

Automation of Clinical Research Administrative Fees for Internal Recovery

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1. Background

Memorial Sloan Kettering's (MSK) Clinical Research program has administrative fees that are recovered internally to support department funds. These fees are typically a component of the budget agreements with the study sponsor(s). There are unique business rules to determine when to apply each fee. The data needed to make these determinations are sourced across applications. The original manual process required significant staff time and effort to access, blend, clean, do quality assurance, and upload the data to our financial systems. Therefore, these fees were typically only recovered on a quarterly basis, and in some scenarios, annually. The delayed recovery often led to additional work to resolve.

2. Goals

Our goal is to automate the internal recovery for all administrative fees in real time. Our secondary goal is to implement a simple reconciliation method for any data quality issues. We chose to implement 24 fees as a subset before expanding.

3. Solutions and Methods

We developed pipelines within our Clinical Research Data Warehouse (CRDW) to stage data across applications, which allows for complex blending of the required data. The initial applications included were our Clinical Trials Management System (CTMS), OnCore by Advarra, and our Protocol Information Management System (PIMS), an in-house developed application. These two applications provide details of subject registrations, protocol rate bases, cost center and funds, and protocol life cycle actions. We created new CRDW tables to record annual pricing of each fee, data errors preventing fee generation, specific protocol exceptions, and the finalized output. The process runs daily at ~1:00 am and stages the data meeting the initial business rules from the last 30 days. CTMS is cross-referenced for the protocol's rate base to calculate the pricing, if applicable. The CC/Fund is then applied from CTMS, and if that fee has not already been written to the final table, the fee is committed. We collaborated with the TIPS development team to access the finalized output table to ingest into their application.

4. Outcomes

The last successful manual upload, for Q4 2022, included 650 events. The average service to upload date was 400.11 days (median: 410). Even after the delay to ensure data quality, 10 more were missing data, and 97 more were rejected due to closed or inactive funds.

In January, we automated 565 events recorded in PIMS, with an average service to upload date of 3.81 days (median: 1). In addition, 3,478 subject tracking events in CTMS were captured (services between 10/1/22 and 1/31/2023).

The manual process of cleaning and uploading the PIMS events accounts for 25 staffing hours each quarter. Additionally, the management of rejected fees within TIPS is an ongoing process, accounting for over 30 hours each year. This automation should significantly reduce the impact of these rejected fees.

5. Lessons Learned and Future Directions

We plan on analyzing if automated fees are rejected due to hitting closed funds, which should no longer

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be an issue due to the tighter turnaround time. Business owner buy-in for logic definitions is paramount in this development process. We are expanding our set of business cases to automate the internal recovery for as many fees as feasible.