Clinical Trials Management and Regulatory Compliance Certificate

This comprehensive program provides rigorous training across the entire clinical trials process, from the perspective of the clinical study site as well as that of the sponsor or monitor. The broad curriculum covers good clinical practices, regulatory requirements and compliance, detecting fraud and misconduct, and statistics for clinical research. Students will build the skills and knowledge to initiate clinical research studies, apply monitoring methods, and write documents and reports, while understanding and abiding by regulations.

Learn From Experts in Clinical Research

Instructors are experts in clinical trials and clinical research. Program instructors average over 10 years experience in the field and have expertise in all areas of clinical trials. Professional affiliations include nurses, managers of clinical trials programs, business executives in related medical companies, and certified American Society for Quality (ASQ) members.

“The clinical trials management and regulatory compliance certificate program exceeded my expectations. The instructors are all extremely knowledgeable and available for discussion while going through the program. They also continue to be a great group of individuals to network with as I pursue my career professional development aspirations. The courses provide a variety of content, almost all of which I have been able to apply in my day to day job responsibilities. Having this certification on my resume has definitely increased my marketability.”

—Michael Jesselson ’14 | Research Specialist, Biological Sciences Division at the University of Chicago

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**Curriculum**

Students must complete 5 required courses and 1 elective to earn the certificate.

**Required Courses**

- Good Clinical Practices
- The Drug Development Process
- Statistical Concepts for Clinical Research
- Fundamentals of Site Management
- Fundamentals of Clinical Monitoring

**Electives**

- Fraud and Misconduct
- Project Management and Leadership in the Healthcare Industry

**Observation Study**

The Observation Study provides a unique opportunity to observe and learn from a clinical trial in progress. This interactive, supervised training is required for students who have less than six months of prior work experience in the field of clinical research. It is offered each quarter at the discretion of the student and program coordinator.

**Program Structure**

Classes are offered in two formats, online or in-person. Students may take all courses online or can take a combination of online and in-person courses.

**Online**

- 3 to 5 weeks course length
- Weekly live class sessions (offered weekday evenings and Saturday mornings)
- Between the weekly synchronous sessions, participants complete required readings, assignments and self-study activities

**In person**

- 3-day seminar format (classes are held Wednesday-Friday from 8:30am-4:30pm with a break for lunch)
- Classes are held at the University of Chicago Gleacher Center in downtown Chicago

**Application Requirements**

Students are invited to register for one course without applying. Admission to the program is required to earn a certificate. Applications are accepted on a rolling basis throughout the year. A bachelor’s degree is a prerequisite for the program.

**Applicants must submit:**

- Completed online application
- $40 application fee (non-refundable)
- Personal statement
- Current resume or CV

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