

# SoCRA Clinical Investigator GCP & Trials Management Conference for Clinical Investigators and Key Research Staff

Agenda for December 1 and 2, 2011 (Thursday and Friday) in New Orleans, LA

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## Thursday, December 1, 2011

- 8:00 – 8:15**      **Registration and Continental Breakfast**
- 8:15 – 9:00**      **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.
- 9:00 – 9:45**      **Investigator / Investigational Site Responsibilities**  
*Gerald F. Meyer, Former Deputy Director, Center for Drug Evaluation and Research, FDA*  
*Pharmaceutical Consultant*  
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.
- 9:45 – 10:00**    **Break (with opportunity for discussion)**
- 10:00 – 10:45**    **Protocol Development**  
*Monika Metzger, MD, MSc, Associate Member, Department of Oncology,*  
*St. Jude Children's Research Hospital*  
Dr. Metzger 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.
- 10:45 – 11:30**    **Developing Grants for Clinical Research**  
*Monika Metzger, MD, MSc, Associate Member, Department of Oncology,*  
*St. Jude Children's Research Hospital*  
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.
- 11:30 – 12:15**    **The Informed Consent Process**  
*John M. Furlong, RN, CCRP, Senior Clinical Nurse Coordinator, Department of Anesthesiology,*  
*Clinical Research Unit, Thomas Jefferson University Hospital, Philadelphia*  
Mr. Furlong will explain the informed consent process, including discussion of various aspects involved in administration and documentation based on established FDA Guidelines. He will also review special considerations that may impact the process and offer suggestions for issues resolution.
- 12:15 – 1:15**      **Lunch (provided) and opportunity for discussion**
- 1:15 – 2:00**      **Informed Consent Forms: Compliance? Communication? Confusion?**  
*Mark Hochhauser, PhD, Readability Consultant*  
The consent process reflects basic conflicts between compliance with federal regulations vs effective subject communications. This presentation will suggest readability and plain language strategies that can help resolve that conflict. Plus, a case study will describe possible liability issues from two confusing consent forms from a single study.
- 2:00 – 2:45**      **Sponsor-Site Interactions - A Key Element to Ensuring Successful Research**  
*Marie Falvo, CCRP, Program Chairperson,*  
*Study Manager, Vision Care, Bausch & Lomb*  
This presentation will provide insight on how understanding the sponsor/site responsibilities foster effective communication and ensures successful research.
- 2:45 – 3:00**      **Break (with opportunity for discussion)**
- 3:00 – 5:00**      **Breakout Sessions**
- BREAKOUT #1**    **Investigator-Initiated Research: Key Steps of Study Conduct**  
*Nancy Wintering, LCSW, CRC, CCRP, Research Program Manager, Thomas Jefferson University*  
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 present critical steps designed to ensure regulatory compliance, to collect high quality data and to assure the protection of human subjects.

## Thursday, December 1, 2011 (continued)

### 3:00 – 5:00 Breakout Sessions (continued)

#### BREAKOUT #3 “The FDA is here”... Are you ready?

*Kimberly M. Kiner, Bsc, CCRA, President, 2K Clinical Consulting, Inc.*

This session will involve a Mock Audit which will simulate an actual FDA GCP audit, including the introduction, review of documents, interview process, the identification of deficiencies and the debriefing portion of the audit. This session is designed to help effectively prepare for and implement a proactive approach to upcoming/future audits.

#### BREAKOUT #3 Clinical Trial Finances

*Angela Fornataro McMahon, JD, CHRC, CHC, CCRA,*

*Director, Research Compliance Program, University of California San Diego*

This session will address the responsibilities that fall upon clinical research professionals working without a clinical trials office/structure. Topics to be discussed will include: How do we budget? What is an allowable expense? Who will oversee the administrative aspects of the trial?

## Friday, December 2, 2011

### 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, CHRC, CHC, 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 – 12:45 Lunch (provided) and opportunity for discussion

### 12:45 - 1:45 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.

### 1:45 – 2:45 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.

### 2:45 - 3:00 Break (with opportunity for discussion)

### 3:00 - 4:00 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.

### 4:00 Closing / Adjournment