

CDISC DDF Controlled Terminology, 2024-09-27

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

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
C188714	DDF Activity Attribute Terminology	DDF Activity Attribute Terminology	A terminology value set relevant to the attributes of the activity.	No
C201253	DDF Address Attribute Terminology	DDF Address Attribute Terminology	A terminology value set relevant to the attributes of the address.	No
C207420	DDF Administration Duration Attribute Terminology	DDF Administration Duration Attribute Terminology	A terminology value set relevant to the attributes of the administration duration.	No
C207421	DDF Agent Administration Attribute Terminology	DDF Agent Administration Attribute Terminology	A terminology value set relevant to the attributes of the agent administration.	No
C188720	DDF Analysis Population Attribute Terminology	DDF Analysis Population Attribute Terminology	A terminology value set relevant to the attributes of the analysis population.	No
C201254	DDF Biomedical Concept Attribute Terminology	DDF Biomedical Concept Attribute Terminology	A terminology value set relevant to the attributes of the biomedical concept.	No
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.	No
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.	No
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.	No
C207422	DDF Characteristic Attribute Terminology	DDF Characteristic Attribute Terminology	A terminology value set relevant to the attributes of the characteristic.	No
C188699	DDF Clinical Study Attribute Terminology	DDF Clinical Study Attribute Terminology	A terminology value set relevant to the attributes of the clinical study.	No
C188722	DDF Code Attribute Terminology	DDF Code Attribute Terminology	A terminology value set relevant to the attributes of the code.	No
C207425	DDF Condition Assignment Attribute Terminology	DDF Condition Assignment Attribute Terminology	A terminology value set relevant to the attributes of the condition assignment.	No
C207424	DDF Condition Attribute Terminology	DDF Condition Attribute Terminology	A terminology value set relevant to the attributes of the condition.	No
C207427	DDF Eligibility Criteria Attribute Terminology	DDF Eligibility Criteria Attribute Terminology	A terminology value set relevant to the attributes of the eligibility criteria.	No
C188713	DDF Encounter Attribute Terminology	DDF Encounter Attribute Terminology	A terminology value set relevant to the attributes of the encounter.	No
C188708	DDF Endpoint Attribute Terminology	DDF Endpoint Attribute Terminology	A terminology value set relevant to the attributes of the endpoint.	No
C188698	DDF Entity Terminology	DDF Entity Terminology	A terminology value set relevant to the entities within the CDISC digital data flow (DDF) model.	No
C188719	DDF Estimand Attribute Terminology	DDF Estimand Attribute Terminology	A terminology value set relevant to the attributes of the estimand.	No
C207428	DDF Geographic Scope Attribute Terminology	DDF Geographic Scope Attribute Terminology	A terminology value set relevant to the attributes of the geographic scope.	No
C207429	DDF Governance Date Attribute Terminology	DDF Governance Date Attribute Terminology	A terminology value set relevant to the attributes of the governance date.	No
C188705	DDF Indication Attribute Terminology	DDF Indication Attribute Terminology	A terminology value set relevant to the attributes of the disease indication.	No
C188721	DDF Intercurrent Event Attribute Terminology	DDF Intercurrent Event Attribute Terminology	A terminology value set relevant to the attributes of the intercurrent event.	No
C207430	DDF Masking Attribute Terminology	DDF Masking Attribute Terminology	A terminology value set relevant to the attributes of the masking.	No
C207426	DDF Narrative Content Attribute Terminology	DDF Narrative Content Attribute Terminology	A terminology value set relevant to the attributes of the narrative content.	No
C188707	DDF Objective Attribute Terminology	DDF Objective Attribute Terminology	A terminology value set relevant to the attributes of the objective.	No
C188702	DDF Organization Attribute Terminology	DDF Organization Attribute Terminology	A terminology value set relevant to the attributes of the organization.	No
C207431	DDF Parameter Map Attribute Terminology	DDF Parameter Map Attribute Terminology	A terminology value set relevant to the attributes of the parameter map.	No
C207432	DDF Population Definition Attribute Terminology	DDF Population Definition Attribute Terminology	A terminology value set relevant to the attributes of the population definition.	No
C188716	DDF Procedure Attribute Terminology	DDF Procedure Attribute Terminology	A terminology value set relevant to the attributes of the procedure.	No
C207433	DDF Quantity Attribute Terminology	DDF Quantity Attribute Terminology	A terminology value set relevant to the attributes of the quantity.	No
C207434	DDF Range Attribute Terminology	DDF Range Attribute Terminology	A terminology value set relevant to the attributes of the range.	No
C207435	DDF Research Organization Attribute Terminology	DDF Research Organization Attribute Terminology	A terminology value set relevant to the attributes of the research organization.	No
C201258	DDF Response Code Attribute Terminology	DDF Response Code Attribute Terminology	A terminology value set relevant to the attributes of the response code.	No
C207436	DDF Scheduled Activity Instance Attribute Terminology	DDF Scheduled Activity Instance Attribute Terminology	A terminology value set relevant to the attributes of the scheduled activity instance.	No
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.	No
C201261	DDF Scheduled Instance Attribute Terminology	DDF Scheduled Instance Attribute Terminology	A terminology value set relevant to the attributes of the scheduled instance.	No
C201259	DDF Schedule Timeline Attribute Terminology	DDF Schedule Timeline Attribute Terminology	A terminology value set relevant to the attributes of the schedule timeline.	No
C207437	DDF Study Amendment Attribute Terminology	DDF Study Amendment Attribute Terminology	A terminology value set relevant to the attributes of the study amendment.	No
C207438	DDF Study Amendment Reason Attribute Terminology	DDF Study Amendment Reason Attribute Terminology	A terminology value set relevant to the attributes of the study amendment reason.	No
C188709	DDF Study Arm Attribute Terminology	DDF Study Arm Attribute Terminology	A terminology value set relevant to the attributes of the study Arm.	No
C207439	DDF Study Cohort Attribute Terminology	DDF Study Cohort Attribute Terminology	A terminology value set relevant to the attributes of the study cohort.	No
C188703	DDF Study Design Attribute Terminology	DDF Study Design Attribute Terminology	A terminology value set relevant to the attributes of the study design.	No
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.	No
C188711	DDF Study Element Attribute Terminology	DDF Study Element Attribute Terminology	A terminology value set relevant to the attributes of the study element.	No
C188710	DDF Study Epoch Attribute Terminology	DDF Study Epoch Attribute Terminology	A terminology value set relevant to the attributes of the study epoch.	No
C188701	DDF Study Identifier Attribute Terminology	DDF Study Identifier Attribute Terminology	A terminology value set relevant to the attributes of the study identifier.	No
C188704	DDF Study Intervention Attribute Terminology	DDF Study Intervention Attribute Terminology	A terminology value set relevant to the attributes of the study interventions.	No
C207440	DDF Study Protocol Document Attribute Terminology	DDF Study Protocol Document Attribute Terminology	A terminology value set relevant to the attributes of the study protocol document.	No
C207441	DDF Study Site Attribute Terminology	DDF Study Site Attribute Terminology	A terminology value set relevant to the attributes of the study site.	No
C207442	DDF Study Title Attribute Terminology	DDF Study Title Attribute Terminology	A terminology value set relevant to the attributes of the study title.	No
C207443	DDF Study Version Attribute Terminology	DDF Study Version Attribute Terminology	A terminology value set relevant to the attributes of the study version.	No
C207444	DDF Subject Enrollment Attribute Terminology	DDF Subject Enrollment Attribute Terminology	A terminology value set relevant to the attributes of the subject enrollment.	No
C207445	DDF Syntax Template Attribute Terminology	DDF Syntax Template Attribute Terminology	A terminology value set relevant to the attributes of the syntax template.	No
C207446	DDF Syntax Template Dictionary Attribute Terminology	DDF Syntax Template Dictionary Attribute Terminology	A terminology value set relevant to the attributes of the syntax template dictionary.	No
C201262	DDF Timing Attribute Terminology	DDF Timing Attribute Terminology	A terminology value set relevant to the attributes of the timing.	No
C188712	DDF Transition Rule Attribute Terminology	DDF Transition Rule Attribute Terminology	A terminology value set relevant to the attributes of the transition rule.	No
C188728	Encounter Type Value Set	Encounter Type Value Set	The terminology relevant to the encounter type.	Yes

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
	Terminology	Terminology		
C188726	Endpoint Level Value Set Terminology	Endpoint Level Value Set Terminology	The terminology relevant to the endpoint level.	No
C207412	Geographic Scope Type Value Set Terminology	Geographic Scope Type Value Set Terminology	The terminology relevant to the geographic scope type value set.	No
C207413	Governance Date Type Value Set Terminology	Governance Date Type Value Set Terminology	The terminology relevant to the governance date type value set.	Yes
C207414	Masking Role Value Set Terminology	Masking Role Value Set Terminology	The terminology relevant to the masking role value set.	Yes
C188725	Objective Level Value Set Terminology	Objective Level Value Set Terminology	The terminology relevant to the objective level.	No
C188724	Organization Type Value Set Terminology	Organization Type Value Set Terminology	The terminology relevant to the organization type.	Yes
C188723	Protocol Status Value Set Terminology	Protocol Status Value Set Terminology	The terminology relevant to the protocol status.	No
C207415	Study Amendment Reason Code Value Set Terminology	Study Amendment Reason Code Value Set Terminology	The terminology relevant to the study amendment reason code value set.	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.	Yes
C207416	Study Design Characteristics Value Set Terminology	Study Design Characteristics Value Set Terminology	The terminology relevant to the study design characteristics value set.	Yes
C207418	Study Intervention Product Designation Value Set Terminology	Study Intervention Product Designation Value Set Terminology	The terminology relevant to the study intervention product designation value set.	No
C207417	Study Intervention Role Value Set Terminology	Study Intervention Role Value Set Terminology	The terminology relevant to the study intervention role value set.	No
C207419	Study Title Type Value Set Terminology	Study Title Type Value Set Terminology	The terminology relevant to the study title type value set.	No
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.	No
C201264	Timing Type Value Set Terminology	Timing Type Value Set Terminology	The terminology relevant to the timing type value set.	No

DDF Activity Attribute Terminology (DDF Activity Attribute Terminology)

NCI Code: C188714, Codelist extensible: No

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
C207458	Clinical Study Activity Label		The short descriptive designation for the study activity.	Study Activity Label
C188842	Clinical Study Activity Name		The literal identifier (i.e., distinctive designation) of the clinical study activity.	Clinical Study Activity Name

DDF Address Attribute Terminology (DDF Address Attribute Terminology)

NCI Code: C201253, Codelist extensible: No

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 Administration Duration Attribute Terminology (DDF Administration Duration Attribute Terminology)

NCI Code: C207420, Codelist extensible: No

C207420		DDF Administration Duration Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207459	Administration Duration Description		A narrative representation of the agent administration duration.	Administration Duration Description
C207460	Administration Duration Quantity Value		The value representing the amount of time over which the administration of an agent occurs.	Administration Duration Quantity Value
C207462	Administration Duration Reason Duration Will Vary	Reason Administration Duration Will Vary	The explanation for why the agent administration duration will vary within and/or across subjects.	Reason Administration Duration Will Vary
C207461	Administration Duration Will Vary Indicator		An indication as to whether the agent administration duration is planned to vary within and/or across subjects.	Administration Duration Will Vary Indicator

DDF Agent Administration Attribute Terminology (DDF Agent Administration Attribute Terminology)

NCI Code: C207421, Codelist extensible: No

C207421		DDF Agent Administration Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207463	Agent Administration Description		A narrative representation of the agent administration.	Agent Administration Description
C167190	Agent Administration Dose		The value representing the amount of an agent given to an individual at one time.	Dose Administered
C207464	Agent Administration Label		The short descriptive designation for the agent administration.	Agent Administration Label
C207465	Agent Administration Name		The literal identifier (i.e., distinctive designation) of the agent administration.	Agent Administration Name
C89081	Dosing Frequency	Dosing Frequency	The number of doses administered per a specific interval.	Dose Frequency
C38114	Route of Administration	Route of Administration	The way in which a pharmaceutical product is taken into, or makes contact with, the body. (CDISC Glossary)	Route of Administration

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

NCI Code: C188720, Codelist extensible: No

C188720		DDF Analysis Population Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188854	Analysis Population Description		The textual representation of the study population for analysis.	Analysis Population Description
C207466	Analysis Population Label		The short descriptive designation for the analysis population.	Analysis Population Label
C207467	Analysis Population Name		The literal identifier (i.e., distinctive designation) of the analysis population.	Analysis Population Name
C207468	Analysis Population Text		An instance of unstructured text that represents the analysis population.	Analysis Population Text

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

NCI Code: C201254, Codelist extensible: No

C201254		DDF Biomedical Concept Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207469	Biomedical Concept Concept Code		A concept unique identifier assigned to a biomedical concept that points to the meaning of that biomedical concept.	Biomedical Concept Code
C207470	Biomedical Concept Label		The short descriptive designation for the biomedical concept.	Biomedical Concept Label
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: No

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		A narrative representation of the biomedical concept category.	Biomedical Concept Category Description
C207471	Biomedical Concept Category Label		The short descriptive designation for the biomedical concept category.	Biomedical Concept Category Label
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: No

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
C202496	Biomedical Concept Property Enabled Indicator		An indication as to whether the biomedical concept property is activated for use within a given usage context for a biomedical concept.	Biomedical Concept Property Enabled Indicator
C207472	Biomedical Concept Property Label		The short descriptive designation for the biomedical concept property.	Biomedical Concept Property Label
C202494	Biomedical Concept Property Name		The literal identifier (i.e., distinctive designation) of the biomedical concept property.	Biomedical Concept Property Name
C202495	Biomedical Concept Property Required Indicator		An indication as to whether the biomedical concept property is required.	Biomedical Concept Property Required Indicator
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: No

C201257		DDF Biomedical Concept Surrogate Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C201320	Biomedical Concept Surrogate Description		A narrative representation of the biomedical concept surrogate.	Biomedical Concept Surrogate Description
C207473	Biomedical Concept Surrogate Label		The short descriptive designation for the biomedical concept surrogate.	Biomedical Concept Surrogate Label
C207474	Biomedical Concept Surrogate Name		The literal identifier (i.e., distinctive designation) of the biomedical concept surrogate.	Biomedical Concept Surrogate Name
C201321	Biomedical Concept Surrogate Reference		A citation to an authoritative source for a biomedical concept surrogate.	Biomedical Concept Surrogate Reference

DDF Characteristic Attribute Terminology (DDF Characteristic Attribute Terminology)

NCI Code: C207422, Codelist extensible: No

C207422		DDF Characteristic Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207475	Characteristic Description		A narrative representation of the characteristic.	Characteristic Description
C207476	Characteristic Label		The short descriptive designation for the characteristic.	Characteristic Label
C207477	Characteristic Name		The literal identifier (i.e., distinctive designation) of the characteristic.	Characteristic Name
C207478	Characteristic Text		An instance of structured text that represents the characteristic.	Characteristic Text

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

NCI Code: C188699, Codelist extensible: No

C188699		DDF Clinical Study Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207479	Clinical Study Label		The short descriptive designation for the clinical study.	Clinical Study Label
C142704	Study Description		A narrative representation of the study.	Study Description
C68631	Study Name		The literal identifier (i.e., distinctive designation) of the study.	Study Name

DDF Code Attribute Terminology (DDF Code Attribute Terminology)

NCI Code: C188722, Codelist extensible: No

C188722 NCI Code	DDF Code Attribute Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C18859	Code System Name		The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes.	Code System Name
C18868	Code System Version		The version of the code system.	Coding System Version
C18858	Code Value		The literal value of a code.	Code Value
C18861	Decode		Standardized or dictionary-derived human readable text associated with a code.	Decode Text

DDF Condition Assignment Attribute Terminology (DDF Condition Assignment Attribute Terminology)

NCI Code: C207425, Codelist extensible: No

C207425		DDF Condition Assignment Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C47953	Logical Condition		An assumption on which rests the validity or effect of something else.	Logical Condition

DDF Condition Attribute Terminology (DDF Condition Attribute Terminology)

NCI Code: C207424, Codelist extensible: No

C207424		DDF Condition Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207481	Condition Description		A narrative representation of the condition.	Condition Description
C207482	Condition Label		The short descriptive designation for the condition.	Condition Label
C207483	Condition Name		The literal identifier (i.e., distinctive designation) of the condition.	Condition Name
C207484	Condition Text		An instance of structured text that represents the condition.	Condition Text

DDF Eligibility Criteria Attribute Terminology (DDF Eligibility Criteria Attribute Terminology)

NCI Code: C207427, Codelist extensible: No

C207427		DDF Eligibility Criteria Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C83016	Study Eligibility Criteria Category		A classification of the inclusion exclusion criterion.	Inclusion Exclusion Criterion Category
C207486	Study Eligibility Criterion Description		A narrative representation of the study eligibility criterion.	Study Eligibility Criteria Description
C207489	Study Eligibility Criterion Identifier		A sequence of characters used to identify, name, or characterize the inclusion or exclusion criterion.	Study Eligibility Criterion Identifier
C207487	Study Eligibility Criterion Label		The short descriptive designation for the study eligibility criterion.	Study Eligibility Criteria Label
C207488	Study Eligibility Criterion Name		The literal identifier (i.e., distinctive designation) of the study eligibility criterion.	Study Eligibility Criteria Name
C207485	Study Eligibility Criterion Text		An instance of structured text that represents the study eligibility criterion.	Study Eligibility Criteria Text

DDF Encounter Attribute Terminology (DDF Encounter Attribute Terminology)

NCI Code: C188713, Codelist extensible: No

C188713		DDF Encounter Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188836	Clinical Encounter Description		A narrative 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
C207490	Study Encounter Label		The short descriptive designation for the study encounter.	Study Encounter Label

DDF Endpoint Attribute Terminology (DDF Endpoint Attribute Terminology)

NCI Code: C188708, Codelist extensible: No

C188708		DDF Endpoint Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188824	Study Endpoint Description		A narrative representation of the study endpoint.	Study Endpoint Description
C207491	Study Endpoint Label		The short descriptive designation for the study endpoint.	Study Endpoint Label
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
C207492	Study Endpoint Name		The literal identifier (i.e., distinctive designation) of the study endpoint.	Study Endpoint Name
C188825	Study Endpoint Purpose		The reason or intention for the study endpoint.	Study Endpoint Purpose
C207493	Study Endpoint Text		An instance of structured text that represents the study endpoint.	Study Endpoint Text

DDF Entity Terminology (DDF Entity Terminology)

NCI Code: C188698, Codelist extensible: No

C188698 NCI Code	DDF Entity Terminology 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
C69282	Administration Duration		The amount of time elapsed during the administration of an agent.	Duration of Administration
C70962	Agent Administration		The act of the dispensing, applying, or tendering a medical product or other agent.	Agent Administration
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
C202493	Biomedical Concept Property		A characteristic from a set of characteristics used to define a biomedical concept.	Biomedical Concept Property
C207590	Biomedical Concept Surrogate		A concept that substitutes for a standard biomedical concept from the designated source.	Biomedical Concept Surrogate
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
C25447	Characteristic		The distinguishing qualities or prominent aspects of an entity.	Characteristic
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
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 Assignment
C25457	Condition		A state of being.	Condition
C41184	Disease/Condition Indication		A health problem or disease that is identified as likely to be benefited by a therapy being studied in clinical trials.	Indication
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
C207591	Geographic Scope		The extent or range related to the physical location of an entity.	Geographic Scope
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
C191278	Masking		The mechanism used to obscure the distinctive characteristics of the study intervention or procedure to make it indistinguishable from the comparator. NOTE: Blinding refers to study participants while masking refers to the study intervention. (CDISC Glossary)	Masking
C207592	Narrative Content		The container that holds an instance of unstructured text and which may include objects such as tables, figures, and images.	Narrative Content
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
C207456	Parameter Map		The paired name and value for a given parameter.	Parameter Map
C207593	Population Definition		A concise explanation of the meaning of a population.	Population Definition
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
C25256	Quantity		How much there is of something that can be measured; the total amount or number.	Quantity
C38013	Range		The difference between the lowest and highest numerical values; the limits or scale of variation.	Range
C93448	Research Organization		An organization that undertakes systematic investigation within a field of study in order to discover facts, establish or revise a theory, test a hypothesis, or develop a plan of action based on the facts discovered.	Research Organization
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
C207457	Study Amendment Reason	Reason(s) for Amendment	The rationale for the change(s) to, or formal clarification of, a protocol.	Study Amendment Reason
C207594	Study Amendment		A written description of a change(s) to, or formal clarification of, a study.	Study Amendment
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
C61512	Study Cohort		A group of individuals who share a set of characteristics (e.g., exposures, experiences, attributes), which logically defines a population under study.	Cohort
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 strategy that specifies the structure of a study in terms of the planned activities (including timing) and statistical analysis approach intended to meet the objectives of the study.	Study Design
C16112	Study Eligibility Criteria	Trial Eligibility Criteria	Characteristics which are necessary to allow a subject to participate in a clinical study, as outlined in the study protocol. The concept covers inclusion and exclusion criteria.	Clinical Trial Eligibility Criteria
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
C207595	Study Governance Date		Any of the dates associated with event milestones within a clinical study's oversight and management framework.	Study Governance Date
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
C93381	Study Protocol Document		A representation of the study protocol (that persists over time) in document form.	Study Protocol Document
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
C80403	Study Site		The location at which a study investigator conducts study activities.	Study Site
C49802	Study Title	Official Study Title;Study Title;Trial Title	The sponsor-defined name of the clinical study.	Trial Title
C188816	Study Version		A plan at a particular point in time for a study.	Study Version
C37948	Subject Enrollment		The act of enrolling subjects into a study. The subject will have met the inclusion/exclusion criteria to participate in the trial and will have signed an informed consent form. (CDISC Glossary)	Enrollment
C207597	Syntax Template Dictionary		A reference source that provides a listing of valid parameter names and values used in syntax template text strings.	Syntax Template Dictionary
C207596	Syntax Template		A standardized pattern used for the arrangement of words and phrases to create well-formed, structured sentences.	Syntax Template
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 group of people in the general population to 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

DDF Estimand Attribute Terminology (DDF Estimand Attribute Terminology)

NCI Code: C188719, Codelist extensible: No

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

DDF Geographic Scope Attribute Terminology (DDF Geographic Scope Attribute Terminology)

NCI Code: C207428, Codelist extensible: No

C207428		DDF Geographic Scope Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207494	Geographic Scope Code		A symbol or combination of symbols which is assigned to the geographic scope.	Geographic Scope Code
C207495	Geographic Scope Type		A characterization or classification of the geographic scope.	Geographic Scope Type

DDF Governance Date Attribute Terminology (DDF Governance Date Attribute Terminology)

NCI Code: C207429, Codelist extensible: No

C207429		DDF Governance Date Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207496	Protocol Approval Date Type		A characterization or classification of the protocol approval date.	Protocol Approval Date Type
C207497	Study Governance Date Description		A narrative representation of the study governance date.	Study Governance Date Description
C207498	Study Governance Date Label		The short descriptive designation for the study governance date.	Study Governance Date Label
C207499	Study Governance Date Name		The literal identifier (i.e., distinctive designation) of the study governance date	Study Governance Date Name
C207500	Study Governance Date Value		The information contained in the date field.	Study Governance Date Value

DDF Indication Attribute Terminology (DDF Indication Attribute Terminology)

NCI Code: C188705, Codelist extensible: No

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	Disease/Condition Indication Description	Indication for Use; Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	A narrative representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication
C207501	Disease/Condition Indication Is Rare Disease Indicator		An indication as to whether the disease/condition indication under study is considered a rare disease.	Disease Indication Is Rare Disease Indicator
C207502	Disease/Condition Indication Label		The short descriptive designation for the disease/condition indication.	Disease Indication Label
C207503	Disease/Condition Indication Name		The literal identifier (i.e., distinctive designation) of the disease/condition indication.	Disease Indication Name

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

NCI Code: C188721, Codelist extensible: No

C188721		DDF Intercurrent Event Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188856	Intercurrent Event Description		A narrative representation of the intercurrent event.	Intercurrent Event Description
C207504	Intercurrent Event Label		The short descriptive designation for the intercurrent event.	Intercurrent Event Label
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 Masking Attribute Terminology (DDF Masking Attribute Terminology)

NCI Code: C207430, Codelist extensible: No

C207430		DDF Masking Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207505	Masking Description		A narrative representation of the study masking strategy, based on a person's role within the study.	Study Masking Description
C207506	Masking Role	Blinded Roles;Blinding Roles	An identifying designation assigned to a masked individual within a study that corresponds with their function.	Study Masking Role

DDF Narrative Content Attribute Terminology (DDF Narrative Content Attribute Terminology)

NCI Code: C207426, Codelist extensible: No

C207426		DDF Narrative Content Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207507	Narrative Content Name		The literal identifier (i.e., distinctive designation) of the narrative content.	Narrative Content Name
C207509	Narrative Content Section Number		The numeric identifier assigned to a particular document section containing narrative content.	Narrative Content Section Number
C207510	Narrative Content Section Title		An identifying designation for the document section containing narrative content.	Narrative Content Section Title
C207508	Narrative Content Text		A textual representation of the narrative content.	Narrative Content Text

DDF Objective Attribute Terminology (DDF Objective Attribute Terminology)

NCI Code: C188707, Codelist extensible: No

C188707		DDF Objective Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C94090	Study Objective Description		A narrative representation of the study objective.	Study Objective Description
C207511	Study Objective Label		The short descriptive designation for the study objective.	Study Objective Label
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
C207512	Study Objective Name		The literal identifier (i.e., distinctive designation) of the study objective.	Study Objective Name
C207513	Study Objective Text		An instance of structured text that represents the study objective.	Study Objective Text

DDF Organization Attribute Terminology (DDF Organization Attribute Terminology)

NCI Code: C188702, Codelist extensible: No

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
C207514	Organization Label		The short descriptive designation for the organization.	Organization Label
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 Parameter Map Attribute Terminology (DDF Parameter Map Attribute Terminology)

NCI Code: C207431, Codelist extensible: No

C207431		DDF Parameter Map Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207516	Programming Tag Reference		The reference for a tag used in programming languages, such as a markup language (e.g., HTML, XML), to store attributes and elements.	Programming Tag Reference
C207515	Programming Tag		Character strings bounded by angle brackets that act as containers for programming language elements.	Programming Tag

DDF Population Definition Attribute Terminology (DDF Population Definition Attribute Terminology)

NCI Code: C207432, Codelist extensible: No

C207432		DDF Population Definition Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207517	Population Definition Description		A narrative representation of the population definition.	Population Definition Description
C207518	Population Definition Includes Healthy Subjects Indicator		An indication as to whether the population definition includes healthy subjects, that is, subjects without the disease or condition under study.	Population Definition Includes Healthy Subjects Indicator
C207519	Population Definition Label		The short descriptive designation for the population definition.	Population Definition Label
C207520	Population Definition Name		The literal identifier (i.e., distinctive designation) of the population definition.	Population Definition Name
C207701	Population Definition Planned Age		The anticipated age of subjects within the population definition.	Population Definition Planned Age
C207521	Population Definition Planned Completion Number		The value representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the population definition.	Population Definition Planned Completion Number
C207522	Population Definition Planned Enrollment Number		The value representing the planned number of subjects to be entered in a clinical trial, within the population definition.	Population Definition Planned Enrollment Number
C207523	Population Definition Planned Sex		The protocol-defined sex within the population definition.	Population Definition Planned Sex

DDF Procedure Attribute Terminology (DDF Procedure Attribute Terminology)

NCI Code: C188716, Codelist extensible: No

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		A narrative representation of the procedure.	Procedure Description
C207524	Procedure Label		The short descriptive designation for the procedure.	Procedure Label
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

DDF Quantity Attribute Terminology (DDF Quantity Attribute Terminology)

NCI Code: C207433, Codelist extensible: No

C207433		DDF Quantity Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C44258	Quantity Unit		The type of unit of measure being used to express a quantity.	Unit of Quantity
C25712	Quantity Value		A numerical quantity measured or assigned or computed.	Value

DDF Range Attribute Terminology (DDF Range Attribute Terminology)

NCI Code: C207434, Codelist extensible: No

C207434		DDF Range Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C25564	Maximum Value		The largest value in quantity or degree in a set of values.	Maximum
C25570	Minimum Value		The smallest value in quantity or degree in a set of values.	Minimum
C25709	Unit of Measure		A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds.	Unit of Measure
C207525	Value Range is Approximate Indicator		An indication as to whether the value range is almost, but not quite, exact.	Value Range is Approximate Indicator

DDF Research Organization Attribute Terminology (DDF Research Organization Attribute Terminology)

NCI Code: C207435, Codelist extensible: No

C207435		DDF Research Organization Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207526	Identifier Provider Research Organization Name		The name of the research organization that provides the identifier for the entity.	Identifier Provider Research 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
C207527	Research Organization Identifier		A sequence of characters used to identify, name, or characterize the research organization.	Research Organization Identifier
C207528	Research Organization Label		The short descriptive designation for the research organization.	Research Organization Label
C207529	Research Organization Name		The literal identifier (i.e., distinctive designation) of the research organization.	Research Organization Name

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

NCI Code: C201258, Codelist extensible: No

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

NCI Code: C207436, Codelist extensible: No

C207436		DDF Scheduled Activity Instance Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207531	Scheduled Activity Instance Description		A narrative representation of the scheduled activity instance.	Scheduled Activity Instance Description
C207532	Scheduled Activity Instance Label		The short descriptive designation for the scheduled activity instance.	Scheduled Activity Instance Label
C207533	Scheduled Activity Instance Name		The literal identifier (i.e., distinctive designation) of the scheduled activity instance.	Scheduled Activity Instance Name

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

NCI Code: C201260, Codelist extensible: No

C201260		DDF Scheduled Decision Instance Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207534	Scheduled Decision Instance Description		A narrative representation of the scheduled Decision instance.	Scheduled Decision Instance Description
C207535	Scheduled Decision Instance Label		The short descriptive designation for the scheduled Decision instance.	Scheduled Decision Instance Label
C207536	Scheduled Decision Instance Name		The literal identifier (i.e., distinctive designation) of the scheduled Decision instance.	Scheduled Decision Instance Name

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

NCI Code: C201261, Codelist extensible: No

C201261		DDF Scheduled Instance Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207453	Scheduled Instance Description		A narrative representation of the scheduled instance.	Scheduled Instance Description
C207454	Scheduled Instance Label		The short descriptive designation for the scheduled instance.	Scheduled Instance Label
C207455	Scheduled Instance Name		The literal identifier (i.e., distinctive designation) of the scheduled instance.	Scheduled Instance Name

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

NCI Code: C201259, Codelist extensible: No

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		A narrative 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
C207530	Schedule Timeline Label		The short descriptive designation for the schedule timeline.	Schedule Timeline Label
C201334	Schedule Timeline Name		The literal identifier (i.e., distinctive designation) of the schedule timeline.	Schedule Timeline Name

DDF Study Amendment Attribute Terminology (DDF Study Amendment Attribute Terminology)

NCI Code: C207437, Codelist extensible: No

C207437		DDF Study Amendment Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207537	Study Amendment Number	Amendment Identifier	A string of numerals that uniquely identifies a protocol amendment.	Study Amendment Number
C207538	Study Amendment Substantial Impact Indicator		An indication as to whether the amendment is likely to have a substantial impact on the safety or rights of study subjects/participants.	Study Amendment Substantial Impact Indicator
C115627	Study Amendment Summary		A short narrative representation describing the changes introduced in the current version of the protocol.	Clinical Trial Protocol Amendment Summary

DDF Study Amendment Reason Attribute Terminology (DDF Study Amendment Reason Attribute Terminology)

NCI Code: C207438, Codelist extensible: No

C207438		DDF Study Amendment Reason Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C207539	Other Reason for Study Amendment		The rationale for the change(s) to, or formal clarification of, a protocol that is not otherwise specified.	Other Reason for Study Amendment	
C207540	Study Amendment Reason Code	Study Amendment Reason Code	A symbol or combination of symbols which is assigned to the study amendment reason.	Study Amendment Reason Code	

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

NCI Code: C188709, Codelist extensible: No

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	A narrative representation of the study arm.	Arm Description
C172456	Study Arm Label	Arm Label	The short descriptive designation for the study arm.	Study Arm Label
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 Cohort Attribute Terminology (DDF Study Cohort Attribute Terminology)

NCI Code: C207439, Codelist extensible: No

C207439		DDF Study Cohort Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207542	Study Cohort Description		A narrative representation of the study cohort.	Study Cohort Description
C207480	Study Cohort Includes Healthy Subjects Indicator		An indication as to whether the study cohort includes healthy subjects, that is, subjects without the disease or condition under study.	Study Cohort Includes Healthy Subjects Indicator
C207543	Study Cohort Label		The short descriptive designation for the study cohort.	Study Cohort Label
C207544	Study Cohort Name		The literal identifier (i.e., distinctive designation) of the study cohort.	Study Cohort Name
C207545	Study Cohort Planned Age		The anticipated age of subjects within the study cohort.	Study Cohort Planned Age
C207546	Study Cohort Planned Completion Number		The value representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the study cohort.	Study Cohort Planned Completion Number
C207702	Study Cohort Planned Enrollment Number		The value representing the planned number of subjects to be entered in a clinical trial, within the study cohort.	Study Cohort Planned Enrollment Number
C207541	Study Cohort Planned Sex		The protocol-defined sex within the study cohort.	Planned Sex of Study Cohort Participants

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

NCI Code: C188703, Codelist extensible: No

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
C207547	Study Design Characteristic		The distinguishing qualities or prominent aspect of a study design.	Study Design Characteristic
C147139	Study Design Description	Overall Design; Study Design Description; Study Design Overview; Summary of Study Design	A narrative representation of the study design.	Study Design Description
C207548	Study Design Label		The short descriptive designation for the study design.	Study Design Label
C201338	Study Design Name		The literal identifier (i.e., distinctive designation) of the study design.	Study Design Name
C70834	Study Design Population Description		A narrative representation of the study design population.	Study Population Description
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: No

C188706		DDF Study Design Population Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207549	Study Design Population Includes Healthy Subjects Indicator		An indication as to whether the study design population includes healthy subjects, that is, subjects without the disease or condition under study.	Study Design Population Includes Healthy Subjects Indicator
C207550	Study Design Population Label		The short descriptive designation for the study design population.	Study Design Population Label
C207553	Study Design Population Name		The literal identifier (i.e., distinctive designation) of the study design population.	Study Design Population Name
C207450	Study Design Population Planned Age		The anticipated age of subjects within the study design population.	Study Design Population Planned Age
C207451	Study Design Population Planned Completion Number		The value representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the study design population.	Study Design Population Planned Completion Number
C207452	Study Design Population Planned Enrollment Number		The value representing the planned number of subjects to be entered in a clinical trial, within the study design population.	Study Design Population Planned Enrollment Number
C207551	Study Design Population Planned Sex		The protocol-defined sex within the study design population.	Study Design Population Planned Sex

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

NCI Code: C188711, Codelist extensible: No

C188711		DDF Study Element Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188834	Study Design Element Description		A narrative representation of the study design element.	Study Design Element Description
C207554	Study Design Element Label		The short descriptive designation for the study design element.	Study Design Element Label
C188833	Study Design Element Name		The literal identifier (i.e., distinctive designation) of the study design element.	Study Design Element Name

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

NCI Code: C188710, Codelist extensible: No

C188710		DDF Study Epoch Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C93824	Study Epoch Description		A narrative representation of the study epoch.	Epoch Description
C207555	Study Epoch Label		The short descriptive designation for the study epoch.	Study Epoch Label
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: No

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 Intervention Attribute Terminology (DDF Study Intervention Attribute Terminology)

NCI Code: C188704, Codelist extensible: No

C188704		DDF Study Intervention Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C98768	Pharmacologic Class	Pharmacologic Class	The pharmacological class of the investigational product.	Pharmacological Class of Investigational Therapy	
C207648	Study Intervention Code		A symbol or combination of symbols which is assigned to the study intervention.	Study Intervention Code	
C207647	Study Intervention Description		A narrative representation of the study intervention.	Study Intervention Description	
C207556	Study Intervention Label		The short descriptive designation for the study intervention.	Study Intervention Label	
C207557	Study Intervention Minimum Response Duration		The value representing the minimum amount of time required to meet the criteria for response to study intervention.	Study Intervention Minimum Response Duration	
C207558	Study Intervention Name		The literal identifier (i.e., distinctive designation) of the study intervention.	Study Intervention Name	
C207559	Study Intervention Product Designation		An indication as to whether the investigational intervention is an investigational medicinal product or an auxiliary medicinal product.	Study Intervention Product Type	
C207560	Study Intervention Role	Study Intervention Use	The intended use of the trial intervention within the context of the study design.	Study Intervention Role	
C98747	Study Intervention Type	Intervention Type	The kind of product or procedure studied in a trial.	Intervention Type	

DDF Study Protocol Document Attribute Terminology (DDF Study Protocol Document Attribute Terminology)

NCI Code: C207440, Codelist extensible: No

C207440		DDF Study Protocol Document Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207561	Study Protocol Document Description		A narrative representation of the study protocol document.	Study Protocol Document Description
C207562	Study Protocol Document Label		The short descriptive designation for the study protocol document.	Study Protocol Document Label
C207563	Study Protocol Document Name		The literal identifier (i.e., distinctive designation) of the study protocol document.	Study Protocol Document Name

DDF Study Site Attribute Terminology (DDF Study Site Attribute Terminology)

NCI Code: C207441, Codelist extensible: No

C207441		DDF Study Site Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207564	Study Site Description		A narrative representation of the study site.	Study Site Description
C207565	Study Site Label		The short descriptive designation for the study site.	Study Site Label
C207566	Study Site Name		The literal identifier (i.e., distinctive designation) of the study site.	Study Site Name

DDF Study Title Attribute Terminology (DDF Study Title Attribute Terminology)

NCI Code: C207442, Codelist extensible: No

C207442		DDF Study Title Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207567	Study Title Text		An instance of unstructured text that represents the study title.	Study Title Text
C207568	Study Title Type		A characterization or classification of the study title.	Study Title Type

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

NCI Code: C207443, Codelist extensible: No

C207443		DDF Study Version 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 Area
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
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
C207570	Study Version Identifier		A sequence of characters used to identify, name, or characterize the study version.	Study Version Identifier
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 Subject Enrollment Attribute Terminology (DDF Subject Enrollment Attribute Terminology)

NCI Code: C207444, Codelist extensible: No

C207444		DDF Subject Enrollment Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207571	Subject Enrollment Code		A symbol or combination of symbols which is assigned to the subject enrollment.	Subject Enrollment Code
C207573	Subject Enrollment Quantity Value		The value representing the number of individuals enrolled in a study.	Subject Enrollment Quantity Value
C207574	Subject Enrollment Type		A characterization or classification of the subject enrollment.	Subject Enrollment Type

DDF Syntax Template Attribute Terminology (DDF Syntax Template Attribute Terminology)

NCI Code: C207445, Codelist extensible: No

C207445		DDF Syntax Template Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207575	Syntax Template Description		A narrative representation of the syntax template.	Syntax Template Description
C207576	Syntax Template Label		The short descriptive designation for the syntax template.	Syntax Template Label
C207577	Syntax Template Name		The literal identifier (i.e., distinctive designation) of the syntax template.	Syntax Template Name
C207578	Syntax Template Text		A structured text string containing prescribed text interspersed with user-defined parameter values.	Syntax Template Text

DDF Syntax Template Dictionary Attribute Terminology (DDF Syntax Template Dictionary Attribute Terminology)

NCI Code: C207446, Codelist extensible: No

C207446		DDF Syntax Template Dictionary Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207579	Syntax Template Dictionary Description		A narrative representation of the syntax template dictionary.	Syntax Template Dictionary Description
C207580	Syntax Template Dictionary Label		The short descriptive designation for the syntax template dictionary.	Syntax Template Dictionary Label
C207581	Syntax Template Dictionary Name		The literal identifier (i.e., distinctive designation) of the syntax template dictionary.	Syntax Template Dictionary Name

DDF Timing Attribute Terminology (DDF Timing Attribute Terminology)

NCI Code: C201262, Codelist extensible: No

C201262		DDF Timing Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C164648	Timing Description		A narrative representation of the biomedical concept category.	Timing Description
C207583	Timing Label		The short descriptive designation for the timing.	Timing Label
C207584	Timing Name		The literal identifier (i.e., distinctive designation) of the timing.	Timing Name
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
C207585	Timing Value Label		The short descriptive designation for the timing value.	Timing Value Label
C201341	Timing Value		The temporal value of the chronological relationship between temporal events.	Timing Value
C207586	Timing Window Label		The short descriptive designation for a time period, or other type of interval, during which a temporal event may be achieved, obtained, or observed.	Timing Window Label
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: No

C188712		DDF Transition Rule Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188835	Transition Rule Description		A narrative representation of the transition rule.	Transition Rule Description
C207587	Transition Rule Label		The short descriptive designation for the transition rule.	Transition Rule Label
C207588	Transition Rule Name		The literal identifier (i.e., distinctive designation) of the transition rule.	Transition Rule Name
C207589	Transition Rule Text		An instance of unstructured text that represents the transition rule.	Transition Rule Text

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

NCI Code: C188728, Codelist extensible: Yes

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: No

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

Geographic Scope Type Value Set Terminology (Geographic Scope Type Value Set Terminology)

NCI Code: C207412, Codelist extensible: No

C207412		Geographic Scope Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C25464	Country		A sovereign nation occupying a distinct territory and ruled by an autonomous government.	Country
C68846	Global		Covering or affecting the whole of a system.	Global
C41129	Region		An area or portion of something with more or less definite boundaries designed or specified according to some established criteria.	Region

Governance Date Type Value Set Terminology (Governance Date Type Value Set Terminology)

NCI Code: C207413, Codelist extensible: Yes

C207413		Governance Date Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207598	Protocol Effective Date		The date and time specifying when the protocol takes effect or becomes operative.	Protocol Effective Date
C132352	Sponsor Approval 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

Masking Role Value Set Terminology (Masking Role Value Set Terminology)

NCI Code: C207414, Codelist extensible: Yes

C207414		Masking Role Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C17445	Care Provider	Caregiver;Carer;Caretaker	The primary person in charge of the care of a patient, usually a family member or a designated health care professional. (NCI)	Caregiver	
C25936	Investigator		A person responsible for the conduct of the study, ensuring adherence to the protocol and good clinical practices. (CDISC Glossary)	Investigator	
C207599	Outcomes Assessor		The individual who evaluates the outcome(s) of interest. (Clinicaltrials.gov)	Outcomes Assessor	
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	
C41189	Study Subject		An individual who is observed, analyzed, examined, investigated, experimented upon, or/and treated in the course of a particular study.	Study Subject	

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

NCI Code: C188725, Codelist extensible: No

C188725		Objective Level Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C163559	Exploratory Objective	Study Exploratory Objective; Trial Exploratory Objective	Additional scientific question(s) within the study that enable further discovery research, beyond the primary and secondary objectives.	Trial Exploratory Objective
C85826	Study Primary Objective	Study Primary Objective; Trial Primary Objective	The main scientific question(s) the study is designed to answer. (CDISC Glossary)	Trial Primary Objective
C85827	Study Secondary Objective	Study Secondary Objective; Trial Secondary Objective	The supportive or ancillary scientific question(s) the study is designed to answer. (CDISC Glossary)	Trial Secondary Objective

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

NCI Code: C188724, Codelist extensible: Yes

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: No

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

Study Amendment Reason Code Value Set Terminology (Study Amendment Reason Code Value Set Terminology)

NCI Code: C207415, Codelist extensible: No

C207415		Study Amendment Reason Code Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207600	Change In Standard Of Care		A change in the standard of care necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	Change In Standard Of Care
C207601	Change In Strategy		A change in the study purpose or intent of the scientific plan necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	Change In Strategy
C207602	IMP Addition		The addition of an investigational medicinal product to a clinical trial design necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	IMP Addition
C207603	Inconsistency And/or Error In The Protocol		An error or inconsistency in the protocol necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	Inconsistency and/or Error In The Protocol
C207604	Investigator/Site Feedback		Feedback from the investigator or study site necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	Investigator/Site Feedback
C207605	IRB/IEC Feedback		Feedback from the institutional review board or independent ethics committee necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	IRB/IEC Feedback
C207606	Manufacturing Change		A change to manufacturing processes of the study agents necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	Manufacturing Change
C207607	New Data Available (Other Than Safety Data)		Previously unavailable data (other than safety data) becomes available, which necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	New Data Available (Other Than Safety Data)
C207608	New Regulatory Guidance		A regulatory agency has published a guidance document that necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	New Regulatory Guidance
C207609	New Safety Information Available		Previously unavailable safety data becomes available, which necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	New Safety Information Available
C207610	Protocol Design Error		A protocol design error necessitates a change(s) to, or formal clarification of, a document. (ICH M11)	Protocol Design Error
C207611	Recruitment Difficulty		Challenges with participant recruitment necessitates a change(s) to, or formal clarification of, the protocol. (ICH M11)	Recruitment Difficulty
C207612	Regulatory Agency Request To Amend		A regulatory agency has expressed a need for a change(s) to, or formal clarification of, the protocol. (ICH M11)	Regulatory Agency Request To Amend

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

NCI Code: C188727, Codelist extensible: Yes

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 Design Characteristics Value Set Terminology (Study Design Characteristics Value Set Terminology)

NCI Code: C207416, Codelist extensible: Yes

C207416		Study Design Characteristics Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C98704	Adaptive		A study design that allows for prospectively planned modifications to one or more aspects of the design based on accumulating data from subjects in the trial. (FDA)	Adaptive Design
C207613	Extension	Roll-over Study	A study design in which subjects enrolled in one study are subsequently continued into a related study for longer term safety, tolerability, and/or effectiveness monitoring.	Extension Study Design
C46079	Randomized		A study design in which interventions are assigned to subjects according to randomization principles.	Randomized Controlled Clinical Trial

Study Intervention Product Designation Value Set Terminology (Study Intervention Product Designation Value Set Terminology)

NCI Code: C207418, Codelist extensible: No

C207418		Study Intervention Product Designation Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C202579	IMP		A medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial. (Regulation (EU) No 536/2014 Article 2 (5))	Investigational Medicinal Product
C156473	NIMP (AxMP)		A medicinal product that is related to the specific needs of the clinical trial as described in the protocol, but not as an investigational medicinal product. NOTE: Auxiliary medicinal products may be authorised for marketing in a country or region or non-authorised. (CDISC Glossary)	Auxiliary Medicinal Product

Study Intervention Role Value Set Terminology (Study Intervention Role Value Set Terminology)

NCI Code: C207417, Codelist extensible: No

C207417		Study Intervention Role Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207614	Additional Required Treatment		A medicinal product that must be administered along with the experimental treatment (e.g., drug studies wherein opioid blockers are administered to prevent overdose).	Additional Required Medicinal Product
C165822	Background Treatment		Medicinal products that are administered to each clinical trial subject, regardless of randomization group, a) to treat the indication which is the object of the study, or b) required in the protocol as part of standard care for a condition that is not the indication under investigation, and is relevant for the clinical trial design. [After Recommendations from the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014' dd 28 June 2017]	Background Treatment
C158128	Challenge Agent		A non-investigational medicinal product (NIMP) given to trial subjects to produce a physiological response that is necessary before the pharmacological action of the investigational medicinal product can be assessed. [After Recommendations from the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014' dd 28 June 2017]	Challenge Agent
C18020	Diagnostic		Any procedure or test used to diagnose a disease or disorder.	Diagnostic Procedure
C41161	Experimental Intervention	Investigational Interventional; Investigational Therapy or Treatment	The drug, device, therapy, procedure, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study (e.g., health-related quality of life, efficacy, safety, pharmacoeconomics). [After https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5224 ; https://grants.nih.gov/policy/clinical-trials/protocol-template.htm] See also test articles, devices, drug product, combination product, treatment, diagnosis. Contrast with investigational medicinal product.	Protocol Agent
C753	Placebo		A pharmaceutical preparation that does not contain the investigational agent and is generally prepared to be physically indistinguishable from the preparation containing the investigational product.	Placebo
C165835	Rescue Medicine		Medicinal products identified in the protocol as those that may be administered to subjects when the efficacy of the investigational medicinal product (IMP) is not satisfactory, the effect of the IMP is too great and is likely to cause a hazard to the patient, or to manage an emergency situation. [After EU-CTR Recommendations from the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014' dd 28 June 2017]	Rescue Medications

Study Title Type Value Set Terminology (Study Title Type Value Set Terminology)

NCI Code: C207419, Codelist extensible: No

C207419		Study Title Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207615	Brief Study Title	Abbreviated Protocol Title	The short descriptive name for the study.	Brief Study Title
C207616	Official Study Title		The formal descriptive name for the study.	Official Study Title
C207617	Public Study Title		The descriptive name of the study that is intended for the lay public, written in easily understood language.	Public Study Title
C207618	Scientific Study Title		A more extensive descriptive name of the study that is intended for medical professionals, written using medical and scientific language.	Scientific Study Title
C207646	Study Acronym	Trial Acronym	A word or words formed from the beginning letters or a combination of syllables and letters of a compound term, which identifies a clinical study.	Study Acronym

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

NCI Code: C201265, Codelist extensible: No

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: No

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