



## Course Description:

This 3-day course prepares CRAs for the challenges of monitoring complex oncology clinical trials. 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 learn strategies for monitoring oncology trials and have the opportunity to apply their skills.

## LEARNING OBJECTIVES

- Describe an overview of the Oncology therapeutic area.
- Identify techniques in monitoring safety data using the CTCAE grading system.
- Discuss the oncology monitoring method and tools to permit a systematic approach to complex trials.
- List common GCP issues and methods of securing compliance.

## COURSE AGENDA & TOPICS

### I. Oncology Overview

- INTRODUCTION TO CANCER:
  - Characteristics of Cancer
  - Cancer Terminology
  - Cancer Classification
- DIAGNOSIS:
  - Medical History, Physical Exam, Lab Tests, Tumor Markers, X-Rays, Imaging, Nuclear Scans, Ultrasound, Endoscopies, Pathology, and Operative Reports
- STAGING:
  - Extent of Disease & Summary Staging
- TREATMENT:
  - Surgery, Radiation, Chemotherapy, Immunotherapy, Hormone Therapy, Biologics, Combination Treatments, Subsequent Therapy, and Alternative Therapies
- FOLLOW UP:

### II. Oncology Trials

- Inclusion/Exclusion Criteria
- Endpoints
- Dose Modifications & Holds
- Common AEs & Toxicities
- Pediatric Trials
- Regulatory & GCP Obligations

### III. Monitoring Oncology Trials

- Monitor Method & Tools
- Documentation & ALCOA
- EMR Auditing
- Informed Consent
- Monitoring Medications & Dosing
- Monitoring AEs & Toxicities: *CTCAE Grading & Special Data Handling*

### IV. Hands-On Monitoring Activity

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

## REGISTRATION

*Fees: \$1,495.00 (15% discount for 3 or more)*

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

Mail to: Medical Research Mgt; 6250 Coral Ridge Drive, Coral Springs, FL 33076

Register by phone at **1-877-633-3322**, Online at **CRA-Training.com**,

or complete and digitally sign this form and email to **info@CRA-Training.com**

Location: **MRM Headquarters, Coral Springs, FL**

Select a date:  March 21-22, 2019

Name: \_\_\_\_\_

Address: \_\_\_\_\_

City/State \_\_\_\_\_ Zip \_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

Email: \_\_\_\_\_

Company Name: \_\_\_\_\_

Method of Payment:

Company Check  MasterCard  VISA  Amex  Discover

Name on Card \_\_\_\_\_

Credit Card # \_\_\_\_\_

Security Code: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Signature \_\_\_\_\_

#### 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. In the event that MRM cancels the seminar, MRM will provide a complete refund or offer a credit voucher that can be used for a future seminar.

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