



CTSUS

Cancer Trials Support Unit

OPEN Slot Reservation Quick Reference Site User Guide

Revision 18

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Document Information

Revision Information for the OPEN Slot Reservation Quick Reference Site User Guide

Revision History

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1. Introduction

This document is designed to provide site staff with an overview of the full version of the slot reservation feature in the Oncology Patient Enrollment Network (OPEN) Portal.

This document provides instructions for subject enrollment onto slot reservation protocols, as well as additional information regarding the slot reservation feature that site users may find useful. Note that the terms *patients* and *subjects* are used interchangeably throughout the document.

1.1 Web Addresses for CTSU Applications

Table 1: Web Addresses for CTSU Applications

Application	URL
OPEN Portal	https://open.ctsu.org
CTSUS Members' website	http://www.ctsu.org

2. How to Enroll a Patient on a Slot Reservation Protocol

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

The slot reservation system allows users to secure a position for subjects on specific protocols (that utilize this feature) in order to assure that a consented subject can participate on the study. This feature is commonly used for Phase I studies, which requires site registrars to reserve a slot prior to discussing or enrolling a subject onto a study.

To enroll a subject on a slot reservation protocol, a site user must obtain an OPEN patient number unless one already exists. Use the OPEN patient number to reserve a slot for the protocol and then use the slot reservation number to enroll the subject onto the protocol. Each subject has only one OPEN patient number and that patient number is used to reserve slots for that subject across all protocols that require a slot reservation. The OPEN patient number is not a Network Group patient ID.

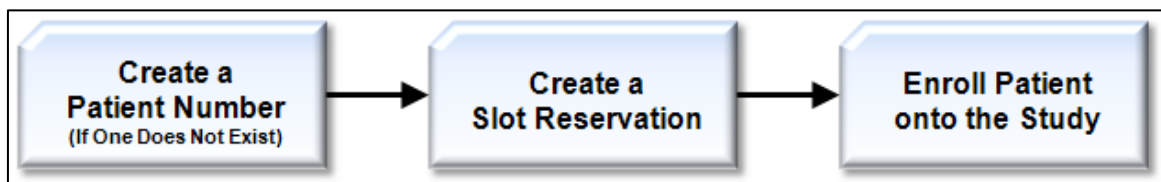


Figure 1: Process for Enrolling a Patient on a Slot Reservation Protocol

The following are important details regarding slot reservations:

- Only pre-determined amounts of slots will be available for each protocol. Slot limits are dictated by the protocol administrators.
- OPEN supports slot reservation for any single protocol step.
- A slot reservation can be performed if a slot is available. If the slot is available upon registration, the user will receive a message stating, that the slot is reserved.
- A slot reservation cannot be performed if a slot is unavailable. If no slots are available and the waiting queue feature is turned on for the protocol, the slot reservation will enter the protocol's waiting queue until a slot opens up.
- A reserved slot expires at a pre-determined amount of time, as dictated by the protocol administrators. A reserved slot expires if the time limit is reached and no subsequent step is performed. Once the slot expires, the slot becomes available for the next reservation.

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

2.1 Getting a Patient Number

If a subject already has an OPEN Patient Number (PT-#####), then a user may proceed to the next section to reserve a slot for their subject (see section 2.2).

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

2.1.1 Instructions for Getting an OPEN Patient Number

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Click the Create New Patient button within the Patients subtab.
- 4) Complete the necessary fields in the Create New Patient screen.
- 5) Click the Continue button.
- 6) Click Ok on the confirmation pop-up window.
- 7) A confirmation page displays the patient number, in the format PT-#####. For added clarity, the user is informed that only a patient number has been created. To reserve a slot for their subject, they need to click the *Reserve Slot* button.

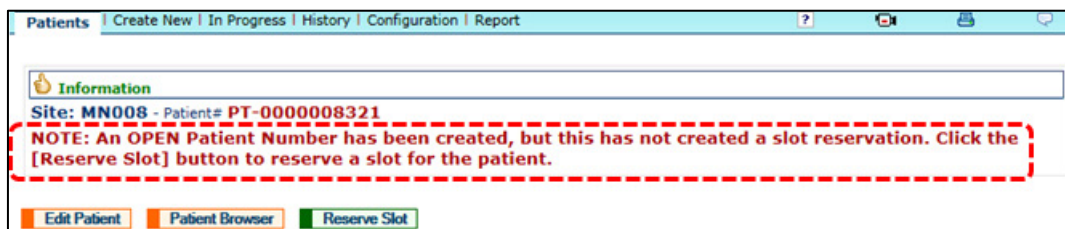


Figure 2: Confirmation Page for the Patients Screen

2.2 Creating a Slot Reservation

The following sub-section provides instructions for creating a slot reservation.

2.2.1 Instructions for Creating a Slot Reservation

After an OPEN patient number is obtained, a slot is reserved for the subject. To create a slot reservation:

- 1) Log in to the OPEN Portal.
- 2) Click the Slot Reservation tab.
- 3) Locate the subject by entering the OPEN 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.

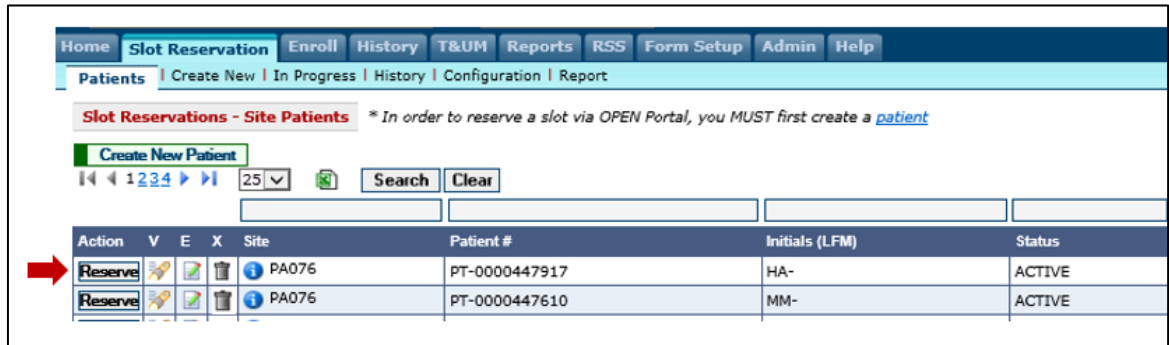


Figure 3: Patient Browser Screen

- 5) The user will arrive at 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.
- 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 Stratum/Dose field.

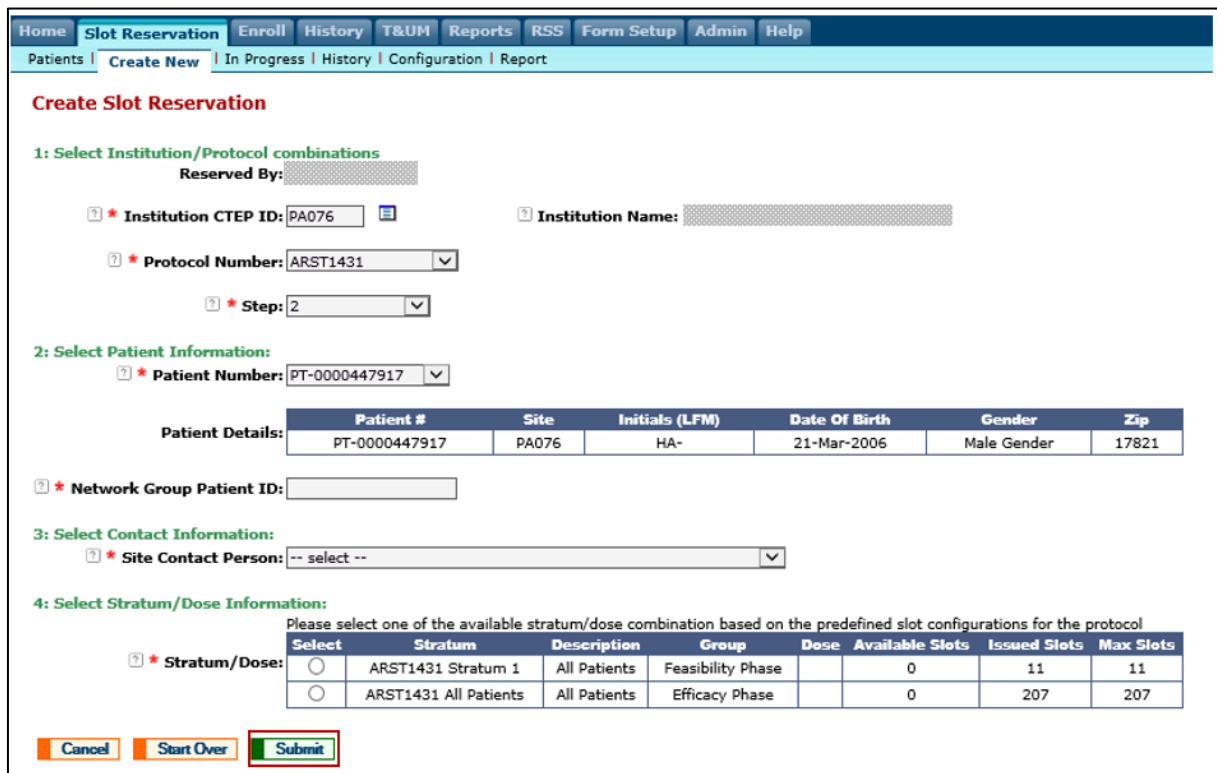


Figure 4: Create Slot Reservation Screen

- 12) Click Submit.

- 13) Click OK on the confirmation pop-up window.
- 14) The user’s request is processed automatically, or after manual approval, based on the Lead Protocol Organization’s (LPO) configuration of the protocol.
 - a) If the slot reservation does not require approval by the LPO, the user arrives at a confirmation page that displays the slot reservation number (in the format: SR - #####), as well as the slot expiration date and time.

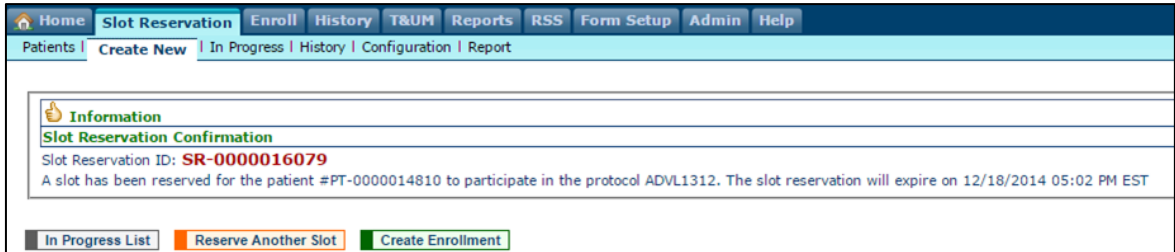


Figure 5: Confirmation Page (For Automatic Approval)

- b) If the slot reservation requires manual approval by the LPO, the user arrives at a confirmation page that displays the slot reservation number, as well as a note stating that the user is informed once a review decision is made via email.

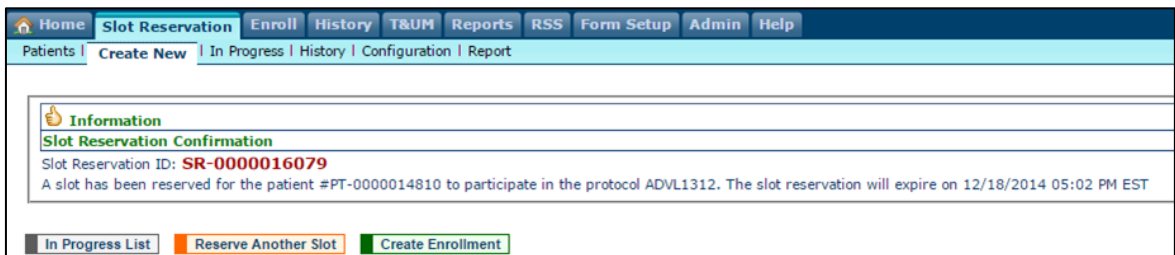


Figure 6: Confirmation Page (For Manual Approval)

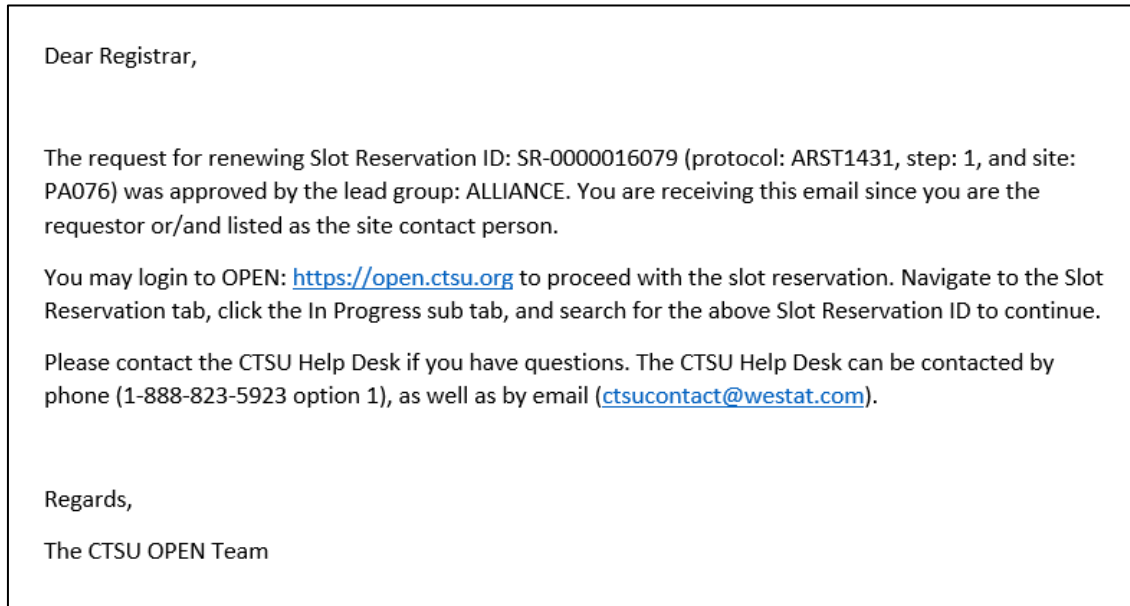


Figure 7: Notification Email Sent To Site User

- 15) The subject enrollment for the slot reservation must be completed before the slot reservation expires. Otherwise, a validation will prevent the user from completing the enrollment (unless the protocol is configured for automatic renewal of slot reservations).

2.2.2 Duplicate Slot Reservation Check

The user encounters a duplicate slot reservation error message if an attempt is made to create a slot reservation for an OPEN Patient ID that already had a slot reservation in a WITHDRAWN, EXPIRED, or CANCELLED status for the same subject in the same study and stratum. A hyperlink to reactivate subject's existing slot reservation is included in the error message, as shown in Figure 8.

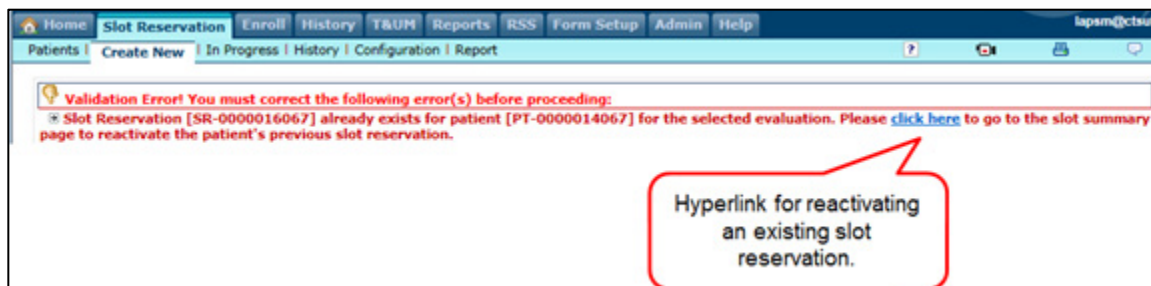


Figure 8: Slot Reservation Reactivation Link in the Duplicate Reservation Error Message

2.3 Completing a Patient Enrollment

After a slot reservation is obtained, the user proceeds with enrolling the subject onto the protocol. The following sub-section provides instructions for enrolling a subject onto a slot reservation protocol.

2.3.1 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 Reservation ID field and click the Search button.
- 5) Click the Select button in the row for the subject's slot reservation.

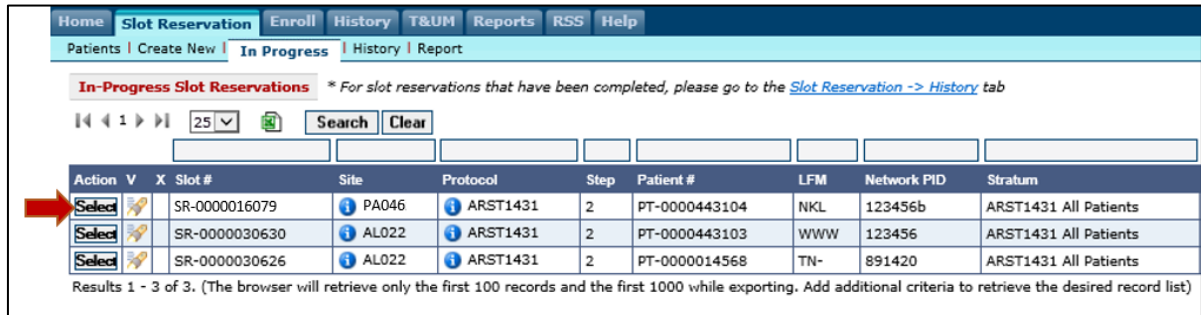


Figure 9: In Progress Screen

- 6) Click the Create Enrollment button.

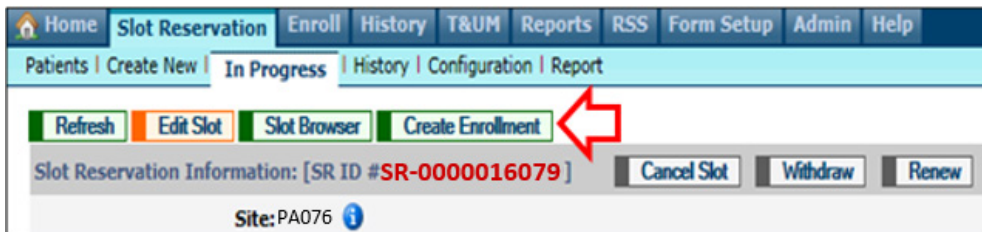


Figure 10: In Progress Summary Screen

- 7) The user is taken to the Create New screen on the Enroll tab (most of the fields are prefilled).

[In Progress](#) | [Create New](#) | [Summary](#) | [Prerequisite](#) | [Demography](#) | [Checklist](#)

1: Select Institution/Protocol combinations

Tracking Number:
 Registrar:

* **Institution CTEP ID:** PA076 **Institution Name:**
 * **Protocol Number:** ARST1431 [Protocols Missing?](#)

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):

* **Registration Step:** 1 - Registration [Steps Missing?](#)

* **Slot Reservation Number:** SR-0000016079 [i](#)

2: Add persons associated with this enrollment

Figure 11: Create New Screen (Enroll Tab)

- 8) Select the appropriate Person Type(s) 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 (if required). Click Continue.
- 11) Click OK on the confirmation pop-up window.
- 12) Click Continue on the tracking number confirmation page.
- 13) Complete the necessary fields on the Demography screen. Click Continue.
- 14) Complete the necessary fields on the Checklist screen. Click Continue.
- 15) Review the data on the Review & Submit screen for accuracy. Click Submit.
- 16) Click OK on the confirmation pop-up window.
- 17) The user arrives at a confirmation screen.

Browse Summary Prerequisite Demography Checklist						
Selected Tracking # 108553 Details Summary						
Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator
ARST1431	481731477	VDD	1	A	PA076	
Information <ul style="list-style-type: none"> 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:	ELIGIBLE					
Ineligibility Reason:	None.					
Patient ID:	481731477					
Treatment Arm:	A					
Site Instruction:	Please send form to the group address.					

Figure 12: Enrollment Confirmation

2.3.2 Slot Reservation Waiting Queue

If a user attempts to make a slot reservation when no slots are available, the subject will be assigned a slot reservation number, and placed into the waiting queue for the protocol (if the waiting queue is turned on for the protocol).

Information Slot Reservation Confirmation Slot Reservation ID: SR-0000001301 No slots are available at this time. The slot reservation for patient #PT-0000000792 has been placed in WAITING status. You will be notified by email once the slot leaves the WAITING queue. Alternatively, you can check the status in OPEN using the slot reservation ID: SR-0000001301.	
In Progress List	Reserve Another Slot

Figure 13: Waiting Queue Confirmation

When a slot becomes available, the slot reservation request will be automatically approved or manually approved by the group, depending on how the study is configured. Once the slot leaves the Waiting queue, the user is notified by email. The user can also check the status by going to the Slot Reservation tab and clicking the In Progress subtab. If multiple subjects are in the Waiting Queue for an evaluation, the subjects will be promoted based on the order they entered the queue (earliest entry is released first, and so on).

3. Additional Information

3.1 Requesting Updates for OPEN Slot Reservation Patient Information

If information needs to be updated for an OPEN Slot Reservation Patient, please contact the CTSU Help Desk (1-888-823-5923, option 1 or ctsucontact@westat.com) to request the update.


The following fields can be updated:

- Institution CTEP ID
- Patient Initials
- Date of Birth
- Gender
- Zip Code

3.2 How to Delete an OPEN Slot Reservation Patient Number

OPEN slot reservation patient numbers can be deleted if no slot reservations are associated with the OPEN slot reservation patient number.

Accessing this Feature:

- 1) Log in to OPEN.
- 2) Click the Slot Reservation tab.
- 3) Click the Patients subtab.
- 4) Locate the Patient # free-text box.
- 5) Click the Delete  button for the patient's record (as shown in Figure 14).

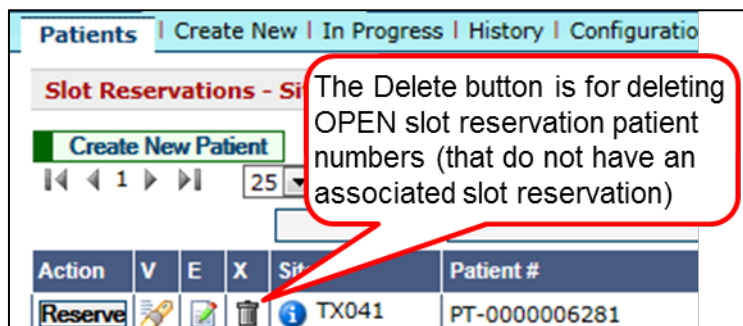


Figure 14: Delete Button for OPEN Slot Reservation Patient Numbers

- 6) A confirmation pop-up window will ask whether to continue with the deletion action. Click Ok.
- 7) A confirmation message will appear acknowledging that the subject's record has been deleted.

3.3 How to Edit a Slot Reservation

Site users have the ability to update the Network Group Patient ID for a slot reservation until an OPEN enrollment is associated with the slot reservation.

Accessing this Feature:

- 1) Log in to OPEN.
- 2) Click the Slot Reservation tab.
- 3) Click the In Progress subtab.
- 4) Locate the slot reservation, and click the Select button for the record's row.
- 5) Click the Edit Slot button.
- 6) Update the value for the Network Group Patient ID field.
- 7) Click the Submit button to save the changes.

If the Site Contact Person needs to be modified for an *In Progress* slot reservation, contact the CTSU Help Desk in order to modify the information. Once slot reservation information is updated, the site user will receive an email notifying them that their slot reservation information was edited.

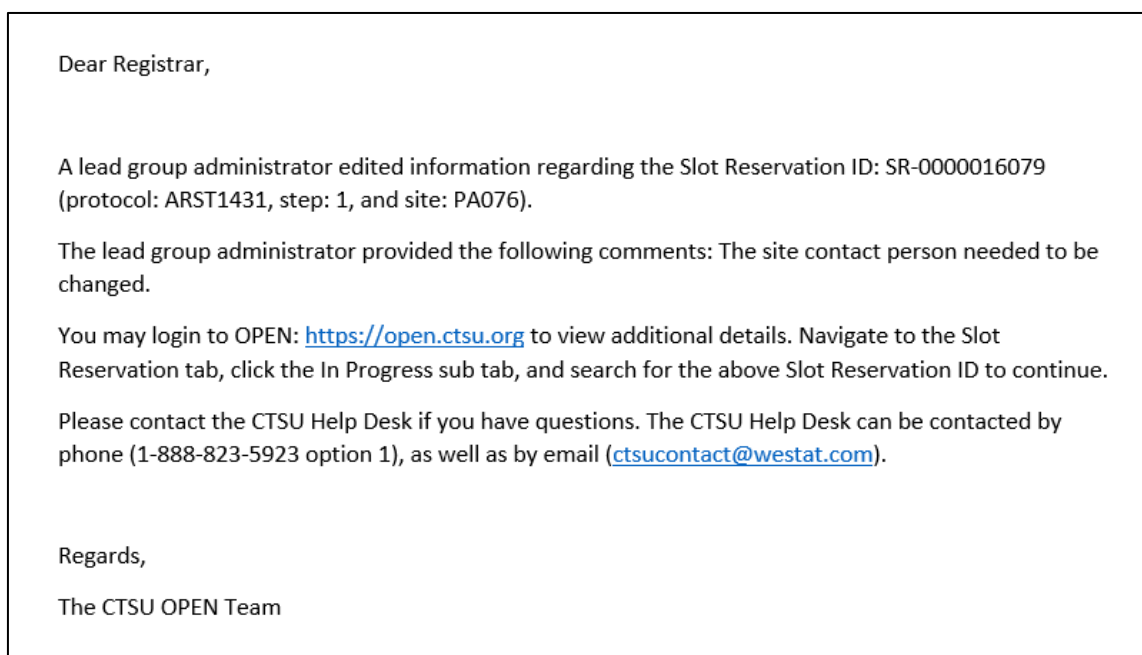


Figure 15: Notification Email Sent To Site User

3.4 How to Renew a Slot Reservation

When a slot reservation is about to expire, site users have the ability to renew the slot reservation to extend the expiration period.

Accessing this Feature:

- 1) Log in to OPEN.
- 2) Click the Slot Reservation tab.
- 3) Click the In Progress subtab.
- 4) Locate the slot reservation and click the Select button in the row associated with the slot reservation.

- Click the Renew button.

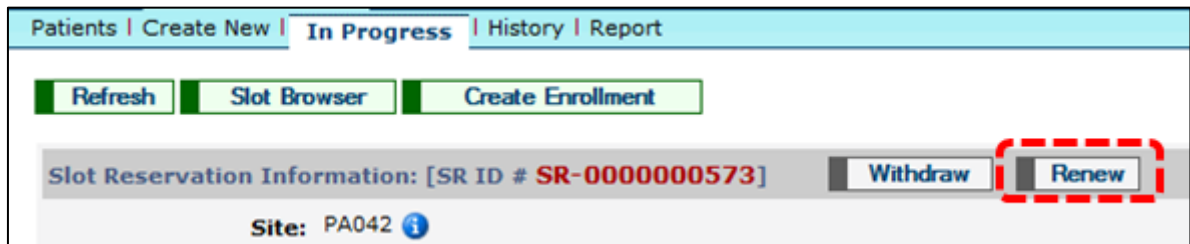


Figure 16: Click the Renew Button

- A pop-up window appears on screen.
- Enter a reason in the Comments field and click the Renew button.

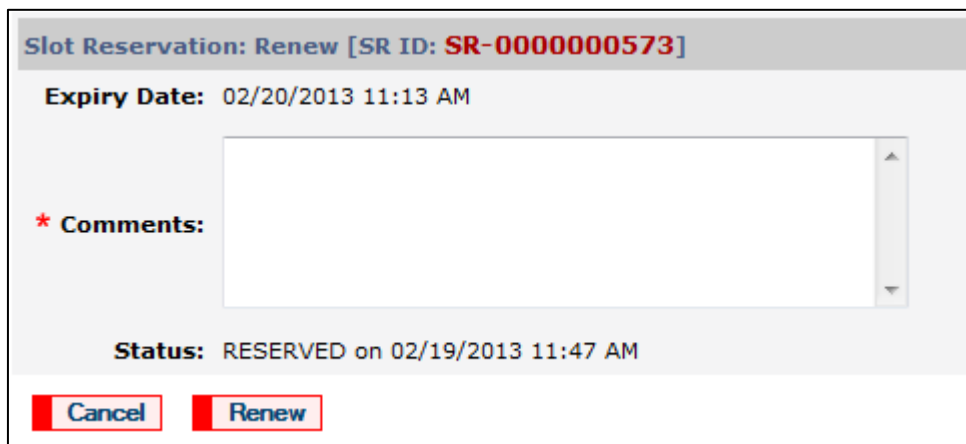


Figure 17: Pop-up Window for Renewing a Slot Reservation

- The user will receive a confirmation message with information on whether the request has automatically been reviewed (as shown in Figure 18) or if the request is sent to the LPO for manual review (as shown in Figure 19).



Figure 18: Confirmation Message for the Slot Renewal Request (Automatic Approval)

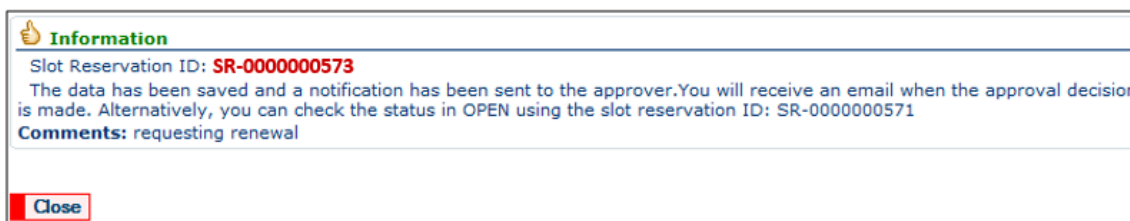


Figure 19: Confirmation Message for the Slot Renewal Request (Manual Approval)

When a slot reservation nears expiration, the site registrar associated with the slot reservation receives an automatic notification email (as shown in Figure 20). The LPO configures when site users receive the automatic notification emails.

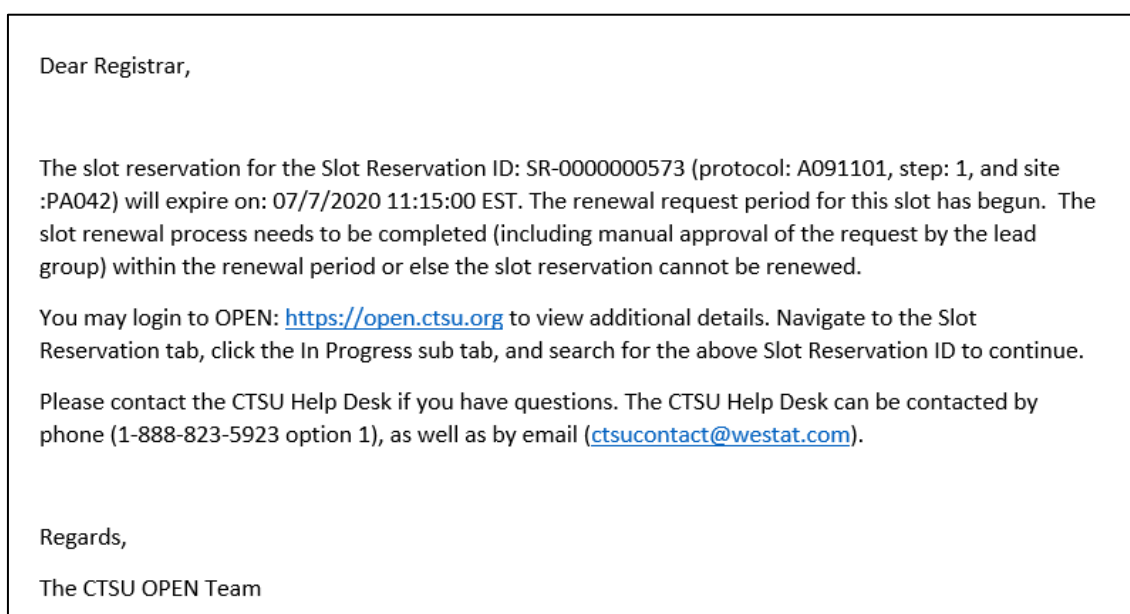


Figure 20: Automatic Renewal Notification Email

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 bypass the process for creating the OPEN Patient Number and Slot Reservation Number.
- Users 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 stratum and dose names, are prefill the first value by default.

Accessing this Feature:

- 1) Log in to OPEN.
- 2) Click the Start Practice button on the Welcome subtab of the Home tab.
- 3) A Practice/Test Registration watermark appears in the background.
- 4) Click the Enroll tab.
- 5) Click the Create New subtab.
- 6) Select the slot reservation protocol number from the Protocol Number drop-down menu.
- 7) Select the Registration Step.
- 8) 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).

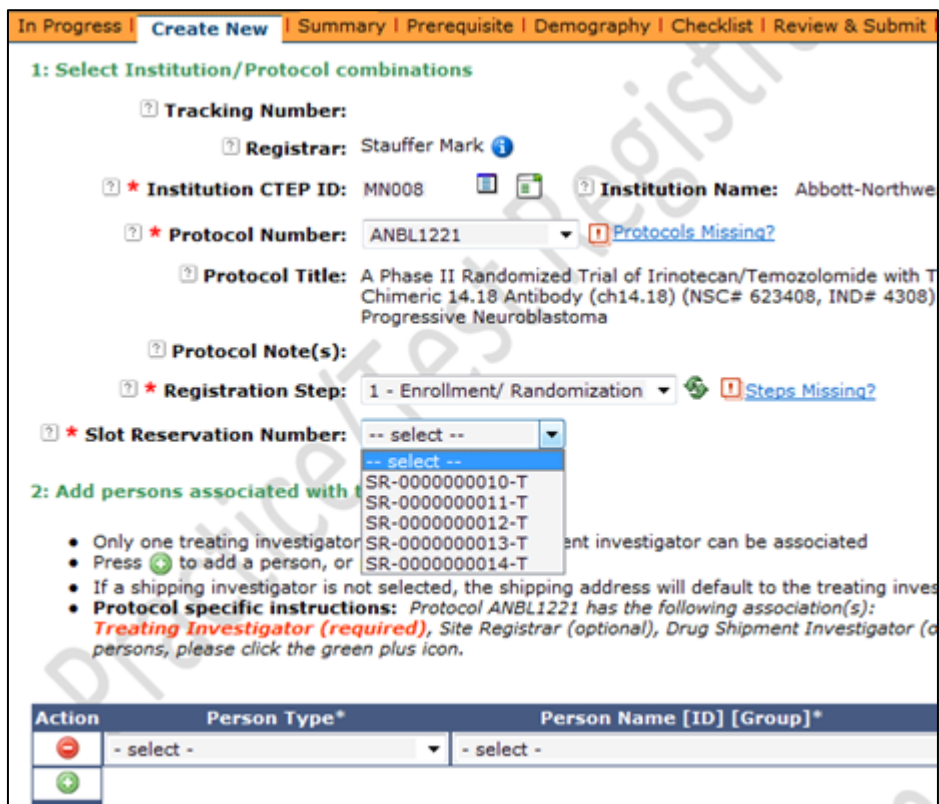


Figure 21: Initiating a Slot Reservation Enrollment in Practice Mode

- 9) 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, also prefill the first valid value by default.

3.6 Slot Reservation Report

The slot reservation report provides slot availability information for slot reservation protocols to which the user has access.

V	Protocol	Step	Group Protocol Status	Slot Type	Stratum Name	Strat
	A041703	0	Active	PROTOCOL	DEFAULT	N/A
	ABTC-1401	1	Active	STRATUM	Part 1	N/A
	ABTC-1401	1	Active	STRATUM	Part 1	N/A
	ABTC-1401	1	Active	STRATUM	Part 1	N/A
	ABTC-1401	1	Active	STRATUM	Part 1	N/A

Figure 22: Slot Reservation Report

In addition to the slot reservation report, a user can access detailed information on slot availability for each evaluation.

Slot #	Site	Network Group	Patient ID	Slot Reservation Status	Created Date	Expiry Date
SR-0000029874	CA249			ENROLLED	06-May-2019 06:18:14 PM EDT	13-May-2019 06:18:14 PM EDT
SR-0000029903	OH007			ENROLLED	08-May-2019 03:06:54 PM EDT	16-May-2019 09:37:27 AM EDT
SR-0000029915	NY018			CANCELLED	10-May-2019 03:15:19 PM EDT	17-May-2019 03:15:19 PM EDT
SR-0000029939	CA249			CANCELLED	16-May-2019 07:57:23 PM EDT	23-May-2019 07:57:23 PM EDT
SR-0000029965	OH007			ENROLLED	22-May-2019 10:32:00 AM EDT	05-Jun-2019 12:59:13 PM EDT
SR-0000029970	KS004			ENROLLED	24-May-2019 01:28:40 PM EDT	31-May-2019 01:28:40 PM EDT
SR-0000030066	OH007			ENROLLED	18-Jun-2019 04:30:54 PM EDT	25-Jun-2019 04:30:54 PM EDT
SR-0000030070	DE002			ENROLLED	21-Jun-2019 02:44:10 PM EDT	28-Jun-2019 02:44:10 PM EDT
SR-0000030131	OH007			ENROLLED	16-Jul-2019 02:06:16 PM EDT	23-Jul-2019 02:06:16 PM EDT
SR-0000030179	OH007			ENROLLED	01-Aug-2019 09:37:12 AM EDT	08-Aug-2019 09:37:12 AM EDT
SR-0000030432	MD015			ENROLLED	08-Oct-2019 01:24:00 PM EDT	15-Oct-2019 01:24:00 PM EDT

Figure 23: A Site User's View Details Screen for a Slot Reservation Evaluation

Accessing this Feature:

- 1) Log in to OPEN.
- 2) Select the Slot Reservation tab.
- 3) Select the Report subtab.
- 4) General information displays for all slot reservation protocol evaluations that the user has access to based on the user's roster affiliations (as shown in Figure 22).
- 5) If information that is more detailed is desired, click the View Slot Reservation Report Information icon in the row for the desired protocol's evaluation.

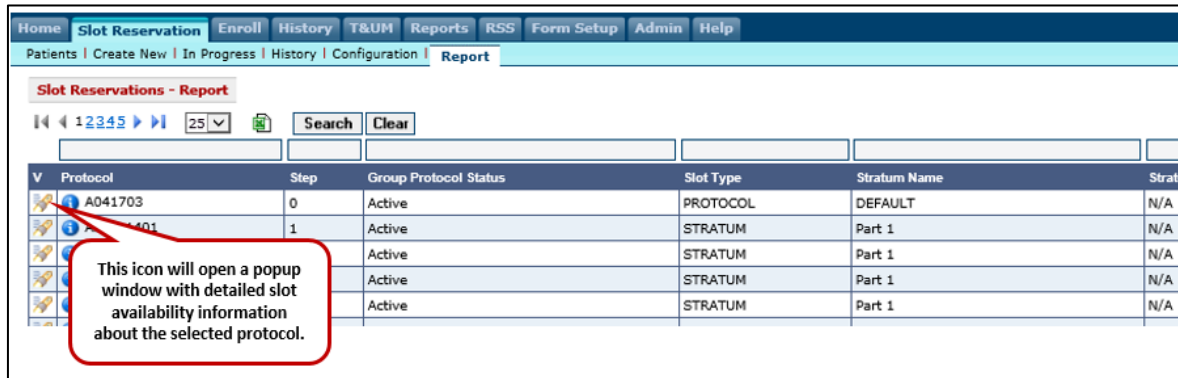


Figure 24: The View Slot Reservation Report for Evaluation Icon Initiates a Detailed Report

6) A detailed slot availability report displays for the user (as shown in Figure 23).

3.7 Slot Reservation Statuses

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

Table 2: Slot Reservation Statuses

Slot Reservation State	Description
RENEW_APPROVAL	<p>A slot is in this state when a renewal request is pending and requires Group approval. Slots in <i>Reserved</i> status or <i>Pre Enroll</i> status can move to Renew_Approval status.</p> <p>(I.e. When a user initiates an enrollment using a reserved slot, but is unable to complete the enrollment prior to the expirations date, the user can request to renew the slot. If a manual approval is required (based on group confirmation) the slot will be in RENEW_APPROVAL state until it is approved by the group.)</p>
NEW_APPROVAL	<p>A slot is in this state when a user requests to reserve a slot for a subject and the protocol is configured to send slot reservation requests to the LPO for a review decision.</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 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>The status which a new slot reservation can enter, if the protocol is configured to allow automatic approval; or, the status which a slot that was in a status of WITHDRAWN, EXPIRED, or CANCELLED can automatically become, at the request of a user, if the protocol is configured for automatic approval.</p> <p>A slot in a RENEW_APPROVAL, NEW_APPROVAL, or REACTIVATE_APPROVAL state becomes RESERVED when approved by the group.</p>

Slot Reservation State	Description
WITHDRAWN	A slot is in a WITHDRAWN state when a user requests to withdraw a reservation that was in a WAITING, RENEW_APPROVAL, or RESERVED state.
EXPIRED	A slot that was previously in a state of RENEW_APPROVAL, NEW_APPROVAL, REACTIVATE_APPROVAL, RESERVED, or PRE_ENROLL reaches its expiration date and time.
CANCELLED	A slot that was in a RENEW_APPROVAL, RESERVED, or PRE_ENROLL state is cancelled by a CTSU or Group OPEN Administrator; or, the status of which a slot that is in a WAITING state can automatically become CANCELLED if the subject is enrolled onto another conflicting protocol. When a subject in a WAITING queue becomes cancelled, the subject's site registrar will automatically be notified by email. If an enrolling site becomes suspended, in progress slot reservations for the enrolling site will enter the CANCELLED state.
PRE_ENROLL	The status which a slot that was in a RESERVED status can enter once a user initiates an enrollment; or, the status which a slot that was in a RENEW_APPROVAL state can enter, after receiving group approval.
WAITING	The status which a slot that was in a WITHDRAWN, EXPIRED, or CANCELLED state can enter, when a reactivation request is automatically approved and no slots are available. Also, a slot for a new reservation can enter this status, if the slot request is automatically approved and no slots are available.
ENROLLED	The status which a slot that was in a PRE_ENROLL state can enter, once the subject is successfully registered onto the protocol.
REJECTED	The status which a slot that was in a NEW_APPROVAL or REACTIVATED_APPROVAL state becomes, when the users slot request is denied by the Group, or when an enrollment is CANCELLED and the slot reservation is delinked.

3.8 Daily Release of Slot Reservations to the Pool of Available Slots

The LPOs have the ability to configure a daily release time 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 will enter the pool of Available Slots. This feature is configured per protocol, and it 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. The information will be shown in the other locations where the slot availability information is displayed, to help reduce the *checking* activities that some site users perform (as shown in Figure 25).

4: Select Stratum/Dose Information:

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

? * Stratum/Dose:

Select	Stratum	Group	Dose	Available Slots	Issued Slots	Max Slots
<input checked="" type="radio"/>	ADVL1212 Part C PK Part 1	N/A		0 ^a	2	2
<input type="radio"/>	ADVL1212 Part C PK Part 2	N/A		3	1	4

^a 1 slots will be released at Thu Jan 14 15:00:00 EST 2016.

If no slots are available for an evaluation, and a slot is pending release to the pool of available slots, the release details will be displayed in the Create New screen of the Slot Reservation tab.

Figure 25: A Message Lists When Slots are Pending Release to the Pool of Available Slots