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

Development and Implementation of Cellular Immunotherapy-Specific Clinical Research Coordinator Training and Education Program

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1. Background

Training to become a clinical research coordinator (CRC) is challenging, as new CRCs must master regulatory guidelines such as the International Council of Harmonisation – Good Clinical Practice (ICH-GCP), while simultaneously managing multi-study workloads. They must quickly learn protocol requirements and various patient-facing responsibilities. Proficiency in technical systems, including electronic medical records (EMRs), clinical trial management systems (CTMS), electronic data capture (EDC) platforms, and institution-specific workflows, is essential. Because even small documentation errors or deviations can have significant regulatory and patient safety consequences, a high level of accuracy is necessary. CRCs must also balance concurrent studies under tight timelines, manage expectations from principal investigators (PIs) and sponsors, and develop effective communication and organizational skills within a high-stakes research environment.

2. Goals

These challenges are heightened in cellular immunotherapy trials, where CRCs coordinate leukapheresis, surgical tumor harvests, chemotherapy, inpatient and/or outpatient treatment, and detailed post-discharge patient monitoring. Their role requires interpreting complex protocols and executing workflows that involve cell therapies, pharmacy, ancillary groups, and financial review teams. The overlapping requirements of institutional, Clinical Trials Office (CTO), and program-level standard operating procedures (SOPs) add to the complexity of nuanced scheduling, safety reporting, and financial compliance. As a result, well-structured and standardized department-level training is critical to reduce variability, strengthen audit readiness, improve care coordination, and safety monitoring.

This department-level training and education program aimed to: (1) establish a standardized curriculum aligned with ICH-GCP guidelines and CTO and institutional cellular immunotherapy SOPs; (2) enhance CRC competencies consistent with certified clinical research professional (CCRP) exam domains; (3) improve communication; (4) increase accuracy in research orders, documentation, and audit readiness; and (5) reduce financial risk by improving understanding of OnCore billing.

3. Solutions and Methods

The program features an eight-session curriculum combining didactic instruction and practical application. An initial orientation provides foundational knowledge of cell therapies, oncology, and the patient journey. Key topics included protocol interpretation, navigation of technical systems, prescreening/screening workflows, eligibility confirmation, collection procedures, inpatient coordination, ancillary team processes, adverse event/serious adverse event (AE/SAE) and deviation reporting, audit preparedness, amendments, study activation, and OnCore financials.

4. Outcomes

Pilot session feedback from seven CRC showed scaffolded instruction improved confidence during the program. Foundational concepts facilitated understanding of advanced operational tasks, while simplified slides with visual examples increased retention. We anticipate hands-on practice with

OnCore, EMR, and Florence will improve documentation accuracy and reporting quality. Participants suggested additional instruction in delegation of authority logs, GCP principles, OnCore billing grids, investigator-initiated trial (IIT)-specific timelines, and post-visit responsibilities. A formal mentorship post-training and an updated 90-day onboarding plan will be essential for sustained competency. Since implementing in January 2026, one newly hired CRC has completed the program.

5. Lessons Learned and Future Directions

Future directions include a structured four-day weekly cycle (teaching, homework, review, shadowing). Sessions will feature interactive assessments, discovery-based activities, live demonstrations, and simulated shadowing scenarios aligned with weekly curriculum. Planned enhancements include updating visuals, developing additional job aids, strengthened mentorship, and competency-based training. Long-term goals include continued mapping to CCRP exam domains, creating a digital resource hub, and operational dashboards to monitor competency.