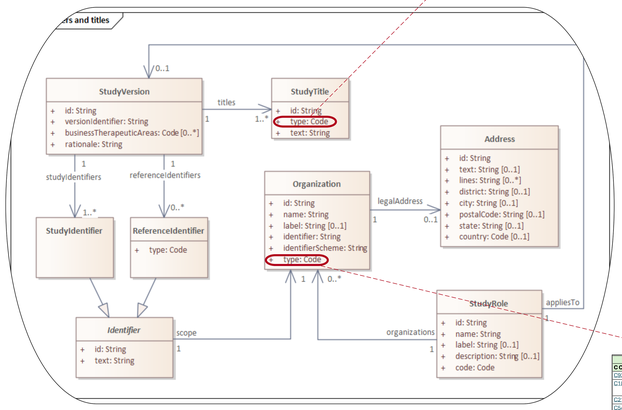
C207419 - CDISC DDF Study Title Type Value Set Terminology

C Code	Submission	Preferred Term	Synonyms	Definition
C207615	Brief Study Title	Brief Study Title	Abbreviated Protocol Title	The short descriptive name for the study.
C207616	Official Study Title	Official Study Title		The formal descriptive name for the study.
C207617	Public Study Title	Public Study Title		The descriptive name of the study that is intended for the lay public, written in easily understood language.
C207618	Scientific Study Title	Scientific Study Title		A more extensive descriptive name of the study that is intended for medical professionals, written using medical and scientific language.
C207646	Study Acronym	Study Acronym	Trial Acronym	A word or words formed from the beginning letters or a combination of syllables and letters of a compound term, which identifies a clinical study.



CNEW - TBD (StudyDefinitionDocument Type)

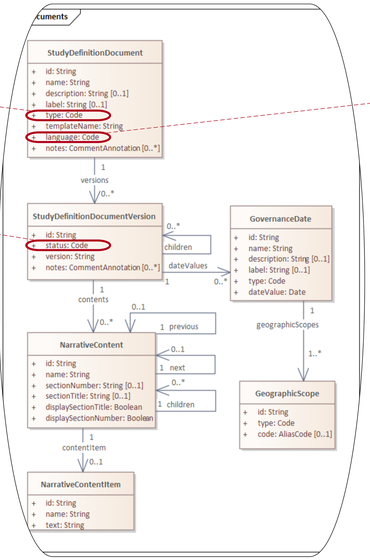
C Code	Submission	Preferred Term	Synonyms	Definition
C70817		Protocol		The formal plan of an experiment or research activity, including the objective, rationale, design, materials and methods for the conduct of the study, intervention description, and method of data analysis.

C188723 - CDISC DDF Protocol Status Value Set Terminology

C Code	Submission	Preferred Term	Synonyms	Definition
C63553	Obsolete	Obsolete		No longer in use or valid; old.
C25425	Approved	Approved		Acceptance as satisfactory by an authoritative body; established by authority; given authoritative approval.
C25508	Final	Final		Conclusive in a process or progression.
C85255	Draft	Draft		A preliminary version of a written work, design, or picture.
C188862	Pending Review	Pending Review	Draft Pending Review	A preliminary version of a written work, design, or picture that is awaiting review.

C188724 - CDISC DDF Organization Type Value Set Terminology

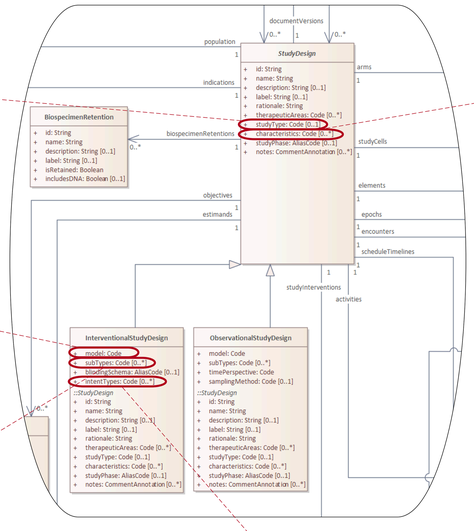
C Code	Submission	Preferred Term	Synonyms	Definition
C93453		Clinical Study Registry		An organization (typically a government agency) that administers the registration of studies. (BRIDG)
C188863		Regulatory Agency	Regulatory Body; Regulator	An organization (typically a government agency) that is responsible for implementing and enforcing laws, licensing and regulating products and services, promoting the use of standards, and ensuring safety and consumer protections.
C21541		Healthcare Facility		The buildings and organizations where healthcare services are provided.
C54149		Pharmaceutical Company		A company licensed to discover, develop, market, and/or distribute drugs.
C37984		Laboratory		An organization with the capability and competency to perform scientific research, experiments, and measurements. (BRIDG)
C54148		Contract Research Organization		A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [ICH E6 Glossary]
C199144		Government Institute		An organization established, funded, and overseen by a government, which has a specific purpose or intent.
C16240		Academic Institution		An organization, such as a college or university, established for the purpose of scholastic pursuit, education, granting degrees, and research.
CNEW		Medical Device Company		A company licensed to discover, develop, market, and/or distribute medical devices.



ISO 369

C99077 - CDISC SDTM Study Type Terminology

C Code	Submission	Preferred Term	Synonyms	Definition
C16084	OBSERVATIONAL	Observational Study	Observational Trial	Study in which the researchers observe the effect of a risk factor (e.g., exposure), diagnostic test, treatment or other covariate within a study population, and where the investigator does not assign specific interventions. (CDISC Glossary)
C98722	EXPANDED ACCESS	Expanded Access Study		Studies that provide a means for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in another clinical study.
C129000	PATIENT REGISTRY	Patient Registry Study		Observational studies which include an organized system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, health care services, and/or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single purpose or on-going data collection programs that address one or more questions. (AHRQ)
C98388	INTERVENTIONAL	Interventional Study	Interventional Trial	Studies in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.



C207416 - CDISC DDF Study Design Characteristics Value Set Terminology

C Code	Submission	Preferred Term	Synonyms	Definition
C207613	Extension	Extension	Roll-over Study	A study design in which subjects enrolled in one study are subsequently continued into a related study for longer term safety, tolerability, and/or effectiveness monitoring.
C48079	Randomized	Randomized		A study design in which interventions are assigned to subjects according to randomization principles.
C98704	Adaptive	Adaptive		A study design that allows for prospectively planned modifications to one or more aspects of the design based on accumulating data from subjects in the trial. (FDA)

C99076 - CDISC SDTM Intervention Model Terminology

C Code	Submission	Preferred Term	Synonyms	Definition
C82639	PARALLEL	Parallel Study	Parallel Trial	A trial design in which subjects are randomised to one of two or more arms, with each arm being allocated a different intervention for the duration of the study.
C82637	CROSS-OVER	Crossover Study		A trial design in which subjects function as their own control and are assigned to receive an investigational product(s) and control(s) in an order determined by randomization, with or without a washout period between the interventions. (CDISC Glossary)
C142568	SEQUENTIAL	Group Sequential Design		A type of adaptive trial design that allows successive interim analyses of the data at particular time points or after a pre-defined number of patients have been enrolled. (CDISC Glossary)
C82640	SINGLE GROUP	Single Group Study	Single Arm Study	All trial participants are assigned to a single treatment group for the duration of the study.
C82638	FACTORIAL	Factorial Study		Two or more interventions, each alone or in combination, are evaluated in parallel against a control group. This study design allows for the comparison of active drug to placebo, presence of drug-drug interactions, and comparison of active drugs against each other.

C66739 - CDISC SDTM Trial Type Terminology

C Code	Submission	Preferred Term	Synonyms	Definition
C49662	PHARMACODYNAMIC	Pharmacodynamic Study		A study of the biochemical and physiological effect of a drug and the mechanism of drug action and the relationship between drug concentration and effect. (NCI)
C49661	PHARMACOGENOMIC	Pharmacogenomic Study		A study that identifies or assesses variations within the entire genome, including DNA, RNA, or transcriptional elements, and its effects on drug response.
C49657	PREVENTION	Prevention Study	Preventive Clinical Trial	A type of study designed to identify actions necessary to permanently eliminate or reduce the long-term risk to human life as a result of a particular medication or treatment regimen.
C49656	TREATMENT	Treatment Study		A type of study designed to evaluate intervention(s) for treatment of disease, syndrome or condition.
C49653	DIAGNOSIS	Diagnosis Study	Diagnostic Study	A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.
C49664	BIO-AVAILABILITY	Bioavailability Study		A study of the degree to which or rate at which a drug or other substance is absorbed or becomes available at the site of physiological activity after administration. (NCI)
C49663	PHARMACOKINETIC	Pharmacokinetic Study	PK Study	A study of the process by which a drug is absorbed, distributed, metabolized, and eliminated by the body. (NCI)
C179257	ECG	Electrocardiographic Study		A study that evaluates the effect of a treatment on cardiac electrical activity, as assessed by electrocardiography.
C165297	THOROUGH QT	Thorough QT Study		A type of study designed to evaluate the ability of an investigational product and/or approved drug to delay cardiac ventricular repolarization as detected by QT prolongation and other ECG parameters.
C49667	SAFETY	Safety Study		A study that assesses the medical risks to a subject. Safety is usually assessed by examining a wide range of clinical parameters, including adverse events, vital signs, physical exam, laboratory tests.
C49666	EFFICACY	Efficacy Study		A study of the relative therapeutic efficacy of treatment of a disease. Usually this is a Phase II or III study. (NCI)
C49665	BIO-EQUIVALENCE	Therapeutic Equivalency Study		A study most often used to compare the efficacy of different formulations to treat a given disease. It is the testing of an old versus a new formulation in healthy volunteers or subjects with the disease under study and usually in one dose. (NCI)
C99493	PHARMACOECONOMIC	Pharmacoeconomic Study		A study that assesses the value associated with a given drug in therapeutic and economic terms. This type of study is multidisciplinary in nature and takes into consideration the social and economic costs (resource utilization costs including direct, indirect, and intangible costs) of drug therapy in addition to its direct therapeutic benefits. Analyses relate the difference in therapeutic benefits to the difference in costs between treatment alternatives. (NCI)
C201484	MASS BALANCE	Mass Balance Study		A type of study designed to evaluate the overall pathways of metabolism and excretion of a drug, and to identify and/or quantify metabolites in plasma and excreta.
C174366	REACTOGENICITY	Reactogenicity Study		A type of study designed to evaluate the expected, acute types of immunological responses, sometimes considered excessive, following agent administration.
C120842	IMMUNOGENICITY	Immunogenicity Study		A study that assesses an agent's ability to provoke an immune response.
C129001	PHARMACOGENETIC	Pharmacogenetic Study		A study that assesses variation in DNA sequence, usually within a single gene, and its effect on drug response.
C161477	POSITION EFFECT	Position Effect Trial		A type of study designed to evaluate the effect of body position during and/or after administration of the investigational product.
C161478	SWALLOWING FUNCTION	Swallowing Function Trial		A type of study designed to evaluate the effect of the investigational product on the physiologic act of swallowing.
C161479	USABILITY TESTING	Usability Testing Study		A type of study designed to evaluate the user experience with a product.
C161480	WATER EFFECT	Water Effect Trial		A type of study designed to evaluate the effects of water on investigational product safety and/or efficacy.
C158283	ADHESION PERFORMANCE	Adhesion Performance Study		A type of study designed to evaluate the strength of the bond between an adhesive and the application surface.
C158284	ALCOHOL EFFECT	Alcohol Effect Study		A type of study designed to evaluate the effects of alcohol on investigational product safety and/or efficacy.
C158290	DOSE PROPORTIONALITY	Dose Proportionality Study		A type of study designed to evaluate the relationship between dose and resulting exposure.
C158289	DOSE FINDING	Dose Finding Study		An early phase clinical study with the objective of determining the optimal dose of an investigational product.
C158288	BIOSIMILARITY	Bioanalarity Study		A type of study designed to evaluate whether a biologic test article is highly similar in function and effect to an existing biologic that has already been clinically tested and approved for use.
C158285	DEVICE-DRUG INTERACTION	Device-Drug Interaction Study		A type of study designed to evaluate the interaction between a device and a drug, where the use of one may affect the disposition, function, efficacy, or safety of the other.
C158286	DRUG-DRUG INTERACTION	Drug-Drug Interaction Study		A type of study designed to evaluate the interaction between drugs, where the use of one may affect the disposition, efficacy, or safety of the other.
C127803	DOSE RESPONSE	Dose Response Study		A study of the effect of dose changes on the efficacy of a drug in order to determine the dose-response relationship and optimal dose of a therapy.
C98729	FOOD EFFECT	Food Effect Study		Studies that are conducted to assess the effect of food on the rate and extent of absorption of a drug, either compared to a fasted state or to a reference drug.
C98791	TOLERABILITY	Tolerability Study		A type of safety study that assesses the degree to which overt adverse effects can be tolerated by the subject.

C66736 - CDISC SDTM Trial Indication Type Terminology

C Code	Submission	Preferred Term	Synonyms	Definition
C15714	BASIC SCIENCE	Basic Research	Basic Science; Basic Science Research	A type of study designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. (ClinicalTrials.gov)
C71486	SCREENING	Screening Study	Screening Trial	A type of study designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). (Clinicaltrials.gov)
C139174	DEVICE FEASIBILITY	Device Feasibility Study		An intervention of a device product is being evaluated to determine the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. (ClinicalTrials.gov)
C49657	PREVENTION	Prevention Study	Preventive Clinical Trial	A type of study designed to identify actions necessary to permanently eliminate or reduce the long-term risk to human life as a result of a particular medication or treatment regimen.
C49656	TREATMENT	Treatment Study		A type of study designed to evaluate intervention(s) for treatment of disease, syndrome or condition.
C15245	HEALTH SERVICES RESEARCH	Health Services Research		A type of study designed to evaluate the delivery, processes, management, organization or financing of health care. (ClinicalTrials.gov)
C49653	DIAGNOSIS	Diagnosis Study	Diagnostic Study	A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.
C71485	SUPPORTIVE CARE	Supportive Care Study	Supportive Care Trial	A type of study designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. (ClinicalTrials.gov)
C49655	MITIGATION	Adverse Effect Mitigation Study		A type of study designed to identify actions necessary to eliminate or reduce the risk to human life or web-being as a result of a particular medication or treatment regimen. (NCI)
C49654	CURE	Cure Study		A type of study designed to evaluate intervention(s) aimed to cure a disease or condition.
C179029	DISEASE MODIFYING	Disease Modifying Treatment Study		A type of study designed to evaluate the effects of treatment(s) intended to cause a change in disease, syndrome, or condition beyond the point of treatment administration.