



Document Title **Representing Controlled Terminology in ODM XML**

Release **Specification**

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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 ADaM (Analysis Data Model), CDASH (Clinical Data Acquisition Standards Harmonization), Define-XML, Glossary, Protocol, SDTM (Study Data Tabulation Model), SEND (Standard for the Exchange of Non-Clinical Data) and ODM (Operational Data Model). All CDISC standards encourage the use of standard CDISC 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 NCI by an automated procedure that creates a report organized into terminology codelists. These codelists correspond to CDISC variables or more general observation classes. CDISC Controlled Terminology is maintained and distributed as part of the NCI Thesaurus on an NCI File Transfer Protocol (FTP) site and is available for direct download in Excel, text, odm.xml, pdf, html, and OWL/RDF formats. This document describes the availability of the codelists in ODM xml format.

To access CDISC Controlled Terminology; go to the CDISC Website:

<https://www.cdisc.org/standards/terminology/controlled-terminology>

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 <i>(Column A)</i>	Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned to individual CDISC controlled terms.
Codelist Code <i>(Column B)</i>	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. **NOTE - light blue highlighting is used to identify the beginning of a new SDTM codelist and its applicable term set.
Codelist Extensible (Yes/No) <i>(Column C)</i>	Defines if controlled terms may be added to the codelist. New terms may be added to existing codelist values when the codelist has "Yes" in Column C as long as the terms 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. For codelists with "No" in Column C sponsor organizations may not add to the published lists. Suggestions for new terms may be requested through the New Term Request Page.
Codelist Name <i>(Column D)</i>	Contains the descriptive name of the codelist. As with the Codelist Code, the Codelist Name is repeated for each controlled term belonging to a codelist.
CDISC Submission Value <i>(Column E)</i>	Contains the descriptive name of the codelist. As with the Codelist Code, the Codelist Name is repeated for each controlled term belonging to a codelist.
CDISC Synonym(s) <i>(Column F)</i>	This identifies the applicable synonyms for the CDISC Submission Value in Column E. These terms should not be submitted, but are included for collection and mapping purposes.**NOTE - this is especially important in instances where a Test name or Parameter Test name contains a corresponding Test Code or Parameter Test Code.
CDISC Definition <i>(Column G)</i>	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).
NCI Preferred Term <i>(Column H)</i>	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 "Severity/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	1; Grade 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	2; Grade 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	3; Grade 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 XML

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

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

	Spreadsheet Column	Example Value	ODM XML XPath expression
Codelist	Code <i>(Column A)</i>	C66769	/ODM/Study/MetaDataVersion/CodeList/@nciodm:ExtCodeID
	Codelist Extensible (Yes/No) <i>(Column C)</i>	No	/ODM/Study/MetaDataVersion/CodeList/@nciodm:CodeListExtensible
	Codelist Name <i>(Column D)</i>	Severity/Intensity Scale for Adverse Events	/ODM/Study/MetaDataVersion/CodeList/@Name
	CDISC Submission Value <i>(Column E)</i>	AESEV	/ODM/Study/MetaDataVersion/CodeList/nciodm:CDISCSubmissionValue
	CDISC Synonym(s) <i>(Column F)</i>	Severity/Intensity Scale for Adverse Events	/ODM/Study/MetaDataVersion/CodeList/nciodm:CDISCSynonym
	CDISC Definition <i>(Column G)</i>	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 <i>(Column H)</i>	CDISC SDTM Severity Intensity Scale for Adverse Event Terminology	/ODM/Study/MetaDataVersion/CodeList/nciodm:PreferredTerm
Codelist Code	Code <i>(Column A)</i>	C41338	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/@nciodm:ExtCodeID
	CDISC Submission Value <i>(Column E)</i>	MILD	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/@CodedValue
	CDISC Synonym(s) <i>(Column F)</i>	Grade 1	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/nciodm:CDISCSynonym
	CDISC Definition <i>(Column G)</i>	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 <i>(Column H)</i>	Mild Adverse Event	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/nciodm:PreferredTerm

4. Rules

The ODM element has a Context attribute which has allowed values “Submission” or “Other”. The value “Submission” means that the Controlled Terminology is used within the context of an electronic submission.

The following Controlled Terminology files have Context=“Submission”: ADaM, CDASH, Define-XML, SDTM, and SEND.

The Controlled Terminology files for the CDISC Glossary and the Protocol Entities have Context=“Other”.

In the case that the Controlled Terminology file has a Context attribute value equal to “Other”, then the nciodm:CodeListExtensible attribute in a CodeList element is optional. In cases where the codelists are shared with SDTM terminology the Codelist extensibility attribute (nciodm:CodeListExtensible attribute) inherits the value from the SDTM terminology publication file.

In the case where the codelist is not shared with SDTM Controlled Terminology the Codelist attribute shall not have a nciodm:CodeListExtensible attribute.

In case the Controlled Terminology file has a Context attribute value equal to “Submission”, then the nciodm:CodeListExtensible attribute in a CodeList is required with a value equal to “Yes” or “No”.

5. 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".

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

```
<?xml version="1.0" encoding="UTF-8"?>
<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"
  FileType="Snapshot"
  FileOID="CDISC_CT.SDTM.2021-12-17"
  Granularity="Metadata"
  CreationDateTime="2021-12-17T11:28:15"
  AsOfDateTime="2021-12-17T00:00:00"
  ODMVersion="1.3.2"
  Originator="CDISC XML Technologies Team (Terminology2ODM converter)"
  SourceSystem="NCI Thesaurus"
  SourceSystemVersion="2021-12-17"
  Context="Submission"
  nciodm:ControlledTerminologyVersion="1.2.0">
<Study OID="CDISC_CT.SDTM.2021-12-17">
  <GlobalVariables>
    <StudyName>CDISC SDTM ControlledTerminology</StudyName>
    <StudyDescription>CDISC SDTM Controlled Terminology, 2021-12-17</StudyDescription>
    <ProtocolName>CDISC SDTM Controlled Terminology</ProtocolName>
  </GlobalVariables>
  <MetaDataVersion OID="CDISC_CT_MetaDataVersion.SDTM.2021-12-17"
    Name="CDISC SDTM Controlled Terminology"
    Description="CDISC SDTM Controlled Terminology, 2021-12-17">

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

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

```
<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>1</nciodm:CDISCSynonym>
    <nciodm:CDISCSynonym>Grade 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>2</nciodm:CDISCSynonym>
    <nciodm:CDISCSynonym>Grade 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>3</nciodm:CDISCSynonym>
    <nciodm:CDISCSynonym>Grade 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>
```

6. Appendix: XML Schema

The XML Schema for Controlled Terminology extends the ODM v3.1.2 XML schema using the same pattern as that employed by the Define-XML 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.

The XML Schema files are available at the GitHub repository at: <https://github.com/cdisc-org/DataExchange-CT>.

Root schema: controlledterminology1-2-0.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"
  version="1.2.0">

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

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

</xs:schema>
```

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"
  version="1.2.0">

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

  <xs:redefine schemaLocation="../../../cdisc-odm-1.3.2/ODM1-3-2-foundation.xsd">

  <!-- ControlledTerminologyVersion as attribute for ODM - mandatory - fixed to "1.2.0" -->
  <xs:attributeGroup name="ODMAttributeExtension">
    <xs:attributeGroup ref="ODMAttributeExtension"/>
    <xs:attribute ref="nciodm:ControlledTerminologyVersion" use="required"/>
    <xs:attribute ref="nciodm:Context" use="required"/>
  </xs:attributeGroup>
</xs:redefine>
</xs:schema>
```

```

</xs:attributeGroup>

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

```

Namespace 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"
  version="1.2.0">

  <xs:import namespace="http://www.cdisc.org/ns/odm/v1.3"
    schemaLocation="../../cdisc-odm-1.3.2/ODM1-3-2-foundation.xsd"/>

  <xs:attribute name="Context" type="nciodm:ODMContext">
    <xs:annotation><xs:documentation>Context in which the Controlled Terminology
    document is used (Submission, Other).</xs:documentation></xs:annotation>
  </xs:attribute>

  <xs:attribute name="ControlledTerminologyVersion" type="odm:text" fixed="1.2.0">
    <xs:annotation><xs:documentation>The version of the CT-XML
    standard.</xs:documentation></xs:annotation>
  </xs:attribute>

  <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>

<!--
+=====+
| Simple Types/Enumerations                               |
+=====+
-->

  <xs:simpleType name="ODMContext">
    <xs:annotation>
      <xs:documentation>Context in which the Define-XML document is
used.</xs:documentation>
    </xs:annotation>
    <xs:restriction base="odm:text">
      <xs:enumeration value="Submission"/>
      <xs:enumeration value="Other"/>
    </xs:restriction>
  </xs:simpleType>

</xs:schema>

```