



CLINICAL RESEARCH TRAINING :

- MONITORING CLINICAL TRIALS
- MEDICAL DEVICES & MONITORING
- MONITORING ONCOLOGY TRIALS
- AUDITING CLINICAL TRIALS



# MEDICAL RESEARCH MANAGEMENT

## *Clinical Research Training Specialists*

### Who is MRM?

Since 1999, MRM has trained thousands of clinical research professionals, from individuals beginning a new career path in the clinical research industry to experienced professionals seeking to expand their knowledge and skills. MRM provides customized training with a global perspective to leading companies in the pharmaceutical, biologic and medical device industries. Courses can be tailored to address the American, European and Japanese regulatory environments. Customized training programs have included GCP-compliant data management, project management, auditing, advanced monitoring, and early phase clinical trials.

MRM's signature program is its Fundamentals of Clinical Research 140-Hour CRA Certificate Program, designed for students without previous experience in clinical research. Unlike other courses that merely define compliance in terms of regulations, MRM focuses on real-world applications and hands-on remediation of compliance issues. All monitoring and auditing programs are based on the MRM Step Method™ which uses custom tools to standardize the monitoring process and ensure GCP compliance. Contributing to the uniqueness of the MRM training program is that it has been developed and used extensively by experts in the clinical research industry. MRM's affiliate company, CRA Solutions Inc., is a full service CRO that uses the step method every day in clinical trial rescue, auditing and monitoring. With use in the CRO the developers are able to continually review, refine and update tools as the industry evolves and changes.

### Medical Research Management

#### *Clinical Research Training Specialists*

- Customized Training for the Medical Device, Biologic and Pharmaceutical Industries
- Global Training Experience: ICH GCP E6, FDA (US), EMA (Europe), PMDA (Japan)
- MRM Step Method™ and Custom Tools for Monitoring Accountability & Management
- CRA Certificate Program: Comprehensive Training & Competency Testing
- Monitoring, Auditing and Oncology training

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## MRM Solution

Both ICH GCP and federal regulations recognize the monitor's key role in ensuring the quality and safety of clinical research. With extensive experience in clinical trial rescue and Corrective Action Preventative Action (CAPA) plans, MRM has identified several common causes of inadequate monitoring that can lead to costly delays and deficiencies in a clinical trial:

- Inexperienced Project Managers
- Lack of an organized process for the selection and qualifying of monitors.
- Inadequate monitor training, mentoring and performance assessments.
- Failure to use standardized monitoring systems, tools and problem-solving strategies.
- Lack of therapeutic area training.

The MRM Step Method™ is a systematic approach to monitoring that encourages critical thinking and thorough documentation. The Step Method™ was developed after extensive review of real-world audit findings and noncompliance issues. MRM recognizes that experience alone is not enough to ensure high-quality monitoring — CRAs require tools, training, mentoring and performance assessments. Comprehensive therapeutic area training is needed for CRAs without a medical background, or without the knowledge of the disease or condition being studied. The MRM system has a long track record of success, even on complex oncology studies using a majority of entry-level CRAs.

MRM's monitor training program utilizes systematic tools and hands-on experience to address the root causes of inadequate monitoring. MRM CRAs learn how to use and design GCP-based tools that are customized for each protocol and CRF. For example, the informed consent tool guides the CRA through an 8-point consent verification designed to establish GCP compliance and reduce audit findings. These standardized tools streamline the report writing process, provide a work product for review, and can be integrated into operational listings and metrics to aid in the management of the overall monitoring process. At the end of a study, monitoring tools can be used to prepare a site for an FDA BIMO inspection.

## Course Developer and Founder

Jill Matzat is a regulatory expert with over 20 years of experience in providing training and consulting services to numerous leading companies in the pharmaceutical/biologic and medical device industries.

Jill is a frequent guest speaker at conferences and seminars, including the Association of Clinical Research Professionals (ACRP) Annual Conference. As an ACRP member, she has participated in the Trainer's Forum (past chairperson), Government Affairs Committee, Education Committee, and Content Expert Subcommittee. Jill held adjunct faculty status at Vanderbilt University from 2004 to 2005 and was the 2008 recipient of the Certificate of Merit Award sponsored by the United States Office for Human Research Protections. In 2011 Health Improvement Institute awarded Medical Research Management, Inc. / CRA Solutions, Inc. for Excellence in Human Research Protection for best practice monitoring.

## Who Attends MRM Courses?

The Fundamentals of Clinical Research course is appropriate for anyone seeking a comprehensive foundation in Good Clinical Practices, monitoring and study management, whether they're new to the clinical research industry or broadening their professional skills.

MRM also offers specialized programs and advanced seminars for:

- Project Managers
- Clinical Research Associates
- Clinical Research Coordinators
- Clinical Research Assistants
- Data Managers
- Clinical Operations Managers







## 140 - HOUR CRA CERTIFICATE PROGRAM

### 140-HOUR CERTIFICATE PROGRAM

#### The Fundamentals of Clinical Research

The **Fundamentals of Clinical Research (FOCR)** is designed for individuals who are new to the clinical research industry, or who are transitioning to monitoring from a different clinical research role. FOCR is one of the only training courses that include ALL of the following:

- Extensive education in ICH Good Clinical Practices and in the federal regulations that pertain to drugs, biologics, medical devices and combination products
- The MRM Step Method™ for standardized, effective monitoring
- One full week of hands-on monitoring using real-world case studies and medical records
- Comprehensive Monitoring Competency and GCP Exam

The one-week classroom session is dedicated to hands-on monitoring of three complete mock cases, including patient medical records, case report forms, regulatory binders and CAPA plans. The classroom session is offered several times a year in three locations (FL, NJ, PA). Graduates will receive résumé review and employment guide/manual.

**The course consists of a self-paced online e-learning and a one-week classroom session.**

**COURSE FEE:** \$2,700

**PART 1 (ONLINE):** \$1,500 required for online access, course text, and materials.

**PART 2 (CLASSROOM):** Remaining \$1,200 due prior to beginning of class.

**DATES AND LOCATIONS:**

Feb. 5-9, 2018	Coral Springs, FL
April 2-6, 2018	Philadelphia, PA
May 2-4, 2018	Coral Springs, FL
Sept. 10-14, 2018	Parsippany, NJ
Nov. 5-9, 2018	Coral Springs, FL

**Topics covered include:**

- The history and purpose of clinical research ethics
- Regulatory pathways to approval for drugs, biologics, medical devices and combination products
- Detailed analysis of international Good Clinical Practice guidelines and FDA regulations
- The roles and responsibilities of the people and organizations involved in clinical research
- The development and management of clinical trials (including management of noncompliance)
- Monitoring methods and professional report writing

**Candidate Requirements:**

MRM courses are open to all students, but CRAs with a science or medical background are generally preferred in the clinical research industry. It is recommended that applicants have at least one of the following:

- Bachelors, Masters or Ph.D. degree in science or allied health field
- Experience as a healthcare professional (e.g. RN, PA, MD, PT, RPh, PharmD, Medical Technologist)

**Criteria for Course Completion:**

During the hands-on portion of the course, the candidate must successfully monitor three case studies and pass a Comprehensive Monitoring Competency and GCP Exam with a minimum score of 70%. The candidate will receive a certificate of completion to document his/her qualification as a Clinical Research Professional.

## AVAILABLE TRAINING OVERVIEW

### 2- and 3-Day Seminars

MRM offers several seminars designed for clinical research professionals. Course offerings include:

- Advanced Quality Monitoring
- Oncology for Monitors
- Quality Auditing of Clinical Trials
- Medical Device GCP & Monitoring
- FDA BIMO Inspection Preparation

These interactive, hands-on training seminars are held in Coral Springs, Florida. All seminars can be customized and brought onsite to your company or institution. Each seminar provides continuing education contact hours that can be applied to RN licensure.

### 90-Minute Webinars

- Writing Effective Monitoring Reports
- ICH GCP E6 2016 Addendum
- Clinical Operations & Management
- GCP for Global Clinical Trials: Japan
- European Union Clinical Trial Regulation 536/2014
- Overview of GCP Compliant Data Management

### Customized Training

- Contact MRM to bring a seminar onsite to your staff.
- Seminars can be customized to client needs assessment and include use of hands-on case studies.
- MRM provides competency testing and performance assessment tools.



Visit our website at  
[www.cra-training.com](http://www.cra-training.com)  
for a schedule of current seminars

## SEMINARS

### THREE-DAY SEMINAR

#### Advanced Quality Monitoring

This three-day seminar is the starting point for quality monitoring. MRM's 3-step monitoring method 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. This course is enhanced by the hands-on training that utilizes simulated case studies, and an investigator study file. These techniques can be applied to all studies whether they are drug, device, or biologic.

**COURSE FEE:** \$1195

**CE:** 11

**DATES:** October 10-12, 2018

**LOCATION:** Coral Springs, FL

### THREE-DAY SEMINAR

#### Monitoring for Oncology Trials

Advanced therapeutic area training is essential for monitors working on complex oncology trials. This 3-day course prepares CRAs for the challenges of monitoring in the oncology field. The course begins with an overview of the pathology, diagnosis, and treatment of cancer. Next, the course will explore the design and management of oncology trials. Finally, students will apply the MRM Step Method™ to oncology case studies. This course is designed for CRAs with a minimum of 6 months monitoring experience, but is open to all students.

**COURSE FEE:** \$1495

**CE:** 16.5

**DATES:** March 21-23, 2018

**LOCATION:** Coral Springs, FL

### THREE-DAY SEMINAR

#### Auditing Clinical Trials

Auditing is an essential part of clinical research quality management. Auditing requires a thorough comprehension of the application of GCP to any observations identified. This class focuses on a systematic approach to auditing, using audit tools, applying standards to observations, and the corrective action plan recommendations. A repository of audit observations and recommendations are reviewed to enhance the learning experience and expand knowledge. Simulated case studies are used along with key line item data to develop the auditing skill set. This 3-day course is designed for new auditors or for experienced research professionals who want to broaden their professional skills. The course is applicable to drug, biologic, and medical device studies.

**COURSE FEE:** \$1495

**CE:** 16.5

**DATES:** May 2-4, 2018

**LOCATION:** Coral Springs, FL



### TWO-DAY SEMINAR

#### FDA BIMO Inspection Preparation

The FDA's Bioresearch Monitoring (BIMO) Program is an agency-wide system of inspections and data audits designed to monitor the conduct and quality of clinical studies at all levels — investigator sites, sponsors, pre-clinical laboratories and IRBs. Inspections may be planned or unannounced, so it is important to maintain inspection readiness at all times. This course is designed to guide monitors/auditors and investigator site personnel through the process of preparing for a BIMO inspection.

**COURSE FEE:** \$1195

**CE:** 16.5

**DATES:** October 4-5, 2018

**LOCATION:** Coral Springs, FL

### TWO-DAY SEMINAR

#### Medical Devices/In-Vitro Diagnostics and Monitoring

This seminar is designed for medical device professionals including those in the In-Vitro Diagnostics Industry. It provides an overview of the device approval pathway for class 1, 2, 3 medical devices as well as IVD/LDT devices. It provides key clinical trial elements and an overview of monitoring including the FDA Guidance on a Risk-based monitoring approach to clinical research. This seminar also provides a solid review of monitoring activities using a focused quality approach and resolving GCP issues using CAPA plans. It consists of a comprehensive review of the GCP obligations of the sponsor and the investigator, the FDA Guidance: Investigator Supervisory Role, the regulations that protect the rights and safety of human subjects. This seminar reviews the key documents and elements of the clinical investigation at the site level, including the Investigator Study File and the Sponsor's Trial Master File, as well as all the report requirements and the reporting timeframes. Informed Consent, CAPA, and AE Exercises are performed to enhance learning.

**COURSE FEE:** \$995

**CE:** 11

**DATES:** March 8-9, 2018

**LOCATION:** Coral Springs, FL

Refer to our website [www.CRA-Training.com](http://www.CRA-Training.com) for current webinar fees.

90 - MINUTE WEBINAR

Writing Effective Monitoring Reports

Monitoring reports are a key part of documenting interactions with research sites and overseeing the progress of a clinical study. Clear, concise writing skills can streamline the report preparation process and facilitate the resolution of site issues. This 90-minute webinar, designed for experienced CRAs, will add professional polish to monitoring reports and letters.

DATE: Feb 7, 2018

Topics

- Monitoring Communication & Documentation
- Developing a Professional Writing Style
- Resolving Action Items

90 - MINUTE WEBINAR

ICH GCP E6 2016 Addendum

This 90-minute webinar offers an overview of the recent changes and additions to Good Clinical Practices. The 2016 addendum expands the guidelines for quality systems, risk-based monitoring, documentation, the sponsor’s oversight role, and the use of electronic systems in clinical studies. Participants will discuss how the new standards will affect their monitoring process.

DATE: April 4, 2018

Topics

- Overview of the 2016 Addendum
- Investigator: Resources, Data & Documentation
- Sponsor: Oversight, Quality Management & Risk
- Monitor: Monitoring Plans, Reports & CAPA
- Risk-Based Monitoring
- Electronic Systems

90 - MINUTE WEBINAR

Overview of GCP Compliant Data Management

This 90-minute webinar will identify the ICH GCP foundations of industry standard clinical trial data management practices, including the 2016 ICH GCP E6 R2 update. The principles of data integrity and the role of data management within the clinical study team will be explored. Recommended sponsor SOPs for data handling will be suggested. The webinar will also describe how GCP addresses recent advances in electronic medical data.

DATE: Oct. 11, 2018

Topics

- GCP Requirements for Data Management
- Clinical Trial Data Flow and the Audit Trail
- Data Management, Monitoring, and Safety Monitoring
- Managing Electronic Source Data and Case Report Forms
- Other Relevant Regulations and Guidelines

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90 - MINUTE WEBINAR

GCP for Global Clinical Trials: Japan

Japan is one of the world’s largest markets for pharmaceuticals and medical devices. This 90-minute webinar begins with a brief overview of Japan’s regulatory agencies and ICH GCP as it applies to multinational studies conducted in Japan. The process by which foreign clinical studies may be submitted in support of a Japanese marketing application will be reviewed. Finally, students will discuss Japan’s regulatory challenges and progress towards greater international harmonization.

DATE: Sept. 12, 2018

Topics

- The Japanese Regulatory Environment
- ICH GCP for Japanese Clinical Studies
- Submitting Foreign Clinical Studies for Japanese Marketing Approval
- Special Considerations for Global Trials in Japan

90 - MINUTE WEBINAR

European Union Clinical Trial Regulation 536/2014

The new European Union Clinical Trial Regulation (EU 536/2014) is scheduled to go into effect in October 2018. This regulation will replace the previous Clinical Trials Directive 2001/20/EC. This 90-minute webinar will cover significant changes between Regulation 536/2014 and the old Clinical Trials Directive, as well as the new regulation’s ties to ICH Good Clinical Practice. The requirements for foreign companies seeking to market medicinal products in Europe will be explored.

DATE: Nov. 7, 2018

Topics

- Challenges in Harmonizing European Clinical Trials
- Differences Between Regulation 536/2014 and the Clinical Trials Directive
- Submitting Foreign Clinical Studies for European Marketing Approval
- CE Marking of Medical Devices
- “Brexit” and Implementation of Regulation 536/2014 in The United Kingdom

90 - MINUTE WEBINAR

Clinical Trial Operations Management

This webinar is designed for clinical operations managers, or for clinical professionals who are transitioning to a management role. The course will begin with the GCP responsibilities of the sponsor and investigator and then focus on the key metrics to managing monitoring resources, data management, with the final goal of lock.

DATE: May 16, 2018

Topics

- The Sponsor-Investigator Relationship
- Role of the Clinical Operations Manager
- GCP Responsibilities
- Metrics and trackers
- Clinical operations management project flow.
- Development of processes to enable efficient monitoring and data quality





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