CTSU

Cancer Trials Support Unit

CTSU Standard Forms ALS v7.1 Release Notes

Version 1.1

May 16, 2022

Document Information

Revision Information for the CTSU Standard Forms ALS v7.1 Release Notes

Revision History

#	Date	By	Description
1.0	08-Mar-2022	Anita Kalavar	Initial draft.
1.1	09-May-2022	Suhela Pandit	Updated sections 4.1 and 5.1.1 to include additional instructions for managing TAC field; updated section 2.3 to clarify expected implementation of ALS v7.1; updated section 5.1.1 to include instructions to modify Central Study CF CTSU_PKG_NAV_TX_doInitialization until Central Study patch is deployed.

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1. References

Table 1: References

#	Document	Location	Description
1)	CTSU Standard Forms ALS v7.1 Release Notes	Collaboration Portal (CTSU Website) **Path:** CTSU→CDMS Support Center →Integrations→General Documents →CTSU-Standard-Forms→v7.1	Specification document for CTSU Standard Forms ALS v7.1 release.
2)	Cancer Therapy Evaluation Program (CTEP) Clinical Data Interchange Standards Consortium (CDISC) Policy Governance Document	Project and Meeting Documentation - NCI CDISC Implementation - NCI Wiki (nih.gov)	CTEP CDISC Policy Governance Document establishes a framework and process for Architect Loader Spreadsheet (ALS) version management, detailing communication pathways, ALS update drivers and rationale, expectations, and compliance requirements.

2. Introduction

2.1 Overview

Medidata Rave was integrated with the National Cancer Institute's (NCIs) Cancer Therapy Evaluation Program – Adverse Event (AE) Reporting System (CTEP-AERS). This integration requires Lead Protocol Organizations (LPOs) to use the CTSU standard forms for the Rave-CTEP-AERS integration that are available in the CTSU Standard Forms Rave ALS v7.1 file. The integration of Rave with the NCI's AE reporting system CTEP-AERS is a web service developed to synchronize the collection of routine AEs in two systems thereby reducing the burden of double data entry. The integration allows for the CTEP-AERS rules evaluation service to display reporting recommendations thus helping to reduce over and under reporting of AEs to the NCI. As of September 20, 2021, all CTEP-Investigational Drug (IND) held trials must use the Rave-CTEP-AERS integration, as direct reporting of AEs for these studies is no longer allowed.

The CTSU Standard Forms ALS v7.1 includes new Pre-Treatment AE forms as well as performance enhancements and modifications to the AE forms as requested by the LPOs.

The CTSU Standard Forms ALS v7.1 Release Notes document provides information regarding modifications of the Rave-CTEP-AERS integration standard forms, and provides the necessary detail to assist LPOs in configuring studies to use this integration. The CTSU standard forms for the Rave-CTEP-AERS integration are CDISC compliant, employing the most recent version for CTEP CDISC Harmonized Common Data Element (CDE) curation.

Note: To access the CDISC links in Table 2 below, log into the CDISC website using your National Institutes of Health (NIH) email address. These links only work for NIH staff members or LPOs that have obtained their own account access.

Table 2: CDISC Version and Links

CDISC Documents	Link
Clinical Data Acquisition Standard Harmonization (CDASH) Model	https://www.cdisc.org/standards/foundational/cdash
CDASH Implementation Guide (CDASHIG)	https://www.cdisc.org/standards/foundational/cdash
CDASH and Standard Data Tabulation Model (SDTM) Controlled Terminology *Note: Controlled Terminology are released quarterly. You can access the prior versions via the CDISC Library Archive.*	https://evs.nci.nih.gov/ftp1/CDISC/SDTM
CDASHIG Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives
Standard Data Tabulation Model (SDTM)	https://www.cdisc.org/standards/foundational/sdtm
SDTM Implementation Guide (SDTMIG)	https://www.cdisc.org/standards/foundational/sdtmig

CDISC Documents	Link
SDTMIG Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives

2.2 Acronyms and Definitions

This section lists acronyms used within the document, as well as common acronyms related to the CTSU program.

Table 3: Acronyms and Definitions

Acronym	Definition
AE	Adverse Events
AER	Expedited Reporting Evaluation Form is used to send Adverse Events Form data to CTEP-AERS for evaluation. The acronym used for this form is AER.
ALS	Architect Loader Specification
caDSR	Cancer Data Standards Registry and Repository
CDASH	Clinical Data Acquisition Standards Harmonization. Basic standards for the collection of clinical trial data and how to implement the standard for specific Case Report Forms. Optimized for data capture, investigator site activities and data cleaning. The CDASH standard includes the CDASHIG (including the metadata) and the CDASH Model.
CDASHIG	CDASH Implementation Guide provides information on the implementation of CDASH standards for specific topics of data. Each topic is represented by a CDASH domain. CDASH domains, variables and controlled terminology are aligned with SDTM. Each CDASHIG domain contains a description of the data topic, a specification table, including standard metadata for data collection, general assumptions/rules, and example forms.
CDASH Model	Provides a general framework and root metadata for creating fields to collect information on forms for which there is not already a domain specified in the CDASHIG. Root metadata includes root variables and root questions. The root CDASH Model variables are intended to facilitate mapping to the SDTMIG variables while addressing specific data collection needs.
CDASH Metadata Table	Includes variables commonly implemented by a significant number of the organizations/companies for a particular topic of data (e.g., Medical History, Adverse Events).
CDE	Common Data Element
CDISC	Clinical Data Interchange Standards Consortium, a standards developing organization (SDO).
CF	Custom Function
CRA	Clinical Research Associate

Acronym	Definition
CTCAE	Common Terminology Criteria for Adverse Events
CTEP	Cancer Therapy Evaluation Program
CTEP-AERS	Cancer Therapy Evaluation Program - Adverse Events Reporting System
CTSU	Cancer Trials Support Unit
DD	Data Dictionary
DSL	Dynamic Search List
EC	Edit Check
EDC	Rave Electronic Data Capture
FDA	Food and Drug Administration
IND	Investigational Drug
LAE	Late Adverse Events
LAER	Late Expedited Reporting Evaluation Form is used to send Late Adverse Events Form data to CTEP-AERS for evaluation. The acronym used for this form is LAER.
LPO	Lead Protocol Organization
NCI	National Cancer Institute
NIH	National Institutes of Health
NRDS	Network Rave Data Standards
OID	Object Identifier
OPEN	Oncology Patient Enrollment Network
PAE	Pre-Treatment Adverse Events
PAER	Pre-Treatment Expedited Reporting Evaluation
RE	Rules Evaluation
SAE	Serious Adverse Event
SDTM	Study Data Tabulation Model
SDTMIG	Study Data Tabulation Model Implementation Guide
SUPP	Supplemental Qualifiers
TAC	Treatment Assignment Code
UI	User Interface

2.3 Scope

The use of CDISC standards is required for data submissions to the US Food and Drug Administration (FDA). A mandate issued by the FDA in 2016 requires data to be submitted to the FDA in Study Data Tabulation Model (SDTM) compliant datasets but does **not** mandate the use of CDISC compliant variables for data collection. NCI/CTEP is transitioning the existing Network Rave Data Standards (NRDS) initiative to the CTEP CDISC Implementation initiative to meet the FDA mandate of submitting clinical study data sets in the SDTM format.

Although the FDA does not require data to be collected in a certain format, the NCI is working in collaboration with CDISC to collect data in the Clinical Data Acquisition Standards Harmonization (CDASH) format. The CTSU, in coordination with the NCI CTEP, has updated the CTSU Standard Form elements to make them CDISC harmonized. Per NCI CTEP, all CTEP IND Studies activated on or after March 1, 2020 shall be CDISC compliant (submit to FDA in SDTM format). The CDISC harmonized CTSU Standard Forms ALS v7.0 or higher is expected to be used for all studies activated after March 1, 2020.

This document outlines the additions and updates to the Rave-CTEP-AERS integration standard forms that are included in the CTSU Standard Forms ALS v7.1.

A CDISC harmonized CTSU Standard Forms ALS (either v7.0 or v7.1) is expected to be used for studies activated after March 1, 2020; ALS v7.1 contains additional Pre-Treatment forms and enhancements to existing AE forms. LPOs are not expected to migrate existing studies to ALS v7.1. The recommendation is for LPOs to use ALS v7.1 for new studies in order to take advantage of the new functionality and bug fixes. There is no cutoff or cutover date identified by which the ALS 7.1 will need to be used.

After the release of ALS v7.1, CTSU will provide support for the following ALS files:

- CDISC harmonized CTSU Standard Forms ALS v7.0
- CDISC harmonized CTSU Standard Forms ALS v7.1
- Rave-CTEP-AERS Integrations ALS v2.3 (not CDISC harmonized)

Please note that only the latest 2 versions of CDISC harmonized ALS files will be supported by the CTSU at any given time, so with the release of ALS v7.2, only ALS v7.1 and v7.2 will be supported. Please refer to the CTEP CDISC Policy Governance Document on the NCI CTEP CDISC Implementation wiki for additional details.

The process of developing Rave forms that are not part of the CTSU Standard Form ALS files is out of the scope of this document.

2.4 Audience

This document is intended for use by LPO operational staff members, managers, and Rave Study Builders.

3. CTSU Standard Forms

The following figure depicts the current 17 CTSU standard forms available within the ALS. LPOs must not alter the elements defined for these forms as that can break various integrations. The forms where Form Object Identifier (OID) is prefixed with CTSUX are optional and can be removed when setting up the study in Rave. The other integration related forms are required for studies using the integration.

The forms in red box in the figure below are Rave-CTEP-AERS integration standard forms.

Form Name	OID
Subject Enrollment	CTSU_SUBJECT_ENROLLMENT
Demography	CTSU_DEMOGRAPHY
Step Information	CTSU_STEP_INFORMATION
Treatment Assignment	CTSU_TREATMENT_ASSIGNMENT
Patient Information for NCI Reporting	CTSU_PATIENT_INFORMATION
Randomization Unblinded	CTSU_RAND
Randomization Blinded	CTSU_RANDBLINDED
Central Monitoring Alert	CTSU_CM_ALERT
Pre-Treatment Adverse Events	CTSU_PAE
Pre-Treatment Expedited Reporting Evaluation	CTSU_PAER
Adverse Events	CTSU_AE
Expedited Reporting Evaluation	CTSU_AER
Late Adverse Events	CTSU_LAE
Late Expedited Reporting Evaluation	CTSU_LAER
Patient Status Form: Baseline	CTSUX_EVENT_BSL
Patient Status Form: Treatment (Intervention)	CTSUX_EVENT_TX
Patient Status Form: Follow-up	CTSUX_EVENT_FUP

Figure 1: CTSU Standard Form Names and OIDs

3.1 Rave-CTEP-AERS Integration Standard Forms

3.1.1 Form Level Definition

All Rave-CTEP-AERS integration standard forms available in ALS 7.1 are not required for every study. A description of each of the CTSU Standard and optional forms available in ALS 7.1 is provided in Table 4.

Table 4: Rave-CTEP-AERS Integration Standard Form Level Definition

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
1	Pre-Treatment Adverse Events	Pre-Treatment	CTEP-AERS	This form along with other forms, edit checks (ECs) and custom functions (CFs) enable Rave studies to integrate with the CTEP-AERS safety reporting system. The PAE Form is used to collect AE data after the subject has signed an informed consent but before treatment has started. This form should be used for studies that require reporting of Pre-Treatment AEs.	No Entry or View Restrictions.
2	Pre-Treatment Expedited Reporting Evaluation	Pre-Treatment	CTEP-AERS	The acronym used for this form is PAER. This form along with other forms, ECs and CFs enable Rave studies to integrate with the CTEP-AERS safety reporting system. The PAER Form is used to send PAE Form data to CTEP-AERS for evaluation. This form should be used for studies that require reporting of Pre-Treatment AEs. For studies for which reporting of Pre-Treatment AEs is not required, LPOs can use the form level restrictions to view restrict the form so it does not display in the Rave Electronic Data Capture (EDC).	No Entry or View Restrictions.
3	Adverse Events	Treatment (Intervention)	CTEP-AERS	This form along with other forms, ECs and CFs enable Rave studies to integrate with the CTEP-AERS safety reporting system. The AE Form is used to collect AE data during a patient's treatment course/cycle. All LPOs are expected to use this form to collect AE data for NEW studies activating after February 1, 2018.	No Entry or View Restrictions.
4	Expedited Reporting Evaluation (AER)	Treatment (Intervention)	CTEP-AERS	The acronym used for this form is AER. This form along with other forms, ECs and CFs enable Rave studies to integrate with the CTEP-AERS safety reporting system. The AER Form is used to send AE Form data to CTEP-AERS for evaluation. All LPOs that need to send the AE data to CTEP-AERS for evaluation are	No Entry or View Restrictions.

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
				expected to use this form. LPOs that do not need to send their AE data to CTEP-AERS for evaluation can use the form level restrictions to view restrict the form so it does not display in the Rave EDC.	
5	Late Adverse Events (LAE)	Follow-Up	CTEP-AERS	This form along with other forms, ECs and CFs enable Rave studies to integrate with the CTEP-AERS safety reporting system. The LAE Form is used to collect AE data during follow up visits. All LPOs are expected to use this form to collect Late AE data.	No Entry or View Restrictions.
6	Late Expedited Reporting Evaluation (LAER)	Follow-Up	CTEP-AERS	The acronym used for this form is LAER. This form along with other forms, ECs and CFs enable Rave studies to integrate with the CTEP-AERS safety reporting system. The LAER Form is used to send LAE Form data to CTEP-AERS for evaluation. All LPOs that need to send the LAE data to CTEP-AERS for evaluation are expected to use this form. LPOs that do not need to send their LAE data to CTEP-AERS for evaluation can use the form level restrictions to view restrict the form so it does not display in EDC.	No Entry or View Restrictions.
7	Patient Status Form: Baseline	Baseline	N/A	This is not a standard form, but is included in ALS to be used for navigation purposes. This form is optional, and is not required for any integration. This form can be used to roll out cycle visit folders.	No Entry or View Restrictions.
8	Patient Status Form: Treatment (Intervention)	Treatment (Intervention)	N/A	This is not a standard form, but is included in ALS to be used for navigation purposes. This form is optional, and is not required for any integration. This form can be used to roll out cycle/follow-up visit folders.	No Entry or View Restrictions.
9	Patient Status Form: Follow-up	Follow-Up	N/A	This is not a standard form, but is included in ALS to be used for navigation purposes. This form is optional, and is not required for any integration. This form can be used to	No Entry or View Restrictions.

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
				roll out additional follow-up visit folders.	

3.1.2 Folder Structure in Rave

Figure 2 displays the folder structure for Rave-CTEP-AERS integration standard forms. LPOs must follow the folder structure displayed in Figure 2 in order for the integrations to successfully work. The folders for Rave-CTEP-AERS integration (Baseline, Course/Cycle 01, Follow-up 01) are configurable.

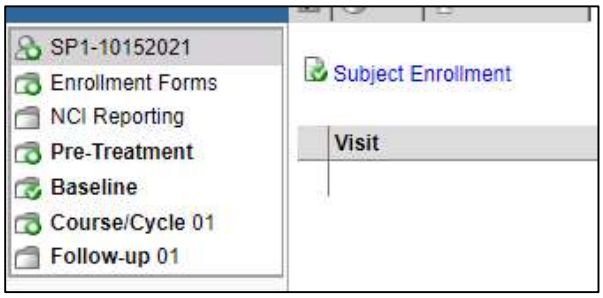

Figure 2: Rave-CTEP-AERS Integration Forms Folder Structure in Rave

4. Enhancements to CTSU Standard Forms ALS v7.1

As per the NCI CDISC implementation, all CTEP IND studies activated on or after March 1, 2020 must be CDISC compliant to satisfy the FDA mandate requiring data sets to be submitted in the CDISC SDTM format. ALS versions 7.0 and higher satisfy this requirement.

The CTSU standard forms used for the Rave-CTEP-AERS integration have been updated in ALS v7.1 and in the associated Central Study version to include new forms, enhancements to existing forms, and bug fixes. The CTSU Standard Forms ALS v7.1 must be set up using the corresponding Central Study v7.1; prior versions of the Central Study will not work with ALS v7.1 and vice-versa. The Folder, Form level, Field level, Data Dictionary, EC, and CF updates made in ALS v7.1 are outlined in this section.

4.1 Summary of Changes

The changes to CTSU Standard Forms ALS v7.1 are summarized below. For details, refer to the subsequent sections. Field Level changes are outlined in section 4.3.

1. Rave-CTEP-AERS integration folder and standard form changes:
    - Added a new folder 'Pre-Treatment'.
    - Added two new forms to be displayed in the 'Pre-Treatment' folder when subject is created:
        - Pre-Treatment Adverse Events (PAE)
        - Pre-Treatment Expedited Reporting Evaluation (PAER)
    - PAE: Treatment assignment code (TAC) - TAC-0 is the default value. Note: During study build LPOs can configure Pre-Treatment AE TAC as defined in the protocol.
        - To allow an update to the default TAC value TAC-0 on the PAE form in Rave EDC, user with Power User role must be granted permission. Entry Restriction for TAC field must be removed for Power User role.
    - Matrix Initial (INIT) updated to include PAE and PAER forms.
    - Updated Field Labels on AE, AER, LAE, and LAER forms to be consistent with curation style guide.
    - Updated Field and Variable OID:
        - AE and LAE forms: Updated OIDs from TAC1 to TAC
    - Removed fields on AE and LAE forms:
        - Field OIDs CTCAE1 and CTCAE2
    - Updated DraftFieldName on AE, AER, LAE, and LAER.
    - Updated ControlType on AE and LAE forms:
        - Field Treatment assignment code (TAC) updated from DropDownList to Text, and entry restricted to Rave role Clinical Research Associate
        - TAC is derived from the Treatment Assignment form

Note: TAC was editable in ALS v7.0, but in ALS v7.1 it is entry restricted to Rave role Clinical Research Associate because it is derived from the Treatment Assignment form.

- TAC field update:
    - 'OTHER' is not a valid TAC and is not supported in ALS 7.1.
    - When migrating study from ALS v7.0 to v7.1, in Amendment Manager configure the Object Mapping for forms AE and LAE, field Treatment assignment code (TAC). Data migration from DropDownList field to Text field results in –
        a. Specify not checked for User Data String in DD: The user selected value from the dropdown migrates to the Text field.
        b. Specify checked for User Data String in DD: User entered value in the specify field migrates to the Text field. The user selected value from the dropdown does not migrate.
- Updated Field Help Text on AE and LAE forms for Field OID SUPPAE_QVAL_AESINTV.
- Updated Sticky Note on AER and LAER forms.

2. Functionality Changes:
    - LAER form fix, user unable to change from CREATE to NONE. If tries to manually enter NONE, a non-conformant error appears (as expected).
    - Query does not open when one or more Outcome fields are inactive or not visible.
    - When there are no standard AEs in the form and logline is inactivated, and next cycle is rolled out. The ongoing confirmation question will not appear because there are no ongoing events on the previous cycle.
    - Fixed issue with disappearing AE Grade Descriptions when the user inactivates and re-activates the record, and then locks and unlocks the form.
    - Null End Date for Ongoing AE: End date will no longer show data as overdue when copied from one cycle to another. CF updated to show End date as submitted from when AE is copied from one cycle to another cycle.
    - Reduce RE call queries: For ongoing AEs when AE End date is entered on a later cycle, the query for RE call triggers only on the AE cycle where the AE End date is entered and the original AE where the ongoing AE was first entered.
    - Special characters are allowed in AE verbatim term and other specify fields.
    - TAC derivation: TAC is derived on AE form based on the Start date of this course/cycle and Event date on the Treatment Assignment form. System compares the Start date of this course/cycle to the Event date of each treatment step to derive the correct TAC.
        - Derive Step 1 TAC: If Start date of this course/cycle is prior to step 2 Event date.
        - Derive Step 2 and subsequent step TAC: If Start date of this course/cycle is on or after Step (e.g., 2) Event date and prior to the next Step (e.g., 3) Event date.

- End date query: Query opens on AE End date field if AE End date is prior to the Course start date for the Cycle/course AE and LAE forms. The user will have to inactivate the AE records on AE and LAE forms where AE End date is prior to the Course start date.
- Made Report ID visible when the recommended action is NONE.

3. Rave-CTEP-AERS integration query text updates were made to match updated field labels.

4.2 Form Level Changes

Table 5: Rave-CTEP-AERS Integration Standard Form Level Changes

#	Form Name	Type of Change	Description of Change
1	Pre-Treatment Adverse Events	New form	New form added to collect Pre-Treatment AEs.
2	Pre-Treatment Expedited Reporting Evaluation	New form	New form added to send Pre-Treatment AEs entered on PAE form to CTEP-AERS for evaluation.
3	Adverse Events, Expedited Reporting Evaluation, Late Adverse Events, Late Expedited Reporting Evaluation	Updated	The change details for these forms are outlined in section 4.3 below.

4.3 Field Level Changes

Note that Field OID and Variable OID updates are not mentioned in Table 8. All other field level changes (e.g., Format, Control Type,) are included in Table 8. Field OID with an integer (e.g., AETOX1) denotes that the variables have multiple occurrences in the same form.

Table 6: Rave-CTEP-AERS Integration Standard Forms Field Level Changes

#	Form Name	Existing Field OID	Type of Change	Change Description
1	Adverse Events, Late Adverse Events	SUPPAE_QVAL_FCYSTDAT	Field Label Updated	Field Label: updated to “Start date of first course/cycle (derived)”
2	Adverse Events, Expedited Reporting Evaluation	SUPPAE_QVAL_CYCLNUM	Field Label Updated	Field Label: updated to “Course/Cycle # (derived)”
3	Late Adverse Events, Late Expedited Reporting Evaluation	SUPPAE_QVAL_CYCLNUM	Field Label Updated	Field Label: updated to “Reporting period # (derived)”
4	Adverse Events, Late Adverse Events	SUPPAE_QVAL_CTCAECD	Field Label and Header Text Updated	Field Label: updated to “MedDRA AE code (CTCAE v5.0) (derived)” Header Text: updated to “MedDRA AE Code (CTCAE 5.0) (derived)”
5	Adverse Events, Late	TAC	Field updated	Field Label: Treatment assignment

#	Form Name	Existing Field OID	Type of Change	Change Description
	Adverse Events			code (TAC) (derived) DD removed, updated field to a free text entry restricted field.
6	Adverse Events, Late Adverse Events	AEONGOP	Field Label Updated	Field Label: updated to "Were any AEs reported as ongoing in the previous cycle? (derived)"
7	Adverse Events	AEONGOC	Field Updated	Updates include: Field Label: updated to "Should ongoing AEs from the previous cycle be copied to this form?" Is Visible: False
8	Late Adverse Events	AEONGOC	Field Label Updated	Field Label: updated to "Should ongoing AEs from the previous cycle be copied to this form?"
9	Adverse Events, Late Adverse Events	AE_AETERM	Field Label and Header Text Updated	Field Label: updated to "Adverse event (verbatim term)" Header Text: updated to "Adverse event (verbatim term)"
10	Adverse Events, Late Adverse Events	AE_AEPRESP	Field Label Updated	Field Label: updated to "Pre-specified adverse event (derived)"
11	Adverse Events, Late Adverse Events	AEPERF	Field Name Updated	Field Name: updated to "Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0_1"
12	Adverse Events, Late Adverse Events	AE_AETOX	Field Label, Field Name and Header Text Updated	Field Label: updated to "CTCAE grade and description of toxicity (derived)" Field Name: updated to "Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0_2" Header Text: updated to "CTCAE grade and description of toxicity (derived)"
13	Adverse Events	AETOX1	Field Label and Header Text Updated	Field Label: updated to "CTCAE grade and description of toxicity (first 120 characters)" Header Text: updated to "CTCAE grade and description of toxicity (first 120 characters)"
14	Adverse Events, Late Adverse Events	AE_AETOXGR	Field Label, Field Name and Header Text Updated	Field Label: updated to "CTCAE grade (derived)" Field Name: updated to "Adverse Event Toxicity Grade

#	Form Name	Existing Field OID	Type of Change	Change Description
				PID6338618_V1_0_2” Header Text: updated to “CTCAE grade (derived)”
15	Adverse Events, Late Adverse Events	AETOXGR1	Field Label Updated	Field Label: updated to “CTCAE grade”
16	Adverse Events, Late Adverse Events	AE_AESTDAT	Field Label and Header Text Updated	Field Label: updated to “Start date” Header Text: updated to “Start date”
17	Adverse Events, Late Adverse Events	AE_AEENDAT	Field Label and Header Text Updated	Field Label: updated to “End date” Header Text: updated to “End date”
18	Adverse Events, Late Adverse Events	AE_AEONGO	Field Label and Header Text Updated	Field Label: updated to “Ongoing (derived)” Header Text: updated to “Ongoing (derived)”
19	Adverse Events, Late Adverse Events	AE_AEREL	Field Updated	Updates include: Format: $10 DD: ATTRIBUTION_SCALE_ PID 2015190 _V4_0F Field Name: CTC Adverse Event Attribution Scale PID 1285_V3_0 Field Label: Attribution to study treatment Header Text: Attribution to study treatment
20	Adverse Events, Late Adverse Events	CTCAE1	Field Removed	N/A
21	Adverse Events, Late Adverse Events	AE_AESLIFE	Field Label and Header Text Updated	Field Label: updated to “Life threatening” Header Text: updated to “Life threatening”
22	Adverse Events, Late Adverse Events	AE_AESDISAB	Field Label and Header Text Updated	Field Label: updated to “Disability or permanent damage” Header Text: updated to “Disability or permanent damage”
23	Adverse Events, Late Adverse Events	AE_AESCONG	Field Label and Header Text Updated	Field Label: updated to “Congenital anomaly or birth defect” Header Text: updated to “Congenital anomaly or birth defect”
24	Adverse Events, Late Adverse Events,	SUPPAE_QVAL_AESINTV	Field Updated	Updates include: Field Label: updated to “Required

#	Form Name	Existing Field OID	Type of Change	Change Description
				intervention (device)" Header Text: updated to "Required intervention (device)" Help Text: updated to "Required intervention to prevent permanent impairment or damage (devices trials only)"
25	Adverse Events, Late Adverse Events	AE_AESMIE	Field Label and Header Text Updated	Field Label: updated to "Other serious (important medical events)" Header Text: updated to "Other serious (important medical events)"
26	Adverse Events, Late Adverse Events	AE_AEACN	Field Label and Header Text Updated	Field Label: updated to "Action taken with study treatment" Header Text: updated to "Action taken with study treatment"
27	Adverse Events, Late Adverse Events	AE_AESPID	Field Label and Header Text Updated	Field Label: updated to "AE number (derived)" Header Text: updated to "AE number (derived)"
28	Adverse Events, Late Adverse Events	SUPPAE_QVAL_SAERPT	Field Label and Header Text Updated	Field Label: updated to "SAE report recommended (derived)" Header Text: updated to "SAE report recommended (derived)"
29	Adverse Events, Late Adverse Events	AE_AEDTC	Field Label and Header Text Updated	Field Label: updated to "Date/Time of collection (derived)" Header Text: updated to "Date/Time of collection (derived)"
30	Adverse Events, Late Adverse Events	AEZONE	Field Label and Header Text Updated	Field Label: updated to "Time zone (derived)" Header Text: updated to "Time zone (derived)"
31	Adverse Events, Late Adverse Events	SUBMITBY	Field Label and Header Text Updated	Field Label: updated to "Submitted by (derived)" Header Text: updated to "Submitted by (derived)"
32	Adverse Events,	AEPERF1	Field Label , Field Name and Header Text Updated	Field Label: updated to "Evaluated (derived)" Field Name: updated to "Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0_2" Header Text: updated to "Evaluated

#	Form Name	Existing Field OID	Type of Change	Change Description
				(derived)"
33	Late Adverse Events	AEPERF1	Field Label , Field Name and Header Text Updated	Field Label: updated to "Evaluated (derived)" Field Name: updated to "Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0" Header Text: updated to "Evaluated (derived)"
34	Adverse Events, Late Adverse Events	CTCAE2	Field Removed	N/A
35	Adverse Events, Late Adverse Events	CO_COVAL	Field Label Updated	Field Label: updated to "AE comment"
36	Adverse Events, Expedited Reporting Evaluation, Late Adverse Events, Late Expedited Reporting Evaluation	AEFRMDTC	Field Label Updated	Field Label: updated to "Form date (derived) "
37	Expedited Reporting Evaluation, Late Expedited Reporting Evaluation	NOTE2	Field Label Updated	Field Label: updated to "A delay is expected when the safety system is called for AE evaluation. Notes: 1) 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 events are entered on the same ticket. 2) All queries on this form will be closed automatically by the system once the form is saved. DO NOT add a comment or close queries manually.
38	Expedited Reporting Evaluation, Late Expedited Reporting Evaluation	N/A	Sticky Note Updated	Sticky Note: Expedited reporting is required if the adverse event (AE) meets seriousness criteria and/or the protocol-specific expedited reporting requirements (e.g. CAEPR/SPEER, AESI - see protocol). If the AE does not meet protocol expedited reporting requirements, change CREATE to NONE and do not submit an expedited report. [QC018]
39	Expedited Reporting Evaluation, Late Expedited Reporting Evaluation	AERPACN1	Field Name Updated	Field Name: Recommended action for report PID6819760_V1_0_2

#	Form Name	Existing Field OID	Type of Change	Change Description
40	Expedited Reporting Evaluation, Late Expedited Reporting Evaluation	SUPPAE_QVAL_AERPACN	Field Name Updated	Field Name: Recommended action for report PID6819760_V1_0_1
41	Expedited Reporting Evaluation, Late Expedited Reporting Evaluation	AE_AEREFID	Field Label and Field Name Updated	Field Label: updated to "Report ID (derived)" Field Name: updated to "Reference ID PID6355961_V1_0"

4.4 Data Dictionary Changes

Table 7: Rave-CTEP-AERS Integration Standard Forms Data Dictionary Changes

#	DD Name	Type of Change	Comments
1	ATTRIBUTION_SCALE_ PID 2015190 _V4_0F	New DD	Replaced DD ADVERSE_EVENT_PID2179504_V3_0F with CDISC compliant DD ATTRIBUTION_SCALE_ PID 2015190 _V4_0F
2	CDISC_SDTM_ACTI_PID6365975_V1 _0F	User Data String	User Data String values updated to follow curation style guide (e.g., Dose Increased to Dose increased)
3	TAC	Removed	DD removed
4	YES_NO_IND_PID3506068_V1_0_2F	DD Name Updated	DD name updated from YES_NO_IND_PID3506068_V1_0_0F to YES_NO_IND_PID3506068_V1_0_2F

4.5 Edit Check Changes in LPO Study ALS

Table 8: Rave-CTEP-AERS Integration Standard Forms Edit Check Changes in LPO Study ALS

#	Form Name	Edit Check Name	Type of Change	Comments
1	Pre-Treatment Adverse Events	CTSU_GRP_QUERY_PAE	New	New EC to execute CF CTSUZ_GRP_ROUTE_doRouteEC
2	Pre-Treatment Expedited Reporting Evaluation	CTSU_PKG_RV_PAER	New	New EC to execute CF CTSUZ_GRP_ROUTE_doRouteEC to send AEs for evaluation
3	Adverse Event Expedited Reporting Evaluation	CTSU_PKG_RV_AER	Updated	Updated EC on Datapoint and AEFRMDTC and AESEVL check box to trigger CF CTSUZ_GRP_ROUTE_doRouteEC customfunction

#	Form Name	Edit Check Name	Type of Change	Comments
4	Pre-Treatment Expedited Reporting Evaluation	CTSU_PKG_RV_PAER_doHandleRptOverride	New	New EC to execute CF CTSUZ_GRP_ROUTE_doRouteEC
5	Pre-Treatment Expedited Reporting Evaluation	CTSU_GRP_AERDSL_RecomAction	Updated	Updated due to Field name change “If Recommended action for report PID6819760_V1_0_2 in Expedited Reporting Evaluation with record position 0 IsPresent then... execute the "CTSUZ_GRP_ROUTE_doRouteDSL" custom function as a DynamicSearchList on field Recommended action for report PID6819760_V1_0_2 in Expedited Reporting Evaluation with record position 0”
6	Late Adverse Events	CTSU_IND_LAE_DeriveCourse1StartDate	Updated	Changed to “If Intervention Occurrence Begin Date PID3028744_V1_0 in Late Adverse Events with record position 0 IsPresent then... execute the "CTSUZ_GRP_ROUTE_doRouteEC" custom function”
7	Pre-Treatment Expedited Reporting Evaluation	CTSU_PKG_RV_AER_doHandleRptOverride	Updated	Updated due to Field name change “If Recommended action for report PID6819760_V1_0_2 in Expedited Reporting Evaluation with record position 0 IsPresent Or Form Date PID6783869_V1_0 in Expedited Reporting Evaluation with record position 0 IsPresent then... execute the "CTSUZ_GRP_ROUTE_doRouteEC" custom function”.
8	Late Expedited Reporting Evaluation	CTSU_PKG_RV_LAER_doHandleRptOverride	Updated	Updated due to Field name change “If Recommended action for report PID6819760_V1_0_2 in Late Expedited Reporting Evaluation with record position 0 IsPresent Or Form Date PID6783869_V1_0 in Late Expedited Reporting Evaluation with record position 0 IsPresent then... execute the "CTSUZ_GRP_ROUTE_doRouteEC" custom function”

4.6 Custom Function Changes in LPO Study ALS

Table 9: Rave-CTEP-AERS Integration Custom Function Changes in LPO Study ALS

#	Custom Function Name	Type of Change	Comments
1	CTSUZ_CONFIG_doMapDefaultOids	Update	Updated Form OIDs and Field OIDs added to the key value collection. Updated the keys to be user friendly and generic
2	CTSUZ_CONFIG_doMapDefaultPAEOids	New	Added to plugin static PAE OIDs
3	CTSUZ_CONFIG_doMapAllOids	Updated	Updated CF to handle PAE and PAER forms. LPO Customizable CF to implement the logic to plugin static Folder OIDs based on the context
4	CTSUZ_CONFIG_doSetUserMessages	Updated	Defines all Error message texts and Query texts to display to users
5	CTSUZ_CONFIG_getCentralCRFVer	Updated	This is a study specific utility custom function.Configure the centralStudyCRFVersion in the LPO_CUSTOMIZATION_SECTION
6	CTSUZ_GRP_ROUTE_doRouteDSL	Updated	Routes EC DSL Action to corresponding CF
7	CTSUZ_GRP_ROUTE_doRouteEC	Updated	Routes EC CF action to corresponding CF

4.7 Custom Function Changes in Central Study ALS

Table 10: Rave-CTEP-AERS Integration Custom Function Changes in Central Study ALS

#	Custom Function Name	Type of Change	Comments
1	CTSU_API_RV_doEvaluateAEs	Update	Updated to account for the updated structure in AE and LAE and inclusion of PAE
2	CTSU_API_RV_doInvokeSoapWebService	Update	Updated to implement increased timeout for Rules Evaluation (RE) call from 30 to 120 seconds
3	CTSU_API_RV_doMakeCourseNodeXml	Update	Updated to support PAER RE call
4	CTSU_API_RV_doValidateInputData	Update	Updated to validate PAE form input data
5	CTSU_API_RV_getRequestXmlTemplate	Update	Updated to include a template for PAE input for RE call because course/first cycle date, course start date, and cycle # is not included in the RE call
6	CTSU_GRP_AEUTIL_doBackFillAEEndDate	New	Copies the end date to all cycles if end date is entered for any persistent AE in any cycle
7	CTSU_GRP_AEUTIL_doCopyAERecToThisAE Form	Update	Modified CF to moved get targeted record functionality to CF CTSU_GRP_AEUTIL_GetTargetRecord
8	CTSU_GRP_AEUTIL_doCopyOngoingAEs	Update	No functionality change, re-organized the CF
9	CTSU_GRP_AEUTIL_doDeriveFullAEGradeD esc	Update	PAE form: Updated to support Grade Description AE and LAE forms: Modified to fix issues with

#	Custom Function Name	Type of Change	Comments
			inactive records
10	CTSU_GRP_AEUTIL_doGetAEDpgFromPrevOrNextCyc	Update	No functionality change, re-organized the CF
11	CTSU_GRP_AEUTIL_doGetAllPersistantAEsforThisAE	Update	No functionality change, re-organized the CF
12	CTSU_GRP_AEUTIL_doGetMappedOIDs	Update	Updated to get the PAE mapped OIDs
13	CTSU_GRP_AEUTIL_doGetSortedAEDatapages	Update	Updated to support PAE
14	CTSU_GRP_AEUTIL_doHandlePersistentAEs	Update	No functionality change, re-organized the CF
15	CTSU_GRP_AEUTIL_doProcessAEUpdates	Update	PAE form: Updated to run derivations and open query on the PAER form when AEs are updated on the PAE form AE and LAE forms: Modified to check if current record is active, then update the form. It will derive value for the derived fields and set query in Expedited Reporting forms
16	CTSU_GRP_AEUTIL_doSetAEDetails	Update	PAE form: Updated to do the required derivations AE and LAE forms: Modified to fix copy forward issues for inactive records
17	CTSU_GRP_AEUTIL_doSetAnyOngoingFlagInNextCycle	Update	No functionality change, re-organized the CF
18	CTSU_GRP_AEUTIL_doSetPartailAEDetails	New	Extension of CTSU_GRP_AEUTIL_doSetAEDetails
19	CTSU_GRP_AEUTIL_doSyncAEData	Update	Modified CF to moved copy matched data point functionality to CF CTSU_GRP_AEUTIL_doCopyMatchedDataPoint
20	CTSU_GRP_AEUTIL_GetTargetRecord	New	Extension of CTSU_GRP_AEUTIL_doCopyAERecToThisAEForm to get target record to copy
21	CTSU_GRP_DSL_getAEGradeDesc	Update	Updated to populates Grade Desc or Grade Dynamic Search List (DSL) for PAE form too
22	CTSU_GRP_QUERY_doQueryOnAEDates	Update	Updated to fire queries on PAE form
23	CTSU_GRP_QUERY_doQueryOnAEEval	Update	Updated to fire queries on PAE form
24	CTSU_GRP_QUERY_doQueryOnGrade	Update	PAE form: Updated to fire Grade related queries AE and LAE forms: Modified to fix issues with inactive records
25	CTSU_GRP_QUERY_doSetRVQueryPAE	New	Added to open query on the PAER form if

#	Custom Function Name	Type of Change	Comments
			applicable
26	CTSU_PKG_NAV_TX_AddAEandAERForm	New	Extension of CTSU_PKG_NAV_TX_doInitialization
27	CTSU_PKG_NAV_TX_doInitialization	Update	Updated to call separate CFs to initialize AE and AER forms on rollout
28	CTSU_PKG_NAV_TX_doInitializationAEForm	New	Added to initialize the AE form upon rollout
29	CTSU_PKG_NAV_TX_doInitializationAERForm	New	Added to initialize the AER form upon rollout. Adds AE and AER forms to current instance if they do not exist.
30	CTSU_PKG_RPT_doHandleRptOverride	Update	Modified CF to include the PAE form
31	CTSU_PKG_RV_doCollectAEData	Update	Updated to collect data on the PAE form
32	CTSU_PKG_RV_doCollectCourseData	Update	Updated to collect course data on the PAE form
33	CTSU_PKG_RV_doEvaluateAEs	Update	Updated to evaluate AEs on the PAE form
34	CTSU_PKG_RV_doValidateCourseData	Update	Updated to display error message for PAE form if course data is not valid Updated error message
35	CTSU_ROUTER_doProcessDSL	Update	Updated to display the DSL values in PAE form fields
36	CTSU_ROUTER_doProcessEC	Update	PAE form: Updated to call the required CFs to fire applicable queries AE and LAE forms: Modified to call CTSU_PKG_NAV_doDeriveTAC to derive TAC based on the cycle start date
37	CTSU_GRP_AEUTIL_doProcessPAEUpdates	New	Added to do required derivations and then sets the query in Expedited Reporting Evaluation Form when the PAE form is updated
38	CTSU_API_RV_isAEDataHasChanges	New	Added to check if the AE data has changed in the PAE, AE and LAE forms
39	CTSU_GRP_AEUTIL_doCopyMatchedDataPoint	New	Copy matched datapoint in the record. It is extension method for the CTSU_GRP_AEUTIL_doSyncAEData
40	CTSU_UTIL_IsLastAuditBySysUser	New	Added CF to find if a given data point is modified by system user
41	CTSU_API_RV_doMakeAENodesXml	Update	Updated to include PAE AE data in the xml used in the RE call
42	CTSU_API_RV_doParseResponse	Update	Modified CF to allow special characters in AE verbatim terms and other specify.
43	CTSU_GRP_AEUTIL_doCheckHasOngoingAE	Update	No functionality change, re-organized the CF

#	Custom Function Name	Type of Change	Comments
	s		
44	CTSU_GRP_QUERY_doQueryOnActionTaken	Update	Updated to ignore if the action taken fields are not found on the AE/LAE forms
45	CTSU_GRP_QUERY_doSetRVQuery	Update	Modified CF to reduce RE calls when End date is entered on any copy forward cycles, and to open RE call query on AER form when Start date of first course/cycle is missing
46	CTSU_MIG_doMigrateToNewCTCAEVer	Update	Updated to exclude deleted fields AETERM1 and AETERM2 in the AE and LAE forms
47	CTSU_PKG_NAV_doDeriveTAC	Update	Updated to derive the latest TAC on the AE form from the treatment assignment form based on the cycle start date and Step Event date
48	CTSU_PKG_RV_doCollectData	Update	Modified to collect PAE form data
49	CTSU_PKG_RV_doEnterREResponse	Update	Updated to enter the RE call response in the PAER form
50	CTSU_PKG_RV_doValidateAEData	Update	Modified CF to allow to do RE call when there are no AEs to submit
51	CTSU_UTIL_IsDpDataChanged	Update	Enhanced functionality to find if datapoint is changed, and to avoid grade becoming empty when the record is inactivated and re-activated
52	CTSU_GRP_DSL_getRVRptAction	Update	Updated to populate the DSL on the LAER and PAER form

5. Configuration Requirements

The configurations mentioned below must be completed for new studies using the Rave-CTEP-AERS integration. Studies already activated using the Rave CTEP-AERS integration do not require any configuration changes.

5.1 PAE/AE/LAE Standard Forms Adaptation Guidelines

The LPO ALS and Central Study ALS released in version 7.1 will support the following study setups:

1) Use PAE/AE/LAE standard forms along with PAER/AER/LAER when implementing the Rave-CTEP-AERS Integration to support collection of Pre-Treatment AEs and Persistent AEs:
   a) include PAE and PAER if protocol requires collection of Pre-Treatment AEs
   b) include Start Date, End Date and Ongoing Flag (to comply with the NCI Start Date guideline); collection of these fields is expected for FDA Registration trials
2) Use PAE/AE/LAE standard forms but not PAER/AER/LAER (when using the AE forms without the Rave-CTEP-AERS Integration).

These setups can be further configured to support solicited AEs or non-solicited AEs. By default the ALS is configured to support collection of solicited AEs.

This section provides guidelines for the basic configuration needed for all supported study setups, guidelines for each individual setup, and additional configuration for solicited AEs.

5.1.1 Basic Configuration for All Studies Using PAE/AE/LAE Standard Forms

1) Make either the *CTCAE grade and description of toxicity* or the *CTCAE grade* field is visible, but not both.
2) The following CTSU standard forms are needed in your study for the Rave-CTEP-AERS Integration:
   a) CTSU_AE
   b) CTSU_LAE
   c) CTSU_AER
   d) CTSU_LAER
3) If your study is required to collect Pre-Treatment AEs, following CTSU standard forms must be used for the Rave-CTEP-AERS Integration:
   a) CTSU_PAE
   b) CTSU_PAER

Refer to Appendix I: Rave-CTEP-AERS Forms Definition

4) The following CTSU Forms are **not** needed in your study for the Rave-CTEP-AERS Integration:
   a) CTSU_DEMOGRAPHY
   b) CTSU_STEP_INFORMATION
   c) CTSU_SUBJECT_ENROLLMENT
   d) CTSU_TREATMENT_ASSIGNMENT

e) CTSU_PATIENT_INFORMATION
f) CTSU_EVENT_BSL
g) CTSU_EVENT_TX
h) CTSU_EVENT_FUP

5) The following CTSU Derivations are needed in your study:
   a) CTSU_Cycle1_StartDate
   b) CTSU_Form_Date
6) The following CTSU ECs are needed in your study:
   a) CTSU_GRP_AEDSL_Grade
   b) CTSU_GRP_AEDSL_GradeDesc
   c) CTSU_GRP_QUERY_PAE (required for PAE form)
   d) CTSU_GRP_QUERY_AE
   e) CTSU_IND_AE_DeriveCourse1StartDate
   f) CTSU_GRP_QUERY_LAE
   g) CTSU_IND_LAE_DeriveCourse1StartDate
   h) CTSU_IND_LAE_doQueryNoReportingPeriodDate
7) The following CTSU ECs are not needed for non-integrated studies:
   a) CTSU_GRP_AERDSL_RecomAction
   b) CTSU_PKG_RV_AER
   c) CTSU_PKG_RV_AER_doHandleRptOverride
   d) CTSU_PKG_RV_LAER
   e) CTSU_PKG_RV_LAER_doHandleRptOverride
   f) CTSUZ_PKG_NAV_LateAEYN_trigger
   g) CTSU_PKG_RV_PAER
   h) CTSU_PKG_RV_PAER_doHandleRptOverride
8) Update the CF CTSUZ_CONFIG_getCentralCRFVer with the version number of the LPO Central Study. Central Study v7.1 must be used with CTSU Standard Forms ALS v7.1.
9) All the Query Texts and Error Messages are standardized. However, if there is a need to update the user messages then update the CF CTSUZ_CONFIG_doSetUserMessages to match the LPO study setup. Messages should be updated if the LPO uses the *CTCAE grade* field instead of the *CTCAE grade and description of toxicity field*.
10) Make necessary code changes to the CF and specify the appropriate input parameters to invoke the Central Study CF CTSU_PKG_NAV_TX_doInitialization when the AE form is rolled out.
11) Make necessary code changes such that when the LAE Form is rolled out, then the Central Study CF CTSU_PKG_NAV_FUP_doInitialization is invoked with input of appropriate parameters.

a) The CF CTSU_PKG_NAV_FUP_doInitialization has the *string startDateOfFirstCourse* added as a 5th parameter. This is an optional parameter.

12) On the LAE form, the Reporting period end date does not have the check for non-conformant setup at the field level in Architect. If a non-conformant date is entered, the non-conformant icon appears. If a non-conformant query is needed, non-conformant field check must be setup in Architect.

13) Field *Required intervention (device)* (OID: SUPPAE_QVAL_AESINTV) is for device trials only and should be hidden for non-device trials.

14) On the PAE form, TAC-0 is the default value. During study build, LPOs can configure Pre-Treatment TAC as defined in the protocol. To allow an update to the default TAC value TAC-0 on the PAE form in Rave EDC, user with Power User role must be granted permission. Entry Restriction for the TAC field must be removed for the Power User role.

15) The ALS v7.1 provides standard configuration to roll out the Course/Cycle folder containing the AE and AER forms, and the Follow-up folder which contains the LAE and LAER forms. There is a known issue with Central Study CF CTSU_PKG_NAV_TX_doInitialization where the AE forms don't roll out when LPOs use their own navigation package and calls the Central Study CF CTSU_PKG_NAV_TX_doInitialization. CTSU plans to address this issue in a Central Study patch to be released in the future (date TBD). If LPOs decide to use their own navigation package to rollout the AE, AER, LAE and LAER forms, and that navigation package calls the Central Study CF CTSU_PKG_NAV_TX_doInitialization, the following modification highlighted in yellow must be made to the Central Study CF until the Central Study patch is deployed. The LPO specified the navigation package must be tested to ensure the forms rollout as expected.

```
int crfVersionId = subThis.CRFVersionID;
eL.AppendLine("Sub");

eL.AppendLine(String.Format("Fetch AE Form:", FORM_AE));
//DataPage dpgAE = instanceCur.DataPages.FindByFormOID(FORM_AE);  // Comment this line and move to the highlighted place.
//Add AE and AER forms if not exists.
CustomFunction.PerformCustomFunction(CF_ADD_AE_AER, centralCrfVer, ThisObject);

DataPage dpgAE = instanceCur.DataPages.FindByFormOID(FORM_AE);

if (dpgAE != null)
{
  //Initialize AE form
  CustomFunction.PerformCustomFunction(CF_INITIALIZE_AE_FORM, centralCrfVer, ThisObject);
```

5.1.2 Configuration for Studies Using the PAE/AE/LAE Standard Forms with PAER/AER/LAER for the Rave-CTEP-AERS Integration and Features to Support Pre-Treatment AEs, Persistent AEs, Start Date, End Date and Ongoing Flag (To Support NCI Start Date Guideline)

According to the CTEP Guidance for Recording Adverse Event Start and End Date in Rave, as of February 1, 2018 all CTEP-IND Registration trials are required to collect the AE Start/End Date to distinctively collect AEs and therefore must use this configuration. LPOs may decide not to use this configuration and continue to collect maximum grade AEs for non-registration trials.

1) Add the following fields to the PAE/AE/LAE forms:
   a) AE_AESTDAT
   b) AE_AEENDAT
   c) AE_AEONGO
   d) AEONGOP (AE/LAE)
   e) AEONGOC (AE/LAE)

FormOID	FieldOID	IsVisible
CTSU_AE	AEONGOP	TRUE
CTSU_AE	AE_AESTDAT	TRUE
CTSU_AE	AE_AEENDAT	TRUE
CTSU_AE	AE_AEONGO	TRUE

Figure 3: Fields on PAE/AE/LAE Forms Set to Visible

5.1.3 Configuration for Studies Using the PAE/AE/LAE Standard Forms with PAER/AER/LAER for the Rave-CTEP-AERS Integration (To Support Non-Registration Trials where Start Date and End Date Collection is Not Required)

According to the NCI Start Date guideline, all CTEP IND studies are required to use this configuration.

1) Set the following fields *IsVisible* property to *False*:
   a) AE_AESTDAT
   b) AE_AEENDAT
   c) AE_AEONGO

FormOID	FieldOID	IsVisible
CTSU_AE	AE_AESTDAT	FALSE
CTSU_AE	AE_AEENDAT	FALSE
CTSU_AE	AE_AEONGO	FALSE

Figure 4: Fields on PAE/AE/LAE Forms Set to Invisible

2) Make the following fields inactive:
   a) AEONGOP
   b) AEONGOC

5.1.4 Configuration for Studies using the PAE/AE/LAE Standard Forms but NOT PAER/AER/LAER (No Rave-CTEP-AERS Integration)

LPOs can still use the standard PAE, AE and LAE Forms for studies that do not use the Rave-CTEP-AERS integration.

1) Remove the following forms from the study draft:
   a) CTSU_PAER
   b) CTSU_AER
   c) CTSU_LAER
2) Remove the following edit checks associated to the PAER, AER and LAER Forms from the study draft:
   a) CTSU_PKG_RV_PAER
   b) CTSU_PKG_RV_PAER_doHandleRptOverride
   c) CTSU_GRP_AERDSL_RecomAction
   d) CTSU_PKG_RV_AER
   e) CTSU_PKG_RV_AER_doHandleRptOverride
   f) CTSU_PKG_RV_LAER
   g) CTSU_PKG_RV_LAER_doHandleRptOverride

5.1.5 Configuration to Remove Solicited AEs

1) Delete all of the CTC_AE_500_CODE_1_0F and the CTC_AE_500_TERM_1_0F dictionary entries.
   a) Under Dictionaries select the dictionary that you will be editing.
   b) Click on entries.
   c) Click edit and delete all the dictionary entries.

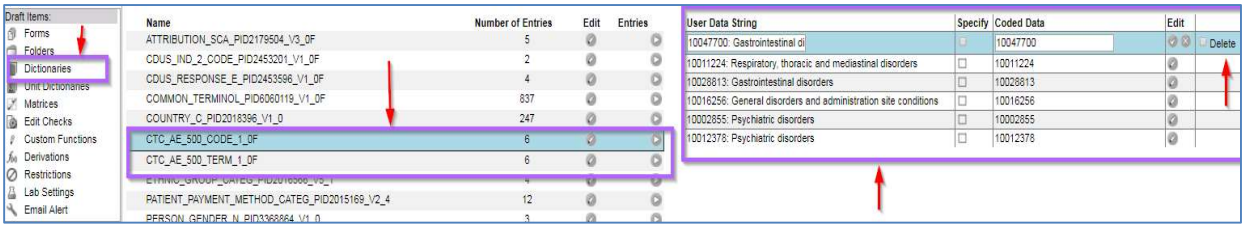

Figure 5: Configuration to Remove Solicited AEs

Note: The data dictionary can also be removed in ALS before uploading in Rave.

5.1.6 Configuration to Add Solicited AEs

1) Update the CTC_AE_500_TERM_1_0F dictionary and CTC_AE_500_CODE_1_0F dictionary entries to include the study-specific solicited AEs.

   a) Under Dictionaries select the dictionary that you will be editing.

   b) Click on entries.

   c) Click on Add Entry to add all the study-specific dictionary entries.

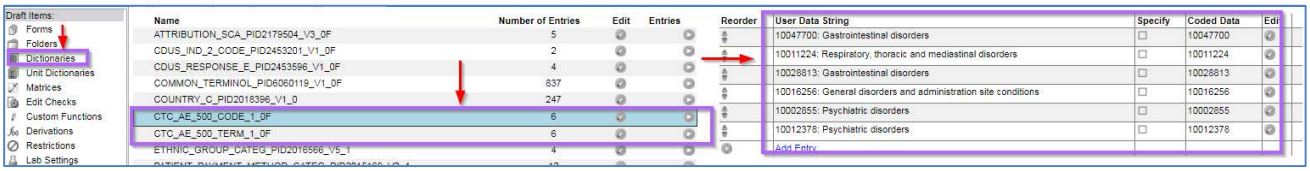

Figure 6: Configuration to Add Solicited AEs

6. Rave-CTEP-AERS Expected Behavior

Below is a list of scenarios for expected behavior in ALS v7.1:

1) Persistent AEs added after many later cycles of AEs have been rolled out will be copied only to the next cycle. It will not be copied recursively to all rolled out AE forms in later cycles.
    - Recursive copy is not implemented because of performance concerns.
    - The AE End Date field by default remains untouched in the next cycle after the AE is copied. This will enforce the user to save the form again at some later point in time, which would then copy the copied Persistent AE to the next cycle. The user will have to repeat this action for all later cycles, to which the persistent AE should be copied, one AE Form at a time.
2) When a query on the AER Form is manually cancelled, the AER Form query will not open again. This is expected behavior in Rave. Recommendation is not to manually close the query.
3) When an AE copied from a previous cycle is inactivated in the current cycle, and the AE has not ended in the previous cycles, then the AE is copied again to a new log line in the current cycle.
4) When an AE copied from a previous cycle is inactivated in the current cycle, it cannot be reactivated again.
5) A combination of special characters '#&' is not allowed in Rave for text fields.

7. CTSU Standard Forms ALS v7.1 Known Issues

CTSU is looking into these issues and expects to do a Central Study update to address these issues.

1. On AE Form, if response to question *CTCAE grade and description of toxicity* for any AE is any value except *(0) None*, and all patient outcome questions (Hospitalization, Life-threatening, Death, Disability, Congenital anomaly/birth defect, and Other) except *Death* are answered, the below query will not open.
   - If *CTCAE Grade* is > 0, then each of the patient outcomes should be answered YES/NO. Please reconcile.[QC015]

2. On AE Form, if response to question *CTCAE grade and description of toxicity* is *(5) Death* for any AE, the below queries will not open.
   - If *CTCAE Grade* is > 0, then Adverse Event *Start Date* is required.[QC021]
   - The *Adverse Event End Date* cannot be before the Adverse Event *Start Date*. Please reconcile.[QC022]
   - *AE Start Date* is prior to the start date of this course/cycle. Please reconcile.[QC024]

Appendix I: Rave-CTEP-AERS Forms Definition

To implement the Rave-CTEP-AERS integration, a Rave study must include the following six standard forms (FORM_OID):

1) PAE (CTSU_PAE)
2) PAER (CTSU_PAER)
3) AE (CTSU_AE)
4) AER (CTSU_AER)
5) LAE (CTSU_LAE)
6) LAER (CTSU_LAER)

These standard forms, along with several ECs and CFs, enable Rave studies to integrate with the CTEP-AERS safety reporting system. These form fields and a description of each are provided in the subsections below.

Pre-Treatment Adverse Events Form

The PAE form is used to collect AE data that occurs after the patient signs the informed consent but before treatment starts.

Table 11: Pre-Treatment Adverse Events Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	*Form Instructions*	This field is used to display the instructions for this form in the help text. Help text is: • The purpose of this form is to capture adverse events occurring after the subject has signed an informed consent but for whom treatment has not yet started. An example might be a protocol where a subject's eligibility can only be determined after the results of a biopsy are known. • This form should not be used to capture baseline abnormalities which the subject presented with at the initial study visit. These conditions which pre-date the subject's involvement with the study but which may be continuing will need to be entered on a baseline or other form. • Pre-treatment adverse events are not associated with any treatment and hence will not have a course/cycle start date. • Adverse events persisting from pre-treatment to cycle 1 treatment will be ended on the pre-treatment form and re-started on cycle 1 AE form. (No copy forward). • Click here to link to the User Guide.
NOTE2 / NOTE2	* Red asterisk before a field denotes that it is required by the system for rules evaluation.	N/A
SUPPAE_QVAL_CYCLNUM / Treatment Cycle Number PID2744948_V1_0	Course/Cycle #	The course/cycle # is defaulted to 0 in this field. This field is not visible.
TAC / Treatment Assignment Code PID1967_V4_0	Treatment assignment code (TAC) (derived)	The Treatment Assignment Code in this field is defaulted to TAC-0. This field is entry restricted to Clinical Research Associate (CRA).

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE3 / NOTE3	REMINDER: 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 bottom right corner of the table. If these options are not available, you are already viewing the entire table.	N/A
AE_AETERM / Adverse Event Reported Term PID6338308_V1_0	Adverse event (verbatim term)	Optional field in Rave. Required field in CTEP-AERS. CTEP-AERS will show an alert: *Missing: Verbatim* if the CRA tries to save the report without a verbatim term. If entered in Rave, is pushed to CTEP-AERS and displayed on CTEP-AERS User Interface (UI) when the AEs are sent for evaluation. CRA can enter the Verbatim term in CTEP-AERS if it is not entered in Rave.
SUPPAE_QVAL_CTCAE / Common Terminology Criteria for Adverse Events Version 5.0 Low Level Term Name PID6063560_V1_0	* Adverse event term (CTCAE v5.0)	This is required by the CTEP-AERS rules evaluation service. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
SUPPAE_QVAL_CTCAECD / Common Terminology Criteria for Adverse Events Version 5.0 Mapped Low Level Term MedDRA Code PID6063561_V1_0	* MedDRA AE code (CTCAE v5.0) (derived)	This is derived when the form is saved. This is required by the CTEP-AERS rules evaluation service. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. CRA cannot edit this field.
AEPERF / Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0_1	* Adverse event evaluated in the PRE-TREATMENT period	This field is invisible. The value is defaulted to *Yes.* It is used for internal purposes.
AETOX1 / Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0_1	CTCAE grade and description of toxicity (first 120 characters)	This displays a list of (numeric) descriptive grades associated with the AE. This displays only the first 120 characters of the descriptive grade to limit the width of the page.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AE_AETOXGR / Adverse Event Toxicity Grade PID6338618_V1_0_2	CTCAE grade (derived)	This is derived when the form is saved. This is the numeric grade (no text) derived from the grade selected by the CRA. This is pushed to CTEP-AERS. The grade and the grade description are displayed on CTEP-AERS UI when the AEs are sent for evaluation. It is used for internal purposes.
AETOXGR1 / Adverse Event Toxicity Grade PID6338618_V1_0_1	CTCAE grade	This displays a list of numeric grades associated with the selected AE. LPOs should only use the *Adverse event grade description (first 120 characters)* field or this field, but not both. CTSU recommends using the *Adverse event grade description (first 120 characters)* field. This field is the better option when the form is in landscape mode to reduce page width. LPOs must hide the field by unchecking *Is visible field* if not used and set view restriction for all roles.
AE_AETOX / Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0_2	CTCAE grade and description of toxicity (derived)	This is derived when the form is saved. This will display the full grade description. CRA cannot edit this field. LPOs can *View Restrict* this field to the CRA.
AE_AESTDAT / Adverse Event Start Date PID6341142_V1_0	Start date	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. This is required for the primary AE when the report is initiated in CTEP-AERS. If not collecting AE Start Date, LPOs should set *Invisible* and *View Restrict* this field to the CRA.
AE_AEENDAT / Adverse Event End Date PID6340298_V1_0	End date	LPOs should set *Invisible* and *View Restrict* this field to the CRA if the AE *Start Date* field is view restricted.
AE_AEONGO / Ongoing Adverse Event PID6343381_V1_0	Ongoing (derived)	This is used for internal purposes. This is view restricted to all EDC roles.
AE_AESHOSP / Initial or Prolonged Hospitalization PID6343376_V1_0	Hospitalization (initial or prolonged)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESLIFE / Is Life Threatening PID6343380_V1_0	Life threatening	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESDTH / Results in Death PID6343382_V1_0	Death	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AE_AESDISAB / Disability or Permanent Damage PID6343379_V1_0	Disability or permanent damage	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESCONG / Congenital Anomaly or Birth Defect PID6343378_V1_0	Congenital anomaly or birth defect	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
SUPPAE_QVAL_AESINTV/ Requires Intervention Device PID 6379837_V1_0	Required intervention (device)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESMIE / Other Medically Important Serious Event PID6343377_V1_0	Other serious (important medical events)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESPID / Adverse Event Sponsor-Defined Identifier PID6379804_V1_0	* AE number (derived)	This is derived when the form is saved. This is a unique ID assigned to each AE. This is pushed to CTEP-AERS when the AEs are sent for evaluation. CRA cannot edit this field.
SUPPAE_QVAL_SAERPT / SAE report recommended PID6824777_V1_0	SAE report recommended (derived)	This is derived after the CRA sends the AE to CTEP-AERS for evaluation. This is set to *Yes* if CTEP-AERS recommends a report. Otherwise, it's set to *No*. CRA cannot edit this field.
AE_AEDTC / Adverse Event First Awareness Occurrence Date PID4358131_V1_0	* Date/Time of collection (derived)	This is derived and indicates the first date/time the AE log line is entered and form saved. CRA cannot edit this field.
AEZONE / Address Time Zone Name PID3014791_V1_0	* Time zone (derived)	This is derived when the form is saved. Used to collect calculations of *Report Due By* by time zone. CRA cannot edit this field.
SUBMITBY / Submitted by PID6783868_V1_0	* Submitted by (derived)	This is derived when the form is saved. This displays the email address of the CRA. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI (as the Reporter) when the AEs are sent for evaluation. CRA cannot edit this field.
AEPERF1 / Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0_1_2	Evaluated (derived)	This is used for internal purposes. This is view restricted to all EDC roles.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE4 / NOTE4	INSTRUCTIONS: When entering new or modifying existing data in this form remember to resubmit the changes to CTEP-AERS for rules evaluation by completing and saving the Pre-Treatment Expedited Reporting Evaluation form in Rave	N/A
CO_COVAL / Comment PID6355806_V1_0	AE comment	Help text: *Maximum of 200 characters allowed*
AEFRMDTC / Form Date PID6783869_V1_0	Form date (derived)	Current date and time is added to this field when the form is saved. This is used for internal purposes. This is view restricted to the CRA.

Pre-Treatment Expedited Reporting Evaluation Form

The PAER Form is used to send PAE Form data to CTEP-AERS for evaluation. All LPOs that need to send the PAE data to CTEP-AERS for evaluation are expected to use this form. LPOs that do not need to send their PAE data to CTEP-AERS for evaluation can use the form level restrictions to view restrict the form, so it does not display in Rave EDC.

Table 12: Pre-Treatment Expedited Reporting Evaluation Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	*Form Instructions*	This variable is used to display the instructions for this form in the help text. Help text is: • This form is used to send AEs recorded in the *Pre-Treatment Adverse Events* form to rules evaluation to determine if expedited reporting is recommended. • Select the check box *Send all AEs for evaluation* and save the form. • Items denoted with a * are required for rules evaluation. Note that the evaluation of the adverse events will not occur if the Adverse Events form has one or more queries or missing items.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		• Following the evaluation of the AEs, if the *Recommended action for report* is NONE but the investigator chooses to report the AE in CTEP-AERS, then select the hyperlink. Click this link to complete the safety report to launch CTEP-AERS and complete the safety report. In this scenario, do not change the *Recommended action for report* to CREATE rather leave as NONE. • Following the evaluation of the AEs, if the *Recommended action for report* is CREATE but the investigator chooses not to report the AE in CTEP-AERS, then change the Recommended action for report to NONE. • When the evaluation of the AEs is complete, a unique Report ID *(derived)* will be displayed on the form. This Report ID **is not** the same as Ticket Number in CTEP-AERS. Instead the Report ID acts as the link between Rave and CTEP-AERS and can be used instead of Ticket Number when managing reports in CTEP-AERS.
NOTE2 / NOTE2	A delay is expected when the safety system is called for AE evaluation. Notes: 1) 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 events are entered on the same ticket. 2) All queries on this form will be closed automatically by the system once the form is saved. DO NOT add a comment or close queries manually.	N/A
AENTERR / Note/Error	Note/Error	This displays notes/error messages when there is an error with the AE data sent to CTEP-AERS and/or the

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		rules evaluation Service. CRA cannot edit this field.
AESEVL / Send all AEs for evaluation	Send all AEs for evaluation	A query is displayed on this field when AEs are entered or updated on the PAE form, and they have to be sent to CTEP-AERS for evaluation. This has to be checked and the form saved to send the AEs to CTEP-AERS rules evaluation service.
SUPPAE_QVAL_AERPACN / Recommended action for report PID6819760_V1_0_1	Recommended action for report	This is a derived field. This displays the recommended action when AEs are sent to CTEP-AERS for Evaluation. It is used for internal purposes. This is view restricted to the CRA.
AERPACN1 / Recommended action for report PID6819760_V1_0_2	Recommended action for report	This is a derived field. This displays the recommended action when AEs are sent to CTEP-AERS for evaluation. It displays options to under or over report the AEs by including: • NONE when the recommended action is CREATE. • CREATE when the recommended action is NONE. This will display a sticky note after AEs are sent to CTEP-AERS for evaluation. The sticky note displays a report action specific custom message and a link. The custom message will ask the user to use the link to navigate to CTEP-AERS and complete the Safety Report. The link is a context sensitive deep link to CTEP-AERS, navigating the user directly to the particular report.
AE_AEREFID / Reference ID PID6355961_V1_0	Report ID (derived)	This is a derived field. This displays the unique Report ID created by CTEP-AERS when the AEs are sent to it for evaluation. CRA cannot edit this field.
SUPPAE_QVAL_AERPTP / Recommended report type PID6819761_V1_0	Recommended report type	This is a derived field. This displays the recommended report when the AEs are sent to CTEP-AERS for evaluation and a report is recommended. This field does not display if recommended action is NONE. CRA cannot edit this field.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AERPDTC / Report due by	Report due by	This is a derived field. This displays the report due by date when AEs are sent to CTEP-AERS for evaluation. This does not display if the recommended action is NONE. CRA cannot edit this field.
AEFRMDTC / Form Date PID6783869_V1_0	Form date (derived)	This is derived when the form is saved. This is view restricted to the CRA.

Adverse Events Form

The AE Form is used to collect AE data during a patient's treatment course/cycle. All LPOs are expected to use this form to collect AE data for **new** studies, activated after February 1, 2018.

Table 13: Adverse Events Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	*Form Instructions*	This field is used to display the instructions for this form in the help text. Help text is: This form contains both solicited and unsolicited AEs. • Solicited AEs are those events expected per protocol. • Solicited AEs are defaulted on this form and denoted by a check mark. • Unsolicited AEs can be added by clicking the *Add a new Log line*. • Trials using the Reporting period end date field should enter an end date when all AEs have been reported for this cycle. • If ongoing AEs were derived from the previous cycle, please confirm they are still ongoing. If still ongoing, save the log line for each ongoing AE by selecting the AE term and save the form. If they are not ongoing, enter the end date and save the form. Click here to link to the User Guide.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE2 / NOTE2	* Red asterisk before a field denotes that it is required by the system for rules evaluation.	N/A
SUPPAE_QVAL_CYCLNUM / Treatment Cycle Number PID2744948_V1_0	* Course/Cycle # (derived)	The course/cycle # is derived to this field when the form is rolled out. LPOs can modify a CF in their study build to calculate this number. This course/cycle # is required by the CTEP-AERS rules Evaluation Service. This course/cycle # is pushed to CTEP-AERS and is displayed on the CTEP-AERS UI. The CRA cannot edit this field in Rave.
SUPPAE_QVAL_CYCENDAT / Treatment Reporting Period End Date PID2992_V4_0	Reporting period end date	This field is not used by most LPOs and hence is optional (may be hidden). If using this field, LPOs will need to make it required.
SUPPAE_QVAL_CYCSTDAT / Intervention Occurrence Begin Date PID3028744_V1_0	* Start date of this course/cycle	This date is required by the CTEP-AERS rules evaluation Service. This date is pushed to CTEP-AERS and is displayed on CTEP-AERS UI when the AEs are sent for rules evaluation.
SUPPAE_QVAL_FCYSTDAT / Treatment First Cycle Begin Date PID61298_V3_0	* Start date of first course/cycle (derived)	When the AE is in the first cycle, the *Start date of this course/cycle* is derived to this field when the form is saved. This *Start date of this course/cycle* is derived to this field when the AE form is rolled out for subsequent cycles. When the *Start date of this course/cycle* of the first active cycle is updated, this date is updated in all subsequent AE forms/cycles. If the AE in the first cycle is not rolled out, this date should be derived from an LPO selected field on a form other than the AE form. This date is required by the CTEP-AERS rules evaluation service. This date is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. The CRA role cannot edit this field in Rave.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
TAC / Treatment Assignment Code PID1967_V4_0	* Treatment assignment code (TAC) (derived)	This Treatment Assignment Code (TAC) is derived from the Oncology Patient Enrollment Network (OPEN) Enrollment *Treatment Assignment* Form when the form is rolled out. This data is required by the CTEP-AERS rules evaluation Service. This data is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
NOTE3 / NOTE3	REMINDER: 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 bottom right corner of the table. If these options are not available, you are already viewing the entire table.	N/A
AEONGOP / Prior Cycle Adverse Event Ongoing Indicator PID6041428_V1_0	Were any AEs reported as ongoing in the previous cycle? (derived)	This field is derived to *Yes* when there are ongoing AEs in the previous cycle. Field is hidden to the CRA role.
AEONGOC / Prior Cycle Ongoing Adverse Event Ongoing Indicator PID6041430_V1_0	Should ongoing AEs from the previous cycle be copied to this form?	This field is displayed when there are ongoing AEs in the previous cycle AE form. Answering *Yes* to this field and saving the form copies ongoing AEs from the previous cycle AE form to this cycle AE form.
AE_AETERM / Adverse Event Reported Term PID6338308_V1_0	Adverse event (verbatim term)	Optional field in Rave. Required field in CTEP-AERS. CTEP-AERS will show an alert: *Missing: Verbatim* if the CRA tries to save the report without a verbatim term. If entered in Rave, is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. CRA can enter the Verbatim term in CTEP-AERS if it is not entered in RAVE.
AE_AEPRESP / Adverse Event Pre-Specified PID6379825_V1_0	Pre-specified adverse event (derived)	This is derived when the form is rolled out. This box is checked for solicited AEs and left unchecked for unsolicited AEs. CRA cannot edit this field.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
SUPPAE_QVAL_CTCAE / Common Terminology Criteria for Adverse Events Version 5.0 Low Level Term Name PID6063560_V1_0	* Adverse event term (CTCAE v5.0)	Solicited AEs are defaulted and soft locked when the form is rolled out. This is enterable for unsolicited AEs. If solicited, the AE terms listed in the CTC_AE_500_TERM_1_0F dictionary are added to this field. CTC_AE_500_TERM_1_0F dictionary entries should be deleted if the study does not collect solicited AEs. This is required by the CTEP-AERS rules evaluation service. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
SUPPAE_QVAL_CTCAECD / Common Terminology Criteria for Adverse Events Version 5.0 Mapped Low Level Term MedDRA Code PID6063561_V1_0	* MedDRA AE code (CTCAE v5.0) (derived)	This is derived for unsolicited AEs only when the form is saved. If solicited, the AE Codes listed in the CTC_AE_500_CODE_1_0F dictionary are added to this field. The coded data of the CTC_AE_500_TERM_1_0F and CTC_AE_500_CODE_1_0F dictionaries should match. CTC_AE_500_CODE_1_0F dictionary entries should be deleted if the study does not collect solicited AEs. This is required by the CTEP-AERS rules evaluation service. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. CRA cannot edit this field.
AEPERF / Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0_1	* Adverse event evaluated this cycle	This value is defaulted to *Pending* for solicited AEs when the form is rolled out. CRA must update this to Yes/No for solicited AEs. This value is defaulted to *Yes* when unsolicited AEs are added. CRA should not update the defaulted value *Yes* for unsolicited AEs.
AETOX1 / Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0_1	* CTCAE grade and description of toxicity (first 120 characters)	This displays a list of (numeric) descriptive grades associated with the AE. This displays only the first 120 characters of the descriptive grade to limit the width of the page. Grade description of *(0) None* will only be on the list for solicited AEs.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AE_AETOXGR / Adverse Event Toxicity Grade PID6338618_V1_0_2	CTCAE grade (derived)	This is derived when the form is saved. This is the numeric grade (no text) derived from the grade selected by the CRA. This is pushed to CTEP-AERS. The grade and the grade description are displayed on CTEP-AERS UI when the AEs are sent for evaluation. It is used for internal purposes. Label is blank because LPOs should *View Restrict* this field to the CRA.
AETOXGR1 / Adverse Event Toxicity Grade PID6338618_V1_0_1	CTCAE grade	This displays a list of numeric grades associated with the selected AE. Grade 0 will only be available for solicited AEs to indicate evaluated-not present. LPOs should only use the *Adverse event grade description (first 120 characters)* field or this field, but not both. CTSU recommends using the *Adverse event grade description (first 120 characters)* field. This field is the better option when the form is in landscape mode to reduce page width. LPOs must hide the field by unchecking *Is visible field* that is not used and set view restriction for all roles.
AE_AETOX / Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0_2	CTCAE grade and description of toxicity (derived)	This is derived when the form is saved. This will display the full grade description. CRA cannot edit this field. LPOs can *View Restrict* this field to the CRA.
AE_AESTDAT / Adverse Event Start Date PID6341142_V1_0	Start date	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. This is required for the primary AE when the report is initiated in CTEP-AERS. If not collecting AE Start Date, LPOs should set *Invisible* and *View Restrict* this field to the CRA.
AE_AEENDAT / Adverse Event End Date PID6340298_V1_0	End date	LPOs should set *Invisible* and *View Restrict* this field to the CRA if the AE *Start Date* field is view restricted.
AE_AEONGO / Ongoing Adverse Event PID6343381_V1_0	Ongoing (derived)	This is a derived field. Derives to *YES* if *End Date* is not entered. Derives to NO if *End Date* is entered. LPOs should set *Invisible* and *View Restrict* this field to the CRA if the AE *Start Date* field is view restricted.
AE_AEREL / CTC Adverse Event Attribution Scale PID 1285_V3_0	Attribution to study treatment	This field has a dropdown with attribution scale.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AE_AESHOSP / Initial or Prolonged Hospitalization PID6343376_V1_0	Hospitalization (initial or prolonged)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESLIFE / Is Life Threatening PID6343380_V1_0	Life threatening	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESDTH / Results in Death PID6343382_V1_0	Death	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESDISAB / Disability or Permanent Damage PID6343379_V1_0	Disability or permanent damage	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESCONG / Congenital Anomaly or Birth Defect PID6343378_V1_0	Congenital anomaly or birth defect	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
SUPPAE_QVAL_AESINTV/ Requires Intervention Device PID 6379837_V1_0	Required intervention (device)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESMIE / Other Medically Important Serious Event PID6343377_V1_0	Other serious (important medical events)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AEACN / Action Taken with Study Treatment PID6366035_V1_0	Action taken with study treatment	Variable AE_AEACN to capture study treatment action is setup as invisible in ALS 7.1. This variable is required for SDTM reporting and should be included in the dataset for reporting. Variable AE_AEACN should be used to capture a single study treatment action. To capture AE Action at the agent level, new custom variables (AEACN1, AEACN2, AEACN3) should be added for each agent and the labels for these fields can be agent specific such as Action taken (Agent 1), Action taken (Agent 2).
AE_AESPID / Adverse Event Sponsor-Defined Identifier PID6379804_V1_0	* AE number (derived)	This is derived when the form is saved. This is a unique ID assigned to each AE. This is pushed to CTEP-AERS when the AEs are sent for evaluation. CRA cannot edit this field.
SUPPAE_QVAL_SAERPT / SAE report recommended PID6824777_V1_0	SAE report recommended (derived)	This is derived after the CRA sends the AE to CTEP-AERS for evaluation. This is set to *Yes* if CTEP-AERS recommends a report. Otherwise, it's set to *No*. CRA cannot edit this field.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AE_AEDTC / Adverse Event First Awareness Occurrence Date PID4358131_V1_0	* Date/Time of Collection (derived)	This is derived and indicates the first date/time the AE log line is entered and form saved. CRA cannot edit this field.
AEZONE / Address Time Zone Name PID3014791_V1_0	* Time zone (derived)	This is derived when the form is saved. Used to collect calculations of *Report Due By* by time zone. CRA cannot edit this field.
SUBMITBY / Submitted by PID6783868_V1_0	* Submitted by (derived)	This is derived when the form is saved. This displays the email address of the CRA. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI (as the Reporter) when the AEs are sent for evaluation. CRA cannot edit this field.
AEPERF1 / Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0_2	Evaluated (derived)	This is used for internal purposes. This is view restricted to all EDC roles.
NOTE4 / NOTE4	INSTRUCTIONS: When entering new or modifying existing data in this form remember to resubmit the changes to CTEP-AERS for rules evaluation by completing and saving the Expedited Reporting Evaluation form in Rave.	N/A
CO_COVAL / Comment PID6355806_V1_0	AE comment	N/A
AEFRMDTC / Form Date PID6783869_V1_0	Form date (derived)	Current date and time is added to this field when the form is saved. This is used for internal purposes. This is view restricted to the CRA.
ENDDTBYSYS / End date modified by system user	Is end date modified by system user?	This is used for internal purposes. This is view restricted to all EDC roles.

Expedited Reporting Evaluation Form

The AER Form is used to send AE Form data to CTEP-AERS for evaluation. All LPOs that need to send the AE data to CTEP-AERS for evaluation are expected to use this form. LPOs that do not need to send their AE data to CTEP-AERS for evaluation can use the form level restrictions to view restrict the form, so it does not display in the Rave EDC.

Table 14: Expedited Reporting Evaluation Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	*Form Instructions*	This variable is used to display the instructions for this form in the help text. Help text is: • This form is used to send AEs recorded in the *Adverse Events* form to rules evaluation to determine if expedited reporting is recommended. • Select the check box *Send all AEs for evaluation* and save the form. • Items denoted with a * are required for rules evaluation. Note that the evaluation of the adverse events **will not** occur if the *Adverse Events* form has one or more queries or missing items. • Following the evaluation of the AEs, if the *Recommended action for report* is NONE but the investigator chooses to report the AE in CTEP-AERS, then select the hyperlink *Click this link to complete the safety report* to launch CTEP-AERS and complete the safety report. In this scenario, **do not** change the *Recommended action for report* to CREATE rather leave as NONE. • Following the evaluation of the AEs, if the *Recommended action for report* is CREATE but the investigator chooses **not** to report the AE in CTEP-AERS, then change the *Recommended action for report to* NONE. • When the evaluation of the AEs is complete, a unique *Report ID (derived)* will be displayed on the form. This Report ID **is not** the same as Ticket Number in CTEP-AERS. Instead the Report ID acts as the link between Rave and CTEP-AERS and can be used instead of Ticket Number when managing reports in CTEP-AERS.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE2 / NOTE2	A delay is expected when the safety system is called for AE evaluation. Notes: 1) Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious AE occurs this course/cycle, amend the report so both events are entered on the same ticket. 2) All queries on this form will be closed automatically by the system once the form is saved. DO NOT add a comment or close queries manually.	N/A
AENTERR / Note/Error	Note/Error	This displays notes/error messages when there is an error with the AE data sent to CTEP-AERS and/or the rules evaluation Service. CRA cannot edit this field.
SUPPAE_QVAL_CYCLNUM / Treatment Cycle Number PID2744948_V1_0	Course/Cycle # (derived)	The cycle # is added to this field when the form is rolled out. This cycle # is required for the CTEP-AERS rules evaluation Service. LPOs can *View Restrict* this field to the CRA and delete the field label.
AESEVL / Send all AEs for evaluation	Send all AEs for evaluation	A query is displayed on this field when AEs are entered or updated, and they have to be sent to CTEP-AERS for evaluation. This has to be checked and the form has to be saved to send the AEs to CTEP-AERS rules evaluation service.
SUPPAE_QVAL_AERPACN / Recommended action for report PID6819760_V1_0_1	Recommended action for report	This is a derived field. This displays the recommended action when AEs are sent to CTEP-AERS for Evaluation. It is used for internal purposes. This is view restricted to the CRA.
AERPACN1 / Recommended action for report PID6819760_V1_0_2	Recommended action for report	This is a derived field. This displays the recommended action when AEs are sent to CTEP-AERS for evaluation. It displays options to under or over report the AEs by including:

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		• NONE when the recommended action is CREATE. • CREATE when the recommended action is NONE. This will display a sticky note after AEs are sent to CTEP-AERS for evaluation. The sticky note displays a report action specific custom message and a link. The custom message will ask the user to use the link to navigate to CTEP-AERS and complete the Safety Report. The link is a context sensitive deep link to CTEP-AERS, navigating the user directly to the particular report.
AE_AEREFID / Reference ID PID6355961_V1_0	Report ID (derived)	This is a derived field. This displays the unique Report ID created by CTEP-AERS when the AEs are sent to it for evaluation. CRA cannot edit this field.
SUPPAE_QVAL_AERPTP / Recommended report type PID6819761_V1_0	Recommended report type	This is a derived field. This displays the recommended report when the AEs are sent to CTEP-AERS for evaluation and a report is recommended. This field does not display only if recommended action is NONE. CRA cannot edit this field.
AERPDTC / Report due by	Report due by	This is a derived field. This displays the report due by date when AEs are sent to CTEP-AERS for evaluation. This does not display if the recommended action is NONE. CRA cannot edit this field.
AEFRMDTC / Form Date PID6783869_V1_0	Form date (derived)	This is derived when the form is saved. This is view restricted to the CRA.

Late Adverse Events Form

The LAE Form is used to collect AE data during follow up visits. All LPOs are expected to use this form to collect Late AE data.

Table 15: Late Adverse Events Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	*Form Instructions*	This field is used to display the instructions for this form in the help text. Help text is: • The Start date of this reporting period is required on this form. If the response is blank, the adverse events entered on the form **will not** be evaluated for seriousness. • Trials using the Reporting period end date field should enter an end date when all adverse events have been reported for this cycle. • If ongoing AEs were derived from the previous cycle, please confirm they are still ongoing. If still ongoing, save the log line for each ongoing AE by selecting the AE term and save the form. If they are not ongoing, enter the end date and save the form. Click here to link to the User Guide.
NOTE2 / NOTE2	* Red asterisk before a field denotes that it is required by the system for rules evaluation.	N/A
SUPPAE_QVAL_CYCLNUM / Treatment Cycle Number PID2744948_V1_0	* Reporting period # (derived)	The cycle # is added to this field when the form is rolled out. This cycle # is required by the CTEP-AERS rules evaluation Service. This cycle # is pushed to CTEP-AERS and displayed on CTEP-AERS UI. CRA cannot edit this field. LPOs can modify the LPO CF to calculate the cycle # and pass it to this field.
AERPDPTP / Report period type PID6783870_V1_0	Report period type	This is defaulted to *Late* when the form is rolled out. CRA cannot edit this field. LPOs can *View Restrict* this field to the CRA.
SUPPAE_QVAL_CYCSTDAT / Intervention Occurrence Begin Date PID3028744_V1_0	* Start date of reporting period	N/A
SUPPAE_QVAL_CYCENDAT / Treatment Reporting Period End Date PID2992_V4_0	Reporting period end date	N/A

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
SUPPAE_QVAL_FCYSTDAT / Treatment First Cycle Begin Date PID61298_V3_0	* Start date of first course/cycle (derived)	This date is required by the CTEP-AERS rules evaluation Service. This date is pushed to CTEP-AERS and is displayed on CTEP-AERS UI when the AEs are sent for evaluation.
TAC / Treatment Assignment Code PID1967_V4_0	* Treatment assignment code (TAC) (derived)	This TAC is derived from the OPEN Enrollment *Treatment Assignment* Form when the form is rolled out. This data is required by the CTEP-AERS rules evaluation Service. This data is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AEONGOP / Prior Cycle Adverse Event Ongoing Indicator PID6041428_V1_0	Were any AEs reported as ongoing in the previous cycle? (derived)	This field is displayed when there are ongoing AEs in the previous cycle.
AEONGOC / Prior Cycle Ongoing Adverse Event Ongoing Indicator PID6041430_V1_0	Should ongoing AEs from the previous cycle be copied to this form?	This field is displayed when there are ongoing AEs in the previous cycle. Answering *Yes* to this field and saving the form copies over ongoing AEs to this cycle.
NOTE3 / NOTE3	REMINDER: 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 bottom right corner of the table. If these options are not available, you are already viewing the entire table.	N/A
AE_AEPRESP / Adverse Event Pre-Specified PID6379825_V1_0	Pre-Specified Adverse Event (derived)	This is a view restricted field for all the EDC roles. This is used for internal purposes.
AE_AETERM / Adverse Event Reported Term PID6338308_V1_0	Adverse event (verbatim term)	This is only required when the report is initiated in CTEP-AERS. CTEP-AERS will show an alert *Missing: Verbatim* if the CRA tries to save the report without a verbatim term. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. CRA can enter the Verbatim term in CTEP-AERS if it is not entered in RAVE EDC.
SUPPAE_QVAL_CTCAE / Common Terminology Criteria for Adverse Events Version 5.0 Low Level Term Name PID6063560_V1_0	* Adverse event term (CTCAE v5.0)	This is required by the CTEP-AERS rules evaluation service. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
SUPPAE_QVAL_CTCAECD / Common Terminology Criteria for Adverse Events Version 5.0 Mapped Low Level Term MedDRA Code PID6063561_V1_0	* MedDRA AE code (CTCAE v5.0) (derived)	This is derived when the form is saved. This is required by the CTEP-AERS rules evaluation service. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AETOX1 /Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0_1	CTCAE grade and description of toxicity (first 120 characters)	This displays a list of (numeric) descriptive grades associated with the AE. This displays only the first 120 characters of the descriptive grade to limit the width of the page.
AE_AETOXGR / Adverse Event Toxicity Grade PID6338618_V1_0_2	CTCAE grade (derived)	This is derived when the form is saved. This is the numeric grade derived from the grade selected by the CRA. This is pushed to CTEP-AERS. The grade and grade description are displayed on CTEP-AERS UI when the AEs are sent for evaluation. It is used for internal purposes. Label is blank because LPOs should *View Restrict* this field to the CRA.
AETOXGR1 / Adverse Event Toxicity Grade PID6338618_V1_0_1	CTCAE grade	This displays a list of numeric grades associated with the selected AE. Grade 0 will only be available for solicited AEs to indicate evaluated-not present. LPOs should only use the *Adverse event grade description (first 120 characters)* field or this field, but not both. CTSU recommends using the *Adverse event grade description (first 120 characters)* field. This field is the better option when the form is in landscape mode to reduce page width. LPOs must hide the field by unchecking *Is visible field* that is not used and set *View Restrict* for all roles.
AE_AETOX / Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0_2	CTCAE grade and description of toxicity (derived)	This is derived when the form is saved. This will display the full grade description. CRA cannot edit this field. LPOs can *View Restrict* this field to CRA.
AE_AESTDAT / Adverse Event Start Date PID6341142_V1_0	Start date	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation. This is required for the primary AE when the report is initiated in CTEP-AERS.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		If not collecting AE Start Date, LPOs should set *Invisible* and *View Restrict* this field to the CRA.
AE_AEENDAT / Adverse Event End Date PID6340298_V1_0	End date	LPOs should set *Invisible* and *View Restrict* this field to the CRA if the AE *Start Date* field is view restricted.
AE_AEONGO / Ongoing Adverse Event PID6343381_V1_0	Ongoing (derived)	This is a derived field. Derives to YES if *End Date* is not entered. Derives to NO if *End Date* is entered. LPOs should set *Invisible* and *View Restrict* this field to the CRA if the AE *Start date* field is view restricted.
AE_AEREL / CTC Adverse Event Attribution Scale PID 1285_V3_0	Attribution to study treatment	N/A
AE_AESHOSP / Initial or Prolonged Hospitalization PID6343376_V1_0	Hospitalization (initial or prolonged)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESLIFE / Is Life Threatening PID6343380_V1_0	Life threatening	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESDTH / Results in Death PID6343382_V1_0	Death	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESDISAB / Disability or Permanent Damage PID6343379_V1_0	Disability or permanent damage	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESCONG / Congenital Anomaly or Birth Defect PID6343378_V1_0	Congenital anomaly or birth defect	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
SUPPAE_QVAL_AESINTV/ Requires Intervention Device PID 6379837_V1_0	Required intervention (device)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AESMIE / Other Medically Important Serious Event PID6343377_V1_0	Other serious (important medical events)	This is pushed to CTEP-AERS and displayed on CTEP-AERS UI when the AEs are sent for evaluation.
AE_AEACN / Action Taken with Study Treatment PID6366035_V1_0	Action taken with study treatment	Variable AE_AEACN to capture study treatment action is setup as invisible in ALS 7.1. This variable is required for SDTM reporting and should be included in the dataset for reporting. Variable AE_AEACN should be used to capture a single study treatment action. To capture AE Action at the agent level, new custom variables (AEACN1, AEACN2, AEACN3) should be added for each agent and the labels for these fields can be agent specific such as Action taken (Agent 1), Action taken (Agent 2).
AE_AESPID / Adverse Event Sponsor-Defined Identifier PID6379804_V1_0	*AE number (derived)	This is derived when the form is saved. This is a unique ID assigned to each AE. This is pushed to CTEP-AERS when the AEs are sent for

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		evaluation. CRA cannot edit this field.
SUPPAE_QVAL_SAERPT / SAE report recommended PID6824777_V1_0	SAE report recommended (derived)	This is derived after the CRA sends the AE to CTEP-AERS for evaluation. This is set to *Yes* if CTEP-AERS recommends a report. Otherwise, it is set to *No*. CRA cannot edit this field.
AE_AEDTC / Adverse Event First Awareness Occurrence Date PID4358131_V1_0	*Date/Time of Collection (derived)	This is derived and indicates the first date/time the AE log line is entered and form saved. CRA cannot edit this field.
AEZONE / Address Time Zone Name PID3014791_V1_0	* Time zone (derived)	This is derived when the form is saved. CRA cannot edit this field.
SUBMITBY / Submitted by PID6783868_V1_0	* Submitted by (derived)	This is derived when the form is saved. This displays the email address of the CRA. This is pushed to CTEP-AERS and displayed on CTEP-AERS UI (as the Reporter) when the AEs are sent for evaluation. CRA cannot edit this field.
AEPERF1 / Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0~~_2~~	Evaluated (derived)	This is used for internal purposes. This is view restricted to all EDC roles.
NOTE4 / NOTE4	INSTRUCTIONS: When entering new or modifying existing data in this form remember to resubmit the changes to CTEP-AERS for rules evaluation by completing and saving the Late Expedited Reporting Evaluation form in Rave.	N/A
CO_COVAL / Comment PID6355806_V1_0	AE comment	N/A
AEFRMDTC / Form Date PID6783869_V1_0	Form date (derived)	This is derived when the form is saved. This is used for internal purposes. This is view restricted to the CRA.
ENDDTBYSYS/ End date modified by system user	Is end date modified by system user?	This is used for internal purposes. This is view restricted to all EDC roles.

Late Expedited Reporting Evaluation Form

The Late Expedited Reporting Evaluation (LAER) Form is used to send LAE form data to CTEP-AERS for evaluation. All LPOs that need to send the LAE data to CTEP-AERS for evaluation are expected to use this form. LPOs that do not need to send their LAE data to CTEP-AERS for evaluation can use the form level restrictions to view restrict the form, so it does not display in EDC.

Table 16: Late Expedited Reporting Evaluation Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	*Form Instructions*	This variable is used to display the instructions for this form in the help text. Help text is: • This form is used to send AEs recorded in the *Late Adverse Events* form to rules evaluation to determine if expedited reporting is recommended. • Select the check box *Send all AEs for evaluation* and save the form. • Items denoted with a * are required for rules evaluation. Note that the evaluation of the AEs **will not** occur if the *Adverse Events* form has one or more queries or missing items. • Following the evaluation of the AEs, if the *Recommended action for report* is NONE but the investigator chooses to report the AE in CTEP-AERS, then select the hyperlink *Click this link to complete the safety report* to launch CTEP-AERS and complete the safety report. In this scenario, **do not** change the *Recommended action for report (derived)* to CREATE rather leave as NONE. • Following the evaluation of the AEs, if the *Recommended action for report* is CREATE but the investigator chooses **not** to report the AE in CTEP-AERS, then change the *Recommended action for report* to NONE. • When the evaluation of the AEs is complete, a unique *Report ID (derived)* will be displayed on the form. This Report ID (derived) **is not** the same as Ticket Number in CTEP-AERS. Instead the

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		Report ID acts as the link between Rave and CTEP-AERS and can be used instead of Ticket Number when managing reports in CTEP-AERS.
NOTE2 / NOTE2	A delay is expected when the safety system is called for AE evaluation. Notes: 1) 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 events are entered on the same ticket. 2) All queries on this form will be closed automatically by the system once the form is saved. DO NOT add a comment or close queries manually.	N/A
AENTERR / Note/Error	Note/Error	This displays notes/error messages when there is an error with the AE data sent to CTEP-AERS and/or the rules evaluation Service. CRA cannot edit this field.
SUPPAE_QVAL_CYCLNUM / Treatment Cycle Number PID2744948_V1_0	Reporting period # (derived)	The cycle # is added to this field when the form is rolled out. This cycle # is required for the CTEP-AERS rules evaluation Service. LPOs can *View Restrict* this field to the CRA and delete the field label.
AESEVL / Send all AEs for evaluation	Send all AEs for evaluation	A query is displayed on this field when AEs are entered or updated. They have to be sent to CTEP-AERS for evaluation. This must be checked and the form is required to be saved to send the AEs to CTEP-AERS rules evaluation service.
SUPPAE_QVAL_AERPACN / Recommended action for report PID6819760_V1_0_1	Recommended action for report	This is a derived field. This displays the recommended action when AEs are sent to CTEP-AERS for evaluation. It is used for internal purposes. This is view restricted to the CRA.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AERPACN1 / Recommended action for report PID6819760_V1_0_2	Recommended action for report	This is a derived field. This displays the recommended action when AEs are sent to CTEP-AERS for evaluation. It displays options to under or over report the AEs by including: • NONE when the recommended action is CREATE. • CREATE when the recommended action is NONE. This will display a sticky note after AEs are sent to CTEP-AERS for evaluation. The sticky note displays a report action specific custom message and a link. The custom message will ask the user to use the link to navigate to CTEP-AERS and complete the safety report. The link is a context sensitive deep link to CTEP-AERS, navigating the user directly to the particular report.
AE_AEREFID / Reference ID PID6355961_V1_0	Report ID (derived)	This is a derived field. This displays the unique Report ID created by CTEP-AERS when the AEs are sent for evaluation. CRA cannot edit this field.
SUPPAE_QVAL_AERPTP / Recommended report type PID6819761_V1_0	Recommended report type	This is a derived field. This displays the recommended report when the AEs are sent to CTEP-AERS for evaluation and a report is recommended. This field does not display only if the recommended action is NONE. CRA cannot edit this field.
AERPDTC / Report due by	Report due by	This is a derived field. This displays the report due by date when AEs are sent to CTEP-AERS for evaluation. This does not display if the recommended action is NONE. CRA cannot edit this field.
AEFRMDTC / Form date PID6783869_V1_0	Form date (derived)	This is derived when the form is saved. This is view restricted to the CRA.

Validations on the PAE/AE/LAE Forms

The AE/LAE Forms contain validations programmed to ensure the data sent to CTEP-AERS for rules evaluation include the required and valid responses. A query is raised on the PAE/AE/LAE Form if data does not meet certain conditions.

Table 17: PAE/AE/LAE Form Validations

Condition	Message	Comments
AE is not evaluated or is pending evaluation for solicited AEs and any of the other questions are answered. Applicable for AE form only.	If the *Adverse event evaluated this cycle?* is *No* or *Pending*, then AE information should be missing. Please reconcile.[QC004]	This validation applies only if the study collects solicited AEs. LPOs should customize this message if: • *CTCAE grade* field is used to collect grades instead of *CTCAE grade and description of toxicity (first 120 characters).* • The study does not collect *Start date*.
The AE is evaluated and the Grade description/Grade is empty. Applicable for AE form only.	If the *Adverse event evaluated this cycle?* is *Yes*, then *CTCAE grade* should NOT be missing. Please reconcile. [QC005]	LPOs should customize this message in LPO CF if: • *CTCAE grade* field is used to collect grades instead of *CTCAE grade and description of toxicity (first 120 characters).*
AE should be evaluated for unsolicited AEs. Applicable for AE form only.	*Adverse event evaluated this cycle?* should be *Yes* for all new Adverse events.[QC006]	N/A
AE grade missing Applicable for PAE and LAE form only.	*CTCAE grade* should NOT be missing. [QC007]	N/A
AE Term missing, Applicable for PAE and LAE form only.	*Adverse event term (CTCAE v5.0)* should not be missing.[QC008]	N/A
The AE term is related to Death and Death has not been checked as a result.	If the *Adverse event term (CTCAE v5.0)* is *Death*, then patient outcome *Death* should be selected as *Yes*. Please reconcile.[QC009]	N/A
Death is checked as a result and correct Grade Description/Grade has not been selected.	If the Adverse event resulted in death, then the *CTCAE grade* should be 5. Please reconcile.[QC010]	LPOs should customize this message if: • *CTCAE grade* field is used to collect grades instead of *CTCAE grade and description of toxicity (first 120 characters).*
Grade Description/Grade is related to death and Death is not	If the patient outcome is selected as *Yes* for *Death*, then the *CTCAE grade* should	LPOs should customize this message if:

Condition	Message	Comments
checked as a result.	be 5. Please reconcile.[QC011]	• *CTCAE grade* field is used to collect grades instead of *CTCAE grade and description of toxicity (first 120 characters).*
Grade indicates death but Death outcome is not checked.	If *CTCAE grade* is 5, then *Death* should be selected as *Yes*. Please reconcile.[QC012]	N/A
Grade Description/Grade is 0 and a result is checked.	If *CTCAE grade* is 0, then patient outcome should be missing. Please reconcile.[QC013]	LPOs should customize this message if: • *CTCAE grade* field is used to collect grades instead of *CTCAE grade and description of toxicity (first 120 characters).*
Grade Description/Grade is not 0 and a result is not checked.	If *CTCAE grade* is > 0, then each of the patient outcomes should be answered YES/NO. Please reconcile.[QC015]	LPOs should customize this message if: • *CTCAE Grade* field is used to collect grades instead of *CTCAE grade and description of toxicity (first 120 characters).*
If grade is > 0, then the AE Start Date is required.	If *CTCAE grade* is > 0, then the *Adverse event (verbatim term)* is required.[QC016]	N/A
Whenever the AE/LAE form is updated, AE/LAE Form has valid data and RE call is not performed.	Whenever the AE form is updated, the adverse events have to be evaluated to determine if expedited reporting is recommended. Please check this check box and save the form to determine if expedited reporting is recommended.[QC017]	N/A
When RE call is performed and CTEP-AERS recommends to submit a report.	Expedited reporting is required if the adverse event (AE) meets seriousness criteria and/or the protocol-specific expedited reporting requirements (e.g. CAEPR/SPEER, AESI - see protocol). If the AE does not meet protocol expedited reporting requirements, change CREATE to NONE and do not submit an expedited report.[QC018]	N/A
When RE call is performed and CTEP-AERS does not recommend to submit a report.	An expedited report is NOT recommended. If the Investigator believes an expedited report is warranted, use the link below to move to CTEP-AERS to complete the expedited report.[QC019]	N/A
When RE call is performed and user overrides the CTEP-AERS recommendation.	Report recommendation OVERRIDDEN. An expedited report was RECOMMENDED from CTEP-AERS; the Investigator believes	N/A

Condition	Message	Comments
	expedited reporting is NOT required. If the decision to not report was made in error, edit the *Recommended action for report* from NONE to CREATE (i.e., original recommendation).[QC020]	
If grade is > 0, then Adverse Event Start Date is required.	If *CTCAE grade* is > 0, then Adverse Event *Start date* is required.[QC021]	N/A
The AE End Date cannot be before the AE Start Date. Please reconcile.	The Adverse Event *End date* cannot be before the Adverse Event *Start date*. Please reconcile.[QC022]	N/A
AE End Date is empty and AE Ongoing is No or empty.	If AE Ongoing (derived) is *Yes* then Adverse Event *End date* should be blank. If AE *Ongoing (derived)* is *No* then Adverse Event *End date* should be entered. Please reconcile.[QC023]	N/A
If AE occurred in this Cycle then AE Start Date cannot be before current Cycle Start Date.	AE *Start date* is prior to the start date of this course/cycle. Please reconcile.[QC024]	N/A
If the AE Grade is 0, then AE start date, End date and AE ongoing should be missing.	If *CTCAE grade* is 0, then AE *Start date*, *End date,* and *Ongoing (derived)* should be missing. Please reconcile.[QC025]	N/A
Duplicate AE. Duplicates are based on AE Term, AE Grade and AE Start Date combination.	Duplicate Adverse Event. Please reconcile.[QC026]	N/A
Attribution to study treatment cannot be missing when Reporting period end date is present. Applicable only to AE//LAE forms	Attribution to study treatment cannot be missing when *Reporting period end date* is present. Please reconcile.[QC027]	N/A
When previous cycle has ongoing AEs and answer to Should ongoing AEs from the previous cycle be copied to this form? in the current cycle is missing. Applicable only to AE//LAE forms	Please confirm the ongoing status of all AEs from the previous cycle then select *Yes*.[QC028]	N/A
If AE grade is 5, then AE End Date cannot be missing.	If *CTCAE grade* is 5, then AE *End date* cannot be missing. Please reconcile.[QC029]	N/A
If AE grade is 0, then Attribution to study treatment should be missing. Applicable only to AE//LAE forms	If *CTCAE grade* is 0, then *Attribution to study treatment* should be missing. Please reconcile.[QC030]	N/A

Condition	Message	Comments
Action Taken with study treatment cannot be missing.	Action taken with study treatment cannot be missing.[QC031]	N/A
If AE grade is 0, then Action Taken with study treatment should be missing.	If *CTCAE grade* is 0, then Action taken with study treatment should be missing. Please reconcile.[QC032]	N/A
End Date is before the start date of the course/cycle Applicable only to AE/LAE forms	End Date should not be prior to the start date of this course/cycle.[QC033]	N/A
End Date is before the start date of this course/cycle and the AE is ongoing in the previous cycle Applicable only to AE/LAE forms	This adverse event is copied to multiple courses/cycles including the end date. The end date of the AE must fall between the beginning and end of the last course/cycle which the AE persisted. [QC034]	N/A
If TAC is 'Other'.	OTHER is not a valid TAC.[QC035]	N/A