LINEBERGER COMPREHENSIVE CANCER CENTER

Stephen Rego, Ph.D.; Nasrin H. Babadi, Ph.D., RAC; Leila Valanejad Kiefer, Ph.D.; Allison Camp, Ph.D.; Michael Roxas; J. Kaitlin Morrison, Ph.D.

Background

Staffing Shortages Persist in Clinical and Translational Research (CTR): Record high turnover in CTR staff during COVID resulted in significant staffing shortages in healthcare workers. Turnover rates of clinical research professionals (CRPs) were especially high in academic medical centers (AMCs). Several issues contribute to the staffing issues for CTR in AMCs, including outdated institutional practices, lack of awareness of the career, and unclear progression pathways. Learning about careers in CTR is difficult because there is low recognition and few dedicated educational pathways. Institutions restrict the candidate pool by requiring previous experience. Programs are needed to introduce potential CRPs to the field and provide valuable hands on experience.



Figure 1: Clinical trial staffing market (Source: Beroe Analysis, 2022).

PhDs Offer an Untapped Pool of Potential new CRPs: PhDs possess valuable knowledge and skills in communication, ethical research design, and problem solving that make them excellent candidates as CRPs. Learning about careers in CTR is difficult because there are few dedicated educational pathways, especially in graduate schools. Programs are needed to introduce potential CRPs to the field and provide valuable hands on experience. AMCs are ideally positioned to offer these programs to PhD students.

Clinical Development Immersion Program to Advance Career Training (ImPACT) Internship: The ImPACT Internship offered through the UNC Training Initiatives in Biomedical and Biological Sciences (TIBBS) program provides PhD students with internships that allow career exploration and professional development opportunities. In 2022, the UNC Lineberger Comprehensive Cancer Center (LCCC) partnered with TIBBS to deploy the inaugural Clinical Development ImPACT Internship. The internship offered an immersive nine week paid program, with dedicated time away from the bench, designed to inform students on different careers in CTR at LCCC.



Addressing the Clinical Research Staffing Shortage: **Clinical Development ImPACT Internship**

Goals To measure the success of the program both quantitative and qualitative data collection via an electronic survey as well as interviews were performed. At the end of the program the intern presented their experience at the ImPACT Internship Showcase. Deliverables (Inaugural Program): Over the nine week program the intern completed activities students. Topics to cover include: that spanned the course of IIT development including (Figure 2); attended > 40 meetings a. Protocol development (advocacy council, IRB, etc.), reviewed > 10 training resources, assisted with three concept b. Amendments and administrative letters development projects, reviewed 10 clinical protocols, reviewed/drafted four protocol amendments, c. Institutional review boards (IRBs) reviewed/drafted five ICFs, and reviewed two FDA submissions. d. Informed consent form (ICF) development regulatory associates Charting the Course: Investigator Initiated Trials idea ·& Funding Source Study Concept Letter of Intent Review Concept Collaboration (Pharma Company, Grant Agency PRC Review **Solutions, and Methods** Protocol Review **Study Team Review** Final Draft Protocol Funding Source 📥 Develop Protocol 🧹 Meeting Approved Review (Study Team Review) 400 PRC Review 🚽 (Scientific Review) IRB Review Study Start-Up FDA Review IBC Review (Safety and Scientific Review of signed, Beacon Build Informed Consent nplete and eCRFs Drafting (Study Team, Patient Advocate, P Figure 2. The process of Investigator Initiated Trials (IIT) (https://unclineberger.org/iit/) Protocol Development Review) Based on pre- and post-knowledge surveys (using a five-point Likert scale) the intern improved their knowledge of several clinical research related concepts (Figure 3). Figure 3. Clinical Development Im IRB applications FDA annual reports IND applications Consent forms Administrative letters Protocol amendments Protocol development Concept development Conclusion The inaugural program demonstrated the importance of collaborative approaches in development and implementation of these types of programs. Future iterations of the internship will identify areas of improvement based on survey results and modularize the program to provide flexibility to interns.

The clinical development ImPACT internship had 4 primary goals: 1) Create an immersive nine week internship in CTR for UNC graduate 3) Connect interns to mentors 4) Conduct surveys to assess knowledge gained by intern

2) Expose interns to different CRPs, such as protocol development and the intern who met at least weekly and other staff were shadowed during the

The internship covered multiple clinical trials and regulatory projects. The Intern learned about the development of clinical documents and participated in review meetings of protocol and/or consent forms. Furthermore, medical/regulatory writing strategies to complete compliant data of sponsor trials submitted to the FDA were covered. A primary mentor was assigned to course of the internship to provide cross-functional training. Design of the inaugural program **Description:** The internship covered multiple clinical trials and regulatory projects in the LCCC clinical development team. The Intern learned the development of clinical protocols, consent forms, and investigational new drug (IND) applications. The Intern reviewed IND applications and protocol/protocol amendments of sponsored clinical research of investigational products from UNC, new treatments given by external pharma, and CAR-T cell therapies. The Intern participated in review meetings of protocol and/or consent forms as opportunities present, including the Patient Advocacy for Research Council, Protocol Review Committee, and Protocol Review Meetings with the operational study team. The Intern also completed an initial IRB application with guidance from regulatory personnel. In addition, the intern attended lectures on clinical trial development, sponsor responsibilities, IND, clinical operations, and the process of investigator initiated trials (IITs). The Intern shadowed staff in different positions to gain the big picture of protocol development. Schedule: This internship lasted 9 weeks and consisted of a combination of presentations, collaborative and individual activities, and assignments. Each week will began with a 1-2 hour meeting between the intern and Senior Protocol Development Associate to go over the topics and expectations for the week. The intern also had biweekly touch points meeting with the Director of UNC Lineberger Sponsored Clinical Research.



Outcomes



nPACT Internship Survey			 Post Pre 	
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