FOR LEARNING FOR LISTENING FOR LIFE

eLearning License Courses

ACRP's competency-based eLearning programs leverage interactive, state-of-the-art adult learning techniques to ensure true comprehension of course content and the ability to apply learning on the job. Online and in the classroom, ACRP training programs are independently accredited (ACCME and CBRN)*, convenient, cost effective, and designed to meet the needs of today's busy professionals.

Clinical Research Essentials

Informed Consent Simulation

This course is approved for 2.0 ACRP Contact Hours

This interactive, simulation-powered training program helps ensure informed consent is obtained by the right subject, with the right forms, by the right people, through the right process, at the right time, and with the right documentation. By playing the roles of patient, study coordinator, investigator, sub-investigator, and study monitor/CRA in a variety of simulated scenarios, course participants gain a 360-degree understanding of informed consent principles while practicing application of associated competencies. Applicable for both site teams and monitors/CRAs working on behalf of study sponsors and CROs, this program provides a comprehensive view of the informed consent process and includes applicable regulatory guidelines including ICH GCP and the Declaration of Helsinki and info sheets and guidelines from the U.S. Food and Drug Administration and the World Health Organization.

Good Clinical Practice (GCP) Simulation

This course is approved for 2.0 ACRP Contact Hours

This interactive simulation-powered training program helps ensure compliance with international standards for Good Clinical Practice in clinical trials (ICH E6). What makes this program unique is its sharp focus on the application of GCP principles rather than the acquisition of knowledge. By immersing learners in a cutting-edge adaptive learning environment, ACRP's GCP Simulation builds strength in the critical thinking and decision making needed to apply GCPs in the real world. Playing the roles of study coordinator, investigator, sub-investigator, research nurse, and study monitor/CRA in a variety of simulated scenarios, course

participants develop a 360-degree understanding of GCP principles while practicing application of associated competencies in a safe environment – before mistakes are made in real studies. For experienced professionals, this program is an ideal solution for GCP training compliance. With a solid foundation in GCP knowledge and application, experienced professionals should be able to progress through scenarios quickly and efficiently – and get back to work. For those new to the field, ACRP's GCP Simulation offers a fun and engaging way to develop GCP competencies by practicing in a risk-free environment. When course correction is required, coaching is immediately provided – including reference to applicable GCP guidelines and contextualization of associated principles.

Introduction to Clinical Trials

No contact hours are offered for this course

Introduction to Clinical Trials is an ideal program for all novice clinical researchers, those interested in the profession, or those indirectly involved in clinical trials. This course provides the foundational knowledge upon which one can develop his/her competence as a clinical research professional. This two-hour online course details how medical products are developed, how volunteer patients are protected, and who plays key roles in the development, research, review, and approval of medical products. In addition to supporting clinical research professionals and organizations, this program is an ideal tool for organizations seeking to help educate the public about clinical research and to raise awareness of clinical trials and the clinical research profession.

Ethics and Human Subject Protection: A Comprehensive Introduction

This course is approved for 5.0 ACRP Contact Hours and 2.2 contact hours for registered nurses

Prevent brand damage and safety issues while protecting your #1 asset. A "must" for all clinical research professionals. Whether you are new to clinical research or in need of a comprehensive refresher, this on-demand eLearning course provides in-depth training on the history and importance of ethical conduct in clinical trials involving human subjects. Complementing Good Clinical Practice: An Introduction to ICH GCP Guidelines, this course takes a deep dive into the ethical considerations facing clinical research professionals and enables them to put the rules into practice to ensure human subject safety and well-being at all times. Learn how to avoid unethical conduct in clinical trials and how to resolve issues pertaining to actual or potential unethical conduct through a thorough review of the historical evolution of ethics in clinical research, the primary guidelines involving ethical considerations in clinical research, the elements of those guidelines, and the consequences of unethical conduct and decisions.

Ethics and Human Subject Protection: A Refresher Course

This course is approved for 1.5 ACRP Contact Hours and 1.0 contact hours for registered nurses

This course provides refresher training to clinical research professionals who have completed the initial comprehensive ACRP Human Subject Protection course titled "Ethics and Human Subject Protection: A Comprehensive Introduction." When in need of a comprehensive refresher, this on-demand eLearning course provides a consolidated overview on the history and importance of ethical conduct in clinical trials involving human subjects.

Investigator Responsibilities

No contact hours are offered for this course

This course will cover various responsibilities of clinical Investigators based on:

- FDA Guidance for Industry: Investigator Responsibilities
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 Guideline
- Regulations set forth in 21 CFR Part 812, 21 CFR Part 312

This course focuses on the most current version of ICH E6(R2) guideline, which is in conjunction with other ICH guidelines relevant to the conduct of clinical trials (e.g., E2A (clinical safety data management), E3 (clinical study reporting), E7 (geriatric populations), E8 (general considerations for clinical trials), E9 (statistical principles), and E11 (pediatric populations)). In addition to FDA Regulations and ICH Guidance Documents, the International Standard ISO 14155:2011E may apply to medical device studies and all other clinical investigations conducted Internationally. Although this document is not referenced within this course, it is important to note its relevance when conducting research on an International level.

The Drug Development Process: Improving Trial Feasibility and Exploring Your Growth Potential

This course is approved for 1.5 ACRP Contact Hours

Develop a better understanding of the overall drug development process and how each study fits into the "big picture" of the development life cycle. The International Conference on Harmonization's (ICH) E8 guidance document General Considerations for Clinical Trials is put to practice in this interactive eLearning course. Upon completion of this course, you will understand the drug development process, and the similarities and differences between various study designs, study objectives and phases of development. This eLearning course

is excellent for those newer to the field of clinical research who need an awareness of the drug development process and how their work fits into the grand scheme. It also benefits those who are preparing for an ACRP Certification exam who need to brush up on their knowledge and application of ICH E8.

Theory to Practice: Operationalize Your Clinical Study Protocol

This course is approved for 1.5 ACRP Contact Hours

What use is a protocol that does not appropriately capture data to support meaningful statistics? Why are study design, conduct and data analysis so important to consider at the protocol development stage? This eLearning course explores the International Conference on Harmonization's E9 guideline Statistical Principles for Clinical Trials. Improve protocol interpretation and implementation by understanding trial scope, design, conduct, data analysis, and the evaluation and reporting of safety and tolerability data. This course is ideal for those newer to the field of clinical research who need to understand protocol development and protocol content and also benefits those preparing for an ACRP examination who need to brush up on their knowledge and application of ICH E9.

Mastering the Event Reporting Cycle: Understanding Your Impact on Patient Safety

This course is approved for 1.5 ACRP Contact Hours

Efficiently identify and report safety events in your clinical trials. Subject safety is top priority in clinical research. As such, safety reporting is the duty of all clinical research professionals, both at the site and sponsor/CRO levels. Appropriate for all clinical research professionals, this course guides you through the complete event reporting cycle and critical timelines, as defined in ICH E2a and E6 Guidelines. Make sure you understand why events are reported and their impact on overall subject and patient safety.

This course is ideal for any of the following situations:

- Introduction to or refresher on roles, responsibilities, definitions and timelines as they relate to safety reporting
- A component of a corrective and preventive action plan following an audit or inspection
- Preparation for an ACRP Certification exam

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Using Metrics to Improve Subject Recruitment and Retention

This course is approved for 1.5 ACRP Contact Hours

Overcome challenges in subject recruitment and retention by learning how to leverage the metrics critical to success. Low subject recruitment and retention are a leading cause of trial delays and failure, but using the right metrics at the right time can help clinical study sites pinpoint areas for improvement and subsequently assess those improvements. Learn which essential measures you should use for every trial in order to benchmark and monitor improvements in specific areas of subject recruitment, accrual and retention. This self-paced, on-demand eLearning course will equip site personnel to assess current site performance and readiness for action, and to implement appropriate metric measurement and monitoring.

ICH Gap Analysis

This course is approved for 2.0 ACRP Contact Hours

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) provides clinical researchers with valuable guidelines to promote the safety, conduct, design, and reporting of clinical trials. This eLearning assessment has been specifically designed to test knowledge of these ICH Guidelines, while assessing your ability to analyze and apply the principals in common clinical research settings. Designed in a game-like format using five ICH categories (listed below), 12 questions per category are presented in multiple choice and true/false format. A score of at least 75% is required in order to advance to each category. A score below 75% results in the option to begin that category again until a passing score is achieved.

ACRP Certification Exam Preparation eLearning Course

No contact hours are offered for this course

This 90-minute comprehensive eLearning course is designed to guide you through preparing for the ACRP Certification of your choice (CCRC, CCRA, CPI and the ACRP-CP). The steps include a review of the resources available to you, strategies to approach the test questions, and a review of the ICH Guidelines covered in the exams.

Specialized Topics

Understanding Clinical Trial Protocols: Key Considerations for Effective Development and Feasibility Review

This course is approved for 1.5 ACRP Contact Hours

An essential course for all clinical research professionals involved in the design and/or feasibility assessment of clinical research protocols. This interactive eLearning course incorporates a high level overview of concepts and real-world scenarios you are likely to encounter when developing a protocol.

Site Quality Management Tools: SOPs, Metrics, and Training

This course is approved for 1.5 ACRP Contact Hours

This comprehensive training program is a must for site personnel involved in quality management and improvement. Building on a solid understanding of the key components of quality management systems (root cause and CAPA) and risk-based decision-making, this course prepares you for the next step of setting up a quality management system at a site. Training topics include:

- Quality risk mitigation
- Comprehensive root cause analysis
- Development and implementation of appropriate corrective and preventive action plans
- Development and implementation of effective Standard Operating Procedures (SOPs)
- Development and delivery of training specific to the CRC role

Risk-Based Monitoring: The Essentials

This course is approved for 1.5 ACRP Contact Hours

Become an expert on quality and risk-management strategies and procedures. Risk-based monitoring (RBM) is being used more often by sponsors and CROs and, undoubtedly, there is an impact on all research professionals. This interactive eLearning course answers the fundamental questions: What is RBM and how is it different from the standard monitoring approach? It then builds on that content to examine the impact on the clinical research site and CRAs in topics related to new approaches to data management, study budget,

and contract considerations. This course benefits all clinical research professionals involved in budget and contract development, resource allocation, conduct of subject visits, and data review, collection, and recording.

Mastering Budgeting at Your Site: Building and Negotiating Clinical Trial Budgets that Make Sense

This course is approved for 1.5 ACRP Contact Hours

An essential course for all clinical research professionals involved in the clinical trial agreement and/or budget process for industry-initiated trials. Although designed from a site perspective, the course outlines key elements for consideration by both sponsors and sites. The course highlights important aspects of creating a budget for a clinical trial such as protocol analysis and per-subject budgeting including start up, variable and hidden costs of a clinical trial. This interactive eLearning course incorporates knowledge checks and real-world scenarios you are likely to encounter during the creation and negotiation of a clinical trial agreement and budget.

Key Skills for Ensuring Quality Control through Risk-Based Decision Making

This course is approved for 1.5 ACRP Contact Hours

Quality control initiatives used to ensure subject safety and data integrity are maintained throughout clinical trials. But finite resources, such as time and personnel, must be deployed carefully and appropriately. Risk-based decision making is a method of ensuring quality control initiatives are rolled out appropriately, according to the levels of posed risks. Gain confidence in making risk-based decisions and implementing actions related to quality control initiatives. Course content covers key aspects related to risks in clinical trials, including:

- Identification
- Analysis
- Categorization
- Management
- Planning
- Assessment
- Communication
- Change management

Trial Feasibility and Selection: Their Impact on Accrual

This course is approved for 1.5 ACRP Contact Hours

Selecting the right trial for your clinical research site is key to the success of your accrual for the trial. This eLearning course will discuss how the menu or portfolio of studies offered at a site has an important impact on accrual and how research professionals can become part of the process.

Tools included:

- Trial Selection/Protocol Review Worksheet
- Trial Selection Process, Best Practice Tip Sheet
- Balanced Trial Menu Worksheet
- Self and Organizational Assessment

Implementing a Patient-Centered Informed Consent Process

This course is approved for 1.5 ACRP Contact Hours

Improve your consent process by learning how to assess a participant's reading level, health literacy, and overall understanding of clinical trial participation and address culture, learning styles, emotional states and language. An effective informed consent process involves more than simply reviewing a document with a potential participant and applying signatures. This critical process lays the foundation for a subject's participation in a clinical trial and directly impacts regulatory compliance and site performance with respect to the ability to meet recruitment requirements, achieve and maintain subject compliance, and retain trial subjects. This eLearning course is essential for those who are directly involved in and responsible for conducting informed consent discussions and developing informed consent forms. Use the included job aids to immediately take positive actions for your next informed consent discussion.

Improving Recruitment, Accrual, and Retention in Clinical Trials

This course is approved for 1.5 ACRP Contact Hours

Do you know how to improve recruitment, accrual and retention in your clinical trials? This eLearning course will provide best practices to help your clinical research site assess how to better communicate with potential participants and begin a critical reflection of your own skills and organizational practices to improve recruitment and retention with a focus on operational efficiency, cultural competency, and patient centricity.

Access the tools necessary to maximize recruitment and retention, including:

- Reflection Checklists for current strategies for recruitment, accrual and retention

- Tip Sheets for pre-screening and retention

Form FDA 1572: Get it Right the First Time

This course is approved for 1.5 ACRP Contact Hours

The Statement of Investigator (Form FDA 1572) doesn't have to be complicated. This course helps you get it right the first time. Ideal for sponsor personnel instructing sites on completion, site staff completing the form and sponsor personnel reviewing it, this course answers the questions of why, when and how to complete the FDA 1572 to make everyone's jobs easier. Use the supplied job aids to ease the regulatory burden of handling the FDA 1572:

- Completion tips
- Decision trees
- FAQs

Inspection Readiness: Best Practices for Managing Clinical Trial Inspections

This course is approved for 1.5 ACRP Contact Hours

Reduce your anxiety by being prepared for clinical trial inspections. Preparing for or responding to an inspection can be daunting. It is best to start prepared and stay prepared. This essential course takes you through the full cycle of a regulatory authority GCP inspection and answers key questions, like:

- Why, when and where are regulatory inspections performed? Who can be inspected?
- What are the objectives of an inspection?
- How do you prepare for and respond to an inspection?

The course focuses specifically on GCP inspections by the U.S. Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA), but the fundamentals can be applied to any regulatory authority inspection.

Building Quality Management Systems for Sites and Sponsors: Root Cause and CAPA

This course is approved for 1.5 ACRP Contact Hours

Implement a Quality Management System (QMS) and prevent findings related to patient safety, data quality and regulatory compliance. With the industry moving away from detecting and fixing problems to preventing them, quality management systems (QMS) play a crucial role. The impact of not implementing or incorrectly using an effective QMS can be substantial and far-reaching, and may include putting human subject integrity

and well-being at risk, inaccurate trial data and regulatory non-compliance. Reduce your risks with this eLearning course. Training topics include:

- Development and application of Corrective and Preventive Action (CAPA) plans
- Conduct of Root Cause Analysis (RCA)
- Development and application of risk management strategies

eResearch: Managing Clinical Trials in an Electronic Environment

This course is approved for 1.5 ACRP Contact Hours

More and more companies are going "paperless." What does this mean in the field of clinical research? This online course examines the challenges of working with electronic documents and how to overcome them. Learn how to set up and manage electronic clinical research documents in compliance with U.S. and EU regulations, and current trends from both the site and sponsor perspectives. Job aids in the form of compliance checklists (CDISC user requirements and site-level electronic records compliance) and website references are included to ensure you achieve compliance in a paperless clinical trial environment.

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*Please see individual course descriptions for detailed accreditation information.