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, 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.

Phone: 314-935-6700
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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<tr>
<th>Code</th>
<th>Title</th>
<th>Units</th>
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<tr>
<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>
<td>3</td>
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<tr>
<td>CRM 515</td>
<td>Medical Writing for Clinical Research</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>
<td>3</td>
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<td>CRM 588</td>
<td>Epidemiology for Clinical Research</td>
<td>3</td>
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Total Units: 24

University College also offers a Graduate 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. Prerequisite: bachelor's degree.

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.

Same as U86 HCARE 309

Credit 3 units.

**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.

**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 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.

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 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 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

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