Clinical Trials: Medical Device and Drug Development Certificate Program

Early Research and Pre-Clinical Testing
- Identify Clinical Trial Type, Protocol, and Design

Phase I: Preliminary Safety Evaluation Studies
- Compliance with Good Clinical Practice

Phase II: Efficacy Evaluation and Short-Term Safety Studies
- Validation of Clinical Data

Phase III: Results Used in Regulatory Approval Application For Market Approval
- Release Clinical Trials Results

Phase IV: Post Market Studies, Approval, and Outcomes Research
PROGRAM DESCRIPTION

Demonstrating the effectiveness and safety of new medical products is a critical part of the medical product development process and requires significant resources to accomplish. UC Irvine Extension’s Clinical Trials Certificate Program fills a growing need for professional learning that ensures designing and implementing clinical trials for success.

The curriculum provides comprehensive knowledge of coordinating, monitoring and managing a clinical trial within a framework of good clinical practices and regulatory requirements. An internship course provides an invaluable capstone experience for the certificate.

UC Irvine Extension is approved by the California Board of Registered Nursing (BRN) for contact hours (provider number 00093).

WHO SHOULD ATTEND

This program benefits a wide variety of Life Science professionals in biomedical, biotech, and clinical arenas who need either specific knowledge of the clinical research process or a broad understanding of clinical trials in the context of medical product development.

- Nurses interested in expanding their career options
- Researchers and technologists seeking to increase earning power in the clinical research field
- Medical product development professionals who need working knowledge of clinical trials
- Healthcare professionals
- Allied health professionals

PROGRAM BENEFITS

- Combine courses, schedules and sequences to fit your business needs
- Earn a certificate recognized by the Society of Clinical Research Associates and the California Board of Registered Nursing in as little as 9 months
- Enhance your career options with a practical credential
- Choose from face-to-face and online options
- UC Irvine Extension is a Regulatory Affairs Professionals Society (RAPS) registered provider for continuing professional development. Earn credits to qualify for RAC recertification from a variety of life sciences professional development courses for regulatory affairs professionals
- Learn from instructors seasoned in practical industry experience who share their knowledge effectively

CERTIFICATE CANDIDACY

Candidates must have a minimum of an associate degree; OR equivalent work experience and consent of the program director.

CERTIFICATE REQUIREMENTS

A certificate is awarded upon completion of 16 credit units (10.5 required and a minimum of 5.5 elective credit units), with a grade point average of “B” or better.

NOTE: Six credit units may be counted toward the Medical Product Development Certificate Program.

It is recommended that candidates complete the required courses prior to the elective courses.

Graduates from UC Irvine Extension’s Clinical Trials Certificate program are eligible to transfer credits to Keck Graduate Institute’s Master’s of Bioscience program.

FOR MORE INFORMATION

Please call (949) 824-5380.

PROFESSIONAL ASSOCIATION OF INTEREST


ADVISORY COMMITTEE

AMY L. BATOOSINGH, Director, Clinical Research, Allergan, Inc.
GINGER CLASBY, Executive Vice President, Clinical and Regulatory Affairs, Promedica International
RUTH MULNARD, D.N.Sc., RN, Associate Program Director of the General Clinical Research Center and an Institutional Review Board Chair at UC Irvine
RICHARD NICHOL, President, Nichol Clinical Technologies Corporation
ALBERT REGO, Scientific Consultant to the Life Sciences Industry
NANCY SCHWARTZ, M.B.A., RN, medical industry consultant for SearchLight Consulting, guest lecturer at the USC School of Pharmacy
DWIGHT TAPP, Director, Research and Business Development, Compassionate Cancer Medical Group

Individuals seeking the designation of Certified Clinical Research Professional, “CCRP”, from The Society of Clinical Research Associates (SoCRA), who hold an Associate’s Degree or Bachelor’s degree in science, health science, pharmacy, or a related (science/healthcare) field, may complete the UC Irvine Extension Clinical Trials Certificate Program in lieu of one year of SoCRA’s eligibility requirement of two years’ work experience in clinical research. For more information about the CCRP designation, please visit the SoCRA web site at http://www.socra.org/certic.htm.
REQUERIED COURSES (10.5 units)

Fundamentals of Clinical Trials
BIOSCI X450 (3 units)
Clinical trials are designed to answer questions concerning the safety and effectiveness of medical products. Get an overview of clinical trials regulated by the FDA. Learn about the planning process underlying the Strategic Clinical Plan and regulatory submissions to the FDA. Explore topics including protocol development and implementation, i.e. study site selection, financial controls, timelines, and management of the site’s operations; proper informed consent; Good Clinical Practices compliance; HIPAA; FDA regulations and guidelines; and post-market support studies.

Human Subjects Safety in Clinical Trials
BME X403 (1.5 units)
The use of human subjects in clinical trials for drug and device development requires sound ethical practices. Explore topics that include FDA regulations and guidance, informed consent process, the make-up and function of Institutional Review Boards (IRB), the IRB review process, and basic biomedical ethics. Course topics are enhanced by guest case studies, small group discussions, and research document reviews.
Prerequisite: BIOSCI X450, Fundamentals of Clinical Trials, or equivalent experience.

Application of Good Clinical Practices
MED X413.4 (3.0 units)
Gain an understanding of the accepted good principles and practices applicable to the development and implementation of drugs and medical devices in a research environment. Enhance your knowledge of topics including: definition of GCPs; the affect of GCPs on the conduct of a clinical trial; applicable regulations from ICH, HHS, FDA, and the state; obligations of investigators, sponsors, monitors, SMOs, CROs, and IRBs in a research engagement; and compliance and accountability during a clinical trial. Learn about the basic elements of the clinical data management process.
Prerequisite: BIOSCI X450, Fundamentals of Clinical Trials, or equivalent experience.

NOTE: CANDIDATES CHOOSE EITHER REGULATORY REQUIREMENTS FOR MEDICAL DEVICES OR REGULATORY REQUIREMENTS FOR PHARMACEUTICAL PRODUCTS. CANDIDATES THAT CHOOSE TO TAKE BOTH COURSES MAY COUNT ONE AS AN ELECTIVE COURSE.

Regulatory Requirements for Medical Devices
EECS X445.2 (3 units)
Increase your understanding of the essential U.S. medical device regulations, including device classification, organizing pre-market notification 510(k), and planning and submitting a Pre-Market Approval (PMA). Enhance your knowledge of topics that include: global vigilance requirements and labeling requirements, European Medical Device Directive 93/42/EEC (MDD), E.U. conformity assessments, meeting E.U. essential requirements, and developing a technical file for the E.U. Get a review of device registrations in Canada, Australia, Japan and Latin America.

ELECTIVE COURSES (Candidates choose a minimum of 5.5 units)

Applied Anatomy and Physiology for Clinical Studies
BME X405 (4 units)
Whether designing investigational drugs and medical devices or conducting clinical trials, it is important to have a basic understanding of the form and function of the human body. Learn about human anatomy and physiology as related to pharmaceuticals and medical device design for clinical studies. Clinical examples and modeling techniques are used to demonstrate the applications of anatomy and physiology in the development of investigational drugs and medical devices. Course focus is on human safety in clinical studies.

Good Laboratory Practices
MED X413.41 (1.5 units)
Gain the knowledge to understand and comply with FDA Good Laboratory Practice (GLP) regulations for the conduct of animal/in vitro safety studies. Enhance your understanding of topics including: regulations from the Code of Federal Regulations (CFRs), European and Japanese regulations, typical methods of compliance, how GLP fits into the drug/device/biologic development process, and ethics regarding animal care. Learn about sponsor obligations and how to evaluate a contract laboratory. Visit a clinical research center to reinforce the importance of GLP guidelines and compliance.

Implementation of Statistics in Clinical Trials
MED X413.42 (3 units)
Increase your statistical literacy and gain an understanding of the role of statistics in clinical trials. Enhance your knowledge of the statistical concepts, terminology, and methods essential to clinical trials including: Statistical aspects of trial design (specification of endpoints, identification of primary hypotheses, the role of randomization, sample size determination, controlling confounds); statistical analysis of trial data (insuring data quality, selecting statistical methods that support design objective(s), interpreting results reported by statistical software); and critiquing the statistical aspects of a trial report.

Clinical Data Management
MED X413.43 (1.5 units)
Learn about the handling, processing, storage, retrieval, and electronic submission of clinical data. Gain an understanding of the issues and implications surrounding database setup and the data management process. Enhance your knowledge of applicable FDA regulations (Part 11) and guidelines, and the documentation necessary to achieve FDA compliance. The course will be of interest to clinical data management professionals, clinical research coordinators, clinical research associates, project managers, and programmers who support the design and development of clinical databases.
Prerequisite: Knowledge of the medical product and/or drug development process, including a basic understanding of clinical trials and the role of the FDA.

Clinical Trials Internship
MED X 413.44
Gain a working knowledge of the clinical trial researcher’s role through an internship position. Interns must attend three meetings with the internship coordinator, work in a clinical research setting for 60 hours, and submit a report of their internship experience based on a daily log kept throughout the quarter. All candidates must attend the Information Meeting to obtain the application packet and eligibility requirements.
Prerequisites: To enroll in this course you must be an official certificate candidate and have completed the following four required courses: Regulatory Requirements for Medical Devices OR Regulatory Requirements for Pharmaceutical Products, Fundamentals of Clinical Trials, Human Subjects Safety in Clinical Trials, and Application of Good Clinical Practices; have a “B” grade point average; and a staff review.

QUARTERLY SCHEDULE OF COURSES

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<th>COURSE #</th>
<th>REQUIRED COURSES (10.5 units)</th>
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<td>BME X403</td>
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<td>EECS X445.26</td>
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*Candidates may take both courses and count one as an elective.

**Clinical Research Associates and Coordinators, Managers, or Investigators with at least two years work experience in clinical trials may substitute BIOSCI X450 Fundamentals of Clinical Trials with a three-unit elective.

Note: Schedules are subject to change. O = Online  C = Classroom  ■ W = Winter  ■ SP = Spring  ■ SU = Summer  ■ F = Fall
You may take as many individual courses as you wish without enrolling in the full certificate program.

Check our catalog or web site (extension.uci.edu) for the most current schedule.
ONLINE FORMAT FREQUENTLY ASKED QUESTIONS

What is an online course?
An online course utilizes the Internet and a web browser as a means of creating a learning environment outside of the traditional classroom. The lectures and discussions will take place on a Distance Learning Center Web site. You will be able to access your course lectures (text based) and communicate with your classmates and instructors through the use of a discussion forum (message board). The online courses follow a classroom structure of covering a lesson a week. You can access your course Web site anytime of the day and place where you have access to the Internet.

What are the online course fees?
Approximately $395 for 1.5 unit courses; $675 for three unit courses.

Who can take online courses?
Anyone can take an online course as long as they have access to a computer with Internet capabilities, have an active email account and have a basic understanding of how a computer works. An online student also has to be motivated to participate in discussion forums and regularly check the Web site and keep up with the course work.

What happens if I fall behind or complete the course early?
It is okay to be a week ahead or behind. You must remember that participation is a very important aspect of your final evaluated grade for the course. Active participation requires you to post and respond to your instructor and fellow classmates’ comments on the discussion forum. If you are too far behind, posting to an old topic will be revisiting something that the majority of your classmates might have discussed.

Are there specific dates that I need to log on to the Web site?
There is a set beginning and end date for your online course. It is suggested that you logon at least 3 times a week to check the discussion forums, to read over assignments and lectures. This is the “asynchronous” aspect of the course.

There might be occasion when the instructor will set a chat time (“synchronous”) where he/she assigns a specific date and time for all the students to try to meet in the chat room to ask questions.

All assignments, quizzes, exams, and projects must be completed within the time frame of the course. The instructor will set individual due dates for your assignments, projects and tests.

How many hours a week do I have to devote to my online course?
Just like a classroom course, to get the most out of any type of learning you must commit a certain amount of time to complete the course. You will most likely spend approximately 10 hours a week going over class lectures, doing assignments and spending time on the discussion forum. Time required for each course will vary.

Will I be able to see my online instructor or communicate with him/her via telephone?
Unless there is an extreme instance, all communications with your instructor will be done either through email, the discussion forums or the chat sessions. Please do not expect your instructor to telephone you.

How do I communicate with my instructor?
You communicate with your instructor by either email, discussion forums, or chat sessions. Students are highly encouraged to use these modes of communications, as faxed or mailed assignments are not accepted.

What happens if I have trouble accessing the URL with my login and password?
Contact the Distance Learning Center (DLC) office at unex-online@uci.edu or 949-824-7613 and we will assess and work to fix any problems in the most expeditious manner. In order to better serve you, please note the problem as it occurred.

Will having a firewall at home or at work prevent me from working on my online course?
Although, this very seldom occurs, your firewall may prevent you from posting to the discussion forum while allowing you to read the lectures and other resources.

Do I need to have cookies enabled?
Yes, it is necessary to have your cookies enabled. To best protect your computer it is suggested that you vary your cookie options to ensure the most secure level.

Can I access my course from anywhere?
You can access the course anywhere that you have Internet access. Some companies have firewalls that prevent you from participating in the chat sessions. Please check with your company before you attempt to access the course.

I have enrolled and I entered my key, but it still won’t let me in.
Many of you will have enrolled prior to the course start date. Courses will not appear until the course start date. Please note that the first week is considered an orientation week where you can become familiar with the course tools. Always make sure to enter a category for the current quarter that you are signed up for. Many times, previous quarters will be available for past students.

When is the last day to drop the course?
The last day to drop a course follows the standard provided in the UCI Extension catalog. There will be an administrative fee accessed for any withdrawals within the allowable period. Please refer to the Extension website at http://unex.uci.edu/services/registration/drops for more information.

What happens if I can’t finish a course?
We understand that certain situations can occur. Please refer to the UCI Extension catalog for procedures, etc.
How do I know which online courses can take the place of classroom courses?
Please visit our website at http://unex.uci.edu for more information about our certificate programs and course offerings.

How do online courses work?
Once you begin your course, you will find that with the use of the course tools, you will be able to navigate from the lecture to the discussion forums or to the weekly outline. You will be able to maneuver through the Web site to post/read assignments and to download/upload files from your instructor. Your instructor will primarily be contacting you by email or through the discussion forum. Once you begin your course, you will find that with your instructor’s help, you will find the benefits of taking a course online.

Help files are found on the Distance Learning Center website with instructions on accessing your online course with information about tools use.

Do I need to purchase books or any additional items?
Some courses do require that you purchase books or software. Please contact the UCI Bookstore for more information about the books for your courses at (949) 824-7810.

What happens after I sign up for a course, how do I get started?
If you enroll through the Web site at http://unex.uci.edu you will receive a confirmation email from our Student Services office with information regarding the steps needed to create your login and password, URL to access your course, and the enrollment key to enter your course.

If you have faxed or telephoned your enrollment, you will receive by U.S. mail a confirmation of your course enrollment. On that confirmation you will find the information regarding access to your online course.

I signed up for this quarter’s term and I can’t find my online course!
Your online course will not be available until the actual course start date. The first week of the course is an orientation week, you will have this time to review the syllabus and become familiar with the course tools.

What is an enrollment key?
An enrollment key is required only for the first time that you enter your online course. Your enrollment key will be given at the same time as the information regarding your course access.

Will the platform for online courses be changing continually every quarter?
There will be changes periodically. Changes occur mainly as a result of student and instructor feedback to our Web site. This is done to maximize the tools.

Is my online course an instructor led course?
Like a traditional course, your online course has an instructor that will conduct the course by giving assignments, answering questions, leading discussions and assigning grades.

Can I get a degree online?
At this time, you can only receive a Master’s Degree in Criminology, Law and Society.

Students intending to transfer UC Irvine Extension course credit for a degree at another college or university should verify acceptance of the course with that institution.

What kind of grade options do I have?
The grading options are exactly the same as that of classroom courses.

Who do I contact if I am having problems with the instructor?
Please contact the DLC office at (949) 824-7613 or unex-online@uci.edu. Your instructor should be very explicit on the course syllabus or welcome message as to their availability. If the instructor is going out of town or will be away from the computer for an extended period of time, he/she must notify the class.

Why do I get emails of the discussion forum postings?
If you are receiving emails from the discussion forums, you are subscribed to that particular forum. You can change this option by going to the forums sections on the left side of the course site under Activities. By selecting forum, you will be able to see all the forums created and to turn on/off the subscription function. There may be a forum that you will not be able to change. More than likely, that will be a place where the instructor will post announcements.

I like getting the forum subscribed emails, but the responses I made are not on the course Web site.
If you prefer to receive the subscribed emails from the forum, please do not reply to the email directly, but post your reply to the specific forum where the posting originated. This will ensure that others, including your instructor, will see your reply or comment.

I am confused and frustrated, I can’t seem to find my way around the Web site. What can I do?
Call us at (949) 824-7613. We will be happy to walk you through the tools and show you everything you need to know.