Implementation of Research Design Using FHIR

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In clinical research traditional Protocol led design has been predicated on a Schedule of activities composed of Visits/Forms/Fields. Enablement of eSource will be streamlined if it is possible to align these archetypes with concepts based on FHIR building blocks, as these may be used to implement a workflow within the healthcare system that aligns directly with research requirements; specific advantages of this include:

- Cost Allocation for Research Activities vs Standard of Care
- Reuse of existing infrastructure/resource planning at the investigational site
- Deep integration with Subject Calendar systems
Research Concepts

Study (ResearchStudy) - an investigation as part of the Clinical Program intended to verify the safety and efficacy of an intervention (to include drugs, devices, therapies, etc) through the collection of data to satisfy study endpoints and lead to study outcomes.

Subject (ResearchSubject) - the subject of the activities defined as part of the Study, source of the data to support the outcomes of the study. The subject consents to having data collected through the process of informed consent.

Schedule of Activities (SoA) - a grid of all research activities to satisfy the research outcomes through the process of data collection. These are generally arranged in order of encounter and assessment.
Research Concepts

Visit - an encounter between the Subject and the Investigator/designee at which study activities are undertaken according to the Protocol

Case Report Form - an encapsulation of related activities around the collection and recording of the clinical data to support endpoints. Form is a legacy concept representing the activity of recording results on a paper form at the site

Epoch - a block of conceptual context defining the major stages in study progress; the common examples are SCREENING, TREATMENT and FOLLOW-UP. Visits will usually be ascribed to a single epoch, and a single epoch can have multiple visits
Research Concepts

Defined Activity - A definition of an activity to be performed (e.g., Vital Signs, Screening Vital Signs, Systolic BP assessment).

Planned Activity - An activity to be performed as part of a clinical protocol execution at a given point, manifested in the SoA.

Performed Activity - the activity undertaken with information about the execution and results of the execution.
Research Models

There is a common model for data definition and collection that has been adopted as an archetype - this is the CDISC Operational Data Model; it is reflective of the natural hierarchy of current data collection practices,

Study -> Subject -> Visit (StudyEvent) -> Form (CRF) -> Item (Datapoint)

(In this case the Form and ItemGroup are being treated synonymously)

The ODM has been extended in a number of cases through the use of XML namespaces to reflect:
- Different Use Cases (eg Study Design, Metadata Submission, etc)
- Vendor specific extensions (eg Presentational elements, derivations, logic implementations)
Proposals
Protocol

Use a single *PlanDefinition* as a parent definitional element for all research activities, this is linked to the *ResearchStudy* through the *protocol* attribute.
The Epochs are defined as part of the overall study. This is optional as Epochs are often imputed in the Study Data Analysis Phase. The Study Epochs will be modelled using nested PlanDefinition resources.
Visit Definitions using PlanDefinition

Planned Visits will be implemented as nested PlanDefinitions within PlanDefinitions. In this example the Visit PD are arranged within Epochs, but this is not required, they might be directly on the Study PD.

Transitions between Visits would be defined using trigger and timing[x] attributes. For example, the transition to Day 1 would have a reference to completion of an activity pertaining to Randomization/Eligibility.
Planned Visit Activities using **PlanDefinition**

Each of the planned activities within a visit would be defined using a *PlanDefinition* which will be referenced as an action for the Visit itself. The constituent activities would be defined using *ActivityDefinition* resources.

The sequencing between activities would be defined using triggers/timing[x] attributes. This may extend to operational activities (eg taking the Blood Pressure **before** drawing bloods for labs).
In the spirit of the ODM definition/reference paradigm, the *PlanDefinition* can be utilised as a reusable unit across a planned protocol definition.
Performed Events

The use of FHIR resources represents an interesting opportunity to utilise the workflow nature of healthcare; research tends to cherry pick the elements of the workflow (results generally) rather than taking into account the end to end process.

We have delegated the act of performing an activity to an implementation of a CarePlan; it is:

- PlanDefinition through definition
- Encounter through context
- Patient through the subject
The target of any data collection is the actual *Observation* (result) itself. For any proposal to make sense we need to be able to link from the *ResearchStudy/ResearchSubject* through definition through to the *Observation* corresponding.

The *Procedure* resource is used capture information about the act of performing the activity itself - this is something often missed in traditional
We have chosen to use the ServiceRequest to represent initiating activities to define the data source/requisition.

The ServiceRequest can be both semi-abstract (perform screening activities) or more concrete (collect systolic BP), the nesting is totally allowed and gives us the power to be very expressive in how we design an execution plan.

This is a novel capability in the realm of conducting clinical research.
Also discussed

- Use of *Group* to represent Study Arm implementation (ie Subject 001 is randomised to Arm A and as such subject to activities assigned to the arm).
  - Would need to reproduce something similar to the SDM Cell concept (cross-section btw Arm and Epoch)
- Use of *Questionnaire* as a ‘CRF’ implementation in the EHR system
  - As opposed to extraction from constituent FHIR resources
- Use of *Task* to track status of a work request - may be something of use for audits
- Use of *Appointment* for patient level engagement
High-level research

Previously evaluated

- Adopting FHIR Workflow Module
- Clinical Decision Support (to a low degree)

Need to focus on:

- Clinical Decision Support
- Evidence based Medicine
- Medications (e.g. IDMP)
Summary

This is a high-level overview of our initial thoughts around the base elements for representation of a Research Plan using FHIR resources.

Items currently under investigation include:

- Representation of different subject paths
- Dynamic Path adaption based on situation
- Alignment with BRIDG
- Alignment between core elements/attributes of CDISC ODM/SDM with FHIR Resources/Attributes (PhUSE Research on FHIR)
- Alignment between Clinical Domains (eg Vitals, Demographics) and FHIR Resources