Tables that show the variables in the CSV files in the context of the define.xml for ADaM

The file standard.csv is used to generate the standard definitions. Table 1 shows the variables in standard.csv.

Variable	Note	Context in Define.xml
OID	Required	<def:standard def:commentoid="COM.STDCT.02" name="CDISC/NCI" oid="STD.CT.02" publishingset="SDTM" status="Final" type="CT" version="2018-06-29"></def:standard>
Name	Required	<pre><def:standard def:commentoid="COM.STDCT.02" name="CDISC/NCI" oid="STD.CT.02" publishingset="SDTM" status="Final" type="CT" version="2018-06-29"></def:standard></pre>
Туре	Required	<def:standard def:commentoid="COM.STDCT.02" name="CDISC/NCI" oid="STD.CT.02" publishingset="SDTM" status="Final" type="CT" version="2018-06-29"></def:standard>
PublishingSet		<def:standard def:commentoid="COM.STDCT.02" name="CDISC/NCI" oid="STD.CT.02" publishingset="SDTM" status="Final" type="CT" version="2018-06-29"></def:standard>
Status	Required	<pre><def:standard def:commentoid="COM.STDCT.02" name="CDISC/NCI" oid="STD.CT.02" publishingset="SDTM" status="Final" type="CT" version="2018-06-29"></def:standard></pre>
Version	Required	<pre><def:standard def:commentoid="COM.STDCT.02" name="CDISC/NCI" oid="STD.CT.02" publishingset="SDTM" status="Final" type="CT" version="2018-06-29"></def:standard></pre>
CommentID		<def:standard def:commentoid="COM.STDCT.02" name="CDISC/NCI" oid="STD.CT.02" publishingset="SDTM" status="Final" type="CT" version="2018-06-29"></def:standard>
Comment		<def:commentdef oid="COM.STDCT.02"></def:commentdef>
		<description></description>
		<pre><translatedtext xml:lang="en">SDTM CT is applicable for variables copied from SDTM to ADaM.</translatedtext></pre>

Table 1. the Variables in standard.csv

The file arm.csv and arm2.csv are used to generate the analysis result metadata section. Table 2 shows the variables in arm.csv; table 3 shows the variables in arm2.csv.

Variable	Note	Context in Define.xml
ID	Required	<arm:resultdisplay name="Table 14-5.02" oid="RD.Table_14-5.02"></arm:resultdisplay>
Name	Required	<arm:resultdisplay name="Table 14-5.02" oid="RD.Table_14-5.02"></arm:resultdisplay>
Description	Required	<arm:resultdisplay <br="" oid="RD.Table_14-5.02">Name="Table 14-5.02"></arm:resultdisplay>
		<description></description>
		<pre><translatedtext xml:lang="en">Incidence of Treatment Emergent Serious Adverse Events by Treatment Group</translatedtext></pre>
Leaf	Required	<def:documentref leafid="LF.CSR" =""></def:documentref>
		<def:pdfpageref <br="" pagerefs="3">Type="PhysicalRef" Title="Table 14-5.02"/></def:pdfpageref>
PageRefs	Required	<def:documentref leafid="LF.CSR"></def:documentref>
		<def:pdfpageref <br="" pagerefs="3">Type="PhysicalRef" Title="Table 14-5.02"/></def:pdfpageref>
Туре	Required	<def:documentref leafid="LF.CSR"></def:documentref>
		<def:pdfpageref pagerefs="3" title="Table 14-5.02" type="PhysicalRef"></def:pdfpageref>
Title	Required	<def:documentref leafid="LF.CSR"></def:documentref>
		<def:pdfpageref <br="" pagerefs="3">Type="PhysicalRef" Title="Table 14-5.02"/></def:pdfpageref>

Table 2. the Variables in arm.csv

Name	Note	Context in Define.xml
OID	Required	<arm:resultdisplay <br="" oid="RD.Table_14-5.02">Name="Table 14-5.02"></arm:resultdisplay>
ID	Required	

		MEASURE">
Parameter		<arm:analysisresult analysispurpose="PRIMARY OUTCOME MEASURE" analysisreason="SPECIFIED IN SAP" oid="AR.Table_14-3.01.R.1" parameteroid="IT.ADQSADAS.PARAMCD"></arm:analysisresult>
AnalysisReason	Required	<arm:analysisresult analysispurpose="PRIMARY OUTCOME MEASURE" analysisreason="SPECIFIED IN SAP" oid="AR.Table_14-3.01.R.1" parameteroid="IT.ADQSADAS.PARAMCD"></arm:analysisresult>
AnalysisPurpose	Required	<arm:analysisresult analysispurpose="PRIMARY OUTCOME MEASURE" analysisreason="SPECIFIED IN SAP" oid="AR.Table_14-3.01.R.1" parameteroid="IT.ADQSADAS.PARAMCD"></arm:analysisresult>
AnalysisDescription	Required	<pre><description xml:lang="en"></description></pre>
CommentID		<arm:analysisdatasets def:commentoid="COM.JOIN-ADSL-ADAE"></arm:analysisdatasets>
Comment		<def:commentdef oid="COM.JOIN-ADSL-ADAE"> <pre></pre></def:commentdef>
		<pre><translatedtext xml:lang="en">Get denominators for percentages from ADSL and counts and numerators from ADAE. Join ADAE with ADSL based on the unique subject identifier (USUBJID) keeping only records in ADAE for the numerator.</translatedtext></pre> /TranslatedText>
Dataset	Required. If there are multiple datasets, separate them with semicolon.	<arm:analysisdataset itemgroupoid="IG.ADQSADAS"></arm:analysisdataset>
		ItemOID="IT.ADQSADAS.CHG"/>

Variable	Required. If there are multiple variables, enter them in the format DATASET.VARIABLE and separate them with semicolon.	<arm:analysisdataset itemgroupoid="IG.ADQSADAS"></arm:analysisdataset>
Documentation	Required	<arm:documentation></arm:documentation>
1		<description></description>
		<pre><translatedtext>Linear model analysis of CHG for dose response; using randomized dose (0 for placebo; 54 for low dose; 81 for high dose) and site group in model. Used PROC GLM in SAS to produce p- value (from Type III SS for treatment dose).</translatedtext></pre> /TranslatedText>
Document	Required	<def:documentref leafid="LF.CSR"></def:documentref>
		<pre><def:pdfpageref pagerefs="4" title="SAP Section 10.1.1" type="PhysicalRef"></def:pdfpageref></pre>
PageRefs	Required	<def:documentref leafid="LF.CSR"></def:documentref>
		<pre><def:pdfpageref pagerefs="4" title="SAP Section 10.1.1" type="PhysicalRef"></def:pdfpageref></pre>
Туре	Required	<def:documentref leafid="LF.CSR"></def:documentref>
		<pre><def:pdfpageref pagerefs="4" title="SAP Section 10.1.1" type="PhysicalRef"></def:pdfpageref></pre>
Title	Required	<def:documentref leafid="LF.CSR"></def:documentref>
		<pre><def:pdfpageref pagerefs="4" title="SAP Section 10.1.1" type="PhysicalRef"></def:pdfpageref></pre>
Context	Required	<arm:programmingcode context="SAS version 9.2"></arm:programmingcode>

	<arm:code>proc glm data = ADQSADAS;</arm:code>
	where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT";
	class SITEGR1;
	model CHG = TRTPN SITEGR1;
	run;
Code	<arm:programmingcode context="SAS version 9.2"></arm:programmingcode>
	<arm:code>proc glm data = ADQSADAS;</arm:code>
	where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT";
	class SITEGR1;
	model CHG = TRTPN SITEGR1;
	run;
File	<arm:programmingcode context="SAS version 9.2"></arm:programmingcode>
	<def:documentref leafid="LF.at14-5-02.sas"></def:documentref>

Table 3. the Variables in arm2.csv

The file defds.csv is used to create the IteGroupDef definition section. Table 4 shows the variables in the defds.csv.

Variable	Note	Context in Define.xml
Dataset	Required	<pre><itemgroupdef def:archivelocationid="LF.ADSL" def:commentoid="COM.ADSL" def:standardoid="STD.01" def:structure="one record per subject" isreferencedata="No" name="ADSL" oid="IG.ADSL" purpose="Analysis" repeating="No" sasdatasetname="ADSL"></itemgroupdef></pre>
Repeating	Required	<pre><itemgroupdef def:archivelocationid="LF.ADSL" def:commentoid="COM.ADSL" def:standardoid="STD.01" def:structure="one record per subject" isreferencedata="No" name="ADSL" oid="IG.ADSL" purpose="Analysis" repeating="No" sasdatasetname="ADSL"></itemgroupdef></pre>

IsReferenceData	Required	<itemgroupdef def:archivelocationid="LF.ADSL" def:commentoid="COM.ADSL" def:standardoid="STD.01" def:structure="one record per subject" isreferencedata="No" name="ADSL" oid="IG.ADSL" purpose="Analysis" repeating="No" sasdatasetname="ADSL"></itemgroupdef>
Purpose	Required	<itemgroupdef def:archivelocationid="LF.ADSL" def:commentoid="COM.ADSL" def:standardoid="STD.01" def:structure="one record per subject" isreferencedata="No" name="ADSL" oid="IG.ADSL" purpose="Analysis" repeating="No" sasdatasetname="ADSL"></itemgroupdef>
Standard	Required	<itemgroupdef def:archivelocationid="LF.ADSL" def:commentoid="COM.ADSL" def:standardoid="STD.01" def:structure="one record per subject" isreferencedata="No" name="ADSL" oid="IG.ADSL" purpose="Analysis" repeating="No" sasdatasetname="ADSL"></itemgroupdef>
Structure	Required	<itemgroupdef def:archivelocationid="LF.ADSL" def:commentoid="COM.ADSL" def:standardoid="STD.01" def:structure="one record per subject" isreferencedata="No" name="ADSL" oid="IG.ADSL" purpose="Analysis" repeating="No" sasdatasetname="ADSL"></itemgroupdef>
Label	Required	<pre><description></description></pre>
Class	Required	<def:class name="SUBJECT LEVEL ANALYSIS DATASET"></def:class>
SubClass		<def:class name="OCCURRENCE DATA STRUCTURE"></def:class>
Comment	Required	<def:commentdef oid="COM.ADSL"> <description> <translatedtext "en"="" ymlulang=""> Careen Failures</translatedtext></description></def:commentdef>
		<pre><translatedtext xml:lang="en">Screen Failures are excluded since they are not needed for this study analysis. See referenced dataset creation program and ADRG</translatedtext></pre>
Doc1	Required	<def:documentref leafid="LF.ADSL.PGM"></def:documentref>
		<def:documentref leafid="LF.ADRG"></def:documentref>
		<def:pdfpageref <br="" pagerefs="6">Type="PhysicalRef"/></def:pdfpageref>

Doc2	<def:documentref leafid="LF.ADSL.PGM"></def:documentref>
	<def:documentref leafid="LF.ADRG" =""></def:documentref>
	<def:pdfpageref pagerefs="6" type="PhysicalRef"></def:pdfpageref>
PageRef2	<def:documentref leafid="LF.ADSL.PGM"></def:documentref>
	<def:documentref leafid="LF.ADRG"></def:documentref>
	<def:pdfpageref pagerefs="6" type="PhysicalRef"></def:pdfpageref>
PageType2	<def:documentref leafid="LF.ADSL.PGM"></def:documentref>
	<def:documentref leafid="LF.ADRG"></def:documentref>
	<def:pdfpageref pagerefs="6" type="PhysicalRef"></def:pdfpageref>

Table 4. the Variables in defds.csv

The defvar.csv is also used to create the ItemGroupDef definition section. Table 5 shows the variables in this file.

Variable	Note	Context in Define.xml
Dataset	Required	<pre><itemref itemoid="IT.ADQSADAS.STUDYID" keysequence="1" mandatory="No" ordernumber="1"></itemref></pre>
Variable	Required	<pre><itemref itemoid="IT.ADQSADAS.STUDYID" keysequence="1" mandatory="No" ordernumber="1"></itemref></pre>
OrderNumber	Required	<itemref itemoid="IT.ADQSADAS.STUDYID" keysequence="1" mandatory="No" ordernumber="1"></itemref>
Mandatory	Required	<itemref itemoid="IT.ADQSADAS.STUDYID" keysequence="1" mandatory="No" ordernumber="1"></itemref>
KeySequence		<itemref itemoid="IT.ADQSADAS.STUDYID" keysequence="1" mandatory="No" ordernumber="1"></itemref>
Method		<itemref itemoid="IT.ADQSADAS.AVISIT" keysequence="4" mandatory="No" methodoid="MT.ADQSADAS.AVISIT" ordernumber="18"></itemref>

Туре	<pre><methoddef name="MT.ADQSADAS.AVISIT" oid="MT.ADQSADAS.AVISIT" type="Computation"></methoddef></pre>
	<description></description>
	<pre><translatedtext>Derived based on windowing algorithm described in SAP, Section 8.2</translatedtext></pre>

Table 5. the Variables in defvar.csv

The file defvar2.csv is used to create the ItemDef and ValueList definitions section. Table 6 shows the variables in devar2.csv.

Variable	Note	Context in Define.xml
Dataset	Required	<itemdef datatype="integer" def:displayformat="date9." length="5" name="TRTSDT" oid="IT.ADAE.TRTSDT" sasfieldname="TRTSDT"></itemdef>
Variable	Required	<itemdef datatype="integer" def:displayformat="date9." length="5" name="TRTSDT" oid="IT.ADAE.TRTSDT" sasfieldname="TRTSDT"></itemdef>
Paramcd	This is for value list definition section.	<itemref itemoid="IT.ADQSADAS.AVAL.ACITM01-
ACITM14" mandatory="No" ordernumber="1"></itemref>
Mandatory	This is for value list definition section.	<itemref itemoid="IT.ADQSADAS.AVAL.ACITM01-
ACITM14" mandatory="No" ordernumber="1"></itemref>
Order	This is for value list definition section.	<itemref itemoid="IT.ADQSADAS.AVAL.ACITM01-
ACITM14" mandatory="No" ordernumber="1"></itemref>
Method	This is for value list definition section.	<methoddef name="MT.ADQSADAS.AVAL.ACTOT" oid="MT.ADQSADAS.AVAL.ACTOT" type="Computation"></methoddef>

I		B
		<description></description>
		<translatedtext>Sum of ADAS scores for items 1, 2, 4, 5, 6, 7, 8, 11, 12, 13, and 14, see ADRG for details on adjusting for missing values.</translatedtext>
Document	This is for	<def:documentref leafid="LF.ADRG"></def:documentref>
	value list definition section.	<def:pdfpageref <br="" pagerefs="3">Type="PhysicalRef"/></def:pdfpageref>
PageRefs	This is for	<def:documentref leafid="LF.ADRG"></def:documentref>
	value list definition section.	<def:pdfpageref <br="" pagerefs="3">Type="PhysicalRef"/></def:pdfpageref>
Туре	This is for	<def:documentref leafid="LF.ADRG"></def:documentref>
	value list definition section.	<def:pdfpageref pagerefs="3" type="PhysicalRef"></def:pdfpageref>
Тур	This is for value list definition section.	<methoddef name="MT.ADQSADAS.AVAL.ACTOT" oid="MT.ADQSADAS.AVAL.ACTOT" type="Computation"></methoddef>
DataType	Required	<itemdef datatype="text" length="19" name="VISIT" oid="IT.ADQSADAS.VISIT" sasfieldname="VISIT"></itemdef>
Length		<itemdef datatype="text" length="19" name="VISIT" oid="IT.ADQSADAS.VISIT" sasfieldname="VISIT"></itemdef>
DisplayFormat		<itemdef datatype="float" def:displayformat="5.1" length="4" name="VISITNUM" oid="IT.ADQSADAS.VISITNUM" sasfieldname="VISITNUM" significantdigits="1"></itemdef>
SignificantDigits		<itemdef datatype="float" def:displayformat="5.1" length="4" name="VISITNUM" oid="IT.ADQSADAS.VISITNUM" sasfieldname="VISITNUM" significantdigits="1"></itemdef>
Comment		<def:commentdef oid="COM.ADQSADAS.AVISITN"></def:commentdef>
		<description></description>
		<pre><translatedtext xml:lang="en">Numeric code for AVISIT</translatedtext></pre>

Label	Required	<itemdef datatype="text" length="100" name="PARAM" oid="IT.ADQSADAS.PARAM" sasfieldname="PARAM"></itemdef>
		<description></description>
		<translatedtext xml:lang="en">Parameter</translatedtext
ValueList	If ValueList='Yes' then we need	<itemdef datatype="integer" length="3" name="AVAL" oid="IT.ADQSADAS.AVAL" sasfieldname="AVAL"></itemdef>
	to generate the	<description></description>
	ValueListOID.	<translatedtext xml:lang="en">Analysis Value</translatedtext>
		<def:valuelistref valuelistoid="VL.ADQSADAS.AVAL"></def:valuelistref>
Format		<itemdef datatype="text" length="1" name="ABLFL" oid="IT.ADQSADAS.ABLFL" sasfieldname="ABLFL"></itemdef>
		<description></description>
		<translatedtext xml:lang="en">Baseline Record Flag</translatedtext>
		<codelistref codelistoid="CL.Y_BLANK"></codelistref>
Origin	Required	<def:origin type="Predecessor"></def:origin>
		<description></description>
		<translatedtext xml:lang="en">QS.QSBLFL</translatedtext
Orgdtl		<def:origin type="Predecessor"></def:origin>
		<description></description>
		<translatedtext xml:lang="en">QS.QSBLFL</translatedtext
Source		<def:origin source="Sponsor" type="Assigned"></def:origin>

Table 6. the Variables in defvar2.csv

The files code.csv and codelist.csv are for the code list definition section.

Table 7 shows the variables in code.csv. Table 8 shows the variables in codelist.csv.

Variable	Note	Context in Define.xml
FMT	Required	<codelist datatype="text" def:standardoid="STD.CT.02" name="Sex" oid="CL.SEX"></codelist>
Fmtname	Required	<codelist datatype="text" def:standardoid="STD.CT.02" name="Sex" oid="CL.SEX"></codelist>
Fmtnci		<alias context="nci:ExtCodeID" name="C66731"></alias>
DataType	Required	<codelist datatype="text" def:standardoid="STD.CT.02" name="Sex" oid="CL.SEX"></codelist>
IsNonStandard		<codelist <br="" datatype="float" name="Visit
Number" oid="CL.VISITNUM">def:IsNonStandard="Yes"></codelist>
Standard		<codelist datatype="text" def:standardoid="STD.CT.02" name="Sex" oid="CL.SEX"></codelist>

Table 7. the Variables in code.csv

Variable	Note	Context in Define.xml
FMT	Required	<codelist <br="" datatype="float" name="Visit
Number" oid="CL.VISITNUM">def:IsNonStandard="Yes"></codelist>
CodedValue	Required, except for dictionary.	<codelist datatype="float" def:isnonstandard="Yes" name="Visit Number" oid="CL.VISITNUM"></codelist>
		<codelistitem <br="" codedvalue="1">OrderNumber="1"></codelistitem>
Valnci		<codelist datatype="text" def:standardoid="STD.CT.02" name="Sex" oid="CL.SEX"></codelist>
		<codelistitem codedvalue="F"></codelistitem>
		<decode></decode>
		<translatedtext>Female</translatedtext>
		<alias context="nci:ExtCodeID" name="C16576"></alias>
Rank		<codelist <br="" datatype="text" name="Disease
Duration Group" oid="CL.DURDISC">def:IsNonStandard="Yes"></codelist>
		<enumerateditem codedvalue="<12" rank="1"></enumerateditem>

	<enumerateditem codedvalue=">=12" rank="2"></enumerateditem>
OrderNumber	<codelist datatype="float" def:isnonstandard="Yes" name="Visit Number" oid="CL.VISITNUM"></codelist>
	<codelistitem codedvalue="1" ordernumber="1"></codelistitem>
Decoded	<codelist datatype="float" def:isnonstandard="Yes" name="Visit Number" oid="CL.VISITNUM"></codelist>
	<codelistitem codedvalue="1" ordernumber="1"></codelistitem>
	<decode></decode>
	<translatedtext>SCREENING 1</translatedtext>
Dictionary	<pre><codelist datatype="text" def:isnonstandard="Yes" name="Adverse Event Dictionary" oid="CL.AEDICT"></codelist></pre>
Version	<codelist datatype="text" def:isnonstandard="Yes" name="Adverse Event Dictionary" oid="CL.AEDICT"></codelist>
	<pre><externalcodelist dictionary="MedDRA" href="http://www.meddra.org/" version="8.0"></externalcodelist></pre>
Href	<codelist datatype="text" def:isnonstandard="Yes" name="Adverse Event Dictionary" oid="CL.AEDICT"></codelist>
	<externalcodelist dictionary="MedDRA" href="http://www.meddra.org/" version="8.0"></externalcodelist>

Table 8. the Variables in codelist.csv

The file leaf.csv is used to generate the leaf definition section. Table 9 shows the variables in leaf.csv.

Variable	Note	Context in Define.xml	
ID	Required	<def:leaf <="" id="LF.ADSL.PGM" td=""><td></td></def:leaf>	
		xlink:href="/programs/adsl-sas.txt">	
		<def:title>adsl.sas</def:title>	

File	Required	<def:leaf id="LF.ADSL.PGM" xlink:href="/programs/adsl-sas.txt"></def:leaf>
		<def:title>adsl.sas</def:title>
Name	Required	<def:leaf id="LF.ADSL.PGM" xlink:href="/programs/adsl-sas.txt"></def:leaf>
		Allikimer ilyprogramo, adoreste s
		<def:title>adsl.sas</def:title>

Table 9. the Variables in leaf.csv

The file where_clause.csv is used to generate the WhereClause definition section. Table 10 shows the variables in where_clause.csv.

Variable	Note	Context in Define.xml
ID	Required	<def:whereclausedef oid="WC.ADQSADAS.DTYPE.ACITM01-ACITM14"></def:whereclausedef>
Dataset	Required	<pre><def:whereclausedef oid="WC.ADQSADAS.DTYPE.ACITM01-ACITM14"></def:whereclausedef></pre>
		<rangecheck comparator="NE" def:itemoid="IT.ADQSADAS.PARAMCD"></rangecheck>
		<checkvalue>ACTOT</checkvalue>
Variable	Required	<def:whereclausedef OID="WC.ADQSADAS.DTYPE.ACITM01-ACITM14"></def:whereclausedef
		<rangecheck comparator="NE" def:itemoid="IT.ADQSADAS.PARAMCD"></rangecheck>
		<checkvalue>ACTOT</checkvalue>
Comparator	Required	<def:whereclausedef OID="WC.ADQSADAS.DTYPE.ACITM01-ACITM14"></def:whereclausedef
		<rangecheck <br="" comparator="NE">def:ItemOID="IT.ADQSADAS.PARAMCD"></rangecheck>
		<checkvalue>ACTOT</checkvalue>

CheckValue	Required. If	<def:whereclausedef< th=""></def:whereclausedef<>
	there are	OID="WC.ADQSADAS.DTYPE.ACITM01-ACITM14">
	multiple values, separate them with	<rangecheck <br="" comparator="NE">def:ItemOID="IT.ADQSADAS.PARAMCD"></rangecheck>
		<checkvalue>ACTOT</checkvalue>
semicolon.		

Table 10. the Variables in where_clause.csv