



SI04 - Analysis Results Metadata 1.0 for Define-XML 2.0 - Benefits to Statistical Analysis

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Analysis Results Metadata for Define-XML?

Purpose of Analysis Results Metadata (ARM)

Generation Method

Conclusions

Q&A



Analysis Results Metadata for Define-XML?

■ *Metadata = definition of data*

■ *CDISC Define-XML*

- *Study Metadata (CDISC & Non-CDISC)*
- *Machine Readable (XML) → Data Exchange*
- *Review by Authorities*

Analysis Results Metadata for Define-XML?

■ *Analysis Results Metadata (ARM) ?*
= *ADaM Define-XML Extension*

■ *Results Description*

- *What ?*
- *How ?*
- *Where ?*

Advantages

■ *Multiple Advantages*

- *Reusable (similar studies)*
- *Added Value: Improve Review, Add information*

■ *Traceability*



Analysis Results Metadata for Define-XML?



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Data *Transparency*

« ***Traceability*** is the ability to track an element, a piece of data, to its origin. »



Data *Understanding*

Traceability

■ *Relationship : analysis results - analysis datasets - SDTM domains*

■ *Path : element - immediate predecessor*

■ *Metadata traceability*

- *Analysis Result – Dataset*
- *Analysis Variable – Source*

■ *Data point traceability*

- *Predecessor*

Table 1 Demographic Data - Per-Protocol

	Treatment 1	Treatment 2
Baseline body mass index (BMI) [kg/m ²]		
N	167	167
Mean	29.08	29.04
SD	4.54	4.80
Min	20.3	16.0
Median	28.69	28.47
Max	40.1	41.2
Baseline BMI (categorical) [N (%)]		
<25 kg/m ²	41 (24.6%)	71 (21.1%)
25~30 kg/m ²	60 (35.9%)	130 (38.7%)
>=30 kg/m ²	66 (39.5%)	135 (40.2%)

Q5=Questionnaires	
CDISC Study CDISC01	Assessment Date: 09/07/2016
CDISC MINI-MENTAL STATE EXAMINATION (MMSE) SUMMARY PAGE	
Instructions: Please transcribe the appropriate scores from the MMSE workbook into the boxes below.	
Future Implies: CDISC TEST PATIENT or SUPPLIER	
A. ORIENTATION	
1. TIME: The range of scores is 0 to 5.	ORIGORRES when Q5TESTCD = MMSE1A Score (total number of correct responses)
2. PLACE: The range of scores is 0 to 5.	ORIGORRES when Q5TESTCD = MMSE1A Score (total number of correct responses)
B. REGISTRATION: The range of scores is 0 to 3.	ORIGORRES when Q5TESTCD = MMSE1B Score (total number of correct responses)
C. ATTENTION AND CALCULATION: The range of scores is 0 to 5.	ORIGORRES when Q5TESTCD = MMSE1C Score (total number of correct responses)
D. RECALL: The range of scores is 0 to 3.	ORIGORRES when Q5TESTCD = MMSE1D Score (total number of correct responses)
E. LANGUAGE: The range of scores is 0 to 9.	ORIGORRES when Q5TESTCD = MMSE1E Score (total number of correct responses)
ORIGORRES when Q5TESTCD = MMSE1F	
Sum of Scores for Sections A through E 	

	STUDYID	SUBSID	SUBID	BMI	BMIGR1	BMIGRIN	BMIGR2	BMIGR2N
2	9999-0001	9999-0001-00001	000001	27.77777778 <30 kg/m ²	1	25-30 kg/m ²	2	2
3	9999-0001	9999-0001-000002	000002	25.50361502 <30 kg/m ²	1	25-30 kg/m ²	2	2
4	9999-0001	9999-0001-000003	000003	26.15194521 <30 kg/m ²	1	25-30 kg/m ²	2	2
5	9999-0001	9999-0001-000004	000004	35.15626 >30 kg/m ²	2	>30 kg/m ²	3	3
6	9999-0001	9999-0001-000005	000005	30.99999999 >30 kg/m ²	2	>30 kg/m ²	3	3
7	9999-0001	9999-0001-000006	000006	36.857816396 >30 kg/m ²	2	>30 kg/m ²	3	3
8	9999-0001	9999-0001-000007	000007	25.626464281 <30 kg/m ²	1	25-30 kg/m ²	2	2
9	9999-0001	9999-0001-000008	000008	30.13086628 >30 kg/m ²	2	>30 kg/m ²	3	3
10	9999-0001	9999-0001-000009	000009	32.26982683 >30 kg/m ²	2	>30 kg/m ²	3	3
11	9999-0001	9999-0001-000010	000010	28.87613387 <30 kg/m ²	1	25-30 kg/m ²	2	2
12	9999-0001	9999-0001-000011	000011	33.72387383 <30 kg/m ²	2	25-30 kg/m ²	3	3
13	9999-0001	9999-0001-000012	000012	27.4688168 <30 kg/m ²	1	25-30 kg/m ²	2	2
14	9999-0001	9999-0001-000013	000013	32.71981983 >30 kg/m ²	2	>30 kg/m ²	3	3
15	9999-0001	9999-0001-000014	000014	28.719723183 <30 kg/m ²	1	25-30 kg/m ²	2	2
16	9999-0001	9999-0001-000015	000015	32.270420377 >30 kg/m ²	2	>30 kg/m ²	3	3

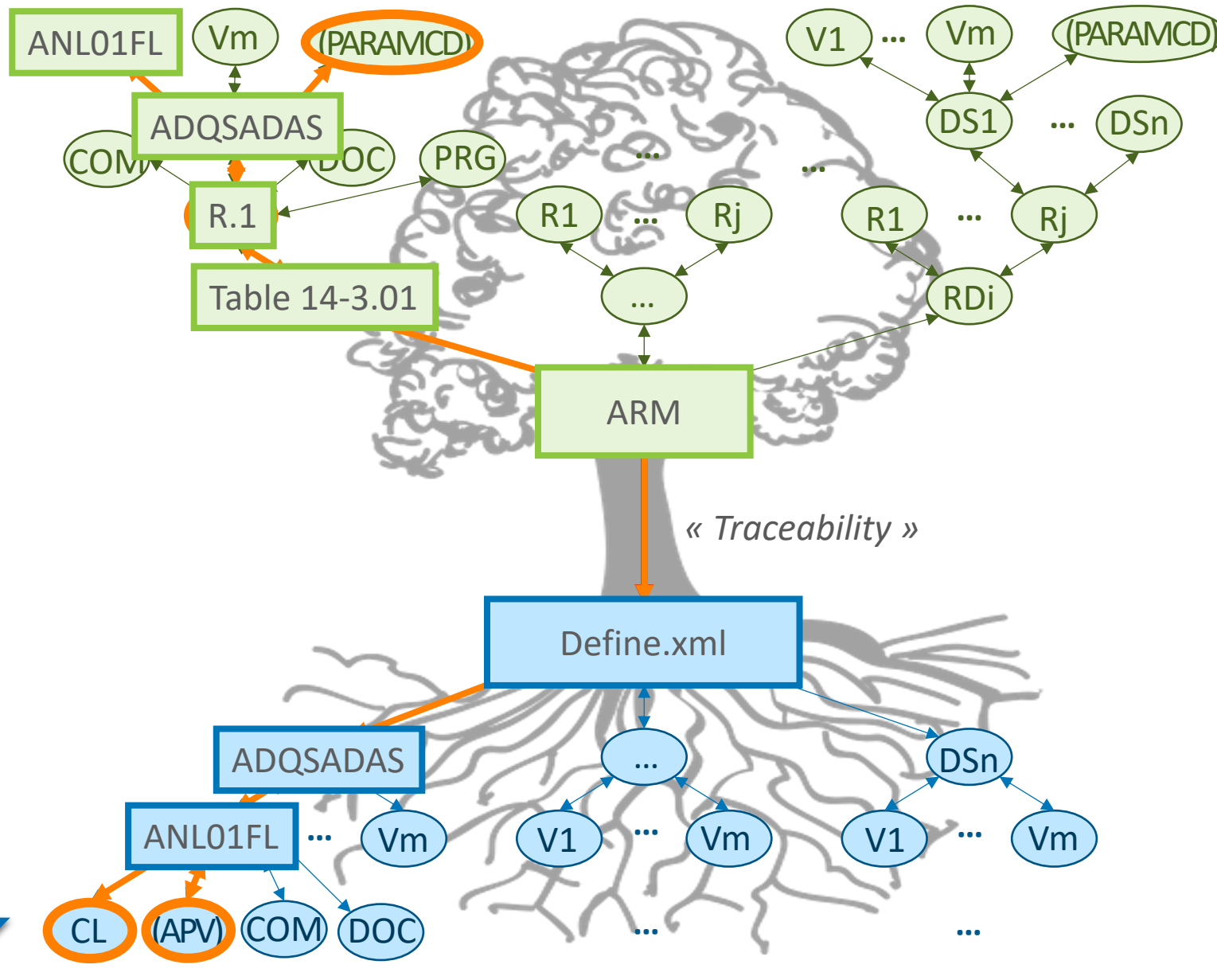
[illegible][illegible]



Branches + Leaves

Trunk

Roots



ARM (Analysis Result Metadata)

RD (Result Display)

R (Result)

DS (DataSet)

V (Variable)

COM (Comments)

DOC (Documents)

APV (Analysis Parameter Value)

CL (Codelist)

PRG (Program)



Analysis Results Metadata for Define-XML?



Purpose of Analysis Results Metadata (ARM)



Generation Method

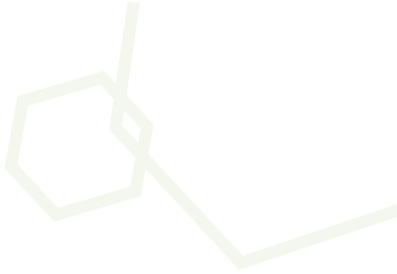


Conclusions



Q&A





Generation Method:

« How to build ARM ? »



Generation Method: « How to build ARM ? »

■ Two Choices

- A. *Direct Map to Define-XML v2.0 (1 Document)*

High structure complexity

Time Consuming

- B. *Transform (2 Documents)*

1) « *Human Readable* » ARM Metadata Specifications + Study Metadata

2) *Transformation to Metadata Compatible with Define-XML v2.0*

■ Advantages: « User Friendly »

- *Lower structure complexity*
- *Readable* (less columns, less rows per result)
- *Time gain*

Practical Example (1)

Table 14-3.01 Display Identifier - Document link & Page(s)/Section	
Display	Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
Analysis Result	Dose response analysis for ADAS-Cog changes from baseline
Analysis Parameter(s)	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)
Analysis Variable(s)	CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADQSADAS [PARAMCD = "ACTOT" and AVISIT = "Week 24" and EFFFL = "Y" and ANL01FL = "Y"]
Documentation	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). SAP Section 10.1.1
Programming Statements	[SAS version 9.2] proc glm data = ADQSADAS; where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run;

Description

Result Description (one Display Identifier to many Result Display)

Parameters

Analysis Variable

Analysis Reason

Analysis Purpose

Datasets & Selection Criteria
Join Description

Documentation Description - Reference & Document link & Page(s)/Selection

Programming Statement OR Program File
+ Programming Language and Version

Practical Example (2)

Table 14-3.01 « one-to-many »

Display	Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)					
Analysis Result	Dose response analysis for ADAS-Cog changes from baseline					
Analysis Parameter(s)	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)					
Analysis Variable(s)	CHG (Change from Baseline)					
Analysis Reason	SPECIFIED IN SAP					
Analysis Purpose	PRIMARY OUTCOME MEASURE					
DisplayIdentifier	xlinkDocument	Page(s)/Section	Description	ResultDescription	Analysis Reason	Analysis Purpose
Table 14-3.01	csr.pdf	1	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE
						ADQSADAS
						CHG
Statements			<pre>proc glm data = ADQSADAS; where EFFF1='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run;</pre>			

Practical Example (3)

Table 14-3.01

Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)							
Display	DisplayIdentifier	Join Description	Selection Criteria	Documentation	DOC-REF	Page(s)/Section	xlinkDOC-REF
Analysis	Table 14-3.01			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).			
Analysis							
Analysis			ADQSADAS [PARAMCD="ACTOT" and AVISIT="Week 24" and EFFF="Y" and ANL01FL="Y"]		SAP Section 10.1.1	42	sap.pdf
Analysis							
Data References (incl. Selection Criteria)	ADQSADAS [PARAMCD = "ACTOT" and AVISIT = "Week 24" and EFFF = "Y" and ANL01FL = "Y"]						
Documentation	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). SAP Section 10.1.1						
Programming Statements	[SAS version 9.2] <pre>proc glm data = ADQSADAS; where EFFF='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run;</pre>						

Practical Example (4)

Table 14-3.01

Display	Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)			
Analysis Result	Dose response analysis for ADAS-Cog changes from baseline			
Analysis Parameter(s)	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)			
Analysis Variable(s)	CHG (Change from Baseline)			
Analysis Reason				
Analysis Purpose	DisplayIdentifier ▾	Programming Statement ▾	Programming Language and Version ▾	Program ▾
Data References				
Selection Criteria				
Documentation	Table 14-3.01	<pre>proc glm data = ADQSADAS; where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run;</pre>	SAS version 9.2	model. Used PROC
Programming Statements	<pre>[SAS version 9.2] proc glm data = ADQSADAS; where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run;</pre>			

Practical Example (5)

« Human friendly » ARM Specifications:

1 Result – 1 Row – 1 « group » of Selection Criteria per dataset – 19 Columns: i.e. 1 group of selection criteria, 1 dataset

DisplayIdentifier	xlinkDocument	Page(s)/Section	Description	ResultDescription	Analysis Reason	Analysis Purpose	Dataset(s)	Analysis Variable	Join Description	Selection Criteria	Documentation
Table 14-3.01	csr.pdf		Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE	ADQSADAS	CHG		ADQSADAS (PARAMCD="ACTOT" and AVISIT="Week 24" and EFFFL="Y" and ANL01FL="Y")	Linear model analysis of CHG for using randomized dose (0 for placebo; 81 for high dose) and site. Used PROC GLM in SAS to produce (from Type III SS for treatment d

ARM Specifications Define-XML 2.0:

1 Result – n Rows per group of Selection Criteria per dataset – 32 Columns: i.e. 4 rows for 1 group of selection criteria for 1 dataset

ResultDisplayOID	Name	Lang	Description	OID	AnalysisDescription	AnalysisReason	AnalysisPurpose	defItemOID	Comparator	CheckValue	Soft	Hard	DocumentsLeaf	Type	PageRefs	FirstPage	LastPage	Docu
RD.T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR.T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE	IT.ADQSADAS.PARAMCD	EQ	ACTOT	Soft		LF.T14301	PhysicalRef	1			LF.SA
RD.T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR.T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE	IT.ADQSADAS.AVISIT	EQ	Week 24	Soft		LF.T14301	PhysicalRef	1			LF.SA
RD.T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR.T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE	IT.ADQSADAS.EFFFL	EQ	Y	Soft		LF.T14301	PhysicalRef	1			LF.SA
RD.T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR.T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE	IT.ADQSADAS.ANL01FL	EQ	Y	Soft		LF.T14301	PhysicalRef	1			LF.SA

ADaM Metadata Specifications + ARM Specifications

ADaM Metadata Specifications Reworked With Metadata Specifications (included)

DisplayIdentifier	LinkDocument	Page(s)/Section	Description	ResultDescription	Analysis Reason	Analysis Purpose	Dataset(s)	Analysis Variable	Join Description	Selection Criteria
Table 14-3.01	csr.pdf		Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE	ADQSADAS	CHG		ADQSADAS [PARAMCD="ACTOT" AVISIT="Week 24" and EFFFL="Y" ANDLOJFL="Y"]



ResultDisplayOID	Name	Lang	Description	OID	AnalysisDescription	AnalysisReason	AnalysisPurpose	defCommentOID	ItemGroupOID	ParameterOID	ItemOID	WhereClauseOID
RD_T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR_T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE		IG.ADQSADAS	IT.ADQSADAS.PARAMCD	IT.ADQSADAS.CHG	WC_T_14301.R.1.ADQSADAS
RD_T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR_T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE		IG.ADQSADAS	IT.ADQSADAS.PARAMCD	IT.ADQSADAS.CHG	WC_T_14301.R.1.ADQSADAS
RD_T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR_T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE		IG.ADQSADAS	IT.ADQSADAS.PARAMCD	IT.ADQSADAS.CHG	WC_T_14301.R.1.ADQSADAS
RD_T_14301	Table 14-3.01	en	Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	AR_T_14301.R.1	Dose response analysis for ADAS-Cog changes from baseline	SPECIFIED IN SAP	PRIMARY OUTCOME MEASURE		IG.ADQSADAS	IT.ADQSADAS.PARAMCD	IT.ADQSADAS.CHG	WC_T_14301.R.1.ADQSADAS

Define-XML v2.0



ADaM-IG 1.0

- Analysis Data Reviewer's Guide
- Analysis Results Metadata
- Analysis Datasets
- Parameter Value Level Metadata
- Controlled Terminology
- Analysis Derivations
- Comments

Date of Define-XML document generation: 2015-01-27T11:51:00
Stylesheet version: 2015-01-16

Standard ADaM-IG 1.0
Study Name CDISC-Sample
Study Description CDISC-Sample Data Definition
Protocol Name CDISC-Sample
Metadata Name Study CDISC-Sample, Data Definitions
Metadata Description Study CDISC-Sample, Data Definitions

Analysis Results Metadata (Summary) for Study CDISC-Sample

Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
Dose response analysis for ADAS-Cog changes from baseline

Analysis Results Metadata (Detail) for Study CDISC-Sample

Display	Table 14-3.01. Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
Analysis Result	Dose response analysis for ADAS-Cog changes from baseline
Analysis Parameter(s)	PARAMCD = "ACTOT" (ADAS-Cog(11) Subscore)
Analysis Variable(s)	CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (Ind. Selection Criteria)	ADQSADAS [PARAMCD = "ACTOT" and AVISIT = "Week 24" and EFFFL = "Y" and ANDLOJFL = "Y"]
Documentation	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). SAP Section 10.1.1
Programming Statements	[SAS version 9.2] proc glm data = ADQSADAS; where EFFFL="Y" and ANDLOJFL="Y" and AVISIT="Week 24" and PARAMCD="ACTOT"; class SITEGR1; model CHG = SITEGR1; run;

- Analysis Data Reviewer's Guide
- Analysis Results Metadata
- Analysis Datasets
- Parameter Value Level Metadata
- Controlled Terminology
- Analysis Derivations
- Comments

Standard	ADaM-IG 1.0
Study Name	CDISC-Sample
Study Description	CDISC-Sample Data Definition
Protocol Name	CDISC-Sample
Metadata Name	Study CDISC-Sample, Data Definitions
Metadata Description	Study CDISC-Sample, Data Definitions

Analysis Results Metadata (Summary) for Study CDISC-Sample

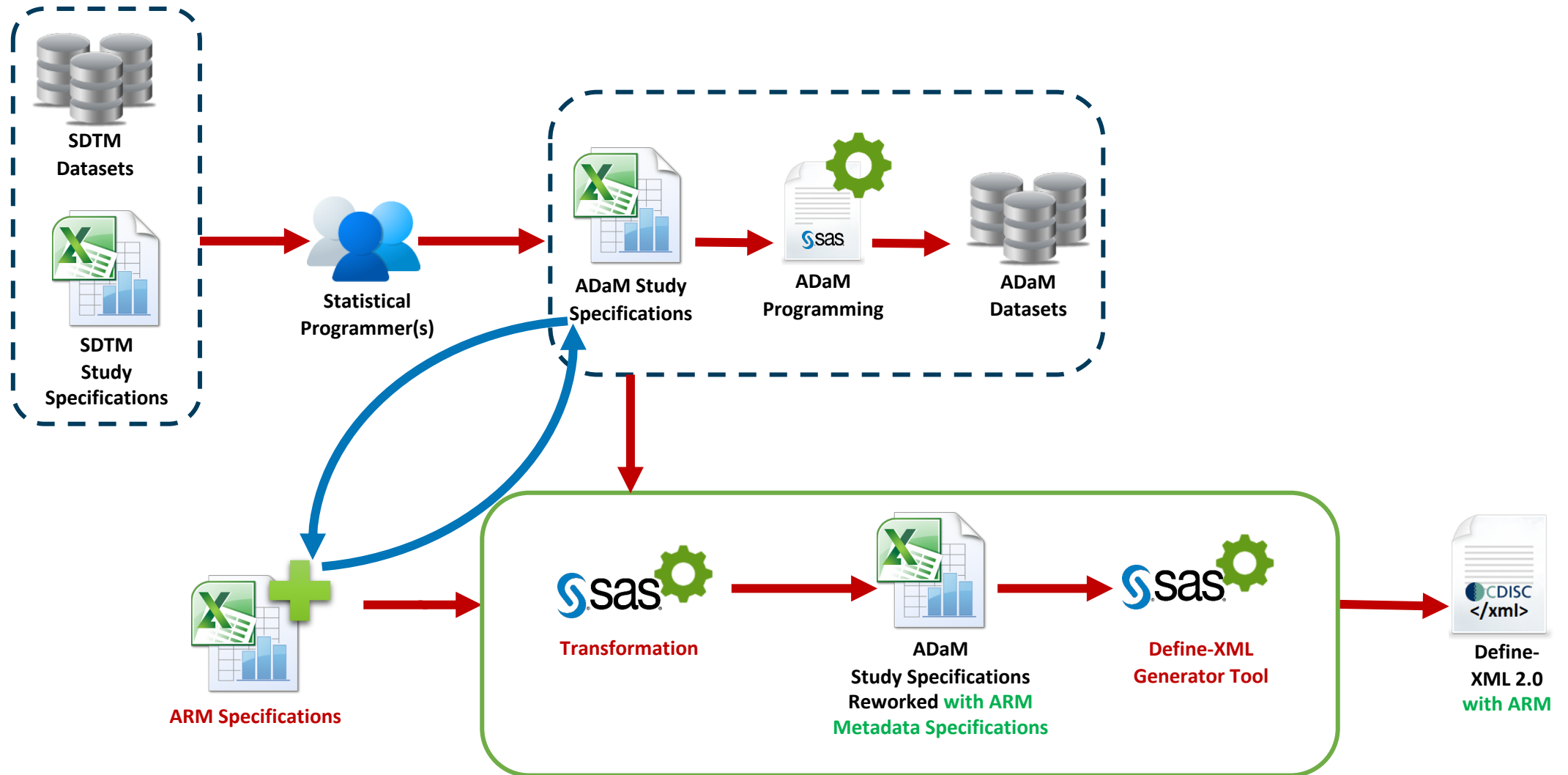
[Table 14-3.01](#) Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
[Dose response analysis for ADAS-Cog changes from baseline](#)

Analysis Results Metadata (Detail) for Study CDISC-Sample

Table 14-3.01

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Analysis Variable(s)	CHG (Change from Baseline)
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Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADQSADAS [PARAMCD = "ACTOT" and AVISIT = "Week 24" and EFFFL = "Y" and ANL01FL = "Y"]
Documentation	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). SAP Section 10.1.1
Programming Statements	[SAS version 9.2] proc glm data = ADQSADAS; where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRIPN SITEGR1; run;

Process Overview



Generation Method

Challenges

- *Traceability*
- *Completion*
- *Display*

Loss of Traceability (1)

■ Root missing !

- Selection Criteria
- Analysis Variable(s)
- Analysis Parameter(s)

i.e. ADQSADAS
[PARAMCD="ACTOT" and
AVISIT="Week 24" and
EFFFL="Y" and
ANL01FL="Y"]

ADAS-Cog Analysis (ADQSADAS) [Location: adqsadas.xpt]

Variable	Label	Key	Type	Length / Display Format	Controlled Terms or Format	Source/Derivation/ Comment
STUDYID	Study Identifier	1	text	12		Predecessor: ADL.STUDYID
SITEID	Study Site Identifier		text	3		Predecessor: ADL.SITEID
USUBJID	Unique Subject Identifier	2	text	11		Predecessor: ADL.USUBJID
TRTP	Planned Treatment		text	20	["Placebo", "Xanomeline Low Dose", "Xanomeline High Dose"] <Actual Treatment>	Predecessor: ADL.TRTP
TRTPN	Planned Treatment (N)		integer	8	[0 = "Placebo", 54 = "Xanomeline Low Dose", 81 = "Xanomeline High Dose"] <Actual Treatment (N)>	Predecessor: ADL.TRTPN
AGE	Age		integer	8		Predecessor: ADL.AGE
RACE	Race		text	32	["WHITE", "BLACK OR AFRICAN AMERICAN", "ASIAN", "AMERICAN INDIAN OR ALASKA NATIVE"] <Race>	Predecessor: ADL.RACE
RACEN	Race (N)		integer	8	[1 = "WHITE", 2 = "BLACK OR AFRICAN AMERICAN", 6 = "AMERICAN INDIAN OR ALASKA NATIVE", 7 = "ASIAN"] <Race (N)>	Predecessor: ADL.RACEN
SEX	Sex		text	1	["F" = "Female", "M" = "Male", "U" = "Unknown"] <Sex>	Predecessor: ADL.SEX
EFFFL	Efficacy Population Flag		text	1	["N" = "No", "Y" = "Yes"] <No Yes Response>	Predecessor: ADL.FASFL
AVISIT	Analysis Visit	4	text	16	["Baseline", "Week 8", "Week 16", "Week 24"] <Analysis Visit>	Derived:
AVISITN	Analysis Visit (N)		integer	8	[0 = "Baseline", 8 = "Week 8", 16 = "Week 16", 24 = "Week 24"] <Analysis Visit (N)>	Assigned: Numeric code for AVISIT
VISIT	Visit Name		text	19	Visit	Predecessor: QS.VISIT
VISITNUM	Visit Number		float	8	Visit Number	Predecessor: QS.VISITNUM
ADY	Analysis Relative Day		integer	8		Derived:
ADT	Analysis Date	5	integer	date9.		Derived:
PARAM	Parameter		text	100	ADAS-Cog Parameter	Assigned:
PARAMCD	Parameter Code	3	text	8	ADAS-Cog Parameter Code	Assigned:
AVAIL	Analysis Value		integer	8		
BAS	Baseline Value		integer	8		Derived:
CHG	Change from Baseline		integer	8		Derived:
PCHG	Percent Change from Baseline		integer	8		Derived:
ABLFL	Baseline Record Flag		text	1	["Y" = "Yes"] <No Yes Response - Y subset>	Predecessor: QS.QSBLFL

Loss of Traceability (2)

Analysis Results Metadata (Detail) for Study CDISC-Sample

Table 14-3.01

Display	Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
Analysis Result	Dose response analysis for ADAS-Cog changes from baseline
Analysis Parameter(s)	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)
Analysis Variable(s)	CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADQSADAS [PARAMCD = "ACTOT" and AVISIT = "Week 24" and EFFFL = "Y" and =] = Missing Root
Documentation	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). SAP Section 10.1.1
Programming Statements	[SAS version 9.2] proc glm data = ADQSADAS; where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; class SITEGR1; model CHG = TRTPN SITEGR1; run;

Completion

■ Selection Criteria: *Expressions not allowed*

- *i.e. $0 < AVAL < 25$*

⇒ *$AVAL > 0$ and $AVAL < 25$*

- *i.e. $(AVISIT\ IN\ ('Week\ 12'\ 'Week\ 24'))$ as $AVISIT$*

⇒ *$AVISIT\ IN\ ('Week\ 12'\ 'Week\ 24')$*

⇒ *Must remain **simple***

■ Selection Criteria: *Not Existing variables or datasets*

■ Programming statements: *Length, indentation, spaces, etc.*

Display (1)

Programming Statements

1

[SAS version 9.2]

```
proc glm data = ADQSADAS;  
  where EFFFIL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT";  
  class SITEGR1;  
  model CHG = TRTPN SITEGR1;  
run;
```

Programming Statements

2

[SAS version 9.2]

```
proc glm data = ADQSADAS;           where EFFFIL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT";           class SITEGR1;
```



Display (2)

■ *Solution in Stylesheet (xsl): Blank Space*

Before

```
.code{  
  font-family:"Courier New", monospace, serif;  
  font-size:1.2em;  
  line-height:150%;  
  white-space:pre;  
  display:block;  
  vertical-align:top;  
  padding:5px;  
}
```

After

```
.code{  
  font-family:"Courier New", monospace, serif;  
  font-size:1.2em;  
  line-height:100%;  
  white-space:pre-wrap;  
  display:block;  
  vertical-align:top;  
  padding:5px;  
}
```

Display (2)

■ *Solution in Stylesheet (xsl): Blank Space*

Programming Statements	[SAS version 9.2] proc glm data = ADQSADAS; class SITEGR1; where EFFFIL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT"; model CHG = TRTPN SITEGR1; run; 
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Analysis Results Metadata for Define-XML?



Purpose of Analysis Results Metadata (ARM)



Generation Method



Conclusions



Q&A



Conclusions

- ✓ *Study Traceability Improvement*
 - ✓ *Data Transparency and Understanding*
- ✓ *Added Value for Sponsors*
 - ✓ *Easier Review*
- ✓ *« Reusable » in similar studies*
- ✓ *Method: Time gain*



Questions...



ROI²
return on investment
through
return on information

 **Business & Decision**
Life **Sciences**

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