

CTSUS

Cancer Trials Support Unit

OPEN Patient Registry Group User Guide

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Document Information

Revision Information for the OPEN Patient Registry Group User Guide

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Table of Contents

OPEN PATIENT REGISTRY GROUP USER GUIDE	I
1. INTRODUCTION.....	1
1.1 Background Information.....	1
1.2 Overview of the Patient Registry Module in OPEN	1
1.3 Organization of this Document.....	1
1.4 Web Addresses for CTSU Applications	2
2. ACCESSING THE PATIENT REGISTRY MODULE.....	3
2.1 Requirements for Accessing the Patient Registry Module	3
2.2 Instructions for Accessing the Patient Registry Module.....	3
3. CREATING PATIENT REGISTRY RECORDS.....	5
3.1 Instructions for Creating Patient Registry Records in OPEN.....	5
3.2 Instructions for Using the Possible Duplicate Screen	8
4. EDITING PATIENT REGISTRY RECORDS	9
4.1 Instructions for Editing Patient Registry Records	9
5. VIEWING PATIENT REGISTRY RECORDS	10
5.1 Instructions for Viewing Patient Registry Records in OPEN	10
6. ADDITIONAL INFORMATION	12
6.1 Patient Registry Record Statuses.....	12
6.2 Process for Creating or Editing Patient Registry Records in OPEN	13
6.3 How to Transfer a Patient Registry Records to a New Site.....	15
6.4 Behavior of the Institution CTEP ID and Registrar Fields.....	16
6.5 Logic for Editable Fields	17
6.6 Validations and Business Rules.....	19
6.7 Roll-Back of a Patient Registry Record.....	20
6.8 Compatibility with the Populate Demography Feature.....	21
6.9 Patient Registry and OPEN Checklist Form Validations	21
6.10 Posting Message of the Day on Patient Registry Home Screen.....	22

List of Figures

FIGURE 1: ACCESSING THE PATIENT REGISTRY MODULE.....	4
FIGURE 2: PATIENT REGISTRY BROWSER SCREEN	5
FIGURE 3: BLANK DEMOGRAPHY FORM FOR A NEW RECORD.....	6
FIGURE 4: DIAGNOSIS FORM FOR A NEW RECORD	7
FIGURE 5: PATIENT REGISTRY CONFIRMATION SCREEN	7
FIGURE 6: POSSIBLE DUPLICATE SCREEN	8
FIGURE 7: DUPLICATE PATIENT REGISTRY RECORDS ARE CHANGED TO A VOID STATUS.....	8
FIGURE 8: THE EDIT BUTTON ALLOWS USERS TO MODIFY PATIENT REGISTRY RECORDS.....	9
FIGURE 9: THE VIEW BUTTON ALLOWS USERS TO SEE DETAILS FOR PATIENT REGISTRY RECORDS	10
FIGURE 10: DETAILS POP-UP FOR A PATIENT REGISTRY RECORD.....	11
FIGURE 11: STATUS WORKFLOW FOR PATIENT REGISTRY RECORDS	12
FIGURE 12: PROCESS FOR CREATING A PATIENT REGISTRY RECORD IN OPEN	14
FIGURE 13: PROCESS FOR EDITING A PATIENT REGISTRY RECORD IN OPEN.....	15
FIGURE 14: ORIGINAL INSTITUTION CTEP ID VALUE.....	16
FIGURE 15: UPDATED INSTITUTION CTEP ID VALUE.....	16
FIGURE 16: CONFIRMATION POP-UP WINDOW THAT INDICATES THE TERMS OF THE ROLLBACK PROCESS	21
FIGURE 17: DISPLAYING MOTD ON PATIENT REGISTRY HOME SCREEN	22

List of Tables

TABLE 1: ORGANIZATION OF THIS DOCUMENT	1
TABLE 2: WEB ADDRESSES FOR CTSU APPLICATIONS.....	2
TABLE 3: ROLES REQUIRED FOR SITE STAFF TO PERFORM ACTIONS IN THE PATIENT REGISTRY MODULE	3
TABLE 4: ROLES REQUIRED FOR COG AND COGC STAFF TO PERFORM ACTIONS IN THE PATIENT REGISTRY MODULE	3
TABLE 5: PATIENT REGISTRY RECORD STATUSES.....	13
TABLE 6: EDITABLE FIELDS FOR RECORDS THAT NEVER ACHIEVED A REGISTERED STATUS.....	17
TABLE 7: EDITABLE FIELDS FOR RECORDS THAT PREVIOUSLY ACHIEVED A REGISTERED STATUS.....	19
TABLE 8: VALIDATIONS FOR THE PATIENT REGISTRY MODULE IN OPEN.....	19
TABLE 9: BUSINESS RULES FOR THE PATIENT REGISTRY MODULE IN OPEN	20

1. Introduction

This document provides instructions for creating, editing, and viewing COG patient registry records in the Patient Registry module of OPEN. This document includes additional information that may be useful for administrative staff.

1.1 Background Information

As part of the Children’s Oncology Group (COG) patient registration process, the COG Patient Registry allows clinical site staff to obtain COG Patient IDs. All patients must obtain a COG Patient ID prior to enrolling on 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 member 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 this Document

Section	Topic
1	Introduction to the Patient Registry module.
2	How to access the Patient Registry module.
3	How to create patient registry records.
4	How to edit patient registry records.
5	How to view patient registry records.
6	Additional information for administrative users.

1.4 Web Addresses for CTSU Applications

Table 2: Web Addresses for CTSU Applications

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

2. Accessing the Patient Registry Module

2.1 Requirements for Accessing the Patient Registry Module

OPEN users must fulfill all of these requirements to utilize the Patient Registry module in OPEN:

- Have an active CTEP-IAM account status.
- Site staff must have an active Lead Protocol Organization (LPO) roster affiliation with their site(s). COG and COGC users (persons who work at COG or COGC) must have an active COG or COGC roster affiliation.
- Site users must have a particular role (see Table 3) at their site to perform actions in the Patient Registry module. For COG and COGC users, see the roles listed in Table 4.

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

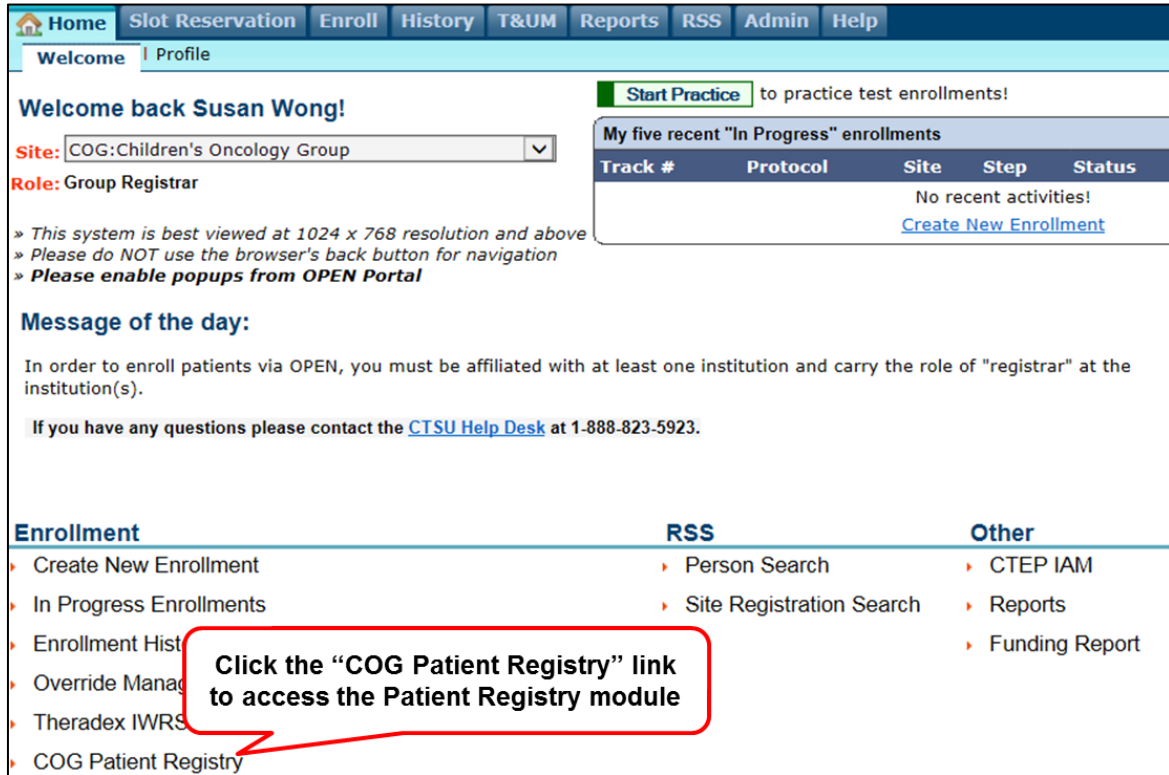
Action	Required Role (CTSUSU or LPO-equivalent roles)
Create records	Site Registrar, Site Admin
Edit records	Site Registrar, Site Admin
View records	Site Registrar, Site Admin, Site Staff, Site Investigator

Table 4: Roles Required for COG and COGC Staff to Perform Actions in the Patient Registry Module

Action	Required Role (CTSUSU or LPO-equivalent roles)
Create records	GROUP_REG, GROUP_REG_ADMIN
Edit records	GROUP_REG, GROUP_REG_ADMIN
View records	GROUP_REG, GROUP_REG_ADMIN, GROUP_DM, GROUP_STAFF

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 in OPEN’s “Practice Mode”.



[Home](#) | [Slot Reservation](#) | [Enroll](#) | [History](#) | [T&UM](#) | [Reports](#) | [RSS](#) | [Admin](#) | [Help](#)

Welcome | Profile

Welcome back Susan Wong!

Site:

Role: Group Registrar

» This system is best viewed at 1024 x 768 resolution and above
 » Please do NOT use the browser's back button for navigation
 » Please enable popups from OPEN Portal

Message of the day:

In order to enroll patients via OPEN, you must be affiliated with at least one institution and carry the role of "registrar" at the institution(s).

If you have any questions please contact the [CTSUSU Help Desk](#) at 1-888-823-5923.

[Start Practice](#) to practice test enrollments!

My five recent "In Progress" enrollments

Track #	Protocol	Site	Step	Status
No recent activities!				
Create New Enrollment				

Enrollment	RSS	Other
▶ Create New Enrollment	▶ Person Search	▶ CTEP IAM
▶ In Progress Enrollments	▶ Site Registration Search	▶ Reports
▶ Enrollment Hist		▶ Funding Report
▶ Override Manag		
▶ Theradex IWRS		
▶ COG Patient Registry		

Click the "COG Patient Registry" link to access the Patient Registry module

Figure 1: Accessing the Patient Registry Module

- 2) The screen refreshes 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 refreshes to the Patient Registry Browser screen (see Figure 2).


Edit	View	Track #	Group PID	Site	Status	Registry Date	Registrar	Modified Date	Modified By
		PT-0000400225	730789	MN008	REGISTERED	01/27/2016 01:46 PM	CHRISTENSONJ	01/27/2016 01:46 PM	LUM
		PT-0000400215	730788	COG	REGISTERED	01/21/2016 03:10 PM	CFWANG	01/21/2016 03:10 PM	CFWANG
		PT-0000400212	730787	IL045	REGISTERED	01/19/2016 04:57 PM	BABYA	01/19/2016 04:57 PM	ARMSTRONGS
		PT-0000400208	730786	IL045	REGISTERED	01/19/2016 03:36 PM	BABYA	01/19/2016 03:36 PM	ARMSTRONGS
		PT-0000400207	730785	MN022	REGISTERED	01/19/2016 03:32 PM	AANDER45	01/19/2016 03:32 PM	ARMSTRONGS
		PT-0000400206	730784	MN022	REGISTERED	01/19/2016 03:29 PM	AANDER45	01/19/2016 03:30 PM	ARMSTRONGS
		PT-0000400205	730783	PA076	REGISTERED	01/19/2016 01:19 PM	FOX E	01/19/2016 01:19 PM	CHAUDHARYH
		PT-0000400204	730782	COG	REGISTERED	01/15/2016 10:10 AM	CWOOD70	01/15/2016 10:10 AM	CWOOD70
		PT-0000400198	730781	COG	REGISTERED	01/11/2016 12:36 PM	DAVISJAM3	01/11/2016 12:36 PM	DAVISJAM3
		PT-0000400197	730780	VA009	REGISTERED	01/07/2016 01:20 PM	HUDSPETHC	01/07/2016 01:20 PM	HAMMA
		PT-0000400190	730779	COG	REGISTERED	01/06/2016 08:19 AM	CWOOD70	01/06/2016 08:24 AM	CWOOD70
		PT-0000400186	730778	COG	REGISTERED	01/04/2016 07:09 PM	HAMMA	01/04/2016 07:09 PM	HAMMA
		PT-0000400181	730777	MI087	REGISTERED	12/28/2015 06:00 PM	CINDYBLACK	12/28/2015 06:00 PM	CARLTONC
		PT-0000400180	730776	PA010	REGISTERED	12/28/2015 05:47 PM	DIBRIDGES	12/28/2015 05:47 PM	CARLTONC
		PT-0000400176	730775	MN022	REGISTERED	12/28/2015 11:54 AM	JDAHL	12/28/2015 12:05 PM	CARLTONC
		PT-0000400175	730774	PA076	REGISTERED	12/28/2015 11:45 AM	CARLSONCL	12/28/2015 11:44 AM	CARLTONC
		PT-0000400171	730773	PA076	REGISTERED	12/24/2015 04:14 PM	ADAMSONP	12/24/2015 05:24 PM	SARMIENTOL
		PT-0000400170	730772	COG	REGISTERED	12/23/2015 04:13 PM	SCONWAYS2	12/23/2015 04:13 PM	SCONWAYS2
		PT-0000400168	730771	PA076	REGISTERED	12/23/2015 02:50 PM	CARLSONCL	12/23/2015 02:50 PM	CARLTONC
		PT-0000400159	730770	COG	REGISTERED	12/21/2015 06:34 PM	CFWANG	12/23/2015 02:00 PM	ADASS
		PT-0000400158	730769	COG	REGISTERED	12/21/2015 06:33 PM	CFWANG	12/23/2015 12:35 PM	CFWANG
		PT-0000400156	730768	COG	REGISTERED	12/21/2015 05:37 PM	CFWANG	12/21/2015 05:37 PM	CFWANG
		PT-0000400154	730767	COG	REGISTERED	12/21/2015 04:48 PM	CFWANG	12/21/2015 04:48 PM	CFWANG
		PT-0000400144	730766	MN022	REGISTERED	12/17/2015 10:41 PM	JDAHL	12/17/2015 11:19 PM	CARLTONC
		PT-0000400141	730765	PA076	REGISTERED	12/17/2015 10:00 PM	ARMSTRONGC	12/17/2015 11:02 PM	ARMSTRONGS


Figure 2: Patient Registry Browser Screen

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

[Back to OPEN home page](#)

New Patient Registry Record - Demography Form

* Institution CTEP ID: 


* Registrar: -- select registrar -- 

Expand/Collapse all Modules

Standard_Patient_Identifier

* Last * First Middle

Standard_Demographics

* Date of Birth / / 

* Ethnicity

Hispanic or Latino
 Not Hispanic or Latino
 Not Reported
 Unknown

* Sex

Female
 Male

* Country

Zip Code (USA Only)


Standard_Race

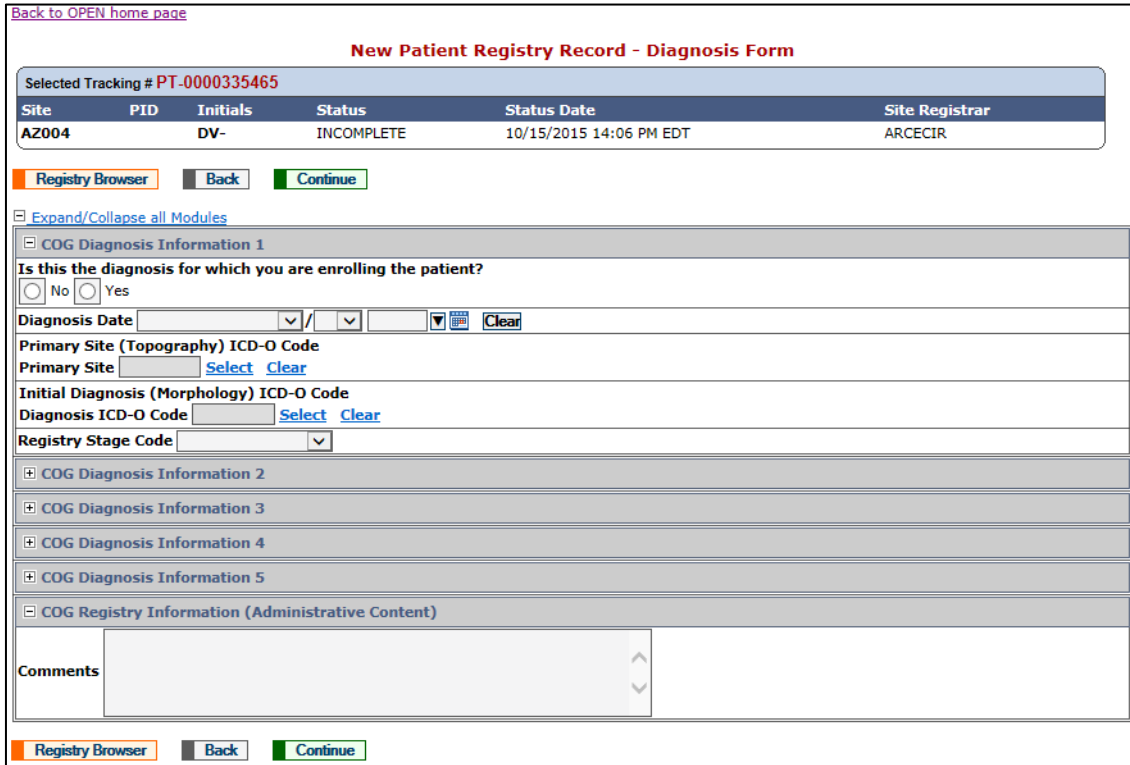
* Race

American Indian or Alaska Native
 Asian
 Black or African American
 Native Hawaiian or Other Pacific Islander
 Not Reported
 Unknown
 White

(Select all that apply)

Figure 3: Blank Demography Form for a New Record

- 4) Answer the required fields on the Demography Form.
 - a) For COG and COGC staff, the Institution CTEP ID field is an editable text-entry box. You can directly enter the NCI Site Code and press the tab key to lock the value (or click the List of Institutions button  to use a group lookup interface to select the site). For site staff, the Institution CTEP ID field prefills based on their preselected site.
 - b) For COG and COGC staff, the Registrar drop-down menu field becomes selectable after a value is provided for the Institution CTEP ID field. For site staff, the Registrar field automatically prefills based on the logged in user's CTEP-IAM account username.
 - c) Answer the remaining necessary fields on the Demography Form.
- 5) Click the Continue button. The screen refreshes to the Diagnosis Form (see Figure 4), which includes the tracking # for the record. The "Tracking #" is different from the COG Patient ID generated for a successfully created patient registry record.



New Patient Registry Record - Diagnosis Form

Selected Tracking # **PT-0000335465**

Site	PID	Initials	Status	Status Date	Site Registrar
AZ004		DV-	INCOMPLETE	10/15/2015 14:06 PM EDT	ARCECIR

Expand/Collapse all Modules

COG Diagnosis Information 1

Is this the diagnosis for which you are enrolling the patient?
 No Yes

Diagnosis Date: [dropdown] / [dropdown] [dropdown] [dropdown] [dropdown]

Primary Site (Topography) ICD-O Code
 Primary Site: [dropdown]

Initial Diagnosis (Morphology) ICD-O Code
 Diagnosis ICD-O Code: [dropdown]

Registry Stage Code: [dropdown]

COG Diagnosis Information 2

COG Diagnosis Information 3

COG Diagnosis Information 4

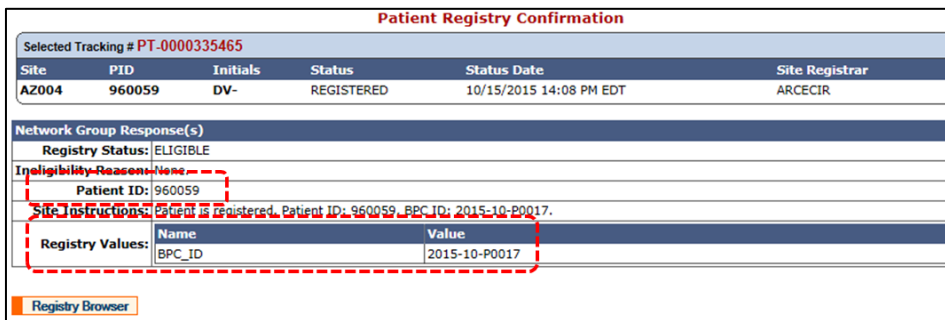
COG Diagnosis Information 5

COG Registry Information (Administrative Content)

Comments: [text area]

Figure 4: Diagnosis Form for a New Record

- 6) Answer the required fields on the Diagnosis Form. An edit check forces COG, COGC, and CTSU staff to provide a value in the Comments field.
- 7) Click the Continue button. The screen refreshes to the Review and Submit screen. If the Possible Duplicate screen appears, refer to section 3.2 for further instructions.
- 8) 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.
- 9) If successful, the screen refreshes to the Patient Registry Confirmation screen (see Figure 5). The screen displays the COG Patient ID, and the BPC ID assigned by the COG Registry node.



Patient Registry Confirmation

Selected Tracking # **PT-0000335465**

Site	PID	Initials	Status	Status Date	Site Registrar
AZ004	960059	DV-	REGISTERED	10/15/2015 14:08 PM EDT	ARCECIR

Network Group Response(s)

Registry Status: ELIGIBLE

Ineligibility Reason: **None**

Patient ID: 960059

Site Instructions: Patient is registered. Patient ID: 960059, BPC ID: 2015-10-P0017.

Name	Value
BPC_ID	2015-10-P0017

Figure 5: Patient Registry Confirmation Screen

- 10) This concludes the process for creating patient registry records within OPEN.

3.2 Instructions for Using the Possible Duplicate Screen

Site staff 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 LPO or site 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

- 2) Review the possible duplicate patient information 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 you 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 refreshes (see Figure 7) and the record being created (or modified) is set to a VOID status. This concludes the process for creating or modifying the patient registry record in OPEN.

Figure 7: Duplicate Patient Registry Records are 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 refreshes 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

- 4) The screen refreshes to the Demography Form. If the record is in a REGISTERED status in the past, the screen title states “Edit Patient Registry Record - Demography Form”. If the record has not been in a REGISTERED status before, the screen title states “New Patient Registry Record - Demography Form”.
- 5) If you need to modify data, make the appropriate updates. Some fields are disabled for COG and COGC staff if the record was previously in a REGISTERED status, including Ethnicity, Country of Residence, ZIP Code, and Race. For information on performing a site transfer, see section 6.3.
- 6) Click the Continue button. A pop-up message appears to inform the user about the rollback process. If a modified record remains in an INCOMPLETE, READY, or SUBMITTED status for 24 hours (and it was previously in a REGISTERED status at some point), the record reverts to a REGISTERED status, and any pending changes will be discarded. See section 6.7 for more information on the rollback process.
- 7) Click the OK button. The pop-up window disappears and the Patient Registry screen refreshes 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 refreshes 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 refreshes 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 refreshes to the Patient Registry Browser screen.
- 3) Locate the desired record, and click the View button  for a record.



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

A complete summary of the record displays in a pop-up window (see

4) Figure 10).

Details for Patient Registry Record PT-0000335737

Selected Tracking # PT-0000335737					
Site	PID	Initials	Status	Status Date	Site Registrar
CA009	951018	AAA	REGISTERED	06/11/2021 10:17 AM EDT	AAMERS

Network Group Response(s)	
Registry Status:	ELIGIBLE
Ineligibility Reason:	
Patient ID:	951018
Site Instructions:	
Registry Values:	
Name	Value
BPC_ID	2019-08-P0008

Standard_Patient_Identifier		
* Last <input type="text" value="A"/>	* First <input type="text" value="A"/>	Middle <input type="text" value="A"/>

Standard_Demographics	
* Date of Birth <input type="text" value="January (01)"/> / <input type="text" value="01"/> / <input type="text" value="2015"/>	* Sex <input type="radio"/> Female <input type="radio"/> Male
* Ethnicity <input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown	* Country <input type="text" value="USA (United States of America)"/> Zip Code (USA Only) <input type="text" value="91016"/>

Standard_Race
* Race <input checked="" type="checkbox"/> American Indian or Alaska Native <input checked="" type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/> White (Select all that apply)

Figure 10: Details Pop-up for a Patient Registry Record

6. Additional Information

6.1 Patient Registry Record Statuses

Patient registry records go through a series of different statuses during the creation or editing process. All patient registry records start in a NEW status, and then changes to an intermediary status, and then the process completes in a terminal status.

Figure 11 depicts the different statuses patient registry records can attain during their lifecycle.

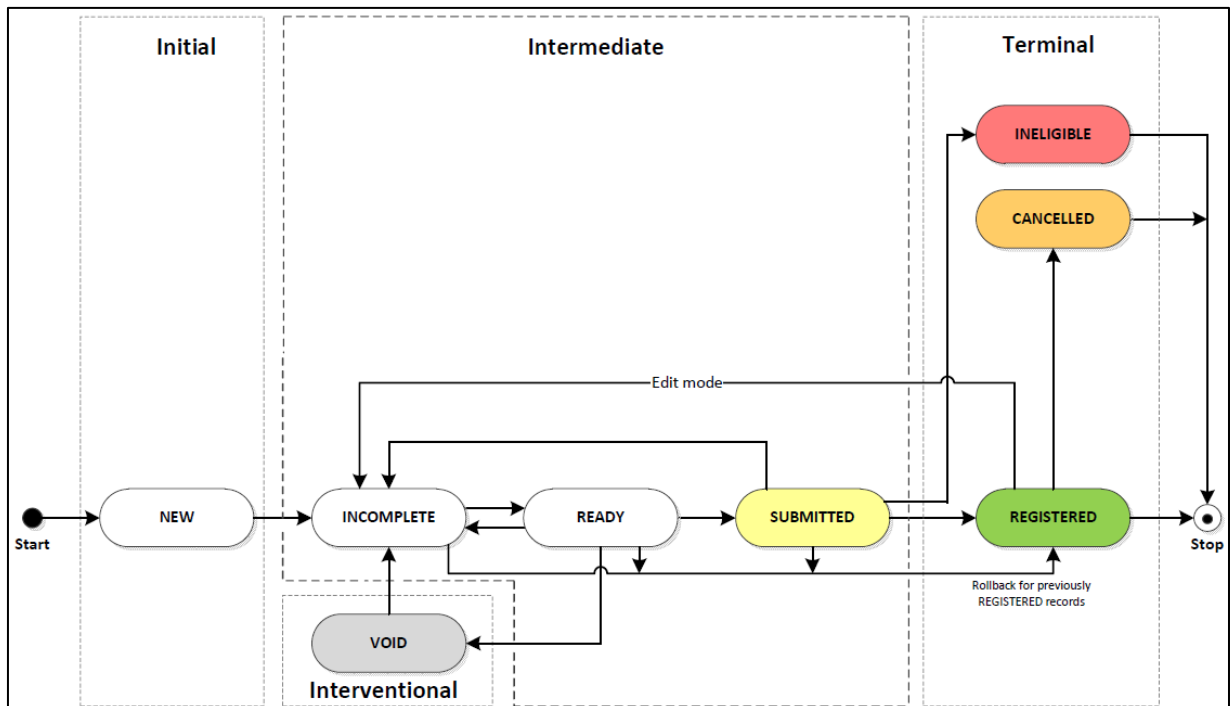


Figure 11: Status Workflow for Patient Registry Records

Table 5 describes each of the statuses that patient registry records can attain.

Table 5: Patient Registry Record Statuses

#	Status Name	Description
1	NEW	When a new patient registry record is initiated, the record momentarily attains this status before entering an INCOMPLETE status. A tracking # is assigned when a record enters a NEW status.
2	INCOMPLETE	A record in an INCOMPLETE status can be: <ul style="list-style-type: none"> • A newly created record (coming from a NEW status). • A record that encounters a RandoNode validation error during the creation of a record. • A record changed out of a VOID status. • A record previously in a REGISTERED state that entered Edit mode.
3	VOID	A record will enter a VOID status if: <ul style="list-style-type: none"> • A LPO or site user identifies the patient registry record as a duplicate. • A record (that had not previously achieved a REGISTERED status) has been in-progress for seven calendar days without user activity.
4	READY	A record that passed all OPEN validations, that is being viewed in the Review and Submit screen.
5	SUBMITTED	A record in a SUBMITTED status can be: <ul style="list-style-type: none"> • A record submitted to the RandoNode, and is awaiting a response. • A record submitted to the RandoNode, but the RandoNode was down.
6	INELIGIBLE	A record that was submitted to the RandoNode and the RandoNode deemed the record ineligible.
7	REGISTERED	A record in a REGISTERED status can be: <ul style="list-style-type: none"> • A record deemed eligible by the RandoNode. • A record rolled back to the last saved “snapshot” after being in an INCOMPLETE, READY, or SUBMITTED status, 24 hours after a user initiated Edit mode (for a record that had previously entered a REGISTERED status). See section 6.7 for more information regarding the record rollback process.
8	CANCELLED	A record manually set to a CANCELLED status by CTSU IT.

6.2 Process for Creating or Editing Patient Registry Records in OPEN

This section contains diagrams that show the process for creating (see Figure 12) and for editing (see Figure 13) patient registry records.

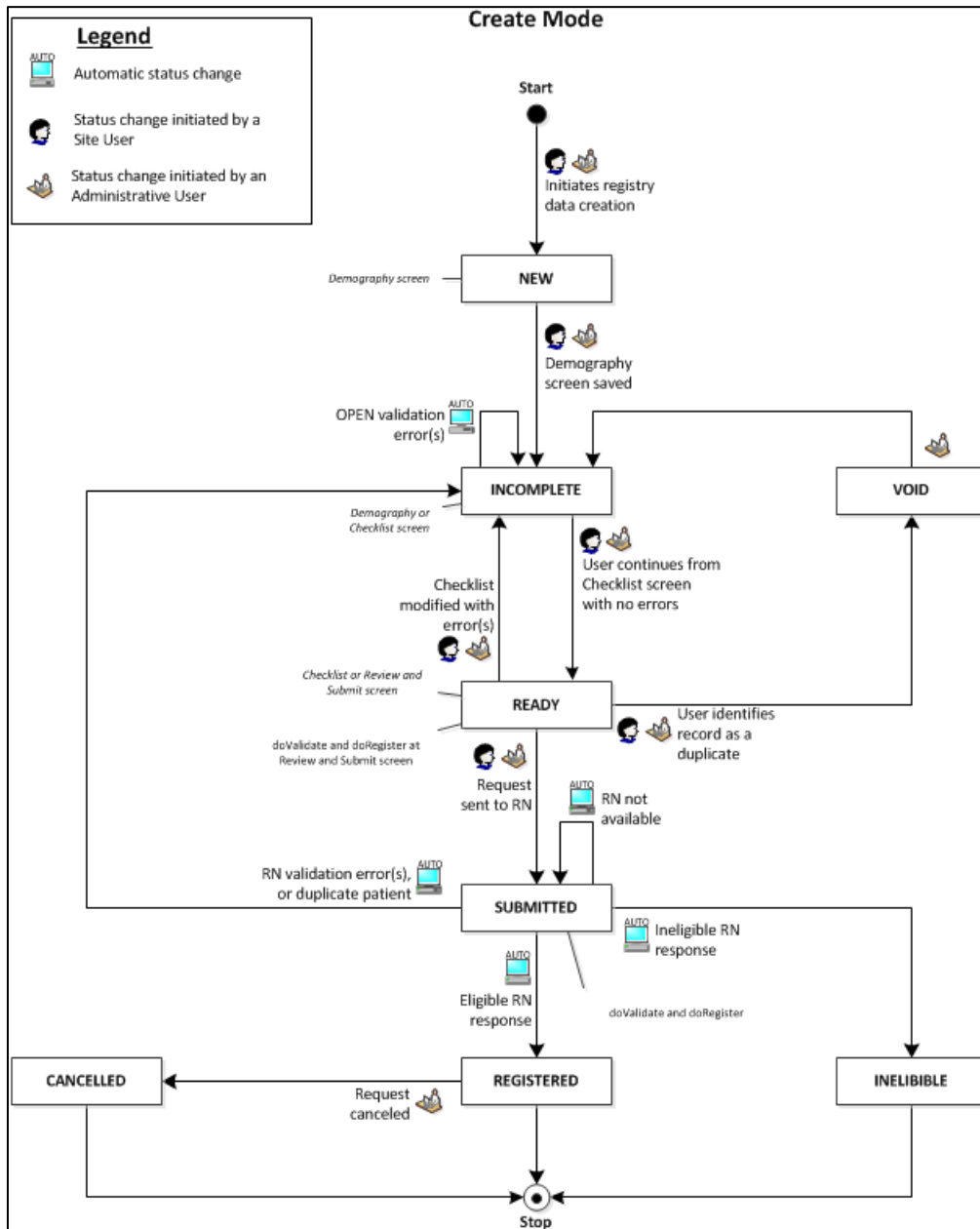


Figure 12: Process for Creating a Patient Registry Record in OPEN

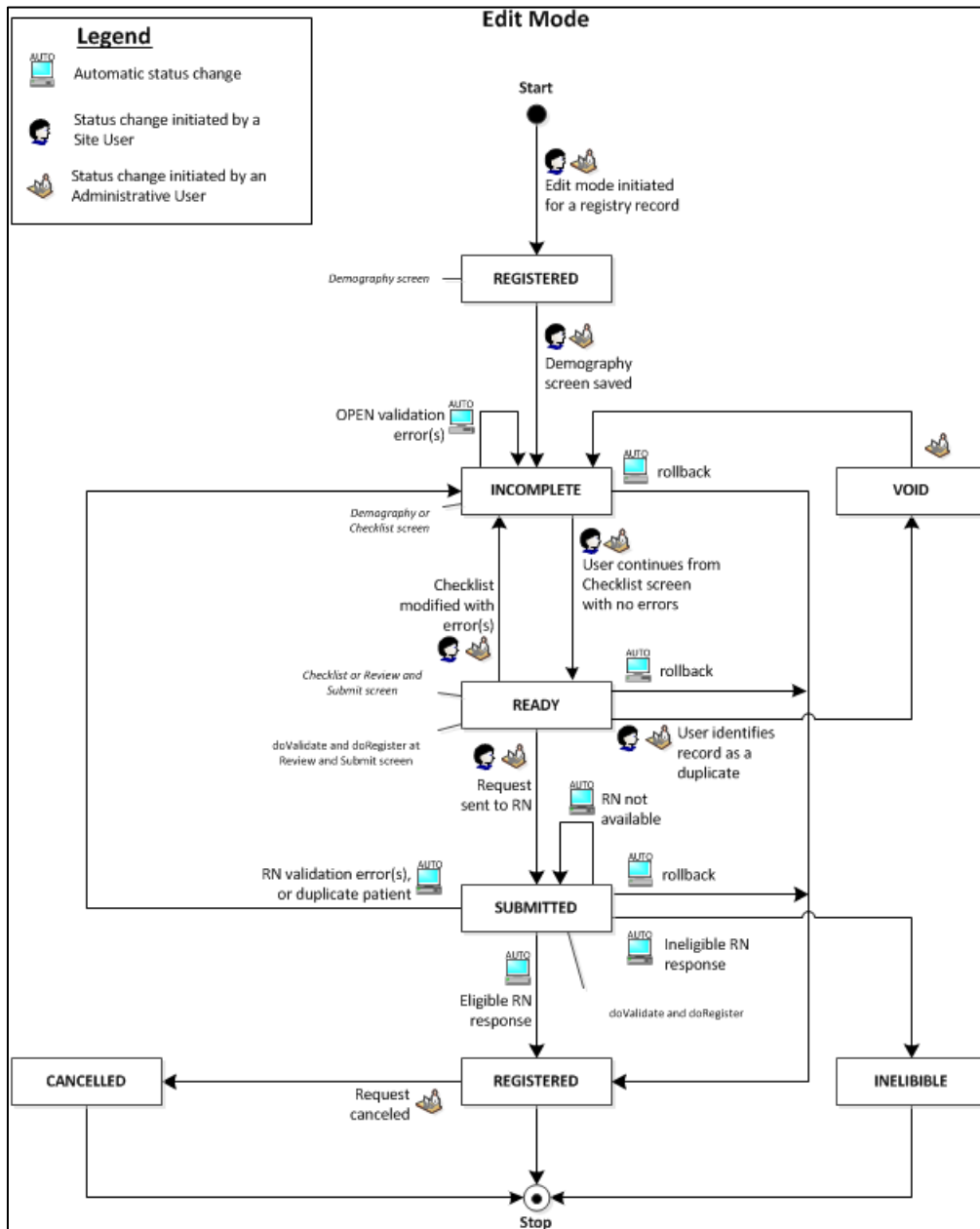




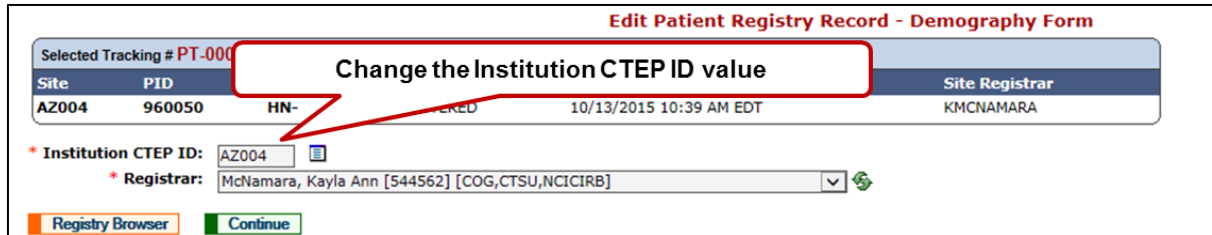
Figure 13: Process for Editing a Patient Registry Record in OPEN

6.3 How to Transfer a Patient Registry Records to a New Site

When a patient registry record needs to be associated with a different site, COG and COGC staff (persons that work at COG and COGC) should follow the steps outlined below:

- 1) Login to OPEN.
- 2) Click the COG Patient Registry hyperlink on the Welcome screen of OPEN.
- 3) Locate the patient in the Patient Registry Browser screen, and click the Edit button .


- 4) Enter the NCI-Site Code value for the patient’s new site in the Institution CTEP ID field, and press the Tab keyboard key to lock the value. Alternatively, click the List of Institutions button  to locate the site, and click the appropriate choice to lock the value. The Registrar drop-down menu refreshes.



Edit Patient Registry Record - Demography Form

Selected Tracking # **PT-000**

Site	PID	Initials	Status	Status Date	Site Registrar
AZ004	960050	HN-	REGISTERED	10/13/2015 10:39 AM EDT	KMCNAMARA

* Institution CTEP ID: 


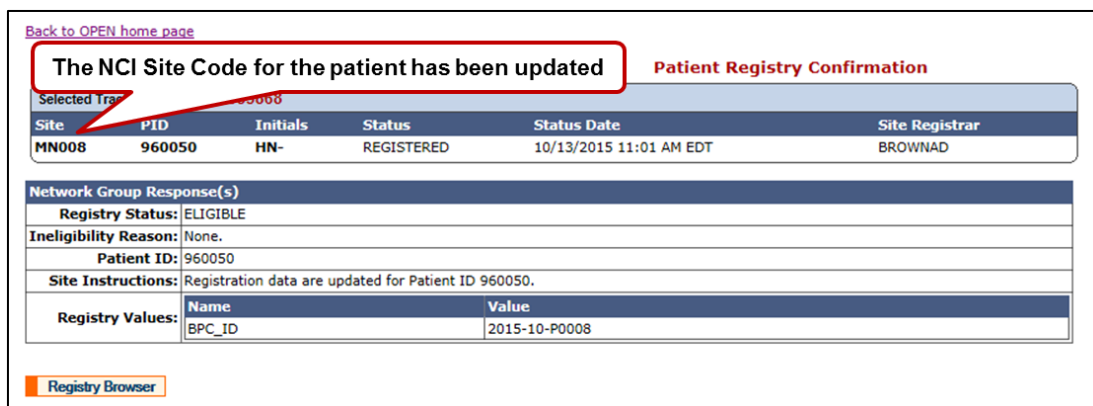
* Registrar: 

Figure 14: Original Institution CTEP ID Value

- 5) Choose a value for the Registrar drop-down menu.
- 6) Click the Continue button to proceed to the Diagnosis Form.
- 7) Click OK for the pop-up window that asks if you want to continue, and the Diagnosis Form loads.
- 8) Provide a value in the Comments field, and click the Continue button. The Review and Submit screen loads.
- 9) Click the Submit button, and the confirmation screen refreshes.



[Back to OPEN home page](#)

The NCI Site Code for the patient has been updated **Patient Registry Confirmation**

Selected Tracking # **PT-000**

Site	PID	Initials	Status	Status Date	Site Registrar
MN008	960050	HN-	REGISTERED	10/13/2015 11:01 AM EDT	BROWNSAD

Network Group Response(s)

Registry Status: ELIGIBLE

Ineligibility Reason: None.

Patient ID: 960050

Site Instructions: Registration data are updated for Patient ID 960050.

Registry Values:	Name	Value
	BPC_ID	2015-10-P0008

Figure 15: Updated Institution CTEP ID Value

- 10) This completes the process for updating the site code for a patient registry record.

6.4 Behavior of the Institution CTEP ID and Registrar Fields

This section describes the behavior of the Institution CTEP ID and Registrar fields, which are located in the Demography Form for a patient registry record. The fields behave differently depending on whether the user is a clinical site staff member, or non-site clinical staff (COG, COGC, or CTSU staff).

Site Users:

- The Institution CTEP ID field is a selectable drop-down menu until a Patient Registry tracking number is associated with the record (then the field becomes read-only).

- The Registrar fields are always not editable for site users.
- When a record is initiated for the first time (no tracking # assigned yet), the Institution CTEP ID prefills with the Site the user selected on the Welcome screen of OPEN.
- When a record has a tracking #, site staff are unable to change the Institution CTEP ID. Non-site staff can transfer a record (see section 6.3).
- The Registrar field prefills to the logged-in site user (whether in create or edit mode).

COG/COGC/CTSUSU Users:

- The Institution CTEP ID and Registrar fields will always be editable for COG, COGC, and CTSUSU users. The Institution CTEP ID will be a text-entry box with a group-lookup list feature. The Registrar field will be a drop-down list that will change depending on the site entered in the Institution CTEP ID field.
- When you initiate a record for the first time (no tracking # assigned yet), the Registrar field has no value selected by default.
- When a record has a tracking #, the Registrar field loads the most recently saved Registrar value (and the field will be editable).
- When a record has a tracking #, and a new value is selected for the Institution CTEP ID, the previous Registrar field value clears, and the list of choices refreshes based on the newly selected Institution CTEP ID.

6.5 Logic for Editable Fields

The fields within the patient registry forms are editable depending on the type of user (site or non-site) and whether the record was previously in a REGISTERED status. Non-site staff are individuals at COG, COGC, or CTSUSU.

Table 6 shows which patient registry fields are editable, for records that never achieved a REGISTERED status.

Table 6: Editable Fields for Records that Never Achieved a REGISTERED Status

Field Name	Site Staff	Non-Site Staff
Institution CTEP ID		Editable
Registrar		Editable
Last	Editable	Editable
First	Editable	Editable
Middle	Editable	Editable
Patient's Date of Birth	Editable	Editable
Ethnicity	Editable	Editable
Sex of a Person	Editable	Editable
Country of Residence	Editable	Editable

Field Name	Site Staff	Non-Site Staff
ZIP Code	Editable	Editable
Race	Editable	Editable
Is this the diagnosis for which you are enrolling the patient?	Editable	Editable
Diagnosis Date	Editable	Editable
Primary Site (Topography) ICD-O Code	Editable	Editable
Initial Diagnosis (Morphology) ICD-O Code	Editable	Editable
Registry Stage Code	Editable	Editable
Comments		Editable

Table 7 shows which fields are editable, for records that have previously achieved a REGISTERED status.

Table 7: Editable Fields for Records that Previously Achieved a REGISTERED Status

Field Name	Site Users	Non-Site Users
Institution CTEP ID		Editable
Registrar		Editable
Last		Editable
First		Editable
Middle		Editable
Patient's Date of Birth		Editable
Ethnicity	Editable	
Sex of a Person		Editable
Country of Residence	Editable	
ZIP Code	Editable	
Race	Editable	
Is this the diagnosis for which you are enrolling the patient?	Editable	Editable
Diagnosis Date	Editable	Editable
Primary Site (Topography) ICD-O Code	Editable	Editable
Initial Diagnosis (Morphology) ICD-O Code	Editable	Editable
Registry Stage Code	Editable	Editable
Comments		Editable

6.6 Validations and Business Rules

Table 8 shows the different validations that OPEN performs on created or edited patient registry records.

Table 8: Validations for the Patient Registry Module in OPEN

#	Validation	Validation Type
1	The ZIP Code must be provided if the patient's Country of Residence is US.	Edit check
2	If any question is answered in a COG Diagnosis Information module, then all questions in the module must be answered (except the Registry Stage Code).	Edit check
3	Only one diagnosis can be marked as the primary diagnosis.	Edit check

#	Validation	Validation Type
4	One primary diagnosis must be indicated.	Edit check
5	If Zip code provided for a US resident, it must be a valid USPS Zip code.	Edit check
6	Any Diagnosis Date value cannot be more than 365 days before the Patient's Date of Birth.	Edit check
7	If Patient Registry records modified by a COG, COGC, or CTSU user, a comment must be added to the Comments field.	Edit check
8	Patient initials can only be letters.	Edit check
9	Future dates are not allowed for the Diagnosis Date fields.	Instant date validation
10	Future dates are not allowed for the Patient's Date of Birth.	Instant date validation

Table 9 shows the business rules for the OPEN Patient Registry module.

Table 9: Business Rules for the Patient Registry module in OPEN

#	Business Rules	Notes
1	The COG Patient Registry hyperlink displays in the OPEN Welcome screen if a site or non-site user passes the CTEP-IAM account validation. Once a user clicks the hyperlink, the roster validation determines which patient registry records to display for the user. Once inside the Patient Registry module, the user's OPEN role(s) will determine whether they can create, edit, and view records. If a site or non-site user attempts to directly access the Patient Registry module by typing in the URL, they will receive an "Unauthorized Access" error message.	
2	Certain fields within the Patient Registry are editable, depending on the type of user and whether the record has previously achieved a REGISTERED status.	See section 6.5 for details.
3	The Institution CTEP ID and Registrar fields display as drop-down menu fields for non-site users, and the values prefill for site users.	See section 6.2 for details.
4	During create or edit mode, any COG Diagnosis Information modules (2 through 5), loads in a minimized view if no saved information is contained within a particular module. In view mode, all of the COG Diagnosis Information modules display in an expanded view, to show all questions.	
5	Overrides cannot be configured for Patient Registry edit checks.	
6	Patient registry records that are in a VOID status are hidden by default in the Patient Registry Browser screen. View VOID records by changing the Status drop-down (in the Patient Registry Browser screen) to VOID.	
7	OPEN automatically changes in-progress OPEN Patient Registry records (that had not previously achieved a REGISTERED status) to a VOID status after 7 calendar days without user activity.	

6.7 Roll-Back of a Patient Registry Record

When you attempt to edit a patient registry record that previously attained a REGISTERED status, the record rolls back to its previous state, if certain conditions are met.

When you click on the Continue button on the Demography Form for the patient registry record that you are editing, a confirmation pop-up window (see Figure 16) displays. If you click the OK button, a “snapshot” of the patient registry record is taken (from the point when the record was last in a REGISTERED status), and the record enters an INCOMPLETE status.

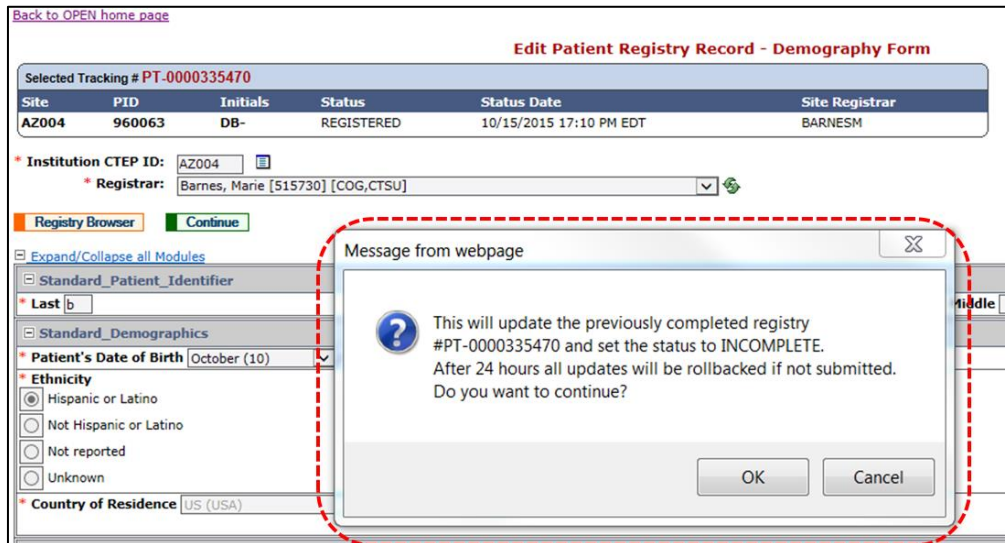


Figure 16: Confirmation Pop-up Window that Indicates the Terms of the Rollback Process

If you click the Cancel button on the confirmation pop-up, or you never click the Continue button on the Demography Form, no changes are saved and the record remains in its previously REGISTERED status.

If the record is in an INCOMPLETE, READY, or SUBMITTED status 24 hours after the user clicked OK on the confirmation pop-up, the record goes into a daily rollback queue to be restored to its last saved snapshot. If you do not successfully complete the edit process before the daily rollback queue runs, the changes to the patient registry record are replaced by the content from the saved snapshot, and the status of the record reverted to a REGISTERED status.

6.8 Compatibility with the Populate Demography Feature

CTSUS’s Westrax RandoNode can use the Populate Demography feature to obtain demographic data from OPEN Patient Registry records, and populate them into the Demography screen of corresponding OPEN enrollments (for COG and COGC studies). Contact the CTSU for assistance with configuring this feature.

6.9 Patient Registry and OPEN Checklist Form Validations

A GET_REGISTRY_RESPONSE expression is available to validate responses between the OPEN Patient Registry, and OPEN patient enrollment Checklist forms. For instructions on creating the edit check, refer to the [OPEN Group User Guide](#).

The edit check only fires on the Checklist of the patient enrollment.

6.10 Posting Message of the Day on Patient Registry Home Screen

OPEN is configured to support posting the Message of the Day (MOTD) specifically on the home page of the COG Patient Registry screen. To post the MOTD, contact CTSU OPEN Administrators at CTSUOPENFORMS@westat.com, and include the message to be posted along with the message expiration date. After the OPEN Administrator processes the request, the MOTD will appear on the home screen of the Patient Registry page, as shown in Figure 17.

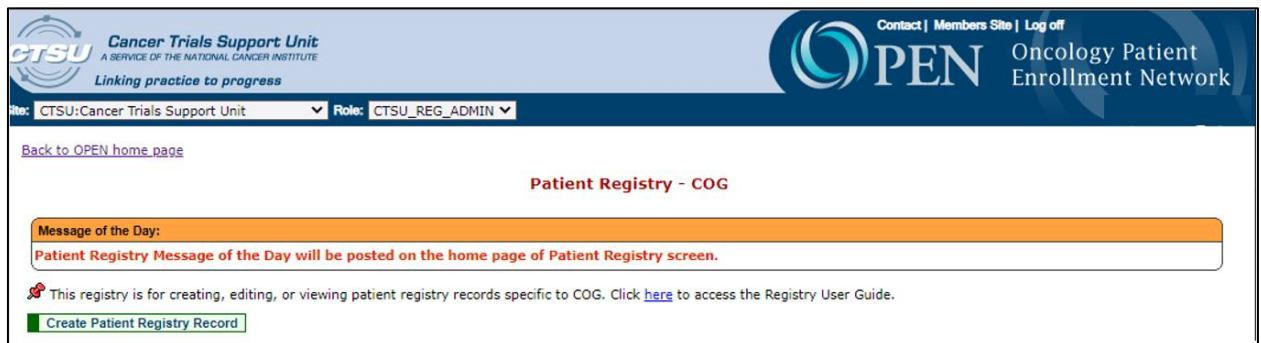


Figure 17: Displaying MOTD on Patient Registry Home Screen