

## **Development of an Adaptive Relational Database Management System for Efficient Study Conduct of Phase I Trials**

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### **1. Background**

Historically, subject and trial management were conducted using multiple isolated spreadsheets. From 2020 to 2022, the Phase I Team at Sidney Kimmel Comprehensive Cancer Center at Jefferson experienced a trial volume growth of 60 percent, with a corresponding increase in enrollment. During this period, the ability to maintain subject and trial data between multiple documents posed a burden to staff. This drove the need for innovation and development of a centralized and effective database management system.

### **2. Goals**

The development of a centralized Phase I database aimed to streamline clinical trial portfolio management via a single platform. The database is critical to maintaining current trial status, subject information, and integration of relevant trial details. Additionally, this innovative instrument facilitates enhanced workflow efficiency and provides opportunity to evolve and grow as new needs become evident.

### **3. Solutions and Methods**

Our team utilized Microsoft Access to build a relational database system that integrates the data of the former individual spreadsheets and provides added functionality. Data normalization and Atomicity, Consistency, Isolation and Durability properties were followed during development. The database was split into a back-end storage and a front-end user interface. The front-end menu categories were grouped by functionality to increase ease-of-use depending on the user's role. This allows for tracking of protocol status through the start-up process: protocol opportunity, Phase I team approval, feasibility review, Protocol Review and Monitoring Committee, site initiation, trial activation, as well as tracking protocol amendments and their implementation.

### **4. Outcomes**

The database has the following capabilities: data normalization, ability to generate parameter specific reports, monitor Phase I studies, and provide a centralized platform for study personnel. These features allow for efficiency in accrual, trial status updates, and cohort management. It generates automation of repetitive actions such as email notifications of consented subjects, new protocol approvals and submissions during study start-up, creation of meeting agendas, and distribution of weekly notifications of current slot availability.

The database was designed to provide a dashboard-style overview of subject enrollment and study start-up status via a Kanban-like interface, allowing for easy visualization. Overall, the database has proven to be an indispensable tool for systematic organization of Phase I team trial data.

### **5. Lessons Learned and Future Directions**

Our Phase I centralized database has significantly contributed to the organization and accessibility of trial data.

*Category: Trial Recruitment and Study Conduct - Completed project*

The database is undergoing a transformative upgrade to boost efficiency in managing patient data and trials. Streamlining patient information input into the calendar system will simplify tracking for easier access to crucial data. Integration of these features will capture relevant details of patients throughout treatment cycles, ensuring a comprehensive overview of their journey.

We are also improving the enrollment process for new patients by implementing a checklist to standardize procedures and enhance efficiency. Tailoring the platform to departmental needs within our organization will further optimize its utility.

Our long-term vision includes extending the database's use beyond Phase I trials, potentially integrating it into other departments. Iterative feedback will refine the system for optimal performance, establishing a gold standard for clinical research data management. Collaboration and innovation will drive future development of this database, improving patient outcomes.

**Figure**

