

Clinical Trials Design and Management

BIOSCIENCES

Free Program Overview

Clinical Trials and Regulatory Affairs

These special information sessions provide opportunities to meet instructors and other students, learn about program prerequisites, philosophy, requirements, and course content.

You will also gain insights into careers in clinical research and regulatory affairs.

Offered January and August

Courses 16650 and 22402

Look to UCSC Extension for Clinical Trials Training

- 10+ years of training excellence
- Expert instructors, each with extensive professional experience in clinical research
- Comprehensive and integrated clinical research curriculum
- Practical focus equips graduates with the tools and knowledge needed to succeed in clinical research roles
- Academic and industry internships



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Training New and Experienced Clinical Trials Professionals in the Bay Area Since 1999

The Bay Area is a hot spot for the global biopharmaceutical and medical device industries. Their continued success relies on the clinical trial—the complex process of ensuring the safety and effectiveness of new and existing medical products.

Clinical trials personnel from all sectors, including academia, clinical practices, industry and government agencies, require specialized knowledge that can be difficult to acquire and is frequently obtained only through on-the-job experience over a number of years. UCSC Extension's Certificate in Clinical Trials Design and Management helps professionals gain an in-depth and practical understanding of the entire clinical trials process as well as a foundation in the scientific principles, regulations, and ethics that are vitally important to the conduct of clinical research.

Who Should Attend This Program

Our comprehensive curriculum, with its intense focus on best practices in the clinical trials process, is appropriate for clinical research associates and study coordinators, clinical program managers and physicians, biomedical and research scientists, nurses, IRB members and administrators, and pharmacists, as well as those new to the field.

Program Benefits:

- Provides a foundation in drug and medical device development and in-depth knowledge of the entire clinical trial process
- Develops a solid understanding of the principles, regulations, and practices central to the conduct of clinical research
- Builds the practical skills needed in clinical research jobs and a portfolio of work to demonstrate acquired knowledge
- Facilitates successful career transitions

Keep Your Professional Certifications and Licenses Current

Many of the required and elective courses in the Clinical Trials Certificate Program qualify for contact hours toward recertification and license renewal.

If you are pursuing the clinical research coordinator (CRC) or clinical research associate (CRA) credentials, you may be able to fulfill educational requirements by completing this program. Professionals certified as CCRAAs and CCRCs through ACRP (Association for Clinical Research Professionals: www.acrpn.net) may be able to use courses in the program to meet recertification contact hour requirements. Many courses also grant BRN credit for **nursing professionals** and RAC recertification points for **regulatory affairs professionals** (Regulatory Affairs Professionals Society: www.RAPS.org).

Program Contact

Applied and Natural Sciences Department
(408) 861-3860
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All courses held in Santa Clara



About UCSC Extension in Silicon Valley

The vital learning community at UCSC Extension in Silicon Valley is well known for its collegial atmosphere and rigorous preparation. Our faculty of expert practitioners teaches state-of-the-art solutions to the everyday problems confronting professionals working in Silicon Valley. The professional education programs we offer build expertise, open doors to new opportunity, and deliver tangible value. Our broad portfolio of open-enrollment courses and certificates, affordable pricing, experience-based instruction, and central location in Silicon Valley help turn jobs into careers.

Clinical Trials Certificate

Certificate Requirements

To obtain the Certificate in Clinical Trials Design and Management, you must complete **six required courses** and **six units of elective courses**, for a minimum total of **19 units**. For GPA requirements and program time limits, see ucsc-extension.edu/student-services.

Recommended Course Sequence

We recommend that you begin the program with "Drug Development Process." From that point on, courses may be taken in any sequence, unless otherwise specified.

Prerequisites

A familiarity with medical terminology is required. Successful completion of "Medical/Clinical Terminology," or equivalent coursework or experience satisfies this requirement. While "Medical/Clinical Terminology" should be taken early in the program, it doesn't need to be taken first. We strongly recommend that students without a medical background take "Human Physiology in Health and Disease" early in their studies.

Certificate Application

Students are encouraged to establish candidacy in the certificate program early in their studies. By doing so, they lock in program requirements, receive notification of program updates and priority enrollment in fully-enrolled courses. Certificate applications can be submitted online. Visit ucsc-extension.edu/certificates.

Courses may be taken individually or as part of the certificate program.

Clinical Research Internship Program

Qualifying students and alumni from the Clinical Trials Design and Management Certificate Program have the opportunity to bring their course work to life and gain valuable experience in a clinical setting. Space in the program is limited. If you would like more information about the program and application process, please e-mail program@ucsc-extension.edu.



Curriculum

Prerequisite Courses

| | Units | Course |
|--|---------|--------|
| Human Physiology in Health and Disease (Recommended) | 3.0 | 6999 |
| Medical/Clinical Terminology | 0.7 CEU | 2928 |

Required Courses

| | Units | Course |
|---|-------|--------|
| Clinical Statistics for Non-Statisticians | 2.0 | 2345 |
| Clinical Trials Site Monitoring I | 2.0 | 0608 |
| Drug Development Process | 2.0 | 6559 |
| Good Clinical Practices | 3.0 | 0458 |
| Medical Devices: Regulatory Strategies and Marketing Pathways | 1.5 | 5939 |
| Science of Clinical Trials Design | 2.5 | 3657 |

Elective Courses (6 units required)

| | Units | Course |
|--|-------|--------|
| Adverse Event and Medication Coding: An Introduction to MedDRA, COSTART, and WHO-Drug | 1.5 | 19976 |
| Case Report Forms Development | 1.0 | 5544 |
| Clinical Data Management | 2.0 | 6291 |
| Clinical Project Management | 2.0 | 2315 |
| Clinical Research: The Study Site Perspective | 1.5 | 18994 |
| Clinical Trials Site Monitoring II | 1.5 | 2687 |
| Contracting with Contract Research Organizations (CROs) | 1.5 | 5479 |
| Development of Clinical Standard Operating Procedures | 1.5 | 1270 |
| Document Preparation: Protocols, Reports, Summaries | 1.5 | 2636 |
| Drug Safety and Adverse Events Reporting | 1.0 | 3990 |
| Electronic Data Capture for Clinical Trials | 1.0 | 20777 |
| Electronic Records for Regulated Environments: Cost-Effective Approaches to Compliance | 1.5 | 19362 |
| Global Conduct of Clinical Trials | 1.5 | 20787 |
| Good Manufacturing Practices | 3.0 | 6328 |
| Medical Device Design and Development | 2.0 | 19977 |
| Medical Writing | 2.0 | 4451 |
| Molecular Diagnostics | 1.5 | 21972 |
| Preparing for FDA Inspections and Conducting Sponsor Audits | 1.5 | 5168 |
| Regulation of Drugs and Biologics | 3.0 | 19007 |
| SAS Programming for Clinical Trials | 3.0 | 4670 |
| SAS for Clinical Trials for the Non-Programmer, Introduction | 3.0 | 2988 |
| Toxicology Basics for Biotechnology | 1.5 | 2310 |

Prerequisite Courses

Human Physiology in Health and Disease

This course introduces the fundamental principles of human physiology in health and disease, and provides insight into the cutting-edge and established therapies being developed and used to treat a range of disease processes. Designed for individuals who have no formal medical training, the course begins with an overview of the hierarchical organization of the body, from cells to coordinated organ systems, and continues with a discussion of the key integrative/homeostatic control mechanisms. With these topics as a foundation, the instructor progresses through the functions of major systems including renal, cardiovascular, respiratory, neuromuscular, digestive, endocrine and reproductive.

Course 6999

Medical/Clinical Terminology

A basic understanding of medical and clinical terminology is essential in clinical trials design and management. This interactive workshop, for individuals with no background in medical/clinical terminology or for those who would like a refresher, reviews common terms associated with medical research and development and clinical trials. Participants review both the meaning of each term and how it is applied within a practical context.

Course 2928

Required Courses

Clinical Statistics for Non-Statisticians

Clinical studies succeed or fail on the strength of their statistics. This course takes a practical and qualitative approach to fundamental statistical concepts essential for non-statisticians involved in clinical research.

Through lectures, discussions and in-class exercises, the instructor explores clinical study designs, hypothesis testing, sample size calculations, assumptions, controls, endpoints, data-management principles, data presentations and analysis plans, methods for analysis, and conclusions. Participants learn how to interpret statistics commonly encountered in clinical research as well as how to communicate effectively with statisticians.

Course 2345

Explore UCSC Extension's Other Bioscience Programs

- Bioinformatics
- Medical Devices
- Biotechnology
- Regulatory Affairs
- Bioscience Business and Marketing



Course Descriptions

Clinical Trials Site Monitoring I

The course introduces the essential elements of monitoring a clinical trial and delineates the roles and responsibilities of the sponsor, study site and the FDA. Participants gain insight into the interactions between sponsors and study sites, and are exposed to the process of site selection, budgeting, initiation visits, source documentation, regulatory documentation, and adverse event reporting. Also addressed are some practical tools for use in tracking compliance, product accountability and medical record review.

Course 0608

Drug Development Process

The development of new drugs is a complex, lengthy, and expensive process. In this course, we examine this process—from discovery to market and beyond—and see what makes the biopharmaceutical industry unique. Infused with real-world examples, lectures address drug discovery; preclinical characterization of new drug entities; the phases and purposes of both pharmacological and clinical development; regulatory filings, compliance and oversight; FDA jurisdiction; and strategic issues in drug development. The course provides an important foundation in drug development for professionals from all disciplines who are currently working in, or are considering a move to, the biopharmaceutical industry.

Course 6559

Good Clinical Practices

History, ethics, and regulations provide a context for the responsible conduct of clinical research. This course focuses on the timely, thorough and ethical conduct of clinical studies. Participants explore the translation of ethical principles into regulations (federal, state and local); recruitment and consent of research subjects; roles and responsibilities of sites, sponsors and institutional review boards; study monitoring; and auditing for compliance.

Course 0458

Medical Devices: Regulatory Strategies and Marketing Pathways

Medical devices are uniquely different from drugs and biologics in their regulation and paths to market. Effective clinical trial conduct for devices requires a solid understanding of these issues. This course provides a foundation in the regulation of medical devices, and it includes discussions of device classification, investigational device exemptions (IDE), 510(K) and PMA submissions, and managing and reporting adverse device events (MDRs).

Course 5939

Science of Clinical Trials Design

This course addresses the science that forms the basis of effective clinical trial design. Topics include classifying and describing trial design by stage in drug and device development; reasons for clinical trials; types of trial designs; defining the hypothesis and study objectives; determining the population and sample size; stopping rules; standards of practice versus FDA requirements; safety information and data safety monitoring boards; scientific and ethical considerations; validity of design, execution, analysis, and reporting.

Course 3657

Clinical Elective Courses

Adverse Event and Medication Coding: An Introduction to MedDRA®, COSTART, and WHO-Drug

Coding dictionaries, particularly MedDRA®, are becoming increasingly important in the U.S. and Europe for the electronic transmission of adverse event reporting, both in the pre- and postmarketing areas and in the coding of clinical trial data. This course provides a unique local opportunity for an introduction into how adverse events and medication terms are coded and the use of commercial coding browsers. Students gain familiarity and hands-on experience with the dictionaries used in the pharmaceutical and biotechnology industries, including MedDRA®, WHO-Drug, SNOMED and COSTART.

Course 19976

Case Report Forms Development

Whether a case report form (CRF) is paper or electronic, it must translate the clinical protocol so as to allow for the collection of data to support the planned analyses. After mapping a clinical study protocol to a CRF structure, this course focuses on the elements of CRF development that impact compliance with the protocol, analyzable data, data-processing and data-cleaning. Students explore many examples and options for CRF modules and thereby see how the CRF impacts all groups involved in the conduct of a clinical trial.

Course 5544

Clinical Data Management

Taking a hands-on approach, this course provides a solid understanding of the steps involved in clinical data management from the time of data collection from investigator sites through data extraction for analysis. Topics include a planned approach to clinical data management; basic design and specification of the database and cleaning rules; required documentation,

standard operating procedures (SOPs), and quality control; compliance with FDA/ICH guidelines; working with other clinical groups and CROs; using electronic data capture; and data security and confidentiality.

Course 6291

Clinical Project Management

This course addresses critical elements in the effective planning and management of clinical trials. Exercises and case studies illustrate how to develop and manage activities, timelines and budgets; examine staffing and resources requirements; and lead and motivate effective teams. The strategic development plan, team and site performance problems, and post-marketing studies are also discussed.

Course 2315

Clinical Research: The Study Site Perspective

This course offers practical insight into the clinical research process from the viewpoint of the study site. Lectures and class exercises explore the roles, responsibilities, interactions, and concerns of study site personnel and highlight important differences in perspective between clinical study sites and industry sponsors. The content applies to all study sites—academic medical centers, community hospitals, rural clinics, physician private practices, hospital networks, and Phase 1 units.

Course 18994

Clinical Trials Site Monitoring II

This course explores a range of approaches to monitoring clinical sites, the development of monitoring plans and some of the more challenging aspects of monitoring clinical trials. Remote data entry, compliance audits, regulatory issues that arise in compliance audits, and fraud and misconduct are also addressed. This course is designed for clinical research associates (CRAs) or those planning to become CRAs.

Course 2687

Contracting with Contract Research Organizations (CROs)

Pharmaceutical and biotechnology companies are more and more frequently using the services of contract research organizations (CROs) to access expertise or technology not available in-house for key clinical services. This course takes a practical look at the identification, selection, and management of CROs in the performance of clinical projects. Other topics of discussion include selecting the best CRO for a project; request for proposal (RFP) components; bid review and negotiation; types of agreements; defining roles and responsibilities; and managing the work once the contract is signed.

Course 5479

Development of Clinical Standard Operating Procedures

The U.S. federal regulations and ICH guidelines for good clinical practice require that all institutions and entities involved in research with human subjects develop and maintain written standard operating procedures (SOPs). However, many companies do not develop policies and SOPs until after human clinical trials are well under way. This course examines the regulatory requirements and the differences between regulations, guidelines, policies and SOPs, and evaluates the components of a well-constructed SOP. Participants develop SOPs for important clinical functions.

Course 1270

Document Preparation: Protocols, Reports, Summaries

This course provides insight into the preparation of effective and compliant clinical trials documentation, including study protocols, reports, and summaries. Participants have opportunities to create sample documents and apply the rules governing clinical trial documentation.

Course 2636

Drug Safety and Adverse Events Reporting

This course introduces the concepts of drug safety and adverse event reporting, in both clinical trials and post-approval period. Students learn to assess adverse events, understand the information needed from reporting sources, and complete the U.S. primary safety report. Topics include why safety reporting is crucial; how to define an adverse event; safety databases; coding dictionaries; and reporting requirements in the U.S. and abroad.

Course 3990

Electronic Data Capture for Clinical Trials

Taking a practical approach, this course examines key issues surrounding the industry's adoption of electronic data capture (EDC). The instructor highlights the major differences between paper and electronic systems; explores benefits associated with EDC; and systematically examines the costs, risks, necessary process changes, and other business and regulatory implications of this shift. Interactive discussions address the process of selection, implementation and maintenance of EDC software, both for in-house and outsourced systems.

Course 20777

Electronic Records for Regulated Environments: Cost-Effective Approaches to Compliance

This interactive two-day course explores proven techniques for reducing costs associated with implementing, using, and maintaining computer systems in regulated environments. The instructor addresses the latest computer industry standards for data security, data transfer, and audit trails. Students see how 21 CFR Part 11 (electronic records and signatures requirements) and HIPAA electronic security regulations for medical records fit into the validation process. Finally, the instructor reviews recent FDA inspection trends and discusses how to streamline SOP production.

Course 19362

Global Conduct of Clinical Trials

Using the U.S. and E.U. as points of reference, the instructor and guest speakers help students develop a framework for examining issues and challenges related to the conduct of clinical trials in established and emerging foreign markets, including Eastern Europe, India, China, and South America. Lectures and case studies explore the current regulatory environment; impact of local laws and requirements; cultural challenges and procedural differences in trial conduct; how to ensure that useful data are collected; and important implications for human subject protection.

Course 20787

Medical Writing

Biopharmaceutical companies must produce scientific reports and summary documents for regulatory agencies. Good documentation should be not only scientifically sound, but also clear, effective and concise. Taking a hands-on approach, this course builds the practical skills needed to write effective documents for the bioscience industry. Topics include a review of the essentials of good writing, including the correct use of grammar and punctuation; drafting user-friendly documents that comply with the regulations; and creating clear and concise content. Exercises are based on documentation used in pharmaceutical development.

Course 4451

Preparing for FDA Inspections and Conducting Sponsor Audits

In the regulated medical industry, inspections by government agencies are often a prerequisite for new product marketing approvals. Knowing what to expect and how to respond to clinical inspections is as critical as conducting sound clinical research. This course helps participants prepare for FDA inspections and conduct sponsor audits. Topics include investigator and sponsor/monitor inspections; how and when inspections occur; FDA inspection procedures and practices; conducting sponsor audits and inspections; how to interact professionally with inspectors; and effective responses to inspectors' observations.

Course 5168

SAS for Clinical Trials for the Non-Programmer, Introduction

This computer lab-based course provides a practical, applied, and non technical introduction to the SAS environment and the use of SAS software as an information resource for non-programmers in clinical research. Through lecture, simulations, group discussion and hands-on lab sessions, clinical research professionals are introduced to the SAS programming environment. Discussion topics include getting data into the SAS system; sorting, printing and summarizing data; modifying and combining SAS datasets; and using basic statistical procedures.

Course 2988

SAS Programming for Clinical Trials

SAS is the primary software standard in the biopharmaceutical industry for the storage, management and manipulation of clinical data and its presentation to the FDA. Processing clinical data in FDA-regulated industries has specific requirements, which introduce unique challenges in comparison to working with data from other industries. This hands-on course prepares individuals with SAS programming experience to process clinical-trials data to meet the increasing demand for these skills in the biotechnology and pharmaceutical industries.

Course 4670

Additional Elective Courses

- Good Manufacturing Practices (Course 6328)
- Medical Device Design and Development (Course 19977)
- Molecular Diagnostics (Course 21972)
- Regulation of Drugs and Biologics (Course 19007)
- Toxicology Basics for Biotechnology (Course 2310)

Visit ucsc-extension.edu/clinicaltrials for course descriptions.

Special Program

Offered Only in the Winter Term

Clinical Trials Essentials: An Intensive Course

Presented in an accelerated format and taught by leaders in the biopharmaceutical industry, this non-credit course provides a unique opportunity for professionals from all disciplines to get a big-picture overview of clinical research. Participants leave with an appreciation of the drug and device development process and good clinical practice (GCP) and other regulations that guide the conduct of trials and protect human volunteers. Also covered are trial phases and design strategies; informed consent and the role of the IRB; investigator responsibilities; study site management and trial monitoring; statistical data analysis; and the role of the FDA.

Course 5433

Enrollment Information

Visit ucsc-extension.edu/biosciences, for the most up-to-date information about all our bioscience courses and programs, including instructor biographies, schedules and textbook requirements.

Enroll online at ucsc-extension.edu.