



Experimental Therapeutics Clinical Trials Network

Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

Steps for Participating Sites in ETCTN Trials

To get started:

- Ensure that investigators and research staff at your site have a CTEP ID and/or a CTEP-IAM account (username and password).
 - Hint: If you can access the [CTSU members' website](#), you have an active CTEP-IAM account.
 - For more information, please see the “ETCTN Person Registration and CTEP Identity and Access Management (CTEP-IAM) Information Sheet” or go to the [Investigator Registration](#) and/or [Associate Registration](#) pages on the CTEP website.

- Ensure that all investigators and research staff at your site who will be involved in the conduct of the study are on the appropriate ETCTN (i.e., LAO) or other participating site roster with the appropriate roles.
 - For more information, please see the “Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Sheet.”

- Access ETCTN educational and informational materials on the CTSU members' website
 - Log in to the [website](#) using CTEP-IAM username and password
 - Education & Resources tab → ETCTN Program folder

- Access protocol documents on the CTSU members' website
 - To view/access a given protocol, you must be on a roster at a site that is part of an LAO or other organization/site officially participating in the trial.
 - Log in to the [website](#) using CTEP-IAM username and password.
 - Protocol tab → By Lead Organization folder → Lead Organization folder → NCI protocol number.
 - For more information, please see the “ETCTN Protocol Access and Communication Information Sheet.”

Protocol-Specific activities:

- Obtain IRB approval and submit regulatory documents to the CTSU Central Regulatory Office
 - CIRB sites: Ensure that your Signatory Institution has an approved Annual Signatory Institution Worksheet about Local Context and the PI that plans to open the trial locally has an approved Annual Principal Investigator Worksheet about Local Context on file with the CIRB.



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- CIRB sites: Ensure that the site preferences set by your Signatory Institution include your site for the protocol in question.
 - CIRB sites: Submit a Study-Specific Worksheet about Local Context to the CIRB and ensure its approval; your site must also comply with any additional protocol-specific requirements via the CTSU Regulatory Office (as directed in the protocol document).
 - Non-CIRB sites **or** all sites opening a study that did not receive CIRB review/approval (i.e., a legacy study that transitioned into the ETCTN): Sites must submit initial, continuing, and designated amendment IRB approvals to the CTSU Regulatory Office and comply with any additional protocol-specific requirements.
 - Sites should confirm they have an “approved” regulatory status via the CTSU members’ website (Regulatory tab → Site Registration sub-tab) prior to attempting to enroll patients.
 - For more information, please see the “ETCTN Regulatory Processing Information Sheet” and the “ETCTN NCI CIRB Initiative Information Sheet.”
- Enroll patients
- Ensure that your site has a status of “approved” and that all appropriate person and/or institution credentials/attributes have been satisfied.
 - Ensure that staff members who will be using the Oncology Patient Enrollment Network (OPEN) to enroll patients have the role of “Registrar” on the person roster and active CTEP-IAM accounts.
 - For more information, please see the “ETCTN Patient Enrollment Information Sheet.”
- Enter and manage patient data via Medidata Rave
- Ensure that staff members who will be using Medidata Rave to enter and manage data have the role of “Rave CRA” on the person roster and active CTEP-IAM accounts.
 - Ensure that investigators who will be using Medidata Rave to enter and manage data and/or *to sign electronic CRFs* have the role of “Rave Investigator” on the person roster and active CTEP-IAM accounts.
 - Ensure that other staff members who need to view patient data in Medidata Rave, but will not be entering or managing data, have the role of “Read Only” on the person roster and active CTEP-IAM accounts.
 - Ensure that staff members who will be using Medidata Rave to enter and manage data have completed the in-application training (eLearning) appropriate for their role. Generally, eLearnings need only be completed once prior to the use of Rave for all NCI trials.
 - For more information, please see the “ETCTN Data Management Information Sheet.”



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On an ongoing basis:

- Make a habit of checking the CTSU members' website and the CTSU Bi-Monthly Broadcast emails for protocol updates.
- If you are participating in the CIRB initiative, ensure that the PI of record submits their Annual PI Worksheet about Local Context to the CIRB and reports any local potential unanticipated problems or serious/continuing noncompliance per CIRB policy.
- If you are not participating in the CIRB initiative, ensure that you obtain and submit IRB approvals for your studies annually as well as for all required amendments to the CTSU Regulatory Office.
- Ensure that all roster members, i.e., physicians and associates, maintain their CTEP registration on an annual basis, and reset their CTEP-IAM passwords every 120 days.

For assistance:

- For most issues, contact the CTSU Help Desk at CTSUContact@Westat.com or 1-888-823-5923
- For CIRB-related issues, contact the CIRB Help Desk at ncicirbcontact@emmes.com or 1-888-675-3711