

Addressing the Clinical Research Staffing Shortage: Clinical Development ImPACT Internship

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1. Background

Staffing Shortages Persist in Clinical and Translational Research (CTR)

Record high turnover in CTR staff during COVID resulted in significant staffing shortages in health care 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 Several issues contribute to the staffing issues for CTR in AMCs, including outdated institutional practices and lack of awareness of the career.

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.

2. Goals

- 1) Create an immersive nine-week internship in CTR for UNC graduate students. Topics to cover include:
 - a. Protocol development
 - b. Amendments and administrative letters
 - c. Institutional review boards (IRBs)
 - d. Informed consent form (ICF) development
- 2) Expose interns to different CRPs, such as protocol development and regulatory associates
- 3) Connect interns to mentors
- 4) Conduct surveys to assess knowledge gained by intern

3. Solutions and Methods

The internship covered multiple clinical trials and regulatory projects. The intern learned about the development of clinical documents and participate 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 the intern who met at least weekly and other staff were shadowed during the course of the internship.

4. Outcomes

Category: Training, Career Development, and Staff Retention – Work in Progress

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: attended > 40 meetings (advocacy council, IRB, etc.), reviewed > 10 training resources, assisted with three concept development projects, reviewed 10 clinical protocols, reviewed/drafted four protocol amendments, reviewed/drafted five ICFs, and reviewed two FDA submissions.

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 1).

5. Lessons Learned and Future Directions

The inaugural program demonstrated the importance of collaborative approaches in development and implementation. Future iterations of the internship will identify areas of improvement based on survey results and modularize the program to provide flexibility to the interns.

Figure

