Medical Research Management
Clinical Research Training Specialists

Advanced Quality Monitoring

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:

☐ March 16-18, 2016

☐ October 12-14, 2016

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 800-763-4103

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 Mgt; 11555 Heron Bay Blvd, Ste 102 Coral Springs, FL 33076**

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.

Medical Research Management
Clinical Research Training Specialists

Medical Devices/In-Vitro Diagnostics and Clinical Research

Course Description

This seminar was 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. A glance at the similarities and differences between the FDA regulations and the ICH GCP (E6) guideline, and a review of some key safety definitions from ISO 14155-1:2011. It also 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 Objectives

1. List the sponsor's, investigator's and IRB's responsibilities in medical device studies and human subject protections.
2. Discuss the monitoring activities performed for an investigational device study.
3. Identify adverse device effects and their reporting requirements.
4. Discuss the differences between the IDE Application versus the 510K and the PMA.
5. Recognize the differences in the regulatory pathway for In-Vitro Diagnostics including Laboratory Developed Tests.

Contact Hours

Florida State Provider #50-11408, Provider approved by the California Board of Registered Nursing, Provider #CEP 13617 for 11 contact hours. Credits can be applied to ACRP certification.

Daily Agenda / Course Topics

Day 1

I. Overview of the Medical Device Approval Process

- History/Legislation
- Device Classification (Class 1,2, and 3)
- IDE Submission
- Overview of the Marketing Clearance, including De Novo
- 510 k (Traditional, Special, Abbreviated, de novo)
- PMA, HDE and PDP
- Overview of In-Vitro Diagnostics including Analytic Special Reagents, General Purpose Reagents, and Laboratory Developed Tests.

II. FDA GCP and ICH GCP

- FDA GCP: Sponsor and Investigator Obligations 21 CFR 812
- FDA Guidance: Investigator Supervisory Role, October 2009
- Overview of ICH GCP (E6) Section 5: Sponsor
- FDA GCP: Investigator Obligations 21 CFR 812
- Overview of ICH GCP (E6) Section 4: Investigator
- Financial Disclosure by Clinical Investigators (21 CFR 54) and the recent FDA Guidance.

Day 2

III. Key Clinical Trial Elements

- Investigator Agreement
- Regulatory Documents: Investigator File versus the Sponsor's Trial Master File
- Clinical Investigational Plan Content
- Study Device Accountability
- Adverse Event definitions (ICH GCP E2A, and ISO 14155-1:2011)
  - — Adverse Device Effects
  - — Serious Adverse Device Effects
  - — Serious Adverse Events
- Unanticipated Adverse Device Effects
- AE Drill Exercise

IV. Protection of Human Subjects

- IRB Role and Responsibility
- Informed Consent Requirements, the use of Exceptions, & Documentation
- ICH GCP (E6) Consent Similarities and Differences
- HIPAA: Research Authorization Requirements
- Informed Consent Compliance Exercise

V. Monitor Role and Responsibilities

- Risk Based Monitoring – FDA Guidance
- Monitoring Visit Types & strategies for Effective Visits
- Monitoring Responsibilities and Techniques including CAPA plan usage
- 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

VI. Fraud and Misconduct

- What is Fraud and Misconduct?
- Fraud prevention

Who Should Take This Course

CRA's and other Device Industry professionals who want to gain knowledge about the device approval process, GCP governing IDE studies, and the monitoring role.

- 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:

☐ March 10-11, 2016

☐ October 6-7, 2016

Fees: $995.00 (15% discount for 3 or more)

Register by phone at 1-877-633-3322, online, or complete the information below and fax to 800-763-4103

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 Mgt; 11555 Heron Bay Blvd, Ste 102 Coral Springs, FL 33076**

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.