

Rosters and Roles for ETCTN 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 under the NCI Early Drug Development Opportunity (EDDO) leadership program. The ETCTN and EDDO organizations use a common infrastructure to participate in ETCTN trials.

Two types of rosters comprise each organization: institution 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 grant holder) 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.

EDDO rosters are smaller, typically containing only a single site (where the grant is based and the study PI is located), possibly with one or two 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). An EDDO organization can only participate on a study for which it is the Lead Protocol Organization.

1.2 Person Rosters

Person rosters consist of the **people** (investigators and site staff) who work at a given ETCTN/EDDO-participating site. Individuals who participate in conducting ETCTN trials (e.g., enrolling patients, receiving drug shipments, treating patients, and entering data) must be on the person roster for a given site(s).

Requirements for inclusion on a site's person roster include

1. An active Cancer Therapy Evaluation Program (CTEP) - Identity and Access Management (CTEP-IAM) account linked to an ID.me account. The [IAM registration](#) page contains more information.
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 (NPPIVR), or Associate Plus (AP). The [RCR](#) page contains more information.
 - a. An additional registration type is available in RCR: the Non-Investigational New Drug/Non-Treatment (NINT). Due to the nature of ETCTN trials, NINTs **cannot** be added to LAO or EDDO rosters.

1.2.1 Person Roles

Specific roles can be assigned based on job activities. In some cases, roles require a certain registration type. These roles confer certain privileges, such as the ability to enroll patients in OPEN (OPEN Registrar role), enter patient data in Medidata Rave (Rave CRA role), or serve as a site's primary contact who can make changes to the site's person roster (Administrator role); in all these cases, the assignee must have at least an AP registration type. The [Site Roles Table displays ETCTN site person roles rights and required registration types](#) (hosted on the CTSU members' website, username and password required).

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. Approved changes will be made to the applicable LAO or EDDO institution roster in CTEP systems and automatically communicated to the CTSU Roster Maintenance application.

Organizational participants on a given LAO-led study are defined in 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 LAOs have two ways to manage their person rosters and roles.

1. CTSU Roster Update Management System (RUMS)
 - Located on the CTSU website, RUMS works in conjunction with the *Roster Maintenance* application.
 - People with Administrator or Data Administer roles at LAO sites can 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

- The person with the Grant Administrator role at the grant operations offices can make person roster and role changes across all sites within their LAO.

2.3 EDDO Person Rosters and Roles

The EDDO site person rosters are managed similarly to the UM1 rosters covered in Section 2.2, with one exception. While EDDO sites have Administrators who can make roster changes in RUMS, Grant Administrators do not exist to make similar changes or approve roster updates directly within the CTSU Roster Maintenance application. Many roster-related requests are automatically approved, but if EDDO rostering assistance is required, contact the CTSU Membership Coordinator via the CTSU Help Desk.

3. For Questions and Support

For questions about institutional and person rosters and roles, 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).