Oncology Clinical Trials Conference

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

8:00 – 8:30  
**Registration and Continental Breakfast**

8:30 – 8:45  
**Introduction to Oncology Clinical Research**  
*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)**

10:05 – 11:15  
**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**

1:15 – 2:00  
**Clinical Trial Site Selection for Oncology Trials and Monitoring from the CRA's**  
*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.

3:30 – 3:45  
**Break**

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  
Ms. Speers will discuss how the advent of personalized medicine, has 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.

4:30 – 4:50  
**Poster Presentation**
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 Poster Winner Presentations

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.

2:20 – 3:05  Immunotherapy: Helping the Immune System Fight Cancer
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. 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.

3:05 – 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. He will also outline ways to build in quality into the study in order to avoid these issues.

4:25 – 4:40  Closing Remarks and Adjournment