

CDISC DDF Controlled Terminology, 2023-03-31

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

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
C171445	CNTMODE	Mode of Subject Contact	Terminology relevant to the means by which interaction occurs between the subject and person or entity.	Yes
C188714	DDF Activity Attribute Terminology	DDF Activity Attribute Terminology	A terminology value set relevant to the attributes of the activity.	
C188720	DDF Analysis Population Attribute Terminology	DDF Analysis Population Attribute Terminology	A terminology value set relevant to the attributes of the analysis population.	
C188699	DDF Clinical Study Attribute Terminology	DDF Clinical Study Attribute Terminology	A terminology value set relevant to the attributes of the clinical study.	
C188722	DDF Code Attribute Terminology	DDF Code Attribute Terminology	A terminology value set relevant to the attributes of the code.	
C188713	DDF Encounter Attribute Terminology	DDF Encounter Attribute Terminology	A terminology value set relevant to the attributes of the encounter.	
C188708	DDF Endpoint Attribute Terminology	DDF Endpoint Attribute Terminology	A terminology value set relevant to the attributes of the endpoint.	
C188698	DDF Entity Terminology	DDF Entity Terminology	A terminology value set relevant to the entities within the CDISC digital data flow (DDF) model.	
C188719	DDF Estimand Attribute Terminology	DDF Estimand Attribute Terminology	A terminology value set relevant to the attributes of the estimand.	
C188705	DDF Indication Attribute Terminology	DDF Indication Attribute Terminology	A terminology value set relevant to the attributes of the disease indication.	
C188721	DDF Intercurrent Event Attribute Terminology	DDF Intercurrent Event Attribute Terminology	A terminology value set relevant to the attributes of the intercurrent event.	
C188704	DDF Investigational Interventions Attribute Terminology	DDF Investigational Interventions Attribute Terminology	A terminology value set relevant to the attributes of the investigational interventions.	
C188707	DDF Objective Attribute Terminology	DDF Objective Attribute Terminology	A terminology value set relevant to the attributes of the objective.	
C188702	DDF Organization Attribute Terminology	DDF Organization Attribute Terminology	A terminology value set relevant to the attributes of the organization.	
C188716	DDF Procedure Attribute Terminology	DDF Procedure Attribute Terminology	A terminology value set relevant to the attributes of the procedure.	
C188709	DDF Study Arm Attribute Terminology	DDF Study Arm Attribute Terminology	A terminology value set relevant to the attributes of the study Arm.	
C188715	DDF Study Data Attribute Terminology	DDF Study Data Attribute Terminology	A terminology value set relevant to the attributes of the study data.	
C188703	DDF Study Design Attribute Terminology	DDF Study Design Attribute Terminology	A terminology value set relevant to the attributes of the study design.	
C188706	DDF Study Design Population Attribute Terminology	DDF Study Design Population Attribute Terminology	A terminology value set relevant to the attributes of the study design population.	
C188711	DDF Study Element Attribute Terminology	DDF Study Element Attribute Terminology	A terminology value set relevant to the attributes of the study element.	
C188710	DDF Study Epoch Attribute Terminology	DDF Study Epoch Attribute Terminology	A terminology value set relevant to the attributes of the study epoch.	
C188701	DDF Study Identifier Attribute Terminology	DDF Study Identifier Attribute Terminology	A terminology value set relevant to the attributes of the study identifier.	
C188700	DDF Study Protocol Version Attribute Terminology	DDF Study Protocol Version Attribute Terminology	A terminology value set relevant to the attributes of the study protocol version.	
C188712	DDF Transition Rule Attribute Terminology	DDF Transition Rule Attribute Terminology	A terminology value set relevant to the attributes of the transition rule.	
C188717	DDF Workflow Attribute Terminology	DDF Workflow Attribute Terminology	A terminology value set relevant to the attributes of the workflow.	
C188718	DDF Workflow Item Attribute Terminology	DDF Workflow Item Attribute Terminology	A terminology value set relevant to the attributes of the workflow item.	
C188728	Encounter Type Value Set Terminology	Encounter Type Value Set Terminology	The terminology relevant to the encounter type.	
C188726	Endpoint Level Value Set Terminology	Endpoint Level Value Set Terminology	The terminology relevant to the endpoint level.	
C99079	EPOCH	Epoch	The name of the EPOCH.	Yes
C99076	INTMODEL	Intervention Model Response	A terminology codelist relevant to the trial design developed to compare treatment groups.	Yes
C188725	Objective Level Value Set Terminology	Objective Level Value Set Terminology	The terminology relevant to the objective level.	
C188724	Organization Type Value Set Terminology	Organization Type Value Set Terminology	The terminology relevant to the organization type.	
C188723	Protocol Status Value Set Terminology	Protocol Status Value Set Terminology	The terminology relevant to the protocol status.	
C127262	SETTING	Environmental Setting	Terminology relevant to the surroundings or environment.	Yes
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.	
C99077	STYPE	Study Type Response	A terminology codelist relevant to the role the study plays in determining the interventions a subject receives.	No
C66736	TINDTP	Trial Intent Type Response	A terminology codelist relevant to the responses for the planned purpose of the therapy, device, or agent under study in the clinical trial.	Yes
C66737	TPHASE	Trial Phase Response	A terminology codelist relevant to the phase, or stage, of the clinical trial.	Yes
C66739	TTYPE	Trial Type Response	A terminology codelist relevant to the type of primary outcome or endpoint that the protocol is designed to evaluate.	Yes

CNTMODE (Mode of Subject Contact)

NCI Code: C171445, Codelist extensible: Yes

C171445		CNTMODE		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C175574	IN PERSON	In-Person	An interaction that takes place in the physical presence of someone else.	In Person
C177933	IVRS	Interactive Voice Response System	A type of automated system in which individuals can access information menus containing pre-recorded or dynamically generated information with voice prompts, without the need for an agent or operator.	Interactive Voice Response System
C171525	REMOTE AUDIO VIDEO		A form of remote communication by audio video technology.	Audio-Videoconferencing
C171524	REMOTE AUDIO		A form of remote communication by audio technology.	Audioconferencing
C171533	SHIPMENT CONFIRMED BY SIGNATURE		Receipt of shipped material was confirmed by signature.	Shipment Confirmed by Signature
C171537	TELEPHONE CALL		Communication by way of telephone.	Telephone Call

DDF Activity Attribute Terminology (DDF Activity Attribute Terminology)

NCI Code: C188714, Codelist extensible:

C188714		DDF Activity Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C70960	Clinical Study Activity Description		The textual representation of the study activity.	Clinical Study Activity Description
C188842	Clinical Study Activity Name		The literal identifier (i.e., distinctive designation) of the clinical study activity.	Clinical Study Activity Name
C188844	Next Activity Identifier		A system identifier assigned to a study activity that occurs immediately after the current study activity.	Next Activity Identifier
C188843	Previous Activity Identifier		A system identifier assigned to a study activity that occurs immediately prior to the current study activity.	Previous Activity Identifier

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

NCI Code: C188720, Codelist extensible:

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

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

NCI Code: C188699, Codelist extensible:

C188699		DDF Clinical Study Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49802	Study Title	Official Study Title;Study Title;Trial Title	The sponsor-defined name of the clinical study.	Trial Title
C142175	Study Type Classification	Study Type;Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	Study Type
C188816	Study Version		A plan at a particular point in time for a study.	Study Version
C48281	Trial Phase	Trial Phase;Trial Phase Classification	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]	Trial Phase

DDF Code Attribute Terminology (DDF Code Attribute Terminology)

NCI Code: C188722, Codelist extensible:

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

DDF Encounter Attribute Terminology (DDF Encounter Attribute Terminology)

NCI Code: C188713, Codelist extensible:

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

DDF Endpoint Attribute Terminology (DDF Endpoint Attribute Terminology)

NCI Code: C188708, Codelist extensible:

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

DDF Entity Terminology (DDF Entity Terminology)

NCI Code: C188698, Codelist extensible:

C188698 NCI Code	DDF Entity Terminology CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C142427	Clinical Encounter		Contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed. Contact may be physical or virtual.	Clinical Encounter
C188811	Clinical Study Data		Data collected in the course of a clinical study.	Clinical Study Data
C15206	Clinical Study		A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [ClinicalTrials.gov] See also clinical trial. (CDISC Glossary)	Clinical Study
C25162	Code		A symbol or combination of symbols which is assigned to the members of a collection.	Code
C188813	Estimand		A precise description of the treatment effect reflecting the clinical question posed by a given clinical trial objective. It summarises at a population level what the outcomes would be in the same patients under different treatment conditions being compared. (ICH E9 R1 Addendum)	Estimand
C188815	Intercurrent Event		An event(s) occurring after treatment initiation that affects either the interpretation or the existence of the measurements associated with the clinical question of interest. (ICH E9 Addendum on Estimands)	Intercurrent Event
C25218	Intervention		The drug, device, therapy, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study (e.g., health-related quality of life, efficacy, safety, pharmacoeconomics). [After https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5224]	Intervention or Procedure
C19711	Organization		A formalized group of persons or other organizations collected together for a common purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose. (BRIDG)	Professional Organization or Group
C98769	Procedure	Medical Procedure	Any activity performed by manual and/or instrumental means for the purpose of diagnosis, assessment, therapy, prevention, or palliative care.	Physical Medical Procedure
C71473	Study Activity		An action, undertaking, or event, which is anticipated to be performed or observed, or was performed or observed, according to the study protocol during the execution of the study.	Study Activity
C174447	Study Arm	Arm	A planned pathway assigned to the subject as they progress through the study, usually referred to by a name that reflects one or more treatments, exposures, and/or controls included in the path.	Study Arm
C188810	Study Design Cell		A partitioning of a study arm into individual pieces, which are associated with an epoch and any number of sequential elements within that epoch.	Study Design Cell
C142735	Study Design Element		A basic building block for time within a clinical study comprising the following characteristics: a description of what happens to the subject during the element; a definition of the start of the element; a rule for ending the element.	Trial Design Element
C15320	Study Design		A plan detailing how a study will be performed in order to represent the phenomenon under examination, to answer the research questions that have been asked, and informing the statistical approach.	Study Design
C25212	Study Endpoint		A defined variable intended to reflect an outcome of interest that is statistically analyzed to address a particular research question. NOTE: A precise definition of an endpoint typically specifies the type of assessments made, the timing of those assessments, the assessment tools used, and possibly other details, as applicable, such as how multiple assessments within an individual are to be combined. [After BEST Resource] (CDISC Glossary)	End Point
C71738	Study Epoch		A named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.	Clinical Trial Epoch
C83082	Study Identifier		A sequence of characters used to identify, name, or characterize the study.	Study Identifier
C142450	Study Objective		The reason for performing a study in terms of the scientific questions to be answered by the analysis of data collected during the study.	Clinical Trial Objective
C93490	Study Protocol Version		A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	Study Protocol Version
C188814	Target Study Population for Analysis		A target study population on which an analysis is performed. These may be represented by the entire study population, a subgroup defined by a particular characteristic measured at baseline, or a principal stratum defined by the occurrence (or non-occurrence, depending on context) of a specific intercurrent event. (ICH E9 R1 Addendum)	Target Study Population for Analysis
C142728	Target Study Population	Target Population	The population within the general population for which the study results can be generalized.	Target Study Population
C82567	Transition Rule		A guide that governs the allocation of subjects to operational options at a discrete decision point or branch (e.g., assignment to a particular arm, discontinuation) within a clinical trial plan.	Transition Rule
C112038	Trial Disease/Condition Indication Description	Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	The textual representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication
C188812	Workflow Item Description		The textual representation of the workflow item.	Workflow Item Description
C42753	Workflow		The operational aspect of a work procedure: how tasks are structured, who performs them, what their relative order is, how they are synchronized, how information flows to support the tasks and how tasks are being tracked.	Workflow

DDF Estimand Attribute Terminology (DDF Estimand Attribute Terminology)

NCI Code: C188719, Codelist extensible:

C188719	DDF Estimand Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188853	Population-Level Summary		A synopsis of the clinical endpoint of interest within the analysis target study population.	Population-Level Summary

DDF Indication Attribute Terminology (DDF Indication Attribute Terminology)

NCI Code: C188705, Codelist extensible:

C188705		DDF Indication Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188822	Disease Indication Code		A short sequence of characters that represents the disease indication.	Disease Indication Code
C112038	Trial Disease/Condition Indication Description	Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	The textual representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication

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

NCI Code: C188721, Codelist extensible:

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

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

NCI Code: C188704, Codelist extensible:

C188704		DDF Investigational Interventions Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C177931	Intervention Description		The textual representation of the study intervention.	Intervention Description
C188821	Investigational Intervention Code		A short sequence of characters that represents the investigational intervention.	Investigational Intervention Code

DDF Objective Attribute Terminology (DDF Objective Attribute Terminology)

NCI Code: C188707, Codelist extensible:

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

DDF Organization Attribute Terminology (DDF Organization Attribute Terminology)

NCI Code: C188702, Codelist extensible:

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

DDF Procedure Attribute Terminology (DDF Procedure Attribute Terminology)

NCI Code: C188716, Codelist extensible:

C188716	DDF Procedure Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C154626	Procedure Code		A symbol or combination of symbols which is assigned to medical procedure.	Procedure Code
C188848	Procedure Type		A characterization or classification of the study procedure.	Study Procedure Type

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

NCI Code: C188709, Codelist extensible:

C188709		DDF Study Arm Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188828	Study Arm Data Origin Description		The textual representation of the study arm data origin.	Study Arm Data Origin Description
C188829	Study Arm Data Origin Type		A characterization or classification of the study arm with respect to where the study arm data originates.	Study Arm Data Origin Type
C93728	Study Arm Description	Arm Description	The textual representation of the arm for the study.	Arm Description
C170984	Study Arm Name		The literal identifier (i.e., distinctive designation) of the study arm.	Planned Study Arm Name
C188827	Study Arm Type Name		The literal identifier (i.e., distinctive designation) of the study arm type.	Study Arm Type Name

DDF Study Data Attribute Terminology (DDF Study Data Attribute Terminology)

NCI Code: C188715, Codelist extensible:

C188715		DDF Study Data Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188846	Clinical Study Data Description		The textual representation of the study data.	Clinical Study Data Description
C188845	Clinical Study Data Name		The literal identifier (i.e., distinctive designation) for the study data.	Clinical Study Data Name
C188847	Electronic Case Report Form Link		The uniform resource locator used to access the digital case report form.	Electronic Case Report Form Uniform Resource Locator

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

NCI Code: C188703, Codelist extensible:

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

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

NCI Code: C188706, Codelist extensible:

C188706		DDF Study Design Population Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C70834	Target Study Population Description		The textual representation of the study population.	Study Population Description

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

NCI Code: C188711, Codelist extensible:

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

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

NCI Code: C188710, Codelist extensible:

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

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

NCI Code: C188701, Codelist extensible:

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

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

NCI Code: C188700, Codelist extensible:

C188700		DDF Study Protocol Version Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C132345	Brief Protocol Title	Abbreviated Protocol Title	The short descriptive name for the protocol.	Brief Protocol Title
C132346	Official Protocol Title		The formal descriptive name for the protocol.	Official Protocol Title
C188818	Protocol Status		A condition of the protocol at a point in time with respect to its state of readiness for implementation.	Study Protocol Status
C94105	Public Protocol Title		The descriptive name of the protocol that is intended for the lay public, written in easily understood language.	Study Protocol Document Version Public Title
C132350	Scientific Protocol Title		A more extensive descriptive name of the protocol that is intended for medical professionals, written using medical and scientific language.	Scientific Protocol Title
C188817	Study Protocol Amendment Effective Date		The date and time specifying when the protocol amendment takes effect or becomes operative.	Study Protocol Amendment Effective Date
C132347	Study Protocol Amendment		A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)	Protocol Amendment
C93490	Study Protocol Version		A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	Study Protocol Version

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

NCI Code: C188712, Codelist extensible:

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

DDF Workflow Attribute Terminology (DDF Workflow Attribute Terminology)

NCI Code: C188717, Codelist extensible:

C188717	DDF Workflow Attribute Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188849	Workflow Description		The textual representation of the workflow.	Workflow Description

DDF Workflow Item Attribute Terminology (DDF Workflow Item Attribute Terminology)

NCI Code: C188718, Codelist extensible:

C188718		DDF Workflow Item Attribute Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C188852	Next Workflow Item Identifier		A system identifier assigned to a workflow item that occurs immediately after the current workflow item.	Next Workflow Item Identifier
C188851	Previous Workflow Item Identifier		A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item.	Previous Workflow Item Identifier
C188812	Workflow Item Description		The textual representation of the workflow item.	Workflow Item Description

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

NCI Code: C188728, Codelist extensible:

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

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

NCI Code: C188726, Codelist extensible:

C188726		Endpoint Level Value Set Terminology		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C170559	Exploratory Endpoint		Endpoint(s) that may include clinically important events that are expected to occur too infrequently to show a treatment effect or endpoints that for other reasons are thought to be less likely to show an effect but are included to explore new hypotheses. (After FDA-NIH Protocol Template)	Exploratory Endpoint
C94496	Primary Endpoint		Endpoint(s) of greatest importance that is the basis for concluding whether the study met its objective(s) and provides a clinically relevant, valid, and reliable measure of the primary objective(s). (After FDA-NIH Protocol Template)	Primary Endpoint
C139173	Secondary Endpoint		Endpoint(s) that may provide supportive information about the effect of the study intervention(s) on the primary endpoint or demonstrate additional effects on the disease or condition. (After FDA-NIH Protocol Template)	Secondary Endpoint

EPOCH (Epoch)

NCI Code: C99079, Codelist extensible: Yes

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

INTMODEL (Intervention Model Response)

NCI Code: C99076, Codelist extensible: Yes

C99076 NCI Code	INTMODEL CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C82637	CROSS-OVER		Participants receive one of two or more alternative intervention(s) during the initial epoch of the study and receive other intervention(s) during the subsequent epoch(s) of the study.	Crossover Study
C82638	FACTORIAL		Two or more interventions, each alone or in combination, are evaluated in parallel against a control group. This study design allows for the comparison of active drug to placebo, presence of drug-drug interactions, and comparison of active drugs against each other.	Factorial Study
C82639	PARALLEL		Participants are assigned to one of two or more treatment groups in parallel for the duration of the study.	Parallel Study
C142568	SEQUENTIAL		Groups of participants are assigned to receive interventions based on prior milestones being reached in the study. (clinicaltrials.gov)	Group Sequential Design
C82640	SINGLE GROUP		All trial participants are assigned to a single treatment group for the duration of the study.	Single Group Study

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

NCI Code: C188725, Codelist extensible:

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

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

NCI Code: C188724, Codelist extensible:

C188724		Organization Type Value Set Terminology			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term	
C93453	Clinical Study Registry		An organization (typically a government agency) that administers the registration of studies. (BRIDG)	Study Registry	
C70793	Clinical Study Sponsor	Clinical Study Sponsor; Sponsor; Study Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study. [After ICH E6, WHO, 21 CFR 50.3 (e), and after IDMP]	Clinical Study Sponsor	
C188863	Regulatory Agency	Regulator; Regulatory Body	An organization (typically a government agency) that is responsible for implementing and enforcing laws, licensing and regulating products and services, promoting the use of standards, and ensuring safety and consumer protections.	Regulatory Agency	

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

NCI Code: C188723, Codelist extensible:

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

SETTING (Environmental Setting)

NCI Code: C127262, Codelist extensible: Yes

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

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

NCI Code: C188727, Codelist extensible:

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

STYPE (Study Type Response)

NCI Code: C99077, Codelist extensible: No

C99077 NCI Code	STYPE CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C98722	EXPANDED ACCESS	Compassionate Use	Studies that provide a means for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in another clinical study.	Expanded Access Study
C98388	INTERVENTIONAL		Studies in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.	Interventional Study
C16084	OBSERVATIONAL		Studies in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.	Observational Study
C129000	PATIENT REGISTRY		Observational studies which include an organized system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, health care services, and/or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single purpose or on-going data collection programs that address one or more questions. (AHRQ)	Patient Registry Study

TINDTP (Trial Intent Type Response)

NCI Code: C66736, Codelist extensible: Yes

C66736 NCI Code	TINDTP CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C15714	BASIC SCIENCE	Basic Research	A type of study designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. (ClinicalTrials.gov)	Basic Research
C49654	CURE		A type of study designed to evaluate intervention(s) aimed to cure a disease or condition.	Cure Study
C139174	DEVICE FEASIBILITY		An intervention of a device product is being evaluated to determine the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. (ClinicalTrials.gov)	Device Feasibility Study
C49653	DIAGNOSIS		A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.	Diagnosis Study
C170629	DISEASE MODIFYING		A type of study designed to evaluate the effects of treatment(s) intended to cause a change in disease, syndrome, or condition beyond the point of treatment administration.	Disease Modifying Treatment Study
C15245	HEALTH SERVICES RESEARCH		A type of study designed to evaluate the delivery, processes, management, organization or financing of health care. (ClinicalTrials.gov)	Health Services Research
C49655	MITIGATION		A type of study designed to identify actions necessary to eliminate or reduce the risk to human life or well-being as a result of a particular medication or treatment regimen. (NCI)	Adverse Effect Mitigation Study
C49657	PREVENTION	Prophylaxis Study	A type of study designed to identify actions necessary to permanently eliminate or reduce the long-term risk to human life as a result of a particular medication or treatment regimen.	Prevention Study
C71485	SCREENING		A type of study designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). (ClinicalTrials.gov)	Screening Study
C71486	SUPPORTIVE CARE		A type of study designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. (ClinicalTrials.gov)	Supportive Care Study
C49656	TREATMENT	Therapy Trial	A type of study designed to evaluate intervention(s) for treatment of disease, syndrome or condition.	Treatment Study

TPHASE (Trial Phase Response)

NCI Code: C66737, Codelist extensible: Yes

C66737 NCI Code	TPHASE CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C54721	PHASE 0 TRIAL	0;Pre-clinical Trial;Trial Phase 0	First-in-human trials, in a small number of subjects, that are conducted before Phase 1 trials and are intended to assess new candidate therapeutic and imaging agents. The study agent is administered at a low dose for a limited time, and there is no therapeutic or diagnostic intent. NOTE: FDA Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies, January 2006 classifies such studies as Phase 1. NOTE: A Phase 0 study might not include any drug delivery but may be an exploration of human material from a study (e.g., tissue samples or biomarker determinations). [Improving the Quality of Cancer Clinical Trials: Workshop summary- Proceedings of the National Cancer Policy Forum Workshop, improving the Quality of Cancer Clinical Trials (Washington, DC, Oct 2007)] (CDISC glossary)	Phase 0 Trial
C15600	PHASE I TRIAL	1;Trial Phase 1	The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. NOTE: These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80. Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. [After FDA CDER Handbook, ICH E8] (CDISC glossary)	Phase I Trial
C15693	PHASE I/II TRIAL	1-2;Trial Phase 1-2	A class of clinical study that combines elements characteristic of traditional Phase I and Phase II trials. See also Phase I, Phase II.	Phase I/II Trial
C198366	PHASE I/II/III TRIAL	1/2/3;Trial Phase 1/2/3	A study that begins as a Phase I study and transitions into Phases II and III based upon successful completion of each previous portion.	Phase I/II/III Trial
C198367	PHASE I/III TRIAL	1/3;Trial Phase 1/3	A study that begins as a Phase I study and transitions into a Phase III study upon successful completion of the Phase I portion.	Phase I/III Trial
C15601	PHASE II TRIAL	2;Trial Phase 2	Phase that includes the controlled clinical trials conducted to evaluate the safety and efficacy of the drug in a limited number of patients with the disease or condition under study. Objectives can be dose-ranging (dose-response, frequency of dosing), type of patients, or numerous other characteristics of safety and efficacy. [After 21 CFR Part 312.21 Phases of an investigation] See also phase, phase 2a, phase 2b. (CDISC Glossary)	Phase II Trial
C15694	PHASE II/III TRIAL	2-3;Trial Phase 2-3	A class of clinical study that combines elements characteristic of traditional Phase II and Phase III trials.	Phase II/III Trial
C49686	PHASE IIA TRIAL	2A;Trial Phase 2A	A clinical research protocol generally referred to as a pilot or feasibility trial that aims to prove the concept of the new intervention in question. (NCI)	Phase IIa Trial
C49688	PHASE IIB TRIAL	2B;Trial Phase 2B	A clinical research protocol generally referred to as a well-controlled and pivotal trial that aims to prove the mechanism of action of the new intervention in question. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind. (NCI)	Phase IIb Trial
C15602	PHASE III TRIAL	3;Trial Phase 3	Phase that includes the controlled clinical trials intended to confirm safety and effectiveness, evaluate the overall benefit-risk relationship, and to provide substantial evidence for regulatory approval and labeling. NOTE: Phase 3 studies usually include from several hundred to several thousand subjects. [After ICH E8; Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products Draft Guidance for Industry. December 2019] See also phase, phase 3b. (CDISC Glossary)	Phase III Trial
C49687	PHASE IIIA TRIAL	3A;Trial Phase 3A	A classification typically assigned retrospectively to a Phase III trial upon determination by regulatory authorities of a need for a Phase III B trial. (NCI)	Phase IIIa Trial
C49689	PHASE IIIB TRIAL	3B;Trial Phase 3B	A subcategory of Phase III trials done near the time of approval to elicit additional findings. NOTE: Dossier review may continue while associated Phase IIIB trials are conducted. These trials may be required as a condition of regulatory authority approval.	Phase IIIb Trial
C15603	PHASE IV TRIAL	4;Trial Phase 4	Post-approval studies to delineate additional information about the drug's risks, benefits, and optimal use that may be requested by regulatory authorities in conjunction with marketing approval. NOTE: Phase 4 studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time. [after FDA CDER handbook, ICH E8] See also phase. (CDISC Glossary)	Phase IV Trial
C47865	PHASE V TRIAL	5;Trial Phase 5	Postmarketing surveillance is sometimes referred to as Phase V.	Phase V Trial

TTYTYPE (Trial Type Response)

NCI Code: C66739, Codelist extensible: Yes

C66739		TTYTYPE		
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C158283	ADHESION PERFORMANCE		A type of study designed to evaluate the strength of the bond between an adhesive and the application surface.	Adhesion Performance Study
C158284	ALCOHOL EFFECT		A type of study designed to evaluate the effects of alcohol on investigational product safety and/or efficacy.	Alcohol Effect Study
C49664	BIO-AVAILABILITY		A study of the degree to which or rate at which a drug or other substance is absorbed or becomes available at the site of physiological activity after administration. (NCI)	Bioavailability Study
C49665	BIO-EQUIVALENCE		A study most often used to compare the efficacy of different formulations to treat a given disease. It is the testing of an old versus a new formulation in healthy volunteers or subjects with the disease under study and usually in one dose. (NCI)	Therapeutic Equivalency Study
C158288	BIOSIMILARITY		A type of study designed to evaluate whether a biologic test article is highly similar in function and effect to an existing biologic that has already been clinically tested and approved for use.	Biosimilarity Study
C158285	DEVICE-DRUG INTERACTION		A type of study designed to evaluate the interaction between a device and a drug, where the use of one may affect the disposition, function, efficacy, or safety of the other.	Device-Drug Interaction Study
C49653	DIAGNOSIS		A type of study designed to evaluate intervention(s) aimed at identifying a disease or condition.	Diagnosis Study
C158289	DOSE FINDING		An early phase clinical study with the objective of determining the optimal dose of an investigational product.	Dose Finding Study
C158290	DOSE PROPORTIONALITY		A type of study designed to evaluate the relationship between dose and resulting exposure.	Dose Proportionality Study
C127803	DOSE RESPONSE		A study of the effect of dose changes on the efficacy of a drug in order to determine the dose-response relationship and optimal dose of a therapy.	Dose Response Study
C158286	DRUG-DRUG INTERACTION		A type of study designed to evaluate the interaction between drugs, where the use of one may affect the disposition, efficacy, or safety of the other.	Drug-Drug Interaction Study
C178057	ECG	Electrocardiographic Study	A study that evaluates the effect of a treatment on cardiac electrical activity, as assessed by electrocardiography.	Electrocardiographic Study
C49666	EFFICACY		A study of the relative therapeutic efficacy of treatment of a disease. Usually this is a Phase II or III study. (NCI)	Efficacy Study
C98729	FOOD EFFECT		Studies that are conducted to assess the effect of food on the rate and extent of absorption of a drug, either compared to a fasted state or to a reference drug.	Food Effect Study
C120842	IMMUNOGENICITY		A study that assesses an agent's ability to provoke an immune response.	Immunogenicity Study
C49662	PHARMACODYNAMIC		A study of the biochemical and physiological effect of a drug and the mechanism of drug action and the relationship between drug concentration and effect. (NCI)	Pharmacodynamic Study
C39493	PHARMACOECONOMIC		A study that assesses the value associated with a given drug in therapeutic and economic terms. This type of study is multidisciplinary in nature and takes into consideration the social and economic costs (resource utilization costs including direct, indirect, and intangible costs) of drug therapy in addition to its direct therapeutic benefits. Analyses relate the difference in therapeutic benefits to the difference in costs between treatment alternatives. (NCI)	Pharmacoeconomic Study
C129001	PHARMACOGENETIC		A study that assesses variation in DNA sequence, usually within a single gene, and its effect on drug response.	Pharmacogenetic Study
C49661	PHARMACOGENOMIC		A study that identifies or assesses variations within the entire genome, including DNA, RNA, or transcriptional elements, and its effects on drug response.	Pharmacogenomic Study
C49663	PHARMACOKINETIC		A study of the process by which a drug is absorbed, distributed, metabolized, and eliminated by the body. (NCI)	Pharmacokinetic Study
C161477	POSITION EFFECT		A type of study designed to evaluate the effect of body position during and/or after administration of the investigational product.	Position Effect Trial
C49657	PREVENTION	Prophylaxis Study	A type of study designed to identify actions necessary to permanently eliminate or reduce the long-term risk to human life as a result of a particular medication or treatment regimen.	Prevention Study
C174366	REACTOGENICITY		A type of study designed to evaluate the expected, acute types of immunological responses, sometimes considered excessive, following agent administration.	Reactogenicity Study
C49667	SAFETY		A study that assesses the medical risks to a subject. Safety is usually assessed by examining a wide range of clinical parameters, including adverse events, vital signs, physical exam, laboratory tests.	Safety Study
C161478	SWALLOWING FUNCTION		A type of study designed to evaluate the effect of the investigational product on the physiologic act of swallowing.	Swallowing Function Trial
C158287	THOROUGH QT	TQT Study	A type of study designed to evaluate the ability of an investigational product and/or approved drug to delay cardiac ventricular repolarization as detected by QT prolongation and other ECG parameters.	Thorough QT Study
C98791	TOLERABILITY		A type of safety study that assesses the degree to which overt adverse effects can be tolerated by the subject.	Tolerability Study
C49656	TREATMENT	Therapy Trial	A type of study designed to evaluate intervention(s) for treatment of disease, syndrome or condition.	Treatment Study
C161479	USABILITY TESTING		A type of study designed to evaluate the user experience with a product.	Usability Testing Study
C161480	WATER EFFECT		A type of study designed to evaluate the effects of water on investigational product safety and/or efficacy.	Water Effect Trial