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CBI's 3rd Forum on

Clinical Trial Registries and Results Databases

Strategies for Clinical Data Transparency and Disclosure within an Evolving Regulatory Framework

April 28-29, 2008 • Sheraton Premier at Tysons Corner • Vienna, VA

Conference Chair:

Jeffrey J. Stoddard, M.D.,
Vice President of Medical and Scientific Affairs, Risk Management and Post Marketing Programs,
Covance

Essential Perspectives Include:

Journal Editor:

Paul W. Ladenson, M.D.,
Editor-in-Chief, The Journal of Clinical Endocrinology & Metabolism,
The Endocrine Society

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, Scientific Advisory Group, International Clinical Trials Registry Platform (ICTRP),
World Health Organization

Patient:

Pat Furlong, President,
Parent Project Muscular Dystrophy

Lia McLean, Ph.D., Head of Practice, Process Design and Implementation,
Pope Woodhead Associates

Pharmaceutical, Biotech and Medical Device Perspectives:

Tracy Beck, Ph.D.,
Global Medical Business Office Consultant; CTR, Results Gatekeeper,
Eli Lilly and Company

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

Cheryl Nauss Karol, Ph.D.,
Global Ethics Liaison for Pharmaceutical Development and Global Director, Ethics in Clinical Research,
Hoffmann-La Roche, Inc

Sarah Doyle Larson,
Program Manager, Biomedical Regulatory Affairs Compliance,
Genzyme

Oladayo O. Oyelola, Ph.D., SC (ASCP),
Deputy Director, Medical Writing,
Sanofi Pasteur, Inc

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

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

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

Beat Widler,
Global Head of Clinical Quality,
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Marc Wilenzick, Senior Corporate Counsel, **Pfizer Inc**

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"This registry conference is a necessary annual forum to keep up with the industry and to keep all stakeholders informed."

— 2007 Conference Attendee, A. Ferguson, Associate Manager, **MedImmune**

MAIN CONFERENCE

Day One — Monday, April 28, 2008

7:30 *Conference Registration and Continental Breakfast Hosted by:* COVANCE THE DEVELOPMENT SERVICES COMPANY

8:30 *Day One Chairman's Opening Remarks*

Jeffrey J. Stoddard, M.D., Vice President of Medical and Scientific Affairs, Risk Management and Post Marketing Programs, **Covance**

In this role, Dr. Stoddard provides medical and scientific leadership to all post-approval research and risk management programs and is responsible for registries operations, epidemiology, biometrics and drug safety functions. Dr. Stoddard has over sixteen years of experience in biopharmaceutical research and development (both registrational and post-marketing) and in risk management program implementation.

Analyze International, Federal, State and ICMJE Laws and Requirements and Apply Internal Governing Practices

8:45 **Identify and Coordinate International Regulations to Streamline the Compliance Process**

New global regulations and standards for clinical trial registration and results databases are forcing companies that conduct clinical trials outside of the U.S. to reevaluate their approach to global clinical trial transparency. Global harmonization of requirements has not occurred. In addition, specific clinical trial websites/databases for particular regions of the world are now common. During this session, review the varying international requirements and understand how a company can approach the challenges of compliance with global clinical trial transparency requirements.

International Regulations

- What countries currently have requirements for clinical trial registration or posting results?
- Suggestions on how to manage varying international requirements at a global company

Sarah Doyle Larson, Program Manager, Biomedical Regulatory Affairs Compliance, **Genzyme**

John McKenney, President, **SEC Associates, Inc.**

9:30 **European Standards for Clinical Trial Registration and Results Publication**

With many clinical trials being conducted in Europe, it's essential to understand European regulations for clinical trial registration and results posting. During this session, a representative from the WHO explains how to register a trial in Europe and comments on leading registry platforms.

European Regulations

- Clinical trial registries in Europe
- The development and current discussion around the EUDRACT Database
- The role of the WHO International Clinical Trials Registry Platform (ICTRP)
- Matching U.S. with European and international standards and expectations

Francis P. Crawley, Executive Director, **Good Clinical Practice Alliance – Europe;**

Member, Scientific Advisory Group, International Clinical Trials Registry Platform (ICTRP), **World Health Organization**

10:15 *Networking and Refreshment Break*

10:45 **Interpreting Title 8 of the FDA Amendments Act of 2007**

On September 27, 2007, President Bush signed the Food and Drug Administration Amendments Act (FDAAA). These amendments qualify as the most comprehensive revision of the Federal Food and Drug Cosmetic Act in the past 40 years. One piece of FDAAA having a major impact on the pharmaceutical industry is Title 8, which focuses on clinical trial databases. During this session, the speaker identifies and analyzes the complexities of FDAAA that are having a major impact on clinical trial disclosure.

Legal Perspective

- Products and studies covered
- Procedures required
- Timelines for implementation
- Consequences of non-compliance
- State level requirements
- How should pharma respond?

Marc Wilenzick, Senior Corporate Counsel, **Pfizer Inc**

11:30 **Understand the Implications of FDAAA Specific to Medical Device Companies**

Medical device development has long been recognized as being "different" than pharmaceutical development as reflected by the regulations. Clinical trial transparency is imperative and must be balanced with unique issues around patent protection and a competitive landscape to preserve innovation and patient access to emerging medical technologies. Developing an approach to public registration and results posting is becoming increasingly complex in a dynamic environment and this session provides points for consideration.

Medical Device Perspective

- Devices are "different"
- Unique medical technology protection issues
- Impacts of the competitive nature of the industry
- Significant and non-significant risk devices
- FDAAA requirements for device trials
- Developing an approach to registration and results posting for medical devices

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

12:15 *Luncheon*

EXTENDED Q&A WITH NIH AND THE STATE OF MAINE

1:30 **ClinicalTrials.gov — NIH Update and In-Depth Discussion with the Chief Architect**

ClinicalTrials.gov contains nearly 50,000 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.

NIH Perspective

- Understand the impact of FDARA on clinical trial registration

- Determine an estimated date of study completion as required by FDAAA
- Prevent over and under estimation
- Avoid posting commercially sensitive information

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

2:15 **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. Maine laws can also be used as a roadmap for compliance with other state regulations. To help companies remain compliant, a representative from the state discusses Maine laws as they pertain to clinical data disclosure.

State Perspective

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

3:00 *Networking and Refreshment Break*

3:30 **Analyze New ICMJE Requirements and Interact with a Journal Editor**

Submitting manuscripts for publication is a key component of the clinical disclosure process. However, understanding the necessary components of a manuscript is a complex task. As a result, journal editors are an essential resource for all clinical trial registries and results stakeholders. During this session, the Editor-in-Chief of the Journal of Clinical Endocrinology & Metabolism discusses new ICMJE requirements and what an editor is looking for in a manuscript submitted for publication.

Journal Editor Perspective

- Dual publication and the Ingelfinger Rule
- Potentially conflicting federal and state legislative requirements
- Understand new ICMJE requirements for trials beginning enrollment after January 1, 2008
  - * conflict boundaries for electronic databases
  - * Phase I inclusion

Paul W. Ladenson, M.D., Editor-in-Chief, The Journal of Clinical Endocrinology & Metabolism, **The Endocrine Society**

4:15 **Evaluate the Need for Clinical Trial Disclosure Policy Statements**

Following the release of the IFPMA Joint Statement in January 2005, many member companies crafted a corporate policy that met and often exceeded the IFPMA Joint Statement. Those clinical trial disclosure policy statements were made public on corporate websites and often heralded in press releases. With the emerging regulations, is there a role for those corporate policy statements moving forward? Is there something unique to the clinical trial disclosure topic that makes a corporate policy helpful, even after the topic has been regulated? This session explores the need for corporate policy statements and analyzes the essential components.

Patricia Teden, MBA, Principal, **Teden Consulting LLC**

5:00 **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 sessions earlier today. 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.

- Review FDAAA Title 8, international and state laws
- Discuss organizational changes resulting from an evolving regulatory framework
- Identify lessons learned and proven strategies for compliant clinical data disclosure

Moderator: Mark Dewyngaert, Ph.D., MBA, Managing Director, **Huron Consulting Group**

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

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

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

Cheryl Nauss Karol, Ph.D., Global Ethics Liaison for Pharmaceutical Development and Global Director, Ethics in Clinical Research, **Hoffmann-La Roche, Inc**

Brian French, Partner, **Nixon Peabody LLP**

5:45 *Close of Day One*

5:45-6:45 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

Day Two — Tuesday, April 29, 2008

7:30 *Continental Breakfast Hosted by:*

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

Jeffrey J. Stoddard, M.D., Vice President of Medical and Scientific Affairs, Risk Management and Post Marketing Programs, **Covance**

8:15 **Integrate Various Disclosure Requirements to Ensure Compliance within an Evolving Regulatory Framework**

Regulatory Recap

As an increasing number of external forces weigh in on the topic of trial registries and results databases, the pharmaceutical industry is caught between a rock and a hard place as they try to be compliant with sometimes conflicting requirements. This session summarizes the similarities and differences between the International Committee of Medical Journal Editors (ICMJE) statement, Maine legislation and the FDA Amendments Act of 2007. The session focuses on necessary considerations and strategies for complying with a myriad of requirements.

Tracy Beck, Ph.D., Global Medical Business Office Consultant; CTR, Results Gatekeeper, **Eli Lilly and Company**

Utilize Enabling Technology for Clinical Trial Registry and Results Compliance and Execution

9:00 **Review the Evolution of EDC and the Impact of Electronic Data Capture on Registries and Observational Studies**

This presentation begins with a review of the adoption of EDC technologies within the pharmaceutical and biotech industries. The session continues with a more detailed discussion of current topics around utilization of EDC in registries and observational studies, as well as thoughts on the future of EDC in the industry. Topics include:

- A cross-sectional view of the EDC market
- Criteria for selection of an EDC vendor for registries
- Case studies and lessons learned from real-world practice in registries and observational studies

Case Studies

Sean D. Kennedy, MPH, Director of Registries and Observational Studies, **Covance Periapproval Services**

9:45 *Networking and Refreshment Break*

Writing Strategies and IP Protection for Clinical Trial Registries and Results Databases

10:15 **Writing for Clinical Trial Registries and Results Databases**

As the focus on clinical trial information and results data transparency continues to rise; the need and importance of simplified (lay language), accurate and non-promotional posting and/or manuscript preparation has become inevitable. During this session, the speaker discusses strategies of meeting these editorial, posting and publishing challenges; since most potential patients may read posted information and may then bring it to their physicians, which makes it just as important for physicians to interpret the information accurately and use it to guide their clients. The presentation focuses on:

- Writing for potential readers at various reading and education levels
- Wording important terminology in consumable forms everyone can understand
- Strategies for keeping postings up to date

Oladayo O. Oyelola, Ph.D., SC (ASCP), Deputy Director, Medical Writing, **Sanofi Pasteur, Inc**

11:00 **Protecting IP in an Era of Disclosure**

Although disclosing clinical trial information can have a positive impact on public perception of the pharmaceutical industry and patient involvement with clinical trials, failure to protect intellectual property (IP) can be extremely detrimental. Commonly considered a double-edged sword, organizations must be extremely cognizant that shared information can't be used for competitive gain. During this session, the speaker explains how to fully comply with posting requirements while still protecting essential IP.

- Discuss potential threats to IP that posting can trigger for:
  * pharmaceutical products * medical devices
- How can registries be used as a source of IP?
- What impact do patients and patient organizations have with regards to balancing IP and transparency?
- Understand how public opinion and the need for increased transparency effects IP

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

11:45 *Luncheon*

Patient Perspectives and Long-Term Benefits of Clinical Trial Disclosure

1:00 **Clinical Trial Registries — Are They Getting the Job Done? Insights from Industry and Patient Groups**

This session reviews the role and usefulness of clinical trial registries from the perspective of the pharmaceutical industry and a number of patient group representatives. Additionally, the session considers possible improvements for the future. Two important goals behind the first clinical trial registries were to increase transparency related to clinical trial activities and to reduce the potential for a bias towards publication of only positive results. Both patients and medical professionals were seen as the main target audiences. In recent years the number of registries available has increased dramatically, many having different posting requirements. This means that obtaining definitive information on ongoing clinical trials may actually have become more complicated rather than less.

Case Study & Survey Results

Roche has developed its own protocol registry and results database and in 2007 undertook a survey of patient groups to find out their opinion of the Roche site as well as cross company sites such as CenterWatch and the IFPMA portal, in order to identify possible areas for improvement. In addition, Pope Woodhead has completed a survey with representatives from a number of pharmaceutical companies regarding their perception of the success or otherwise of the currently available clinical trial registries, their impact on the target audiences, as well as their views on future developments.

Jacqueline Sayers, Ph.D., Head of Quality Projects, Pharma Development Quality, **Roche Products Ltd.**
Lia McLean, Ph.D., Head of Practice, Process Design and Implementation, **Pope Woodhead Associates**

1:45 **Access and Transparency in Clinical Research — The Patient's Point of View**

New therapeutics are on the horizon for both rare and common conditions. The excitement for new treatments brings the challenge of developing clinical studies with sensitivity for the issues and concerns of the patients who will be needed to participate in clinical trials in order to determine if the new therapies are effective. Involving the patient community is an essential first step in the process. This session expounds on the importance of patient involvement and proven strategies for designing studies with the patients in mind.

Pat Furlong, President, **Parent Project Muscular Dystrophy**

2:30 *Close of Conference*

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April 28-29, 2008

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- An analysis of FDAAA (Title 8) for the pharmaceutical, biotech and medical device industries
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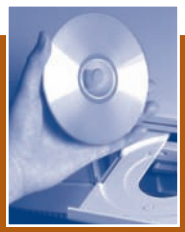

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