



# CTSUS

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Cancer Trials Support Unit

## OPEN Slot Reservation Quick Reference Group User Guide

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# Table of Contents

<b>OPEN SLOT RESERVATION QUICK REFERENCE GROUP USER GUIDE .....</b>	<b>I</b>
1. INTRODUCTION .....	1
1.1 Web Addresses for CTSU Applications .....	1
2. SLOT RESERVATION SYSTEM IMPLEMENTATION.....	2
3. HOW TO ENROLL A SUBJECT ON A SLOT RESERVATION PROTOCOL .....	3
3.1 Getting a Patient Number for Patient-level Configurations .....	3
3.1.1 Instructions for Getting a Slot Reservation Patient Number.....	3
3.2 Creating a Patient-Level Slot Reservation.....	4
3.2.1 Instructions for Creating Patient-Level Slot Reservation.....	5
3.2.2 Duplicate Slot Reservation Check .....	7
3.3 Creating a Site-Level Slot Reservation .....	7
3.4 Completing a Patient Enrollment.....	9
3.4.1 Instructions for Enrolling a Patient onto a Slot Reservation Protocol.....	9
3.5 How to Perform a Practice Mode Slot Reservation Enrollment .....	11
4. CONFIGURING SLOT RESERVATION SETTINGS.....	13
4.1 Configuring Group Level Slot Reservation Settings .....	13
4.1.1 Instructions for Configuring Group Level Slot Reservation Settings .....	13
4.2 Configuring Protocol Level Slot Reservation Settings.....	16
4.2.1 Instructions for Configuring Protocol Level Slot Reservation Settings.....	16
4.2.2 Using CDE Information to Configure Category Name and Dose Name.....	25
4.3 Configuring Protocol Level Slot Reservation Settings for Cohort Management Studies.....	26
4.4 Configuring Slot Reservation Prefill Field Types in Form Setup.....	27
4.4.1 Instructions for Configuring Slot Reservation Prefill Field Types .....	28
4.5 Configuring a Daily Time for Releasing Slots to the Available Pool .....	29
5. ADDITIONAL ADMINISTRATIVE ACTIONS .....	30
5.1 How to Approve or Reject User Requests .....	30
5.1.1 Instructions for Approving or Rejecting User Requests .....	30
5.2 How to Edit Patient Information for Patient-Level Slot Reservations .....	32
5.2.1 Instructions for Editing Patient Information .....	32
5.3 How to Delete an OPEN Slot Reservation Patient Number .....	35
5.4 How to Edit a Slot Reservation .....	35
5.4.1 Instructions for Editing a Slot Reservation .....	35
5.5 Accessing the Slot Usage Report .....	38
5.5.1 Instructions for Accessing the Slot Usage Report.....	38
5.6 The Report Subtab .....	39
6. ROLES AND STATUSES .....	41
6.1 Slot Reservation States Diagram.....	41
6.2 Slot Reservation States .....	42
6.3 OPEN Roles for Slot Reservation.....	44
7. NOTIFICATION EMAILS .....	46

# List of Figures

FIGURE 1: PROCESS FOR ENROLLING A SUBJECT ON A SLOT RESERVATION PROTOCOL.....	3
FIGURE 2: CREATE PATIENT.....	4
FIGURE 3: CONFIRMATION PAGE FOR THE PATIENTS SCREEN .....	4
FIGURE 4: PATIENT BROWSER SCREEN.....	5
FIGURE 5: CREATE SLOT RESERVATION SCREEN.....	6
FIGURE 6: CONFIRMATION PAGE (AUTOMATIC APPROVAL).....	6
FIGURE 7: CONFIRMATION PAGE (MANUAL APPROVAL).....	7
FIGURE 8: ERROR MESSAGE FOR MULTIPLE-RESERVATIONS FOR THE SAME SUBJECT (WHEN NOT PERMITTED) .....	7
FIGURE 9: SLOT RESERVATION REACTIVATION LINK IN THE DUPLICATE RESERVATION ERROR MESSAGE.....	7
FIGURE 10: CREATE NEW SCREEN FOR SITE-LEVEL SLOT RESERVATION .....	8
FIGURE 11: CONFIRMATION PAGE FOR SITE-LEVEL SLOT RESERVATION (AUTOMATIC APPROVAL).....	8
FIGURE 12: IN PROGRESS SCREEN .....	9
FIGURE 13: IN PROGRESS SUMMARY SCREEN.....	9
FIGURE 14: CREATE NEW SCREEN (ENROLL TAB).....	10
FIGURE 15: ENROLLMENT CONFIRMATION .....	11
FIGURE 16: INITIATING A SLOT RESERVATION ENROLLMENT IN PRACTICE MODE.....	12
FIGURE 17: CONFIRMATION SCREEN FOR GROUP LEVEL SETTINGS.....	15
FIGURE 18: SELECTING A PROTOCOL FROM THE BROWSER SCREEN .....	16
FIGURE 19: PROTOCOL LEVEL CONFIGURATION SCREEN .....	17
FIGURE 20: PROTOCOL SETTINGS CONFIRMATION SCREEN.....	19
FIGURE 21: EXAMPLE OF THE CATEGORY SCREEN.....	21
FIGURE 22: CONFIRMATION THAT CATEGORY / DOSE SETTINGS WERE SAVED .....	22
FIGURE 23: CATEGORY SCREEN.....	23
FIGURE 24: EVALUATION SCREEN .....	23
FIGURE 25: EVALUATION CONFIRMATION SCREEN .....	24
FIGURE 26: INFORMATIVE ERROR ICONS AND A TOOL-TIP WITH DESCRIPTION ON THE EVALUATION SCREEN.....	24
FIGURE 27: SELECTING QUESTIONS ON THE QUESTIONS SCREEN (FORM SETUP TAB) .....	25
FIGURE 28: POPUP WINDOW FOR SELECTING CATEGORY NAME VALUES .....	26
FIGURE 29: POPUP WINDOW FOR SELECTING (DOSE) NAME VALUES.....	26
FIGURE 30: CONFIGURING A QUESTION TO USE THE PREFILL WIDGET .....	28
FIGURE 31: A MESSAGE LISTS WHEN SLOTS ARE PENDING RELEASE TO THE POOL OF <i>AVAILABLE SLOTS</i> .....	29
FIGURE 32: ABILITY TO CONFIGURE A DAILY TIME FOR RELEASING SLOTS TO THE POOL OF "AVAILABLE SLOTS" ....	29
FIGURE 33: IN PROGRESS SCREEN .....	30
FIGURE 34: SLOT RESERVATION SUMMARY SCREEN.....	31

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FIGURE 35: APPROVE/REJECT SCREEN.....	31
FIGURE 36: APPROVE / REJECT CONFIRMATION SCREEN.....	32
FIGURE 37: NOTIFICATION EMAIL SENT TO SITE USER .....	32
FIGURE 38: PATIENT BROWSER SCREEN.....	33
FIGURE 39: EDIT PATIENT SCREEN .....	34
FIGURE 40: EDIT PATIENT CONFIRMATION SCREEN .....	35
FIGURE 41: DELETE BUTTON FOR OPEN SLOT RESERVATION PATIENT NUMBERS .....	35
FIGURE 42: IN PROGRESS SCREEN .....	36
FIGURE 43: SLOT RESERVATION SUMMARY SCREEN.....	36
FIGURE 44: EDIT SLOT RESERVATION SCREEN.....	37
FIGURE 45: SLOT RESERVATION CONFIRMATION SCREEN.....	37
FIGURE 46: NOTIFICATION EMAIL SENT TO A SITE USER .....	38
FIGURE 47: LOCATE AND CLICK THE REPORT BUTTON .....	38
FIGURE 48: SLOT USAGE REPORT .....	39
FIGURE 49: SLOT RESERVATION REPORT SCREEN .....	39
FIGURE 50: SLOT RESERVATION REPORT FOR AN EVALUATION .....	40
FIGURE 51: SLOT RESERVATION STATES DIAGRAM .....	42

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# List of Tables

TABLE 1: WEB ADDRESSES FOR CTSU APPLICATIONS .....	1
TABLE 2: FIELDS ON THE GROUP CONFIGURATION SCREEN .....	13
TABLE 3: FIELDS ON THE PROTOCOL CONFIGURATION SCREEN .....	17
TABLE 4: PREFILL FIELD TYPES FOR SLOT RESERVATION .....	27
TABLE 5: SLOT RESERVATION STATES .....	43
TABLE 6: OPEN ROLES FOR SLOT RESERVATION .....	44
TABLE 7: NOTIFICATION EMAILS.....	46

## 1. Introduction

This document is designed to provide CTSU and Network Group staff with an overview of the full version of the Slot Reservation feature in the Oncology Patient Enrollment Network (OPEN) Portal.

This document will provide instructions for the process of enrolling a subject onto a slot reservation protocol, how to configure group and protocol level settings, how to perform common administrative actions, and a description of the different slot reservation states and the OPEN roles necessary for accessing the different features. Note that the terms *patients* and *subjects* are used interchangeably throughout the document, and that the term *stratum* was updated to *category*.

### 1.1 Web Addresses for CTSU Applications

**Table 1: Web Addresses for CTSU Applications**

Application	URL
OPEN Portal	<a href="https://open.ctsu.org">https://open.ctsu.org</a>
CTSUS Members' website	<a href="http://www.ctsu.cancer.gov">http://www.ctsu.cancer.gov</a>

## **2. Slot Reservation System Implementation**

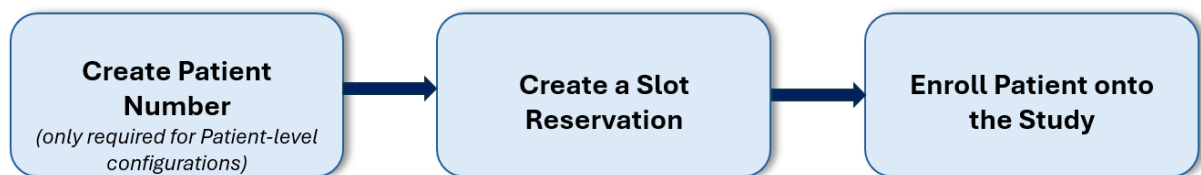
The Slot Reservation System allows users with registrar access to create and reserve a slot for a subject on any study that is configured to use the feature. OPEN has the capability to support slot reservations prior to enrolling a subject onto a protocol. Using this system, the user can register a subject for slot reservation, reserve a slot and create an enrollment using the reserved slot.

Group Administrators and Registrars have the access rights to configure the group and protocol level settings for slot reservation. This section will provide details on the processes necessary to configure and use the slot reservation system.

### 3. How to Enroll a Subject on a Slot Reservation Protocol

For protocols that are configured for slot reservation at a patient-level, a slot must be reserved for a subject before OPEN will allow them to proceed with enrolling onto the protocol's initial step.

To enroll a subject on a slot reservation protocol a site user would have to obtain a patient number (unless one already exists), use the patient number to reserve a slot for the protocol, and then use the slot reservation to enroll the subject onto the protocol. A subject will have only one patient number in OPEN and that patient number will be used to reserve all slots for that subject. For protocols that are configured for slot reservation at site-level, creation of a patient number is not required.



**Figure 1: Process for Enrolling a Subject on a Slot Reservation Protocol**

The sub-sections that follow will provide general instructions for completing the steps necessary for enrolling a subject on a slot reservation protocol.

In addition to enrolling subjects onto slot reservation studies using the regular mode of OPEN, slot reservation enrollments can also be created in Practice mode. Enrollments created in Practice mode are not real, which is useful for testing and training purposes. Practice mode is initiated by clicking the Start Practice button on the Welcome subtab (of the Home tab) of OPEN, and then initiating the enrollment on the Create New screen of the Enroll tab.

If a subject already has a slot reservation patient number (PT-#####), then a user may proceed to the next section to reserve a slot for their subject. If a subject does not have a slot reservation patient number, the user must create one for their subject.

#### 3.1 Getting a Patient Number for Patient-level Configurations

If a subject already has a slot reservation patient number (PT-#####), then a user may proceed to the next section to reserve a slot for their subject.

If a subject does not have a slot reservation patient number, the user must create one for their subject. The next sub-section provides instructions for creating a patient number.

##### 3.1.1 Instructions for Getting a Slot Reservation Patient Number

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the Create New Patient button in the Patients subtab.
- 4) Complete the necessary fields in the Create New Patient screen.
- 5) Click the Continue button. A validation will fire if the Year for the Patient's Date of Birth is less than 4 characters or if the year is less than 1900.

**How to Enroll a Subject on a Slot Reservation Protocol**

- 6) Click Ok on the confirmation pop-up window.
- 7) A confirmation page will display the slot reservation patient number, in the format PT-#####. For added clarity, the user will be informed that only a Patient Number has been created and to reserve a slot for their subject, they would need to click the *Reserve Slot* button.

The screenshot shows the 'Create New Patient' form. At the top, there is a navigation bar with tabs: Home, Slot Reservation (selected), Enroll, History, T&UM, Reports, RSS, Form Setup, Admin, and Help. Below this is a sub-menu: Patients | Create New | In Progress | History | Configuration | Report. The main heading is 'Create New Patient'. The form contains the following fields and options:

- Institution CTEP ID:** A text input field with a help icon.
- First Initial:** A text input field.
- Last Initial:** A text input field.
- Middle Initial:** A text input field.
- Patient's date of birth:** Two dropdown menus labeled '--- Select ---' followed by a text input field and a 'Clear' button.
- Sex:** Three radio button options: Female, Male, and Unknown.
- Zip code:** A text input field with a help icon.

At the bottom of the form are three buttons: 'Cancel' (orange), 'Start Over' (orange), and 'Continue' (green).

**Figure 2: Create Patient**

The screenshot shows the confirmation page. At the top, there is a navigation bar: Patients | Create New | In Progress | History | Configuration | Report. Below this is an 'Information' section with the following text:

Site: MN008 - Patient#: PT-0000008321

**NOTE: An OPEN Patient Number has been created, but this has not created a slot reservation. Click the [Reserve Slot] button to reserve a slot for the patient.**

At the bottom are three buttons: 'Edit Patient' (orange), 'Patient Browser' (orange), and 'Reserve Slot' (green).

**Figure 3: Confirmation Page for the Patients Screen**

### 3.2 Creating a Patient-Level Slot Reservation

After a slot reservation patient number is obtained, a slot may be reserved for the subject. The next subsection provides directions for reserving a slot for an existing subject.

### 3.2.1 Instructions for Creating Patient-Level Slot Reservation

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Locate the subject by entering the slot reservation patient number in the Patient # free-text box and click the Search button.
- 4) Click the Reserve button adjacent to the row for the subject.

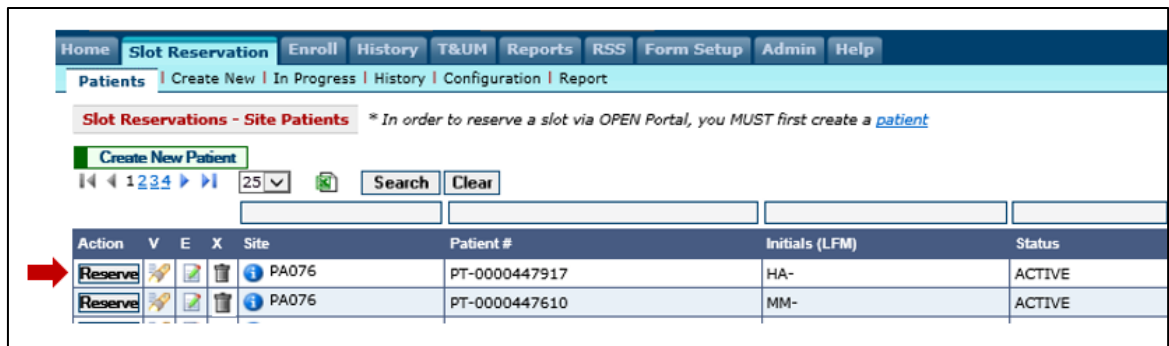


Figure 4: Patient Browser Screen

- 5) The user will be taken to the Create Slot Reservation screen.
- 6) Select the protocol from the Protocol Number field.
- 7) Select step number.
- 8) If available, enter a Network Group Patient ID.
- 9) Select a person in the Site Contact Person field (only persons with an Associate Person Type will display in the Site Contact Person field. Investigators will not display).
- 10) The user's name will be prefilled in the Site Contact Person field if the user is a site registrar.
- 11) Make a selection in the Category/Dose field.

How to Enroll a Subject on a Slot Reservation Protocol

**Create Slot Reservation**

1: Select Institution/Protocol combinations

Reserved By: [Redacted]

\* Institution CTEP ID: PA076      \* Institution Name: [Redacted]

\* Protocol Number: ARST1431

\* Step: 2

2: Select Patient Information:

\* Patient Number: PT-0000447917

Patient #	Site	Initials (LFM)	Date Of Birth	Gender	Zip
PT-0000447917	PA076	HA-	21-Mar-2006	Male Gender	17821

\* Network Group Patient ID: [Redacted]

3: Select Contact Information:

\* Site Contact Person: -- select --

4: Select Evaluation Information:

Please select one of the available stratum/dose combination based on the predefined slot configurations for the protocol

Select	Category	Description	Group	Dose	Available Slots	Issued Slots	Max Slots
<input type="radio"/>	ARST1431 Stratum 1	All Patients	Feasibility Phase		0	11	11
<input type="radio"/>	ARST1431 All Patients	All Patients	Efficacy Phase		0	207	207

Buttons: Cancel, Start Over, Submit

Figure 5: Create Slot Reservation Screen

- 12) Click Submit.
- 13) Click OK on the confirmation pop-up window.
- 14) The user’s request will be processed automatically, or after manual approval, depending on the way the protocol was configured.
  - a) If configured for automatic approval, the user will arrive at a confirmation page that will display the slot reservation number (in the format SR-#####) and the expiration date and time.

**Information**

**Slot Reservation Confirmation**

Slot Reservation ID: SR-0000016079

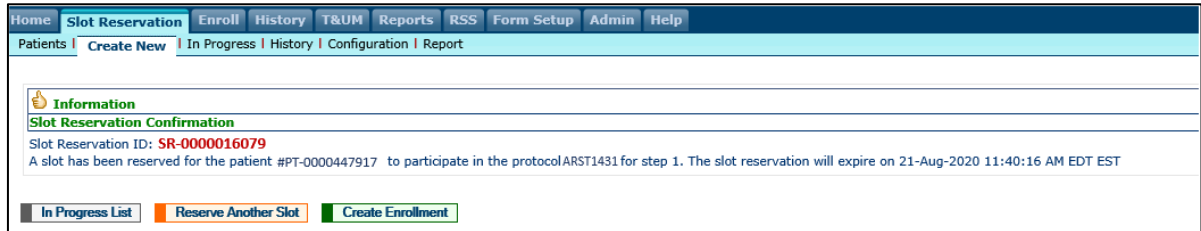
A slot has been reserved for the patient #PT-0000447917 to participate in the protocol ARST1431 for step 1. The slot reservation will expire on 21-Aug-2020 11:40:16 AM EDT EST

Buttons: In Progress List, Reserve Another Slot, Create Enrollment

Figure 6: Confirmation Page (Automatic Approval)

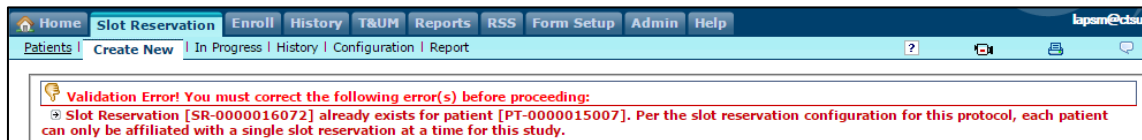
- b) If configured for manual approval, the user will arrive at a confirmation page that will display the slot reservation number as well as a note stating that the user will be informed once a

review decision has been made.



**Figure 7: Confirmation Page (Manual Approval)**

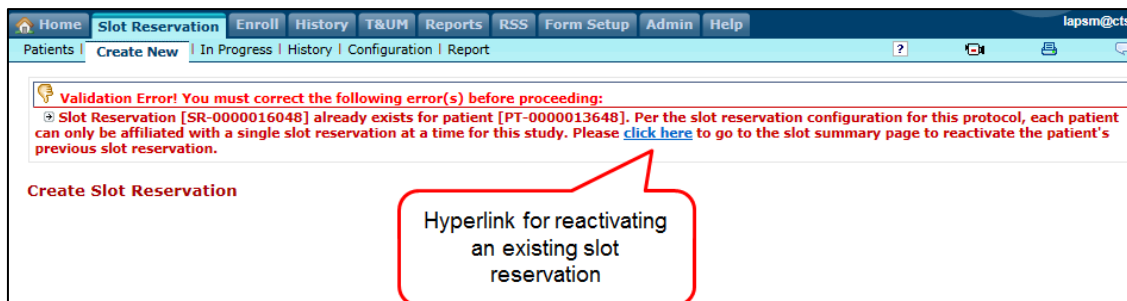
- c) If the slot reservation protocol is configured to not allow multiple reservations to the same study by the same subject, the user will encounter an error message, as shown in Figure 8.



**Figure 8: Error Message for Multiple-Reservations for the Same Subject (when not permitted)**

### 3.2.2 Duplicate Slot Reservation Check

If a user attempts to create a slot reservation for a slot reservation Patient ID that already had a slot reservation in a WITHDRAWN, EXPIRED, or CANCELLED status for the same subject (for the same study and category) a duplicate slot reservation error message will display and include a hyperlink to reactivate the subject’s existing slot reservation (see Figure 9).



**Figure 9: Slot Reservation Reactivation Link in the Duplicate Reservation Error Message**

## 3.3 Creating a Site-Level Slot Reservation

Creating a Site-Level slot reservation does not require obtaining a patient number.

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click on Create New subtab.

## How to Enroll a Subject on a Slot Reservation Protocol

- 4) Complete all required fields, including Institution CTEP ID, Protocol Number, Step, Site Contact Person, and Category/Dose, as shown in **Figure 10**.

**Figure 10: Create New Screen for Site-level Slot Reservation**

- 5) Click Submit
- 6) Click OK on the confirmation pop-up window.
- 7) The user’s request will be processed automatically, or after manual approval, depending on how protocol was configured.
  - a) If configured for automatic approval, the user will arrive at a confirmation page that will display the slot reservation number (in the format SR-#####) and the expiration date and time.

**Figure 11: Confirmation Page for Site-Level Slot Reservation (Automatic approval)**

**How to Enroll a Subject on a Slot Reservation Protocol**

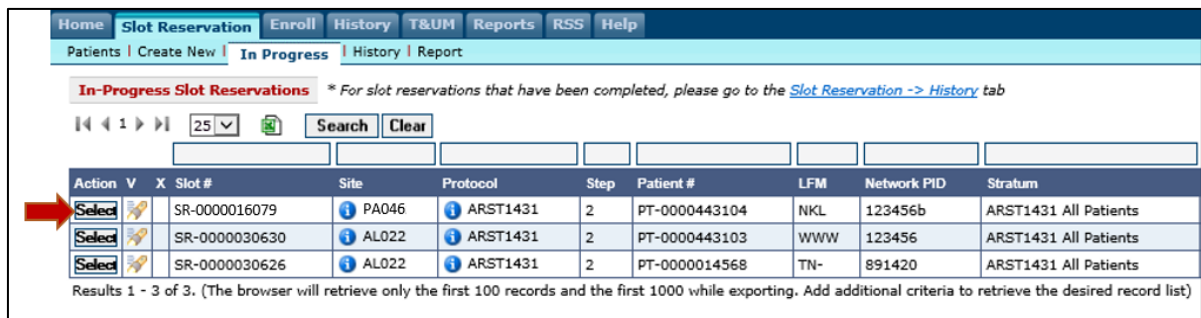
- b) If configured for manual approval, the user will arrive at a confirmation page that will display the slot reservation number as well as a note stating that the user will be informed once a review decision has been made.

### 3.4 Completing a Patient Enrollment

After a subject obtains a slot reservation, the user may proceed with enrolling the subject onto the protocol. The next sub-section provides directions for enrolling a subject onto a slot reservation protocol.

#### 3.4.1 Instructions for Enrolling a Patient onto a Slot Reservation Protocol

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the In Progress subtab.
- 4) Enter the subject’s slot reservation ID in the free-text box above the Slot # field and click the Search button.
- 5) Click the Select button in the row for the subject’s slot reservation.



**Figure 12: In Progress Screen**

- 6) Click the Create Enrollment button.



**Figure 13: In Progress Summary Screen**

- 7) The user will be taken to the Create New screen on the Enroll tab (most of the fields in section 1 will be pre-filled and not-editable, such as the Slot Reservation Number field).

How to Enroll a Subject on a Slot Reservation Protocol

The screenshot shows the 'Create New' screen with the following fields and values:

- Tracking Number:** [Redacted]
- Registrar:** [Redacted]
- Institution CTEP ID:** PA076
- Institution Name:** [Redacted]
- Protocol Number:** ARST1431
- Protocol Title:** A Phase I Study of Intravenous Carboplatin/P... Combination with Continuous or Intermittent/ Supplied Agent Bevacizumab (NSC #704865) Ovarian, Fallopian Tube or Primary Peritoneal
- Protocol Note(s):** [Redacted]
- Registration Step:** 1 - Registration
- Slot Reservation Number:** SR-0000016079

Navigation tabs at the top: In Progress | **Create New** | Summary | Prerequisite | Demography | Checklist

Section 1: Select Institution/Protocol combinations

Section 2: Add persons associated with this enrollment

Figure 14: Create New Screen (Enroll Tab)

- 8) Select the appropriate answer from the Person Type(s) field along with the corresponding choice(s) in the Person Name field.
- 9) Select a group to receive credit in the Network Group Credit field.
- 10) Select a physician in the Credit Investigator field.
- 11) Click Continue.
- 12) Click OK on the confirmation pop-up window.
- 13) Click Continue on the tracking number confirmation page.
- 14) Complete the necessary fields on the Demography screen.
- 15) Click Continue.
- 16) Complete the necessary fields on the Checklist screen.
- 17) Click Continue.
- 18) Review the data on the Review & Submit screen for accuracy.
- 19) Click Submit.
- 20) Click OK on the confirmation pop-up window.
- 21) The user will arrive at a confirmation screen.

Browse | **Summary** | Prerequisite | Demography | Checklist

Selected Tracking # **108553** [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	S
GOG-9923	481731477	VDD	1	A	MN008	Anderson, Casandra	R

**Information**

- Group response for tracking # **108553**
- This registration can now be found in the HISTORY section
- Click on [View Summary] to view the complete registration summary

Group Response(s)	
Eligibility:	<b>ELIGIBLE</b>
Ineligibility Reason:	<b>None.</b>
Patient ID:	<b>481731477</b>
Treatment Arm:	<b>A</b>
Site Instruction:	<b>Please send form to the group address.</b>

Figure 15: Enrollment Confirmation

### 3.5 How to Perform a Practice Mode Slot Reservation Enrollment

OPEN users have the ability to create slot reservation enrollments in Practice mode, which simulates the enrollment process without creating a real enrollment.

A Practice mode slot reservation enrollment differs from the process for creating a real slot reservation enrollment in the following ways:

- Users will bypass the process for creating the Slot Reservation Patient Number and Slot Reservation Number.
- Users will select a system-generated Slot Reservation Number at the Create New screen of the Enroll tab.
- Questions in the OPEN Eligibility Checklist that prefill slot reservation values (such as category and dose names) will prefill the first value by default.

Follow these steps to perform a slot reservation enrollment in Practice mode:

- 1) Log in to OPEN.
- 2) On the Welcome subtab of the Home tab, click the Start Practice button.
- 3) A Practice/Test Registration watermark will appear in the background.
- 4) Click the Enroll tab.
- 5) Click the Create New subtab.
- 6) Enter the site code of the enrolling institution in the Institution CTEP ID field.
- 7) Select the slot reservation protocol number from the Protocol Number drop-down menu.
- 8) Select the Registration Step.
- 9) Select any Slot Reservation Number from the Slot Reservation Number drop-down menu (the Slot Reservation Numbers are system-generated by OPEN during Practice Mode).

How to Enroll a Subject on a Slot Reservation Protocol

**1: Select Institution/Protocol combinations**

Tracking Number:

Registrar: Laps Matthew

\* Institution CTEP ID: CA139      Institution Name: Lucile Packard Children's Hospital Stanford

\* Protocol Number: ANBL1221      Protocols Missing?

Protocol Title: A Phase II Randomized Trial of Irinotecan/Temozolomide with Temsirolimus (NSC# 683864, IND# 610 (NSC# 764038, IND# 4308) in Children with Refractory, Relapsed or Progressive Neuroblastoma

Protocol Note(s): Please remember to click the 'Populate Demography' button on the Demography screen after entering this field. Clicking 'Continue' without pressing this button will prevent your enrollment from taking place.

\* Registration Step: 1 - Enrollment/ Randomization      Steps Missing?

\* Slot Reservation Number: -- select --

**2: Add persons associated with**

- Only one treating investigator can be associated
- Press + to add a person, or - to remove a person
- If a shipping investigator is not selected, the shipping address will default to the treating investigator address
- Protocol specific instructions:** Protocol ANBL1221 has the following association(s):  
**Treating Investigator (required)**, Site Registrar (optional), Drug Shipment Investigator (optional). To add optional persons, please click the green plus icon.

Action	Person Type*	Person Name [ID] [Network Group]*
-	- select -	- select -
+		

Figure 16: Initiating a Slot Reservation Enrollment in Practice Mode

- Perform the remainder of the enrollment like a regular enrollment. Please note that questions in the OPEN Eligibility Checklist, which use slot reservation prefill widgets, will prefill the first valid value by default.

## 4. Configuring Slot Reservation Settings

The Slot Reservation System allows users with registrar access to create and reserve a slot for a subject on any study that is configured to use the feature. OPEN has the capability to support slot reservation prior to enrolling a subject onto a protocol, for any single step (per protocol). Using this system, the user can register a subject for slot reservation, reserve a slot and create an enrollment using the reserved slot.

Network Group staff (with the Group Registrar or Group OPEN Administrator role) should configure the slot reservation settings in OPEN User Acceptance Testing (UAT) and Production environments for their studies. CTSU will assist group staff with configuring the settings for their first slot reservation protocol, as well as providing general support regarding OPEN’s slot reservation feature.


The group and protocol level slot reservation settings must be independently configured in both OPEN UAT and Production (the settings do not transfer automatically between the environments).

### 4.1 Configuring Group Level Slot Reservation Settings

Group level settings are automatically applied to a Network Group’s protocol when it is being configured initially. After the group level settings have been applied, the group user may proceed to configure the protocol level settings. Group level slot reservation settings must be finalized before any of the Network Group’s protocols are configured.

The next sub-section will describe how to configure slot reservations settings at the group level.

#### 4.1.1 Instructions for Configuring Group Level Slot Reservation Settings

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the Configuration subtab.
- 4) Click the Network Group Configuration button.
- 5) Select the appropriate group in the Network Group field.
- 6) Make the appropriate selections for the necessary fields on the page (the table below provides a description for each of the fields, and each field also has a help  button that contains a pop-up description).

**Table 2: Fields on the Group Configuration Screen**

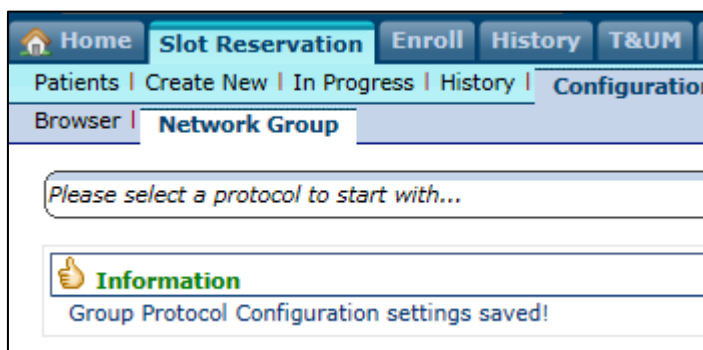
Field	Description
Network Group	Group for which the settings are being configured.

Field	Description
Slot Type	<p>Whether the slot reservation is Protocol or Stratum based.</p> <p>Protocol-based slot reservation is meant for protocols where all subjects receive the same treatment, whereas Stratum-based slot reservation is meant for protocols where subjects have more than one treatment option.</p> <p>In OPEN, the only difference between selecting Protocol versus Stratum for the Slot Type field is that if Protocol is chosen, when a new row is added to the Stratum Configuration section the Stratum Name will automatically be prefilled with DEFAULT, and the Stratum Group and Description fields will prefill with N/A.</p>
Expiry days	The number of calendar days until a RESERVED slot automatically enters an EXPIRED state.
Automatic reservation?	If answered Yes, a user's request to reserve a slot will automatically be evaluated by OPEN (if slots are available the request will be approved). If answered No, the user's request will be sent to the LPO for a review decision.
Expiry day count starts from approval queue?	<p>If manual approval is necessary to reserve a slot:</p> <p>If answered Yes, then the expiry day count will be calculated from the time the user makes the request to reserve or reactivate a slot. If answered No, the expiry day count will be calculated from the time the user's request is approved by the group.</p>
Automatic renewal?	If answered Yes, a user's request to renew a slot will automatically be approved. If answered No, a user's request to renew a slot will require manual approval.
Renewal period	The number of hours before a slot expires that a user can begin to renew their slot reservation. An email is also sent to the site user at this time to inform them that their slot can be renewed.
Minimum slots for automatic renewal	If the protocol is configured to renew slots automatically, this is the minimum number of slots that must be available for slot renewal requests to continue to be automatically approved.
Allow Waiting queue?	If answered Yes, subjects will enter the waiting queue (the status of the slot will be WAITING) if no slots are available. If answered No, the waiting queue will be unavailable for the protocol. If a user attempts to create a slot reservation and no slots are available, and no waiting queue is available, the user will receive a message informing them of that fact. A Category must be active for a subject to enter the Waiting queue.
Maintain waiting list subjects after evaluations become inactive?	If answered Yes, subjects will remain on the Waiting Queue after the protocol's evaluation enters an INACTIVE status. If a Waiting Queue is used without this feature, Waiting Queue patients will enter a CANCELLED status after their evaluation becomes INACTIVE.

**Configuring Slot Reservation Settings**

Field	Description
Configure waiting period for reactivating a slot?	If answered Yes, a user must wait a specified amount of time before they can request to reactivate their slot after it enters an EXPIRED, WITHDRAWN, or CANCELLED status for the same protocol. If answered No, a user can request to reactivate their slot without going through a waiting period.
Minimum waiting period for reactivating a slot	If a waiting period is required, it is the number of calendar days a user must wait before they can reactivate their slot.
Minimum number of available slots required to bypass a waiting period	If a waiting period is required, it is the minimum number of slots that must be available for the slot reactivation waiting period to be bypassed.
Automatic cancellation?	If answered YES, and a subject has multiple reservations for the same group, enrollment onto one of the group's studies will automatically cancel the subject's remaining slot reservations for that group. If answered NO, and a subject has multiple reservations for the same group, enrollment onto one of the studies will not cancel the subject's remaining slot reservations for the same group.
Capture dose information?	Whether dose information will be available for configuration in the Category and Evaluation screen.
Support multiple reservations for same protocol?	Whether a subject can reserve slots on more than one evaluation for the same protocol.  OPEN will count a subject's slot as a slot reservation, regardless of the status; until it is deleted (ENROLLED and REJECTED statuses cannot be deleted).
Collect Network Group patient identifier	Whether the Network Group Patient ID field on the Create Slot Reservation screen will be not required, optional, or mandatory.
Comments (if any)	Comments for the selected group.

- 7) Click Save.
- 8) Click OK on the confirmation pop-up window.
- 9) User will arrive at the confirmation page.



**Figure 17: Confirmation Screen for Group Level Settings**

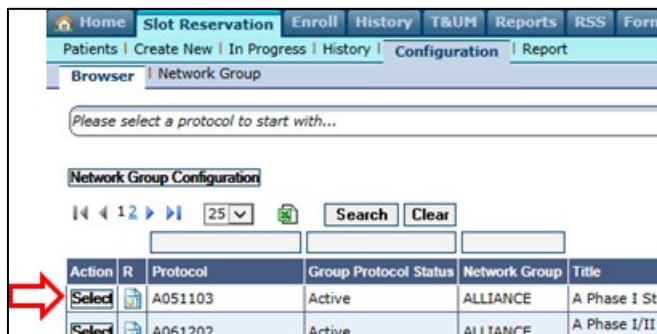
## 4.2 Configuring Protocol Level Slot Reservation Settings

If group-level protocol settings exist for a protocol’s lead group, a user may proceed with configuring protocol level settings for a slot reservation protocol. If a user attempts to configure protocol-level slot reservation settings before the group-level settings have been configured, the user will encounter an error message that will direct the user to the group-level configuration page.

The next sub-section will describe how to configure slot reservations settings at the protocol level.

### 4.2.1 Instructions for Configuring Protocol Level Slot Reservation Settings

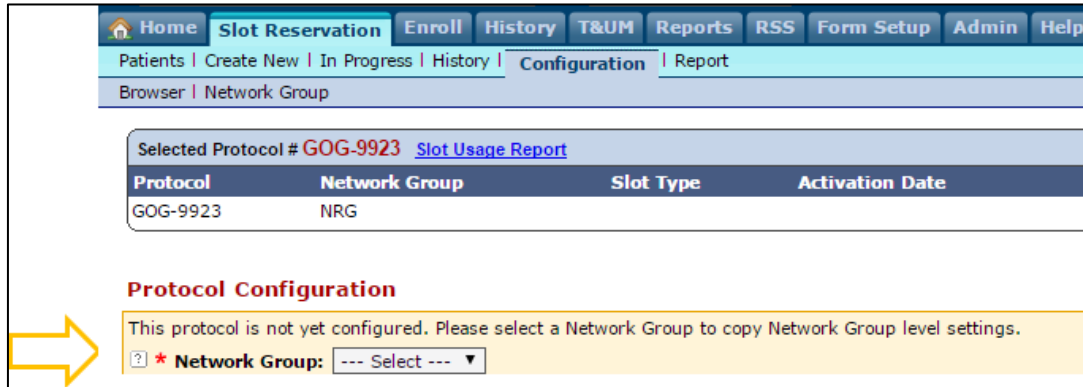
- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the Configuration subtab, the user will default to the Browser sub-tab.
- 4) Protocols with an *Active* Group Protocol Status will display by default. Protocols with non-active statuses can be displayed if the user selects a status from the Group Protocol Status column, and the results will refresh automatically.
- 5) Enter the protocol number in the free-text box above the Protocol field, and press the Search button.
- 6) Click the Select button for the Protocol.




**Figure 18: Selecting a Protocol from the Browser Screen**

- 7) If a protocol is being configured for the first time the user will have to select the lead group in the Network Group field, and then the Group level settings will be applied to the protocol.

Configuring Slot Reservation Settings



**Figure 19: Protocol Level Configuration Screen**

- 8) Make the appropriate selections for the necessary fields on the page (the table below provides the description for each of the fields, and each field also has a help  button that contains a pop-up description).

**Table 3: Fields on the Protocol Configuration Screen**

Field	Description
Network Group	Group for which the settings are being configured. This field is only visible the first time a protocol is configured.
Slot Type	Whether the slot reservation is Protocol or Stratum based. Protocol-based slot reservation is meant for protocols where all subjects receive the same treatment, whereas Stratum-based slot reservation is meant for protocols where subjects have more than one treatment option. In OPEN, the only difference between selecting Protocol versus Stratum for the Slot Type field is that if Protocol is chosen, when a new row is added to the Stratum Configuration section the Stratum Name will automatically be prefilled with "DEFAULT", and the Stratum Group and Description fields will prefill with N/A.
Reservation Type	Allows user to select SITE or PROTOCOL value. If SITE value is selected, then the user will not need to create a Slot Reservation Patient ID before reserving a slot for a protocol in focus.
Expiry days	The number of calendar days until a RESERVED slot automatically enters an EXPIRED state.
Automatic reservation?	If answered Yes, a user's request to reserve a slot will automatically be evaluated by OPEN (if slots are available the request will be approved). If answered No, the user's request will be sent to the LPO for a review decision.

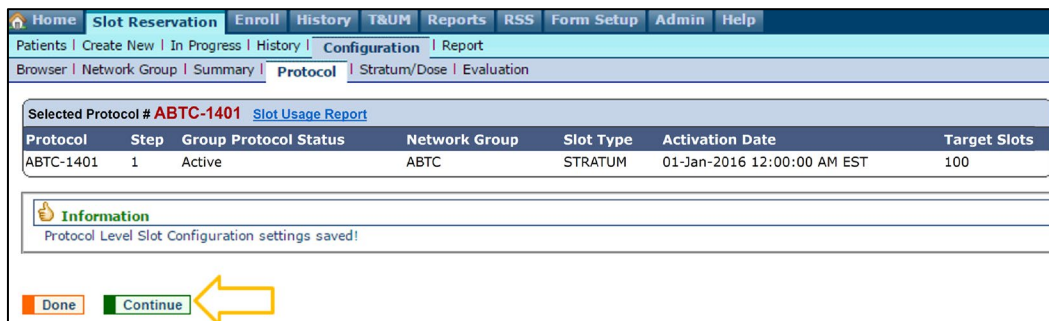
## Configuring Slot Reservation Settings

Field	Description
Expiry day count starts from approval queue?	If manual approval is necessary to reserve a slot: If answered Yes, then the expiry day count will be calculated from the time the user makes the request to reserve or reactivate a slot. If answered No, the expiry day count will be calculated from the time the user's request is approved by the group.
Automatic renewal?	If answered Yes, a user's request to renew a slot will automatically be approved. If answered No, a user's request to renew a slot will require manual approval.
Renewal period	It is the number of hours before a slot expires that a user can begin to renew their slot reservation. An email is automatically sent to the site user at this time to inform them that their slot can be renewed.
Minimum slots for automatic renewal	If the protocol is configured to renew slots automatically, this is the minimum number of slots that must be available for slot renewal requests to continue to be automatically approved.
Allow waiting queue?	If answered Yes, subjects will enter the waiting queue (the status of the slot will be WAITING) if no slots are available. If answered No, the waiting queue will be unavailable for the protocol. If a user attempts to create a slot reservation and no slots are available and no waiting queue is available, the user will receive a message informing them of that fact.
Maintain waiting list subjects after evaluations become inactive?	If answered Yes, subjects will remain on the Waiting Queue after the protocol's evaluation enters an INACTIVE status. If a Waiting Queue is used without this feature, Waiting Queue subjects will enter a CANCELLED status after their evaluation becomes INACTIVE.
Configure waiting period for reactivating a slot?	If answered Yes, a user must wait a specified amount of time before they can request to reactivate their slot after it enters an EXPIRED, WITHDRAWN, or CANCELLED status for the same protocol. If answered No, a user can request to reactivate their slot without going through a waiting period.
Minimum waiting period for reactivating a slot	If a waiting period is required, it is the number of calendar days a user must wait before they can reactivate their slot.
Minimum number of available slots required to bypass a waiting period	If a waiting period is required, it is the minimum number of slots that must be available for the slot reactivation waiting period to be bypassed.
Capture dose information?	Whether dose information will be available for configuration in the Category and Evaluation screen. Note, this field will NOT be available for Cohort Management studies.
Support multiple reservations for same protocol	Whether a subject can reserve slots on more than one evaluation for the same protocol. OPEN will count a subject's slot as a slot reservation, regardless of the status; until it is deleted (ENROLLED and REJECTED statuses cannot be deleted).

**Configuring Slot Reservation Settings**

Field	Description
Collect Network Group subject identifier	Whether the Network Group Patient ID field on the Create Slot Reservation screen will be not required, optional, or mandatory.
Activation Date	The date and time (EST) that slot reservations may begin to be created.
Release time for Cancelled, Withdrawn, Expired, and Rejected slots.	The daily release time (EST) that slot reservations that have entered a CANCELLED, EXPIRED, WITHDRAWN, or REJECTED status will be moved to the pool of <i>Available Slots</i> . For more information, see Section 4.4.
Target number of slots	The maximum number of subjects that can enroll per protocol. The Target number of slots can be increased after a study is Active and accruing subjects. Note, the Target number of slots will NOT be editable for Cohort Management studies and will be automatically calculated in the Protocol application.
Exclusive protocols?	If a subject reserves a slot on this protocol, OPEN will no longer allow a subject to reserve a slot for the protocols selected in the field. Also, if a subject reserves a slot for a protocol that is selected in the field, then the subject will not be able to reserve a slot on the protocol that is being configured.
Reservation maintenance mode?	If answered Yes, slot reservations cannot be created, updated, approved, or rejected for the selected protocol. This feature can be useful when a group is making changes to a protocol's configuration.

- 9) Click Save.
- 10) Click OK on the pop-up confirmation window.
- 11) The user will arrive at a screen that confirms the settings have been saved.




**Figure 20: Protocol Settings Confirmation Screen**

- 12) Click Continue.
- 13) Configure the Category Configuration section:
  - (1) Within the Category Configuration section, click the **+** button to add a blank row.
  - (2) Enter the Category Name (*Default* will automatically be prefilled if the protocol is a protocol-based slot reservation protocol).

- (3) Enter a value for the Category Group (N/A may be entered if this field is not applicable).
- (4) Enter a Description for the purpose of elaborating on the Category (N/A may be entered if this is protocol based).
- (5) Enter a Disease Code if applicable.
- (6) Choose a Category Status (slot reservations can only be created for Category with an *Active* status) for the Category.
- (7) Add more rows for additional Category, if needed.
- (8) The Category Name and CategoryGroup combination(s) must be unique.

14) Configure the Dose Configuration section (if applicable):

- (1) Within the Dose Configuration section, click the  button to add a blank row.
- (2) Enter a Name.
- (3) Enter a Description.
- (4) Enter a Level (decimal values are supported).
- (5) Enter a Unit, if applicable.
- (6) Enter a Frequency, if applicable.
- (7) Select a Status (*Active* or *Inactive*).
- (8) Add more rows, if needed.
- (9) The (dose) Name and Level combination(s) must be unique.

Configuring Slot Reservation Settings

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 # [Slot Usage Report](#)

Protocol	Step	Group Protocol Status	Network Group	Slot Type	Activation Date	Target Slots
ABTC-1401	1	Active	ABTC	STRATUM	16-Aug-2019 09:00:00 AM EDT	300

**Protocol Level Evaluation Configuration**

- Note:
  - Press the to add a row
  - Press the corresponding to remove the particular row
  - Unused rows will be removed when the [Save] is clicked

**Category Configuration**

Action	Category Name*	Category Group*	Description*	Disease code	Category Status*
	Part 1	N/A	Dose Finding		ACTIVE
	Part 3	N/A	Treatment Schedule		ACTIVE
	Part 2	N/A	Drug Distribution		--- Select ---

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 # [Slot Usage Report](#)

Protocol	Step	Group Protocol Status	Network Group	Slot Type	Activation Date	Target Slots
ABTC-1401	1	Active	ABTC	STRATUM	16-Aug-2019 09:00:00 AM EDT	300

**Protocol Level Evaluation Configuration**

- Note:
  - Press the to add a row
  - Press the corresponding to remove the particular row
  - Unused rows will be removed when the [Save] is clicked

**Category Configuration**

Action	Category Name*	Category Group*	Description*	Disease code	Category Status*
	Part 1	N/A	Dose Finding		ACTIVE
	Part 3	N/A	Treatment Schedule		ACTIVE
	Part 2	N/A	Drug Distribution		--- Select ---

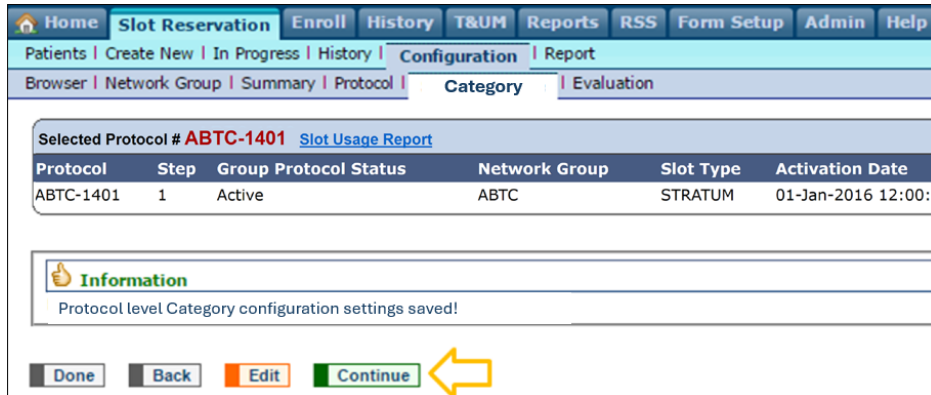
**Dose Configuration**

Action	Name*	Description*	Level*	Unit	Frequency	Dose Status*
	DL3	3600 mg/day	3600.0	mg	qd	ACTIVE
	DL4	6000 mg/day	6000.0	mg	qd	ACTIVE
	DL2	2400 mg/day	2400.0	mg	qd	ACTIVE
	DL-1	900 mg/day	900.0	mg	qd	ACTIVE
	DL1	1200 mg/day	1200.0	mg	qd	ACTIVE

Figure 21: Example of the Category Screen

- 15) Click Save.
- 16) Click OK on the confirmation pop-up window.
- 17) User will arrive at a screen that confirms the Category/Dose settings were saved.


**Configuring Slot Reservation Settings**



**Figure 22: Confirmation That Category / Dose Settings Were Saved**

18) Click Continue.

19) Setup the Protocol Level Evaluation Configuration section:

- (1) Click the  button to add a blank row.
- (2) Select the Category Name.
- (3) Select the Dose Name.
- (4) Enter the Max Slots.
- (5) Select a Status (slot reservations are only permitted for category and dose combinations that have an *Active* status).
- (6) Add more rows if necessary.
- (7) The Category Name and Dose Name combination(s) must be unique.

Configuring Slot Reservation Settings

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 # **8811** [Slot Usage Report](#)

Protocol	Network Group	Slot Type	Activation Date	Target Slots	Status
8811	SWOG	PROTOCOL	05/15/2013 12:00 AM	31	ACTIVE

**Protocol Level Category/Dose Configuration**

- Note:
  - Press the to add a row
  - Press the corresponding to remove the particular row
  - Unused rows will be removed when the [Save] is clicked

**Category Configuration**

Action	Category Name *	Category Group *	Description *	Disease Code	Status*
	DEFAULT	N/A	N/A		ACTIVE

**Dose Configuration**

Action	Name*	Description*	Level*	Unit	Frequency	Status*
	ABT-8888	Level -1	20.0	mg	Twice daily	INACTIVE
	ABT-8888	Level 0	40.0	mg	Twice daily	INACTIVE
	ABT-8888	Level 2	120.0	mg	Twice daily	INACTIVE
	ABT-8888	Level 3	160.0	mg	Twice daily	INACTIVE
	ABT-8888	Level 1	80.0	mg	Twice daily	ACTIVE

Cancel Back Save

Figure 23: Category Screen

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 # **ABTC-1401** [Slot Usage Report](#)

Protocol	Step	Group	Protocol Status	Network Group	Slot Type	Activation Date	Target Slots
ABTC-1401	1	Active		ABTC	STRATUM	01-Jan-2016 12:00:00 AM EST	100

**Protocol Level Evaluation Configuration**

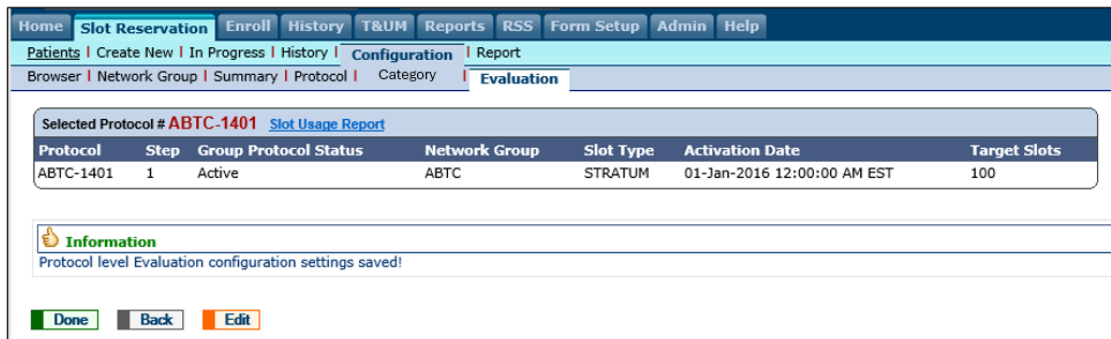
- Note:
  - Press the to add an evaluation
  - Press the corresponding to remove the particular evaluation
  - If additional slots are necessary for a category and dose combination, add the additional slot numbers with the existing "Max slots" value
  - For example if the current Max Slots value is 5 and 3 more slots are needed, change the value to 8
  - The sum of the Max Slots of ACTIVE Evaluations must be lesser or equal to target slots of the protocol
  - Only evaluation records that have an ACTIVE status can be used for reserving slots

Action	Category Name (Group) *	Dose Name (Level)*	Max Slots*	Evaluation Status*
	Part 1 (N/A)	DL3 (3600.0)	3	INACTIVE
	Part 1 (N/A)	DL2 (2400.0)	7	INACTIVE
	Part 1 (N/A)	DL4 (6000.0)	3	INACTIVE
	Part 1 (N/A)	DL1 (1200.0)	3	INACTIVE

Cancel Back Save

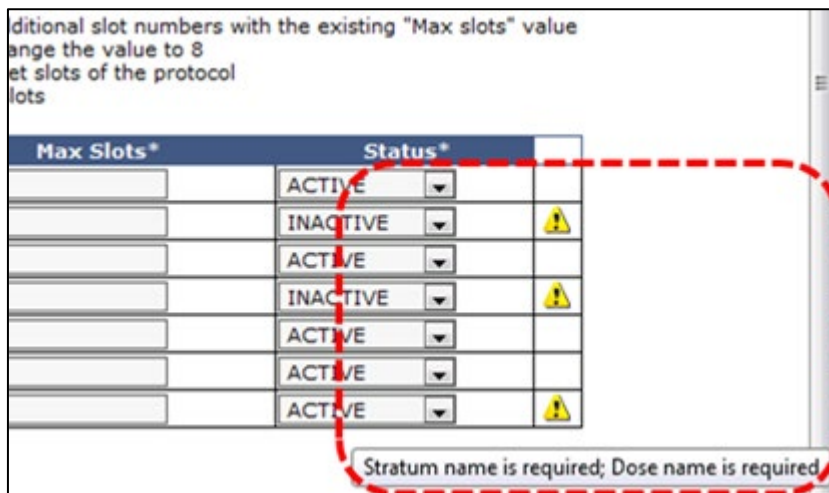
Figure 24: Evaluation Screen

- 20) Click Save.
- 21) Click OK on the configuration pop-up window.
- 22) Validations will occur.
  - a) If the validations pass, the user will arrive at the confirmation screen.



**Figure 25: Evaluation Confirmation Screen**

- b) If all validations are not passed, the user will see error messages on the Evaluations screen that indicate what needs to be addressed.



**Figure 26: Informative Error Icons and a Tool-Tip with Description on the Evaluation Screen**

This concludes the process for configuring slot reservation settings at the protocol level.

OPEN will automatically change the status of an ACTIVE evaluation to INACTIVE once (1) the maximum number of slot reservations for the evaluation have been reached, and (2) the status for all of the reserved subjects for the evaluation have entered an *ENROLLED* status. LPO users can manually adjust an INACTIVE evaluation back to ACTIVE using the Evaluation configuration subtab for the protocol.

### 4.2.2 Using CDE Information to Configure Category Name and Dose Name

OPEN provides the ability for Group OPEN Administrators to configure the Category Name and (dose) Name fields (in the Category subtab) for a protocol using valid value information from questions in the protocols OPEN Eligibility Checklist. This is especially useful when slot reservation prefill widgets (see Section 4.4) are used since the Category Name and (dose) Name values that are configured must exactly match the valid values for the corresponding question(s) in the OPEN EC. The Slot Configuration field will automatically appear in the Questions screen (under the Form Setup tab) for Slot Reservation protocols. The drop-down menu for the Slot Configuration field will appear for questions that have valid values. If any slot reservations for the study enter an ENROLLED status, the drop-down menus in the Slot Configuration column will become disabled. To enable a disabled Slot Configuration? Column, the form would need to be re-downloaded into OPEN and (the newly downloaded form) must be set to an Active status.

Instructions for configuring the Category Name and (dose) Name fields using CDE Information:

- 1) Log in to the OPEN Portal.
- 2) Click the Form Setup tab.
- 3) Locate the form for the study and click Select.
- 4) Click the Questions subtab.
- 5) Locate the question whose valid values will be used for configuring the slot reservation configuration field(s).
- 6) In the row for the applicable question select either CATEGORY or DOSE from the drop-down in the Slot Configuration column (as shown in Figure 26). Only one question can be configured for either of those choices.

Que ID	Question Name (Instruction)										Slot Configuration
	Data Type	Reqd. Y/N?	Edit Y/N?	Hide Y/N?	Upper Y/N?	Min. Max.	# V.Values	Default	Widget Type		
24905	ADVL1213 Stratum										
	CHARACTER	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		160	2		Prefill: Slot Stratum	STRATUM
24907	Treatment Start Date Please provide the projected treatment start date. To be eligible, this date must be within five calendar days of enrollment.										
	DATE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		8	0		Date Field 3 Part	- SELECT - DOSE STRATUM
24906	ADVL1213 Treatment Assignment										
	CHARACTER	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		160	5		Prefill: Slot Dose	DOSE

Figure 27: Selecting Questions on the Questions Screen (Form Setup tab)

- 7) Click the Save Question Setup button.
- 8) Click the Slot Reservation tab.
- 9) Click the Configuration subtab.
- 10) Locate the study and click the Select button in the row for the protocol.
- 11) Click the Category subtab.
- 12) If the Category Name will be configured, click the Category CDE Values icon (📄) next to the Category Name field (otherwise skip to step 16 to configure the dose Name).
- 13) Click the desired value from the Name column of the popup window, and the value will prefill into the Category Name field.

Configuring Slot Reservation Settings

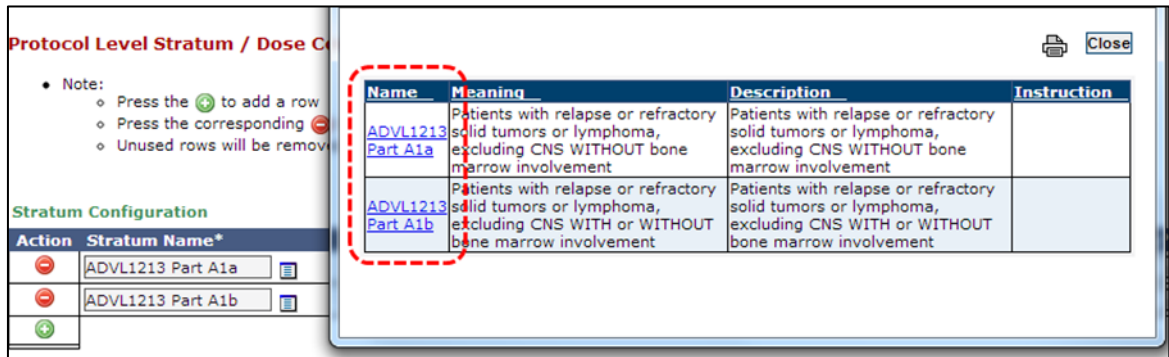


Figure 28: Popup Window for Selecting Category Name Values

- 14) Fill in the remaining necessary fields in the row.
- 15) Perform the previous step until all Categories has been configured.
- 16) If the (dose) Name will be configured, click the Dose CDE Values icon (📄) next to the (dose) Name field (otherwise skip to step 20).
- 17) Click the desired value from the Name column of the popup window, and the value will prefill into the (dose) Name field.
- 18) Fill in the remaining necessary fields in the row.

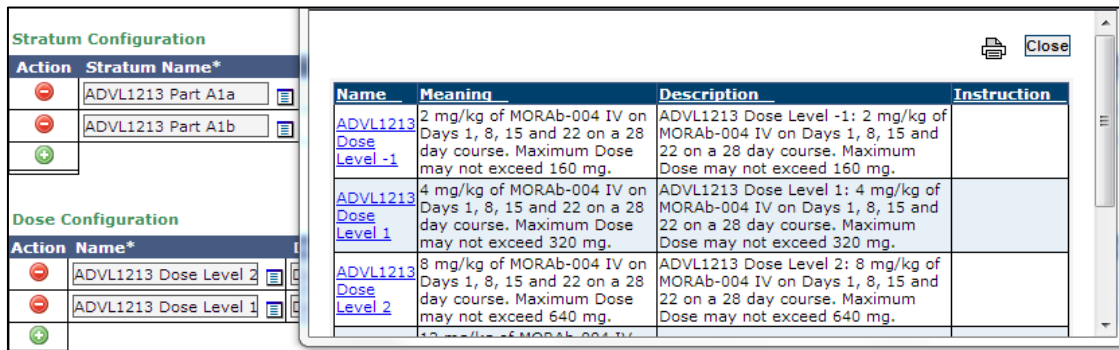


Figure 29: Popup Window for Selecting (Dose) Name Values


- 19) Perform the previous step until all doses have been configured.
- 20) Click the Save button.

This concludes the process for configuring the Category Name and (dose) Name fields using CDE information.

### 4.3 Configuring Protocol Level Slot Reservation Settings for Cohort Management Studies

Use Protocol application to complete protocol setup activities for Cohort Management studies (see Help Topics section within the Protocol application.)

To complete protocol level slot reservation settings for cohort management studies in OPEN, proceed with the following steps:

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the Configuration subtab, the user will default to the Browser subtab.
- 4) Protocols with an *Active* Group Protocol Status will display by default. Protocols with non-active statuses can be displayed if the user selects a status from the Group Protocol Status column, and the results will refresh automatically.
- 5) Enter the protocol number in the free-text box above the Protocol field and press the Search button.
- 6) Click the Select button for the Protocol (refer to Figure 18).
- 7) If a protocol is configured for the first time the user will have to select the lead group in the Network Group field, and then the Group level settings will be applied to the protocol (refer to Figure 19).
- 8) Make the appropriate selections for the necessary fields on the page (Table 3 provides the description for each of the fields, and each field also has a help  button that contains a pop-up description). Note, Capture Dose Information field will not be available for Cohort Management Studies, and Target number of slots field will not be editable and will be automatically calculated in the Protocol application.
- 9) Click Save.
- 10) Click OK on the pop-up confirmation window.
- 11) The user will arrive at a screen that confirms the settings have been saved. Note, Category and Evaluation configurations will not be available (will be disabled) for Cohort Management studies. These configurations will need to be completed in the Protocol application.

#### 4.4 Configuring Slot Reservation Prefill Field Types in Form Setup

An OPEN enrollment form for a slot reservation protocol can be configured to pull data that a user selected from the Create Slot Reservation screen, and prefill that information into a question on the subject’s OPEN EC.

There is a total of five Field Types in the Questions & Layout screen in Form Setup that can be configured for a particular question on the form.

**Table 4: Prefill Field Types for Slot Reservation**

Slot Reservation Configuration Field	Field Type
Name (from the Dose Configuration section)	Prefill: Slot Dose
Frequency (from the Dose Configuration section)	Prefill: Slot Dose Frequency
Level (from the Dose Configuration section)	Prefill: Slot Dose Level
Unit (from the Dose Configuration section)	Prefill: Slot Dose Unit
Stratum Name (from the Stratum Configuration section)	Prefill: Slot Stratum

Slot Reservation Configuration Field	Field Type
Stratum Group (from the Stratum Configuration section)	Prefill: Slot Stratum Group

If slot reservation prefill field types are used on OPEN Eligibility Checklist questions that have valid values, and the valid values do not exactly match the values that were entered in the slot reservation configuration screens, the question(s) in the EC that use the prefill field type will not prefill (the corresponding fields in the OPEN EC will be left empty).

For instance, if the Category Name field was configured with a value of A (in the Category/Dose subtab), and a question in the form’s EC was setup as the Prefill: Slot Category (but the question has a valid value of A-1 that was configured in caDSR) the prefill will not occur and the person enrolling the subject will need to provide an answer in the OPEN EC.

### 4.4.1 Instructions for Configuring Slot Reservation Prefill Field Types

Below are the steps that a person with the CTSU\_REG\_ADMIN or GROUP\_REG\_ADMIN role needs to follow to configure the slot reservation prefill field types for a slot reservation protocol:

- 1) Log in to the OPEN Portal.
- 2) Click the Form Setup tab.
- 3) Click the Select button next to the appropriate form.
- 4) Click the Questions subtab.
- 5) Locate the question that will utilize the prefill widget.
- 6) Click the Widget Type drop-down menu.

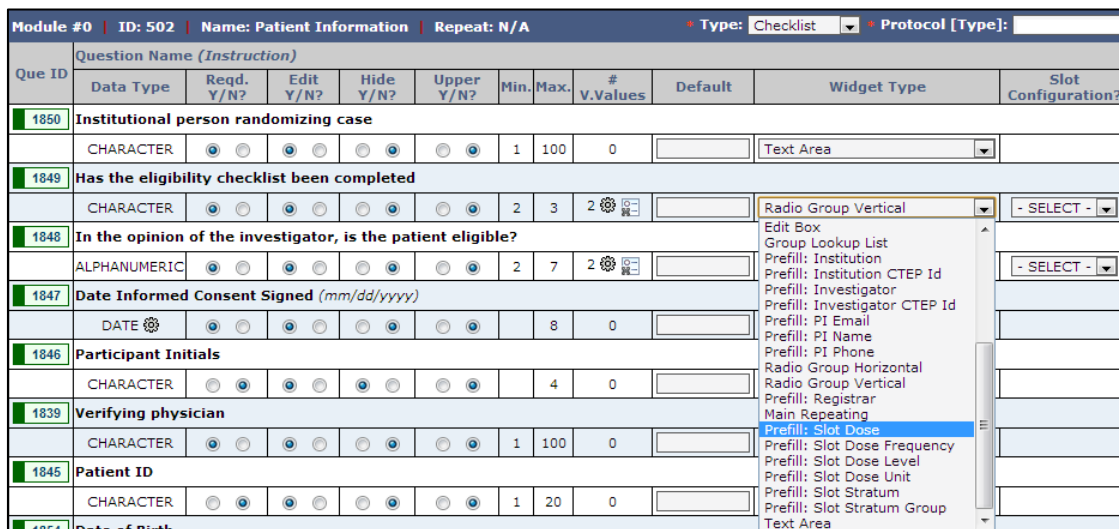


Figure 30: Configuring a Question to Use the Prefill Widget

- 7) Select the appropriate slot reservation prefill widget.
- 8) Click the Save Question Setup button.

This concludes the process for configuring a question in the OPEN EC to utilize a slot reservation prefill widget.

### 4.5 Configuring a Daily Time for Releasing Slots to the Available Pool

A daily release time can be configured (at the protocol-level) for moving slot reservations that enter a CANCELLED, EXPIRED, WITHDRAWN, or REJECTED status, to the pool of *Available Slots*. This feature allows OPEN users to know when slot reservations (in the aforementioned statuses) will enter the pool of *Available Slots*, thus reducing the amount of *checking* activities that site users often perform. The feature cannot be used in conjunction with the Waiting Queue feature.

If the feature is enabled (and a slot reservation is pending in a CANCELLED, EXPIRED, WITHDRAWN, or REJECTED status), OPEN users will be informed of pending slot releases when they attempt to reserve a slot (as shown in Figure 30). The information will also be shown in the other locations where the slot availability information is displayed.

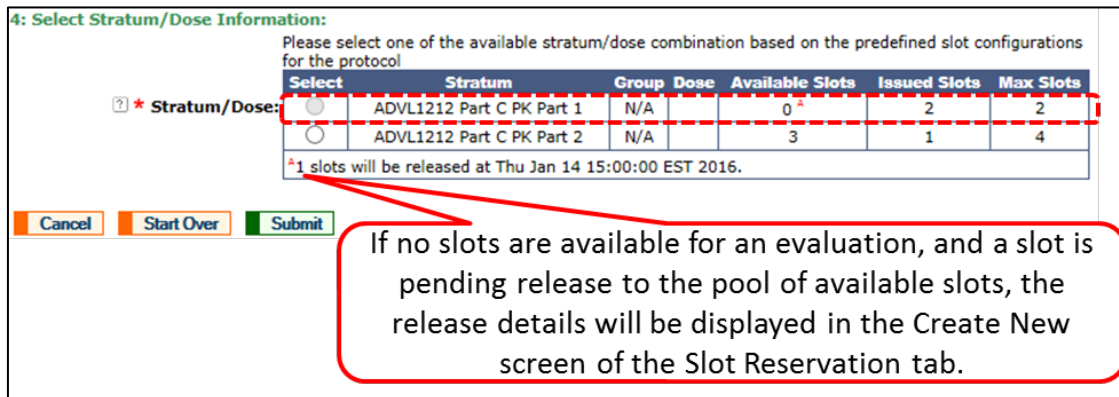


Figure 31: A Message Lists When Slots are Pending Release to the Pool of *Available Slots*

This feature can be configured in the Protocol subtab (of the Configuration subtab, of the Slot Reservation tab), using the *Release time for Cancelled, Withdrawn, Expired, and Rejected slots* configuration field (as shown in Figure 31).

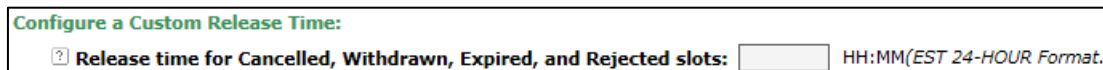


Figure 32: Ability to Configure a Daily Time for Releasing Slots to the Pool of "Available Slots"

For information on configuring slot reservation settings, see Section 4.2.

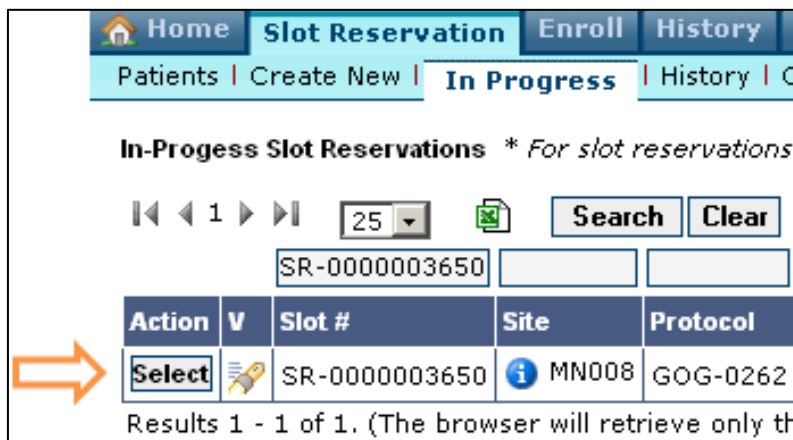
## 5. Additional Administrative Actions

### 5.1 How to Approve or Reject User Requests

Group staff with the GROUP\_REG OPEN role will be able to accept or reject slot reservation requests that require manual approval (which include manual requests to renew, reactivate, and requests to reserve a new slot). The appropriate lead group staff will be notified by email when a site user makes a request which requires manual review. The next sub-section provides instructions on how to accept or reject a user’s request.

#### 5.1.1 Instructions for Approving or Rejecting User Requests

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the In Progress subtab.
- 4) Locate the slot reservation by entering the Slot Reservation ID into the free text field above the Slot # column and click Search.



**Figure 33: In Progress Screen**

- 5) Click the Select button next to the slot reservation.
- 6) Click the Approve/Reject button.

Additional Administrative Actions

Patient #	Initials (LFM)	Date Of Birth	Gender	Zip
PT-0000448406	AA-	04-Jan-1990	Male Gender	20850

Category	Description	Group	Dose	Available Slots	Issued Slots	Max slots	Status
ANBL1232 Stratum 1	Group A1	Group A1		52	113	165	ACTIVE

Figure 34: Slot Reservation Summary Screen

The pop-up window allows the user to Accept or Reject the site user’s request; if rejecting a request enter a reason in the Comments field.

Figure 35: Approve/Reject Screen

- 7) Click the Approve or Reject button to complete the review decision.
- 8) Click OK on the confirmation pop-up window.
- 9) A confirmation screen will display the result.

**Information**

Slot Reservation ID: **SR-0000003650**

Slot #SR-0000003650 for patient PT-0000448406 of site MD004 has been approved for the protocol CITN-12 for step 1. The slot reservation status has been updated to RESERVED. Site will be notified via email.

**Comments:** Approving.

**Close**

Reservation Workflow					
Date	Action	By	From State	To State	Value
15-Sep-2012 02:07:31 PM	NEW	SMITHK	--	NEW_APPROVAL	
15-Sep-2012 03:05:00 PM	UPD_STATUS	STAUFF	NEW_APPROVAL	RESERVED	Slot reservation reserved

**Figure 36: Approve / Reject Confirmation Screen**

10) An email will be sent to the site user informing them of the decision.

Dear Registrar,

The request for Slot Reservation ID: SR-0000003650 (protocol: GOG-0262, step: 1 and site: MN008) was approved by the lead group: COG. You are receiving this email since you are the requestor or/and listed as the site contact person.

You may login to OPEN: <https://open.ctsu.org> to proceed with the slot reservation. Navigate to the Slot Reservation tab, click the In Progress sub tab, and search for the above Slot Reservation ID to continue.

Please contact the CTSU Help Desk if you have questions. The CTSU Help Desk can be contacted by phone (1-888-823-5923 option 1), as well as by email ([ctscontact@westat.com](mailto:ctscontact@westat.com)).

Regards,

The CTSU OPEN Team

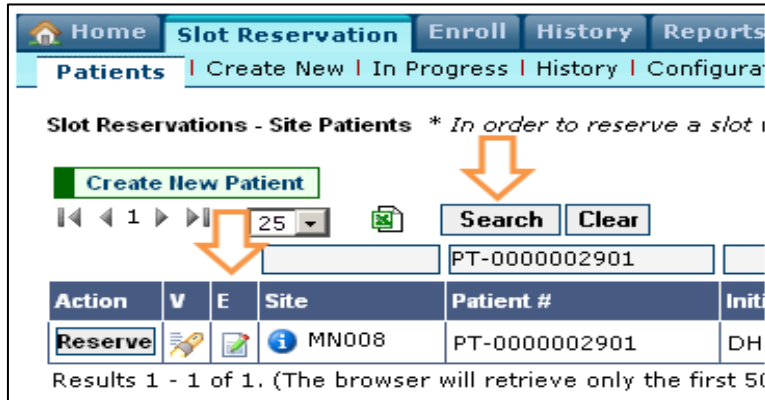
**Figure 37: Notification Email Sent To Site User**

## 5.2 How to Edit Patient Information for Patient-Level Slot Reservations

If information for a patient needs to be updated, group staff with a GROUP\_REG role can perform the update on behalf of the site user.

### 5.2.1 Instructions for Editing Patient Information

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the Patients subtab.
- 4) Locate the patient by entering the Slot Reservation Patient Number into the free text field above the Patient # column and click Search.



**Figure 38: Patient Browser Screen**

- 5) Click the Update Patient icon (📄✎) for the patient.
- 6) Update the appropriate field(s).
  - Please note that the Institution CTEP ID field can be updated until a slot reservation is created for a Slot Reservation Patient Number.
- 7) Provide a reason for the changes in the Edit Reason field.

**Figure 39: Edit Patient Screen**

- 8) Click Continue.
- 9) Click OK on the confirmation pop-up window.
- 10) The screen will refresh to show a message confirming that the changes were made.

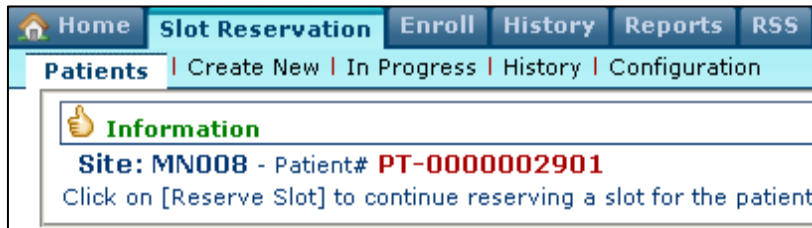


Figure 40: Edit Patient Confirmation Screen

### 5.3 How to Delete an OPEN Slot Reservation Patient Number

OPEN slot reservation patient numbers can be deleted (if no slot reservations have been associated with the OPEN slot reservation patient number).

Steps to Delete a Slot Reservation Patient Number for Slot Reservation:

- 1) Log in to OPEN.
- 2) Click the Slot Reservation tab.
- 3) Click the Patients subtab.
- 4) Locate the patient #.
- 5) Click the Delete button for the patient’s record.

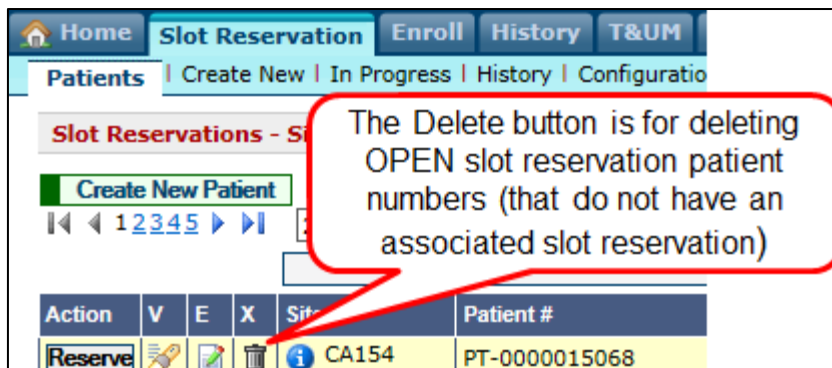


Figure 41: Delete Button for OPEN Slot Reservation Patient Numbers

- 6) A confirmation pop-up window will ask whether to continue with the deletion action. Click OK.
- 7) A confirmation message will appear in OPEN acknowledging that the patient record has been deleted.

### 5.4 How to Edit a Slot Reservation

If the Network Group Patient ID or the Site Contact Person needs to be modified for an *in progress* slot reservation, group staff with the GROUP\_REG role can modify the information.

#### 5.4.1 Instructions for Editing a Slot Reservation

- 1) Log in to the OPEN Portal.

- 2) Click the Slot Reservation tab.
- 3) Click the In Progress subtab.
- 4) Locate the slot by entering the Slot Reservation ID into the free text field above the Slot # column and click Search.

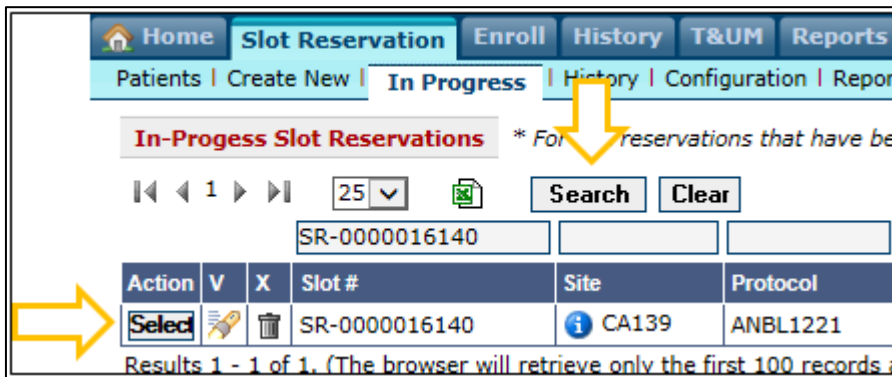


Figure 42: In Progress Screen

- 5) Click the Select button for the slot reservation.

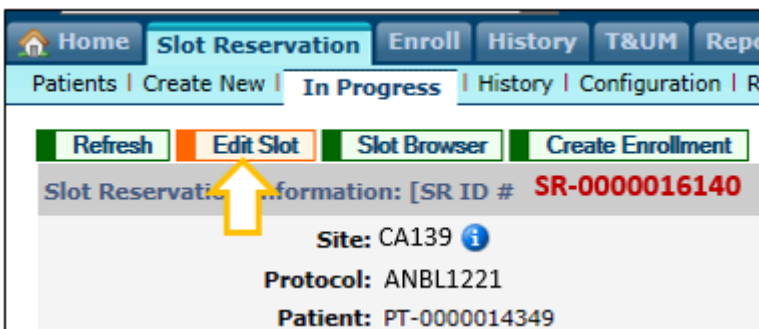


Figure 43: Slot Reservation Summary Screen

- 6) Click the Edit Slot button.
- 7) Adjust either the Network Group Patient ID and/or the Site Contact Person.
- 8) Provide a reason for the change in the Edit Reason field.

**Edit Slot Reservation # SR-0000016140**

1: Select Institution/Protocol combinations  
 Reserved By: [Redacted]  
 \* Institution CTEP ID: CA169      \* Institution Name: [Redacted]  
 \* Protocol Number: ANBL1221  
 \* Step: 1

2: Select Patient Information:  
 \* Patient Number: PT-0000014349

Patient #	Site	Initials (LFM)	Date Of Birth	Gender	Zip
	CA169	AA-	04-Jan-1990	Male Gender	20850

\* Network Group Patient ID: 11111

3: Select Contact Information:  
 \* Site Contact Person: [Redacted]

4: Select Evaluation Information:  
 \* Evaluation

Select	Category	Description	Group	Dose	Available Slots	Slots Issued	Max slots
<input checked="" type="radio"/>	ANBL1232 Stratum 1	Group A1	Group A1		52	113	165

\* Edit Reason: [Text Area]  
 Created By: [Redacted]  
 Modified By: [Redacted]

Buttons: Cancel, Start Over, Submit

Figure 44: Edit Slot Reservation Screen

- 9) Click Submit.
- 10) Click OK on the pop-up confirmation window.
- 11) A confirmation page will display to confirm that the changes have been saved.

**Information**  
**Slot Reservation Confirmation**  
 Slot Reservation ID: **SR-0000016140**  
 A slot has been reserved for the patient #PT-0000014349 to participate in the protocol ANBL1221 for step 1. The slot reservation will expire on 11-Aug-2020 04:49:14 PM EDT EST

Buttons: In Progress List, Reserve Another Slot, Create Enrollment

Figure 45: Slot Reservation Confirmation Screen

- 12) The site user will receive an email notifying them that their Slot Reservation information has been edited.

Dear Registrar,

A lead group administrator edited information regarding the Slot Reservation ID: SR0000016140 (protocol: ANBL1221, step: 1, and site: CA169).

The lead group administrator provided the following comments: The site contact person needed to be changed.

You may login to OPEN: <https://open.ctsu.org> to view additional details. Navigate to the Slot Reservation tab, click the In Progress sub tab, and search for the above Slot Reservation ID to continue.

Please contact the CTSU Help Desk if you have questions. The CTSU Help Desk can be contacted by phone (1-888-823-5923 option 1), as well as by email ([ctsucontact@westat.com](mailto:ctsucontact@westat.com)).

Regards,  
 The CTSU OPEN Team

Figure 46: Notification Email Sent to a Site User

## 5.5 Accessing the Slot Usage Report

The Slot Usage Report provides up to date information on slot usage for each slot reservation protocol to which the user has access. This section will provide instructions on how to access the report.

### 5.5.1 Instructions for Accessing the Slot Usage Report

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the Configuration subtab.
- 4) Select the protocol on the Browser screen and click on Slot Usage Report.

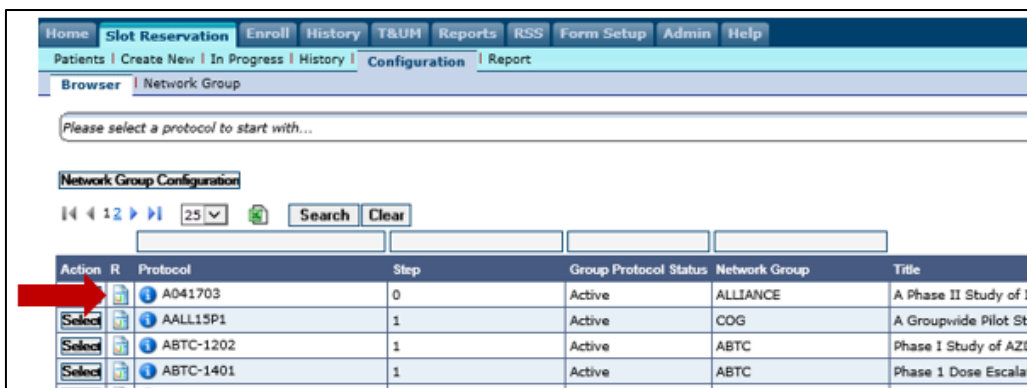


Figure 47: Locate and Click the Report Button

- 5) Click the Report button for the study.
- 6) The Slot Usage Report will open in a separate pop-up window.

**Slot Usage Report**

Selected Protocol # 10486

Protocol	Step	Group Protocol Status	Network Group	Slot Type	Activation Date	Target Slots
10486	0	Active	LAO-TX035	PROTOCOL	24-Oct-2025 12:00:00 AM EDT	20

**Evaluation(s) Summary**

EVALUATIONS		SLOTS											
Category NAME	Dose NAME	MAXIMUM	AVAILABLE	ISSUED	ENROLLED	PRE_ENROLL	RESERVED	APPROVED	WAITING	REJECTED	EXPIRED	WITHDRAWN	CANCELLED
c1		4	0	4	4	0	0	0	0	0	1	2	0
c1		5	5	0	0	0	0	0	0	0	0	0	0
c2		1	0	1	1	0	0	0	0	0	0	0	0
c2		15	15	0	0	0	0	0	0	0	0	0	0
c2L		0	0	0	0	0	0	0	0	0	0	0	0

**Evaluation(s)**

Category Name: c1  
Dose Name:  
Maximum Slots: 4  
Evaluation Status: INACTIVE  
Slots Information:

**Reservations:**

Slot Number	Slot Reservation Status
SR-0000039956	ENROLLED
SR-0000039957	ENROLLED
SR-0000040078	EXPIRED
SR-0000040123	ENROLLED
SR-0000040223	WITHDRAWN
SR-0000040224	WITHDRAWN
SR-0000040251	ENROLLED

Figure 48: Slot Usage Report

## 5.6 The Report Subtab


The Report subtab (of the Slot Reservation tab) displays evaluation information regarding each Slot Reservation evaluation (see Figure 48) for the LPO.


















V	Protocol	Step	Group Protocol Status	Slot Type	Stratum Name	Stratum Group	Dose Name	Evaluation Status	Available Slots	Issued Slots	Max Slots
1	A041703	0	Active	PROTOCOL	DEFAULT	N/A		ACTIVE	2	9	11
1	AALL15P1	1	Active	PROTOCOL	AALL15P1 Stratum 2	2		ACTIVE	1	43	44
1	AALL15P1	1	Active	PROTOCOL	AALL15P1 Stratum 3	3		ACTIVE	1	2	3
1	AALL15P1	1	Active	PROTOCOL	stratum 1	All patients		INACTIVE	27	31	58
1	ABTC-1202	1	Active	STRATUM	Combination Dose Cohort	N/A	DL 1.5/DL5	INACTIVE	0	7	7
1	ABTC-1202	1	Active	STRATUM	Combination Dose Cohort	N/A	DL 2	INACTIVE	0	12	12
1	ABTC-1202	1	Active	STRATUM	Intratumoral Drug Distribution Stage 1	N/A	DL2/DL5	INACTIVE	0	13	13
1	ABTC-1202	1	Active	STRATUM	Intratumoral Drug Distribution Stage 2	N/A	DL 5	ACTIVE	1	2	3

Figure 49: Slot Reservation Report Screen

The screen will display the evaluations for studies that have an *Active* Group Protocol Status first. The user can filter the results for a particular protocol status by selecting it from the Group Protocol Status column and then the results will automatically refresh.

### Additional Administrative Actions

A detailed Slot Reservation Report is available for each evaluation, simply by clicking the view  icon for an evaluation.

Slot Reservation Report						
<b>Protocol:</b> A051901 						
<b>Step:</b> 1						
<b>Category Name:</b> DEFAULT						
<b>Category Group:</b> N/A						
<b>Dose Name:</b> Schedule B DL 3						
<b>Available Slots:</b> 182						
<b>Issued Slots:</b> 0						
<b>Max Slots:</b> 182						
<b>Evaluation Status:</b> ACTIVE						
<b>Created By:</b>  VANHORNN on 31-May-2024 09:44:11 AM EDT						
<b>Modified By:</b>  RALBERSHARDT on 20-Jun-2025 02:08:04 PM EDT						
<b>Slot Reservations:</b>						
Slot #	Site	Network Group	Patient ID	Slot Reservation Status	Created Date	Expiry Date
SR-0000038974 	OK003 			CANCELLED	27-Mar-2025 01:54:00 PM EDT	03-Apr-2025 01:54:00 PM EDT
SR-0000039003 	NY141 			CANCELLED	03-Apr-2025 11:29:17 AM EDT	
SR-0000039056 	ME048 			CANCELLED	11-Apr-2025 05:58:16 PM EDT	24-Apr-2025 06:31:53 PM EDT
SR-0000039057 	RI005 			CANCELLED	14-Apr-2025 08:12:48 AM EDT	
SR-0000039068 	NY141 			CANCELLED	14-Apr-2025 02:55:38 PM EDT	21-Apr-2025 02:55:38 PM EDT
SR-0000039094 	CA385 			CANCELLED	17-Apr-2025 02:59:56 PM EDT	24-Apr-2025 02:59:56 PM EDT
SR-0000039108 	WI029 			CANCELLED	21-Apr-2025 10:15:56 AM EDT	28-Apr-2025 10:15:56 AM EDT

**Figure 50: Slot Reservation Report for an Evaluation**

## 6. Roles and Statuses

This section contains a diagram of the different states that a slot reservation can enter, descriptions for the different slot reservation states, and the OPEN roles that are necessary for accessing the slot reservation feature.

### 6.1 Slot Reservation States Diagram

The diagram in Figure 50 visually represents the different states that a slot reservation can travel through during its lifecycle.

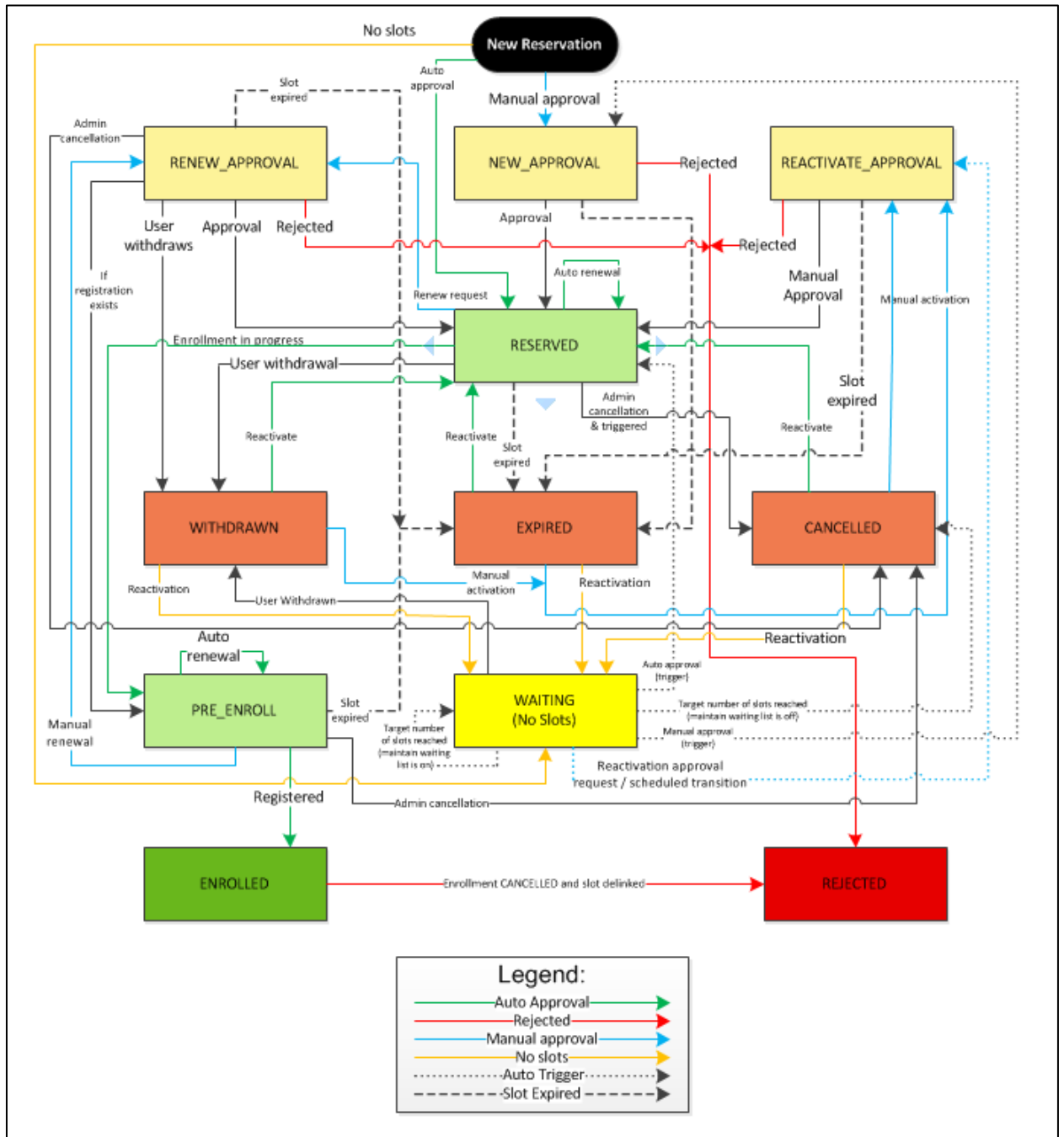


Figure 51: Slot Reservation States Diagram

## 6.2 Slot Reservation States

A slot reservation can enter eleven different states during its lifecycle. The table below lists each of the eleven states as well as their descriptions.

**Table 5: Slot Reservation States**

Slot Reservation State	Description
RENEW_APPROVAL	<p>A slot that was in a RESERVED state, for which the user requested the renewal of the expiry date (which requires manual approval).</p> <p>A slot that was in a PRE_ENROLL state (the slot is associated with an enrollment), which the user requested the renewal of the expiry date, which requires manual approval.</p>
NEW_APPROVAL	<p>A slot that is newly requested that requires manual approval.</p> <p>A slot that is in the waiting queue can also reach this state when a new slot opens up (provided WAITING was the first state that the reservation entered into).</p>
REACTIVATE_APPROVAL	<p>A slot that is in a WITHDRAWN, EXPIRED, or CANCELLED state can enter a REACTIVATE_APPROVAL state when a user requests to reactivate the slot and manual approval is required.</p> <p>A slot in a WAITING state can enter REACTIVATE_APPROVAL when a new slot opens up and manual approval is required provided it was previously once in the RESERVED state.</p>
RESERVED	<p>A slot in a RENEW_APPROVAL, NEW_APPROVAL, or REACTIVATE_APPROVAL state become RESERVED if manually approved.</p> <p>A slot that was in a status of WITHDRAWN, EXPIRED, or CANCELLED can automatically become RESERVED at the request of a user, if the protocol is configured for automatic approval.</p> <p>A new slot reservation can enter a RESERVED state if the protocol is configured to allow automatic approval.</p>
WITHDRAWN	<p>A slot that was in a WAITING, RENEW_APPROVAL, or RESERVED state can become WITHDRAWN at the request of the user.</p>
EXPIRED	<p>A slot that was in a state of RENEW_APPROVAL, NEW_APPROVAL, REACTIVATE_APPROVAL, RESERVED, or PRE_ENROLL can enter this state when the slot reaches its expiration date and time.</p>
CANCELLED	<p>A slot that was in a RENEW_APPROVAL, RESERVED, or PRE_ENROLL state that was cancelled by an admin.</p> <p>A slot that is in a WAITING state can automatically become CANCELLED if a patient completes an enrollment onto another protocol.</p> <p>A slot that is in a WAITING state will automatically become CANCELLED if the evaluation for the slot becomes INACTIVE.</p> <p>When a slot becomes CANCELLED the number of available slots for the evaluation will increase by 1 (the “Target number of slots” and “Max Slots” will remain the same).</p>
PRE_ENROLL	<p>A slot that was in a RENEW_APPROVAL state can enter the PRE_ENROLL state after receiving manual approval.</p> <p>A slot that was in a RESERVED status can enter the PRE_ENROLL state once a user initiates an enrollment.</p>

Slot Reservation State	Description
WAITING	A slot that was in a WITHDRAWN, EXPIRED, or CANCELLED state can enter the WAITING state when a reactivation request is automatically approved and no slots are available. Also, a slot for a new reservation can enter the WAITING state if the slot request is automatically approved and no slots are available. The waiting queue is always available for evaluations until they become INACTIVE.
ENROLLED	A slot that was in a PRE_ENROLL state can enter the ENROLLED state once the subject successfully enrolls onto the protocol.
REJECTED	A slot that was in a NEW_APPROVAL or REACTIVATED_APPROVAL state can become REJECTED when the user’s request is denied, or when an enrollment is CANCELLED and the slot reservation is delinked.

Patients in a WAITING queue will become CANCELLED once all the slots for their evaluation (or for the protocol) have all been enrolled. If this occurs, the patient’s site registrar will receive a notification email.

If the evaluation becomes ACTIVE again, CANCELLED slots that were previously in the WAITING queue would need to be manually reactivated.

If multiple patients are in the Waiting queue for an evaluation, the patients are promoted based on the order they entered the queue (earliest entry is released first, and so on).

Group staff have the option to receive the slot reservation renewal alert emails that are sent to the patient’s site registrar, for the groups protocol. Contact [CTSUOPENFORMS@westat.com](mailto:CTSUOPENFORMS@westat.com) if you would like the configuration setup for your organization.

Slots that are in a RENEW\_APPROVAL, NEW\_APPROVAL, REACTIVATE\_APPROVAL, RESERVED, or PRE\_ENROLL status will count as issued slots (which will count against the number of available slots).

Please note that slot renewal requests (slots in a RENEW\_APPROVAL status) that are rejected will return to their previous state (either PRE\_ENROLL or RESERVED) with their existing expiry dates.

### 6.3 OPEN Roles for Slot Reservation

Certain roles are necessary for using the slot reservation feature in OPEN. The table below lists the privileges that each OPEN role has access to within the Slot Reservation tab.

**Table 6: OPEN Roles for Slot Reservation**

#	Role	Create Site Patient	Create Slot Reservation	Edit Site Patient	Edit Slot Reservation	Reactivate Slot	Renew Slot	Approve Slot Reservation	Reject Slot Reservation	Cancel Slot Reservation	Withdraw Slot Reservation	Configure Group Settings	Configure Protocol
1	CTEP_STAFF												
2	CTSUSU_DM												
3	CTSUSU_REG	X	X			X	X				X		

### Roles and Statuses

#	Role	Create Site Patient	Create Slot Reservation	Edit Site Patient	Edit Slot Reservation	Reactivate Slot	Renew Slot	Approve Slot Reservation	Reject Slot Reservation	Cancel Slot Reservation	Withdraw Slot Reservation	Configure Group Settings	Configure Protocol
4	CTSU_REG_ADMIN	X	X	X	X	X	X	X	X	X	X	X	X
5	CTSU_STAFF												
6	GROUP_DM												
7	GROUP_REG	X	X	X	X	X	X	X	X	X	X	X	X
8	GROUP_REG_ADMIN	X	X	X	X	X	X	X	X	X	X	X	X
9	GROUP_STAFF												
10	HELP_DESK												
11	SITE_STAFF												
12	SITE_INV												
13	SITE_REG	X	X			X	X				X		
14	SITE_ADMIN	X	X			X	X				X		
15	SYS_ADMIN	X	X	X	X	X	X	X	X	X	X	X	X

## 7. Notification Emails

Table 7 lists the different email notifications that OPEN sends to users.

**Table 7: Notification Emails**

Email Type	Sent To
Manual Reservation / Reactivation – Request for Approval	Group contact person
Manual Reservation/ Reactivation – Approved	Registrar, CC: Site Contact Person
Manual Reservation / Reactivation – Rejected	Registrar, CC: Site Contact Person
Manual Renewal – Request for Approval	Group contact person
Manual Renewal – Approved	Registrar, CC: Site Contact Person
Manual Renewal – Rejected	Registrar, CC: Site Contact Person
Renewal Alert	Registrar, CC: Site Contact Person
Reservation Withdrawn	Group Contact Person
Waiting Promoted	Registrar, CC: Site Contact Person
Evaluation Target Reached	Group Contact Person
Slots in Waiting Cancelled as Evaluation is Reached	Registrar, CC: Site Contact Person
Protocol Target Reached	Registrar
Slot Reservation is Edited	Registrar, CC: Site Contact Person