# HL7 BR&R BRIDG Architecture and Usability Subgroup

Conference Call Minutes: 21-December-2017

Attendees: Julie Evans, Boris Brodsky, Wendy Ver Hoef, Smita Hastak, Bill Friggle

Notes from 12/21/2017 meeting:

1. Need to coordinate and collaborate on the use case work done between the BR&R Subgroup and the TCB FHIR BioPharma group. Geoff has connected the 2 groups and call is being setup to discuss the collaboration.
2. Ensure that the HL7 wiki pages reflect all the use cases in clinical research. TCB use cases for FHIR connectathon are currently published here -- <http://wiki.hl7.org/index.php?title=201801_Clinical_Research#Clinical_Research>
3. Identify a way to add the BR&R subgroup use cases on HL7 wiki and then connect with the HL7 BR&R main webpage -- <http://www.hl7.org/Special/committees/rcrim/index.cfm>
4. Julie will find a way to add the BR&R subgroup usage scenarios on BR&R wiki
5. Research the progress on FHIR Confluence wiki setup. Should the BR&R subgroup use cases be on that new FHIR wiki?
6. Decision was to no longer develop these use cases in the subgroup, but take it to the BR&R WG meetings and calls for additional input.
7. Re-focus this Thursday subgroup calls on Architectural and usability consideration for the January calls (cancelling the 12/28 subgroup call)
8. Boris will look into using the HL7 BR&R Tuesday phone number for the Thursday BR&R subgroup call with the NCI WebEx session.

Notes from 12/14/2017 meeting:

1. Geoff L provided updates on the work TCB group is doing in developing use cases for the January 2018 FHIR Connectathon. He walked thru some of these use cases. The use cases are being documented here -- <http://wiki.hl7.org/index.php?title=201801_Clinical_Research#Clinical_Research>
2. Geoff suggested that he will connect the TCB lead (Trisha) from the BioPharma group with this BR&R subgroup so we can coordinate the various activities.
3. The subgroup continued the discussion on Scenario 5 – please see those notes below under Scenario 5 (in blue font)

## Overall Agenda/Plan for Scenarios

1. Review the current scenarios – Propose additional scenarios for consideration
2. Prioritize selected scenarios
3. For the top scenarios, develop use cases sufficiently granular for implementation
4. Bring use cases for the May 2018 Connectathon
5. Clarify scoping considerations to support data exchange scenarios
   * Coordinate with Geoff and TCB
6. For each use case, determine which FHIR resources may need to be developed or extended
7. Draft resource lists may need to be prepared offline once the use cases are identified

*Note: The group focused on the Scenario 5 on 12/07 to start this process. Will modify the process as we go. Need to touch base with the TCB/Geoff use cases that are being considered for January 2018 FHIR connectathon.*

## Scenarios under consideration

1. Submission of study data (such as HCT trials from trial sites) to a central repository
2. Clinical trial participant registration, and submission of the registration data to ClinicalTrials.gov and other international registries

### Notes

* + Jose: If there is a FHIR implementation, there might be pressure on the registries to all use the same thing. Right now, there is different implementation for each registry.
  + Discuss at January WGM

1. Submitting data to research repositories, such as oncology data for the SEER Registry

### Notes

* 1. Amy: HL7 CIC working on CDEs for registries primarily for EHR and then secondarily for research (Common Registry Framework). Thinks this will move very quickly. We should collaborate with this group.
  2. Discuss this with CIC during January 2018 WGM at the joint meeting

1. Submit subject lab data to CRO and/or sponsor *(similar to TCB Use case 3)*

### Notes

* 1. May help support the FDA / NIH/ CDISC LOINC effort
     1. Is this being done to compliment the CDASH/SDTM effort? Ask Boris
  2. Amy talked about lab tests resulted within EHR vs resulted by 3rd party
  3. Amy suggested collaborating with others on this

### Priority

* 1. This may be a lower priority relative to other scenarios

1. Study setup, management, and site network management (12/07/2017 – worked on this scenario at high level)
   1. Several use cases here (the current world, not the future world):
   2. Next Level Use Cases:
      1. Identify Project/Study Milestones > When was the first subject treated on this study at a site (This could be executed at Coordinating site level also – provide all the subjects that were treated on this study at every site)
         1. Use Case: Milestones within project: As site manager, might want to know when the first patient has been treated with study drug at site, country, study. (need to flesh out further)
         2. Actors: Site Coordinator/Site Manager; CTMS
         3. Data Elements in the Query: Study Id, Site id
         4. Data Elements Returned in the Query: Study Id, Study Drug Name, Drug Administration date, Site Name, Site Address, *will need to identify additional data elements to complete this query result*
         5. Current Candidate FHIR Resources:
         6. Additional Resources or Extending current resources (profiles):
   3. Additional notes from 12/14/2017
      1. Amy may be interested in this from EHR point of view
      2. There will be many milestones associated to this use case – identify the various milestones. Hugh/Parexel building out this scenario in their platform – identifying the milestone and timing
         * 1. Study Start
           2. First site recruited for a study
           3. First patient recruited at site
           4. First dose
           5. Data lock
           6. Study end [Closing the study, last intervention, etc.] May need standardization of what “Study End” means. Overall would be good to get standardization for all Study milestones
         1. Need between EHR (events/interactions are being documented) and CRMS (milestone being documented)
         2. Look into Consent Resource [being developed O&O]
      3. Visit schedule part of Study Design: Visit schedule is important.
      4. Study description as part of Study Design: Need to describe the study with potential sites.
      5. Management of individual investigators in terms of recruiting

### Notes

* + 1. Hugo L --- The Plan Definition Resource appears to define the Protocol structure and then the ResearchStudy Resource defines the Study, but there appears to be a gap in identifying a set of FHIR resources that would be needed for building the study and conducting the study, for example, Encounter resource could be leveraged, but not sure if it has the all the pieces needed from Clinical Research scenarios.
    2. Research Subject resource: Hugo will add the de-identification comment/question to the HL7 FHIR GForge tracker.

### Priority

* + 1. Amy puts this at the top of the list, registries second, AE third

1. Sharing protocol and CRF metadata and subject data among trial stakeholders

### Notes

* 1. Amy: It would be beneficial to enter data in only one system and not both the EHR and CRMS.
  2. The Plan Definition Resource would be of interest in this scenario. We would need to identify the work flow of the clinical trial when we get into this.
  3. Hugo is part of FHIR implementation team in Australia. National Clinical Terminology Service (NCTS) part of Digital Health Agency in Australia --- looking at FHIR resources – SNOMET CT, LOINC, etc. Focused on terminology aspect of FHIR. He is interested in Clinical Research resources for Clinical Trial Management System (CTMS).

1. Adverse Event reporting

### Notes

* 1. May duplicate the ongoing FHIR AE resource development by the Patient Care
  2. Amy: very interesting use case – connecting to AE systems.
  3. Amy: Interfacing EIRB, CRMS, and EHR systems – one update to all 3 at the same time