

AGENDA DAY ONE: THURSDAY

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

8:00-9:00am - Welcome and Expectations

- What is "good clinical practice"
- The "spirit" of the conference
- Great change in the Industry
- Pharma Industry overview/drug approval process

9:00-10:15am - Good Clinical Practice: Obligations of the Sponsor and Monitor

- Basic Principals
- International Conference on Harmonization
- Investigator's Responsibilities
- Monitor's Responsibilities
- Company SOPs
- Record Retention

10:15-10:30am - Break

10:30-11:45am - Ethical Considerations

- Institutional Review Boards
- Informed Consents
- Financial Disclosure

11:45-12:45pm - Lunch (provided)

12:45-2:00pm - Investigator Recruitment and Selection

- Investigator Recruitment
- Potential Investigative Sites
- Investigator Selection Factors
- Site Selection Visits

2:00-3:45pm - Study Start-Up and Site Initiation Activities (Break - 2:45-3:00pm)

- Budget / Contract Negotiations
- Essential Documents
- Site Initiation
- Subject Recruitment Planning

3:45-5:00pm - Monitoring Activities and Site Visits

- Purpose
- Preparation
- On-site Document Review
- Visit Summary with Study Personnel
- Visit Report and Follow-up
- Monitoring Activities

AGENDA DAY TWO: FRIDAY

8:15-8:30am - Continental Breakfast (provided)

8:30-10:30am - Monitoring Activities and Site Visits (continued)

- Case Studies
- Exercises

10:30-10:45am - Break

10:45-12:00pm - Risk Based Monitoring

- Budget and Contacts - The Basics
- Essential Documents
- Site Initiation
- Subject Recruitment Planning

12:00-1:00pm - Lunch

1:00-2:00pm - Risk Based Monitoring (continued)

2:00-3:00pm - Quality Assurance Audit

- Difference between Auditing and Monitoring
- Sponsor Audits
- Preparing for an Audit
- FDA Inspections
- FDA Warning Letters
- QA Exercise

3:00-3:15pm - Break

3:15-4:30pm - Case Studies

COURSE FACULTY

James Simmer, BSN, MBA

Jim Simmer 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

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.