PP22: Scheduling on FHIR – An Update on the PHUSE/Vulcan FHIR(R) Accelerator Schedule of Activities Working Group

Geoff Low - Co-lead of the PHUSE/Vulcan Schedule of Activities Working Group

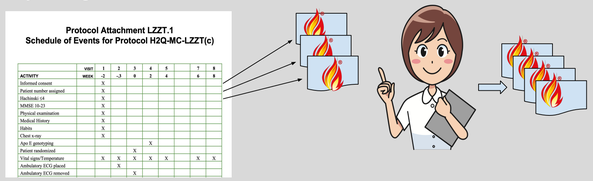
PHUSE/Vulcan FHIR(R) Schedule of Activities Working Group

The PHUSE FHIR(R) project was started in 2015, looking at the FHIR(R) standard and working out how we could best integrate it in current and future Clinical Trial workflows.

Initial focus was on how we can access the data and present it; this included:

- Integrating FHIR(R) data with Electronic Data Capture Systems [1]
- Building SDTM Datasets from FHIR(R) Data [2]
- Building ADaM Datasets from FHIR(R) Data [3]

Since 2019, we have focused on the Clinical Protocol Schedule of Activities (SoA) - how might we use FHIR(R) move away from status quo document exchange of clinical protocols to digitally represent the **WHAT** and **WHEN** of the study design as a workflow.



How could a FHIR SoA change the paradigm?

Within the working group we came up with value benefits for Sponsors, Sites and Vendors. The following were identified as benefits of a FHIR(R) based SoA representation:

- Efficiency
 - Single reusable representation using common resources/patterns
 - Introspection of ongoing trial processes
 - Streamline Site Payments using common patterns/resources
 - Automate Data Retrieval based on a EHR based provenance
- Integration and execution
 - Evaluating Site budgets based on common terminologies
 - Calendaring Scheduling using FHIR(R) workflow semantics
 - Executable Study Design using FHIR(R) workflow semantics
- Optimisation
 - Site Feasibility based on
 - Automated Cohort Identification based on CDS-like semantics
 - Site/patient Load based on Activity definitions

What is HL7 FHIR(R)?

Fast Healthcare Interoperability Resources (FHIR(R)) is a specification for the **exchange** of Healthcare data using Resources and Web Operations. A FHIR ® server is an API endpoint for the resources, or for terminology supporting the specification

It provides some common **generic** representations of Healthcare Resources, examples include:

- Patient - the common patient resource (ie DM)
- Observation - the common clinical findings resource (ie VS/LB/EG)
- Conditions - Health condition information (ie AE/MH)

To use FHIR for a use case, the team create **extensions** and **profiles;** these change the underlying resources to:

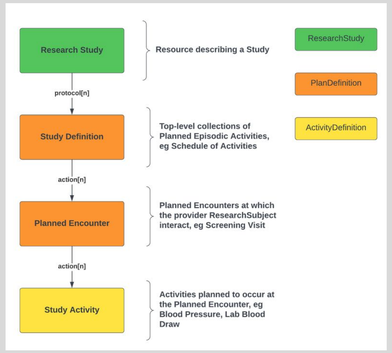
- Constrain permissible values
- Add additional attributes
- Add different operations

Use cases and any implementation artifacts are bundled together into a document called an Implementation Guide (IG), available for public use to deploy, query and implement on a FHIR(R) Server.

PHUSE/Vulcan SoA Implementation Guide

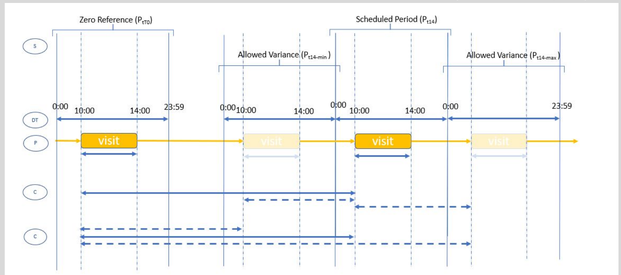
We published the Vulcan SoA Implementation Guide in 2023. The scope was to provide a roadmap for using FHIR(R) resources to plan a clinical trial.

Primarily, we presented a pattern for an implementation of a research plan using FHIR resources as shown here:



The ***ResearchStudy*** resource is a record of a Study.
A ***PlanDefinition*** resource represents a set of activities to execute when transformed into a ***CarePlan.***
An ***ActivityDefinition*** resource represents an activity or task to be performed after being transformed.

We also addressed the concept of visit windowing using a FHIR(R) extension; enabling a queryable framework for adherence and scheduling capabilities similar to those mandated in the M11 (for example).



And finally, we presented a path for linking activities to Study Interventions.



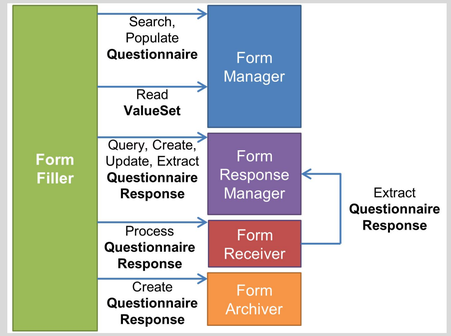
References:

[1] RW02: Use of HL7 FHIR as eSource to Pre-populate CDASH Case Report Forms Using a CDISC ODM API, Sam Hume et al, PHUSE 2018
[2] RW04: Use of Fast Healthcare Interoperability Resources (FHIR) in the Generation of Real-World Evidence, Jeff Abolafia et al, Connect 2017
[3] RW04 Use of FHIR in Clinical Research: From Electronic Medical Records to Analysis, Jeff Abolafia et al, Connect 2019

Current Status

The project is now focused on implementation; we have continued to use the current high-level structure shown aside; however in the interest of acceleration we have pivoted from solely looking at ***ActivityDefinition*** resources to incorporating ***Questionnaire*** resources.

A driver for ***Questionnaire*** resources is the use as part of the Structured Data Capture (SDC) implementation; the overview of the SDC is shown here:



This approach has benefits for the project as it takes advantage of the *existing* workflow capabilities provided by SDC; including:

- Integrated workflow
- Integrated dynamic capabilities
- Automated population
- Data Extraction
- Data Archival

We are positioning the Vulcan SoA to be a component for the Vulcan Utilising the Digital Protocol (UDP) project as well as implementation projects for the other Vulcan Projects.

The UDP project is particularly important as a lever for bringing the ICH M11 benefits to the whole Clinical Research pathway (such as Investigational Sites). The development and implement of the digital protocol is a pivotal change and as such, interest is very high.

What is HL7 Vulcan?

HL7 Vulcan is an Accelerator that is tasked with prioritisation of projects that represent use cases where FHIR(R) presents a clear opportunity for augmenting Clinical Research.

Vulcan serves a user community focused on integrating clinical research and clinical care through the adoption of FHIR(R).

In addition to the SoA project, Vulcan supports a number of others, including:

- Retrieval of Real World Evidence for Research
- FHIR to OMOP
- Utilising the Digital Protocol (UDP)
- Adverse Events for Research
- Electronic Medicinal Product Information (ePI)

For Further Information

- Join the working Group: 1000 EST
 - Contact: geoff.low@3ds.com for an invite
- Check out the following:
 - HL7 Vulcan Site: https://hl7vulcan.org
 - Vulcan SoA Wiki: https://tinyurl.com/4zm8fp9b
 - SoA IG: https://hl7.org/fhir/uv/vulcan-schedule/

Acknowledgements

The working group has been blessed with a number of contributors including (but not limited to) the following:

- Trisha Simpson
- Andy Richardson
- Jeff Abiolafa
- Mike Ward
- Mike Hamidi
- Rebecca Baker
- Hugh Glover
- Shani Sampson
- Surabhi Dutta
- Gustav Vella
- Mike Buckley