Development and Implementation of an Evidence-Based Clinical Orientation Program

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1. Background
Until early 2020, the clinical research staff at the Laura & Isaac Perlmutter Cancer Center lacked a formalized orientation program for clinical research nurses (CRN) and clinical research coordinators (CRC). A survey conducted in 2019 revealed that 34.5 percent of the clinical team had not received a formal orientation. This led to varied and inconsistent training approaches, confusion about role delineation, and workflow standardization challenges.

2. Goals
The primary goal of this initiative was to develop a comprehensive, evidence-based orientation program for clinical staff, ensuring better preparedness for their roles and enhancing overall staff satisfaction.

3. Solutions and Methods
In early 2020, an orientation program was developed and implemented to address the identified gaps. Using didactic, problem-based, and experiential learning, the program aligned with the Association of Clinical Research Professionals CRC competency domains. Topics covered include scientific concepts, ethical and participant safety concerns, investigational product development and regulation, clinical study operations (Good Clinical Practice), study and site management, data management and informatics, leadership and professionalism, and communication and teamwork.

The program expanded in 2021 to include shadowing opportunities with the Research Biospecimen Management Unit, enhancing understanding of workflows and fostering collaboration. In 2022, the clinical program manager position was developed, a role dedicated to CRC supervision, onboarding, and education. In Spring 2023, the program transitioned from being based on a shared drive and in paper packets to a SharePoint platform, enhancing accessibility and usability. Beginning in Fall 2023, the length of the training plan was tailored to each new hire based upon their level of experience, with a target length of five weeks for those with prior oncology research experience, and eight weeks for those without. At the same time, all clinical orientees began to spend five (eight-hour) days per week on site for the first four weeks of their orientation to maximize exposure to different clinical scenarios, even though most are hired under a flexible work model.

4. Outcomes
A 2023 survey revealed notable improvements, with 72.4 percent of CRNs (n=21) and 73.7 percent of CRCs (n=14) expressing satisfaction with their training, a significant increase compared to 2019. Additionally, the timeline for the orientation, which initially took an average of 14 weeks (n=9), has been successfully reduced by 26.4 percent to 10.3 weeks (n=9), reflecting increased efficiency and proficiency in staff preparation. Further highlighting this enhanced readiness and expertise, there has been a remarkable 60 percent reduction in preventable Reportable New Information (RNI) incidents stemming from the care of trial patients between 2019 (n=20) and 2023 (n=8). This achievement is particularly significant considering the substantial growth in our portfolio and operations over the same period, with a 25 percent increase in treatment accruals and a 40 percent increase in the activation of treatment trials in 2023 compared to 2019.

5. Lessons Learned and Future Directions
With a structured training program tailored to the individual's experience, along with clear goals and expectations, efficiency in training has proved feasible. Continuous improvement remains a key focus, with an emphasis on learning modules and self-graded testing through the FOCUS learning platform, incorporation of video resources, and interactive group sessions. Future plans include developing tailored orientations for the unique needs of CRNs, nurse practitioners, and an eventual sub-Investigator orientation program.

References: American Academy of Clinical Research Professionals. "Core Competency Guidelines for Clinical Research Coordinators (CRCs)." ACRP Partners Advancing the Clinical Research Workforce. Accessed February 12, 2024. https://acrpnet.org/employer-resources/our-services/acrp-partners-advancing-the-clinical-research-workforce/core-competency-guidelines-clinical-research-coordinators-crcs/