



# CTSUS

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Cancer Trials Support Unit

## OPEN Portal Group User Guide

Revision 30

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## Document Information

Revision Information for the OPEN Portal Group User Guide

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# 1. Overview of OPEN

The Oncology Patient Enrollment Network (OPEN) Portal provides a central location for site registrars to enroll subjects onto NCI-sponsored clinical trials activated within the system. (Note that the terms *subject* and *patient* are used interchangeably in this document). For Lead Protocol Organization (LPO) users, OPEN allows:

- An individual with administrator rights to perform all of the tasks assigned to subject registrars, on a given clinical trial;
- Performance of various administrative tasks associated with maintaining a website;
- Changes to the visual appearance and the layout of the protocol forms;
- Testing and modification of the validation rules (edit checks) for these protocol forms.

## 1.1 Minimum System Requirements

Table 1: Minimum System Requirements

Type	Minimum Requirement
Operating System	Windows 2000 and up
Memory	1 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

Figure 1 displays the OPEN Portal business process.

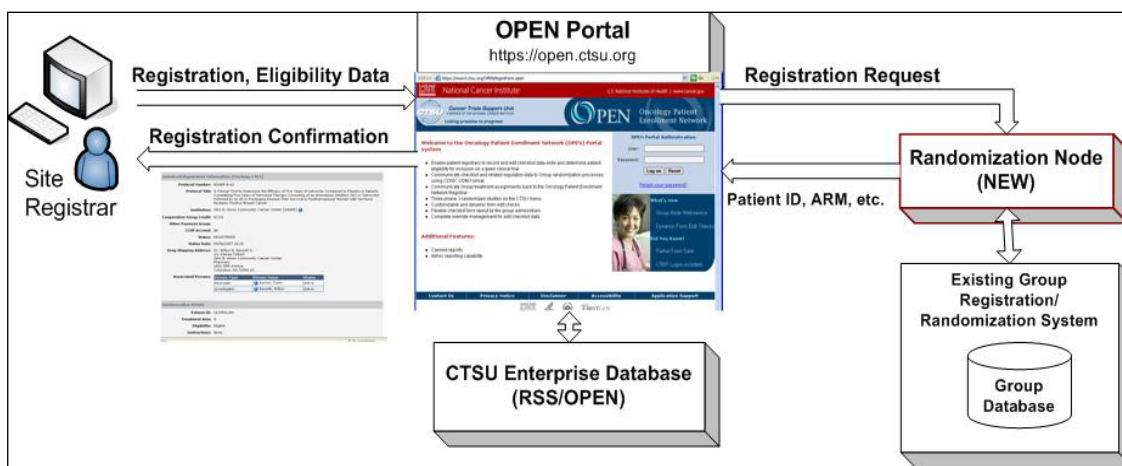


Figure 1: OPEN Portal Business Process

### 1.3 Organization of this Document

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

**Table 2: Organization of this 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 using administrative features in the Enroll tab.
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 using the features in the Reports tab.
8	RSS	Instructions for using the features in the RSS tab.
9	Form Setup	Instructions for using the features in the Form Setup tab.
10	Admin	Instructions for using the features in the Admin tab.
11	Help	Provides an overview of the Help tab.

LPO users have access to additional tabs that site users are unable to access (the Form Setup and Admin tabs).

The goal of this document is to provide instructions for using administrative features available to LPO users. For information on using site user features (within the Home, Enroll, History, Reports, RSS, and Help tab), access the OPEN [Site User Guide](#).

### 1.4 Web Addresses for CTSU Applications

**Table 3: Web Addresses for CTSU Applications**

Application	URL
OPEN Portal	<a href="https://open.ctsu.org">https://open.ctsu.org</a>
CTSU Members’ website	<a href="https://www.ctsu.org">https://www.ctsu.org</a>

## 1.5 Acronyms

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

**Table 4: List of Acronyms**

Acronym	Description
ALS	Architect Loader Specification
caDSR	Cancer Data Standards Repository
CCDR	Cancer Care Delivery Research
CD	Care Delivery
CDE	Common Data Element
CDISC	Clinical Data Interchange Standards Consortium
CDMS	Clinical Data Management System
CDUS-A	Clinical Data Update System Abbreviated
CENTER	CTSUS Enterprise Network Transaction Engine for Rave
COG	Children’s Oncology Group
CPQOL	Contact Person Quality of Life
CPSM	Contact Person for Sample Submission
CTEP	Cancer Therapy Evaluation Program
CTEP-AERS	Cancer Therapy Evaluation Program-Adverse Event Reporting System
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
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
PSR	Protocol Specific Requirement
RSS	Regulatory Support System
SQL	Structured Query Language
SSO	Single Sign On

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Acronym	Description
T&UM	Transfer and Update Module
WSDL	Web Services Description Language

## 2. Accessing OPEN and the Home Tab

All persons accessing OPEN must have an active Cancer Therapy Evaluation Program –Identity and Access Management (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, by using the OPEN URL or by going through the CTSU members’ website. Both methods are described below.

### 2.1 Logging in to the OPEN Portal

To log in to the OPEN Portal:

- 1) Launch a new Internet Explorer window.
- 2) Type in the URL for OPEN Portal located in the URLs section 1.2.
- 3) The Login screen will be displayed and the User ID and password is requested (Figure 2).

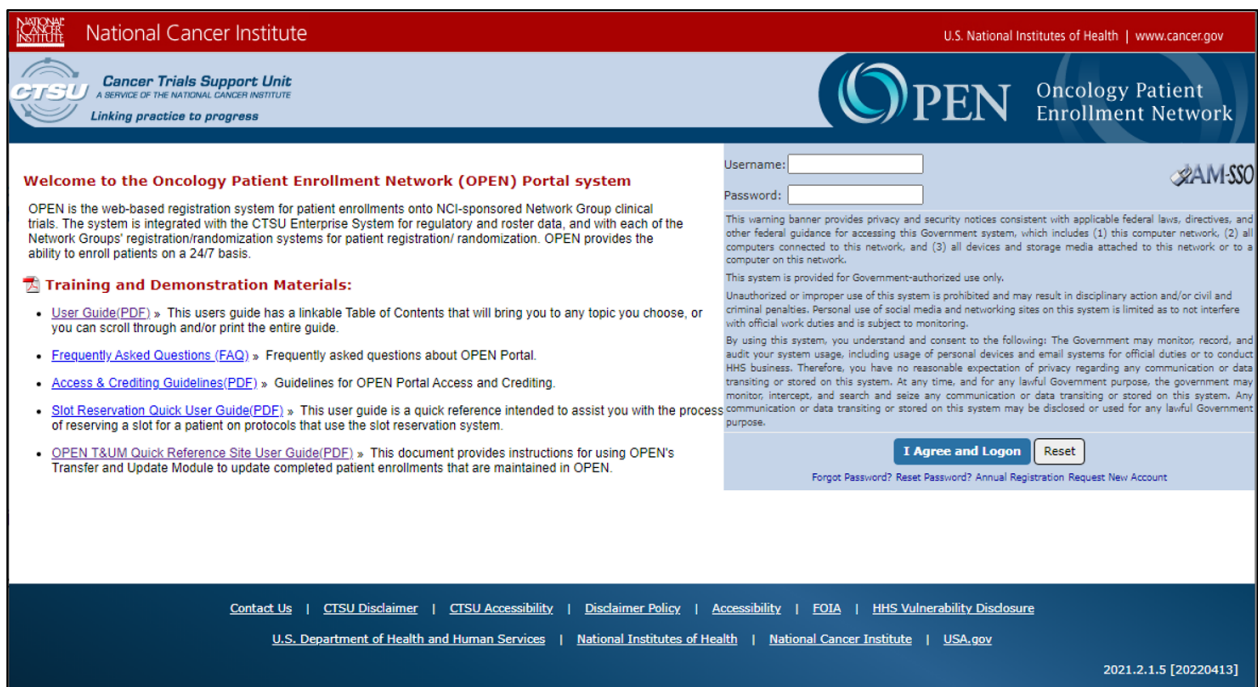


Figure 2: Logon Screen

- 4) Enter your Identity and Access Management (IAM) username in the IAM User field and your associated password in the password field (these are the same username and password credentials you use to enter the CTSU members’ website).
- 5) Press the I Agree and Logon button to enter the system.

OR

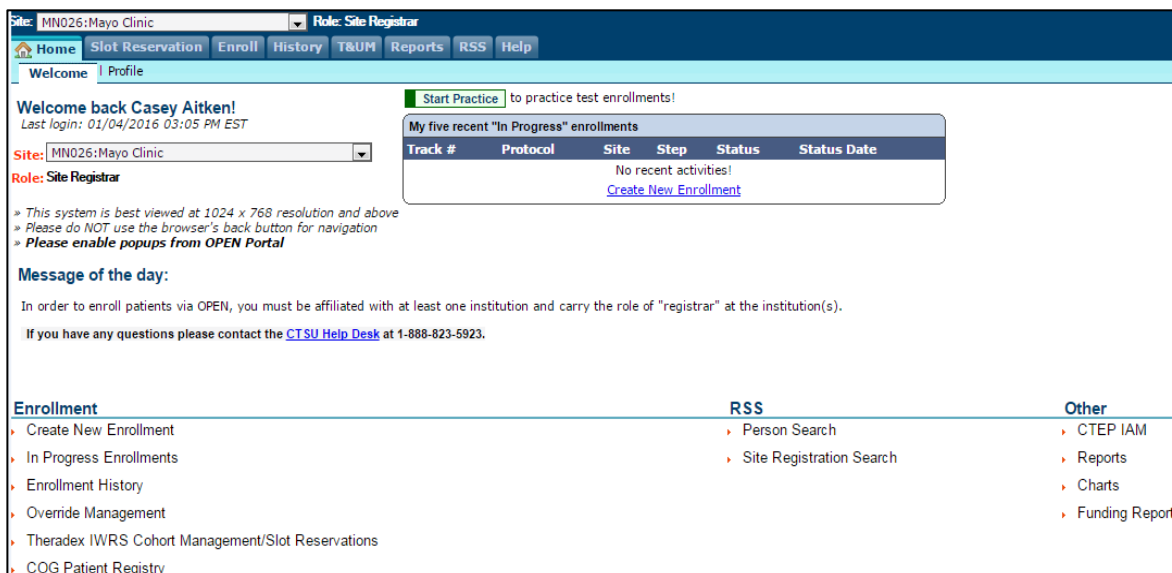
6) Press the Reset button to clear the entered fields.

The Logon button validates the entered IAM ID and password and allows the user to enter the OPEN Portal. Then the welcome screen displays (this may appear different depending on the roles assigned (see Figure 3 and Figure 4). The user’s last log in date and time will appear under their name.

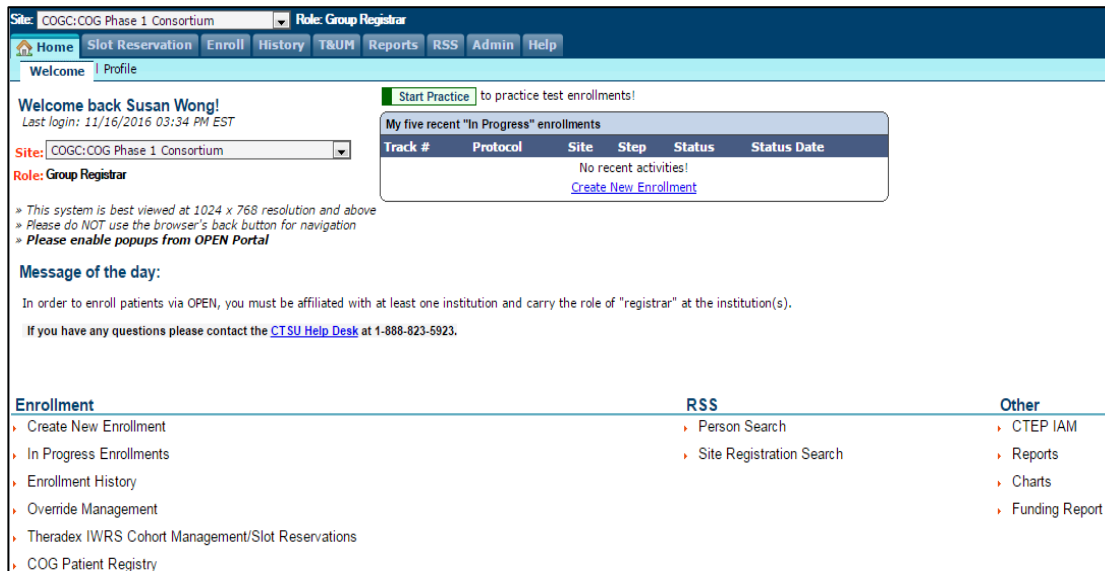
If the IAM username and password entered is invalid, OPEN returns the message, “Invalid username or password”. The user is able to re-enter the IAM username and password.

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 in to the OPEN Portal, please contact the CTSU Help desk for assistance at 1-888-823-5923.



**Figure 3: Welcome Screen - (Site User)**



**Figure 4: Welcome Screen – (Group Administrator)**

## 2.2 Log in through the CTSU Members Website

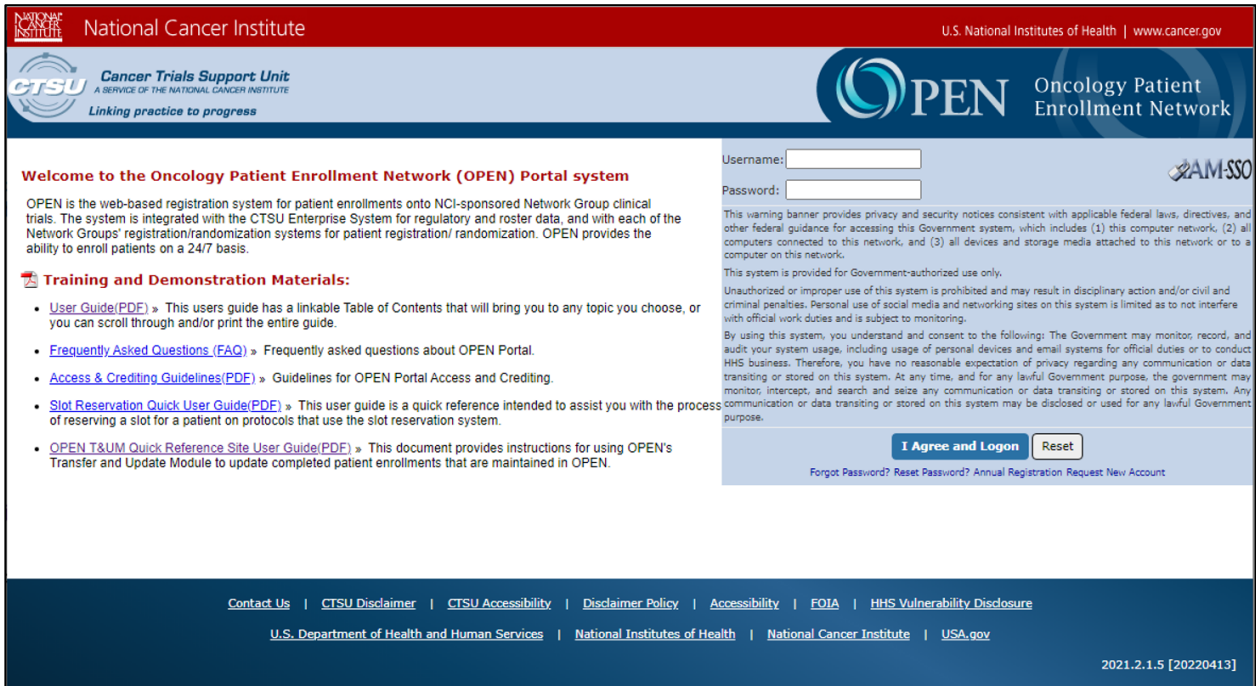
Users can also log in to the OPEN Portal via the CTSU members’ website.

- 1) Open a new internet browser window.
- 2) Log in to the CTSU member’s website (see the URLs in Table 3).
- 3) Go to and click on the OPEN link. This link will display information specific to OPEN and provide a button to enter the OPEN Portal.
- 4) Press the OPEN button. The OPEN Portal will launch displaying the welcome tab (see Figure 3 and Figure 4).

## 2.3 CTEP Single Sign-On in OPEN using the CTSU Single Sign-On Starter Kit

As part of the Clinical Data Management System (CDMS) Rave integration for the Network Groups and other lead organizations, a CTEP IAM based Single Sign-On (SSO) authentication system authenticates OPEN Portal users. The OPEN Portal implemented the CTSU SSO with an iFrame approach.

In this approach, the IAM login page is embedded within the OPEN Portal login page (see Figure 5).



The screenshot shows the OPEN Portal system login page. At the top, there are logos for the National Cancer Institute and the Cancer Trials Support Unit (CTSUS). The main header includes the OPEN Oncology Patient Enrollment Network logo. Below the header, there is a welcome message and a list of training and demonstration materials. On the right side, there are input fields for Username and Password, and a button for 'I Agree and Logon'. At the bottom, there are links for 'Forgot Password?', 'Reset Password?', 'Annual Registration Request', and 'New Account'.

**Welcome to the Oncology Patient Enrollment Network (OPEN) Portal system**

OPEN is the web-based registration system for patient enrollments onto NCI-sponsored Network Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Network Groups' registration/randomization systems for patient registration/ randomization. OPEN provides the ability to enroll patients on a 24/7 basis.

**Training and Demonstration Materials:**

- [User Guide\(PDF\)](#) » This users guide has a linkable Table of Contents that will bring you to any topic you choose, or you can scroll through and/or print the entire guide.
- [Frequently Asked Questions \(FAQ\)](#) » Frequently asked questions about OPEN Portal.
- [Access & Crediting Guidelines\(PDF\)](#) » Guidelines for OPEN Portal Access and Crediting.
- [Slot Reservation Quick User Guide\(PDF\)](#) » This user guide is a quick reference intended to assist you with the process of reserving a slot for a patient on protocols that use the slot reservation system.
- [OPEN T&UM Quick Reference Site User Guide\(PDF\)](#) » This document provides instructions for using OPEN's Transfer and Update Module to update completed patient enrollments that are maintained in OPEN.

Username:

Password:

[I Agree and Logon](#) [Reset](#)

[Forgot Password?](#) [Reset Password?](#) [Annual Registration Request](#) [New Account](#)

2021.2.1.5 [20220413]

Figure 5: iFrame Approach used in the OPEN Interface

### 2.3.1 Flow Diagram Explaining the SSO Authentication Process

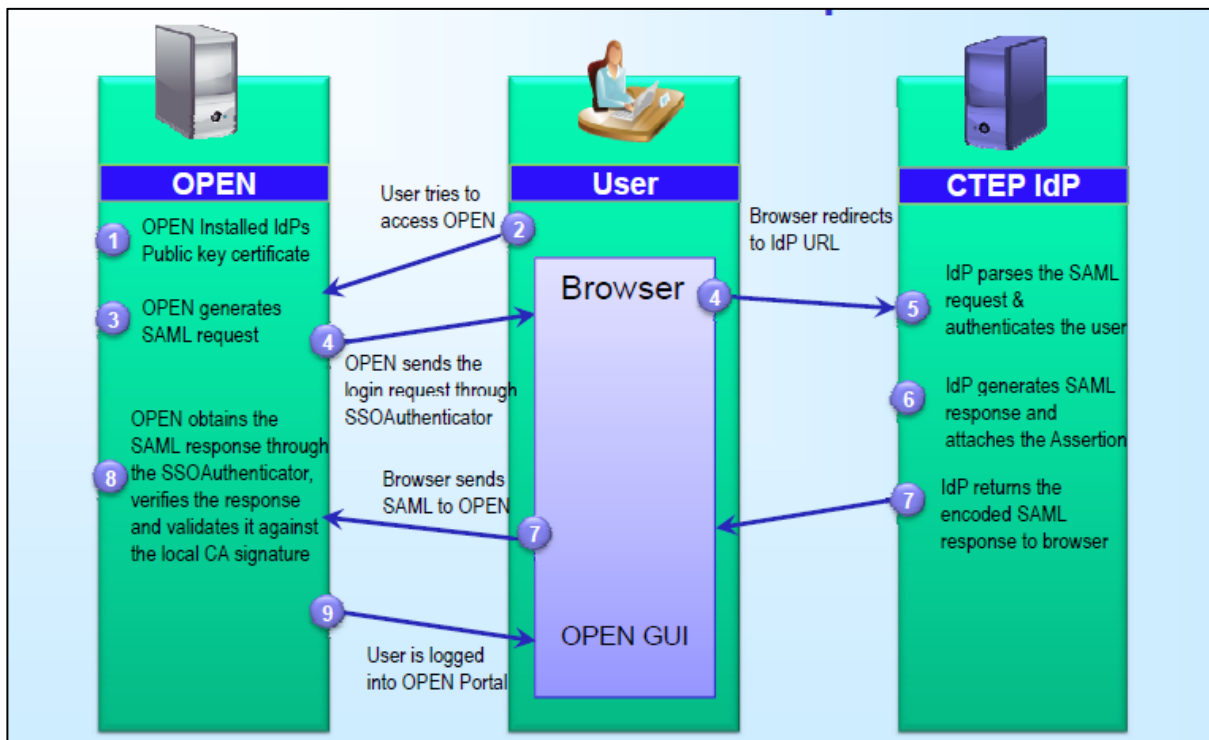


Figure 6: SSO Authentication with OPEN

### 2.3.2 Deep Linking Support

Deep linking support allows OPEN users to enter a subject’s Summary page within OPEN via a link in another CTEP application (such as a Network Group enterprise application) that uses the CTEP-IAM Single Sign-On (SSO).

To deep link into a subject’s Summary page in OPEN, one of the following criteria are given:

- OPEN tracking #;
- Protocol, step number, and patient ID.

For instance, if a CTEP user logs into a Group system that uses the CTEP-IAM SSO, and clicks the OPEN tracking number link for a subject, the user transfers to the Summary screen for the subject in OPEN without needing to retype their CTEP-IAM login credentials. If the enrollment cannot be located in OPEN, the user arrives at an error page.

This feature works automatically and requires no configuration. Only users with an active CTEP-IAM account and proper roster/role affiliations can successfully deep link into a subject’s Summary page in OPEN.

## 2.4 The Impersonate User Feature

Group users with the GROUP\_REG\_ADMIN role have the ability to switch to another user within their own group roster. This feature is useful for testing and troubleshooting purposes.

Please note that the Submit button will be unavailable from the following features, while the Impersonate User feature is being used:

- Subject enrollment;
- Funding screen;
- T&UM;
- Patient Registry;
- Slot Reservation.

### Accessing this Feature:

- 1) Log in to the OPEN Portal.
- 2) Click the **Preferences** subtab (of the Home tab).
- 3) Choose the user with one of two methods:
  - a) Enter the user's name (last name, first name) in the **Enter User's Last Name** field.

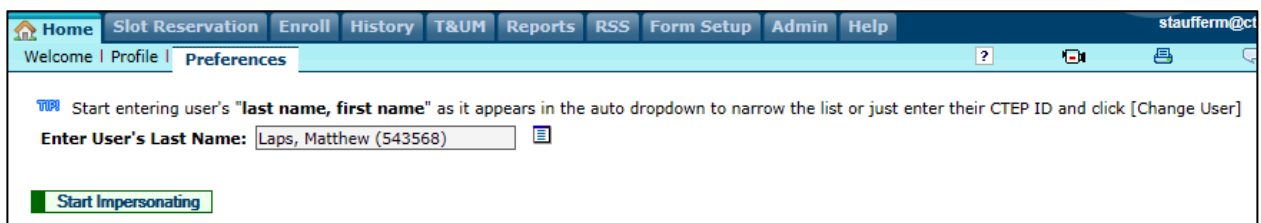

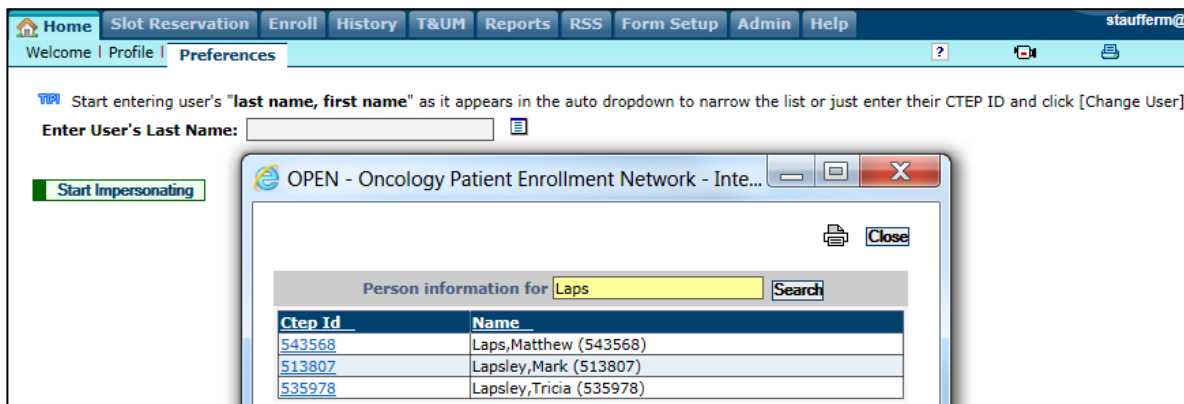


Figure 7: Impersonate User by Typing the User's Name

OR

- b) Click the **List of Users**  button.
  - i) Type the user's last name in the pop-up window.
  - ii) Click OK.
  - iii) A new pop-up window appears with a list of users with the last name provided in the previous pop-up window.



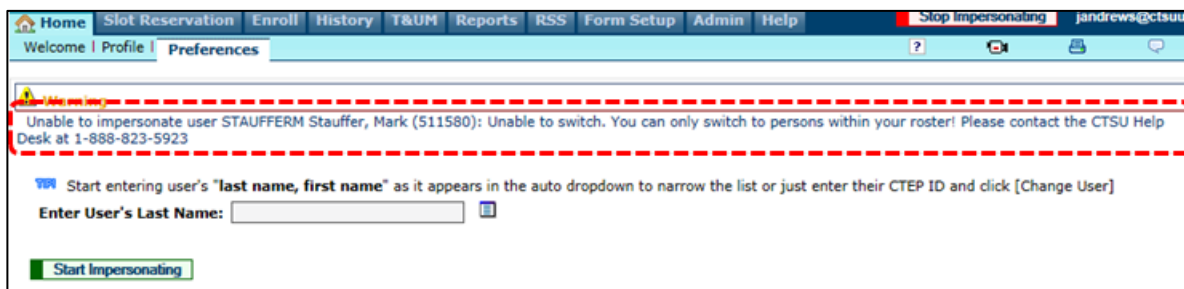
**Figure 8: Impersonate User by using the List of Users Option**

- iv) Click the CTEP ID next to the user that you need to switch to.
- v) The value populates into the **Enter User's Last Name Field**.
- 4) Click the **Impersonate User** button.
- 5) The system processes the request and validates whether the selected person is on your group roster.
  - a) In the validation passes, the user arrives at the **Welcome** subtab (of the Home tab) as the selected individual.



**Figure 9: An Impersonate User Request was Successfully Completed**

- b) If the validation does not pass, the user encounters an error message (Figure 10).



**Figure 10: Example of an Impersonate User Request that did not Pass Validation**

6) To exit the Impersonate User feature, click the Stop Impersonating button (see Figure 11).

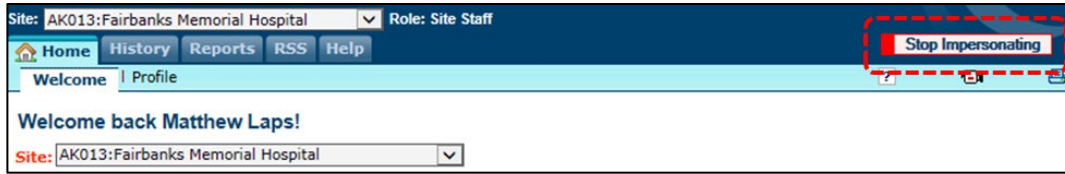


Figure 11: Click the Stop Impersonating Button to Exit the Impersonate User Feature

## 2.5 Accessing the Patient Registry Module

The Patient Registry module allows for creating, editing, and viewing COG Patient Registry records in OPEN.

The screenshot displays the 'Patient Registry - COG' interface. It includes a 'Back to OPEN home page' link, a 'Create Patient Registry Record' button, and search filters. The main table lists patient records with the following columns: Edit, View, Track #, Group PID, Site, Status, Registry Date, Registrar, Modified Date, and Modified By. The table contains 25 records, with the first 100 records retrieved.

Edit	View	Track #	Group PID	Site	Status	Registry Date	Registrar	Modified Date	Modified By
		PT-0000335596		MN008	INCOMPLETE		CHURNESSJ	08/28/2015 03:32 PM	KAMATUS
		PT-0000335595	951039	MN008	REGISTERED	08/28/2015 01:12 PM	ALEXANDERN	08/28/2015 04:06 PM	KAMATUS
		PT-0000335594		PA076	SUBMITTED		ADAMSONP	08/28/2015 01:01 PM	CHAUDHARYH
		PT-0000335592	951038	MN026	REGISTERED	08/28/2015 12:51 PM	BROWNSAD	08/28/2015 12:51 PM	CHAUDHARYH
		PT-0000335591		MN026	INCOMPLETE		WONGS	08/28/2015 02:29 PM	THUN
		PT-0000335551		MN026	SUBMITTED	08/27/2015 06:40 PM	WONGS	08/27/2015 06:41 PM	WONGS
		PT-0000335532	951037	MN026	REGISTERED	08/27/2015 01:43 PM	WONGS	08/27/2015 01:45 PM	WONGS
		PT-0000335531	951036	MN026	READY	08/27/2015 05:26 PM	WONGS	08/28/2015 04:26 PM	WONGS
		PT-0000335516	951035	CA009	REGISTERED	08/26/2015 06:24 PM	BASKINJ	08/26/2015 06:24 PM	BEELEST
		PT-0000335515	951034	MN022	REGISTERED	08/26/2015 06:21 PM	JDAHL	08/26/2015 06:21 PM	BEELEST
		PT-0000335514	951033	MN022	REGISTERED	08/26/2015 06:11 PM	ELANDSV1	08/26/2015 06:11 PM	BEELEST
		PT-0000335513	951032	MN022	REGISTERED	08/27/2015 12:06 PM	AANDER45	08/27/2015 12:06 PM	WONGS
		PT-0000335512	951031	MN026	REGISTERED	08/26/2015 03:10 PM	ARNDC	08/26/2015 03:10 PM	WONGS
		PT-0000335511	951030	CA006	INCOMPLETE	08/27/2015 01:11 PM	WONGS	08/27/2015 01:11 PM	WONGS
		PT-0000335509	851901	11147	REGISTERED	05/25/2015 12:00 AM	HERSHONL		
		PT-0000335508	851900	03055	REGISTERED	05/24/2015 12:00 AM	MCINTYREJ	08/28/2015 12:06 AM	RANDOHUB
		PT-0000335507	851899	MN010	REGISTERED	05/24/2015 12:00 AM	HALLERC		
		PT-0000335506	851898	TX011	REGISTERED	05/23/2015 12:00 AM	DTATESOZ		
		PT-0000335505	851897	IL202	REGISTERED	05/23/2015 12:00 AM	SUSZEKJ		
		PT-0000335504	851896	AZ004	REGISTERED	05/23/2015 12:00 AM	DPETERSON		
		PT-0000335503	851895	CA009	REGISTERED	05/22/2015 12:00 AM	HMYEPEZ		
		PT-0000335502	851894	CA009	REGISTERED	05/22/2015 12:00 AM	HMYEPEZ		
		PT-0000335501	851893	WA031	REGISTERED	05/22/2015 12:00 AM	HADCOXR		
		PT-0000335500	851892	ID003	REGISTERED	05/22/2015 12:00 AM	TESLINGE		
		PT-0000335499	851891	TX035	REGISTERED	05/22/2015 12:00 AM	MOTEE		

Results 1 - 25 of 100. (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 12: Patient Registry Module

For information on the Patient Registry module, access the OPEN [Patient Registry Group 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 13 provides an overview of the process for enrolling a subject on a slot reservation study in OPEN.



**Figure 13: Process for Enrolling a Subject on a Slot Reservation Protocol in OPEN**

If an OPEN protocol uses the slot reservation feature, and the protocol is configured for slot reservation at a patient level, a user must first create an OPEN Patient Number for their patient. Next, the OPEN Patient 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.

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 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 detailed instructions regarding slot reservation, access the [OPEN Slot Reservation Quick Reference Group User Guide](#).

## 4. Enroll Tab

### 4.1 In Progress Subtab

#### 4.1.1 How to Reset the Status of an In Progress Enrollment

When enrollment is in the status of VOID, SUBMITTED, or INCOMPLETE, the reset status option allows you to reset the statuses from:

- VOID to INCOMPLETE;
- SUBMITTED to INCOMPLETE; or
- INCOMPLETE to VOID.

**Steps for using the status reset feature:**


- 1) From the In Progress screen, search for and select the enrollment that needs a status change.
- 2) From the summary screen, press the Reset Status button.
- 3) Press OK to confirm the status update request is valid.
- 4) A new screen appears. Enter a comment for resetting the enrollment’s status, and press the Reset button (see Figure 14).

**Figure 14: Reset Status Screen**

- 5) Press OK to confirm the status update request is valid.
- 6) A successful status reset message will display when the reset is complete.

#### 4.1.2 The Duplicate Registration Feature

While in Practice Mode, or while in a non-production environment of OPEN, users can expedite testing by copying an existing OPEN enrollment. This feature is only available for initial-step enrollments that do not have associated ancillary studies.

- 1) From the In Progress subtab (of the Enroll tab), or the Browse subtab (of the History tab), click the Duplicate Registration icon  associated with the desired enrollment.
- 2) Press the OK button on the confirmation pop-up to confirm the copy.
- 3) The user receives a message that the enrollment was successfully copied.



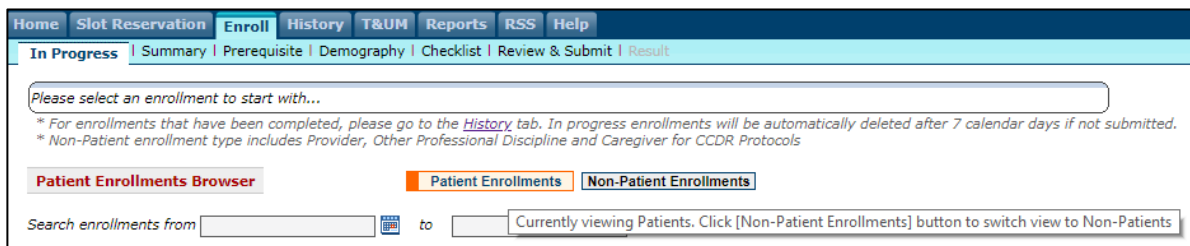
**Figure 15: Message Confirming that the Enrollment was Successfully Duplicated**

- 4) Once the enrollment is copied from either the In Progress or the History tabs, the enrollment can be found in the In Progress screen with the status of NEW. The copied enrollment can be manipulated and submitted as desired.

### 4.1.3 The Patient / Non-Patient Toggle

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 nurse, nutritionist), for patients that are enrolled in OPEN. Both patient and non-patient CCDR enrollments are supported in Rave. OPEN sends data for the enrollments (including the linkages between CCDR patient and non-patient enrollments) from OPEN to Rave across multiple steps through CENTER. Once the data is received in Rave, it automatically prepopulates the Rave CCDR Subject Enrollment Form.

Within the In Progress subtab (of the Enroll tab) of OPEN, there are toggle buttons for Patient Enrollments and Non-Patient Enrollments. The toggle buttons will allow users to either view patient enrollment data or non-patient enrollment data (see Figure 16).



**Figure 16: Patient/Non-Patient Enrollment Toggle for CCDR Enrollments**

## 4.2 Create New Subtab

For instructions on how to create OPEN enrollments, view section 4 of the OPEN [Site User Guide](#).

## 4.3 Checklist Subtab

### 4.3.1 How to Use the Manual Registration Feature

- A Manual Registration can be performed if the enrollment, for any reason, was enrolled at the Group manually. For example, if OPEN (or the LPO RandoNode) is not available, the Groups can manually process the enrollment, bypassing the OPEN portal. When OPEN becomes available, the sites can use the Manual registration feature in OPEN to reconcile this enrollment so that the information in OPEN synchronizes with the information in the Group's system.

- 1) Select the enrollment from the In Progress screen if the enrollment has already been initiated. If the enrollment has not been initiated, it must be initiated from the Create New screen (of the Enroll tab).
- 2) Select the Manual Registration option from the summary screen.

**Step 1 Registration Information: [Tracking # 51930]** **Manual Registration**

<b>Protocol Number:</b> ACOSOG-Z1041	<b>Protocol Title</b>
<b>Patient ID:</b> Not yet assigned	A Randomized Phase III Trial of Paclitaxel Plus Trastuzumab Followed by FEC-75 Plus Trastuzumab
<b>Treatment Arm:</b> Not yet assigned	
<b>Registration Step:</b> 1 (Registration)	
<b>Institution:</b> Upper Valley Medical Center [OH221] ⓘ	

**Figure 17: The Manual Registration Button**

- 3) Click the OK option on the pop-up confirmation window.
- 4) Enter the Patient ID, Treatment Arm, and Drug ID (if applicable) provided by the Group. If the Checklist form(s) have not been completed, fill in the form. If the checklist form(s) have been completed, the associated data will display.
- 5) Select the Validate and Register button.

Refresh Checklist | **Validate & Register** | Normal Registration

**Manual registration process should only be used when a patient has already been registered at the group manually!**

**Group Patient Information**

Patient ID: PAT1234  
 Treatment Arm: B  
 Drug ID: DRUG12  
 Registration Date: 03/09/2011 (mm/dd/yyyy)  
 Site Instructions: Site Instructions can be entered here.  
 Registration Comments: Registration Comments can be entered here.

Expand/Collapse all Modules

**Eligibility**

\* Has the eligibility checklist been completed

No  
 Yes

**Figure 18: Manual Registration Screen**

- 6) A summary window will appear for your review. If all is acceptable, press the Register Manually button. If changes are necessary, select the Checklist button to make the changes.

The screenshot shows a web interface for manual registration. At the top, there is a 'Review Message(s)' section with instructions. Below that is a yellow warning banner: 'Manual registration process should only be used when a patient has already been registered at the group manually!'. The main area is titled 'Group Patient Information' and contains fields for Patient ID (PAT1234), Treatment Arm (B), Drug ID (DRUG12), Registration Date (05/23/2011), Site Instructions, and Registration Comments. At the bottom, there is a 'Step 1 Registration Information' section with a 'Tracking # 82216' and a 'Register Manually' button highlighted with a red circle. Below the button, it shows 'Patient ID: Not yet assigned', 'Treatment Arm: Not yet assigned', and 'Institution: Northeast Georgia Medical Center [GA024]'.

Figure 19: Register Manually

- 7) To change from the Manual Registration mode to a Normal Registration mode, click on the Normal Registration button at the top of this screen.

## 4.4 Overrides Subtab

### 4.4.1 Override Management

Overrides to protocol requirements may be available on certain studies per LPO guidelines. Administrators can approve or deny overrides as needed. To approve or deny an override, you will receive an email indicating an override is requested.

#### Steps for Managing an Override Request:

- 1) Navigate to the Enroll tab and select the Overrides option from the list of subtabs.
- 2) Locate the appropriate override and hit the Edit button associated with that override (see Figure 20).

The screenshot shows the 'Overrides' subtab in the system. It features a search bar and a table with columns: Edit View, O. #, Track #, Protocol, Site, Edit Check, O. Code, and Status. Two rows are visible, both with a status of 'REQUESTED'. The first row has O. # 421, Track # 194670, Protocol PACCT-1, Site IA003, and Edit Check 'Patient last initial must be a letter.'. The second row has O. # 401, Track # 189902, Protocol E5103, Site NY003, and Edit Check 'Patient last initial must be a letter.'. A red circle highlights the 'Edit' icon in the first row.

Edit View	O. #	Track #	Protocol	Site	Edit Check	O. Code	Status
	421	194670	PACCT-1	IA003	Patient last initial must be a letter.	STEP 3	REQUESTED
	401	189902	E5103	NY003	Patient last initial must be a letter.		REQUESTED

Figure 20: Override Screen

- 3) Select from the Override Status drop-down list the status to give this override.
  - Approved – the override is accepted, the enrollment can proceed.
  - Denied – the override request is denied, the error must be corrected before the registration can proceed.
  - On Hold – An override is pending or holding.

- Inactive – The edit check was inactivated after the override request, and the override is no longer required. Resubmit the Eligibility Checklist (EC).

**Figure 21: Override Status Screen**

- 4) Enter comments in the Reviewer Comments field. This field is mandatory and must be completed.
- 5) Click the Save button to submit.
- 6) You will receive a confirmation message indicating the override information was saved. The override requester will also receive an email indicating the override has been processed and what the status of the override is.




**Figure 22: Confirmation**

## 5. History Tab

### 5.1 Browse Subtab

#### 5.1.1 The Duplicate Registration Feature

While in Practice Mode, or while in a non-production environment of OPEN, users can expedite testing by copying an existing OPEN enrollment. This feature is only available for initial-step enrollments that do not have associated ancillary studies.

- 1) From the In Progress or the History tab, press the duplicate icon  associated with the enrollment that needs to be copied.
- 2) Press the OK button on the confirmation pop-up to confirm the copy.
- 3) The user receives a message that the enrollment is successfully copied.

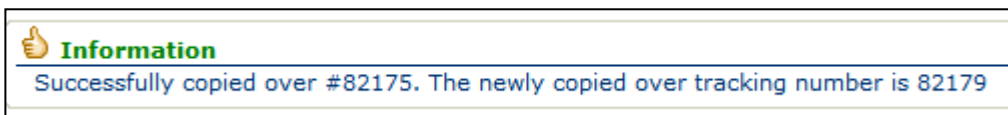


Figure 23: Message that Confirms the Enrollment was Successfully Duplicated

- 4) Once the enrollment is copied from either the In Progress subtab (of the Enroll tab), or the Browse subtab (of the History tab), the enrollment can be found in the In Progress screen with the status of NEW. This copied enrollment can be manipulated and submitted as desired.

#### 5.1.2 The Patient / Non-Patient Toggle

Within the Browse subtab (of the History tab) of OPEN, there are toggle buttons for Patient Enrollments and Non-Patient Enrollments. The toggle buttons will allow users to either view patient enrollment data, or non-patient enrollment data (see Figure 24).

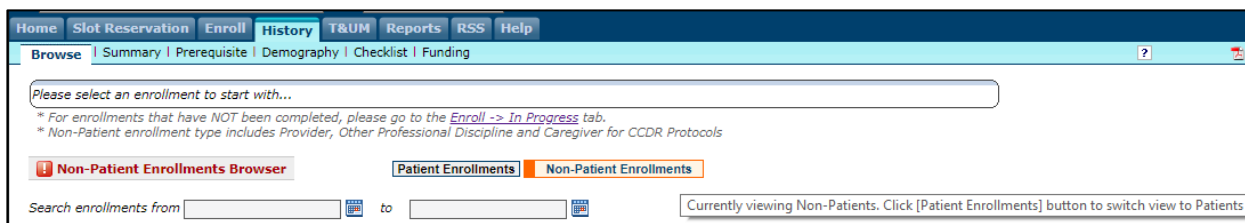


Figure 24: Patient/Non-Patient History Toggle for CCDR Enrollments

## 5.2 Summary Subtab

### 5.2.1 Rave Transaction Log

A transaction appears in the Rave system for successfully created OPEN enrollments.

Users can verify the transaction was successful by viewing the Summary screen in OPEN. The Rave Transactions Logs table lists all of the transaction details for the registered protocol.


Date	Ancillary Protocol	Operation	Created By	Status	Comments	Manual Xfer	Rave Environment
07/18/12 12:04:06 PM	N/A	Transfer Checklist Data	RUDDB	COMPLETED		NO	UAT
07/18/12 12:04:05 PM	N/A	Initialize Patient	RUDDB	COMPLETED		NO	UAT
07/18/12 12:14:50 PM	N/A	Initialize Patient	RUDDB	COMPLETED		YES	DEV
07/18/12 12:16:13 PM	N/A	Transfer Checklist Data	RUDDB	COMPLETED		YES	DEV
07/18/12 12:16:29 PM	N/A	Initialize Patient	RUDDB	COMPLETED		YES	TST
07/18/12 12:17:01 PM	N/A	Transfer Checklist Data	RUDDB	COMPLETED		YES	TST
07/18/12 12:17:12 PM	N/A	Initialize Patient	RUDDB	FAILED	Subject already exists.	YES	DEV

Figure 25: Rave Transactions Log on the Enrollment's Summary Screen

### 5.2.2 Data Transfer Feature

A data transfer can be done if it becomes necessary to resend the clinical data of an already registered patient back to the Group.

- 1) Select the enrollment that needs to be sent to the Group from the Browse subtab (of the History tab).
- 2) Click the Data Transfer button on the enrollment's Summary subtab.
- 3) Press the OK button on the confirmation pop-up box confirming the data transfer to the Group.
- 4) A confirmation message displays when the transfer is complete.

 **Information**  
Data transfer request completed successfully for tracking #28217

---

**Registration Workflow** ▾

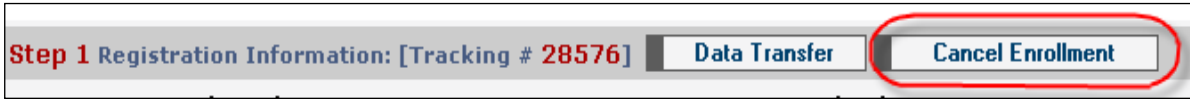
Date	Action	By	From State	To State	Value
02/11/09 11:56:27 AM	NEW	RUDDB	--	NEW	NSABP-B-42-1-GA024-37032-CTSUS-NO_PATIENT
02/11/09 11:57:51 AM	UPD_STATUS	RUDDB	NEW	INCOMPLETE	Partial Worksheet entered or Worksheet has errors
02/11/09 11:57:57 AM	UPD_STATUS	RUDDB	INCOMPLETE	READY	Worksheet saved with no errors
02/11/09 11:58:49 AM	UPD_STATUS	RUDDB	READY	SUBMITTED	Registration submitted
02/11/09 11:59:05 AM	UPD_KEY	RUDDB	SUBMITTED	REGISTERED	NSABP-B-42-1-GA024-37032-CTSUS-827943998
02/11/09 11:59:05 AM	UPD_STATUS	RUDDB	--	REGISTERED	Patient registration is Complete
02/16/09 02:05:26 PM	DATA_TRANSFER	RUDDB	--	REGISTERED	Clinical data transferred to the group
02/16/09 03:40:20 PM	DATA_TRANSFER	RUDDB	--	REGISTERED	Clinical data transferred to the group

Figure 26: Data Transfer

### 5.2.3 Cancel Enrollments Feature

Follow the steps below to cancel OPEN enrollments that have entered a REGISTERED or INELIGIBLE status.

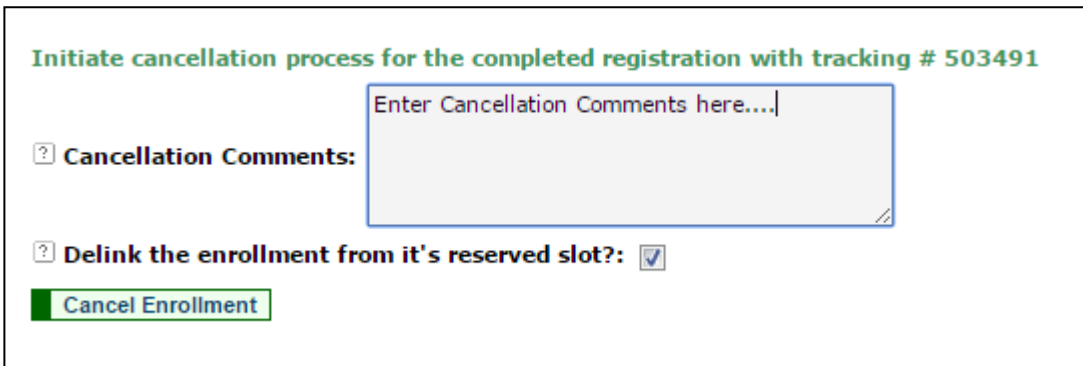
- 1) Go to the History → Browser tab.
- 2) Select the enrollment that needs to be canceled by pressing the associated select button.
- 3) The Summary page is presented.
- 4) Press the Cancel Enrollment button.



**Figure 27: Cancel Enrollment Button on the Summary screen**

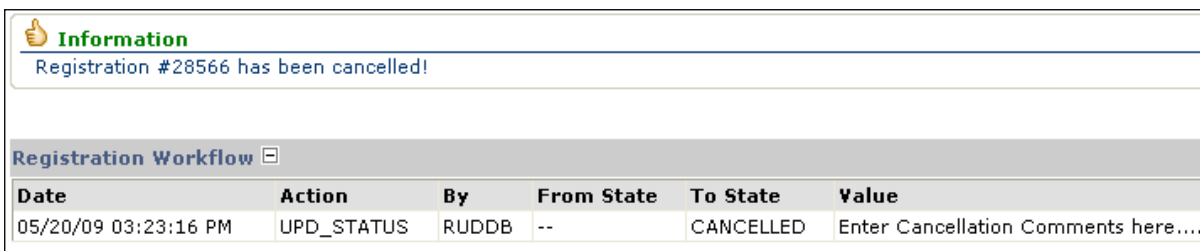
- 5) Press the OK button on the pop-up window to confirm the cancellation of the enrollment.
- 6) Insert cancellation comments as necessary (this is a required field) and press the Cancel Enrollment button.

**NOTE: The option to “Delink the enrollment from its reserved slot?” will only display if a slot reservation is linked to the enrollment.** If the checkbox is marked, the slot reservation will disassociate from the enrollment, the slot reservation’s status becomes REJECTED, and it returns to the pool of available slots. If the checkbox is not selected, the slot reservation remains associated with the enrollment, the status of the slot remains ENROLLED, and it will not return to the pool of available slots.



**Figure 28: Cancellation of an Enrollment for a Slot Reservation Protocol**

- 7) Press the OK button on the second pop-up message to confirm the cancellation of the enrollment.
- 8) A verification page is presented to acknowledge the enrollment is canceled.



**Figure 29: Cancellation Acknowledgement**

### 5.2.3.1 Cancel Ancillary Enrollments Feature

Follow the steps below to cancel an OPEN ancillary study enrollment.

- 1) Click the History tab and the Browser subtab loads by default.

- 2) Select the enrollment that needs to be canceled, and click the record's select button.
- 3) The screen refreshes to the record's Summary page.
- 4) Press the Cancel Ancillary button.

Ancillary Protocol(s) for A011106							
Ancillary Protocol(s):	Protocol	Group #	Type	Reqd?	Status	Status Date	Title
	A011106-E-01	A011106-ST1	EMBEDDED	N	REGISTERED	08/09/2016	Alternate Ap (ALTERNATE)

**Figure 30: Cancel Ancillary Enrollment Button on the Summary Screen**

- 5) Press the OK button on the pop-up window to confirm the cancellation of the enrollment.
- 6) Insert cancellation comments as necessary (this is a required field) and press the Cancel Ancillary button (see Figure 31).

Initiate the process to cancel the REGISTERED ancillary enrollment [A011106-E-01] that is associated with main study enrollment tracking # [518044]. This will not cancel the enrollment for the main study.

**Figure 31: Cancellation of an Ancillary Study**

- 7) Press the OK button on the second pop-up message to confirm cancellation of the ancillary study.
- 8) A verification page acknowledges the enrollment has been canceled (see Figure 32).

<p><b>Information</b>                  Ancillary registration #518045 has been successfully cancelled.</p> <p><input type="button" value="Close"/></p>							
Ancillary Protocol(s) for A011106							
Ancillary Protocol(s):	Protocol	Group #	Type	Reqd?	Status	Status Date	Title
	A011106-E-01	A011106-ST1	EMBEDDED	N	CANCELLED	12/06/2016	Alternate Approaches for Clinical Stage II or III E (ALTERNATE) in postmenopausal women: A phase

**Figure 32: Cancellation Acknowledgement**

### 5.2.4 Transfer to Rave Feature

The ability to manually transmit the patient data from the OPEN interface to Rave auxiliary environments can be accomplished using the Transfer to Rave button. This feature allows users to initialize patients in Auxiliary environments from practice mode and regular mode of the OPEN test instance.

This button is available only for data records of registered patients that have a Rave protocol.

### 5.2.4.1 Transfer Data to Rave for a Single-Step Protocol

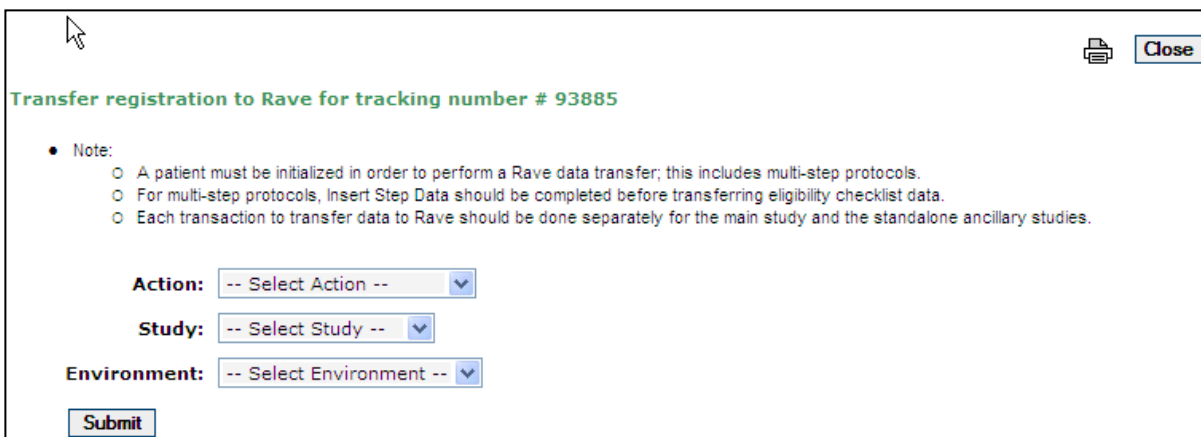
In order to transfer patient data to Rave for a single-step protocol, perform the following steps:

- 1) Select the History tab.
- 2) Under the Browse tab, press Select to select a tracking number with a Rave protocol.
- 3) Select the Transfer to Rave button (see Figure 33).



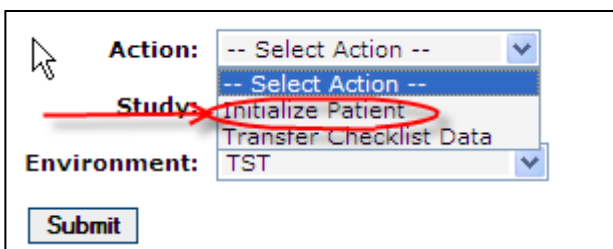
**Figure 33: Transfer to Rave Button on Summary Screen**

- 4) The Transfer registration to Rave screen appears, identifying the tracking number of the patient data.



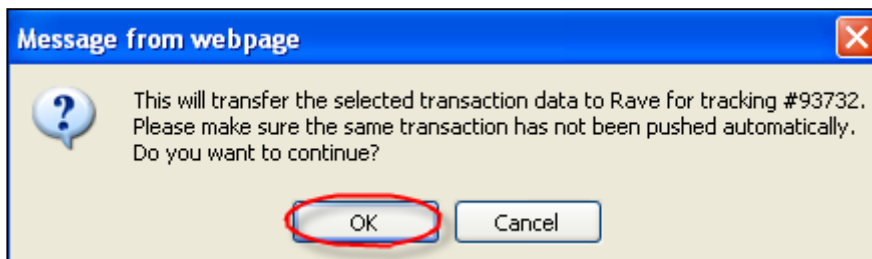
**Figure 34: Transfer Registration to Rave Screen**

- 5) Select the Action: Initialize Patient from the drop-down list.



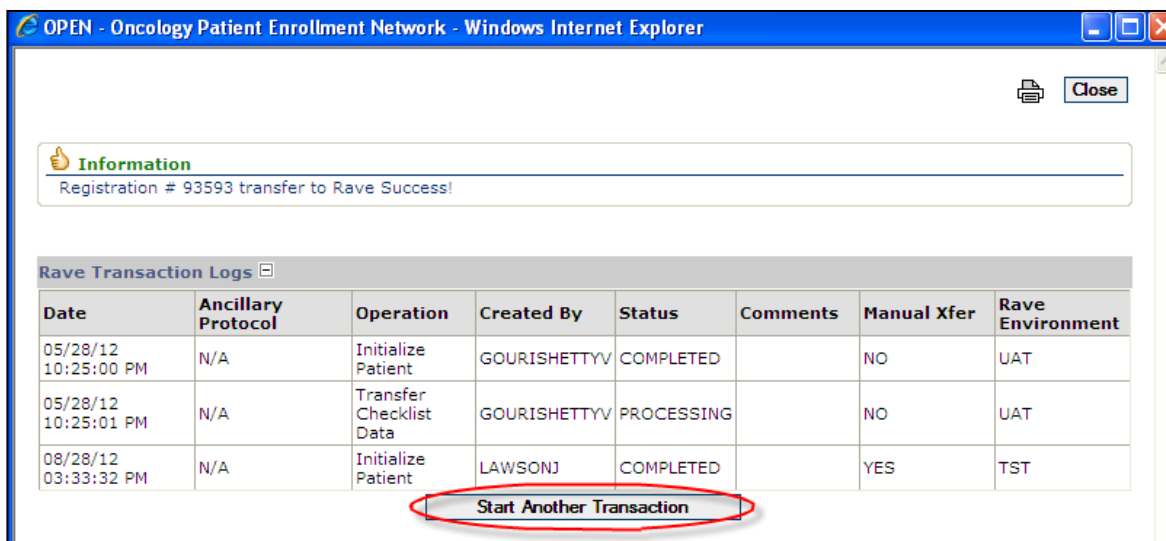
**Figure 35: Action Dropdown Option: Initialize Patient**

- 6) Select the desired Study from the drop-down list.
- 7) Select the desired Environment from the drop-down list of auxiliary environments.
- 8) Press the Submit button. A pop-up message displays, asking for confirmation of the transfer of the selected data to Rave.



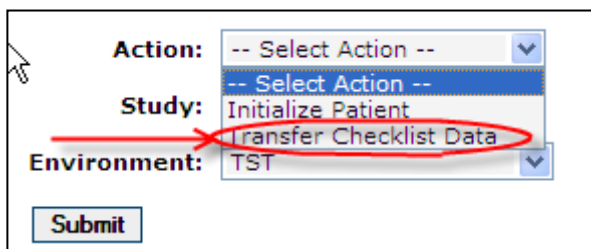
**Figure 36: Message to Transfer Data to Rave**

- 9) Press OK to continue.
- 10) The Rave Transaction Log appears, indicating the success of the transaction.



**Figure 37: Rave Transaction Log**

- 11) Select Start Another Transaction. The Transfer Registration to Rave screen is redisplayed.
- 12) Select Action: Transfer Checklist Data from the drop-down list.



**Figure 38: Action Drop-down Option: Transfer Checklist Data**

- 13) Select the desired Study from the drop-down list.

- 14) Select the desired Environment from the drop-down list of auxiliary environments.
- 15) Press the Submit button. A pop-up message displays, asking if you are sure that you want to transfer the selected data to Rave.
- 16) Press OK to continue.
- 17) The Rave Transaction Log is displayed, indicating the success of the transaction.
- 18) Select Close to close the log.

### 5.2.4.2 Transferring Data to Rave for a Multi-Step Protocol

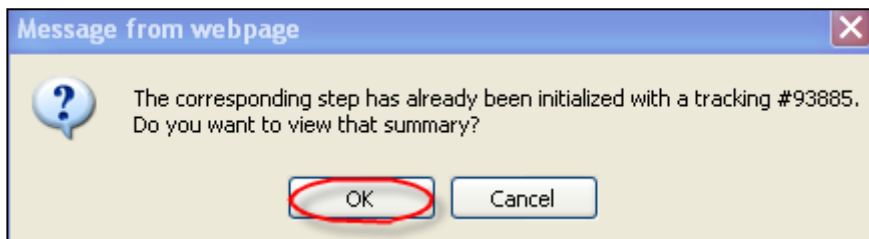
To transfer data to Rave for a protocol’s subsequent step, you must Initialize Patient for Step 1 as defined in section 5.2.4.1 prior to performing the following steps:

- 1) Using the selected record from section 5.2.4.1, select Go to Step 2.



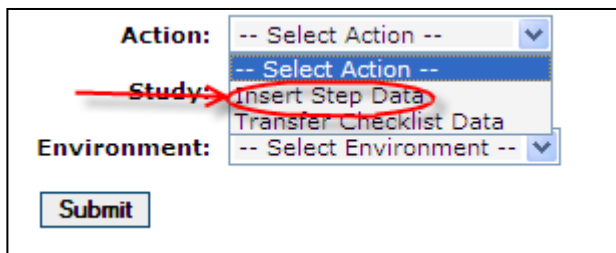
**Figure 39: Go to Step 2 Button**

- 2) A pop-up message appears, asking if you want to view the summary for that step.



**Figure 40: Message to View Step 2 Summary**

- 3) Select OK. The Summary page for Step 2 displays for that patient.
- 4) Select the Transfer to Rave button. The Transfer registration to Rave screen appears, identifying the tracking number of the patient data.
- 5) Select the Action: Insert Step Data.



**Figure 41: Message to View Step 2 Summary**

- 6) Select the desired Study from the drop-down list.

- 7) Select the desired Environment from the dropdown list of auxiliary environments.
- 8) Press the Submit button. A pop-up message appears, asking if you are sure that you want to transfer the selected data to Rave.
- 9) Press OK to continue.
- 10) The Rave Transaction Log appears, indicating the success of the transaction.
- 11) Select Start Another Transaction. The Transfer Registration to Rave screen is redisplayed.
- 12) Select Action: Transfer Checklist Data from the drop-down list.
- 13) Select the desired Study from the drop-down list.
- 14) Select the desired Environment from the drop-down list of auxiliary environments.
- 15) Press the Submit button. A pop-up message appears, asking if you are sure that you want to transfer the selected data to Rave.
- 16) Press OK to continue.
- 17) The Rave Transaction Log appears, indicating the success of the transaction.
- 18) Select Close to close the log.

### 5.2.5 Site Instructions from the Group RandoNode

Groups can display a Site Instruction message after the doCredential call for an OPEN enrollment. To use this feature, a group must subscribe to the doCredential method in OPEN. Once enabled, a site instruction from the group RandoNode will display when a user initializes an enrollment (at the Create New screen confirmation page). The site instruction message can also be viewed in the Summary screen.

Network Group Response(s)	
Eligibility:	ELIGIBLE
Ineligibility Reason:	None.
Patient ID:	7e5151b1-ec3f-4acb
Treatment Arm:	Test
Treatment Assignment Code:	
Disease Code:	10008238
Site Instruction:	This is NON-NCTN RandoNode.

Figure 42: Summary Screen Showing a Site Instruction from a Group RandoNode

### 5.2.6 Exceptional Responder Studies

Cancer treatment trials that support exceptional responder studies will create a patient record in Rave when the user submits their patient enrollment in OPEN. At the enrollment confirmation screen in

OPEN, the user encounters a hyperlink at the bottom of the page that deep-links the user directly into the patient’s record in Rave. The user must click the link to complete the data collection process (see Figure 43).

Selected Tracking # **167563** Details Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status
S1001	247952	GHN	1	2	IL017	Abood, Gerard	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
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.
Site Instruction:	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 PATHSHP - Pathology Report - Including CD20 expression -- Posted: 02/10/2014 - Due: 03/17/2014 CTSCAN - CT Scan Report - Baseline PET/CT -- Posted: 02/10/2014 - Due: 04/17/2014

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

[View Summary](#)

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

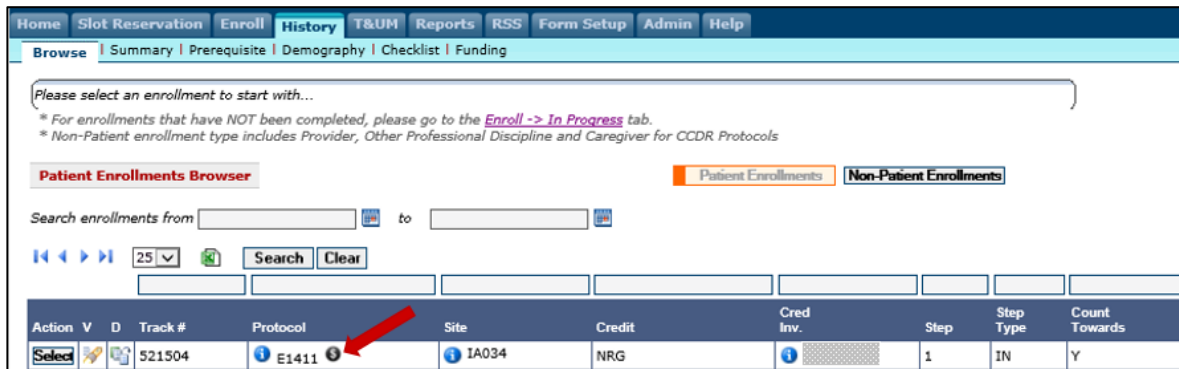
Figure 43: Example of the Rave Hyperlink for Exceptional Responder Studies

## 5.3 Funding Subtab

Studies with additional NCI-approved Per-Case funding requires the site staff to enter the completion dates for the funding types.

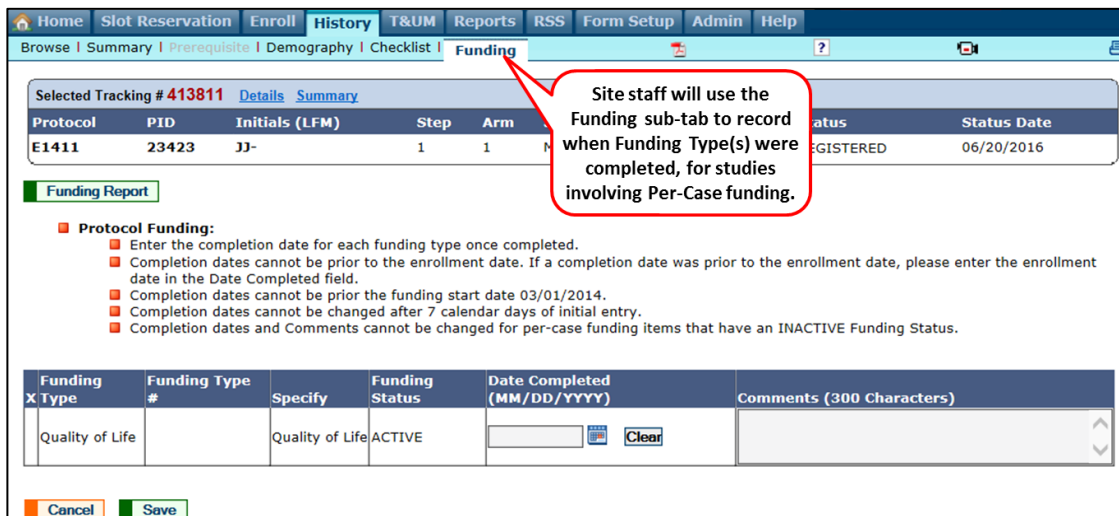
### 5.3.1 Accessing the Funding Subtab

- 1) Log in to the OPEN Portal and click the History tab.
- 2) Locate the subject enrolled on a study that involves Per-Case funding.



**Figure 44: Dollar-Sign Icon Indicates the Enrollment Involves Per-Case Funding**

- 3) Click the Select button for the subject’s row and click the Funding subtab.



**Figure 45: Funding Subtab**

For additional information on the Funding subtab, access the [Funding Screen User Guide](#).

## 6. Transfer and Update Module

Subject enrollment information for an NCI-sponsored cancer clinical trial 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's Clinical Data Management System (CDMS). This process took a significant amount of time and coordination.

The Transfer and Update Module (T&UM) within OPEN is 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 approve requests (when configured). Per NCI's requirement, demography data should not be updated after the enrollment is complete, unless the updates are to correct data entry error, or if sites becomes aware of additional demography information after the enrollment is completed. The T&UM automatically updates (when possible) systems outside of OPEN that contain the subject's data (such as Rave, and the LPO RandoNodes).

The Create New subtab of the T&UM tab contains a message (see Figure 46) 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 staff must follow the existing process for data updates.

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). <b>⚠ 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&amp;UM tab of OPEN. All outstanding data up to this point must be submitted by the transferring site and all queries must be resolved.</b>
<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. <b>⚠ 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.</b>

Figure 46: The T&UM Create New Subtab Includes an Automated List of LPOs that Participate in the

**T&UM**

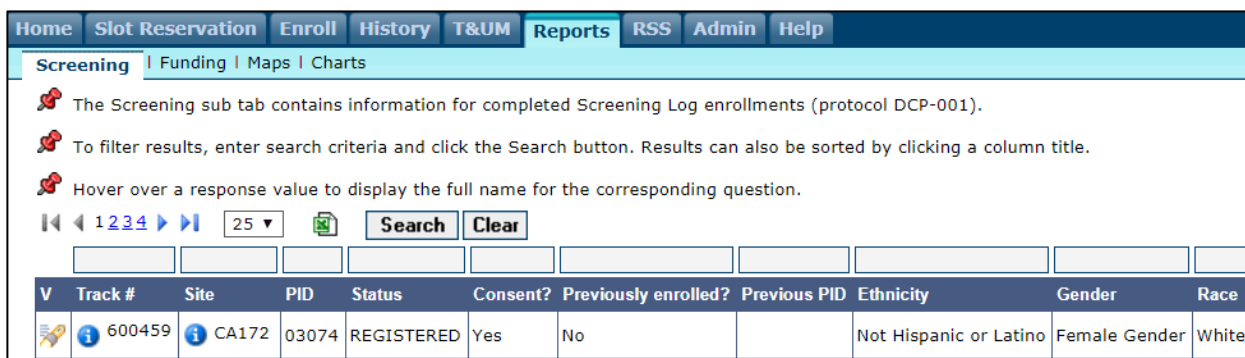
## **6.1 The T&UM Group User Guide**

For information on the T&UM Group User Guide, access the [T&UM Group User Guide](#).

## 7. Reports Tab

### 7.1 Screening Subtab

The Screening subtab contains subject enrollment information for completed Screening Log enrollments (for protocol DCP-001). In addition to general information about the enrollment, all questions from the Screening Log enrollment are available within the screen, and are searchable.



**Figure 47: Screening Subtab Displays Screening Log Enrollment Data**

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 future development of protocols that better meet subject needs and increase accrual rates.

Table 5 specifies the Screening Log enrollment data accessed by OPEN users (based on the type of user).

**Table 5: Access to Screening Log Enrollment Data**

User Type	Screening Log Data that can be Accessed
Site	Screening Log enrollment data that corresponds to sites that the user has Active roster affiliations with.
LPO	Screening Log enrollment data that corresponds to (Protocols for) their organization.
NCI and CTSU	All Screening Log enrollment data. User will have the option of Report Type to view.

#### 7.1.1 Additional Reports for NCI Users

NCI staff can select from the following reports for subjects enrolled to the DCP-001 study:

- NCORP Package Report: Complete data report by NCORP Package Name;
- Demographic Report: Demography specifics;

- Enrollment Report: Enrollment eligibility criteria;
- Screening Report: Completed Screening Log enrollments (protocol DCP-001 and ancillary studies DCP-001-E01 and DCP-001-E02).

A Trial Type is required for the NCORP Package, Demographic, and Enrollment reports.

- Cancer Control/Prevention - If the response to the question “The patient is being enrolled on” in the Eligibility Checklist (EC) is adult or pediatric cancer control/prevention/CCDR, and the protocol selected does not contain Care Delivery (CD) in the CTEP protocol number;
- CCDR - If the response to the question “The patient is being enrolled on” on the EC is adult or pediatric cancer control/prevention/CCDR, and the protocol selected contains CD in the CTEP protocol number;
- Treatment - If the response to the question “The patient is being enrolled on” on the EC is adult or pediatric treatment trial.

The data may be filtered using a start and end date. See Figure 48 for an example of the available reports for NCI staff.

The screenshot shows the 'Reports' tab interface. At the top, there are navigation tabs: Home, Enroll, History, T&UM, Reports (selected), RSS, and Help. Below this, there are sub-tabs: Screening (selected), Funding, Maps, Charts, and CDUS. A help section provides instructions on filtering and sorting. Below the help, there are filters for Report Type (Demographic Report), Trial Type (CCDR), and Screening Date. There are 'Submit' and 'Reset' buttons. Below the filters, there are pagination controls (25 items per page) and 'Search' and 'Clear' buttons. The main content is a table with the following data:

V	Site	NCORP Package	PID	Ethnicity	Gender	Race	Age	Rural	Education
	NV034	NCRF	04561	Hispanic or Latino	Male Gender	White	18	No	Not high school graduate
	NV034	NCRF	04553	Not Hispanic or Latino	Male Gender	Black or African American	17	No	High school graduate (in
	HI012	HAWAII	04377	Not Hispanic or Latino	Female Gender	Asian	15	Yes, lack of proximity to cancer practice/center	Some college or associat
	HI012	HAWAII	04221	Not Hispanic or Latino	Female Gender	Asian	35	No	Some college or associat
	HI012	HAWAII	04084	Hispanic or Latino	Female Gender	American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, White	14	Yes, lack of proximity to cancer practice/center	Some college or associat

**Figure 48: Reports for NCI and CTSU Staff**

## 7.2 Funding Subtab

The Funding subtab is included under the Reports tab. This enhancement enables OPEN users (LPO, site, NCI staff, etc.) to access the Funding Report (Figure 49). Oral Agent information is also included in the Funding Report.

Site	Protocol	Credit Network Group	Investigator	Patient ID	Enrollment Date	Funding Type	Funding #	Funding Status	Specify	Completion Date	Comments	Completed By
ID013	A031201	ALLIANCE	Kevin Mulvey (20700)	69541	07/08/2014 05:08 PM	Advanced Imaging		ACTIVE	Advanced Imaging - Other - A031201-IM1	07/08/2014		GUSTINR
ID013	A031201	ALLIANCE	Kevin Mulvey (20700)	69541	07/08/2014 05:08 PM	Biospecimen	1	ACTIVE	Biospecimen - Other - ST1, PP1, PP2	07/08/2014		GUSTINR

Figure 49: 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.

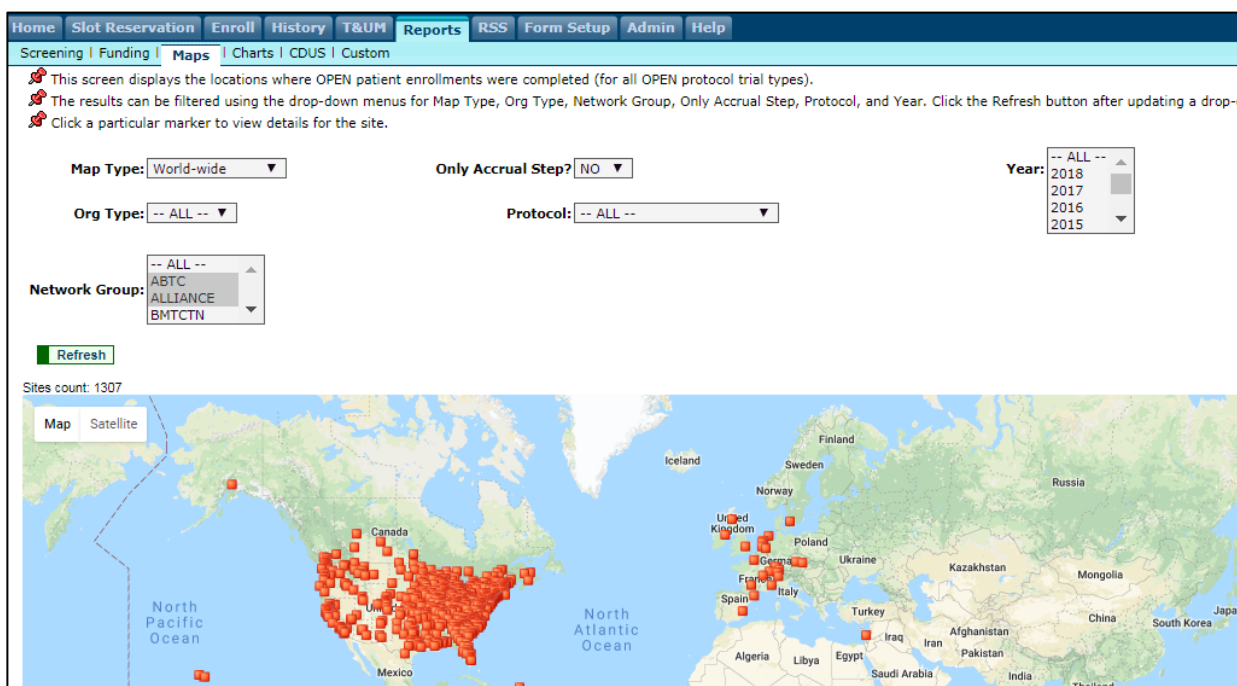


Figure 50: The Maps Subtab Displays Locations Where OPEN Enrollments Have Occurred

Content within the Maps subtab can be filtered 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 51: 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.

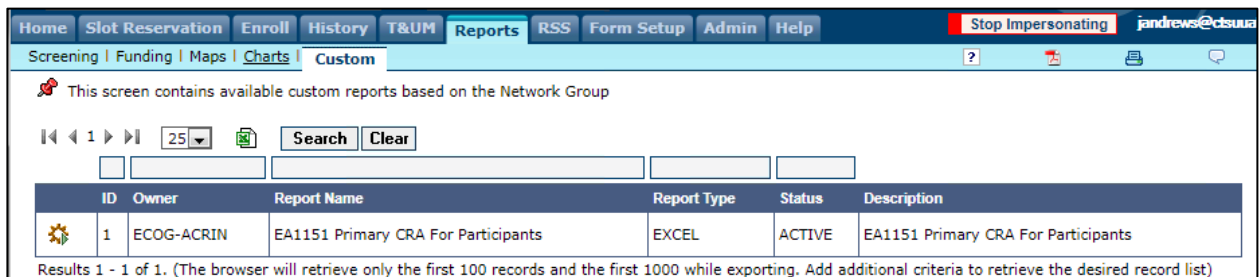
The data can be filtered by the following criteria:

- 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.

## 7.5 Custom Subtab

The Custom subtab (of the Reports tab) displays custom reports for LPO staff, based on their Network Group affiliation(s).

The LPO submits a request for a new report to be added to the Custom report screen; once approved, CTSU IT staff adds the report to the grid in the Custom reports subtab, and it is only available for a designated LPO.



**Figure 52: Custom Subtab**

**Instructions:**

- 1) Log in to OPEN and click the Reports tab.
- 2) Click the Custom subtab.
- 3) Click the Generate Custom Report button (⚙️) to see run and save the desired report (as a CSV file).

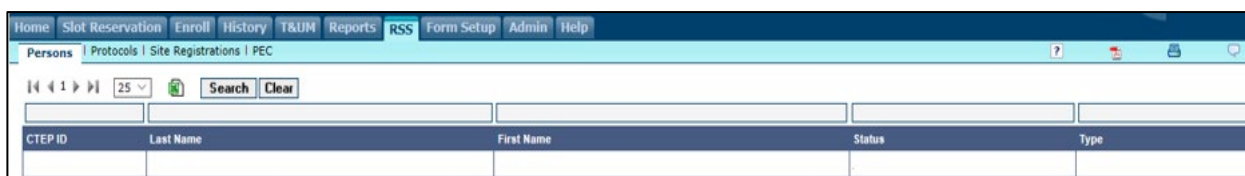
## 8. RSS Tab

### 8.1 Persons Subtab

The Persons subtab (of the RSS Tab in OPEN) provides the ability to search for individuals using a variety of search criteria. Simply place the cursor in the free-text entry box above the field in question, enter the text, and press the Search button.

The list of the criteria that can be used for searching include:

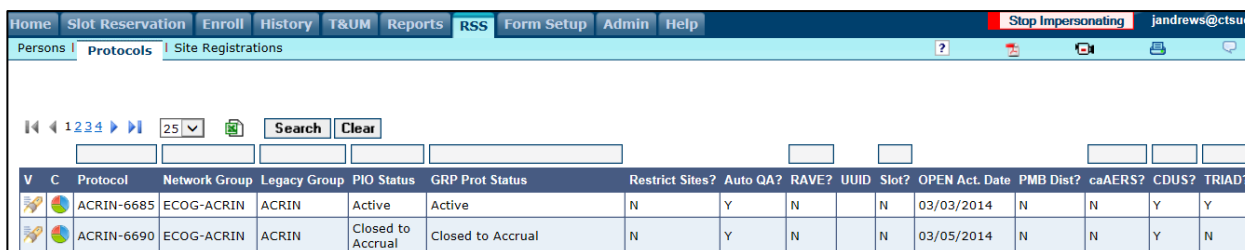
- CTEP-ID;
- Last Name;
- First Name;
- Status;
- Type.



**Figure 53: The Persons Subtab Allows for Searches Based on a Variety of Different Criteria**

### 8.2 Protocols Subtab

Previously, CTSU and LPO staff accessed multiple locations within OPEN (or load the Regulatory Support System [RSS] application) to obtain protocol information. A Protocols subtab (to the RSS tab) allows efficient access to detailed protocol information regardless of role.



**Figure 54: Protocols Subtab**

This enables all NCI, site, and CTSU staff to access detailed information regarding OPEN protocols. CTSU and NCI staff can view all OPEN protocols. LPO staff can view their organization’s protocols. Site staff can view protocols for which their institution has site registrations.

### 8.3 Site Registrations Subtab

The Site Registrations subtab of the History tab provides access to Site Registration information.

Site	Protocol	Site Name	Status	Status Date	Comments	IRB Expiry	IRB Status	Missing Requirements
GA024	PACCT-1	Northeast Georgia Medical Center	Approved	04/17/2009	Complied with all items; IRB Expires 06/15/2009	06/15/2009	Expires in 26 day (s)	
GA024	GOG-0209	Northeast Georgia Medical Center	Approved	01/27/2009	Complied with all items	09/04/2009	Renewed on 10/23/08	
GA024	C80405	Northeast Georgia Medical Center	Approved	01/27/2009	Complied with all items	09/14/2009	Renewed on 12/05/08	
GA024	RTOG-0521	Northeast Georgia Medical Center	Approved	01/27/2009	Complied with all items	10/02/2009	Renewed on 01/08/09	

**Figure 55: The Browser on the Site Registration Subtab**

The searchable fields include:

- Site Number;
- Protocol;
- Status.

**Accessing this Feature:**

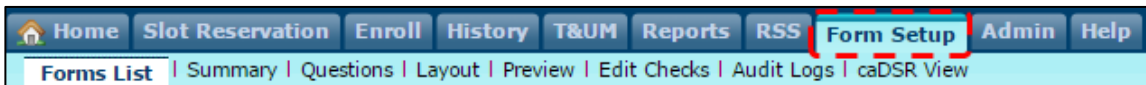
- 1) Click the Site Registration Search link on the Welcome page, or the RSS tab.
- 2) Click on the Site Registrations subtab.
- 3) Enter the search criteria in the search field(s).
- 4) Click the Search button. The browser results refresh based on the search content.

## 9. Form Setup Tab

The Form Setup tab gives the Administrator the means to create, control, manipulate, and test their associated forms and edit checks in OPEN.

Click the Form Setup tab and the following subtabs are displayed (Figure 56):

- Forms List;
- Summary;
- Questions;
- Layout;
- Preview;
- Edit Checks;
- Audit Logs;
- caDSR View.



**Figure 56: Forms Setup Subtabs**

### 9.1 Forms List Subtab

The Forms List subtab displays the list of protocol forms currently offered through OPEN.

Table 6 provides a description of the different statuses for OPEN enrollment forms.

**Table 6: OPEN Form Statuses**

Status	Description
ACTIVE	An active form is complete and ready for current use. This is the version that is currently being used to create enrollments.
INACTIVE	An inactive form is in an unused state. This form was created but never used to create an enrollment. This form may eventually be activated for future use or be deleted.
RETIRED	A retired form has been used to create at least one registration. As a result, the form cannot be inactivated; it can only be retired. A retired form cannot be modified or deleted.

The Forms List subtab only displays ACTIVE forms by default. However, the drop-down list above the Status column can be used to change the status filter to display results that have a different status.

If there are not any OPEN protocols for a specific Group, a message within the Forms List screen appears.

The Select button selects a specific form (see Figure 57), and then you will be taken to the form's Summary screen.

Selecting a form allows operation of the other subtabs. The subtabs in the Form Setup screen now only relates to the selected form.

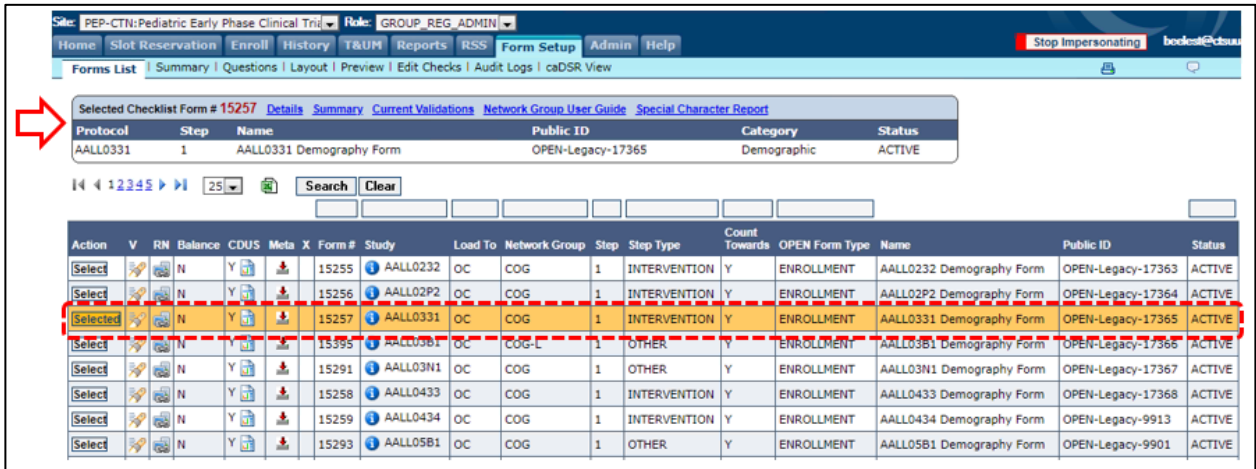


Figure 57: Selected Form Highlighted

Group OPEN Administrators can only access forms for the Group(s) in which they have been assigned the OPEN Administrator role.

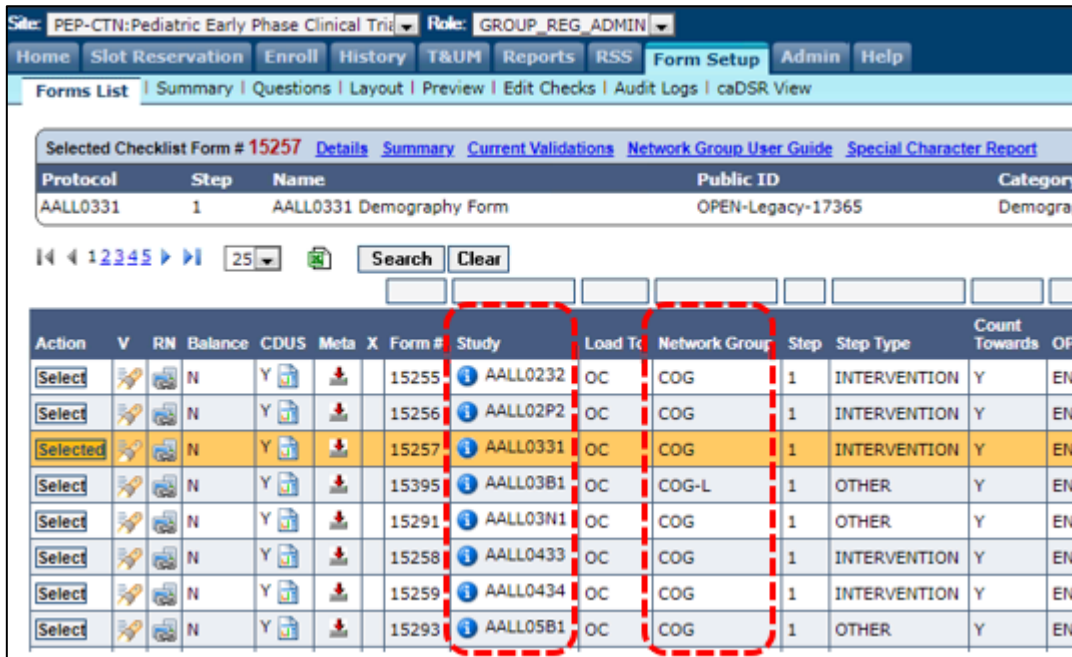


Figure 58: Forms List Screen Shows Forms for the User's Group

### 9.1.1 Retrieving Form Data for a Particular Network Group

A network group search can be performed on the Forms List screen to minimize the data returned.

- 1) Click on the box above the Network Group field.
- 2) A drop-down menu is displayed.
- 3) Select the desired Group.

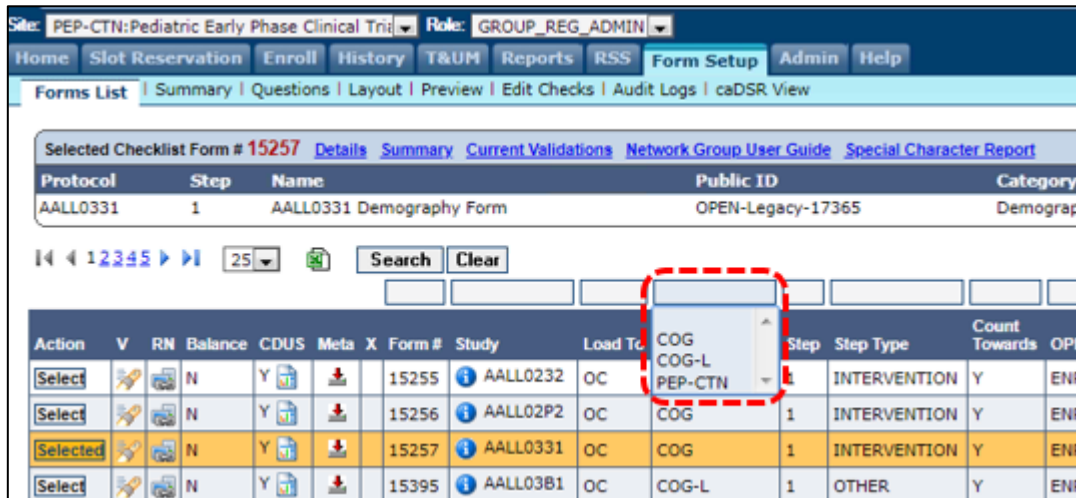




Figure 59: Network Group Drop-down Menu on Forms List

- 4) Once a drop-down option is selected, by either typing in a letter or by selecting an option in the Network Group box, the items for that group appears.

## 9.1.2 RandoNode Report

The RandoNode Report  displays the target RandoNode information (at the form level) to which a protocol step is configured to send the enrollment data. This reduces the time and effort required to determine a form’s RandoNode settings.

### Accessing this Feature:

- 1) Log in to OPEN.
- 2) Click the Form Setup tab.
- 3) In the Forms List subtab, click the View RandoNode Linkage  button for a particular form.
- 4) The RandoNode Summary for the selected step and study appears in a popup window.

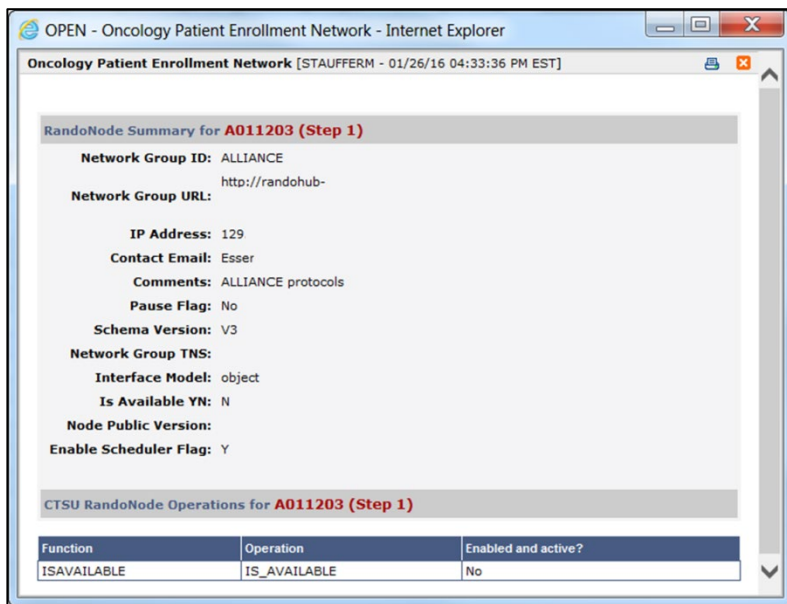


Figure 60: RandoNode Summary Popup Window

### 9.1.3 CDUS-A Compliance Information

Since OPEN will become the source of information for the Clinical Data Update System Abbreviated (CDUS-A) reporting, the enrollment information collected must comply with the CDUS-A reporting standards. The CDUS column (see Figure 61) displays whether the protocol for each form can participate in CDUS-A reporting.

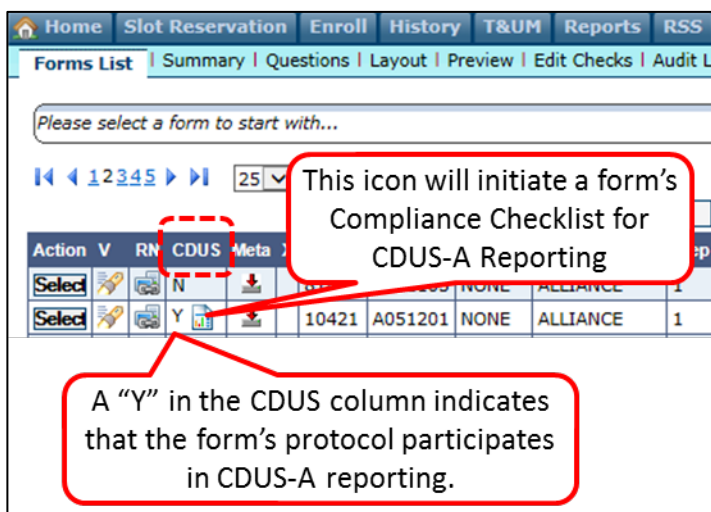

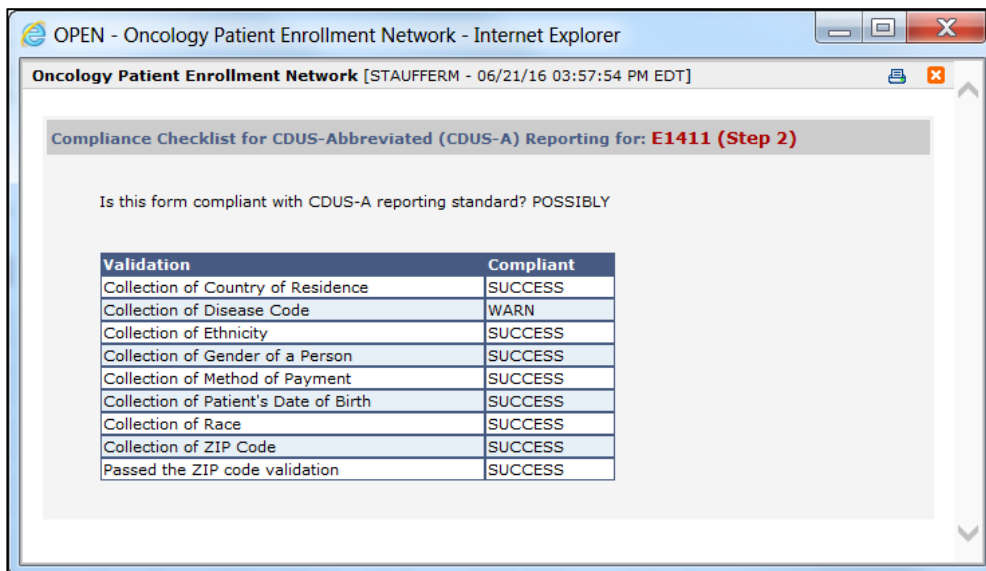


Figure 61: The CDUS Column

A Compliance Checklist icon  is available for each participating protocol's form (within the CDUS column), which launches a detailed CDUS-A compliance report for the form (see Figure 62).



**Figure 62: Compliance Checklist for CDUS-Abbreviated Reporting**

For the Compliance Checklist, the question “Is this form compliant with CDUS-A reporting standards?” will display an overall grade for the form’s compliance with CDUS-A reporting standards. Table 7 describes the different possible grades for the form’s overall compliance.

**Table 7: Description of Compliance Checklist Grades**

Grade	Description
Yes	This value indicates that the form is compliant with all CDUS-A reporting standards. The value will be YES if all nine validations have a SUCCESS result in the selected form, or any validations that have a WARN or FAILURE result in the selected form have a SUCCESS result in any of the previous-step forms for the same protocol (that have an ACTIVE form status).
Possibly	This value indicates that the form may be compliant with all CDUS-A reporting standards. The reason that OPEN cannot be certain that the form is fully compliant with CDUS-A reporting standards is that the Disease Code might not be collected on the Demography screen (and returned by the LPO at the time of patient enrollment). The value is POSSIBLY if the Disease Code validation has a WARN result for the selected form (or if the Disease Code validation fails for the selected form but has a WARN result, and no SUCCESS results, for any previous-step forms for the same protocol that has an ACTIVE form status), and the other eight validations have a SUCCESS result for the selected form (or if a previous-step form, for the same protocol, with an ACTIVE form status, has a SUCCESS result for the same validation).
No	This value indicates that the form is not compliant with all CDUS-A reporting standards. The value is NO if any of the validations have a FAILURE result for the selected form (and none of the previous-step forms for the same protocol, that have an ACTIVE form status, have a WARN or SUCCESS result for that validation).

Table 8 explains the logic for the nine validations.


**Table 8: Description of the Compliance Checklist Validations**

Validation	Description
Collection of Country of Residence <sup>1</sup>	The field must be configured as visible and required in the Demography screen. If the form passes this validation, the result will be SUCCESS, otherwise FAIL.
Collection of Disease Code <sup>1</sup>	The following criteria pertains to the Demography screen field: Required and visible = SUCCESS Required and hidden = WARN Not required and hidden = FAIL Not required and visible = FAIL
Collection of Ethnicity <sup>1</sup>	The field must be configured as visible and required in the Demography screen. If the form passes this validation, the result will be SUCCESS, otherwise FAIL.
Collection of Gender of a Person <sup>1</sup>	The field must be configured as visible and required in the Demography screen. If the form passes this validation, the result will be SUCCESS, otherwise FAIL.
Collection of Method of Payment <sup>1</sup>	The field must be configured as visible and required in the Demography screen. If the form passes this validation, the result will be SUCCESS, otherwise FAIL.
Collection of Patient’s Date of Birth <sup>1</sup>	The field must be configured as visible and required in the Demography screen. If the form passes this validation, the result will be SUCCESS, otherwise FAIL.
Collection of Race <sup>1</sup>	The field must be configured as visible and required in the Demography screen. If the form passes this validation, the result will be SUCCESS, otherwise FAIL.
Collection of ZIP Code <sup>1</sup>	The field must be configured as visible to be SUCCESS, otherwise FAIL.
Pass the ZIP code validation <sup>1</sup>	All of the following criteria must be met in the same form to have a SUCCESS result, otherwise a FAIL result: (1) the “Collection of Country of Residence” validation must be SUCCESS, (2) the “Collection of ZIP Code” validation must be SUCCESS, (3) the expression must contain VALIDATE_POSTAL_CODE, (4) the edit check status must be Active, and (5) the edit check’s Failure Type must be “ERROR”.

<sup>1</sup> CTSU uses rollup of collected enrollment data (across all enrollment steps for the same protocol and patient) for the purposes of CDUS-A reporting. If the validation result is not SUCCESS for the selected form, but the validation result is SUCCESS for a previous step Active form for the same study, the SUCCESS result applies to the selected form’s validation.

### 9.1.4 Downloading the Metadata

Within the Form Setup tab, metadata files for OPEN enrollment forms can be downloaded from the Forms List subtab, as well as from the Questions subtab.

To download a metadata file from the Forms List subtab, click the Meta column icon  for the desired form (see Figure 63), and the option to open or save the file appears.

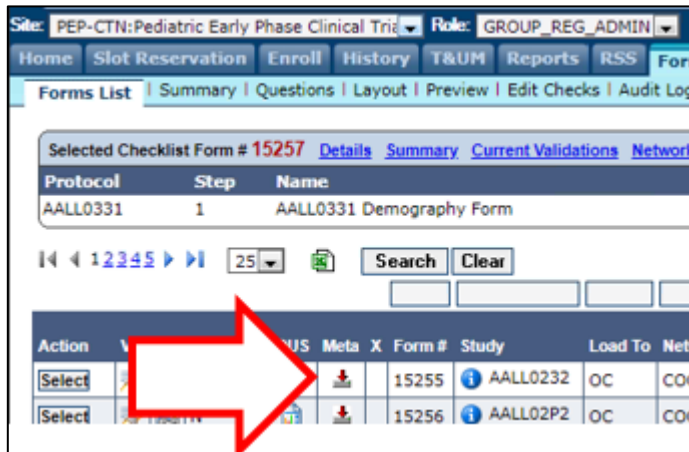



Figure 63: Use the Download Meta Icon to Download a Form's Metadata

To download a metadata file from the Questions subtab, click the Download Metadata link (Figure 71) to open or save the file.

### 9.1.5 The Rave Configuration Checklist

The Rave Configuration Checklist displays Rave configuration information for a particular OPEN enrollment form. The checklist can be accessed for a study by clicking the View Rave Configuration Details  icon in the Load To column for a study (in the Forms List subtab of the Form Setup tab). See Figure 64.

The screenshot shows the 'Form Setup' tab in the application. At the top, there are navigation tabs: Home, Slot Reservation, Enroll, History, T&UM, Reports, RSS, Form Setup (selected), Admin, and Help. Below these is a breadcrumb trail: Forms List | Summary | Questions | Layout | Preview | Edit Checks | Audit Logs | caDSR View. A sub-header indicates 'Selected Checklist Form # 14368' with links for Details, Summary, Current Validations, Network Group User Guide, and Special Character. A table lists forms with columns: Protocol, Step, Name, Public ID, and Ca. Below the table is a search area with a dropdown set to '25', a search icon, and 'Search' and 'Clear' buttons. A main table lists actions (Select, V, RN, CDUS, Meta, X, Form #, Study, Load To) for various forms. A red callout box points to a gear icon in the 'Load To' column of the row for Form # 10503, ADVL1211, with the text: 'This icon will open the Rave Configuration Checklist screen for a protocol.'

Figure 64: View Rave Configuration Details Icon

The Rave Configuration Checklist screen displays the Rave configurations (for both main and ancillary studies) found in RSS, OPEN, and the CTSU Enterprise Network Transaction Engine for Rave (CENTER). The checklist also identifies the Rave ALS Version used for the protocol's form (see Figure 65).

The screenshot shows the 'Rave Configuration Checklist for Study S1115 - Step 1'. It features a sub-header 'Selected Checklist Form # 5581' and a table with columns: Protocol, Step, Name, Public ID, Category, and Status. Below this are sections for RSS, OPEN, and CENTER configurations, each with a list of configuration items and their values. The RSS section includes 'OPEN to load to Rave?', 'S1115 - Step 1 load to Rave?', and 'Study UUID configured?'. The OPEN section includes 'Process Rave Transactions?', 'Rave Study Name (Production Environment)', 'Rave Study Name (Practice Environment)', 'RandoNode', and 'ALS Version'. The CENTER section includes 'RAVE Study Group', 'Target Configured?', and 'RAVE Study Group Target Operations' with a sub-table of operation names and URLs.

Figure 65: Example of the Rave Configuration Checklist Screen

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### 9.1.6 Skip-Step Feature

The Skip-Step feature enables administrative OPEN users to configure enrollment step-skipping at the protocol level, depending on whether the protocol was in an active or non-active status. This feature can be used on multi-step protocols. For example, for an active 3-step protocol, a configuration could be added on step 3, so that subjects who enrolled on step 1 can enroll directly onto step 3 (skipping step 2 enrollment).

Each configuration will have a required future expiration date (and it will not have a future-date limitation). Configurations will expire at the start of the day after the expiration date.

For skip-step configurations that are configured for non-approved site registrations, OPEN will only allow skip-step enrollments to proceed if the Missing Enrollments flag is unchecked for the enrolling site's site registration. The Missing Requirements validation requires no configuration; it is automatically applied to all OPEN skip-step configurations that allow non-approved site registrations. The validation will not run for skip-step configurations involving approved site registrations.

LPOs may add Blocking Amendments to protocols if a critical issue is identified (such as an adverse event), and they require an immediate halt to new patient enrollments until sites obtain IRB approval for the amendment. For COG and Pediatric Early Phase Clinical Trials Network (PEPCTN) protocols, until a site obtains approval for the blocking amendment:

- Sites will not be able to enroll patients onto protocol steps 0 and 1 (and also, not use skip-step configurations).
- Sites will be able to enroll patients (that are already enrolled to the study) onto steps 2 and higher.

The configuration of this feature is performed upon request by the CTSU OPEN Registrar team.

### 9.1.7 Step Type Column

A Step Type column (see Figure 66) counts accruals for all OPEN trials. The Step Type (SCREENING, INTERVENTION, or OTHER) allows the Count Towards flag to be selected for multiple steps in the same study.

All logic in OPEN using the count accrual flag was changed to use the new count towards flag (see Figure 67). The step type identifies which category of accrual the enrollment will be counted towards. In addition to the step type, the count towards flag indicates whether the step will be counted towards accrual for the particular step type.

Selected Checklist Form # 15257 Details Summary Current Validations Network Group User Guide Special Character Report

Protocol	Step	Name	Public ID	Category	Status
AALL0331	1	AALL0331 Demography Form	OPEN-Legacy-17365	Demographic	ACTIVE

Action	V	RN	Balance	CDUS	Meta	X	Form #	Study	Load To	Network Group	Step	Step Type	Count Towards	OPEN Form Type	Name	Public ID	Status
Select			N	Y			15255	AALL0232	OC	COG	1	INTERVENTION	Y	ENROLLMENT	AALL0232 Demography Form	OPEN-Legacy-17363	ACTIVE
Select			N	Y			15256	AALL02P2	OC	COG	1	INTERVENTION	Y	ENROLLMENT	AALL02P2 Demography Form	OPEN-Legacy-17364	ACTIVE
Select			N	Y			15257	AALL0331	OC	COG	1	INTERVENTION	Y	ENROLLMENT	AALL0331 Demography Form	OPEN-Legacy-17365	ACTIVE

Figure 66: The Accrual Step Column in the Forms List Subtab

Please select a form to start with...

Action	V	RN	Balance	CDUS	Meta	X	Form #	Study	Load To	Network Group	Step	Step Type	Count Towards	OPEN Form Type	Name	Public ID	Status
Select			N	Y			14444	AALL0232	OC	COG	1	INTERVENTION	Y	ENROLLMENT	AALL0232 Demography Form	OPEN-Legacy-14444	ACTIVE
Select			N	Y			14445	AALL02P2	OC	COG	1	INTERVENTION	Y	ENROLLMENT	AALL02P2 Demography Form	OPEN-Legacy-14445	ACTIVE
Select			N	Y			14446	AALL0331	OC	COG	1	INTERVENTION	Y	ENROLLMENT	AALL0331 Demography Form	OPEN-Legacy-14446	ACTIVE

Figure 67: The Count Towards Column in the Forms List Subtab

## 9.2 Summary Subtab

When selecting a form from the Form List, the Summary screen displays summary information about that particular form (Figure 68).

Form ID: 7362  
 Study: ADVL1111  
 Step: 1  
 Form Name: ADVL1111 Eligibility  
 Definition: ADVL1111 Eligibility  
 Context: CTEP  
**OPEN Form Type:** ENROLLMENT  
 Type: CRF  
 Instruction: Reminder: Prior to enrolling a patient on ADVL1111, please ensure that all Screening ar 3.0 of the protocol document. The eligibility criteria below are to be interpreted literally  
 Category: Registration  
 Public ID: 3489518  
 Version: 1.0  
 Owner:  
 Form Status: ACTIVE on 05/01/2013 01:34 PM EDT  
 Updated By: LEL on 05/01/2013 01:34 PM EDT

Form Version:	Version ID	Version Date (YYMMDD)
	8747	130429

Compare form setup/edit checks:  
 Compare current form with:

**Figure 68: Summary Screen**

In this mode, some details can be edited by clicking on the Edit Summary button. Clicking on the Edit Summary button allows the option to activate, inactivate, or retire the selected form (see Figure 69). Activating an inactive form automatically inactivates or retires the active form for the corresponding study/step combination. The OPEN Form Type is also selectable.

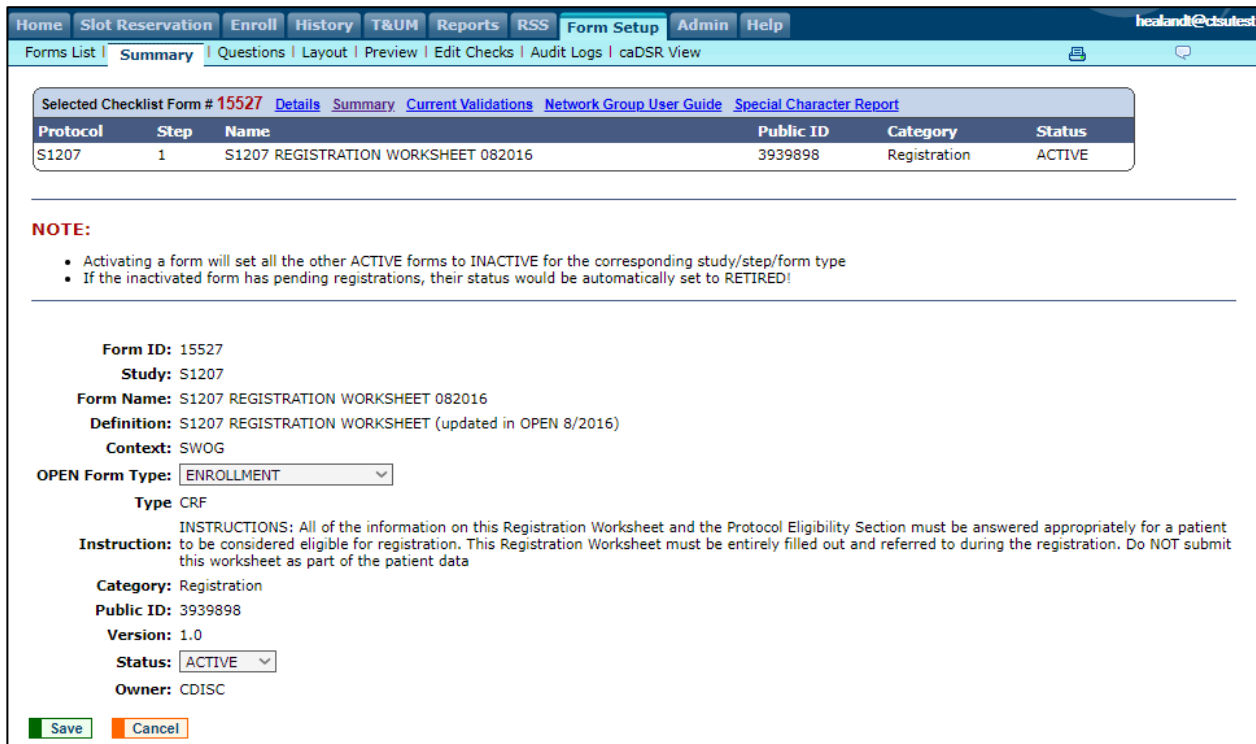


Figure 69: Edit Summary



From the Summary screen, there is an option print a blank form for the associated protocol. Clicking on the Print Blank Form button provides a printable page of the specified protocols checklist values. This form shows the Credentialing, Demography, and EC fields on a single form. Any drop-down lists in these forms appear as radio buttons so that they are visible.

### 9.2.1 Form Comparison Feature

At the bottom of the Summary screen, there is a drop-down listing that allows a comparison of the current forms Question screen, Layout screen, and Edit Check screen with a different version of the same form (see Figure 70).

The questions shown in the first table (Target Question/Layout Setup Differences) are only those that have the same module name and question Common Data Element (CDE) in both the source and target form.

To use the Form Comparison feature:

- 1) Select a version to compare against from the **Compare current form with** drop-down menu.
- 2) Click the Compare button.
- 3) A new screen appears showing the values that are the same and the values that are different.
- 4) The green check  indicates that the values in the two forms are the same.
- 5) The red  indicates the values in the two forms are different.

**Form Comparisons:**

- ✔ indicates that the source and target question's setup are the **SAME**
- ✘ indicates that the source and target question's setup **DIFFERS**

Form setup comparison results for source form #7637 and target form 7724:

- 🖱 Mouse over the CDE to display the question/instruction (if any)

-- Target Question/Layout Setup Differences --																		
Source Que #	Target Que #	CDE #	Reqd.	Edit	Hide	Upper	Default	Widget	Note	Note Loc.	Tooltip	Date Valid.	Width	Height	Row Order	Column Order	Cell Order	
66816	67485	2488869	✔	✔	✔	✔	✔	✔	✔	✔	✔	✘	✔	✔	✔	✔	✔	
66817	67486	2465291	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66818	67487	2842684	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66819	67488	2201705	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66820	67489	944	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66821	67490	88	✔	✔	✔	✔	✔	✔	✘	✔	✔	✔	✔	✔	✔	✔	✔	
66822	67491	2003852	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66823	67492	62	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66824	67493	2746723	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66825	67494	2179986	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66826	67495	3293767	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66827	67496	2950587	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66828	67497	656	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66829	67498	1235	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66830	67499	2003309	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66837	67506	905	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66838	67507	780	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66839	67508	2658163	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66840	67509	2658182	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66841	67510	2658183	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66842	67511	793	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66843	67512	2200604	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
66844	67513	2192217	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	

Form Edit Check comparison results for source form #7637 and target form 7724:

- NOTE: Edit checks are compared based on the test order.

-- Target Edit Check Differences --														
Test Order	# Aliases	Module	Question	Status	Alias	Alias Count	Check Type	Desc.	Fail. Type	Fail. Message	Expression	Override	Primary	
1	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
2	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
3	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
4	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
5	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
6	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
7	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
8	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
9	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
10	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
11	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
12	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
13	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
14	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
15	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
16	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
17	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
18	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
19	2	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
20	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
21	1	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	

Figure 70: Form Comparisons

## 9.2.2 How to Migrate Patient Enrollments to the Latest Version of a Protocol's Form

CTSU OPEN Administrators can migrate in-progress OPEN enrollments created under an older version of a form, to a protocol’s latest Active form. This also prevents site users from submitting an older version of the EC when the Network Groups support only one active version of EC. If assistance is needed with migrating an In Progress OPEN enrollment to the latest version of the form, contact the CTSU OPEN Registrar team.

### 9.3 Questions Subtab

The Questions subtab allows for configuration of a form’s questions. The attributes and requirements of each question associated with that form are specified in this page.

Figure 71: Questions Screen

If applicable, any question module can be associated with an embedded or standalone ancillary or main protocol by assigning the module to a study (Figure 71). The protocols available for selection appear in the Protocol Type drop-down (Figure 72). These protocols are listed per the protocol set up in RSS. To assign a question module to a particular protocol go to that module, click on the drop-down and select the appropriate protocol from the drop-down.

OPEN has a single form combining the main study and ancillary studies. OPEN provides the ability to differentiate the ancillary study modules from the main modules (see Figure 72). The caDSR view screen provides more information including CDE public id, version, and valid values.

Figure 72: Appended Ancillary Study Module

**NOTE:** The radio selection buttons for the Hide question feature (within the Questions subtab of the Form Setup tab) automatically disables updates after an OPEN enrollment initiates for the OPEN form. This ensures that T&UM synchronization transactions to the LPO RandoNode are successful.

### 9.3.1 Viewing and Configuring a Question's Settings

Questions subtab provides the following data:

- Que ID – The ID of the question in the database. Pressing the associated Que ID button (see Figure 73) displays the CDE details for that question. This includes the public ID, version details, and valid values of a question;
- Question name – the long name of the question;
- Question Data type – the form the data entered will take;
- Character;
- Number;
- Alphanumeric;
- Date (see section 9.3.1.2 Configuring Date Fields for further details).

Using a Yes or No format, specify whether the associated field is:


- Mandatory (Required);
- Editable (Edit);
- Hidden (Hide);
- Uppercase (Upper).

Question's CDE Details:																															
<b>OPEN Question ID:</b>	3544																														
<b>CDE Public ID:</b>	2916439																														
<b>Version:</b>	1.0																														
<b>Long Name:</b>	Name of VATS lobectomy credentialed surgeon																														
<b>Instruction:</b>	If VATS lobectomy is planned, provide the following:																														
<b>Display Order:</b>	0																														
<b>Preferred Definition:</b>	the name of the credentialed surgeon performing endoscopic surgery of the pleural cavity performed with visualization via video transmission.																														
<b>Data Element Details:</b>	<table border="1"> <tbody> <tr> <td>Version:</td> <td>1.0</td> </tr> <tr> <td>Preferred Name:</td> <td>INDS_NAME</td> </tr> <tr> <td>Data Type:</td> <td>CHARACTER</td> </tr> <tr> <td>Format:</td> <td></td> </tr> <tr> <td>High Value:</td> <td></td> </tr> <tr> <td>Low Value:</td> <td></td> </tr> <tr> <td>Min Length:</td> <td>1</td> </tr> <tr> <td>Max Length:</td> <td>100</td> </tr> <tr> <td>Decimal Place:</td> <td></td> </tr> <tr> <td>UOM:</td> <td></td> </tr> <tr> <td>Context:</td> <td>CTEP</td> </tr> <tr> <td>Data Type Desc:</td> <td>A character string of letters, symbols, and/or numbers</td> </tr> <tr> <td>Data Type Annot:</td> <td></td> </tr> <tr> <td>Origin:</td> <td></td> </tr> <tr> <td>Character Set:</td> <td></td> </tr> </tbody> </table>	Version:	1.0	Preferred Name:	INDS_NAME	Data Type:	CHARACTER	Format:		High Value:		Low Value:		Min Length:	1	Max Length:	100	Decimal Place:		UOM:		Context:	CTEP	Data Type Desc:	A character string of letters, symbols, and/or numbers	Data Type Annot:		Origin:		Character Set:	
Version:	1.0																														
Preferred Name:	INDS_NAME																														
Data Type:	CHARACTER																														
Format:																															
High Value:																															
Low Value:																															
Min Length:	1																														
Max Length:	100																														
Decimal Place:																															
UOM:																															
Context:	CTEP																														
Data Type Desc:	A character string of letters, symbols, and/or numbers																														
Data Type Annot:																															
Origin:																															
Character Set:																															
<b>Valid Values:</b>	No permissible values available																														

**Figure 73: caDSR Question CDE Details**

The Min. and Max. columns are predetermined and are not editable.

In the next field # V. Values, determine whether to display the valid value's long name, meaning, or description.

If the valid values count is greater than zero (0), OPEN will display this configuration  icon.

Clicking that icon displays the configuration window for the associated data type. The configuration window shows all of the question's valid values and their details.

Change the display value by selecting the value's name, meaning, or description from the Reset Display drop-down list. The selected value becomes the primary display on the checklist form.

An optional display appears within parenthesis. Using this, can display the value's name, meaning or description, or any associated instructions.

**Use this screen to configure the way you want certain questions to behave:**

**Question:** Patient Gender

**Valid Values as downloaded from caDSR**

- Select the format in which the values need to be displayed
- Not selecting any will default to the "Name" alone
- Click [OK]
- Then click [Save] on the main questions screen to save the settings!

Name	Meaning	Description	Instruction
FEMALE	Female Gender	An individual who reports belonging to the cultural gender role distinction of female.	
MALE	Male Gender	An individual who reports belonging to the cultural gender role distinction of male.	

**Current Display:** Name

**Reset Display:** -- select -- ( optional display )

**Note:** This setting is for only for display purpose. In the EC form(s), only "Name" will be saved in the database as the question's response


OK Cancel

**Figure 74: Configuration Screen**

This is only for display purposes on the checklist form. When the value saves in the database, only the Name field associates with it.

Specifications include:

- Any default value(s) that appears in the EC when the form generates while registering a subject;
- The Widget Type of the field (Please see the Widget section 9.3.1.3 for more details).

On standard checklist forms, certain Groups may need to limit selection of values. Clicking on the associated  icon will hide invalid values from the form.

- Click on the associate icon located in the # V.Values column.

Patient Hospital No.										
CHARACTER						1	25	0	<input type="text"/>	Edit Box
Gender										
CHARACTER						1	7	2		Radio Group Vertical
Race (Mark all that apply)										
CHARACTER						5	41	6		Check Box Vertical
Ethnicity (Mark one)										
CHARACTER						7	22	3		Check Box Vertical
Patient Zip Code										
CHARACTER						null	10	0	<input type="text"/>	Edit Box

**Figure 75: Valid Values Icon**

- When clicking on the desired icon, a new window appears with all the valid values for the question. In the drop-down beside the question value, select Yes to hide that value. The No value is the default value and does not hide the value. In the example shown in Figure 76, the Unknown value is hidden and not displayed on the screen.

**Question:** Gender of a Person

---

**Valid Values as downloaded from caDSR**

- By default all valid values for a question will be displayed in the EC
- Select "Yes" to hide that valid value from being displayed
- Click [Save] to save the settings and re-generate the EC (You don't need to save the Question setup again)

- **You will not be able to hide any valid values that have been used with a completed or pending enrollment for this form. Downloading the form again would allow a valid value that has been used to be hidden.**
- **All valid values WITHIN A QUESTION cannot be hidden. To hide all valid values of a question, hide the question instead.**

Order	Name	Hide Y/N
0	Female Gender	No <input type="button" value="v"/>
1	Male Gender	No <input type="button" value="v"/>
2	Unknown	Yes <input type="button" value="v"/>

**Figure 76: Select Values to Hide**

Notes can also be entered. See Figure 77 for examples of entries that have note fields that accompany the associated field name on the enrollment form.

The position of the note can be changed in respect to the associated field title. Use the drop-down under the Note Position column to change to location of the note to the top, bottom, left, or right of the field title.

Tooltip messages can be added using this screen (shown in Figure 77). The tooltip field allows the display of any message when the mouse cursor is pointing to that field name.

The Note, Note Position, and Tooltip columns can be expanded and collapsed by clicking on the +/- marks associated with the desired column.

Note	Note Position	Tooltip
Testing Notes Field Maximum characters: 2000	Top	
	Top	Tool Tip functionality - When Curs
	Top	

**Figure 77: Questions Screen Continued**

The results of entering data in these fields (see Figure 78).

Header			
Testing Notes Field Last *	First * <input type="checkbox"/>	Middle <input type="checkbox"/>	Patient Birth Date * <input type="checkbox"/>
Site Name Northeast Georgia Medical Center	Tool Tip functionality - When Curser is pointing at the First Initial		
Treating physician Kallab, Andre			
Patient Social Security Number (USA Only) <input type="text"/>			

**Figure 78: Checklist Form when Notes and Tooltip options are entered**

### 9.3.1.1 Configuring a Module for the Prerequisite Screen

For some protocols, there are special requirements for a subject to be eligible to participate in that protocol. Within OPEN, the Prerequisite screen separates the modules from other checklist modules and displays those selected modules only on the Prerequisite screen. If the prerequisite conditions are not met, then the registration can be stopped at this point.

For example, if a protocol requires that a subject be already registered in another protocol, then the prerequisite screen can ask the patient ID number to verify this special requirement.

The Prerequisite tab and associated data can be configured from the Question screen by assigning the desired module the Type = Prerequisite.

- Bring up the form in the Questions screen that requires Prerequisite data.
- Change the Data Type field drop-down value to Prerequisite (Figure 71). For the module that will be displayed in the Prerequisite tab there must be at least one Checklist module and no Prerequisite module can be associated with an ancillary study.

### 9.3.1.2 Configuring Date Fields

Configure the date field to validate the user input by using the date validation screen. Click on the icon located next to the date that needs to be configured.

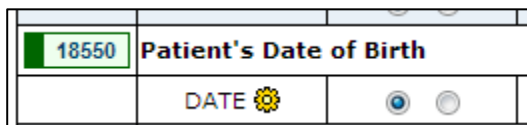


Figure 79: Date Field and Icon

Use this screen to configure date validations:

**NOTE:** Currently validations are only for DATE datatypes and can be associated with only one question (alias). If multiple alias needs to be linked, you'll need to write an edit check. Validations will fire instantly on the screen whereas edit checks will fire after saving.

**Question:** Patient's Date of Birth

**Instruction:**

**Validation Constructor** [?](#)

- **Short Cuts:**  Past Dates Only  Future Dates Only
- The "No. of Units" field accepts only number which indicates the number of days/months/years
- If Start/End date number's are zero, then it means the validation is either for past or future only dates
- End date fields will only be enabled if a condition of "AND" is selected
- To include/exclude current date in validation, set the "Include Today" to YES/NO
- **Click on [Review] button to review your date validation in plain English**
- To remove an existing validation, click [Clear], then [OK] to close the screen and finally click [Save] on the questions screen

	No. of Units	Units	Operator	Date	Include Today?
* Start Date:	0	DAY(S)	BEFORE	CURRENT DATE (TODAY)	YES
† Condition:	-- condition --				
† End Date:		-- select --	-- select --	CURRENT DATE (TODAY)	-- select --
* Message:	Date must occur on or before today's date.				
† If condition is specified, then end date fields also need to be filled in					
<b>Note: Please use the "Preview" tab under "Form Setup" to test out these validations!</b>					
<input type="button" value="Review"/> <input type="button" value="OK"/> <input type="button" value="Clear"/> <input type="button" value="Cancel"/>					

Figure 80: Date Configuration Screen

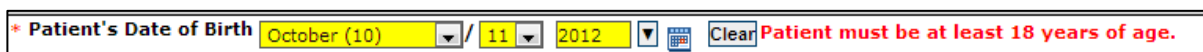
The date validation configuration screen is presented, and determinations can be made regarding how a particular date field functions.

There are multiple functions in this screen:

- Specify that this date is only valid if the date is in the past by pressing the Past Dates Only button.
- Specify that this date is only valid if the date is in the future by pressing the Future Dates Only button.
- Specify specific date criteria by filling in the fields.
  - The No. of Units field indicates how many units is used in the calculation.
  - The Units indicates the selected timeframe. There is an option of choosing the timeframe of days, months, or years to validate against.

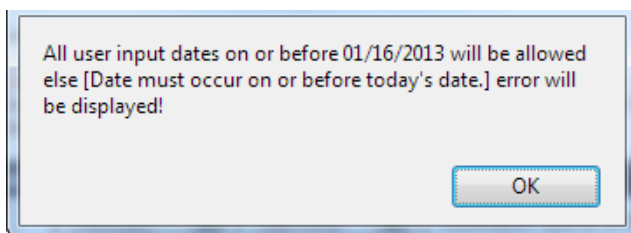
- The Operator field indicates when the date criteria is functional. There is an option of choosing a time period before 'today's' date or after 'today's' date.
- The date always calculates from the current days date.
- There is an option to include the current date in the calculation. In the Include Today field, indicate whether the calculation begins with the current date by selecting YES in the drop-down menu, or indicate that the current date should not be included in the calculation by selecting NO in the drop-down menu.
- An appropriate message must be entered in the Message field. The data entered in the message field is shown to the user if an invalid date is entered in the associated date field.

For example, in Figure 80, this configuration says that the Date Informed Consent Signed date field is only accepted if the date is '5 days before today, including today AND 10 days after today including today'. If this validation is not satisfied, then the data provided in the message field is presented to the site staff member for further action (see Figure 81).



**Figure 81: Error Message**

Pressing the Review Button shows the correct range of user input dates (as well as the user-created error message) according to the configurations (see Figure 82).



**Figure 82: Date Configuration Review**

- Press OK to save the date configuration screen.
- Press Clear to delete changes.

The Questions screen must be saved to see the changes made in the associated form. The validations can be tested using the Preview screen.

### 9.3.1.3 Configuring a Question's Widget Type

The term widget describes various visual components (graphical display elements) that present information to the OPEN user. Some widgets have the capability to display significant amounts of data, such as paragraphs of text, while others are little more than 'switches' that accept a **Yes** or a **No** answer to questions on a form. The following subsections describe common widget types:

### 9.3.1.3.1 Radio Group Widget

For a specific form question, two or more options are available as possible choices; each has a small circle (radio button) by it. Clicking a circle with the cursor marks it, to indicate the choice (see Figure 83). Only one button within a radio group can be selected. Clicking a second button negates the first. In Figure 84, only one payment method can be selected.

**Method of Payment (mark primary method only) \***

- Private Insurance
- Medicare
- Medicare and Private ← Radio button selected
- Medicaid
- Medicaid and Medicare
- Other
- Military or Veterans Sponsored, Not Otherwise Specified (NOS)
- Military Sponsored (including CHAMPUS & TRICARE)
- Veterans Sponsored
- Self Pay (No Insurance)
- No means of payment (no insurance)
- Unknown

Figure 83: Widget Example - Radio Group

### 9.3.1.3.2 Check Box (Single) Widget

The simplest data entry item, a check box, indicates the affirmation of a question (e.g., I am at least 18 years of age). A small square box is placed beside the question. Clicking the cursor on it marks it with a check mark.

### 9.3.1.3.3 Check Box (Multiple) Widget

When a question can have more than one answer, a check box is placed beside each option. As many boxes may be checked as necessary (see Figure 84). This instruction is clearly marked on the form.

**Protocol Eligibility (mark all that apply). All criteria must be met (see Protocol Section 4.0) \***

- Postmenopausal
- Disease-free from initial breast cancer diagnosis
- Primary tumor was pathologic or clinical Stage I, II or IIIA invasive breast carcinoma documented by core needle or open biopsy
- Primary tumor was ER-positive and/or PgR-positive
- No other malignancies within past 5 years
- No history of non-traumatic osteoporotic bone fractures
- No diagnosis of contralateral breast cancer
- Not currently on sex hormonal therapy
- No current estrogen or progesterone-replacement therapy or oral contraceptives
- All other protocol criteria met

Multiple check boxes selected

Figure 84: Widget Example - Check Boxes

If the Checkbox widget type is used, and a question has 16 or more valid values, then the valid values are divided into two columns for display to make it easier for users to view the choices. If a valid value is too long, it will wrap to the next line.

### 9.3.1.3.4 Edit Box Widget

An edit box is a small rectangle of varying length into which data can be entered. It is commonly used to enter initials, dates, names, addresses, etc. (see Figure 85). Usually there are conditions or limitations programmed into these fields, (e.g., the number and type of characters, the formatting of the field).

Last * <input type="text" value="R"/>	First * <input type="text" value="j"/>	Middle <input type="text" value="A"/>	Patient Birth Date * <input type="text" value=""/> / <input type="text" value=""/> <input type="text" value=""/>
Site Name			
Treating physician			
Patient Social Security Number (USA Only) <input type="text" value="123"/> <input type="text" value="45"/> <input type="text" value="6789"/>			

**Figure 85: Widget Example - Edit Boxes**

### 9.3.1.3.5 Text Area Widget

A text area is an expanded edit box that is capable of holding many lines of data, limited only by the constraint of size programmed into the code (see Figure 86). Comment and explanation boxes are the most commonly used text areas.

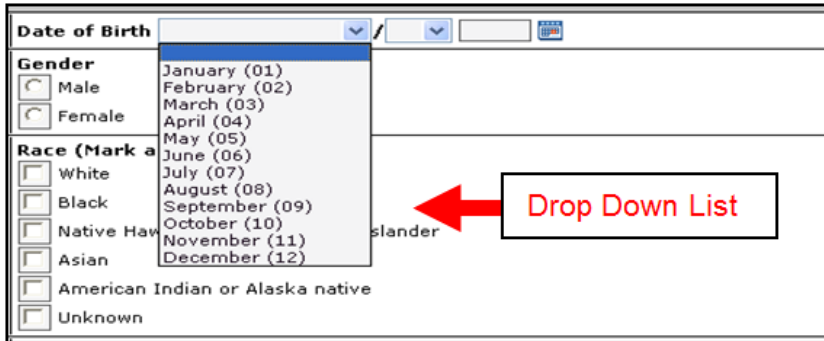
Cardiac History		
Medical Condition	Medications (in the 12 months prior to study entry) *	Comments (Optional)
hypertension	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Ischemic Heart Disease	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Congestive Heart Failure	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Atrial Arrhythmia	<input type="checkbox"/> Yes <input type="checkbox"/> No	come to the aid of their parties. The quick brown fox jumps over the lazy old dog. When in the course of events, it is determined

Text Area

**Figure 86: Widget Example - Text Area**

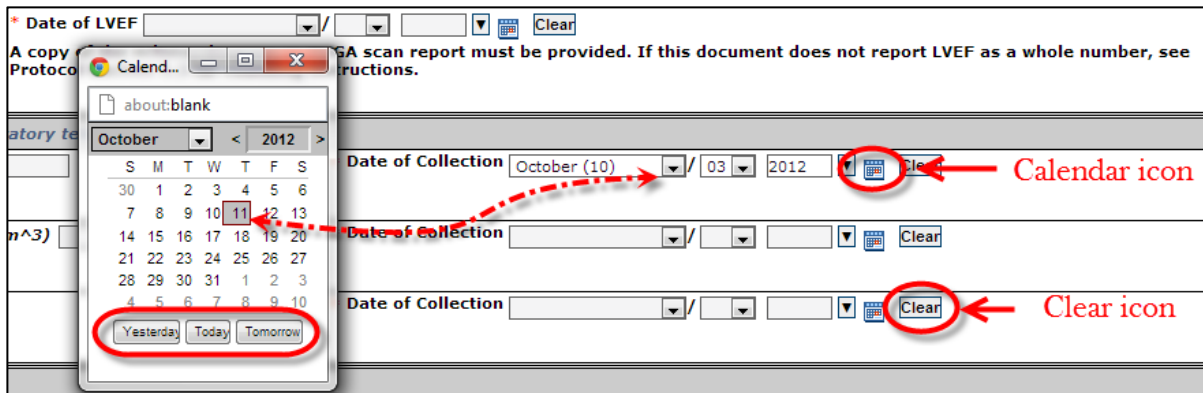
### 9.3.1.3.6 Drop-Down List Widget

Click the down arrow at the right side of an edit box and a list of possible answers opens. Click a choice to display in the field. Only one selection allowed. This type of drop-down widget lists of dates (months, days, years), States, etc., (see Figure 87).



**Figure 87: Widget Example – Drop-Down**

With date fields, there is an added icon, which when clicked, displays a small calendar. When a specific date on the calendar is selected and clicked, the date auto-fills the accompanying edit fields (Figure 88). Clicking on the Yesterday, Today, and Tomorrow buttons automatically populates those respective dates in the date field.



**Figure 88: Widget Example - Calendar Date Option**

### 9.3.1.3.7 Multi Select List Widget

Multiple choices are displayed in a fixed window. There may be a scroll bar that can be used to display additional options. More than one choice can be selected from the list of values.

### 9.3.1.3.8 Prefill Widgets

Prefill widgets allows certain data to prefill within fields in the Prerequisite or Checklist screens of OPEN. For instance, if there is a field within the Checklist screen that requires the user to enter the Investigator, to save the user’s time and reduce the chance of error, assigning the appropriate prefill widget allows OPEN to automatically answer the question for the user with the value they provided in the Create-New screen. Table 9 provides a list of the different prefill widgets that derive values from the Create-New screen.

**Table 9: Create-New Screen Prefill Widgets**

Prefill Widget	Field that the Value is Derived From
Prefill: Credit Recipient Group	The selected Network Group Credit
Prefill: Disease code	The Disease Code selected on the Demography screen.
Prefill: Institution	The name of the selected Institution
Prefill: Institution CTEP ID	The selected Institution CTEP ID
Prefill: Investigator	The name of the selected Treating Investigator
Prefill: Investigator CTEP ID	The CTEP ID of the selected Treating Investigator
Prefill: IRB Approval Date	The IRB Approval Date for the site registration
Prefill: IRTF Description	The IRTF Description of the provider associated with the enrollment
Prefill: IRTF Type	The IRTF Type of the provider associated with the enrollment
Prefill: PI Email	The email address of the selected Principal investigator for study
Prefill: PI Name	The name of the selected Principal investigator for study
Prefill: PI Phone	The phone number for the selected Principal investigator for study
Prefill: Registrar	The name of the selected Site Registrar
Prefill: Slot Dose	The name of the selected slot reservation Dose.
Prefill: Slot Dose Frequency	The Frequency of the administered selected slot reservation Dose
Prefill: Slot Dose Level	The Level for the selected slot reservation Dose.
Prefill: Slot Dose Unit	The Unit for the selected slot reservation Unit.
Prefill: Slot Stratum	The Stratum Name for the selected slot reservation Stratum.
Prefill: Slot Stratum Group	The Stratum Group for the selected slot reservation Stratum.
Prefill: Today's Date	Today's date

**Steps to Assign a Prefill Widget to a Field:**

- 1) Log in to OPEN.
- 2) Click the Form Setup tab.
- 3) Locate the necessary form in the Forms List subtab.
- 4) Click the Select button for the form.
- 5) Click the Questions subtab.

- 6) For the necessary field, select the appropriate Prefill widget from the Widget Type drop-down menu for that field (see Figure 89).
- 7) Click the Save Question Setup button.

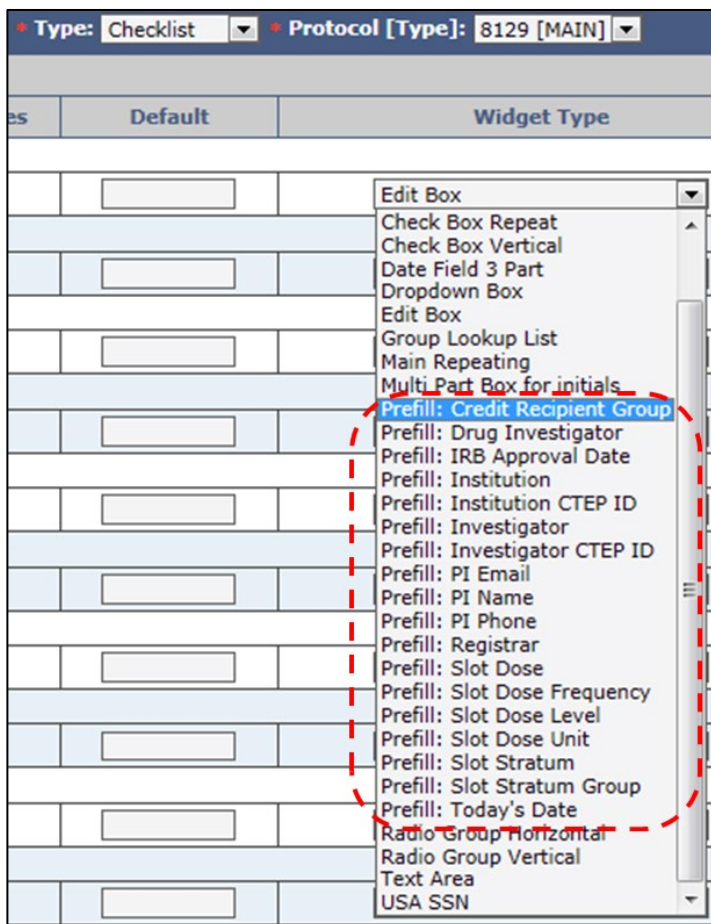


Figure 89: Prefill Widget Type Choices

### 9.3.1.3.9 USA SSN Widget

Use the USA SSN widget for the Patient SSN field in the Demography screen. The CDE has an embedded format of ###-##-####, and the widget enforces that the entered values are numeric.

### 9.3.1.3.10 Group Lookup List Widget

OPEN allows for the backend configuration of the Group Lookup List column names for each question that uses the Group Lookup List widget. Contact the CTSU OPEN Registrar team for assistance with configuring custom column names.

### 9.3.1.4 Widget Param Column (for Limiting IRTF Results by Modality)

For some background, the Imaging and Radiation Treatment Facility (IRTF) prefill widgets (Prefill: IRTF Description, Prefill: IRTF Providers, Prefill IRTF Type) will display the subject’s applicable IRTF information that was selected by registrars (in an enrollment’s Create New screen), at the question that is configured for the prefill widget.

Since some subjects can have multiple IRTF values, the Widget Param column can be used to limit the displayed results to a specific modality.

**Instructions:**

- 1) Log in to the applicable OPEN environment, and click the Form Setup tab.
- 2) Select the desired protocol form, and click the Questions subtab.
- 3) Locate the desired question that uses an IRTF prefill widget.
- 4) Enter the modality information in the Widget Param field for the question, and click the Save Question Setup button to save the setting.

Module #4   ID: 28159   Name: Planned Radiation Therapy   Repeat: N/A   Type: Checklist   Protocol [Type]: NRG-GI002 [MAIN]												
Que ID	Question Name (Instruction)											
	Data Type	Reqd. Y/N?	Edit Y/N?	Hide Y/N?	Upper Y/N?	Min.	Max.	# V.Values	Default	Widget Type	Widget Param	
108899	Planned radiation therapy											
	CHARACTER	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1	50	2				
108900	RT Facility Code											
	CHARACTER	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	15	0			Prefill: IRTF Providers	DWBO	

Figure 90: Insert the Modality Information in the Widget Param Field

### 9.3.2 The Disease Code Field

With the release of OPEN 7.0, the Disease Code field (within the Standard\_NCI\_Reporting module, which is part of the Demography screen) was added to every active form within OPEN. This field collects information needed for CTSU to perform CDUS Abbreviated (CDUS-A) reporting to the NCI (thus alleviating the need for the LPOs to perform this task).

Forms downloaded into OPEN UAT (starting October 10, 2014) had the field attached (and set as visible by default), and field was added to all the existing forms that were active (but the field was configured by default to be hidden from view).

The Disease Code field uses the Group Lookup List widget (configured by default) to collect a Simplified Disease Code value from CTEP, which the user selects from a popup list.

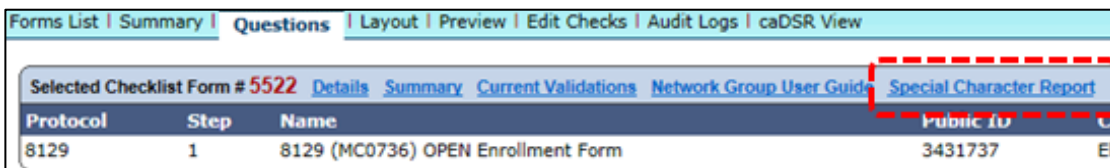
If a question in the EC asks for the disease code, it can be prefilled from the value that was selected from the field in the Demography screen, by using a prefill widget (Prefill: Disease code) for the EC field.

### 9.3.3 Special Character Report

When special characters are part of a form’s metadata, issues may arise when RandoNodes are processing the data. The Special Character Report checks an OPEN enrollment form and lists any special characters that are present in the form’s metadata, thus preventing any potential issues.

**Accessing the Special Character Report:**

- 1) Log in to OPEN.
- 2) Click the Form Setup tab.
- 3) Select the desired form.
- 4) Click the Questions subtab.
- 5) Click the Special Character Report link.



**Figure 91: The Link to the Special Character Report is on the Questions Subtab**

- 6) The Special Character Report appears in a pop-up window.

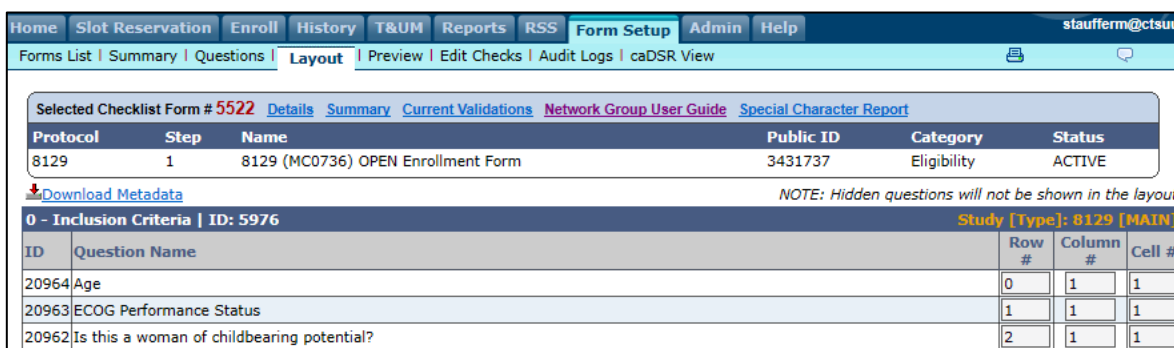
Special Character Report for form #5522 - 8129 (Step 1) [Public #3431737]

Module Name	Question Name	Special Character	Location(^)	Question Public ID
No special characters found				

**Figure 92: The Special Character Report**

## 9.4 Layout Subtab

The **Layout** module enables OPEN administrators to specify where questions will appear within a protocol form.



**Figure 93: Layout Screen**

**Row #** – This column dictates the row in the module where the item appears. Figure 93, shows the last, first, and middle initials will all be on the first row; site name on the second row; treating physician on the third row, etc.

**Column #** – This column dictates the column in the module where the item appears. Figure 93, shows the last initial is in column 1, the first initial is in column 2, and the middle initial is in column 3. Site name appears in column 1 of row 2, etc.

**Cell #** – The display cell column dictates the stacking order of the questions within a cell where items are located. This is usually done when an item is grouped as one but have different values. For example, entering the month and year, the date field will be one item but the month will be in display cell 1 and the year will be in display cell 2. This indicates the month should proceed the year in the displayed order.

48	Tamoxifen Treatment End Year	1	2	2
49	Tamoxifen Treatment End Month	1	2	1

**Figure 94: Display Cell Column**

Following the layout previously described, the layout appears as shown in Figure 95.

Header				
Last *	First *	Middle	Patient Birth Date *	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Name Northeast Georgia Medical Center				
Treating physician				
Patient Social Security Number (USA Only)				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**Figure 95: Output of the Layout Screen**

## 9.5 Preview Subtab

Select the **Preview** tab to get a view of the formatted form according to the specifications that were updated and saved in the **Questions** and **Layout** screens. Incremental modifications can be checked in this way.

- 1) Make changes in the Questions and/or Layout screens.
- 2) Save the changes on the respective screen.
- 3) Press the Preview tab to view the changes that were made to the form.
- 4) Repeat these steps until the form appears as desired.

Figure 96: Preview Screen

## 9.6 Edit Checks Subtab

The Edit Checks subtab allows administrative OPEN staff to configure additional validations using proprietary Structured Query Language (SQL) expressions to check user-responses to OPEN enrollment questions. OPEN allows a maximum of 10,000 edit checks per form. The edit checks can be configured such that all edit check validations must be passed in order for the enrollment to be successfully submitted to the Group RandoNode (by setting the Failure Type for all edit checks to ERROR).


Edit	X	View	Test	#	Description	Expression	Ovr?	Status	F.Type	Failure Message
				0000	The patient's birth year must be after 1915.	SUBSTR(:A1, 1, 4) <= '1915'	NO	ACTIVE	ERROR	The patient's b
				0001	Patient's last initial must be a letter (A-Z).	IS_ALPHA_YN(:A1)='NO'	NO	ACTIVE	ERROR	Patient's last ir
				0002	Patient's middle initial must be a letter (A-Z).	IS_ALPHA_YN(:A1)='NO' and (:A1) is not null	NO	ACTIVE	ERROR	Patient's middl
				0003	Patient's first initial must be a letter (A-Z).	IS_ALPHA_YN(:A1)='NO'	NO	ACTIVE	ERROR	Patient's first ir
				0005	Patient is > 84 years old. Please verify with PI that life expectancy is 10 years.	AGE(:A1) > 84	NO	ACTIVE	ALERT	Patient is > 84 expectancy is 1
				0006	Patient is <18 years old. Consent form must be signed by guardian.	AGE(:A1) < 18	NO	ACTIVE	ALERT	Patient is <18 guardian.

Figure 97: List of Edit Checks

The Edit Checks screen shows the following:

- Type of edit;
- Description of the scenario the system checks;
- The expression used to determine if the data entered is valid;

- Whether the edit check can be overridden (a yes in this column gives the user the override option in the checklist form);
- Status of the edit check;
- Failure type;
- Failure Message (displayed to the user if invalid data entered in the checklist form).

Existing edit checks can be updated by clicking the edit icon  that is associated with the desired edit check (see the Creating a New Edit Check in section 9.6.1 for details).

**1. Define Expression**    2. Associate Questions    3. Confirmation

---

**\* Edit Check Type:** GENERIC

**\* Edit Check Status:** ACTIVE ▼

**\* Allow Override:**  Yes  No

**\* Test Order:** 0

**\* Description:** The patient's birth year must be after 1915. ▲▼


**\* Failure Type:** ERROR ▼

**\* Failure Message:** The patient's birth year must be after 1915. ▲▼ *(\* Display message for user)*

**\* Expression:** SUBSTR(:A1, 1, 4) <= '1915' ▲▼ Expression Library

*(\* Check that will cause the error)*

**Figure 98: Configuring an Edit Check**

To delete an unwanted edit check, click on the trash icon  associated with that specific edit check. A pop-up message requires confirmation of the deletion. Pressing OK on this pop-up message deletes the edit check as desired.

View edit check information by clicking on the  icon.

**Form Edit Check Details:**

**Check Type:** GENERIC  
**Description:** The patient's birth year must be after 1915.  
**Test Order:** 0  
**Allow Override:** NO  
**Failure Type:** ERROR  
**Failure Message:** The patient's birth year must be after 1915.  
**Expression:** SUBSTR(:A1, 1, 4) <= '1915'  
**Owner:** CTSU  
**Group Validation:** NO  
**Status:** ACTIVE  
**Created User:** RANDOHUB  
**Created Date:** 02/19/2009 10:23 AM EST  
**Modified User:** RANDOHUB  
**Modified Date:** 06/25/2009 07:24 PM EDT


**Associated Modules/Questions:**

Module	Question	Alias
Header	Patient Birth Date	:A1

**Edit Check History:**

Action	Timestamp	#	Type	Ovr?	Expression	Failure Message	Status	Created By	Modified By
UPDATE	06/25/09 19:24	0	ERROR	NO	SUBSTR(:A1, 1, 4) <= '1915'	The patient's birth year must be after 1915.	ACTIVE	RANDOHUB on 02/19/2009 10:23	RANDOHUB on 06/25/2009 19:24
INSERT	02/19/09 10:23	0	ERROR	NO	SUBSTR(:A1, 1, 4) <= '1915'	The patient's birth year must be after 1915.	ACTIVE	RANDOHUB on 02/19/2009 10:23	

Figure 99: Viewing an Edit Check

Testing of an edit check is also possible. To test an edit check from this screen, press the  icon associated with that specific edit check. Test values can be entered to confirm the edit check performs correctly. These tests are logged in the Audit Logs screen.

**Form Edit Check Details:**

**Check Type:** GENERIC **Failure Type:** ERROR **Status:** ACTIVE  
**Test Order:** 0  
**Description:** The patient's birth year must be after 1915.  
**Failure Message:** The patient's birth year must be after 1915.  
**Expression:** SUBSTR(:A1, 1, 4) <= '1915'  
**Created By:** RANDOHUB on 02/19/2009 10:23 **Modified By:**

**Associated Modules/Questions:**

Module	Question	Alias	Value
Header	Patient Birth Date	:A1	<input type="text" value="Enter Test Value here!!"/>

Figure 100: Edit Check Test

### 9.6.1 Creating a New Edit Check

The New Edit Check module provides the opportunity to create a specific error or alert condition.

- 1) Click the New Edit Check button.

- The Define Expression screen displays the various fields used for the edit check (for an example of how the fields appear when completed, see Figure 98).

**1. Define Expression**    2. Associate Questions    3. Confirmation

\* **Edit Check Type:** GENERIC

\* **Edit Check Status:** ACTIVE

\* **Allow Override:**  Yes  No

\* **Test Order:** 0

\* **Description:** [Text Area]

\* **Failure Type:** ERROR

\* **Failure Message:** [Text Area] (\* Display message for user)

\* **Expression:** [Text Area] (\* Check that will cause the error)

**Expression Library**

**Figure 101: New Edit Check Screen**

- When the fields are completed, click the Next button to go to Associate Questions screen (Figure 102). Using the drop-down menu in the Module column, select the specific Module that you wish to use in the edit check.
- In the next drop down menu, select an option under [Row #] Question (Figure 102). The drop-down menu filters to show only items that correspond to the Module selected in step 3.
- Enter in the Alias; this identifies the field in the checklist form. For example, the edit check statement might read "UPPER(:A2) = 'US' and (TRIM(:A1) is null or LENGTH(TRIM(:A1)) < 9)" - Here :A1 and :A2 are the Alias values.

1. Define Expression    **2. Associate Questions**    3. Confirmation

>> [Toggle Summary](#)

**Edit Check Summary**

**Test Order:** 0

**Check Type:** GENERIC

**Failure Type:** ERROR

**Expression:** jj

**Failure Message:** jj

**Note:**

- Press the to add a question
- Press the corresponding to remove a particular question
- Unused rows will be removed when the [Save] is clicked
- Edit check failure message will be displayed against the primary question selected

Action	Module*	[Row #] Question*	Alias*	Primary?
	▼	▼	▼	▼
	▼	▼	▼	▼
	▼	▼	▼	▼

**Figure 102: Associate Questions**

- 6) Enter the Primary data from the drop-down. The Primary data indicates what field the edit check flags when the edit check is utilized. For example, in Figure 103, the Primary field for the First initial is YES, therefore in the checklist form, the edit check goes against the First initial field if the edit check activates.
- 7) If two or more edit checks share the same Primary? question, only one edit check failure message can display at a time in an OPEN enrollment (if two or more of those edit checks are triggered to fire simultaneously).

1. Define Expression    **2. Associate Questions**    3. Confirmation

>> [Toggle Summary](#)

**Edit Check Summary**

**Test Order:** 1  
**Check Type:** GENERIC  
**Failure Type:** ERROR  
**Expression:** IS\_ALPHA\_YN(:A1) = 'NO'  
**Failure Message:** Patient's initial must be a letter.

• Note:

- Press the to add a question
- Press the corresponding to remove a particular question
- Unused rows will be removed when the [Save] is clicked
- Edit check failure message will be displayed against the primary question selected

Action	Module*	[Row #] Question*	Alias*	Primary?*
	Standard_Patient_Identifier	Last	A1	NO
	Standard_Patient_Identifier	Middle	A2	NO
	Standard_Patient_Identifier	First	A3	YES

**Figure 103: Primary Edit Check Field**

- 8) Finally, click on the Save button to confirm that the edit check record you created has been executed and saved.
- 9) Once the confirmation screen displays (see Figure 104), click on the test button to test that the edit check works as expected.

1. Define Expression    2. Associate Questions    **3. Confirmation**

**Information**  
 Edit Check record saved!

**Done**    **Test**

**Figure 104: Edit Check Confirmation**

## 9.6.2 Importing Edit Checks

To expedite edit check creation, edit checks can be imported from other forms. This includes forms within a specific Group or across Groups.

- 1) To import edit checks to a form, select the form the edit checks should be imported into from the Form Setup → Forms List subtab. The summary screen displays that form’s details.
- 2) Click on the Edit Checks subtab.
- 3) Click on the Import Edit Checks Button. A new screen pops up (see Figure 105).
- 4) The user’s current Group displays by default. If desired, select another Group from the Group drop-down list. This provides a list of the selected Group’s forms.

- Select the form to be copied from the Source Form drop-down list. The forms shown in this list correlate to the Group selected in step 4.

**Import Edit Checks:**

- Select the group and the source form from which you would like to import the edit checks from.
- Check the edits that need to be imported to the target form #462
- Click [Import] to initiate the import
- NOTE:** Manual linking of the questions to the alias is necessary if the question/module combination differs across forms

\* **Target Form:** [462] A0 HQ Confirmation - TEST!! I wouldn't recommend using this! thx Brenda (Step 1) [ACTIVE] [2904861]

\* **Group:** CALGB

Representation of the list below: [ID] [Form Name] [STATUS] [PUBLIC ID]

\* **Source Form:** [82] CALGB 40601 REGISTRATION WORKSHEET [ACTIVE] [2680365]



<input type="checkbox"/>	V	#	Description	Expression	Ovr?	Status	Type	Failure Message
<input type="checkbox"/>	<input checked="" type="checkbox"/>	1	Either Social Security Number or Patient Hospital No. is required.	(:A1) is null and (:A2) is null	NO	ACTIVE	ERROR	Either Social Security Number or Patient Hospital No. is required.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	2	Projected Treatment Start Date cannot be in the past.	IS_PAST_DATE_YN(:A1)='YES'	NO	INACTIVE	ERROR	Projected Treatment Start Date cannot be in the past.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	3	HIPAA Authorization Date cannot be a future date.	IS_FUTURE_DATE_YN(:A1)='YES'	NO	ACTIVE	ERROR	HIPAA Authorization Date cannot be a future date.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	4	Date Informed Consent Signed cannot be a future date.	IS_FUTURE_DATE_YN(:A1)='YES'	NO	ACTIVE	ERROR	Date Informed Consent Signed cannot be a future date.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	5	First initial must be a letter.	IS_ALPHA_YN(:A1)='NO'	NO	ACTIVE	ERROR	First initial must be a letter.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	6	HIPAA Authorization Date is required for US residents only.	Upper(:A1)<>'US' AND Upper(:A2) is not null	NO	ACTIVE	ERROR	HIPAA Authorization Date is required for US residents only.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	7	Middle initial must be a letter.	IS_ALPHA_YN(:A1)='NO'	NO	ACTIVE	ERROR	Middle initial must be a letter.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	8	Last initial must be a letter.	IS_ALPHA_YN(:A1)='NO'	NO	ACTIVE	ERROR	Last initial must be a letter.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	9	HIPAA Authorization Date is required for US residents.	(:A1) is null and Upper (:A2)='US'	NO	ACTIVE	ERROR	HIPAA Authorization Date is required for US residents.


**Import**

Figure 105: Import Edit Check screen

- The edit checks associate with the selected form are shown on the table.
- Select the top most checkbox to select all of the shown edit checks.

OR

- Using the check box beside each edit check, select the individual edit check question to be copied. A green check  on the edit check row indicates the edit check has a corresponding question in the target form. A yellow sign  indicates that there is not a corresponding question in the target form and this question, if chosen, needs to be manually linked to a question in the target form.
- When all the desired edit checks are chosen, click on the Import button located at the bottom of the screen.
- Once the import is complete, there will be confirmation that the edit checks transferred.

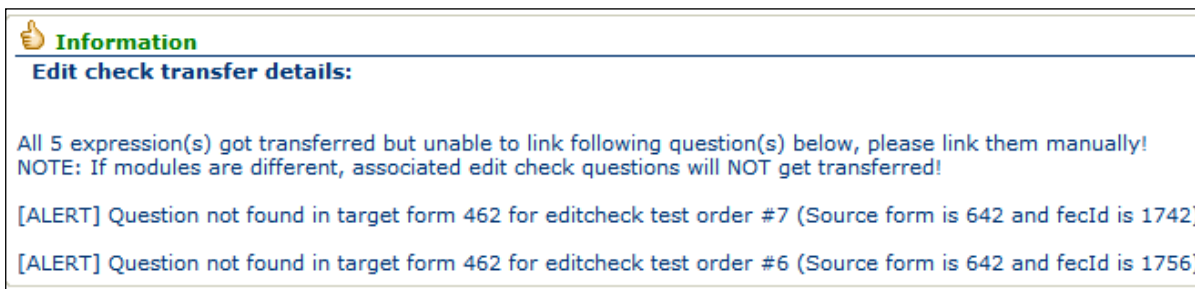
 **Information**

**Edit check transfer details:**

Successfully transferred all 2 edit check(s) from form 541 to form 462!

Figure 106: Successful Edit Check Transfer

- Any edit check chosen that does not have corresponding edit checks in the target form (as described in step 8) appears in the edit check transfer details notification (Figure 107).

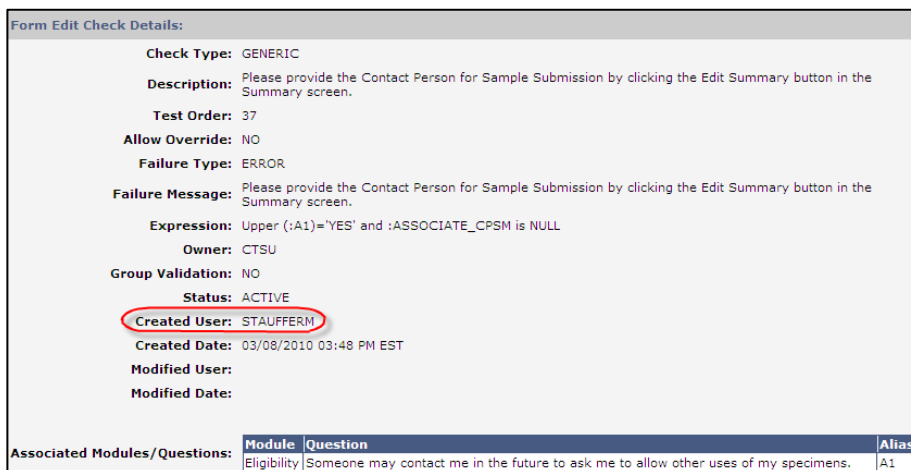


**Figure 107: Edit Check Transfer Confirmation**

- Click on the [x] button to close the screen and return to the edit checks screen. The newly imported edit checks appears on this screen beginning after the last original edit check. Manipulate the newly imported edit checks as desired.

### 9.6.3 Retaining the Created User of Edit Checks When Migrating Forms

During protocol setup in OPEN, the Group and CTSU OPEN administrators/testers need to copy/migrate a form from one system to another. When the forms are copied, the edit checks originally created are also copied. Now the created user, which is displayed in the Edit Check details screen, should have the user name of the person who originally created the edit check.



**Figure 108: Created User Information is Retained When Doing a Form Copy**

### 9.6.4 Edit Check Library of Expressions

Standard expressions implemented simplifies the writing of expressions required for edit checks. Additions to the standard expressions are made as necessary. Table 10 gives the standard expressions that are available and the typical uses.

Access the library of expressions by clicking on the Expression Library button located on the Form Setup → Edit Checks screen. Selecting an expression automatically populates the Failure Message and Expression fields on the Edit Checks screen.

**Table 10: Edit Check Library of Expressions**

Category	Expression	# Alias	Failure Message	Description
CUSTOM	EXCLUSION	0	Answer must be No.	Enforce non-acceptance on all questions
CUSTOM	INCLUSION	0	Eligibility Criteria (All answers must be Yes)	Enforce acceptance on all questions
CUSTOM	RESTRICT_RESPONSE_COUNT(1)	0	Only one response is required for race	Enforce # of response selections (this expression only works in the EC)
CUSTOM	RESTRICT_VALIDVALUE('Not Reported')	0	Not Reported is not a valid response	Exclude certain valid values as response (this expression only works in the EC)
DATE	AGE(:A1,'YEAR') < 18	1	The subject must be at least 18 years old.	Validate date range by year alone
DATE	IS_FUTURE_DATE_YN(:A1) = 'YES'	1	The Date of Birth cannot be in the future.	Validate futuristic dates
DATE	TO_DATE(:A1,'YYYYMMDD') NOT BETWEEN TRUNC(ADD_MONTHS(SYSDATE, -6)) AND TRUNC(SYSDATE)	1	Date must be within the past 6 months.	Validate date range
DATE	TO_DATE_VALUE(:A1) - TO_DATE_VALUE(:A2) > 14	2	Date A2 must be within 14 days prior to date A1.	Validate date range
DATE	TO_DATE_VALUE(:A1) < TRUNC(SYSDATE)	1	Must be today's date or in the future.	Validate date range
DATE	TO_DATE_VALUE(:A1) > (TRUNC(SYSDATE)+90)	1	Date must be within 90 days from today.	Validate date range
GENERIC	(:A1) <> 'US' AND (:A2) IS NOT NULL	2	If the Country of Residence is not US, the ZIP Code must be left blank.	Enforce mandatory on one of the inputs

Category	Expression	# Alias	Failure Message	Description
GENERIC	(:A1) = 'US' AND (:A2) IS NULL	2	If Country of Residence is US, the ZIP Code field must be answered.	Enforce mandatory on one of the inputs
GENERIC	(:A1) IS NOT NULL AND LENGTH(:A1) <> 9	2	The SSN must be 9 digits in length.	Validate length of the input
GENERIC	(:A1) IS NULL AND (:A2) IS NULL	2	Either a SSN or Patient Hospital No. must be provided.	Enforce mandatory on one of the inputs
GENERIC	:CREDIT_GROUP = 'SWOG' AND UPPER(:A1) = 'NO'	1	If the credit recipient is SWOG, the response to the SWOG institution question must be yes.	Enforce relation between question responses
GENERIC	:INST_CTEP_ID like '11%' AND UPPER(:A1) NOT LIKE 'EXEMPT%'	1	HIPAA Authorization should be exempt for Non-US sites.	Enforce site based restrictions
GENERIC	:PATIENT_ID <> (:A1)	1	Patient ID must match the ECOG sequence number.	Enforce response check with another question response
GENERIC	ISINTEGER(:A1) = 'NO'	1	Answer must be a number.	Validate whether input is numeric
GENERIC	IS_ALPHA_YN(:A1) = 'NO'	1	Patient's initial must be a letter.	Validate whether input is alphabetic
GENERIC	LENGTH(:A1) < 5 or LENGTH(:A1) > 10	2	The ZIP Code must be between 5 and 9 digits in length.	Validate length of the input
GENERIC	UPPER(:A1) = 'YES'	1	Must answer No.	Enforce a known response
GENERIC	UPPER(:A1) = 'YES' and :ASSOCIATE_CPQOL IS NULL	1	A contact person quality of life must be selected if consented to quality of life.	Enforce Contact Person Quality of Life"(CPQOL) associate selection

Category	Expression	# Alias	Failure Message	Description
GENERIC	UPPER(:A1) = 'YES' and :ASSOCIATE_CPSM IS NULL	1	A1 relates to the answer for if the patient consented to sample submission but did not select a contact person	Enforce Contact Person for Sample Submission" (CPSM) associate selection
GENERIC	VALIDATE_POSTAL_CODE(:A1,:A2) = 'NO'	2	Invalid [:A1] zip code [:A2]	Country (A1) zip code (A2) validation
CUSTOM	VALIDATE_EMAIL(:A1, ',') = 'NO'	1	Invalid email address list.	This expression validates if the email list value follows a valid format. The format is <a href="#">x@y.z,x@y.z</a> , where x and y can be alphanumeric characters of any length, and z must be no more than 3 characters.

The postal code field verifies that the entered zip code formats correctly. If formatted incorrectly, then a validation error displays.

### 9.6.5 Detailed Information Regarding OPEN Edit Check Expressions

This section provides detailed information on some of the OPEN Edit Checks. See Table 11 for an overview of the expressions described within this section.

**Table 11: List of OPEN Edit Check Expressions Described in this Section**

Edit Check Expression	Description
INST_COUNTRY_CODE	Validates whether the NCI Site Code of the enrolling site is part of a specific country code.
IS_PSR_COMPLIED	Validates whether certain questions must be answered (or left blank), based on the enrolling site's compliance with a Protocol Specific Requirement (PSR).
IS_REGISTRY_SITE_PID_YN	Validates a COG Patient ID in an OPEN enrollment against the OPEN Patient Registry.
IS_VALID_PID	The IS_VALID_PID expression validates whether a Patient Identifier (PID) used for an In Progress enrollment was also used for another study and step combination, and the enrolling site used for that completed enrollment must be the same site that is used for the In Progress enrollment.
GET_IRTF_PROVIDERS	The GET_IRTF_PROVIDERS expression allows OPEN to retrieve IRTF provider information for studies RSS, to allow site users to have information for selecting persons in RSS.

Edit Check Expression	Description
GET_PREV_STEP_RESPONSES	For multi-step protocols, the expression compares a question response in one-step against the same question in another step, for the same subject.
GET_PREVIOUS_ARM	Validates previous enrollment treatment arm against current OPEN enrollment form.
GET_REGISTRY_RESPONSE	Validates enrollment data in the Checklist versus Patient Registry data.
GET_SELECTED_ANCILLARIES	Validates a variety of scenarios, including: (1) one ancillary and one EC question, (2) one ancillary and multiple EC questions, (3) the combination of multiple GET_SELECTED_ANCILLARIES expressions within the same edit check.
LIMIT_ENROLLMENTS	Configure the maximum number of enrollments that can occur for a protocol (for a particular step).
PREV_STEP_CREDIT_GROUP	This custom expression enables an edit check to compare the credited group for the subject's prior-step enrollment (for the same study), with their current step enrollment.
PREV_STEP_DAYS	Validates the number of days between enrollment steps, for the same subject.
PREV_STEP_INST_CTEP_ID	This custom expression enables an edit check to compare the NCI Site Code for the subject's prior-step enrollment (for the same study), with the current step enrollment.
VALIDATE_PREVIOUS_STEP_RESPONSE	For multi-step protocols, the expression compares a question response in one-step against the same question in another step, for the same subject.

### 9.6.5.1 INST\_COUNTRY\_CODE Expression

The INST\_COUNTRY\_CODE expression validates whether the NCI Site Code of the enrolling site is part of a specific country code (for instance, if the enrolling site is part of the US country code).

#### To setup the INST\_COUNTRY\_CODE edit check:

- 1) Log in to OPEN.
- 2) Click the Form Setup tab, select the desired form, and then click the Edit Checks subtab.
- 3) Click the New Edit Check button to go to the Define Expression screen.
- 4) Provide a value for the Test Order, Description, and Failure Message.
- 5) Enter the edit check expression in the Expression field (see Figure 109).

**1. Define Expression**    2. Associate Questions    3. Confirmation

\* **Edit Check Type:** GENERIC

\* **Edit Check Status:** ACTIVE

\* **Allow Override:**  Yes  No

\* **Test Order:** 0

\* **Description:** This edit check will ensure that the enrolling site's NCI Site Code is for a US institution.

\* **Failure Type:** ERROR

\* **Failure Message:** Only US institutions may participate on this study. (\* Display message for user)

\* **Expression:** INST\_COUNTRY\_CODE != 'US' [Expression Library](#)  
(\* Check that will cause the error)

**Next**    **Cancel**    **Undo**

**Figure 109: Configuring the “INST\_COUNTRY\_CODE” Edit Check in the Define Expression Screen**

- 6) Click the Next button to proceed to the Associate Questions screen.
- 7) Select a required question (preferably from a module in the Demography screen), and configure the Alias and Primary fields (see Figure 110).

**1. Define Expression**    **2. Associate Questions**    3. Confirmation

[Toggle Summary](#)

**Edit Check Summary**

Test Order: 0  
Check Type: GENERIC  
Failure Type: ERROR  
Expression: INST\_COUNTRY\_CODE != 'US'  
Failure Message: Only US institutions may participate on this study.

Note:

- Press the to add a question
- Press the corresponding to remove a particular question
- Unused rows will be removed when the [Save] is clicked
- Edit check failure message will be displayed against the primary question selected

Action	Module*	[Row #] Question*	Alias*	Primary?*
	Standard_Patient_Identifier	[0] Last	:A1	YES
				NO
				NO

**Previous**    **Save**    **Cancel**

**Figure 110: Configuring the Edit Check in the Associate Questions Screen**

- 8) Click the Save button to complete the configuration process.

### 9.6.5.2 IS\_PSR\_COMPLIED Expression

#### Expression Overview:

Validates whether certain questions must be answered (or left blank), based on the enrolling site's compliance with a PSR.

Edit check expression:

```
(IS_PSR_COMPLIED(:TRACK_NUM, 'PSR_CODE') = '[YES/NO]') AND (:A1 is [NOT NULL/NULL])
```

- Validate additional questions by adding on to the end of the expression.
- Multiple instances of the edit check can be combined (for instance, to ensure that a site complies with multiple PSRs).

Example edit check:

```
IS_PSR_COMPLIED(:TRACK_NUM, 'TNT-Plus_Site') = 'YES') AND ((:A1 is NULL) AND (:A2 is NULL))
```

- Description of the example: if the enrolling site complies with PSR TNT-Plus\_Site, and questions A1 and A2 are left blank, the edit check will fire.

### 9.6.5.3 IS\_REGISTRY\_SITE\_PID\_YN

#### Expression Overview:

Validates a COG Subject ID in an OPEN enrollment against the OPEN Patient Registry.

Edit check expression:

```
IS_REGISTRY_SITE_PID_YN(:PATIENT_ID)
```

- This is a standalone edit check. Note: this edit check cannot be combined with other validation expressions.
- This expression will return a failure message, given:
  - The enrolling lead group is not COG.
  - The PID is not specified in the COG Patient ID EC question.
  - The PID specified in the COG Patient ID EC question does not exist in the COG patient registry.
  - The enrolling site does not match with the patient registry site.

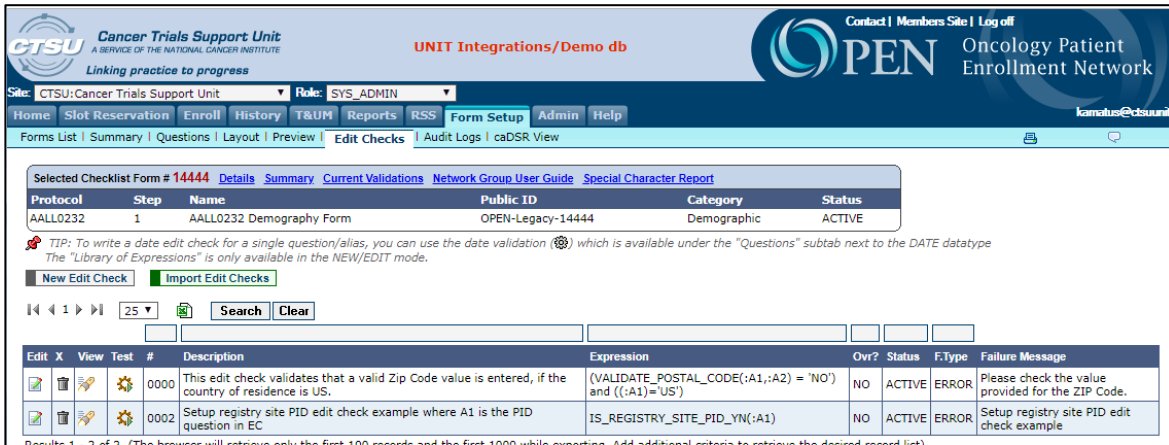


Figure 111: Example of IS\_REGISTRY\_SITE\_PID\_YN Expression

### 9.6.5.4 IS\_VALID\_PID Expression

#### Expression Overview:

The IS\_VALID\_PID expression validates whether a PID used for an In Progress enrollment exists in another study and step combination, and the enrolling site used for that completed enrollment must be the same site used for the In Progress enrollment. If necessary, configure the expression to exclude the enrolling site from the validation.

```
IS_VALID_PID(:A1, :TRACK_NUM, STUDY, STEP, ENFORCE_SAME_SITE_YN)='NO'
```

- Where :A1 is assigned to the patient ID question used for the In Progress enrollment.
- :TRACK\_NUM will be left as is when writing the expression.
- The admin user updates the STUDY and STEP values to a particular study and step, and the values are within single quotes.
- ENFORCE\_SAME\_SITE\_YN will be either written as YES (completed enrollment's site must match the In Progress enrollment's site) or NO (completed enrollment's site can differ from the In Progress enrollment's site), and the value will be within single quotes. Also, if the ENFORCE\_SAME\_SITE\_YN parameter is not provided, then it defaults to YES which in the In Progress enrolling site must match the enrolling site for the Study and Step combination.

### 9.6.5.5 GET\_IRTF\_PROVIDERS Expression

A GET\_IRTF\_PROVIDERS expression enables administrative LPO staff to configure validations for the IRTF providers selected for the study's enrollments.

A Prefill: IRTF Providers widget was added so administrative LPO staff can configure EC fields to display the IRTF provider that was selected by site staff in the Create New subtab (of the Enroll tab).

#### Accessing this Feature:

- 1) Log in to OPEN.
- 2) Click the Form Setup tab, and select the desired form within the Forms List subtab.
- 3) Click the Edit Checks subtab.
- 4) Click the New Edit Check button, and the screen refreshes to the Define Expression section.
- 5) When configuring the GET\_IRTF\_PROVIDERS expression, use the format GET\_IRTF\_PROVIDERS (:TRACK\_NUM, :CREDENTIAL\_TYPE).
- 6) Complete the remaining edit check configurations and test the edit check (see Figure 112).

\* Edit Check Type: GENERIC

\* Edit Check Status: ACTIVE

\* Allow Override:  Yes  No

\* Test Order: 18

\* Description: testing

\* Failure Type: ERROR

\* Failure Message: The provider must have active credentials (\* Display message for user)

\* Expression: GET\_IRTF\_PROVIDERS(:TRACK\_NUM, '3D') != GET\_IRTF\_PROVIDERS(:TRACK\_NUM, 'IMRT') (\* Check that will cause the error)

Next Cancel Undo

Figure 112: Example of the New GET\_IRTF\_PROVIDERS Edit Check Expression

**NOTE:** The OPEN IRTF Provider Setup on the RSS Logistics page for the protocol in question must also be setup in order for the expression to work properly (see Figure 113).

Credential Description	Credential Type
8171	8171
3D	3D
F151	F151

Figure 113: OPEN IRTF Provider Setup in RSS

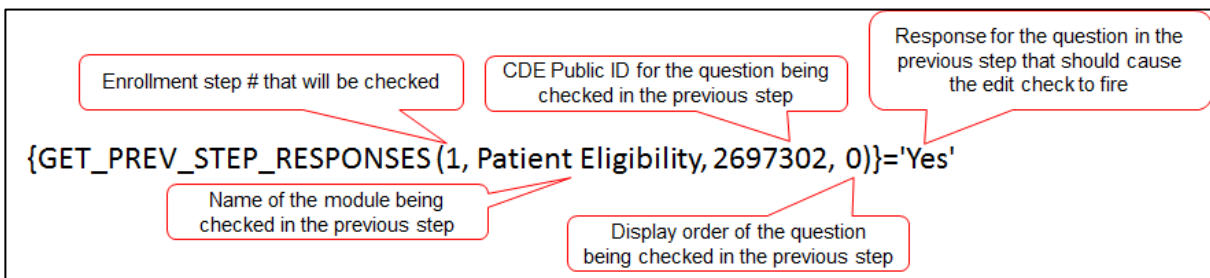
### 9.6.5.6 GET\_PREV\_STEP\_RESPONSES Expression

You can use the GET\_PREV\_STEP\_RESPONSES expression multi-step protocols to check a question's response in a previous step (for the same subject). If the expression criteria are met, then the edit check fires in the current enrollment step.

For example, when an individual enrolls a subject on step 3 of a multi-step protocol, an edit check can be configured to check the answer that was given for a question in step 1 or step 2 of that subject's enrollment. The edit check fires under conditions specified in the edit check during step 3, next to a question specified during the edit check's configuration.

**To setup the GET\_PREV\_STEP\_RESPONSES edit check:**

- 1) Log in to OPEN.
- 2) Click the Form Setup tab.
- 3) Select the form in the Forms List subtab.
- 4) Click the Edit Checks subtab.
- 5) Click the New Edit Check button.
- 6) Provide the appropriate responses for the required fields in the Define Expression screen.
  - a) In the Expression field, make the following entries:



**Figure 114: GET\_PREV\_STEP\_RESPONSES Expression**

- b) Click the Next button.
- 7) On the Associate Questions screen, choose the question that the failure message should display next to for the current step.
- 8) Click the Save button.

**9.6.5.7 GET\_PREVIOUS\_ARM Expression**

The GET\_PREVIOUS\_ARM expression allows the subject's previous treatment arm assignment from OPEN to be validated against OPEN enrollment forms.

When configuring the GET\_PREVIOUS\_ARM expression, use the format GET\_PREV\_ARM (Tracking-Number, Step-Number).

Example Expression:

```
GET_PREVIOUS_ARM(:track_num, 1) = 'Arm A' AND :A1 = 'B'
```

The screenshot shows the 'Form Setup' tab in the CTSU system. At the top, there are navigation links for Home, Slot Reservation, Enroll, History, T&UM, Reports, RSS, Form Setup, Admin, and Help. Below this is a table for 'Selected Checklist Form # 9913' with columns for Protocol, Step, Name, Public ID, Category, and Status. The table contains one row: AALL0434, 1, AALL0434 Demography Form, OPEN-Legacy-9913, Demographic, ACTIVE. Below the table is a tip about date edit checks and buttons for 'New Edit Check' and 'Import Edit Checks'. At the bottom, there is a table of expressions with columns for Edit, X, View, Test, #, Description, Expression, Ovr?, Status, F.Type, and Failure Message. The table contains one row with ID 0001, description 'Example of setting up treatment arm match between steps.', and expression 'GET\_PREVIOUS\_ARM(:TRACK\_NUM, '0') = 'Arm A' and UPPER(:A1) != 'ARM A''. The status is 'ACTIVE' and the failure message is 'Example of setting up treatment arm match between steps.'.

Figure 115: Screenshot of the GET\_PREVIOUS\_ARM Expression

### 9.6.5.8 GET\_REGISTRY\_RESPONSES Expression

The GET\_REGISTRY\_RESPONSE expression allows an edit check to get responses from the OPEN Patient Registry, which can be used to validate against the OPEN enrollment Checklist forms.

When configuring the GET\_REGISTRY\_RESPONSES expression, use the format GET\_REGISTRY\_RESPONSES (Registry-Module-Name, CDE-Public-ID-Of-Registry-Question) and include the necessary question reference(s) to the Checklist.

Example Expression:

```
((to_date({GET_REGISTRY_RESPONSES('COG Diagnosis Information 1', 2178801)}, 'YYYYMMDD') - to_date(:A2, 'YYYYMMDD') < 365*8) OR (to_date({GET_REGISTRY_RESPONSES('COG Diagnosis Information 1', 2178801)}, 'YYYYMMDD') - to_date(:A2, 'YYYYMMDD') > 365*31) ) AND UPPER(:A1) = 'YES'
```

- The above expression will validate the answer to a subject’s OPEN enrollment Checklist question (“Is patient age greater than, equal to 8 and less than, or equal to 30 years of age at time of diagnosis”), against a specific value in the associated patient’s OPEN Patient Registry record.

### 9.6.5.9 GET\_SELECTED\_ANCILLARIES Expression

The GET\_SELECTED\_ANCILLARIES expression can validate a variety of scenarios, including: (1) one ancillary and one EC question, (2) one ancillary and multiple EC questions, (3) the combination of multiple GET\_SELECTED\_ANCILLARIES expressions within the same edit check.

The expression has an input parameter of the enrollment tracking number, and the output will be the CSV of all the selected ancillary studies for the tracking number. If no ancillary studies are selected, the output will be an empty string.

Example Expression:

```
GET_SELECTED_ANCILLARIES(:TRACK_NUM) NOT LIKE '%S1418-E-01%' AND (:A1) = 'Yes'
```

- The above expression would fire if the ancillary study S1418-E-01 was not selected for the enrollment, and the EC question (:A1) was answered Yes.
- S1418-E-01 is the ancillary study.
- (:A1) is the EC question.

### 9.6.5.10 LIMIT\_ENROLLMENTS Expression

The LIMIT\_ENROLLMENTS expression can be configured to control the maximum number of enrollments that can occur for a protocol (for a particular step). This expression will not function during practice mode.

Example of the expression:

```
LIMIT_ENROLLMENTS <= 12
```

- An edit check failure message triggers during the 13<sup>th</sup> (or higher) enrollment attempt for the protocol and step combination.
- The A1 alias assignment for this expression can be linked in the Prerequisite, Demography, or Checklist screens. Link the alias assignment to a required question.

### 9.6.5.11 PREV\_STEP\_CREDIT\_GROUP

The custom expression PREV\_STEP\_CREDIT\_GROUP enables an edit check to compare the credited group for the subject's prior-step enrollment (for the same study), with their current step enrollment.

This edit check expression will fire if the credited group for the subject's prior-step enrollment differs from the credited group for the current step enrollment:

```
PREV_STEP_CREDIT_GROUP (:TRACK_NUM) != :CREDIT_GROUP
```

Associate the A1 alias with a question that is required in the protocol's form.

### 9.6.5.12 PREV\_STEP\_DAYS Expression

A custom edit check checks the number of days between enrollment steps. This would be useful in a situation where a subject must wait a certain number of days before enrolling onto the next step of a protocol.

The edit check expression is:

```
PREV_STEP_DAYS (p_days)
```

Within the expression, p\_days is the number of days that must pass before the subject enrolls onto the next step. For instance, if the expression states PREV\_STEP\_DAYS(10) and the next step performs less than 10 days after the previous step, the edit check fires.

When configuring the edit check, remember to choose a question in the Associate Questions screen that must be answered, such as Last initial in the Standard\_Patient\_Identifier module. Assign it to the A1 alias, and set the question as the Primary question.

Figure 116: Example of the PREV\_STEP\_DAYS Edit Check Firing

### 9.6.5.13 PREV\_STEP\_INST\_CTEP\_ID

The custom expression PREV\_STEP\_INST\_CTEP\_ID enables an edit check to compare the NCI Site Code for the subject’s prior-step enrollment (for the same study), with the current step enrollment.

This edit check expression will fire if the NCI Site Code for the subject’s prior-step enrollment differs from the current step enrollment:

```
PREV_STEP_INST_CTEP_ID (:TRACK_NUM) = :INST_CTEP_ID
```

Associate the A1 alias with a question that is required in the protocol’s form.

### 9.6.5.14 VALIDATE\_PREVIOUS\_STEP\_RESPONSE Expression

The VALIDATE\_PREVIOUS\_STEP\_RESPONSE expression confirms a question’s response in a previous step enrollment (for the same subject) matches the question response (for the same question) for an In Progress enrollment. If the values do not match, the expression fires. If needed, use this edit check for validating multiple questions using the same edit check.


This expression operates when creating a regular and practice mode enrollments.

## 9.6.6 Exporting a List of Edit Checks for a Form

An excel file containing a list of an OPEN enrollment form’s edit checks can be generated from within OPEN.

### Instructions for Exporting a List of Edit Checks for a Form:

- 1) Log in to the OPEN Portal.
- 2) Click the Form Setup tab.
- 3) Click the Select button next to the form for which the list of edit checks should be generated.
- 4) Click the Edit Checks tab.

5) Click the Excel Export  button.

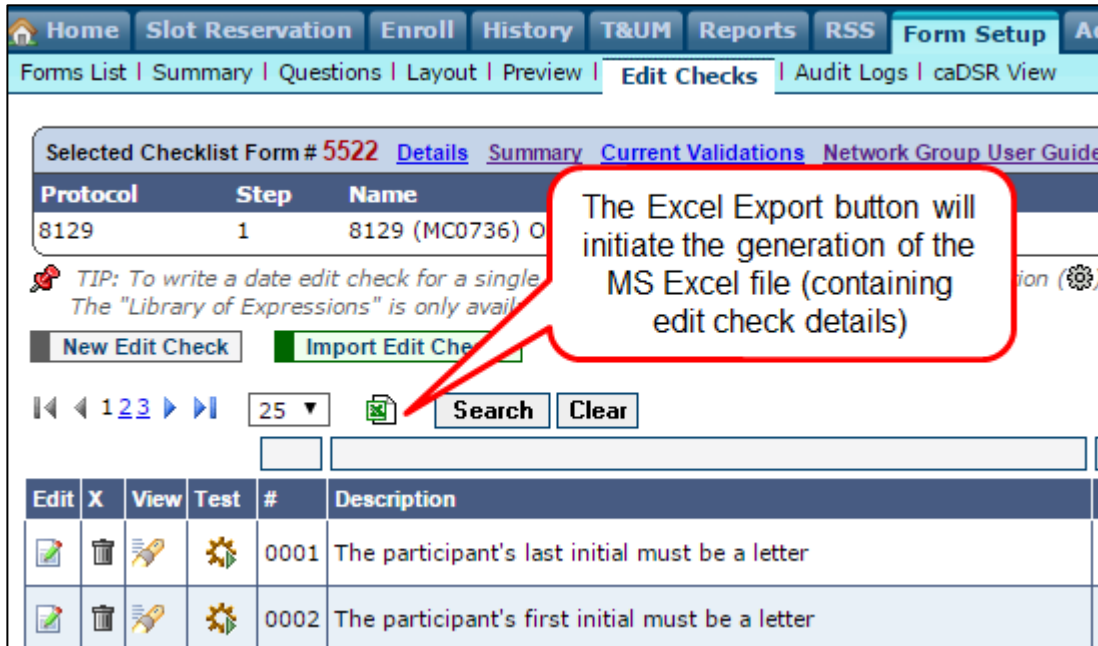


Figure 117: Excel Export Button Generates a List of Edit Checks

6) When prompted, Save the file.

## 9.7 Audit Log Subtab

The Audit Logs subtab contains a log of edit check testing, for both manual and automatic (AUTO) testing. Manual testing occurs when a user clicks the test button for an edit check, in the Edit Checks subtab). Automatic testing occurs when someone tests an edit check (and the edit check failure message triggers) during an OPEN enrollment. Persons with administrative OPEN access have the ability to view edit checks audit logs in the Audit Logs subtab.

When copying forms from one OPEN environment to another, manual testing audit logs retain the original tester's name in the target system; however, the AUTO audit log records are not retained.

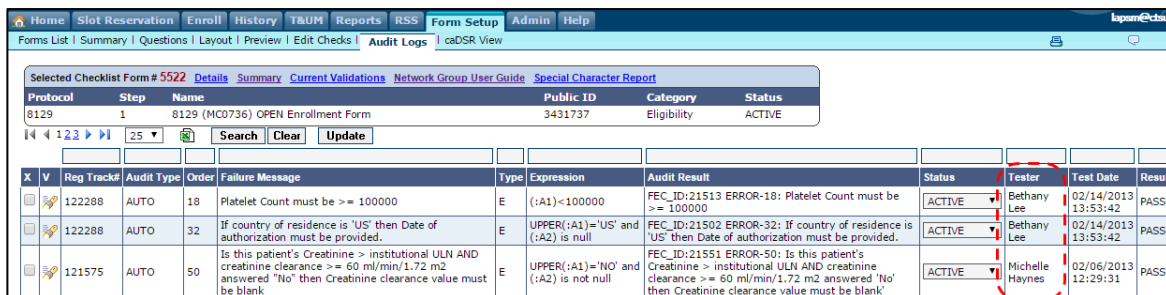


Figure 118: Copied Audit Log when doing a Form Copy

Table 12 describes the columns from the Audit Logs subtab.

**Table 12: Description of the Columns from the Audit Logs Subtab**

Field	Description
Audit Type	An AUTO value indicates that the edit check fired during an OPEN enrollment and a MANUAL value indicates an edit check was tested in the Edit Checks subtab (of the Form Setup tab).  During OPEN enrollments (AUTO), by default, an audit log record is only generated when an edit check is triggered to fire (otherwise, the OPEN log file would be overwhelmed with entries stating the edit check was not triggered to fire).
Order	Corresponds to the edit check #.
Failure Message	The message that was configured to display when the edit check is triggered to fire (when the logic in the expression is met).
Type	Indicates the Failure Type configuration for the edit check. It can be either Error (E) or Alert (A).  If it is set to Error, then the user would have to resolve the issue that is causing the edit check to fire before the enrollment can proceed.  If it is set to Alert, the user would see the failure message; however, completion of the enrollment can proceed.
Audit Result	When an edit check is tested manually, or during an OPEN enrollment, the field will display the edit check #, followed by the failure message.  If an edit check is tested manually and the edit check is not triggered to fire, then the Audit Result will be PASS.
Status	Status is always ACTIVE by default; however, the value can be changed to INACTIVE so that a user can sort by the two statuses. For instance, if an edit check was not functioning properly and the developer wants to hide those records from the displayed results.
Result	The value is always PASS, unless in manual mode when a user selects “Test did not work as expected” (in which case it would state FAIL).

Audit Logs are stored for all tests performed on the edit checks. The user is able to view all edit checks that were tested manually through the edit check screen and all edit checks tested directly from the checklist form.

To delete a test record, click on the box in the ‘x’ column that corresponds to the test that should be deleted, and press the Update button.

Home Slot Reservation Enroll History T&UM Reports RSS Form Setup Admin Help staufferm@ctsuu												
Forms List   Summary   Questions   Layout   Preview   Edit Checks   Audit Logs   caDSR View												
Selected Checklist Form # 9961 Details Summary Current Validations Network Group User Guide Special Character Report												
Protocol	Step	Name	Public ID	Category	Status							
ACRIN-6698	1	ACRIN 6698 Eligibility Checklist	4060874	Eligibility	ACTIVE							
<input type="text"/> 25 <input type="button" value="Search"/> <input type="button" value="Clear"/> <input type="button" value="Update"/>												
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>												
X	V	Reg Track#	Audit Type	Order	Failure Message	Type	Expression	Audit Result	Status	Tester	Test Date	Result
<input type="checkbox"/>	<input type="checkbox"/>		MANUAL	11	ISPY2 Participant ID # must be at least 6 digits	E	NO DATA FOUND	PASSED	ACTIVE	Marcella Bell	02/26/2014 15:51:00	PASS
<input type="checkbox"/>	<input type="checkbox"/>		MANUAL	11	ISPY2 Participant ID # must be at least 6 digits	E	NO DATA FOUND	PASSED	ACTIVE	Marcella Bell	02/26/2014 15:50:54	PASS

Figure 119: Audit Log Screen

Forms List   Summary   Questions   Layout   Preview   Edit Checks   Audit Logs   caDSR View											
Selected Checklist Form # 5522 Details Summary Current Validations Network Group User Guide Special Character Report											
Protocol	Step	Name	Public ID	Category	Status						
8129	1	8129 (MC0736) OPEN Enrollment Form	3431737	Eligibility	ACTIVE						
<input type="text"/> 25 <input type="button" value="Search"/> <input type="button" value="Clear"/> <input type="button" value="Update"/>											
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>											
X	V	Reg Track#	Audit Type	Order	Failure Message	Type	Expression	Audit Result	Status		
<input type="checkbox"/>	<input type="checkbox"/>	122288	AUTO	18	Platelet Count must be >= 100000	E	(:A1)<100000	FEC_ID:21513 ERROR-18: Platelet Count must be >= 100000	ACTIVE		
<input type="checkbox"/>	<input type="checkbox"/>	122288	AUTO	32	If country of residence is 'US' then Date of authorization must be provided.	E	UPPER(:A1)='US' and (:A2) is null	FEC_ID:21502 ERROR-32: If country of residence is 'US' then Date of authorization must be provided.	ACTIVE		
<input type="checkbox"/>	<input type="checkbox"/>	121575	AUTO	50	Is this patient's Creatinine > institutional ULN AND creatinine clearance >= 60 ml/min/1.72 m2 answered 'No' then Creatinine clearance value must be blank	E	UPPER(:A1)='NO' and (:A2) is not null	FEC_ID:21551 ERROR-50: Is this patient's Creatinine > institutional ULN AND creatinine clearance >= 60 ml/min/1.72 m2 answered 'No' then Creatinine clearance value must be blank	ACTIVE		

Figure 120: Audit Logs Screen

## 9.8 caDSR View Subtab

The Cancer Data Standard Repository (caDSR) screen allows viewing the CDE information of a selected form. Opening the screen reveals a field with a drop-down list of the possible forms (see Figure 121). To see the CDE information of a form, select the form name from the drop-down list provided, and press the search button.

1. Select a form and click [Search] to view the CDE information

\* Form Name: -- select form --

Form #1161 [5522] 8129 (MC0736) OPEN Enrollment Form

[1161] 8214: Registration Information Form

[1721] 8214: Registration Information Form

[2441] 8214: Registration Information Form

[2941] 8214: Registration Information Form

[3001] 8214: Registration Information Form

[1781] Eligibility/Pre-Registration Worksheet

[1821] Eligibility/Pre-Registration Worksheet

[3181] Eligibility/Pre-Registration Worksheet

[5921] S1206 Registration Worksheet Step 1

[5922] S1206 Registration Worksheet Step 2

[4621] 9177 Eligibility Checklist Form

[6921] 9177 Eligibility Checklist Form

[11741] 9177 Eligibility Checklist Form

[11241] EC9571

[11941] EC9608

[11581] ER Eligibility Checklist

[7921] A011104 OPEN Enrollment Form

[7922] A011104 OPEN Enrollment Form

Owner:

Module: Header Module

Study [Type]: 8214 [MAIN]

Display Order: 0

Instruction:

Repetitions:

Question: Institution CTEP ID

Figure 121: caDSR View screen

## 9.9 Stand-Alone Studies in OPEN

### 9.9.1 Introduction to Stand-Alone Studies in OPEN

Stand-alone ancillary studies compliment a main study, and participation on the stand-alone study can be either required or optional. Sites that want to participate on a stand-alone study would need to obtain an IRB approval for the stand-alone study (in addition to the IRB approval for the main study).

Enrolling a subject on a study that involves a stand-alone study is similar to performing an enrollment onto a regular OPEN enrollment, except site staff must select the stand-alone study at the Create-New screen (see Figure 122) for the stand-alone study modules to appear on the Checklist screen of the subject's enrollment.



The screenshot shows a form configuration interface. On the left, there is a 'Type' dropdown menu set to 'Checklist'. To its right is a 'Protocol [Type]' dropdown menu currently set to 'CALGB-9665 [STAND\_ALONE]'. A red dashed box highlights this dropdown menu, which is open to show a list of options: 'A041202 [MAIN]', 'A041202-E-01 [EMBEDDED]', 'A041202-E-02 [EMBEDDED]', and 'CALGB-9665 [STAND\_ALONE]'. Below these, there is a 'Date Field 3 Part' dropdown menu.

Figure 124: Stand-Alone Study Modules Designated in the Questions Screen

## 10. Admin Tab

The Admin tab gives the Administrator the means to view and monitor data associated with their respective Groups.

Click the **Admin** tab and the following subtabs are displayed (Figure 125):

- Services;
- Monitor;
- Settings.

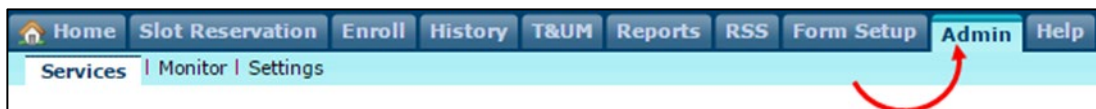


Figure 125: Admin - Sub-Tabs

### 10.1 Services Subtab

The Services subtab on the Admin screen allows the user to download the Metadata of a specified Protocol and Step combination.

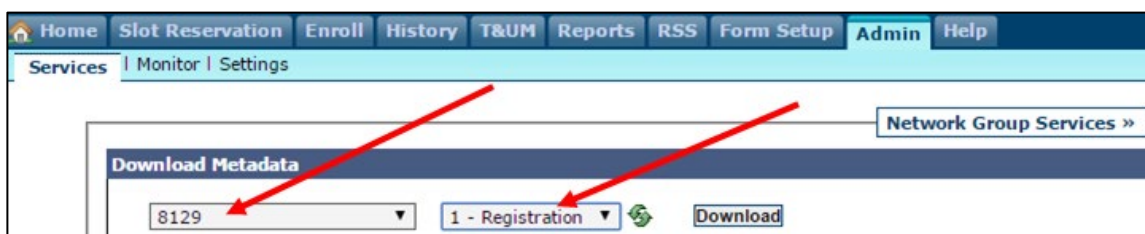


Figure 126: Download Metadata

- 1) Click on the Admin tab.
- 2) Select the desired protocol and step from the corresponding drop-down boxes.
- 3) Click the Download Button.
- 4) Select Open to open the file in the current window, or select Save to save the file.

The Services tab allows you to download clinical data information for a particular enrollment by entering the tracking number of the REGISTERED enrollment, and clicking on the Download button. Click the back button on the browser to return to the OPEN Portal.



Figure 127: Download Clinical Data

## 10.2 Monitor Subtab

The Monitor subtab on the Admin screen allows for monitoring of the Group RandoNode Statuses. Administrators of more than one Group, will have all Groups listed.

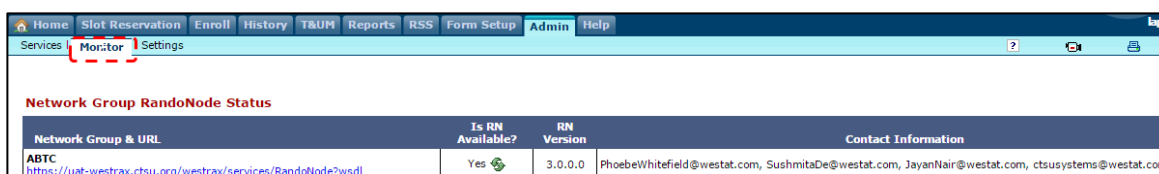


Figure 128: Monitor Screen

The monitor shows:

- Network Group & URL – clicking on this URL will access the RandoNode and show the RandoNode service details.
- Is RN Available – displays whether the RandoNode is available – Yes or No.
- RN Version – displays the RandoNode version.
- Contact Information – displays any contact information associated with the RandoNode.

## 10.3 Settings Subtab

Each RandoNode can selectively implement a subset of features supported by OPEN. Using this feature, view the Group RandoNode’s subscribed list of OPEN features in OPEN.

The Group Administrator can also subscribe to receive email notification of selected events.

### 10.3.1 Service Subscribe Subtab

Each RandoNode can selectively implement a subset of features supported by OPEN. The Service Subscribe screen on Admin->Settings->Service Subscribe subtab allows the user to view the list of OPEN features in which the Group’s RandoNode subscribes. Currently, this screen has the ability to display the protocol-specific configurations as well, however OPEN will support protocol-specific configurations in

future releases. This screen allows the user to sort and search the subscriptions, and export the table to an excel file.

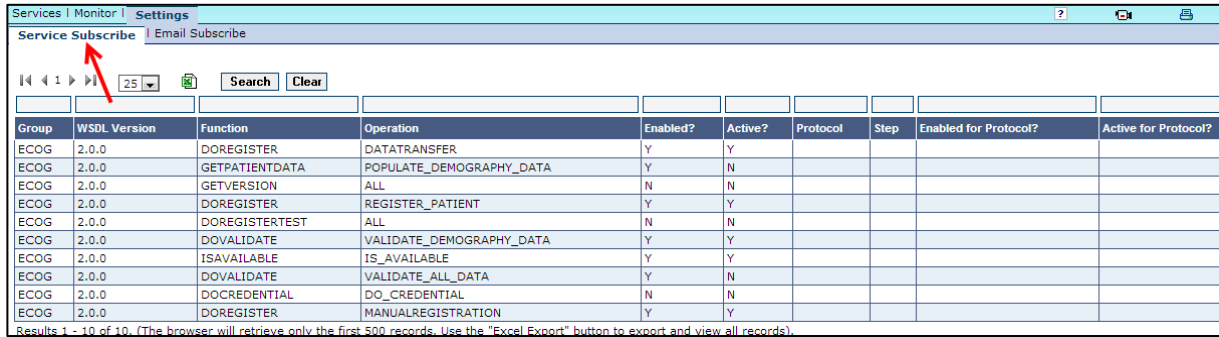


Figure 129: Service Subscribe

Table 13 provides the details of the RandoNode features used in the Service Subscribe screen.

Table 13: RandoNode Subscriptions for OPEN Features

Feature	Function	Operation	Comments
Regular Enrollments	DOREGISTER	REGISTER_PATIENT	Should be active for all LPOs.
Manual Registrations	DOREGISTER	MANUALREGISTRATION	
Data Transfers	DOREGISTER	DATATRANSFER	Supported by multiple LPOs.
Duplicate Patient Check (Performed by the LPO system)	DOVALIDATE	VALIDATE_DEMOGRAPHY_DATA	Not available for Web Services Description Language (WSDL) Version 1.0.0
Duplicate Patient Check (Performed by OPEN)	OPEN_DOVALIDATE	VALIDATE_DEMOGRAPHY_DATA	Contact <a href="mailto:CTSUOPENFORMS@westat.com">CTSUOPENFORMS@westat.com</a> for assistance with having this feature configured.
Group validates the Checklist Data when the checklist Save & Validate or Continue button is clicked.	DOVALIDATE	VALIDATE_ALL_DATA	Currently not supported by LPOs, and disabled in OPEN
Populate demography data by existing patient id	GETPATIENTDATA	POPULATE_DEMOGRAPHY_DATA	Not available for WSDL Version 1.0.0
Group RandoNode credentialing	DOCREIDENTIAL	DO_CREDENTIAL	
Checks availability of the Group RandoNode	ISAVAILABLE	IS_AVAILABLE	Should be active for all LPOs.

Feature	Function	Operation	Comments
Practice Registrations thru doRegisterTest	DOREGISTERTEST	ALL	Should be active for all new LPOs joining OPEN. A few LPOs support this feature using doRegister with a test parameter, which is not recommended any more.
Retrieve RandoNode Version from the Group RandoNode	GETVERSION	ALL	Currently not active for LPOs.

### 10.3.2 Email Subscribe Subtab

This Email Subscribe screen on Admin->Settings->Email Subscribe subtab allows administrators to view the detail of Groups’ subscription to OPEN automated emails. Group Administrators have the capability to add or delete. Users can subscribe to a specific study or to ALL studies for the selected Group. This screen allows the user to sort and search the subscriptions, and export the subscriptions table to an Excel file.

Using the settings tab, subscribe to receive emails for a particular Group and category.

- 1) Click on the Settings → Email Subscribe tab.
- 2) Select the desired Group from the drop-down list.
- 3) Click on the Add Subscription button.
- 4) Select an option from the Email Category drop-down list that you would like to see emails for.
- 5) Select a protocol from the Study drop down list.
- 6) Press the Add Me button. Emails will be received for selected scenario. All the email subscriptions for a user’s Group can be viewed, but only the user can add or delete subscriptions.

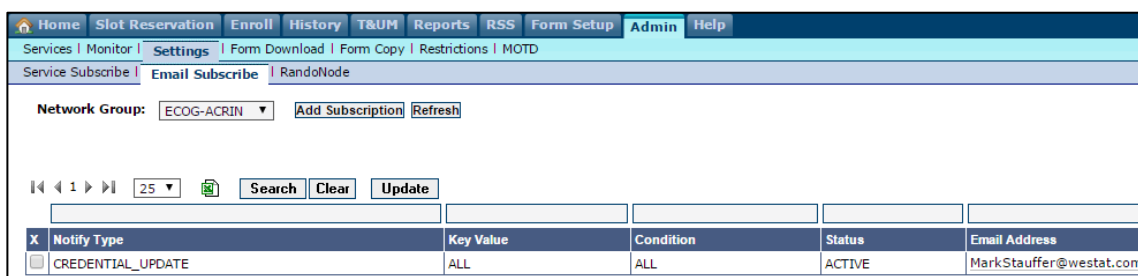


Figure 130: Email Subscribe

## 10.4 Additional OPEN Capabilities

### 10.4.1 Ability to Transfer Data to Multiple Rave URLs

OPEN has the ability to initialize and push EC question data for completed OPEN enrollments to multiple Rave URLs. This is useful when the LPO for an embedded or standalone study differs from the LPO for

the main study. Contact the OPEN Registrar team for assistance with configuring a protocol to a protocol's enrollment data to multiple Rave URLs.

#### **10.4.2 Ability to Skip Optional Enrollment Steps**

OPEN Registrars can skip enrollment steps that are configured in RSS as optional. Contact the OPEN Registrar team if assistance is required for configuring optional enrollment steps.

#### **10.4.3 Ability to Enroll When a Protocol's Status is Closed to Accrual**

Contact CTSU if a protocol's status is Closed to Accrual but enrollment for subsequent protocol steps is permissible (for subjects already enrolled on the protocol).

#### **10.4.4 Balance RandoNode Support**

Balance (a Medidata product) is a standalone RandoNode that resides within Rave. Unlike conventional RandoNodes that are maintained by the LPO IT staff, Balance can be configured and operated by non-IT staff.

OPEN supports subject enrollment activities for protocols configured to use the Balance RandoNode. Contact CTSU for assistance with configuring a protocol for use with the Balance RandoNode.

# 11. Help Tab

The Help tab contains user documentation and OPEN release information.

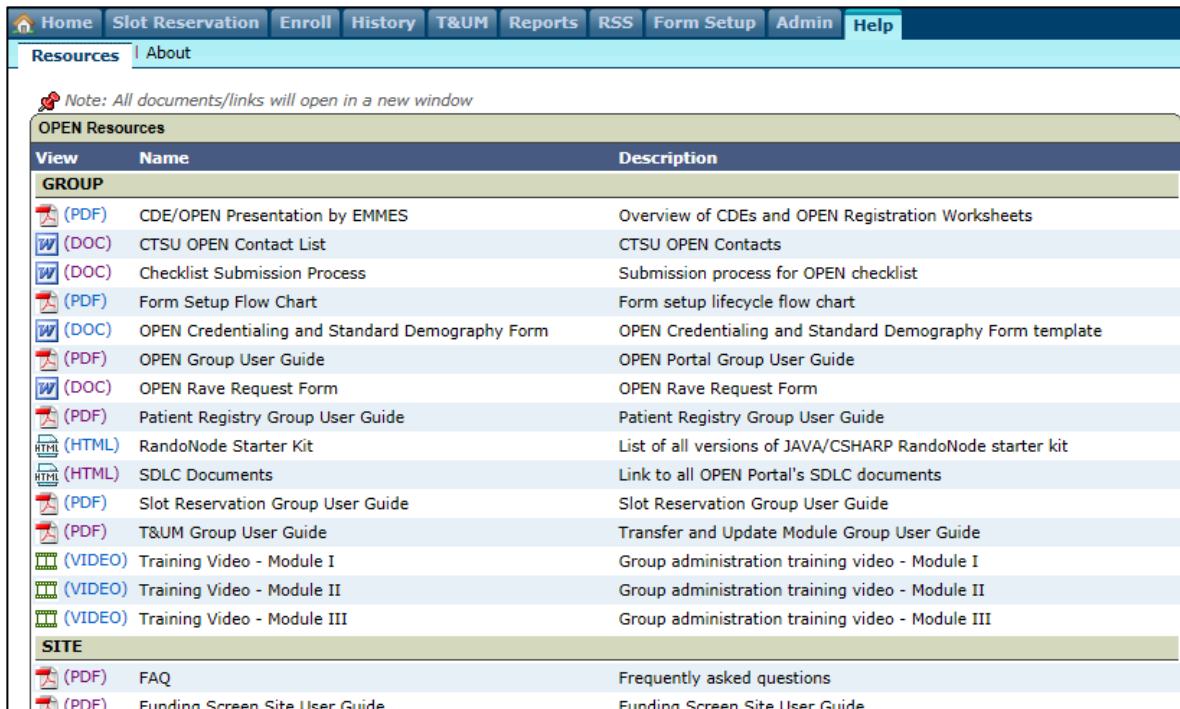


Figure 131: The Help Tab of OPEN

## 11.1 Resources Subtab

The Resources subtab contains documentation for clinical site staff, as well as LPO staff.

New OPEN users (from the LPOs) are encouraged to read the applicable user documentation (starting with the OPEN Group User Guide and OPEN Site User Guide).

## 11.2 About Subtab

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