

ID-SPECTACKLE: A TOOL FOR FASTER AND SMOOTHER CREATION OF ADAM SPECIFICATIONS AND ADRG

PHUSE SDE 2025

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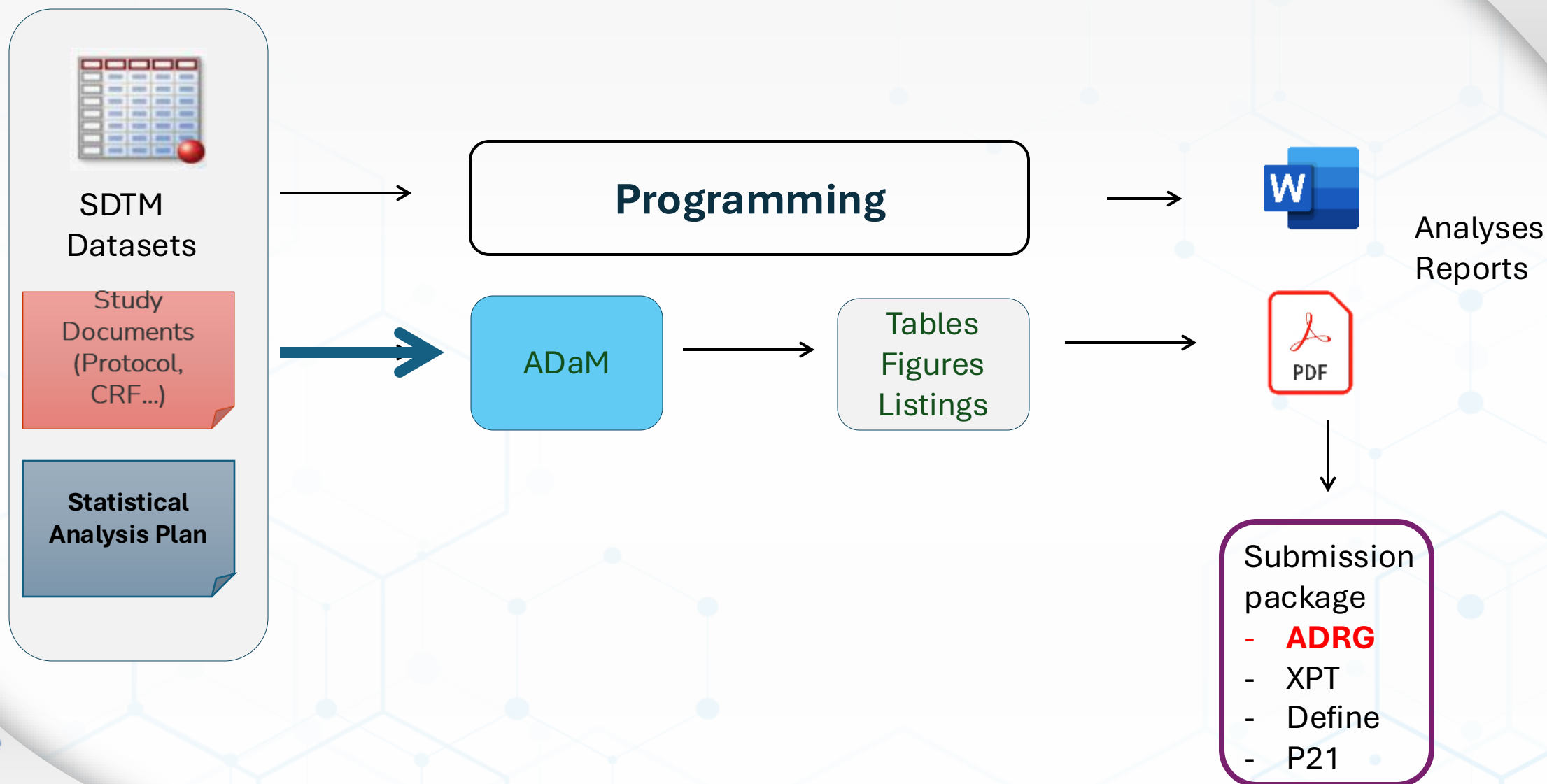
AGENDA

- Introduction
- Global Idea
- %ADAM and %HeaderMacroScan macro
- ID-Spectackle
- Conclusion



INTRODUCTION

INTRODUCTION



ADRG SECTIONS

- ▢ 1. Introduction
 - ▢ 1.1 Purpose
 - ▢ 1.2 Acronyms
 - ▢ 1.3 Study Data Standards and Dictionary Inventory
 - ▢ 1.4 Source Data Used for Analysis Dataset Creation
- ▢ 2. Protocol Description
 - ▢ 2.1 Protocol Number and Title
 - ▢ 2.2 Protocol Design in Relation to ADaM Concepts
- ▢ 3. Analysis Considerations Related to Multiple Analysis Datasets
 - ▢ 3.1 Comparison of SDTM and ADaM Content
 - ▢ 3.2 Core Variables
 - ▢ 3.3 Treatment Variables
 - ▢ 3.4 Subject Issues that Require Special Analysis Rules
 - ▢ 3.5 Use of Visit Windowing, Unscheduled Visits, and Record Selection
 - ▢ 3.6 Imputation/Derivation Methods

- ▢ 4. Analysis Data Creation and Processing Issues
 - ▢ 4.1 Split Datasets
 - ▢ 4.2 Data Dependencies
 - ▢ 4.3 Intermediate Datasets
 - ▢ 4.4 Variable Conventions
- ▢ 5. Analysis Dataset Descriptions
 - ▢ 5.1 Overview
 - ⊕ ▢ 5.2 Analysis Datasets
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 - ▢ 6.1 Conformance Inputs
 - ▢ 6.2 Issues Summary
- ▢ 7. Submission of Programs
- ▢ 8. Appendix



Not as simple as it sounds



Specifications



ADRG



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

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



an IDea...
ID-SPECTACKLE



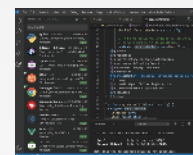


GLOBAL IDEA

GLOBAL IDEA



AD--



 %ADaM &
%HeaderMacroScan



ID Spectackle

Study: SPCTACKLE_DEMO_STAT

Report selection (Type/DB): Phuse, DB, Phuse

Info: Last change on 20240311 at 12:42:51 CEST by subkeyan (update)

23 Datasets

In use	delete	DATASET	DESCRIPTION	CLASS	SUBCLASS (only XML2.1)	STRUCTURE	KEY	STANDARD (only XML2.1)	HASNOOATA (only XML2.1)	REPEATING	COMMENT
yes		ADSL	Subject Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET		One record per subject	USUBJID	ADaM R3 1.2	no	no	
yes		ADPAG	ADQ and antibody Analysis Dataset	ADAM OTHER		One record per subject	USUBJID	ADaM R3 1.2	no	yes	
yes		ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	One record per subject per adverse event	USUBJID, AETID, ASTOT, AERSON, PARACAT, VISITNUM	ADaM R3 1.2	no	yes	
yes		ADCE	Infusion Rate Dataset	STRUCTURE		One record per subject per parameter	USUBJID, PARACAT, VISITNUM	ADaM R3 1.2	no	yes	
yes		ADCM	Concomitant Analysis Dataset	E DATA		One record per subject per concomitant medication	USUBJID, CMCD, CMCDT, CMCDN	ADaM R3 1.2	no	yes	
yes		ADOV	Protocol Devs Dataset				USUBJID, DTCAT, DTCATN, DTCATM	ADaM R3 1.2	no	yes	
yes		ADFO	ECG Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter per visit	USUBJID, ASTO	ADaM R3 1.2	no	yes	
yes		ADER	Exposure Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter	USUBJID, PARACATN, PARACATM, ASQ	ADaM R3 1.2	no	yes	
yes		ADLE	Inc./EAC QTY Not Met Analysis Dataset	OCCURRENCE DATA STRUCTURE		One record per subject	USUBJID, IBCAT, ITEST	ADaM R3 1.2	no	yes	
yes		ADIS	ADA Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter	USUBJID, AESTTN, ATPN, IMPRACD	ADaM R3 1.2	no	yes	
yes		ADLB	Laboratory Test Results Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter per visit	USUBJID, IMPRACATL	ADaM R3 1.2	no	yes	



Specifications.xlsx



define.xml



ADRG



%ADAM

%HEADERSCANMAC

%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

%ADAM

•How to use?

```
%_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;
```



%ADAM

•How to use?

- 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, ...)

%HEADERSCANMAC

- Identify all SAS programs and macros used in the analysis
- Save the list of macros in an excel file
- Used in creation of metaboards in ID-Spektackle

How to use?

```
%HeaderMacroScan(type=Derived,  
                  folder=&pathDerivedPGM.,  
                  macfolder=&pathMacPGM.,  
                  outxlsx=%str(&pathspecadrg.\&studyid._HeaderMACS.xlsx),  
                  debug=N);
```

%ADAM AND %HEADERSCANMAC

- The main goal of the macro is to collect metadata.

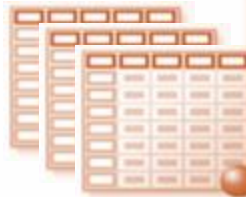


AD--

%ADaM



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



Metadataset.sas7bdat
Metavariable.sas7bdat
Metacodelist.sas7bdat
Metamacpgm.sas7bdat
Metamac.sas7bdat



ID-Spectackle WebUI

- 1.4 Source Data Used for Analysis Dataset Creation
- 2. Protocol Description
 - 2.1 Protocol Number and Title
 - 2.2 Protocol Design in Relation to ADaM Concepts
- 3. Analysis Considerations Related to Multiple Analy...
 - 3.1 Core Variables
 - 3.2 Treatment Variables
 - 3.3 Subject Issues that Require Special Analysis R...
 - 3.4 Use of Visit Windowing, Unscheduled Visits, a...
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 - 5.2.1 ADSL – Subject Level Analysis Dataset
 - 5.2.x Dataset – Dataset Label
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 - 6.1 Conformance Inputs
 - 6.2 Issues Summary
- 7. Submission of Programs
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 - 7.2 Analysis Output Programs
 - 7.3 Macro Programs
- 8. Appendix

ID-SPECTACKLE

User-friendly graphical interface

INTERFACE

 ID Spectackle TEST

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SPECTACKLE_DEMO_STAT ▼

Report selection (Type/DB)

Demo_DB_xx ▼

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P21 tools <

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>> ADRG

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✉ Email

SPECTACKLE_DEMO_STAT Demo_DB_xx

Summary

13 Datasets
692 Variables

Last metadata: 2024-04-10 11:42:02 CEST
Latest update: 2025-05-27 15:07:31 CEST ✓

IMPORTING DATA FROM CORRECT FOLDERS

 ID Spectackle TEST

Study Selection

SPECTACKLE_DEMO_STAT

Report selection (Type/DB)

Demo_DB_xx

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Paths

(*) Paths that does not exist

Metadata Library	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Datasets/Demo/DB_xx/metadata	Open
ID Spectackle	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/SDS_Spec/Demo_DB_xx	Open
ID Imagine	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/SDS_Dictionnary/Demo_DB_xx	Open

Derived

Derived	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Datasets/Demo/DB_xx	Open
Programs	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Programs/Demo/Analysis Datasets	Open

Tables

Tables	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Outputs/Demo/DB_xx/Tables	Open
Programs	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Programs/Demo/Tables	Open

Graphs

Graphs	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Outputs/Demo/DB_xx/Figures	Open
Programs	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Programs/Demo/Figures	Open

Listings

Listings	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Outputs/Demo/DB_xx/Listings	Open
Programs	V:/ID-Imagine Test/SPECTACKLE_DEMO/STAT/Analysis Programs/Demo/Listings	Open

STUDY BOARD

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SPECTACKLE_DEMO_STAT

Report selection (Type/DB)

Demo_DB_xx

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Info

Study board last edited on: 20250527 at 15:09:48 CEST by sgiammanco

Study Name	DEMOStudy
Study Description	This is a test metadata for ADRG from ID-Spectackle
Protocol Name	DEMOProtocol
Standard Name	ADaMIG
Standard Version	1.2
Language	en
Sponsor Name	IDDI
Protocol Version	Test 2025-02-06, Test 2025-02-06 (amendment 1)
Core Variables	STUDYID USUBJID SUBJID SAFFL TRTSDT TRTEDT
SDTM	v2.0/IG 3.4
SDTM Controlled Terminology	CDISC/NCI SDTM 2024-09-27
ADaM	v2.1/IG 1.2
ADaM Controlled Terminology	CDISC/NCI ADaM 2024-09-27
Data Definitions	define.xml v 2.0
TAUG	NA
Medications Dictionary	WHODD June 2024
Medical Events Dictionary	v25.0
AE toxicity grading	CTCAE v5.0

1. Introduction

1.1 Purpose

1.2 Acronyms

1.3 Study Data Standards and Dictionary Inventory

1.4 Source Data Used for Analysis Dataset Creation

2. Protocol Description

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3. Analysis Considerations Related to Multiple Analysis Datasets

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3.3 Treatment Variables

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3.5 Use of Visit Windowing, Unscheduled Visits, and Record Selection

3.6 Imputation/Derivation Methods

METABOARD - DATASETS

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

Info Last change on: 20250527 at 15:07:31 CEST by sgiammanco (Update)
13 Datasets

in use delete DATASET DESCRIPTION CLASS SUBCLASS STRUCTURE KEY STANDARD HASNODATA REPEATING

in_use	delete	DATASET	DESCRIPTION	CLASS	SUBCLASS (only XML2.1)	STRUCTURE	KEY	STANDARD (only XML2.1)	HASNODATA (only XML2.1)	REPEATING
yes	☐	ADAO	Audiometry Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per !! to be updated !! per parameter per visit per date per datetime per source sequence	USUBJID, PARCAT1, PARAMCD, PARAM, AVISITN, AVISIT, ADT, ADTM, SRCSEQ			yes
yes	☐	ADCM	Concom./Prior Medicat. Analysis Dataset	OCCURRENCE DATA STRUCTURE		One record per subject per !! to be updated !! per preferred term per start date per end date	USUBJID, CMSEQ, CMDECOD, ASTDT, AENDT			yes
yes	☐	ADDV	Protocol Deviation Analysis Dataset	OCCURRENCE DATA STRUCTURE		One record per subject per !! to be updated !!	USUBJID, DVSTDTC			yes
yes	☐	ADEG	ECG Results Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter per visit per date per datetime	USUBJID, PARAMN, AVISITN, ADT, ADTM			yes
yes	☐	ADEX	Exposure Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter per visit	USUBJID, PARAM, PARAMCD, AVISIT, AVISITN			yes
yes	☐	ADIE	Inc./Exc. Crit. Not Met Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per !! to be updated !!	USUBJID, IESEQ			yes
yes	☐	ADLB	Laboratory Test Results Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per !! to be updated !! per parameter per visit per date	USUBJID, PARCAT1, PARAMCD, AVISITN, ADT			yes
yes	☐	ADMH	Medical History Analysis Dataset	OCCURRENCE DATA STRUCTURE		One record per subject per preferred term per body system per start date per end date per !! to be updated !!	USUBJID, MHDECOD, MHBODSYS, ASTDT, AENDT, MHSEQ			yes
yes	☐	ADPE	Physical Examination Analysis Dataset	BASIC DATA STRUCTURE		One record per subject per parameter per date per visit per timepoint	USUBJID, PARAMN, PARAMCD, PARAM, ADT, ADTM			yes

METABOARD - VARIABLES

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

Info Last change on: 20250527 at 15:07:31 CEST by sgiammanco (Update)
692 Variables

☐ delete ☐ O ☐ DATA ☐ VARI ☐ LABE ☐ CORE ☐ CODI ☐ COMMO ☐ ORIG ☐ SOURCE ☐ PRE_MET_COM ☐ HASNOI

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)
yes	☐	1	ADAE	STUDYID	Study Identifier	text	12			Req			Predecessor		ADSL.STUDYID	
yes	☐	2	ADAE	SITEID	Study Site Identifier	text	4			Perm			Predecessor		ADSL.SITEID	
yes	☐	3	ADAE	SUBJID	Subject Identifier for the Study	text	9			Perm			Predecessor		ADSL.SUBJID	
yes	☐	4	ADAE	USUBJID	Unique Subject Identifier	text	22			Req			Predecessor		ADSL.USUBJID	
yes	☐	5	ADAE	AGE	Age	integer	2			Perm			Predecessor		ADSL.AGE	
yes	☐	6	ADAE	SEX	Sex	text	1			Perm			Predecessor		ADSL.SEX	
yes	☐	7	ADAE	RACE	Race	text	5			Perm			Predecessor		ADSL.RACE	
yes	☐	8	ADAE	SAFFL	Safety Population Flag	text	1			Perm			Predecessor		ADSL.SAFFL	
yes	☐	9	ADAE	ITTFL	Intent-To-Treat Population Flag	text	1			Perm			Predecessor		ADSL.ITTFL	
yes	☐	10	ADAE	ARM	Description of Planned Arm	text	36			Perm			Predecessor		ADSL.ARM	
yes	☐	11	ADAE	ACTARM	Description of Actual Arm	text	36			Perm			Predecessor		ADSL.ACTARM	
yes	☐	12	ADAE	TRT01P	Planned Treatment for Period 01	text	23			Perm			Predecessor		ADSL.TR01P	

METABOARD - VALUELEVEL



Study Datasets Variables ValueLevel Codelists Dictionaries Documents Refresh														
Info Last change on: 20250527 at 15:07:31 CEST by sgiammanco (Update)														
FROM keep_4_specs DATA/ VARL VAR_WI VALL CODELIST ORIG SOURCE														
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)
Codelist	☒	1	ADAE	ACTARM	PARAMCD	EQ	SYSBP	Description of Actual Arm	36				▼	
Codelist	☒	2	ADAE	ACTARM	PARAMCD	EQ	DIABP	Description of Actual Arm	36				▼	
Codelist	☒	3	ADAE	ACTARM	PARAMCD	EQ	HR	Description of Actual Arm	36				▼	
Codelist	☒	1	ADAE	ADECOD	PARAMCD	EQ	SYSBP	Analysis Dictionary-Derived Term	24				▼	
Codelist	☒	2	ADAE	ADECOD	PARAMCD	EQ	DIABP	Analysis Dictionary-Derived Term	24				▼	
Codelist	☒	3	ADAE	ADECOD	PARAMCD	EQ	HR	Analysis Dictionary-Derived Term	24				▼	
Codelist	☒	1	ADAE	AEACN	PARAMCD	EQ	SYSBP	Action Taken with Study Treatment	14				▼	
Codelist	☒	2	ADAE	AEACN	PARAMCD	EQ	DIABP	Action Taken with Study Treatment	14				▼	
Codelist	☒	3	ADAE	AEACN	PARAMCD	EQ	HR	Action Taken with Study Treatment	14				▼	
Codelist	☒	1	ADAE	AEBDSYCD	PARAMCD	EQ	SYSBP	Body System or Organ Class Code	8				▼	
Codelist	☒	2	ADAE	AEBDSYCD	PARAMCD	EQ	DIABP	Body System or Organ Class Code	8				▼	
Codelist	☒	3	ADAE	AEBDSYCD	PARAMCD	EQ	HR	Body System or Organ Class Code	8				▼	
Codelist	☒	1	ADAE	AEBODSYS	PARAMCD	EQ	SYSBP	Body System or Organ Class	52				▼	
Codelist	☒	2	ADAE	AEBODSYS	PARAMCD	EQ	DIABP	Body System or Organ Class	52				▼	
Codelist	☒	3	ADAE	AEBODSYS	PARAMCD	EQ	HR	Body System or Organ Class	52				▼	
Codelist	☒	1	ADAE	AEDECOD	PARAMCD	EO	SYSBP	Dictionary-Derived Term	24				▼	

METABOARD – CODELISTS AND DICTIONARIES

Study Datasets Variables ValueLevel **CodeLists** Dictionaries Documents Refresh

Info Last change on: 20250527 at 15:07:31 CEST by sgiammanco (Update)

in_use delete keep_4_specs ID NAME NCI_CODE DATA_TYPE TERMINOLOGY COMMENT ORDER TERM NCI_TERM_CODE DECODED_VALUE ValueLevel

in_use	delete	keep_4_specs	ID	NAME	NCI_CODE	DATA_TYPE	TERMINOLOGY	COMMENT	ORDER	TERM	NCI_TERM_CODE	DECODED_VALUE	ValueLevel
yes	☐	☒	ACLSIG	Analysis Clinical Significant		text			1	ABNORMAL			☐
yes	☐	☒	ACLSIG	Analysis Clinical Significant		text			2	ABNORMAL, NOT CLINICALLY SIGNIFICANT			☐
yes	☐	☒	ACLSIG	Analysis Clinical Significant		text			3	NORMAL			☐
yes	☐	☒	ACLSIGN	Analysis Clinical Significant (N)		integer			1	1		NORMAL	☐
yes	☐	☒	ACLSIGN	Analysis Clinical Significant (N)		integer			2	2		ABNORMAL, NOT CLINICALLY SIGNIFICANT	☐
yes	☐	☒	ACLSIGN	Analysis Clinical Significant (N)		integer			3	3		ABNORMAL	☐

Study Datasets Variables ValueLevel **CodeLists** **Dictionaries** Documents Refresh

Info Dictionaries board last saved on 20250527 at 15:07:31 CEST by sgiammanco

ID	Name	Data_type	Dictionary	Version	keep_4_specs
AEDICT_F	Adverse Event Dictionary	text	MedDRA	v25.0	☐
DRUGDICT_F	Drug Dictionary	text	WHODRUG	WHODD June 2024	☐

SPECIFICATIONS

Specifications

Destination folder

Open

V:\ID-Imagine Test\SPECTACKLE_DEMO\STAT\SDS_Spec/Demo_DB_xx/Spec - Define/Specification

Filename

SPECTACKLE_DEMO_STAT_ 20250530_Specifications .xlsx

Include all datasets or uncheck to exclude

☒ ADSL ☒ ADAE ☒ ADAU ☒ ADCM ☒ ADDV ☒ ADEG ☒ ADEX ☒ ADIE ☒ ADLB ☒ ADMH ☒ ADPE ☒ ADPR ☒ ADVS

Generate Specifications

Error summary

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SPECTACKLE_DEMO_STAT

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Analysis Data Reviewers Guide

Before prefilling ADRG, make sure that **metastudy**, **metamac** and **metamacpgm** are made.
These should be produced by the macro %headermacroscan (at the end of master.sas) when all ADaM passed QC

Folder

Open V:\ID-Imagine Test\SPECTACKLE_DEMO\STAT\SDS_Spec/Demo_DB_xx/Spec - Define/ADRG

Filename

Analysis Data Reviewers Guide_fromIDSPEC_20250530.docx

Pre-fill from template

Examples See here for some examples of completed ADRG

The parts of the ADRG that can be pre-filled are: Cover page, headers, table 1.3, paragraph 2.1, table 3.1, table 5.2, paragraph 6.1, tables 6.2, 7.1 and 7.3
Pre-filling depends on information available (metastudy, metamac, metamacpgm, P21 report)
Note: pre-filling is partial. After creation, the ADRG needs checking and completion of remaining sections.

Optional: choose P21 reports

Used for paragraphs 6.1 & 6.2

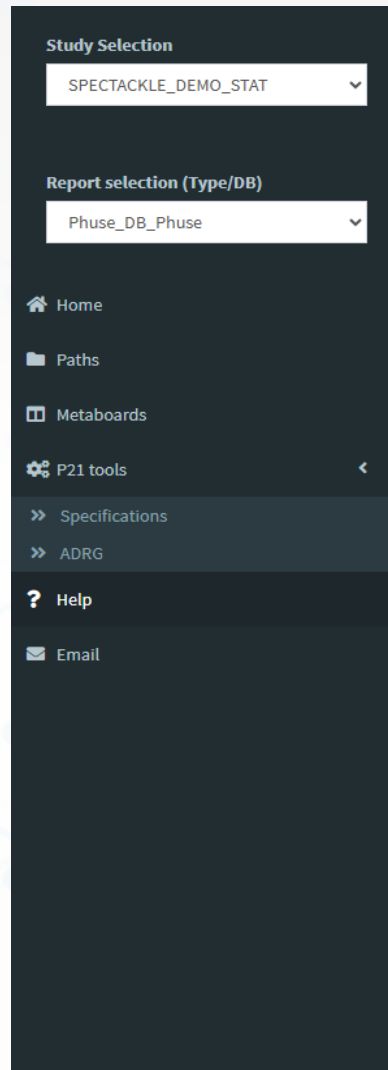
P21 reports should be in V:\ID-Imagine Test\SPECTACKLE_DEMO\STAT\SDS_Spec/Demo_DB_xx/Spec - Define/Validation

Nothing selected

Prefill ADRG

- 4. Analysis Data Creation and Processing Issues
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SUPPORTING DOCUMENTATION



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SPECTACKLE_DEMO_STAT

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Phuse_DB_Phuse

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Get started
ID-Spectackle setup
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Get started

The study needs to be already setup in ID-Imagine.

From the **Home** button, check/uncheck studies as you would normally do and [Save Profile](#).

Selected studies are available from the Study Selection dropdown. When a study is selected, the reports/DB that exist in ID-Imagine are available in the second dropdown.

ID-Spectackle setup

There is a warning panel if metadata is not found in the expected folder .../Analysis Datasets/Report/DB/metadata.

If so, please ensure there is metadata in the appropriate folder and try again.

To initialize Spectackle for a new report simply click [Create/complete Spectackle setup](#)

AC001_STATIB_DSUR01_U_20220119

Warning

No metadata found

Please check Derived datasets folder:

N:\ID-Imagine Test\AC001\STAT\Analysis Datasets\IB_DSUR01\U_20220119\metadata

use ID-Imagine to modify or set Paths

OUTPUT

UNLICENSED PRODUCT Most features are turned off because a shared computer license isn't available. To use these features, close Word, restart it, and sign in with your Microsoft 365 account. [Get help](#)

Navigation

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 - 5.2.6 ADEG - ECG Results Analysis Dataset
 - 5.2.7 ADEX - Exposure Analysis Dataset
 - 5.2.8 ADIE - Inc./Exc. Crit. Not Met Analysis D...
 - 5.2.9 ADLB - Laboratory Test Results Analysis...
 - 5.2.10 ADMH - Medical History Analysis Data...
 - 5.2.11 ADPE - Physical Examination Analysis...
 - 5.2.12 ADPR - Procedure Analysis Dataset
 - 5.2.13 ADVS - Vital Signs Analysis Dataset
- 6. Data Conformance Summary

Confidential

Analysis Data Reviewer's Guide

IDDI

DEMO-ADRG-001 DEMO-ADRG-001
ADRG Template Version 2025-05-20

SAMPLE ADRG

Study < Protocol Number >

Analysis Data Reviewer's Guide

1. Introduction

1.1 Purpose

This document provides context for the analysis datasets and terminology that benefit from additional explanation beyond the Data Definition document (define.xml) for an individual study. In addition, this document provides a summary of ADaM conformance findings. *[Legacy Conversion: Optional details]*

1.2 Acronyms

Acronym	Translation
aCRF	Annotated Case Report Form
ADaM	Analysis Dataset Model
ADRG	Analysis Data Reviewer's Guide
eCRF	Electronic Case Report Form
eDT	Electronic Data Transfer (e.g. central lab data, ECG vendor data, PK data, etc.)
IG	Implementation Guide
NA	Not Applicable
SDTM	Study Data Tabulation Model
TAUG	Therapeutic Area User Guide

Comments

New

32 items

Note: Certain ADRG Sections include a series of questions intended to aid FDA Reviewers. Provide complete answers to all questions. Do not delete the primary questions from the final document.

The inclusion of all sections both maintains numbering convention and removes any doubt that sections were 'forgotten'. A simple statement stating 'Not applicable' should suffice.

May 23, 2025, 5:39 AM

Reply

Also included are details regarding <legacy analysis data conversion to ADaM> / <legacy tabulation data conversion to SDTM> and then to ADaM

Reply

This optional section documents any industry standard acronyms, sponsor-specific or non-industry standard acronyms used in the ADRG

Reply

CONCLUSION

CONCLUSION

Goal

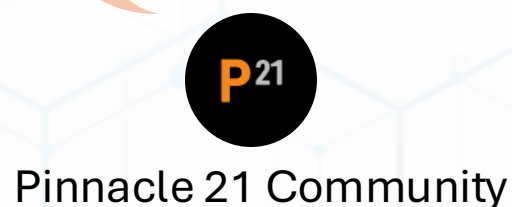
- Automate the generation of Specifications ,Define.xml and prefill of ADRG

ID-Spectackle

- Combination of a SAS® Macro and a web-interface.



**Specifications follow dynamically
the updates of ADaM Datasets
⇒ Full circle**



CONCLUSION

- Less time and effort
- Visual cues
- Inter-connection between metadata
- 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

THANK YOU!

Questions ?

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