Understanding the causes and impacts of CRP turnover are critical to meeting the current needs of clinical research. Further work is being done to calculate the cost of turnover to make the business case.

528

Midwest Translational Science (MTS): Building a regional CTSA community

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OBJECTIVES/GOALS: Our vision is to build community amongst the Midwest CTSAs, harnessing our collective expertise to collaborate on translational science challenges and meet the needs of our region. We aim to create opportunities to network, share ideas, brainstorm solutions, address translational science topics, and achieve a range of deliverables. METHODS/STUDY POPULATION: Three individuals from the Chicago CTSAs (NUCATs, CCTS, and ITM) had been networking for a year and desired to increase opportunities to collaborate amongst other CTSAs. We developed an initial vision for a new group that would extend across the region, and we invited the TIN POCs from 16 Midwest CTSAs to join. In September, 2022, the group was launched with 20 members from 12 CTSAs. We hosted 12 monthly meetings via Zoom to discuss various topics (i.e., staffing, career training, e-consent, research design, and recruitment tools) via round tables or presentations. We developed a Google Sites website with resources, a discussion forum, and a group calendar. We solicited feedback via survey and follow-up discussion (i.e., most valuable about the group and what can be improved). RESULTS/ANTICIPATED RESULTS: During the past year, our membership grew to more than 30 participants, representing 16 CTSAs in nine Midwest states (IL, IA, IN, MI, MN, MO, KT, OH, WI). We engaged a total of 45 individuals at our meetings, with an average of 11 participants per meeting. Our discussions were lively and stimulated additional conversations, requests for guidance, sharing resources, etc., beyond the meetings. Feedback from the group was overwhelmingly positive. Members found many aspects of the group to be valuable (i.e., learning initiatives, processes, and best practices at other CTSAs) and provided practical suggestions for improvement (i.e., themes across a quarter or year). Members expressed interest in additional collaborations such as subcommittees, papers, and other initiatives. DISCUSSION/SIGNIFICANCE: We created a regional CTSA community that is very enthusiastic to convene, share innovations developed at their CTSA hubs, and assist one other. Future directions include an in-person retreat in the spring. Our approach can serve as a potential roadmap for developing regional CTSA collaborative groups across the nation.

529

Implementation of a Clinical Research Feasibility Program at an Academic Medical Center

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OBJECTIVES/GOALS: The objectives are 1) to describe the creation and implementation of a Clinical Research Feasibility Program at the University of Miami Miller School of Medicine (UMMSOM), and 2) to share early findings demonstrating its effectiveness in improving research operations which may be helpful for other academic medical centers. METHODS/STUDY POPULATION: Many clinical trials are closed prematurely because of low accrual or not being able to meet the target enrollment. The Miami CTSI and UMMSOM Executive Dean for Research office collaborated to establish the Research Feasibility Committee (RFC) focusing on clinical trial selection with upfront feasibility and recruitment planning. Program implementation included: 1) selecting faculty with successful clinical trial track records as committee members; 2) developing processes, tools, and governance; 3) feasibility pilot testing; and 4) feasibility program roll out and refinement. The feasibility review process starts with the PI/Designee completing a REDCap study intake form, followed by an administrative review to ensure completeness of the form. The RFC chair assigns reviewers for the studies. RESULTS/ANTICIPATED RESULTS: The RFC went live on September 1, 2022 reviewing industry sponsor clinical research studies. The RFC conducts a systematic feasibility assessment of the study protocol, operational requirements, enrollment barriers, institutional resources, and study budget (if available) for all applicable research studies prior to IRB submission and contract negotiation at the UMMSOM. To date, the RFC has received over 270 submissions. Based on feedback from users, the committee has made changes to improve the comprehension of questions and added questions to ensure capturing of critical information to assess study feasibility. Initial metrics suggest simply implementing the review process has decreased the number of clinical trial submissions: average number of studies per quarter was 41 pre-RFC vs 24 post RFC. DISCUSSION/SIGNIFICANCE: The development and implementation of the RFC involved many stakeholders from the research enterprise. Clear and frequent communication to the research community was a key factor in the program's success. The next phase is assessing the impact of the RFC, such as preserving vital resources for trials more likely to be successful.

530

Understanding Strengths and Weaknesses of Clinical Research Operations in Regional Settings

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OBJECTIVES/GOALS: An environmental scansoughtto understand research processes, areas for improvement, and opportunities for collaborative quality improvement (QI)across the Northwest Participant and Clinical Interactions Network (NW PCI). METHODS/STUDY POPULATION: NW PCI site champions were invited for semi-structured single and group Zoom-based interviews. Interviewers asked participants about local research processes, strengths and weaknesses, existing infrastructure to support QI, and interest in collaborative QI across the Network. Audio transcripts were coded using Dedoose and analyzed with deductive

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