Category: Clinical Trial Operations – Completed Project

Utilizing the Clinical Trial Management System (CTMS) to Batch Load Accrual Data to the Clinical Trials Reporting Program (CTRP) System

M. Aguilar[1], S. Antony[1], E. Williams[1], S. Nonemaker-Cox[2]

[1]Simmons Comprehensive Cancer Center, UT Southwestern Medical Center; [2]Essex Management

1. Background

The Clinical Trials Reporting Program (CTRP) is a comprehensive database of information on all National Cancer Institute (NCI)-supported interventional clinical trials open to accrual as of January 1, 2009. A major benefit of the system is the consistent reporting to the NCI across centers, related to ongoing clinical trial activities funded by the NCI.

Accrual reporting is the responsibility of the lead organization for institutional, externally peer-reviewed, national (NCI-managed) studies or participating site for abbreviated/imported (e.g., industrial) trials. At UTSW, we utilize the effort of multiple people across the team to enter and report accrual in a timely manner.

Patient information is entered into our Clinical Trial Management System (CTMS) by the enrolling coordinator (any one of 60+ FTEs) and data is also required to be reported to CTRP. Reporting to CTRP can only be done by team members who are authorized CTRP users.

CTRP can accept accrual information in batched loads using the CTRP Accrual Batch File Tool, however, the system requires a specific format for submission to CTRP.

2. Goals

1. Reduce time/ effort taken to report accrual data on timely basis.
2. Reduce incorrect data entry discrepancies due to human error.
3. Create a reporting mechanism to push accrual from our CTMS to CTRP.

3. Solutions and Methods

UTSW with the cooperation of the CTRP team implemented a semi-automated process to assist with the upload of accrual data for trials submitted to CTRP. The first step to achieving this task was to ensure that the data residing within the CTMS was in a format acceptable for receipt by the CTRP system. The next step was to create two separate batch files, one configured to assist with the complete (protocol provided) patient-level accrual update, and the second for abbreviated/imported trials. The final step was to email the de-identified files weekly to the UTSW CTRP Administrator who could then download the file and upload to the CTRP accrual website.

4. Outcomes

This new process eliminates the need to track what patient information was previously updated, as each upload ensures the most updated counts and/or information is loaded to CTRP for trials and patients referenced for that period. Doing so helps to have more timely reconciliation for important annual NCI-required Cancer Center Support Grant (CCSG) data tables, for example.

The time utilized to batch load the accrual data versus entering each accrual individually has been reduced from an average of 4.5 to 1.5 hours, including time and effort needed to investigate and correct error messages that may be received.

5. Lessons Learned

Lessons learned:

1. This process benefits from active collaboration between the CTRP administrators and Center technical teams.
2. To have a successful CTRP accrual batch load implementation, it is imperative to ensure the CTMS patient profile information is in a format acceptable by CTRP.
3. In CTRP, once a trial is registered under a particular ICD code, the value cannot be changed without a data migration effort and/or nullification of the existing accrual data and submitted under a new ICD code.