**Study Submission and Data Validation Meeting 2019-12-18**

Topics

* Build on current work validating SEND DM domain using Linked Data Shapes Constraint Language (SHACL)
* Develop Prototype based **Technical Rejection Criteria** for Study Data
* Model Technical Rejection Criteria to:
  + Facilitate submission conformance
  + Metadata collection for submission. Potential tie-in with Stanford CEDAR Metadata Center <https://metadatacenter.org/>
  + Shared Sponsor/Regulatory validation would enable:
    - Sponsor review prior to submission
    - Automation at FDA
    - Build-out of additional data validation

The current PhUSE SEND Conformance project contains data from 9 independent studies. In order to prototype submission criteria, the PhUSE team requires a Module 4 SEND eCTD containing:

1. Mock or open data from a minimum of 2 studies (preferably 3)

2. DM.XPT and TS.XPT for each study

2. Study Tagging File

3. Define.xml

Additional Notes

* OBI plans to publish a process checklist. Can this checklist become integrated into the prototype?
* While virtually any technology could be used for the prototype, adoption of Linked Data will demonstrate practical value in a defined scope before extending the technology along the broader data lifecycle.
* The Technical Rejection Criteria Self-Check worksheet could become part a metadata collection form, leveraging experience from Stanford's CEDAR initiative.

**Action Items**

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| **Person** | **Task** | **Due** |
| LR | Work with FDA staff to develop eCTD example as described above. Available in early 2020. | 2020-01-31 |
| LR | Identify additional FDA participants | 2020-01-20 (prior to next meeting) |
| LR | Request Aung Htun to schedule next meeting for January | 2019-12-31 |
| TW | Communicate to Mark Musen to determine if Stanford is still interested and willing to participate within a CRADA framework. | 2019-12-19 |
| TW | Reorganize the SENDConform GitHub and website into two sub-projects: Submission, Data Validation | 2020-01-31 |
| TW + AO | Review Technical Rejection Criteria documentation and start to develop SHACL validation models. | Q1 2020 |