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FDA

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

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Pfizer Global Research and Development

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PhRMA

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In collaboration with

AMIA American Medical Informatics Association — Leaders Shaping the Future of Health Information Technology

CORAR

Medical Imaging Contrast Agent Association

PhRMA

From an ongoing series of conferences held May 2005, Fall 2006, and the June 2007 Medical Imaging Roundtable comes this collaborative effort for the ongoing development of imaging and utilization to support surrogate endpoints for therapeutic drugs as well as diagnostic development.

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

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Accreditation and Credit Designation

Monitor the DIA website for information on CE credits to be offered.

Learning Objectives: At the conclusion of this conference, participants should be able 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.
- Identify and 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.
- Expand the scope of objective number one (1) to include other therapeutic areas.
- Facilitate the development of FDA (and other regulatory agency) Guidance Documents.
- Provide 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.
- Identify and describe the consistency required among the study protocol, the charter, and the statistical analysis plan.

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice.
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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
Statistical Team Leader, Oncology Drugs Division, CDER, FDA

SESSION RECORDER

12:00-1:00 PM **LUNCHEON**

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

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
Statistical Team Leader, 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
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Jeffrey Siegel
Medical Team Leader, FDA

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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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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

Event ID #07021

Marriott Conference Center

University of Maryland, Adelphi, MD, USA

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Tutorial = $50

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