Automation of Clinical Research Administrative Fees for Internal Recovery

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Background

- Our institution's Clinical Research program utilizes administrative fees for internal recovery 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 based on data sourced from multiple 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 (TIPS), which is managed by another department.
- 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.
- 24 fees were selected for the initial implementation due to familiarity with the logic and accessibility of the data.

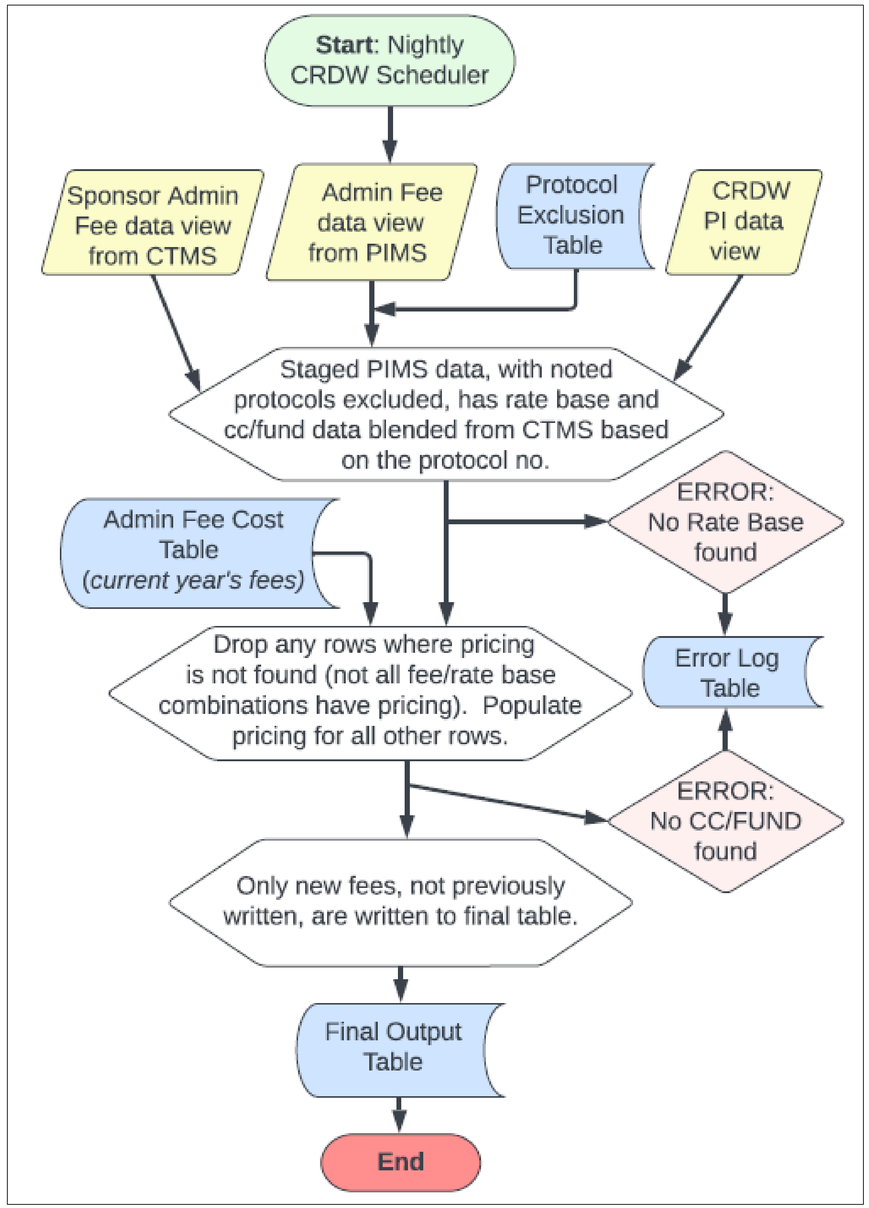
Goals

- Our primary goal was to automate the internal recovery for all administrative fees in real time.
- The secondary goal was to implement a simple reconciliation method for any data quality issues.

Fees for Internal Units

Internal Unit	Fee Type Count
Clinical Research Compliance	1
Department Protocol Development and Planning	1
Developmental Therapeutic Unit	3
Human Research Protection Program	9
Medicare Coverage Analysis	1
Pharmacy Administration	3
Protocol Activation Core	3
Regulatory Oversight and Product Development	3

Methodology



- Our Clinical Research Data Warehouse (CRDW) has pipelines to stage data from multiple applications, allowing for data blending. This allows us to write complex SQL to incorporate business logic into views on top of the data from the source systems.

Methodology (continued)

- Tables were created in CRDW to facilitate additional transformation and logging of annual pricing of each fee type (1), data errors preventing fee generation (2), specific protocol exceptions (3), and the final output recovery records (4).
- The process runs daily ~1am. TIPS ingests new data incrementally from this table each morning. TIPS will then run additional processes to recover the money to the applicable fund.

Systems / Data Sources

- An in-house developed clinical research application, the Protocol Information Management System (PIMS), manages all steps involved with the protocol life cycle.
- A vendor product, OnCore by Advarra, is our Clinical Trials Management System (CTMS) for subject tracking and financial management. This includes protocol specific rate bases and financial cost center / fund numbers (CC/Fund).

Pre and Post Assessment *(Average Days)*

Timeframe	Date of Service to TIPS Upload	Date of TIPS Upload to Processing	Count
2020-2022	158.49	19.57	19,064
2023	6.19	12.47	2,961

- Example: The last manual upload sample, of 2022 annual fees, consisted of 757 fee records. Of those, 10 fees were excluded due to missing data, and an additional 97 were rejected because they hit closed or inactive funds. This accounted for 14% of the sample, providing an example of the degree of manual reconciliation still required.

Time and Effort Savings

- The manual process of cleaning and uploading the PIMS events accounts for **100 staff hours each year**.
- Additionally, the management of rejected fees within TIPS is an ongoing process, accounting for over **30 staff hours each year** (not including study team time and effort). The expectation is that the automation will significantly reduce the impact of these rejected fees.

Lessons Learned and Next Steps

- Business owner buy-in for logic definitions is paramount in this development process.
- Prove our hypothesis that rejected fees will be significantly reduced due to more real time processing.
- Continue to expand the fees associated with internal recovery that are automated.