

Enhance *your skills*
Change *your career direction*
Add *to your expertise*



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AND CLICK THE COURSE CATALOG.

About IUPUI

Indiana University – Purdue University Indianapolis (IUPUI) is Indiana's most comprehensive university campus. IUPUI was formed in 1969, but several programs have provided Central Indiana with quality education and services for much of the century. IUPUI is a premier urban institution and offers students courses year round at times during days, evenings and weekends that meet the demanding schedules of adult learners.



WHERE **IMPACT** IS MADE

About Community Learning Network

The IUPUI Community Learning Network provides hundreds of continuing education classes and serves over 7,000 learners annually in Central Indiana with more than 15 certificate programs.

Continuing Education Programs

IUPUI COMMUNITY LEARNING NETWORK

620 Union Drive, Room 142
Indianapolis, IN 46202
Phone: (317) 278-7600
Fax: (317) 274-2638
Online: www.cln.iupui.edu

*For information about additional certificate programs,
please visit us online or call our offices.*

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INDIANA UNIVERSITY-PURDUE UNIVERSITY
INDIANAPOLIS

Clinical Research

Certificate Program



**YOUR LIFELONG
LEARNING CONNECTION**

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INDIANAPOLIS

Clinical Research

Clinical research involves the processes by which a drug or medical device is developed and tested for effectiveness and safety. Clinical trials are the last stage in the development and require detailed planning to ensure safety and accurate results. Many participants must work together in every phase of development.

If you are considering entering this challenging and rewarding field and have some healthcare, science, or medical background, this certificate program offers a curriculum that will acquaint you with the terminology and the overall procedure used by the many professionals working in clinical research. Gaining a general understanding of the entire process will assist you in making the move to a new career area.

Fees and Enrollment

The one-time Certificate Program Fee of \$35.00 is due upon registration. Learner must pay individual course fees or additional fees listed during website registration.

Refer to course numbers listed in the catalog.

Core Courses

Learners are required to complete the following five (5) core courses in the order listed plus two additional courses in the Business and/or Medical sections. It is suggested that you take Introduction to Project Management, offered in the Business section or Medical Terminology if you are not in the medical field. *Refer to certificate #CERT99N07.*

INTRODUCTION TO CLINICAL RESEARCH

In this class, you will learn the basics of planning, organizing, and monitoring projects. New research is being funded all the time. In taking this class, you can be part of the solution to many of the health problems facing our world today. Pharmaceutical firms invest enormous sums of money into the development of new drugs requiring independent studies for FDA approval. This course covers the basics of clinical research and identifies the key activities involved in the clinical research process.

ROLES AND GOALS IN CLINICAL RESEARCH

Learn how the drug development business works. This course will familiarize you with the responsibilities, goals, and motivations of participants in the development of pharmaceuticals, such as the sponsoring drug company, the Food and Drug Administration, clinical site administrators, review boards and global drug development participants. Discover the variety of scenarios in which all or some of these participants interact.

Certificate Requirements

Learners must attend a minimum of 75% of class sessions for each individual class. Learners will receive Continuing Education Unit certificates after the successful completion of each class. Final certificate will be awarded to learners in good standing *only* after completion of all classes.

THE CLINICAL TRIAL PROCESS

Discover the how's and why's of a clinical research study from Phase I through Phase IV. The course will also review the sources and content of applicable regulations, development of protocols, site management issues, and the processes and tools for tracking and reporting results. The ethical considerations will also be addressed.

THE ETHICS OF CLINICAL RESEARCH

This course will introduce the principle ethical issues involved in the design, conduct, review, and evaluation of a clinical trial. It also looks at ethical concerns related to the marketing of a new drug or therapy. Specific topics will include: Study design (the use of placebos), subject recruitment, conflicts of interest, and obligations of pharmaceutical companies.

BUDGETING FOR CLINICAL TRIALS

Budgeting is a key component in any clinical trial. This course discusses the various cost factors affecting the budget process for clinical trials. Learn which costs may change and the degree of change as it relates to the clinical trial. This course will also discuss those factors that may be negotiated when putting together a clinical trial budget. Whether you are directly or indirectly involved in budgeting issues, this seminar will provide valuable insight into how trials are funded.

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