Imaging in Oncology Clinical Trials: Central Audit Methods for Site Interpretation

October 1–2

Bethesda North Marriott Hotel & Convention Center
Bethesda, MD

As of September 28, 2015

PROGRAM CHAIR:

Annette Schmid, PhD
Senior Director Scientific & Medical Services, Head of Oncology Imaging Strategy
PAREXEL International

PROGRAM COMMITTEE:

Andrea Perrone, MD
Head of Clinical Imaging, Translational Medicine
Merck & Co.

David I. Raunig, PhD
Senior Vice President, Medical & Scientific Affairs
ICON

Susanta Sarkar, PhD
President
CadenzaMed LLC

Steven Sun, PhD
Director
Janssen R&D

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OVERVIEW:

Close to three years after the July 24, 2012 ODAC (Oncologic Drug Advisory Committee) Meeting on the "Evaluation of Radiologic Review of Progression-free Survival in Non-Hematologic Malignancies" that encouraged further investigation of the merits of possible audit implementations that identify presence or absence of bias in the local evaluator of patient status- many questions still remain.

The aim of this conference is to discuss what we have learned thus far on the audit methods: when, what and how an audit plan (rather than a full independent review) should be implemented. The program is designed to facilitate discussions and participants should leave with a better understanding of the audit method options, the key challenges and advantages and some tools for cost-benefit analysis of the implementation of such audit plans. A report of the insights and recommendations of this group is an expected outcome of the conference.

FEATURED TOPICS:

- Statistics
- Trial Recommendations
- Financial Implications
- Operational Considerations
- Cost Benefit Analysis

LEARNING OBJECTIVES:

At the conclusion of this conference, participants should be able to:

- Describe options for audit method and key advantages and challenges of each
- Determine considerations for potentially suitable indications and trial settings for implementing central audit methods
- Compare the impact of central audit methods to that of traditional independent review approaches on metrics such as cost, time of development, and probability of success
- Provide strategies for a better cost-benefit analysis for central audits in the context of clinical trials

DIA DEVELOP INNOVATE ADVANCE
800 Enterprise Road
Suite 200
Horsham, PA 19044 USA

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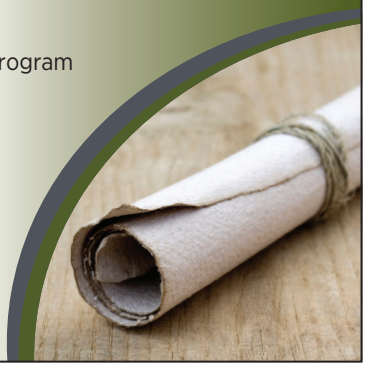

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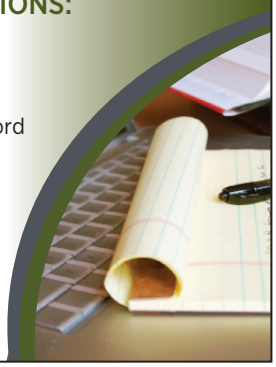

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THURSDAY, OCTOBER 1

7:30AM–6:00PM **REGISTRATION**

7:30–8:30AM **CONTINENTAL BREAKFAST**

8:45–9:00AM **WELCOME REMARKS**

Annette Schmid, PhD
Senior Director Scientific & Medical Services
Head of Oncology Imaging Strategy
PAREXEL International

9:00–9:30AM **INTRODUCTION AND CONFERENCE OVERVIEW**

Why is this Discussion of Audit Methods Important? Virtual Presentation

Jenny Zhang, PhD
Senior Manager, Biostatistics
Gilead

Q&A Discussion

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Steven Sun, PhD
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Janssen R&D

9:30–10:00AM **REFRESHEMENT & NETWORKING BREAK**

10:00–11:30AM **SESSION 2: STATISTICAL SESSION (PRACTICAL)**

CHAIR:

David Raunig, PhD
Senior Vice President, Medical & Scientific Affairs
ICON

This session will focus on practical application and case studies demonstrating implementation to include: current audit options (both published and non-published) and the advantages, disadvantages, challenges, and tactical pieces

Case Study: POLOMA-3 Trials

Ke Zhang, PhD
Director of Biostatistics
Pfizer Inc.

A Case Study of PFS Audit Strategy in Metastatic Breast Cancer Patients

Na Xu, PhD
Senior Statistical Scientist
Genentech, A Member of the Roche Group

Q&A Panel Discussion

11:30AM–1:00PM **NETWORKING LUNCHEON**

1:00–2:30PM SESSION 3: STATISTICAL SESSION (THEORETICAL)

CHAIR:

Steven Sun, PhD
Director
Janssen R&D

Since the July 2012 ODAC (Oncologic Drug Advisory Committee) Meeting on "Evaluation of Radiologic Review of Progression-free Survival in Non-Hematologic Malignancies," two audit methods, the "Pharm method" and the "NCI method" have been widely used. This session will provide a comprehensive review of these two audit methods and highlight recent progress on new methodologies. The focus will be on the merits and challenges of each method and more importantly on recommendations for when to use which method.

Independent Review of Progression-free Survival: Progress and Pitfalls

Ohad Amit, PhD
Senior Director, Clinical Statistics
GlaxoSmithKline

Model Free Audit Methodology for Bias Evaluation of Tumor Progression in Oncology

Euan Macpherson, MSc
Principal Statistician
AstraZenca
United Kingdom

Q&A Panel Discussion

2:30–3:00PM REFRESHEMENT & NETWORKING BREAK

3:00PM–4:30PM SESSION 4: RECOMMENDATIONS ON POTENTIALLY SUITABLE AUDIT TRIALS

CHAIR:

Andrea Perrone, MD
Head of Clinical Imaging, Translational Medicine
Merck & Co.

The session will focus on clinical aspects related to optimal trial types for an audit including criteria considerations, metastatic v. adjuvant trial setting, and endpoints. Operational aspects such as the workflow to incorporate clinical data and technology to minimize reader bias as well as suggestions to mitigate reader variability in an audit setting will be presented.

Operational Aspects for Consideration

Andrea Perrone, MD
Head of Clinical Imaging, Translational Medicine
Merck & Co.

Clinical Aspects of Audits based on Disease Indication and Trial Design

Lawrence H. Schwartz, MD
Chairman, Department of Radiology
Columbia University College of Physicians and Surgeons

Reader Variability in the "Ideal Setting" v. Audit

Gregory Goldmacher, MD, PhD, MBA
Senior Director, Translational Biomarkers
Merck & Co.

Q&A Panel Discussion

4:30–5:00PM END OF DAY ONE SUMMARY

David Raunig, PhD
Senior Vice President, Medical & Scientific Affairs
ICON

Steven Sun, PhD
Director
Janssen R&D

Andrea Perrone, MD
Head of Clinical Imaging, Translational Medicine
Merck & Co.

5:00–6:00PM NETWORKING RECEPTION

FRIDAY, OCTOBER 2

7:30AM–2:45PM **REGISTRATION**

7:30–8:30AM **CONTINENTAL BREAKFAST**

8:30–8:35AM **WELCOME TO DAY 2**

Annette Schmid, PhD
Senior Director Scientific & Medical Services
Head of Oncology Imaging Strategy
PAREXEL International

8:35–10:05AM **SESSION 5: FINANCIAL IMPLICATIONS OF THE NEW APPROACH – WILL THERE BE NET SAVINGS?**

CHAIR:

Susanta Sarkar, PhD
President
CadenzaMed LLC

This session will feature experiences from CRO and pharma and discussions on what it means financially if you do an audit versus a central read or cost of reads vs overall costs, cost of reading under compressed timelines, and cost of delay to market.

Did the Audit Save Money? Data from a Range of Trials

Elizabeth Dalton
Associate Director, Medical Imaging Client Operations
PAREXEL International

Centralized Reads

Rick Patt, MD
Principle
RadMD

Q&A Panel Discussion

10:05–10:30AM **REFRESHEMENT & NETWORKING BREAK**

10:30AM–12:00PM **SESSION 6: LOGISTICAL AND OPERATIONAL BENEFITS AND CHALLENGES OF AN AUDIT METHOD**

CHAIR:

Annette Schmid, PhD
Senior Director Scientific & Medical Services
Head of Oncology Imaging Strategy
PAREXEL International

This session critically evaluates the advantages, limitations and practical implications of implementing an audit method in oncology clinical trials. What does this mean with respect to the predictability and reliability of the process? How might it impact the management of timelines, quality and risk, and the success of a regulatory submission? What steps should be put in place in advance of any reads? Are there implications for patients? Perspectives from the pharma sponsor, core laboratory industry, and the site clinical trial reader will be presented.

An iCRO Perspective

Robert Ford, MD
Principle and Founder
Clinical Trials Imaging Consulting, LLC

An Industry Sponsor Perspective

S. Peter Eggleton, MD, FFPM
Medical Director, GCDC Oncology
Merck Kgaa
Germany

A Site Reader Perspective

Ira Smalberg, MD
Radiologist
Tower Saint Johns Imaging

12:00–1:00PM **NETWORKING LUNCHEON**

1:00–2:30PM **SESSION 7: SUMMARY: COST-BENEFIT ANALYSIS**

This is a key session in this conference. During this session a panel of experts, each with a unique perspective on central audit, will summarize the key discussion and agreement points from the prior sessions to formulate with the attendees recommendations on whether and when to implement a central audit methods.

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Steven Sun, PhD
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2:30–2:45PM **CLOSING REMARKS**

Annette Schmid, PhD
Senior Director Scientific & Medical Services
Head of Oncology Imaging Strategy
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