

SoCRA - CLINICAL INVESTIGATOR GCP & TRIALS MANAGEMENT CONFERENCE
For Clinical Investigators and Key Research Staff

Thursday, December 3, 2009

- 8:15 – 8:30** ***Registration and Continental Breakfast***
- 8:30 – 9:15** **Welcome and Introduction to the Drug Development Process**
Carole Sampson-Landers, MD, Program Chairperson
Director, Global Clinical Development, Women's HealthCare, Bayer HealthCare Pharmaceuticals
Dr. Sampson-Landers will review the product development process and discuss how clinical trials are integrated into that process.
- 9:15 – 10:15** **Investigator / Investigational Site Responsibilities**
Gerald F. Meyer, Former Deputy Director, Center for Drug Evaluation and Research, FDA
Senior Consultant, AAC Kandle Regulatory Group
Mr. Meyer will highlight the importance of investigator and investigational site responsibilities, and relate Good Clinical Practice compliance to successful completion of clinical studies in support of New Drug Applications. He will describe how to prepare for an audit by FDA staff, how to address deficiencies, and will share past audit experiences.
- 10:15 – 10:30** **Break (with opportunity for discussion)**
- 10:30 – 11:30** **Protocol Development**
Lesley Mitchell, Associate Professor of Pediatrics, University of Alberta
Lesley Mitchell will present fundamental guidelines for producing a protocol that is comprehensive and clear. She will discuss the required components of the protocol including considerations related to research methodology, plans for analysis, budget preparation, and study timelines.
- 11:30 – 12:30** **Developing Grants for Clinical Research**
Lesley Mitchell, Associate Professor of Pediatrics, University of Alberta
The speaker will describe a successful format for organizing a competitive grant application. She will discuss format and required components of a writing plan. She will present techniques and tips on writing *for the reviewers* and insight into the grant review process.
- 12:30 – 1:15** **Lunch (provided) and opportunity for discussion**
- 1:15 – 2:15** **The Informed Consent Process**
John M. Furlong, RN, CCRP, Clinical Research Nurse Coordinator
Department of Anesthesiology, Thomas Jefferson University Hospital
Mr. Furlong will explain the informed consent process, including discussion of various aspects involved in administration and documentation. He will also review special considerations that may impact the process and offer suggestions for issues resolution.
- 2:15 – 2:30** **Break (with opportunity for discussion)**
- 2:30 – 3:30** **Informed Consent Forms: Rights, Rites, and Rewrites**
Mark Hochhauser, PhD, Readability Consultant
Because investigators must present consent forms both to IRBs and prospective subjects, they should: 1) Understand the IRB "rite of passage," 2) Recognize conflicts between regulatory compliance and subject communication, 3) Make sure consent forms (including HIPAA) are written using plain English principles, 4) Proof consent forms to eliminate confusing grammar and syntax errors, and 5) Rewrite consent forms based on reader feedback (if possible).
- 3:30 – 4:30** **Investigator-Initiated Research: Key Steps of Study Conduct from Concept to Publication**
Nancy Wintering, MSW, CCRP, Manager Research Project B
HUP Radiology and Nuclear Medicine, University of Pennsylvania
Ms. Wintering will provide an overview of the key steps involved in Investigator-initiated research. The roles and responsibilities of a Sponsor-Investigator will be discussed. Ms. Wintering will emphasize management strategies and approaches designed to ensure high quality data and to assure the protection of human subjects.

Thursday, December 3, 2009 (Continued)

4:30 – 5:00

Successful Research - What Does It Take?

Marie Falvo, CCRP, Program Chairperson
Health Project Coordinator, Pediatric Hematology/Oncology,
University of Rochester Medical Center

This presentation will offer a site's perspective on the key elements needed to run a successful clinical trial program.

Friday, December 4, 2009

8:15 – 8:30

Continental Breakfast

8:30 – 9:30

Safety Reporting (Adverse Events / Serious Adverse Events)

Jackie Busheikin, RN, CCRP, President, Jana Research

This session will review the definitions of adverse events and serious adverse events and adverse drug reactions. We will discuss the reporting requirements and evaluate scenarios related to safety reporting.

9:30 – 10:30

Source Documentation and Record Retention

George D'Addamio, PhD, President, PharmConsult, Inc.

This session will discuss source documentation required for clinical research. Topics of discussion will include the regulatory requirements, examples of source documents, and some of the challenges associated with ensuring compliance with the regulations. Practical considerations for managing the research efforts will be offered.

10:30 – 10:45

Break (with opportunity for discussion)

10:45 - 11:45

Clinical Trial Budgets and Finance

Angela Fornataro McMahon, JD, CHC, CHRC, CCRA,
Director, Research Compliance Program, University of California San Diego

This session will address issues involved in developing a comprehensive clinical trial budget. The speaker will address financial considerations and risk areas.

11:45 – 12:30

Lunch (provided) and opportunity for discussion

12:30 - 1:30

Clinical Study Agreements

Thomas Babbo, JD, Partner, Hogan Marren, Ltd.

Mr. Babbo will discuss the most common and problematic terminology inherent in agreements with research sponsors that study personnel need to be aware of in order to assure that the interests of their site and researchers are protected. He will consider negotiating terms and tools that will inform and educate the attendee so that they may be better prepared to negotiate contracts. He will present replacement terminology that will assure better understanding and long-term compatibility among sponsors, contract research organizations, and clinical research sites.

1:30 – 2:30

Monitoring Visits and Audits: Different Perspectives to Ensure High Quality Research

George D'Addamio, PhD, President, PharmConsult, Inc.

This session will discuss differences and similarities of monitoring visits and audits, two activities performed by sponsors to ensure high quality research. The relationships between laws, regulations, guidelines, and standard operating procedures will be discussed. The purposes of various types of monitoring visits will be described, as will the objectives and activities associated with a sponsor audit or FDA inspection.

2:30 - 2:45

Break (with opportunity for discussion)

2:45 - 3:30

Standard Operating Procedures for the Research Site

Jackie Busheikin, RN, CCRP, President, Jana Research

Current GCP guidelines recommend that research sites develop and follow Standard Operating procedures. This session will review the philosophy and rationale of SOPs, discuss various SOP templates and evaluate a sample SOP.

3:30

Closing / Adjournment