BARNETT INTERNATIONAL

Clinical Research Training Weeks

Core Role-Based Training for Clinical Researchers

VIRTUAL



Learn ◆ **Engage** ◆ **Network**

SUMMER 2025: June 2 – June 27, 2025

Special Pricing Available for Groups from the Same Company!

- Auditing Techniques for Clinical Research Professionals
- Clinical Project Management: Advanced Concepts in Project Management
- Clinical Project Management: Fundamentals of Project Management
- Clinical Trial Assistant Fundamentals
- Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators
- Comprehensive Monitoring for Medical Devices
- Conducting Clinical Trials Under ICH GCP E6
- CRA & CRC: Beginner Program
- Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance
- Introduction to Clinical Research
- Monitoring Clinical Drug Studies: Beginner
- Monitoring Clinical Drug Studies: Intermediate
- Monitoring Clinical Drug Studies: Advanced
- Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management
- Statistical Concepts for Non-Statisticians
- Trial Master Files: Why They Are Important and How to Organize Them Workshop

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Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance

Dates: Dates: June 2 - 3, 2025

Instructor: Indu Kayarat

Learning Objectives:

- Describe regulatory requirements for product safety
- Signal detection, risk assessment and management functions
- Define how to collect, assess, report, and analyze adverse events
- Demonstrate the importance of good adverse event data collection in identifying signals
- Signaling analyses based on FDA Good Pharmacovigilance Practices
- Introduce FDA Good Pharmacovigilance Practices and EMA Good Pharmacovigilance (GVP) Modules and their relevance to Aggregate Reporting, Risk Management, and Signal Detection
- Identify differences between U.S. and European regulatory requirements

Course Modules:

- What is Pharmacovigilance
- What is an Adverse Event Drug Reaction
- Global Regulatory References and Expectations
- Regulatory Reporting
- PV Audits and Audit Issues
- Signaling
- Characteristics of a Good Case Report
- Risk Management

Statistical Concepts for Non-Statisticians

Dates: June 2 - 3, 2025

Instructor: Misha Eliasziw, Ph.D.

Learning Objectives:

- Determine what information the statistician needs to determine the sample size
- Identify the appropriate sample statistical designs for a study
- Employ statistical terms used in clinical research
- Define the role of the statistician in the study design
- Determine the approach to become comfortable talking to statisticians

Course Modules:

- Elements in Choice of Statistical Method Descriptive Statistics
- Methods for Preserving Objectivity
- Inference, Generalizing to a Population
- Study Design
- Hypothesis Testing
- Power and Sample Size
- Choice of Statistical Method
- Specialized Topics
- Interpreting the Statistical Report

Trial Master Files: Why They Are Important and How to Organize Them Workshop

Dates: June 3, 2025

Instructors: Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C., Jim Markley, Laura Wiggins, M.B.A.

Learning Objectives:

- Describe the required components of a Trial Master File
- Recognize the importance of a well-organized Trial Master File
- Implement strategies for effective filing of required documents
- Identify processes that support the effective management of the Trial Master File
- Investigate common deficiencies in filing systems
- Participate in filing some key documents and discuss the rationale for the placement of such documents

Course Modules

- Required Components of Trial Master File
- Set Up and Maintenance of a Trial Master File
- SOP Review and Critique
- Practical Experience Filing Using a Sample Trial Master File
- Discussion of Common Deficiencies and Review of Challenges Presented by Participants

Monitoring Clinical Drug Studies: Beginner

Dates: June 4 - 6, 2025

Instructors: Nikki Christison, B.S., C.C.R.A., T.I.A.C.R., Sonja Cooper, Ph.D., M.B.A., Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., Lily Romero, P.A., C.C.R.C.

Learning Objectives:

- Discuss the role the CRA plays in the drug development process
- State the "letter" and "spirit" of FDA regulations as well as ethical considerations pertinent to conducting clinical trials
- Identify and select qualified investigators and the investigative site
- Prepare for and conduct Site Selection/Qualification, Site Initiation, Routine Monitoring, and Study Close-Out Visits
- Manage and report adverse events (AEs)
- List study documentation requirements and standards for collecting and reporting clinical trial data

Course Modules:

- Overview of Drug Development and ICH GCP
- The Clinical Research Team
- The Site Selection Process and Site Qualification Visits
- IRBs/IECs and the Protocol Approval Process
- Study Subject Recruitment, and the Informed Consent Document and Process
- Investigator's Meetings and Study Initiation Visits
- Managing and Reporting Adverse Events
- Investigational Product Accountability and Essential Documents
- Routine Monitoring Visits and Source Data Verification
- Clinical Data Management Overview, Trip Reports, and Study Close-out Visits

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Auditing Techniques for Clinical Research Professionals

Dates: June 4 - 5, 2025

Instructor: Shana Zink, B.S., C.C.R.A.

Learning Objectives:

- Apply auditing standards based in current law, regulations, and guidelines
- Utilize electronic systems to enhance your auditing techniques, allowing more efficiency in your daily monitoring or auditing activities
- Understand the role of quality systems in GCP, including techniques for detecting root causes of performance deficiencies and developing and implementing effective Corrective and Preventive Action (CAPA)
- Select investigators and records for auditing or special monitoring emphasis
- Conduct clinical investigator audits
- Detect, prove, and prevent scientific fraud and misconduct
- Learn techniques for writing audit plans and reports

Course Modules:

- The Standards: Important aspects of GCP-related law and regulations
- Trial Center Auditing Methods
- Fraud and Misconduct
- Data Trend Analysis
- Auditing Techniques Exercise
- Essential Documents
- Enforcers and Enforcement
- Summary of Auditing and QS Processes

Introduction to Clinical Research

Dates: June 4 - 5, 2025

Instructors: Nikki Christison, B.S., C.C.R.A.,T.I.A.C.R., Sonja Cooper, Ph.D., M.B.A., Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., Lily Romero, P.A., C.C.R.C.

Learning Objectives:

- Identify the members of the clinical research team and describe their primary roles and responsibilities
- Describe the difference between drug development and medical device development
- Discuss the historical events and importance of Good Clinical Practice (GCP) in clinical research conducted throughout the world
- Identify key FDA and EU regulations that pertain to clinical research
- Describe what a clinical protocol, informed consent, investigator's brochure, and essential documents are and their importance in clinical trials
- Identify how safety information is collected and reviewed during clinical trials
- Identify key resources and databases for information on clinical trials

Course Modules:

- The Evolution of Research Ethics
- Good Clinical Practice
- Investigational Product Development
- Clinical Research Team
- Elements of a Good Clinical Study
- Informed Consent and Confidentiality
- Clinical Trials and Safety Information
- Audits and Inspections

Clinical Project Management: Fundamentals of Project Management

Dates: June 9 - 10, 2025

Instructors: Shelley Marti, M.S.N., P.M.P. , M. Rosado MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Learning Objectives:

- Describe project management as it applies to clinical research
- Explore stakeholder and team engagement in project lifecycle management
- Define scope management and tools utilized by project managers, including the work breakdown structure, process mapping, and schedule management
- Identify how project managers work with the clinical operations team and stakeholders in risk identification, risk planning, and risk management
- Define effective vendor management and sponsor oversight in clinical trial projects

Course Modules:

- Introduction to Clinical Project Management
- Project Planning
- Effective Schedule Management
- Budget Planning
- Project Risk and Quality Management
- Vendor Management

What attendees are saying about Clinical Research Training Weeks:

"A good synthesis of presentation material and highlighting examples of what could occur in real-life situations."

- Barnett Clinical Research Training Weeks course graduate

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Comprehensive Monitoring for Medical Devices

Dates: June 11 - 13, 2025

Instructors: Heather Marshall, M.S.N., B.S.N., R.N., Shana Zink, B.S., C.C.R.A.

Learning Objectives:

- Discuss the FDA regulations pertaining to clinical research and describe the ICH structure and function
- Define the common terms used in the field of device clinical research and identify the three ways devices are characterized
- Prepare and conduct a pre-investigation visit, an investigator's meeting, an initiation visit, a periodic visit, and a closeout visit
- List the types of regulatory and study documents required for the sponsor and for the investigator
- List both the sponsor's and investigator's obligations as they relate to device accountability
- Describe the differences between adverse events, adverse device effects, and unanticipated adverse device effects
- Discuss the FDA inspection process and what can be learned from issued warning letters

Course Modules:

- Introduction to the FDA and the Medical Device Approval Process
- US Good Clinical Practices
- IRB Approval & Informed Consent Process
- Pre-Study Processes
- Study Documentation
- Monitoring
- Device Accountability
- Close-out Visits
- Managing and Reporting Adverse Events
- FDA Inspections

Monitoring Clinical Drug Studies: Intermediate

Dates: June 11 - 12, 2025

Instructors: Nikki Christison, B.S., C.C.R.A.,T.I.A.C.R., Sonja Cooper, Ph.D., M.B.A., Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., Lily Romero, P.A., C.C.R.C.

Learning Objectives:

- Describe various sponsor interpretations of FDA regulations and practical application of the ICH GCP E6 Guideline
- Discuss current trends in clinical research
- Evaluate and develop more efficient study tracking and management tools
- Identify more effective mentoring and CRA assessments
- Manage your sites more effectively and ensure their optimum performance
- Identify strategies for managing issues including root cause analysis and corrective and preventive action plans (CAPA)
- Develop effective monitoring plans and best practices
- Prepare sites for an FDA/Regulatory Authority inspection
- Describe how FDA/Regulatory Authority assess sponsor monitoring during inspections

Course Modules:

- Regulatory Recap and Update
- Monitoring and CRA Assessment, Monitoring Tools and Tracking Systems
- Successful Site Management
- Monitoring Plan Development and Best Practices
- Problem Solving and Prioritizing Monitoring Challenges
- FDA Inspections and Site Preparation

Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management

Dates: June 12 - 13, 2025

Instructor: Nikki Christison, B.S., C.C.R.A., T.I.A.C.R., Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., Lily Romero, P.A., C.C.R.C.

Learning Objectives:

- Define investigator and site noncompliance
- Describe performance management concepts and skills for effective site risk management
- Integrate prevention of performance issues and ensure adequate site issues management
- Implement Gilbert's Behavioral Engineering Model for a diagnostic root cause analysis process
- Apply performance management concepts in case studies with a focus on prevention and issues management
- Recognize components of effective corrective action planning and documentation
- Identify examples of corrective action planning for different site noncompliance case scenarios
- Discuss successful preventive action planning and implementation

Course Modules:

- Defining Investigator Noncompliance
- Performance Management Concepts
- Root Cause Analysis
- Application of Root Cause Analysis Concepts
- Application of Performance Management Concepts
- Corrective and Preventive Action Plans (CAPA) – Concepts and Examples
- Documenting Investigator Noncompliance
- Exercises in Concept Application

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Clinical Project Management: Advanced Concepts in Project Management

Dates: June 16 - 17, 2025

Instructors: Shelley Marti, M.S.N., P.M.P., Nazma M. Rosado MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Learning Objectives:

- Explain project management tools and principles used in clinical trials
- Formulate project priorities and approaches to manage project needs effectively
- Develop effective communication and leadership skills for the project needs
- Identify critical to quality factors and risks in a clinical trial project
- Appraise effective stakeholder and vendor management in clinical trials
- Describe effective leadership skills in leading project teams

Course Modules:

- Introduction
- Importance of the Project Team
- Prioritization Management
- Managing Projects
- Project Risk and Critical to Quality Factors – ICH GCP E6 (R3) and ICH E8 (R1) in the conduct and management of a clinical trial
- Project Vendor Management and Oversight

Clinical Trial Assistant Fundamentals

Dates: June 16 - 17, 2025

Instructors: Nikki Christison, B.S., C.C.R.A.,T.I.A.C.R., Sonja Cooper, Ph.D., M.B.A., Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Learning Objectives:

- Review FDA regulations and the ICH GCP E6 Guideline for Good Clinical Practice (GCP)
- Describe the role the Clinical Trial Assistant and other team members in clinical research
- Describe the investigational product development process: Drug and device
- List essential documentation required in the conduct of clinical research
- Describe the Trial Master File
- Develop tracking tools used in clinical research
- Define investigational product management and accountability in clinical research

Course Modules:

- ICH GCP and FDA Regulations
- Roles and Responsibilities of the Clinical Research Team
- Investigational Product Development: Drug and Device Approval Process
- Investigational Product: Accountability, Management, and Issues Management
- Trial Master File: Set up, Maintain, and Manage
- Clinical Trial Start Up Process and Essential Documentation
- Clinical Trial Maintenance and Essential Documentation
- Clinical Trial Close Out and Essential Documentation

Monitoring Clinical Drug Studies: Advanced

Dates: June 17 - 18, 2025

Instructors: Nikki Christison, B.S., C.C.R.A.,T.I.A.C.R., Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., Lily Romero, P.A., C.C.R.C.

Learning Objectives:

- Explain the most recent regulations and guidance documents that govern clinical research
- Discuss current issues that affect clinical monitoring
- Describe effective mentoring techniques
- Discuss ways of assessing monitor skills
- Develop techniques to manage stakeholders
- Define techniques to promote successful site management
- Identify, manage, and report study-related issues
- Describe how to manage situations involving fraudulent data
- Discuss FDA's BIMO program for sponsor and investigator inspections

Course Modules:

- Regulatory Update
- Monitoring Visits Update
- Monitoring Plans
- Mentoring, Communication, and Negotiating Skills
- Co-Monitoring/Assessing Monitoring Skills
- Managing Stakeholders
- Site Management (Performance)
- Identifying, Reporting and Managing Study-Specific Issues/Corrective and Preventive Action Plans
- Managing Situations Involving Fraudulent Data
- Regulatory Compliance

What attendees are saying about Clinical Research Training Weeks:

"Great learning experience, enjoyed learning from the presenter and the other participants."

- Barnett Clinical Research Training Weeks course graduate

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CRA & CRC: Beginner Program

Dates: June 24 - 26, 2025

Instructors: Nikki Christison, B.S., C.C.R.A., T.I.A.C.R., Sonja Cooper, Ph.D., M.B.A., Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., Lily Romero, P.A., C.C.R.C.

Learning Objectives:

- Describe the investigational product development process
- Review FDA regulations and the ICH GCP E6 Guideline for Good Clinical Practices (GCPs)
- Describe the roles and responsibilities of the Clinical Research Associate and the Clinical Research Coordinator before, during, and after a clinical trial
- Identify the requirements of the Investigator in supervising clinical research
- Discuss the role of an Institutional Review Board, its composition, and responsibilities in the clinical trial process
- Define the informed consent process, the elements of the informed consent document
- Describe an overview of the different types of Monitoring Visits, including preparation, activities, and monitoring visit follow-up
- Define source documents and Case Report Forms (CRFs) in relation to CRF completion and source document verification
- Describe definitions related to safety management, identification of adverse events, and reporting requirements
- Describe the difference between a sponsor audit and an FDA inspection and preparation

Course Modules:

- Introduction to Clinical Research
- Clinical Research Team
- Investigational Product (IP) Development
- Good Clinical Practice
- The Clinical Study Protocol and Study Feasibility
- The Principal Investigator, Site Selection, and Study Initiation
- Institutional Review Board, the Consent of Human Volunteers, and HIPAA
- Safety Reporting
- IP Accountability, Essential Documents, and Routine Monitoring Visits
- Source Document Verification, Data Management, and the Trial Close-out Visit
- Interactive Exercises I and II
- Regulatory Compliance & Quality Assurance

Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators

Dates: June 26 - 27, 2025

Instructors: Nikki Christison, B.S., C.C.R.A.,T.I.A.C.R.,, Shana Zink, B.S., C.C.R.A.

Learning Objectives:

- Identify project requirements and risks
- Create tools and templates for clinical trial startup planning
- Identify three benefits of a communication plan
- Examine a WBS in clinical trial start-up
- Identify situations where a WBS would have a positive impact on clinical trial start-up planning

Course Modules:

- Defining Protocol Requirements and Risks
- Development of Protocol Specific Tools
- Creation of Communication Plans
- Work Breakdown Structure: Effective planning tool for your team and investigative site
- Application of the Start-Up Process: Development of a Work Breakdown Structure from time of site selection through IRB/IEC, budget/clinical trial agreement approval, and scheduling of site initiation visit
- Lessons Learned: Discussion and review of application

Conducting Clinical Trials Under ICH GCP E6

Dates: June 26 - 27, 2025

Instructors: Sonja Cooper, Ph.D., M.B.A., Lily Romero, P.A., C.C.R.C.

Learning Objectives:

- Summarize Good Clinical Practice (GCP)
- Identify Clinical Research Team Roles and Responsibilities
- Recognize how GCP impacts the clinical research process through review of key documents and necessary information for clinical trials
- Apply concepts of root cause analysis and corrective and preventive actions for quality management
- Discuss key elements for monitoring reports and written documentation in GCP
- Review regulatory compliance, audit preparation and inspections

Course Modules:

- Introduction to ICH and FDA GCPs
- Clinical Research Team Roles and Responsibilities
- Informed Consent and Essential Documents
- Root Cause Analysis & Corrective and Preventive Actions for Quality Management
- Compliance, Audits, Inspections & Conclusions

What attendees are saying about Clinical Research Training Weeks:

"I enjoyed the activities in the breakout sessions the most to engage with other participants."

- Barnett Clinical Research Training Weeks course graduate

Your Barnett Trainers

Nikki Christison
B.S., C.C.R.A.,T.I.A.C.R.

Nikki has worked extensively with both sponsors and CROs as a Study Coordinator, CRA, Project Manager, Auditor, and Director of Clinical Operations over the past 20 years, and has published articles in both The Monitor and The Journal of Clinical Research Best Practices on Risk Based Monitoring, Operational Advisory Boards, Study Feasibility, and CRO Relationship Management. Nikki has conducted hundreds of study visits and developed and facilitated training in multiple international venues. Nikki is an experienced speaker and has presented and conducted workshops at Association of Clinical Research Professionals (ACRP) Global Conferences, MAGI, Cambridge Healthtech Institute, iBIG, and Outsourcing Clinical Trials (OCT).

Sonja Cooper Ph.D., M.B.A.

Dr. Cooper has 20+ years of experience in clinical research and the pharmaceutical industry. She has extensive working knowledge of clinical research trials inclusive of procurement, program management, study start-up, recruitment tactics and challenges, clinical trial management, employee retention strategies, and audit processes. Dr. Cooper is well versed in building and fostering key relationships that lead to performance improvements, DEI initiatives, and constructing strategic alliances. She has held roles as Sr. Clinical Operations Manager, Project Manager, Trial Manager, Lead CRA, and CRA. Dr. Cooper serves as an expert in creating clinical monitoring processes such as monitoring evaluation programs, CRA oversight programs, central monitoring (risk-based) departments, role specific competencies learning sessions, and CPA-CRA-CTM step ladder promotion programs. Additionally, she serves as a mentor for Morehouse School of Medicine - Clinical Trials Office and has worked in higher education as an administrator and professor for 8 years.

Donna W. Dorozinsky
R.N., M.S.N., C.C.R.C.

Donna has over 25 years of experience in study operations that includes clinical operations, safety, data management, biostatistics, clinical supply management, and TMF management. She spent 15 years at SmithKline Beecham in early development and in 2005 founded DWD & Associates, Inc., which has most recently became Just in Time GCP. She has led the implementation of eSource and electronic Trial Master File solutions, and has expertise in clinical validation of these systems. She recently served as chair of the revisions to Zone 4 of the TMF Reference Model. Donna has presented numerous training programs in topics of GCP compliance, Quality Management Systems, and TMF Management and is a dynamic educator.

Misha Eliasziw Ph.D.

Dr. Eliasziw is a biostatistician who has over 30 years of experience in the design, management, and analysis of clinical trials and longitudinal cohort studies. Dr. Eliasziw has applied her skills to a wide spectrum of research areas, including acute and secondary prevention of stroke, multiple sclerosis, advanced brain imaging, cancer biomarkers, prevention of substance use among adolescents, reduction of traffic-related air pollution through filtration, prenatal nutrition, and prevention of obesity among children with autism spectrum disorder and intellectual disabilities. She has published over 250 peer-reviewed articles, and paralleling her research efforts, Dr. Eliasziw has taught biostatistics to graduate students, postgraduate medical education trainees, healthcare professionals, and clinical faculty. In recognition of her exemplary teaching abilities, she has received several teaching awards. Currently, she is an Associate Professor in the Department of Public Health and Community Medicine at Tufts University in Boston, Massachusetts. Dr. Eliasziw graduated from the University of Western Ontario with a doctorate in Epidemiology and Biostatistics and completed her post-doctoral training in biostatistics at Harvard University.

Janet E. Holwell
C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Ms. Holwell specializes in maximizing excellence in GCP quality, compliance and training for both sites and industry. She works with domestic and international clients to provide training and mentoring in the clinical research process, specializing in ICH-GCP compliance and quality oversight. She prepares clients for inspections/ audits as well as helps them write effective CAPAs and SOPs, develop quality plans and create internal QA processes. She began her career as a clinical research coordinator in academia over 35 years ago. She has held positions as a clinical research associate, site selection specialist, study manager with oversight of vendor CRAs, clinical operations quality management and trainer for several pharmaceutical companies. She is a fellow and dual-certified by the ACRP. Ms. Holwell has been an active member of ACRP since 1992, having served on the board of trustees, North American Council and various forums.

Indu Kayarat

Indu is an experienced drug safety professional with over 12 years of pharmacovigilance, project management, busi¬ness development and people management. She currently is em¬ployed as Associate Director with a leading global provider of clinical research services in their Aggregate Report Department. Her primary responsibilities involve project management, client interface, quality review of periodic reports, mentoring, training and contributing to leadership initiatives and innovations. She has also been involved in automation, preparing SOPs/guidance documents and process up¬dates within her domain. She is also involved in people management and mainly responsible for performance of direct reports (quality, compliance, productivity, profitability, and utilization to name few). Indu has an undergraduate degree in Biotechnology and a postgradu¬ate degree in Pharmaceutical Management.

Your Barnett Trainers

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Jim Markley

Jim assists clients in the management of their TMFs and maintaining oversight throughout the life of their studies. He has worked in the clinical research industry for the past eight years and has applied his ICH-GCP knowledge at a clinical site, large CRO, and in support of several sponsors. He has experience helping clients prepare for and manage FDA, EMA, MHRA and PMDA inspections.

Heather Marshall M.S.N., B.S.N., R.N.

Heather has over 20 years of research experience in the pharmaceutical and medical device arena focused on global Clinical Research in various roles and therapeutic areas including cardiovascular, CT surgery, neurology, and orthopedic surgery. As the Director of Clinical Affairs for a leading medical device company, Heather is leading numerous clinical studies, ensuring compliance with regulatory standards and advancing innovations in orthopedics. Prior to this role Mrs. Marshall led a safety team for a medical device CRO working with Medical Monitors, Data Safety Monitoring Boards, and Clinical Events Committees. In addition to her professional accomplishments, she is an experienced educator, having taught continuing education courses for cardiac nurses. Her commitment to education and her ability to convey complex concepts in an accessible manner make her an exceptional instructor for our research training programs. Participants can look forward to gaining insights from her vast experience and leadership in clinical research and medical device development. Mrs. Marshall holds an M.S.N in Nursing Leadership and Administration from the University of Phoenix.

Shelley Marti M.S.N., P.M.P.

Shelley has extensive background in global pharmaceutical corporations with proven expertise in GCP and GCLP standards, worldwide health authority regulations, and quality assurance/compliance systems. Shelley has leveraged deep operational knowledge of drug development to empower and drive performance with cross-functional teams, ensuring companies achieve strategic goals while maintaining high-level quality/efficiency through strategic target setting, focus on execution and creating strong collaborations with stakeholders at all levels. Shelley is inclusive, practical, organized and a solution-oriented contributor known for leading by example with a positive 'can-do' attitude. Areas of expertise include: Quality, Audit Plan Strategies (Risk Based), Quality Agreements / Oversight Plans, Global Quality Project Leadership, Lead & Manage Quality Governance Frameworks, Quality Dashboard Development & Execution, Inspection Readiness Efforts, Investigation & Management of Quality Events, Onboarding & Training Strategies (Internal / External) and Quality Insight Analysis.

Lily Romero P.A., C.C.R.C.

Lily has over 30 years of experience in clinical research. Her experience includes positions as Director of Global Development Training at Elan Pharmaceuticals, an Associate Director of Clinical Operations at Quintiles, Inc., a Clinical Research Coordinator and Research Administrator at the Allergy & Asthma Medical Group and Research Center, and a P.C. in San Diego, CA. She has worked on Phase I-IV clinical trials including pediatric studies. She was an instructor for and assisted in the development of an investigator GCP training workshop for the American Academy of Pharmaceutical Physicians. She is on the Advisory Board and an instructor for the Clinical Trials Design and Management certificate program at the University of California at San Diego (UCSD) Extension. Currently, she is a member of the Academy Board for the Associates of Clinical Research Professionals (ACRP).

Nazma M. Rosado MAOL, P.M.P., CPLP, 6σ

Ms. Rosado has over 27 years of experience in the Biopharma industry having worked with companies such as Pfizer, Medimmune, Genentech, Astellas, EMD Serono/Merck KGaA, Janssen, Alexion, CuraGen, and various consulting companies. Ms. Rosado was involved with TransCelerate Biopharma, Inc. for 2 years and served as a Co-Lead for the Change Management Council and as the Change Champion for Astellas Pharma. She has been a Program Manager, Project Manager, Study Manager, and CRA before her move to leadership positions. She is an Adjunct Professor at Suffolk University Law School where she teaches a course on Pharmaceutical Development. She also teaches at MassBioEd's Apprenticeship program. Ms. Rosado has a B.A. in Neuroscience and a B.A. in Psychology from Colgate University and an M.A. in Organizational Leadership from Gonzaga University.

Laura Wiggins M.B.A.

Laura has over 20 years of experience in the clinical research and marketing industries. Her earlier work included patient recruitment, media planning and buying, participant outreach, business development and medical writing within the Phase 1 and multi-site CRO space. Laura currently coordinates TMF management activities and works with clients to analyze, develop and implement processes that support business use of electronic clinical systems to ensure TMF quality and completeness. Laura has a passion for organization and collaboration with her colleagues and clients to achieve results.

Shana Zink B.S., C.C.R.A.

Shana has over 25 years of research experience in the pharmaceutical and medical device arena with the past 15 years focused on global Clinical Research in various therapeutic areas including cardiovascular, orthopedic surgery, bariatric, oncology and plastic surgery. From 2013- 2018, Shana was Vice President of Clinical Affairs at AtriCure, Inc., an innovative leader in the treatment of atrial fibrillation. Prior to AtriCure, she held positions with a variety of responsibilities including Quality Assurance and Clinical Affairs at J&J, Proctor & Gamble and Searle Pharmaceuticals (a Monsanto Company). Ms. Zink holds a B.S. in Biological Sciences from Northern Illinois University and obtained a certificate in Project Management from Boston University Corporate Education Center.

Virtual Event Information

Clinical Research Training Weeks | Summer 2025

Clinical Research Training Weeks offers clinical research professionals the opportunity to participate in instructor-led, core clinical research training courses in a dynamic virtual environment. This interactive setting features engaging content that requires hands-on interaction with our instructors and other learners through case studies, continuous knowledge checks and assessments, and group breakout room assignments. Learners will be able to ask questions, chat, and interact throughout the sessions.

WHY ATTEND?

- Engage in live, instructor-led training where you can interact with industry experts
- Connect from anywhere and participate in hands-on learning that leverages cutting-edge technology for an interactive learning experience
- Learn through real-world, application-based content with job aids and tools that can be implemented immediately in your setting
- Ability to ask questions and learn from others' experiences and challenges
- Opportunity to network with other participants in the clinical research field

Who Should Attend?

Barnett's courses are widely attended by Clinical Research, Data Management, Project Management, Regulatory Affairs and Quality personnel who require an understanding of how to perform their tasks within a GCP-regulated environment. The courses will also benefit other personnel who need to be familiar with the essentials of clinical research processes and requirements.

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education (ACPE). Core Curriculum participants will receive continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

COURSE PRICING:

EARLY BIRD PRICING

1-day courses	$850
2-day courses	$1,675
3-day courses	$1,795

Use promo code **CRTWV10** to **receive 10% off** your registration!

BEGINNING: May 10, 2025

1-day courses	$1050
2-day courses	$1,875
3-day courses	$1,995

GROUP DISCOUNTS: Special pricing is available for groups from the same company. Contact Barnett customer service for a group quote.

BONUS DISCOUNT: Call Customer Service at (800) 856-2556 to register for two courses and receive 20% off the second course!*

About Barnett International:

Our values and mission statement are simple: Barnett's goal is to further the capabilities of the clinical research industry and improve the lives of patients through excellence in education and training. The "Barnett Difference" is evident through our high-quality content, instructors who are not only trainers experienced in adult learning but are also subject matter experts working in the field, and our deep organizational understanding of the clinical research process.

**Discount for Second Core Curriculum Course will be applied to the lowest priced course.*

How to Register:

Online: BarnettInternational.com/Clinical-Research-Training-Weeks
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Email: customer.service@barnettinternational.com