Study FHIR Resource Proposal

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

**Owning committee name**

Regulated_Clinical_Research_Information_Management

**Committee Approval Date:**

Pending

**Contributing or Reviewing Work Groups**

- BRIDG

**FHIR Resource Development Project Insight ID**

Pending?

**Scope of coverage**

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**

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**

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**

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

**Content sources**

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

**Example Scenarios**

- 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**

- 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**

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

**gForge Users**

Rik Smithies, Lloyd McKenzie (already have committer access)

**When Resource Proposal Is Complete**

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