ReadMe

This is Version 1.0 of the CDISC CTR-XML standard. CTR-XML 1.0 is a provisionally approved standard model based on the CDISC Operational Data Model (ODM) used for clinical trial registry submissions to the World Health Organization (WHO), the European Medicines Agency (EMA) EudraCT Registry and the United States' ClinicalTrials.gov registry. CTR-XML provides an approach for generating harmonized messages to each of these 3 registries.

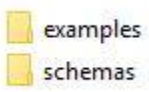
CTR-XML v1.0 has been released as a provisional standard while the CDISC Controlled Terminology is still out for comment (until June – see readme appendix for details) and while the standard is implemented and tested. CDISC will be happy to work with implementation vendors to update the standard where any issues are found. Please reference the latest version of the CDISC Controlled Terminology when using the CTR-XML specification.

Download Folder Structure

The top-level folder of the CTR-XML download package includes the following files:

- CTR-XML-1-0-Specification.pdf
- ReadMe.pdf

The top-level folder also includes the following sub-folders:



The *examples* folder contains 2 example CTR-XML files. The *schemas* folder contains all the XML schema files needed to validate a CTR-XML file.

Schema Validation

The example files included with the specification have been validated using Xerces 2.11.0 with the XML schema files included in the download package. The purpose of including the examples is to illustrate specific model concepts. They do not represent fully valid submissions to any particular registry.

Appendix: Terminology

Table 1 below shows the terms which were included in the publication release on 25Mar2015. There is one test name highlighted in yellow that was too long and had to be abbreviated. The correction is in red and this will be available in the June 24 release subject to comments.

The terms in **Table 2** went out for public review on 18Mar2016. Public review will last 4 weeks. These terms will be included in the publication release on 24Jun2016.

Table 1.

TESTCD	TEST	CDISC Definition	NCI/EVS Request Number	ClinicalTrial.gov Preferred Term	EudraCT Preferred Term
THERAREA	Therapeutic Area	A knowledge field that focuses on research and development of specific treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of an individual.	CDISC-2049		Therapeutic Area
EURSBIND	EudraCT Resubmission Indicator	An indication as to whether the trial being submitted to the EudraCT is a trial that has been previously submitted to the EudraCT system.	CDISC-2070		Is Resubmission
RESUBLTR	Resubmission Letter	An alphabetic character that describes the incremental order of trial resubmissions.	CDISC-2070		Resubmission Letter
PIPIND	Pediatric Investigation Plan Indicator	An indication as to whether the trial is part of a pediatric investigation plan (PIP).	CDISC-2070		Trial Part of a PIP
EMPIPDCN	EMA Decision Number for PIP	An alphanumeric code assigned by the European Medicines Agency (EMA) to an EMA regulatory decision for a pediatric investigation plan (PIP).	CDISC-2070		PIP Decision Number

TESTCD	TEST	CDISC Definition	NCI/EVS Request Number	ClinicalTrial.gov Preferred Term	EudraCT Preferred Term
SRNCAIND	SUSAR Reporting to NCA Indicator	An indication as to whether suspected unexpected serious adverse reactions (SUSAR) will be reported to national competent authorities (NCA).	CDISC-2070		SUSAR Reporting to NCAs
SREVIND	SUSAR Reporting to EVCTM Indicator	An indication as to whether suspected unexpected serious adverse reactions (SUSAR) will be reported to a EudraVigiliance clinical trial module (EVCTM).	CDISC-2070		SUSAR Reporting to EVCTM
EVSNDID	EudraVigilance Sender ID	A unique identifier assigned to the organization that is transmitting an adverse drug reaction report to the EudraVigilance system.	CDISC-2070		EV Sender ID
EVSNDORG	EudraVigilance Sender Organization	The name of the group or institution that is transmitting an adverse drug reaction report to the EudraVigilance system.	CDISC-2070		EV Sender Organization
RDIND	Rare Disease Indicator	An indication as to whether the condition under study is considered a rare disease.	CDISC-2070		Condition a Rare Disease
KEYWORD	Protocol Keyword	A word or small set of words designed to convey the focus of the protocol.	CDISC-2070	Keywords	
SSTDYIND	Substudy Planned Indicator	An indication as to whether a study performed on a subgroup of subjects included in the original trial (substudy) is planned for the current study.	CDISC-2070		Has a Sub-study
SSTDYDTL	Substudy Details	A textual description of the substudy.	CDISC-2070		Sub-study Details

TESTCD	TEST	CDISC Definition	NCI/EVS Request Number	ClinicalTrial.gov Preferred Term	EudraCT Preferred Term
OBSMODEL	Observational Model	The trial design developed to compare biomedical and/or health outcomes in pre-defined and non-assigned groups of individuals.	CDISC-2070	Observational Study Model	
OBSTIMP	Observational Time Perspective	The temporal relationship between the observation period and time of subject enrollment. (ClinicalTrials.gov)	CDISC-2070	Time Perspective	
BIOSPRET	Biospecimen Retention Contains DNA	A textual description as to whether a biospecimen is retained and/or contains DNA.	CDISC-2070	Biospecimen Retention	
RTSPCDES	Retained Biospecimen Description	A textual description of the specimen types that are retained as reserve samples.	CDISC-2070	Biospecimen Description	
TRGFUDUR	Target Follow-Up Duration	The anticipated time period over which each study participant is to be followed. (ClinicalTrials.gov)	CDISC-2070	Target Follow-Up Duration	
NCOHORT	Number of Groups/Cohorts	The number of groups or cohorts that are part of the study.	CDISC-2070	Number of Groups/Cohorts	
OBSTPOPD	~~Observational Study Population Description~~ Obs Study Population Description	A description of the population from which the groups or cohorts will be selected within an observational study.	CDISC-2070	Study Population Description	
OBSTSMM	Observational Study Sampling Method	The sampling method used to assign study participants into groups or cohorts within an observational study.	CDISC-2070	Sampling Method	
OBSTSMMD	Obs Study Sampling Method Description	A textual description of the sampling method used to assign study participants into groups or cohorts	CDISC-2070	Sampling Method Detailed Description	

TESTCD	TEST	CDISC Definition	NCI/EVS Request Number	ClinicalTrial.gov Preferred Term	EudraCT Preferred Term
		within an observational study.			
TTYPE	Trial Type	The type of clinical trial performed e.g. efficacy, safety. (NCI)	CDISC-2070	Study Classification	Trial Scope

Table 2.

TESTCD	TEST	CDISC Definition	NCI/EVS Request Number	ClinicalTrial.gov Preferred Term	EudraCT Preferred Term
CMSPSTAT	Commercial Sponsor Status	The state or condition of the sponsor as pertains to whether the sponsor is considered a commercial entity.	CDISC-2070		Sponsor Status
EXPASTAT	Expanded Access Status	Status indicating availability of an experimental drug or device outside any clinical trial protocol. (clinicaltrials.gov)	CDISC-2142	Expanded Access Status	
EXPARECN	Expanded Access Record NCT Number	The unique alphanumeric identifier for the study with associated expanded access record, as assigned by the clinicaltrials.gov protocol registration and results system (PRS).	CDISC-2142	Expanded Access Record	
SSEUTIND	Single Site EU State Trial Indicator	An indication as to whether the clinical study is being conducted at only one site within the European Union member state concerned by the application.	CDISC-2142		Single Site Trial
MSEUTIND	Multiple Site EU State Trial Indicator	An indication as to whether the clinical study is being conducted at multiple sites within the European Union member state	CDISC-2142		Multiple Site Trial

TESTCD	TEST	CDISC Definition	NCI/EVS Request Number	ClinicalTrial.gov Preferred Term	EudraCT Preferred Term
		concerned by the application.			
NUMSEUST	Number of Trial Sites EU State	The total number of trial sites within the European Union member state concerned by the application.	CDISC-2142		Number of Sites in MS
DMCIND	Data Monitoring Committee Indicator	An indication as to whether the clinical trial has an appointed data monitoring committee.	CDISC-2142	Data Monitoring Committee?	Trial has independent data monitoring committee
PLNTRDUR	Planned Trial Duration	The approximate period of time over which the clinical trial is expected to occur.	CDISC-2142		Estimated trial duration
PUBMEDID	PubMed ID for Citation Used in Study	A globally unique identifier for a biomedical article, as assigned by PubMed.	CDISC-2142	PubMed Identifier	
CITNSTDY	Citation Used in Study	A bibliographical reference related to a particular study.	CDISC-2142	Citation	
URLSTDY	URL Related to Study	The uniform resource locator (URL) related to a particular study.	CDISC-2142	URL	
URLSTDYD	URL Related to Study Description	A textual description of the uniform resource locator (URL) related to a particular study.	CDISC-2142	Description	
RXMLCIND	Request for XML Copy of Study Indicator	An indication as to whether the registrant would like to receive an XML copy of their study as saved on EudraCT.	CDISC-2172		Send XML Copy
EMAILXML	E-mail Address for XML File	The E-mail address to which copies of the XML format of the EudraCT application should be sent.	CDISC-2172		XML Copy Email x5

TESTCD	TEST	CDISC Definition	NCI/EVS Request Number	ClinicalTrial.gov Preferred Term	EudraCT Preferred Term
SDXMLIND	Secure Delivery XML Required Indicator	An indication as to whether the XML copy of the EudraCT application requires secure E-mail delivery.	CDISC-2172		XML copy is secure