CDISC DDF Controlled Terminology, 2023-09-29

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

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
C171445	CNTMODE	Mode of Subject Contact	Terminology relevant to the means by which interaction occurs between the subject and person or entity.	Yes
C188714	DDF Activity Attribute Terminology	DDF Activity Attribute Terminology	A terminology value set relevant to the attributes of the activity.	
C201253	DDF Address Attribute Terminology	DDF Address Attribute Terminology	A terminology value set relevant to the attributes of the address.	
C188720	DDF Analysis Population Attribute Terminology	DDF Analysis Population Attribute Terminology	A terminology value set relevant to the attributes of the analysis population.	
C201254	DDF Biomedical Concept Attribute Terminology	DDF Biomedical Concept Attribute Terminology	A terminology value set relevant to the attributes of the biomedical concept.	
C201255	DDF Biomedical Concept Category Attribute Terminology	DDF Biomedical Concept Category Attribute Terminology	A terminology value set relevant to the attributes of the biomedical concept category.	
C201256	DDF Biomedical Concept Property Attribute Terminology	DDF Biomedical Concept Property Attribute Terminology	A terminology value set relevant to the attributes of the biomedical concept property.	
C201257	DDF Biomedical Concept Surrogate Attribute Terminology	DDF Biomedical Concept Surrogate Attribute Terminology	A terminology value set relevant to the attributes of the biomedical concept surrogate.	
C188699	DDF Clinical Study Attribute Terminology	DDF Clinical Study Attribute Terminology	A terminology value set relevant to the attributes of the clinical study.	
C188722	DDF Code Attribute Terminology	DDF Code Attribute Terminology	A terminology value set relevant to the attributes of the code.	
C188713	DDF Encounter Attribute Terminology	DDF Encounter Attribute Terminology	A terminology value set relevant to the attributes of the encounter.	
C188708	DDF Endpoint Attribute Terminology	DDF Endpoint Attribute Terminology	A terminology value set relevant to the attributes of the endpoint.	
C188698	DDF Entity Terminology	DDF Entity Terminology	A terminology value set relevant to the entities within the CDISC digital data flow (DDF) model.	
C188719	DDF Estimand Attribute Terminology	DDF Estimand Attribute Terminology	A terminology value set relevant to the attributes of the estimand.	
C188705	DDF Indication Attribute Terminology	DDF Indication Attribute Terminology	A terminology value set relevant to the attributes of the disease indication.	
C188721	DDF Intercurrent Event Attribute Terminology	DDF Intercurrent Event Attribute Terminology	A terminology value set relevant to the attributes of the intercurrent event.	
C188704	DDF Investigational Interventions Attribute Terminology	DDF Investigational Interventions Attribute Terminology	A terminology value set relevant to the attributes of the investigational interventions.	
C188707	DDF Objective Attribute Terminology	DDF Objective Attribute Terminology	A terminology value set relevant to the attributes of the objective.	
C188702	DDF Organization Attribute Terminology	DDF Organization Attribute Terminology	A terminology value set relevant to the attributes of the organization.	
C188716	DDF Procedure Attribute Terminology	DDF Procedure Attribute Terminology	A terminology value set relevant to the attributes of the procedure.	
C201258	DDF Response Code Attribute Terminology	DDF Response Code Attribute Terminology	A terminology value set relevant to the attributes of the response code.	
C201260	DDF Scheduled Decision Instance Attribute Terminology	DDF Scheduled Decision Instance Attribute Terminology	A terminology value set relevant to the attributes of the scheduled decision instance.	
C201261	DDF Scheduled Instance Attribute Terminology	DDF Scheduled Instance Attribute Terminology	A terminology value set relevant to the attributes of the scheduled instance.	
C201259	DDF Schedule Timeline Attribute Terminology	DDF Schedule Timeline Attribute Terminology	A terminology value set relevant to the attributes of the schedule timeline.	
C188709	DDF Study Arm Attribute Terminology	DDF Study Arm Attribute Terminology	A terminology value set relevant to the attributes of the study Arm.	
C188703	DDF Study Design Attribute Terminology	DDF Study Design Attribute Terminology	A terminology value set relevant to the attributes of the study design.	
C188706	DDF Study Design Population Attribute Terminology	DDF Study Design Population Attribute Terminology	A terminology value set relevant to the attributes of the study design population.	
C188711	DDF Study Element Attribute Terminology	DDF Study Element Attribute Terminology	A terminology value set relevant to the attributes of the study element.	
C188710	DDF Study Epoch Attribute Terminology	DDF Study Epoch Attribute Terminology	A terminology value set relevant to the attributes of the study epoch.	
C188701	DDF Study Identifier Attribute Terminology	DDF Study Identifier Attribute Terminology	A terminology value set relevant to the attributes of the study identifier.	
C188700	DDF Study Protocol Version Attribute Terminology	DDF Study Protocol Version Attribute Terminology	A terminology value set relevant to the attributes of the study protocol version.	
C201262	DDF Timing Attribute Terminology	DDF Timing Attribute Terminology	A terminology value set relevant to the attributes of the timing.	
C188712	DDF Transition Rule Attribute Terminology	DDF Transition Rule Attribute Terminology	A terminology value set relevant to the attributes of the transition rule.	
C188728	Encounter Type Value Set Terminology	Encounter Type Value Set Terminology	The terminology relevant to the encounter type.	
C188726	Endpoint Level Value Set Terminology	Endpoint Level Value Set Terminology	The terminology relevant to the endpoint level.	
C99079	EPOCH	Epoch	The name of the EPOCH.	Yes
C99076	INTMODEL	Intervention Model Response	A terminology codelist relevant to the trial design developed to compare treatment groups.	Yes
C188725	Objective Level Value Set Terminology	Objective Level Value Set Terminology	The terminology relevant to the objective level.	
C188724	Organization Type Value Set Terminology	Organization Type Value Set Terminology	The terminology relevant to the organization type.	
C188723	Protocol Status Value Set Terminology	Protocol Status Value Set Terminology	The terminology relevant to the protocol status.	
C127262	SETTING	Environmental Setting	Terminology relevant to the surroundings or environment.	Yes
C66732	SEXPOP	Sex of Participants Response	A terminology codelist relevant to the specific sex, either male, female, or mixed of the subject group being studied.	No
C188727	Study Arm Data Origin Type Value Set Terminology	Study Arm Data Origin Type Value Set Terminology	The terminology relevant to the study arm data origin type.	
C174222	Study Arm Type Value Set Terminology	Study Arm Type Value Set Terminology	The terminology relevant to the identification of the kind of arm.	
C99077	STYPE	Study Type Response	A terminology codelist relevant to the role the study plays in determining the interventions a subject receives.	No
C66735	TBLIND	Trial Blinding Schema Response	A terminology codelist relevant to the type of blinding for the trial.	Yes
C201265	Timing Relative To From Value Set Terminology	Timing Relative To From Value Set Terminology	The terminology relevant to the timing relative to from value set.	
C201264	Timing Type Value Set Terminology	Timing Type Value Set Terminology	The terminology relevant to the timing type value set.	
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

CNTMODE (Mode of Subject Contact)

NCI Code: C171445, Codelist extensible: Yes

C171445	CNTMODE			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25170	E-MAIL	Electronic Mail	Composing, sending, and receiving messages over electronic communication systems.	E-mail
C175574	IN PERSON	In-Person	An interaction that takes place in the physical presence of someone else.	In Person
C177933	IVRS	Interactive Voice Response System	A type of automated system in which individuals can access information menus containing pre-recorded or dynamically generated information with voice prompts, without the need for an agent or operator.	Interactive Voice Response System
C70805	LETTER		A written message addressed to a person or organization.	Letter
C171525	REMOTE AUDIO VIDEO		A form of remote communication by audio video technology.	Audio-Videoconferencing
C171524	REMOTE AUDIO		A form of remote communication by audio technology.	Audioconferencing
C171533	SHIPMENT CONFIRMED BY SIGNATURE		Receipt of shipped material was confirmed by signature.	Shipment Confirmed by Signature
C171537	TELEPHONE CALL		Communication by way of telephone.	Telephone Call
C157352	TEXT MESSAGE		A short electronic communication, usually sent and received by a mobile phone.	Text Message

DDF Activity Attribute Terminology (DDF Activity Attribute Terminology)

NCI Code: C188714, Codelist extensible:

C188714	DDF Activity Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C70960	Clinical Study Activity Description		The textual representation of the study activity.	Clinical Study Activity Description
C188842	Clinical Study Activity Name		The literal identifier (i.e., distinctive designation) of the clinical study activity.	Clinical Study Activity Name
C201308	Study Activity is Conditional Reason		The explanation for why the study activity is subject to or dependent upon something else.	Study Activity is Conditional Reason
C201307	Study Activity is Conditional		An indication as to whether the study activity is subject to or dependent upon something else.	Study Activity is Conditional Indicator
C201310	Study Activity is Optional Reason		The explanation for why the study activity is available to be performed but is not obligatory.	Study Activity is Optional Reason
C201309	Study Activity is Optional		An indication as to whether the study activity is available to be performed but is not obligatory.	Study Activity is Optional Indicator

DDF Address Attribute Terminology (DDF Address Attribute Terminology)

NCI Code: C201253, Codelist extensible:

C201253	DDF Address Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201311	Address Full Text		A standardized representation of the complete set of components denoting the physical address of the person, business, building, or organization.	Address Full Text
C25690	Address Line		The street name and number, building number, apartment or unit number, or post office box number where an entity is physically located.	Street Address
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
C176229	District		An administrative or territorial division of a city, town, county, parish, state, country, or other locality based on a shared characteristic.	District
C25621	Postal Code		An alphanumeric code assigned to a mail delivery area.	Postal Code
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

DDF Analysis Population Attribute Terminology (DDF Analysis Population Attribute Terminology)

NCI Code: C188720, Codelist extensible:

C188720	DDF Analysis Population Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188854	Target Study Population for Analysis Description		The textual representation of the study population for analysis.	Target Study Population for Analysis Description

DDF Biomedical Concept Attribute Terminology (DDF Biomedical Concept Attribute Terminology)

NCI Code: C201254, Codelist extensible:

C201254	DDF Biomedical Concept Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201312	Biomedical Concept Name		The literal identifier (i.e., distinctive designation) of the biomedical concept.	Biomedical Concept Name
C201313	Biomedical Concept Reference		A citation to an authoritative source for a biomedical concept.	Biomedical Concept Reference
C201314	Biomedical Concept Synonym		A word or an expression that serves as a figurative, symbolic, or exact substitute for a biomedical concept, and which has the same meaning.	Biomedical Concept Synonym

DDF Biomedical Concept Category Attribute Terminology (DDF Biomedical Concept Category Attribute Terminology)

NCI Code: C201255, Codelist extensible:

C201255	DDF Biomedical Concept Category Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201315	Biomedical Concept Category Code		A symbol or combination of symbols which is assigned to the biomedical concept category.	Biomedical Concept Category Code
C201316	Biomedical Concept Category Description		The textual representation of the biomedical concept category.	Biomedical Concept Category Description
C201317	Biomedical Concept Category Name		The literal identifier (i.e., distinctive designation) of the biomedical concept category.	Biomedical Concept Category Name

DDF Biomedical Concept Property Attribute Terminology (DDF Biomedical Concept Property Attribute Terminology)

NCI Code: C201256, Codelist extensible:

C201256	DDF Biomedical Concept Property Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201318	Biomedical Concept Property Concept Code		A concept unique identifier assigned to a biomedical concept property that points to the meaning of that biomedical concept property.	Biomedical Concept Property Concept Code
C201319	Biomedical Concept Property Response Data Type		The structural format of the biomedical concept property response value. The datatype is carried in the attribute and influences the set of allowable values the attribute may assume. (After HL7)	Biomedical Concept Property Response Data Type

DDF Biomedical Concept Surrogate Attribute Terminology (DDF Biomedical Concept Surrogate Attribute Terminology)

NCI Code: C201257, Codelist extensible:

C201257	DDF Biomedical Concept Surrogate Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201320	Biomedical Concept Surrogate Description		The textual representation of the biomedical concept surrogate.	Biomedical Concept Surrogate Description
C201321	Biomedical Concept Surrogate Reference		A citation to an authoritative source for a biomedical concept surrogate.	Biomedical Concept Surrogate Reference

DDF Clinical Study Attribute Terminology (DDF Clinical Study Attribute Terminology)

NCI Code: C188699, Codelist extensible:

C188699	DDF Clinical Study Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201322	Business Therapeutic Areas		A therapeutic area classification based on the structure and operations of the business unit.	Business Therapeutic Areas
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
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
C49802	Study Title	Official Study Title;Study Title;Trial Title	The sponsor-defined name of the clinical study.	Trial Title
C142175	Study Type Classification	Study Type;Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	Study Type
C188816	Study Version		A plan at a particular point in time for a study.	Study Version
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

DDF Code Attribute Terminology (DDF Code Attribute Terminology)

NCI Code: C188722, Codelist extensible:

C188722	DDF Code Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188859	Code System Name		The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes.	Code System Name
C188868	Code System Version		The version of the code system.	Coding System Version
C188858	Code Value		The literal value of a code.	Code Value
C188861	Decode		Standardized or dictionary-derived human readable text associated with a code.	Decode Text

DDF Encounter Attribute Terminology (DDF Encounter Attribute Terminology)

NCI Code: C188713, Codelist extensible:

C188713	DDF Encounter Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188836	Clinical Encounter Description		The textual representation of the protocol-defined clinical encounter.	Clinical Encounter Description
C171010	Clinical Encounter Name		The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.	Clinical Encounter Name
C188839	Clinical Encounter Type		A characterization or classification of contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed.	Clinical Encounter Type
C188841	Contact Mode		The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).	Contact Mode
C188840	Environmental Setting		The environment/setting where the event, intervention, or finding occurred.	Environmental Setting
C188838	Next Encounter Identifier		A system identifier assigned to a clinical encounter that occurs immediately after the current clinical encounter.	Next Clinical Encounter Identifier
C188837	Previous Encounter Identifier		A system identifier assigned to a clinical encounter that occurs immediately prior to the current clinical encounter.	Previous Clinical Encounter Identifier

DDF Endpoint Attribute Terminology (DDF Endpoint Attribute Terminology)

NCI Code: C188708, Codelist extensible:

C188708	DDF Endpoint Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188824	Study Endpoint Description		The textual representation of the study endpoint.	Study Endpoint Description
C188826	Study Endpoint Level		A characterization or classification of the study endpoint that determines its category of importance relative to other study endpoints.	Study Endpoint Level
C188825	Study Endpoint Purpose Description		The textual representation of the study endpoint purpose.	Study Endpoint Purpose Description

DDF Entity Terminology (DDF Entity Terminology)

NCI Code: C188698, Codelist extensible:

C188698	DDF Entity Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25407	Address		A standardized representation of the location of a person, business, building, or organization. (NCI)	Address
C201344	Alias Code		An alternative symbol or combination of symbols which is assigned to the members of a collection.	Alias Code
C201346	Biomedical Concept Category		A grouping of biomedical concepts based on some commonality or by user defined characteristics.	Biomedical Concept Category
C201345	Biomedical Concept		A unit of biomedical knowledge created from a unique combination of characteristics that include implementation details like variables and terminologies, used as building blocks for standardized, hierarchically structured clinical research information.	Biomedical Concept
C142427	Clinical Encounter		Contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed. Contact may be physical or virtual.	Clinical Encounter
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
C25162	Code		A symbol or combination of symbols which is assigned to the members of a collection.	Code
C188813	Estimand		A precise description of the treatment effect reflecting the clinical question posed by a given clinical trial objective. It summarises at a population level what the outcomes would be in the same patients under different treatment conditions being compared. (ICH E9 R1 Addendum)	Estimand
C188815	Intercurrent Event		An event(s) occurring after treatment initiation that affects either the interpretation or the existence of the measurements associated with the clinical question of interest. (ICH E9 Addendum on Estimands)	Intercurrent Event
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
C19711	Organization		A formalized group of persons or other organizations collected together for a common purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose. (BRIDG)	Professional Organization or Group
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
C201347	Response Code		A symbol or combination of symbols representing the response to the question.	Response Code
C201349	Schedule Timeline Exit		To go out of or leave the schedule timeline.	Schedule Timeline Exit
C201348	Schedule Timeline		A chronological schedule of planned temporal events.	Schedule Timeline
C201350	Scheduled Activity Instance		A scheduled occurrence of an activity event.	Scheduled Activity Instance
C201351	Scheduled Decision Instance		A scheduled occurrence of a decision event.	Scheduled Decision Instance
C201299	Scheduled Instance		A scheduled occurrence of a temporal event.	Scheduled Instance
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
C188810	Study Design Cell		A partitioning of a study arm into individual pieces, which are associated with an epoch and any number of sequential elements within that epoch.	Study Design Cell
C142735	Study Design Element		A basic building block for time within a clinical study comprising the following characteristics: a description of what happens to the subject during the element; a definition of the start of the element; a rule for ending the element.	Trial Design Element
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
C25212	Study 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
C71738	Study Epoch		A named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.	Clinical Trial Epoch
C83082	Study Identifier		A sequence of characters used to identify, name, or characterize the study.	Study Identifier
C142450	Study Objective		The reason for performing a study in terms of the scientific questions to be answered by the analysis of data collected during the study.	Clinical Trial Objective
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
C188814	Target Study Population for Analysis		A target study population on which an analysis is performed. These may be represented by the entire study population, a subgroup defined by a particular characteristic measured at baseline, or a principal stratum defined by the occurrence (or non-occurrence, depending on context) of a specific intercurrent event. (ICH E9 R1 Addendum)	Target Study Population for Analysis
C142728	Target Study Population	Target Population	The population within the general population for which the study results can be generalized.	Target Study Population
C80484	Timing		The chronological relationship between temporal events.	Timing
C82567	Transition Rule		A guide that governs the allocation of subjects to operational options at a discrete decision point or branch (e.g., assignment to a particular arm, discontinuation) within a clinical trial plan.	Transition Rule
C112038	Trial Disease/Condition Indication Description	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

DDF Estimand Attribute Terminology (DDF Estimand Attribute Terminology)

NCI Code: C188719, Codelist extensible:

C188719	DDF Estimand Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188853	Population-Level Summary		A synopsis of the clinical endpoint of interest within the analysis target study population.	Population-Level Summary
C201323	Variable of Interest		The variable identified as the focus for developing the estimand.	Variable of Interest for the Estimand

DDF Indication Attribute Terminology (DDF Indication Attribute Terminology)

NCI Code: C188705, Codelist extensible:

C188705	DDF Indication Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188822	Disease Indication Code		A short sequence of characters that represents the disease indication.	Disease Indication Code
C112038	Trial Disease/Condition Indication Description	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

DDF Intercurrent Event Attribute Terminology (DDF Intercurrent Event Attribute Terminology)

NCI Code: C188721, Codelist extensible:

C188721	DDF Intercurrent Event Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188856	Intercurrent Event Description		The textual representation of the intercurrent event.	Intercurrent Event Description
C188855	Intercurrent Event Name		The literal identifier (i.e., distinctive designation) of the intercurrent event.	Intercurrent Event Name
C188857	Intercurrent Event Strategy		A textual description of the planned strategy to manage and/or mitigate intercurrent events.	Intercurrent Event Strategy

DDF Investigational Interventions Attribute Terminology (DDF Investigational Interventions Attribute Terminology)

NCI Code: C188704, Codelist extensible:

C188704	DDF Investigational Interventions 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
C188821	Investigational Intervention Code		A short sequence of characters that represents the investigational intervention.	Investigational Intervention Code

DDF Objective Attribute Terminology (DDF Objective Attribute Terminology)

NCI Code: C188707, Codelist extensible:

C188707	DDF Objective Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C94090	Study Objective Description		The textual representation of the study objective. (BRIDG)	Study Objective Description
C188823	Study Objective Level		A characterization or classification of the study objective that determines its category of importance relative to other study objectives.	Study Objective Level

DDF Organization Attribute Terminology (DDF Organization Attribute Terminology)

NCI Code: C188702, Codelist extensible:

C188702	DDF Organization Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188819	Identifier Provider Organization Name		The name of the organization that provides the identifier for the entity.	Identifier Provider Organization Name
C93401	Organization Identifier		A unique symbol that establishes identity of the organization. (BRIDG)	Organization Identifier
C93874	Organization Name		A non-unique textual identifier for the organization. (BRIDG)	Organization Name
C188820	Organization Type		A characterization or classification of the formalized group of persons or other organizations collected together for a common purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose.	Organization Type

DDF Procedure Attribute Terminology (DDF Procedure Attribute Terminology)

NCI Code: C188716, Codelist extensible:

C188716	DDF Procedure Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C154626	Procedure Code		A symbol or combination of symbols which is assigned to medical procedure.	Procedure Code
C201324	Procedure Description		The textual representation of the procedure.	Procedure Description
C201325	Procedure Name		The literal identifier (i.e., distinctive designation) of the procedure.	Procedure Name
C188848	Procedure Type		A characterization or classification of the study procedure.	Study Procedure Type
C201327	Study Procedure is Conditional Reason		The explanation for why the study procedure is subject to or dependent upon something else.	Study Procedure is Conditional Reason
C201326	Study Procedure is Conditional		An indication as to whether the study procedure is subject to or dependent upon something else.	Study Procedure is Conditional Indicator
C201329	Study Procedure is Optional Reason		The explanation for why the study procedure is available to be performed but is not obligatory.	Study Procedure is Optional Reason
C201328	Study Procedure is Optional		An indication as to whether the study procedure is available to be performed but is not obligatory.	Study Procedure is Optional Indicator

DDF Response Code Attribute Terminology (DDF Response Code Attribute Terminology)

NCI Code: C201258, Codelist extensible:

C201258	DDF Response Code Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25162	Code		A symbol or combination of symbols which is assigned to the members of a collection.	Code
C201330	Response Code Enabled Indicator		An indication as to whether the response code is activated for use within a given usage context.	Response Code Enabled Indicator

DDF Scheduled Decision Instance Attribute Terminology (DDF Scheduled Decision Instance Attribute Terminology)

NCI Code: C201260, Codelist extensible:

C201260	DDF Scheduled Decision Instance Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201335	Condition Assignments		An allotting or appointment to a set of conditions that are to be met in order to make a logical decision.	Condition Assignments

DDF Scheduled Instance Attribute Terminology (DDF Scheduled Instance Attribute Terminology)

NCI Code: C201261, Codelist extensible:

C201261	DDF Scheduled Instance Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201336	Schedule Sequence Number		A numeral or string of numerals expressing a relative sequence of scheduled temporal events.	Schedule Sequence Number
C201337	Scheduled Instance Type		A characterization or classification of the scheduled instance.	Scheduled Instance Type

DDF Schedule Timeline Attribute Terminology (DDF Schedule Timeline Attribute Terminology)

NCI Code: C201259, Codelist extensible:

C201259	DDF Schedule Timeline Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201331	Main Timeline Indicator		An indication as to whether the timeline or timeline component is part of the central or principal timeline.	Main Timeline Indicator
C201332	Schedule Timeline Description		The textual representation of the schedule timeline.	Schedule Timeline Description
C201333	Schedule Timeline Entry Condition		A logical evaluation on which rests the validity of entry into a schedule timeline.	Schedule Timeline Entry Condition
C201334	Schedule Timeline Name		The literal identifier (i.e., distinctive designation) of the schedule timeline.	Schedule Timeline Name

DDF Study Arm Attribute Terminology (DDF Study Arm Attribute Terminology)

NCI Code: C188709, Codelist extensible:

C188709	DDF Study Arm Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188828	Study Arm Data Origin Description		The textual representation of the study arm data origin.	Study Arm Data Origin Description
C188829	Study Arm Data Origin Type		A characterization or classification of the study arm with respect to where the study arm data originates.	Study Arm Data Origin Type
C93728	Study Arm Description	Arm Description	The textual representation of the arm for the study.	Arm Description
C170984	Study Arm Name		The literal identifier (i.e., distinctive designation) of the study arm.	Planned Study Arm Name
C172457	Study Arm Type	Arm Type	A characterization or classification of the study arm.	Study Arm Type

DDF Study Design Attribute Terminology (DDF Study Design Attribute Terminology)

NCI Code: C188703, Codelist extensible:

C188703	DDF Study Design Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C98746	Intervention Model Type	Intervention Model	The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov)	Intervention Model
C147139	Study Design Description	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
C201338	Study Design Name		The literal identifier (i.e., distinctive designation) of the study design.	Study Design Name
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
C101302	Therapeutic Areas	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
C49658	Trial 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
C49652	Trial Intent Type	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	Clinical Study by Intent
C49660	Trial Type	Trial Scope;Trial Type	The nature of the interventional study for which information is being collected.	Trial Type

DDF Study Design Population Attribute Terminology (DDF Study Design Population Attribute Terminology)

NCI Code: C188706, Codelist extensible:

C188706	DDF Study Design Population Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49694	Planned Maximum Age of Subjects	Planned Maximum Age of Subjects	The anticipated maximum age of the subjects to be entered in a clinical trial. (NCI)	Planned Maximum Age of Subjects
C49693	Planned Minimum Age of Subjects	Planned Minimum Age of Subjects	The anticipated minimum age of the subjects to be entered in a clinical trial. (NCI)	Planned Minimum Age of Subjects
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
C49696	Sex of Participants	Sex of Participants	The specific sex, either male, female, or mixed of the subject group being studied. (NCI)	Sex of Study Group
C70834	Target Study Population Description		The textual representation of the study population.	Study Population Description

DDF Study Element Attribute Terminology (DDF Study Element Attribute Terminology)

NCI Code: C188711, Codelist extensible:

C188711	DDF Study Element Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188834	Study Design Element Description		The textual representation of the study design element.	Study Design Element Description
C188833	Study Design Element Name		The literal identifier (i.e., distinctive designation) of the study design element.	Study Design Element Name
C201339	Transition End Rule		A criterion that establishes the end of a subject transition within a study workflow.	Transition End Rule
C201340	Transition Start Rule		A criterion that establishes the beginning of a subject transition within a study workflow.	Transition Start Rule

DDF Study Epoch Attribute Terminology (DDF Study Epoch Attribute Terminology)

NCI Code: C188710, Codelist extensible:

C188710	DDF Study Epoch Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188832	Next Epoch Identifier		A system identifier assigned to the epoch that occurs immediately after the current epoch.	Next Epoch Identifier
C188831	Previous Epoch Identifier		A system identifier assigned to the epoch that occurs immediately prior to the current epoch.	Previous Epoch Identifier
C93824	Study Epoch Description		The textual representation of the study epoch.	Epoch Description
C93825	Study Epoch Name		The literal identifier (i.e., distinctive designation) of the study epoch, i.e., the named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.	Epoch Name
C188830	Study Epoch Type		A characterization or classification of the study epoch, i.e., the named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.	Study Epoch Type

DDF Study Identifier Attribute Terminology (DDF Study Identifier Attribute Terminology)

NCI Code: C188701, Codelist extensible:

C188701	DDF Study Identifier Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C83082	Study Identifier		A sequence of characters used to identify, name, or characterize the study.	Study Identifier

DDF Study Protocol Version Attribute Terminology (DDF Study Protocol Version Attribute Terminology)

NCI Code: C188700, Codelist extensible:

C188700	DDF Study Protocol Version Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
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
C188818	Protocol Status		A condition of the protocol at a point in time with respect to its state of readiness for implementation.	Study Protocol Status
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
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
C188817	Study Protocol Amendment Effective Date		The date and time specifying when the protocol amendment takes effect or becomes operative.	Study Protocol Amendment Effective Date
C132347	Study Protocol Amendment		A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)	Protocol Amendment
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

DDF Timing Attribute Terminology (DDF Timing Attribute Terminology)

NCI Code: C201262, Codelist extensible:

C201262	DDF Timing Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C164648	Timing Description		The textual representation of the chronological relationship between temporal events.	Timing Description
C201297	Timing Relative To From		The name of the reference event used to define the temporal relationship with another event.	Timing Relative To From Name
C201298	Timing Type		A characterization or classification of the chronological relationship between temporal events.	Timing Type
C201341	Timing Value		The temporal value of the chronological relationship between temporal events.	Timing Value
C48921	Timing Window		A time period, or other type of interval, during which a temporal event may be achieved, obtained, or observed.	Window
C201342	Timing Window, Lower		The earliest chronological value of an allowable period of time during which a temporal event takes place.	Lower Timing Window
C201343	Timing Window, Upper		The latest chronological value of an allowable period of time during which a temporal event takes place.	Upper Timing Window

DDF Transition Rule Attribute Terminology (DDF Transition Rule Attribute Terminology)

NCI Code: C188712, Codelist extensible:

C188712	DDF Transition Rule Attribute Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188835	Transition Rule Description		The textual representation of the transition rule.	Transition Rule Description

Encounter Type Value Set Terminology (Encounter Type Value Set Terminology)

NCI Code: C188728, Codelist extensible:

C188728	Encounter Type Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25716	Visit		The act of going to see some person or place or thing; it can cover a short or long period but refers to a non-permanent arrangement.	Visit

Endpoint Level Value Set Terminology (Endpoint Level Value Set Terminology)

NCI Code: C188726, Codelist extensible:

C188726	Endpoint Level Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
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

EPOCH (Epoch)

NCI Code: C99079, Codelist extensible: Yes

C99079	EPOCH			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C125938	BASELINE		A period in a clinical study after eligibility has been met and before the start of treatment, at which baseline measurements are collected.	Baseline Epoch
C102255	BLINDED TREATMENT		A period in a clinical study during which subjects receive blinded therapeutic treatment.	Blinded Treatment Epoch
C123452	CONTINUATION TREATMENT	Continuation Phase	A period in a clinical study during which subjects receive continuation treatment.	Continuation Therapy Epoch
C99158	FOLLOW-UP		A period in a clinical study during which information about the health status of an individual is obtained after study interventions have concluded.	Clinical Study Follow-up
C123453	INDUCTION TREATMENT	Induction Phase;Intensive Phase	A period in a clinical study during which subjects receive induction treatment.	Induction Therapy Epoch
C16032	LONG-TERM FOLLOW-UP		A period in a clinical study during which information about the health status of an individual is obtained long after study interventions have concluded.	Long-term Follow-up
C165873	OBSERVATION		A period in a clinical study during which subjects are observed, without any planned intervention.	Observation Study Epoch
C102256	OPEN LABEL TREATMENT		A period in a clinical study during which subjects receive open label therapeutic treatment.	Open Label Treatment Epoch
C199844	PRE-SCREENING		A period in a clinical study during which subjects are evaluated prior to entering the full screening period.	Pre-Screening Epoch
C98779	RUN-IN		A period in a clinical study that occurs after screening and before randomization, during which the subject is further evaluated and/or prepared for the commencement of the clinical study investigation.	Run-in Period
C48262	SCREENING		A period in a clinical study during which subjects are evaluated for participation in the study.	Trial Screening
C101526	TREATMENT		A period in a study during which subjects are receiving investigational therapy or treatment.	Treatment Epoch
C42872	WASHOUT		A period of time during a study when a subject is taken off of the investigational therapy or treatment in order to reduce the amount of investigational product within the body.	Washout Period

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

Objective Level Value Set Terminology (Objective Level Value Set Terminology)

NCI Code: C188725, Codelist extensible:

C188725	Objective Level Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C85826	Study Primary Objective	Study Primary Objective;Trial Primary Objective	A principle objective of the study.	Trial Primary Objective
C85827	Study Secondary Objective	Study Secondary Objective;Trial Secondary Objective	An auxiliary objective of the study.	Trial Secondary Objective

Organization Type Value Set Terminology (Organization Type Value Set Terminology)

NCI Code: C188724, Codelist extensible:

C188724	Organization Type Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C93453	Clinical Study Registry		An organization (typically a government agency) that administers the registration of studies. (BRIDG)	Study Registry
C70793	Clinical Study 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
C188863	Regulatory Agency	Regulator;Regulatory Body	An organization (typically a government agency) that is responsible for implementing and enforcing laws, licensing and regulating products and services, promoting the use of standards, and ensuring safety and consumer protections.	Regulatory Agency

Protocol Status Value Set Terminology (Protocol Status Value Set Terminology)

NCI Code: C188723, Codelist extensible:

C188723	Protocol Status Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25425	Approved		Acceptance as satisfactory by an authoritative body; established by authority; given authoritative approval.	Approval
C85255	Draft		A preliminary version of a written work, design, or picture.	Draft
C25508	Final		Conclusive in a process or progression.	Final
C63553	Obsolete		No longer in use or valid; old.	Obsolete
C188862	Pending Review	Draft Pending Review	A preliminary version of a written work, design, or picture that is awaiting review.	Pending Review

SETTING (Environmental Setting)

NCI Code: C127262, Codelist extensible: Yes

C127262	SETTING			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C127785	CHILD CARE CENTER		An establishment that provides care for infants and children.	Childcare Center
C51282	CLINIC		A health care facility where subjects or patients may receive assessments, procedures, or treatments that are provided by physicians and other healthcare providers.	Clinic
C48953	FARM		A tract of land cultivated for the purpose of agricultural production or devoted to the raising and breeding of domestic animals.	Farm
C102650	FIELD		A setting outside the clinic or a comparable health care facility, e.g. a doctor's office, the subject's home or workplace, a school, a public park, or a restaurant.	In the Field
C21541	HEALTH FACILITY		The buildings and organizations where healthcare services are provided.	Healthcare Facility
C18002	HOME		A person's place of residence.	Home
C16696	HOSPITAL		An institution that provides medical, surgical, or psychiatric care and treatment for the sick or the injured.	Hospital
C102647	HOUSEHOLD ENVIRONMENT		The area in which an individual lives.	Household Environment
C41206	INSTITUTION		An established society, corporation, foundation or other organization founded and united for a specific purpose, e.g. for health-related research; also used to refer to a building or buildings occupied or used by such organization.	Institution
C181529	MOTOR VEHICLE		A motorized conveyance for people and goods.	Motor Vehicle
C102679	NON-HOUSEHOLD ENVIRONMENT		An area outside of that in which an individual lives.	Non-household Environment
C181530	NOT IN CLINIC		Any environmental setting outside of a clinic.	Not In Clinic
C16281	OUTPATIENT CLINIC		A medical care center that provides healthcare services on an outpatient basis.	Ambulatory Care Facility
C85862	PRISON		An institution where persons are confined for punishment and to protect the public.	Correctional Institution
C17118	SCHOOL		An educational institution.	School
C85863	SHELTER		Temporary housing for displaced or at-risk persons.	Shelter
C102712	SOCIAL SETTING		The surroundings or environment in which social activities occur.	Social Setting
C17556	WORKSITE		Place or physical location of work or employment.	Worksite

SEXPOP (Sex of Participants Response)

NCI Code: C66732, Codelist extensible: No

C66732	SEXPOP			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49636	BOTH		One and the other; relating to or being two in conjunction. (NCI)	Both
C16576	F	Female	A person who belongs to the sex that normally produces ova. The term is used to indicate biological sex distinctions, or cultural gender role distinctions, or both. (NCI)	Female
C20197	M	Male	A person who belongs to the sex that normally produces sperm. The term is used to indicate biological sex distinctions, cultural gender role distinctions, or both. (NCI)	Male

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

NCI Code: C188727, Codelist extensible:

C188727	Study Arm Data Origin Type Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C188866	Data Generated Within Study		Data that are generated from the current study.	Data Generated Within Study
C188864	Historical Data		Data from studies that have occurred in the past.	Historical Data
C165830	Real World Data		Data relating to patient health status and/or the delivery of health care routinely collected from sources other than traditional clinical trials. NOTE: Examples of sources include data derived from electronic health records (EHRs); medical claims and billing data; data from product and disease registries; patient-generated data, including from in-home-use settings; and data gathered from other sources that can inform on health status, such as mobile devices. [After 21 U.S.C. 355g(b)).5 and Framework for FDA's Real-World Evidence Program December 2018] See also Real-World Evidence (RWE)	Real-world Data
C176263	Synthetic Data		Data that are artificially created rather than being generated by actual events. NOTE: Data are often created with the help of algorithms and used for a wide range of activities, including as test data for new products and tools, for model validation, and in AI optimization. [After The Ultimate Guide to Synthetic Data in 2020, August 29, 2020]. See also artificial intelligence.	Synthetic Data
C188865	Virtual Data		Data that are generated from virtual encounters between investigators and subjects.	Virtual Data

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

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

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

Timing Relative To From Value Set Terminology (Timing Relative To From Value Set Terminology)

NCI Code: C201265, Codelist extensible:

C201265	Timing Relative To From Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201352	End to End		A timing relationship defined as the end of one event to the end of another event.	End to End
C201353	End to Start		A timing relationship defined as the end of one event to the start of another event.	End to Start
C201354	Start to End		A timing relationship defined as the start of one event to the end of another event.	Start to End
C201355	Start to Start		A timing relationship defined as the start of one event to the start of another event.	Start to Start

Timing Type Value Set Terminology (Timing Type Value Set Terminology)

NCI Code: C201264, Codelist extensible:

C201264	Timing Type Value Set Terminology			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C201356	After		A type of time point relationship that follows a point or period of time within a timeline.	After Timing Type
C201357	Before		A type of time point relationship that comes before a point or period of time within a timeline.	Before Timing Type
C201358	Fixed Reference		A type of time point relationship that is fixed with respect to a timeline.	Fixed Reference Timing Type

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	Early Phase 2 trials that focus on a proof-of-concept assessment of efficacy and safety in a small number of patients. [After FDA Guidance for industry end of Phase 2a meetings, September 2009] (CDISC Glossary)	Phase IIa Trial
C49688	PHASE IIB TRIAL	2B;Trial Phase 2B	Later Phase 2 trials, in transition to Phase 3, where the study populations more closely reflect the population, dosage, and condition for intended use. [Clarification of FDA Guidance for industry end of Phase 2a meetings, September 2009; Discussion in Peter B. Gilbert. SOME DESIGN ISSUES IN PHASE 2B VERSUS PHASE 3 PREVENTION TRIALS FOR TESTING EFFICACY OF PRODUCTS OR CONCEPTS. Stat Med. 2010 May 10; 29(10): 1061-1071.]	Phase IIb Trial
C15602	PHASE III TRIAL	3;Trial Phase 3	Phase that includes the controlled clinical trials intended to confirm safety and effectiveness, evaluate the overall benefit-risk relationship, and to provide substantial evidence for regulatory approval and labeling. NOTE: Phase 3 studies usually include from several hundred to several thousand subjects. [After ICH E8; Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products Draft Guidance for Industry. December 2019] See also phase, phase 3b. (CDISC Glossary)	Phase III Trial
C49687	PHASE IIIA TRIAL	3A;Trial Phase 3A	A classification typically assigned retrospectively to a Phase III trial upon determination by regulatory authorities of a need for a Phase III B trial. (NCI)	Phase IIIa Trial
C49689	PHASE IIIB TRIAL	3B;Trial Phase 3B	Later Phase 3 trial done near the time of approval to elicit additional findings. NOTE: Dossier review may continue while associated Phase 3b trials are conducted. These trials may be required as a condition of regulatory authority approval. Phase 3a is in common usage but not reflected in regulatory guidance. (CDISC Glossary)	Phase IIIb Trial
C15603	PHASE IV TRIAL	4;Trial Phase 4	Post-approval studies to delineate additional information about the drug's risks, benefits, and optimal use that may be requested by regulatory authorities in conjunction with marketing approval. NOTE: Phase 4 studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time. [after FDA CDER handbook, ICH E8] See also phase. (CDISC Glossary)	Phase IV Trial
C47865	PHASE V TRIAL	5;Trial Phase 5	Postmarketing surveillance is sometimes referred to as Phase V.	Phase V Trial

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
C201484	MASS BALANCE		A type of study designed to evaluate the overall pathways of metabolism and excretion of a drug, and to identify and/or quantify metabolites in plasma and excreta.	Mass Balance Study
C49662	PHARMACODYNAMIC		A study of the biochemical and physiological effect of a drug and the mechanism of drug action and the relationship between drug concentration and effect. (NCI)	Pharmacodynamic Study
C39493	PHARMACOECONOMIC		A study that assesses the value associated with a given drug in therapeutic and economic terms. This type of study is multidisciplinary in nature and takes into consideration the social and economic costs (resource utilization costs including direct, indirect, and intangible costs) of drug therapy in addition to its direct therapeutic benefits. Analyses relate the difference in therapeutic benefits to the difference in costs between treatment alternatives. (NCI)	Pharmacoeconomic Study
C129001	PHARMACOGENETIC		A study that assesses variation in DNA sequence, usually within a single gene, and its effect on drug response.	Pharmacogenetic Study
C49661	PHARMACOGENOMIC		A study that identifies or assesses variations within the entire genome, including DNA, RNA, or transcriptional elements, and its effects on drug response.	Pharmacogenomic Study
C49663	PHARMACOKINETIC		A study of the process by which a drug is absorbed, distributed, metabolized, and eliminated by the body. (NCI)	Pharmacokinetic Study
C161477	POSITION EFFECT		A type of study designed to evaluate the effect of body position during and/or after administration of the investigational product.	Position Effect Trial
C49657	PREVENTION	Prophylaxis Study	A type of study designed to identify actions necessary to permanently eliminate or reduce the long-term risk to human life as a result of a particular medication or treatment regimen.	Prevention Study
C174366	REACTOGENICITY		A type of study designed to evaluate the expected, acute types of immunological responses, sometimes considered excessive, following agent administration.	Reactogenicity Study
C49667	SAFETY		A study that assesses the medical risks to a subject. Safety is usually assessed by examining a wide range of clinical parameters, including adverse events, vital signs, physical exam, laboratory tests.	Safety Study
C161478	SWALLOWING FUNCTION		A type of study designed to evaluate the effect of the investigational product on the physiologic act of swallowing.	Swallowing Function Trial
C158287	THOROUGH QT	TQT Study	A type of study designed to evaluate the ability of an investigational product and/or approved drug to delay cardiac ventricular repolarization as detected by QT prolongation and other ECG parameters.	Thorough QT Study
C98791	TOLERABILITY		A type of safety study that assesses the degree to which overt adverse effects can be tolerated by the subject.	Tolerability Study
C49656	TREATMENT	Therapy Trial	A type of study designed to evaluate intervention(s) for treatment of disease, syndrome or condition.	Treatment Study
C161479	USABILITY TESTING		A type of study designed to evaluate the user experience with a product.	Usability Testing Study
C161480	WATER EFFECT		A type of study designed to evaluate the effects of water on investigational product safety and/or efficacy.	Water Effect Trial