National Cancer Institute (NCI)
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

CTSU Pre-Activation Activities

Contents

Introduction

The Cancer Trials Support Unit (CTSU) provides administrative services for ETCTN studies. These services include centralized regulatory support, communication, and document posting. When DF/HCC is leading an ETCTN trial, the study team must work closely with the CTSU on a number of tasks required prior to CTEP activation.

Procedure

1) CTSU Approval on Hold Notification
    a) When CTEP issues the initial Protocol Approval on Hold, the CTSU notifies participating organizations that the study has received approval on hold, and is therefore expected to be activated in near future. The CTSU attaches a copy of the draft protocol (the version that has received Approval on Hold) as a courtesy so that participating sites can begin the internal site processes that are required for activating a study locally (e.g., sending to internal committees, setting up billing and medical records systems, etc.).
        i) The Protocol Chair and DF/HCC Study Coordinator's contact information are included in the notification in the event sites who are considering participation have questions about the study. The DF/HCC study team should be prepared to provide guidance and address questions from participating sites.
2) Presentation at ETCTN Monthly Meeting
    a) The CTSU contacts the Protocol Chair and DF/HCC Study Coordinator and invites them to present (via webcast) the protocol to other ETCTN organizations' leadership at an upcoming ETCTN meeting.
        i) The presentation is generally a 10-15 minute protocol overview with particular focus on any unique aspects of the study.

ii) The CTSU provides a slide template which includes suggested topics but the study team also has the option to use their own slides.

b) The CTSU records the presentation so that it can be posted on the CTSU website within the Education and Promotion folder for staff at participating organizations to view in the future.

3) Training Slides
   a) The Protocol Chair and DF/HCC Study Team prepare site initiation training materials for participating sites. The study team can build upon the slides prepared for the ETCTN Monthly Meeting or use their own training slides.
   b) The site initiation training instructions are sent to the CTSU during Regulatory Support System Study Set-up for posting within the Protocol Requirements folder on the CTSU website.
4) Regulatory Support System (RSS) Study Set-up
   a) While the study is under review by the NCI CIRB, the CTSU Protocol Setup Coordinator contacts the DF/HCC Study Coordinator to start discussing issues related to the study's set-up in RSS.
   b) The DF/HCC study team should use the template language and instructions below as a guide when responding to the CTSU Regulatory Group.
      1. Protocol Number: *CTEP Protocol #*
      2. Release Date: *Anticipated date of study activation (if final CTEP approval is still pending however, use "Pending CTEP Final Approval")*
      3. Protocol Version Date: *From the current CTEP/CIRB approved protocol document*
      4. Protocol-specific Requirements (PSRs):

Protocol-specific requirements (PSRs) are any additional requirements (beyond IRB approval if applicable for a site) that participating sites must complete prior to enrolling patients. They can be study-specific, as well as person and /or institution requirements. PSRs gives DF/HCC the ability to require anything from participating sites that we feel is essential to running a successful trial, and via RSS, the CTSU would ensure that the requirement is met.

<u>Suggested List</u>

1) *IRB approvals (Initial, Amendments, & Continuing Reviews) if not using the NCI CIRB*
2) *Final Study Completion Form*
3) *Informed Consents*
4) *Documentation of Drug Specific Training for Pharmacy Staff*
5) *Study Chair (or his/her designee) Approval for limited-participation studies*
6) *CTSU Site Contact Form for Protocol*
7) *Verification of Completion of Protocol Training Form*
8) *Site initiation teleconference instructions*

Also, if participant list includes Canadian site University Health Network Princess Margaret Cancer Center LAO:

1) *Clinical Trials Site Information Form*
2) *Qualified Investigator Undertaking*
3) *Research Ethics Board Attestation*
4) *Group Application Canada Participation*
5) *CTEP International Committee Site Approval Canada*

And for Radiation Protocols:

1) *Radiation Facility Certification Number*
2) *Radiation Facility Certification Form (RTFI Form)*

a. Requirement Name: *List all requirements that apply (e.g., Site Initiation Teleconference, CTSU Contact Info Form, Approval by Lead Group, RTFI Form, etc.)*
b. Requirement Description on CTSU Website (if chosen to be different than the RSS): *The description of the requirement seen by sites on the CTSU website can differ from the description of the requirement in the RSS, if desired. The description in the RSS is used by CTSU regulatory processors and is seen by RSS stakeholders only (e.g., "ICF for Arm A").*
c. CTSU Processing Instructions: *Unique CTSU processing instructions and/or a DF/HCC contact can be established for each PSR. (e.g., "Sites are to provide copies of all versions of IRB Approved Consents with Institutional approval stamp /version date matching IRB approval letter").*
d. LPO Contact for PSR, if applicable: *Disease Group Manager or Study Coordinator*

5. Non-MD PI Permitted: *Yes/No (For treatment studies, always select "No")*
6. LPO Contact: *Disease Group Manager or Study Coordinator*
   a. Name: *Disease Group Manager or Study Coordinator Name*
   b. Phone Number: *Disease Group Manager or Study Coordinator Phone Number*
   c. Email Address: *Disease Group Manager or Study Coordinator Email Address*
7. IND Type: (Options: CTEP held IND, IDE, IDE exempt, IND exempt, No Agent, and Non-CTEP held IND): *The DF/HCC study team should refer to the protocol document when determining which IND Type option(s) to select*
   a. For Non-CTEP Held INDs:
      i. Agent:
      ii. IND Holder Name:
      iii. IND Number:
8. Anticipated Primary Completion Date:

9. Collect IRB Approvals Post Closure: *Always select "Yes" to continue to collect information for the study until all research is completed at the site(s)*
10. FDA Registration Trial: *yes/no The DF/HCC study team should confirm with CTEP if the study will be used as a registration trial.*
    **A study is designated as a registration trial if the data will be used to support a marketing application (NDA/BLA) to the FDA if the trial meets its primary endpoint*

5) Activation Memo
   a) The CTSU Operations team drafts an activation memo which the DF/HCC study team must review and approve.
6) Confirmation of Readiness to Activate
   a) Once the NCI CIRB and CTEP have issued protocol approval, the CTSU Operations team contacts the Protocol Chair to review and attest to (via email) a list of requirements toward study activation.
   b) The Protocol Chair must respond to the CTSU and attest that all requirements necessary for activation have been met.
      i) For grant tracking purposes, the DFCI Site Administrator, Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu), must be included on the Protocol Chair's reply.
7) Study Status Update
   a) Once the Protocol Chair attests that all activation requirements are met, the DFCI Site Administrator, Sharon Atkinson, changes the study status to "Active" in RSS.
   b) The CTSU sends the activation notice to primary contacts at all participating organizations, the key stakeholders at CTEP, the CIRB, CTMS, and the CTSU. The activation notice is posted in the protocol updates section of the CTSU website and will be included in the next CTSU Bi-Monthly Broadcast.
8) Protocol Page on CTSU Website
   a) The CTSU finalizes the protocol page on the CTSU website and all CIRB approved documents are posted.

Links

CTSU Website: https://www.ctsu.org