

Study Designs using FHIR – Schedule of Activities exchange using FHIR Resources

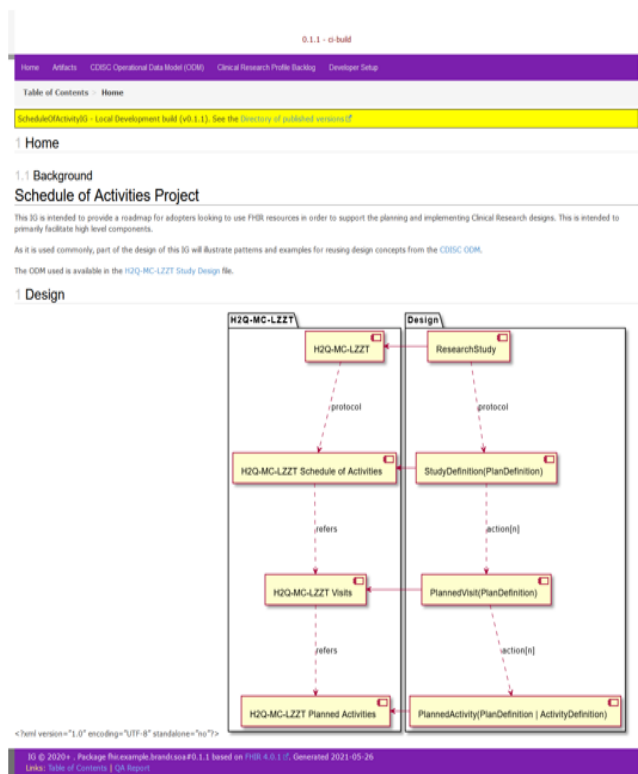
PP10

Andy Richardson¹, Geoff Low², Mike Ward³ and the PHUSE Research on FHIR Working Group

The PHUSE Research On FHIR Project – Goals

- Schedule of Activities Project
 - Develop an approach to migrate Protocol Study Designs to Healthcare Systems
 - Serves as a key pipeline for driving and delivering implementation of Clinical Research use cases in Healthcare Systems
- Specific Activities
 - Proof of design for Approach
 - Proof of concept for Approach
 - Develop an Implementation Guide

Develop an Implementation Guide (IG)



The IG is used by implementers to drive how they can support and adopt the defined Use Case .

It is a published artifact that can be use to confirm that specific implementations meet the IG specification

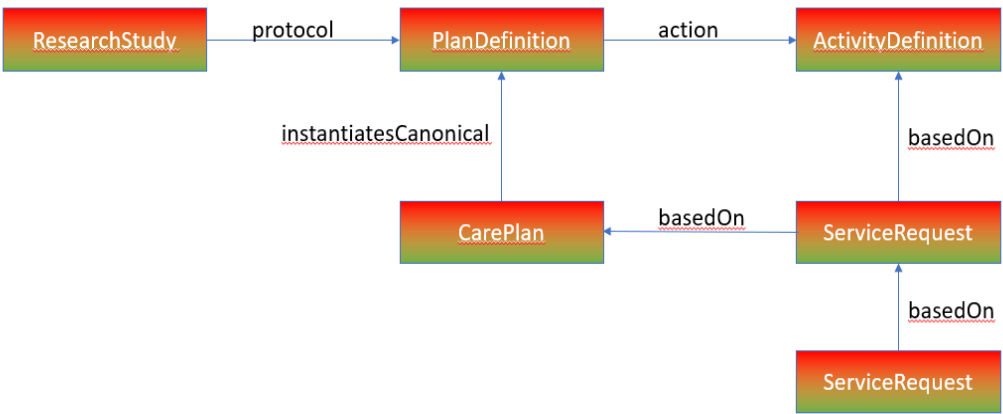
Modelling Approach

- Used FHIR Shorthand (FSH) as a way of generating the resources as is much easier to create and read
- Reuse CDISC Operational Data Model (ODM) study design document
- Provided tutorials/overviews on ODM/FSH for all team members.

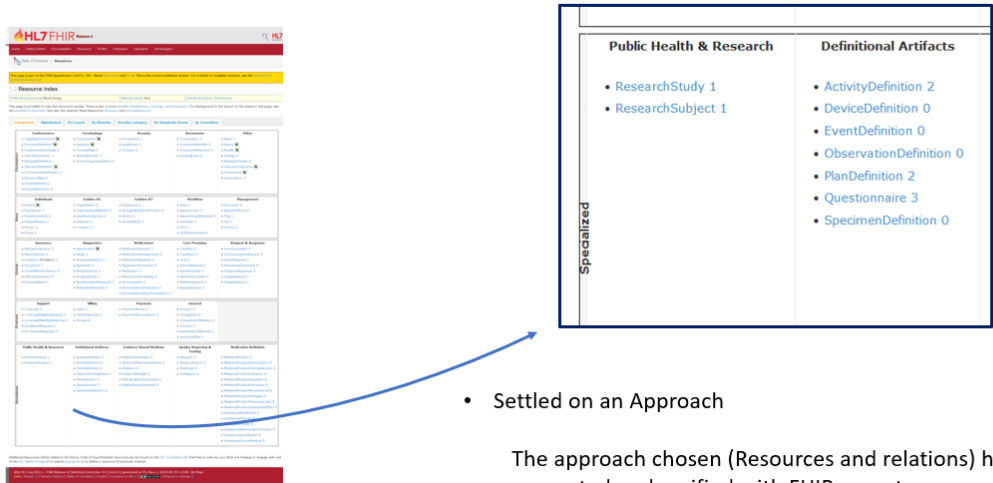
```
Instance: HQ-MC-LZZT-Study-Visit-1
InstanceOf: SOAPPlanDefinition
Usage: #example
Title: "Visit-1"
Description: "Planned Visit [Visit-1]"
+ identifier[1].value = "VISIT-1"
+ identifier[1].type = #PIAC
+ identifier[1].use = #usual
+ identifier[1].value = "SE_SCREENING_VISIT"
+ identifier[1].system = "http://www.cdisc.org/ns/odm/v1.3/StudyDef#"
+ identifier[1].type.coding[0].system = "http://www.cdisc.org/ns/odm/v1.3#"
+ identifier[1].type.coding[0].display = "OID"
+ identifier[1].type.text = "OID"
+ identifier[1].use = #secondary
+ extension[plannedStudyDay].valueInteger = -14
+ status = #active
+ action[1].title = "Record Visit Date"
+ action[1].definitionUri = "ActivityDefinition/HQ-MC-LZZT-Visit-Date"
+ action[1].id = "VISIT-1-HQ-MC-LZZT-Visit-Date"
```

Proof of Design

- Using FHIR Resources to model planned activities



Towards a SoA Implementation Guide



Project Progress

- A Schedule of Activities Implementation Guide has been built. Publicly available at:
 - <https://phuse-org.github.io/fhir-schedule-of-activities-ig/artifacts.html>
- The SoA IG models:
 - The LZZT study overview as a FHIR ResearchStudy
 - The LZZT protocol participant visit schedule as a FHIR PlanDefinition
 - The activities at each LZZT visit as linked FHIR PlanDefinitions
 - Activity outcomes as FHIR ActivityDefinitions with CDISC ODM associations
- and various investigations into how to model SoA concepts

SoA Proof of Concept

- Loading generated SoA FHIR Resources to a FHIR Server



Engagement

- Working with HL7 Vulcan
 - Heavily engaged with HL7 events
 - FHIR Connectathon
 - Collaboration with other working groups
 - Evidence based medicine
 - Clinical Decision Support
- Collaboration with external groups
- Always looking for more contributors

¹ Zenetar, ²Medidata, ³ Transcelerate