

CDISC Protocol Controlled Terminology, 2017-06-30

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 |
|-----------------|--|--|--|----------------------------|
| C132308 | Physical Address Attribute Terminology | Physical Address Attribute Terminology | A terminology value set relevant to the attributes of the physical address entity. | NA |
| C132310 | Protocol Entity Terminology | Protocol Entity Terminology | A terminology value set relevant to the entities within a protocol. | NA |
| C132309 | Study Protocol Attribute Terminology | Study Protocol Attribute Terminology | A terminology value set relevant to the attributes of the study protocol entity. | NA |

Physical Address Attribute Terminology (Physical Address Attribute Terminology)

NCI Code: C132308, Codelist extensible: NA

| C132308 Physical Address Attribute Terminology | | | | |
|---|-------------------------------|----------------------|--|---------------------------|
| NCI Code | CDISC Submission Value | CDISC Synonym | CDISC Definition | NCI Preferred Term |
| C25160 | City | | A relatively large and/or densely populated area of human habitation with administrative or legal status that may be specified as a component of a postal address. | City |
| C25464 | Country | | A sovereign nation occupying a distinct territory and ruled by an autonomous government. | Country |
| C87189 | Geographic Locality | | A distinct geographic area in the immediate vicinity of a particular place, such as a city, neighborhood or district. | Locality |
| C16632 | Geographic Region | | Any demarcated area of the Earth; may be determined by both natural and human boundaries, such as a state or province. | Geographic Area |
| C25621 | Postal Code | | An alphanumeric code assigned to a mail delivery area. | Postal Code |
| C25632 | Province | | A sub-division of a country created by the central government for administrative purposes. Provinces are usually, but not always, less autonomous than states, and must obey the laws of the central government. | Province |
| C87194 | State | | A sub-division of a country that forms part of a federal union. States are usually, but not always, more autonomous than provinces and may have different laws from the central government. | State |
| C25690 | Street Address | | The street name and building number where an entity is located. | Street Address |

Protocol Entity Terminology (Protocol Entity Terminology)

NCI Code: C132310, Codelist extensible: NA

| C132310 Protocol Entity Terminology | | | | |
|--|-------------------------------|----------------------|---|---------------------------|
| NCI Code | CDISC Submission Value | CDISC Synonym | CDISC Definition | NCI Preferred Term |
| C25407 | Physical Address | | A standardized representation of the location of a person, business, building, or organization. (NCI) | Address |
| C70817 | Study Protocol | | The formal plan of an experiment or research activity, including the objective, rationale, design, materials and methods for the conduct of the study, intervention description, and method of data analysis. | Study Protocol |

Study Protocol Attribute Terminology (Study Protocol Attribute Terminology)

NCI Code: C132309, Codelist extensible: NA

| C132309 Study Protocol Attribute Terminology | | | | |
|---|--------------------------------------|---|---|--|
| NCI Code | CDISC Submission Value | CDISC Synonym | CDISC Definition | NCI Preferred Term |
| C132344 | Alternate Protocol Identifier | | A unique code assigned by an affiliated governing body or other organization that identifies a specific protocol (e.g., grant number, national number). | Alternate Protocol Identifier |
| 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 |
| C132347 | Protocol Amendment | | A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6) | Protocol Amendment |
| C51853 | Protocol Author | | A person who is the writer of a structured research study protocol. | Protocol Author |
| C115628 | Protocol Synopsis | Protocol Scientific Summary | A scientific summary of the key points of the protocol. | Clinical Trial Protocol Synopsis |
| 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 |
| C132348 | Registry Protocol Identifier | | A unique code assigned by a clinical trial registry that identifies a specific protocol. | Registry Protocol Identifier |
| C132349 | Schedule of Activities | Schedule of Events;SoA | A standardized representation of planned clinical trial activities including interventions (e.g., administering drug, surgery) and study administrative activities (e.g., obtaining informed consent, distributing clinical trial material and diaries, randomization) as well as assessments. (CDISC Glossary) | Schedule of Activities |
| 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 |
| C132351 | Sponsor Protocol Identifier | Sponsor Protocol Code;Sponsor Protocol Number | A unique code assigned by the sponsor that identifies a specific protocol. | Sponsor Protocol Identifier |
| C94108 | Study Acronym | Trial Acronym | A word or words formed from the beginning letters or a combination of syllables and letters of a compound term, which identifies a clinical study. | Study Protocol Version Acronym |
| 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 |
| C132352 | Study Protocol Version Approval Date | | The date on which a version of the protocol was finalized or approved by the sponsor. | Protocol Approval Date |