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Project #47: Centralization of Clinical Trial Budgeting has Resulted in Optimization

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Introduction

Fee schedules used to negotiate clinical trials budgets across the health system have historically been very different. Clinical care fees are standardized based on the hospital charge master, however administrative fees for staff time and effort have been extremely variable due to a decentralization approach. This has resulted in sub-optimal budget negotiations for clinical trials due to multiple factors:

- Under-estimation of costs
- Lack of trained staff in each Department to review and negotiate clinical trial budgets
- Hindered negotiations secondary to established precedence with sponsors

Actionable Items

A centralized and standardized fee schedule was developed to tackle this problem. In order to accomplish this the following steps were taken:

- A benchmark analysis was conducted with comparable institutions to ensure proposed fee schedule was comprehensive and on target with other institutions.
- Budgeting practices were assessed in each department with a focus on usual charges for administrative time and effort fees.
- Upon completion of discovery calls with each department, fees were compared, combined and assessed for duplication, optimization and completeness.
- A standardized fee schedule was implemented 7/1/23 for all new industry sponsored clinical trial budgets.
- The Clinical Trials Office centrally managed all industry sponsored clinical trial budget negotiations.

Challenges Faced

- System resistance to centralize and standardize budgeting functions.
- Collecting fee schedule data in a decentralized healthcare environment.
- Differences in training, experience, and knowledge of clinical trial budgeting processes across departments.
- Accounting for the unique needs of each department while trying to standardize the fee schedule.
- Varying staffing models in each department made it difficult to standardize time and effort fees

Implementations

- An administrative fee schedule was standardized across all departments.
- Standard justification was developed for each administrative fee.
- A central budget team was created in Research Administration.
- Industry sponsored clinical trial budget negotiations were centralized across the health system as of 7/1/23.

Example of Standardized Fees

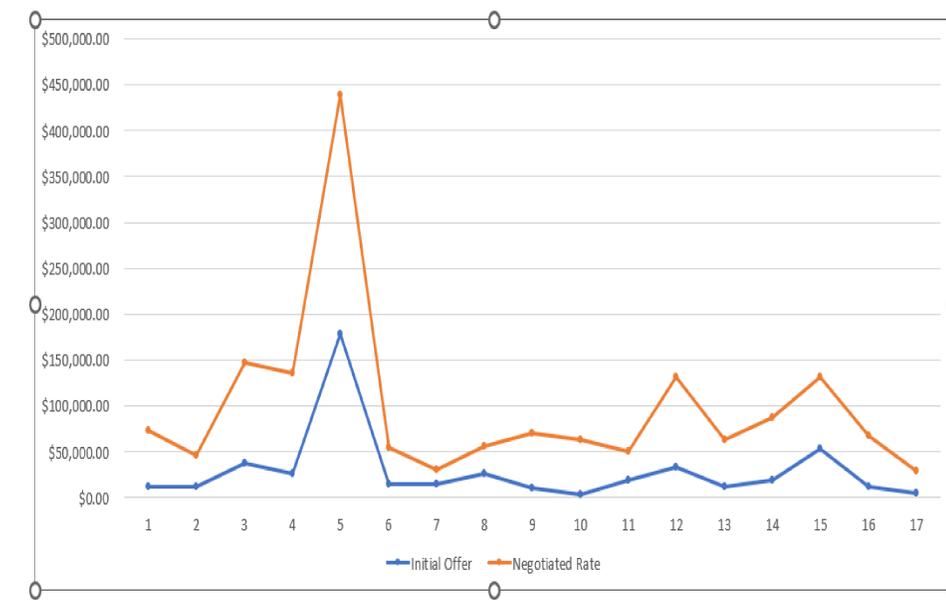
Study Start-up Fee	Pre-qualification visit, Site initiation visit, protocol training with all delegated staff, budget and contract effort and any additional requirements to process study start up.	\$16,000.00
Regulatory Start-up Fee	Negotiation of informed consent to meet local standards, preparation and submission of documents to IRB/WIRB, preparation and submission of all regulatory documents (1572, CV, Licenses, etc.). Includes SIP fees, if applicable.	\$6,000.00

Results

- The percentage of increase for administrative fees was tracked in comparison to the initial sponsor budget offer.
- Clinical trial negotiations for administrative fees increased an average of 269%, between 7/1/23 and 12/31/23 (see figure 1).

Figure 1

Initial Offer Compared to Negotiated Rate Administrative Fees for 17 Clinical Trials



Acknowledgements

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