profiles: https://build.fhir.org/ig/mtnlotus/pco-ig/artifacts.html#structures-resource-profiles

3.0.4 Structures: Resource Profiles

These define constraints on FHIR resources for systems conforming to this implementation guide.

PCO Goal Attainment Scaling (GAS) score	The follow-up score indicates how a patient, caregiver, or practitioner rated progress on goal attainment scaling.
Patient-Reported Outcome Measure (PROM) score	This observation records how a patient rated their own progress score using a PROM assessment.
Person-Centered Care Plan	A person-centered care plan SHALL reference a person-centered goal and SHALL include action steps that support progress toward achievement of the plan's goals and desired outcomes. A plan SHOULD address the person's stated priorities for what matters most to them. Action steps may include both treatment procedures and self-care steps identified by the person.
Person-Centered GAS Goal	Person-centered goal with goal attainment scaling.
Person-Centered Goal	Person-centered goal focused on what matters most to an individual. A Person-centered goal SHALL include either a Person-Centered Outcome category, or address a What Matters assessment.
Person-Centered PROM Goal	Person-centered goal with a Patient-Reported Outcome Measure (PROM) score target.
Person-Centered Progress Score	A progress score observation for a person-centered goal.
What Matters Assessment	Assessment observation for one aspect of What Matters Most to a person, with component values rating where a person is now and where they would like to be in the future.

PCO IG Examples: https://build.fhir.org/ig/mtnlotus/pco-ig/artifacts.html#example-example-instances

3.0.8 Example: Example Instances

These are example instances that show what data produced and consumed by systems conforming with this implementation guide might look like.

Care Plan for PCO Anxiety Goal	Care Plan for a person-centered goal using a PROM score measure.
Care Plan for person-centered goal	Care Plan for a person-centered goal with action steps for achieving what matters most to that person.
Care Plan: Action step for mindfulness program	Care Plan activity: Mindfulness coaching to support anxiety management
Care Plan: Anti-Inflammatory Medication	Care Plan activity: Anti-inflammatory gel for knee pain to enable walking
Care Plan: Clinical action step for PT	Care Plan activity: Physical therapy to relieve pain related to walking
Care Plan: Personal action step	Care Plan activity: Initial personal action step toward goal of walking dog outside
Example Patient Camila	Camila Lopez
Example Patient Dorothy	Dorothy Jones
GAD-7 PROM Follow-up Score	Follow-up GAD-7 PROM score observation recorded by a Patient showing goal progress.
GAS Baseline Score	Baseline GAS score observation at start of goal.
Goal for GAD-7 PROM Outcome	Person-centered goal with a PROM outcome target for GAD-7 score.
Goal with GAS	Person-centered goal with attainment scaling extensions
Goal without GAS or PROM	Person-centered goal without attainment scaling or PROM
Health & Wellness Coach	Maria Gonzalez, NBC-HWC
Patient GAS Follow-up Score	Follow-up GAS score observation recorded by a Patient showing goal progress.
Practitioner GAS Follow-up Score	Follow-up GAS score observation recorded by a Practitioner showing goal progress.
Primary Care Physician	John Anderson, MD
What Matters: Family & Friends	What Matters assessment observation recorded by a Patient as preparation for creating PCO goals and CarePlan action steps.
What Matters: Moving the Body	What Matters assessment observation recorded by a Patient as preparation for creating PCO goals and CarePlan action steps.

- **Discovered issues / questions**
    - How do you distinguish between a goal that is expressed by the patient vs a goal that's been interpreted by the person entering the goal?
        - We will consider adding an extension in the PCO IG for Goal.enteredBy.
        - We may need to validate further the definitions for "expressed by", "entered by", "contributed by", and "authored by".
    - When can a goal be considered "achieved" from the perspective of the patient, caregiver, clinician, or combination of the above?
        - For example, if a patient feels the goal was achieved but the clinician doesn't, should the goal be considered achieved? etc. for all the combinations of the roles involved.
    - How do you identify patients with "complex needs"?
        - Depending on the population, a value set would be provided that would reference the diagnoses of each individual with a complex care need.

- **Now what?**
    - Submitted a Project Proposal for the Person-Centered Outcomes (PCO) FHIR IG: https://jira.hl7.org/browse/PSS-2461
    - Make pending changes to the PCO IG.
    - Develop additional test cases.

Helios Public Health Track

What was the track trying to achieve?

- The track will test the FHIR query and response operation to streamline workflows and support public health data acquisition use cases. It aims to:
    - Test a generic FHIR query and response workflow for use cases applicable to public health investigations with both a public health agency to electronic health record and a facilitated FHIR approach
    - Test the use of USCDI-based FHIR APIs for public health data access.
    - Test TEFCA query from PHA to EHR(s) one-to-one and one-to-many facilitated by eHealth Exchange TEFCA QHIN
    - Test standardized use case specific queries using Skylight TEFCA Viewer Tool
    - Find issues and questions that may arise in real-world applications and discuss with public health subject matter experts

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

Notable achievements (by use case)

Cancer Registry Use Case (CAP/CDC/Topology):

- We were able to query several EHR(s) and a TEFCA QHIN to pull supplemental initial pathology information.
- The response was refined to prioritize data elements from the mCODE profiles of interest

Sexually Transmitted Infections (JMC/South Carolina):

- We created synthetic data and updated ELR messages to match the synthetic data created.
- We were able to call out to 2 additional FHIR servers to demonstrate a more accurate use case representing the need for PHAs to request supplemental data from multiple EHRs.
- We updated the xpath to retrieve data from more FHIR resource elements

Sexually Transmitted Infections (NYC):

- The FHIR client can query the HIE for patient, encounter and labs information using an iterative approach called 'reference chasing'.
- We interacted with FHIR users and other experts to 1) identify FHIR resources (e.g. `Condition`, `Observation` and `Encounter`) and references (e.g. `Visit Type`, like hospitalization) 2) understand dependencies between these resources and 3) improve our reference chasing approach to identify clinical information specific to the cases of interest, and to conform to the various clinical scenarios in which data may be available.

Sexually Transmitted Infections (MDHHS/Altarum):

- Primarily gained FHIR knowledge around Public Health Agency (PHA) to Electronic Health Record (EHR) queries, synthetic data platform (MELD), query client tools, and TEFCA QHIN facilitated queries.

RESP-NET (WA DOH):

- Used DIBBS Skylight V2 to FHIR converter to convert ELR HL7v2 message to FHIR. Used Postman to successfully post HL7v2 message to the DIBBS API which returned a FHIR bundle
- Sent FHIR query through TEFCA Viewer and TEFCA QHIN connected EHR MELD sandbox and received requested supplemental patient data back from EHR.

Screenshots and/or links to further information

- Please see Helios Public Health Track Page

Discovered issues / questions (if there are any)

Cancer Registry Use Case (CAP/CDC/Topology):

- Rhapsody will need to expand the mappings of fields to retrieve the needed elements as the data may be represented in various fields based on which FHIR server the data is coming from (example: coding element display vs text field)
- A known issue that we've identified with our testing process is that the FHIR sandbox servers already have the predetermined resources in the system at the time of the query. In a real world scenario, some resources may not exist at the time of ELR receipt, such as medication. For example, the provider may not have had a chance to prescribe the proper treatment at the time the ELR is received in the PHA system.

Sexually Transmitted Infections (JMC/South Carolina):

- Synthetic data missing text fields (JSON)
- Data may not be available on first query to EHR. Re-polling may be needed.

Sexually Transmitted Infections (NYC):

- FHIR R4 does not support search query encounters based on a condition with reason code. This has been added in FHIR R5 (possbily FHIR R4B?).

RESP-NET (WA DOH):

- DIBBS Skylight HL7v2 to FHIR Converter required that we remove escaped characters from the HL7v2 message in order to be processed by the converter
- The resources that get referenced in the query, need to be sequenced before the resources that reference them, for the MELD EHR server to consume the bundle. This needs to be handled before calling the MELD EHR API. The MELD EHR consumed the messages when the referential integrity was maintained in the bundle between the resources.

Now what?

Cancer Registry Use Case (CAP/CDC/Topology):

- Medication list - medications associated with condition. Unable to search medication based on condition. HL7 Jira ticket has been documented.
- We will be mapping the output to a Surveillance system import process such as MIF (Maven Integration Format), for ingestion into PHA surveillance systems.
- We will determine a way to store the data elements retrieved and use the information to determine if further querying triggers are warranted (example: if medication is missing, further scheduled querying will need to occur).

Sexually Transmitted Infections (JMC/South Carolina):

- Evaluate re-polling for data not yet available (e.g. too soon after ELR is reported).

Sexually Transmitted Infections (NYC):

- FHIR resources and data "reference chasing" for data 1) identify FHIR resources (e.g. `Condition`, `Observation` and `Encounter`) and references (e.g. `Visit Type`, like hospitalization) 2) understand dependencies between these resources and 3) improve our reference chasing approach to identify clinical information specific to the cases of interest, and to conform to the various clinical scenarios in which data may be available.

Overall Topics for Discussion:

- Medication list - medication associated with condition. Unable to search medication based on condition. (CAP)
- A temporary connection was established between the existing eMaRC software and the CR-SOFA app. We will be building a more established, sustainable connection. (CAP)
- Work on incorporating the patient data received in the HL7 FHIR bundle response into the CCR database. (CAP)
- Re-polling for data not yet available. (JMC)
- Reference Chasing - are there alternatives? (NYC)
- Synthetic data is "too clean". Need to test with messy data and other more realistic data. (All)
- STLT to STLT Data queries & sharing (All)

International Patient Summary

Participants

1. **Cameron, Allana (Canada)**
2. **Cangioli, Giorgio (Italy)**
3. **Carter, John S (New Zealand)**
4. **D'Amore, John (USA)**
5. **Daniels, Reuben (Australia)**
6. **Donaldson, Ed (USA)**
7. **Gottlieb, Dan (USA)**
8. **Gardeen, Isiaah (USA, MEDITECH)**
9. **Hausam, Rob (USA)**
10. **Jordan, Peter (New Zealand)**
11. **Kaye, Martin (Canada, VeroSource)**
12. **Kerry, Pat (Canada, VeroSource)**

13. **Kramer, Ewout (Firely, Netherlands)**
14. **Liu, Andrew (Canada, Health InfoWay)**
15. **Liu, Darren (Canada, Verto)**
16. **Lober, Bill (USA, UW)**
17. **Lorigan, Daniel (USA, UW)**
18. **Lu, Hanhong (USA, Epic)**
19. **Marzura, Ivana (Canada, Verto)**
20. **Mavin, Ryan (Australia)**
21. **Nicolas Sayago, Abigail (USA, Microsoft)**
22. **Persaud, Martin (Canada, Verto Health)**
23. **Rahn, Matthew (USA)**
24. **Rocha, David (USA**
25. **Robert, Mark (USA, CARIN)**
26. **Sinn, Ken (Canada)**
27. **Teixeira, Jose Costa (Belgium)**
28. **Vogt, Jason (USA, MEDITECH)**
29. **Weich, Christian (Austria)**

What was the track trying to achieve?

Our goals for the IPS were to advance testing among vendors supporting the IPS and work through issues discovered in implementation feedback. Aims for September included:

1. Examine approach for narrative linking in IPS.
2. Creation of fuller examples including new sections
3. Coordination between IPS and International Patient Access (IPA)
4. Discuss approach to filtering and data inclusion
5. Demo NLP to extract data for IPS generation
6. Work on IPS generation and consumption
7. SMART Health Links Discussion

Notable achievements

· **Decision for vendors to move toward id/idref pattern for narrative linking. All vendors expressed support (or no opposition) to this approach. See https://chat.fhir.org/#narrow/stream/207835-IPS/topic/Referencing.20from.20IPS.20narrative.20to.20data**

- **Advanced discussion on the evolution of MustSupport in the IPA/IPS joint session. No opposition expressed in breakout room with 30+ participants for IPS to use obligations. Discussion around how to redefine Actors from IPA for inclusion into IPS. Plans to address in 2.0.0-ballot ballot reconciliation activities**

- **New JIRA on Result status: https://jira.hl7.org/browse/FHIR-48336**

- **New (and now resolved) JIRA on $summary operation https://jira.hl7.org/browse/FHIR-48351**

- **Notes from discussion on data filtering and inclusion:**

    - **The IPS can be built on a set of inclusion / exclusion rules - time window (e.g. last 1 year for meds), resource types and content (e.g. exclude resolved allergies)...**

    - **creation of an IPS based on these rules could also be "assisted" or iterated by the author that could override and deliberately include/exclude some content.**

    - **The rules for creating the IPS can be presented as free text (notes) or they can be structured;**

    - **in both cases, these would be metadata or not necessarily in the foreground**

    - **If the rules are expressed in a structured way (but not in implementation code), this would allow for receiving systems understand what they are receiving (and know what to expect)**

    - **it could also be used for noting to the viewer the limits of the data**

    - **we should avoid the tempation of "why not adding all data just in case and let everyone filter" - that is not the goal of the IPS.**

    - **However, if we have an IPS and the associated provenance (sources and rules), and if the rules are structured, we can actually allow receiving systems to use those rules to expand the content . For example:**

    - **fetch older data if the sources are available**

    - **fetch same data to see if there were updates since the IPS was authored**

- **Breakout with SMART Health Links (SHL) discussion. Recording made and will be included if Zoom cooperates (there were Zoom issues). Notable topics**

    - **Why patient-mediated IPS exchange works well with SHL**

    - **Review of work from state of Washington and from VeroSource vendors on IPS with SHL. Demo from US vendor HikeHealth on insurance cards using SHL**

    - **How to format/present a QR code so users know what will happen**

- **Considerations for internationalization of QR codes**

- **Open-source tools session**
  - **Review of IPS Viewer**
  - **Review of HAPI FHIR including international adaptation**

- Screenshots and/or links to further information

Discovered issues / questions (if there are any)

New JIRA as documented above.

Continuing questions and discussion (TBD on Zulip) for generation strategy discussion

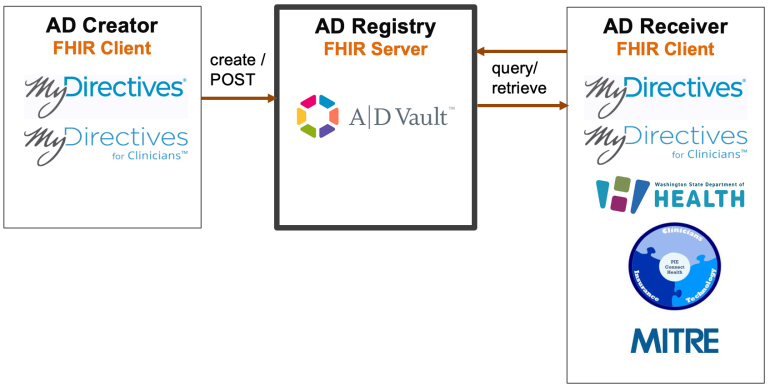
Now what?

- Grahame to update next validator release with new id/idref logic
- Continue ballot reconciliation
- Add idref strategy to HAPI reference implementation
- Review IPS Viewer and open requests

PACIO Advance Directive Interoperability (ADI)

- What was the track trying to achieve?
    - Sharing partially machine-processable Portable Medical Orders (PMO). It builds upon previous Connectathon tracks which included the exchange of unstructured state Advance Directives and Mental Health/Psychiatric Advance Directives (MHADs/PADs).
- List of participants (with logos)

Connectathon Test Environment



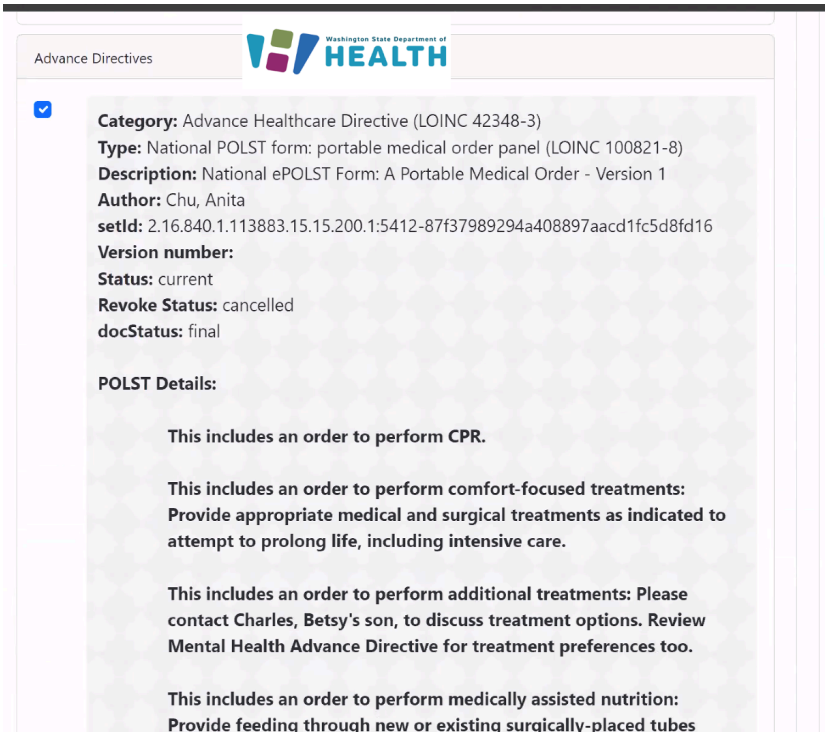
- Notable achievements

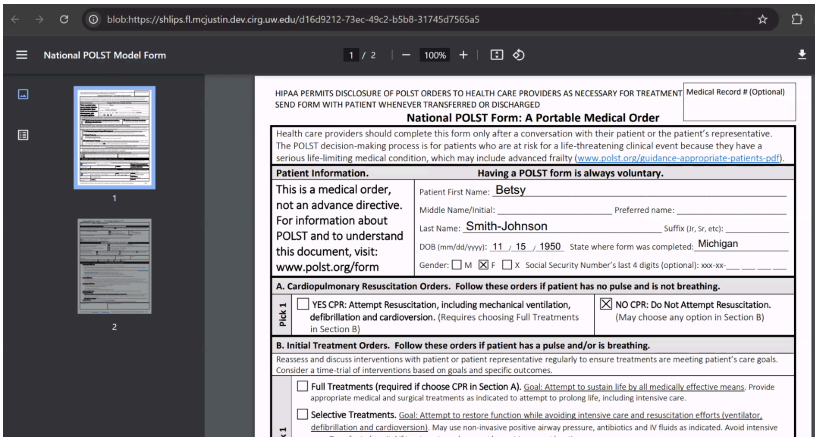
Notable Achievements

- Tested partial structured PMO data exchange between 5 systems
- Collaboration with other tracks on ADI design
  - structured documents
  - CCDA to FHIR
  - behavioral health
- Achieved group consensus on several ADI Structured PMO design options
  - PMO ServiceRequest representation of category and intent.

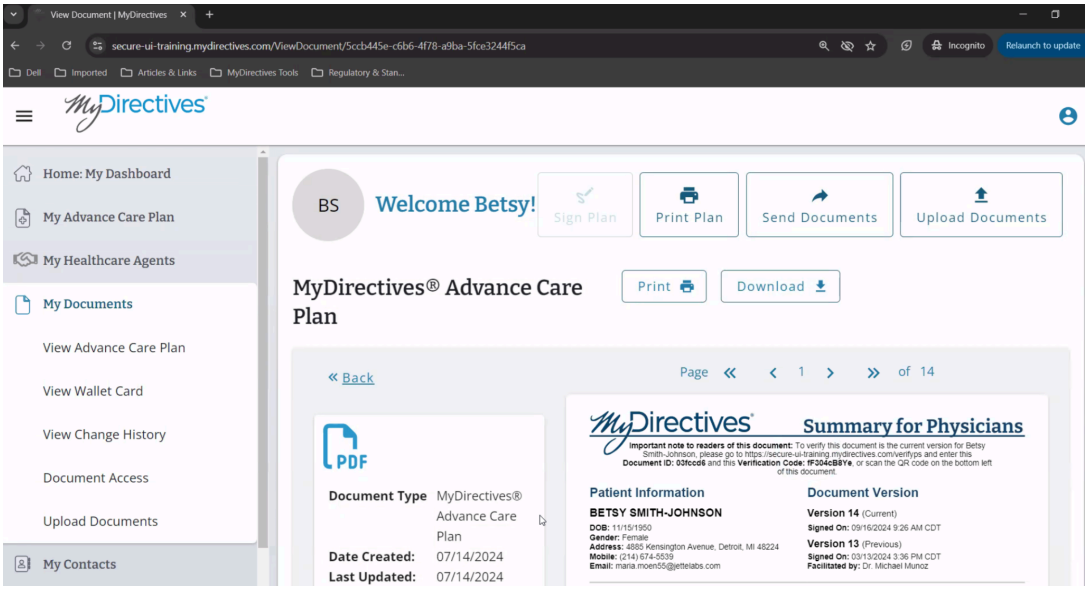
- Screenshots and/or links to further information
  The screenshots reflect a series of use case scenes in the ADI track.

Washington State Department of Health Demo

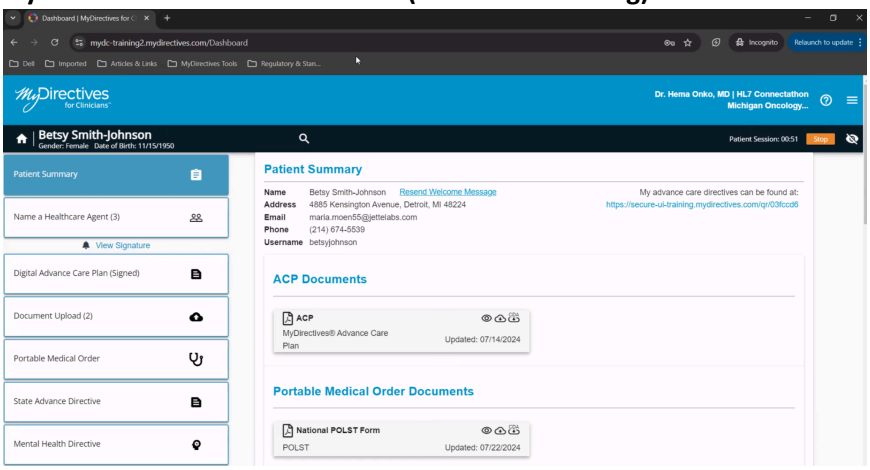




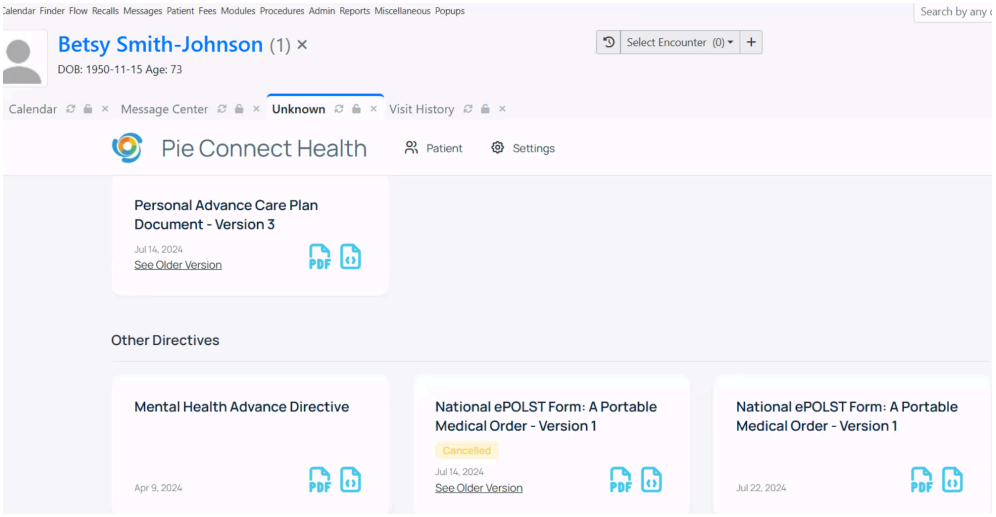
MyDirectives Demo (Consumer-facing)

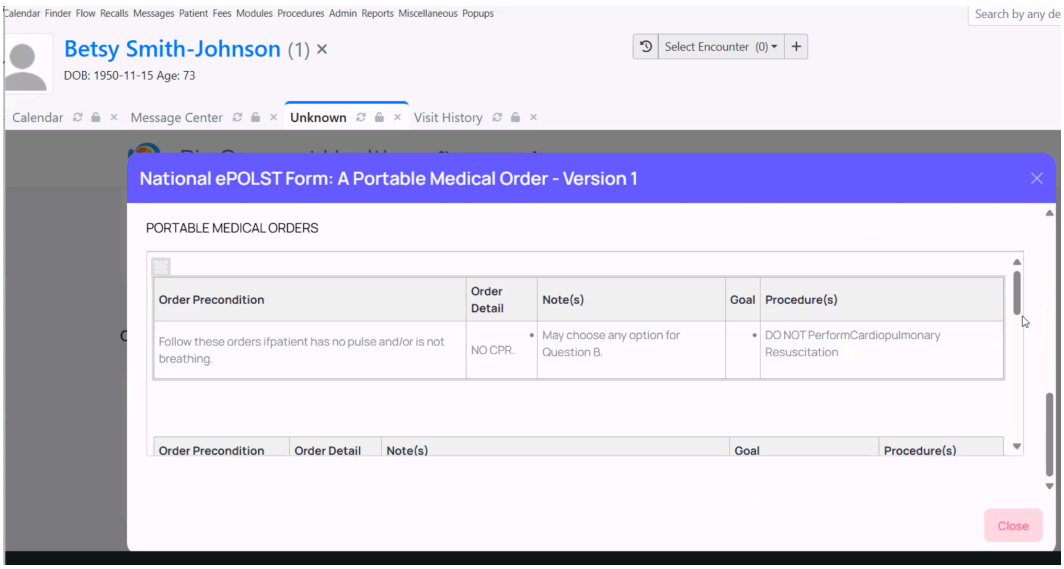


MyDirectives for Clinicians Demo (Practitioner-facing)

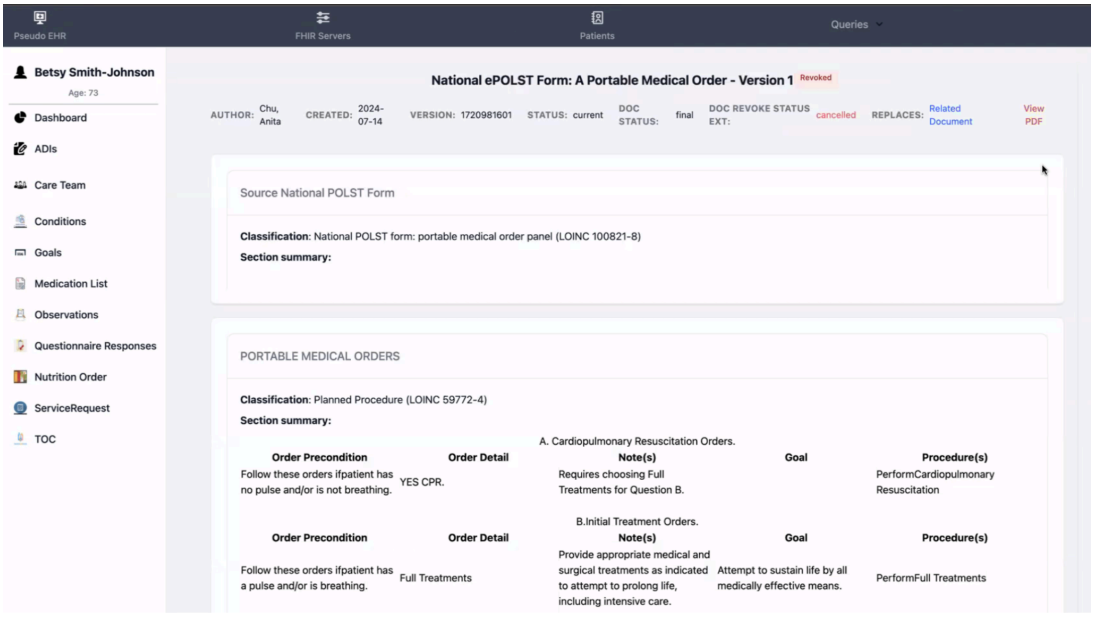


PIE Connect Health





MITRE Pseudo-EHR reference implementation



- Discovered issues / questions (if there are any)

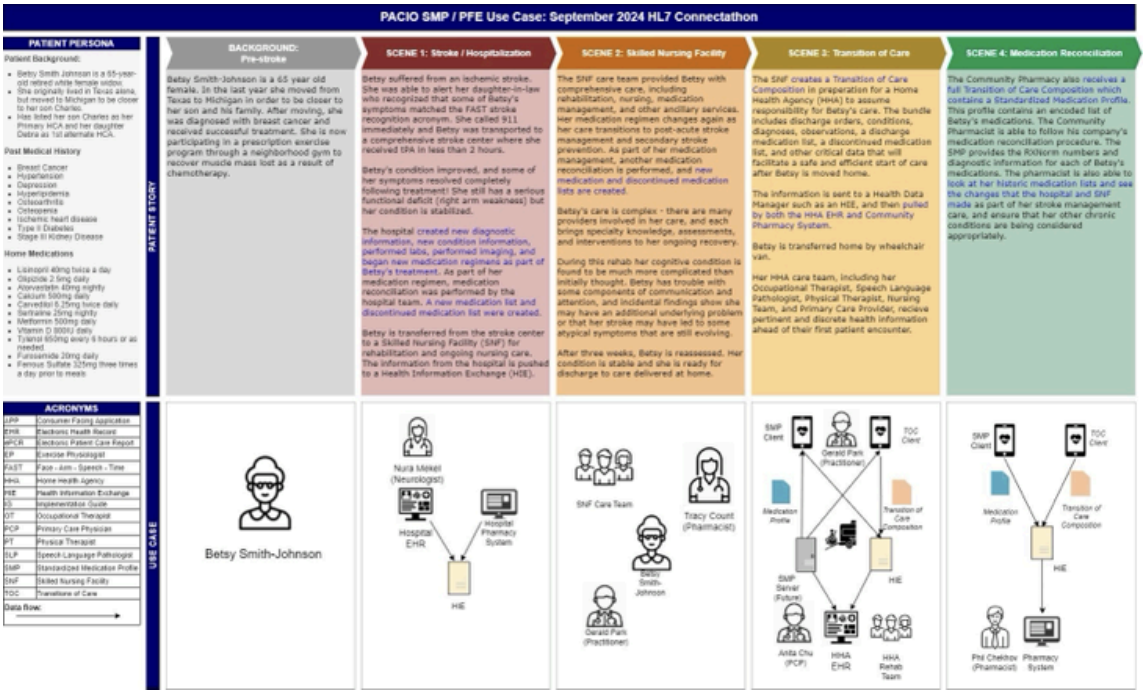
Lessons Learned

- **Process**
  - improve/change:
    - keep past stories, add new, different, multiple personas. Rather than versioning stories, add new stories so they don't overlap. Resetting the system with the same patient name is cumbersome and doesn't fully test features.
    - pause during the video recording to take demo screenshots
    - possibly do a dry run before the video recording
- **Technical**
  - improve/change:
    - create a library of multiple personas. goal to exercise all the functionality.
- **Open topics**
  - good/do more
    - having open topics allowed us to further explore where we can evolve our standard.
    - connecting interacting with other tracks that refer to Advance Directives;
  - improve/change:
    - investigate opportunities and pre-work of other track goals and arrange breakouts ahead of time

- Now what?
  - JIRA Ticket Cleanup
    - Immediate: "tickle" the old PACIO ADI JIRA tickets
    - Revisit Ticket cleanup – every other Wednesday and cadence for PEWG Block Vote to apply changes
  - Schedule follow-up meetings with cross-project teams:
    - Behavioral Health project team to align their support for MHAD
      - Behavioral Health meet Wednesdays at 4p.
      - implications are informing USCDI+
    - Goal-Directive Care Planning on representing ADI Goals

PACIO SMP and PFE

- What was the track trying to achieve?
  - To advance interoperable health information exchange to, from, and between acute care and long-term post-acute care providers by establishing a Personal Functioning and Engagement (PFE) Model for Data, establishing PFE / Standardized Medication Profile (SMP) profiles, and using them to build a more complete picture of patient care and needs across settings during the patient care journey. New testing will include verifying the exchange of additional important data, such as more complex nutrition orders, cognition observations, a wider degree of communication data, and Functional Communication Measures (FCMs).
  - Test a Post-Acute Care Assessment Apps ability to collect CMS Data Element Library assessment data and test the ability of Large Language Models (LLMs) to help reduce provider burden in filling out assessment forms.
  -

- 

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

ActualMeds

PatientCentricSolutions

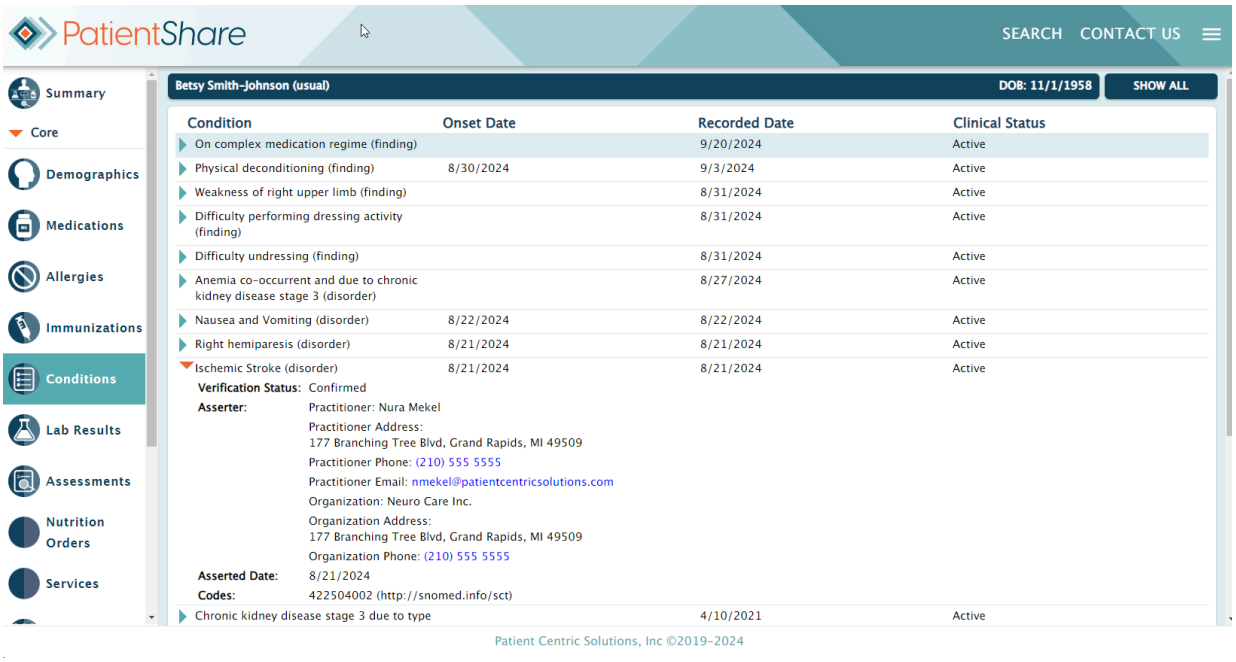
INTEROPERABILITY INSTITUTE

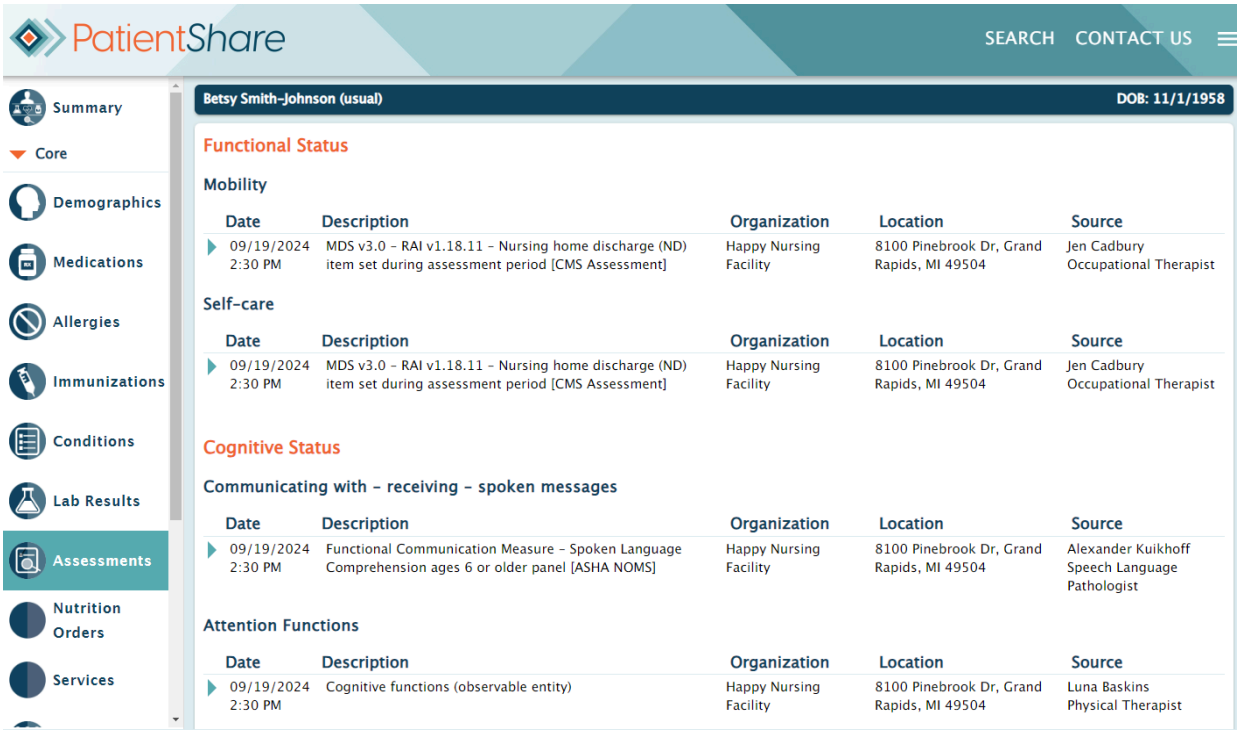
MITRE

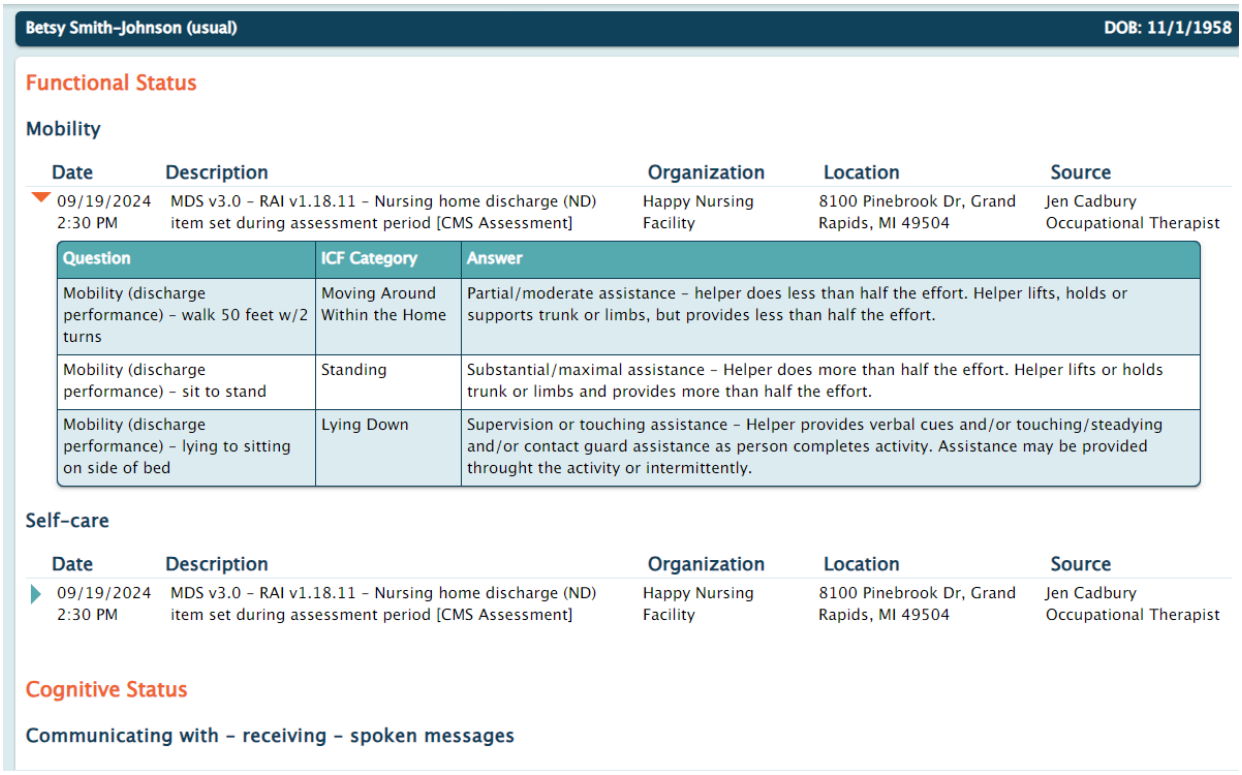
- Notable achievements
  - Tested exchange of additional important data:
    - Nutrition Order
    - Cognition Observations
    - Wider degree of communication data
    - Functional Communication Measures (FCMs)
  - Medication reconciliation
    - Incorporated conditions and other information in addition medication data to highlight risks in the reconciled report

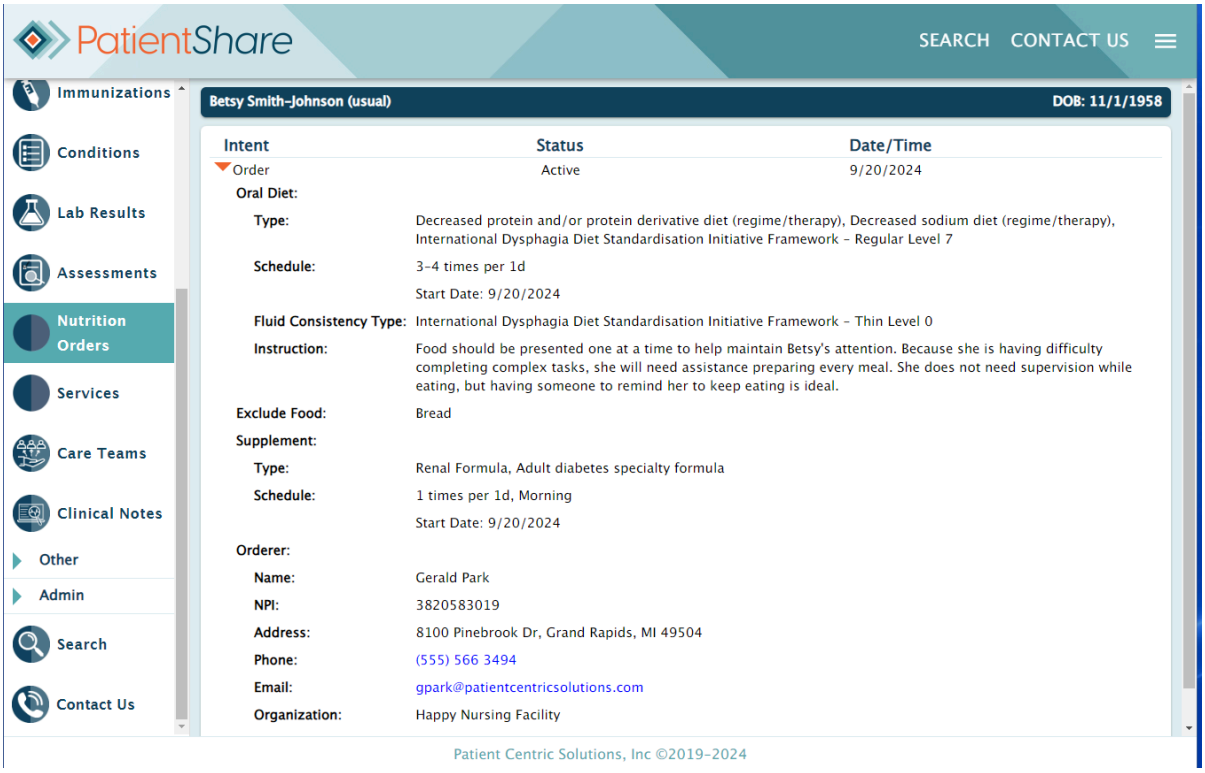
- Screenshots and/or links to further information
    - Scenario Screenshots

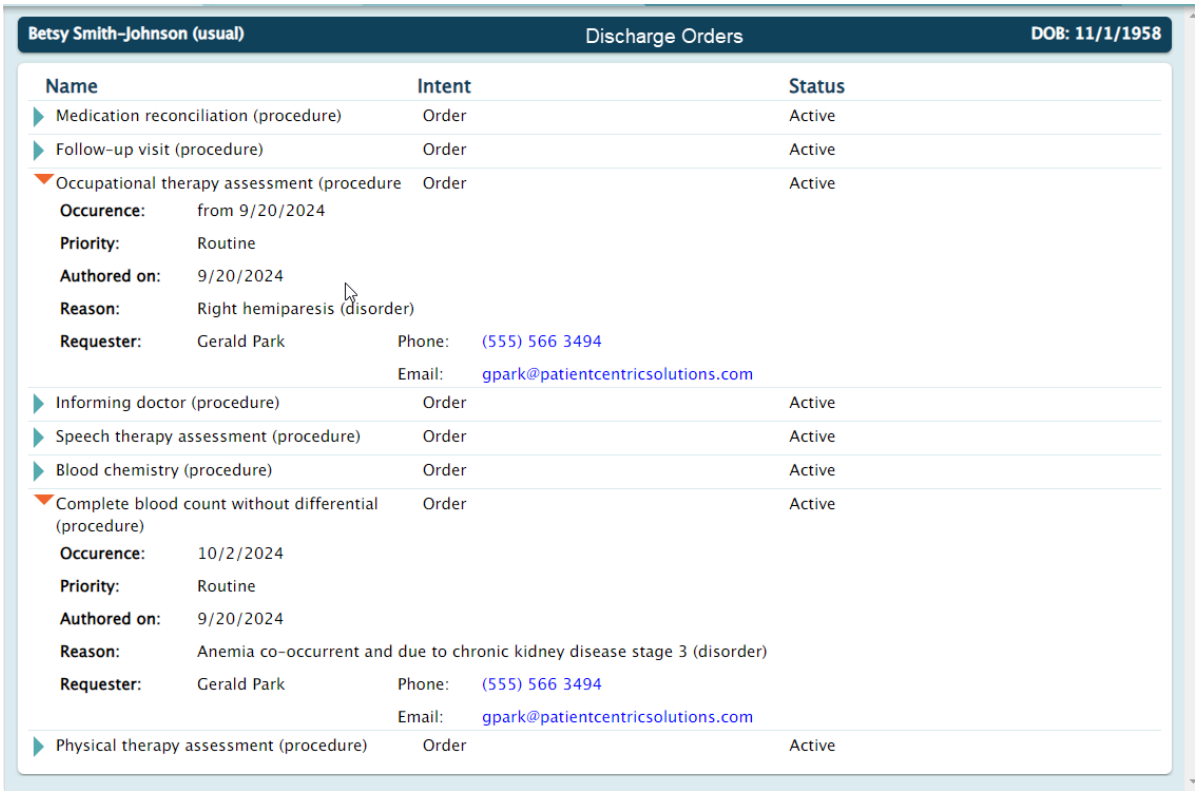
Patient Centric Solutions (Transitions of Care)




PatientShare
SEARCH
CONTACT US
Summary
Core
Demographics
Medications
Allergies
Immunizations
Conditions
Lab Results
Assessments
Nutrition Orders
Services
Betsy Smith-Johnson (usual)
DOB: 11/1/1958
Functional Status
Mobility
Date
Description
Organization
Location
Source
09/19/2024 2:30 PM
MDS v3.0 - RAI v1.18.11 - Nursing home discharge (ND) item set during assessment period [CMS Assessment]
Happy Nursing Facility
8100 Pinebrook Dr, Grand Rapids, MI 49504
Jen Cadbury Occupational Therapist
Self-care
Date
Description
Organization
Location
Source
09/19/2024 2:30 PM
MDS v3.0 - RAI v1.18.11 - Nursing home discharge (ND) item set during assessment period [CMS Assessment]
Happy Nursing Facility
8100 Pinebrook Dr, Grand Rapids, MI 49504
Jen Cadbury Occupational Therapist
Cognitive Status
Communicating with - receiving - spoken messages
Date
Description
Organization
Location
Source
09/19/2024 2:30 PM
Functional Communication Measure - Spoken Language Comprehension ages 6 or older panel [ASHA NOMS]
Happy Nursing Facility
8100 Pinebrook Dr, Grand Rapids, MI 49504
Alexander Kuikhoff Speech Language Pathologist
Attention Functions
Date
Description
Organization
Location
Source
09/19/2024 2:30 PM
Cognitive functions (observable entity)
Happy Nursing Facility
8100 Pinebrook Dr, Grand Rapids, MI 49504
Luna Baskins Physical Therapist


Betsy Smith-Johnson (usual)
DOB: 11/1/1958
Functional Status
Mobility
Date
Description
Organization
Location
Source
09/19/2024 2:30 PM
MDS v3.0 - RAI v1.18.11 - Nursing home discharge (ND) item set during assessment period [CMS Assessment]
Happy Nursing Facility
8100 Pinebrook Dr, Grand Rapids, MI 49504
Jen Cadbury Occupational Therapist
Question
ICF Category
Answer
Mobility (discharge performance) - walk 50 feet w/2 turns
Moving Around Within the Home
Partial/moderate assistance - helper does less than half the effort. Helper lifts, holds or supports trunk or limbs, but provides less than half the effort.
Mobility (discharge performance) - sit to stand
Standing
Substantial/maximal assistance - Helper does more than half the effort. Helper lifts or holds trunk or limbs and provides more than half the effort.
Mobility (discharge performance) - lying to sitting on side of bed
Lying Down
Supervision or touching assistance - Helper provides verbal cues and/or touching/steadying and/or contact guard assistance as person completes activity. Assistance may be provided throught the activity or intermittently.
Self-care
Date
Description
Organization
Location
Source
09/19/2024 2:30 PM
MDS v3.0 - RAI v1.18.11 - Nursing home discharge (ND) item set during assessment period [CMS Assessment]
Happy Nursing Facility
8100 Pinebrook Dr, Grand Rapids, MI 49504
Jen Cadbury Occupational Therapist
Cognitive Status
Communicating with - receiving - spoken messages


PatientShare
SEARCH
CONTACT US
Immunizations
Conditions
Lab Results
Assessments
Nutrition Orders
Services
Care Teams
Clinical Notes
Other
Admin
Search
Contact Us
Betsy Smith-Johnson (usual)
DOB: 11/1/1958
Intent
Status
Date/Time
Order
Active
9/20/2024
Oral Diet:
Type:
Decreased protein and/or protein derivative diet (regime/therapy), Decreased sodium diet (regime/therapy), International Dysphagia Diet Standardisation Initiative Framework - Regular Level 7
Schedule:
3-4 times per 1d
Start Date: 9/20/2024
Fluid Consistency Type:
International Dysphagia Diet Standardisation Initiative Framework - Thin Level 0
Instruction:
Food should be presented one at a time to help maintain Betsy's attention. Because she is having difficulty completing complex tasks, she will need assistance preparing every meal. She does not need supervision while eating, but having someone to remind her to keep eating is ideal.
Exclude Food:
Bread
Supplement:
Type:
Renal Formula, Adult diabetes specialty formula
Schedule:
1 times per 1d, Morning
Start Date: 9/20/2024
Orderer:
Name:
Gerald Park
NPI:
3820583019
Address:
8100 Pinebrook Dr, Grand Rapids, MI 49504
Phone:
(555) 566 3494
Email:
gpark@patientcentricsolutions.com
Organization:
Happy Nursing Facility
Patient Centric Solutions, Inc ©2019-2024


Betsy Smith-Johnson (usual)
Discharge Orders
DOB: 11/1/1958
Name
Intent
Status
Medication reconciliation (procedure)
Order
Active
Follow-up visit (procedure)
Order
Active
Occupational therapy assessment (procedure
Order
Active
Occurence:
from 9/20/2024
Priority:
Routine
Authored on:
9/20/2024
Reason:
Right hemiparesis (disorder)
Requester:
Gerald Park
Phone:
(555) 566 3494
Email:
gpark@patientcentricsolutions.com
Informing doctor (procedure)
Order
Active
Speech therapy assessment (procedure)
Order
Active
Blood chemistry (procedure)
Order
Active
Complete blood count without differential (procedure)
Order
Active
Occurence:
10/2/2024
Priority:
Routine
Authored on:
9/20/2024
Reason:
Anemia co-occurrent and due to chronic kidney disease stage 3 (disorder)
Requester:
Gerald Park
Phone:
(555) 566 3494
Email:
gpark@patientcentricsolutions.com
Physical therapy assessment (procedure)
Order
Active
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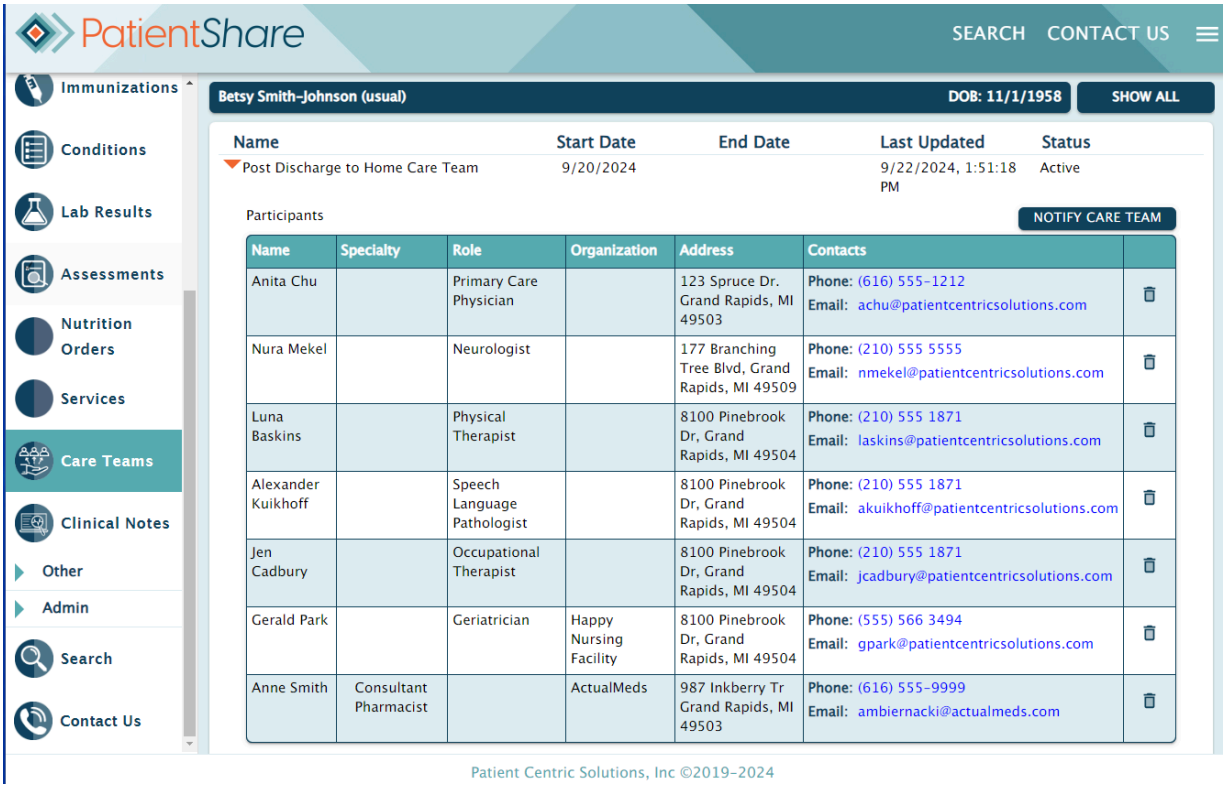
PatientShare
SEARCH
CONTACT US
Immunizations
Conditions
Lab Results
Assessments
Nutrition Orders
Services
Care Teams
Clinical Notes
Other
Admin
Search
Contact Us
Betsy Smith-Johnson (usual)
DOB: 11/1/1958
SHOW ALL
Name
Start Date
End Date
Last Updated
Status
Post Discharge to Home Care Team
9/20/2024
9/22/2024, 1:51:18 PM
Active
Participants
NOTIFY CARE TEAM
Name
Specialty
Role
Organization
Address
Contacts
Anita Chu
Primary Care Physician
123 Spruce Dr. Grand Rapids, MI 49503
Phone: (616) 555-1212
Email: achu@patientcentricsolutions.com
Nura Mekel
Neurologist
177 Branching Tree Blvd, Grand Rapids, MI 49509
Phone: (210) 555 5555
Email: nmekel@patientcentricsolutions.com
Luna Baskins
Physical Therapist
8100 Pinebrook Dr, Grand Rapids, MI 49504
Phone: (210) 555 1871
Email: laskins@patientcentricsolutions.com
Alexander Kuikhoff
Speech Language Pathologist
8100 Pinebrook Dr, Grand Rapids, MI 49504
Phone: (210) 555 1871
Email: akuikhoff@patientcentricsolutions.com
Jen Cadbury
Occupational Therapist
8100 Pinebrook Dr, Grand Rapids, MI 49504
Phone: (210) 555 1871
Email: jcadbury@patientcentricsolutions.com
Gerald Park
Geriatrician
Happy Nursing Facility
8100 Pinebrook Dr, Grand Rapids, MI 49504
Phone: (555) 566 3494
Email: gpark@patientcentricsolutions.com
Anne Smith
Consultant Pharmacist
ActualMeds
987 Inkberry Tr Grand Rapids, MI 49503
Phone: (616) 555-9999
Email: ambiernacki@actualmeds.com
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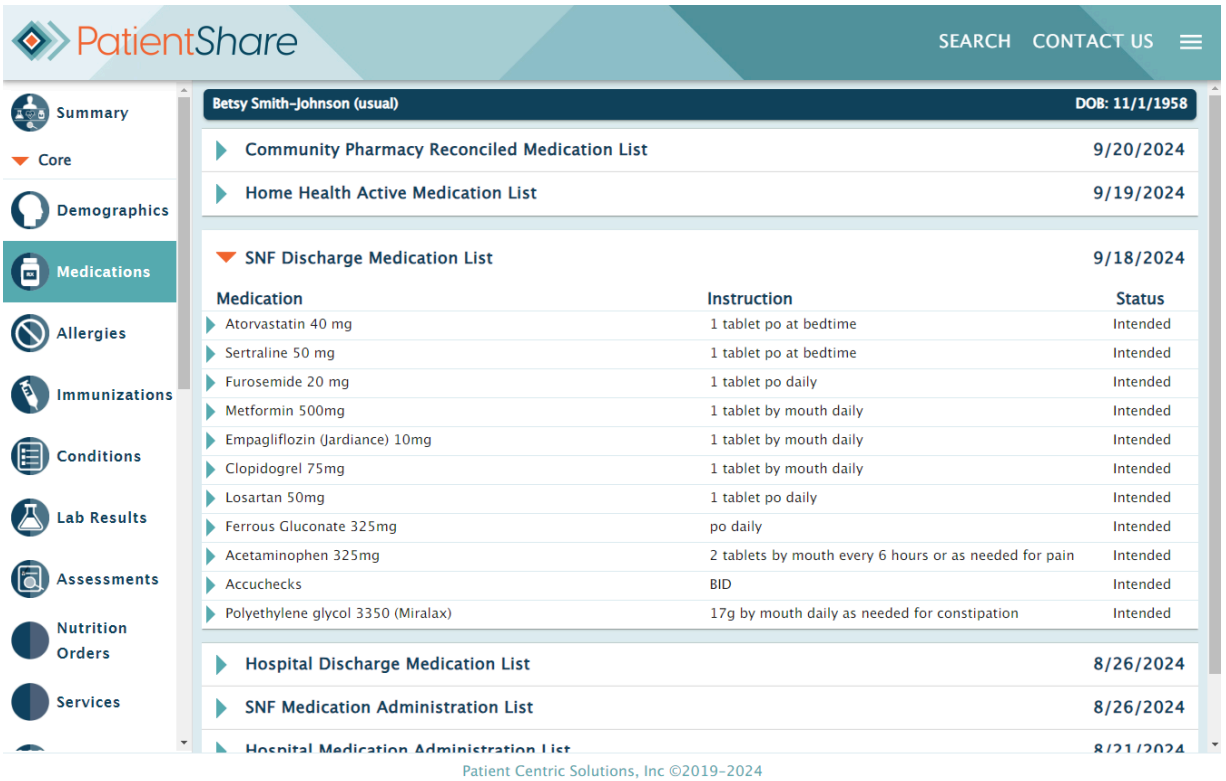
PatientShare
SEARCH
CONTACT US
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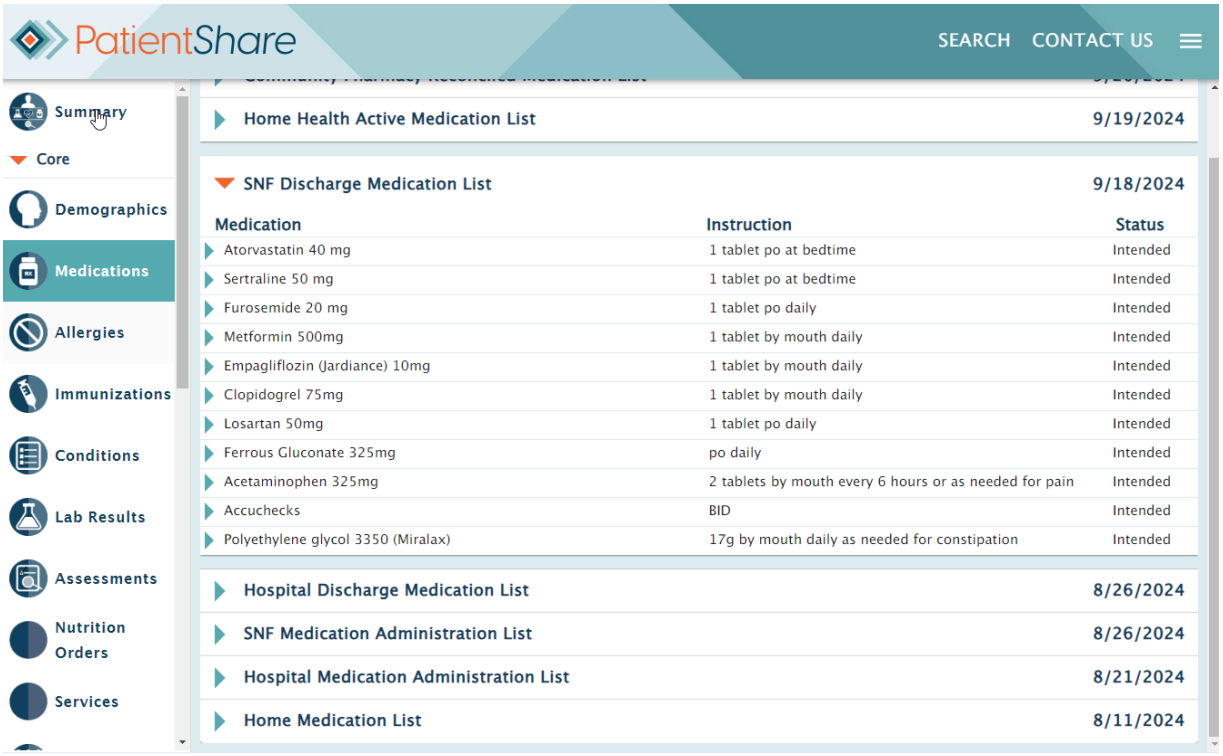
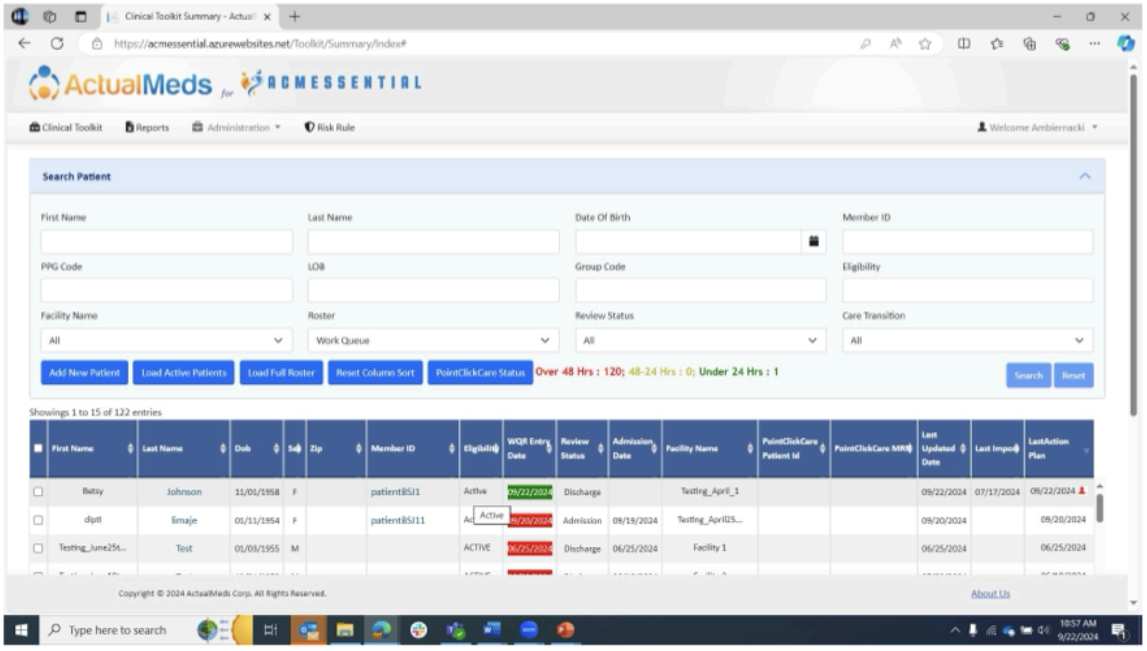
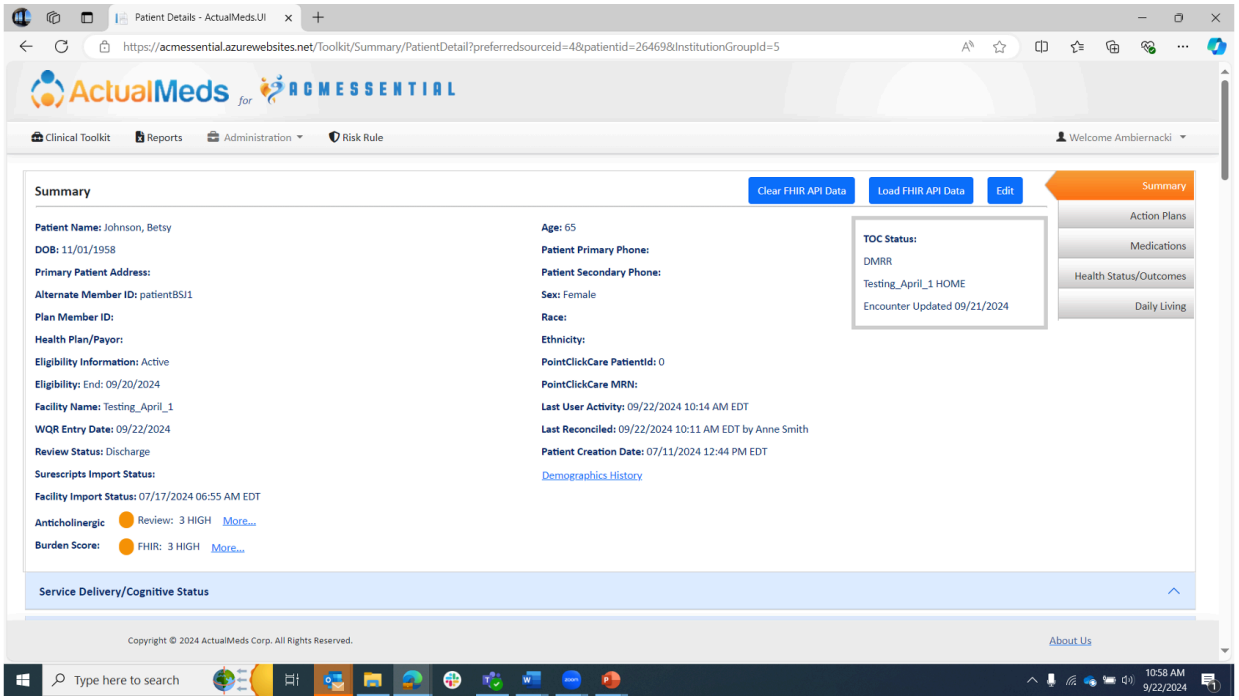
Demographics
Medications
Allergies
Immunizations
Conditions
Lab Results
Assessments
Nutrition Orders
Services
Betsy Smith-Johnson (usual)
DOB: 11/1/1958
Community Pharmacy Reconciled Medication List
9/20/2024
Home Health Active Medication List
9/19/2024
SNF Discharge Medication List
9/18/2024
Medication
Instruction
Status
Atorvastatin 40 mg
1 tablet po at bedtime
Intended
Sertraline 50 mg
1 tablet po at bedtime
Intended
Furosemide 20 mg
1 tablet po daily
Intended
Metformin 500mg
1 tablet by mouth daily
Intended
Empagliflozin (Jardiance) 10mg
1 tablet by mouth daily
Intended
Clopidogrel 75mg
1 tablet by mouth daily
Intended
Losartan 50mg
1 tablet po daily
Intended
Ferrous Gluconate 325mg
po daily
Intended
Acetaminophen 325mg
2 tablets by mouth every 6 hours or as needed for pain
Intended
Accuchecks
BID
Intended
Polyethylene glycol 3350 (Miralax)
17g by mouth daily as needed for constipation
Intended
Hospital Discharge Medication List
8/26/2024
SNF Medication Administration List
8/26/2024
Patient Centric Solutions, Inc ©2019-2024



Actual Meds (Medication Reconciliation)




Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
ActualMeds for ACMESSENTIAL
Clinical Toolkit
Reports
Administration
Risk Rule
Welcome Ambiernacki
Summary
Clear FHIR API Data
Load FHIR API Data
Edit
Summary
Action Plans
Medications
Health Status/Outcomes
Daily Living
Patient Name: Johnson, Betsy
DOB: 11/01/1958
Primary Patient Address:
Alternate Member ID: patientBSJ1
Plan Member ID:
Health Plan/Payor:
Eligibility Information: Active
Eligibility: End: 09/20/2024
Facility Name: Testing_April_1
WQR Entry Date: 09/22/2024
Review Status: Discharge
Surescripts Import Status:
Facility Import Status: 07/17/2024 06:55 AM EDT
Anticholinergic Review: 3 HIGH More...
Burden Score: FHIR: 3 HIGH More...
Age: 65
Patient Primary Phone:
Patient Secondary Phone:
Sex: Female
Race:
Ethnicity:
PointClickCare PatientId: 0
PointClickCare MRN:
Last User Activity: 09/22/2024 10:14 AM EDT
Last Reconciled: 09/22/2024 10:11 AM EDT by Anne Smith
Patient Creation Date: 07/11/2024 12:44 PM EDT
Demographics History
TOC Status:
DMRR
Testing_April_1 HOME
Encounter Updated 09/21/2024
Service Delivery/Cognitive Status
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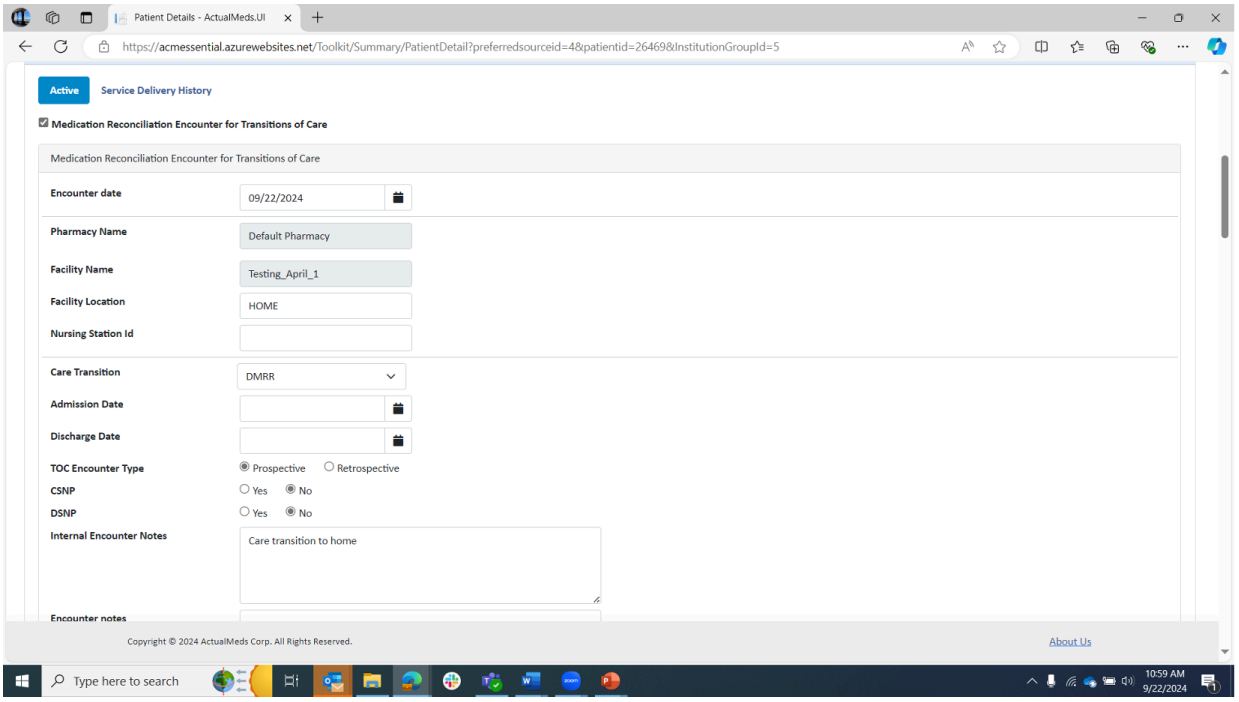
About Us
Type here to search
10:58 AM
9/22/2024


Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
Active
Service Delivery History
Medication Reconciliation Encounter for Transitions of Care
Medication Reconciliation Encounter for Transitions of Care
Encounter date
09/22/2024
Pharmacy Name
Default Pharmacy
Facility Name
Testing_April_1
Facility Location
HOME
Nursing Station Id
Care Transition
DMRR
Admission Date
Discharge Date
TOC Encounter Type
Prospective
Retrospective
CSNP
Yes
No
DSNP
Yes
No
Internal Encounter Notes
Care transition to home
Encounter notes
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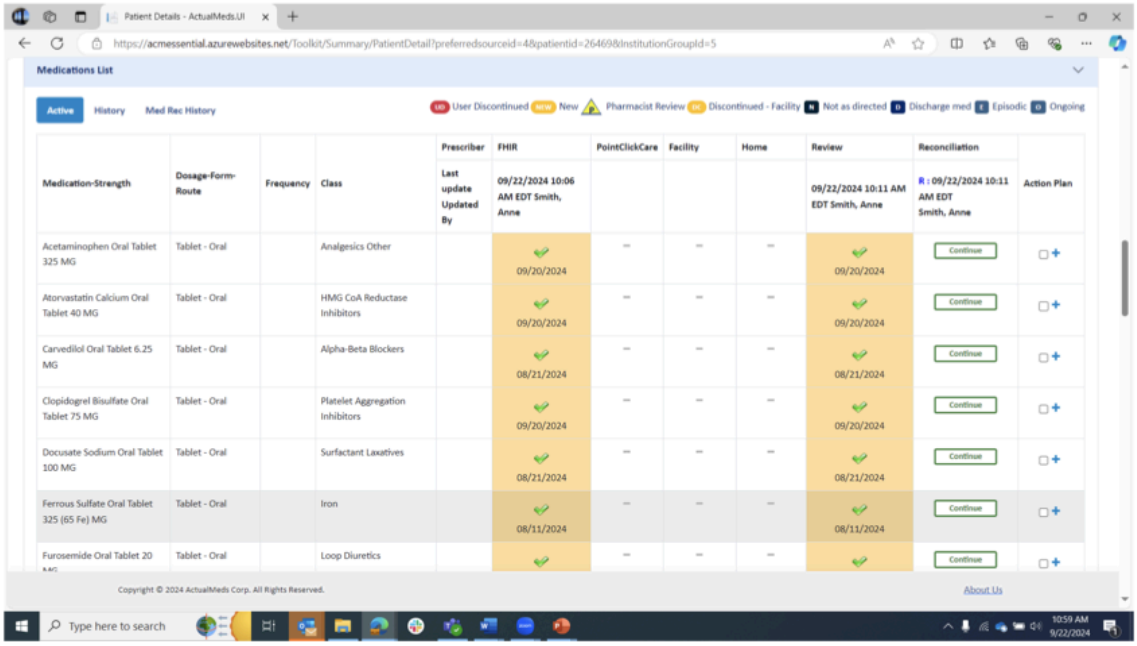
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Medications List
Active
History
Med Rec History
User Discontinued
New
Pharmacist Review
Discontinued - Facility
Not as directed
Discharge med
Episodic
Ongoing
Medication-Strength
Dosage-Form-Route
Frequency
Class
Prescriber
FHIR
PointClickCare
Facility
Home
Review
Reconciliation
Action Plan
Last update Updated By
09/22/2024 10:06 AM EDT Smith, Anne
09/22/2024 10:11 AM EDT Smith, Anne
R : 09/22/2024 10:11 AM EDT Smith, Anne
Acetaminophen Oral Tablet 325 MG
Tablet - Oral
Analgesics Other
09/20/2024
Continue
Atorvastatin Calcium Oral Tablet 40 MG
Tablet - Oral
HMG CoA Reductase Inhibitors
09/20/2024
Continue
Carvedilol Oral Tablet 6.25 MG
Tablet - Oral
Alpha-Beta Blockers
08/21/2024
Continue
Clopidogrel Bisulfate Oral Tablet 75 MG
Tablet - Oral
Platelet Aggregation Inhibitors
09/20/2024
Continue
Docusate Sodium Oral Tablet 100 MG
Tablet - Oral
Surfactant Laxatives
08/21/2024
Continue
Ferrous Sulfate Oral Tablet 325 (65 Fe) MG
Tablet - Oral
Iron
08/11/2024
Continue
Furosemide Oral Tablet 20
Tablet - Oral
Loop Diuretics
Continue
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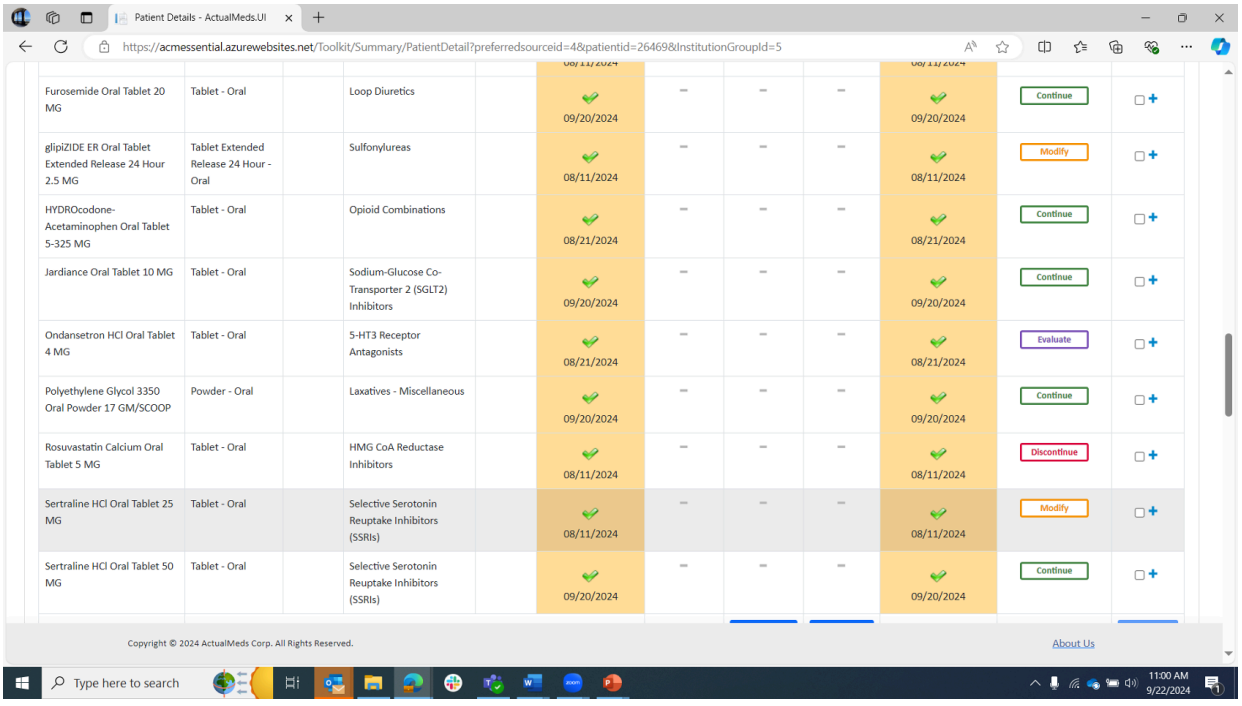
Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
Furosemide Oral Tablet 20 MG
Tablet - Oral
Loop Diuretics
09/20/2024
Continue
glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG
Tablet Extended Release 24 Hour - Oral
Sulfonylureas
08/11/2024
Modify
HYDROcodone-Acetaminophen Oral Tablet 5-325 MG
Tablet - Oral
Opioid Combinations
08/21/2024
Continue
Jardiance Oral Tablet 10 MG
Tablet - Oral
Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
09/20/2024
Continue
Ondansetron HCl Oral Tablet 4 MG
Tablet - Oral
5-HT3 Receptor Antagonists
08/21/2024
Evaluate
Polyethylene Glycol 3350 Oral Powder 17 GM/SCOOP
Powder - Oral
Laxatives - Miscellaneous
09/20/2024
Continue
Rosuvastatin Calcium Oral Tablet 5 MG
Tablet - Oral
HMG CoA Reductase Inhibitors
08/11/2024
Discontinue
Sertraline HCl Oral Tablet 25 MG
Tablet - Oral
Selective Serotonin Reuptake Inhibitors (SSRIs)
08/11/2024
Modify
Sertraline HCl Oral Tablet 50 MG
Tablet - Oral
Selective Serotonin Reuptake Inhibitors (SSRIs)
09/20/2024
Continue
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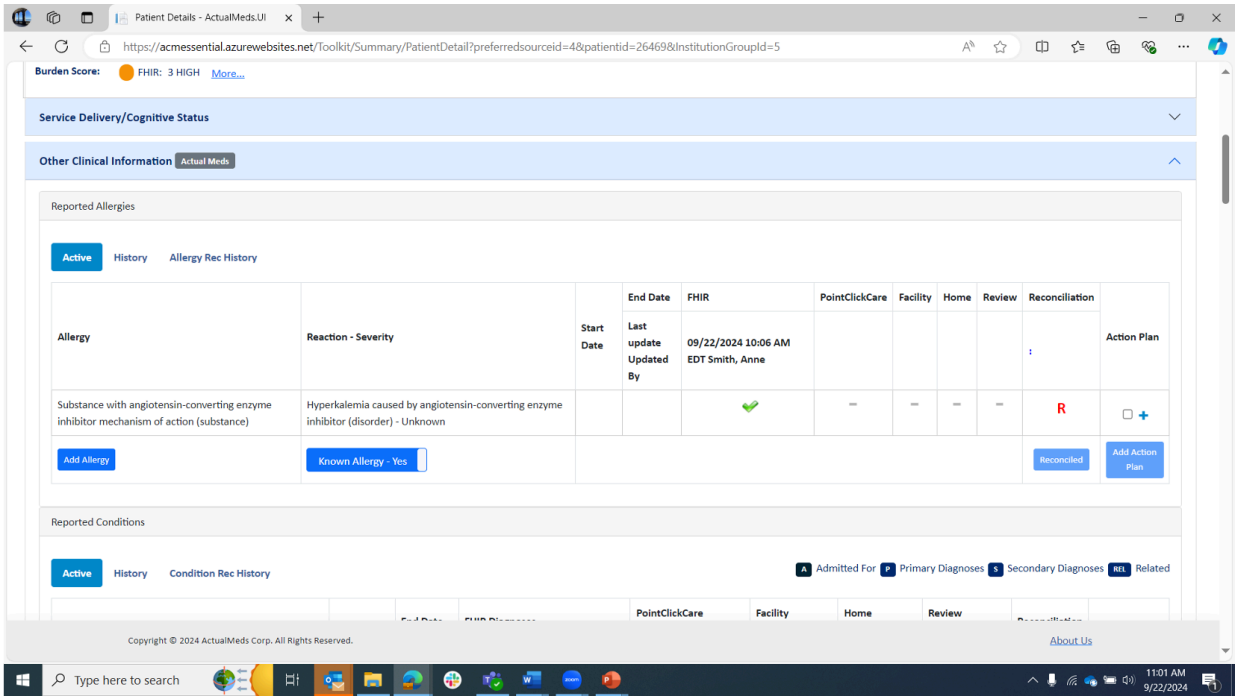
Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
Burden Score: FHIR: 3 HIGH More...
Service Delivery/Cognitive Status
Other Clinical Information Actual Meds
Reported Allergies
Active History Allergy Rec History
Allergy
Reaction - Severity
Start Date
End Date
Last update Updated By
FHIR
09/22/2024 10:06 AM EDT Smith, Anne
PointClickCare
Facility
Home
Review
Reconciliation
Action Plan
Substance with angiotensin-converting enzyme inhibitor mechanism of action (substance)
Hyperkalemia caused by angiotensin-converting enzyme inhibitor (disorder) - Unknown
R
Add Allergy
Known Allergy - Yes
Reconciled
Add Action Plan
Reported Conditions
Active History Condition Rec History
A Admitted For P Primary Diagnoses S Secondary Diagnoses REL Related
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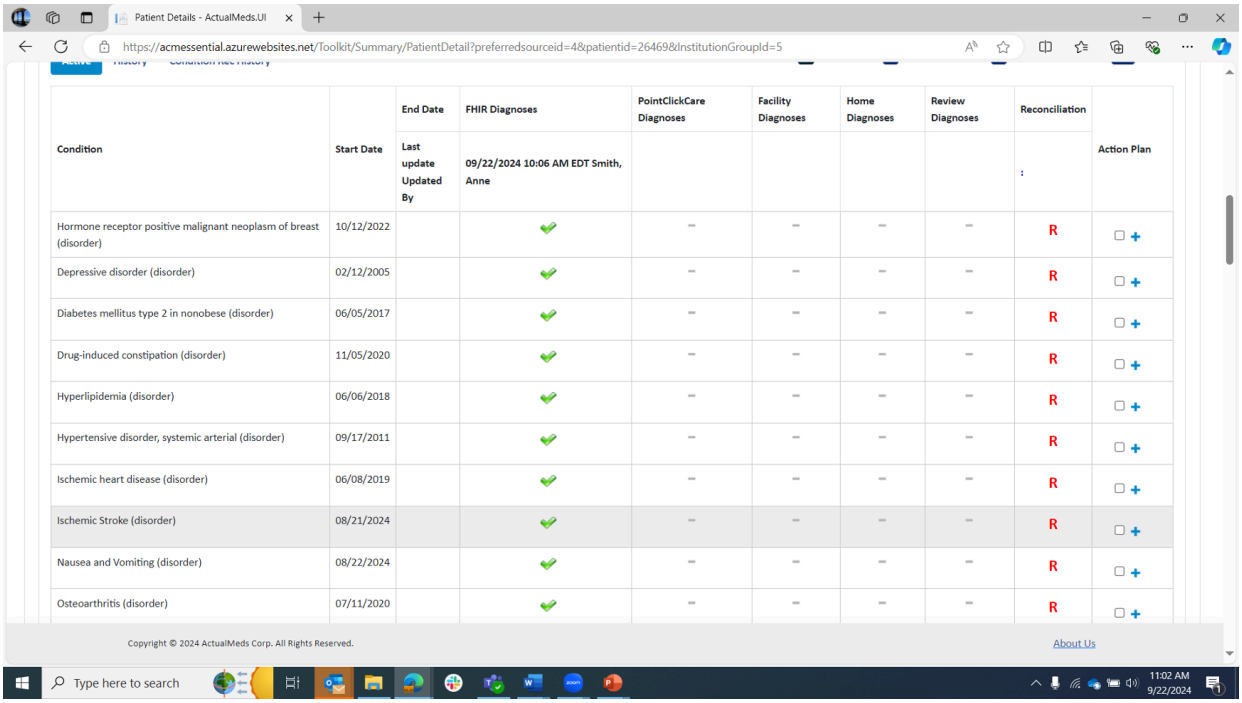
Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
Condition
Start Date
End Date
Last update Updated By
FHIR Diagnoses
09/22/2024 10:06 AM EDT Smith, Anne
PointClickCare Diagnoses
Facility Diagnoses
Home Diagnoses
Review Diagnoses
Reconciliation
Action Plan
Hormone receptor positive malignant neoplasm of breast (disorder) 10/12/2022
Depressive disorder (disorder) 02/12/2005
Diabetes mellitus type 2 in nonobese (disorder) 06/05/2017
Drug-induced constipation (disorder) 11/05/2020
Hyperlipidemia (disorder) 06/06/2018
Hypertensive disorder, systemic arterial (disorder) 09/17/2011
Ischemic heart disease (disorder) 06/08/2019
Ischemic Stroke (disorder) 08/21/2024
Nausea and Vomiting (disorder) 08/22/2024
Osteoarthritis (disorder) 07/11/2020
R
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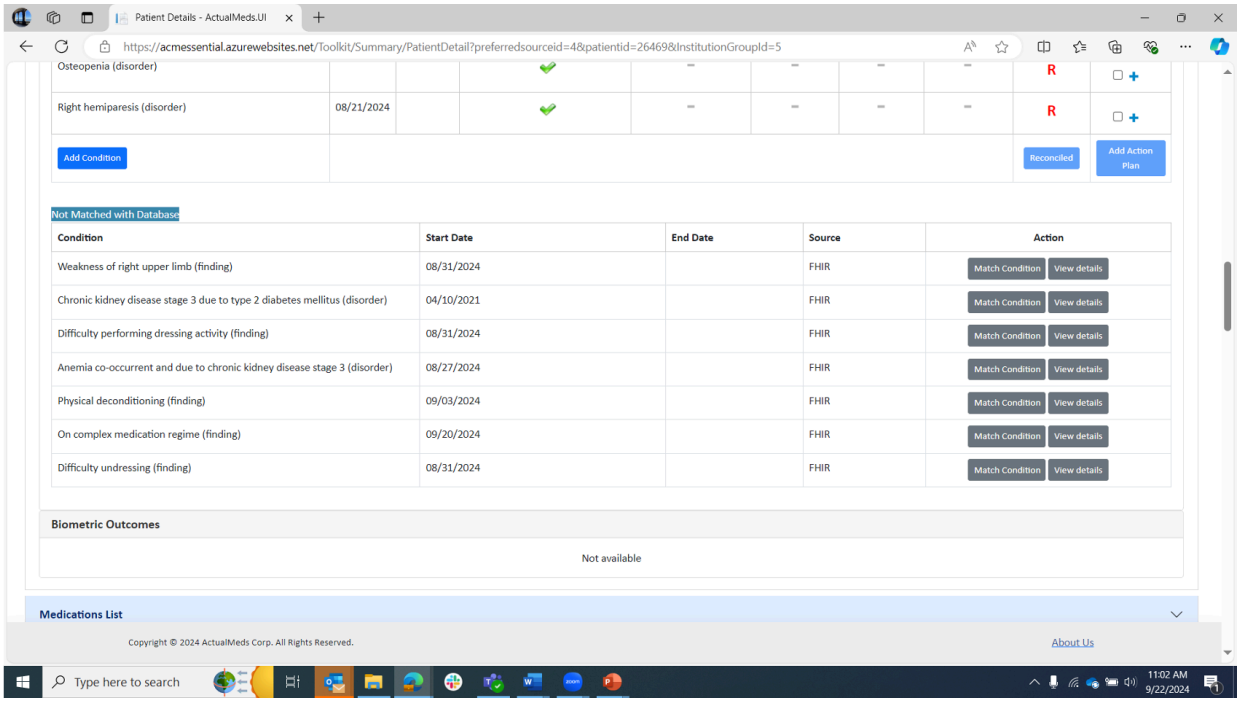
Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
Osteopenia (disorder)
Right hemiparesis (disorder) 08/21/2024
Add Condition
Reconciled
Add Action Plan
Not Matched with Database
Condition | Start Date | End Date | Source | Action
Weakness of right upper limb (finding) 08/31/2024 FHIR
Chronic kidney disease stage 3 due to type 2 diabetes mellitus (disorder) 04/10/2021 FHIR
Difficulty performing dressing activity (finding) 08/31/2024 FHIR
Anemia co-occurrent and due to chronic kidney disease stage 3 (disorder) 08/27/2024 FHIR
Physical deconditioning (finding) 09/03/2024 FHIR
On complex medication regime (finding) 09/20/2024 FHIR
Difficulty undressing (finding) 08/31/2024 FHIR
Match Condition
View details
Biometric Outcomes
Not available
Medications List
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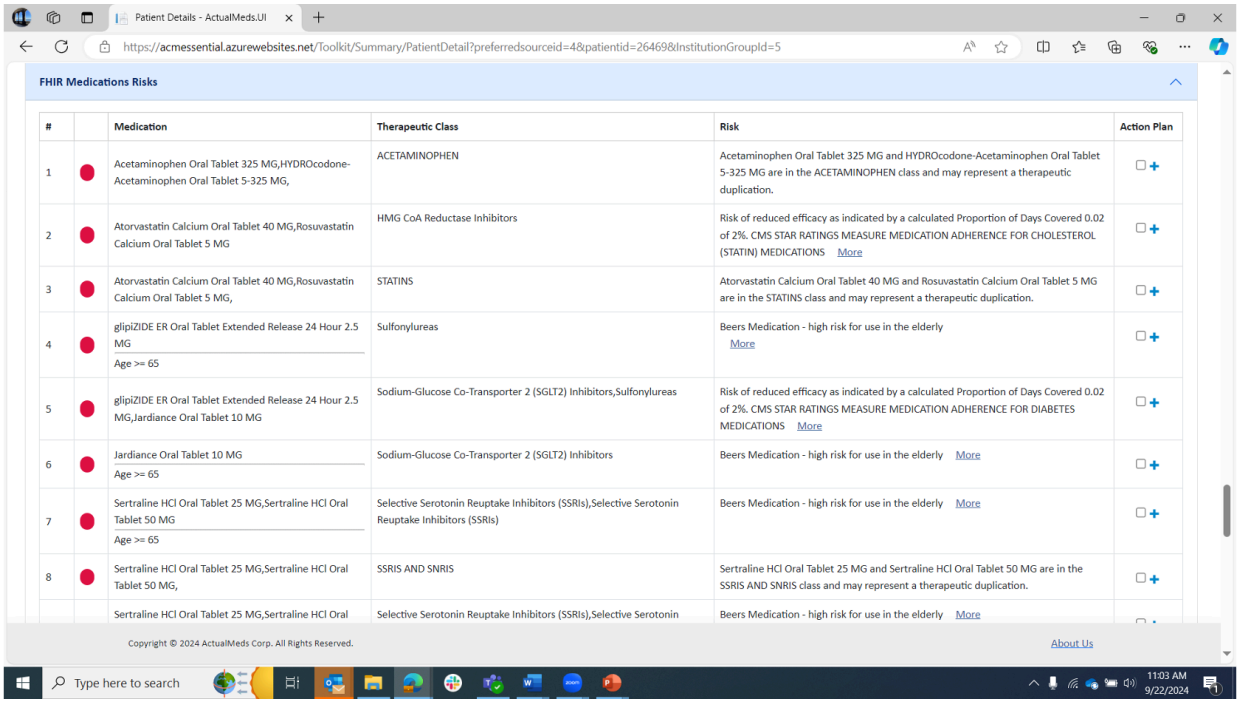
Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
FHIR Medications Risks
| Medication | Therapeutic Class | Risk | Action Plan
1 Acetaminophen Oral Tablet 325 MG,HYDROcodone-Acetaminophen Oral Tablet 5-325 MG, ACETAMINOPHEN Acetaminophen Oral Tablet 325 MG and HYDROcodone-Acetaminophen Oral Tablet 5-325 MG are in the ACETAMINOPHEN class and may represent a therapeutic duplication.
2 Atorvastatin Calcium Oral Tablet 40 MG,Rosuvastatin Calcium Oral Tablet 5 MG HMG CoA Reductase Inhibitors Risk of reduced efficacy as indicated by a calculated Proportion of Days Covered 0.02 of 2%. CMS STAR RATINGS MEASURE MEDICATION ADHERENCE FOR CHOLESTEROL (STATIN) MEDICATIONS More
3 Atorvastatin Calcium Oral Tablet 40 MG,Rosuvastatin Calcium Oral Tablet 5 MG, STATINS Atorvastatin Calcium Oral Tablet 40 MG and Rosuvastatin Calcium Oral Tablet 5 MG are in the STATINS class and may represent a therapeutic duplication.
4 glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG Age >= 65 Sulfonylureas Beers Medication - high risk for use in the elderly More
5 glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG,Jardiance Oral Tablet 10 MG Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors,Sulfonylureas Risk of reduced efficacy as indicated by a calculated Proportion of Days Covered 0.02 of 2%. CMS STAR RATINGS MEASURE MEDICATION ADHERENCE FOR DIABETES MEDICATIONS More
6 Jardiance Oral Tablet 10 MG Age >= 65 Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors Beers Medication - high risk for use in the elderly More
7 Sertraline HCl Oral Tablet 25 MG,Sertraline HCl Oral Tablet 50 MG Age >= 65 Selective Serotonin Reuptake Inhibitors (SSRIs),Selective Serotonin Reuptake Inhibitors (SSRIs) Beers Medication - high risk for use in the elderly More
8 Sertraline HCl Oral Tablet 25 MG,Sertraline HCl Oral Tablet 50 MG, SSRIS AND SNRIS Sertraline HCl Oral Tablet 25 MG and Sertraline HCl Oral Tablet 50 MG are in the SSRIS AND SNRIS class and may represent a therapeutic duplication.
Sertraline HCl Oral Tablet 25 MG,Sertraline HCl Oral Selective Serotonin Reuptake Inhibitors (SSRIs),Selective Serotonin Beers Medication - high risk for use in the elderly More
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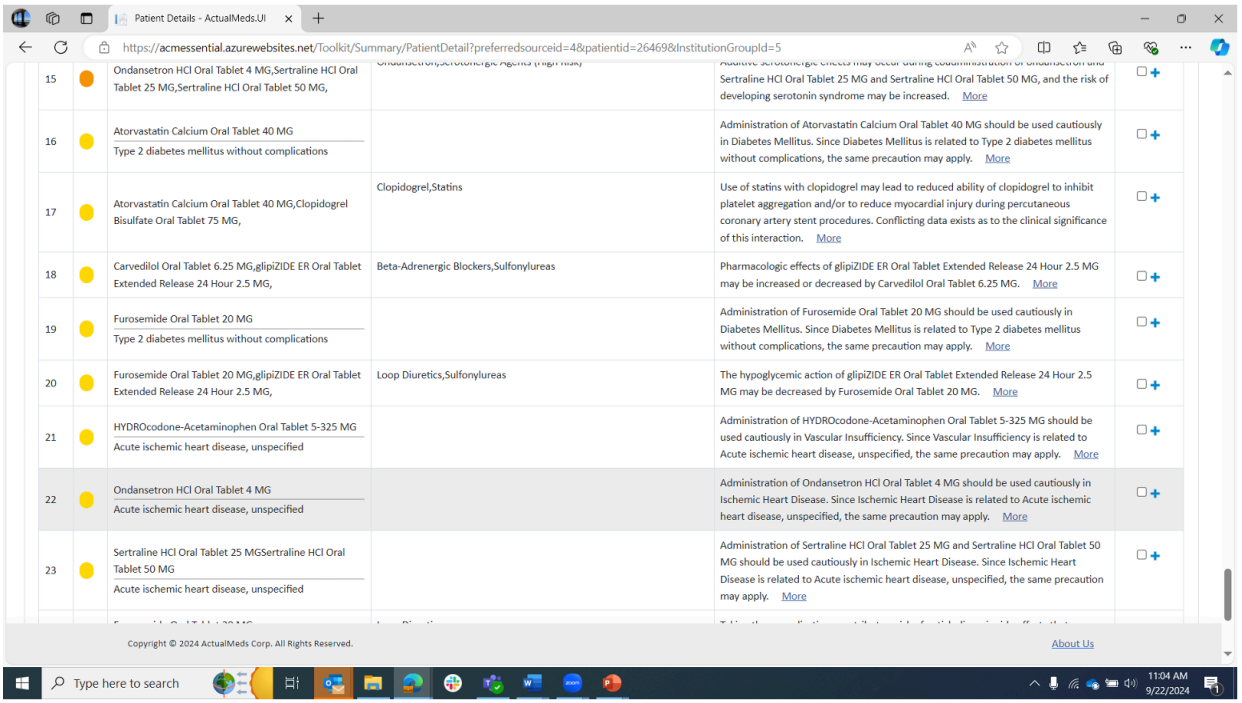
9/22/2024


Patient Details - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/Summary/PatientDetail?preferredsourceid=4&patientid=26469&InstitutionGroupId=5
15 Ondansetron HCl Oral Tablet 4 MG,Sertraline HCl Oral Tablet 25 MG,Sertraline HCl Oral Tablet 50 MG,
Sertraline HCl Oral Tablet 25 MG and Sertraline HCl Oral Tablet 50 MG, and the risk of developing serotonin syndrome may be increased. More
16 Atorvastatin Calcium Oral Tablet 40 MG
Type 2 diabetes mellitus without complications
Administration of Atorvastatin Calcium Oral Tablet 40 MG should be used cautiously in Diabetes Mellitus. Since Diabetes Mellitus is related to Type 2 diabetes mellitus without complications, the same precaution may apply. More
17 Atorvastatin Calcium Oral Tablet 40 MG,Clopidogrel Bisulfate Oral Tablet 75 MG,
Clopidogrel,Statins
Use of statins with clopidogrel may lead to reduced ability of clopidogrel to inhibit platelet aggregation and/or to reduce myocardial injury during percutaneous coronary artery stent procedures. Conflicting data exists as to the clinical significance of this interaction. More
18 Carvedilol Oral Tablet 6.25 MG,glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG,
Beta-Adrenergic Blockers,Sulfonylureas
Pharmacologic effects of glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG may be increased or decreased by Carvedilol Oral Tablet 6.25 MG. More
19 Furosemide Oral Tablet 20 MG
Type 2 diabetes mellitus without complications
Administration of Furosemide Oral Tablet 20 MG should be used cautiously in Diabetes Mellitus. Since Diabetes Mellitus is related to Type 2 diabetes mellitus without complications, the same precaution may apply. More
20 Furosemide Oral Tablet 20 MG,glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG,
Loop Diuretics,Sulfonylureas
The hypoglycemic action of glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG may be decreased by Furosemide Oral Tablet 20 MG. More
21 HYDROcodone-Acetaminophen Oral Tablet 5-325 MG
Acute ischemic heart disease, unspecified
Administration of HYDROcodone-Acetaminophen Oral Tablet 5-325 MG should be used cautiously in Vascular Insufficiency. Since Vascular Insufficiency is related to Acute ischemic heart disease, unspecified, the same precaution may apply. More
22 Ondansetron HCl Oral Tablet 4 MG
Acute ischemic heart disease, unspecified
Administration of Ondansetron HCl Oral Tablet 4 MG should be used cautiously in Ischemic Heart Disease. Since Ischemic Heart Disease is related to Acute ischemic heart disease, unspecified, the same precaution may apply. More
23 Sertraline HCl Oral Tablet 25 MGSertraline HCl Oral Tablet 50 MG
Acute ischemic heart disease, unspecified
Administration of Sertraline HCl Oral Tablet 25 MG and Sertraline HCl Oral Tablet 50 MG should be used cautiously in Ischemic Heart Disease. Since Ischemic Heart Disease is related to Acute ischemic heart disease, unspecified, the same precaution may apply. More
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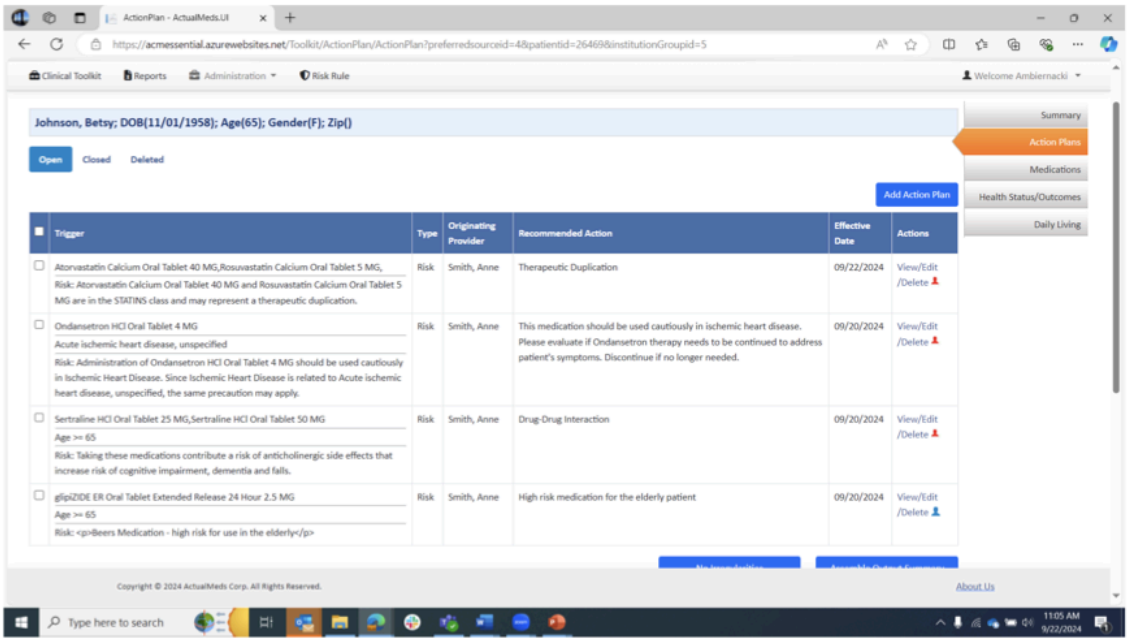
ActionPlan - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/ActionPlan/ActionPlan?preferredsourceid=4&patientid=26469&institutionGroupid=5
Clinical Toolkit
Reports
Administration
Risk Rule
Welcome Ambiernacki
Johnson, Betsy; DOB(11/01/1958); Age(65); Gender(F); Zip()
Summary
Action Plans
Medications
Health Status/Outcomes
Daily Living
Open
Closed
Deleted
Add Action Plan
Trigger
Type
Originating Provider
Recommended Action
Effective Date
Actions
Atorvastatin Calcium Oral Tablet 40 MG,Rosuvastatin Calcium Oral Tablet 5 MG,
Risk: Atorvastatin Calcium Oral Tablet 40 MG and Rosuvastatin Calcium Oral Tablet 5 MG are in the STATINS class and may represent a therapeutic duplication.
Risk
Smith, Anne
Therapeutic Duplication
09/22/2024
View/Edit /Delete
Ondansetron HCl Oral Tablet 4 MG
Acute ischemic heart disease, unspecified
Risk: Administration of Ondansetron HCl Oral Tablet 4 MG should be used cautiously in Ischemic Heart Disease. Since Ischemic Heart Disease is related to Acute ischemic heart disease, unspecified, the same precaution may apply.
Risk
Smith, Anne
This medication should be used cautiously in ischemic heart disease. Please evaluate if Ondansetron therapy needs to be continued to address patient's symptoms. Discontinue if no longer needed.
09/20/2024
View/Edit /Delete
Sertraline HCl Oral Tablet 25 MG,Sertraline HCl Oral Tablet 50 MG
Age >= 65
Risk: Taking these medications contribute a risk of anticholinergic side effects that increase risk of cognitive impairment, dementia and falls.
Risk
Smith, Anne
Drug-Drug Interaction
09/20/2024
View/Edit /Delete
glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG
Age >= 65
Risk: Beers Medication - high risk for use in the elderly
Risk
Smith, Anne
High risk medication for the elderly patient
09/20/2024
View/Edit /Delete
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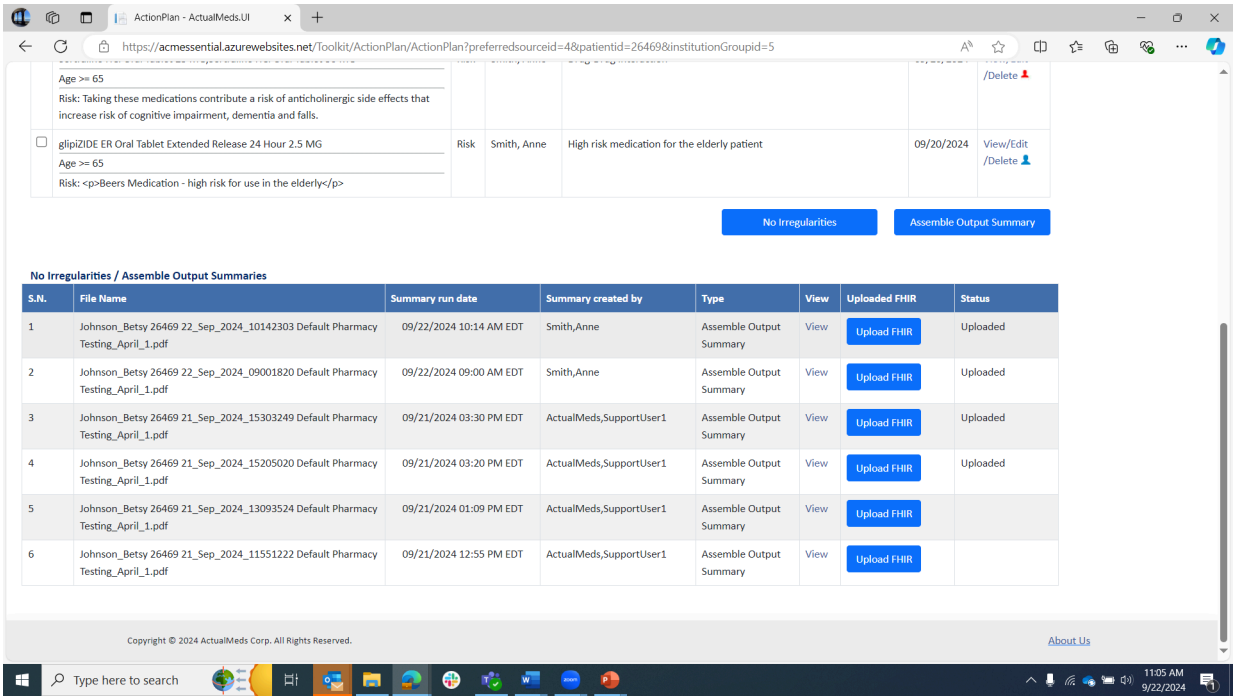
ActionPlan - ActualMeds.UI
https://acmessential.azurewebsites.net/Toolkit/ActionPlan/ActionPlan?preferredsourceid=4&patientid=26469&institutionGroupid=5
Age >= 65
Risk: Taking these medications contribute a risk of anticholinergic side effects that increase risk of cognitive impairment, dementia and falls.
/Delete
glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG
Age >= 65
Risk: Beers Medication - high risk for use in the elderly
Risk
Smith, Anne
High risk medication for the elderly patient
09/20/2024
View/Edit
/Delete
No Irregularities
Assemble Output Summary
No Irregularities / Assemble Output Summaries
S.N.
File Name
Summary run date
Summary created by
Type
View
Uploaded FHIR
Status
1
Johnson_Betsy 26469 22_Sep_2024_10142303 Default Pharmacy Testing_April_1.pdf
09/22/2024 10:14 AM EDT
Smith,Anne
Assemble Output Summary
View
Upload FHIR
Uploaded
2
Johnson_Betsy 26469 22_Sep_2024_09001820 Default Pharmacy Testing_April_1.pdf
09/22/2024 09:00 AM EDT
Smith,Anne
Assemble Output Summary
View
Upload FHIR
Uploaded
3
Johnson_Betsy 26469 21_Sep_2024_15303249 Default Pharmacy Testing_April_1.pdf
09/21/2024 03:30 PM EDT
ActualMeds,SupportUser1
Assemble Output Summary
View
Upload FHIR
Uploaded
4
Johnson_Betsy 26469 21_Sep_2024_15205020 Default Pharmacy Testing_April_1.pdf
09/21/2024 03:20 PM EDT
ActualMeds,SupportUser1
Assemble Output Summary
View
Upload FHIR
Uploaded
5
Johnson_Betsy 26469 21_Sep_2024_13093524 Default Pharmacy Testing_April_1.pdf
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ActualMeds,SupportUser1
Assemble Output Summary
View
Upload FHIR
6
Johnson_Betsy 26469 21_Sep_2024_11551222 Default Pharmacy Testing_April_1.pdf
09/21/2024 12:55 PM EDT
ActualMeds,SupportUser1
Assemble Output Summary
View
Upload FHIR
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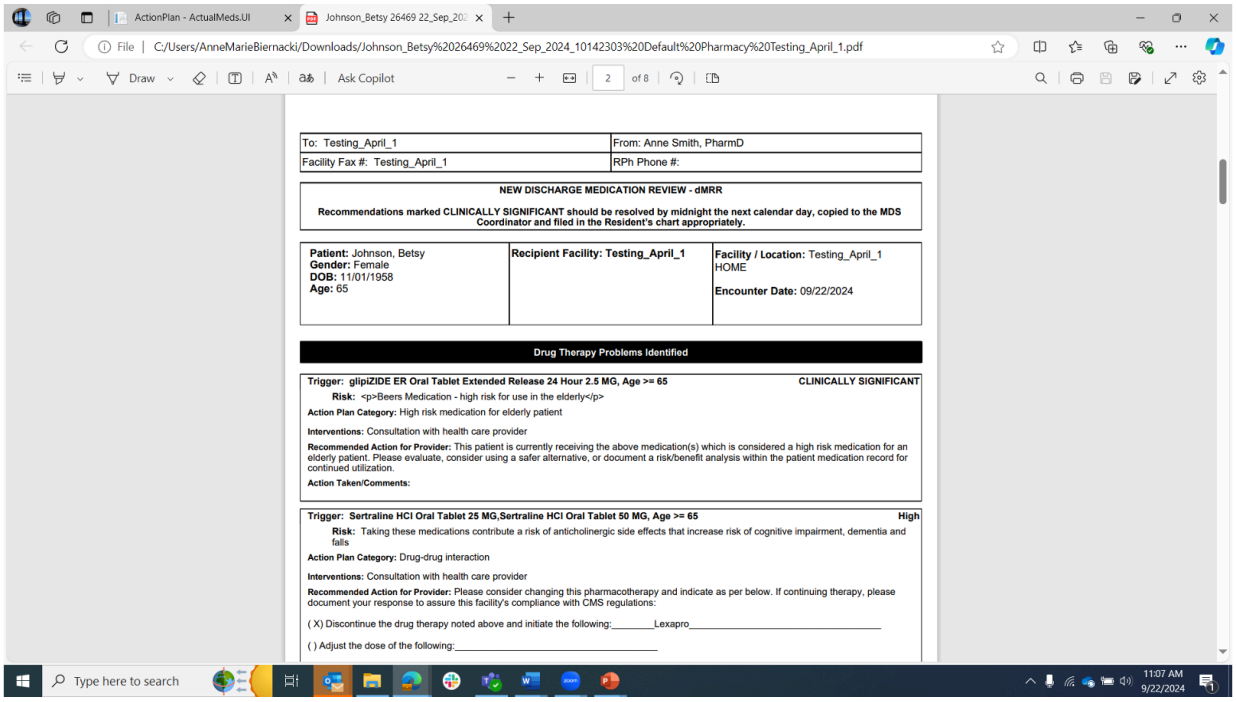
ActionPlan - ActualMeds.UI
Johnson_Betsy 26469 22_Sep_20
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Draw
Ask Copilot
2
of 8
To: Testing_April_1
From: Anne Smith, PharmD
Facility Fax #: Testing_April_1
RPh Phone #:
NEW DISCHARGE MEDICATION REVIEW - dMRR
Recommendations marked CLINICALLY SIGNIFICANT should be resolved by midnight the next calendar day, copied to the MDS Coordinator and filed in the Resident's chart appropriately.
Patient: Johnson, Betsy
Gender: Female
DOB: 11/01/1958
Age: 65
Recipient Facility: Testing_April_1
Facility / Location: Testing_April_1 HOME
Encounter Date: 09/22/2024
Drug Therapy Problems Identified
Trigger: glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG, Age >= 65
CLINICALLY SIGNIFICANT
Risk: Beers Medication - high risk for use in the elderly
Action Plan Category: High risk medication for elderly patient
Interventions: Consultation with health care provider
Recommended Action for Provider: This patient is currently receiving the above medication(s) which is considered a high risk medication for an elderly patient. Please evaluate, consider using a safer alternative, or document a risk/benefit analysis within the patient medication record for continued utilization.
Action Taken/Comments:
Trigger: Sertraline HCl Oral Tablet 25 MG,Sertraline HCl Oral Tablet 50 MG, Age >= 65
High
Risk: Taking these medications contribute a risk of anticholinergic side effects that increase risk of cognitive impairment, dementia and falls
Action Plan Category: Drug-drug interaction
Interventions: Consultation with health care provider
Recommended Action for Provider: Please consider changing this pharmacotherapy and indicate as per below. If continuing therapy, please document your response to assure this facility's compliance with CMS regulations:
(X) Discontinue the drug therapy noted above and initiate the following:_____Lexapro_____
( ) Adjust the dose of the following:_____
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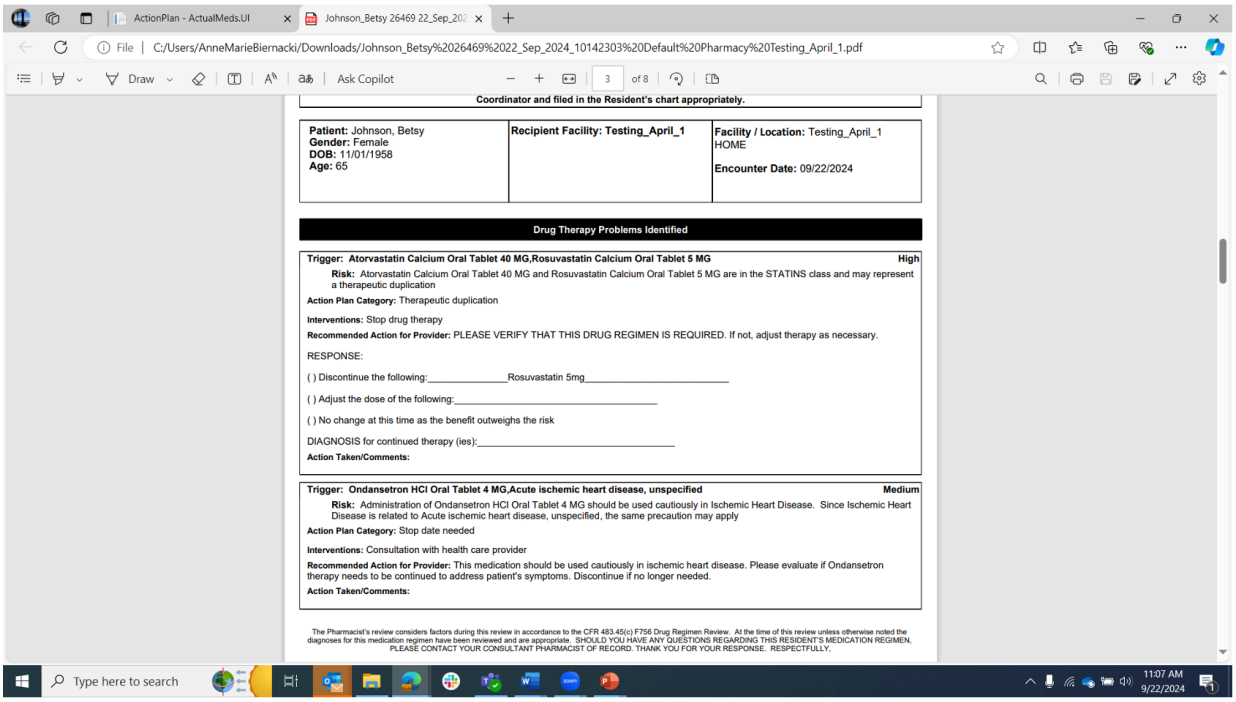
9/22/2024



Coordinator and filed in the Resident's chart appropriately.

Patient: Johnson, Betsy **Gender:** Female **DOB:** 11/01/1958 **Age:** 65	**Recipient Facility: Testing_April_1**	**Facility / Location:** Testing_April_1 HOME **Encounter Date:** 09/22/2024

Drug Therapy Problems Identified

Trigger: Atorvastatin Calcium Oral Tablet 40 MG,Rosuvastatin Calcium Oral Tablet 5 MG — **High**

Risk: Atorvastatin Calcium Oral Tablet 40 MG and Rosuvastatin Calcium Oral Tablet 5 MG are in the STATINS class and may represent a therapeutic duplication

Action Plan Category: Therapeutic duplication

Interventions: Stop drug therapy

Recommended Action for Provider: PLEASE VERIFY THAT THIS DRUG REGIMEN IS REQUIRED. If not, adjust therapy as necessary.

RESPONSE:

( ) Discontinue the following:_____Rosuvastatin 5mg_____

( ) Adjust the dose of the following:_____

( ) No change at this time as the benefit outweighs the risk

DIAGNOSIS for continued therapy (ies):_____

Action Taken/Comments:

Trigger: Ondansetron HCl Oral Tablet 4 MG,Acute ischemic heart disease, unspecified — **Medium**

Risk: Administration of Ondansetron HCl Oral Tablet 4 MG should be used cautiously in Ischemic Heart Disease. Since Ischemic Heart Disease is related to Acute ischemic heart disease, unspecified, the same precaution may apply

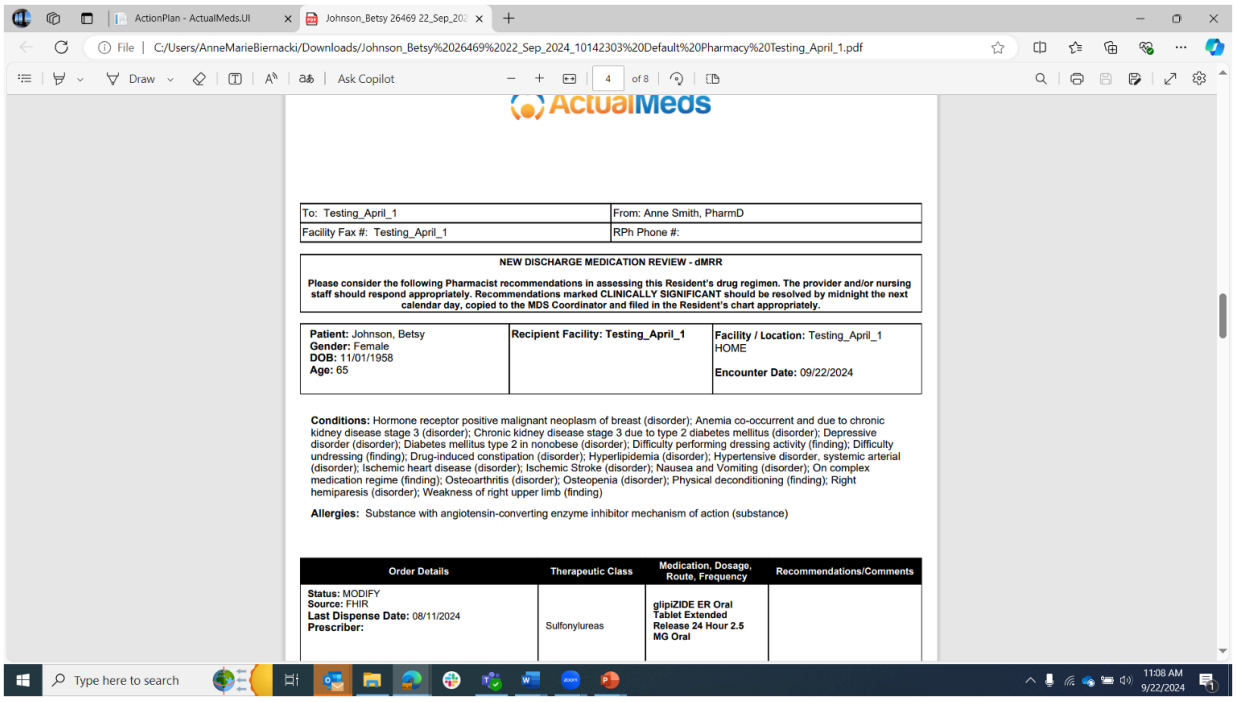
Action Plan Category: Stop date needed

Interventions: Consultation with health care provider

Recommended Action for Provider: This medication should be used cautiously in ischemic heart disease. Please evaluate if Ondansetron therapy needs to be continued to address patient's symptoms. Discontinue if no longer needed.

Action Taken/Comments:

The Pharmacist's review considers factors during this review in accordance to the CFR 483.45(c) F756 Drug Regimen Review. At the time of this review unless otherwise noted the diagnoses for this medication regimen have been reviewed and are appropriate. SHOULD YOU HAVE ANY QUESTIONS REGARDING THIS RESIDENT'S MEDICATION REGIMEN, PLEASE CONTACT YOUR CONSULTANT PHARMACIST OF RECORD. THANK YOU FOR YOUR RESPONSE. RESPECTFULLY,



ActualMeds

To: Testing_April_1	From: Anne Smith, PharmD
Facility Fax #: Testing_April_1	RPh Phone #:

NEW DISCHARGE MEDICATION REVIEW - dMRR

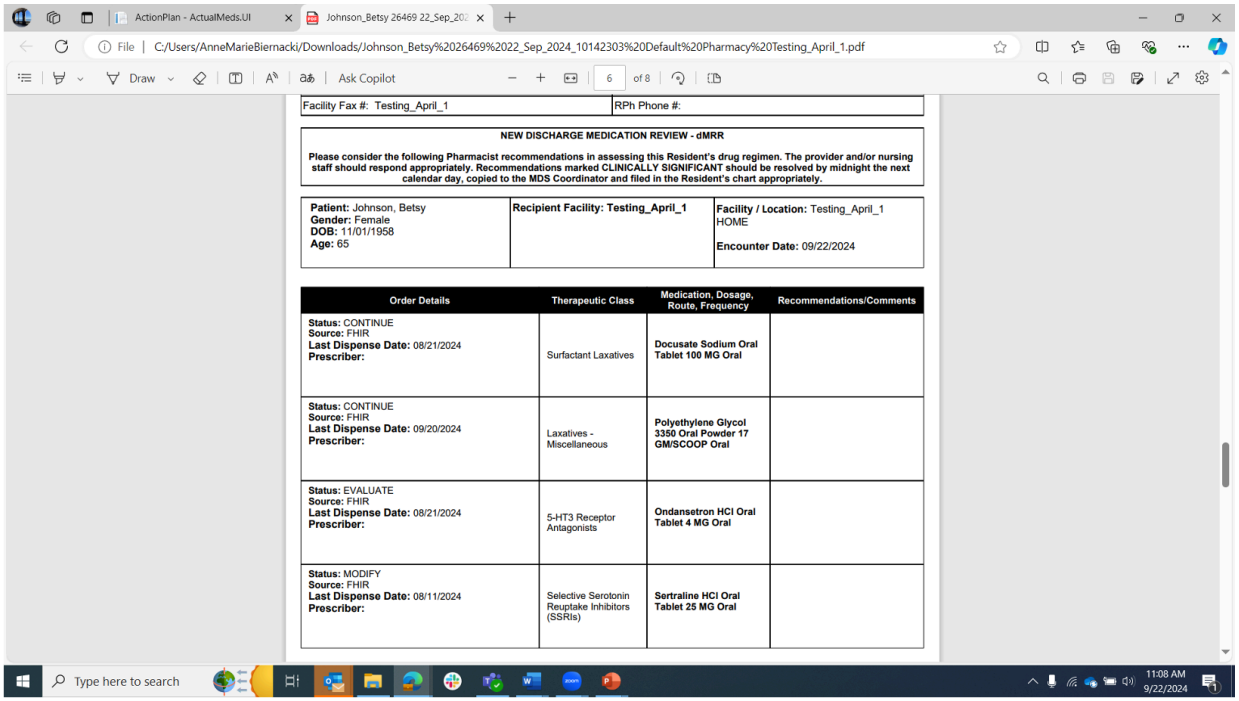
Please consider the following Pharmacist recommendations in assessing this Resident's drug regimen. The provider and/or nursing staff should respond appropriately. Recommendations marked CLINICALLY SIGNIFICANT should be resolved by midnight the next calendar day, copied to the MDS Coordinator and filed in the Resident's chart appropriately.

Patient: Johnson, Betsy **Gender:** Female **DOB:** 11/01/1958 **Age:** 65	**Recipient Facility: Testing_April_1**	**Facility / Location:** Testing_April_1 HOME **Encounter Date:** 09/22/2024

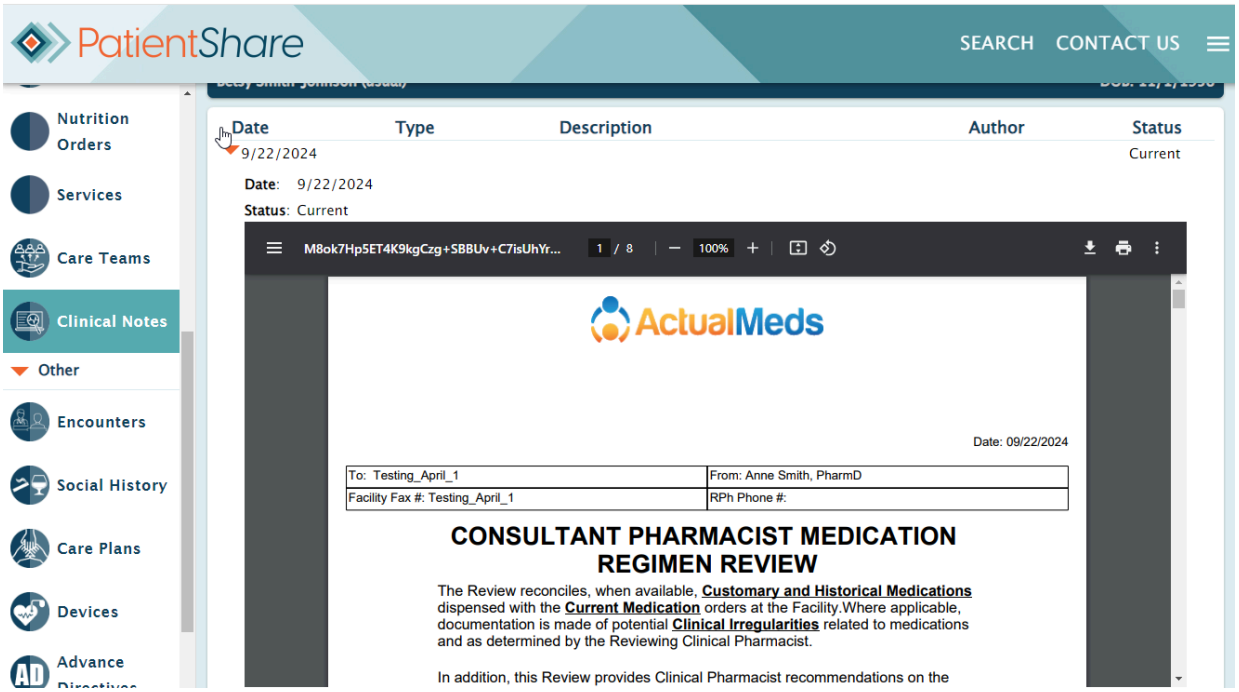
Conditions: Hormone receptor positive malignant neoplasm of breast (disorder); Anemia co-occurrent and due to chronic kidney disease stage 3 (disorder); Chronic kidney disease stage 3 due to type 2 diabetes mellitus (disorder); Depressive disorder (disorder); Diabetes mellitus type 2 in nonobese (disorder); Difficulty performing dressing activity (finding); Difficulty undressing (finding); Drug-induced constipation (disorder); Hyperlipidemia (disorder); Hypertensive disorder, systemic arterial (disorder); Ischemic heart disease (disorder); Ischemic Stroke (disorder); Nausea and Vomiting (disorder); On complex medication regime (finding); Osteoarthritis (disorder); Osteopenia (disorder); Physical deconditioning (finding); Right hemiparesis (disorder); Weakness of right upper limb (finding)

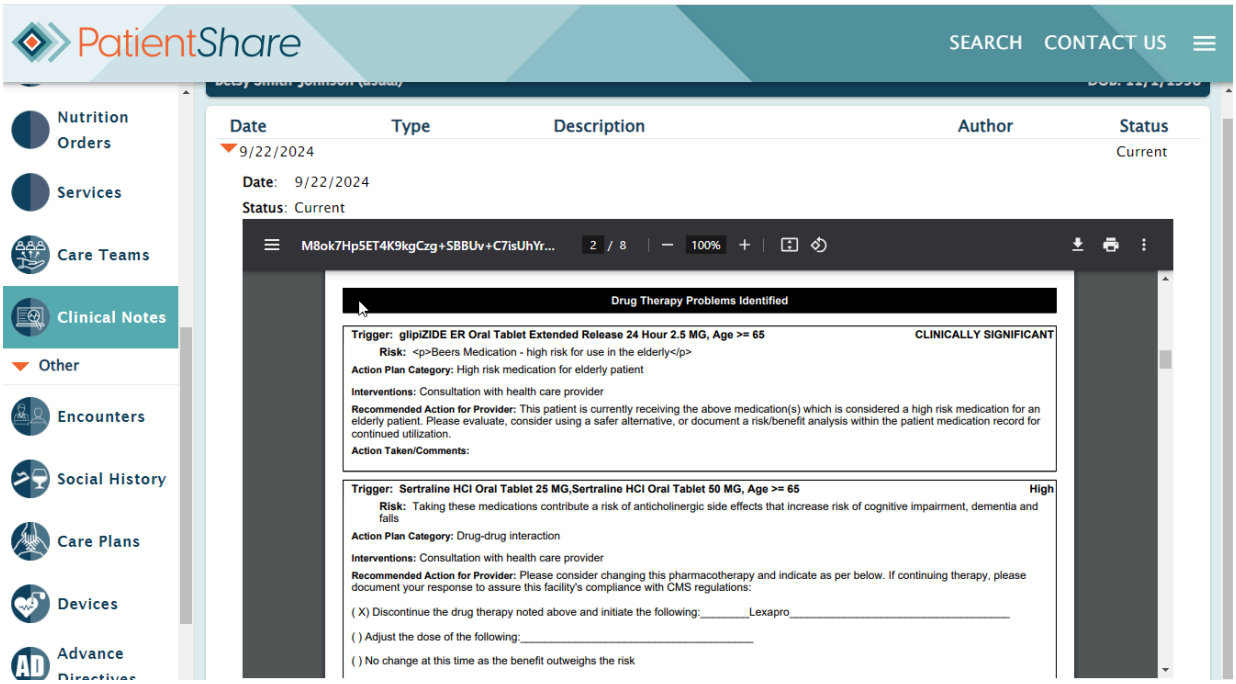
Allergies: Substance with angiotensin-converting enzyme inhibitor mechanism of action (substance)

Order Details	Therapeutic Class	Medication, Dosage, Route, Frequency	Recommendations/Comments
Status: MODIFY **Source:** FHIR **Last Dispense Date:** 08/11/2024 **Prescriber:**	Sulfonylureas	**glipiZIDE ER Oral Tablet Extended Release 24 Hour 2.5 MG Oral**	

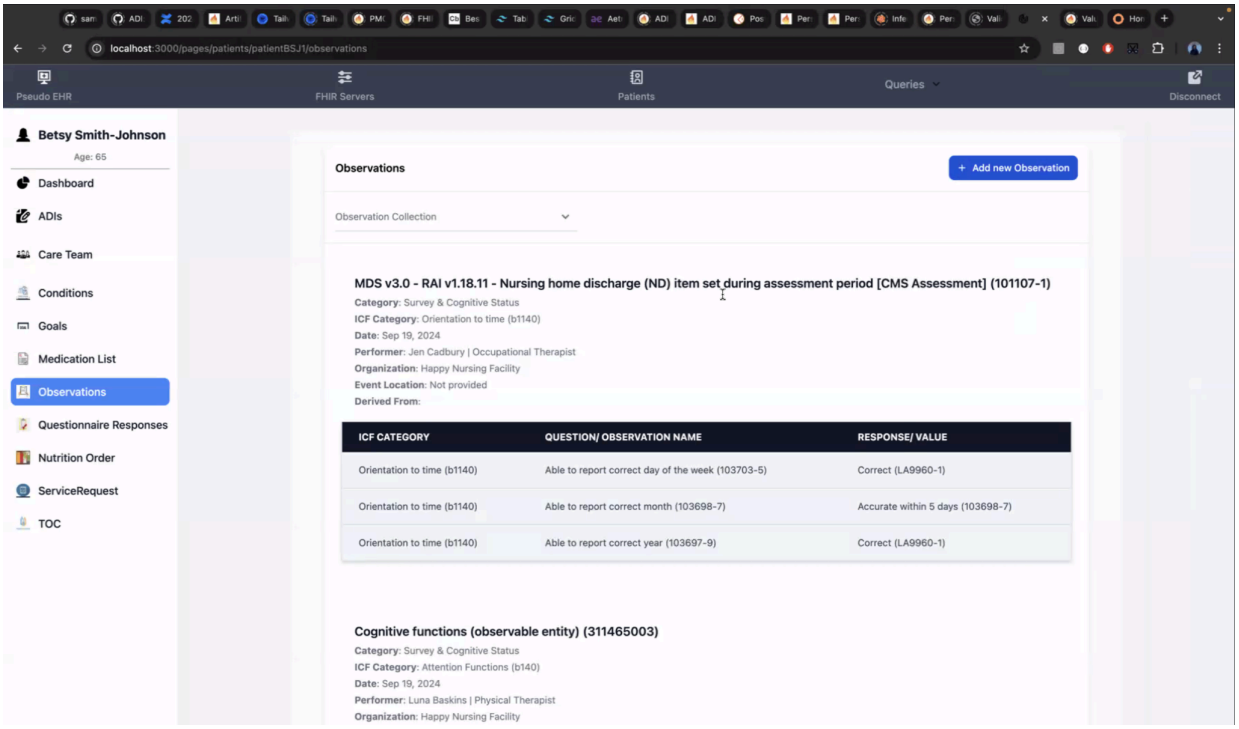


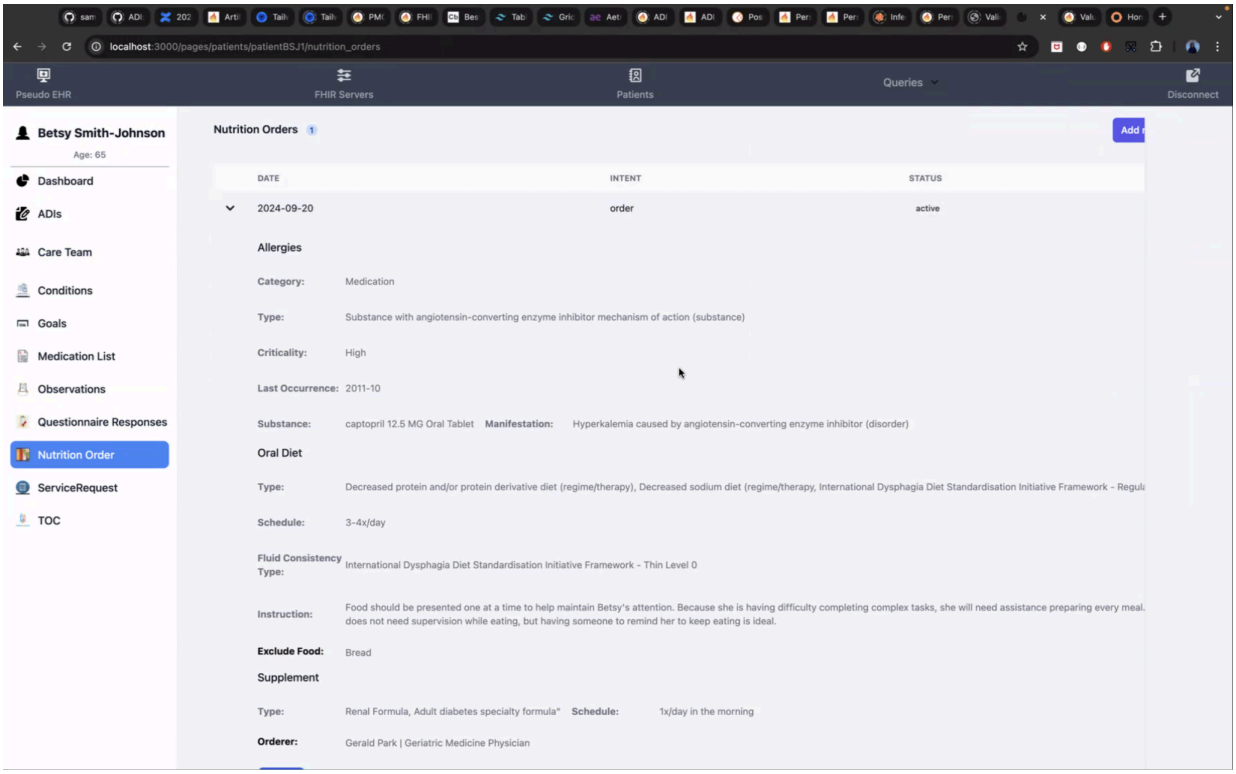
Patient Centric Solutions showing exchanged medication reconciliation report

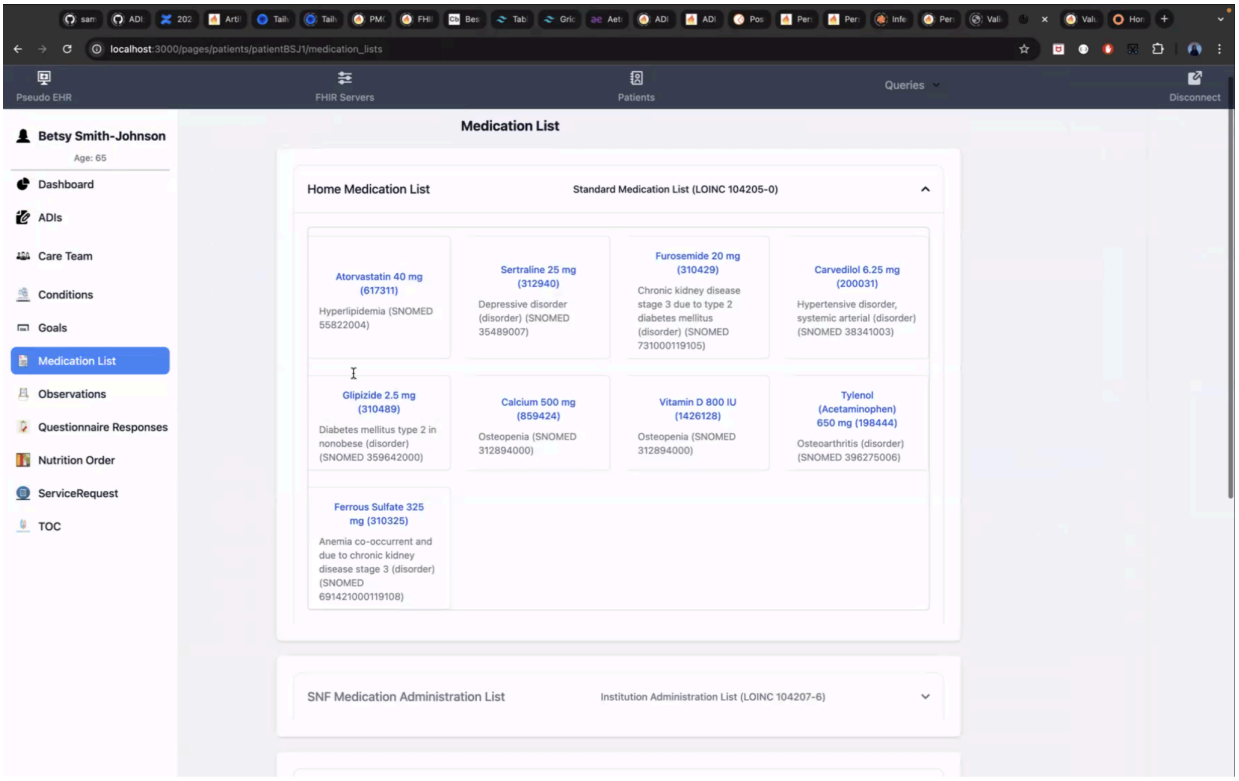


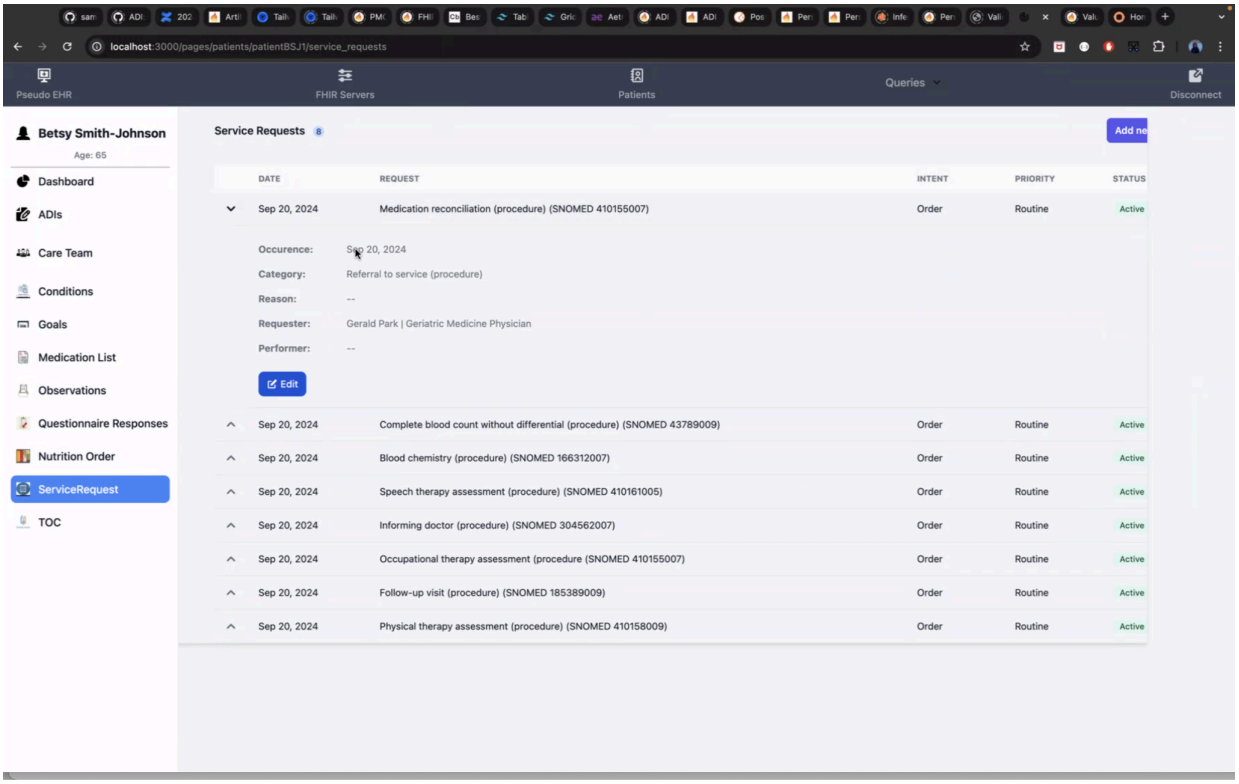


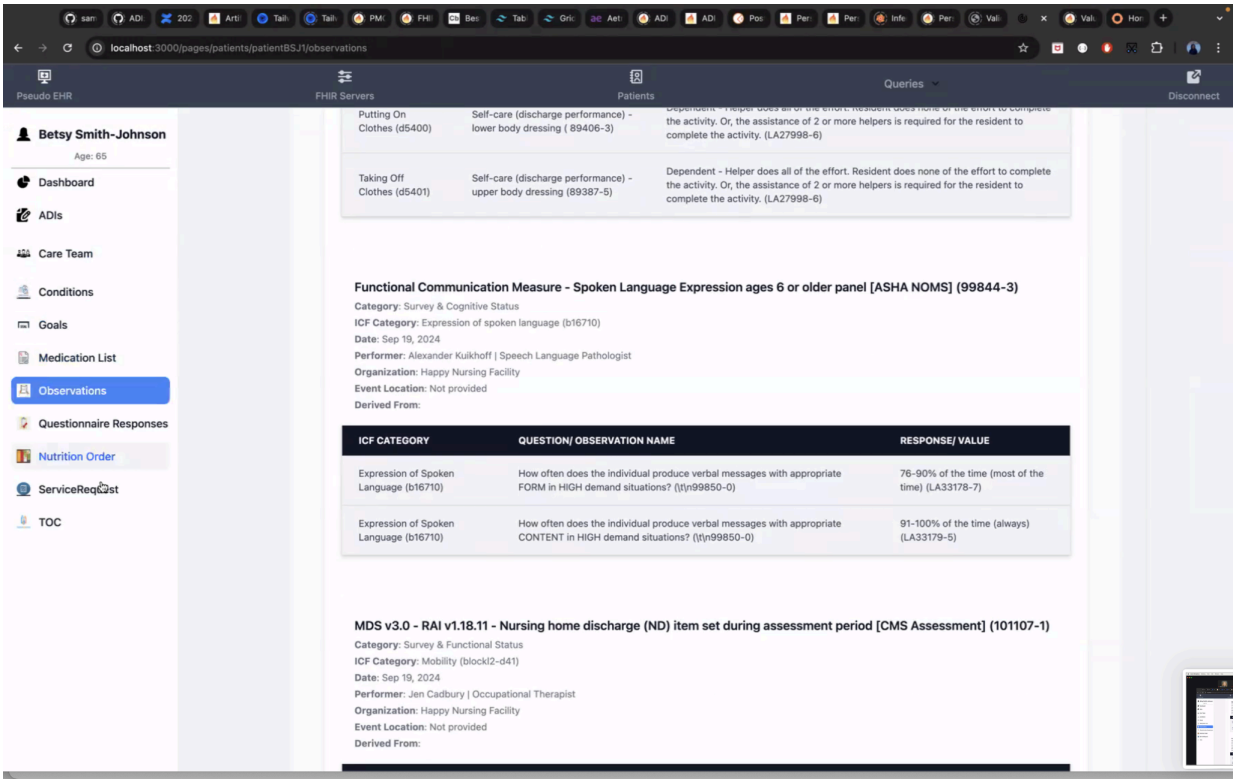
MITRE Reference Implementation




localhost:3000/pages/patients/patientBSJ1/nutrition_orders
Pseudo EHR
FHIR Servers
Patients
Queries
Disconnect
Betsy Smith-Johnson
Age: 65
Dashboard
ADIs
Care Team
Conditions
Goals
Medication List
Observations
Questionnaire Responses
Nutrition Order
ServiceRequest
TOC
Nutrition Orders
DATE
INTENT
STATUS
2024-09-20
order
active
Allergies
Category: Medication
Type: Substance with angiotensin-converting enzyme inhibitor mechanism of action (substance)
Criticality: High
Last Occurrence: 2011-10
Substance: captopril 12.5 MG Oral Tablet
Manifestation: Hyperkalemia caused by angiotensin-converting enzyme inhibitor (disorder)
Oral Diet
Type: Decreased protein and/or protein derivative diet (regime/therapy), Decreased sodium diet (regime/therapy, International Dysphagia Diet Standardisation Initiative Framework - Regul
Schedule: 3-4x/day
Fluid Consistency Type: International Dysphagia Diet Standardisation Initiative Framework - Thin Level 0
Instruction: Food should be presented one at a time to help maintain Betsy's attention. Because she is having difficulty completing complex tasks, she will need assistance preparing every meal. does not need supervision while eating, but having someone to remind her to keep eating is ideal.
Exclude Food: Bread
Supplement
Type: Renal Formula, Adult diabetes specialty formula"
Schedule: 1x/day in the morning
Orderer: Gerald Park | Geriatric Medicine Physician

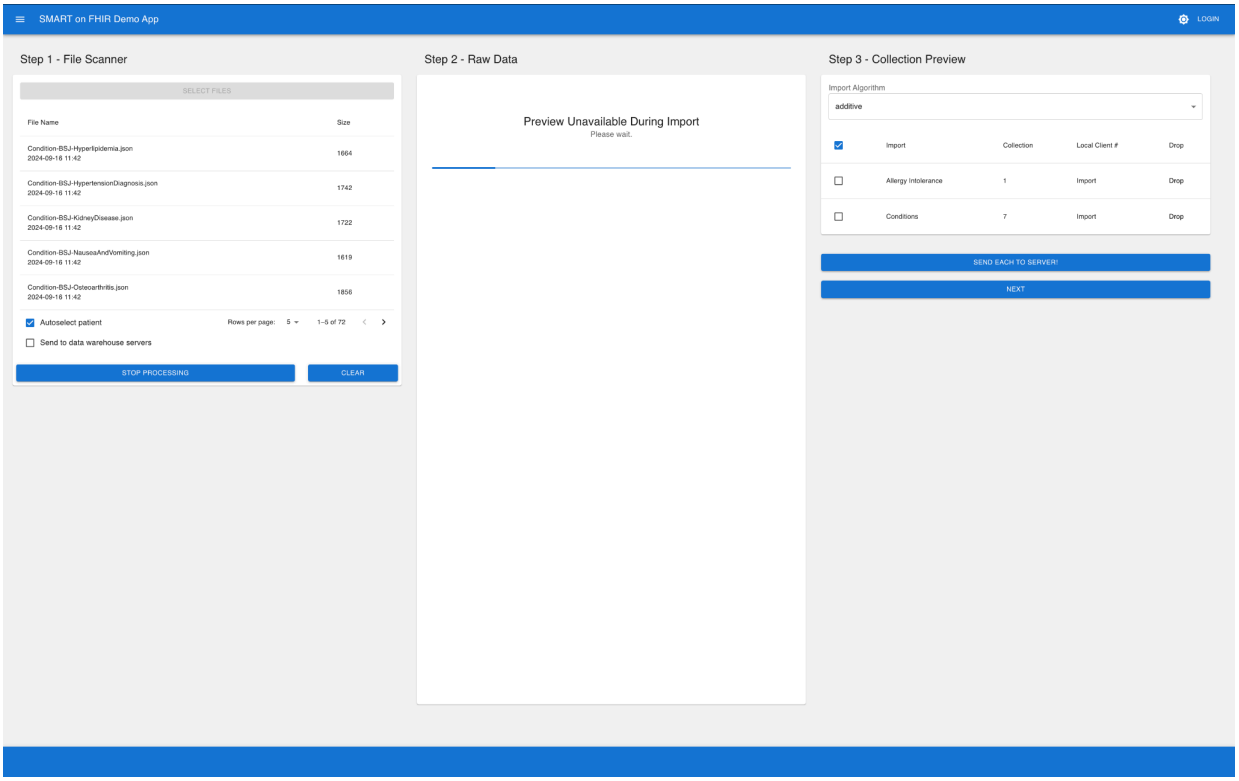

localhost:3000/pages/patients/patientBSJ1/medication_lists
Pseudo EHR
FHIR Servers
Patients
Queries
Disconnect
Betsy Smith-Johnson
Age: 65
Dashboard
ADIs
Care Team
Conditions
Goals
Medication List
Observations
Questionnaire Responses
Nutrition Order
ServiceRequest
TOC
Medication List
Home Medication List
Standard Medication List (LOINC 104205-0)
Atorvastatin 40 mg (617311)
Hyperlipidemia (SNOMED 55822004)
Sertraline 25 mg (312940)
Depressive disorder (disorder) (SNOMED 35489007)
Furosemide 20 mg (310429)
Chronic kidney disease stage 3 due to type 2 diabetes mellitus (disorder) (SNOMED 731000119105)
Carvedilol 6.25 mg (200031)
Hypertensive disorder, systemic arterial (disorder) (SNOMED 38341003)
Glipizide 2.5 mg (310489)
Diabetes mellitus type 2 in nonobese (disorder) (SNOMED 359642000)
Calcium 500 mg (859424)
Osteopenia (SNOMED 312894000)
Vitamin D 800 IU (1426128)
Osteopenia (SNOMED 312894000)
Tylenol (Acetaminophen) 650 mg (198444)
Osteoarthritis (disorder) (SNOMED 396275006)
Ferrous Sulfate 325 mg (310325)
Anemia co-occurrent and due to chronic kidney disease stage 3 (disorder) (SNOMED 691421000119108)
SNF Medication Administration List
Institution Administration List (LOINC 104207-6)



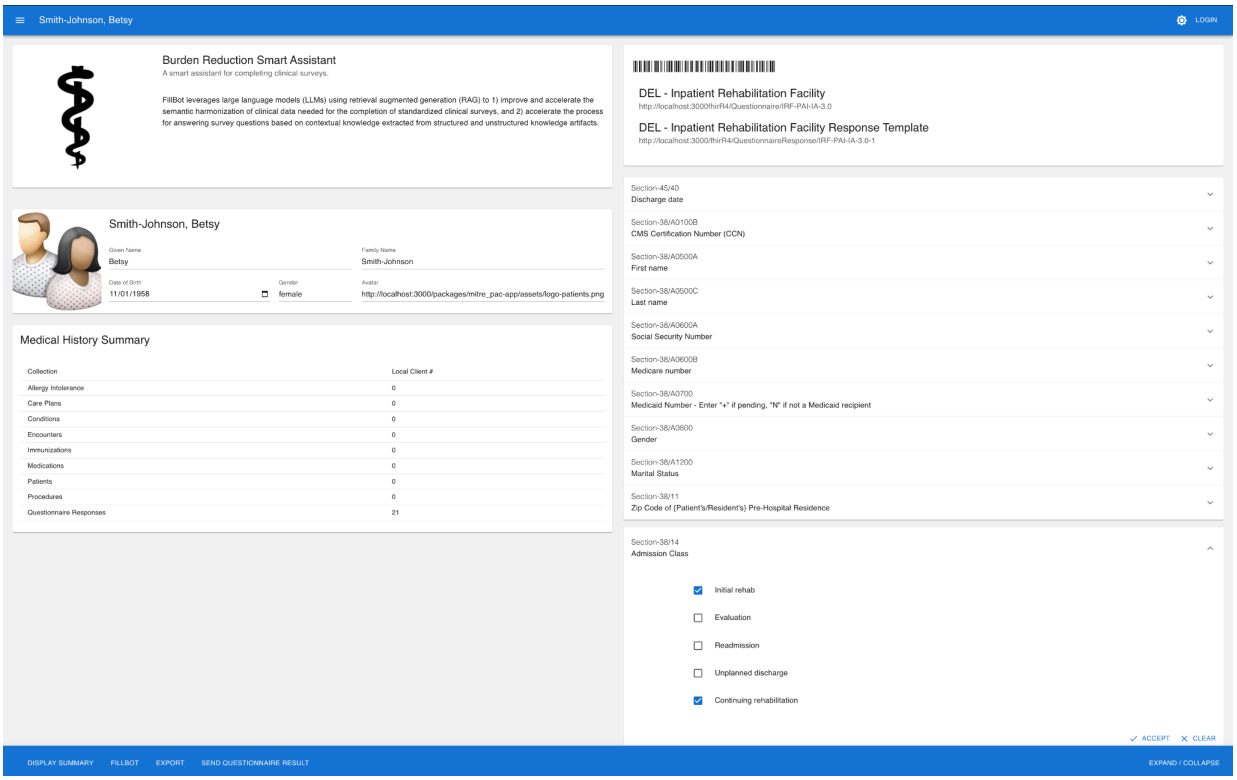


PAC Assessment App:

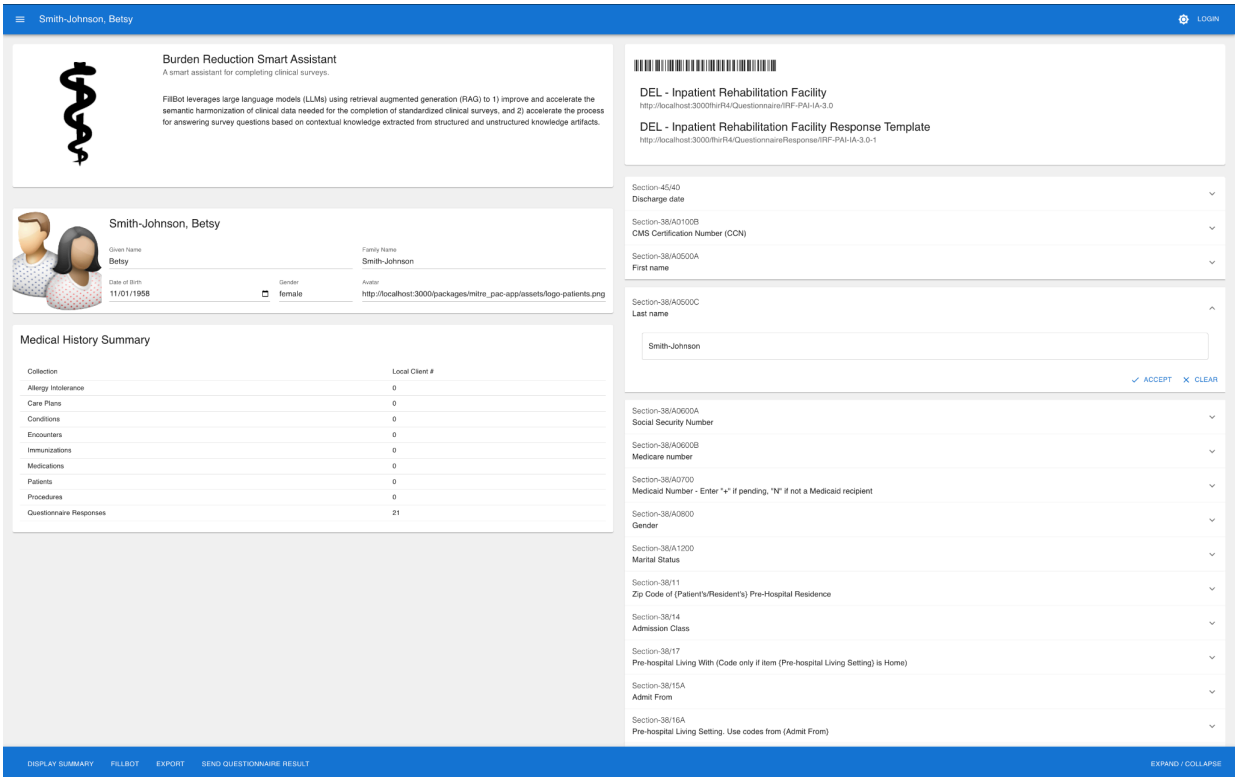
Import Page



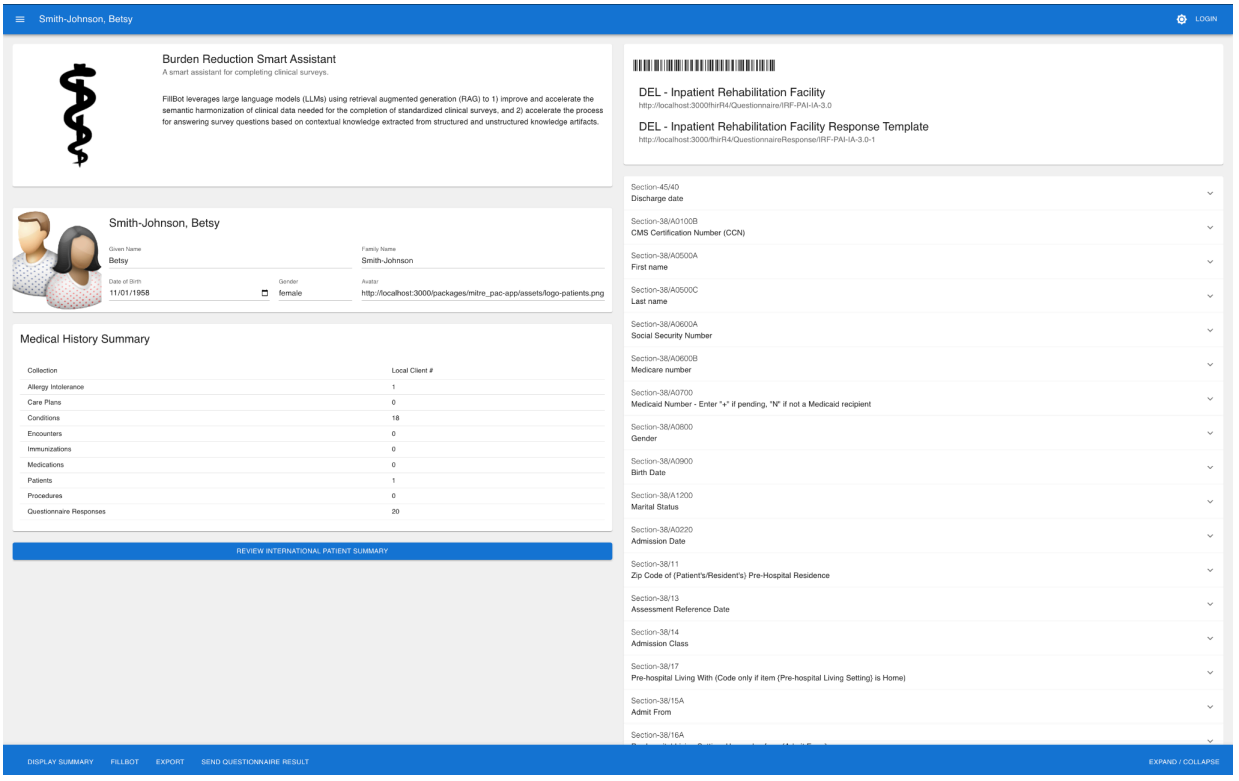
Main Page - Data Element Library In-patient Rehabilitation Facility Multiple Choice Question Answered



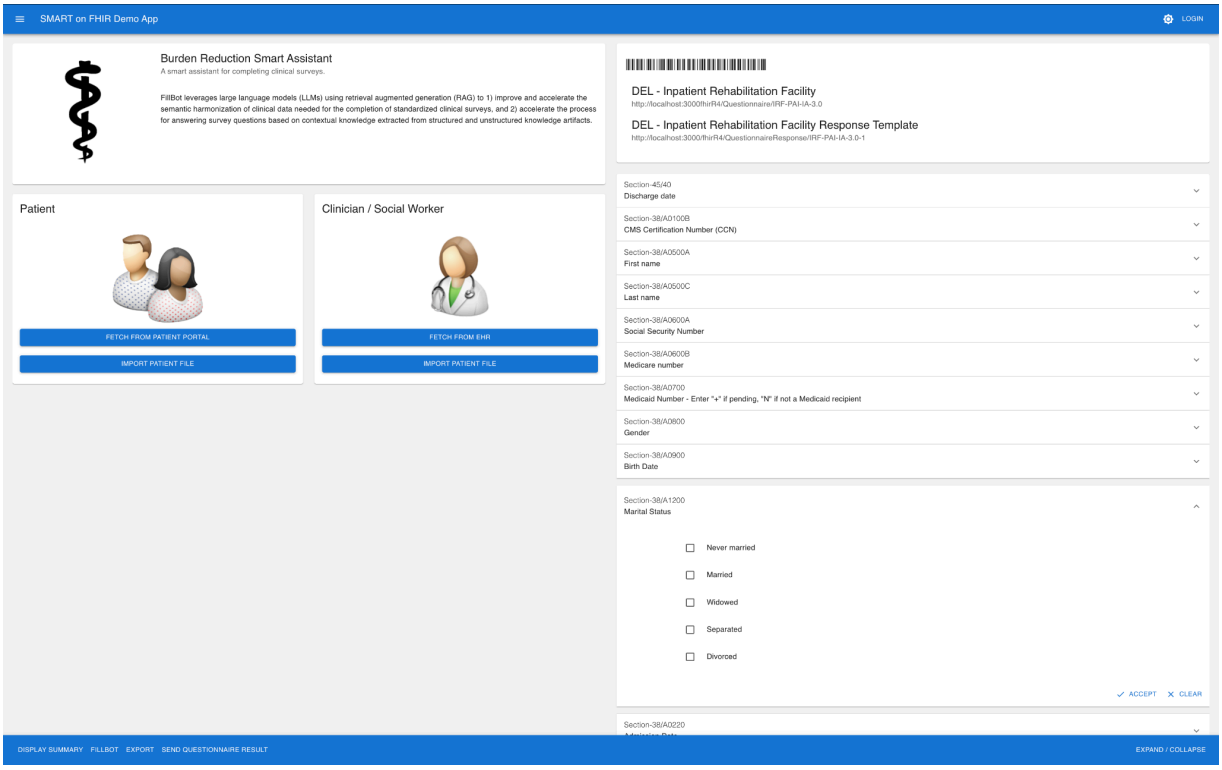
Main Page - Data Element Library In-patient Rehabilitation Facility Multiple Choice String Value Answered



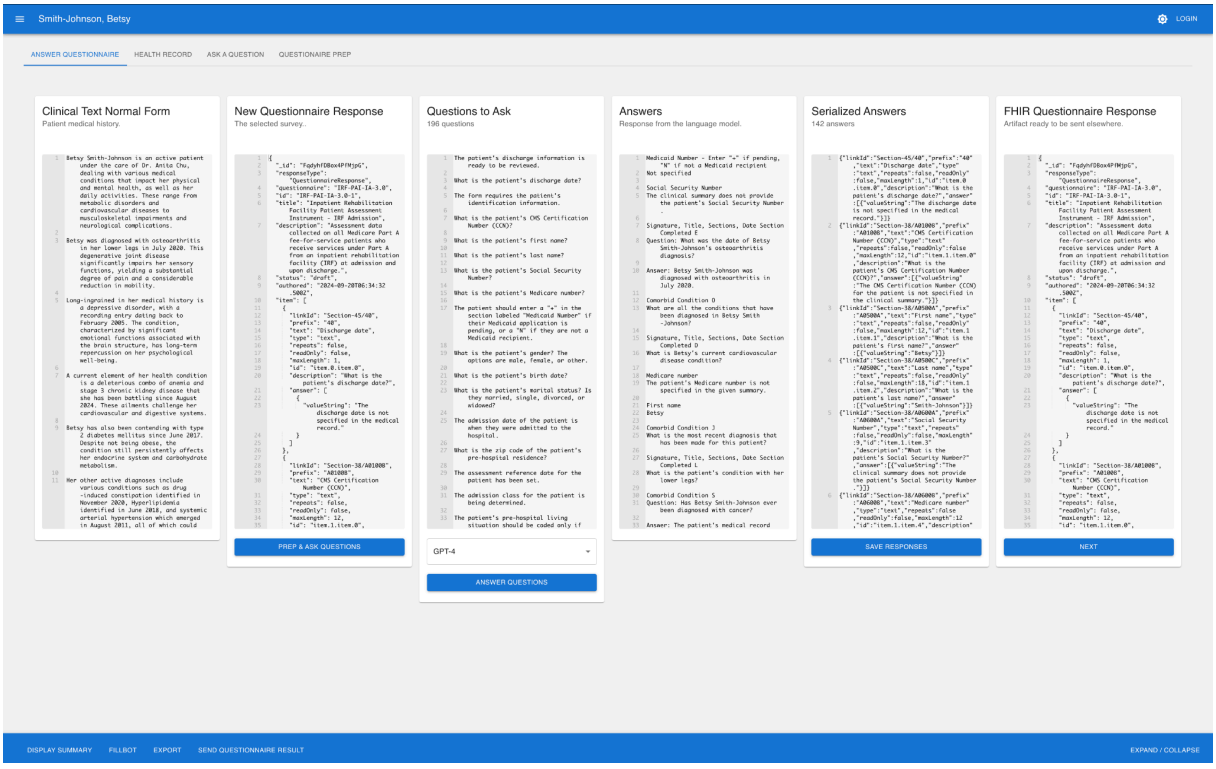
Main Page - Patient



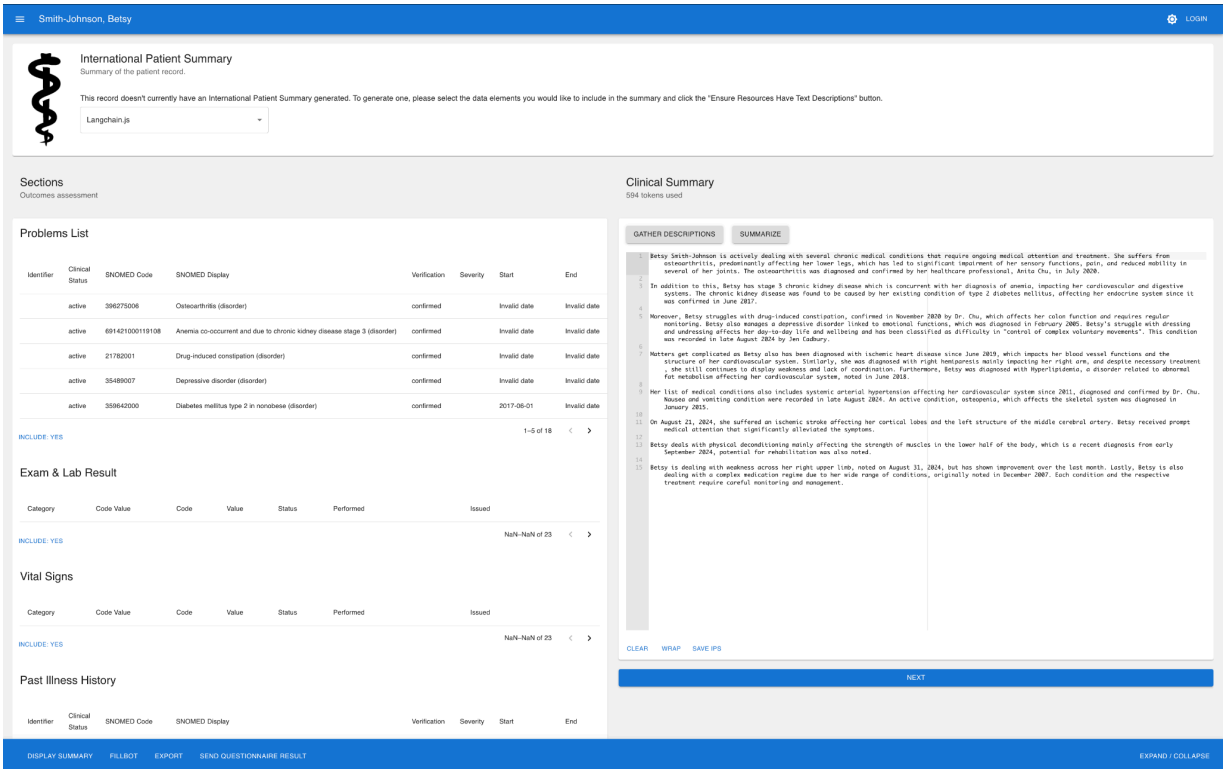
Main Page - Data Element Library / In-patient Rehabilitation Facility



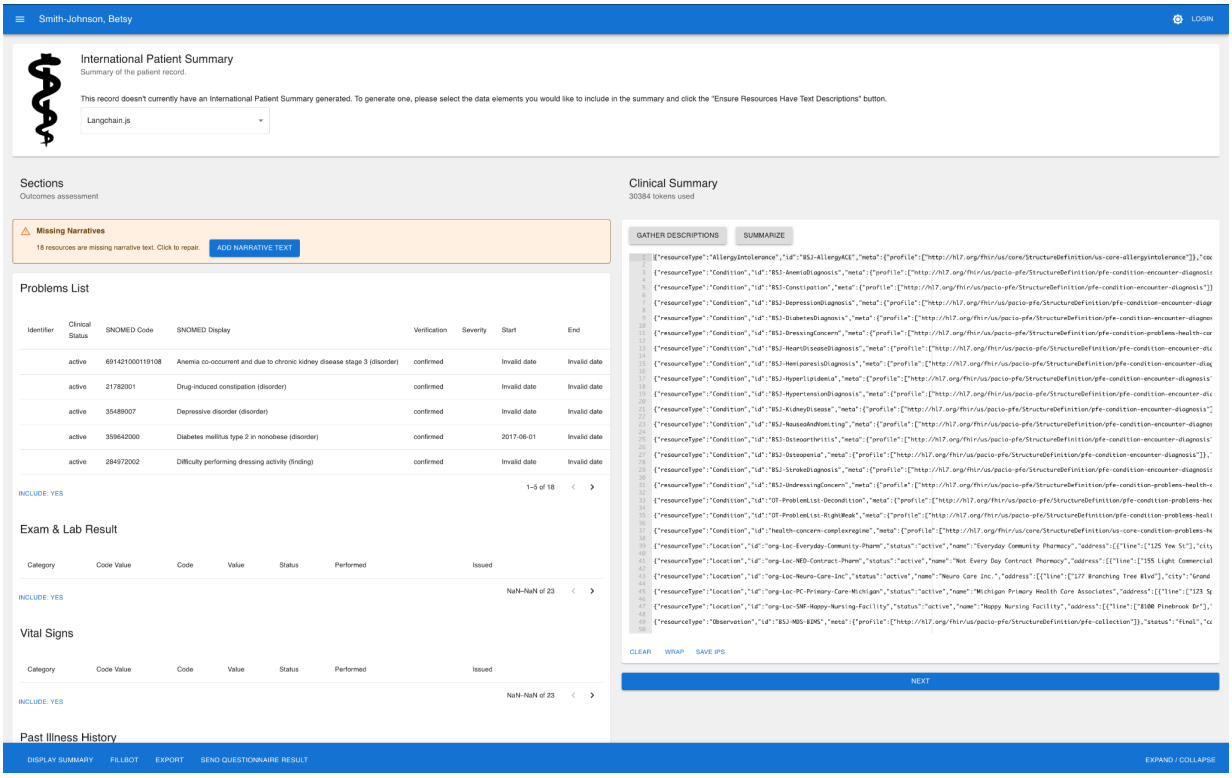
Fillbot



International Patient Summary - Betsy Smith Johnson



International Patient Summary - Missing Narratives



- Accomplishments:
    - Successfully exchanged scenario data incorporating Personal Functioning and Engagement (functional status, cognition status using NIH ontology, speech, language, cognitive communication, and hearing data, nutrition order), Standardized Medication Profile (medication lists), and Transitions of Care (discharge service requests)
    - Successfully demonstrated how all that data could be used to generate a medication reconciliation and risk assessment report that could be shared with the EHR system.
    - Demonstrate scenario exchanges between three different systems.
    - Demonstrated how the PAC Assessment app (independently or through SMART on FHIR) could use patient data and large language models to prefill CMS Data Element Library assessments to reduce provider burden.
- Discovered issues / questions (if there are any)
    - Prioritizing the display ICF categories in the UI when more than one ICF category is represented
        - Can it be done algorithmically?
            - ☐ More specific ICF categories higher priority than more general ICF categories?
- Now what?
    - Schedule follow-up meetings with cross-project teams
        - Broader integration of PACIO IGs with other FHIR IGs by other projects to plan a large integration track for the January 2025 HL7 Connectathon
    - Further Inferno testing

Questionnaires

- What was the track trying to achieve?
    - Further the maturity of the Definition based $extract operation
    - Help others with SDC
- List of participants (with logos if you have time and energy)
    - Thimo Holter (Charité BIH, Berlin)
    - Brian Postlethwaite (Microsoft) - FhirPath Lab
    - Brenin Rhodes (Smile CDR)
    - David Hay
    - Paul Lynch (US National Library of Medicine)
    - Ye Wang (US National Library of Medicine)
- Notable achievements
    - Definition based extractions got a lot of attention and tested between 4 different systems/implementations!
    - Additional testing of pre-population between systems (found issues in both)
    - CPG discussions on the plan definition Questionnaire generation to get better alignment with the core SDC profiles/approaches

    - Introduction of proposal to add a definition based prepopulate approach
    - Investigated the feasibility of adding CQL/ELM support to LHC-Forms using existing open source libraries.
    - Open Demonstrations session:
        - Questionnaire demo session on NLM's Questionnaire Tools
        - Thimo's work on Questionnaires with definition-based extraction
        - a new Questionnaire-related tool David Hay is adding to ClinFhir which converts logical models to questionnaires, then renders those with the fhirpath-lab for testing and extract testing (using the definition approach)
        - Brian's work on implementing $extract with the definition approach
        - Brenin's work on $extract with the definition approach
- Screenshots and/or links to further information
- Discovered issues / questions (if there are any)
    - FHIR-48335 Support Definition based pre-population
    - FHIR-48334 $extract should be able to support an optional questionnaire parameter
    - FHIR-48339 Invalid canonical references in examples
    - FHIR-48337 Add ability to definition based $extract to support fixed/dynamic values without hidden items
- Now what?
    - The issues discovered in the definition based extract and pre-population will be further discussed on the SDC weekly calls
    - The CPG IG will be further reviewed by SDC implementers

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
Bimla Siwakoti	Deloitte Consulting LLP
Lauren Cleaver	Deloitte Consulting LLP
Russell Ott	Deloitte Consulting LLP

Keith Campbell	FDA / VA
Rafal Korytkowski	Open Concept Lab
Joe Amlung	Regenstrief
Jeff Miller	Safe Health Systems, Inc
Ravinder Singh	Safe Health Systems, Inc
Mark Laurent	Safe Health Systems, Inc

- Notable achievements
  - 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 changesets by a Forms platform to update local terminology references
  - Authored net new concepts, including their defining semantics, and demonstrated export from one source and import to another system.
- Screenshots and/or links to further information
  - Test Scenario 1
  - Test Scenario 2
- Discovered issues / questions (if there are any)
  - Continue to discuss best way to indicate to a system that a Code System is a change set
    - There is not currently a documented way in FHIR to define a Code System extension
    - Currently a change set is defined using content-mode = fragment, but there are conflicts with uri requirements for fragments that complicate its use
    - An elegant approach is needed for defining and maintaining the property values appropriate to use with each CodeSystem
  -

- Now what?
    - Continue with ballot comment reconciliation and publication of the Terminology Change Set Exchange IG

Testing - Aligning Implementation Coverage with Test Coverage

- What was the track trying to achieve?
  Provide an opportunity for the implementers at the Connectathon to share challenges and successes experienced over the course of implementation, to identify weaknesses and highlight areas of potential improvement.

  Schedule a 30-minute window for a discussion with each Connectathon track to discuss testing experience and feedback (including pre-Connectathon testing and post-Connectathon reporting) on the current Connectathon test coverage as it aligns with implementation efforts.

- List of participants (with logos if you have time and energy)
    - AEGIS.net, Inc.
    - CGM Clinical Austria
    - HL7 Austria

- Notable achievements
    - Breakout Session - FHIR RI Best Practices & Maturity - 11:30 - 12:30 EDT Saturday 09/21
    - Breakout Session - HL7 FHIR Foundry: New and Upcoming Products & Policies - 13:00 - 14:00 EDT Saturday 09/21

- Screenshots and/or links to further information
  N/A

- Discovered issues / questions (if there are any)
  The following high level questions and summarized answers were asked and recorded of a sampling of six (6) other Tracks.

  Are you testing?
    - Yes (6)

  How long have you been testing:
    - Min: 1 year
    - Max: 4+ years
    - Average: 2+ years

Do you use one or more testing platforms?

- Yes (3)
    - Inferno (MITRE)
    - Touchstone (AEGIS)

- No (3) - Common responses
    - Not ready for formal testing
    - Did not know about publicly available test platforms

Do you have RI systems to facilitate testing?

- Yes (5)
    - HAPI FHIR
    - NodeJS
    - Custom clients and/or servers

- No (1)

- How are the RIs deployed?
    - Cloud
    - On premise (internal, behind firewall)

Do you test with system to system interactions?

- Yes (6)

Do you test with other tools?

- Yes (6)
    - Postman (most common)
    - Custom clients and/or servers

- Now what?

Uniform Data System Plus (UDS+)

What was the track trying to achieve?

We met to test partial submissions, incremental submissions, and replacing submissions across multisource submissions. We also discussed potential approaches to deduplicating deidentified data to meet the UDS+ requirements.

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

Organization	Participants
HRSA	• Braedyn Kromer • Haleh Sepasi
ONC	• Matt Rahn • Leliveld “Lee” Emeni
ONC Contractors: Acrosystems, Drajer, and Leap Orbit	• Nagesh “Dragon” Bashyam • Arun Krishnamurthy • Mike Hunter
NextGen	• Jill Meredith
Visualutions	• Amy McKinley • Heather Turner
Greenway Health	• Todd Tringen • Maulin Patel
DHIT	• Matt Dugal • Sumanth Bandaru • Raychelle
eClinicalWorks	• Madhav Darji
Epic	• Cooper Thompson • Anthony Galba
Next Level Health Solutions	• Llew Brown
SonIS	• Matthew Son • Malachi Son

Notable achievements

- Successfully tested the changes to the IG for partial submissions, incremental submissions, and replacing submissions across multisource submissions
- Gathered feedback from vendors about which may be valuable to implement for the next HRSA reporting year
- Identified potential approaches to deduplicating deidentified data to meet the UDS+ requirements

Screenshots and/or links to further information

- https://bphc.hrsa.gov/data-reporting/uds-training-and-technical-assistance/uniform-data-system-uds-modernization-initiative
- https://fhir.org/guides/hrsa/uds-plus/index.html

Discussion Notes

Scenarios feedback

- Incremental will be the most helpful to have for CY 2024 Reporting
- Partial submissions/multisource submissions will be less helpful
    - Since the minimum required data for 2024 is medical patients only
    - Until deduplication has been resolved
- For the most part, the IG requirements were clear; although, some vendors identified minor issues that they will enter as tickets after the Connectathon
- One idea suggested for partial submissions during the meeting: identify the segment of data (e.g., medical patient data, dental patient data, etc.) in each manifest, so that UDS+ will know when it has all the data to apply the final validations and close the submission

Comparison reports

- HRSA does not expect UDS+ calculations to match the EHB measures since the minimum data is less than the full population
- Need to be provided with enough information to put results of the calculations in context relative to the EHB measures
- Many vendors would like a separate API (in the future) that provides the information in the comparison reports

Deduplication

- Currently, HRSA only needs to deduplicate across a health center, not across vendors or geographic areas
- Comparing across health centers and geographic regions is a future aspiration
- Options should also address how to handle “split year” scenarios:
    - Both the old and new EHR support UDS+
    - Only the new EHR supports UDS+
- After solving this for demographic data, we need to solve it for other resources (for example, using a hash of a fully-qualified date in a resource could help)
- Options suggested during the session
    - If the health center has an MPI: encrypt the MPI’s linkage ID as the pseudonym
    - Hash some combination of the demographic information
        - Need to determine how health centers obtain a shared secret to use with each of their vendors: perhaps the private key of a public/private key pair
    - Provide an external tool that allows health centers to export demographic data or a selected data elements and create a pseudonym for each patient to share with their vendors

Now what?

- Prioritize what, if any, of what we tested to include in the production feature set for the next HRSA reporting year
- Continue synthetic data testing to prepare for the next HRSA reporting year
- Meet again to discuss the pros and cons of each deduplication option
- Determine which of the deduplication options to begin to specify for a proof of concept

US Behavioral Health Profiles

What was the track trying to achieve?

This track focused on testing the US Behavioral Health Profiles Implementation Guide (IG). The Behavioral Health (BH) IG is an informational FHIR IG developed in 2024, based on data elements developed to support the United States Core Data for Interoperability Plus (USCDI+) BH initiative. The USCDI + BH dataset aims to enhance the exchange and interoperability of behavioral health information across U.S. healthcare systems.

Key Testing Objectives:

- Identify opportunities to improve the user stories within the IG and their relevance to the USCDI+ BH data elements
- Evaluate the ease of mapping USCDI+ BH data elements to FHIR
- Assess the IG's capability to handle various data types and scenarios relevant to behavioral health.

Testing Activities:

- Entered each element in the IG in a commercial EHR to simulate point-of-care documentation of a BH client encounter.
- Reviewed the representation of each USCDI+ BH data element in the IG in FHIR
- Tested API-based transmission of FHIR resources in the IG between clients and servers

Participants

Claudia Hall (Next Level Health Innovations) (Track lead)

Patrick Joyce (Lantana) (Track co-lead)

Vivian Horn (Next Level Health Innovations)

Llew Brown (Next Level Health Innovations)

Matt Switzler (Epic)

Maria Moen (MyDirectives)

Lisa Nelson (MyDirectives)

May Terry (MITRE)

Chris Muir (Assistant Secretary for Technology Policy)

Liz Turi (Assistant Secretary for Technology Policy)

Track Page

https://confluence.hl7.org/display/FHIR/2024+-+09+US+Behavioral+Health+Profiles

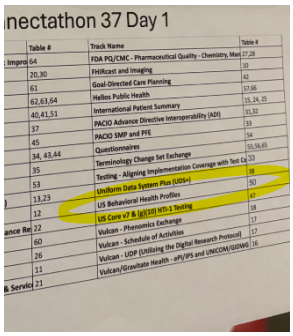
Notable achievements

- Confirmed the behavioral health user story embedded within the US Behavioral Health Profiles IG provided a good framework to discuss and test the USCDI+ BH data elements and behavioral health workflows, helping everyone understand how the IG would work in practice.

- Received vendor feedback on USCDI+ BH data elements used in the US Behavioral Health Profile IG and confirmed they represented a comprehensive perspective of both physical and behavioral health care.
- Obtained crucial feedback from vendor on the IG's clarity, feasibility, and potential challenges in real-world implementations.
- The team documented ~90% of the USCDI+ BH data element list in an EHR vendor system using typical documentation workflows.
- Transmitted ~70% of the documented USCDI+ data elements via FHIR API (using client-server interactions) with Postman transactions.
- Able to successfully generate and transmit BH Health Status Assessments such as the Depression Assessment (PHQ9) and Anxiety Assessment (GAD-7), Mental Trauma and PTSD Assessment (ACES), Interpersonal Violence (HARK).

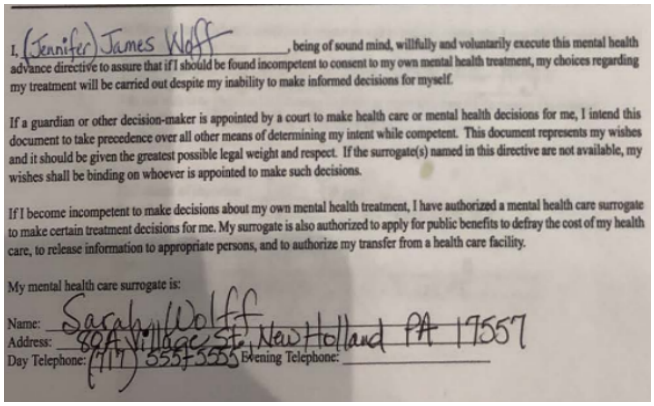
- Bonus achievement: Collaborated with the PACIO track to generate and transmit a Mental Health Advanced Care Directive, based on our user story, to explore potential inclusion of a Mental Health specific advanced directive in future versions of the Behavioral Health Profiles IG. Able to represent and transmit components from our IG, treatment intervention preferences and care experience preferences, within the advance directive.

Screenshots




Welcome to the
HL7® FHIR®
Connectathon
WiFi: HL7-WiFi
PW: HealthLevel7


HealthLevel7
60



I, (Jennifer) James Wolff, being of sound mind, willfully and voluntarily execute this mental health advance directive to assure that if I should be found incompetent to consent to my own mental health treatment, my choices regarding my treatment will be carried out despite my inability to make informed decisions for myself.

If a guardian or other decision-maker is appointed by a court to make health care or mental health decisions for me, I intend this document to take precedence over all other means of determining my intent while competent. This document represents my wishes and it should be given the greatest possible legal weight and respect. If the surrogate(s) named in this directive are not available, my wishes shall be binding on whoever is appointed to make such decisions.

If I become incompetent to make decisions about my own mental health treatment, I have authorized a mental health care surrogate to make certain treatment decisions for me. My surrogate is also authorized to apply for public benefits to defray the cost of my health care, to release information to appropriate persons, and to authorize my transfer from a health care facility.

My mental health care surrogate is:

Name: Sarah Wolff
Address: 80A Village St, New Holland PA 17557
Day Telephone: (717) 555-5555 Evening Telephone: _____

Issues/Challenges

- Some resources did not return the expected resources/data elements via API transmission. For example, veteran status and sexual orientation.
    - Likely due to challenges mapping vendor-defined concepts to concepts in FHIR
- Occasionally received vendor specific errors in Postman when requesting resources, likely due to business logic configuration. Example: "User not authorized for QuestionnaireResponse - Patient Entered Questionnaires. Search results of this type have not been included."
- Unable to transmit new profiles (Mental Health Clinical Notes Profile and Grant Information Observation) in Behavioral Health Profiles IG.
- Difficulty capturing more granular SDOH data elements such as food insecurity and housing instability separately.
- Difficulty transmitting Treatment Preferences and Care Experience Preferences as expected from EHR vendor.
- Uncertainty of how to best capture behavioral health therapeutic activities such as harm reduction activities, peer coaching and mentoring, and recovery planning within the EHR.
- The variety of types of behavioral health assessments used in real world settings may not match data element transmission used in this connectathon.

US Core v7 & (g)(10) HTI-1 Testing

- 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?

Vulcan - Phenomics Exchange

- What was the track trying to achieve?
    - Provide a small set of FHIR resource profiles (and related conformance resources) to facilitate the exchange of phenotypic information. For example, the FHIR Observation resource is being used to represent patient-level phenotypes coded with the Human Phenotype Ontology as the preferred coding system.
    - Provide guidance and mappings for interoperability with the GA4GH Phenopackets Schema to facilitate the exchange of phenotypic information between these two standards. This includes the development of a logical model to represent the GA4GH model in order to facilitate the development of formal FHIR mappings in both directions.
    - Advance and test the WIP Vulcan Phenomics Exchange IG.
    - Establishing collaborations with interested parties
- List of participants (with logos if you have time and energy)
    - Shahim Essaid
    - Julian Sass - BIH@Charité

        - ■
    - Coordinating collaboration TransCelerate BioPharma
- Notable achievements
    - Spent a lot of time exploring the possibilities of using FHIR Logical Models in the IG to describe the underlying data model. In the end developed a script that transforms the Phenopacket protobuf spec into FSH files.
    - Explored the flexible semantics the Phenopackets model provides for representing time elements and understanding how to build FHIR extensions to capture this information in FHIR. For example, an approach to capture the Phenopackets TimeElement information in the context of a Phenopacket PhenotypicFeature was established in the form of a FHIR Period extension to be used in the profiling of FHIR Observation.effective[x].
    - Reviewing issues with the current IG content that need to be fixed or refactored to adopt better conventions.
- Screenshots and/or links to further information
    - https://github.com/HL7/phenomics-exchange-ig/

- Discovered issues / questions (if there are any)
    - The current narrative content in the IG needs to be rewritten and refactored to separate the initial focus on the GA4GH Phenopackets community in order to adopt a more agnostic and a pure FHIR perspective. The focus on the Phenopackets standard will be moved into separate narrative pages and more formal mappings.
- Now what?
    - Continue to develop the IG in preparation for a May 2025 Informative Ballot.
    - Develop tooling to interoperate with the GA4GH Phenopackets data format.

Vulcan - Schedule of Activities

This track was merged with Vulcan UDP (Utilizing the Digital Protocol)

- 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?

Vulcan - UDP (Utilizing the Digital Research Protocol)

- What was the track trying to achieve?

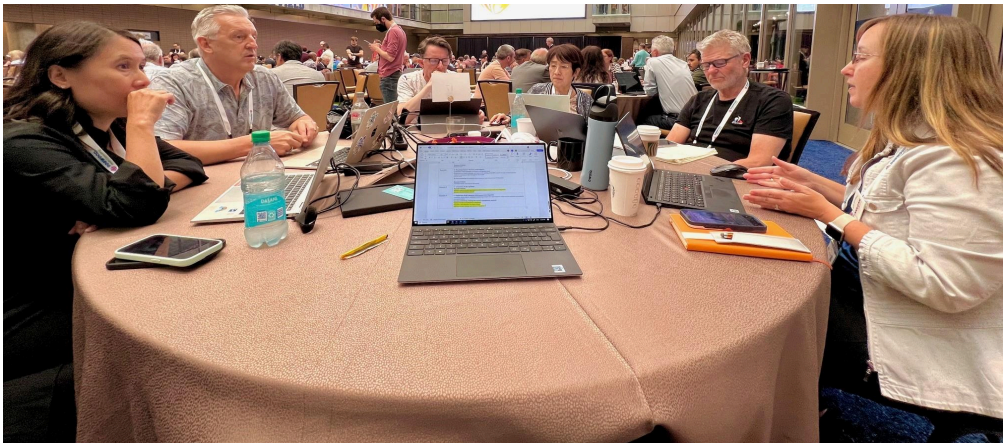
This is the second of a series of Connectathons which aims to build experience and test implementation guidance. The first iteration looked at the transfer of a clinical trial protocol from sponsor to regulator according to the development being done by ICH M11/M2, CDISC and TransCelerate.

- Transfer of a clinical trial protocol from sponsor to regulator according to the development being done by ICH M11/M2, CDISC and TransCelerate.
- Look looked at use of profiles of a composition resource to enable transfer of protocol document sections
- Build experience and test implementation guidance

This connectathon expands on the use of profiles of a composition resource to enable transfer of an ICH M11 structured protocol from a sponsor to a regulator. Specifically, it will look at transferring portions of the unstructured composition as structured data (title page elements, eligibility criteria, and objectives/endpoints/estimands).

- List of participants

- Rik Smithies, HL7 UK Co-TRACK LEAD
- Stacy Tegan, TransCelerate Co-TRACK LEAD
- Hugh Glover, Vulcan
- Dave Iberson-Hurst, CDISC
- Rob Ferendo, TransCelerate
- Enam Rahman, TransCelerate
- Mary Lynn Mercado, TransCelerate/Novartis
- Khalid Shahin, Computable Publishing
- Brian Alper, Computable Publishing
- Mihoko Okada, Idial



- Notable achievements

Tooling Development:

- The team further developed the tooling to convert as well as display the protocol, the display tool can also now identify/detect any missing data

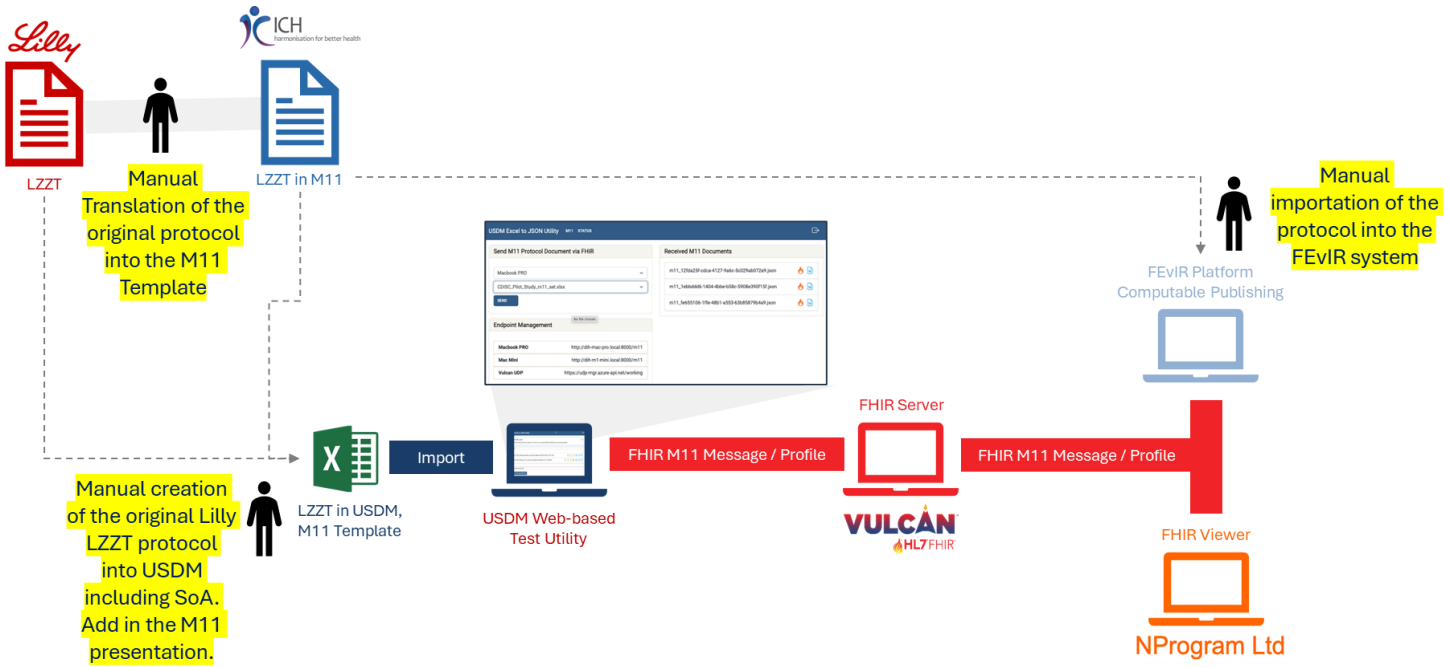
Scenario Testing:

- A full FHIR message for the ICBJ example protocol was achieved - this has the Title Page, as well as the Primary and Secondary objectives, along with some basic Estimands
  The full example of IGBJ is here (as raw data):
  https://fs-01.azurewebsites.net/Bundle/ICH-M11-Template-IGBJ-Bundle
- Inclusion / Exclusion criteria - Protocol can be sent to the server, we can also get it back from the server and can also display it. Hence all 3 systems are interacting as expected meeting the success criteria
  The full example of IGBJ as a rebuilt document is here:
  https://vhewer.com/study?url=https://fs-01.azurewebsites.net/Bundle/ICH-M11-Template-IGBJ-Bundle

- We have received several other partial messages (with the full text and a structured title page) that display Title Page - within the 3 different systems (Sponsor sends an instance to a Regulator, Regulator asks Sponsor to make change, Sponsor makes change and sends to Regulator)

End to End Testing:

- Coverage achieved of testing scenarios (1-5) that we want to cover in this Connectathon - We are currently in the process of completing an end to end process to validate all the previous testing over the past two days, see below for process diagram:



- Screenshots and/or links to further information

- For further information on the UDP Project please see: [UDP — HL7 Vulcan]
- There will be a Webinar taking place on October 15th where we have a spotlight on the connectathon and you can ask any questions during our live moderated Q&A. See poster below for speaker details and how to register:

- Discovered issues / questions (if there are any)

- We will take an action to update the 5 protocol examples we have using during this connectathon with a new iteration that reflect the current M11 Template

- M11 will come with some terminology, currently to some extent we are making up our own terminology, when we get an Implementation Guide (IG) we will update our own terminology to reflect that of the IG.

- Now what?

- Public Webinar 15 October 2024 to raise awareness of progress to date (including outcomes of this Connectathon)
- Expand vendor participation
- Work closer with the SoA team - Conduct deeper analysis so we can ensure UDP and SoA are aligned
- To understand the structured document approach taken by EPI and PQ/CMC in order to inform UDP
- Early thinking on 2026 Connectathon Topics: SoA, Mapping to data capture tools, utilization of ODM

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

What was the track trying to achieve?

This track is the latest in a series meant to facilitate implementation of the FHIR electronic Medicinal Product information (ePI) in connection with ISO IDMP's Pharmaceutical Product Identifier (PhPID).

This track is part of the HL7 Vulcan Accelerator's ePI project which is delivered in collaboration Gravitate Health (an Innovative Medicines Initiative (IMI) funded project), Uppsala Monitoring Centre (UMC), World Health Organization (WHO), the European Medicines Agency (EMA), and the Global IDMP Working Group (GIDWG) initiative.

Track objectives were to address and test the following topics:

1. ePI, PhPID, and GTIN Lifecycle and version control
2. Technical validation rules
3. API exchange capabilities
4. Style Guide and style sheet
5. ePI terminology server

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

Datapharm	Datapharm	**Pfizer**	Pfizer
Gravitate Health	Gravitate Health	**University of Oslo**	UNIVERSITY OF OSLO
GS1 Global	GS1	**University of Portugal**	U.PORTO
HL7 Europe	HL7 Europe	**Uppsala Monitoring Centre (UMC)**	Uppsala Monitoring Centre
ISO TC215 WG6	ISO		

Notable achievements

ePI

ePIs should include images for primary pack, secondary pack, and the product. This should be done to facilitate use cases like https://www.tictac.org.uk/, DailyMed, Felleskatalogen.

Medication statement is used to describe what the patient is currently taking (i.e., dose schedule).

- GTIN should be placed in the Packaged Product Definition.packaging.identifier
    - ACTION: update the ePI IG to include instructions that this is where and how the GTIN should be added

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-2_en.pdf#page=153

- Plan to incorporate GTIN into ePIs. Need to provide recommendations on best practices to make this effective.
- GTIN associated with the supply chain of the product.
    - GTINs are the same in a shared pack scenario but different if the packs are different.
    - New GTINs are assigned when certain attributes change; e.g., pack size.
- GTIN is a 14 digit number that links to a database with detailed product information
    - The number includes digits for a country code and organization code
- MAH assigns GTINs to their products and the MAH decides when to change the GTIN for any given market
- Each manufacturer has their own GTIN lookup database
- ISO 16791 Health Informatics – requirements for international machine-readable coding of medicinal product package identifiers. This standard is being developed to facilitate use of Data Matrix codes to create a physical link between the physical drug product to digital info about the product.
- Data carriers and URI - Content of the data carrier needs to include the GS1 identifier which notifies the scanner to follow the GS1 rules.
- ePI PhPID may get out of sync. ePI may contain a superseded PhPID version. In this case, if user looks up an old PhPID version they should be given notice that it is old and should be presented with the current version.
- ePI always links to the current PhPID. Therefore, the ePI should only include the PhPID itself and not any information about its version.
- The following demonstrates how to express a PhPID in an ePI with the system and code. An ePI can have multiple PhPIDs depending what products and strengths are being referenced. In the ePI, the PhPID is placed in the Classification element of the MedicinalProductDefinition resource.

```
"classification": [ {
    "coding": [ {
       "system": "http://who-umc.org/idmp/level4-phpid",
       "code": "10DD499443FAE493691301348AFDDDF3"
     } ]
  } ]
```

- ePI version control (and List)
    - Same Bundle id, companies can include business ids if they like
    - Keep Approved separate from the drafts under assessment. Approved Bundles have their own id and drafts have their own id.
    - Use status to help differentiate between the drafts under review vs. the approved branch

NOTE

- ePI should consider using SNOMED or ICD or ICPC for the Clinical Use Definition resources
- The profile rules are good enough for the baseline
- Incorporate the QRD template elements into the validation rules
    - Section headings and codes
    - Mandatory text; e.g., date of approval, date of last updated
- Technical validation rules
    - The profile rules are good enough for the baseline
    - Incorporate the QRD template elements into the validation rules
        - Section headings and codes
        - Mandatory text; e.g., date of approval, date of last updated

ePI IG Comparison

Update IG to align with how EMA handles dates. Date of last revision in the composition and date of approval on the bundle.

Nordic IG Nordic ePI IG v0.1.0 (fhir.org)
EMA IG at Home - European Medicines Regulatory Network (EMRN) Electronic Product Information (ePI) Implementation Guide v0.3.0 (europa.eu)
Datapharm IG at Datapharm UK ePI IG

Topic	ePI Implementation Guides			
	Nordic	**UK**	**EMA**	**UMC PhPID**
URL	Introduction - Nordic ePI IG v0.1.0 (fhir.org)	Datapharm ePI IG	Home - European Medicines Regulatory Network (EMRN) Electronic Product Information (ePI) Implementation Guide	WHO-UMC IDMP Management and Publish API - WHO-UMC IDMP Management and Publish API v0.1.0 (fhir.org)

Topic	ePI Implementation Guides			
	Nordic	**UK**	**EMA**	**UMC PhPID**
			v0.3.0 (europa.eu)	
Date	27/09/2024	27/09/2024	27/09/2024	27/09/2024
Status	CI Build Preview	CI Build Preview	CI Build Preview	CI Build Preview
Purpose				WHO-UMC IDMP Management and Publish API
Scope	MPD, Composition, PackagedProduct, RegulatedAuth	MPD, Composition, RegulatedAuth, Organisation, Ingredient, Substance	Bundle, Composition, List, RegulatedAuth, +SPOR	
Composition.Section	section[sectionPackageLeaflet], ..section[agelimitation] ..section[additionalmonitoring] ..section[ghrules] ..section[ghtoc] ..section[section1] ..section[section2] .. +additional 8 subsections ..section[section3] .. +additional 4 subsections ..section[section4] .. +additional 2 subsections ..section[section5] ..section[section6] .. +additional 7 subsections	section. section. section	section. section. section. section. section	

TO DO:

- Look at worked examples of Compositions in the different IGs.
- Expand on items to be harmonised

ePI Style Sheet and Style Guide

Team designed a plan to deliver a style sheet and style guide for ePI. The plan includes a timeline, deliverables, and scope.

Deliverables

1. Style guide document that will leverage content from Austria's CDA style guide; include accessibility recommendations (e.g., WCAG compliance); and include validation rules defining what should be done vs. shall be done.
2. Style sheet (CSS, XSLT) that will convert FHIR XML to (a) HTML output that works across devices and screen sizes; and (b) PDF output for printing

In-scope for version 1.0

- EU/EC languages plus Japanese. Support for Arabic to be added after v1.0
- EMA's QRD template v10.4. Support for JPI template to be added after v1.0
- Support for Chrome, Mozilla, Safari
- HTML output for mobile and desktop; PDF for printable version with pagination
- Accessibility compliance with WCAG 2.1 to comply with EU requirements

Timeline

1. 27 Sep 2024 - Deliver visual design mockup
2. 16 Oct 2024 - Deliver first draft of style sheet proof of concept for comment
3. 14 Jan 2025 - Finalize stylesheet version 1.0 at January connectathon

StyleSheet on the sandbox:

- We developed a place for testing different stylesheets on the hl7 europe's sandbox. https://sandbox.hl7europe.eu/gravitate-health/

- This tool will facilitate testing and sharing different stylesheets for the data existing in the server. Our idea is that loading different stylesheet (blue button on the top left side) can instantly visualize different stylesheets and how they affect the content of the epi in different languages (top left grey button)
- This will be updated as needed with the stylesheet development.

PhPID

- We also developed a mapping mechanism of using ePI data to request a PhPID. This was done under the HL7 Europe's sandbox and can be seen in : https://sandbox.hl7europe.eu/unicom/web/apps/prodbrowser.html
- The necessary mappings and issues detected are:
  - The requirements of referring an "attachedDocument"
  - The requirement of jurisdiction
  - Mapping for domain: conceptMap available at: https://build.fhir.org/ig/hl7-eu/gravitate-health/ConceptMap-domain-spor-hl7.html
  - Mapping for country: ConceptMap available at: https://build.fhir.org/ig/hl7-eu/gravitate-health/ConceptMap-country-iso-spor.html
  - The need for GSID id and/or codesystem (solved during FCAT)

- At the current time, the button “Request” under PhPID creates successfully a task of a request of PhPID.

- Regulator assigns the PhPID together with the authorization of the MAH’s Clinical Trial Application or with an MAA. Regulator publishes the PhPID alongside their publication of any other authorization information.
- Regulatory assigns the PhPID upon request from the MAH (e.g., for legacy drugs that may not have any submissions planned).
- Regulators and UMC may proactively generate PhPIDs for existing drugs.
- PhPID includes a version (similar versioning model as MPID and SID).
    - PhPID is versioned for administrative updates
    - A new PhPID is generated for substantial changes
- Recommendation: Anyone should be able to request a PhPID. However, the Request API is not public. The requesting organization must first register with the UMC or other maintenance organization before accessing the API.
- Operations
    - Lookup PhPID
    - Request new PhPID (using a FHIR Task)
    - Request update to PhPID (using a FHIR Task)

The task request required the MPD, Ingredient(s) and Organisation. The organisation must be the MAH.

The task request is always asynchronous. i.e. even if the request is for an existing PhPID the request will still return a task response.

For complex products, there would be more than one MPD and perhaps this could be solved by using an APD in the task request. How should the request look?

- E.g., a possible example of this scenario is one PhPID assigned for a powder and a second PhPID for the diluent. Subject of debate how to handle the third PhPID for the reconstituted solution.

Refer to this Zulip thread on the subject:
https://chat.fhir.org/#narrow/stream/179308-BRR---Pharmacy-model/topic/Different.20usecases.20of.20AdministrableProductDefinition
~~Jira~~Jira issue to add classification element https://jira.hl7.org/browse/FHIR-42068
https://jira.hl7.org/browse/FHIR-42068

The response for the PhPID is a L4 code that has is to be used as an additional identifier in the Classification on the MPD.
What would happen with the complex product example? Where would the result PhPID be added in the APD?

System will allow bottom-up searches (substance up to MPD) or top-down searches (MPD down to substance).

Authentication is required to initiate a task. There are privacy features that ensure users can only see Tasks they are subscribed to and cannot see another users' tasks.

Add cross-reference to FDA's report called *Results of Testing IDMP PhPID Request APIs*. Notes from the testing:

- FDA using FHIR R4B and everyone else is using R5
- FDA is using UNII for SID. UMC will accept UNII and other substances codes as long as free text on the substance name is allowed
- UMC will remove the cardinality restriction on names to allow proprietary and nonproprietary names in the same search.
- UMC will update their system to align with the Profile in the UMC's PhPID profile
- UMC will require a reference to an ePI as a source when requesting a PhPID

TESTS:

- Creation of a PhPID request for a Nordic + 1 medicinal product, Victoza (https://www.medicines.org.uk/emc/product/6585) yielded a PhPID=91B3CA582581F57E4092F13AAF476215. This successfully proves that a request with a text-only ingredient, coded dose form and strength with a code system of https://dmd.nhs.uk validated with the WHO-UMC request service. (Example code be uploaded to Github)

1. 1.1 Tests performed with Datapharm UK examples

The following tool was used to perform a set of HTTP request tests.

- Visual Studio Code with extension called Rest Client by Huachao Mao. Link at https://marketplace.visualstudio.com/items?itemName=humao.rest-client

Test 1 – create request

https://gist.github.com/datapharm-pmichiels/aa932b8cd8950b02610b1ec029fc6832

Please note that the request above, will require you to create a new GUID for the apikey which is used to group and track your requests.

The ingredient can be provided in text form only should the GSID not be available.

Once the request has been sent successfully you will receive an HTTP response 200 code, together with a Task ID. This can be used to track the status of your task request.

Example response is:

```
1  HTTP/1.1 200 OK
2  Content-Length: 5987
3  Content-Type: application/json
4  Date: Fri, 27 Sep 2024 14:26:48 GMT
5  Server: Kestrel
6  Cache-Control: no-store, no-cache
7  Content-Location: https://idmp.who-umc.org/fhir/Task/c9c7f5a5-87a3-4128-8d66-f5cfa43c9a24
```

Please note the Content-Location is the URL you can use to check the status of the request. The status of the Task is returned in the “status” element.

```
203      "status": "requested",
```

The https://idmp.who-umc.org/fhir/UpdateTask/ endpoint can be called to manually advance the status of the request. Once the status of the request is “completed”, the PhPID Level 4 is available in the following element:

```
261      "valueReference": {
262        "reference": "AdministrableProductDefinition/91B3CA582581F57E4092F13AAF476215",
263        "identifier": {
264          "type": {
265            "coding": [
266              {
267                "system": "http://who-umc.org/idmp/CodeSystem/php-level",
268                "code": "PhPIDLevel4",
269                "display": "Level 4 - Substance, strength and form specified"
270              }
271            ]
272          },
273          "system": "http://who-umc.org/idmp/phpid",
274          "value": "91B3CA582581F57E4092F13AAF476215"
275        }
276      }
277    },
```

Where the PhPID level 4 is displayed on line 274.

The resulting PhPID can then be used to look up matching product classifications:

GET
https://idmp.who-umc.org/fhir/MedicinalProductDefinition?product-classification=http://who-umc.org/idmp/level4-phpid|91B3CA582581F57E4092F13AAF476215
Ocp-Apim-Subscription-Key: {{apikey}}

Please note that it is also possible to use a callback mechanism to alert the caller when the Task request completes. This is either sent back to the caller as an e-mail or a Rest API call (webhook).

The alert mechanism is set up by creating a subscription resource as follows:

```
3   ### FCAT 37 - Create new subscription
    Send Request
4   POST  https://idmp.who-umc.org/fhir/Subscription
5   Ocp-Apim-Subscription-Key: {{apikey}}
6
7   {
8       "resourceType": "Subscription",
9       "id": "datapharm-subscription-webhook",
10      "meta": {
11          "profile": [
12              "http://who-umc.org/idmp/StructureDefinition/Subscription-IdmpEvent"
13          ]
14      },
15      "identifier": [
16          {
17              "system": "http://medicines.org.uk/example/product",
18              "value": "6585"
19          }
20      ],
21      "name": "Datapharm subscription",
22      "status": "requested",
23      "topic": "http://who-umc.org/idmp/SubscriptionTopic/task",
24      "contact": [
25          {
26              "system": "email",
27              "value": "caller@example.com"
28          }
29      ],
30      "end": "2024-09-25T18:48:06.147752+00:00",
31      "reason": "To demonstrate how a subscription works",
32      "channelType": {
33          "system": "http://terminology.hl7.org/CodeSystem/subscription-channel-type",
34          "code": "rest-hook"
35      },
36      "endpoint": "https://xxxxxxxxxx.x.pipedream.net",
37      "timeout": 30,
38      "content": "id-only"
39  }
```

The variables that need to be changed are on line 27, line 34 and line 36.

Line 34 defines the channelType.code and is either “email” or “rest-hook”.

Line 36 defines the endpoint and is either the email address, or web REST endpoint to which the payload of the REST call will be POSTed.

Once the subscription is successfully created, the event will be triggered whenever the task completes.

ACTIONS:

- UMC (Asa, Magnus, Joao) to consider how to implement search parameters for lookup of PhPID:
    - Substance, DoseForm and strength:
        - http://who-umc.org/idmp/StructureDefinition/basic-dose-form
        - http://who-umc.org/idmp/StructureDefinition/administration-method
        - Substance
- Analyse the need of an operation that would look up a PhPID if it already existed and creates the task if it does not.
- UMC (Asa, Magnus, Joao) to consider how to implement search parameters for lookup for products based on PhPID and country/jurisdiction
- UMC (Asa, Magnus, Panayiotis) to resolve how the requests for PhPID from centrally authorized products should be handled for queries and tasks, for first registration and variations.
- Look into structuring the request for source information; e.g., terminology for source document type; document format type. Consider using these document types from EMA's Product Information Document Type in RMS: RMS Web UI (europa.eu)
- Goals: UMC to update their system to address FDA test results and repeat the same tests to ensure issues have been addressed.
- Task acceptance with a suitable HTTP response to indicate task has been accepted for an asysnchrounous response or an immediate response stating the request yields an existing match for PhPID?

FDA SPL-FHIR report on differences with UMC system

- UMC PhPID IG includes a value set for Jurisdiction that includes normal ISO country codes plus extras like "EU"

ACTIONS:

- Confirm with FDA if it is foreseen that they would request PhPIDs on any other level besides 4?

Screenshots and/or links to further information

See notes sections above

Discovered issues / questions (if there are any)

No significant issues

Now what?

ePI Actions

- Follow-up with EMA on the addition of the extra granular QRD sections
- Confirm with regional regulators on whether the FHIR XML can be the official source of truth
- Confirm what patient information is commonly used outside of ePI (E.g., Patient Card, RMM, videos) and determine what metadata would be needed to support them in FHIR.

ePI style sheet and style guide Actions

- 16 Oct 2024 - Deliver first draft of style sheet proof of concept for comment
- 14 Jan 2025 - Finalize version 1.0 of the stylesheet and style guide at the January connectathon

PhPID Actions

- Confirm with FDA if it is foreseen that they would request PhPIDs on any other level besides 4?
- Analyse the need of an operation that would look up a PhPID if it already existed and creates the task if it does not.

US Behavioral Health Profiles

What was the track trying to achieve?

This track focuses on testing an informational FHIR Implementation Guide (IG) for Behavioral Health (BH), based on data elements developed for USCDI+ BH. The United States Core Data for Interoperability (USCDI)+ Behavioral Health dataset aims to enhance the exchange and interoperability of behavioral health information across U.S. healthcare systems.

Key Testing Objectives:

- Evaluate the mapping and usage of USCDI+ BH data elements in FHIR
- Document user stories built around USCDI+ BH data elements
- Assess the IG's capability to handle various data types and scenarios relevant to behavioral health.
-

Testing Activities:

- Explore how USCDI+ BH data elements are represented in FHIR
- Test API-based transmission of FHIR resources between clients and servers

Participants

Claudia Hall (Next Level Health Innovations)

Patrick Joyce (Lantana)

Vivian Horn (Next Level Health Innovations)

Llewelyn Brown (Next Level Health Innovations)

Matt Switzler (Epic)

Maria Moen (MyDirectives)

Lisa Nelson (MyDirectives)

May Terry (MITRE)

Chris Muir (Assistant Secretary for Technology Policy)

Liz Turi (Assistant Secretary for Technology Policy)

Track Page

https://confluence.hl7.org/display/FHIR/2024+-+09+US+Behavioral+Health+Profiles

Notable achievements

- Validated that the behavioral health user story embedded within the US Behavioral Health Profiles IG provided a good framework to discuss and test the USCDI+ BH data elements and behavioral health workflows, helping everyone understand how the IG would work in practice.
- Received vendor feedback on USCDI+ BH data elements used in the US Behavioral Health Profile IG and confirmed they represented a comprehensive perspective of both physical and behavioral health care.
- Able to document ~90% of the USCDI+ BH data element list in an EHR vendor system using usual documentation workflows.

- Able to transmit ~70% of the documented USCDI+ data elements via FHIR API (using client-server interactions) with Postman collections.
- Vendor participation provided crucial feedback on the IG's clarity, feasibility, and potential challenges in real-world implementations.
- We were able to successfully generate and transmit BH Health Status Assessments such as the Depression Assessment (PHQ9) and Anxiety Assessment (GAD-7), Mental Trauma and PTSD Assessment (ACES), Interpersonal Violence (HARK).

- Bonus achievement: Collaborated with the PACIO track to generate and transmit a Mental Health Advanced Care Directive, based on our user story, to explore potential inclusion of a Mental Health specific advanced directive in future versions of the Behavioral Health Profiles IG. Able to represent and transmit components from our IG, treatment intervention preferences and care experience preferences, within the advance directive.
- Bonus: Demonstrated Connectathon Track activities to participants of CDC’s Public Health Data Modernization track.

Screenshots

I, (Jennifer) James Wolff, being of sound mind, willfully and voluntarily execute this mental health advance directive to assure that if I should be found incompetent to consent to my own mental health treatment, my choices regarding my treatment will be carried out despite my inability to make informed decisions for myself.

If a guardian or other decision-maker is appointed by a court to make health care or mental health decisions for me, I intend this document to take precedence over all other means of determining my intent while competent. This document represents my wishes and it should be given the greatest possible legal weight and respect. If the surrogate(s) named in this directive are not available, my wishes shall be binding on whoever is appointed to make such decisions.

If I become incompetent to make decisions about my own mental health treatment, I have authorized a mental health care surrogate to make certain treatment decisions for me. My surrogate is also authorized to apply for public benefits to defray the cost of my health care, to release information to appropriate persons, and to authorize my transfer from a health care facility.

My mental health care surrogate is:

Name: Sarah Wolff
Address: 80A Village St, New Holland PA 17557
Day Telephone: (717) 555-5555 Evening Telephone: _____

Issues

- Some resources did not return the expected resources/data elements via API transmission. For example, veteran status and sexual orientation.

- Occasionally received vendor specific errors in Postman when requesting resources, likely due to business logic configuration. Example: "User not authorized for QuestionnaireResponse - Patient Entered Questionnaires. Search results of this type have not been included."
- Unable to transmit new profiles (Mental Health Clinical Notes Profile and Grant Information Observation) in Behavioral Health Profiles IG.
- Difficulty capturing more granular SDOH data elements such as food insecurity and housing instability separately.

Challenges

- Mapping of vendor-defined concepts to FHIR concepts.
- Difficulty transmitting Treatment Preferences and Care Experience Preferences as expected from EHR vendor.
- Uncertainty of how to best capture behavioral health therapeutic activities such as harm reduction activities, peer coaching and mentoring, and recovery planning.
- The variety of types of behavioral health assessments used in real world settings may not match data element transmission used in this connectathon.