imarc UNIVERSITY
CLINICAL RESEARCH EDUCATION

TRAINING GUIDE & COURSE CATALOG

IN-PERSON AND WEB-BASED TRAINING
COURSES, HYBRID TRAINING, AND
CUSTOMIZED TRAINING

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imarc UNIVERSITY
CLINICAL RESEARCH EDUCATION

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WE'LL EARN YOUR APPROVAL.

TRAINING

Never Stop Learning

Your Site. Our Eyes. A well-trained staff is key to the success and integrity of your clinical study. That's why IMARC University offers comprehensive training that can be customized to meet the needs of your team or individual staff members. Our training includes cost-effective in-person training, teleconferencing, and convenient online courses available 24/7.

Train … Prepare … Accelerate

IMARC University's training programs have been developed to ensure clinical researchers understand the regulations as well as best practices and how to apply them using critical-thinking skills.

Our training staff brings a broad range of perspectives, with backgrounds ranging from nursing, engineering, medical technology, laboratory research, and more, to their roles as research professionals. Many have worked in the research industry for years as research coordinators, monitors, auditors, and project managers, and bring a variety of experiences to training programs.

TRAINING
is in Our DNA.

TRAINING SESSIONS

Expand your regulatory knowledge of study operations with these courses:

- Clinical Site Management
- Human Subject Protection
- Monitoring Device Studies
- Device vs. Drug Studies
- Monitoring Team Roles for Global Studies
- Warning Letters… and the Implications for You

TRAINING TECHNIQUES

IMARC training solutions are designed to provide you with a better understanding of your specific research setting and how it functions. These informative, interactive and inspirational solutions include:

- Didactic Presentations
- Group Activities
- Case Study Discussions
- Warning Letter Reviews & Discussions
- Games & Quizzes
- Virtual Study Experiences

Online Training, Courses on Your Schedule

Whether your team members need to prepare for new roles in clinical research or just need a refresher course in the regulations, IMARC University offers affordable, convenient online courses for individuals and teams. Learners can access their courses online anytime and complete them at their own pace.

IMARC University's online courses prepare individuals for a variety of roles within the clinical research field. With a well-trained staff, your team will be using a consistent process that meets the most stringent standards of patient safety and compliance.

In-Person Training Solutions

Need to onboard an entire team or provide them with specialized training in specific areas? IMARC University delivers practical, experience-based training from clinical research professionals working in the trenches.

Training can be customized to meet the unique needs (and schedules!) of teams of all sizes. We will bring experienced, dynamic trainers to your team or desired location, or host groups at our training facility in Strongsville, Ohio.

Remote Training, Live via Web Conferencing

When interactive training is a must, remote web conference training offers an alternative to in-person methods to allow for questions in real time, from anywhere in the world.

Bring your global team together for remote training, covering a wide variety of clinical research topics.

Hybrid Training

Hybrid Training programs incorporate multiple types of learning, utilized to boost the benefits of instructor-led training and our IMARC University online courses or teleconference sessions. Learners can review the basics ahead of more in-depth training in person.

Perhaps you're interested in a 2-day training package, however, your team's time is limited. We can customize a web-based and one day in-person package to meet your needs!

TRAINING SOLUTIONS FOR ANY ROLE

Our training is ideal for clinical research professionals in a variety of roles at the Sponsor, CRO and Site levels, including:

- Monitors
- Research Coordinators
- Investigators
- Project Managers
- Auditors
- IRB Staff
- Other Sponsor and Vendor Staff Members

TRAINING FOR TRIALS WORLDWIDE

- Human Subject Protection
- GCP Compliance
- Monitoring 101 & 102
- GCP, JGCP and ICH Guidelines
- FDA Regulations: 21 CFR 11, 50, 54, 56, 312 and 812

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WE'LL EARN YOUR APPROVAL.

BLUEPRINT FOR SUCCESS:

CREATE THE BEST CLINICAL RESEARCH TRAINING FOR YOUR TEAM

It is difficult to know where to start when implementing a training program for your department or team. What topics should be covered? Which members of the team need what kind of instruction? What resources offer high-quality education in a cost-effective way? How will effectiveness be measured? And how will the training fit into the busy schedules of your colleagues?

Our primary goal at IMARC is to help organizations and individuals to assess specific training needs and develop a training blueprint. By using a blueprint approach to map out and capture the important details, a training package well-suited for your specific situation can be identified.

HOW TO USE THE CATALOG

Assess Your Needs

What type of training does your clinical research team need to ensure compliance with the highest regulatory and ethical standards? What is the gap between current and desired level of performance?

Each of our training agendas include: Scope, Objectives, Module Topics, Knowledge Level, and Audience. Agendas are organized by audience and topics for a variety of roles at the Sponsor/CRO and Site levels. Levels range from “The Essentials” for beginners to “Advanced Concepts” for experienced clinical research professionals, as well as “Comprehensive” multi-day trainings. Customized content can be developed to your unique needs upon request.

Develop Your Training Blueprint

In-Person Training Solutions

Remote Training
Live via Web Conferencing

Online Training
Courses on Your Schedule

Hybrid Training

How will training fit into your team’s schedule? In-person at your site or at IMARC? Live web-based? Online training, courses on your schedule? Or, maybe a combination learning program would be most effective.

Each training agenda indicates the ‘Type’, however, they allow for customization to meet your team schedules, geographic locations, and other factors that can impact your training needs. A tailored training program can be designed to meet your needs.

Taking the Next Step

A well-trained staff is key to the success and integrity of a clinical study. That’s why IMARC offers comprehensive training that can be customized to meet the needs of your team or individual staff members. Advance your team’s skills and teach them to think critically so you can be confident all compliance standards are being met.

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GENERAL TOPICS

I. BEING INSPECTION READY: UNDERSTANDING THE FDA BIMO INSPECTION PROCESS FOR SITES AND SPONSORS

COURSE DESCRIPTION:

The goal of this training is to provide insight on the importance of Good Clinical Practice (GCP) to help ensure sites and sponsors are prepared for the FDA. Learners will understand what the FDA is looking for during inspections, what to expect, and provide case studies and exercises to prepare for the FDA's arrival. Attendees will also gain an appreciation for how to be inspection ready throughout a study.

LEARNING OBJECTIVES:

- Anticipate FDA GCP expectations for drug and medical device studies by reviewing the FDA BIMO Guidances
- Recognize sponsor/CRO/investigator responsibilities applicable to compliant studies
- Describe best practices for creating and maintaining high quality documentation in research at sites and in sponsor files
- Understand the mechanics of FDA inspections and describe at least three (3) recommendations to help sites and sponsors be inspection ready
- Recognize how to think like an FDA inspector

COURSE OUTLINE

AGENDA: 9:00am – 3:00pm

- Mechanics of an FDA inspection
- Common FDA Warning Letter Findings
- Review of the FDA BIMO Inspection Guidances for Sponsors/CROs and Investigative Sites
- Preparing For and Hosting Successful Inspections
- Responding to an FDA Form 483

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 5.0 hours (0.5 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Experienced

AUDIENCE

- Sponsors/CROs working with investigative sites for overall study inspection readiness
- Project Managers and Clinical Research Associates
- Auditors/Monitors

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

GENERAL TOPICS

II. INFORMED CONSENT: DRILLING IT DOWN

COURSE DESCRIPTION:

This course provides a detailed overview of the regulations and best practices surrounding informed consent. We go beyond the basics of ICH GCP and the regulatory requirements to provide practical tools and methodologies to enhance the informed consent process.

LEARNING OBJECTIVES:

- Discuss the guidance and regulations surrounding informed consent and human subject protection
- Discuss how to enhance the informed consent process
- Navigate through the requirements governing clinical research using critical thinking skills
- Describe best practices for creating and maintaining high quality documentation

COURSE OUTLINE

AGENDA: 4 hours, flexible (for example, 8:30 – 12:30pm or 12:30 – 4:30pm Eastern) or in 2 web sessions

- Good Clinical Practice and U.S. FDA Regulations Refresher
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Situations
- Human Subject Protection
  - Drilling Down 21 CFR Part 50: Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI): HIPAA and HITECH
- Conducting and Documenting Informed Consent: Best Practices

ADDITIONAL WEB-BASED COURSE ADD-ONS

- History of Clinical Research
- Maintaining the Sponsor TMF
- Critical Thinkings in Critical Research
- FDA Inspectional Findings

TYPE

- In Person Training – At IMARC or Your Location
- Remote, live via web conferencing (2, 2-hour sessions)

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 4.0 hours (0.4 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate

AUDIENCE

- Principal Investigators and Sub-Investigators
- Research Nurses, Study Coordinators, and Clinical Research Staff conducting and documenting patient consent

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

GENERAL TOPICS

III. RISK-BASED MONITORING: THE ESSENTIALS

COURSE DESCRIPTION:

Recent regulatory guidance and industry initiatives are promoting a modern approach to clinical trial monitoring and how to apply risk-based thinking. The course is designed for clinical research professionals across the continuum of research organizations and experience levels. Participants will learn and understand risk-based monitoring and be able to apply the strategies to day to day operational activities.

LEARNING OBJECTIVES:

- Compare and contrast traditional monitoring with risk-based monitoring
- Identify clinical study risks and how risks might be mitigated
- Develop a monitoring plan which focuses on mitigating risks at both the program and study levels
- Describe approaches and techniques for central/remote monitoring
- Apply risk management in real-world case scenarios

COURSE OUTLINE

AGENDA: 4 hours in person or in 2 web sessions

- Risk-Based Monitoring Overview: FDA Guidance and ICH GCP E6
- Conducting Risk Assessment: Identifying, Evaluating, and Mitigating Risks
- Developing Monitoring Plans: Planning and Implementation
- Risk-Based Monitoring Throughout a Study: Best Practices & Methods
- Building Quality into Clinical Research Studies

ADDITIONAL WEB-BASED COURSE ADD-ONS

- GCP & U.S. FDA Regulations Refresher
- Critical Thinking in Clinical Research
- FAIR ShakeTM
- Site Management
- Monitoring with an Auditing Perspective
- FDA Inspectional Findings

TYPE

- In Person Training – At IMARC or Your Location
- Webinar (2, 2-hour sessions)

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 4.0 hours (0.4 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate

AUDIENCE

- Sponsors/CROs Clinical Operations Staff, Project Managers
- Clinical Research Associates and Managers
- Clinical Data Management Staff
- Sponsor-Investigators

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

GENERAL TOPICS

IV. CRITICAL THINKING FOR CLINICAL RESEARCH PROFESSIONALS: MASTER CLASS

COURSE DESCRIPTION:

This dynamic workshop-style course provides clinical research professionals with a foundation for understanding critical thinking skills, tools to improve their thinking practices, and practical applications for the clinical research industry. Advanced concepts will be presented and will be tailored to the audience to explore how sponsor, CRO, and/or site staff can effectively assess problems, gather information, and use disciplined thinking to improve the quality of their research studies.

LEARNING OBJECTIVES:

- Define critical thinking, list six core skills, and identify active processes for applying them
- Understand the importance of using critical thinking within the clinical research framework
- Identify key US regulations required for running clinical trials
- Recall the elements of the FAIR Shake™ Method and discuss the importance of basing clinical research decisions in a regulatory foundation
- Exercise critical thinking skills in real world case scenarios
- Recall strategies for building quality into your clinical trial, using risk assessment and mitigation techniques during the planning phase, and the importance of ongoing analysis during a study
- Demonstrate an ability to evaluate risks and implement mitigation techniques in sample scenarios
- Recall the process of FDA inspections and strategies for successful preparation throughout a study and at the time of inspection

ADDITIONAL WEB-BASED COURSE ADD-ONS

- History of Clinical Research
- Effective Study Management
- Adverse Event Classification and Reporting
- FDA Inspectional Findings

COURSE OUTLINE

AGENDA: 8:00am – 5:00pm

- Critical Thinking for Clinical Researchers Overview and the FAIR Shake™ Method
- Setting Your Study Up for Success Before Day 1
  - Planning Phase: Quality Approaches, Risk Assessment and Mitigation Planning
  - Group Exercise: What's on Your Plate? Assess risks and mitigation strategies for YOUR studies
- A Well-Laid Plan – Is it Enough for Continued Success?
  - Implementation Phase of a Study
  - Case Study: Worst Case Scenario – When Research Goes Off the Rails, and How to Get Back on Track
  - Group Exercise: Dealing with Curveballs for YOUR studies
- The End Game – Are We Ready?
  - Study Close-out Phase
  - Regulatory Inspection Preparation
- Wrap Up – Q&A – Review Action Plans

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 8.0 hours (0.8 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Experienced

AUDIENCE

- Project Managers, CRAs, Auditors, Team Managers, Data Managers, Research Coordinators, Research Managers, Investigators

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

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MEDICAL DEVICE CLINICAL RESEARCH PACKAGES

I. COMPARING DRUG AND MEDICAL DEVICE CLINICAL RESEARCH REQUIREMENTS: FOR SPONSORS/CROS

COURSE DESCRIPTION:

The goal of the training is to provide an introduction to medical device research requirements. Comparisons will be made between drug and device development, research requirements in 21 CFR Parts 312 and 812, as well as product accountability and AE reporting differences. The course is structured for individuals moderately experienced in drug development and/or research transitioning into device research.

LEARNING OBJECTIVES:

- Describe and discuss differences in FDA regulations for investigational new drug and investigational devices
- Explains roles and responsibilities of Sponsors and Investigators in Investigational Device Exemption studies
- Identify similarities and differences between Parts 312 and 812
- Understand the developmental pathways of new drugs and new devices
- Discuss requirements for product accountability and Adverse Event reporting for device clinical studies
- Identify the differences in the daily workings of drug and device studies

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- Medical Device Regulatory Requirements
  - Comparing Drug and Device Development Pathways
  - Understanding Device Research Requirements: 21 CFR Part 812
  - INDs vs IDEs: Comparing 21 CFR Parts 312 vs 812
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Day to Day Differences in Medical Device Studies vs. Investigational Drug Studies
  - Assembling and Training Your Team
  - Selection of Sites and Investigators
  - Training of Site Teams
  - Adverse Event Reporting and Product Complaints: 'Is It Reportable?'
  - Product Accountability: Where does the Pharmacy fit?
  - High Quality Documentation and TMF Considerations
  - Monitoring and Risk-Based Strategies for Compliant Device Studies
- International Guidance for Medical Devices
  - ISO 14155: Overview of the Standard
  - 21 CFR 812 vs. ISO 14155: Key Differences

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Intermediate

AUDIENCE

- Clinical Quality and Compliance Professionals
- Clinical Research Associates and Project Managers
- Sponsor/CRO Clinical Operations staff
- Sponsor-Investigators

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

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MEDICAL DEVICE CLINICAL RESEARCH PACKAGES

II. GOOD CLINICAL PRACTICE: AN INTRODUCTION TO MEDICAL DEVICE RESEARCH

COURSE DESCRIPTION:

This course provides an overview of medical device clinical trial activities and applicable Good Clinical Practices including, FDA 21 CFR 812: IDEs, ISO 14155, ICH GCP E6 Guideline and E6(R2) Addendum. The information presented is ideal for those new to clinical research or those new to medical device industry requiring understanding relating to the regulatory and practical aspects of medical device clinical research.

LEARNING OBJECTIVES:

- Recognize regulatory pathways for medical devices
- Discuss how to comply with the requisites of Good Clinical Practice (GCP)
- Explore the practical day to day activities of conducting a medical device trial under GCP

COURSE OUTLINE

AGENDA: 8:00 – 5:00pm

- Introduction to Good Clinical Practice: ICH GCP Guidelines
- Understanding Medical Device Regulatory Requirements
  - 21CFR Parts 812, 50, 56, 54 and 11
  - INDs vs IDEs: Comparing 21 CFR Parts 312 vs. 812
- International Guidance for Medical Devices
  - ISO 14155: Overview of the Standard
  - 21 CFR 812 vs. ISO 14155: Key Differences
- Human Subject Protection
  - Drilling Down 21 CFR Part 50: Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI): HIPAA and HITECH
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Key Roles and Responsibilities in Clinical Research Overview
  - Project Manager, Monitor, Primary Investigator, Clinical Research Coordinator, Data Manager, and Statistician
- Day-to-Day Best Practices
  - Adverse Event Classification and Reporting
  - Investigational Device Accountability
  - High Quality Documentation and Maintaining the Sponsor TMF

ADDITIONAL WEB-BASED COURSE ADD-ONS

- History of Clinical Research
- Critical Thinking in Clinical Research
- Monitoring Overview
- FDA Inspectional Findings

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 8.0 hours (0.8 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate

AUDIENCE

- Clinical Research Associates, Project Managers, or clinical trial staff wanting a greater understanding of regulatory and daily activities around medical device clinical trials
- Clinical research staff new to the device industry and clinical trials

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

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MEDICAL DEVICE CLINICAL RESEARCH PACKAGES

III. MEDICAL DEVICE CLINICAL RESEARCH: COMPREHENSIVE TRAINING

COURSE DESCRIPTION:

The goal of the training is to provide learners new to the device industry an introduction to regulations and responsibilities of investigational device studies by the FDA. Learners will review the key requirements of 21 CFR Part 812, identify similarities and differences with 21 CFR Part 312, and compare developmental pathways of new drugs and new devices. The training will additionally walk through other important differences in day to day of device and drug studies, such as site assessment, investigator training, monitoring, documentation and the trial master file.

LEARNING OBJECTIVES:

- Identify applicable ICH GCP E6 R2 and ISO 14155 guidelines and FDA regulations governing medical device research
- Understand the development pathways of new drugs vs new devices
- Navigate through the requirements governing clinical research using critical thinking skills
- Describe best practices for creating and maintaining high quality documentation in research at sites
- Recall requirements and methods for maintaining a compliant trial master file

COURSE OUTLINE

DAY ONE: 8:00 – 5:00pm

- Introduction to Good Clinical Practice: ICH GCP Guidelines
- Understanding Medical Device Regulatory Requirements
  - 21 CFR Parts 812, 50, 56, 54 and 11
  - INDs vs IDEs: Comparing 21 CFR Parts 312 vs. 812
- International Guidance for Medical Devices
  - ISO 14155: Overview of the Standard
  - 21 CFR 812 vs. ISO 14155: Key Differences
- Human Subject Protection
  - Drilling Down 21 CFR Part 50: Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI):HIPAA and HITECH
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Key Roles and Responsibilities in Clinical Research Overview
  - Project Manager, Monitor, Primary Investigator, Clinical Research Coordinator, Data Manager, and Statistician
- Day to Day Best Practices
  - Adverse Event Classification and Reporting
  - Investigational Device Accountability
  - High Quality Documentation and Maintaining the Sponsor TMF

DAY TWO: 8:00 – 1:30pm

- Developing Risk-Based Strategies for Device Studies
- Securing Compliance in Device Studies: Effective Monitoring and Site Management
- Safety Monitoring and Oversight: DSMBs, CECs and Medical Monitors
- Building Quality into Device Studies
- FDA's BIMO Program: Inspection of Sponsors, CROs, and Monitors – "Preparing for Inspection Success from Day 1"

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TYPE

- In Person Training – At IMARC or Your Location
- Hybrid training: web-based courses plus in-person training

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 12.0 hours (1.2 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate, Experienced

AUDIENCE

- Clinical Research Professionals experienced in drug trials but new to device industry
- Clinical Research Associates, Clinical Research Coordinators, and Project Managers
- Sponsor/CRO staff members new to the device industry

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

HYBRID AGENDA

IMARC University Courses

- Foundation Package:
  - The History of Clinical Research
  - Introduction to Good Clinical Practice
  - Introduction to U.S. FDA Regulations
    - Introduction to U.S. FDA Regulations Part I: 21 CFR Parts 312 and 812
    - Introduction to U.S. FDA Regulations Part II: 21 CFR Parts 50, 56, 54 and 11
    - Comparing 21 CFR Part 312 and 21 CFR Part 812
  - Human Subjects Protection
    - Human Subject Protection: Drilling Down 21 CFR Part 50
    - Introduction to HIPAA and HITECH
  - The FAIR ShakeTM Method
- Key Roles and Responsibilities in Clinical Research
  - Project Manager Overview
  - Monitor Overview
  - Primary Investigator Overview
  - Research Coordinator Overview

One Day Agenda: 8:00 – 5:00pm

- International Guidance for Medical Devices
  - ISO 14155: Overview of the Standard
  - 21 CFR 812 vs. ISO 14155: Key Differences
- Day to Day Best Practices
  - Adverse Event Classification and Reporting
  - Investigational Device Accountability
  - High Quality Documentation and Maintaining the Sponsor TMF
- Developing Risk-Based Strategies for Device Studies
- Securing Compliance in Device Studies: Effective Monitoring and Site Management
- Safety Monitoring and Oversight: DSMBs, CECs and Medical Monitors
- Building Quality into Device Studies
- FDA's BIMO Program: Inspection of Sponsors, CROs, and Monitors – "Preparing for Inspection Success from Day 1"

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MEDICAL DEVICE CLINICAL RESEARCH PACKAGES

IV. MEDICAL DEVICE CLINICAL RESEARCH: BEYOND THE BASICS BOOT-CAMP FOR CRAs AND PMs

COURSE DESCRIPTION:

The goal of the training is to provide a refresher on GCP and regulations governing medical device clinical research, as well as an energizing exploration of the importance of good monitoring and site management practices, methods for thinking strategically and critically, and industry trends and best practices. The theme of the training will be to highlight the importance of supporting site compliance, efficiency, timelines, enrollment, data quality, and ultimately, the approval of an investigational device.

LEARNING OBJECTIVES:

- Identify applicable ICH GCP E6 R2 and ISO 14155 guidelines and FDA regulations governing clinical research
- Navigate through the requirements governing clinical research using critical thinking skills
- Explain the important role of clinical research monitors and those conducting site management activities and how they can secure compliance on behalf of the sponsor
- Describe best practices for creating and maintaining high quality documentation in research at sites
- Discuss 'controversial' topics in research, such as using notes-to-file, delegation logs and consent notes effectively using well-supported arguments
- Recall requirements and methods for maintaining a compliant trial master file
- Understand the mechanics of FDA inspections and describe at least three (3) recommendations to help sites and sponsors be inspection ready

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- Good Clinical Practice and U.S. FDA Regulations Refresher
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Best Practices for Effective Monitoring and Site Management
  - Take Your Monitoring from GOOD to GREAT
  - High Quality Documentation and Maintaining the Sponsor ™F
  - Adverse Event Reporting for Medical Device Trials
  - Writing Excellent Reports
  - Treating Your Sites Like Customers
  - Follow-up and Follow Through: Effective Site Management
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites and Sponsors

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Experienced

AUDIENCE

- Clinical Research Associates and Project Managers

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

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CLINICAL RESEARCH SITES: INVESTIGATORS & COORDINATORS

I. CLINICAL RESEARCH COORDINATOR: THE ESSENTIALS

COURSE DESCRIPTION:

This one-day course provides an excellent introduction to clinical research and CRC job responsibilities. New or aspiring clinical research coordinators (CRCs) will be introduced to regulations, best practices, and their roles and responsibilities within a clinical trial.

LEARNING OBJECTIVES:

- Review FDA regulations and the ICH GCP E6 Guideline for Good Clinical Practice (GCPs)
- Describe the roles and responsibilities of the Clinical Research Coordinator, Principal Investigator, and Sponsor (PM and CRA)
- Review the different types of Monitoring Visits, including preparation, conduct, documentation and follow-up
- Describe definitions related to safety management, identification of adverse events, and reporting requirements
- Recall the elements of the FAIR Shake™ Method, apply the method to potential compliance concerns, and understand the importance of supporting recommendations with the FAIR Shake™ Method.
- Identify best practices and skills to be an effective research coordinator

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- The History of Clinical Research
- Introduction to Good Clinical Practice: ICH GCP Guidelines
- Introduction to the U.S. FDA Regulations for Clinical Research
  - 21 CFR Parts 312, 812, 50, 56, 54, and 11
  - INDs vs IDEs: Comparing 21 CFR Parts 312 and 812
- Human Subject Protection
  - Drilling Down 21 CFR Part 50: Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI): HIPAA and HITECH
- The FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Key Roles and Responsibilities in Clinical Research Overview
  - Project Manager, Monitor, Primary Investigator, Clinical Research Coordinator, Data Manager, and Statistician
- Monitoring Visits: Hosting and Follow-up
- High Quality Documentation and Study Records
  - Source Documentation
  - Adverse Event Classification and Reporting
  - Investigational Product Accountability
- Day in The Life of an Effective Clinical Research Coordinator: Best Practices

TYPE

- In Person Training

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate

AUDIENCE

- Clinical Research Coordinators with limited experience in managing industry-sponsored studies
- Experienced Coordinators seeking to review the fundamentals of clinical research regulations

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

CLINICAL RESEARCH SITES: INVESTIGATORS & COORDINATORS

II. CLINICAL RESEARCH COORDINATOR: COMPREHENSIVE TRAINING

COURSE DESCRIPTION:

This course provides in-depth training of the roles and responsibilities of the clinical research coordinator (CRC) participating in medical device studies. This course is ideal to onboard new CRCs, as well as for experienced CRCs transitioning from drug studies to device studies.

LEARNING OBJECTIVES:

- Review FDA regulations and the ICH GCP E6 Guideline for Good Clinical Practice (GCPs)
- Recognize critical elements of human subject protection, safety reporting requirements, and good documentation
- Review the different types of Monitoring visits and understand what to expect and how to work well with your monitor
- Identify best practices and skills to be an effective research coordinator
- Understand how to prepare your site for FDA BIMO inspections and sponsor audits

COURSE OUTLINE

DAY ONE: 8:30 – 4:30pm

- The History of Clinical Research
- Introduction to Good Clinical Practice: ICH GCP Guidelines
- Introduction to the U.S. FDA Regulations for Clinical Research
  - 21 CFR Part 312, 812, 50, 56, 54, and 111
  - INDs vs IDEs: Comparing 21 CFR Parts 312 and 812
- Human Subject Protection
  - Drilling Down 21 CFR Part 50: Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI): HIPAA and HITECH
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Key Roles and Responsibilities in Clinical Research Overview
  - Project Manager, Monitor, Primary Investigator, Clinical Research Coordinator, Data Manager, and Statistician
- High Quality Documentation and Study Records
  - Source Documentation
  - Adverse Event Classification and Reporting
  - Investigational Product Accountability
- Day in The Life of an Effective Clinical Research Coordinator: Best Practices

DAY TWO: 8:30 – 3:30 pm

- Monitoring Visits: Hosting and Follow-up
- Site Selection and Initiation Visits
- Study Close-Out and Beyond
- Conducting and Documenting Informed Consent: Best Practices
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
- Corrective and Preventative Action Plans: Identifying, Documenting, and Implementing to Improve Site Compliance
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites

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TYPE

- In Person Training - At IMARC or Your Location
- Hybrid training: web-based courses plus in-person training

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 12.0 hours (1.2 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate

AUDIENCE

- Clinical Research Coordinators with limited experience in managing clinical trials
- Experienced Coordinators seeking to enhance or refresh their skills to more effectively and efficiently manage studies

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

HYBRID AGENDA

IMARC University Courses

- Foundation Package:
  - The History of Clinical Research
  - Introduction to Good Clinical Practice
  - Introduction to U.S. FDA Regulations
    - Introduction to U.S. FDA Regulations Part I: 21 CFR Parts 312 and 812
    - Introduction to U.S. FDA Regulations Part II: 21 CFR Parts 50, 56, 54 and 11
    - Comparing 21 CFR Part 312 and 21 CFR Part 812
  - Human Subjects Protection
    - Human Subject Protection: Drilling Down 21 CFR Part 50
    - Introduction to HIPAA and HITECH
  - The FAIR Shake™ Method
- Key Roles and Responsibilities in Clinical Research
  - Project Manager Overview
  - Monitor Overview
  - Primary Investigator Overview
  - Research Coordinator Overview

One Day Agenda: 8:00 – 5:00pm

- Day in The Life of an Effective Clinical Research Coordinator: Best Practices
- Monitoring Visits: Hosting and Follow-up
- Site Selection and Initiation Visits
- Study Close-Out and Beyond
- High Quality Documentation and Study Records
  - Source Documentation
  - Adverse Event Classification and Reporting
  - Investigational Product Accountability
- Conducting and Documenting Informed Consent: Best Practices
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
- Corrective and Preventative Action Plans: Identifying, Documenting, and Implementing to Improve Site Compliance
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites

CLINICAL RESEARCH SITES: INVESTIGATORS & COORDINATORS

III. CLINICAL RESEARCH COORDINATOR: ADVANCED CONCEPTS

COURSE DESCRIPTION:

This course provides a refresher and additional training for the experienced clinical research coordinator (CRC). We will start with a refresher on GCP and the key regulations and guidelines governing medical device clinical research. Then we will explore the importance of good study management and documentation, industry trends and best practices at the research site. We will also cover inspection preparation, as well as CAPA planning and implementation.

LEARNING OBJECTIVES:

- Identify applicable ICH GCP E6 R2 and ISO 14155 guidelines and FDA regulations governing clinical research
- Explore 'controversial' topics in research, such as using notes-to-file, delegation logs and consent notes effectively using well-supported arguments
- Discuss study management and best practices for securing compliance in device studies
- Understand the mechanics of FDA inspections and describe at least three (3) recommendations to help sites and sponsors be inspection ready.

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- Good Clinical Practice and U.S. FDA Regulations Refresher
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Securing Compliance in Device Studies: Effective Study Management
  - Best Practices: Informed Consent, Adverse Event Managing and Reporting, and Maintaining Study Documentation
  - Protocol Deviations: Identifying, Documenting and Reporting
  - Corrective and Preventative Action Plans: Identifying, Documenting and Implementing to Improve Site Compliance
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites

TYPE

- In Person Training - At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Experienced

AUDIENCE

- Clinical Research Coordinators, nurse coordinator, site manager, or investigator with solid background in FDA and GCP
- Staff involved in or manages daily operation of clinical research at a trial site

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

CLINICAL RESEARCH SITES: INVESTIGATORS & COORDINATORS

IV. PRINCIPAL INVESTIGATOR TRAINING

COURSE DESCRIPTION:

Attendees will be able to describe the responsibilities of a principal investigator, understand the requirements they must follow when conducting a clinical study, understand how responsibilities may be delegated to other study personnel with proper oversight, and recall common warning letter findings. The PI Package includes our signature FAIR Shake(TM) technique, which teaches the learner to take an otherwise complicated maze of requirements and break them down into four simple areas that can be applied to solving clinical research questions. Attendees will understand how to protect research subjects and how and when to report adverse events.

LEARNING OBJECTIVES:

- Review FDA regulations and ICH GCP E6 Guideline for Good Clinical Practice (GCP)
- Describe Investigator responsibilities in the context of study protocol oversight and GCP compliance
- Recognize critical elements of human subject protection
- Discuss the requirements for investigational product management and maintenance of adequate and accurate records
- Recognize key requirements for patient safety management and regulatory reporting
- Examine recent trends in non-compliance and BIMO Inspections

COURSE OUTLINE

AGENDA: 8:00 – 5:00pm

- Introduction to Good Clinical Practice: ICH GCP Guidelines
- Introduction to the U.S. FDA Regulations for Clinical Research
  - 21 CFR Parts 312, 812, 50, 56, 54, and 11
  - INDs vs IDEs: Comparing 21 CFR Parts 312 and 812
- Human Subject Protection
  - Drilling Down 21 CFR Part 50:Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI): HIPAA and HITECH
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Key Roles and Responsibilities in Clinical Research Overview
  - Project Manager, Monitor, Primary Investigator, Clinical Research Coordinator, Data Manager, and Statistician
- High Quality Documentation and Study Records
  - Source Documentation
  - Adverse Event Classification and Reporting
  - Investigational Product Accountability
- Hosting Sponsor Monitors and Auditors
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites
- Day In The Life of an Effective Principal Investigator: Best Practices

ADDITIONAL WEB-BASED COURSE ADD-ONS

- History of Clinical Research
- Critical Thinking in Clinical Research
- Monitoring Overview
- Maintaining the Sponsor TMF
- Introduction to Risk-Based Monitoring
- FDA Inspectional Findings

TYPE

- In Person Training - At IMARC or Your Location

AUDIENCE

- New or current investigators who need training on their research responsibilities

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 8.0 hours (0.8 CEUs)

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

KNOWLEDGE LEVELS

- Beginner, Intermediate

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CLINICAL RESEARCH SITES: INVESTIGATORS & COORDINATORS

V. BEST PRACTICES FOR EXPERIENCED INVESTIGATORS AND COORDINATORS

COURSE DESCRIPTION:

The goal of the training is to provide a refresher on GCP and regulations governing clinical research, as well as an energizing exploration of the importance of ensuring compliance, methods for thinking strategically and critically, and industry trends and best practices. The theme of the training will be to highlight the importance of conducting trials in compliance with the protocol and GCP, improve study coordination, and reduce the risk of inspection findings.

LEARNING OBJECTIVES:

- Identify applicable ICH GCP E6 R2 and ISO 14155 guidelines and FDA regulations governing clinical research
- Navigate through the requirements governing clinical research using critical thinking skills
- Understand what to expect from monitor visits and how to work well with your monitor
- Describe best practices for creating and maintaining high quality documentation in research using ALCOA-C
- Discuss 'controversial' topics in research, such as using notes-to-file, delegation logs and consent notes effectively using well-supported arguments
- Understand the mechanics of and how to prepare your site for FDA inspections and Sponsor audits

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- Good Clinical Practice and U.S. FDA Regulations Refresher
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Best Practices for an Effective Site
  - Human Subject Protection and Informed Consent
  - High Quality Documentation
  - Adverse Event Classification and Reporting
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
- Understanding Clinical Research Monitoring
  - How to work well with your monitors
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Experienced

AUDIENCE

- Investigators and Site Personnel
- Experienced Coordinators seeking to enhance or refresh their skills to more effectively and efficiently manage studies

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

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CLINICAL RESEARCH ASSOCIATES

I. CLINICAL RESEARCH ASSOCIATES: THE ESSENTIALS

COURSE DESCRIPTION:

This one-day course provides an excellent introduction to clinical research for entry level CRAs. New and aspiring clinical research associates will be introduced to regulations, best practices, and their roles and responsibilities within a clinical trial.

LEARNING OBJECTIVES:

- Recall FDA regulations and Good Clinical Practices
- Identify differences between drug and device clinical studies
- Describe the different types of Monitoring Visits and responsibilities of monitors, including preparation, conduct, documentation, and site management
- Recall the elements of the FAIR Shake™ Method, apply the method to potential compliance concerns, and understand the importance of supporting recommendations with the FAIR Shake™ Method.
- Identify best practices and skills to be an effective monitor

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- The History of Clinical Research
- Introduction to Good Clinical Practice: ICH GCP Guidelines
- Introduction to the U.S. FDA Regulations for Clinical Research
  - 21 CFR Parts 312, 812, 50, 56, 54, and 11
  - INDs vs IDEs: Comparing 21 CFR Parts 312 and 812
- Human Subject Protection
  - Drilling Down 21 CFR Part 50: Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI): HIPAA and HITECH
- The FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Key Roles and Responsibilities in Clinical Research: CRA Focused
- Monitoring Visits Overview:
  - Visit Types: Site Assessment Visits, Site Initiation Visits, Periodic Site Visits, and Close Out Visits
  - Visit Preparation, Conduct, Documentation, and Follow-up
- Day In the Life of an Effective Clinical Research Associate: Best Practices
  - Adverse Event Classification and Reporting
  - Investigational Product Accountability
  - High Quality Documentation and Maintaining the Sponsor TMF

TYPE

- In Person Training: At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Beginner

AUDIENCE

- Aspiring Clinical Research Associates
- New Clinical Research Associates with limited experience

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

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CLINICAL RESEARCH ASSOCIATES

II. CLINICAL RESEARCH ASSOCIATES: COMPREHENSIVE TRAINING

COURSE DESCRIPTION:

This course provides an in-depth overview of the role of the Clinical Research Associate (CRA) in monitoring medical device studies. This course is ideal to onboard your new CRAs/Monitors, as well as for experienced CRAs transitioning from drug studies to device studies.

LEARNING OBJECTIVES:

- Discuss FDA regulations and Good Clinical Practices and identify differences between drug and device clinical studies
- Describe the different types of Monitoring Visits and responsibilities of monitors, including preparation, conduct, documentation, and site management
- Describe definitions related to safety management, identification of adverse events, and reporting requirements
- Identify best practices for effective monitoring and critical thinking skills for clinical researchers
- Understand the mechanics of FDA inspections and describe at least three (3) recommendations to help sites and sponsors be inspection ready

COURSE OUTLINE

DAY ONE: 8:30 – 4:30pm

- The History of Clinical Research
- Introduction to Good Clinical Practice: ICH GCP Guidelines
- Introduction to the U.S. FDA Regulations for Clinical Research
  - 21 CFR Parts 312, 812, 50, 56, 54, and 11
  - INDs vs IDEs: Comparing 21 CFR Parts 312 and 812
- Human Subject Protection
  - Drilling Down 21 CFR Part 50: Conducting and Documenting Proper Informed Consent
  - Protecting Subject Protected Health Information (PHI): HIPAA and HITECH
- The FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Key Roles and Responsibilities in Clinical Research: CRA Focused
- High Quality Documentation and Maintaining the Sponsor TMF

DAY TWO: 8:30 – 4:30pm

- Site Selection and Initiation Visits
- Monitoring Visits
  - Site Visit Preparation and Monitoring Tools
  - Periodic Site Visits: Regulatory Review, Consent Review, Source Data Verification, Product Accountability
- Adverse Event Classification and Reporting
- Post Visit Documentation

DAY THREE: 8:30 – 4:30pm

- Follow-up and Follow Through: Effective Site Management
- Study Close-Out
- Monitoring Best Practices
  - Taking Your Monitoring From GOOD to GREAT
  - Treating Your Sites Like Customers
  - Writing Excellent Reports
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites and Sponsors
- Day In the Life of an Effective Clinical Research Associate: Best Practices
  - Adverse Event Classification and Reporting
  - Investigational Product Accountability
  - High Quality Documentation and Maintaining the Sponsor TMF

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TYPE

- In Person Training – At IMARC or Your Location
- Hybrid training: web-based courses plus in-person training

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 21.0 hours (2.1 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate

AUDIENCE

- New Clinical Research Associates with limited or no experience monitoring medical device studies
- Experienced CRAs beginning to monitor device studies

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

HYBRID AGENDA

IMARC University Courses

- Foundation Package:
  - The History of Clinical Research
  - Introduction to Good Clinical Practice
  - Introduction to U.S. FDA Regulations
    - Introduction to U.S. FDA Regulations Part I: 21 CFR Parts 312 and 812
    - Introduction to U.S. FDA Regulations Part II: 21 CFR Parts 50, 56, 54 and 11
    - Comparing 21 CFR Part 312 and 21 CFR Part 812
  - Human Subjects Protection
    - Human Subject Protection: Drilling Down 21 CFR Part 50
    - Introduction to HIPAA and HITECH
  - The FAIR Shake™ Method
- Monitoring Overview
- Maintaining the Sponsor TMF

One Day Agenda: 8:30 – 4:30pm

- Monitoring Best Practices
  - Taking Your Monitoring From GOOD to GREAT
  - Treating Your Sites Like Customers
  - Writing Excellent Reports
- Follow-up and Follow Through: Effective Site Management
- Being Inspection Ready: Understanding the FDA BIMO Inspection Process for Sites and Sponsors
- Day In the Life of an Effective Clinical Research Associate: Best Practices
  - Adverse Event Classification and Reporting
  - Investigational Product Accountability
  - High Quality Documentation and Maintaining the Sponsor TMF

IMARC University Courses, or Live Web Conferences(s)

- Site Selection and Initiation Visits
- Monitoring Visits
  - Site Visit Preparation and Monitoring Tools
  - Periodic Site Visits: Regulatory Review, Consent Review, Source Data Verification, Product Accountability
- Adverse Event Classification and Reporting
- Post Visit Documentation
- Study Close-Out

CLINICAL RESEARCH ASSOCIATES

III. THE LEAD CLINICAL RESEARCH ASSOCIATE (TEAM LEADER)

COURSE DESCRIPTION:

This one day course prepares you to successfully lead your team through effective communication, use of best practices, critical and risk-based thinking, all while focusing on compliance. The course topics focus on strengthening and refining your people and communication skills, while developing strategies for successful team performance and management of the project.

LEARNING OBJECTIVES:

- Demonstrate effective communication skills
- Examine best practices for effective leading of projects/CRA teams by exploring ways to enhance time management and communication skills
- Understand the concept of and how to implement risk-based thinking throughout monitoring of a clinical study
- Identify methods to improve site compliance through implementation of CAPAs

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- Lead Clinical Research Associate Role and Responsibilities
- Being an Effective Lead CRA
  - Fostering Excellent Report Writers and Ensuring Timelines Are Met
  - Protocol Deviations: Identifying, Documenting, Managing and Reporting
  - Leading Teams: Managing Different Personalities and Having Challenging Conversations
  - Time Management: Strategies for Leads and the CRAs on their Team
- Corrective and Preventative Action Plans: Identifying, Documenting, and Implementing to Improve Site Compliance
- Risk-Based Thinking
  - Risk-Based Monitoring Throughout a Study: Best Practices & Methods
  - Monitoring with an Auditing Perspective

ADDITIONAL WEB-BASED COURSE ADD-ONS

- GCP & US FDA Regulations Refresher
- Critical Thinking in Clinical Research
- FAIR Shake™
- Dealing with Difficult Sites

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Advanced

AUDIENCE

- Lead CRAs, Team Leaders, Project Managers, Clinical Project Coordinators, and/or those responsible for managing a project with a team of CRAs
- Experienced CRAs who are becoming involved in managing projects/teams
- Managers of Lead CRAs, Team Leaders, Project Managers, Clinical Project Coordinators

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

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CLINICAL PROJECT MANAGERS

I. CLINICAL PROJECT MANAGER: THE ESSENTIALS

COURSE DESCRIPTION:

The goal of this 2 day training is to provide the essentials of project management, and to go beyond the basics and explore the importance of good project management practices. The course will provide an overview of the PM role and responsibilities, and introduce concepts and tools to aid in effective project management throughout a clinical study. The theme of the training highlights start-up and close-out, strategies for effective communication, documentation best practices, and general tips and tricks.

LEARNING OBJECTIVES:

- Explain the important role of the project manager throughout a clinical study and how to secure compliance on behalf of the sponsor
- Explore concepts and tools to aid in day to day activities of project management
- Describe best practices for managing documentation throughout a clinical study
- Utilize effective communication and leadership skills for successful study management

COURSE OUTLINE

DAY ONE: 8:30 – 4:30pm

- Clinical Research Studies Refresher
  - Good Clinical Practice and U.S. FDA Regulations Refresher
  - Comparing Drug and Device Development Pathways
  - INDs vs IDEs: Comparing 21 CFR Parts 312 vs. 812
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Project Manager Overview: Key Roles and Responsibilities
- Clinical Research Project Management: Planning and Start-up
  - Creating the Project Plan and Work Breakdown Structure
  - Assessing Risks and Developing Mitigation Strategies
  - Developing Study Documents and Site Files
  - Study Site Start-up: Assessment, Selection, and Initiation
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
  - Thinking Critically about Requirements, Best Practices, and Pitfalls
- Ongoing Project Management: Documentation
  - Maintaining the Sponsor TMF
  - Documentation in Clinical Research for Sites: What is REALLY Needed
  - What Does GREAT Monitoring Look Like?: "Take Your Team's Monitoring from GOOD to GREAT!"
  - Excellent Monitoring Reports: What to Look For?
  - Follow-up and Follow Through: Ensuring Effective Site Management by Vendors

DAY TWO: 8:30 – 4:30pm

- Ongoing Project Management: Tools, Strategies, and Effective Communication
  - Effective Metrics: Benefits for Tracking Clinical Study Details
  - Schedule Management and Time Management
  - How to Run Effective Meetings: 8 Steps to a Successful Meeting
  - Leading Teams: Managing Difficult Personalities and Having Challenging Conversations
- Project Close-Out: Getting to the Finish Line
- Research Off the Rails: Getting Your Clinical Study Back on Track
  - "What do I do when I realize there is a problem?"
- Project Management in Practice: 5 Things That Aren't (Normally) Taught in PM Class

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TYPE

- In Person Training – At IMARC or Your Location
- Hybrid training: web-based courses plus in-person training

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 14.0 hours (1.4 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Experienced

AUDIENCE

- Project Managers
- Experienced Project Managers without formal project management training
- Clinical Research personnel interested in transitioning into a Clinical Manager role

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

HYBRID AGENDA

IMARC University Courses

- Clinical Research Refresher
- Comparing 21 CFR Part 312 and 21 CFR Part 812
- The FAIR ShakeTM Method
- Project Manager Overview

One Day Agenda: 8:00 – 5:00pm

- Ongoing Project Management: Documentation
  - Maintaining the Sponsor TMF
  - Documentation in Clinical Research for Sites: What is REALLY Needed
  - What Does GREAT Monitoring Look Like?: "Take Your Team's Monitoring from GOOD to GREAT!"
- Excellent Monitoring Reports: What to Look For?
- Follow-up and Follow Through: Ensuring Effective Site Management by Vendors
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
- Thinking Critically about Requirements, Best Practices, and Pitfalls
- Ongoing Project Management: Tools, Strategies, and Effective Communication
  - Effective Metrics: Benefits for Tracking Clinical Study Details
  - Schedule Management and Time Management
  - How to Run Effective Meetings: 8 Steps to a Successful Meeting
  - Leading Teams: Managing Difficult Personalities and Having Challenging Conversations
- Project Close-Out: Getting to the Finish Line
- Research Off the Rails: Getting Your Clinical Study Back on Track
  - "What do I do when I realize there is a problem?"
- Project Management in Practice: 5 Things That Aren't (Normally) Taught in PM Class

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CLINICAL PROJECT MANAGERS

II. CLINICAL PROJECT MANAGER: COMPREHENSIVE TRAINING

COURSE DESCRIPTION:

The goal of this three-day training is to provide a comprehensive overview of the project management role and responsibilities. This course will provide new or aspiring clinical research project managers with the skills as well as necessary tools and processes to successfully manage projects in clinical research settings. The course review the FDA regulations and GCP, emphasizes the differences between key roles in clinical research, and provides tools to aid in application of clinical project management concepts and principles.

LEARNING OBJECTIVES:

- Review FDA regulations and ICH GCP E6 Guideline for Good Clinical Practice (GCP)
- Describe project management as it applies to clinical research and in the management of clinical trials
- Develop a monitoring plan which focuses on mitigating risks at both the program and study levels
- Utilize effective communication and leadership skills for successful study management

COURSE OUTLINE

DAY ONE: 8:30 – 4:30pm

- Clinical Research Studies Refresher
  - Good Clinical Practice and U.S. FDA Regulations Refresher
  - Comparing Drug and Device Development Pathways
  - INDs vs IDEs: Comparing 21 CFR Parts 312 vs. 812
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Day to Day Differences in Medical Device Studies vs Investigational Drug Studies
  - Adverse Event Reporting and Product Complaints: “Is It Reportable?”
  - Product Accountability: “Where does the Pharmacy fit?”
  - Special Considerations for Securing Compliance
- Debate Club: Notes-to-File, Delegation Logs, Consent Notes
  - Thinking Critically about Requirements, Best Practices, and Pitfalls
- Key Roles and Responsibilities in Clinical Research Overview
  - Project Manager, Monitor, Primary Investigator, Clinical Research Coordinator, Data Manager and Statistician
- Risk-Based Monitoring (RBM)
  - RBM Overview: FDA Guidance and ICH GCP E6
  - Developing Monitoring Plans: Planning and Implementation
  - Risk-Based Monitoring Throughout a Study: Best Practices & Methods

DAY TWO: 8:30 – 4:30pm

- Clinical Research Project Management: Planning
  - Creating the Project Plans and Work Breakdown Structure
  - Assessing Risks and Developing Mitigation Strategies
  - Project Budget Considerations: Planning and Oversight
  - Assembling and Training the Sponsor Team
- Clinical Research Clinical Project Management: Start-up
  - Vendor Selection and Management
  - Developing Study Documents and Site Files
  - Site Assessment and Selection
  - Site Start-up and Initiation
- Research Off the Rails: Getting Your Clinical Study Back on Track
  - “What do I do when I realize there is a problem?”

CLINICAL PROJECT MANAGERS

DAY THREE: 8:30 – 4:30 pm

- Ongoing Project Management: Documentation
  - Maintaining the Sponsor TMF
  - Documentation in Clinical Research for Sites: What is REALLY Needed
- Ongoing Project Management: Tools, Strategies, and Effective Communication
  - Effective Metrics: Benefits for Tracking Clinical Study Details
  - Schedule and Time Management
  - How to Run Effective Meetings: 8 Steps to a Successful Meeting
  - Leading Teams: Managing Difficult Personalities and Having Challenging Conversations
- Ongoing Project Management: Vendor Oversight and Expectations
  - What Does GREAT Monitoring Look Like?: "Take Your Team's Monitoring from GOOD to GREAT!"
  - Excellent Monitoring Reports: What to Look For?
  - Follow-up and Follow Through: Ensuring Effective Site Management by Vendors
  - Working with Your Monitors to Ensure Timeliness, Quality, and Study/Site Compliance
- Project Close-Out: Getting to the Finish Line
- Project Management in Practice: 5 Things That Aren't (Normally) Taught in PM Class

TYPE

- In Person Training – At IMARC or Your Location
- Hybrid training: web-based courses plus in-person training

CONTINUING EDUCATION CONTACT HOURS (CEUS)

- 14.0 hours (1.4 CEUs)

KNOWLEDGE LEVELS

- Beginner, Intermediate

AUDIENCE

- New clinical research Project Managers
- Experienced Project Managers without formal project management training
- Newly hired Clinical or Project Leads who will be managing at the sponsor, CRO, or investigational site
- Clinical Research Associates, Data Managers or other research personnel interested in transitioning into a Clinical Project Management role

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

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CLINICAL PROJECT MANAGERS

III. CLINICAL PROJECT MANAGER: ADVANCED CONCEPTS

COURSE DESCRIPTION:

This course provides the experienced Clinical Project Manager with the advanced project management and leadership skills to effectively lead project teams to their optimal performance. Advanced concepts will be presented to explore how project managers can effectively prioritize project needs, lead project teams and utilize best practices for decisions. Topics explored include assessment of risk, project quality, effective study management, and corrective and preventive action (CAPA) plans.

LEARNING OBJECTIVES:

- Manage projects and quality risks
- Formulate project priorities and approach to building quality into project needs
- Describe effective leadership skills in leading study teams

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- Good Clinical Practice and U.S. FDA Regulations Refresher
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Building Quality into Clinical Research Studies
  - Conducting Risk Assessment: Identifying , Evaluating, and Mitigating Risks
  - Risk Management: Implementing Approaches for Compliance
  - Risk-Based Monitoring Throughout a Study: Best Practices
  - Corrective Actions Plans: Identifying, Documenting, and Implementing to Improve Site Compliance
- Effective Project Management: Tools and Strategies
  - Effective Metrics: Benefits for Tracking Clinical Study Details
  - Schedule and Time Management
  - How to Run Effective Meetings: 8 Steps to a Successful Meeting
  - Working with Your Monitors to Ensure Timeliness, Quality, and Study/Site Compliance
  - Leading Teams: Managing Difficult Personalities and Having Challenging Conversations
- Research Off the Rails: Getting Your Clinical Study Back on Track
  - "What do I do when I realize there is a problem?"
- Project Management in Practice: 5 Things That Aren't (Normally) Taught in PM Class
- FDA's BIMO Program: Inspection of Sponsors, CROs, and Monitors – "Preparing for Inspection Success from Day 1"

ADDITIONAL WEB-BASED COURSE ADD-ONS

- Critical Thinking in Clinical Research
- Project Manager Overview
- Maintaining the Sponsor TMF
- FDA Inspectional Findings
- Comparing 21 CFR Part 312 and 21 CFR Part 812

TYPE

- In Person Training – At IMARC or Your Location

AUDIENCE

- Experienced Project Managers

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References
- Certificate of Completion

KNOWLEDGE LEVELS

- Intermediate, Experienced

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CLINICAL RESEARCH AUDITOR

I. CLINICAL RESEARCH AUDITORS: COMPREHENSIVE TRAINING

COURSE DESCRIPTION:

The goal of the training is to provide an introduction to the job function of the Clinical Research Auditor. The course is structured for individuals seeking to learn more about GCP auditing, including site and sponsor/CRO audits, as well as vendor audits.

LEARNING OBJECTIVES:

- Describe and discuss FDA regulations and Good Clinical Practice
- Explains roles and responsibilities of a Clinical Research Auditor
- Describes types of audits, and the responsibilities of the auditor in preparation, activities, and follow-up
- Examine and apply the FDA's methods for inspection of Clinical Investigators, and Sponsor/CROs
- Discuss Inspectional Findings, regulatory compliance, quality issues and documentation

COURSE OUTLINE

AGENDA: 8:30 – 4:30pm

- Good Clinical Practice and U.S. FDA Regulations Refresher
- FDA BIMO Inspections and Guidances
- FAIR Shake™ Critical Thinking Method for Answering Challenging Research Questions
- Auditing Overview
- Audit Preparation: Developing the Audit Plan and Preparing for the Audit
- Conducting Audits
  - Investigative Sites
  - Sponsor/CRO
  - Clinical Vendor Assessments
- Spot Checking: Sampling Documents and Data For Trend Analysis
- Audit Report Writing and Post Audit Documentation
- Communicating Findings with Auditees and Clients

TYPE

- In Person Training – At IMARC or Your Location

CONTINUING EDUCATION CONTACT HOURS (CEUs)

- 7.0 hours (0.7 CEUs)

KNOWLEDGE LEVELS

- Intermediate, Experienced

AUDIENCE

- Clinical Quality and Compliance Professionals
- New and Aspiring Auditors
- Clinical Research Associates and Project Managers

WHAT'S INCLUDED

- Interactive Presentations
- Case Studies and Scenarios
- Handouts and References (Whitepapers and Infographics)
- Certificate of Completion

IMARC UNIVERSITY
Training Tips

TIP 1

Consider training when it's convenient for you.

As clinical professionals, we all understand the importance of continuing our training. Unfortunately, our professional and personal schedules are so busy we lose sight of this important career-building step.

TIP 2

Research time commitment and pricing.

Mentally, you've toyed with the idea of continuing your training. After carefully researching some of the online training offerings, you realize you cannot afford it. IMARC University's goal is to offer affordable, online training to clinical professionals.

TIP 3

Look for courses designed for your role.

IMARC University training courses were designed for your specific role in clinical research. We offer role-based packages for Research Coordinators, Monitors and coming soon for PIs, Project Managers and Advance Monitoring.

TIP 4

Stay on top of compliance and your career with continuing education.

Do you want to learn how to be a better Monitor, transition to a new role, or expand your skills of clinical research? Check out IMARC University, a series of affordable online training and continuing education courses designed to prepare you and your team for clinical research compliance.

TIP 5

Learn the ropes before transitioning.

Are you looking to transition into a new role in the clinical research field? IMARC University can offer you a firm foundation – all based within the regulations. We focus on competency-based education that teaches you how to do the job.

TIP 6

Build confidence in your understanding with quiz based training.

If you struggle with comprehension of material, IMARC University includes a quiz to assess your grasp of the content. We allow you to review the material and retake the quiz so you'll feel confident in your understanding.

TIP 7

Earn while you learn.

IMARC University training documents that you have successfully completed a course and provides valuable contact hours toward maintaining your nursing license or professional certification.

TIP 8

Stay fresh in your understanding of clinical research requirements.

IMARC University allows you to select courses on topics that include FDA regulations, Good Clinical Practice, Human Subject Protection and much more. These affordable, online courses can refresh your understanding of critical clinical research requirements.

TIP 9

Expect flexibility in choosing courses that meet your training needs.

IMARC University offers you flexibility in choosing courses that are right for you. You can select from training packages or individual courses for a tailored set of training that meets your needs.

TIP 10

Demand quality with practical examples.

IMARC University courses are developed by experienced clinical research professionals who are certified in their field. Practical examples based on their real-world experiences help you to assimilate skills needed to be successful in your role.

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CLINICAL RESEARCH EDUCATION

ONLINE TRAINING

COURSE CATALOG

ON-DEMAND, WEB-BASED COURSES
ON YOUR SCHEDULE

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CLINICAL RESEARCH TRAINING
On Your Own Time

IMARC is a leading contract research organization that assists researchers with obtaining the approvals necessary to bring the latest medical devices, technology or pharmaceutical drugs to those who need them most.

We provide cost-effective monitoring, auditing, training and consulting services. Through IMARC University, a series of online training courses for clinical research professionals, **you can now access this training when it's most convenient for you.**

Because our staff frequently spends time at clinical research sites, we relied upon our own extensive experiences and insights in developing each course. This course catalog provides an overview of the material covered in our role-based training courses, course packages and individual courses.

We invite you to browse these course descriptions as you decide what type of training is right for you or your team.

Please note that our course catalog may change as we develop additional courses. For the most updated listing of our course offerings, visit imarcuniversity.com.

If you have questions, feel free to contact us.

ph (440) 801-1540

email university@imarcresearch.com

ROLE-BASED TRAINING

1 ADVANCED MONITOR PACKAGE

FOR:

Experienced monitors looking to expand their knowledge and skills.

OBJECTIVES:

Apply the quality assurance techniques of auditors to monitoring. List six core critical thinking skills and identify active processes for applying critical thinking skills in research studies. Understand risk-based monitoring approaches and best practices for developing plans. Explain approaches for effectively dealing with challenging research sites to maintain compliance.

COURSES:

a. Monitoring with an Auditing Perspective
b. Critical Thinking in Clinical Research
c. Risk-Based Monitoring (RBM) Overview
d. Developing a RBM Plan
e. Adverse Event Reporting and Classification
f. Dealing With Difficult Sites

2 PROJECT MANAGER PACKAGE

FOR:

New clinical research Project Managers or those without formal training looking to review important concepts in running compliant studies and demonstrate understanding.

OBJECTIVES:

Compare and contrast the key roles in a research study including the Project Manager, Monitor, Investigator, and Research Coordinator.

COURSES:

a. Project Manager Overview
b. Monitor Overview
c. PI Overview
d. RC Overview
e. The FAIR Shake Method
f. FDA Inspectional Findings

ROLE-BASED TRAINING

3

RESEARCH COORDINATOR PACKAGE

FOR:

New research coordinators and those who need to review the fundamentals of clinical research regulations.

OBJECTIVES:

Introduce new or aspiring research coordinators to their roles and responsibilities within a clinical trial and provide a thorough understanding of the regulations they rely on to perform their duties. Understand how to protect research subjects and how and when to report adverse events.

COURSES:

a. Research Coordinator Overview

b. Foundation Package

c. Adverse Event Classification and Reporting

4

MONITOR PACKAGE

FOR:

New monitors and those who need to review the fundamentals of clinical research regulations

OBJECTIVES:

Provide an understanding of clinical research procedures and requirements that is based in regulations. Help monitors prioritize tasks during site visits and help the trial progress while off site. Understand what FDA inspectors need to know and be able to provide them with information as requested. Gain the confidence to answer questions or challenges regarding research procedures.

COURSES:

a. Monitoring Overview

b. Foundation Package

c. Monitoring 101 Package

d. Monitoring 102 Package

ROLE-BASED TRAINING

5

PRINCIPAL INVESTIGATOR PACKAGE

FOR:

New and experienced Investigators who need training on their research responsibilities. The Foundation Package is included to provide a solid knowledge base for conducting clinical research with human subjects.

OBJECTIVES:

Learners will be able to describe the responsibilities of a principal investigator, understand the requirements they must follow when conducting a clinical study, understand how responsibilities may be delegated to other study personnel with proper oversight, and recall common warning letter findings. The Foundation Package includes two introductory courses on the FDA regulations, a good clinical practice course with an overview of the history of clinical research, a course in human subjects protection, and our signature FAIR Shake(TM) technique, which teaches the learner to take an otherwise complicated maze of requirements and break them down into four simple areas that can be applied to solving clinical research questions.

COURSES:

a. Principal Investigator Overview

b. Foundation Package

TRAINING PACKAGES

1

FOUNDATION PACKAGE

FOR:

Sponsor organizations and their project managers, sales professionals, research coordinators, monitors and anyone else involved in the clinical research process

OBJECTIVES:

Provide a solid knowledge base for conducting clinical research with human subjects. Includes two introductory courses on the FDA regulations. One covers 21 CFR Parts 312 and 812, and the other covers 21 CFR Parts 50, 56, 54, and 11. Also includes a course comparing 21 CFR Parts 312 and 812, as well as a more in-depth course on Human Subjects Protection as required under Part 50. Additionally, the Foundation Package includes courses on good clinical practice, HIPAA in research, and an overview of the history of clinical research. The Package concludes with a course on our signature FAIR Shake™ technique, which teaches the learner to take an otherwise complicated maze of requirements and break them down into four simple areas that can be applied to solving clinical research questions.

COURSES:

a. Introduction to the U.S. FDA Regulations
   - **i.** Part I: 21 CFR Parts 312 and 812
   - **ii:** Part II: 21 CFR Parts 50, 56, 54, and 11
   - **iii.** Comparing 21 CFR Parts 312 and 812

b. Introduction to Good Clinical Practice

c. Introduction to HIPAA/HITECH

d. The History of Clinical Research

e. Human Subjects Protection: Drilling Down 21 CFR Part 50

f. The FAIR Shake™ Method

2

MONITORING 101 PACKAGE

FOR:

New monitors or monitors who need to review regulations

OBJECTIVES:

Provide the learner with an overview of what it means to be a clinical research monitor. Understand the four traditional types of monitoring visits: Site Assessment, Site Initiation, Periodic, and Close-Out. Learn what to do between visits to help a clinical trial progress and remain compliant.

COURSES:

a. Site Assessment Visits
b. Site Initiation Visits
c. Periodic Monitoring Visits
d. Close-Out Visits
e. Site Management

3

MONITORING 102 PACKAGE

FOR:

New monitors who have taken Monitoring 101 or experienced monitors who want to dive deeper into the requirements for informed consent, documents review, source data verification and more.

OBJECTIVES:

Increase competency on and off site. Be able to think critically and spot potential errors before they become violations. Learn how to perform key monitoring activities.

COURSES:

a. How to Review Informed Consent
b. How to Review Essential Documents
c. How to Verify Source Data
d. How to Conduct Product Accountability
e. Risk-Based Monitoring Overview

INDIVIDUAL COURSES

I: INTRODUCTION TO U.S. FDA REGULATIONS

This course covers the US FDA Regulations pertaining to research in Title 21 of the Code of Federal Regulations. The parts covered include 312, 812, 50, 54, 56, and 11. This course also includes comparisons between parts 312 and 812 for drug and device regulations.

COURSES:

a. Introduction to U.S. FDA Regulations Part I: 21 CFR Parts 312 and 812
b. Introduction to U.S. FDA Regulations Part II: 21 CFR Parts 50, 56, 54, and 11
c. Comparing 21 CFR Part 312 and 21 CFR Part 812

II: GOOD CLINICAL PRACTICE

This course provides an introduction to the main tenets of good clinical practice as well as a history of clinical research and the importance of research standards. The FAIR Shake Method is included to give learners a tool for applying critical thinking skills to difficult compliance questions.

COURSES:

a. The History of Clinical Research
b. Introduction to Good Clinical Practice
c. The FAIR Shake™ Method

III: HUMAN SUBJECTS PROTECTION

This course examines human subjects protection in more detail, with an in depth look at 21 CFR Part 50 as well as an introduction to the HIPAA and HITECH regulations. Learners will gain a thorough understanding of the important role of informed consent and privacy protection in clinical research.

COURSES:

a. Human Subjects Protection: Drilling Down 21 CFR Part 50
b. Introduction to HIPAA and HITECH

INDIVIDUAL COURSES

IV: FDA INSPECTIONS

This course provides learners with information about why, when, and how FDA inspections of clinical investigation sites and sponsors occur. Learners will gain a detailed understanding of the FDA's compliance program guidance manual, the items assessed by FDA inspectors, and best practices to help research teams prepare for and host inspections.

OBJECTIVES:

Learners will understand how to prepare for and host an FDA inspection, comprehend potential inspection outcomes for investigators, describe key topics assessed in the FDA's BIMO Guidelines for Site inspections and connect these with examples of evidence the FDA will review, and understand the guideline as a foundation for quality assurance activities.

COURSES:

a. FDA Inspections 101

b. FDA Inspections 102

COURSE DESCRIPTIONS

DEALING WITH DIFFICULT SITES

This course was designed as an intermediate level course to give learners an understanding of how to deal with challenging clinical trial sites as a sponsor representative. At the conclusion of this course, attendees should be able to identify common challenges that sites experience, develop an overall strategy to deal with a problematic site, and recommend specific resolutions to correct a particular problem and prevent it from recurring.

DEVELOPING A RISK-BASED MONITORING (RBM) PLAN

This course was designed as an advanced level course to give learners a roadmap to creating a monitoring plan based on careful and thorough risk-assessment of the clinical study being conducted. By the end of this course participants will be able to identify clinical study risks, and discuss how these risks may impact the monitoring plan. Learners will be able to describe important considerations for developing a Risk-Based Monitoring Plan, along with being able to verbalize understanding of how to draft a monitoring plan. Lastly, at the conclusion of the course participants will be able to discuss best practices for implementing a risk-based monitoring plan.

CRITICAL THINKING IN CLINICAL RESEARCH

This course was designed as an intermediate level course to give learners an understanding of critical thinking skills and their application to research. At the conclusion of this course learners should be able to define critical thinking, list six core critical thinking skills and identify active processes for applying critical thinking skills.

MONITORING WITH AN AUDITING PERSPECTIVE

This course was designed as an intermediate level course to give learners a perspective of the relationship between monitoring and auditing. This course examines techniques from auditing that can be applied to monitoring. At the conclusion of this course participants should be able to: identify the objective of an FDA Bioresearch Monitoring inspection, describe the differences between monitoring and auditing, and define corrective and preventive action as applied to clinical research. This presentation focuses on teaching monitors what the FDA is looking for when inspecting clinical research entities, and leveraging this information to employ auditing strategies to address site issues.

PROJECT MANAGER OVERVIEW

This course was designed as an introductory level course to give learners an overview of the role and responsibilities of a Project Manager of a clinical study. At the completion of this course learners should be able to: describe the requirements for the Sponsor and Project Manager of the oversight and management of both drug and device studies, describe the responsibilities of a Project Manager throughout the full lifecycle of a clinical investigation, and describe the qualities (inherent and learned) of a Clinical Trial Project Manager.

MAINTAINING THE SPONSOR TMF

This course has been designed as an intermediate level course to give learners insight into maintaining the Sponsor Trial Master File. This course will provide the learner with an understanding of the documents required as well as tips for maintaining a successful Trial Master File. At the conclusion of this course, learners should be able to recall the essential documents to be included in the trial master file (or, TMF), understand how to maintain a successful TMF, and compare the electronic approach to the TMF with traditional paper TMFs.

FDA INSPECTIONAL FINDINGS

This course has been designed as an intermediate level course to familiarize learners with FDA warning letters and the FDA Form 483. In addition, this course will describe best practices to avoid receiving citations or warning letters from FDA. At the completion of this course, learners should be able to demonstrate familiarity with FDA regulations cited in recent Warning Letters, demonstrate familiarity with the structure and language of FDA Warning Letters, understand the purpose of FDA Form 483, describe the best practices to avoid receiving a 483 or FDA Warning Letter.

RESEARCH COORDINATOR OVERVIEW

This course has been designed as an introductory level course to give learners an overview of the role of a clinical research coordinator. Learners will be able to describe the typical activities and responsibilities of a CRC, and understand the requirements they must abide by when conducting a clinical research study.

ADVERSE EVENT CLASSIFICATION AND REPORTING

This course has been designed as an introductory level course to give learners a basic understanding of what adverse events are, and how they are classified and reported. Learners will be able to define serious adverse events, and indicate whether or not they are required to be reported based on whether or not they are considered related, expected, or serious.

MONITORING OVERVIEW

This course has been designed as an introductory level course to give learners an overview of monitoring activities, and how they are performed. Learners will be able to explain why monitoring is performed, recall what a monitoring plan is, and identify the four types of monitoring visits.

SITE ASSESSMENT VISITS

This course has been designed as an intermediate level course to give learners an explanation of the activities that sponsor representatives, including monitors, may be asked to conduct during a site assessment visit. Learners will be able to describe site assessment activities and explain their significance, describe tools and best practices used for Site Assessments, and outline the steps for conducting Site Assessment visits.

SITE INITIATION VISITS

This course has been designed as an intermediate level course to give learners an understanding of how to prepare for and conduct a site initiation visit. Learners will understand how to prepare for a site initiation visit, be able to summarize study training and important items of discussion that should take place, and list documents to be collected during the visit.

PERIODIC MONITORING VISITS

This course has been designed as an intermediate level course to give learners an introduction to conducting periodic monitoring visits. Learners will understand how to plan and prepare for a periodic monitoring visit, describe what takes place during a visit, and comprehend how visit activities are documented.

CLOSE-OUT VISITS

This course has been designed as an intermediate level course to give learners an understanding of how to prepare for and conduct a close-out visit. Learners will understand how to plan and prepare for a close-out visit, describe what takes place during a visit, and comprehend how visit activities are documented.

SITE MANAGEMENT

This course has been designed as an introductory level course to give learners an understanding of the activities a monitor routinely performs during the course of an investigation between monitoring visits. Learners will be able to determine best practices for documenting site communication, manage activities that take place in between monitoring visits such as data retrieval and query resolution, and measure the progress of action items to ensure their resolution.

HOW TO REVIEW INFORMED CONSENT

This course has been designed as an intermediate level course to give learners information regarding how a monitor reviews subject informed consent forms during a monitoring visit to ensure they have been consented properly.

HOW TO VERIFY SOURCE DATA

This course has been designed as an intermediate level course to give learners an explanation of how to verify source data during a monitoring visit. Learners will be able to define Source Data, identify where Source Data can be found, describe tools and best practices used by monitors for Source Data Verification, and develop queries that are clear and objective.

HOW TO REVIEW ESSENTIAL DOCUMENTS

This course has been designed as an intermediate level course to give learners an understanding of how a monitor reviews an investigative site's study files to ensure they are accurate, current, and complete. Learners will be able to identify essential documents, recall how a monitor should document the essential documents review process, and comprehend how a table of notes can be used to review IRB correspondence.

HOW TO CONDUCT PRODUCT ACCOUNTABILITY

This course has been designed as an intermediate level course to give learners an understanding of how a monitor helps to ensure that the investigational products supplied by the Sponsor to an Investigator are accounted for during a clinical research study. Learners will be able to identify product accountability requirements for Investigators, recall items needed to perform product accountability, and recall examples of inadequate accountability that have resulted in FDA warning letters.

RISK-BASED MONITORING OVERVIEW

This course has been designed as an intermediate level course to give learners a basic understanding of risk based monitoring. Learners will be able to define Risk Based Monitoring, list the approaches used in Risk Based Monitoring, and explain a risk-based approach for a hypothetical medical device trial.

INTRODUCTION TO U.S. FDA REGULATIONS PART I: 21 CFR PARTS 312 AND 812

This course has been designed as an introductory level course to give learners an overview of these parts of the Code of Federal Regulations Title 21 that pertain to investigational new drugs and investigational device exemptions. Learners will understand regulation of investigational new drugs and investigational devices by the FDA, and explain the responsibilities of Sponsors and Investigators in Investigational New Drug and Investigational Device Exemption studies.

INTRODUCTION TO U.S. FDA REGULATIONS PART II: 21 CFR PARTS 50, 56, 54, AND 11

This course has been designed as an introductory level course to give learners an overview of these parts of the Code of Federal Regulations Title 21 that apply when conducting an investigational new drug or investigational device exemption clinical research trial. Learners will understand the role of informed consent in ensuring human subject protection, the required elements of and documentation process for informed consent, the requirements for IRB composition, operation and compliance, the goals of disclosing financial interest, and required controls for electronic records and signatures.

COMPARING 21 CFR PART 312 AND 21 CFR PART 812

This course has been designed as an intermediate level course to give learners an understanding of the similarities and differences between these parts of the code of federal regulations related to clinical studies of investigational drugs and devices. Learners will review the key requirements of 21 CFR Parts 312 and 812, identify the primary similarities and differences, and understand the development pathways of new drugs and new devices.

THE HISTORY OF CLINICAL RESEARCH

This course has been designed as an introductory level course to give learners a deeper understanding of the events in history, both good and bad, that helped shape the clinical research industry. Learners will be able to recall significant events in history that influenced clinical research, match significant advances in regulation to what caused them, and explain the continued importance of research regulations.

INTRODUCTION TO GOOD CLINICAL PRACTICE

This course has been designed as an introductory level course on the concept of good clinical practice to give learners information about conducting clinical research in accordance with international guidelines. Learners will be able to define and explain Good Clinical Practice, identify the various guidelines and standards that comprise GCP, and describe the principles of the Belmont Report.

FAIR SHAKE™

This course has been designed as an introductory level course to give learners a tool for answering compliance concerns and questions. Using the acronym F-A-I-R, members of the research team will understand how to determine whether an issue is a true violation of research requirements. Learners will be able to recall the elements of the FAIR Shake Method, apply the method to potential compliance concerns, and understand the importance of supporting recommendations with the FAIR Shake Method.

INTRODUCTION TO HIPAA AND HITECH

This course has been designed as an introductory level course to give learners an overview of Private Health Information and protection of individual confidentiality as governed by HIPAA and HITECH. Learners will be able to describe HIPAA and HITECH legislative acts, list individually identifiable data elements that are protected under HIPAA and HITECH, and explain the impact that HIPAA and HITECH have on clinical research.

HUMAN SUBJECTS PROTECTION: DRILLING DOWN 21 CFR PART 50

This course is designed to provide the learner with an in-depth analysis of the requirements of 21 CFR Part 50 that pertain to informed consent of human subjects.

FDA INSPECTIONS 101

This course has been designed as an introductory level course to give learners information about why, when, and how FDA inspections of clinical investigative sites and Sponsors occur. Learners will be able to find the Bioresearch Monitoring Program (BIMO) inspectional guides, understand how to prepare for an FDA inspection, recall the mechanics of an FDA inspection, and comprehend potential inspection outcomes.

FDA INSPECTIONS 102: WALKING THROUGH THE BIMO INSPECTIONAL GUIDANCE FOR INVESTIGATIVE SITES

This course has been designed as an intermediate level course to give learners a detailed understanding of the FDA's compliance program guidance manual and the items assessed by FDA inspectors. Learners will be able to describe key topics assessed in FDA's BIMO guidance for site inspections, connect key topics with examples of evidence the FDA will review, and understand the guide as a foundation for quality assurance activities.

PRINCIPAL INVESTIGATOR OVERVIEW

This course has been designed as an introductory level course to give learners an overview of the role and responsibilities of a Principal Investigator of a clinical study. Learners will be able to describe the responsibilities of a Principal Investigator, understand the requirements they must follow when conducting a clinical study, understand how responsibilities may be delegated to other study personnel with proper oversight, and recall common warning letter findings.

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Building the Business Case for Clinical Research Training

Achieving Buy-in, Setting a Budget, and Demonstrating ROI

Most clinical research study sponsors recognize that having a properly trained clinical research staff is essential to ensuring compliance and bringing their device to market faster.

However, a lack of the three Bs—buy-in, bandwidth and budget—and concerns about whether training will produce a sufficient return on investment often keep them from moving forward.

As a leader in the area of clinical research training, IMARC Research has been preparing research professionals to understand and apply regulations and best practices for nearly two decades now. This guide is written by our own clinical research professionals, for other clinical research professionals. It will address the impact clinical research training has on study compliance and drug and device approvals. It will also cover:

- Key competencies clinical research professionals must master
- Common obstacles companies face when implementing training
- Guidelines for budgeting for training and developing more efficient, cost-effective training solutions
- Guidelines for measuring training outcomes and return on investment

The Impact of Clinical Research Training on Compliance

In the past two decades, the clinical research industry has taken steps to acknowledge the importance of training and equip researchers with the information they need to be successful.

A number of professional organizations now provide certification for clinical research associates and others in the field. Universities now offer degrees in clinical research administration, clinical monitoring and other related fields of studies. Continuing education options are available for a variety of roles and topics in research as well. Although there are still no standard requirements for training, the consequences of failing to provide it are serious and far-reaching.

Every trial occurs in multiple phases with a number of individuals involved, presenting many opportunities for human error. These errors can collectively result in:

- Illness, injury or even death of human subjects in the most severe cases
- Suspension of the clinical trial
- Lawsuits and/or regulatory fines
- Incorrect or incomplete study data
- A warning letter from the FDA
- Delays in bringing the device to market, leading to lost revenue potential
- Loss of credibility and reputational damage for the sponsor organization

These issues occur at various stages of the trials, illustrating the larger need for staff to undergo comprehensive clinical research training. Issues that result from improperly or inadequately trained research professionals can quickly snowball into bigger problems that can jeopardize an entire study.

Some Important Numbers to Consider

- Consider the fact that the cost of implementing, conducting and monitoring a large clinical research trial can cost as much as $1 million per site.[1]
- Failing to follow the protocol at the site level can invalidate data, potentially resulting in hundreds of thousands of dollars in wasted resources. That's not counting the loss of revenue resulting from a delay.
- More than 80% of clinical trials experience delays of 1-6 months, costing companies upward of $35,000 per day, per trial. For a trial delayed by six months, that's a cost of $6.3 million![2]

Clinical trials require substantial investment, which is why it is important to avoid risking delays caused by improperly trained staff that could be prevented through more effective education.

Key Competencies Clinical Research Professionals Must Master

Having a properly trained clinical research team minimizes the many risks companies face when executing trials. Although there are no standardized training requirements that apply to all clinical researchers, professional organizations have recommended all staff receive training in these fundamentals:

U.S. Code of Federal Regulations (21 CFR) for Clinical Research

- Part 312: Understanding investigational drug regulations, safety reporting requirements and researcher responsibilities
- Part 812: Understanding federal regulations for investigational medical devices, safety reporting requirements and researcher responsibilities
- Parts 50, 54, 56, and 11: Understanding guidelines for the protection of human subjects and consent, IRB requirements, financial disclosures and electronic records and signatures

Good Clinical Practice Guidelines

Human Subjects Protection and Proper Informed Consent

Subject Confidentiality—HIPAA and HITECH

The History of Clinical Research

How to Think Critically to Answer Compliance Questions and Concerns

Training your internal staff in these fundamentals demonstrates your organization's commitment to the highest standards of quality, ethics and professionalism.

It also fulfills continuing education requirements for clinical research professionals, which are often required to maintain employment or keep their certifications current.

Obstacles Companies Face When Implementing Training

Not surprisingly, cost is the most significant concern for many of the companies we encounter at IMARC Research. Companies are reluctant to invest substantial money to train staff when turnover rates within the industry tend to be high. Additionally, they are concerned that, as the field evolves, regulations and best practices can change and training will become outdated.

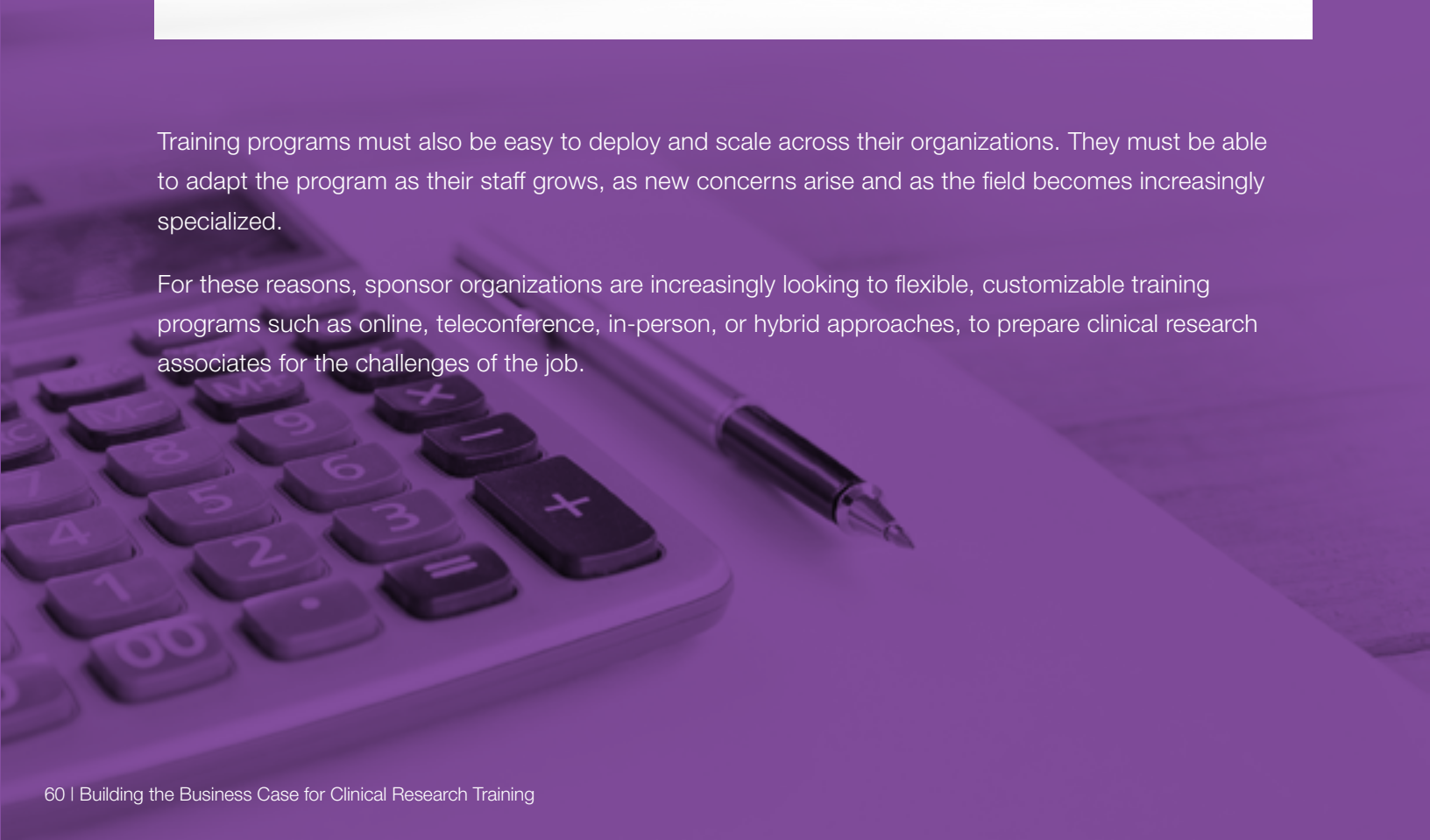
Companies want to ensure training is not only up to date, but immediately applicable within the field.

Other common obstacles include:

- Providing customized training for staff with varying levels of experience
- Finding the time for training, which can be a logistical nightmare for large companies or a difficult trade-off for smaller companies as it can mean missing critical tasks
- Determining what topics are critical and where credible training options are available

Training programs must also be easy to deploy and scale across their organizations. They must be able to adapt the program as their staff grows, as new concerns arise and as the field becomes increasingly specialized.

For these reasons, sponsor organizations are increasingly looking to flexible, customizable training programs such as online, teleconference, in-person, or hybrid approaches, to prepare clinical research associates for the challenges of the job.



Achieving Buy-In For Training

The best training programs can only be effective if individual team members see their value and are willing to invest the time and effort required to complete them. Here are some recommendations for bringing your team on board.

1. Involve Team Members and Key Stakeholders in the Discussion Early

It's not wise to spend weeks developing a training program or proposal without first having preliminary discussions about the budget, the scope of the program, and the timeline. The titles and roles of those who need to be involved will vary depending on the size and type of your organization, but here are some key stakeholders to consider:

- VP/Director of Clinical Research
- Clinical Team Supervisor
- Human Resources Manager
- Your Clinical Research Organization or partner responsible for training

Assemble a meeting with these critical team members and any others who are essential to the process. Consider forming a training committee to meet regularly as you consider options and develop a program.

Remember, it's just as critical to get feedback from team members who will actually be participating in the training. Consider including several team members on your training committee or distributing a survey to learn more about their preferences for training topics, formats and times.

2. Ensure Training Is Role-Based and Relevant to All Team Members

Among of the biggest complaints companies hear from employees about training:

"We didn't learn anything new."
"This was a waste of time."
"These are great ideas in theory, but they won't work for us in practice."
"This is good to know, but it doesn't apply to me or my job."

To ensure training is relevant for everyone, make it specific to individual roles within your team. Sponsor representatives should be familiar with the roles and responsibilities of all other study team members, including monitors, investigators and research coordinators, in order to ensure compliance of all parties throughout the study.

Here are some guidelines for sponsor training requirements.

Monitors are highlighted in each of the regulations as a group that needs to be qualified by training and experience. According to guidelines outlined in the International Conference on Harmonisation (ICH) and U.S. Code of Federal Regulations, "monitors should be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor the trial adequately. A monitor's qualifications should be documented."

Additionally, sponsors should select monitors qualified by training and experience to monitor the investigational study. With the exception of monitors, the U.S. regulations remain silent on any additional training requirements of the internal sponsor study teams. However, failure to ensure appropriate training for key individuals, such as the project manager in-house CRAs, medical reviewers or others interacting with the sites and/or data, could lead to compliance issues for a study. Training should be commensurate with the responsibilities of the role. And as staff roles and responsibilities can change during the course of a multi-year clinical study, it is critical to document ongoing training efforts.

SPONSOR PERSONNEL				
REQUIREMENT	21 CFR 312	21 CFR 812	ISO 14155	ICH GCP
Monitors shall be qualified by training and experience	*21 CFR 312.53 (d)*	*21 CFR 812.43 (d)*	*8.2.4.2*	*5.18.2*
All study team members shall be qualified…	*Guidance for Industry-Investigator Responsibilities (section III.A.2)*		*5.1*	*2.8*

In addition to providing relevant role-based training, make it practical by using experienced staff who currently work in the field and incorporating real-world examples wherever possible.

3. Remind Team Members What's In It for Them

Training is an opportunity for team members to improve their confidence on the job, gain the respect of their peers and advance their professional goals. Training opportunities help build employee CVs and improve eligibility for exciting projects. Not only will it help them be more proficient in their roles now, it will make them more marketable for promotions or future opportunities.

In addition to reminding team members of what's in it for them, create excitement around training by tying it into a social event at the company, such as a special lunch or employee appreciation day. Add activities, quiz questions, case studies, helpful handouts, and small prizes to the training program to keep learners engaged.

Setting a Budget

How much should your company spend on training? There are no hard and fast rules, but there are some benchmarks and guidelines.

In general, investments in new technology have made training more affordable.

While companies spent less per learner, they provided more hours of training, recognizing that employees require continuing education to stay current. On average, U.S. employees across industries received 53.8 hours of training in 2015, 13 more hours than last year, according to the 2015 Training Industry Report.[3]

As you set a budget for your training program, here are a few important questions to ask:

- Do you have in-house instructors with the right expertise to cover each skill set, or will you need to hire a trainer or organization to lead the training?
- Will you host training in-person, online, via teleconference, or a combination?
- Will you use a learning management system (LMS) that is hosted on an internal server, or a cloud-based LMS that associates can log into from anywhere?
- Will participation be optional or mandatory? Who will receive the training?
- How many team members will participate, and how will you ensure those who sign up will attend?
- If hosting in-person training, are there travel costs associated for any of your team members or for the trainer?
- If working with a training partner, are there discounts for large groups?
- If working with a training partner, is the training considered 'off-the shelf' or tailored to meet the needs of your team?
- Consider whether the program will be offered once or on an on going basis?

Taking the time to assess the training needs and answer the questions above will help guide development of a reasonable training budget that identifies internal resources or a need for external assistance. When setting a budget, you may identify a per-person cost or range to stay within, or you may issue a request-for-proposal to identify a cost-effective partner.

Training In-House Vs. Outsourcing: A Cost Comparison

Take inventory of your team's internal and external resources and conduct a gap analysis to determine what you are missing expertise or bandwidth. Next, compare the costs of hosting an in-house training program with the cost of outsourcing. The average salary for a training and development manager is $72,700 per year, according to PayScale[4], and the investment of time and resources to develop internal training materials may not be trivial. Then compare to the cost of hosting a one-time training program, which can range from $200-$3,000 per employee depending on the type, duration, and location of the training. Consider these costs and efforts and determine if training can be handled in-house or if outsourcing is the next step.

Making Training Flexible and Affordable: Four Stories

1. A large medical device company was searching for a solution to ensure all team members received standardized training in regulations and critical skill sets. The company had previously conducted in-person training with IMARC Research, but the clinical research director wanted to make the training more flexible and adaptable to everyone's schedules. IMARC Research provided the company with access to an online training portal where the company could select from a variety of self-guided courses covering a range of important topics for sponsor representatives. Approximately 20 team members participated at a cost of $1,500 per user.

2. In another case, a clinical research director knew her team required an in-depth refresher on GCP concepts. Approximately 35 team members were granted access to an online training portal to complete selected courses at a cost of $275 per user.

3. A medical device company wanted to ensure its 10 team members all understood the fundamentals of good clinical practice. IMARC Research hosted a one-day, intensive refresher course at the site for a cost of $1,000 per person.

4. An international CRO wanted to provide customized training on FDA regulations to its 20 staff members. IMARC Research developed two 2-hour teleconference training sessions at a cost of $350 per person.

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Measuring Success and Demonstrating ROI of Training

With some investments, the return is obviously visible and measurable over time. With investments in training, it can be more difficult to determine. However, it is important to find meaningful ways to measure success so you will be able to make the case for future investments in training.

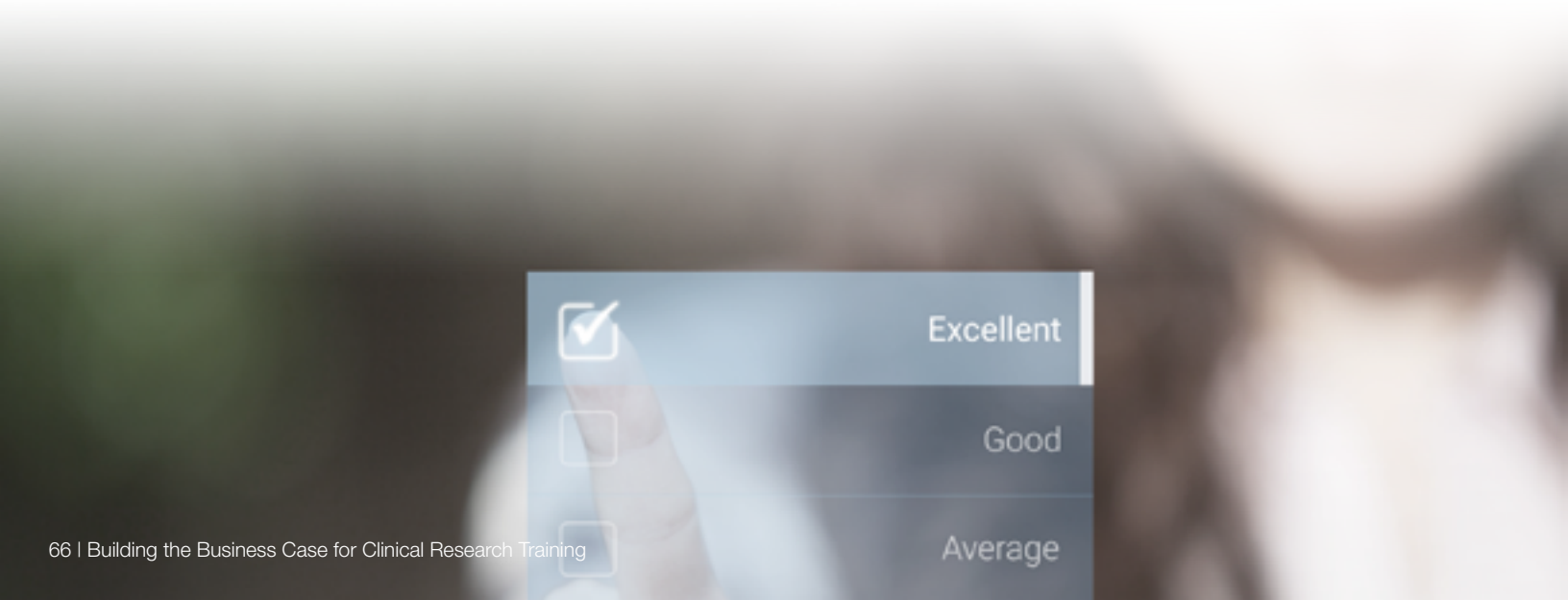
Here are a few ways to do that.

1. **Conduct knowledge assessments before and after training.** Your training provider can offer guidance on what participants will be expected to learn and may even be able to offer questions.

2. **Conduct post-training surveys.** It's important to gather feedback from participants, even if it's subjective. Include a mix of open-ended questions and questions you can measure, such as, "On a scale of one to five, how confident are you in your ability to perform this task after training?"

3. **Review data from performance evaluations.** If your company conducts regular performance evaluations, you can incorporate questions based on some of the skills covered in training. Ask participants' supervisors to give feedback on whether they have seen these skills improve.

4. **Track nonconformances with internal policies and standards.** Using a quality management approach, tracking these issues in a non-punitive way helps companies measure performance over time, as well as to identify gaps in training and opportunities for improvement.



Taking the Next Step

A well-trained staff is key to the success and integrity of your clinical study. That's why IMARC offers comprehensive training that can be customized to meet the needs of your team or individual staff members. Our training includes cost-effective in-person training, teleconferencing, and convenient online courses available through our IMARC University web portal.

IMARC's training programs have been developed to ensure clinical researchers understand the regulations as well as best practices and how to apply them using critical-thinking skills.

Training through IMARC is ideal for clinical research associates in a variety of roles, including:

- Project Managers
- Monitors
- Other Sponsor Study Team Members
- Research Coordinators
- Investigators

Training can be customized to meet the unique needs and backgrounds of teams of all sizes.

Whether you're working with new staff or experienced veterans, we offer training to advance their skills and teach them to think critically so you can be confident your study meets all compliance standards.

imarc
WE'LL EARN YOUR APPROVAL.

Learn more about training offered through IMARC University

Contact us for a free consultation to discuss your customized training needs. >

[1] National Center for Biotechnology Information
[2] Applied Clinical Trials Online
[3] 2015 Training Report
[4] PayScale.com