T&UM LPO FAQ

1. What is the Transfer and Update Module (T&UM)?

The Transfer and Update Module (T&UM) is a new module being developed in the Oncology Patient Enrollment Network (OPEN) system. Once implemented, it will become the central location requesting and managing Institution Changes, Credentialing Data Updates, and Demographic Data Updates for completed patient enrollments that are maintained in OPEN.

2. What patient data can be updated using the T&UM?

The T&UM allows users to create three types of data update requests for patients that are affiliated with a user's institution:

- **Patient Transfer:**
  - Institution Change requests, for moving a patient to a different institution. This may also result in changes to persons associated with the patient, the credited organization, and express courier information (if applicable).
- **Credentialing Data:**
  - Credentialing Data Update requests, for updating persons associated with a patient, the credited organization, and express courier information (if applicable). Unlike Institution Change requests, these requests are for patients that stay at the same institution.
- **Demographic Data:**
  - Demographic Data Update requests, for updating patient demographic information. All Demography screen fields can be updated (except stratification factors such as the Disease Code, and any other fields that were disabled by the Lead Protocol Organization (LPO)).

3. Will T&UM update data for all of a patient's enrollment steps?

Approved T&UM requests will only update data for the most recent enrollment step (and any ancillary study enrollments connected with the updated main study step) for a patient's enrollment.

4. Will the T&UM update data for ancillary (correlative) study enrollments?

Ancillary study (embedded and stand-alone) data will be updated for the approved T&UM requests that are linked to the main study enrollment step that is being updated by the T&UM request.

5. What roles are necessary for using the T&UM?

The following OPEN roles allow users to create T&UM requests:

1) Site Administrator
2) Site Registrar
3) LPO Registrar and LPO Registrar Admin

6. How to start a T&UM request for an OPEN patient?

1) Login to OPEN at http://open.ctsu.org
2) Click the T&UM tab.
3) Click the Create Request sub tab.
4) Select an action (Institution Change, Credentialing Data Update or Demographic Data Update).
5) Locate and select a patient for the request.
6) Complete the online form and submit the request.
7) The T&UM request is created, and the user should review the information on the request's Summary page for further instructions (if needed).

7. How to Review a pending T&UM request?

Once a T&UM request is created it may require review by another organization (either the Receiving Institution or the LPO). The organization that requires review will receive an automatic email notification with instructions. The following steps will be followed by the reviewing user:

1) Login to OPEN at http://open.ctsu.org
2) Click the T&UM tab.
3) Locate and select the pending T&UM request in the In Progress sub tab.
4) Click the Review Request button on the request's Summary page.
5) Complete the online form and make a review decision.
6) The reviewing user will arrive at the summary page and should review the information for any further instructions.

8. Who can view a patient's record after an Institution Change request occurs?

Once an institution change request is approved (and the changes are implemented in OPEN and RSS) the Receiving Institution will see the entire patient's record in the History tab of OPEN (and the patient's T&UM summary record in the T&UM History sub tab). The Transferring Institution will lose the ability to view the patient's record in the History tab of OPEN, however they will be able to see the patient's T&UM summary record in the History sub tab of the T&UM tab of OPEN.

9. When can a T&UM request be created for a patient in OPEN?

A T&UM request can be created if ALL of the following conditions are met:

- The patient enrollment in OPEN has a REGISTERED status.
- The patient enrollment does not have a pending enrollment for the same protocol.
- No pending T&UM requests exist for the patient's enrollment.

10. Which T&UM requests involve LPO review?

Institution Change requests require LPO review by default, however this can be set to auto approval (once the Receiving Institution accepts the request) in the Configurations sub tab of the T&UM tab.

Credentialing Data Update requests are automatically approved and do not involve LPO review.

Demographic Data Update requests require LPO review by default, however this can be set to auto approval in the Configurations sub tab of the T&UM tab.

11. Can T&UM Request Types be disabled at the LPO level?

T&UM request types (Institution Change, Credentialing Data Update, and Demographic Data Update requests) can be disabled at the LPO level. Use the Configurations sub tab of the T&UM tab to modify these settings.

12. Can the Demographic Data Update fields be configured?

The fields that users can update for Demographic Data Update requests can be configured at both the LPO level, as well as at the protocol level (using protocol exceptions). Use the Configurations sub tab of the T&UM tab to modify these settings.

Stratification factor fields (such as the Disease Code) are not updateable using the T&UM.

13. Which users are sent T&UM automatic email notifications?

View the T&UM Workflow Diagram for a list of email notification recipients.

The requestor, all LPO staff with the Operations role of "Transfer Coordinator" and all the Site staff with the following NCTN lead roles at the transferring and receiving (if applicable) institutions will be notified through email:

- ALLIANCE roles: Lead Clinical Research Professional (CRP), Second Lead CRP
- COG roles: CRA (Lead), PI
- CTSU roles: Data Administrator, Site Administrator
- ECOG-ACRIN roles: Senior Administrator
- NRG roles: Co-Lead RA, Lead Research Associate (RA), Local Lead RA
- SWOG roles: Head Clinical Research Associate (CRA)

14. Can the T&UM be used to update Eligibility Checklist question response?

The T&UM module does not allow for the update of Eligibility Checklist data. At this time there are no plans to introduce this feature.

15. Can the "Network Group Credit" be changed?

The Network Group Credit can be updated for Institution Change requests (when the patient is moving from one institution to another).

For Credentialing Data Update requests:

- If the patient has not yet enrolled onto any protocols steps that involve funding, the Network Group Credit may be updated.
- Once a patient enrolls onto the protocol step that involves funding the Network Group Credit can only be changed within 7 calendar days from the date the patient enrolls onto the protocol's initial funding step.

16. How are the LPO RandoNodes updated for T&UM requests?

Once an LPO RandoNode subscribes to receive T&UM transactions, OPEN's Data Transfer feature will send approved T&UM transactions to the LPO's RandoNode. A flag will distinguish T&UM transactions from regular data transfer transactions.

17. Will Institution Change requests update Rave automatically?

CTSU is working with Medidata to obtain the API that would allow for OPEN to update Rave for Institution Change requests. Until the ability for OPEN to update Rave for Institution Change requests is added, the LPOs will need to manually update the data in Rave for their patients.

18. Will OPEN's T&UM be the only place for updating patient enrollment data?

The T&UM will be the only place for updating patient enrollment data for completed patient enrollments that reside in OPEN.

19. Do T&UM requests automatically expire?

Unlike OPEN patient enrollments, T&UM requests do not expire.

20. When an Institution Change request is Queried by the LPO, are both the Transferring and Receiving institutions notified?

Yes, persons at the Transferring and Receiving institutions will automatically be notified by email when their T&UM request is Queried by the LPO.

21. Will LPO contact information be provided for Site staff that need assistance with locating a new site for their patient?

Yes, the LPO Help Desk phone number and email address will be displayed in the "Help Tool for Locating Receiving Institutions", which the Site staff use for locating Receiving Institutions. A note will also be added in the tool that encourages the Site staff to contact the LPO if further assistance is needed with finding a Receiving Institution.

22. What T&UM training resources are available for Site staff?

The Help sub tab of the T&UM tab will contain a T&UM Site FAQ, T&UM Workflow Diagrams, T&UM Site User Guide, and (once developed) an instructional video.