

ETCTN Protocol Access and Communication Information Page

1. Introduction

The [Cancer Trials Support Unit \(CTSU\) members' website](#) serves as a central repository for all materials related to the conduct of trials supported by the CTSU, including all study-related documents. Furthermore, the website serves as the gateway, using single-sign-on functionality, to the applications necessary to conduct ETCTN trials (e.g., the Oncology Patient Enrollment Network [OPEN] and Medidata Rave). The ETCTN uses the website as the access point for study documents.

The materials for all **new** trials opened under the ETCTN program will be posted on the CTSU members' website. All trials activated **prior to** the implementation of the ETCTN program that have not transitioned into the ETCTN mechanism, will be posted and maintained in their current manner.

All protocols posted to the CTSU website using CTSU's support services will contain detailed information on participation procedures such as central regulatory submission, patient enrollment in OPEN, and data management in Rave.

2. Protocol Postings

2.1 Site Staff Requirements

To access ETCTN protocols on the CTSU website, site staff must meet the following requirements:

- Active Cancer Therapy Evaluation Program (CTEP) registration with the credentials necessary to access secure NCI/CTSU Information Technology (IT) systems, and when applicable, active registration in the Registration and Credential Repository (RCR). Refer to [CTEP Identity and Access Management system](#) and [RCR webpage](#) for more information; and
- To access an individual study, staff must be on an ETCTN roster at a site that is a member of either the study's lead organization or a participating organization (refer to the [Rosters and Roles for ETCTN Participants \[Institution Rosters and Person Rosters\] Information Page](#) for more information).

2.2 Posted Documents and Locations

All protocol documents and supporting documents are posted on the CTSU members' website. The Protocols section contains a folder structure on the left-hand side of the page which includes a folder for the ETCTN. The folders can be filtered by Lead Organization, or simply enter the protocol number in the search field at the top of the section. Refer to the [Protocols Help Topics](#) for more information.

Posted documents include, but are not limited to:

- NCI Central Institutional Review Board (CIRB)-related documents including the protocol, informed consents, and patient materials and forms either given to or read to the patients (e.g., quality of life questionnaires, surveys). For a complete list, refer to [Uniform Document Posting for CIRB-Reviewed Studies](#);
- General Lead Academic Organization memoranda and other study related communication;
- Site registration documents;
- Patient enrollment documents;
- Case Report Forms (not to be given or read to patients);
- Drug safety notices;
- Education and promotion materials; and
- Pharmacy documents.

2.3 Study-related Announcements

Participating organizations will receive the following email notifications about studies:

- Monthly ETCTN Pipeline Report - provides a list of all studies that are in development and active for the ETCTN, including study lead and expected participation information;
- Activation notices - notify sites that a particular study is available on the CTSU website for local activation and patient enrollment; and
- Targeted broadcasts - provide investigators and research associates with important trial-specific communications.

All other information related to studies will be communicated on the CTSU website and in the CTSU Bi-Monthly Broadcast emails, as well as other ad hoc communications. **ETCTN members must check the CTSU website and review the CTSU Bi-Monthly Broadcast to remain aware of activities related to their studies.**

2.3.1 CTSU Website Homepage

All announcements related to studies, including new activations, closures, amendments, and other updates are listed in the **Protocol Updates** section on the CTSU members' website homepage. All new protocol-specific documents and memoranda are posted on the website's Protocols section under the appropriate protocol folder.

2.3.2 Bi-Monthly Broadcast

In addition to the postings under the Protocol Updates section, the CTSU distributes a Bi-Monthly Broadcast of all study-related announcements and updates. This broadcast is distributed on the 8th and 22nd of each month and goes out to all CTSU members; it is also posted on the CTSU members' website

under the Broadcast/Newsletter link on the homepage. All ETCTN-related announcements are listed in an ETCTN section of the broadcast.

2.3.3 Drug Safety Notifications

Drug Safety Notifications (DSNs) are posted to the CTSU members' website for applicable protocols under the *Drug Safety Notification* page **and** included in the CTSU Bi-Monthly Broadcast.

3. For Questions and Support

For questions about the CTSU website and protocol posting, contact the CTSU Help Desk:

CTSU Help Desk: 1-888-823-5923; CTSUContact@westat.com; CTSU Help Desk hours are 9:00 am – 6:00 pm ET Monday-Friday (excluding holidays).