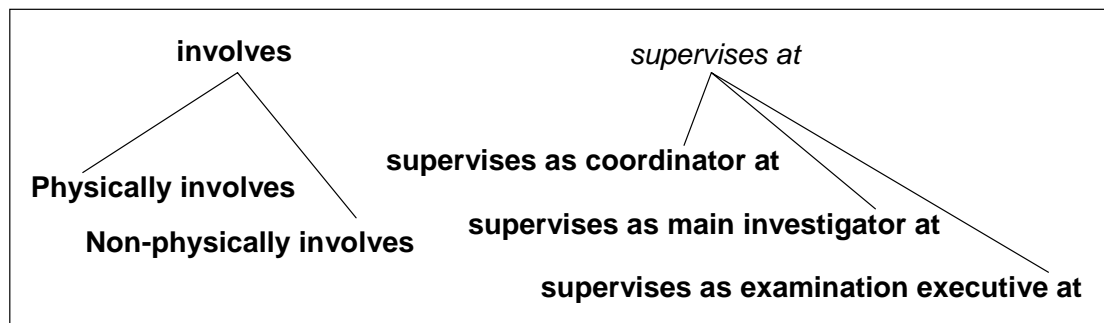


Study-OS

// Metadata

Name	Study-OS
Keywords	Clinical study, Study with examination, Multi-centre study, Researcher, Coordinator, Main investigator, Centre, Ethics Committee authorization
Creation date	September 5 th , 2008
Has contributor	Michel Dojat, Bernard Gibaud, Pascal Girard, Gilles Kassel, Lynda Temal
Used ontology engineering methodology	OntoSpec
Is of type	Domain ontology
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Has ontology language	OntoSpec
Has formality level	Semi-informal
Ressource locator	http://www.laria.u-picardie.fr/IC/site/IMG/pdf/Study-OS.pdf
Version	1.0
Number of concepts (classes)	17
Number of relations (properties)	6

// Relations



Involves

Properties

[EP/DR & RR] A STUDY *involves* a SUBJECT. [EP/NSMC] x *involves* y iff there exist a CONCEPTUALIZATION c and TIME INTERVALS t and t' such that x *has for data* c at t and c *references* y at t' . [EP/IVL] *Involves* mutually implies *is involved in*.

Comment

[DEF] A STUDY *involves* a SUBJECT whenever knowledge about the SUBJECT is used for the STUDY.

Physically involves

Properties

[EP/DR & RR] A STUDY WITH EXAMINATION *physically involves* a SUBJECT.
[EP/NSMC] *x physically involves y* iff there exist an EXAMINATION *e* and a TIME INTERVAL *t* such that *x has for proper part e* and *e affects y at t*. [EP/IVL] *Physically involves* mutually implies *is physically involved in*.

Comment

[DEF] A STUDY *physically involves* a SUBJECT whenever the SUBJECT undergoes an EXAMINATION during the STUDY and the resulting knowledge is used for the STUDY.

Non-physically involves

Properties

[EP/DR & RR] A STUDY *non-physically involves* a SUBJECT. [EP/NSMC] *x non-physically involves y* iff there exist no EXAMINATION *e* and no TIME INTERVAL *t* such that *x has for proper part e* and *e affects y at t*. [EP/IVL] *Non-physically involves* mutually implies *is non-physically involved in*.

Comment

[DEF] A STUDY *non-physically involves* a SUBJECT whenever the SUBJECT has undergone an EXAMINATION during another STUDY and the resulting knowledge is used for the present STUDY.

Supervises as coordinator at

Properties

[EP/R1 & R2 & R3] A COORDINATOR *supervises as coordinator* a STUDY at a TIME INTERVAL. [EP/SL] *x supervises as coordinator y at t* implies that *x supervises y at t*.

Supervises as main investigator at

Properties

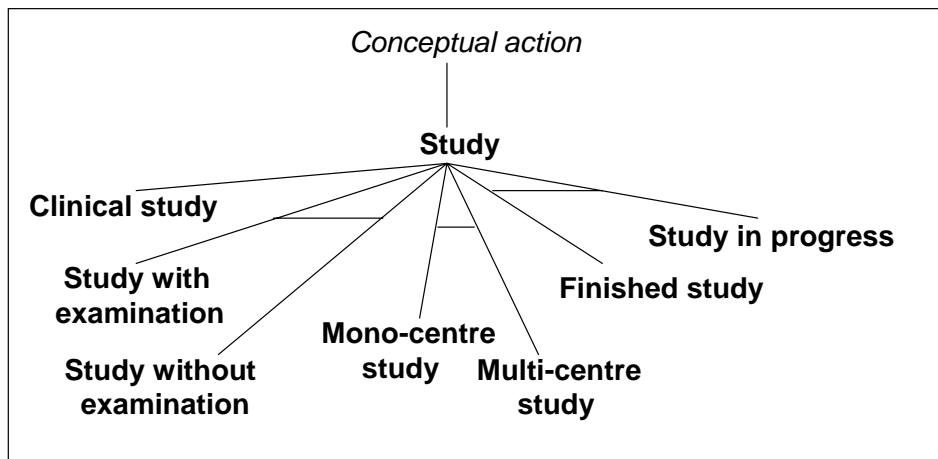
[EP/R1 & R2 & R3] A MAIN INVESTIGATOR *supervises as main investigator* a STUDY at a TIME INTERVAL. [EP/SL] *x supervises as main investigator y at t* implies that *x supervises y at t*.

Supervises as examination executive at

Properties

[EP/R1 & R2 & R3] An EXAMINATION EXECUTIVE *supervises as examination executive* an EXAMINATION at a TIME INTERVAL. [EP/SL] *x supervises as examination executive y at t* implies that *x supervises y at t*.

// Concepts



Study

Meta-properties

STUDY is RIGID (+**R**). STUDY is EXTERNALLY-DEPENDENT (+**D**). STUDY WITH EXAMINATION and STUDY WITHOUT EXAMINATION is a non trivial partition of STUDY. MONO-CENTRE STUDY and MULTI-CENTRE STUDY is a non trivial partition of STUDY. FINISHED STUDY and STUDY IN PROGRESS is a non trivial partition of STUDY.

Properties

[EP/SL] A STUDY is a CONCEPTUAL ACTION. [EP/ER] Every STUDY involves at least one SUBJECT. [EP/EER] Every STUDY is supervised by at least one MAIN INVESTIGATOR or COORDINATOR at a TIME INTERVAL. [EP/ER] Every STUDY has for name a NAME.

Comment

[DEF] A STUDY is a research investigation (therefore a CONCEPTUAL ACTION) involving human subjects that is designed to answer specific questions about brain functions or dysfunctions.

[SA] STUDIES are divided into STUDIES WITH EXAMINATION and STUDIES WITHOUT EXAMINATION according to whether the STUDY includes at least one EXAMINATION.

[SA] STUDIES are divided into MONO-CENTRE STUDIES and MULTI-CENTRE STUDIES according to whether the STUDY is performed by exactly one, or at least two, CENTRE(S).

[SA] STUDIES are divided into FINISHED STUDIES and STUDIES IN PROGRESS according to whether they are finished or not.

Clinical study

Meta-properties

CLINICAL STUDY is RIGID (+**R**). CLINICAL STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A CLINICAL STUDY is a STUDY.

Comment

[DEF] CDISC Clinical Research Glossary: a clinical study is a research investigation involving human subjects that is designed to answer specific questions about the safety and

efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device.

Study with examination

Meta-properties

STUDY WITH EXAMINATION is RIGID (+**R**). STUDY WITH EXAMINATION is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A STUDY WITH EXAMINATION is a STUDY which *has for proper part* at least one EXAMINATION. [EP/ER] Every STUDY WITH EXAMINATION *is referred to by* an ETHICS COMMITTEE AUTHORIZATION. [EP/ER] Every STUDY WITH EXAMINATION *is supervised by* at least one MEDICAL DOCTOR *at* a TIME INTERVAL.

Study without examination

Meta-properties

STUDY WITHOUT EXAMINATION is RIGID (+**R**). STUDY WITHOUT EXAMINATION is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A STUDY WITHOUT EXAMINATION is a STUDY which *has* no EXAMINATION *for proper part*.

Mono-centre study

Meta-properties

MONO-CENTRE STUDY is RIGID (+**R**). MONO-CENTRE STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A MONO-CENTRE STUDY is a STUDY which *has for agent* exactly one CENTRE *at* a TIME INTERVAL. [EP/ER] Every MONO-CENTRE STUDY *is supervised by* exactly one MAIN INVESTIGATOR *at* a TIME INTERVAL.

Multi-centre study

Meta-properties

MULTI-CENTRE STUDY is RIGID (+**R**). MULTI-CENTRE STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A MULTI-CENTRE STUDY is a STUDY which *has for agent* at least two CENTRES *at* a TIME INTERVAL. [EP/ER] Every MULTI-CENTRE STUDY *is supervised by* exactly one COORDINATOR *at* a TIME INTERVAL.

Finished study

Meta-properties

FINISHED STUDY is ANTI-RIGID (~**R**). FINISHED STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A FINISHED STUDY is a STUDY.

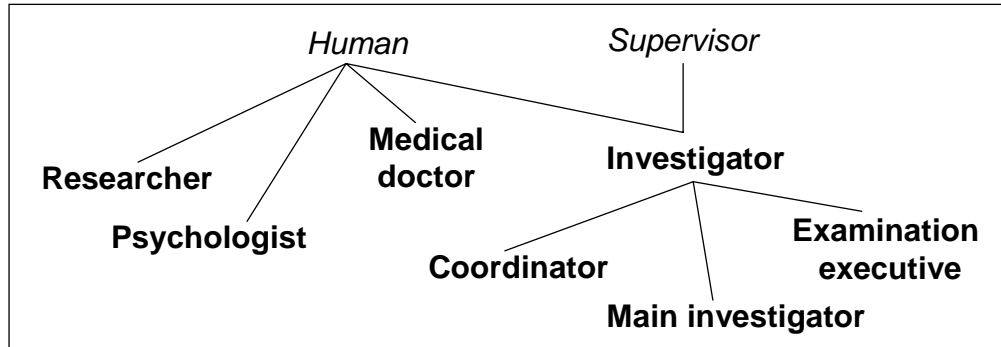
Study in progress

Meta-properties

STUDY IN PROGRESS is ANTI-RIGID ($\sim R$). STUDY IN PROGRESS is EXTERNALLY-DEPENDENT (+D).

Properties

[EP/SL] A STUDY IN PROGRESS is a STUDY.



Researcher

Meta-properties

RESEARCHER is ANTI-RIGID ($\sim R$). RESEARCHER is CARRYING AN IDENTITY CRITERION (+I). RESEARCHER is EXTERNALLY-DEPENDENT (+D).

Properties

[EP/SL] A RESEARCHER is a HUMAN.

Psychologist

Meta-properties

PSYCHOLOGIST is ANTI-RIGID ($\sim R$). PSYCHOLOGIST is CARRYING AN IDENTITY CRITERION (+I). PSYCHOLOGIST is EXTERNALLY-DEPENDENT (+D).

Properties

[EP/SL] A PSYCHOLOGIST is a HUMAN.

Medical doctor

Meta-properties

MEDICAL DOCTOR is ANTI-RIGID ($\sim R$). MEDICAL DOCTOR is CARRYING AN IDENTITY CRITERION (+I). MEDICAL DOCTOR is EXTERNALLY-DEPENDENT (+D).

Properties

[EP/SL] A MEDICAL DOCTOR is a HUMAN.

Investigator

Meta-properties

INVESTIGATOR is ANTI-RIGID ($\sim R$). INVESTIGATOR is CARRYING AN IDENTITY CRITERION (+I). INVESTIGATOR is EXTERNALLY-DEPENDENT (+D).

Properties

[EP/SLD] An INVESTIGATOR is a HUMAN and a SUPERVISOR who *supervises* a STUDY or an EXAMINATION *at* a TIME INTERVAL.

Comment

[DEF] An INVESTIGATOR is a person responsible for the conduct of a STUDY or an EXAMINATION at a CENTRE.

Main investigator

Meta-properties

MAIN INVESTIGATOR is ANTI-RIGID ($\sim\mathbf{R}$). MAIN INVESTIGATOR is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). MAIN INVESTIGATOR is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SL] A MAIN INVESTIGATOR is an INVESTIGATOR who *supervises at* a TIME INTERVAL *as main investigator* either a MONO-CENTRE STUDY or the *part of* a MULTI-CENTRE STUDY which has for agent one CENTRE at a TIME INTERVAL.

[EP/NMC] Every MAIN INVESTIGATOR who *supervises as main investigator* a STUDY WITH EXAMINATION *at* a TIME INTERVAL is necessarily a MEDICAL DOCTOR.

Comment

[DEF] Modified from CDISC Clinical Research Glossary: when a STUDY (either Mono or Multi-centre) is conducted by a team of individuals at a CENTRE, the responsible leader of the team is called the MAIN INVESTIGATOR.

Coordinator

Meta-properties

COORDINATOR is ANTI-RIGID ($\sim\mathbf{R}$). COORDINATOR is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). COORDINATOR is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SLD] A COORDINATOR is an INVESTIGATOR which *supervises as coordinator* a MULTI-CENTRE STUDY *at* a TIME INTERVAL. [EP/NMC] Every COORDINATOR who *supervises as coordinator* a STUDY WITH EXAMINATION *at* a TIME INTERVAL is necessarily a MEDICAL DOCTOR.

Comment

[DEF] Modified from CDISC Clinical Research Glossary: an INVESTIGATOR assigned the responsibility for the coordination of INVESTIGATORS at different CENTRES participating a MULTI-CENTRE STUDY.

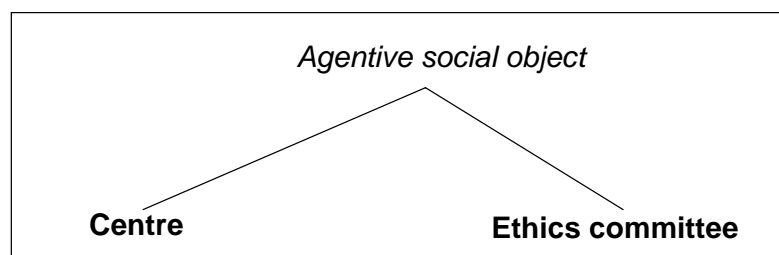
Examination executive

Meta-properties

EXAMINATION EXECUTIVE is ANTI-RIGID ($\sim\mathbf{R}$). EXAMINATION EXECUTIVE is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). EXAMINATION EXECUTIVE is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SLD] An EXAMINATION EXECUTIVE is an INVESTIGATOR who *supervises as examination executive* an EXAMINATION *at* a TIME INTERVAL.



Centre

Meta-properties

CENTRE is RIGID (+**R**). CENTRE is not EXTERNALLY-DEPENDENT (-**D**).

Properties

[EP/SL] A CENTRE is an AGENTIVE SOCIAL OBJECT. [EP/ER] Every CENTRE *has for name* a NAME.

Ethics committee, Independent ethics committee, independent review board (IRB), Consultative committee for the protection of human subjects, in France: Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale (CCPP)

Meta-properties

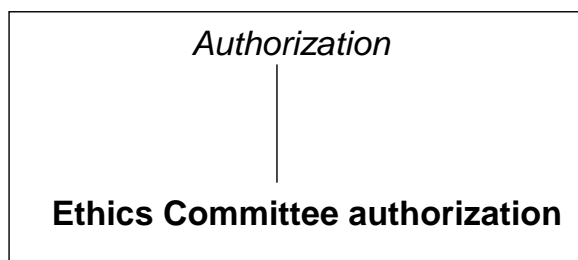
ETHICS COMMITTEE is RIGID (+**R**). ETHICS COMMITTEE is not EXTERNALLY-DEPENDENT (-**D**).

Properties

[EP/SL] An ETHICS COMMITTEE is an AGENTIVE SOCIAL OBJECT.

Comment

[DEF] CDISC Clinical Research Glossary: An independent body (a review board or a committee, institutional, regional, national, or supranational) constituted of medical/scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material used in obtaining and documenting informed consent of the trial subjects.



Ethics Committee authorization

Meta-properties

ETHICS COMMITTEE AUTHORIZATION is RIGID (+**R**). ETHICS COMMITTEE AUTHORIZATION is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] An ETHICS COMMITTEE AUTHORIZATION is an AUTHORIZATION which *has for author* an ETHICS COMMITTEE.