Clinical Trials

Play an active role in developing safe and effective drugs, therapies, and vaccines.

THE UNIVERSITY OF CHICAGO

Clinical trials are essential to helping researchers determine whether a new treatment—like a new drug, device, or intervention—is safe and effective for people. Today's ever-changing global healthcare environment is fueling the clinical research industry's growth—and the demand for professionals equipped with the right clinical trial-related skills is soaring.

Clinical Trials

Clinical research is a highly regulated field that involves testing the safety and effectiveness of investigational drugs, biological products, and medical devices. Clinical trials are an essential step in making advances in diagnosing, treating, and preventing diseases and medical conditions. There are multiple processes and regulatory procedures that must be shared and followed globally to bring a drug to market. The immense collaborative effort across the various stakeholders within the clinical research enterprise plays a critical role in the clinical trial process.

Course Details

Tuition: USD $2,800

Format: Online with live, interactive sessions

Duration: Eight weeks

Language: English, Spanish, and Portuguese

Instructor: Lauren Wall, MSc; Director of Clinical Research Operations, University of Chicago Medicine

About the Course

Our eight-week Clinical Trials online course introduces key terms and concepts of clinical research and provides an overview of the principles and practice of clinical trials from a global perspective. Participants will gain a complete understanding of the clinical trial process, from study start-up to trial close-out. Upon completing the course, students will be able to apply their new knowledge and skills to thrive in a highly controlled and regulated work environment.

You will learn to:

- Understand the clinical trial process from study start-up to trial close-out;
- Explain the critical historical events that led to the globalized standardization of the research conducted worldwide;
- Describe the core ethical principles of clinical research to ensure that the rights and safety of human subjects are protected;
- Define the clinical trial protocol's purpose and develop standards for data collection and data quality to ensure data integrity in a clinical trial;
- Understand key terms, concepts, and acronyms associated with clinical research so that you can effectively communicate with key stakeholders in the industry.

Who Should Attend?

This course is designed for healthcare, medical, and research professionals looking to start or advance their clinical research careers. It is preferable for practioners in other fields interested in the course content to have a life science background.

Meet your Instructor

Lauren Wall has more than fifteen years of experience in hematology/oncology clinical research operations spanning industry and academic healthcare. She currently oversees the clinical research operations in the hematology/oncology section at the University of Chicago. Her primary responsibilities include planning, organizing, directing, and managing daily clinical research operations for over 300 clinical trials. Prior to taking over her role in the academic setting, Wall worked at an oncology clinical research organization, where she gained clinical trial monitoring and project management experience. In addition, Wall traveled to several NCI-designated cancer centers to conduct site visit audits. earned an MSc in clinical research administration from George Washington University. Wall has a strong passion for teaching and mentoring others about exciting career opportunities in the field of clinical research.

Lauren Wall, MSc; Director of Clinical Research Operations, University of Chicago Medicine

Why the University of Chicago?

Becoming a member of the University of Chicago community means gaining access to world-class instructors and a cohort of curious, diverse individuals.

Through a firm grounding in core principles and a rigorous approach to problem-solving, our teaching method—the Chicago Approach—will give you the tools you need to make sense of complex data and turn ideas into impact. Course participants will receive a certificate of completion and join a global network of thought leaders.

The University of Chicago Approach to Online Learning

Our online programs are crafted to support your specific professional development goals. Courses combine e-learning with live, interactive sessions to strengthen your skill set while maximizing your time. We couple academic theory and business knowledge with practical, real-world application.

Through online sessions, you will have an opportunity to interact with University of Chicago instructors and your peers.

Career Outlook

The global clinical trials market—currently valued at 46.8 billion dollars—is expected to grow at a CAGR of 5.1% from 2022 to 2030. In this thriving field, key drivers like the globalization of clinical trials and new, personalized treatments continue to impact market growth, while demand for skilled professionals widens the job market. The need for clinical trials professionals will continue to outpace that for similar roles.

$68k

The average base pay for a clinical trial associate in the United States

409k

The number of clinical studies registered globally as of March 2022

$47B

The expected size of the global clinical trials market in 2028

Potential Job Titles for Global Clinical Research Professionals

- Analyst
- Clinical Operations Director
- Clinical Research Associate
- Clinical Research Coordinator
- Clinical Research Manager
- Clinical Trial Assistant
- Clinical Trial Associate
- Data Manager
- Drug Safety Associate
- Research Nurse

Weekly Schedule

The Clinical Trials course covers the following topics:

Module 1: Introduction to Global Clinical Research

- Defining clinical research and understanding the current landscape of the industry
- The ethical framework that guides the conduct of clinical research
- The historical events and importance of Good Clinical Practice (GCP) in clinical research conducted around the world
- How we protect the rights and safety of human subjects
- Recognizing the need for globalized standards in clinical research

Module 2: Clinical Trial Phases and Design

- Overall goals and types of clinical trials
- The different phases of a clinical trial (Phase I, II, III, and IV trials)
- Ethical considerations in the design and execution of international clinical trials

Module 3: Protocol Development

- Assessing characteristics of a good research question
- Examining the essential elements of a clinical trial protocol and their significance
- Determining key factors that trigger a protocol amendment

Module 4: Informed Consent

- Ethical principles that guide the informed consent document and process
- Essential elements that should be included in both the informed consent discussion and written informed consent
- Challenges in the informed consent process

Module 5: Study Activation and Study Conduct

- Roles and responsibilities of clinical trial investigators, clinical trial sponsors, and Contract Research Organizations (CROs)
- Key steps in planning and activating a clinical trial
- The role of monitoring to ensure that a trial complies with international regulations, standards, and guidelines

Module 6: Independent Review Committees in Clinical Trials

- Roles and responsibilities of Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs) about human subject research
- Recognizing the role of Data Safety Monitoring Boards (DSMBs) and identifying regulations that guide them
- A real-world example of the role the DSMB plays in clinical trial oversight

Module 7: Data Collection and Data Management

- The importance of data collection and setting data quality standards for clinical research
- Developing strategies to ensure high-quality data
- Analyzing critical data points and risk indicators

Module 8: Clinical Trial Close-Out and Reporting

- Visualizing the overall clinical trial timeline from start to finish
- Understanding the importance of study close-out and results reporting

Course outline may be subject to change based on academic adjustments.

Complement your studies:

If you would like to gain further clinical trials knowledge, our nine-month to three-year, part-time Clinical Trials Management and Regulatory Compliance Online Certificate will help take your career to the next level.

This certificate program provides training in clinical procedures across the entire clinical trial process, enabling you to master the procedures and administration and providing you with clinical trial tools you need to lead clinical research studies.

Learn more

To schedule an appointment with admissions, contact **admissions@online.professional.uchicago.edu** or, alternatively, you can let us know when we can call you **here**. Visit **online.professional.uchicago.edu** to learn more.