Clinical Research Monitoring and GCP Workshop
for Site Coordinators, Monitors and Auditors

Day 1-

7:45-8:00am  Registration and Continental Breakfast (provided)

8:00-9:45am  Good Clinical Practice: Obligations of the Sponsor and Monitor
               • Basic Principles
               • International Conference on Harmonisation
               • Investigator’s Responsibilities
               • Sponsor’s Responsibilities
               • Monitor’s Responsibilities
               • Record Retention
               • Basic Requirements for Conducting Studies in Canada

9:45-10:00am Break

10:00-11:00am Investigator Recruitment and Selection: What is the Sponsor Looking For?
               • Investigator Recruitment
               • Potential Investigative Sites
               • Investigator Selection Factors
               • Site Selection Visits

11:00-12:00pm Ethical Considerations
               • Institutional Review Boards
               • Financial Disclosure

12:00-1:00pm Lunch (provided)

1:00-2:00pm Informed Consent
           This session will review the informed consent process, including discussion of
           requirements in the FDA regulations and the ICH E6 guideline, and some of the
           challenges in obtaining informed consent.

2:00-3:00pm Study Initiation Activities
            • Budget/Contract Negotiation
            • Essential Document Definitions and Collection Mechanisms

3:00-3:15pm Break

3:15 – 5:00 Monitoring Activities and Site Visits
          • Purpose
          • Preparation
          • On-site Document Review
          • Visit Summary with Study Personnel
          • Visit Report and Follow-up Correspondence

Day 2-

7:45-8:00am Continental Breakfast (provided)

8:00-10:00am Monitoring Activities and Site Visits CONTINUED

10:00-10:15am Break
Day 2 - continued

10:15-11:30am  The Quality Assurance Audit – Audit Preparedness
• Distinguishing Auditing from Monitoring
• Sponsor Audits
• Getting Ready for an Audit
• FDA Inspections
• FDA Warning Letters

11:30am-12:15pm  Quality Assurance Exercise

12:15-1:15pm  Lunch

1:15-2:30pm  Completion and Discussion of Exercise

2:30-2:45pm  Break

2:45-3:45pm  Proactive Study Management
• Expecting the Unexpected
• Addressing Specific Challenges
• Improving Performance

3:45-5:00pm  Question & Answer; Discussion: Investigator Initiated Research
• Pros and Cons of Investigator Initiated Research
• Informed Consent / IRB Oversight
• Protocol Development / Protocol Approval
• Budgeting: Funds, Supplies, Personnel
• Is an IND/IDE Required?
• Sponsor-Investigator Responsibilities
• Data Management / Report Development / Publishing
• Adverse Event Reporting

Course Faculty

James Simmer, BSN, MBA, is founder and President of Research Answers, a clinical research consulting company whose mission is to assist physicians develop clinical research programs based on sound structure, consistency, efficiency, and accountability. Prior to founding Research Answers, Jim held positions as a Clinical Research Associate, then project manager in the pharmaceutical industry. After obtaining his MBA from Temple University, he was Research Director within a large medical center as well as a physician private practice.

Gretchen Gall is a Clinical Operations Manager at Novella Clinical, an international CRO focused on the unique needs of oncology, medical device, and dermatology sponsors. Companies that she has worked for include, Novella Clinical, Astellas Pharmaceuticals, and Novo Nordisk Inc. Additionally, she has been a consultant in the clinical research industry specializing in monitoring services, research site development, and audit preparation. Ms. Gall began her career in clinical research interning at a research site assisting with data entry and regulatory management. In 1999, she began her professional career in clinical research as a CRA. Ms. Gall brings 20 years of experience in the industry including experience in project operations management, clinical trial management, monitoring, FDA audits, process improvement, and ICH/GCP training.