MEDICAL IMAGING STAKEHOLDERS CALL FOR ACTION:
Harmonization of Imaging Review Charters and Integration of Imaging in Therapeutic Development
Pharmaceutical Industry, CRO, FDA, and Allied Working Groups
Collaborate for Regulatory Guidance

October 16-17, 2007 | Marriott Conference Center, University of Maryland, Adelphi, MD

Program Chairs

Mostafa Analoui, PhD
Senior Director
Pfizer Global Research and Development

Darrick Fu
Associate Vice President, Science & Regulatory Affairs
PhRMA

George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting
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Former Director, Division of Medical Imaging and Hematology Products, CDER, FDA

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Founder and Chief Medical Officer
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Association of Clinical Research Organizations

John Warner, JD, MPA
MICAA
Compliance Manager
Guerbet LLC

Louis Marzella, MD, PhD
Medical Officer, FDA

Rafael Dwayne Rieves
Acting Director, FDA

Program Overview

Medical imaging stakeholders will collaborate for a call to action for harmonization and standardization of medical imaging in therapeutic development for the draft regulatory guidance to reach consensus on the common elements of imaging review charters required to meet the FDA review process.

The medical imaging conference will provide an opportunity for pharmaceutical, academic and other allied working groups to discuss key aspects of Medical Imaging Charters (IRC). IRCs are technical protocols used to guide the acquisition, processing and interpretation of medical imaging data in efficacy trials that use images for assessment of efficacy endpoints. The objective is to identify best practices that can be standardized in order to facilitate the use of medical imaging in clinical drug development.

Specific objectives are:

1. Identify areas where either practice or technology has progressed to near common use where a standard or best-practice can be adopted to increase efficiency and effectiveness for all parties involved and
2. Identify the components of an imaging charter which can be standardized or harmonized in order to assure imaging quality and simplify charter creation, user utilization, and regulatory review.

Session Topics

1) Standardization of imaging review charters (IRCs) across therapeutic areas: Oncology, Cardiovascular, CNS and Rheumatology
2) Medical Imaging: Good Review Practices (GRP);
3) Technical management of the site-core lab interface, and;
4) Contents of data integrity and statistical analysis plan.

Target Audience

- Academic, industry and government professionals
- Decision makers in drug development
- Clinical research, regulatory and imaging specialists

Contact Information

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Visit www.diahome.org for a complete schedule of events!
MONDAY • OCTOBER 15

4:00-6:00 PM  REGISTRATION

TUESDAY • OCTOBER 16

7:00-8:00 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:10 AM  WELCOME AND OPENING REMARKS
Pharmaceutical Working Group
Darrick Fu
Associate Vice President, Science and Regulatory Affairs
PhRMA
Mostafa Analoui
Senior Director
Pfizer Global Research and Development
Louis Marzella, MD, PhD
Medical Officer, FDA

8:10-8:20 AM  SUMMARY OF THE CONFERENCE
Louis Marzella, MD, PhD
Medical Officer, FDA

8:20-9:00 AM  KEYNOTE ADDRESS I
CALL FOR ACTION: HARMONIZATION ACROSS KEY ELEMENTS – STAKEHOLDERS COLLABORATE FOR REGULATORY GUIDANCE
FDA Speaker Invited

9:00-10:30 AM  SESSION I
STANDARDIZATION OF IMAGING CHARTERS
OBJECTIVE: To identify and describe the various content categories deemed necessary by regulatory agencies (FDA) for inclusion in independent imaging review charters for adequate and well controlled clinical trials. The objective will be sought through a pre-competitive, interactive consensus process with all stakeholders utilizing the Uniform Protocols for Imaging in Clinical Trials (UPICT) Template, Version 2.1 [October, 2006] as a starting point for the development of a Table of Contents (TOC) for imaging review charters. A supporting lexicon will also be developed to define potentially ambiguous words necessary to label the various content categories.

Panel Discussion Leaders:
SESSION CHAIRPERSON
George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting Perceptive Informatics/PARAXEL, Former Director, Division of Medical Imaging and Hematology Products, CDER, FDA
SESSION CO-CHAIRPERSON
Patricia E. Cole, MD, PhD
Senior Director and Head of Imaging, Eisai Global Clinical Development, Eisai Medical Research

FDA REPRESENTATIVES
Louis Marzella, MD, PhD
Medical Officer, FDA
Scheldon Kress, MD
Medical Officer, CDER, FDA

SESSION RECORDER

10:30-11:00 AM  REFRESHMENT BREAK

11:00 AM-12:30 PM  SESSION 2
MEDICAL IMAGING: GOOD REVIEW PRACTICES (GRP)

OBJECTIVE: (a) To identify review issues, discuss processes, suggest recommendations and gain consensus with regulatory authorities related to Independent Review (IR) of images and other clinical data in oncology clinical trials. This objective should be accomplished in a generic manner.

(b) To expand the scope of objective number one (1) to include other therapeutic areas.

(c) This work should facilitate the development of FDA (and other regulatory agency) Guidance Documents.

Panel Discussion Leaders:

CHAIRPERSON
Robert Ford
Founder and Chief Medical Officer, Radpharm

SESSION CO-CHAIRPERSON
P. David Mozley, MD
Senior Director, Imaging, Merck Research Laboratories

FDA REPRESENTATIVES
Barbara Stinson, MD
Medical Officer, FDA
Alex Gorovets, MD
Medical Officer, FDA

SESSION RECORDER

12:30-1:30 PM  LUNCHEON

1:30-3:00 PM  WORKING BREAKOUT SESSIONS:
DRAFT WHITE PAPER REVIEW AND INTERACTIVE FORUM

SESSION 1A
STANDARDIZATION OF IMAGING REVIEW CHARTERS (IRCs)

SESSION CHAIRPERSON
George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting Perceptive Informatics/PARAXEL, Former Director, Division of Medical Imaging and Hematology Products, CDER, FDA

SESSION CO-CHAIRPERSON
Patricia E. Cole, MD, PhD
Senior Director and Head of Imaging, Eisai Global Clinical Development, Eisai Medical Research
Scheldon Kress, MD
Medical Officer, CDER, FDA

SESSION RECORDER

SESSION 2A

MEDICAL IMAGING: GOOD REVIEW PRACTICES (GRP)

SESSION CHAIRPERSON
Robert Ford
Founder and Chief Medical Officer, Radpharm

SESSION CO-CHAIRPERSON
P. David Mozley, MD
Senior Director, Imaging, Merck Research Laboratories

FDA REPRESENTATIVES
Alex Gorovets, MD
Medical Officer, FDA
Barbara Stinson, MD
Medical Officer, FDA

SESSION RECORDER

3:00-3:30 PM  REFRESHMENT BREAK

3:30-4:00 PM  Recap and Next Steps
STANDARDIZATION OF IMAGING REVIEW CHARTERS (IRCs)

SESSION CHAIRPERSON
George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting Perceptive Informatics/PARAXEL, Former Director, Division of Medical Imaging and Hematology Products, CDER, FDA

SESSION CO-CHAIRPERSON
Patricia E. Cole, MD, PhD
Senior Director and Head of Imaging, Eisai Global Clinical Development, Eisai Medical Research

4:00-4:30 PM  Recap and Next Steps
MEDICAL IMAGING: GOOD REVIEW PRACTICES (GRP)

SESSION CHAIRPERSON
Robert Ford
Founder and Chief Medical Officer, Radpharm

SESSION CO-CHAIRPERSON
P. David Mozley, MD
Senior Director, Imaging, Merck Research Laboratories

4:30-5:30 PM  PANEL DISCUSSION
George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting Perceptive Informatics/PARAXEL, Former Director, Division of Medical Imaging and Hematology Products, CDER, FDA
Patricia E. Cole, MD, PhD
Senior Director and Head of Imaging, Eisai Global Clinical Development, Eisai Medical Research
Robert Ford
Founder and Chief Medical Officer, Radpharm
P. David Mozley, MD
Senior Director, Imaging, Merck Research Laboratories

5:30-6:30 PM  NETWORKING RECEPTION
WEDNESDAY • OCTOBER 17

8:00-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:15 AM WELCOME AND OPENING REMARKS
Pharmaceutical Speaker(s) have been invited

8:15-9:45 AM SESSION 3
KEY POINTS TO CONSIDER FOR CORE LABORATORIES (IRCS) MANAGING SITE INTERFACES

OBJECTIVE: To identify high priority areas of concern related to interfacing with sites with respect to image acquisition and transfer that can be addressed through pre-competitive consensus and standardization.

Panel Discussion Leaders:
SESSION CO-CHAIRPERSONS
David Clunie, MD
Chief Technical Officer, Radpharm
Stefan Baumann
Imaging Infrastructure Manager
Novartis Pharma AG
Ed Ashton, PhD
Chief Scientific Officer, VirtualScopics

FDA REPRESENTATIVE
Aldo Badano, PhD
Director, Imaging Physics Laboratory, FDA

SESSION RECORDER
9:45-10:15 AM REFRESHMENT BREAK

10:15 AM-12:00 PM SESSION 4:
DATA INTEGRITY AND STATISTICS ANALYSIS PLAN (SAP) REQUIREMENTS

OBJECTIVE: To identify and describe the consistency required among the study protocol, the charter, and the statistical analysis plan.

With this objective in mind, all stakeholders will engage in a pre-competitive, interactive consensus process in support of regulatory agencies (FDA) for inclusion in statistical analysis plans to ensure data integrity for adequate and well-controlled clinical trials involving medical imaging.

Panel Discussion Leaders
SESSION CHAIRPERSON
Edward Gastineau, PhD
Chief Executive Officer, ICON Medical Imaging

SESSION CO-CHAIRPERSON
Wen-Lin Luo
Statistician, Merck Research Laboratories

FDA REPRESENTATIVES
Jyoti Zalkikar, PhD
Mathematical Statistician, FDA
Rajeshwari Sridhara, PhD
Deputy Division Director, Office of Biostatistics, Oncology Drugs Division, CDER, FDA

SESSION Recorder

1:00-2:30 PM WORKING BREAKOUT SESSIONS:
DRAFT WHITE PAPER REVIEW AND INTERACTIVE FORUM

BREAKOUT SESSION 3A
KEY POINTS TO CONSIDER FOR CORE LABORATORIES (IRCS) MANAGING SITE INTERFACES

SESSION Co-CHAIRPERSONS
David Clunie, MD
Chief Technical Officer, Radpharm
Stefan Baumann
Imaging Infrastructure Manager
Novartis Pharma AG
Ed Ashton, PhD
Chief Scientific Officer, VirtualScopics

FDA REPRESENTATIVES
Jyoti Zalkikar, PhD
Mathematical Statistician, FDA
Rajeshwari Sridhara, PhD
Deputy Division Director, Office of Biostatistics, Oncology Drugs Division, CDER, FDA

SESSION Recorder

BREAKOUT SESSION 4A
DATA INTEGRITY AND STATISTICS ANALYSIS PLAN (SAP) REQUIREMENTS

SESSION CHAIRPERSON
Edward Gastineau, PhD
Chief Executive Officer, ICON Medical Imaging

SESSION CO-CHAIRPERSON
Wen-Lin Luo
Statistician, Merck Research Laboratories

FDA REPRESENTATIVES
Jyoti Zalkikar, PhD
Mathematical Statistician, FDA
Rajeshwari Sridhara, PhD
Deputy Division Director, Office of Biostatistics, Oncology Drugs Division, CDER, FDA

SESSION Recorder

2:30-3:00 PM REFRESHMENT BREAK
3:00-3:30 PM  Recap and Next Steps
Key Points to Consider for Core Laboratories (IRCs)
Managing Site Interfaces
Session Co-chairpersons
David Clunie, MD
Chief Technical Officer, Radpharm
Stefan Baumann
Imaging Infrastructure Manager
Novartis Pharma AG
Ed Ashton, PhD
Chief Scientific Officer, VirtualScopics

3:30-4:00 PM  Recap and Next Steps
Data Integrity and Statistics Analysis Plan (SAP)
Requirements
Session Chairperson
Edward Gastineau, PhD
Chief Executive Officer, ICON Medical Imaging
Session Co-chairperson
Wen-Lin Luo
Statistician, Merck Research Laboratories

4:00-4:45 PM  Panel Discussion
David Clunie, MD
Chief Technical Officer, Radpharm
Stefan Baumann
Imaging Infrastructure Manager
Novartis Pharma AG
Ed Ashton, PhD
Chief Scientific Officer, VirtualScopics
Edward Gastineau, PhD
Chief Executive Officer, ICON Medical Imaging
Wen-Lin Luo
Statistician, Merck Research Laboratories

4:45-5:30 PM  FDA and Allied Working Group Panel Discussion: Formal Response for Regulatory Guidance and Action Items
Session Chairperson
Louis Marzella, PhD, MD
Medical Officer, FDA
Session Co-chairperson
Rafel Dwayne Rieves
Acting Director, FDA
FDA Medical Imaging Representatives
Alex Gorovets, MD
Medical Officer, FDA
Scheldon Kress, MD
Medical Officer, CDER, FDA
Jeffrey Siegel
Medical Team Leader, FDA
Barbara Stinson, MD
Medical Officer, FDA
Rajeshwari Sridhara, PhD
Deputy Division Director, Office of Biostatistics
Statistical Team Leader, Oncology Drugs Division, CDER, FDA
Jyoti Zalkikar, PhD
Mathematical Statistician, FDA

5:30 PM  Closing Remarks and Workshop Adjourned

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and Integration of Imaging in Therapeutic Development
Pharmaceutical Industry, CRO, FDA, and Allied Working Groups Collaborate for Regulatory Guidance

Event ID #07021
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University of Maryland, Adelphi, MD, USA
OCTOBER 16-17, 2007

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