## **CDISC Protocol Controlled Terminology, 2017-03-31**

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
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. ( ${\sf NCI}$ )	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).	
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. $% \label{eq:control}%$	Protocol Author
C115628	Protocol Synopsis	Protocol Scientific Summa ry	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