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CBI's 5th Forum on

Clinical Trial Registries and Results Databases

Best Practices for Clinical Data Disclosure within an Evolving Global Regulatory Framework

April 26-27, 2010 • Doubletree Crystal City • Arlington, VA

"Excellent, comprehensive conference discussing U.S. and international requirements and updates regarding registration and result disclosure of clinical trials."

— 2009 Attendee, Shalini Jain, Associate Director, **Gilead Sciences, Inc.**

Conference Chairperson:

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

National Registry Perspectives:

Marisol Navarrete Couble, M.D., National Commission for Scientific and Technological Research, **Chile Registry of Clinical Trials**

Prathap Tharyan, M.D., MRCPsych, Professor of Psychiatry, **Christian Medical College, Vellore, India;** Director, **South Asian Cochrane Network & Centre, Clinical Trial Registry India (CTRI)**

Marcel Kenter, Ph.D., Executive Director, Central Committee on Research Involving Human Subjects (CCMO), **CCMO Register**

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

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

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

Nicholas Ide, Chief Architect, **ClinicalTrials.gov**

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

Alan G. Minsk, Partner, **Arnall Golden Gregory LLP**

Paul Ngai, Clinical Trial Registry Consultant, **Johnson & Johnson**

Detlef Niese, M.D., Ph.D., Head of External Affairs, Clinical Development and Medical Affairs, **Novartis**

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

Carol Slusser, Senior Director, Medical Communications, Clinical Submissions and Documentation, **Schering Plough**

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

Ellen Travis, FNP, MSN, Clinical Research, **Abbott Vascular**

Tania Walton, Principal Programmer, CIS Programming, **AstraZeneca Pharmaceuticals**

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

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"This was a fantastic opportunity to meet other colleagues who are facing the same challenges and network with them."

— 2009 Attendee, Kay Meyers, Medical Information Specialist, **Bausch & Lomb**

MAIN CONFERENCE

Day One — Monday, April 26, 2010

7:30 *Conference Registration and Continental Breakfast*

8:30 *Chairperson's Opening Remarks*

Pamela Rose, Associate Director, Clinical Trial Registration and Results Disclosure, **Takeda Global Research and 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. She 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.

Domestic and International Requirements for Clinical Trial Registration and Results Disclosure

LEGAL ADDRESS

8:45 **Understand the Legal Perspective on Clinical Trial Transparency for Bio/Pharmaceutical and Medical Device Companies**

There are a myriad of requirements for sponsors to satisfy in order to run a compliant global data disclosure operation. Because of the complex and diverse nature of these requirements, covering all bases can be a difficult task. However, companies must navigate these often murky regulatory waters in order to promote their products in the desired markets. During this address, the speaker provides a legal perspective that helps attendees ensure regulatory compliance without disclosing more than might be necessary.

Alan G. Minsk, Partner, **Arnall Golden Gregory LLP**

EudraCT JOINT OPERATIONS GROUP PERSPECTIVE

9:45 **Analyze the Current Efforts of the EudraCT Joint Operations Group**

Throughout the industry, those responsible for disclosing clinical trial information are desperate for guidance and new legislation that will make their lives easier. Although the regulatory landscape remains complex, the EudraCT Joint Operations Group is doing everything in their power to streamline the process for trial registration. During this session, a representative explores the most recent initiatives of the EudraCT Joint Operations Group.

- Identify and discuss major changes expected during the summer of 2010 related to trial registration

Detlef Niese, M.D., Ph.D., Head of External Affairs, Clinical Development and Medical Affairs, **Novartis**

10:30 *Networking and Refreshment Break*

11:00 **Overcome Ambiguities in Data Disclosure Laws and Requirements**

The movement towards increased clinical trial transparency was initiated by those who were passionate about the need for public access to clinical trial information. Although many of the individuals responsible trial registration and results disclosure are equally passionate, the expectations of an ever-changing global regulatory framework can be frustrating. In order to eliminate some of the ambiguities, it's essential for industry leaders to come together and identify and find solutions for the most perplexing disclosure requirements. Through candid discussion, this panel is designed to identify best practices and pave the way for future harmonization. Attendees are encouraged to submit questions and discussion topics to CBI in advance of the panel. Potential topics include, but are not limited to:

PANEL

- Registering trials prior to 2004
- Rules and best practices for investigator initiated studies
  - * what are you responsible for when providing drugs to independent investigators?
- Disclosing data from observational studies
  - * Maine requirements
- Post-hoc analyses

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

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

Carol Slusser, Senior Director, Medical Communications, Clinical Submissions and Documentation, **Schering Plough**

IRB PERSPECTIVE

11:45 **The Role of Ethics Committees and Institutional Review Boards Regarding Clinical Trial Registration and Results Publications**

The European EudraCT Database was developed within a formal Good Clinical Practice context that provided clear procedures for clinical trial registration and oversight, including the place of ethics committees (ECs)/institutional review boards (IRBs) within the process. The ongoing discussion regarding transparency in clinical trials, including increasing requirements for results publications, brings new concerns and perhaps new roles for ECs/IRBs. This session focuses on the impact of new legislation and practices regarding clinical trial databases in Europe, the U.S. and other countries on EC/IRB practices and expectations in their initial and ongoing review of clinical trials.

- Understand the perspective of EC/IRB members toward clinical trial registration and results publication

- Evaluate the role and expectations of ECs/IRBs with regard to transparency in clinical research
- Hear experiences in Europe and the U.S. regarding relations between clinical trial databases, researchers and regulatory authorities
- Learn about experiences in China, India and other countries regarding the inter-relations between ECs/IRBs and clinical trial databases
- Future perspectives on EC/IRB development vis-à-vis transparency in clinical research

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

12:30 *Luncheon*

1:45 **Develop SOPs and Internal Training Programs for Clinical Data Disclosure**

The experience level related to clinical data disclosure varies significantly from company to company. However, even the most advanced groups can benefit from hearing industry best practices for things like SOP development and internal training. During this session, the speaker explains how to get the most out of your clinical trial transparency team.

- Develop guidelines for internal training of new staff members
- Learn how to initiate a registry process
- Create SOPs for clinical trial transparency with lessons learned from industry leaders

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

2:30 **Technology Considerations for Clinical Data Disclosure**

As the global regulatory framework for clinical data disclosure becomes increasingly complex, just remaining up to date poses a major challenge. To help facilitate compliance, many organizations have begun implementing emerging technologies designed to manage the disclosure process. However, depending on the corporate culture and size of the organization, the type of technology used varies extensively. For example, many organizations with limited budgets are getting by with very basic technology like Excel spreadsheets. Alternatively, some organizations with larger budgets have purchased platform technologies or built internal systems to help manage the disclosure process. During this session, hear varying approaches to technology.

- Building the business case for an investment in technology
- Build, buy or rent enabling technology
  * pros and cons of building an internal system
  * pros and cons of purchasing from a vendor
  * SAAS — software as a service
- Technology validation and operational efficiencies
  * validate internal systems/vendor solutions
  * best practices
  * linking to source systems like CTMS and SAS

Tania Walton, Principal Programmer, CIS Programming, **AstraZeneca Pharmaceuticals**

3:15 *Networking and Refreshment Break*

NIH PERSPECTIVE

3:45 **ClinicalTrials.gov — NIH Update and Q&A**

Nicholas Ide, Chief Architect, **ClinicalTrials.gov**

4:30 **Develop Best Practices for Disclosing Clinical Trial Results**

PANEL

Like trial registration, requirements for results disclosure are designed to provide public access to clinical trial information. Although essential for improving public opinion of the bio/pharmaceutical industry, results disclosure presents many significant challenges for those charged with publicizing the information. In order to develop best practices, this panel is designed to explore industry experience with results disclosure to-date.

- FDA and EMEA requirements
- Anticipated rule-making for September 2010
  * will this occur?
  * what are the implications?
- Emerging global requirements
- Publication planning

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

Panelists: Suzanne Heyd, MA, MFA, Clinical Trial Results Analyst, **Bristol-Myers Squibb**

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

Ellen Travis, FNP, MSN, Clinical Research, **Abbott Vascular**

Paul Ngai, Principal, **Ngai Consulting**

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 — Tuesday, April 27, 2010

7:30 *Continental Breakfast*

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

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

Manage the Proliferation of Emerging Clinical Trial Registries in Key Countries

8:15 **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. As the national demand for unique clinical trial websites/databases continues to rise, it becomes increasingly important to hear directly from representatives of these emerging registries. After brief introductory remarks on the importance of national registries, speakers from India, Chile and the Netherlands help industry comply with their unique clinical data disclosure requirements.

- Current status of the registry
- Posting requirements
- Timelines
- Language and translational issues
- Essential technical and operational considerations

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

8:30 **Chile**

Marisol Navarrete Couble, M.D.,
National Commission for Scientific and Technological Research,
Chile Registry of Clinical Trials

9:15 **Netherlands**

Marcel Kenter, Ph.D., Executive Director,
Central Committee on Research involving Human Subjects (CCMO),
CCMO Register

10:00 *Networking and Refreshment Break*

10:30 **India**

Prathap Tharyan, M.D., MRCPsych, Professor of Psychiatry,
Christian Medical College, Vellore, India; *Director,*
South Asian Cochrane Network & Centre,
Clinical Trial Registry India (CTRI)

11:15 **Compare and Contrast Key Registry Requirements to Streamline Global Data Disclosure Operations**

Moderator:
John C. McKenney, President, **SEC Associates, Inc.**

PANEL

Panelists:
Marisol Navarrete Couble, M.D., National Commission for Scientific and Technological Research, **Chile Registry of Clinical Trials**

Marcel Kenter, Ph.D., Executive Director, Central Committee on Research involving Human Subjects (CCMO), **CCMO Register**

Prathap Tharyan, M.D., MRCPsych, Professor of Psychiatry, Christian Medical College, Vellore, India, Director,
South Asian Cochrane Network & Centre,
Clinical Trial Registry India (CTRI)

Nicholas Ide, Chief Architect, **ClinicalTrials.gov**

12:00 *Luncheon*

HL7 PERSPECTIVE

1:15 **Understand the Importance and Identify the Challenges of Standardizing Registry Requirements**

As the global regulatory environment for clinical data disclosure continues to evolve, harmonization and standardization grow increasingly important. To help pave the way for the future, HL7 has been working diligently to create a uniform set of standards designed to reduce regulatory ambiguities and promote compliance. During this session, a representative of the leadership team discusses a high level view of the status of their project to-date.

- Discuss HL7's role in global harmonization
- Analyze key milestones from the HL7 working group

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

200 **Transparency in Clinical Research — Exploring New Opportunities**

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 recent developments related to 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, Clinical Quality, **F. Hoffmann-La Roche Ltd.**

2:45 *Close of Conference*

To Register Call Toll Free 800-817-8601 (339-298-2100 outside the U.S.) or Fax 781-939-2490. Register on our website at www.cbinet.com/ctr

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:

- Clinical Trial Registries/ Clinical Trial Registration (CTR)
- Clinical Data Disclosure
- Regulatory Affairs
- Compliance
- Clinical Trial Information
- Medical Affairs
- Medical Writing
- Document Management
- Publications
- Medical Information
- Clinical Operations
- Medical Business Operations
- Clinical Quality Assurance
- Medical Affairs
- Project Management

This conference will also interest contract research organizations, registries and results databases and technology vendors who implement registries and databases.

ACCLAIM FROM PREVIOUS ATTENDEES

"The conference provided an excellent opportunity to share experiences and network regarding clinical trial disclosure."

— Robert Paarlberg, Director,

UCB

"Kudos to CBI for this conference. It is getting better and bigger with more information and updates from major players and stakeholders."

— Oladayo Oyelola, Deputy Director, Medical Writing,

Sanofi-Pasteur

"Timely topics. Well informed speakers."

— Katherine Tiku, Associate Vice President,

sanofi-aventis

"Fantastic conference."

— Karen Durrant, Manager, Clinical Trial Registries,

Astellas

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

— Adrian Ferguson, Associate Manager,

MedImmune

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"A highly informative and educational forum for anybody wanting to learn about or keep up with rapidly emerging global clinical trials disclosure requirements."

— *2009 Attendee, Penny Clarke, Head of Integrated Systems Support,* **GlaxoSmithKline**

TOP REASONS TO ATTEND:

- Network with industry thought-leaders just after the release of EudraCT Version 8
- Explore the requirements of registries in Germany, Czech Republic and Latin America
- Understand how to align EMEA disclosure requirements with FDA regulations
- Formulate a disclosure strategy for adverse event data

PLUS! Analyse the Efforts of the EMEA EudraCT Joint Operations Group

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Top Reasons to Attend:

- **Hear directly from representatives of CCMO, CTRI and the Chile Registry of Clinical Trials**
- **Obtain best practices and proven strategies from 10 industry speakers**
- **Explore the latest initiatives HL7 and the EudraCT Joint Operations Group**

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If you are unable to attend the conference or you would like extra copies for your colleagues, you can order your conference CD-Rom today. Don't miss out on the valuable information presented by industry leaders exclusively at this event. The CD-Rom is available for only $198 and includes the conference agenda, presentations and speaker biographies. Simply fill out the order form and the CD-Rom will be shipped to you 2 weeks after the conference occurs.

Photo by: Keith Brofsky / Getty Images

- **Registration Fee:**

	Standard	Advantage Pricing
2-day Conference	$1,995	$1,695

Advantage Pricing — Register by February 19, 2010 and SAVE $300.
Fee includes continental breakfast, lunch, wine and cheese reception, refreshments and CD-Rom Compendium. Please make checks (in U.S. funds drawn on a U.S. bank) payable to **CBI Research, Inc.** (No personal checks accepted) Advantage Pricing may not be combined with other discount offers, special category rates or promotions. Discounts only apply to standard rates.

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