MEDPACE

CRA TRAINING PROGRAM

Experts. Experience. Execution.

Discover the POWER OF X

PACE
Professionals Achieving CRA Excellence

Setting the PACE of CRA Training

Clinical Research Associates (CRAs) play a crucial part in the success of a clinical trial. CRAs ensure the data is scientifically sound and in-line with industry regulations and best practice guidelines.

Since 2003, Medpace has been committed to developing competent and highly skilled CRAs through a comprehensive training curriculum, referred to as Professionals Achieving CRA Excellence (PACE). CRAs in the PACE program are assessed on their ability to learn and apply core principles, while also using key monitoring skills that are aligned with each study's objectives and endpoints, ICH-GCP, and local regulations. PACE CRAs are trained to monitor according to the assessed risk, identified critical variables, and standards for maintaining patient safety and data quality throughout the entire lifecycle of a project. We invest 6-12 months to train every CRA in the PACE program.

Throughout PACE CRAs undergo training through a variety of proven learning strategies including instructor-led seminars, hands-on workshops, interactive mock visit practicums, in-field training visits, and competency based testing modules so they can develop the skills they need from the start and refine them throughout training and beyond.

The same rigorous and comprehensive training is applied to newly hired experienced CRAs, yet in a more expedited fashion. Fast PACE is geared towards experienced clinical research professionals and contains all the same principles as PACE to ensure experienced CRAs meet Medpace standards and understand best practices in the industry.

Clients have indicated they were generally impressed by the quality of Medpace's internally trained staff. Several clients have implemented rules to never allow a CRO to use a CRA with less than two years of experience, but allowed Medpace to break this rule due to the rigorous CRA training program. They further commented that the inexperienced CRAs have yet to create issues and their performance has been above expectations.

The aim of the PACE is to ensure our CRAs demonstrate competence in all aspects of their work. This goes beyond the tasks of source data verification and protocol compliance. By training CRAs about study timelines, database locks, data management, as well as how to confidently read and interpret study protocols, we mold CRAs to monitor with the critical study data and risk assessment in mind every step of the way. This big picture perspective allows CRAs to see and understand how their work, and the work of the sites, contributes to each study's results and ultimately to patient safety.

As an extension of PACE, Medpace offers additional opportunities for CRAs to apply their knowledge and skills through PACE Rotations and PACE supplementary curricula. In PACE Rotations, CRAs receive cross-training in key departments or with specific tasks to better understand the interrelationship of core Medpace functions. These rotations may either be department-specific or project/task specific.

PACE Rotation Examples	
Data Management	Document Center
Proposals & Feasibilities	Clinical Pharmacology Unit
Commercial Operations	Lead CRA Support
Study Start-up/Regulatory Submissions	Training & Development

PACE supplementary programs are designed with a tiered training approach, starting with introductory topics at the foundation and capping off with advanced courses. PACE supplementary curricula are currently offered in the areas of oncology (including a certificate program) and medical device monitoring and targeted to CRAs with specific background or necessary skillset to monitor in these complex indications. See below for a snapshot of the current supplementary curricula. Another supplementary curriculum in infectious disease will be available soon.

	PACE Oncology	PACE Medical Device
Tier 1	Introductory foundation included in PACE training: • Basics of oncology • CRA role in monitoring oncology studies • RECIST 1.1	Introductory foundation included in PACE training: • Global medical device industry regulations/directives • Unique trial design components • Visit-specific considerations and practical monitoring tips • Adverse device effects and related Medpace SOPs
Tier 2	Oncology monitoring certificate program: • Tumor assessment methods • Treatment overviews • Immunotherapy • Trial management considerations	Self-directed study: • Device specific regulations/directives (FDA/EU) and ISO14155 • Device study document examples • Misc. industry articles and resources • Therapeutic area modules
Tier 3	Advanced curriculum: • Various cancer indications • Other miscellaneous oncological areas of interest	Device accountability exercise

For our Sponsors, our training program demonstrates our commitment to quality. We believe our in-house program is the best in the industry and we've heard that echoed time and again. Our Sponsors also benefit from lower turnover rates as our CRAs are well prepared for success with higher levels of job satisfaction.

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its physician-led, high-science, and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective. Headquartered in Cincinnati, Ohio, Medpace employs approximately 2,500 people across 35 countries.