

Define.xml v1.0

Header, Study and MetaDataVersion Sections

ODM Versions – where it all began...

```
1 <?xml version="1.0" encoding="ISO-8859-1"?>
2
3 <?xml-stylesheet type="text/xsl" href="define.xsl"?>
4
5 <ODM xmlns="http://www.cdisc.org/ns/odm/v1.2"
6   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
7   xmlns:xlink="http://www.w3.org/1999/xlink"
8   xmlns:def="http://www.cdisc.org/ns/def/v1.0"
9   xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.2 define.xsd"
10  FileOID="SponsorCode+Projectnr+Trialno" <!--Example Unique File Identifier-->
11  ODMVersion="1.2"
12  FileType="Snapshot"
13  CreationDateTime = "2016-03-15T09:30:00">
```

define.xml v1.0

```
1 <?xml version="1.0" encoding="UTF-8"?>
2 <?xml-stylesheet type="text/xsl" href="../stylesheets/define2-0-0.xsl"?>
3
4 <!-- ***** File: define2-0-0-example-sdtm.xml *****-->
5 <ODM
6   xmlns="http://www.cdisc.org/ns/odm/v1.3"
7   xmlns:xlink="http://www.w3.org/1999/xlink"
8   xmlns:def="http://www.cdisc.org/ns/def/v2.0"
9   ODMVersion="1.3.2"
10  FileOID="www.cdisc.org.Studydisc01-Define-XML_2.0.0"
11  FileType="Snapshot"
12  CreationDateTime="2013-03-03T17:04:44"
13  Originator="CDISC XML Technologies Team"
14  SourceSystem="MH-System"
15  SourceSystemVersion="2.0.1"
16 >
```

define.xml v2.0

ODM Version vs Define.xml Specification

On CDISC.org published Versions...

ODM	Published		Define.xml	Published
1.3.2	??? 2013	←	2.0	Apr 2014
1.3.1	??? 2010	←	1.0	Feb 2005
1.3	May 2010 (2006?)	←		
1.2.1	Jan 2005	←		
1.2	Jan 2004	←		
1.1	Apr 2002	←		

A diagram illustrating the relationship between ODM versions and Define.xml specifications. A red arrow points from Define.xml 2.0 to ODM 1.3.2. Dashed blue arrows point from Define.xml 1.0 to ODM 1.3.1, 1.3, 1.2.1, 1.2, and 1.1. A large red question mark is placed between the two tables.

...and SDM-XML (Study/Trial Design Model)

...and Dataset-XML (Study/Trial Design Model)

How does all fit together?

Define.xml Header Section

```
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7 xmlns:xlink="http://www.w3.org/1999/xlink"
8 xmlns:def="http://www.cdisc.org/ns/def/v1.0"
9 xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.2 define1-0-0.xsd"
10 FileOID="SponsorCode+Projectnr+Trialno" <!--Example Unique File Identifier-->
11 ODMVersion="1.2"
12 FileType="Snapshot"
13 CreationDateTime = "2016-03-15T09:30:00">
14
15 <Study OID = "GCUG 0815-001">
25994 </ODM>
```

ODM XML Header Section (CRT-DDS-1-0-0*)

ODM Root Attributes	Status	Description
FileType	Required	Type of transmission. Valid value is "Snapshot".
FileOID	Required	An unique identifier for this file. See the ODM Specification for a discussion of FileOID recommendations.
CreationDateTime	Required	Date and Time when the define.xml file was <u>last modified</u> (datetime).
PriorFileOID	Optional	Reference to the previous file (if any). Relevant if FileType would be "Incremental" as e.g. for CDISC-LAB Model)
ODMVersion	Required	The ODM Version number For define v1.0 <u>always</u> "1.2" and for define.xml v2.0 <u>always</u> "1.3.2"
Originator	Optional	The organization that generated the define.xml file So far not used, but should be used if external data provider involved.
SourceSystem	Optional	The computer system, database management system, etc. that is the source of the define.xml information.
SourceSystemVersion	Optional	The version of the "SourceSystem" above.
ODM Child Element		
Study	Required	A logical collection of domains included within a submission.

* CRT-DDS = Case Report Tabulation Data Definition Specification

Define.xml Header Section

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6 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
7 xmlns:xlink="http://www.w3.org/1999/xlink"
8 xmlns:def="http://www.cdisc.org/ns/def/v1.0"
9 xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.2 definel-0-0.xsd"
10 FileOID="SponsorCode+Projectnr+Trialno" <!--Example Unique File Identifier-->
11 ODMVersion="1.2"
12 FileType="Snapshot"
13 CreationDateTime = "2016-03-15T09:30:00">
14
15 <Study OID = "GCUG 0815-001">
16
17 <GlobalVariables>
18
19 <MetaDataVersion OID="CDISC.SDTM.3.1.3" (plus NCI CT-Version? Or better Sponsor Standard version?)
20 Name="GCUG 0815-001, Data Definitions"
21 Description="German User Group Training"
22 def:DefineVersion="1.0.0"
23 def:StandardName="CDISC SDTM"
24 def:StandardVersion="3.1.3">
25
26 </Study>
27
28 </ODM>
```

ODM XML Header Section (CRT-DDS-1-0-0*)

Study Attributes	Status	Description
OID	Required	The unique ID of the Study.
Study Child Elements		
GlobalVariables	Required	Contains the global variables
MetadataVersion	Required	The MetaDataVersion metadata
MetaDataVersionAttributes		
OID	Required	The unique ID of the MetaDataVersion
Name	Required	Name of the MetaDataVersion
Description	Required	The description of the data definition document (e.g. "Study <insert>, Data Definitions").
def:DefineVersion	Required	The define.xml schema version used (e.g., "1.0.0")
def:StandardName	Required	Short name of the MetaDataVersion (e.g., "CDISC SDTM", "CDISC SEND", "CDISC ADaM")
def:StandardVersion	Required	The version of an external standard to which the data conforms (e.g., "3.1.0")

Global Variables Section

```
1  <?xml version="1.0" encoding="ISO-8859-1" ?>
2
3  <?xml-stylesheet type="text/xsl" href="define.xsl"?>
4
5  <ODM xmlns="http://www.cdisc.org/ns/odm/v1.2"
6  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
7  xmlns:xlink="http://www.w3.org/1999/xlink"
8  xmlns:def="http://www.cdisc.org/ns/def/v1.0"
9  xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.2 define1-0-0.xsd"
10 FileOID="SponsorCode+Projectnr+Trialno" <!--Example Unique File Identifier-->
11 ODMVersion="1.2"
12 FileType="Snapshot"
13 CreationDateTime = "2016-03-15T09:30:00">
14
15 <Study OID = "GCUG 0815-001">
16
17 <GlobalVariables>
18 <StudyName>GCUG 0815-001</StudyName>
19 <StudyDescription>WonderDrug 0-8-15 for German CDISC User Group</StudyDescription>
20 <ProtocolName>GCUG 0815-001</ProtocolName>
21 </GlobalVariables>
22
23 <MetaDataVersion OID="CDISC.SDTM.3.1.3"
24 Name="GCUG 0815-001, Data Definitions"
25 Description="German User Group Training"
26 def:DefineVersion="1.0.0"
27 def:StandardName="CDISC SDTM"
28 <def:StandardVersion="3.1.3">
25993 </Study>
25994 </ODM>
```


ODM XML Header Section (CRT-DDS-1-0-0*)

Global Variables Child Elements		
StudyName	Required	Name of the study
StudyDescription	Required	Description of the study
ProtocolName	Required	The protocol Name

Reminder - Special Characters in XML

XML has five characters that must be treated specially depending on where they appear in a document; that is, in some places they may not occur in their symbol form since they carry special meaning in XML.

Check any text (derivation rules etc.) before copy!

The five special characters are:

Ampersand	&	⇒	&
Apostrophe	'	⇒	'
Quote	“	⇒	"
Less than	<	⇒	<
Greater than	>	⇒	>

Thank You

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