

CTSUS Resources and Tips

SWOG ORP Open Forum – October 17, 2024

Support Links and Contacts

- CTSUS Help Desk: ctsuscontact@westat.com; 1-888-823-5923
- CTSUS Regulatory Help Desk: CTSUSRegHelp@coocg.org; 1-868-651-2878
- CTEP-IAM Help Desk: ctepreghelp@ctep.nci.nih.gov; 703-738-9171
- RCR Help Desk: RCRHelpDesk@nih.gov; 703-738-9150
- ID.me Support: CTEPHelp@nih.gov (General questions and linking CTEP-IAM with ID.me) [ID.me Help Center](#) (ID.me account)
- Information on the ID.me: CTEP Website - [NCI CTEP IAM User Access Update](#)
- NCI CIRB Help Desk: support@ncicirbcontact.zendesk.com; 1-888-657-3711
- TRIAD Help Desk: triad-support@acr.org; 703-390-9858

CTSUS Resources

- [Resources Page](#) of the CTSUS members' website
- [New Staff Training](#) (Resources > CTSUS Operations Information > General Procedures and Training > Site Staff Orientation Slides)
- [Getting Started with the CTSUS](#)
- [Expanded Researcher Resources](#) (Resources > Researcher Resources)
- [CTSUS Frequently Asked Questions \(FAQs\)](#)
- [Glossary and Acronyms](#)
- **New Site-facing CLASS Training Status Report** (from the CLASS page on the CTSUS members' website)
- **New Serious Adverse Event reporting-related FAQs** (Resources > FAQs)

CTEP = Cancer Therapy Evaluation Program; CTEP-IAM = CTEP Identity Access Management; RCR = Registration and Credential Repository; NCI CIRB = NCI Central Institutional Review Board; TRIAD = Transfer of Images and Data application; CLASS = Compliance, Learning, and SOP Solutions application; FAQ = Frequently Asked Question.

A Few Things the CTSU Help Desk Wants You to Know

1. You can locate help and usage instructions in the **Help Topics** that appear on the right side of nearly every screen within the CTSU members' website and the modernized applications (e.g., the Delegation of Tasks Log [DTL] and Source Document Portal [SDP]). Help Topics contain page-specific information on how website areas or applications work. The Oncology Patient Enrollment Network (OPEN) is a bit different, but all associated **user guides** are available under the OPEN link on the CTSU members' website, on the OPEN login screen, or by clicking on the Help tab once logged in to the application.
2. To **access the CTSU members' website** you must have a CTEP account and [ID.me](#) (which incorporates Identity Proofing (IP) and Multi-Factor Authentication (MFA) into the registration process) and also be claimed on a roster. See [Instructions for Getting Started With the CTSU](#) for more information, located on the public website under Resources.
3. You can subscribe/unsubscribe from the **Bi-Monthly Broadcast** using the **My Account** button on the banner bar of CTSU members' website.
4. If your **institution's name or public contact information** has changed, reach out to the [Enterprise Core Unit \(ECU\) Help Desk](#) to update this information centrally.
5. The CTSU cannot expedite **rostering requests** for most of the rostering organizations, including the major groups such as SWOG, ECOG-ACRIN, etc. Users should reach out to the rostering organization directly for this.
6. You can check to see which of your site staff have **linked their CTEP-IAM accounts with ID.me** by clicking on the [RUMS link](#) on the CTSU website, selecting a roster in the first filter, and exporting the resulting grid by clicking on the Excel link above the upper right corner of the grid. The last two columns of the export contain the ID.me-related information.
7. The CTSU sends site participation information to the **Clinical Trials Reporting Program (CTRP)**, but does not do so until a site has a site registration status of *Approved* for the study. If your site is missing from ClinicalTrials.gov, ensure that it received site registration approval in CTSU systems before reaching out to the CTSU or the Clinical Trials Reporting Office (CTRO).
8. **CIRB Documents** (location: protocol-specific page > Documents > CIRB Approved Documents) are posted by the CIRB; questions about posting dates or potentially

missing items should be directed to the [CIRB via email](#). If you have questions about the content of protocol documents, contact the Lead Protocol Organization (LPO).

9. The **Regulatory Submission Portal** has technical limitations preventing the submission of files with the following characteristics:
 - a. Larger than 25 MB;
 - b. More than 35 characters total in the filename; and
 - c. Special characters, including periods, in the filename.

See the [Regulatory Submission Portal User Guide](#) under the Regulatory page Help Topics (Regulatory Submission section) for more information about using the Portal.

10. You can check your site's **regulatory status** for a given study, including whether there are any missing requirements (and what they are), on the CTSU website by going to Regulatory > [Site Registration](#). Enter the site and study, and look at the Status Reason column as well as the *i* button in the *Missing Reqs* column.
11. If you are looking for a certain **site DTL** in the Site DTL Browser and can't find it, update the DTL Status column filter to include *Retired* DTLs; these are not included in the default view. Similarly, if you cannot find a certain task assignment within an individual site DTL or the Task Assignment Browser, update the Task Status column filter to include *Inactive* tasks, which are not included in the default view.
12. Not all task assignments on the DTL require **Clinical Investigator (CI) signature**. If you make some new task assignments and notice that you are not able to notify the CI to approve the updated DTL, refer to the DTL Master Task List to confirm that the new assignments do not require approval (some key examples include the OPEN Registrar and Rave CRA tasks).
13. When submitting requests related to OPEN or any other patient-specific topic, please ensure you **do not include any personally identifiable information (PII)** in an unsecured email; this includes patient initials and date of birth. Be mindful of any PII you might inadvertently include in screenshots (e.g., from OPEN or Rave).
14. To **update or correct an enrollment in OPEN**:
 - a. If you want to transfer a patient, update credentialing information (e.g., change to a different investigator at the same site) or update demography information, this can *typically* be done via the **Transfer & Update Module (T&UM)** in OPEN. See the [T&UM User Guide](#) for details about this process.
 - b. If you need to update information within the eligibility checklist, [email the CTSU Help Desk](#) with the enrollment information, including: protocol #, step #, tracking #, patient ID #, question that requires correction and the correct answer. Be careful with PII as noted in #13 above.

15. Know that **funding information must be entered in OPEN within one year** of the date of the specimen or test. NCI used to have a grace period for this, but is no longer making any exceptions. See the [Open Funding Screen Site User Guide](#) for more information.
16. Most **protocol-specific questions** (*especially* clinical ones) are best answered by the study team at the LPO; the CTSU is not able to answer protocol-specific questions of this type. The LPO contact, usually the Protocol Coordinator, is often indicated in the protocol document.
17. If you have the **Rave CRA** role but notice that you have **Read Only access** to a study in Rave (e.g., fields or forms appear “locked”) **check to see if the study has a DTL**. Rave CRAs must have an active *Rave CRA* task assignment on the site DTL to have write access to the study in Rave.
 - a. *If a DTL is not the issue*, and forms or fields are locked in Rave, please reach out to the **Data Manager** for the study at the LPO; the CTSU is unable to access Rave and unlock or otherwise manage items in that application.
18. Questions on how to **resolve Data Quality Portal (DQP) queries** should be directed to the Data Manager for the study. This includes situations where you have addressed a query or delinquency in Rave but it is still appearing on the DQP; the Data Manager should be able to confirm that and then reach out internally to the LPO’s DQP Administrator to remove the item from the DQP.
19. When entering **Adverse Events (AEs) in Rave**, **do not use symbols** in the *Verbatim Term* field or the *Other Specify* field. While Rave allows symbols in free text fields, the CTEP Adverse Event Reporting System (CTEP-AERS) does not, and you will receive an error when you try to submit AEs for evaluation. For example, enter “Nausea and Vomiting,” not “Nausea & Vomiting.”