Finding Out about Findings About

PP06

FA is a SDTM Findings domain:

- **FATESTCD (Test Code)**
- **FATEST (Test Name)**
- **FAORRES (Result)**

Use FAOBJ (Object of Test / Result) to link to:

Events (examples):

AETERM (AE Verbatim Text)
CETERM (Clinical Event)
DSTERM (Disposition Event)

Interventions (Examples):

CMTRT (Medication Name)
SUTRT (Substance of Abuse Name)
EXTRT (Investigational Product Name)

Findings about should be used when:

1) Findings are from a different time point to the event itself
2) Data about the Event / Intervention better fit the Findings structure (have units / method)
3) Findings are about an Event / Intervention that is not recorded on the CRF (such as disease under study)
4) Recording related symptoms / descriptions about the Event / Intervention (such as the existence of nausea for a migraine)
5) Information relating to pre-specified AEs that may or may not have occurred.

Example CRF page:

SDTM Annotations

CE = Clinical Events

FA = Findings About

Daily Headaches Recording:

CETERM = HEADACHE

FAOBJ = HEADACHE

1) CESPID FASPID

Headache Type: List: HDTYPE CEDECOD

Date of Headache: □□-□□□-□□□□ Time of Headache: □□:□□

DD-MON-YYYY CEDTC HH:MM

Duration of Headache: □□ Hours CEDUR

Severity of Headache 5 minutes before dosing: List: HDSEV

Severity of Headache 15 minutes after dosing: List: HDSEV

Severity of Headache 30 minutes after dosing: List: HDSEV

Severity of Headache 60 minutes after dosing: List: HDSEV

Check box if another headache to record: □

<eCRF note: if box checked repeat questions>

FAORRES where FATESTCD = SEV; FATPT = 5m PRE-DOSE

FAORRES where FATESTCD = SEV; FATPT = 15M POST-DOSE

FAORRES where FATESTCD = SEV; FATPT = 30M POST-DOSE

FAORRES where FATESTCD = SEV; FATPT = 60M POST-DOSE

Example datasets:

STUDYID	USUBJID	CESPID	CETERM	CEDECOD	CEDUR	CEDTC
WOND123	W123-001	001	HEADACHE	MIGRAINE	PT6H	2015-08-31
WOND123	W123-001	002	HEADACHE	CLUSTER	PT3H	2015-09-02

STUDYID	USUBJID	FASPID	FATESTCD	FATEST	FAOBJ	FAORRES	FATPT
WOND123	W123-001	001	SEV	SEVERITY	HEADACJE	SEVERE	5M PRE-DOSE
WOND123	W123-001	001	SEV	SEVERITY	HEADACJE	MODERATE	*15M POST-DOSE*
WOND123	W123-001	001	SEV	SEVERITY	HEADACJE	MODERATE	30M POST-DOSE
WOND123	W123-001	001	SEV	SEVERITY	HEADACJE	MILD	*60M POST-DOSE*

Findings about should not be used when:

1) You have data you are not sure what to do with, i.e. you cannot easily identify FAOBJ.

Example CRF page:

SDTM Annotations

XM = Custom domain

Visit 8

6 MINUTE WALK TEST:

1 MINUTE POST-DOSE : □□□.□□ XMORRES

XMTEST = 6 MINUTE WALK TEST

XMTPT = 1M POST-DOSE

15 MINUTES POST-DOSE: □□□.□□ XMORRES

XMTEST = 6 MINUTE WALK TEST

XMTPT = 15M POST-DOSE

Here there is no apparent object you are measuring, the data should go into a custom domain, as annotated.

STUDYID	USUBJID	XMTESTCD	XMTEST	XMORRES	XMTPT	VISIT
WOND123	W123-001	SXMINWK	6 MINUTE WALK TEST	4.07	1M POST-DOSE	VISIT 8
WOND123	W123-001	SXMINWK	6 MINUTE WALK TEST	10.87	15M POST-DOSE	*VISIT 8*
WOND123	W123-001	SXMINWK	6 MINUTE WALK TEST	5.1	1M POST-DOSE	VISIT 10
WOND123	W123-001	SXMINWK	6 MINUTE WALK TEST	9.32	15M POST-DOSE	VISIT 10

So what are Clinical Events…?

Clinical events of interest that are not captured as Adverse Events:

1) Episodes of the disease under study (migraines, epileptic seizures).
2) Signs and symptoms that might lead to an Adverse Event, but not be classed as an Adverse Events themselves.

So, in the example above, as headaches are the disease under study, they are captured in the CE domain, rather than as AEs.

As with other SDTM domains, variables CEOCCUR and CEPRESP can be used to capture the occurrence of pre-specified Clinical Events of interest.

Caroline Clark-Steel
Sunshine Programming Ltd
sunshineprog@yahoo.co.uk