CDISC Protocol Controlled Terminology, 2023-06-30

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	Biological Sample Attribute Terminology	Biological Sample Attribute Terminology	A terminology value set relevant to the attributes of the biological sample.	
C142191	Clinical Study Attribute Terminology	Clinical Study Attribute Terminology	A terminology value set relevant to the attributes of the clinical study entity.	
C139020	Clinical Trial Attribute Terminology	Clinical Trial Attribute Terminology	A terminology value set relevant to the attributes of the clinical trial entity.	
C170440	Endpoint Attribute Terminology	Endpoint Attribute Terminology	A terminology value set relevant to the attributes of the endpoint entity.	
C170441	Endpoint Type Value Set Terminology	Endpoint Type Value Set Terminology	The terminology relevant to the type of endpoint for the study.	
C187682	Expanded Access Attribute Terminology	Expanded Access Attribute Terminology	A terminology value set relevant to the attributes of the expanded access entity.	
C187683	Expanded Access Study Type Value Set Terminology	Expanded Access Study Type Value Set Terminology	The terminology relevant to the type of expanded access study.	
C184334	Informed Consent Attribute Terminology	Informed Consent Attribute Terminology	A terminology value set relevant to the attributes of the informed consent.	
C177906	Ingredient Attribute Terminology	Ingredient Attribute Terminology	A terminology value set relevant to the attributes of the ingredient.	
C177907	Ingredient Type Value Set Terminology	Ingredient Type Value Set Terminology	The terminology relevant to the identification of the kind of ingredient.	
C177905	Intervention Attribute Terminology	Intervention Attribute Terminology	A terminology value set relevant to the attributes of the intervention.	
C99076	INTMODEL	Intervention Model Response	A terminology codelist relevant to the trial design developed to compare treatment groups.	Yes
C99078	INTTYPE	Intervention Type Response	A terminology codelist relevant to the kind of product or procedure studied in a trial.	No
C66742	NY	No Yes Response	A term that is used to indicate a question with permissible values of yes/no/unknown/not applicable.	No
C127259	OBSSMO	Observational Study Model	The terminology relevant to the trial design for observational studies.	Yes
C165641	Outcome Measure Attribute Terminology	Outcome Measure Attribute Terminology	A terminology value set relevant to the attributes of the outcome measure entity.	
C170442	Outcome Measure Type Value Set Terminology	Outcome Measure Type Value Set Terminology	The terminology relevant to the type of outcome measure for the study.	
C165642	Oversight Entity Value Set	Oversight Entity Value Set	The terminology relevant to the type of oversight entity for the study.	
C147068	Participant Allocation Value Set	Participant Allocation Value Set	A terminology codelist for the method of assigning participants, or subjects, to groups or categories within a clinical study.	
C199649	Pharmacology Attribute Terminology	Pharmacology Attribute Terminology	A terminology value set relevant to the attributes of the pharmacology entity.	
C132308	Physical Address Attribute Terminology	Physical Address Attribute Terminology	A terminology value set relevant to the attributes of the physical address entity.	
C181167	Protocol Amendment Attribute Terminology	Protocol Amendment Attribute Terminology	A terminology value set relevant to the attributes of the protocol amendment.	
C154681	Protocol Contact Role Value Set	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	Protocol Entity Terminology	Protocol Entity Terminology	A terminology value set relevant to the entities within a protocol.	
C181168	Protocol Statement Attribute Terminology	Protocol Statement Attribute Terminology	A terminology value set relevant to the attributes of the protocol statement.	
C147069	Randomization Type Value Set	Randomization Type Value Set	A terminology codelist relevant to the types of randomization schemas associated with a randomized controlled trial.	
C184333	Reference Attribute Terminology	Reference Attribute Terminology	A terminology value set relevant to the attributes of the reference.	
C190866	Study Activity Attribute Terminology	Study Activity Attribute Terminology	A terminology value set relevant to the attributes of the study activity entity.	
C172329	Study Arm Attribute Terminology	Study Arm Attribute Terminology	A terminology value set relevant to the attributes of the study arm entity.	
C174222	Study Arm Type Value Set Terminology	Study Arm Type Value Set Terminology	The terminology relevant to the identification of the kind of arm.	
C189268	Study Blinding and Unblinding Attribute Terminology	Study Blinding and Unblinding Attribute Terminology	A terminology value set relevant to the attributes of the study blinding and unblinding entity.	
C154682	Study Contact Information Attribute Terminology	Study Contact Information Attribute Terminology	A terminology value set relevant to the attributes of the study contact information entity.	
C147066	Study Design Attribute Terminology	Study Design Attribute Terminology	A terminology value set relevant to the attributes of the study design entity.	
C163026	Study Monitoring Attribute Terminology	Study Monitoring Attribute Terminology	A terminology value set relevant to the attributes of the study monitoring entity.	
C165640	Study Oversight Entity Attribute Terminology	Study Oversight Entity Attribute Terminology	A terminology value set relevant to the attributes of the study oversight entity.	
C160921	Study Population Attribute Terminology	Study Population Attribute Terminology	A terminology value set relevant to the attributes of the study population entity.	
C177904	Study Product Administration Attribute	Study Product Administration Attribute	A terminology value set relevant to the attributes of the study product administration.	
C174220	Study Product Attribute Terminology	Study Product Attribute Terminology	A terminology value set relevant to the attributes of the study product.	
C174221	Study Product Type Value Set Terminology	Study Product Type Value Set Terminology	The terminology relevant to the identification of the kind of study product.	
C132309	Study Protocol Attribute Terminology	Study Protocol Attribute Terminology	A terminology value set relevant to the attributes of the study protocol entity.	
C147067	Study Purpose Value Set	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	Study Subject Discontinuation Attribute Terminology	Study Subject Discontinuation Attribute Terminology	A terminology value set relevant to the attributes of the subject discontinuation.	
C99077	STYPE	Study Type Response	A terminology codelist relevant to the role the study plays in determining the interventions a subject receives.	No
C185850	Subject Replacement Attribute Terminology	Subject Replacement Attribute Terminology	A terminology value set relevant to the attributes of the subject replacement.	
C197998	Substudy Attribute Terminology	Substudy Attribute Terminology	A terminology value set relevant to the attributes of the substudy entity.	
C66735	TBLIND	Trial Blinding Schema Response	A terminology codelist relevant to the type of blinding for the trial.	Yes
C66736	TINDTP	Trial Intent Type Response	A terminology codelist relevant to the responses for the planned purpose of the therapy, device, or agent under study in the clinical trial.	Yes
C66737	TPHASE	Trial Phase Response	A terminology codelist relevant to the phase, or stage, of the clinical trial.	Yes
C66739	TTYPE	Trial Type Response	A terminology codelist relevant to the type of primary outcome or endpoint that the protocol is designed to evaluate.	Yes

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

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 may exclude a potential subject from participation in a study. (CDISC glossary)	Exclusion Criteria
C25532	Inclusion Criteria		The criteria in a protocol that prospective subjects must meet to be eligible for participation in a study. NOTE: Exclusion and inclusion criteria define the study population. See also exclusion criteria. (CDISC glossary)	Inclusion Criteria
C127796	Planned Trial Duration	Planned Trial Duration	The approximate period of time over which the clinical trial is expected to occur.	Planned Trial Duration
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	Trial Disease/Condition Indication;Trial Disease/Condition Indication Description	The textual representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication
C49652	Trial Intent	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	Clinical Study by Intent
C48281	Trial Phase	Trial Phase;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	A principle objective of the study.	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	An auxiliary objective of the study.	Trial Secondary Objective
C85838	Trial Site	Investigative Site;Investigator Site	Any healthcare organization, institution, facility or provider directly involved in conducting or facilitating a particular clinical trial. (NCI)	Clinical Trial Site
C49660	Trial Type	Trial Scope;Trial Type	The 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	Endpoint Attribute Terminology			
NCI Code	**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: https://www.fda.gov/media/84987/download)	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	Ingredient Attribute Terminology			
NCI Code	**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	INTMODEL			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C82637	CROSS-OVER		Participants receive one of two or more alternative intervention(s) during the initial epoch of the study and receive other intervention(s) during the subsequent epoch(s) of the study.	Crossover Study
C82638	FACTORIAL		Two or more interventions, each alone or in combination, are evaluated in parallel against a control group. This study design allows for the comparison of active drug to placebo, presence of drug-drug interactions, and comparison of active drugs against each other.	Factorial Study
C82639	PARALLEL		Participants are assigned to one of two or more treatment groups in parallel for the duration of the study.	Parallel Study
C142568	SEQUENTIAL		Groups of participants are assigned to receive interventions based on prior milestones being reached in the study. (clinicaltrials.gov)	Group Sequential Design
C82640	SINGLE GROUP		All trial participants are assigned to a single treatment group for the duration of the study.	Single Group Study

INTTYPE (Intervention Type Response)

NCI Code: C99078, Codelist extensible: No

C99078	INTTYPE			
NCI Code	**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
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
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	Introduction of genetic material into cells in order to correct or treat an inherited or acquired disease.	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	OBSSMO			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C15197	CASE CONTROL		A study that compares groups of people with generally similar characteristics, those with the condition under study (case) and those without the condition under study (control).	Case-Control Study
C127779	CASE CROSSOVER		A study in which the subject characteristics of the case, immediately prior to disease onset (sometimes called the hazard period), are compared to characteristics of same case at a prior time (i.e., control period). (ClinicalTrials.gov)	Observational Case-Crossover Study
C15362	CASE ONLY		A study in which the subject with the condition under study (the case) is compared against a theoretical/historical model of distribution that serves as a control.	Case Study
C15208	COHORT		A study in which subjects are grouped based on a predefined personal or administrative characteristic.	Cohort Study
C127780	ECOLOGIC OR COMMUNITY		A study in which geographically distinct study populations are compared with respect to a particular outcome.	Ecologic or Community Based Study
C15407	FAMILY BASED		A study in which related or non-related family members are compared with respect to a particular outcome.	Family Study

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

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	Pharmacogenetics	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 building number where an entity is 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	Protocol Contact Role Value Set			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C154709	Biostatistician		A person who is responsible for the statistical aspects of the clinical or pre-clinical study. (NCI)	Biostatistician
C154708	Clinical Informaticist	Clinical Informatician	An individual that designs, implements, evaluates and/or analyzes information technology in a healthcare or research setting. (NCI)	Clinical Informaticist
C51811	Clinical Research Coordinator	CRC	A person to whom a clinical investigator delegates routine administrative requirements of a protocol. The duties and responsibilities of a clinical research coordinator may vary across different infrastructures. Generally, the coordinator manages the subject's clinical trial participation and provides a vital linkage between the subject, the investigator, and the sponsor. (NCI)	Clinical Coordinator
C127526	Contact for Public Queries		The study contact person who is responsible for questions from the public.	Public Queries Study Contact
C51818	Coordinating Investigator		An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multi-center trial. While a single-center study would not include a coordinating investigator, the investigator at the site would fulfill the same responsibilities as a principal investigator. (after ICH E6)	Coordinating Investigator
C51820	Data Manager		An individual who is responsible for the development and implementation of architectures, policies and procedures for the effective management of data across its business lifecycle.	Data Manager
C25936	Investigator		A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at the trial site, the investigator is the responsible leader of the team and may be called the principal investigator.	Investigator
C127532	Legal Representative for the Study		An individual with expertise in the law who provides legal counsel and representation for a study.	Legal Representative for the Study
C51836	Medical Monitor		A sponsor representative who has medical authority for the evaluation of the safety aspects of a clinical trial. (CDISC Glossary)	Medical Monitor
C154706	National Coordinating Investigator		In the case of a multinational study, a person who has the responsibilities of the sponsor of the study in his/her country and will be responsible for the coordination of the principal investigators at different sites within that member state. (EMA)	National Coordinating Investigator
C70794	Primary Sponsor		The individual, organization, group or other legal person taking responsibility for securing the arrangements to initiate and/or manage a study (including arrangements to ensure that the study design meets appropriate standards and to ensure appropriate conduct and reporting). In commercial trials, the primary sponsor is normally the main applicant for regulatory authorization to begin the study. It may or may not be the main funder. (NCI)	Primary Clinical Study Sponsor
C19924	Principal Investigator		A person who has the primary responsibility for the conduct of a clinical study and study-related personnel at a study site. While a single-center study would not include a coordinating investigator, the investigator at the site would fulfill the same responsibilities as a principal investigator.	Principal Investigator
C70795	Secondary Sponsor		Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed to take on all the responsibilities of sponsorship jointly with the primary sponsor; or to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or to act as the sponsor's legal representative in relation to some or all of the study sites; or to take responsibility for the accuracy of study registration information submitted.	Secondary Clinical Study Sponsor
C70793	Sponsor	Clinical Study Sponsor;Sponsor;Study Sponsor	An 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	Protocol Entity Terminology			
NCI Code	**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
C15206	Clinical Study		A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [ClinicalTrials.gov] See also clinical trial. (CDISC Glossary)	Clinical Study
C71104	Clinical Trial		1) A research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device). 2) A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.(1. modified from ICH E6 Glossary, Directive 2001/20/EC. 2. NIH revised definition 2015) (CDISC Glossary)	Clinical Trial
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
C16735	Informed Consent		Consent given by a subject, or in the case of an individual that can only give assent, by a parent or legal guardian, for the participation in a clinical study only after having achieved an understanding of both the relevant medical facts and the relevant risks involved.	Informed Consent
C51981	Ingredient		Any component that constitutes a part of a compound or mixture.	Ingredient
C25218	Intervention		The drug, device, therapy, 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 https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5224]	Intervention or Procedure
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		Events or experiences that clinicians or investigators examining the impact of an intervention or exposure measure because they believe such events or experiences may be influenced by the research intervention or exposure. Outcome is a general term in that it does not necessarily relate to a planned objective of the study. (FDA)	Outcome
C25407	Physical Address		A standardized representation of the location of a person, business, building, or organization. (NCI)	Address
C16974	Pharmacology	Pharmacology	The study of characteristics, effects, and uses of drugs and their interactions with living organisms.	Pharmacology
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 plan detailing how a study will be performed in order to represent the phenomenon under examination, to answer the research questions that have been asked, and informing the statistical approach.	Study Design
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	Randomization Type Value Set			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C147126	Adaptive Randomization		A type of randomization schema in which the group assignment probability of a 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	Reference Attribute Terminology			
NCI Code	**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	Study Arm Attribute Terminology			
NCI Code	**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	The textual representation of the arm for the study.	Arm Description
C172456	Study Arm Label	Arm Label	The given name of the arm for the study. (NCI)	Study Arm Label
C172457	Study Arm Type	Arm Type	The identification of the kind of arm(s) for the study. (NCI)	Study Arm Type

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

NCI Code: C174222, Codelist extensible:

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		An arm describing the intervention or treatment plan for a group of participants in the study. Treatment may consist of either experimental or control products under investigation.	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		A study event during which the treatment assignment is made known to the subject, investigator, and/or other trial personnel.	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	Summary description of the overall study plan and design, should include treatments studied, population studied, level and method of blinding/unmasking, kind of controls, method of assignment to treatment, sequence and duration of study periods, any safety, data monitoring or special steering or evaluation committees, and interim analyses. (ICH E3)	Study Design Description
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 to be entered in a clinical trial. (NCI)	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 made to explain certain observations or facts, which requires further investigation or exploration within a clinical study. (NCI)	Research Hypothesis
C147141	Study Primary Purpose		The principal reason or intention for the execution of an interventional or non-interventional clinical study. (NCI)	Study Primary Purpose
C147142	Study Secondary Purpose		The ancillary reason or intention for the execution of an interventional or non-interventional clinical study. (NCI)	Study Secondary Purpose

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**
C115753	Clinical Monitoring Plan		A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial. (ICH E6(R2) Glossary Addendum)	Clinical Trial 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		A systematic, prioritized approach that involves identifying, assessing, monitoring and mitigating the risks that could affect the quality of the study or safety of the study participants.	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 study population that is defined for the purpose of comparison to the treatment group in a controlled trial. In an epidemiological study, a study population that does 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	An individual who is or becomes a participant in a research study and has no significant health-related issues. (NCI)	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 population within the general population for 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	The physical form in which active and/or inert ingredient(s) are presented.	Pharmaceutical Dosage Form
C142516	Dosage Regimen		The schedule of doses of a therapeutic agent per unit of time, including: the time between doses (e.g., every 6 hours) or the time when the dose(s) are to be given (e.g., at 8 a.m. and 4 p.m. daily), and the amount of a medicine (e.g., number of capsules) to be given at each specific time. (Segen's Medical Dictionary)	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 pathway by which a substance is administered in order to reach the site of action in the body.	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 material (such as a drug, biologic, or device) produced by or resulting from a process, which is being tested in a study. This may also include 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]	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.	Official Protocol Title
C132347	Protocol Amendment		A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)	Protocol Amendment
C51853	Protocol Author		A person who is the writer of a structured research study protocol.	Protocol Author
C115628	Protocol Synopsis	Protocol Scientific Summary	A scientific summary of the key points of the protocol.	Clinical Trial Protocol Synopsis
C94105	Public Protocol Title		The descriptive name of the protocol that is intended for the lay public, written in easily understood language.	Study Protocol Document Version Public Title
C132348	Registry Protocol Identifier		A unique code assigned by a clinical trial registry that identifies a specific protocol.	Registry Protocol Identifier
C132349	Schedule of Activities	Schedule of Events;SoA	A standardized representation of planned clinical trial activities including interventions (e.g., administering drug, surgery) and study administrative activities (e.g., obtaining informed consent, distributing clinical trial material and diaries, randomization) as well as assessments. (CDISC Glossary)	Schedule of Activities
C132350	Scientific Protocol Title		A more extensive descriptive name of the protocol that is intended for medical professionals, written using medical and scientific language.	Scientific Protocol Title
C132351	Sponsor Protocol Identifier	Sponsor Protocol Code;Sponsor Protocol Number	A unique code assigned by the sponsor that identifies a specific protocol.	Sponsor Protocol Identifier
C94108	Study Acronym	Trial Acronym	A word or words formed from the beginning letters or a combination of syllables and letters of a compound term, which identifies a clinical study.	Study Protocol Version Acronym
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	Study Purpose Value Set			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C15714	Basic Science	Basic Research	A type of study designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. (ClinicalTrials.gov)	Basic Research
C139174	Device Feasibility		An intervention of a device product is being evaluated to determine the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. (ClinicalTrials.gov)	Device Feasibility Study
C15220	Diagnosis	Diagnostic	The investigation, analysis and recognition of the presence and nature of disease, condition, or injury from expressed signs and symptoms; also, the scientific determination of any kind; the concise results or summary of such an investigation. (NCI)	Diagnosis
C147146	Exploratory Research		Any action or process to perform research on a hypothetical or theoretical idea in order to determine whether the phenomena is new (which may lead to additional studies) or can be explained by an existing and well-substantiated theory. (NCI)	Exploratory Research
C15245	Health Services Research		A type of study designed to evaluate the delivery, processes, management, organization or financing of health care. (ClinicalTrials.gov)	Health Services Research
C147147	Hypothesis Generation		Any action or process to create a tentative proposal to explain certain observations or facts, and which requires further investigation to be verified. (NCI)	Hypothesis Generation
C15843	Prevention	Prophylaxis	Any action or response to modify or stop the development of a disease.	Preventive Intervention
C15419	Screening		Any action or process to identify a condition, or risk factors for a condition, in humans who are not yet known to have the condition or risk factor. (clinicaltrials.gov)	Disease Screening
C15747	Supportive Care		Any action or process to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. (clinicaltrials.gov)	Supportive Care
C70742	Treatment		Any action or process to improve or remedy a syndrome, disease, or condition.	Treat

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	STYPE			
NCI Code	**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		Studies in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.	Observational Study
C129000	PATIENT REGISTRY		Observational studies which include an organized system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, health care services, and/or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single purpose or on-going data collection programs that address one or more questions. (AHRQ)	Patient Registry Study

Subject 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	Substudy Attribute Terminology			
NCI Code	**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	TBLIND			
NCI Code	**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	TINDTP			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C15714	BASIC SCIENCE	Basic Research	A type of study designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. (ClinicalTrials.gov)	Basic Research
C49654	CURE		A type of study designed to evaluate intervention(s) aimed to cure a disease or condition.	Cure Study
C139174	DEVICE FEASIBILITY		An intervention of a device product is being evaluated to determine the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. (ClinicalTrials.gov)	Device Feasibility Study
C49653	DIAGNOSIS		A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.	Diagnosis Study
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	TPHASE			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C54721	PHASE 0 TRIAL	0;Pre-clinical Trial;Trial Phase 0	First-in-human trials, in a small number of subjects, that are conducted before Phase 1 trials and are intended to assess new candidate therapeutic and imaging agents. The study agent is administered at a low dose for a limited time, and there is no therapeutic or diagnostic intent. NOTE: FDA Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies, January 2006 classifies such studies as Phase 1. NOTE: A Phase 0 study might not include any drug delivery but may be an exploration of human material from a study (e.g., tissue samples or biomarker determinations). [Improving the Quality of Cancer Clinical Trials: Workshop summary-Proceedings of the National Cancer Policy Forum Workshop, improving the Quality of Cancer Clinical Trials (Washington, DC, Oct 2007)] (CDISC glossary)	Phase 0 Trial
C15600	PHASE I TRIAL	1;Trial Phase 1	The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. NOTE: These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase I studies varies with the drug, but is generally in the range of 20 to 80. Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. [After FDA CDER Handbook, ICH E8] (CDISC glossary)	Phase I Trial
C15693	PHASE I/II TRIAL	1-2;Trial Phase 1-2	A class of clinical study that combines elements characteristic of traditional Phase I and Phase II trials. See also Phase I, Phase II.	Phase I/II Trial
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	A clinical research protocol generally referred to as a pilot or feasibility trial that aims to prove the concept of the new intervention in question. (NCI)	Phase IIa Trial
C49688	PHASE IIB TRIAL	2B;Trial Phase 2B	A clinical research protocol generally referred to as a well-controlled and pivotal trial that aims to prove the mechanism of action of the new intervention in question. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind. (NCI)	Phase IIb Trial
C15602	PHASE III TRIAL	3;Trial Phase 3	Phase 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	A subcategory of Phase III trials done near the time of approval to elicit additional findings. NOTE: Dossier review may continue while associated Phase IIIB trials are conducted. These trials may be required as a condition of regulatory authority approval.	Phase IIIb Trial
C15603	PHASE IV TRIAL	4;Trial Phase 4	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

TTYPE (Trial Type Response)

NCI Code: C66739, Codelist extensible: Yes

C66739	TTYPE			
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
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