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

Revision History

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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

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

![Figure 1: The T&UM Tab of OPEN](image)
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.

![Figure 2: The T&UM Create New Subtab](image)

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);
- 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.

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

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**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.

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.

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 7: Complete the Site Transfer Request Form**

**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 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](image)

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.
Figure 12: Complete the Review Request Form for a Site Transfer
8) 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.

9) 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.

10) Select a Receiving Site Contact.

11) 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

   The Transplant Credit field will appear from T&UM site transfers, when a receiving site user is reviewing a request for COG and COGC protocols.

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

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

14) 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 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 (if within seven calendar days of the subject’s enrollment onto the selected enrollment step);
- 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).

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

![Figure 15: Credentialing Data Update Process Workflow](image)

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

4.1 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.
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.

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.

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.
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.

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![Figure 20: High-Level Overview of the Demographic Data Update Process](image-url)

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

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1 Requesting Site may cancel the request while it is in a REQUESTED status.
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.

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.

![First Page of the Demographic Data Update Request Form](image)

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.
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 24: Second Page of the Demographic Data Update Request Form**

**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)](image)

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)](image)
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).

4) The T&UM Patient History Report will load in a pop-up window (see Figure 31).
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).
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.
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.

![Details Popup for the T&UM Help Tool](image)

**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:**

1) Log in 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.

![The T&UM Type Column Identifies Enrollments with Approved T&UM Requests](image)

**Figure 35: 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 36: 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 37).

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

<table>
<thead>
<tr>
<th>#</th>
<th>Status Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>REQUESTED</td>
<td>The initial T&amp;UM status for all requests. During this stage the request ID is generated and the request enters the In-Progress subtab.</td>
</tr>
<tr>
<td>2</td>
<td>CANCELLED</td>
<td>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&amp;UM History subtab.</td>
</tr>
<tr>
<td>3</td>
<td>ACCEPTED</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>REJECTED</td>
<td>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&amp;UM History subtab. No updates will be applied. This status only applies to site transfer and demographic data update requests.</td>
</tr>
<tr>
<td>5</td>
<td>QUERIED</td>
<td>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.</td>
</tr>
<tr>
<td>6</td>
<td>APPROVED</td>
<td>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&amp;UM History subtab.</td>
</tr>
</tbody>
</table>

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:
  
  o 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).

  o 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.

  o 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.