2022 09 WGM Agenda

Work Group: BR&R

Joint/Shared sessions are in RED. When hosted by another group entry is italicised

Questionable, Definite

Times

Meeting is in Eastern time

Location is Baltimore

Agenda

Tentative  Suggested  Confirmed

Attendance Log: 2022-09-22 BRR WGM Attendance Log

FHIR-I

<table>
<thead>
<tr>
<th>Session</th>
<th>Joint with</th>
<th>Event</th>
<th>Comments/Minutes</th>
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<tbody>
<tr>
<td>19th Sept</td>
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<tr>
<td>Mon Q1</td>
<td>n/a</td>
<td>not meeting - General Plenary Session</td>
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<td>Mon Q2</td>
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<tr>
<td>Mon Q3</td>
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| Mon Q4 | Pharmacy / Patient Care | • Unicom  
SPL FHIR Project Update  
Medication related resources  
ePI (Vulcan) | • Unicom - Christian Hay (30) (330-4)  
National competent authorities submit data  
Testing being completed  
ISO has completed gap analysis  
IHE to prepare conformance testing tools  
IDMP work to be leveraged for global standard  
Gap - there aren’t any HL7 projects related to UNICOM  
Waiting for UNICOM to drive changes to FHIR resources, standards etc.  
Request to see gap analysis presented by ISO at future HL7 WGM rather than project update  
Would like to see JIRA tickets, gap analysis in FHIR resources  
Christian - to send out gap analysis (attached)  
Pharmacy/BR&R/Unicom to have gap analysis prep meeting before January WGM  
DADI pilot going live pilot next week  
URIS Database update  
UNICOM and IHE (SNOMED, HL7, ISO) - gap analysis being completed between the standards organizations  
UNICOM introduced at IHE Connectathon last week  
Substance data is currently non-congruent. Work in progress in EU, USA, WHO to develop single way to identify substances.  
Discussion  
Next WGM - Gap analysis presented at joint Pharmacy/BRR call  
It issues identified by UNICOM. Can UNICOM tag be made in Jira?  
UNICOM gap analysis must be reviewed by WGs to understand HL7 acceptance as true gap. Provide expertise and feedback  

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<tr>
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<th>Chair / Minute Taker</th>
<th>Co-chairs unavailable</th>
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SPL FHIR Project Update - Jean D (30 total) (4-430/45)

• Connectathon Update  
• SPL to FHIR, FHIR to SPL  
• FHIM to SPL has gaps  
• Connectathon goal - test the mappings and the transforms  
• Demo app - http://splfhir-demo.com.s3-website.us-east-2.amazonaws.com  
• Includes FDA style sheet conversion of FHIR to HTML  
• Utilize to ballot in January  
  • Produces XSL transforms as part of the IG  
  • Difficult to represent graphically  
  • Unclear if balloting at all. Consider providing profiles to the EPI project and having a single IG/Balloting effort  
  • FDA would still create own IG (not through HL7)  
  • Mapping done with Altova Mapforce, similar to XML spy

ePI (Vulcan - Craig Anderson  

• Goal is for IG to be single IG for what all regional health authorities would use. Common elements shared, separate profiles for specific regional needs  
• Shell of IG has been developed  
• Working on profiles, guidance  
• Achievement - working model for allergies and interactions  
• Gap - EU substance info access SPOR. Using FDA G-SRS to continue development  
• Connectathon feedback to be included in IG  
• POC with real data in Norway being planned  
• Balloting by end of year
- Medication related resources (15-20) (4:30/45-5)
- For data on servers already: https://idmp-viewer.azurewebsites.net/display-product
- For cut and paste of data: https://idmp-viewer.azurewebsites.net/display-product-paste
- Not much structural resources change since last WGM/R4B ballot
- Changes to diagrams etc.
- IDMP Viewer

UNICOM.@IHE.Exp.day.pptx

UNICOM_Gap-Analysis.draft.v12.pdf

2022-09-19 Gravi...ew FCATS 31.pptx
Schedule of Activities (Vulcan)
Rebecca Baker
CODEx Trial Matching Project Update
Caroline Pottsager/Su Chen
PQ/CMC Project Update
Scott Gordon

Vulcan SOA
- Targeting January Ballot
- InterSystems (sender)
- CRIO (Receiver)
- Implementations of IP planning and execution
- Defining and detecting unscheduled activities
- IG development in progress
- Implementers for Ballot - both participated in connectathon
- Connectathon 31

Trial Matching
- Using apps available from UCS CAN rather than including Gravity profiles in CodeX IG
- Not all STU 2 data elements yet
- Phase 2 - prospective study with UTSW
- Gravity standard to be used for SDOH
- UTSW will be using extractor tool for pilot
- Epic App Orchard tool being developed
- Epic Structured Data Capture
- Redcap being used in UTSW pilot since the tool was already available at site
- Amgen funding secured
- UTSW site commitment
- IRB protocol reviewed and approved by trial matching advisory committee
- UTSW IRB expected by first week of November
- Applicants documents for future sites released by end of September

PQ/CMC
- Phase 1 data standardization and structuring is complete
- Controlled terminology developed and published
- Designing profiles to support eCTD v 3.2.2 and v4.0 sections/subsections
- https://build.fhir.org/ig/HL7/FHIR-us-pq-cmc/

Vulcan SoA Sept WGM 2022.pdf
- FHIR to OMOP
  - Constrained to USCDI & SNOMED International Patient Summary
  - Would only create new map if doesn't exist and is needed
  - FHIR to OMOP transformations only
  - Reviewing existing mapping efforts, providing summary and recommendation of 'good' maps
  - Targeting January as first connectathon
  - Working with OHDSI to determine process to resolve gaps (if exist)
  - How/Where to publish?
  - Action: Michael to publish Vulcan calls on conference center
  - Action: future call to review and discuss publishing (review FHIR/CDISC IG)

- RWD
  - IG Based on IPS
  - Mapping to FDA study data requirements
  - FHIR IG: [https://build.fhir.org/ig/HL7/vulcan-rwd/](https://build.fhir.org/ig/HL7/vulcan-rwd/)
  - Intent to submit for ballot January 2023

- Phenopackets
  - Goal: computable phenotypic exchange
  - [http://phenopackets.org/core-ig/](http://phenopackets.org/core-ig/)
  - Action: future BRR call to review IG

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**Vulcan FHIR-to-OM...project Update.pdf**

**Vulcan RWD Track...onnectathon.pptx**
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