Revision Information for the OPEN Patient Registry Site User Guide

Revision History

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1. Introduction

This document provides instructions for creating, editing, and viewing COG patient registry records in the Patient Registry module of OPEN.

1.1 Background Information

The Children’s Oncology Group (COG) Patient Registry was used for performing the COG patient registration process, to obtain COG Patient IDs. All patients must obtain a COG Patient ID prior to enrolling onto COG and Children’s Oncology Group Consortium (COGC) protocols.

COG offers Adolescent and Young Adult (AYA) trials, which allow COG member sites, COGC member sites, and adult National Clinical Trial Network (NCTN) member sites to participate. Previously, when an Adult NCTN site was not a COG or COGC member (or a site was a COG or COGC member and an Adult NCTN member), CTSU performed the COG patient registration process on behalf of the site. For those cases, CTSU manually validated institution roster affiliations, investigator roster affiliations, and site registration status information, prior to completing the patient registration process in COG’s system. The validation information could only be obtained from CTSU’s Regulatory Support System (RSS).

The logistical challenges for enabling adult NCTN sites to access the COG Patient Registry led to the integration of the Patient Registry within OPEN. The integration leverages the information from RSS to allow the COG, COGC, and CTSU to handle the increasing AYA trial participation.

1.2 Overview of the Patient Registry Module in OPEN

The Patient Registry module in OPEN provides a central location for site users to create, edit, and view COG Patient Registry records. The module allows persons from COG and COGC member sites, and adult NCTN member sites, to obtain COG Patient IDs for their patients using OPEN.

1.3 Organization of this Document

Table 1 describes the organization of this document.

Table 1: Organization of the Document

<table>
<thead>
<tr>
<th>Section</th>
<th>Topic</th>
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<tr>
<td>1</td>
<td>Introduction to the Patient Registry module.</td>
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### 1.4 Web Addresses for CTSU Applications

<table>
<thead>
<tr>
<th>Application</th>
<th>URL</th>
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<tbody>
<tr>
<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>
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</table>
2. Accessing the Patient Registry Module

2.1 Requirements for Accessing the Patient Registry Module

A site user must fulfill all of these requirements to utilize the Patient Registry module in OPEN:

- Have an active CTEP-IAM account status.
- Have an active Lead Protocol Organization (LPO) roster affiliation with their site(s).
- Have a particular role (see Table 3) at their site to perform actions in the Patient Registry module.

Table 3: Roles Required for Site Users to Perform Actions in the Patient Registry Module

<table>
<thead>
<tr>
<th>Action</th>
<th>Required Role (CTSU or LPO-equivalent roles)</th>
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<tbody>
<tr>
<td>Create records</td>
<td>Site Registrar, Site Admin</td>
</tr>
<tr>
<td>Edit records</td>
<td>Site Registrar, Site Admin</td>
</tr>
<tr>
<td>View records</td>
<td>Site Registrar, Site Admin, Site Staff, Site Investigator</td>
</tr>
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</table>

2.2 Instructions for Accessing the Patient Registry Module

1) To access the Patient Registry module, click the “COG Patient Registry” hyperlink at the bottom of the OPEN Welcome screen (see Figure 1). Please note that the OPEN Patient Registry module is not accessible when OPEN’s “Practice Mode” is engaged.

![Figure 1: Accessing the Patient Registry Module](image)

2) The screen will refresh to the Patient Registry Browser screen (see Figure 2).
3. Creating Patient Registry Records

This section provides instructions for creating COG Patient Registry records in the Patient Registry module of OPEN, as well as using the Possible Duplicate screen.

3.1 Instructions for Creating Patient Registry Records in OPEN

1) Login to OPEN.

2) Click the “COG Patient Registry” link on the Welcome screen (of the Home tab). The screen will refresh to the Patient Registry Browser screen (see Figure 2).

3) Click the “Create Patient Registry Record” button. The screen will refresh to a blank Demography Form (see Figure 3).

Figure 2: Patient Registry Browser Screen

3) Click the “Create Patient Registry Record” button. The screen will refresh to a blank Demography Form (see Figure 3).
4) The Institution CTEP ID and Registrar fields shown at the top of the screen will automatically prefill, based on the logged in user and their selected site.
   a) To associate a different site with a patient registry record:
      i) Click the “Back to OPEN home page” hyperlink.
      ii) Click the Site drop-down menu, and select the desired site.
      iii) Enter the Patient Registry module again, and click the Create Patient Registry Record button.

5) Answer the required fields on the Demography Form.

6) Click the Continue button. The screen will refresh to the Diagnosis Form (see Figure 4), which will include the tracking # for the record. The “Tracking #” is different from the COG Patient ID that will be generated when the patient registry record is created successfully.
Figure 4: Diagnosis Form for a New Record

7) Answer the required fields on the Diagnosis Form.

8) Click the Continue button. The screen will refresh to the Review and Submit screen. If the Possible Duplicate screen appears, refer to section 3.2 for further instructions.

9) Review the patient’s information on the Review and Submit screen. Click the Back button if changes need to be made, or click the Submit button to proceed.
   a) Please note that OPEN will automatically change in-progress records (that had not previously achieved a REGISTERED status) to a VOID status after 7 calendar days without user activity.

10) If successful, the screen will refresh to the Patient Registry Confirmation screen (see Figure 5). The screen will display the COG Patient ID, and the BPC ID that were assigned by the COG Registry node.

Figure 5: Patient Registry Confirmation Screen

11) This concludes the process for creating patient registry records within of OPEN.
3.2 Instructions for Using the Possible Duplicate Screen

A user will encounter the Possible Duplicate screen when clicking the Continue button on the Diagnosis Form, if information in their patient registry record matches information in another patient registry record.

Instructions for Using the Possible Duplicate Screen:

1) Upon arriving at the Possible Duplicate screen (see Figure 6), the user will be presented with any existing patient registry records that are possibly duplicates of the record that is being created (or modified).

![Figure 6: Possible Duplicate Screen](image)

2) Review the possible duplicate patient information that is shown. Decide whether the patient (that is being created or modified) is a duplicate of any of the patients that are shown under the “Yes, this is a duplicate patient registry record” section.

   a) If the patient is not a duplicate, click the radio button for the “No” response, and click the Continue button. The screen will refresh, and the user will continue to the Review and Submit screen.

   b) If the patient is a duplicate, click the radio button for the “Yes” response, and click the Continue button. The screen will refresh (see Figure 7) and the record that is being created (or modified) will be set to a VOID status. This will conclude the process for creating or modifying the patient registry record in OPEN.
Figure 7: A Duplicate Patient Registry Record will be Changed to a VOID Status
4. Editing Patient Registry Records

This section provides instructions for modifying patient registry records in OPEN.

4.1 Instructions for Editing Patient Registry Records

1) Login to OPEN.

2) Click the “COG Patient Registry” link on the Welcome screen (of the Home tab). The page will refresh to the Patient Registry Browser screen.

3) Locate the record that needs to be modified, and click the corresponding Edit button (see Figure 8).

![Figure 8: The Edit Button Allows Users to Modify Patient Registry Records](image)

4) The screen will refresh to the Demography Form. If the record was in a REGISTERED status in the past, the screen title will state “Edit Patient Registry Record - Demography Form”. If the record has not been in a REGISTERED status before, the screen title will state “New Patient Registry Record - Demography Form”.

5) If any data needs to be modified, make the appropriate update(s). Some fields will be disabled for site users if the record was previously in a REGISTERED status, including: initials, Patient’s Date of Birth, and Gender of a Person. For assistance with updating any of the disabled fields (or transferring a patient to a new site), please email the COG Help Desk (HelpDesk@childrensoncologygroup.org).

6) Click the Continue button. A popup message will appear to inform the user about the roll-back process. If a record is being modified and it remains in an INCOMPLETE, READY, or SUBMITTED status for 24 hours (and it was previously in a REGISTERED status at some point) the record will revert to a REGISTERED status, and any pending changes will be discarded.

7) Click the OK button. The popup window will disappear and the Patient Registry screen will refresh to the Diagnosis Form.

8) If any data needs to be modified, make the appropriate update(s).

9) Click the Continue button, and the screen will refresh to the Review and Submit screen. If the Possible Duplicate screen appears, refer to section 3.2 for further instructions.

10) After reviewing the information on the Review and Submit screen, click the Submit button.

11) The page will refresh to the Patient Registry Confirmation screen.
5. Viewing Patient Registry Records

This section provides instructions on how to view details for patient registry records within OPEN.

5.1 Instructions for Viewing Patient Registry Records in OPEN

1) Login to OPEN.

2) Click the “COG Patient Registry” link on the Welcome screen (of the Home tab), and the page will refresh to the Patient Registry Browser screen.

3) Locate the desired record, and click the View button for a record.

![The View button]

Figure 9: The View Button Allows Users to See Details for Patient Registry Records

4) A complete summary of the record will display in a popup window (see Figure 10).
**Figure 10: Details Popup for a Patient Registry Record**