Recipe for Efficiency: Standards + Metadata = Automation

Chris Ridley

Matthew Brierley

PHUSE 2023

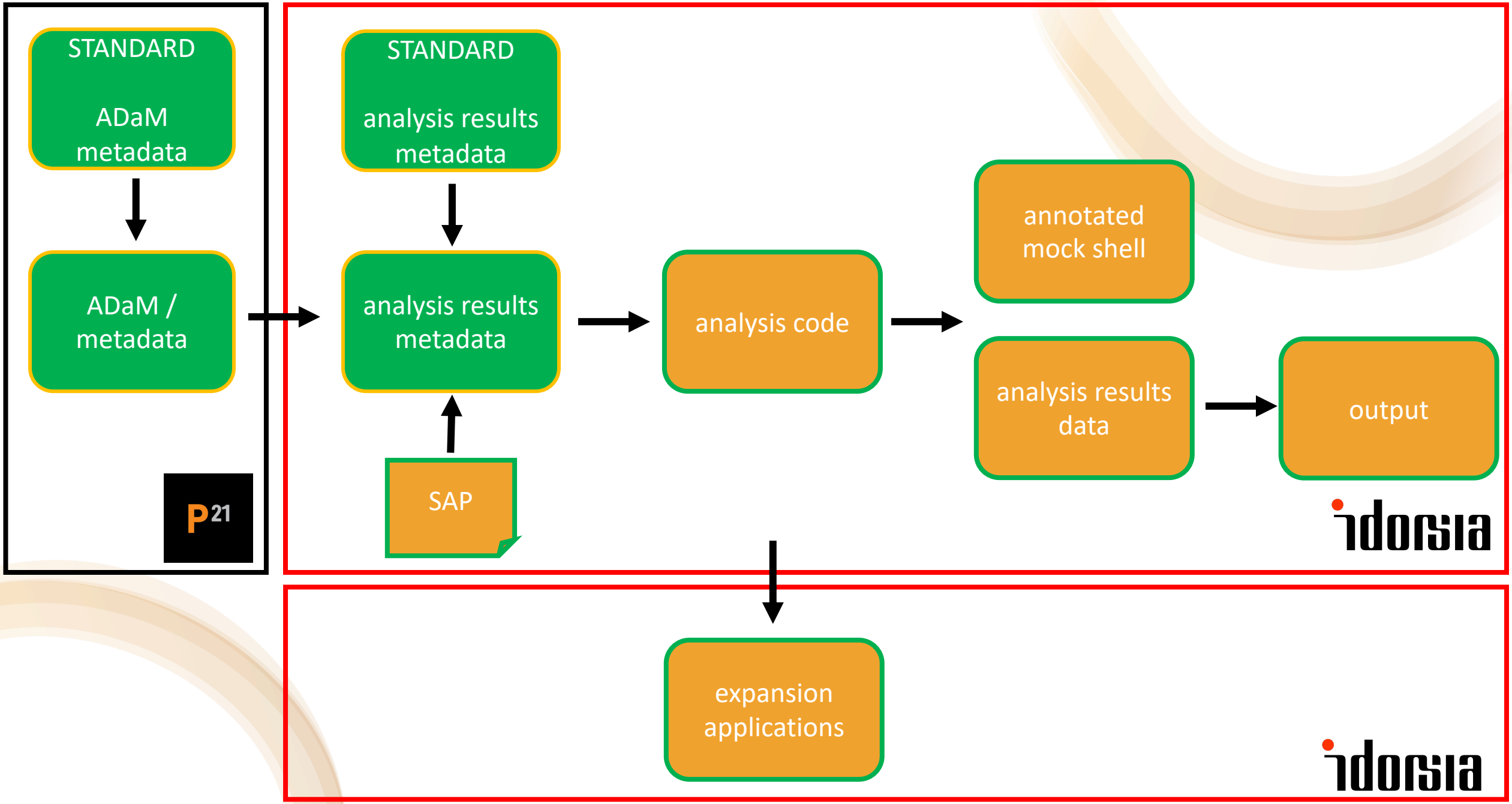
Laying the path for efficiency gains

3 key concepts

Capturing analysis results metadata enables output automation

Strong standards enable quicker metadata entry

Machine readable metadata is extremely useful for building supportive tools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Metadata sources for output generation

Define.xml

- API import from Pinnacle 21
- Analysis Datasets
- Analysis Variables
- Codelists

analysis results metadata

ARM

Calculation rules

- Analysis Methods
- Analysis Datasets
- Analysis Variables
- Analysis Groupings
- Data filtering clauses

Presentation rules

- Titles and Footnotes
- Report layout schemas
- Table formatting rules

Reference

- Programming notes
- SAP destination

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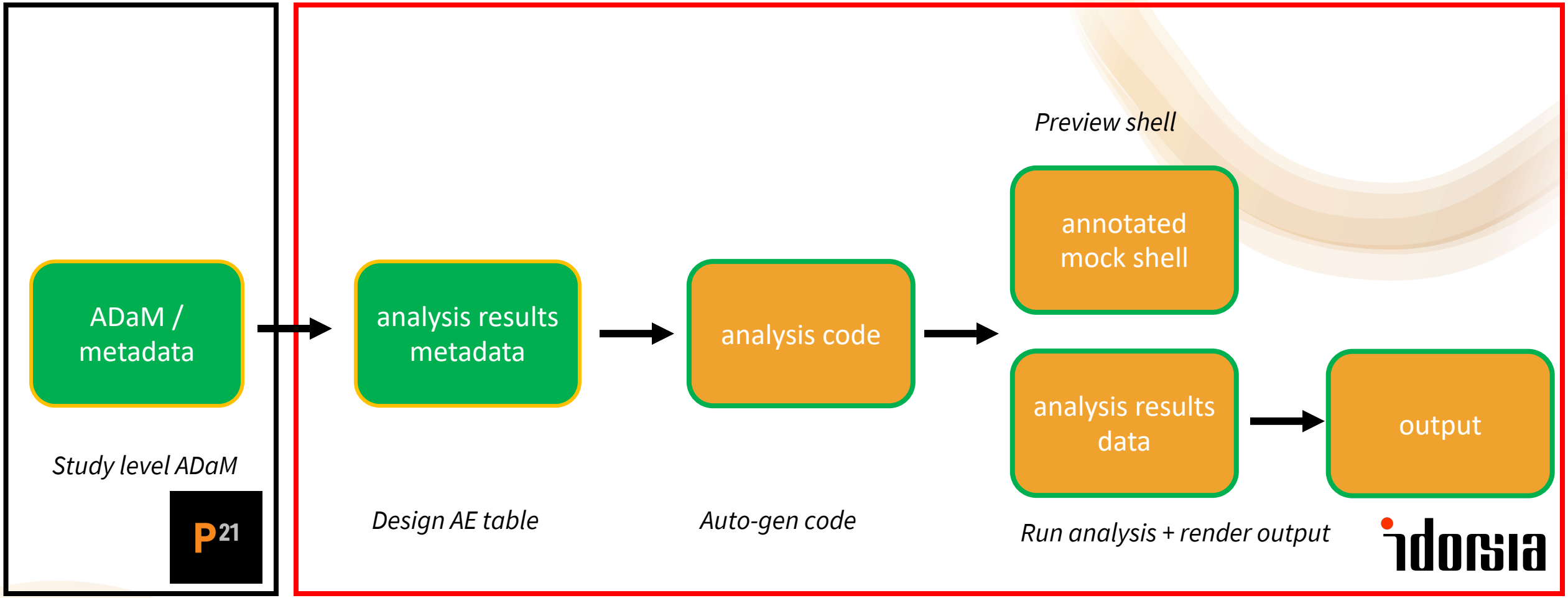
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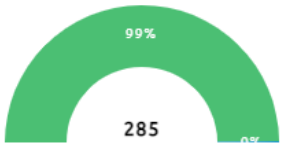

ARM_OID	TYPE	NUMBER	TITLE	POPULATION	PRIORITY	IN-TEXT	STATE	CREATED	LAST UPDATE	ACTIONS
T_ENROL01_SCR	Table	15.1.1-1.1	Overview of recruitment by country and site	Screened Analysis Set	2	✕	●	2022-05-09 ridlech1	6 months ago ridlech1	
T_ENROL01_RND	Table	15.1.1-1.2	Overview of recruitment by country and site	Randomized Analysis Set	2	✕	●	2022-05-24 ridlech1	6 months ago ridlech1	
T_ENROL01_PH_FAS	Table	15.1.1-1.3	Overview of recruitment by country and site	Full Analysis Set	2	✕	●	2023-06-28 ridlech1	4 weeks ago ridlech1	
T_DISP02_RND	Table	15.1.1-2.1	Disposition of subjects	Randomized Analysis Set	0	✓	●	2022-08-30 ridlech1	7 months ago ridlech1	
T_FAIL01_SCR	Table	15.1.1-3.1	Reasons for screening failure	Screened Analysis Set	2	✕	●	2022-05-23 ridlech1	6 months ago ridlech1	
T_DISP03_STUDY_RND	Table	15.1.1-4.1	Reasons for premature study discontinuation	Randomized Analysis Set	2	✕	●	2022-05-24 ridlech1	6 months ago ridlech1	
T_DISP04_TRT_FAS	Table	15.1.1-5.1	Reasons for premature study treatment discontinuation	Full Analysis Set	0	✓	●	2022-05-10 ridlech1	7 months ago ridlech1	
T_PLNDTRT_RND	Table	15.1.2-1.1	Analysis sets - according to planned treatment group	Randomized Analysis Set	2	✕	●	2022-05-23 ridlech1	6 months ago ridlech1	
T_ACTUTRT_SS	Table	15.1.2-2.1	Analysis sets - according to actual treatment group	Safety Set	2	✕	●	2022-05-23 ridlech1	6 months ago ridlech1	

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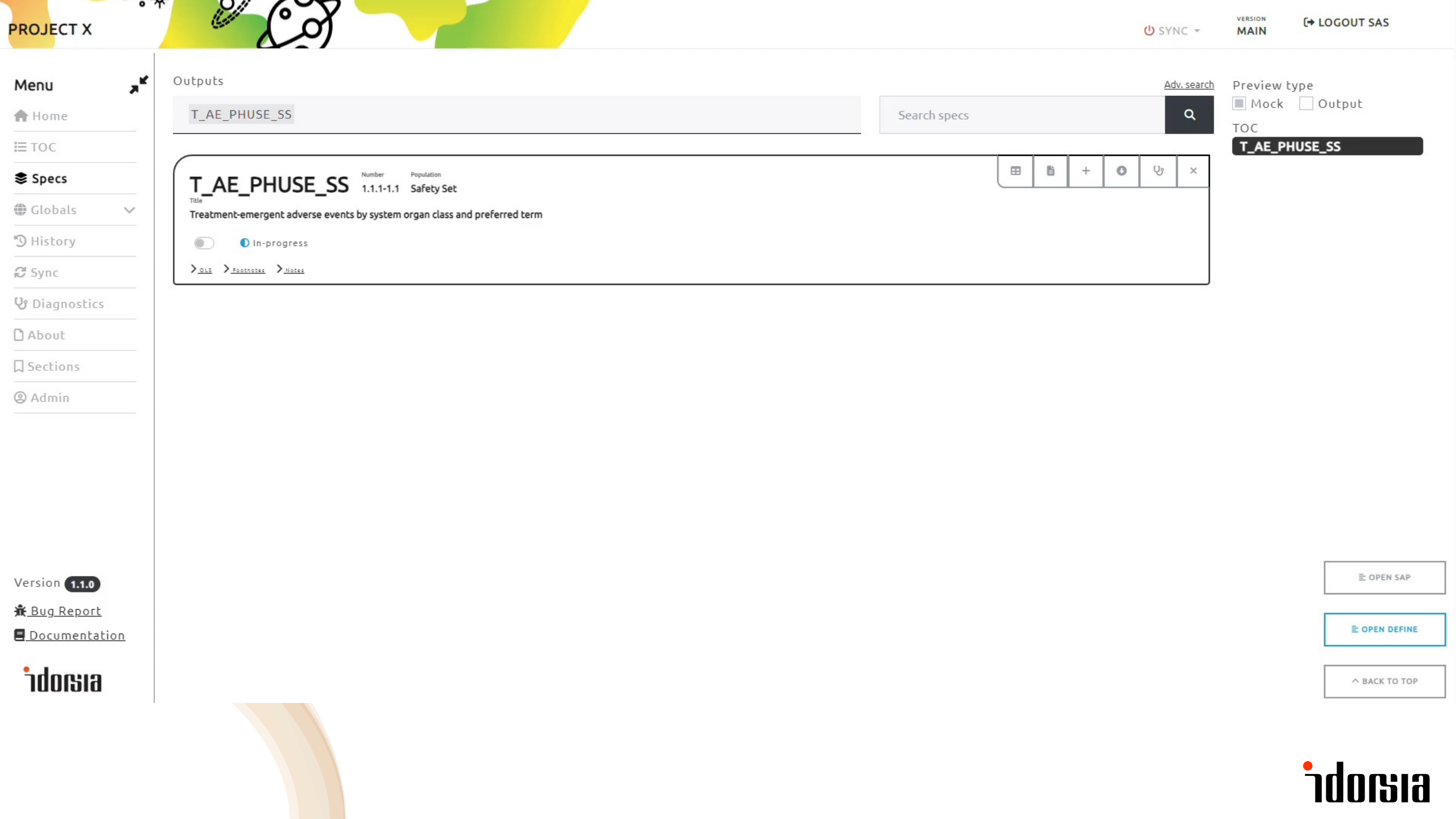
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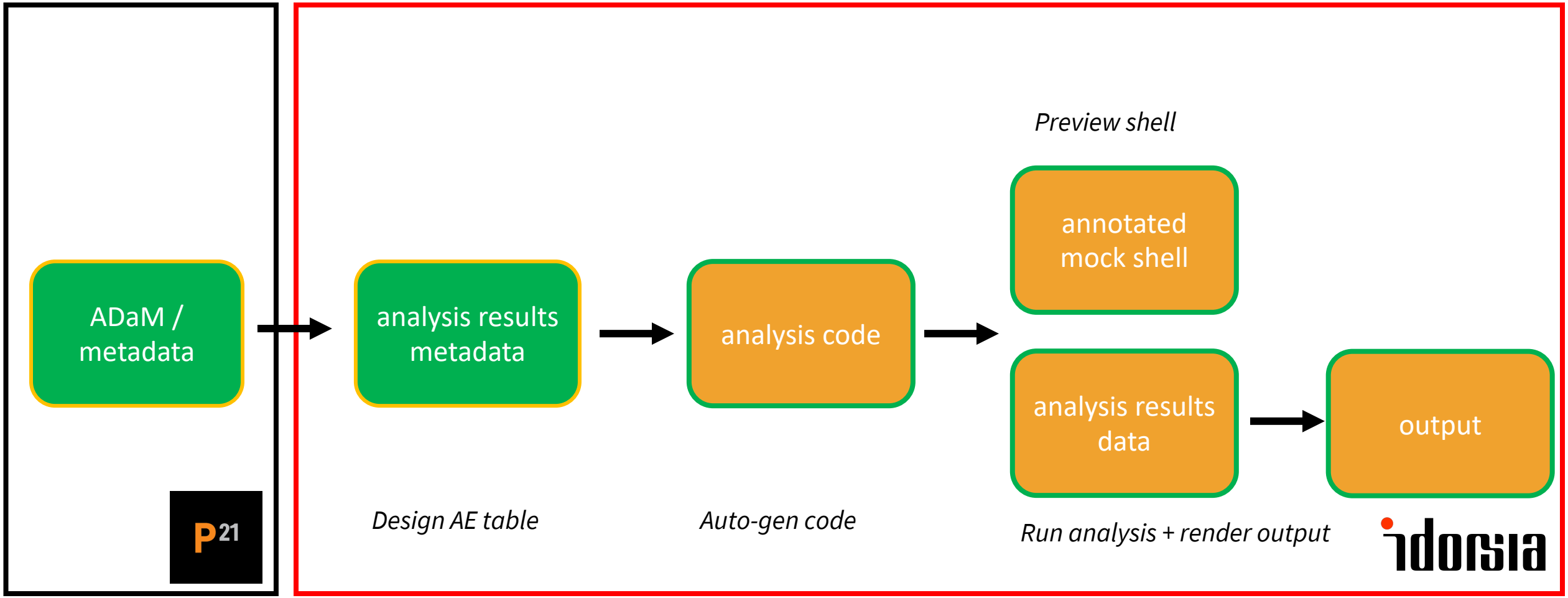
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Machine readable metadata is extremely useful for building supportive tools

mock shells should be a product from the components stated in your standard guidelines…

Table 15.1.4-1.1 - Demographic characteristics
Full Analysis Set WHERE: [FASFL EQ 'Y']

	Treatment A N=XXX [ADSL.TRT02AN = 1]	Treatment B N=XXX [ADSL.TRT02AN = 2]	Treatment C N=XXX [ADSL.TRT02AN = 3]	Treatment D N=XXX [ADSL.TRT02AN = 4]	Placebo N=XXX [ADSL.TRT02AN = 5]
Age at screening (years) [n (%)] [ADSL.AGEGR1]					
n	xx	xx	xx	xx	xx
< 18	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
18 - < 65	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
65 - < 75	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
75 - < 85	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>= 85	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
<Missing>	xx	xx	xx	xx	xx
Sex [n (%)] [ADSL.ASEXN]					
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Analysis Method	Analysis Option	Rule	Description
Categorical	NonMissing	001	n is the number of non-missing subjects and is used as the denominator in categorical percentage calculations
Categorical	NonMissing	002	the number of missing is always presented where there are non-zero counts to present
Categorical	BigN	001	small n is not presented and population counts are used as a denominator

…your standard guideline components serve as the analysis reporting metadata inputs

…and specification for your analysis reporting codebase

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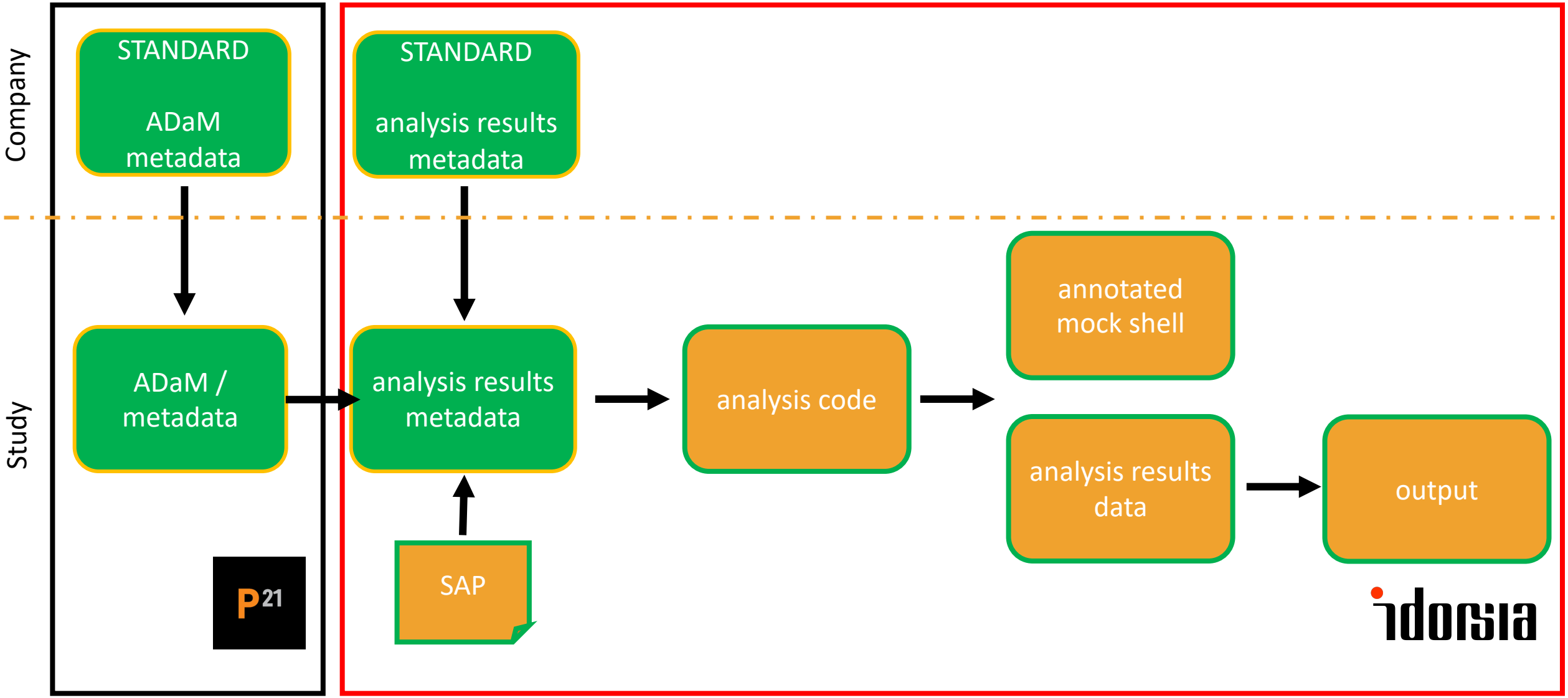
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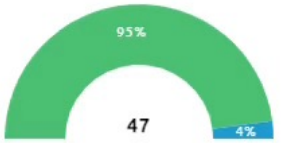

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ARM_OID	TYPE	NUMBER	TITLE	POPULATION	PRIORITY	IN-TEXT	STATE	CREATED	LAST UPDATE	ACTIONS
T_ENROL01_SCR	Table	15.1.1-1.1	Recruitment by country and site	Screened Analysis Set	9	×		2022-12-20 ridlech1	3 months ago ridlech1	
T_ENROL01_FAS	Table	15.1.1-1.2	Recruitment by country and site	Full Analysis Set	9	×		2023-05-15 ridlech1	3 months ago ridlech1	
T_FAIL_SCR	Table	15.1.1-2.1	Reasons for screening failure	Screened Analysis Set	9	×		2022-12-30 ridlech1	3 months ago ridlech1	
T_DISP01_FAS	Table	15.1.1-3.1	Disposition of participants	Full Analysis Set	9	×		2023-05-15 ridlech1	3 months ago ridlech1	
T_DISP01_SAF	Table	15.1.1-3.2	Disposition of participants	Safety Set	9	×		2023-05-16 ridlech1	3 months ago ridlech1	
T_PLNDTRT_FAS	Table	15.1.2-1.1	Analysis sets - according to planned treatment group	Full Analysis Set	9	×		2023-05-15 ridlech1	3 months ago ridlech1	
T_ACTUTRT_SAF	Table	15.1.2-2.1	Analysis sets - according to actual treatment group	Safety Set	9	×		2023-05-16 ridlech1	3 months ago ridlech1	
T_DV01_IMP_FAS	Table	15.1.3-1.1	Important protocol deviations	Full Analysis Set	9	×		2022-12-20 ridlech1	3 months ago ridlech1	
T_DV01_ALL_FAS	Table	15.1.3-2.1	Protocol deviations	Full Analysis Set	9	×		2022-12-20 ridlech1	3 months ago ridlech1	

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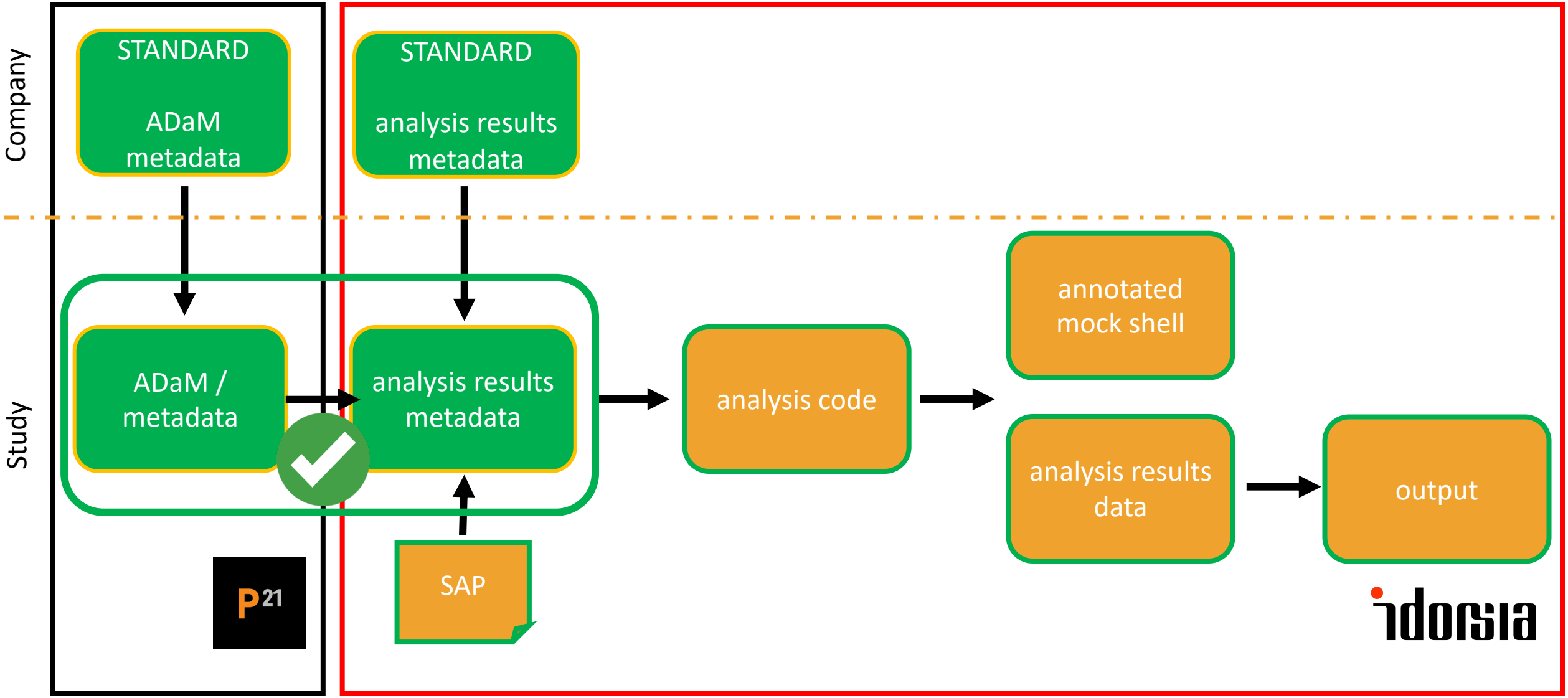
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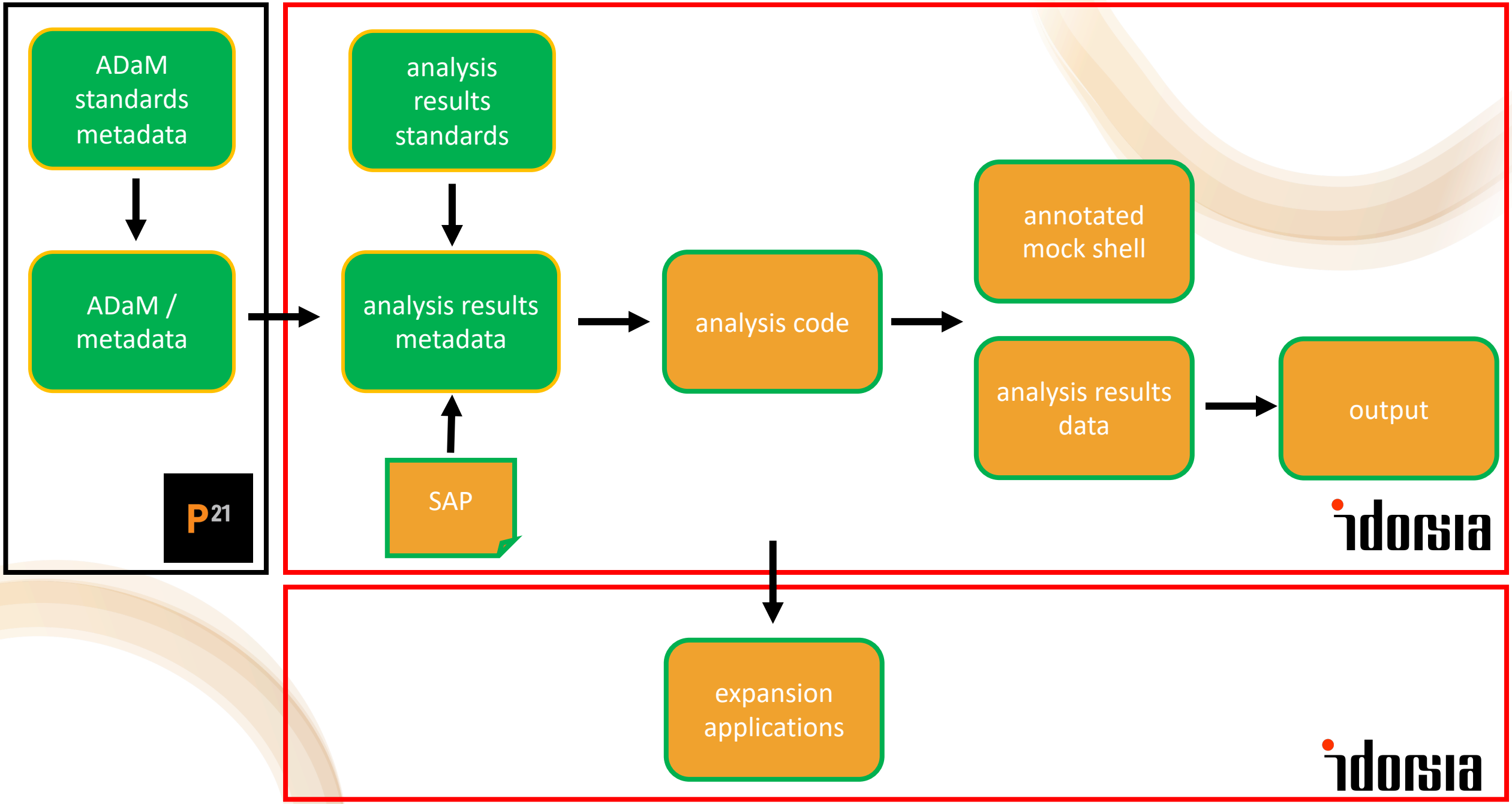
Capturing output level metadata enables automation of shell and output programs

Strong standards enable quicker metadata entry

Machine readable metadata is extremely useful for building supportive tools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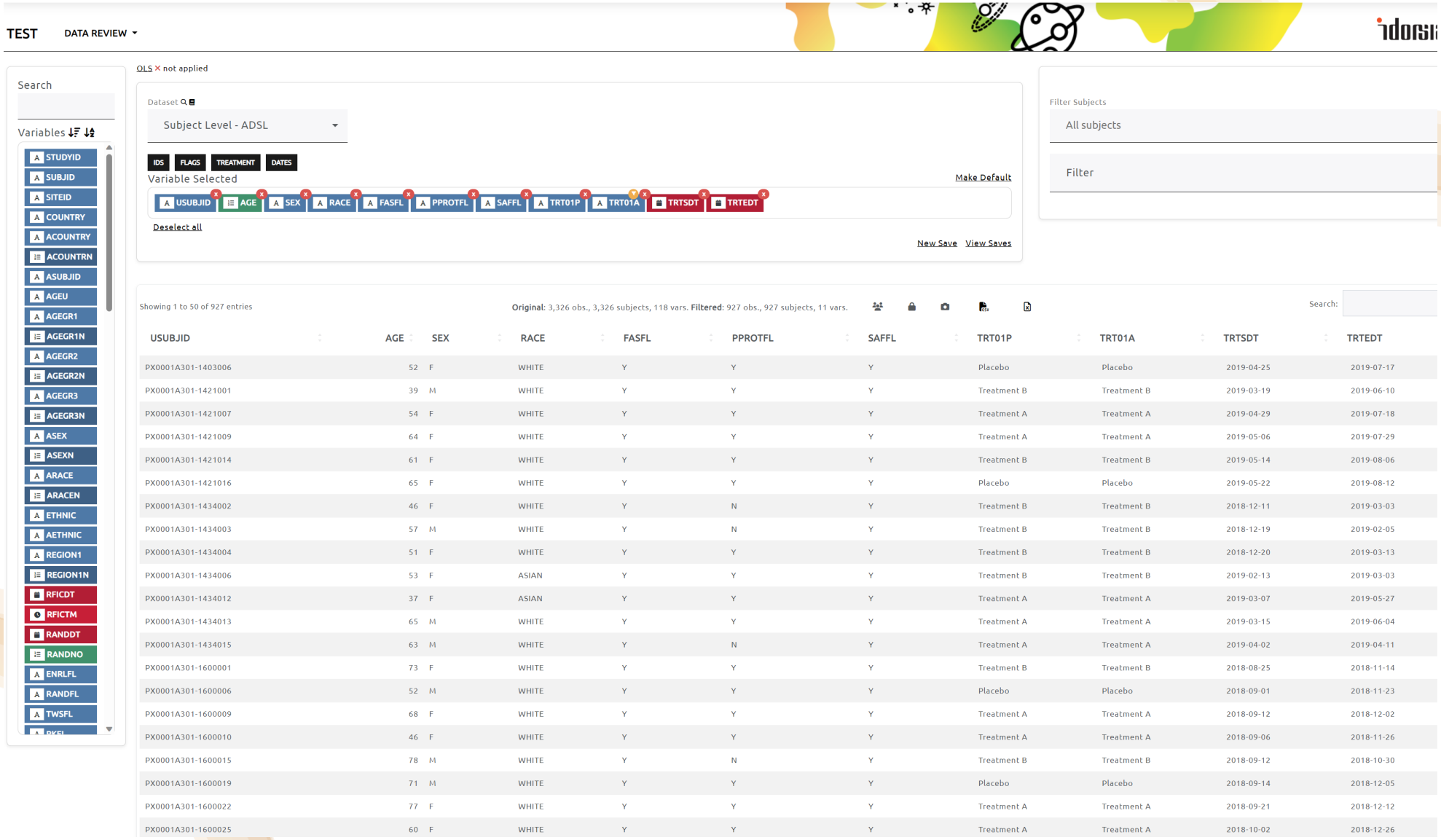
Linking to a data viewer app



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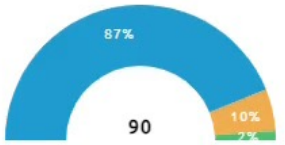

Main | Footnotes

ARM_OID	TYPE	NUMBER	TITLE	POPULATION	PRIORITY	IN-TEXT	STATE	CREATED	LAST UPDATE	ACTIONS
T_AE_PHUSE_SS	Table	1.1.1-1.1	Treatment-emergent adverse events by system organ class and preferred term	Safety Set	0	×	◐	2023-07-25 ridlech1	2 weeks ago ridlech1	
L_LISTING_TEST	Listing	15.1.1-1.1	Listing Test	Safety Set	2	×	○	2023-02-10 coenejo1	5 months ago coenejo1	
L_TESTING_2	Listing	15.1.1-1.2	Listing Test 2	Full Analysis Set	9	×	◐	2023-06-06 marqujo1	3 months ago marqujo1	
T_DISP03_DB_SS	Table	15.1.1-1.3	Reasons for premature study treatment discontinuation: Double-blind	Safety Set	1	×	◐	2021-10-08 ridlech1	3 weeks ago ridlech1	
T_ENROL01_AGE_FAS	Table	15.1.1-1.4	Recruitment of patients by country and site, by age category	Full Analysis Set	1	×	◐	2021-10-08 ridlech1@idorsia.com	2 months ago coenejo1	
T_DISP02_FAS	Table	15.1.1-1.6	Disposition of patient	Full Analysis Set	2	×	◐	2021-10-08 ridlech1	5 months ago ridlech1	
T_DISP01_SCR	Table	15.1.1-2.1	Screening failures test	Screened Analysis Set	9	×	●	2021-10-08 ridlech1@idorsia.com	5 months ago coenejo1	
T_ANSET_FAS	Table	15.1.2-1.1	Summary of analysis sets according to treatment randomized	Full Analysis Set	1	×	◐	2021-10-08 ridlech1	5 months ago ridlech1	
T_ANSET_SS	Table	15.1.2-1.2	Summary of analysis sets according to treatment received	Safety Set	0	×	◐	2021-10-08 ridlech1	5 months ago coenejo1	

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Summary

Metadata and standards unlock potential for automation

Endless possibilities to build on top of your metadata

Proven success: do more with less, faster

How do you use your metadata?

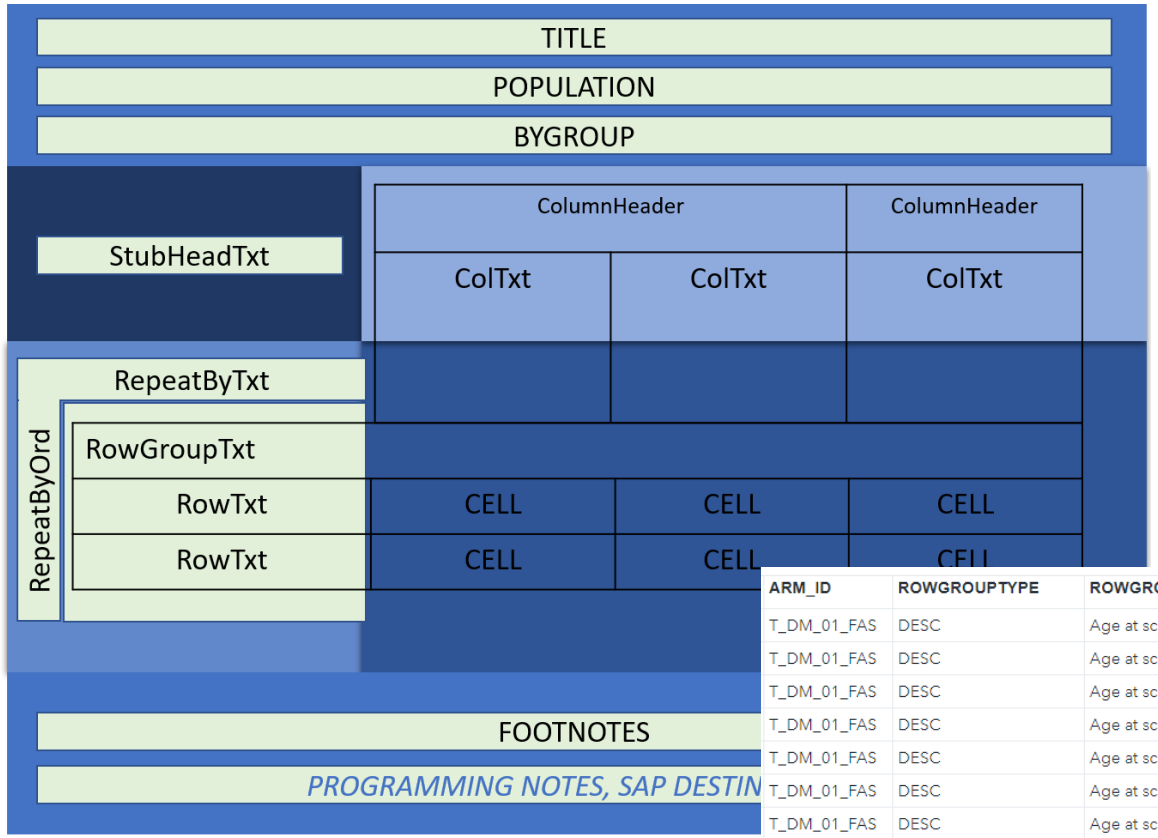
Acknowledgments

- John Coene: Application developer

Questions?

DISCUSSION SLIDES

Table schema to ARD

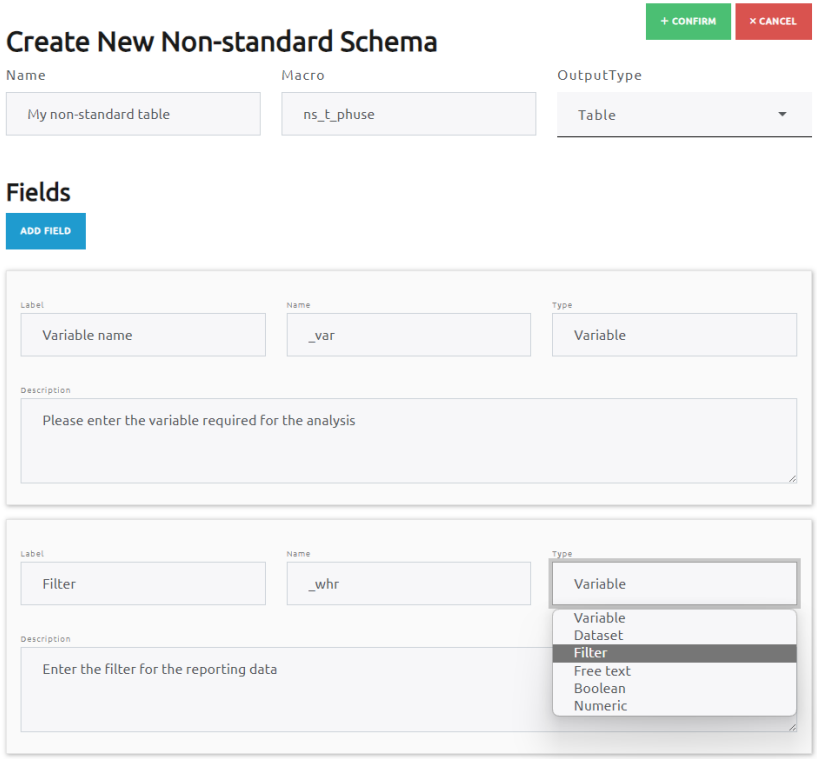


Default table schema…

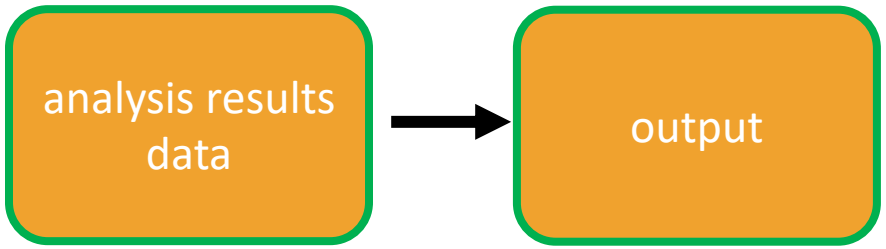
ARM_ID	ROWGROUPTYPE	ROWGROUPTXT	ROWORD	ROWTXT	INDENT	ANALYSEBYTXT	COLUMNHEAD	COLTXT	CELL	PAGENUMBER
T_DM_01_FAS	DESC	Age at screening (years)	100	n	1	Treatment A	Treatment A@N=310		310	1
T_DM_01_FAS	DESC	Age at screening (years)	100	n	1	Treatment B	Treatment B@N=310		310	1
T_DM_01_FAS	DESC	Age at screening (years)	100	n	1	Placebo	Placebo@N=310		310	1
T_DM_01_FAS	DESC	Age at screening (years)	100	n	1	Total	Total@N=930		930	1
T_DM_01_FAS	DESC	Age at screening (years)	200	Mean	1	Treatment A	Treatment A@N=310		55.6	1
T_DM_01_FAS	DESC	Age at screening (years)	200	Mean	1	Treatment B	Treatment B@N=310		54.7	1
T_DM_01_FAS	DESC	Age at screening (years)	200	Mean	1	Placebo	Placebo@N=310		56.0	1
T_DM_01_FAS	DESC	Age at screening (years)	200	Mean	1	Total	Total@N=930		55.4	1
T_DM_01_FAS	DESC	Age at screening (years)	300	SD	1	Treatment A	Treatment A@N=310		14.2	1
T_DM_01_FAS	DESC	Age at screening (years)	300	SD	1	Treatment B	Treatment B@N=310		16.2	1
T_DM_01_FAS	DESC	Age at screening (years)	300	SD	1	Placebo	Placebo@N=310		15.5	1
T_DM_01_FAS	DESC	Age at screening (years)	300	SD	1	Total	Total@N=930		15.3	1
T_DM_01_FAS	DESC	Age at screening (years)	400	Q1	1	Treatment A	Treatment A@N=310		46	1
T_DM_01_FAS	DESC	Age at screening (years)	400	Q1	1	Treatment B	Treatment B@N=310		42	1
T_DM_01_FAS	DESC	Age at screening (years)	400	Q1	1	Placebo	Placebo@N=310		46	1
T_DM_01_FAS	DESC	Age at screening (years)	400	Q1	1	Total	Total@N=930		45	1
T_DM_01_FAS	DESC	Age at screening (years)	500	Median	1	Treatment A	Treatment A@N=310		58	1
T_DM_01_FAS	DESC	Age at screening (years)	500	Median	1	Treatment B	Treatment B@N=310		58	1
T_DM_01_FAS	DESC	Age at screening (years)	500	Median	1	Placebo	Placebo@N=310		60	1
T_DM_01_FAS	DESC	Age at screening (years)	500	Median	1	Total	Total@N=930		59	1
T_DM_01_FAS	DESC	Age at screening (years)	600	Q3	1	Treatment A	Treatment A@N=310		67	1
T_DM_01_FAS	DESC	Age at screening (years)	600	Q3	1	Treatment B	Treatment B@N=310		68	1
T_DM_01_FAS	DESC	Age at screening (years)	600	Q3	1	Placebo	Placebo@N=310		68	1
T_DM_01_FAS	DESC	Age at screening (years)	600	Q3	1	Total	Total@N=930		68	1

…sets the framework for ARD

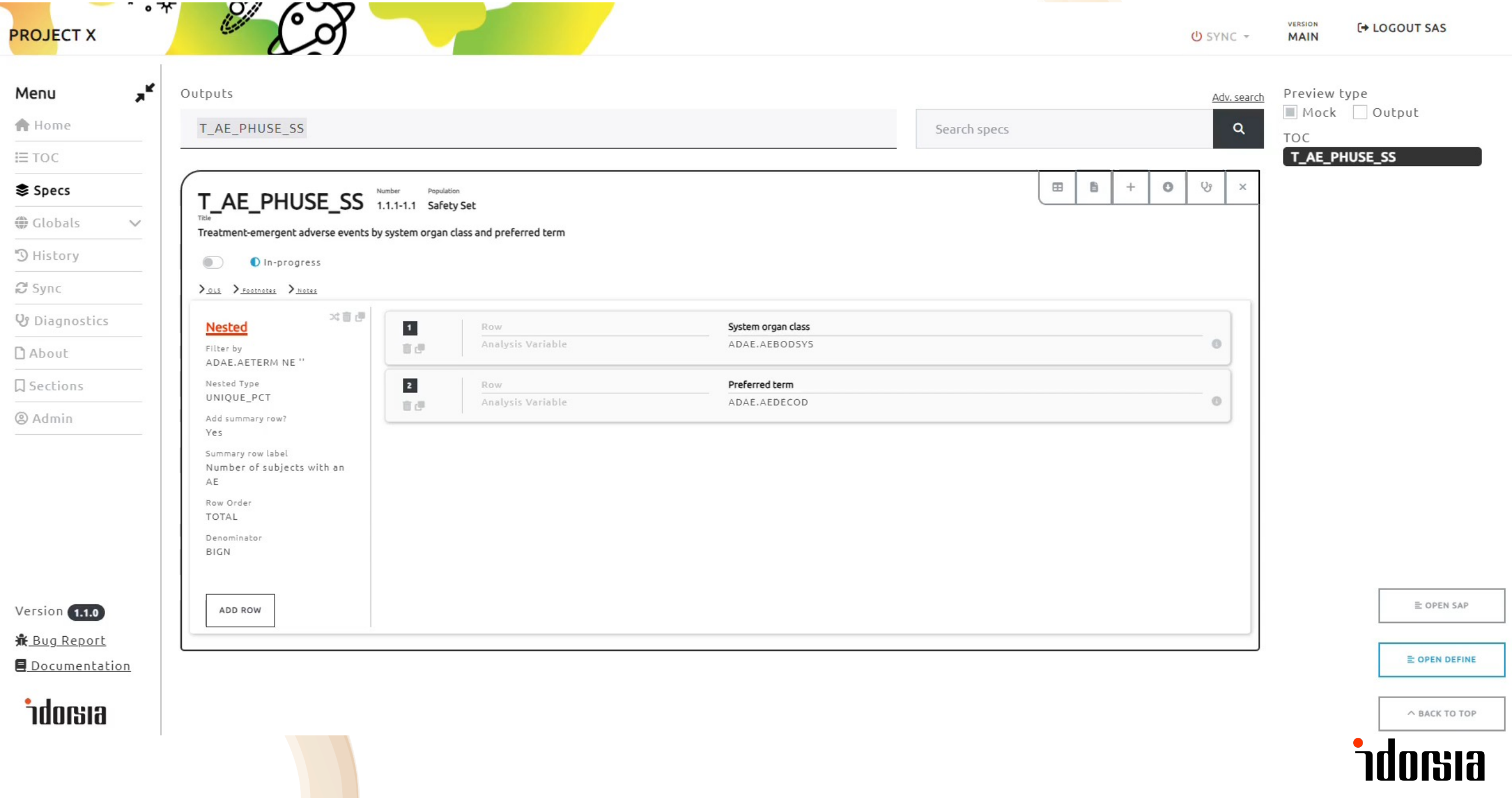
Non-Standard




```
/**
  @file ns_t_phuse.sas
  @brief Non-standard macro required for PHUSE
  @details

  @version SAS Studio 9.4
  @author Chris Ridley
  @source https://github.com/Idorsia-CHAL/ProjectX_sas

  #### Version history ##

  Version       | Change
  ------------- | ----------------------------
  1.0           | BCE release

*****************************************************;


**/

%macro ns_t_phuse(_var=
                  _whr=);


   xxxxxxxxxxxxxxxxxxxxxxxxxxxxx
   xxxxxxxxxxxxxxxxxxxxxxxxx
   xxxxxxxxxxxxxxx
   RUN;
```



Demo x: Enter once, use many times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Summary row label
Number of subjects with an AE
Row Order
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BIGN
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