

CDISC SME Meeting

Review Standard AE Form (CTSU_AE)

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Meeting Plan

- **Review Standard AE form within the context of CDISC standards**
 - LPOs have been using these standard forms for a couple of years
- **Review the process for applying CDISC standards to CTSU_AE: Discussions with CDISC SME to understand the meaning of each item for the purpose of determining whether it maps to SDTM or whether it is only used for internal systems**
- **Understand what has *not* changed**
 - Still the same data items that you have been using
- **Understand what *has* changed**
 - Field OIDs / Variable OIDs have been aligned with CDASH *for those data items that will be mapped to SDTM*
 - *Where applicable*, PreText modified to align with CDASH
- **Apply CDISC standards requirements *beyond the CTSU_AE requirements***

Disclaimers

- **The Standard Forms ALS you will receive in July has been significantly updated from the March version you reviewed, so what you will see today may be quite different.**
- **The version you will receive in a few weeks is not quite final (so additional changes will be made from what we see today)**

**Out of scope for this meeting is any discussion specific to CTSU *Integrations* (non-CDISC items)
E.g., Instructional notes or other items that are used only in the NCI internal systems and would not be considered “clinical data”**

Types of Field-Level Requirements

- Those fields that are required for the CTEP-AERS Integration
 - These fields are marked with a red asterisk (*****) in the Rave form and you must always use them and they have to be entered
 - These fields may or may not be required for CDASH/SDTM
 - These fields may or may not even map to CDASH/SDTM
- Those fields that are required for CDASH and/or SDTM
 - These fields have core designations in the CDISC standards that tell us whether they are required
 - If they don't already exist in the AE form, you will need to add them for CDISC conformance
- Those fields that are in the CTSU_AE ALS, but not required for either the CTEP-AERS Integration or for CDASH/SDTM
 - You may choose to use these, or not

Overview of AE Standard Form CTSU_AE (1 of 3)

Subject: Subject
Page: Adverse Events

Form Instructions ?

* Red asterisk before a field denotes that it is required by the system for rules evaluation.

* Course/Cycle #

Reporting period end date

* Start date of this course/cycle

* Start date of first course/cycle

* Treatment assignment code

REMEMBER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the right corner of the table. If these options are not available, you are already viewing the entire table.

Were any AEs reported as ongoing in the previous cycle?

Please confirm AEs reported as ongoing in the previous cycle are still ongoing. ?

Currently viewing line 1 of 1
Click here to return to "Complete View".

Adverse Event (Verbatim term)

Pre-Specified Adverse Event

* Adverse event term (CTCAE v5.0)

* MedDRA adverse event code (CTCAE v5.0)

* Adverse event evaluated this cycle?

* What is the description of the toxicity? (first 120 characters)

CTCAE Grade

CTCAE Grade

What is the description of the toxicity?

Start Date

End Date

Ongoing

Red asterisk indicates fields required for the integration (i.e., these are the fields that drive the system functionality for reportable AEs)

CDASH(/SDTM) items *in this form* that should be collected for CDASH/SDTM conformance:

- **Adverse Event (Verbatim term)**
- **Start Date**
- **End Date**

Overview of AE Standard Form CTSU_AE (2 of 3)

The screenshot shows a web form for 'Ongoing' with the following fields and sections:

- Relationship to Study Treatment (highlighted in red)
- Adverse event term (CTCAE v5.0)
- Severity and seriousness criteria (highlighted in red):
 - Hospitalization (initial or prolonged) [?]
 - Life Threatening [?]
 - Death [?]
 - Disability or Permanent Damage [?]
 - Congenital Anomaly or Birth Defect [?]
 - Concomitant or Additional Trtmt Given [?]
 - Other Serious (Important Medical Events)
- What action was taken with study treatment?
- * AE Number
- SAE report recommended
- * Date/Time of Collection (highlighted in blue)
- * Time zone
- Adverse event term (CTCAE v5.0)
- * Submitted by (highlighted in blue)
- Evaluated
- INSTRUCTIONS: After entering new or modified
- AE Comment [?]
- Form Date
- Printable Version Icon Key
- RF Version 1564 - Page Generated: 09 Jul 2019 14:43:05 Green

Two callout boxes provide additional information:

- Red box:** The following should be collected for CDASH/SDTM conformance:
 - Relationship to Study Treatment
 - SAE Criteria
 - Action taken with study treatment
- Blue box:** Some of the data items may be required for Integrations purposes, *not **required** for SDTM, but **if collected** would be mapped to SDTM*
 - Date/Time of Collection (AE_AEDTC)

Other items required for integrations would **not** map to SDTM (e.g. Submitted by)

Overview of AE Standard Form CTSU_AE (3 of 3)

Subject: Subject
Page: Expedited Reporting Evaluation

Form Instructions

A delay is expected when the safety system is called for AE evaluation.

Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both are entered on the same ticket.

Note/Error

Course/Cycle #

Send all AEs for evaluation

Recommended action for report

Recommended action for report

Report ID

Recommended report type

Report due by

Form Date

Some of the fields on the CTSU_AE standard form will not need to be mapped into SDTM - they are only used to drive the system integration processes.

[Printable Version](#) [Icon Key](#)

CRF Version 1564 - Page Generated: 09 Jul 2019 14:47:03 Greenwich Standard Time

How the CDISC Standards Have Been Applied to CTSU_AE

- CTSU reviewed all data items in the CTSU_AE ALS with CDISC SME
 - Discussed and determined the purpose and meaning of each item
 - Determined whether it was appropriate to place the data from each item into SDTM (i.e., *is this clinical data? Or is it operational data used to drive the integration process?*)
- *For every data item that could be mapped to **SDTM CTSU created a variable name with the SDTM dataset prefix:***
 - ***AE_AETERM, AE_AESTDAT***
- Data items that do not belong in SDTM do not have a dataset name prefix
 - These do not need to have any mapping applied - they are only used to drive the Integrations process

[Review CTSU AE FieldOIDs \(examples with and without prefixes\)](#)

Prefix dataset name indicates SDTM mapping

EXAMPLES (not exhaustive)

Field OID	Prefixed SDTM Dataset	SDTM Mapping
AE_AETERM	AE	Maps to the AETERM variable in the AE domain (dataset)
AE_AESTDAT AE_AESTTIM	AE	AESTDAT and AESTTIM are concatenated and reformatted to ISO 8601 and then mapped to AESTDTC
SUPPAE_QVAL _CYCLNUM	SUPPAE	Maps to a Supplemental Qualifier record for the AE domain, using CYCLNUM as the QNAM.
AEPERF	None	This is used only to indicate whether the AEs of interest were evaluated. This does not map to SDTM

- Use the ALS “as is” - this will ensure you are all doing it the same way.
- If there is no pre-fix, it is an “administrative” or “operational” field and does not map to SDTM.

Data Collection Requirements for CDASH/SDTM/FDA

- The CTSU_AE form does not include all the data that you need to collect for your SDTM AE dataset for CDASH/SDTM conformance
- You can reference the CDASH and SDTM standards to determine which fields should be on your study-level AE forms and which variables have to be included in SDTM:
 - [CDASHIG: \(Filter metadata on the AE HR and R/C fields\)](#)
 - [SDTMIG: \(Filter metadata on the AE Req and Exp fields\)](#)

Review metadata for AE domain in both CDASH and SDTM

Fields that are required for CDASH/SDTM*

CTSU_AE or GLIB Field OID	CDASH Variable	HR or R/C	SDTM Variable	Req or Exp
AE_AETERM	AETERM	HR	AETERM	Req
AE_AESTDAT	AESTDAT	HR	AESTDTC	Exp
AE_AESTTIM	AESTTIM	R/C	AESTDTC	Exp (but start time is only included if collected)
AE_AEREL	AEREL	HR	AEREL	Exp
AE_AEOUT	AEOUT	HR	AEOUT	Perm
AE_AEENDAT	AEENDAT	R/C	AEENDTC	Exp
AE_AEENTIM	AEENTIM	R/C	AEENDTC	Exp (but start time is only included if collected)
AE_AEACN	AEACN	R/C	AEACN	Exp

*May not be “required” for the Standard Form / Integration, but should be collected for CDASH/SDTM/FDA conformance

Fields that are required for CDASH/SDTM*

CTSU_AE or GLIB Field OID	CDASH Variable	HR or R/C	SDTM Variable	Req or Exp
AE_AESEV or AE_AETOXGR	AESEV or AETOXGR	R/C (must collect either Severity or Toxgr)	AESEV AETOXGR	Perm Perm
AE_SER or all AE Serious Criteria	AESER, AESDTH, AESDISAB, AESCONG, AESHOSP, AESLIFE, AESMIE	R/C (must collect seriousness)	AESER Serious Criteria (AESDTH, etc.)	Exp FDA expects to see the criteria that made AESER=Y
MedDRA coding is not intended to be collected	All levels of MedDRA coding to assign values	R/C	All levels of MedDRA coding (Origin=Assigned)	Exp

*May not be “required” for the Standard Form / Integration, but should be collected for CDASH/SDTM/FDA conformance

Summary

- The CTSU standard forms, including CTSU_AE, have been set up to drive system integrations for AE/SAE
- All the fields in the CTSU_AE form have *already been evaluated* for mapping to CDASH/SDTM
 - Those fields that will map to CDASH/SDTM have a prefixed SDTM dataset name (e.g., AE_xxxxx)
 - Those fields that are only used to drive the internal system integrations will (intentionally) not have a prefixed SDTM dataset name
 - *All the SDTM mappings have already been done for you in both the Standard Forms ALS and the GLIB ALS*
- Requirements differ for Integration and SDTM
 - There are some AE questions you will need to collect for SDTM even if they are not required for the Integration activities
 - Required for Integration activities - marked with a red asterisk in Rave
 - Required for CDASH/SDTM - reference the CDASH/SDTM standards



Q&A

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