

Creating ARM using Visual Define-XML Editor

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Analysis Results Metadata

What is ARM?

ARM stands for Analysis Results Metadata. Similar to how Define-XML describes ADaM or SDTM datasets, ARM describes tables and figures.

Purpose

- Describe key outputs supporting study endpoints
- Provide additional information for reviewers
- Clarify complex statistical methods

Structure

- Extension of Define-XML standard
- Compatible with Define-XML versions 2.0 and 2.1
- Table or figure is represented by a result display, which contains one or more analysis results (e.g., specific summary in a table)

Data and Metadata

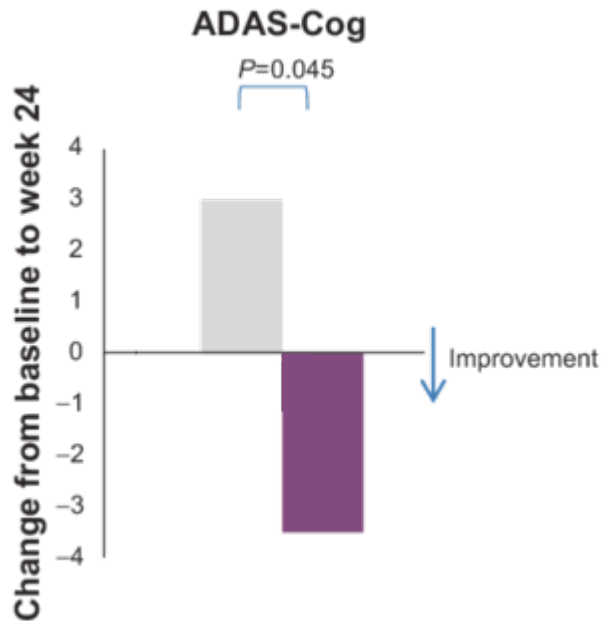


Figure 14-3.01

Display	Figure 14-3.01 [2] 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)	ADQSADAS.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; 1 for treatment) in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose). SAP Section 10.1.1 [4]
Programming Statements	[SAS version 9.4] proc glm data = adQsAdas; where effFl='Y' and anl01Fl='Y' and aVisit='Week 24' and paramCd="ACTOT"; model chg = trtPn; run;

Common ARM Issues

Selection Criteria

- Limitation of Define-XML where clauses:
where `<condition1>` [and `<condition2>` and `<condition3>` ...]

where `aVisit > 1` or `aBIFI = "Y"`



where `anIO1FI = "Y"`

Common ARM Issues

Selection Criteria

- Lack of supportive variables

Condition: $\langle \text{Variable} \rangle \langle = | \neq | < | \leq | \geq | > | \text{IN} | \text{NOTIN} \rangle \langle \text{Value(s)} \rangle$

where $\text{prxMatch} (\text{"/total/"}, \text{paramCd})$
and $\text{compFuzz} ((\text{aval} - \text{base}) / \text{base}, 0.1) = 1$



where $\text{paramCat1} = \text{"TOTAL"}$ and $\text{pChgCat1} = \text{"10%"}$

Common ARM Issues

Programming code

```
proc LIFETEST DATA= %if &TYPE eq pfs %Then %DO;
%if &tab = 3.15 %then %do;
    alpha = 0.01 CONFTYPE = loglog
%end; %else %if &tab ^= 3.10 %then %DO; alpha = 0.025
confBAND = Hw %end;
%else %if &sens ~= 1 %then %do; ALPHA=0.025 %end;
%if &tab = 3.17 %then %do;
    confBAND = Hw %end; outSurv = tab_&crit. ;
%if %upcase( &group ) = AGE %then %do; STRATA = &group.; %end;
time &var. = &cnsr ( 0 %if &paramCd. = TOS %THEN %DO;1 %end; %else
%do; 0 %end;)
RUN;
```

Common ARM Issues

Programming code

```
%justDolt( tabNum=3.11 );
```

The programming code should allow to understand how the results were calculated and replicate them if needed.

- Write a readable programming code
- Use consistent coding style
- Add meaningful comments

ARM Timeline

Initial Preparation

Identify a list of outputs for which ARM will be created

Writing Code

Write clear and readable code
Follow a style guide
Add meaningful comments

ADaM

Define-XML

Before
Programming

Dataset Development

TLF

Writing ARM

Follow the analysis-ready principle when creating datasets, especially for those used by ARM outputs

Link outputs and datasets
Reference SAP and other documentation
Provide details for statistical methods used

Visual Define-XML Editor

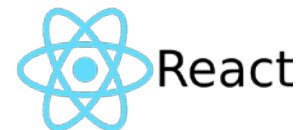
Visual Define-XML Editor

VDE is an independent open-source project with a goal to simplify Define-XML writing process.

- Supports Define-XML 2.0 and ARM 1.0 standards
- What you see is what you get
- Enhanced editing and review features
- Integration with CDISC Library
- Built-in browser for CDISC Standards and NCI/CDISC Controlled Terminology



ELECTRON



<https://github.com/defineEditor/editor>

Creating ARM

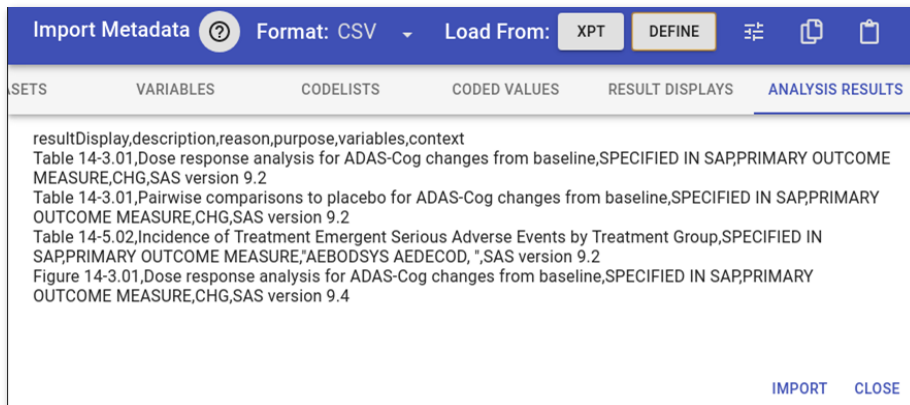
- Write from scratch
- Copy within the same Define-XML
- Copy between Define-XMLs
 - Update referenced documents
 - Some of variables might not be present in the target Define-XML
 - Create a library of ARM outputs

The screenshot shows a web-based form for adding an analysis result. At the top, there is a button labeled 'ADD ANALYSIS RESULT' and two circular icons. The form is divided into several sections:

- Description:** 'Dose response analysis for ADAS-Cog changes from baseline'
- Analysis Reason:** 'Specified in SAP' (with a pencil icon)
- Analysis Purpose:** 'Primary Outcome Measure' (with a pencil icon)
- Parameter:** 'ADQSADAS.PARAMCD' (with a dropdown arrow)
- Datasets Comment:** Includes a plus icon, a link icon, and a share icon.
- Datasets:** Includes a plus icon, a link icon, and a minus icon.
 - Dataset:** 'ADQSADAS' (with a dropdown arrow)
 - Selection Criteria:** 'PARAMCD EQ "ACTOT" AND AVISIT EQ "Week 24" AND EFFFLEQ EQ "Y" AND ANL01FL EQ "Y"' (with a pencil icon)
 - Analysis Variables:** Includes a plus icon, a minus icon, and a link icon.
 - Value: 'CHG (Change from Baseline)'
- Documentation:** Includes a minus icon and a link icon.
 - Text:** 'Linear model analysis of CHG for dose response; using randomized dose (0 for placebo; 1 for treatment) in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose).'
 - Document:** 'SAP Section 10.1.1' (with a dropdown arrow and a PDF icon)
 - Reference Type:** 'Physical Reference' (with a dropdown arrow and a plus icon)
 - Pages (space separated):** '4' (with a toggle switch)

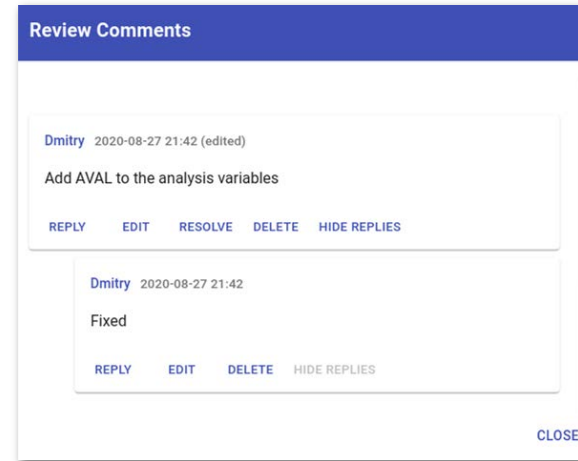
Editing ARM

- Syntax highlighting for SAS, R, Python
- Copy-paste between VDE and Excel
- Import CSV, JSON data



Reviewing ARM

- Review comments
- Preview with a standard CDISC stylesheet
- Check links to files and PDF pages



The End

- Visit defineeditor.com to download the latest version
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