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CBI's 6th Forum on Clinical Trial Registries and Results Databases

Manage Regulated Content and Clinical Data Disclosure

April 27-28, 2011
Crowne Plaza Downtown • Philadelphia, PA

Conference Chairman:

Craig A. Metz, Ph.D., Former Vice President, U.S. Regulatory Affairs, **GlaxoSmithKline;** President, **Metz Regulatory Services**

Keynote Address:

Evaluate the Industry's Approach to Transparency

Frank Rockhold, Ph.D., Senior Vice President, Global Clinical Safety and Pharmacovigilance, **GlaxoSmithKline;** Member, **NLM Board of Regents Working Group on Clinical Trials Reporting**

Elite Industry Perspectives From:

Tracy Beck, Ph.D., Consultant, **Eli Lilly and Company;** Member, **HL7 Clinical Trial Registries and Results Working Group**

Daniel Boisvert, Principal Programmer, **Genzyme Corporation**

Maureen Garrity, Director, Publications, **Astellas Pharma Global Development**

Suzanne Heyd, Clinical Trial Results Analyst, **Bristol-Myers Squibb**

Jean-Philippe Keunebroek, Head, Clinical Trial Regulatory Management, **sanofi-aventis**

Craig McHenry, Director CI Specialty Care Market Analytics, **Pfizer Inc**

Denis Michel, Director, Statistical Programming, **Janssen Pharmaceutical Companies of Johnson & Johnson**

Detlef Niese, Head, Global Development External Affairs, **Novartis**

Oladayo Oyelola, Ph.D., SC(ASCP), Clinical Trial Information Disclosure Director, **Sanofi Pasteur**

Shawn M. Pelletier, Associate Director, Clinical Trial Transparency, **Bristol-Myers Squibb**

Rosemary Wagner, Global Operations Lead, Clinical Registry, Process & Systems Department, **Johnson & Johnson Pharmaceutical Research & Development LLC**

Program Highlights:

- Ensure consistency of disclosed trial information across registries
- Examine key registry developments worldwide to determine which are mandatory
- Analyze the impact of EudraCT disclosure with existing national disclosure sites
- Refine and streamline the process of clinical data transparency and publication planning
- Discuss how competitors as well as the financial community are able to access and utilize registration and results information
- Compare how two companies have developed statistical programming to meet results-posting requirements
- Determine best practices for effectively managing ClinicalTrials.gov feedback

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December 6, 2010

Dear Colleague,

Since the advent of transparency initiatives for clinical trial registries and results databases, CBI has provided an important and timely forum for the exchange of information and best practices for those charged with meeting and managing a dazzling array of disclosure requirements. As the regulatory and legal environment evolves, growing in complexity, large companies struggle with best practices and appropriating resources to maintain compliance. Smaller companies face even greater challenges with fewer persons delegated with the task of managing regulated content and clinical data transparency.

With global harmonization of registries a highly desirable, yet unrealized goal, companies must continue to evaluate their current practices for providing regionally appropriate information arising from the conduct of clinical research while diligently exploring ways to more efficiently utilize resources.

For the 6th consecutive year, CBI offers stakeholders a forum to come together and learn how the industry and other key stakeholders are addressing the evolving FDAAA, ClinicalTrials.gov and EudraCT requirements and how statistical programming can be utilized for meeting these requirements. Additionally, attendees are able to evaluate emerging global registries and come away with best practices for maintaining compliance with registration in multiple countries. There is also the opportunity to learn how to receive and respond to CT.gov feedback.

While we all know how difficult it is to take time away from the office, it is important that we take this opportunity to thoughtfully reflect on our current processes for complying with the requirements for clinical research transparency and return to work with an improved understanding and ability to overcome the ever-changing challenges of clinical information disclosure.

I look forward to seeing you April 27-28, 2011 at the Crowne Plaza in Philadelphia!

Sincerely,

Craig A. Metz

Craig A. Metz, Ph.D.
Former Vice President, U.S. Regulatory Affairs
GlaxoSmithKline
President, **Metz Regulatory Services**

P.S. Don't miss the discussion on Capturing Patient Experience Data

MAIN CONFERENCE

Day One — Wednesday, April 27, 2011

7:30 *Conference Registration and Continental Breakfast*

8:30 *Chairman's Opening Remarks*

Craig A. Metz, Ph.D., Former Vice President, U.S. Regulatory Affairs, **GlaxoSmithKline;** *President,* **Metz Regulatory Services**

Dr. Metz is a regulatory consultant to the pharmaceutical industry. Prior to his retirement from GlaxoSmithKline in November 2010, he was Vice President of U.S. Regulatory Affairs and led the group responsible for providing strategic regulatory support to early stage pharmaceutical development activities conducted by GSK's Centers for Excellence in Drug Discovery. Dr. Metz has a Ph.D. in Health Sciences with a doctoral thesis focused on the use on anti-inflammatory agents for the treatment of sepsis related syndromes. Dr. Metz has thirty-eight years of pharmaceutical industry experience including eighteen years of clinical development research at ***The Upjohn Company*** *and Glaxo and eighteen years in Regulatory Affairs with GlaxoSmithKline and its heritage companies. His clinical and regulatory experience includes cardiovascular, gastrointestinal, metabolic/ endocrine, oncology, critical care, anti-inflammatory and dermatological development programs. Dr. Metz assumed a leadership role in assisting with the development and launch of the GSK Clinical Trial Register in 2004 which, at the time of launch, was the first of its type in the pharmaceutical industry. Prior to his retirement from GSK, Dr. Metz chaired the steering committee responsible for data disclosure and has had a number of publications and public presentations on the topic of clinical research transparency.*

Modernize Registration and Results Posting Processes in Response to Evolving Regulations

KEYNOTE ADDRESS

8:45 **Evaluate the Industry's Approach to Transparency**

As global transparency requirements and clinical data disclosure regulations continuously evolve, the industry is challenged to remain compliant without over extending their resources. Companies must be committed to maintaining oversight of clinical data disclosure to serve the interests of patients, physicians and regulators. During this keynote address, hear the need to promote and enforce data transparency throughout the industry.

- Evaluate the industry's current transparency requirements
- Review best practices for establishing and monitoring data transparency

Frank Rockhold, Ph.D., Senior Vice President, Global Clinical Safety and Pharmacovigilance, **GlaxoSmithKline;** *Member,* **NLM Board of Regents Working Group on Clinical Trials Reporting**

Dr. Rockhold is currently Senior Vice President, Global Clinical Safety and Pharmacovigilance at GlaxoSmithKline Pharmaceuticals Research and Development. This includes case management, signal detection, safety evaluation, risk management and co-chair of the GSK Global Safety Board. In his twenty years at GSK, he has also held management positions within the Statistics & Epidemiology Department and Clinical Operations both in R&D and in the U.S. Pharmaceutical Business. Dr. Rockhold has previously held positions of Research Statistician, ***Lilly Research Laboratories*** *(1979-1987) and Executive Director of Biostatistics, Data Management and Health Economics,* ***Merck Research Laboratories****, (1994-1997). Dr. Rockhold has BA in Statistics, from the University of Connecticut, Sc.M. in Biostatistics, from Johns Hopkins University, and a Ph.D. in Biostatistics, from the*

Medical College of Virginia. He has held several academic appointments in his career at ***Butler University, Indiana University*** *and currently is Adjunct Professor of Health Evaluation Sciences,* ***Penn State University*** *and Adjunct Scholar in the Department of Epidemiology and Biostatistics at the* ***University of Pennsylvania****. Dr. Rockhold is currently Chairman of the Board of Directors of the Clinical Data Interchange Standards Consortium (CDISC) and a member of the National Library of Medicine Advisory group for ClinicalTrials.Gov. He is Past-President, Society for Clinical Trials, Past Chair, PhRMA Biostatistics Steering Committee and a member of the ICH E-9 and E-10 Expert Working Groups and previously served as Associate Editor for Controlled Clinical Trials. He is a Fellow of the American Statistical Association and a Fellow of the Society for Clinical Trials. Dr. Rockhold is also a recipient of the PhRMA Career Achievement award. He has over 140 publications and abstracts.*

9:30 **Optimize Resources to Meet ClinicalTrials.gov and FDAAA Requirements**

The amount of resources required for managing the evolving requirements for ClinicalTrials.gov (CT.gov) and FDAAA can be significant. Understanding the best practices for registration and results-posting allows companies to meet the requirements more efficiently. This session discusses recent updates to CT.gov and FDAAA, and provides an overview of how to best manage the evolving regulations.

- Review changes for posting requirements to CT.gov in the past few months
- Discuss best practices for meeting FDAAA requirements as requirements for transparency increase
- Understand how implementing best practices will optimize resources
- Review potential impact on industry for proposed FDAAA expansion

Paul Ngai, Principal, **180 Global Consulting, LLC.**

10:15 *Networking and Refreshment Break*

10:45 **Preparation for the New World of EudraCT**

There has been much anticipation regarding the release of version 8 of the EudraCT database and still further anticipation regarding the version 9, not due out until the end of 2011. As companies prepare for versions 8 and 9 of the EudraCT database, they must be aware of the challenges they may face when the versions are implemented. This session addresses the latest trends and issues resulting from EudraCT's database update and how companies should be prepared to respond.

- Review the latest updates and resulting effects on registration processes
- Discuss experience with submitting data with version 8
- Determine the potential implications of the public results database
- Analyze the impact of EudraCT disclosure with existing national disclosure sites

Jean-Philippe Keunebroek, Head, Clinical Trial Regulatory Management, **sanofi-aventis**

11:30 **Anticipate the Public Utilization of Clinical Trial Registration and Results Data**

PANEL

CT.gov is a vast resource of clinical trial registry and results information available to the public. The FDA Amendments Act of 2007 (FDAAA) further requires that NIH issue regulations addressing whether or not results for unapproved products will also need to be posted on CT.gov. The European Medicines Agency will be implementing a public clinical trial registry and results database, which will include clinical trial results for both approved and unapproved products. Competitors, as well as the financial community, are able to access and analyze this public information which impacts the competitive intelligence landscape as well as impacting potential decisions by the investment community. During this panel, the following is addressed:

- Discuss how competitive intelligence may be affected
- Understand how this information may be utilized by the investment community
- Review how companies will be analyzed differently
- Know the unintended consequences for reporting study results for unapproved products

Moderator: Robert Paarlberg, Principal, **Paarlberg & Associates, LLC**
Panelists: Craig McHenry, Director CI Specialty Care Market Analytics, **Pfizer Inc**
Shacker Mourad, R.Ph.,MBA, Adjunct Professor of Pharmaceutical and Healthcare Business, **University of the Sciences in Philadelphia;** *Founding President,* **NOAHSPHARM;**
In-patient Pharmacist, **VA Medical Center**
Ross Muken, Director, Healthcare Services & Technology, **Deutsche Bank Securities Inc**

12:15 *Luncheon*

Disclosure Initiatives to Support and Advance Global Transparency

1:30 **Progression of Health Level Seven (HL7) — Moving Toward Harmonization**

The HL7 Clinical Trial Registries and Results Working Group has been collaborating over the past years to standardize the registration process. While the project has not yet been finalized, the possibility for standardization holds great implications for the future of the registration process. During this session, hear from a member of the working group on the status of this project and what the future holds for standardization.

- Discuss the progress of this project
- Address issue of fields not matching
- Analyze if this is a useful tool
- Evaluate the impact on future CT disclosure

Tracy Beck, Ph.D., Consultant, **Eli Lilly and Company;** *Member,* **HL7 Clinical Trial Registries and Results Working Group**

2:15 **IFPMA Priorities and Accomplishments in Supporting Transparency**

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is comprised of 25 leading international research-based

pharmaceutical companies including the biotech and vaccine sectors companies and 46 national and regional R&D industry associations covering developed and developing countries whose purpose is to foster collaborative relationships with international organizations, national institutions, governments and non-governmental organization with the goal of encouraging global policy and improving public health. In committing to transparency and access to information about investigational and marketed medicinal products, IFPMA members place great importance on respecting and protecting the safety of research participants and the public at large. IFPMA adopted as set of voluntary Principles to clarify our members' relationships with other individuals and entities involved in clinical and anti-doping research processes. This includes the release in June 2010 of an IFPMA position statement requiring for submission for publication as a manuscript in peer-reviewed journal the results of all their industry-sponsored phase III clinical trials, as well as the results of other trials of significant medical importance regardless of whether the outcome was positive or negative. It builds on the previous Joints Positions on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases, revised in November 2009.

- Review the status of IFPMA positions supporting transparency
- Discuss their implementations including which clinical trials should be published and/or disclosed
- Determine where the IFPMA will go from here

Detlef Niese, Head, Global Development External Affairs, **Novartis**

3:00 *Networking and Refreshment Break*

3:30 **Examine Current Transparency Initiatives in Specific Countries**

As countries around the world develop new clinical trial registries and results databases, each with unique demands, it is important to stay on top of requirements for emerging and evolving registries. During this session, learn the status of key registry developments so that you can better prepare yourself and your organization to meet the challenges.

- Discover the latest global registry developments
- Analyze which registries are mandatory and which are voluntary
- Assess the sponsor's role in the registration process
- Review future initiatives on the horizon

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

Sustaining Data Transparency and Optimizing Internal Department Collaboration

4:15 **Maintaining Compliance with Registration in Multiple Countries**

From the global emergence of new registries arises the need for understanding different country registration requirements. Specific registry requirements are explored which compare and contrast the varying requirements and submission timelines. This information will enable your company to understand the challenges, and how to overcome them to remain compliant.

- Review the issues when dealing with many different countries
- Share best practices for ensuring compliance with select registries
- Discuss difficulties with translation and linking fields
- Understand the differences that account for communication errors

Rosemary Wagner, Global Operations Lead, Clinical Registry, Process & Systems Department, **Johnson & Johnson Pharmaceutical Research & Development LLC**

5:00 *Close of Day One*

5:00-6:00 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

Photo by: Photolink / Getty Images

Day Two — Thursday, April 28, 2011

8:00 *Continental Breakfast*

8:30 *Chairman's Review of Day One*

Craig A. Metz, Ph.D., Former Vice President, U.S. Regulatory Affairs, **GlaxoSmithKline;** *President,* **Metz Regulatory Services**

8:45 **Utilizing In-House Statistical Programming Resources to Meet CT.gov Requirements**

Companies are facing increased challenges and resource consumption in meeting registry requirements. In order to remain compliant without unnecessarily sacrificing resources, some companies have taken the initiative to use statistical programming to link clinical databases with the registry. During this case study, learn how one company used their resources in-house to develop a program for automating results disclosure to CT.gov.

Case Study

- Learn how statistical programming was incorporated into process
- Hear the benefit from a cost-perspective — How has this reduced the need for time and resources spent on results disclosure?
- Understand the benefit from a quality perspective — How is consistency between results disclosure and clinical study reports achieved?
- Explore the challenges of automating primary and secondary outcomes results posting
- Discuss the future outlook of utilizing statistical programming globally with other registries

Denis Michel, Director, Statistical Programming, **Janssen Pharmaceutical Companies of Johnson & Johnson**

9:30 **Cross-Functional Collaboration Leveraging Statistical Programming for Posting Results**

The increasing demands of results posting have sent the industry scrambling to figure out a way to report the necessary results for thousands of clinical trials and millions of data points in a short timeframe. In most companies, responsibility for this task has been placed with regulatory affairs, who alone has tried to meet the challenges. Ideas such as outsourcing data entry to hiring a huge team of data entry personnel have been considered. During this case study, hear how Genzyme opted to leverage the internal resources of the Statistical Programming department to meet this daunting task.

Case Study

- Learn how statistical programming was incorporated into the process
- Hear the benefit from a cost and quality perspective
- Learn how manual data entry of results can be eliminated

Daniel Boisvert, Principal Programmer, **Genzyme Corporation**

10:00 *Networking and Refreshment Break*

10:30 **Meeting Disclosure Requirements — Maintaining Consistency of Disclosed Information**

In addition to the challenges of study protocol writing to effectively communicate the science and procedures, the issue of maintaining consistency of disclosed trial information across the various registries has also evolved. How is this issue managed in the industry? This session discusses how clinical teams and those managing trial disclosure can minimize this problem.

- What information is needed and at what time?
- What aspects of disclosure prove problematic for protocol writing?
- Strategies for ensuring consistency of disclosed trial information across registries

Oladayo Oyelola, Ph.D., SC(ASCP), Clinical Trial Information Disclosure Director, **Sanofi Pasteur**

11:15 **Best Practices for Managing CT.gov Feedback**

Companies face the challenge of providing requested information per CT.gov's feedback in a timely manner, but the exact criteria required is not always clear. During this session, discuss how CT.gov's quality assurance and expectations could be communicated further to avoid getting an error on results entry and how to manage the process of providing feedback most effectively.

- Discuss the common errors
- Hear the methods for most effectively managing feedback
- Understand why there is variance on data being requested
- Learn how to save time managing feedback

Shawn M. Pelletier, Associate Director, Clinical Trial Transparency, **Bristol-Myers Squibb**
Suzanne Heyd, Clinical Trial Results Analyst, **Bristol-Myers Squibb**

12:00 *Luncheon*

1:15 **Preparing for FDA Audit on Registration**

Understanding what is involved with FDA audit on registration is necessary for preparedness and prevention of issues. Through recognition of what this process entails, companies can save time and resources by taking precautions during the registration process. During this session, the following questions are answered:

- What is the purpose of the audit? Are they only triggered by "bad" things or are they performed for information gathering as well?
- What are the current expectations in recordkeeping? (CT.gov sees all changes, what would they look for in records to support changes?)
- What information will be reviewed?
- In the event of sanctions, how are they decided upon and meted out?

Barbara Godlew, President and Principal Analyst, **The FAIRE Company**

2:00 **Clinical Data Transparency and Publication Planning**

Through good publication practices, transparency, accuracy and ownership of publications is achieved. Managing these good publication practices takes time and ideally the publications would be out before results posting. Therefore, companies face a huge challenge to ensure guidelines and good practices are followed, while meeting strict deadlines. This session reviews practical measures to refine and streamline the process.

- Understand how authors, publication managers, statisticians, medical writers and regulatory affairs professionals collaborate
- Discuss how processes can be evolved and tools put into place for process improvement
- Hear ways to ensure deadlines are met and good practice followed

Maureen Garrity, Director, Publications, **Astellas Pharma Global Development**

2:45 *Close of Conference*

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Conference Highlights:

- Explore the challenges of automating primary and secondary outcomes results posting
- Review the latest trends and issues resulting from EudraCT's database update
- Discuss the progress of the HL7 Working Group
- Examine disclosure initiatives supporting and advancing global transparency

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- **Venue:**
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