

Steps for Coordinating Centers to Open ETCTN Trials

This checklist contains steps taken by the Coordinating Center and Study Principal Investigator (PI) leading up to ETCTN study activation. For a checklist of steps involved in site *participation* in an ETCTN trial (e.g., obtaining regulatory approval, enrolling patients, entering data), refer to [Steps for Participating Sites in ETCTN Trials](#). During the lead-up to study activation described in this document, the Study PI's site should prepare for study participation according to the site participation document.

Upon Cancer Therapy Evaluation Program (CTEP) Approval on Hold pending Food and Drug Administration (FDA) review, Central Institutional Review Board (CIRB) approval, and study build in the Oncology Patient Enrollment Network (OPEN)/Interactive Web Response System (IWRS)/Rave:

- The CTSU will announce *Approval on Hold* from CTEP in the CTSU Bi-Monthly Broadcast.
- For studies being filed to a new Investigational New Drug (IND), CTEP will submit the protocol to the FDA. You may be asked to respond to FDA comments and/or submit a revision while simultaneously undergoing CIRB review.

Note: FDA review and approval will take four to five weeks. This activity must be included in study activation timelines (i.e., Operational Efficiency Working Group [OEWG] timelines).

- CTEP will submit the protocol and consent to the CIRB concurrently with FDA review.
- The CIRB will contact the Study PI (or the Centralized Protocol Writing Support (CPWS) program team) to submit the CIRB application. If a protocol revision is requested, it should be sent directly to the CIRB. Refer to [Steps for Developing an ETCTN Trial Concept from Letter of Intent to Study Activation](#).

- Theradex will build OPEN eligibility forms and Medidata Rave database and forms. Once drafts are available, Theradex will contact the PI/Coordinating Center for approval of the forms and to clarify any other study-related issues necessary for study build and activation.

Note: CIRB review/approval and study build in OPEN and Rave will take four to six weeks and will be done concurrently. These activities must be included in study activation timelines (i.e., OEWG deadlines).

- The Protocol and Information Office (PIO) will forward the protocol to the NCI Clinical Trial Reporting Office (CTRO), which will register the trial at ClinicalTrials.gov and obtain a National Clinical Trial (NCT) number for the study.
- Once the CIRB grants approval, CTEP will review any modifications made during the CIRB review.
- Once CIRB and CTEP have approved the protocol documents, CTEP will submit the protocol to the FDA (if it was not previously submitted as part of the IND filing process).
- The Coordinating Center or the Lead Protocol Organization (LPO) will create and submit a study-specific Delegation of Tasks Log (DTL) template to CTEP via the DTL application on the [CTSU members' website](#). For more information, refer to the [DTL Template Browser Help \(for LPOs\)](#). An approved DTL template is required to obtain CTEP approval for the study.
- The PIO will issue a CTEP approval letter upon receipt of FDA approval of a new IND, or submission of protocol to existing IND and completion of Rave build and resolution of any remaining hold issue such as drug supply or PI registration.

Upon CTEP approval:

- CTSU Operations staff will contact the Coordinating Center to prepare for study activation and web posting. This communication will include an explanation of the remaining steps.
- CTSU Regulatory staff will work with the study team and set up the protocol in the [Protocol application](#) to allow for the proper collection of regulatory approvals and other study-related documentation.

Note: These activities can take several days to complete and should be included in the protocol activation timelines.

Leading up to study activation:

- The Study PI should send a brief email to the CIRB at earlyphasecirb@emmes.com to include the following (or similar) language: “NCI Protocol #123 is CTEP-approved and ready for distribution for IRB review at the participating organizations listed on the protocol cover page.” Please copy CTSU on this email at ctsuprotocol@westat.com and ctsuregsetup@coccg.org.
- CTSU Operations and Regulatory staff will communicate with the study team to finalize the Study Activation Memo and to confirm/finalize the study setup in the [Protocol application](#).
- CTSU Operations staff will request that the study team review all requirements for study activation via email.
- When ready to open to enrollment, and in close collaboration with the study team, the Lead Academic Organization’s (LAO) Grant Administrator will access the *Change Request to PIO* feature in the [Protocol application](#) to change the study status to *Active*.
- CTSU Operations staff will complete the posting of supporting documentation on the CTSU members’ website protocol page.
- The CIRB documents will post to the protocol page on the CTSU members’ website using an automated process based on the activation/release date conveyed by the study team and recorded in the *Protocol application* by the CTSU Regulatory Office.

Upon study activation:

- All study documentation, including CIRB documentation, will be available on the CTSU members’ website protocol page.
- The CIRB’s Study Specific Worksheet for Local Context will be available via [IRBManager](#).
- The study will be released in OPEN/Theradex IWRS and ready to enroll patients (*Active* studies).
- Medidata Rave study invitations will be sent to those persons holding Rave roles at approved sites.
- The CTSU will send a notification of study activation to all appropriate Grant/Contract PIs and Grant Administrators and will include notice of the activation on the CTSU members’ website and in the next CTSU Bi-Monthly Broadcast.

Upon CTEP/CIRB approval of study amendments and study status changes (ongoing basis):

- CTSU Operations staff will contact the study team to prepare for amendment releases.
- CTSU Regulatory staff will work with the study team to set up study amendments in the [Protocol application](#).
- CTSU Operations staff will complete the posting of protocol and supporting documentation on the CTSU members’ website protocol page, and will include notice of the amendment activation on the members’ website and in the next CTSU Bi-Monthly Broadcast.
- The Coordinating Center and Study PI or designee (i.e., the study team) should notify the CTSU Protocol Team ctsuprotocol@westat.com of trial status changes after initial activation (e.g., closure to accrual) and inform the OPEN (CTSUOPENFORMS@westat.com), Rave (CTMSSupport@theradex.com), and Regulatory (CTSURegSetup@coccg.org) teams prior to the actual status change.
- CTSU Operations staff will communicate with the study team to obtain a status change memo.
 - Per NCI’s directive, the CTSU will submit the memo to CTEP PIO for approval prior to posting/distribution.
- CTSU Operations will also update the Group Protocol Status in the [Protocol application](#) on behalf of the LAO, send a notification of trial status change to all appropriate Grant/Contract PIs and Grant Administrators in case of immediate temporary or permanent closure, and include notice of the status change in the next CTSU Bi-Monthly Broadcast.