Findings About: De-mystifying the When and How

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ABSTRACT

CDISC offers Findings About (FA) and Supplemental Qualifiers (SuppQual) to handle information that doesn't fit into standard domains – or 'Non-standard variables'. They are however, quite distinct from each other and the appropriate use for each may still lead to confusion.

"When should FA be created?" or "When is it best to use SUPPQUAL?" These are important questions that can only be answered by asking additional data questions. When the data does not fit into the parent domain, it may only be mapped to SUPPQUAL if it relates to one parent record. However, almost all other situations are covered by FA – wherein data relates to multiple records, or when a two-way relationship is needed etc.   FA would be the right approach then, because it has versatility beyond what's offered by SUPPQUAL.   For example, FA would provide a way of storing symptoms along with the time that they began and relating each back to the AETERM in the AE dataset.

In addition, FA as a stand-alone domain is also the only place to store information surrounding an event or intervention that has not been captured within any specific domain. This paper will present examples from a few different therapeutic areas or domain relationships to highlight the proper use of FA.   Another scenario will look into hoe FA accommodates a many to many relationship. Such examples should clarify mysteries surrounding when and how to best use or create FA.

INTRODUCTION

Findings About (FA) is a CDISC SDTM domain that has great utility but has been misunderstood and under-utilized. FA is used to capture findings related to an event or intervention that cannot be represented in an event / intervention domain or within SuppQual. Prior to the introduction of FA, SuppQual remained the only domain dedicated to storing non-standard variables. This paper will present examples of using FA to address different challenges posed by data.

EXAMPLE 1. CREATING SUPPQUAL FOR A NON-STANDARD VARIABLE

How do you decide if your situation calls for SuppQual or Findings About? Let's look at a study with an adverse event collected for the dreaded Standard Aversion.

Verbatim Term	Standards Aversion
Start Date:	3/12/2019
End Date:	6/19/2019
Severity	Severe
outcome	Recovered

Relation to Implementation Guide	Possibly related
Action taken	Dose increased

STUDYID	USUBJID	AETERM	AESTDTC	AEENDTC	AESEV	AEOUT	AEREL	AEACN
Phama123	101	Standards Aversion	2019-03-12	2019-06-19	Severe	Recovered	Not related	Dose increased

So far, this is a standard example of our Standards Aversion AE. Now let us collect another piece of information. Since sleep deprivation is known to contribute to stress and irritability, maybe it plays a factor in standards aversion. Let's add an item to our CRF.

Verbatim Term	Standards Aversion
Start Date:	3/12/2019
End Date:	3/13/2019
Severity	Severe
outcome	Recovered
Relation to Implementation Guide	Possibly related
Action taken	Dose increased
Was subject sleep deprived?	Yes

Where would be put this in the AE domain? It is not a standard variable. Our first choice would be SuppQual. Let's see how that would look:

STUDYID	SUBJID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLQBEL	QVAL	QORIG	QEVAL
Pharma123	101	AE	AESEQ	1	SLPDP	Sleep deprived	Yes	CRF	

EXAMPLE 2. CREATING FA FOR A VARIABLE WITH A QUALIFIER

So far, so good. Let's keep going. We can probe this sleep deprivation further. How much sleep did the subject get the night before:

Verbatim Term	Standards Aversion	
Start Date:	3/12/2019	
End Date:	6/19/2019	
Severity	Severe	
outcome	Recovered	
Relation to Implementation Guide	Possibly related	
Action taken	Dose increased	
How much sleep did the subject get the night before onset?	Amount(3.5)	Units (Hrs)

The additional information has 2 parts: the amount and units. Let's map this to SUPPAE below:

STUDYID	SUBJID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLQBEL	QVAL	QORIG	QEVAL
Pharma123	101	AE	AESEQ	1	SLPAMT	Sleep amount	3.5	CRF	
Pharma123	101	AE	AESEQ	1	SLPAMTU	Sleep Amount unit	Hrs	CRF	

This looks OK, but let's give it more thought. We now have two SuppQual records: one for the amount of sleep; the other, the unit of this amount. Both rows are related to the parent record in the parent AE domain but how do these records relate to each other? They do not, and this is a problem. The unit variable is on the same row on the CRF page for a reason: it qualifies the result. We know that the subject got 3.5 hours of sleep, not 3.5 minute or 3.5 days. So how can we map this variable and it's qualifier and preserve the relationship? Let's see what this looks like when it is mapped to Findings About (FA):

STUDYID	USUBJID	FAOBJ	FATESTCD	FATEST	FAORRES	FAORRESU
Pharma123	101	Standards aversion	SLPAMT	Sleep amount	3.5	Hrs

Since FA is a findings domain, it contains a unit variable – FAORRESU - that qualifies the original result. The structure of FA should look familiar: it has the typical findings domain structure with one variable that is a bit more mysterious. Now you might wonder – "how should I use FAOBJ"? Notice that the more familiar FATEST / FATESTCD describe the measurement or evaluation - in this case, it's the 'Amount of sleep'. FAOBJ, on the other hand, describes what this measurement or evaluation is related to, or the 'object of the measurement'. Here, it is the AETERM 'Standards aversion' – as is typically the case for 'findings about an event'. FAOBJ takes the value of --TERM or, in the case of coded variables, --DECOD from the parent domain when conveying additional information about an event – as we are

doing here. Since both FATEST/FATESTCD and FAOBJ are needed to fully describe the topic of the record, they are both 'required' in FA.

EXAMPLE 3. CREATING FA FOR SYMPTOMS OF AN ADVERSE EVENT THAT HAVE TIMING THAT DIFFERS FROM THE ADVERSE EVENT.

Let's add to our CRF and actually collect information about individual symptoms experienced during this adverse event:

Symptom	No	Yes	Start
Spinning head		x	3/12/2019 01:05
Irritability		X	3/12/2019 13:30
Shaking like a leaf	X		
Nausea	X		
headache	X		
phobophobia		X	3/12/2019 12:00

Now each symptom assessed for this episode of standards aversion has its own timing that is differs from the date time captured for the overall adverse event. This would make SuppQual a poor choice. FA can easily convey the individual symptoms and their timing.

Row	STUDYID	USUBJID	FACAT	FAOBJ	FATESTCD	FATEST
1	Pharma123	101	Standards Aversion Symptoms	Spinning head	OCCUR	Occurrence
2	Pharma123	101	Standards Aversion Symptoms	Irritability	OCCUR	Occurrence
3	Pharma123	101	Standards Aversion Symptoms	Shaking like a leaf	OCCUR	Occurrence
4	Pharma123	101	Standards Aversion Symptoms	Nausea	OCCUR	Occurrence
5	Pharma123	101	Standards Aversion Symptoms	headache	OCCUR	Occurrence
6	Pharma123	101	Standards Aversion Symptoms	phobophobia	OCCUR	Occurrence

Table contd…

Row	FAORRES	FASTRESC	FADTC
1(cont)	Y	Y	2019-03-12:T01:05:00
2(cont)	Y	Y	2019-03-12:T13:30:00
3(cont)	N	N	
4(cont)	N	N	

5(cont)	N	N	
6(cont)	Y	Y	2019-03-12:T12:00:00

EXAMPLE 4. CREATING FA FOR A PRE-SPECIFIED AE THAT MAY NEVER OCCUR.

What if we decided that the last 3 symptoms, headache, nausea and phobophobia, were actually separate AEs? We are still interested in them because that are common with those predisposed to standards aversion so we specifically ask about them on the CRF. We collect all the information needed for an adverse even such as start date and stop date but here we will just show the events, whether or not they occurred and the severity for each one.

Adverse Event	No	Yes	Severity
Nausea	X		
headache	X		
phobophobia		X	Severe

We can modify our CRF to collect information about these adverse events of interest.

ADVERSE EVENT	
Nausea	N
Start Date:	
End Date:	
Severity	
outcome	
Relation to Implementation Guide	
Action taken	
headache	N
Start Date:	
End Date:	
Severity	
outcome	
Relation to Implementation Guide	
Action taken	
phobophobia	Y
Start Date:	3/12/2019
End Date:	3/13/2019
Severity	Severe
outcome	Recovered
Relation to Implementation Guide	Possibly related
Action taken	Dose increased

Now we are ready to map this page to our AE domain. It seems straightforward. AE even has a variable, 'AEPRESP {Pre-Specified Adverse Event} that distinguishes these specified adverse events from others. But let's look at this closer. AE can only contains records for adverse events that have occurred. Therefore, AE can only accommodate the last record for the occurrence of phobophobia. What about 'nausea' and 'headache'? Neither AE occurred. We need FA. FA will store all the pre-specified AEs and their occurrence. AE will contain only the adverse event, phobophobia, which actually occurred:

STUDYID	USUBJID	FAOBJ	FATESTCD	FATEST	FAORRES
Pharma123	101	Nausea	OCCUR	Occurrence	N
Pharma123	101	Headache	OCCUR	Occurrence	N
Pharma123	101	Phobophobia	OCCUR	Occurrence	Y

Row	STUDYID	USUBJID	AETERM	AESEV	AEACN	AEREL
1	Phama123	101	Phobophobia	Severe	Dose increased	Possibly related

Row	AEOUT	AESTDTC	AEENDTC
1(cont)	Recovered	3-12-2019	6-19-2019

The response to all 3 pre-specified events are captured in FA. Only the event that occurred, however, is also entered into AE.

EXAMPLE 5: CREATING FA FOR A MANY TO MANY RELATIONSHIP BETWEEN A CLINICAL EVENT AND IT'S DETAILS

Here is an example from a cardiovascular study that collected events categorized as clinical events. The Clinical Events (CE) domain contains 3 clinical events: venous thrombosis, deep vein thrombosis and arterial thrombosis. For each event, we have 4 rows of additional details for each event. These details relate to each other for a specific clinical event. If you look at the details in FA for any event in CE you will see that all the rows in FA for that event are needed to convey that a symptom was present, what the symptom was as well as the method used for diagnosis. All 4 FA records then relate back to the event event in CE.

CETERM	CEDECOD	CECAT	CESPID	CEPRESP	CEOCCUR	CESTDTC	CEENDTC
Venous thrombosis	Venous thrombosis	THROMBOSIS	AB1	Y	Y	2019-04-26	2019-04-27
Deep vein thrombosis	Deep vein thrombosis	THROMBOSIS	AB2	Y	Y	2019-04-27	2019-04-28
Arterial thrombosis	Arterial thrombosis	THROMBOSIS	AB3	Y	Y	2019-04-28	2019-04-29

FAOBJ	FACAT	FATESTCD	FATEST	FAORRES	FASTRESC	FADTC
Venous thrombosis	THROMBOSIS	SYMPME	Symptomatic medical event	Y	Y	2019-04-26

Venous thrombosis	THROMBOSIS	CLNSGSYM	Clinical Signs / Symptoms	Swelling	Swelling	2019-04-26
Venous thrombosis	THROMBOSIS	DIAGMETH	Method of diagnosis	Ultrasound	Ultrasound	2019-04-26
Venous thrombosis	THROMBOSIS	CATHREL	Thrombosis Catheter Related	Y	Y	2019-04-26
Deep vein thrombosis	THROMBOSIS	SYMPME	Symptomatic medical event	Y	Y	2019-04-27
Deep vein thrombosis	THROMBOSIS	CLNSGSYM	Clinical Signs / Symptoms	Tenderness	Tenderness	2019-04-27
Deep vein thrombosis	THROMBOSIS	DIAGMETH	Method of diagnosis	MRI	MRI	2019-04-27
Deep vein thrombosis	THROMBOSIS	CATHREL	Thrombosis Catheter Related	Y	Y	2019-04-27
Arterial thrombosis	THROMBOSIS	SYMPME	Symptomatic medical event	Y	Y	2019-04-27
Arterial thrombosis	THROMBOSIS	CLNSGSYM	Clinical Signs / Symptoms	Erythema	Erythema	2019-04-28
Arterial thrombosis	THROMBOSIS	DIAGMETH	Method of diagnosis	CT scan	CT scan	2019-04-28
Arterial thrombosis	THROMBOSIS	CATHREL	Thrombosis Catheter Related	Y	Y	2019-04-28

EXAMPLE 6: CREATING FA FOR FINDINGS OBTAINED FROM A PROCEDURE.

In this example we collect information on the findings of a vascular ultrasound procedure. The Procedure (PR) domain collects information about the procedure: the name of the procedure (PRTRTP, the category (ultrasound), a subcategory (Doppler), that it was pre-specified on the CRF (PRPRESP), that it occurred (PROCCUR), the anatomical location that the procedure was performed on (PRLOC) as well as the start date of the procedure (PRSTDTC). The findings obtained from this procedure, however, do not fit into the PR domain. The finding is a measurement that consists of both a result and unit.

Findings about the Procedure" (FAPR) are being recorded in this CRF about Ultrasound:

PRTRT	PRCAT	PRSCAT	PRPRESP	PROCCUR	PRLOC	PRSTDTC
Vascular Ultrasound	Ultrasound	Doppler	Y	Y	Artery	2019-404-26

FATEST	FATESTCD	FACAT	FAOBJ	FAORRES	FAORRESU	FADTC
Vascular function parameter	VASFUNPM	Ultrasound	Vascular Ultrasound	23	mm	2019-04-26

EXAMPLE 7: CREATING FA FOR STUDY DRUG DOSING DETAILS AND A SUPPQUAL FOR BOTH EC AND FA

This example is for a study of a drug used for post-surgical pain management. Below are data collected during the administration of study drug during the surgical procedure. Exposure as Collected (EC) contains information about the administration of study drug. Here, 2 types of variables that are not within the scope of EC. The item 'Planned dose fully administered?' is a non-standard variable that does not fit into EC. Where should it go? It does not have it's own qualifiers. It relates to only the record that captures the information for that administration of study drug. In this case, SuppQual is the correct choice. Now we also have information concerning the surgery and complications that may have occurred during that surgery. One piece of information is a measurement with a unit. SuppQual would not be helpful here. FA is the way to go. The information about complications that we map to FA also has an additional piece of information asking us to specify the complication. This is an example of a non-standard variable within FA. Yes, FA can have non-standard variables that we put into SuppQual. In this example, we have a SuppQual for EC for a relationship between one record and a non-standard variable as well as fields mapped to Findings About (FA) to convey information related to EC that has it's own qualifiers and a further relationship within FA that needs an FA SuppQual.

Study Drug Administration CRF for a post-surgery pain medication which collects more findings related to the surgical site:

ECTRT	ECCAT	ECECESP	ECOCCUR	ECMOOD	ECDOSE	ECDOSU	ECSTDTC
ABC123	Study Drug	Y	Y	PERFORMED	30	mL	2019-04-26

RDOMAIN	QNAM	QLABEL	QVAL	QORIG	QEVAL
EC	PLDSFUAD	Planned Dose Fully Administered	Y	CRF	

FAOBJ	FACAT	FATEST	FATESTCD	FAORRES	FAORRESU	FADTC
Wound site	Study Drug	Length	LENGTH	5	cm	2019-04-26
Wound closure	Study Drug	Complications	COMPLCTN	Y		2019-04-26

RDOMAIN	QNAM	QLABEL	QVAL	QORIG	QEVAL
FA	COMPSPC	Complications, Specify	Infection	CRF	

CONCLUSION

You should now have a better idea of when to use SuppQual and when to create FA.   Both are powerful tools but the situation determines which domain is best. A road becomes more familiar, the more often you travel it. We encourage you to consider our guidelines when deciding where to put variables. Additional resources are the CDISC SDTM Implementation Guide as well as the CDISC website that offers on-line courses on topics including an introduction to Findings About.

REFERENCES

SDTM Version 1.4 and SDTMIG Version 3.2

CONTACT INFORMATION

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