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**Chair:** Smita  
**Scribe:** Maryam  
**Attendees:** See consolidated list  

**Transcript**

### Agenda Topics

*Timeboxing: AR - as required  ITA - if time allows*

<table>
<thead>
<tr>
<th>Timebox</th>
<th>Agenda Item</th>
<th>Meeting Minutes from Discussion</th>
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<tr>
<td>5 min</td>
<td>Call to order, Agenda, Meeting minutes approval from 08/23/2022</td>
<td>Minutes from 08/23/2022 approved by general consensus.</td>
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| 5 min   | Final Ballot content deadline – Sept 4, 2022 -  
All changes in resources by 8/26  
Review Resources – 8/29 - 8/31  
Make updates – 9/1 - 9/3 | Reminder for the group. |
| 40 min  | Review the following 3 elements from ResearchStudy Resource:  
Keyword  
Focus (backbone element)  
ComparisonGroup (backbone element) | **Keyword:**  
* (Rik) Some systems can search on all of the resources, so you may not need to specifically add search terms to workaround that, but you may still want to add some keyword tag that is not there in the data otherwise, maybe for use as a search term.  
* Option 1:  
  * Delete Keyword from ResearchStudy  
  * Move to Classifications (already exists as "type")  
  * Vote: In favor (4)  
* Option 2:  
  * Keep Keyword in ResearchStudy  
  * Delete Keyword from Classification  
  * Determine Value Set  
  * Vote: In favor (9)  
* Option 3:  
  * Delete Keyword from the base Resource  
  * Create an Extension  
  * Vote: In favor (0)  
  * Abstain: (1)  
* **Final Decision:** Option 2 selected.  
  * (Brian A.) Need at least an example valueset  
  * (Rik) Keyword is going to be a string of text, even though it is a CodeableConcept  
  * (Rebecca B.) Suggestion: How about: Response criteria, Solid tumors, Guidelines, RECIST guideline  
  * (Smita) - Question: Is Keycloak going to remain as a CodeableConcept? – Yes, will reference Rebecca’s example list. |
• Classification (backbone element):
  • (Brian A.) Meant to handle any number of classifications without having to create individual extensions for each classification.
  • Proposal:
    • Remove Classifier as a Backbone Element
    • Add a new element to the base ResearchStudy resource: ResearchStudy.classifier
    • Cardinality: Keep 0...*
    • Change as a CodeableConcept
    • (Smita) Rationale for having this as part of the base resource: to allow for future classification for a research study.
    • (Rik) Rule for the new Classifier element: Can not / Should not use this element to support existing semantics that are already supported through other explicit elements in the resource
  • Vote: Hugh G. / Brian A. (15-0-0)

• Formal vote for ResearchStudy.category: (refer to discussion from 2022-08-23 Conference Call)
  • Renaming ResearchStudy.category to .studyDesign
  • StudyDesign valueset - binding will be Preferred and use the 72 terms from the Scientific Evidence variable as the values for ResearchStudy.studyDesign value set.
  • Cardinality: 0...*
  • CodeableConcept
  • Vote: Hugh G. / Catherine H. (15-0-0)

• Focus (backbone element):
  • (Rik) I recently had a case to link focus.productCode to a resource, via a reference not via a code e.g. to a Medicinal Product Definition
  • Original Question: Do we need the Focus data element? – Decision: Yes
  • Proposal:
    • Keep the Focus backbone element.
    • At this time – leave the definition as is.
    • No need to vote at this time.
  • Future Considerations:
    • Update the definition for Focus so that it is clear what it is meant to represent.
    • Suggestion: "The medication(s), food(s), therapy(ies), device(s) or other concerns or interventions that the study is seeking to gain more information about. This is for identifying what factors are being studied. Example: the focus may be of the dose adjustment of the study medication." (add the last 2 sentences to update the definition)
    • (Brian) ComparisonGroup has an "Intended Exposure" data element that somewhat already covers the "Focus" concept.
    • (Rebecca B.) Suggestion: It may benefit from the description as Hugh described. "the focus may be of the dose adjustment of the study med" – The factor portion is what I was trying to get at.

• Last minute items from chat:
  • (Wendy) Someone mentioned suggesting opening up the cardinality of factor - is there a reason it has to be only 1? If not, shouldn't it be 0..*?
  • (Rik) Text doesn't need to be 0..*
  • (Hugh) The whole factor backbone is 0..*
  • (Rik) I would be in favour of switching to CodeableReference but don't see that it needs to not be a backbone. We would be losing 'factor' I don't see that the case for that is made.

10 min Review and vote on the following

- FHIR-37641 - Revise definition of ResearchStudy.
  location APPLIED

- FHIR-37691 - Replace RS.currentState and RS.statusDate with RS.studyStatus
  statusDate with RS.
  studyStatus APPLIED
  - changes applied
Action items

Action:

- **Smita** to add the AssociatedParty proposed change to JIRA.
- **FHIR-37814** - Delete Sponsor, PI and Contact elements from ResearchStudy
- **Brian/Gustav** to send out doodle poll to Eligibility Criteria connectathon / workshop
- **Brian/Gustav** to advertise the connectathon / workshop on Zulip and BR&R Listserv
- Smita will email Mary Ann (cc Anne & LLoyd) to inform HL7 HQ & FMG that this connectathon / workshop will be taking place (and confirm the "weight" holds).
- Smita will start the preproposal PSS for Eligibility Criteria IG in preparation for Thursday’s meeting.
- Hugh to follow-up re: ScientificEvidence CodeSystem work
- **Catherine** - Will review/research further prior to making a decision re: a JIRA ticket to add values. (FHIR-37876)
- **Smita** - Create a JIRA ticket to delete Phase from the description of the Classification.type backbone element.