CDISC Def-XML Controlled Terminology, 2019-12-20

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
C165636	BDSISC	ADaM Integrated Basic Data Structure Subclass	Purpose of a specific analysis result described in ADaM analysis results metadata.	No
C165635	BDSSC	ADaM Basic Data Structure Subclass	Terminology relevant to the subclasses of the ADaM basic data structure.	No
C66788	DICTNAM	Dictionary Name	A name given to a reference source that lists words and gives their meaning. (NCI)	Yes
C103329	GNRLOBSC	General Observation Class	Terminology related to the classification of a CDISC domain.	No

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	Exploratory measures that will be used to evaluate the intervention(s) or, for observational studies, that are exploratory of the study.	Exploratory Outcome Measure
C98772	PRIMARY OUTCOME MEASURE	Primary Outcome Measure	The primary measurement(s) or observation(s) used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment. These are the outcome measures used to assess the primary objective(s).	Primary Outcome Measure
C98781	SECONDARY OUTCOME MEASURE	Secondary Outcome Measure	Secondary measures that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study. These are the outcome measures used to assess the secondary objective(s).	Secondary Outcome Measure

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

BDSISC (ADaM Integrated Basic Data Structure Subclass)

NCI Code: C165636, Codelist extensible: No

C165636	BDSISC			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C165637	TIME-TO-EVENT	TTE	A dataset containing data that is used for Time-to-Event analyses.	Time-to-Event Dataset

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**
C165637	TIME-TO-EVENT	TTE	A dataset containing data that is used for Time-to-Event analyses.	Time-to-Event Dataset

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 clinical trials. The CTCAE contains a grading scale for each adverse event term representing the severity of the event.	Common Terminology Criteria for Adverse Events
C134003	D-U-N-S NUMBER	DUNS Numbers;Data Universal Number System	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
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	MedDRA is an international medical terminology designed to support the classification, retrieval, presentation, and communication of medical information throughout the medical product regulatory cycle. MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The MedDRA Maintenance and Support Services Organization (MSSO) holds a contract with the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) to maintain and support the implementation of the terminology. (NCI)	MedDRA
C53489	SNOMED	Systematized Nomenclature of Medicine	A multiaxial, hierarchical classification system for diseases in man developed by the College of American Pathologists. (NCI)	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

C66788	DICTNAM			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
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

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		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	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
C103372	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
C103373	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
C135396	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
C132357	INTEGRATED BASIC DATA STRUCTURE	IBDS	The Integrated Basic Data Structure is the ADaM data structure including POOL as defined in the integrated SAP. If the IBDS class is needed then IADSL is required. See the study-level BDS class for further details.	CDISC Integrated Basic Data Structure Dataset
C132358	INTEGRATED OCCURRENCE DATA STRUCTURE	IOCCDS	The Integrated Occurrence Data Strucutre is the ADaM data structure including POOL as defined in the integrated SAP. If the IOCCDS class is needed then IADSL is required. See the study-level OCCDS class for further details.	CDISC Integrated Occurrence Data Structure Dataset
C132359	INTEGRATED SUBJECT LEVEL	IADSL	The Integrated Subject-Level Analysis Dataset is one record per subject per pool as defined in the integrated SAP and allows multiple records per subject. The integrated ADSL dataset, similar to the study-level ADSL dataset, contains variables that describe subject demographic characteristics and group the subjects for analysis, and is the primary source for subject-level variables included in other analysis datasets such as population flags and treatment variables.	CDISC Integrated Subject Level Dataset
C103374	INTERVENTIONS		This SDTM class captures investigational, therapeutic and other treatments that are administered to the subject (with some actual or expected physiological effect) 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
C123454	OCCURRENCE DATA STRUCTURE	OCCDS	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
C103376	RELATIONSHIP		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	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 and SV.	CDISC Special Purpose Class
C147271	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

C103329	GNRLOBSC			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C103378	SUBJECT LEVEL ANALYSIS DATASET	ADSL	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		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