

Clinical Trials Workshop 2010: Molecular Imaging in Clinical Trials - Part I: Radiopharmaceutical Production in Multicenter Clinical Trials

SPONSORED BY THE CLINICAL TRIALS NETWORK

AMA PRA Category 1 Credit(s)[™]:

ACPE:

CAMPEP:

VOICE:
Category A+:

Session Leaders

Organizers: Michael M. Graham, PhD, MD; Peter S. Conti, MD, PhD; John M. Hoffman, MD

Moderators: AM session - Sally W. Schwarz, MS, RPh, BCNP
PM session - John M. Hoffman, MD

Summary

This categorical includes lectures aimed at providing important regulatory information to manufacturers as well as procedures and guidelines for all clinical site personnel involved in imaging research. Speakers with expertise in a variety of fields will present topics that are of significant interest to facilities engaged in biomarker production for clinical research and those involved in management and implementation of research activities at clinical sites. The day will be divided into two main sessions:

- Regulatory and audit guidelines affecting manufacturers involved in radiopharmaceuticals production for multicenter clinical trials
- Manufacturing perspectives from industry and academic facilities

These exceptional presentations are essential to advancing awareness and understanding of using biomarkers in therapeutic clinical trials and the need for compliance with regulatory guidelines in research..

Objectives

Upon completion of this activity, the participant will be able to:

1. Discuss the FDA, Academic and Industry perspectives on Current Manufacturing Practices (cGMP) for PET
2. Describe how manufacturers and imaging sites can best prepare for an FDA inspection / audit.
3. Review expectations of the imaging site when participating in multicenter clinical trials.
4. Discuss the importance of using biomarker imaging agents in therapeutics trials.

Presentations

7:30 AM - 8:30 AM	FDA Perspective on cGMP for PET: 212 Dwayne Rieves, MD; Wendy Sanhai, PhD
8:30 AM - 9:00 AM	Considerations for Chemistry Manufacturing & Controls (CMC) Eldon Leutzinger, PhD
9:00 AM - 9:15 AM	Submitting a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) Sally W. Schwarz, MS, RPh, BCNP
9:15 AM - 10:00 AM	Industry Perspective on Manufacturing Anwer A. Rizvi, RT (N); Steven Zigler, PhD ; Daniel Skovronsky, MD, PhD
10:00 AM - 10:15 AM	Morning Break
10:15 AM - 10:45 AM	Academic Perspective Jeffrey A. Clanton, MS, DPh, BCNP
10:45 AM - 11:15 AM	Audits and Inspections Overview for the Manufacturing Site David W. Dick, PhD

Clinical Trials Workshop 2010: Molecular Imaging in Clinical Trials - Part II: Critical Elements of Imaging in High Quality Multicenter Clinical Research

SPONSORED BY THE CLINICAL TRIALS NETWORK

Presentations

12:15 PM - 12:30 PM	Overview of the SNM Clinical Trials Network Peter S. Conti, MD, PhD
12:30 PM - 12:45 PM	Overview of Clinical Trials - Therapeutic and Diagnostic Imaging Agents James M. Mountz, MD, PhD
12:45 PM - 1:05 PM	Importance of Imaging in Therapeutic Trials (Imaging as a Biomarker) Daniel C. Sullivan, MD
1:05 PM - 1:25 PM	Protocol Design and Imaging Manuals David A. Mankoff, MD, PhD
1:25 PM - 1:45 PM	Scanner Validation and Why It Is Important Paul E. Christian, CNMT, BS, PET
1:45 PM - 2:05 PM	IRB Approval and Informed Consent Process - Expectations of the Imaging Site John Stillman, MPC
2:05 PM - 2:25 PM	Source Documentation and Case Report Forms – An Imaging CRO Perspective Toni T. Handzel, MS, MBA
2:25 PM - 2:45 PM	Data Handling and Image Transfer / Blinded Reads Jeffrey T. Yap, PhD
2:45 PM - 3:00 PM	Afternoon Break
3:00 PM - 3:20 PM	Adverse Event Reporting and the DSMB Barbara Galen, CRNP, CNMT,MSN
3:20 PM - 3:40 PM	Preparing the Imaging Site for Inspections and Audits LisaAnn Trembath, MSM, CNMT, NCT, CCRA
3:40 PM - 4:05 PM	Overview of Regulatory Issues for the Imaging Site John M. Hoffman, MD
4:05 PM - 4:15 PM	Summary and Final Remarks Michael M. Graham, PhD, MD
