CDISC SME Meeting

Review Standard AE Form (CTSU_AE)

Shannon Labout

NIH NATIONAL CANCER INSTITUTE

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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)**

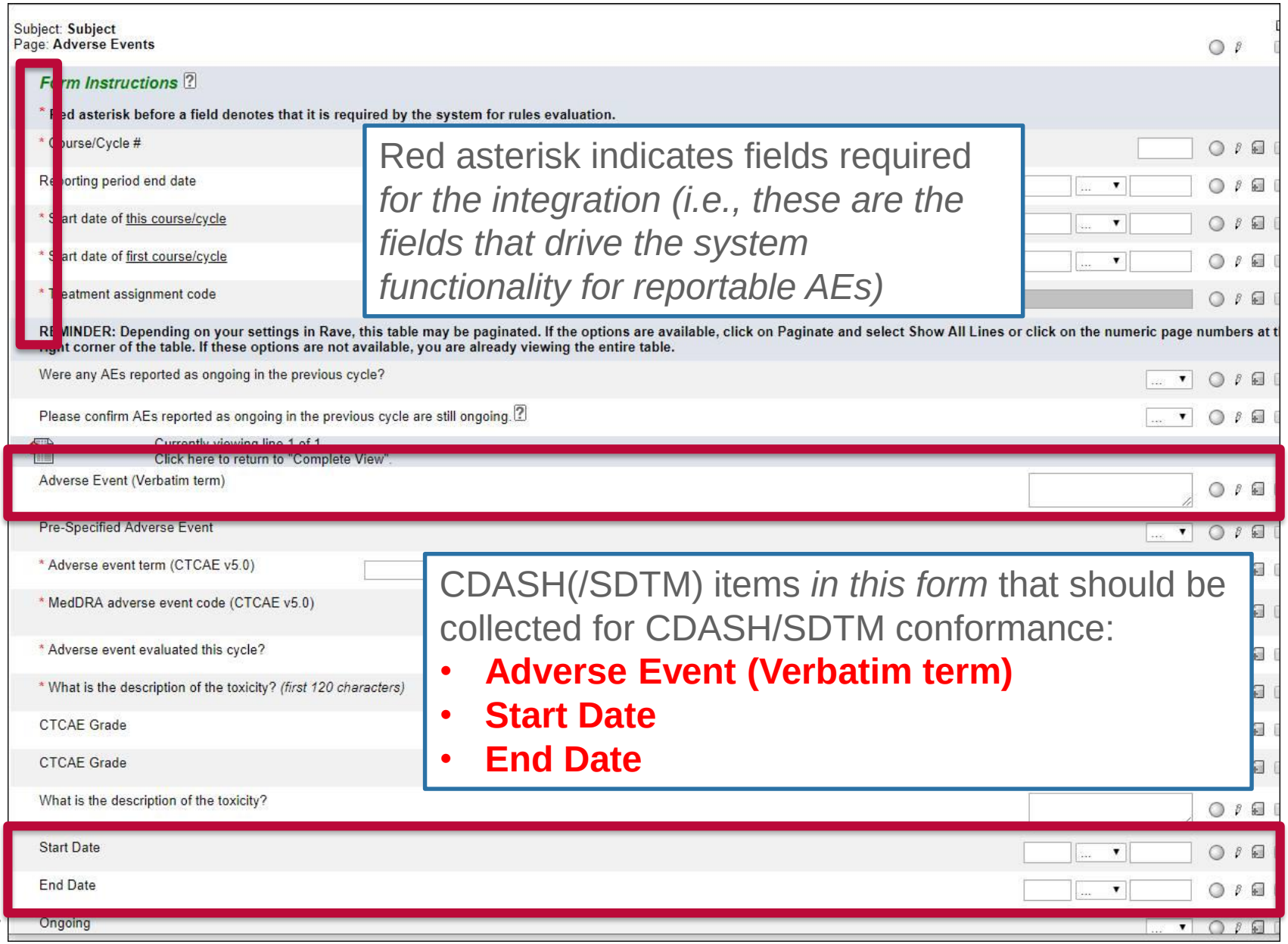
Out of scope for this meeting is any discussion specific to CTSU *Integrations* (non-CDISC items)

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)

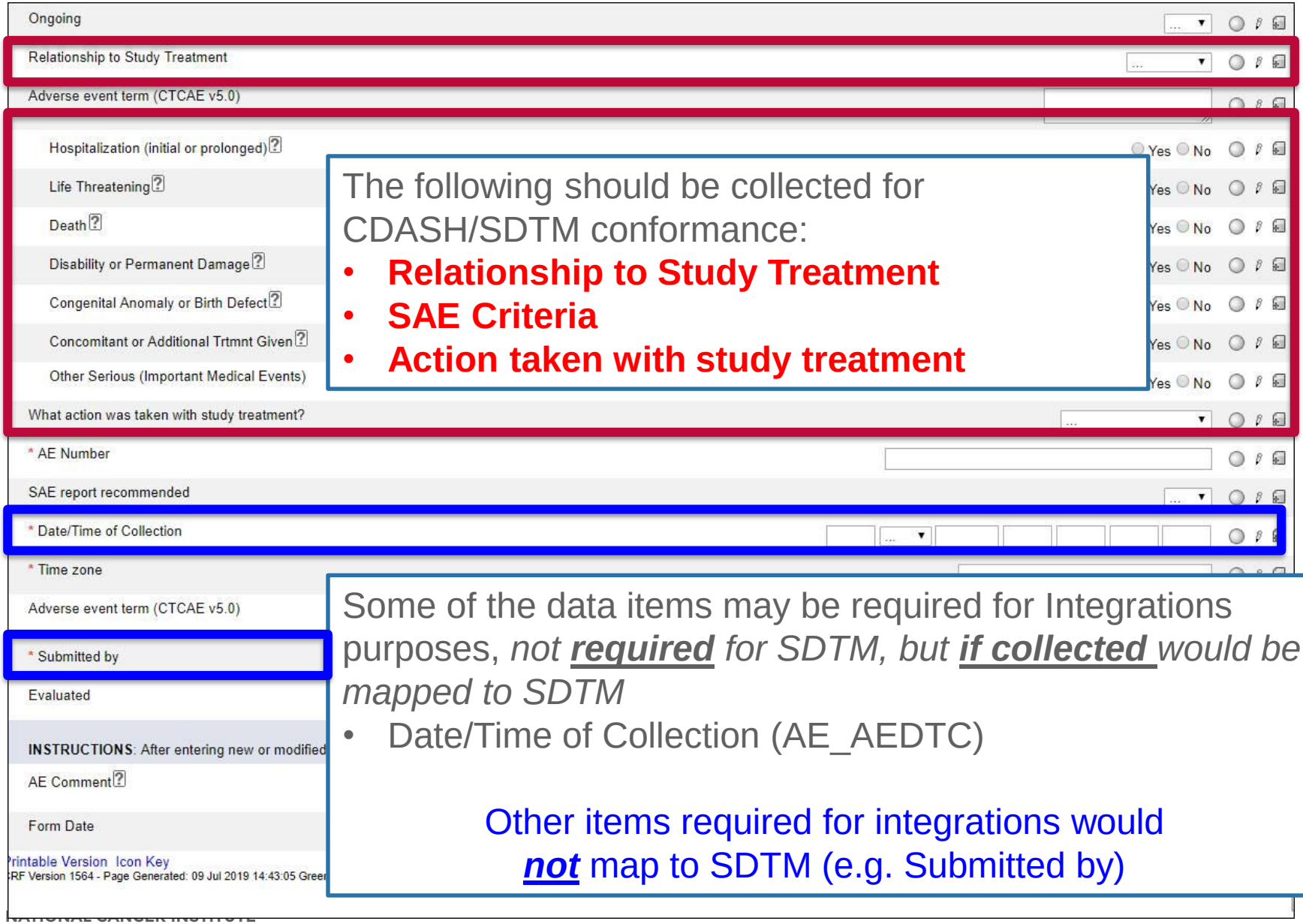


Red asterisk indicates fields required *for the integration (i.e., these are the fields that drive the system functionality for reportable AEs)*

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 following should be collected for CDASH/SDTM conformance:

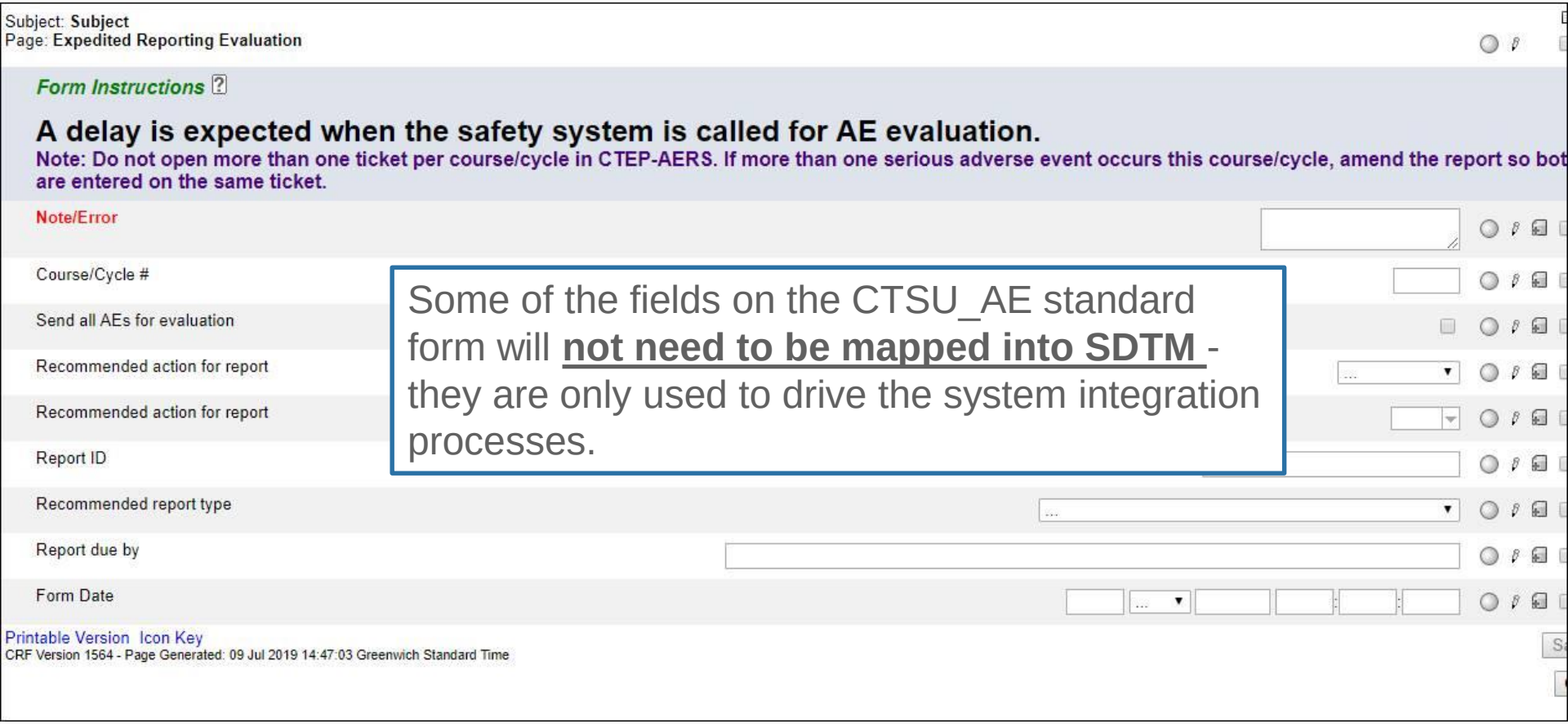
- **Relationship to Study Treatment**
- **SAE Criteria**
- **Action taken with study treatment**

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)



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.

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

NCICDISCSupport@nih.gov

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