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CRA Training Academy

Clinical Research Associates (CRAs) – On the endangered species list?
Anyone who runs clinical studies – sponsors and Contract Research Organizations (CROs) alike – knows CRAs are difficult to train, find, and retain. A recent article in Clinical Leader identifies a "growing plague" for pharma and CROs: "the lack of qualified clinical research staff." John Lewis, spokesperson for the Association of Clinical Research Organizations (ACRO), comments, "the greatest global shortage is for clinical trial associate (CTA) and CRA roles." CRAs are the proverbial lynch pin to running successful clinical trials,and for more than 10 years, this crisis has been brewing. Neither pharma nor CROs are providing enough competency based training to meet the industry's research needs.

How do we bridge the training gap and re-tool our clinical studies with qualified CRAs?
To address this growing problem, the Life Science Training Institute (LSTI) has developed the CRA Training Academy. This intensive 10-week blended learning solution gives sponsors and CROs a comprehensive CRA development solution that will groom effective monitors in a cost-efficient manner. The Academy's interactive curriculum blends case studies, SOPs, foundational regulatory information and experience-based content to ensure participants are ready to begin monitoring activities on day one. Furthermore, the training modules are based on core competencies required of clinical research professionals to conduct high quality, ethical, and compliant clinical research established by the multi-stakeholder Joint Task Force (JTF) for Clinical Trial Competency.

The CRA Training Academy
is a comprehensive 10-week blended learning program for clinical research professionals.

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CRA Training Academy Learning Objectives

- Establish the foundational knowledge needed to ensure the compliant monitoring of in-human clinical studies – from patient recruitment to ongoing post-marketing activities – underlining the critical importance of the role.
- Provide the fundamental to advanced tools and best practices needed to ensure successful trial monitoring and provide the groundwork for continuous improvement.
- Ensure that CRA candidates are ready to begin monitoring work immediately after program completion through knowledge checks, assessments, and instructor "check-backs."

CRA Training Academy Curriculum

This is a comprehensive, 10-week blended learning program consisting of live, instructor-led classroom and web-based training, three assessments, independent studies, and practicums.

Assessment	Pre-Assessment
Module 1	The Role of the CRA in Managing Clinical Research Sites *Classroom, full day*
Module 2	Overview of Protocols and Monitoring Amendments *Webinar, 3hrs*
Module 3	Monitoring A Study *Webinar, 3hrs*
Module 4	Monitoring the Informed Consent & Privacy Statement (two parts) *Webinar, 3hrs*
Practicum	Review Modules 1-4 and Supplemental Activities *Classroom, full day*
Self-Study	Independent Study Assignment (begins Week 4, due Week 5)
Module 5	Monitoring and Safety Reporting *Webinar, 3hrs*
Assessment	Mid-Course Assessment
Module 6	Monitoring Investigational Product (IP) Accountability *Webinar, 3hrs*
Practicum	Review Independent Study and practical application of Modules 4-6
Module 7	Source Data Verification & Quality Review (two parts) *Classroom, full day*
Module 8	Managing Site Non-compliance: The CRA's Role in Preventing Inspection Findings *Webinar, 3hrs*
Module 9	Rules for Quality Documentation of Monitoring Activities *Webinar, 3hrs*
Self-Study	Independent Study Assignment (begins Week 9, due Week 10)
Module 10	Source Data Review & Verification Practicum/Simulation *Classroom, full day*
Assessment	Final Course Assessment