Study FHIR Resource Proposal

Unknown macro: 'cloak'

- 1 Study[edit | edit source]
  - 1.1 Owning committee name[edit | edit source]
  - 1.2 Committee Approval Date:[edit | edit source]
  - 1.3 Contributing or Reviewing Work Groups[edit | edit source]
  - 1.4 FHIR Resource Development Project Insight ID[edit | edit source]
  - 1.5 Scope of coverage[edit | edit source]
  - 1.6 RIM scope[edit | edit source]
  - 1.7 Resource appropriateness[edit | edit source]
  - 1.8 Expected implementations[edit | edit source]
  - 1.9 Content sources[edit | edit source]
  - 1.10 Example Scenarios[edit | edit source]
  - 1.11 Resource Relationships[edit | edit source]
  - 1.12 Timelines[edit | edit source]
  - 1.13 gForge Users[edit | edit source]
  - 1.14 When Resource Proposal Is Complete[edit | edit source]

Study[edit | edit source]

(Could also do ResearchStudy if there's a concern about confusion with ImagingStudy)

Owning committee name[edit | edit source]

Regulated_Clinical_Research_Information_Management

Committee Approval Date:[edit | edit source]

Pending

Contributing or Reviewing Work Groups[edit | edit source]

- BRIDG

FHIR Resource Development Project Insight ID[edit | edit source]

Pending?

Scope of coverage[edit | edit source]

This covers the management of clinical (human) and pre-clinical (animal) research studies, including both the study design phase and the study execution phase. (Note that for veterinary studies, the clinical/pre-clinical distinction may not be relevant.) It covers all types of studies (drug, device, therapy, etc.) and both prospective and retrospective analyses and is international in scope. It excludes bench research and experiments.

RIM scope[edit | edit source]

Observation[classCode=CLNTRL, moodCode=EVN] (even when planned, the study is specific to a particular planned execution so is essentially an event in "new" state)

Resource appropriateness[edit | edit source]

Clinical studies are a widely used structure in healthcare. Patients are linked as participants in studies. Clinical study designs are shared. Observations and Questionnaires are linked to studies. Results of clinical studies are submitted. Registries of clinical studies are searched. Queries are made to find patients who are potentially relevant to studies.

Studies always have some sort of identifier. Clinical studies will reference other resources (e.g. protocols, patients, practitioners, but have their own status and can be maintained independently. While the potential number of elements on Study is large, the number of "core" elements common across most types of studies in most jurisdictions will hopefully fall into the <50 data element range.

Expected implementations[edit | edit source]

Needed for DAF research IG to support pCOREnet queries. Also needed to support BRIDG to FHIR mapping and CDISC to FHIR mapping

Content sources[edit | edit source]

BRIDG, SDTM/SEND, pCOREnet, clinicaltrials.gov, who.int/ictrp, clinicaltrialsregister.eu

Example Scenarios[edit | edit source]

- Clinical trial with multiple arms comparing a drug to a placebo
- Animal trial evaluating different doses of a medication
- Trial comparing the long-term outcomes of a medical device
- Retrospective trial examining impact of use of surgery vs. physiotherapy on patient outcomes for patients with a particular condition

Resource Relationships[edit | edit source]

- Will reference PlanDefinition for the protocol that guides the study
- Will reference StudyParticipation to capture information about enrolled participants (Patient)
- Will be referenced (by extension) by various resources to link clinical data relevant to the study to the study

Timelines[edit | edit source]

Intention is to have a draft included in the STU 3 publication (for DAF Research) as a placeholder. STU in release 4

gForge Users[edit | edit source]

Rik Smithies, Lloyd McKenzie (already have committer access)

When Resource Proposal Is Complete[edit | edit source]

When you have completed your proposal, please send an email to FMGcontact@HL7.org