and situational awareness strategies and trainings. DISCUSSION/SIGNIFICANCE: As research teams become increasingly diverse, there is a need to better support them and ensure that the research field and work settings are safe, inclusive environments with articulated policies that mitigate/prevent discrimination, bias and harassment perpetrated by study participants.

518

Improving Clinical Trial Activation Timelines through Parallel Processing and Key Stakeholder Involvement

Michelle Monosmith, Cierra White, Julie Byrne, Aaron Mangold, Kelly Avery, Naveen Pereira and Audi Chokkalingam
Mayo Clinic

OBJECTIVES/GOALS: A strategic initiative of Mayo Clinic is to decrease clinical trial activation timelines by 25% from 2022 levels. The team's goal is to streamline activation via parallel processing, improved collaboration with business units, project manager facilitation, and early study coordinator involvement. METHODS/STUDY POPULATION: The workgroup targeted industry trials, focusing on key financial, regulatory, and operational elements. Current state process workflows and pain points were prepared and opportunities for concurrent activities or automation identified. The scope of the project manager role from the Office of Clinical Trials was extended to guide each activation team, who have varying levels of experience, to maintain timelines until the trial is opened. Coordinators responsible for study conduct engaged in key operational discussions earlier to ensure the trial will be run successfully. A Pilot program is utilizing the identified concurrent activities, project manager support, and earlier coordinator involvement to gauge effectiveness of the proposed solutions. RESULTS/ANTICIPATED RESULTS: The goal is for 120 industry clinical trials to join the Pilot program and to open enrollment in less than 30 weeks from being document ready. As of Q3 2023, 109 clinical trials across multiple Mayo sites have enrolled in the pilot. Thirty-five (85 percent) of 41 Pilot trials have opened to enrollment and have met the goal, with a median timeline of 24 weeks. Twenty-one (21) trials opened to enrollment in Q3 2023 with a median timeline of 23 weeks, representing 24% of all industry clinical trials opened that quarter. Opening trials and monitoring is ongoing and PI and study team feedback is positive. DISCUSSION/SIGNIFICANCE: Using a team-based approach, we identified key areas for optimization and parallel processing. The solution reduces trial activation timelines, increases patient access to experimental therapies, and has been positively received by study staff. Future projects will focus on enterprise implementation, optimization, and automation.

519

Strategic Reinvestment of Sponsored Trials Residuals for Research Portfolio Development

David R. Friedland, Justin Nebel, Doriel Ward and Reza Shaker
Medical College of Wisconsin

OBJECTIVES/GOALS: Academic research is often viewed as a necessary core mission but a financial loss requiring central or clinical funds support. We present cases as evidence of sustaining academic unit research endeavors through strategic planning and reinvestment of sponsored clinical trials residuals. METHODS/STUDY POPULATION: Successful endeavors are presented that demonstrate strategic reinvestment of clinical trials residuals to develop robust academic self-sustaining research programs. A multi-year strategic plan was developed leveraging residuals from sponsored clinical trials to build an academic research infrastructure supporting extramural grant applications, pilot studies, pre- and post-award management, equipment investment, and faculty incentives. RESULTS/ANTICIPATED RESULTS: Example 1, pooling four existing department clinical trials generated yearly profits that expanded clinical trials capacity and used residuals to support a grant coordinator. Over 7 years, trial volume increased to near 50, revenue increased to $2.5 million annually, staffing increased to 20 FTEs, and extramural grant applications increased from 16 to 50. Example 2 started with a department with no infrastructure. Central support was leveraged for 6-months to support a coordinator to initiate a clinical trials program. The initial investment was offset by trials earnings by year 2, breaking even financially, while establishing a nascent yet robust infrastructure to build autonomously without additional central funding requests. DISCUSSION/SIGNIFICANCE: Utilizing sponsored clinical trials as a strategic investment fund, academic units can realize fiscally responsible expansion of research activities and national recognition through acquisition of extramural funding and investigator-initiated investigations.

520

Johns Hopkins Institute for Clinical and Translational Research (ICTR) - Research Personnel Onboarding Program

Mais Hamdawi and Anthony Keyes
Johns Hopkins University

OBJECTIVES/GOALS: In Sep 2022, Johns Hopkins Research Coordinator Support Service launched Research Personnel Onboarding Program. The program on board in experienced individuals in 6-8 weeks, tailoring training plans to Investigator and study needs. It also offers Ongoing Support to enhance sustainability and adaptability. METHODS/STUDY POPULATION: * Assess Principal Investigator (PI)'s need Evaluate study's need Understand trainee's background Develop a personalized training plan (~6-8 weeks) Weekly updates Ongoing mentorship Research staff spend 200+ training hours, depending on their need. Training encompasses various modalities: Interactive 1:1 onboarding sessions, Online, and Instructor-led trainings and sessions cover a wide range of topics, including: * Mandatory JHU/Institutional Review Board trainings * Good Clinical Practice * Regulatory submissions * Screening/Consenting * Monitoring/Auditing * Visit conduct * Clinical skills * Soft Skills Figure 1. Chart shows cumulative onboarding hours that focus on "How" to do tasks Figure 2. Chart shows cumulative training hours that focus on regulations, ethics and "Why" for tasks RESULTS/ANTICIPATED RESULTS: * The program contributed nearly 4000 hrs. of research staff training in the past 1 year * The program received 26 requests from investigators; 14 Completed the onboarding program, 1 Active, 5 Projected (Future start date), and 6 Cancelled (HR issues, lack of fund, or hired a trained staff) * 22 requests opted in the "Ongoing Support" * Ongoing Support, is averaged at 1 hr./month for the first 3-6 months. This indicates program success in empowering independent task performance * Developing REDCap request had significantly reduced meetings and paperwork * Web-Based Clockify invoicing has drastically reduced monthly manually invoicing processing time DISCUSSION/SIGNIFICANCE: * Grow the next generation of clinical research professionals * Centralize and standardize expert onboarding throughout the University

https://doi.org/10.1017/cts.2024.441 Published online by Cambridge University Press