

MRCatalog



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

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 Training and Education program, successfully graduating over 1,000 professionals. This program is designed for the professional who wants to transition into a CRA position or enter the clinical research industry. It offers a 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 10 years of clinical research experience including all aspects of monitoring clinical trials, investigator recruitment, monitoring plan and report development, protocol and CRF development, SOP writing, development of study specific educational materials, and project management. She received certification as a Clinical Research Associate from the Association of Clinical Research Professionals in 1996.

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 (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 was a guest speaker at the ACRP Annual Conference. She held Clinical Adjunct Faculty status at Vanderbilt University from 2004-2005.

Jill is currently Chairperson of the ACRP Trainer's Forum and is 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 Training Course

Fundamentals of Clinical Researchpage 3

Fundamentals of Clinical Research, an interactive program providing online and classroom training for the clinical research professional, begins with the history of legislation and regulations that govern clinical research and an overview of 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.

"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).
- "Hands-On" Training for CRA, and related professions.
- Assistance with Job Placement and Résumé Preparation. (Only for participants not sponsored by their Company).

E-Learning

Online Courses & Comprehensive Training page 5

Seminars

1-, 2-, & 3-Day Seminarspage 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 various locations nationwide. Each seminar provides continuing education contact hours that can be applied to RN licensure and ACRP / SoCRA Certification.

Fundamentals of Clinical Research

140 Hour CRA Training Certificate Program

Course Structure

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 5:00 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 three-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.
- **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 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

The cost of the Clinical Research Associate Education and Training Program is \$3,495. This includes tuition, course materials, course text-books, online course access, résumé evaluation, job placement assistance, and access to the MRM Alumni service.

Payment Schedule

- \$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.

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.
- 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

CE's and Accreditation



Registered Nurses will receive 70 continuing education credits upon successful completion of the course.
FL State Provider # NCE 3423 • 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 352-000-05-001-H03, 7 continuing education units (CEU's) are available for the online program, initial release date: 12/26/2005.

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 that is accessible to over 1,000 prospective employers.

Résumé and Job Placement

Medical Research Management assists all graduates with job placement and résumé preparation.

- 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.
- Provides excellent training for employers to use to train entry level employees.

About 70% of graduates obtained employment as Clinical Research Professionals (e.g. CRA, CRC, CDM, Drug Safety Specialists).

E-Learning

Learning Management System

MRM has designed a web-based Learning Management System (LMS) with a library of clinical research education modules and comprehensive training programs. The LMS is used to launch the courseware, track your training and archive your training documentation. It can be used by the individual and by clinical research organizations.

Clinical research organizations can purchase a bulk number of courses, provide the desired employee with access; and track and archive the employees training. The LMS was designed to assist companies in managing their staffs training and re-certification contact hours. Individuals can use the system to track their ongoing training and professional development as well as tracking their re-certification contact hours.

Courseware Design and Development

- Medical Research Management, Inc. has modified and adapted the Instruction Systems Design (ISD) model to develop courseware used to train clinical research professionals. MRM takes into consideration Bloom's learning domains of cognitive, affective, and psychomotor in the design of learning objectives, activities, and test questions.

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.



CE's are available for RN's and may be applied to ACRP/SoCRA certification.

www.CRA-Training.com/e-learnings

Visit our website for more details.

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

Seminars

Advanced Quality Monitoring

Course Description:

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

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

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

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

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

Florida State Provider # NCE 3423 / California State Provider # CEP 13617

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



SEMINAR REGISTRATION APPLICATION

Coordinating a Clinical Trial:

- Jan 8-9, 2009
- Apr 16-17, 2009
- Jun 25-26, 2009
- Aug 13-14, 2009
- Oct 15-16, 2009
- Dec 10-11, 2009

Writing Professional Monitoring Reports:

- Jan 14, 2009
- Apr 29, 2009
- Sep 9, 2009

Advanced Quality Monitoring:

- Jan 15-17, 2009
- Apr 30-May 2, 2009
- Sep 10-12, 2009

Drug/Biologic GCP and Monitoring:

- Feb 12-13, 2009
- Jun 18-19, 2009
- Oct 1-2, 2009

Medical Device GCP and Monitoring:

- Mar 12-13, 2009
- Aug 20-21, 2009
- Dec 3-4, 2009

Location:

Coral Springs, Florida

Hotel Info:

Marriot Coral Springs Hotel

2009 MRM Student nightly rate:

January 1 - March 31, 2009 - \$149.00

April 1 - December 31, 2009 - \$109.00

Register by phone at 877-633-3322, online, or complete the information below and fax to 954 -346-2791

Name: _____

Address: _____

City: _____ State: _____ Zip _____

Phone: _____

Email: _____

Company Name: _____

Method of Payment:

Company Check MasterCard VISA Amex Discover

Credit Card # _____

Name on card _____

Billing Address: (Same as above) _____

City: _____ State: _____ Zip _____

Expiration Date: _____

Signature _____

Make checks payable to **Medical Research Management**.

Mail to: **Medical Research Management; PO Box 8629; Coral Springs, FL 33075**

Cancellations and Substitutions

Cancellations by registrants must be provided in writing prior to the start date of the seminar, such registrants shall receive a credit voucher toward a future MRM seminar. Companies may substitute someone registered with another participant at any time. MRM reserves the right to cancel a seminar due to poor enrollment or acts of nature and shall not be responsible for any airfare, hotel, or other costs. MRM shall offer a credit voucher to a future seminar or a complete refund for MRM Seminar cancellations. Seminar topics and speakers may be subject to change without any prior notice.

Fundamentals of Clinical Research

140 hour CRA Training Certificate Program

Register by phone at 877-633-3322, online,
or complete the information below and fax to 954 -346-2791

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Daytime Phone: _____

Evening Phone: _____

E-mail: _____

Company Name: _____

List All Degrees Obtained and Name of Institution / Certification Background: _____

Fee: \$3,495.

PART 1 (ONLINE): \$1,995 required for online access, course text, and materials.

PART 2 (CLASSROOM) : Remaining \$1,500 due prior to beginning of class.

Payment Method: Company Check MasterCard VISA Amex Discover

Credit Card # _____

Name on card _____

Billing Address: (Same as above) _____

City: _____ State: _____ Zip _____

Expiration Date: _____

Signature: _____

Make checks payable to **Medical Research Management.**

Mail to: **Medical Research Management; PO Box 8629; Coral Springs, FL 33075**

Cancellations and Substitutions

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PART 2 - DATES AND LOCATIONS

Jan 26 - Feb 6, 2009 / Boca Raton, FL . . .

Hotel Info: Courtyard Marriott - Boca Raton
MRM Student nightly rate: \$159.00

Mar 23 - Apr 3, 2009 / Philadelphia, PA . .

Hotel Info: Courtyard Marriott - King of Prussia
MRM Student nightly rate: \$149.00

May 11- 22, 2009 / Coral Springs, FL . . .

Hotel Info: Marriott Coral Springs Hotel
MRM Student nightly rate: \$109.00

Jun 8 - 19, 2009 / Las Vegas, NV.

Hotel Info: TBD
MRM Student nightly rate: TBD

Aug 17 - 28, 2009 / Coral Springs, FL . . .

Hotel Info: Marriot Coral Springs Hotel
MRM Student nightly rate: \$109.00

Sep 14 - 25, 2009 / Parsippany, NJ.

Hotel Info: Courtyard Marriott - Parsippany NJ,
MRM Student nightly rate: \$119.00

Oct 5 - 16, 2009 / Chicago, IL.

Hotel Info: TBD
MRM Student nightly rate: TBD

Oct 19 - 30, 2009 / Raleigh-Durham, NC . .

Hotel Info: TBD
MRM Student nightly rate: TBD

Nov 9 - 20, 2009 / Coral Springs, FL

Hotel Info: Marriott Coral Springs Hotel
MRM Student nightly rate: \$109.00

CRA certificate program
140 hour - fundamentals of clinical research

e-learning
online courses

Seminars
1-, 2- & 3-day seminars