BRIDG Architecture & Usability

Recommendations for re-structuring BRIDG

HL7 BR&R Sub-group 01/04/2018

Work done on BRIDG Architecture Review FDA Grant -- U01FD005846

Attendees

- Boris
- Julie
- Wendy
- Hugh
- Robinette
- Smita
- Bill Friggle

Candidate Architecture & Usability Ideas

- 1. Use case based re-structuring
 - Consider the 12 use cases presented earlier as BRIDG foundational use cases. Evaluate and identify classes/attributes/associations that do not support any of the 12 use cases and mark them for deletion.
 - Mapping spreadsheets from older harmonized projects and BRIDG tags could be leveraged for making some of these decisions
 - Notes: Maybe a good way to identify the first set. May identify new use cases besides the 12 whose semantics maybe useful to keep. Consider doing structuring first and then packaging
- 2. "Lack of usage" based re-structuring
 - Classes/attributes/associations in BRIDG that do not appear to be used by anyone. E.g., Statistical, parts of Regulatory domain, Molecular biology, Experiment, etc.
 - Notes: FDA Data Standards Program mentions Statistical semantics. Research it further and poll the WG members if this is being used
- 3. FHIR-based modifications for attributes
 - Re-visit BRIDG Naming conventions remove data types in names, shorten names
 - Notes: Changing attribute or class names may create confusion with existing users. Could use some EA functionality to display a better name

Candidate Architecture & Usability Ideas

- 4. Other packaging constructs
 - Based on smaller and implementable business use cases (e.g., registration of a trial, submission of AE report, etc.)
 - Based on logical groupings (E.g., Organization, Product, etc.)
 - Parexel Suggestion
 - Notes: Some literature exists that could provide ideas on how to leverage a DIM for implementation.
- 5. Re-visit the Pillar structures
 - Remove Schedule Pillar??
 - Consider moving some key attributes out of Defined Pillar and remove the Defined Pillar??
- 6. Re-visit the Activity inheritance structure
 - Explore flattening the activity inheritance. Have some additional thoughts on how we could approach this
- 7. Re-visit StudyProtocol and StudyProtocolVersion classes & attributes

To Do

- Are there other ideas to consider?
- Prioritize the list
- New items:
- 1. Add terminology binding
 - Could we consider adding CDISC terminology binding for business terminology
 - Business vs structural terminology
 - Could support the collapsing the Activity model by providing structural terminology.
 - Was discussed 2 years during Archutecture sub-group calls