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

The Power of Support: Improving Clinical Trial Efficiency and Compliance Through a Clinical Research Assistant Role

S. McCoy, E. Ernest, A. McCormack, O. Vigran, E. White, Z. Swainson, B. Bodin, A. Joshi, J. Mehnert, B. Pothuri

Laura and Isaac Perlmutter Cancer Center at NYU Langone Health

1. Background

NYU Langone Health (NYULH) Perlmutter Cancer Center (PCC) serves thousands of patients and provides access to a broad portfolio of clinical trials. In 2025, the clinical trial office (CTO) successfully accrued 864 patients to trials across all disease management groups (DMGS). To mitigate onboarding barriers and enhance operational support, our Clinical Coordination Unit (CCU) introduced a new entry-level clinical research assistant (CRA) role into our clinical research ladder. This role was designed to support our growing CTO while also integrating candidates into the talent pipeline earlier in their professional career.

2. Goals

The goal of establishing this role was to provide additional support to our clinical teams while simultaneously creating an entry point to the CCU. Many traditional clinical research positions require prior clinical experience or specialized credentials; however, many routine trial tasks are administrative and do not require that level of expertise. The CRA role was designed to address this gap by supporting key operational functions without requiring protocol-level responsibilities. Through a structured CRA orientation program, the CRAs gain foundational knowledge of trial operations while working under clinical research coordinators (CRCs).

3. Solutions and Methods

Management conducted a needs-based assessment across all DMGs to map the core competencies required for CRCs success and used these findings to define a scope of practice for the CRA role, focused on non-patient-facing tasks. Based on this assessment, a comprehensive orientation and competency-based training program was developed incorporating good clinical practice (GCP) education, data integrity fundamentals, and mentorship from experienced CRCs.

4. Outcomes

To measure the success of this role, we evaluated two key tasks assigned to the CRAs and calculated the following efficiency metrics: (1) timeliness of document uploads and (2) rates of billing noncompliance. Since implementing the CRA role, source document upload frequency has increased by 200 percent (n=two times per week to n=four times per week), which has reduced queries related to source document availability. Additionally, there has been a 58 percent reduction in the monthly average of billing non-compliance cases from May 2025 (n=152) to January 2026 (n=63). Our overall department compliance is 94.4 percent from September to December 2025, compared to 91.5 percent. CRAs have played a critical role in piloting new workflows and integrating new tools, including an audit prep tracker that identifies documentation gaps before monitoring reviews. Quality assurance initiatives were strengthened by conducting secondary reviews of visit preparation, research sample kit placement,

and tracking trial related reimbursements. These initiatives have strengthened the structure and efficiency of our clinics, while improving coordination across the CTO.

5. Lessons Learned and Future Directions

The addition of the CRA role has made a significant impact on our clinical operations. Urgent support can be provided to the site with this position as the orientation process is four to eight weeks shorter than the CRC position. The regulatory burden is minimal as they are not added to the delegation log. This position provides exposure to clinical research and growth opportunities within the clinical program which aims to improve staff retention rates. The model is scalable and provides a replicable framework for institutions aiming to build a diverse, sustainable research workforce while supporting the workload of busy clinical teams as enrollment increases.