Document Title **Representing Controlled Terminoloy in ODM**

Release **Draft Specification**

Change Control Log

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1. Introduction

This document describes the ODM XML representation of CDISC Controlled Terminology.

The objective of the CDISC controlled terminology is to enable semantic interoperability of the CDISC data models, across the clinical trial continuum, including the PRG (Protocol), SDTM (Study Data Tabulation Model), CDASH (Clinical Data Acquisition Standards Harmonization), ADaM (Analysis Data Model), SEND (Standard for the Exchange of Non-Clinical Data) and ODM (Operational Data Model). All CDISC standards encourage the use of standard CDSIC controlled terminology. Please refer to specific data models for additional terminology implementation requirements.
A common vocabulary is essential to the interoperability and cross study usage of the CDISC data standards. The data elements (in the dependent models, listed above) are linked to a single terminology superset where possible.

2. Format in Excel

CDISC controlled terminology is extracted from the NCIt by an automated procedure that creates a report organized into terminology codelists. These codelists correspond to CDISC variables or more general observation classes. Controlled terminology is available for download in both text and Excel format.
This document describes the availability of the codelists in ODM xml format.

To access CDISC Controlled Terminology; go to the CDISC Website, click on Standards & Innovations, Terminology and click on:

NCI EVS Terminology Resources (access to CDISC, FDA and other terminology)

Three subsets of the master CT set are maintained for CDISC by NCI EVS:

- SDTM - this is the super set of codelists that are used to both collect and submit SDTM data.
- ADaM - this is a terminology set that supports efficient generation, replication, review and submission of analysis results from clinical trial data
- CDASH - this is a subset of the SDTM codelists and is intended to aid implementation by subsetting the SDTM codelists to the most commonly-collected terms. The implementer in CDASH is not limited to the CDASH subsets, but may use any values from the SDTM superset for data collection.

The controlled terminology file is composed of columns that contain information regarding terminology arranged in rows.
Table 1 describes these columns in the Excel format for the SDTM subset.

Table 1 Column descriptions in the Controlled Terminology Excel format (SDTM subset)

Column	Description
Code *(Column A)*	Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned to individual CDISC controlled terms.
Codelist Code *(Column B)*	Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned to the SDTM parent codelist names. This code is repeated for each controlled term (aka permissible value) belonging to a codelist. As of 9/22/2008, this code was dropped for parent codelist entries, where it created confusion. **NOTE - light blue highlighting is used to identify the beginning of a new SDTM codelist and its applicable term set.
Codelist Extensible (Yes/No) *(Column C)*	Defines if controlled terms may be added to the codelist. New terms may be added to existing codelist values as long as they are not duplicates or synonyms of existing terms. The expectation is that sponsors will use the published controlled terminology as a standard baseline and codelists defined as “extensible” (or "Yes") may have terms added by the sponsor internally.
Codelist Name *(Column D)*	Contains the descriptive name of the codelist which is also referred to as the codelist label in the SDTM IG. As with the Codelist Code, the Codelist Name is repeated for each controlled term belonging to a codelist.
CDISC Submission Value *(Column E)*	**IMPORTANT COLUMN: Currently (as per SDTMIG 3.1.2) this is the specific value expected for submissions. Each value corresponds to a SDTM Codelist Name as indicated by light blue shading.**
CDISC Synonym(s) *(Column F)*	This identifies the applicable synonyms for a CDISC Preferred Term in Column F. **NOTE - this is especially important in instances where a Test name or Parameter Test name contains a corresponding Test Code or Parameter Test Code. Examples include: TSPARM rows 761-785, VSTEST rows 826-841, LBTEST rows 1429-2010 and EGTEST rows 2231-2277.
CDISC Definition *(Column G)*	This identifies the CDISC definition for a particular term. In many cases an existing NCI definition has been used. The source for a definition is noted in parentheses (e.g. NCI, CDISC glossary, FDA).
NCI Preferred Term *(Column H)*	This identifies the NCI preferred name for a term as identified in NCIt. **NOTE - This column designates the human readable, fully specified preferred term corresponding to the NCI c-code, and is especially helpful for searching NCIt to get the entire concept with links to all instances of the term.

Table 2 shows an example of the spreadsheet for the "Severy/Intensity Scale for Adverse Events" codelist.

Table 2 Severity/Intensity Scale for Adverse Events codelist

A	B	C	D	E	F	G	H
Code	**Codelist Code**	**Codelist Extensible (Yes/No)**	**Codelist Name**	**CDISC Submission Value**	**CDISC Synonym(s)**	**CDISC Definition**	**NCI Preferred Term**
C66769		No	Severity/Intensity Scale for Adverse Events	AESEV	Severity/Intensity Scale for Adverse Events	A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCI)	CDISC SDTM Severity Intensity Scale for Adverse Event Terminology
C41338	C66769		Severity/Intensity Scale for Adverse Events	MILD	Grade 1; 1	A type of adverse event that is usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living.	Mild Adverse Event
C41339	C66769		Severity/Intensity Scale for Adverse Events	MODERATE	Grade 2; 2	A type of adverse event that is usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort but poses no significant or permanent risk of harm to the research participant.	Moderate Adverse Event
C41340	C66769		Severity/Intensity Scale for Adverse Events	SEVERE	Grade 3; 3	A type of adverse event that interrupts usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention.	Severe Adverse Event

3. Mapping to ODM XL

Table 3 shows the mapping of the Excel columns to ODM XML elements and attributes.

Table 3 Mapping of Excel Colums to ODM XML elements and attributes

	Spreadsheet Column	Example Value	ODM XML XPath expression
Codelist	**Code** *(Column A)*	C66769	/ODM/Study/MetaDataVersion/CodeList/@nciodm:ExtCodeID
	Codelist Extensible (Yes/No) *(Column C)*	No	/ODM/Study/MetaDataVersion/CodeList/@nciodm:CodeListExtensible
	Codelist Name *(Column D)*	Severity/Intensity Scale for Adverse Events	/ODM/Study/MetaDataVersion/CodeList/@Name
	CDISC Submission Value *(Column E)*	AESEV	/ODM/Study/MetaDataVersion/CodeList/nciodm:CDISCSubmissionValue
	CDISC Synonym(s) *(Column F)*	Severity/Intensity Scale for Adverse Events	/ODM/Study/MetaDataVersion/CodeList/nciodm:CDISCSynonym
	CDISC Definition *(Column G)*	A scale that defines the degree or state of disease existing in a patient as a result of the occurrence of an adverse event. (NCI)	/ODM/Study/MetaDataVersion/CodeList/Description/TranslatedText

	Spreadsheet Column	Example Value	ODM XML XPath expression
	NCI Preferred Term *(Column H)*	CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	/ODM/Study/MetaDataVersion/CodeList/nciodm:PreferredTerm
Codelist Code	**Code** *(Column A)*	C41338	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/@nciodm:ExtCodeID
	CDISC Submission Value *(Column E)*	MILD	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/@CodedValue
	CDISC Synonym(s) *(Column F)*	Grade 1	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/nciodm:CDISCSynonym
	CDISC Definition *(Column G)*	A type of adverse event that is usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living.	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/nciodm:CDISCDefinition
	NCI Preferred Term *(Column H)*	Mild Adverse Event	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/nciodm:PreferredTerm

4. Controlled Terminology in ODM XML

The namespace URI for the CDISC Controlled Terminology in ODM XML is:
http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC
All ODM elements are referenced as being in the default namespace (they have no namespace prefix).
Elements in the Controlled Terminology namespace are assigned the prefix "nciodm".

```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet type="text/xsl" href="xsl/controlledterminology1-0-0.xsl"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
   xmlns:xs="http://www.w3.org/2001/XMLSchema-instance"
   xmlns:nciodm="http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC"
   xs:schemaLocation="http://www.nci.nih.gov/EVS/CDISC schema/controlledterminology1-0-0.xsd"
   FileType="Snapshot"
   FileOID="CDISC_CT.SDTM.2011-04-08"
   Granularity="Metadata"
   CreationDateTime="2011-04-06T08:56:42"
   AsOfDateTime="2011-04-08T00:00:00"
   ODMVersion="1.3.1"
   Originator="CDISC XML Technologies Team (SAS 9.02.02M3P04132010)"
   SourceSystem="NCI Thesaurus"
   SourceSystemVersion="2011-04-08">
  <Study OID="CDISC_CT.SDTM.2011-04-08">
    <GlobalVariables>
      <StudyName>CDISC SDTM ControlledTerminology</StudyName>
      <StudyDescription>CDISC SDTM Controlled Terminology, 2011-04-08</StudyDescription>
      <ProtocolName>CDISC SDTM Controlled Terminology</ProtocolName>
    </GlobalVariables>
    <MetaDataVersion OID="CDISC_CT_MetaDataVersion.SDTM.2011-04-08"
                     Name="CDISC SDTM Controlled Terminology"
                     Description="CDISC SDTM Controlled Terminology, 2011-04-08">

      <CodeList …
      </CodeList>
…
    </MetaDataVersion>
  </Study>
</ODM>
```

Example 1: Overall structure of an ODM document containing NCI Controlled Terminology.

```
<CodeList OID="CL.C66769.AESEV" Name="Severity/Intensity Scale for Adverse Events"
DataType="text" nciodm:ExtCodeID="C66769" nciodm:CodeListExtensible="No">
     <Description>
       <TranslatedText xml:lang="en">A scale that defines the degree or state of
disease existing in a patient as a result of the occurrence of an adverse event.
(NCI)</TranslatedText>
     </Description>
     <EnumeratedItem CodedValue="MILD" nciodm:ExtCodeID="C41338">
       <nciodm:CDISCSynonym>Grade 1</nciodm:CDISCSynonym>
       <nciodm:CDISCSynonym>1</nciodm:CDISCSynonym>
       <nciodm:CDISCDefinition>A type of adverse event that is usually transient
and may require only minimal treatment or therapeutic intervention. The event does
not generally interfere with usual activities of daily
living.</nciodm:CDISCDefinition>
       <nciodm:PreferredTerm>Mild Adverse Event</nciodm:PreferredTerm>
     </EnumeratedItem>
     <EnumeratedItem CodedValue="MODERATE" nciodm:ExtCodeID="C41339">
       <nciodm:CDISCSynonym>Grade 2</nciodm:CDISCSynonym>
       <nciodm:CDISCSynonym>2</nciodm:CDISCSynonym>
       <nciodm:CDISCDefinition>A type of adverse event that is usually alleviated
with additional specific therapeutic intervention. The event interferes with usual
activities of daily living, causing discomfort but poses no significant or
permanent risk of harm to the research participant.</nciodm:CDISCDefinition>
       <nciodm:PreferredTerm>Moderate Adverse Event</nciodm:PreferredTerm>
     </EnumeratedItem>
     <EnumeratedItem CodedValue="SEVERE" nciodm:ExtCodeID="C41340">
       <nciodm:CDISCSynonym>Grade 3</nciodm:CDISCSynonym>
       <nciodm:CDISCSynonym>3</nciodm:CDISCSynonym>
       <nciodm:CDISCDefinition>A type of adverse event that interrupts usual
activities of daily living, or significantly affects clinical status, or may
require intensive therapeutic intervention.</nciodm:CDISCDefinition>
       <nciodm:PreferredTerm>Severe Adverse Event</nciodm:PreferredTerm>
     </EnumeratedItem>
     <nciodm:CDISCSubmissionValue>AESEV</nciodm:CDISCSubmissionValue>
     <nciodm:CDISCSynonym>Severity/Intensity Scale for Adverse
Events</nciodm:CDISCSynonym>
     <nciodm:PreferredTerm>CDISC SDTM Severity Intensity Scale for Adverse Event
Terminology</nciodm:PreferredTerm>
</CodeList>
```

Example 2: A codelist in the Controlled Terminology ODM XML.

5. Appendix: XML Schema

The XML Schema for Controlled Terminoloy extends ODM using the same pattern as that employed by the CRT-DDS standard. There is a root schema, an extension schema (which defines the extensions to existing ODM elements such as Protocol), and an 'ns' schema, which defines those elements and attributes specific to study design.

1.2 Root schema: controlledterminology1-0-0.xsd

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema targetNamespace="http://www.cdisc.org/ns/odm/v1.3"
           xmlns="http://www.cdisc.org/ns/odm/v1.3"
           xmlns:xs="http://www.w3.org/2001/XMLSchema"
           xmlns:nciodm="http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC"
           elementFormDefault="qualified" attributeFormDefault="unqualified">

    <!-- import core XML schema -->
    <xs:import namespace=http://www.w3.org/XML/1998/namespace
               schemaLocation="foundation/xml.xsd"/>

    <!-- include Controlled Terminology extensions to core ODM -->
    <xs:include schemaLocation="controlledterminology-extension.xsd"/>

</xs:schema>
```

2.2 Extension schema: controlledterminology-extension.xsd

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema targetNamespace="http://www.cdisc.org/ns/odm/v1.3"
           xmlns="http://www.cdisc.org/ns/odm/v1.3"
           xmlns:xs="http://www.w3.org/2001/XMLSchema"
           xmlns:nciodm="http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC"
           elementFormDefault="qualified" attributeFormDefault="unqualified">

    <xs:import namespace=http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC
               schemaLocation="controlledterminology-ns.xsd"/>

    <xs:redefine schemaLocation="foundation/ODM1-3-1.xsd">

    <!--
          CodeList
      -->
      <xs:attributeGroup name="CodeListAttributeExtension">
          <xs:attributeGroup  ref="CodeListAttributeExtension"/>
          <xs:attributeGroup  ref="nciCommonAttributes"/>
          <xs:attribute ref="nciodm:CodeListExtensible" use="required"/>
      </xs:attributeGroup>

      <xs:group name="CodeListElementExtension">
            <xs:sequence>
              <xs:group ref="CodeListElementExtension"/>
              <xs:group ref="nciCommonElements"/>
            </xs:sequence>
      </xs:group>
```

```
    <!--
          CodeListItem
      -->
      <xs:attributeGroup name="CodeListItemAttributeExtension">
          <xs:attributeGroup  ref="CodeListItemAttributeExtension"/>
          <xs:attributeGroup  ref="nciCommonAttributes"/>
      </xs:attributeGroup>

      <xs:group name="CodeListItemElementExtension">
            <xs:sequence>
                <xs:group ref="CodeListItemElementExtension"/>
                <xs:group ref="nciCommonItemElements"/>
            </xs:sequence>
      </xs:group>

    <!--
          EnumeratedItem
      -->
      <xs:attributeGroup name="EnumeratedItemAttributeExtension">
          <xs:attributeGroup  ref="EnumeratedItemAttributeExtension"/>
          <xs:attributeGroup  ref="nciCommonAttributes"/>
      </xs:attributeGroup>

      <xs:group name="EnumeratedItemElementExtension">
            <xs:sequence>
              <xs:group ref="EnumeratedItemElementExtension"/>
              <xs:group ref="nciCommonItemElements"/>
            </xs:sequence>
      </xs:group>

    </xs:redefine>

    <xs:attributeGroup name="nciCommonAttributes">
        <xs:attribute ref="nciodm:ExtCodeID" use="optional"/>
    </xs:attributeGroup>

    <xs:group name="nciCommonElements">
        <xs:sequence>
            <xs:element ref="nciodm:CDISCSubmissionValue"
                        minOccurs="0" maxOccurs="1"/>
            <xs:element ref="nciodm:CDISCSynonym"
                        minOccurs="0" maxOccurs="unbounded"/>
            <xs:element ref="nciodm:PreferredTerm" minOccurs="0" maxOccurs="1"/>
        </xs:sequence>
    </xs:group>

    <xs:group name="nciCommonItemElements">
        <xs:sequence>
            <xs:element ref="nciodm:CDISCSynonym"
                        minOccurs="0" maxOccurs="unbounded"/>
            <xs:element ref="nciodm:CDISCDefinition" minOccurs="0" maxOccurs="1"/>
            <xs:element ref="nciodm:PreferredTerm" minOccurs="0" maxOccurs="1"/>
        </xs:sequence>
    </xs:group>

</xs:schema>
```

3.2 ns schema: controlledterminology-ns.xsd

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema targetNamespace="http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC"
           xmlns:xs="http://www.w3.org/2001/XMLSchema"
           xmlns:odm="http://www.cdisc.org/ns/odm/v1.3"
           xmlns:nciodm="http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC"
           elementFormDefault="qualified" attributeFormDefault="unqualified">

    <xs:import namespace=http://www.cdisc.org/ns/odm/v1.3
               schemaLocation="foundation/ODM1-3-1.xsd"/>

    <xs:attribute name="ExtCodeID"
                  type="nciodm:NCIsimpleTypeDefinition-ExtCodeID"/>
    <xs:attribute name="CodeListExtensible"
                  type="odm:YesOrNo"/>

    <xs:element name="CDISCSubmissionValue"
                type="nciodm:NCIsimpleTypeDefinition-CDISCSubmissionValue" />
    <xs:element name="CDISCSynonym"
                type="nciodm:NCIsimpleTypeDefinition-CDISCSynonym" />
    <xs:element name="PreferredTerm"
                type="nciodm:NCIsimpleTypeDefinition-PreferredTerm" />
    <xs:element name="CDISCDefinition"
                type="nciodm:NCIsimpleTypeDefinition-CDISCDefinition" />

    <xs:simpleType name="NCIsimpleTypeDefinition-ExtCodeID">
      <xs:restriction base="odm:text" />
    </xs:simpleType>

    <xs:simpleType name="NCIsimpleTypeDefinition-CDISCSubmissionValue">
      <xs:restriction base="odm:text" />
    </xs:simpleType>

    <xs:simpleType name="NCIsimpleTypeDefinition-CDISCSynonym">
      <xs:restriction base="odm:text" />
    </xs:simpleType>

    <xs:simpleType name="NCIsimpleTypeDefinition-PreferredTerm">
      <xs:restriction base="odm:text" />
    </xs:simpleType>

    <xs:simpleType name="NCIsimpleTypeDefinition-CDISCDefinition">
      <xs:restriction base="odm:text" />
    </xs:simpleType>

</xs:schema>
```