

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



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## Background

- Clinical Research Coordinator (CRC) onboarding is complex and high-stakes, requiring mastery of ICH-GCP, protocol requirements, regulatory documentation, technical proficiency across multiple systems, and simultaneous management of multiple studies.
- Cellular immunotherapy trials significantly increase complexity, with CRCs coordinating leukapheresis, surgical procedures, chemotherapy, treatment administration, and intensive post-discharge monitoring across many departments.

## Goals

- Establish a standardized CRC training curriculum aligned with ICH-GCP, Clinical Trials Office (CTO) requirements, and institutional cellular immunotherapy SOPs.
- Strengthen CRC competencies across domains aligned with the Certified Clinical Research Professional (CCRP) exam framework.
- Improve communication and coordination among CRCs, investigators, and operational stakeholders.
- Increase accuracy and audit readiness through improved research order entry, documentation practices, and regulatory compliance.
- Reduce financial risk by enhancing CRC understanding of OnCore billing and clinical trial financial workflows.

## Solutions and Methods

- Piloted and implemented an eight-session curriculum to include a foundational orientation covering cell therapies, oncology principles, and the end-to-end patient journey with targeted training on core CRC workflows and included specialized sessions on regulatory and operational readiness.

## Curriculum Template:

### Objectives

Objective 1	Objective 2	Objective 3
Ex) SAE Reporting	Ex) Deviations	Ex) Admission Scheduling

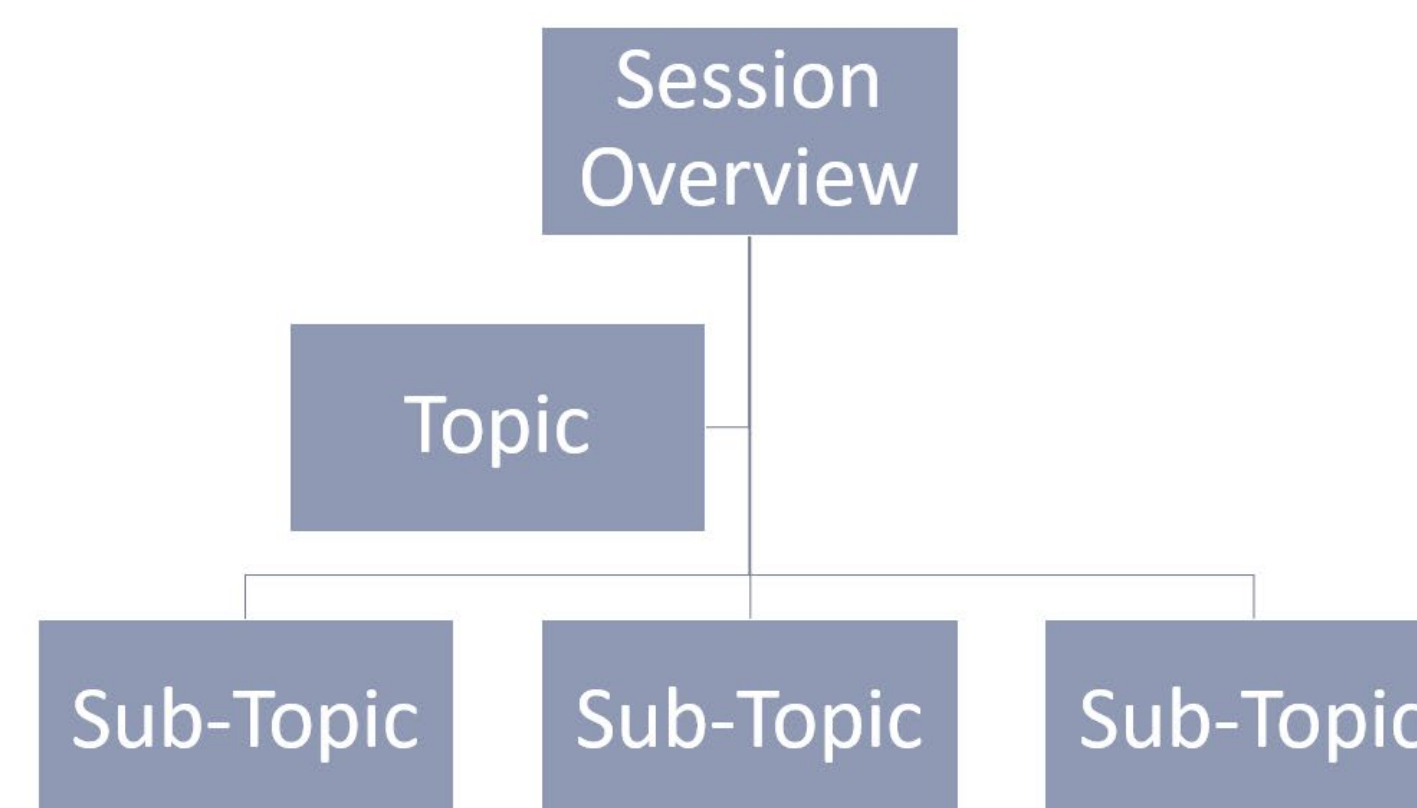


### Key Details to Include

Objective	Resources	Collaborators
<ul style="list-style-type: none"> <li>What are key details to keep in mind for your topic?</li> <li>Why is this topic relevant?</li> <li>How do you complete this topic?</li> <li>Additional CRC responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>What resources are available for this topic?</li> <li>What resources are available through Moffitt and the Clinical Trials Office?</li> </ul>	<ul style="list-style-type: none"> <li>What are their roles?</li> <li>How do they support the CRC?</li> <li>What are the expectations between them and CRCs?</li> </ul>



### General Overview, Outline, or Flow Chart



## Outcomes and Implementation

### Pilot (October 2025) Feedback:

- Participants reported the program was beneficial, applicable to CRC responsibilities, and valuable as an ongoing resource
- Strengths: Visual aids and step-by-step instructions enhance understanding, workflow-aligned content supported real-world application, and structured, interactive sessions improved engagement and learning.
- Challenges/Improvements: Complex topics are difficult to absorb without hands-on practice, introduce foundational overview early in program, increase interactivity and visual aids, add practical job aids, and re-sequence content to introduce advanced topics later.

### First Live Session (April 2026) Feedback:

- 100% of participants reported the program was beneficial, clear and applicable, with high confidence in using it as a future resource.
- Strengths: Engaging, effective visual and interactive learning, and hands-on practice with real-time feedback.
- Skill Reinforcement: Homework and applied exercises supported practical skill development.

## Lessons Learned and Future Directions

- Enhancement Opportunities: Incorporate a start-to-finish CRC workflow to align with curriculum, expand live practice (ex. simulated shadowing scenarios) with competency-based training, and include additional targeted content for more advanced topics.
- 1 Year Follow Up to include: compare number of CCRP certified CRCs, audit findings, financial audit findings, and Oncore recertification metrics pre and post implementation of education program.