CDISC Define-XML Controlled Terminology, 2024-09-27

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
C117745	ANLPURP	Analysis Purpose	Purpose of a specific analysis result described in Define-XML analysis results metadata.	Yes
C117744	ANLREAS	Analysis Reason	Reason for reporting a specific analysis result described in Define-XML analysis results metadata.	Yes
C165635	BDSSC	ADaM Basic Data Structure Subclass	Terminology relevant to the subclasses of the ADaM basic data structure.	No
C172331	CTSTDTYP	CDISC Controlled Terminology Standard Type	Terminology relevant to the classification of the CDISC controlled terminology standard described in the Define-XML document.	No
C66788	DICTNAM	Dictionary Name	Terminology relevant to the names given to a reference source that lists words and gives their meaning.	Yes
C103329	GNRLOBSC	General Observation Class	Terminology related to the classification of a CDISC domain.	No
C177903	MDBDSSC	ADaM Medical Device Basic Data Structure Subclass	Terminology relevant to the subclasses of the ADaM device level basic data structure.	No
C176227	OCCSC	ADaM Occurrence Data Structure Subclass	Terminology relevant to the subclasses of the ADaM occurrence data structure.	No
C170448	ODMCNTX	ODM Context	Terminology relevant to the context in which the Define-XML document is used.	No
C170450	ORIGINS	Origin Source	Terminology relevant to the origin source for datasets in the Define-XML document.	No
C170449	ORIGINT	Origin Type	Terminology relevant to the origin type for datasets in the Define-XML document.	No
C160924	SDTMIGRS	SDTMIG Version Response	A terminology codelist relevant to the version of the CDISC Study Data Tabulation Model implementation guide that is being used in the study submission.	Yes
C170452	STDNAM	Standard Name	Terminology relevant to the name of the standard described in the Define-XML document.	No
C172332	STDSTAT	Standard Status	Terminology relevant to the development or publication status of the standard.	Yes
C170451	STDTYP	Standard Type	Terminology relevant to the classification of the standard described in the Define-XML document.	No

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ANLPURP (Analysis Purpose)

NCI Code: C117745, Codelist extensible: Yes

	C117745	ANLPURP			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C98724		EXPLORATORY OUTCOME MEASURE	Exploratory Outcome Measure	The outcome measure(s) that is part of a pre-specified analysis plan used to evaluate the exploratory endpoint(s) associated with exploratory study objective(s) and/or any other measures, excluding post-hoc measures, that are a focus of the study. (After clinicaltrials.gov)	Exploratory Outcome Measure
C98772		PRIMARY OUTCOME MEASURE	Primary Outcome Measure	The outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation, to evaluate the primary endpoint(s) associated with the primary study objective(s). (After Clinicaltrials.gov)	Primary Outcome Measure
C98781		SECONDARY OUTCOME MEASURE	Secondary Outcome Measure	The outcome measure(s) that is part of a pre-specified analysis plan used to evaluate the secondary endpoint(s) associated with secondary study objective(s) and/or used to evaluate any measure(s) ancillary to the primary or secondary endpoint(s). (After Clinicaltrials.gov).	Secondary Outcome Measure

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ANLREAS (Analysis Reason)

NCI Code: C117744, Codelist extensible: Yes

C117744	ANLREAS			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C117750	DATA DRIVEN		The analysis was triggered by findings in the data.	Data Driven Analysis
C117751	REQUESTED BY REGULATORY AGENCY		The analysis has been requested by a regulatory agency.	Analysis Requested by Regulatory Agency
C117752	SPECIFIED IN PROTOCOL		The analysis is specified in a protocol.	Analysis Specified in Protocol
C117753	SPECIFIED IN SAP		The analysis is specified in a statistical analysis plan.	Analysis Specified in Statistical Analysis Plan

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BDSSC (ADaM Basic Data Structure Subclass)

NCI Code: C165635, Codelist extensible: No

C165635	BDSSC			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C172452	NON-COMPARTMENTAL ANALYSIS	NCA	A dataset containing data that is used for non-compartmental analyses.	Non-Compartmental Analysis Dataset
C189348	POPULATION PHARMACOKINETIC ANALYSIS	РРК	A dataset containing data that is used for population pharmacokinetic analyses.	Population Pharmacokinetic Analysis Dataset
C165637	TIME-TO-EVENT	TTE	A dataset containing data that is used for Time-to-Event analyses.	Time-to-Event Dataset

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CTSTDTYP (CDISC Controlled Terminology Standard Type)

NCI Code: C172331, Codelist extensible: No

	C172331	CTSTDTYP			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C180548		ADaM		The controlled terminology standard subset that includes terms pertaining to the Clinical Data Interchange Standards Consortium (CDISC) Analysis Data Model (ADaM).	CDISC ADaM Standard Terminology
C180549		CDASH		The controlled terminology standard subset that includes terms relevant to the Clinical Data Interchange Standards Consortium (CDISC) Clinical Data Acquisition Standards Harmonization (CDASH) group.	CDISC CDASH Standard Terminology
C180550		DEFINE-XML		The controlled terminology standard subset that includes terms relevant to the Clinical Data Interchange Standards Consortium (CDISC) Define-XML standard.	CDISC Define-XML Standard Terminology
C180551		SDTM		The controlled terminology standard subset that includes terms pertaining to the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM).	CDISC SDTM Standard Terminology
C180552		SEND		The controlled terminology standard subset that includes terms relevant to the Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Non-clinical Data (SEND) group.	CDISC SEND Standard Terminology

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DICTNAM (Dictionary Name)

NCI Code: C66788, Codelist extensible: Yes

	C66788	DICTNAM			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C163415		CDISC CT	CDISC Controlled Terminology;Clinical Data Interchange Standards Consortium Controlled Terminology	A standard terminology developed and maintained by Clinical Data Interchange Standards Consortium (CDISC) and the National Cancer Institute Enterprise Vocabulary Services (NCI-EVS) to support CDISC models, domains and specifications for data representation in regulated research.	Clinical Data Interchange Standards Consortium Controlled Terminology
C49471		COSTART	Coding Symbols for a Thesaurus of Adverse Reaction Terms	A terminology developed and used by the Food and Drug Administration (FDA) for the coding, filing and retrieving of post marketing adverse reaction reports. (NCI)	Thesaurus of Adverse Reaction Term Coding Symbols
C49704		CTCAE	Common Terminology Criteria for Adverse Events	A standard terminology developed and maintained by the National Cancer Institute to report adverse events occurring in cancer clinical trials. The CTCAE contains a grading scale for each adverse event term representing the severity of the event. (NCI)	Common Terminology Criteria for Adverse Events
C134003		D-U-N-S NUMBER	Data Universal Number System;DUNS Numbers	A proprietary system developed and regulated by Dun & Bradstreet that assigns a unique nine digit numeric identifier to a single business entity location.	Data Universal Numbering System
C49474		ICD	International Classification of Diseases	A system of categories to which morbid entries are assigned according to established criteria. Included is the entire range of conditions in a manageable number of categories, grouped to facilitate mortality reporting. It is produced by the World Health Organization (from ICD-10, p1). The Clinical Modifications, produced by the United States Dept. of Health and Human Services, are larger extensions used for morbidity and general epidemiological purposes, primarily in the U.S. (MSH2005_2004_10_12)	International Classification of Diseases
C37978		ICD-O	International Classification of Diseases for Oncology	A World Health Organization (WHO) multi-axial classification of the site, morphology, behaviour, and grading of neoplasms.	International Classification of Diseases for Oncology
C81895		ISO 21090		An international standard for harmonized data types for information interchange, developed and maintained by the International Organization for Standards (ISO).	ISO 21090
C209537		ISO 3166		An international standard for country and subdivision codes, developed and maintained by the International Organization for Standards (ISO).	ISO 3166
C49476		LOINC	Logical Observation Identifiers Names and Codes	Published by The Regenstrief Institute, the Logical Observation Identifiers Names and Codes covers clinical and clinical laboratory terminology. (NCI)	Logical Observation Identifiers Names and Codes
C163416		MED-RT	Medication Reference Terminology;NDF-RT	A standard terminology developed and maintained by the Veterans Health Administration (VHA) that includes terminology to support the mechanism of action, physiologic effect, and asserted pharmacologic classification relationships of medications. MED-RT incorporates terminology from RxNORM, MeSH, and SNOMED CT.	Medication Reference Terminology
C43820		MedDRA	Medical Dictionary for Regulatory Activities	An international medical terminology designed to support the classification, retrieval, presentation, and communication of medical information, particularly to regulatory authorities.	MedDRA
C53489		SNOMED	Systematized Nomenclature of Medicine	A structured nomenclature and classification of the terminology used in human and veterinary medicine developed by the College of Pathologists and American Veterinary Medical Association. (CDISC Glossary)	Systematized Nomenclature of Medicine
C163417		UNII	SRS-UNII;Substance Registration System-Unique Ingredient Identifier	A standard terminology developed and maintained by the Department of Veterans Affairs/Veterans Health Administration designated federal collaborative Structured Product Labeling Interagency Expert Panel (SPLIEP). It contains terminology to support the mechanism of action, physiologic effect, and asserted pharmacologic classification relationships of drug ingredients and food allergens.	Substance Registration System- Unique Ingredient Identifier
C154331		WHO ATC CLASSIFICATION SYSTEM	Anatomical Therapeutic Chemical Classification System	A World Health Organization (WHO) classification system, developed and maintained by the WHO Collaborating Centre for Drug Statistics Methodology, for medicinal substances where active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological, and chemical properties.	Anatomical Therapeutic Chemical Classification System
C49468		WHOART	World Health Organization Adverse Reaction Terms	A terminology implemented by the World Health Organization to describe adverse reactions to a prescribed medication or treatment regimen. (NCI)	World Health Organization Adverse Reaction Terminology
C49475		WHODD	WHODrug Global;World Health Organization Drug Dictionary	A reference source of drugs and drug associated information maintained by the World Health Organization. (NCI)	World Health Organization Drug Dictionary

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GNRLOBSC (General Observation Class)

NCI Code: C103329, Codelist extensible: No

	C103329	GNRLOBSC			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C103375		ADAM OTHER	ADaM Other	An analysis dataset that doesn't conform to a pre-defined ADaM dataset structure (e.g. ADSL, BDS or OCCDS).	CDISC Other ADaM Dataset
C103371		BASIC DATA STRUCTURE	Basic Data Structure;BDS	An ADaM BDS dataset contains one or more records per subject, per analysis parameter, per analysis time point. Variables include the value being analyzed (e.g., AVAL) and the description of the value being analyzed (e.g., PARAM). Other variables in the dataset provide more information about the value being analyzed (e.g., the subject identification) or describe and trace the derivation of it (e.g., DTYPE) or support the analysis of it (e.g., treatment variables, covariates).	CDISC Basic Data Structure Dataset
C177921		DEVICE LEVEL ANALYSIS DATASET	ADDL;Device Level Analysis Dataset	The Device-Level Analysis Dataset (ADDL) is a one-record-per-device or one-record-per-subject- per-device dataset which contains variables that describe device characteristics and timing, and group the devices for analysis. ADDL is the primary source for device-level variables included in other analysis datasets.	CDISC Device Level Analysis Dataset
C103372		EVENTS	Events	This SDTM class captures planned protocol milestones such as randomization and study completion, and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history).	CDISC Events Class
C135396		FINDINGS ABOUT	Findings About	This SDTM class is a specialization of the findings general observation class. It is intended, as its name implies, to be used when collected data represent findings about an event or intervention that cannot be represented within an event or intervention record or as a supplemental qualifier to such a record.	CDISC Findings About Class
C103373		FINDINGS	Findings	This SDTM class captures the observations resulting from planned evaluations to address specific tests or questions such as laboratory tests, ECG testing, and questions listed on questionnaires.	CDISC Findings Class
C103374		INTERVENTIONS	Interventions	This SDTM class captures investigational, therapeutic and other products that are administered to the subject either as specified by the study protocol (e.g., exposure to study drug), coincident with the study assessment period (e.g., concomitant medications), or self-administered by the subject (such as use of alcohol, tobacco, or caffeine).	CDISC Interventions Class
C177922		MEDICAL DEVICE BASIC DATA STRUCTURE	MDBDS;Medical Device Basic Data Structure	The Medical Device Basic Data Structure (MDBDS) supports the analysis needs by adding SPDEVID as a required key variable and USUBJID a conditionally required variable. See the BDS class for further details.	CDISC Medical Device Basic Data Structure
C177923		MEDICAL DEVICE OCCURRENCE DATA STRUCTURE	MDOCCDS;Medical Device Occurrence Data Structure	The Medical Device Occurrence Data Structure (MDOCCDS) supports the analysis needs by adding SPDEVID as a required identifier and allowing USUBJID be a conditionally required variable. See the OCCDS class for further details.	CDISC Medical Device Occurrence Data Structure
C123454		OCCURRENCE DATA STRUCTURE	OCCDS;Occurrence Data Structure	The Occurrence Data Structure (OCCDS) is the ADaM data structure for occurrence analysis. Occurrence analysis is the counting of subjects with a record or term, and often includes a structured hierarchy of dictionary coding categories.	CDISC Occurrence Data Structure
C204611		REFERENCE DATA STRUCTURE	RDS;REFERENDS	The Reference Data Structure (RDS) is the ADaM data structure for reference data. Reference data captures historic trends and results that are used as input for study analyses.	Reference Data Structure
C103376		RELATIONSHIP	Relationships	This SDTM class provides a means to link related records between datasets. It includes the RELREC and SUPPQUAL datasets.	CDISC Relationship Class
C103377		SPECIAL PURPOSE	Special Purpose;SPECIAL- PURPOSE	This SDTM class contains a set of domains which do not conform to the Findings, Events or Interventions observation classes. The domains included are DM, CO, SE, SJ, SM and SV.	CDISC Special Purpose Class
C147271		STUDY REFERENCE	Study Reference	This special purpose SDTM class contains further descriptions of study-specific identifiers that will be used in subject based domains.	CDISC Study Reference Class
C103378		SUBJECT LEVEL ANALYSIS DATASET	ADSL;Subject Level Analysis Dataset	The Subject-Level Analysis Dataset (ADSL) is a one-record-per-subject dataset which contains variables that describe subject demographic characteristics and group the subjects for analysis. ADSL is the primary source for subject-level variables included in other analysis datasets such as population flags and treatment variables.	CDISC Subject Level Analysis Dataset
C103379		TRIAL DESIGN	Trial Design	This SDTM class describes the plan for the procedures to be followed in a clinical trial, including planned and actual timing of events, control group, method of allocating treatments, blinding methods, assignment of epochs that subjects pass through in the course of a trial.	CDISC Trial Design Class

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MDBDSSC (ADaM Medical Device Basic Data Structure Subclass)

NCI Code: C177903, Codelist extensible: No

C177903	MDBDSSC			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C177920	MEDICAL DEVICE TIME-TO- EVENT	MDTTE	A dataset containing data that is used for medical device Time-to-Event analyses.	Medical Device Time-to-Event Dataset

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OCCSC (ADaM Occurrence Data Structure Subclass)

NCI Code: C176227, Codelist extensible: No

C176227	occsc			
NCI Code	CDISC Submission Value	CDISC	onym CDISC Definition	NCI Preferred Term
C176265	ADVERSE EVENT	AE	A dataset containing data that is used for adverse event analyses.	Adverse Event Dataset

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ODMCNTX (ODM Context)

NCI Code: C170448, Codelist extensible: No

	C170448	ODMCNTX			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C17649		Other	Other	Different than the one(s) previously specified or mentioned. (NCI)	Other
C70885		Submission		An assembly of one or more regulatory submission units supporting a specific regulatory purpose or decision. In most cases, the compilation of the submission units is utilized in the assessment of a regulated medical product quality, safety and/or effectiveness.	Regulatory Submission

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ORIGINS (Origin Source)

NCI Code: C170450, Codelist extensible: No

	C170450	ORIGINS			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C25936		Investigator		A person responsible for the conduct of the study, ensuring adherence to the protocol and good clinical practices. (CDISC Glossary)	Investigator
C70793		Sponsor	Clinical Study Sponsor;Sponsor;Study Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study. [After ICH E6, WHO, 21 CFR 50.3 (e), and after IDMP]	Clinical Study Sponsor
C41189		Subject		An individual who is observed, analyzed, examined, investigated, experimented upon, or/and treated in the course of a particular study.	Study Subject
C68608		Vendor		A person or agency that promotes or exchanges goods or services for money. (NCI)	Vendor

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ORIGINT (Origin Type)

NCI Code: C170449, Codelist extensible: No

0.170.1.10	
C170449	ORIGINT

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NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C170547	Assigned		A value that is derived through designation, such as values from a look up table or a label on a CRF.	Assigned Value
C170548	Collected		A value that is actually observed and recorded by a person or obtained by an instrument.	Collected Value
C170549	Derived		A value that is calculated by an algorithm or reproducible rule, and which is dependent upon other data values.	Derived Value
C126101	Not Available		A value that is not discoverable or accessible.	Not Available
C17649	Other	Other	Different than the one(s) previously specified or mentioned. (NCI)	Other
C170550	Predecessor		A value that is copied from another variable.	Copied Value
C170551	Protocol		A value that is included as part of the study protocol.	Protocol Value

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SDTMIGRS (SDTMIG Version Response)

NCI Code: C160924, Codelist extensible: Yes

	C160924	SDTMIGRS			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C161432		3.1.1	SDTMIG Version 3.1.1	Version 3.1.1 of the CDISC Study Data Tabulation Model (SDTM) Implementation Guide.	CDISC SDTM Implementation Guide Version 3.1.1
C161433		3.1.2	SDTMIG Version 3.1.2	Version 3.1.2 of the CDISC Study Data Tabulation Model (SDTM) Implementation Guide.	CDISC SDTM Implementation Guide Version 3.1.2
C161435		3.1.3	SDTMIG Version 3.1.3	Version 3.1.3 of the CDISC Study Data Tabulation Model (SDTM) Implementation Guide.	CDISC SDTM Implementation Guide Version 3.1.3
C161436		3.2	SDTMIG Version 3.2	Version 3.2 of the CDISC Study Data Tabulation Model (SDTM) Implementation Guide.	CDISC SDTM Implementation Guide Version 3.2
C161437		3.3	SDTMIG Version 3.3	Version 3.3 of the CDISC Study Data Tabulation Model (SDTM) Implementation Guide.	CDISC SDTM Implementation Guide Version 3.3
C189638		3.4	SDTMIG Version 3.4	Version 3.4 of the CDISC Study Data Tabulation Model (SDTM) Implementation Guide.	CDISC SDTM Implementation Guide Version 3.4
C161434		Version 3.1.2 Amendment 1	SDTMIG Version 3.1.2 Amendment	Amendment 1 of the 3.1.2 version of the CDISC Study Data Tabulation Model (SDTM) Implementation Guide.	CDISC SDTM Implementation Guide Version 3.1.2 Amendment 1

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STDNAM (Standard Name)

NCI Code: C170452, Codelist extensible: No

	C170452	STDNAM			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C170552		ADaMIG		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Analysis Data Model standard.	ADaM Implementation Guide
C191213		BIMO	Bioresearch Monitoring Technical Conformance Guide	The US Food and Drug Administration's (US FDA) dataset specification Bioresearch Monitoring Technical Conformance Guide.	Bioresearch Monitoring Technical Conformance Guide
C163415		CDISC/NCI	CDISC Controlled Terminology;Clinical Data Interchange Standards Consortium Controlled Terminology	A standard terminology developed and maintained by Clinical Data Interchange Standards Consortium (CDISC) and the National Cancer Institute Enterprise Vocabulary Services (NCI-EVS) to support CDISC models, domains and specifications for data representation in regulated research.	Clinical Data Interchange Standards Consortium Controlled Terminology
C170455		SDTMIG		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model standard.	SDTM Implementation Guide
C170553		SDTMIG-AP		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model Associated Persons standard.	SDTM Implementation Guide- Associated Persons
C170554		SDTMIG-MD		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model Medical Devices standard.	SDTM Implementation Guide- Medical Devices
C170456		SENDIG		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data standard.	SEND Implementation Guide
C181230		SENDIG-AR		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data Animal Rule standard.	SEND Implementation Guide- Animal Rule
C170556		SENDIG-DART		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data Developmental and Reproductive Toxicology standard.	SEND Implementation Guide- Developmental and Reproductive Toxicology
C199687		SENDIG-GENETOX		The implementation guide for the Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data (SEND) Genetic Toxicology standard.	SEND Implementation Guide- Genetic Toxicology

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STDSTAT (Standard Status)

NCI Code: C172332, Codelist extensible: Yes

C172332	STDSTAT	

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	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C172453		DRAFT		A preliminary version of a CDISC standard that has not yet completed the CDISC standards development process. (NCI)	CDISC Draft Standard
C172455		FINAL		A final version of a CDISC standard that has completed the CDISC standards development process. (NCI)	CDISC Final Standard
C172454		PROVISIONAL		A version of a CDISC standard whose conclusiveness is dependent upon the fulfillment of some contingency or final alteration. (NCI)	CDISC Provisional Standard

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STDTYP (Standard Type)

NCI Code: C170451, Codelist extensible: No

	C170451	STDTYP			
	NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C163415		СТ	CDISC Controlled Terminology;Clinical Data Interchange Standards Consortium Controlled Terminology		Clinical Data Interchange Standards Consortium Controlled Terminology
C170454		IG	CDISC Implementation Guide	A standard document developed and maintained by Clinical Data Interchange Standards Consortium (CDISC) that contains instructions and requirements for the organization, structure, and format of standard clinical and non-clinical trial tabulation and analysis datasets.	CDISC Implementation Guide

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