

CTSUS

Cancer Trials Support Unit

Oncology Patient Enrollment Network Site User Guide

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All screenshots are sourced from [OPEN Portal](#).

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1. Overview of OPEN

The Oncology Patient Enrollment Network (OPEN) Portal:

- Enables subject registrars to enter eligibility checklist data and determine subject eligibility for a given clinical trial.
- Communicates eligibility checklist and related regulatory data to the Lead Protocol Organization (LPO) subject enrollment systems, using industry standards: XML and CDISC schema.
- Communicates Group subject enrollment output data (such as treatment assignment, subject ID, and enrollment notes) back to the OPEN Portal user.

The OPEN Portal provides a central location for registrars to enroll subjects on NCI-sponsored clinical trials that have been activated within the system.

Note that the terms *study* and *protocol* are used interchangeably throughout the document.

1.1 System Requirements

Table 1: Minimum System Requirements

Type	Specification
Operating System	Windows 2000 and up
Memory	2 GB of RAM minimum
Display	Super VGA (1024 x 768) or higher-resolution monitor
Browser	Internet Explorer version 8 (and higher), Google Chrome, Mozilla Firefox, Opera, and Safari.

1.2 Business Process

The OPEN Portal business process is shown in Figure 1:

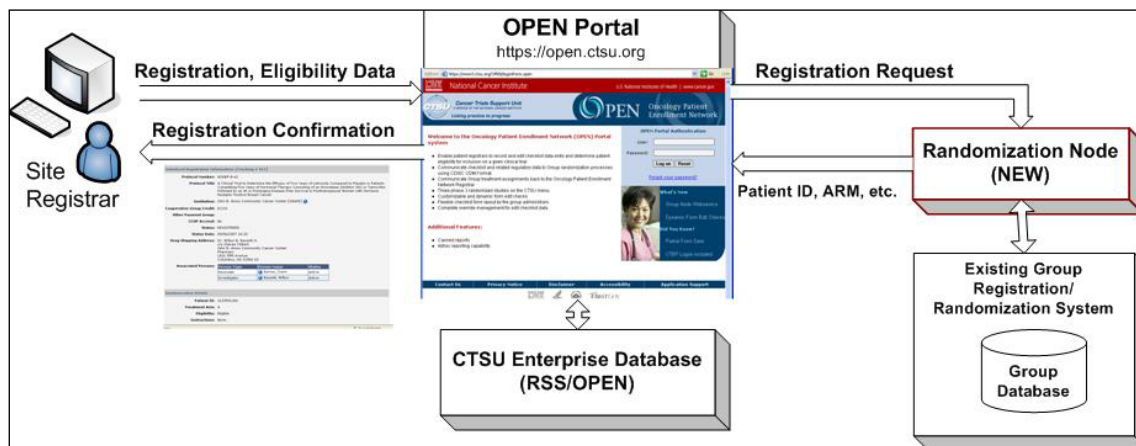


Figure 1: OPEN Portal Business Process

1.3 Organization of this Document

The content within this user guide is organized by the OPEN tabs that are accessible to the site users. Table 2 describes the major sections of the document.

Table 2: Organization of the Document

Section	OPEN Tab	Description
2	Home	Instructions for accessing OPEN, as well as navigating the Home tab.
3	Slot Reservation	Provides a summary of the Slot Reservation module and a link to the full user guide.
4	Enroll	Instructions for creating subject enrollments in OPEN.
5	History	Instructions for accessing completed enrollments in OPEN.
6	T&UM	Provides a summary of the Transfer and Update Module and a link to the full user guide.
7	Reports	Instructions for utilizing the features on the Reports tab.
8	RSS	Instructions for utilizing the features in the RSS tab.
9	Help	Instructions for utilizing the features in the Help tab.
10	Appendix	Provides additional information regarding OPEN.

1.4 Web Addresses for CTSU Applications

Table 3: Web Addresses for CTSU Applications

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

1.5 Acronyms

Table 4 provides a description for the acronyms used within this document.

Table 4: List of Acronyms

Acronym	Description
CCDR	Cancer Care Delivery Research
CD	Care Delivery
CDISC	Clinical Data Interchange Standards Consortium
CDMS	Clinical Data Management System
COG	Children's Oncology Group
CTEP	Cancer Therapy Evaluation Program
CTEP-IAM	Cancer Therapy Evaluation Program-Identity and Access Management
CTSUS	Cancer Trials Support Unit
DCP	Division of Cancer Prevention
DCP-CCOP	Division of Cancer Prevention Community Clinical Oncology Program
EC	Eligibility Checklist
ER	Exceptional Responder
IRB	Institutional Review Board
IRTF	Imaging and Radiation Treatment Facility
LPO	Lead Protocol Organization
NCI	National Cancer Institute
OPEN	Oncology Patient Enrollment Network
PI	Principal Investigator
PMB	Pharmaceutical Management Branch
RSS	Regulatory Support System
SSO	Single Sign On
T&UM	Transfer and Update Module

2. Accessing OPEN and the Home Tab

All persons accessing OPEN must have an active CTEP-IAM account and maintain the account via the policies outlined by CTEP. For a list of business rules for the different OPEN Person Types, see the [OPEN Person Types and Business Rules](#) document.

There are two ways to access the OPEN Portal:

- The OPEN URL
- The CTSU members’ website.

Both methods are described below.

2.1 Accessing the OPEN Portal Using the OPEN URL

To log in to the OPEN Portal using the OPEN URL:

- 1) Launch a new internet browser window.
- 2) Access the OPEN website.
- 3) The Login screen will load, and a User ID and password will be requested (as shown in Figure 2).

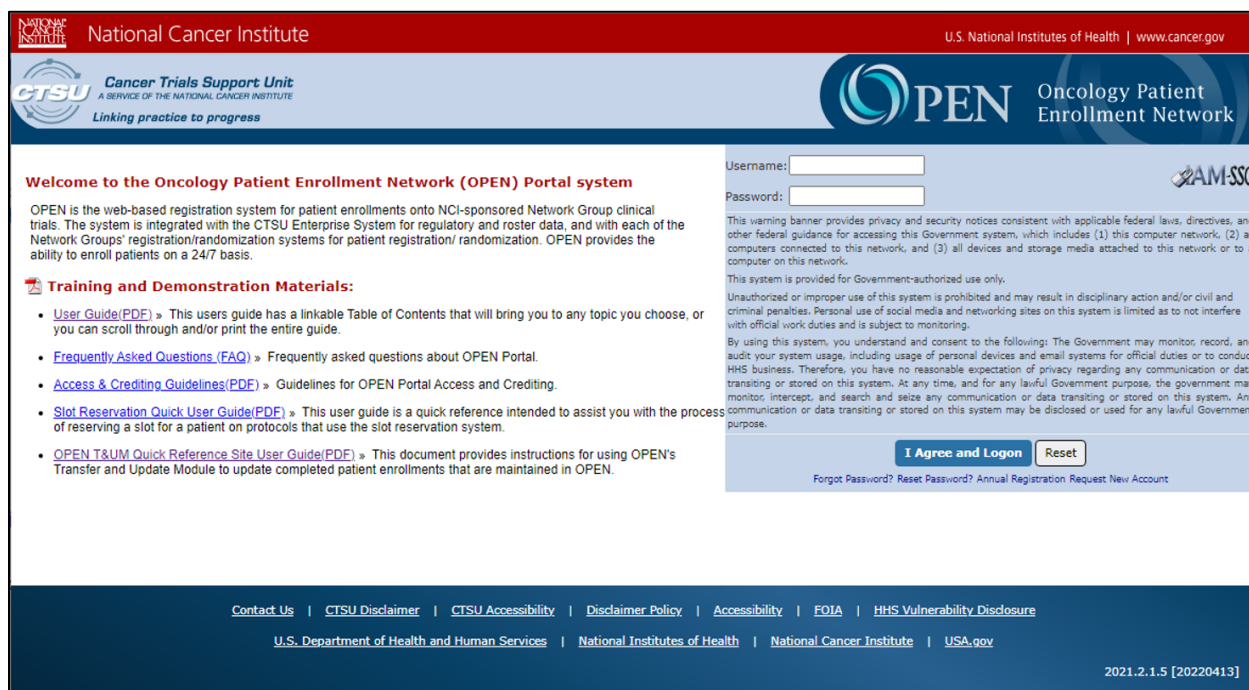


Figure 2: Login Screen

- 4) Enter your CTEP-IAM username in the Username field, as well as the associated password in the Password field (these are the same username and password used for the CTSU Members’ website).
- 5) Click the *I Agree and Logon* button to enter the system.

OR

- 6) Click the *Reset* button to clear the entered fields.

The *Logon* button validates the entered CTEP-IAM ID and password, and allows the user to enter the OPEN Portal. If successful, the Welcome screen will display by default (as shown in Figure 3 and Figure 4). The date and time of the user’s last login will display below their name.

If the CTEP-IAM ID and password that were entered are invalid, OPEN returns the message *Invalid username or password*. The user is able to re-enter the IAM username and password.

If the user does not have an appropriate OPEN role, the user will encounter an error message that indicates no roles were found and to contact the CTSU Help Desk. If you have additional problems logging into the OPEN Portal, please contact the CTSU Help Desk for assistance at 1-888-823-5923, option 1.

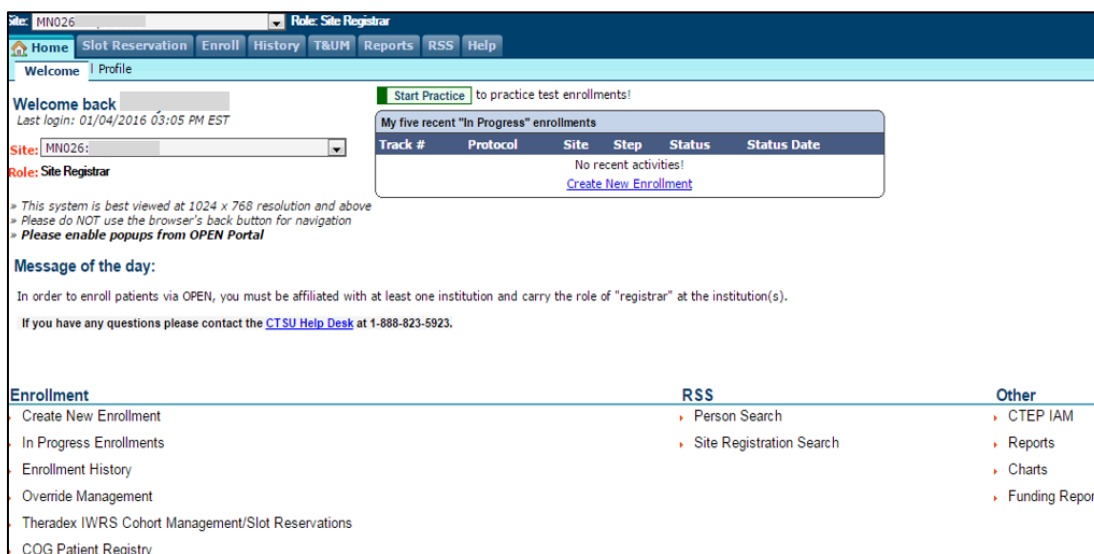


Figure 3: The Welcome Screen for a User with Multiple Sites and a Single Role

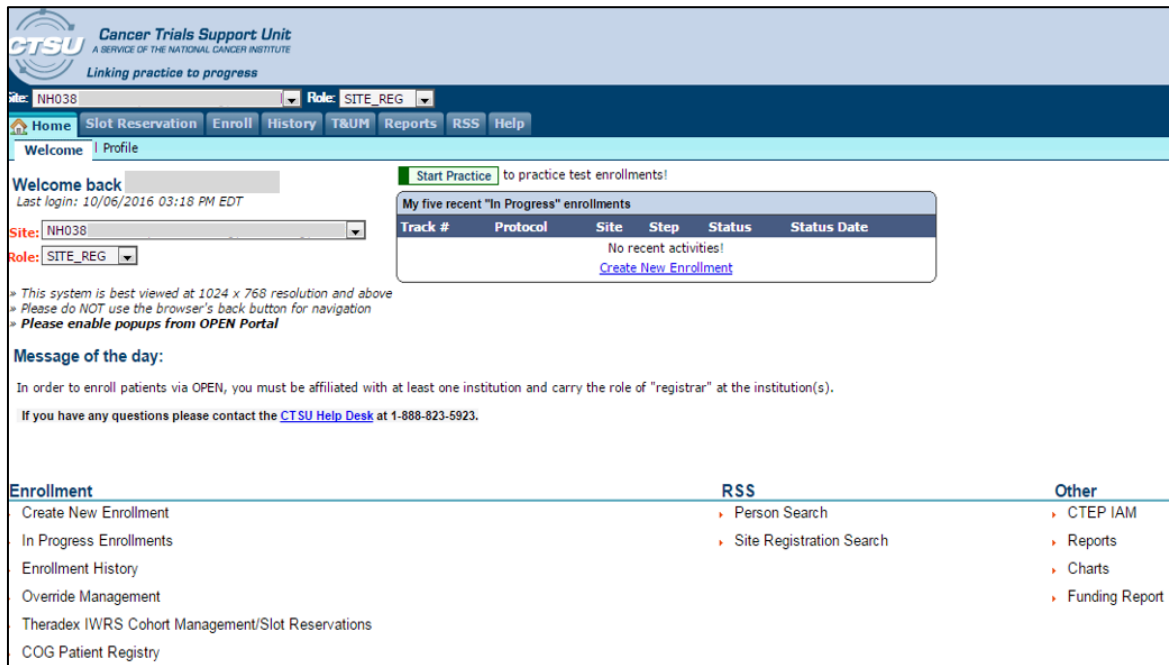


Figure 4: The Welcome Screen for a User with Multiple Sites and Roles

2.2 Logging in to OPEN via the CTSU Members' Website

The OPEN Portal is accessed from the CTSU members' website.

- 1) Open a new internet browser window.
- 2) Log in to the CTSU members' website: <https://www.ctsu.org/>
- 3) Click on the OPEN tab. This tab displays information specific to the OPEN Portal and provides a link to OPEN.
- 4) Click on the Connect to OPEN link to launch the OPEN Portal and display the Welcome tab (as shown in Figure 3 or Figure 4).

2.3 Viewing a User's Profile Information

The profile section displays information associated with the CTEP-IAM account for the person who logs into OPEN. All existing data associated with the user's CTEP-IAM account is displayed. It is blank if there is no data for that listing.

Accessing this Feature:

- 1) Log in to the OPEN Portal.
- 2) Click the Profile subtab on the Home tab.
- 3) The following fields will display:

- Last Name
- First Name
- RSS Role
- Person Type
- Account Name
- Account Status
- Status Date
- Registration Expires
- Password Expires
- CTEP ID
- CTEP Investigator ID
- CTEP Title

2.4 Resetting a User's Password

Users may reset their passwords in the OPEN Portal. Please note that resetting a password in OPEN updates the password associated with the CTEP-IAM account ID (thus the password changes for all systems that use that CTEP-IAM account ID, such as the CTSU Members' website).

Accessing this Feature:

- 1) Log in to the OPEN Portal.
- 2) Click on the Profile tab.
- 3) Click on the *Reset Password* button.
- 4) Verify that the pre-populated username is accurate.
- 5) Enter the current password.
- 6) Enter the desired password according to the password rules presented on the screen.
- 7) Confirm the password.
- 8) Click on the *Submit* button.

2.5 Accessing the Patient Registry Module

The Patient Registry module was added to OPEN for creating, editing, and viewing Children's Oncology Group (COG) Patient Registry records.

For information on the Patient Registry module, access the [OPEN Patient Registry Site User Guide](#).

3. Slot Reservation Tab

The Slot Reservation tab within OPEN is for reserving slots for certain OPEN protocols that require a slot reservation prior to subject enrollment. Figure 5 provides an overview of the process for enrolling a subject on a slot reservation study in OPEN.

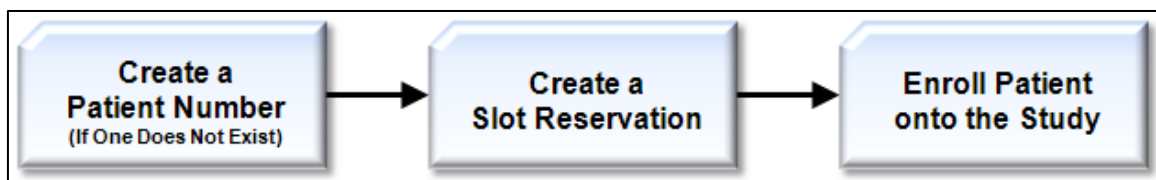


Figure 5: Process for Enrolling a Subject on a Slot Reservation Protocol in OPEN

If an OPEN protocol uses the slot reservation feature, a user must first create an OPEN Subject Number for their subject. Next, the OPEN Subject Number is used to obtain a Slot Reservation for the protocol. Once a slot has been reserved for the subject, the user can proceed to enroll their subject on the protocol, using the Enroll tab of OPEN (see section 4.1 for more information).

Please note that **Theradex slot-reservation studies** use a different slot reservation process. For these studies, the user must first reserve a slot for their subject in the Theradex’s Cohort Management System. After the user obtains a slot reservation, they may proceed with creating a subject enrollment in the Enroll tab of OPEN.

For information on using the Slot Reservation module, access the [OPEN Slot Reservation Site User Guide](#).

4. Enroll Tab

The Enroll tab is for enrolling subjects on to NCI-sponsored cancer clinical trials that are available within OPEN. This section provides instructions for creating enrollments in OPEN, as well as the various enrollment-related features that are accessible within this tab.

Please note that a user can create practice mode enrollments to simulate the enrollment process. For detailed instructions on creating practice mode enrollments, as shown in section 4.2.9.

4.1 Instructions for Creating Enrollments in OPEN

- 1) Log in to the OPEN Portal.
- 2) Verify the site and role in the Site and Role fields (as shown in Figure 6). If a user is affiliated with more than one site or has multiple roles for a site, a drop-down list is shown (as shown in Figure 7). If a drop-down list is present (and a different site or role needs to be selected), click the drop-down list and select the appropriate option. Only the user's active site and role affiliations display in the drop-down lists. The screen refreshes with new information after selecting a value from the drop-down list.

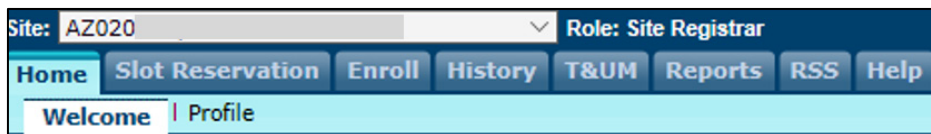


Figure 6: Site and Role

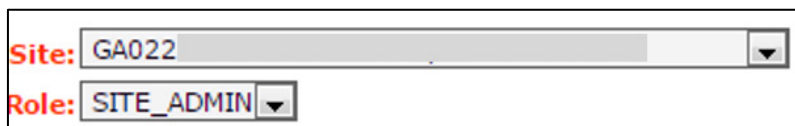


Figure 7: Site and Role

- 3) Click on the *Create New Enrollment* link at the bottom of the Welcome page, or click on the Enroll tab and click the Create New subtab. The Create New (Credentialing) screen appears in view.
- 4) The site name in the Site menu automatically prefills into the Institution and Institution Name fields (as shown in Figure 8).

Figure 8: The Create New Screen

- 5) Select the protocol number in which the subject is enrolling. Only protocols for which the institution has approval are listed. The *Protocol's Missing?* link displays a pop-up with a list of all protocols with a site registration status for the selected site (regardless of the site registration status). If an institution or protocol number is not appearing that should be listed, please contact the CTSU Help Desk for assistance at 1-888-823-5923, option 1. This is a mandatory field.
- 6) Select the protocol step number using Registration Step drop-down list. The *Steps Missing?* link displays a list of all steps that are configured by the LPO for the protocol. This is a mandatory field. If an optional ancillary protocol is associated with the protocol's enrollment step, the user will receive a pop-up reminder (as shown in Figure 9).

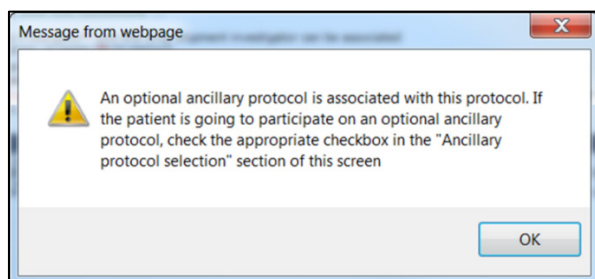


Figure 9: Pop-up Reminder for Optional Ancillary Protocols

Note: For OPEN studies that are configured for Imaging and Radiation Treatment Facility (IRTF), an *IRTF selection* section will appear. Users are required to select at least one combination of values for the *Credential* and *IRTF* fields (as shown in Figure 10).

Site: GA020 Role: Site Registrar

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

In Progress Create New Summary Prerequisite Demography Checklist Review & Submit Result Overrides

1: Select Institution/Protocol combinations

Tracking Number:

Registrar: Stauffer Mark

* Institution CTEP ID: GA020 Institution Name:

* Protocol Number: NRG-GY017 Protocols Missing?

Protocol Title: Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently with Extended Field Chemoradiotherapy for No Advanced Cervical Cancer

Protocol Note(s):

* Registration Step: 1 - Randomization Steps Missing?

* Registration Type: Patient

IRTF Selection

- Select the IRTF provider(s)
- Press + to add a IRTF, or press - to remove

Action	Credential*	IRTF*
-	If using IMRT, who is the credentia	RTF-1800

Figure 10: IRTF Selection

Notes about CCDR protocols:

- The Division of Cancer Prevention (DCP) developed Cancer Care Delivery Research (CCDR) trials to collect questionnaire information about caregivers, practices (sites), providers (physicians, nurse practitioners), and other professional disciplines (research nurses, nutritionists), for patients that are enrolled in OPEN. Both patient and non-patient CCDR enrollments are supported in Rave (OPEN sends data for the enrollments from OPEN to Rave through CENTER).
- For OPEN protocols that are configured for Cancer Care Delivery Research (CCDR), the Registration Type field will become a drop-down menu, from which users must select either Patient or Non-Patient (as shown in Figure 11). If Non-Patient is selected, a mandatory Non-Patient Type drop-down menu will appear with the four non-patient type choices (Caregivers, Other Professional Disciplines, Providers, and Practice). CCDR trials can be identified by the suffix CD in the protocol number.

The screenshot shows the 'Enroll' tab in the OPEN system. The navigation bar includes 'Home', 'Slot Reservation', 'Enroll', 'History', 'T&UM', 'Reports', 'RSS', and 'Help'. Below the navigation bar, there are tabs for 'In Progress', 'Create New', 'Summary', 'Prerequisite', 'Demography', 'Checklist', 'Review & Submit', 'Result', and 'Overrides'. The main content area is titled '1: Select Institution/Protocol combinations' and contains the following fields and instructions:

- Tracking Number:** ?
- Registrar:** Fukaya Erin ⓘ
- * Institution CTEP ID:** HI046 ?
- Institution Name:** Hawaii Oncology Inc-POB I ?
- * Protocol Number:** S1417CD ? **Protocols Missing?** ⓘ
- Protocol Title:** Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer ?
- Protocol Note(s):** The patient's full name, address and social security number are required for S1417CD registration. ?
- Registration Step:** 1 - Registration ? **Steps Missing?** ⓘ
- Registration Type:** Non-Patient ?
- * Non-Patient Type:** -- select Non-Patient Type -- ?
 - Caregiver
 - Other Professional Discipline
 - Practice
 - Provider

Below the 'Non-Patient Type' dropdown, there are instructions: 'Enter the patient's street address (House Number and Street Name) as two separate components. Example: If the patient's address is 1100 Fairview Avenue N enter House Number as 1100 and the Street Name as Fairview Ave N.' and 'Press + to add a person'. Below these are '2: Add persons associated' instructions: 'If a shipping investigator is selected, the shipping investigator address will default to the treating investigator address' and 'Protocol specific instructions: Protocol S1417CD has the following association(s): Treating Investigator (required), Site Registrar (required), Consenting Person (required)'.

Figure 11: The Non-Patient Type Field For Non-Patient CCDR Enrollments

Explanations for the four non-patient types for CCDR protocols:

- Caregivers are family and other non-medical professionals involved with patient care.
 - Other Professional Disciplines are other professionals involved with the care of patients.
 - Practices are the sites enrolling non-patients.
 - Providers are physicians, physician assistants, and nurse practitioners.
- 7) Select the applicable Person Type(s) and Person Name(s) from the drop-down lists. The number of persons and person types that are required is designated by the LPO. See section 10.1 for a list of validations that OPEN performs on individuals that are selected in the Create New screen.
 - a) The *Add persons associated with this enrollment* section preloads with the number of rows that are needed to accommodate all the mandatory person types.
 - b) Click the + plus button to add additional associated people to the enrollment. A new row will display on screen. Click the - minus button to delete a row.
 - 8) Select a Network Group from the *Network Group Credit* drop-down list. This is the Network Group that receives credit for the enrollment. This is a mandatory field.
 - 9) The Treating Investigator selected in step 7 will automatically populate the *Credit Investigator* field once the user selects a Network Group Credit choice. If the Treating Investigator is not a member of

the credited group, then the Treating Investigator will not pre-populate, and the user must select a Credit Investigator from the *Credit Investigator* drop-down menu. This is a mandatory field.

- 10) The value for the NCORP Accrual field is automatically prefilled.
- 11) Any additional details is entered in the Case Notes box and the enrollment Summary displays the information. This is an optional field for site users and the information entered in the field will not be submitted to the LPO with the enrollment data.
- 12) Click the *Continue* button and the user receives a pop-up message that asks them to confirm if the user wants to proceed with initializing the enrollment (as shown in Figure 12).

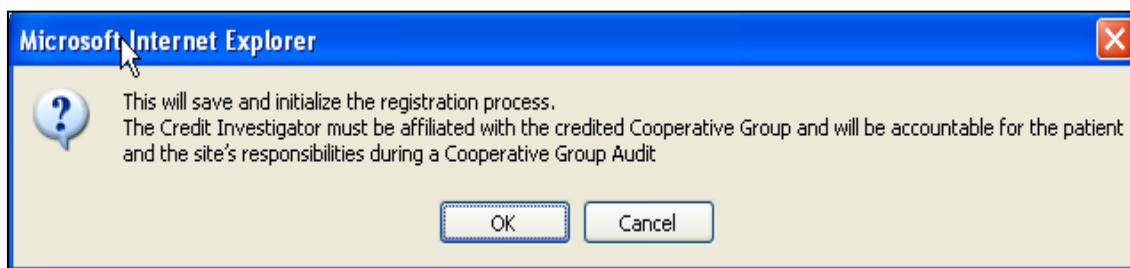


Figure 12: Confirmation Message for Initializing the Enrollment

- 13) Click the *OK* button to initialize the enrollment. Once the enrollment is initialized, a record appears in the In Progress subtab (of the Enroll tab).
- 14) Once the enrollment is initialized, the user is given a tracking number for the enrollment. The tracking number is used for uniquely identifying the enrollment in OPEN.
- 15) Once the tracking number is obtained, the user can:
 - Edit the Create New screen information for the enrollment by clicking the Edit Summary button (as shown in Figure 13).
 - View Summary information for the enrollment by clicking the View Summary button (as shown in Figure 13).
 - Continue with the enrollment process by clicking the Continue button (as shown in Figure 13).

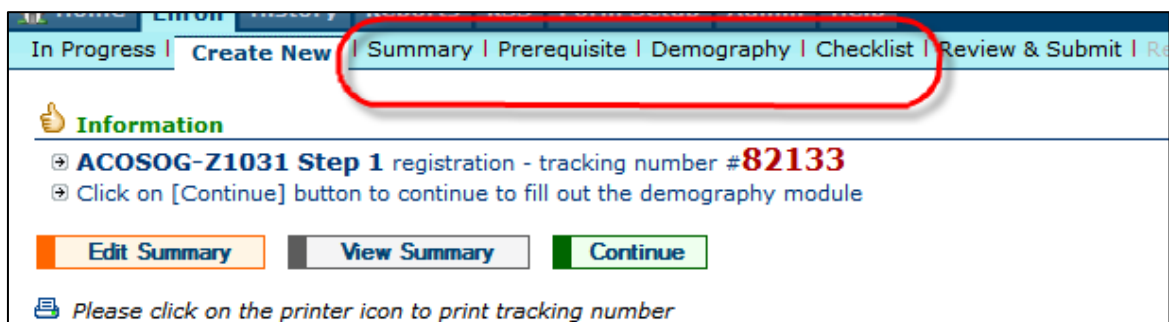
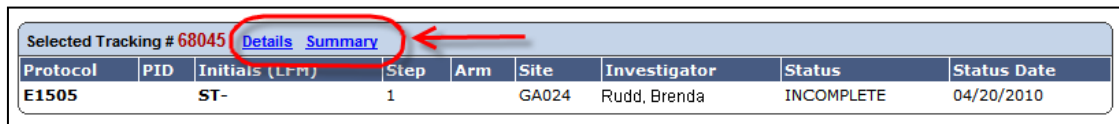


Figure 13: Confirmation that an Enrollment was initialized

- 16) The Summary, Prerequisite (if available for the protocol step), Demography, and Checklist forms for the enrollment are accessed by clicking the subtabs, while the enrollment is selected.
- 17) Once an enrollment is initiated and a tracking number is assigned, the identifying enrollment information displays in the header (as shown in Figure 14). Click on the Details or Summary links for additional information.



Protocol	PID	Initials (LPM)	Step	Arm	Site	Investigator	Status	Status Date
E1505		ST-	1		GA024	Rudd, Brenda	INCOMPLETE	04/20/2010

Figure 14: Enrollment Header Information

4.1.1 Completing the Prerequisite Screen

The Prerequisite screen is used when information needs to be collected before the Demography and Checklist screens are completed. The Prerequisite screen will only appear for protocols that are configured for its use by the LPO.

- 1) Access the Prerequisite screen by clicking the Prerequisite tab (if the first section of the enrollment has not been completed, follow the steps in section 4.1).
- 2) Once the Prerequisite screen is displayed, enter the requested data per the requirements of the protocol.
- 3) OPEN returns a validation error if any of the data on the form is invalid or incomplete. Each protocol can have different validations, which are determined by the LPO. Below are error message examples that result from LPO validations:
 - Mandatory fields are not completed.
 - Dates are not within a required timeframe.
 - Fields responses are inconsistent with another.
 - Provided responses do not meet protocol eligibility requirements.
- 4) There are multiple ways to save a In Progress enrollment, including:
 - Click the Save button. The user receives a message verifying that the data is saved (as shown in Figure 15). An enrollment that has not been submitted remains active for seven calendar days from the time it was last saved. After seven calendar days, the enrollment enters a VOID status.



Figure 15: Save Alert Message

- Click the Save & Validate button. The Save & Validate option saves and reviews the data for any validation errors. The data is saved even if validation errors are identified. Errors are present in the module where the error occurred. Note that the modules can

expand and collapse by clicking the *Expand/Collapse all Modules* link (as shown in Figure 16).

Figure 16: Save & Validate Messages

- 5) Once the Prerequisite screen is complete, click the Continue button to proceed to the Demography screen.
 - **For Theradex slot reservation studies**, the site registrar needs to reserve a slot for their subject in Theradex’s Cohort Management System. Then the user proceeds to create the enrollment in the Create New screen of the Enroll tab in OPEN. A verification is performed on the Prerequisite screen (for Theradex slot reservation studies) to see whether a slot reservation was created for the subject in Theradex’s Slot Reservation system. If a slot was reserved for the subject then OPEN allows the user to proceed to the Demography screen. If a slot was not reserved the user encounters an error message that includes a hyperlink for creating a slot reservation in Theradex’s Slot Reservation system (as shown in Figure 17).

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

In Progress | Create New | Summary | Prerequisite | Demography | Checklist | Review & Submit | Result | Overrides

Selected Tracking # 112771 [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
AMC-078		---	1		PA121		READY	09/26/2013

Back Save Save & Validate Continue

Validation Error! You must correct the following error(s) before proceeding:
 Group Validation Message: FAILURE - You must reserve a slot prior to enrollment. Please click this link to reserve a slot

Prerequisite

- Cohort
- Cohort 1: Liposarcoma
- Cohort 2: Leiomyosarcoma (non-uterine)
- Cohort 3: Undifferentiated sarcoma
- Cohort 4: Malignant peripheral nerve sheath tumor
- Cohort 5: Other sarcomas

Back Save Save & Validate Continue

Figure 17: (Theradex Slot Reservation Studies Only) Error Message Stating the User Must Reserve a Slot for their Subject

4.1.2 Completing the Demography Screen

The Demography screen (as shown in Figure 18) displays the demography form that is associated with the study and step that was selected earlier in the enrollment process. After completing the demography form (which is mandatory), the user proceeds to the Checklist screen.

Patient Demography	
<input type="checkbox"/> Standard_Patient_Identifier	
Last <input type="text"/>	First <input type="text"/> Middle <input type="text"/>
Social Security Number (USA Only) <input type="text"/>	Hospital No. <input type="text"/>
<input type="checkbox"/> Standard_Demographics	
* Date of Birth <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="button" value="Clear"/>	
* Ethnicity <input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown	* Sex <input type="radio"/> Female <input type="radio"/> Male <input type="radio"/> Unknown <input type="radio"/> Intersex
* Country <input type="text"/>	Zip Code (USA Only) <input type="text"/>
<input type="checkbox"/> Standard_Race	
* Race <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/> White	
<input type="checkbox"/> Standard_Method_of_Payment	
* Method of Payment <input type="radio"/> PRIVATE INSURANCE <input type="radio"/> MEDICARE <input type="radio"/> MEDICARE AND PRIVATE INSURANCE <input type="radio"/> MEDICAID <input type="radio"/> MEDICAID AND MEDICARE <input type="radio"/> MILITARY OR VETERANS SPONSORED NOS <input type="radio"/> MILITARY SPONSORED (INCLUDING CHAMPUS & TRICARE) <input type="radio"/> VETERANS SPONSORED <input type="radio"/> SELF PAY (NO INSURANCE) <input type="radio"/> NO MEANS OF PAYMENT (NO INSURANCE) <input type="radio"/> OTHER <input type="radio"/> Unknown	
<input type="checkbox"/> Standard_NCI_Reporting	
* Disease Code <input type="text"/> <input type="button" value="Select"/> <input type="button" value="Clear"/>	

Figure 18: The Demography Screen

- 1) Access the Demography screen by clicking the Demography tab. If the first section of the enrollment has not been completed, follow the steps in section 4.1.
- 2) Once the Demography screen is on display, enter the subject demographic information using one of the following methods:
 - Manually enter the subject’s demography information per the requirements of the protocol.
 - If the subject already has an LPO-assigned patient ID, enter the patient ID in the *Existing Patient ID* field and click the *Populate Demography* button. The demography

screen information automatically populates. **This is available only for protocols where the LPO supports prefilling of the demography information.**

- For multi-step protocols, when demographic data is available from the previous enrollment step, the data automatically populates the Demography screen when enrolling to the subsequent step. If all the required responses in the demographic screen are complete, OPEN automatically hides the *Populate Demography* button. A message appears on the demography screen that states *All matching patient demographic data from the previous step has been populated! Click [Save & Validate] in the Demography screen to validate the data.* (as shown in Figure 19).

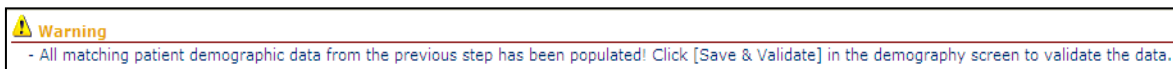


Figure 19: Message Stating that the Demographic Data was Pre-populated from a Previous Enrollment Step

- 3) Some Demography forms have a Disease Code question. To provide a response, click the Select link, and a pop-up window displays a list of the Simplified Disease Code choices. Click the Select button for the Simplified Disease Code that applies for the subject and the value prefills into the Disease Code field (as shown in Figure 20).

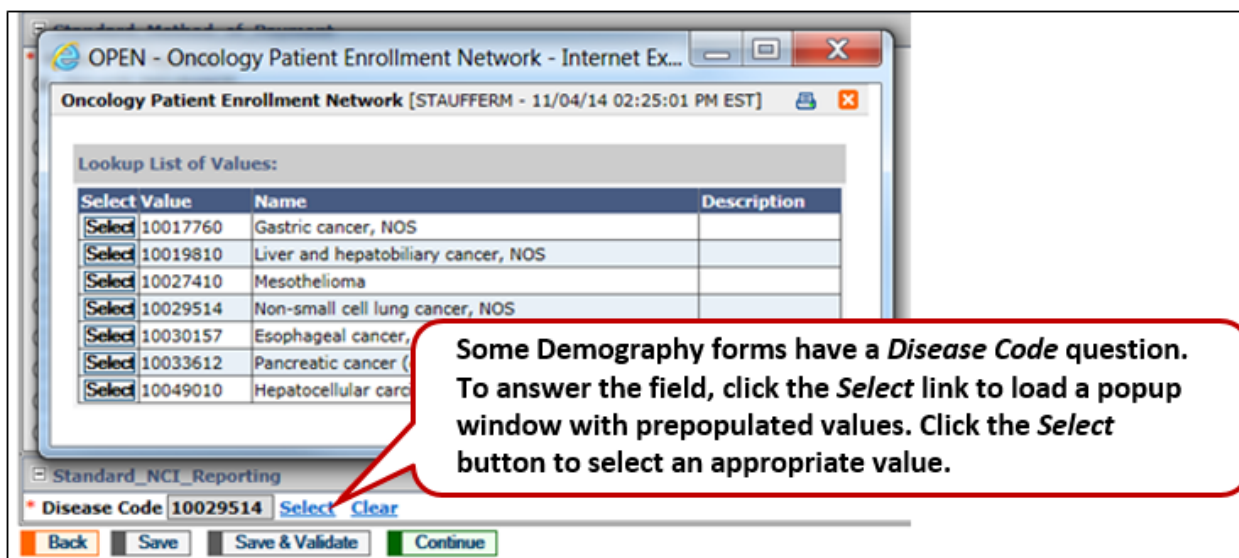


Figure 20: Click the *Select* Link to Answer a Disease Code Question

- 4) There are multiple ways to save the In Progress enrollment:
 - Click the Save button. The user receives a message verifying that the data is saved (as shown in Figure 21). An enrollment that has not been submitted remains active for 7 calendar days from the time it was last saved. After 7 calendar days the enrollment enters a VOID status.



Figure 21: Save Alert Message

- Click the Save & Validate button. The Save & Validate option saves and reviews the data for any validation errors. The data is saved even if validation errors are identified. Errors are present in the module where the error occurred. Note that the modules can expand and collapse by clicking the *Expand/Collapse all Modules* link (as shown in Figure 22).

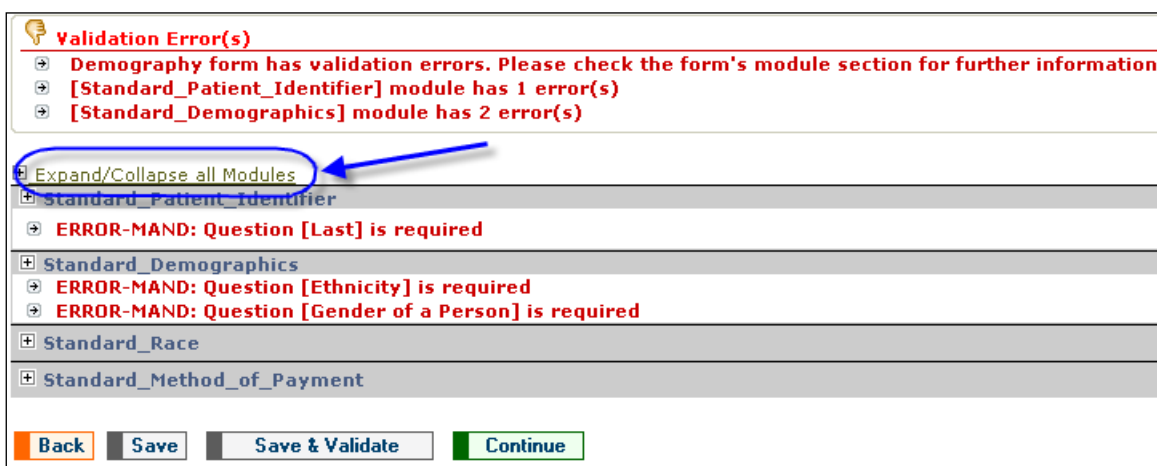


Figure 22: Save & Validate Messages

- 5) The system returns a validation error if any of the data on the form is invalid or incomplete. Each protocol can have different validation checks that are determined by the LPO.
- 6) Once the Demography screen is complete, click the Continue button to proceed to the Eligibility Checklist.

4.1.3 Completing the Eligibility Checklist

The Checklist subtab (Eligibility Checklist) will display the eligibility checklist form that is associated with the study and step combination that was selected at the Create New screen. Completing and submitting the Checklist form completes the final portion of the enrollment process.

- 1) Open the Checklist screen.
- 2) Once the Checklist is displayed, the user is responsible for entering the subject data, per the requirements of the protocol.

- 3) The system return a validation error message if any of the data on the form is invalid or incomplete. Each protocol can have different validation checks, which are determined by the LPO. Examples of errors that could be included are:
- Mandatory fields were not completed.
 - Dates are not within a required timeframe.
 - Fields containing data that are inconsistent with the data in another field.
 - Fields that do not meet the eligibility requirements.
- 4) Some protocols are configured with eligibility checklist questions that have prefilled responses. This is because the answer to a question is determined earlier in the enrollment process. If the prefilled response is out-of-date (due to the value being updated after the prefill process occurred), click the Refresh button next to the question to update the value (as shown in Figure 23).

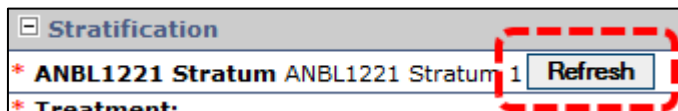


Figure 23: The Refresh Button will Display an Updated value for a Question that Uses the Prefill Feature

- 5) There are multiple ways to save the In Progress enrollment:
- Click the Save button. The user receives a message verifying that the data is saved (as shown in Figure 24). An enrollment that has not been submitted remains active for seven calendar days from the time it was last saved. After seven calendar days the enrollment enters a VOID status.



Figure 24: Save Alert Message

- Click the Save & Validate button. The Save & Validate option saves and reviews the data for any validation errors. The data is saved even if validation errors are identified. Errors are present in the module where the error occurred. Note that the expand and collapse by clicking the Expand/Collapse all Modules link (as shown in Figure 25).

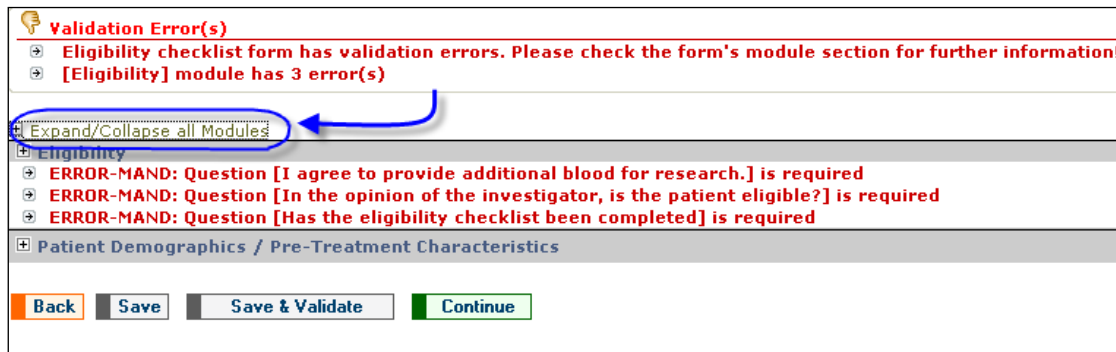


Figure 25: Save & Validate Messages

- 6) The checklist is retrievable from the Enroll -> In Progress tab by selecting the desired enrollment and clicking on the Checklist tab.

4.1.4 Submitting the Eligibility Checklist

After completing the Checklist (Eligibility Checklist) screen, the user submits the enrollment to the LPO to complete the enrollment process.

- 1) Click the Continue button (as shown in Figure 26).



Figure 26: Click the Continue Button on the Checklist Screen

- 2) The Checklist screen is validated for errors. If a validation error is found, the user must fix the errors or request an override (if available) in order to continue. See 4.2.7 for details on requesting an override. The user also receives alert messages. Unlike error messages, alert messages do not block the enrollment process from continuing and they are only for informational purposes.
- 3) If no validation errors are found, the user receives a summary of all the data that was entered for the subject enrollment. The user is asked to confirm their submission.
- 4) If changes are necessary, click the subtab (Prerequisite, Demography, or Checklist) to return to the desired form and make the necessary updates.
- 5) If no changes are needed, click the Submit button.
- 6) Click on the OK button and the enrollment is submitted to the LPO for validation.
- 7) A confirmation of the enrollment and details is displayed (including the Patient ID, Treatment Arm, and Site Instructions, if any) (as shown in Figure 27).

Selected Tracking # 55889 Details								
Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1505	15605	FF-	1	B	GA024	Rudd, Brenda	REGISTERED	03/26/2010

Information

- Group response for tracking #55889
- This registration can now be found in the HISTORY section

Group Response(s)	
Eligibility:	ELIGIBLE
Ineligibility Reason:	Eligibility Completed
Patient ID:	15605
Treatment Arm:	B
Site Instruction:	REAL REGISTRATION - Planned chemotherapy + Bevacizumab
Comments:	

Figure 27: Enrollment Confirmation Screen

8) The completed enrollment is found on the History screen.

4.2 Additional Features within the Enroll Tab

This section contains instructions for using additional features within the Enroll tab.

4.2.1 Resubmitting an Enrollment

If the LPO’s system is not functioning properly, when an In Progress OPEN enrollment is sent to the LPO for validation, the enrollment enters a SUBMITTED status (and the enrollment process will be incomplete). The Resubmit button allows users to resubmit their enrollment (when it is in a SUBMITTED status) to complete the enrollment process.

Selected Tracking # 54970 Details Summary								
Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
PACTT-1		DD-	1		VT004		SUBMITTED	07/28/2009

Alert Message(s)

The form has already been submitted and cannot be edited. Resubmit

Eligibility

**** PLEASE READ IMPORTANT INSTRUCTIONS****
 This registration worksheet must be completed and all questions must be answered by the institution prior to patient checklist found in the protocol must be completed prior to patient registration and kept in the patient’s chart. ECOG monitoring patient eligibility at study entry. The registration worksheet and eligibility checklist must be signed by the patient files at the institution if the checklist is to be used as source documentation. Do not submit these forms to the

Has the eligibility checklist been completed *

No

Yes

Figure 28: Resubmitting an Enrollment

Accessing this Feature:

- 1) Select the enrollment (which has a SUBMITTED status) from the In Progress screen.
- 2) Click on the Checklist subtab.
- 3) Once on the Checklist form, click the Resubmit button (as shown in Figure 28).
- 4) Review the enrollment information on the Review and Submit screen and click the Resubmit button.
- 5) Click OK on the confirmation pop-up window.
- 6) If the resubmission is successful, the user receives an ELIGIBLE response from the LPO system (as shown in Figure 29).

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

Selected Tracking # **82221** [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Site
E3805	1065120431	DD-	1	A	GA024		REGISTERED	05/

Information

- ⊕ Group response for tracking #**82221**
- ⊕ 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:	1065120431
Treatment Arm:	A
Site Instruction:	Please send form to the group address.

Figure 29: Enrollment Confirmation for a Successful Resubmission

4.2.2 Using the Group Lookup List Feature

The Group Lookup List widget in OPEN displays a list of values when a user clicks on the Select link next to the question.

Accessing this Feature:

- 1) Log in to OPEN.
- 2) Enter the In Progress enrollment screen; locate the question that uses the Group Lookup List feature.
- 3) Click the Select link next to the question (as shown in Figure 30).

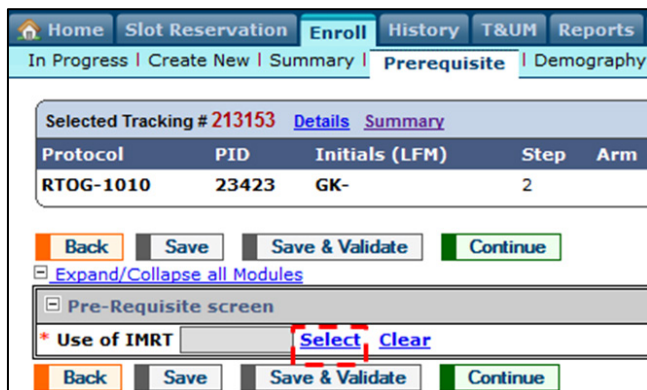


Figure 30: Click the *Select* Link to Initiate the Group Lookup List Pop-up

- 4) A Group Lookup List pop-up window appears on screen (as shown in Figure 31).

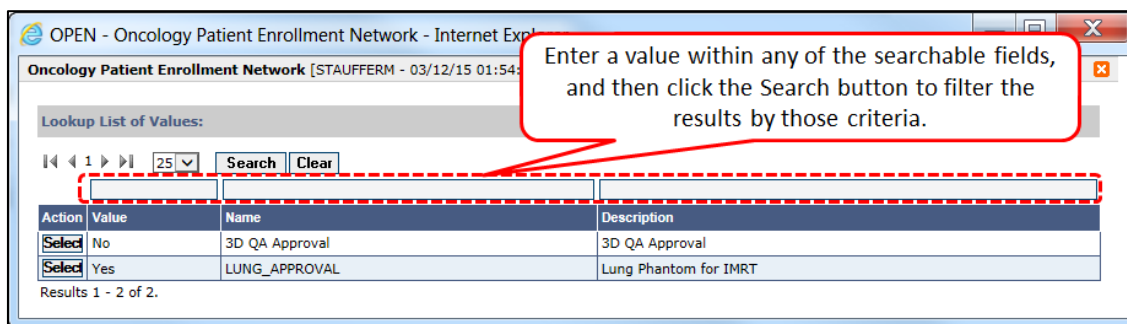


Figure 31: The Value, Name, and Description Fields are Searched

- 5) The results filter by entering a value into the Value, Name, and Description fields, and then clicking the Search button (as shown in Figure 32).

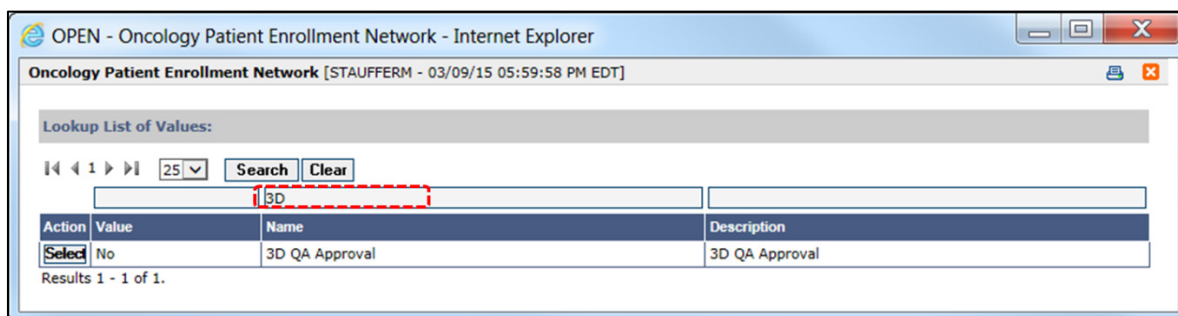


Figure 32: The Search Feature Filters the Group Lookup List Results

4.2.3 Completing a Multiple Step Enrollment

There are two options available to complete a next step enrollment for a multiple step protocol.

4.2.3.1 Option 1 for Enrolling a Subject on a Next-Step Enrollment

- 1) Follow the steps in section 4.1 of this User Guide to complete the initial step enrollment.
- 2) Click on the History tab.
- 3) Select the enrollment.
- 4) In the Summary screen, select the Create Step... button. The next valid step displays Step 1 Registration Information (as shown in Figure 33).



Figure 33: Create Next Step Enrollment by Clicking the Create Step... Button

- 5) Click OK to copy the enrollment details from the previous step (as shown in Figure 34).

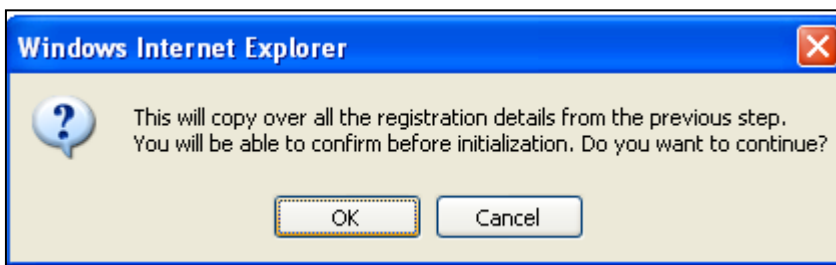


Figure 34: Copy Details Confirmation

- 6) Review the pre-populated data.
- 7) Make updates to the Create New screen, if needed. Only the associated persons section, the specify credits section, the express courier sections (if applicable), and the case notes will update.
- 8) Click the Continue button.
- 9) Click the OK button on the pop-up window.
- 10) A new tracking number is assigned to the enrollment step.
- 11) Click the Continue button.
- 12) Once the Demography screen is displayed, either:
 - a) Enter the subject demography information per the requirements of the protocol.
 - b) Click the Populate Demography button and this will populate the demographic data for the subject from the prior enrollment step. The Populate Demography feature is only available for LPOs that support the feature (as shown in Figure 35). Note if the *Existing Patient ID* field is available, the patient ID from the prior step enrollment is prefilled in the Existing Patient ID field.

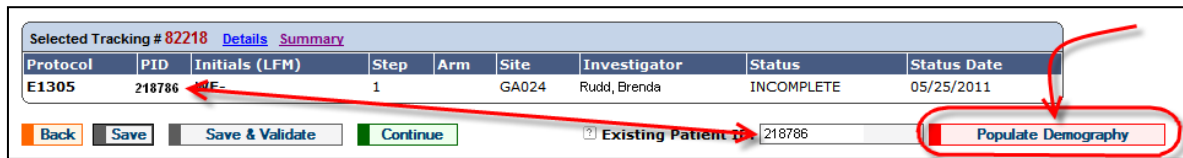


Figure 35: Populate Data Feature

- 13) Click the OK button on the Confirmation pop-up screen to prefill the demographic data.
- 14) Click the Continue button to proceed to the next screen.
- 15) Complete the Checklist (Eligibility Checklist) screen.
- 16) Click the Continue button.
- 17) Click the Submit button on the Review and Submit screen.
- 18) Click the OK button on the confirmation pop-up window.
- 19) The enrollment result displays on screen.

4.2.3.2 Option 2 for Enrolling a Subject on a Next-Step Enrollment

- 1) Follow the steps in section 4.1 of this User Guide to complete the initial step enrollment.
- 2) Click the Enroll tab and click the subtab for the Create New (Credentialing) screen.
- 3) Select the desired protocol number.
- 4) Select the appropriate enrollment step.
- 5) A new screen appears, requesting the patient ID from the previous step. Enter the patient ID in the Patient ID box.
- 6) Click the Search button. The enrollments that match the entered data is returned.
- 7) Click the Select button for the record that matches the correct enrollment.
- 8) The Create New screen refreshes with the patient ID and the associated credentialing screen data that was entered in the previous enrollment step.
- 9) If needed, make updates to the credentialing data. Only the associated persons section, the specify credits section, the express courier section (if applicable), and the case notes is updated.
- 10) Click the Continue button and the user is taken to the Demography screen.
- 11) Once the Demography screen is displayed, either:
 - a) Enter the subject demography information per the requirements of the protocol.
 - b) Click the Populate Demography button and this populates the demographic data for the subject from the prior enrollment step. The Populate Demography feature is available for LPOs that support the feature (as shown in Figure 36). Note if the Existing Patient ID field is available, the patient ID from the prior step enrollment is prefilled in the Existing Patient ID field.

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1305	218786	WE	1		GA024	Rudd, Brenda	INCOMPLETE	05/25/2011

Selected Tracking # 82218 [Details](#) [Summary](#)

Buttons: Back, Save, Save & Validate, Continue

Existing Patient: 218786

Figure 36: Populate Data Feature

- 12) Click the OK button on the Confirmation pop-up screen to prefill the demographic data.
- 13) Click the Continue button to proceed to the next screen.
- 14) Complete the Checklist (Eligibility Checklist) screen.
- 15) Click the Continue button.
- 16) Click the Submit button on the Review and Submit screen.
- 17) Click the OK button on the confirmation pop-up window.
- 18) The enrollment result displays on screen.

4.2.4 Completing an Ancillary Study

Some OPEN studies may be linked to ancillary studies, which are either embedded or stand-alone. These studies may be mandatory at the time of enrollment, or they may be available after enrollment to the main study. Embedded studies do not require a separate IRB approval, whereas stand-alone studies do require a separate IRB approval.

All associated ancillary studies are listed in the Create New screen when an enrollment is being initiated.

Steps for enrolling on an ancillary study:

- 1) Click on the Create New Registration link on the Welcome page, or click on the Enroll tab and select the Create New subtab.
- 2) Enter the Protocol Number and select the Registration Step.
- 3) If the entered protocol number has embedded or stand-alone ancillary studies, a new section appears (Figure 37). The *Ancillary protocol selection* section displays the associated ancillary protocols.
- 4) Enrollments that require ancillary embedded or stand-alone protocols are automatically selected and are not editable. The user must enter the information for these protocols at the same time the main study enrollment is being completed.
- 5) If a protocol has an optional ancillary study then the checkbox is blank by default. Checking the checkbox allows that optional ancillary study to be included in the current enrollment (as shown in Figure 37).

1: Select Institution/Protocol combinations

Tracking Number:
Registrar: Rudd Brenda (Associate) ⓘ

*** Institution CTEP ID:** MD015 **Institution Name:** _____

*** Protocol Number:** CALGB-140503 ⓘ **Protocols Missing?**

Protocol Title: A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (<= 2 cm) Peripheral Non-small Cell Lung Cancer

*** Registration Step:** 1 - Registration ⓘ **Steps Missing?**

*** Registration Type:** Patient

Patient ID: _____ (Please enter the patient ID if available)

Ancillary protocol selection ⓘ

- All required ancillary stand-alone/embedded protocols will be auto selected by default

Select	Type	# Days	Reqd.?	Protocol	Title
<input checked="" type="checkbox"/>	STAND_ALONE	15	YES	580602	Embedded Ancillary Study
<input type="checkbox"/>	STAND_ALONE	15	NO	CALGB-140503-E-06	
<input checked="" type="checkbox"/>	EMBEDDED	0	YES	CALGB-140503-E-01	
<input checked="" type="checkbox"/>	EMBEDDED	0	YES	CALGB-140503-E-02	

Figure 37: The Ancillary Protocol Selection Section on the Create New Screen

- 6) If an associated optional ancillary study is not selected for an enrollment, then an informational message is displayed at the top of the Prerequisite, Demography, and Checklist screens (as shown in Figure 38). The message will not prevent users from continuing with enrollment.

In Progress | Create New | Summary | Prerequisite | **Demography** | Checklist | Review & Submit | Result | Overrides

Selected Tracking # **600500** [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Stat
S1207		---	1		CA222		NEW

Information: Click [here](#) to view or change the optional ancillary studies that are linked to this enrollment.

Back **Save** **Save & Validate** **Continue** Existing Patient ID: _____

Expand/Collapse all Modules

Standard_Patient_Identifier

Figure 38: Users Sees a Message When an Optional Ancillary Study is Not Selected

- 7) The Patient ID field is optional for any initial step enrollment; however, this information is necessary when performing a delayed enrollment. Please see section 4.2.5 of this document for more details regarding the delayed enrollment process.
- 8) Complete the Create New screen and continue to the Demography screen. Please see section 4.1.2 of this document for more detailed information.
- 9) Complete the Demography screen and continue to the Checklist (Eligibility Checklist) screen. Please see section 4.1.1 of this document for more detailed information.
- 10) All ancillary studies are included in the Checklist screen. Embedded and selected optional studies are displayed with the name of the protocol listed in the header before the module name (as shown in Figure 39).

Figure 39: Embedded Ancillary Protocols in the Checklist Screen

- 11) Complete the Checklist screen and click the Continue button. See section 4.1.3 of this document for detailed information.
- 12) Review the enrollment information on the Review and Submit screen, and click the Submit button.
- 13) Click the **OK** button on the confirmation pop-up window.
- 14) The enrollment result displays on screen.

4.2.5 Skipping an Optional Enrollment Step

Some multi-step protocols permit subjects to skip optional enrollment steps. Follow the steps below to skip an optional enrollment step:

- 1) Log in to OPEN.
- 2) Click the Create New Registration link on the Welcome screen, or click the Enroll tab and select the Create New subtab.
- 3) Ensure the proper Institution CTEP ID.
- 4) Select the Protocol Number.
- 5) Select the step from the Registration Step drop-down menu. OPEN display all steps for the protocol in the drop-down menu. If an enrollment step is configured as optional, the user can skip the enrollment step.

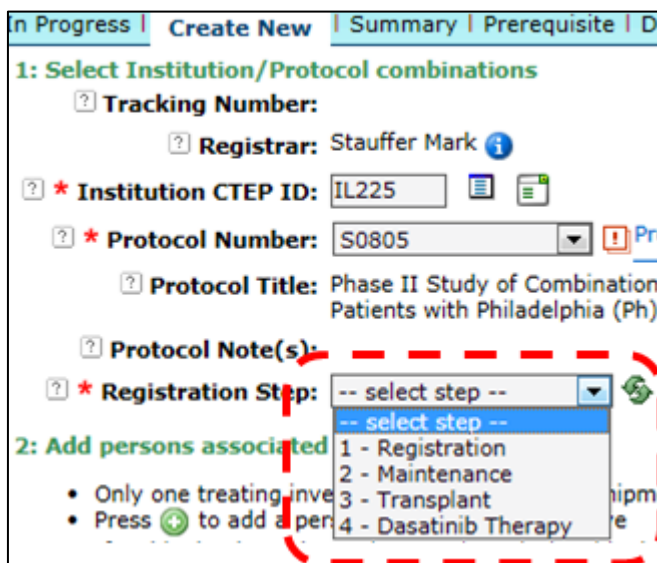


Figure 40: OPEN will Display all Protocol Steps

- 6) Enter the subject's previously assigned patient ID in the Patient ID field and click the Search button.

1: Select Institution/Protocol combinations

? Tracking Number:

? Registrar: Stauffer Mark ⓘ

? * Institution CTEP ID: IL225 ⓘ ⓘ

? * Protocol Number: S0805 ⓘ

? Protocol Title: Phase II Study of Combina with Philadelphia (Ph) Chrc

? Protocol Note(s):

? * Registration Step: 3 - Transplant ⓘ

? * Patient ID: 100234 Search

Please verify the previous step registration details

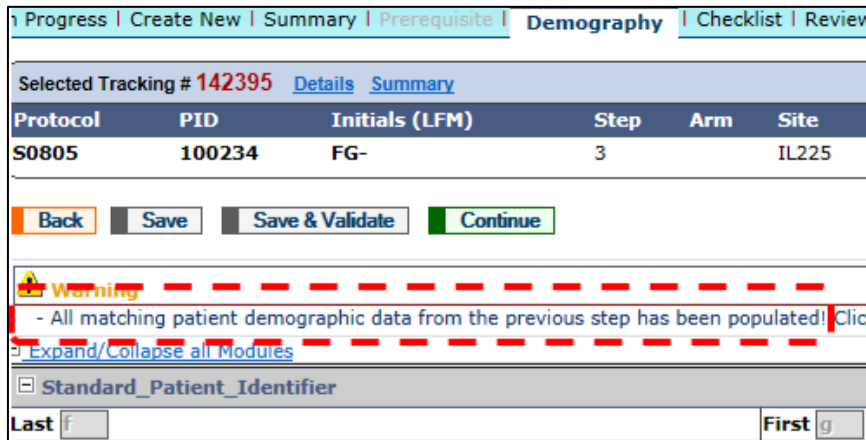
Matching record(s) found - Please verify the details and

Action	Track #	Protocol	Step
Select	142394	S0805	1

Figure 41: Users Must Provide a Patient ID when Skipping Steps

- 7) OPEN retrieves the list of enrollments for the entered patient ID.
- 8) Click the Select button for the subject's previous step enrollment. OPEN fills in the additional fields based on what was previously selected during the subject's previous enrollment step.
- 9) Click the Continue button.

10) OPEN creates the new tracking number and populate details from the previous step for that subject (as shown in Figure 42).



Protocol	PID	Initials (LFM)	Step	Arm	Site
S0805	100234	FG-	3		IL225

Warning - All matching patient demographic data from the previous step has been populated! Click Expand/Collapse all Modules

Figure 42: OPEN Populated the Subject’s Demography Information from a Previous Step to the New Tracking Number

11) Complete the remainder of the enrollment like a normal OPEN enrollment.

4.2.6 Creating a Delayed Enrollment to an Ancillary Study

If the protocol is configured to allow delayed enrollment to an ancillary study, the user is able to enroll on protocols up to a set number of days from the completion of the original enrollment, as specified in the protocol setup.

Accessing this Feature:

- 1) Click on the Create New Registration link on the Welcome screen, or click on the Enroll tab and select the Create New subtab.
- 2) Enter the Institution CTEP ID and the Protocol Number of the main study that the ancillary study is linked with, this should match the site and protocol number of the original enrollment.
- 3) Select the step for which the delayed enrollment needs to be completed.
- 4) Enter in the Patient ID that corresponds with the main study enrollment (as shown in Figure 43) and click the *Tab* key on your keyboard.
- 5) Enrollments matching the entered data is displayed in a new section. Click the Select button to select the record that matches the enrollment and click the Continue button.
- 6) The Create New screen refreshes the information.
- 7) Select the ancillary protocol by checking the corresponding checkbox (as shown in Figure 43).

1: Select Institution/Protocol combinations

Tracking Number:
Registrar: Rudd Brenda (Associate)

Institution CTEP ID: MD015 **Institution Name:**

Protocol Number: CALGB-140503 **Protocols Missing?**

Protocol Title: A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (<= 2 cm) Peripheral Non-small Cell Lung Cancer

Registration Step: 1 - Registration **Steps Missing?**

Registration Type: Patient

Patient ID: 901009360 (Please enter the patient ID if available)

Ancillary protocol selection

- All required ancillary stand-alone/embedded protocols will be auto selected by default

Select	Type	# Days	Reqd.?	Protocol	Title
<input checked="" type="checkbox"/>	STAND_ALONE	15	NO	580602	Embedded Ancillary Study
<input type="checkbox"/>	STAND_ALONE	15	NO	CALGB-140503-E-06	
<input checked="" type="checkbox"/>	EMBEDDED	0	YES	CALGB-140503-E-01	
<input checked="" type="checkbox"/>	EMBEDDED	0	YES	CALGB-140503-E-02	

Figure 43: Delayed Ancillary Study

- 8) Click the Continue button to proceed.
- 9) The Checklist screen appears and the delayed ancillary study checklist form is displayed.

Selected Tracking # 55487 [Details](#) [Summary](#)

Protocol	PID	Initials (LFN)	Step	Arm	Site	Investigator	Status	Status Date
CALGB-140503	1043200588	FGG	1	B	MD015	Brenda Rudd	REGISTERED ^A	01/12/2010

[Back](#) [Continue](#)

[Expand/Collapse all Modules](#)

[580602] Registration Information

CALGB Patient ID (Assigned)

Registration Date / /

[Back](#) [Continue](#) [Full Checklist](#) [Full Checklist](#)

Figure 44: Delayed Ancillary Study Checklist

- 10) Complete the checklist.
- 11) If desired, click the Full Checklist button to review the original enrollment's Checklist screen entries for the main study.
- 12) Click the Continue button to proceed to the Review and Submit screen.
- 13) After reviewing the enrollment information, click the Submit button.
- 14) Click the OK button on the confirmation pop-up window.
- 15) The enrollment result displays on screen.

4.2.7 How to Request an Override to a Validation Error

Overrides to protocol validations are available for certain studies, as configured by the LPO. During an enrollment, if a validation error message displays and a *Request Override* button appears, then the user may request an override to the validation error.

Accessing this Feature:

- 1) Located to the left of the question, an override indicator is present. Placing the mouse cursor over the indicator displays override status information (as shown in Table 5).

Table 5: Override Icons and their Descriptions

Icon	Description
	Indicates a question is eligible for an override.
	Indicates an override request has been initiated.
	Indicates a question has multiple overrides associated with it.
	Indicates an override has been approved.
	Indicates an override has been denied.
	Indicates an override is on hold or is pending.

- 2) Click the Request Override button (as shown in Figure 45) for the desired validation error.

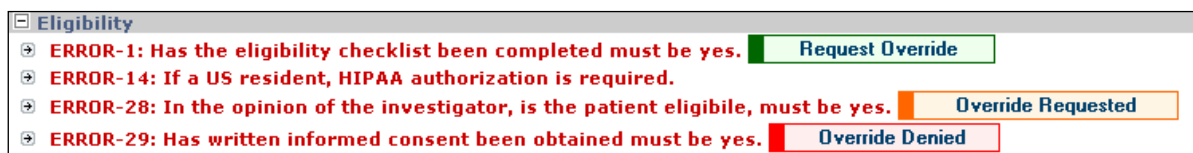


Figure 45: Validation Errors on Eligibility Checklist

3) A new window appears on screen (as shown in Figure 46).

Please enter an override code or a request reason:

Failure Message: ERROR-1: Patient initials must be letters.

Failure Description: Patient initials must be letters.

Override Code:

Request User: Rudd Brenda (Associate)

Request Reason:

Override Status: REQUESTED

Reviewer:

Reviewer Comments:

Figure 46: Override Request

- 4) If an override code is known, enter the override code in the Override Code field (which is an optional field).
- 5) Enter the reason for the override request in the Request Reason field (as shown in Figure 46).
- 6) Click the Submit button. The override request goes to the LPO for review.
- 7) The requesting user and the LPO receives an email notification indicating that an override was requested for the enrollment.
- 8) The Request Override button turns into an orange Override Requested button, to indicate that an override was requested for the validation.
- 9) Once the LPO reviews the override and assigns a status (i.e., approved, denied), the user receives an email notification.
- 10) If needed, the Override Requested button in the eligibility checklist can be used to view the override status for that specific validation error.

Please enter an override code or a request reason:

Failure Message: ERROR-1: Patient initials must be letters.

Failure Description: Patient initials must be letters.

Override Code:

Request User: Rudd Brenda (Associate)

Request Reason:

Override Status: APPROVED

Reviewer: RUDDB

Reviewer Comments: This Override is Approved

Figure 47: Override Approved

11) If the override request is approved, return to the Checklist screen and click the Continue button. If no other validation errors are present, the user can complete the enrollment process. If the override is denied the Override Requested button turns red and the verbiage changes to state *Override Denied* (as shown in Table 5), and the user is unable to complete the enrollment process. Other status possibilities are:

- ON HOLD (an override is pending or holding).
- INACTIVE (the validation was inactivated after the override request was created, and the enrollment process no longer is halted by the validation).

4.2.8 The Duplicate Patient Check

Possible Duplicate Patient Check:

If a patient is entered in the Demography screen that closely resembles a patient that has been previously registered, the system flags the enrollment as a possible duplicate, and the user is notified. The user has the option to state that the enrollment is not a duplicate patient (which allows the user to proceed with the enrollment), or confirm that the enrollment involves a duplicate patient (in which case the enrollment process cannot continue and is voided).

Exact Duplicate Patient Check:

If a patient is entered in the Demography screen that exactly matches a patient that had been previously been enrolled, the system flags the enrollment and notify the user. The user is unable either confirm that the enrollment involves a duplicate patient (and the in progress enrollment is voided), or the user can place the enrollment on hold for further investigation (the enrollment becomes an INCOMPLETE status).

4.2.9 Performing a Practice Enrollment

Users are able to perform a practice mode enrollment in the OPEN Portal to simulate the enrollment process. **Enrollments created in practice mode do not create real enrollment information** and are for instructional purposes.

Accessing this feature:

- 1) On the Welcome page of OPEN, click the Start Practice button (as shown in Figure 48).

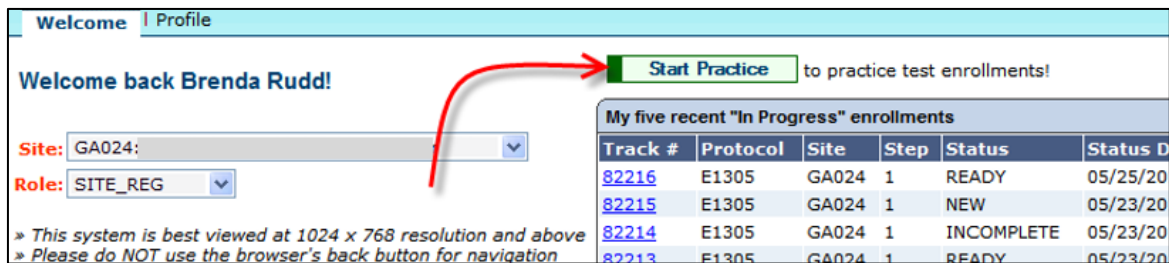


Figure 48: Start Practice button

- 2) The screen refreshes and all screens within OPEN use an orange color scheme along with a Practice/Test Registration watermark, and a Stop Practice button that appears next to the Role field (as shown in Figure 49).

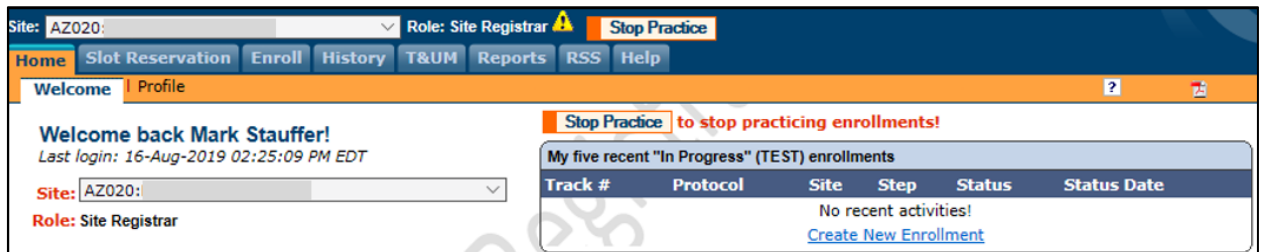


Figure 49: Practice Mode

- 3) While the system is in practice mode, only the Enroll, History, and Help screens are active. If other tabs are clicked, a message displays text that reads *Not available during practice or test mode!*
- 4) All enrollments created in practice mode have a super script **T** attached to the tracking number to indicate that the enrollment is a practice mode enrollment (as shown in Figure 50).

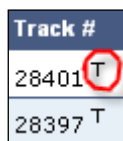


Figure 50: Practice Mode Tracking Numbers include a T

- 5) While in practice mode, the user is able to duplicate an existing enrollment. This feature is only available for step 1 studies that do not have ancillary studies. To use the Duplicate Enrollment feature:
 - a) From the In Progress subtab (of the Enroll tab) or the History tab, click the Duplicate Enrollment icon associated with the enrollment that is copied.
 - b) Click the OK button on the confirmation pop-up window and a pop-up message confirms the enrollment is successfully duplicated (as shown in Figure 51).



Figure 51: Confirmation Message Indicating an Enrollment was Successfully Duplicated

- c) Once an enrollment is duplicated, it is found on the In Progress screen of the Enroll tab.
- 6) The user can proceed with completing the enrollment process for a practice mode enrollment.
- 7) Upon final submission of the enrollment, a confirmation pop-up window reminds the user that the enrollment is being created in practice mode (as shown in Figure 52).

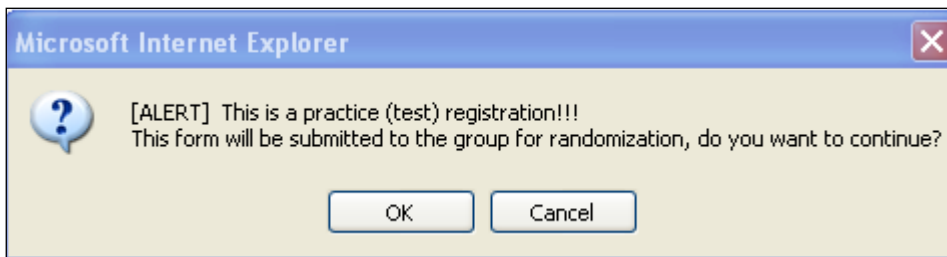


Figure 52: Message Reminding the User that the Enrollment is Being Created in Practice Mode

4.2.10 Automatic Session Timeout

If a user is logged into OPEN for 24 minutes without activity (such as clicking a tab or subtab, moving to a new screen, or saving their data), they receive a pop-up message (as shown in Figure 53) stating that their session is about to expire, and they need to click OK to avoid being automatically logged out of OPEN (six minutes later).

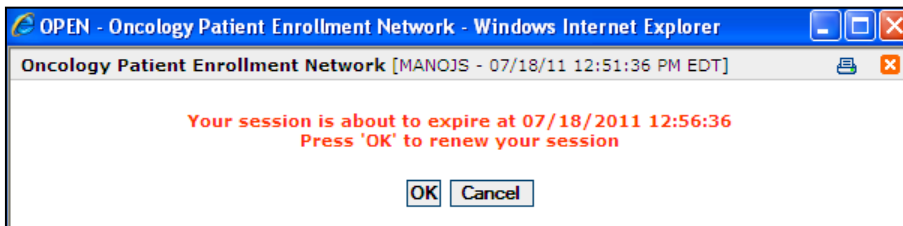


Figure 53: Session Timeout Alert

If the user remains inactive after receiving the session timeout pop-up, their data will automatically be saved at minute 28, prior to the automatic log out that occurs after 30 minutes of inactivity.

For users of the Google Chrome browser, pop-up blocking is enabled by default. In such cases, the session timeout pop-up message will be blocked. Follow these steps to disable pop-up blocking in Google Chrome:

- 1) Click the wrench icon on the browser toolbar (as shown in Figure 54).

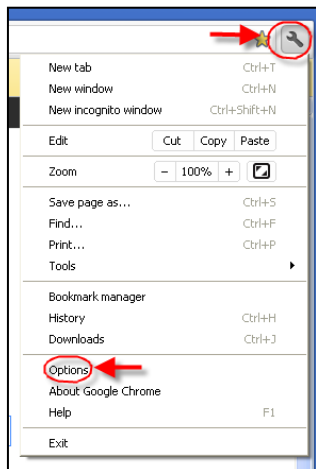


Figure 54: Select Options

- 2) Select the *Options* choice (as shown in Figure 54).
- 3) Click the *Under the Hood* tab (as shown in Figure 55).
- 4) In the Privacy section, click *Content Settings* (as shown in Figure 55).
- 5) In the Pop-ups section, click *Allow all sites to show pop-ups*. Once the settings are changed to allow pop-ups in the Chrome browser, this feature works similar to Internet Explorer (as shown in Figure 55).

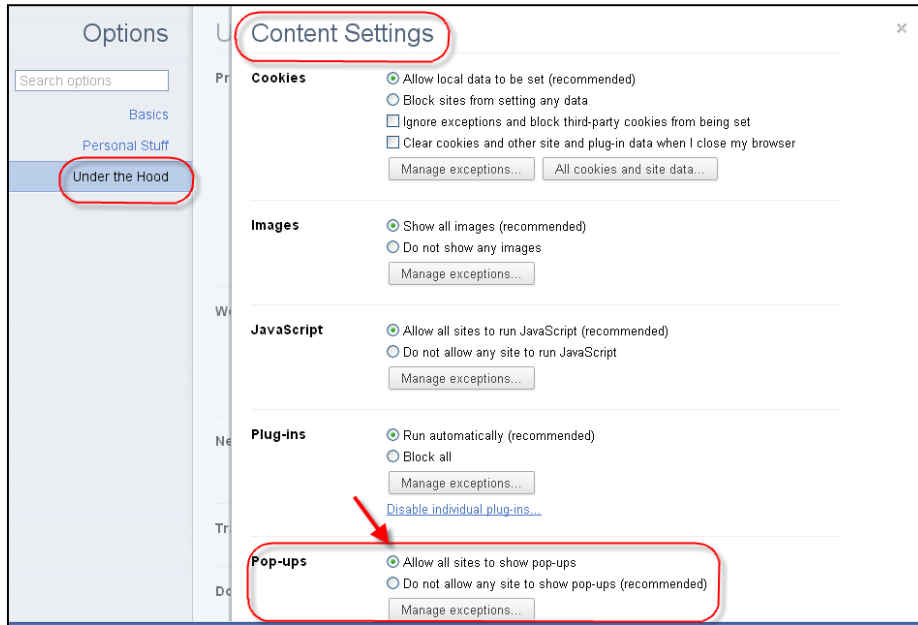


Figure 55: Allow Pop-ups

4.2.11 Using the In Progress Subtab

The In Progress subtab of the Enroll tab allows users to view and complete In Progress enrollments for any institutions with which the user is associated. The In Progress subtab can either show patient enrollments (as shown in Figure 56) or non-patient enrollments (as shown in Figure 57).

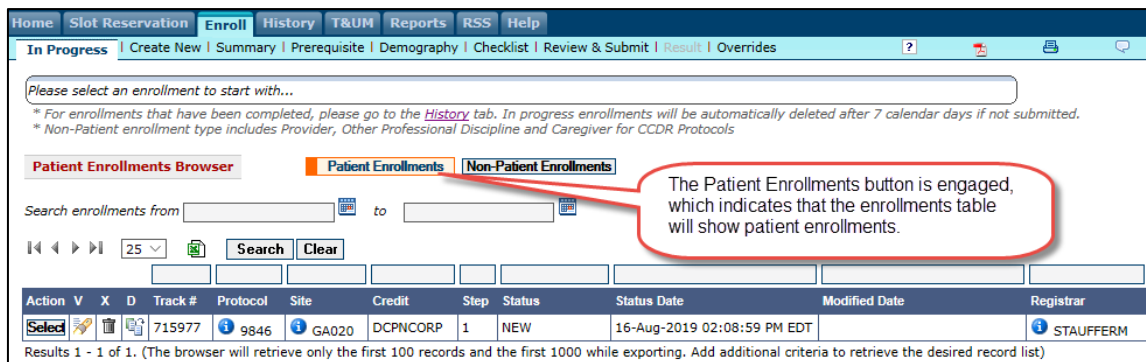


Figure 56: The In Progress Subtab Displaying Patient Enrollments

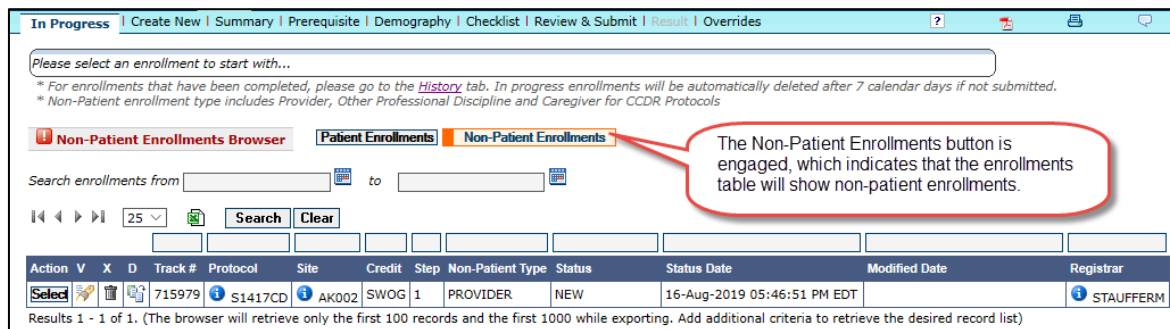


Figure 57: The In Progress Subtab Displaying Non-Patient Enrollments

The In Progress screen browser displays the following information:

- Tracking #
- Protocol
- Site CTEP ID
- Credited Organization
- Enrollment step
- Enrollment status
- Date and time the enrollment was initialized
- Date and time the enrollment was modified
- User who initiated the enrollment

Accessing this feature:

- 1) Click on the Enroll tab and the In Progress screen shows by default.
- 2) If the desired enrollment is not listed, the user can:
 - Search for the enrollment by their patient ID or Tracking number.
 - Navigate to the next range of records.
 - Change the number of records listed at a time to 50 or 75 (from the default 25).
- 3) Click the Select button in the row that corresponds to the enrollment that is accessed.
- 4) The screen refreshes and the user will be on the Summary screen for the selected enrollment. The user can continue the enrollment process by clicking the Continue button.

4.2.11.1 Statuses for In Progress Enrollments


Each OPEN enrollment has an assigned status (as shown in Table 6).

Table 6: Enrollment Statuses


Enrollment Status	Description
NEW	An enrollment is given the status of NEW when the enrollment is saved for the first time (the demography or eligibility checklist has not yet been started).
INCOMPLETE	This status is assigned after the corresponding checklist form has been started but has not been submitted or has validation.
REGISTERED	This status is assigned when a delayed ancillary enrollment is in progress and the main enrollment has already been completed.
READY	An enrollment is given the status of READY when the eligibility checklist has been successfully validated and saved and is ready for submission.
SUBMITTED	An enrollment is given the status of SUBMITTED when it has been forwarded to the LPO but the LPO's system was not able to receive the data.
VOID	When an enrollment has been saved but never submitted, the enrollment automatically changes to a VOID status after seven calendar days.

4.2.12 Deleting In Progress Enrollments


In Progress enrollment records (except those that have a SUBMITTED status) are deleted. Once an enrollment is deleted, it cannot be recovered. Enrollments in the History tab are set to a CANCELLED status by administrative users (enrollments cannot be deleted in the History tab).

- 1) Select the In Progress subtab of the Enroll tab.
- 2) Locate the record that should be deleted.
- 3) Click the trashcan  icon for the row that corresponds to the enrollment that is deleted.
- 4) Click the OK button on the confirmation pop-up screen to delete the enrollment.

4.2.13 View Item Information

Information about a specific item is displayed by clicking the  At-A-Glance (AAG) button associated with that item. This button appears on multiple screens in OPEN.

Accessing this Feature:

- 1) The user locates the item requiring more information.
- 2) Click the  AAG button that is adjacent to the particular field.
- 3) The item's AAG information pop-up window appears on screen (as shown in Figure 58).

Close

CTSU_ID: 509790
Name: Rudd, Brenda
NCI Site #:
NCI Status: Active

CTSU ID:
Site Name:
Status DATE: 27-MAY-08

Contact Data:

CTEP	Email	brendarudd@westat.com
CTEP	Office fax	
CTEP	Office phone	

Associate (CTEP):

Active Membership:

Group	P	Site CTEP #	Site Name	Study Type	Status	Date	Drug
CTSU	N	CTSU		Treatment	Active	11/08/2006	N
CTSU	N	ECOG		Treatment	Active	06/30/2008	N
CTSU	N	GA024		Treatment	Active	08/07/2008	N
CTSU	N	MI014		Treatment	Active	08/07/2008	N
CTSU	N	PA074		Treatment	Active	08/07/2008	N
CTSU	N	VT004		Treatment	Active	06/30/2008	N

Workflow:

Date	Action	By	From State	To State	Value
No workflow information available.					

Figure 58: AAG Information Pop-up Window

4.2.14 Using the Search Feature in the Browser Screens

Users can filter Browser screen results (such as in the In Progress or History screens) using the search feature. A user can use a single field or multiple fields.

Accessing this feature:

- 1) Click on the In Progress subtab of the Enroll tab or the History tab.
- 2) Locate the field(s) in the Browser screen that needs to be filtered (as shown in Figure 59):
 - Tracking Number
 - Study
 - Site CTEP ID
 - Credit
 - Registration Step
 - Patient ID Number (History Tab only)
 - Registration Status
 - Status Date
 - Modified Date (In Progress Tab only)
 - Registrar

Action	V	X	D	Track #	Protocol	Site	Credit	Step	Status	Status Date	Modified Date	Registrar
Select				240259	ACCRN07	GA022	COG	1	INCOMPLETE	03/25/2015 11:49 AM	03/25/2015 11:51 AM	LAPSM
Select				240253	S1400	MN008	ALLIANCE	1	INCOMPLETE	03/25/2015 11:27 AM	03/25/2015 11:27 AM	LEUNGV

Figure 59: In Progress Enrollment Search Screen

- 3) Enter the corresponding field information into the appropriate field(s) (as shown in Figure 59). The percent sign % expands the search field content and the number of results that are returned. However, adding multiple search criteria will further reduce the number of enrollments returned.
- 4) Click the Search button and the screen refresh with the filtered results.

4.2.15 Editing Credentialing Information for an In Progress Enrollment

A user can edit the Create New (Credentialing) screen information for an In Progress enrollment as long as the record is not in a SUBMITTED or REGISTERED status.

Accessing this feature:

- 1) Click the Enroll tab and the screen defaults to the In Progress subtab.
- 2) Locate the desired enrollment and click the Select button for its corresponding row.
- 3) The screen defaults to the Summary screen for the selected enrollment.
- 4) Click on the Edit Summary button.
- 5) Update the information as needed. All sections of the Create New screen updates after the enrollment is initiated except for section 1 (Select Institution/Protocol combinations).
- 6) Click the Continue button.
- 7) Click the OK button on the pop-up confirmation box.
- 8) Proceed with the enrollment process.

4.2.16 Exceptional Responder Studies

A record is created in Rave when an enrollment for an Exceptional Responder (ER) study is completed in OPEN. At the enrollment confirmation screen in OPEN, the user encounters a hyperlink at the bottom of the page that provided a direct link into the subject’s record in Rave, so the user does not have to log in to Rave and navigate to the appropriate form. The user must click the link to complete the data collection process (as shown in Figure 60).

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

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

Selected Tracking # **167563** Details Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status
S1001	247952	GHN	1	2	IL017		REGISTERED

Information

- Network Group response for tracking # **167563**
- This registration can now be found in the HISTORY section
- Click on [View Summary] to view the complete registration summary

Network Group Response(s)

Eligibility:	ELIGIBLE
Ineligibility Reason:	None.
Patient ID:	247952
Treatment Arm:	2

Site Instruction:

Assigned Treatment: 2 = R-CHOP x 6

Study End Notes

See Section 15.2 of S1001 protocol for information on FDG-PET image sub central review of FDG-PET imaging.

Expectations for this registration

BTASSES - Baseline tumor assessment - -- Posted: 02/10/2014 - Due: 02/17/2014

CTSCAN - CT Scan Report - Baseline PET/CT -- Posted: 02/10/2014 - Due: 02/17/2014

PRESTUDY - Prestudy form - -- Posted: 02/10/2014 - Due: 02/17/2014

SXPATHTQ - Pre-reg Pathology Report - Including CD20 expression -- Posted: 02/10/2014 - Due: 02/17/2014

PATHS... -- Posted: 02/10/2014 - Due: 03/10/2014

CTSC... -- Posted: 02/10/2014 - Due: 04/10/2014

Please let us know your enrollment status, which should not take more than 2 weeks.

[View Summary](#)

Successfully pushed the Exceptional Responder Study to Rave. Please [click here](#) to go to the Rave study/site listing page

Figure 60: Example of the Rave Hyperlink for ER Studies

4.2.17 Support for Molecular Analysis for Therapy Choice Integrations

NCI Molecular Analysis for Therapy Choice (MATCH) is a Precision Medicine Initiative (PMI) where oncology patients receive treatments according to the genetic changes found in their tumors. PMI studies require exchange of trial data between various applications, including OPEN.

Sites may enroll eligible subjects to the combo MATCH and myeloMATCH screening studies and their corresponding treatment studies.

For MATCH studies, sites can upload and review CLIA and Pathology Reports from the Summary Screen.

PATH Reports using the Upload/Review button

Accessing this feature:

- 1) Click on the History Module and Browse screen. Select the appropriate MATCH enrollment by clicking on *Select* button to be taken to the Summary Screen.
- 2) From the Summary Screen, click on *Upload/Review Reports* button, as shown in Figure 61.
- 3) Click on *Choose File* button to select the file, and select either CLIA or Pathology for the Report Type dropdown, and include Sample Collection Date, as in Figure 62. Click on *Upload* button to upload the report.
- 4) To review the report, select the same enrollment for which the report was uploaded to be taken to the Summary screen. Select *Upload/Review* button. The report should be available from the Uploaded Report section of the screen. Click on the Download action button to download the report, as shown in Figure 63.

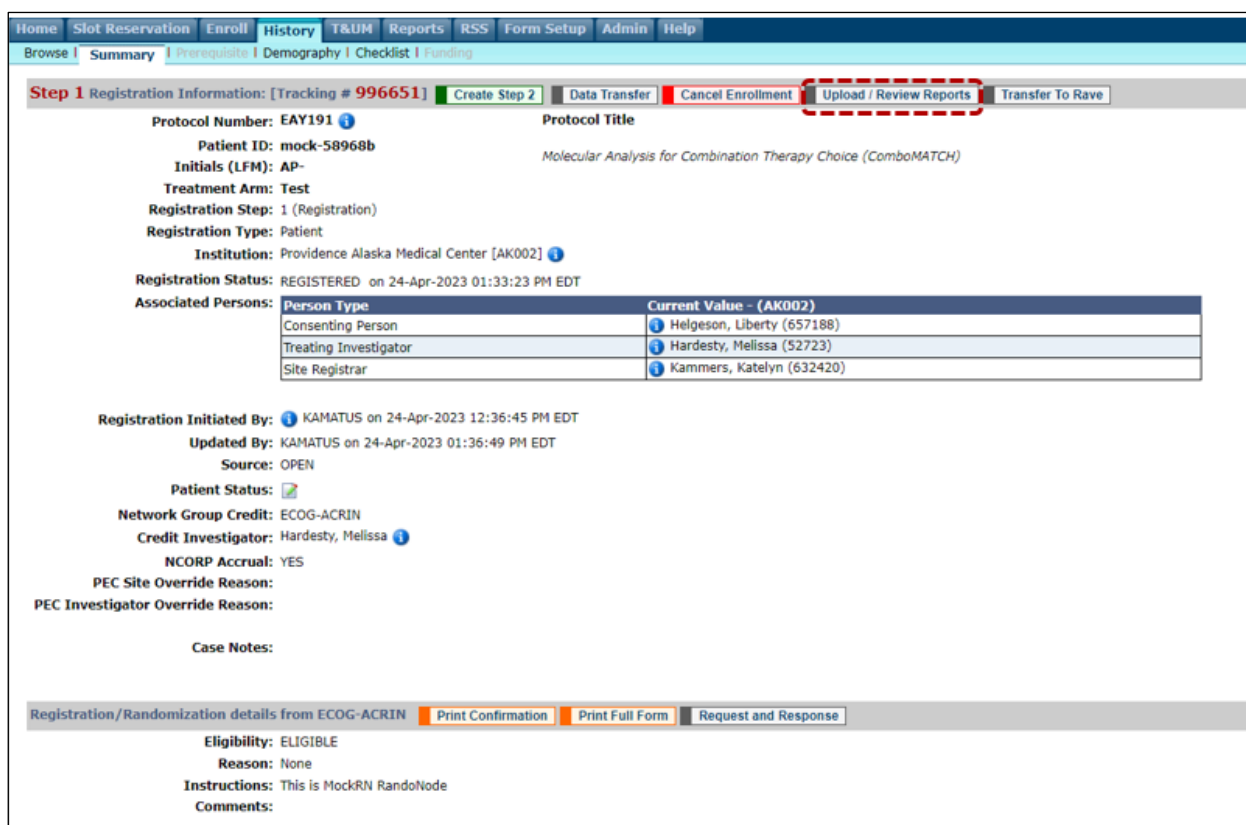


Figure 61: Accessing Upload/Review Button from Summary Screen

Matchbox Reports: [Patient ID # **mock-58968b**]

- Please use the uploader to attach the following reports:**
 - Pathology Report
 - CLIA Report
- Maximum file size is 50MB per attachment
- Accepted upload file type is PDF

Choose File **Report-CLIA.pdf**

* Report Type: CLIA

* Sample Collected Date: 11-April-2023

Comments: Uploading CLIA Report

Upload

Uploaded Reports:

Action	File Name	Report Type	Sample Collected Date	Uploaded By	Uploaded Date	Comment
No reports found						

Refresh


Figure 62: Uploading CLIA/Pathology Reports

Matchbox Reports: [Patient ID # **mock-58968b**]

- Please use the uploader to attach the following reports:**
 - Pathology Report
 - CLIA Report
- Maximum file size is 50MB per attachment
- Accepted upload file type is PDF

Choose File **No file chosen**

Uploaded Reports:

Action	File Name	Report Type	Sample Collected Date	Uploaded By	Uploaded Date	Comment
	Report-CLIA.pdf	clia	11-Apr-2023	Makbul, Lela A.	24-Apr-2023 04:52:14 PM EDT	Uploading CLIA Report

Refresh

Figure 63: Downloading CLIA/Pathology Reports

In addition, within the Summary page, the MATCHBox Assignment/Enrollment section will display details about the including treatment assignment, assignment status, cohort, stratum, and reason. Treatment Study enrollment details will also be displayed if a patient successfully enrolled on to a treatment trial, as illustrated in Figure 64.

MatchBOX Assignments/Enrollments						
Assignment:	Name	Value				
	Name	EAY191				
	Treatment assignment	EAY191-N4				
	Assignment status	SELECTED				
	Cohort	C1				
	Stratum	S1				
Reason	Participant matches to inclusion nucleotide on GENOMIC HGVS: GENE_SYMBOL: NF1, PROTEIN_HGVS: NP_001035957.1:p.Arg1204Trp, GENOMIC_HGVS: NC_000017.11:g.31233115C>T, ALLELE_FREQUENCY: 0.6687, ALLELE_FREQUENCY_CUTOFF: 0.05, SAMPLE_TYPE: SOMATIC, VARIANT_SOURCE: SUBPROTOCOL. Participant matches to inclusion nucleotide on GENOMIC HGVS: GENE_SYMBOL: MAP2K1, PROTEIN_HGVS: NP_002746.1:p.Leu42_Lys57del, GENOMIC_HGVS: NC_000015.10:g.66435071_66435118del, ALLELE_FREQUENCY: 0.505, ALLELE_FREQUENCY_CUTOFF: 0.1, SAMPLE_TYPE: SOMATIC, VARIANT_SOURCE: SUBPROTOCOL. Participant matches to inclusion disease: MORPHOLOGY_CODE: 8441, MORPHOLOGY_TERM: Serous cystadenocarcinoma, NOS, BEHAVIOR_CODE: 3, GRADE_CODE: 1, TOPOGRAPHY_SITE: C56, TOPOGRAPHY_SUBSITE: 9, TOPOGRAPHY_TERM: Ovary, TOPOGRAPHY_CATEGORY: C51-C58 FEMALE GENITAL ORGANS, MORPHOLOGY_CATEGORY: 844-849 Cystic, mucinous and serous neoplasms. Participant matches to inclusion disease: MORPHOLOGY_CODE: 8441, MORPHOLOGY_TERM: Serous cystadenocarcinoma, NOS, BEHAVIOR_CODE: 3, GRADE_CODE: 1, TOPOGRAPHY_SITE: C56, TOPOGRAPHY_SUBSITE: 9, TOPOGRAPHY_TERM: Ovary, TOPOGRAPHY_CATEGORY: C51-C58 FEMALE GENITAL ORGANS, MORPHOLOGY_CATEGORY: 844-849 Cystic, mucinous and serous neoplasms. Participant satisfies AGE AT REGISTRATION requirement: AGE_AT_REGISTRATION: 53, AGE_RANGE: >=18. Participant satisfies ECOG SCORE requirement: ECOG_SCORE: 2, MIN-MAX_VALUE: 0-2. There are no VARIANT EXCLUSIONS specified for this TREATMENT PROTOCOL. There are no DISEASE EXCLUSIONS specified for this TREATMENT PROTOCOL. There are no PRIOR THERAPY INCLUSIONS specified for this TREATMENT PROTOCOL. Participant has no prior therapy exclusions for this TREATMENT PROTOCOL.					
Treatment Study Enrollment(s):	Protocol	Site	Step	Treatment PID	Treatment Assignment Status	Enrollment Date
	EAY191-N4	AK002	1	mock-c43e88	Test REGISTERED	15-Feb-2023

Figure 64: MatchBOX Assignment and Enrollment Information

5. History Tab

The History tab allows users to view the details for completed OPEN enrollments. This section discusses the various subtabs and features found in the History tab.

A green delta symbol appears next to questions that had their responses updated post-enrollment, so OPEN users are aware of post-enrollment data updates (as shown in Figure 65).

Figure 65: Green Delta Symbol Indicates Fields with Post-Enrollment Updates

5.1 Browse Subtab

The Browse subtab allows the user to view a list of all enrollments that have been completed at any institution where the user has a roster affiliation (as shown in Figure 66).

Action	V	D	Track #	Protocol	Site	Credit	Cred Inv.	Step	Step Type	Count Towards	PID	Arm	Status	Randomized Date	NCORP	T&UM Type	Enrolling Site	Enrolling Credit	Enroll Cred Inv.	Source
Select			A041703	ECOG-ACRIN	IL017			1	IN	Y		Test	REGISTERED	24-Aug-2020	NO		IL017	ECOG-ACRIN		OPEN
Select			A041703	ECOG-ACRIN	IL017			0	O	N		Test	REGISTERED	24-Aug-2020	NO		IL017	ECOG-ACRIN		OPEN
Select			S1803	ALLIANCE	NJ146			1	IN	N		Test	REGISTERED	24-Aug-2020	NO		NJ146	ALLIANCE		OPEN
Select			S1501	ALLIANCE	IL017			1	SC	Y		Test	REGISTERED	24-Aug-2020	NO		IL017	ALLIANCE		OPEN
Select			S1501	ALLIANCE	IL017			1	SC	Y		Test	REGISTERED	24-Aug-2020	NO		IL017	ALLIANCE		OPEN

Figure 66: Browse Subtab (of the History Tab)

The definitions for the Source column are as follows:

- OPEN - enrollments completed in OPEN by the enrolling site staff.
- Non-OPEN:
 - Registrar - enrollments completed by a CTSU registrar and loaded in OPEN.
 - Load Payment - enrollments used to process past payments and loaded in OPEN.
 - Load LPO - enrollments received by the LPO and loaded in OPEN.

Select either the Patient Enrollments or Non-Patient Enrollments button to switch between viewing enrollment data for patient and non-patient enrollments.

Enrollments are filtered, sorted, and searched based on search criteria (as shown in Figure 67).

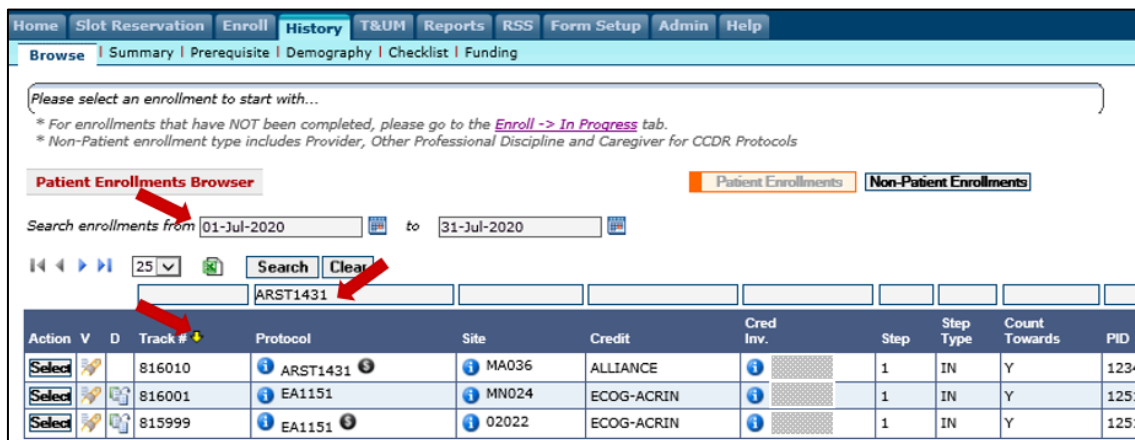


Figure 67: Filter, Sort, and Search Features in OPEN

The following fields will be displayed:

- Track #
- Protocol
- Site
- Credit
- Step
- Step Type
- Count Towards
- PID (Patient ID number)
- Arm (Treatment Arm)

- Eligibility
- Status (of the enrollment)
- Randomized Date (date and time the enrollment was completed)
- T&UM Type (whether a Transfer & Update Module (T&UM) request is associated with an enrollment)
- Registrar (the user who completed the enrollment)

To view a Summary for an enrollment:

- 1) Click on the History tab or click the Registration History link on the Welcome page.
- 2) The History tab refreshes and the Browse subtab displays by default.
- 3) Click the *Select* button for the desired enrollment and to display the Summary screen. The user then selects the Demography or Checklist subtabs to access the information for those screens. For more information on locating enrollment records (as shown in section 4.2.14).

5.1.1 Statuses for Enrollments in the History Tab

Table 7 describes the different statuses assigned to enrollments that are found in the History tab of OPEN.

Table 7: List of OPEN Enrollment Statuses (for Enrollments in the History Tab)

Status	Description
REGISTERED	This status is assigned after an enrollment is submitted to the LPO and a patient ID and treatment arm is returned and received by OPEN.
INELIGIBLE	The enrollment is deemed ineligible by the associated LPO.
CANCELLED	This status is assigned when a completed enrollment is withdrawn. Only administrators are able to cancel a completed enrollment.

5.1.2 The T&UM Type Menu

The T&UM Type column in the Browse subtab allows OPEN users to identify which subject enrollments involve and approve T&UM requests. The type of T&UM request is indicated in the T&UM Type column (as shown in Figure 68).

Instructions for using the T&UM Type column:

- 1) Log in to OPEN.
- 2) Click the History tab. The Browse subtab displays by default. The T&UM Type column has one or more designations for enrollments that have an approved T&UM request. If no approved T&UM requests are associated with an enrollment, the T&UM Type value for the enrollment is blank.

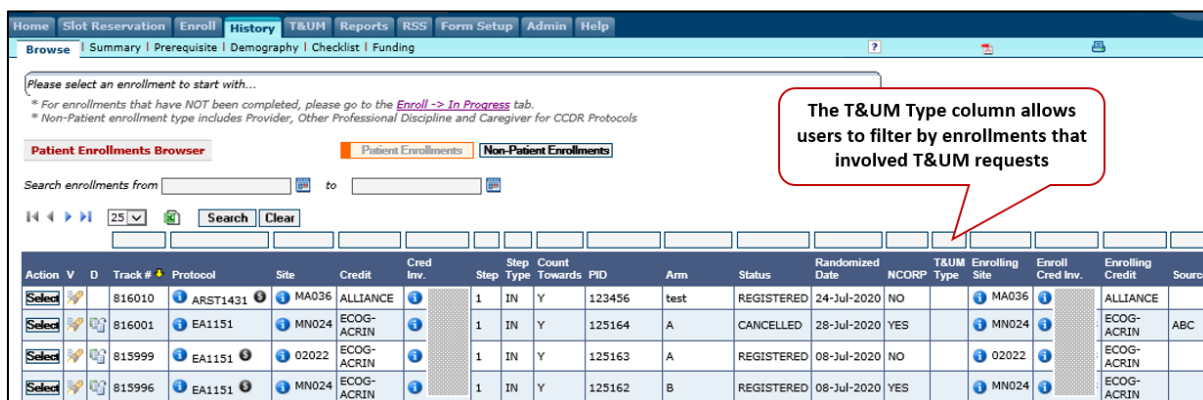


Figure 68: The T&UM Type Column Identifies Enrollments with Approved T&UM Requests

- 3) To filter through the enrollments by a particular T&UM Type (none, Credentialing Data Update, Demographic Data Update, Site Transfer), click the text-entry box above the T&UM Type column and select the appropriate choice (as shown in Figure 69).

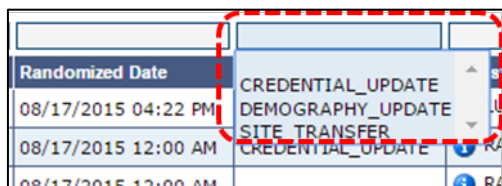


Figure 69: Results are Filtered by the T&UM Type

- After making a selection in the text-entry box above the T&UM Type column, the results refresh as requested (as shown in Figure 70).

Please select an enrollment to start with...
* For enrollments that have NOT been completed, please go to the [Enroll -> In Progress](#) tab.
* Non-Patient enrollment type includes Provider, Other Professional Discipline and Caregiver for CCDR Protocols

Patient Enrollments Browser Patient Enrollments Non-Patient Enrollments

Search enrollments from to

25

Action	V	D	Track #	Protocol	Site	Credit	Cred Inv.	Step	Step Type	Count Towards	PID	Arm	Status	Randomized Date	NCORP	T&UM Type	Enrolling Site	Enroll Credit Inv.	Enrolling Credit	Source
Select			815408	APECL14B1	PA076	COG	11337	1	O	Y	896060	Not applicable	REGISTERED	05-Jul-2020	NO	S	PA076	43277	COG	OPEN
Select			814492	EAZ171	MI202	ECOG-ACRIN	39046	1	IN	Y	10039	A	REGISTERED	30-Jun-2020	YES	S	MI202	39046	ECOG-ACRIN	Non-OPEN

Figure 70: The Filtered Results for the T&UM Type

5.2 Summary Subtab

This section discusses topics relating to the Summary subtab of the History tab.

5.2.1 ER Push

Enrollments for the ER protocol 9671 are performed in OPEN. Upon completion of those enrollments (unlike other Rave studies), OPEN immediately initializes the ER subjects to Rave. The action is noted in the Registration Workflow with MANUAL_RAVE_TX. If the initialization fails, site users use the ER Push feature to manually retry the patient initialization to Rave.

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

Browse | Summary | Prerequisite | Demography | Checklist | Funding

Step 2 Registration Information: [Tracking # 670634] [Go to Previous Step](#) [Data Transfer](#) [Cancel Enrollment](#) [T&UM Report](#) [Email](#)

Protocol Number: A011401 ⁱ
 Patient ID:
 Initials (LFM):
 Treatment Arm: 2
 Treatment Assignment Code: OTHER
 Treatment Assignment Description: 2 Year Health Education Intervention + Supervised Weight Loss Intervention
 Registration Step: 2 (Randomization)
 Registration Type: Patient
 Institution: [CA194] ⁱ
 Registration Status: REGISTERED on 07-Aug-2018 06:45:18 PM EDT

Associated Persons:

Person Type	Current Value - (CA194)	Initial Value - (CA668)
Treating Investigator	ⁱ	ⁱ
Site Registrar	ⁱ	ⁱ

Drug Shipping Address: Initial Value:
 Registration Initiated By:
 Updated By:
 Source: OPEN
 Patient Status:
 Network Group Credit: Initial Value:
 Credit Investigator: Initial Value:
 NCORP Accrual: NO
 Case Notes:

Registration/Randomization details from ALLIANCE [Print Confirmation](#) [Print Full Form](#) [Request and Response](#)

Eligibility: ELIGIBLE
 Reason:
 Instructions: Study A011401: Arm Information: Education + Weight Loss
 Comments:

Checklist Form Details

Form Name: A011401 OPEN Enrollment: Randomization (Step 2)
 Step: 2
 Category: Eligibility
 Type: CRF
 Version: 1.0
 Latest Version: YES
 Status: ACTIVE
 Instruction:

Overrides associated with this registration
 No overrides requested

ⁱ Registration Workflow

Date	Action	Value
05-Mar-2019 02:14:08 PM	UPD_KEY	
05-Mar-2019 02:14:08 PM	SITE_TRANSFER	TUM-0000007877

RDTS [Generate RDTS TX](#)

No RDTS change log found!

The *Email* button will generate an enrollment email to the logged-in user.

This button will send a *Real-time Data Transfer System (RDTS)* transaction to the LPO.

Figure 71: Summary Subtab of the History Module

5.3 Per-Case Funding

Studies with additional NCI-approved per-case funding requires site staff to enter the completion dates for the funding types. This information is captured in the History tab of OPEN.

Steps for entering completion dates for funding types:

- 1) Log in to the OPEN Portal.
- 2) Click the History tab.
- 3) Locate the subject that was enrolled on a study that involves per-case funding (as shown in Figure 72).

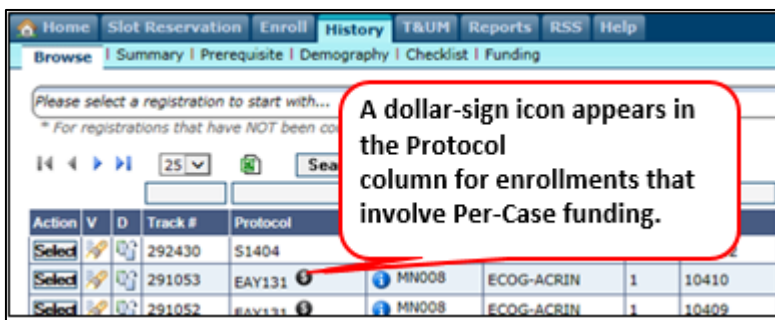


Figure 72: Dollar-Sign Icon Indicates the Enrollment involves Per-Case Funding

- 4) Click the Select button for the subject’s row.
- 5) Click the Funding subtab (as shown in Figure 73).

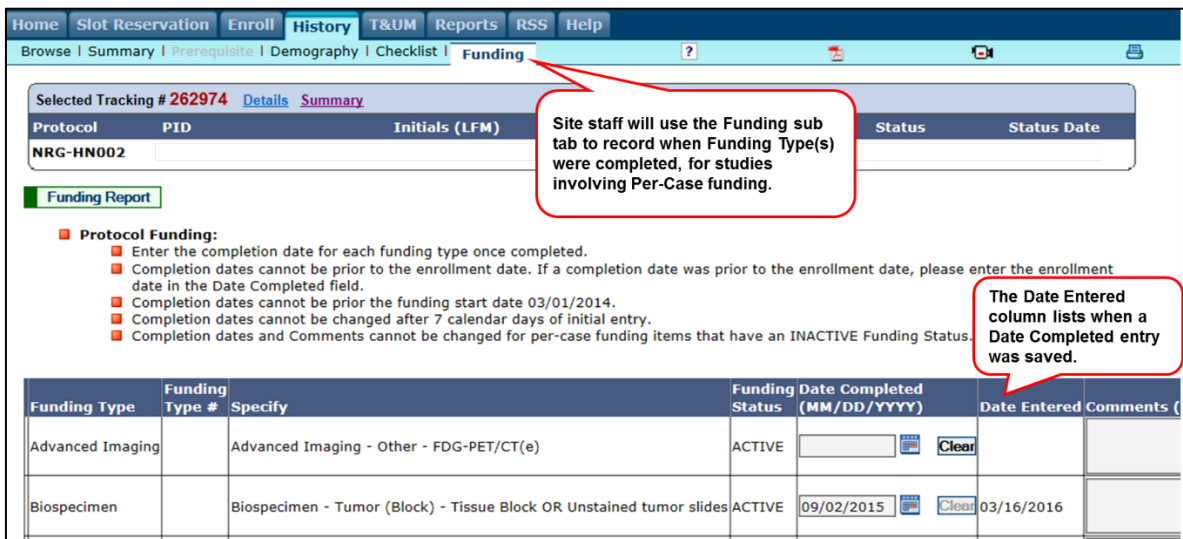


Figure 73: Funding Subtab

- 6) Enter the Date Completed for the individual Funding Type(s).

- 7) Enter a value in the Comments field (if needed) for saving a note for internal purposes. These comments are not sent to the LPOs, nor are they included in any LPO accrual reports.
- 8) Click the Save button.
- 9) Once the screen refreshes, a confirmation message displays on screen and the *Date Entered* value populates for the newly saved entry (to indicate when the Date Completed was saved).


For further information on using the Funding Screen, view the Funding Screen Site User Guide:

https://www.ctsu.org/open/Site_Resources/Training/Users_Manual/FundingScreenSiteUserGuide.pdf

5.3.1 Funding Report

Since a site may have many subjects on studies that involve per-case funding, a Funding Report is available to provide a list of all per-case funding items for a particular institution. Oral Agent funding information will also be displayed in the Funding Report.

Accessing the funding report:

- 1) Log in to OPEN.
- 2) Click the History tab and the user will be brought to the Browse subtab.
- 3) Click the Per-Case Funding  icon for a subject enrollment (as shown in Figure 74). The per-case funding item results is for the site that is linked to the subject enrollment that is selected.

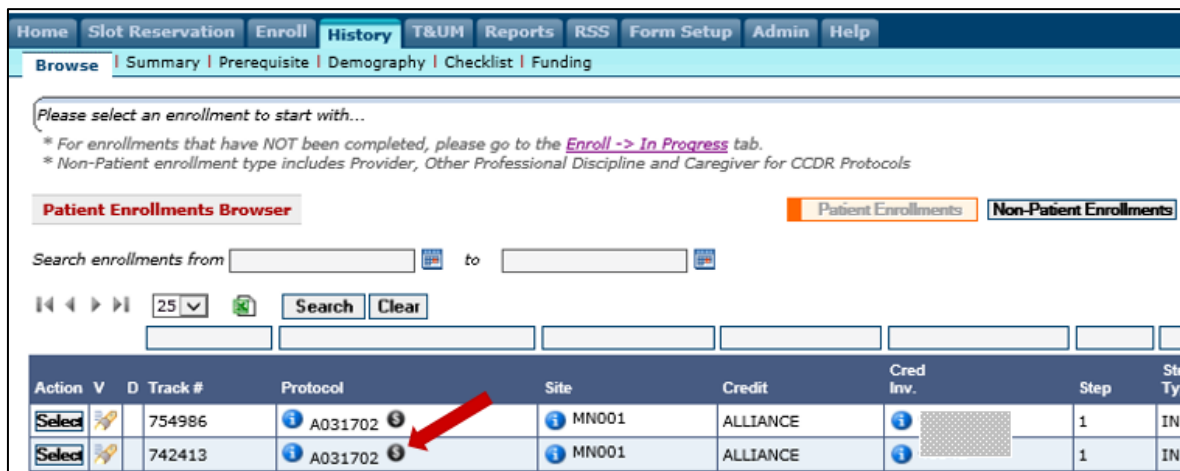


Figure 74: Click the Per-Case Funding Icon to Launch the Funding Report

The Funding Report will launch in a separate pop-up window, displaying all of the per-case funding items for a single selected site or multiple selected sites (as shown in Figure 75).

Funding Report for [redacted] (MN001)

To sort the results by Completion Date, click the header of "Completion Date" column.
 To show results for a particular site, enter the NCI Site Code in the Site column, and click the Search button.
 The Excel Export feature for the Funding Report will display a maximum of 5,000 records for all sites that the user has roster affiliations with.

Search funding from [] to []

25 Search Clear

Site	Protocol	Credit Network Group	Investigator	Patient ID	Enrollment Date	Funding Type	Funding #	Collect Type	Funding Status	Specify
MN001	A011202	ALLIANCE	[redacted]	9122953	19-Feb-2019 05:18:00 PM EST	Quality of Life		Optional	ACTIVE	Quality of Life - lymphedema companion study
MN001	A011401	ALLIANCE	[redacted]	9110158	28-Oct-2016 02:39:34 PM EDT	Biospecimen		Optional	ACTIVE	Biospecimen - Tissue - Tissue blocks
MN001	A011401	ALLIANCE	[redacted]	9110158	28-Oct-2016 02:39:34 PM EDT	Biospecimen		Optional	ACTIVE	Biospecimen - Whole Blood
MN001	A011401	ALLIANCE	[redacted]	9110158	28-Oct-2016 02:39:34 PM EDT	Quality of Life		Mandatory	INACTIVE	Quality of Life - Patient Reported Outcomes substudy (A011401-H01)

Figure 75: Funding Report

The site users are able to search Funding reports that occur between specific date ranges. The Collect Type column includes the following values: mandatory, mandatory requests, optional, and conditional. The Funding Status column of the Funding Report allows a user to identify which per-case funding items still need to be collected. The Funding Status can be either Active or Inactive. Completion Dates need to be collected for per-case funding items that have an ACTIVE Funding Status.

The Site column in the Funding Report is a searchable field, so users may enter either a single or multiple site(s) (which they have roster affiliations with), as illustrated in Figure 76.

Funding Report for Multiple Sites

To sort the results by Completion Date, click the header of "Completion Date" column.
 To show results for a particular site, enter the NCI Site Code in the Site column, and click the Search button.
 The Excel Export feature for the Funding Report will display a maximum of 5,000 records for all sites that the user has roster affiliations with.

Search funding from 11-Jul-2019 to []

25 Search Clear

Funding data can be downloaded using Excel export feature

Funding Report can display data for multiple sites

Site	Protocol	Credit Network Group	Investigator	Patient ID	Enrollment Date	Funding Type	Funding #	Collect Type	Funding Status	Specify	Completion Date	Date Entered
MN001,MN002	A031702	ALLIANCE	[redacted]	9125379	12-Jul-2019 03:43:52 PM EDT	Non-NCI/DCTD Funding		Mandatory	INACTIVE	Other - EKG		
MN001	A031702	ALLIANCE	[redacted]	9125379	12-Jul-2019 03:43:52 PM EDT	Biospecimen		Mandatory	ACTIVE	Biospecimen - Tumor (Slides)	18-Jul-2019	18-Jul-2019
MN001	A031702	ALLIANCE	[redacted]	9125379	12-Jul-2019 03:43:52 PM EDT	Biospecimen		Optional	ACTIVE	Biospecimen - Peripheral Blood - Peripheral blood and plasma at baseline, Cycle 2 Day 1, and Cycle 3 day 1	18-Jul-2019	18-Jul-2019
MN001	A031702	ALLIANCE	[redacted]	9125379	12-Jul-2019 03:43:52 PM EDT	Biospecimen		Optional	ACTIVE	Biospecimen - Tissue - FFPE Tumor at baseline	18-Jul-2019	18-Jul-2019

Figure 76: The Site Field Allows Users to See Results for their Different Sites

The Excel export feature (for the Funding Report) exports a maximum of 5,000 records, for all of the sites in which the user has roster affiliations.

5.4 The Print Confirmation and Print Full Form Features

When an enrollment is completed in the Enroll tab of OPEN, an enrollment confirmation screen is displayed. If a user wants to access the enrollment confirmation later they can access the Print Confirmation feature in the History tab of OPEN.

In addition, the user has the ability to access a printable record that lists all information for the subject’s enrollment (except the enrollment confirmation screen).

Accessing these features:

- 1) Click the History tab and the screen refreshes to the Browse subtab by default.
- 2) Select the desired enrollment and the user is brought to the Summary screen for the enrollment.
- 3) Click the Print Confirmation or the Print Full Form button (as shown in Figure 77).



Figure 77: Print Confirmation and Print Full Form Buttons on an Enrollments Summary Screen

5.5 Linking Completed Cancer Care Delivery Research Patient and Non-Patient Enrollments

For CCDR protocols, site users can link (or unlink) completed OPEN enrollments for non-patients to patients, or patients to non-patients, using the *Link or Unlink Non-patients/Link or Unlink Patients* buttons in the Summary screen (of the History module).

Once the linking/unlinking is complete and saved in OPEN, it is also automatically updated in Rave (within Rave CCDR Subject Enrollment Form).

Instructions for linking CCDR Patient enrollments to CCDR Non-Patient enrollments):

- 1) Click the History module and the screen will refresh to the Browse screen by default.
- 2) Select the *Non-Patient Enrollments* button to ensure that the Non-Patient enrollment browser is displayed.
- 3) Select the desired patient enrollment in order to be taken to the Summary screen for the enrollment.
- 4) Click the *Link or Unlink Non-patients* button (as shown in Figure 78).

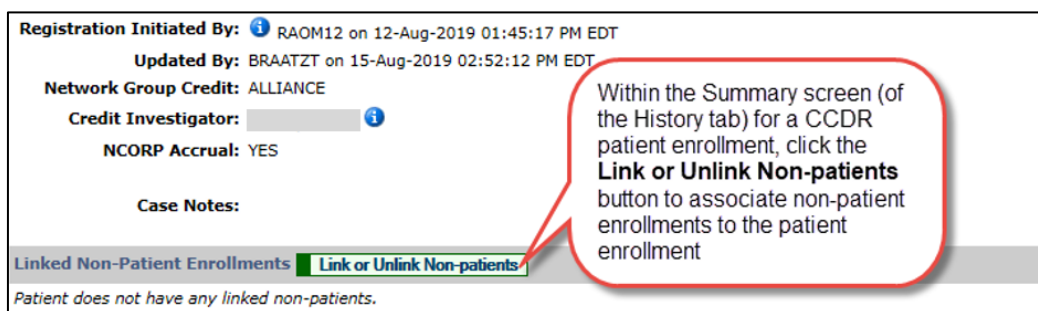


Figure 78: The Link or Unlink Non-patients Button for Linking Non-Patients to Patients

- 5) A pop-up will appear, allowing users to link non-patients to their patient enrollment (as shown in Figure 79).

Patient ID mock-4f69a8 Tracking # **715925**

Edit	Tracking number	Non-Patient Type	Type/Category	Specialty	Component/Affiliate
<input checked="" type="checkbox"/>	715995	PROVIDER	Medical Doctor/Doctor of Osteopathy (MD/DO)	Pediatric Oncology/Hematology	Pediatric Oncology/Hematology

Results 1 - 1 of 1. (The browser will retrieve only the first 100 records and the first 1000 while exporting. Add additional criteria to retrieve the desired record list)

Figure 79: Pop-Up Window Displaying Non-Patient Enrollments

- 6) Click the Edit checkbox to select a non-patient, click the *Save* button, and close the pop-up window.
- 7) The Summary screen will refresh and the non-patient enrollment will now display in the Linked Non-Patient Enrollments section (as shown in Figure 80).

Network Group Credit: ALLIANCE

Credit Investigator: ⓘ

NCORP Accrual: YES

Case Notes:

Linked Non-Patient Enrollments

Non-Patient Type	Tracking #	Type/Category	Specialty	Component/Affiliate
<input checked="" type="checkbox"/> PROVIDER	<input checked="" type="checkbox"/> 715995	Medical Doctor/Doctor of Osteopathy (MD/DO)	Pediatric Oncology/Hematology	Pediatric Oncology/Hematology

A non-patient enrollment associated with the patient enrollment

Figure 80: The Associated Non-Patient Enrollment in the Summary Screen

Instructions for linking CCDR Non-Patient enrollments to CCDR Patient enrollments:

- 1) Click the History module and the screen will refresh to the Browse screen by default.
- 2) Select the *Non-Patient Enrollments* toggle button to ensure that Non-Patient enrollments are displayed in the browser.
- 3) Select the desired Non-Patient enrollment in order to be taken to the Summary screen for the enrollment.
- 4) Click the *Link or Unlink Patients* button (as shown in Figure 81).

Network Group Credit: WAKE
 Credit Investigator: [Redacted] ⓘ
 NCORP Accrual: YES
 PEC Site Override Reason:
 PEC Investigator Override Reason:
 Case Notes: test non patient push

Within the Summary screen (of the History tab for a CCDR Patient Enrollment, click the **Link or Unlink Patient** button to associate patient enrollment to the non-patient enrollment.

Linked Patient Enrollments **Link or Unlink Patients**

Non-patient does not have any linked patients.

Figure 81: The Link or Unlink Patients Button for Linking Patients to Non-Patients

- 5) A pop-up will appear, allowing users to link patients to their non-patient enrollment (as shown in Figure 82).

Subject ID NP-mock-6a2c6c Tracking # **774683**

25 Search Clear

Edit	Tracking number	Patient ID	Protocol	Step	Treatment Arm	Randomized Date
<input type="checkbox"/>	774672	mock-98d33a	WF-1804CD	1	Test	10-Dec-2020
<input type="checkbox"/>	774678	mock-8b6c02	WF-1804CD	1	Test	14-Dec-2020
<input checked="" type="checkbox"/>	774671	mock-6e5905	WF-1804CD	1	Test	10-Dec-2020
<input type="checkbox"/>	774668	mock-3a5a3c	WF-1804CD	1	Test	08-Dec-2020
<input type="checkbox"/>	774665	mock-b6b3ce	WF-1804CD	1	Test	08-Dec-2020
<input type="checkbox"/>	774662	mock-0e920c	WF-1804CD	1	Test	04-Dec-2020
<input type="checkbox"/>	774659	mock-3ed717	WF-1804CD	1	Test	04-Dec-2020

Figure 82: Pop-Up Window That Displays CCDR Patient Enrollments

- 6) Click the *Edit* checkbox to select a patient, click the *Save* button, and close the pop-up window.
- 7) The Summary screen will refresh, and the patient enrollment will now display in the Linked Patient Enrollments section (as shown in Figure 83).

Credit Investigator: [Redacted]
 NCORP Accrual: YES
 PEC Site Override Reason:
 PEC Investigator Override Reason:
 Case Notes: test non patient push

A patient enrollment associated with non-patient enrollment

Linked Patient Enrollments **Link or Unlink Patients**

Tracking #	Patient ID	Protocol
774671	mock-6e5905	WF-1804CD

Figure 83: The Associated Patient Enrollment in the Summary Screen

6. T&UM Tab

Subject enrollment information for completed OPEN enrollments may need to be updated or corrected. Previously, the update requests were manually processed using the combined efforts of the CTSU, the Network Groups, and the Pharmaceutical Management Branch (PMB). After the changes were validated and approved, the updates were made in multiple electronic systems (OPEN, RSS, NCI systems) and the LPO Clinical Data Management System (CDMS). This process took a significant amount of time and coordination.

The Transfer and Update Module (T&UM) within OPEN was created as the central location for site staff to request data changes (Site Transfers, Credentialing Data Updates, and Demographic Data Updates) for completed subject enrollments that are maintained in OPEN. Each request undergoes automatic validations, and the system allows LPO staff to manually approve requests (per their preference). Note that no updates should be made to the demography data after the enrollment is completed, unless the updates are to correct data entry errors or unless site becomes aware of additional demography information after the enrollment. The T&UM automatically updates (when possible) systems outside of OPEN that also contain the subject's data (such as Rave, and the LPO RandoNodes).

The Create New subtab of the T&UM tab contains an automated message (as shown in Figure 84) that lists all of the LPOs that use the T&UM for enrollment data updates. For the LPOs that do not use the T&UM, site users must follow the existing process for data updates.

Home
Slot Reservation
Enroll
History
T&UM
Reports
RSS
Help

In Progress
Create New
History
Help Tool

- The Transfer and Update Module(T&UM) handles data update requests (involving updates to a patient's institution, credentialing data, and demographic data) for completed patient enrollments that are maintained in OPEN.
- [Click here](#) to access the tool for locating new sites for moving patients.
- The T&UM can update enrollment data for these organizations: [ABTC](#), [ALLIANCE](#), [BMTCTN](#), [CITN](#), [COG](#), [COGC](#), [ECOG-ACRIN](#), [NCI](#), [NCIC](#), [NCICCR](#), [NCIDTC](#), [NCILYMB](#), [NRG](#), [PBTC](#), [PEP-CTN](#), [SWOG](#), [USMCI](#). Click the hyperlink for an organization to view their T&UM Configuration Report.

Select the type of T&UM request that you would like to perform:

T&UM Request Type	Description
<input type="radio"/> Site Transfer	Update the institution associated with a patient enrollment (this may involve updates to credentialing data). <div style="border: 1px solid orange; padding: 5px; background-color: #fff9c4;"> For changes to a patient's institution, the transferring sites must initiate a conversation with potential receiving sites on accepting their patients, and confirm agreement prior to initiating the site transfer process in the T&UM tab of OPEN. All outstanding data up to this point must be submitted by the transferring site and all queries must be resolved. </div>
<input type="radio"/> Credentialing Data Update	Update credentialing data for a patient that will remain at the same institution.
<input type="radio"/> Demographic Data Update	Update demographic data for a patient. <div style="border: 1px solid orange; padding: 5px; background-color: #fff9c4;"> Demography data in OPEN should reflect the patient status at the time of enrollment. Corrections should be made only for data entry errors or if additional demography information becomes available after enrollment. </div>

Figure 84: The T&UM Create New Subtab Lists the LPOs that Participate in the T&UM

Access the [OPEN T&UM Site User Guide](#) to view detailed instructions for using the T&UM.

7. Reports Tab

The Reports tab contains statistical and report data for OPEN enrollment data.

7.1 Screening Subtab

The Screening subtab contains information for completed Screening Log (protocol DCP-001) enrollments that were completed at institutions where the site user has active roster affiliations (as shown in Figure 85).

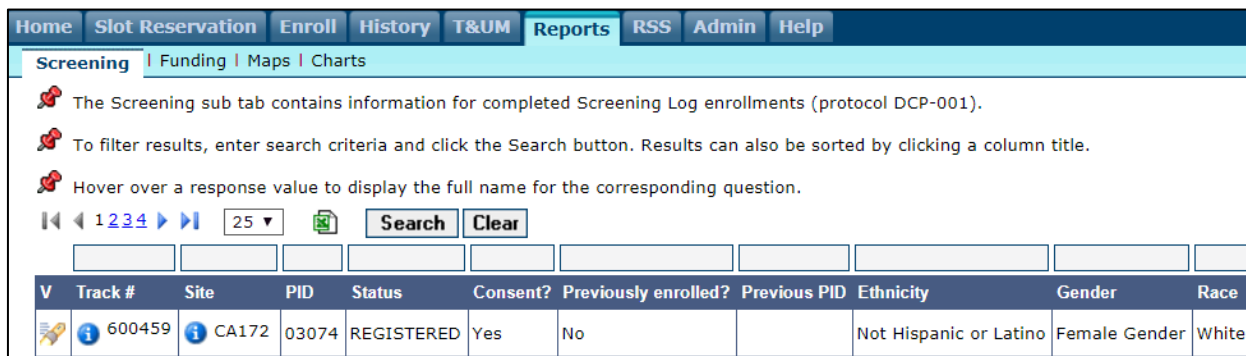


Figure 85: The Screening Subtab of the Reports Tab

The Screening Log protocol collects information about subject demography, how subjects were diagnosed, whether the subject accrued to the trial, (and if applicable) why subjects that did not accrue and if there were any language barriers. The form does not contain Personally Identifiable Information (PII).

The Screening Log informs sites, researchers, and the NCI, on the challenges of clinical trial recruitment. The information guides the future development of protocols that better meet subject needs and increase accrual rates.

7.2 Funding Subtab

The Funding subtab is included under the Reports tab. This enhancement enables OPEN users to efficiently access the Funding Report for their selected site (as shown in Figure 86). Oral Agent Funding information will be included in the Funding Report.

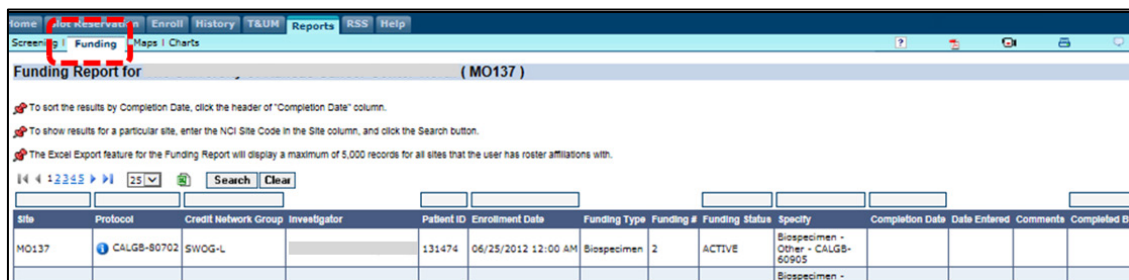


Figure 86: The Funding Report Subtab of the Reports Tab

7.3 Maps Subtab

The Maps subtab (of the Reports tab) displays the locations where OPEN enrollments were completed.

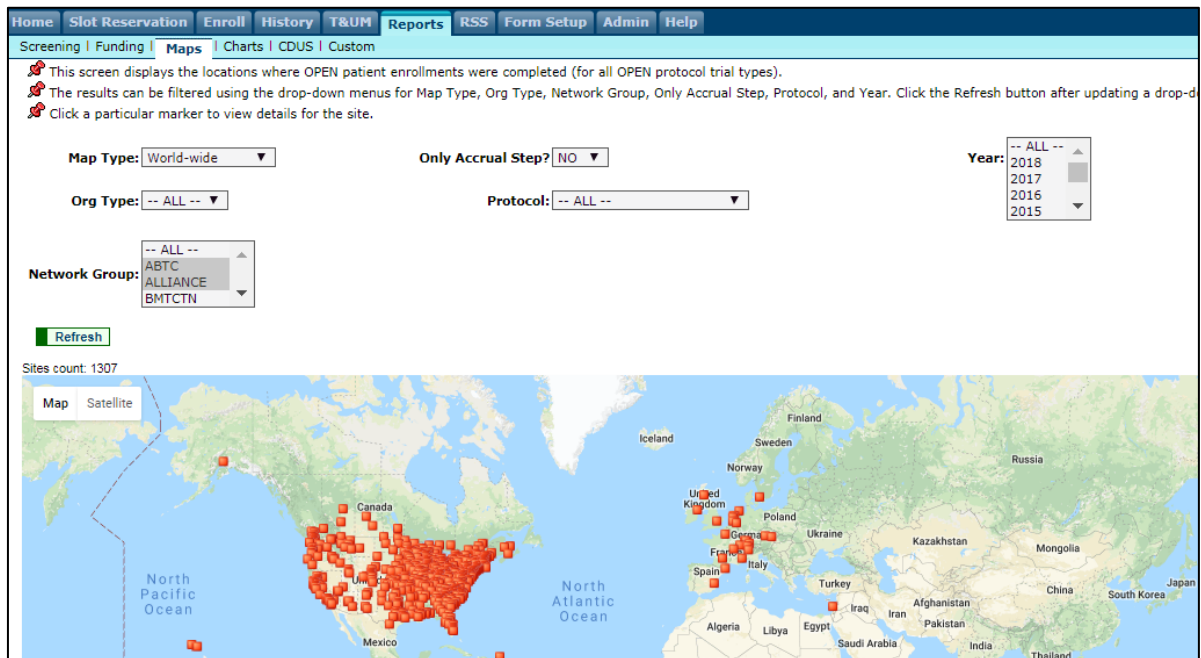


Figure 87: The Maps Subtab Displays Locations Where OPEN Enrollments Have Occurred

Content within the Maps subtab filters by the following criteria:

- Map Type
- Org Type
- Network Group (multiple selections allowable)
- Only Accrual Step
- Protocol
- Year (multiple selections allowable)

7.4 Charts Subtab

The Charts subtab (of the Reports tab) displays OPEN enrollment information using graphs. The data is from March 1, 2014 (the inception date of the NCTN) and onward.

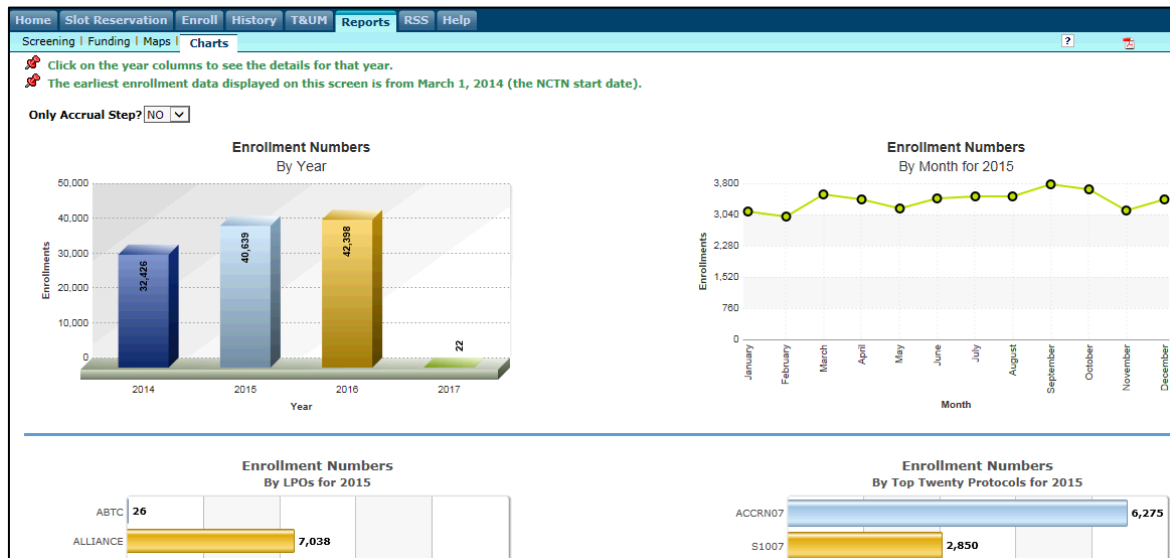


Figure 88: The Charts Subtab Displays OPEN Enrollment Numbers

There are four types of enrollment data displayed within the Charts subtab:

- Enrollments by year.
- Enrollments by month for a specific year.
- Enrollment numbers by LPO for a specific year.
- The top twenty enrolling protocols for a specific year.

The data filters by the following criteria:

- Year (click a specific year within the *Enrollment numbers by year* chart).
- Accrual step (make a selection from the drop-down menu *Only Accrual Step?*), to choose whether only accrual step enrollment data is displayed.

8. RSS Tab

The RSS tab contains searchable browser screens for Person and Site Registration information.

8.1 Persons Subtab

The Persons subtab allows users to locate an individual using the search feature (as shown in Figure 89).

CTEP ID	Last Name	First Name	Status	Type
40261			Active	IVR
548556			Active	Associate

Figure 89: The Persons Subtab

The searchable fields include:

- CTEP ID
- Last Name
- First Name
- Status
- Type

Accessing this feature:

- 1) Click on the Person Search link on the Welcome page or click the RSS tab. The Persons subtab will refresh by default.
- 2) Enter the search content in the appropriate fields.
- 3) Click the Search button and the browser content filters by the search content. See section 4.2.14 for more information on using the search feature.

8.2 Protocols Subtab

The Protocols subtab provides detailed information regarding OPEN protocols and it is available to all users (as shown in Figure 90). Users can view detailed information about a protocol by clicking the View Details icon or they can filter the table results using the text-entry search boxes above each table column (and then clicking the Search button). Site users can view protocols for which their institution has site registrations.

V	C	Protocol	Network Group	Legacy Group	PIO Status	GRP Prof Status	Restrict Sites?	Auto QA?	RAVE?	UUID	Slot?	OPEN Act. Date	PMB Dist?	caAERS?	CDUS?	TRIAD?
		S1605	SWOG		Active	Active	N	Y	Y	a67073d7-8d82-433b-9d13-ebad6236901f	N	07-Feb-2017	Y	N	Y	N

Results 1 - 1 of 1. (The browser will retrieve only the first 100 records and the first 1000 while exporting. Add additional criteria to retrieve the desired record list)

Figure 90: Protocols Subtab

8.3 Site Registrations Subtab

The Site Registrations subtab of the History tab allows users the ability to locate site registration information (as shown in Figure 91).

Site	Protocol	Site Name	Status	Status Date	Comments	IRB Expiry	IRB Status	Missing Requirements	Where to Enroll?
GA020	NSABP-B-42		Closed, Cont Rvw	06-Jan-2010	Protocol is Closed to Accrual	02-May-2019	Expired	IRB EXPIRED	OPEN

Figure 91: The Browser on the Site Registration Subtab

The searchable fields include:

- Site Number
- Protocol
- Status

Accessing this feature:

- 1) Click the *Site Registration Search* link on the Welcome page or the RSS tab.
- 2) Click on the Site Registrations subtab.
- 3) Enter the search criteria in the search field(s).
- 4) Click the Search button and the browser results refresh based on the search content. See section 4.2.14 for more information on using the search feature.

9. Help Tab

The Help tab contains user documentation and OPEN release information (as shown in Figure 92).

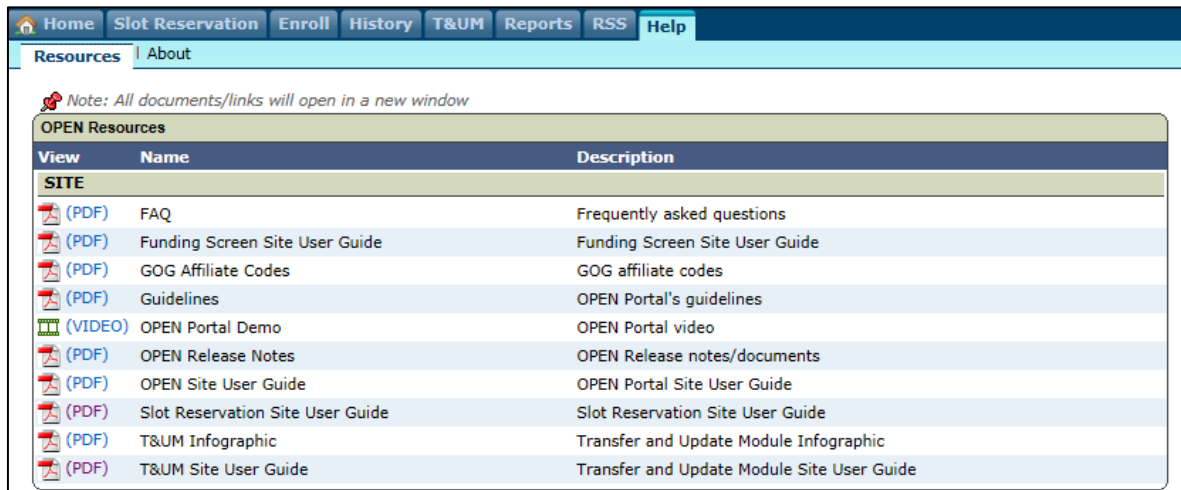


Figure 92: The Help Tab of OPEN

9.1 Resources Subtab

The Resources subtab contains documentation for site users. New users are encouraged to read the user documentation.

9.2 About Subtab

The About subtab lists the notable enhancements and fixes that were applied with each release of the OPEN Portal.

10. Appendix

This section provides additional information regarding OPEN validations.

10.1 OPEN Validations

Table 8 provides a list of validations that are performed, in the Create New screen of the Enroll tab, when a user is attempting to initiate an OPEN subject enrollment.

Table 8: Validations for the Create New Screen

#	Validation Information
1	For a list of validations and business rules for the OPEN Person Types, view the OPEN Person Types and Business Rules document.
2	COG sites that are enrolling onto COGC protocols that have a participation restriction for COG sites, must credit COGC. OPEN will force COG sites (that do not have COGC roster affiliations) to credit COGC for these enrollment scenarios.