**Experience certainty** 





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# Agenda

01 Example from FINDINGS class

#### FINDINGS ABOUT SDTM

- Findings about Events or Interventions: Specialized Findings class from General Observations
- To be used when data can not be represented in the events or interventions or it's SUPP dataset
- ▶ It has all the variables from FINDINGS CLASS, in addition also provide −OBJ variables
- **Structure:** One record per finding per object per time point per time point reference per visit per subject.

#### FA SDTM METADATA

fa.xpt, Findings About Events or Interventions — Findings Sub-Class, Version 3.1.2. One record per finding, per object, per time point, per visit per

subject Tabulation

Variable Name	Variable Label	Туре	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	FA	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
FASEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
FAGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
FASPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a CRF.	Perm
FATESTCD	Findings About Test Short Name	Char	(FATESTCD)		Short name of the measurement, test, or examination described in FATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in FATESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). FATESTCD cannot contain characters other than letters, numbers, or underscores. Example: SEV, OCCUR.	Req

## FA SDTM METADATA

			rolled				
Variable Nam			elist	Role	CDISC Notes	Cor	
FATEST	FATESTCD it d	conjunction with FATESTCD it describes the Topic of observation			Verbatim name of the test or examination used to obtain the measurement or finding. The value in FATEST cannot be longer than 40 characters. Examples: Severity/Intensity, Occurrence	Req	
FAOBJ	Oriect the Topic of Ob	Servati		Record Qualifier	Used to describe the object or focal point of the findings observation that is represented byTEST. Examples: the term (such as Acne) describing a clinical sign or symptom that is being measured by a Severity test, or an event such as VOMIT where the volume of Vomit is being measured by a VOLUME test.	Req	
FACAT	Category for Findings About	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: GERD, PRE-SPECIFIED AE.	Perm	
FASCAT	Subcategory for Findings About	Char	*	Grouping Qualifier	A further categorization of FACAT.	Perm	
FAORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the test as originally received or collected.		
FAORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for FAORRES.	Perm	
FASTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from FAORRES in a standard format or standard units. FASTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in FASTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in FAORRES and these results effectively have the same meaning; they could be represented in standard format in FASTRESC as "NEGATIVE".		
FASTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from FASTRESC. FASTRESN should store all numeric test results or findings.	Perm	
FASTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for FASTRESC and FASTRESN.	Perm	
FASTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that the measurement was not done. Should be null if a result exists in FAORRES.	Perm	
FAREASND	Reason Not Performed	Char		Record Qualifier	Describes why a question was not answered. Example: subject refused. Used in conjunction with FASTAT when value is NOT DONE.	Perm	
FALOC	Location of the Finding About	Char	(LOC)	Record Qualifier	Used to specify the location of the clinical evaluation. Example: ARM	Perm	
ALAT	Laterality of Location of the Finding About	Char	(LAT)	Result Qualifier	Qualifier for anatomical location or specimen further detailing laterality. Examples: RIGHT, LEFT, BILATERAL		
FABLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Perm	

# Example 1

In this example
Migraine is not
reported as AE but
is a Clinical event

Migraine Symptoms Diary	is a Cliffical event	
Migraine Reference Number		xx
When did the migraine start		DD-MMM-YYYY 'H:MM
Answer the following 5 Minute Severity of Migraine	Collected data shows occurrences of related	Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light	symptoms	○ No ○ Yes
Sensitivity to sound Nausea Aura		<ul> <li>No ○ Yes</li> <li>No ○ Yes</li> <li>No ○ Yes</li> </ul>
Answer the following 30 Minutes A	AFTER Dosing	
Severity of Migraine Associated Symptoms:	Data collected at n	derate o Severe
Sensitivity to light Sensitivity to sound	time points	
Nausea Aura		Yes O No O Yes
Answer the following 90 Minutes A	AFTER Dosing	
Severity of Migraine		Mild ○ Moderate ○ Severe
Associated Symptoms: Sensitivity to light Sensitivity to sound	FATESTCD=OCCUR FAOBJ=Symptom Description	Yes Tes
Nausea Aura		Yes No ○ Yes

# Example 1 : DATA SNAPSHOT

This is Clinical event information, it will get mapped into CF

Migraine Symptoms Diary	mapped into CE					
Migraine Reference Number	xx					
When did the migraine start	DD-MMM-YYYY HH:MM					
Answer the following 5 Minutes BEFORE Dosing						
Severity of Migraine	<ul> <li>o Mild ○ Moderate ○ Severe</li> </ul>					
Associated Symptoms:						
Sensitivity to light	○ No ○ Yes					
Sensitivity to sound	○ No ○ Yes					
Nausea	○ No ○ Yes					
Aura	○ No ○ Yes					
Answer the following 30 Minutes AFTER Dosing						
Severity of Migraine	<ul> <li>○ Mild ○ Moderate ○ Severe</li> </ul>					
Associated Symptoms:						
Sensitivity to light	○ No ○ Yes					
Sensitivity to sound	○ No ○ Yes					
Nausea	○ No ○ Yes					
Aura	○ No ○ Yes					
Answer the following 90 Minutes AFTER Dosing						
Severity of Migraine	○ Mild ○ Moderate ○ Severe					
Associated Symptoms:						
Sensitivity to light	○ No ○ Yes					
Sensitivity to sound	○ No ○ Yes					
Nausea	○ No ○ Yes					
Aura	○ No ○ Yes					

ce.xpt

		-							
	Row	STUDYID	DOMAIN	USUBJID	CESEQ	CESPID	CETERM	CEDECOD	CESTDTC
4	1	ABC	CE	ABC-123	1	90567	Migraine	Migraine	2007-05-16T10:30

## Example 1 : DATA SNAPSHOT

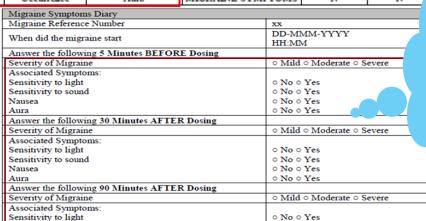
Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC
1	ABC	FA	ABC-123	1	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	SEVERE	SEVERE
2	ABC	FA	ABC-123	2	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	Y	Y
3	ABC	FA	ABC-123	3	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
4	ABC	FA	ABC-123	4	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	Y	Y
5	ABC	FA	ABC-123	6	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	Y	Y
6	ABC	FA	ABC-123	7	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	MODERATE	MODERATE
7	ABC	FA	ABC-123	8	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	Y	Y
8	ABC	FA	ABC-123	9	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
9	ABC	FA	ABC-123	10	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	N	N
10	ABC	FA	ABC-123	12	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	Y	Y
11	ABC	FA	ABC-123	13	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	MILD	MILD
12	ABC	FA	ABC-123	14	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	N	N
13	ABC	FA	ABC-123	15	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
14	ABC	FA	ABC-123	16	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	N	N
15	ABC	FA	ABC-123	18	90567	OCCUR	Осситенсе	Aura	MIGRAINE SYMPTOMS	N	N

Sensitivity to sound

Nausea

Aura

Row	FADTC	FATPT	FAELTM	FATPTREF
1 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
2 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
3 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
4 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
5 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
6 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
7 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
8 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
9 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
10 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
11 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
12 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
13 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
14 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
15 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING



This is finding more about Clinical event Rash and will be mapped in FA as FATESTCD=OCCUR or FATESTCD=SEV

9

o No o Yes

o No o Yes

○ No ○ Yes

#### RELREC

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	CE		CESPID		ONE	1
2	ABC	FA		FASPID		MANY	1

- ✓ A dataset level Relationship is displayed using RELREC dataset.
- ✓ --SPID is used as identifier variable
- ✓ As you can see Relation Type is <u>MANY</u> for FA dataset and <u>ONE</u> for CE dataset

## Example 2

Papules

Vesicles

Pustules

Scabs

Scars

#### As you can see Rash Assessment CRF page on CRF page Rash is This CRF collects details about rash e olved. collected as an Rash Assessment Adverse Event D-MMM-YYYY Date of Assessment Associated AE reference number Rash Size o in $\circ$ cm Lesion Type & Comt o 26 to 100 Macules o 1 to 25 o 101 to 200 o 201 to 300 0 > 300 0 0 Can I store this

26 to 100

26 to 100

o 26 to 100

o 26 to 100

o 26 to 100

o 1 to 25

o 1 to 25

1 to 25

o 1 to 25

o 1 to 25

0 0

0 0

0 0

0 0

0 0

information in

AE dataset?

101 to 200

o 101 to 200

o 101 to 200

o 101 to 200

o 101 to 200

201 to 300

201 to 300

o 201 to 300

o 201 to 300

o 201 to 300

0 >300

0 > 300

0 >300

0 >300

0 > 300

## Example 2 : DATA SNAPSHOT

This is Adverse event information, it will get mapped into AE

	mapped into AE
Rash Assessment	
Date of Assessment	DD-MMM-YYYY
Associated AE reference number	
Rash Size	ocm oin
Lesion Type & Count	
Macules	○ 0 ○ 1 to 25 ○ 26 to 100 ○ 101 to 200 ○ 201 to 300 ○ >300
Papules	○ 0 ○ 1 to 25 ○ 26 to 100 ○ 101 to 200 ○ 201 to 300 ○ >300
Vesicles	○ 0 ○ 1 to 25 ○ 26 to 100 ○ 101 to 200 ○ 201 to 300 ○ >300
Pustules	○ 0 ○ 1 to 25 ○ 26 to 100 ○ 101 to 200 ○ 201 to 300 ○ >300
Scabs	○ 0 ○ 1 to 25 ○ 26 to 100 ○ 101 to 200 ○ 201 to 300 ○ >300
Scars	○ 0 ○ 1 to 25 ○ 26 to 100 ○ 101 to 200 ○ 201 to 300 ○ >300

ae.xpt

STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AETERM	AEDECOD	AEBODSYS	AELOC	AESEV	AESER	AEACN	AESTDTC
XYZ	AE	XYZ-789	47869	5	Injection site rash	Injection site rash	General disorders and administration site conditions	LEFT ARM	MILD	N	NOT APPLICABLE	2007-05-10

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### Example 2 : DATA SNAPSHOT

mapped in FA, as we are finding more Rash Assessment This information gets information about an Date of Assessment DD-MMM-YYYY mapped in FA, as we AE Rash Associated AE reference number are finding more information about an Rash Size  $\circ$  in  $\circ$  cm AE Rash Lesion Type & Count o 201 to 300 Macules o 101 to 200 0 >300  $\circ 0$ 0 1 to 25 o 26 to 100 **Papules** o 1 to 25 o 26 to 100 o 101 to 200 o 201 to 300 0 >300 0 0 Vesicles 0 1 to 25 o 26 to 100 o 101 to 200 o 201 to 300 0 > 300  $\circ$  0 Pustules o 1 to 25 o 26 to 100 o 101 to 200 o 201 to 300 0 > 300 0 0 Scabs 0 1 to 25 o 26 to 100 o 101 to 200 o 201 to 300 0 > 300  $\circ$  0 o 26 to 100 o 101 to 200 o 201 to 300 Scars 0 0 o 1 to 25 0 > 300

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Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	VISIT	FADTC
1	XYZ	FA	XYZ-789	123451	5	SIZE	Size	Injection Site Rash	2.5	IN	VISIT 3	2007-05-12
2	XYZ	FA	XYZ-789	123452	5	COUNT	Count	Macules	26 to 100		VISIT 3	2007-05-12
3	XYZ	FA	XYZ-789	123453	5	COUNT	Count	Papules	1 to 25		VISIT 3	2007-05-12
4	XYZ	FA	XYZ-789	123454	5	COUNT	Count	Vesicles	0		VISIT 3	2007-05-12
5	XYZ	FA	XYZ-789	123455	5	COUNT	Count	Pustules	0		VISIT 3	2007-05-12
6	XYZ	FA	XYZ-789	123456	5	COUNT	Count	Scabs	0		VISIT 3	2007-05-12
7	XYZ	FA	XYZ-789	123457	5	COUNT	Count	Scars	0		VISIT 3	2007-05-12
8	XYZ	FA	XYZ-789	123459	5	SIZE	Size	Injection Site Rash	1	IN	VISIT 4	2007-05-19
9	XYZ	FA	XYZ-789	123460	5	COUNT	Count	Macules	1 to 25		VISIT 4	2007-05-19
10	XYZ	FA	XYZ-789	123461	5	COUNT	Count	Papules	1 to 25		VISIT 4	2007-05-19
11	XYZ	FA	XYZ-789	123462	5	COUNT	Count	Vesicles	0		VISIT 4	2007-05-19
12	XYZ	FA	XYZ-789	123463	5	COUNT	Count	Pustules	0		VISIT 4	2007-05-19
13	XYZ	FA	XYZ-789	123464	5	COUNT	Count	Scabs	0		VISIT 4	2007-05-19
14	XYZ	FA	XYZ-789	123465	5	COUNT	Count	Scars	0		VISIT 4	2007-05-19
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# Thank You