



SDTMIG V3.3, REVIEW BATCH 2

ALTERNATE HANDLING OF SUPPLEMENTAL QUALIFIERS

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ALTERNATE HANDLING OF SUPPLEMENTAL QUALIFIERS BACKGROUND

- **As an alternative to submitting non-standard variables (NSVs) in separate SUPP-- datasets, they may be represented in the parent datasets**
- First draft has been in SDTMIG v3.2 Batch 2
- Should replace section 8.4.4 in SDTMIG v3.2 „When Not to Use Supplemental Qualifiers“, which will be then section 8.4.5
- **There are often problems with Supplemental Qualifiers**
 - Extra programming task to transpose the structure
 - Sometimes a challenge to link information to the parent domain
 - All information have to be listed as characters
 - For some parties it's incomprehensibly how to combine that information, and why some data are „here“ and the rest is „there“

ALTERNATE HANDLING OF SUPPLEMENTAL QUALIFIERS ACTUAL STRUCTURE (1)

- At the annotation of source data you have to check what could be mapped into the parent domain, what belongs to the SUPP--

Variable	Variable Label
HOSEQ	Sequence Number
HOTERM	Term
HOSTDT	Start (Admission) Date/Time
HOENDT	End (Discharge) Date/Time
HODUR	Duration
AEREPF	AE Reported This Episode?
MEDSFL	Meds Prescribed?
PROCFL	Procedures Performed?
PROVNM	Provider Name
SPUNFL	Any Time in Spec. Unit?
SPUNCD	Specialized Unit Type
RLCNDF	Visit Related to Study Med Cond.?

Event Variables

SUPPQUAL Variables

ALTERNATE HANDLING OF SUPPLEMENTAL QUALIFIERS ACTUAL STRUCTURE (2)

- In SDTM that results in parent domain HO

STUDYID	USUBJID	DOMAIN	HOSEQ	HOTERM	HOSTDTC	HOENDTC	HODUR
1999001	0001	HO	1	Hospitalization	2004-01-05	2004-01-12	P1W
1999001	0001	HO	2	Hospitalization	2004-01-23	2004-02-07	P15D
1999001	0002	HO	1	Hospitalization	2004-01-21	2004-01-22	P1D

- ...and SUPPHO

STUDYID	USUBJID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1999001	0001	HO	HOSEQ	1	AEREPFL	AE Reported This Episode?	Y	CRF	
1999001	0001	HO	HOSEQ	1	MEDSFL	Meds Prescribed?	Y	CRF	
1999001	0001	HO	HOSEQ	1	PROCFL	Procedures Performed?	Y	CRF	
1999001	0001	HO	HOSEQ	1	PROVNM	Provider Name	General Hospital	CRF	
1999001	0001	HO	HOSEQ	1	SPUNCD	Specialized Unit Type	ICU	CRF	
1999001	0001	HO	HOSEQ	1	SPUNFL	Any Time in Spec. Unit	Y	CRF	
1999001	0001	HO	HOSEQ	1	RLCNDFL	Related to Study Cond.?	Y	CRF	
1999001	0001	HO	HOSEQ	2	AEREPFL	AE Reported This Episode?	Y	CRF	
1999001	0001	HO	HOSEQ	2	MEDSFL	Meds Prescribed?	Y	CRF	
1999001	0001	HO	HOSEQ	2	PROCFL	Procedures Performed?	Y	CRF	
1999001	0001	HO	HOSEQ	2	PROVNM	Provider Name	University Hospital	CRF	
1999001	0001	HO	HOSEQ	2	SPUNCD	Specialized Unit Type	CCU	CRF	
1999001	0001	HO	HOSEQ	2	SPUNFL	Any Time in Spec. Unit	Y	CRF	
1999001	0001	HO	HOSEQ	2	RLCNDFL	Related to Study Cond.?	Y	CRF	
1999001	0002	HO	HOSEQ	1	AEREPFL	AE Reported This Episode?	Y	CRF	
1999001	0002	HO	HOSEQ	1	MEDSFL	Meds Prescribed?	Y	CRF	
1999001	0002	HO	HOSEQ	1	PROCFL	Procedures Performed?	Y	CRF	
1999001	0002	HO	HOSEQ	1	PROVNM	Provider Name	General Hospital	CRF	
1999001	0002	HO	HOSEQ	1	SPUNCD	Specialized Unit Type	ICU	CRF	
1999001	0002	HO	HOSEQ	1	SPUNFL	Any Time in Spec. Unit	Y	CRF	
1999001	0002	HO	HOSEQ	1	RLCNDFL	Related to Study Cond.?	Y	CRF	

ALTERNATE HANDLING OF SUPPLEMENTAL QUALIFIERS NEW STRUCTURE

- Using the new method, the annotation has to be different

new structure...

...instead of

Non-Standard Variables			
HOAERPFL	AE Reported This Episode?	AEREPF	AE Reported This Episode?
HOMEDSFL	Meds Prescribed?	MEDSFL	Meds Prescribed?
HOPROCFL	Procedures Performed?	PROCFL	Procedures Performed?
HOPROVNM	Provider Name	PROVNM	Provider Name
HOSPUFL	Any Time in Spec. Unit?	SPUNFL	Any Time in Spec. Unit?
HOSPUTYP	Specialized Unit Type	SPUNCD	Specialized Unit Type
HORLCNDF	Visit Related to Study Med Cond.?	RLCNDF	Visit Related to Study Med Cond.?

- Including the NSVs in the parent domain HO it should look like this:

Row	STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOSTDTC	HOENDTC	HODUR
1	1999001	HO	0001	1	Hospitalization	2004-01-05	2004-01-12	P1W
2	1999001	HO	0001	2	Hospitalization	2004-01-23	2004-02-07	P15D
3	1999001	HO	0002	1	Hospitalization	2004-01-21	2004-01-22	P1D

Row	HOAERPFL	HOMEDSFL	HOPROCFL	HOPROVNM	HOSPUFL	HOSPUTYP	HORLCNDF
1	Y	Y	Y	General Hosp	ICU	Y	Y
2	Y	Y	N	Univ Hosp	CCU	Y	Y
3	Y	N	Y	St. Mary's	ICU	N	Y

ALTERNATE HANDLING OF SUPPLEMENTAL QUALIFIERS

WHY SHOULD THAT STRUCTURE BE CHANGED?

- **Structure**

- NSV variables have to start with the domain abbreviation too
- New variables have to be listed after the timing variables

- **Benefits**

- Permitting direct viewing of standard variables and NSVs within the same structure, eliminating the need for tools or the writing of programs to display the data together
- Eliminating some current SUPP-- structural limitations, e.g. allowing numerical variables and shortening each variables as needed
- No structural reprogramming needed for ADaM datasets

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POSSIBLE IMPACTS

- **Optional structure**

- By now there are no instructions or rules in place if the old new structure could be mixed, e.g. adding a clinical significance flag to the parent domain, but information for the whole measurement stay in the SUPPxx
- ...or is it one or the other structure?
- Is it expected to have the same sorting order by variable types for the NSV variables as for the SDTM variables?

- **Possible problems**

- Naming space – each company will have their own terms
- Any available information might be added again
- Different mappings are possible – e.g. Ongoing flag as time points or as one additional NSV variable
- Soakes the SDTM standard

ALTERNATE HANDLING OF SUPPLEMENTAL QUALIFIERS

ADDITIONAL IMPLEMENTATION RULES

- **To avoid this additional implementation rules are requested:**
- NSVs may be added only to General-Observation-Class domains and Demographics
- Sponsors must not seek this implementation as a method for representing NSVs that would not have previously been represented in SUPP-- datasets
- Complete metadata must be provided for each NSV in the same way it's required for standard variables
- Variable lengths for character NSVs should be set to the appropriate length for that variable, as with all standard character variables
- Metadata roles for NSVs are defined appropriately, based upon the SDTM variables roles, and must be one of the following Roles:
 - a. Non-Standard Identifier
 - b. Non-Standard Qualifier
 - c. Non-Standard Timing
- NSVs would be ordered after the standard variables, and ordered as shown above. The order within each of the non-standard Roles should be consistent within the dataset and the define.xml

THANK YOU