Oncology Clinical Trials Conference

Assuring Research Regulatory Compliance
Assuring Trial Integrity and Research Subject Wellbeing

March 30 and 31, 2017

Newport Beach, CA USA
Hyatt Regency Newport Beach
1107 Jamboree Rd., Newport Beach, CA 92660
GOAL: The Society of Clinical Research Associates (SOCRA) recognizes the continuing need for education for Clinical Research Professionals responsible for the activities at the research site or institution. The purpose of this workshop is to assist Research Professionals in improving their skills and their understanding of the responsibilities of conducting oncology clinical research.

OBJECTIVE: The goal will be accomplished through lecture and practical application facilitated by clinical research professionals. Information will be presented and discussed regarding the administration of oncology clinical trials according to regulation, guidance, policy and procedure.

Learning Objectives
The attendee should be able to:

- Discuss current trends in oncology clinical research and identify how these trends are influencing oncology trials.
- Discuss the challenges of conducting oncology clinical research.
- Discuss the complexity of oncology trials and tools and techniques for managing these trials.
- Discuss regulatory requirements for oncology research including the NCI policies and guidelines for protocol development.
- Discuss the basic principles of clinical trial design.
- Discuss the standard approach to response evaluation in oncology.
- Describe sponsor expectations of oncology research sites.
- Discuss site selection from pre-qualification through initiation and site ready status.
- Describe the importance of Pharmacokinetics (PK) evaluations in oncology research.
- Discuss the use of personalized medicine and target therapies in oncology research.
- Describe the process of reporting adverse events, including special NCI reporting requirements.
- Discuss the standard approach to response evaluation in oncology research.
- Discuss the Investigator’s responsibilities for conducting safe, ethical, and successful research.
- Discuss the changing methodology used for conducting Phase 1 oncology trials.

SOCRA designates this educational activity for a maximum of 13.3 Continuing Education Credits for SOCRA CE and Nurse CNE. SOCRA designates this live activity for a maximum of 13.3 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Accreditation Statements:

CME for Physicians: The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CNE for Nurses: Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation.
Oncology Clinical Trials Conference

Agenda for March 30 and 31, 2017 (Thursday and Friday) in Newport Beach, CA

8:00 – 8:30 Registration and Continental Breakfast

8:30 – 8:50 Introduction to Oncology Clinical Research
Matthew Neseth, MA, CCRP, CIP, Research Compliance Manager/ interim Research Subject Advocate, Mayo Clinic

Ms. Neseth will provide an introduction and overview of the Oncology Clinical Research Conference. During this time there will be discussion to assist the faculty in getting to know the attendees and their learning objectives.

8:50 – 9:50 Challenges and Opportunities in Oncology Research
Scott Okuno, M.D., Consultant in Department of Oncology, Mayo Clinic

Dr. Okuno will discuss the challenges of oncology research and suggest ways to address new opportunities.

9:50 – 10:05 Break (with opportunity for discussion)

10:05 – 11:15 Regulatory Considerations in Oncology Research
Joshua Schoppe MPH, CCRP, Senior Director, Regional Network Office, Thomas Jefferson University

Mr. Schoppe will give an overview of the regulatory requirements and management strategy of running a multi-site community based research network. This presentation will focus on the management of clinical trials at satellite institutions, the utilization of the NCI Central Institutional Review Board, and the challenges facing large research networks.

11:15 – 12:15 Budgeting and Staffing Oncology Trials
Teresa Stewart, M.S., Executive Director, New Mexico Cancer Care Alliance

In this session, Ms. Stewart will address the evolving and increasing complexity of oncology trials. She will discuss how a site assesses workload and effectively negotiate budgets to successfully manage a trial.

12:15 – 1:00 Lunch (provided) and opportunity for discussion

1:00 – 1:45 Clinical Trial Site Selection for Oncology Trials and Monitoring from the CRA's Perspective
Aubri Lang, CCRP, Senior Clinical Research Associate, TESARO

This presentation will share sponsor expectations for a successful oncology clinical trial. Site selection from pre-qualification through initiation and site-ready status will be discussed. The speaker will also provide examples of monitoring findings along with a few tips and tools that can be used decrease future findings.

1:45 – 3:15 Pharmacology 101: An Introduction to Pharmacokinetics, Pharmacodynamics and Sample Stability for Clinical Research Professionals
Gregory Staios, M.Sc., Research Monitor, Centre for Addiction and Mental Health Assurance Coordinator

Mr. Staios will discuss how drugs interact within the biological system and in turn how the biological system acts on the drug. This presentation will also provide an introduction to pharmacokinetic evaluations and how they are used to characterize the dose response relationships for new pharmaceutical products. The importance of sample integrity and stability and their future use will also be discussed.

3:15 – 3:30 Break

3:30-4:15 Correlative Science: The Promise of Personalized Medicine for Cancer Treatment
Vanessa Speers, MSc, BEd, Manager, Correlative Studies Program, Princess Margaret Cancer Centre

Ms. Speers will discuss the procurement, processing, and quality of biospecimens as it relates to the advent of personalized medicine which exponentially increased the number of biospecimens that are being collected in clinical trials. Matched with the ideology of personalized medicine, with its specialized portfolio of services, a need has been generated for a centralized specimen management program to govern the collection and processing of biospecimens. This presentation will discuss the logistics of managing correlative science in detail.

4:15 – 4:45 Day 1 Q&A with Day One Speakers
Day Two: Friday, March 31, 2017

8:00 – 8:30  Continental Breakfast
8:30 – 9:30  Improving the Oncology Research Participant Experience
  Tammy Neseth, MA, CCRP, CIP, Research Compliance Manager/ interim Research Subject Advocate, Mayo Clinic
  Ms. Neseth will focus on gaining a better understanding of the point of view of the oncology research participant. Participants’ stories will be shared in order to understand what makes a research experience positive or negative. Ms. Neseth will include practical advice and participant suggestions on how to improve the overall research experience.

9:30 – 10:30  Adverse Event Reporting for Oncology Trials
  Jasmine Grant, M.Ed, BHSc, CCRP Education Specialist Lead, Princess Margaret Cancer Centre
  Ms. Grant will discuss the Common Terminology Criteria for Adverse Events (CTCAE) coding dictionary for adverse events, its use in oncology research, and challenges faced in coding. Tips on navigating the CTCAE dictionary will be discussed. Special NCI reporting requirements will also be covered.

10:30 – 10:45  Break (with opportunity for discussion)

10:45 – 11:45  Basic principles of clinical trial design, conduct and choice of endpoints
  Sumithra J. Mandrekar, PhD, Professor of Biostatistics and Oncology, Mayo Clinic
  This presentation will review the basic principles of clinical trial design. Dr. Mandrekar will explain the importance for upfront investment in planning by the study in terms of endpoints, data collection and analyses. Dr. Mandrekar will also provide the audience with a few do’s and don’ts of clinical trial monitoring.

11:45 – 12:30  Response Evaluation Criteria in Oncology
  Jasmine Grant, M.Ed, BHSc, CCRP Education Specialist Lead, Princess Margaret Cancer Centre
  In this session, Ms. Grant will review the standard approach to response evaluation in oncology. Criterion such as RECIST, Chesson, Immune related, and MacDonald criteria will be discussed as well as definitions for objective assessment of change in tumor size for use in adult oncology trials.

12:30 – 1:15  Lunch (provided) and opportunity for discussion

1:15 – 1:30  Poster Winner Presentations

1:30 – 2:15  Phase 1 Clinical Oncology Trials
  Joyce Tungol, BS, CCRP, Associate Project Director, Early Phase, University of Kansas Cancer Center
  A Phase I clinical oncology trial is the first step in testing an investigational treatment approach, as it determines a drug’s safety, dosage, tolerability, and side effects. This session will provide an overview of the importance, purpose, and objectives of Phase I clinical trials. Early phase study design, logistics/characteristics and challenges will also be discussed. Additionally, we will cover the Phase I study coordinator perspective and the common day-to-day challenges encountered in the Phase I clinical trial environment.

2:15 – 3:00  The Next Generation: Immunotherapy and Personalized Medicine
  Jamie Harper, MHA, CCRP, Director of Clinical Research, Illinois CancerCare
  Immunotherapy is an emerging class of cancer treatment that uses the body’s own immune system to help fight cancer cells. Using treatments designed to target specific tumor markers, the goal is to boost or restore the body’s immune function in some manner. This session will give an overview of immunotherapy and cancer, the different approaches currently available and how this information is used to develop a personalized treatment regimen.

3:00 – 3:25  Break (with opportunity for discussion)

3:25 – 4:25  Actively Incorporating Good Clinical Practices (GCP) into Oncology Clinical Trial Management
  Bryce Mansfield, PhD, Clinical Compliance – Senior Manager, Gilead Sciences, Inc.
  This session will examine common FDA findings during clinical investigator BIMO inspections. Dr. Mansfield will discuss what these findings mean and the unique challenges in Oncology studies. Dr. Mansfield will also outline ways to build in quality into the study in order to avoid these issues.

4:25 – 4:45  Day Two Q&A with Day Two Speakers

4:45 – 4:50  Closing Remarks and Adjournment
# Oncology Clinical Trials Conference

**Agenda for March 31 and April 1, 2016 (Thursday and Friday) in Miami Beach, FL**

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<td>8:00 – 8:30</td>
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*Tammy Neseth, MA, CCRP*, Operations Manager - IRB Regulatory Compliance, Mayo Clinic  
*Susanna Sellmann, BSc, CCRP, MRT*, Quality Manager, Cancer Clinical Research Unit, Princess Margaret Hospital  

Ms. Neseth and Ms. Sellmann will provide an introduction and overview of the Oncology Clinical Research Conference. During this time there will be discussion to assist the faculty in getting to know our attendees and their learning objectives.
8:50 – 9:50  Challenges and Opportunities in Oncology Research  
*Scott Okuno, M.D., Consultant in Department of Oncology, Mayo Clinic*  
Dr. Okuno will discuss the challenges of oncology research and suggest ways to address new opportunities.

9:50 – 10:05  Break (with opportunity for discussion)
Regulatory Considerations in Oncology Research

Joshua Schoppe MPH, CCRP, Senior Outreach Coordinator, Thomas Jefferson University Hospital

Mr. Schoppe will give an overview of the regulatory requirements and management strategy of running a multi-site community based research network. This presentation will focus on the management of clinical trials at satellite institutions, the utilization of the NCI Central Institutional Review Board, and the challenges facing large research networks.”
11:15 – 12:15  **Staffing Oncology Trials**

**Teresa Stewart, M.S., Executive Director, New Mexico Cancer Care Alliance**

In this session, Ms. Stewart will address the evolving and increasing complexity of oncology trials. She will discuss how a site may use project management skills to negotiate budgets and determine workload.

12:15 – 1:15  **Lunch (provided) and opportunity for poster review and discussion**
Clinical Trial Site Selection for Oncology Trials and Monitoring from the CRA's Perspective

Bonnie Shenaer, BSc, PRA/Merck

Ms. Shenaer will share sponsor expectations for a successful oncology clinical trial. Site selection from pre-qualification through initiation and site-ready status will be discussed. Ms. Shenaer will also provide examples of monitoring findings along with a few tips and tools that can be used to decrease future findings.
2:00 – 3:30  Pharmacokinetics, Pharmacodynamics and Sample Stability: Applications to Clinical Research
Gregory Staios, M.Sc., Research Monitor,
Centre for Addiction and Mental Health Assurance Coordinator
Mr. Staios will discuss how drugs interact within the biological system and in turn how the biological system acts on the drug. This presentation will also provide an introduction to pharmacokinetic evaluations and how they are used to characterize the dose response relationships for new pharmaceutical products. The importance of sample integrity and stability and their future use will also be discussed.

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3:45 - 4:30      Correlative Science: The Promise of Personalized Medicine for Cancer Treatment

Vanessa Speers, MSc, BEd, Manager, Correlative Studies Program, Princess Margaret Cancer Centre

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4:30 – 4:50      Day 1 Q&A
Day Two: Friday, April 1, 2016

8:00 – 8:30  Continental Breakfast

8:30 – 9:30  Improving the Oncology Research Participant Experience

*Cheryl Thomas, MS, CGC, Research Subject Advocate, Mayo Clinic*

Ms. Thomas will focus on gaining a better understanding of the point of view of the oncology research participant. Participants' stories will be shared in order to understand what makes a research experience positive or negative. Ms. Thomas will include practical advice and participant suggestions on how to improve the overall research experience.
9:30 – 10:30  **Adverse Event Reporting for Oncology Trials**

*Lindsay Philip, Hons BSc, CCRP, Education Specialist/Quality Assurance Coordinator, Princess Margaret Cancer Centre*

Ms. Phillip will discuss the Common Terminology Criteria for Adverse Events (CTCAE) coding dictionary for adverse events, its use in oncology research, and challenges faced in coding. Tips on navigating the CTCAE dictionary will be discussed. Special NCI reporting requirements will also be covered.

10:30 – 10:45  **Break (with opportunity for discussion)**
10:45 – 11:30  **Response Evaluation Criteria in Oncology**

*Lawrence Schwartz, M.D., James Picker Professor and Chairman, Columbia University*

Dr. Schwartz will discuss the standard approach to response evaluation in oncology research.
11:30 – 12:30  Investigator Responsibilities- Pertaining to Participants, The Oncology Protocol and the Use of Investigational Agents

Loren Tschetter, M.D., Chair Sanford System Oncology IRB and Member NCI IRB

The individual investigator and the responsible Principle Investigator at a site are key to the proper selection of research subjects, the proper use of the protocol, the collection of toxicity data and changes to dosing based on this toxicity, and the proper use of investigational agents. What is required is an ethical investigator. The IRB system is intended to assure that the protocol is ethical in its structure. Protocol adherence and proper Informed consent processes are essential to the safe and ethical conduct of trials. Finally the proper ordering, storage, accountability and use of investigational agents is the responsibility of the individual investigator and his staff.

12:30 – 1:30  Lunch (provided) with an opportunity for discussions
1:30 – 2:20  Phase 1 Clinical Oncology Trials

Joyce Tungol, BS, CCRP, Early Phase Clinical Research Coordinator, The University of Kansas Cancer Center

A Phase I clinical oncology trial is the first step in testing an investigational treatment approach, as it determines a drug’s safety, dosage, tolerability, and side effects. This session will provide an overview of the importance, purpose, and objectives of Phase I clinical trials. Early phase study design, logistics/characteristics and challenges will also be discussed. Additionally, we will cover the Phase I study coordinator perspective and the common day-to-day challenges encountered in the Phase I clinical trial environment.
Immunotherapy is an emerging class of cancer treatment that uses the body's own immune system to help fight cancer cells. Through treatment vaccines, monoclonal antibodies, and several other immunotherapy approaches, the goal is to boost or restore the body's immune function in some manner. This session will give an overview of immunotherapy and cancer, and the different approaches currently available and under investigation.
3:25 – 4:25  Actively Incorporating Good Clinical Practices (GCP) into Oncology Clinical Trial Management

Bryce Mansfield, PhD, Clinical Compliance – Senior Manager, Gilead Sciences, Inc.
This session will examine common FDA findings during clinical investigator BIMO inspections. Dr. Mansfield will discuss what these findings mean and the unique challenges in Oncology studies. He will also outline ways to build in quality into the study in order to avoid these issues.

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