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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