

CTSUS

Cancer Trials Support Unit

OPEN T&UM Quick Reference Site User Guide

Revision 16

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Document Information

Revision Information for the OPEN T&UM Quick Reference Site User Guide

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All screenshots are sourced from [OPEN Portal](#).

Table of Contents

OPEN T&UM QUICK REFERENCE SITE USER GUIDE.....	I
1. INTRODUCTION.....	1
1.1 Organization of this Document.....	1
1.2 Web Addresses for CTSU Applications	1
2. OVERVIEW OF THE T&UM	2
2.1 Background	2
2.2 Accessing the T&UM.....	2
3. SITE TRANSFER REQUESTS	5
3.1 Initiating a Site Transfer Request.....	6
3.1.1 Site Transfers for Patients in a Follow-up Case Status	8
3.1.2 Cancelling a Site Transfer Request	8
3.2 Review of the Site Transfer Request by the Receiving Site	8
3.3 Review of the Site Transfer Request by the Lead Protocol Organization (If Applicable)	12
4. CREDENTIALING DATA UPDATE REQUESTS	13
4.1 Requirements for Updating Network Credit Group	13
4.2 Creating a Credentialing Data Update Request.....	13
5. DEMOGRAPHIC DATA UPDATE REQUESTS	17
5.1 Initiating a Demographic Data Update Request.....	18
6. ADDITIONAL INFORMATION REGARDING THE T&UM.....	22
6.1 List of Organization that Participate in the T&UM	22
6.2 T&UM History Subtab.....	23
6.3 T&UM Patient History Report.....	24
6.4 T&UM Help Tool	25
6.5 Locating T&UM Requests in the History Tab of OPEN.....	27
6.6 T&UM Statuses	29
6.7 T&UM Roles	29
6.8 Systems that are Automatically Updated	29
6.9 T&UM Data Validations	30

List of Figures

FIGURE 1: THE T&UM TAB OF OPEN.....	2
FIGURE 2: THE T&UM CREATE NEW SUBTAB	3
FIGURE 3: THE T&UM HISTORY SUBTAB	4
FIGURE 4: THE T&UM HELP TOOL SUBTAB.....	4
FIGURE 5: HIGH-LEVEL WORKFLOW FOR A SITE TRANSFER REQUEST.....	5
FIGURE 6: SELECT THE SITE TRANSFER OPTION TO BEGIN A SITE TRANSFER REQUEST.....	6
FIGURE 7: COMPLETE THE SITE TRANSFER REQUEST FORM.....	7
FIGURE 8: T&UM SITE TRANSFER REQUEST INITIATED.....	7
FIGURE 9: CANCELLING A SITE TRANSFER THAT IS IN A REQUESTED STATUS	8
FIGURE 10: CLICK THE REVIEW REQUEST BUTTON TO REVIEW THE SITE TRANSFER REQUEST	9
FIGURE 11: CLICK THE REVIEW REQUEST BUTTON FOR A SITE TRANSFER.....	9
FIGURE 12: COMPLETE THE REVIEW REQUEST FORM FOR A SITE TRANSFER.....	10
FIGURE 13: A TRANSPLANT CREDIT QUESTION WILL APPEAR FOR COG AND COGC PROTOCOLS.....	11
FIGURE 14: MESSAGE CONFIRMS THAT THE SITE TRANSFER WAS ACCEPTED, AND AWAITING LPO REVIEW	11
FIGURE 15: CREDENTIALING DATA UPDATE PROCESS WORKFLOW	13
FIGURE 16: SELECT THE CREDENTIALING DATA UPDATE CHOICE.....	14
FIGURE 17: SELECT A SUBJECT ENROLLMENT.....	14
FIGURE 18: MAKE THE NEEDED UPDATES ON THE CREDENTIALING DATA UPDATE REQUEST FORM.....	15
FIGURE 19: SCREEN CONFIRMING THE CREDENTIALING DATA UPDATE WAS APPROVED	16
FIGURE 20: HIGH-LEVEL OVERVIEW OF THE DEMOGRAPHIC DATA UPDATE PROCESS	17
FIGURE 21: SELECT THE DEMOGRAPHIC DATA UPDATE CHOICE	18
FIGURE 22: SELECT THE SUBJECT ENROLLMENT.....	19
FIGURE 23: FIRST PAGE OF THE DEMOGRAPHIC DATA UPDATE REQUEST FORM.....	19
FIGURE 24: SECOND PAGE OF THE DEMOGRAPHIC DATA UPDATE REQUEST FORM	20
FIGURE 25: MESSAGE CONFIRMING REQUEST CREATED, AND AWAITING LPO REVIEW	20
FIGURE 26: AUTOMATED LIST OF ORGANIZATIONS THAT PARTICIPATE IN THE T&UM.....	22
FIGURE 27: T&UM CONFIGURATION DETAILS FOR AN ORGANIZATION	22
FIGURE 28: THE BROWSE SCREEN SHOWS SUBJECTS THAT ARE STILL AT THE USERS SITE(S).....	23
FIGURE 29: THE ARCHIVE SCREEN SHOWS SUBJECTS THAT ARE NO LONGER AFFILIATED WITH THE USERS SITE(S).	23
FIGURE 30: THE T&UM REPORT BUTTON LAUNCHES THE T&UM PATIENT HISTORY REPORT	24
FIGURE 31: T&UM PATIENT HISTORY REPORT	25
FIGURE 32: ENTER SEARCH CRITERIA IN THE T&UM HELP TOOL	26
FIGURE 33: T&UM HELP TOOL RESULTS	26
FIGURE 34: DETAILS POPUP FOR THE T&UM HELP TOOL.....	27

FIGURE 35: THE T&UM TYPE COLUMN IDENTIFIES ENROLLMENTS WITH APPROVED T&UM REQUESTS 27

FIGURE 36: RESULTS CAN BE FILTERED BY THE T&UM TYPE..... 28

FIGURE 37: THE FILTERED RESULTS FOR THE T&UM TYPE..... 28

List of Tables

TABLE 1: WEB ADDRESSES FOR CTSU APPLICATIONS..... 1
TABLE 2: T&UM STATUSES..... 29

1. Introduction

This document provides information for using the Oncology Patient Enrollment Network (OPEN) Transfer and Update Module (T&UM), including instructions for creating T&UM requests, reviewing T&UM requests, and additional background information regarding the T&UM. (Note that terms *patient* and *subject* are used interchangeably throughout the document.)

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
CTSUSU Members' website	http://www.ctsu.org

2. Overview of the T&UM

2.1 Background

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

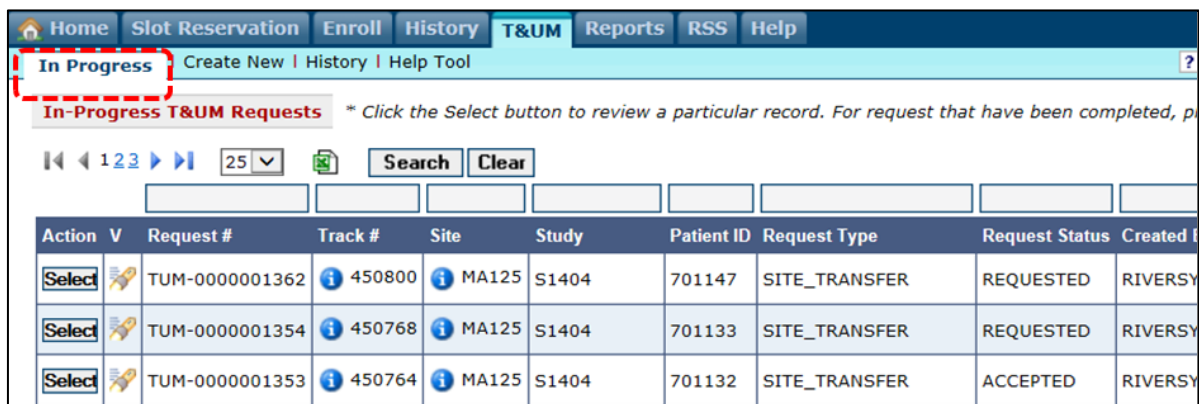
The T&UM within OPEN was created as the central location for site staff to request data changes (Site Transfers, Credentialing Data Updates, and Demographic Data Updates) for completed subject enrollments that are maintained in OPEN. Each request will undergo automatic validations and the system allows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

2.2 Accessing the T&UM

The T&UM is located within its own tab of OPEN and it is accessible to site users with either the Site Registrar or Site Admin OPEN roles.

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

When a user clicks the *T&UM* tab they will be defaulted to the T&UM’s *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 to the review of existing requests.



The screenshot shows the 'T&UM' tab selected in the top navigation bar. Below it, the 'In Progress' subtab is active and highlighted with a red dashed box. The page displays 'In-Progress T&UM Requests' with a search bar and a table of requests. The table has columns for Action, Request #, Track #, Site, Study, Patient ID, Request Type, Request Status, and Created. Three requests are listed, all for 'SITE_TRANSFER' at site 'MA125' for study 'S1404'.

Action	Request #	Track #	Site	Study	Patient ID	Request Type	Request Status	Created
Select	TUM-0000001362	450800	MA125	S1404	701147	SITE_TRANSFER	REQUESTED	RIVERSY
Select	TUM-0000001354	450768	MA125	S1404	701133	SITE_TRANSFER	REQUESTED	RIVERSY
Select	TUM-0000001353	450764	MA125	S1404	701132	SITE_TRANSFER	ACCEPTED	RIVERSY

Figure 1: The T&UM Tab of OPEN

The T&UM's *Create New* subtab (see Figure 2) enables site users to initiate T&UM requests and to view the list of LPOs that participate on the T&UM.

The Transfer and Update Module(T&UM) handles data update requests (involving updates to a patient's institution, credentialing data, and demographic data) for completed patient enrollments that are maintained in OPEN.

[Click here](#) to access the tool for locating new sites for moving patients.

The T&UM can update enrollment data for these organizations: [ABTC](#), [ALLIANCE](#), [BMTCTN](#), [CITN](#), [COG](#), [COGC](#), [ECOG-ACRIN](#), [NCI](#), [NCIC](#), [NCICCR](#), [NCIDTC](#), [NCILYMB](#), [NRG](#), [PBTC](#), [PEP-CTN](#), [SWOG](#), [USMCI](#). Click the hyperlink for an organization to view their T&UM Configuration Report.

Select the type of T&UM request that you would like to perform:

T&UM Request Type	Description
<input type="radio"/> Site Transfer	Update the institution associated with a patient enrollment (this may involve updates to credentialing data). ⚠ For changes to a patient's institution, the transferring sites must initiate a conversation with potential receiving sites on accepting their patients, and confirm agreement prior to initiating the site transfer process in the T&UM tab of OPEN. All outstanding data up to this point must be submitted by the transferring site and all queries must be resolved.
<input type="radio"/> Credentialing Data Update	Update credentialing data for a patient that will remain at the same institution.
<input type="radio"/> Demographic Data Update	Update demographic data for a patient. ⚠ Demography data in OPEN should reflect the patient status at the time of enrollment. Corrections should be made only for data entry errors or if additional demography information becomes available after enrollment.

Figure 2: The T&UM Create New Subtab

The T&UM's *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. The T&UM History subtab also shows records that were previously associated with the user's sites (but have since moved due to a T&UM Site Transfer).

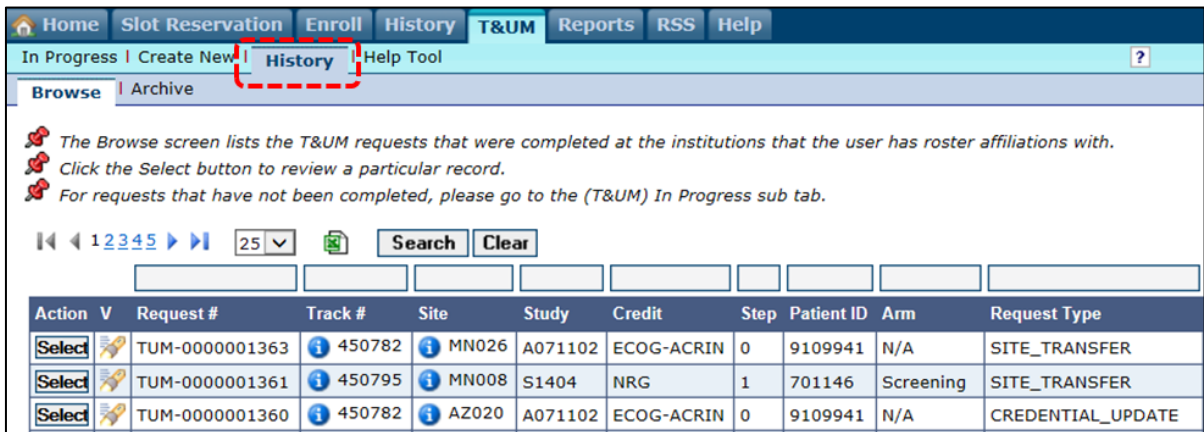


Figure 3: The T&UM History Subtab

The T&UM's *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).

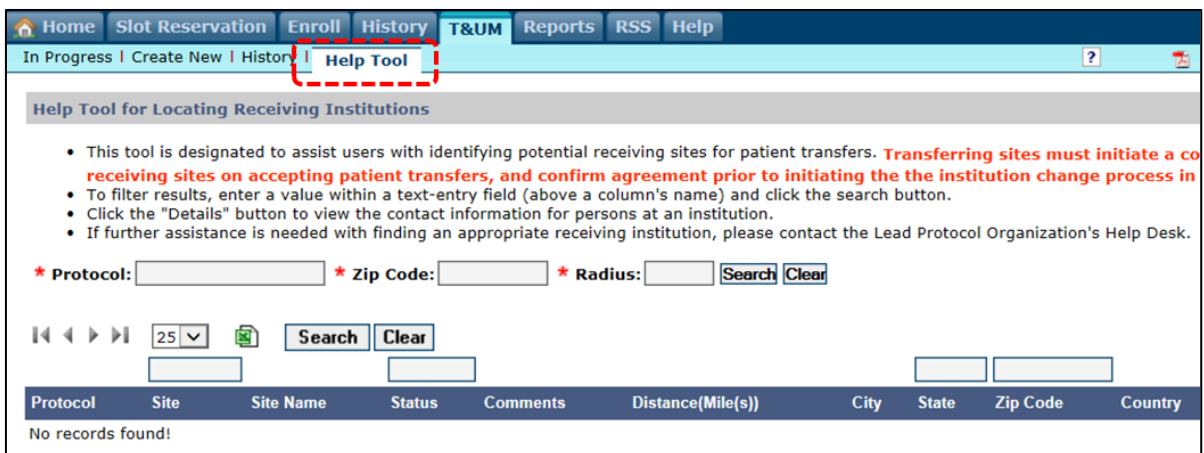


Figure 4: The T&UM Help Tool Subtab

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 (note some fields may not be updateable per the LPO):

- 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 the site 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.

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.

Figure 5 provides a high-level overview of a site transfer requests workflow.

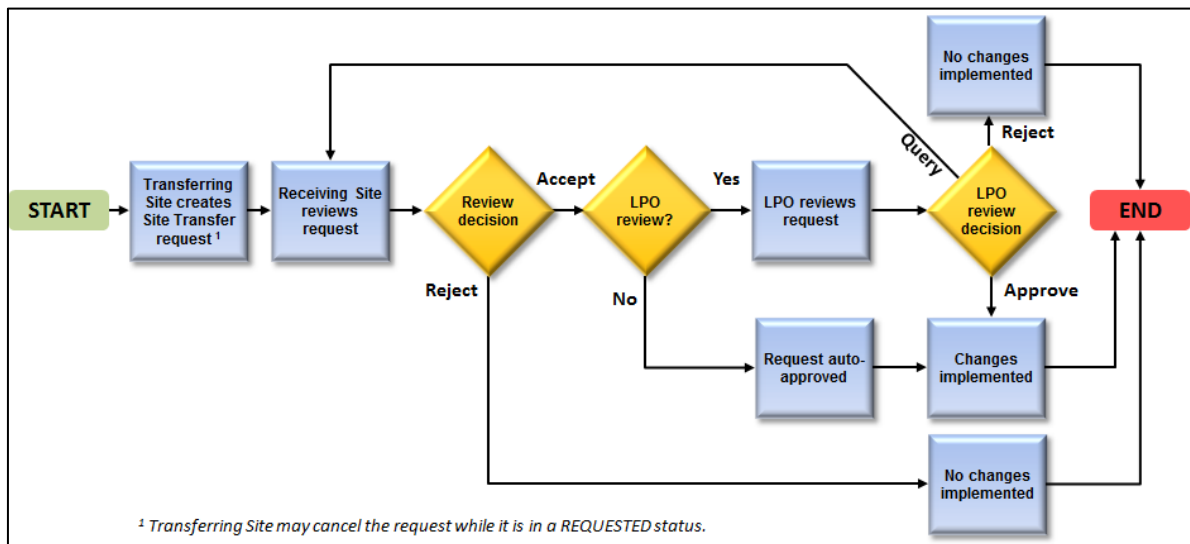


Figure 5: High-Level Workflow for a Site Transfer Request

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).

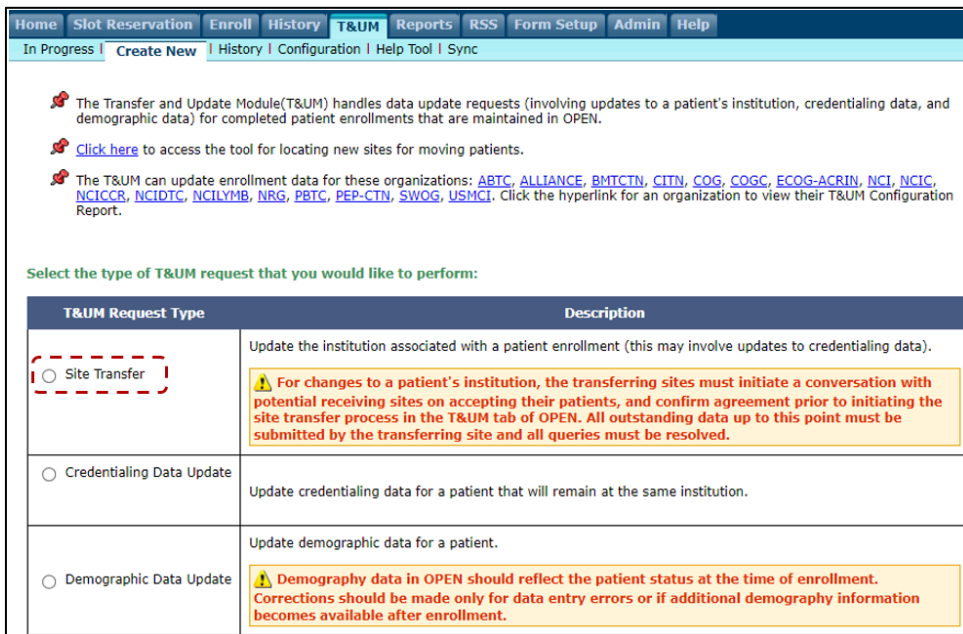
3.1 Initiating a Site Transfer Request

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 may create T&UM requests.

A user from the transferring site can use the Help Tool (which is located in the T&UM's Help Tool subtab or within the T&UM's 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 *T&UM's* Create New subtab.
- 4) Click the *Site Transfer* option.



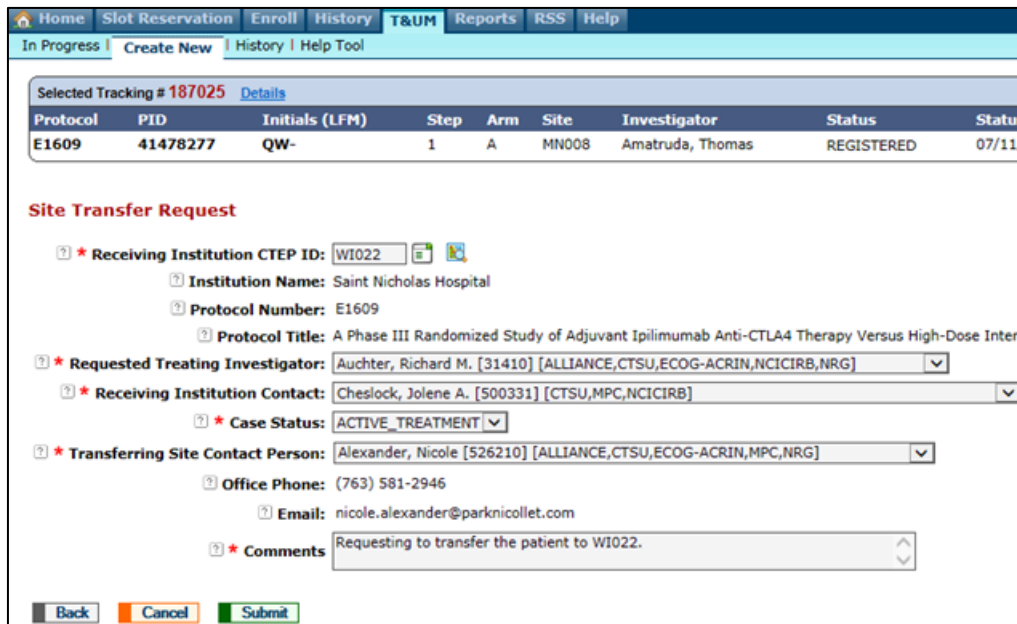
The screenshot shows the 'T&UM' section of the OPEN system. The 'Create New' subtab is active. Below the navigation tabs, there are instructions about the T&UM module and a list of organizations it supports. A section titled 'Select the type of T&UM request that you would like to perform:' contains a table with three options: 'Site Transfer', 'Credentialing Data Update', and 'Demographic Data Update'. The 'Site Transfer' option is selected, indicated by a red dashed box around its radio button. A yellow warning box is visible next to the 'Site Transfer' option, stating: 'For changes to a patient's institution, the transferring sites must initiate a conversation with potential receiving sites on accepting their patients, and confirm agreement prior to initiating the site transfer process in the T&UM tab of OPEN. All outstanding data up to this point must be submitted by the transferring site and all queries must be resolved.'

T&UM Request Type	Description
<input checked="" type="radio"/> Site Transfer	Update the institution associated with a patient enrollment (this may involve updates to credentialing data). ⚠ For changes to a patient's institution, the transferring sites must initiate a conversation with potential receiving sites on accepting their patients, and confirm agreement prior to initiating the site transfer process in the T&UM tab of OPEN. All outstanding data up to this point must be submitted by the transferring site and all queries must be resolved.
<input type="radio"/> Credentialing Data Update	Update credentialing data for a patient that will remain at the same institution.
<input type="radio"/> Demographic Data Update	Update demographic data for a patient. ⚠ Demography data in OPEN should reflect the patient status at the time of enrollment. Corrections should be made only for data entry errors or if additional demography information becomes available after enrollment.

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.



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

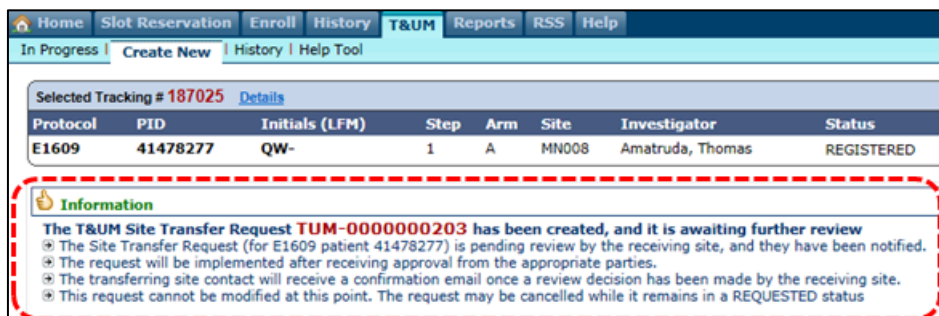
Site Transfer Request

* Receiving Institution CTEP ID: WI022
 Institution Name: Saint Nicholas Hospital
 Protocol Number: E1609
 Protocol Title: A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interf...
 * Requested Treating Investigator: Auchter, Richard M. [31410]
 * Receiving Institution Contact: Cheslock, Jolene A. [500331]
 * Case Status: ACTIVE_TREATMENT
 * Transferring Site Contact Person: Alexander, Nicole [526210]
 Office Phone: (763) 581-2946
 Email: nicole.alexander@parknicollet.com
 * Comments: Requesting to transfer the patient to WI022.

Back Cancel Submit

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.



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

Information

The T&UM Site Transfer Request TUM-000000203 has been created, and it is awaiting further review

- The Site Transfer Request (for E1609 patient 41478277) is pending review by the receiving site, and they have been notified.
- The request will be implemented after receiving approval from the appropriate parties.
- The transferring site contact will receive a confirmation email once a review decision has been made by the receiving site.
- This request cannot be modified at this point. The request may be cancelled while it remains in a REQUESTED status

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 without activity.

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

The following are site transfer requirements for patients with follow-up case status where 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 as long as it remains in a REQUESTED status. Complete these steps to cancel a site transfer request:

- 1) Log in to OPEN.
- 2) Click the *T&UM* tab, arrive at the T&UM's 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.

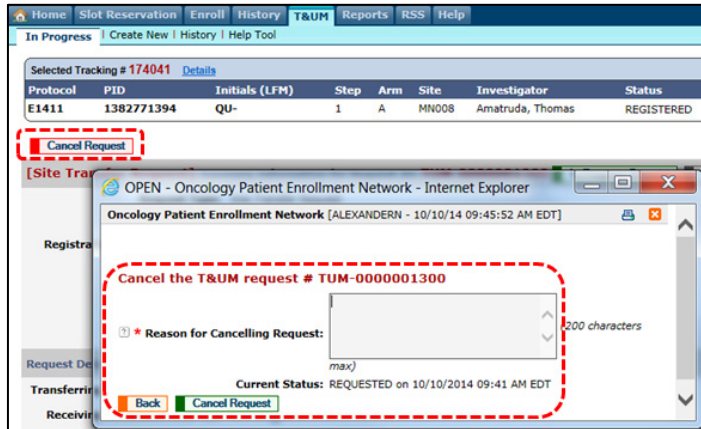


Figure 9: Cancelling a Site Transfer that is in a REQUESTED Status

- 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.

Receiving site users will complete these steps to review pending site transfer requests:

- 1) Login to OPEN.
- 2) Click the *T&UM* tab, arrive at the T&UM's In Progress subtab by default.
- 3) Locate the request and click the *Select* button for its row.

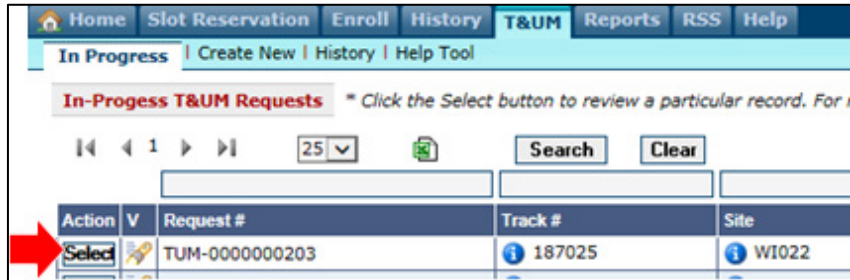


Figure 10: Click the Review Request Button to Review the Site Transfer Request

- 4) Click the *Review Request* button.



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

- 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.

[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-000000203** [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,CTSUSU,ECOG-ACRIN,NCICIRB,NRG]
	Contact person sample submission	Davies, Brenda L. [509653] [ALLIANCE,CTSUSU,ECOG-ACRIN,NRG]
	Consenting Person	Auchter, Richard M. [31410] [ALLIANCE,CTSUSU,ECOG-ACRIN,NCICIRB,NRG]
	Site Registrar	Davies, Brenda L. [509653] [ALLIANCE,CTSUSU,ECOG-ACRIN,NRG]

(If Accepting) Select the Credited Group and Credit Investigator

- Network Group Credit:
- Credit Investigator:

Provide the Contact Information for the Individual at the Receiving Site

- Receiving Site Contact:
- Office Phone: (920) 433-8272
- Email:

Provide Comments Regarding this Request

- Reviewer Comments: (Not required when accepting)

[Back](#) | [Reject Request](#) | [Accept Request](#)

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

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 subjects care.
 - 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) to allow the user to specify whether transplant credit is involved.

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).

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator
E1609	41478277	QW-	1	A	MN008	Amatruda,

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 may not require LPO review, in which case this step is not needed, and accepted requests are automatically set to an approved status and the data updates are applied.

Site and LPO users will be notified by email when a decision has been made regarding the T&UM request.

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.

Below is a list of data points that can be updated with a credentialing data update request (note that the LPO may have set 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 (RTF) Provider.

Figure 15 provides a high-level overview of the credentialing data update request process.

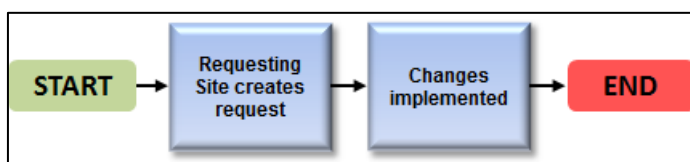


Figure 15: Credentialing Data Update Process Workflow

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 should 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) Login to OPEN.
- 2) Click the *T&UM* tab, arrive at the In Progress subtab by default.
- 3) Click the *T&UM's* Create New subtab.
- 4) Select the *Credentialing Data Update* action.

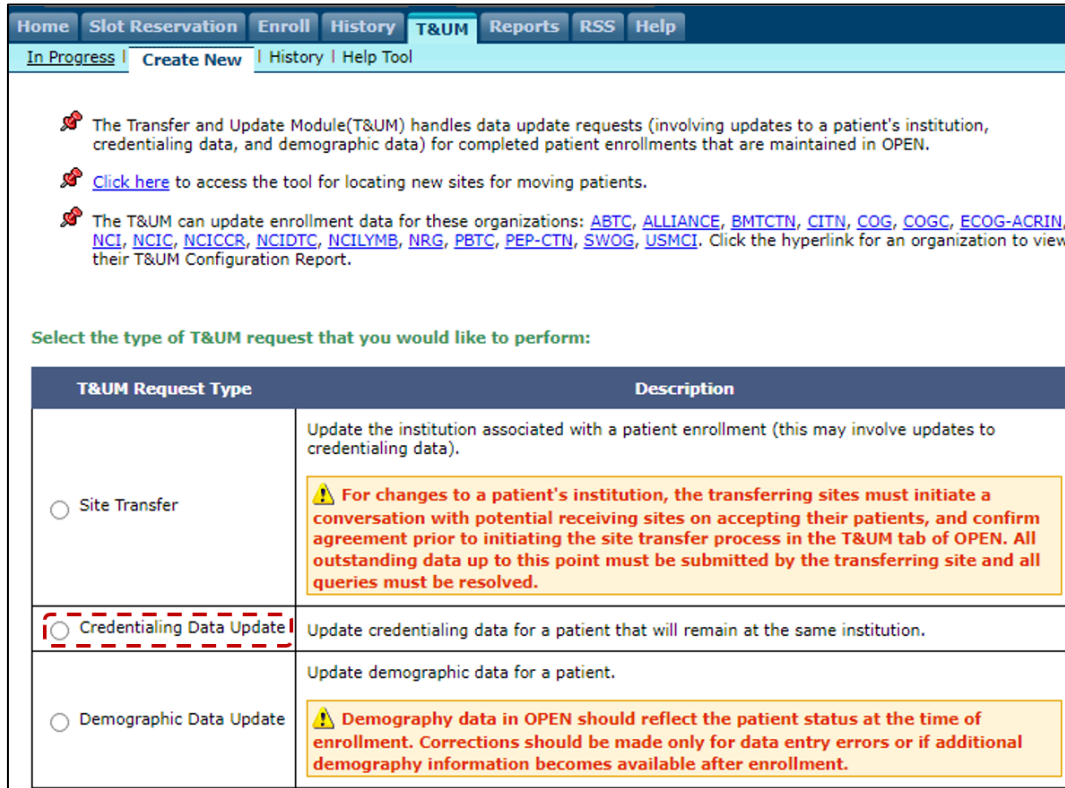


Figure 16: Select the Credentiaing Data Update Choice

- 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's enrollment and click the *Select* button for the enrollment's row.

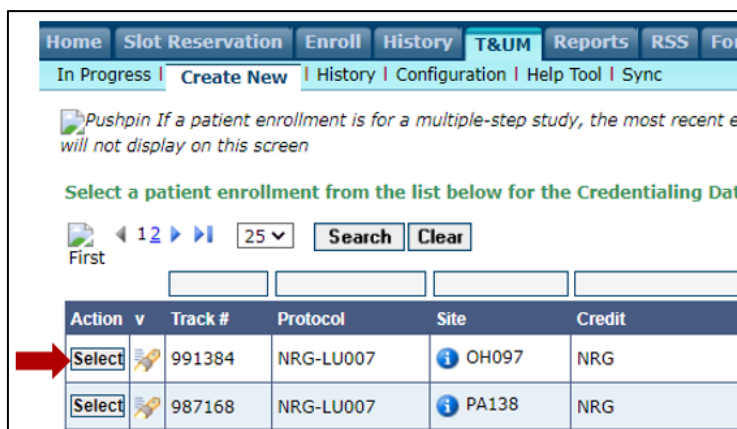


Figure 17: Select a Subject Enrollment

- 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).

- a) Please note: if the Network Group Credit is for pre-NCTN organization (e.g., the former Cooperative Groups such as GOG, ECOG, NSABP), the Network Group Credit and the Credit Investigator fields will not be updateable. This is because the seven calendar day rule requires the group to remain the same and the cooperative group rosters no longer exist.

Credentialing Data Update Request

Selected Tracking # 991384 Details

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
NRG-LU007	OH097-LU007-00033	SD-	1	Atezolizumab	OH097	Saltzman, Joel	REGISTERED	06/10/2022

Make the appropriate changes to the patient enrollment's credentialing data, and provide comments regarding this update

Credentialing Data Update Request

- Select the RT/I provider(s)
- Press to add a RT/I, or press to remove
- Protocol specific instructions:** Protocol NRG-LU007 has the following association(s): **IMRT (required), 3D (required).**

Action	Credential*	RT/I*
	IMRT	RTF-1851

- Press to add a person, or press to remove
- Protocol specific instructions:** Protocol NRG-LU007 has the following association(s): **Treating Investigator (required), Site Registrar (required).**
- Please specify a "Consenting Person" when necessary or press to remove the "Person Type" selection.

Action	Person Type*	Person Name [ID] [Registration Type] [Network Group] [IRB Match]*
	Site Registrar	Slanoc, Emilie [657273] [AP] [NRG,SWOG][]
	Consenting Person	Slanoc, Emilie [657273] [AP] [NRG,SWOG][]
	Treating Investigator	Blair, Henry F. [25899] [IVR] [NRG,SWOG][Y]

Network Group Credit: NRG *Note: The credit can only be changed within 7 calendar days from the date of enrollment.*

Credit Investigator: Blair, Henry F. [25899] [IVR] [NRG,SWOG][Y]

Requesting Contact Person: Agwa, Eberechi Sandra [57765] [IVR] [NRG,SWOG]

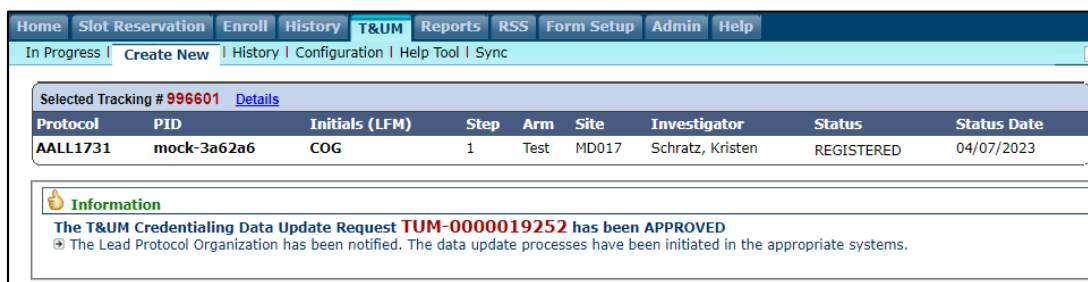
Office Phone: (216) 491-6438

Email: agwae@ccf.org

Comments: Updated Treating Investigator.

Figure 18: 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.



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

[In Progress](#) | [Create New](#) | [History](#) | [Configuration](#) | [Help Tool](#) | [Sync](#)

Selected Tracking # **996601** [Details](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
AALL1731	mock-3a62a6	COG	1	Test	MD017	Schratz, Kristen	REGISTERED	04/07/2023

Information
 The T&UM Credentialing Data Update Request **TUM-0000019252** has been **APPROVED**
 ⓘ The Lead Protocol Organization has been notified. The data update processes have been initiated in the appropriate systems.

Figure 19: 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
- Gender/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 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 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.

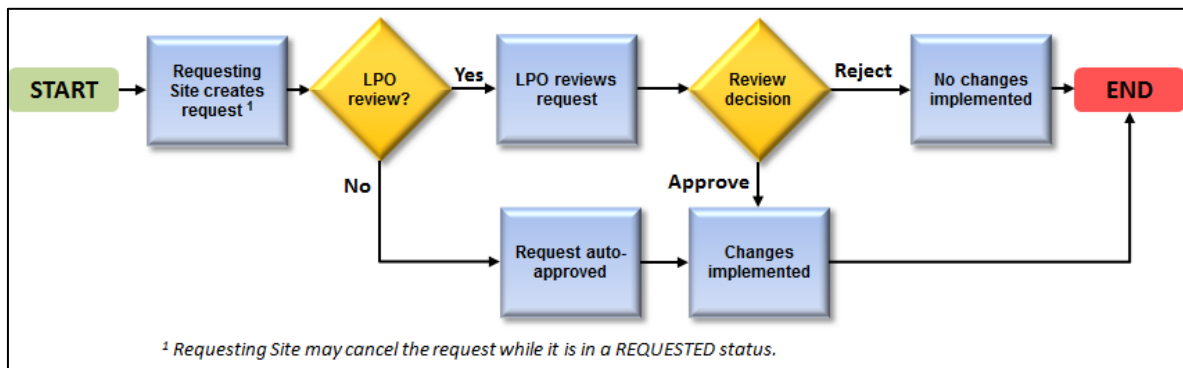


Figure 20: High-Level Overview of the Demographic Data Update Process

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 required).

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 *T&UM's* Create New subtab.
- 4) Select the *Demographic Data Update* action.

The screenshot shows the 'T&UM' section of the OPEN system. It includes a navigation bar with 'Home', 'Slot Reservation', 'Enroll', 'History', 'T&UM', 'Reports', 'RSS', and 'Help'. Below this is a sub-tab bar with 'In Progress', 'Create New', 'History', and 'Help Tool'. The main content area contains introductory text about the T&UM module and a list of organizations it supports. Below this is a section titled 'Select the type of T&UM request that you would like to perform:' which contains a table with three rows. The 'Demographic Data Update' row is highlighted with a red dashed border and has a red warning icon next to it.

T&UM Request Type	Description
<input type="radio"/> Site Transfer	Update the institution associated with a patient enrollment (this may involve updates to credentialing data). ⚠ For changes to a patient's institution, the transferring sites must initiate a conversation with potential receiving sites on accepting their patients, and confirm agreement prior to initiating the site transfer process in the T&UM tab of OPEN. All outstanding data up to this point must be submitted by the transferring site and all queries must be resolved.
<input type="radio"/> Credentialing Data Update	Update credentialing data for a patient that will remain at the same institution.
<input checked="" type="radio"/> Demographic Data Update	Update demographic data for a patient. ⚠ Demography data in OPEN should reflect the patient status at the time of enrollment. Corrections should be made only for data entry errors or if additional demography information becomes available after enrollment.

Figure 21: 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's row.



Figure 22: 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.

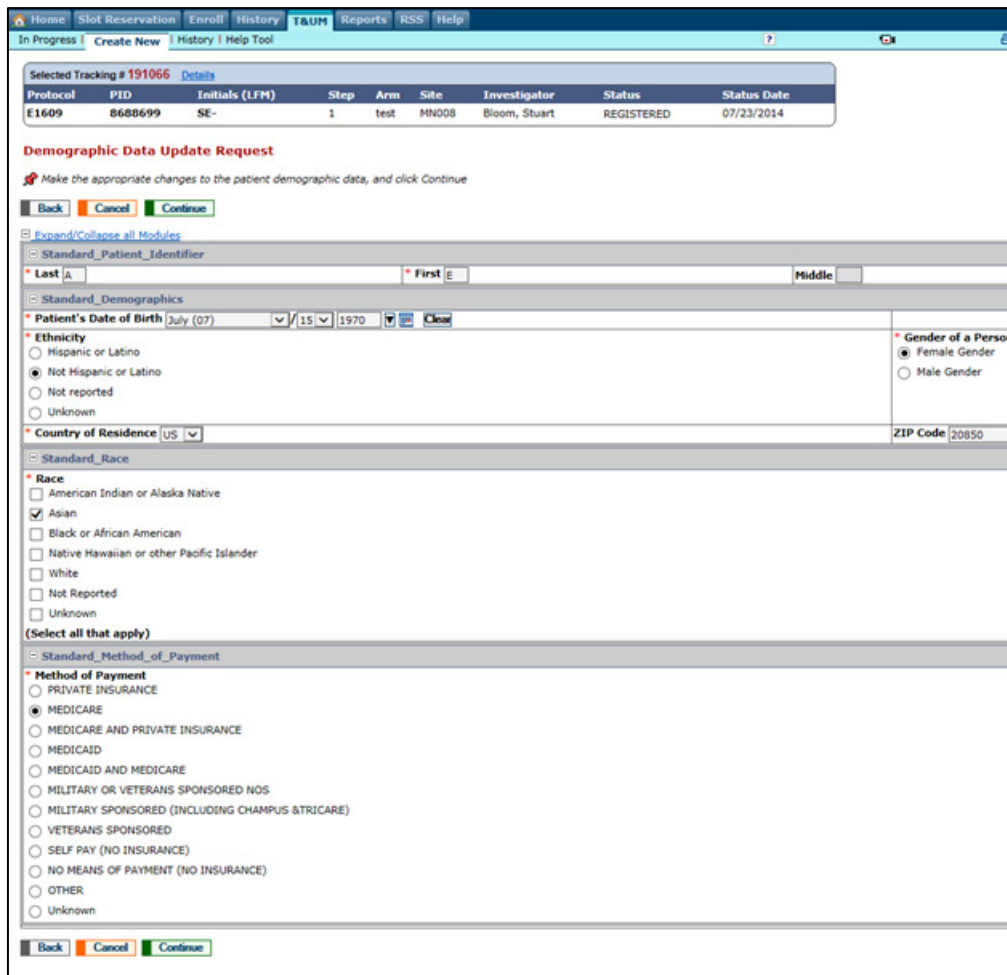
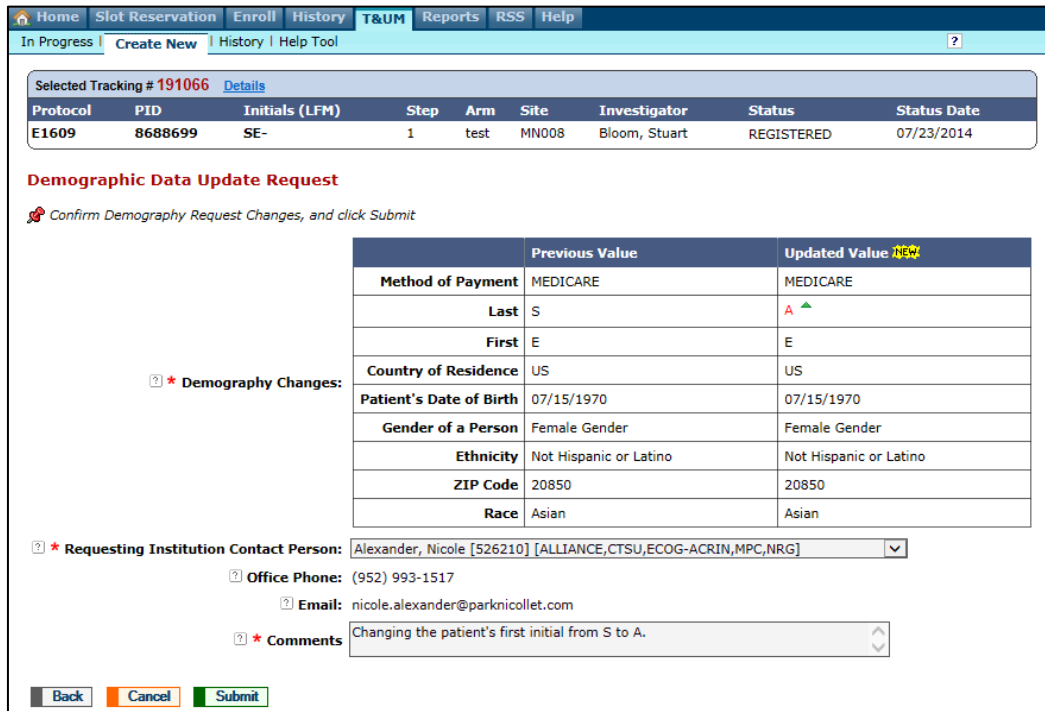


Figure 23: First Page of the Demographic Data Update Request Form

- 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.



Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1609	8688699	SE-	1	test	MN008	Bloom, Stuart	REGISTERED	07/23/2014

	Previous Value	Updated Value NEW
Method of Payment	MEDICARE	MEDICARE
Last	S	A ▲
First	E	E
Country of Residence	US	US
Patient's Date of Birth	07/15/1970	07/15/1970
Gender of a Person	Female Gender	Female Gender
Ethnicity	Not Hispanic or Latino	Not Hispanic or Latino
ZIP Code	20850	20850
Race	Asian	Asian

* Requesting Institution Contact Person: Alexander, Nicole [526210] [ALLIANCE,CTS,ECOG-ACRIN,MPC,NRG]

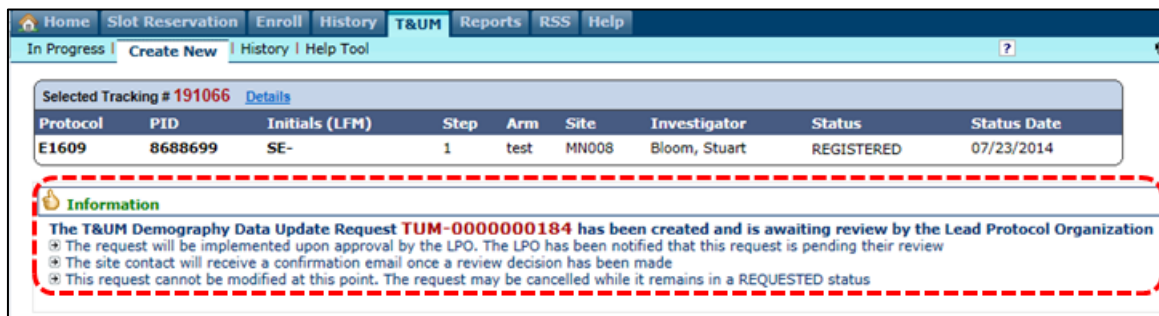
Office Phone: (952) 993-1517

Email: nicole.alexander@parknicollet.com

Comments: Changing the patient's first initial from S to A.

Figure 24: 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.



Information
 The T&UM Demography Data Update Request **TUM-000000184** has been created and is awaiting review by the Lead Protocol Organization

- The request will be implemented upon approval by the LPO. The LPO has been notified that this request is pending their review
- The site contact will receive a confirmation email once a review decision has been made
- This request cannot be modified at this point. The request may be cancelled while it remains in a REQUESTED status

Figure 25: 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.
- 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.

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 26) of LPOs that participate in the T&UM.

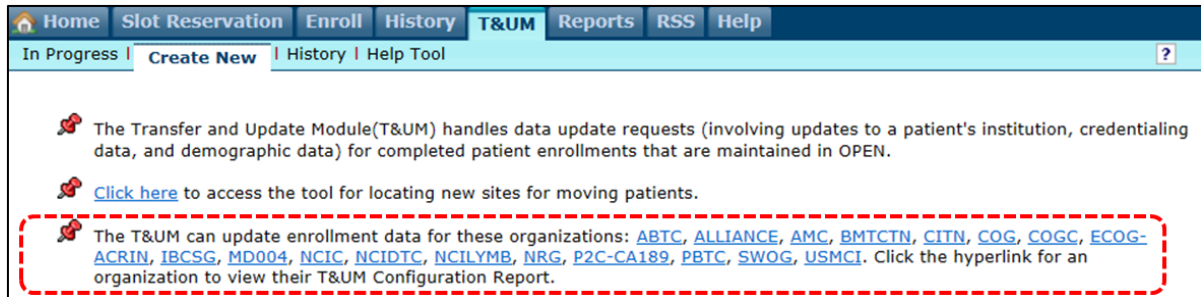


Figure 26: Automated List of Organizations that Participate in the T&UM

To view the T&UM configuration details (including any protocol-level exceptions) for any of the listed organizations, click their hyperlink (see Figure 27) 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.

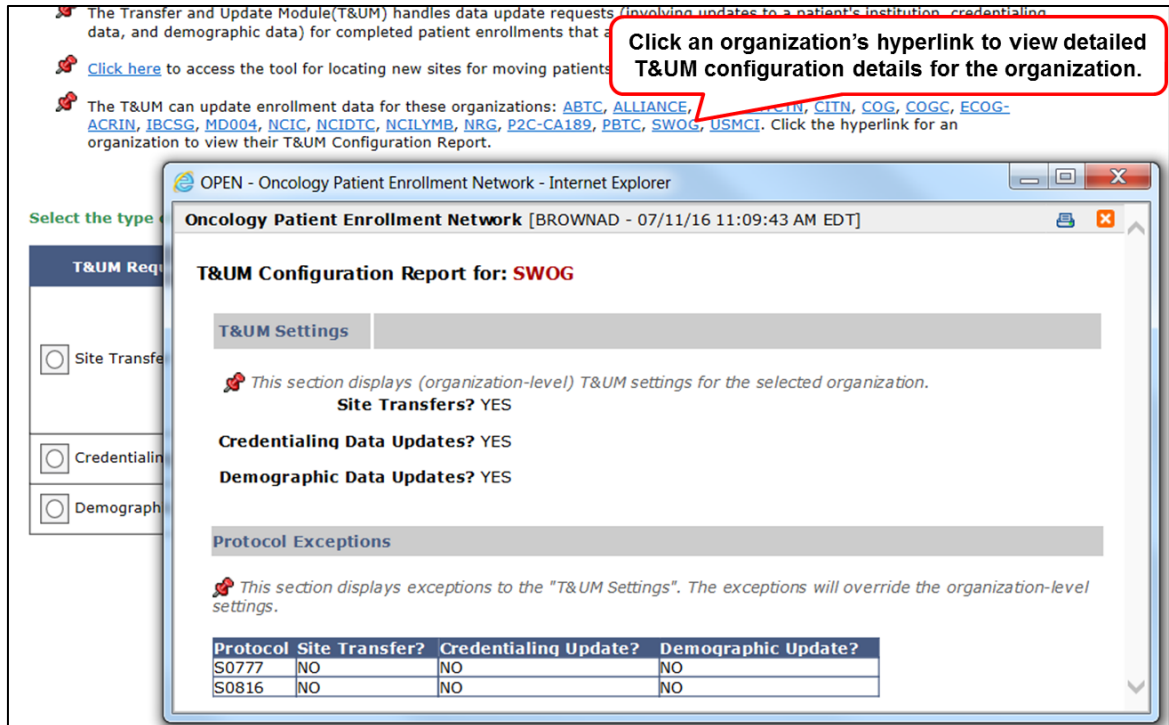


Figure 27: T&UM Configuration Details for an Organization

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.

For site users, the T&UM History subtab is divided into the Browse subtab, and the Archive subtab.

- The Browse subtab contains T&UM requests that are associated with the users site affiliations.
- The Archive subtab contains T&UM requests that were previously associated with the users site affiliations but have since been transferred to an unrelated site (due to a T&UM site transfer).

Accessing this Feature:

- 1) Login to OPEN.
- 2) Click the *History* subtab of the T&UM tab. The Browse subtab will display by default (see Figure 28).
 - a) To view a summary for a T&UM request, click the corresponding records Select button.

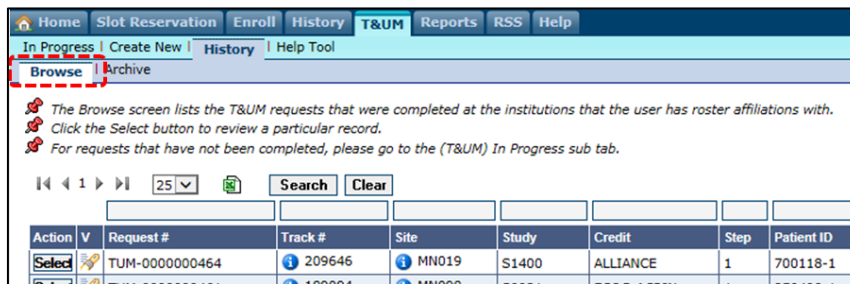


Figure 28: The Browse Screen Shows Subjects that are Still at the Users Site(s)

- b) To view a list of T&UM requests for subjects that are no longer affiliated with the users site, click the *Archive* subtab (see Figure 29). To view a summary for a T&UM request in the Archive screen, click the records corresponding Select button.

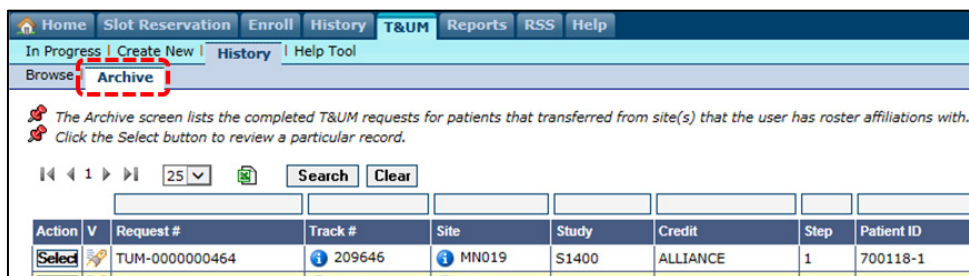


Figure 29: The Archive Screen Shows Subjects that are No Longer Affiliated with the Users Site(s)

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.

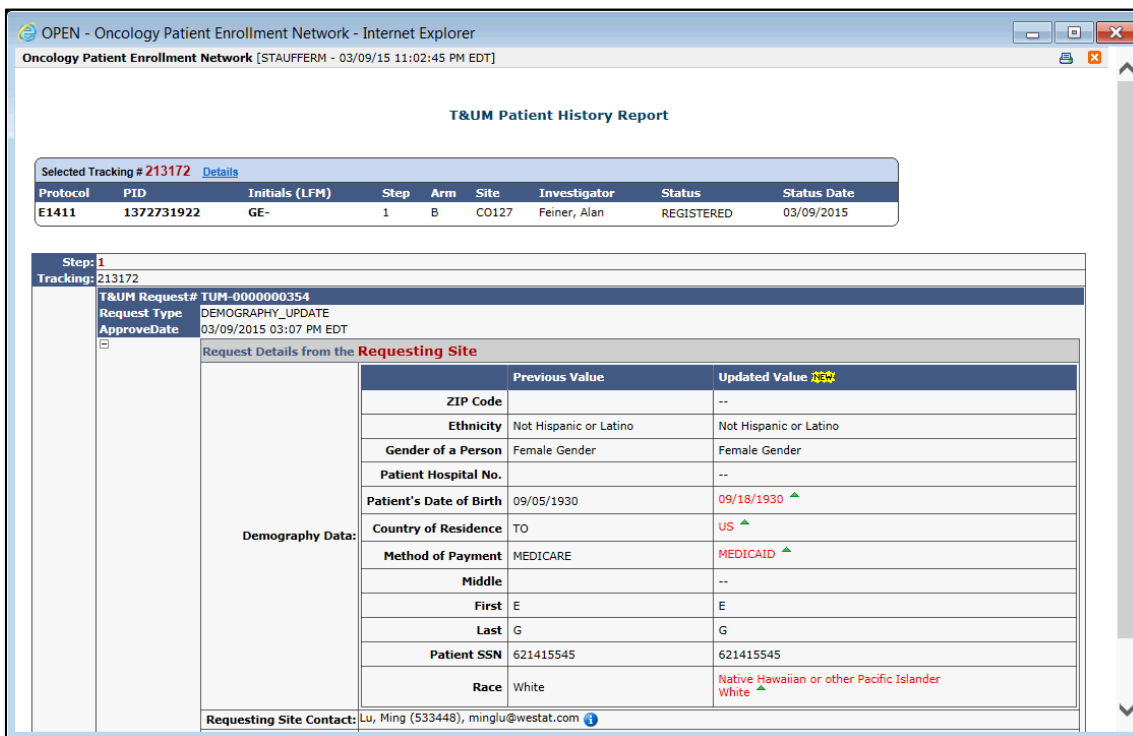
Accessing this Feature:

- 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 30: 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 (see Figure 31).



T&UM Patient History Report






Selected Tracking # **213172** [Details](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1411	1372731922	GE-	1	B	CO127	Feiner, Alan	REGISTERED	03/09/2015

Step: **1**
Tracking: **213172**

T&UM Request# TUM-000000354
Request Type DEMOGRAPHY_UPDATE
ApproveDate 03/09/2015 03:07 PM EDT

Request Details from the **Requesting Site**

	Previous Value	Updated Value 
Demography Data:		
ZIP Code		--
Ethnicity	Not Hispanic or Latino	Not Hispanic or Latino
Gender of a Person	Female Gender	Female Gender
Patient Hospital No.		--
Patient's Date of Birth	09/05/1930	09/18/1930 
Country of Residence	TO	US 
Method of Payment	MEDICARE	MEDICAID 
Middle		--
First	E	E
Last	G	G
Patient SSN	621415545	621415545
Race	White	Native Hawaiian or other Pacific Islander White 


Requesting Site Contact: Lu, Ming (533448), minglu@westat.com 

Figure 31: T&UM Patient History Report

6.4 T&UM Help Tool

The T&UM Help Tool assists with locating potential receiving sites for patients 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) Log in 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 32).

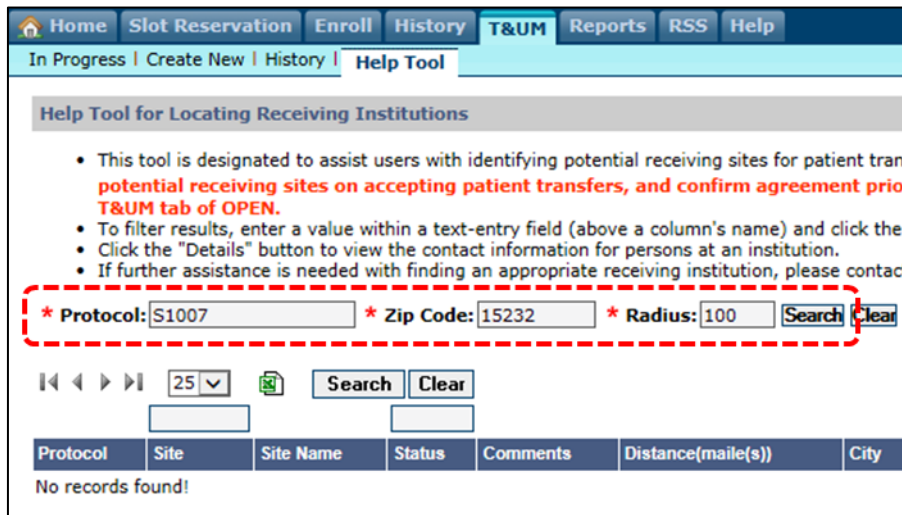


Figure 32: Enter Search Criteria in the T&UM Help Tool

- 5) Click the *Search* button.
- 6) The screen will refresh and display results using the Google Map interface (see Figure 33). 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.

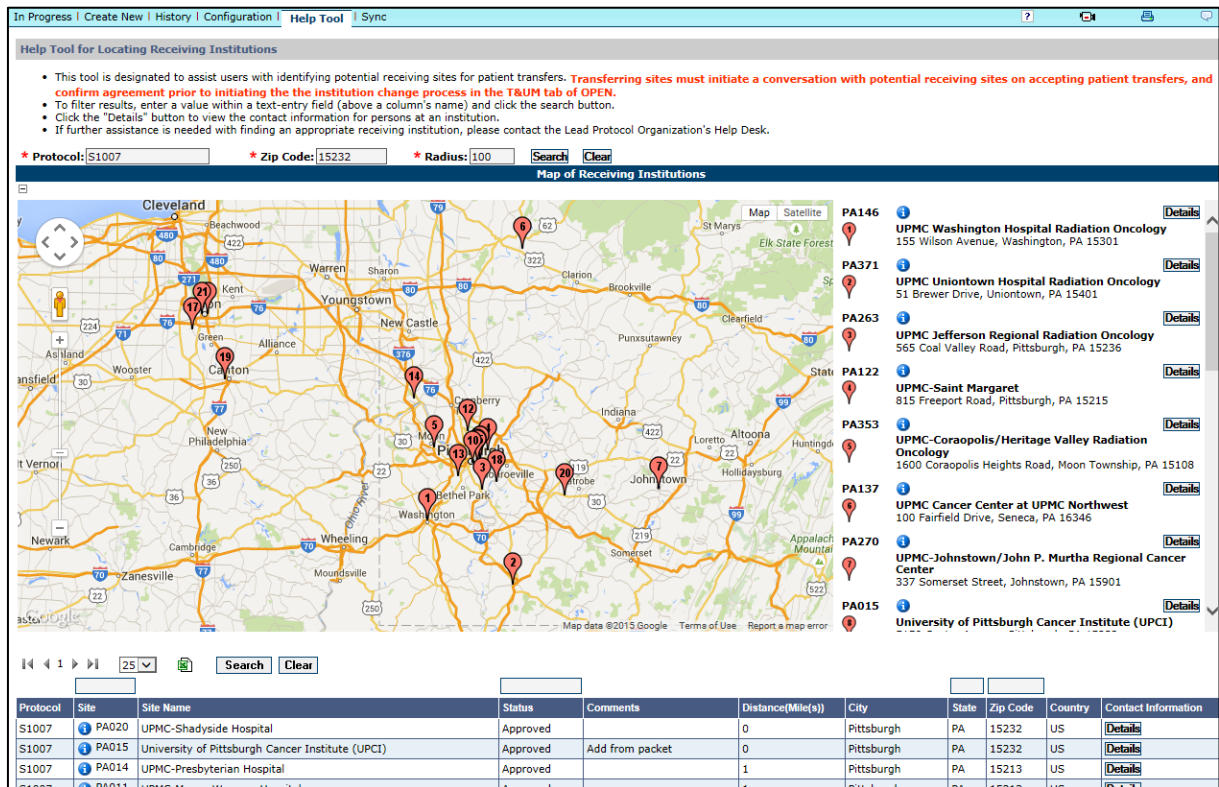


Figure 33: T&UM Help Tool Results

- 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.

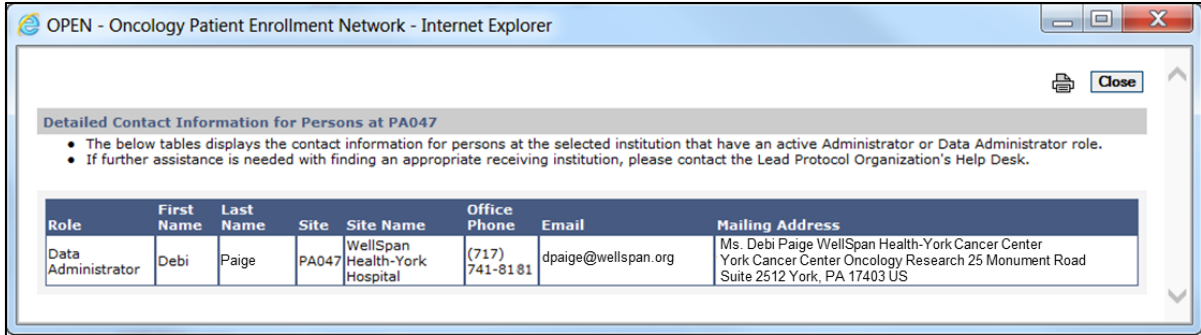


Figure 34: Details Popup for the T&UM Help Tool

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:

- Log in to OPEN.
- Click the *History* tab. The Browse subtab will display by default.
- 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.

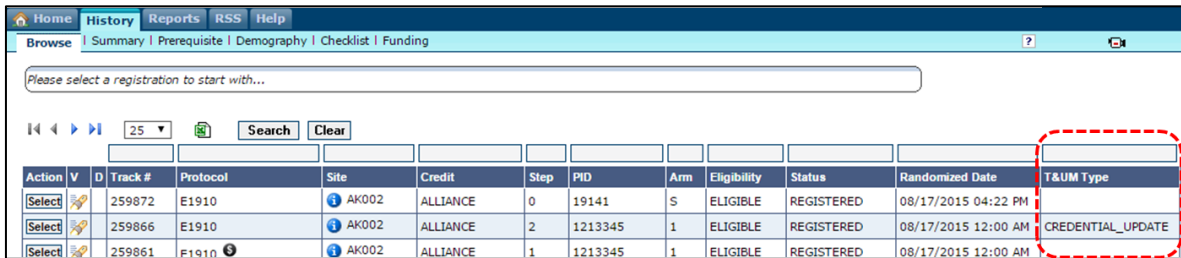
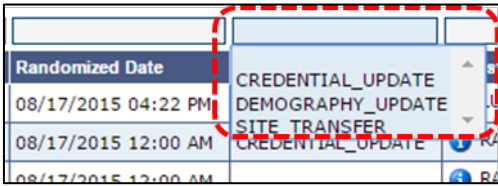


Figure 35: The T&UM Type Column Identifies Enrollments with Approved T&UM Requests

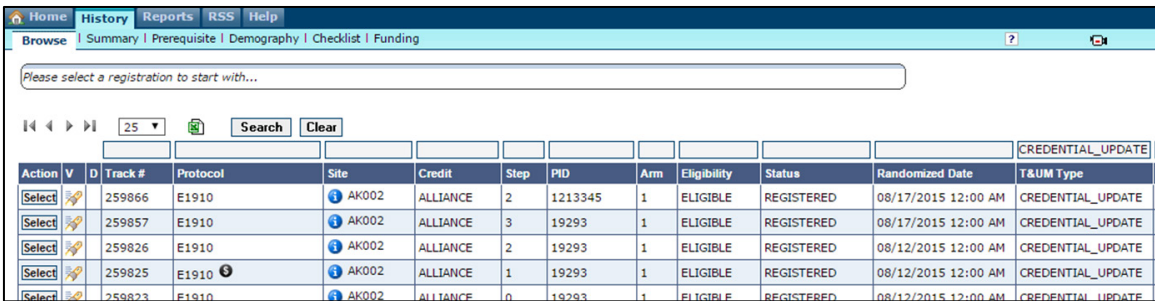
- To filter through the enrollments by a particular T&UM Type (none, Credentialing Data Update, Demographic Data Update, Site Transfer), click the text-entry box above the T&UM Type column and select the appropriate choice.



Randomized Date	T&UM Type
08/17/2015 04:22 PM	CREDENTIAL_UPDATE
08/17/2015 12:00 AM	DEMOGRAPHY_UPDATE
08/17/2015 12:00 AM	SITE_TRANSFER
08/17/2015 12:00 AM	CREDENTIAL_UPDATE

Figure 36: Results can be Filtered by the T&UM Type

- After making a selection in the text-entry box above the T&UM Type column, the results will refresh as requested (see Figure 37).



Action	D	Track #	Protocol	Site	Credit	Step	PID	Arm	Eligibility	Status	Randomized Date	T&UM Type
Select		259866	E1910	AK002	ALLIANCE	2	1213345	1	ELIGIBLE	REGISTERED	08/17/2015 12:00 AM	CREDENTIAL_UPDATE
Select		259857	E1910	AK002	ALLIANCE	3	19293	1	ELIGIBLE	REGISTERED	08/17/2015 12:00 AM	CREDENTIAL_UPDATE
Select		259826	E1910	AK002	ALLIANCE	2	19293	1	ELIGIBLE	REGISTERED	08/12/2015 12:00 AM	CREDENTIAL_UPDATE
Select		259825	E1910	AK002	ALLIANCE	1	19293	1	ELIGIBLE	REGISTERED	08/12/2015 12:00 AM	CREDENTIAL_UPDATE
Select		259823	E1910	AK002	ALLIANCE	0	19293	1	ELIGIBLE	REGISTERED	08/12/2015 12:00 AM	CREDENTIAL_UPDATE

Figure 37: The Filtered Results for the T&UM Type

6.6 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. Table 2 describes the different T&UM 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 T&UM 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 T&UM 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 T&UM History subtab.

6.7 T&UM Roles

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:

- Site Registrar;
- Site Admin.

6.8 Systems that are Automatically Updated

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

- OPEN/RSS.
- LPO RandoNodes (some LPOs will manually apply the T&UM requests to their databases).
- Rave (exceptions: the LPOs will manually apply site transfer updates to Rave and LPO's that initialize patients to Rave will perform the T&UM updates to Rave for those patients).

6.9 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 patient 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 subject case status is active treatment, the receiving site must have an IRB approval in the RSS and must comply with all Protocol Specific Requirements (PSRs).
 - If the subject 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 subject 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 patient 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 treating 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 a T&UM request, even if the study is active or the IRB approval is valid.
- If the patient enrollment was completed more than seven 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 configured by the LPO will validate the data. If any of the validations fail, the user will receive an error message.