CDISC Protocol Controlled Terminology, 2018-09-28

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
C142191	Clinical Study Attribute Terminology	Clinical Study Attribute Terminology	A terminology value set relevant to the attributes of the clinical study entity.	NA
C139020	Clinical Trial Attribute Terminology	Clinical Trial Attribute Terminology	A terminology value set relevant to the attributes of the clinical trial entity.	NA
C99076	INTMODEL	Intervention Model Response	A terminology codelist relevant to the trial design developed to compare treatment groups.	Yes
C66742	NY	No Yes Response	A term that is used to indicate a question with permissible values of yes/no/unknown/not applicable.	No
C127259	OBSSMO	Observational Study Model	The terminology relevant to the trial design for observational studies.	Yes
C132308	Physical Address Attribute Terminology	Physical Address Attribute Terminology	A terminology value set relevant to the attributes of the physical address entity.	NA
C154681	Protocol Contact Role Response	Protocol Contact Role Response	The terminology relevant to the role that the individual or entity plays with respect to being a contact within a study protocol.	NA
C132310	Protocol Entity Terminology	Protocol Entity Terminology	A terminology value set relevant to the entities within a protocol.	NA
C147069	Randomization Type Response	Randomization Type Response	A terminology codelist relevant to the types of randomization schemas associated with a randomized controlled trial.	NA
C154682	Study Contact Information Attribute Terminology	Study Contact Information Attribute Terminology	A terminology value set relevant to the attributes of the study contact information.	NA
C147066	Study Design Attribute Terminology	Study Design Attribute Terminology	A terminology value set relevant to the attributes of the study design entity.	NA
C132309	Study Protocol Attribute Terminology	Study Protocol Attribute Terminology	A terminology value set relevant to the attributes of the study protocol entity.	NA
C147067	Study Purpose Response	Study Purpose Response	A terminology codelist relevant to the reason(s) or intention(s) for the execution of an interventional or non-interventional clinical study.	NA
C99077	STYPE	Study Type Response	A terminology codelist relevant to the role the study plays in determining the interventions a subject receives.	No
C147068	Subject Allocation Response	Subject Allocation Response	A terminology codelist for the method of assigning subjects to groups or categories within a clinical study.	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 Study Attribute Terminology (Clinical Study Attribute Terminology)

NCI Code: C142191, Codelist extensible: NA

C142191	Clinical Study Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C70794	Primary Clinical Study Sponsor		The individual, organization, group or other legal person taking responsibility for securing the arrangements to initiate and/or manage a study (including arrangements to ensure that the study design meets appropriate standards and to ensure appropriate conduct and reporting). In commercial trials, the primary sponsor is normally the main applicant for regulatory authorization to begin the study. It may or may not be the main funder. (NCI)	Primary Clinical Study Sponsor
C70795	Secondary Clinical Study Sponsor		Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed to take on all the responsibilities of sponsorship jointly with the primary sponsor; or to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or to act as the sponsor's legal representative in relation to some or all of the study sites; or to take responsibility for the accuracy of study registration information submitted.	Secondary Clinical Study Sponsor
C71473	Study Activity		An action, undertaking, or event, which is anticipated to be performed or observed, or was performed or observed, according to the study protocol during the execution of the study.	Study Activity
C94122	Study Rationale	Study Purpose	A statement describing the overall rationale of the study. This field describes the contribution of this study to product development, i.e., what knowledge is being contributed from the conduct of this study.	Study Protocol Version Purpose Statement
C93682	Study Schematic Diagram	Study Schema	A diagram that outlines the decision points (e.g. randomization, response evaluation) that define the different paths a subject could take through the study. This is typically a block diagram and may include epochs, timing of randomization, treatment arms, and duration of treatments.	Study Schematic
C142175	Study Type	Study Type	Describes the role the study plays in determining the interventions a subject receives.	Study Type

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

INTMODEL (Intervention Model Response)

NCI Code: C99076, Codelist extensible: Yes

C99076	INTMODEL			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C82637	CROSS-OVER		Participants receive one of two or more alternative intervention(s) during the initial epoch of the study and receive other intervention(s) during the subsequent epoch(s) of the study.	Crossover Study
C82638	FACTORIAL		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.	Factorial Study
C82639	PARALLEL		Participants are assigned to one of two or more treatment groups in parallel for the duration of the study.	Parallel Study
C142568	SEQUENTIAL		Groups of participants are assigned to receive interventions based on prior milestones being reached in the study. (clinicaltrials.gov)	Group Sequential Design
C82640	SINGLE GROUP		All trial participants are assigned to a single treatment group for the duration of the study.	Single Group Study

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;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C49488	Y	Yes	The affirmative response to a question. (NCI)	Yes

OBSSMO (Observational Study Model)

NCI Code: C127259, Codelist extensible: Yes

C127259	OBSSMO			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C15197	CASE CONTROL		A study that compares groups of people with generally similar characteristics, those with the condition under study (case) and those without the condition under study (control).	Case-Control Study
C127779	CASE CROSSOVER		A study in which the subject characteristics of the case, immediately prior to disease onset (sometimes called the hazard period), are compared to characteristics of same case at a prior time (i.e., control period). (ClinicalTrials.gov)	Observational Case-Crossover Study
C15362	CASE ONLY		A study in which the subject with the condition under study (the case) is compared against a theoretical/historical model of distribution that serves as a control.	Case Study
C15208	COHORT		A study in which subjects are grouped based on a predefined personal or administrative characteristic.	Cohort Study
C127780	ECOLOGIC OR COMMUNITY		A study in which geographically distinct study populations are compared with respect to a particular outcome.	Ecologic or Community Based Study
C15407	FAMILY BASED		A study in which related or non-related family members are compared with respect to a particular outcome.	Family Study

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 Contact Role Response (Protocol Contact Role Response)

NCI Code: C154681, Codelist extensible: NA

C154681	Protocol Contact Role Response			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C154709	Biostatistician		A person who is responsible for the statistical aspects of the clinical or pre-clinical study. (NCI)	Biostatistician
C154708	Clinical Informaticist	Clinical Informatician	An individual that designs, implements, evaluates and/or analyzes information technology in a healthcare or research setting. (NCI)	Clinical Informaticist
C51811	Clinical Research Coordinator	CRC	A person to whom a clinical investigator delegates routine administrative requirements of a protocol. The duties and responsibilities of a clinical research coordinator may vary across different infrastructures. Generally, the coordinator manages the subject's clinical trial participation and provides a vital linkage between the subject, the investigator, and the sponsor. (NCI)	Clinical Coordinator
C127526	Contact for Public Queries		The study contact person who is responsible for questions from the public.	Public Queries Study Contact
C51818	Coordinating Investigator		An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multi-center trial. While a single-center study would not include a coordinating investigator, the investigator at the site would fulfill the same responsibilities as a principal investigator. (after ICH E6)	Coordinating Investigator
C51820	Data Manager		An individual who is responsible for the development and implementation of architectures, policies and procedures for the effective management of data across its business lifecycle.	Data Manager
C25936	Investigator		A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at the trial site, the investigator is the responsible leader of the team and may be called the principle investigator.	Investigator
C127532	Legal Representative for the Study		An individual with expertise in the law who provides legal counsel and representation for a study.	Legal Representative for the Study
C51836	Medical Monitor		A sponsor representative who has medical authority for the evaluation of the safety aspects of a clinical trial. (CDISC Glossary)	Medical Monitor
C154706	National Coordinating Investigator		In the case of a multinational study, a person who has the responsibilities of the sponsor of the study in his/her country and will be responsible for the coordination of the principal investigators at different sites within that member state. (EMA)	National Coordinating Investigator
C70794	Primary Sponsor		The individual, organization, group or other legal person taking responsibility for securing the arrangements to initiate and/or manage a study (including arrangements to ensure that the study design meets appropriate standards and to ensure appropriate conduct and reporting). In commercial trials, the primary sponsor is normally the main applicant for regulatory authorization to begin the study. It may or may not be the main funder. (NCI)	Primary Clinical Study Sponsor
C19924	Principal Investigator		A person who has the primary responsibility for the conduct of a clinical study and study-related personnel at a study site. While a single-center study would not include a coordinating investigator, the investigator at the site would fulfill the same responsibilities as a principal investigator.	Principal Investigator
C70795	Secondary Sponsor		Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed to take on all the responsibilities of sponsorship jointly with the primary sponsor; or to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or to act as the sponsor's legal representative in relation to some or all of the study sites; or to take responsibility for the accuracy of study registration information submitted.	Secondary Clinical Study Sponsor
C70793	Sponsor	Clinical Study Sponsor;Sponsor;Study Sponsor	An entity that is responsible for the initiation, management, and/or financing of a clinical study.	Clinical Study Sponsor

C154681	Protocol Contact Role Response			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C51878	Study Chair	Study Director	A person who has overall responsibility for the technical conduct of a study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control. (FDA)	Study Chair
C54622	Subinvestigator		Any member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). (ICH)	Subinvestigator
C154707	Technical Lead		An individual who is responsible for the delivery of technical aspects of a project. (NCI)	Technical Lead

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**
C15206	Clinical Study		A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [ClinicalTrials.gov] See also clinical trial. (CDISC Glossary)	Clinical Study
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
C154705	Study Contact Information		Information regarding the means of contacting a person or group that performs a function within a clinical study.	Study Contact Information
C15320	Study Design		A plan detailing how a study will be performed in order to represent the phenomenon under examination, to answer the research questions that have been asked, and informing the statistical approach.	Study Design
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

Randomization Type Response (Randomization Type Response)

NCI Code: C147069, Codelist extensible: NA

C147069	Randomization Type Response			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C147126	Adaptive Randomization		A type of randomization schema in which the group assignment probability of a subject is adjusted based on the group assignments of those subjects already randomized in the trial. (NCI)	Adaptive Randomization
C147127	Block Randomization	Constrained Randomization	A type of adaptive randomization in which a pre-specified number of subjects is assigned to a block containing the same pre-specified number of balanced group assignments in random order.	Block Randomization
C147143	Minimization Randomization	Covariate Adaptive Randomization	A type of adaptive randomization in which the subject is assigned to the treatment group in an attempt to minimize imbalances in the number of subjects for each stratification covariate across treatment groups.	Minimization Randomization
C147144	Simple Randomization	Unrestricted Randomization	A type of randomization schema in which each subject has the same chance of being randomized into any one group as all other subjects. (NCI)	Simple Randomization
C147145	Stratified Randomization		A type of block randomization in which subjects are stratified into groups based on prognostic variables and then randomized into balanced treatment groups. (NCI)	Stratified Randomization
C142743	Unequal Randomization		A type of randomization schema in which unequal numbers of subjects are purposely assigned to multiple treatment groups.	Unequal Randomization

Study Contact Information Attribute Terminology (Study Contact Information Attribute Terminology)

NCI Code: C154682, Codelist extensible: NA

C154682	Study Contact Information Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25354	Academic Degree		An academic rank conferred by a college, university, or other postsecondary education institution as official recognition for the successful completion of a program of studies.	Academic Degree
C25191	Contact Name	Individual's Name;Person Name	A word or group of words indicating the identity of a person usually consisting of a first (personal) name and a last (family) name with an optional middle name. In some cultural traditions the family name comes first.	Person Name
C42775	E-mail Address	Email Address	A text string identifier for a location to which electronic mail can be delivered. (NCI)	E-mail Address
C42879	Fax Number	Facsimile Number	A telephone number that is used for identifying a specific fax machine in a telephone network.	Fax Number
C154704	Organizational Affiliation		The name of the organization or entity that the person or group has an established relationship with.	Organizational Affiliation Name
C25407	Physical Address		A standardized representation of the location of a person, business, building, or organization. (NCI)	Address
C48835	Role		The usual or expected function of something; the part something plays in an action or event. (NCI)	Role
C40978	Telephone Number	Phone Number	A sequence of decimal digits (0-9) that is used for identifying a specific telephone line or other device in a telephone network.	Telephone Number

Study Design Attribute Terminology (Study Design Attribute Terminology)

NCI Code: C147066, Codelist extensible: NA

C147066	Study Design Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49068	Blinding	Masking	A process to limit bias by preventing subjects and/ or study personnel from identifying which treatments or procedures are administered, or from learning the results of tests and measures undertaken as part of a clinical investigation. (CDISC Glossary)	Blinded
C98746	Interventional Study Design	Intervention Model	The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov)	Intervention Model
C147138	Observational Study Design	Observation Model	The general design of the strategy for identifying and following up with participants during observational studies. (clinicaltrials.gov)	Observational Study Model
C147139	Overall Study Design	Overall Design;Study Design Description;Study Design Overview;Summary of Study Design	Summary description of the overall study plan and design, should include treatments studied, population studied, level and method of blinding/unmasking, kind of controls, method of assignment to treatment, sequence and duration of study periods, any safety, data monitoring or special steering or evaluation committees, and interim analyses. (ICH E3)	Study Design Description
C98771	Planned Number of Arms	Planned Number of Arms	The planned number of intervention groups.	Planned Number of Arms
C147137	Planned Number of Cohorts		The planned number of study groups.	Planned Number of Cohorts
C49692	Planned Number of Subjects	Anticipated Enrollment;Planned Enrollment;Planned Number of Subjects;Target Enrollment	The planned number of subjects to be entered in a clinical trial. (NCI)	Planned Subject Number
C147140	Randomization Type		The type of randomization method used to assign subjects to treatment groups or cohorts. (NCI)	Randomization Method
C25689	Stratification		Grouping defined by important prognostic factors measured at baseline. (ICH E9)	Stratification
C16153	Stratification Factor	Stratification Factor	Selected factors that are used during randomization to ensure there is balance of these factors across all subjects within each arm of a study. The subject level values of these factors may be used as fixed effects in statistical models and for sensitivity analyses.	Stratification Factors
C142705	Study Design Rationale		Reason(s) for choosing the study design. This may include reasons for the choice of control or comparator, as well as the scientific rationale for the study design.	Study Design Rationale
C142668	Study Hypothesis		A supposition or proposal made to explain certain observations or facts, which requires further investigation or exploration within a clinical study. (NCI)	Research Hypothesis
C147141	Study Primary Purpose		The principal reason or intention for the execution of an interventional or non-interventional clinical study. (NCI)	Study Primary Purpose
C147142	Study Secondary Purpose		The ancillary reason or intention for the execution of an interventional or non-interventional clinical study. (NCI)	Study Secondary Purpose
C52580	Subject Allocation		The process of assigning subjects to particular treatment groups or cohorts in a clinical study.	Allocation
C49658	Trial Blinding Schema	Trial Blinding Schema	The type of experimental design used to describe the level of awareness of the clinical trial subjects and/or investigators of the intervention(s) that they are receiving and/or administering.	Trial Blinding Schema

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

Study Purpose Response (Study Purpose Response)

NCI Code: C147067, Codelist extensible: NA

C147067	Study Purpose Response			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C15714	Basic Science	Basic Research	A type of study designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. (ClinicalTrials.gov)	Basic Research
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
C15220	Diagnosis	Diagnostic	The investigation, analysis and recognition of the presence and nature of disease, condition, or injury from expressed signs and symptoms; also, the scientific determination of any kind; the concise results or summary of such an investigation. (NCI)	Diagnosis
C147146	Exploratory Research		Any action or process to perform research on a hypothetical or theoretical idea in order to determine whether the phenomena is new (which may lead to additional studies) or can be explained by an existing and well-substantiated theory. (NCI)	Exploratory Research
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
C147147	Hypothesis Generation		Any action or process to create a tentative proposal to explain certain observations or facts, and which requires further investigation to be verified. (NCI)	Hypothesis Generation
C15843	Prevention		Any action or response to modify or stop the development of a disease.	Preventive Intervention
C15419	Screening		Any action or process to identify a condition, or risk factors for a condition, in humans who are not yet known to have the condition or risk factor. (clinicaltrials.gov)	Disease Screening
C15747	Supportive Care		Any action or process to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. (clinicaltrials.gov)	Supportive Care
C70742	Treatment		Any action or process to improve or remedy a syndrome, disease, or condition.	Treat

STYPE (Study Type Response)

NCI Code: C99077, Codelist extensible: No

C99077	STYPE			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C98722	EXPANDED ACCESS		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. Expanded Access studies include individual-patient IND, treatment IND, compassionate use, emergency use or continued access.	Expanded Access Study
C98388	INTERVENTIONAL		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.	Interventional Study
C16084	OBSERVATIONAL		Studies in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.	Observational Study
C129000	PATIENT REGISTRY		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)	Patient Registry Study

Subject Allocation Response (Subject Allocation Response)

NCI Code: C147068, Codelist extensible: NA

C147068	Subject Allocation Response			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C93043	Nonrandomized		Participants are expressly assigned to intervention groups through a non-random method. (clinicaltrials.gov)	Nonrandomized Clinical Trial
C48660	Not Applicable	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C25196	Randomized	Trial is Randomized	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. NOTE: Unequal randomization is used to allocate subjects into groups at a differential rate; for example, three subjects may be assigned to a treatment group for every one assigned to the control group. [ICH E6 1.48] See also balanced study. (CDISC glossary)	Randomization

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	Basic Research	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
C71485	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)	Screening Study
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