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| *Society for Clinical Data Management*  eSource Implementation Consortium- Technical | March 30, 201811a EDTTeleconference |

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| Co-chairs: | Don Jennings, Lilly; Hugh Dai, Lilly | Type of meeting: | Technical |
| Facilitator: | Hugh Dai, Lilly | Note taker: | Linda King, SCDM |
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| Attendees: | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Org | Name | Attendance |  | Org | Name | Attendance | | MSKCC | Mike Buckley |  |  | MSKCC | Matt Koch |  | | Novartis | Rakesh Maniar | X |  | MSKCC | Joe Lengfellner |  | | SCDM | Linda King | X |  | BMS | Mari Clovis |  | | Pfizer | Brett Wilson |  |  | Novartis | Rajesh Modi |  | | Partners | Chris Custer | X |  | Lilly | Ed Rausch |  | | Duke | Cory Ennis | X |  | Yale | Rhoda Arzoomanian |  | | Lilly | Hugh Dai | X |  | Novartis | Saurin Mehta |  | | Duke | Denise Snyder |  |  | Partners | S Movin |  | | Pfizer | Demetris Zambas |  |  | Yale | Tesheia Johnson |  | | Lilly | Einav Leberknight |  |  | Pfizer | Tim Joy |  | | BMS | Elsie Mathews |  |  | HL7 | Wayne Kubick | X | | Lilly | Begona Gonzalez |  |  | Novartis | Aruna Vattikola |  | | Partners | Holly Barr-Vermilya |  |  | Merck | TBD |  | | Lilly | Don Jennings | X |  | WashU | Albert Lai | X | | WashU | Yi Zhang |  |  | WashU | Sherry Lassa-Claxton |  | | WashU | Brad Bevanoff |  |  | Forte | Shannon Roznoski |  | | Partners | Stephen Wiviott | X |  |  |  |  | |
| Please read: | Agenda |
| Please bring: | N/A |

# Minutes

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| Agenda item: | **HL7 Biomedical Research and Regulatory (BR&R)**  **Workstream and Use Cases for modeling data domains with FHIR standards** | Presenter: | Don Jennings, Lilly |

#### Discussion:

#### Don presented slides (posted on BaseCamp) from the HL7 BR&R workstream. The workstream has 7 use cases using the BRIDG model to map from EHR to clinical research. Of note, PhUSE (Jeff Lowe and Sam Hume leading) has a team that is skipping BRIDG and directly mapping HL7 content standards to CDISC content standards (CDASH). Also, the TransCelerate eSource workstream (19 pharma companies) are deciding on Monday as to whether they will be working with the BR&R workstream to develop 4 of the 7 Use Cases into HL7 Implementation Guides for FHIR resource data domain representations.

#### Don provided context- FHIR has approximately 150 resources defined. BR&R is starting w/ 7 use cases and starting w/ existing resources being applied for different clinical research use cases. We would like to focus on Use Cases 4, 5, 6 and 7 as the use cases w/ the greatest ROI for our team. Use Case 4 is moving lab data from site to sponsor; Use Case 5 is about site setup for protocols etc and having a 2 way communication; Use Case 6 is about sharing metadata and subject data (demographics); Use Case 7 is for AE’s.

#### What outcomes should we be focused on w/ these Use Cases? Don proposed that it should be Implementation Guides (Draft Version 0.1) and Data Profile VS looking to change the FHIR Core specifications. FHIR Core specs are released every 18 months so if we wanted to change current Core specs it will be until the middle of 2020 before they are official. Wayne clarified and presented a potential timeline of activities to get the biggest ROI and quickest:

#### Produce a draft Implementation Guide (IG) and data profiling (using extensions if needed of core specs) for each of the 4 use cases -- ideally by the end of August. If IGs for all four Use Cases cannot be ready by September then we will prioritize Use Cases 4 (Labs) and 6 (demographics).

#### Test the IGs in the September HL7 connectathon

#### If goes well, can do an initial ballot in Nov/Dec 2018

#### Ballot test can occur at January HL7 connectathon

#### If goes well, a Normative Ballot can happen in June 2019 so approx. 15 months from now approved IG’s/profiling

#### GOAL: Get our testing and ballot out there so EHR vendors put it in their plans- for example- research subject and research resources and make sure privacy is taken into account

USE CASE 4- Labs

* BR&R are evaluating if extensions to FHIR core are needed; BRIDG doesn’t help a lot here.
* If no extensions are required, SCDM eSource Implementation Consortium Local Lab subteam work can progress and we can release this information on the SCDM website.
* Of note- LOINC as a standard is already factored in (has been for a while in EHRs due to meaningful use). Our solution would use LOINC as de-facto standard but we can also transfer anything to sponsor and sponsor can map on back end.

USE CASE 5- Site setup and management

* Can we push data to the sites? That is can we push a Schedule of Events from the protocol so the site can then set up data collection on their side. IS THERE INTEREST BY SITES? Partners has not explored to date per Chris.
* Use case is especially interesting for Observational or Phase IV research- lowers overhead and costs for both site and sponsor.
* There is already a FHIR resource to use a lean ‘protocol’. It’s a level 2 resource. PCORI used it to test. Epic and Cerner have proven capabilities to ingest meds, problems/conditions, allergies etc w/ it.

USE CASE 6- Share metadata and subject data

* First use of this may be demographic data sent to the sponsor’s EDC system
* In September 2017 connectathon, TransCelerate and Oracle worked on prepopulating an InForm CRF starting w/ a FHIR server to an InForm API to InForm CRF. Unfortunately, Oracle did not share code and we’d have to try to duplicate Oracle model code (or ask them for it).
* Idea is to have each tech vendor use their own APIs to bring data into their system (backend) while we focus on the front end of the FHIR model.
* In order to get front end aligned so we don’t have multiple instantiations, important to work w/ teams like Project Argonaut/ US core specs for integration so as to align what comes out of each system. Key is to provide visibility to what we are doing and therefore drive consistency. Per Wayne, ONC is leading the standards piece through healthcare world so need to get research engaged.
* One idea is to expand templates used by EHRs for data collection to include research needs- however, need to make sure that there is no undue burden on sites- 21st Century Cures Act- ie., can’t ask them to change their approach to data collection for all patient’s demographics when research only impacts a small percentage of patients.

USE CASE 7- Adverse Events (AEs)

* The challenge with this use case is the multiple FHIR resources that could contribute to what sponsor’s need sites to capture as AEs. For example, reason for visit, diagnosis, conditions, problems, allergies etc. Also, research needs ALL AEs – no matter how seemingly minor (couldn’t sleep last night) or vague (feeling fuzzy headed) etc. May need way to augment CRF with these additional AEs not traditionally found in an EHR.
* Good news- There is a common model representation of AEs created by NIH but it is at Level 0 draft.
* Also the CDC may be exploring this domain as well to help w/ public health outbreaks.
* Wash U/Albert- interesting to look at.

| Action items | Person responsible | Deadline |
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| * Decide how our group wants to work with the HL7 standard BR&R team on Use Cases using BRIDG * MOU with TransCelerate?- determine if we will partner with TransCelerate or just keep each other informed through overlapping members | Don, Rakesh, Mike  Rakesh, Mike | Discuss Ops meeting April 13th  Discuss Ops meeting April 13th |
| * Decide how our group wants to work with PhUSE on direct mapping from HL7 to CDISC | Don, Rakesh, Mike | Discuss Ops meeting April 13th |
| * Put site subteam together to explore how they would be interesting in using their EHRs to capture AEs (Use case 7) and also to bidirectional communication (Use case 5) * Socialize these ideas w/in your organizations- may have vote as early as next Ops meeting- April 13th | Don and Hugh to help get sites together (Linda to help as needed)  ALL | Email out to site members before April 13th- discuss at Ops meeting  Bring back feedback to Ops meeting April 13th |

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| Agenda item: | **Followup from March 2nd meeting on picking next domain** | Presenter: | Don Jennings, Hugh Dai, Lilly |

#### Discussion:

Reminder- Need to determine- which domain is next- See discussion from March 2nd meeting below:

**Topic: where everyone sees the next domain target(s) beyond local labs?**

Using the domain examples posted on the agenda, here is the cross-references from HL7 FHIR resources:

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| **Domains** | **FHIR Resource** | **Maturity** | **eCRF Volume (%)** | **Data Elements** |
| demographics | Patient | 5 | 1.3 | YOB; Gender; Race (and subcategory); Ethnicity (and subcategory) |
| vital signs | Observation | 5 | 8 | WT; HT; BP; Temp; RR; Pulse |
| allergies | AllergyIntolerance | 3 |  |  |
| procedures | Procedure | 3 | 4 |  |
| immunizations | Immunization | 3 |  |  |
| medications | Medication | 3 | 3.5 |  |

Both demographics and VS have the highest maturity level (5), and providers (MSK, Partners, and WU) are all capable to produce the structured datasets, and feeding data to other programs such as Meaningful Use (MU). Specific challenges:

* Demographics: subcategory data (race/ethnicity) is not routinely recorded and differed among EHRs. For example Asian category in race may be further defined in subcategory as Vietnamese and Japanese.
* VS: plenty data points from the same patient, need to use the ‘right’ one representing the clinical research visit.
* Are other regions such as EU and Japan capture the same structured data like in US?

Other domains have less-maturity levels, among them medication data was in conversations in the past. Close examination of how the data is captured today highlighted the ‘hybrid’ nature of medication domain:

1. Name/Therapy
   1. Dose
   2. Unit
   3. Freq
   4. Route
2. Start date
3. Still ongoing?
4. End date
5. End reason
   * AE
   * Completed
   * No response
   * Abnormal lab
   * Other
6. Indication
   * Primary study
   * AE
   * Prophylaxis
   * Med history

Items 1-4 can be extracted from EHRs without major issues (data quality may differ about start/end dates). Items 5 and 6, however, are not captured today or only in note section. Forte shared their test case last year where EHR medication data was fed into the CTMS; users entered the indication data into the CTMS case report form; then export out for EDC. On the other hand, FHIR resource’s definition for medication end date may not be the same as in patient care environment.

Additional data domains are mentioned such as medical history. WU provided common practice in this area: patients come in with prior diagnosis/treatment from other hospitals, in many cases WU obtains past history via fax or scanned documents. Even the ones entered into EHRs are often buried in the notes. Thus it requires EDC to capture based on user’s experiences and interpretations.

#### Conclusions:

#### Need to vote on next domain(s), and how we will work with HL7, PhUSE and TransCelerate on next domains. Goal is to publish our findings as our case studies but also contribute to the Implementation Guides and data profiling for HL7 so as to help w/ the adoption of the FHIR standards.

| Action items | Person responsible | Deadline |
| --- | --- | --- |
| * See below- carry over from March 2nd meeting * Didn’t get to last agenda item on Checklist for Sponsors Using EHRs as source for clinical research – put on next meeting April 27 | n/a  Don Jennings, Hugh Dai | n/a  April 27, 2018 |

**Past Action Items and Status- Technical**

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| **Meeting Date** | **Ops/Tech** | **Action items** | **Person responsible** | **Deadline** | **Status** |
| 2-Mar-18 | Tech | Determine next domains - Ops team vote | Mike and Rakesh | Discuss Ops meeting April 13th |  |
| 2-Mar-18 | Tech | Establish domain subteams | Mike, Rakesh, Don, Hugh, Linda | Discuss Ops meeting April 13th |  |
| 2-Mar-18 | Tech | Work with EHR vendors to create common/standard templates for domains | Don, Hugh, domain subteam | TBD |  |
| 2-Mar-18 | Tech | Work with EHRs to enforce additional mandatory fields | Don, Hugh, domain subteam | TBD |  |
| 2-Mar-18 | Tech | Create standard templates among consortium members (demographics and VS); agreement on data mapping (procedure; prior hx, AE, etc.) | Don, Hugh, domain subteam | TBD |  |
| 2-Mar-18 | Tech | Some institutes are still separating clinical research from routine patient care practice, learn more about the situation updates and prepare approaches accordingly. | Site subteam | TBD |  |
| 30-Mar-18 | Tech |   Decide how our group wants to work with the HL7 standard BR&R team on Use Cases using BRIDG | Don, Rakesh, Mike | Discuss Ops meeting April 13th |  |
| 30-Mar-18 | Tech |   MOU with TransCelerate?- determine if we will partner with TransCelerate or just keep each other informed through overlapping members | Rakesh, Mike | Discuss Ops meeting April 13th |  |
| 30-Mar-18 | Tech |   Decide how our group wants to work with PhUSE on direct mapping from HL7 to CDISC | Don, Rakesh, Mike | Discuss Ops meeting April 13th |  |
| 30-Mar-18 | Tech |   Put site subteam together to explore how they would be interesting in using their EHRs to capture AEs (Use case 7) and also to bidirectional communication (Use case 5) | Don and Hugh to help get sites together (Linda to help as needed) | Email out to site members before April 13th- discuss at Ops meeting |  |
| 30-Mar-18 | Tech |   Socialize these ideas w/in your organizations- may have vote as early as next Ops meeting- April 13th | ALL | Bring back feedback to Ops meeting April 13th |  |
| 30-Mar-18 | Tech | Checklist for sponsors using EHR as source data in clinical research’ will be discussed in the next technical call on Friday March 30th. | Don, Hugh | Next Tech call on April 27th |  |

# Other Information

#### Observers:

n/a

#### Resources:

n/a

#### Special notes:

n/a