



Experimental Therapeutics Clinical Trials Network
Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

TRIAL CONDUCT

Intended for those at clinical sites
conducting ETCTN trials

ETCTN Cancer Trials Support Unit (CTSU) Information Sheet

1. Introduction

The Cancer Trials Support Unit (CTSU) is a service of the NCI that supports clinical trial management and conduct. The CTSU provides services to a number of Cancer Therapy Evaluation Program (CTEP)-supported networks, including the ETCTN. Services provided by the CTSU include:

- Institution and person roster support;
- CTSU website support for posting of protocols and information dissemination;
- Site registration and regulatory document tracking and management support;
- Patient enrollments through the Oncology Patient Enrollment Network (OPEN);
- Clinical Data Management Support (CDMS) for the Medidata Rave data management system via the CDMS Support Center (CSC);
- Single-sign-on access directly from the CTSU website to other applications necessary to conduct an ETCTN trial (e.g., OPEN, Rave); and
- Customer service support through Help Desk, regulatory, membership, and patient registration services.

Most new trials opened under the ETCTN program will receive full CTSU support.

Trials activated prior to the implementation of the ETCTN program will continue to follow their existing procedures for the areas listed above, whether they are handled through the CTSU or not. Following the initial launch of the ETCTN, some currently active trials have or will transition to various levels of CTSU support. Sites will be notified in advance of any such transitions.

Each protocol document will include logistical information on the conduct of that trial, including which CTSU support services are being utilized.

2. Person Registration and Account Maintenance

Please refer to the “ETCTN Person Registration and CTEP Identity and Access Management (CTEP-IAM) Information Sheet” for information on person registration with CTEP and the CTSU. In summary:

- To participate in CTEP- and CTSU-supported trials, investigators must be registered with the CTEP Pharmaceutical Management Branch (PMB). Investigators are defined as an MD or DO that are participating on CTEP-supported trials. Registration is annual and is done via hard copy paper forms with original signatures. Information on investigator registration is located at http://ctep.cancer.gov/investigatorResources/investigator_registration.htm.



Investigators are also strongly encouraged to obtain an account with CTEP Identity and Access Management (CTEP-IAM; they must first be registered with PMB as above. If an investigator has never registered for a CTEP-IAM account they will be required to create a new account at <https://eapps-ctep.nci.nih.gov/iam>.

- Research staff or associates must be registered through the CTEP-IAM process. Associates are defined as administrative and clinical site staff who are responsible for performing functions on clinical trials. A current CTEP-IAM account is also required to access the members' section of the CTSU website, OPEN, the CTEP online drug ordering system, and Rave. For more information on associate registration via CTEP-IAM, please visit http://ctep.cancer.gov/branches/pmb/associate_registration.htm.
- Several CTSU coordinated applications require specific user roles to gain access in addition to an active CTEP-IAM account. These applications include OPEN, Rave, and the Transfer of Image and Data (TRIAD) system. Organizational affiliations may be viewed on the CTSU website under the RUMS (Roster Update Management System) tab. For some roster members (Site Administrators and Site Data Administrators), functionality is available via RUMS to maintain roles and request the addition or withdrawal of persons. For more information on rosters and roles, please see the "Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Sheet."

3. CTSU Website and Broadcast Emails

Please see the "ETCTN Protocol Access and Communication Information Sheet" for more information on protocol posting on the CTSU website. In summary:

- After registering with CTEP and credentialing by the CTSU, the CTSU members' website may be accessed at www.ctsu.org. The website is the primary vehicle for communicating with clinical site staff information on protocols available through the CTSU and includes information on site rosters, regulatory submissions, accrual, data management, and general CTSU educational materials. In addition, the website includes tabs for OPEN and Rave, which provide access to the applications as well as resources.
- The CTSU Bi-Monthly Broadcast is the primary vehicle for communicating study-related updates to clinical sites (including study status changes, arm and cohort closures, safety notifications, and amendments). The Bi-Monthly Broadcast is released on the 8th and 22nd of each month. In addition, targeted broadcasts are used to reach investigators and research associates on important trial-specific communications between the Bi-Monthly Broadcasts. The CTSU also releases a tri-annual newsletter.

4. Regulatory Document Submission

Please see the "ETCTN Regulatory Processing Information Sheet" for more information on central regulatory processing through the CTSU. In summary:



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- The CTSU's Regulatory Support System (RSS) is utilized by Lead Protocol Organizations (LPOs) to identify all of the regulatory requirements for a given protocol. These protocol specific requirements (PSRs) will dictate each site's registration status. All site registration documents are to be submitted to the CTSU Regulatory Office where they will be reviewed and entered into RSS (IRB approvals [but not other PSRs] will be submitted automatically for sites participating in the NCI CIRB program). Once an institution has complied with all of the PSRs for a study, the site will be designated with an "Approved" Site Registration status in RSS.
- The CTSU does not send formal notification when sites are designated with an "Approved" status by the CTSU Regulatory Office; however, an institution's Site Registration status may be checked at any time by querying the RSS Site Registration status page located under the [Regulatory tab](#) of the CTSU members' website.

5. Patient Enrollment

Please see the "ETCTN Patient Enrollment Information Sheet" for more information on the CTSU's patient enrollment system, including its integration with Theradex's Interactive Web Response System (IWRS) for slot reservations and cohort management. In summary:

- Patient registration will be conducted using OPEN as outlined in the Registration Procedures section of the protocol and on the [OPEN tab](#) of the CTSU members' website. Enrollments may be credited to an organization participating on the study in which the institution and the credited investigator are active members.
- To perform an enrollment, the site user must have an active CTEP-IAM account and be assigned the 'Registrar' role on an ETCTN roster. OPEN can be accessed from the CTSU website or using the OPEN URL: <https://open.ctsu.org/open/home.open>. A user guide and training are available on the [OPEN tab](#) of the CTSU members' website and within the [OPEN portal](#).

6. Data Management

Please see the "ETCTN Data Management Information Sheet" for more information on the centralized data management system. In summary:

- Data for all new trials will be entered and queries managed electronically by LPOs using the Rave electronic data capture system. The iMedidata portal controls access to studies in Rave based on the CTEP-IAM system, role assignments in RSS, and completion of Rave eLearning assignments. Instructions for accessing Rave are provided on the [Rave tab](#) of the CTSU members' website.
- Information regarding iMedidata accounts, FAQs and other helpful resources and announcements can be found within the [Rave tab](#) of the CTSU members' website as well as on the [Theradex website](#).



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7. CTSU Contact Information

CTSU Regulatory Office (for the submission of site registration documents)

1818 Market Street, Suite 1100

Philadelphia, PA 19103

Phone: 1-866-651-CTSU (1-866-651-2878)

Fax: 215-569-0206

E-mail (for regulatory submissions only): CTSURegulatory@ctsu.coccg.org

CTSU Help Desk:

Phone: 1-888-823-5923

Email: ctsucontact@westat.com

All calls and correspondence will be triaged to the appropriate CTSU representative.

CTSU Help Desk hours are 9:00 am – 6:00 pm. E.T. Mon-Fri (excluding holidays).

Patient eligibility or treatment-related questions should be directed to the LPO designee indicated in the protocol document.

The CTSU Public Web site is located at www.ctsu.org. A CTEP-IAM username and password is required to access the members' section of the website.