Clinical Research

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PROGRAM DESCRIPTION

The Master of Advanced Studies (MAS) in Clinical Research offers a broad-based curriculum in clinical research methodology and integrates classroom instruction with practical training to provide students with the knowledge and skills necessary to produce valid, credible research. Linking the academic and professional scientific communities, the program is appropriate for physicians, pharmacists, nurses with advanced training, psychologists, and biomedical scientists employed in biomedical firms, hospitals, and pharmacies. The program aims to accommodate the varying needs of the students through its modular approach to instruction, a part-time year-round schedule, and a choice of general electives organized by tracks.

The MAS in Clinical Research is a part-time, self-supporting degree program with a flexible course schedule designed for working professionals and academics. The UC San Diego graduate division confers the MAS degree and the Department of Medicine in the UCSD School of Medicine is responsible for the academic management of the curriculum. UCSD Extension administers the program and provides student advising and career counseling services.

ADMISSION

New students are admitted in the winter and summer quarter of each academic year. Prospective candidates should submit and complete the official UCSD online graduate application for admission, the application fee, one set of official transcripts from each institution attended after high school, three letters of professional letters of recommendation, and a current resume or c.v. The GRE/GMAT is not required; however, it is strongly recommended that candidates possess, or currently be pursuing, a graduate degree in a scientific or healthcare related field and also have some level of experience in scientific or clinical research. In some instances candidates without an advanced degree may be admitted to the program if they have demonstrated substantial professional experience in the field at increasing levels of responsibility. The application deadlines are September 17 (winter) and April 15 (summer).

PROGRAM OF STUDY

The part-time master's degree program is designed to be completed in eighteen to thirty months, depending upon a participant's time to devote to the program. Classes are typically scheduled in the late afternoons and evenings. The thirty-six-unit degree is comprised of eighteen units of core clinical modules, four units of seminar courses, four units of directed studies, four units of advanced statistics electives, and six units of an independent study project.

COURSES

For course descriptions not found in the UC San Diego General Catalog, 2010–11, please contact the department for more information.

CLRE 250. Patient-Oriented Research I (2)
This course will develop and apply the theory of clinical trials design and analysis, discuss the practical issues of financing and implementing clinical trials, and describe issues of monitoring trials and working in cooperative groups. The scholar will design and present to a group of peers a concept sheet for a phase I/II and phase II/III clinical trial.

CLRE 251. Epidemiology I (2)
Scholars will recognize and understand different types of study designs, the relative strengths and limitations of each, and the proper choice of study design in conducting their own research. They will also be able to identify and calculate the correct measure of risk for each study design. Participants will recognize major sources of bias, confounding and misclassification, and understand design and analysis methods of dealing with each. They will also be familiar with criteria to differentiate association from causation.

CLRE 252. Health Services Research (2)
Scholars will evaluate relevant outcomes in patient-oriented research from the patient (quality of life) and societal (economic) perspectives and locate potential resources for assessing the relevant outcomes in a wide variety of study designs. They will also be able to describe the relative strengths of different health services research approaches to a clinical problem. Finally, they will understand the components of clinical practice guidelines, including patient preferences, and how these guidelines both depend upon as well as inform patient-oriented research.

CLRE 253. Biostatistics I (2)
Scholars will understand principles of measurement of clinical data, recognize data types, and correctly identify statistical methods appropriate for analysis of a given clinical data set. They will gain experience in assembling a clinical dataset in formats suitable for analysis by STATA or other comparable statistical packages. They will learn skills to conduct graphical and numerical exploratory data analysis, comparative tests of categorical, ordinal, and continuous data, linear and logistic regression analysis, and survival analysis by life table and Kaplan-Meier techniques.

CLRE 254. Biostatistics II (2)
Scholars will understand and conduct advanced biostatistical analyses including: multiple linear and logistic regression, survival analysis, and Cox and extended Cox regression. The scholar will also be familiar with person-time rate analysis with Poisson regression and longitudinal data analysis in the presence of missing values and varying measurement times. **Prerequisites:** Biostatistics I, CLRE 253.

CLRE 255. Data Management and Informatics (2)
This course provides an orientation to database design and management and covers key issues regarding data handling for clinical research and clinical trials. Scholars will also become familiar with technology assessment and decision-making methods and analysis.

CLRE 256. Patient-Oriented Research II (2)
This course will review the ethics and basic regulatory issues for research involving human subjects; the principles of data management for clinical research, including architecture, access and confidentiality, and integrity of databases; and skills in graphic and verbal presentation of research data. Scholars will prepare a mock submission to an IRB for peer review and practice presenting graphic and tabular data. **Prerequisites:** Patient-Oriented Research I, CLRE 250.

CLRE 257. Epidemiology II (2)
Scholars will select the appropriate sampling method and determine the sample size necessary for specific projects and adjust for confounding. Participants will be familiar with several specialized analytic techniques, including matched, cluster, and meta-analyses. They will also be familiar with methodological issues, unique to ecological, behavioral, and genetic studies. **Prerequisites:** Epidemiology I, CLRE 251.

CLRE 258. Professional Development in Clinical Research (2)
Students participate in a series of seminars on professional development topics that will focus on skills and knowledge to enhance the ability of clinical researchers to be successful. Seminar topics may include research management, team building and collaboration, leadership skills, career development in the clinical research field, negotiation skills, research project management, and research budgeting/financial management. **Prerequisite:** MAS Program or permission of department.

CLRE 259. Scientific Communication Skills (2)
This course covers the key elements of scientific communication skills that are designed to enhance the clinical research's ability to be successful. Topics include secrets of making good oral presentations and engaging the audience, how to write and prepare abstracts, basics of grant writing and submission, and how grants are reviewed. Course includes mock grant study section. **Prerequisite:** MAS Program or permission of department.

CLRE 260. Directed Studies in Clinical Research (2)
Faculty member will direct a student's study in selected professional development topics in clinical research. Specific content will be tailored to the student's particular needs and interests. Students must make arrangements with the program and individual faculty member prior to enrolling in the course. **Prerequisite:** MAS Program or permission of department.

CLRE 261. Applied Quantitative Analysis (4)
Students will understand and conduct advanced statistical analyses for clinical research. The course will develop the students' technical and conceptual skills in cost effectiveness analysis and decision analysis including the creation and evaluation of decision trees, use of sensitivity analysis and the incorporation of patient preferences through utility analysis. **Prerequisites:** CLRE 253, CLRE 254.

CLRE 296. Independent Study Project (6)
The Independent Study Project (ISP) is the cornerstone of the MAS program. Students will be involved in a high-level clinical research projet that integrates what they have learned in their formal course work. The ISP will be an independent and creative scholarly activity in an area related to one or more of the topics covered in the formal curriculum. Students' work will be evaluated by a committee of faculty, and, in some cases, industry advisors.