

CTSUS

Cancer Trials Support Unit

OPEN Portal v2025.1.0 Release Notes

Revision 1

This document was prepared by:

WESTAT

7501 Wisconsin Avenue

Suite 1000E

Bethesda, MD 20814-6527

Table of Contents

OPEN PORTAL V2025.1.0 RELEASE NOTES I

- 1. INTRODUCTION 1
 - 1.1 OPEN Application Overview 1
 - 1.2 Organization of this Document 1
- 2. ACRONYMS 2
- 3. MAJOR ENHANCEMENTS 3
 - 3.1 Experimental Therapeutics Clinical Trials Network Cohort Management and Slot Reservations 3

List of Figures

FIGURE 1: UPDATED IWRS LINK.....	4
FIGURE 2: SLOT RESERVATION IN PROGRESS VIEW.....	5
FIGURE 3: SLOT RESERVATION HISTORY VIEW	5
FIGURE 4: SLOT USAGE REPORT.....	6
FIGURE 5: SLOT RESERVATION REPORT.....	7
FIGURE 6: SLOT RESERVATION CONFIGURATION SUMMARY SCREEN.....	9

List of Tables

TABLE 1: LIST OF ACRONYMS..... 2

1. Introduction

The Oncology Patient Enrollment Network (OPEN) team at the Cancer Trials Support Unit (CTSUS) wants to thank the leadership at the National Cancer Institute (NCI) and the Network Groups, for their exceptional support, resources, ideas, and constructive feedback throughout the development and various releases of OPEN. This support helps make OPEN a successful platform for patient enrollment for cancer clinical trials.

This document describes enhancements and bug fixes that were included in version 2025.1.0 of the OPEN portal.

1.1 OPEN Application Overview

The development of OPEN is a joint effort between the CTSUS and the Network Groups, with the support of the Cancer Therapy Evaluation Program (CTEP). The main goal of OPEN is to provide a standardized web-based environment, available 24/7, for the enrollment of patients in clinical trials across the NCI-sponsored clinical trials program.

1.2 Organization of this Document

The content of this document is divided into the following sections:

- [Section Two](#) contains a list of acronyms.
- [Section Three](#) describes the major enhancements.

2. Acronyms

Table 1: List of Acronyms

Acronym	Description
CA	Client Administrator
CTEP	Cancer Therapy Evaluation Program
CTSUS	Cancer Trials Support Unit
ETCTN	Experimental Therapeutics Clinical Trials Network
IWRS	NCI Interactive Web Response System
LPO	Lead Protocol Organization
NCI	National Cancer Institute
NCTN	NCI National Clinical Trials Network
OPEN	Oncology Patient Enrollment Network
PI	Principal Investigator

3. Major Enhancements

This section describes the major enhancements that were included in version 2025.1.0 of OPEN.

3.1 Experimental Therapeutics Clinical Trials Network Cohort Management and Slot Reservations

Requested By: NCI

Available to: Lead Protocol Organizations (LPOs), Sites

Background: It was requested by the NCI that Theradex and CTSU standardize cohort management and slot reservation tasks between NCI National Clinical Trials Network (NCTN) and Experimental Therapeutics Clinical Trials Network (ETCTN) trials. The following enhancements were implemented in OPEN to support cohort management integration:

- An update was made to ensure that accrual data in the Protocol application matches the data in OPEN. In addition, count of reserved slots will now be synchronized between OPEN and Protocol applications.
- The following new subscriptions are now available in the OPEN Email Subscribe screen (to be configured at a study level):
 - [STUDY]_RESERVATION_APPROVAL_REQ subscription will send notifications to Principal Investigator (PI) and Client Administrator (CA) when slot reservation will require approval.
 - [STUDY]_EVAL_TARGET_REACHED subscription will send notifications to the PI and CA when the last slot available for the protocol is reserved.
 - [STUDY]_RENEWAL_APPROVAL_REQ subscription will notify PI and CA when slot reservation renewal is requested.
 - [STUDY]_RESERVATION_WITHDRAWAL subscription will notify PI and CA when slot reservation is withdrawn.
- A text was added on the homepage of OPEN under the Theradex NCI Interactive Web Response System (IWRS) Cohort Management/Slot Reservation link to note that IWRS is being phased out for ETCTN trials, as shown in Figure 1:

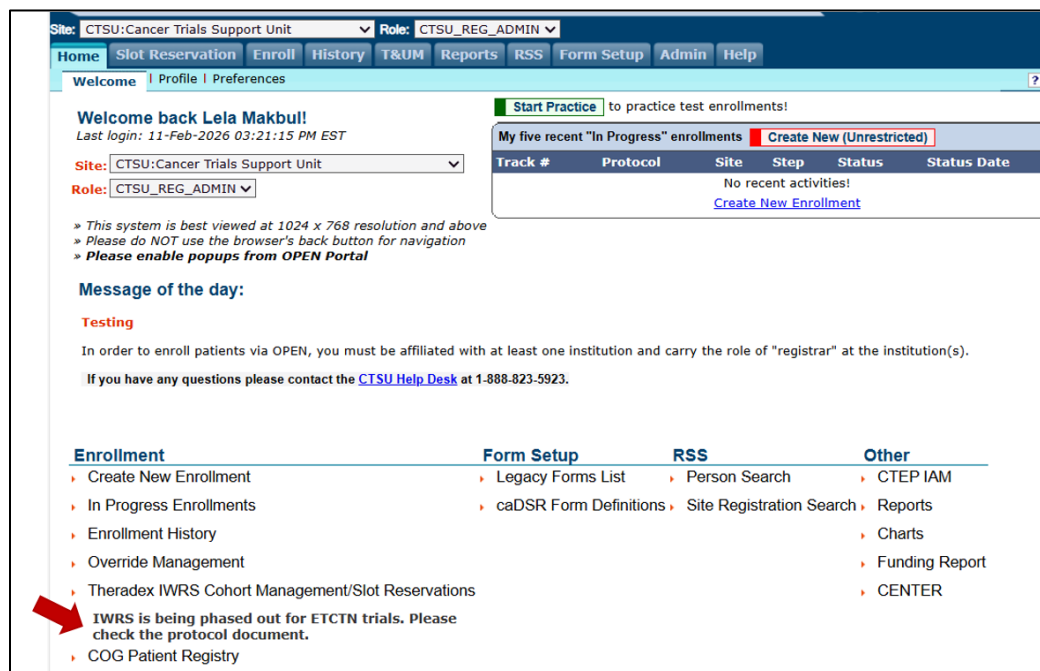


Figure 1: Updated IWRS Link

- The following new validations were added in OPEN:
 - When the cohort is closed at the time of an enrollment, an error message will be displayed prompting the user to update the cohort selected to an Open status in the Protocol application.
 - When the target accrual is reached, an error message will be generated, notifying the user that the enrolled slot for the cohort exceeds maximum target accrual limit.
- The Stratum label and Stratum/Cohort labels were updated to Category label, and the Dose label was updated to Dose/Arm label in the following screens (as shown in Figure 2, Figure 3, Figure 4, and Figure 5):
 - Slot Reservation/In Progress/View
 - Slot Reservation/History/View
 - Slot Reservation/Configuration/Browser/Slot Usage Report
 - Slot Reservation/Report

Major Enhancements

Site: CTSU:Cancer Trials Support Unit Role: CTSU_REG_ADMIN

Home Slot Reservation **Enroll** History T&UM Reports RSS Form Setup Admin Help

Patients | Create New | In Progress | History | Configuration | Report

Refresh Slot Browser

Slot Reservation Information: [SR ID # **SR-000040514**] **Reactivate**

Site: CA009

Protocol: ANHL2121

Step: 1

Patient: PT-0000846828

Patient Details:

Patient #	Initials (LFM)	Date Of Birth	Sex	Zip
PT-0000846828	HS-	14-Feb-2006	Male	20871

Network Group Patient ID: 453453

Site Contact Person: Aamer Syed Ali

Evaluation:

Category	Description	Group	Dose	Available Slots	Issued Slots	Max slots	Status
c1		c1		200	0	200	ACTIVE

Status: WITHDRAWN

Status Text: Automation Testing for slot withdraw

Expiry Date: 19-Feb-2026 05:20:55 AM EST

Created By: CTSUQA on 14-Feb-2026 05:20:55 AM EST

Modified By: CTSUQA on 14-Feb-2026 05:21:06 AM EST

Reservation Workflow

Date	Action	By	From State	To State	Value
14-Feb-2026 05:21:06 AM	UPD_STATUS	CTSUQA	RESERVED	WITHDRAWN	Slot reservation withdrawn

Figure 2: Slot Reservation in Progress View

Site: CTSU:Cancer Trials Support Unit Role: CTSU_REG_ADMIN

Home Slot Reservation **Enroll** History T&UM Reports RSS Form Setup Admin Help

Patients | Create New | In Progress | **History** | Configuration | Report

Refresh Slot Browser **Enrollment #1213810**

Slot Reservation Information: [SR ID # **SR-000040505**]

Site: CA011

Protocol: 10358

Step: 0

Site Contact Person: Artura Alexandra

Evaluation:

Category	Description	Group	Dose	Available Slots	Issued Slots	Max slots	Status
6	users should be able to verify	6		8	1	9	ACTIVE

Status: ENROLLED

Status Text:

Created By: CTSUQA on 11-Feb-2026 03:01:56 PM EST

Modified By: CTSUQA on 11-Feb-2026 03:08:03 PM EST

Reservation Workflow

Date	Action	By	From State	To State	Value
11-Feb-2026 03:02:41 PM	UPD_STATUS	CTSUQA	RESERVED	PRE_ENROLL	Registration enrollment in progress
11-Feb-2026 03:05:29 PM	UPD_STATUS	CTSUQA	PRE_ENROLL	ENROLLED	Registration enrollment completed

Figure 3: Slot Reservation History View

Major Enhancements

Slot Usage Report

Selected Protocol # 10292

Protocol	Step	Group	Protocol Status	Network Group	Slot Type	Activation Date	Target
10292	1	Active		LAO-NCI	PROTOCOL	30-Jan-2026 12:00:00 AM EST	119

Evaluation(s) Summary

EVALUATIONS		SLOTS									
Category NAME	Dose NAME	MAXIMUM AVAILABLE	ISSUED	ENROLLED	PRE_ENROLL	RESERVED	APPROVED	WAITING	REJECTED		
C1		75	75	0	0	0	0	0	0	0	0
Cr2		44	44	0	0	0	0	0	0	0	0

Evaluation(s)

Category Name: C1
Dose Name: Cr2
Maximum Slots: 75
Evaluation Status: ACTIVE

Slots Information:

Reservations:	
Slot Number	Slot Reservation Status
SR-0000040416	EXPIRED

Category Name: Cr2
Dose Name: Cr2
Maximum Slots: 44
Evaluation Status: ACTIVE

Protocol	Step	Group	Protocol Status	Network Group	Description
10444	1	Active		NCICCR	Feasibility of Evaluating Abemaciclib Neuropharmacokinetics of Diffuse Midline Glioma Using Microdialysis
10486	0	Active		LAO-TX035	Phase 2 Trial of the Combination of the BET Inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor, Talazoparib, in Patients with Molecularly-Selected Solid Tumors (CombET)
10487	0	Active		LAO-MD017	A Phase II Study of Lutetium Lu 177 Dotatate in Metastatic Prostate Cancer with Neuroendocrine Differentiation

Figure 4: Slot Usage Report

Major Enhancements

The screenshot displays the 'Slot Reservations - Report' interface. At the top, there are navigation tabs: Home, Slot Reservation, Enroll, History, T&UM, Reports, RSS, Form Setup, Admin, and Help. Below these are links for Patients, Create New, In Progress, History, Configuration, and Report. A search bar contains the number '25' and buttons for Search and Clear. A table on the left lists various protocols (10020, 10161, 10186, 10204, 10237, 10292, 10301). The main report area shows details for Protocol 10237, Step 1, with Category Name and Category Group both set to 'c2'. Other details include Dose Name, Available Slots (33), Issued Slots (0), Max Slots (33), and Evaluation Status (INACTIVE). It also lists the user who created and modified the report. At the bottom, a table header for 'Slot Reservations' is shown with columns: Slot #, Site, Network Group, Patient ID, Slot Reservation Status, Created Date, and Expiry Date. The table content indicates 'No Slot Reservation Found!'.

Figure 5: Slot Reservation Report

Major Enhancements

- Target Number of Slots value will be forced as 1 if cohorts are not yet configured in the Protocol application. If the cohorts are configured, then the Target Number of Slots value should be a sum of all open cohorts, as shown in Figure 6.
- Whenever a new cohort is created and saved in the Protocol application, OPEN will add a new row to the Category table in the Slot Reservation Configuration Summary screen, as shown in Figure 6.
- Whenever a Cohort Management study is configured in the Protocol application for slot reservation, the following fields in OPEN should display Cohort values from the Protocol application (see Category grid and Evaluation grid in Figure 6).
 - Category Grid:
 - Category Name
 - Category Group
 - Description
 - Category Status
 - Evaluation grid:
 - Category Name
 - Max Slots
 - Evaluation Status
- Users with the Group Registrar (GROUP_REG) role and Protocol Principal Investigator (PROTPI) or Protocol Client Administrator (PROTCA) roles will not be able to create enrollments in OPEN.
- Category and Evaluations tabs in the Slot Reservation Configuration screen are now disabled for Cohort Management trials. A tooltip was added to instruct users to access the Protocol application to configure protocol categories.

Site: CTSU: Cancer Trials Support Unit Role: CTSU_REG_ADMIN

Home Slot Reservation Enroll History T&UM Reports RSS Form Setup Admin Help

Patients | Create New | In Progress | History | Configuration | Report

Browser | Network Group | Summary | Protocol | Category | Evaluation

Selected Protocol # **10161** [Slot Usage Report](#)

Protocol	Step	Group Protocol Status	Network Group	Slot Type	Activation Date	Target Slots
10161	1	Active	LAO-TX035	PROTOCOL	09-Dec-2025 12:00:00 AM EST	12

Protocol Configuration Summary

- Slot type: PROTOCOL
- Reservation type: SITE
- Activation date: 09-Dec-2025 12:00:00 AM EST
- Expiry days: 9 (in calendar days)
- Automatic reservation: YES
- Expiry day count starts from approval queue: YES
- Automatic renewal: NO
- Renewal period: 2 (in hours)
- Minimum slots for automatic renewal: 0
- Allow waiting queue: NO
- Maintain waiting list patients after evaluations become inactive: NO
- Configure waiting period for reactivating a slot: NO
- Minimum waiting period for reactivating a slot: 0 (in calendar days)
- Minimum number of available slots required to bypass a waiting period: 0
- Capture dose information: YES
- Exclusive protocols:
- Release time for Cancelled, Withdrawn, Expired, and Rejected slots: *slots will be re-released as they become available*
- Target number of slots: 12
- Reservation maintenance mode: NO

Category:

Category Name	Category Group	Description	Category Status
C1	C1	Cohort 1	ACTIVE
C2	C2	Cohort 2	INACTIVE

Doses:

Name	Description	Level	Unit	Frequency	Dose Status
No Dose Found!					
Add Dose					

Evaluations:

Category Name	Max Slots	Evaluation Status
C1	12	ACTIVE
C2	0	INACTIVE

Figure 6: Slot Reservation Configuration Summary screen