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CBI's 4th Forum on

Clinical Trial Registries and Results Databases

Clinical Data Transparency and Disclosure Techniques for Compliance within an Evolving Regulatory Framework

April 21-22, 2009 • The Westin Arlington Gateway • Arlington, VA

Conference Chairperson:

Pamela A. Rose, Associate Director, Clinical Trial Registration and Results Disclosure
Takeda Global Research & Development Center, Inc

Key Regulatory Perspectives:

NIH:

Nicholas Ide, Chief Architect, ClinicalTrials.gov,
National Institutes of Health

State:

Jude Walsh, Special Assistant, Government Office of Health Policy and Finance, **State of Maine**

WHO:

Francis P. Crawley, Executive Director,
Good Clinical Practice Alliance – Europe;
Member of the Former Scientific Advisory Group, International Clinical Trials Registry Platform (ICTRP),
World Health Organization

Industry Perspectives:

Gerard Lynch, Global Manager, AstraZeneca Clinical Trials Website, **AstraZeneca**

Shawn Pelletier, Associate Director, R&D Operations, **Bristol-Myers Squibb**

Beat Widler, Global Head, Clinical Quality, **F. Hoffmann-La Roche Ltd.**

Craig Metz, Ph.D., Vice President, Centers of Excellence in Drug Discovery, U.S. Regulatory Affairs, **GlaxoSmithKline, Inc.**

Margaret Cobb, Global Leader, J & J Clinical Registry, **Johnson & Johnson Pharmaceutical Research & Development, LLC**

Stephanie Read, Director, Medical Affairs, **MedImmune**

Lisa Griffin Vincent, Ph.D., Senior Director, Corporate Clinical Research and Development, **Medtronic**

Carla Helaszek, Senior Director, Policy and Relationship Management, External Affairs, Global Development Operations, **Novartis Pharmaceuticals Corporation**

Detlef Niese, M.D., Ph.D., Head, External Affairs, Global Development, **Novartis Pharmaceuticals AG, Switzerland**

Jacqueline Sayers, Ph.D., Head of Quality Projects, Pharma Development Quality, **Roche Products Ltd.**

Patrick Cullinan. Ph.D., Senior Manager, Medical Writing Department, **Takeda Global Research & Development**

Mary Howkins, Regulatory Intelligence Analyst, **Teva Pharmaceuticals**

Robert Paarlberg, MS, Director, Global Regulatory Policy and Intelligence, **UCB, Inc.**

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MAIN CONFERENCE

Day One — Tuesday, April 21, 2009

7:30 *Conference Registration and Continental Breakfast*

8:30 *Chairperson's Opening Remarks*

Pamela A. Rose, Associate Director,
Clinical Trial Registration and Results Disclosure,
Takeda Global Research & Development Center, Inc.
Ms. Rose is currently the Associate Director of Clinical Trial Information Registries at Takeda Global Research and Development Center Inc, Lake Forest, IL. With over twenty-five years experience in the drug development industry, Ms. Rose has held leadership positions in the clinical development, clinical quality assurance and clinical trial registry areas and her most challenging and rewarding experience was overseeing the clinical development for Prevacid. Ms. Rose is an RN and Family Nurse Practitioner and is certified as an ISO 9001:2000 Lead Auditor and ASQ Manager of Quality and Organizational Excellence.

Day One Opening Address

8:45 **Transparency and Clinical Trials — Are We Setting the Right Priorities?**

There are few who question the importance of transparency in clinical trials. Transparency promises widespread access to novel treatments, more efficient patient recruitment, less study duplication and greater scientific integrity. However, despite all the advantages, the concept of transparency sparks a debate between trial sponsors and those on the periphery of clinical research. During this address, the speaker discusses a brief history of transparency in clinical research and analyzes the current direction of stakeholders around the world.

- Review the evolution of transparency and clinical trial registries
- Understand the impact of the proliferation of national trial registries
- Discuss ways to optimize transparency in clinical trials
  - * review the possibility of a global trial registry
  - * identify the goals of various stakeholders

Beat Widler, Global Head of Clinical Quality,
F. Hoffmann-La Roche Ltd.
(session pre-recorded)
Dr. Widler joined Hoffmann-La Roche in 1986 as an International Drug Regulatory Affairs Officer. Three years later, Dr. Widler moved into the International Clinical Research Department where he assumed the position of Senior Research Scientist participating in the planning and conduct of a major international drug development program. During this time, Dr. Widler also acted as a coordinator for the review of clinical safety data. In 1993, Dr. Widler joined the International Clinical Quality Assurance department where he was primarily responsible for clinical trial centers and adverse event reporting system audits. In November 1994, Dr. Widler became Head of the CQA group in Basel, responsible for five international clinical auditors located in Switzerland, and in January 1997 he was promoted to Head of the CQA group Europe. In September 1997, Dr. Widler was appointed International Head of Clinical Quality Assurance. Since 2002 he has been the Head of the Department for Quality, Ethics and Systems in ***Roche Pharma Development****. In addition to his functional responsibilities, he was nominated Head of the Welwyn Garden City (UK) Development site in September 2002, giving leadership to a group of about 600 development professionals.*

Domestic Regulations and Requirements for Clinical Data Disclosure

State Perspective

9:30 **Ensure Compliance with Maine's Clinical Trial Disclosure Laws**

On the state level, Maine continues to be a regulatory benchmark when it comes to clinical trial registries and results posting. If industry organizations would like to sell products in Maine, they must comply with stringent guidelines. To help companies remain compliant, a representative from the state discusses Maine laws as they pertain to clinical data disclosure.

Jude Walsh, Special Assistant,
Government Office of Health Policy and Finance, **State of Maine**

10:15 *Networking, Refreshment Break*

NIH Perspective

10:45 **ClinicalTrials.gov — NIH Update and In-Depth Discussion with the Chief Architect**

ClinicalTrials.gov contains nearly 60,000 trials sponsored by the National Institutes of Health, other federal agencies and private industry (clinicaltrials.gov). Because of evolving regulatory guidelines, clinical trial protocol posting requirements can appear very complex. During this session, the audience has the opportunity to interact with, and ask questions directly to, the Chief Architect of ClinicalTrials.gov.

- Impact of FDARA
- FDAAA requiring estimated date of study completion
  - * study teams over and under estimating
  - * concerns surrounding posting commercially sensitive information

Nicholas Ide, Chief Architect, ClinicalTrials.gov,
National Institutes of Health

Medical Device Perspective

11:30 **Understand the Unique Requirements for Clinical Data Disclosure in the Medical Device Industry**

One of the interesting aspects of FDAAA is the attention given to the medical device industry. No longer grouped with pharma, medical device companies must now comply with their own regulations. During this session, the speaker

from a medical device company extracts and analyzes the components of FDAAA that pertain to the organization.

- Unique IP issues
- Significant versus non-significant devices
- Impacts of the competitive nature of the industry

Lisa Griffin Vincent, Ph.D., Senior Director, Corporate Clinical Research and Development, **Medtronic**

12:15 *Luncheon*

International Regulations and Requirements for Clinical Data Disclosure

1:30 **Introduction to Eudra Systems and an Update on EMEA Disclosure Regulations**

It can sometimes feel as if all of the attention on the topic of disclosure has been focused on the U.S., specifically on FDAAA and ClinicalTrials.gov. However there are also European regulations that everyone working in this area need to be aware of. There is a family of databases that house clinical trial and adverse event data in the European Economic Area. Until now, the EudraCT database has only been accessible to the Competent Authorities but this is set to change with the implementation of article 41 of Regulation No. (EC) 1901/2006 for pediatric trials and article 57.2 of Regulation No (EC) 726/2004 for other clinical trials. As a result, specific data from clinical trials applications and results data will be made publicly available. This session provides an overview of the Eudra systems and also discusses the recent developments with respect to public disclosure of clinical trial information.

- Identify and discuss the three Eudra systems related to clinical trials
- Learn the process for obtaining a EudraCT number
- Understand the implications of changes to EudraCT and the implementation of the pediatric regulation.

Jacqueline Sayers, Quality Projects Manager, PDQ, **Roche Products Ltd.**

2:15 **Identify and Tackle Challenges in International Disclosure Requirements**

Ever-expanding global regulations and standards for clinical trial registration and results disclosure require continuous monitoring and process changes for companies that conduct clinical trials outside the U.S. Global harmonization of transparency requirements is no closer now than it was in 2005. If anything, nationalistic demands for unique clinical trial websites/databases are increasing. This session examines various international public disclosure requirements, explains similarities and differences, and offers ideas on how to approach the challenges of compliance with global clinical trial transparency requirements as well as challenges to ensure consistency of clinical trial information being provided in the public domain.

- Identify countries that currently have requirements for clinical trial registration or posting results
- Analyze the approach used by mid-sized pharma companies to ensure consistent clinical trial information is being provided across various public venues
- Elevate the impact of transparency on existing procedures

Robert Paarlberg, MS., Director, Global Regulatory Policy and Intelligence, **UCB, Inc.**
John McKenney, President, **SEC Associates, Inc.**

3:00 *Networking and Refreshment Break*

3:30 **Obtain a Global Perspective on Clinical Data Disclosure and Understand How the Change to the Declaration of Helsinke Is Impacting Ethics Committees**

- Analyze the leading global perspectives
  * WHO
  * PhRMA
  * IFPMA
  * EFPIA
- Declaration of Helsinke
- Ethics committees
- Pediatric studies

Francis P. Crawley, Executive Director, **Good Clinical Practice Alliance – Europe;** *Member of the Former Scientific Advisory Group, International Clinical Trials Registry Platform (ICTRP),* **World Health Organization**

4:30 **How Should the Bio/Pharmaceutical and Medical Device Industries Respond to the Evolving Regulatory Framework for Clinical Trial Registries and Results Databases?**

PANEL

The first day of the conference features many valuable and diverse perspectives. To ensure that no questions are left unanswered, this panel discussion has been created to further analyze hot topics and key issues that were overlooked or put on hold during the earlier sessions. The audience is encouraged to interact and challenge each panelist with questions related to the evolving regulatory framework for clinical trial registries and results posting.

Moderator:
Pamela A. Rose, Associate Director, Clinical Trial Registration and Results Disclosure, **Takeda Global Research & Development Center, Inc.**

Panelists:
Margaret Cobb, M.D., Group Leader, J&J Registry, **Johnson & Johnson Pharmaceutical Research and Development**
Mary Howkins, Regulatory Intelligence Analyst, **Teva Pharmaceuticals**
Stephanie Read, Director of Medical Affairs, **MedImmune**
Detlef Niese, M.D., Ph.D., Head, External Affairs, Global Development, **Novartis Pharmaceuticals AG, Switzerland**

5:15 *Close of Day One*

5:15-6:15 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

photo by: Photolink / Getty Images

Day Two — Wednesday, April 22, 2009

7:30 *Continental Breakfast*

8:00 *Chairperson's Review of Day One*

Pamela A. Rose, Associate Director, Clinical Trial Registration and Results Disclosure, **Takeda Global Research & Development Center, Inc.**

Day Two Opening Address

8:15 **The Evolution of Clinical Research Transparency — What Does the Future Hold in Store for Us?**

The clinical research transparency initiative began in earnest approximately five years ago and has been codified recently under the mandates included in the FDA Amendments Act (FDAAA). Having established the foundation for transparency in clinical research a number of key issues need to be explored as we move forward from this point. This presentation explores the following themes:

- What do we know about the utility of this information to the key customers?
- How can/should the information being provided currently be revised to better address customer needs and who would be responsible for driving the evaluation to support these revisions?
- The population of the clinicaltrials.gov database with study results will provide the basis for the conduct and publication of meta-analyses. Who will provide oversight on the accuracy and interpretation of these analyses?
- What needs to be done at the present time to prepare for eventually providing the lay study summaries described in the FDA Amendments Act?
- How will the industry address the increasing demand for access to "raw" data from clinical trials?

Craig Metz, Ph.D., Vice President, Centers of Excellence in Drug Discovery, U.S. Regulatory Affairs, **GlaxoSmithKline, Inc.**

Best Practices for Posting and Publishing Clinical Study Results

9:00 **Overcome the Challenges Associated with Posting Clinical Trial Results**

The requirements for posting clinical trial results are diverse and it can be challenging to remain compliant. In addition, to having an understanding of the various statutory and key influencer requirements, it is important to understand how data from your companies systems can or cannot be transferred to a publicly viewable database. During this session, the speaker reviews the results posting processes and provides suggestions on how to comply with the changing global landscape.

- Review U.S. statutory requirements, key influencer positions and pending EudraCT requirements
- Discuss how a lack of data standards can cause compliance challenges
- Discuss ways that organizations can optimize resources to achieve compliance
- Discuss roadblocks to successful implementation of data disclosure requirements

Carla Helaszek, Senior Director, Policy and Relationship Management, Global Development External Affairs, **Novartis Pharmaceuticals Corporation**

9:45 *Networking and Refreshment Break*

10:15 **Understand the Medical Writer's Role in Results Disclosure — The Who and the How… and the What and the When… and the Why Me?!?**

Medical Writers play a key role in results disclosure. From understanding what to disclose to managing the workload, medical writers must control the quality of clinical data and make sure it is consistent with registry, submissions and publication data. During this session, a medical writer discusses the role he plays at his organization and how the role of an MW can be optimized at other companies.

- Develop processes for disclosing results on clinicaltrials.gov
- Understand what to disclose
  * primary and secondary endpoints
  * baseline characteristics
  * adverse event data
- Manage source information
- Respond to internal and external QC comments
- Manage the internal documentation release process
  * develop a signoff process
- Prevent resource competition by effectively managing the disclosure workload
- Understand the role of the medical writer for submissions in the EU

Patrick Cullinan, Ph.D., Senior Manager, Medical Writing Department, **Takeda Global Research & Development**

11:00 **Understanding the ICMJE's Updated Position on Trial Registration and Results Posting**

The ICMJE have been a leading proponent for trial registration with their position moving to greater transparency in the last few years. During this session the speaker reviews its recent position, explains how it compares to other requirements and discusses the challenges of meeting regulatory requirements while ensuring effective publications.

- Understand ICMJE's position on trial disclosure
- Review ICMJE's evolving position on trial registration and its recent update on what the ICMJE considers and doesn't consider pre-publication
- Understand how the changing regulatory requirements have posed and continue to pose challenges to publishing clinical trial results

Gerard Lynch, Global Manager, AstraZeneca Clinical Trials Website, **AstraZeneca**

11:45 *Luncheon*

Enabling Technology for Clinical Data Disclosure

1:00 **Ensure Regulatory Compliance and Streamline the Disclosure Process with Enabling Technology**

Case Study

- Automate registry and results posting
- Integrate patient response mechanisms
- Utilize technology to increase compliance

Tim Bacon, President and Chief Executive Officer, **PeerView**

1:45 **Assess the Benefits and Applications of Utilizing Technology to Manage the Disclosure Process**

PANEL

As regulations governing the clinical data disclosure process become more stringent, it's becoming increasingly difficult to remain compliant. However, many organizations have begun implementing emerging technologies designed to manage the disclosure process. During this discussion, the panelists field questions from the audience, discuss their experience with enabling technology and provide answers to the following questions:

- What does the technology need to be able to do?
- Where is it best to use technology?
- What tasks should be completed by humans instead of technology?
- How do you encourage management-buy in?
  * how can you build the business case for this technology?
- To what degree do you connect to source systems?
  * CTMS, SAS
- Should this be a hosted or installed solution?
  * third party host, build or buy?

Moderator: *Pamela A. Rose, Associate Director, Clinical Trial Registration and Results Disclosure,* **Takeda Global Research & Development Center, Inc.**

Panelists: *Tim Bacon, President and Chief Executive Officer,* **PeerView**

Thomas Wicks, Business Development Manager, **Intrasphere**

Joan Mariotti, Manager, Regulatory Information Management, **Teva Neuroscience, Inc.**

Shawn Pelletier, Associate Director, R&D Operations, **Bristol-Myers Squibb**

2:30 *Close of Conference*

Who Should Attend

You will benefit from this event if you are a Vice President or Director/Manager at a pharmaceutical, biotech or medical device company with responsibilities in the following areas:

- Disclosure
- Transparency
- Medical Business Operations
- Medical Writing
- Registries
- Medical Information
- Clinical Research
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- Global Medical Affairs
- Policy
- Clinical Trials
- Publication
- Clinical Trial Information
- Clinical Affairs
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- Clinical Science
- Business Development
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- Information Management
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This conference will also interest contract research organizations, registries and results databases and technology vendors who implement registries and databases.

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The Top 5 Reasons to Attend:

1. Hear 12 industry perspectives providing insight into the disclosure process
2. Take part in Q&A with Nick Ide of ClinicalTrials.gov
3. Obtain proven strategies for managing the international disclosure process
4. Hear critical information on the Eudra Systems and the future role of EudraCT
5. Walk through an analysis of the ICMJE's new policy statement and obtain strategies for publication planning

PLUS!
A detailed case study and ensuing discussion about technology designed to manage the disclosure process

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