

SoCRA - 20th Annual Conference

Pre-Conference Seminars

Thursday, September 22, 2011 - 1:00PM to 5:15PM
Registration: 12:30PM - 1:00PM

How to Prepare for an FDA Audit

Steven Steinbrueck, MPH, President, Stonebridge GCP Consulting, Inc.

This interactive workshop will help you understand and prepare for an audit/inspection by the FDA. Following a brief introduction to the FDA, it will include a detailed review of Investigator and site staff responsibilities. The session will focus on how to anticipate and fulfill regulatory requirements and expectations regarding adherence to Good Clinical Practice, including the protection of the rights and welfare of research participants, protocol adherence, documentation and records management, and investigational product management. Participants will gain insights on understanding the selection of sites for audit, the inspection process, common inspection findings, and the FDA's auditors. We will address questions such as: What might make it more likely that my site will be selected for inspection and what might make FDA suspicious? Who are the auditors and how are they trained? What actually happens during an inspection? The workshop will end with a discussion and practical suggestions about developing an overall strategy for preparing your site for a possible inspection and how to coordinate an actual inspection. 001

IRBs and the Informed Consent Process

George D'Addamio, PhD, President, PharmConsult Inc

Initial and continuing ethical review by institutional review boards (IRBs) or independent ethics committees (IECs) and the informed consent process are the cornerstones for protecting the human research subject. Regulations establish requirements clinical research professionals must follow, and the International Conference on Harmonization Good Clinical Practice Guideline provides guidance on complying with national or regional regulations. Dr. D'Addamio will discuss the regulatory requirements for IRBs and the informed consent process, challenges in obtaining informed consent, and challenges in keeping pace with technologically-evolving clinical research. Lessons learned from past experiences and regulatory enforcement actions taken to strengthen the systems for protecting the research subject will be discussed. 002

Clinical Research Administration, Budgeting, Contract Negotiation and Finance: A Site's Perspective

Bryan Soronson, MPA, BS, FACMPE, CRA, Senior Administrator, University of Maryland Hospital
Lisa Benson, BS, CCRP, Director of Grants & Sponsored Programs, Department of Research, Connecticut Children's Medical Center

This session will discuss the elements of a clinical trial protocol, budget and contract, and the impact of these elements on the conduct of a trial. The administrative and financial aspects of the trial will be covered with special emphasis on the study administration, effective budget development and management and contract negotiations. This session will be interactive with participation from attendees to include developing and negotiating the study budget.. 003

GCP 101 for Sites - New Study Coordinator Workshop

Jacqueline Busheikin, CCRP, RN, Independent CRA, Jana Research

In an effort to enhance quality assurance at academic institutions, private practices or government-supported sites, SoCRA is offering a workshop for research personnel who are new to the field, or for those coordinators who want to refresh their understanding of GCP in the ever-changing world of clinical research. This four-hour interactive workshop will include presentations, group discussion and Q & A. The workshop will provide essential tools for coordinating and managing a research project. The material will range from understanding terminology to tackling a new project. 004

Presentation Skills Workshop

Richard Sloane, MS

Public speaking is considered one of our biggest fears. Hear simple techniques useful in overcoming this fear and begin to speak with confidence! Learn to give better introductions, use visual aids, give effective technical presentations, and even practice some extemporaneous speaking! Hands-on exercises will be used extensively. 005

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SOP Development and Implementation

Donna Headlee, BSN, CCRP, RN

The purpose of this workshop is to introduce, explain, and discuss fundamental concepts and current issues in the development and successful implementation of Standard Operating Procedures (SOPs) at the investigational site. The purpose of this workshop is to introduce the participant to SOP development and the process of SOP implementation at the clinical research site. The workshop will explain the basic principles and current challenges encountered during the implementation and development of investigational site SOPs. There will be discussion of writing techniques for effective SOPs. During the workshop the participant will develop a relevant investigational site SOP. The learning objectives will be accomplished through lecture, discussion, and "hands-on" exercises. Critical information will be presented and discussed including investigational site best business practices, the necessity for SOPs, SOP development, prioritizing SOPs, and implementing the SOPs at the investigational site. Discussion of SOP strategies for approval process, tracking SOPs, and development of the training program and continuous process improvement plan will complete this exceptional training workshop. 006

Legal Issues involving Researchers, including Fraud and Misconduct

Jason Kaar, JD, Associate General Counsel/ Assistant Professor, Uniformed Services University of Health Sciences

Traditionally research has been the one area in medicine where, other than the regulatory process, there has been little interaction with the legal system; however in recent years this has changed. Within the U.S. and internationally there have been increases in civil and criminal actions against researchers. This session will provide an overview of recent problem areas, as well as insights on how to avoid them. 007

Grant Writing and Protocol Development Workshop

Lesley Mitchell, Associate Professor of Pediatrics, University of Alberta

This session provides an overview of the development of grant applications and of protocol development. Getting started, avoiding common pitfalls, and identifying strategies to strengthen grant review scores will be addressed. Strategies for the development of defensible protocols will be presented. The session will be in a seminar format. Participants are free to bring new ideas as well as issues that have arisen in their own successful and/or unsuccessful development efforts for discussion. 008

Statistics in Clinical Research - Understanding Protocols and Statistical References

Lynn Babin, MSN, AAS, PhD Candidate, RN, CCRP, Senior CRA, PharmaNet

Do you skip over the statistical section of protocols? Does the thought of having to explain why certain analyses are going to be performed on your study make you wish you could crawl into a hole? If so, you are not alone. This very practical section is designed to be a low-stress, non-intimidating, entertaining, and fun (yes fun!) way to understand what the statistical terms in a protocol really mean. No equations and no math! This course is designed simply to understand the basic concepts. 009

Device Basics

Kathi Durdon, BA, MA, CCRP, Clinical Operations Associate, Welch Allyn, Inc.

Eddy Lyons, BSE, CCRP, Manager CRA Group, BIOTRONIK Inc.

This workshop is designed for those new to research or for those who would like to have a refresher on the device clinical research regulations and guidances. This workshop will be a comprehensive overview for those interested in device clinical research. 010

Project Management & Process Standardization in Clinical Trials

Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP Senior Director Clinical Operations, University of California San Francisco Immune Tolerance Network (UCSF ITN)

Cynthia Stowe, MPM, CCRP, Project Manager, Wake Forest University Health Sciences

In the last few years, it has become more and more important to use solid project management principles in clinical trials. Process standardization is also important to ensure that clinical trials are run in the most efficient way possible with as much consistency used across similar studies as possible. This pre-conference workshop will introduce users to an overview of project management principles following PMI guidelines, as well as an overview of basic process standardization techniques (using six sigma methodology) that will be relevant in clinical trials. Situational examples will be provided where possible. 011