

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

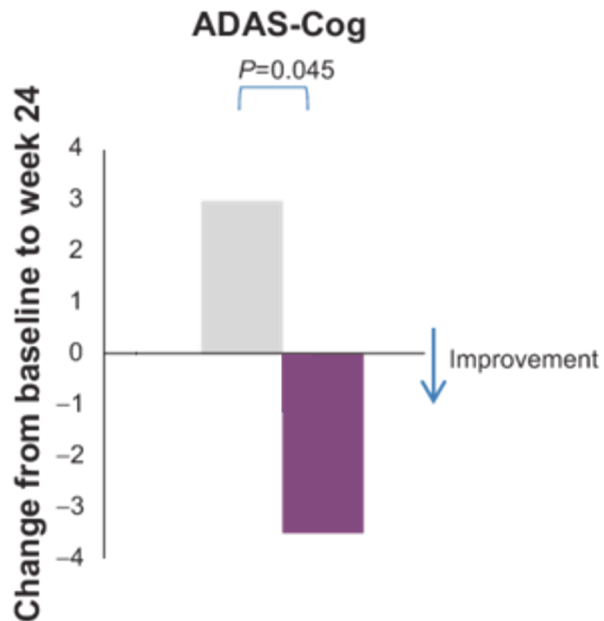


Figure 14-3.01

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 `aBlFl = "Y"`



where `anl01Fl = "Y"`

Common ARM Issues

Selection Criteria

- Lack of supportive variables

Condition: `<Variable> <=|≠|<|≤|≥|>|IN|NOTIN> <Value(s)>`

where `prxMatch("/total/", paramCd)`
and `compFuzz((aval - base)/base, 0.1) = 1`



where `paramCat1 = "TOTAL"` and `pChgCat1 = "10%"`

Common ARM Issues

Programming code

```
proc LIFETEST DATA= %if &TYPE eq pfs %Then %D0;  
%if &tab = 3.15 %then %do;  
    alpha = 0.01 CONFTYPE = loglog  
%end; %else %if &tab ^= 3.10 %then %D0; 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 %D0; 1 %end; %else  
%do; 0 %end;)  
RUN;
```

Common ARM Issues

Programming code

```
%justDoIt( 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 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 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

Is it FAIR?

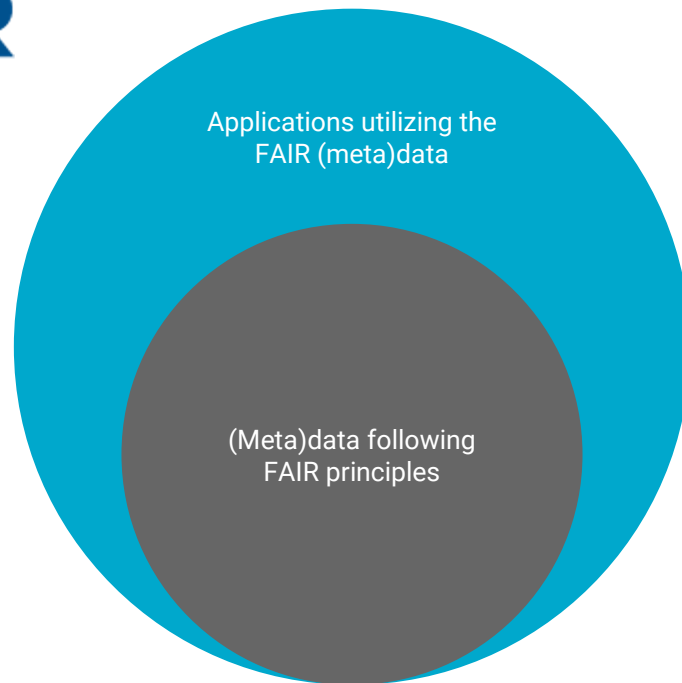


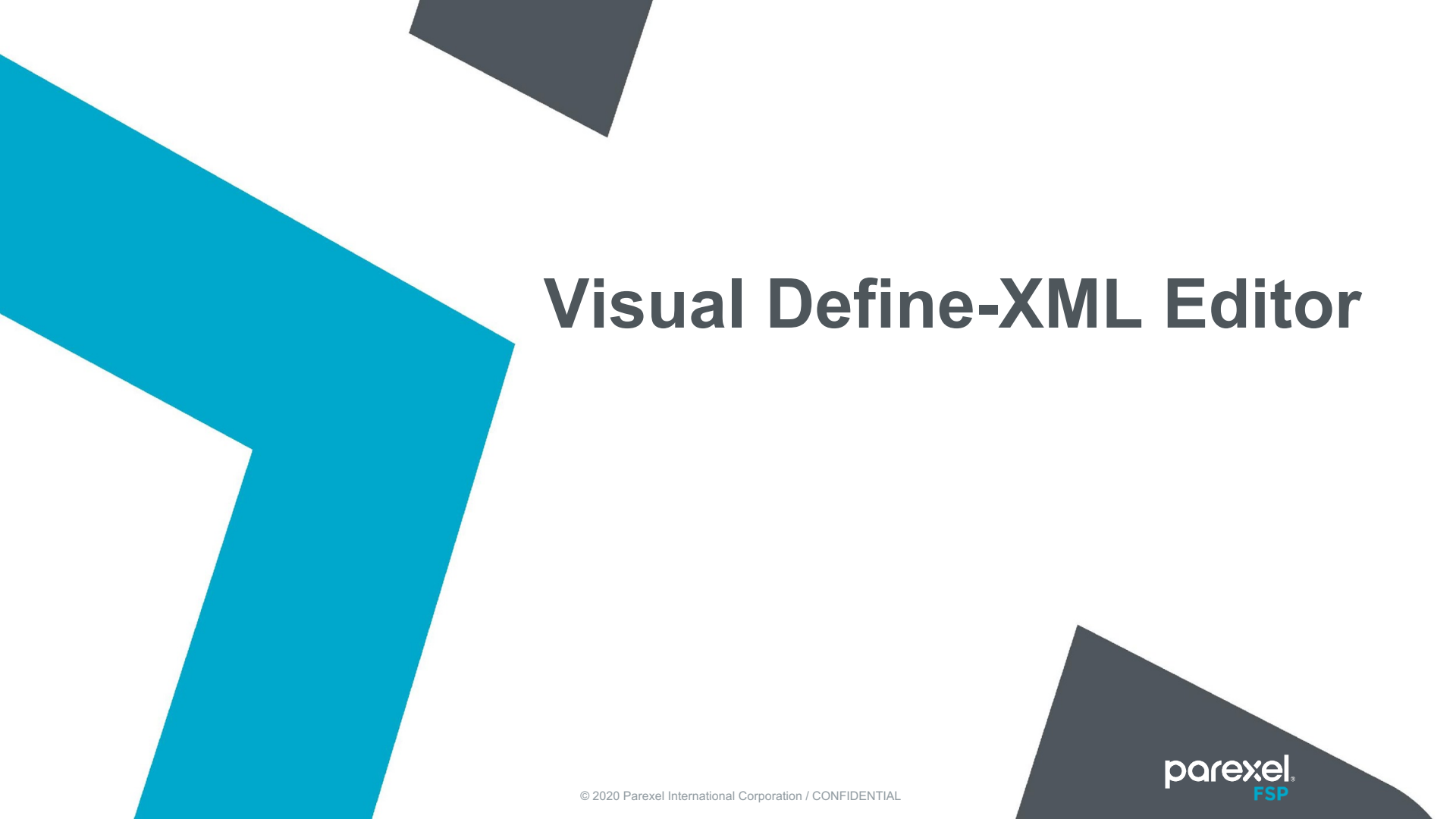
Findable

Accessible

Interoperable

Reusable





Visual Define-XML Editor

Visual Define-XML Editor

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

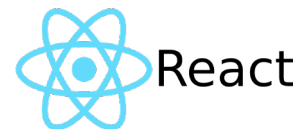
- Supports Define-XML 2.0 and ARM 1.0 standards
- What you see is what you get
- Enhanced editing and review features
- Integration with CDISC Library
- Built-in browser for CDISC Standards and NCI/CDISC Controlled Terminology



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



ELECTRON



Creating ARM

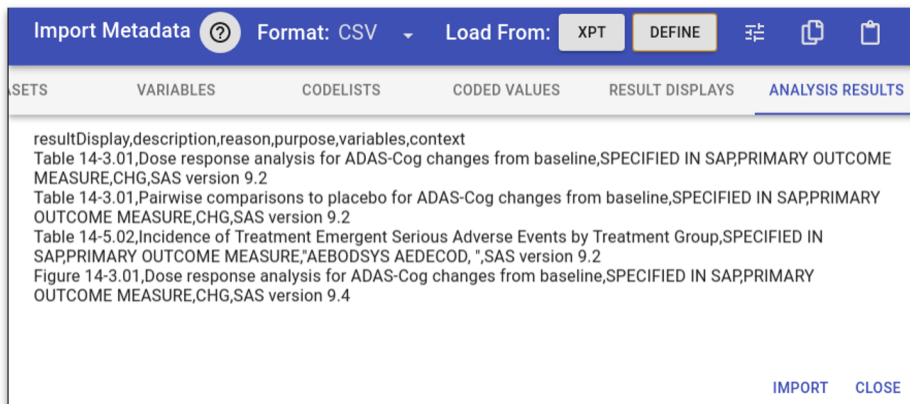
- Write from scratch
- Copy within the same Define-XML
- Copy between Define-XMLs
 - Update referenced documents
 - Some of variables might not be present in the target Define-XML
 - Create a library of ARM outputs

The screenshot shows a web-based form titled "ADD ANALYSIS RESULT". The form is organized into several sections:

- Description:** "Dose response analysis for ADAS-Cog changes from baseline".
- Analysis Reason:** "Specified in SAP" (with a dropdown arrow).
- Analysis Purpose:** "Primary Outcome Measure" (with a dropdown arrow).
- Parameter:** "ADQSADAS.PARAMCD" (with a dropdown arrow).
- Datasets Comment:** A text area with icons for adding (+), linking (chain), and unlinking (square).
- Datasets:** A section with a plus icon and a list icon.
 - Dataset:** "ADQSADAS" (with a dropdown arrow and a minus icon).
 - Selection Criteria:** "PARAMCD EQ 'ACTOT' AND AVISIT EQ 'Week 24' AND EFFFL EQ 'Y' AND ANL01FL EQ 'Y'" (with a plus icon).
 - Analysis Variables:** "CHG (Change from Baseline)" (with plus, minus, and list icons).
- Documentation:** A section with 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)." (with a plus icon).
 - Document:** "SAP Section 10.1.1" (with a dropdown arrow, a minus icon, and a PDF icon).
 - Reference Type:** "Physical Reference" (with a dropdown arrow, a plus icon, and a toggle switch).
 - Pages (space separated):** "4" (with a text input field).

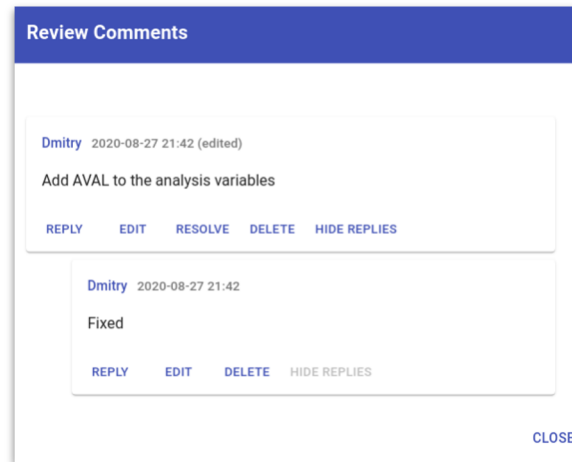
Editing ARM

- 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 Is Near

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