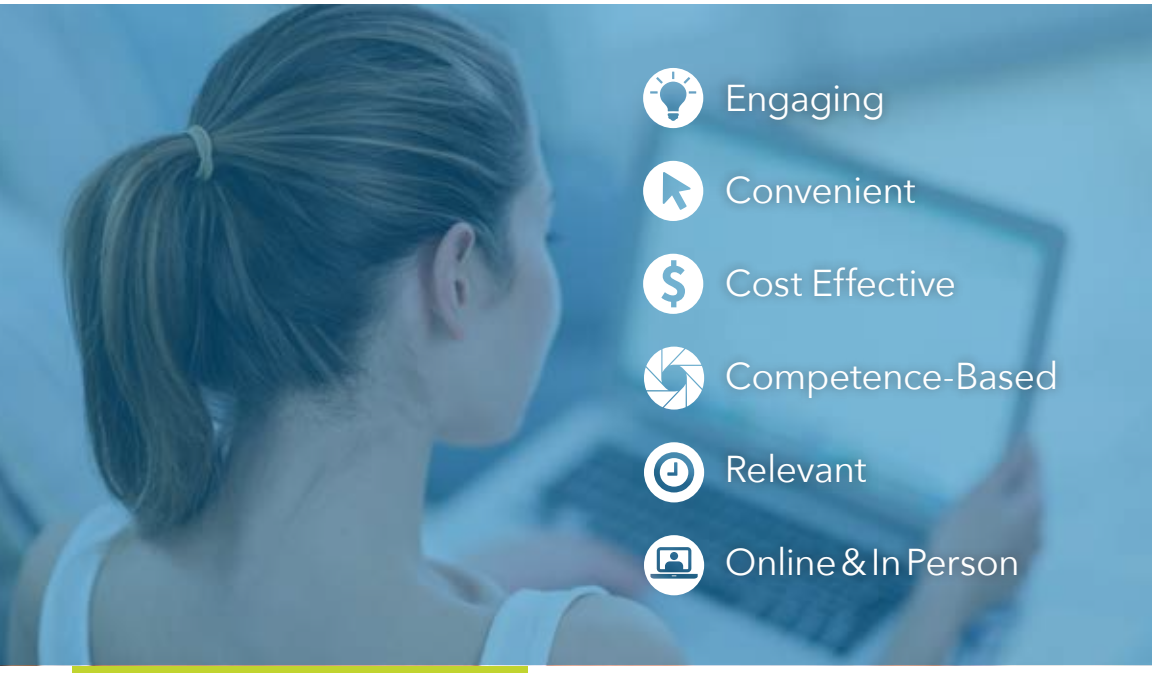
ACRP
ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

TRAINING SOLUTIONS

FOR CLINICAL RESEARCH PROFESSIONALS



2015 CATALOG

- HUMAN SUBJECT PROTECTION & GOOD CLINICAL PRACTICE
- CLINICAL RESEARCH ESSENTIALS
- SPECIALIZED TOPICS
- ACRP BUSINESS SOLUTIONS

www.acrpnet.org/training

CHOOSE QUALITY. CHOOSE ACRP.

The Association of Clinical Research Professionals is defining the future of clinical research training as the global leader in quality training solutions for clinical trials staff. Put our 40+ years of experience to work for you.

Engaging

Say goodbye to voiceover slides, and hello to truly interactive courses – online and in the classroom – that build competency, address real-world issues, and improve performance. ACRP is the only training provider offering a true eLearning experience for the clinical research profession.

Convenient

ACRP's online, on-demand training modules work with working professionals. 60-minute eLearning training modules available online and on-demand everywhere in the world, and local classroom courses in select areas.

Cost Effective

ACRP eLearning courses are just $99 and classroom courses are competitively priced. Group rates and tiered pricing structures are available for institutions to fit any budget.

Relevant

Designed specifically to remedy common regulatory inspection findings related to protocol compliance, safety reporting, data integrity, and more.

BUILDING PROFESSIONAL COMPETENCE

ACRP's training programs are designed to help clinical trials staff build the core competencies required of clinical research professionals, as defined by the Joint Task Force for Clinical Trial Competency, which includes representation from ACRP, Alliance for Clinical Research Excellence and Safety, Clinical Trials Transformation Initiative, Consortium for Academic Programs in Clinical Research, Multi-Regional Clinical Trial Center at Harvard, Pfizer, and more*.

Source: Joint Task Force for Clinical Trial Competency

* Sonstein S, Seltzer J, Li R, Silva H, Thomas Jones C, Daemen E. 2014. Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional: *Clinical Researcher* June 2014: 17-23

HUMAN SUBJECT PROTECTION & GOOD CLINICAL PRACTICE

Ethics and Human Subject Protection

In-depth training on the importance of ethical conduct in clinical trials involving human subjects. 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. This eLearning course allows you to put the rules into practice to ensure human subject safety and well-being at all times.

ETHICAL AND PATIENT SAFETY CONSIDERATIONS

www.acrpnet.org/hsp

Good Clinical Practice: An Introduction to ICH GCP Guidelines

Formal training on the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), the globally recognized standard for the conduct of clinical trials, for clinical research professionals with less than one year of experience. This eLearning course equips clinical research professionals with not only an understanding of the core concepts of GCP, but how to put those concepts into action through a series of ongoing knowledge checks and real-world scenarios likely to be encountered during a clinical trial.

Recognized by TransCelerate BioPharma Inc.

CLINICAL TRIALS OPERATIONS (GCPs)

www.acrpnet.org/gcp_intro

GCP for the Experienced CRA: Improving Monitoring Efficiency and Effectiveness

This course improves monitoring skills by breaking down GCP into four memorable categories (Verify, Ensure, Determine and Communicate) to enable easy recall and application of the GCP E6 guideline. By providing real-world illustrations and examples of efficient, effective monitoring approaches, this eLearning course improves monitoring skills and enhances the value of CRAs.

Recognized by TransCelerate BioPharma Inc.

CLINICAL TRIALS OPERATIONS (GCPs)

www.acrpnet.org/gcp_cra

GCP TEST-OUT CHALLENGE

You need to complete and pass Good Clinical Practice training, and you know you already have the necessary knowledge and skills but you have no way to prove it… Think again! This fun game assesses your GCP knowledge, application, and analysis skills, and provides you with verification for your employer. Progress through four increasingly difficult levels of GCP questioning and ultimately earn your 'Gold Badge' confirmation of GCP knowledge.

CLINICAL TRIALS OPERATIONS (GCPs)

www.acrpnet.org/gcp_testout

GCP for the Experienced CRC: Partnering with Your Investigator to Reduce Risk and Avoid Common Inspection Findings

Avoid today's most common inspection findings through practical, memorable application of GCP guidelines, and as a result reduce risk and attract more clinical trials to your research site. By highlighting today's most common inspection findings – and providing you with best practices, illustrations and examples to avoid them through correct application of GCP guidelines – this eLearning course better prepares CRCs for audits/inspections.

Recognized by TransCelerate BioPharma Inc.

CLINICAL TRIALS OPERATIONS (GCPs)

www.acrpnet.org/gcp_crc

GCP for the Experienced Investigator: Reducing Risks and Avoiding Common Inspection Findings

Avoid today's most common inspection findings through practical, memorable application of GCP guidelines, and as a result reduce risk and attract more clinical trials to your research site. By highlighting today's most common inspection findings – and providing you with best practices, illustrations and examples for avoiding them through correct application of GCP guidelines this eLearning course better prepares investigators for audits/inspections.

Recognized by TransCelerate BioPharma Inc.

CLINICAL TRIALS OPERATIONS (GCPs)

www.acrpnet.org/gcp_investigator

Advanced GCP: Assessing Compliance Risk

GCP compliance is all about avoiding or resolving issues related to risks that could potentially jeopardize patient safety, quality of data, and regulatory compliance. This interactive one-day classroom course allows clinical trials staff to put risk assessment and reduction practices into action through collaborative instructor-led group exercises and real-world scenarios. Participants will identify GCP compliance risks, assign levels of risk to the sponsor, site, and IRB/IEC, and define actions required to resolve and prevent compliance problems.

CLINICAL TRIALS OPERATIONS (GCPs)

www.acrpnet.org/advanced_gcp

CLINICAL RESEARCH ESSENTIALS

Fundamentals of Clinical Research

This interactive two-day classroom course provides the core knowledge and practical insight needed by all clinical research professionals. Following an introduction to clinical research, this course covers ethical concerns and human subject protection; regulatory obligations; essential documents, including research records; clinical trials start up and conduct; quality control, focusing on the monitoring of clinical trials; adverse experiences; and subject recruitment.

CLINICAL TRIALS OPERATIONS (GCPs); ETHICAL AND PATIENT SAFETY CONSIDERATIONS; DATA MANAGEMENT AND INFORMATICS; SCIENTIFIC CONCEPTS AND RESEARCH DESIGN; MEDICINES DEVELOPMENT AND REGULATION

www.acrpnet.org/fundamentals

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

This eLearning course allows clinical research professionals to more efficiently and readily identify and report safety events during the conduct of a clinical trial. By guiding learners through an interactive exploration of the event reporting cycle – from identification to sponsor notification, and from regulatory reporting to Investigator Brochure updates – this course enables full comprehension of the roles and responsibilities of site, sponsor and CRO personnel (as defined in the E2a and E6 guidelines) and how all clinical research professionals ultimately contribute to patient safety.

CLINICAL TRIALS OPERATIONS (GCPs); ETHICAL AND PATIENT SAFETY CONSIDERATIONS

www.acrpnet.org/e2a

NOT SURE WHERE TO BEGIN? START WITH THE ICH GAP ANALYSIS TOOL

This fun game helps assess knowledge and skill levels related to ICH guidelines (E2a, E6, E8, and E9) and the Declaration of Helsinki. Participants progress through four increasingly difficult levels of ICH guideline questioning and ultimately earn a 'Gold Badge' confirmation of knowledge. A great resource for identifying strengths and weaknesses related to ICH guidelines to help focus future training efforts.

CLINICAL TRIALS OPERATIONS (GCPs)

www.acrpnet.org/gap_analysis

COURSES ACCREDITED FOR CBRN & ACCME CONTACT HOURS/CREDITS

ACRP training programs are accredited to provide Accreditation Council for Continuing Medical Education (ACCME) and California Board of Registered Nursing (CBRN) contact hours/credits for continuing education.

Theory to Practice: Operationalize Your Clinical Study Protocol

Improve and enhance protocol interpretation and conduct, as well as protocol feasibility studies. By guiding learners through a mock protocol review, this eLearning course ensures clinical research professionals are exposed to statistical considerations for clinical trials (as defined in the E9 Guideline) and are able to operationalize study protocols through comprehension of clinical trial development and design, data analysis, safety and tolerability evaluations, and reporting requirements.

SCIENTIFIC CONCEPTS AND RESEARCH DESIGN

www.acrpnet.org/e9

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

This eLearning course helps improve site feasibility and protocol evaluation practices and prepares clinical research professionals to effectively consider potential avenues for business growth by breaking into additional phases of clinical research. By following a mock drug through a review of the drug development process, this course provides a holistic perspective – from the pre-clinical beginning through the four phases of clinical research and beyond, as defined in the E8 guideline – and easy-to-apply tools for evaluating a site's feasibility to conduct research in each trial phase, as well as protocol feasibility, to meet drug development plan goals.

MEDICINES DEVELOPMENT AND REGULATION

www.acrpnet.org/e8

Site Quality Management Tools: SOPs, Metrics, and Training

This eLearning course builds on a solid understanding of the key components of quality management systems (Root Cause and CAPA) and risk-based decision making by providing the guidance and information needed to start setting up a Quality Management System at the site.

Learners should be able to describe the importance of quality processes in clinical research conduct by providing a framework for the necessary elements and systems that should be implemented by a site to ensure quality, such as Root Cause Analysis and Quality Management Systems, including the steps of quality processes and a pro-active approach, amongst others.

Participants take away actual tools necessary to set up and measure a quality process at the site, including recommended lists of site SOPs, sample SOPs, guidance on how to put SOPs in practice, sample quality-related metrics, and guidance for organizing useful training sessions.

Course content is provided in a fun and interactive way using a fictional site manager and mentor named 'Lynn,' who answers questions asked by CRC 'Cathy' while guiding learners through the course.

DATA MANAGEMENT AND INFORMATICS

www.acrpnet.org/site_quality_tools

NEW IN 2015

KEEP AN EYE OUT FOR THESE NEW eLEARNING COURSES!

eResearch: Managing Clinical Trials in a Tech-Driven Environment

Inspection Readiness: Best Practices for Managing Clinical Trial Inspections

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

Managing Billing Compliance Risks: Navigating Medicare in Clinical Trials

Improving Recruitment, Accrual, and Retention in Clinical Trials: Best Practices

CRC Onboarding Curriculum

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

Interested or involved in designing a clinical study and want to be better acquainted with some of the terms and methodology? Want to learn some of the aspects of protocol development and review to help when reviewing a study you plan to participate in or are considering opening? This high-level overview of protocol development and review addresses both needs.

This eLearning course reviews what a protocol is, its components, and how these vary depending on the research need. It helps develop a better understanding of study protocol design and helps clinical research professionals review and assess an existing study. By appreciating the form and function of a study protocol, learners will be able to achieve both objectives.

"Lucy," a virtual trainer, and her classroom students guide participants through the different course modules. Knowledge checks, graphics, case studies, and job aids are provided throughout. Learners will perform a specific case study involving construction of a protocol to answer a simple question that will aid learning retention and knowledge assessment: Will a well-known home remedy treat the common cold?

Study design is complicated. We simplified it in this highly interactive online course that is the course to take before entering any protocol writing and feasibility assessments projects.

SCIENTIFIC CONCEPTS AND RESEARCH DESIGN

www.acrpnet.org/protocol_development

SPECIALIZED TOPICS

Form FDA 1572: Get It Right the First Time

FDA officials responsible for the agency's Good Clinical Practices program have long emphasized that few, if any, GCP-related areas generate as much industry uncertainty as Form FDA 1572-Statement of Investigator. Throughout many years the challenges remain the same: understanding how, when, and why to complete this form.

This interactive course provides a one-stop-shop solution to help make you comfortable with the document, its completion and management, and with your understanding of who should be on this form (and who should not) so you get it right the first time for all your studies requiring Form 1572. Equip yourself with relevant and complete reference information, examples, job aids (such as completion tips and decision trees), FAQs, and exercises that allow you to practice and check your understanding of the information application.

After completing this course, you will be equipped to get Form 1572 right the first time!

CLINICAL TRIALS OPERATIONS (GCPs); MEDICINES DEVELOPMENT AND REGULATION

www.acrpnet.org/form_1572

Building Quality Management Systems for Sites and Sponsors

This eLearning course will develop or enhance your ability to contribute to the improved quality of your clinical trials by using tools such as 'Corrective Action Preventive Action (CAPA)' and 'Root Cause Analysis (RCA),' and by applying methodologies and key factors such as documentation best practices and risk management strategies that support and enhance the excellence of a quality management system.

Not implementing quality management systems, or not using them correctly, could jeopardize the desired outcomes of your trials; for example, not safeguarding human integrity and wellbeing, accuracy of trial data, and budget and regulatory compliance.

Quality management systems are required for trial success no matter the monitoring strategy (risk-based, remote, centralized, on-site or a combination), but are important in more risk-based approaches as they help identify and avoid or mitigate risks.

ETHICAL AND PATIENT SAFETY CONSIDERATIONS; DATA MANAGEMENT AND INFORMATICS

www.acrpnet.org/quality_systems

ALSO AVAILABLE AS A CLASSROOM COURSE

ACRP's one-day classroom course provides an interactive exploration of quality management systems and prepares you to build them in both site and sponsor settings to improve clinical trial operations efficiency and accuracy. The companion eLearning course is included as part of the course and is the pre-requisite, foundational learning for this classroom discussion of quality management systems from both site and sponsor perspectives. Course attendees will be asked to use the knowledge gained in the eLearning component of this course to collaboratively solve problems presented in multiple scenarios through selection, development, and implementation of quality management systems. The classroom course will begin with a brief review of key components and tools as presented in the eLearning Course that will be used to complete scenarios presented.

SPECIALIZED TOPICS

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

Risk-Based Monitoring (RBM) is an approach to quality control conducted by the sponsors of clinical trials that has grown in popularity in recent years, impacting both site and sponsor personnel. Overall trial execution in itself hasn't been affected by this change. We all have the same end goals in mind: ensuring that trial subjects are safe at all times and that the products that make it to market do so based on decisions that have their origin in accurate and complete data. Quality control is and always has been a key task to meet these goals.

A key skill to ensure risk-based strategies and to provide the most secure quality control is the ability to make risk-based decisions. You should take this eLearning Course because it will help you to make the right risk-based decision at the right time, ensuring no harm is done.

This course shows in detail the standard process of risk-based decision making – from risk identification, analysis, categorization, risk management, and planning to risk-based decisions, assessments, and communication. But the process alone is not sufficient to succeed. This course will also enhance your insights into the changes required for successful risk management, and thus decision making, such as attitude changes, targeting current skills differently and/or the need for developing potentially new skills like quality control, trial management, change management, and motivational skills. Current sponsor and site tasks are carefully untangled and each role's responsibility is being revisited in light of these required changes, providing you with the insights and tools you need to make the right risk-based decisions with confidence.

ETHICAL AND PATIENT SAFETY CONSIDERATIONS; DATA MANAGEMENT AND INFORMATICS

www.acrpnet.org/key_skills

ALSO AVAILABLE AS A CLASSROOM COURSE

ACRP's one-day Classroom Course provides an interactive exploration of how the skills currently used to conduct clinical trials in the traditional sense (pre–Risk-Based Monitoring) can be adapted and elevated to conduct trials in the evolving clinical research landscape. The companion eLearning course is included and is the pre-requisite, foundational learning for this classroom discussion focused around risk-based decision making. Course attendees will be asked to use the knowledge gained in the eLearning component of this course to collaboratively solve problems presented in multiple scenarios through identification and implementation of key skills and best practices, with an emphasis on risk-based decision making. The classroom course will begin with a brief review of key components and tools as presented in the eLearning Course that will be used to complete scenarios presented.

Risk-Based Monitoring: The Essentials

For CRAs

This eLearning course empowers Clinical Research Associates (CRAs) to successfully prepare for and execute Risk-Based Monitoring plans. This course provides learners with a brief history on how Risk-Based Monitoring came about, how it is defined across the world, and most importantly how it will affect their work as a CRA.

For CRCs

This eLearning course prepares Clinical Research Coordinators (CRCs) to make the necessary adjustments at their site for execution of Risk-Based Monitoring and equips learners to work effectively with Clinical Research Associates (CRAs) carrying out this monitoring approach. This course provides learners with a brief history on how Risk-Based Monitoring came about, how it is defined across the world, and most importantly how it will affect their work as a CRC (or research nurse, clinical trial assistant, trial assistant, project assistant).

For Investigators

ACRP's on-demand eLearning Course empowers Investigators, to modify their site quality control plans and to adjust processes in preparation for executing Risk-Based Monitoring strategies. This course provides learners with a brief history on how Risk-Based Monitoring came about, how it is defined across the world, and most importantly how it will affect their work as an Investigator.

CLINICAL TRIALS OPERATIONS (GCPs); ETHICAL AND PATIENT SAFETY CONSIDERATIONS; DATA MANAGEMENT AND INFORMATICS

www.acrpnet.org/rbm

SPECIALIZED TOPICS

Webinars – Live & On-Demand

Keep pace with regulatory developments and industry trends affecting your clinical trials, or take a deeper exploration of specialized clinical research topics, without travel expenses or time away from the office. Brief, instructor-led, interactive, live and recorded online sessions. Sample titles include:

- Are You Inspection Ready? Understanding Inspection Focus Areas and the Evaluation of Investigator Oversight
- Cracking the Code for Clinical Trial Recruitment: A Sponsor's Perspective
- Setting Your Sites Up for Success: Industry Trends and Best Practices for Sponsors and CROs
- FDA/EMA Inspection Lessons Learned: Protocol Deviations – Why They Occur and How to Handle Them
- Updating Your Patient Recruitment Strategy: The Importance of Implementing Social Media and Online Campaigns

www.acrpnet.org/webinars

200+ RECORDED PRESENTATIONS

Access more than 200 presentations on more than 17 topic areas recorded live at ACRP's annual conference in the Online Conference Library. Listen along to recorded presentations and download slides, job aids, handouts, and more. A valuable resource for those looking to keep pace with current trends in the field and diversify their knowledge base.

www.acrpnet.org/ocl

HERE'S WHAT COURSE PARTICIPANTS SAY!

"The new eLearning offerings are very impressive and indicate ACRP's commitment to providing high-quality training. These courses have been carefully developed with adult learning principles in mind and engage the learner in an interesting and interactive manner. As a clinical research trainer, I am a critical evaluator of GCP courses but am pleased to recommend these offerings."

– PAUL R. BELOW, MS, CCRA

"An excellent refresher on ICH/GCP, covering important topics in detail and providing good job references."

Good Clinical Practice: An Introduction to ICH GCP Guidelines Participant

"I really think it was absolutely incredible and I'm so happy ACRP has provided this learning opportunity."

Building Quality Management for Sites & Sponsors Participant

"I was truly excited about the quality. After 10 years of taking intro to GCP courses, it was more than refreshing."

GCP for the Experienced Investigator Participant

"As a CRC, this will help me prepare for monitor visits at my site… and increase my knowledge of current practices."

GCP for the Experienced CRA Participant

"Reinforces my skills and competence. I can contribute more... I know what to look out for when assessing feasibility of a study."

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

"Very impressed with the design and content. The interactive component was well done and helped me to learn."

Building Quality Management for Sites & Sponsors Participant

AT A GLANCE

Here's a quick view of ACRP training programs, along with recommendations from select ACRP Interest Group leaders.

	GCP & Ethics	Regulatory Affairs	Site Management & Coordination
Ethics & Human Subject Protection	✖		
Fundamentals of Clinical Research	✖		
Good Clinical Practice: An Introduction to ICH GCP Guidelines	✖	✖	
GCP for the Experienced CRA: Improving Monitoring Efficiency and Effectiveness	✖	✖	
GCP for the Experienced CRC: Partnering with Your Investigator to Reduce Risk and Avoid Common Inspection Findings	✖	✖	✖
GCP for the Experienced Investigator: Reducing Risks and Avoiding Common Inspection Findings	✖	✖	✖
Advanced GCP: Assessing Compliance Risk	✖	✖	
Project Management for Clinical Research Professionals			✖
Key Skills for Ensuring Quality Control through Risk-Based Decision Making			✖
Building Quality Management Systems for Sites and Sponsors: Root Cause and CAPA			✖
Form FDA 1572: Get It Right the First Time		✖	
GCP Test-Out Challenge	✖	✖	
Site Quality Management Tools: SOPs, Metrics, and Training			✖
Understanding Clinical Trial Protocols: Key Considerations for Effective Development and Feasibility Review			
Mastering the Event Reporting Cycle: Understanding Your Impact on Patient Safety			
Risk-Based Monitoring: The Essentials for CRAs		✖	
Risk-Based Monitoring: The Essentials for CRCs		✖	✖
Risk-Based Monitoring: The Essentials for Investigators		✖	✖
The Drug Development Process: Improving Trial Feasibility and Exploring Your Growth Potential			
Theory to Practice: Operationalize Your Clinical Study Protocol			✖
ICH Gap Analysis Tool	✖	✖	
Certification Exam Preparation	✖		
eResearch: Managing Clinical Trials in a Tech-Driven Environment			✖
Inspection Readiness: Best Practices for Managing Clinical Trial Inspections			✖
Mastering Budgeting at Your Site: Building and Negotiating Clinical Trials Budgets that Make Sense			✖
Improving Recruitment, Accrual and Retention in Clinical Trials: Best Practices			✖
Managing Billing Compliance Risks: Navigating Medicare in Clinical Trials			✖
CRC Onboarding Curriculum	✖		✖

Sponsor/CRO Monitoring & Trial Management	Quality Management & Assurance	Project Management	Data Management	Physician Issues	Investigator Research	Clinical Trials Recruitment
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ACRP BUSINESS SOLUTIONS

Training your clinical research team has never been easier, or more affordable. ACRP Business Solutions lets you choose the program that fits with your organization and best meets the training needs of your employees. With a wide variety of licensing options and courses, every organization, regardless of size or system capabilities, can provide best-in-class training to employees.

Licensing Saves You Time & Money

Enroll your employees in training programs, track their progress, and produce on-demand reports with ACRP licensing options that put the power and resources in your organization's hands. And with options that can bring the total cost of coursework to approximately $5 per employee, ACRP Business Solutions saves you money.

eLEARNING LICENSING

Make ACRP's LMS Your LMS

Sub-licensing ACRP's learning management system gives you a branded lite version of ACRP's LMS and gives your employees unlimited access to all ACRP eLearning programs for a flat annual fee. You can even load your own training programs into the LMS to create a centralized training resources for your team.

Our Courses Love Your LMS, Too!

ACRP eLearning courses are SCORM compliant. So if you already have an LMS that you rely on, we offer a license that allows you to host our courses in your LMS. No complicated data feeds. No integration costs. Just a fantastic addition to your current curriculum. Courses are offered in multiple packages; choose one, or combine several to create a program that meets your team's unique training needs.

CLASSROOM LICENSING

Our Courses at Your Site

ACRP delivers trainers and course materials. You provide facilities and organize your learners. The result is a trusted ACRP live course with no travel required.

We Train Your Trainers

Already have qualified trainers within your organization? ACRP trains your trainers to deliver ACRP programs to you employees as often and wherever you like.

Custom Coursework

If you have needs that pre-developed coursework will not meet, ACRP will work with you to create the perfect program. Whether you need an online program, a classroom course, or even a webinar, we have a network of subject matter experts who will ensure you receive high-quality programs, even if you need niche content.

LET'S TALK

ACRP's mission to promote excellence in clinical research can only be met if we are able to create excellent clinical researchers. We invite you to work with us to create teams of excellence within your organization.

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ACRP PROMOTES EXCELLENCE
IN CLINICAL RESEARCH
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