



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

ETCTN Patient Enrollment Information Sheet

1. Introduction

The Oncology Patient Enrollment Network (OPEN) is the web-based registration system for patient enrollments onto NCI-sponsored clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with Theradex's registration/randomization system for patient registration/randomization. OPEN provides the ability to enroll patients on a 24/7 basis. Access to the OPEN system is controlled through the CTEP-IAM system and through role assignments in the CTSU Regulatory Support System (RSS).

All new trials opened under the ETCTN program will utilize OPEN for the enrollment of patients. For slot reservations and cohort management, OPEN will contain a link to Theradex's Interactive Web Response System (IWRS), providing seamless transfer between the two systems for both users and data. Furthermore, patient enrollment data entered in OPEN and IWRS will automatically transfer to the NCI's clinical data management system, Medidata Rave, so users don't need to enter data more than once.

All trials activated prior to the implementation of the ETCTN program will continue to follow their existing procedures for patient enrollment, although some of these trials will transition into OPEN at a later date.

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

2. Use of OPEN and IWRS

2.1 User Requirements

In order to use OPEN/IWRS, 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).
- To enroll patients or request slot reservations: Be on an ETCTN Lead or Participating Organization roster with the role of Registrar (see the "Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Sheet" for more information).
- To approve slot reservations or access cohort management: Be identified to Theradex as the "Client Admin" for the study.
- Have regulatory approval for the conduct of the study at their site (see the "ETCTN Regulatory Processing Information Sheet" for more information).



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2.2 User Training

There are a number of resources related to the use of OPEN and IWRS for patient enrollments.

Please see the OPEN tab on the CTSU members' website (username and password required) for an overview of OPEN. Both this page and the OPEN website welcome screen (no password required) contain OPEN-related training materials, including a Site User Guide and demo videos.

- OPEN tab on CTSU members website (username and password required):
https://www.ctsu.org/OPEN_SYSTEM/Default.aspx?nodeID=6
- OPEN website welcome screen: <https://open.ctsu.org>

Theradex has developed a Slot Reservations and Cohort Management User Guide, which is available on the Theradex website: <http://www.theradex.com/downloads/IWRS%20User%20Guide.pdf>. This link to the Theradex website is also on the CTSU website OPEN tab.

3. For Questions and Support

For questions about OPEN or the entire patient enrollment process, contact the CTSU Helpdesk.

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

For questions about the use of IWRS for slot reservations, contact the Theradex Helpdesk:

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