CTSU

Cancer Trials Support Unit

OPEN T&UM Quick Reference Guide for Group Users

Revision 23

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Document Information

Revision Information for the OPEN T&UM Quick Reference Guide for Group Users

Revision History

#	Date	By	Description
1	2014/07/29	Mark Stauffer	Created initial version.
2	2014/09/11	Mark Stauffer	Updated Site Transfer terminology, and updated the email notification table.
3	2014/10/20	Mark Stauffer	Updated the Additional Information section content.
4	2014/10/24	Mark Stauffer	Added the T&UM validations.
5	2014/10/27	Mark Stauffer	Reviewed and made minor enhancements to the document.
6	2014/11/06	Mark Stauffer	Accepted reviewer updates.
7	2014/11/19	Mark Stauffer	Updated the list of T&UM validations.
8	2015/01/02	Mark Stauffer	Added a clarification regarding access to Site Transfer records.
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20	2022/01/21	Lela Makbul	Updated Section 2.2 (page 5); Section 4 (page 18); Section 6.9 (page 39).
21	2023/04/21	Lela Makbul	Updated screenshots on pages 6, 11, 17, 18, and 19.

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			Updated language on page 5, 8, 16, and 37.
22	2024/07/16	Lela Makbul	Updated Section 3.1 on page 8.
23	2025/01/31	Lela Makbul	Updated Section 5 and Section 6.6. Updated Figure 32.

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1. Introduction

This document is designed to provide Network Group staff with an overview of OPEN's Transfer and Update Module (T&UM). Also included are instructions for creating T&UM requests, reviewing T&UM requests, configuring T&UM settings, and additional background information regarding the T&UM.

1.1 Organization of this Document

Section two provides an overview of the T&UM.

Section three describes and provides instructions regarding Site Transfer requests.

Section four describes and provides instructions regarding Credentialing Data Update requests.

Section five describes and provides instructions regarding Demographic Data Update requests.

Section six contains additional information regarding the T&UM.

1.2 Web Addresses for CTSU Applications

Table 1: Web Addresses for CTSU Applications

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

2. Overview of the T&UM

2.1 Background

Subject enrollment information for NCI-sponsored cancer clinical trials may need to be updated or corrected. Previously, update requests were manually processed using the combined efforts of the CTSU, the Network Groups, and the Pharmaceutical Management Branch (PMB). After changes were validated and approved, updates were made in multiple electronic systems (OPEN, Regulatory Support System (RSS), NCI systems) and the Lead Protocol Organization's (LPOs) Clinical Data Management System (CDMS). This process took a significant amount of time and coordination.

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 will undergo automatic validations and, when configured, the system allows LPO staff to manually approve requests. The T&UM will automatically update (when possible) systems outside of OPEN that also contain the subject's data (e.g., Rave, LPO RandoNodes).

2.2 Accessing the T&UM

The T&UM is located within its own tab of OPEN and it is accessible to LPO users with OPEN roles of Group Registrar, Group Registrar Admin, or Group Staff.

Access to the T&UM tab is controlled by the OPEN role of the user, as well as their institution roster affiliation(s).

Users with the following OPEN roles will have the ability to create and review T&UM transactions (Group review is only permitted if the user is on the Group roster):

- CTSU_REG
- CTSU_REG_ADMIN
- GROUP_REG
- GROUP_REG_ADMIN
- SITE_REG
- SITE_ADMIN
- SYS_ADMIN

Users with the following OPEN roles will only have the ability to view T&UM transactions (read-only access):

- CTSU_STAFF
- HELP_DESK

The structure of the T&UM tab is similar to the Enroll tab (both have In Progress, Create New, and History subtabs); however they contain different types of data.

When a user clicks the T&UM tab they will be defaulted to the **In Progress** subtab (see Figure 1), which lists the In-Progress T&UM requests that the user may access based on their active roster affiliations and allows the review of existing requests.

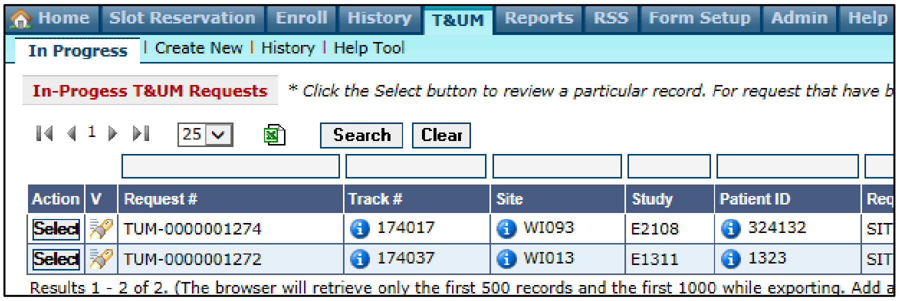


Figure 1: The T&UM Tab of OPEN

The T&UM **Create New** subtab (see Figure 2) enables OPEN users to initiate T&UM requests and to view the list of lead organizations that participate on the T&UM.

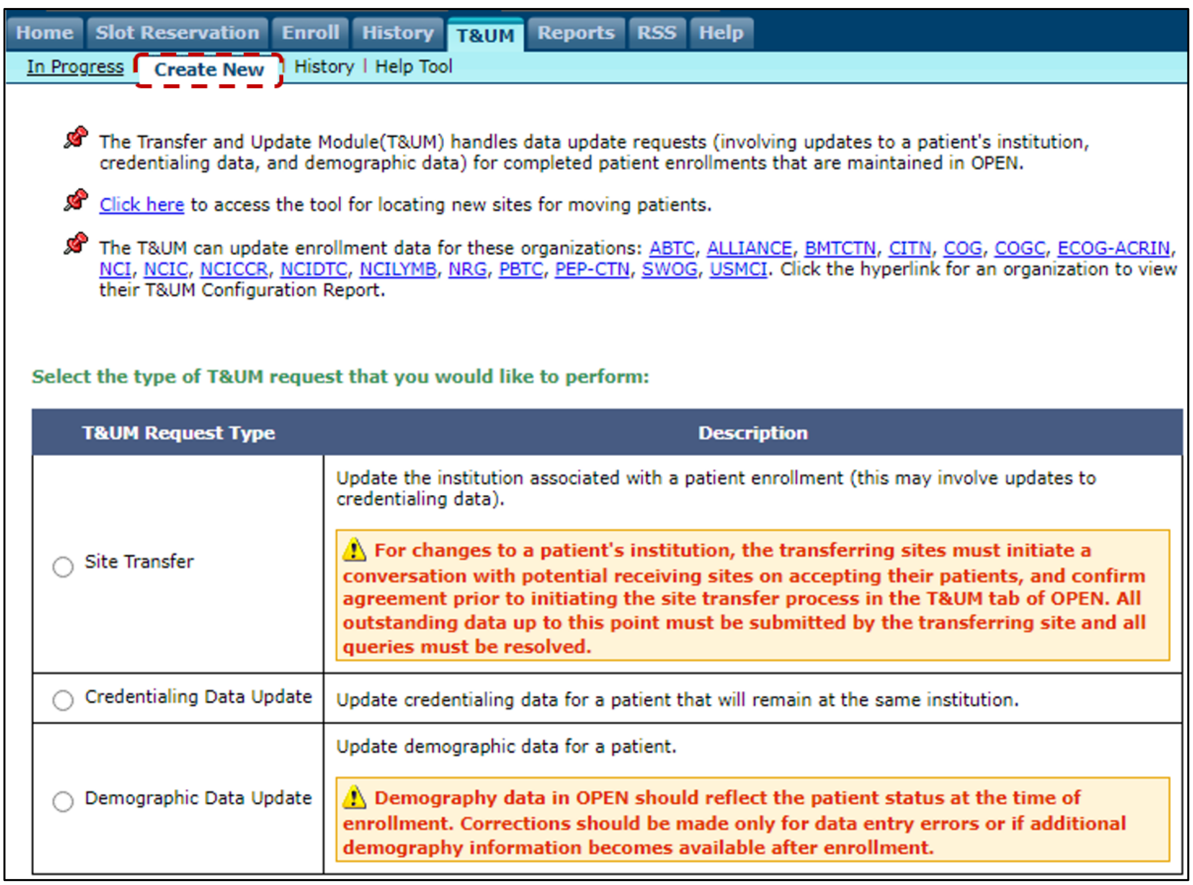


Figure 2: The T&UM Create New Subtab

The T&UM **History** subtab (see Figure 3) lists T&UM requests that have entered a terminal status (CANCELLED, REJECTED, APPROVED) for the institutions with which the user has active roster affiliations.

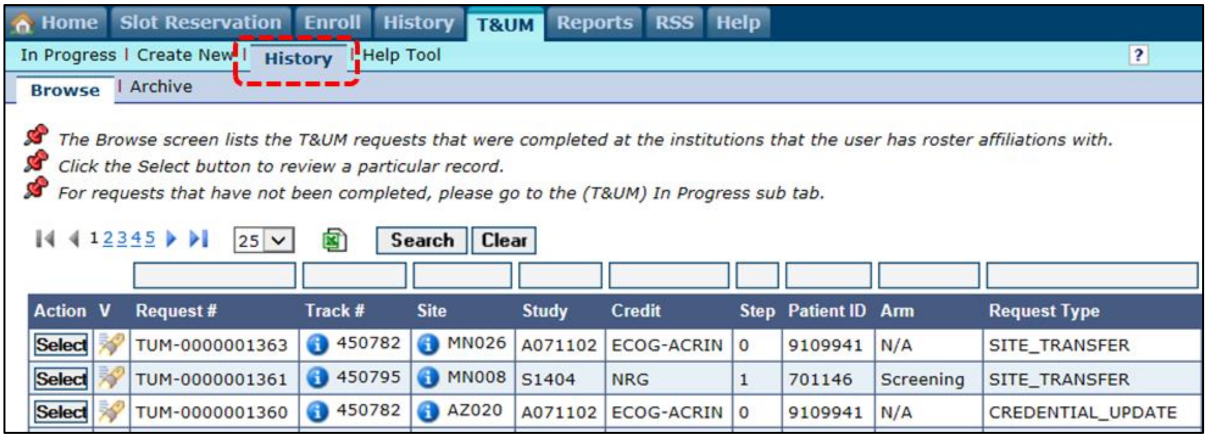


Figure 3: The T&UM History Subtab

The T&UM **Help Tool** subtab (see Figure 4) contains a tool to assist with locating receiving sites for subjects that will be moving and require a replacement site.

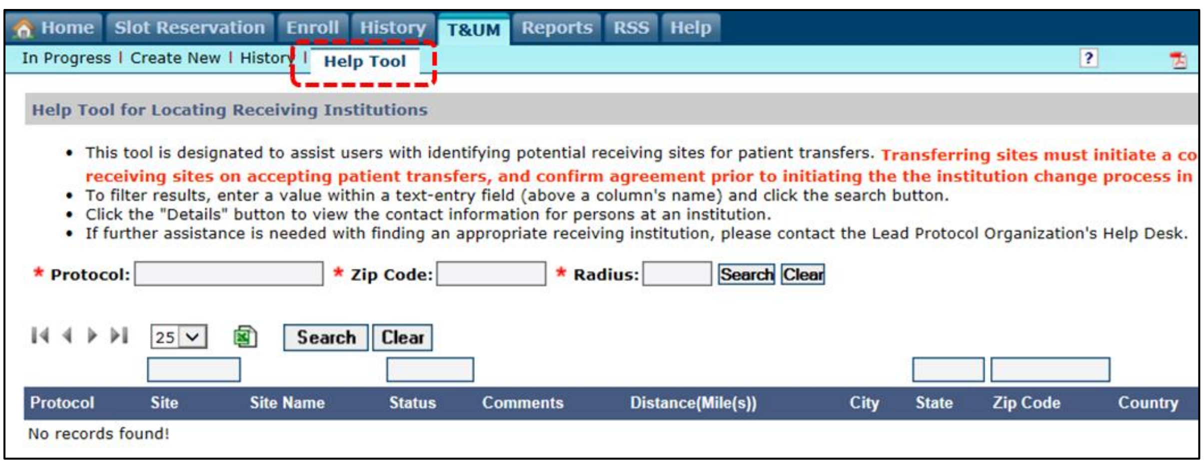


Figure 4: The T&UM Help Tool Subtab

3. Site Transfer Requests

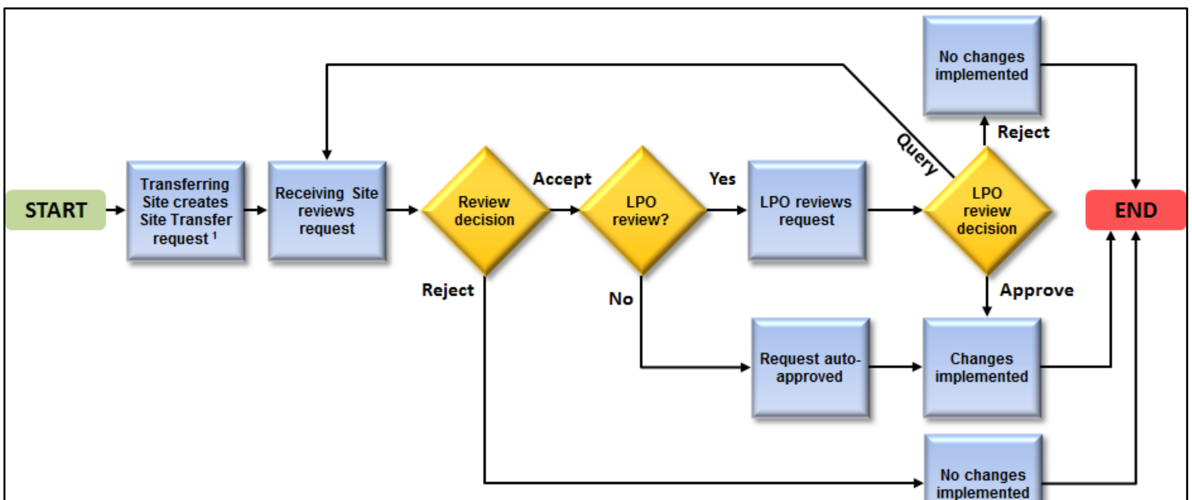
Site Transfer requests are for transferring a subject to a different site, which may also involve a change to credentialing information.

Data points that can be updated with a site transfer request include:

- Institution Code;
- Persons associated with the subject (treating investigator, site registrar, etc., per each study's setup);
- Network Group Credit (the credit must remain the same if the receiving site is a member of the Network Group that was credited for the enrollment, otherwise they may credit any other participating Network Group of which they are a member. See 4.1 regarding further requirements for updating the Network Credit Group);
- Credit Investigator;
- Courier Account Name (if the field is configured as available for the study);
- Courier Account Number (if the field is configured as available for the study).

Once a site transfer has been approved, the only OPEN users that will have access to the subject's information will be those that have a roster affiliation with the subject's new institution (or LPO and CTSU staff).

Figure 5 provides a high-level overview of a site transfer request's workflow.



[1] Transferring Site may cancel the request while it is in a REQUESTED status.

Figure 5: High-Level Workflow for a Site Transfer Request

The remainder of this section provides instructions for the three main processes that are involved with creating and completing a site transfer request:

1) Initiation of the site transfer request by the transferring site.

2) Review of the site transfer request by the receiving site.

3) Review of the site transfer request by the LPO (if required).

3.1 Initiating a Site Transfer Request

The first step in the process for a site transfer request is the initiation of the request by the transferring site (the site that the subject will move from) user. Site users with the OPEN Site Registrar or OPEN Site Admin role (at the transferring site) may create T&UM requests.

A user from the transferring site can use the Help Tool (which is located in the Help Tool subtab or within the Create New screen for a site transfer request) to locate potential receiving sites and the contact information for those institutions. After the transferring site user communicates with the receiving site and comes to an unofficial agreement regarding the transfer of the subject, the transferring site user will initiate the site transfer request in OPEN.

Steps that transferring site will follow to initiate site transfer requests:

1) Log in to OPEN.

2) Click the T&UM tab and arrive at the In Progress subtab by default.

3) Click the Create New subtab.

4) Click the Site Transfer option.

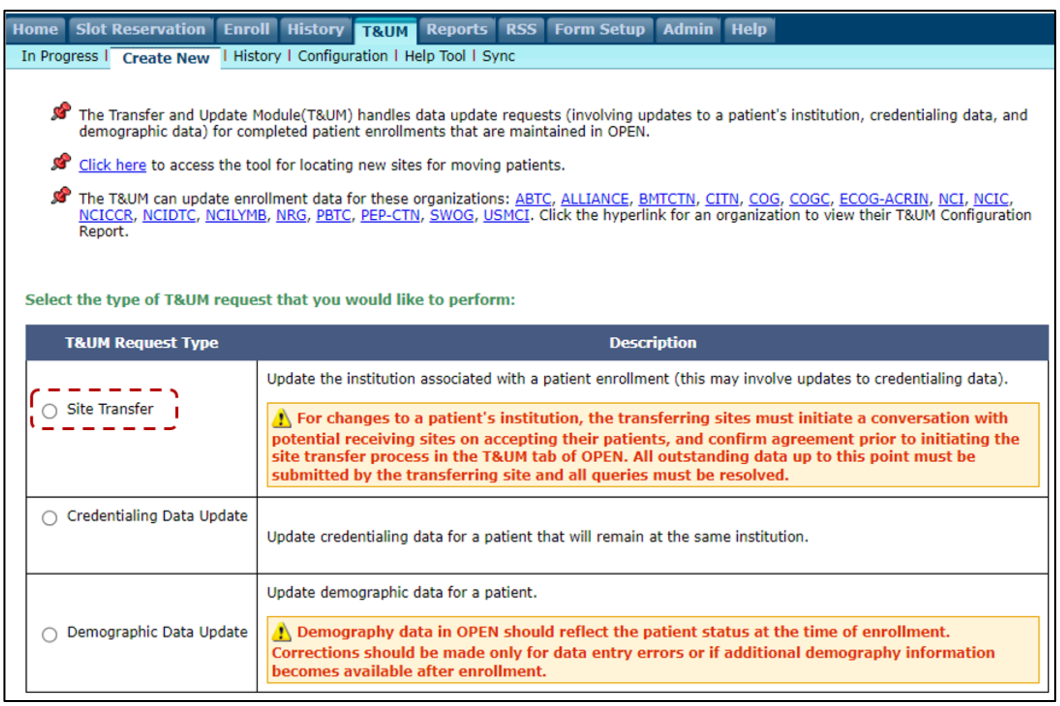


Figure 6: Select the Site Transfer Option to Begin a Site Transfer Request

5) Locate the subject enrollment and click the Select button for the subject. For multi-step protocols, only the most recent subject enrollment step is displayed (the prior enrollment steps are not updated using the T&UM).
6) Enter the code for the *Receiving Institution CTEP ID* field and press the Tab key or use the Help Tool to select the code.
7) Make selections for following fields:
    a) Requested Treating Investigator
    b) Receiving Institution Contact
    c) Case Status
    d) Transferring Site Contact Person
8) Provide a response in the Comments field.
9) When done, click the Submit button to validate and create the site transfer request.

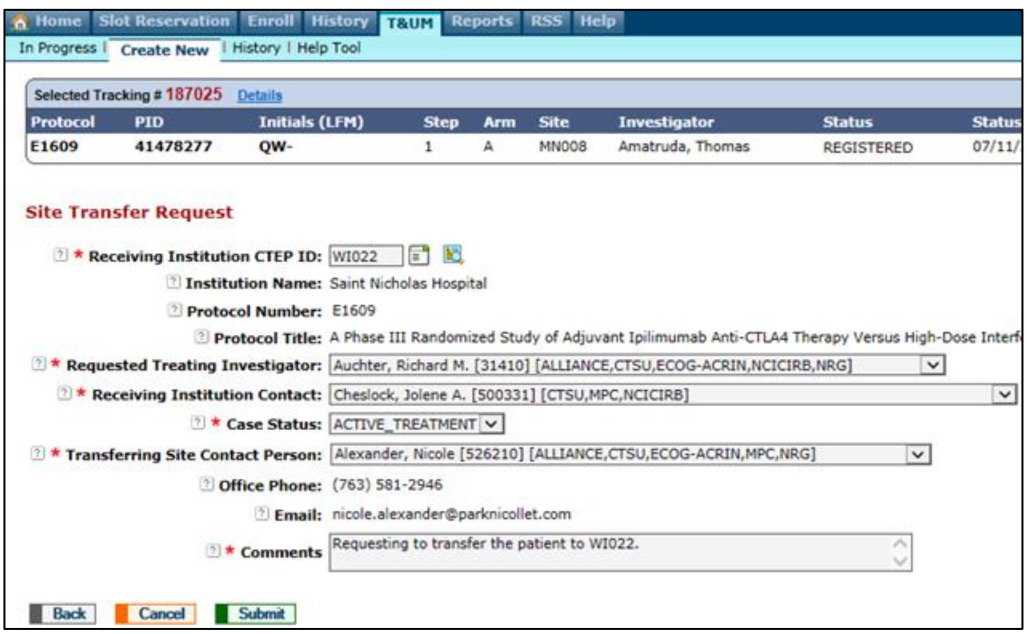


Figure 7: Complete the Site Transfer Request Form

10) The screen will refresh with a T&UM request number, informing the user that the receiving site will review the request and a complete summary of the request will be provided.

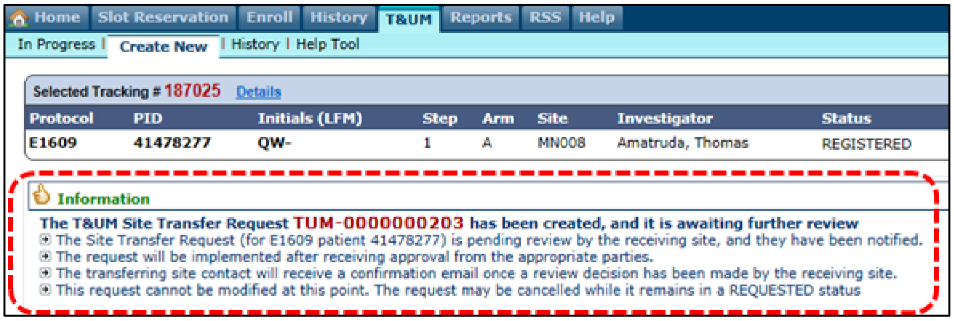


Figure 8: T&UM Site Transfer Request Initiated

NOTE: Email recipients will be sent a reminder notification every 14 days that a request remains in progress. Automatic cancellation will occur for T&UM requests that have been in the In Progress subtab for 45 days (90 days for COG studies) without activity.

3.1.1 Site Transfers for Patients in a Follow-up Case Status

The following are site transfer requirements for patients with a follow-up case status where the protocol is closed to accrual and later:

- Site must have a current (unexpired) IRB approval on file for the protocol.
- Site is not required to have all Protocol-Specific Requirements (PSRs) complied.
- Site must have an approved DTL if required (regardless of protocol status).

If the trial is temporary closed to accrual, then all standard business rules apply, regardless of the case status.

3.1.2 Cancelling a Site Transfer Request

Transferring Site users have the ability to cancel a Site Transfer request so long as it remains in a REQUESTED status. Follow the steps below to cancel a Site Transfer request:

1) Login to OPEN.
2) Click the T&UM tab, arrive at the In Progress subtab by default.
3) Locate the T&UM request and click the request's Select button.
4) Enter a comment in the Reason for Cancelling Request field.
5) Click the Cancel Request button.

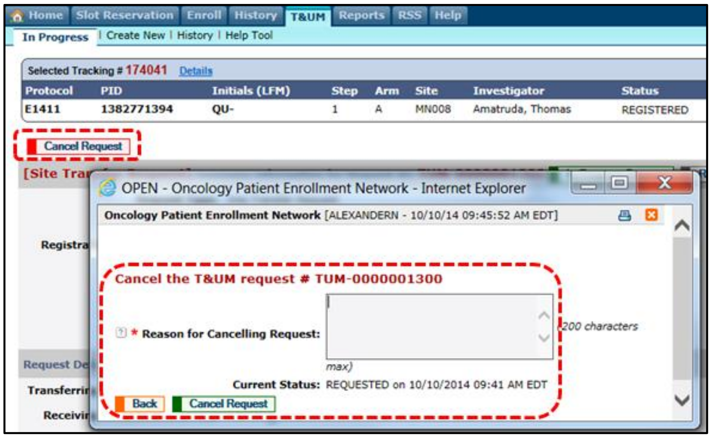


Figure 9: Cancelling a Site Transfer that is in a REQUESTED Status

6) Click *OK* on the confirmation pop-up window to complete the cancellation request.

3.2 Review of the Site Transfer Request by the Receiving Site

The second step in the process for a site transfer request is the review of the request by the receiving site (the site to which the subject will transfer).

Users at the receiving site will automatically be notified by email that a T&UM request is pending their review.

Site users with the OPEN Site Registrar or OPEN Site Admin role (at the receiving site) may review T&UM Site Transfer requests that are in a REQUESTED status.

Below are the steps that receiving site users will follow to review pending site transfer requests:

1) Log in to OPEN.
2) Click the T&UM tab, arrive at the In Progress subtab by default.
3) Locate the request and click the Select button for its row.

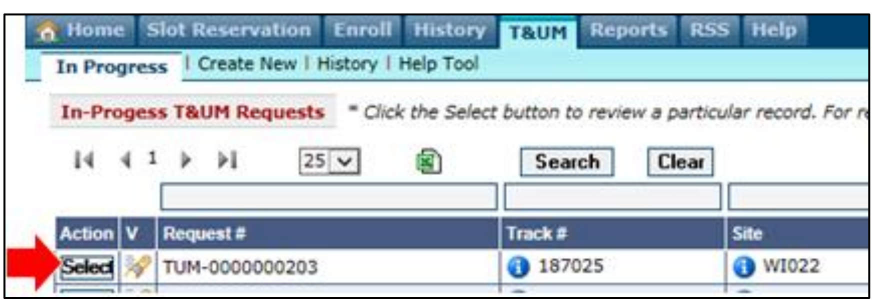


Figure 10: Click the Review Request Button to Review the Site Transfer Request

4) Click the *Review Request* button. The screen will refresh with the site transfer request.
5) Read the *Review Patient Information* section.

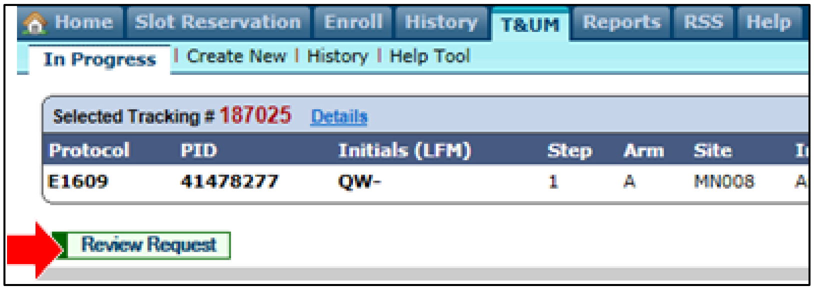
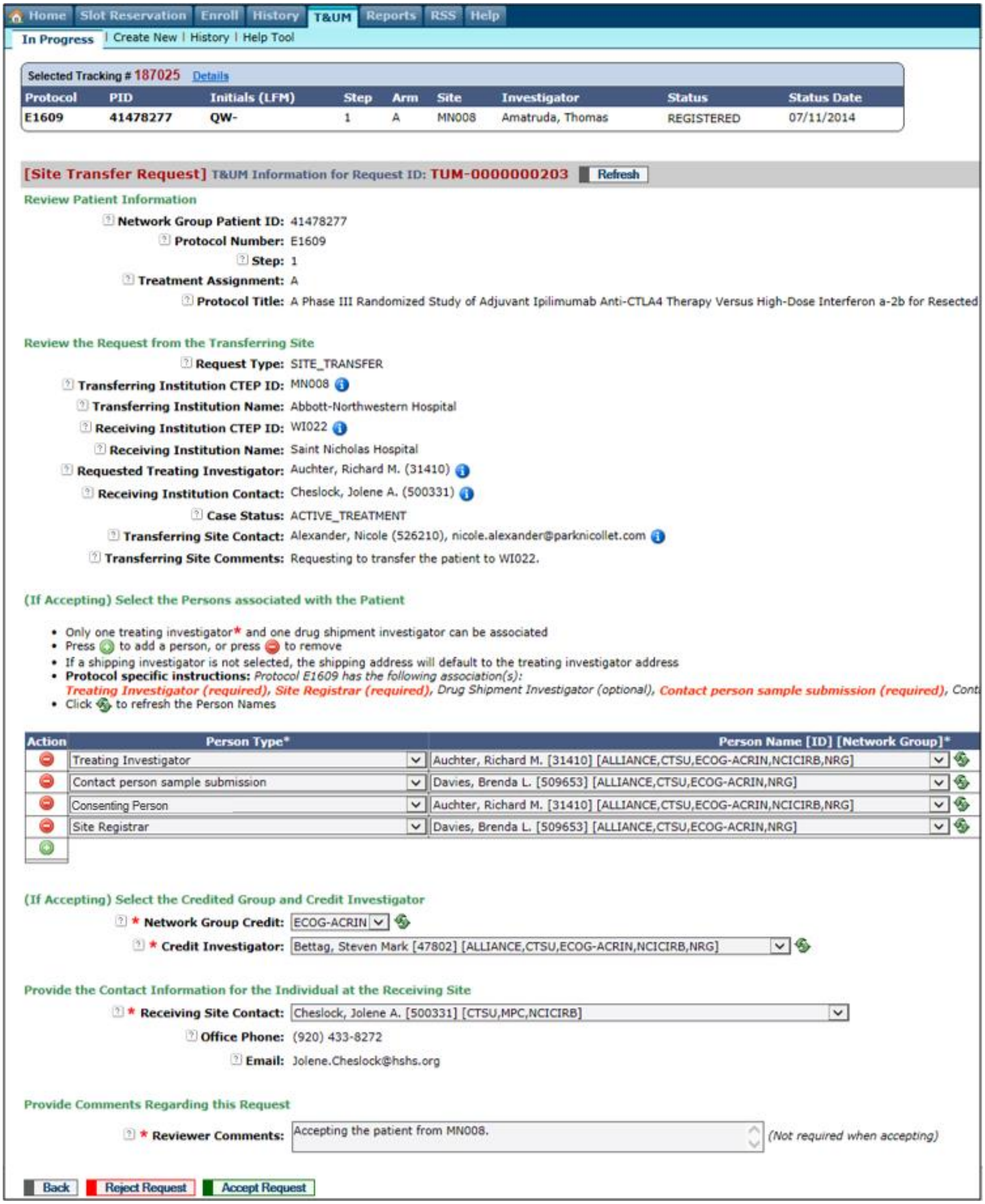


Figure 11: Click the Review Request Button for a Site Transfer

6) Read the Review the Request from the Transferring Site section.



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

In Progress | Create New | History | Help Tool

Selected Tracking # 187025 Details

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1609	41478277	QW-	1	A	MN008	Amatruda, Thomas	REGISTERED	07/11/2014

[Site Transfer Request] T&UM Information for Request ID: TUM-0000000203 Refresh

Review Patient Information

Network Group Patient ID: 41478277
Protocol Number: E1609
Step: 1
Treatment Assignment: A
Protocol Title: A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon a-2b for Resected

Review the Request from the Transferring Site

Request Type: SITE_TRANSFER
Transferring Institution CTEP ID: MN008
Transferring Institution Name: Abbott-Northwestern Hospital
Receiving Institution CTEP ID: WI022
Receiving Institution Name: Saint Nicholas Hospital
Requested Treating Investigator: Auchter, Richard M. (31410)
Receiving Institution Contact: Cheslock, Jolene A. (500331)
Case Status: ACTIVE_TREATMENT
Transferring Site Contact: Alexander, Nicole (526210), nicole.alexander@parknicollet.com
Transferring Site Comments: Requesting to transfer the patient to WI022.

(If Accepting) Select the Persons associated with the Patient

- Only one treating investigator* and one drug shipment investigator can be associated
- Press to add a person, or press to remove
- If a shipping investigator is not selected, the shipping address will default to the treating investigator address
- **Protocol specific instructions:** *Protocol E1609 has the following association(s):*
Treating Investigator (required), Site Registrar (required), Drug Shipment Investigator (optional), Contact person sample submission (required), Cont
- Click to refresh the Person Names

Action	Person Type*	Person Name [ID] [Network Group]*
	Treating Investigator	Auchter, Richard M. [31410] [ALLIANCE,CTSU,ECOG-ACRIN,NCICIRB,NRG]
	Contact person sample submission	Davies, Brenda L. [509653] [ALLIANCE,CTSU,ECOG-ACRIN,NRG]
	Consenting Person	Auchter, Richard M. [31410] [ALLIANCE,CTSU,ECOG-ACRIN,NCICIRB,NRG]
	Site Registrar	Davies, Brenda L. [509653] [ALLIANCE,CTSU,ECOG-ACRIN,NRG]

(If Accepting) Select the Credited Group and Credit Investigator

* Network Group Credit: ECOG-ACRIN
* Credit Investigator: Bettag, Steven Mark [47802] [ALLIANCE,CTSU,ECOG-ACRIN,NCICIRB,NRG]

Provide the Contact Information for the Individual at the Receiving Site

* Receiving Site Contact: Cheslock, Jolene A. [500331] [CTSU,MPC,NCICIRB]
Office Phone: (920) 433-8272
Email: Jolene.Cheslock@hshs.org

Provide Comments Regarding this Request

* Reviewer Comments: Accepting the patient from MN008. *(Not required when accepting)*

Back | Reject Request | Accept Request

Figure 12: Complete the Review Request Form for a Site Transfer

7) If Accepting the site transfer request:

   a) Complete the *Select the Persons associated with the Patient* section. The treating investigator selected by the transferring site will automatically prefill; however, it is at the discretion of the receiving site as to which staff are associated with the subject's care. Person Types can be removed, depending whether they were configured as required or optional in RSS.

   b) Complete the *Select the Credited Group and Credit Investigator* section. If the receiving site is a member of the group credited with the initial enrollment, the credited group for the subject transfer must remain the same. Credited group can only change if the receiving site is not a member of the original credited group.

8) If rejecting the site transfer request:

   a) If rejecting the request, skip the *Select the Persons associated with the Patient* and *Select the Credited Group and Credit Investigator* sections.

9) Select a *Receiving Site Contact*.

10) Provide a comment regarding the review decision in the "Reviewer Comments" field. If the LPO for the protocol is COG or COGC, a mandatory "Transplant Credit" question will appear below the Reviewer Comments field (see Figure 13).

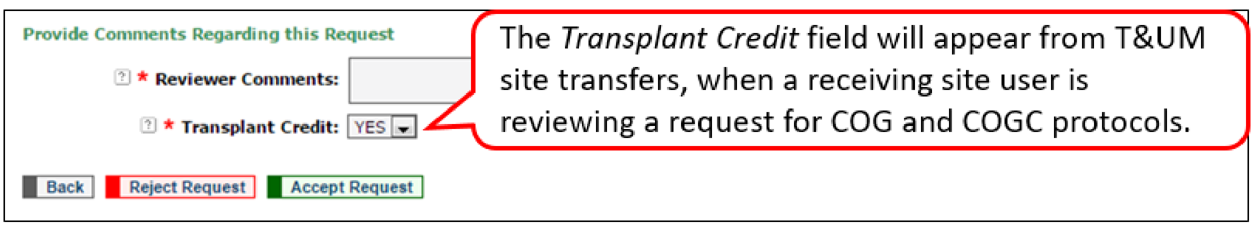


Figure 13: A Transplant Credit Question Will Appear for COG and COGC Protocols

11) Click either the Reject Request or Accept Request buttons to make a review decision.

12) Review the message in the pop-up window and click the OK button.

13) The screen will refresh and the outcome of the request submission will display at the top of the screen. Accepted requests may require LPO review (this information would be displayed at the top of the screen as an informational note).

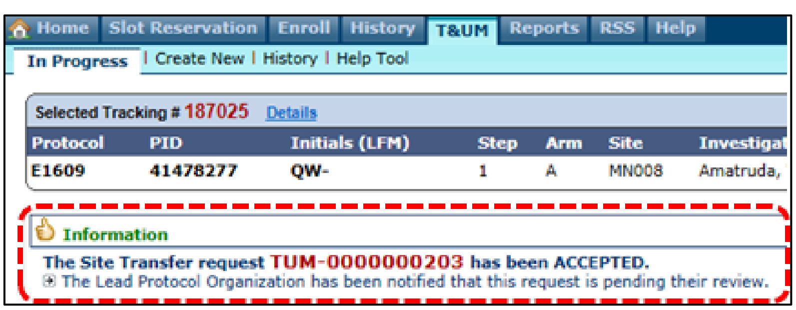


Figure 14: Message Confirms that the Site Transfer was Accepted, and Awaiting LPO Review

3.3 Review of the Site Transfer Request by the Lead Protocol Organization (If Applicable)

The third step in the process for a site transfer request is review of the accepted site transfer request by the LPO. Some protocols are not configured for LPO review, in which case this step is not needed, and accepted requests are automatically set to an approved status. LPO users with the OPEN Group Registrar or OPEN Group Registrar Admin roles have the ability to review T&UM requests.

Users at the LPO will automatically be notified by email that a T&UM request is pending their review.

Below are the steps that LPO users will follow to review pending site transfer requests:

1) Log in to OPEN.
2) Click the T&UM tab, arrive at the In Progress subtab by default.
3) Locate the request and click the Select button for its row.

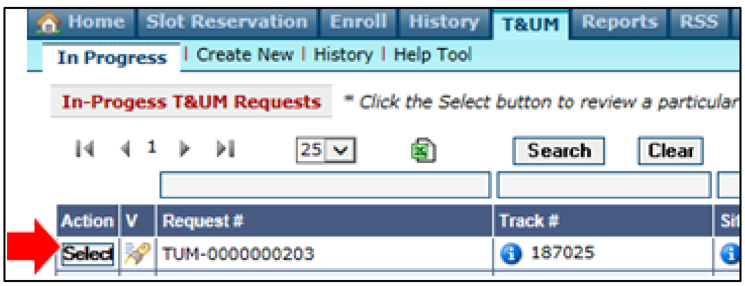


Figure 15: Select the T&UM Request in the In Progress Subtab of the T&UM Tab

4) Click the Review Request button.

Figure 16: Click the Review Request Button to Review the Accepted Request

5) The screen will refresh with the site transfer request.
6) Read the Review Patient Information section.
7) Read the Review the Request from the transferring site section.
8) Read the Review Response Details from the receiving site section.
9) Select a Network Group Contact using the drop-down menu in the field.
10) Provide a comment in the LPO Comments field regarding the review decision.

11) Make a review decision of Query, Reject, or Approve.

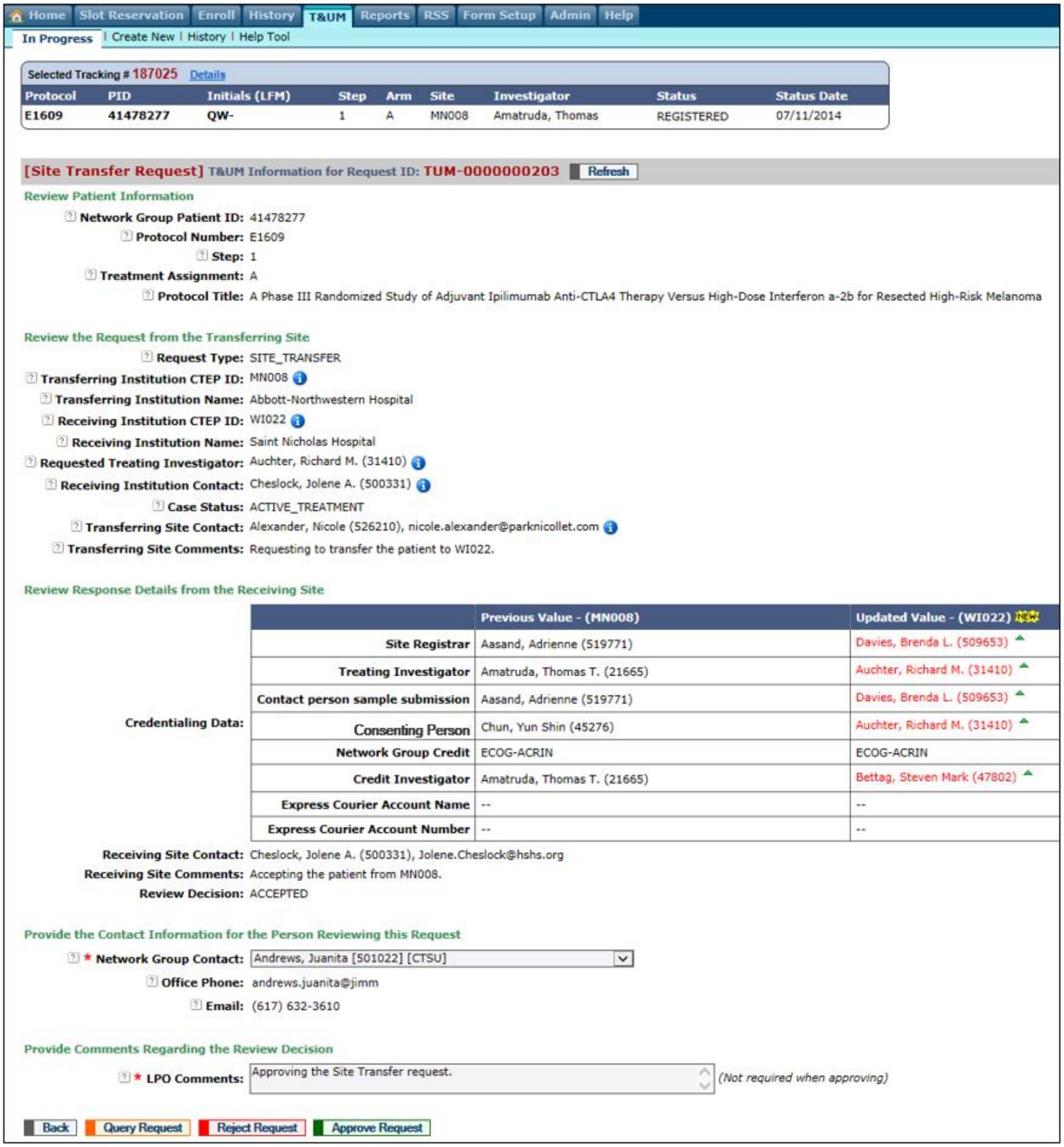


Figure 17: After Reviewing the Request, the LPO User Must Make a Review Decision

a) If something about the request needs correction:

i) Make a comment in the LPO Comments field that indicates what the receiving site needs to correct.

ii) Click the Query Request button to send the request back to the receiving site for review.

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

iv) The screen will refresh and the user will be informed that the request has been sent to the receiving site. Once the user at the receiving site resolves and again accepts the request, the LPO staff will receive an automated notification email, at which point the LPO can re-review the request.

b) If the request is unacceptable:

i) Click the Reject Request button.

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

iii) The screen will refresh, the user will be informed that the request is rejected, and that users at the transferring and receiving sites have been notified.

c) If the request is acceptable:

i) Click the Approve Request button.

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

iii) The screen will refresh, and the user will be informed that the request has been approved, the appropriate parties have been notified, and the data update processes have begun.

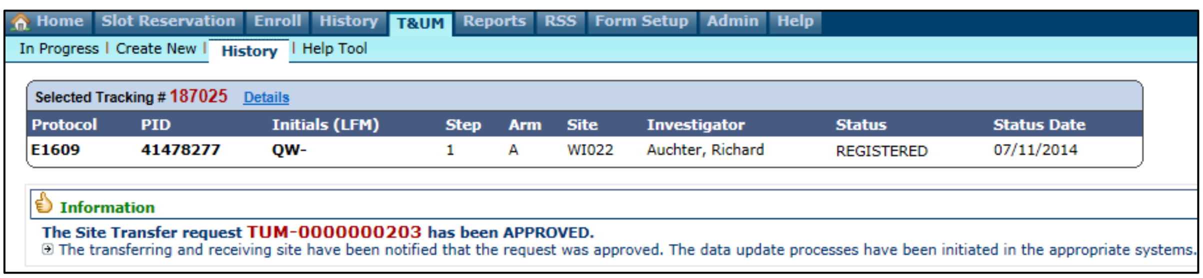


Figure 18: A Message that Confirms the Site Transfer Request was APPROVED

12) If the LPO user approved or rejected the request, the site transfer process for the request is complete.

4. Credentialing Data Update Requests

Credentialing data update requests are used for changing credentialing information for a subject that is staying at the same site. Site users with the OPEN Site Registrar or the OPEN Site Admin role may create T&UM requests. Unlike a site transfer request, the institution code for the subject cannot be changed with this type of request and this request type does not involve a review process by additional parties.

A list of data points that can be updated with a credentialing data update request include (note that the LPO may have configured some of these fields to be non-updateable):

- Persons associated with the subject (treating investigator, site registrar, etc., per each study's setup);
- Network Group Credit (see section 4.1 for details));
- Credit Investigator;
- Radiotherapy Facility Provider (RTF) Provider.

Figure 19 provides a high-level overview of the credentialing data update request process.

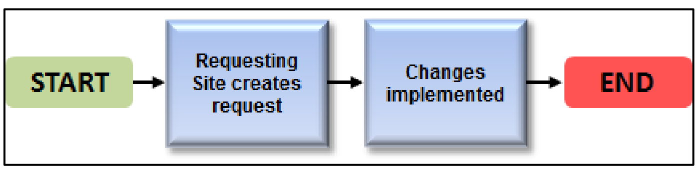


Figure 19: Credentialing Data Update Process Workflow

The remainder of this section will provide instructions for creating and completing a credentialing data update request.

4.1 Requirements for Updating Network Credit Group

- Credit for subsequent steps must be credited to the same group as the initial step even if the subsequent enrollment is within seven days of the initial step.
- For single-step trials, T&UM will allow credit updates within seven days of the enrollment.
- For multi-step trials, T&UM will allow credit updates within seven days of the initial step. If the initial enrollment step and a subsequent step(s) are completed within seven days (from initial step), T&UM will allow credit update in the last step, and OPEN should update any previous steps to the same group (as well as Credit Investigator and Treating Investigator if updated in T&UM).

4.2 Creating a Credentialing Data Update Request

1) Log in to OPEN.
2) Click the T&UM tab, arrive at the In Progress subtab by default.
3) Click the Create New subtab.
4) Select the Credentialing Data Update action.

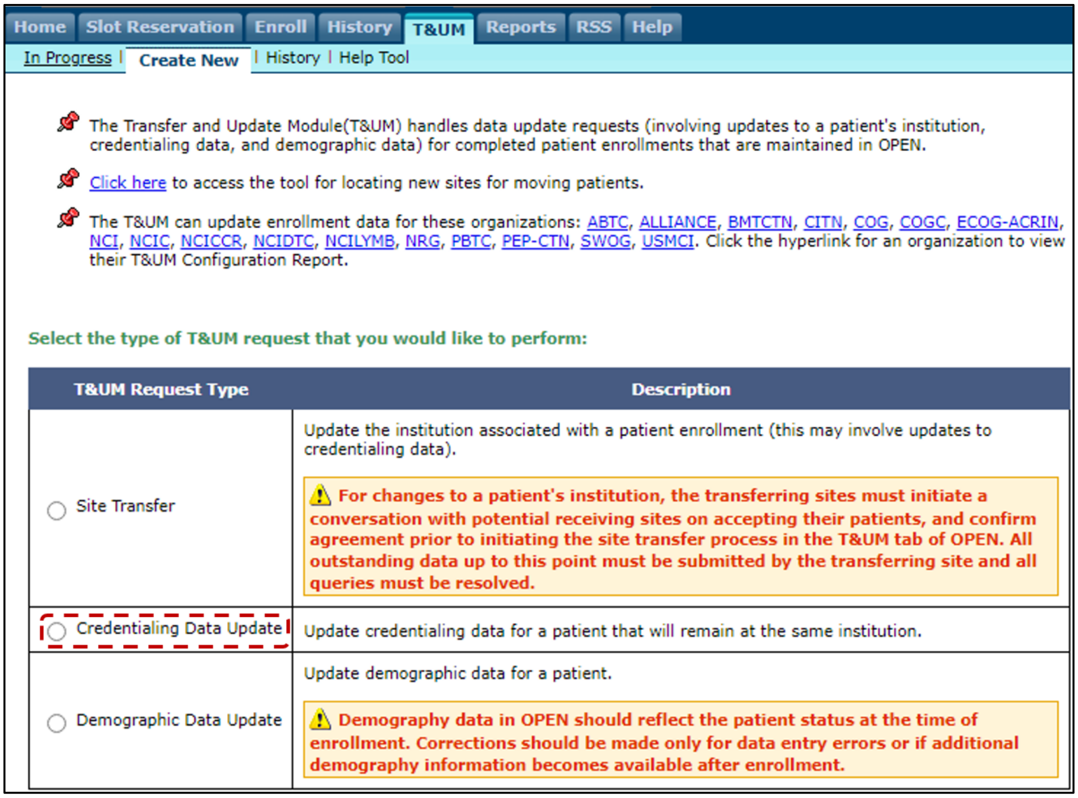


Figure 20: Select the Credentialing Data Update Choice

5) The screen will refresh to display a list of subjects that are at the institution(s) with which the user has active roster affiliations.

6) Locate the desired subject enrollment and click the Select button for the enrollment row.

Figure 21: Select a Subject Enrollment

7) The screen will refresh.

8) Make the necessary change(s) to the data using the available fields and complete the required fields (those which contain a red asterisk). Person Types can be removed, depending whether they were configured as required or optional in RSS.

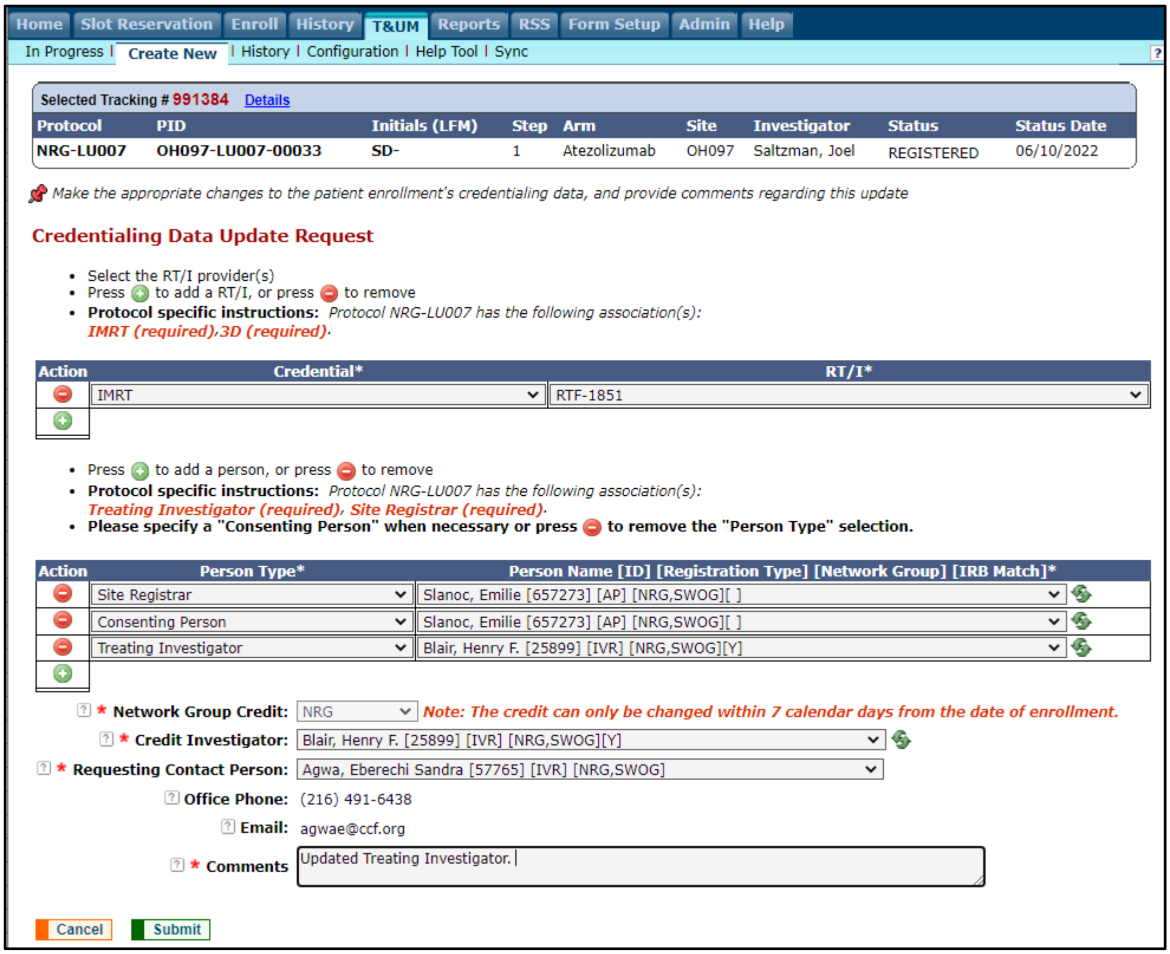


Figure 22: Make the Needed Updates on the Credentialing Data Update Request Form

9) Click the *Submit* button.

10) The screen will refresh and the user will be informed that the LPO has been notified, and the data changes are being implemented. This completes the process for creating a credentialing data update request.

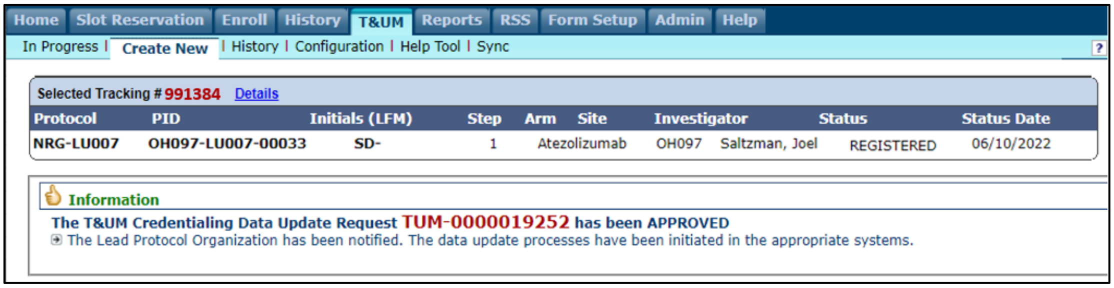


Figure 23: Screen Confirming the Credentialing Data Update was Approved

5. Demographic Data Update Requests

Demographic Data Update requests can be used for correcting or in rare instances changing some of the demography data so long as the following requirements are followed:

No updates should be made to the demography data after the enrollment is completed, unless the updates are to correct data entry errors or unless the site became aware of additional demography information after the enrollment was completed. Below is the list of demography data that can only be changed to correct data entry errors:

- Date of Birth
- Ethnicity
- Sex
- Race
- Zip code
- Country
- Method of payment

If the subject's zip code, country, or method of payment change after the enrollment is completed, then these changes should not be entered in OPEN.

For multi-step protocols, demography data entered in the initial step will be copied over to subsequent steps. In addition, every time a subject is enrolled to a subsequent step, OPEN will run a validation to ensure that the demography data matches between all steps.

If a registrar attempts to update the demography data in subsequent steps during an enrollment process where the T&UM is enabled, a warning message will be displayed stating that the demography data cannot be updated in subsequent steps and that they must make the demography data correction in the T&UM first, before proceeding with the subsequent enrollment.

For studies not using the T&UM, if a registrar attempts to update demography data during an enrollment process, a warning message will be displayed stating that demography updates cannot be made in subsequent steps and if corrections need to be made to the demography data, the registrar will need to contact the CTSU Help Desk.

For demographic data updates, if a standard demography field (with the exception of the Disease Code) has an editable T&UM configuration, it will override the Form Setup configuration for the field (thus enabling updates to the field in the T&UM as long as the field was configured as visible in Form Setup).

Figure 24 provides a high-level overview of the Credentialing Data Update request process.

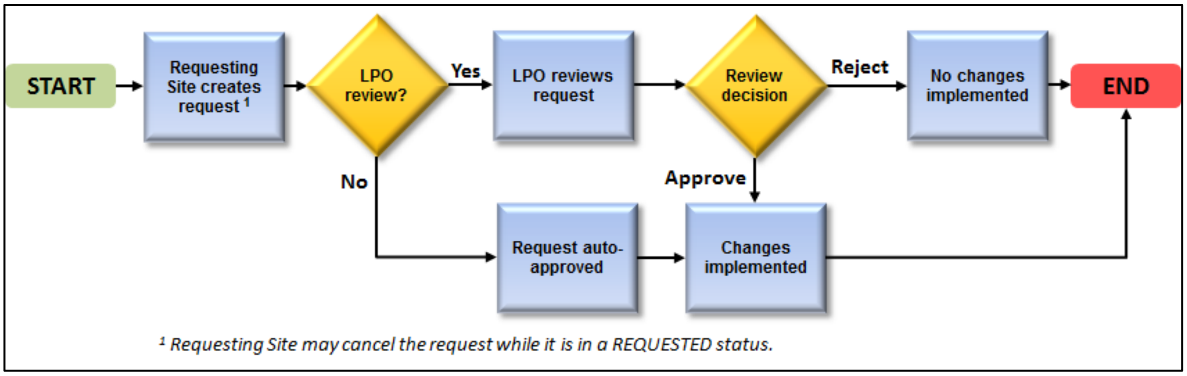


Figure 24: High-Level Overview of the Demographic Data Update Process

The remainder of this section will provide instructions for the two main processes that are involved with creating and completing a demographic data update request:

1) Initiation of the Demographic Data Update request by the requesting site.
2) Review of the Demographic Data Update request by the LPO (if configured).

5.1 Initiating a Demographic Data Update Request

1) Log in to OPEN.
2) Click the T&UM tab, arrive at the In Progress subtab by default.
3) Click the Create New subtab.
4) Select the Demographic Data Update action.

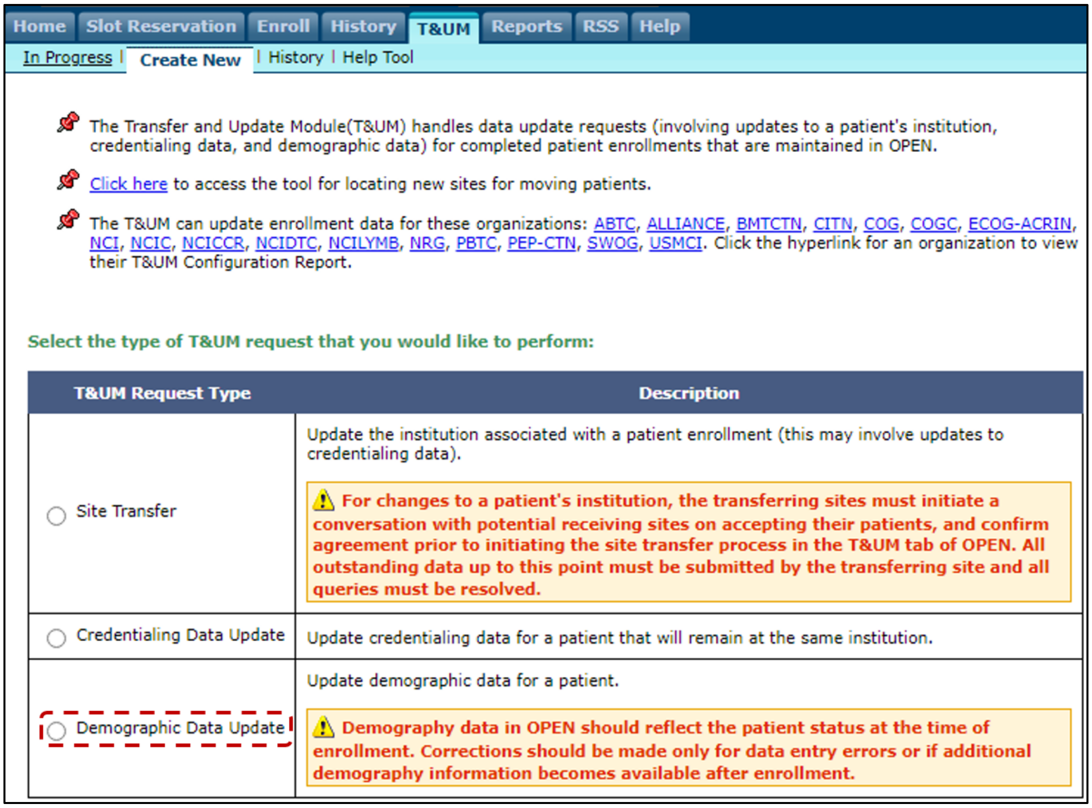


Figure 25: Select the Demographic Data Update Choice

5) The screen will refresh to display a list of subjects that are at the site(s) with which the user has active roster affiliations.
6) Locate the desired subject's enrollment and click the Select button for the enrollment row.

Figure 26: Select the Subject Enrollment

7) The screen will refresh.
8) Make the necessary changes or corrections to the Demography screen data and click the Continue button.

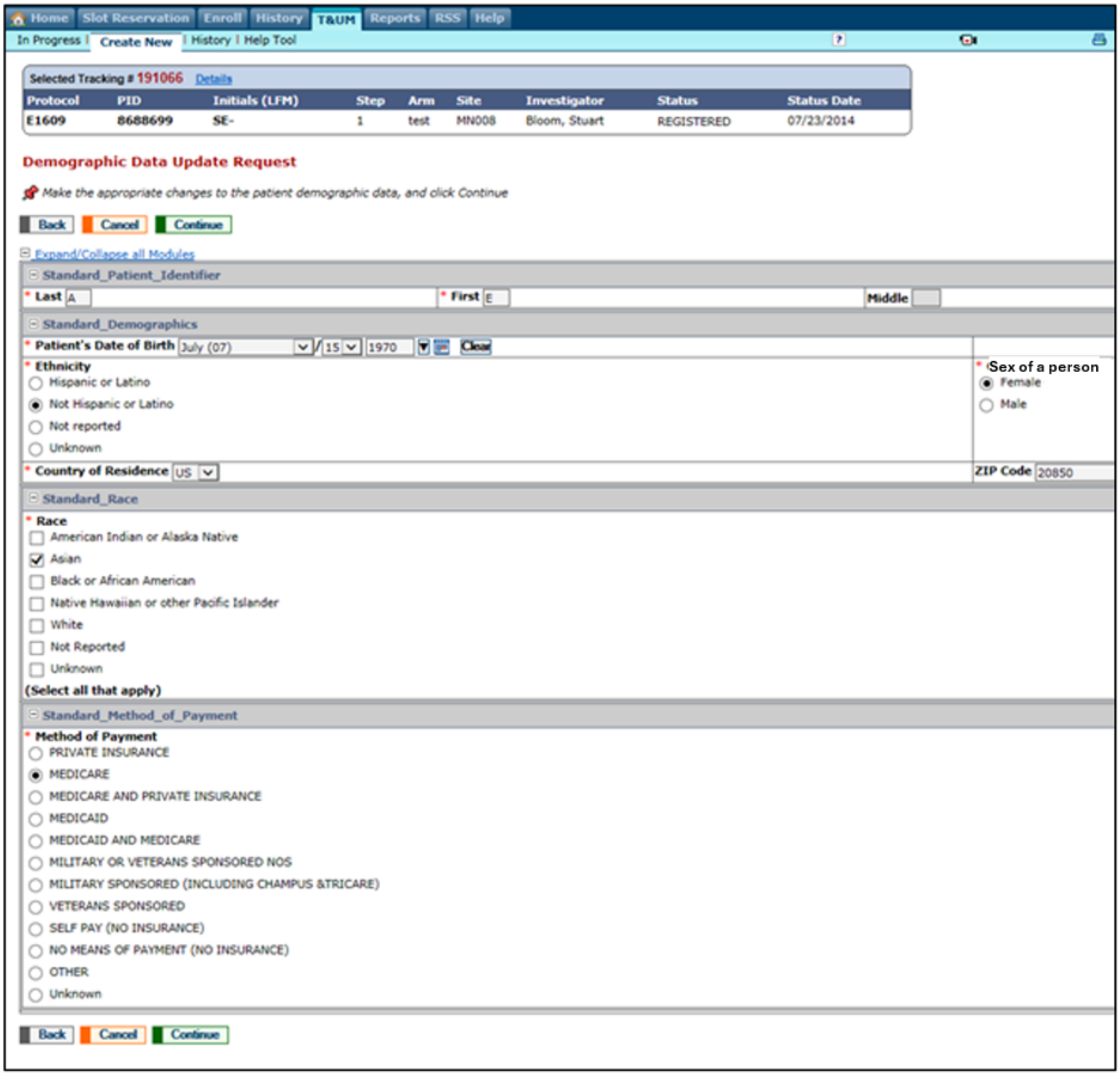


Figure 27: First Page of the Demographic Data Update Request Form

9) The screen will refresh.
10) Review the summary of the requested changes.
11) Select a Requesting Institution Contact Person.
12) Provide a comment regarding the change in the Comments field.

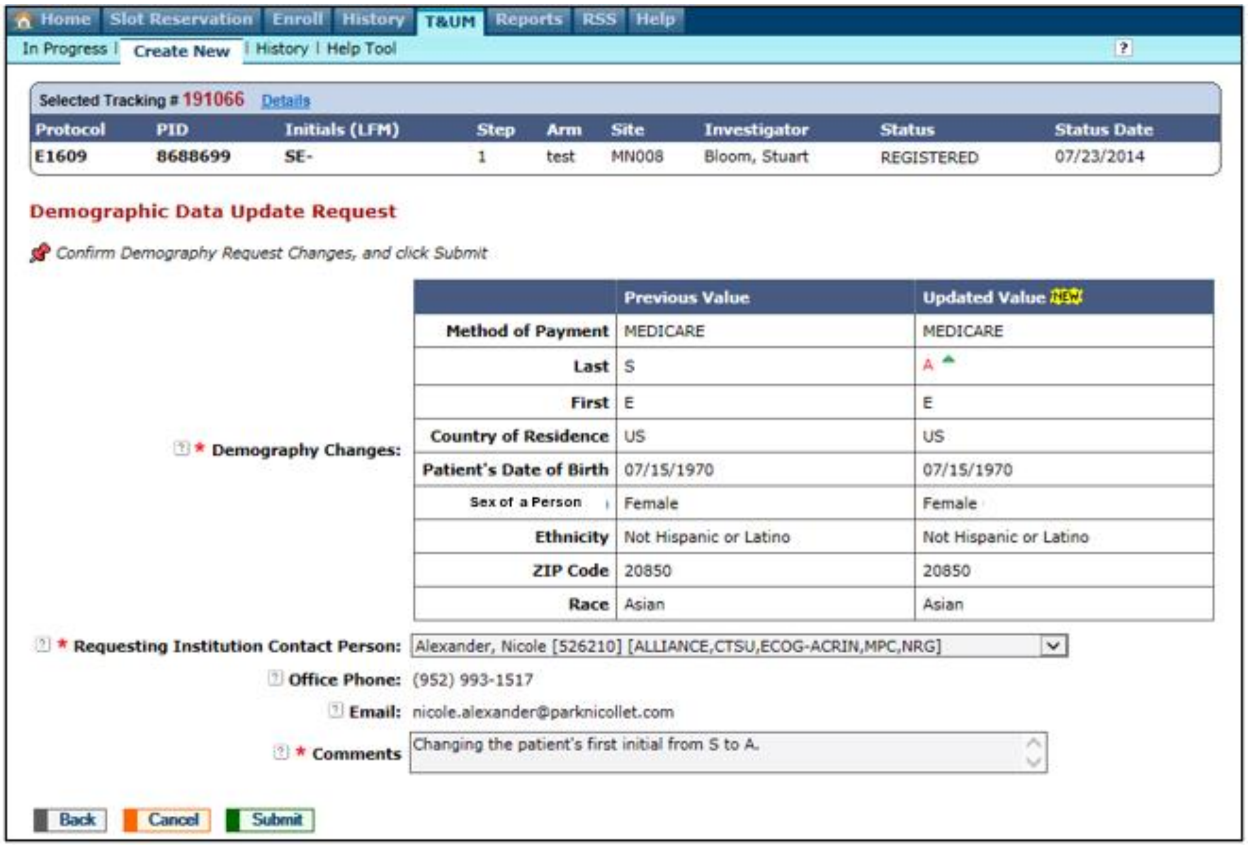


Figure 28: Second Page of the Demographic Data Update Request Form

13) Click the Submit button.

14) Click OK on the confirmation pop-up window.

15) The screen will refresh, providing a T&UM request ID.

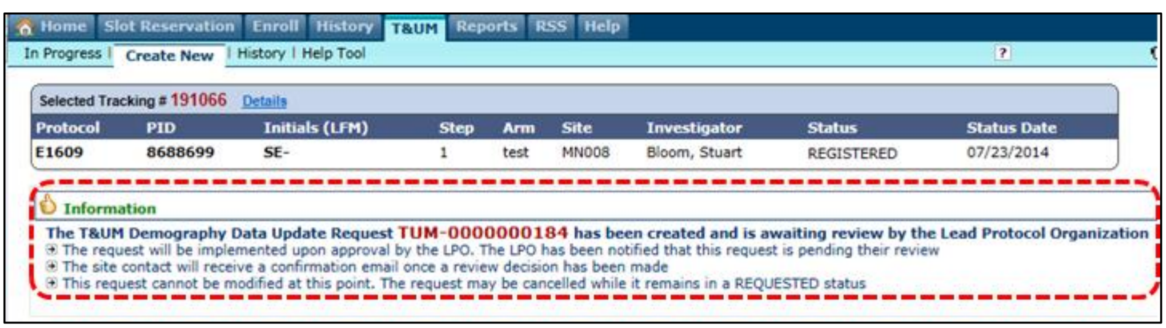


Figure 29: Message Confirming Request Created, and Awaiting LPO Review

NOTE: Email recipients will be sent a reminder notification every 14 calendar days that a request remains In Progress. Automatic cancellation will occur for T&UM requests that have been in the *In Progress* subtab for 45 days without activity.

16) LPO review of the request may be necessary:
    a) If LPO review is needed, the user will be informed when the screen refreshes. The next section will provide instructions for LPO staff on how to review pending demographic data update requests.
    b) If LPO review is not needed, the user will be informed that the request will be auto-approved, changes implemented, and the LPO will be notified. Under this circumstance, the process for creating a demographic data update request will be complete.

5.2 LPO Review of the Demographic Data Update (If applicable)

The second step in the process for a demographic data update request (if configured) is a review by the LPO. Some protocols are not configured for LPO review, in which case this step is not needed. Users at the LPO will automatically be notified by email that a T&UM request is pending their review. LPO users with the OPEN Group Registrar or OPEN Group Registrar Admin roles have the ability to review T&UM requests.

Below are the steps that LPO users will take to review pending demographic data update requests:

1) Login to OPEN.
2) Click the T&UM tab arrive at the In Progress subtab by default.
3) Locate the request and click the Select button for its row.

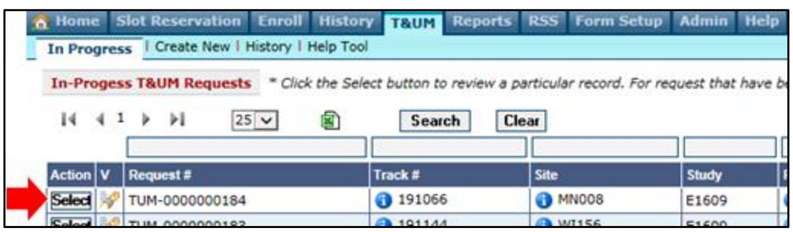


Figure 30: Select the Subject from the In Progress Subtab of the T&UM Tab

4) Click the Review Request button.

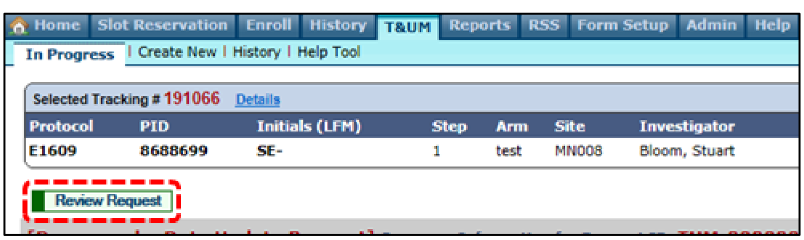


Figure 31: Click the Review Request Button

5) The screen will refresh with the Demographic Data Update request summary.

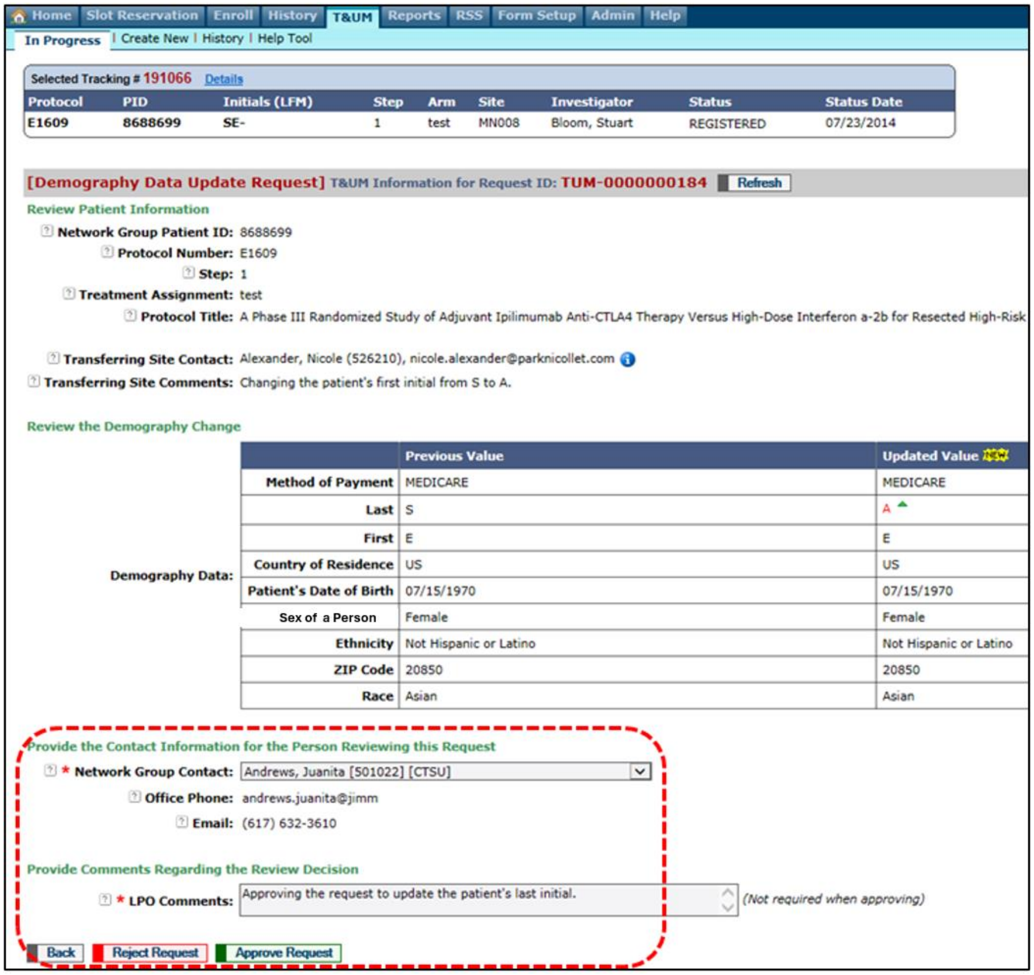


Figure 32: Complete the Review Request Screen and Make a Review Decision

6) Read the Review Patient Information section.
7) Read the Review the Demography Change section.
8) Select a Network Group Contact using the field's drop-down menu.
9) In the LPO Comments field, provide comments regarding the review decision.
10) Make a review decision of Reject or Approve.
    a) If the request is unacceptable:
        i) Click the Reject Request button.
        ii) Click the OK button on the confirmation pop-up window.
        iii) The screen will refresh, the user is told that the request is rejected, and that the requesting site has been notified. This completes the demographic data update process.

Figure 33: Rejected Demographic Data Update Request

b) If the request is ready for approval:

i) Click the Approve Request button.

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

iii) The screen will refresh and the user will be informed that the request has been approved, the appropriate parties have been notified, and the data update processes have begun. This completes the demographic data update process.

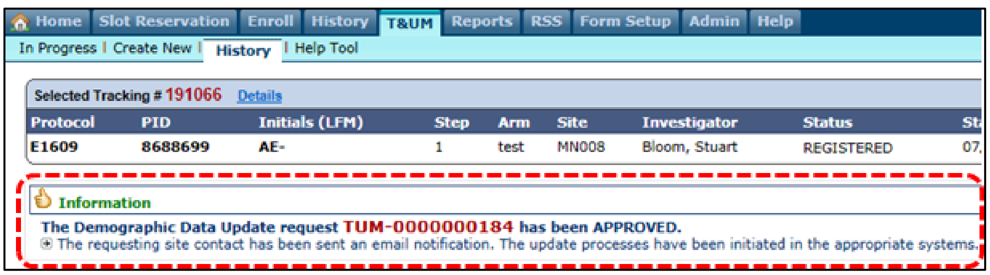


Figure 34: Approved Demographic Data Update

6. Additional Information Regarding the T&UM

6.1 List of Organization that Participate in the T&UM

The T&UM Create New subtab provides an automated list (see Figure 35) of lead organizations that participate in the T&UM.

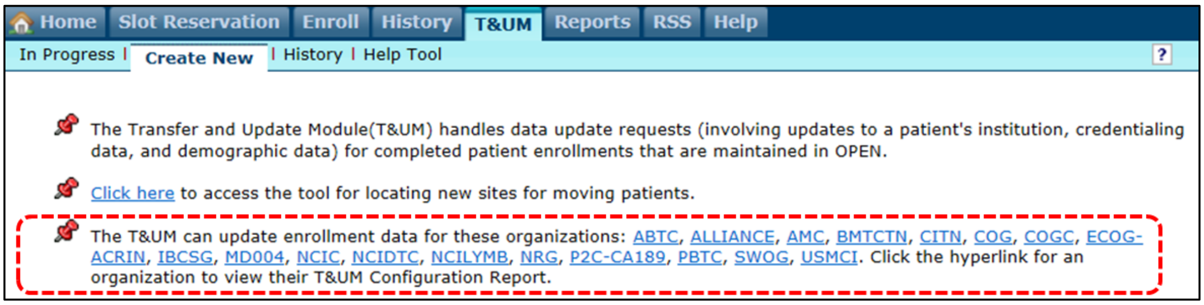


Figure 35: Automated List of Organizations that Participate in the T&UM

To view the T&UM configuration details (including any protocol-level exceptions) for any of the listed organizations, click their hyperlink (see Figure 36) to view a T&UM Configuration Report. The report will list which T&UM request types the organization participates in and the report will list any protocol-level exceptions.

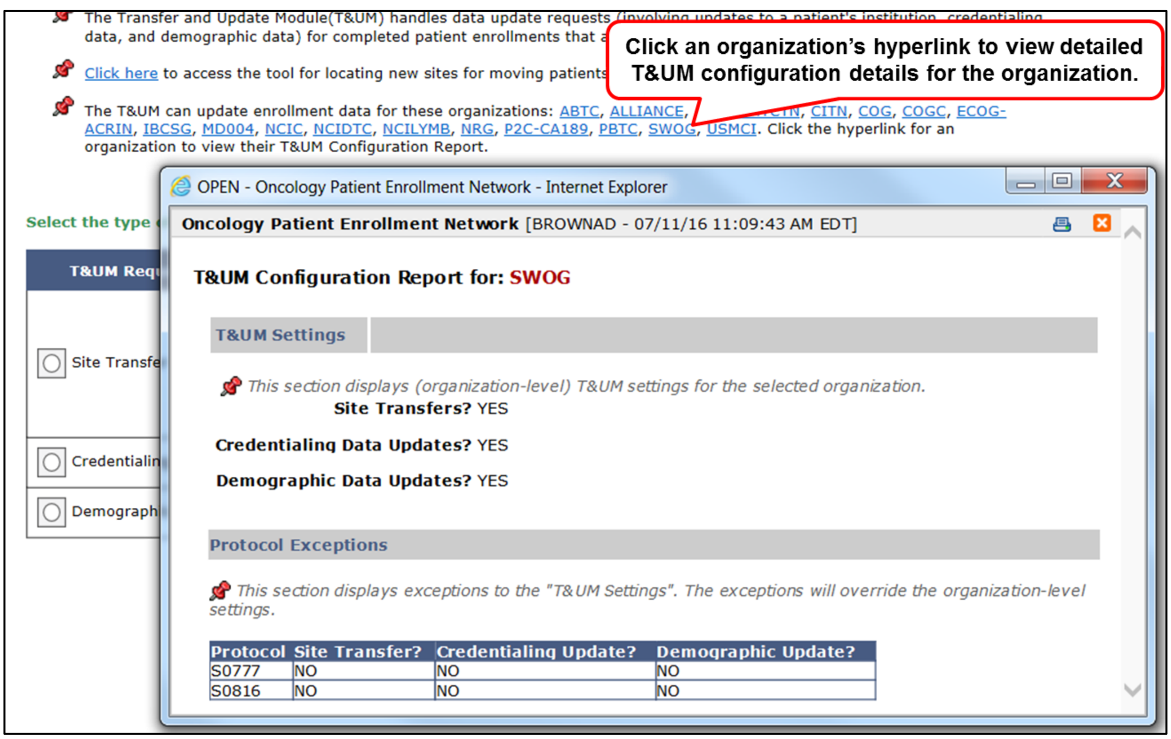


Figure 36: T&UM Configuration Details for an Organization

6.2 T&UM History Subtab

The T&UM History subtab contains information on T&UM requests that have entered an APPROVED, REJECTED, or CANCELLED status.

Accessing this Feature:

1) Login to OPEN.
2) Click the History subtab of the T&UM tab.

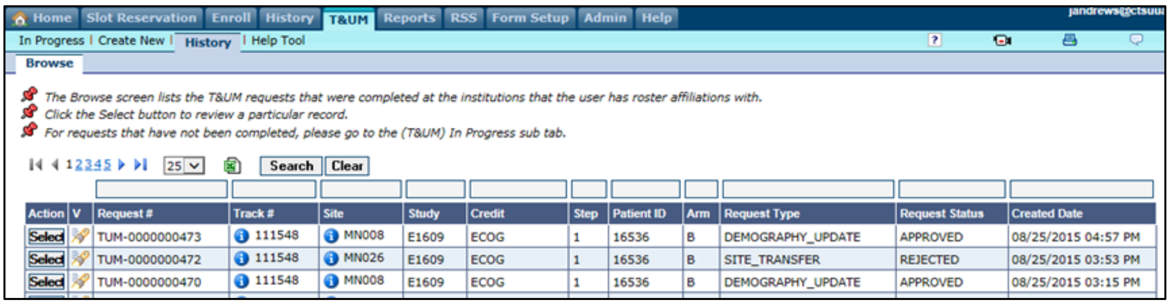


Figure 37: T&UM History Subtab

3) To view a summary for a T&UM request, click the corresponding record's Select button. The screen will refresh with a detailed summary for the record.

6.3 T&UM Patient History Report

A T&UM Patient History Report is available in the Summary screens in the History tab of OPEN for patient enrollments that have approved T&UM requests. Once a user clicks the T&UM Report button, a report will appear in a pop-up window that lists all of the T&UM changes that are associated with the patient. This provides users with the ability to have a complete picture of the T&UM changes that were applied to their patient, across all enrollment steps.

Accessing this Feature:

1) Login to OPEN.
2) Select a patient from the Browse subtab of the History tab.
3) In the Summary screen, click the T&UM Report button (if present).

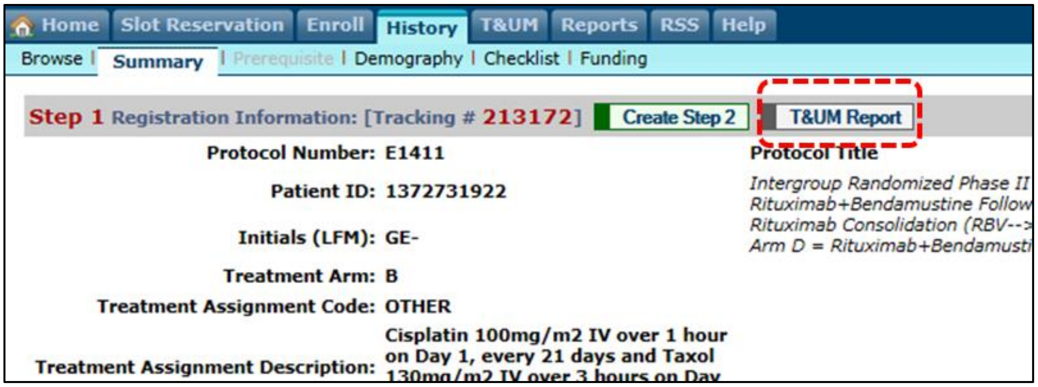


Figure 38: The T&UM Report button launches the T&UM Patient History Report

4) The T&UM Patient History Report will load in a pop-up window.

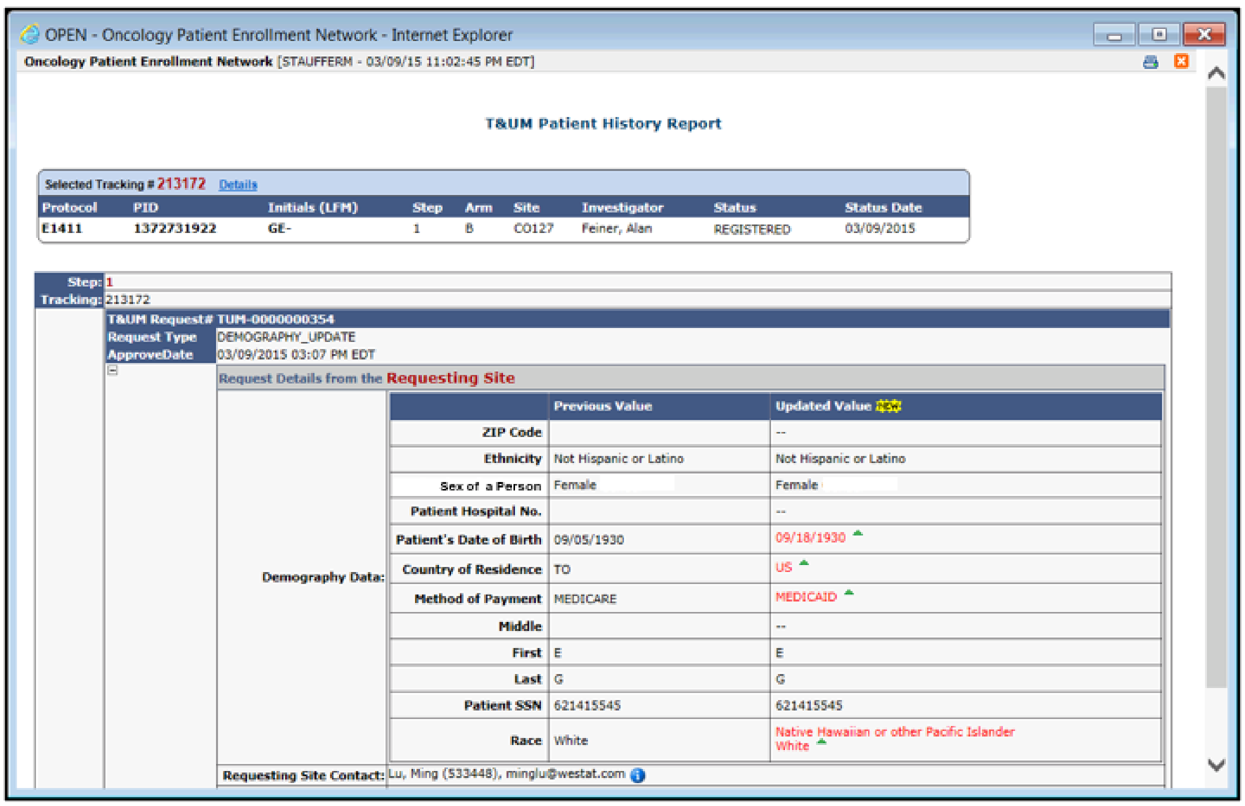


Figure 39: T&UM Patient History Report

6.4 T&UM Help Tool

The T&UM Help Tool assists with locating potential receiving sites for subjects that need to move to a different site. Site users may contact the LPO if additional assistance is needed with locating a receiving site for their subject.

Google Maps functionality was integrated into the T&UM Help Tool so OPEN users can see where potential receiving sites are located.

Accessing this Feature:

1) Login to OPEN.
2) Click the T&UM tab.
3) Click the Help Tool subtab.
4) Provide the necessary values for the Protocol, Zip Code, and Radius fields (see Figure 40).

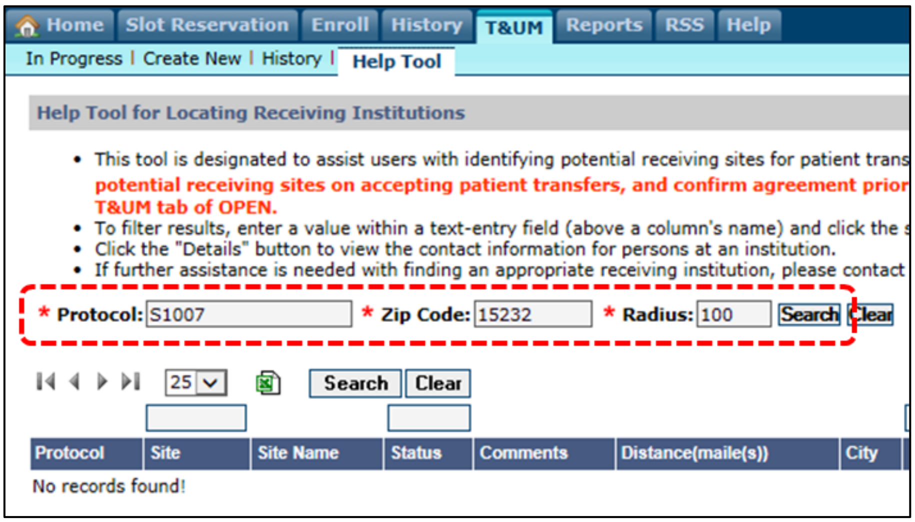


Figure 40: Enter Search Criteria in the T&UM Help Tool

5) Click the Search button.
6) The screen will refresh and display results using the Google Map interface (see Figure 41). The Google Map will display on the left side of the screen and a list of the different receiving sites (complete with their addresses) will display on the right side of the screen. A searchable list of all the results will display at the bottom of the screen.

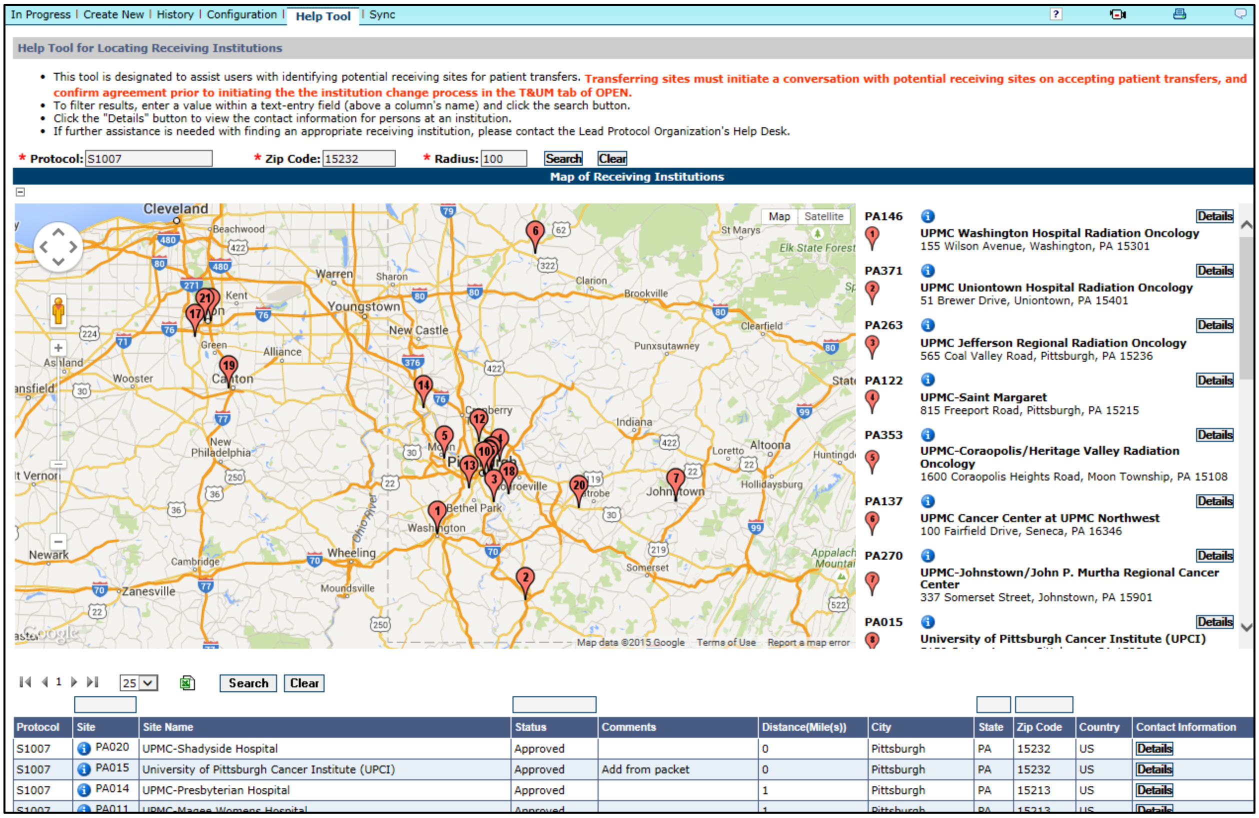


Figure 41: T&UM Help Tool Results

7) To see contact information for a particular site, click the corresponding Details button. A pop-up window will appear with the contact information for the Administrator and Data Administrator (if available) for the site.

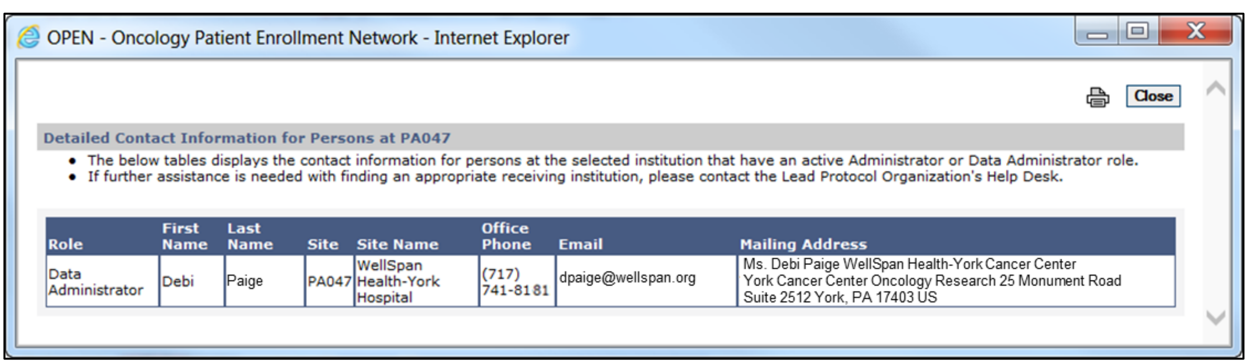


Figure 42: Details Pop-up for the T&UM Help Tool

6.5 Locating T&UM Requests in the History Tab of OPEN

The T&UM Type column in the History tab of OPEN can be used for identifying enrollments that are associated with Approved T&UM requests.

Accessing this Feature:

1) Login to OPEN.
2) Click the History tab. The Browse subtab will display by default.
3) Enrollments that have an approved T&UM request will have a designation (or multiple designations) in the T&UM Type column. Enrollments that have not involved any approved T&UM requests will have no entries in the T&UM Type column.

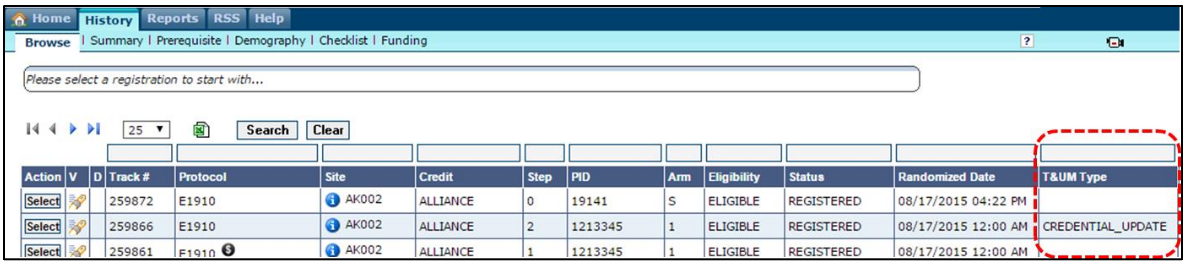


Figure 43: The T&UM Type Column Identifies Enrollments with Approved T&UM Requests

4) 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.

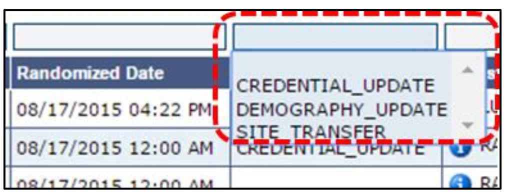


Figure 44: Results can be Filtered by the T&UM Type

5) After making a selection in the text-entry box above the T&UM Type column, the results will refresh as requested (see Figure 45).

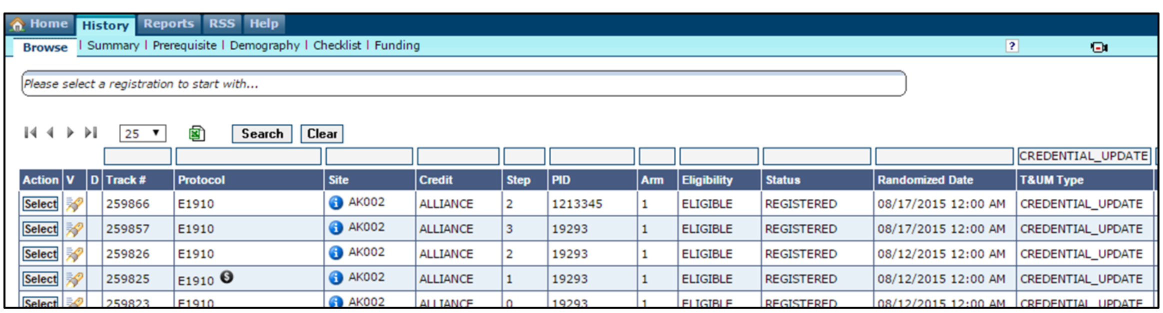


Figure 45: The Filtered Results for the T&UM Type

6.6 T&UM Configurations

This section details the T&UM settings that can be configured. All of these settings are configured at the LPO-level. Protocol-level exceptions can be created to override LPO-level settings (if the corresponding T&UM Request Type is enabled at the LPO-level). Contact the CTSU for assistance with configuring the T&UM settings.

T&UM Request-Type Settings:

- Enable or disable the Site Transfer action.
- Enable or disable the Credentialing Data Update action.
- Enable or disable the Demographic Data Update action.
- Manual or automatic approval of Site Transfer requests.
- Manual or automatic approval of Demographic Data Update requests.

T&UM Demographic Data Update Fields that can be enabled/disabled from Update:

- Last
- First
- Middle
- Subject SSN
- Subject Hospital Number
- Subject Date of Birth
- Ethnicity
- Sex of a Person
- Country of Residence
- Zip Code
- Rave
- Method of Payment

Please note that the Demographic Data Update fields listed above are the only Demography fields that OPEN users are permitted to update. The Disease Code field cannot be updated using the T&UM.

6.7 T&UM Statuses

During the lifecycle of a T&UM request, the request will go through a series of statuses. The status begins with REQUESTED, it can enter a series of intermediary statuses, and then it ends in a terminal status. The diagram in Figure 46 shows the different statuses that a T&UM request will go through. Table 2 describes the different T&UM statuses.

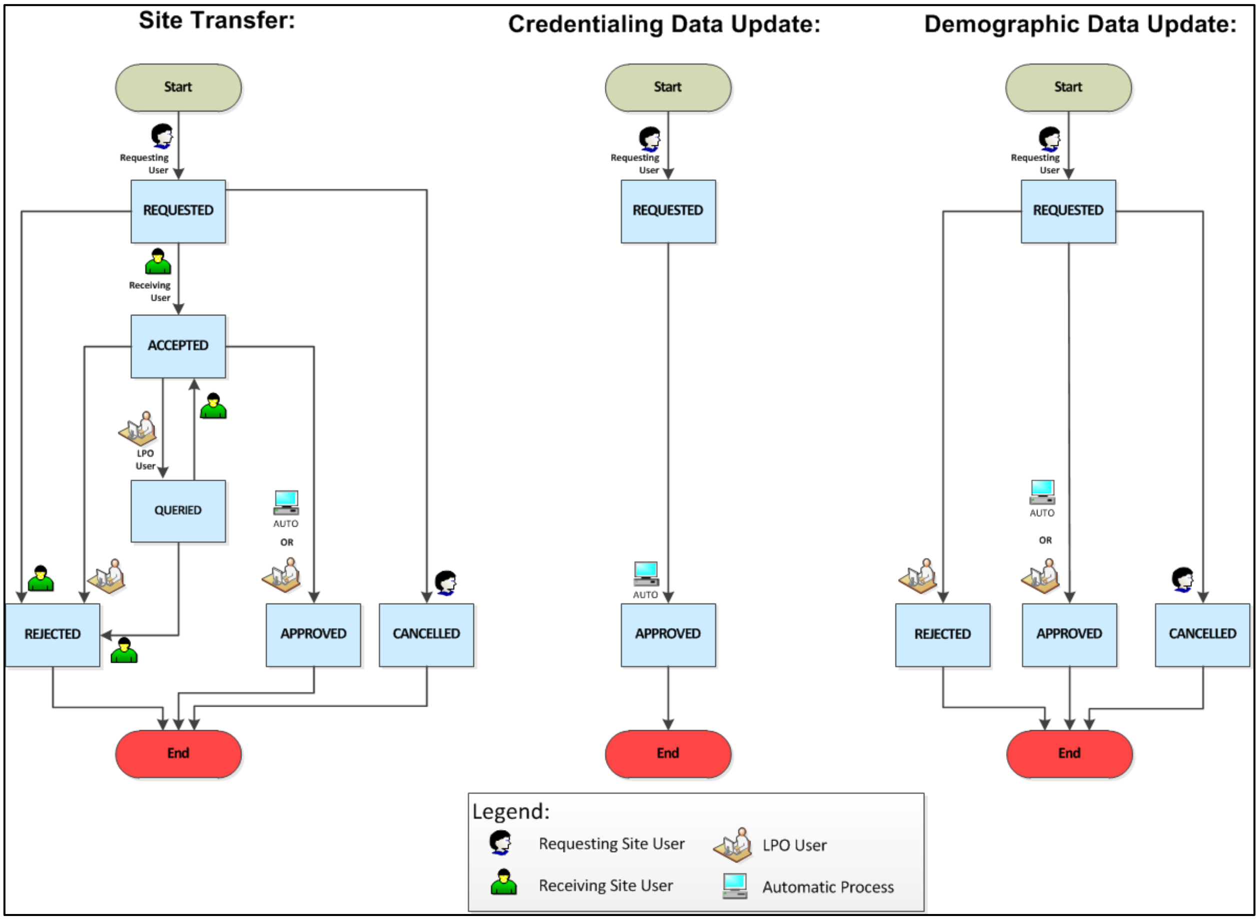


Figure 46: T&UM Request Statuses

Table 2: T&UM Statuses

#	Status Name	Description
1	REQUESTED	The initial T&UM status for all requests. During this stage the request ID is generated, and the request enters the In-Progress subtab.
2	CANCELLED	A user from the transferring or requesting site cancelled the request while it was in a REQUESTED status. This is a terminal status (these requests cannot be re-activated). The request will enter the History subtab.
3	ACCEPTED	A site transfer request was accepted by the receiving site. Depending upon the configurations, this request will either go to the LPO for manual review, or automatically enter an APPROVED status. This status only applies to site transfer requests.
4	REJECTED	A request that is not accepted or approved by the reviewing party (either the receiving site or the LPO). This is a terminal status. The request will enter the History subtab. No updates will be applied. This status only applies to site transfer and demographic data update requests.
5	QUERIED	A site transfer request that was sent back to the receiving site for review. These requests will remain in the In-Progress subtab. This status only applies to site transfer requests.
6	APPROVED	A request that was approved by the LPO reviewer or was automatically approved due to configurations. This is a terminal status. The request will enter the History subtab.

6.8 Notification Emails

During the lifecycle of a T&UM request CTSU staff, LPO staff, the PMB, and site staff may be sent automated emails so that the appropriate parties are aware of pertinent information regarding a T&UM request.

Table 3 describes when automated notification emails are sent and to which users.

Contact CTSU for assistance with subscribing email addresses for T&UM email notifications. CTSU must enable non-Westat email addresses for the non-production environments (such as for User Acceptance Testing (UAT) within uat-open.ctsu.org)

Table 3: List of Email Notification Triggers and their Recipients

T&UM Event	Email Recipients
Site Transfer (request created by the transferring site)	Contact at the transferring site, contact at the receiving site and persons with the LPO lead roles at the transferring and receiving sites.
Site Transfer (request accepted by the receiving site)	Contact at the transferring site, contact at the receiving site, persons with the LPO lead roles at the transferring and receiving sites, and subscribed users.
Site Transfer (request rejected by the receiving site)	Contact at the transferring site, contact at the receiving site, and persons with the LPO lead roles at the transferring and receiving sites.

T&UM Event	Email Recipients
Site Transfer (request queried by the LPO)	Contact at the transferring site, contact at the receiving site, persons with the LPO lead roles at the transferring and receiving sites, contact at the LPO, and subscribed users.
Site Transfer (request rejected or approved by the LPO)	Contact at the transferring site, contact at the receiving site, persons with the LPO lead roles at the transferring and receiving sites, contact at the LPO, subscribed users, and the PMB (when CTEP holds the IND.
Site Transfer (request cancelled by the transferring site)	Contact at the transferring site, contact at the receiving site, and persons with the LPO lead roles at the transferring and receiving sites.
Credentialing Date Update (request is automatically approved)	Contact at the requesting site, persons with the LPO lead roles at the requesting site, subscribed users, and the PMB (when CTEP holds the IND.
Demographic Data Update (request created by the requesting site)	Contact person at the requesting site, persons with LPO lead roles at the requesting site, and subscribed users.
Demographic Data Update (request is rejected or approved by the LPO)	Contact person at the requesting site, persons with LPO lead roles at the requesting site, subscribed users, and the LPO contact person.
Demographic Data Update (request is cancelled by the requesting site)	Contact person at the requesting site, persons with LPO lead roles at the requesting site, and subscribed users.
A T&UM synchronization request (for a RandoNode or Rave target) entered a FAILED status.	Subscribed LPO users (contact CTSU for assistance).

6.9 Systems that are Automatically Updated

After T&UM requests are approved, the updates are automatically applied to the following systems:

- OPEN/RSS.
- LPO RandoNodes:
    - For LPO RandoNodes to be automatically updated when T&UM transactions are approved, the LPO must either update their RandoNode Starter Kit to version 3.0 or update their existing RandoNode to support the new doRegister operations for the T&UM (TRANSFER_SITE, UPDATE_CREDENTIALING_DATA, UPDATE_DEMOGRAPHY_DATA). Please note that CTSU's support of RandoNode Starter Kits prior to version 3.0 ended on December 31, 2014, so it is recommended that the LPOs upgrade their RandoNode Starter Kit prior to that date.
    - When OPEN demography data are updated, they are synchronized in all steps within OPEN. Once Randonode receives a transaction specifying which demography data were updated, it is up to RandoNode to ensure that the

demographic data are updated across all protocol steps within their local databases.

- Rave:
    - For LPOs that initialize subjects to Rave, the LPO will be responsible for updating the data in Rave for the approved T&UM requests. LPO staff that subscribe to email notifications for approved T&UM requests will be notified. The LPO staff will manually perform the T&UM updates in Rave.
    - For LPOs where OPEN initializes subjects in Rave, CTSU will push the T&UM transactions to Rave for Credentialing Data Updates and Demographic Data Updates. Site transfer requests cannot be automatically updated in Rave until an Application Programming Interface (API) is obtained from Medidata; once obtained, a future version of OPEN will support the automatic update of site transfer requests to Rave. The LPOs are responsible for manually updating T&UM requests in Rave for site transfer requests. The LPO will be notified by email regarding approved site transfer requests.

When a RandoNode or Rave synchronization transaction fails in CENTER, it will automatically re-queue within 5 minutes (initially). For subsequent failures, the transaction will automatically re-queue at a longer interval (which increases incrementally after each failure).

If the Disease Code question is hidden in the OPEN enrollment form that is associated with a T&UM request, the field will not be included in the clinical data that is generated for the T&UM RandoNode synchronization request.

6.10 T&UM Data Validations

This section lists the validations that are performed on the data included in T&UM requests.

General Validations:

- If a patient enrollment has an In Progress next-step OPEN patient enrollment, a T&UM request cannot be created for that subject enrollment.
- If a patient enrollment has an In Progress T&UM request, another T&UM request cannot be created for that subject enrollment.
- If an In Progress T&UM request exists for a subject enrollment, a next-step OPEN subject enrollment cannot be initiated for that subject’s enrollment.
- The person drop-down menus will load persons who have an active roster affiliation with the site in question (for all persons except Credit Investigator).

Site Transfer Validations

When a user clicks the *Submit* button to initiate a site transfer request, the following validation will run:

- For studies with a Protocol Information Office (PIO) status other than active, the receiving site must have a current Institutional Review Board (IRB) Approval.
- The treating investigator at the receiving site must have an active status with CTEP.

- Receiving sites with a Withdrawn site registration status will not be allowed, even if the study is active or the receiving Site has a valid IRB Approval.
- The treating investigator must have an active roster affiliation with a participating organization.

During a site transfer request, when a site user clicks the Accept button for a request, or a LPO user clicks the Approve button for a request, the following validations will run:

- For protocols with Non-Active statuses:
  - If the case status is Active Treatment, the receiving site must have an Institutional Review Board (IRB) approval in the RSS and must comply with all PSRs.
  - If the case status is Follow-up, the receiving site must have an IRB approval in RSS and all PSRs do not need to be complied.
  - If the protocol requires a Delegation of Tasks Log (DTL), regardless of the case status, the receiving site must have an approved DTL. This is a separate check completed in OPEN.
- For studies with an active status, the receiving site must have an approved site registration status for the study regardless of the subject case status.
- The treating investigator at the receiving site must have an active status with CTEP.
- The receiving site must be an Active Treatment member of the organization receiving follow-up credit.
- The Credit Investigator at the receiving site must have an active status on the credited organizations roster for the receiving site.
- Receiving sites with a withdrawn site registration status will not be allowed, even if the study is active or the receiving site has a valid IRB Approval.
- If the receiving site is a member of the Network Group that was credited by the transferring site, the credited organization must stay the same.
- For pre-NCTN enrollments, the credited group must be the post-NCTN Network Group that replaced the pre-NCTN Cooperative Group; however, if the receiving site is not a member of the post-NCTN Network Group, another group may be selected.
- The treating investigator must have an active roster affiliation with a participating organization.

Credentialing Data Update Validations

During a Credentialing Data Update, when a site user clicks the Submit button, the following validations will run:

- For studies with an active status, the site must have an approved site registration status.
- For studies with a status other than active, the site must have a current IRB approval.
- The treating investigator must have an active status with CTEP.

- The site must be an active treatment member of the organization receiving follow-up credit.
- The treating investigator is active on the credited organization roster for the site.
- Sites with a Withdrawn status cannot complete and T&UM request, even if the study is active or the IRB Approval is valid.
- If the subject enrollment was completed more than 7 calendar days ago, the credited Network Group must stay the same.
- The credit investigator drop-down menu will only display persons that are active on the credited organization’s roster.
- If the credited group is an NCTN organization, a validation will run when a user clicks the continue button, to ensure that the credit investigator is active on the credited group’s roster. If the credited group is a pre-NCTN Cooperative Group, the credit investigator validation will not run because the credit investigator is no longer on the pre-NCTN Cooperative Group’s roster (and the Network Group Credit field will not be updateable).

Demographic Data Update Validations

During a demographic data update, when a site user clicks the Submit button, Demography screen validations (edit checks) configured by the LPO will validate the data. If any of the validations fail, the user will receive an error message.

Only edit checks that have the primary question configured for a Demography screen question will operate for Demographic Data Update validations.