

Medidata Rave and OPEN Eligibility Forms Build

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Introduction

ETCTN studies use the NCI Cancer Trials Support Unit (CTSU) Oncology Patient Enrollment Network (OPEN) system for participant enrollments and Medidata Rave as the clinical data management system. Theradex builds the OPEN eligibility forms along with the Medidata Rave website and forms for each ETCTN study. The study build is done concurrently with the initial NCI CIRB review/approval and takes approximately 4-6 weeks.

Refer to the [DF/HCC ETCTN Participant Enrollment](#) and [DF/HCC ETCTN Data Management Guides](#) for details regarding OPEN and Medidata Rave access and training materials.

Procedure

- 1) The NCI CTEP Protocol and Information Office (PIO) notifies Theradex once the CTEP review of the protocol and model consent form is complete. The Protocol Chair is copied on this communication.
- 2) Theradex begins the build of the participant enrollment and data management system while the study is under review by the NCI Central Institutional Review (CIRB).
 - a) Theradex contacts the Protocol Chair if any study-related clarification or additional information is needed.
 - b) Theradex notifies the Protocol Chair once draft forms are available for review.
- 3) The Protocol Chair reviews the forms and the Protocol Chair provides approval to Theradex.
- 4) Once NCI CIRB approval is granted and CTEP PIO confirms there are no outstanding issues holding up final CTEP protocol approval, Theradex completes the study builds.
- 5) Theradex is notified when the study is activated in the CTEP system (refer to the [DF/HCC ETCTN CTSU Pre-Activation Activities](#) for activation instructions) and the study is released in OPEN and Rave. Please note that this activation is different from local DF/HCC study activation.
- 6) Medidata Rave study invitations are sent by Theradex to those persons holding Rave CRA or Rave Site Investigator roles at approved study sites.

- 7) Refer to the [DF/HCC ETCTN Participant Enrollment](#) and [DF/HCC ETCTN Data Management Guides](#) for instructions on enrolling participants and entering participant information into Medidata Rave.

Links

Steps for Coordinating Centers to Open ETCTN Studies:

https://ctep.cancer.gov/initiativesPrograms/etctn_information_checklists.htm