StudyParticipation FHIR Resource Proposal

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StudyParticipation[edit | edit source]

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 resource manages the linkage between a study subject (Patient) and a particular study. It covers both human and animal subjects and captures information about their participation in the study - what arm they were assigned to, what arm they actually completed, when they started and stopped participation, etc.

RIM scope[edit | edit source]

Observation[classCode=CLNTRL, moodCode=EVN] (A StudyParticipation is essentially a mini clinical trial with a subject of 1 from a RIM perspective)

Resource appropriateness[edit | edit source]

A key aspect of tracking research studies is tracking the involvement of the individual study subjects. This information is relevant to care delivery (is my patient a member of any clinical trials), trial management and trial result reporting. Each participation has its own status. Access permissions may vary for different sets of participants for different users. Each participation can have its own id, though these are typically captured on the study subject themselves (i.e. the patient). This resource is needed to support DAF research, for mapping BRIDG to FHIR and for mapping CDISC specifications to FHIR. The number of data elements should be closer to the 20 side than the 50 side.

Expected implementations[edit | edit source]

DAF research, BRIDG and CDISC mappings, and potential future use in clinical research submission specificaitons.

Content sources[edit | edit source]

BRIDG, SDTM/SEND, pCOREnet

Example Scenarios[edit | edit source]

Track study enrollment, current patient status, what arm the patient was assigned to, what stage of the trail the patient is in, when they left the trial, reason for leaving the trial, etc.

Resource Relationships[edit | edit source]

Will always be linked to a Study and a Patient. May be linked to other relevant data (though more likely to have data linked directly to 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