

CDISC DDF Controlled Terminology, 2025-09-26

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
C215479	Administrable Product Property Type Value Set Terminology	Administrable Product Property Type Value Set Terminology	The terminology relevant to the administrable product property type value set.	Yes
C215483	Administrable Product Sourcing Value Set Terminology	Administrable Product Sourcing Value Set Terminology	The terminology relevant to the administrable product sourcing value set.	Yes
C215456	DDF Abbreviation Attribute Terminology	DDF Abbreviation Attribute Terminology	A terminology value set relevant to the attributes of the abbreviation.	No
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
C215459	DDF Administrable Product Attribute Terminology	DDF Administrable Product Attribute Terminology	A terminology value set relevant to the attributes of the administrable product.	No
C215460	DDF Administrable Product Identifier Attribute Terminology	DDF Administrable Product Identifier Attribute Terminology	A terminology value set relevant to the attributes of the administrable product identifier.	No
C215461	DDF Administrable Product Property Attribute Terminology	DDF Administrable Product Property Attribute Terminology	A terminology value set relevant to the attributes of the administrable product property.	No
C207421	DDF Administration Attribute terminology	DDF Administration Attribute terminology	A terminology value set relevant to the attributes of the agent administration.	No
C215451	DDF Alias Code Attribute Terminology	DDF Alias Code Attribute Terminology	A terminology value set relevant to the attributes of the alias code.	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
C215465	DDF Assigned Person Attribute Terminology	DDF Assigned Person Attribute Terminology	A terminology value set relevant to the attributes of the assigned person.	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
C215475	DDF Biospecimen Retention Attribute Terminology	DDF Biospecimen Retention Attribute Terminology	A terminology value set relevant to the attributes of the biospecimen retention.	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
C215452	DDF Comment Annotation Attribute Terminology	DDF Comment Annotation Attribute Terminology	A terminology value set relevant to the attributes of the comment annotation.	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
C215468	DDF Document Content Reference Attribute Terminology	DDF Document Content Reference Attribute Terminology	A terminology value set relevant to the attributes of the document content reference.	No
C216966	DDF Duration Terminology	DDF Duration Attribute Terminology	A terminology value set relevant to the attributes of the event duration.	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
C215476	DDF Eligibility Criterion Item Attribute Terminology	DDF Eligibility Criterion Item Attribute Terminology	A terminology value set relevant to the attributes of the eligibility criterion item.	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
C215458	DDF Identifier Attribute Terminology	DDF Identifier Attribute Terminology	A terminology value set relevant to the attributes of the identifier.	No
C188705	DDF Indication Attribute Terminology	DDF Indication Attribute Terminology	A terminology value set relevant to the attributes of the disease indication.	No
C215464	DDF Ingredient Attribute Terminology	DDF Ingredient Attribute Terminology	A terminology value set relevant to the attributes of the ingredient.	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
C215473	DDF Interventional Study Design Attribute Terminology	DDF Interventional Study Design Attribute Terminology	A terminology value set relevant to the attributes of the interventional study design.	No
C207430	DDF Masking Attribute Terminology	DDF Masking Attribute Terminology	A terminology value set relevant to the attributes of the masking.	No
C215470	DDF Medical Device Attribute Terminology	DDF Medical Device Attribute Terminology	A terminology value set relevant to the attributes of the medical device.	No
C215471	DDF Medical Device Identifier Attribute Terminology	DDF Medical Device Identifier Attribute Terminology	A terminology value set relevant to the attributes of the medical device identifier.	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
C215453	DDF Narrative Content Item Attribute Terminology	DDF Narrative Content Item Attribute Terminology	A terminology value set relevant to the attributes of the narrative content item.	No
C188707	DDF Objective Attribute Terminology	DDF Objective Attribute Terminology	A terminology value set relevant to the attributes of the objective.	No
C215474	DDF Observational Study Design Attribute Terminology	DDF Observational Study Design Attribute Terminology	A terminology value set relevant to the attributes of the observational study design.	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
C216965	DDF Person Name Attribute Terminology	DDF Person Name Terminology	A terminology value set relevant to the attributes of the person name.	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
C215472	DDF Product Organization Role Attribute Terminology	DDF Product Organization Role Attribute Terminology	A terminology value set relevant to the attributes of the product organization role.	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
C215457	DDF Reference Identifier Attribute Terminology	DDF Reference Identifier Attribute Terminology	A terminology value set relevant to the attributes of the reference identifier.	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

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
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
C215463	DDF Strength Attribute Terminology	DDF Strength Attribute Terminology	A terminology value set relevant to the attributes of the strength.	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
C215469	DDF Study Amendment Impact Attribute Terminology	DDF Study Amendment Impact Attribute Terminology	A terminology value set relevant to the attributes of the study amendment impact.	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
C215467	DDF Study Change Attribute Terminology	DDF Study Change Attribute Terminology	A terminology value set relevant to the attributes of the study change.	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
C215454	DDF Study Definition Document Attribute Terminology	DDF Study Definition Document Attribute Terminology	A terminology value set relevant to the attributes of the study definition document.	No
C215455	DDF Study Definition Document Version Attribute Terminology	DDF Study Definition Document Version Attribute Terminology	A terminology value set relevant to the attributes of the study definition document version.	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
C215466	DDF Study Role Attribute Terminology	DDF Study Role Attribute Terminology	A terminology value set relevant to the attributes of the study role.	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
C215462	DDF Substance Attribute Terminology	DDF Substance Attribute Terminology	A terminology value set relevant to the attributes of the substance.	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 Terminology	Encounter Type Value Set Terminology	The terminology relevant to the encounter type.	Yes
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
C215484	Medical Device Identifier Type Value Set Terminology	Medical Device Identifier Type Value Set Terminology	The terminology relevant to the medical device identifier type value set.	Yes
C215482	Medical Device Sourcing Value Set Terminology	Medical Device Sourcing Value Set Terminology	The terminology relevant to the medical device sourcing value set.	Yes
C188725	Objective Level Value Set Terminology	Objective Level Value Set Terminology	The terminology relevant to the objective level.	No
C215486	Observational Study Design Subtype Value Set Terminology	Observational Study Design Subtype Value Set Terminology	The terminology relevant to the observational study design subtype value set.	Yes
C188724	Organization Type Value Set Terminology	Organization Type Value Set Terminology	The terminology relevant to the organization type.	Yes
C207418	Product Designation Value Set Terminology	Product Designation Value Set Terminology	The terminology relevant to the product designation value set.	No
C215485	Product Organization Role Code Value Set Terminology	Product Organization Role Code Value Set Terminology	The terminology relevant to the product organization role code value set.	Yes
C215478	Reference Identifier Type Value Set Terminology	Reference Identifier Type Value Set Terminology	The terminology relevant to the reference identifier type value set.	Yes
C215481	Study Amendment Impact Type Value Set Terminology	Study Amendment Impact Type Value Set Terminology	The terminology relevant to the study amendment impact type value set.	Yes
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.	Yes
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
C215477	Study Definition Document Type Value Set Terminology	Study Definition Document Type Value Set Terminology	The terminology relevant to the study definition document type value set.	Yes
C188723	Study Definition Document Version Value Set Terminology	Study Definition Document Version Value Set Terminology	The terminology relevant to the study definition document version status.	No
C207416	Study Design Characteristics Value Set Terminology	Study Design Characteristics Value Set Terminology	The terminology relevant to the study design characteristics value set.	Yes
C207417	Study Intervention Role Value Set Terminology	Study Intervention Role Value Set Terminology	The terminology relevant to the study intervention role value set.	No
C215480	Study Role Code Value Set Terminology	Study Role Code Value Set Terminology	The terminology relevant to the study role code terminology value set.	Yes
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

Administrable Product Property Type Value Set Terminology (Administrable Product Property Type Value Set Terminology)

NCI Code: C215479, Codelist extensible: Yes

C215479	Administrable Product Property Type Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C45997	pH	pH	The negative logarithm (base 10) of the concentration of hydronium ions, which is used as a measure of the acidity or alkalinity of a fluid.	pH

Administrable Product Sourcing Value Set Terminology (Administrable Product Sourcing Value Set Terminology)

NCI Code: C215483, Codelist extensible: Yes

C215483	Administrable Product Sourcing Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215659	Centrally Sourced		An indication that the entity is obtained from a central source.	Centrally Sourced Indicator
C215660	Locally Sourced		An indication that the entity is obtained from a local source.	Locally Sourced Indicator

DDF Abbreviation Attribute Terminology (DDF Abbreviation Attribute Terminology)

NCI Code: C215456, Codelist extensible: No

C215456		DDF Abbreviation Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215569	Abbreviation Long Name		The full literal representation of the abbreviation.	Abbreviation Long Name	
C215570	Abbreviation Notes		A brief written record relevant to the abbreviation.	Abbreviation Note	
C215487	Text Abbreviation Value		The literal value of an instance of unstructured text that is used as the abbreviation.	Text Abbreviation Value	

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
C215519	Activity Notes		A brief written record relevant to the activity.	Activity Note
C70960	Study Activity Description		The textual representation of the study activity.	Clinical Study Activity Description
C207458	Study Activity Label		The short descriptive designation for the study activity.	Study Activity Label
C188842	Study Activity Name		The literal identifier (i.e., distinctive designation) of the 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 Administrable Product Attribute Terminology (DDF Administrable Product Attribute Terminology)

NCI Code: C215459, Codelist extensible: No

C215459		DDF Administrable Product Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215574	Administrable Product Definition Description		A narrative representation of the administrable product.	Administrable Product Definition Description	
C215575	Administrable Product Definition Label		The short descriptive designation for the administrable product.	Administrable Product Definition Label	
C215573	Administrable Product Definition Name		The literal identifier (i.e., distinctive designation) of the administrable product.	Administrable Product Definition Name	
C215576	Administrable Product Dose Form		The physical form in which formulated ingredient(s) are presented in the administrable product.	Administrable Product Dose Form	
C215580	Administrable Product Notes		A brief written record relevant to the administrable product.	Administrable Product Note	
C215577	Administrable Product Pharmacologic Class		The pharmacological class of the administrable product.	Administrable Product Pharmacologic Class	
C215579	Administrable Product Product Designation		An indication as to whether the administrable product is an investigational medicinal product or an auxiliary medicinal product.	Administrable Product Designation Indicator	
C215578	Administrable Product Sourcing		An indication as to whether the administrable product is obtained from a local or central source.	Administrable Product Sourcing Indicator	

DDF Administrable Product Identifier Attribute Terminology (DDF Administrable Product Identifier Attribute Terminology)

NCI Code: C215460, Codelist extensible: No

C215460	DDF Administrable Product Identifier Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215581	Administrable Product Identifier Text		An instance of structured text that represents the administrable product.	Administrable Product Identifier Text

DDF Administrable Product Property Attribute Terminology (DDF Administrable Product Property Attribute Terminology)

NCI Code: C215461, Codelist extensible: No

C215461	DDF Administrable Product Property Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215582	Administrable Product Property Name		The literal identifier (i.e., distinctive designation) of the administrable product property.	Administrable Product Property Name
C215584	Administrable Product Property Quantity Value		The numeric value associated with an administrable product property.	Administrable Product Property Quantity Value
C215583	Administrable Product Property Text		An instance of structured text that represents the administrable product property.	Administrable Product Property Text
C215585	Administrable Product Property Type		A characterization or classification of the administrable product property.	Administrable Product Property Type

DDF Administration Attribute terminology (DDF Administration Attribute terminology)

NCI Code: C207421, Codelist extensible: No

C207421		DDF Administration Attribute terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C207463	Administration Description		A narrative representation for the administration of a product, agent, or therapy.	Agent Administration Description
C167190	Administration Dose		The value representing the amount of an agent given to an individual at one time.	Dose Administered
C69282	Administration Duration		The amount of time elapsed during the administration of an agent.	Duration of Administration
C207464	Administration Label		The short descriptive designation for the administration of a product, agent, or therapy.	Agent Administration Label
C207465	Administration Name		The literal identifier (i.e., distinctive designation) for the administration of a product, agent, or therapy.	Agent Administration Name
C215544	Administration Notes		A brief written record relevant to the administration of the product, agent, or therapy.	Agent Administration Note
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 Alias Code Attribute Terminology (DDF Alias Code Attribute Terminology)

NCI Code: C215451, Codelist extensible: No

C215451	DDF Alias Code Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215529	Standard Code Aliases		Alternative combinations of symbols used to represent aliases or alternatives to the standard code.	Standard Code Alias
C215528	Standard Code		A combination of symbols that is used to represent the standard code.	Standard Code

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		A narrative representation of the analysis population.	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	
C215525	Analysis Population Notes		A brief written record relevant to the analysis population.	Analysis Population Note	
C207468	Analysis Population Text		An instance of unstructured text that represents the analysis population.	Analysis Population Text	

DDF Assigned Person Attribute Terminology (DDF Assigned Person Attribute Terminology)

NCI Code: C215465, Codelist extensible: No

C215465		DDF Assigned Person Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215597	Assigned Person Description		A narrative representation of the assigned person.	Assigned Person Description	
C215599	Assigned Person Job Title		An identifying designation related to the assigned person's occupation.	Assigned Person Job Title	
C215598	Assigned Person Label		The short descriptive designation for the assigned person.	Assigned Person Label	
C215596	Assigned Person Name		The literal identifier (i.e., distinctive designation) of the assigned person.	Assigned Person Name	
C216993	Assigned Person Person Name	Assigned Person Human Name	A word or group of words indicating the identity of an assigned person usually consisting of a first (personal) name and a last (family) name with an optional middle name. In some cultural traditions the family name comes first.	Assigned Person Person Name	

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	
C215530	Biomedical Concept Notes		A brief written record relevant to the biomedical concept.	Biomedical Concept Note	
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	
C215533	Biomedical Concept Category Notes		A brief written record relevant to the biomedical concept category.	Biomedical Concept Category Note	

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	
C215531	Biomedical Concept Property Notes		A brief written record relevant to the biomedical concept property.	Biomedical Concept Property Note	
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
C215532	Biomedical Concept Surrogate Notes		A brief written record relevant to the biomedical concept surrogate.	Biomedical Concept Surrogate Note
C201321	Biomedical Concept Surrogate Reference		A citation to an authoritative source for a biomedical concept surrogate.	Biomedical Concept Surrogate Reference

DDF Biospecimen Retention Attribute Terminology (DDF Biospecimen Retention Attribute Terminology)

NCI Code: C215475, Codelist extensible: No

C215475		DDF Biospecimen Retention Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C181231	Biospecimen Retention Description	Biospecimen Retention	A narrative representation of the biospecimen retention.	Biological Sample Retention Description	
C127777	Biospecimen Retention Includes DNA Indicator	Biospecimen Retention Contains DNA Ind	An indication as to whether retained biospecimens contain DNA.	Retained Biospecimen Contains DNA Indicator	
C164620	Biospecimen Retention Indicator	Biospecimen Retention Indicator	An indication as to whether biospecimens were retained.	Biospecimen Retention Indicator	
C215646	Biospecimen Retention Label		The short descriptive designation for the biospecimen retention.	Biospecimen Retention Label	
C215645	Biospecimen Retention Name		The literal identifier (i.e., distinctive designation) of the biospecimen retention.	Biospecimen Retention Name	

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	
C215548	Characteristic Notes		A brief written record relevant to the characteristic.	Characteristic Note	
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
C142704	Clinical Study Description		A narrative representation of the clinical study.	Study Description
C207479	Clinical Study Label		The short descriptive designation for the clinical study.	Clinical Study Label
C68631	Clinical Study Name		The literal identifier (i.e., distinctive designation) of the clinical study.	Study Name

DDF Code Attribute Terminology (DDF Code Attribute Terminology)

NCI Code: C188722, Codelist extensible: No

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

DDF Comment Annotation Attribute Terminology (DDF Comment Annotation Attribute Terminology)

NCI Code: C215452, Codelist extensible: No

C215452	DDF Comment Annotation Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215556	Comment Annotation Code		A symbol or combination of symbols which is assigned to the comment annotation.	Comment Annotation Code
C215555	Comment Annotation Text		An instance of unstructured text that represents the comment annotation.	Comment Annotation 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	
C215552	Condition Notes		A brief written record relevant to the condition.	Condition Note	
C207484	Condition Text		An instance of structured text that represents the condition.	Condition Text	

DDF Document Content Reference Attribute Terminology (DDF Document Content Reference Attribute Terminology)

NCI Code: C215468, Codelist extensible: No

C215468		DDF Document Content Reference Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215609	Document Content Reference Section Number		The numeric identifier of a particular section for the document content reference.	Document Content Reference Section Number
C215610	Document Content Reference Section Title		An identifying designation for a particular section for the document content reference.	Document Content Reference Section Title

DDF Duration Terminology (DDF Duration Attribute Terminology)

NCI Code: C216966, Codelist extensible: No

C216966	DDF Duration Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C217011	Duration Quantity Value		The value representing the amount of time over which the event occurs.	Duration Quantity Value
C217008	Duration Text		An instance of unstructured text that represents the event duration.	Duration Text
C217009	Duration Will Vary Indicator		An indication as to whether the event duration is planned to vary within and/or across subjects.	Duration Will Vary Indicator
C217010	Reason Duration Will Vary		The explanation for why the event duration will vary within and/or across subjects.	Reason Duration Will Vary

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
C215537 C83016		Eligibility Criterion Notes		A brief written record relevant to the eligibility criterion.	Eligibility Criterion Note
		Study Eligibility Criterion Category	Study Eligibility Criteria Category	A classification of the inclusion exclusion criterion.	Inclusion Exclusion Criterion Category
C207486		Study Eligibility Criterion Description	Study Eligibility Criteria 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	Study Eligibility Criteria Label	The short descriptive designation for the study eligibility criterion.	Study Eligibility Criteria Label
C207488		Study Eligibility Criterion Name	Study Eligibility Criteria Description	The literal identifier (i.e., distinctive designation) of the study eligibility criterion.	Study Eligibility Criteria Name

DDF Eligibility Criterion Item Attribute Terminology (DDF Eligibility Criterion Item Attribute Terminology)

NCI Code: C215476, Codelist extensible: No

C215476		DDF Eligibility Criterion Item Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215649	Eligibility Criterion Item Description		A narrative representation of the eligibility criterion item.	Eligibility Criterion Item Description	
C215650	Eligibility Criterion Item Label		The short descriptive designation for the eligibility criterion item.	Eligibility Criterion Item Label	
C215647	Eligibility Criterion Item Name		The literal identifier (i.e., distinctive designation) of the eligibility criterion item.	Eligibility Criterion Item Name	
C215651	Eligibility Criterion Item Notes		A brief written record relevant to the eligibility criterion item.	Eligibility Criterion Item Note	
C215648	Eligibility Criterion Item Text		An instance of structured text that represents the eligibility criterion item.	Eligibility Criterion Item 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	
C188841	Contact Mode		The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).	Contact Mode	
C215518	Encounter Notes		A brief written record relevant to the study encounter.	Study Encounter Note	
C188840	Environmental Setting		The environment/setting where the event, intervention, or finding occurred.	Environmental Setting	
C188836	Study Encounter Description		A narrative representation of the protocol-defined study encounter.	Clinical Encounter Description	
C207490	Study Encounter Label		The short descriptive designation for the study encounter.	Study Encounter Label	
C171010	Study Encounter Name		The literal identifier (i.e., distinctive designation) for a protocol-defined study encounter.	Clinical Encounter Name	
C188839	Study Encounter Type		A characterization or classification of the study encounter.	Clinical Encounter Type	

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
C215514	Endpoint Notes		A brief written record relevant to the study endpoint.	Study Endpoint Note
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	DDF Entity Terminology		CDISC Definition	NCI Preferred Term
NCI Code	CDISC Submission Value	CDISC Synonym		
C42610	Abbreviation		A set of letters that are drawn from a word or from a sequence of words and that are used for brevity in place of the full word or phrase. (CDISC Glossary)	Abbreviation
C25407	Address		A standardized representation of the location of a person, business, building, or organization. (NCI)	Address
C215493	Administrable Product Identifier		A sequence of characters used to identify, name, or characterize the administrable product.	Administrable Study Product Identifier
C215494	Administrable Product Property		A characteristic from a set of characteristics used to define an administrable product.	Administrable Study Product Property
C215492	Administrable Product		Any study product that is formulated and presented in the form that is suitable for administration to a study participant.	Administrable Study Product
C25409	Administration		The act of dispensing, applying, or tendering a product, agent, or therapy.	Administration
C201344	Alias Code		An alternative symbol or combination of symbols which is assigned to the members of a collection.	Alias Code
C188814	Analysis Population	Study Target Population for Analysis;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
C215496	Assigned Person		An individual person who is allotted or appointed to a particular role, function, or other entity.	Assigned Person
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
C215505	Biospecimen Retention		The continued possession, cataloging, and storage of collected biological specimens beyond their initial use.	Biospecimen Retention
C25447	Characteristic		The distinguishing qualities or prominent aspects of an entity.	Characteristic
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. (CDISC Glossary)	Clinical Study
C25162	Code		A symbol or combination of symbols which is assigned to the members of a collection.	Code
C44272	Comment Annotation		An explanatory or critical comment, or other in-context information (e.g., pattern, motif, link), that has been associated with data or other types of information.	Annotation
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		The disease or condition the intervention is intended to diagnose, treat, prevent, cure, or mitigate.	Indication
C215499	Document Content Reference		A citation pointing to the location of specific content within a document.	Document Content Reference
C25330	Duration	Duration;Time;Time Duration	The length of time during which something continues.	Duration
C215506	Eligibility Criterion Item		An individual item within the container that holds an instance of an eligibility criterion.	Eligibility Criterion Item
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
C25364	Identifier		One or more characters used to identify, name, or characterize the nature, properties, or contents of a thing.	Identifier
C51981	Ingredient		Any component that constitutes a part of a compound or mixture.	Ingredient
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
C215503	Interventional Study Design		The strategy that specifies the structure of an interventional trial in terms of the planned activities (including timing) and statistical analysis approach intended to meet the objectives of the study.	Interventional Study Design
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
C215501	Medical Device Identifier		A sequence of characters used to identify, name, or characterize the medical device.	Medical Device Identifier
C16830	Medical Device	Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for, one or more specific medical purpose(s). [After REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices]	Medical Device
C215489	Narrative Content Item		An individual item within the container that holds an instance of unstructured text and which may include objects such as tables, figures, and images.	Narrative Content Item
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
C215504	Observational Study Design		The strategy that specifies the structure of an observational study in terms of the planned activities (including timing) and statistical analysis approach intended to meet the objectives of the study.	Observational Study Design
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
C25191	Person Name	Human Name;Individual's Name;Name	A word or group of words indicating the identity of a person usually consisting of a first (personal) name and a last (family) name with an optional middle name. In some cultural traditions the family name comes first.	Person Name
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
C215502	Product Organization Role		A designation that identifies the function of an organization within the context of the product.	Product Organization Role
C217000	Quantity or Range		The total amount (number), or the limits (minimum and maximum) of a variation.	Quantity or Range
C25256	Quantity		How much there is of something that can be measured; the total amount or number.	Quantity
C38013	Range		An expression that defines the lower and upper limits of a variation.	Range
C82531	Reference Identifier		A sequence of characters used to identify, name, or characterize the reference.	Reference ID
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
C215500	Study Amendment Impact		The effect or consequence of an amendment on some aspect of the study.	Study Amendment Impact
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
C215498	Study Change		The act of alteration or modification to a study.	Study Change
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
C215491	Study Definition Document Version		A representation of a particular edition or snapshot of the study definition document as it exists at a particular point in time.	Study Definition Document Version
C215490	Study Definition Document		Any physical or electronic document that is related to defining a study or part of a study.	Study Definition Document
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
C142728	Study Design Population	Target Population	The group of people in the general population to which the study results can be generalized.	Target Study Population
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 Criterion	Study Eligibility Criteria;Trial Eligibility Criteria;Trial Eligibility Criterion	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
C215488	Study Encounter		Any physical or virtual contact between two or more parties involved in a study, at which an assessment or activity takes place.	Study Encounter
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

C188698		DDF Entity Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C207649	Study Intervention	Investigational Trial Intervention	Any agent, device, or procedure being tested or used as a reference or comparator in the conduct of a clinical trial.	Trial Intervention	
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	
C215497	Study Role		A designation that identifies the function of study personnel or an organization within the context of the study.	Study Role	
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	
C215495	Substance Strength		The content of a substance expressed quantitatively per dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical dose form of the product.	Substance Strength	
C45306	Substance		Any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical.	Substance	
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	
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
C215523	Estimand Description		A narrative representation of the estimand.	Estimand Description
C215524	Estimand Label		The short descriptive designation for the estimand.	Estimand Label
C215522	Estimand Name		The literal identifier (i.e., distinctive designation) of the estimand.	Estimand Name
C215521	Estimand Notes		A brief written record relevant to the study estimand.	Estimand Note
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	
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	
C207496	Study Governance Date Type		A characterization or classification of the study governance date	Study Governance Date Type	
C207500	Study Governance Date Value		The information contained in the date field.	Study Governance Date Value	

DDF Identifier Attribute Terminology (DDF Identifier Attribute Terminology)

NCI Code: C215458, Codelist extensible: No

C215458	DDF Identifier Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215450	Identifier Text		An instance of structured text that represents the identifier.	Identifier Text

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/Condition 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
C215509	Indication Notes		A brief written record relevant to the disease/condition indication.	Disease Or Condition Indication Note

DDF Ingredient Attribute Terminology (DDF Ingredient Attribute Terminology)

NCI Code: C215464, Codelist extensible: No

C215464	DDF Ingredient Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215595	Ingredient Role		The intended use of the ingredient within the context of the compounded substance or mixture.	Ingredient Role

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
C215527	Intercurrent Event Notes		A brief written record relevant to the intercurrent event.	Intercurrent Event Note
C188857	Intercurrent Event Strategy		A textual description of the planned strategy to manage and/or mitigate intercurrent events.	Intercurrent Event Strategy
C215526	Intercurrent Event Text		An instance of structured text that represents the intercurrent event.	Intercurrent Event Text

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

NCI Code: C215473, Codelist extensible: No

C215473		DDF Interventional 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	
C215632	Interventional Study Design Characteristics		The distinguishing qualities or prominent aspects of an interventional study design.	Interventional Study Design Characteristic	
C215627	Interventional Study Design Description		A narrative representation of the interventional study design.	Interventional Study Design Description	
C215628	Interventional Study Design Label		The short descriptive designation for the interventional study design.	Interventional Study Design Label	
C215626	Interventional Study Design Name		The literal identifier (i.e., distinctive designation) of the interventional study design.	Interventional Study Design Name	
C215634	Interventional Study Design Notes		A brief written record relevant to the interventional study design.	Interventional Study Design Note	
C215629	Interventional Study Design Rationale		Reason(s) for choosing the interventional study design. This may include reasons for the choice of control or comparator, as well as the scientific rationale for the study design.	Interventional Study Design Rationale	
C215630	Interventional Study Design Study Phase		The study phase associated with the interventional study design.	Interventional Study Design Study Phase	
C215631	Interventional Study Design Study Type		The study type associated with the interventional study design.	Interventional Study Design Study Type	
C215633	Interventional Study Design Therapeutic Areas		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, which is associated with the interventional study design.	Interventional Study Design Therapeutic Areas	
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 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
C215554	Masked Indicator		An indication as to whether the study role is masked.	Study Role Masked Indicator
C215553	Masking Text		An instance of unstructured text that represents how the masking is performed and maintained.	Masking Text

DDF Medical Device Attribute Terminology (DDF Medical Device Attribute Terminology)

NCI Code: C215470, Codelist extensible: No

C215470		DDF Medical Device Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215617	Hardware Version		A form or variant of hardware; one of a sequence of copies of the physical components from which a computer is constructed, each incorporating new modifications.	Hardware Version
C215615	Medical Device Description		A narrative representation of the medical device.	Medical Device Description
C215616	Medical Device Label		The short descriptive designation for the medical device.	Medical Device Label
C215614	Medical Device Name		The literal identifier (i.e., distinctive designation) of the medical device.	Medical Device Name
C215618	Medical Device Notes		A brief written record relevant to the medical device.	Medical Device Note
C215619	Medical Device Sourcing		An indication as to whether the medical device is obtained from a local or central source.	Medical Device Sourcing Indicator
C111093	Software Version	Software Version	A form or variant of software; one of a sequence of copies of a software program, each incorporating new modifications. (NCI)	Software Version

DDF Medical Device Identifier Attribute Terminology (DDF Medical Device Identifier Attribute Terminology)

NCI Code: C215471, Codelist extensible: No

C215471	DDF Medical Device Identifier Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215620	Medical Device Identifier Text		An instance of structured text that represents the medical device identifier.	Medical Device Identifier Text
C215621	Medical Device Identifier Type		A characterization or classification of the medical device identifier.	Medical Device Identifier Type

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	
C215535	Narrative Content Section Number Display Indicator		An indication as to whether the section number is to be displayed in the document containing narrative content.	Narrative Content Section Number Display Indicator	
C207509	Narrative Content Section Number		The numeric identifier assigned to a particular document section containing narrative content.	Narrative Content Section Number	
C215534	Narrative Content Section Title Display Indicator		An indication as to whether the section title is to be displayed in the document containing narrative content.	Narrative Content Section Title Display Indicator	
C207510	Narrative Content Section Title		An identifying designation for the document section containing narrative content.	Narrative Content Section Title	

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

NCI Code: C215453, Codelist extensible: No

C215453		DDF Narrative Content Item Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215557	Narrative Content Item Name		The literal identifier (i.e., distinctive designation) of the narrative content item.	Narrative Content Item Name
C215558	Narrative Content Item Text		An instance of unstructured text that represents the narrative content item.	Narrative Content Item 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
C215513	Objective Notes		A brief written record relevant to the study objective.	Study Objective Note
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 Observational Study Design Attribute Terminology (DDF Observational Study Design Attribute Terminology)

NCI Code: C215474, Codelist extensible: No

C215474		DDF Observational Study Design Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C147138	Observation Study Design Model Type	Observation Model	The general design of the strategy for identifying and following up with participants during observational studies. (clinicaltrials.gov)	Observational Study Model	
C215642	Observational Study Design Characteristics		The distinguishing qualities or prominent aspects of an observational study design.	Observational Study Design Characteristics	
C215637	Observational Study Design Description		A narrative representation of the observational study design.	Observational Study Design Description	
C215638	Observational Study Design Label		The short descriptive designation for the observational study design.	Observational Study Design Label	
C215636	Observational Study Design Name		The literal identifier (i.e., distinctive designation) of the observational study design.	Observational Study Design Name	
C215644	Observational Study Design Notes		A brief written record relevant to the observational study design.	Observational Study Design Note	
C215639	Observational Study Design Rationale		Reason(s) for choosing the observational study design. This may include reasons for the choice of control or comparator, as well as the scientific rationale for the study design.	Observational Study Design Rationale	
C215640	Observational Study Design Study Phase		The study phase associated with the observational study design.	Observational Study Design Study Phase	
C215641	Observational Study Design Study Type		The study type associated with the observational study design.	Observational Study Design Study Type	
C215643	Observational Study Design Therapeutic Areas		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, which is associated with the observational study design.	Observational Study Design Therapeutic Area	
C126067	Observational Study Sampling Method	Observational Study Sampling Method	The sampling method used to assign study participants into groups or cohorts within an observational study.	Observational Study Sampling Method	
C215635	Observational Study Type		The nature of the observational study for which information is being collected.	Observational Study Type	
C126065	Observational Time Perspective	Observational Time Perspective	The temporal relationship between the observation period and time of subject enrollment. (ClinicalTrials.gov)	Observational Time Perspective of Study	

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 Person Name Attribute Terminology (DDF Person Name Terminology)

NCI Code: C216965, Codelist extensible: No

C216965		DDF Person Name Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C40975	Person Family Name	Person Surname	A word or group of words indicating a person's last (family) name.	Last Name
C40974	Person Given Name		A word or group of words indicating a person's first (personal or given) name; the name that precedes the surname.	First Name
C217002	Person Name Prefix	Human Name Text	An affix occurring at the start of the person name string, usually denoting a title or honorific.	Person Name Prefix
C217003	Person Name Suffix		An affix occurring at the end of the person name, usually denoting educational or professional degrees and certifications, and/or filial rank.	Person Name Suffix
C217001	Person Name Text		An instance of structured text that represents the person's full name.	Person Name Text

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	
C215551	Population Definition Notes		A brief written record relevant to the population definition.	Population Definition Note	
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	
C215520	Procedure Notes		A brief written record relevant to the procedure.	Procedure Note	
C188848	Procedure Type		A characterization or classification of the study procedure.	Study Procedure Type	

DDF Product Organization Role Attribute Terminology (DDF Product Organization Role Attribute Terminology)

NCI Code: C215472, Codelist extensible: No

C215472	DDF Product Organization Role Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215625	Product Organization Role Code		A symbol or combination of symbols which is assigned to the product organization role.	Product Organization Role Code
C215623	Product Organization Role Description		A narrative representation of the product organization role.	Product Organization Role Description
C215624	Product Organization Role Label		The short descriptive designation for the product organization role.	Product Organization Role Label
C215622	Product Organization Role Name		The literal identifier (i.e., distinctive designation) of the product organization role.	Product Organization Role Name

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	
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 Reference Identifier Attribute Terminology (DDF Reference Identifier Attribute Terminology)

NCI Code: C215457, Codelist extensible: No

C215457	DDF Reference Identifier Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215572	Reference Identifier Text		An instance of structured text that represents the reference identifier.	Reference Identifier Text
C215571	Reference Identifier Type		A characterization or classification of the reference identifier.	Reference Identifier Type

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	
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	
C216999	Response Code Label		The short descriptive designation for the response code.	Response Code Label	
C216998	Response Code Name		The literal identifier (i.e., distinctive designation) of the response code.	Response Code Name	
C217013	Response Code Value		The literal value of a response code.	Response Code Value	

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	
C217012	Scheduled Timeline Planned Duration		The period of time over which the scheduled timeline is intended to take place.	Schedule Timeline Planned Duration	

DDF Strength Attribute Terminology (DDF Strength Attribute Terminology)

NCI Code: C215463, Codelist extensible: No

C215463		DDF Strength Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C80489	Denominator		The divisor of a fraction.	Denominator	
C80490	Numerator		The dividend of a fraction.	Numerator	
C215591	Substance Strength Description		A narrative representation of the substance strength.	Substance Strength Description	
C215592	Substance Strength Label		The short descriptive designation for the substance strength.	Substance Strength Label	
C215590	Substance Strength Name		The literal identifier (i.e., distinctive designation) of the substance strength.	Substance Strength 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	
C216996	Study Amendment Description	Amendment Identifier	A narrative representation of the study amendment.	Study Amendment Description	
C216997	Study Amendment Label		The short descriptive designation for the study amendment.	Study Amendment Label	
C216995	Study Amendment Name		The literal identifier (i.e., distinctive designation) of the study amendment.	Study Amendment Name	
C215538	Study Amendment Notes		A brief written record relevant to the study amendment.	Study Amendment Note	
C207537	Study Amendment Number		A string of numerals that uniquely identifies a protocol amendment.	Study Amendment Number	
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 Impact Attribute Terminology (DDF Study Amendment Impact Attribute Terminology)

NCI Code: C215469, Codelist extensible: No

C215469	DDF Study Amendment Impact Attribute Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215613	Study Amendment Impact Notes		A brief written record relevant to the study amendment impact.	Study Amendment Impact Note	
C207538	Study Amendment Impact Substantial Indicator		An indication as to whether the study amendment's impact on the study is substantial.	Study Amendment Substantial Impact Indicator	
C215611	Study Amendment Impact Text		An instance of unstructured text that represents the study amendment impact.	Study Amendment Impact Text	
C215612	Study Amendment Impact Type		A characterization or classification of the study amendment impact.	Study Amendment Impact Type	

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
C215515	Study Arm Notes		A brief written record relevant to the study arm.	Study Arm Note
C172457	Study Arm Type	Arm Type	A characterization or classification of the study arm.	Study Arm Type

DDF Study Change Attribute Terminology (DDF Study Change Attribute Terminology)

NCI Code: C215467, Codelist extensible: No

C215467	DDF Study Change Attribute Terminology				
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215605	Study Change Description		A narrative representation of the study change.	Study Change Description	
C215606	Study Change Label		The short descriptive designation for the study change.	Study Change Label	
C215604	Study Change Name		The literal identifier (i.e., distinctive designation) of the study change.	Study Change Name	
C215608	Study Change Rationale		An explanation as to the logical reasons for why a study change has occurred.	Study Change Rationale	
C215607	Study Change Summary		A short narrative representation describing the changes introduced in the current version of the study.	Study Change Summary	

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
C215547	Study Cohort Notes		A brief written record relevant to the study cohort.	Study Cohort Note
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 Definition Document Attribute Terminology (DDF Study Definition Document Attribute Terminology)

NCI Code: C215454, Codelist extensible: No

C215454		DDF Study Definition Document Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215560	Study Definition Document Description		A narrative representation of the study definition document.	Study Definition Document Description
C215561	Study Definition Document Label		The short descriptive designation for the study definition document.	Study Definition Document Label
C215563	Study Definition Document Language		The language in which the study definition document is written.	Study Definition Document Language
C215559	Study Definition Document Name		The literal identifier (i.e., distinctive designation) of the study definition document.	Study Definition Document Name
C215565	Study Definition Document Notes		A brief written record relevant to the study definition document.	Study Definition Document Note
C215562	Study Definition Document Template Name		The literal identifier (i.e., distinctive designation) of the study definition document template.	Study Definition Document Template Name
C215564	Study Definition Document Type		A characterization or classification of the study definition document.	Study Definition Document Type

DDF Study Definition Document Version Attribute Terminology (DDF Study Definition Document Version Attribute Terminology)

NCI Code: C215455, Codelist extensible: No

C215455		DDF Study Definition Document Version Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215567	Study Definition Document Status		A condition of the study definition document at a point in time with respect to its state of readiness for implementation.	Study Definition Document Status	
C215566	Study Definition Document Version Identifier		A sequence of characters used to identify the version of the study definition document.	Study Definition Document Version Identifier	
C215568	Study Definition Document Version Notes		A brief written record relevant to the study definition document version.	Study Definition Document Version Note	

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
C207547	Study Design Characteristic	Overall Design;Study Design Description;Study Design Overview;Summary of Study Design	The distinguishing qualities or prominent aspect of a study design.	Study Design Characteristic
C147139	Study Design Description		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
C215508	Study Design Notes		A brief written record relevant to the study design.	Study Design Note
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
C142175	Study Type	Study Type;Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	Study Type
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
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 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	
C70834	Study Design Population Description		A narrative representation of the study design population.	Study Population Description	
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	
C215512	Study Design Population Notes		A brief written record relevant to the study design population.	Study Design Population Note	
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
C215517	Study Element Notes		A brief written record relevant to the study element.	Study Element Note

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
C215516	Study Epoch Notes		A brief written record relevant to the study epoch.	Study Epoch Note
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
C215507	Study Identifier Text		An instance of structured text that represents the study identifier.	Study Identifier Text

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
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
C215543	Study Intervention Notes		A brief written record relevant to the study intervention.	Study Intervention Note
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 Role Attribute Terminology (DDF Study Role Attribute Terminology)

NCI Code: C215466, Codelist extensible: No

C215466		DDF Study Role Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215603	Study Role Code		A symbol or combination of symbols which is assigned to the study role.	Study Role Code	
C215601	Study Role Description		A narrative representation of the study role.	Study Role Description	
C215602	Study Role Label		The short descriptive designation for the study role.	Study Role Label	
C215600	Study Role Name		The literal identifier (i.e., distinctive designation) of the study role.	Study Role Name	
C216994	Study Role Notes		A brief written record relevant to the study role.	Study Role Notes	

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	
C170990	Country of Study Site		The country in which the study site is located.	Country of Investigational Site	
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
C207570		Study Version Identifier		A sequence of characters used to identify, name, or characterize the study version.	Study Version Identifier
C215539		Study Version Notes		A brief written record relevant to the study version.	Study Version Note

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	
C215541	Subject Enrollment Description		A narrative representation of the subject enrollment.	Subject Enrollment Description	
C215542	Subject Enrollment Label		The short descriptive designation for the subject enrollment.	Subject Enrollment Label	
C215540	Subject Enrollment Name		The literal identifier (i.e., distinctive designation) of the subject enrollment.	Subject Enrollment Name	
C207573	Subject Enrollment Quantity Value		The value representing the number of individuals enrolled in a study.	Subject Enrollment Quantity Value	

DDF Substance Attribute Terminology (DDF Substance Attribute Terminology)

NCI Code: C215462, Codelist extensible: No

C215462	DDF Substance Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215589	Substance Code		A symbol or combination of symbols which is assigned to the substance.	Substance Code
C215587	Substance Description		A narrative representation of the substance.	Substance Description
C215588	Substance Label		The short descriptive designation for the substance.	Substance Label
C215586	Substance Name		The literal identifier (i.e., distinctive designation) of the substance.	Substance Name

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	
C215536	Syntax Template Notes		A brief written record relevant to the syntax template.	Syntax Template Note	
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
C71476	Approval Date		The date on which the entity receives official approbation, recognition, or acceptance as satisfactory.	Approval Date
C215663	Effective Date		The date on which the entity becomes active, goes into effect, or is slated to begin use.	Effective Date
C215664	Issued Date		The date on which the entity is officially released, made available, or delivered to its intended recipient.	Issued Date

Medical Device Identifier Type Value Set Terminology (Medical Device Identifier Type Value Set Terminology)

NCI Code: C215484, Codelist extensible: Yes

C215484		Medical Device Identifier Type Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C104504	Batch Number	Batch Identifier;Batch Number	A distinctive alpha-numeric identification code assigned by the manufacturer or distributor to a specific quantity of manufactured material or product that is produced in a manner that is expected to render it homogeneous.	Batch Number
C112279	FDA Unique Device Identification	FDA Unique Device Identification	A UDI is a unique numeric or alphanumeric code that includes a device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date. (FDA)	FDA Unique Device Identifier
C70848	Lot Number	Lot Identifier;Lot Number	A distinctive alpha-numeric identification code assigned by the manufacturer or distributor to a specific quantity of manufactured material or product within a batch.	Lot Number
C99285	Model Number	Model Identifier;Model Number	The identifier assigned to a particular design of a device, usually an alphanumeric text string.	Model Number

Medical Device Sourcing Value Set Terminology (Medical Device Sourcing Value Set Terminology)

NCI Code: C215482, Codelist extensible: Yes

C215482		Medical Device Sourcing Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C215659	Centrally Sourced		An indication that the entity is obtained from a central source.	Centrally Sourced Indicator	
C215660	Locally Sourced		An indication that the entity is obtained from a local source.	Locally Sourced Indicator	

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	

Observational Study Design Subtype Value Set Terminology (Observational Study Design Subtype Value Set Terminology)

NCI Code: C215486, Codelist extensible: Yes

C215486		Observational Study Design Subtype Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215657	Clinical Education		A study that assesses the effectiveness of health information on reducing ill health and enhancing good health by influencing beliefs, attitudes, and behavior of individuals and communities.	Clinical Education Study
C215654	Disease Determinants		A study that assesses the variables that influence the occurrence frequency and/or population distribution of a given disease, condition, or injury	Disease Determinants Study
C215658	Disease Etiology		A study that assesses the causative factors associated with a disease, condition, or injury.	Disease Etiology Study
C215653	Disease Incidence		A study that assesses the occurrence of new cases of disease, condition, or injury in a defined population over a specified period of time.	Disease Incidence Study
C215675	Disease Prevalence		A study that assesses the proportion of persons in a population who have a particular disease, condition, or injury at a specified point in time or over a specified period of time. (CDC)	Disease Prevalence Study
C215655	Disease Prognosis		A study that assesses the prediction of the probable course and outcome of a disease, condition, or injury.	Disease Prognosis Study
C215656	Drug Utilization		A study that assesses drug usage patterns for prophylaxis or treatment of health problems, or promoting maintenance of health and well-being.	Drug Utilization Study
C49667	Safety		A study that assesses the medical risks to a subject. Safety is usually assessed by examining a wide range of clinical parameters, including adverse events, vital signs, physical exam, laboratory tests.	Safety Study

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
C18240	Academic Institution		An organization, such as a college or university, established for the purpose of scholastic pursuit, education, granting degrees, and research.	Academia
C93453	Clinical Study Registry		An organization (typically a government agency) that administers the registration of studies. (BRIDG)	Study Registry
C54148	Contract Research Organization		A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [ICH E6 Glossary]	Contract Research Organization
C199144	Government Institute		An organization established, funded, and overseen by a government, which has a specific purpose or intent.	Governmental Agency or Group
C21541	Healthcare Facility		The buildings and organizations where healthcare services are provided.	Healthcare Facility
C37984	Laboratory		An organization with the capability and competency to perform scientific research, experiments, and measurements. (BRIDG)	Laboratory
C215661	Medical Device Company		A company licensed to discover, develop, market, and/or distribute medical devices.	Medical Device Company
C54149	Pharmaceutical Company		A company licensed to discover, develop, market, and/or distribute drugs.	Drug Company
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

Product Designation Value Set Terminology (Product Designation Value Set Terminology)

NCI Code: C207418, Codelist extensible: No

C207418		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	AxIMP	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

Product Organization Role Code Value Set Terminology (Product Organization Role Code Value Set Terminology)

NCI Code: C215485, Codelist extensible: Yes

C215485		Product Organization Role Code Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C25392	Manufacturer	Manufacturer	The organization defined as being responsible for creating the product as stated on the package in which the product is supplied. (BRIDG)	Manufacturer	
C43530	Supplier		An individual or organization whose business is to supply a particular service or commodity.	Supplier	

Reference Identifier Type Value Set Terminology (Reference Identifier Type Value Set Terminology)

NCI Code: C215478, Codelist extensible: Yes

C215478		Reference Identifier Type Value Set Terminology			
NCI Code		CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C142424		Clinical Development Plan	CDP	A document that describes the collection of clinical studies that are to be performed in sequence, or in parallel, with a particular active substance, device, procedure, or treatment strategy, typically with the intention of submitting them as part of an application for a marketing authorization. (CDISC Glossary)	Clinical Development Plan
C215674		Pediatric Investigation Plan	PIP	A development plan aimed at ensuring that the necessary data are obtained to support the authorisation of a medicine for children, through studies in children. (EMA)	Pediatric Investigation Clinical Development Plan

Study Amendment Impact Type Value Set Terminology (Study Amendment Impact Type Value Set Terminology)

NCI Code: C215481, Codelist extensible: Yes

C215481	Study Amendment Impact Type Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C215667	Study Data Reliability		The completeness and accuracy of data as a measure of how well it can be counted on to be consistent and free from errors across time and sources. (IBM)	Study Data Reliability
C215668	Study Data Robustness		The data's ability to remain accurate and relevant despite changes or disruptions to the data environment.	Study Data Robustness
C215666	Study Subject Rights	Participant Rights	A study subject's moral, ethical, and legal entitlements before, during, and after the study.	Study Subject Rights
C215665	Study Subject Safety	Participant Safety	The condition in which a study subject is free from harmful effects which may arise as a result of study participation.	Study Subject Safety

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

NCI Code: C207415, Codelist extensible: Yes

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	
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable	
C17649	OTHER	Other	Different than the one(s) previously specified or mentioned. (NCI)	Other	
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 within 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

Study Definition Document Type Value Set Terminology (Study Definition Document Type Value Set Terminology)

NCI Code: C215477, Codelist extensible: Yes

C215477	Study Definition Document Type Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C70817	Protocol		The formal plan of an experiment or research activity, including the objective, rationale, design, materials and methods for the conduct of the study, intervention description, and method of data analysis.	Study Protocol

Study Definition Document Version Value Set Terminology (Study Definition Document Version Value Set Terminology)

NCI Code: C188723, Codelist extensible: No

C188723		Study Definition Document Version 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 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
C217005	Multicentre		A clinical study conducted according to a single protocol but at more than one study site.	Multicenter Study
C217007	Multiple Countries		Of, or pertaining to, an occurrence in more than one country.	Multiple Countries
C46079	Randomized		A study design in which interventions are assigned to subjects according to randomization principles.	Randomized Controlled Clinical Trial
C217006	Single Country		Of, or pertaining to, an occurrence in one country.	Single Country
C217004	Single-Centre		A clinical study that is conducted at a single study site.	Single-Center Study
C25689	Stratification		Grouping defined by important prognostic factors measured at baseline. (ICH E9)	Stratification
C147145	Stratified Randomisation		A type of block randomization in which participants are stratified into groups based on prognostic variables and then randomized into balanced treatment groups.	Stratified Randomization

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
C68609	Active Comparator	Active Control	A type of control, which has a demonstrated effect, administered as a comparator to subjects in a clinical trial. [From ICH E10]	Active Comparator
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 Role Code Value Set Terminology (Study Role Code Value Set Terminology)

NCI Code: C215480, Codelist extensible: Yes

C215480		Study Role Code Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C78726	Adjudication Committee		An external committee whose purpose is to evaluate study data and decide whether a study endpoint or other criterion has been met. (NCI)	Adjudication Committee
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
C215672	Clinical Trial Physician	Study Doctor	Any physician that is associated with clinical trial.	Clinical Trial Physician
C215669	Co-Sponsor		An individual, company, institution, or organization that is designated by the study sponsor as a vested partner in the study.	Study Co-Sponsor
C215662	Contract Research		Research that is conducted by an individual or organization on behalf of another organization through a contracting mechanism.	Contract Research
C142489	Data Safety Monitoring Board	Data and Safety Monitoring Board;Data and Safety Monitoring Committee DSMB;Data Monitoring and Oversight Committee;DMC;DMOC;DSMC;IDMC;Independent Data Monitoring Committee	A group of independent experts who are appointed to monitor the safety and scientific integrity of a research intervention, protect the confidentiality of participant data, and to make recommendations to the sponsor regarding the stopping of the trial for safety, efficacy, or for futility. (After clinicaltrials.gov; Committee for Medicinal Products for Human Use (CHMP), 2005, EMA; FDA Guidance for Industry: Design and Operation of Clinical Trial Data Monitoring Committees. March 2006)	Data Monitoring Committee
C215671	Dose Escalation Committee		A committee established to assess whether a dose adjustment is appropriate and to determine whether the maximum-tolerated dose had been attained, based on a review of available safety and efficacy data at specified time points.	Dose Escalation Committee
C142578	Independent Data Monitoring Committee		A committee established by the sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy variables and recommend to the sponsor whether to continue, modify, or terminate the trial. [ICH E9] (CDISC Glossary)	Independent Data Monitoring Committee
C25936	Investigator		A person responsible for the conduct of the study, ensuring adherence to the protocol and good clinical practices. (CDISC Glossary)	Investigator
C37984	Laboratory		An organization with the capability and competency to perform scientific research, experiments, and measurements. (BRIDG)	Laboratory
C215670	Local Sponsor		The sponsor's legal representative at a geographical region within which the sponsor has no legal presence. (ICH M11)	Local Legal Sponsor
C25392	Manufacturer	Manufacturer	The organization defined as being responsible for creating the product as stated on the package in which the product is supplied. (BRIDG)	Manufacturer
C51876	Medical Expert		A physician or health care provider selected by the sponsor to be readily available to advise clinical trial officials on trial related medical questions or problems.	Sponsor Medical Expert
C207599	Outcomes Assessor		The individual who evaluates the outcome(s) of interest. (Clinicaltrials.gov)	Outcomes Assessor
C215673	Pharmacovigilance		A group that is responsible for monitoring the safety of medicines and taking action to reduce their risks and increase their benefits.	Pharmacovigilance Group
C19924	Principal investigator		The study investigator who has the primary responsibility for the conduct of a study and for the study-related personnel at the participating site(s).	Principal Investigator
C51851	Project Manager	Project Coordinator	A staff member who is responsible for the overall integration and interaction of different people and different components of subject matter associated with a specific project.	Project Coordinator
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
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
C51877	Statistician		A professional who specializes in applying statistical principles to experimental design and data analysis.	Statistician
C80403	Study Site		The location at which a study investigator conducts study activities.	Study Site
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

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	Trial Acronym	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		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