

ID-SPECTACKLE

Making ADaM Specifications 'Fun'

SM14

13 November 2024

PHUSE EU Connect 2024

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Company: IDDI

AGENDA

- Introduction
- Global idea
- %ADaM
- ID-Spectackle
- Conclusion

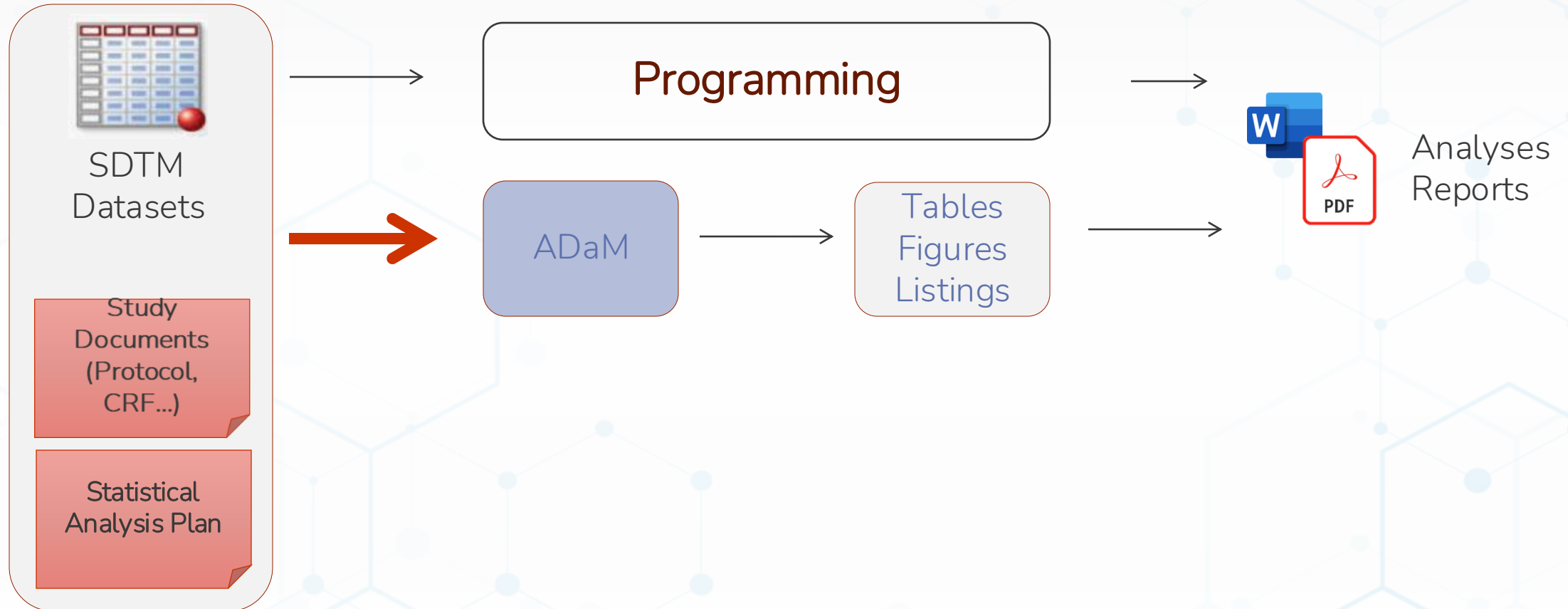


INTRODUCTION

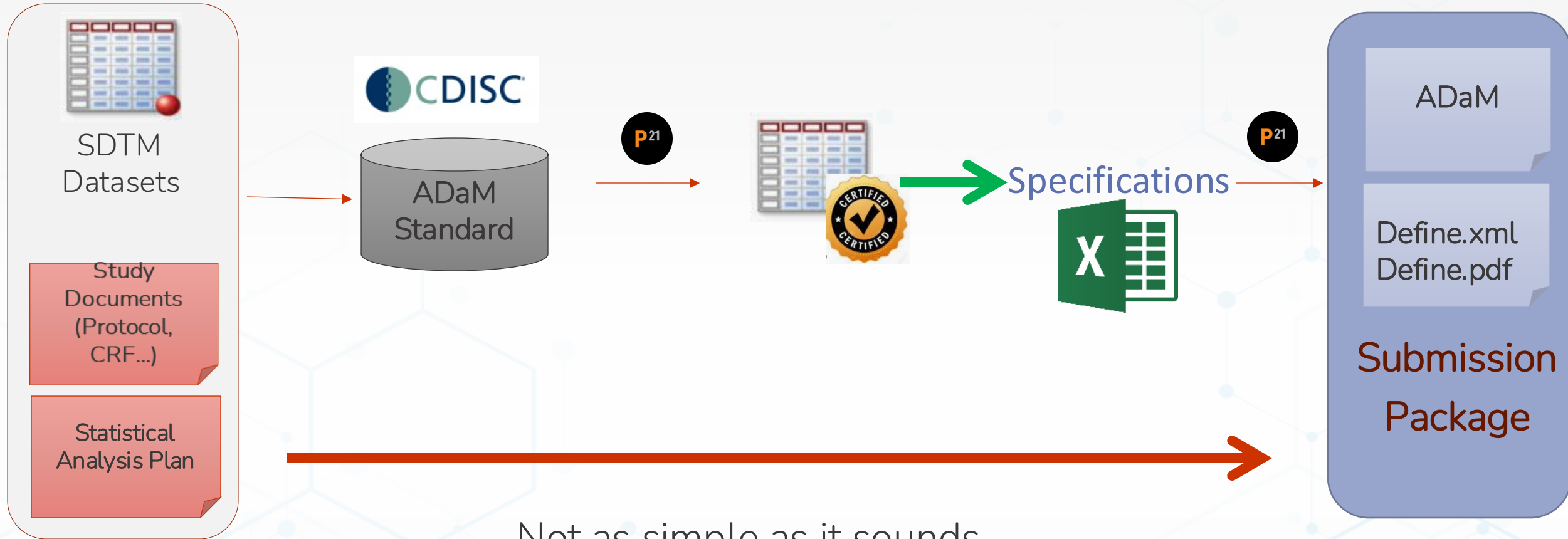
INTRODUCTION

- ID-SPECTACKLE small story

Not as simple as it sounds



INTRODUCTION



Not as simple as it sounds

INTRODUCTION

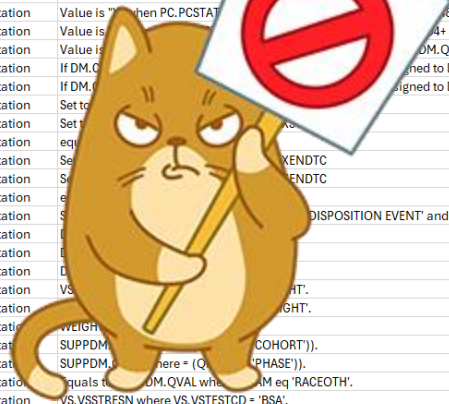
Not as simple as it sounds



Specifications



ID	Name	Type	Description	Expression Context	Expression Code	Document	Pages
ADSL.AGEGR1	ADSL.AGEGR1	Computation	Set to "18 to <65" if age greater than or equal to 18 and age less than 65; else set to ">=65 to <75" if age greater than or equal to 65 and age less than 75; otherwise value is "N".				
ADSL.SAFL	ADSL.SAFL	Computation	Value is "Y" when DM.RFICDTC and EC.ECSTDT are not missing. Otherwise value is "N".				
ADSL.ITFL	ADSL.ITFL	Computation	Value is "Y" when DS.DSTERM equals "RANDOMIZED". Otherwise value is "N".				
ADSL.ITTSFL	ADSL.ITTSFL	Computation	Value is "Y" when DS.DSTERM equals "RANDOMIZED" and SUPPDM.QNAM = "POSTRSAM". Else value is "N".				
ADSL.RESFL	ADSL.RESFL	Computation	Value is "Y" when (DM.DTHFL="1" and EC.ECSTDT < EC.ECENDTC) or (DM.DTHFL="2" and EC.ECSTDT < EC.ECENDTC). Otherwise value is "N".				
ADSL.RESSFL	ADSL.RESSFL	Computation	Value is "Y" when RESFL = "Y" and SUPPDM.QNAM = "POSTRSAM". Else value is "N".				
ADSL.PKFL	ADSL.PKFL	Computation	Value is "Y" when PC.PCSTAT equals "PERFORMED" and EC.ECSTDT < EC.ECENDTC. Otherwise value is "N".				
ADSL.PDFL	ADSL.PDFL	Computation	Value is "Y" when PC.PCSTAT equals "PERFORMED" and EC.ECSTDT < EC.ECENDTC. Otherwise value is "N".				
ADSL.JDEFL	ADSL.JDEFL	Computation	Value is "Y" when PC.PCSTAT equals "PERFORMED" and EC.ECSTDT < EC.ECENDTC. Otherwise value is "N".				
ADSL.TRT01P	ADSL.TRT01P	Computation	If DM.COUNTRY = "JAF" then DUMMYA and DUMMYB. If DM.COUNTRY = "JAF" then DUMMYA and DUMMYB. If DM.COUNTRY = "JAF" then DUMMYA and DUMMYB.				
ADSL.TRT01A	ADSL.TRT01A	Computation	If DM.COUNTRY = "JAF" then DUMMYA and DUMMYB. If DM.COUNTRY = "JAF" then DUMMYA and DUMMYB. If DM.COUNTRY = "JAF" then DUMMYA and DUMMYB.				
ADSL.TRTSDT	ADSL.TRTSDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.TRTSTM	ADSL.TRTSTM	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.TRTSDTM	ADSL.TRTSDTM	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.TRTEDT	ADSL.TRTEDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.TRTETM	ADSL.TRTETM	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.TRTEDTM	ADSL.TRTEDTM	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.EOSDT	ADSL.EOSDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.RFICDT	ADSL.RFICDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.DTHDT	ADSL.DTHDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.DTHCAUS	ADSL.DTHCAUS	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.HEIGHT	ADSL.HEIGHT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.WEIGHT	ADSL.WEIGHT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.BMI	ADSL.BMI	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.COHORT	ADSL.COHORT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.PHASE	ADSL.PHASE	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.RACEOTH	ADSL.RACEOTH	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.BSA	ADSL.BSA	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.ECOG	ADSL.ECOG	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.TRASDT	ADSL.TRASDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.TRAEDT	ADSL.TRAEDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.EOTDT	ADSL.EOTDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.EOTDY	ADSL.EOTDY	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.EOTFL	ADSL.EOTFL	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.ALXSDTM	ADSL.ALXSDTM	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.ALXSDT	ADSL.ALXSDT	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				
ADSL.ALXSTM	ADSL.ALXSTM	Computation	Set to the date part of minimum of EC.ECSTDT after sorting the dataset by USUBJID ECSTDT when EC.ECSTDT = "ALX148".				



INTRODUCTION

Not as simple as it sounds



Specifications



Automate the generation of specification and Define-XML
And provide a user friendly Web User Interface (WebUI)

- ✓ Reduce the amount of time to produce specification and Define-XML
- ✓ Improve quality
- ✓ Engage programmer into timely accurate documentation



an IDea...
ID-SPECTACKLE



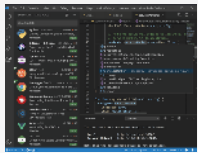


GLOBAL IDEA

GLOBAL IDEA



AD--



%ADaM



ID Spectackle

Study: SPECTACLE_DEMO_STAT
Report selection (Type/DB): Phase_DB_Phase

Info: Last change on: 20240911 at 12:42:31 CEST by sdekeyser (Update)
23 Datasets

in_use	delete	DATASET	DESCRIPTION	CLASS	SUBCLASS (only XML2.1)	STRUCTURE	KEY	STANDARD (only XML2.1)	HASNOODATA (only XML2.1)	REPEATING	COMMENT
yes	☐	ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET		One record per subject	USUBJID	AdAm-IG 1.2	no	no	
yes	☐	ADABO	ABO and antibody Analysis Dataset	ADAM OTHER		One record per subject	USUBJID	AdAm-IG 1.2	no	yes	
yes	☐	ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	One record per subject per adverse event	USUBJID, AETERM, ASTDT, MISSYGRN	AdAm-IG 1.2	no	yes	
yes	☐	ADCE	Infection React Dataset	STRUCTURE		One record per subject per parameter	USUBJID, PARAMCD, VISITNUM	AdAm-IG 1.2	no	yes	
yes	☐	ADCM	Concomitant I Analysis Dataset	DATA		One record per subject per concomitant medication	USUBJID, CHSCCD, CHSCDT	AdAm-IG 1.2	no	yes	
yes	☐	ADCV	Protocol Devic Dataset	DATA		One record per subject per device	USUBJID, DISCDEV, DVCAT, DVTERR	AdAm-IG 1.2	no	yes	
yes	☐	ADEG	ECG Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter per visit	USUBJID, ASEQ	AdAm-IG 1.2	no	yes	
yes	☐	ADEX	Exposure Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter	USUBJID, PARCAT1N, PARAMN, ASEQ	AdAm-IG 1.2	no	yes	
yes	☐	ADIE	Inc./Exc. Crit. Not Met Analysis Dataset	OCCURRENCE DATA STRUCTURE		One record per subject	USUBJID, IECAT, IETEST	AdAm-IG 1.2	no	yes	
yes	☐	ADIS	ADA Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter	USUBJID, AVISITN, ATPT, PARAMCD	AdAm-IG 1.2	no	yes	
yes	☐	ADLB	Laboratory Test Results Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter per visit	USUBJID, PARCAT1	AdAm-IG 1.2	no	yes	



Specifications.xlsx



define.xml





%ADAM

%ADAM

- One Macro to rule them All (Metadata) !
 - **Consistency checks** (missing label, in model or not, label length, duplicates from key, ...)
 - **Collects Metadata** (datasets, variables, codelists): **Main Purpose**
 - **Finalize** (+xpt)

⇒ Heavy lifting done for the user

⇒ Less human error

⇒ Information in Specs are what is in Dataset

- Requirements :
 - ADaM + SDTM **Model Files**
 - Set :
 - Implementation Guide (IG) Versions
 - Controlled Terminologies (CT) Versions
 - Controlled Terminologies (direct from **NCI Online Repository**)
 - *Codelists*:
 - imposed by **SDTM/ADaM IG**, OR...
 - Custom codelists: **Everything is Codelist**
 - Unless... above threshold of **20 terms (default)**
 - OR **ADaM specific variables** (Parameters, Analysis Visits, ...)

- Initialise

Set before ADaM Programming

```
25 %macro minit /SECURE;  
26     *** only used for ID-SPEC - XML 2.1 in %adam ***;  
27     %global adamig adamct sdtmig sdtmct;  
28     %let adamig = 1.3;      /*Mandatory: valid numbers: 1.1, 1.2, 1.3 */  
29     %let adamct = ;        /*Leave empty for latest version, else complete by version yyyy-mm-dd*/  
30     %let sdtmig = 3.4;     /*Mandatory for SDTM CT auto-completion: valid numbers: 3.2, 3.3, 3.4 */  
31     %let sdtmct = ;        /*Leave empty for latest version, else complete by version yyyy-mm-dd - Should be checked with DM team*/  
32 %mend minit;
```

- Import NCI Controlled Terminologies

```
51 filename fout "&file";
52 filename hdrs temp;
53 proc http
54     %if %length(&version)=0 %then %do;
55         url="https://evs.nci.nih.gov/ftp1/CDISC/&CDISC./&CDISC.%20Terminology.xls"
56     %end;
57     %else %do;
58         url="https://evs.nci.nih.gov/ftp1/CDISC/&CDISC./Archive/&CDISC.%20Terminology%20&version..xls"
59     %end;
60     method="get" out=fout headerout=hdrs; debug level=1;
61 run;
62
63 data _null_;
64     infile hdrs scanover truncover;
65     input @'HTTP/1.1' code 4. message $255.;
66     call symputx('status_code',code,'g');
67 run;
68
69 %if &status_code.^=404 %then %do;
70     libname XLWBK excel "&file." access=readonly;
71     proc sql noprint;
72         select distinct memname into:sheetname trimmed from dictionary.tables where upcase(LIBNAME)="XLWBK" and upcase(memname) like '%TERMINOLOGY%';
73     quit;
```

%ADAM

- Call

```
%_BefrPgm;  
  
%let pnam=adtte;  
%putlog(file=&pathDerivedLog\&pnam..log);  
%macro ADTTE;  
    %sas_options;  
  
    /*Complete your program here*/  
  
    /* Finalize  
    * Note: Please add dataset label to 'final' dataset before call to ADaM Macro */  
    %ADAM(ds_  
        ,adam_=derived.adtte  
        ,libsdm_=data  
        ,class_=&_class. /*ADSL,BDS,OTHER,OCCDS*/  
        ,popfl_=FASFL SAFFL ITTFL  
        ,newkey_/*unique key*/  
        ,modlord_=Y  
        ,forcexpt_=N);  
%mend ADTTE;  
%ADTTE;  
%printlog;
```



- Dataset + %ADaM = METADATA Prefilled !

PHUSE.METADATASET x PHUSE.METAVARIABLE x PHUSE.METACODELIST x

View: Column names Filter: (none)

Total rows: 23 Total columns: 11

	DATASET	DESCRIPTION	CLASS	SUBCLASS	STRUCTURE	KEY	STANDARD	HASNODAT
1	ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET		One record per subject	USUBJID	ADaM-IG 1.2	No
2	ADABO	ABO and antibody Analysis Dataset	ADAM OTHER		One record per subject	USUBJID	ADaM-IG 1.2	No
3	ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	One record per subject per adverse e	USUBJID, AETERM, ASTDT, MXSEVGRN	ADaM-IG 1.2	No

PHUSE.METADATASET x PHUSE.METAVARIABLE x PHUSE.METACODELIST x

View: Column names Filter: DATASET="ADAE" x

Total rows: 1630 Total columns: 16 Filtered rows: 186

	ORDER	DATASET	VARIABLE	LABEL	DATA_TYPE	LENGTH	SIGN_DIGIT	FORMAT	CORE	ASSIGNEDVALUE	CODELIST	ORIGIN	SOURCE	COMMENT	PRE_MET_COM
1	1	ADAE	STUDYID	Study Identifier	text	8	.		Req			Predecessor			ADSL.STUDYID
2	2	ADAE	USUBJID	Unique Subject Identifier	text	18	.		Req			Predecessor			ADSL.USUBJID
3	3	ADAE	SUBJID	Subject Identifier for the Study	text	9	.		Perm			Predecessor			ADSL.SUBJID
4	4	ADAE	SITEID	Study Site Identifier	text	4	.		Perm			Predecessor			ADSL.SITEID
5	5	ADAE	AGE	Age	integer	2	.		Perm			Predecessor			ADSL.AGE

PHUSE.METADATASET x PHUSE.METAVARIABLE x PHUSE.METACODELIST x

View: Column names Filter: ID like '%AE%' x

Total rows: 2474 Total columns: 10 Filtered rows: 14

	ID	NAME	NCI_CODE	DATA_TYPE	TERMINOLOGY	TERM	NCI_TERM_CODE	DECODED_VALUE	PARAMCD	ORDER
1	AEOUTN	Outcome of Adverse Event (N)		integer		1		NOT RECOVERED/NOT RESOLVED		1
2	AEOUTN	Outcome of Adverse Event (N)		integer		2		RECOVERING/RESOLVING		2
3	AEOUTN	Outcome of Adverse Event (N)		integer		3		RECOVERED/RESOLVED WITH SEQUELAE		3
4	AEOUTN	Outcome of Adverse Event (N)		integer		4		RECOVERED/RESOLVED		4
5	AEOUTN	Outcome of Adverse Event (N)		integer		5		FATAL		5

- Collecting Metadata : Main Goal



AD--

%ADaM



Dataset: Name, label, key, ...
Variables: Name, label, length, type, order, format (if any), origin,
codelists (+ Terminology), ...



Metadataset.sas7bdat
Metavariable.sas7bdat
Metacodelist.sas7bdat



ID-Spectackle WebUI

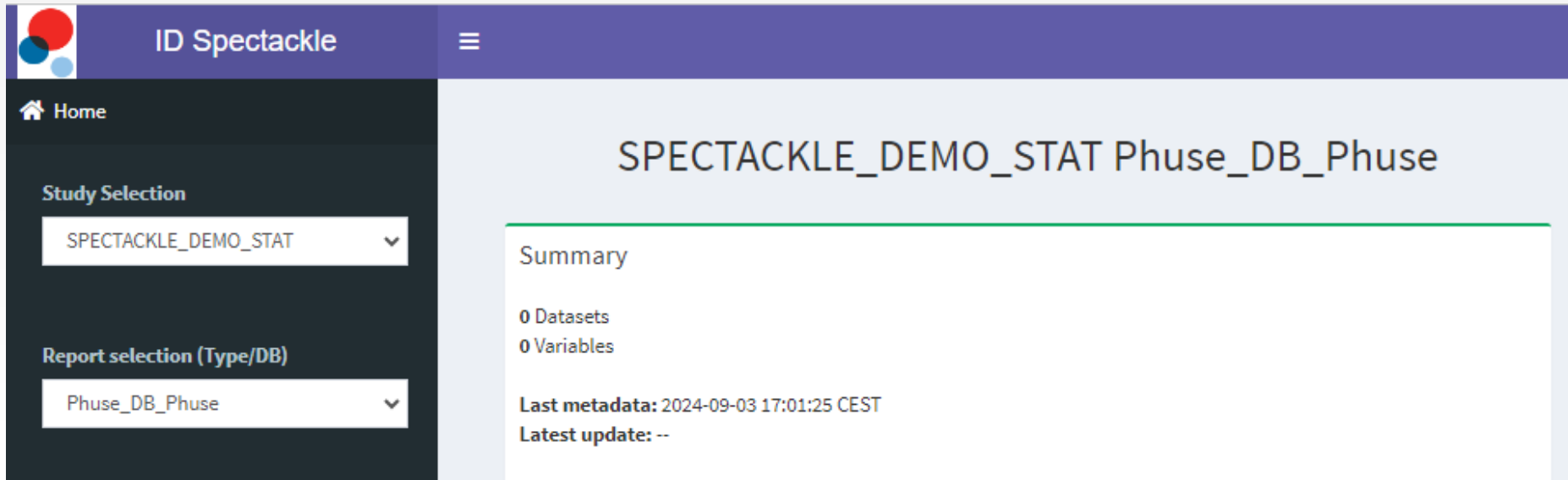
ID-SPECTACKLE

User-friendly graphical interface

ID-SPECTACKLE User-friendly graphical interface

The screenshot displays the ID Spectackle web application interface. On the left is a dark sidebar with the following elements: a home icon and 'Home' text; a 'Study Selection' section with a dropdown menu currently showing 'TEST'; a 'Report selection (Type/DB)' section with a dropdown menu currently showing 'DEMO'; a 'Help' link with a question mark icon; and an 'Email' link with an envelope icon and a green 'new' badge. Two blue arrows point to the 'Study Selection' and 'Report selection' dropdowns. The main content area has a purple header bar with the 'ID Spectackle' logo and a hamburger menu icon. Below the header, the title 'TEST DEMO' is centered. The main area contains two warning boxes. The first box, titled 'Warning', states 'No metadata found' in red text, followed by a message to check the 'Derived datasets folder' at the path `U:/BiostatisticalServices/Working/ID-Imagine/SANDBOX/STAT/4_Derived_Datasets/DEMO(*)/metadata` and to use ID-Imagine to modify or set paths. The second box, also titled 'Warning', states 'Spectackle setup missing' in blue text, followed by a message: 'There is no Spectackle setup yet, use the button below to create/complete setup'. At the bottom of this second box is a purple button labeled 'Create/complete Spectackle setup'.

ID-SPECTACKLE User-friendly graphical interface



The screenshot shows the ID Spectackle web application. The header is purple with the ID Spectackle logo and a hamburger menu icon. The left sidebar is dark blue with a 'Home' icon and two dropdown menus: 'Study Selection' (set to 'SPECTACKLE_DEMO_STAT') and 'Report selection (Type/DB)' (set to 'Phuse_DB_Phuse'). The main content area has a light blue header with the text 'SPECTACKLE_DEMO_STAT Phuse_DB_Phuse'. Below this is a white box with a green border containing a 'Summary' section. The summary shows '0 Datasets' and '0 Variables'. It also displays 'Last metadata: 2024-09-03 17:01:25 CEST' and 'Latest update: --'.

ID Spectackle

Home

Study Selection

SPECTACKLE_DEMO_STAT

Report selection (Type/DB)

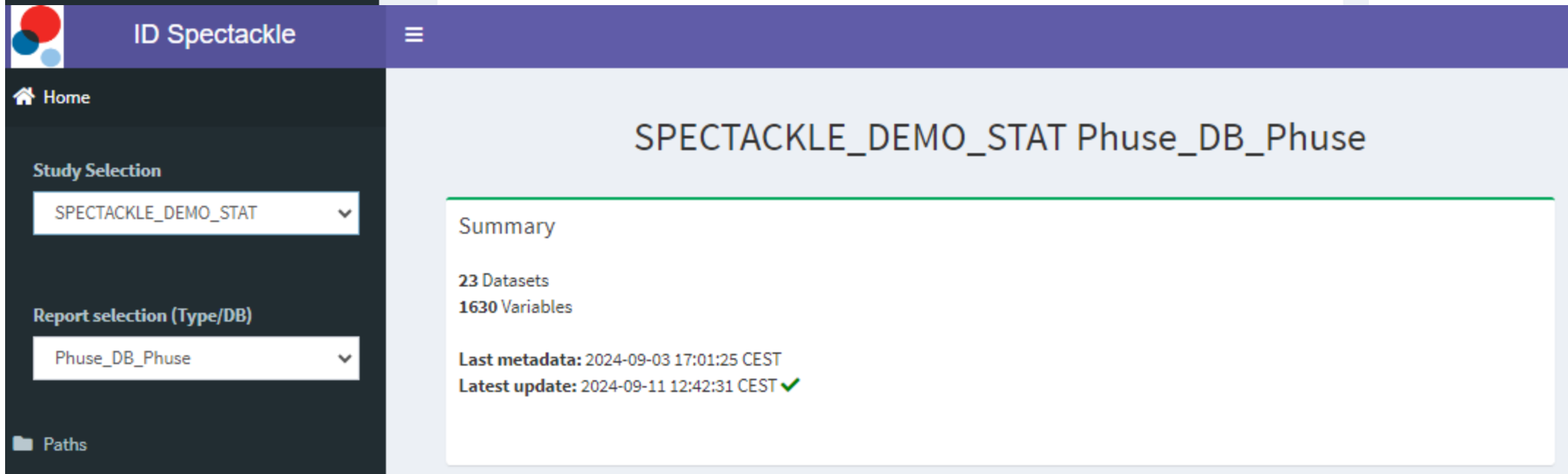
Phuse_DB_Phuse

SPECTACKLE_DEMO_STAT Phuse_DB_Phuse

Summary

0 Datasets
0 Variables

Last metadata: 2024-09-03 17:01:25 CEST
Latest update: --



This screenshot shows the same ID Spectackle interface as the previous one, but with updated data. The 'Summary' section now shows '23 Datasets' and '1630 Variables'. The 'Latest update' timestamp is '2024-09-11 12:42:31 CEST' with a green checkmark, indicating a successful update.

ID Spectackle

Home

Study Selection

SPECTACKLE_DEMO_STAT

Report selection (Type/DB)

Phuse_DB_Phuse

SPECTACKLE_DEMO_STAT Phuse_DB_Phuse

Summary

23 Datasets
1630 Variables

Last metadata: 2024-09-03 17:01:25 CEST
Latest update: 2024-09-11 12:42:31 CEST ✓

ID Spectackle

- Home
- Study Selection

SPECTACKLE_DEMO_STAT
- Report selection (Type/DB)

Phuse_DB_Phuse
- Paths
- Metadata
- P21 tools
- Specifications
- Help
- Email new

Study

Datasets

Variables

ValueLevel

Codelists

Dictionaries

Documents

Refresh

Info

Attribute	Value
StudyName	SPECTACKLE_DEMO_STAT
StudyDescription	!!!Copy protocol title here!!!
ProtocolName	SPECTACKLE_DEMO_STAT
StandardName	ADaM-IG
StandardVersion	1.X
Language	en

Metadataset.sas7bdat
 Metavariable.sas7bdat
 Metacodelist.sas7bdat

PHUSE.METADATASET x PHUSE.METAVARIABLE x PHUSE.METACODELIST x

View: Column names | Filter: (none)

Total rows: 23 Total columns: 11

	DATASET	DESCRIPTION	CLASS	SUBCLASS	STRUCTURE	KEY	STANDARD	HASNODATA
1	ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET		One record per subject	USUBJID	ADaM-IG 1.2	No
2	ADABO	ABO and antibody Analysis Dataset	ADAM OTHER		One record per subject	USUBJID	ADaM-IG 1.2	No
3	ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	One record per subject per adverse e	USUBJID, AETERM, ASTDT, MXSEVGRN	ADaM-IG 1.2	No

 ID Spectackle

Home

Study Selection

SPECTACKLE_DEMO_STAT

Report selection (Type/DB)

Phuse_DB_Phuse

Paths

Metadata

P21 tools

Specifications

Study

Datasets

Variables

ValueLevel

Codelists

Dictionaries

Documents

Refresh

Info

Last change on: 20240911 at 12:42:31 CEST by sdekeyser (Update)

23 Datasets

delete

DATASET

DESCRIPTION

CLASS

SUBCLASS

STRUCTURE

KEY

STANDARD

HASNODATA

REPEAT

COMMENT

in_use	delete	DATASET	DESCRIPTION	CLASS	SUBCLASS (only XML2.1)	STRUCTURE	KEY	STANDARD (only XML2.1)	HASNODATA (only XML2.1)	REPEATING	COMMENT
yes	☐	ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET		One record per subject	USUBJID	ADaM-IG 1.2	no	no	
yes	☐	ADABO	ABO and antibody Analysis Dataset	ADAM OTHER		One record per subject	USUBJID	ADaM-IG 1.2	no	yes	
yes	☐	ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	One record per subject per adverse event	USUBJID, AETERM, ASTDT, MXSEVGRN	ADaM-IG 1.2	no	yes	
yes	☐	ADCE	Infusion Reaction Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per	USUBJID, PARAMCD	ADaM-IG 1.2	no	yes	

 ID Spectackle

sdekeyser Read-Only

Study Datasets Variables ValueLevel Codelists Dictionaries Documents

Refresh

Info

Last change on: 20240911 at 12:42:31 CEST by sdekeyser (Update)

1630 Variables

delete

0

ADAE

VARI

LABEL

CORE

CODI

COMMO

ORIG

SOURCE

PRE_MET_COM

HASNOI

COMMENT

in_use	delete	ORDER	DATASET	VARIABLE	LABEL	DATA_TYPE	LENGTH	SIGN_DIGIT	FORMAT	CORE	CODELIST	COMMON (only XML2.1)	ORIGIN	SOURCE (only XML2.1)	Predecessor/Method	HASNODATA (only XML2.1)	COMMENT	DOCUMENT	PAGES
yes	☐	1	ADAE	STUDYID	Study Identifier	text	8			Req			Predecessor		ADSL.STUDYID	no			
yes	☐	2	ADAE	USUBJID	Unique Subject Identifier	text	18			Req			Predecessor		ADSL.USUBJID	no			
yes	☐	3	ADAE	SUBJID	Subject Identifier for the Study	text	9			Perm			Predecessor		ADSL.SUBJID	no			
yes	☐	4	ADAE	SITEID	Study Site Identifier	text	4			Perm			Predecessor		ADSL.SITEID	no			
yes	☐	5	ADAE	AGE	Age	integer	2			Perm			Predecessor		ADSL.AGE	no			
yes	☐	6	ADAE	SEX	Sex	text	1			Perm	SEX		Predecessor		ADSL.SEX	no			
yes	☐	7	ADAE	COUNTRY	Country	text	3			Perm			Predecessor		ADSL.COUNTRY	no			
yes	☐	8	ADAE	SAFFL	Safety Population Flag	text	1			Perm	NY		Predecessor		ADSL.SAFFL	no			

 ID Spectackle 

sdekeyser Read-Only

Study Datasets Variables ValueLevel Codelists Dictionaries Documents Refresh

Info Last change on: 20240911 at 12:42:31 CEST by sdekeyser (Update)
1630 Variables

   **ADAE**  

CORE  CODI  COMMO  ORIG  SOURCE  PRE_MET_COM  HASNOI  COMMENT 

in_use	delete	ORDER	DATASET	VARIABLE	LABEL	DATA_TYPE	LENGTH	SIGN_DIGIT	FORMAT	CORE	CODELIST	COMMON (only XML2.1)	ORIGIN	SOURCE (only XML2.1)	Predecessor/Method	HASNODATA (only XML2.1)	COMMENT	DOCUMENT	PAGES
yes	☐	38	ADAE	AETERM	Identifier Reported Term for the Adverse Event	text	82			Req			Predecessor		AE.AETERM	no			
yes	☐	39	ADAE	AEDECOD	Dictionary- Derived Term	text	43			Req	AEDICT_F		Predecessor		AE.AEDECOD	no			
yes	☐	40	ADAE	ADECOD	Analysis Dictionary- Derived Term	text	43			Perm			Derived	Sponsor		no			
yes	☐	41	ADAE	AEBODSYS	Body System or Organ Class	text	67			Req	AEDICT_F		Predecessor		AE.AEBODSYS	no			
yes	☐	42	ADAE	AESOC	Primary System Organ Class	text	67			Cond	AEDICT_F		Predecessor		AE.AESOC	no			



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ID Spectackle



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Study Datasets Variables ValueLevel Codelists Dictionaries Documents

Refresh

Info

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1630 Variables

delete

0

ADAE

VARI

LABEL

CORE

CODI

COMMO

ORIG

SOURCE

PRE_MET_COM

HASNOI

COMMENT

in_use	delete	ORDER	DATASET	VARIABLE	LABEL	DATA_TYPE	LENGTH	SIGN_DIGIT	FORMAT	CORE	CODELIST	COMMON (only XML2.1)	ORIGIN	SOURCE (only XML2.1)	Predecessor/Method	HASNODATA (only XML2.1)	COMMENT	DOCUMENT	PAGES
					Event														
yes	☐	48	ADAE	ASTDT	Analysis Start Date	integer	5		DATE9.	Cond			Derived	Sponsor	AE.AESTDTC converted to sas date	no			
yes	☐	49	ADAE	ASTDTF	Analysis Start Date Imputation Flag	text	1			Cond	DATEFL		Derived	Sponsor	ASTDTF = M if year is present and month is imputed. ASTDTF = D if only day is imputed for analysis start date.	no			
yes	☐	50	ADAE	ASTDY	Analysis Start Relative Day	integer	3			Cond			Derived	Sponsor	ASTDY = ASTDT- TRTSDT+1, if ASTDT>= TRTSDT. Otherwise, ASTDY = ASTDT-TRTSDT.	no			
yes	☐	51	ADAE	AENDT	Analysis End Date	integer	5		DATE9.	Cond			Derived	Sponsor	AE.AEENDTC converted to sas date	no			
yes	☐	52	ADAE	AENDY	Analysis End Relative Day	integer	3			Perm			Derived	Sponsor	AENDY = AENDT- TRTSDT+1, if AENDT>= TRTSDT. Otherwise, AENDY = AENDT-TRTSDT.	no			
yes	☐	53	ADAE	ADURN	Analysis Duration (N)	integer	3			Perm			Derived	Sponsor	AENDT-ASTDT + 1	no			
yes	☐	54	ADAE	ADURU	Analysis Duration Units	text	4			Cond	UNIT		Assigned	Sponsor		no			
yes	☐	55	ADAE	PREFL	Pre-treatment Flag	text	1			Cond	Y_BLANK		Derived	Sponsor		no			
		56	ADAE	TRTEMFL	Treatment Emergent Analysis Flag	text	1			Cond	Y_BLANK		Derived	Sponsor		no			

Info

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FROM

keep_4_specs

DATAS

VARIABLE

VAR_WHERE

VALUE

CODELIST

ORIGIN

SOURCE

PRE_MET_CO

FROM	keep_4_specs	ORDER	DATASET	VARIABLE	VAR_WHERE	COMPARATOR	VALUE	DESCRIPTION	LENGTH	SIGN_DIGIT	ASSIGNEDVALUE (only XML2.1)	CODELIST	ORIGIN	SOURCE (only XML2.1)	PRE_MET_COM	DOCUMENT	PAGES
Codelist	☒	1	ADEG	AVALCAT1	PARAMCD	EQ	QT	Analysis Value Category 1	34			AVALCAT1_ADEG_PARAMCD					
Codelist	☒	2	ADEG	AVALCAT1	PARAMCD	EQ	QTCF	Analysis Value Category 1	34			AVALCAT1_ADEG_PARAMCD					
Codelist	☒	1	ADEG	CHGCAT1	PARAMCD	EQ	QTCF	Change from Baseline Category 1	57			CHGCAT1_ADEG_PARAMCD					
Codelist	☒	2	ADEG	CHGCAT1	PARAMCD	EQ	QT	Change from Baseline Category 1	57			CHGCAT1_ADEG_PARAMCD					
Codelist	☒	1	ADEG	CRIT2	PARAMCD	EQ	QTCF	Analysis Criterion 2	52			CRIT2_ADEG_PARAMCD					
Codelist	☒	1	ADEG	CRIT3	PARAMCD	EQ	QT	Analysis Criterion 3	29			CRIT3_ADEG_PARAMCD					

Add new rows

DATASET	VARIABLE	VAR_WHERE	COMPARATOR	VALUE
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Info

Last change on: 20240911 at 12:42:31 CEST by sdekeyser (Update)

in_use

delete

keep_4_specs

AE

NAME

NCI_CD

DATA_TYPE

TERMINOLOGY

COMMENT

ORI

TERM

NCI_TERM_CD

DECODED_VALUE

ValueLevel

PARAMCD

in_use	delete	keep_4_specs	ID	NAME	NCI_CODE	DATA_TYPE	TERMINOLOGY	COMMENT	ORDER	TERM	NCI_TERM_CODE	DECODED_VALUE	ValueLevel	PARAMCD
yes	☐	☒	AEOUTN	Outcome of Adverse Event (N)		integer			1	1		NOT RECOVERED/NOT RESOLVED	☐	
yes	☐	☒	AEOUTN	Outcome of Adverse Event (N)		integer			2	2		RECOVERING/RESOLVING	☐	
yes	☐	☒	AEOUTN	Outcome of Adverse Event (N)		integer			3	3		RECOVERED/RESOLVED WITH SEQUELAE	☐	
yes	☐	☒	AEOUTN	Outcome of Adverse Event (N)		integer			4	4		RECOVERED/RESOLVED	☐	
yes	☐	☒	AEOUTN	Outcome of Adverse Event (N)		integer			5	5		FATAL	☐	
yes	☐	☒	AEOUTN	Outcome of Adverse Event (N)		integer			6	6		UNKNOWN	☐	
yes	☐	☒	AETHNI	Analysis Ethnicity		text			1	Hispanic or Latino			☐	
yes	☐	☒	AETHNI	Analysis Ethnicity		text			2	Not Hispanic or Latino			☐	
yes	☐	☒	AETHNI	Analysis Ethnicity		text			3	Unknown			☐	
yes	☐	☒	AETHNIN	Analysis Ethnicity (N)		integer			1	1		Hispanic or Latino	☐	
yes	☐	☒	AETHNIN	Analysis Ethnicity (N)		integer			2	2		Not Hispanic or Latino	☐	
yes	☐	☒	AETHNIN	Analysis Ethnicity (N)		integer			3	3		Unknown	☐	
yes	☐	☒	AEVAL	Evaluator		text			1	INDEPENDENT ASSESSOR			☐	
yes	☐	☒	AEVAL	Evaluator		text			2	INVESTIGATOR			☐	

Add new rows

ID	TERM	DECODED_VALUE
----	------	---------------

Page:

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of 1

 ID Spectackle





EDITION

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Study Datasets Variables ValueLevel Codelists **Dictionaries** Documents

Update

Info

ID	Name	Data_type	Dictionary	Version	keep_4_specs
AEDICT_F	Adverse Event Dictionary	text	MedDRA		☐
AEDICTN_F	Adverse Event Dictionary (N)	integer	MedDRA		☐
DRUGDICT_F	Drug Dictionary	text	WHODRUG		☐
DRUGDICTN_F	Drug Dictionary (N)	integer	WHODRUG		☐

 ID Spectackle 

 EDITION sdekeyser

[Study](#) [Datasets](#) [Variables](#) [ValueLevel](#) [Codelists](#) [Dictionaries](#) [Documents](#) [Update](#)

Info

 No documents yet

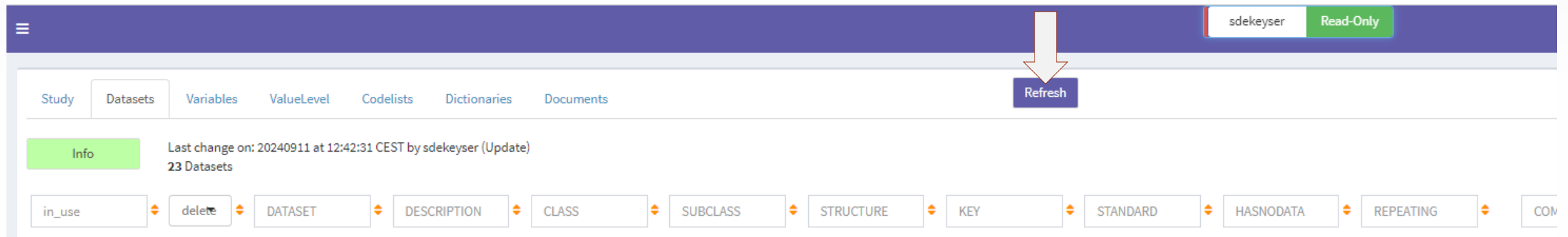
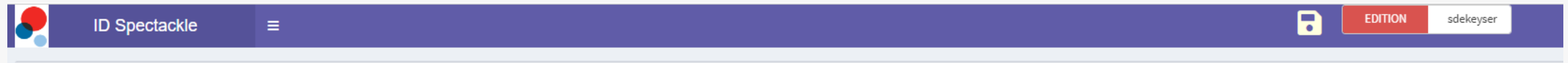
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☐ Delete

Add/update document

ID-SPECTACKLE User-friendly graphical interface



ID-SPECTACKLE User-friendly graphical interface

 ID Spectackle



Home

Study Selection

SPECTACKLE_DEMO_STAT

Report selection (Type/DB)

Phuse_DB_Phuse

Paths

Metadata

P21 tools

Specifications

Help

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sdekeyser

Read-Only

Specifications

Destination folder

Open V:\ID-Imagine Test\SPECTACKLE_DEMO\STAT\SDS_Spec\Phuse_DB_Phuse\Spec - Define\Specification

Filename

SPECTACKLE_DEMO_STAT_20240916_Specifications.xlsx

Include all datasets or uncheck to exclude

☒ ADSL

☐ ADABO

☒ ADAE

☐ ADCE

☐ ADCM

☐ ADDV

☒ ADEG

☐ ADEX

☐ ADIE

☐ ADIS

☐ ADLB

☐ ADLV

☐ ADMH

☐ ADPC

☐ ADPE

☐ ADPHD

☐ ADPP

☐ ADPR

☐ ADQS

☐ ADRS

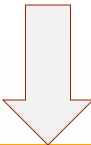
☐ ADTR

☐ ADTTE

☐ ADVS

Generate Specifications

Error summary



 SPECTACKLE_DEMO_STAT_20240916_Specifications.xlsx

Dataset Label		Class	SubClass	Structure
ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET		One record per subject
ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	One record per subject
ADEG	ECG Analysis Dataset	BASIC DATA STRUCTURE		One record per subject

< >

Define

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Comments

Documents

+

ID-SPECTACKLE -> DEFINE.XML

 SPECTACKLE_DEMO_STAT_20240916_Specifications.xlsx

Dataset	Label	Class	SubClass	Structure
ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET		One record per subject
ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	One record per subject
ADEG	ECG Analysis Dataset	BASIC DATA STRUCTURE		One record per subject

<

>

Define

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P21

SPECTACKLE_DEMO_STAT

- Standards
- > **Datasets**
- > Controlled Terminology
- > Methods

Expand all VLM

Collapse all VLM

Study Name SPECTACKLE_DEMO_STAT

Study Description !!!Copy protocol title here!!!

Protocol Name SPECTACKLE_DEMO_STAT

Metadata Name Study SPECTACKLE_DEMO_STAT Data Definitions

Date/Time of Define-XML document generation: 2024-09-20T15:13:17+02:00
Define-XML version: 2.1.0
Define-XML Context: Submission
Stylesheet version: 2019-02-11

Standards for Study SPECTACKLE_DEMO_STAT

Standard	Type	Status	Documentation
CDISC/NCI ADaM 2024-03-29	CT	FINAL	
ADaM-IG 1.2	IG	FINAL	
CDISC/NCI SDTM 2021-12-17	CT	FINAL	

Datasets

Dataset	Description	Class - SubClass	Structure	Purpose	Keys	Documentation	Location
ADSL [ADaM-IG 1.2]	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET	One record per subject	Analysis	USUBJID		adsl.xml @
ADEG [ADaM-IG 1.2]	ECG Analysis Dataset	BASIC DATA STRUCTURE	One record per subject per parameter per visit	Analysis	USUBJID, ASEQ		adeo.xml @
ADAE [ADaM-IG 1.2]	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE - ADVERSE EVENT	One record per subject per adverse event	Analysis	USUBJID, AETERM, ASTDT, MXSEVGRN		adae.xml @

Go to the [100](#) of the Define-XML document

ADSL (Subject-Level Analysis Dataset) - [ADaM-IG 1.2]

Location: [adsl.xml](#) @

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	8		Predecessor: DM.STUDYID
USUBJID	Unique Subject Identifier	text	18		Predecessor: DM.USUBJID

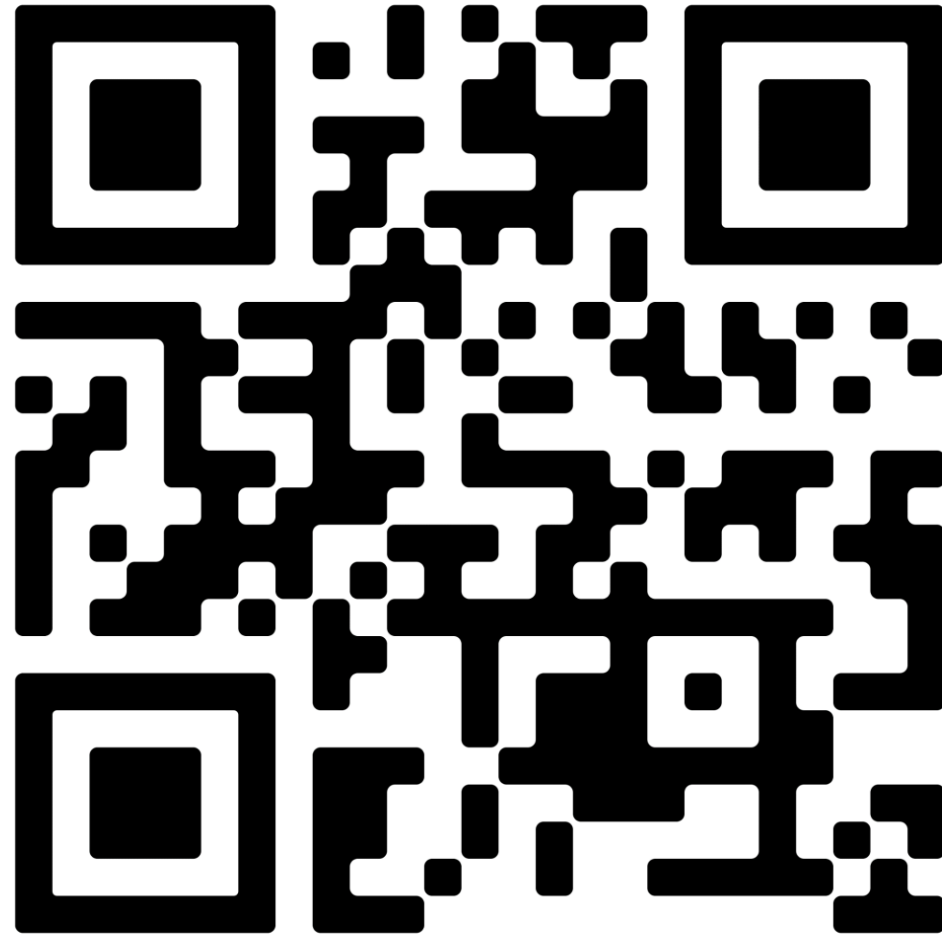
ID-SPECTACKLE

CONTINUOUS UPDATE CYCLE

- Automatic metadata update
 - At each Dataset update (program rerun)
 - Keep manual entries in Specs



ID-SPECTACKLE - QR CODE (DEMONSTRATION)

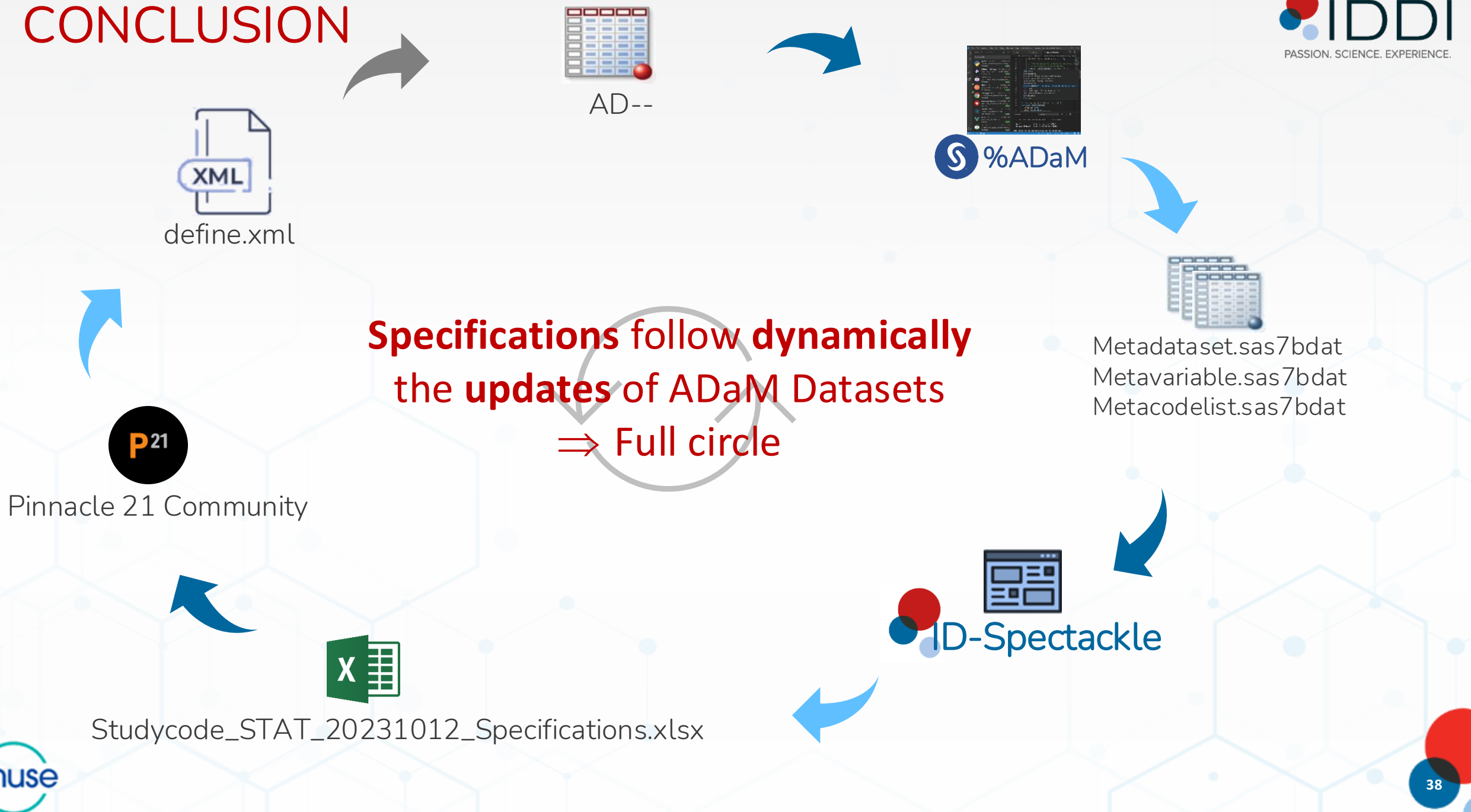


CONCLUSION

CONCLUSION

- Goal
 - Automate the generation of Specifications & Define.xml
- ID-Spectackle
 - Combination of a SAS® Macro and a web-interface.

CONCLUSION



CONCLUSION

- Less time and effort
- Visual cues
- Inter-connection between metadatas
- Quality and CDISC compliance
- Traceability
- Always up-to-date
- Follows standard template from P21
- Extractions of partial metadata
- Material for validation
- Reusability of specifications
- User-friendly

CONCLUSION

FUN



CONCLUSION

... until AI does it for us



THANK YOU!

WE WOULD LIKE TO THANK IDDI AND MORE SPECIFICALLY OUR COLLEAGUES OF THE DEPARTMENT OF BIostatISTICS, OUR COLLEAGUE STEFANIA GIAMMANCO FOR HER KNOWLEDGE AND EXPERIENCE IN R FOR THE MAINTENANCE OF THE INTERFACE, AND OUR ESTIMATE COLLEAGUES' PROGRAMMERS WHO TOOK THE TIME TO READ AND PROVIDE FEEDBACK ON THIS PRESENTATION.

Questions ?

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