

# Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Page

## 1. Introduction

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.

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 a number of affiliated treatment sites, all of which are part of the LAO-CT018 institution roster.

In order 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 document cover page).

### 1.2 Person Rosters

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

In order for an individual to be included on a site's person roster, they must be 1.) registered with the Cancer Therapy Evaluation Program (CTEP) in the Registration and Credential Repository (RCR) as an investigator (IVR), non-physician investigator (NPIVR), or Associate Plus (AP); and have a CTEP- Identity and Access Management (IAM) account; or 2.) registered as an Associate (A) using the CTEP-IAM process. 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 the account 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). Access 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 UM1 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 handled through CTEP's Enterprise Core Unit (ECU) Help Desk and reviewed by ETCTN program leadership. Approved changes will then be made to the applicable LAO institution roster in the CTEP systems and the Regulatory Support System (RSS).

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 RSS.

### 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 RSS.

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 RSS.
  - 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 RSS by the Grant Administrator).
2. CTSU RSS
  - 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.

## 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](mailto:CTSUContact@westat.com); CTSU Help Desk hours are 9:00 am – 6:00 pm EST Monday-Friday (excluding holidays).