HL7 FHIR Connectathon January 2021
-Track Kickoff-

Track: Real World Data Submission to FDA
Vulcan Project

January 13, 2021
1:00 PM – 2:00 PM Pacific
4:00 PM – 5:00 PM Eastern

Charles Yaghmour
Samvit Solutions
Agenda

• Track Objectives
• Use Case Description
• Use Case Data Flow
• Demo Track Team’s Approach to Addressing the Use Case
• How can you participate?
Real World Data (RWD) Submission to FDA
Use Case / Track Objectives

1. Develop HL7 FHIR capabilities to fulfill the study data submission requirements and to use standardized RWD by biopharmaceutical sponsors

2. Generate evidence from Real World Data submitted to the FDA using established guidelines
High Level Track Steps

1. Retrieve patient’s medication record from a FHIR EHR server
2. Create the SDTM Concomitant Medication* (CM) and Demographics (DM) domain files**
3. Validate created SDTM datasets

(*) Concomitant Medications A drug or biological product, other than a study drug, taken by a subject during a clinical trial. The protocol normally defines a specific reporting period in which the subject’s use of concomitant medications is documented, e.g., from 60 days prior to signing the informed consent until the last study visit.

(**) This step will use the CDISC FHIR mapping (https://wiki.cdisc.org/display/FHIR2CDISCUG/FHIR-to-CDISC+Mapping+Home).
Use Case Data Flow

Start

Retrieve patient medication record

Patient medication record
FHIR XML

Convert FHIR XML to SDTM files

SDTM files

Submit the files via the FDA Gateway for validation

End
Track Team Approach

Develop prototype application to accomplish the following:

1. Search for a patient in the EHR FHIR server*
2. Retrieve patient’s medication record(s)
3. Display medication record(s) on the UI
4. Show the FHIR JSON, or XML, representation of the medication record(s)
5. Convert the FHIR medication record(s) to create the SDTM DM and CM domain files
6. Validate the created SDTM files via the FDA Gateway / Pinnacle 21

(*) For the purpose of the connectathon the EHR FHIR server will be a FHIR server loaded with test EHR data. It will be possible to point the prototype to any FHIR server with EHR data that contains MedicationStatement resource records as well as Patient resource records.

Note: Steps above may vary.
FHIR Resources

• The prototype will use the following FHIR resources:
  - Patient
  - Medication
  - MedicationRequest
  - MedicationStatement -renamed to MedicationUsage in R5

• The prototype maybe modified to evaluate data in all medication-related resources that exist for the patient such as:
  - MedicationAdministration
  - MedicationDispense
  - MedicationKnowledge
  - MedicationRequest
Demo

Track Team’s Approach to Addressing the Use Case
Prototype UI - Home

- Select a FHIR server to search
- Use the “Configure” tab to add a new FHIR server

Select which medication resource to search for:
- MedicationStatement
- MedicationRequest

Note: FHIR servers vary in how they store medication data

Track Team loaded 10 test patient records onto the hapi.fhir.org server. All patient last names start with “RWC”
Prototype UI - Home

Add a new FHIR server to which the application could point and search.

Specify default values for mandatory SDTM variables. Values do not exist in a typical EHR server.
Only patients with MedicationStatement records will be returned
Prototype UI – Patient Details

Limited patient demographics data

Corresponding CDISC SDTM Demographics (DM) domain dataset. Can be downloaded to a .csv file

Medication records

Corresponding CDISC SDTM Concomitant Medication (CM) domain dataset. Can be downloaded to a .csv file

View medication records in JSON format

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CDISC SDTM Dataset Validation
CDISC SDTM Dataset – Validation Completed

Validating Data

Validation Complete!
Validation took 28 second(s)
5 records were examined across all datasets
2 of 2 datasets were validated
18 messages were generated
836 checks were performed

The full report is stored in: C:\Users\Hisham.Yaghoum\Documents\Pinnacle 21 Community\reports
CDISC SDTM Validation Results

Pinnacle 21 Validator Report

<table>
<thead>
<tr>
<th>Domain</th>
<th>Label</th>
<th>Class</th>
<th>Source</th>
<th>Records</th>
<th>Rejects</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLOBAL</td>
<td>Global Metadata</td>
<td>--</td>
<td>--</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>CM</td>
<td>Concomitant/Prior Medications</td>
<td>INTERVENTIONS</td>
<td>CM.csv</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>DM</td>
<td>Demographics</td>
<td>SPECIAL</td>
<td>PURPOSE</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

All transformed records are valid

2 rejection due to missing define.xml and TS domain files. Both are out of scope for the use case.
How Can You Participate?

1. Explore and use the prototype
2. Point the prototype to a different FHIR server
3. Use definition of the use case, and resources on the following slides, to develop your own transformation method
4. How does your method compare to the team’s approach?
5. **Share your feedback Please**
References

• Vulcan – HL7 FHIR
  http://www.hl7.org/vulcan/

• CDISC SDTM Implementation Guide v3.3 *(CDISC login required)*
  https://www.cdisc.org/system/files/members/standard/foundational/SDTMIG_v3.3_FINAL.pdf

• SDTM Validation Tool – Pinnacle 21
  https://www.pinnacle21.com/

• CDISC FHIR Mappings
  https://wiki.cdisc.org/display/FHIR2CDISCUG/FHIR-to-CDISC+Mapping+Home

• Connectathon Track Page
  https://confluence.hl7.org/display/FHIR/2021-01+Vulcan+-+Real+World+Data+%28RWD%29+Submission+to+FDA

• CDISC – FHIR to CDISC Mapping FHIR IG – targeted for January 2021 ballot cycle
Track Contributors

• Mitra Rocca – FDA
  Mitra.Rocca@fda.hhs.gov
• Scott Gordon – FDA
  Gideon.Gordon@fda.hhs.gov
• Helena Sviglin – FDA
  Helena.Sviglin@fda.hhs.gov
• Hugh Glover – HL7
  hugh_glover@bluewaveinformatics.co.uk
• Charles Yaghmour – Samvit Solutions
  cyaghanoum@Samvit-solutions.com
• Rik Smithies – Samvit Solutions
  rik@nprogram.co.uk
• Debi Willis – PatientLink
  debi@mypatientlink.com
• Jay Gustafson – PatientLink
  jayg@mypatientlink.com
• Angela Unruh – PatientLink
  angelaw@mypatientlink.com
• Brian Beahan – PatientLink
  brianb@mypatientlink.com
How to Access the Prototype?

https://mylinks-prod-sdtmtool.azurewebsites.net/

Password: Testing123