Clinical Research Management

The Master of Science in Clinical Research Management is designed for experienced professionals working in academic research centers or private sector who seek to extend their knowledge or advance their careers. The program addresses the science of clinical research through topics such as epidemiologic principles and tools, research design, ethical issues, and data analysis, as well as the business of clinical research through topics such as regulatory requirements, product development, and grant funding.

As an experienced health science or related business professional, students will update skills, strategies, and resources for developing and managing products, treatment protocols, and other processes associated with clinical research and patient care. With the Master of Science in Clinical Research Management, students will prepare for leadership positions in academic and health-care research centers or related private sector organizations, such as the pharmaceutical, diagnostic, and medical device industries.

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Website: https://ucollege.wustl.edu/programs/graduate/masters-clinical-research-management

Degree Requirements

Master of Science in Clinical Research Management

The Master of Science in Clinical Research Management is a 30-unit program, including 24 units of required course work and 6 units of authorized electives.

Required Courses: 24 units

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<td>CRM 500</td>
<td>Fundamentals of Clinical Research Management</td>
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<td>CRM 512</td>
<td>Advanced Data &amp; Information Management in Health Sciences</td>
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<td>CRM 518</td>
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<td>CRM 522</td>
<td>Compliance, Legal, and Regulatory Issues</td>
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<td>CRM 555</td>
<td>Health Care Reform and Policy</td>
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<td>CRM 562</td>
<td>Leadership and Change in Health Care Services</td>
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University College also offers a Graduate Certificate in Clinical Research Management (http://bulletin.wustl.edu/prior/2016-17/grad/ucollege/cert-clinical-research).

Courses


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<td>Epidemiology for Clinical Research</td>
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Total units 24

U80 CRM 500 Fundamentals of Clinical Research Management

This course provides the basic foundation for the application, concepts and theories of clinical research. We explore the historical evolution of research, linking it to current regulations and guidelines for good clinical practice. Additional course topics include research roles and responsibilities, institutional review boards, phases of drug development, the informed consent process, human subject protections, and an overview of study conduct. Students will complete institutional review board paperwork, including writing an informed consent and developing source documents. Prerequisite: bachelor's degree.

Credit 3 units. UColl: OLH, OLI

U80 CRM 507 Introduction to Biomedical Informatics and Its Application to Clinical and Translational Research

Same as M17 CLNV 507

Credit 3 units.

U80 CRM 509 Health and Society

This course examines how personal health and well-being are affected by institutional and societal forces. We use an historical perspective in studying, for example, how sleep, leisure, and other aspects of personal health have been changed by industrial, economic, political, and cultural developments such as urban planning, food processing, animal husbandry, and the role of the family doctor. We also take a close look at environmental factors (e.g., global warming) and related political and economic forces that produce and exacerbate chronic diseases. Finally, we critique how personal health and the health care industry have been influenced by major institutional forces such as the insurance and pharmaceutical industries, professional licensure, government-sponsored research, and the media. We read case studies and medical journals to understand and discuss related ethical and policy questions.

Same as U86 HCARE 309

Credit 3 units.

U80 CRM 512 Advanced Data & Information Management in Health Sciences

Credit 3 units.

U80 CRM 513 Designing Outcomes of Clinical Research

This 34-hour course is led by Brian Gage, MD, MSc, Associate Professor of Medicine. The course includes lectures and small group instruction from faculty members in the departments of Medicine, Surgery, and Pediatrics. DOC Research covers how to select a clinical research question, write a research
protocol, and execute a clinical study. Topics include subject selection, observational end experimental study design, sample size estimation, clinical measurements, questionnaires and quality-of-life measurement, and data management. The course is designed for fellows and junior faculty who wish to conduct outcomes, epidemiologic, and patient-oriented clinical research. Students receive ongoing feedback as they incorporate research design concepts into their own research proposals. At the end of the course, students are required to submit a research protocol or a draft of a manuscript describing their research. The course consists of both lectures and small group discussions. Each student gives an oral presentation and presents a written paper or grant protocol for discussion and critique by faculty and other students.

Same as M17 CLNV 513
Credit 3 units.

U80 CRM 515 Medical Writing for Clinical Research
This is a graduate-level intensive writing course that will guide students in developing a competitive research grant proposal. Written work, guided by each student's needs and interests, will cover all sections of a research grant application, manuscript writing, progress reports, and other forms of reporting scientific findings to the public. We also will compose mock NIH grant applications. By the end of the course, each student will produce a comprehensive portfolio that includes a grant proposal, manuscript, and press release to the public.
Credit 3 units.

U80 CRM 518 Drug and Device Development
This course will provide an overview of the commercial development pathways for both pharmaceuticals and medical devices, from inception to market. Through lectures and discussions, students will gain an appreciation for the role clinical study programs play in the broader scope of product development. Class topics will include preclinical, clinical, regulatory, and marketing factors which influence discovery and development of new medical products.
Credit 3 units.

U80 CRM 520 Trends in Health Care Policy
This course examines important and complex developments in contemporary health care policy. We begin with an historical overview, then look at the structure of current health care delivery, and identify political and economic challenges moving forward. In particular, we will critically examine methods and principles for evaluating health care costs and measuring policy effectiveness. The course also addresses unintended consequences of health care policies, special interests and potential new or amended regulation in clinical research compliance. Students will also be able to identify areas of concern and potential new or amended regulation in clinical research.
Credit 3 units.

U80 CRM 529 Industry Partnering: Collaborations in Translational Research
Innovative new products are the life blood of the biopharmaceutical industry. In the U.S., most discovery research originates at the university level and is transferred via licensing agreements to industry partners or to start-up biotech companies for final development and commercialization. The process of moving this innovation from the lab to industry and then to the patient is the focus of this course. The course examines the market for intellectual property that exists between academic institutions and the private sector and explores commercialization of translational research through collaboration with industry partners. In addition to studying the complex relationship between science and business, the course employs a case study methodology to illustrate specific examples of the translational process from lab to marketed product.
Credit 3 units.

U80 CRM 530 Introduction to Biomedical Informatics and its Application to Clinical and Translational Research
Biomedical Informatics (BMI) is a multidisciplinary field that encompasses individual areas of bioinformatics, computational biology, translational informatics, imaging informatics, medical informatics, and hospital informatics. It involves all aspects of medical research, including the management process; managerial decision making, analysis, organization, and sharing of information in health care and biomedical science. This course aims to provide an overview of biomedical informatics and its application in facilitating clinical and translational research and in accelerating the application of research findings to clinical practice. The course will consist of introductory lectures outlining the principles of biomedical informatics, current use of informatics in clinical and translational research and quality improvement initiatives, and practical hands-on training in the use of local informatics tools to manage and execute biomedical research studies.
Same as M17 CLNV 530
Credit 3 units.

U80 CRM 532 Principles of Management in Health Care
This course enables students to explore the theoretical framework and practical application of classic management principles so that they can function effectively in a variety of organizational settings in the provision of health care services. Topics include the management process; managerial decision making and planning; negotiation skills; organization design; and leadership.
Same as M88 AHBR 532
Credit 3 units.

U80 CRM 555 Health Care Reform and Policy
This course examines important and complex developments in contemporary health care policy. We begin with an historical overview, then look at the structure of current health care delivery, and identify political and economic challenges moving forward. In particular, we will critically examine methods and principles for evaluating health care costs and measuring policy effectiveness. The course also addresses unintended consequences of health care policies, special interests and
political agendas, and the influence of major institutional forces on clinical and translational research. Cases studies and guest speakers will help illustrate current ethical dilemmas and other real challenges to contemporary health care and reform. Although this course meets over two weekends, students are expected to complete much of the course reading prior to the weekend sessions, and complete a paper after the weekend session.
Credit 3 units.

U80 CRM 588 Epidemiology for Clinical Research
The purpose of this course is to provide individuals an understanding of the use of epidemiological concepts and methods both in clinical research, in clinical issues, and in understanding medical literature concerning these issues. The course includes 1) discussion of theoretical concepts related to the application of epidemiology in clinical research, and 2) practical applications of the concepts covered.
Same as M88 AHBR 588
Credit 3 units.