
ETCTN Data Management Information Page

1. Introduction

Medidata Rave is the clinical data management system used across the NCI Cancer Therapy Evaluation Program (CTEP) for the entry and management of clinical data for most NCI network trials, including those run by the ETCTN. Theradex, the organization that serves as the Clinical Trials Monitoring Service (CTMS) for the ETCTN, manages the Rave study databases for the ETCTN trials. Furthermore, the ETCTN Rave databases are integrated with the ETCTN patient enrollment system to seamlessly receive patient enrollment data so that patient information does not need to be re-entered.

The iMedidata application is a portal application to access Medidata products including Rave. It allows sites and Lead Protocol Organization (LPO) staff to access studies across multiple Rave URLs by providing a single point of entry. Access to iMedidata and Rave is controlled through the CTEP Identity and Access Management (IAM) system and through role assignments in the Cancer Trials Support Unit (CTSU) *Roster Maintenance* application.

All new trials opened under the ETCTN program will use Rave for the submission and management of patient-level trial data.

All trials activated **prior to** the implementation of the ETCTN program will continue to follow their existing procedures for data management, whether those trials are managed in Rave or a different data management system.

Each protocol document will include information on which data management system is used for that trial.

2. Use of Medidata Rave

2.1 Requirements

To access Rave, site staff must meet the following requirements.

- Active CTEP registration with the credentials necessary to access secure NCI/CTSU Information Technology (IT) systems. Refer to the [CTEP IAM system](#) for more information.
- Must be registered as Associate Plus (AP) or higher registration type in the Registration and Credential Repository (RCR) for write access to the application. Refer to the NCI [RCR webpage](#) and [RCR System](#) for more information.
- Assigned one of the following Rave roles on the relevant Lead or Participating Organization (e.g., Lead Academic Organization (LAO)) roster:
 - Rave CRA role to enter subject data and respond to queries;
 - Rave Read Only role to simply view data;

- Rave Investigator role to enter subject data, respond to queries, and electronically sign forms;
- Rave CRA (LabAdmin) role to enter subject data, respond to queries, and maintain local lab data; or
- Rave SLA role to simply view data and maintain local lab data.

Refer to [Rosters and Roles for ETCTN Participants \(Institution Rosters and Person Rosters\) Information Page](#) for more information on obtaining roles.

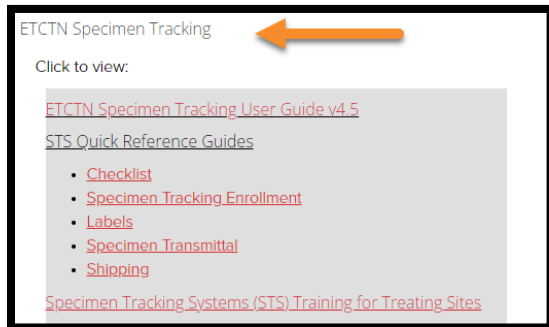
- If the study uses a Delegation of Tasks Log (DTL), users requiring write access to Rave must also be assigned the appropriate Rave tasks on the DTL.
- Have regulatory approval for the conduct of the study at their site (refer to the [ETCTN Regulatory Processing Information Page](#) for more information).
- Have received an invitation both to the system overall as well as to each individual study.
- Have completed the mandatory eLearnings within Rave as appropriate for their role, as described in section 2.2.2.

2.2 Training

2.2.1 Resources and User Guides

The Rave Home section located in the [Data Management](#) section on the CTSU members' website (username and password required) contains general information on Rave, a list of the studies available in Rave, and links to several educational resources. This section of the CTSU website also includes a direct link to Medidata Rave; users accessing Rave in this way will not need to re-enter their username and password since they are already logged into the CTSU website.

Theradex has developed the *Clinical Trial Monitoring Service (CTMS) Rave User Guide*, *Specimen Tracking System (STS) User Guide*, and five quick reference guides for STS. These reference materials are available on the NCI page of the [Theradex](#) website under the *ETCTN Specimen Tracking* and *CTMS Rave* headings.



2.2.2 eLearnings

Medidata Rave contains eLearnings that are required before site staff can access and enter patient data. The eLearnings are role-specific as shown in the image below. For more information, refer to the Rave Home page located under the [Data Management](#) section of the CTSU members' website.

Role	Definition	Standard eLearning
Rave CRA	Enter subject data and Respond to queries	Medidata Classic Rave EDC Essentials for Clinical Research Coordinators
Rave Investigator	Enter subject data, Respond to queries and Sign eCRFs	Medidata Classic Rave EDC Essentials for Investigators with Data Entry
Rave Read Only	Read only access to data	Medidata Classic Rave EDC Essentials for Read-Only Users
Rave CRA (LabAdmin)	Rave CRA Role plus local lab maintenance	Medidata Classic Rave EDC Essentials for Clinical Research Coordinators plus Rave EDC Lab Data Handling, as appropriate
Rave SLA	Read Only Role and local lab maintenance	Medidata Classic Rave EDC Essentials for Read-Only Users plus Rave EDC Lab Data Handling, as appropriate

Once these eLearnings are completed upon initial entry to Medidata Rave, they do not need to be repeated for subsequent studies. However, it is possible that some studies will have protocol-specific eLearnings.

A temporary role of CRA Specimen Tracking allows site staff to enter specimen tracking data in addition to performing the tasks defined for a Rave CRA. This temporary role requires the additional viewing of a Specimen Tracking Training video. In the future, the Rave CRA role will be expanded to allow entry of specimen tracking data and will have the required eLearning incorporated into the learning management system.

3. Closing out Trial(s) Locally

Participating sites interested in closing out trials locally should confirm that all data has been entered and there are no outstanding data queries with Theradex and the LPO/LAO before

closing a study locally. Applicable sites should complete the *LPO Approval of Early Closure Form* and submit the completed form to the LPO/LAO and Theradex at CTMS-DM@theradex.com. Refer to [Steps for Participating Sites in ETCTN Trials](#) for more information on opening/closing a study.

4. Questions and Support

For questions about Rave roles, contact the CTSU Help Desk:

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

For technical questions about the use of the system, contact the Theradex Help Desk:

- Theradex Help Desk: 855-828-6113 (for immediate response) or Theradex main number 609-799-7580;
- STS support: STS.Support@theradex.com;
- Data Management support: CTMS-DM@theradex.com; and
- For all other issues: CTMSSupport@theradex.com.