WEST TEXAS & SOUTHERN NEW MEXICO
NEW INVESTIGATOR (PI) TRAINING

Course Description

MCA **CTA's New Investigator Training** program provides **research naïve physicians** (MDs, DOs), Dentists (DDS, DMD), and **mid-tier healthcare professionals** (NP's, Pas, PharmDs, and PhD's) licensed to practice medicine in the US and residing in West Texas and Southern New Mexico, with **eLearning**, **group instruction, and site startup support** needed to begin participating in clinical research and stand up a successful research site. The overall purpose of the MCA's CTA program is to grow and diversify our region's clinical research workforce and the number of healthcare clinics offering clinical research as a care option to patients.

eLearning:
Selected participants will have 24/7 access to Association for Clinical Research Professionals (ACRP)'s full suite of clinical research courses via ACRP's online eLearning portal through December 2023 at No cost.
To obtain a **"Certificates of Completion"** for this program, participants **will be required to complete nine (9) ACRP courses** listed below. The NEW Investigator Training "Certificate of Completion" indicates to the industry that you have taken the initiative to obtain the basic knowledge needed to engage in clinical trials. That said, participants will have access to a variety of other clinical research topics and are highly encouraged to take more ACRP courses throughout the calendar year should they have an interest.

9 -Required ACRP eLearning Modules

(Participants must obtain a passing exam score of 80% + or higher for each eLearning module to obtain their "Certificate of Completion" for this Course)

- Intro to Clinical Trials
- Ethics and Human Subject Protection
- The Drug Development Process
- GCP Simulation
- Informed Consent Simulation
- FDA Form 1572
- Investigator Responsibilities
- e-Research in Managing Clinical Trials in an Electronic Environment
- Mastering the Event Reporting Cycle: Understanding Your Impact on Patient Safety (ICH, E2A)

Recommended ACRP eLearning Modules & Webinar Resources

(Participant access to ACRP's full suit of eLearning courses, conference proceedings, and webinars available on-line 24/7 thru 12/14/2023)

- Trial Feasibility & Selection & Their Impact on Accrual
- Knock Knock…the FDA is Here AGAIN: Be Prepared for a Regulatory Inspection
- Becoming a Successful Clinical Trial Investigator
- Building Quality Management Systems for Sites & Sponsors
- Secrets to Site Operations Success
- Study Start-up Innovation

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Group Instruction & Coaching (Virtual meetings, 1.5 hours /month, 8 MOS)

- Along with book learning, participants are highly encourage to participate in eight (8) virtual group coaching sessions, 1X/month for 1.5 hours per session (see schedule below)
- Group coaching looks to tie together book learning to the reality on the ground and will **focus on clinical research in real life!**
- Our instructor pool is comprised of seasoned local and national clinical research professionals with over 20 years of experience in the field to impart.
- Instead of a didactic lecture, group coaching will provide practical advice around key clinical research questions, tools, trends, case examples,
- business strategy, and tricks of the trade.
- Participants will also have an opportunity to take and thereafter share professional and facility assessment findings with the group for further
- discussion, feedback, and questions should they have an interest.

Startup & On-Going Support

- Participants can also receive post-training resources and assistance to access on-the-job training, business partners, and site startup support via the MCA's Clinical Trial Consortium comprised of multiple industry stakeholders including sites, site networks, academic institutions, healthcare providers, CTA instructors, students, and graduates, sponsors, CROs, industry leaders, and other industry partners.
- This effort often begins with a meeting with you, your clinic, or group to further understand your overall goals and the general approach you wish to take so we can work together to help you outline a successful clinical research strategy.
- Depending on your goals and the availability of MCA funding, a CTA instructor may also be assigned to conduct a facility, patient feasibility, and professional qualifications assessment to determine your readiness for conducting clinical research. Following this assessment, the CTA instructor will discuss with your team areas of improvement and propose solutions for addressing any clinical research training, staffing, facilities, and operational gaps that need to be addressed prior to become site ready.

Qualifications/ Requirements:

Individuals with the following qualifications are invited to apply www.mcamericas.org/clinical-trials/academy. This is an invitation only program as there a limited number of training slots we can award. Apply and secure your seat today!

- US Medical License
- US Citizen & resident of West Texas or Southern New Mexico
- Physician (MD, DO), Dentist (DDS, DMD), & Mid-Tier Healthcare Professionals (PharmD, NP, PA) or PhD with healthcare subject matter expertise.
- Highly motivated to offer clinical research as a care option to patients.

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CTA Instructor Pool:

Below is the list of highly experienced clinical research professionals—most of which are residents of West Texas and Southern New Mexico, who will be helping to train our regions new investigators:

1. Sergio Guerrero, MD, CRA, ICON, Independent Consultant
2. Deborah Clegg, PhD, VP Research, Texas Tech University Health Sciences Center, El Paso (TTUHSC-EP)
3. Wenoah Veikley, Owner, CEO, Chief Clinical Officer, BScN, Access Research & President Diversity Research Solutions
4. Kate Morton, PharmD, Suib-I, COO, Axces Research & VP Operations, Diversity Research Solutions
5. Allen Savedra, CRA, ICON, Independent Consultant, SoCRA El Paso Chapter Leader
6. Yvonne Rodriguez, CRA, Owner, CEO, Egality Sciences, LLC
7. Laura Herrera, Sub-I, DNP, Western Sky Medical Research
8. Catherine Posey, CCRC, COO, Western Sky Medical Research
9. Sandra Smith, Senior VP, Clinical Solutions & Strategic Partnerships, WCG-Clinical
10. Andrea Rodriguez, CCRC, Director of Research, Axces Research

Investigator Group Coaching Schedule

(8, 1.5 hr. Virtual Sessions, 1X/month; ** session dates/times may be adjusted to fit group availability, possible site tours and in-person meetings will be explored per the request of course participants).*

Meeting	Day	Date	Time	Location Format	Course Modules	Instructors
Kickoff	Friday	4/14/2023	1:00-2:30 PM	Zoom-Virtual	**Getting to know you and your clinic: Why Research and Why Now?** • What is clinical research? What are the biggest barriers to entry? • What can clinical research add to your patient care and your practice? • What are the various clinical research career pathways and what makes the most sense for you? What options are available to you in clinical research? • What did you learn from your personal, facility, and professional clinical research assessment(s)? Did anything in the personal, facility, and professional assessments frighten or reassure you? • What were the key takeaways from the ACRP courses?	**Wenoah Veikley** **Allen Savedra**

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Clinical Trial Academy

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Meeting	Day	Date	Time	Location Format	Course Modules	Instructors
Group Coaching	Friday	5/19/2023	1:00-2:30 PM	Zoom-Virtual	**Research in real life:** How to lay a rock-solid foundation. Best practices and how to handle or avoid challenging patient care, legal, ethical, & consent issues	**Wenoah Veikley Sergio Guerrero**
Group Coaching	Friday	6/23/2023	1:00-2:30 PM	Zoom-Virtual	**Startup essentials & tricks of the trade?** What should my priorities be for facilities, staffing and workflow?	**Allen Savedra Sergio Guerrero**
Group Coaching	Friday	7/28/2023	1:00-2:30 PM	Zoom-Virtual	**The 50K Question:** How can exceptional patient care through clinical research add to my bottom line? • Patient Recruitment, Retention, & Diversity in Clinical Trials • Contracts & Budgets • Trial Pipeline & Marketing	**Yvonne Rodriguez Sergio Guerrero**
Group Coaching	Friday	8/25/2023	1:00-2:30 PM	Zoom-Virtual	**The study floodgates open, my time is precious, how do we decide?** • What to consider when looking at study opportunities • Case Studies – Botox Study, Vaccines, Sexually Transmitted Study, etc. • Protocol Complexity/ Capabilities • Risk Identification, Management & Mitigations, Safety Reporting & Quality Assurance	**Wenoah Veikley Deborah Clegg**
Group Coaching	Friday	9/22/2023	1:00-2:30 PM	Zoom-Virtual	**Bringing your A game** • Being an investigator can raise your professional profile, elevate your clinical care, attract patients & exceptional staff. • But being a PI is serious business. There are unintended consequences of not taking the work seriously. PI's who take a super laid back approach are often one (1) and done. • Understanding the specifics of Investigator oversight & the PI role: Informed consent, paperwork, ALCOA, staffing, delegation logs, 1572s, training, supervision (staff & 3rd parties) and communication.	**Laura Herrera Wenoah Veikley**
Group Coaching	Friday	10/20/2023	1:00-2:30 PM	Zoom-Virtual	**Topic – Open TBD– Pick your poison:** What do YOU want to understand the most about clinical research?	**Yvonne Rodriguez Deborah Clegg**
Group Coaching	Friday	11/17/2023	1:00-2:30 PM	Zoom-Virtual	**Topic – Open TBD**	**ALL**

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