eSource Implementation Consortium meeting minutes 2/3/2018

1**. Discuss what people want out of the technical meetings -- what should we concentrate on in the future?** The following ideas were proposed.

1. Periodically discuss the current state of each institution’s technical capabilities, questions and implementation issues. Use the meeting time as a chance to ask others for advice.
2. Align on specifications and workflows, where Site/Sponsor systems need to integrate
3. Establish a shared repository of code to tackle common needs. Note, as a start, shared code for reading HL7 FHIR lab data from a server instance and converting it to CDISC LDM can be found here: https://github.com/jennindg/MDIT\_FHIR\_LDM/
4. Discuss upcoming meetings and who will attend, with the goal of arranging and piggybacking face-to-face discussions.

2**. Data Exchange specifications -- where we are at and what needs to be done next**

* The attendees discussed several higher-level principles of data exchange that could be addressed in an eventual Implementation Guide (IG). A summary of the principles and outcomes are below. Also, see the attached pptx slide.
* **Principle 1:** Align on FHIR Resource representations of data domains
  + General agreement from the attendees this was a good place to invest effort
* **Principle2:** Support different integration scenarios per site --with and without FHIR
  + Agreement that many sites, especially ones with small clinical research operations, will not be able to exchange data in the most high tech way; e.g. via FHIR. Therefore, an IG should support multiple exchange methods from simple to advanced.
* **Principle 3:** Multi-Country trials -- support for different languages
  + General experience was that use of a single language on a trial, even a multi-country trial, is typical. At the very least an IG should start with the assumption of one language for simplify; but the IG should not make any design decisions that rule out multiple languages in the future.
* **Principle 4:** No installation of software required of Sites by Sponsors, and no modifications of Site networks required
  + Agreement that Sponsors should not expect sites to install new software or change their network configurations for the exchange of trial data. The use of exchange standards – e.g. HL7 FHIR – should govern the exchange contract between organizations, not specific technology instantiations.
* **Principle 5:** Investigators and Site staff control the Data Flow for reasons of data security and privacy
  + The principle is generally acknowledged; however, a number of technology solutions can mitigate the need for direct and manual based release of data to Sponsors. For example, the Study PIs agree to and review automated release logic, or Sites create separate FHIR server instances with only the data a given Sponsor should access. The goal is to automate data exchange, as well as protect data privacy.
* **Principle 6:** Site Feasibility for EHR Integration
  + Consensus was in favor of considering common site feasibility assessment criteria. This can range from a common Data Transfer Agreement template to common test cases.
* **Principle 7**: Access Control and Security
  + Attendees agreed that EHR systems are the domain of the Sites, and should be a “black box” to the sponsors; therefore, Sponsors should not expect direct access to EHR systems. Using standards such as HL7 FHIR, the back-end technology can be abstracted from Sponsors. The data exchange interface standards are of importance to principle adherence.
* **Principle 8:** Bulk Data Access
  + Use of 3rd party data aggregators could be a requirement in some countries for handing bulk data exchange. Good discussion but no firm alignment on how to proceed on this principle. But it was acknowledged that this topic is relevant to an IG.

3. **Begin creating a list of data domains (e.g. Adverse Events, Con Meds) to tackle after Labs *(did not address, for next meeting)***

**4. Summary of interactions with the HL7 BR&R team**

* Don Jennings reported on recent TransCelerate-eSource team driven interactions with the HL7 Biomedical Research and Regulatory (BR&R) workstream.
* The BR&R team has stewardship for several FHIR resources of interest to Clinical Research, and is interested in collaborating on how to evolve the resources.
* This team also holds the relevant membership for building and formalizing data models that express Clinical Research data domains in terms of FHIR resources, (e.g. lab data, adverse events, vital signs, con meds).
* Several phone meetings have been held to date and work continues.