Relationships Among - -ORRES and Other CDISC Variables (Part 1 of 3)

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ABSTRACT

Many CDISC variables are related to each other and understanding those relationships helps both programming and QC. This example-based paper concentrates on how changes in the circumstances/characteristics surrounding the collection of the - -ORRES variable (original results) affects other variables in the domain. The CDISC implementation guide gives rules and examples that focus on entering values into specific variables. The contribution of this paper is the study of the relationships among variables.

Several characteristics of the - -ORRES variable start a logical cascade that affects how values are entered in other variables. First, the value to be entered in - -ORRES can be on the CRF or calculated programmatically (derived). Second, the value of interest, - -ORRES, is stored as character in the domain, but may be collected as character or numeric. If the value is collected as numeric, it will need to be programmatically converted to character. Third, the value of - -ORRES can be collected in standard units (SI), or in conventional/US units. Fourth, the measurement that produces the - -ORRES value can be taken or not. Finally, the value collected can be in the range or out of range. These characteristics lead to 32 (2 to the 5th) different states of nature that should be examined in studying the - -ORRES variable and this paper will provide examples for those states of nature. This paper is first in a short series of papers discussing relationships among CDISC variables.

INTRODUCTION

The - -ORRES variable records values of measurements taken and is central to a clinical trial. The characteristics of this variable and circumstances of its measurement affect how values are entered in several related variables. Values in these related variables, eg., unit of measurement or range of normal values, make the value in the - -ORRES variable meaningful in terms of the clinical trial. This paper, using an imaginary study of a freckle remover, uses many examples to explore the different characteristics of - -ORRES and how the characteristics of its collection can affect other variables in the CDISC domains.

The primary endpoint in the study is the reduction in freckles on females. Freckles are counted before and after treatment with the study drug, Fehrer's Freckle Fader, manufactured by the Three F Company. The number of freckles in two 1-inch squares, one on the forehead and one on the shoulder of the subject, are given a number by comparison to the standard freckled folks on the FFS scale below. The higher number, shoulder or forehead, is used as the measured value, defining the Fehrer Freckle Scale and is entered in - -ORRES as a character value.

The characteristics of - -ORRES and its collection that will be explored in this paper are:

- Is - -ORRES on the CRF or was it derived
- Is - -ORRES inherently Character or Numeric
- Is - -ORRES collected in Std Units
- Is the measurement done or not done
- Is the result in the normal range or not

These five characteristics, all binary, give rise to 32 states of nature (two to the fifth equals 32) that must be studied to completely explore the coding of - -ORRES. Since the logic of the Done / Not Done characteristic is so simple, only 16 examples will be presented as Done / Not Done examples, showing how this characteristic affects variable values will be folded in with the examples illustrating other characteristics.

This paper will provide 16 examples of recording - -ORRES and will split the examples into two groups: examples where - -ORRES is derived or programmatically calculated, ie., not recorded on the CRF, and examples where - -ORRES is recorded on the CRF by the investigator and are entered directly from the CRF during data entry.

SAMPLE CRF

To create examples for this paper we used created a data collection process that had derived character and numeric variables, as well as non-derived character and numeric variables. Values of these derived variables are determined programmatically. Two derived scales are uses in this study and must be shown if their use in the examples that follow is to be understood.

The Sunburn Sensitivity Scale is a numeric variable and is the average of two comparisons of skin color (measured where the “sun don’t shine”) to a standard color scale (shown below) after 15 minutes at the tanning salon. This is used as a covariate in statistical analysis.

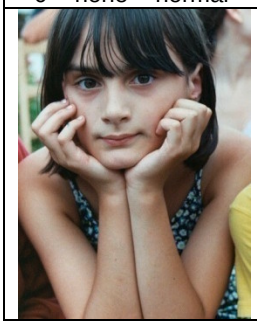
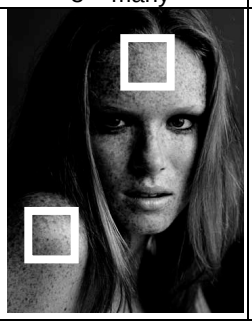
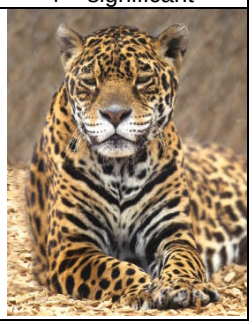
0=Complexion like Peaches and Cream	**1=Stays Pale as a Programmer**	**2=ouch, Ouch, OUCH**	**3=Burns to a *Crisp***	**4=Fries like Bacon-and-Eggs**

Left Cheek Value _____ Right Cheek Value_____

The Fehrer Freckle Scale is used to record a derived variable that is inherently character.

The standard freckled folks who make up the Fehrer Freckle Scale, FFS, are shown below. To implement the FFS, freckling in two places, shoulder and forehead as shown below, is assigned a number by a comparison to the standard freckled folks pictured in the scale. The higher of the two numbers is taken as the FFS value to be entered in - -ORRES. Measurement areas are shown on image for “many”. The difference in the FFS is the primary endpoint. The FFS data are collected in the QS (Questionnaire) Domain.

The Fehrer Freckle Scale of Freckled Folks (derived character variable)

0 = none = normal	1 = few	2 = some	3 = many	4 = significant
				

Record F.F.S. values in spaces to right: Shoulder Area: _____ Forehead Area: _____

Other measurements were recorded on the CRF by the investigator or were collected from lab reports and are entered in the LB (Laboratory) Domain. These variables are not derived and are entered directly from a central laboratory or from a CRF page.

To make the examples easier to read some information about the tests, both laboratory and questionnaire, used in this study is provided below.

Test	**Standard Range (SI)**	**Non-Standard or Conventional (US)**
Sunburn Sensitivity Scale (numeric)	Normal Range 1, Out of Range=2, 3, 4	Normal Range 1, Out of Range=2, 3, 4
Fehrer Freckle Scale (character)	Normal Range 0, Out of Range=2, 3, 4	Normal Range 0, Out of Range=2, 3, 4
BSA	Normal is generally taken as 1.7 m^2 Mosteller formula: kg & cm: =Sqrt((weight*height) / 3600)	Normal is generally taken as 1.7 m^2 Mosteller formula: pounds & inches: =Sqrt((weight*height) / 3125)
BMI	For adults 20 years or older: <18.5 Underweight 18.5 <= 24.9 Normal 25.0 <= 29.9 Overweight >=30.0 Obese =weight (in kg.) / height**2 (in meters)	For adults 20 years or older: <18.5 Underweight 18.5 <= 24.9 Normal 25.0 <= 29.9 Overweight >=30.0 Obese =703 * (weight (in lb.) / height**2 (in inches))
Casts (Urinalysis)	Normal range: 0; Out of range: +, ++, +++	Normal range: 0; Out of range: trace,1, 2

Test	Standard Range (SI)	Non-Standard or Conventional (US)
Crystals (Urinalysis)	Normal range: 0; Out of range: +, ++, +++	Normal range: 0; Out of range: trace,1, 2
Hemoglobin	Men:130-180 g/L Women: 120-160 g/L Conversion US to SI: value *10	Men:13-18 g/dL Women: 12-16 g/dL
Total Bilirubin	μmol/L Conversion US to SI: value * 17.1	1.0 mg/dL

Normally we would create examples for all the states of nature. Studying *all* the states of nature for a problem and providing examples for *all* the states of nature allow us to know we have explored *all* the complexities in the problem. However, the logic associated for test Done / Not Done is so simple, a decision was made not to develop examples for all 32 (2 to the 5th) states of nature. Examples for Done / Not Done were folded into the examples for the other variables and 16 examples have been created and discussed. The examples where the test was done are bolded in the table below. It is suggested that these examples are more complex and more worth studying than the examples where the test was not done.

	State of Nature	Derived or on CRF	Character or Numeric	Standard Units or Not	Test Done or Not Done	In Range or Not
	1	Derived	Char	Std.	Done	Yes
	2	Derived	Char	Std.	Not Done	N/A
	3	Derived	Char	Non-Std.	Done	No
	4	Derived	Char	Non-Std.	Not Done	N/A
	5	Derived	Num	Std.	Done	Yes
	6	Derived	Num	Std.	Not Done	N/A
	7	Derived	Num	Non-Std.	Done	No
	8	Derived	Num	Non-Std.	Not Done	N/A
	9	On CRF	Char	Std.	Done	Yes
	10	On CRF	Char	Std.	Not Done	N/A
	11	On CRF	Char	Non-Std.	Done	No
	12	On CRF	Char	Non-Std.	Not Done	N/A
	13	On CRF	Num	Std.	Done	Yes
	14	On CRF	Num	Std.	Not Done	N/A
	15	On CRF	Num	Non-Std.	Done	No
	16	On CRF	Num	Non-Std.	Not Done	N/A

The main deliverable of the paper is to lay out most of the possible combinations and all of the interesting possible combinations of characteristics surrounding the collection of the - -ORRES variable and to comment on how the data were recorded.

Examples for states of nature 1 to 8, derived or programmatically calculated variables, are shown in Example 1 through Example 9. To make the characteristics of the problem clear, this section has multiple examples for the first state of nature. Accordingly, the state of nature number will differ from the example number. The state of nature, example number, and characteristics of the state of nature being investigates are summarized in the table below.

State of Nature – Example #	Character or Numeric	Standard Units or Not	Test Done or Not Done	In Range or Not	Test	Value (std or non-std units, in range or out of range)
SN1–Ex1	**Char**	**Std.**	**Done**	**Yes**	**Sunburn Sensitivity Scale**	**0 - in range**
SN1–Ex2	**Char**	**Std.**	**Done**	**No**	**Sunburn**	**4 (Fries like**

State of Nature – Example #	Character or Numeric	Standard Units or Not	Test Done or Not Done	In Range or Not	Test	Value (std or non-std units, in range or out of range)
					Sensitivity Scale	**Bacon and Eggs) - out of range**
SN2-Ex3	Char	Std.	Not Done	N/A	Sunburn Sensitivity Scale	N/A
SN3-Ex4	**Char**	**Non-Std**	**Done**	**No**	**Fehrer Freckle Scale**	**3 (Many), Forehead - out of range**
SN4-Ex5	Char	Non-Std	Not Done	N/A	Fehrer Freckle Scale	N/A
SN5-Ex6	**Num**	**Std.**	**Done**	**Yes**	**BSA**	**1.6m**2 – Low Value**
SN6-Ex7	Num	Std.	Not Done	N/A	BSA	N/A
SN7-Ex8	**Num**	**Non-Std**	**Done**	**No**	**BMI**	**30.1 – out of range**
SN8-Ex9	Num	Non-Std	Not Done	N/A	BMI	N/A

Values coded into the variables in the CDISC questionnaire domain are shown below. Since so many variables are related to - -ORRES, the table wraps three times. Endnotes link to comments below the table explain the reasons for why the variable was coded as it was.

State of Nature - Example #	Character or Numeric	Standard Units or Not	Done / Not Done	In Range or Not	Test	Value	Location
SN1–Ex1	**Char**	**Yes**	**Yes**	**Yes**	**Sunburn Sensitivity Scale**	**0**	**Derriere (L & R)**
SN1–Ex2	**Char**	**Yes**	**Yes**	**No**	**Sunburn Sensitivity Scale**	**4**	**Derriere (L & R)**
SN2-Ex3	Char	Yes	No	N/A	Sunburn Sensitivity Scale	N/A	N/A
SN3-Ex4	**Char**	**No**	**Yes**	**No**	**Fehrer Freckle Scale**	**3**	**Forehead / Left Shoulder**
SN4-Ex5	Char	No	No	N/A	Fehrer Freckle Scale	N/A	N/A
SN5-Ex6	**Num**	**Yes**	**Yes**	**Yes**	**BSA**	**1.6m**2**	N/A
SN6-Ex7	Num	Yes	No	N/A	BSA	N/A	N/A
SN7-Ex8	**Num**	**No**	**Yes**	**No**	**BMI**	**30.1**	N/A
SN8-Ex9	Num	No	No	N/A	BMI	N/A	N/A

Variables coded in CDISC domain (continued)

State of Nature - Example #	--TESTCD	--TEST	--ORRES	--ORRESU	--STRESC	--STRESN	--STRESU
SN1–Ex1	**SSS**	**Sunburn Sensitivity Scale**	***leave blank*[a]**	***leave blank*[b]**	**Complexion like Peaches-and-Cream[c]**	**0[d]**	**Degree of redness**

State of Nature - Example #	--TESTCD	--TEST	--ORRES	--ORRESU	--STRESC	--STRESN	--STRESU
SN1–Ex2	**SSS**	**Sunburn Sensitivity Scale**	***leave blank***[a]	***leave blank***[b]	**Fries like Bacon And Eggs**[c]	**4**[d]	**Degree of redness**
SN2-Ex3	SSS	Sunburn Sensitivity Scale	*leave blank*[a]	*leave blank*[b]	*leave blank*[e]	*leave blank*[f]	*leave blank*[g]
SN3-Ex4	**FFS**	**Fehrer Freckle Scale**	***leave blank***[a]	***leave blank***[b]	**Many**[h]	**3**[i]	**Sommer-sprosse**
SN4-Ex5	FFS	Fehrer Freckle Scale	*leave blank*[a]	*leave blank*[b]	*leave blank*[e]	*leave blank*[f]	*leave blank*[g]
SN5-Ex6	**BSA**	**Body Surface Area**	***leave blank***[a]	***leave blank***[b]	**1.6**[j]	**1.6**[k]	**m**2**
SN6-Ex7	BSA	Body Surface Area	*leave blank*[a]	*Leave blank*[b]	*leave blank*[e]	*leave blank*[f]	*leave blank*[g]
SN7-Ex8	**BMI**	**Body Mass Index**	***leave blank***[a]	***leave blank***[b]	**30.1**[j]	**30.1**[k]	***leave blank***[l]
SN8-Ex9	BMI	Body Mass Index	*leave blank*[a]	*leave blank*[b]	*leave blank*[e]	*leave blank*[f]	*leave blank*[g]

Variables coded in CDISC domain (continued)

State of Nature - Example #	--STAT	--REASND	--LOC	--DRVFL
SN1–Ex1	***leave blank***[m]	***leave blank***[n]	**Derriere (L & R)**	**Y**
SN1–Ex2	***leave blank***[m]	***leave blank***[n]	**Derriere (L & R)**	**Y**
SN2-Ex3	NOT DONE	Pt was on vacation in the Bahamas	*leave blank*[o]	*leave blank*
SN3- Ex4	***leave blank***[m]	***leave blank***[n]	**L Shoulder / Forehead**	**Y**
SN4- Ex5	NOT DONE	Pt won lottery	*leave blank*[o]	*leave blank*[q]
SN5-Ex6	***leave blank***[m]	***leave blank***[n]	***leave blank***[p]	**Y**
SN6-Ex7	NOT DONE	Weight not taken	*leave blank*[o]	*leave blank*[q]
SN7- Ex8	***leave blank***[m]	***leave blank***[n]	***leave blank***[o]	**Y**
SN8- Ex9	NOT DONE	Just did not show up	*leave blank*[o]	*leave blank*[q]

[a] Data element is derived so - -ORRES is left blank
[b] Data element is derived so - -ORRESU is left blank
[c] Character decode of number to right
[d] Collected as numeric
[e] Test is not done so - -STRESC is left blank (character representation of standard value)
[f] Test is not done so - -STRESN is left blank (numeric representation of standard value)
[g] Test is not done so - -STRESU is left blank (standard unit)
[h] Collected as character
[i] Numeric decode of character variable to the left
[j] Character representation of derived variable based on numeric values of height and weight
[k] Numeric representation of derived variable based on numeric values of height and weight
[l] Standard units are blank
[m] Test was done, so - -STAT (done or not done) is left blank

[n] Test was done, so - -REASND (reason why test not done) is left blank
[o] Test was not done so - -LOC is left blank (location of test)
[p] - -LOC is not part of test so it is left blank
[q] Test is not done so - -DRVFL (derived flag) is left blank

Examples for states of nature 9 to 16, are for variables on the CRF, and are shown in examples 9 through 16. The following examples are for variables that are recorded on the CRF or on a lab report. The state of nature, example number, and characteristics of the state of nature being investigated are summarized in the table below.

State of Nature Example #	**Character or Numeric**	**Standard Units or Not**	**Test Done-/ Not Done**	**In Range or Not**	**Test**	**Value (std or non-std units: in range or not in range)**
SN9 –EX10	**Char**	**Std.**	**Done**	**Yes**	**Casts**	**0 - std & in range**
SN10- Ex11	Char	Std.	Not Done	N/A	Casts	N/A
SN11- Ex12	**Char**	**Non-Std**	**Done**	**No**	**Crystals**	**Trace - non-std & out of range**
SN12- Ex13	Char	Non-Std	Not Done	N/A	Crystals	N/A
SN13- Ex14	**Num**	**Std.**	**Done**	**Yes**	**Hemoglobin**	**140 - std & in range**
SN14- Ex15	Num	Std.	Not Done	N/A	Hemoglobin	N/A
SN15- EX16	**Num**	**Non-std**	**Done**	**No**	**Total Bilirubin**	**1.5 - non-std & out of range**
SN16- EX17	Num	Non-std	Not Done	N/A	Total Bilirubin	N/A

Values coded into the variables in the CDISC LB Domain are show below. Since so many variables are related to - -ORRES, the table word-wraps twice. Letters in parenthesis link to sentences below the table that comment on the reasons for why the variable was coded as it was.

State of Nature Example #	**--TESTCD**	**--TEST**	**--ORRES**	**--ORRESU**	**--STRESC**
SN9 –EX10	**CASTS**	**CASTS/LPF**	**0[a]**	***leave blank[b]***	**0[c]**
SN10-Ex11	CASTS	CASTS/LPF	*leave blank[d]*	*leave blank[bd]*	*leave blank[d]*
SN11-Ex12	**CRYSTALS**	**CRYSTALS/HPF**	**TRACE[e]**	***leave blank[b]***	**+[f]**
SN12-Ex13	CRYSTALS	CRYSTALS/HPF	*leave blank[d]*	*leave blank[bd]*	*leave blank[d]*
SN13-Ex14	**HGB**	**HEMOGLOBIN**	**140[g]**	**g/L[h]**	**140[i]**
SN14-Ex15	HGB	HEMOGLOBIN	*leave blank[d]*	*leave blank[d]*	*leave blank[d]*
SN15-EX16	**TBILI**	**TOTAL BILIRUBIN**	**1.5[j]**	**mg/dL[k]**	**25.65[l]**
SN16-EX17	TBILI	TOTAL BILIRUBIN	*leave blank[d]*	*leave blank[d]*	*leave blank[d]*

Variables coded in CDISC domain (continued)

State of Nature Example #	**--STRESN**	**--STRESU**	**--STNRLO**	**--STNRHI**	**--STNRC**
SN9 -EX10	***leave blank[m]***	***leave blank[n]***	***leave blank[o]***	***leave blank[o]***	**0[p]**
SN10-Ex11	*leave blank[dm]*	*leave blank[dn]*	*leave blank[o]*	*leave blank[o]*	*leave blank[d]*

State of Nature Example #	--STRESN	--STRESU	--STNRLO	--STNRHI	--STNRC
SN11-Ex12	***leave blank***[m]	***leave blank***[n]	***leave blank***[o]	***leave blank***[o]	**0**[p]
SN12-Ex13	*leave blank*[dm]	*leave blank*[dn]	*leave blank*[o]	*leave blank*[o]	*leave blank*[d]
SN13-Ex14	**140**[q]	**g/L**[r]	**120**[s]	**160**[s]	***leave blank***[t]
SN14-Ex15	*leave blank*[d]	*leave blank*[d]	*leave blank*[d]	*leave blank*[d]	*leave blank*[d]
SN15-EX16	**25.65**[u]	**μmol/L**[v]	**0**[w]	**17.1**[x]	***leave blank***[t]
SN16-EX17	*leave blank*[d]	*leave blank*[d]	*leave blank*[d]	*leave blank*[d]	*leave blank*[d]

Variables coded in CDISC domain (continued)

State of Nature Example #	--NRIND	--STAT	--REASND	--METHOD	--DRVFL
SN9 -EX10	***leave blank***[y]	***leave blank***[d]	***leave blank***[d]	**MIDSTREAM CATCH**[z]	***leave blank***[aa]
SN10-Ex11	*leave blank*[d]	NOT DONE[d]	VACATION[d]	*leave blank*[d]	*leave blank*[aa]
SN11-Ex12	**HIGH** [bb]	***leave blank***[d]	***leave blank***[d]	**MIDSTREAM CATCH**[z]	***leave blank***[aa]
SN12-Ex13	*leave blank*[d]	NOT DONE[d]	REFUSED[d]	*leave blank*[d]	*leave blank*[aa]
SN13-Ex14	***leave blank***[y]	***leave blank***[d]	***leave blank***[d]	***leave blank***[dd]	***leave blank***[aa]
SN14-Ex15	*leave blank*[d]	NOT DONE[d]	VACATION[d]	*leave blank*[d]	*leave blank*[aa]
SN15-EX16	**HIGH**[cc]	***leave blank***[d]	***leave blank***[d]	***leave blank***[dd]	***leave blank***[aa]
SN16-EX17	*leave blank*[d]	NOT DONE[d]	BUSINESS TRIP[d]	*leave blank*[d]	*leave blank*[aa]

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[a] Casts is character with allowed values of 0 (normal), +, ++, +++ . Just because the normal value is zero, do not think this is numeric. These data are generally collected on the CRF or central laboratory transfer.
[b] Casts and Crystals have no units so this variable is blank.
[c] The standard result in character format is a character 0.
[d] If the test was not done, there is no reading to be recorded. If the test was not done - -ORRES will not be valued and it will create a logic cascade that causes many variables associated with this observation to be left blank. Status is left blank if the test was done and has a value of "NOT DONE" if the test was not done. If the test was done - -REASND (reason not done) is blank. - -REASND contains the reason for not doing the test, if the test was not done (eg., equipment failure).
[e] CRYSTALS/HPF is character with standard values of 0 (normal), +, ++, +++. Just because the normal value is 0, do not think this is numeric. Here we illustrate a reading that is both non-standard and out of range. The string TRACE is not one of the standard values for recording this test.
[f] This variable holds - -ORRES recorded in the standard way of representing values. The values of 0, Trace, 1, and 2 in - -ORRES are not standard and must be converted to 0, +, ++ and +++ to be recorded in - -STRESC.
[g] This is a numeric variable taken from the CRF and so it has a value in - -ORRES. The value recorded in - -ORRES is in standard units and will be in range.
[h] The unit of the - -ORRES is g/L.
[i] - -ORRES was collected in standard units and we do not have to apply a conversion. This example shows - -ORRES in a character format.
[j] This is a numeric variable and it has a value in - -ORRES. The value is in non-standard units and will be out of range.
[k] The standard unit for this test is μmol/L. Data are often recorded in mg/dL and the conversion factor from mg/dL to standard units is 17.1.
[l] This is the value of the test after converting twice. First - -ORRES is multiplied by 17.1 to convert it to standard units and then the value of 26.65 is converted into character format.
[m] There are no calculations to be done with this value. Casts and Crystals are character and we will not record a numeric zero. While the recorded value of zero looks as if it could be numeric and might be recorded here, it is obvious that a value of ++ could not be converted into a numeric value.
[n] Again, Casts and Crystals do not have units. They do not have units in the "recorded unit" variable or the "standard unit" variables.

[o] The variables - -STNRLO and - -STNRHI are for use with numeric values. If the variable is numeric, the lower and upper values for the standard range are recorded in these variables.
[p] The Standard Normal Range for a character variable is the list of character strings that are acceptable as a describing a normal reading. Sometimes several words can be used to describe a normal reading and the investigator has a choice of the word to use. Examples of synonyms to describe a liquid might be: “Clean”, “Clear”, “Not-Cloudy”, “Un-Clouded”,”Transparent”, et al.
[q] - -ORRES was collected in standard units and we do not have to apply a conversion. This example shows - -ORRES in a numeric format.
[r] This value is the standard unit for the test.
[s] These two variables contain the lower and upper limits for the numerically recorded tests in standard units.
[t] In this case we leave the variable - -STNRC blank because we have a numeric variable. - -STNRC is used to record the list of strings that are considered normal for a character value test.
[u] This is the value of - -ORRES after multiplying by 17.1, stored in a numeric format. The value of - -ORRES has been converted by multiplying by 17.1 but has been left in a numeric format.
[v] This variable contains the standard unit for the test.
[w] The lowest normal value in standard units for this test is zero.
[x] The highest normal value in standard units for this test is 17.1.
[y] Since the reading is in the normal range, this variable is left blank.
[z] Values of this variable describe how the test was done. Midstream Catch is a way to collect a urine sample.
[aa] This variable has the value of “Y” if the - -ORRES value was derived. In the examples in this section, all the - -ORRES values are on the CRF.
[bb] This reading is out of the normal range and is on the high side.
[cc] The collected value is out of the normal range on the high side. It is suggested that calculating if a value is in or out of range be calculated with - -ORRES and not the standard values. This avoids the admittedly rarely encountered problem that rounding can cause a standard value to be out of range when the - -ORRES value is in range.
[dd] The method of collecting blood is a puncture. It is very common and has few options. Because there is no need to tell researchers the details of this common process and slight variations in the collection process are very unlikely to affect the outcome, it need not be described.

SUMMARY

We feel that it is difficult to create rules for coding data without considering conditions under which the data were collected. The contribution of this paper is to establish the conditions under which the data were collected and creating rules for each condition. Despite our hesitance to give simple rules, we include some rules to collect - -ORRES. We believe complete understanding is best created by studying the rules and examples of both.

Variables in the CDISC domains are related and - -ORRES has one of the most complicated series of relationships. This paper is the first in the series to illustrate relationships among CDISC variables. We hope that the level of detail provided is useful.

One way to analyze the complexity of the - -ORRES variable is to determine the states of nature, the characteristics of how the data are collected. Important characteristics of how the data are collected are:

1) Derived or on CRF
2) Character or Numeric
3) Standard Units or Not
4) Test Done or Not Done
5) In range or Not

While there is a need to study the situation surrounding the collection of the - -ORRES variable before valuing it, there are some general rules that can be abstracted for - -ORRES.

- -ORRES is an expected variable and should always be populated except in two situations:

1) when the - -ORRES value is derived by the sponsor
2) when the test is not done and there is no value to record.

Derived variables can be complex and take values from one visit or several visits. If the variable is derived by the sponsor, - -ORRES is blank and a derived flag (- -DVFL) is raised. When the value is derived from more than one visit or over time the value of VISITNUM should have the correct time sequence and the logic for “correctness” is left to the sponsor.

When - -ORRES has a value, the variable - -STRESC must have a value regardless if the value in - -ORRES is character or numeric. The value in - -ORRES is converted to standard units and the result is stored in - -STRESC. If the standard value is converted to a numeric value that value must be stored in - -STRESN.

Sometimes the acceptable values of - -ORRES are printed in code on the CRF and the decoded value is entered in - -ORRES as in our study. If the code values are statistically significant, as they might be if they come from a validated scale. - -ORRES may contain the decode and - -STRESC and - -STRESN may contain scores.

If the recorded value contains a mixture of character and numeric values (<100) the sponsor has the job of creating a logically consistent method for converting the value. In the case of a "<" , one procedure might be to subtract a value (100-10) or to multiply the value by a number (100*.9). The sponsor should use the same logic in all studies.

REFERENCES

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