

ONLINE COURSE - Clinical Research Monitoring and Coordination

Contact Hours: 33

Cost - \$1,875 including textbook

The Clinical Research Associate (CRA) and Clinical Research Coordinator (CRC) support the work of clinical investigators who conduct research for potential new drugs. Also known as monitors and study coordinators, these professionals unify efforts to support the completion of investigational study trials.

This self-paced online course provides a thorough overview of the roles and responsibilities of the clinical research monitor and coordinator. It has been developed to provide you with key skills, job criteria, and industry expectations of both job roles. Upon completion, you will have the basic training to: participate in the drug development process, identify ethical issues in clinical research, and understand sound clinical practices as they relate to studies designed to support medications awaiting world-wide marketing.

Target Audience

Healthcare Professionals such as: (RNs, BSNs, Physicians, Dentists, Pharmacists, Therapists, or Laboratory professionals), who has a life science background who plans to work in the pharmaceutical industry. It is an excellent refresher for professionals already working in the research field who need updated training in the US and International standards.

Course Objectives

Upon completion of this course, participants will be able to:

- Describe the drug development process and roles/opportunities in Clinical Research.
- Identify ethical issues in clinical research and their impact on the development of new products.
- Institute and obtain proper Informed Consent.
- Understand the latest Good Clinical Practices.
- Learn to employ efficient subject recruitment methods.
- Develop a suitable clinical trial protocol and suitable study budget.
- Identify adverse effects and proper reporting format.
- Appreciate the types of sponsor-investigator site visits.

This course is offered in collaboration with Applied Quality Solutions. Applied Quality Solutions is an independent education company that designs, produces and presents continuing education courses to the pharmaceutical and biotech industries across the country. The course is nationally accredited. For specific course content questions, please contact Juliet at appliedqualitysolutions@yahoo.com.

Register

To register, please contact Shelley Neiner at 610-647-4400 ext. 3212 or e-mail sneiner@immaculata.edu.

See next page for Frequently Asked Questions:

CLINICAL RESEARCH MONITORING AND COORDINATION FAQ

● Course Information

How do I register for the CRCM course?

Registration is all done on-line with minimal effort. Here are the items you will need: Credit Card, and your email address.

How is the course set up and organized?

There are ten chapters and two exams. Those chapters start with a video introduction and then followed by a slide show with voice over. Please note that the first two slides are deliberately left silent because they were discussed in the video. Each chapter has a home work assignment. The course materials including the text will be sent to you when you register for the course.

How much does the course cost?

The cost of the entire program is \$1,875.

Am I eligible for a refund if I don't complete the course?

Once you receive course materials, refunds are not available.

How much are the textbooks? Where can I purchase them?

The price of the course includes all required course materials. Textbooks will be sent via USPS priority mail upon registering for the course.

How long does it take? How long do I have to finish the course?

It should take the average learner about 33 hours. You can spread those 33 hours over a period of time as needed. **The maximum time we allow is four months.**

● Fees and Payment Options

What payment options are available? Do I need to pay for the whole course at one time?

We accept checks, credit cards, and purchase orders. All payments must be received upon registration, prior to beginning the course.

Do you offer Financial Aid?

Immaculata University does not offer financial aid for continuing education courses.

Can I get a student loan?

Yes, as long as the lender gives you the check and they make the check out to either you or Immaculata University. Because you are not a matriculated student, student loans that have to be processed through the Office of Financial Aid, are not available.

Which credit cards do you take?

American Express, Discover, Mastercard and Visa.

● Continuing Education Credits

Will I receive Nursing Continuing Education contact hours (CE) for this program?

Yes, this program is approved for 33 Nursing Continuing Education contact hours by the ANCC.

How many college credits is this course?

This is a non-credit continuing education course.

Is this an accredited course?

Yes. This course is designed for professionals wishing to enter the clinical research field or to update their resumes. It can be used as a prep course prior to taking one of the various industry group certification exams. Most of these certifications require that individuals must meet additional experience requirements before qualifying to sit for the exam. The FDA does recommend continuing education, but does not require any type of certification to work in research.

How long does it take to get my certificate?

After you have successfully completed the course, it takes about two weeks for us to send you the certificates

● **CRCM Course Specific Questions**

What does this course cover to advance my skills in clinical research?

This course provides a thorough overview of the roles and responsibilities of the clinical research monitor and coordinator. It has been created to provide you with the key skills, job criteria and industry expectations of both job roles. Upon completion, you will have the basic training to participate in the drug development; identify ethical issues in clinical research; and understand good clinical practices as they relate to studies designed to support medication awaiting worldwide marketing. This course will also provide you with a certificate that shows potential employers and the FDA that you have current training from MSU College of Nursing, a nationally recognized and accredited university.

What does a clinical research coordinator do?

Clinical Research Coordinators work directly with physicians during clinical trials. These CRCs ensure proper treatment and care of patients who participate in the tens of thousands of ongoing worldwide research trials.

What does a clinical research associate or monitor do?

Clinical Research Associates (CRAs) or Monitors are critical pharmaceutical team representatives who oversee ethical treatment of patients while assuring quality conduct of the trials: exciting travel and professional networking highlight the breadth of this career opportunity.

I am not sure I need to take the CRCM course. Who should take this course?

Life Science majors, nurses and physicians are the major audience. Other science degreed individuals should consider enrollment since the pharmaceutical industry employs such persons that have a diverse understanding of scientific principles needed for the wide-range of therapeutics and medical devices currently being developed. Other professionals that may consider this course include: Chemists, Engineers, Pharmaceutical Sales Representatives, Medical Technologists, Laboratory Technicians, Clinical Research Associates, Physicians, Dentists, Physician Assistants, Medical Monitors, Pharmacists, Pharmacologists, Physical Therapists, Respiratory Therapists, Psychologists, Biologists, Medical Writers and Data Managers.

Are there any prerequisites for this course?

A Bachelors degree is typically required to be hired as a CRA. If you have some type of life sciences background, you will be able to better understand the medical science side of the course, but it is not strictly necessary. You do not need medical training to be a CRA. If you do not have a Bachelors Degree, contact appliedqualitysolutions@yahoo.com discuss your eligibility.