# The Importance of a Dedicated Clinical Trainer in the Hybrid Environment

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## Introduction

University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) Clinical Trial Office (CTO) transitioned to a hybrid environment in 2020, limiting onsite support and training for study coordinators (SCs). Training needs were further exacerbated by onboarding 87 clinical staff from 2020 to 2023 to replace losses from the Great Resignation and to grow the clinical team by 34.4% from 2019 to 2023.

## Solutions/Methods

To address these challenges, LCCC needed to develop a productive method to provide training for new clinical staff and to re-train existing clinical staff. The goals of this project along with the responsibilities of the new role of a Clinical Trainer were established (**Figure 1**).

### Figure 1. Goals and Responsibilities

| Goals |
| --- |
| Create a subject matter expert clinical trainer position |
| Assess the current training structure |
| Address the challenges of training in a hybrid environment |
| Ease the training burden for other roles |
| Create a robust, structured clinical training program |

| Clinical Trainer Responsibilities |
| --- |
| Provide hands-on onboarding and training to clinical research staff to ensure safe and efficient conduct of oncology clinical trials |
| Provide expert level knowledge in clinical trial practices and regulations |
| Serve as a frontline expert to develop the performance and expertise of new staff |
| Support the assessment of existing staff in ensuring compliant clinical trial coordination |
| Champion a collaborative relationship with staff and other departments |

The clinical trainer implemented multiple training solutions. The Resources and Remedies Club (The R&R Club) is a biweekly meeting where new staff members can get to know colleagues at various training stages, receive practical training, and ask questions. New staff members' attendance is required but all staff are welcome to participate in lectures and hands-on practical curriculum (**Figure 2**). There has been 60 members, including 40 new staff members.

The trainer provides onsite training support for study visits followed by an assessment and action plan. The role incorporates lecture-based training classes for the CTO, including creation of a new course (**Figure 4**). A workload threshold of five SCs and two data coordinators paired with one trainer was established to prevent overload and burnout. A biweekly communication plan was implemented between managers and clinical trainers to share training progress, induct new staff into the training program, and request re-training of current staff (**Figure 5**).

### Figure 2. The R&R Club Curriculum

| Lectures | Team Building | Technology Integration | Practical Application |
| --- | --- | --- | --- |
| Subject 101: Coordination from pre-screening to survival | Icebreakers in Breakout Rooms | PollEverywhere | 6 Worksheets Corresponding with Subject 101 |
| CTCAE 101: Practical Instruction and Case Studies | Surveys | Interactive Games | Case Studies |
| SOP and Work Instructions Application | Question and Answering Session | Zoom Breakout Rooms | Step-by-Step Instructions |
| | Group Activities and Problem Solving | Screensharing | Assessments |
| | | Epic Playground | |
| | | OnCore | |
| | | OneNote | |

## Solutions/Methods

### Figure 3. ASC Mentorship Program

| Monday | Tuesday | Wednesday | Thursday | Friday |
| --- | --- | --- | --- | --- |
| Chat with Mentor and check-in regarding today's tasks. | Chat with Mentor and check-in regarding today's tasks. | Chat with Mentor and check-in regarding today's tasks. | Chat with Mentor and check-in regarding today's tasks. | Chat with Mentor and check-in regarding today's tasks. |
| Update OnCore for today's patient visits | Update OnCore for today's patient visits | Update OnCore for today's patient visits | Update OnCore for today's patient visits | Update OnCore for today's patient visits |
| Reach out to team regarding which patients need kits for the upcoming week and deliver and/or build those kits | Binder maintenance (new consents that need new binders built, what from the hoteling space can be filed?) | Add patient visits to the POD Outlook calendar | Review patients for the upcoming week and determine assessments needed per protocol and prepare/complete documents. | Ensure all required assessments are performed per protocol |
| Enter any deviations into OnCore | Enter any SAEs into OnCore | Add patient visits to the lab Outlook calendar | Submit archival tissue requests to TPF if applicable | Submit CPR-OR requests if applicable |
| Redact source documents | Maintain kit inventory lists/Order kits | Complete long term follow up survival phone calls & document telephone encounter in Epic | Specimen and QOL completion for cooperative groups | Request imaging uploads to sponsors from Rad Core |
| Potential Patients:<br>1. Maintain protocol-specific lists of potential patients<br>2. Obtain medical records for eligibility review<br>3. Review UNC medical chart for eligibility<br>4. Pre-screen patients | Assist in any upcoming monitor visits:<br>1. Schedule with CPO Admin<br>2. Submit Epic request for monitor<br>3. Take monitors to IDS and PI appointments if onsite | Assist in study activation:<br>1. Second check of lab flowsheets<br>2. Participate/attend SIV and start up meetings<br>3. Ensure delivery of kits and equipment<br>4. Work on site-readiness<br>5. Participate in Beacon build validation meetings | Request imaging discs | Request imaging uploads to sponsors from Rad Core |

The Assistant Study Coordinator (ASC) Mentorship Program provides structure and one-to-one mentorship for junior-level positions who wish to advance their careers. Competencies, evaluations, resources, and group training are provided for both ASCs and mentors (**Figure 3**).

### Figure 4. CTCAE 101 Case Study Examples

DOS: 6/10/2022

Ms. Applegate returns to the clinic today for consideration of C7D1 on the A70154 trial. She reports that loss of appetite and nausea began the day after C6D1 (5/20/22) and has not improved. She has lost 10 pounds since her last visit due to this. Baseline weight is 180 lbs., and she is 170 lbs. today. She states that most food taste bad, and she must force herself to eat. She has been supplementing with Ensure. She had one episode of vomiting on 5/21/22 which resolved with Zofran. She also reports increased diarrhea that began around 5/25/22. She is having 7 stools per day (baseline is 2 per day). Fatigue has remained about the same, and she states that it does not limit any of her activities if she takes a nap in the afternoon. She does continue to get out of breath when she exerts herself but is still able to walk her dogs for 2 miles. She reports getting moderate migraines, worse when she is not able to eat much, and reports this has been occurring intermittently since 3/10/22.

Adverse Event Log

| AE | Date Started | Date Ended | Grade | Attribution | Clinically Significant? (Y / N) |
| --- | --- | --- | --- | --- | --- |
| Fatigue | 2/3/22 | | 1 | Possibly Related | N |
| Dyspnea | 2/6/22 | | 1 | Unlikely Related | N |

| Date | 5/17/2022 | | |
| --- | --- | --- | --- |
| Cycle/Day | C7D1 | Normal Range | Grade |
| WBC | 3 | 3.6-11.2 | |
| RBC | 4.34 | 3.95-5.13 | |
| Hemoglobin | 9.9 | 11.3-14.9 | |
| Hematocrit | 36.5 | 34.0-44.0% | |
| Platelet Count | 49 | 150-450 | |
| ANC | 1.4 | 1.8-7.8 | |
| Abs Lymphocytes | 2.1 | 1.1-3.6 | |
| Abs. Monocytes | 0.4 | 0.3-0.8 | |
| Abs. Eosinophils | 0 | 0.0-0.5 | |
| Abs. Basophils | 0.1 | 0.0-0.1 | |
| Sodium | 153 | 135-145 | |
| Potassium | 3.1 | 3.4-4.8 | |
| Chloride | 104 | 98-107 | |
| CO2 | 29 | 20.0-31.0 | |
| BUN | 12 | 9.0-23.0 | |
| Creatinine | 0.96 | 0.60-0.80 | |
| Glucose | 114 | 70-179 | |

Using CTCAE v.5.0, perform a lab check on the values listed. Some may not be listed in the CTCAE but try seeing if you can find them regardless. Crtrl+F is a great way to quickly search. You can either use the medical term or search the provided test (hyponatremia vs sodium). If you do not know the medical term, you can look it up in your search engine. Only grade what is outside the normal range. Keep track of the grades so you can check your work.

Helpful Hints: Remember your symbols! >,<,≥,≤ Write down your work if that helps you: write down the formula and see which grade range the test value falls into. Remember that there are different ways to calculate the grade for ALT, AST, Alk. Phos, creatinine.

### Figure 5. Biweekly Training Assessment Template

Please use the template below to assess training needs for your team members every other week. This can be completed for each member and emailed to Crissey and Diana. Thanks for your collaboration to ensure all staff members are being supported.

Name:

Area(s) of improvement since last update:

Area(s) that are in process, but independent status has not been reached:

Area(s) that need training:

Priority level for training (Red-ASAP), (Yellow-within 1 week), (Green-within 2 weeks), (Blue-greater than 2 weeks):

Date/time requested for in-person training:

## Results

The Resources and Remedies Club has improved our culture by creating a sense of community in a hybrid environment, encouraging shared learning, and focusing on training new coordinators to be successful in their role (**Figure 6**). The Assistant Study Coordinator Mentorship Program has provided a global viewpoint of clinical research for employees and enables them to gain experience to advance their careers. An onsite presence improved the office culture, eased the training burden on other employees, and led to the discovery and resolution of office-wide training gaps. Biweekly assessments have increased collaboration and ensured harmonious communication amongst leadership to best aid new staff. The Clinical Trainer role has supported the training of 80 staff members since initiation of the role, including 57 new staff members (**Figure 7**). In part due to the success of the clinical training program, since 2020, 60 staff were hired as contract, 30 converted to permanent positions, and 12 are in the process of being invited to convert to permanent positions (**Figure 8**).

### Figure 6. R&R Club Impact

**The R&R Club's Impact on Staff Reaching an Independent Status**
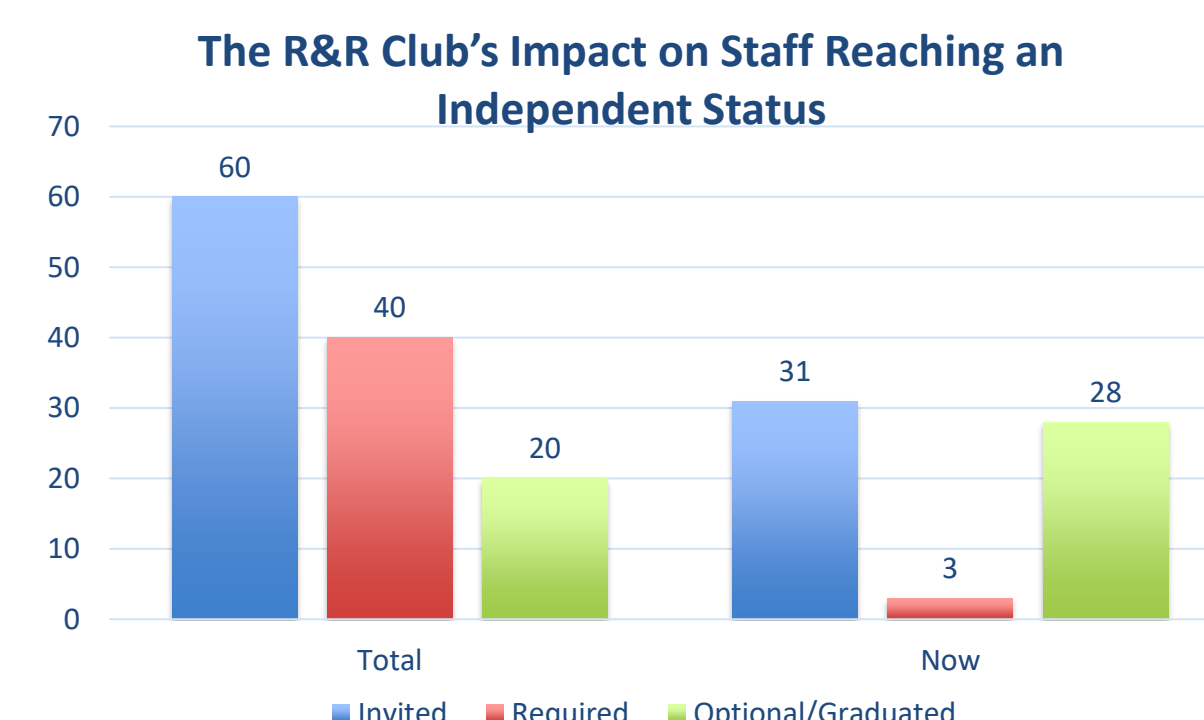


A total of 20 R&R Club meetings were held for 60 members, 40 of which were required to attend until they were deemed independent in their role, at which time they may still be invited as an optional participant. There has been a decrease to 3 members out of 31 who are required to attend due to high rate of transition to an independent status. A total of 581 invites have been sent, and the average per an attendee is 9.5 invites.

### Figure 7. Staff Trained During First Year of Role

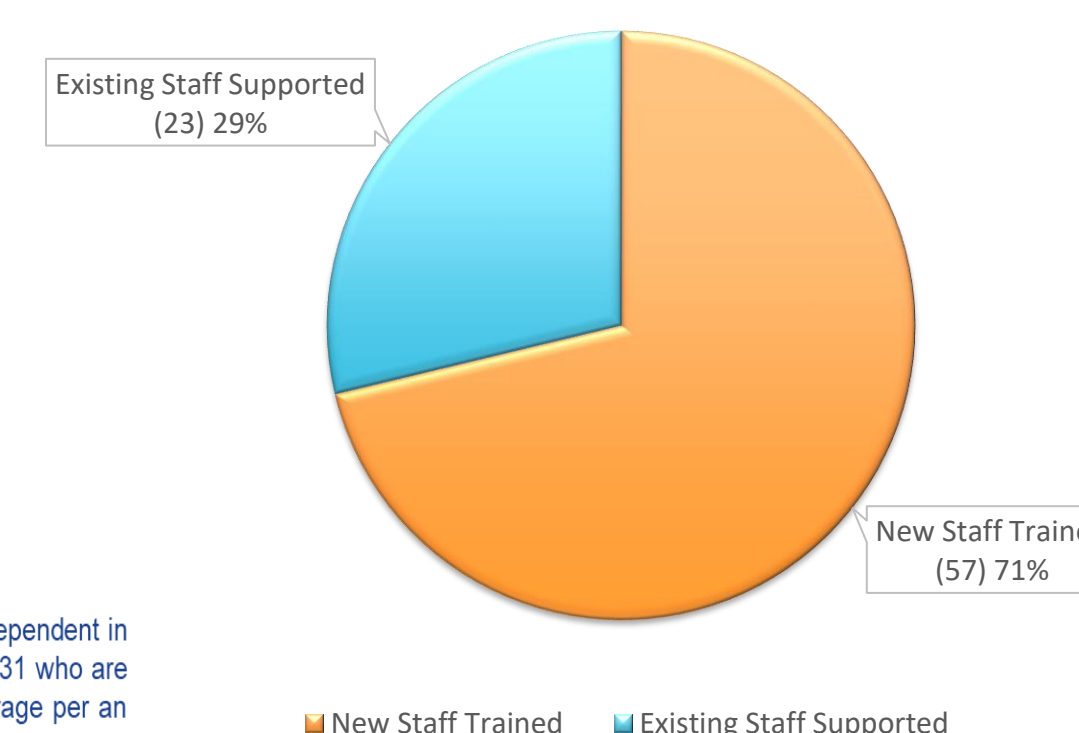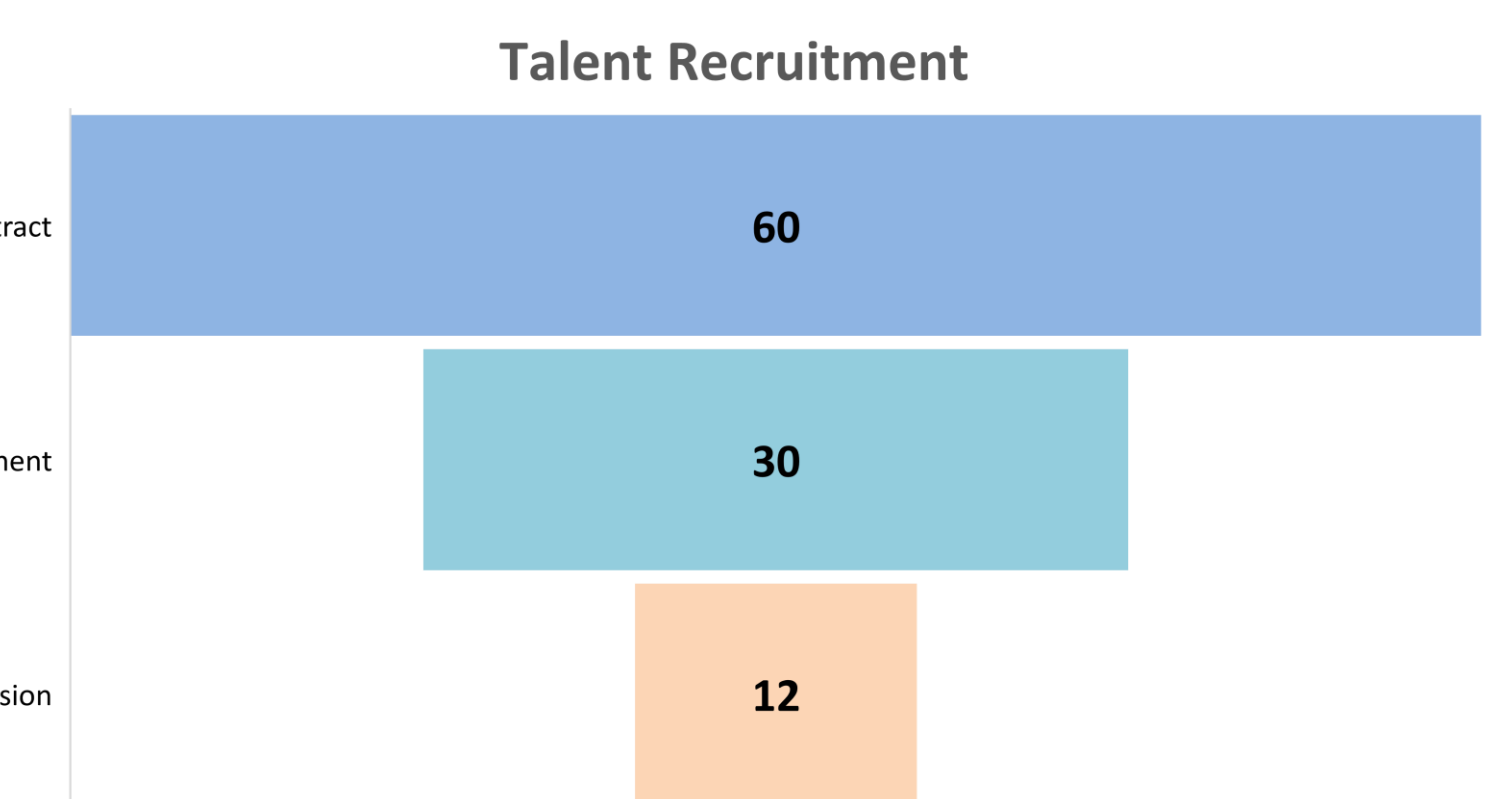**80 Staff Trained Since Initiation of Role**



Existing Staff Supported (23) 29%
New Staff Trained (57) 71%

### Figure 8. Clinical Operations Talent Recruitment

**Talent Recruitment**



| | |
| --- | --- |
| Hired as Contract | 60 |
| Converted to Permanent | 30 |
| In Process of Conversion | 12 |

## Conclusions

The success of the clinical trainer subject matter expert training role led to the expansion of trainers into other units (e.g., regulatory). Future directions include recruitment of a training program manager to oversee the subject matter expert trainers and program within each functional group, and to educate trainers on best practices for training adult learners.

## Contact

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