



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 Protocol Access and Communication Information Sheet

1. Introduction

The Cancer Trials Support Unit (CTSU) members' website (<https://www.ctsu.org>) 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, via single sign on functionality, to the applications necessary to conduct ETCTN trials, e.g., the Oncology Patient Enrollment Network and Medidata Rave. The ETCTN will utilize the website as the access point for its study documents as described below.

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 will be posted and maintained in their current manner (note that some legacy Phase 2 Consortia (P2C) trials are posted on the CTSU website).

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

2. Protocol Postings

2.1 User Requirements

In order to access ETCTN protocols on the CTSU website, users must meet the following requirements:

- To access the website: Have a valid CTEP-IAM account (i.e., username and password; please see the "ETCTN Person Registration and CTEP Identity and Access Management (CTEP-IAM) Information Sheet" for more information).
- To access an individual study: Be on an ETCTN roster at a site that is a member of either the study's lead organization or a participating organization (please see the "Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Sheet" for more information).

2.2 What Gets Posted and Where?

All protocol documents and supporting documents are posted on the CTSU members' website. Under the [Protocol tab](#) there is a "protocol tree" that contains a folder for the ETCTN. Users can also search the tree by Lead Organization, or can simply enter the protocol # in the Search field at the top of the tree.





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Posted documents include:

- Protocol and memoranda
- Site registration documents, including informed consent forms
- Patient enrollment documents
- Case Report Forms
- Drug safety notices
- NCI CIRB-related documents (in the CIRB Documents folder)
- Education and promotion materials

2.3 Study-related Announcements

Participating organizations will receive the following email notifications about studies:

- Monthly ETCTN Pipeline Report: To provide a list of all studies that are in development and active for the ETCTN, including study lead and expected participation information
- Upon CTEP Approval on Hold (AOH): To provide advance notice that a particular study has been submitted for CIRB review and system build and will be activated in the near future
- Upon activation and posting on the CTSU members' website: To notify sites that a particular study is available on the CTSU website for local activation and patient enrollment

Otherwise, nearly all information related to studies will be communicated via the CTSU website and the CTSU Bi-Monthly Broadcast emails, as well as any other ad hoc communications. Announcements related to study amendments, closures, etc., will no longer come directly from the lead organization/institution. ETCTN members must become accustomed to checking the CTSU website and reviewing the CTSU Bi-Monthly Broadcast to remain aware of activities related to their studies.

2.3.1 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 documents and memoranda, etc., are posted on the website's Protocol tab 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 or around 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 tab on the homepage. All ETCTN-related announcements will be listed in an ETCTN section of the broadcast.



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2.3.3 Drug Safety Notifications

Standard Drug Safety Notifications (DSNs) are posted on the CTSU website under the appropriate protocol folder → Drug Safety Notification sub-folder and announced via the CTSU Bi-Monthly Broadcast emails. Any safety notifications that require a 24 hour response and/or will result in an immediate closure of a study (whether temporary or permanent) will be distributed to all enrolling and registered sites via a special targeted broadcast email from the CTSU.

3. For Questions and Support

For questions about the CTSU website and protocol posting, contact the CTSU Helpdesk.

- CTSU Help Desk: 1-888-823-5923; CTSUContact@westat.com