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Mapping and navigating translational resources with generative AI

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OBJECTIVES/GOALS: Translational researchers often struggle to navigate a complex constellation of institutional resources spanning the IRB to bioinformatics units. We had two aims 1) Systematically map all institution-wide research support units and 2) leverage this database within a generative AI virtual concierge tailored to local investigator queries and needs. METHODS/STUDY POPULATION: This study leveraged mixed methods approach. First, we conducted needs assessments of local study teams to identify barriers to translation, revealing that research resources are often unknown to study teams. Second, we identified all investigators, institutional units, and offices offering such resources that we call research support units (RSUs). RSUs were surveyed, collecting contact information (leadership, website, physical location), services provided, type of research supported, and performance metrics. Third, the resource database was integrated into a large language model (LLM, e.g., ChatGPT4o) using a retrieval augmented generation (RAG) system within an R Shiny application called virtual concierge. Queries and responses are recorded for quality improvement. RESULTS/ANTICIPATED RESULTS: Needs assessment focus groups consisted of clinical and basic science investigators, study team members (e.g., clinical research assistants), core directors, and administrators (n = 26). Six sessions were conducted in Spring 2024. A major resultant theme was difficulty finding RSUs "by trial and error" and lacking a "clear defined pathway" for accessing RSUs. This prompted a survey-based environmental scan to identify institutional research resources. There were 122 diverse RSUs ranging from the IRB, to grant writing, to single cell sequencing. Each research unit offered a median of 6 service types, totaling 410 service types overall. The resultant Virtual Concierge meaningfully responds to investigator resource queries with appropriate contact and access information. Usability testing is underway. DISCUSSION/SIGNIFICANCE OF IMPACT: Linking researchers with translational resources requires mutual understanding, timely communication, and coordination across teams. We systematically filled these information gaps between investigators and institutional resources. Our Virtual Concierge AI bot can help researchers navigate resources through the translational process.

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Optimize efficiency in clinical trial development by assessing and forecasting operationally associated risks utilizing REDCap

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OBJECTIVES/GOALS: Mayo Clinic Florida's Clinical Research Units develop over 200 clinical studies on average annually. Almost 30% of these projects are developed and then are unable to activate due to a variety of operational factors. To increase the success rate, a scoring tool was created to assess the risk associated with the development of these research projects. METHODS/STUDY POPULATION: A project team comprised of members of research administration and physician leadership developed a rapid project management (RPM) scoring tool to assess operational risk factors. The scoring algorithm was embedded into an existing REDCap database, using a combination of identified variables and calculated fields. All noncancer industry sponsor-initiated clinical studies were scored at intake. According to the following categories: enrollment timelines, study team capacity, and previous experience with the Sponsor. Studies with a score greater than the established threshold were referred to physician leadership for transparent discussions with the principal investigator regarding the identified study development-related risks. RESULTS/ANTICIPATED RESULTS: The RPM tool has assessed close to 200 projects since implementation in June 2022. An interim analysis is being conducted of all projects assessed by the RPM tool dating from implementation to May 2024 to compare the outcomes of these studies with the given RPM score. We anticipate based on anecdotal evidence gathered during the course of this pilot project that the RPM tool will show a correlation between risks identified and study outcomes as defined as successful activation of trials, or rationale of project development failures. We anticipate a reduction in the amount of time elapsed and effort expended developing projects with scores reflecting identified project development-related risk factors. DISCUSSION/SIGNIFICANCE OF IMPACT: The RPM tool provides an opportunity to allocate resources to studies with the greatest potential for successful activation. In the future, the RPM tool may be used to identify risk factors associated with enrollment and accrual of participants.

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Digital pill diaries in an electronic health record system: Enhancing chemotherapy adherence monitoring in decentralized clinical trials

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OBJECTIVES/GOALS: Mayo Clinic's Clinical Trials Beyond Walls™ (CTBW) program collaborates with study teams to implement decentralized elements in clinical trials, enabling participation from home or local settings. In cancer treatment trials, traditional paper pill diaries are replaced with real-time digital tracking solutions to monitor chemotherapy adherence. METHODS/STUDY POPULATION: The CTBW team developed a solution to deliver electronic pill diaries to research participants using the electronic health record (EHR) system Epic and patient portal MyChart1. The solution includes a portal message to remind participants to take chemotherapy. Medication dose, date taken, and reasons for missed doses (e.g., "I forgot" or "side effects were bothersome") are captured. An automated in-basket notification system alerts the study team when predefined conditions are met. Configurable medication schedules ensure diaries are sent according to the prescribed frequency. Reports were generated to allow study teams to monitor all participant diaries. RESULTS/ANTICIPATED RESULTS: The CTBW team implemented this digital pill diary in neuro-oncology trial NCT066250472. We anticipate the pill diary in the patient portal will enhance chemotherapy adherence by capturing real-time data in a platform widely used by Mayo Clinic patients. This patient-reported data is stored in the EHR, where it is accessible to providers

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and study teams. This allows for continuous monitoring, which facilitates a streamlined review of potential adverse events, improved compliance visibility, and timely treatment adjustments compared to paper-based or external solutions. The system also streamlines data entry, reducing human error and eliminating manual transcription. The created language and workflow templates allow the CTBW to scale this approach to future cancer trials DISCUSSION/SIGNIFICANCE OF IMPACT: Decentralized clinical trial participants may never visit Mayo Clinic, making digital recording essential. The EHR-based digital pill diary enables continuous monitoring within a familiar system for providers and patients, increasing study team visibility, and allowing for earlier intervention in cases of noncompliance or adverse events.

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The design and operation of a robust clinical trials unit information system: 15 years strong and evolving

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OBJECTIVES/GOALS: The operation of a clinical trials unit involves multifaceted tasks and stakeholders. A competent information system is critical to daily operations while ensuring smooth conduct of clinical research. We share 15 years of experience in the design and implementation of such a system at Mayo Clinic to inform other institutions with similar interests. METHODS/STUDY POPULATION: The Informatics team collaborated closely with nurse leaders and elicited input from additional stakeholders including nurse unit coordinators, lab managers, schedulers, investigators, study coordinators, and regulatory specialists throughout the phases of system design, development and continuous enhancements, and expansion. The stakeholders offered insights on the corresponding requirements throughout the study life cycle, from engaging with the study sponsor, operational review for protocol execution, development of study budgets, human subject protection and risk mitigation, data management and integration, to outcome monitoring, and regulatory reporting. The activities were then translated into functional components and implemented as a seamless and effective solution. RESULTS/ANTICIPATED RESULTS: Patient safety, scientific rigor, operation automation, efficiency, and regulatory requirements were all considered in developing an integrated system, or the clinical research trials unit (CRTU) Tools. Our institution has leveraged the system for essential tasks from the study start-up, visit scheduling and execution, specimen collection and tracking, to individual protocol metrics and billing. We adopted a measure-as-we-go methodology so that data such as visit census, resource usage, and protocol deviation are tracked and collected during routine use of the system. Specifically, an issues/concerns/exceptions (ICE) tool is used for quality control and patient safety. Moreover, data quality greatly benefits from a task dictionary, standardizing the study activities that can be ordered and executed. DISCUSSION/SIGNIFICANCE OF IMPACT: The implementation of a well-rounded clinical trials unit information system not only improves the operation efficiency and team productivity but also ensures scientific rigor and contributes to patient safety. We believe the experience can be informative to other institutions. More details will be shared in the poster.

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Efficiencies in coordinator float pool management at Johns Hopkins University

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OBJECTIVES/GOALS: Create opportunities for early-stage research apprentices to obtain real-world knowledge expand float pool to meet unmet research staffing needs, and decrease investigator burden Increase operational efficiencies, decrease start-up time, establish metrics, and ensure transparency responsible fiscal stewardship to approach cost neutrality METHODS/STUDY POPULATION: The Research Coordinator Support Service (RCSS) is a pool of research staff available for hire on an hourly basis by Johns Hopkins University (JHU) investigators. RCSS consists of Apprentices we train on the job as well as Coordinators and Senior staff who have completed the apprenticeship program. Started in 2012, RCSS was placed under new management in November 2020. An expansion proposal was submitted to senior leadership for additional financial and human resources. After approval new systems were implemented and additional hires were made. Several efficiencies were introduced in start-up, study assignment, transparency, invoicing, and overall operations to address the waitlist of 25 studies. Senior leadership now required extensive metric reporting to evaluate program success. RESULTS/ANTICIPATED RESULTS: To address the waitlist, current staff was redirected from purely educational to study-related activities and several new hires were made. The waitlist reduced steadily over time and more research occurred. Average hours of research support per month more than doubled from under 500 to over 1,000. When our Administrator left, we implemented an automated hours-based reporting and invoicing tool resulting in substantial cost-savings over rehiring the position. Apprentices, now with rapid onboarding and early study assignments are reporting high satisfaction and many have been promoted to Coordinator positions. Detailed spreadsheets with relevant metrics were created which are accessible, and regularly reported, to senior leadership for decisions on promotions and additional hires. DISCUSSION/SIGNIFICANCE OF IMPACT: Budget belt-tightening requires organizations to reduce expenses while continuing to provide the essential services investigators need. This focus has caused RCSS to examine our program and add efficiencies. We hope others looking to build or expand their float pools will benefit from our experiences and the specific efficiencies we implemented.

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Optimizing clinical trial recruitment: A dashboard for accrual and oversight

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OBJECTIVES/GOALS: To identify clinical trial teams that are at risk of not meeting their recruitment goals as early in the recruitment period as possible, this project aims to provide timely accrual information and projected forecasts for accruals by the end of the recruitment period across all trials at USC. METHODS/STUDY POPULATION: This project aggregates recruitment accrual data periodically from OnCore to create per-study accrual pages that

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