

## CDISC Protocol Controlled Terminology, 2024-09-27

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
C179587	<a href="#">Biological Sample Attribute Terminology</a>	Biological Sample Attribute Terminology	A terminology value set relevant to the attributes of the biological sample.	
C201266	<a href="#">Biomarker Attribute Terminology</a>	Biomarker Attribute Terminology	A terminology value set relevant to the attributes of the biomarker entity.	
C201267	<a href="#">Biomarker Category Value Set Terminology</a>	Biomarker Category Value Set Terminology	The terminology relevant to the categorization of the biomarker relevant to the study.	
C142191	<a href="#">Clinical Study Attribute Terminology</a>	Clinical Study Attribute Terminology	A terminology value set relevant to the attributes of the clinical study entity.	
C139020	<a href="#">Clinical Trial Attribute Terminology</a>	Clinical Trial Attribute Terminology	A terminology value set relevant to the attributes of the clinical trial entity.	
C170440	<a href="#">Endpoint Attribute Terminology</a>	Endpoint Attribute Terminology	A terminology value set relevant to the attributes of the endpoint entity.	
C170441	<a href="#">Endpoint Type Value Set Terminology</a>	Endpoint Type Value Set Terminology	The terminology relevant to the type of endpoint for the study.	
C187682	<a href="#">Expanded Access Attribute Terminology</a>	Expanded Access Attribute Terminology	A terminology value set relevant to the attributes of the expanded access entity.	
C187683	<a href="#">Expanded Access Study Type Value Set Terminology</a>	Expanded Access Study Type Value Set Terminology	The terminology relevant to the type of expanded access study.	
C184334	<a href="#">Informed Consent Attribute Terminology</a>	Informed Consent Attribute Terminology	A terminology value set relevant to the attributes of the informed consent.	
C177906	<a href="#">Ingredient Attribute Terminology</a>	Ingredient Attribute Terminology	A terminology value set relevant to the attributes of the ingredient.	
C177907	<a href="#">Ingredient Type Value Set Terminology</a>	Ingredient Type Value Set Terminology	The terminology relevant to the identification of the kind of ingredient.	
C177905	<a href="#">Intervention Attribute Terminology</a>	Intervention Attribute Terminology	A terminology value set relevant to the attributes of the intervention.	
C99076	<a href="#">INTMODEL</a>	Intervention Model Response	A terminology codelist relevant to the general design of the strategy for assigning interventions to participants in a clinical study.	Yes
C99078	<a href="#">INTTYPE</a>	Intervention Type Response	A terminology codelist relevant to the kind of product or procedure studied in a trial.	No
C66742	<a href="#">NY</a>	No Yes Response	A term that is used to indicate a question with permissible values of yes/no/unknown/not applicable.	No
C127259	<a href="#">OBSSMO</a>	Observational Study Model	A terminology codelist relevant to the trial design developed to compare biomedical and/or health outcomes in pre-defined and non-assigned groups of individuals.	Yes
C165641	<a href="#">Outcome Measure Attribute Terminology</a>	Outcome Measure Attribute Terminology	A terminology value set relevant to the attributes of the outcome measure entity.	
C170442	<a href="#">Outcome Measure Type Value Set Terminology</a>	Outcome Measure Type Value Set Terminology	The terminology relevant to the type of outcome measure for the study.	
C165642	<a href="#">Oversight Entity Value Set</a>	Oversight Entity Value Set	The terminology relevant to the type of oversight entity for the study.	
C147068	<a href="#">Participant Allocation Value Set</a>	Participant Allocation Value Set	A terminology codelist for the method of assigning participants, or subjects, to groups or categories within a clinical study.	
C199649	<a href="#">Pharmacology Attribute Terminology</a>	Pharmacology Attribute Terminology	A terminology value set relevant to the attributes of the pharmacology entity.	
C132308	<a href="#">Physical Address Attribute Terminology</a>	Physical Address Attribute Terminology	A terminology value set relevant to the attributes of the physical address entity.	
C181167	<a href="#">Protocol Amendment Attribute Terminology</a>	Protocol Amendment Attribute Terminology	A terminology value set relevant to the attributes of the protocol amendment.	
C154681	<a href="#">Protocol Contact Role Value Set</a>	Protocol Contact Role Value Set	The terminology relevant to the role that the individual or entity plays with respect to being a contact within a study protocol.	
C132310	<a href="#">Protocol Entity Terminology</a>	Protocol Entity Terminology	A terminology value set relevant to the entities within a protocol.	
C181168	<a href="#">Protocol Statement Attribute Terminology</a>	Protocol Statement Attribute Terminology	A terminology value set relevant to the attributes of the protocol statement.	
C147069	<a href="#">Randomization Type Value Set</a>	Randomization Type Value Set	A terminology codelist relevant to the types of randomization schemas associated with a randomized controlled trial.	
C184333	<a href="#">Reference Attribute Terminology</a>	Reference Attribute Terminology	A terminology value set relevant to the attributes of the reference.	
C190866	<a href="#">Study Activity Attribute Terminology</a>	Study Activity Attribute Terminology	A terminology value set relevant to the attributes of the study activity entity.	
C172329	<a href="#">Study Arm Attribute Terminology</a>	Study Arm Attribute Terminology	A terminology value set relevant to the attributes of the study arm entity.	
C174222	<a href="#">Study Arm Type Value Set Terminology</a>	Study Arm Type Value Set Terminology	The terminology relevant to the identification of the kind of arm.	Yes
C189268	<a href="#">Study Blinding and Unblinding Attribute Terminology</a>	Study Blinding and Unblinding Attribute Terminology	A terminology value set relevant to the attributes of the study blinding and unblinding entity.	
C154682	<a href="#">Study Contact Information Attribute Terminology</a>	Study Contact Information Attribute Terminology	A terminology value set relevant to the attributes of the study contact information entity.	
C147066	<a href="#">Study Design Attribute Terminology</a>	Study Design Attribute Terminology	A terminology value set relevant to the attributes of the study design entity.	
C163026	<a href="#">Study Monitoring Attribute Terminology</a>	Study Monitoring Attribute Terminology	A terminology value set relevant to the attributes of the study monitoring entity.	
C165640	<a href="#">Study Oversight Entity Attribute Terminology</a>	Study Oversight Entity Attribute Terminology	A terminology value set relevant to the attributes of the study oversight entity.	
C160921	<a href="#">Study Population Attribute Terminology</a>	Study Population Attribute Terminology	A terminology value set relevant to the attributes of the study population entity.	
C177904	<a href="#">Study Product Administration Attribute</a>	Study Product Administration Attribute	A terminology value set relevant to the attributes of the study product administration.	
C174220	<a href="#">Study Product Attribute Terminology</a>	Study Product Attribute Terminology	A terminology value set relevant to the attributes of the study product.	
C174221	<a href="#">Study Product Type Value Set Terminology</a>	Study Product Type Value Set Terminology	The terminology relevant to the identification of the kind of study product.	
C132309	<a href="#">Study Protocol Attribute Terminology</a>	Study Protocol Attribute Terminology	A terminology value set relevant to the attributes of the study protocol entity.	
C147067	<a href="#">Study Purpose Value Set</a>	Study Purpose Value Set	A terminology codelist relevant to the reason(s) or intention(s) for the execution of an interventional or non-interventional clinical study.	
C185851	<a href="#">Study Subject Discontinuation Attribute Terminology</a>	Study Subject Discontinuation Attribute Terminology	A terminology value set relevant to the attributes of the subject discontinuation.	
C99077	<a href="#">STYPE</a>	Study Type Response	A terminology codelist relevant to the nature of the investigation for which study information is being collected.	No
C185850	<a href="#">Subject Replacement Attribute Terminology</a>	Subject Replacement Attribute Terminology	A terminology value set relevant to the attributes of the subject replacement.	
C197998	<a href="#">Substudy Attribute Terminology</a>	Substudy Attribute Terminology	A terminology value set relevant to the attributes of the substudy entity.	
C66735	<a href="#">TBLIND</a>	Trial Blinding Schema Response	A terminology codelist relevant to the type of experimental design used to describe the level of awareness of the study subjects and/ or study personnel as it relates to the respective intervention(s) or assessments being observed, received or administered.	Yes
C66736	<a href="#">TINDTP</a>	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	<a href="#">TPHASE</a>	Trial Phase Response	A terminology codelist relevant to a step in the clinical research and development of a therapy from initial clinical trials to post-approval studies.	Yes
C66739	<a href="#">TTYPE</a>	Trial Type Response	A terminology codelist relevant to the type of primary outcome or endpoint that the protocol is designed to evaluate.	Yes

**Biological Sample Attribute Terminology (Biological Sample Attribute Terminology)**

NCI Code: C179587, Codelist extensible:

C179587		Biological Sample Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C179744	Biological Sample Accountability		The activities describing the documentation of the storage, inventory tracking, and disposition of the biological sample.	Biospecimen Handling Accountability Record
C70700	Biological Sample Collection Method		A description of the methodology by which biological material is obtained from a subject.	Biospecimen Collection Method
C178869	Biological Sample Collection Timing		A description of the timing for the collection of a biological sample, in relation to a study-specific event or time period.	Biospecimen Collection Time
C70945	Biological Sample Collection		The activities describing biological sample collection, such as specimen type, timing and methodology.	Biospecimen Collection
C179745	Biological Sample Handling	Biospecimen Handling; Handling of Biological Samples; Handling of Biological Specimens	A description of the management of biological sample handling, including methods of collection, processing, shipping, and storage.	Biospecimen Handling
C179746	Biological Sample Preparation		The activities describing how the biological sample is made ready for storage, processing, and/or analysis.	Biospecimen Preparation
C181231	Biological Sample Retention	Biospecimen Retention	A textual description as to whether and/or how biological samples are retained for research purposes.	Biological Sample Retention Description
C179747	Biological Sample Shipping	Biological Sample Shipment; Biological Sample Transport	The activities describing the logistical considerations for transporting a biological sample from the sender to the receiver.	Biospecimen Shipping
C179748	Biological Sample Storage		The activities describing the physical or environmental conditions under which the biological sample is maintained.	Biospecimen Storage

### Biomarker Attribute Terminology (Biomarker Attribute Terminology)

NCI Code: C201266, Codelist extensible:

C201266 NCI Code	Biomarker Attribute Terminology		CDISC Definition	NCI Preferred Term
	CDISC Submission Value	CDISC Synonym		
C201359	Biomarker Category		A characterization or classification of the biomarker.	Biomarker Category
C164706	Biomarker Name	Type of Biomarker	The literal identifier (i.e., distinctive designation) of the biomarker.	Biomarker Name

**Biomarker Category Value Set Terminology (Biomarker Category Value Set Terminology)**

NCI Code: C201267, Codelist extensible:

C201267		Biomarker Category Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C201361	Diagnostic Biomarker		A biomarker used to detect or confirm presence of a disease or condition of interest or to identify individuals with a subtype of the disease. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Diagnostic Biomarker
C201362	Monitoring Biomarker		A biomarker measured repeatedly for assessing status of a disease or medical condition or for evidence of exposure to (or effect of) a medical product or an environmental agent. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Monitoring Biomarker
C201365	Pharmacodynamic Biomarker		A response biomarker that indicates biologic activity of a medical product or environmental agent without necessarily drawing conclusions about efficacy or disease outcome or necessarily linking this activity to an established mechanism of action. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Pharmacodynamic Biomarker
C201364	Predictive Biomarker		A biomarker used to identify individual who are more likely than similar individuals without the biomarker to experience a favorable or unfavorable effect from exposure to a medical product or an environmental agent. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Predictive Biomarker
C201363	Prognostic Biomarker		A biomarker used to identify likelihood of a clinical event, disease recurrence, or progression in patients who have the disease or medical condition of interest. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Prognostic Biomarker
C201303	Response Biomarker		A biomarker used to show that a biological response, potentially beneficial or harmful, has occurred in an individual who has been exposed to a medical product or an environmental agent. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Response Biomarker
C201367	Safety Biomarker		A biomarker measured before or after an exposure to a medical product or an environmental agent to indicate the likelihood, presence, or extent of toxicity as an adverse effect. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Safety Biomarker
C201366	Surrogate Endpoint Biomarker		A response biomarker that is an endpoint used in clinical trials as a substitute for a direct measure of how a patient feels, functions, or survives. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Surrogate Endpoint Biomarker
C201360	Susceptibility Biomarker	Risk Biomarker	A biomarker that indicates the potential for developing a disease or medical condition in an individual who does not currently have clinically apparent disease or the medical condition. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Susceptibility Biomarker

**Clinical Study Attribute Terminology (Clinical Study Attribute Terminology)**

NCI Code: C142191, Codelist extensible:

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 participant 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; Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	Study Type

## Clinical Trial Attribute Terminology (Clinical Trial Attribute Terminology)

NCI Code: C139020, Codelist extensible:

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 participants are located when enrolling in a trial or study.	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. [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 makes a potential subject ineligible to participate in a study.	Exclusion Criteria	
C25532	Inclusion Criteria		The criteria in a protocol that prospective subjects must meet to be eligible to participate in a study.	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	
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	
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 categorization of a disease, disorder, or other condition based on common characteristics and often associated with a medical specialty focusing on research and development of specific therapeutic interventions for the purpose of treatment and prevention.	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	Indication for Use; Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	A narrative representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication	
C163559	Trial Exploratory Objective	Study Exploratory Objective; Trial Exploratory Objective	Additional scientific question(s) within the study that enable further discovery research, beyond the primary and secondary objectives.	Trial Exploratory Objective	
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; Trial Phase Classification	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]	Trial Phase	
C85826	Trial Primary Objective	Study Primary Objective; Trial Primary Objective	The main scientific question(s) the study is designed to answer. (CDISC Glossary)	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	Study Secondary Objective; Trial Secondary Objective	The supportive or ancillary scientific question(s) the study is designed to answer. (CDISC Glossary)	Trial Secondary Objective	
C85838	Trial Site	Investigative Site; Investigator Site	A physical location (e.g., healthcare organization, institution, or facility) directly involved in conducting or facilitating a particular clinical trial.	Clinical Trial Site	
C49660	Trial Type	Trial Scope; Trial Type	The nature of the interventional study for which information is being collected.	Trial Type	

## Endpoint Attribute Terminology (Endpoint Attribute Terminology)

NCI Code: C170440, Codelist extensible:

C170440 NCI Code	Endpoint Attribute Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C170557	Endpoint Type		A characterization or classification of the defined variable intended to reflect an outcome measure of interest that is statistically analyzed to address a particular research question.	Study Endpoint Type
C170558	Justification for Endpoint		The rationale or explanation for why each study endpoint was chosen.	Justification for Study Endpoint

## Endpoint Type Value Set Terminology (Endpoint Type Value Set Terminology)

NCI Code: C170441, Codelist extensible:

C170441		Endpoint Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C170561	Composite Endpoint	Combined Endpoint	Endpoint(s) constructed from two or more endpoints that represents an overall clinically relevant measure of clinical benefit.	Composite Endpoint
C170560	Direct Endpoint		Endpoint(s) used in clinical studies to directly measure how a patient feels, functions, or survives. These endpoint(s) in themselves represent or characterize the clinical outcome of interest. (FDA: <a href="https://www.fda.gov/media/84987/download">https://www.fda.gov/media/84987/download</a> )	Direct Endpoint
C170559	Exploratory Endpoint		Endpoint(s) that may include clinically important events that are expected to occur too infrequently to show a treatment effect or endpoints that for other reasons are thought to be less likely to show an effect but are included to explore new hypotheses. (After FDA-NIH Protocol Template)	Exploratory Endpoint
C94496	Primary Endpoint		Endpoint(s) of greatest importance that is the basis for concluding whether the study met its objective(s) and provides a clinically relevant, valid, and reliable measure of the primary objective(s). (After FDA-NIH Protocol Template)	Primary Endpoint
C139173	Secondary Endpoint		Endpoint(s) that may provide supportive information about the effect of the study intervention(s) on the primary endpoint or demonstrate additional effects on the disease or condition. (After FDA-NIH Protocol Template)	Secondary Endpoint
C68772	Surrogate Endpoint		An endpoint that is used in clinical trials as a substitute for a direct measure of how a patient feels, functions, or survives. A surrogate endpoint does not measure the clinical benefit of primary interest in and of itself, but rather is expected to predict that clinical benefit or harm based on epidemiologic, therapeutic, pathophysiologic, or other scientific evidence. (NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource)	Surrogate Endpoint



## Expanded Access Attribute Terminology (Expanded Access Attribute Terminology)

NCI Code: C187682, Codelist extensible:

C187682	Expanded Access Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C187705	Expanded Access Study Type		A characterization or classification of the 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 Study Type

**Expanded Access Study Type Value Set Terminology (Expanded Access Study Type Value Set Terminology)**

NCI Code: C187683, Codelist extensible:

C187683		Expanded Access Study Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C187706	Continued Access		Expanded access to an investigational medical product (drug, biologic, or medical device) for treatment use in subjects after the controlled clinical trial has been completed and while the marketing application is being prepared by the sponsor or reviewed by the regulator.	Continued Access Study
C182399	Individual Patient IND	Individual Basis Treatment;Single Patient IND	Expanded access to an investigational medical product (drug, biologic, or medical device) for treatment use by a single patient submitted under a new Investigational New Drug (IND) application. (FDA: Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers Guidance for Industry, June 2016)	Compassionate Single Patient Indicator
C187707	Treatment IND	Expanded Access Treatment IND;Large Population Treatment IND	Expanded access to an investigational medical product (drug, biologic, or medical device) for treatment use by a large (widespread) population, submitted under a new Investigational New Drug (IND) application. (FDA: Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers Guidance for Industry, June 2016)	Treatment Investigational New Drug Study

## Informed Consent Attribute Terminology (Informed Consent Attribute Terminology)

NCI Code: C184334, Codelist extensible:

C184334		Informed Consent Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C161418	Assent	Informed Assent	Assent given by a minor or adult who is unable to give informed consent on their own behalf, to participate in a clinical trial. Assent must be accompanied by consent from a parent or legal guardian for full participation in the study.	Informed Assent
C16468	Informed Consent Form	Informed Consent Document	A formal document used during the informed consent process explaining the potential risks and benefits of participation in a study and the rights and responsibilities of the parties involved, in a manner that is understandable to the subject or their legally authorized representative.	Consent Form
C184390	Informed Consent Process	Informed Consent Procedure	The procedure by which informed consent is obtained and documented by means of a written, signed, and dated informed consent form. This process may include obtaining assent from subjects with legally authorized representatives. (ICH GCP)	Informed Consent Process

## Ingredient Attribute Terminology (Ingredient Attribute Terminology)

NCI Code: C177906, Codelist extensible:

C177906 NCI Code	Ingredient Attribute Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C177929	Drug Product Component	Component	Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. (FDA 21 CFR 314.3(a))	Drug Product Component
C177928	Ingredient Type		A characterization or classification of the component that constitutes a part of a compound or mixture.	Ingredient Type

### Ingredient Type Value Set Terminology (Ingredient Type Value Set Terminology)

NCI Code: C177907, Codelist extensible:

C177907		Ingredient Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C82533	Active Ingredient		Any component of a drug product intended to exert pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. (After 21 CFR 210.3(b)(7))	Active Ingredient
C42637	Inactive Ingredient	Inert Ingredient	Any component of a study product other than an active ingredient. (After FDA 21 CFR 210.3(b)(8))	Pharmaceutical Excipient

## Intervention Attribute Terminology (Intervention Attribute Terminology)

NCI Code: C177905, Codelist extensible:

C177905		Intervention Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C177931	Intervention Description		The textual representation of the study intervention.	Intervention Description
C177930	Intervention Name		The identifying name for the study intervention.	Intervention Name
C98747	Intervention Type	Intervention Type	The kind of product or procedure studied in a trial.	Intervention Type

**INTMODEL (Intervention Model Response)**

NCI Code: C99076, Codelist extensible: Yes

C99076 NCI Code	INTMODEL CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C82637	CROSS-OVER		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)	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		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.	Parallel Study
C142568	SEQUENTIAL		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)	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

## INTTYPE (Intervention Type Response)

NCI Code: C99078, Codelist extensible: No

C99078 NCI Code	INTTYPE CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C15184	BEHAVIORAL THERAPY		A technique used to change the behavior of a subject (e.g., psychotherapy, lifestyle counseling, or hypnosis).	Behavioral Intervention
C307	BIOLOGIC		A product of biological origin applicable to the prevention, treatment, or cure of a disease or condition, for example: virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product. (FDA 21 CFR 600.3)	Biological Agent
C54696	COMBINATION PRODUCT		A product composed of two or more different types of medical products (i.e., a combination of a drug, device, and/or biological product with one another and are referred to as "constituent parts" of the combination product). NOTE: A combination product might be a single-entity product, a co-packaged product or a cross-labeled product. [After 21 CFR 3.2 (e)] (CDISC Glossary)	Combination Product
C16830	DEVICE	Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for, one or more specific medical purpose(s). [After REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices]	Medical Device
C18020	DIAGNOSTIC TEST		Any procedure or test used to diagnose a disease or disorder.	Diagnostic Procedure
C1505	DIETARY SUPPLEMENT		Preparations containing ingredient(s) intended to supplement the diet.	Dietary Supplement
C1909	DRUG		An active natural, synthetic or semi-synthetic ingredient including endogenous body substance that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient (21 CFR 314.3(b)).	Pharmacologic Substance
C15238	GENETIC	Gene Therapy	Ex vivo or in vivo gene modification of cells in order to correct or treat an inherited or acquired disease or condition. (CDISC Glossary)	Gene Therapy
C17649	OTHER	Other	Different than the one(s) previously specified or mentioned. (NCI)	Other
C98769	PROCEDURE	Medical Procedure	Any activity performed by manual and/or instrumental means for the purpose of diagnosis, assessment, therapy, prevention, or palliative care.	Physical Medical Procedure
C15313	RADIATION	Radiation Therapy;Radiotherapy	Use of targeted or whole body radiation to treat a disease.	Radiation Therapy



**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 NCI Code	OBSSMO CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C15197	CASE CONTROL		Retrospective study in which individuals with an outcome (cases) are compared to those who do not have the outcome (controls). (CDISC Glossary)	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		Study of a group of individuals, some of whom are exposed to a variable of interest, in which subjects are followed over time. (CDISC Glossary)	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

## Outcome Measure Attribute Terminology (Outcome Measure Attribute Terminology)

NCI Code: C165641, Codelist extensible:

C165641		Outcome Measure Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C165138	Outcome Measure Description		A full description of the outcome measure.	Study Outcome Measure Description
C165859	Outcome Measure Time Frame		The period of time over which the study outcome measure is assessed.	Outcome Measure Time Frame
C165860	Outcome Measure Title		The descriptive name of the outcome measure.	Outcome Measure Title
C165861	Outcome Measure Type		A characterization or classification of the specific key measurement(s) or observation(s) used to measure the effect of experimental variables on the participants in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment.	Outcome Measure Type

**Outcome Measure Type Value Set Terminology (Outcome Measure Type Value Set Terminology)**

NCI Code: C170442, Codelist extensible:

C170442		Outcome Measure Type Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C98724	Exploratory Outcome Measure	Exploratory Outcome Measure	The outcome measure(s) that is part of a pre-specified analysis plan used to evaluate the exploratory endpoint(s) associated with exploratory study objective(s) and/or any other measures, excluding post-hoc measures, that are a focus of the study. (After clinicaltrials.gov)	Exploratory Outcome Measure	
C98772	Primary Outcome Measure	Primary Outcome Measure	The outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation, to evaluate the primary endpoint(s) associated with the primary study objective(s). (After Clinicaltrials.gov)	Primary Outcome Measure	
C98781	Secondary Outcome Measure	Secondary Outcome Measure	The outcome measure(s) that is part of a pre-specified analysis plan used to evaluate the secondary endpoint(s) associated with secondary study objective(s) and/or used to evaluate any measure(s) ancillary to the primary or secondary endpoint(s). (After Clinicaltrials.gov).	Secondary Outcome Measure	

**Oversight Entity Value Set (Oversight Entity Value Set)**

NCI Code: C165642, Codelist extensible:

C165642 NCI Code	Oversight Entity Value Set CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C142489	Data Monitoring Committee	Data and Safety Monitoring Board;Data and Safety Monitoring Committee DSMB;Data Monitoring and Oversight Committee;DMC;DMOC;DSMC;IDMC	A group of independent experts who are appointed to monitor the safety and scientific integrity of a research intervention, protect the confidentiality of participant data, and to make recommendations to the sponsor regarding the stopping of the trial for safety, efficacy, or for futility. (After clinicaltrials.gov; Committee for Medicinal Products for Human Use (CHMP), 2005, EMA; FDA Establishment and Operation of Clinical Trial Data Monitoring Committees. March 2006)	Data Monitoring Committee
C142579	Independent Ethics Committee	IEC	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a study and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the study protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the study subjects. The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in the ICH E6 guideline. (ICH E6 R2)	Independent Ethics Committee
C165865	Independent Safety Monitor	ISM	An independent physician or health-care professional who evaluates individual and cumulative participant data to make recommendations regarding the safe continuation of the study. (NIH)	Independent Safety Monitor
C16741	Institutional Review Board	IRB	An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a study by, among other things, reviewing, approving, and providing continuing review of study protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the study subjects. (ICH E6 R2)	Institutional Review Board
C165866	Observational Study Monitoring Committee	Observational Study Monitoring Board;OSMB;OSMC	A group of independent experts who are appointed to monitor the safety and scientific integrity of an observational study, including protecting the confidentiality of participant data and to make recommendations regarding the stopping of the study for safety or for futility. (clinicaltrials.gov)	Observational Study Monitoring Committee
C165867	Safety Monitoring Committee	Safety Assessment Committee;Safety Monitoring Board;SMC	Group of individuals with pertinent expertise that reviews, on a regular basis, accumulating safety data from an ongoing clinical study. This independent committee monitors the safety of participants during the study.	Safety Monitoring Committee

**Participant Allocation Value Set (Participant Allocation Value Set)**

NCI Code: C147068, Codelist extensible:

C147068 NCI Code	Participant Allocation Value Set 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

**Pharmacology Attribute Terminology (Pharmacology Attribute Terminology)**

NCI Code: C199649, Codelist extensible:

C199649	Pharmacology Attribute Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C64774	Area Under the Curve	AUC	The area between the x-axis and the curve given by the integrand, equal to the definite integral of a function. For the purpose of pharmacokinetic measurements, the area under the curve (AUC) is the area under the curve in a plot of concentration of a drug in tissue, blood, or other body fluid against time.	Area Under Curve	
C16975	Clinical Pharmacology		The study of assessing therapeutic value of a drug in humans, including properties (absorption, distribution, metabolism, and excretion (ADME)), effects, reactions, and uses.	Clinical Pharmacology	
C79369	Drug Absorption	Absorption;FDA RPS Pharmacokinetics: Absorption	The branch of pharmacokinetics that studies the process by which a drug is absorbed by the body.	Pharmacokinetics: Absorption	
C199691	Drug Binding Affinity		The strength of the binding interaction between a drug and its target(s).	Drug Binding Affinity	
C70913	Drug Bioavailability	Bioavailability	The rate and extent to which the active drug ingredient or therapeutic moiety is absorbed from a drug product and becomes available at the site of drug action. (US FDA 21 CFR 320.1)	Bioavailability	
C199688	Drug Clearance	Clearance	The rate at which a drug is removed or cleared from the whole or part of the body.	Drug Clearance	
C199678	Drug Concentration		The quantity of a drug in a unit volume or weight of another substance.	Drug Concentration	
C79370	Drug Distribution	Distribution;FDA RPS Pharmacokinetics: Distribution	The branch of pharmacokinetics that studies the process by which a drug is distributed within the body.	Pharmacokinetics: Distribution	
C79372	Drug Excretion	Excretion;FDA RPS Pharmacokinetics: Excretion	The branch of pharmacokinetics that studies the process by which a drug is eliminated from the body.	Pharmacokinetics: Excretion	
C79371	Drug Metabolism	FDA RPS Pharmacokinetics: Metabolism;Metabolism	The branch of pharmacokinetics that studies the process by which a drug is metabolized by the body.	Pharmacokinetics: Metabolism	
C199690	Half Maximal Effective Concentration	50% Effective Concentration;EC50;Half-maximal Effective Concentration	A measure of the potency of a compound, expressed as the concentration of the compound that induces a response halfway between the baseline and maximum.	Half Maximal Effective Agent Concentration	
C191279	Half Maximal Inhibitory Concentration	50% Inhibitory Concentration;Half-maximal Inhibitory Concentration;IC50	The concentration of the inhibitory molecule that results in a 50% or greater reduction in infectivity, biological, or biochemical function.	Fifty Percent Inhibitory Concentration	
C199689	Maximal Effect	Emax;Maximum Effect	The greatest effect that a compound can produce regardless of dose exposure or concentration.	Maximal Effect	
C70918	Maximum Concentration	Cmax;Max Conc;Maximum Concentration	The maximum concentration occurring at Tmax.	Cmax	
C85579	Minimum Concentration	Cmin;Min Conc;Minimum Concentration	The minimum concentration between dose time and dose time plus Tau (at Tmin).	Cmin	
C15720	Pharmacodynamics	PD	The study of the biochemical and physiological effects of a drug and its mechanisms of action, including the correlation of those effects and actions with its chemical structure.	Pharmacodynamics	
C20050	Pharmacogenomics		The study of inherited variations in genes that determine and can be used to predict how an individual will respond to a drug or treatment.	Pharmacogenomics	
C15299	Pharmacokinetics	Pharmacokinetics	The characteristic movements of drugs within biological systems, as affected by absorption, distribution, binding, elimination, biotransformation, and excretion; particularly the rates of such movements. (NCI)	Pharmacokinetics	
C70919	Time of Maximum Concentration	Time of CMAX;Time of CMAX Observation	The time of maximum observed concentration sampled during a dosing interval.	Tmax	
C85825	Time of Minimum Concentration	Time of CMIN;Time of CMIN Observation	The time of minimum observed concentration sampled during a dosing interval.	Tmin	
C102394	Trough Concentration	Conc Trough;Concentration Trough;Ctrough;Trough Level	Concentration at end of a dosing interval, immediately before the next dose is administered.	Trough Concentration	

**Physical Address Attribute Terminology (Physical Address Attribute Terminology)**

NCI Code: C132308, Codelist extensible:

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 number, building number, apartment or unit number, or post office box number where an entity is physically located.	Street Address



**Protocol Amendment Attribute Terminology (Protocol Amendment Attribute Terminology)**

NCI Code: C181167, Codelist extensible:

C181167		Protocol Amendment Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C181233	Brief Rationale for Protocol Change	Brief Rationale for Protocol Modification; Brief Rationale for Protocol Revision	A concise explanation justifying an individual change in the protocol.	Brief Rationale for Protocol Change
C181234	Overall Rationale for Protocol Amendment	Overall Justification for Amendment	A summarized explanation justifying a protocol amendment.	Overall Rationale for Protocol Amendment
C132352	Study Protocol Version Approval by Sponsor Date	Protocol Amendment Approval by Sponsor Date; Study Protocol Version Approval Date	The date on which a version of the protocol was finalized or approved by the sponsor.	Protocol Approval by Sponsor Date
C181232	Study Protocol Version Number	Study Protocol Amendment Number	A string of numerals that uniquely identifies a specific version of a study protocol.	Study Protocol Version Number

**Protocol Contact Role Value Set (Protocol Contact Role Value Set)**

NCI Code: C154681, Codelist extensible:

C154681 NCI Code	Protocol Contact Role Value Set		CDISC Definition	NCI Preferred Term
	CDISC Submission Value	CDISC Synonym		
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 qualified study staff member who manages the participation of subjects according to the study protocol.	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 study, ensuring adherence to the protocol and good clinical practices. (CDISC Glossary)	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		The study investigator who has the primary responsibility for the conduct of a study and for the study-related personnel at the participating site(s).	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 individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study. [After ICH E6, WHO, 21 CFR 50.3 (e), and after IDMP]	Clinical Study Sponsor
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:

C132310 NCI Code	Protocol Entity Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C70699	Biological Sample	Biological Sample;Biological Specimen;Biospecimen;Sample	Any material collected from a biological entity for testing, diagnostic, propagation, treatment, or research purposes.	Biospecimen
C16342	Biomarker		A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. Categories of biomarkers include: susceptibility/risk biomarker; diagnostic biomarker; monitoring biomarker; prognostic biomarker; predictive biomarker; safety biomarker; pharmacodynamic/response biomarker. [NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource, <a href="https://www.ncbi.nlm.nih.gov/books/NBK338448/">https://www.ncbi.nlm.nih.gov/books/NBK338448/</a> ] (CDISC Glossary)	Biomarker
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		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). NOTE: NIH Office of Science Policy further specifies that a clinical trial is a type of research study that prospectively assigns subjects to interventions, and the EU clinical trial regulations set forth 3 specific conditions, any one of which qualifies a study as a clinical trial. These conditions include applying diagnostic or monitoring procedures not used in normal clinical practice to subjects. [After ICH E6 [R2], EU CTR 2014] (CDISC Glossary)	Clinical Trial
C25212	Endpoint		A defined variable intended to reflect an outcome of interest that is statistically analyzed to address a particular research question. NOTE: A precise definition of an endpoint typically specifies the type of assessments made, the timing of those assessments, the assessment tools used, and possibly other details, as applicable, such as how multiple assessments within an individual are to be combined. [After BEST Resource] (CDISC Glossary)	End Point
C98722	Expanded Access	Compassionate Use	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 Study
C41161	Experimental Intervention	Investigational Interventional;Investigational Therapy or Treatment	The drug, device, therapy, procedure, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study (e.g., health-related quality of life, efficacy, safety, pharmacoeconomics). [After <a href="https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5224">https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5224</a> ; <a href="https://grants.nih.gov/policy/clinical-trials/protocol-template.htm">https://grants.nih.gov/policy/clinical-trials/protocol-template.htm</a> ] See also test articles, devices, drug product, combination product, treatment, diagnosis. Contrast with investigational medicinal product.	Protocol Agent
C16735	Informed Consent		A process that provides the subject with explanations that will help in making decisions about whether to begin or continue participating in a study, after having achieved an understanding of the potential risks and benefits. Informed consent is an ongoing, interactive process rather than a one-time information session.	Informed Consent
C51981	Ingredient		Any component that constitutes a part of a compound or mixture.	Ingredient
C93407	Outcome Measure		Specific key measurement(s) or observation(s) used to measure the effect of experimental variables on the participants in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment. (BRIDG)	Study Outcome Measurement
C20200	Outcome		A measurable characteristic that is influenced or affected by an individual's baseline state or an intervention, as in a clinical trial or other exposure. (BEST Resource)	Outcome
C16974	Pharmacology	Pharmacology	The study of characteristics, effects, and uses of drugs and their interactions with living organisms.	Pharmacology
C25407	Physical Address		A standardized representation of the location of a person, business, building, or organization. (NCI)	Address
C132347	Protocol Amendment		A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)	Protocol Amendment
C181183	Protocol Statement		A written message providing an official assurance, account, or assertion within the study protocol.	Protocol Statement
C15381	Quality Assurance	QA	All those planned and systematic actions that are established to ensure that the study is performed and the data are generated, documented (recorded), and reported in compliance with good clinical practice (GCP) and the applicable regulatory requirement(s). (ICH)	Quality Assurance
C15311	Quality Control	QC	The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the study related activities have been fulfilled. (ICH)	Quality Control
C184397	Reference	Reference List	The curated list of sources that are cited within the reference section of the document.	Reference List
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
C174447	Study Arm	Arm	A planned pathway assigned to the subject as they progress through the study, usually referred to by a name that reflects one or more treatments, exposures, and/or controls included in the path.	Study Arm
C189351	Study Blinding and Unblinding		A methodology to limit bias by preventing subject(s) and/or study personnel from identifying which treatments or procedures are administered and the circumstances in which the blind would be broken for subject(s) and/or study personnel.	Study Blinding and Unblinding
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 strategy that specifies the structure of a study in terms of the planned activities (including timing) and statistical analysis approach intended to meet the objectives of the study.	Study Design
C142707	Study Monitoring		The act of overseeing the progress of a clinical study and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), good clinical practice (GCP), and regulatory requirement(s) where applicable. [after ICH E6 Glossary]	Study Monitoring
C93450	Study Oversight Entity		A group of individuals that approves, monitors and reviews biomedical research to protect the rights, safety and welfare of the study participants, by providing critical scientific, ethical, and/or regulatory oversight functions.	Study Oversight Authority
C70833	Study Population		A group of individuals taken from the general population who share a set of common characteristics, such as age, sex, or health condition, precisely defined in the study protocol. This is a population to which the study results could be reasonably generalized.	Study Population
C177924	Study Product Administration		The act of the dispensing, applying, or tendering a study product to the participant. (NCI)	Study Product Administration
C174271	Study Product		The material artifact(s), such as the trial product, interventional product, study drug, device, or procedure and their comparator(s), that is the focus of the study.	Study Product
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
C142444	Study Subject Discontinuation		The act of concluding participation by an enrolled subject prior to completion of all protocol-required elements in a study. NOTE: Four categories of discontinuation are distinguished: a) dropout: Active discontinuation by a subject (also a noun referring to such a discontinued subject); b) investigator initiated discontinuation (e.g., for cause); c) loss to follow-up: cessation of participation without notice or action by the subject; d) sponsor initiated discontinuation. Note that subject discontinuation does not necessarily imply exclusion of subject data from analysis. "Termination of subject" has a history of synonymous use, but is now considered nonstandard. [After ICH E3, section 10.1 and FDA Guidance for Industry: Submission of Abbreviated Reports & Synopses in Support of Marketing Applications, IV A] (CDISC Glossary)	Study Subject Discontinuation
C142738	Subject Replacement	Study Subject Replacement	The act of enrolling a new study subject to compensate for a subject who is no longer participating.	Trial Subject Replacement
C198230	Substudy	Sub-study	A subordinate study within the scope of the parent study that researches a separate question from, and contributes to, the overarching study objectives and involves all or a subset of the parent study participants or specimens.	Substudy

**Protocol Statement Attribute Terminology (Protocol Statement Attribute Terminology)**

NCI Code: C181168, Codelist extensible:

C181168		Protocol Statement Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C181244	Biological Sample Use Statement	Biological Specimen Use Statement;Biospecimen Use Statement	A written message within the study protocol that describes the provisions for use of biological samples for the duration of the study and, as applicable, for future use.	Biological Sample Use Statement
C181240	Conflict of Interest Statement		A written message within the study protocol that describes how the study will manage actual or perceived conflicts of interest, including report to regulatory authorities and oversight entities.	Conflict of Interest Statement
C181237	Data Integrity Statement		A written message within the study protocol that asserts that the data are complete, consistent, accurate, trustworthy, and reliable throughout the life cycle of the study.	Data Integrity Statement
C184394	Data Sharing Statement		A written message within the study protocol that asserts compliance with data sharing policies.	Data Sharing Compliance Policy Statement
C181241	Financial Disclosure Statement		A written message within the study protocol that asserts how any and all financial interests of the study stakeholders will be managed in relation to the study.	Study Protocol Financial Disclosure Statement
C181236	Protocol Confidentiality Statement		A written message within the study protocol that asserts a statement of non-disclosure, such that information contained within the protocol document may only be shared with authorized parties.	Protocol Confidentiality Statement
C181235	Protocol Regulatory Compliance Statement	Regulatory Compliance Statement	A written message within the study protocol that asserts that the study will be conducted in compliance with Good Clinical Practice (GCP) guidelines, study protocol, and any other applicable regulatory requirements.	Protocol Regulatory Compliance Statement
C184393	Publication Policy Statement		A written message within the study protocol that describes the policies pertaining to the publication of study results.	Publication Policy Statement
C181239	Statement of Ethical Conduct		A written message within the study protocol that asserts that the study will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and applicable regional regulations and guidelines.	Statement of Ethical Conduct
C181238	Statement of Progress Reporting		A written message within the study protocol that asserts timely communication of study progress and results to the study stakeholders as well as regulatory authorities and study registries.	Statement of Progress Reporting
C184392	Study Investigator Conduct Statement	Investigator Statement;Study Investigator Statement	A written message within the study protocol that asserts that a study investigator will be responsible for the performance and conduct of the study as described in the protocol, and in accordance with relevant laws, regulations, and guidelines.	Study Investigator Conduct Statement
C184391	Study Sponsor Conduct Statement	Sponsor Statement;Study Sponsor Statement	A written message within the study protocol that asserts that the study sponsor will be responsible for overseeing all aspects of study conduct.	Study Sponsor Conduct Statement
C181243	Subject Data Confidentiality Statement	Study Participant Data Confidentiality Statement	A written message within the study protocol that asserts compliance with applicable regulations and guidelines to preserve and maintain study data confidentiality.	Subject Data Confidentiality Statement
C181242	Subject Privacy Statement	Study Participant Privacy Statement	A written message within the study protocol that asserts compliance with applicable regulations and guidelines regarding the protection of study subject, or participant, privacy.	Subject Privacy Statement

## Randomization Type Value Set (Randomization Type Value Set)

NCI Code: C147069, Codelist extensible:

C147069 NCI Code	Randomization Type Value Set 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 participant is adjusted based on the group assignments of those participants already randomized in the trial.	Adaptive Randomization
C147127	Block Randomization	Constrained Randomization	A type of adaptive randomization in which a pre-specified number of participants 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 participant is assigned to the treatment group in an attempt to minimize imbalances in the number of participants for each stratification covariate across treatment groups.	Minimization Randomization
C147144	Simple Randomization	Unrestricted Randomization	A type of randomization schema in which each participant has the same chance of being randomized into any one group as all other participants.	Simple Randomization
C147145	Stratified Randomization		A type of block randomization in which participants are stratified into groups based on prognostic variables and then randomized into balanced treatment groups.	Stratified Randomization
C142743	Unequal Randomization		A type of randomization schema in which unequal numbers of participants are purposely assigned to multiple treatment groups.	Unequal Randomization

**Reference Attribute Terminology (Reference Attribute Terminology)**

NCI Code: C184333, Codelist extensible:

C184333 NCI Code	Reference Attribute Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C41196	Citation		A reference to an authoritative source.	Citation

## Study Activity Attribute Terminology (Study Activity Attribute Terminology)

NCI Code: C190866, Codelist extensible:

C190866		Study Activity Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C25217	Study Assessment	Study Observation	A measurement, evaluation, observation, or judgment of a study variable pertaining to the status of a subject. [After BEST Resource] (CDISC Glossary)	Assessment
C82437	Study Day		A relative day, in reference to the protocol-defined study start point, on which an intervention, procedure, assessment, and/or collection of other study data occurs.	Study Day
C191215	Study Visit Window	Visit Window	The allowable period of time before and/or after a planned or scheduled study visit, during which the actual study visit shall occur.	Study Visit Window
C191214	Study Visit	Visit	A protocol-defined clinical encounter that encompasses planned and contingent study interventions, procedures, and assessments that may be performed on a subject. [SDTM]	Study Visit

## Study Arm Attribute Terminology (Study Arm Attribute Terminology)

NCI Code: C172329, Codelist extensible:

C172329 NCI Code	Study Arm Attribute Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C172458	Planned Number of Subjects Per Study Arm		The total number of subjects intended to be included within each arm for the study. (NCI)	Planned Number of Subjects Per Study Arm
C93728	Study Arm Description	Arm Description	A narrative representation of the study arm.	Arm Description
C172456	Study Arm Label	Arm Label	The short descriptive designation for the study arm.	Study Arm Label
C172457	Study Arm Type	Arm Type	A characterization or classification of the study arm.	Study Arm Type



## Study Arm Type Value Set Terminology (Study Arm Type Value Set Terminology)

NCI Code: C174222, Codelist extensible: Yes

C174222		Study Arm Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C174267	Active Comparator Arm		An arm describing the active comparator.	Active Comparator Arm
C174226	Control Arm		An arm describing the intervention or treatment plan for a group of participants in the study receiving a control. The control may comprise a non-investigational product (active control) or regimen, placebo, or no treatment.	Control Arm
C174266	Experimental Arm	Investigational Arm	An arm describing the intervention or treatment plan for a group of participants in the study receiving test product(s).	Investigational Arm
C174270	No Intervention Arm		A study arm without an intervention or treatment.	No Intervention Arm
C174268	Placebo Comparator Arm	Placebo Control Arm	An arm describing the placebo comparator.	Placebo Control Arm
C174269	Sham Comparator Arm	Sham Intervention Arm	An arm describing the sham comparator.	Sham Comparator Arm
C15538	Treatment Arm		A planned pathway through the study to which subjects are assigned, and that describes treatments, exposures, controls, and/or observations.	Protocol Treatment Arm

## Study Blinding and Unblinding Attribute Terminology (Study Blinding and Unblinding Attribute Terminology)

NCI Code: C189268, Codelist extensible:

C189268		Study Blinding and Unblinding Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C142408	Masked Medication	Blinded Medication	A study product whose appearance and characteristics are the same between each investigational agent and control.	Blinded Medication
C189349	Study Blinding Procedure		The methodology used for enacting study blinding.	Study Blinding Procedure
C49658	Study Blinding Schema	Study Blinding Design; Study Blinding Schema; Study Masking Design; Trial Blinding Design; Trial Blinding Schema; Trial Masking Design	The type of experimental design used to describe the level of awareness of the study subjects and/or study personnel as it relates to the respective intervention(s) or assessments being observed, received or administered.	Trial Blinding Schema
C49068	Study Blinding	Trial Blinding	A procedure 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
C189350	Study Unblinding Procedure		A description of the methodology used for planned or unplanned unblinding of the study.	Study Unblinding Procedure
C142742	Study Unblinding		Identification of the treatment assignment to the subject, investigators, and/or other trial personnel. (CDISC Glossary)	Unblinding

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

NCI Code: C154682, Codelist extensible:

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
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
C25191	Person Name	Individual's Name;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
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:

C147066		Study Design Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
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	A narrative representation of the study design.	Study Design Description
C52580	Participant Allocation	Subject Allocation	The process of assigning participants to particular treatment groups or cohorts in a clinical study.	Allocation
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 Participants	Anticipated Enrollment; Planned Enrollment; Planned Number of Subjects; Target Enrollment	The planned number of subjects intended to be enrolled within a study to reach a pre-specified sample size (in any cohort or the entire study).	Planned Subject Number
C147140	Randomization Type		A characterization or classification of 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.	Randomization Method
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
C25689	Stratification		Grouping defined by important prognostic factors measured at baseline. (ICH E9)	Stratification
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 based on observations or facts that requires further investigation or exploration to answer a research question. (After 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

**Study Monitoring Attribute Terminology (Study Monitoring Attribute Terminology)**

NCI Code: C163026, Codelist extensible:

C163026		Study Monitoring Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C208439	Clinical Monitoring Plan		A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial. (ICH E6(R2) Glossary Addendum)	Clinical Monitoring Plan
C163406	Data and Safety Monitoring Plan	Data Safety Monitoring Plan; DSMP; Safety Data Monitoring Plan	A written plan that prospectively identifies and documents monitoring activities intended to protect the safety of the participants, the validity of the data and the integrity of the research study. The DSMP may also identify when to terminate a participant's participation (i.e. individual stopping rules) and/or the appropriate termination of a study (i.e. study stopping rules). (Mayo Clinic)	Data and Safety Monitoring Plan
C142488	Data Monitoring		Process by which clinical data are examined for completeness, consistency, and accuracy for the duration of the study lifecycle.	Data Monitoring
C163407	GCP Adherence Statement	Good Clinical Practice Adherence Statement	A written message that asserts, affirms, or declares that the study is conducted in accordance with Good Clinical Practice (GCP).	GCP Adherence Statement
C142674	Risk Monitoring	Risk-based Monitoring	Study monitoring that focuses on preventing or mitigating important and likely risks to investigation quality, including risks to human subject protection and data integrity. [After FDA Guidance: A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers, 2019] (CDISC Glossary)	Risk Based Monitoring
C163408	Safety Data Monitoring		Review of cumulative safety data to identify possible safety concerns.	Safety Data Monitoring
C163409	Safety Monitoring		Review of safety data to ensure safety of the individuals who are participating in the study, or to identify potential safety concerns for the duration of the study lifecycle.	Safety Monitoring
C184395	Study Audit Statement		A written message within the study protocol that describes the auditing activities that are to occur within a study and the intent to address findings from an audit report.	Study Audit Statement
C184396	Study Audit		A systematic and independent examination of study-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). (ICH E6 Glossary)	Study Audit
C163410	Study Monitoring Statement		A written message that asserts, affirms, or declares that the study will be monitored in adherence to a clinical monitoring plan and in accordance with Good Clinical Practice (GCP).	Study Monitoring Statement
C163411	Suicidal Risk Monitoring		A systematic approach to identify and assess the risks of participant suicidal ideation and/or suicide.	Suicidal Risk Monitoring
C15789	Trial Monitoring		The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). [ICH E6 Glossary]	Clinical Trials, Monitoring

## Study Oversight Entity Attribute Terminology (Study Oversight Entity Attribute Terminology)

NCI Code: C165640, Codelist extensible:

C165640		Study Oversight Entity Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C165862	Study Oversight Entity Approval Date		The date on which the study oversight entity grants approval.	Study Oversight Entity Approval Date
C165863	Study Oversight Entity Approval Status		The state of the study oversight entity approval process.	Study Oversight Entity Approval Status
C165864	Study Oversight Entity Type		A characterization or classification of the group of individuals that approves, monitors and reviews biomedical research to protect the rights, safety and welfare of the study participants, by providing critical scientific, ethical, and/or regulatory oversight functions.	Study Oversight Entity Type

## Study Population Attribute Terminology (Study Population Attribute Terminology)

NCI Code: C160921, Codelist extensible:

C160921		Study Population Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C161320	Comorbid Condition		Medical or health condition that is concomitant or concurrent with the primary condition or disease under study.	Comorbid Condition
C161319	Condition or Disease under Study		Primary disease(s) or condition(s) being studied in the trial, or the focus of the study. (clinicaltrials.gov)	Condition or Disease under Study
C28143	Control Group		A cohort of study participants that is defined for the purpose of comparison to the treatment group in a controlled trial. In an epidemiological study, this cohort may or may not have the outcome of interest.	Control Group
C161324	Demographic Group		A descriptive characterization of the study population (e.g., age, sex, race, education, etc.).	Demographic Group
C161323	Experimental Group		A study population that receives the intervention that is the focus of the study.	Experimental Group
C161316	Females of Childbearing Potential	FOCBP;WOCBP;Women of Childbearing Potential	Female study subjects or patients who have the potential to become pregnant, i.e., those who have experienced menarche and who have not undergone surgical sterilization and are not postmenopausal.	Female of Childbearing Potential
C16669	General Health Status		The state of a subject's mental or physical condition.	Health Status
C49651	Healthy Volunteer	Healthy Subject	A person with no significant health-related issues who agrees to participate as a subject in a clinical study.	Healthy Subject
C161318	Justification of Special Population		An explanation with defensible proof as to the reason why a special population of subjects is included in the clinical study.	Justification of Special Population
C161317	Population Rationale		An explanation as to the logical reasons for why a specific population of subjects is being considered for inclusion in a clinical study.	Population Rationale
C161321	Reference Group	Reference Group for Study Sample Population	The study population that is defined for the purpose of comparison to the population under investigation.	Reference Group
C142728	Target Study Population	Target Population	The group of people in the general population to which the study results can be generalized.	Target Study Population
C161322	Treatment Group		A study population that receives an intervention(s) within a trial. This could include the investigational product(s) or a comparator (e.g., placebo or an approved intervention).	Treatment Group
C142747	Vulnerable Population		Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples include subordinate members of a group with a hierarchical structure, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. (ICH)	Vulnerable Subjects

**Study Product Administration Attribute (Study Product Administration Attribute)**

NCI Code: C177904, Codelist extensible:

C177904		Study Product Administration Attribute		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C42636	Dosage Form	Dose Form	Physical characteristics of a drug product, (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. (CDISC Glossary)	Pharmaceutical Dosage Form
C142516	Dosage Regimen		The schedule of doses of an agent per unit of time, including the number of doses per given time period and the elapsed time between doses. NOTE: For example, every six hours or the time that the doses are to be given (for example, at 8 a.m. and 4 p.m. daily); and/or the amount of a medicine (the number of capsules, for example) to be given at each specific dosing time. [After AMA Manual of Style]	Dosage Regimen
C89081	Dose Frequency	Dosing Frequency	The number of doses administered per a specific interval.	Dose Frequency
C25488	Dose	Dose Level;Dose per Administration	The amount of study drug (or placebo) administered to a patient or test subject to be taken at one time or at stated intervals.	Dose
C177925	Justification for Dosage		The rationale or explanation for the planned dose(s).	Justification for Planned Dosage
C177926	Justification of Administration		The rationale or explanation for the planned mode of delivery.	Justification of Planned Administration
C38114	Route of Administration	Route of Administration	The way in which a pharmaceutical product is taken into, or makes contact with, the body. (CDISC Glossary)	Route of Administration



## Study Product Attribute Terminology (Study Product Attribute Terminology)

NCI Code: C174220, Codelist extensible:

C174220		Study Product Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C176267	Study Product Accountability		The act or process for documenting the storage, inventory tracking, and disposition of the study product.	Study Product Accountability
C176266	Study Product Acquisition		The act or process by which the study product is obtained by the study site or investigator.	Study Product Acquisition
C176269	Study Product Appearance		The outward or visible aspect of the study product.	Study Product Appearance
C176268	Study Product Formulation		The composition of the study product, which may include active and inactive ingredients, dose, and dosage form.	Study Product Formulation
C176271	Study Product Labeling		The written, printed, or graphic matter on, or accompanying, the study product or its packaging.	Study Product Labeling
C176275	Study Product Manufacturer		The enterprise or entity that produces the study product.	Study Product Manufacturer
C176270	Study Product Packaging		The material type and configuration used to contain the study product.	Study Product Packaging
C98768	Study Product Pharmacologic Class	Pharmacologic Class	The pharmacological class of the investigational product.	Pharmacological Class of Investigational Therapy
C176274	Study Product Preparation		Instructions for the act of making ready the study product for use or administration.	Study Product Preparation
C176273	Study Product Stability		The parameters under which the study product retains the same properties and characteristics that it possessed at the time of its manufacture for its intended use or administration. (After Anissa W. Wong, Aruna Datla.13-Assay and Stability Testing, Editor(s): Satinder Ahuja, Michael W. Dong, Separation Science and Technology, Academic Press, Volume 6, 2005, Pages 335-358)	Study Product Stability
C176272	Study Product Storage		The physical or environmental conditions under which the study product is maintained.	Study Product Storage
C177927	Study Product Therapeutic Class	Study Product Therapeutic Category	The classification of a study product based on the disease, disorder, or condition it is intended to treat.	Study Product Therapeutic Class
C174265	Study Product Type		The characterization or classification of the material artifact(s) that is the focus of the study.	Study Product Type

## Study Product Type Value Set Terminology (Study Product Type Value Set Terminology)

NCI Code: C174221, Codelist extensible:

C174221		Study Product Type Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C68609	Active Comparator	Active Control	A type of control, which has a demonstrated effect, administered as a comparator to subjects in a clinical trial. [From ICH E10]	Active Comparator	
C142703	Control Product		A comparator product against which the study treatment is evaluated [e.g., concurrent (placebo, no treatment, dose-response, active), and external (historical, published literature)]. [After ICH E10]	Study Control	
C142587	Investigational Product	Experimental Product	A drug, biologic, placebo, or device being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. [After ICH E6]	Investigational Product	
C49648	Placebo Comparator	Placebo;Placebo Control	An inactive, identical-appearing drug or treatment that does not contain the test product.	Placebo Control	
C116527	Sham Comparator	Sham Intervention	A procedure or device that appears to be the same as the actual procedure or device being studied but does not contain active processes or components.	Sham Intervention	

## Study Protocol Attribute Terminology (Study Protocol Attribute Terminology)

NCI Code: C132309, Codelist extensible:

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 that contains key elements of the study.	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	
C208440	Protocol Synopsis	Protocol Scientific Summary	A scientific summary of the key points of the protocol.	Protocol Synopsis	
C94105	Public Protocol Title		The brief descriptive name for the protocol that is intended for the public 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	
C207646	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 Acronym	
C181245	Study Protocol Version Approval by Oversight Committee Date		The date on which a version of the protocol was finalized or approved by the study oversight committee.	Study Protocol Version Approval by Oversight Committee Date	
C132352	Study Protocol Version Approval by Sponsor Date	Protocol Amendment Approval by Sponsor Date;Study Protocol Version Approval Date	The date on which a version of the protocol was finalized or approved by the sponsor.	Protocol Approval by Sponsor Date	
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	

**Study Purpose Value Set (Study Purpose Value Set)**

NCI Code: C147067, Codelist extensible:

C147067 NCI Code	Study Purpose Value Set 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	A process to identify the disease, condition, or injury that explains the symptoms and signs occurring in a patient.	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	Prophylaxis	Practices or interventions used to maintain health and prevent disease or injury. (CDISC Glossary)	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

## Study Subject Discontinuation Attribute Terminology (Study Subject Discontinuation Attribute Terminology)

NCI Code: C185851, Codelist extensible:

C185851	Study Subject Discontinuation Attribute Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C185956	Conditions of Subject Withdrawal		A description of the provisions or stipulations under which the subject may withdraw themselves from the study, following local and national regulations.	Conditions of Subject Withdrawal	
C185957	Follow-up for Withdrawn Subject		A description of the process by which information about the health status of a subject is obtained after that subject has withdrawn from the study.	Withdrawn Subject Follow-Up Process Description	
C185958	Lost to Follow-up Criteria		The set of protocol-defined criteria that qualifies a study subject as being lost to follow-up.	Lost to Follow-up Criteria	
C48227	Lost to Follow-up		The loss or lack of continuation of a subject to follow-up.	Lost To Follow-Up	
C49627	Reason for Study Discontinuation		The explanation for why the enrolled subject concluded participation, prior to completion of all protocol-required elements, in a study.	Reason for Study Discontinuation	
C185959	Reason for Subject Withdrawal from Study		The explanation or rationale as to why the subject withdrew from the study.	Reason for Subject Withdrawal from Study	
C185960	Study Subject Discontinuation Criteria		The set of protocol-defined criteria that serves to determine whether and how an enrolled subject may conclude participation in a study, prior to completion of all protocol-required elements.	Study Subject Discontinuation Criteria	
C185961	Subject Discontinuation Process	Subject Discontinuation Procedure	A description of the stepwise set of actions taken when a subject discontinues participation in a study.	Subject Discontinuation Process Description	
C176342	Subject Withdrawal of Consent	Informed Consent Withdrawn	An indication that the consent to participate in the study, or one or more components of the study, has been revoked.	Study Consent Withdrawn	
C49634	Subject Withdrawal	Dropout	The subject-initiated act of discontinuing participation in the study as a whole or one or more aspects of the study (e.g., a study period or use of biospecimens).	Withdrawal by Subject	

**STYPE (Study Type Response)**

NCI Code: C99077, Codelist extensible: No

C99077 NCI Code	STYPE CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C98722	EXPANDED ACCESS	Compassionate Use	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 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		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)	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 Replacement Attribute Terminology (Subject Replacement Attribute Terminology)

NCI Code: C185850, Codelist extensible:

C185850		Subject Replacement Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C185962	Subject Replacement Criteria	Study Subject Replacement Criteria	A description of the scenario(s) that would justify subject replacement.	Study Subject Replacement Criteria	
C185963	Subject Replacement Statement	Study Subject Replacement Statement	A statement asserting whether subject replacement is permitted within a study.	Study Subject Replacement Statement	

### Substudy Attribute Terminology (Substudy Attribute Terminology)

NCI Code: C197998, Codelist extensible:

C197998 NCI Code	Substudy Attribute Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C165770	Master Protocol		A protocol designed for a parent study that provides the plan for coordinated conduct across the entirety of the study, with one or more substudies, which may have different objectives, to evaluate one or more investigational drugs and/or diseases within the overall trial structure. (FDA Guidance Document: Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics Guidance for Industry)	Master Protocol
C198229	Substudy Protocol	Sub-Protocol	The protocol describing the formal plan of the substudy.	Substudy Protocol



**TBLIND (Trial Blinding Schema Response)**

NCI Code: C66735, Codelist extensible: Yes

C66735 NCI Code	TBLIND CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C15228	DOUBLE BLIND	Double Masked;Double-Masked	A study in which neither the subject nor the study personnel interacting with the subject or data during the study knows what intervention a subject is receiving.	Double Blind Study
C187674	OBSERVER BLIND		A study in which the study personnel who measure, record, or assess the subject do not know which intervention the subject is receiving or, in the context of observational studies, do not know the external factors to which a subject has been exposed.	Observer Blind Study
C156592	OPEN LABEL TO TREATMENT AND DOUBLE BLIND TO IMP DOSE		A study in which the therapeutic treatment is open label but the dosing information of the investigational medicinal product (IMP) is double-blinded.	Open Label for Treatment And Double Blind to Dose
C49659	OPEN LABEL		A study in which subjects and study personnel know which intervention each subject is receiving.	Open Label Study
C28233	SINGLE BLIND	Single Masked;Single-Masked	A study in which one party, either the subject or study personnel, does not know which intervention is administered to the subject.	Single Blind Study

**TINDTP (Trial Intent Type Response)**

NCI Code: C66736, Codelist extensible: Yes

C66736 NCI Code	TINDTP 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
C170629	DISEASE MODIFYING		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.	Disease Modifying Treatment 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 NCI Code	TPHASE CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C54721	EARLY PHASE I	0;Phase 0 Trial;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
C48660 C15600	NOT APPLICABLE PHASE I TRIAL	NA;Not Applicable 1;Trial Phase 1	Determination of a value is not relevant in the current context. (NCI) 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 1 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)	Not Applicable 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
C198366	PHASE I/II/III TRIAL	1/2/3;Trial Phase 1/2/3	A study that begins as a Phase I study and transitions into Phases II and III based upon successful completion of each previous portion.	Phase I/II/III Trial
C198367	PHASE I/III TRIAL	1/3;Trial Phase 1/3	A study that begins as a Phase I study and transitions into a Phase III study upon successful completion of the Phase I portion.	Phase I/III Trial
C199990	PHASE IA TRIAL	1A;Trial Phase 1A	A type of phase 1 trial with a single ascending dose (dose escalation) in a smaller group of patients (in comparison to a Phase 1B).	Phase Ia Trial
C199989	PHASE IB TRIAL	1B;Trial Phase 1B	A type of phase 1 trial with multiple ascending doses (dose expansion) in a larger group of patients (in comparison to a Phase 1A).	Phase Ib Trial
C15601	PHASE II TRIAL	2;Trial Phase 2	Phase that includes the controlled clinical trials conducted to evaluate the safety and efficacy of the drug in a limited number of patients with the disease or condition under study. Objectives can be dose-ranging (dose-response, frequency of dosing), type of patients, or numerous other characteristics of safety and efficacy. [After 21 CRF Part 312.21 Phases of an investigation] See also phase, phase 2a, phase 2b. (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	Early Phase 2 trials that focus on a proof-of-concept assessment of efficacy and safety in a small number of patients. [After FDA Guidance for industry end of Phase 2a meetings, September 2009] (CDISC Glossary)	Phase IIA Trial
C49688	PHASE IIB TRIAL	2B;Trial Phase 2B	Later Phase 2 trials, in transition to Phase 3, where the study populations more closely reflect the population, dosage, and condition for intended use. [Clarification of FDA Guidance for industry end of Phase 2a meetings, September 2009; Discussion in Peter B. Gilbert. SOME DESIGN ISSUES IN PHASE 2B VERSUS PHASE 3 PREVENTION TRIALS FOR TESTING EFFICACY OF PRODUCTS OR CONCEPTS. Stat Med. 2010 May 10; 29(10): 1061-1071.]	Phase IIB Trial
C15602	PHASE III TRIAL	3;Trial Phase 3	Phase that includes the controlled clinical trials intended to confirm safety and effectiveness, evaluate the overall benefit-risk relationship, and to provide substantial evidence for regulatory approval and labeling. NOTE: Phase 3 studies usually include from several hundred to several thousand subjects. [After ICH E8; Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products Draft Guidance for Industry. December 2019] See also phase, phase 3b. (CDISC Glossary)	Phase III Trial
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	Later Phase 3 trial done near the time of approval to elicit additional findings. NOTE: Dossier review may continue while associated Phase 3b trials are conducted. These trials may be required as a condition of regulatory authority approval. Phase 3a is in common usage but not reflected in regulatory guidance. (CDISC Glossary)	Phase IIIB Trial
C15603	PHASE IV TRIAL	4;Trial Phase 4	Post-approval 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: Phase 4 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] See also phase. (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

**TTYTYPE (Trial Type Response)**

NCI Code: C66739, Codelist extensible: Yes

C66739		TTYTYPE		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C158283	ADHESION PERFORMANCE		A type of study designed to evaluate the strength of the bond between an adhesive and the application surface.	Adhesion Performance Study
C158284	ALCOHOL EFFECT		A type of study designed to evaluate the effects of alcohol on investigational product safety and/or efficacy.	Alcohol Effect Study
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
C158288	BIOSIMILARITY		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.	Biosimilarity Study
C158285	DEVICE-DRUG INTERACTION		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.	Device-Drug Interaction Study
C49653	DIAGNOSIS		A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.	Diagnosis Study
C158289	DOSE FINDING		An early phase clinical study with the objective of determining the optimal dose of an investigational product.	Dose Finding Study
C158290	DOSE PROPORTIONALITY		A type of study designed to evaluate the relationship between dose and resulting exposure.	Dose Proportionality 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
C158286	DRUG-DRUG INTERACTION		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.	Drug-Drug Interaction Study
C178057	ECG	Electrocardiographic Study	A study that evaluates the effect of a treatment on cardiac electrical activity, as assessed by electrocardiography.	Electrocardiographic 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
C201484	MASS BALANCE		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.	Mass Balance 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
C161477	POSITION EFFECT		A type of study designed to evaluate the effect of body position during and/or after administration of the investigational product.	Position Effect Trial
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
C174366	REACTOGENICITY		A type of study designed to evaluate the expected, acute types of immunological responses, sometimes considered excessive, following agent administration.	Reactogenicity 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
C161478	SWALLOWING FUNCTION		A type of study designed to evaluate the effect of the investigational product on the physiologic act of swallowing.	Swallowing Function Trial
C158287	THOROUGH QT	TQT 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.	Thorough QT 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
C161479	USABILITY TESTING		A type of study designed to evaluate the user experience with a product.	Usability Testing Study
C161480	WATER EFFECT		A type of study designed to evaluate the effects of water on investigational product safety and/or efficacy.	Water Effect Trial