



Stats programming: In with the old, in with the new

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PHUSE SDE Basel – 21 June 2022



CI / CD

Metadata
driven
reporting

End-to-end
data flow

Language
agnostic

Serverless!

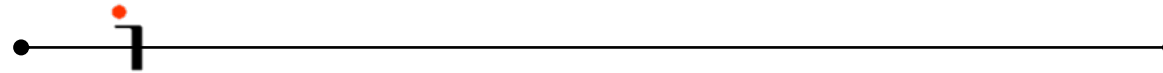


WHERE ARE WE GOING?

WHERE TO BEGIN

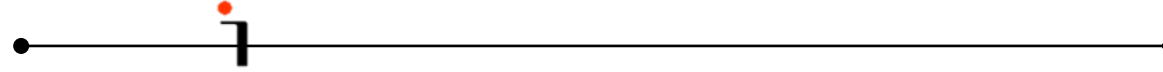
... depends on where you are coming from. Where does your company sit?

SAS only



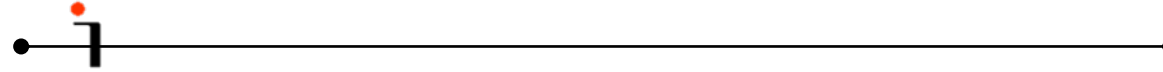
Multi-lingual

In-house



Outsourced

Small programming group



Large global footprint

No standards



Well defined standards

Cautious of change



Adaptive

WHERE TO BEGIN [1]

WHAT WE LIKED



PX0001 / PX0001A301

MOCK LAYOUT

Page x of y

Table 21.0.6-20.22 - PHUSE Single Day Event - Basel
Full Analysis Set WHERE: [FASFL EQ 'Y']

	Treatment A N=XXX [ADSL.TRT01AN = 1]	Treatment B N=XXX [ADSL.TRT01AN = 2]	Placebo N=XXX [ADSL.TRT01AN = 3]
Sex [n (%)] [ADSL.ASEXN]			
n	xx	xx	xx
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
<Missing>	xx	xx	xx
Body weight at screening (kg) [ADVS.AVAL] WHERE: [ADVS.ABLFL EQ 'Y' AND ADVS.PARAMCD EQ WEIGHT]			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x
Q1	xx	xx	xx
Median	xx	xx	xx
Q3	xx	xx	xx
Min	xx	xx	xx
Max	xx	xx	xx

CODE GENERATED ANNOTATED SHELLS



WHERE TO BEGIN [2]

WHAT WE DID NOT LIKE



Variable level					
ARM		ARM+			
ARM_VARIABLE_	KEYSEQ_	CODELIST_	VAR_DISPLAY_	VAR_WHERE_	VAR_MACRO_
Enter the full variable address. E.g. ADSLACOUNTRY	This should start at 1 and then run sequentially within each output. In most cases, the variable with lowest key seq is presented first	This could be pre-populated from ADAM META with drop down list. Will need to update ADAM_IMPORT with complete metadata., delete if not applying		Variable level where clause Currently will need to control the signs (EQ, NE etc) and handling AND Use single quotes not double	associated macro - output level
ADSLAGE	01		Age at screening (years)		m_mixed
ADSLAGEGR1N	02	CLAGEGR1N	Age at screening (years)		m_mixed
ADSLAGEGR2N	03	CLAGEGR2N	Age stratification group (years)		m_mixed
ADSLASEXN	04	CLASEXN	Sex		m_mixed
ADSLARACEN	05	CLARACEN	Race		m_mixed
ADSLAETHNIC	06	CLETHNIC CLAEETHNIC	Ethnicity		m_mixed
ADSLHGTSC	07		Height (cm) at screening		m_mixed
ADSLWGTSC	08		Body weight (kg) at screening		m_mixed
ADSLBMISC	09		Body mass index (kg/m^2) at screening		m_mixed
ADSLBMISCCTN	10	CLADSL_BMISCCTN	Body mass index (kg/m^2) at screening		m_mixed
ADSLREGION1N	11	CLREGION1N	Region		m_mixed

- Excel used to store / develop ARM+ metadata
- Tools used independently: SAS, Excel, Pinnacle 21, Adobe
- No version control
- No user input control
- No concurrent users

DEMO

PROJECT X

Menu

Space

Logo

T_PHUSE_SDE_FAS

Partial

Full

Close

PK0001 / PK0001A301

PREVIEW MODE

MOCK LAYOUT

Page x of y

Table 21.0.6-20.22 - PHUSE Single Day Event - Basel

Full Analysis Set WHERE: [FASFL EQ 'Y']

	Treatment A N=XXX [ADSL.TRT01AN = 1]	Treatment B N=XXX [ADSL.TRT01AN = 2]	Placebo N=XXX [ADSL.TRT01AN = 3]
Sex [n (%)] [ADSL.ASEXN]			
n	XX	XX	XX
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Missing>	XX	XX	XX
Body weight at screening (kg) [ADVS.AVAL] WHERE: [ADVS.PARAMCD EQ WEIGHT]			
n	XX	XX	XX
Mean	XX.X	XX.X	XX.X
SD	XX.X	XX.X	XX.X
Q1	XX	XX	XX
Median	XX	XX	XX
Q3	XX	XX	XX
Min	XX	XX	XX
Max	XX	XX	XX
Age at screening (years) [ADSL.AGE]			
n	XX	XX	XX
Mean	XX.X	XX.X	XX.X
SD	XX.X	XX.X	XX.X
Q1	XX	XX	XX
Median	XX	XX	XX
Q3	XX	XX	XX
Min	XX	XX	XX
Max	XX	XX	XX
Age at screening (years) [n (%)] [ADSL.AGEGRI]			
n	XX	XX	XX
< 18	XX (XX.X)	XX (XX.X)	XX (XX.X)
18 - < 65	XX (XX.X)	XX (XX.X)	XX (XX.X)
65 - < 75	XX (XX.X)	XX (XX.X)	XX (XX.X)
75 - < 85	XX (XX.X)	XX (XX.X)	XX (XX.X)
>= 85	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Missing>	XX	XX	XX

Program: <T_PHUSE_SDE_FAS.sas>. Temporary footnote: Mock generated on 17JUN22 08:57.

- Menu
- Home

TOC

Specs

Globals

History

Sync

Diagnostics

About

Admin

Synchronisation with BCE

Details

SYNC SELECTED

QUEUE

Output

Mock

Both

Show 999 entries

Search:

Sync	ARM OID	Number	Title	Up to date	Clean SAS Log	BCE State	Sync time	SAS log	Type
☐	T_AE_OV_SS	15.3.2-1.1	Overview of adverse events	✓	✓	✓	08 Jun 2022 11:35	+	mock
☐	T_AE_PT_SS	15.3.2-1.3	Treatment-emergent adverse events by preferred term	✓	✓	✓	08 Jun 2022 10:48	+	mock
☐	T_AE_SOC_PT_AGE_SS	15.3.2-1.8	Treatment-emergent adverse events by system organ class and preferred term by Age group at screening	✓	✓	✗	11 Apr 2022 10:16	+	mock
☐	T_AE_SOC_PT_BMI_SS	15.3.2-1.9	Treatment-emergent adverse events by system organ class and preferred term by BMI group at screening	✓	✓	✗	11 Apr 2022 10:16	+	mock
☐	T_AE_SOC_PT_FAT_SS	15.3.3-1.1	Treatment-emergent adverse events with fatal outcome by system organ class and preferred term	✓	✓	✓	08 Jun 2022 13:01	+	mock
☐	T_AE_SOC_PT_INT_SS	15.3.2-1.7	Adverse events leading to temporary interruption of study treatment by system organ class and preferred term	✓	✓	✗	11 Apr 2022 09:26	+	mock
☐	T_AE_SOC_PT_PREM_SS	15.3.2-1.6	Adverse events leading to premature discontinuation of study treatment by system organ class and preferred term	✓	✓	✗	11 Apr 2022 09:23	+	mock
☐	T_AE_SOC_PT_REL_FAT_SS	15.3.3-1.2	Treatment-emergent adverse events related to study treatment with fatal outcome by system organ class	✓	✓	✗	11 Apr 2022 11:59	+	mock

OBSERVATIONS FROM WORKING IN A GUI

- Reporting standards are key
- Reliant on good ADaM metadata
- IT involvement integral for connectivity
- Define the boundary between a supportive app and a SCE

IN SUMMARY

We are convinced that Metadata first approach is the key to success for embracing our current and future needs

If you are on top of your metadata, then tech and choice of language is less critical!

ACKNOWLEDGEMENTS

Idorsia Biometry department

John Coene – chief application developer

THANK YOU &
QUESTIONS?

BACKUP

WHAT WE DID [1]

