UNC LINEBERGER COMPREHENSIVE CANCER CENTER

The Great Rebound: Successful Clinical Trials Office (CTO) Staffing Recovery Strategies

Background & Goals

Great Resignation affected all industries, leading to a record-breaking turnover rate. As a result of this trend, the University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) experienced an unprecedented staffing shortage. This was further exacerbated by pre-existing local, regional and industry factors such as UNC LCCC's location in the Research Triangle Park where competition for clinical research professionals is fierce and pharmaceutical pay, benefits and flexibility historically far exceeded academic research centers. LCCC's staffing crisis was further compounded by a hold on raises for state employees during this timeframe, and a lack of a commensurate increase in staff to support substantial portfolio growth in 2019 during which the number of open to accrual studies and interventional treatment accruals increased by 58% and 34%, respectively. In May 2021, LCCC hit its staffing low with 62 vacancies out of 174 positions. By spring 2022, clinical and regulatory vacancies led to accrual and clinical trial activation holds.

The goal of this initiative was to quickly onboard qualified staff and to increase office capacity while also retaining current staff to enable the LCCC Clinical Trial Office (CTO) to fulfill our mission: Extraordinary Research. Exceptional Care.

Solutions & Methods

Staff Recruitment: To address immediate staffing needs several initiatives were put into effect: 1. Increased use of contracting agencies (Figure 1), 2. Expanded use of direct reach out as a recruitment tool, 3. Development of roles that required no prior research experience which created an entry point for undergraduate students to join the workforce (Figure 2, 3 and 4), 4. Creation of remote/hybrid roles to allow for nation-wide recruitment (Figure 3), 5. Development of a workforce pipeline through internships (**Table 1**), and 6. Realignment of salaries to appropriate benchmarks (**Figure 5**).

Figure 1. Contract Agencies

2019	2022			
Advanced Group	Advanced Group			
Actalent	Actalent			
Medix	Medix			
Piper	Piper			
Procom	Procom			
University Temporary Services	University Temporary Services			
	Astrix			
	Insight Global			
	WCG			
	Medasource			



Figure 1. The CTO increased use of contracting agencies expanding from 6 to 10 agencies tasked with recruiting contract staff to join the CTO in a variety of positions ranging from study coordinators (SC) to regulatory associates (RA) to OnCoreTM pre-award financial analysts. These contracting agencies recruited for both direct placement and 6-12 month contract roles. This substantially increased the # of contractors hired into the CTO in 2022.

Senior staff with the CTO also focused on recruiting former peers and friends to join the CTO, with one staff member recruiting a remarkable 7 applicants leading to 3 permanent hires for senior-level positions within a 9-month period.

Staff Retention: To retain research staff, several initiatives were put into effect: 1. Metered enrollment based on staff morale and bandwidth, 2. Creation of a trial activation slot system based on CTO capacity, 3. New/expanded career ladders in key functional groups (Figure 4), 4. Salary increases via formal HR job reclassifications (Figure 5), 5. Transition to remote work for non-patient facing staff and hybrid work for patient facing staff (Figure 3), 6. In-person and remote teambuilding activities to re-shape office culture (Figure 6), 7. New career growth opportunities outside of personnel management (Figure 3 and 4), and 8. Professional development offerings for CTO leadership (Figure 7).

Figure 2. Entry-Level Assistant Study Coordinators

12 Month Period of Incremental Learning					Training Support		
Foundational S	kills Intermediate			int	Clinical Trainer	SWAT SC	
ALCOA Chart Review Lab Kit Inventory CTMS Maintenance Monitoring Visits	Prescreening Tumor Logs Patient Scheduling Audit Preparation Lab results 2 nd QA	Advanced EKGs on Sponsor Machines Administer QOLs Remote Re-consent Patient Reimbursement		Advanceme	On Site Support R&R Club 1:5 SC Ratio Shadowing Practical & Classroom Curriculum	Remote Support Activation Tasks SWAT Data Entry Classroom Curriculum CAPA Development & Training	

Table 1. Building the Pipeline Internships

Figure 2. An Assistant Study Coordinator role was developed and 6 FTEs were hired as a solution to offset coordinator burnout and create a feeder pool of employees who would spend a year gaining incrementally more advanced experience within the office. Two dedicated training roles were developed to support the training of 50 staff hired in 2022 alone. A dedicated on-site trainer bridged the gap for employees unfamiliar with our campus due to being hired in a hybrid work environment. A SME professional track was created and serves as an alternative to the previously established management professional track for advancement.

Internship Name	UNC Lineberger & North Carolina Central University (NCCU)- Building Oncology Workforce Summer Internship	UNC Lineberger Clinical Development ImPACT Internship	Office of Clinical Translational Research Internship		
Brief Description	2-year longitudinal summer internship for 5 North Carolina Central University (NCCU) undergraduate students that focuses on longitudinal mentorship as well as exposure to cancer clinical research, clinical care of cancer patients, and professional development activities.	Internship offered through the UNC Training Initiatives in Biomedical and Biological Sciences (TIBBS) Program, which provides PhD students with internships that allow career exploration and professional development opportunities.	The TSHS Clinical Research Internship is a semester-long program that is designed to provide undergraduate		
Target Interns Paid/Unpaid Curriculum Description	BIPOC Undergraduate Students, from NCCU, an HBU Stipend Clinical research courses Career panels Lecture series Clinical rotations SC shadowing 1:1 Mentorship Professional development seminars	 UNC Life Science PhD Candidates Salary Support Asynchronous clinical development/regulatory courses Clin dev/regulatory shadowing Training on medical writing with assigned projects to complete Oversight Committee/IRB meeting attendance 1:1 Mentorship 	UNC Undergraduate Students 1 st Cohort Paid SC, lab & provider shadowing Clinical research workshops		

Table 2. Pipelines of future clinical research staff were developed by training students at UNC and NCCU in clinical research

. Kaitlin Morrison, PhD; Stephanie Ladd, CCRP; Jessica Huamani-Bundy, MS, CCRC; Chris Hilliard, CCRP; Leslie Schreiner; Nicole Whitman, CCRP; Michael Roxas, MPH; Shaw Scott, JD; Blair Adams, MS, CCRP; Erica Moore, BSN, RN, OCN, CCRC; Julianna M. Maccarone, MPH, MA, CCRP; Erin Kelly, MPH, RD, LDN; Jamie Mayfield, MA; Erica Riley, BSN, RN; Megan Laffan, MA, CCRP; Coleman Tew, MPA; Pavita Derebail, JD; Stephen Rego, PhD; Leila Kiefer, PhD; Tracey Conrad, CPA; Briana Marini; Gretchen Harrison, MA; Wendy Sarratt, DrPH; Lisa A. Carey, MD; Victoria Bae-Jump, MD; Carrie Lee, MD, MPH

Me

Direct

 Treatm • Transla Service Data C Addition Clinica SWAT

• Projec • Progra

Addition Assista

Team Prin 100% Hybrid

Figure 3. Additional subject matter expert (SME) positions were added within each functional group to allow for continued growth and development of staff outside of management of direct repots. In response to the pandemic, UNC's School of Medicine (SOM) added flexibility in staff primary work locations, increasing the CTO's ability to create hybrid and remote roles. Each functional group was reevaluated by the CTO to determine the business needs for onsite presence resulting in all non-patient facing teams being transitioned to remote work. Clinical teams remained hybrid work with additional flexibility to work from home more frequently. To meet the business needs, each disease group is required to have 1 member of the clinical team onsite and readily available to consent newly identified patients. Furthermore, for all in person visits, clinical staff come on site to support study subjects. These onsite SCs with scheduled visits are in addition to the onsite consenting support for the disease group. Not only did transitioning to more flexible work improve the work/life balance and satisfaction of the CTO team, creating an inducement for clinical research staff interviewing for CTO roles to accept them, it also enabled nation-wide searches for high quality and hard to find talent.

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Salary	20
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Figure 5. CTO salaries were realigned to appropriate benchmarks to recruitment new talent and retain current talent. *2023 projected increases.







The most successful recruitment efforts were the increased use of contractors from a variety of agencies and the creation of entry-level positions allowing for recruitment of undergraduate students. Salary increases and career ladders were the most successful retention methods when coupled with a positive workplace culture. Building workplace culture was driven by teambuilding activities, decreasing the staff to manager ratio allowing for increased staff support, and creating subject matter expert training positions to alleviate the training burden placed on managers and staff. To ensure the continuation of staff recruitment and retention efforts, LCCC clinical research conducted strategic planning in 2022. Strategic planning led LCCC to initiate organizational structure optimization including hiring a Director of Workforce Development & Administration to lead and sustain focus on staff recruitment, development and belonging.

Solutions & Methods

Figure 3. Functional Group Recruitment/Retention Methods

			Chief Me	dical Officer, LCCC Clin	ical Research			
Executive Director, LCCC Clinical Research								
ledical Director, Site Operations Medical Director, Sponsor Operations								
ctor, Clinical Operations		r, Regulatory erations	Director, Sponsor Operations	Director, Clinical Trial Activation	Bioinformatics Facility Director	Director, Clinical Development	Director, Work Force Development & Administra	
tment Trial Coordination slational Sciences & Health ices Coordination Coordination onal SME Positions: nical Trainer AT ject Coordinator gram Manager onal Entry Level Positions: istant SCs	 Regulate Regulate Multice Additiona Regula Trainee Regula Trainee Regula Trainee 	tee Submissions ory Documents ory Compliance nter Regulatory I SME Positions: tory Associate tory Assistant	 Multicenter Operations Monitoring Compliance Committee Oversight Additional SME Positions: Senior Monitor Senior Project Manager Team Primary Work Location: 100% Remote	 Activation Project Management Pre-Award Finance OnCore Calendars Additional SME Positions: Activation Project Managers Team Primary Work Location: 100% Remote 	 Clinical Data Management Clinical Data Standards Clinical Trial Systems Additional SME Positions: eCRF Developer Florence Administrator SDTM Programmer CT.gov Administrator Team Primary Work Location: 100% Remote 	 Protocol Development & Medical Writing Clinical Translation IND Management Patient Education Medical Science Liaising Additional SME Positions: Research Science Liaisons Team Primary Work Location: 100% Remote	 Training Program Management Onboarding Program Manage Office Management Additional SME Positions: Training Program Manager Onboarding Program Manager Onboarding Program Manager Clinical Entry Level Positions: Clinical Research Associate Team Primary Work Locations: 100% Hybrid 	
Primary Work Location:	L		l		-			

Figure 5. CTO Salary Growth



Figure 6. CTO Teambuilding





Outcomes

Figure 8. CTO Vacancies, Growth, Attrition & Re-staffing



Learns Learned & Future Directions

Figure 8. 2019 was a banner year for the CTO, with the number of open to accrual studies and interventional treatment accruals increasing by 58% and 34%, respectively leading to the need to increase the workforce to support this additional workload. (A) The number of positions within the CTO grew from 137 to 199 from 2019 to 2022. % vacancy increased from 2019 to 2021 before reducing to an all-time low in 2022, with only new leaderlevel positions needing to be filled. (B) The % increase in the # of positions in the CTO (2029 compared to 2022) as a whole and each functional group to cover the increased workload and provide further opportunity for CTO portfolio and accrual growth. (C) Vacancies due to increasing the size of the office were further compounded by an increase in the attrition rate. Attrition rate is defined as the # of staff leaving the CTO for an external opportunity ÷ total staff in CTO. Attrition rate was high (12%) in 2019 due to the increase in workload without the subsequent increase in staffing leading to burnout. Attrition rate decreased in 2020 due to the covid-19 pandemic, but then skyrocketed to a 4-year high of 13% during the Great Resignation. The attrition rate was then substantially decreased in 2022 by 4.5% (8.5% attrition).

Activation Capacity (2023 compared to 2019 & 2022) Increased 23 additional interventional treatment trial slots