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

Closing an ETCTN Study when DF/HCC is a Participating Site

Contents

Introduction

The study closure process for ETCTN Studies must follow both DF/HCC Study completion requirements outlined in Policies RCL-100, RCL-101 and Operation RCL-OP-1 as well as NCI CIRB Requirements. When a DF/HCC site decides to close, they must also obtain approval from the study's Lead Protocol Organization (LPO) and Theradex and include the documentation in the submission of an NCI CIRB Study Closure Worksheet. Only when CTEP confirms all research-related interventions or interactions have been completed, and all data collection, submissions, queries and analysis have been concluded may a study be considered completed and closed.

Procedure

DF/HCC Site Closure for Multiple DF/HCC Sites Which Were Opened Under a single Study Specific Worksheet

1) The study team must inform Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu) and Shelby Watterworth (Shelbya_Watterworth@dfci.harvard.edu) when a Site requests to close an ETCTN Study at DFCI, MGH, or BIDMC and provide the rational for closure or early closure.

2) The study team will follow policies outlined in Policies RCL-100, RCL-101 and Operation RCL-OP-1 and ensure all DF/HCC completion requirements are met and all participants are off treatment and off study in Oncore for the identified site.
3) The study team follows the instructions on and completes the CTSU Early Study Closure Confirmation Form. They then and submit the form to the study's Lead Protocol Organization (LPO) and Theradex for approval.
    a) Once approval is received, the study team forwards the documentation to Sharon Atkinson and Shelby Watterworth.
4) Sharon or Shelby will contact the CTSU Regulatory Group to adjust the site preference list (which shows to which sites NCI CIRB approval applies) and provide CTSU with the Early Study Closure Confirmation Form approval.
5) The CTSU will issue a response confirming the adjustment and re-application of protocol specific site approval. Sharon or Shelby will then forward the approval to the study team for their records.
6) Upon receipt of the CTSU's confirmation of the adjustments made to the site preference list and the CTSU Early Study Closure Form approval, the study team will submit the study completion request in iRIS.
7) ODQ issues a notification of completion, and the local study status is changed to complete.

DF/HCC Study Closure for DF/HCC Sites Opened Under their Own Site-Specific SSW (ie- when there is one SSW per site)

1) The study team must inform Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu) and Shelby Watterworth (Shelbya_Watterworth@dfci.harvard.edu) when the Site Principal Investigator(s) request to close an ETCTN Study at their site and the rational for closure.
2) The core study team will follow the standard DF/HCC process outlined in Policies RCL-100, RCL-101 and Operation RCL-OP-1 ensuring all local participants are off study in Oncore and all local requirements are met.
3) The study team follows the instructions on and completes the CTSU Early Study Closure Confirmation Form. They then and submit the form to the study's Lead Protocol Organization (LPO) and Theradex for approval.
    a. Once approval is received, the study team forwards the documentation to Sharon Atkinson and Shelby Watterworth.
4) Sharon or Shelby will submit the Study Closure Worksheet to the NCI CIRB via the CIRB Manager system, including the Early Study Closure Confirmation Form approval which confirms all study closure requirements have been met for the identified study.
5) The CIRB will issue an approval for the Study Closure Worksheet, Sharon or Shelby will then forward the approval to the study team for their records.
6) Upon receipt of the CTSU Early Study Closure Confirmation Approval and NCI CIRB Study Closure Worksheet Approval, the core study team will submit the Study Closure Documents

and the study completion request in iRIS.

7) ODQ issues a notification of completion, and the local study status is changed to complete.

NCI CIRB Initiated Study Closure and Completion Process

1) The CTSU will issue a Notice of Closure on behalf of the National Chair and post a Memorandum to the CTSU website confirming a study's closure.
2) Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu) or Shelby Watterworth (Shelbya_Watterworth@dfci.harvard.edu) will provide the notice of closure to the core study team.
3) The core study team will follow the standard DF/HCC process outlined in Policies RCL-100, RCL-101 and Operation RCL-OP-1 ensuring all local participants are off treatment and off study in Oncore.
4) The study team follows the instructions on and completes the CTSU Early Study Closure Confirmation Form. They then and submit the form to the study's Lead Protocol Organization (LPO) and Theradex for approval.
    - Once approval is received, the study team forwards the documentation to Sharon Atkinson and Shelby Watterworth.
5) Sharon or Shelby will submit the Study Closure Worksheet to the NCI CIRB via the CIRB Manager system, including the Early Study Closure Confirmation Form approval which confirms all study closure requirements have been met for the identified study.
6) Upon receipt of the CTSU Early Study Closure Confirmation Approval and NCI CIRB Study Closure Worksheet Approval, the core study team will submit the Study Closure Documents and the study completion request in iRIS.
7) ODQ issues a notification of completion and the local study status is changed to completed.

Study Closure with no Accruals

The Study Closure Processes outlined above still apply when closing studies which have not accrued participants, except for the steps of moving DF/HCC participants to off study in Oncore. Even if a study is cancelled or closed before it begins, as long as it was officially opened at your site by the NCI CIRB, steps must be taken to officially close it via the CTSU Early Study Closure Form, Study Closure Worksheet or any other steps that apply as outlined in Policies RCL-100, RCL-101 and Operation RCL-OP-1 and the steps described in the processes above.

Links

NCI CIRB IRBManager: https://nci.my.irbmanager.com/Login.aspx

iRIS Wiki: https://wiki.dfci.harvard.edu:8443/prms

DF/HCC Document Library - Preparation for Site Close out (RCL-100):
https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library?tx_hcc_search%5Bquery%5D=RCL-100

DF/HCC Document Library – Record Retention for Completed Research (RCL-101):
https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library?tx_hcc_search%5Bquery%5D=RCL-101

DF/HCC Document Library - Procedures for Study Completion (Operation RCL-OP-1):
https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library?tx_hcc_search%5Bquery%5D=RCL-OP-1