Note: This copy of the draft Section 8.4.4, Alternative Representation of Non-Standard Variables, has undergone minor corrections and formatting since the public review period, but it is otherwise unchanged.

8 Representing Relationships and Data

8.4 Relating Non-Standard Variables Values to a Parent Domain

8.4.4 Alternative Representation of Non-Standard Variables

new section, inserted before former Section 8.4.4 in SDTMIG v3.2

8.4.4.1 Background

As an alternative to submitting non-standard variables (NSVs) in separate SUPP-- datasets, they may be represented in the parent datasets. This method provides some additional benefits. These include the following:

- 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 by allowing:
  - Numeric NSVs to be represented in a numeric data type
  - Character NSVs to be defined with an appropriate length for each variable, rather than the typical default of $200 for QVAL
- Allowing metadata for NSVs (including Controlled Terminology) to be applied at the variable level instead of the value-level.

8.4.4.2 Implementation Rules

In order to use the alternative described above, the following implementation rules must be followed:

- The list domains to which NSVs may be added does not change. NSVs may be added only to general-observation-class domains and Demographics.
- The same considerations must be used in assessing the number of NSVs represented, regardless of whether they are represented in SUPP-- datasets or in the parent domains. In other words, 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 in the bullet above. The order within each of the non-standard Roles should be consistent within the dataset and the define.xml.

Example
Hospitalization data with non-standard variables
This example shows three hospitalization records, two for Subject 0001, and one for Subject 0002. In the collected data, there are standard variables from the SDTM: Identifiers from Table 2.2.4, Event Qualifiers from Table 2.2.2 of the SDTM, Timing variables from Table 2.2.5. In addition, there are the following non-standard variables:

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

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42 Two methods are shown for the representation and submission of these data: the method of submitting NSVs in
43 SUPPHO and the new method of submitting NSVs in the parent domain.

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45 1. Existing Method Using SUPP--

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47 *ho.xpt: Healthcare Encounters*

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

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49 *suppho.xpt*

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1999001	HO	0001	HOSEQ	1	HOAERPFL	AE Reported This Episode	Y	CRF	
2	1999001	HO	0001	HOSEQ	1	HOMEDSFL	Meds Prescribed	Y	CRF	
3	1999001	HO	0001	HOSEQ	1	HOPROCFL	Procedures Performed	Y	CRF	
4	1999001	HO	0001	HOSEQ	1	HOPROVNM	Provider Name	General Hosp	CRF	
5	1999001	HO	0001	HOSEQ	1	HOSPUFL	Specialized Unit Type	ICU	CRF	
6	1999001	HO	0001	HOSEQ	1	HOSPUTYP	Any Time in Spec. Unit	Y	CRF	
7	1999001	HO	0001	HOSEQ	1	HORLCNDF	Visit Related to Study Med Cond.	Y	CRF	
8	1999001	HO	0001	HOSEQ	2	HOAERPFL	AE Reported This Episode	Y	CRF	
9	1999001	HO	0001	HOSEQ	2	HOMEDSFL	Meds Prescribed	Y	CRF	
10	1999001	HO	0001	HOSEQ	2	HOPROCFL	Procedures Performed	N	CRF	
11	1999001	HO	0001	HOSEQ	2	HOPROVNM	Provider Name	Univ Hosp	CRF	
12	1999001	HO	0001	HOSEQ	2	HOSPUFL	Specialized Unit Type	CCU	CRF	
13	1999001	HO	0001	HOSEQ	2	HOSPUTYP	Any Time in Spec. Unit	Y	CRF	
14	1999001	HO	0001	HOSEQ	2	HORLCNDF	Visit Related to Study Med Cond.	Y	CRF	
15	1999001	HO	0002	HOSEQ	1	HOAERPFL	AE Reported This Episode	Y	CRF	
16	1999001	HO	0002	HOSEQ	1	HOMEDSFL	Meds Prescribed	N	CRF	
17	1999001	HO	0002	HOSEQ	1	HOPROCFL	Procedures Performed	Y	CRF	
18	1999001	HO	0002	HOSEQ	1	HOPROVNM	Provider Name	St. Mary's	CRF	
19	1999001	HO	0002	HOSEQ	1	HOSPUFL	Specialized Unit Type	ICU	CRF	
20	1999001	HO	0002	HOSEQ	1	HOSPUTYP	Any Time in Spec. Unit	N	CRF	
21	1999001	HO	0002	HOSEQ	1	HORLCNDF	Visit Related to Study Med Cond.	Y	CRF	

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51   <u>2. New Method with Non-Standard Variables Included in Parent Domain</u>

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53   *ho.xpt: Healthcare Encounters*

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

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

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56   *HO NSV Metadata*

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Origin	Role	Evaluator	Comments
HOAERPFL	AE Reported This Episode	Char	No Yes Response	CRF	Non-Standard Qualifier		
HOMEDSFL	Meds Prescribed	Char	No Yes Response	CRF	Non-Standard Qualifier		
HOPROCFL	Procedures Performed	Char	No Yes Response	CRF	Non-Standard Qualifier		
HOPROVNM	Provider Name	Char		CRF	Non-Standard Qualifier		
HOSPUFL	Specialized Unit Type	Char		CRF	Non-Standard Qualifier		
HOSPUTYP	Any Time in Spec. Unit	Char	No Yes Response	CRF	Non-Standard Qualifier		
HORLCNDF	Visit Related to Study Med Cond.	Char	No Yes Response	CRF	Non-Standard Qualifier		

57   # 8.4.5 When Not to Use Non-Standard Variables   previously 8.4.4, When Not to Use Supplemental Qualifiers

58   Examples of data that should <u>not</u> be submitted as Supplemental Qualifiers are the following:

59   •   Subject-level objective data that fit in Subject Characteristics (SC). Examples include Marital Status, Skin
60   Classification, Education Level.
61   •   Findings interpretations that should be added as an additional test code and result. An example of this
62   would be a record for ECG interpretation where EGTESTCD = "INTP", and the same EGGRPID or
63   EGREFID value would be assigned for all records associated with that ECG (see Section 4: 4.1.5.5,
64   Clinical Significance For Findings Observation Class Data).
65   •   Comments related to a record or records contained within a parent dataset. Although they may have been
66   collected in the same record by the sponsor, comments should instead be captured in the CO special-
67   purpose domain.
68   •   Data not directly related to records in a parent domain. Such records should instead be captured in either a
69   separate general observation class or special purpose domain.