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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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