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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contain an up-to-date accrual chart, metrics like expected and actual accrual per month, and projected recruitment based on an X-month moving average (3 months by default). Trials at risk are identified as early as possible by using these projections to classify risk. In this initial phase, we've classified trials as medium risk (80%–99% accrual) or high risk (less than 80% accrual). The dashboard is currently available for all clinical trials at USC and users are automatically restricted to the studies that they administer or work on depending on their role. RESULTS/ANTICIPATED RESULTS: The dashboard will provide visibility across the institution for the current accrual for all clinical trials in a standard, user-friendly format and use the same metrics and definitions of risk for trial accruals not meeting their targets. This will allow the institution to identify trials that need intervention to get back on track using a single set of criteria across all research teams. Users in different roles, whether department heads, principal investigators, or study coordinators can view the current accrual for all the trials that they administer or work on in one central location. The dashboard will also help to identify quality issues in OnCore by performing data quality checks nightly. DISCUSSION/SIGNIFICANCE OF IMPACT: By providing a central location for role-based access to timely clinical trial accrual for the institution, the dashboard helps to identify trials at risk of not meeting their recruitment targets as early as possible to provide corrective advice/measures.

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Collaborative pathways: Insights from an Academic Medical Center (AMC) – Historically Black Colleges & Universities (HBCU) Translational Research Collaborative Pilot Funding Program

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OBJECTIVES/GOALS: Collaborations between Academic Medical Centers (AMCs) and Historically Black Colleges & Universities (HBCUs) are critical to addressing health disparities and building research capacity. Herein, we examine the Duke-NCCU Collaborative Translational Research pilot funding program [2018–2023] to identify opportunities, challenges, and lessons learned from querying key stakeholders. METHODS/STUDY POPULATION: The Duke-NCCU collaborative pilot funding program was launched to support new inter-institutional collaborations that aim to accelerate research discoveries into testing in clinical or population settings. Eight one-year, $50,000 collaborative grants were awarded. Each funded team was assigned a CTSI Project Leader (PL) for project management support. To evaluate the program, we developed surveys targeting principal investigators (PI) and PLs. Questions covered collaboration motivation, goals, outcomes, operational processes, project management support, institutional differences, and challenges. Qualitative analysis will be employed to evaluate the responses and identify common themes. RESULTS/ANTICIPATED RESULTS: The PI survey examines aspects of inter-institutional collaborations, focusing on common themes, such as authorship, definition of success, and institutional culture. The PL survey prompts feedback on managing inter-institutional teams, expectations, and challenges. Select questions were shared between both surveys to capture both perspectives. Surveys were reviewed by members of the Duke CTSI evaluation and team science teams. The PI survey will be disseminated to 16 investigators, while the PL survey will reach 5 project leaders. Built on Qualtrics, each survey takes 20–30 minutes to complete. To encourage participation, incentives will be offered as two $100 gift card drawings. Respondents can choose to complete the survey on Qualtrics or through a recorded and transcribed Zoom session. DISCUSSION/SIGNIFICANCE OF IMPACT: AMC-HBCU inter-institutional collaborations drive innovation, workforce development, and equitable dissemination of outcomes. This study exemplifies collaboration, offering insights into translational research collaborations critical to advance equitable healthcare and improving population health.

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Improving communication and collaboration: Strategies for reducing non-accruing trials

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OBJECTIVES/GOALS: In January 2023, Mayo Clinic set a goal to have 10% of studies open for six months or more without accrual. At that time, Mayo Clinic Florida had 19% non-accruing studies and 18% non-accruing clinical trials. Research administration implemented strategies to improve accrual outcomes. METHODS/STUDY POPULATION: Two strategies were developed to address non-accruing trials: a clean-up approach and a proactive approach. The clean-up approach involves escalating studies that haven't been enrolled in over 6 months, identifying barriers, and escalating communication with the principal investigator (PI) and research administration alongside a physician partner. The proactive approach targets studies at the 3-month mark to address issues before reaching 6 months without accrual. Both strategies aim to reduce the cost and effort of non-accruing studies by either creating an enrollment plan or closing the study. RESULTS/ANTICIPATED RESULTS: Since implementation, Mayo Clinic Florida's non-accruing study portfolio decreased by 10%, and its clinical trials non-accruing portfolio decreased by 7% as of October 2024. Research Administration tracks key metrics (reasons for no enrollment, justifications, and actions) to identify trends and mitigate future accrual risks. A REDCap electronic data capture tool hosted at Mayo Clinic (supported by CCaTS grant UL1TR002377)1 notifies principal investigators when their studies are non-accruing. Future plans include establishing an API with Mayo Clinic's portfolio management system to streamline the process while maintaining awareness and collaboration. DISCUSSION/SIGNIFICANCE OF IMPACT: Through increased monitoring, enhanced communication, and deeper collaboration, Mayo Clinic Florida effectively reduced non-accruing studies in its research portfolio. This approach minimizes effort and costs associated with under-enrolled studies while tracking key metrics to inform future study development.

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The development and establishment of a Centralized Clinical and Translational Research Infrastructure at an Academic Medical Center

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OBJECTIVES/GOALS: Historically, the Univ. of Missouri (MU) Sch. of Medicine (SOM) is known for its strong clinical and

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