

SoCRA 17th Annual Conference Schedule of Events

Wednesday, September 24

Certification Preparation and Review Course

8:30 AM to 5:00 PM

Prep Course Registration and Session
Registration is separate from Annual Conference
Please visit www.socra.org/html/education.htm

Thursday, September 25

Certification Examination

8:00 AM to 12:00 PM

CCRP Certification Examination

Please note: Registration deadline for exam was Aug. 14. Applications are no longer being accepted for this date/location. Visit www.socra.org/html/certific.htm for future dates/locations.

Pre-conference Seminars

12:30 PM to 5:00 PM

Pre-conference seminar registration and sessions

Welcome Reception and Annual Conference Registration

6:00 PM to 7:00 PM

Reception and Registration

Friday, September 26

General Session

7:30 AM to 5:00 PM

Registration

8:00 AM to 8:30 AM

Continental Breakfast

8:30 AM to Noon

Welcome, Introduction and Opening Plenary Session

10:00 AM to 10:30 AM

Morning Break with Exhibitors

10:00 AM to 5:00 PM

Exhibits Open

Noon to 1:30 PM

Luncheon / Exhibit Session

1:30 PM to 5:00 PM

Breakout Sessions

3:00 PM to 3:30 PM

Afternoon Break with Poster Presenters and Exhibitors

Night-Out Event

6:00 to 9:00 PM

Optional Event - Dinner in Stanley Park at the
Sequoia Grill at the Teahouse Conservatory

Pre-registration required

See http://www.socra.org/html/SoCRA_Annual_Conference.htm

Saturday, September 27

General Session

7:30 AM to 5:00 PM

Registration

8:00 AM to 8:30 AM

Continental Breakfast

8:30 AM to 5:00 PM

Breakout Sessions

10:00 AM to 10:30 AM

Morning Break with Exhibitors

10:00 AM to 5:00 PM

Exhibits and Poster Session

Noon to 1:30 PM

Luncheon / Exhibit and Poster Session

3:00 PM to 3:30 PM

Afternoon break with Exhibitors

5:00PM

Exhibit and Poster Session Ends

Sunday, September 28

General Session

8:00 AM to 8:30 AM

Continental Breakfast

8:30 AM to Noon

Closing Plenary

10:00 AM to 10:30 AM

Morning Break

12:00 Noon

Program Adjourns

SoCRA 17th Annual Conference Schedule of Breakout Sessions by Track

Friday, September 26

Opening Plenary - General Session - Location: Grand Ballroom (Level 1)

Time/Track	Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8
Location	Grand Ballroom Salon A (Level 1)	Grand Ballroom Salon B (Level 1)	Grand Ballroom Salon C (Level 1)	Grand Ballroom Salon D (Level 1)	Grand Ballroom Salon E (Level 1)	Grand Ballroom Salon F (Level 1)	Cypress Room (Level 2)	Oak Room (Level 2)
1:30 to 3:00	Canadian Regulatory	Academic Research	Clinical Trials/Health Quality	Device Research	Regulatory	IRB Management	Monitoring	Advanced Management
3:30 to 5:00	Data Technologies	Finance	Clinical Trials/Health Quality	Device Research	Regulatory	IRB Management	Monitoring	Advanced Management

Saturday, September 27

Time/Track	Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8
Location	Grand Ballroom Salon A (Level 1)	Grand Ballroom Salon B (Level 1)	Grand Ballroom Salon C (Level 1)	Grand Ballroom Salon D (Level 1)	Grand Ballroom Salon E (Level 1)	Grand Ballroom Salon F (Level 1)	Cypress Room (Level 2)	Oak Room (Level 2)
8:30 to 10:00	Enrollment	Finance	Project Management	Device Research	Safety/Pharmacovigilance	Quality Assurance	Management	Advanced Management
10:30 to 12:00	Enrollment	Finance	Project Management	Oncology Research	Safety/Pharmacovigilance	Quality Assurance	Management	Advanced Management
1:30 to 3:00	Enrollment	Finance	Project Management	Oncology Research	Safety/Pharmacovigilance	Quality Assurance	International Research	Advanced Management
3:30 to 5:00	Enrollment	Finance	Project Management	Oncology Research	Safety/Pharmacovigilance	Chapter Interest/Development	International Research	Advanced Management

Sunday, September 28

Closing Plenary - General Session - Location: Grand Ballroom (Level 1)

8:00 - 12:00								
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Schedule-at-a-Glance

Friday MORNING and AFTERNOON, September 26, 2008

8:00 AM - 8:30 AM Continental Breakfast

8:30 to 9:15 Page

Welcome and Introduction - Donna Headlee, RN, BSN, CCRP- President, SoCRA and Joanne Goldberg, MSc, CCRP, pht, President- Elect, SoCRA, Annual Conference Chair

9:15 to 10:00 Page

Clinical Trial Inspections - Stephanie Reid, BS

10:00 - 10:30 PM Morning Break

10:30 to 11:15 Page

OHRP Update: International Research and the Regulatory Responsibilities of Ethics Boards - Ivor A. Pritchard, PhD

11:15 to 12:00 Page

Listening to Human Subjects: Reflections on Ethics in Clinical Research - Michael McDonald, PhD

12:00 - 1:00 PM LUNCHEON

1:00 PM - 1:30 PM Exhibitor/Poster Session

Track 1 - Canadian Regulatory

1:30 to 2:15 Page

Modernizing Canada's Health Products Regulatory System
Agnes Klein, MD, DPH

2:15 to 3:00 Page

Bringing National Clinical Research Groups and Investigative Sites Together to Establish National Standards
Karen Arts, BSN, RN, CCRP

Track 2 - Academic Research

1:30 to 2:00 Page

A Drug's Chilling Path to Market
Sherry Reuter, MSHS, BSN, RN

2:00 to 2:30 Page

Hospital Research Department... Incubator to Clinical Product Lines
Ellen McDowell, MSA, RN

2:30 to 3:00 Page

Physician Investigator's Perspectives at an Academic Medical Center
Tyler Stevens, MD

Track 3 - Clinical Trials/Health Quality

1:30 to 2:15 Page

Why is Quality Essential in Systematic Reviews?
James M. Wright, MD, PhD, CRCP (C)

2:15 to 3:00 Page

Healthcare Quality: Room for Improvement
Leann Lesperance, MD, PhD, FAAP

Track 4 - Device Research

1:30 to 3:00 Page

CDRH BIMO Inspections: The Good, the Bad, the Intriguing
Donna J. Headlee, RN, BSN, CCRP
Catherine E. Parker, RN, BSN

Track 5 - Regulatory

1:30 to 2:15 Page

Recent Developments in Research Privacy Regulations and Ethics
Anthony Perez, JD, MBA

2:15 to 3:00 Page

Investigator Initiated Trials
Daniel E. Redline, BA, COA, CCRG, CCRP

Track 6 - IRB Management

1:30 to 2:15 Page

SACHRP's Recommendations on Human Research Protections
Felix Khin-Maung-Gyi, PharmD, MBA, CIP, RAC

2:15 to 3:00 Page

Guidelines and Management - Tips from the Inside
Matt Baker, BA, CIM CIP

Track 7 - Monitoring

1:30 to 2:15 Page

Peaks and Pitfalls: Being an Independent Consultant in the Real World
Valerie Willets, RN, BSN, CCRA, CCRT
Jean Hendrickson

2:15 to 3:00 Page

Integrating Layered Data Validation for Multi-Site Clinical Trials
Alan Bauck, BS

Track 8 - Advanced Management

1:30 to 2:15 Page

Clinical Trial Financial and Compliance Issues
Bryan M. Soronson, MPA, BS, CMPE, CRA

2:15 to 3:00 Page

Streamlining the Negotiation of Clinical Trials Contracts: A Model to Dramatically Improve the Time to Full Execution of a Contract
Jason G. Jones, BS, MS, CCRP

3:00 - 3:30 PM Afternoon Break

Track 1 - Data Technologies

3:30 to 4:15 Page
Applying Emerging Technologies to Improve Clinical Data Collection
 Stephen D. Litavec, MBA, BS, CCRP

4:15 to 5:00 Page
The Role of the Data Monitoring Committee (DMC)
 Ron Kershner, PhD

Track 2 - Finance

3:30 to 5:00 Page
Compliance and Finance
 Angela Formataro McMahon, JD, CHC, CCRA
 Harriett Singer, MS
 Germaine Luyckx, CCRP

Track 3 - Clinical Trials/Health Quality

3:30 to 4:00 Page
Clinical Trials Registries
 Belinda Vandersluis, BA

4:00 to 4:30 Page
Implementation Research: A New Kind of Clinical Trial?
 Catarina Kiefe, MD, PhD

4:30 to 5:00 Page
Personalized Healthcare
 Albert J. Di Rienzo, BSCS, CMMI

Track 4 - Device Research

3:30 to 4:15 Page
Innovation in a Regulated Healthcare Environment: A View from Somebody who Studies Diseases of the Brain
 Robert J. Corona, DO, CPE, FCAP, FASCP

4:15 to 5:00 Page
Working on Your Creativity Muscle: How to Improve Your Creativity and Become More Innovative in Your Organization
 Bill Evans, MDE, MDes

Track 5 - Regulatory

3:30 to 4:00 Page
Managing Health Canada CTAs in Academic Clinical Trials: Square Peg Round Hole
 Katherine Brodeur-Robb, BA

4:00 to 4:30 Page
Beyond the Clinical Study: Regulatory Submissions to an IND
 Marcia Wolf, PhD, RAC

4:30 to 5:00 Page
Regulatory Compliance for GLP/GCP
 Maria F. Malone, BA, CCRP

Track 6 - IRB Management

3:30 to 4:15 Page
Strategies for Working with an IRB
 Cynthia S. Way, CIP, CCRP

4:15 to 5:00 Page
What Constitutes an Ethical Review of a Protocol (or What Is the IRB Looking for with Your Protocol Submission)
 Suzanne Pursley-Crotteau, PhD, RN

Track 7 - Monitoring

3:30 to 4:15 Page
PI Responsibilities Regarding Fraud via Data Collection
 Charles H. Pierce, MD, PhD, FCP, CPI

4:15 to 5:00 Page
Monitoring Panel Discussion with open Q & A

Track 8 - Advanced Management

3:30 to 4:15 Page
Organizing for Research Compliance
 Ellen Hyman-Browne, JD, MPH

4:15 to 5:00 Page
Evidence-Based Management of Clinical Research: Using Research Methods to Explore and Document Best Practices
 Georgine Burke, PhD

8:00 AM - 8:30 AM

Continental Breakfast

Track 1 – Enrollment

8:30 to 9:15 Page
Ethics of Clinical Research
 Faith Fitzgerald, MD, BA, MACP

9:15 to 10:00 Page
Ensuring Diversity in Clinical Research
 Daniel Bustillos, JD, PhD

Track 2 – Finance

8:30 to 9:15 Page
Budgeting for Clinical Trials
 Lisa A. Benson, BS, CCRP

9:15 to 10:00 Page
Clinical Research Budgeting: Hidden or Forgotten Costs Incurred
 Patricia D. Kirkpatrick, MSN, CCRP, CCRA, RN

Track 3 –Project Management

8:30 to 9:15 Page
Essentials of Effective Clinical Trial Planning and Execution: The Project Manager's Perspective
 Sonja Kasapinovic, MSc, CCRP

9:15 to 10:00 Page
How to Be a Successful Project Manager
 Natalie Currie, BSc

Track 4 –Device Research

8:30 to 9:00 Page
Designing Efficient and Effective Studies
 Carla L. Purves

9:00 to 9:30 Page
Step-by-Step Process on How to Prepare an IDE as a Sponsor/ Investigator
 Harvey M. Arbit, PharmD, MBA, BS, CCRP, RAC

9:30 to 10:00 Page
What Are the Main Differences in Regulations in the Member States - Medical Device Studies in Europe
 Joris Bannenbergh, MD, PhD

Track 5 –Safety/Pharmacovigilance

8:30 to 9:15 Page
An Overview of Safety Concerns in Clinical Trial Research
 Armin D. Weinberg, PhD

9:15 to 10:00 Page
The Value of Pharmacovigilance
 Jacqueline Edwards, BS, RN, CCRA

Track 6 –Quality Assurance

8:30 to 9:15 Page
Institutional Clinical Research Quality Assurance and Improvement Program: A BC-PHSA Initiative
 Jean-Paul Collet, MD, PhD

9:15 to 10:00 Page
Auditing in a Monitored World
 Doreen McGirl, BA

Track 7 –Management

8:30 to 9:15 Page
The Legal Fundamentals of Clinical Research Agreements
 Peggy Beat, JD, RN

9:15 to 10:00 Page
The Development and Management of a Clinical Research Program
 Christine Carter, PhD, MPH

Track 8 –Advanced Management

8:30 to 9:15 Page
Interim Monitoring and Data Monitoring Committees
 Mark Krailo, PhD

9:15 to 10:00 Page
ROI: The Value of Implementing Standardized Procedures
 Carolyn E. Rugloski, BA, MSc, CCRP

10:00 - 10:30 PM Morning Break

Schedule-at-a-Glance **Saturday MORNING, September 27, 2008**
(Continued)

10:00 - 10:30 PM Morning Break

<p>Track 1 – Enrollment</p> <p>10:30 to 11:00 Page Ethical Principles, Challenges, and Dilemmas S. Vann Smith, MS, BA, BS, GCP, HIPAA, ACLS</p> <p>11:00 to 11:30 Page Minorities in Research: The Past, Present, and Future Patricia Kaufert, PhD</p> <p>11:30 to 12:00 Page Research in Mental Illness: How Vulnerable Are Subjects? Padraig Darby, MB, MRCPsych, FRCPC</p>	<p>Track 2 –Finance</p> <p>10:30 to 11:15 Page Trends in Investigative Site Overhead and Fixed Fees Sondra A. Pepe, CCRP</p> <p>11:15 to 12:00 Page Advanced Cash Flow Management Techniques for the Research Site Andrew T. Snyder, MBA, FACMPE, PMP</p>	<p>Track 3 –Project Management</p> <p>10:30 to 11:15 Page Staffing Plans Belinda Vandersluis, BA</p> <p>11:15 to 12:00 Page Harmonization of Clinical Trial Agreements in Clinical Research Karen Arts, BSN, RN, CCRC</p>	<p>Track 4 –Oncology Research</p> <p>10:30 to 11:15 Page After All These Years, Why Don't We Know More About "Best Practices in Clinical Trial Recruitment:." An Overview of Two Studies Conducted by NCI. Rose Mary Padberg, MA, BA, RN</p> <p>11:15 to 12:00 Page Introduction of the Cancer Adverse Event Reporting System (caAERS): An Open Source Software Tool that is Used to Collect, Process and Report Adverse Events that Occur During Trials Ann Setser, BSN, MEd</p>
<p>Track 5 –Safety/Pharmacovigilance</p> <p>10:30 to 11:15 Page The Shared Responsibility for Safety Neila Smith, MD</p> <p>11:15 to 12:00 Page Safety and Pharmacovigilance from a Biotech Perspective Bruno Gagnon, BPharm, MSc</p>	<p>Track 6 –Quality Assurance</p> <p>10:30 to 11:15 Page External Audit Response Kathy Welchel, BS, CQA, MT</p> <p>11:15 to 12:00 Page Internal Inspections as Part of the Quality Assurance Program Roseanne Schott, MBA , BSN, RN, CCRP</p>	<p>Track 7 –Management</p> <p>10:30 to 11:15 Page Proactive Site Management Practices Elizabeth Chesnut, BA</p> <p>11:15 to 12:00 Page Investigator Initiated Research Mark Barnes, JD, LL.M</p>	<p>Track 8 –Advanced Management</p> <p>10:30 to 11:15 Page Building Bridges: Key to Development of a Research Program in the Private Practice Setting Cheryl I. Jacobs, BA, CCRP</p> <p>11:15 to 12:00 Page How To Write a Grant Proposal Lesley Mitchell</p>

12:00 - 1:00 PM LUNCHEON
1:00 PM - 1:30 PM Exhibitor/Poster Session

12:00 - 1:00 PM LUNCHEON

1:00 PM - 1:30 PM Exhibitor/Poster Session

Track 1 – Enrollment		Track 2 –Finance		Track 3 –Project Management		Track 4 –Oncology Research	
1:30 to 2:00	Page	1:30 to 2:15	Page	1:30 to 2:15	Page	1:30 to 2:15	Page
Using Children in Medical Research?		Financial Interplay of Academic Administration and Research		Research Support in Diagnostic Imaging		Recruitment Challenges to Oncology Trials: Overcoming Barriers to Increase Accrual	
Aideen Moore, MD, MHSc, FRCPC		Thomas C. Richardson, BA, MS		Wendy M. Doda, CCHRA, CCRP		Laureen Johnson, RN	
2:00 to 2:30	Page	2:15 to 3:00	Page	2:15 to 3:00	Page	2:15 to 3:00	Page
You Need GUINEA PIGS? : Count Me In!		Finding Funding Sources and Grant Writing for Small Studies		Managing and Maintaining Timelines in Collaborative Government Network Sponsored Trials		Selection and Training of the PI and Study Site for a Global Oncology Trial	
Audrey Jusko Friedman, MSW, MRT(T)		Virginia M. Miller, PhD		Nariman A. Nasser, BS, CCRP		Christine Mackay, PhD	
2:30 to 3:00	Page						
Informed Consent Forms							
Felix Khin-Maung-Gyi, PharmD, MBA, CIP							
Track 5 –Safety/Pharmacovigilance		Track 6 –Quality Assurance		Track 7 –International Research		Track 8 –Advanced Management	
1:30 to 3:00	Page	1:30 to 2:15	Page	1:30 to 2:15	Page	1:30 to 2:15	Page
Essential Training in Safety and Pharmacovigilance for Clinical Trial Professionals		Quality Management Innovation in Clinical Research: Acceptance and Implementation		Ethical Imperialism in Clinical Research		Developing an Effective Research Team	
Karen G. Davenport, MS, BSN, CCRG, RN Carolyn E. Rugloski, BA, MSc, CCRP Cheryl I. Jacobs, BA, CCRP		Meta Mitchell, PhD, BSc		Faith Fitzgerald, MD, BA, MACP		Tammy S. Neseth, BS	
		2:15 to 3:00	Page	2:15 to 3:00	Page	2:15 to 3:00	Page
		How to Develop a National Set of SOPs for Clinical Research		Clinical Trials Research in the Developing World		Hiring for Success	
		Karen Arts, BSN, RN, CCRG		Mark Barnes, JD, LLM		Susan I. Devine, CCRP	

3:00 - 3:30 PM Afternoon Break

3:00 - 3:30 PM Afternoon Break

Track 1 – Enrollment	Track 2 – Finance	Track 3 –Project Management	Track 4 –Oncology Research
<p>3:30 to 4:00 Page Standardization of Informed Consent Documents Across a Multi-Centered, NIH-Sponsored, International Trial: The ACCORD Experience Angela R. Kimel, BS, MBA, CCRP</p> <p>4:00 to 4:30 Page Retention Strategies: Help! Can Anyone Hear Me? Maria J. Figueroa, MBA, CCRP</p> <p>4:30 to 5:00 Page How to Achieve Accreditation - Challenges for Research Sites Marjorie Speers, PhD</p>	<p>3:30 to 4:15 Page Budgets and Negotiation: It's Not Personal, Just Good Business! Kathi Goodwin Durdon, BA, MA, CCRP</p> <p>4:15 to 5:00 Page Finance Panel and Discussion with open Q & A</p>	<p>3:30 to 4:15 Page Life Is Short....Get a GRIP! Ellen McDowell, MSA, RN</p> <p>4:15 to 5:00 Page Project Management Panel Discussion with open Q & A</p>	<p>3:30 to 4:15 Page Clinical Trials in Children with Cancer Michael Link, MD</p> <p>4:15 to 5:00 Page Acupuncture and Laser Therapy of Lymphedema Barbara Ann Phibbs, RN, LAc, OMD</p>
Track 5 –Safety/Pharmacovigilance	Track 6 – Chapter Interest/Development	Track 7 –International Research	Track 8 –Advanced Management
<p>3:30 to 4:00 Page Management of Safety Reporting in Multicenter Clinical Trials Anatoly V. Gorkoun, MD, PhD</p> <p>4:00 to 5:00 Page Protecting Subjects through Monitoring Nariman A. Nasser, BS, CCRP Denise Owensby, BS, CCRP Patti Tosta, MS, RN, CCRA</p>	<p>3:30 to 4:15 Page Chapter Orientation Session</p> <p>4:15 to 5:00 Page Chapter Orientation for Areas Other Than the US and Canada</p>	<p>3:30 to 4:15 Page International Translational Research Environment: Challenges and Opportunities Juan C. Salazar, MD, MPH</p> <p>4:15 to 5:00 Page Local Experience: The Challenge of Implementing Good Clinical Practice Guidelines in Saudi Arabian Tertiary Care Hospital Highlighting Sophisticated Cultural Differences Abdallah A. Adlan, PhD, BSc, CCRP</p>	<p>3:30 to 4:15 Page Orienting New Staff and Mentoring Ashley R. Kattilus, BSc, CCRP</p> <p>4:15 to 5:00 Page Advanced Management Panel Discussion with open Q & A</p>

Schedule-at-a-Glance SUNDAY, September 28, 2008

8:00 AM - 8:30 AM Continental Breakfast

8:30 to 9:00 Page
Politics and Women's Health Research
Virginia M. Miller, PhD

9:00 to 9:30 Page
Issues in In-Patient Trials
Lynn A. Babin, MSN, BSN, AAS, RN, APWCA

9:30 to 10:00 Page
Introduction to Nonprescription Drug Products
Leah Christl, PhD

10:00 -10:30 PM Morning Break

10:30 to 11:00 Page
Increasing the Effective Use of Non-RN's in Research
Susie A. Bullock, MPH, BSc, RN,CCRP

11:00 to 11:30 Page
**Balancing Work and Family/Avoiding Burnout/Managing Stress -
Sprints and Marathons: "Winning" the Drug Development Race**
Robert B. Huizinga, MSc, RN, NNC, CNeph(C)

11:30 to 12:00 Page
"To Sleep, Perchance to Dream..."
Janet C. Johnson, BA, RN

12:00 Noon
17th Annual Conference Adjourns

CONFERENCE NOTES:

SoCRA - 17th Annual Conference *Pre-Conference Seminars*

Thursday, September 25 - 1:00 to 5:00PM

How to Prepare for an FDA Audit

Speaker: Erin Krohl, MPH, MS, BS, EHKrohl Consulting Inc.

Discussion and workshop addressing FDA (Food and Drug Administration) perspectives and the regulations regarding adherence to protocol, records management, patient rights, drug and product management and record keeping, and regulatory issues related to an FDA audit. This workshop will educate the attendee in Good Clinical Practice requirements and the FDA audit expectations, in order to prepare for an FDA GCP audit. This interactive workshop will provide the following: A brief introduction to the FDA; Overview of clinical research, including the Federal Regulations covering clinical research and clinical investigator obligations; Discussion on Trial Site Roles and Responsibilities; Explanation of the FDA's Bioresearch Monitoring Program, focusing on the Clinical Investigator inspection; Insight on understanding the FDA GCP inspection: Who is the FDA auditor? What makes FDA suspicious? Common FDA inspection findings at the clinical site audit; Specific examples of FDA-483 observations; FDA inspection strategy

IRBs and the Informed Consent Process

Speaker: George D'Addamio, PhD, PharmConsult Inc.

We have witnessed serious criticisms regarding the IRB over the last few years and have heard and read of its inadequacies in protecting the human research subject. As health care providers we are expected to do the right thing. As health care consumers we expect to be protected from harm and that our care will never be compromised by clinical investigators failing to adhere to the standards of good clinical research practices. Dr. D'Addamio will discuss the lessons learned from past experiences and from the regulatory enforcement actions taken to strengthen the system for protecting the research subject. He will examine what is expected of the contemporary IRB as it keeps pace with the technologically-evolving clinical research landscape. He will also examine current operational interactions with the institutional review board that will maximize their efficiency and effectiveness to ensure maximum protection of the human research subject.

Presentation Skills Workshop

Speaker: Richard A. 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.

Research Project Management and Budgeting

Speaker: Bryan M. Soronson, MPA, BS, CMPE, CRA

University of Maryland Hospital

This session will discuss the elements of a protocol and the impact of these elements on the conduct of a trial. Research design, subject enrollment, project management, the administrative and financial aspects of the trial will be covered with emphasis on the study budget.

GCP 101 for Sites - New Study Coordinator Workshop

Speaker : Jacqueline K. Busheikin, CCRP, RN, 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 experienced coordinators who want to re-examine the ever-changing basics of research. This four-hour workshop will include presentations, hands-on training, and discussion. 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.

SOP Development and Implementation

Speaker: Donna, J. Headlee, RN, BSN, CCRP

This workshop for Senior Clinical Research Professionals will 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.

Legal Issues Involving Researchers, Including Fraud and Misconduct

Speaker: Jason Kaar, JD

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 has been an increase in civil and criminal actions against researchers. This session will provide an overview of recent problem areas, as well as insight on how to avoid them.

Grant Writing and Protocol Development Workshop

Speaker: Lesley Mitchell, 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.

Statistics in Clinical Research- Understanding Protocols and Statistical References

**Speaker: Lynn Babin, MSN, BSN, AAS, RN, APWCA
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.

SoCRA 17th Annual Conference

Session Descriptions

Friday, September 26, 2008

Welcome and Opening Plenary Descriptions

Fri. Sept. 26 - Track 1 Opening Plenary - 8:30 to 9:15

Welcome and Introduction

Donna Headlee, RN, BSN, CCRP, President- SoCRA

Joanne Goldberg, MSc, pht, CCRP, President Elect- SoCRA - Annual Conference Chair

Fri. Sept. 26 - Track 1 Opening Plenary - 9:15 to 10:00

Clinical Trial Inspections

Stephanie Reid, BS, Manager, Good Clinical Practices Unit

Health Products and Food Branch Inspectorate, Health Canada National Coordination Centre

The Health Products and Food Branch Inspectorate conducts inspections of clinical trials in Canada in order to verify and assess compliance to Division 5 of the Food and Drug Regulations. This presentation will provide an overview of the inspection process and will include a summary of findings from inspections completed in the past few years. ¹⁰¹

Fri. Sept. 26 - Track 1 Opening Plenary - 10:30 to 11:15

OHRP Update: International Research and the Regulatory Responsibilities of Ethics Boards

Ivor A. Pritchard, PhD, Acting Director, Office for Human Research Protections, U.S. Department of Health and Human Services

This update will review current activities of the Office for Human Research Protections related to research taking place outside the United States. Education efforts, policy developments, and compliance oversight activities will be included. The presentation will also discuss cooperative arrangements involving research ethics boards within the United States and at institutions outside of the United States. ¹⁰²

Fri. Sept. 26 - Track 1 Opening Plenary - 11:15 to 12:00

Listening to Human Subjects: Reflections on Ethics in Clinical Research

Michael McDonald, PhD, Maurice Young Chair of Applied Ethics, University of British Columbia

In practice, clinical research ethics is often reduced to complying with rules and regulations regarding informed consent, ethics review, adverse event reporting, and the like. Nevertheless, human subjects are at the heart of the clinical research endeavor. Drawing upon research that our team is now conducting, I will talk about what we are hearing from research subjects (as well as from researchers, research coordinators, ethics committee members, and others) to offer reflections on central themes in clinical research ethics. ¹⁰³

Friday September 26, 2008 Breakout Sessions

Track 1 - Canadian Regulatory

Fri. Sept. 26 - Track 1 - 1:30 to 2:15

Modernizing Canada's Health Products Regulatory System

Agnes V. Klein, MD, DPH

Director, Centre for Evaluation of Radiopharmaceuticals & Biotherapeutics, Health Products and Food Branch

The Blueprint for Renewal is Health Canada's Health Products and Food Branch undertaking a review of our approach to regulating health products and food. Our existing approach has evolved incrementally over time and dates back over 50 years. Transforming our legislative, regulatory, and policy frameworks will make the Branch more efficient, effective, and responsive to help us meet the evolving needs of Canadians in a world of fast-paced change. The Blueprint for Renewal includes the following initiatives: Registration and Disclosure of Clinical Trial Information; Review of the Regulatory Framework for Clinical Trials; Cost Recovery to analyze and improve upon the current cost recovery regime that covers the regulation, licensing, and post market surveillance of health products; and Progressive Licensing Project of Drug Products. ¹⁰⁴

Fri. Sept. 26 - Track 1 - 2:15 to 3:00

Bringing National Clinical Research Groups and Investigative Sites Together to Establish National Standards

Karen Arts, BSN, RN, CCRC, Director of Business Development, Ontario Institute for Cancer Research

N2 is a Canadian initiative seeking to bring national clinical research groups and investigative sites together and promote the country as a high quality global clinical research center. ¹⁰⁵

Track 1 - Data Technologies

Fri. Sept. 26 - Track 1 - 3:30 to 4:15

Applying Emerging Technologies to Improve Clinical Data Collection

Stephen D. Litavec, MBA, BS, CCRP

Senior Research Analyst, RTI International

This presentation will be an informative, non-technical discussion to assist clinical researchers in determining if emerging technologies can improve their projects' productivity, effectiveness, and data accuracy. Topics include how technologies have evolved, promising new technologies, and a review of the most current tools available. This presentation will examine how the latest technologies have improved and expanded data collection methodologies. ¹⁰⁶

Fri. Sept. 26 - Track 1 - 4:15 to 5:00

The Role of the Data Monitoring Committee (DMC)

Ron Kershner, PhD

Vice President, Biostatistics & Data Mgmt, AAI Pharma, Inc.

The DMC plays a critical role in the protection of human subjects during the conduct of the clinical trial. During this session, the key responsibilities of the DMC, the applicable regulations and guidances, and the critical evaluation and decision-making roles played by the members of the DMC team will be reviewed. ¹⁰⁷

Track 2 - Academic Research

Fri. Sept. 26 - Track 2 - 1:30 to 2:00

A Drug's Chilling Path to Market

Sherry Reuter, MSHS, BSN, RN, Independent Consultant
Sherry Reuter & Associates, LLC

The speaker will discuss the Ketek case and the flawed process that led to its approval. Fraud and other uncovered problems underscore the need for better checks and balances in clinical trials. This presentation will illustrate how to possibly prevent this case's string of unfortunate circumstances at the site, industry, and regulatory level, and how to recognize the warning signals. ²⁰¹

Fri. Sept. 26 - Track 2 - 2:00 to 2:30

Hospital Research Department... Incubator to Clinical Product Lines

Ellen McDowell, MSA, RN

Clinical Director, Saint Luke's Hospital

An emphasis on the importance of research at a large tertiary care hospital can result in legal, financial, and regulatory compliance challenges for all involved – the hospital, the investigators, the study staff, and the study sponsor. During this presentation, learn how one hospital is meeting these challenges and how the research department is helping grow the research enterprise. The department, the Center for Innovation and Research (CIR), serves as an incubator to assist product lines to develop and/or enhance their research endeavors. Learn more about the core business of CIR – providing key support services enabling clinical research to be successful and compliant at Saint Luke's Hospital. ²⁰²

Fri. Sept. 26 - Track 2 - 2:30 to 3:00

Physician Investigator's Perspectives at an Academic Medical Center

Tyler Stevens, MD

Associate Staff Physician, Cleveland Clinic

This presentation will discuss the barriers and rewards involved in carrying out clinical research at a large academic medical center. The speaker will discuss personal successes and failures, as well as his thoughts on the current and future direction of clinical research. ²⁰³

Track 2 - Finance

Fri. Sept. 26 - Track 2 - 3:30 to 5:00

Compliance and Finance

Angela Fornataro McMahill, JD, CHC, CCRA, Director, Research Compliance Office, UCSD Healthcare Enterprise

Harriett Singer, MS, Instructor, Department of Pediatrics
Baylor College of Medicine

Germaine Luyckx, CCRC

Senior Clinical Research Associate, Kendle International, Inc.

Compliance activities at many institutions focus on human subjects protection and confidentiality concerns. Principal investigators and study coordinators who may develop study budgets often are not trained in financial principles and billing compliance requirements. Staff in central clinical trials offices may be too far removed within the organization from the day-to-day activities of the clinical research study and therefore may not be aware of the multiplicity of operational issues. With multiple opportunities for financial risk and multiple layers of staff responsibilities for portions of the enterprise, many opportunities exist for financial risks to be unrecognized. This session will discuss compliance risks in clinical trial finances and suggest approaches and some best practice models to ameliorate those risks. ^{204, 205, 206}

Track 3 -Clinical Trials/Health Quality

Fri. Sept. 26 - Track 3 - 1:30 to 2:15

Why is Quality Essential in Systematic Reviews?

James M. Wright, MD, PhD, CRCP(C)

Professor, Anesthesiology, Pharmacology & Therapeutics
University of British Columbia

Clinical trials are subject to a number of forms of bias. If that bias is not detected, it will be magnified in a systematic review. The presentation will focus on the latest methods being developed and promoted by the Cochrane Collaboration to deal with this problem (eg. risk of bias tables) in order to assist clinical trialists to learn how to address the issue of bias proactively. ³⁰¹

Fri. Sept. 26 - Track 3 - 2:15 to 3:00

Healthcare Quality: Room for Improvement

Leann Lesperance, MD, PhD, FAAP

Assistant Professor, University of Binghamton

This presentation will explore contemporary issues and shortcomings that our modern American healthcare crises present, as noted in various research commission reports. Dr. Lesperance's presentation will evaluate the effectiveness of current and upcoming strategies to improve healthcare innovation and quality from a highly interdisciplinary perspective. ³⁰²

Fri. Sept. 26 - Track 3 - 3:30 to 4:00

Clinical Trials Registries

Belinda Vandersluis, BA

Operations Director, NCIC Clinical Trials Group

The International Committee of Medical Journal Editors (ICMJE) now requires that Phase II and III trials be listed in a publicly available registry as a condition for acceptance of trial results for publication. Institutional Review Boards (IRBs) and Research Ethics Boards (REBs) are now beginning to require proof that trials are registered as well. This session will describe the acceptable registries along with processes and details necessary to ensure trials are registered appropriately. ³⁰³

Fri. Sept. 26 - Track 3 - 4:00 to 4:30

Implementation Research: A New Kind of Clinical Trial?

Catarina Kiefe, MD, PhD, Professor of Medicine and Biostatistics, University of Alabama at Birmingham

Evidence from traditional clinical trials may take years to be translated into practice, and in some cases may never be taken up at all. This results in less than optimal quality of care. Implementation research tests hypotheses about how to translate evidence into practice. A powerful method to test such hypotheses is the group-randomized trial. We will compare and contrast implementation research with the classical clinical trial by way of examples from ongoing and/or completed research. ³⁰⁴

Fri. Sept. 26 - Track 3 - 4:30 to 5:00

Personalized Healthcare

Albert J. Di Rienzo, BSCS, CMMI

President & CEO, Blue Highway

Personalized healthcare is all about improving quality of care as well as quality of life in the most efficient, cost effective manner possible; it's the ultimate in convergence. This talk provides an overview of personalized healthcare, including its benefits, opportunities, and challenges. ³⁰⁵

Track 4 - Device Research

Fri. Sept. 26 - Track 4 - 1:30 to 3:00

CDRH BIMO Inspections: The Good, the Bad, the Intriguing

Catherine E. Parker, RN, BSN

Consumer Safety Officer, U.S. Food and Drug Administration

Donna J. Headlee, RN, BSN, CCRP

This session is designed to be a fun, competitive, interactive session to learn about the Bioresearch Monitoring Program at CDRH. It will introduce, explain, and discuss fundamental CDRH BIMO inspections and their impact upon the regulatory review process and the clinical site. Topics will include, how to prepare for an FDA inspection, regulatory and compliance trends in the device clinical trials industry, and tips for conducting a quality clinical trial. ⁴⁰¹

Fri. Sept. 26 - Track 4 - 3:30 to 4:15

Innovation in a Regulated Healthcare Environment: A View from Somebody who Studies Diseases of the Brain

Robert J. Corona, DO, CPE, FCAP, FASCP

Vice President, Chief Medical Officer, Welch Allyn, Inc.

This session will define sustaining and disruptive innovation and review how the human brain innovates. We will also discuss innovation in the future healthcare delivery system. ⁴⁰²

Fri. Sept. 26 - Track 4 - 4:15 to 5:00

Working on Your Creativity Muscle: How to Improve Your Creativity and Become More Innovative in Your Organization

Bill Evans, MDE, MDes, President, Bridge Design, Inc.

In this day and age of increasing competitiveness and the globalization of the economy, organizations and individuals need abilities that differentiate them from the masses. Increasingly, creativity is being seen as the key to unlocking innovative solutions with social and economic value to society. Some activities like design and artistic endeavors are immediately thought of as benefiting from the creativity of contributors – but creativity can be brought to bear in all walks of business and personal life to improve what we do, how we communicate with others, and ultimately how successful we are as either individuals or as part of our companies and families. The speaker believes that we all have creative abilities beyond how we usually see ourselves. This stimulating presentation will look at many simple ways you can exercise and improve your creativity and then how to apply what you learn to enhance the way your company innovates. ⁴⁰³

Track 5 - Regulatory

Fri. Sept. 26 - Track 5 - 1:30 to 2:15

Recent Developments in Research Privacy Regulations and Ethics

Anthony Perez, JD, MBA

Chief Health Sciences Counsel, UCSD Health System

This session will discuss recent changes in privacy practices related to clinical research such as new California laws regarding subject notification for privacy breaches, new VA regulations for IRBs and researchers, and new ethical issues related to expanded use of electronic medical record systems for clinical research. ⁵⁰¹

Fri. Sept. 26 - Track 5 - 2:15 to 3:00

Investigator Initiated Trials

Daniel E. Redline, BA, COA, CCRC, CCRP

Pre-Market Clinical Project Manager, Volcano Corporation

Investigator-initiated trials (IITs) continue to be an important part of clinical research. But with resources often lacking for these innovative, collaborative, and sometimes controversial studies, how can sponsors, investigators, and sites assure proper oversight and subject protection? This session will cover the key aspects of IITs and the necessary steps to take to ensure compliance with Federal Regulations and the ICH Guidelines for Good Clinical Practice and protection of human subjects. Topics will include: Study Design, Protocol Development, Safety Reporting, Monitoring, SOPs, and IRBs. ⁵⁰²

Fri. Sept. 26 - Track 5 - 3:30 to 4:00

Managing Health Canada CTAs in Academic Clinical Trials: Square Peg Round Hole

Katherine Brodeur-Robb, BA, Executive Director

C¹⁷ Research Network/Pediatric Onc/Hem

Since the 2001 changes to the Food and Drug Regulations, Division 5 "Drugs for Clinical Trials Involving Human Subjects", all academic trials that use drugs out of indication are required to file a CTA with Health Canada. The situation is particularly complex in pediatrics, as very few drugs have any pediatric indications, and many have multiple generics. The Children's Oncology Group currently has over 130 clinical trials on file with Health Canada, all using investigational or off-label drugs, most that will stay open to collect data on patients for 5-10 years. This talk will go through some of the ways that academic researchers and regulatory personnel can manage a process that was designed for pharmaceutical companies. ⁵⁰³

Fri. Sept. 26 - Track 5 - 4:00 to 4:30

Beyond the Clinical Study: Regulatory Submissions to an IND

Marcia Wolf, PhD, RAC, Chief, Department of Regulatory Affairs, Walter Reed Army Institute of Research

Although clinical data is the crux of investigating a new drug, much additional information must be submitted to the FDA. Learn basic requirements for an IND. Manufacturing and nonclinical information will be emphasized, especially as they relate to clinical studies. ⁵⁰⁴

Fri. Sept. 26 - Track 5 - 4:30 to 5:00

Regulatory Compliance for GLP/GCP

Maria F. Malone, BA, CCRP

Manager, Regulatory Compliance, MedImmune

This presentation will review the history of Good Laboratory Practices and Good Clinical Practices and will help the attendee understand the philosophy and principles of GLP and GCP. The presenter will examine the implication of noncompliance with GLP and GCP and will explain key components of these regulations. ⁵⁰⁵

Track 6 - IRB Management

Fri. Sept. 26 - Track 6 - 1:30 to 2:15

SACHRP's Recommendations on Human Research Protections

Felix Khin-Maung-Gyi, PharmD, MBA, CIP, RAC

CEO, Chesapeake Research Review Inc

This session will review the regulatory requirements and demystify the process to improve site compliance and human subject protection. This session will explain how document approval relates to human subject protection and identify the current regulations regarding documents to be approved. ⁶⁰¹

Fri. Sept. 26 - Track 6 - 2:15 to 3:00

Guidelines and Management - Tips from the Inside

Matt Baker, BA, CIM, CIP, President / CEO, Compass IRB

Submitting to an IRB is an essential aspect of clinical research. Meaningful submissions will enable the IRB to make informed decisions regarding research. This presentation will review the regulations that govern IRBs and outline what exactly should and/or must be submitted to an IRB. Attention will not only be centered on what must be submitted but, more importantly, how excess and unnecessary submissions can actually hinder the IRB's responsibilities. ⁶⁰²

Fri. Sept. 26 - Track 6 - 3:30 to 4:15

Strategies for Working with an IRB

Cynthia S. Way, CIP, CCRP

Manager, Regulatory Services for Global Clinical Pharmacology, Covance

Why does the IRB have so many rules? Why does it take so many revisions before my study gets final IRB approval? Why doesn't the IRB seem to care about getting my study going sooner? These are common questions that bewilder study management staff across the board. This presentation will seek to explain how IRBs "think," and identify strategies for mutually satisfactory outcomes. ⁶⁰⁴

Fri. Sept. 26 - Track 6 - 4:15 to 5:00

What Constitutes an Ethical Review of a Protocol (or What Is the IRB Looking for with Your Protocol Submission)

Suzanne Pursley-Crotteau, PhD, RN

Senior Program Analyst, Office of Human Subjects Research National Institutes of Health

The presentation will address the standards for an IRB ethical review. The presenter will identify the standards that every IRB must meet as outlined in the regulations. Based on these regulatory standards, the presenter will address what an IRB is looking for in the context of their review and make specific recommendations to ensure that the standards are met within the body of the protocol or in the consent form. ⁶⁰⁵

Track 7 - Monitoring

Fri. Sept. 26 - Track 7 - 1:30 to 2:15

Peaks and Pitfalls: Being an Independent Consultant in the Real World

Valerie Willetts, RN, BSN, CCRA, CCRT

President & CEO, ASKA Research

Jean Hendrickson, Division Head, eReady Monitors

Are you considering or have you decided to become an independent consultant? Are you really ready for what is involved when you are in business for yourself? Who do you market yourself to? How do you handle your finances? When do you make time for your personal life? These are all real-life issues that face the consultants that we work with every day. It's easy to create a plan but, as we all know, life cannot be planned or predicted. In this presentation we will provide effective and efficient strategies for being an independent consultant based on personal and professional experience as well as discuss the advantages and disadvantages of being in business for yourself.

701, 702

Fri. Sept. 26 - Track 7 - 2:15 to 3:00

Integrating Layered Data Validation for Multi-Site Clinical Trials

Alan Bauck, BS, Technical Director, Kaiser Permanente

This presentation will describe a layered approach to data validation which ensures better data quality by identifying and resolving problems along a continuum of automated and human checks. Integrating these validations into a single presentation system for clinical sites facilitates communication and resolution of data errors.

703

Fri. Sept. 26 - Track 7 - 3:30 to 4:15

PI Responsibilities Regarding Fraud via Data Collection

Charles H. Pierce, MD, PhD, FCP, CPI

Adj. Associate Professor, University of Cincinnati

This session will consider documentation in clinical research as the key to having reliable data and how to spot fraud.

704

Fri. Sept. 26 - Track 7 - 4:15 to 5:00

Monitoring Panel Discussion with open Q & A

Track 8 - Advanced Management

Fri. Sept. 26 - Track 8 - 1:30 to 2:15

Clinical Trial Financial and Compliance Issues

Bryan M. Soronson, MPA, BS, CMPE, CRA,

Senior Administrator, University of Maryland Hospital

The conduct of clinical trials has gotten more complex over the last several years. It is becoming more critical for the study budget to cover all project related costs. The focus of this session is a discussion on how to accomplish this. Proper budgeting for the site should consider all costs including those expenses incurred before the contract is designed, and should involve the PI, study coordinator and administrator. This session will discuss site budgeting in detail. The link of budgeting to billing compliance for clinical trials will also be covered. Billing for study related items and services is challenging due to the confusing rules and regulations, and the relationship between research and clinical entities. It is critical that this is done correctly.

Fri. Sept. 26 - Track 8 - 2:15 to 3:00

Streamlining the Negotiation of Clinical Trials Contracts: A Model to Dramatically Improve the Time to Full Execution of a Contract

Jason G. Jones, BS, MS, CCRP

Senior Research Program Manager, Medicis, Inc.

The speaker will present a model for agreements that uses plug-and-play. Pre-approved legal language will be demonstrated and discussed.

802

Fri. Sept. 26 - Track 8 - 3:30 to 4:15

Organizing for Research Compliance

Ellen Hyman-Browne, JD, MPH

Research Compliance Officer

The Children's Hospital of Philadelphia

Academic medical centers and research hospitals are facing new challenges in building research compliance programs that address the risks incurred in conducting research programs and also meet the requirements of the OIG and Sentencing Guidelines. The following questions will be addressed in this presentation: How to incorporate research compliance into an institutional compliance program; How to allocate responsibility between institutional compliance and management/administration; How to fulfill fiduciary responsibilities to the Board of Trustees.

803

Fri. Sept. 26 - Track 8 - 4:15 to 5:00

Evidence-Based Management of Clinical Research: Using Research Methods to Explore and Document Best Practices

Georgine Burke, PhD, Director of Research

Connecticut Children's Medical Center

The application of methods from health services research to study the conduct and management of clinical trials offers numerous opportunities for both professional development and improvements to practice. This session will summarize current research findings on subject recruitment and retention, staffing levels, and role responsibilities, and suggest both directions for future research as well as methodology to develop successful studies.

804

**Saturday
September 27, 2008
Breakout Sessions**

Track 1 - Enrollment

Sat. Sept. 27 - Track 1 - 8:30 to 9:15

Ethics of Clinical Research

Faith Fitzgerald, MD, BA, MACP

Professor of Med/Assoc Dean Humanities/Bioethics

UC Davis School of Medicine

Clinical research is essential to the well-being of patients, present and future. It is also fraught with ethical hazards, as evidenced by the experience of patients past. The protection of patients in the present who agree to be research subjects is a vital and ongoing struggle. 108

Sat. Sept. 27 - Track 1 - 9:15 to 10:00

Ensuring Diversity in Clinical Research

Daniel Bustillos, JD, PhD, Assistant Professor of Health Care Ethics, St. Louis University

The use (and abuse) of certain underprivileged groups in American medical research has had a long and sordid history. This talk will apprise attendees about this history in order to form a foundation upon which to speak about current regulatory and policy environments for the recruitment and retention of certain underrepresented groups. It will give an overview of how abuse of certain groups in our history has paved the way for current FDA and NIH regulations and policies that may have had the inadvertent effect of creating a class that are now underrepresented in possibly beneficial clinical trials. 109

Sat. Sept. 27 - Track 1 - 10:30 to 11:00

Ethical Principles, Challenges, and Dilemmas

S. Vann Smith, MS, BA, BS, GCP, HIPAA, ACLS

Senior Project/Research Manager, Clinical Affairs, Dey LP

The purpose of the research ethics presentation is to develop a deeper understanding of ethical principals that can guide clinical research professionals, as well as facilitate a better understanding of the ethical challenges and dilemmas that can occur in clinical research. Case study examples, current topics, and insightful humor from the wit of Mark Twain will be used to make this presentation both very interesting, useful, and an enjoyable learning experience. 110

Sat. Sept. 27 - Track 1 - 11:00 to 11:30

Minorities in Research: The Past, Present, and Future

Patricia Kaufert, PhD, Professor, Dept of Community Health Sciences, University of Manitoba

This presentation will discuss the importance of recruiting minorities for research, the difficulties in recruitment faced by researchers, but also some of the techniques recommended as aids to successful recruitment. Drawing on material from the project, Centering the Human Subject in Research, these techniques will be reviewed from the perspective of those responsible for recruitment (the research coordinators and research nurses) and from the standpoint of the minority community targeted for recruitment. 111

Sat. Sept. 27 - Track 1 - 11:30 to 12:00

Research in Mental Illness: How Vulnerable Are Subjects?

Padraig Darby, MB, MRCPsych, FRCPC

President, National Council on Ethics in Human Research
Patients/clients suffering from mental illness are invariably included in populations viewed as "vulnerable" and requiring extra protection from IRBs/REBs. Assumptions of vulnerability often are applied to all such potential subjects. The literature on the extent to which they may be more vulnerable to being coerced into agreeing to research is somewhat contradictory. An approach that examines issues on a case-by-case basis is more justified. 112

Sat. Sept. 27 - Track 1 - 1:30 to 2:00

Using Children in Medical Research?

Aideen Moore, MD, MHSc, FRCPC

Neonatologist, Hospital for Sick Children - Toronto

The rationale for including children in clinical research will be discussed briefly. Other themes will include the perspective of clinical investigators on planning research in children and the key issues for Institutional Review Boards when reviewing this research. Lastly, the issue of obtaining consent from children at different ages will be addressed. 113

Sat. Sept. 27 - Track 1 - 2:00 to 2:30

You Need GUINEA PIGS?: Count Me In!

Audrey Jusko Friedman, MSW, MRT(T), Director of Patient Education & Survivorship, Princess Margaret Hospital

While studies of patient and public populations have reported high levels of support for clinical trials and the use of human subjects in trials, fewer people are willing to personally be randomized into trials. Patient education interventions intended to raise awareness, reduce fears, and dispel myths about participating in clinical trials will be discussed. 114

Sat. Sept. 27 - Track 1 - 2:30 to 3:00

Informed Consent Forms

Felix Khin-Maung-Gyi, PharmD, MBA, CIP, RAC

CEO, Chesapeake Research Review Inc

The process of "informed consent" forms the core of human subject protection. The multiple applications of ICFs have sometimes compromised their ability to communicate with the average subject. This presentation will compare and contrast the scales used to assess readability and will discuss their application to writing readable ICFs. 115

Sat. Sept. 27 - Track 1 - 3:30 to 4:00

Standardization of Informed Consent Documents

Across a Multi-Centered, NIH-Sponsored,

International Trial: The ACCORD Experience

Angela R. Kimel, BS, MBA, CCRP

Research Associate, Wake Forest University Health Sciences

Clinical sites participating in multicenter studies are required to follow the same protocol. Therefore, the basic elements of the informed consent documents should be the same. This presentation will describe the processes developed in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial to ensure that information essential to the trial is included in all consent forms used at 77 clinical sites across the United States and Canada. Specific topics addressed include the identification of key elements, review of all local consent documents before standardization, description of key findings from the review, processes used to improve the consent forms found deficient, and lessons learned from such a review. 116

Sat. Sept. 27 - Track 1 - 4:00 to 4:30

Retention Strategies: Help! Can Anyone Hear Me?

Maria J. Figueroa, MBA, CCRP

Project Director, EMMES Corporation

Coordinators play a significant role in participant retention in clinical trials -- but not the only role. Other key support groups such as responsive study management, physicians, and statisticians can help make the coordinator's work more productive. This presentation will discuss some novel retention processes, including some technology-driven, that were implemented in the SCORE study, a Phase III NIH-sponsored ophthalmic study, and are applicable to many other trials. ¹¹⁷

Sat. Sept. 27 - Track 1 - 4:30 to 5:00

How to Achieve Accreditation - Challenges for Research Sites

Marjorie Speers, PhD, Executive Director, AAHRPP

This presentation will describe the accreditation process, describe ways that research sites can overcome challenges in meeting the accreditation standards, and describe the benefits and costs of accreditation for a research site. ¹¹⁸

Track 2 - Finance

Sat. Sept. 27 - Track 2 - 8:30 to 9:15

Budgeting for Clinical Trials

Lisa A. Benson, BS, CCRP

Associate Director of Research Administration

Connecticut Children's Medical Center

How centralized services and budgeting for research impact the investigator, study site, and sponsor. This session will explain how to review a protocol, determine study related procedures, and how to develop a study budget that will cover the site's costs. We will look at the relationship of centralized services and billing compliance. The session will review the different types of expenses that are associated with the startup, closeout, and management of a trial. Lastly, we will address the importance of industry relationships and effective negotiations of study budgets. ²⁰⁷

Sat. Sept. 27 - Track 2 - 9:15 to 10:00

Clinical Research Budgeting: Hidden or Forgotten Costs Incurred

Patricia D. Kirkpatrick, MSN, CCRP, CCRA, RN

Director of Clinical Research Programs

Scott & White Memorial Hospital

What are the costs to be recognized when putting together a clinical research budget. A few questions to ponder: What are overhead expenses? What are the true costs of recruitment? Advertising comes in many forms, are you paid for the entire effort? Standard rates of personnel versus actual rates? ²⁰⁸

Sat. Sept. 27 - Track 2 - 10:30 to 11:15

Trends in Investigative Site Overhead and Fixed Fees

Sondra A. Pepe, CCRP

Client Relations Specialist, Medidata Solutions Worldwide

A presentation of recent trends in overhead with special emphasis on costs that were not typically itemized in budgets of the past (including study startup fees, archiving/storage fees, etc.). This presentation will discuss potential drivers of these trends and best practice approaches for grant negotiation in this new environment. ²⁰⁹

Sat. Sept. 27 - Track 2 - 11:15 to 12:00

Advanced Cash Flow Management Techniques for the Research Site

Andrew T. Snyder, MBA, FACMPE, PMP

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

This presentation will focus on cash flow management concerns faced by clinical research sites. This lecture will provide attendees with advanced information and 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 executive financial reporting. This lecture will share processes that clinical research site managers and coordinators can immediately implement to the benefit of their organizations. ²¹⁰

Sat. Sept. 27 - Track 2 - 1:30 to 2:15

Financial Interplay of Academic Administration and Research

Thomas C. Richardson, BA, MS

Senior Director, Strategic Planning & Business

Development, Connecticut Children's Medical Center

Treating clinical, research, and academic functions as silos limits an institution's ability to create first class, multifaceted programs by leveraging resources. This session will focus on strategies to identify and, where possible, quantify the benefits of taking an integrated approach to clinical research and academic functions. Topics will include faculty recruitment, succession planning, institutional visibility, growth, and planned versus opportunistic integration. ²¹¹

Sat. Sept. 27 - Track 2 - 2:15 to 3:00

Finding Funding Sources and Grant Writing for Small Studies

Virginia M. Miller, PhD, Professor of Surgery &

Physiology, Mayo Graduate School of Medicine

This presentation will provide multiple sources for researchers to pursue funding for exploratory, preliminary, and small research studies. Clinical, bench, and community-based participatory research (CBPR) projects will be discussed. Contacting potential funding sources, writing the proposal, and grant management will be included for pharmaceutical, non-profit, and state agencies. ²¹²

Sat. Sept. 27 - Track 2 - 3:30 to 4:15

Budgets and Negotiation: It's Not Personal, Just Good Business!

Kathi Goodwin Durdon, BA, MA, CCRP

Clinical Operations Associate, Welch Allyn, Inc.

This presentation will review all sides involved in the budgeting process and discover ways to deal fairly with each other. Open communication and a proactive process makes the going easier, more effective, and less stressful. ²¹³

Sat. Sept. 27 - Track 2 - 4:15 to 5:00

Finance Panel Discussion with open Q & A

Track 3- Project Management**Sat. Sept. 27 - Track 3 - 8:30 to 9:15****Essentials of Effective Clinical Trial Planning and Execution: The Project Manager's Perspective****Sonja Kasapinovic, MSc, CCRP****Clinical Research Manager**, University Health Network

Systematic development of a project plan is essential for guiding the successful execution of a clinical trial. A complete plan must contain specifications for management of project scope, time, cost, quality, human resources, risk, procurement, and communications between project stakeholders. 306

Sat. Sept. 27 - Track 3 - 9:15 to 10:00**How to Be a Successful Project Manager****Natalie Currie, BSc****President**, Natalie Currie Clinical Research Consulting Inc

This session describes the principles of project management and how project management tools can be applied to ensure the success of clinical research projects. Attendees will learn techniques on negotiation, managing without authority, and how to develop effective communication strategies. Clinical research case studies will be used to demonstrate how process improvement techniques can be applied to ongoing and new projects. 307

Sat. Sept. 27 - Track 3 - 10:30 to 11:15**Staffing Plans****Belinda Vandersluis, BA****Operations Director**, NCIC Clinical Trials Group

Staffing plans are an important tool for research administrators and researchers to use in building budgets and for strategic and succession planning. This session will present an overview of how staffing plans are developed and will provide two methods of developing staffing plans for your organization. 308

Sat. Sept. 27 - Track 3 - 11:15 to 12:00**Harmonization of Clinical Trial Agreements in Clinical Research****Karen Arts, BSN, RN, CCRC****Director of Business Development**

Ontario Institute for Cancer Research

Through a collaborative approach a Canadian initiative is seeking to decrease the delays caused by protracted contract negotiations. By developing principles and sharing best practices, this initiative aims to set a national standard and decrease the time involved in developing acceptable clinical trial agreements for clinical trials. Methods will be discussed. 309

Sat. Sept. 27 - Track 3 - 1:30 to 2:15**Research Support in Diagnostic Imaging****Wendy M. Doda, CCHRA, CCRP****Senior Project Manager, Research**, Hospital for Sick Children

The speaker will share her experience of setting up a Research Support Office within the Department of Diagnostic Imaging at the Hospital for Sick Children. Key items are establishing a research support structure, providing tools to facilitate research, and implementing standard methods for conducting research. 310

Sat. Sept. 27 - Track 3 - 2:15 to 3:00**Managing and Maintaining Timelines in Collaborative Government Network Sponsored Trials****Nariman A. Nasser, BS, CCRP****Associate Director of Clinical Operations**

Immune Tolerance Network

The collaborative group matrices in these networks often lead to stretched timelines for trial development and implementation activities. Tips for managing tasks and personalities during the development process will be reviewed. Methods for developing and maintaining timelines in this structure while serving the team as a whole will be explored. 311

Sat. Sept. 27 - Track 3 - 3:30 to 4:15**Life Is Short....Get a GRIP!****Ellen McDowell, MSA, RN****Clinical Director**, Saint Luke's Hospital

Today professionals must cope with multiple demands and a laser-fast pace. Our attitudes, perceptions, and thinking patterns program us for optimal performance or for failure in our action-packed lives. This fun, entertaining program is designed to examine the "stress mindset"; ignite the desire to turn negative thinking into positive contributions; identify methods of diminishing the energy drain stress creates; and encourage each individual to recognize the personal lifespan implications of a less stressful life. Participants will have an opportunity to explore how thought traps and perceptions can sabotage critical thinking; learn to use attitude adjusters to overcome the "stress mindset"; and gain abilities to tap into the energy created by stress and convert it into positive action. 312

Sat. Sept. 27 - Track 3 - 4:15 to 5:00**Project Management Panel Discussion with open Q & A**

Track 4 - Device Research

Sat. Sept. 27 - Track 4 - 8:30 to 9:00

Designing Efficient and Effective Studies

Carla L. Purves

Spine Program Manager, PhDx Systems Inc

This presentation will cover guidelines for efficient study design, reviewing the differences between patient record documents and database research, protocol driven vs. outcomes studies, in addition guidelines for CRF design, validity rules and identifying research questions. This session will be based on experiences while implementing multi-center global studies. 404

Sat. Sept. 27 - Track 4 - 9:00 to 9:30

Step-by-Step Process on How to Prepare an IDE as a Sponsor/Investigator

Harvey M. Arbit, PharmD, MBA, BS, CCRP, RAC

Director, IND/IDE Assistance Program

University of Minnesota

There are no sponsor-investigator forms for IDE applications as there are for IND applications (forms FDA 1571 and 1572). A sponsor for a significant risk IDE must include certain required information. This information must demonstrate that there is reason to believe that the risks are outweighed by the anticipated benefits and demonstrate the importance of the knowledge to be gained, that the investigation is scientifically sound, and there is reason to believe that the device will be effective. 405

Sat. Sept. 27 - Track 4 - 9:30 to 10:00

What Are the Main Differences in Regulations in the Member States - Medical Device Studies in Europe

Joris Bannenberg, MD, PhD

Medical Director/COO, Factory CRO for Medical Devices

What are the characteristics of device studies in Europe? What are the main differences in regulations in the Member States? 406

Track 4 - Oncology Research

Sat. Sept. 27 - Track 4 - 10:30 to 11:15

After All These Years, Why Don't We Know More About "Best Practices in Clinical Trial Recruitment:"

An Overview of Two Studies Conducted by NCI

Rose Mary Padberg, MA, BA, RN

Chief of Cancer Education, NIH/NCI

The speaker will present NCI study results looking at best practices in recruitment. 407

Sat. Sept. 27 - Track 4 - 11:15 to 12:00

Introduction of the Cancer Adverse Event Reporting System (caAERS): An Open Source Software Tool that is Used to Collect, Process and Report Adverse Events that Occur During Trials

Ann Setser, BSN, MEd

Nurse Consultant, National Cancer Institute

The NCI CaBIG Clinical Trials Management Systems (CTMS) Workspace is developing a comprehensive set of modular, interoperable, and standards-based tools designed to meet diverse clinical trials management needs and respond to four informatics-focused recommendations made by NCI's Clinical Trials Working Group (CTWG). This presentation will introduce CaAERS, developed by the Data Reporting and Sharing Workspace. 408

Sat. Sept. 27 - Track 4 - 1:30 to 2:15

Recruitment Challenges to Oncology Clinical Trials: Overcoming Barriers to Increase Accrual

Laureen Johnson, CRN

Clinical Research Nurse, Tom Baker Cancer Center

Despite the overwhelming need to improve cancer therapies, approximately only 5% of adult cancer patients participate in clinical trials. Cited barriers include lack of patient knowledge, clinical trial infrastructure, and limited enrollment of older persons and minorities. This presentation will provide a review of the literature that identifies potential barriers to enrollment, discusses current recruitment methods and offers possibilities that may increase accrual. 409

Sat. Sept. 27 - Track 4 - 2:15 to 3:00

Selection and Training of the PI and Study Site for a Global Oncology Trial

Christine Mackay, PhD

Project Director, Worldwide Clinical Research

This presentation will review the process by which investigative sites are chosen to participate in clinical trials, including site requirements and evaluation methods. Once a site has been chosen, ensuring the study personnel are appropriately trained is key in producing and collecting high quality data. Training of key personnel will be reviewed as well as a discussion on the impact of a site's performance as part of the global trial. 410

Sat. Sept. 27 - Track 4 - 3:30 to 4:15

Clinical Trials in Children with Cancer

Michael Link, MD

Professor of Pediatrics

Stanford University School of Medicine

Outcomes of children with cancer have improved dramatically in the past two decades, largely as a result of clinical trials. This presentation will review the unique features of cancers in children and the problems/concerns of conducting clinical trials in children, as well as the contribution of clinical trials to the spectacular results that are now achieved in children with cancer. 411

Sat. Sept. 27 - Track 4 - 4:15 to 5:00

Acupuncture and Laser Therapy of Lymphedema

Barbara Ann Phibbs, RN, LAc, OMD

Acupuncturist/Office Manager, Garth D. Phibbs, MD

This presentation will discuss the treatment of lymphedema, morbidity reduction in the lymphedema patient, and improvement of quality of life in the lymphedema patient. 412

Track 5 - Safety/Pharmacovigilance**Sat. Sept. 27 - Track 5 - 8:30 to 9:15****An Overview of Safety Concerns in Clinical Trial Research****Armin D. Weinberg, PhD****Professor of Medicine and Director of Chronic Disease Prevention & Control Research Center**

Baylor College of Medicine

In today's world of clinical research, where increased participation of previously underrepresented populations occur, new challenges to participant safety must be identified and addressed. In this presentation, an overview of these emerging safety concerns will be presented. Case studies providing solutions will be provided. 506

Sat. Sept. 27 - Track 5 - 9:15 to 10:00**The Value of Pharmacovigilance****Jacqueline Edwards, BS, RN, CCRA****Senior Clinical Research Associate**

inVentiv Clinical Solutions

The critical role of pharmacovigilance in the world of clinical R&D today will be presented. Several case studies will be provided to illustrate the current industry trends in pharmacovigilance from the pharmaceutical and regulatory perspective. 507

Sat. Sept. 27 - Track 5 - 10:30 to 11:15**The Shared Responsibility for Safety****Neila Smith, MD****Senior Medical Director of Clinical Safety**

Takeda Pharmaceuticals

During the conduct of clinical trials, there is a shared responsibility for subject safety between the sponsor, study site, monitor, DMC, and regulatory agencies involved. This responsibility starts from the initial project startup through the postmarketing evaluation with risk management considerations evaluated throughout the duration of drug development. This presentation will cover the responsibilities of each player and present an overview within the context of a global clinical trial project. 508

Sat. Sept. 27 - Track 5 - 11:15 to 12:00**Safety and Pharmacovigilance from a Biotech Perspective****Bruno Gagnon, BPharm, MSc****Senior Director, Clinical Operations**

FibroGen Inc

This presentation will provide a brief overview of safety and pharmacovigilance considerations from drug discovery to submission from a biotechnology perspective. 509

Sat. Sept. 27 - Track 5 - 1:30 to 3:00**Essential Training in Safety and Pharmacovigilance for Clinical Trial Professionals****Karen G. Davenport, MS, BSN, CCRC, RN****Senior Clinical Research Coordinator**

University of Virginia School of Medicine

Carolyn E. Rugloski, BA, MSc, CCRP**Director, Medical Organization Training & Compliance**

MedImmune

Cheryl I. Jacobs, BA, CCRP**Director, Clinical Research, Breastlink**

The panel will discuss the essential training aspects related to safety and pharmacovigilance and provide key highlights of successful training programs in the field. Covering the viewpoints from a university clinical trial setting, a private study site, and a CRO perspective, the panel members will present several program highlights revealing critical training components used for on-the-job training. 510, 511, 512

Sat. Sept. 27 - Track 5 - 3:30 to 4:00**Management of Safety Reporting in Multicenter Clinical Trials****Anatoly V. Gorkoun, MD, PhD****Clinical Project Manager, PSI Co Ltd.**

One of the project manager's responsibilities is to make sure that safety reporting procedures are in place before the study starts and followed during the course of the trial, though it can be a challenge for big trials where the safety reports must be submitted to regulatory authorities in different countries with sensible differences in their reporting procedures. How to set up the process of proper and timely safety report submissions as well as the respective tools for quality control will be discussed. 513

Sat. Sept. 27 - Track 5 - 4:00 to 5:00**Protecting Subjects Through Monitoring****Nariman A. Nasser, BS, CCRP, Associate Director of Clinical Operations, Immune Tolerance Network****Denise Owensby, BS, CCRP, Senior Clinical Research Coordinator, Clinical & Translational Science Center, UC Davis****Patti Tosta, MS, RN, CCRA, Clinical Operations Manager Immune Tolerance Network**

This panel will comprise a Government Network Sponsor member, a site monitor and an IRB monitor. A brief overview of standard and targeted monitoring will be followed by a discussion on the pros and cons of each in protecting subjects, from the perspective of the panel members. The panel will include information on how best to support subjects and ensure safety for all trials regardless of monitoring methods. 514, 515, 516

Track 6 - Quality Assurance

Sat. Sept. 27 - Track 6 - 8:30 to 9:15

Institutional Clinical Research Quality Assurance and Improvement Program: A BC-PHSA Initiative

Jean-Paul Collet, MD, PhD

Director, BC Children's and Women's Health Center

The research environment has become increasingly strict and complex with many rules and regulations designed to protect patients' safety and rights as well as the scientific integrity of the study. The Children's and Women's Health Center (CW) of British Columbia, has, over the next two years, committed to implement a quality assurance - quality improvement (QA-QI) program that may lead to a formal accreditation for "clinical research quality". The program includes: 1) Establishing the infrastructure: a) Implementing a regulatory guidelines training program; b) Ensuring standard operating procedures (SOPs) are implemented; c) Assuring that operational requirements are met. 2) Implementing processes related to: a) Establishing a minimum infrastructure wherever patients are recruited b) Organizing "risk based" monitoring c) Using the principles and tools of "root cause analysis" (RCA) to systematically investigate all serious problems with the objective to understand their cause and propose solutions to prevent future occurrence. ⁶⁰⁶

Sat. Sept. 27 - Track 6 - 9:15 to 10:00

Auditing in a Monitored World

Doreen McGirl, BA

GCP Manager, Schering Plough

The auditor and the monitor perform activities to assure the quality of the data being generated by clinical investigators. This presentation offers insight into how auditors prepare for, and conduct, clinical investigator site audits, with additional discussion on sponsor obligations. ⁶⁰⁷

Sat. Sept. 27 - Track 6 - 10:30 to 11:15

External Audit Response

Kathy Welch, BS, CQA, MT

Quality Director, Blood Systems Laboratory

External audits performed by the FDA are available to the public through the Freedom of Information Act. The report may be read by individuals not present during the audit or close out meetings. They may be people from other institutions and different professions than the medical field. This makes it critical that the responses to the observations in the report accurately reflect what was actually observed by the auditor and lead to the citation. ^{608, 609}

Sat. Sept. 27 - Track 6 - 11:15 to 12:00

Internal Inspections as Part of the Quality Assurance Program

Roseanne Schott, MBA, BSN, RN, CCRP

Nurse Researcher, Cleveland Clinic

The talk aims to address what types of items should be audited. In addition, collaboration with other departments such as the compliance and billing offices will be discussed. The feedback process and accountability are an important part of the equation that will also be considered in the context of an internal audit. ⁶¹⁰

Sat. Sept. 27 - Track 6 - 1:30 to 2:15

Quality Management Innovation in Clinical Research: Acceptance and Implementation

Meta Mitchell, PhD, BSc, Director of Quality Assurance

ASKA Research

What happens when QMS is implemented? The acceptance and implementation of quality assurance practices through SOPs and CAPA are essentially systems management of the quality management process: Writing the SOPs, training the relevant clinical research team members, assignment of accountability for the follow-up process, and their initiation and successful completion. What is the perceived value of the CAPA system -- and is it different on either side of the Atlantic Ocean? ⁶¹¹

Sat. Sept. 27 - Track 6 - 2:15 to 3:00

How to Develop a National Set of SOPs for Clinical Research

Karen Arts, BSN, RN, CCRC

Director of Business Development

Ontario Institute for Cancer Research

N2 is a Canadian initiative seeking to bring national clinical research groups and investigative sites together. By sharing best practices, N2 aims to set a national standard and raise the bar for the quality of support Canada will be able to offer in the conduct of clinical trials. One area N2 addressed was the development of a set of SOPs applicable to any clinical research area. Methods will be discussed. ⁶¹²

Track 6 -Chapter Interest/Development

Sat. Sept. 27 - Track 6 - 3:30 to 4:15

Chapter Orientation Session

Sat. Sept. 27 - Track 6 - 4:15 to 5:00

Chapter Orientation for Areas Other Than the US and Canada

Track 7 - Management**Sat. Sept. 27 - Track 7 - 8:30 to 9:15****The Legal Fundamentals of Clinical Research Agreements**

Peggy Beat, JD, RN, The Cleveland Clinic Foundation
The speaker will discuss essential clinical research contract concerns. Key legal principles in research contracting will be identified. This session will identify and discuss the legal guidelines governing implications of relationships with research sponsors. 705

Sat. Sept. 27 - Track 7 - 9:15 to 10:00**The Development and Management of a Clinical Research Program**

Christine Carter, PhD, MPH
Director of Surgical Research, George Washington University
We built a research program, where none existed, in the Department of Surgery at the George Washington University in 2004. This presentation is designed to offer research program development guidance that may serve to inform and inspire others involved in clinical medicine. 706

Sat. Sept. 27 - Track 7 - 10:30 to 11:15**Proactive Site Management Practices**

Elizabeth Chesnut, BA, Clinical Team Manager
Pharmaceutical Product Development Inc
Review of site management practices that have been shown to show positive results, as compared to a review of practices that tend to fail. This discussion will include site staff's complaints about common CRO practices. 707

Sat. Sept. 27 - Track 7 - 11:15 to 12:00**Investigator Initiated Research**

Mark Barnes, JD, LL.M., Ropes & Gray LLP
This session will provide an overview of the many regulatory and management issues involved in investigator initiated research, including FDA requirements, contracting with sites, and monitoring of trial conduct. 708

Track 7 - International Research**Sat. Sept. 27 - Track 7 - 1:30 to 2:15****Ethical Imperialism in Clinical Research**

Faith Fitzgerald, MD, BA, MACP, Professor of Med/Assoc Dean Humanities/Bioethics, UC Davis School of Medicine
Many therapies are needed in the developing world, and they must be the clinical test sites for translational research because that's where the patient population is. Many such places, however, have different authority relationships between doctors and patients than do Western European and North American countries due to low rates of literacy, differences in the concept of autonomy for women, different histories of previous experiences with medicine, and the like. Can Western ethical constraints in clinical research apply to other nations and peoples? And how shall American investigators approach new Americans with similar divergent backgrounds and beliefs? 709

Sat. Sept. 27 - Track 7 - 2:15 to 3:00**Clinical Trials Research in the Developing World**

Mark Barnes, JD, LL.M., Ropes & Gray LLP
The world's largest pharmaceutical firms conducted nearly half of their clinical trials outside of the U.S. as of August 2005, and there is widespread consensus that this trend is growing. While emerging clinical trial markets present distinct advantages, they also present legal, business, and public relations risks that are unique to their setting. This session will explore the benefits and risks of conducting clinical trials in developing countries. In doing so, it will expose traps for the unwary and provide proven strategies for maximizing the benefits and minimizing, or at least anticipating, the risks for these studies. 710

Sat. Sept. 27 - Track 7 - 3:30 to 4:15**International Translational Research Environment: Challenges and Opportunities**

Juan C. Salazar, MD, MPH
Director of Pediatric & Youth HIV Program
Connecticut Children's Medical Center
This presentation will include discussion about a translational study being conducted between the University of Connecticut and a research institute in South America. The speaker will discuss the particular challenges and opportunities in conducting such studies. Emphasis will be placed on current GCP and NIH funding difficulties and solutions to these problems. Some key ethical issues will also be reviewed. 711

Sat. Sept. 27 - Track 7 - 4:15 to 5:00**Local Experience: The Challenge of Implementing Good Clinical Practice Guidelines in Saudi Arabian Tertiary Care Hospital Highlighting Sophisticated Cultural Differences**

Abdallah A. Adlan, PhD, BSc, CCRP
Sr Research Coordinator, National Guard Health Affairs
This presentation will highlight nine years of experiencing major differences between the clinical research international guidelines, represented by the GCP versus the local culture perception of good clinical practice, in terms of informed consent wording, pediatric assent, clinical trial insurance, financial disclosure, etc. The presentation will also share how such conflicts were managed by the Saudi research centers. 712

Track 8 - Advanced Management

Sat. Sept. 27 - Track 8 - 8:30 to 9:15

Interim Monitoring and Data Monitoring Committees

Mark D. Krailo, PhD

Statistician

Children's Oncology Group Southern California

This session will review various approaches to the monitoring of clinical trial study data to assure action may be taken when there are early definitive differences between treatments in adverse event rates or efficacy, or it is clear that the treatment outcomes are not different. The speaker will also describe data and safety monitoring committees, their composition, how they work and how they use interim monitoring techniques to assess the emerging results from ongoing clinical research. ⁸⁰⁵

Sat. Sept. 27 - Track 8 - 9:15 to 10:00

ROI: The Value of Implementing Standardized Procedures

Carolyn E. Rugloski, BA, MSc, CCRP

**Director, Medical Organization Training and Compliance
MedImmune**

Return on investment (ROI) will be discussed related to the implementation of policies and standard operating procedures related to clinical trial management. Management considerations and business metric considerations will be presented through case study scenarios. ⁸⁰⁶

Sat. Sept. 27 - Track 8 - 10:30 to 11:15

Building Bridges: Key to Development of a Research Program in the Private Practice Setting

Cheryl I. Jacobs, BA, CCRP

Director, Clinical Research, Breastlink

A private practice is an island. Gaps in understanding and services will exist. Building processes and relationships both within and external to the practice in order to bridge these gaps is essential to the development of a successful research program within this setting. ⁸⁰⁷

Sat. Sept. 27 - Track 8 - 11:15 to 12:00

How To Write a Grant Proposal

Lesley Mitchell

Associate Professor of Pediatrics

University of Alberta

Competition for grants is increasingly competitive. A grant that will be competitive relies on great ideas but where investigators can fail is in the communication of those ideas when writing the grant. The talk will guide you through the peer review process, the writing of the proposal, and what to do if the grant is not funded the first go around. ⁸⁰⁸

Sat. Sept. 27 - Track 8 - 1:30 to 2:15

Developing an Effective Research Team

Tammy S. Neseth, BS

Compliance Coordinator, Mayo Clinic

The presentation includes the definition of an effective team, the members of the research team, the challenges teams encounter, and a personal experience of an effective research team. ⁸⁰⁹

Sat. Sept. 27 - Track 8 - 2:15 to 3:00

Hiring for Success

Susan I. Devine, CCRP

CTSU Manager, Hospital for Sick Children

This session will consider hiring and interviewing for new team members; getting the right person for the job. Contents of this talk will include hiring processes, writing a job posting, reviewing resumes, interview questions/techniques, checking references, and making the offer while avoiding common pitfalls. ⁸¹⁰

Sat. Sept. 27 - Track 8 - 3:30 to 4:15

Orienting New Staff and Mentoring

Ashley R. Kattlus, BSc, CCRP

Clinical Research Associate, Hospital for Sick Children

The speaker will discuss the orientation and mentoring of a new research coordinator at an academic site. Often the success of a new employee depends on how they are oriented to a new position and what mentoring and training is available to support them in the early weeks/months. While it can be a moving target based on an individual's prior education and experience, a well organized, multi-disciplinary approach is key in moving from a new hire to a qualified, well-established team member. ⁸¹¹

Sat. Sept. 27 - Track 8 - 4:15 to 5:00

Advanced Management Panel Discussion with open Q & A

Sunday, September 28, 2008

Closing Plenary Session

Sun. Sept. 28 - Track 1 Closing Plenary - 8:30 to 9:00

Politics and Women's Health Research

Virginia M. Miller, PhD, Professor of Surgery & Physiology, Mayo Graduate School of Medicine

This presentation will review how politics have influenced science across the ages with particular emphasis on present day clinical trials enrolling women. 119

Sun. Sept. 28 - Track 1 Closing Plenary - 9:00 to 9:30

Issues in In-Patient Clinical Trials

Lynn A. Babin, MSN, BSN, AAS, RN, APWCA, Senior CRA, PharmaNet

This presentation will focus on the inpatient subject, and the issues related to the psychology of (interactions with) the subject/family/staff. Issues regarding the nurse, hospital staff, and procedures will be discussed in relation to the enrollment, retention, and study compliance of hospitalized subjects. 120

Sun. Sept. 28 - Track 1 Closing Plenary - 9:30 to 10:00

Introduction to Nonprescription Drug Products

Leah Christl, PhD, Associate Director for Regulatory Affairs, FDA CDER

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 how nonprescription drug product advertisement is regulated. 121

Sun. Sept. 28 - Track 1 Closing Plenary - 10:30 to 11:00

Increasing the Effective Use of Non-RNs in Research

Susie A. Bullock, MPH, BSc, RN, CCRP, Research Nurse Manager, MD Anderson Cancer Center

Learn how to increase the effective workload of staff, such as data managers and non-RN study coordinators. The speaker will offer her firsthand experience in the revamping of the data coordinator role at MD Anderson Cancer Center. This presentation will show how the department's increased responsibilities led to additional staff training. 122

Sun. Sept. 28 - Track 1 Closing Plenary - 11:00 to 11:30

Balancing Work and Family/Avoiding Burnout/Managing Stress - Sprints and Marathons: "Winning" the Drug Development Race

Robert B. Huizinga, MSc, RN, NNC, CNeph(C), Senior Director of Clinical Affairs, Isotechnika Inc

In the marathon of timely drug development, how do we balance the sprints needed by the sponsor, CRO and Investigator with our own ability to complete the race successfully? This presentation will look at preparing for the race, strategy during the race, and how to stand on the podium at the end in a way that brings home the gold for all partners. At the end of the session, participants will understand how to balance the needs of our professional development and interpersonal development. 123

Sun. Sept. 28 - Track 1 Closing Plenary - 11:30 to 12:00

"To Sleep, Perchance to Dream..."

Janet C. Johnson, BA, RN, Patient Education Specialist, Mayo Clinic Rochester

Before Thomas Edison invented the light bulb, people slept an average of 10 hours a night. Today that number has decreased to fewer than 7 hours, according to the National Sleep Foundation. This session will discuss the nature of sleep, why we need sleep, and review practical suggestions for getting good sleep. 124

Sun. Sept. 28 - Track 1 Closing Plenary - 12:00 Noon

17th Annual Conference Adjourns