# CDISC DDF Controlled Terminology, 2023-06-30

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

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

## DDF Encounter Attribute Terminology (DDF Encounter Attribute Terminology)

NCI Code: C188713, Codelist extensible:

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

## DDF Endpoint Attribute Terminology (DDF Endpoint Attribute Terminology)

NCI Code: C188708, Codelist extensible:

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

## DDF Entity Terminology (DDF Entity Terminology)

NCI Code: C188698, Codelist extensible:

| C188698 | DDF Entity Terminology | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| 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 | EPOCH | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C125938 | BASELINE | | A period in a clinical study after eligibility has been met and before the start of treatment, at which baseline measurements are collected. | Baseline Epoch |
| C102255 | BLINDED TREATMENT | | A period in a clinical study during which subjects receive blinded therapeutic treatment. | Blinded Treatment Epoch |
| C123452 | CONTINUATION TREATMENT | Continuation Phase | A period in a clinical study during which subjects receive continuation treatment. | Continuation Therapy Epoch |
| C99158 | FOLLOW-UP | | A period in a clinical study during which information about the health status of an individual is obtained after study interventions have concluded. | Clinical Study Follow-up |
| C123453 | INDUCTION TREATMENT | Induction Phase;Intensive Phase | A period in a clinical study during which subjects receive induction treatment. | Induction Therapy Epoch |
| C16032 | LONG-TERM FOLLOW-UP | | A period in a clinical study during which information about the health status of an individual is obtained long after study interventions have concluded. | Long-term Follow-up |
| C165873 | OBSERVATION | | A period in a clinical study during which subjects are observed, without any planned intervention. | Observation Study Epoch |
| C102256 | OPEN LABEL TREATMENT | | A period in a clinical study during which subjects receive open label therapeutic treatment. | Open Label Treatment Epoch |
| C199844 | PRE-SCREENING | | A period in a clinical study during which subjects are evaluated prior to entering the full screening period. | Pre-Screening Epoch |
| C98779 | RUN-IN | | A period in a clinical study that occurs after screening and before randomization, during which the subject is further evaluated and/or prepared for the commencement of the clinical study investigation. | Run-in Period |
| C48262 | SCREENING | | A period in a clinical study during which subjects are evaluated for participation in the study. | Trial Screening |
| C101526 | TREATMENT | | A period in a study during which subjects are receiving investigational therapy or treatment. | Treatment Epoch |
| C42872 | WASHOUT | | A period of time during a study when a subject is taken off of the investigational therapy or treatment in order to reduce the amount of investigational product within the body. | Washout Period |

## INTMODEL (Intervention Model Response)

NCI Code: C99076, Codelist extensible: Yes

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

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

NCI Code: C188725, Codelist extensible:

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

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

NCI Code: C188724, Codelist extensible:

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

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

NCI Code: C188723, Codelist extensible:

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

## SETTING (Environmental Setting)

NCI Code: C127262, Codelist extensible: Yes

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

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

## TINDTP (Trial Intent Type Response)

NCI Code: C66736, Codelist extensible: Yes

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

## TPHASE (Trial Phase Response)

NCI Code: C66737, Codelist extensible: Yes

| C66737 | TPHASE | | | |
|---|---|---|---|---|
| **NCI Code** | **CDISC Submission Value** | **CDISC Synonym** | **CDISC Definition** | **NCI Preferred Term** |
| C48660 | NOT APPLICABLE | NA;Not Applicable | Determination of a value is not relevant in the current context. (NCI) | Not Applicable |
| C54721 | PHASE 0 TRIAL | 0;Pre-clinical Trial;Trial Phase 0 | First-in-human trials, in a small number of subjects, that are conducted before Phase 1 trials and are intended to assess new candidate therapeutic and imaging agents. The study agent is administered at a low dose for a limited time, and there is no therapeutic or diagnostic intent. NOTE: FDA Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies, January 2006 classifies such studies as Phase 1. NOTE: A Phase 0 study might not include any drug delivery but may be an exploration of human material from a study (e.g., tissue samples or biomarker determinations). [Improving the Quality of Cancer Clinical Trials: Workshop summary-Proceedings of the National Cancer Policy Forum Workshop, improving the Quality of Cancer Clinical Trials (Washington, DC, Oct 2007)] (CDISC glossary) | Phase 0 Trial |
| C15600 | PHASE I TRIAL | 1;Trial Phase 1 | The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. NOTE: These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase I studies varies with the drug, but is generally in the range of 20 to 80. Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. [After FDA CDER Handbook, ICH E8] (CDISC glossary) | Phase I Trial |
| C15693 | PHASE I/II TRIAL | 1-2;Trial Phase 1-2 | A class of clinical study that combines elements characteristic of traditional Phase I and Phase II trials. See also Phase I, Phase II. | Phase I/II Trial |
| C198366 | PHASE I/II/III TRIAL | 1/2/3;Trial Phase 1/2/3 | A study that begins as a Phase I study and transitions into Phases II and III based upon successful completion of each previous portion. | Phase I/II/III Trial |
| C198367 | PHASE I/III TRIAL | 1/3;Trial Phase 1/3 | A study that begins as a Phase I study and transitions into a Phase III study upon successful completion of the Phase I portion. | Phase I/III Trial |
| C199990 | PHASE IA TRIAL | 1A;Trial Phase 1A | A type of phase 1 trial with a single ascending dose (dose escalation) in a smaller group of patients (in comparison to a Phase 1B). | Phase Ia Trial |
| C199989 | PHASE IB TRIAL | 1B;Trial Phase 1B | A type of phase 1 trial with multiple ascending doses (dose expansion) in a larger group of patients (in comparison to a Phase 1A). | Phase Ib Trial |
| C15601 | PHASE II TRIAL | 2;Trial Phase 2 | Phase that includes the controlled clinical trials conducted to evaluate the safety and efficacy of the drug in a limited number of patients with the disease or condition under study. Objectives can be dose-ranging (dose-response, frequency of dosing), type of patients, or numerous other characteristics of safety and efficacy. [After 21 CRF Part 312.21 Phases of an investigation] See also phase, phase 2a, phase 2b. (CDISC Glossary) | Phase II Trial |
| C15694 | PHASE II/III TRIAL | 2-3;Trial Phase 2-3 | A class of clinical study that combines elements characteristic of traditional Phase II and Phase III trials. | Phase II/III Trial |
| C49686 | PHASE IIA TRIAL | 2A;Trial Phase 2A | A clinical research protocol generally referred to as a pilot or feasibility trial that aims to prove the concept of the new intervention in question. (NCI) | Phase IIa Trial |
| C49688 | PHASE IIB TRIAL | 2B;Trial Phase 2B | A clinical research protocol generally referred to as a well-controlled and pivotal trial that aims to prove the mechanism of action of the new intervention in question. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind. (NCI) | Phase IIb Trial |
| C15602 | PHASE III TRIAL | 3;Trial Phase 3 | Phase that includes the controlled clinical trials intended to confirm safety and effectiveness, evaluate the overall benefit-risk relationship, and to provide substantial evidence for regulatory approval and labeling. NOTE: Phase 3 studies usually include from several hundred to several thousand subjects. [After ICH E8; Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products Draft Guidance for Industry. December 2019] See also phase, phase 3b. (CDISC Glossary) | Phase III Trial |
| C49687 | PHASE IIIA TRIAL | 3A;Trial Phase 3A | A classification typically assigned retrospectively to a Phase III trial upon determination by regulatory authorities of a need for a Phase III B trial. (NCI) | Phase IIIa Trial |
| C49689 | PHASE IIIB TRIAL | 3B;Trial Phase 3B | A subcategory of Phase III trials done near the time of approval to elicit additional findings. NOTE: Dossier review may continue while associated Phase IIIB trials are conducted. These trials may be required as a condition of regulatory authority approval. | Phase IIIb Trial |
| C15603 | PHASE IV TRIAL | 4;Trial Phase 4 | Post-approval studies to delineate additional information about the drug's risks, benefits, and optimal use that may be requested by regulatory authorities in conjunction with marketing approval. NOTE: Phase 4 studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time. [after FDA CDER handbook, ICH E8] See also phase. (CDISC Glossary) | Phase IV Trial |
| C47865 | PHASE V TRIAL | 5;Trial Phase 5 | Postmarketing surveillance is sometimes referred to as Phase V. | Phase V Trial |

## TTYPE (Trial Type Response)

NCI Code: C66739, Codelist extensible: Yes

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