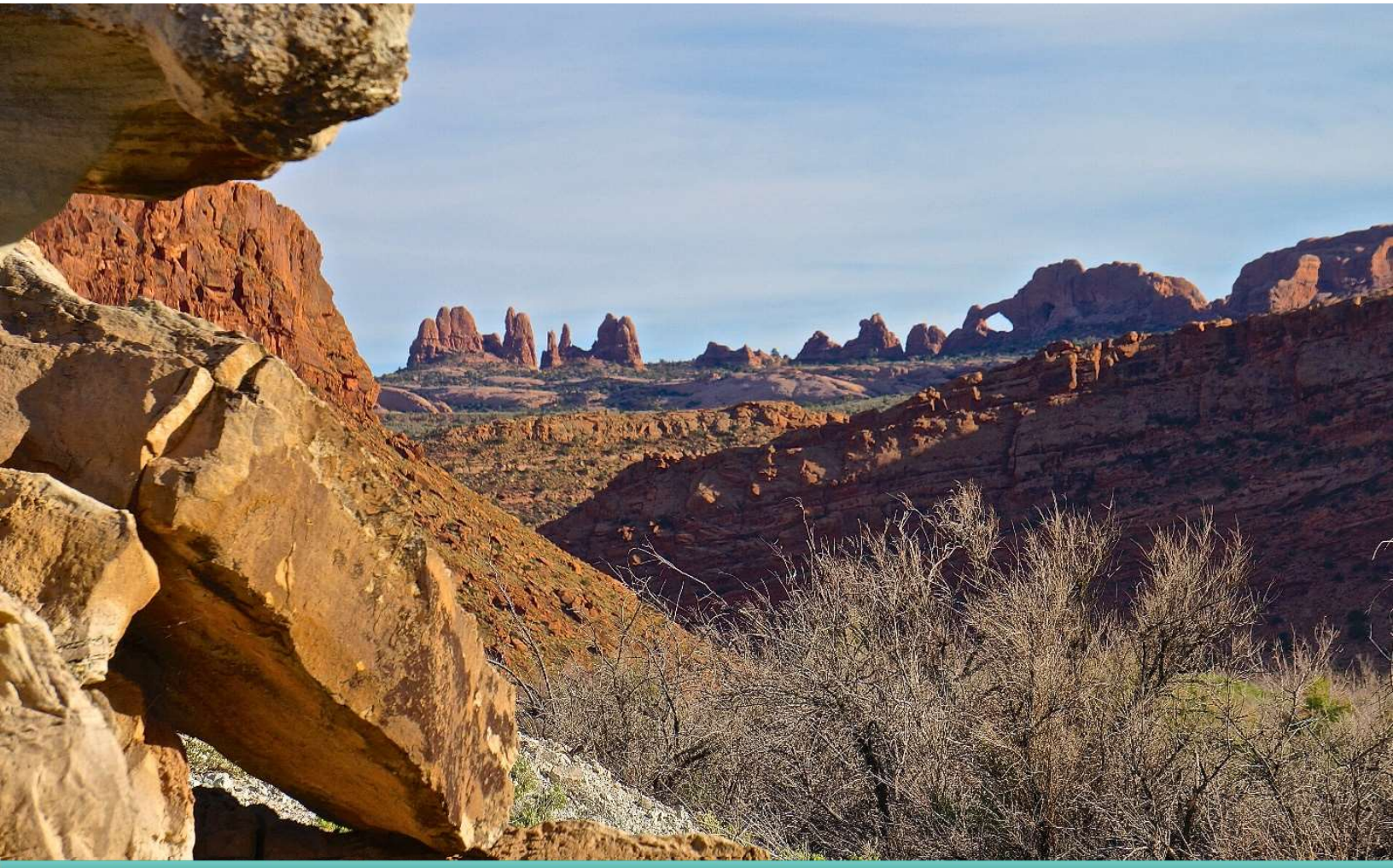
Clinical Pathways

Course Catalog 2023



Welcome to the

Training Course Catalog

for Clinical Pathways

Your guide to effective quality training through eLearning courses and webinars for a variety of audiences within the global clinical research industry: Sponsors, CROs, Research Sites, IRBs, and more.

Clinical Pathways Training Catalog

In-person or Online, Webinar, eLearning, and Customized Training!

Clinical Pathways offers a variety of clinical trial training courses that can be deployed various ways, including live in-person (or live online), remote webinar, and eLearning on-demand training. Clinical Pathways eLearning offerings are growing and any course can be customized to your needs and company branding. Look through the course catalog for courses that are offered in various formats, indicated by the icons.

Enterprise Training Solutions

Clinical Pathways builds courses to meet your company's training needs. We can use your content to create new trainings for in-person or live online, web-based, or eLearning formats. We can also update our off-the-shelf courses to include your processes, SOPs, and branding.

Want a faster and more affordable option? Clinical Pathways offers convenient course bundles of off-the-shelf eLearning at a discounted rate.

eLearning Trainings

Clinical Pathways has developed convenient and affordable off-the shelf training to meet sponsors', CROs' and sites' needs. All Clinical Pathways eLearning trainings are in an on-demand, interactive format for training on the go. Trainings can also be presented live for your teams.

- Our eLearning courses use real-life case scenarios to help you understand how it applies to your career.
- Each course comes with a certificate of completion as evidence of your training for audit readiness.

Purchase courses available in our store with the 'Purchase' link (if available) or by contacting us at info@clinicalpathwaysresearch.com for enterprise options.

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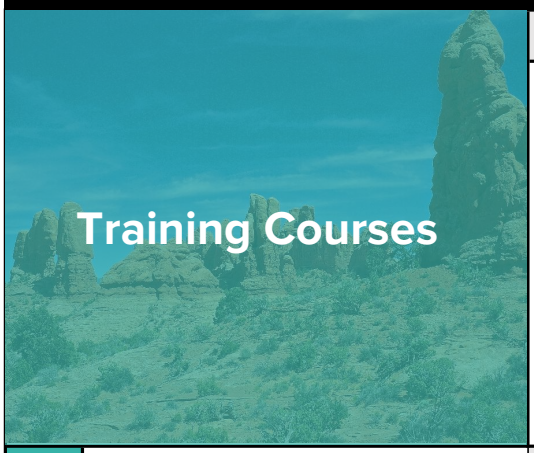
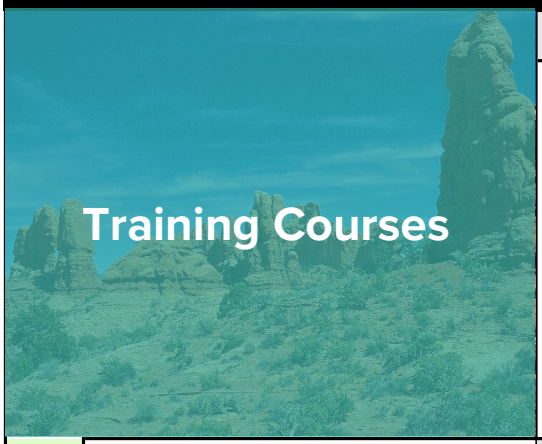


	Training Courses	Core Competencies							
		Scientific Concepts and Research Design	Ethical and Participant Safety Considerations	Investigational Products Deveolpment and Regulation	Clinical Study Operations (GCPs)	Study and Site Management	Data Management and Informatics	Leadership and Professionalism	Communication and Teamwork
GCP Training Services	Good Clinical Practice Training (GCP): ICH E6(R2)	✓	✓	✓	✓	✓	✓		✓
	Good Clinical Practice (GCP) Training: Refresher	✓	✓	✓	✓	✓	✓		✓
	ICH E6(R2) GCP for Investigator Site Personnel	✓	✓	✓	✓	✓	✓		✓
	ISO 14155:2020 Medical Device Standard	✓	✓	✓	✓	✓	✓		
	Medical Device vs. Drug: Comparing and Contrasting	✓	✓	✓	✓	✓	✓		
	Investigator Initiated Clinical Trials	✓	✓	✓	✓	✓	✓	✓	✓
	GDPR and Clinical Trials	✓					✓	✓	✓
	Overview of Medical Device 21 CFR Part 812 and ISO 14155 GCP	✓	✓	✓	✓	✓	✓	✓	✓
	Regulatory Requirements for Clinical Trials in Europe(Directive to Regulation)	✓	✓	✓	✓	✓	✓	✓	✓
	Special Considerations in Pediatric Trials	✓	✓	✓					
	Good Documentation Practices and ALCOA-C					✓	✓	✓	✓
	CRO Oversight	✓			✓	✓	✓	✓	✓
	HIPAA Training for Clinical Trial Professionals				✓	✓	✓		
	Use and Disclosure of PHI in Clinical Trials (HIPAA)				✓	✓	✓		
	ICH E2A Clinical Safety Data Management		✓	✓	✓	✓	✓		✓
	Structure and Clinical Study Reports (ICH E3)			✓	✓	✓	✓		✓
	Overview of 21 CFR 50 Human Subject Protection and 21 CFR 56 IRB/EC	✓	✓	✓	✓	✓		✓	✓
	Overview of 21 CFR 312 IND & 21 CFR Part 314 Post-Market Drug Approval	✓	✓	✓	✓	✓	✓	✓	✓
	Overview of 21 CF 54 Financial Disclosure and Part 11 Electronic Data Signatures			✓	✓	✓		✓	✓
	Overview of ICH E8(R1), General Consideration for Clinical Studies	✓	✓	✓	✓	✓			✓

Clinical Pathways

Training Courses		Core Competencies							
		Scientific Concepts and Research Design	Ethical and Participant Safety Considerations	Investigational Products Development and Regulation	Clinical Study Operations (GCPs)	Study and Site Management	Data Management and Informatics	Leadership and Professionalism	Communication and Teamwork
Monitoring and Auditing	Role of the Monitor in Managing Clinical Research	✓	✓	✓	✓	✓	✓	✓	✓
	Monitoring a Study	✓	✓	✓	✓	✓	✓	✓	✓
	Essential Study Documents: Before, During, and At Study Close			✓	✓	✓	✓	✓	✓
	Monitoring Clinical Study Protocols and Amendments: Promoting Site Compliance	✓	✓	✓	✓	✓	✓	✓	✓
	Monitoring Informed Consent and Privacy Statement	✓	✓	✓	✓	✓	✓	✓	✓
	Monitoring Investigational Product (IP) Accountability		✓	✓	✓	✓	✓	✓	✓
	Monitoring and Safety Reporting		✓	✓	✓	✓		✓	✓
	Source Data Review and Verification		✓	✓	✓	✓	✓	✓	✓
	Managing Site Non-compliance: The Monitor's Role in Preventing Inspection Findings				✓	✓	✓	✓	✓
	Monitoring Report Writing and Quality Documentation				✓	✓	✓		✓
	Preparing for Sponsor FDA BIMO Inspections				✓	✓	✓	✓	✓
	Preparing Research Sites for FDA BIMO Inspections				✓	✓	✓	✓	✓
	Remote Monitoring of Source Data and Maintaining HIPAA, FDA, and GCP		✓		✓	✓	✓		✓
	Remote Monitoring Operations and Maintaining HIPAA, GCP, and COVID-19 Restrictions		✓		✓	✓	✓		✓

Clinical Pathways



		Core Competencies							
		Scientific Concepts and Research Design	Ethical and Participant Safety Considerations	Investigational Products Deveolpment and Regulation	Clinical Study Operations (GCPs)	Study and Site Management	Data Management and Informatics	Leadership and Professionalism	Communication and Teamwork
Performance Management	DIGR-ACT® Featured Product	✓	✓	✓	✓	✓	✓	✓	✓
	Critical Thinking for Clinical Research Professionals	✓	✓	✓	✓	✓	✓	✓	✓
	Corrective and Preventive Actions (CAPA) Planning for Clinical Research Professionals	✓			✓	✓		✓	✓
	Root Cause Analysis (RCA) for Clinical Research Professionals	✓			✓	✓	✓	✓	✓
	Introduction to Risk-Based Quality Management (RBQM) within Clinical Trials	✓	✓	✓	✓	✓	✓	✓	✓

DIGR-ACT®

Description

DIGR-ACT® is a solution for those looking to improve their critical thinking skills in relation to clinical trials. It helps clinical trial team members manage issues and risks that matter, to dig through and map information to root cause, then to come to valid conclusions on how to act effectively. DIGR-ACT® is a process developed by industry experts that addresses this gap of critical thinking skills needed specifically for clinical trials.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Describe how critical thinking is needed for managing risks and issues in clinical trials
2. Identify immediate actions and the need for further in-depth analysis
3. Recognize the 6 categories of factors that when not supported cause poor performance
4. Perform better Root Cause Analysis (the DIGR part of the DIGR-ACT® solution) and be aware of the principles of practice
5. Perform steps to act on the root cause(s), measure effectiveness and transfer knowledge (The ACT part of the DIGR-ACT® solution)

Purchase

Course Content

DIGR-ACT® is an exciting composite of well-tested approaches from other industries synthesized specifically for the clinical trial professional.

Critical Thinking for Clinical Research Professionals: A Companion to DIGR-ACT®

Description

In clinical research, critical thinkers are more likely to identify risks that matter rather than react to problems. It is necessary to apply critical thinking to processes so that clinical trials stay on track, thus minimizing risks to study participants and data quality, shortening timelines, and reducing costs.

Course Length

15 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Recognize the essential components of critical thinking and why it matters in clinical trials.
2. Identify the essential components of critical thinking.

Purchase

Course Content

Recommended to use this course as a prelearning before the DIGR-ACT® Solution to expand critical thinking knowledge.

Good Clinical Practice Training (GCP): ICH E6(R2)

Description

This ICH GCP E6 R2 (GCP) course presents key components of the requirements of GCP for clinical trials found in ICH E6 (R2) related to the role and responsibilities of the investigator, sponsor, and other stakeholders. Content includes an overview of GCP; major regulatory agencies in the United States, the European Union, and Japan; essential documentation; and good documentation practices including ALCOA-C.

Course Length

75 minutes

Available

Webinar | In-person | eLearning

Learning Objectives for the Participant

1. Apply critical thinking techniques for effective implementation of the global Good Clinical Practice Guideline, ICH E6 R2.
2. Discover how the ICH global guideline affects your role.
3. Reflect on challenges and opportunities in implementing the GCP Guideline.
4. Identify practical applications of the guideline in your work processes including identifying methods to assess quality systems, and documentation.

Purchase

Course Content

This ICH E6 (R2) GCP Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Good Clinical Practice Training (GCP): Refresher

Description

This Good Clinical Practice (GCP) Refresher course reviews the major requirements of GCP for clinical trials according to the global guideline ICH E6(R2) related to roles and responsibilities using industry case scenarios to support application and critical thinking.

Course Length

35 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Apply critical thinking when applying the global Good Clinical Practice Guideline, ICH E6(R2) guideline to clinical trial roles and responsibilities.
2. Confirm how the ICH global guideline affects your role.
3. Reflect on challenges and opportunities in implementing Good Clinical Practice, or the GCP Guideline.

Purchase

Course Content

This ICH E6 (R2) GCP Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

ICH GCP E6(R2) Training for Investigator Site Personnel

Description

This Investigator Site Personnel Good Clinical Practice (GCP) course covers the requirements of GCP for clinical trials found in ICH E6 (R2) related to the role of the investigator and site personnel and briefly covers roles of other stakeholders.

Course Length

60 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Discover the Global Good Clinical Practice Guideline ICH E6 (R2) and how it affects your role.
2. Reflect on challenges and opportunities in implementing the GCP Guideline.
3. Identify practical applications of the Guideline in your work processes.

Purchase

Course Content

This ICH E6 (R2) GCP Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

ISO 14155:2020 Medical Device Standard

Description

This course covers the ISO 14155:2020 standard for medical device GCP. Content includes an overview of the Standard, Clinical Investigation Planning, Sponsor Responsibilities, Responsibilities of the Investigator, Clinical Investigation Conduct, and Suspension, Termination, and Close-out of Clinical Investigation.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Describe the ISO 14155:2020 standard requirements for medical device GCP
2. Recognize how the ISO 14155:2020 standard applies to activities related to site monitoring and investigator responsibilities
3. Apply the ISO 14155:2020 standard to study activities

Purchase

Course Content

The ISO 14155 Standard is presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Medical Device vs. Drug: Comparing and Contrasting

Description

This course covers comparing and contrasting medical device and drug clinical trials from an FDA (U.S.-centered) perspective and covering GCP and some global regulatory perspectives. Content includes major differences between medical device and drug clinical trials, including key definitions, regulatory approval and application processes, and safety reporting.

Course Length

60 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Describe key definitions related to drug and device clinical investigations
2. Learn about the regulatory development and approval process
3. Identify key differences in safety reporting, IRB duties, and oversight

Purchase

Course Content

Content includes major differences between medical device and drug clinical trials and is presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Investigator Initiated Clinical Trials

Description

This course covers investigator initiated trials (IIT). The content includes identifying roles and expectations in IITs, steps involved in conducting an IIT, and identification of actions to mitigate risks of common pitfalls.

Course Length

30 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Recognize the importance of identifying roles in investigator initiated trials and ensuring clear expectations
2. Review the steps involved in initiating an investigator initiated trial
3. Identify actions that can help minimize risks associated with investigator initiated trials by identifying and learning to prevent common pitfalls

Purchase

Course Content

The required activities related to roles and expectations in IITs are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

GDPR and Clinical Trials

Description

This course covers the exchange of personal data from the European Union (EU) to the United States (US) while following the requirements of the EU's General Data Protection Regulation. Content includes what is applicable to stakeholders in clinical trials, how to protect data subject personal information collected and analyzed in clinical trials, and impacts to clinical trials and your organization.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Determine the importance of subject data protection related to the General Data Protection Regulation (GDPR)
2. Describe the process to collect and analyze private data and ensure its security under the GDPR
3. Recognize potential impacts of the GDPR and how it affects your organization

Purchase

Course Content

The required activities related to compliance with GDPR in EU clinical trials are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Overview of Medical Device 21 CFR 812 & ISO 14155

Description

This course covers medical devices under FDA's 21 CFR Part 812 and ISO 14155: 2011 global GCP Standard for medical devices. Content includes comparing devices versus drugs, the FDA regulation and the global ISO standard, an overview of ISO 14155, and safety procedures under the ISO standard regarding medical devices.

Course Length

45 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Apply critical thinking techniques for effective implementation of 21 CFR Part 812 and ISO 14155 GCP.
2. Learn how 21 CFR Part 812 and ISO 14155 affect your role in clinical research.
3. Discuss challenges and opportunities in implementing 21 CFR Part 812 and ISO 14155.

Course Content

The required activities related to medical devices and drugs are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Regulatory Requirements for Clinical Trials in Europe (Directive to Regulation)

Description

From the EU Clinical Trials Directive to the Clinical Trials Regulation, the content includes requirements for the conduct of clinical trials in the European Union, the EU Regulation and ICH E6(R2), the EU Portal and Database, highlights of the EU Regulation 536/2014, and running clinical trials in the EU.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Explain an overview of how clinical trials are conducted in Europe and to recognize some major changes.
2. Discuss the transition between Directive 2001/20/EC and Regulation EU No 536/2014.
3. Review the current GCP guidelines.
4. Describe the revisions to the Clinical Trials Directive.

Purchase

Course Content

The required activities related to the EU Regulation are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Special Considerations in Pediatric Trials

Description

This Special Considerations in Pediatric Clinical Trials course covers highlights in pediatric clinical research legislation, physiological and developmental differences between children and adults, unique study procedure issues in pediatric populations, IRB review- informed consent: permission and assenting, and enrollment issues in pediatric studies.

Course Length

90 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Discuss a brief history of pediatric clinical trial legislation.
2. Understand key physiological/developmental differences between children and adults.
3. Discuss considerations in protocol design when developing a pediatric clinical trial.
4. Understand the unique IRB review processes and consenting issues encountered in pediatric trials.
5. Understand enrollment challenges and potential ways to work with these challenges.

Purchase

Course Content

The required activities related to considerations for pediatric clinical trials are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Good Documentation Practices and ALCOA-C

Description

In this course, you will learn about good documentation practices, including the ALCOA-C principles from ICH E6(R2), notes to file, and other general documentation procedures. Good Documentation Practices are necessary to ensure product quality and product safety.

Course Length

60 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Practice applying ALCOA-C to paper and electronic documentation
2. Identify methods to assess quality documentation to support inspection of clinical trials
3. Recognize appropriate ways to address deficiencies in documentation

Purchase

Course Content

Activities related to good documentation practices are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

CRO Oversight

Description

The training provides an overview of the key concepts and best practices for CRO management in a global clinical trial setting. It also includes information about the global regulatory landscape regarding CRO management, primarily focusing on EMA, FDA, and ICH E6(R2).

Course Length

60 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Describe the Sponsor regulatory requirements for oversight of CROs.
2. Recognize key components for effective Sponsor CRO oversight.
3. Identify adequate CRO oversight procedures, oversight plans, and documentation management.

Purchase

Course Content

A foundation training applicable for all sponsor clinical team members and contractors who work with CROs and vendors. Real life case scenarios included.

HIPAA Training for Clinical Trial Professionals

Description

The course covers a foundation of HIPAA relevant for clinical research. Sections include key terminology, Covered Entities, Protected Health Information (PHI), waiver of authorization, Security vs. Privacy Rules, Enforcement Rule, and responsibilities of the study team. Scenarios are presented to further understanding of the key concepts.

Course Length

60 minutes

Available

Webinar | In-person | eLearning

Learning Objectives for the Participant

1. Define key terminology and concepts specific to the HIPAA Privacy Rule in clinical research.
2. Describe when sites are covered entities and the sponsor roles and responsibilities related to the HIPAA Privacy Rule.
3. Discuss the requirements of the Privacy Rule relating to clinical research source documentation use and disclosure.

Purchase

Course Content

This course is designed as a foundation for training clinical research team member in onboarding and can also be used for annual or regular training to meet organizational requirements.

Use and Disclosure of PHI in Clinical Trials (HIPAA)

Description

HIPAA's use and disclosure of PHI during the conduct of a clinical trial is not simple and depends on the situation. But there is a way to use a core set of principles and questions that provide an ability to manage and facilitate the needs of all stakeholders. The regulatory authorities of HIPAA and FDA agree that the two sets of regulations work well together. HIPAA does not restrict the GCP requirements of a site.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Recognize how the roles and responsibilities of sponsors, CROs and sites impacts the use and disclosure of PHI.
2. Apply the essential concepts and requirements of Use and Disclosure of PHI in clinical trials.
3. Answer specific questions provided in advance related to HIPAA and PHI.

Course Content

Includes applicable scenarios and answers to specific questions submitted in advance of live training – in person or live online - or during Q&A of webinars.

ICH E2A Clinical Safety Data Management

Description

This course covers the international guideline ICH E2A, which relates to Clinical Safety Data Management. Content includes a review of ICH and an introduction to ICH E2A; Definitions and Terminology; standards for expedited reporting; reporting time frame, the procedures for reporting, managing blinded therapy cases, miscellaneous issues, and informing Ethics Committees and Investigators; and Quality Management Systems.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Apply critical thinking techniques for effective implementation of the ICH E2A guidelines
2. Reflect on how the ICH E2A global guidance affects your role in clinical research
3. Discuss challenges and opportunities in implementing the ICH E2A guidance

Purchase

Course Content

The required activities related clinical safety data management are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Structure and Content of Clinical Study Reports (ICH E3)

Description

This course covers the ICH E3 Guidance as well as the E3 Questions and Answers complement. Content includes an overview of ICH E3, an overview of the clinical study report or CSR, the body of the clinical study report, conclusions and other topics related to the CSR, and the 2012 ICH E3: Structure and Content of Clinical Study Reports Questions and Answers document.

Course Length

45 minutes

Available

Webinar | In-person | eLearning

Learning Objectives for the Participant

1. Apply critical thinking techniques for effective implementation of the ICH E3 Guideline
2. How the ICH E3 global Guideline affects your role in clinical research
3. Challenges and opportunities in implementing the ICH E3 Guideline

Purchase

Course Content

The required activities related to the Structure and Content of Clinical Study Reports are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

21 CFR 50 Human Subject Protection and 21 CFR 56 IRB/IEC

Description

This course covers an Overview of 21 CFR Part 50 Human Subject Protection and 21 CFR Part 56 IRB/IEC. Content includes key components of human subject protection, definitions and scope for Part 50, informed consent requirements, elements, and language; the informed consent process; exceptions to informed consent; vulnerable populations; and 21 CFR 56 - the regulation section for Institutional Review Boards.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Apply critical thinking techniques for effective implementation of 21 CFR Part 50 and 56.
2. Learn how 21 CFR Part 50 and 56 affect your role in clinical research.
3. Discuss challenges and opportunities in implementing these regulations.

Purchase

Course Content

The required activities related to human subject protection are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Overview of IND and NDA

Description

This course covers an overview of 21 CFR 312 Investigational New Drug Application (IND) and 21 CFR 314 Application for FDA Approval to Market a New Drug (NDA). Content includes 21 CFR Part 312 relating to IND Definitions, Part 312 – Subpart D about Responsibilities of Sponsors and Investigators, parts of 21 CFR Part 314 –NDA as it relates to clinical operations, and other essentials regarding cross functional readiness.

Course Length

60 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Apply critical thinking techniques for effective implementation of 21 CFR Part 312 and 314.
2. Learn how 21 CFR Part 312 and 314 affect your role in clinical research.
3. Discuss challenges and opportunities in implementing 21 CFR Part 312 and 314.

Purchase

Course Content

The required activities related to IND and NDA are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Overview of Financial Disclosure and Electronic Data Signatures

Description

This course covers Overview of 21 CFR Part 54 Financial Disclosure and Part 11 Electronic Data Signatures. This course's main topics are financial disclosure, electronic records, and electronic signatures under FDA's 21 CFR Part 54 and Part 11.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Apply critical thinking techniques for effective implementation of 21 CFR Part 54 and Part 11.
2. Reflect on how 21 CFR Part 54 and Part 11 affect your role in clinical research.
3. Discuss challenges and opportunities in implementing 21 CFR Part 54 and Part 11.

Purchase

Course Content

The required activities related to financial disclosure and electronic data signatures are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Overview of ICH E8(R1): General Considerations for Clinical Studies

Description

The key purpose of ICH E8(R1) is to design quality into clinical trials, which is supported by the establishment of an appropriate framework for the identification and review of Critical to Quality factors at the time of design and planning of the study, and throughout its conduct, analysis, and reporting.

Course Length

45 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Recognize how ICH E8(R1), the Guideline for General Considerations for Clinical Studies, has changed organizational processes.
2. Apply the Guideline to key concepts in clinical trials.
3. Discuss implementation challenges and opportunities regarding the updates in the Guideline.

Purchase

Course Content

This course covers the importance of ICH and why a revision to E8 was needed, overarching themes of changes, the introduction of Quality by Design and Critical to Quality applied to clinical trials, an overview of the Guideline, and scenarios.

The Role of the Monitor in Managing Clinical Research Sites

Description

This course covers the Role of the Monitor in Managing Clinical Research Sites. Content includes global guidelines and principles that comprise monitoring Good Clinical Practice, roles and responsibilities of the monitor, the importance of Quality Site Management for positive study outcomes, and key site performance management skills for exceptional site management.

Course Length

120 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Identify the global guidelines and principles that comprise monitoring Good Clinical Practices.
2. Describe the roles and responsibilities of the monitor.
3. Discuss the importance of site management and review how this impacts the overall study outcome.
4. Describe key site performance management skills for exceptional site management.

Course Content

The required activities related to the roles of the monitor in managing research sites are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Monitoring a Study

Description

This course covers Monitoring a Study, an overview and purpose of various types of monitoring visits. Content includes the principles of monitoring, site qualification visits, site initiation visits, interim monitoring visits, and close out visits.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Relate key principles of quality monitoring to the role of the monitor.
2. Define the objectives of the site qualification, site initiation, interim monitoring, and study close-out visits.
3. Describe unique requirements of preparing for and monitoring an EDC study.
4. Discuss various monitoring activities during a visit, remote monitoring between visits, and follow-up to outstanding issues and essential documentation.

Course Content

The required activities related to the monitor's roles and responsibilities are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Essential Study Documents

Description

This course covers Essential Study Documents: Before, During, and at Study Close and reviews the essential documents of Good Clinical Practice (GCP) for conducting a study.

Course Length

30 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Detail essential documentation requirements at clinical research sites
2. Identify important components of certain site essential documents

Course Content

The content includes interactive exercises to promote recognition of the study, essential documents that must be filed at sites, and key document content essential to the monitor.

Monitoring Clinical Study Protocol(s) & Amendments

Description

This course covers Monitoring Clinical Study Protocol(s) & Amendments. Content includes definitions related to protocols and defining roles and responsibilities of various stakeholders and strategies for working with difficult sites and how to best prevent investigator compliance issues.

Course Length

60 minutes

Available

Webinar

In-person

Learning Objectives for the Participant

1. Discuss the monitor's role in setting clear expectations for site study staff regarding site protocol compliance.
2. Identify potential areas of the protocol and other GCP requirements which may be a challenge to sites.
3. Identify strategies for managing a difficult site including use of facilitation core practices and tools.
4. Develop strategies to promote protocol compliance.

Course Content

The required activities for the roles and responsibilities for monitors related to protocols and amendments are presented with interactive content and case studies to reinforce key concepts

Monitoring Informed Consent and Privacy Statement

Description

This course covers Monitoring Informed Consent and Privacy Statement. The focus is on the monitor's role in the monitoring of the informed consent process, including the collection, documentation, and management of informed consents at the site level. Attention is paid to the process and documentation of informed consent, including circumstances involving vulnerable populations.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Review informed consent and release of protected health information (PHI) to ensure regulatory and IRB/IEC requirements are met.
2. Verify the informed consent process and authorization for release of PHI documentation meets applicable regulatory requirements, including ensuring proper informed consent has taken place when there are special circumstances.
3. Discuss problems and issues regarding informed consent and authorizations for release of PHI.

Course Content

The required activities for the roles and responsibilities for monitors related to informed consent and privacy are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Monitoring Investigational Product Accountability

Description

This course covers Monitoring Investigational Product (IP) Accountability. Sections include investigator obligations for IP, monitor obligations for IP, and strategies for resolving IP deficiencies.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Describe the investigational product accountability requirements and regulatory considerations.
2. Define the responsibilities of the research site in investigational product accountability.
3. Develop strategies for identifying and solving the investigational product accountability errors or deficiencies.

Course Content

The required activities for the roles and responsibilities for monitors related to the IP are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Monitoring and Safety Reporting

Description

This course covers Monitoring and Safety Reporting. Content includes defining adverse events, safety recording and reporting requirements for the clinical investigator, serious adverse events and effects, device deficiency, and adverse event monitoring.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Explain key safety reporting definitions, concepts, timelines, and key criteria.
2. Describe the consequences of incorrect or inadequate adverse event reporting.
3. Evaluate key factors in determining whether an adverse event should or should not be reported.
4. Evaluate decisions about subject safety beyond individual adverse events and adequate medical care.
5. Review the steps in monitoring adverse events.

Course Content

The required activities for the roles and responsibilities for monitors related to safety reporting are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Source Data Review and Verification

Description

This course covers Source Data Review and Verification. Content includes source data verification, electronic source data, case report forms, source documentation, required characteristics of data, and common root causes of source documentation deficiencies.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Describe the process of source document review (SDR) and source data verification (SDV).
2. Identify a source document and what is pertinent for a study.
3. Define essential characteristics of source data known as "ALCOA-C" as applied to paper and electronic sources.

Course Content

The required activities for monitors related to source data review and verification are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Managing Site Noncompliance

Description

This course covers Managing Site Noncompliance, including the monitor's role in preventing inspection findings. Content includes GCP Quality Systems; site management supporting quality and investigator responsibilities; sponsors, monitoring and quality management; site compliance management; site qualification and initiation; facilitator core practices; 5 whys and the CAPAs; and management of noncompliance.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Describe site inspection and regulatory authority expectations related to quality systems.
2. Describe the importance of the SQV and SIV to anticipate and avoid future negative findings in audits and inspections.
3. Define a noncompliant site and approaches for effectively managing noncompliance at a site.
4. Review the process of RCA relating to adequate intervention assignment for noncompliance and responses to deficiencies.
5. Apply the components of an investigator's compliance plan when managing a site.

Course Content

The required activities for monitors related to managing site noncompliance are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Monitoring Report Writing and Quality Documentation

Description

This course covers Report Writing and Quality Documentation of Monitoring Activities. Content reviews the effect of poor report writing and emphasizes that the monitoring visit report is both a tool for documentation and a critical site management tool for the monitor. Sections include monitoring documentation, scientific writing, and essential rules for supporting quality monitoring documentation.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Write effective, comprehensive monitoring documentation.
2. Create continuity in monitoring documentation.
3. Utilize monitoring documentation to demonstrate timely identification of issues, preventive actions, resolution of issues, and the escalation of issues when necessary.
4. Effectively communicate issues in documentation to the site using quality writing skills.

Course Content

The required activities for monitors related to report writing and quality documentation are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Preparing for Sponsor FDA BIMO Inspections

Description

Included in the training is an example of a process flow of inspection preparedness and conduct incorporation templates to support knowledge transfers storyboards. A risk-mindset is supported, focusing on critical to success factors and common pitfalls are presented related to preparation in relevant case scenarios so the learner can apply actions to their current work and role. The session also includes examples of recent and common inspection focus and findings related to sponsors, including CRO and vendor oversight.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Review the value and purpose of inspection readiness using pertinent case scenarios for BIMO inspections.
2. Review and apply the inspection readiness process and tools.
3. Identify why inspection preparedness supports positive performance during inspection and improves future trial processes.

Course Content

The goal of the training is to provide a foundation of best practices, tools and templates for sponsor inspection readiness. The session also includes examples of recent and common inspection focus and findings related to sponsors, including CRO and vendor oversight.

Preparing Research Sites for FDA BIMO Inspections

Description

This course provides information to help a clinical research site prepare for successful FDA inspections. It includes information about understanding the triggers of inspection, common findings, preparing for inspection with a risk-based approach, and the mechanics of an inspection.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Write effective, comprehensive monitoring documentation.
2. Create continuity in monitoring documentation.
3. Utilize monitoring documentation to demonstrate timely identification of issues, preventive actions, resolution of issues, and the escalation of issues when necessary.
4. Effectively communicate issues in documentation to the site using quality writing skills.

Course Content

The goal of the training is to provide a foundation of best practices, tools and templates for site inspection readiness.

Remote Monitoring of Source Data: Maintaining HIPAA, FDA, and GCP

Description

The course presents the feasibility of remote monitoring and includes 1) the pros and cons for investigational sites and sponsors, 2) the elements in a quality system that need to be in place at trial sites and sponsors to initiate this successfully, and 3) how to ensure audit readiness for all. The focus is on maintaining HIPAA, FDA, and GCP requirements.

Course Length

90 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Identify how to evaluate the feasibility of remote monitoring of site source data.
2. Promote better remote monitoring practices and documentation.
3. Clarify what data are accessible remotely from HIPAA covered entities.
4. Develop agreements between stakeholders to support remote source review.

Course Content

The required activities for monitors and sites for remote monitoring of source data in compliance with predicate rules, including HIPAA, FDA, and mandates outside the US, are presented with case scenarios.

Remote Monitoring Operations and Maintaining HIPAA, GCP, and COVID-19 Restrictions

Description

This course discusses the real feasibility of remote monitoring of the quality of original source data in compliance with clinical trial predicate rules, including HIPAA and FDA. The review of source data in a risk-based regulatory environment is centered on the quality of the documentation – not the comparison of the source to the electronic case report form.

Course Length

90 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Clarify what data are accessible remotely from HIPAA covered entities.
2. Develop agreements between stakeholders to support remote source review.
3. Identify how to evaluate the feasibility of remote monitoring of the quality of site source data without threat of security breach.
4. Promote better remote monitoring practices and documentation.

Purchase

Course Content

The required activities for monitors and sites for remote monitoring of source data in compliance with predicate rules, including HIPAA, FDA, and mandates outside the US, are presented with case scenarios.

Corrective and Preventive Action (CAPA) Planning for Clinical Research Professionals

Description

Sponsors, CROs, and research sites are required by regulatory authorities and GCP to have an effective process to manage significant noncompliance through corrective and preventive action (CAPA) plans. These stakeholders should have procedures to support their CAPA system and documentation. Team members must understand a CAPA process and how it links into quality risk management. This training is designed to provide this understanding and is an essential companion to training on a company specific CAPA system. It is also a foundation for the CAPA process and supports understanding through GCP industry specific case scenarios and other application exercises in each section.

Course Length

60 minutes

Available


Webinar


In-person


eLearning

Learning Objectives for the Participant

1. Recognize why corrective and preventive actions are essential in maintaining quality in a clinical trial.
2. Apply the steps of the CAPA process in clinical trial scenarios.
3. Discuss challenges in performing CAPA activities and review potential solutions.

Purchase

Course Content

The required activities related to implementing Corrective and Preventive Actions and applying it to your role are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Root Cause Analysis (RCA) for Clinical Research Professionals

Description

This course covers Root Cause Analysis (RCA). Content includes an overview the background, rationale, and benefits of Root Cause Analysis; RCA Concepts and Gilbert's Behavior Engineering Model; and RCA techniques.

Course Length

30 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Identify why root cause analysis is an essential activity for clinical trial risk assessment and issues management.
2. Recognize why root cause analysis is not an inherent skill set and is more than using tools like '5 Whys'.
3. Explore the science of root cause analysis and how to choose the best combination of tools.
4. Apply and practice various root cause analysis techniques to clinical trial scenarios.

Course Content

The required activities related to implementing Root Cause Analysis and applying it to your role are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.

Introduction to Risk-Based Quality Management (RBQM) within Clinical Trials

Description

This training on RBQM covers what risk is and how it relates to clinical trials, followed by an in-depth explanation with relevant, real life industry examples covering the seven steps in RBQM per ICH E6(R2) section 5.0.

Course Length

60 minutes

Available


Webinar


In-person

Learning Objectives for the Participant

1. Recognize why a risk mindset is essential for working in clinical research.
2. Review the concepts of risk-based quality management within a clinical trial setting.
3. Practice applying risk-based quality management core concepts using an industry example.

Course Content

The required activities related to implementing Risk Based Quality Management and applying it to your processes are presented with interactive content and case studies to reinforce key concepts and emphasize critical activities.