CTSU

Cancer Trials Support Unit

CTSU Standard Forms ALS v7.0 Release Notes

Version 1.0

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Document Information

Revision Information for the CTSU Standard Forms ALS v7.0 Release Notes

Revision History

#	Date	By	Description
1.0	31-July-2019	Suhela Pandit	Initial Release.

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1. References

Table 1: References

#	Document	Location	Description
1)	CTSU Standard Forms ALS v7.0 Release Notes	Collaboration Portal (CTSU Website) **Path:** CTSU→CDMS Support Center →Integrations→General Documents →CTSU-Standard-Forms→v7.0	Specification document for CTSU Standard Forms ALS v7.0 release.

2. Introduction

2.1 Overview

Medidata Rave® was integrated with the Oncology Patient Enrollment Network (OPEN) in 2012 to implement the patient enrollment and distribute the randomization capability of OPEN with the clinical data management capability of Rave. To support the OPEN-Rave integrations, Cancer Trials Support Unit (CTSU) Standard Forms are required to be used by Lead Protocol Organizations (LPOs). These forms are available in the CTSU Standard Forms Rave Architect Loader Specification (ALS) v7.0 file.

Rave was also integrated with National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP). The Rave-Cancer Therapy Evaluation Program-Adverse Events Reporting System (CTEP-AERS) integration also requires LPOs to use the CTSU Standard Forms, which are available in the CTSU Standard Forms Rave ALS v7.0 file.

The CTSU Standard Forms ALS v7.0 Release Notes provides information about the changes and enhancements to the OPEN-Rave integration and Rave-CTEP-AERS integration Standard Forms, and contains configuration details to assist LPOs in configuring their studies to use these integrations. This document also outlines changes made to the CTSU Standard Forms to be Clinical Data Interchange Standards Consortium (CDISC) compliant as required by NCI. The CTSU Standard Forms are complaint with the CDISC version mentioned in the *CDISC Version and Links* table.

Instruction: To access the links, first log in to the CDISC website using your 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 Version	Link
Clinical Data Acquisition Standard Harmonization (CDASH) Model v1.0	https://www.cdisc.org/standards/foundational/cdash/cdash-model-10
CDASH Implementation Guide (CDASHIG) v2.0	https://www.cdisc.org/standards/foundational/cdash/cdash-20
CDASH and Standard Data Tabulation Model (SDTM) Controlled Terminology package 37 released on March 29, 2019 (35 and 36 were previously incorporated into ALS v7.0) *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 v2.0 Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives

CDISC Version	Link
SDTM Model v1.7	https://www.cdisc.org/standards/foundational/sdtm/sdtm-v1-7
SDTM Implementation Guide (SDTMIG) v3.3	https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3
SDTMIG v3.3 Metadata Table	https://www.cdisc.org/cdisc-library https://www.cdisc.org/members-only/cdisc-library-archives

2.1.1 Background of OPEN and Rave RTSM Integration

OPEN provides a standardized web-based environment for the enrollment of all patients in clinical trials across the NCI-sponsored Clinical Trials Program. OPEN is integrated with NCI's Regulatory Support System (RSS) and acts as gatekeeper to ensure access, participation, and regulatory requirements are met prior to patient enrollment onto a protocol. OPEN is a front end to collect credentialing, demographics, and eligibility data while the patient randomization happens in the RandoNode, a web service hosted by the LPOs. This allows the LPOs to control the registration, randomization, and treatment assignment for their protocols. Medidata Rave's Randomization and Trial Supply Management (RTSM) solution (previously known as Balance) lets user create randomization designs across studies, sites, factors, and cross-factor strata. Rave RTSM offers a choice of pre-validated randomization methods for rapid study planning and start-up. Rave RTSM may be used to randomize the subjects in Rave by bypassing RandoNode or through RandoNode. In order to support the integration, a Randomization form is required to integrate with Rave RTSM to randomize the subject and retrieve the Arm information.

2.1.2 Background of OPEN and Central Monitoring Integration

OPEN provides a standardized web-based environment for the enrollment of all patients in clinical trials across the NCI-sponsored Clinical Trials Program. OPEN is integrated with NCI's Regulatory Support System (RSS) and acts as gatekeeper to ensure access, participation, and regulatory requirements are met prior to patient enrollment onto a protocol. OPEN is a front end to collect credentialing, demographics, and eligibility data while the patient randomization happens in the RandoNode, a web service hosted by the LPOs. This allows the LPOs to control the registration, randomization, and treatment assignment for their protocols. The Central Monitoring (CM) integration provides a streamlined process for remote data monitoring. The CM integration is designed to provide an efficient way for sites to manage and track document submission for CM review, and for LPOs to manage and track the uploaded documents for CM review. The Source Document Portal (SDP) is a gateway on the CTSU website that facilitates remote CM activities. The SDP allows site users to upload source documents to a central location, which provides accessibility to monitors to review source documents against data entered in Rave. The CM review activity is also electronically recorded in Rave by the monitors.

2.1.3 Background of Rave and Cancer Therapy Evaluation Program-Adverse Events Reporting System Integration

The CTSU is coordinating the integration of Rave with the NCI adverse event reporting systems such as CTEP-AERS to enable users to report Serious Adverse Events (SAEs) and routine Adverse Events (AEs) using Rave. To make this happen, the SAE reporting interface is built in Rave where all AEs are entered as well as managed. This SAE reporting interface seamlessly communicates with CTEP-AERS to report the AE and SAE data to the NCI's safety systems.

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.
ANDA	Abbreviated New Drug Application
ALS	Architect Loader Specification
BLA	Biologics License Application
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 (CRFs). 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

Acronym	Definition
	organization (SDO).
CDUS	Clinical Data Update System
CF	Custom Function
CM	Central Monitoring
CMP	Central Monitoring Portal
CRA	Clinical Research Associate
CRFs	Case Report Forms
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
DDs	Data Dictionaries
DD	Data Dictionary
DM	Demographics
EC	Edit Check
EDC	Rave Electronic Data Capture
FDA	Food and Drug Administration
GLIB	Global Library
IND	Investigational New 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
NDA	New Drug Application
NRDS	Network Rave Data Standards
OID	Object Identifier
OPEN	Oncology Patient Enrollment Network
RE	Rules Engine
RSS	Regulatory Support System
RTSM	Randomization and Trial Supply Management
SAE	Serious Adverse Event
SAR	Site Audit Reporting
SAS	Statistical Analysis System

Acronym	Definition
SDP	Source Document Portal
SDTM	Study Data Tabulation Model
SDTMIG	Study Data Tabulation Model Implementation Guide
SUPP	Supplemental Qualifiers
TAC	Treatment Assignment Code
TAD	Treatment Assignment Description
TCG	Technical Conformance Guide
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 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 CDISC Implementation initiative to meet the FDA mandate of submitting clinical study data sets in the Study Data Tabulation Model (SDTM) format.

The Study Data Technical Conformance Guide (TCG) provides specifications, recommendations, and general considerations on how to submit standardized study data using FDA-supported data standards located in the FDA Data Standards Catalog. The TCG supplements the guidance for industry providing Regulatory Submissions in Electronic Format — Standardized Study Data and provides technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format in investigational new drug (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs). Refer to Study Data TCG for more information.

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, has updated the CTSU Standard Form elements to make them CDISC compliant. This document outlines the changes and enhancements included in the CTSU Standard Forms ALS v7.0 which includes OPEN-Rave and Rave-CTEP-AERS integration forms. The CTSU Standard Forms ALS v7.0 is to be used for studies activating after January 1, 2020. The CTSU will provide support to LPOs to use CTSU Standard Forms ALS v7.0 on one or more CDISC compliant pilot studies.

For legacy studies, defined as any study that is activated prior to January 1, 2020, LPOs can continue to use the previous ALS versions:

- OPEN-Rave Integration ALS v6.0
- Rave-CTEP-AERS Integrations ALS RE 2.3 (LPOs are expected to use this ALS version for all CTEP IND studies.). Any study activating after January 1, 2020 should use ALS 7.0.

Please note that objects related to Rave RTSM and CM integrations are not required for studies unless they are using these integrations.

The process of developing other Rave forms (Case Report Forms (CRFs)) 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 15 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.

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
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 Form Level Definition

All forms available in ALS 7.0 are not required for every study. The forms are required based on the integration the study is using (e.g., CM and Patient Information for NCI Reporting form is required for CM integration). A description of each of the CTSU Standard and optional forms available in ALS 7.0 is provided in Table 4.

Table 4: CTSU Standard Form Level Definition

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
1	Subject Enrollment	N/A	OPEN-Rave	This is the primary form available at the Subject level, and is required for	No View Restrictions. Entry Restricted for all Rave

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
				patient initialization in Rave. All the data points in this form are populated programmatically from OPEN.	roles except for Power User and Data Manager.
2	Demography	Enrollment Forms	OPEN-Rave	This form is required for patient initialization in Rave. All the data points in this form are populated programmatically from OPEN.	No View Restrictions. Entry Restricted for all Rave roles except for Power User and Data Manager.
3	Step Information	Enrollment Forms	OPEN-Rave	This form is required for patient initialization in Rave. All the data points in this form are populated programmatically from OPEN.	No View Restrictions. Entry Restricted for all Rave roles except for Power User and Data Manager.
4	Treatment Assignment	Enrollment Forms	OPEN-Rave	This form is required for patient initialization in Rave. All the data points in this form are populated programmatically from OPEN.	No View Restrictions. Entry Restricted for all Rave roles except for Power User and Data Manager.
5	Patient Information for NCI Reporting	NCI Reporting	OPEN-Rave, Site Audit Reporting (SAR), CM	All the data points in this form are populated programmatically. Clinical Research Associates (CRAs) do not have access to this form.	View Restricted for Rave roles Clinical Research Associate and CRA (LabAdmin). Entry Restricted for all Rave roles except for Power User.
6	Randomization Unblinded	Enrollment Forms Sub-folder: Rand-Step1	Rave RTSM (unblinded studies)	For each new step, a new folder needs to be created following the standard naming convention by appending the step number to the Folder Name and Folder OID. For Example: for Step2, the Folder Name is *Rand-Step2* and the Folder OID is *RANDSTEP2*.	View Restricted for Rave roles Clinical Research Associate and CRA (LabAdmin). Entry Restricted for all Rave roles except for Power User and Data Manager.
7	Randomization Blinded	Enrollment Forms Sub-folder: Rand-Step1	Rave RTSM (blinded studies)	For each new step, a new folder needs to be created following the standard naming convention by appending the step number to the Folder Name and Folder OID. For Example: for Step2, the Folder Name is *Rand-Step2* and the Folder OID is *RANDSTEP2*.	View Restricted for Rave roles Clinical Research Associate, and CRA (LabAdmin). Entry Restricted for all Rave roles except for Power User and Data Manager.
8	Central Monitoring Alert	Configured by LPO	CM	Rolls out in folders configured by LPOs that have data for CM review.	No Entry or View Restrictions.

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
9	Adverse Events	Treatment (Intervention)	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 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.
10	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 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 Electronic Data Capture (EDC).	No Entry or View Restrictions.
11	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.
12	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	No Entry or View Restrictions.

#	Form Name	Folder	Required for Integration	Description	Entry and View Restrictions
				the form so it does not display in EDC.	
13	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.
14	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.
15	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 roll out additional follow-up visit folders.	No Entry or View Restrictions.

3.2 Folder Structure in Rave

3.2.1 OPEN and CTEP-AERS Integration Forms

Figure 2 displays the folder structure for CTSU Standard Forms used for various integrations. LPOs must follow the folder structure displayed in Figure 2 in order for the integrations to successfully work. The folders for OPEN forms (Enrollments Forms and NCI Reporting) should adhere to the ALS, otherwise the integration will not work. The folders for CTEP-AERS integration (Baseline, Course/Cycle 01, Follow-up 01) are configurable.

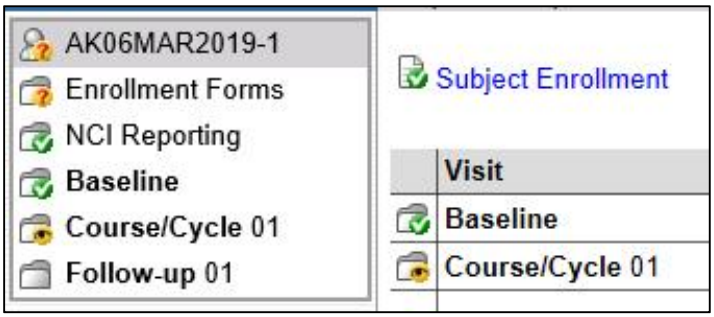

Figure 2: Folder Structure in Rave

3.2.2 Randomization (Blinded and Unblinded) Forms

Figure 3 displays the folder structure for Randomization (blinded and unblinded) Forms. Folder *Rand-Step1* holds the Randomization Form for the Rave RTSM Integration. For each new step, a new folder needs to be created following the standard naming convention by appending the step number to the Folder Name and Folder OID. For Example: for Step2, the Folder Name is *Rand-Step2* and the Folder OID is *RANDSTEP2*. For Step 3, the Folder Name is *Rand-Step3* and the Folder OID is *RANDSTEP3*. For an unblinded study, all the Rand-Step# folders will hold the *Randomization Unblinded* form. For a blinded study, all the Rand-Step# folders will hold the *Randomization Blinded* form.

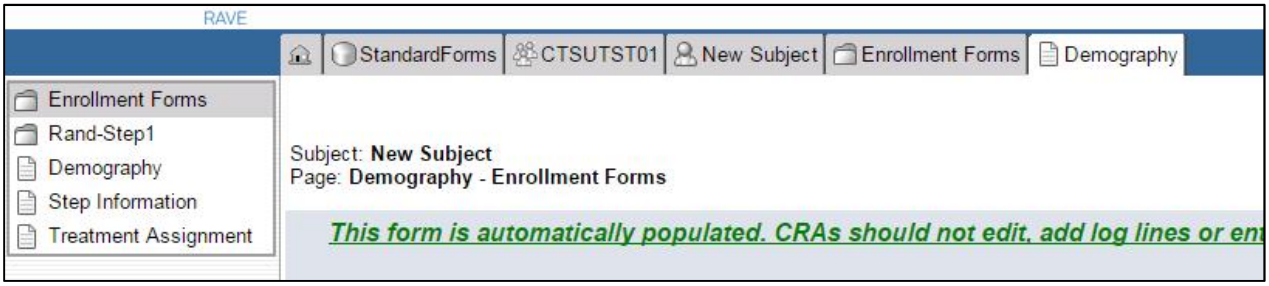

Figure 3: Folder Structure for Randomization Forms

4. Enhancements to CTSU Standard Forms ALS v7.0

As per the NCI CDISC implementation, all CTEP IND studies activated on or after January 1, 2020 must be CDISC compliant to satisfy the FDA mandate requiring data sets to be submitted in the CDISC SDTM format. The CTSU Standard Forms have been updated to be CDISC complaint as required by NCI, and additional updates were made to the form definitions for enhancement and bug fixes. The Form level, Field level, Data Dictionary, EC, and CF updates are outlined in section 4.1.

4.1 Summary of Changes

The changes to CTSU Standard Forms ALS v7.0 are summarized below. For details, refer to the subsequent sections.

1. Prefixed all Form OIDs with CTSU for consistency.
2. Field level changes include updated Field OID, Variable OID, Field Name including Common Data Element (CDE), Format, Data Dictionary Name, Control Type, Field Label, Header Text, Help Text, and SAS Label.
3. Statistical Analysis System (SAS) Label added for all fields on the CTSU Standard Forms.
4. Pattern-based naming is used for variables that are mapped to and included in the SDTM dataset. These variables are pre-fixed with SDTM target dataset name, the target variable name, and an optional pre-specified topic value [datasetName_targetvariable(_optionalPrespecifiedTopicValue)] (e.g., SC_SCORRES_PAYMETH). Refer to section Pattern-Based Naming for details on why pattern-based naming is used.
5. Pattern-based naming is not required for the following variables types:
   - Variables included in the Trial level domains (e.g., Trial Arms);
   - Variables used for integration/internal programming purposes only; and
   - Variables not reportable and not included in the SDTM dataset.
6. Pattern-based naming is not applied to the following CTSU Standard Form variables because an NCI decision is still pending regarding implementation and use of these variables. For now these are included in the ALS as place holders:
   - CARM
   - TAC
   - TAC1
   - TAD
7. Instructions from the Field Label (Pre-text) have been removed (e.g., Pre-text in ALS v2.3 *Course/Cycle # (derived)* has been updated in ALS v7.0 to *Course/Cycle #*).
8. ControlType Checkbox has been replaced with RadioButton or DropDownList.
9. Data Dictionary (DD) names have been replaced with CDISC compliant DDs. For details refer to the Data Dictionary Changes section 4.8.
10. Rave-CTEP-AERS integration form changes:
    - Field TAC is now editable.

- The Data Dictionary TAC with default values TAC-0 and Other is attached to the TAC field, and LPOs are required to configure the data dictionary values with protocol specific TACs. CRAs are allowed to update TAC using the available values from the drop-down.

11. Rave-CTEP-AERS Central Study ALS Changes:
    - CTSU_GRP_AEUTIL_doCopyOngoingAEs — Updated the CF so that Ongoing AEs (copied to next cycle) are sent to CTEP-AERS only in the first cycle in which they were reported and query will not open in the next cycle to alert the user to resend the AEs to CTEP-AERS. Example: If an AE starts in cycle 1 but continues to cycle 2, query will not open in cycle 2 to alert the user to send the AE to CTEP-AERS. For any new or modified AEs at cycle 2 (non-copied) query will open to alert the user to send the AE to CTEP-AERS.
    - CTSU_GRP_AEUTIL_doSetAnyOngoingFlagInNextCycle — Updated the CF so that Field Please confirm AEs reported as ongoing in the previous cycle are still ongoing goes invisible when all ongoing AEs from previous cycle are ended. Expected behavior is when Yes is answered to this question, it should remain visible.
    - CTSU_GRP_QUERY_doSetRVQuery — Updated the CF so that the query on the AER form closes when a valid AE with grade greater than 0 is sent to the rules engine (RE) service, and when the user adds another solicited AE with Grade 0, the query on the AER form does not re-open.
    - CTSU_GRP_QUERY_doSetRVQuery() — Successful rules evaluation call must not fail due to queries on non-standard fields in Rave.
    - CTSU_GRP_AEUTIL_doCopyAERecToThisAEForm — Support copy of ongoing AEs from non-standard fields to the subsequent cycles.
12. For Rave-CTEP-AERS integration, text for queries has been updated to match the CDISC compliant field labels.

4.2 Form Level Changes

Table 5: CTSU Standard Form Level Changes

#	Form Name	Type of Change	Description of Change	Change Reason
1	Subject Enrollment	Form OID Updated	Form OID updated from SUBJECT_ENROLLMENT to CTSU_SUBJECT_ENROLLMENT	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms.
2	Demography	Form OID Updated	Form OID updated from DEMOGRAPHY to CTSU_DEMOGRAPHY	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms.
3	Step Information	Form OID Updated	Form OID updated from STEP_INFORMATION to CTSU_STEP_INFORMATION	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms.

#	Form Name	Type of Change	Description of Change	Change Reason
4	Treatment Assignment	Form OID Updated	Form OID updated from TREATMENT_ASSIGNMENT to CTSU_TREATMENT_ASSIGNMENT	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms.
5	Patient Information for NCI Reporting	Form OID Updated	Form OID updated from PATIENT_INFORMATION_FOR_NCI_REPORTING to CTSU_PATIENT_INFORMATION	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms, and updated Form OID to shorten it.
6	Randomization Unblinded	Form OID Updated	Form OID updated from RAND to CTSU_RAND	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms.
7	Randomization Blinded	Form OID Updated	Form OID updated from RANDBLINDED to CTSU_RANDBLINDED	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms.
8	Central Monitoring Alert	Form OID Updated	Form OID updated from CM_ALERT to CTSU_CM_ALERT	Prefixed Form OID with CTSU to make it consistent with other CTSU Standard Forms.
9	Patient Status Form: Baseline	Form OID Updated	Form OID updated from CTSU_EVENT_BSL to CTSUX_EVENT_BSL	Added X to CTSU prefix to indicate form is optional.
10	Patient Status Form: Treatment (Intervention)	Form OID Updated	Form OID updated from CTSU_EVENT_TX to CTSUX_EVENT_TX	Added X to CTSU prefix to indicate form is optional.
11	Patient Status Form: Follow-up	Form OID Updated	Form OID updated from CTSU_EVENT_FUP to CTSUX_EVENT_FUP	Added X to CTSU prefix to indicate form is optional.

4.3 CDISC Compliance Updates

To make the CTSU Standard Forms CDISC complaint, the field definitions have been updated.

For CTSU Standard Form fields that have a direct match to CDISC CDASH and SDTM CDEs curated in the Cancer Data Standards Registry and Repository (caDSR), the following field definitions have been updated:

- Field OID
- Variable OID
- Field Name including CDE
- Format
- Field Label

- SAS Label

Custom variables were created for CTSU Standard Form fields that do not have a direct match to a CDASH or SDTM variable. For these fields, Field OID, Variable OID, Field Label and/or SAS Label have been updated. These fields will continue to use existing CDEs. The CDEs are being updated in the caDSR to add Alternate Question text and/or Alternate Name to make them CDISC complaint. All other Field level changes are discussed in the following Field Level Changes section 4.7.

4.4 Pattern-Based Naming

To simplify data collection for a study, there might be a need to mix domains on a single CRF and/or to collect specific tests/measurements as per study requirements. SDTM programming requires predictability of incoming data because it makes programming efficient and allows use of standardized programming. Pattern-based naming provides the needed balance between data collection and SDTM programming.

The recommended pattern-based variable naming is [datasetName_targetvariable(_optionalPrespecifiedTopicValue)].

- 28 character target dataset name (REQUIRED);
- Target variable name (REQUIRED); and
- Value of the topic variable (OPTIONAL).

4.5 CDISC Deviations

CDISC recommends using the published CDASH Question Text or Prompt for Rave PreText values to display on the form. PreText values that deviate from CDISCs recommendation should, at a minimum, share the same meaning as the SDTM variable to which the CDASH variable will be mapped. Table 6 lists the CTSU Standard Form variables for which their PreText (questions) do not exactly match the recommended CDASH Question Text or Prompt along with the reason for the deviation.

Table 6: CDISC Deviations

#	Form Name	Updated Field OID (CDASH Variable)	Existing PreText	CDASH Question Text or Prompt	Reason Field PreText Not Updated
1	Adverse Events, Late Adverse Events	AE_AETERM	Adverse Event (Verbatim term)	What is the adverse event term? OR Adverse Event	The CDASH and SDTM meaning of the AETERM variable is verbatim AE *as reported*. Since the standard AE form uses AE to mean the Common Terminology Criteria for Adverse Events (CTCAE) reported term, the words *Verbatim Term* are added to the label to differentiate from the CTCAE term.
2	Step Information, Treatment	DS_DSSPID	Step No	Sponsor-Defined Identifier	Use of suggested CDASH Prompt ([Line Number/AE Number]) is ambiguous and does not indicate the variable meaning as used in the NCI implementation. Since

#	Form Name	Updated Field OID (CDASH Variable)	Existing PreText	CDASH Question Text or Prompt	Reason Field PreText Not Updated
	Assignment				this field is user-defined CDASH may be updated to allow more flexibility in the Prompt. The *Step No* label indicates the correct Sponsor-defined meaning of the data for this field.
3	Expedited Reporting Evaluation	AE_AEREFID	Report ID	Reference ID	The current CDASH Prompt does not include the word *Report*, although a *Report ID* is within the valid use of this variable. The CDASH Prompt for *AEREFID* may be updated to allow more flexibility. The *Report ID* label indicates the correct meaning of the data for this field.

4.6 CDASH Variable Implementation Guidelines

Table 7 lists CDASH variables and provides guidance on how these should be used in study build and SDTM reporting.

Table 7: CDISC Variable Implementation Guidelines

#	Form Name	CDASH Variable	Existing Field Label	CDASH Variable Implementation Guidelines
1	Adverse Events	AE_AEPRESP	Solicited (derived)	AE_AEPRESP is a CDASH variable used when specific AEs of interest have been defined at the Study level - in this case the list of expected or solicited AEs for a subject on study. The value YES is derived when one of those AEs of interest is selected in the Adverse Event Term (CTCAE v5.0) field to indicate that this AE was asked to the subject *did you experience this AE*. If a pre-specified AE is not selected or is NO, or the AE selected is not a pre-specified one, AE_AEPRESP should remain blank/null in SDTM. The variable AE_AEPRESP should be included as part of the AE record when mapping to SDTM.
2	Adverse Events, Late Adverse Events	AEPERF	Adverse event evaluated this cycle?	AEPERF is a custom CDASH variable used to indicate whether the site asked the subject about the pre-specified AEs. The value collected is used for operational purposes and does not map to SDTM.
3	Adverse Events, Late Adverse Events	AE_AEACN	What action was taken with study treatment?	Variable AE_AEACN used to capture study treatment action is set up as invisible in ALS 7.0. This variable is required for SDTM reporting and should be included in the dataset for reporting. The LPO is responsible for making the field visible AND updating the view

#	Form Name	CDASH Variable	Existing Field Label	CDASH Variable Implementation Guidelines
				restrictions. Variable AE_AEACN should be used to capture a single study treatment action using controlled terminology from NCI codelist C66767. To capture AE Action at the agent level, new custom variables (AE_AEACN1, AE_AEACN2, AE_AEACN3) should be added for each agent and the labels for these fields can be agent specific such as Action taken with (Agent 1), Action Taken with (Agent 2).
4	Demography	DM_CRACE	Race	Demographics (DM) domain contains RACE with SDTM CT (NCI codelist C74457). For FDA reporting, map Collected Race to Race values.
5	Subject Enrollment	CSITE_CTEPID	Current Site CTEP ID	CSITE_CTEPID is the variable to capture the current Site CTEP ID. Add Current Site as Supplemental Qualifiers (SUPP--) to domains/records that were NOT collected at the Site associated with SITEID in the DM record. SDTM programmers should create the SUPP - records for multiple sites associated with the subject (e.g., enrolling site, current site, etc.). In DM records, recommendation is to use the site associated with the majority of records for that subject.

4.7 Field Level Changes

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

Table 8: CTSU Standard Forms Field Level Changes

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
1	Subject Enrollment	PT_ID	SUBJID	Field Updated	Updates include – Format: $40 Field Label: Subject SAS Label: Subject Identifier for the Study
2	Subject Enrollment	ENROLLING_SITE_ID	SITE_CTEPID	Field Updated	Updates include – Format: $40 Field Label: Enrolling Site CTEP ID SAS Label: Enrolling Site CTEP ID
3	Subject Enrollment	PARTIC_ENROL_DT	DS_DSSTDAT	Field Updated	Updated SAS Label: Start Date of Disposition Event

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
4	Subject Enrollment	ENROLL_TIME	DS_DSSTTIM	Field Updated	Updated SAS Label: Start Time of Disposition Event
5	Demography	PT_INITIALS_NAME	SC_SCORRES_PTINIT	Field Updated	Updates include – Field Label: Subject Initials (LFM) SAS Label: Subject Initials
6	Demography	PER_BIR_DT	DM_BRTHDAT	Field Updated	Updated Field Label: Birth Date
7	Demography	ETHN_GRP_CAT_TXT	DM_ETHNIC	Field Updated	Updates include – Format: $100 DD: CDISC_SDTM_ETHN_PID6338301_V1_0F Help Text: Hyperlink removed
8	Demography	PERSON_GENDER	DM_SEX	Field Updated	Updates include – Format: $50 DD: CDISC_SDTM_SEX_PID6343354_V1_0F Field Label: Sex SAS Label: Sex Help Text: Hyperlink removed
9	Demography	COUNTRY_CD	SC_SCORRES_CNTRYRES	Field Updated	Updates include – ControlType: SearchList Help Text: Hyperlink removed
10	Demography	PAYMENT_METHOD	SC_SCORRES_PAYMETH	Field Updated	Updates include – DD: METHOD_OF_PAYM_PID2016946_V3_0F SAS Label: Method of Payment
11	Demography	RACE_CAT_TXT	DM_CRACE	Field Updated	Updates include – Format: $100 DD: CDISC_SDTM_COLL_PID6409709_V1_0F SAS Label: Collected Race

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
					Help Text: Hyperlink removed
12	Step Information	REG_STEP_NUM	DS_DSSPID	Field Updated	Updates include – Format: $40 Field Label: Step No SAS Label: Step Number
13	Step Information	EVENT_DESC	DS_DSTERM	Field Updated	Updates include – Format: $200 SAS Label: Reported Term for the Disposition Event
14	Step Information	TRACKING_NUM	DS_DSREFID	Field Updated	Updates include – Format: $40 Field Label: Reference ID SAS Label: Reference ID Help Text: OPEN Tracking Number
15	Step Information	INVESTIGATOR_NAME	DM_INVNAM	Field Updated	Updates include – Field Label: Investigator Name SAS Label: Investigator Name
16	Step Information	PROT_TX_ARM_ASS_TXT	CARM	Field Updated	Updated SAS Label: Collected Arm
17	Step Information	EVENT_DATE	DS_DSSTDAT	Field Updated	Updated SAS Label: Start Date of Disposition Event
18	Step Information	EVENT_TIME	DS_DSSTTIM	Field Updated	Updated SAS Label: Start Time of Disposition Event
19	Treatment Assignment, Randomization Unblinded, Randomization Blinded	PROT_TX_ARM_ASS_TXT	CARM	Field Updated	Updated SAS Label: Collected Arm
20	Treatment Assignment	REG_STEP_NUM	DS_DSSPID	Field Updated	Updated Format: $40
21	Treatment Assignment	EVENT_DESC	DS_DSTERM	Field Updated	Updates include – Format: $200 SAS Label: Reported Term for the Disposition Event
22	Treatment	TRT_ARM_ASGN_DA	DS_DSSTDAT	Field	Updates include –

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
	Assignment	TE		Updated	Field Label: Event Date SAS Label: Start Date of Disposition Event
23	Treatment Assignment	EVENT_TIME	DS_DSSTTIM	Field Updated	Updates include – SAS Label: Start Time of Disposition Event
24	Step Information, Treatment Assignment, Randomization Unblinded, Randomization Blinded	TX_ASSIGN_CD	TAC	Field Updated	Colon (:) removed from PreText (Treatment Assignment Code (TAC)).
25	Step Information, Treatment Assignment, Randomization Unblinded, Randomization Blinded	TX_ASSIGN_TXT	TAD	Field Updated	Colon (:) removed from PreText (Treatment Assignment Description (TAD)).
26	Randomization Unblinded, Randomization Blinded, Patient Information for NCI Reporting	MEDDRA_CODE	SUPPMH_QVAL_MHDSXCD	Field Updated	Updated Format: 15
27	Patient Information for NCI Reporting	PRO_TX_CUR_REC_CD, ZUBROD_PERF_STAT_SC, LAST_TX_DT, PT_BSL_ABN_IND3, DZ_EVAL_RESP_CD	N/A	Fields Deleted	Fields have been deleted from the Patient Information for NCI Reporting form because they are not being used by LPOs; fields were added to the form to facilitate Clinical Data Update System (CDUS) submission, but now the CDUS submission is made using a different application.
28	Patient Information for NCI Reporting	DZ_DX_NM	SUPPMH_QVAL_MHDSX	Field Updated	Updated Format: $200
29	Patient Information for	CTSU_INT_Q1	CTSU_INT_Q1	Field Updated	Field properties updated except for Field OID and

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
	NCI Reporting				Variable OID. This field will be used for Eligibility Review integration.
30	Patient Information for NCI Reporting	CTSU_INT_Q3	CTSU_INT_Q3	New Field	Place holder question for future integration.
31	Adverse Events, Late Adverse Events	TX_ASSIGN_CD	TAC1	Field Updated	Removed Entry restriction from TAC field for CRA to allow data updates. Other updates include – Format: $10 DD: TAC Control Type: DropDownList
32	Adverse Events, Late Adverse Events	TX_ASSIGN_TXT	N/A	Field Deleted	This field is deleted because the Treatment Assignment Code (TAC1) field was updated to allow site CRA to enter other specify for TAC.
33	Adverse Events, Late Adverse Events	PR_CYC_AE_ONGO_IND	AEONGOP	Field Updated	Updates include – Format: $2 Default Value: N SAS Label: AEs Reported as Ongoing in Previous Cycle
34	Adverse Events, Late Adverse Events	PRCYC_ONG_AE_ONG_IND	AEONGOC	Field Updated	Updates include – Format: $2 SAS Label: Ongoing AEs Confirmed Reported in Previous Cycle
35	Adverse Events, Late Adverse Events	AE_VERBATIM_TRM_TXT	AE_AETERM	Field Updated	Updates include – Field Label: Adverse Event (Verbatim term) Header Text: Adverse Event (Verbatim term) SAS Label: Reported Term for the Adverse Event
36	Adverse Events,	DEFAULT_SOLICITED	AE_AEPRESP	Field Updated	Updates include – Format: $2 Field Label: Pre-Specified Adverse Event DD:

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
					CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: DropDownList Header Text: Pre-Specified Adverse Event SAS Label: Pre-Specified Adverse Event
37	Adverse Events	AE_CURR_CYCL_CD_IND	AEPERF	Field Updated	Updated SAS Label: Adverse event evaluated this cycle
38	Adverse Events	CTCAE_SEV_GD_TXT	AETOX1	Field Updated	Updates include – Field Label: What is the description of the toxicity? (first 120 characters) Header Text: What is the description of the toxicity? (first 120 characters) SAS Label: Toxicity (first 120 characters)
39	Adverse Events, Late Adverse Events	AE_SEV_GD	AE_AETOXGR	Field Updated	Updates include – Field Label: CTCAE Grade SAS Label: Standard Toxicity Grade
40	Adverse Events, Late Adverse Events	AE_SEV_GD1	AETOXGR1	Field Updated	Updates include – Field Label: CTCAE Grade SAS Label: Standard Toxicity Grade (derived)
41	Adverse Events, Late Adverse Events	CTCAE_SEV_GD_TXT1	AE_AETOX	Field Updated	Updates include – Field Label: What is the description of the toxicity? Header Text: What is the description of the toxicity? SAS Label: Toxicity
42	Adverse Events, Late Adverse Events	AE_SM_BEG_DT	AE_AESTDAT	Field Updated	Updates include - Field Label: Start Date Header Text: Start Date SAS Label: Start Date of Adverse Event
43	Adverse Events, Late Adverse Events	AE_SM_END_DT	AE_AEENDAT	Field Updated	Added SAS Label: End Date of Adverse Event

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
44	Adverse Events, Late Adverse Events	AE_ONGOING_EVENT_IND	AE_AEONGO	Field Updated	Updates include – Format: $2 DD: CDISC_SDTM_Yes_PID6343337_V1_0F Field Label: Ongoing Header Text: Ongoing SAS Label: Ongoing Adverse Event
45	Adverse Events, Late Adverse Events	CTC_AE_ATTR_SCALE	AE_AEREL	Field Updated	Updates include – Format: $1 DD: ADVERSE_EVENT_PID2179504_V3_0F Field Label: Relationship to Study Treatment Header Text: Relationship to Study Treatment SAS Label: Causality
46	Adverse Events, Late Adverse Events	CTCAE5_LLT_NM1	CTCAE1	Field Updated	SAS Label updated to MedDRA Adverse Event (CTCAE v5.0) 1
47	Adverse Events, Late Adverse Events	NO_SAE_CK_IND	N/A	Field Deleted	Field was removed to make the form CDISC compliant.
48	Adverse Events, Late Adverse Events	SAE_HOSP_CK_IND	AE_AESHOSP	Field Updated	Updates include – Format: $2 DD: CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: RadioButton Indent Level: 2 Field Label: Hospitalization (initial or prolonged) Header Text: Hospitalization (initial or prolonged) SAS Label: Requires or Prolongs Hospitalization
49	Adverse Events, Late Adverse Events	SAE_LIFE_THRT_CK_IND	AE_AESLIFE	Field Updated	Updates include – Format: $2 DD:

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
					CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: RadioButton Field Label: Life Threatening Header Text: Life Threatening SAS Label: Is Life Threatening
50	Adverse Events, Late Adverse Events	SAE_DEATH_CK_IND	AE_AESDTH	Field Updated	Updates include – Format: $2 DD: CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: RadioButton SAS Label: Results in Death
51	Adverse Events, Late Adverse Events	SAE_DISABILTY_CK_IND	AE_AESDISAB	Field Updated	Updates include – Format: $2 DD: CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: RadioButton Field Label: Disability or Permanent Damage Header Text: Disability or Permanent Damage SAS Label: Persist or Signif Disability/Incapacity
52	Adverse Events, Late Adverse Events	SAE_CONG_ABNL_CK_IND	AE_AESCONG	Field Updated	Updates include – Format: $2 DD: CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: RadioButton Field Label: Congenital Anomaly or Birth Defect Header Text: Congenital Anomaly or Birth Defect SAS Label: Congenital Anomaly or Birth Defect
53	Adverse Events, Late Adverse Events	SAE_INTVN_REQ_CK_IND	SUPPAE_QVAL_AESINTV	Field Updated	Updates include – Format: $2 DD:

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
					CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: RadioButton Field Label: Required Intervention Header Text: Required Intervention SAS Label: Requires Intervention Device
54	Adverse Events, Late Adverse Events	SAE_OTX_RES_CK_IND	AE_AESMIE	Field Updated	Updates include – Format: $2 DD: CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: RadioButton Field Label: Other Serious (Important Medical Events) Header Text: Other Serious (Important Medical Events) SAS Label: Other Medically Important Serious Event
55	Adverse Events, Late Adverse Events	N/A	AE_AEACN	New Field	Added new data collection field required for SDTM reporting. It is setup as invisible, and LPOs can hide this field if not collected.
56	Adverse Events, Late Adverse Events	AE_SEQ_ID_NUM	AE_ AESPID	Field Updated	Updates include – Field Label: AE Number Header Text: AE Number SAS Label: AE Number
57	Adverse Events, Late Adverse Events	IS_SAE	SUPPAE_QVAL_SAERPT	Field Updated	Updates include – Format: $2 DD: CDISC_SDTM_Yes_PID6343337_V1_0F
58	Adverse Events, Late Adverse Events	AE_FRST_AWARENS_DT	AE_AEDTC	Field Updated	Updates include – Field Label: Date/Time of Collection Header Text: Date/Time of Collection SAS Label: Date/Time of

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
					Collection
59	Adverse Events, Late Adverse Events	CTCAE5_LLT_NM2	CTCAE2	Field Updated	SAS Label updated to MedDRA Adverse Event (CTCAE v5.0) 2
60	Adverse Events, Late Adverse Events	RSCH_COMMENTS_TXT	CO_COVAL	Field Updated	Updates include – Field Label: AE Comment SAS Label: AE Comment
61	Adverse Events, Late Adverse Events	SYS_COMMENTS, ERR_FLD	N/A	Field Deleted	Removed redundant field (System comments and Error) from AE/LAE forms.
62	Late Adverse Events	DEFAULT_SOLICITED	AE_AEPRESP	Field Updated	Updates include – Format: $2 Field Label: Pre-Specified Adverse Event DD: CDISC_SDTM_Yes_PID6343337_V1_0F Control Type: DropDownList SAS Label: Pre-Specified Adverse Event
63	Late Adverse Events	CTCAE_SEV_GD_TXT	AETOX1	Field Updated	Updates include – Field Label: What is the description of the toxicity? (first 120 characters) Header Text: What is the description of the toxicity? (first 120 characters) SAS Label: Toxicity (first 120 characters)
64	Late Adverse Events	TX_CRSE_BEG_DT	FCYSTDAT	Field Updated	Added SAS Label: Start Date of First Cycle
65	Expedited Reporting Evaluation	NOTE1	NOTE1	Field Updated	Help Text Updates – 1) Send all AEs for evaluation
66	Late Expedited Reporting Evaluation	NOTE1	NOTE1	Field Updated	Help Text Updates – 1) Send all AEs for evaluation 2) Form name to read Late Adverse Event
	Expedited Reporting	RV_RECMND_ACTIO	SUPPAE_QVAL_A	Field	Updates include –

#	Form Name	Existing Field OID	Updated Field OID	Type of Change	Change Description
	Evaluation, Late Expedited Reporting Evaluation	N_RPT	ERPACN	Updated	Field Label: Recommended action for report DD: RECOMMENDED_AC_PID6819741_V1_0F
67	Expedited Reporting Evaluation, Late Expedited Reporting Evaluation	RV_RECMND_ACTION_RPT2	AERPACN1	Field Updated	Added SAS Label: Recommended Action for Report 2.
68	Expedited Reporting Evaluation	RV_RPT_PRD_ID	AE_AEREFID	Field Updated	Added SAS Label: Report ID
	Expedited Reporting Evaluation, Late Expedited Reporting Evaluation	RV_RECMND_RPT	SUPPAE_QVAL_AERPTP	Field Updated	Updates include – Field Label: Recommended report type DD: RECOMMENDED_RE_PID6819744_V1_0F
69	Patient Status Form: Follow-up	GD2_GD3_NO_RP_CD_IND	N/A	Field Updated	Updates include – DD: YES_NO_CODED_IN_PID2183836_V1_0F SAS Label: Grade 2 Hospitalization or Grade 3+ Previously Reported
70	Patient Status Form: Follow-up	POST_TX_FU_CY_CD_IND	N/A	Field Updated	Added SAS Label: Patient Followed for another Post-treatment Reporting Period

4.8 Data Dictionary Changes

Table 9: CTSU Standard Forms Data Dictionary Changes

#	DD Name	Type of Change	Comments
1	ATTRIBUTION_SCA_PID2179504_V3_0F	Deleted/Replaced	DD name updated to ADVERSE_EVENT_PID2179504_V3_0F.
2	ETHNIC_GROUP_CATEG_PID2016566_V5_1F	Deleted/Replaced	Replaced with CDISC compliant DD CDISC_SDTM_ETHN_PID6338301_V1_0F.
3	CDISC_SDTM_ACTI_PID6365975_V1_0F	New DD	New CDISC compliant DD added.

#	DD Name	Type of Change	Comments
4	PATIENT_PAYMENT_METHOD_CATEG_PID2015169_V2_4F	Name updated	DD name updated to PATIENT_PAY_PID2015169_V2_4F.
5	RACE_CATEG_PID2015164_V6_0F	Deleted/Replaced	Replaced with CDISC compliant DD CDISC_SDTM_COLL_PID6409709_V1_0F.
6	PERSON_GENDER_N_PID3368864_V1_0F	Deleted/Replaced	Replaced with CDISC compliant DD CDISC_SDTM_SEX_PID6343354_V1_0F.
7	TAC	New DD	New DD added to allow CRAs to select the TAC. Default values are TAC-0 and Other; LPOs are required to configure the dictionary values based on study needs.
8	YES_NO_CHARACTE_PID2181608_V1_0F, YES_NO_PID2018320_V1_0F	Deleted/Replaced	Replaced with DD CDISC_SDTM_Yes_PID6343337_V1_0F.
9	CDUS_IND_2_CODE_PID2453201_V1_0F	Deleted	Field removed from the Patient Information for NCI Reporting Form.
10	ZUBROD_PERFORMA_PID2178471_V1_1F	Deleted	Field removed from the Patient Information for NCI Reporting Form.
11	YES_NO_UNKNOWN_PID3506034_V1_0F	Deleted	Field removed from the Patient Information for NCI Reporting Form.
12	CDUS_RESPONSE_E_PID2453596_V1_0F	Deleted	Field removed from the Patient Information for NCI Reporting Form.
13	CDISC_SDTM_Yes_PID6343337_V1_0F	New DD	New CDISC compliant DD added for Field OID CTSU_INT_Q1 on the Patient Information for NCI Reporting form. Field OID CTSU_INT_Q1 will be used for Eligibility Review integration.
14	YES_NO_CODED_I2_PID2183836_V1_0F	Deleted/Replaced	YES_NO_CODED_IN_PID2183836_V1_0F.
15	RECOMMENDED_ACTION	Deleted/Replaced	Replaced with CDISC compliant DD RECOMMENDED_AC_PID6819741_V1_0F.
16	RECOMMENDED_REPORT	Deleted/Replaced	Replaced with CDISC compliant DD RECOMMENDED_RE_PID6819744_V1_0F.

4.9 Edit Check Changes in LPO Study ALS

Table 10: CTSU Standard Forms Edit Check Changes in LPO Study ALS

#	Form Name	Edit Check Name	Type of Change	Comments
1	Central Monitoring Alert	CTSU_CM_doHandleCMQuery	Update	Updated the Form OID.

#	Form Name	Edit Check Name	Type of Change	Comments
2	Central Monitoring Alert	CTSU_CM_onPatientCMSelectionChanged	Update	Updated the Form OID.
3	Randomization Unblinded	CTSU_RAND_SetTxARM_Unblinded	Update	Updated the Form OID and Field OIDs.
4	Randomization Blinded	CTSU_RANDBLINDED_SetTxARM_Blinded	Update	Updated the Form OID and Field OIDs.
5	Randomization Unblinded	CTSUZ_RAND_RandomizeSubject_Unblinded	Update	Updated the Form OID and Field OIDs.
6	Randomization Blinded	CTSUZ_RANDBLINDED_RandomizeSubject_Blinded	Update	Updated the Form OID and Field OIDs.
7	Step Information	CTSU_TREATMENT_ASSIGNMENT_PopulateData_FromStepInfo	Update	Updated the Form OID and Field OIDs.
8	Late Adverse Events	CTSU_IND_LAE_doQueryNoReportingPeriodDate	Update	1) Updated the Field OID. 2) Data Format updated to use UserValue.
9	Adverse Events, Late Adverse Events	CTSU_GRP_AEDSL_Grade	Update	Updated the Field OIDs.
10	Adverse Events, Late Adverse Events	CTSU_GRP_AEDSL_GradeDesc	Update	Updated the Field OIDs.
11	Adverse Events	CTSU_GRP_QUERY_AE	Update	Updated the Field OIDs.
12	Late Adverse Events	CTSU_GRP_QUERY_LAE	Update	Updated the Field OIDs.
13	Expedited Reporting Evaluation	CTSU_GRP_AERDSL_RecomAction	Update	Updated the Field OIDs.
14	Adverse Events	CTSU_IND_AE_DeriveCourse1StartDate	Update	Updated the Field OIDs.
15	Expedited Reporting Evaluation	CTSU_PKG_RV_AER	Update	Updated the Field OIDs.
16	Late Expedited Reporting Evaluation	CTSU_PKG_RV_LAER	Update	Updated the Field OIDs.
17	Expedited Reporting Evaluation	CTSU_PKG_RV_AER_doHandleRptOverride	Update	Updated the Field OIDs.

#	Form Name	Edit Check Name	Type of Change	Comments
18	Late Expedited Reporting Evaluation	CTSU_PKG_RV_LAER_doHandleRptOverride	Update	Updated the Field OIDs.
19	Patient Status Form: Baseline	CTSUZ_PKG_NAV_BSL	Update	Updated the Form OID.
20	Patient Status Form: Follow-up	CTSUZ_PKG_NAV_FUP	Update	Updated the Form OID.
21	Patient Status Form: Treatment (Intervention)	CTSUZ_PKG_NAV_TX	Update	Updated the Form OID.
22	Patient Status Form: Follow-up	CTSUZ_PKG_NAV_LateAEYN_trigger	Update	Updated the Form OID.

4.10 Custom Function Changes in LPO Study ALS

Table 11: CTSU Standard Forms Custom Function Changes in LPO Study ALS

#	Custom Function Name	Type of Change	Comments
1	CTSU_CM_doHandleCMForm	Update	Updated Form OIDs.
2	CTSU_CM_onPatientCMSelectionChanged	Update	Updated to rollout the CM Alert form for all rolled out subfolders that are configured for the study.
3	CTSU_RAND_doPopulateStepInfo	Update	Updated Form OIDs and Field OIDs.
4	CTSU_RAND_doUpdateTACInfo	Update	Updated Form OIDs and Field OIDs.
5	CTSU_RAND_SetTxARM_Blinded	Update	Updated Field OID.
6	CTSU_RAND_SetTxARM_Unblinded	Update	Updated Field OID.
7	CTSU_TxAssign_doPopulateDetails	Update	Updated Form OIDs and Field OIDs.
8	CTSUZ_CM_isInstanceCMSelected	Update	Updated kvcOids Keys.
9	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.

4.11 Custom Function Changes in Central Study ALS

Table 12: CTSU Standard Forms 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.
2	CTSU_API_RV_doMakeAENodesXml	Update	Added new nodes Attribution, AeAction and

#	Custom Function Name	Type of Change	Comments
			isFollowupYn in AENode.
3	CTSU_API_RV_doMakeCourseNodeXml	Update	Added new nodes CTCAE Version in AENode.
4	CTSU_API_RV_doMakeOutcomeNodeXml	Update	Outcome node XML selected Yes values sending in the outcome node xml (previously when checked the value is populating).
5	CTSU_API_RV_doMakeRequestXml	Update	Made changes in the input params object to handle CTCAE Version isFollowupYN.
6	CTSU_API_RV_getRequestXmlTemplate	Update	Added new nodes Attribution, AeAction and isFollowupYn and CTCAE Version.
7	CTSU_API_RV_doValidateInputData	Update	Made changes in the input params object to handle CTCAE Version isFollowupYN.
8	CTSU_GRP_AEUTIL_doCheckHasOngoingAEs	Update	Updated to derive the updated coded data to the Ongoing field.
9	CTSU_GRP_AEUTIL_doCopyAERecToThisAEForm	Update	Updated the coded data value for the default solicited.
10	CTSU_GRP_AEUTIL_doCopyOngoingAEs	Update	Updated to check the modified coded data in the Ongoing field. Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids. Updated the CF so that Ongoing AEs (copied to next cycle) are sent to CTEP-AERS only in the first cycle in which they were reported and query will not open in the next cycle to alert the user to resend the AEs to CTEP-AERS. Example: If an AE starts in cycle 1 but continues to cycle 2, query will not open in cycle 2 to alert the user to send the AE to CTEP-AERS. For any new or modified AEs at cycle 2 (non-copied) query will open to alert the user to send the AE to CTEP-AERS.
11	CTSU_GRP_AEUTIL_doDeriveFullAEGradeDesc	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
12	CTSU_GRP_AEUTIL_doGetAEDpgFromPrevOrNextCyc	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
13	CTSU_GRP_AEUTIL_doGetAllPersistantAEsforThisAE	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
14	CTSU_GRP_AEUTIL_doGetMappedOIDs	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
15	CTSU_GRP_AEUTIL_doGetSortedAEDatapages	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
16	CTSU_GRP_AEUTIL_doHandlePersistentAEs	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.

#	Custom Function Name	Type of Change	Comments
17	CTSU_GRP_AEUTIL_doProcessAEUpdates	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
18	CTSU_GRP_AEUTIL_doSetAEDetails	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
19	CTSU_GRP_AEUTIL_doSetAEId	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
20	CTSU_GRP_AEUTIL_doSetAnyOngoingFlagInNextCycle	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids. Updated the CF so that Field *Please confirm AEs reported as ongoing in the previous cycle are still ongoing* goes invisible when all ongoing AEs from previous cycle are ended. Expected behavior is when *Yes* is answered to this question, it should remain visible.
21	CTSU_GRP_AEUTIL_doSyncAEData	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
22	CTSU_GRP_DSL_getAEGradeDesc	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
23	CTSU_GRP_DSL_getRVRptAction	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
24	CTSU_GRP_QUERY_doQueryDuplicateAEs	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
25	CTSU_GRP_QUERY_doQueryOnAEDates	Update	Updated the hard coded string EVAL_Y to match the updated coded data of the Evaluated field.
26	CTSU_GRP_QUERY_doQueryOnAEEval	Update	Updated the hard coded string EVAL_Y and VAL_Y to match the updated coded values.
27	CTSU_GRP_QUERY_doQueryOnDeath	Update	Updated the hard coded string EVAL_Y to match the updated coded value of the Evaluated field.
28	CTSU_GRP_QUERY_doQueryOnGrade	Update	Updated the hard coded string EVAL_Y and CHKD to match the updated coded values.
29	CTSU_GRP_QUERY_doReactivateSolicitedAE	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
30	CTSU_GRP_QUERY_doSetRVQuery	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids. Updated the CF so that the query on the AER form closes when a valid AE with grade greater than 0 is sent to the RE service, and when the user adds another solicited AE with Grade 0, the query on the AER form does not re-open.
31	CTSU_IND_AE_doUpdateCourse1StartDat	Update	Updated the keys to match the new keys in the

#	Custom Function Name	Type of Change	Comments
	e		LPO CF CTSUZ_CONFIG_doMapDefaultOids.
32	CTSU_MIG_doMigrateToNewCTCAEVer	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
33	CTSU_PKG_NAV_doDeriveTAC	Update	Updated the Form OID of the Treatment Assignment form. Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
34	CTSU_PKG_NAV_FUP_doInitialization	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
35	CTSU_PKG_NAV_TX_doInitialization	Update	Updated the coded data values for the default solicited and the *Adverse event evaluated this cycle?* Fields.
36	CTSU_PKG_RPT_doHandleRptOverride	Update	Updated the hard coded string to be derived to the *Evaluated* field to match the updated coded data.
37	CTSU_PKG_RV_doCollectAEData	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
38	CTSU_PKG_RV_doCollectCourseData	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
39	CTSU_PKG_RV_doCollectData	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
40	CTSU_PKG_RV_doEnterREResponse	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
41	CTSU_PKG_RV_doEvaluateAEs	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
42	CTSU_PKG_RV_doValidateAEData	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
43	CTSU_PKG_RV_doValidateCourseData	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
44	CTSU_PKG_RV_doValidateData	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
45	CTSU_ROUTER_doProcessDSL	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
46	CTSU_ROUTER_doProcessEC	Update	Updated the keys to match the new keys in the LPO CF CTSUZ_CONFIG_doMapDefaultOids.
47	CTSU_GRP_QUERY_doSetRVQuery()	Update	Successful rules evaluation call must not fail due to queries on non-standard fields in Rave.

5. Configuration Requirements

In CTSU Standard Forms ALS v7.0, there are no configuration changes required for legacy studies. For new study setup, the configurations mentioned below must be completed for studies using these integrations.

Refer to *Appendix I: OPEN-Rave Integration – Standard Forms* for OPEN-Rave Standard Forms setup.

5.1 Rave RTSM Integration

ALS version 7.0 includes ECs to randomize the subject and retrieve the Arm information. The EC names are appended with either *Blinded* or *Unblinded*. The appropriate checks should be selected based on the study type. For example – Unblinded studies will need only the ECs/derivations ending with *Unblinded*.

The CF populates Arm name, Event Date, Event Time, TAC, and TAD from the Randomization Form into the Step Information Form.

Note: The ECs to randomize the subject do not include the fields needed for stratification. LPOs are expected to modify the EC based on the study need.

Refer to Appendix II: Rave RTSM Randomization Responses.

5.1.1 Randomization Forms

Two randomization forms (Randomization Unblinded and Randomization Blinded) are available in the ALS to support the OPEN and Rave RTSM integration, one for use in blinded studies and one for use in unblinded studies. Depending on the type of study, the appropriate Randomization Form should be selected. The only difference between the two forms is in the Arm Name of the blinded form. The *Collected Arm Name* is defaulted as *Blinded* and is not returned by Rave RTSM in the blinded form. OPEN will focus on pushing the Randomization trigger and retrieving the *Collected Arm Name* and *Randomization date* only. It is the LPOs responsibility to populate the other fields in the Randomization Form.

5.1.1.1 Randomization Unblinded Form

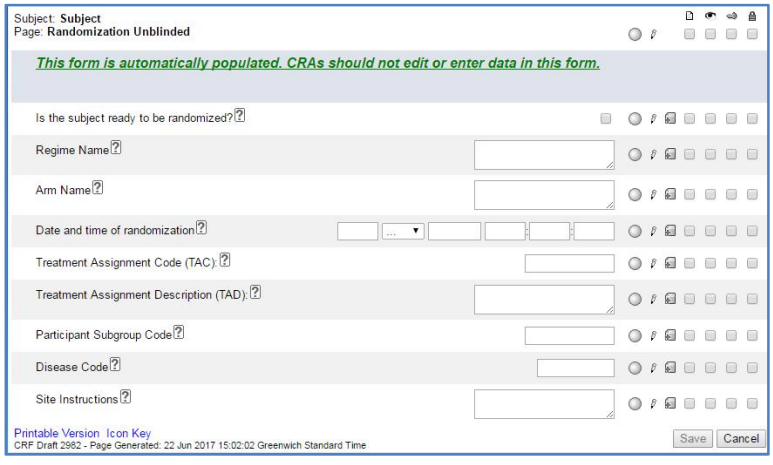

Figure 4: Randomization Unblinded Form

5.1.1.2 Randomization Blinded Form

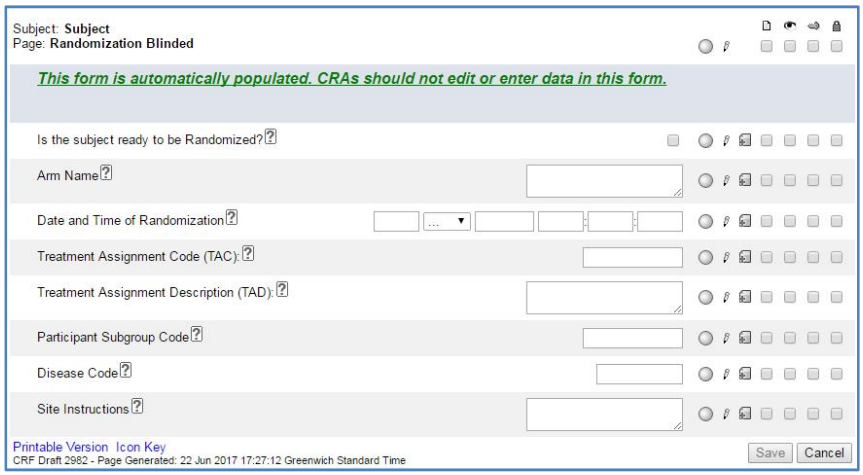

Figure 5: Randomization Blinded Form

5.2 Central Monitoring Integration

The CTSU Standard Forms ALS includes the *Central Monitoring Alert* Form. This form is required for studies using the CM integration. This form needs a few configuration changes during study build.

1) Field NOTE1: is configurable and can be used by the LPO to add study-specific instructions for site users. This field can also be used to add a deep link from Rave to the CM Document Collection Setup Screen on the SDP for site users to view the fields (data points) in Rave, and the associated documents expected for CM review.
2) CF: CTSU_CM_onPatientCMSelectionChanged is called whenever the question response on the *Patient Information for NCI Reporting* Form is answered or changed. It calls the CTSU_CM_doHandleCMForm CF to add/reactivate/inactivate the *Central Monitoring Alert* Form based on the question response on the *Patient Information for NCI Reporting* Form. It adds/reactivates/inactivates the *Central Monitoring Alert* Form only in the folders and subfolders defined in the CTSUZ_CM_isInstanceCMSelected CF. It adds/reactivates the *Central Monitoring Alert* Form if the response is *Yes* and Inactivates the *Central Monitoring Alert* Form if the response is not *Yes*. It calls the CTSU_CM_doHandleCMQuery CF to open or close the query on the *Central Monitoring Alert* Form after the form is added/reactivated.
3) CF: CTSUZ_CM_isInstanceCMSelected is called to determine if the current folder/sub folder is configured for adding or reactivating the *Central Monitoring Alert* Form. The LPO can configure this CF to roll out the *Central Monitoring Alert* Form for all or specific instances of a folder/subfolder.

5.2.1 Central Monitoring Alert Form

Figure 6: Central Monitoring Alert Form

5.3 AE/LAE Standard Forms Adaptation Guidelines

The LPO ALS and Central Study ALS released in version 7.0 will support the following study setups:

1) Use AE/LAE Standard Forms with AER/LAER for CTEP-AERS Integration and features to support collection of Persistent AEs, Start Date, End Date and Ongoing Flag (to comply with the NCI Start Date guideline).
2) Use AE/LAE Standard Forms with AER/LAER for CTEP-AERS Integration (when building Non Registration trials where Start Date and End Date collection is not required).
3) Use AE/LAE Standard Forms but not AER/LAER (when not using the CTEP-AERS Integration).

These setups can be further configured to support:

1) Solicited AEs or no Solicited AEs.
    a) By default the released ALS is configured to support collection of Solicited AEs.

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

5.3.1 Basic Configuration for All Studies Using AE/LAE Standard Forms

1) Make either the *What is the description of the toxicity?* or the *CTCAE Grade* field visible, but not both.
2) View restrict the second and third occurrences of the *Adverse event term (CTCAE v5.0)* to the CRA if they are not needed.
3) The following CTSU Forms are needed in your study for CTEP-AERS Integration:
    a) CTSU_AE
    b) CTSU_LAE
    c) CTSU_AER
    d) CTSU_LAER

Refer to *Appendix III: Rave-CTEP-AERS Forms Definition*.

4) The following CTSU Forms are **not** needed in your study for 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_AE
   d) CTSU_IND_AE_DeriveCourse1StartDate
   e) CTSU_GRP_QUERY_LAE
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
8) Update the CF CTSUZ_CONFIG_getCentralCRFVer with the version number of the LPO Central Study.
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 *What is the description of the 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 been updated in this release. The *string startDateOfFirstCourse* has been added as a 5th parameter. This is an optional parameter.

5.3.2 Configuration for Studies Using the AE/LAE Standard Forms with AER/LAER for CTEP-AERS Integration and Features to Support 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 AE/LAE forms:
   a) AE_AESTDAT
   b) AE_AEENDAT
   c) AE_AEONGO
   d) AEONGOP
   e) AEONGOC

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

Figure 7: Fields on AE/LAE Forms Set to Visible

5.3.3 Configuration for Studies Using the AE/LAE Standard Forms with AER/LAER for 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 8: Fields on AE/LAE Forms Set to Invisible

2) Delete the following fields from the draft:

a) AEONGOP

b) AEONGOC

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

LPOs should still use the standard AE and LAE Forms for studies that do not use the CTEP-AERS integration.

1) Remove the following forms from the study draft:
   a) CTSU_AER
   b) CTSU_LAER
2) Remove the following edit checks associated to the AER and LAER Forms from the study draft:
   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

5.3.5 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.

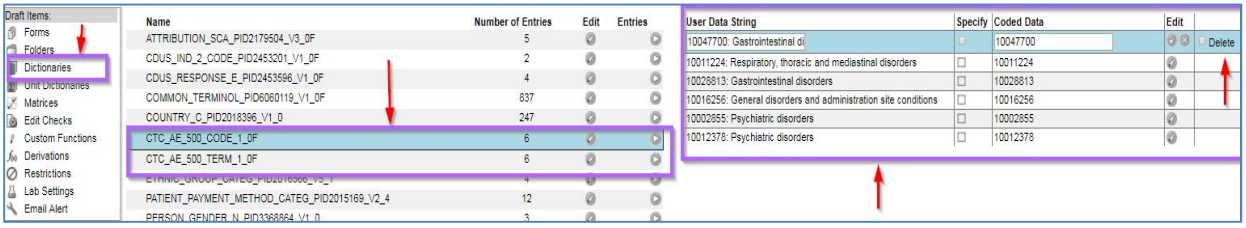

Figure 9: Configuration to Remove Solicited AEs

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

5.3.6 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.

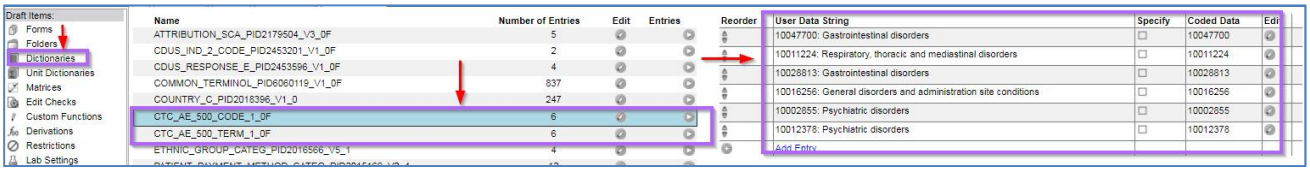

Figure 10: Configuration to Add Solicited AEs

6. Rave-CTEP-AERS Expected Behavior

Below is a list of scenarios for expected behavior in ALS v7.0:

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. If the calendaring functionality is implemented for the folder, the overdue icon will be displayed for the newly copied AE. 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) The AE End Date field by default remains untouched in the next cycle after the AE is copied. The AE End Date field will be overdue for all copied AEs when calendaring is set up for the folder. Edit every copied AE and save it in order to clear the overdue icon.
3) When a query on the AER Form is manually cancelled, the AER Form query will not open again. This is expected behavior in Rave.
4) 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.
5) When an AE copied from a previous cycle is inactivated in the current cycle, it cannot be reactivated again.

7. CTSU Standard Forms ALS v7.0 Known Issues

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

1. On AE/LAE Forms, if response to question *What is the description of the 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/LAE Forms, if response to question *What is the description of the 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: OPEN-Rave Integration – Standard Forms

Forms Definition

To implement OPEN-Rave Integrations, Rave study must include the following eight CTSU Standard Forms:

1) Subject Enrollment
2) Demography
3) Step Information
4) Treatment Assignment
5) Patient Information for NCI Reporting
6) Randomization Unblinded
7) Randomization Blinded
8) Central Monitoring Alert

Subject Enrollment

Subject Enrollment is the primary Rave form for all the CTEP studies. OPEN transfers the primary form data into Rave during patient initialization. This form contains the primary enrollment information.

Table 13: Subject Enrollment Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit or enter data in this form.	This field is used to display form instructions.
SUBJID / Subject Identifier for the Study PID6380049_V1_0	Subject	OPEN transfers this data into Rave during patient initialization.
SITE_CTEPID / Study Site Identifier PID6380048_V1_0	Enrolling Site CTEP ID	OPEN transfers this data into Rave during patient initialization.
SPONSOR / Lead Institution PID2192796_V1_0	Lead Organization	OPEN transfers this data into Rave during patient initialization.
CSITE_CTEPID / Current Site CTEP ID PID3314243_V1_0	Current Site CTEP ID	OPEN transfers this data into Rave during patient initialization.
DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Enrollment Date	OPEN transfers this data into Rave during patient initialization.
DS_DSSTTIM / Start Time of Disposition Event PID6341397_V1_0	Enrollment Time	OPEN transfers this data into Rave during patient initialization.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
GRPDATA / Group Type PID3212399_V1_0	Group Data	OPEN transfers this data into Rave during patient initialization.
SRCAPP / Source Application PID3302840_V1_0	Source Application	OPEN transfers this data into Rave during patient initialization.

Demography

The Demography Form contains the standard demography elements defined in OPEN. Identifiable personal information such as Social Security and Patient Hospital Number are not included on this form. The data on this form is pushed from OPEN.

Race is defined as a log line to collect multiple values. Registration systems will programmatically add a new log line to enter multiple race values.

Table 14: Demography Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit or enter data in this form.	This field is used to display form instructions.
SC_SCORRES_PTINIT / Participant Initials PID2001039_V4_0	Subject Initials (LFM)	Self-explanatory. Middle initial will be -, if not available. This specific format will help users to compare the initials with OPEN.
DM_BRTHDAT / Date of Birth PID6341138_V1_0	Birth Date	Self-explanatory.
DM_ETHNIC / Ethnicity PID6338619_V1_0	Ethnicity	Self-explanatory.
DM_SEX / Sex PID6343385_V1_0	Sex	Self-explanatory.
SC_SCORRES_CNTRYRES / Country of Residence (if not USA) PID2006183_V2_0	Country of Residence	Self-explanatory.
SC_SCORRES_ZIPCD / ZIP Code PID2179606_V2_0	ZIP Code	Self-explanatory.
SC_SCORRES_PAYMETH / Payment Method PID2003309_V3_0	Method of Payment	Self-explanatory.
DM_CRACE / Collected Race PID6412503_V1_0	Race	Self-explanatory. May have more than one response value.

Step Information

This form is defined as a log form, and form data can change between steps. A new record will be added for each enrolling step. The data on this form is pushed from OPEN.

Table 15: Step Information Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit, add log lines or enter data in this form.	This field is used to display form instructions.
DS_DSSPID / Sponsor-Defined Identifier PID6635863_V1_0	Step No	Associated step number.
DS_DSTERM / Disposition Event Reported Term PID6355980_V1_0	Event Description	Description for the corresponding step. In case patient transfer occurs without involving a step, a new record needs to be entered with the description *Patient Transfer*.
DS_DSREFID / Reference ID PID6636037_V1_0	Reference ID	Source system's tracking number to identify an enrollment. E.g., This field contains the OPEN tracking #/registration ID, if patient is initialized by OPEN.
SUPPDM_QVAL_TRTINV / Treating Physician Or Participating Investigator Name PID2740424_V1_0	Treating Investigator	The physician involved with the patient's treatment for an enrollment. Drugs will be shipped to him/her by default, in case another investigator is not selected for drug shipment.
SUPPDM_QVAL_REGNAM / Registrar PID2172_V3_0	Site Registrar	Registrar associated from the enrolling site.
SUPPDM_QVAL_CGRPNAM / Organization Name PID2152_V3_0	Crediting Group	Group receiving credit for the enrollment.
DM_INVNAM / Investigator Name PID6355987_V1_0	Investigator Name	Physician selected for assigning the cooperative group credit for an enrollment. The Credit Investigator will be accountable for the patient and the site's responsibilities during a cooperative group audit.
CARM / Assigned Treatment Arm PID2001626_V3_0	Arm Name	Arm name assigned by the Group registration system. Groups can populate N/A in case they do not have a specific arm for a step, and Blinded for the blinded studies.
DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Event Date	Date on which the step enrollment (or patient transfer) was completed. OPEN will transfer the Date when enrollment response was received from RandoNode. Groups can extract this from their own system in case

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		Group system pushes the data.
DS_DSSTTIM / Start Time of Disposition Event PID6341397_V1_0	Event Time	Time on which the step enrollment (or patient transfer) was completed. OPEN will transfer the Time when enrollment response was received from RandoNode. Groups can extract this from their own system in case Group system pushes the data.
TAC / Treatment Assignment Code PID1967_V4_0	Treatment Assignment Code (TAC)	TAC is a coded value representing a treatment assigned, to be uniformly administered to a group of study subjects for separate statistical analysis.
TAD / Other Treatment Assignment PID2002699_V5_0	Treatment Assignment Description (TAD)	TAD is a free-text field to describe the patient's assigned treatment, including dose level and duration. TAD value is populated only when the TAC value is OTHER.

Treatment Assignment

Treatment Assignment Form is a log form and the data is derived from the Step Information and Crossover forms. LPOs requested a mechanism to view the treatment arm change history at a single place, which brought up the need for this form.

Registration systems will not enter data directly on this form, but will derive the data from the Step Information Form, using a Rave custom function that is provided within the Architect Loader file. A new record will be added whenever data is populated in the Step Information Form from the registration system. Each log record will display the change history of the arm updates.

For crossover scenarios, LPOs will need to create a CF to update the data from the crossover form, which will be a study-specific form created only for studies that require crossover.

Table 16: Treatment Assignment Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit, add log lines or enter data in this form.	This field is used to display form instructions.
CARM / Assigned Treatment Arm PID2001626_V3_0	Arm Name	Arm name assigned by the Group registration system. Groups can populate N/A in case they do not have a specific arm for a step, and Blinded for the blinded studies.
DS_DSSPID / Sponsor-Defined Identifier PID6635863_V1_0	Step No	Step number associated with the arm assignment. Null for crossovers.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
DS_DSTERM / Disposition Event Reported Term PID6355980_V1_0	Event Description	Event that generated the arm, e.g., Randomization, Crossover, etc.
DS_DSSTDAT / Disposition Event Start Date PID6384212_V1_0	Event Date	Date on which arm was assigned by the Group registration system. OPEN will transfer the date when the response was received.
DS_DSSTTIM / Start Time of Disposition Event PID6341397_V1_0	Event Time	Time on which arm was assigned by the Group registration system. OPEN will transfer the time when the response was received.
TAC / Treatment Assignment Code PID1967_V4_0	Treatment Assignment Code (TAC)	TAC is a coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.
TAD / Other Treatment Assignment PID2002699_V5_0	Treatment Assignment Description (TAD)	TAD is a free-text field to describe the patient's assigned treatment, including dose level and duration. TAD value is populated only when the TAC value is OTHER.

Patient Information for NCI Reporting

The Patient Information for NCI Reporting Form has been updated to include one new data point. The value of the new data point, *Is the Subject Identified for Central Monitoring Review?* is automatically populated by the CTSU CM system.

Table 17: Patient Information for NCI Reporting Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit or enter data in this form.	This field is used to display form instructions.
SC_SCORRES_PTSUBGRP / Patient Subgroup Code PID1925_V2_31	Participant Subgroup Code	Pushed from OPEN/LPO Registration System to Rave. Subgroup (stratum) is a unique patient characteristic that will be utilized to uniformly group patients for separate analysis or treatment. Each subgroup should have a unique code for identification. The investigator will provide a code (up to characters) for each subgroup with the Protocol Submission Checklist.
SUPPMH_QVAL_MHDSXCD / MedDRA Code PID2004425_V4_0	Disease Code	Pushed from OPEN/LPO Registration System to Rave. Disease Code has the MedDRA code number describing a medical condition and/or anatomic location.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
SUPPMH_QVAL_MHDSX / Disease Diagnosis Term Name PID2186204_V2_0	Disease Name	Pushed from OPEN/LPO Registration System to Rave. Disease Name is the name to capture the disease diagnosis of an individual using MedDRA terms.
REQ_AUDIT / Is the Subject identified for audit?	Is the Subject identified for audit?	The value of this data point is automatically populated by the CTSU Site Audit Reporting integration system.
CTSU_INT_Q1 / Is the Subject confirmed to be Eligible?	Is the Subject confirmed to be Eligible?	Place holder question 1 for future integration.
CTSU_INT_Q2 / CTSU Integration Question 2	CTSU Integration Question 2	Place holder question 2 for future integration.
CTSU_INT_Q3 / CTSU Integration Question 3	CTSU Integration Question 3	Place holder question 3 for future integration.
REQ_CM / Is the Subject identified for Central Monitoring Review?	Is the Subject identified for Central Monitoring Review?	The value of this data point is automatically populated by the CTSU CM integration system.

Randomization Unblinded

This form supports the OPEN and Rave RTSM integration and is used for unblinded studies.

Table 18: Randomization Unblinded Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit or enter data in this form.	This field is used to display form instructions.
RANDTRIG / Randomization Trigger	Is the subject ready to be randomized?	This is pushed from OPEN/LPO Registration System to Rave. It is a trigger to randomize the subject.
REGIME_NAME / Regime Name	Regime Name	The Rave RTSM field returning Arm.
CARM / Assigned Treatment Arm PID2001626_V3_0	Arm Name	This field is derived from Regime Name. The text field for the assigned protocol treatment arm.
RANDOMIZED_AT / Randomization Date and Time	Date and Time of Randomization	The Rave RTSM field returning date and time (dd MMM yyyy HH:nn:ss) the subject is randomized.
TAC / Treatment Assignment Code PID1967_V4_0	Treatment Assignment Code (TAC)	This field is derived by LPO. A coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
TAD / Other Treatment Assignment PID2002699_V5_0	Treatment Assignment Description (TAD)	Derived by LPO. The free-text field to capture the assignment to a specific treatment.
SC_SCORRES_PTSUBGRP / Patient Subgroup Code PID1925_V2_31	Participant Subgroup Code	This field is derived by LPO. The subgroup (stratum) is a unique patient characteristic that will be utilized to uniformly group patients for separate analysis or treatment. Each subgroup should have a unique code for identification. The investigator will provide a code (up to characters) for each subgroup with the Protocol Submission Checklist.
SUPPMH_QVAL_MHDSXCD / MedDRA Code PID2004425_V4_0	Disease Code	This field is derived by LPO. Disease Code has the MedDRA code number describing a medical condition and/or anatomic location.
SITEINST / Site Instructions	Site Instructions	Instructions for sites added by LPO.

Randomization Blinded

This form supports the OPEN and Rave RTSM integration and is used for blinded studies.

Table 19: Randomization Blinded Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	This form is automatically populated. CRAs should not edit or enter data in this form.	This field is used to display form instructions.
RANDTRIG / Randomization Trigger	Is the subject ready to be randomized?	This is pushed from OPEN/LPO Registration System to Rave. It is a trigger to randomize the subject.
CARM / Assigned Treatment Arm PID2001626_V3_0	Arm Name	This field is defaulted to *Blinded*. The text field for the assigned protocol treatment arm.
RANDOMIZED_AT / Randomization Date and Time	Date and Time of Randomization	The Rave RTSM field returning date and time (dd MMM yyyy HH:nn:ss) the subject is randomized.
TAC / Treatment Assignment Code PID1967_V4_0	Treatment Assignment Code (TAC)	This field is derived by LPO. A coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.
TAD / Other Treatment Assignment PID2002699_V5_0	Treatment Assignment Description (TAD)	Derived by LPO. The free-text field to capture the assignment to a specific treatment.
SC_SCORRES_PTSUBGRP / Patient	Participant Subgroup	This field is derived by LPO. The subgroup (stratum) is a

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
Subgroup Code PID1925_V2_31	Code	unique patient characteristic that will be utilized to uniformly group patients for separate analysis or treatment. Each subgroup should have a unique code for identification. The investigator will provide a code (up to characters) for each subgroup with the Protocol Submission Checklist.
SUPPMH_QVAL_MHDSXCD / MedDRA Code PID2004425_V4_0	Disease Code	This field is derived by LPO. Disease Code has the MedDRA code number describing a medical condition and/or anatomic location.
SITEINST / Site Instructions	Site Instructions	Instructions for sites added by LPO.

Central Monitoring Alert

The CM form is used for CM integration and is configured by the LPO to roll out for folders and subfolders that require CM review.

Table 20: Central Monitoring Alert Form Fields

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
NOTE1 / NOTE1	[Instructions added by LPO – FOR LPO USE ONLY] Click here: to view the list of Rave data points that require Central Monitoring review and source documents required to be submitted for these data points	This field is used to display study-specific instructions added by the LPO to indicate the datapoints requiring CM review. The direct link available takes the user to the SDP.
FORM_COMP_IND / Form Complete Indicator PID2184835_V1_0	Upload Source Documents to <a href='https://www.ctsu.org/public/loginsp.aspx?mode=CM&study=[Protocol Number]'	Checkbox indicates if the required documents have been upload to the SDP. The direct link available takes the user to the SDP to upload documents.

Initial Standard Forms Setup for LPOs

Below are the steps LPOs must follow in order to set up the OPEN-Rave integration forms in their Rave URL for the first time:

1) Update the existing project name to the relevant test protocol number in the Architect Loader Excel file on the CRF Draft worksheet.
2) Load the Architect Loader spreadsheet data in a test project in your Rave instance.
3) Add the following folders and forms within the Default matrix. The primary Subject Enrollment Form should not be assigned to any folder or subject. The primary form gets added to the subject by default. The Default Matrix is not included as part of the ALS, for allowing LPOs to include OPEN-Rave Integration forms in any existing Rave study Default Matrix. This will also give them flexibility to select a default Matrix Name and OID, based on their specific need.
   a) Add Demography, Step Information, and Treatment Assignment Forms under the *Enrollment Forms* folder.
   b) Add the Patient Information for NCI Reporting Form under the *NCI Reporting* folder.
   c) Add the Randomization Form under the *Rand-Step1* folder. Select the Randomization Unblinded or Randomization Blinded Form based on the study type. If the study has additional steps, create the Rand-Step (append Step Number) folder specific to each step, and assign the Randomization Form to these folders.
   d) Configure the CF to rollout the Central Monitoring Alert Form as per CM requirements for the study.

	Subject	Enrollment Forms	NCI Reporting	Rand-Step1	Rand-Step2
Demography	☐	☑	☐	☐	☐
Step Information	☐	☑	☐	☐	☐
Subject Enrollment	☐	☐	☐	☐	☐
Treatment Assignment	☐	☑	☐	☐	☐
Patient Information for NCI Reporting	☐	☐	☑	☐	☐
Randomization Unblinded	☐	☐	☐	☑	☑
Randomization Blinded	☐	☐	☐	☐	☐
Central Monitoring Alert	☐	☐	☐	☐	☐

Figure 11: Example Folder and Form Entries for Default Matrix

4) Update the CTSU_UTIL_ExceptionHandler CF to display the Study Name, Site Name, and Subject ID in the body of the exception message. The CF should also be updated to enter email recipients and the LPO name. The following updates are expected from LPOs for the *LPO_CUSTOMIZATION_SECTION*:
   a) Define PROD_EMAIL_LIST constant to add email IDs of additional emails recipients if an exception occurs in the production environment. If an LPO wants to enter multiple email IDs, the email IDs should be separated by a comma.

b) Define AUX_EMAIL_LIST constant to add email IDs of additional emails recipients if an exception occurs in the non-production environment. If an LPO wants to enter multiple email IDs, the email IDs should be separated by a comma.

c) Define study LPO variable and indicate the LPO name.

```
/**** Begin LPO CUSTOMIZATION****/

// If lpo/study owner wants to get the email then add a comma separated email
address to this list
      // Example: PROD_EMAIL_LIST =
"rave_systems_prod@westat.com,JohnDoe@lpo.com";
      // Example AUX_EMAIL_LIST =
"rave_systems@westat.com,JaneRoe@lpo.com";

const string PROD_EMAIL_LIST = "rave_systems_prod@westat.com";
const string AUX_EMAIL_LIST = "rave_systems@westat.com";

// Enter the lead group
string studyLPO = "CTSU";

/**** End LPO CUSTOMIZATION****/
```

5) Make sure the Batch Upload role is enabled while populating the data from OPEN. Also, ensure the selected LPO users have the ability to enter data in all the CTSU Standard Forms, to allow any post-enrollment data correction. No site users should be allowed to edit these forms.

6) Select *Subject Enrollment* as the primary form and provide a Default Matrix value as part of CRF Draft settings. Enter a Confirmation Message and Signature Prompt in the same screen.

7) Add any derivations or ECs specific to your forms that are derived from the data on the OPEN-Rave integration forms.

8) Update the CTSU_CM_isInstanceCMSelected CF to specify the instance name and the number of instances to which the *Central Monitoring Alert* Form can be added.

```
public KeyValueCollection GetCMConfig()
{


    /**** Begin LPO CUSTOMIZATION ****/

    KeyValueCollection kvcCMConfig = new KeyValueCollection();
    // Format :
    // kvcCMConfig.Add(new KeyValue("FODLER OID", "Instance Number CSV"));
    // Example 1: kvcCMConfig.Add(new KeyValue("TX", "*")); // All folders with TX OID
    // Example 2: kvcCMConfig.Add(new KeyValue("TX", "1,2,5")); // Folders with TX OID and with
curance of 1,2 and 5
    // For non repeating folder the CSV should always be "*"
    kvcCMConfig.Add(new KeyValue("ENROLLMENT_FORMS", "*"));
    //kvcCMConfig.Add(new KeyValue("CYCLE", "1,2"));

    // If the study CM review for all rolled out folders then use as this example:
    // Example 3: kvcCMConfig.Add(new KeyValue("*", "*")); // All folders with all fodler OIDs

    /**** End LPO CUSTOMIZATION ****/
```

Figure 12: Example CF Displaying Addition of Instance Name & Number Of Instances to Roll Out The *Central Monitoring Alert* Form

9) Once the LPO-specific forms setup is complete, publish the draft and push it to sites.

10) Verify all Fields and DDs of the Standard OPEN Enrollment forms, along with the LPO-specific forms.

11) After successful testing, move a copy to the Global Library for all subsequent study use.

Appendix II: Rave RTSM Randomization Responses

Randomization Failures

In cases where Rave RTSM is not able to randomize patients, Rave RTSM raises an *Entry Error* query with the details on the *Is the subject ready to be randomized?* question as shown in Figure 13. The message that will be shown to the registrar in OPEN is shown in Figure 14. OPEN does allow for the registrar to resubmit the enrollment at a later time once the issue has been resolved in Rave RTSM.

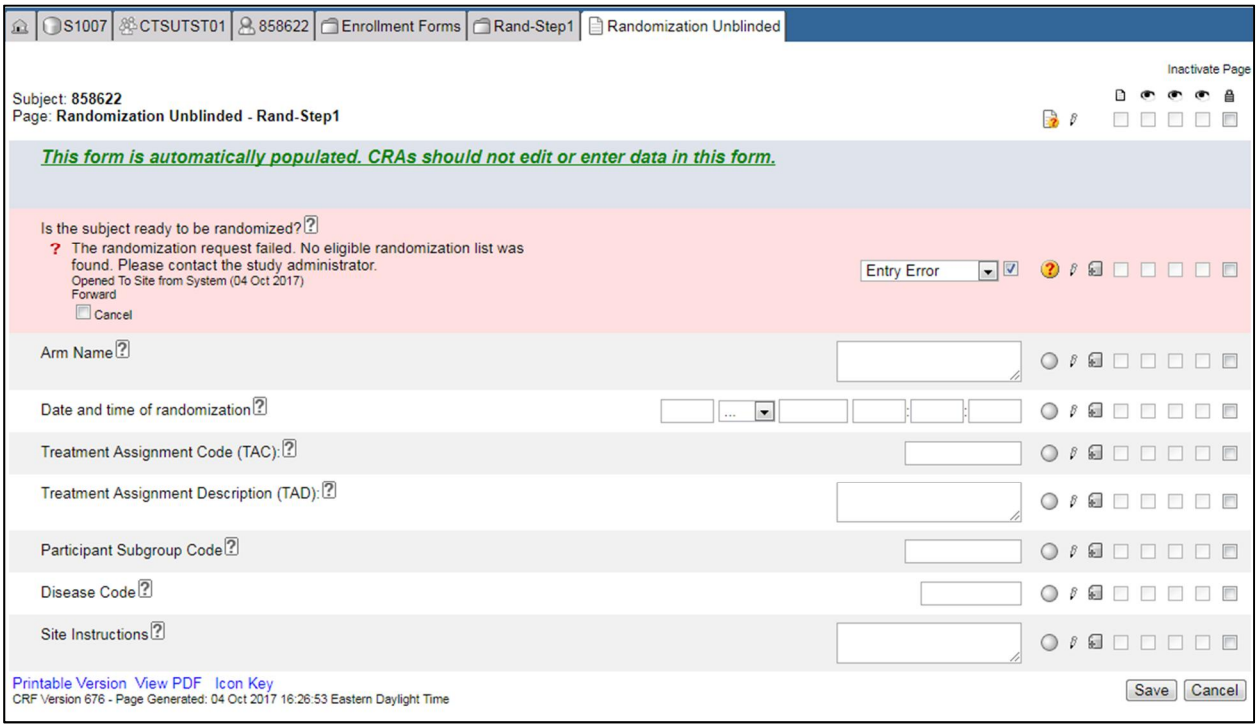

Figure 13: Randomization Failure Screen in Rave

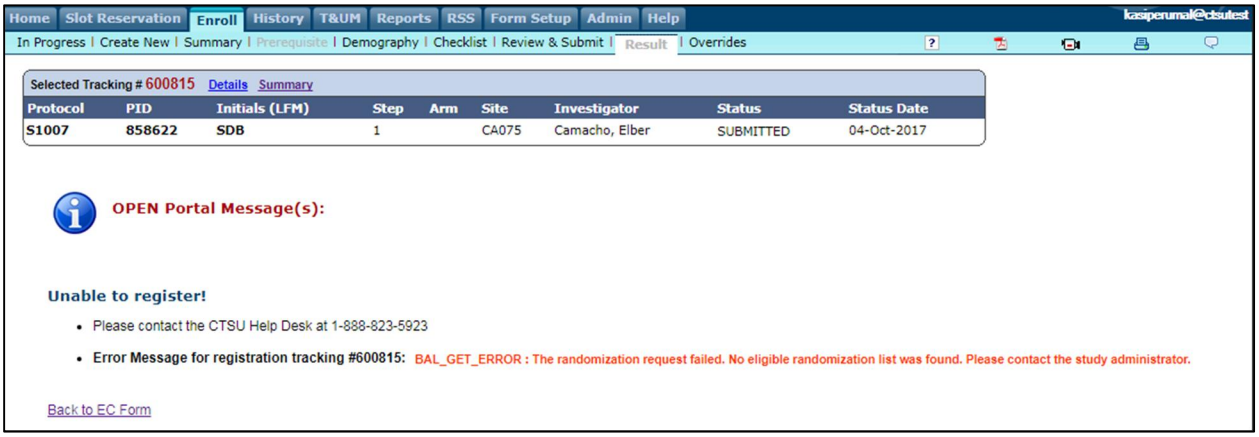

Figure 14: Randomization Failure Screen in OPEN

Appendix III: Rave-CTEP-AERS Forms Definition

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

1) AE (CTSU_AE)
2) AER (CTSU_AER)
3) LAE (CTSU_LAE)
4) 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.

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 21: 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 Expedited Safety Reporting Rules Evaluation User Guide.
NOTE2 / NOTE2	* Red asterisk before a field denotes that it is required by the system for rules evaluation.	

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
SUPPAE_QVAL_CYCLNUM / Treatment Cycle Number PID2744948_V1_0	* Course/Cycle #	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 User Interface (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	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
TAC1 / Treatment Assignment Code PID1967_V4_0	* Treatment assignment code	This Treatment Assignment Code is derived from the OPEN Enrollment *Treatment Assignment* Form when the form is rolled out, and the CRA has the option to change the value by selecting TAC from the drop-down. 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.	
AEONGOP / Prior Cycle Adverse Event Ongoing Indicator PID6041428_V1_0	Were any AEs reported as ongoing in the previous cycle?	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	Please confirm AEs reported as ongoing in the previous cycle are still ongoing.	This field is displayed when there are ongoing AEs in the previous cycle. 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.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AE_AEPRESP / Adverse Event Pre-Specified PID6379825_V1_0	Pre-Specified Adverse Event	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.
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 adverse event code (CTCAE v5.0)	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.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AEPERF / Adverse Event Current Cycle Assessment Indicator PID5273131_V1_0	* 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	* What is the description of the 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.
AE_AETOXGR / Adverse Event Toxicity Grade PID6338618_V1_0	CTCAE Grade	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.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AE_AETOX / Common Terminology Criteria for Adverse Events Severity/Intensity Scale for Adverse Events Severity Grade Text PID2747999_V1_0	What is the description of the toxicity?	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	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 / Adverse Event Attribution Code PID2179609_V4_0	Relationship to Study Treatment	
CTCAE1 / Common Terminology Criteria for Adverse Events Version 5.0 Low Level Term Name PID6063560_V1_0_1	Adverse event term (CTCAE v5.0)	This is derived from the * *Adverse event term (CTCAE v5.0)* field. This is derived: • for solicited AEs when the form is rolled out • for unsolicited AEs when the form is saved This is placed in the middle of the page so the CRA can track the AE. LPOs should *View Restrict* this field to the CRA and delete the field label and header text. CRA cannot edit this field.
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.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
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	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	What action was taken with study treatment?	Variable AE_AEACN to capture study treatment action is setup as invisible in ALS 7.0. 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	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	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	This is derived and indicates the first date/time the AE log line is entered and form saved. CRA cannot edit this field.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
AEZONE / Address Time Zone Name PID3014791_V1_0	* Time zone	This is derived when the form is saved. Used to collect calculations of *Report Due By* by time zone. CRA cannot edit this field.
CTCAE2 / Common Terminology Criteria for Adverse Events Version 5.0 Low Level Term Name PID6063560_V1_0_2	Adverse event term (CTCAE v5.0)	This is derived from the * *Adverse event term (CTCAE v5.0)* field. This is derived when the form is rolled out for solicited AEs and saved for unsolicited AEs. This is placed near the end of the page so the CRA can track the AE. LPOs can *View Restrict* this field to CRA. CRA cannot edit this field.
SUBMITBY / Submitted by PID6783868_V1_0	* Submitted by	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 / WAS_EVALUATED	Evaluated	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 CRF in Rave.	
CO_COVAL / Comment PID6355806_V1_0	AE Comment	
AEFRMDTC / Form Date PID6783869_V1_0	Form Date	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.

Expedited Reporting Evaluation Form

The Expedited Reporting Evaluation (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 22: 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. • 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

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		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. Note: 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.	
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 #	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.
SUPP_QVAL_AERPACN / Recommended action for report PID6819760_V1_0	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 / PID6819760_V1_0_1	Recommended action for report	This is a derived field. This displays the recommended action when AEs are

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		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 / Report ID	Report ID	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.
SUPP_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	This is derived when the form is saved. This is view restricted to the CRA.

Late Adverse Events Form

The Late Adverse Events (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 23: 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. • Trials using the AE Start/ End date fields must enter a response of *Yes* in the AE ongoing field when the adverse event persists to the next 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 Expedited Safety Reporting Rules Evaluation User Guide.
NOTE2 / NOTE2	* Red asterisk before a field denotes that it is required by the system for rules evaluation.	
SUPPAE_QVAL_CYCLNUM / Treatment Cycle Number PID2744948_V1_0	* Reporting period #	The cycle # is added to this field when the form is rolled out. This cycle # is required by the CTEP-AERS

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		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	
SUPPAE_QVAL_CYCENDAT / Treatment Reporting Period End Date PID2992_V4_0	Reporting period end date	
SUPPAE_QVAL_FCYSTDAT / Treatment First Cycle Begin Date PID61298_V3_0	* Start date of first 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 evaluation.
TAC1 / Treatment Assignment Code PID1967_V4_0	* Treatment assignment code	This TAC is derived from the OPEN Enrollment *Treatment Assignment* Form when the form is rolled out, and the CRA has the option to change the value by selecting TAC from the drop-down. 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?	This field is displayed when there are ongoing AEs in the previous cycle.
AEONGOC / Prior Cycle Ongoing Adverse Event Ongoing Indicator PID6041430_V1_0	Please confirm AEs reported as ongoing in the previous cycle are still ongoing.	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	

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
	table. If these options are not available, you are already viewing the entire table.	
AE_AEPRESP / Adverse Event Pre-Specified PID6379825_V1_0	Pre-Specified Adverse Event	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.
SUPPAE_QVAL_CTCAECD / Common Terminology Criteria for Adverse Events Version 5.0 Mapped Low Level Term MedDRA Code PID6063561_V1_0	* MedDRA adverse event code (CTCAE v5.0)	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	What is the description of the 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	CTCAE Grade	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.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
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	What is the description of the toxicity?	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. 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	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 / Adverse Event Attribution Code PID2179609_V4_0	Relationship to Study Treatment	
CTCAE1 / Common Terminology Criteria for Adverse Events Version 5.0 Low Level Term Name PID6063560_V1_0_1	Adverse event term (CTCAE v5.0)	This is derived from the *Adverse event term (CTCAE v5.0)* field. This is derived when the form is saved. This is placed in the middle of the page so the

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		CRA can keep track of the AE. LPOs can *View Restrict* this field to the CRA and delete the field label and header text. CRA cannot edit this field.
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	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	What action was taken with study treatment?	Variable AE_AEACN to capture study treatment action is setup as invisible in ALS 7.0. 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	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.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
SUPPAE_QVAL_SAERPT / SAE report recommended PID6824777_V1_0	SAE report recommended	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	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	This is derived when the form is saved. CRA cannot edit this field.
CTCAE2 / Common Terminology Criteria for Adverse Events Version 5.0 Low Level Term Name PID6063560_V1_0_2	Adverse event term (CTCAE v5.0)	This is derived from the *Adverse event term (CTCAE v5.0)* field. This is derived when the form is rolled out for solicited AEs and saved for unsolicited AEs. This is placed near the end of the page so the CRA can track the AE. LPOs can *View Restrict* this field to the CRA. CRA cannot edit this field.
SUBMITBY / Submitted by PID6783868_V1_0	* Submitted by	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 / WAS_EVALUATED	Evaluated	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.	
CO_COVAL / Comment PID6355806_V1_0	AE Comment	
AEFRMDTC / Form Date PID6783869_V1_0	Form Date	This is derived when the form is saved. This is used for internal purposes. This is view restricted to the CRA.

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 24: 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 rule evaluation to determine if expedited reporting is recommended. • Select the check box *Send all AEs for evaluation* and save the form. • 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*

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		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* 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	

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
	safety system is called for AE evaluation. Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.	
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 #	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.
SUPP_QVAL_AERPACN / Recommended action for report PID6819760_V1_0	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 / 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 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.

Field OID/Field Name (+PID+CDE#+Ver#)	Field Label/Column Header	Notes
		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 / Report ID	Report ID	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.
SUPP_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	This is derived when the form is saved. This is view restricted to the CRA.

Validations on the 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 AE/LAE Form if data does not meet certain conditions.

Table 25: AE/LAE Form Validations

Condition	Message	Comments
AE is not evaluated or is pending	If the *Adverse event evaluated this cycle?* is	This validation applies only if the

Condition	Message	Comments
evaluation for solicited AEs and any of the other questions are answered. Applicable for AE form only.	*No* or *Pending*, then AE information should be missing. Please reconcile.[QC004]	study collects solicited AEs. LPOs should customize this message if: • *CTCAE Grade* field is used to collect grades instead of *What is the description of the 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 *What is the description of the 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]	
AE Grade missing Applicable for LAE form only.	*CTCAE Grade* should NOT be missing. [QC007]	
AE Term missing, Applicable for LAE form only.	*Adverse event term (CTCAE v5.0)* should not be missing.[QC008]	
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]	
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 *What is the description of the toxicity? (first 120 characters).*

Condition	Message	Comments
Grade Description/Grade is related to death and Death is not checked as a result.	If the patient outcome is selected as *Yes* for *Death*, then the *CTCAE Grade* should be 5. Please reconcile.[QC011]	LPOs should customize this message if: • *CTCAE Grade* field is used to collect grades instead of *What is the description of the 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]	
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 *What is the description of the 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 *What is the description of the 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]	
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]	
When RE call is performed and CTEP-AERS recommends to submit a report.	An expedited report is RECOMMENDED. If the Investigator believes an expedited report is not warranted, (e.g., per protocol, commercial agent/arm, medical judgement, etc.), edit the *Recommended action for report*	

Condition	Message	Comments
	field to indicate NONE.[QC018]	
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]	
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 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]	
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]	
AE End Date is empty and AE Ongoing is No or empty.	If AE Ongoing is *Yes* then Adverse Event *End Date* should be blank. If AE *Ongoing* is *No* then Adverse Event *End Date* should be entered. Please reconcile.[QC023]	
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]	
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* should be missing. Please reconcile.[QC025]	
Duplicate AE. Duplicates are based on AE Term, AE Grade and AE Start Date combination.	Duplicate Adverse Event. Please reconcile.[QC026]	
Attribution to study intervention cannot be missing when Reporting period end date is present.	*Relationship to Study Treatment* cannot be missing when *Reporting period end date* is present. Please reconcile.[QC027]	
When previous cycle has ongoing AEs and answer to *Please confirm AEs reported as ongoing in the previous cycle are still ongoing*, in the current cycle is missing.	Please confirm the ongoing status of all AEs from the previous cycle then select *Yes*.[QC028]	
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]	

Condition	Message	Comments
If AE grade is 0, then Attribution to study intervention should be missing.	If *CTCAE Grade* is 0, then *Relationship to Study Treatment* should be missing. Please reconcile.[QC030]	
Action Taken with study treatment cannot be missing.	*Action Taken with study treatment* cannot be missing.[QC031]	
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]	