Clinical Research Management

The Master of Science (MS) in Clinical Research Management is designed for experienced professionals working in academic research centers or private industry who seek greater depth and breadth of study in the science and business of clinical research.

The curriculum encompasses in-depth coverage of essential skills and processes required for the management of studies that develop drugs, devices and treatment protocols for patient care. Major topics include regulatory requirements, ethical issues, product development, the business of clinical research, grant funding and manuscripts, epidemiologic principles and tools, research design and data analysis, all in the context of human subjects in clinical trials.

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Degree Requirements

Master of Science in Clinical Research Management

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

Required Courses: 24 units

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Units</th>
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<tbody>
<tr>
<td>CRM 500</td>
<td>Fundamentals of Clinical Research Management</td>
<td>3</td>
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<tr>
<td>CRM 512</td>
<td>Advanced Data &amp; Information Management in Health Sciences</td>
<td>3</td>
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<tr>
<td>CRM 515</td>
<td>Medical Writing for Clinical Research</td>
<td>3</td>
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<td>CRM 518</td>
<td>Drug and Device Development</td>
<td>3</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 Policy</td>
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<td>CRM 562</td>
<td>Leadership and Change in Health Care Services</td>
<td>3</td>
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<tr>
<td>CRM 588</td>
<td>Epidemiology for Clinical Research</td>
<td>3</td>
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<tr>
<td>Total Units</td>
<td></td>
<td>24</td>
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University College also offers an Advanced Certificate in Clinical Research Management (http://bulletin.wustl.edu/grad/ucollege/cert-clinical-research/).

Courses

Visit online course listings to view semester offerings for U80 CRM (https://courses.wustl.edu/CourseInfo.aspx?sch=U&dept=U80&crslvl=5:8).

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. Undergraduate students register for U80 250 Credit 3 units. UColl: OLH, OLI

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. Credit 3 units. UColl: OLI

U80 CRM 512 Advanced Data & Information Management in Health Sciences

This course will cover the education and training in data and information management as it applies to Health Sciences, pulling from aspects of different fields: domain specific (clinical or public health) and analytic (biostatistics and database management) using different software tools. We will examine data types and data repositories to include best practices in data acquisition and management. This course will scrutinize tools for data storage and data manipulation and delve into relational and non-relational databases. Concepts in epidemiology and biostatistics will be presented along with discussion on health informatics. Credit 3 units. UColl: OLI

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. UColl: OLI

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 522 Compliance, Legal, and Regulatory Issues
This course will examine the legal framework governing clinical research with human subjects in the United States. An overview of the legal system including U.S. sources of law, the interplay between the federal and state systems and the role of case law, legislatures and regulatory agencies in shaping current law and policy will be provided. Federal and state law governing clinical research from proposal to completion will be examined. At the conclusion of this course, students will be able to identify the current sources of law, policy and persuasive authority 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. UColl: OLI

U80 CRM 525 Research Ethics and Regulatory Affairs
This course will provide an understanding of the ethical guidelines, issues, and challenges of conducting research on human subjects. We will explore issues such as conflicts of interest, genetic testing, limits of confidentiality, risk, and the distinction between compliance and ethics. As we learn about protecting research groups and interests and explaining rights and liabilities, we will study health care legislation and regulations, guidelines, contractual matters, and the complex regulatory framework that governs human subject research. Finally, we will learn to use an ethical problem-solving model in clinical research.
Credit 3 units. UColl: ML, OLI

U80 CRM 526 Drug-Induced Diseases: Detection, Prevention, and Management
A drug-induced disease (DID) is the unintended effect of a drug that results in mortality or morbidity with symptoms sufficient to prompt a patient to seek medical attention and/or require hospitalization. There have been great advances in drug therapy that have had tremendous beneficial impact on patient outcomes. However, the effects of drugs are not always beneficial; drugs are also capable of causing new diseases or exacerbating those that already exist. Some of these diseases are well known and transient (e.g., diarrhea, weight gain). Others, like liver disease and diabetes, are neither. This course will explore these issues in a novel, disease-specific way that will be accessible to a wide range of students: clinical research managers, medical students, nurses, pharmacists and other allied health professionals. The course will include weekly readings from the textbook or other sources. Regular group discussions will be important, addressing how this new knowledge can be applied to students' professional or personal practices.
Credit 3 units. UColl: OLI

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 5430 The Business of Clinical Research
An overview of the business elements of clinical research, this course covers drug and device development, the regulatory environment, finance, corporate structures, and the clinical trials office. We will consider stakeholders including pharmaceutical and device industries, academic and private research centers, government agencies such as the National Institutes of Health, nonprofit agencies and a variety of other organizations such as American Diabetes Association and the National Cancer Institute. We also will study local, state, and federal regulations, as well as international and global issues that impact the business of clinical research.
Same as U80 CRM 330
Credit 3 units.

U80 CRM 555 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 political agendas, and the influence of major institutional forces on clinical and translational research. Case studies and guest speakers will help illustrate current ethical dilemmas and other real challenges to contemporary health care and reform.
Credit 3 units. UColl: OLI

U80 CRM 562 Leadership and Change in Health Care Services
Students engage in the advanced study of leadership, integrating theory, research, and application in a diagnostic approach. Leadership skills for managing planned organizational change are developed through group discussions, class exercises, case studies, and the application of organizational approaches to change and innovation. Topics include personal effectiveness, team building, and creating learning environments in organizations.
Same as M88 AHBR 562
Credit 3 units.

**U80 CRM 588 Epidemiology for Clinical Research**

The purpose of this course is to provide an understanding of the use of epidemiological concepts and methods in clinical research. Two primary foci are included: 1) common applications of epidemiologic principles and analytic tools in evaluating clinical research questions; and 2) student development of skills to review and interpret the medical literature and utilize publicly available datasets to address clinical research questions.

Same as M88 AHBR 588
Credit 3 units.