

An Animated Guide: the logical cascade through the --Orres variable Russ Lavery, Numeric Resources

ABSTRACT

This paper explores some of the complexity in the recording of the --ORRES variable in the Study Data Tabulation Model (SDTM) domains. It offers the idea that properly valuing --ORRES variables is difficult because there is a logical link among five characteristics surrounding how an ORRES value was collected, and values in a “logical cascade” of fourteen other variables. This paper explores the relationships surrounding --ORRES and the resulting rules for valuing --ORRES and the fourteen other variables in the --ORRES “logical cascade”.

INTRODUCTION

This paper explores some of the complexity in the recording of the --ORRES variable in SDTM domains. It offers the idea that properly valuing --ORRES variables is difficult because there is a logical link among five characteristics surrounding how the data was collected, the value for --ORRES and values in a “logical cascade” of fourteen other variables. The characteristics surrounding the collection of the data, that this paper will explore, are:

- 1) Was the --ORRES value derived from multiple observations (via formula or logic) or simply copied from a single variable on the Case Report Form (CRF) or data source.
- 2) Is the value to be recorded in the --ORRES “basically” a character string or “basically” a numeric value
- 3) Were the results recorded in standard units or not (practically, a provision must be made for the person recording values to make a mistake - and use improper units (pounds instead of Kilograms etc.)
- 4) Was the test value in the normal range, or not
- 5) Was the test done, or not.

The above binary characteristics combine to form thirty-two (2^5) different combinations (called states of nature) and if we want to understand --ORRES we should study how --ORRES should be valued for each of the states of nature.

Additionally, this paper suggests that there is a logical cascade, or relationship, starting from the thirty-two different states of nature and proceeding through --ORRES to fourteen other variables. This paper suggests that when valuing --ORRES, a programmer should consider the following list of variables to be a related group. The fact that --ORRES is related to all the variables below is the meaning of the phrase “logical cascade”.

ORRES	ORRESUORRESNRLO	ORRESNRHI	
STRESC	STNRC		
STRESN	STRESU STRNRLO	STNRHI	
NRDIND			
STAT	REASND	METHOD	DRVFL

There are other factors/issue, not discussed in this paper, that add to the complexity of recording values from the CRF. Hopefully; these can be addressed in future work. Readers are warned that this paper does not attempt to cover the issues listed below and, as such, is flawed in how it covers the topic.

Factors/Issues not discussed (and comments about these factors from the SDTM Implementation Guide) are:

- 1) When the CRF says “Specify other values”, values can be put in the associated SUPP—domain or the original code list can be expanded.
- 2) For a Result Qualifier (and there are only three --ORRES, --STRESC, and --STRESN), if multiple values are recorded for an observation in a findings domain, the multiple values are to be entered into the domain and identified with a sequencer or through use of a sequencing variable.
- 3) For a Non-Result Qualifier (e.g. Sex and Race in Demographics, serious event flags in Adverse Events) the values can be concatenated or put in SUPP—with “multiple” for the value of the non-result qualifier in the original domain,

CONVENTIONAL AND SI UNITS

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Several CDISC domains (examples follow) have variables allowing for the recording of values in units that differ from the units to be used for analysis or table creation.

Conversion tables (examples to right) are published and can be used to convert odd units to SI units. To convert from conventional units to the SI units, multiply by the conversion factor.

Test or Component	Conventional Unit	Conversion Factor	SI Unit
Acetaminophen	µg/mL	6.62	µmol/L
Acetoacetic acid	mg/dL	0.098	mmol/L

THE CLINICAL STUDY

In an effort to make the concepts more concrete, imagine that the data was collected as part of a study for a new type of athletic equipment designed to boost performance. Tests will be run on exertion, weight, BMI, and other lab tests associated with physical effort and fitness.

“Is the variable copied or derived” is the first of the five characteristics to be mentioned and examples of derived variable examples are shown below. Below, find a discussion of a “character derived variable” and a “numeric derived variable” from this imaginary study.

This is an example of a character derived variable.

The perspiration level is observed at two times and the maximum level is to be used in analysis. Standard values are recorded as: “NO”, “MILD”, “MOD”, “SEV”. Strings not in this list are considered to be “non-standard character values.”

Standard Sweaty Scale- Measures Exertion: Measure at midpoint of game and at end of game: Select Max Value: Codes are in blue italic & underlined				
				Midpoint of Game <u>MOD</u>
				End of game <u>SEV</u>
				Max <u>SEV</u>
<u>No</u> Exertion	<u>Mild</u> Exertion	<u>Moderate</u> Exertion	<u>Severe</u> Exertion	Normal Range

Examples of “Derived variables”: Two “raw values” are used to determine the value to be reported. The variable ORRES IS A CHARACTER VARIABLE in all domains. The 85, below, would be a character 85 in ORRES, but we (awkwardly) say this ORRES

This is an example of a numeric derived variable. Pulse rate is recorded at two times and the average is used in analysis.

Average Pulse Rate - measure of exertion: Measure at midpoint of game and at end : Select Average Value:	At Midpoint of Game
Normal Range is 60 to 100 BPM	80
	At End of game 90
	Avg 85

Ranges shown above have no basis in fact and are only for the purpose of this example

We will use these variables in examples of recording variables. The table below provides units/ranges for other examples. These other ranges can be used if the reader wants to create their own examples.

NOTE: Since ORRES is a character variable. Since the value being put into ORRES can be basically character (“MILD”) or basically numeric (85.0), our phrasing is often clumsy. It is both common, and awkward, when ORRES holds a number, to say that “ORRES is numeric” even though ORRES is a character variable in all domains.

Test	Standard Units and Range (SI)	Non-Standard Units or Conventional (US) units
Std. Sweaty Scale (character)	Normal Range: Mild, Moderate Out of Range: No, Severe	Nada, Not a drop, none dripping with perspiration, excessive, gross
Avg. Pulse Rate (numeric)	Normal Range 60-100, Out of Range=LT 60/ GT 100	15 beats in 15 seconds
Casts (Urinalysis)	Normal range 0; Out of range +, ++, +++	trace,1, 2

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Test	Standard Units and Range (SI)	Non-Standard Units or Conventional (US) units
Crystals (Urinalysis)	Normal range 0; Out of range +, ++, +++	trace, 1, 2
HGB Hemoglobin	Men: 130-180 g/L Women: 120-160 g/L Conversion = *10	Men: 13-18 g/dL Women: 12-16 g/dL

REVIEW OF RULES

It would be proper to review the rules for valuing the above fifteen variables before applying the rules. This section collects rules from various places in the SDTM Implementation Guide (I.G.) into a series of tables.

NOTICE THAT THE DESCRIPTIONS OF THE VARIABLES DIFFER DEPENDING ON THE DOMAIN BEING DESCRIBED AND SOMETIMES VARIABLES ARE NOT PRESENT IN A PARTICULAR DOMAIN.

Please use the tables below to **compare and contrast** how the variables are described in different places in the I.G. The reason for reviewing all the places where rules for a variable are given is that sometimes the explanations differ from domain to domain.

Most of the rules are taken from places in the implementation guide that describe domains- except for two important exceptions. About page 15 and about pages 54-55, several *examples* are given in the I.G. These examples are especially useful and instructive. Lessons to be learned from the example sections are included for each variable. The use of yellow background emphasized that information is from an “examples” section. Domain abbreviations are separated from the variable “name base” (e.g. LB ORRES) to emphasize both the domain and the variable.

ORRES Pg 15 Result of Measurement as originally received, or collected. E.g. 120 or <1
ORRES Pg 54-55 Shows several character and numeric examples. It shows that if value is INTENDED to be Character, no units are needed. If a numeric value is entered as “LT 1000”, the row will have units in another variable.
LB ORRES Pg 137 Result of measurement as originally received, or collected.
PE ORRES Pg 143 Text description of any abnormal finding. If the result was normal the value should be “NORMAL”
QS ORRES Pg 147 Finding as originally received (e.g. “RARELY”, “SOMETIMES”). When sponsors apply code lists to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 Questionnaires, ORRES will contain the DECOD format and QSSTRESC and QSSTRESN may contain the standardized values or scores.
SC ORRES Pg 153 Result of subject characteristic as originally collected.
VS ORRES Pg 157 Result of subject characteristic as originally collected.
DA ORRES Pg 160 Result of Drug Accountability Assessment as originally collected.
MBMS ORRES Pg 163-167 Result of Microbiology measurement as collected.
PCPP ORRES Pg 175-177 Result of measurement or finding as originally collected.
EG ORRES Pg 129 Result of ECG measurement as originally collected.
IE ORRES Pg 134 Original response to Inclusion/exclusion criteria not met.
CF ORRES Pg 196 Result of test as originally received or collected

Comment: ORRES is, generally speaking, the result of the measurement. The ORRES variable is stored as character. ORRES can contain values like “MILD” or “87.9” (which looks like a number), but ORRES is character.

ORRESU Pg 15 Units for ORRES
ORRESU Pg 54-55 Shows several character and numeric examples. Note: If the ORRES is INTENDED to be Character, no

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units are shown. This also shows how to value ORRES and ORRESU if a numeric value is entered as "LT 1000",
LB ORRESU Pg 137 Original units in which the data were collected. Unit for LBORRES.
PE ORRESU Pg 144 Original units in which the data were collected.
QS ORRESU Pg 148 Original Units in which the data were collected, the Unit for ORRES such as minutes or seconds or the units associated with a visual analog scale.
SC ORRESU Pg 153 Original Units in which data were collected, the Unit for ORRES.
VS ORRESU Pg 156 Original Units in which data were collected, the Unit for ORRES.
DA ORRESU Pg 160 Unit for DAORRES.
MBMS ORRESU Pg 164-167 Unit for MBMSORRES.
PCPP ORRESU Pg 175-177 Unit for PCPPORRES.
EG ORRESU Pg 129 Unit for EGPPORRES.
IE ORRESU Pg 134 Not in domain.
CF ORRESU Pg 197 Original units in which the data were collected. The unit for CFORRES.

Comment: ORRESU is the units for ORRES, as recorded by physician. The physician might NOT have followed instructions on units to be recorded. ORRESU could be in conventional units or in SI units (incorrect or correct units).

ORNRLO ORNRHI Pg 15 Lower/Upper ends of normal range for values stored in ORRES (in the units in which ORRES was collected. These units can be correct or incorrect).	
ORNRLO ORNRHI Pg 54-55 Not shown in this section.	
LB ORNRLO ORNRHI Pg 137 Lower/Upper ends of reference range of <i>continuous measurements in original units. Should only be populated for continuous results.</i>	
PE ORNRLO ORNRHI Pg 144 Not in the domain	QS ORNRLO ORNRHI Pg 148 Not in the domain
SC ORNRLO ORNRHI Pg 153 Not in the domain	VS ORNRLO ORNRHI Pg 157 Not in the domain
DA ORNRLO ORNRHI Pg 161 Not in the domain	MBMS ORNRLO ORNRHI Pg 164-167 not in domain
PCPP ORNRLO ORNRHI Pg 175-177 not in domain	EG ORNRLO ORNRHI Pg 129 Not in the domain
IE ORNRLO ORNRHI Pg 135 Not in th domain	CF ORNRLO ORNRHI Pg 196 Not in the domain

Comment: These variables describe the normal range for **NUMERIC** ORRES variables-in units that were used by physician. The Physician might NOT have followed instructions on units. ORNRLO ORNRHI could be in conventional units or in SI units. These variables are valued only for continuous (numeric) variables. These variables should be "Null" If – ORRES is character.

STRESC Pg 15 Result, in character format, of ALL (character/numeric) findings, in standard format /standard units. Numeric results, should ALSO be stored in STRESN. If character, this decodes to controlled terminology.
STRESC Pg 54-55 Examples. Shows controlled terminology for ORRES. Shows how to handle "<4000" being entered for what was intended to be a numeric test (see examples 11A-11F).

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LB STRESC Pg 137 Result, in character format, of ALL findings, copied or derived from LBORRES, in a standard format or standard units. If LBORRES numeric, This value should ALSO be stored in STRESN. If the variable is character, LBSTRESC should contain a decode to controlled terminology.
PE STRESC Pg 144 If findings are for a body system, and if findings are dictionary coded, the dictionary preferred term should appear here. If PEORRES is “Null”, PESTRESC should be “Null”.
QS STRESC Pg 148 Contains the findings for all questions or sub-scores, copied or derived from QSORRES in a standard format or standard units. QSSTRESC should store all findings in a character format. If findings are Numeric, they should also be stored in numeric format in QSSTRESN. If question scores are derived from the original finding, then the standard format IS the score.
SC STRESC Pg 153 Contains the findings copied or derived from SCORRES, in a standard format or standard units. SCSTRESC should be in a character format. If findings are Numeric, they should also be stored in numeric format in SCSTRESN. If “NONE” or “NEG” are in ORRES they can all be decoded to “NEGATIVE” in SCSTRESC.
VS STRESC Pg 158 Contains the result values for all findings, copied or derived, from VSORRES in a standard format or standard units. VSSTRESC should store all results or findings in character format. If results are numeric, they should also be stored in numeric format in VSSTRESN. If “NONE”, “NEG” or “ZERO” appear in ORRES (on different rows) they can all be decoded to “NEGATIVE” in VSSTRESC.
DA STRESC Pg 161 Contains the result values for all Drug Accountability Assessments, copied or derived, from DAORRES in a standard format or standard units. DASTRESC should store all results or findings in character format. If results are numeric, they should also be stored in numeric format in DASTRESN.
MBMS STRESC Pg 164-167 Similar to above - A decode for MBORRES / MSORRES.
PCPP STRESC Pg 175-177 Similar to above - A decode for PCORRES/PPORRES.
EG STRESC Pg 129 Similar to above - A decode for EGORRES.
IE STRESC Pg 135 Similar to above - A decode for IEORES.
CF STRESC Pg 196 Contains the result value for all findings, copied or derived from CFORRES in a standard format or standard units. CFSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in CFSTRESN. If a test has results 'NONE', 'NEG', and 'NEGATIVE' in CFORRES and these results effectively have the same meaning, they could be represented in standard format in CFSTRESC as 'NEGATIVE'.

Comment: No matter if the value to be stored in ORRES is character or numeric, STRESC (a character variable) should be valued – but valued after ORRES has been converted to a standard value (into standard units).

As an example; if the value in ORRES is. 6.0 with units of mg/dL and the standard unit for the test is mg/L, then STRESC will be a **character** 60.0 (and STRESN will be a numeric 60.0). If the value in ORRES is recorded. on the CRF, as a character “Neg”, “None” or. “ZERO”, a “standardized character” representation/decode of these values to a character STRESC might have them all valued as “NEGATIVE”.

STRESN Pg 15 Used for continuous or numeric results of findings in STANDARD format copied in numeric format from STRESC. STRESN should store all numeric test results or findings.	
STRESN Pg 54-55 Examples show controlled terminology for ORRES. An example shows how to value “<4000” being entered for what was intended to be a numeric test (see examples 11A-11F).	
LB STRESN Pg 137 Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings. Another phrasing might be “Take LBORRES and convert it to SI units. Enter the value, after conversion, into LBSTRESN.”	
PE STRESN Pg 144 Not in domain.	
QS STRESN Pg 144 Used for continuous or numeric findings in standard format; copied in numeric format from QSSTRESC. QSSTRESN should store all numeric results or findings.	
SC STRESN Pg 154 Same as above.	VS STRESN Pg 158 Same as above
DA STRESN Pg 160 Same as above.	MBMS STRESN Pg 164-167 Same as above
PCPP STRESN Pg 175-177 Same as above.	EG STRESN Pg 129 Same as above
IE STRESN Pg 135 Same as above.	CF STRESN Pg 196 Same as above

Comment: 1) If ORRES is numeric,
 after you have converted the value collected into “standard” (SI) units
 or 2a) if ORRES is character and
 2b) you do a character to numeric conversion of the character value,
 then put that numeric value in STRESN.

STRESU Pg 16 Standardized units for STRESC and STRESN. <i>Differences between the units in which the data was collected and SI Units create a need to standardize the data.</i>
STRESU Pg 54-55 Good examples of unit conversion are shown on Pg 55.
LB STRESU Pg 137 Standardized unit used for LBSTRESC or LBSTRESN.
PE STRESU Pg 144 Not in domain.

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QS STRESU Pg 148 Standardized unit used for QSSTRESC or QSSTRESN.
SC STRESU Pg 155 Standardized unit used for SCSTRESC or SCSTRESN.
VS STRESU Pg 158 Standardized unit used for VSSTRESC or VSSTRESN.
DA STRESU Pg 161 Standardized units used for DASTRESC or DASTRESN.
MBMS STRESU Pg 164-167 Standardized unit used for MB/MS STRESC or MB/MS STRESN.
PCPP STRESU Pg 175-177 Standardized unit used for PC/PP STRESC or PC/PP STRESN.
EG STRESU Pg 129 Standardized units used for EGSTRESC or EGSTRESN.
IE STRESU Pg 135 Not in domain.
CF STRESU Pg 196 Standardized unit used for CFSTRESC or CFSTRESN.

Comment: Standardized units are abbreviated “SI” Units. They are the units in which we hoped the tests had been collected.

STNRLO STNRHI Pg 16 Upper and lower end of normal range for results that were stored in STRESN. These values are in Standard Units.	
STNRLO STNRHI Pg 54-55 not shown	
LB STNRLO STNRHI Pg 137 Lower end/Upper end of reference range of <i>continuous measurements in standardized format or units</i> . Populated only for continuous units.	
PE STNRLO STNRHI Pg 144 Not in domain.	QS STNRLO STNRHI Pg 148 Not in domain.
SC STNRLO STNRHI Pg 155 Not in domain.	VS STNRLO STNRHI Pg 158 Not in domain.
DA STNRLO STNRHI Pg 161 Not in domain.	MBMS STNRLO STNRHI Pg 164-167 Not in domain.
PCPP STNRLO STNRHI Pg 175-177 Not in domain.	EG STNRLO STNRHI Pg 129 Not in domain.
IE STNRLO STNRHI Pg 135 Not in domain.	CF STNRLO STNRHI Pg 196 Not in domain.

Comment: Recorded in SI Units. These variables hold low and high values for numeric test measurements.

These variables are valued only for continuous variables.

They are valued as “Null” if --ORRES is character.

STNRC Pg 16 For normal range or reference range values for results stored in STRESC that are character, in ordinal or categorical scale. E.g Negative to trace	
STNRC Pg 54-55 Not shown.	
LB STNRC Pg 137 For normal range or reference range values for results stored in LBSTRESC that are character in ordinal or categorical scale. E.g “-1 to 1” or “Negative to Trace”	
PE STNRC Pg 144 Not in domain.	QS STNRC Pg 148 Not in domain.
SC STNRC Pg 154 Not in domain.	VS STNRC Pg 158 Not in domain.
DA STNRC Pg 161 Not in domain.	MBMS STNRC Pg 164-167 Not in domain.
PCPP STNRC Pg 171-175 Not in domain.	EG STNRC Pg 129 Not in domain.
IE STNRC Pg 135 Not in domain.	CF STNRC Pg 196 Not in domain.

Comment: It can take a bit of thinking to understand how this variable is valued.

Consider the task of communicating standard ranges for character variables. STNRC simply contains a *list* of character strings that describe the normal range of a character variable. STNRC contains the *list of words* commonly used to describe a “normal” sample.

Imagine that a normal sample is not supposed to have any sediment/”suspended solids”, and that a technician should be able to easily see through a test tube containing a normal sample.

In the above case, the list in STNRC might be: “Clean”, “Transparent” “Un-clouded”, “not cloudy”.

In another test, with the Character list “-1”, “0”, “+1”, “+2” as normal, STNRC values could be “-1 to 2” or “-1 to +2”.

This variable is linked to STRESC and only has meaning if --ORRES is character. If --ORRES is numeric, STNRC should be “Null”.

NRIND Pg 16 Indicates the value is OUTSIDE the normal range or reference range. May be defined by ORNRLO or ORNRHI or other objective criteria Examples Y,N,HIGH,LOW	
NRIND Pg 54-55 not shown	
LB NRIND Pg 137 Indicates where value falls w/ respect to ref. range defined in ORNRLO/HO or STNRLO/HI or by LBSTNRC. Sponsors should specify, in study metadata, if LBRIND refers to original/SI ranges & results.	
PE NRIND Pg 144 Not in domain.	QS NRIND Pg 148 Not in domain.

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SC NRIND Pg 154 Not in domain.	VS NRIND Pg 158 Not in domain.
DA NRIND Pg 161 Not in domain.	MBMS NRIND Pg 164-167 Not in domain.
PCPP NRIND Pg 175-177 Not in domain.	EG NRIND Pg 129 Not in domain.
IE NRIND Pg 135 Not in domain.	CF NRIND Pg 196 Not in domain.

Comment: Good practice suggests raising this flag by comparing *ORRES*, *without converting*, to the normal range in the units in which *ORRES* was collected. This avoids the rare issue, where conventional and SI units produce different answers due to rounding. You must report which hi/low range was used in the raising this flag. The comment about “other objective criteria” could only be found in one place in the I.G.

STAT Pg 16 Indicates that a question was not done. Valued as “Null” or “NOT DONE”	
STAT Pg 54-55 not shown	
LB STAT Pg 137 Indicates that a question was not done. Valued: “Null” or “NOT DONE”	
PE STAT Pg 144 Indicates that a question was not done. Should be “Null” if a result exists in PEORRES.	
QS STAT Pg 148 Used to indicate a questionnaire or response to a questionnaire was not done. “Null” if a result exists in QSORRES.	PE STAT Pg 154 Used to indicate exam not done. Should be “Null” if a result exists in ORRES.
VS STAT Pg 158 Used to indicate that a vital sign measurement was not done. “Null” if a result exists in VSORRES.	DA STAT Pg 161 Used to indicate that a drug accountability assessment was not done. Valued as “Null” or “NOT DONE.”
MBMS STAT Pg 164-167 Used to indicate Microbiology was not done, or a test was not done. Should be “Null” or have a value of NOT DONE.	PCPP STAT Pg 171-177 Used to indicate a result was not obtained. Should be “Null” if a result exists in PCORRES.
EG STAT Pg 129 Used to indicate an ECG was not done, or an ECG measurement was not taken. Should be “Null” if a result exists in EGORRES.	IE STAT Pg 135 Not in domain.
CF STAT pg 196 Used to indicate that the measurement was not done. Should be null if a result exists in CFORRES.	

Comment: STAT should be valued as either “Null” (if the test was performed or the measurement was taken) or “NOT DONE” if it was not done. Logically, STAT should be “Null” if a result was entered in ORRES, STRESC or STRESN. This variable is linked to REASND (reason not done)

REASND Pg 16 Reason not done. Valued when stat is valued as NOT DONE	
REASND Pg 54-55 not shown	
LB REASND Pg 137 Describes why measurement or test was not performed such as BROKEN MACHINE or SUBJECT REFUSED. Valued when stat is valued as “NOT DONE”.	
PE REASND Pg 144 Describes why an examination was not performed or a body system not examined. BROKEN MACHINE or SUBJ. REFUSED. Valued when stat is valued “NOT DONE”.	
QS REASND Pg 148 Describes why a question not asked.	
SC REASND Pg 154 Describes why the observation had no result. E.G. Subj Refused.	
VS REASND Pg 158 Describes why the assessment was not performed.	
DA REASND Pg 161 Describes why the assessment was not performed.	
MBMS REASND Pg 164-167 Describes why the assessment was not performed.	
PCPP REASND Pg 171-177 Describes why the assessment was not performed.	
EG REASND Pg 129 Describes why the assessment was not performed.	
IE REASND Pg 135 Describes why the assessment was not performed.	
CF REASND Pg 96 Describes why a question was not answered. Example: subject refused. Used in conjunction with CFSTAT when value is “NOT DONE”.	

Comment: Contains the reason why the test was not done or is “Null” if test was done. REASND should be “Null” if STAT is null. This variable is linked to STAT (status of test) and to ORRES, STRESC or STRESN.

METHOD Pg 16 not shown	METHOD Pg 54-55 not shown
LB METHOD Pg 137 Method of the test or examination. e.g. EIA, ELECTORPHORESIS, DIPSTICK	
PE METHOD Pg 144 Not in domain.	QS METHOD Pg 148 Not in domain.
SC METHOD Pg 154 Not in domain.	VS METHOD Pg 158 Not in domain.
DA METHOD Pg 161 Not in domain.	
MBMS METHOD Pg 164-167 Method of the test or examination. e.g. BROTH	
PCPP METHOD Pg 171-177 Method of the test or examination. e.g. ELISA Should have sufficient granularity to	EG METHOD Pg 129 Method for the EG test- e.g. MONITORING 1-LEAD, 12-LEAD

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allow differentiation of different methods	
IE METHOD Pg 135 Not in domain.	CF METHOD Pg 196 Not in domain.
Comment: The method/procedure used in the examination or collection of the specimen (e.g. mid-stream catch).	
DRVFL Pg. 16 Used to indicate a derived record (e.g. a record that represents an average of other records). These other records must also be included in the domain. Valued as "Y" when value of the observation is derived.	
DRVFL Pg. 54-55 Interesting examples are in 4.1.5.1.2 and 4.1.5.1.4 and 4.1.5.1.5 (on 4.1.5.1.5, study lines 5 to 7. These lines show the records used in the calculation and also the calculation itself.	
LB DRVFL Pg 138 Used to indicate a derived record. The value should be "Y" or "Null". Records that represent the average of other records, or do not come from the CRF, or are not as originally received or collected, are examples of records that might be derived for the submission data sets. If LBDRVFL="Y" then LBSORRES MAY be "Null", with LBSTRESC and, if numeric, LBSTRESN having the desired values.	
PE DRVFL Pg 144 Not in domain	
QS DRVFL Pg148 Used to indicate a derived record. The value should be "Y" or "Null". Records that represent the average of other records, or do not come from the CRF, or are not as originally received or collected, are examples of records that might be derived for the submission data sets. If QSDRVFL="Y" then QSORRES MAY be "Null" with QSSTRESC and, if numeric, QSSTRESN having the desired values.	
SC DRVFL Pg 154 Not in domain	
VS DRVFL Pg 158 Used to indicate a derived record. The value should be "Y" or "Null". Records that represent the average of other records, or do not come from the CRF or are not as originally received or collected are examples of records that might be derived for the submission data sets. If VSDRVFL="Y" then VSORRES MAY be "Null" with VSSTRESC, and if numeric) VSSTRESN having the desired values.	
DA DRVFL Pg. 161 Not in domain	
MBMS DRVFL Pg. 164-167 Used to indicate a derived record, Value should be "Y" or "Null". Records that represent the average of other records or some other derivation, and those do not come from the CRF, are examples of records that would be derived for the submission data sets if MBDRVFL="Y" the MBORRES MAY be "Null".	
PCPP DRVFL Pg 175-177 Used to indicate a derived record. Value should be "Y" or "Null". Records that represent the average of other records or some other derivation, and those do not come from the CRF, are examples of records that would be derived for the submission data sets if PCDRVFL="Y" the PCORRES SHOULD be "Null".	
EG DRVFL Pg 129 Used to indicate a derived record, Value should be "Y" or "Null". Records that represent the average of other records, or are not as originally collected or received, are examples of records that would be derived for the submission data sets. If GDRVFL="Y" then EGORRES COULD be null with EGSTRESC and, if numeric, EGSTRESN having the derived value.	
IE DRVFL Pg 135 Not in domain	CF DRVFL Pg 135 Not in domain

Notice the colored words above. The differences in the wording of the SDTM I.G., lead to questions.

Organizationally, would the comments about valuing –ORRES be better in the areas devoted to the description of the ORRES variable than in this section, on derived flags?

Additionally, If –ORRES is "Null", how should we value ORRESU (units of –ORRES), ORNRLO, ORNRHI, STNRLO, STNRHI and STRESU. One issue often discussed is how many rows of data are entered into a domain for a derived variable and a short discussion is now in order.

The Standard Sweaty Scale (SSS) is shown in a graphic on page 2 and is the maximum of two observations. Since everything collected on the CRF should end up in a table each recording of the SSS creates three rows of data in the domain, with one row having –DRVFL = "Y" to indicate the derived value. A sequencer is also needed.

The Average Pulse Rate (APR) test is the average of two observations and is also shown in a graphic on page 2. Since everything collected on the CRF should end up in a table each recording of the APR creates three rows of data, with one row having –DRVFL = "Y" to indicate the derived value. A sequencer is also needed.

Sections 4.1.5.1. 4 and 4.1.5.1.5 in the Implementation Guide, show examples of how to enter derived variables and give a short explanation of how these types of observations should be handled. Unfortunately, these examples do not include all the variables in the logical cascade.

EXAMPLES

This example shows a derived character variable that is in standard units and is “in the normal range”. ORRES is a character variable and ORRES is valued as “Mod”. “Mod” is decoded into “MODERATE” in --STRESC.

If the sponsor wants a numeric value, it can be calculated and --STRESN and --STRESU can be valued.

Since ORRES is character, the normal range is established by putting a list of values in --STNRLO.

The value is “Normal” and that is recorded in --NRIND.

--ORNRLO, --ORNRHI, --STNRLO and --STNRHI are only valued if ORRES is numeric and so are “Null”.

STAT and REASND are “Null”. Method shows the procedure used and “Y” in --DRVFL indicates that the value of ORRES is derived.

Example	Char or Num	Non-std / Std. Units	Test Done / Not Done	In / out of Range	Test	Value
SN 1	Char	Std	Test	In Range	SSS	Mod as char - normal
SN 1 Derived	Char	Std. Units	Test Done	OUT	SSS	NADA as char - G
SN 2 Derived	Char	Std. Units	Not Done	N/A	SSS	Not done

Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units.	holds normal range values for character vars.	Numeric Coded Value	Std. units	Upper/lower end of normal range for continuous measurements in standardized units. Should be populated only for continuous results.
--	---	---------------------	------------	---

Exmpl	--TESTCD	--TEST	--ORRES	--ORRESU	--ORNRLO	--ORNRHI
SN1-EX1	SSS	STD. SWEATY SCALE	MOD	Blank	Blank	Blank
				Derived (Max), so all 3 are blank		

Exmpl	--STRESC	--STNRLO	--STRESN	--STRESU	--STNRLO	--STNRHI
SN1-EX1	Moderate Exertion	“MILD”, “MOD”	3	Metric Sweat Drop	Blank	Blank

Exmpl	--NRIND	--STAT	--REASND	--METHOD	--DRVFL
SN1-EX1	NORMAL	Blank	Blank	Visual Exam	Y

Indicates where value falls with respect to reference range defined by --ORNRLO and --ORNRHI or by --STNRLO.	Method of the test or examination. Examples: SWAB, NEEDLE PUNCTURE, BRONCHIAL BRUSHING.
--	---

See 4.1.5.1.5 - to 4.1.5.1.7 for examples of derived variables

This next example shows a derived character variable that is not in standard units and is “out of normal range”. ORRES is a character variable and ORRES is oddly valued as “NADA”.

NADA is decoded into “NO EXERTION” in --STRESC. If the sponsor assigns a numeric value, --STRESN and --STRESU can be valued as are shown here.

Since ORRES is character, the normal range is established by putting a list of values in --STNRLO.

The value is “LOW” and that is recorded in --NRIND. --ORNRLO, --ORNRHI, --STNRLO and --STNRHI are all only valued if ORRES is numeric and so are “NULL”.

STAT and REASND are “Null”.

Method shows the procedure used and “Y” in --DRVFL indicates that the value of ORRES is derived.

Example	Char or Num	Non-std / Std. Units	Test Done / Not Done	In / out of Range	Test	Value
SN 1	Char	Std	Test	In Range	SSS	Mod as char - normal
SN 1 Derived	Char	Std. Units	Test Done	OUT	SSS	NADA as char - OUT
SN 2 Derived	Char	Std. Units	Not Done	N/A	SSS	Not done

Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units.	holds normal range values for character vars.	Numeric Coded Value	Std. units	Upper/lower end of normal range for continuous measurements in standardized units. Should be populated only for continuous results.
--	---	---------------------	------------	---

Exmpl	--TESTCD	--TEST	--ORRES	--ORRESU	--ORNRLO	--ORNRHI
SN1-EX2	SSS	STD. SWEATY SCALE	NADA	Blank	Blank	Blank
				Derived (Max), so all 3 are blank		

Exmpl	--STRESC	--STNRLO	--STRESN	--STRESU	--STNRLO	--STNRHI
SN1-EX2	No Exertion	“MILD”, “MOD”	0	Metric Sweat Drop	Blank	Blank

Exmpl	--NRIND	--STAT	--REASND	--METHOD	--DRVFL
SN1-EX2	LOW	Blank	Blank	Visual Exam	Y

Indicates where value falls with respect to reference range defined by --ORNRLO and --ORNRHI or by --STNRLO.	Method of the test or examination. Examples: SWAB, NEEDLE PUNCTURE, BRONCHIAL BRUSHING.
--	---

See 4.1.5.1.5 - to 4.1.5.1.7 for examples of derived variables

The SSS is the maximum of two observations. Since everything collected on the CRF should end up in a table, a SSS observation creates three rows of data, with one having --DRVFL = “Y” flagging the derived value.

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A numeric derived value would use logic similar to that above. Sections 4.1.5.1.4 and 4.1.5.1.5 s of the I.G. show examples of derived variables.

This example shows a derived character variable that “NOT DONE”.

“Not done” has a powerful effect on ORRES and the “logical cascade”.

Variables are left blank except for four variables:

TESTCD and TEST.

as well as

STAT and REASND are valued.

Example	Char or Num	Non-std / Std. Units	Test Done Not Done	In /out of Range	Test	Value
SN 1	Char	Std	Test	In Range	SSS	Mod as char - normal
SN 1 Derived	Char	Std Units	Test Done	OUT	SSS	NADA as char - OUT
SN 2 Derived	Char	Std Units	Not Done	N/A	SSS	Not done

↑
This Example

Example	--TESTCD	--TEST	--ORRES	--ORRESU	--ORNRL0	--ORNRI
SN2- EX1	SSS	STD. SWEATY SCALE	Blank	Blank	Blank	Blank

We want to record the “not doneness of the test”

Example	--STRESC	--STNRC	--STRESN	--STRESU	--STNRLO	--STNRHI
SN2-EX1	Blank	Blank	Blank	Blank	Blank	Blank

Note the Powerful effect of “not done”

Example	--NRIND	--STAT	--REASND	--METHOD	--DRVFL
SN2-EX1	Blank	NOT DONE	Subj. In trainer room	Blank	Blank

We record the fact that the test was not done and the reason why.

This example shows a non-derived numeric variable that is in standard units and is “in normal range”.

ORRES is a character variable in all domains and ORRES is valued as “140”.

“140” is copied into LBSTRESC as “140” and LBSTRESN as a numeric 140.

ORRESU and LBSTRESU contain the same value. LBORNRL0 and LBSTNRLO have the same value, as do LBORNRI and LBSTNRHI.

STNRC is only valued if ORRES is character, and so is “Null”.

The reading is “NORMAL” and that is recorded in LBNRIND.

Example	Char or Num	Non-std / Std. Units	Test Done Not Done	In /out of Range	Test	Value
SN 12 on CRF	Char	Non-std	Not Done	N/A	CRYSTALS	Not done
SN 13 on CRF	Num	Std. Units	Test Done	In Range	HGB	140 =std & IN
SN 15 on CRF	Num	Non-std	Test Done	OUT	TBILI	1.5 Non-std units and OUT

↑
This Example

Example	--TESTCD	--TEST	--ORRES	--ORRESU	--ORNRL0	--ORNRI
SN13- EX1	HGB	HEMOGLOBIN	140	g/L	120	160

Recorded in Std Units

Example	--STRESC	--STNRC	--STRESN	--STRESU	--STNRLO	--STNRHI
SN13- EX1	140	Blank	140	g/L	120	160

Example	--NRIND	--STAT	--REASND	--METHOD	--DRVFL
SN13- EX1	NORMAL	Blank	Blank	Blank	Blank

Method of the test or examination. Examples: SWAB, NEEDLE PUNCTURE, BRONCHIAL BRUSHING. (Here not collected on CRF)

STAT and REASND are blank. Method is “Null” and a “Null” in LBNRIND indicates that the value of ORRES is not derived.

This example shows a non-derived numeric variable that is in non-standard units and is “out of normal range”.

ORRES is a character variable in all domains and ORRES is valued as character “1.5”.

That “1.5” i(n “mg/dL”) is converted into SI and the resulting 26.65 is copied into LBSTRESC and LBSTRESN.

ORRESU and LBSTRESU contain different values. LBORNRL0 and LBSTNRLO hold different values, as do LBORNRLHI and LBSTNRHI.

STNRC is only valued if ORRES is character.

The reading is “HIGH” and that is recorded in LBNRIND.

Example	Char or Num	Non-std / Std. Units	Test Done / Not Done	In / out of Range	Test	Value
SN 12 on CRF	Char	Non-std	Not Done	N/A	CRYSTALS	Not done
SN 13 on CRF	Num	Std. Units	Test Done	In Range	HGB	140 =std & IN
SN 15 on CRF	Num	Non-std	Test Done	OUT	TBILI	1.5 Non-std units and OUT

For values that are character or numeric. This is a Character Decode to standard value.		ONLY for normal range values that are character.		Numeric value in standard units (converted by multiplying by 17.1)		This Example
---	--	--	--	--	--	--------------

Example	--TESTCD	--TEST	--ORRES	--ORRESU	--ORNRL0	--ORNRLHI
SN15-EX1	T BILI	TOTAL BILIRUBIN	1.5	mg/dL	0	1.0

Non-Std Units

Upper/lower end of normal range for continuous measurements in Original and standard units. Should be populated only for continuous results.

Example	--STRESC	--STNRC	--STRESN	--STRESU	--STNRLO	--STNRHI
SN15-EX1	26.65	Blank	26.65	μmol/L	0	17.1

Std Units

Example	--NRIND	--STAT	--REASND	--METHOD	--DRVFL
SN15-EX1	HIGH	Blank	Blank	Blank	Blank

Indicates where value falls w/ respect to reference range defined by --ORNRL0 and --ORNRLHI or by --STNRC.

Method of the test or examination. Examples: SWAB, NEEDLE PUNCTURE, BRONCHIAL BRUSHING. (Here not collected on CRF)

STAT and REASND are “Null”. Method is “Null” and a “Null” in LBDRVFL indicates that ORRES is not derived.

As a high level summary, we will review some situations and use color to group/code the variables. Remember the purpose of this paper is to emphasize the logical relationships (the cascade) among these variables. Also remember; our phrasing concerning ORRES is sometimes clumsy. With that as a caveat, it is both common, and awkward, when ORRES holds a number, to say that “ORRES is numeric” even though ORRES is a character variable in all domains.

If ORRES is numeric, we expect the green boxes to be valued and the red boxes to NOT be valued in the graphic to the right

ORRES should be valued as should ORRESU, ORNRL0 and ORNRLHI. After conversion to standard units, --STRESC and STRESN STRESU, STNRLO, STNRHI and NRIND should be valued. METHOD and DRVFL will be valued if appropriate

If --ORRES is character, we expect the green boxes to be valued and the red boxes to NOT be valued in the graphic to the right

The original character value is put in ORRES. The standardized character value is put in STRESC and the explanation of what is “normal” is put in STNRC. NRIND should be valued. METHOD and DRVFL will be valued if appropriate

Numeric						
Example	--TESTCD	-- TEST	--ORRES	--ORRESU	--ORNRL0	--ORNRLHI
Num. Examp.						
Example	--STRESC	--STNRC	--STRESN	--STRESU	--STNRLO	--STNRHI
Num. Examp.						
Example	--NRIND	--STAT	--REASND	--METHOD	--DRVFL	
Num. Examp.						

Character						
Example	--TESTCD	-- TEST	--ORRES	--ORRESU	--ORNRL0	--ORNRLHI
Char. Examp.						
Example	--STRESC	--STNRC	--STRESN	--STRESU	--STNRLO	--STNRHI
Char. Examp.						
Example	--NRIND	--STAT	--REASND	--METHOD	--DRVFL	
Char. Examp.						

STAT and REASND have a powerful effect and, when valued, all other variables except TESTCD and TEST should be “Null”.

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CONCLUSIONS

Five conditions create “states of nature” determining how –ORRES and many other variables are valued. The conditions are:

- 1) Was the –ORRES value derived or copied from a single variable on the CRF.
- 2) Is the –ORRES variable character or numeric
- 3) Were the results recorded in standard units or not (provision must be made for the person doing the recording of values to make a mistake and use improper units (pounds instead of Kilograms etc.)
- 4) Was the test value in the normal range, or not
- 5) Was the test done, or not.

It is helpful to think of the variables below as a related group when doing edit checks of data.

ORRESORRESU	ORRESNRLO	ORRESNRHI		
STRESC	STNRC			
STRESN	STRESU	STRNRLO	STNRHI	NRDIND
STAT	REASND	METHOD	DRVFL	

REFERENCES

CDISC implementation Guide 3.1.2 (for review).

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