



Science For A Better Life

**PASSION
TO
INNOVATE** | **POWER
TO
CHANGE**

Out-of-the-box %defineXML

Just a Simple SAS Macro

PhUSE / October 2016 / Katja Glaß

A full-page background image showing a diver on the left, holding a camera, surrounded by a large school of fish in clear blue water. The text 'PASSION TO INNOVATE' is in yellow and 'POWER TO CHANGE' is in blue, separated by a vertical line.

**PASSION
TO
INNOVATE** | **POWER
TO
CHANGE**

Agenda

- Introduction
- Getting Started
- %DefineXML
- Collaborate
- Summary

Introduction

“Define-XML transmits metadata for SDTM, SEND and ADaM datasets; ... datasets, variables, controlled terms, and other specified metadata ...”

CDISC – Define-XML definition



Introduction

Define.xml Web View

SDTM-IG 3.1.2

Date of document generation: 2013-03-03T17:04:44

Stylesheet version: 2013-04-24

[Annotated Case Report](#)

[Reviewers Guide](#)

[Complex Algorithms](#)

► [Tabulation Datasets](#)

► [Value Level Metadata](#)

► [Controlled Terminology](#)

► [Computational Algorithms](#)

► [Comments](#)

Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt	
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCOD	te.xpt	
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt	
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt	
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide

Introduction

Define.xml Text View

```
<Study OID="cdisc01">
  <GlobalVariables>
    <StudyName>CDISC01</StudyName>
    <StudyDescription>CDISC Test Study</StudyDescription>
    <ProtocolName>CDISC01</ProtocolName>
  </GlobalVariables>
  <MetaDataVersion OID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2"
    Name="Study CDISC01, Data Definitions"
    Description="Study CDISC01, Data Definitions"
    def:DefineVersion="2.0.0"
    def:StandardName="SDTM-IG"
    def:StandardVersion="3.1.2">

    <!-- ***** -->
    <!-- Supporting Documents -->
    <!-- ***** -->

    <def:AnnotatedCRF>
      <def:DocumentRef leafID="LF.blankcrf"/>
    </def:AnnotatedCRF>

    <def:SupplementalDoc>
      <def:DocumentRef leafID="LF.ReviewersGuide"/>
      <def:DocumentRef leafID="LF.ComplexAlgorithms"/>
    </def:SupplementalDoc>
```

Getting Started

Requirement:

create a submission ready define.xml file

How:

- various tools
- various possible processes



Final Goal:

- complete transparency, automation, regular updates

Solution:

- Do it yourself! Create a SAS macro!



Getting Started

Internet Search



Define-XML-2-0_
ReleasePackage20140424



ARM-for-Define-XML

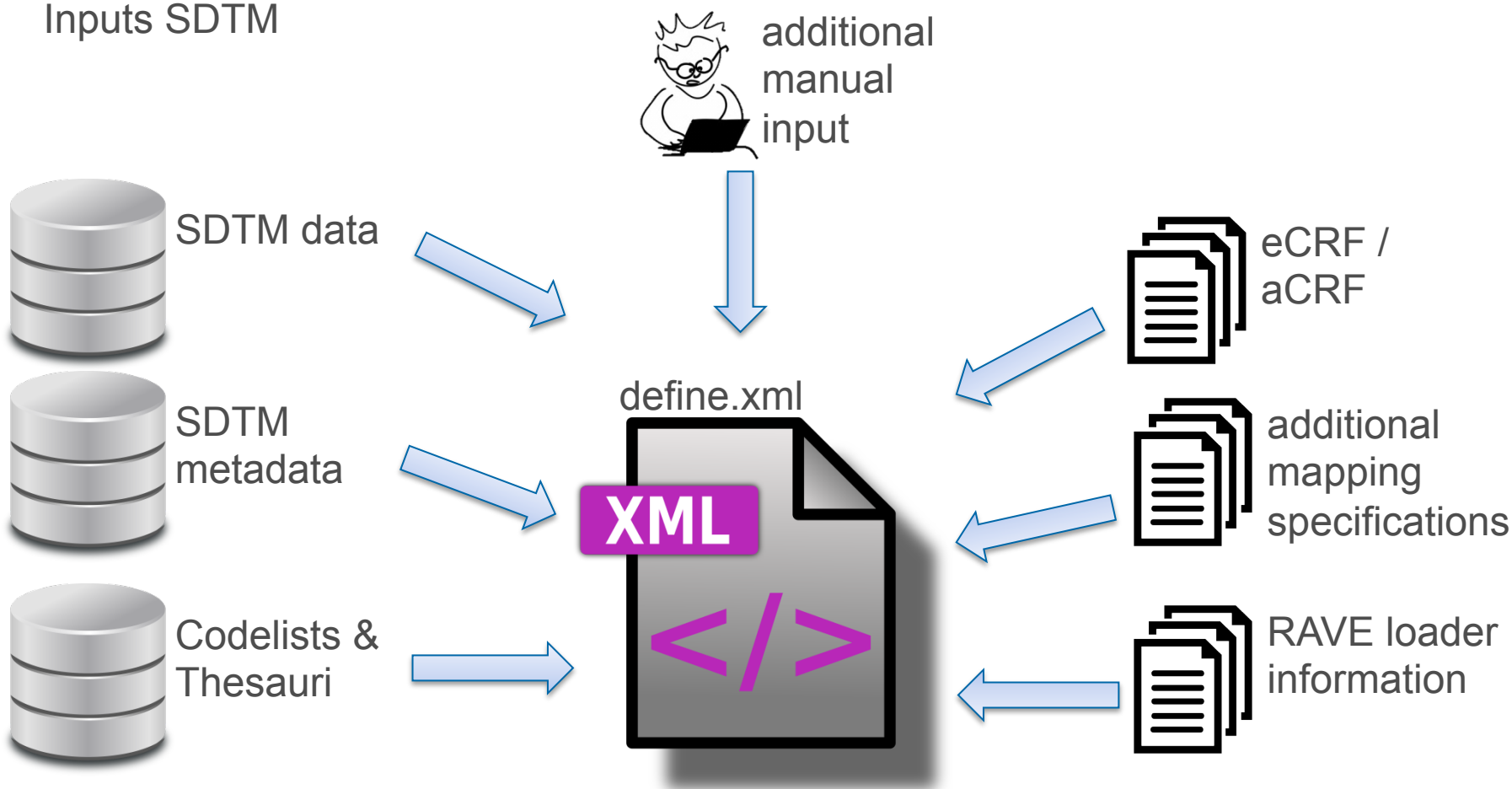


Define Papers

*“Creating Define.xml v2
Using SAS® for FDA
Submissions”*

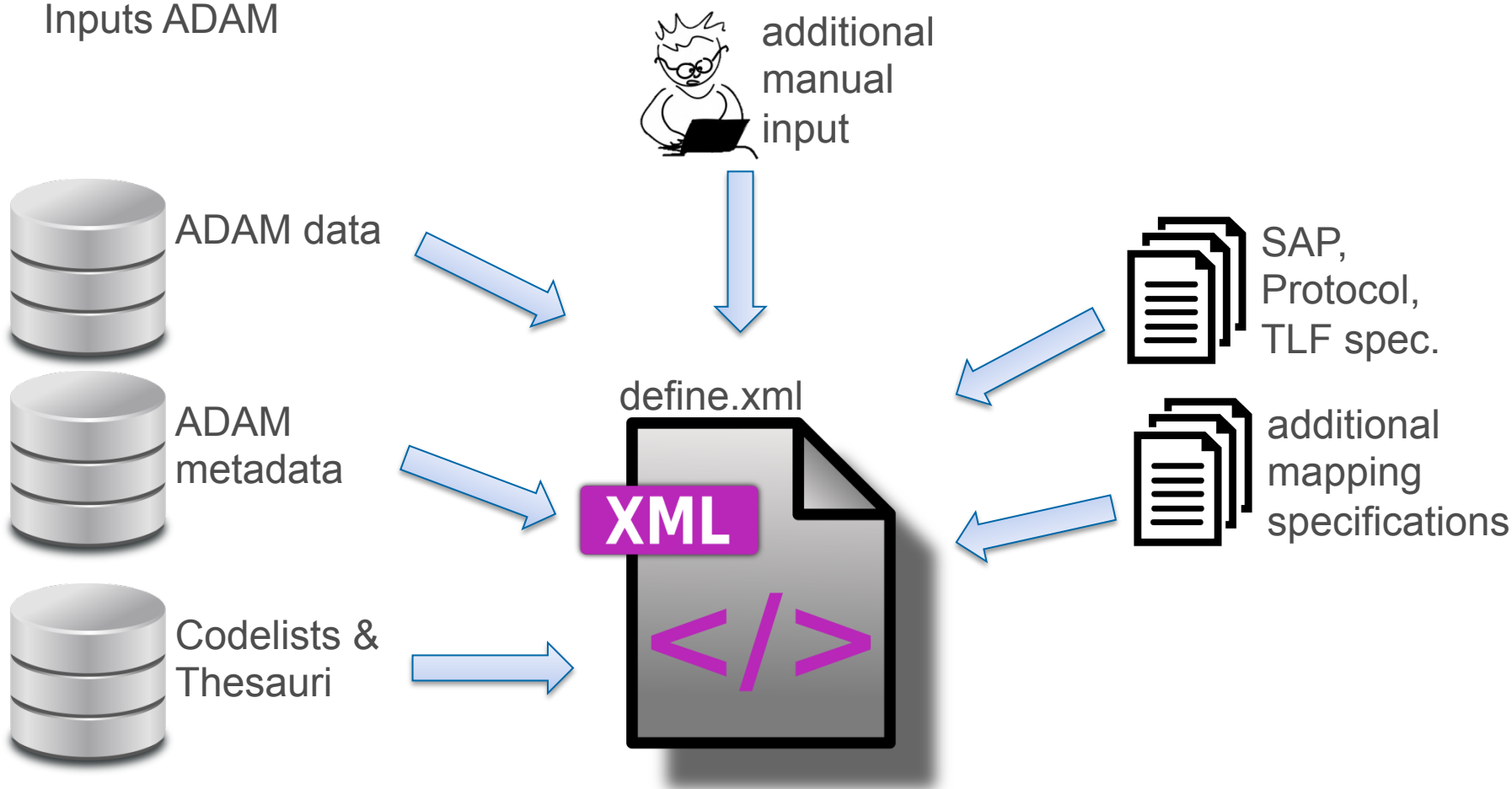
Getting started

Inputs SDTM



Getting started

Inputs ADAM



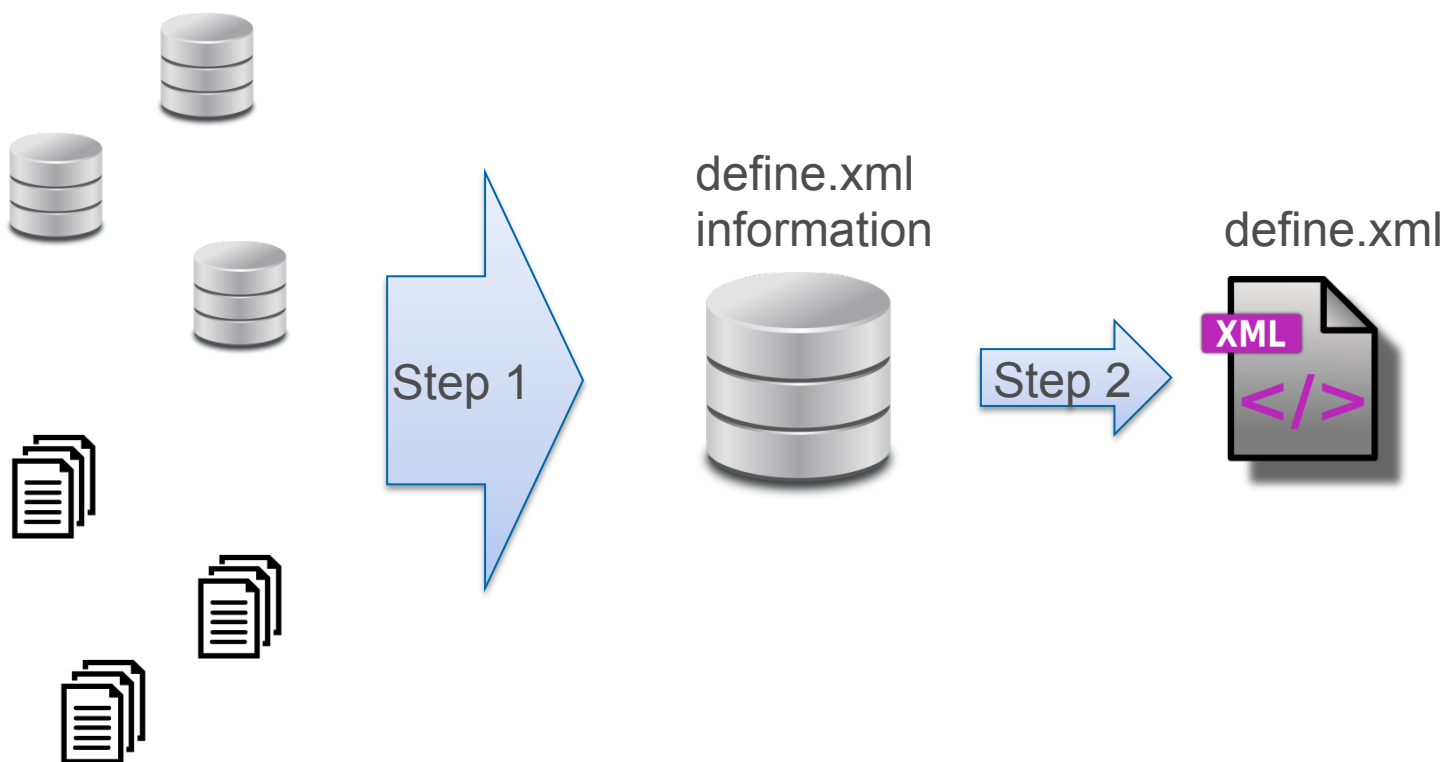
Getting started

Inputs ADAM



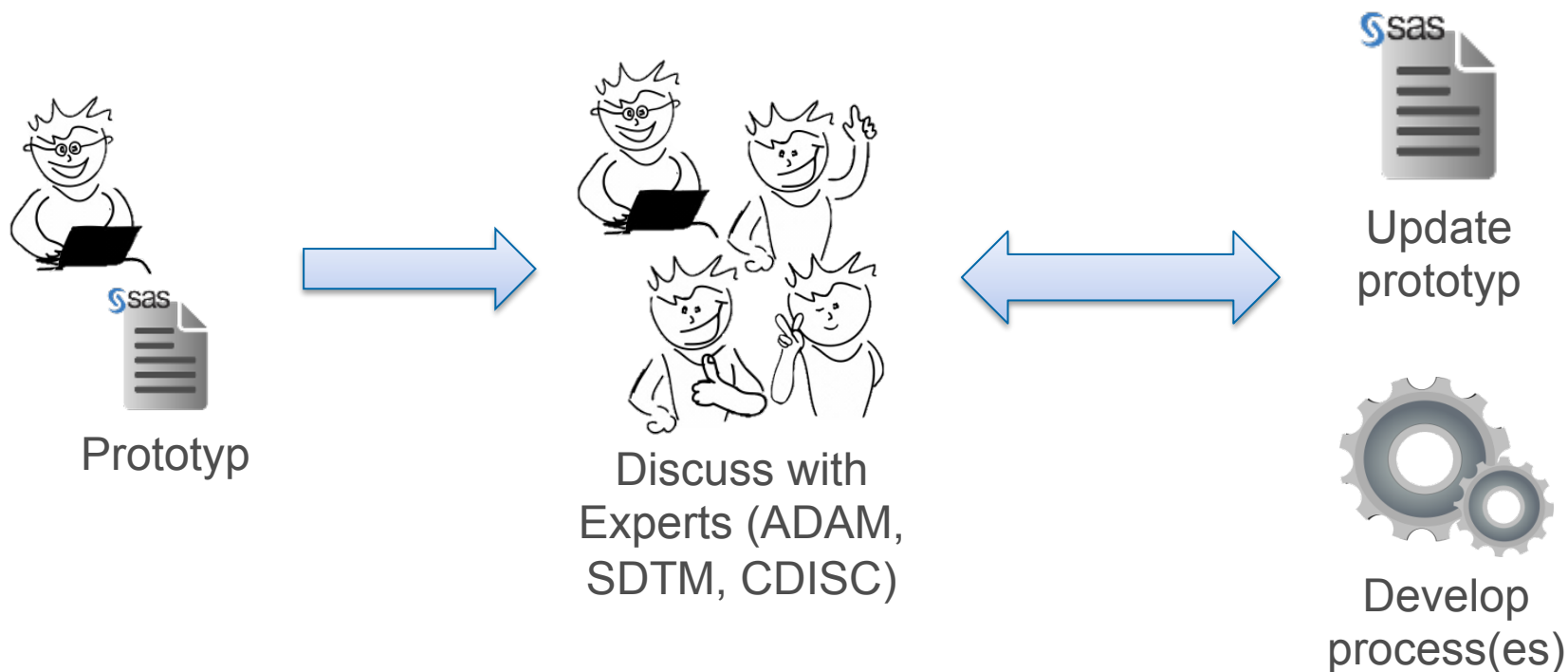
Getting started

Simplified process



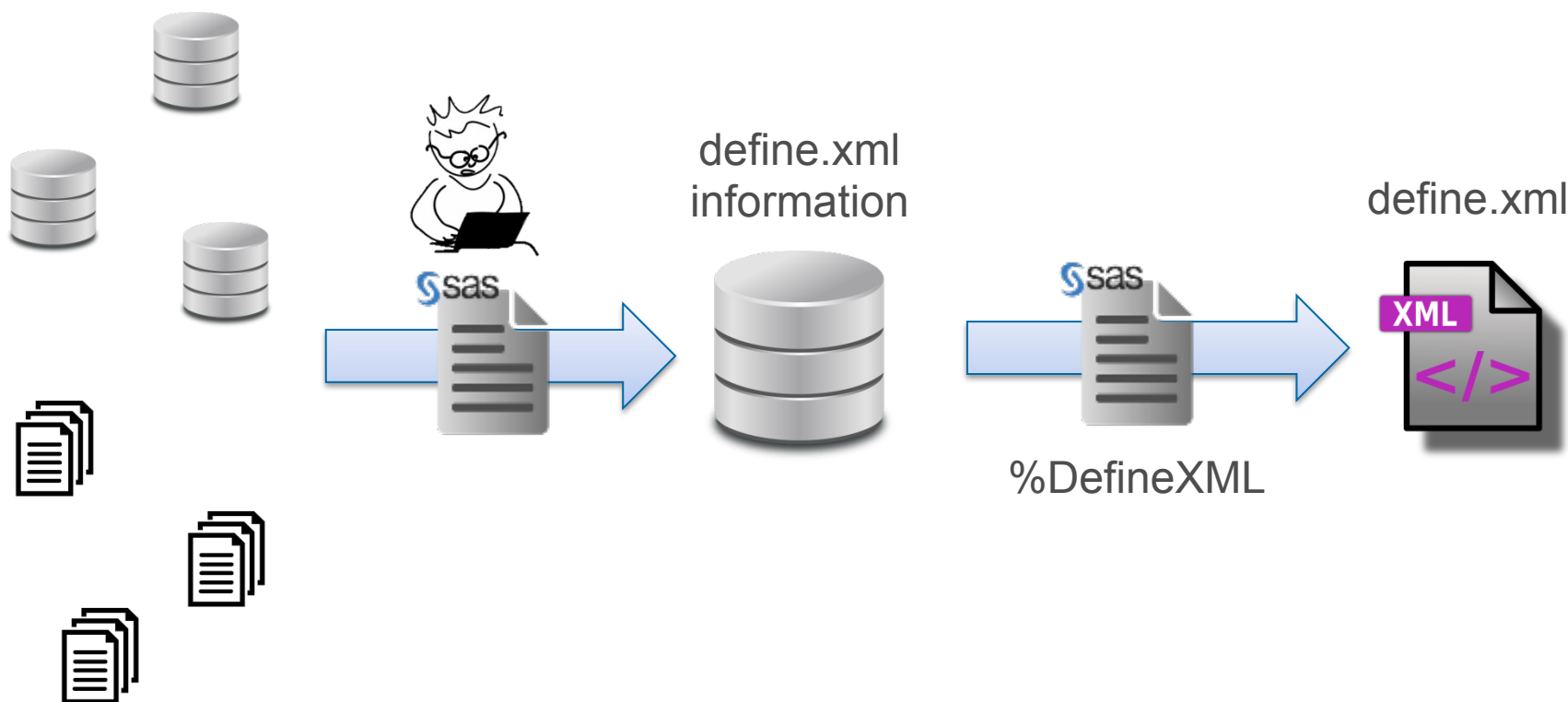
Getting Started

Macro Development



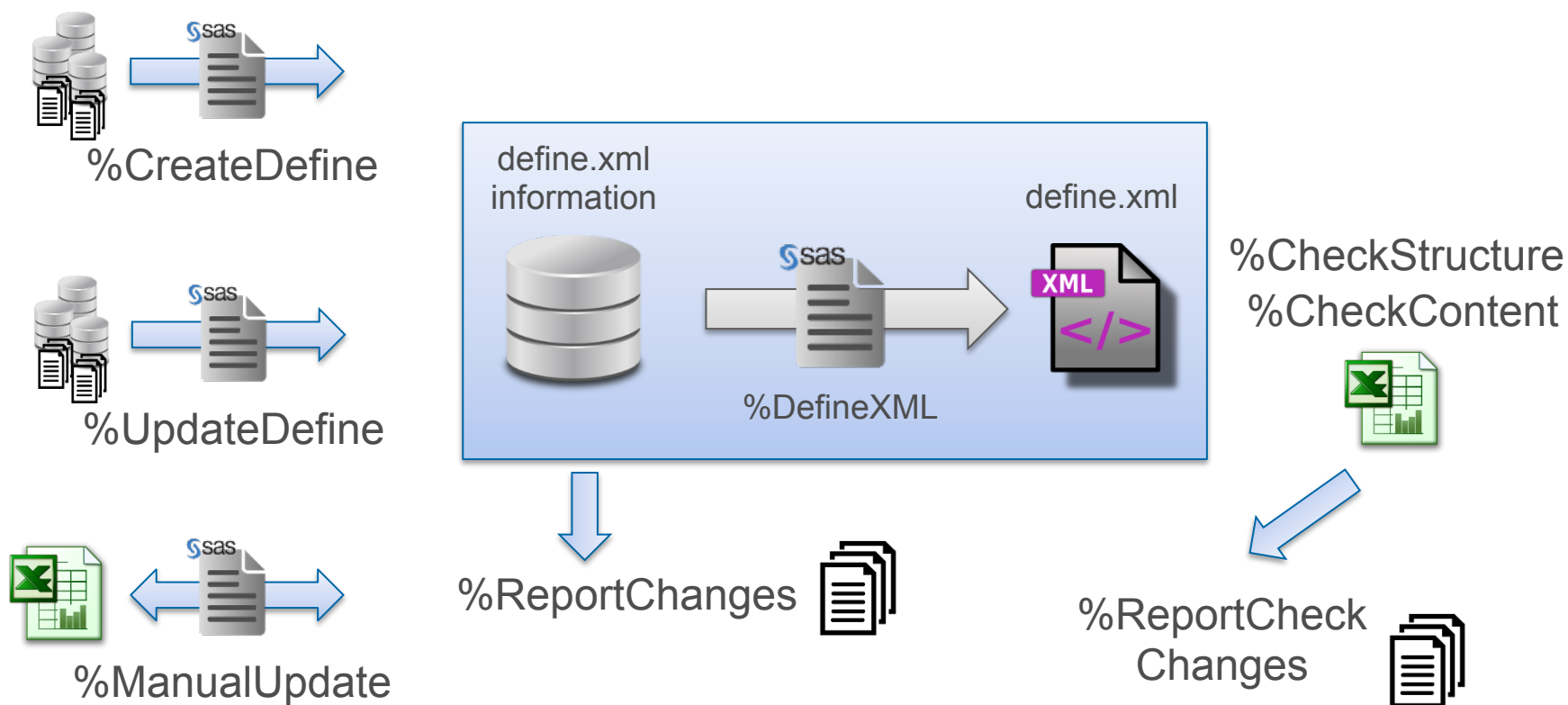
Getting Started

Short Term Process



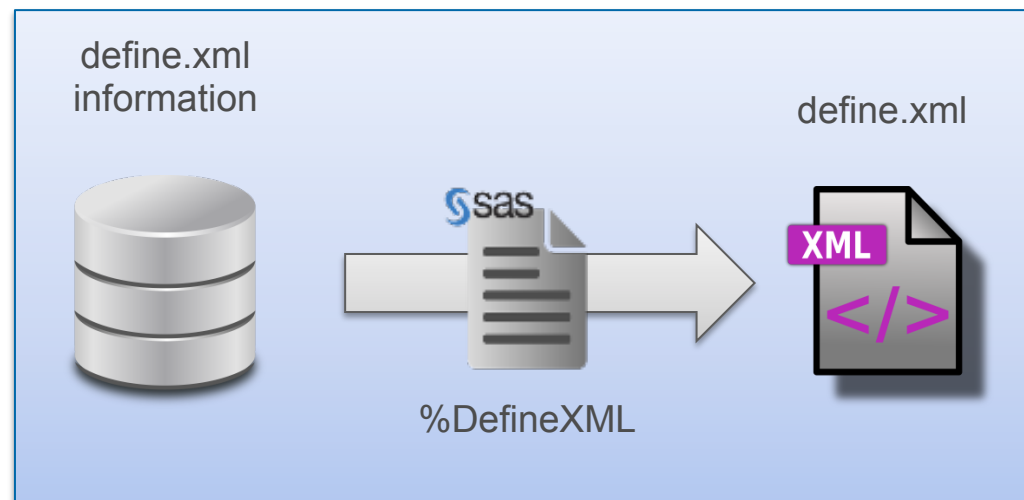
Getting started

Long Term Process



%DefineXML

- Scope:
 - Translation of information into XML format according CDISC specifications
 - As interface SAS datasets are used
 - Similar as Pinnacle21 tool, but using SAS and adding functionality



%DefineXML

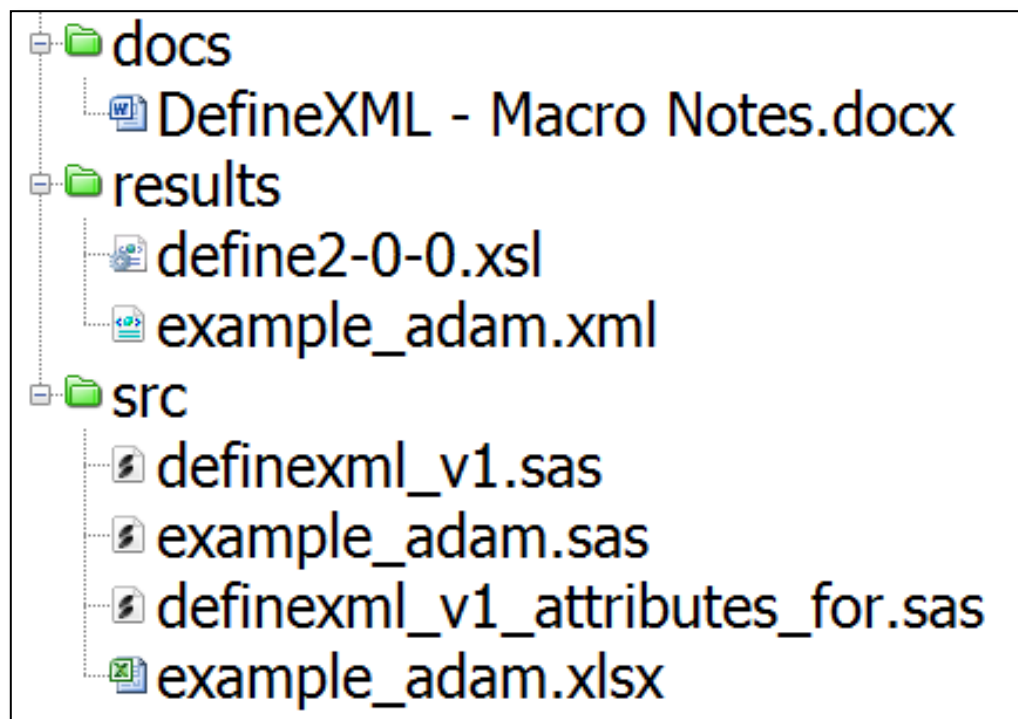
Interface through datasets (similar as Pinnacle21):

- General
- Datasets
- Variables
- Value Level (including WhereClause)
- Codes & Terms
- Methods
- Comments
- Documents

%DefineXML

Available through PhUSE Script Repository

- ❖ Macros
- ❖ Example
- ❖ Documentation



phuse-scripts / lang / SAS / datahandle / defineXML

%DefineXML

definexml_v1.sas

```
PUT @5 '<ItemDef OID="' itemoid +(-1) ' "' /
    @7 'Name="' valuname +(-1) ' "' /
    @7 'SASFieldName="' valuname +(-1) ' "' /
    @7 'DataType="' type +(-1) ' "' /
    @7 'Length="' length +(-1) ' "' ;
IF significantdigits NE ''
    THEN PUT @7 'SignificantDigits="' significantdigits +(-1) ' "' ;
```

%DefineXML

definexml_v1_attributes_for.sas

```
%ELSE %IF %UPCASE(&data.) = DOCUMENTS
%THEN %DO;
    ATTRIB PDFLEAF          LENGTH = $200 FORMAT = $200. LABEL = 'PDF Leaf ID' ;
    ATTRIB PDFLINK          LENGTH = $200 FORMAT = $200. LABEL = 'PDF Link' ;
    ATTRIB PDFTITLE         LENGTH = $200 FORMAT = $200. LABEL = 'PDF Title' ;
    ATTRIB ANNOTATEDCRF     LENGTH = 8      FORMAT = 8.      LABEL = 'Annotated CRF' ;
%END;
```

%DefineXML

example_adam.sas

```
DATA DOCUMENTS;  
    %definexml_v1_attributes_for(documents);  
    INPUT PDFLEAF $ 1-21 PDFLINK $ 23-36 PDFTITLE $ 38-66 ANNOTATEDCRF 68-79;  
DATALINES4;  
LF.AdamReviewersGuide 12345_ADRG.pdf Analysis Data Reviewers Guide .  
LF.SAP 12345_SAP.pdf Statistical Analysis Plan .  
;;;  
RUN;  
  
%definexml_v1(outfile = &path./results/phuse_example.xml);
```

%DefineXML

example_adam.xlsx

2	Domain	Description	Class	Structure	Purpose
3	ADSL	Subject Level Analysis Dataset	SUBJECT LEVEL ANALYSIS	One record per Subject	Analysis
4	ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	One record per subject per event	Analysis
5	ADEX	Exposure Analysis Dataset	BASIC DATA STRUCTURE	One or more records per subject	Analysis

◀ ▶
HEADER
DATASETS
VARIABLES
VALUELEVEL
CODES
METHODS
COMMENTS
DOCUMENTS
|||

%DefineXML

example_adam.xml

define2-0-0.xsl

ADaM-IG 1.0

Date of Define-XML document generation: 2016-09-28T09:17:43

Stylesheet version: 2015-01-16

Analysis Data Rev

Statistical Analysis:

► Analysis Datasets

► Parameter Value 1

► Controlled Termin

► Analysis Derivatio

Standard

Study Name

Study Description

Protocol Name

Metadata Name

Metadata Description

ADaM-IG 1.0

Study 12345

This is the study description, this study is a dummy study used as example for the define.xml generation.

Protocol 98765/12345

Study 12345, Data Definitions

Study 12345, Data Definitions

Analysis Datasets for Study Study 12345 (ADaM-IG 1.0)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADSL	Subject Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET	One record per Subject	Analysis	STUDYID, USUBJID	adsl.xpt	

%DefineXML

DefineXML - Macro Notes.docx

The folloing XML Attributes are set for the MethodDef definition:

XML Attribute	Origin
OID	ComputationMethodoID
Name	ComputationMethodName
Type	ComputationMethodType
Description TranslatedText	Description
def:DocumentRef leafID	PDFLeaf (if provided)
def:PDFPageRef PageRefs	PDFPage (if provided)
Type	“PhysicalRef”
def:PDFPageRef PageRefs	PDFDestination (if provided and PDFPage not)
Type	“NamedDestination”

%DefineXML

- Macro is Open Source (MIT-License)
- Validation:
 - Validate Define.XML result!
- Just use it!



Collaboration

Room for improvements:

Define Programming:

- Interface as Pinnacle21 Excel structure (%definexml_v2)
- Analysis Results Level metadata support
- Examples SDTM
- Examples ADAM / Update example

Define-related Programming

- %ReadDefineXML
- %CreateInitialDefineData (proc contents, ...)



Collaboration

Room for improvements:

Documentation:

- Programming Specification
- Guidance or How-to Document
- FAQ



Summary

No more manual define.xml updates!

Define.xml creation with correct structure can easily be done by the macro!

Ready for use!

Full Transparency!

Easy to change!

Out of the box!



Questions?





Science For A Better Life



Thank you!



PhUSE / 11. October 2016 / Katja Glaß