
The logo consists of a cluster of small squares in various shades of blue and brown, arranged in a roughly circular pattern.

Clinical Metadata

Leveraging the power of your metadata
June 2019 Andrew Ndikom

Agenda

- Project background (5 minutes).
- Clinical Metadata apps overview (17 minutes).
- Questions.

Background

- CDISC formed in 1997.
- Now mandatory for submissions.
- Intended to deliver a 50% reduction in analysis and reporting time.
- Efficiencies not realised due to legacy systems and workflows.

Making metadata work for you

Two key ways in which the efficiency savings when implementing CDISC can be achieved are:

- Standardisation.
- Using metadata to drive your processes.

Obstacles?

- Creating new tools involves an upfront investment of time and resources.
- Transforming our processes can be difficult.
- We may not be able to rely on our existing technology platform.

Clinical Metadata apps

Clinical Metadata apps are free to use tools designed to help users leverage the power of their metadata.

Our initial three apps are designed to integrate seamlessly into the clinical trial reporting process and help users get more from their Define.xmls.

App #1 - Dataset shells

Generates SAS code that can be used to align dataset metadata with Define.xml specified metadata.

App #2 – Codelist check

Generates a report showing the Define.xml codelist metadata alongside the CDISC defined terminology.

App #3 – Define compare

Generates an interactive report highlighting the differences and similarities between two Define.xmls.

Clinical Metadata apps

Licence:

- Free to use.

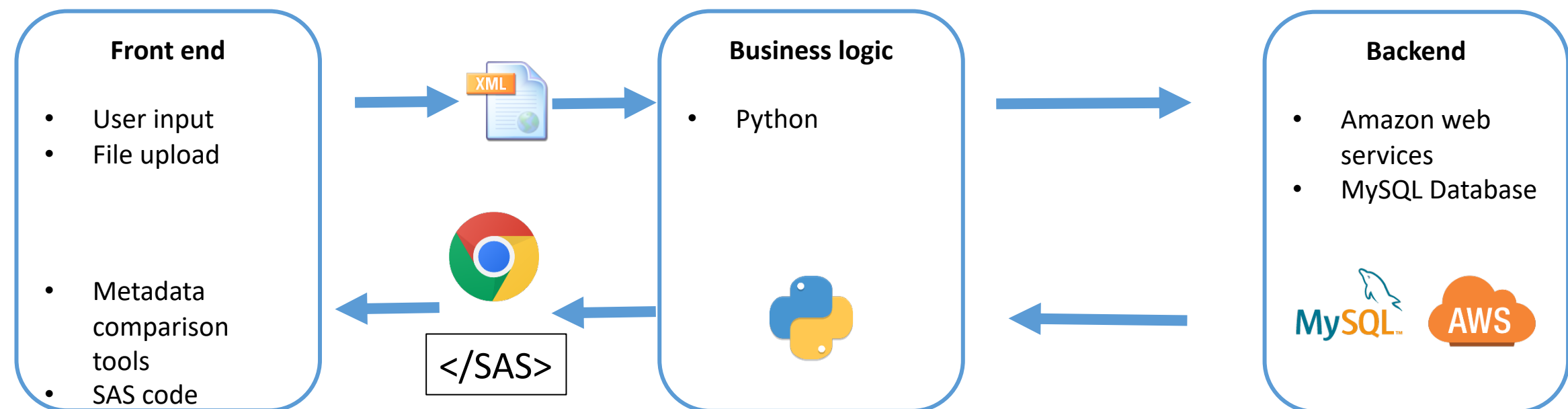
Technology:

- Software as a Service.
- Hosted in the cloud.

User interface:

- Quick to learn and intuitive to use

Architecture



Dataset Shells

Use case

- Aligning dataset metadata with metadata specified within a Define.xml is a key part of CDISC compliance.

Process

- User uploads a Define.xml.
- System generates the SAS code that can be used to assign the Define.xml metadata to a dataset.

Dataset Shells

Generates the SAS code that aligns dataset metadata with Define.xml specified metadata.

Subject-Level Analysis (ADSL) [Location: [adsl.xpt](#)]

Variable	Label	Type	Length / Display Format	Controlled Terms or Format	Source/Derivation/Comment
STUDYID	Study Identifier	text	12		Predecessor: DM.STUDYID
USUBJID	Unique Subject Identifier	text	11		Predecessor: DM.USUBJID
SUBJID	Subject Identifier for the Study	text	4		Predecessor: DM.SUBJID
SITEID	Study Site Identifier	text	3		Predecessor: DM.SITEID



```
*****ADSL Shell*****;  
%MACRO ADSL(lib_out=,dset_in=);  
  ***Sort the input dataset***;  
  PROC SORT DATA = &dset_in;  
    BY STUDYID USUBJID;  
  RUN;  
  ***Create a permanent output dataset***;  
  DATA &lib_out..ADSL(LABEL='Analysis Dataset Subject Level' KEEP = STUDYID USUBJID  
    ATTRIB STUDYID LABEL = 'Study Identifier' LENGTH = $200  
           USUBJID LABEL = 'Unique Subject Identifier' LENGTH = $200  
           SITEID LABEL = 'Study Site Identifier' LENGTH = $200  
           SUBJID LABEL = 'Subject Identifier for the Study' LENGTH = $200  
           AGE LABEL = 'Age' LENGTH = 8  
           ...
```


Codelist check

Use case

- There are almost 30,000 standard codelist values defined for use across CDASH, SDTM and ADaM.
- Ensuring each codelist has been used as expected can be difficult.

Process

- User uploads a Define.xml.
- System generates a report showing the CDISC definitions, where available, for each selected coded term.

Demonstration

Codelist check – codelist level example

Summary

- Filename: define2-0-0-example-adam-results.xml
- Codelists within the Define.xml were compared against SDTM Terminology 2019-03-29.
- There are 29 codelists within the Define.xml.
- 7 codelists were present in the SDTM Terminology 2019-03-29
- 22 codelists were not present in the SDTM Terminology 2019-03-29

Summary information

Codelists

Show 50 entries

Search: Age

CDISC Codelist	Name	Type	CDISC Code	Extensible	CDISC Submission value	CDISC Synonym	CDISC Definition	NIC Pref
Yes	Age Unit	text	C66781	No	AGEU	Age Unit	Those units of time that are routinely used to express the age of a subject.	CDISC SDTM Age Unit Terminology
Yes	Ethnic Group	text	C66790	No	ETHNIC	Ethnic Group	A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features may be reflected in their experience of health and disease. (NCI)	CDISC SDTM Ethnic Group Terminology
Yes	Sex	text	C66731	No	SEX	Sex	The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female. (NCI)	CDISC SDTM Sex of Individual Terminology
No	Age Group	text						
No	Age Group (N)	integer						

Showing 1 to 5 of 5 entries (filtered from 29 total entries)

Previous 1 Next

Codelists metadata for codelists present in the CDISC terminology. Note the additional fields merged on from CDISC terminology.

Codelist metadata for codelists not present in CDISC terminology.

Codelist check – codelist item example

App #2 – Codelist check

Generates a report showing the CDISC defined metadata associated with each codelist value.

CDISC Codelist	Name	Coded Value	Translated Text	CDISC Codelist	CDISC Synonym	CDISC Definition	NCI Pref
Yes	Sex	F	Female	C16576	Female	A person who belongs to the sex that normally produces ova. The term is used to indicate biological sex distinctions, or cultural gender role distinctions, or both. (NCI)	Female
Yes	Sex	M	Male	C20197	Male	A person who belongs to the sex that normally produces sperm. The term is used to indicate biological sex distinctions, cultural gender role distinctions, or both. (NCI)	Male
Yes	Sex	U	Unknown	C17998	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
Yes	No Yes Response	N	No	C49487	No	The non-affirmative response to a question. (NCI)	No
Yes	No Yes Response	Y	Yes	C49488	Yes	The affirmative response to a question. (NCI)	Yes

Codelist item metadata read from the Define.xml.

Additional codelist item metadata merged on from CDISC terminology.

Define Compare

Use case

- A first step when pooling data is to understand how metadata differ across studies.
- Prior to starting programming for a new study, it can be useful to understand how the proposed metadata differ from the metadata on previous studies.

Process

- User uploads two Define.xml files.
- System generates a report showing the differences and similarities between the two files.
- Graphs and interactive filtering allow the user to understand the differences between the files.

Define compare example

Global Metadata

Define A

- Filename: define2-0-0-with_changes.xml
- Study: CDISC-Sample - with some updates
- Description: CDISC-Sample Data Definition - with some updates
- Protocol: CDISC-Sample

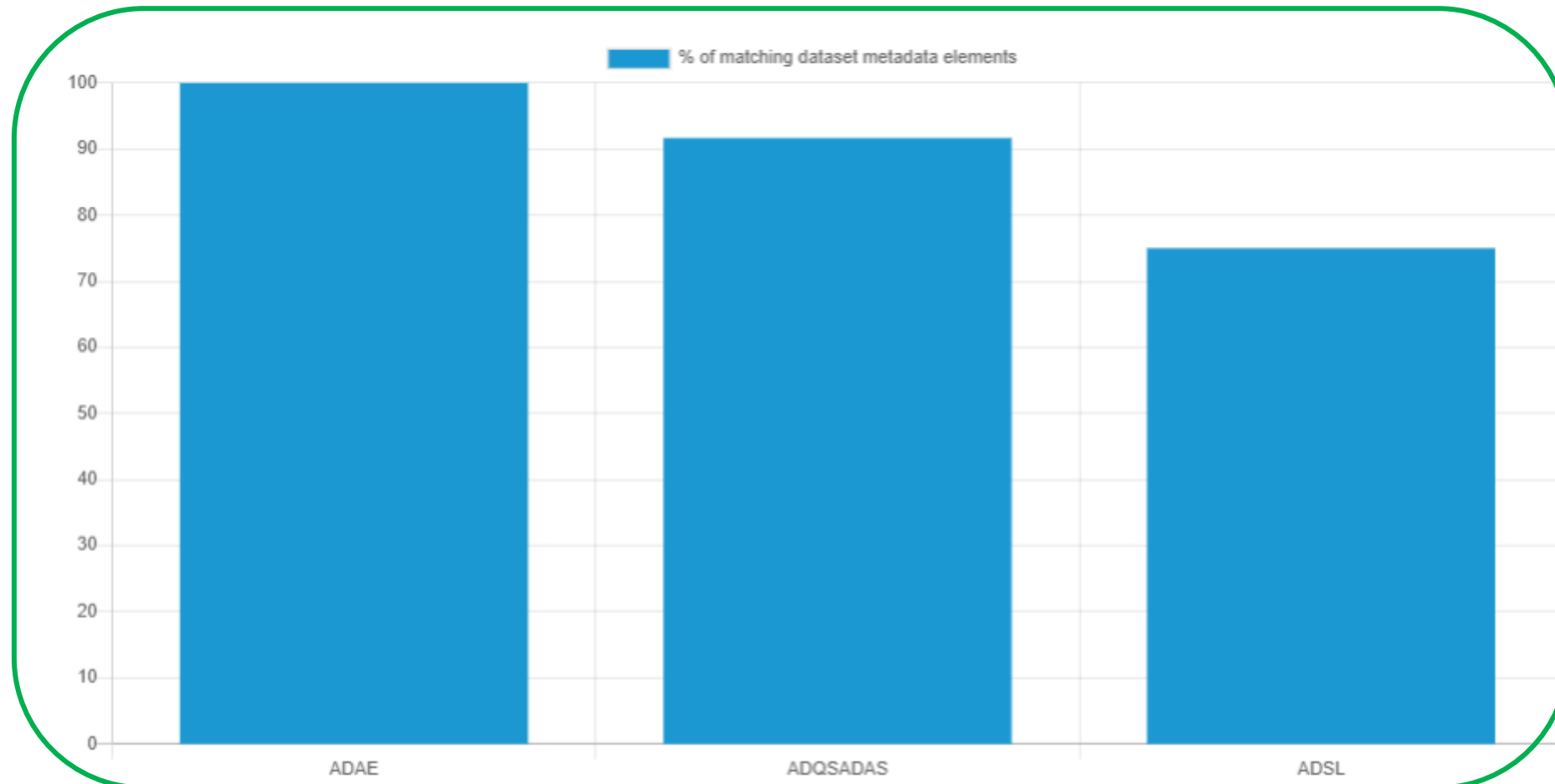
Define B

- Filename: define2-0-0-example-adam-results.xml
- Study: CDISC-Sample
- Description: CDISC-Sample Data Definition
- Protocol: CDISC-Sample

Global metadata

Graphs showing percentage of dataset level metadata that matches across Define.xmls

Datasets



Define compare example

- Table showing differences across Define.xmls. Differences are highlighted in red.

Group	Name	Domain	Label	Keys	Class	Structure	Comment
Match	ADAE	Not defined	Adverse Events Analysis Dataset	STUDYID, USUBJID, ASTDT, AETERM, AESEQ	OCCURRENCE DATA STRUCTURE	one record per subject per adverse event	See SAS program
Differences	ADQSADAS	Not defined	ADAS-Cog Analysis	STUDYID, USUBJID, AVISIT, ADT, PARAMCD	BASIC DATA STRUCTURE	Here's another update One record per subject per parameter per analysis visit per analysis date	See referenced dataset creation program and Analysis Data Reviewer's Guide, Section 2.1

Group	Variable	Label	Length	Variable Type	Codelist	Origin	Comment
Differences	AWTARGET	Analysis Window Target	8 82	integer	Not defined	Assigned	Target day within the window, specified in the SAP.
Differences	AWLO	Analysis Window Beginning Timepoint	8 84	integer text	Not defined	Assigned	Start day of the window, specified in the SAP.
Differences	AVISIT	Analysis Visit Analysisdasds Visit	16	text	Analysis Visit	Derived	Derived based on windowing algorithm described in SAP, Section 8.2
Differences	AWTDIFF	Analysis Window Diff from Target	8 38	integer	Not defined	Derived	Absolute difference between AWTARGET and ADY
Differences	AWRANGE	Analysis Window Valid Relative Range	9	text	Not defined	Assigned	Window range, specified in the SAP. Window rNot the samen the SAP.

Summary

- Clinical Metadata apps are a suite of free apps designed to help users leverage the power of their metadata.
- First three apps focus on helping users get more from their Define.xmls.
 - Dataset Shells
 - Codelist Check
 - Define Compare
- Apps are Software as a Service and hosted within the AWS cloud.
- More apps will be released over the coming months.

Questions?

www.clinicalmetadata.com