



ETCTN Data Management Information Sheet

1. Introduction

Medidata Rave® is the clinical data management system utilized across the NCI Cancer Therapy Evaluation Program (CTEP) for the entry and management of clinical data for a number of NCI network trials, including those run by the ETCTN. The Rave study databases for the ETCTN trials are managed by Theradex, the organization that serves as the Clinical Trials Monitoring Service (CTMS) for the ETCTN. Furthermore, the ETCTN Rave databases will be integrated with the ETCTN patient enrollment system to seamlessly receive patient enrollment data so that users don't need to enter the same patient information more than once.

The iMedidata application is a portal application to access Medidata products including Rave. It allows site and Lead Protocol Organization (LPO) users to access studies across multiple Rave URLs by providing a single point of entry. Access to iMedidata and Rave is controlled through the CTEP-IAM system and through role assignments in the CTSU Regulatory Support System (RSS) for site users.

All new trials opened under the ETCTN program will utilize 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 User Requirements

In order to access Rave, users must meet the following requirements:

- Have a valid CTEP-IAM account (i.e., username and password; please see the "ETCTN Person Registration and CTEP Identity and Access Management (CTEP-IAM) Information Sheet" for more information).
- Be on the Lead or Participating ETCTN site (i.e., LAO) roster with one of the following roles (please see the "Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Sheet"):
 - *Rave Read Only* to be able to access and view data, but not change it
 - *Rave CRA* to be able to enter and manage data



- *Rave Site Investigator* to be able to view, enter, and manage data and sign eCRFs
- Have regulatory approval for the conduct of the study at their site (see the “ETCTN Regulatory Processing Information Sheet” 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 (see below).

2.2 User Training

2.2.1 Resources and User Guides

The [Rave tab](#) 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 a number of educational resources.

Theradex has developed the CTMS Rave User Guide, which is available on the Theradex website: <http://www.theradex.com/downloads/CTMS%20Rave%20User%20Guide%20Version%201.pdf>. This link to the Theradex website is also available on the CTSU website Rave tab.

2.2.2 eLearnings

Medidata Rave contains eLearnings that are required before users are able to access and enter patient data. These eLearnings are role-specific as below:

Role	Definition	Standard eLearning
Rave CRA	Enter subject data Respond to queries	EDC Essentials for CRC
Site Investigator	Enter subject data Respond to queries Sign eCRFs	EDC Essentials for Investigators with Data Entry
Read Only	Read only access to data	EDC Essentials for Read-only

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.



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3. For Questions and Support

For questions about Rave user roles, contact the CTSU Helpdesk.

- CTSU Help Desk: 1-888-823-5923; CTSUContact@westat.com

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

- Theradex Help Desk: 609-619-7802 or Theradex main number 609-799-7580;
CTMSSupport@theradex.com