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.

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

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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.

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Strategic Reinvestment of Sponsored Trials Residuals for Research Portfolio Development

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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.

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

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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

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* Improve outcomes, enhanced productivity, knowledge sharing, collaboration, and innovation * Decrease frustration and enhance satisfaction of trainees and departments

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Bringing UCSF Research Resources to Community Health Systems: CTSI Research Infrastructure Network (RIN)

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OBJECTIVES/GOALS: The CTSI Research Infrastructure Network (RIN) expands CTSI's reach into the regional health systems to provide our services to a broad and diverse translational science community. We create and support research collaborations that span multiple geographies and patient populations and serve as a bridge between the affiliate sites and CTSI programs. METHODS/STUDY POPULATION: We conducted needs assessments at each site (n=6) via in-depth, semi-structured interviews with key stakeholders. Informants (n=40) included investigators, study personnel, and research administrators. Investigators were selected across a variety of departments and career stages. Interview transcripts and notes were analyzed using matrix-based qualitative methods to identify both the common and unique research infrastructure needs of each site. Individualized support plans were shared with each site and a comprehensive summary report was presented to CTSI leadership. RIN met with UCSF's Comprehensive Cancer Center, which conducts clinical trials at 2 sites, to coordinator our effort and services. When possible, RIN addressed service requests in real time that arose during interviews. RESULTS/ANTICIPATED RESULTS: We identified heterogeneous needs across multiple sites. However, among the community health systems with non-academic clinicians, there were common needs for research training, consultations in biostatistics/study design, and finding academic collaborators. The needs of sites with UCSF academic faculty differed from those of community sites and mainly included improved awareness and access to CTSI programs, ease of use of data extraction services, training programs, and assistance with regulatory approvals. Site needs are best addressed with individual plans created with CTSI Program leaders. A developing governance structure will include representation on a CTSI advisory committee and an annual conference to facilitate the sharing of best practices and foster collaboration across member sites. DISCUSSION/SIGNIFICANCE: Providing an individualized, site-specific approach to expanding CTSI services to regional health systems, will increase research collaborations across Northern California through building relationships, addressing unique infrastructure needs and sharing best practices throughout the network.

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Measuring the Impact of an Operations Manager on a Study Team

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OBJECTIVES/GOALS: Having a strong leader in the form of an operations manager is crucial to lead and motivate teams. They're an additional set of problem-solving eyes to identify and address challenges. This poster demonstrates coordination techniques involved to work with teams of researchers, ensuring effective communication, deadlines met, and impact. METHODS/STUDY POPULATION: Stories, course corrections, publications, presentations and other metrics related to various projects and studies in the Lab will show such as the National Drug Early Warning System (NDEWS), Program to Alleviate National Disparities in Ethnic and Minority Immunizations in the Community (PANDEMIC, CDC), Polysubstance Use Study (PSU), and All of Us Consortium of CTSA/PACER Community Network. Additional data will be collected with project managers and students from each respective project to evaluate the effectiveness of an Operations Manager on the team across all studies in Our Lab. RESULTS/ANTICIPATED RESULTS: By sharing these results, showing the benefit to having an Operations Manager and the stories collected and shared for this poster, course corrections will set an example for future operations managers and their teams to continue to optimize efforts. Tis Could be a Special Interest Group (SIG)-related effort that would facilitate success to many labs. DISCUSSION/SIGNIFICANCE: Operations management focuses on effectively managing resources, ensuring that we meet deadlines, reduce delays, and maximize team productivity. By sharing our experiences, this can be a more standard practice among research labs to have smooth operations, and increase overall reputation of our team among those in the field.

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Navigator: Providing a foundation for cross team collaboration and custom research service through the CTSA Hub

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OBJECTIVES/GOALS: The Oregon Clinical and Translational Research Institute (OCTRI) Clinical Research Navigator program provides a single point of entry for clinical and translational research services, support, advice and guidance. We provide data to illustrate the Navigator model at OHSU and examine continued opportunities to optimize research resources. METHODS/STUDY POPULATION: Requests and activities performed by the OCTRI Navigator program, staffed by 3 FTE (2 Assistant Navigators and 1 Assistant Director) were analyzed. Navigator receives requests through multiple methods: a digital form (REDCap®), email, phone calls. Requests for services and support include focused need for a core or a broad request for multiple services for start-up: informatics, the clinical and translational research center, regulatory knowledge and support, recruitment, qualitative methods, community research, biostatistics or broad consultations. Requests are tracked in SPARCRequest. Navigator also supports wayfinding to institutional resources outside of the CTSA, matchmaking for sponsors seeking investigators, and serves as a connector and facilitator across programs. RESULTS/ANTICIPATED RESULTS: OCTRI Clinical Research Navigator triaged an average of 964 research requests for 613 projects with 388 unique investigators annually between 2018-2022. Navigator also fields more than 80 calls each year that are unrelated to CTSA projects. Project requests are examined to illustrate trends in projects requesting multiple services and display how Navigator simplifies project intake and connects researchers to resources they may have not recognized they needed. Project attributes including funding type and funding status are included in this review. DISCUSSION/SIGNIFICANCE: CTSA resources are essential to the infrastructure available to researchers. While absolute numbers of requests provide little insight into the impact each CTSA hub may have, the timing and clustering trends of projects with multiple program requests shows how a combination of technology and experienced staff can efficiently support researchers.

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