Clinical Research Management

The Master of Science in Clinical Research Management is designed for experienced professionals working in academic research centers or private industry 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.

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRM 500</td>
<td>Fundamentals of Clinical Research Management</td>
<td>3</td>
</tr>
<tr>
<td>CRM 512</td>
<td>Advanced Data &amp; Information Management in Health Sciences</td>
<td>3</td>
</tr>
<tr>
<td>CRM 515</td>
<td>Medical Writing for Clinical Research</td>
<td>3</td>
</tr>
<tr>
<td>CRM 518</td>
<td>Drug and Device Development</td>
<td>3</td>
</tr>
<tr>
<td>CRM 522</td>
<td>Compliance, Legal, and Regulatory Issues</td>
<td>3</td>
</tr>
<tr>
<td>CRM 555</td>
<td>Health Care Reform and Policy</td>
<td>3</td>
</tr>
<tr>
<td>CRM 562</td>
<td>Leadership and Change in Health Care Services</td>
<td>3</td>
</tr>
</tbody>
</table>

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

Credit 3 units.

U80 CRM 513 Designing Outcomes of Clinical Research

This course covers how to select a clinical research question, outline a research protocol, and execute a clinical study. Topics include: subject selection, observational and experimental study designs, sample size estimation, clinical measurement, bias and confounding, and data management. The course is designed for health care professionals who wish to conduct patient-oriented clinical research. Students incorporate research design concepts into their own research proposal. The course consists of lectures, weekly problem sets, weekly reading assignments, outlining a research protocol, and a final exam.

Same as M17 CLNV 513
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 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.
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 lifeblood 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 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 530
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.
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.