



Experimental Therapeutics Clinical Trials Network

Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

TRIAL CONDUCT

Intended for those at clinical sites
conducting ETCTN trials

Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Sheet

1. Introduction

The ETCTN comprises 13 different Lead Academic Organizations (LAOs). These LAOs are the Phase 1 grantees who were awarded UM1 grants in March 2014, and have since been expanded to include Phase 2 supplement sites (as of March 2016).

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 a Lead Academic Organization (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 associates) who work at a given 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 a) registered with the CTEP Pharmaceutical Management Branch (PMB) (investigators only) or b) have a CTEP-IAM account (associates only; see the "ETCTN Person Registration and CTEP Identity and Access Management (CTEP-IAM) Information Sheet" for more information).

1.2.1 Person Roles

Individuals on a site's person roster may have certain roles assigned to them. These roles confer certainly privileges, e.g., 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). ETCTN site person roles and the rights they confer are included in the table in Attachment 1 at the end of this Information Sheet.



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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 (upon award) via a data collection process led by the Cancer Trials Support Unit (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.

- CTSU Roster Update Management System (RUMS)
 - CTSU website front-end to the RSS application (select the RUMS tab)
 - Allows persons at LAO sites with the Site Administrator or Site Data Administer role to make roster changes to their site(s) staff (can update roles and can request the addition or withdrawal of persons; the latter must be approved in RSS by the Grant Administrator).
- 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

Attachment 1

ETCTN ROSTERS - ROLES AND ACCESS (UM1-specific)

Role	Mandatory	Level	Managed in RUMS?	General Contact	DM Correspondence	OPEN (incl. IWRS slot res.)	IWRS Cohort Mgt. and Slot Res. Approvals	View ETCTN Rave URL (for approp. studies)	Enter Data to Rave URL (for approp. studies)	View Web Reporting Data for a Site, Across Studies	View Web Reporting Data for a Study, Across Sites	View Web Reporting Data for a Grant, Across Sites and Studies	View RUMS (Roster Update Management System)	Update RUMS	Update RSS Application	Restrictions
ETCTN Grant PI	Yes	Grant Organization		✓									✓			Can be multiple per grant; only one primary contact grant PI
ETCTN Grant Administrator	Yes	Grant Organization		✓									✓		✓	One per grant (must be at LAO and can be same person as Site Admin or Data Admin at LAO site) or one per Grant PI site (in multi-PI grants)
Site Administrator	Yes	Institutional		✓									✓	✓		One per institution; can be same as Data Admin, and if at LAO/lead site, can be same as GrantAdmin
Data Administrator	Yes	Institutional		✓	✓								✓	✓		One per institution; can be same as Site Admin, and if at LAO/lead site, can be same as Grant Admin
OPEN Registrar	Yes	Institutional	✓			✓										Every site must have at least one to enroll patients in OPEN
IWRS Slot Reservation and Cohort Manager*	No	Protocol					✓									
Rave Read-Only	No	Institutional	✓					✓								None
Rave CRA	Yes	Institutional	✓					✓	✓							Every site must have at least one to manage data in Rave

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Rave Site Investigator	No	Institutional	✓					✓	✓							None
Web Reporting	No	Institutional	✓							✓						None
LPO Web Reporting*	No	Protocol									✓					
LAO Web Reporting*	No	Grant Organization										✓				
Data Manager	No	Protocol	✓		✓								✓			One per protocol/institution combination
CRA	No	Institutional	✓										✓			None
Investigator	No	Institutional and Protocol	✓										✓			None
Nurse	No	Institutional	✓										✓			None
Pathologist	No	Institutional	✓										✓			None
Pharmacist	No	Institutional	✓										✓			None
Statistician	No	Institutional	✓										✓			None
Study PI	No	Organization/Protocol	✓													One per protocol
* Managed by Theradex, not in RSS																