



SI05

Challenges and Solutions in SDTM Implementation and Programming of the Ophthalmic Examinations (OE) Domain

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PHUSE US Connect 2021

Ophthalmic Examinations (OE)



INTRODUCED IN SDTMIG V3.3



FINDINGS ABOUT A SUBJECT'S
OCULAR HEALTH AND VISUAL
STATUS



TESTS INCLUDE VISUAL ACUITY,
COLOR VISION, CONTRAST
SENSITIVITY, INTRAOCULAR
PRESSURE, LENS OPACITY ETC.

OE - Example

USUBJID	FOCI D	OESEQ	OECAT	OETESTC D	OETEST	OEORES	OESTRESC	OELC	OELAT	OEMETHO D	VISITNUM	VISIT	OEDTC
XXX- 110-020	OS	1	SLIT LAMP EXAM	SLECOR N	Cornea LLY INSIGNIFICANT Grading ABNORMALITY		0	EYE	LEFT	SLIT LAMP	100001 MONTH 0		2018-12- 13
XXX- 110-020	OS	2	SLIT LAMP EXAM	SLECOR N	Cornea LLY INSIGNIFICANT Grading ABNORMALITY		0	EYE	LEFT	SLIT LAMP	100001 MONTH 0		2018-12- 13
XXX- 110-020	OD	3	SLIT LAMP EXAM	SLECOR N	Cornea LLY INSIGNIFICANT Grading ABNORMALITY		0	EYE	RIGHT	SLIT LAMP	100001 MONTH 0		2018-12- 13
XXX- 110-020	OU	4	SLIT LAMP EXAM	SLECOR N	Cornea LLY INSIGNIFICANT Grading ABNORMALITY		0	EYE	BOTH	SLIT LAMP	100001 MONTH 0		2018-12- 13

Challenges and Solutions to program OE

High volume of data and controlled terminology as well as complexity can lead to lengthy programs and run times



Creation of format catalogs, macros to create standard SDTM variables, array processing

Data is mapped from various external sources leading to inconsistencies in data collection



Detailed pre-processing plan, creation of intermediate datasets to reduce code, look-up tables for direct mapping

Repeated measures for same visit and FOCID



Use of grouping and identification variables such as OEGRPID and OESPID to easily interpret repeated measure data

Programming Challenge: High Volume and Complexity of Data

Eye	Sphere	O.D.	CYL	Axis	Add
O.D.	-9.00				
O.S.	-9.00	-4.00	X180		
		-4.25	X10		

Distance Only
Readers Only
if

Programming Solution: High Volume and Complexity of CRF Data

- Formats
 - Identify variables that need to be assigned a format and create a format catalog to reformat data as per controlled terminology (i.e. OETESTCD, OETEST, OETSTDTL, UNIT)
 - Apply formats for laterality since much of the data is collected separately for the right and left eye
- Macros
 - Standard macros can be used where possible to eliminate lengthy coding
- Arrays
 - Use array processing to loop similar code through several raw data variables. Within do loop code, use formats

Programming Solution: High Volume and Complexity of CRF Data

```
DATA OE7;
  %ATTRIB(VARS=STUDYID DOMAIN STUDYID USUBJID VISIT OECAT OEMETHOD
  OELOC OELAT OEDTC OETESTCD OETEST OEORES OEORESU OESTRESC
  OESTRESN OESTRESU OETSTDTL OESPID OESTAT OESREASND);
  SET RAWDIR.OE_SL
  OECAT = "SLIT LAMP EXAM";
  OEMETHOD = "SLIT LAMP";
  %DATE(INDT=OEDAT_SL_RAW,INTM=,OUTDT=OEDTC);
  FOCID = STRIP(OELOC_STD);

  IF OELOC_STD = "OD" THEN
    OELAT = "RIGHT";
  ELSE IF OELOC_STD = "OS" THEN
    OELAT = "LEFT";
  ELSE OELAT = " ";

  IF OEPERF_SL_STD = "N" THEN DO;
    OETESTCD = "OEALL";
    OETEST = "Ophthalmologic Exam Findings";
    OESTAT = "NOT DONE";OUTPUT;
  END;

  ELSE IF OEPERF_SL_STD = "Y" THEN
    DO;
  ARRAY RAWTEST[9] $200. CORNEA CONJ IRIS LENS ANT ANTCHM_HYPO
  ANTCHM_CELLS ANTCHM_FLARE INFLAM;

  ARRAY RAWTEST2[9] $200 CORNEA_STD CONJ_STD IRIS_STD LENS_STD
  ANT_STD ANTCHM_HYPO_STD ANTCHM_CELLS ANTCHM_FLARE_STD INFLAM_STD;

  DO I=1 to 9;
    OETESTCD=STRIP(PUT(VNAME(RAWTEST(I)), $TESTCD.));
    OETEST=STRIP(PUT(VNAME(RAWTEST(I)), $TEST.));
    OEORES=STRIP(UPCASE(RAWTEST(I)));
    OESTRESC=STRIP(UPCASE(RAWTEST2(I)));
    OESTRESN=INPUT(OESTRESC, ??BEST.);
    OEMETHOD= STRIP(PUT(VNAME(RAWTEST(I)), $METHOD.));
    OUTPUT;
  END;
END;

RUN;
```

- Arrays to shorten code
- Read in formats provided for TEST, TESTCD, METHOD

Programming Challenge: Handling Data from External Sources



Programming Solution: Handling Data from External Sources



Sample Raw External Data

SPONSOR	IMGNAME	SUBJID	ACCSNM	VISIT	WORKSHEET	OECAT	EYE	OETEST	ANSWER	UNITMEASURE
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP		Capture Date	20171004	NA
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OD	Focus/Clarity	A	NA
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OD	Field Definition	A	NA
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OS	Focus/Clarity	A	NA
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OS	Field Definition	A	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP		Capture Date	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Focus/Clarity	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Field Definition	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Stereopsis	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Exposure	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Contrast	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Focus/Clarity	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Field Definition	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Stereopsis	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Exposure	NA	NA
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Contrast	NA	NA

Sample Intermediate Dataset

SPONSOR	IMGNAME	SUBJID	ACCSNM	VISIT	WORKSHEET	OECAT	EYE	OETEST	ANSWER	UNITMEASURE	DTC
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP		Capture Date	20171004	NA	20171004
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OD	Focus/Clarity	A	NA	20171004
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OD	Field Definition	A	NA	20171004
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OS	Focus/Clarity	A	NA	20171004
ABC Pharma	DIRC	XXXXX	100370	SCREENING	IQR	MP	OS	Field Definition	A	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP		Capture Date	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Focus/Clarity	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Field Definition	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Stereopsis	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Exposure	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OD	Contrast	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Focus/Clarity	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Field Definition	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Stereopsis	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Exposure	NA	NA	20171004
ABC Pharma	DIRC	XXXXX	100750	SCREENING	IQR	FP	OS	Contrast	NA	NA	20171004

Look-Up Table for Direct Mapping

	B	STUDYID	DOMAIN	USUBJID	OSEQ	OEGRPID	OEREFID	OESPID	OELNKID	OELNKGRP	OETESTCD	OETEST	OETSTDTL
1	FAF, IQR: Focus/Clarity	<Studyid>	OE	<Usbjid>	<##>						FOCCLRTY	Focus/Clarity	
2	FAF, IQR: Field Definition	<Studyid>	OE	<Usbjid>	<##>						FIELDDEF	Field Definition	
3	FAF, IQR: Exposure	<Studyid>	OE	<Usbjid>	<##>						EXPOSURE	Exposure	
4	FAF, IQR: Contrast	<Studyid>	OE	<Usbjid>	<##>						CONTRAST	Contrast	
5	FAF, Grading: Was this modality captured at this visit?	<Studyid>	OE	<Usbjid>	<##>						MODALYN	Modality Captured	
6	FAF, Grading: Total Area of Preserved Autofluorescence	<Studyid>	OE	<Usbjid>	<##>						TOTAREA	Total Area	
7	FAF, Grading: Is the total area of Preserved AF fully captured within graded fram...	<Studyid>	OE	<Usbjid>	<##>						FCGF	Fully Captured w/in Graded...	
8	FAF, Grading: Distance from FC to nearest border of preserved AF (m)	<Studyid>	OE	<Usbjid>	<##>						DISTANCE	Distance	FOVEAL CEN...
9	FAF, Grading: Location of lesion in relation to FC	<Studyid>	OE	<Usbjid>	<##>						LESNLOC	Lesion Location	RELATION TO...
10	FAF, IQR: TOF Present	<Studyid>	OE	<Usbjid>	<##>				<FAFGD001...		TOFPRES	Targeted Ocular Findings Pr...	
11	FAF, Accession: Completeness of FAF Images	<Studyid>	OE	<Usbjid>	<##>				<FAFAD001...		COMPLETE	Completeness	
12	SDOCT, IQR: Centration	<Studyid>	OE	<Usbjid>	<##>						CENTRAT	Centration	
13	SDOCT, IQR: Tilt	<Studyid>	OE	<Usbjid>	<##>						TILT	Tilt	
14	SDOCT, IQR: Motion Artifacts	<Studyid>	OE	<Usbjid>	<##>						MOTNARTF	Motion Artifacts	
15	SDOCT, IQR: Signal Strength	<Studyid>	OE	<Usbjid>	<##>						SGNLSTRG	Signal Strength	
16	SDOCT, Grading: Foveal Subfield Thickness (m)	<Studyid>	OE	<Usbjid>	<##>						FSTHICK	Foveal Subfield Thickness	
17	SDOCT, Grading: Total Macular Volume (mm3)	<Studyid>	OE	<Usbjid>	<##>						TMACVOL	Total Macular Volume	
18	SDOCT, Grading: Central Horizontal Ellipsoid Width (m)	<Studyid>	OE	<Usbjid>	<##>						WIDTH	Width	CENTRAL HO...
19	SDOCT, Grading: Central Ellipsoid Area (mm2)	<Studyid>	OE	<Usbjid>	<##>						AREA	Area	CENTRAL ELL...
20	SDOCT, Grading: Is the EZ area quantifiable? (Y/N)	<Studyid>	OE	<Usbjid>	<##>						EZAREAQ	Ellipsoid Zone Area Quantifi...	
21	SDOCT, Grading: Choroidal Thickness At Foveal Center (m)	<Studyid>	OE	<Usbjid>	<##>						CHOTHICK	Choroidal Thickness	AT FOVEAL C...
22	SDOCT, Grading: Vitreo-Macular Interface Disease	<Studyid>	OE	<Usbjid>	<##>						VMIDISEA	Vitreo-Macular Interface Dis...	
23	SDOCT, Grading: Intraretinal Hyper-Reflective Spots	<Studyid>	OE	<Usbjid>	<##>						IHRS	Intraretinal Hyper-Reflective...	
24	SDOCT, Grading: Cystoid Macular Edema	<Studyid>	OE	<Usbjid>	<##>						CME	Cystoid Macular Edema	
25	SDOCT, Grading: Subretinal Fluid	<Studyid>	OE	<Usbjid>	<##>						SRF	Subretinal Fluid	
26	SDOCT, Grading: Subretinal Hyper-Reflective Material	<Studyid>	OE	<Usbjid>	<##>						SHRM	Subretinal Hyper-Reflective...	
27	SDOCT, Grading: Pigment Epithelial Detachment	<Studyid>	OE	<Usbjid>	<##>						PED	Pigment Epithelial Detachm...	
28	SDOCT, Grading: TOF Present	<Studyid>	OE	<Usbjid>	<##>				<SDOCTGOD...		TOFPRES	Targeted Ocular Findings Pr...	
29		<Studyid>	OE	<Usbjid>	<##>						MODALYN	Modality Captured	
30	SDOCT, Accession: Completeness of SDOCT Images	<Studyid>	OE	<Usbjid>	<##>				<SDOCTAOD0...		COMPLETE	Completeness	
31	MP, IQR: Focus/Clarity	<Studyid>	OE	<Usbjid>	<##>						FOCCLRTY	Focus/Clarity	
32	MP, IQR: Field Definition	<Studyid>	OE	<Usbjid>	<##>						FIELDDEF	Field Definition	
33	MP, IQR: Fixation Location	<Studyid>	OE	<Usbjid>	<##>						FIXLOC	Fixation Location	
34	MP, Accession: Completeness of MP Images	<Studyid>	OE	<Usbjid>	<##>				<MPAOD001 o...		COMPLETE	Completeness	
35	FP, IQR: Focus/Clarity	<Studyid>	OE	<Usbjid>	<##>						FOCCLRTY	Focus/Clarity	
36	FP, IQR: Field Definition	<Studyid>	OE	<Usbjid>	<##>						FIELDDEF	Field Definition	
37	FP, IQR: Stereopsis	<Studyid>	OE	<Usbjid>	<##>						STEREOPS	Stereopsis	
38	FP, IQR: Exposure	<Studyid>	OE	<Usbjid>	<##>						EXPOSURE	Exposure	
39	FP, IQR: Contrast	<Studyid>	OE	<Usbjid>	<##>						CONTRAST	Contrast	
40	FP, Grading: Was this modality captured at this visit?	<Studyid>	OE	<Usbjid>	<##>						MODALYN	Modality Captured	
41	FP, Grading: RPE Hyperplasia	<Studyid>	OE	<Usbjid>	<##>						RPEHYPER	Retinal Pigment Epithelium...	
42	FP, Grading: Retinal Arteriolar Narrowing	<Studyid>	OE	<Usbjid>	<##>						RETARTNR	Retinal Arteriolar Narrowing	
43	FP, Grading: Retinal Vessel Sheathing	<Studyid>	OE	<Usbjid>	<##>						RETVASSH	Retinal Vessel Sheathing	
44	FP, Grading: Optic Atrophy/Pallor	<Studyid>	OE	<Usbjid>	<##>						OPATRPAL	Optic Atrophy, Pallor	
45	FP, Grading: Optic Disc Swelling	<Studyid>	OE	<Usbjid>	<##>						OPDSCSWL	Optic Disc Swelling	
46	FP, IQR: TOF Present	<Studyid>	OE	<Usbjid>	<##>				<FPGD001 o...		TOFPRES	Targeted Ocular Findings Pr...	
47	FP, Accession: Completeness of FP Images	<Studyid>	OE	<Usbjid>	<##>						COMPLETE	Completeness	
48	MP, 2nd: Y_Deg	<Studyid>	OE	<Usbjid>	<##>	<ID padded 3.>	<Confirmation>				YCOORD	Y-Coordinate	S

Programming Challenge: Handling data with Repeated Measures

USUBJID	DOMAIN	VISIT	OECAT	OESCAT	OEMETHOD	OEDTC	FOCID	OELOC	OELAT	OETESTCD	OETEST	OERRES	OETSTDTL
XXXX-251	OE	1	VISUAL ACUITY	ETDRS	ETDRS EYE CHART	2019-08- 15OS		EYE	LEFT	NUMLC	Number of Letters Correct	0	CHART DISTANCE 1 m
XXXX-251	OE	1	VISUAL ACUITY	ETDRS	ETDRS EYE CHART	2019-08- 15OS		EYE	LEFT	NUMLC	Number of Letters Correct	0	CHART DISTANCE 1 m
XXXX-251	OE	1	VISUAL ACUITY	ETDRS	ETDRS EYE CHART	2019-08- 15OS		EYE	LEFT	NUMLC	Number of Letters Correct	0	CHART DISTANCE 1 m

Programming Solution: Handling data with Repeated Measures

USUBJID	DOMAIN	VISIT	OESPID	OECAT	OESCAT	OEMETHOD	OEDTC	FOCID	OELOC	OELAT	OETESTCD	OETEST	OERRES	OETSTDTL
XXXX-251	OE	1	001	VISUAL ACUITY	ETDRS	ETDRS EYE CHART	2019-08-15	OS	EYE	LEFT	NUMLC	Number of Letters Correct	0	CHART DISTANCE 1 m
XXXX-251	OE	1	002	VISUAL ACUITY	ETDRS	ETDRS EYE CHART	2019-08-15	OS	EYE	LEFT	NUMLC	Number of Letters Correct	0	CHART DISTANCE 1 m
XXXX-251	OE	1	003	VISUAL ACUITY	ETDRS	ETDRS EYE CHART	2019-08-15	OS	EYE	LEFT	NUMLC	Number of Letters Correct	0	CHART DISTANCE 1 m

- OESPID – Adding sponsor defined key will make triplicate records meaningful

Conclusion – Tools for OE Mapping and Programming

- OE has some complexities due to the nature of ophthalmic data collection
- Formats, macros and arrays are useful tools to increase programming efficiency
- Intermediate Datasets and look-up tables can be useful to reduce code length
- OESPID as a key variable can improve readability of repeated measures data and avoid duplicate warnings in P21

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