

Rosters and Roles for ETCTN/EDDOP- Participants (Institution Rosters and Person Rosters) Information Page

1. Introduction

The National Cancer Institute (NCI) has formed partnerships in the pharmaceutical industry, academic institutions, and individual investigators for the early clinical evaluation of innovative cancer therapies. The Experimental Therapeutics Clinical Trials Network (ETCTN) was created to evaluate these therapies using a coordinated, collaborative, and inclusive team-based approach to early phase experimental therapeutic clinical trials. The ETCTN comprises nine different Lead Academic Organizations (LAOs). These LAOs participate in a Phase 1 Program supported by UM1 grants, integrated with a Phase 2 Program supported by cooperative agreements as supplements to the existing Phase 1/UM1 grant. By integrating Phase 1 and Phase 2 Program activities and administrative operations under the UM1 structure, ETCTN awardees have the flexibility to expand Phase 1 studies quickly upon detecting early activity signals. Additionally, any NCI-designated Cancer Center (NCI-CC) not affiliated with the ETCTN may still be able to participate in ETCTN trials as a lead clinical site or as a participating site under the NCI Early Drug Development Opportunity Program (EDDOP) leadership or accrual program. The EDDOP accrual program comprises eight different NCI-CCs. The ETCTN and EDDOP organizations use a common infrastructure to participate in ETCTN trials.

There are two types of rosters that make up each of the LAOs, institution rosters and person rosters.

1.1 Institution Rosters

Institution rosters consist of the **sites** that make up a given grantee organization. The Phase 1/UM1 grantees each have an LAO (the holder of the grant) and may also have Integrated Components and/or Affiliated Organizations *under the same grant*. For example, the Yale Cancer Center LAO has an institution roster that consists of Yale University (CT018, the main member) as well as several affiliated treatment sites, all of which are part of the LAO-CT018 institution roster.

The EDDOP has its own institution roster, which includes the eight EDDOP grantees as affiliated organizations in addition to their integrated components.

For a site to participate on a given ETCTN trial, it must be on the institution roster for either the Lead or Participating Organization for that trial (as dictated by the protocol cover page).

1.2 Person Rosters

Person rosters consist of the **people** (investigators and site staff) who work at a given ETCTN/EDDOP-participating site. Individuals who participate in the conduct of ETCTN trials (e.g., enroll patients, receive drug shipments, treat patients, and enter data) must be on the person roster for a given site or sites.

The following is required to be included on a site's person roster:

1. At a minimum, active Cancer Therapy Evaluation Program (CTEP) registration status; and
2. For those with significant roles in the conduct of research at the site, registration in the Registration and Credential Repository (RCR) as an Investigator (IVR), Non-Physician Investigator (NPIVR), or Associate Plus (AP). See the [RCR guide](#) for more information.

1.2.1 Person Roles

Individuals on a site's person roster may have certain roles assigned to them based on their registration type. These roles confer certain privileges, such as the ability to access the Oncology Patient Enrollment Network (OPEN) and enroll patients (OPEN Registrar role), the ability to access Medidata Rave to enter patient data (Rave CRA role), and the ability to serve as a site's primary contact person and make changes to the site's person roster (Site Administrator role). View the ETCTN site person roles and the rights they confer on the Cancer Trials Support Unit (CTSU) members' website (username and password required): [Site Roles Table](#).

2. Managing Rosters and Roles

2.1 Institutional Rosters

The institution rosters for the Phase 1/UM1 grants are *dictated by the grants themselves*. Individual sites must be part of an initial grant application or a Phase 2 supplement application to be considered part of the grant and included on a grant's institution roster. Any changes to the list of sites included under a grant (i.e., adding or removing a site) must be reviewed and approved by ETCTN program leadership and handled through CTEP's Enterprise Core Unit (ECU) Help Desk. Approved changes will then be made to the applicable LAO institution roster in the CTEP systems and the CTSU Roster Maintenance application.

The same is true for any updates to the EDDOP institution roster; all changes in terms of sites participating in the EDDOP program must be approved by CTEP and managed through the channels described above.

Organizational participants on a given LAO-led study are defined by the protocol (i.e., by organizations listed on the cover page of that protocol). Institutions associated with these organizations are defined in the institution rosters in CTEP systems, including the CTSU Roster Maintenance application.

2.2 UM1 Person Rosters and Roles

The site person rosters for the Phase 1/UM1 grants were initially built using a data collection process led by the CTSU. The CTSU collected names and roles for all site staff members and built the rosters in the *Roster Maintenance* application.

Following the initial roster build and maintenance by the CTSU, the LAOs have two different ways to manage their person rosters and roles.

1. CTSU Roster Update Management System (RUMS)
 - Located on the CTSU website in the RUMS link, RUMS works in conjunction with the *Roster Maintenance* application.

- Allows those with the Site Administrator or Site Data Administer role at LAO sites to make roster changes to site staff, update roles, and request the addition or withdrawal of persons (must be approved in the *Roster Maintenance* application by the Grant Administrator).
2. CTSU *Roster Maintenance* application
 - Allows persons at the grant operations offices with the role of Grant Administrator to make person roster and role changes across all sites within their LAO organization.

2.3 EDDOP Person Rosters and Roles

The site person rosters for the EDDOP sites are managed similarly to the UM1 rosters covered in Section 2.2, with one exception. While EDDOP sites have Site Administrators who can make roster changes to site staff in RUMS, there are no Grant Administrators to make similar changes or approve roster updates directly within the CTSU Roster Maintenance application. Many roster-related requests are automatically approved, but if EDDOP rostering assistance is required the CTSU Membership Coordinator is available via the CTSU Help Desk.

3. For Questions and Support

For questions about institutional and person rosters and roles, please contact the CTSU Help Desk:

- CTSU Help Desk: 1-888-823-5923 or CTSUContact@westat.com; CTSU Help Desk hours are 9:00 am – 6:00 pm ET Monday-Friday (excluding holidays).