

SoCRA 19th Annual Conference Session Descriptions

Friday, September 24, 2010 Welcome and Opening Plenary Descriptions

Fri. Sept. 24 - Opening Plenary - 8:30 to 9:15

Welcome and Introduction

John Petrich, MS, RPh, President- SoCRA

Angela Kimel, MBA, CCRP, President Elect- SoCRA - Annual Conference Chair

Fri., Sept. 24- Opening Plenary- 9:15 to 10:00

The Law and Ethics of Informed Consent

Jerry Menikoff, MD, JD, Director, HHS, Office of Human Research Protections

Beyond what the federal regulations require, there are certain categories of information that law or ethics might indicate should be provided to prospective subjects. This talk will provide examples of these categories of information and discuss ways to make consent more effective. ¹⁰¹

Fri., Sept. 24- Opening Plenary- 10:45 to 11:30

Ethical Challenges in Clinical Trials

Steven Joffe, MD, PhD, Attending Physician, Hospital Ethicist, Dana Farber Cancer Institute

This talk will outline a conceptual framework for understanding the ethics of clinical research, present a systematic approach to assessing the ethics of a clinical trial, suggest ways to ensure excellence in informed consent, and highlight the special ethical features of clinical research involving children. ¹⁰²

Fri., Sept. 24- Opening Plenary- 11:30 to 12:15

Translational Research

Thomas Pearson, MD, MPH, PhD, Albert D. Kaiser Professor, Department of Community & Preventive Medicine; Senior Associate Dean for Clinical Research, University of Rochester Medical Center;

Director, Rochester Clinical and Translational Science Institute

Federal and private funders of research are increasingly insistent on accelerating the process of translating discoveries at the basic science levels to diagnostic and therapeutic modalities contributing to human health. Each of the necessary steps from basic to human, human to clinical, clinical to community have their own demands on the academic infrastructure. The Rochester Clinical and Translational Science Institute will be discussed as one set of strategies to assure the practical application of basic discoveries at the University of Rochester. ¹⁰³

Friday
September 24, 2010
Breakout Sessions

Track 1 - Advanced Management

Fri., Sept. 24- Advanced Management- 1:30 to 2:15
Successful Phase I Study Management
Erica Elefant, MSW, BSN, RN

Senior Clinical Scientist, Bristol Myers Squibb

Because the early life of a compound is dependent on the data and analysis derived from Phase I studies, it is imperative that these trials are managed and conducted with the highest quality and care. Therefore, well honed project management skills that can address the unique issues associated with Phase I studies are necessary. This session will examine the importance of Phase I studies in drug development and general considerations commonly associated with conducting a Phase I study. In addition, project management best practices specific to overseeing a Phase I study will be discussed. 104

Fri., Sept. 24- Advanced Management- 2:15 to 3:00
Dealing with Difficult Findings/Issues from the Clinical Site, Sponsor, and Monitor Perspectives
Dana Austin, BSN, MSA, RN

Project Manager, Pharmaceutical Product Development, Inc.

The speaker will explore methodologies for working through difficult site findings and issues from a clinical site, sponsor, and monitor's perspective to achieve positive outcomes. 106

Fri., Sept. 24- Advanced Management- 3:30 to 4:15
Submitting and Conducting a Sponsor-Investigator IND - Lessons Learned....the Hard Way
Bambi Grilley, RPh, CCRP, CCRC, CIP

Director, Texas Children's Cancer Center

Investigator initiated studies are complicated and require a well developed clinical research infrastructure. This is especially true of investigator-initiated studies conducted under a sponsor-investigator IND. This session will describe the different issues to be considered and addressed when implementing/conducting an investigator-initiated study. 108

Fri., Sept. 24- Advanced Management- 4:15 to 5:00
Generic Drug Trial Management and Regulatory Considerations
Emily Graham, MA, BA, CCRP

Project Leader – Global Clinical Development, Kendle International

In light of the current healthcare reform initiative, the need for more cost-effective drug options has become increasingly important. This session will provide an overview of the evolving generic drug market, trial design, execution challenges, and governing regulations. Particular attention will be given to ANDA submissions, in vivo bioequivalence (BE) & bioavailability (BA) trials, and drug retention requirements. 110

Track 2 - Academic Research

Fri., Sept. 24- Academic Research- 1:30 to 2:15
Recruitment and Retention: The Key to Research
Michelle Garcia, BSN, RN

Research Coordinator, Cleveland Clinic

Susan Thomas, MSN, RN, CCRP

Research Administrator, Cleveland Clinic Foundation

This session will provide information on recruitment and retention of research subjects. Included will be novel recruitment strategies, methods to increase enrollment, and how to maximize screening. Creative methods to retain subjects and diminish "study fatigue" will be discussed. 204

Fri., Sept. 24- Academic Research- 2:15 to 3:00
Creating and Using Source Document Templates
Leann Speering, MS, BS, CCRP

Clinical Research Coordinator, Summa Health System

The use of source document templates improves efficiency, standardizes data collection processes at both the site level as well as across sites, and impacts data integrity. Examples of useful templates, logs, data collection tools, etc. will be presented. The presentation will be from a site's perspective including investigator-initiated studies and industry-sponsored trials. Attendees will practice developing their own templates during this session. 206

Fri., Sept. 24- Academic Research- 3:30 to 4:15
Leveraging E-Tool Technology to Maximize Participant Accrual and Create Operational Efficiencies

Ruben Rodarte, MBA, MS, CCRP, Clinical Projects

Director, Pennington Biomedical Research Center

This presentation will evaluate the efficacy of an e-tool application developed to screen potential participants for a specific study while seamlessly matching them to alternative studies in cases when they are ineligible for the study they originally inquired about. The e-tool's capacity to screen participants for multiple studies simultaneously has significantly reduced recruitment study timelines and associated costs. The advantages of the new "cooperative" approach versus the traditional "silo" recruitment approach will also be explored. 208

Fri., Sept. 24- Academic Research- 4:15 to 5:00
Development of a Translational Research Program in Optical Imaging

Milton Marshall, PhD, DABT, RQAP-GLP, CCRP

Director of Quality Assurance & Compliance,

University of Texas Health Science Center

Our group uses near infrared light to activate fluorescent dyes to map the lymphatic system, and we are developing molecularly targeted agents to use in clinical trials. Challenges of the program include manufacturing products under Good Manufacturing Practice regulations, conducting preclinical safety testing under Good Laboratory Practice regulations, Investigator-initiated IND submissions, and conducting clinical trials. An overview of these components of our development program will be provided. 210

Track 3 - Research Ethics

Fri., Sept. 24- Research Ethics- 1:30 to 2:15

From World War II Until Now:

Why We Protect People in Clinical Trials

David Hucks, AS, CCCP, CCRP

Clinical Trials Coordinator, Cook Biotech Inc

This talk will explain the Nazi experiments and the Nuremberg trials. Additional information concerning the relatively unknown Japanese human experiments during WWII will be given. A timeline from the war through the Tuskegee incident to modern day ethics will be presented. 304

Fri., Sept. 24- Research Ethics- 2:15 to 3:00

Ethical Conduct of Research:

It Applies to Research Coordinators/Staff, Too

Gail Mayo, CCRP, RN

Research Services Consultant,

Vanderbilt University Medical Center

The speaker will define Responsible Conduct of Research (RCR), describe recent Office of Research and Integrity (ORI) citations, and discuss application to research staff. 306

Fri., Sept. 24- Research Ethics- 3:30 to 4:15

Legal and Ethical Issues in Research

Jason Kaar, JD

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

Newspaper headlines have been filled with claims of unethical behavior by scientists and researchers. This presentation will explore some of the many ethical challenges that researchers face throughout the research process. Topics will include conflicts of interest, informed consent, full consent, and preservation and use of research data. 308

Fri., Sept. 24- Research Ethics- 4:15 to 5:00

Captivating Ethics and Human Subject Protection

Training Like You've Never Seen Before

Tammy Neseth, BS, CCRP

Compliance Coordinator, Mayo Clinic Cancer Center

We all must be certified in human subject protection training, but how do we present it to our staff in a way that they will participate in training and retain the information once they leave the training. 310

Track 4 - Pediatric Oncology

Fri., Sept. 24- Pediatric Oncology- 1:30 to 2:15

Advances in Pediatric Cancer

Susan Cohn, MD

Professor and Director of Clinical Sciences,
University of Chicago

This talk will provide an overview of advances made in the treatment and outcome of various pediatric cancers over the past ten years. The speaker will also provide a glimpse into the future of pediatric cancer clinical research areas of interest. 404

Fri., Sept. 24- Pediatric Oncology- 2:15 to 3:00

Issues in Adolescents and Young Adults: Focus on Bone Tumors

Abha Gupta, MD, MSc

Staff Oncologist, Hospital for Sick Children

This session will present an overview of the issues specific to adolescents and young adults with an emphasis on bone tumors. 406

Fri., Sept. 24- Pediatric Oncology- 3:30 to 4:15

Industry Trials in a Cooperative Group Setting

Dori Triplett, MPH

Manager, Industry-Sponsored Trials Program,
Children's Oncology Group

This talk will present the nuances of collaborations between industry and cooperative oncology groups, specifically with regard to GCPs and sponsor obligations. 408

Fri., Sept. 24- Pediatric Oncology- 4:15 to 5:00

Protecting Patients' Interest - Interim Monitoring and Data and Safety Monitoring Committees (DSMCs)

Mark Krailo, PhD

Professor of Preventive Medicine,
University of Southern California

Data and safety monitoring committees (DSMCs) are charged with protecting patients' interests while patients are enrolled and follow-up data are being obtained on a clinical trial. We will examine the methods which are used to summarize data and how these are used by the DSMC. We will review some case studies in DSMC monitoring of randomized clinical trials. 410

Track 5 - Project Management

Fri., Sept. 24- Project Management- 1:30 to 2:15 Using Good Practices of Project Management for Managing Clinical Trials

Cynthia Stowe, MPM, CCRP

Project Manager, Wake Forest University School of Medicine

There are essential tools that can be utilized by a project management professional in clinical research. The ability to apply project management processes could be highly valuable to a project manager and to scientific research. Good practices of project management in the lifecycle of a project are relevant to clinical trials research. The processes generally accepted for most projects and accepted as good practice in the project management industry will be outlined in this talk. ⁵⁰⁴

Fri., Sept. 24- Project Management- 2:15 to 3:00 Ripple Effect in Clinical Trials

Cynthia Yones, BS, RN

Associate Director, Bristol Myers Squibb

Erica Elefant, MSW, BSN, RN

Senior Clinical Scientist, Bristol Myers Squibb

A single change to a final protocol may affect one or many aspects of a clinical trial. If this is not recognized at the time of change, it may have extensive repercussions later in the study once the change is implemented. This is because a clinical study encompasses a variety of components: scientific, regulatory, and operational, to name a few. Change management is a systematic approach to dealing with change. This approach will provide a systematic and proactive method to address protocol modifications. ⁵⁰⁶

Track 5 - Quality Management

Fri., Sept. 24- Quality Management- 3:30 to 4:15 Quality Management in Research

Deborah Hunter, BSN, RN, CCRC

Manager, Clinical Trials, Vanderbilt University Medical Center

Quality management is an overall system for evaluating clinical research processes, managing the protocol activities and accuracy of the data collected, and ensuring the protection of human subjects. Quality management activities in clinical research are part of an onsite management tool to measure, evaluate, and improve site performances. These measurements are achieved by implementing quality control and quality assurance checks across the continuum of the protocol. ⁵⁰⁸

Fri., Sept. 24- Quality Management- 4:15 to 5:00

Quality Assurance vs. Quality Control - What's the Difference?

Michael Lytwyn, PhD, RQAP-GCP

Senior Global Clinical Auditor,

Bayer Healthcare Pharmaceuticals Inc

Quality assurance (QA) and quality control (QC) are two important, but different, processes. Both are important parts of an overall clinical quality system. Monitoring can be considered as the sponsor's QC of the clinical trial at the investigator clinical site. In the classical sense of QA/QC, an audit of an investigator trial site can be considered as an audit of the QC process at that site, i.e. more an audit of the CRA's work in fulfilling the sponsor's QC requirements than an audit of the investigator. The ramifications of this approach will be discussed. ⁵¹⁰

Track 6 - Site Management

Fri., Sept. 24- Site Management- 1:30 to 2:15

Streamlining GCP Regulatory Affairs

Deidra Poucher, BSN, MSHS, CCRC, RN

President, D. Poucher Consulting

This presentation will examine the regulations and ICH guidelines governing the conduct of clinical trials and provide definitions of the different reporting requirements for drug, device, and biologic studies associated with GCP regulatory affairs. Ms. Poucher will define key regulatory documents and discuss a site's readiness for start ups and inspections. The development of a streamlined approach to regulatory record keeping based on observations from her experience as a GCP Quality Assurance Auditor will also be presented. ⁶⁰⁴

Fri., Sept. 24- Site Management- 2:15 to 3:00

Meaningful Metrics that Objectively Demonstrate Value to Sponsors

Sondra Pepe, CCRP

Senior Client Relations Specialist, Medidata Solutions Inc

It is commonly understood and frequently lamented that less than half the sites in a study contribute 3/4 of the subject enrollment. Even worse, almost 1/5 of sites contribute little or nothing to enrollment. In response, sponsors have begun to utilize various metrics to help them identify the high-performing sites before the trial begins. Sites want to understand how they are being evaluated and where they stand up in this new era of objective trial metrics. ⁶⁰⁶

Fri., Sept. 24- Site Management- 3:30 to 4:15

Source Documents: The Good, The Bad, and The Ugly

Yvonne McCracken, MPH, CCRC

President, Carolinas Research Associates

The cornerstone of Federal Regulations for source documents is "ALCOA" - Attributable, Legible, Contemporaneous, Original and Accurate. Why do many sites have difficulty reaching this level of compliance? We will explore the world of source documents and what the regulations require as essential. ⁶⁰⁸

Fri., Sept. 24- Site Management- 4:15 to 5:00
Best Practices of Monitoring Visits: Being ALCOA and FDA Compliant

Dana Austin, BSN, MSA, RN, Project Manager,
Pharmaceutical Product Development, Inc.

This presentation will discuss best quality practices of monitoring visits from a site and monitor's perspective; including collaborative efforts to achieve ultimate goals, ensuring subject safety and quality data. Essential components of a site visit and visit report writing are discussed from an FDA perspective. 610

Track 7 - Training and Education

Fri., Sept. 24- Training and Education- 1:30 to 2:15
What Does "Current" Really Mean in Regulated Training?

Shirley Roach MSHS, RN, CCRP
Regulatory Trainer, US Army, USAMMDA

We often require lots of annual GCP training in our organization. If cGCP training is so valuable, why are FDA findings always related to the same issues? We need to concentrate on "current" and learn from what works and what does not work. 704

Fri., Sept. 24- Training and Education- 2:15 to 3:00
Supervisory Responsibilities of Principal Investigators

Bruce Ross, PA-C, RQAP-GCP
President and CEO, Premier Clinical Research Inc

The speaker will identify key roles, delegation of authority, and responsibilities of research team members. Practical tools for the supervision of clinical trials will also be discussed. 706

Fri., Sept. 24- Training and Education- 3:30 to 4:15
Using Tool Development to Support Standard Operating Procedures and Staff Training at Clinical Trial Sites

Lenore Jackson-Pope, BSN, ACRN, CCRP
Director of Research Strategy & Development

Community Research Initiative of New England
Clinical trial site staff juggle multiple roles and perform an assortment of tasks while under pressure to meet enrollment and data deadlines. Ms. Jackson-Pope will discuss requirements for the streamlining of source documentation, provide examples of reminder checklists, and present information sheets for documentation purposes and task reminders at the site. Examples of tool development that support and streamline your operation will be given. The attendee will find that using tool development strategies in evaluating needs of the site, developing tools to support those needs and including the tools in standard operating procedures will support staff, enhance training, and help ensure GCP compliance. 708

Fri., Sept. 24- Training and Education- 4:15 to 5:00
Online Learning for Clinicians

Aleta Hodge, BS, MBA, Senior Medical Writer, Covidien

The speaker will discuss instructional strategies, learning objectives, content readiness for online learning for clinicians, and course evaluation methods for online training programs. 710

Track 8 - IRB

Fri., Sept. 24- IRB- 1:30 to 2:15
Hot Topics Impacting IRB Review

Ada Sue Selwitz, MA
Director, Office of Research Integrity, University of Kentucky

The objective of this presentation is to update coordinators on issues impacting IRB review. 804

Fri., Sept. 24- IRB- 2:15 to 3:00
Are You Human? Federal Regulations Defining Human Research, Categories of Exemption and Requirements for Waiver of Consent

V. Reid Sutton, MD
Associate Professor, Baylor College of Medicine

This is an interactive session focusing on common issues of IRB review of research. The presentation will cover; what qualifies as human subjects research, what defines research, what types of research are exempt, and which studies may qualify for a waiver of informed consent. Information to empower research associates in dealing with their IRB on these issues will be reviewed. 806

Fri., Sept. 24- IRB- 3:30 to 4:15
Common Pitfalls in Informed Consent Writing

Ruth SoRelle, MPH
Chief Science Editor, Baylor College of Medicine

The consent form is the only information you provide to your research subject. Writing a consent form should take time, but simple steps can make it easier – for you and the ultimate consumer – the person taking part in the study. Keep it simple – short paragraphs, short words, short sentences. 808

Fri., Sept. 24- IRB- 4:15 to 5:00
What Happens Behind Closed Doors? Is My Study Approved by the IRB Yet?

Wendy Lloyd, BA, CCRP, LPN, CIP
Regulatory Affairs & Compliance Specialist,

Vanderbilt University Medical Center-IRB
The speaker will explain the "bumps" in the road that delay IRB final approvals for protocol submissions. The speaker will also walk attendees through the many processes occurring during the approval process. The attendees will learn ways they can help speed up the process. 810

**Saturday
September 25, 2010
Breakout Sessions**

Track 1 - Advanced Management

**Sat., Sept. 25- Advanced Management- 8:30 to 9:15
Protocol Design - The Critical Groundwork for a
Smooth Operation**

Anne Martien, MBA, CCRP, CRCP
Clinical Research Associate, C-TASC

The content and design of a protocol will be thoroughly evaluated. Steps in the process will be defined. Errors to avoid will be discussed. Samples of excellently written sections will be available in handouts. The absolutely critical elements of a thoroughly thought-out plan followed by detailed writing will be emphasized. ¹¹²

**Sat., Sept. 25- Advanced Management- 9:15 to 10:00
Case Study of a Possible Seeding Trial**

Mark Hochhauser, PhD

Readability Consultant

Seeding trials are marketing strategies designed to encourage research physicians to prescribe study drugs after FDA approval. To work, such seeding trials must deceive researchers, subjects, and IRBs. This presentation 1) describes a possible seeding trial reviewed by our IRB and 2) includes 12 criteria that can help distinguish possible seeding trials from legitimate clinical trials.

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**Sat., Sept. 25- Advanced Management- 10:45 to 11:30
Lessons Learned from Ketek**

Jerri Perkins, MD

President and Founder, Perkins & Perkins Inc

This session will discuss FDA expectations related to GCP inspections. This interactive session will include strategies to develop and implement policies to assist investigational sites to be prepared for GCP inspections. ¹¹⁶

**Sat., Sept. 25- Advanced Management- 11:30 to 12:15
The NIH GWAS Policy: What Is It and What Does It
Mean for You?**

Laura Rodriguez, PhD

Acting Director, Office of PCE,

NIH/National Human Genome Research Institute

An overview of the NIH data sharing policy for genome-wide association studies will be provided. The underlying principles and scientific opportunity will be discussed. An outline of the investigator and institutional responsibilities under the policy will be presented. ¹¹⁸

**Sat., Sept. 25- Advanced Management- 1:30 to 2:15
Basic Physiological Research -
21 CFR 812 Does Not Apply**

Harvey Arbit, PharmD, MBA, BS, CCRP, RAC
Director, IND/IDE Assistance Program

University of Minnesota Academic Health Center

In addition to significant risk (SR), non-significant risk (NSR), and IDE exempt studies, there are basic physiological research (BPR) studies. 21 CFR 812 does not apply to BPR studies as these studies are not designed to determine safety and effectiveness. How the protocol is written may make a difference. ¹²⁰

**Sat., Sept. 25- Advanced Management- 2:15 to 3:00
Process Standardization in Clinical Trials:**

Basic Tools and Tips

Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP
Senior Director, Clinical Operations

Immune Tolerance Network, UCSF

In the last few years, process standardization has become 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 session will introduce users to an overview of basic process standardization techniques (using six sigma methodology, e.g DMAIC) that will be relevant in clinical trials. Basic tools used in process standardization will also be introduced (process maps, RACIs, etc.). Situational examples will be provided where possible. ¹²²

**Sat., Sept. 25- Advanced Management- 3:30 to 4:15
Introduction to Nonprescription Drug Products**

Leah Christl, PhD

Associate Director for Regulatory Affairs,

FDA, Center for Drug Evaluation and Research

The speaker will present an overview on what nonprescription drug products are, how nonprescription drug products are regulated by CDER, how nonprescription drug products are reviewed and labeled, and considerations for clinical researchers related to nonprescription products. ¹²⁴

**Sat., Sept. 25- Advanced Management- 4:15 to 5:00
Consumer Studies Conducted to Support Approval of
Nonprescription Products**

Laura Shay, PhD, RN, C-ANP

Social Science Analyst,

FDA, Center for Drug Evaluation and Research

The speaker will present an overview of the study design and analyses behind consumer studies that are often conducted to support FDA approval of nonprescription products. These studies include label comprehension studies, self-selection studies, and actual use studies. ¹²⁶

Track 2 - Enrollment

Sat., Sept. 25- Enrollment- 8:30 to 9:15
'Git R Done' - High Enrollment, But Only for the
Exceptional Research Coordinator
Lynn Blair-Anton, BSN, CCRP
Research Nurse Specialist IV

Vanderbilt University Medical Center

Over the past seven years that Ms. Blair Anton has been in research, she has developed two separate research sites into consistently high enrolling study sites. These proven techniques can be used by any group that is serious about being a high enrolling site for almost any study. It may not always be easy, but it can always be fun! ²¹²

Sat., Sept. 25- Enrollment- 9:15 to 10:00
Meeting the Needs of Non-English Speaking
Research Participants in the US:
The Informed Consent Process
Patricia Sweet, RN, MSN, CCRP, CIP
Nurse Consultant, NIH/NHLBI/OCA

This presentation will discuss the challenges of obtaining proper informed consent of non-English speaking research participants, regulatory requirements, GCP regarding use of the short form and long form translations. Challenges with obtaining translations and processes developed to address these issues will be presented. ²¹⁴

Sat., Sept. 25- Enrollment- 10:45 to 11:30
Successful and Not So Successful
Recruiting Methods for an Outpatient
Healthy Volunteer Clinical Trial
Jody Green, PhD, CCRP

Associate Research Director, Denver Health RMPDC

Subject recruitment for outpatient healthy volunteer clinical trials is challenging in that traditional recruitment methods for therapeutic trials in target populations are generally not as useful. In general, wider nets must be cast to recruit nonspecific targets resulting in diverse and creative recruitment efforts for fewer patients enrolled. This session will discuss alternative recruitment methods as well as an evaluation of their success.

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Sat., Sept. 25- Enrollment- 11:30 to 12:15
Consenting Research Participants Who May Have
Reduced Capacity to Provide Consent
Teddy Warner, PhD

Research Ethicist/Research Associate Professor,
University of New Mexico

Research must sometimes be conducted involving individuals with illnesses that impair their decision-making abilities. Several ethical and practical issues must be considered when attempting to enroll adults who are decisionally impaired or who are at risk for becoming impaired during the research. Consensus national standards, specific federal regulations, or specific OHRP guidelines are not available to guide IRBs or investigators in determining decision-making capacity or competence to provide informed consent. However, several written guidelines available for assisting researchers and IRBs in working with individuals with reduced decision-making capacity will be reviewed in brief.

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Sat., Sept. 25- Enrollment- 1:30 to 2:15
Special Circumstances in Informed Consent
Nancy Wintering, MSW, LCSW, CCRP, CRC

Manager Research Projects, University of Pennsylvania

This presentation will provide an overview of special circumstances in informed consent: vulnerable subjects, cognitively impaired subjects, assent, consent waiver, short forms, non-native speakers, translations, working with proxies and designated signatories and the documentation related to these topics. Examples will include samples of language in the informed consent, related CFR, IRB notifications, authorizations, and source note documentation. Concepts of Therapeutic Misconception and cultural sensitivity will be addressed. ²²⁰

Sat., Sept. 25- Enrollment- 2:15 to 3:00
Using EHR (Electronic Health Record) Databases for
Research and Quality Improvement
Bob White, MD, MPH

Medical Director of Clinical Informatics, LCF Research
An EHR becomes much more valuable when its information can be extracted to examine the practice's population of patients for activities and characteristics of interest to researchers and quality improvement staff. This is especially valuable when preparing for research to identify potential patients for a clinical study. Another benefit is actually conducting research on the EHR database when clinical detail is sufficiently robust. ²²²

Track 2 -Chapter Interest/Development and International Development

Sat., Sept. 25 - Chapter Development - 3:30 to 4:15
Chapter Orientation Session
Joyce Arnold-Avant, AAS, CCRP
Senior Management Assistant, Cato Research ²²⁴

Sat., Sept. 25 - Int'l Member Development- 4:15 to 5:00
Orientation Session: International Members Development (Specifically for members from areas other than the US and Canada)
Joanne Goldberg, MSc, BSc, CCRP, pht
Associate Scientific Director,
Fonds de la recherche en santé du Québec ²²⁶

Track 3 - Poster Session

Sat., Sept. 25- Poster Session- 8:30 to 10:00
Poster Award Program and Presentations
Joanne Goldberg, MSc, BSc, CCRP, pht
Associate Scientific Director,
Fonds de la recherche en santé du Québec
Selected poster presenters will present a synopsis of their work related to Clinical Trials and Clinical Trials Management. ³¹²

Track 3 - AE Reporting

Sat., Sept. 25- AE Reporting- 10:45 to 11:30
SAE Training for Large Multi Center Behavioral Intervention Clinical Trials
Judy Bahnson, BA, CCRP
Research Associate, Wake Forest University Health Sciences
SAE reporting for Behavioral Intervention trials present many challenges. This talk will describe the use of narrative case studies and pre/post tests for staff training and certification required for serious adverse event reporting in multi-center behavioral intervention clinical trials. ³¹⁶

Sat., Sept. 25- AE Reporting- 11:30 to 12:15
IRB Review of AEs, Violations, and Incidents: Reporting Unanticipated Problems and Serious and/or Noncompliance
Lisa Denney, MPH, CIP
Assistant Director HRPP,
University of California San Francisco
This presentation will discuss post-approval events and how they can be managed through the IRB process. Decision making and examples of how IRBs develop a serious and/or continuing noncompliance determination; and discussion on the overall reporting process to government, sponsors, and within the institution will be addressed. ³¹⁸

Track 3 - Monitoring

Sat., Sept. 25- Monitoring- 1:30 to 2:15
Monitoring to Make the Project Manager's Life Easier
Monica Acree, MEd, BS, CCRP
Senior Clinical Research Associate,
Tribe Clinical Development, Inc.
This session will describe how the monitor can be of value to the project manager in areas of site selection, enrollment, data management, and communications to the site. Specific methods that the CRA may use to assist sites in reaching the ultimate study goals of the sponsor will be outlined. ³²⁰

Sat., Sept. 25- Monitoring- 2:15 to 3:00
Effective Chart Review: Start at the Source
Jane Ferguson, MN, RN, CCRP
Quality Control CRA/Coordinator, Westat

The goal of efficient chart review is to ensure that the protocol has been followed, and that data reported are accurate, thorough, and complete. The role of chart review is not just to compare the CRFs with what is in the source documents. What is the best way to do this? Monitors: Come learn this effective method. Study coordinators: Come learn what we are looking for in our chart reviews. ³²²

Sat., Sept. 25- Monitoring- 3:30 to 5:00
"CSI" for Chart Review and Review of Medical Terminology for Monitors
Lynn Babin, MSN, RN, CCRP
Senior CRA, Pharmanet

This lecture will focus on reviewing/learning the skills for accurate and efficient chart monitoring of both out-patient and in-patient research. The presentation is also helpful for study coordinators with limited medical/nursing background. ³²⁴

Track 4 - Pediatric Oncology

Sat., Sept. 25- Pediatric Oncology- 8:30 to 9:15
COG Biopathology Center - Specimen Collection and Handling
Lisa Beaverson, BA, CCRP
Protocol & Education Coordinator,
Nationwide Children's Hospital

This presentation will provide information on collecting specimens for cooperative cancer group trials. This will include information on topics such as where to find specimen information in the protocol, how to collect the specimens (including handling and labeling) and how to ship specimens following the International Air Transport Association (IATA) regulations. The importance of providing high quality specimens for both clinical and translational research will also be discussed.

412

Sat., Sept. 25- Pediatric Oncology- 9:15 to 10:00
Site Coordination and Interactive Learning for New CRAs

Dawn Borgerson, BSN, CCRP, RN

Clinical Research Coordinator, Toledo Children's Hospital

This session will provide the basic foundation necessary to coordinate pediatric oncology clinical trials for members who are new to the profession. Interactive teaching methods will be used to discuss the roles and responsibilities of patient enrollment, data monitoring and regulatory requirements. Resources will be integrated to offer guidance and direction. 414

Sat., Sept. 25- Pediatric Oncology- 10:45 to 11:30
Practical Aspects of GCP for the Cooperative Group Site

Susan Devine, CCRP

Senior Manager CTSU, Hospital for Sick Children

This GCP talk will review the guidelines in practical terms as they relate to the multi-center oncology site. What does GCP mean to me? How do I comply with this guidance? 416

Sat., Sept. 25- Pediatric Oncology- 11:30 to 12:15
Pediatric Oncology Track - "Developing Institutional Policies Based on Group and Industry Requirements"
Ashley Mehta, Hons. BSc, CCRP

Supervisor, Clinical Trials Support Unit,

Hospital for Sick Children

The development of institutional standard operating procedures is necessary and vital for documenting a standard approach to specific clinical trial duties. A number of unique circumstances should be considered when developing site policies while working within a consortium research group. These considerations, the methodical approach to developing policies and the key to understanding policy needs will be examined throughout this presentation. 418

Track 4 - Oncology

Sat., Sept. 25- Oncology- 1:30 to 2:15
NCI and Industry Adverse Event Reporting Harmonization Initiative

Ann Setser, BSN, MEd

Nurse Consultant, National Cancer Institute

Based on recommendations from the caBIG® Clinical Trials Management Systems (CTMS) Steering Committee, representatives from NCI, industry, and FDA worked to define and compare AE components and processes of CTCAE and MedCRA use, to explore the feasibility of broad use of the NCA caAERS (Cancer Adverse Event Reporting System). 420

Sat., Sept. 25- Oncology- 2:15 to 3:00
Central IRB Review of Oncology Trials: The NCI's Model

Jeanne Adler, MPH, RN

Nurse Consultant, NIH/National Cancer Institute

To eliminate redundant reviews and streamline workload for IRBs and research staff participating in NCI-sponsored Cooperative Group trials, the NCI established the Central IRB (CIRB). In public presentations, this model provides study participant protections using a partnership between the local IRB and the NCI's CIRB. 422

Sat., Sept. 25- Oncology- 3:30 to 4:15
Key Coordinating and Monitoring Tips and Techniques

Jill Petro, BS, CCRA, CCRC, CRCP

Senior Clinical Research Associate,
Aureus Research Consultants

Oncology trials hold their own unique and complex issues for a coordinator and monitor. The speaker will review some of the distinctive challenges for both the coordinator and the monitor of an oncology trial. In addition, some possible solutions will be presented and time for feedback from the audience on best practices from others will be discussed. 424

Sat., Sept. 25- Oncology- 4:15 to 5:00
The Three Ms of Pharmacy -- Maintenance, Management, and Monitoring

Linda Knowlton, AA, CCRP

Assistant Project Manager,

Coalition of Cancer Cooperative Groups

During the presentation, Ms. Knowlton will review the audit guidelines for the pharmacy component that are provided to the cancer cooperative groups by the Clinical Trials Monitoring Branch. Common areas of pharmacy noncompliance will be reviewed. In addition, hints/tips for the daily management/maintenance of the pharmacy and how to keep yourself ready for an audit will be provided. 426

Track 5 - Global Research

Sat., Sept. 25- Global Research- 8:30 to 9:15
Globalization of Clinical Research: What Opportunities Lie Ahead?

Natalie Currie, BSc

Instructional Designer & Facilitator,

Natalie Currie/Clinical Research Inc

This presentation will examine the opportunities and challenges of conducting clinical trials in a global environment. Following a discussion of the ethical, regulatory and practical considerations of conducting trials in emerging countries, you will discover what lies ahead for clinical trials in North America. 512

Sat., Sept. 25- Global Research- 9:15 to 10:00
International Trials and ICH - Outsourcing Clinical Trials to China

Wenting (Wendy) Zhang, MD

CEO, SinoCure, LLC

This presentation will describe clinical trial applications in China and how to work with China's State Food and Drug Administration (SFDA) and follow the FDA, ICH and GCP regulations in China. The speaker will also address how to select the investigators, hospitals, and patients within the low cost, huge market in China as well as how to keep data secure and confidential. ⁵¹⁴

Sat., Sept. 25- Global Research- 10:45 to 11:30
Conducting Clinical Trials in Brazil

Herbene de Tolosa, MD, CCRP

Medical Director, PharmaDeal/BD&C Research

Dr. de Tolosa will present an overview of the Brazilian scenario on clinical trials including the regulatory environment, sites and patients availability, and infrastructure such as clinical labs and sample transportation possibilities. ⁵¹⁶

Sat., Sept. 25- Global Research- 11:30 to 12:15
The Challenges of Conducting Clinical Trials in Emerging Markets

J. Salvador Velasco, MD, PhD

Regional Manager, Roche Mexico

Emerging markets face different challenges during the feasibility, start up, conduction, and closure of clinical trials. Dr. Velasco will present an overview of those challenges and how we face them. ⁵¹⁸

Track 5 - Health Information Exchange

Sat., Sept. 25- Health Info. Exchange- 1:30 to 2:15
Care Coordination: The Role of Regional and National Health Information Networks in Health Reform
Jeff Blair, MBA, ACMI, HIMSS Fellow

Director of Health Informatics, LCF Research

President Obama has said that meaningful use of health information technology advanced by the American Recovery and Reinvestment Act (ARRA) is the "down payment" on health reform. Care coordination facilitated by health information exchange networks is one of the major areas of meaningful use defined by ARRA. In fact, ARRA funding will accelerate the implementation of electronic health record systems, e-prescribing networks, and health information exchange networks in a manner that will not only improve the quality of care at the point of care; it will also accelerate the transition to clinically specific data which can be communicated more quickly and inexpensively to clinical research organizations in the coming years. ⁵²⁰

Sat., Sept. 25- Health Info. Exchange- 2:15 to 3:00
Health Information Exchange Networks: A Valuable Tool for Patient Care and Research

Margaret Gunter, PhD

President and Executive Director, LCF Research

Health information exchange (HIE) networks have been evolving in recent years to bring together scattered electronic health care information from multiple organizations to help providers reduce medical errors and improve patient care and efficiency. Today, HIEs are more high-profile than ever, given the Obama administration's emphasis on developing health information technology as an important tool to reduce the cost escalation of health care. This presentation will discuss the benefits of HIEs, issues in their implementation, and their applications in both patient care and research. A case example of a developing HIE will be provided. ⁵²²

Track 5 - Regulatory

Sat., Sept. 25- Regulatory- 3:30 to 4:15
Clinical Trial Registration

Ellen Travis, MSN, NP/PA

Medical Information Coordinator, Abbott Vascular

This presentation will aid the attendee in understanding the clinical trial registration and results posting policies from an industry perspective. The speaker will discuss which trials are required to be registered and, if required, when, where, and how to register those clinical trials to be in compliance with FDAAA and the International Committee of Medical Journal Editors (ICMJE) and the potential repercussions for non-compliance. ⁵²⁴

Sat., Sept. 25- Regulatory- 4:15 to 5:00
Clinical Trial Registration and Results Reporting at ClinicalTrials.gov

Rebecca Williams, PharmD, MPH

Assistant Director ClinicalTrials.gov,
National Library of Medicine

Clinical trial registration is recognized as a component of international ethics codes, scientific publication policies, and is required by US federal law. Under Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) most Phase II-IV trials conducted in the US must be registered within 21 days of patient enrollment and certain clinical trials must report results within one year of the completion date. This session will review the specific legal requirements as well as the practical aspects of providing results information to ClinicalTrials.gov. ⁵²⁶

Track 6 - Site Management

Sat., Sept. 25- Site Management- 8:30 to 9:15

What Not to Record on a Case Report Form: An Investigator's Real-Life Nightmares

Jody Green, PhD, CCRP

Associate Research Director, Denver Health RMPDC

A Case Report Form (CRF) is intended to capture the participant's experience in a clinical trial. All entries on this essential document should be clear, concise and accurate but most importantly purposeful. This presentation will provide real-life examples of the types of information that do not meet these criteria and discuss value-added alternatives to consider. ⁶¹²

Sat., Sept. 25- Site Management- 9:15 to 10:00

Internal Audits

Doreen Appunn, MSN, RN

Manager, Research Compliance,

H. Lee Moffitt Cancer Center & Research Institute

There is just no nice way to discuss audit deficiencies. How we audit, what we report, and who we report to is inconsistent among institutions. Let's search for the right answers so we can benchmark best practice. ⁶¹⁴

Sat., Sept. 25- Site Management- 10:45 to 11:30

Whose Responsibility Is It....Really?

Stacey Basham, RN, RQAP-GCP

President, Rialto Quality Group LLC

Melissa Farrell, BSN, RN, CCRC

Consultant Study Coordinator, Rialto Quality Group LLC

This session will review the October 2009 FDA Guidance on Investigator Responsibilities, as it ties to the FDA Form 1572 and the delegation of responsibilities. Differences between education, training, and qualifications will be discussed. Case studies on over- and under-delegation, some of which are represented in recent warning letters, will be presented. ⁶¹⁶

Sat., Sept. 25- Site Management- 11:30 to 12:15

When the IRB Shuts Down your Clinical Study: Making Lemonade from Lemons

Christine Carter, PhD, MPH

Director of Surgical Research, George Washington University

The Department of Surgery at The George Washington University conducts hospital-based studies that require skilled nursing involvement to complete study protocols. One of our five hospital-based studies, with a particularly challenging set of procedures, received a suspension from enrollment due to a number of protocol deviations and deficiencies related to enrollment of our first (and only) patient onto study. This workshop describes the identified problems, the recommendations and stipulations from the IRB, our action plan to address the deficiencies, and a detailed description of the "take-home" messages that came out of the experience. ⁶¹⁸

Sat., Sept. 25- Site Management- 1:30 to 2:15

The Marriage of Research and the Out-Patient Clinic

Wendi Mason, MSN, CCRP, ACNP

Nurse Practitioner, Vanderbilt University Medical Center

This presentation will discuss the advantages to the patient and the benefit to the university/facility when a disease-specific program of research mixed with standard of care is developed. ⁶²⁰

Sat., Sept. 25- Site Management- 2:15 to 3:00

Hospital System Review and Approval of Human Subject Research Studies

Cheryl Chanaud, PhD, CCRP, CCRA

Executive Director, Memorial Hermann Hospital - TMC

Hospitals are sites for increasing numbers of clinical research studies. This talk will be a presentation of the formal research and review process conducted by a major hospital system with nine acute care hospitals and six specialty facilities. Topics will include inpatient studies, hospital operational issues, liability and financial considerations, and hospital responsibilities toward the support of research and research participants. ⁶²²

Sat., Sept. 25- Site Management- 3:30 to 4:15

Audit Preparedness

LisaDiane Etheredge, BA

Training Specialist III, PPD

This session will discuss various ways of preparing for an audit or inspection. We will consider the steps that site staff and monitors can take to be fully prepared for any audit at any time. ⁶²⁴

Sat., Sept. 25- Site Management- 4:15 to 5:00

Best Practices for Sites and Sponsors to Reduce Budget Negotiation Cycle Times

Rochelle Redding, BA, CMA, CCA

Clinical Research Coordinator, Institute of Addiction Medicine

This speaker brings a unique perspective to this topic after having served as a study coordinator/site manager and working as a consultant assisting sponsors with budget creation. Sponsors and sites agree on one thing: budget negotiations often delay clinical trial starts. This presentation will share best practices in use on both sides of the budget. What process improvements can sponsors and sites consider implementing to streamline the process without losing the personal touch? ⁶²⁶

Track 7 - Training and Education

Sat., Sept. 25- Training and Education- 8:30 to 9:15

Growth of a Research Nurse Orientation Program

Leni Mathews, MSN, RN, OCN, CCRC, CCRA

Clinical Research Educator,

The University of Texas, MD Anderson Cancer Center
The Office of Research Education and Regulatory Management has recently implemented a Clinical Research Nurse Orientation Program. Research nursing is not something that is taught in schools and therefore must be learned on the job. The hope is that a comprehensive orientation program including assignment of a preceptor, classroom lectures, departmental in-services, and individual and online training will promote federal regulation and good clinical practice compliance. Once the orientation program is evaluated in the research nurse population, the team hopes to expand the program to other titles including research data coordinators and study coordinators. 712

Sat., Sept. 25- Training and Education- 9:15 to 10:00

Training - It's in the Regs...or Is It?

Sandra Maddock, BSN, RN, CCRA

CEO, IMARC Research Inc

Literature suggests that many research professionals have never received formal training on the regulations. Using real-world examples, this session challenges attendees to critically think through the decisions they make on a daily basis and apply the regulations. Say, "It's in the regs" with confidence. 714

Sat., Sept. 25- Training and Education- 10:45 to 11:30

Drug Management for Clinical Trials

Clay Hurtubise, BSPHarm

Clinical Drug Trial Coordinator, Maine Medical Center

Mr. Hurtubise will present tips on how to standardize drug trials at your institution. Binder set up, labeling, and creation of e-learns and work flow to maximize results and lower stress on staff pharmacists will also be addressed. 716

Sat., Sept. 25- Training and Education- 11:30 to 12:15

The Adverse Events World Tour:

Making Research Training Fun

Leni Mathews, MSN, RN, OCN, CCRC, CCRA

Clinical Research Educator,

The University of Texas, MD Anderson Cancer Center

Richard Morse, ADN, RN, CCRP

Supervisor,

The University of Texas, M. D. Anderson Cancer Center
New Employees often have to sit through hours of Human Subject Protection Training. Often times, the training involves speakers who conduct lectures with PowerPoint slides. Over the past two years, our research education group has worked to integrate activities into research training. This presentation will explain how this was achieved. 718

Track 7 - Device Research

Sat., Sept. 25- Device Research- 1:30 to 2:15

Device Development:

How Corporate, Venture Capital, and Academic Goals Interact in Device Development

Arthur Wallace, MD, PhD

Attending Anesthesiologist and Professor,

University of California San Francisco

Research in academic medicine requires a search for money to fund development. Development is effected by the conflicting goals of grants, venture capitalists, corporations, academics, and science. A number of device development projects will be discussed as examples of the interacting and possible synergism of these competing forces. 720

Sat., Sept. 25- Device Research- 2:15 to 3:00

Technologies that Really Improve Health

Clifford Goldsmith, MD, BSc

Healthcare Strategist, Microsoft Corporation

Healthcare transformation is all about us. We hear a lot today that technology will be the key to lowering costs while maintaining or improving quality of care. The news is full of references to healthcare systems like hospital information systems, electronic medical records, health information exchanges, and personal health records. How do these all fit together? What really works? How can clinical research leverage innovative Health 2.0 technologies for efficiency and effectiveness? 722

Sat., Sept. 25- Device Research- 3:30 to 4:15

Managing Use Error Risk: Human Factors' Role in Device Submissions

William Muto, PhD, CPE

Principal Human Factors Engineer, Abbott Laboratories

Device safety risks extend to the interaction between users and the devices they operate. The FDA's Office of Device Evaluation (ODE) has increased monitoring and review of human factors as a core discipline in the control and mitigation of use error risks in 510k and PMA submissions. This presentation will review the current regulatory position on human factors and expected research, evaluation, and testing throughout the Design Controls process that provides evidence that manufacturers have assessed user-device interaction safety issues. 726

Sat., Sept. 25- Device Research- 4:15 to 5:00

Lessons Learned with Medical Device Research

Donna Headlee, RN, BSN, CCRP

Kathi Durdon, MA, CCRP

Clinical Operations Associate, Welch Allyn, Inc.

This interactive competitive session is designed to highlight and review basic concepts of medical devices and medical device research and lessons learned. 728

Track 8 - IRB

Sat., Sept. 25- IRB- 8:30 to 9:15

Changing IRB Operations to Address New CMS Billing and FDAAA Reporting Requirements

Paul Papagni, JD

Executive Director Clinical Research,

M. D. Anderson Cancer Center

CMS modifiers are required for Medicare billing for clinical trials. This creates a greater need for coordination of budgets, coverage analyses, and contracts with protocols, consents and amendments within the IRB process. Clinical Trial Registration has been expanded under FDAAA to include greater detail, demographics, outcomes and Adverse Event reporting.

Are Investigators prepared for this added burden? Who is responsible for ensuring reporting is timely and complete? What is the responsibility of the IRB to review? report? and/or monitor the reporting effort? What should legal do to minimize the burden? What does compliance need to know? Discussion will include operational changes and system modifications initiated to assist in the coordination of different areas needed to comply with these new mandates. ⁸¹²

Sat., Sept. 25- IRB- 9:15 to 10:00

Giving Voice to Research Participants: Should IRBs Hear From Research Participant Representatives?

Michael Hadskis, LL.B, LL.M

Assistant Professor, Dalhousie University Law School

The IRB decision-making framework for the review of biomedical research does not effectively allow for the voice of research participants to be heard before decisions are made that can affect the safety, rights, and wellbeing of these individuals. Thus, alternative decision-making models that would give greater voice to participants and enhance the likelihood of IRBs realizing their principal mandate must be explored. ⁸¹⁴

Track 8 - Finance

Sat., Sept. 25- Finance- 10:45 to 11:30

Cash Flow Tools and Techniques for Advanced Research Sites

Andrew Snyder, MBA, FACMPE, PMP

Director of Research Finance, St. Paul Heart Clinic, PA

This presentation will focus on cash flow management concerns faced by busy clinical research sites. This lecture will provide attendees with advanced and realistic tools to assist their daily payment management activities. Specific topics to be reviewed include revenue identification, research accounts receivable tools, cash flow management techniques and collections. The goal of this lecture will include sharing processes that clinical research site managers and coordinators can immediately implement to the benefit of their organizations. ⁸¹⁶

Sat., Sept. 25- Finance- 11:30 to 12:15

Effective Budgeting and Contract Negotiations for Clinical Trials

Lisa Benson, BS, CCRP

Director of Grants & Sponsored Programs,

Connecticut Children's Medical Center

Effective budget negotiation requires preparation: knowing your costs and developing the infrastructure and methodology to consistently maximize revenues to your site. Conducting negotiations with sponsors can be challenging and this session will provide attendees some helpful negotiation strategies. This presentation will also be helpful for research sponsors. ⁸¹⁸

Sat., Sept. 25- Finance- 1:30 to 2:15

Clinical Trial Budgeting

Rachael Holley, RN, CCRA, CCRC, CHC

Supervisor Clinical Research Finance,

The University of Texas, MD Anderson Cancer Center

This session will review the clinical trial budgeting and negotiating process. It will focus on the various phases of clinical trials and the potential funding required. ⁸²⁰

Sat., Sept. 25- Finance- 2:15 to 3:00

Considerations for Clinical Trial Budgeting in Light of Physician Payment Reporting Legislation

Sondra Pepe, CCRP

Senior Client Relations Specialist, Medidata Solutions Inc

With state and federal regulations requiring disclosure of identified physician payment data for public availability, how has the sunshine law changed clinical trial budgeting for sites and sponsors? Results of a novel survey asking lay public and clinical trial industry professionals to interpret physician payment reports will be shared. Discussion will also revolve around what sites and sponsors have changed about their clinical trial budgeting processes in response to the increased transparency. ⁸²²

Sat., Sept. 25- Finance- 3:30 to 4:15

Research Billing

Mary Veazie, MBA, BS, CPA, CHC

Director/Clinical Research Finance,

The University of Texas, MD Anderson Cancer Center

This presentation will review the charge capture process for clinical trials. It will focus on the entire research billing process, the regulations, and how to maintain compliance. ⁸²⁴

Sat., Sept. 25- Finance- 4:15 to 5:00

Medicare Modifiers: The Impact on Clinical Research

Susie Bullock, MPH, BSN, RN, CCRP

Research Nurse Manager,

The University of Texas, MD Anderson Cancer Center

This presentation will discuss the evolution of Medicare modifiers related to clinical trials. Share the experience of MDACC in the development of procedures to accommodate the requirement. Associated problems and the impact of noncompliance will be discussed. ⁸²⁶

Sunday, September 26, 2010

Closing Plenary Session

Sun., Sept. 26- 8:30 to 9:00

Importance of Diversity Among Investigators and Trial Subjects in Clinical Trial Research

Lynn Harding, BS, CEO, LCH Clinical Research LLC

Minorities make up the intricate detail within the tapestry of the United States population; however, they are grossly under represented in many areas, clinical research being one of them. Within the African-American community, travesties such as the Tuskegee Experiment plague us when it comes to seeking medical advice or attention. For this insecurity to be breached it is imperative that minority physicians are educated and trained on the importance of clinical research and how minorities respond differently to medications due to their different genetic makeup, which is a contributing factor. ⁹⁰¹

Sun., Sept. 26- 9:00 to 9:30

Battle of the Regulations: OHRP versus FDA versus ICH

Quincy Byrdsong, EdD, CIM, CCRP, CIP

Executive Director of Research Administration, Virginia Commonwealth University

This talk is designed to discuss the concepts of applicability and designations of what regulates clinical research activity; identify the key differences between these regulations; and identify strategies which will best manage the overlapping nature of federal regulations to ensure optimal compliance. ⁹⁰²

Sun., Sept. 26- 9:30 to 10:00

The Case for Centralized Clinical Trials

Elizabeth Nugent, MSPH, CCRP, Senior Manager Clinical Trials, Kaiser Permanente

Rafael Veintimilla, MD, CCRP, Clinical Trials Implementation Manager, Kaiser Permanente Clinical Trials

Using innovation and sound business principles, a decentralized clinical trials department can be restructured into an organization with more efficiency, better compliance, increased capacity and improved financial return. This presentation will review a case study where the return on investment for clinical research went from negative to positive in only one year. The attendees will learn practical steps and avoid pitfalls when attempting to improve the overall functioning of their clinical trials enterprise. ⁹⁰³

Sun., Sept. 26- 10:30 to 11:00

Psychological Issues in Clinical Research

Nancy Wintering, MSW, LCSW, CCRP, CRC, Manager Research Projects, University of Pennsylvania

The goals of this session are to help attendees build basic competencies to work more effectively in emotionally charged situations. Psychological issues may arise unexpectedly. The participants will develop strategies to work effectively with patients with difficult behavior, recognize non-verbal signals (distress, anxiety, anger), as well as develop strategies to manage stress when life throws you a curve. This session will address psychological issues for staff who are losing subjects through death and advancing illness and help them to learn to recognize and resolve conflict proactively. Tools and training will be provided. ⁹⁰⁴

Sun., Sept. 26- 11:00 to 11:30

Integrating Sleep Testing into Clinical Trials

Robyn Woidtke, RN, BS, RPSGT, President, RVW Consulting Sleep Synergy

This presentation will provide the research professional with an overview of sleep, its disorders and the relevance to clinical trial data. The discussion will also review screening and testing options. Sleep disorders, specifically sleep apnea, can negatively impact most of the major body systems, i.e. cardiovascular, endocrine, immune/healing responses, respiratory, and cognition. Many diseases that we research fall into these categories. Only approximately 10% of those with sleep apnea have been diagnosed and treated; thus many of those recruited into studies will have this substantial co-morbid condition. ⁹⁰⁵

Sun., Sept. 26- Closing Plenary- 11:30 to 12:00

CDASH - Standardized CRFs - Everyone's a Winner

Rhonda Facile, BA, Director, CDASH Project, CDISC

This presentation will focus on how CDASH (Clinical Data Acquisition Standards Harmonization) can optimize and streamline data collection at clinical sites. The session will provide a brief history of the CDASH project, the key assumptions, and survey of a few domains with a focus on innovative approaches. ⁹⁰⁶