ScienceMedia

SMi Source™ Training Resource

Building a Better CRA: The Critical Role of CRA Training in Delivering Successful Clinical Trials

Increasing clinical competency with the training CRAs want and need.

Clinical Research Associates (CRAs) are critical to clinical trial quality and execution—yet many are underperforming. In this white paper, we unpack some of the common reasons for failure, as well as discuss the challenges associated with training CRAs. We will also offer actionable advice on how to leverage a CRA-tested and top 5 CRO-endorsed training platform that can help improve trial conduct and sponsor satisfaction.

I. The CRA Shortfall: Why CRAs Aren't Meeting Expectations

Whether your company is a Contract Research Organization (CRO) or a pharmaceutical discovery Sponsor in the development phase, the Clinical Research Associates (CRAs) can make or break the quality of your trial. CRAs play a crucial monitoring role in the outcome of your clinical trials, including ensuring site regulatory and protocol compliance, and data quality and integrity. Generalized CRA training to support monitoring readiness is a key determinant in the quality of work. However, recent data gathered by one global CRO, using an objective monitoring simulation administered by an independent CRA assessment organization, reveal that CRAs are consistently underperforming—especially in areas critical to maintaining site compliance, data integrity, and quality—regardless of the level of experience. ["CRA Skills Lacking in Critical Areas." *Applied Clinical Trials*. May 22, 2018]. A deficiency in training creates a multitude of issues related to comparative clinical competency with clinical site personnel, clinically-relevant communication, and overall peer-level respect for CRAs.

Shortage of Experienced CRAs

One reason for this shortfall is the reality of assigning CRAs to trials without adequate training, which can be exacerbated by staffing shortages. The demand for CRAs—expected to grow 1.52%, annually, in 2018—has resulted in many sponsors and CROs finding themselves in a never-ending recruitment cycle for qualified CRAs. This shortage is compounded by the continued outsourcing trend, where many sponsors are outsourcing the CRA role to CROs. In fact, it is estimated that by 2020 over 70% of trials will be outsourced. One of the biggest factors contributing to the global shortage of experienced CRAs is the lack of training opportunities for clinical professionals to begin and continue their careers as CRAs. Many pharmaceutical companies have tabled their new CRA training programs, requiring instead that CROs have experienced CRAs on staff.

Sponsors prefer—and often demand—CRAs who have years of trial monitoring experience assigned to their projects. As part of their service contracts with CROs, sponsors usually specify preferred qualifications for CRAs assigned to their studies, typically requiring a minimum of two to four years of monitoring experience, often with expertise in specific therapeutic areas or disease states.

> **"The CRA shortage means that sites are sometimes faced with absent or under-qualified CRAs," said Christine Pierre, then president of the Society for Clinical Research Sites (SCRS). "Consequences of this reality are that sites report negative impact on study operations, timelines and even quality. Collectively, this reality ultimately impacts all stakeholders." For this reason, we must think about how to effectively deploy resources not only to train new CRAs, but also to continuously train existing CRAs while they are in the field.**

CRA Turnover and Increased Cycle Times

The overall average turnover at CROs (all job types) in the U.S. inched up to 21% in 2016, compared to 20.1% in 2015. Outside the U.S., the overall average turnover rate increased to 18.7% in 2016, versus 17% the prior year. ["Clinical Monitor Turnover Rates, Salaries Continue to Climb." ACRP Blog. November 3, 2017].

Due to the high demand for CRAs, many organizations are finding it challenging to keep longer-running trials consistently staffed with CRAs and Clinical Trial Managers (CTMs) who are familiar with the study diseases, patients, and sites. One recent audit suggests, "For a single two-year study, more than one-third of your sites will deal with CRA turnover. That should be a concern for anyone conducting clinical trials." ["3 Ways to Manage Excessive CRA Turnover." *Clinical Leader*. June 8, 2016.]

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Data suggest that the length of trials (cycle time) has doubled in the past decade [Getz, K. Tufts Center for the Study of Drug Development, 2015]. Encumbered by significantly more trial complexity, more regulatory oversight, more clinical endpoint data gathering, and a higher percentage of rare disease trials with fewer available patients enrolling, the length of trials and the requisite number of years a ClinOps/CRA team needs to remain engaged increases the likelihood of turnover. The demand for accessible continuous training to keep changing teams competent is again a growing mandate.

This high level of turnover also presents specific issues for training competency. While the logistics of holding group training in person is cost-prohibitive and further delays trial execution, classic webinar-training has proven to be highly ineffective. Post-event testing demonstrates low retention rates, and the training for new CRAs/CTMs, provided by existing staff, is often lacking in thoroughness. The need for continuously accessible training has never been more evident.

Establishing Trust and Effective Communication with Sites

Another factor affecting CRA performance is a lack of mutual understanding and respect between them and the rest of the team—which leads to issues with communication and trust.

1. CRA Competency: Within a clinical trial, especially those lasting multiple years, problems in communication and trust can develop when site personnel interact with CRAs who are not well-versed on pertinent aspects of the study disease, the patient journey, or common treatments in their clinical practice. The ability of the CRA to be competent when responding to perfunctory questions, without having to research the response or check with the sponsor or medical monitor, is key to gaining operational respect. At risk is the fact that in many sites where multiple protocols from other sponsors are in place, site personnel simply stop asking and focus their attention on studies where there may be a more competent CRA and better CRA/site interactions.

2. Site Personnel Competency: Conversely, the CRA is an expert on the protocol and can have difficulty engaging the site personnel well enough for them to fully grasp the study, its participants, and the required steps of the protocol. This leads to protocol errors or the incorrect inclusion/omission of study participants. Rectifying this knowledge gap requires further site education, which delays the study.

ScienceMedia has developed and effectively deployed eLearning solutions to address these circumstances: 1) to help ensure CRA and ClinOps staff clinical competency and 2) to help CRAs effectively engage sites in order to optimize performance.

II. The Challenge of CRA Training

Field-based CRAs have a challenging workload and, frequently, a challenging geography that might involve as much as 80% travel to monitor and audit sites. Depending on the size of the CRO and the number of sites in the geography, many CRAs are tasked with monitoring several protocols with varying degrees of source data verification. Training under these circumstances must be accessible and flexible to meet the "road warrior" conditions of late-night arrivals in hotels and early morning site visits.

While high priority trials may command the more experienced CRAs, the vast majority of trials are staffed with less-experienced CRAs, some without scientific educational backgrounds and many without direct trial experience in the disease states for which they are currently assigned. Keep in mind, the CRA training requirements are already burdensome in order to ensure they understand regulations, Good Clinical Practice (GCP) guidance, and unique company policies including travel and expense reporting.

Even in the better developed CRA training programs within CROs or sponsor organizations, formal training is often too general and too superficial with regard to disease states and drug mechanisms. Average training for new CRAs is frequently only two weeks until they are made "billable" for assignment to a trial. Refresher training for more experienced senior CRAs is often left to supervisors who clearly have other priorities.

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Because resourcing for clinical trials is a significant labor management challenge in any CRO, an individual CRA may frequently be reallocated from one client study to a different client and disease state, yet is expected to quickly be at peak performance.

III. What Is the Current CRA Training Approach?

The question that faces CROs is this: How can we help the CRA to understand the details of the disease, standard of care, and clinical practice to a level where she or he can effectively communicate, and problem solve with sites?

We've talked with dozens of Learning and Development professionals in the life sciences industry and the clinical development arena and they all agree: despite all of the technological and regulatory opportunities to advance learning and clinical training, much of CRA training remains as it was a decade ago.

More frequently than not, the medical monitor or clinical trial manager will build a PowerPoint deck before sites are initiated and use that to train the full study team, and the CRAs, on all aspects of the study, including the disease state. Yet, the reality is that each deck is different and the quality and consistency of training material is at risk. Depending on the disease and trial protocol, potentially hundreds of details are covered, and due to the volume of material, little on the disease or molecule is retained, even in some of the better delivered training sessions.

Current practice shows that many of these PowerPoint slide decks are archived, sometimes in their Learning Management Systems (LMS) for future "similar" trials and become cannibalized to form other poorly-referenced and inconsistent training resources. CRAs are then subjected to poorly-documented, pieced-together, and sometimes incomplete "webinars" or recorded presentations. You, yourself, have likely been presented with this scenario and know firsthand the shortcomings of this methodology.

Even if a novice CRA gets value from this approach, it is neither learner-friendly nor typically effective in the field, especially weeks later. There is an even more pronounced deficit in this approach with more experienced, senior CRAs who might be looking for specific training support or a refresher on a specific topic.

Think also about the fact that certain clinical frontlines are moving very rapidly, such as immuno-oncology trials, and the need to provide up-to-date, well-referenced, and easy-to-understand training is paramount in creating effective CRA training.

IV. Training that Works and CRAs will Want!

To be effective, we have learned over the past two years, from hundreds of clinical operations personnel, that CRA training must possess the following qualities, at a minimum:

1. Continuously available;
2. Accessible anywhere and on any device;
3. Feature up-to-the-minute and fully-vetted curated content;
4. Possess an engaging multi-media interface;
5. Have rapid and intuitive search capabilities; and
6. Work well with your existing LMS.

ScienceMedia has developed a CRA-tested and CRO-endorsed training platform that meets all of these criteria, which is currently deployed at some of the largest, fastest-growing clinical development organizations in the world.

SMi Source is a powerful, mobile, on-demand learning library consisting of over 200+ full courses and 15,000+ microlearning topics covering a vast array of disease and therapeutic areas. It combines Google-type navigation simplicity with accurate, reliable, and fully referenced multimedia learning content presented in an engaging YouTube-like format.

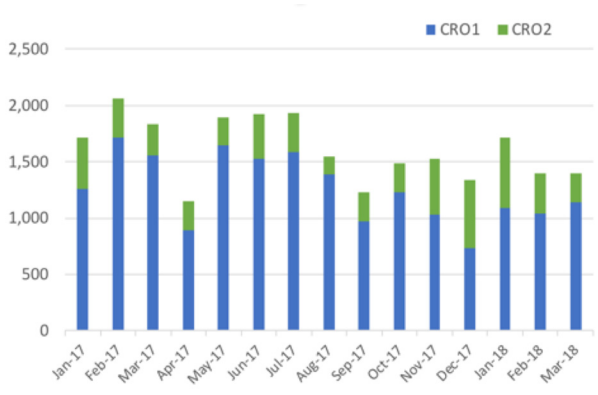
SMi Source is designed to provide a quick search and retrieval of critical information, drive self-directed learning and engagement that can be applied on-the-job, and free resources from the time and cost burdens of building, updating, and maintaining learning content. SMi Source is accessible anytime, anywhere, on any device, and can be integrated with any LMS.

Features that Help CRAs Perform Better and Enjoy Learning

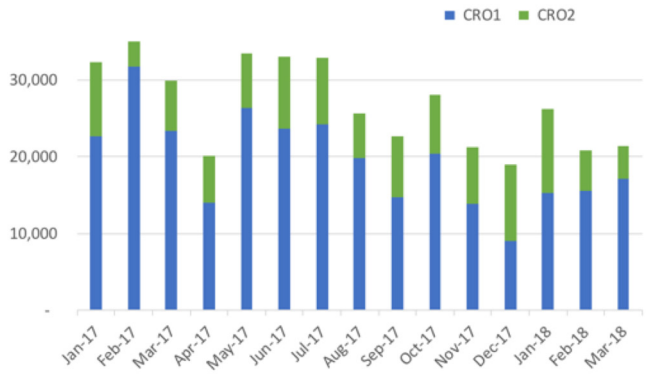
1. An engaging multi-media interface with appropriate charts and graphs accompanying instructional animation. Memorable and easy to digest.
2. Current, up to date, and ever-expanding content. Over 200 full courses and 15,000 clinical and scientific topics are housed in this cloud-based resource.
3. The content is available through your LMS for assignment and tracking or can come with our proprietary SMi LMS.
4. A rapid search capability for refresher training.
5. Custom curation with our integrated tools to build/assemble new courses from existing content that meets specific needs.
6. Effective content to include in CRO bid defenses and to educate BD/proposal teams.

Rapid Adoption and Broad Utilization with Current Development Clients

SMi Source Usage in Clinical Organizations



1,612 Lesson Views / Month
Every 6 minutes



27,002 Topic Views / Month
Every 21 seconds

Results that Improve Trial Conduct and Sponsor Satisfaction

- Validated, knowledge-enabled CRA teams
- Enhance CRA retention by increasing competency and providing state-of-the-art training resources
- Provide useful material in one place that can be leveraged and configured without significant effort
- Assemble a fully customized training course in less than a day, which typically takes more than 4 months and $35,000
- Frees medical monitors to do high value work rather than building PowerPoint presentations from scratch
- Instructionally designed content that is consistent, referenced, illustrated, and ever growing
- Deploy foundational and continuous global training to CRAs and remote ClinOps staff to support a broad array of clinical studies
    - Continuous training supports the goals of the Joint Task Force for Clinical Trial Competency (JTF) to align competency-based efforts (i.e. education, training, and workforce development)

Joint Task Force for Clinical Trial Competency Goals

"The SMi Source catalogue and quality of standard disease-state, anatomy/physiology, and general biology modules were beyond my expectation. For example, they had modules that, as a foundation for a specialized deck, would cut short the time of producing such materials from scratch by a substantial amount. They were accurate, logically ordered, and told a coherent story in a visually digestible way."

~ Director, Medical Affairs—Top 10 Pharma Company

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SMi Source has a team of dedicated scientific writers and professionals to ensure that content is reliable, relevant, and current.

Our advanced search engine is designed for efficiency

Whether you need help finding scientific answers, refining your expertise, or learning an entirely new topic, SMi Source has you covered.

Dependable, confirmable, and validated

All material is referenced to support medical, legal, and regulatory views

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Fill your training gaps, modify or build new lessons from existing topics, or enhance the learning experience with multimedia content from SMi Source.

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Support your global workforce

Provide primary assets to support training localization.

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Today's Clinical Development Professionals?

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About ScienceMedia & SMi Source

For nearly 25 years, ScienceMedia has been delivering innovative learning solutions aimed at improving clinical competency throughout life sciences' R&D, clinical, medical affairs, and commercial organizations worldwide.

SMi Source is the industry's only cloud-based, on-demand, multimedia training content library of 15,000+ microlearning topics and 200+ full courses.