



Experimental Therapeutics Clinical Trials Network

Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

Steps for Coordinating Centers to Open ETCTN Trials

Please Note: This checklist pertains to steps taken by the Coordinating Center and Study PI leading up to ETCTN study activation. For a checklist of steps involved in actual site participation in an ETCTN trial (e.g., obtaining regulatory approval, enrolling patients, and entering data), please see “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 CTEP Approval on Hold pending FDA review, CIRB approval, and study build in OPEN/IWRS/Rave:

- The CTSU will distribute notification of an Approval on Hold from CTEP to participating organizations.
- For studies being filed to a new IND, CTEP will submit the protocol to the FDA. You may be asked to respond to FDA comments and/or submit a revision. Please note: FDA review and approval will take 4-5 weeks. This activity must be included in study activation timelines (i.e., related to OEWG timelines).
- Upon completion of FDA review, CTEP will submit the protocol and consent to the CIRB.
- The CIRB will contact you to submit the CIRB application.
 - You may be asked to submit a protocol revision; this should be sent directly to the CIRB.
- Theradex will build your Oncology Patient Enrollment Network (OPEN) eligibility forms and your Medidata Rave website 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.
- Please note: CIRB review/approval and study build in OPEN and Rave take 4-6 weeks and will be done concurrently. These activities must be included in study activation timelines (i.e., related to OEWG deadlines).
- Once CIRB approval is granted and the study build is complete, CTEP will submit the protocol to the FDA.
- 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, PIO will issue a CTEP approval letter.
- The NCI Clinical Trial Reporting Office (CTRO) will register the trial at ClinicalTrials.gov and obtain an NCT number for the study.

Upon CTEP approval:

- CTSU Operations staff will contact you to prepare for study activation and web posting; this communication will include an explanation of the remaining steps.
- CTSU Regulatory staff will work with you to set up your protocol in the Regulatory Support System (RSS) to allow for the proper collection of regulatory approvals and other study-related documentation.
- Please note: These activities can take several days to complete, and should be included in 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 the CTSU on this email at ctsuprotocol@westat.com and ctsuregsetup@ecogchair.org.
- CTSU Operations and Regulatory staff will communicate with the Study Team to finalize the Study Activation Memo, and to confirm/finalize the study set-up in RSS.
- CTSU Operations staff will complete the posting of protocol and supporting documentation on the CTSU website protocol page.
- CTSU Operations staff will request that the Study Team review and attest to, via email, all requirements for study activation.
- When ready to open to enrollment, and in close collaboration with the Study Team, the LPO's Grant Administrator will access the Change Request to PIO feature in RSS to change the study status to Active.
- The CIRB will post all CIRB documents to the CTSU website on the protocol page (this can take 24-48 hours after release).

Upon study activation:

- All study documentation, including CIRB documentation, will be available on the CTSU website protocol page (again, CIRB documents may take 24-48 hours to appear on the website).
- The CIRB's Study Specific Worksheet for Local Context will be available via IRBManager.
- The study will be released in OPEN/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/P2C Administrators, and will include notice of the activation on the CTSU website and in the next CTSU Bi-monthly Broadcast.

On an ongoing basis - Upon CTEP/CIRB approval of study amendments:

- Send amendment setup request to the CTSU Regulatory staff
- Contact CTSU Operations staff to prepare for amendment release and site notification via web posting and CTSU Bi-monthly Broadcast.
- Notify the CIRB of amendment release/activation