Investigating the Use of FHIR in Clinical Research

Project Scope

Increasing interest in eSource keeps the issue of data integration between Research Systems (EDC, CTMS, CDMS, etc) and healthcare systems (EHR, etc) as a consistent want for Sponsors of Clinical Investigators and Regulators. Previous efforts to make this a repeatable, scalable solution have not met with wide-scale adoption, for a variety of reasons.

Some common historical points of view have included:

- That the quality of the data that can be retrieved from the Healthcare sites is insufficient to meet research needs.
- That uptake of electronic systems at investigative sites has been slow, expensive, and not delivering real value to healthcare practises.
- Types of data captured in healthcare have been more operational rather than clinical.
- Enabling the Necessary interfaces is an expensive and process-heavy undertaking.
- There is not a suitable, generally supported electronic exchange format, with a number of standard representations being supported in recent memory.

Many of these issues are on the path to being resolved; government programs have pushed the adoption and accessibility of electronic health records. In addition, there are a number of stakeholders in the Research Industry that are making the use of healthcare resources a priority for the future; examples include Transcelerate eSource initiative and HL7 Vulcan Accelerator.

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Objectives & Deliverables	Timelines
Review FHIR Specification for applicability as a Research Standard	Q12021
Identify 3-6 use cases which illustrate how FHIR Resources can enable effective data sharing between Healthcare and Research Systems	Q12021
Presentation at FHIR DeyDays	Q22022
May FHIR Connectathon	Q22022
IG for ballot	Q12023

CURRENT STATUS **Q12022**

- Planning for EU Connect
- Developing relationship with Vulcan
- Coordinating with Real World Evidence team (Vulcan)
- Reaching out to vendors (Epic, Flatiron)

Published Deliverables	Date
Use of HL7 FHIR as eSource to Pre-populate CDASH Case Report Forms Using a CDISC ODM API	2018

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Project Members	Organisation
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Recommended Solutions

- The FHIR resource-based view of healthcare data is much more aligned to the research 'view' of data; research considers study using CRFs, artificially aligned with clinical data element domains. In the future, these two views of the same data will be more closely aligned from capture through to submission. There is a need for external activities to assist in this alignment (such as mapping to or extending of submission formats, alternative data management processes, focus on the lifecycle of a datapoint, etc). These tasks should be solved in a pre-competitive manner and shared with all stakeholders.
- Increasing government engagement in personal healthcare data has focussed on the need for seamless exchange (including access, consent, format, understandability, etc). Most guidance has recognised that the technology is a key foundation and have chosen FHIR as their preferred format. This is an initiative that the research industry can leverage to more closely engage with the participants in clinical research.

Stakeholders/Initiatives

- HL7 Vulcan
- HL7 Biomedical Research and Regulatory (BR&R)
- CDISC to FHIR Joint Mapping IG

Specific Actions

- Identify gaps and opportunities between the Healthcare and Research realms with a view to providing a shared vocabulary and platform to enable better collaboration.
- Prepare White Papers for Biopharmaceutical Companies providing sample use cases for where the adoption of FHIR will improve the experience of Sponsors, Technology firms and most importantly sites and site users.
- Work with stakeholders to socialise and formalise (e.g. through HL7 FHIR Profiles/Implementation Guides) the technology /approach.