

CDISC Protocol Controlled Terminology, 2017-09-29

Source: NCI EVS Terminology Resources website: <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
C139020	Clinical Trial Attribute Terminology	Clinical Trial Attribute Terminology	A terminology value set relevant to the attributes of the clinical trial entity.	NA
C66742	NY	No Yes Response	A term that is used to indicate a question with permissible values of yes/no/unknown/not applicable.	No
C132308	Physical Address Attribute Terminology	Physical Address Attribute Terminology	A terminology value set relevant to the attributes of the physical address entity.	NA
C132310	Protocol Entity Terminology	Protocol Entity Terminology	A terminology value set relevant to the entities within a protocol.	NA
C132309	Study Protocol Attribute Terminology	Study Protocol Attribute Terminology	A terminology value set relevant to the attributes of the study protocol entity.	NA
C66736	TINDTP	Trial Intent Type Response	A terminology codelist relevant to the responses for the planned purpose of the therapy, device, or agent under study in the clinical trial.	Yes
C66737	TPHASE	Trial Phase Response	A terminology codelist relevant to the phase, or stage, of the clinical trial.	Yes
C66739	TTYPE	Trial Type Response	A terminology codelist relevant to the type of primary outcome or endpoint that the protocol is designed to evaluate.	Yes

Clinical Trial Attribute Terminology (Clinical Trial Attribute Terminology)

NCI Code: C139020, Codelist extensible: NA

C139020 Clinical Trial Attribute Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C139170	Country of Recruitment		The country in which subjects are located when enrolling in a trial or study. (NCI)	Country of Recruitment
C139171	Date of First Enrollment		Date or date and time of first subject enrollment into a study, as verifiable by a convention that is consistent with authoritative regulatory criteria. Compare with study start. [Modified from ICH E3] (CDISC Glossary)	Date of First Enrollment into Study
C25370	Exclusion Criteria		List of characteristics in a protocol, any one of which may exclude a potential subject from participation in a study. (CDISC glossary)	Exclusion Criteria
C25532	Inclusion Criteria		The criteria in a protocol that prospective subjects must meet to be eligible for participation in a study. NOTE: Exclusion and inclusion criteria define the study population. See also exclusion criteria. (CDISC glossary)	Inclusion Criteria
C127796	Planned Trial Duration	Planned Trial Duration	The approximate period of time over which the clinical trial is expected to occur.	Planned Trial Duration
C94496	Primary Endpoint		The principal endpoint associated with the study or trial.	Primary Endpoint
C139168	Primary Sponsor Name		The name of the entity that is considered the primary sponsor for the trial or study. (NCI)	Primary Study Sponsor Name
C139173	Secondary Endpoint		An auxiliary endpoint associated with the study or trial.	Secondary Endpoint
C139169	Secondary Sponsor Name		The name of the entity that is considered the secondary sponsor for the trial or study. (NCI)	Secondary Study Sponsor Name
C139167	Source of Monetary or Material Support for Study		The major organizations providing monetary or material support for the conduct of the trial, including, but not limited to, funding, design, implementation, data analysis and reporting. (EudraCT)	Source of Monetary or Material Support for Study
C139172	Target Sample Size		The total number of planned participants in a study or trial.	Target Sample Size
C101302	Therapeutic Area	Therapeutic Area	A knowledge field that focuses on research and development of specific treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of an individual. (NCI)	Therapeutic Area
C15787	Trial Design		The detailed planning of a study of the safety, efficacy, or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices, or techniques selected according to predetermined criteria of eligibility and observed for predefined evidence of favorable and unfavorable effects. (NCI)	Clinical Trials Design
C112038	Trial Disease/Condition Indication	Trial Disease/Condition Indication	The condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication
C49652	Trial Intent	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	Clinical Study by Intent
C48281	Trial Phase	Trial Phase Classification	Any defined stage in the lifecycle of a clinical trial.	Trial Phase
C85826	Trial Primary Objective	Trial Primary Objective	The principal purpose of the trial.	Trial Primary Objective
C139166	Trial Registration Indicator		An indication as to whether the clinical trial has been registered with a trial registry system.	Trial Registration Indicator
C85827	Trial Secondary Objective	Trial Secondary Objective	The auxiliary purpose of the trial.	Trial Secondary Objective
C85838	Trial Site	Investigative Site;Investigator Site	Any healthcare organization, institution, facility or provider directly involved in conducting or facilitating a particular clinical trial. (NCI)	Clinical Trial Site
C49660	Trial Type	Trial Scope;Trial Type	The type of primary outcome or endpoint that the protocol is designed to evaluate. (clinicaltrials.gov)	Trial Type

NY (No Yes Response)

NCI Code: C66742, Codelist extensible: No

C66742 NY				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49487	N	No	The non-affirmative response to a question. (NCI)	No
C48660	NA	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	U	U;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C49488	Y	Yes	The affirmative response to a question. (NCI)	Yes

Physical Address Attribute Terminology (Physical Address Attribute Terminology)

NCI Code: C132308, Codelist extensible: NA

C132308 Physical Address Attribute Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C25160	City		A relatively large and/or densely populated area of human habitation with administrative or legal status that may be specified as a component of a postal address.	City
C25464	Country		A sovereign nation occupying a distinct territory and ruled by an autonomous government.	Country
C87189	Geographic Locality		A distinct geographic area in the immediate vicinity of a particular place, such as a city, neighborhood or district.	Locality
C16632	Geographic Region		Any demarcated area of the Earth; may be determined by both natural and human boundaries, such as a state or province.	Geographic Area
C25621	Postal Code		An alphanumeric code assigned to a mail delivery area.	Postal Code
C25632	Province		A sub-division of a country created by the central government for administrative purposes. Provinces are usually, but not always, less autonomous than states, and must obey the laws of the central government.	Province
C87194	State		A sub-division of a country that forms part of a federal union. States are usually, but not always, more autonomous than provinces and may have different laws from the central government.	State
C25690	Street Address		The street name and building number where an entity is located.	Street Address

Protocol Entity Terminology (Protocol Entity Terminology)

NCI Code: C132310, Codelist extensible: NA

C132310 Protocol Entity Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C71104	Clinical Trial		1) 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). 2) A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.(1. modified from ICH E6 Glossary, Directive 2001/20/EC. 2. NIH revised definition 2015) (CDISC Glossary)	Clinical Trial
C25407	Physical Address		A standardized representation of the location of a person, business, building, or organization. (NCI)	Address
C70817	Study 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.	Study Protocol

Study Protocol Attribute Terminology (Study Protocol Attribute Terminology)

NCI Code: C132309, Codelist extensible: NA

C132309 Study Protocol Attribute Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C132344	Alternate Protocol Identifier		A unique code assigned by an affiliated governing body or other organization that identifies a specific protocol (e.g., grant number, national number).	Alternate Protocol Identifier
C132345	Brief Protocol Title	Abbreviated Protocol Title	The short descriptive name for the protocol.	Brief Protocol Title
C132346	Official Protocol Title		The formal descriptive name for the protocol.	Official Protocol Title
C132347	Protocol Amendment		A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)	Protocol Amendment
C51853	Protocol Author		A person who is the writer of a structured research study protocol.	Protocol Author
C115628	Protocol Synopsis	Protocol Scientific Summary	A scientific summary of the key points of the protocol.	Clinical Trial Protocol Synopsis
C94105	Public Protocol Title		The descriptive name of the protocol that is intended for the lay public, written in easily understood language.	Study Protocol Document Version Public Title
C132348	Registry Protocol Identifier		A unique code assigned by a clinical trial registry that identifies a specific protocol.	Registry Protocol Identifier
C132349	Schedule of Activities	Schedule of Events;SoA	A standardized representation of planned clinical trial activities including interventions (e.g., administering drug, surgery) and study administrative activities (e.g., obtaining informed consent, distributing clinical trial material and diaries, randomization) as well as assessments. (CDISC Glossary)	Schedule of Activities
C132350	Scientific Protocol Title		A more extensive descriptive name of the protocol that is intended for medical professionals, written using medical and scientific language.	Scientific Protocol Title
C132351	Sponsor Protocol Identifier	Sponsor Protocol Code;Sponsor Protocol Number	A unique code assigned by the sponsor that identifies a specific protocol.	Sponsor Protocol Identifier
C94108	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.	Study Protocol Version Acronym
C93490	Study Protocol Version		A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	Study Protocol Version
C132352	Study Protocol Version Approval Date		The date on which a version of the protocol was finalized or approved by the sponsor.	Protocol Approval Date

TINDTP (Trial Intent Type Response)

NCI Code: C66736, Codelist extensible: Yes

C66736 TINDTP				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C15714	BASIC SCIENCE		A type of study designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. (ClinicalTrials.gov)	Basic Research
C49654	CURE		A type of study designed to evaluate intervention(s) aimed to cure a disease or condition.	Cure Study
C139174	DEVICE FEASIBILITY		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)	Device Feasibility Study
C49653	DIAGNOSIS		A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.	Diagnosis Study
C15245	HEALTH SERVICES RESEARCH		A type of study designed to evaluate the delivery, processes, management, organization or financing of health care. (ClinicalTrials.gov)	Health Services Research
C49655	MITIGATION		A type of study designed to identify actions necessary to eliminate or reduce the risk to human life or well-being as a result of a particular medication or treatment regimen. (NCI)	Adverse Effect Mitigation Study
C49657	PREVENTION	Prophylaxis Study	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.	Prevention Study
C48262	SCREENING		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)	Trial Screening
C71486	SUPPORTIVE CARE		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)	Supportive Care Study
C49656	TREATMENT	Therapy Trial	A type of study designed to evaluate intervention(s) for treatment of disease, syndrome or condition.	Treatment Study

TPHASE (Trial Phase Response)

NCI Code: C66737, Codelist extensible: Yes

C66737 TPHASE				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C54721	PHASE 0 TRIAL	0;Pre-clinical Trial;Trial Phase 0	First-in-human trials, in a small number of subjects, that are conducted before Phase 1 trials and are intended to assess new candidate therapeutic and imaging agents. The study agent is administered at a low dose for a limited time, and there is no therapeutic or diagnostic intent. NOTE: FDA Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies, January 2006 classifies such studies as Phase 1. NOTE: A Phase 0 study might not include any drug delivery but may be an exploration of human material from a study (e.g., tissue samples or biomarker determinations). [Improving the Quality of Cancer Clinical Trials: Workshop summary-Proceedings of the National Cancer Policy Forum Workshop, improving the Quality of Cancer Clinical Trials (Washington, DC, Oct 2007)] (CDISC glossary)	Phase 0 Trial
C15600	PHASE I TRIAL	1;Trial Phase 1	The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. NOTE: These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase I studies varies with the drug, but is generally in the range of 20 to 80. Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. [After FDA CDER Handbook, ICH E8] (CDISC glossary)	Phase I Trial
C15693	PHASE I/II TRIAL	1-2;Trial Phase 1-2	A class of clinical study that combines elements characteristic of traditional Phase I and Phase II trials. See also Phase I, Phase II.	Phase I/II Trial
C15601	PHASE II TRIAL	2;Trial Phase 2	Phase 2. Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. NOTE: Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. [After FDA CDER Handbook, ICH E8] (CDISC glossary)	Phase II Trial
C15694	PHASE II/III TRIAL	2-3;Trial Phase 2-3	A class of clinical study that combines elements characteristic of traditional Phase II and Phase III trials.	Phase II/III Trial
C49686	PHASE IIA TRIAL	2A;Trial Phase 2A	A clinical research protocol generally referred to as a pilot or feasibility trial that aims to prove the concept of the new intervention in question. (NCI)	Phase IIa Trial
C49688	PHASE IIB TRIAL	2B;Trial Phase 2B	A clinical research protocol generally referred to as a well-controlled and pivotal trial that aims to prove the mechanism of action of the new intervention in question. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind. (NCI)	Phase IIb Trial
C15602	PHASE III TRIAL	3;Trial Phase 3	Phase 3. Studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to confirm efficacy and evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. NOTE: Phase 3 studies usually include from several hundred to several thousand subjects. [After FDA CDER Handbook, ICH E8] (CDISC glossary)	Phase III Trial

C66737 TPHASE				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49687	PHASE IIIA TRIAL	3A; Trial Phase 3A	A classification typically assigned retrospectively to a Phase III trial upon determination by regulatory authorities of a need for a Phase III B trial. (NCI)	Phase IIIa Trial
C49689	PHASE IIIB TRIAL	3B; Trial Phase 3B	A subcategory of Phase III trials done near the time of approval to elicit additional findings. NOTE: Dossier review may continue while associated Phase IIIB trials are conducted. These trials may be required as a condition of regulatory authority approval.	Phase IIIb Trial
C15603	PHASE IV TRIAL	4; Trial Phase 4	Phase 4. Postmarketing (Phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use that may be requested by regulatory authorities in conjunction with marketing approval. NOTE: These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time. [After FDA CDER Handbook, ICH E8] (CDISC glossary)	Phase IV Trial
C47865	PHASE V TRIAL	5; Trial Phase 5	Postmarketing surveillance is sometimes referred to as Phase V.	Phase V Trial

TTYPE (Trial Type Response)

NCI Code: C66739, Codelist extensible: Yes

C66739		TTYPE		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49664	BIO-AVAILABILITY		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)	Bioavailability Study
C49665	BIO-EQUIVALENCE		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)	Therapeutic Equivalency Study
C49653	DIAGNOSIS		A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.	Diagnosis Study
C127803	DOSE RESPONSE		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.	Dose Response Study
C49666	EFFICACY		A study of the relative therapeutic efficacy of treatment of a disease. Usually this is a Phase II or III study. (NCI)	Efficacy Study
C98729	FOOD EFFECT		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.	Food Effect Study
C120842	IMMUNOGENICITY		A study that assesses an agent's ability to provoke an immune response.	Immunogenicity Study
C49662	PHARMACODYNAMIC		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)	Pharmacodynamic Study
C39493	PHARMACOECONOMIC		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)	Pharmacoeconomic Study
C129001	PHARMACOGENETIC		A study that assesses variation in DNA sequence, usually within a single gene, and its effect on drug response.	Pharmacogenetic Study
C49661	PHARMACOGENOMIC		A study that identifies or assesses variations within the entire genome, including DNA, RNA, or transcriptional elements, and its effects on drug response.	Pharmacogenomic Study
C49663	PHARMACOKINETIC		A study of the process by which a drug is absorbed, distributed, metabolized, and eliminated by the body. (NCI)	Pharmacokinetic Study
C49657	PREVENTION	Prophylaxis Study	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.	Prevention Study
C49667	SAFETY		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.	Safety Study
C98791	TOLERABILITY		A type of safety study that assesses the degree to which overt adverse effects can be tolerated by the subject.	Tolerability Study
C49656	TREATMENT	Therapy Trial	A type of study designed to evaluate intervention(s) for treatment of disease, syndrome or condition.	Treatment Study