Oncology Patient Enrollment Network
Site User Guide
Revision 18

September 1, 2020
### Revision History

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<th>By</th>
<th>Description</th>
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<td>1.0</td>
<td>19-SEP-2013</td>
<td>Mark Stauffer</td>
<td>Updated document to have the latest styles.</td>
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<tr>
<td>1.1</td>
<td>23-OCT-2013</td>
<td>Mark Stauffer</td>
<td>Added new content relating to version 5.3 of OPEN.</td>
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<td>Mark Stauffer</td>
<td>Added new content relating to version 6.0 of OPEN. Updated terminology for NCTN and ETCTN.</td>
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<td>2</td>
<td>04-NOV-2014</td>
<td>Mark Stauffer</td>
<td>Added the content for version 7.0 of OPEN, including the T&amp;UM section.</td>
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<td>3</td>
<td>11-FEB-2015</td>
<td>Matthew Laps</td>
<td>Updated screenshots, and updated the T&amp;UM and Slot Reservation sections.</td>
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<td>4</td>
<td>25-MAR-2015</td>
<td>Mark Stauffer</td>
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<td>5</td>
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<td>6</td>
<td>28-AUG-2015</td>
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<td>7</td>
<td>02-DEC-2015</td>
<td>Mark Stauffer</td>
<td>Updated the formatting for the Patient Registry link.</td>
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<td>8</td>
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<td>Mark Stauffer</td>
<td>Added the OPEN 7.3 content.</td>
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<td>9</td>
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<td>Mark Stauffer</td>
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<td>10</td>
<td>12-DEC-2016</td>
<td>Thomas Healand, Mark Stauffer</td>
<td>TH 2016/12/05: began living document. Added the OPEN 7.5 content. MS 2016/12/12 reviewed the document.</td>
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<td>11</td>
<td>03-APR-2017</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 7.7 content.</td>
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<td>12</td>
<td>20-JUL-2017</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 7.8 content, and upgraded to the latest template and CTSU styles.</td>
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<td>13</td>
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<td>Mark Stauffer</td>
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<td>17</td>
<td>12-AUG-2019</td>
<td>Mark Stauffer</td>
<td>MS 12-Aug-2019: Added the OPEN 9.0 changes for CDISC and CCDR. Added an acronyms section.</td>
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<tr>
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<td>Date</td>
<td>By</td>
<td>Description</td>
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This document was prepared by:
WESTAT, Cancer Trials Support Unit  
1600 Research Boulevard  
Rockville, Maryland 20850
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1. Overview of OPEN

The Oncology Patient Enrollment Network (OPEN) Portal:

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

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

1.1 System Requirements

Table 1: Minimum System Requirements

<table>
<thead>
<tr>
<th>Type</th>
<th>Specification</th>
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</thead>
<tbody>
<tr>
<td>Operating System</td>
<td>Windows 2000 and up</td>
</tr>
<tr>
<td>Memory</td>
<td>2 GB of RAM minimum</td>
</tr>
<tr>
<td>Display</td>
<td>Super VGA (1024 x 768) or higher-resolution monitor</td>
</tr>
<tr>
<td>Browser</td>
<td>Internet Explorer version 8 (and higher), Google Chrome, Mozilla Firefox, Opera, and Safari.</td>
</tr>
</tbody>
</table>
1.2 Business Process

The OPEN Portal business process is shown in Figure 1:

![Figure 1: OPEN Portal Business Process]

1.3 Organization of this Document

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

Table 2: Organization of the Document

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

Table 3: Web Addresses for CTSU Applications

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

1.5 Acronyms

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

Table 4: List of Acronyms

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

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

There are two ways to access the OPEN Portal:

- The OPEN URL
- The CTSU members’ website.

Both methods are described below.

2.1 Accessing the OPEN Portal Using the OPEN URL

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

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

![Figure 2: Login Screen](image)
4) Enter your CTEP-IAM username in the Username field, as well as the associated password in the Password field (these are the same username and password used for the CTSU Members’ website).

5) Click the I Agree and Logon button to enter the system.

OR

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

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

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

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

![Figure 3: The Welcome Screen for a User with Multiple Sites and a Single Role](image-url)
2.2 Logging in to OPEN via the CTSU Members’ Website

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

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

2.3 Viewing a User's Profile Information

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

Accessing this Feature:

1) Log in to the OPEN Portal.
2) Click the Profile subtab on the Home tab.
3) The following fields will display:
   - Last Name
   - First Name
2.4 Resetting a User’s Password

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

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

2.5 Accessing the Patient Registry Module

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

For information on the Patient Registry module, access the OPEN Patient Registry Site User Guide.
3. **Slot Reservation Tab**

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

![Figure 5: Process for Enrolling a Subject on a Slot Reservation Protocol in OPEN](image)

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

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

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

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

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

4.1 Instructions for Creating Enrollments in OPEN

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

![Figure 6: Site and Role](image1)

![Figure 7: Site and Role](image2)

3) Click on the Create New Enrollment link at the bottom of the Welcome page, or click on the Enroll tab and click the Create New subtab. The Create New (Credentialing) screen appears in view.
4) The site name in the Site menu automatically prefills into the Institution and Institution Name fields (as shown in Figure 8).
5) Select the protocol number in which the subject is enrolling. Only protocols for which the institution has approval are listed. The Protocol's Missing? link displays a pop-up with a list of all protocols with a site registration status for the selected site (regardless of the site registration status). If an institution or protocol number is not appearing that should be listed, please contact the CTSU Help Desk for assistance at 1-888-823-5923, option 1. This is a mandatory field.

6) Select the protocol step number using Registration Step drop-down list. The Steps Missing? link displays a list of all steps that are configured by the LPO for the protocol. This is a mandatory field. If an optional ancillary protocol is associated with the protocol's enrollment step, the user will receive a pop-up reminder (as shown in Figure 9).

Figure 8: The Create New Screen

Figure 9: Pop-up Reminder for Optional Ancillary Protocols
Note: For OPEN studies that are configured for Imaging and Radiation Treatment Facility (IRTF), an IRTF selection section will appear. Users are required to select at least one combination of values for the Credential and IRTF fields (as shown in Figure 10).

![Figure 10: IRTF Selection](image)

Figure 10: IRTF Selection

Note: For OPEN protocols that are configured for Cancer Care Delivery Research (CCDR), the Registration Type field will become a drop-down menu, from which users must select either Patient or Non-Patient (as shown in Figure 11). If Non-Patient is selected, a mandatory Non-Patient Type drop-down menu will appear with the three non-patient type choices (Caregivers, Other Professional Disciplines, and Providers, and Practice). CCDR trials can be identified by the suffix CD in the protocol number.
Enroll Tab

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

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

- Caregivers are family and other non-medical professionals involved with patient care.
- Other Professional Disciplines are other professionals involved with the care of patients.
- Practices are the sites enrolling non-patients.
- Providers are physicians, physician assistants, and nurse practitioners.

7) Select the applicable Person Type(s) and Person Name(s) from the drop-down lists. The number of persons and person types that are required is designated by the LPO. See section 10.1 for a list of validations that OPEN performs on individuals that are selected in the Create New screen.

a) The Add persons associated with this enrollment section preloads with the number of rows that are needed to accommodate all the mandatory person types.

b) Click the plus button to add additional associated people to the enrollment. A new row will display on screen. Click the minus button to delete a row.

c) When a Treating Investigator or a Drug Shipment Investigator is selected, the drug shipment information populates in the Drug Shipping Address section. The address defaults to the Treating Investigator’s address if a user does not select a Drug Shipment Investigator. If a Drug Shipment Investigator is added, that individual’s address populates in the Drug Shipping Address field.
8) Select a Network Group from the Network Group Credit drop-down list. This is the Network Group that receives credit for the enrollment. This is a mandatory field.

9) The Treating Investigator selected in step 7 will automatically populate the Credit Investigator field once the user selects a Network Group Credit choice. If the Treating Investigator is not a member of the credited group, then the Treating Investigator will not pre-populate, and the user must select a Credit Investigator from the Credit Investigator drop-down menu. This is a mandatory field.

10) The value for the NCORP Accrual field is automatically prefilled.

11) Any additional details is entered in the Case Notes box and the enrollment Summary displays the information. This is an optional field for site users and the information entered in the field will not be submitted to the LPO with the enrollment data.

12) The Express Courier Information for Drug Shipment section will appear as section 4 of the Create New screen if it was configured by the LPO (as shown in Figure 12). The fields are optional or mandatory, depending on the configuration by the LPO.

13) Click the Continue button and the user receives a pop-up message that asks them to confirm if the user wants to proceed with initializing the enrollment (as shown in Figure 13).
Click the **OK** button to initialize the enrollment. Once the enrollment is initialized, a record appears in the In Progress subtab (of the Enroll tab).

Once the enrollment is initialized, the user is given a tracking number for the enrollment. The tracking number is used for uniquely identifying the enrollment in OPEN.

Once the tracking number is obtained, the user can:

- Edit the Create New screen information for the enrollment by clicking the Edit Summary button (as shown in Figure 14).
- View Summary information for the enrollment by clicking the View Summary button (as shown in Figure 14).
- Continue with the enrollment process by clicking the Continue button (as shown in Figure 14).

The Summary, Prerequisite (if available for the protocol step), Demography, and Checklist forms for the enrollment are accessed by clicking the subtabs, while the enrollment is selected.

Once an enrollment is initiated and a tracking number is assigned, the identifying enrollment information displays in the header (as shown in Figure 15). Click on the Details or Summary links for additional information.
4.1.1 Completing the Prerequisite Screen

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

1) Access the Prerequisite screen by clicking the Prerequisite tab (if the first section of the enrollment has not been completed, follow the steps in section 4.1).

2) Once the Prerequisite screen is displayed, enter the requested data per the requirements of the protocol.

3) OPEN returns a validation error if any of the data on the form is invalid or incomplete. Each protocol can have different validations, which are determined by the LPO. Below are error message examples that result from LPO validations:
   - Mandatory fields are not completed.
   - Dates are not within a required timeframe.
   - Fields responses are inconsistent with another.
   - Provided responses do not meet protocol eligibility requirements.

4) There are multiple ways to save a In Progress enrollment, including:
   - Click the Save button. The user receives a message verifying that the data is saved (as shown in Figure 16). An enrollment that has not been submitted remains active for seven calendar days from the time it was last saved. After seven calendar days, the enrollment enters a VOID status.

• Click the Save & Validate button. The Save & Validate option saves and reviews the data for any validation errors. The data is saved even if validation errors are identified. Errors are present in the module where the error occurred. Note that the modules can expand and collapse by clicking the Expand/Collapse all Modules link (as shown in Figure 17).
5) Once the Prerequisite screen is complete, click the Continue button to proceed to the Demography screen.

- **For Theradex slot reservation studies**, the site registrar needs to reserve a slot for their subject in Theradex’s Cohort Management System. Then the user proceeds to create the enrollment in the Create New screen of the Enroll tab in OPEN. A verification is performed on the Prerequisite screen (for Theradex slot reservation studies) to see whether a slot reservation was created for the subject in Theradex’s Slot Reservation system. If a slot was reserved for the subject then OPEN allows the user to proceed to the Demography screen. If a slot was not reserved the user encounters an error message that includes a hyperlink for creating a slot reservation in Theradex’s Slot Reservation system (as shown in Figure 18).
Figure 18: (Theradex Slot Reservation Studies Only) Error Message Stating the User Must Reserve a Slot for their Subject
4.1.2 Completing the Demography Screen

The Demography screen (as shown in Figure 19) displays the demography form that is associated with the study and step that was selected earlier in the enrollment process. After completing the demography form (which is mandatory), the user proceeds to the Checklist screen.

![Demography Screen](image)

**Figure 19: The Demography Screen**

1) Access the Demography screen by clicking the Demography tab. If the first section of the enrollment has not been completed, follow the steps in section 4.1.
2) Once the Demography screen is on display, enter the subject demographic information using one of the following methods:

- Manually enter the subject’s demography information per the requirements of the protocol.
- If the subject already has an LPO-assigned patient ID, enter the patient ID in the Existing Patient ID field and click the Populate Demography button. The demography screen information automatically populates. **This is available only for protocols where the LPO supports prefilling of the demography information.**
- For multi-step protocols, when demographic data is available from the previous enrollment step, the data automatically populates the Demography screen when enrolling to the subsequent step. If all the required responses in the demographic screen are complete, OPEN automatically hides the Populate Demography button. A message appears on the demography screen that states **All matching patient demographic data from the previous step has been populated! Click [Save & Validate] in the Demography screen to validate the data.** (as shown in Figure 20).

![Figure 20: Message Stating that the Demographic Data was Pre-populated from a Previous Enrollment Step](image)

3) Some Demography forms have a Disease Code question. To provide a response, click the Select link, and a pop-up window displays a list of the Simplified Disease Code choices. Click the Select button for the Simplified Disease Code that applies for the subject and the value prefills into the Disease Code field (as shown in Figure 21).

![Figure 21: Click the Select Link to Answer a Disease Code Question](image)
4) There are multiple ways to save the In Progress enrollment:

- Click the Save button. The user receives a message verifying that the data is saved (as shown in Figure 22). An enrollment that has not been submitted remains active for 7 calendar days from the time it was last saved. After 7 calendar days the enrollment enters a VOID status.

![Information]

Data saved. The data will be deleted after 7 calendar days if it is not submitted!

Figure 22: Save Alert Message

- Click the Save & Validate button. The Save & Validate option saves and reviews the data for any validation errors. The data is saved even if validation errors are identified. Errors are present in the module where the error occurred. Note that the modules can expand and collapse by clicking the Expand/Collapse all Modules link (as shown in Figure 23).

![Validation Error(s)]

- Demography form has validation errors. Please check the form's module section for further information.
- [Standard_Patient_Identifier] module has 1 error(s)
- [Standard_Demographics] module has 2 error(s)

Figure 23: Save & Validate Messages

5) The system returns a validation error if any of the data on the form is invalid or incomplete. Each protocol can have different validation checks that are determined by the LPO.

6) Once the Demography screen is complete, click the Continue button to proceed to the Eligibility Checklist.

4.1.3 Completing the Eligibility Checklist

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

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

3) The system returns a validation error message if any of the data on the form is invalid or incomplete. Each protocol can have different validation checks, which are determined by the LPO. Examples of errors that could be included are:
   - Mandatory fields were not completed.
   - Dates are not within a required timeframe.
   - Fields containing data that are inconsistent with the data in another field.
   - Fields that do not meet the eligibility requirements.

4) Some protocols are configured with eligibility checklist questions that have prefilled responses. This is because the answer to a question is determined earlier in the enrollment process. If the prefilled response is out-of-date (due to the value being updated after the prefill process occurred), click the Refresh button next to the question to update the value (as shown in Figure 24).

![Figure 24: The Refresh Button will Display an Updated value for a Question that Uses the Prefill Feature](image)

5) There are multiple ways to save the In Progress enrollment:
   - Click the Save button. The user receives a message verifying that the data is saved (as shown in Figure 25). An enrollment that has not been submitted remains active for seven calendar days from the time it was last saved. After seven calendar days the enrollment enters a VOID status.

   ![Information](image)
   - Data saved. The data will be deleted after 7 calendar days if it is not submitted!

   ![Figure 25: Save Alert Message](image)

   - Click the Save & Validate button. The Save & Validate option saves and reviews the data for any validation errors. The data is saved even if validation errors are identified. Errors are present in the module where the error occurred. Note that the expand and collapse by clicking the Expand/Collapse all Modules link (as shown in Figure 26).
6) The checklist is retrievable from the Enroll -> In Progress tab by selecting the desired enrollment and clicking on the Checklist tab.

### 4.1.4 Submitting the Eligibility Checklist

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

1) Click the Continue button (as shown in Figure 27).

![Figure 27: Click the Continue Button on the Checklist Screen](image)

2) The Checklist screen is validated for errors. If a validation error is found, the user must fix the errors or request an override (if available) in order to continue. See 4.2.7 for details on requesting an override. The user also receives alert messages. Unlike error messages, alert messages do not block the enrollment process from continuing and they are only for informational purposes.

3) If no validation errors are found, the user receives a summary of all the data that was entered for the subject enrollment. The user is asked to confirm their submission.

4) If changes are necessary, click the subtab (Prerequisite, Demography, or Checklist) to return to the desired form and make the necessary updates.

5) If no changes are needed, click the Submit button.

6) Click on the OK button and the enrollment is submitted to the LPO for validation.

7) A confirmation of the enrollment and details is displayed (including the Patient ID, Treatment Arm, and Site Instructions, if any) (as shown in Figure 28).
8) The completed enrollment is found on the History screen.

4.2 Additional Features within the Enroll Tab

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

4.2.1 Resubmitting an Enrollment

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

1) Select the enrollment (which has a SUBMITTED status) from the In Progress screen.
2) Click on the Checklist subtab.
3) Once on the Checklist form, click the Resubmit button (as shown in Figure 29).
4) Review the enrollment information on the Review and Submit screen and click the Resubmit button.
5) Click OK on the confirmation pop-up window.
6) If the resubmission is successful, the user receives an ELIGIBLE response from the LPO system (as shown in Figure 30).

![Figure 30: Enrollment Confirmation for a Successful Resubmission](image)

4.2.2 Using the Group Lookup List Feature

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

Accessing this Feature:

1) Log in to OPEN.
2) Enter the In Progress enrollment screen; locate the question that uses the Group Lookup List feature.
3) Click the Select link next to the question (as shown in Figure 31).
4) A Group Lookup List pop-up window appears on screen (as shown in Figure 32).

5) The results filter by entering a value into the Value, Name, and Description fields, and then clicking the Search button (as shown in Figure 33).
4.2.3 Completing a Multiple Step Enrollment

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

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

1) Follow the steps in section 4.1 of this User Guide to complete the initial step enrollment.
2) Click on the History tab.
3) Select the enrollment.
4) In the Summary screen, select the Create Step... button. The next valid step displays Step 1 Registration Information (as shown in Figure 34).

   ![Figure 34: Create Next Step Enrollment by Clicking the Create Step... Button](image)

5) Click OK to copy the enrollment details from the previous step (as shown in Figure 35).

   ![Figure 35: Copy Details Confirmation](image)

6) Review the pre-populated data.
7) Make updates to the Create New screen, if needed. Only the associated persons section, the specify credits section, the express courier sections (if applicable), and the case notes will update.
8) Click the Continue button.
9) Click the OK button on the pop-up window.
10) A new tracking number is assigned to the enrollment step.
11) Click the Continue button.
12) Once the Demography screen is displayed, either:
   a) Enter the subject demography information per the requirements of the protocol.
   b) Click the Populate Demography button and this will populate the demographic data for the subject from the prior enrollment step. The Populate Demography feature is only available for LPOs that support the feature (as shown in Figure 36). Note if the Existing Patient ID field is available, the patient ID from the prior step enrollment is prefilled in the Existing Patient ID field.
Enroll Tab

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

1) Follow the steps in section 4.1 of this User Guide to complete the initial step enrollment.
2) Click the Enroll tab and click the subtab for the Create New (Credentialing) screen.
3) Select the desired protocol number.
4) Select the appropriate enrollment step.
5) A new screen appears, requesting the patient ID from the previous step. Enter the patient ID in the Patient ID box.
6) Click the Search button. The enrollments that match the entered data is returned.
7) Click the Select button for the record that matches the correct enrollment.
8) The Create New screen refreshes with the patient ID and the associated credentialing screen data that was entered in the previous enrollment step.
9) If needed, make updates to the credentialing data. Only the associated persons section, the specify credits section, the express courier section (if applicable), and the case notes is updated.
10) Click the Continue button and the user is taken to the Demography screen.
11) Once the Demography screen is displayed, either:
   a) Enter the subject demography information per the requirements of the protocol.
   b) Click the Populate Demography button and this populates the demographic data for the subject from the prior enrollment step. The Populate Demography feature is available for LPOs that support the feature (as shown in Figure 37). Note if the Existing Patient ID field is available, the patient ID from the prior step enrollment is prefilled in the Existing Patient ID field.

Figure 36: Populate Data Feature

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

4.2.4 Completing an Ancillary Study

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

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

Steps for enrolling on an ancillary study:

1) Click on the Create New Registration link on the Welcome page, or click on the Enroll tab and select the Create New subtab.
2) Enter the Protocol Number and select the Registration Step.
3) If the entered protocol number has embedded or stand-alone ancillary studies, a new section appears (Figure 38). The Ancillary protocol selection section displays the associated ancillary protocols.
4) Enrollments that require ancillary embedded or stand-alone protocols are automatically selected and are not editable. The user must enter the information for these protocols at the same time the main study enrollment is being completed.
5) If a protocol has an optional ancillary study then the checkbox is blank by default. Checking the checkbox allows that optional ancillary study to be included in the current enrollment (as shown in Figure 38).
6) If an associated optional ancillary study is not selected for an enrollment, then an informational message is displayed at the top of the Prerequisite, Demography, and Checklist screens (as shown in Figure 39). The message will not prevent users from continuing with enrollment.

7) The Patient ID field is optional for any initial step enrollment; however, this information is necessary when performing a delayed enrollment. Please see section 4.2.5 of this document for more details regarding the delayed enrollment process.
8) Complete the Create New screen and continue to the Demography screen. Please see section 4.1.2 of this document for more detailed information.

9) Complete the Demography screen and continue to the Checklist (Eligibility Checklist) screen. Please see section 4.1.1 of this document for more detailed information.

10) All ancillary studies are included in the Checklist screen. Embedded and selected optional studies are displayed with the name of the protocol listed in the header before the module name (as shown in Figure 40).

11) Complete the Checklist screen and click the Continue button. See section 4.1.3 of this document for detailed information.

12) Review the enrollment information on the Review and Submit screen, and click the Submit button.

13) Click the OK button on the confirmation pop-up window.

14) The enrollment result displays on screen.

### 4.2.5 Skipping an Optional Enrollment Step

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

1) Log in to OPEN.

2) Click the Create New Registration link on the Welcome screen, or click the Enroll tab and select the Create New subtab.
3) Ensure the proper Institution CTEP ID.

4) Select the Protocol Number.

5) Select the step from the Registration Step drop-down menu. OPEN display all steps for the protocol in the drop-down menu. If an enrollment step is configured as optional, the user can skip the enrollment step.

![Figure 41: OPEN will Display all Protocol Steps](image)

6) Enter the subject’s previously assigned patient ID in the Patient ID field and click the Search button.
7) OPEN retrieves the list of enrollments for the entered patient ID.

8) Click the Select button for the subject’s previous step enrollment. OPEN fills in the additional fields based on what was previously selected during the subject’s previous enrollment step.

9) Click the Continue button.

10) OPEN creates the new tracking number and populate details from the previous step for that subject (as shown in Figure 43).

Figure 42: Users Must Provide a Patient ID when Skipping Steps

Figure 43: OPEN Populated the Subject’s Demography Information from a Previous Step to the New Tracking Number
11) Complete the remainder of the enrollment like a normal OPEN enrollment.

4.2.6 Creating a Delayed Enrollment to an Ancillary Study

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

Accessing this Feature:

1) Click on the Create New Registration link on the Welcome screen, or click on the Enroll tab and select the Create New subtab.

2) Enter the Institution CTEP ID and the Protocol Number of the main study that the ancillary study is linked with, this should match the site and protocol number of the original enrollment.

3) Select the step for which the delayed enrollment needs to be completed.

4) Enter in the Patient ID that corresponds with the main study enrollment (as shown in Figure 44) and click the Tab key on your keyboard.

5) Enrollments matching the entered data is displayed in a new section. Click the Select button to select the record that matches the enrollment and click the Continue button.

6) The Create New screen refreshes the information.

7) Select the ancillary protocol by checking the corresponding checkbox (as shown in Figure 44).

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

![Figure 45: Delayed Ancillary Study Checklist](image)

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

### 4.2.7 How to Request an Override to a Validation Error

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

**Accessing this Feature:**

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

**Table 5: Override Icons and their Descriptions**

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Icon1" /></td>
<td>Indicates a question is eligible for an override.</td>
</tr>
<tr>
<td><img src="image" alt="Icon2" /></td>
<td>Indicates an override request has been initiated.</td>
</tr>
<tr>
<td><img src="image" alt="Icon3" /></td>
<td>Indicates a question has multiple overrides associated with it.</td>
</tr>
<tr>
<td><img src="image" alt="Icon4" /></td>
<td>Indicates an override has been approved.</td>
</tr>
<tr>
<td><img src="image" alt="Icon5" /></td>
<td>Indicates an override has been denied.</td>
</tr>
<tr>
<td><img src="image" alt="Icon6" /></td>
<td>Indicates an override is on hold or is pending.</td>
</tr>
</tbody>
</table>
2) Click the Request Override button (as shown in Figure 46) for the desired validation error.

<table>
<thead>
<tr>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERROR-1: Has the eligibility checklist been completed must be yes. Request Override</td>
</tr>
<tr>
<td>ERROR-14: If a US resident, HIPAA authorization is required.</td>
</tr>
<tr>
<td>ERROR-20: In the opinion of the investigator, is the patient eligible, must be yes. Override Requested</td>
</tr>
<tr>
<td>ERROR-29: Has written informed consent been obtained must be yes. Override Denied</td>
</tr>
</tbody>
</table>

Figure 46: Validation Errors on Eligibility Checklist

3) A new window appears on screen (as shown in Figure 47).

![Override Request Form](image)

Please enter an override code or a request reason:

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

**Failure Description:** Patient initials must be letters.

**Override Code:**

**Request User:** Rudd Brenda (Associate)

**Request Reason:** Enter reason for the override request here...

**Override Status:** REQUESTED

**Reviewer:**

**Reviewer Comments:**

Submit Back to EC Back to Summary

Figure 47: Override Request

4) If an override code is known, enter the override code in the Override Code field (which is an optional field).

5) Enter the reason for the override request in the Request Reason field (as shown in Figure 47).

6) Click the Submit button. The override request goes to the LPO for review.

7) The requesting user and the LPO receives an email notification indicating that an override was requested for the enrollment.

8) The Request Override button turns into an orange Override Requested button, to indicate that an override was requested for the validation.

9) Once the LPO reviews the override and assigns a status (i.e., approved, denied), the user receives an email notification.

10) If needed, the Override Requested button in the eligibility checklist can be used to view the override status for that specific validation error.
If the override request is approved, return to the Checklist screen and click the Continue button. If no other validation errors are present, the user can complete the enrollment process. If the override is denied the Override Requested button turns red and the verbiage changes to state Override Denied (as shown in Table 5), and the user is unable to complete the enrollment process. Other status possibilities are:

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

### 4.2.8 The Duplicate Patient Check

#### Possible Duplicate Patient Check:

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

#### Exact Duplicate Patient Check:

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

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

**Accessing this feature:**

1) On the Welcome page of OPEN, click the Start Practice button (as shown in Figure 49).

![Figure 49: Start Practice button](image)

2) The screen refreshes and all screens within OPEN use an orange color scheme along with a Practice/Test Registration watermark, and a Stop Practice button that appears next to the Role field (as shown in Figure 50).

![Figure 50: Practice Mode](image)

3) While the system is in practice mode, only the Enroll, History, and Help screens are active. If other tabs are clicked, a message displays text that reads **Not available during practice or test mode!**

4) All enrollments created in practice mode have a super script $T$ attached to the tracking number to indicate that the enrollment is a practice mode enrollment (as shown in Figure 51).

![Figure 51: Practice Mode Tracking Numbers include a $T$](image)
5) While in practice mode, the user is able to duplicate an existing enrollment. This feature is only available for step 1 studies that do not have ancillary studies. To use the Duplicate Enrollment feature:
   a) From the In Progress subtab (of the Enroll tab) or the History tab, click the Duplicate Enrollment icon associated with the enrollment that is copied.
   b) Click the OK button on the confirmation pop-up window and a pop-up message confirms the enrollment is successfully duplicated (as shown in Figure 52).

<table>
<thead>
<tr>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successfully copied over #82175. The newly copied over tracking number is 82179</td>
</tr>
</tbody>
</table>

Figure 52: Confirmation Message Indicating an Enrollment was Successfully Duplicated

c) Once an enrollment is duplicated, it is found on the In Progress screen of the Enroll tab.

6) The user can proceed with completing the enrollment process for a practice mode enrollment.

7) Upon final submission of the enrollment, a confirmation pop-up window reminds the user that the enrollment is being created in practice mode (as shown in Figure 53).

<table>
<thead>
<tr>
<th>Microsoft Internet Explorer</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ALERT] This is a practice (test) registration!!!</td>
</tr>
<tr>
<td>This form will be submitted to the group for randomization, do you want to continue?</td>
</tr>
<tr>
<td>OK Cancel</td>
</tr>
</tbody>
</table>

Figure 53: Message Reminding the User that the Enrollment is Being Created in Practice Mode

4.2.10 Automatic Session Timeout

If a user is logged into OPEN for 24 minutes without activity (such as clicking a tab or subtab, moving to a new screen, or saving their data), they receive a pop-up message (as shown in Figure 54) stating that their session is about to expire, and they need to click OK to avoid being automatically logged out of OPEN (six minutes later).

<table>
<thead>
<tr>
<th>OPEN - Oncology Patient Enrollment Network - Windows Internet Explorer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology Patient Enrollment Network [MANO15 - 07/18/11 12:51:36 PM EDT]</td>
</tr>
<tr>
<td>Your session is about to expire at 07/18/2011 12:56:36</td>
</tr>
<tr>
<td>Press 'OK' to renew your session</td>
</tr>
<tr>
<td>OK Cancel</td>
</tr>
</tbody>
</table>

Figure 54: Session Timeout Alert
If the user remains inactive after receiving the session timeout pop-up, their data will automatically be saved at minute 28, prior to the automatic log out that occurs after 30 minutes of inactivity.

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

1) Click the wrench icon on the browser toolbar (as shown in Figure 55).

![Figure 55: Select Options](image)

2) Select the **Options** choice (as shown in Figure 55).
3) Click the **Under the Hood** tab (as shown in Figure 56).
4) In the Privacy section, click **Content Settings** (as shown in Figure 56).
5) In the Pop-ups section, click **Allow all sites to show pop-ups**. Once the settings are changed to allow pop-ups in the Chrome browser, this feature works similar to Internet Explorer (as shown in Figure 56).
4.2.11 Using the In Progress Subtab

The In Progress subtab of the Enroll tab allows users to view and complete In Progress enrollments for any institutions with which the user is associated. The In Progress subtab can either show patient enrollments (as shown in Figure 57) or non-patient enrollments (as shown in Figure 58).

![Figure 56: Allow Pop-ups](image)

**Figure 56: Allow Pop-ups**

**Figure 57: The In Progress Subtab Displaying Patient Enrollments**

![Figure 57](image)
Figure 58: The In Progress Subtab Displaying Non-Patient Enrollments

The In Progress screen browser displays the following information:

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

Accessing this feature:

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

4.2.11.1 Statuses for In Progress Enrollments

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

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

4.2.12 Deleting In Progress Enrollments

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

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

4.2.13 View Item Information

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

Accessing this Feature:

1) The user locates the item requiring more information.
2) Click the AAG button that is adjacent to the particular field.
3) The item’s AAG information pop-up window appears on screen (as shown in Figure 59).
4.2.14 Using the Search Feature in the Browser Screens

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

Accessing this feature:

1) Click on the In Progress subtab of the Enroll tab or the History tab.
2) Locate the field(s) in the Browser screen that needs to be filtered (as shown in Figure 60):

- Tracking Number
- Study
- Site CTEP ID
- Credit
- Registration Step
- Patient ID Number (History Tab only)
- Registration Status
- Status Date
- Modified Date (In Progress Tab only)
- Registrar
Figure 60: In Progress Enrollment Search Screen

3) Enter the corresponding field information into the appropriate field(s) (as shown in Figure 60). The percent sign % expands the search field content and the number of results that are returned. However, adding multiple search criteria will further reduce the number of enrollments returned.

4) Click the Search button and the screen refresh with the filtered results.

4.2.15 Editing Credentialing Information for an In Progress Enrollment

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

Accessing this feature:

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

4.2.16 Exceptional Responder Studies

A record is created in Rave when an enrollment for an Exceptional Responder (ER) study is completed in OPEN. At the enrollment confirmation screen in OPEN, the user encounters a hyperlink at the bottom of the page that provided a direct link into the subject’s record in Rave, so the user does not have to log in to Rave and navigate to the appropriate form. The user must click the link to complete the data collection process (as shown in Figure 61).
Figure 61: Example of the Rave Hyperlink for ER Studies
5. History Tab

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

A green delta symbol appears next to questions that had their responses updated post-enrollment, so OPEN users are aware of post-enrollment data updates (as shown in Figure 62).

![Figure 62: Green Delta Symbol Indicates Fields with Post-Enrollment Updates](image)

5.1 Browse Subtab

The Browse subtab allows the user to view a list of all enrollments that have been completed at any institution where the user has a roster affiliation (as shown in Figure 63).
The definitions for the Source column are as follows:

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

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

Enrollments are filtered, sorted, and searched based on search criteria (as shown in Figure 64).

The following fields will be displayed:
- Track #
- Protocol
- Site
- Credit
- Step
- Step Type
- Count Towards
- PID (Patient ID number)
- Arm (Treatment Arm)
- Eligibility
- Status (of the enrollment)
- Randomized Date (date and time the enrollment was completed)
- T&UM Type (whether a Transfer & Update Module (T&UM) request is associated with an enrollment)
- Registrar (the user who completed the enrollment)

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

5.1.1 Statuses for Enrollments in the History Tab

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

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REGISTERED</td>
<td>This status is assigned after an enrollment is submitted to the LPO and a patient ID and treatment arm is returned and received by OPEN.</td>
</tr>
<tr>
<td>INELIGIBLE</td>
<td>The enrollment is deemed ineligible by the associated LPO.</td>
</tr>
<tr>
<td>CANCELLED</td>
<td>This status is assigned when a completed enrollment is withdrawn. Only administrators are able to cancel a completed enrollment.</td>
</tr>
</tbody>
</table>
5.1.2 The T&UM Type Menu

The T&UM Type column in the Browse subtab allows OPEN users to identify which subject enrollments involve and approve T&UM requests. The type of T&UM request is indicated in the T&UM Type column (as shown in Figure 65).

**Instructions for using the T&UM Type column:**

1) Log in to OPEN.

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

3) To filter through the enrollments by a particular T&UM Type (none, Credentialing Data Update, Demographic Data Update, Site Transfer), click the text-entry box above the T&UM Type column and select the appropriate choice (as shown in Figure 66).

4) After making a selection in the text-entry box above the T&UM Type column, the results refresh as requested (as shown in Figure 67).

---

**Figure 65: The T&UM Type Column Identifies Enrollments with Approved T&UM Requests**

<table>
<thead>
<tr>
<th>Action</th>
<th>V</th>
<th>D</th>
<th>Track #</th>
<th>Protocol</th>
<th>Site</th>
<th>Credit</th>
<th>Assn</th>
<th>Step Type</th>
<th>Count Site</th>
<th>PKO</th>
<th>Assn</th>
<th>Status</th>
<th>Randomization Date</th>
<th>T&amp;UM Type</th>
<th>E科尔</th>
<th>Enroll</th>
<th>E科尔</th>
<th>Enroll</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

---

**Figure 66: Results are Filtered by the T&UM Type**

---

**Figure 67:**
5.2 Summary Subtab

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

5.2.1 ER Push

Enrollments for the ER protocol 9671 are performed in OPEN. Upon completion of those enrollments (unlike other Rave studies), OPEN immediately initializes the ER subjects to Rave. The action is noted in the Registration Workflow with MANUAL_RAVE_TX. If the initialization fails, site users use the ER Push feature to manually retry the patient initialization to Rave.
Figure 68: Summary Subtab of the History Module

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

- This button will send a **Real-time Data Transfer System (RDTs)** transaction to the LPO.
5.3 Per-Case Funding

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

Steps for entering completion dates for funding types:

1) Log in to the OPEN Portal.
2) Click the History tab.
3) Locate the subject that was enrolled on a study that involves per-case funding (as shown in Figure 69).

![Figure 69: Dollar-Sign Icon Indicates the Enrollment involves Per-Case Funding]

4) Click the Select button for the subject’s row.
5) Click the Funding subtab (as shown in Figure 70).

![Figure 70: Funding Subtab]

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

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

5.3.1 Funding Report

Since a site may have many subjects on studies that involve per-case funding, a Funding Report is available to provide a list of all per-case funding items for a particular institution.

Accessing the funding report:

1) Log in to OPEN.
2) Click the History tab and the user will be brought to the Browse subtab.
3) Click the Per-Case Funding icon for a subject enrollment (as shown in Figure 71). The per-case funding item results is for the site that is linked to the subject enrollment that is selected.

Figure 71: Click the Per-Case Funding Icon to Launch the Funding Report

The Funding Report will launch in a separate pop-up window, displaying all of the per-case funding items for a single selected site or multiple selected sites (as shown in Figure 72).
Figure 72: Funding Report

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

The Site column in the Funding Report is a searchable field, so users may enter either a single or multiple site(s) (which they have roster affiliations with), as illustrated in Figure 73.

Figure 73: The Site Field Allows Users to See Results for their Different Sites

The Excel export feature (for the Funding Report) exports a maximum of 5,000 records, for all of the sites in which the user has roster affiliations.
5.4 The Print Confirmation and Print Full Form Features

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

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

Accessing these features:
1) Click the History tab and the screen refreshes to the Browse subtab by default.
2) Select the desired enrollment and the user is brought to the Summary screen for the enrollment.
3) Click the Print Confirmation or the Print Full Form button (as shown in Figure 74).

![Figure 74: Print Confirmation and Print Full Form Buttons on an Enrollments Summary Screen](image)

5.5 Linking Non-Patient Enrollments to Patient Enrollments for Cancer Care Delivery Research Protocols

For CCDR protocols, site users can use the Link or Unlink non-patients button to link (or un-link) non-patient enrollments to the corresponding patient enrollment.

Accessing this feature:
1) Click the History tab and the screen will refresh to the Browse subtab by default.
2) Select the desired patient enrollment and the user is brought to the Summary screen for the enrollment.
3) Click the Link or Unlink non-patients button (as shown in Figure 75).

![Figure 75: Click the Link or Unlink Non-patients Button to Link Non-Patients to Patients](image)

4) A pop-up will appear, allowing users to link non-patients to their patient enrollment (as shown in Figure 76).
5) Click the Edit checkbox to select a non-patient, click the Save button, and close the pop-up window.

6) The Summary screen will refresh for the patient, and the non-patient enrollment will now display in the Linked Non-Patient Enrollments section (as shown in Figure 77).

---

**Figure 76: Pop-Up Window Displaying Non-Patient Enrollments**

5) Click the Edit checkbox to select a non-patient, click the Save button, and close the pop-up window.

6) The Summary screen will refresh for the patient, and the non-patient enrollment will now display in the Linked Non-Patient Enrollments section (as shown in Figure 77).

---

**Figure 77: The Associated Non-Patient Enrollment In The Patient Enrollment's Summary Screen**
6. T&UM Tab

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

The Transfer and Update Module (T&UM) within OPEN was created as the central location for site staff to request data changes (Site Transfers, Credentialing Data Updates, and Demographic Data Updates) for completed subject enrollments that are maintained in OPEN. Each request undergoes automatic validations, and the system allows LPO staff to manually approve requests (per their preference). The T&UM automatically updates (when possible) systems outside of OPEN that also contain the subject’s data (such as Rave, and the LPO RandoNodes).

The Create New subtab of the T&UM tab contains an automated message (as shown in Figure 78) that lists all of the LPOs that use the T&UM for enrollment data updates. For the LPOs that do not use the T&UM, site users must follow the existing process for data updates.

Access the OPEN T&UM Site User Guide to view detailed instructions for using the T&UM.
7. Reports Tab

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

7.1 Screening Subtab

The Screening subtab contains information for completed Screening Log (protocol DCP-001) enrollments that were completed at institutions where the site user has active roster affiliations (as shown in Figure 79).

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

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

7.2 Funding Subtab

The Funding subtab is included under the Reports tab. This enhancement enables OPEN users to efficiently access the Funding Report for their selected site (as shown in Figure 80).
7.3 Maps Subtab

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

Figure 81: The Maps Subtab Displays Locations Where OPEN Enrollments Have Occurred

Content within the Maps subtab filters by the following criteria:

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

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

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

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

The data filters by the following criteria:

- Year (click a specific year within the Enrollment numbers by year chart).
- Accrual step (make a selection from the drop-down menu Only Accrual Step?), to choose whether only accrual step enrollment data is displayed.
8. RSS Tab
The RSS tab contains searchable browser screens for Person and Site Registration information.

8.1 Persons Subtab
The Persons subtab allows users to locate an individual using the search feature (as shown in Figure 83).

![Figure 83: The Persons Subtab](image)

The searchable fields include:
- CTEP ID
- Last Name
- First Name
- Status
- Type

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

8.2 Protocols Subtab
The Protocols subtab provides detailed information regarding OPEN protocols and it is available to all users (as shown in Figure 84). Users can view detailed information about a protocol by clicking the View Details icon or they can filter the table results using the text-entry search boxes above each table column (and then clicking the Search button). Site users can view protocols for which their institution has site registrations.
8.3 Site Registrations Subtab

The Site Registrations subtab of the History tab allows users the ability to locate site registration information (as shown in Figure 85).

Accessing this feature:

1) Click the Site Registration Search link on the Welcome page or the RSS tab.
2) Click on the Site Registrations subtab.
3) Enter the search criteria in the search field(s).
4) Click the Search button and the browser results refresh based on the search content. See section 4.2.14 for more information on using the search feature.
9. Help Tab
The Help tab contains user documentation and OPEN release information (as shown in Figure 86).

![Figure 86: The Help Tab of OPEN](image)

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

9.2 About Subtab
The About subtab lists the notable enhancements and fixes that were applied with each release of the OPEN Portal.
10. Appendix
This section provides additional information regarding OPEN validations.

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

Table 8: Validations for the Create New Screen

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