

Course Description

The starting point in creating a quality monitoring process is using a systematic approach. This course trains the CRA on MRM's three step monitoring method to facilitate consistency and standardization in performing the monitoring responsibilities. Another important aspect of monitoring is learning how to bring a non-compliant investigator into compliance using Corrective Action and Preventative Action (CAPA) plans and documenting such plans in a professional and effective monitoring report 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 Objectives

1. Identify the methods used in Source Documentation Verification (SDV).
2. Discuss the monitoring activities involved with investigational medicinal product accountability.
3. Review the criteria used to validate the Research Authorization and Informed Consent Form.
4. Recognize the documentation used to demonstrate monitoring activities.

Contact Hours

Florida State Provider #50-11408, Provider approved by the California Board of Registered Nursing, Provider #CEP 13617 for 16.5 contact hours. Credits can be applied to ACRP certification.

Daily Agenda / Course Topics

Day 1

I. Overview of Monitoring and Preparation for the Case Studies

- Monitoring Visit Types & Strategies for Effectiveness
- Monitoring Responsibilities and Techniques
- MRM Step Monitoring Method, the 8 R's to Consent GCP Compliance Verification, the 5 R's to HIPAA Compliance Verification
- Monitoring Plan Content and Documentation
- Developing Corrective and Preventative Action Plans (CAPA) for GCP ICH non-compliance
- Protocol and CRF Review for Case Study Exercises on Day 2 and Day 3

Day 2

II. Case Study # 1 –

- Applying Monitoring Technique and Tools
- Monitor SV1, SV2, V1, AEs, and CC meds
- Case Study # 1 – Review and Discussion of Deficiencies, Remedies, and Prevention (CAPA)

III. Case Study # 2 – Applying Monitoring Technique and Tools

- Monitor SV1, SV2, V1, AEs, and CC meds
- Case Study #2 – Review and Discussion of Deficiencies, Remedies, and Prevention (CAPA)
- Potential Issue/Problem Exercise

Day 3

IV. Investigator Study File Review including the Regulatory reason and different SOP requirements

- ISF Case Study – Monitoring
- ISF Case Study – Review and Discussion of Deficiencies, Remedies, and Prevention

V. Monitor Report and Follow-up Letter

- Content “What goes in a report” and Writing Style
- Writing Reports using the CAPA style (Corrective Action and Preventative Action) to document the securing of compliance

Who Should Take This Course

This course is designed for individuals with a minimum of 6 months clinical research experience. CRAs that do not have formal training, but are interested in learning skills that will enhance their monitoring activities and those who are transitioning into a CRA position will benefit from this course.

- Course hours are from 9 AM - 4 PM
- Continental breakfast (8:30 AM) and lunch are provided

Fees / Registration

Location: *MRM Headquarters, Coral Springs, FL*

Select a date:

- Oct 27-29, 2011 January 19-21, 2012
 March 29-31, 2012 July 12-14, 2012
 October 25-27, 2012

Fees: \$1.195.00 (15% discount for 3 or more)

Register by phone at 1-877-633-3322, online, or complete the information below and fax to 954 -346-2791

Name: _____

Address: _____

Tel: _____ Fax: _____

Email: _____

Company Name: _____

Method of Payment:

Company Check MasterCard VISA Amex Discover

Name on card _____

Credit Card # _____

Security Code: _____ 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.