

MRM Course Catalog



CRA Training

140 Hour CRA Certificate Program
Fundamentals of Clinical Research



One-, Two- and Three-day Clinical Research Seminars

- Advanced Quality Monitoring
- Coordinating a Clinical Trial
- Drug/Biologic GCP and Monitoring
- Medical Device GCP and Monitoring
- Writing Professional Monitoring Reports



Clinical Research E-Learning

- Investigator's Training Program
- Coordinator's Training Program
- HIPAA Privacy Rule
- GCP from the Investigator's Perspective

Visit website to see expanding eLearning library

Medical Research Management - Who We Are

MRM is one of the nation's leading providers of clinical research education and customized training to leading CROs; Pharmaceutical, Medical Device, and Biotechnology Companies; and Research Sites and Universities. Many Companies are currently using MRM's e-learning courses as a requirement for new employees or ongoing GCP/ICH training.

Since 1999, Medical Research Management Inc. (MRM) has offered the course "Fundamentals of Clinical Research," a 140 Hour CRA Certificate program, successfully graduating thousands of professionals. This program is designed for the professional who wants to transition into a CRA position or enter the clinical research industry. It offers comprehensive Education and "Hands-On" Training of the clinical research process, the FDA regulations, GCP (Good Clinical Practice), and the International Conference of Harmonization (ICH) guidelines.

MRM assists graduates of Fundamentals with résumé preparation and job placement and also offers Employers complimentary job posting to our Alumni and access to our résumé database.

Jill Matzat, RN, BSN, Certified CRA and ACRP Credentialed Clinical Research Trainer. Course Designer & Founder

Jill Matzat holds a Bachelor of Science in Biochemistry from the State University of New York at Stony Brook, as well as a Bachelor of Science in Nursing from Barry University in Florida. She has over two decades of clinical research experience including all aspects of monitoring and managing clinical trials, investigator recruitment, clinical investigational plans, regulatory strategy, IDE / HDE / IND submissions, report development, protocol and CRF development, SOP writing, development of study specific educational materials, and project management. Her experience includes biologics, drugs, devices and combination products.

In 1998, Jill founded Medical Research Management, Inc. and developed "Fundamentals of Clinical Research." She is also one of the founders of a Contract Research Organization, CRA Solutions, Inc. (www.cra-solutions.com) that currently offers consulting services to Medical Device, Pharmaceutical, and Biotechnology companies internationally in the capacity of project management and monitoring.

Jill is a frequent guest speaker at conferences and seminars. She addressed a conference sponsored by the Office of Human Rights Protection and is a guest speaker at MAGI and the ACRP Annual Conference. She had Clinical Adjunct Faculty status at Vanderbilt University from 2004-2005.

Jill is a former Chairperson of the ACRP Trainer's Forum and was a member of the Government Relations Committee, Government Affairs Committee, Content Expert Subcommittee, and former member of Education.

What Is A Clinical Research Associate (CRA)?

A Clinical Research Associate, also known as a Monitor, oversees the progress and conduct of a clinical trial usually implemented by physicians at a hospital, clinic, or physician's office. The CRA is required to oversee the initiation, progress, and conduct of the trial to ensure the integrity of the scientific data collected, in addition to protecting the rights, safety, and well-being of the human study subjects.

The CRA's responsibilities include, but are not limited to, the following:

- Monitoring the physician's adherence to Good Clinical Practices and the study protocol.
- Performing study drug accountability.
- Verifying the documentation of the informed consent process for each study subject.
- Ensuring that non-serious and serious adverse experiences are properly documented and reported.
- Comparing the case report form to the subject's medical record to assure completeness and accuracy.
- Ensuring the filing and maintenance of the required regulatory documents.



CRA's often have a health care or science background (e.g. nurse, medical technologist, or physical therapist; or Bachelor's, Masters, or a Ph.D. in a science). The CRA is usually employed by a pharmaceutical company, contract research organization, academic institution, or site management organization. A CRA can work either in-house or in the field, requiring 50-70% travel. A field monitor will visit multiple sites and interacts with the study coordinator and the investigator conducting the trial.

TABLE OF CONTENTS

140 Hour CRA Certificate Program

Fundamentals of Clinical Research.....page 3

Fundamentals of Clinical Research, an interactive nationwide program providing online and two weeks, 70 hours, of hands on classroom training for the clinical research professional. It begins with the history of legislation and regulations that govern clinical research and an overview of monitoring reports, drug, biologic, and device development. Course participants develop a thorough knowledge base of Good Clinical Practices and International Conference of Harmonization guidelines (E6, E2A), gaining a solid understanding of clinical trial development and management. During Part Two, participants learn the MRM Step-Monitoring Method, a methodical, standardized approach to monitoring, that increases efficiency and accuracy. MRM also teaches the soft skills. It begins with being a CRA and how to write monitor reports.

"Fundamentals of Clinical Research" is one of the only known courses that offers **ALL** of the following:

- Extensive Clinical Research Education, including device and drugs/biologic regulations (see curriculum).
- Two weeks "Hands-On" Training for CRA, and related professions.
- Assistance with Job Placement and Résumé Preparation. (Only for participants not sponsored by their Company).
- Three tests:
 - Monitoring Competency Exam
 - FDA GCP / ICH GCP Exam

Successful completion of the 140 Hour Program is dependent on passing the two MRM exams.

- MRM Step Monitoring Method
- Nationwide

E-Learning

Online Courses & Comprehensive Training page 5

Seminars

1-, 2-, & 3-Day Seminars.....page 6

Target Audience:

Clinical Research Professionals in the Device, Drug, and Biologic Industry.

Seminars:

- **Advanced Quality Monitoring**
- **Coordinating a Clinical Trial**
- **Drugs/Biologics GCP & Monitoring**
- **Medical Devices GCP & Monitoring**
- **Writing Professional Monitoring Reports**

These interactive, hands-on training seminars are held in Coral Springs, Florida. Each seminar provides continuing education contact hours that can be applied to RN licensure and ACRP / SoCRA Certification. Visit our website at www.CRA-Training.com for the latest seminars.

Fundamentals of Clinical Research

140 Hour CRA Certificate Program

Course Structure



Course Objectives: The participant will be able to:

1. Describe the medical product path starting with discovery and ending with marketing approval.
2. Identify the GCP obligations in protecting the rights of study subjects.
3. Distinguish the different roles and GCP obligations between the Investigator, Sponsor, and IRB.
4. Explain the 'ideal' elements used in coordinating a clinical trial
5. Demonstrate the ability to perform monitoring and coordinating activities and detect GCP deficiencies.
6. Choose the different problem-solving techniques in resolving GCP deficiencies.

Fundamentals of Clinical Research consists of two parts:

Part 1 / Education (Online Course)

The Part 1 "Education" consists of a comprehensive online course covering chapters one through seven (see curriculum on page 4).

- Available at any time and completed at the student's desired pace and schedule.
- Requires passing each chapter quiz prior to advancing to the next chapter.
- The student must complete and pass all seven chapter quizzes before attending the Part 2 "Training" class.
- Estimated completion time: 70-100 hours.
- **Free Demo** available on web site: www.CRA-Training.com.
- Prepares for the Core Knowledge Assessment offered by ACRP.
- Online Course Assistance is available.

Part 2 / Training (Classroom Setting)

The Part 2 "Training" session requires two consecutive weeks of classroom attendance, Monday through Friday 9:30 to 5:30 PM, times may vary based on location. This session applies the knowledge acquired from the online course utilizing case studies, training exercises, and group discussions.

- Perform monitoring activities applying the MRM Step Monitoring Method.
- Monitoring of six study subjects and three Investigator Study Files across two therapeutic areas.
- Resolving GCP related issues via Corrective Action and Preventative Action (CAPA) to secure compliance.
- Writing professional and effective monitoring reports to document the securing of GCP compliance.
- Discussions on the differences between drug/biologic versus medical device studies.
- Nationwide locations.
- Résumé preparation and job placement assistance program. (Does not apply to employer-sponsored students.)
- **Prerequisite:** Part 1 "Fundamentals Education" online course.

Candidate Requirements

Applicants for the Clinical Research Associate Training Program are recommended to have one of the following:

- Bachelor's, Masters, or a Ph.D. in a Science or Allied Health Field
- **OR**
- Healthcare Professional (e.g. RN, PA, MD, PT, RPh, PharmD, or Medical Technologist)

Criteria for Course Completion

- Comprehensive cumulative core knowledge exam to validate the online education, based on Chapters 1 through 7 with a minimum score of 70%.
- Monitoring competency exam measured by monitoring a subject's case history and the investigator study file identifying a minimum of 80% deficiencies.
- GCP Regulatory/ICH Guideline exam with a minimum score of 70%.

The candidate will receive a certificate of completion as a Clinical Research Professional, in addition to another certificate of recognition for passing the GCP Regulatory/ICH Guideline exam.

Scholarship Drawing!

- Enter online contest to receive a **\$1,500 tuition reduction**.
- Random drawings held monthly. See website for details.

Registration and Fees

Cost of the Clinical Research Associate Education and Training Program is \$3,495.

- \$1,995 is required for Part 1. This provides the applicant with access to the online course. The Fundamentals of Clinical Research textbook and course materials are sent via express mail.
- \$1,500 is due on, or prior to, the Part 2 starting date.
- Volume Discounts starting at Three or More Registrations

Part Two Location Schedule

February 2 - 13, 2015	Coral Springs, FL
March 16 - 27, 2015	Philadelphia, PA
May 11 - 22, 2015	Coral Springs, FL
September 14 - 25, 2015	Parsippany, NJ
November 9 - 20, 2015	Coral Springs, FL

Payment methods include check or credit card (MasterCard, Visa, American Express, and Discover). Applicant may mail or fax the application, or apply by phone at (877) 633-3322.

Part 1 - Fundamentals Online Education Curriculum

1. Food and Drug Administration Past and Present

- The Establishment of the Food and Drug Administration.
- The History of the Legislation and Regulations, which Govern the Clinical Research Process.
- The History of the Legislation and Regulations, which Protect the Rights, Safety, and Well-Being of Human Subjects.

2. Overview of Medicinal Product Research and Development

- Drug Discovery and Pre-Clinical Research.
- The Clinical Research and New Drug Application Approval Process.
- The Biologics Research, Development, and Licensing Process.
- Medical Device Research, Development, and Marketing Approval/ Clearance.

3. Good Clinical Practice (GCP)

- Investigational New Drug Application 21 CFR 312: Sponsor's Obligations.
- Investigational New Drug Application 21 CFR 312: Investigator's Obligations.
- Investigational Device Exemption 21CFR 812.
- Institutional Review Boards 21 CFR 56.
- Protection of Human Subjects 21 CFR 50.
- Financial Disclosure 21 CFR 54.

4. International Conference of Harmonization

- The History of the International Conference of Harmonization.
- The ICH Good Clinical Practice Consolidated Guideline (E6).
- The ICH Clinical Safety Data Guideline (E2).

The Regulatory Reference CD-ROM includes documentation on Regulations, Guidelines and Directives, FDA Information Sheets and more.

The Regulatory Reference CD-ROM is also available individually for \$29.95 plus shipping and handling.



5. Clinical Trial Development

- Protocol Design and Development
- Case Report Form Design and Development
- Principals of Data Management and the Query Resolution Process
- The Study Types Providing Expanded Access to Investigational Products

6. Clinical Trial Management

Investigator Site Perspective: Coordinating a Clinical Trial at the Site

- Essentials of Source Documentation.
- Maintaining and Managing Essential Documents.
- Recording and Reporting Non-Serious and Serious Adverse Events.

Sponsor's Perspective: Managing a Clinical Trial

- Electing Investigators and Monitors.
- Maintaining and Managing Essential Documents (e.g. FDA Form 1572).
- Case Report Form Data Transmission and Generation of the Clinical Study Report.
- Reviewing and Reporting of Serious Unexpected Adverse Drug Experiences.
- Implementing a Monitoring Plan and Performing Quality Assurance Audits.
- Preparing for an FDA Audit.

7. Monitoring Obligations and Methods

- Monitoring Role and Responsibilities According to the FDA Guideline and the ICH GCP (E6) Guideline.
- Monitoring Responsibilities: Type of Monitoring Visits, Monitoring Activities Pre-Visit, On-Site, and Post Visit.
- MRM Step Monitoring Method: Implementing a Systematic Monitoring Approach to Effectively Monitor a Multi-Center Trial.
- Problem Solving and Trouble Shooting GCP / ICH Issues.
- Writing Strategic Monitoring Reports and Follow-Up Visit Letters.
- Electronic Data Capture and 21 CFR 11.

Fundamentals Part 1 Course Materials:

- Fundamentals Course Manual
- Regulatory Reference CD-ROM
- Reference Materials

CE's and Accreditation



Registered Nurses will receive 70 continuing education credits upon successful completion of the course.
FL State Provider # 50-11408 • CA State Provider # CEP 13617

Medical Research Management, Inc. is accredited by The Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
ACPE Universal Program Number 352-000-08-002-H03-P, 7 continuing education units (CEU's) are available for the online knowledge based program.

Part 2 - Fundamentals Career Assistance

Alumni Career Center

After course completion, MRM's web-based Alumni Career Center will serve as an ongoing career guide and resource.

- Access to job postings.
- Links to potential employer web sites for résumé submission.
- Industry news and career information.
- Access to monitoring tools and templates are available for graduates.
- Alumni résumés are entered into a database using Résumé Wizard. They are then accessible to over 1,000 prospective employers.

Résumé and Job Placement

Please note that job placement assistance is not available for employer sponsored students.

- Students are provided with a résumé writing guideline.
- Students have their résumé evaluated by experienced Clinical Research Professionals.
- Successful graduates have their résumé distributed to hundreds of potential employers (pharmaceutical companies, contract research organizations, academic institutions, and research sites).
- Résumés will be posted on MRM's website for free access by employers.
- Graduates have access to job postings and career guidance through the new Alumni Career Center.

E-Learning

Courseware Design & Development

The courseware is designed to maximize the e-learning experience and includes the following:



- Pre-examination to evaluate the learner's Skills, Knowledge or Attitude (SKA) prior to training.
- Content and layout strategies include behavioral learning objectives, key terms, diagrams, flow charts, and tables highlighting key points, example documents, workbook activities and examination review guides.
- The learner has access to examination review guides prior to taking the post exam.
- Post examination to evaluate the learner's Skills, Knowledge or Attitude (SKA) acquired from training.
- The post examinations provide feedback with correct and incorrect answers.
- The learner evaluates if the course has met each behavioral learning objective.
- Incorporates applicable parts of 21 CFR 11 with respect to training records, course access, and security.
- Learn the methods of complying with GCP from the Investigator's perspective.

CEs are available for RNs and may be applied to ACRP / SoCRA certification.

E-Learning modules also available for as low as \$200. Please visit our website at www.cra-training.com for more information.

Check website for MRM Monitoring Tools that are available for purchase.

Course Fees start as low as \$250
per course, per user.

Investigator Training Program \$445

- Learn the roles that the Investigator, Monitor, Coordinator, and Sponsor play in the clinical trial process; the methods and strategies used to conduct the ideal clinical trial; know the regulations governing clinical trials; and list the steps involved in the investigator's assessment and reporting AEs and SAEs.

Complying with the HIPAA Privacy Rule in Research \$245

- Discuss the covered entity's HIPAA requirements and its research impact with respect to the Notice of Privacy Practices, Access to Medical Records, and Business Associates; list the permitted use and disclosure of protected health information without an individual's authorization; and discuss the steps necessary to prepare and conduct a HIPAA-compliant trial from the investigator and sponsor of CRO's perspective.

A Coordinator's Guide to Conducting Clinical Research \$295

- Describe the role that the Coordinator, Investigator, Monitor, and Sponsor play in the clinical research process; discuss and identify the regulations governing a clinical trial, and recognize the methods and strategies used to conduct the ideal clinical trial.

GCP From The Investigator's Perspective \$200

- Learn the methods of complying with GCP from the Investigator's perspective.



Seminars

All are in Coral Springs, FL

Advanced Quality Monitoring

Course Description:

This three-day seminar is the starting point for quality monitoring is a systematic approach that includes the CRA's organization and application of methods to facilitate standardization and assessment, complying with GCP, ICH, and HIPAA. Developing monitoring skills involves learning valuable time management tips and acquiring tools that facilitate consistency in performing the responsibilities of a CRA. The student will learn how to write professional and effective monitoring reports and follow-up visit correspondence. This 3-day course is enhanced by the hands-on training that utilizes simulated case studies, an investigator study file, and report writing exercises. These techniques can be applied to all studies whether they are drug, device, or biologic.

Course Fee: \$1,195

16.5* CE Hours

Dates:

March 5-7, 2015

October 8-10, 2015

Coordinating a Clinical Trial

Course Description:

This two-day course is designed to provide a brief overview of clinical research with a comprehensive review of FDA GCP and ICH GCP (E6) and the fundamental elements involved in coordinating a clinical trial. It provides practical tips and suggestions that can be applied to promote a GCP and HIPAA compliant clinical trial, including preventative measures and problem solving techniques of some of the most common GCP non-compliance issues.

Course Fee: \$995

11* CE Hours

Dates:

February 26-27, 2015

October 22-23, 2015

Drug/Biologic GCP and Monitoring

Course Description:

This 2-day seminar is designed for those who desire an understanding of the drug/biologic approval process, the regulations that govern IND studies, and the CRA's role in monitoring these studies. The course provides a solid overview of the drug/biologic development process, presenting GCP obligations of the sponsor, investigator, and IRB together with a review of the regulatory documents, study documents, and drug accountability. A comprehensive review of the roles and responsibilities of the monitor and the types of site visits will be discussed along with an example of FDA audit findings.

Course Fee: \$995

11* CE Hours

Dates:

April 23-24, 2015

Medical Device GCP and Monitoring

Course Description:

This 2-day seminar is designed for those who desire an understanding of the device approval process, the regulations that govern IDE studies and the CRA's role in monitoring. The course consists of a comprehensive overview of the medical device development process and the GCP obligations of the sponsor, investigator, and IRB; including the regulatory documents, study documents, and device accountability. A comprehensive review of the role and responsibilities of the monitor, the type of site visits, and a discussion on example FDA audit findings.

Course Fee: \$995

11* CE Hours

Dates:

January 29-30, 2015

September 3-4, 2015

Writing Professional Monitoring Reports

Course Description:

Monitoring is a sponsor's regulatory obligation therefore the monitoring report and follow up visit letter are the regulatory documents to demonstrate the sponsor's compliance with this obligation. These reports may be audited by the FDA and should be written to cover all monitoring activities in the monitoring plan, in a neutral tone, and document any GCP non-compliance using the concept of (CAPA) Corrective Action and Preventative Action Plan. The documentation using CAPA demonstrates the securing of compliance of that investigator. The participant of this one-day program will be asked to write mock reports covering several GCP non-compliance using CAPA plans as a resolution. In addition, we will learn how to write Memo-to-Files that are left at the site to explain an issue or provide clarification.

Course Fee: \$595

6* CE Hours

Dates:

October 7, 2015

Florida State Provider # 50-11408 / California State Provider # CEP 13617

*Continuing education credits are available for RN's and may be applied to ACRP / SoCRA certification.

New seminars are coming soon!! Go to www.cra-training.com to see the latest courses and dates.

CRA Solutions, Inc. is a full service Contract Research Organization (CRO) providing consulting and CRA services to the Medical Device, Biotechnology, and Pharmaceutical Companies. CRA Solutions has a strategic alliance with a European CRO to offer its services on a global scale. Our organization was founded in 2000 by Jill Matzat. RN, BSN, CCRA, CCRT and is female-owned and owner-managed, providing personalized attention and communication to meet our customers' needs. CRA Solutions is able to offer focus, flexibility and a rapid response time that will please the most discerning client.



Some of the services offered include the following:

- **Medical Devices, Combination Products, Biologics, and Pharmaceutical Studies (All Phases)**
- **Study Feasibility Assessments and Gap Analysis**
- **Clinical Investigational Plan/Protocol Development in Compliance with International Standards**
- **Case Report Form Development**
- **Set Up and Attend Pre-IDE and IND Meetings**
- **FDA Strategy and Regulatory Submissions**
- **Complete Study and Project Management**
- **All Aspects of Site Monitoring Using the MRM Step Monitoring Method**
- **Subject Recruitment Strategies**
- **Investigator Identification and Qualification**
- **Study Specific Training with Competency Assessments**
- **Medical Writing**
- **Setting Up and Managing the DSMB**
- **Study Rescue and Clean Up, including Cost Saving Analysis**

Please contact us at 877-633-3322 or visit our website at www.cra-solutions.com

CRA Fellowship Program™ Components

- Education and training
- Strict selection criteria
- Competency testing
- Mentoring
- Accountability
- Ongoing performance evaluations
- Assessed for the “best fit” for your company.
- Candidates are paired with a Trained Clinical Monitoring Mentor



CRA
SOLUTIONS, Inc.
Your Partner in Clinical Trial Management
from Submission to Approval
www.cra-solutions.com

CRA Solutions, Inc. also offers the CRA Fellowship Program™, a cost-effective, quality approach to monitoring. Our Fellows are graduates of our 140-Hour Fundamentals of Clinical Research Program and are tested on core knowledge, monitoring competency, and knowledge of FDA GCP/ ICH GCP. To learn more or to receive a proposal, please contact us at (877) 633-3322 or visit our website at www.cra-solutions.com

CRA Fellowship Program™

The applicant is a graduate of the 140 Hour CRA Certificate Program that is part e-learning and two weeks of hands on monitoring across two protocols. Graduates selected to apply for the fellowship are recommended to have achieved an 80% passing score of the following:

- Monitor Competency Exam
- FDA GCP & ICH GCP Exam

Applicants are pre-screened using behavioral interviewing techniques and a monitor report writing activity. This activity can be customized to your organizations processes. This aids in assessing the CRA's compatibility with your organization.

The Fellows are paired with an MRM Clinical Monitoring Mentor (CMM). The CMM has greater than 4 years monitoring experience and has received “Train the Trainer” training. CMM can accompany the Fellow on a training-performance evaluation visit. This is a structured documented visit that includes assessment tools, trainee instructional guide, and CMM leader's guide.

This visit can occur with your organization or may occur on a different protocol. The CMM acts as a mentor during the two year fellowship; this includes reviewing reports to assess ongoing quality and reviewing monitoring tools for completion.

To enhance knowledge, experience, and maintain cutting edge monitoring strategies, the Fellows are required to research FDA Warning letters, summarizing their findings in quarterly GCP ICH roundtable discussions. They must present strategies to correct and prevent such deficiencies.



www.cra-training.com