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Finding out about Findings About

Caroline Clark-Steel, Sunshine Programming Ltd, Gloucester, UK

ABSTRACT

In CDISC (Clinical Data Integration Standards Consortium) Study Data Tabulation Model (SDTM) Implementation Guide (IG) version 3.12 the Findings About (FA) and Clinical Events (CE) domains were introduced. Unlike previous SDTM safety domains, it is not immediately apparent what data should be mapped / collected in these domains. Whilst working on studies for various sponsors, it is obvious that interpretations of these domains can vary significantly. The poster gives an example of data that can be captured in Findings About, which will be expanded on here. The poster also uses a Clinical Event as the event for which the FA data is captured, so a brief overview of CE data is also given.

INTRODUCTION

If you work with clinical data, you will be (eventually, inevitably) be working with the CDISC SDTM and ADaM (Analysis Data Model) standards. SDTM is intended to be data as it is captured from the CRF. However, it is acknowledged that SDTM is not a data capture-friendly standard and hence the invention of the CDASH data collection standard. This means that some mapping of the data is necessary to meet the SDTM requirements. In order to do this, CDISC has published SDTM Implementation Guides (IG) detailing how the data should be grouped and what the variable names and attributes should be. Most domains are straightforward, for example Adverse Event data is mapped into the AE domain, laboratory results data is mapped to LB and so on. However, as the standards develop to meet the needs of more challenging and non-standard data, the domains require more interpretation and careful mapping. Two of these domains are Findings About Events or Interventions (FA) and Clinical Events (CE). From their names you can see that it is not immediately apparent what data should be mapped to these domains.

Findings About (FA)

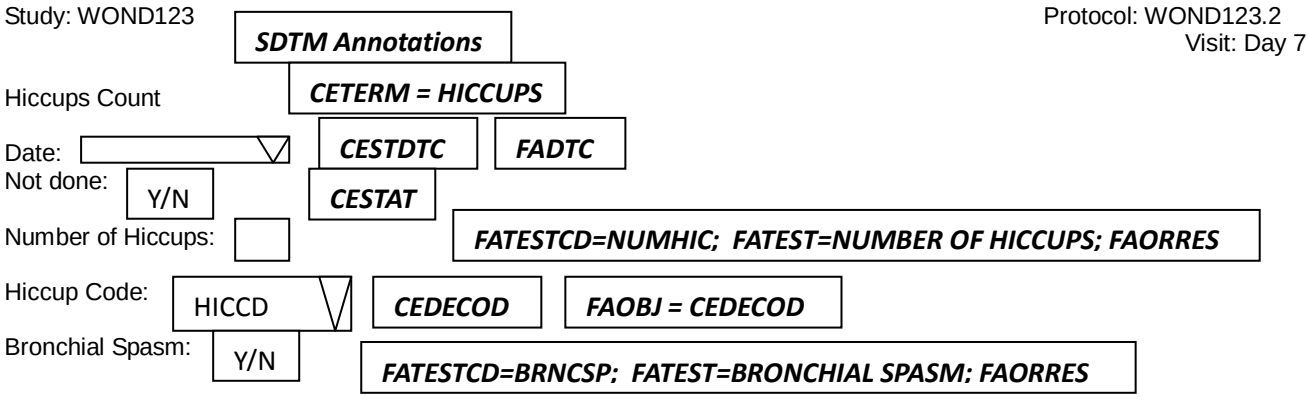
The FA domain is a Findings Structure domain (topic variable is the --TESTCD with a result variable --ORRES). It is intended to capture data about events or interventions that will not fit in the proscribed SDTM events or interventions domain. The link between the record in the event or intervention domain and Findings About is through the FAOBJ variable. This will match the --TERM or --TRT variable in the event or intervention domain. However, if the domain is routinely coded, then FAOBJ will match the coded term --DECOD.

Findings about should be used when:

1. The 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 the 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.

The poster gives an example of findings about the clinical event of a headache (see later why this is a Clinical Event and not an Adverse Event). The reason that this data is mapped to the Findings About domain, is that the data is collected at discreet time points after the event has occurred. There is nowhere in the events domain structure where this data can be collected, hence the normalised structure of the findings domain is utilised.

Another example is collecting data about the disease under investigation. This is typically collected once in the Medical History events domain. Then, throughout the trial, ocurrences of the disease will be captured to assess the drug efficacy (for example). This data may be captured as a combination of CE and FA data:



Not Findings About

I have worked with some findings data that has been mapped to FA rather than a custom domain. This is a common mistake and a misunderstanding of what the FA domain is supposed to contain. If you do not have an event or intervention for which you are collecting this data (for example it is an efficacy test or Patient Reported Outcome not linked directly to the disease under study) then a custom findings domain should be developed.

In the poster this is illustrated in the CRF section for the 6 minute walk test. Rather than being mapped to the FA domain, this data should be included in a Sponsor custom domain, utilisting the Findings domain structure (using a test code, test name and results variables). So, similar variables will be used, but the domain prefix will be different and there is no need to include the --OBJ variable.

Clinical Events (CE)

The definition of Clinical Events in the SDTM Implementation Guide is ´The intent of the domain model is to capture clinical events of interest that would not be classified as adverse events. The data may be data about episodes of symptoms of the disease under study (often known as signs and symptoms), or about events that do not constitute adverse events in themselves, though they might lead to the identification of an adverse event.´. So what then do we map to a Clinical Event? And how is this different to an Adverse Event? The example given in the poster is of a headache. As this is the disease under investigation, the Sponsor does not want to capture these events in the AE domain, so CE is used. Again, the occurrence of the headache is captured in CE and then the symptoms of interest at pre-specified time points are collected in FA.

An expanded example of the dataset, using the CEPRESP and CEOCCUR variables, is:

STUDYID	USUBJID	CESPID	CETERM	CEDECOD	CEPRESP	CEOCCUR	CEDUR	CEDTC
WOND123	W123-001	001	HEADACHE	MIGRAINE	Y	Y	PT6H	2015-08-31
WOND123	W123-001	002	HEADACHE	CLUSTER	Y	Y	PT3H	2015-09-02
WOND123	W123-001	003	HEADACHE		Y	N		

Not Clinical Events

The Clinical Events domain is difficult to map, as you must be sure that these events constitute Clinical Events and not Adverse Events (AEs). AEs must be reported on the AE page and Serious AEs (SAEs) expedited according to the study protocol. As the SDTM IG states: ´Sponsors must ensure that all adverse events are recorded in the AE domain´.

CONCLUSION

Use of these domains should be carefully considered and the data evaluated before mapping. Care should be taken that Adverse Events are mapped to AE and not CE and comply with Regulatory requirements. Findings About should not be used in place of a custom domain. Ensure that there is an associated event or intervention (even if it is not explicitly captured on the CRF) that is the object (FAOBJ) of the FA domain.