

HOW TO AVOID CONFORMANCE ISSUES WHEN METADATA VARIES ACROSS PARAMETERS

SI08 – PHUSE EU Connect 2022



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AGENDA

- **Introduction**
 - Basic Data Structure (BDS)
- **Conformance Rules**
- **Tips and Tricks to create BDS variables**
 - PARAMCD
 - PARCATy
 - PARAM
- **Conclusions**



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#DataStrategy #DataIntegration
#DataViz #DataStandards
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#LifeSciencesExperts
#Whodrug #MedDRA
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#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

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INTRODUCTION

BASIC DATA STRUCTURE

- One or more records per subject [USUBJID]
 - per analysis parameter [PARAM]
 - (per analysis timepoint [AVISIT, ADY])
- Includes observations for required analysis
 - Observed
 - Derived

INTRODUCTION

BASIC DATA STRUCTURE

- Core variables:
 - PARAMCD/PARAM(N)
 - AVAL/AVALC/BASE/CHG
- Other PARAM related variables:
 - PARCATy(N)
 - PARAMTYP

INTRODUCTION

BASIC DATA STRUCTURE

USUBJID	PARAMCD	PARAM	PARAMTYP	AVISIT	AVAL	BASE	CHG
A00031001	HEIGHT	Height [Inches]		Baseline	62,1	62,1	
A00031001	HEIGHT	Height [Inches]		3 Months	63,5	62,1	1,4
A00031001	HEIGHT	Height [Inches]		6 Months	64,2	62,1	2,1
A00031001	WEIGHT	Weight [lbs]		Baseline	116	116	
A00031001	WEIGHT	Weight [lbs]		3 Months	133,2	116	17,2
A00031001	WEIGHT	Weight [lbs]		6 Months	146,6	116	30,6
A00031001	BMI	BMI [kg/m2]	DERIVED	Baseline	21,1	21,1	
A00031001	BMI	BMI [kg/m2]	DERIVED	3 Months	23,2	21,1	2,1
A00031001	BMI	BMI [kg/m2]	DERIVED	6 Months	24,9	21,1	3,8

Which Conformance rules should be considered to create compliant analysis parameters?

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CONFORMANCE RULES

PARAMCD (Required)

- Maximum length of 8 characters
- Start with a letter and not contain anything other than letters, underscore and numbers
- 1:1 relationship with PARAM(N) within one dataset

PARAM (Required)

- Not restricted to 40 characters, can be up to 200 characters long
- 1:1 relationship within one dataset to PARAMCD, PARAMN

Have unique parameters (PARAM(N)/PARAMCD) within dataset

CONFORMANCE RULES

PARCATy (Permissible)

- Categorization of PARAM within a dataset
- PARAM to PARCATy is a many to one mapping
 - Any given PARAM may be associated with at most one level of PARCATy

PARAMTYP (Permissible)

- Included in ADaMIG v1.0 and v1.1 but removed from ADaMIG v1.2
- Controlled Terminology ('DERIVED')

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TIPS AND TRICKS TO CREATE BDS VARIABLES

CHALLENGES RELATED TO PARAMCD

- No Controlled Terminology
 - Leads to a lot of flexibility
- If possible, PARAMCD should be meaningful
 - Use a unique pattern or logic within datasets
 - Easy to relate to the associated PARAMs
- Handling analysis parameters for multiple tests in PARAMCD

TIPS AND TRICKS TO CREATE BDS VARIABLES

SDTM

VSTESTCD	VSTEST
HEIGHT	Height
WEIGHT	Weight
DIABP	Diastolic Blood Pressure

LBTESTCD	LBTEST	LBCAT
BILI	Bilirubin	CHEMISTRY
BILI	Bilirubin	URINALYSIS

--TESTCD = PARAMCD



CATEGORY

--TESTCD || substr(--CAT,1,1)



ADAM

PARAMCD	PARAM
HEIGHT	Height (m)
WEIGHT	Weight (kg)
DIABP	Diastolic Blood Pressure (mmHg)

PARAMCD	PARAM
BILIC	Chemistry: Bilirubin (umol/L)
BILIU	Urinalysis: Bilirubin (umol/L)

TIPS AND TRICKS TO CREATE BDS VARIABLES

USE A MACRO FOR CREATING PARAMCD

```
1  %macro paramcd(domain=,in=,out=);  
2  %let concat=;  
3  
4  data _null_;  
5      dsid=open("SDTM.&domain.");  
6      check=varnum(dsid,"&domain.cat");  
7      if check ne 0 then do;  
8          call symput('cat',"&domain.CAT") ;  
9          call symput('catn',1) ;  
10         call symput('concat',"and a.&domain.cat=b.&domain.cat") ;  
11     end;  
12     else put 'Category variable does not exist';  
13 run;  
14  
15 proc sql;  
16     create table data1 as select &domain.testcd, count(&domain.testcd) as cnt &cat.  
17         from (select distinct(&domain.testcd) &cat. from sdtm.&domain.)  
18     group by &domain.testcd;  
19 quit;
```

Count Number of Unique Combinations (--TESTCD/--CAT)

TIPS AND TRICKS TO CREATE BDS VARIABLES

OUTPUT: NUMBER OF UNIQUE COMBINATIONS –TESTCD/--CAT

Total rows: 83 Total columns: 3

	LBTESTCD	cnt	LBCAT
1	INTP	3	CHEMISTRY
2	INTP	3	HEMATOLOGY
3	INTP	3	URINALYSIS
4	BILI	2	CHEMISTRY
5	BILI	2	URINALYSIS
6	GLUC	2	CHEMISTRY
7	GLUC	2	URINALYSIS
8	PROT	2	CHEMISTRY
9	PROT	2	URINALYSIS
10	RBC	2	HEMATOLOGY
11	RBC	2	URINALYSIS
12	WBC	2	HEMATOLOGY
13	WBC	2	URINALYSIS
14	ALB	1	CHEMISTRY
15	ALP	1	CHEMISTRY
16	ALT	1	CHEMISTRY

TIPS AND TRICKS TO CREATE BDS VARIABLES

USE A MACRO FOR CREATING PARAMCD

```
21 data data2;  
22 set data1;  
23 if cnt = 1 then PARAMCD=&domain.testcd;  
24 else if cnt>1 then do;  
25 if PARAMCD=cats(substr(&domain.testcd,1,7),substr(&domain.cat,1,1));  
26 end;  
27 run;  
28  
29 proc sql;  
30 create table &out. as select a.*,b.paramcd  
31 from &in. a left join data2 b on a.&domain.testcd=b.&domain.testcd &concat. ;  
32 quit;  
33 %mend paramcd;  
34 %paramcd(domain=LB,in=lb01,out=lb);
```

PARAMCD = --TESTCD

PARAMCD = --TESTCD || --CAT

TIPS AND TRICKS TO CREATE BDS VARIABLES

Generalize the Macro further based on the Needs of the Project

SDTM

LBTESTCD	LBTEST	LBCAT	LBSTRESU
BILI	Bilirubin	CHEMISTRY	mmol/L
BILI	Bilirubin	CHEMISTRY	mg/dL
BILI	Bilirubin	URINALYSIS	mmol/L

CATEGORY + UNIT



--TESTCD || --CAT || UNIT

ADAM

PARAMCD	PARAM
BILIC1	Chemistry: Bilirubin (mmol/L)
BILIC2	Chemistry: Bilirubin (mg/dL)
BILIU1	Urinalysis: Bilirubin (mmol/L)

General

- Identify the SDTM variables that are needed to identify unique PARAMCD in your project
- Create count variables
- Create unique PARAMCDs by concatenating the SDTM variables of interest

TIPS AND TRICKS TO CREATE BDS VARIABLES

STUDYID	USUBJID	AVISIT	PARAMCD	PARAM	AVAL
XXX111	102	Week 5	ACITM01	ADAS-Cog Item 01	1
XXX111	102	Week 5	ACITM02	ADAS-Cog Item 02	2
XXX111	102	Week 5	ACITM03	ADAS-Cog Item 03	1
XXX111	102	Week 5	ACITM04	ADAS-Cog Item 04	0
XXX111	102	Week 5	ACITM05	ADAS-Cog Item 05	0
XXX111	102	Week 5	ACITM06	ADAS-Cog Item 06	2
XXX111	102	Week 5	ACITM07	ADAS-Cog Item 07	3
XXX111	102	Week 5	ACITM08	ADAS-Cog Item 08	2
XXX111	102	Week 5	ACITM09	ADAS-Cog Item 09	0
XXX111	102	Week 5	ACITM10	ADAS-Cog Item 10	1
XXX111	102	Week 5	ACITM11	ADAS-Cog Item 11	2
XXX111	102	Week 5	ACTOT11	ADAS-Cog Item Total Score	14

DERIVED

Individual Scores
from
Questionnaire

TIPS AND TRICKS TO CREATE BDS VARIABLES

PARCATy

- Can help to group parameters for analysis perspective
- Check if there are certain groupings based on shells which can help you do the analysis

TIPS AND TRICKS TO CREATE BDS VARIABLES

CHALLENGES RELATED TO PARAM

- PARAM must specify the analysis value in a proper way
- Keep yourself to the length maximum length of 200

STRATEGY TO CREATE PARAM

- Use Mock shells to create appropriate PARAMs
 - To make identification of parameters easier when creating or reviewing results

TIPS AND TRICKS TO CREATE BDS VARIABLES

Table 14.3.4.2.2.2.3.1. Blood chemistry by visit: Pre-albumin - Safety Set

PARAM = LBCAT: LBTEST (UNIT)

<Parameter (unit)>		Drug X (N=XXX)			Placebo (N=XXX)	
	Baseline	Observed Data	Change from Baseline	Baseline	Observed Data	Change from Baseline
Baseline value ^a						
n		xx			xx	
Mean (SD)		xx.x (xx.x)			xx.x (xx.x)	
Median		xx.x			xx.x	
Q1, Q3		xx.x, xx.x			xx.x, xx.x	
Min, Max		xx.x, xx.x			xx.x, xx.x	
Week 3 (Visit 3)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 6 (Visit 4)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
...						
a: Baseline is defined as last measurement before study drug administration.						
Source: Listing xx.x.xx, Dataset: ADLB, Program: xxxxxx.sas, Output: xxxx.rtf, Generated on: DDMMYYYY HH:MM						
Page x of y						

[Programming note: Analyze each visit (v3-v10). Split pages after every two visits.]

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CONCLUSIONS

PARAM and PARAMCD

- Core variables of the BDS structure
- Uniquely describe what is in AVAL and AVALC
- To avoid Conformance Issues:
 - Check Mock Shells
 - Use Macros

PARCATy and PARAMTYP

- Understand the data better
- Perform the analysis more efficiently



THANK YOU FOR YOUR ATTENTION
Q&A

CONTACT



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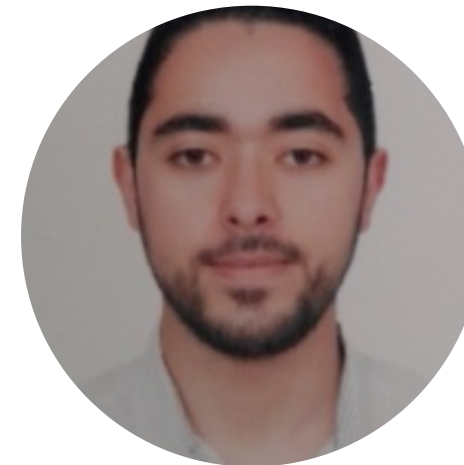
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