

## Steps for Participating Sites in ETCTN Trials

### To get started:

- Ensure that investigators and research staff at your site have an active Cancer Therapy Evaluation Program (CTEP) registration with the credentials necessary to access secure NCI/CTSU Information Technology (IT) systems, and if applicable, are registered in the Registration and Credentialing Repository (RCR). The RCR recognizes five types of registered users: Investigators (IVR), Non-Physician Investigators (NPIVR), Associate Plus (AP), Associate (A), and Associate Basic (AB), but only the first three must register in RCR. Refer to the [Registration Procedures and CTSU Website Access](#) page, the CTEP [RCR page](#), and/or the CTEP [Associate Registration](#) page for more information. Refer to [CTEP Identity and Access Management \(CTEP-IAM\)](#) page to check on your CTEP-IAM account status.
- 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., Lead Academic Organization [LAO]) or other participating site roster with the appropriate roles.
  - For more information, refer to the [Rosters and Roles for ETCTN Participants \(Institution Rosters and Person Rosters\) Information Page](#).
- Access ETCTN educational and informational materials on the CTSU members' website.
  - Log in to the [CTSU members' website](#).
  - Go to the Resources section → 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 the LAO or other participating organization, or a site that is officially participating in the trial.
  - Log in to the [CTSU members' website](#).
  - Use folders in the protocol tree to search for protocols by *Lead Organization, Cancer Type, Study Type, Phase, or Network* (e.g., ETCTN). Or, use the search bar and begin to enter the protocol number; a drop-down will populate with protocols that match what you are typing, select the protocol and click Go!.
  - For more information, refer to the [ETCTN Protocol Access and Communication Information Page](#) and [Protocols Help Topics](#).

### Protocol-specific activities:

- Obtain Institutional Review Board (IRB) approval and submit regulatory documents to the CTSU Regulatory Office
  - NCI Central Institutional Review Board (CIRB) sites:

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- Ensure that your Signatory Institution has an approved Annual Signatory Institution Worksheet about Local Context and the Principal Investigator (PI) that plans to open the trial locally has an approved Annual Principal Investigator Worksheet about Local Context on file with the CIRB.
  - Ensure that the site preferences set by your Signatory Institution include your site for the protocol in question.
  - 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 by submitting them to 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 IRB approvals for initial, continuing review, and designated amendments to the CTSU Regulatory Office and comply with any additional protocol-specific requirements.
  - For most ETCTN trials, sites must complete and maintain a Delegation of Tasks Log (DTL); an approved DTL is required for site registration approval. For more information on DTLs, refer to the Help Topics under the Delegation Log link on the CTSU members' website.
  - Sites should confirm they have an **approved** regulatory status via the CTSU members' website (Regulatory → Site Registration) prior to attempting to enroll patients.
  - For more information, refer to the [ETCTN Regulatory Processing Information Page](#) and the [ETCTN NCI CIRB Initiative Information Page](#).
- 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 active CTEP registration with the credentials necessary to access secure NCI/CTSU IT systems, are registered in the RCR with registration type of AP or higher, hold the role of Registrar on the person roster of a participating organization, and when applicable, are included on the site's DTL with the OPEN Registrar task assignment. Refer to [Registration Procedures and CTSU Website Access](#) page and/or CTEP [RCR page](#) for more information.
  - For more information, refer to the [ETCTN Patient Enrollment Information Page](#).
- Enter and manage patient data in Medidata Rave:
- Ensure that staff members who will be using Medidata Rave to enter and manage data have active CTEP registration with the credentials necessary to access secure NCI/CTSU IT systems, the role of Rave CRA on the person roster of a participating organization (which requires a registration type of AP or higher), and when applicable, are included on the site's DTL with the Rave CRA task assignment.
  - Ensure that investigators who will be using Medidata Rave to enter and manage data and/or to sign electronic Case Report Forms (CRFs) have active CTEP registration with the credentials necessary to

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access secure NCI/CTSUS IT systems, a role of Rave Investigator on the person roster of a participating organization (which requires a registration type of NPVR or IVR), and when applicable, are included on the site's DTL with the Rave Investigator task assignment.

- Ensure that other staff members who need to view patient data in Medidata Rave, but will not be entering or managing data, have active CTEP registration with the credentials necessary to access secure NCI/CTSUS IT systems (and RCR accounts if applicable to their registration type), and a role of Rave Read Only on the person roster of a participating organization.
- Ensure that staff members who will be accessing Medidata Rave have completed the in-application training (eLearning) appropriate for their role. Generally, eLearnings need only to be completed once prior to the use of Rave for all NCI trials.
- For more information, refer to the [ETCTN Data Management Information Page](#).

#### Closing studies:

Participating sites may choose to end their participation in a trial prior to the overall study's termination by the Coordinating Center, which is acceptable as long as they provide valid justification. This justification generally requires that one of the following criteria is met:

1. There were never any patients enrolled at the institution and the study is now closed to accrual;  
or
2. All patients who were enrolled to the study have completed treatment and follow up and no further data management activities or accruals are anticipated.

The CTSU Regulatory Office must be notified of the site's decision to end their participation in the study so that the necessary updates can be made in the Regulatory application. Note that withdrawing from a study will set a site's DTL to a *Retired* status and will therefore remove the site's access to the study in Rave.

The process to withdraw from a study varies slightly for US participants and the Canadian participant. For more information, refer to the guidelines included below.

#### US Participants:

- If an entire Signatory Institution is closing an ETCTN study for all sites under their signatory, the signatory should submit the closure request to the NCI CIRB via [IRB Manager](#).
  - Authorization from the Lead Protocol Organization (LPO) and the ETCTN data management contractor, Theradex, to close the study is required and must be submitted with the closure request.
  - Once the CIRB approves the closure of the signatory for the trial(s), the CIRB pushes the documentation necessary for permanently closing the trial at all sites under the signatory institution to the CTSU.
  - In these situations, the site contacts do not have to submit any documentation to the CTSU.
  - Following the CTSU's processing of a Signatory Institution's protocol closure the study is set to a *Withdrawn* status in the Regulatory application at all the Affiliate and Component sites that were participating in the study under the Signatory Institution.

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- Alternatively, an affiliate or component site(s) may want to permanently close an ETCTN study at their institution, independent of the other sites under the Signatory organization. This can be accommodated if the Signatory site preferences are set as protocol-specific.
    - To do this, the site contact may send an email to the CTSU at [CTSUSubRegPref@coocg.org](mailto:CTSUSubRegPref@coocg.org) indicating the site(s) and protocol(s) combination they wish to close and the justification for the closure.
    - Authorization to close the study from the LAO leading the study and the ETCTN data management contractor, Theradex, is required and must be submitted with the closure request.
  - If the site contact does not prefer to send an email to the above address, they may submit a memo via the CTSU Regulatory Submission Portal that is indexed for the site/protocol combination(s) they wish to close and indicate on the memo or in the *Comments* box in the Portal the closure justification.
  - Affiliate or Component sites may also choose to submit the [CTSU Optional Form 1: Withdrawal from Protocol Participation form](#) (posted on the on CTSU members' website under Resources > CTSU Operation Information > CTSU Forms) to the CTSU via the Regulatory Submission Portal to indicate their desire to withdraw from participation in the study. As with the options above, a valid closure justification and LPO and Theradex authorization must be provided.
  - Once one of the above methods is utilized to notify the CTSU of an individual Affiliate or Component site's withdrawal from participation in a study, a CTSU Regulatory Specialist will perform the closure by setting the Site Registration status to *Withdrawn* and updating the Signatory Institution's site preference settings to remove the site(s) that withdrew from participation in the study. At this time, no further enrollments will be able to occur for the withdrawn site. If there are any questions regarding the closure, the CTSU Regulatory Specialist will reach out to the contact directly to resolve any issues.
- Canadian Sites (University Health Network-Princess Margaret Hospital – 11030):
- As a Canadian site, University Health Network-Princess Margaret Hospital (11030) cannot use the NCI CIRB as their IRB of record, so 11030 should submit their closure request to their local Research Ethics Board (REB) for review and approval.
    - It is recommended that the site contact the LPO prior to initiating the closure process. Authorization to close the study from the LAO leading the study and the ETCTN data management contractor, Theradex, is required and must be submitted with the closure request.
    - Once the local REB approves the protocol closure at 11030 the REB's approval letter and/or the [CTSU Optional Form 1: Withdrawal from Protocol Participation form](#) should be submitted to the CTSU via the Regulatory Submission Portal on the CTSU website. As noted above, a valid closure reason must be provided with the submission of the closure.
    - Upon receipt of the approved protocol closure from 11030 the CTSU will update the Regulatory application to change the status of the study at 11030 to *Withdrawn*.

On an ongoing basis:

- Check 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. Refer to the [ETCTN Regulatory Processing Information Page](#).
- If you have the Site Administrator or Site Data Administer role at the LAO site, review your site roster periodically to ensure that it is current and if needed, add/remove people (and/or their roles) for your site.
- If you are the DTL Administrator on any DTLs at the site, ensure that they are kept up to date and are signed by the Clinical Investigator when necessary to maintain an Approved status.
- Ensure that all staff maintain their CTEP registrations on an annual basis.

For assistance:

- For most issues, contact the CTSU Help Desk at [CTSUContact@Westat.com](mailto:CTSUContact@Westat.com) or 1-888-823-5923; regulatory issues can be sent to the CTSU Regulatory Help Desk at [CTSURegHelp@coccg.org](mailto:CTSURegHelp@coccg.org) or 1-866-651-2878. CTSU Help Desk hours are 9:00 am – 6:00 pm ET Monday-Friday (excluding holidays).
- For CIRB-related issues, contact the CIRB Help Desk at [support@ncicirbcontact.zendesk.com](mailto:support@ncicirbcontact.zendesk.com) or 1-888-657-3711.
- For RCR-related issues, contact the RCR Help Desk at [RCRHelpDesk@nih.gov](mailto:RCRHelpDesk@nih.gov) or 703-738-9171.