ONCOLOGY CLINICAL TRIALS CONFERENCE AGENDA

PRECONFERENCE WORKSHOPS: WEDNESDAY, MARCH 4, 2020

Two (2) - Optional ½ Day Workshops
Good Clinical Practice (GCP) E6 (R2) Basics
Oncology Research Fundamentals
** Requires Separate Registration

GOOD CLINICAL PRACTICE (GCP) E6 (R2) BASICS PRECONFERENCE WORKSHOP

7:30 – 8:00 - Registration and Continental Breakfast

8:00 – 11:30 - Good Clinical Practice (GCP) E6 (R2) Basics
(Break 9:45 - 10:00)
This half-day workshop, which also meets the NIH requirements for GCP Training, will teach to the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants.

11:30 – 12:00 - Registration and Welcome

12:00 – 12:40 - Basics of Oncology Research
This session will provide a basic overview Oncology Research. Topics include: Cancer statistics, Oncology terminology, development of cancer, understanding cancer diagnosis, staging and grading, and what makes oncology trials unique.

12:40 – 1:20 - Treatment Modalities
This session will look at the goals for cancer treatment as well as the different options available, such as surgery, radiation therapy, chemotherapy, immunotherapy and other medical treatments.

1:20 – 2:00 - Response Criteria in Oncology Research
In this session, we will review the standard approach to response evaluation in oncology. Response Evaluation Criteria in Solid Tumors (RECISIT) will be discussed as well as definitions for objective assessment of change in tumor size for use in oncology trials.

2:00 – 2:20 - Break

2:20 – 3:00 - Adverse Events in Oncology Research
This presentation 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.

3:00 – 3:40 - Oncology Protocol Review
This session will inform how to critically review a protocol concentrating on specific sections such as, the schema, primary and secondary objectives, eligibility, dosing and adverse events. We will discuss the how to read and then build a test schedule on the protocol provided.

3:40 – 4:20 - Oncology Case Study
This session will be an interactive activity incorporating the information gained throughout today’s program.

4:20 – 4:35 - Helpful resources and tips for a new oncology professional

4:35 – 4:55 - Question and Answer Session
This session is an opportunity to discuss questions and answers related to the topics presented in preconference.
MAIN CONFERENCE - DAY I: THURSDAY, MARCH 5, 2020

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

8:30 – 8:45 - Introduction to SOCRA
Susanna Sellman, RTT, BS, CCRP, Quality Assurance Manager, Princess Margaret Cancer Center
Ms. Sellman will provide an introduction to the Society of Clinical Research Associates (SOCRA) and review the benefits of being a SOCRA member.

8:45 – 9:05 - Oncology Clinical Research
Tammy Neseth, MA, CCRP, CIP, Research Compliance Manager, 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.

9:05 – 10:05 - Challenges and Opportunities in Oncology Research
Scott Okuno, MD, Consultant, Department of Oncology, Mayo Clinic
Dr. Okuno will discuss the challenges of oncology research and suggest ways to address new opportunities.

10:05 – 10:20 - Break (with opportunity for poster review)

10:20 – 11:20 - Regulatory Considerations in Oncology Research
Connie Szczepanek, BSN, RN, CCRP, Director, Cancer Research Consortium of West Michigan NCORP
This session will provide overview of the regulatory requirements and management strategy of running a multi-site community based research network. Mrs. Szczepanek will focus on the management of clinical trials at satellite institutions, the utilization of the NCI Central Institutional Review Board, and the challenges facing research networks.

11:20 – 12:20 - Budgeting and Staffing Oncology Trials
Teresa Stewart, MS, Vice President, Mantos Consulting, Inc.
In this session, Ms. Stewart will address the evolving and increasing complexity of oncology trials. We will discuss how a site assesses workload and effectively negotiate budgets to successfully manage a trial.

12:20 – 1:05 - Lunch (Provided)

1:05 – 1:50 - Clinical Trial Site Selection for Oncology Trials and Monitoring from the CRA's Perspective
Kara Lee McWatters, BSC, MSC, CCRP, RQAP-GCP, Director/Consultant, Stiris Research Inc/McWatters Clinical Research Consulting
Ms. McWatters will discuss common challenges in conducting and managing Oncology trials. Common management issues and monitoring findings will be reviewed. Strategies to reduce findings, improve efficiency and communication as well as strengthen the Sponsor-site relationship will be discussed. Participants will leave with recommendations that can be implemented in current and future trials.

1:50 – 2:35 - Pharmacology 101: An Introduction to Pharmacokinetics, Pharmacodynamics and Research Professionals
Jeff Doi, HonBSc, BScPharm, RPh, BCPS, Clinical Trials Pharmacist, Princess Margaret Cancer Centre, UHN
Mr. Doi 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.

2:35 - 3:20 Correlative Science: The Business of Quality Specimen Management
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 managing correlative science in detail.

3:20 – 3:35 Break (with opportunity for poster review)

3:35 – 4:20 Phase 1 Clinical Oncology Trials
Joyce Tungol, BS, CCRP, Clinical Research Associate, Duke Cancer Network
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.

4:20 – 4:50 Day 1 Wrap-up
MAIN CONFERENCE - DAY II: FRIDAY, MARCH 6, 2020

8:00 – 8:30 - Continental Breakfast

8:30 – 9:15 - Improving the Oncology Research Participant Experience
Tammy Neseth, MA, CCRP, CIP, Research Compliance Manager, Mayo Clinic
This session 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.

9:15 – 10:00 - Hematologic Malignancies
Joseph Vadakara, MD, Hematology/Oncology Physician/Director of Hematology/Oncology Fellowship Program, Geisinger
This session will focus on therapeutic advances over the years. Dr. Vadakara will discuss challenges and opportunities in clinical trials in this field.

10:00 – 10:15 - Break (with opportunity for poster review)

10:15 – 11:15 - Basic Principles of Clinical Trial Design, Conduct and Choice of Endpoints
Jennifer Le-Rademacher, PhD, Professor of Biostatistics and Oncology, Mayo Clinic
This presentation will review the basic principles of clinical trial design. Dr. Le-Rademacher will explain the importance for upfront investment in planning by the study in terms of endpoints, data collection and analyses. Dr. Le-Rademacher will also provide the audience with a few do’s and don’ts of clinical trial monitoring.

11:15 – 12:15 - Imaging in Oncology Clinical Trials
Scott Okuno, MD, Mayo Clinic
Dr. Okuno will discuss imaging in oncology clinical trials. The topics covered include modalities, response assessment metrics and changes to response criteria.

12:15 – 1:00 - Lunch (Provided)

1:00 – 1:15 - Poster Winner Presentations

1:15 – 2:00 - Proton Beam Therapy
Mark McDonald, MD, Medical Director, Associate Professor, Winship Cancer Institute of Emory University
More than half of all people with cancer receive radiation therapy. This session will discuss the alternative to conventional radiation therapy. Proton beam therapy uses the positively charged particles in an atom (protons) that release their energy within the tumor.

2:00 – 2:45 - 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. Ms. Harper 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.

2:45 – 3:15 - Adverse Events of Oncologic Immunotherapy and Their Management
Julie Gundry, RN, MSc(A), Nurse Manager, Princess Margaret Cancer Centre
Ms. Gundry will provide an overview of immunotherapy related adverse events with a focus on checkpoint inhibitors, CAR-T and BiTE therapy. Assessment and management of immune related AEs as well as patient education needs specific to immunotherapy will be discussed using examples from clinical case scenarios.

3:15 – 3:35 - Break (with opportunity for discussion)

3:35 – 4:35 - Regulatory Inspection Minimizing Findings by Actively Incorporating Good Clinical Practices (GCP)
Bryce Mansfield, PhD, Associate Director, Gilead Sciences
Dr. Mansfield will examine common FDA findings during clinical investigator BIMO inspections. We will discuss what these findings mean and the unique challenges in Oncology studies. We will also outline ways to build in quality into the study in order to avoid these issues.

4:35 – 4:50 - Day Two Wrap-up

4:50 – 5:00 - Closing Remarks and Adjournment