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CBI's 2nd Premier Forum on

Clinical Trial Registries and Results Databases

Compliant Clinical Data Transparency and Disclosure Strategies to Enhance Public Perception and Increase Patient Participation

April 30 – May 1, 2007 • DoubleTree Hotel • Washington, D.C.

Featured FDA Presentation:

Theresa Toigo, R.Ph., MBA, Director, Office of Special Health Issues, **Food and Drug Administration**

Regulatory Perspectives:

Francis P. Crawley, Director General, **Good Clinical Practice Alliance, Europe;** Member, Scientific Advisory Group, International Clinical Trials Registry Platform, **World Health Organization**

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

Christopher J. Badgley, Vice President, State Government Affairs, **PhRMA**

Alan Goldhammer, Ph.D., Associate Vice President, Regulatory Affairs, **PhRMA**

Marjorie E. Powell, Senior Assistant General Counsel, **PhRMA**

Ida Sim, M.D., Ph.D., Past Project Coordinator, International Clinical Trials Registry Platform (RPC/EIP), **World Health Organization**

State Perspectives:

Paula C. Hollinger, **Maryland State Senator**

Jude Walsh, Special Assistant, Governor's Office of Health Policy and Finance, **State of Maine**

Amy Muhlberg, Professional Staff Member, **Senate Committee on Health, Education, Labor and Pensions, Ranking Minority Member Michael B. Enzi** *(R-WY) (invited)*

Pharmaceutical, Biotech and Medical Device Perspectives:

Michael Rubison, Ph.D., Senior Director, Global Medical Research and Registration, Global Medical Affairs, **Abbott**

Jacob Lee, Director, Planning and Technical Services, **Amgen Inc.**

Carolyn Severns, Senior Planning and Technical Services Specialist, **Amgen Inc.**

James A. Ruggles, Ph.D., Director of Scientific Disclosures, **Amylin Pharmaceuticals, Inc.**

Sandra Raff, M.D., MBA, FACP, FACE, Senior Director, Clinical Research, **AstraZeneca**

Tracy J. Beck, Ph.D., Associate Medical Business Operations Consultant, Clinical Trial Registry Results Gatekeeper, **Eli Lilly**

Maureen Strange, Medical Business Operations Consultant, Clinical Trial Registry, **Eli Lilly**

Beat E. Widler, Ph.D., Global Head of Clinical Quality, **F. Hoffmann-La Roche**

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

Margaret M. Cobb, M.D., Ph.D., Senior Director, Global Leader of Clinical Registry, **Johnson & Johnson Medicines and Nutritionals**

Jodi Scott, Legal Counsel for FDA Regulatory Matters, Legal Regulatory, **Medtronic, Inc.**

Natalie Jones, Associate Director, Clinical Trial Disclosure Group, Safety and Risk Management, **Pfizer Inc**

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

Chris Haigh, BSc, Ph.D., DIC, Corporate Director, Worldwide Medical Communications, **Serono International**

Pamela A. Rose, RN, FNP, ASQ-CMQOE, Director, Clinical Trial Information Registries, Research and Development, **TAP Pharmaceuticals**

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"Overall this conference was excellent. The selection of speakers was well-rounded and they provided excellent expertise."

— 2006 Attendee, A. Ferguson, Associate Project Manager, **MedImmune**

MAIN CONFERENCE

Day One — Monday, April 30, 2007

7:30 *Main Conference Registration & Continental Breakfast*

8:30 *Chairperson's Welcome and Opening Remarks*

Pamela A. Rose, RN, FNP, ASQ-CMQOE, Director, Clinical Trial Information Registries, Research and Development, **TAP Pharmaceuticals**

With over 25 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. She is a RN and Family Nurse Practitioner and is certified as an ISO 9001:2000 Lead Auditor and ASQ Manager of Quality and Organizational Excellence.

8:45 **Strategies for Medical Writing to Reach All Audiences**

Most clinical trial registries and results databases are viewed by the general public, therefore, it is imperative to make the material posted consumable for all readers. This session provides tools to write clinical trial registries and results database summaries.

Case Study

- Disseminate important clinical terminology in consumable forms for all readers
- Medical writing strategies that assist in writing clinical trial information
- Translation methods for international research

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

9:30 **Mitigate the Risks of Promotional Language when Posting Clinical Information**

Occasionally, if data are not comprehended correctly, patients may go to their physicians and make demands on how they wish to be medicated. This leads regulatory bodies and physicians to view the information posted as promotional. Therefore, pharmaceutical companies need to be careful to ensure they are not crossing the lines of drug promotion laws. Apply different approaches on writing summaries to mitigate the risk of clinical data being perceived as an advertisement.

Case Studies

- Understand the risks involved when the public has access to clinical data
- Analyze how readers interpret registry data as being promotional
- Create non promotional clinical registry and results summaries
- Use a disclaimer to educate registry readers on what stage a drug is in

Tracy J. Beck, Ph.D., Associate Medical Business Operations Consultant, Clinical Trial Registry Results Gatekeeper, **Eli Lilly**

10:15 *Networking and Refreshment Break*

10:45 **Maintain Information Posted to Ensure Current Information**

Clinical trial registry guidelines require that information is posted either before, or shortly after, the start of patient recruitment. Monitoring and updating registries and databases is both time and resource consuming since trials are dynamic and information constantly changes. Leaving trial information posted when it is outdated or incorrect can be a risk since viewing old or incorrect information on a drug or trial can provide invalid information and jeopardize the image of the pharmaceutical company. Hear the experiences of how both a pharmaceutical and a biotech company maintained current clinical trial information posted on registries and results databases.

Case Studies

- Ensure posting is prompt
- Do not compromise future publications with posted data
- Avoid duplicate posting of trials by multiple stakeholders
- Post results following completion of the trial
- Keep registries and databases up-to-date

Chris Haigh, BSc, Ph.D., DIC, Corporate Director, Worldwide Medical Communications, **Serono International**

Maureen Strange, Medical Business Operations Consultant, Clinical Trial Registry, **Eli Lilly**

11:30 **Use Independent Third Party Audits to Verify Accurate and Comprehensive Disclosure**

In order to maximize the value of these registries both for the company and the public, some sponsors have engaged independent third party auditors to audit the published information and validate that registries are accurate and complete. The importance of verifying the database information is echoed in pending legislative efforts as well. Examine how to establish and manage an effective third party audit program to verify that clinical information databases are accurate and comprehensive.

Case Study

- Understand why pharmaceutical manufacturers engage a third party auditor as a standard part of registry and results database practices
- Use self audits to identify and resolve issues arising from publication of the clinical data
- Key elements of a third party audit
- Examination of audits programs used by companies today
- Analyze industry and legislative trends for clinical trial registries and results databases

Jill Alvarez, Esq., Partner, **Nixon Peabody LLP**

John McKenney, CIPP, Senior Vice President, **SEC Associates, Inc.**

12:15 *Networking Luncheon*

1:15 **Solutions for Registering and Posting Results of Phase I Research**

Most Phase I trials are excluded from the registration process because the primary goal is to assess major unknown toxicity levels or determine pharmacokinetics. However, registering information for these early stage trials can be very helpful in increasing transparency. This speaker educates attendees on how to post data for Phase I trials, when these trials are known to have a lot of statistical and specified information with terminology that is not common knowledge to average registry readers.

- Learn what pieces of information are best to post for Phase I clinical research
- Post results of Phase I research without implying specifics on the future implications and effects of the drug
- Hear case studies and success stories of publishing Phase I data to registries

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

2:00 **Design and Implement a Corporate Results Posting Policy**

Identifying appropriate stakeholders for the design of a corporate policy for disclosing clinical trial results is extremely important to clinical trial results posting strategy. In this session, learn the "What, Where and When" of how clinical trials results should be disclosed based on current PhRMA and other guidelines and how these results databases may be impacted when working with a business partner. Also, develop a flexible process that ensures summaries and publications are posted in a timely manner once products are approved.

- Understand the current guidelines that impact disclosing of clinical trial results
- Hear about the interplay between publications and disclosing clinical trial results
- Implement an efficient results posting process with an emphasis on utilizing existing processes
- Learn about future concerns with clinical trial registries and results databases that can impact posting regulations and requirements

James A. Ruggles, Ph.D., Director of Scientific Disclosures, **Amylin Pharmaceuticals, Inc.**

2:45 **Partnerships for Trust — Situating Clinical Trial Registries and Results Publications in a Good Clinical Practice Context**

The growing call for transparency and accountability in clinical trials is based on a wide-felt need for increased trust in clinical trials. Clinical trial registries and results databases have the potential to contribute to this public need for confidence in research. Behind the questions of information disclosure and results reporting lie larger questions concerning responsibilities in clinical trials. This session examines the responsibilities of the different parties involved in clinical trial registries and results publications such as sponsors, investigators, ethics committees, DMCs/DSMBs and ethics committees, as well as the responsibilities of patients, registries and publishers. Only in a context of partnerships in research, where responsibilities are clearly delineated, is it possible to arrive at a firm understanding as to how clinical trial registries and results databases and publications contribute to improved medicines development.

- Know who is responsible for registering clinical trials
- Understand who is responsible for reporting and publishing the results of clinical trials
- Learn about the role of ethics committees and DMCs/DSMBs
- Explore the responsibilities (and limits) of clinical trial registries
- Hear the responsibilities (and limits) of medical journals
- Identify the responsibilities of patients in clinical trial posting

Francis P. Crawley, Director General, **Good Clinical Practice Alliance, Europe;** *Member, Scientific Advisory Group, International Clinical Trials Registry Platform,* **World Health Organization**

3:30 *Networking and Refreshment Break*

4:00 **Leverage Technology to Support Clinical Trial Registries and Study Results Postings**

Evaluating existing or new processes, forming a team, creating or revising policies and implementing solutions are complex and cumbersome undertakings, especially in an area, such as clinical trial registries and results databases, that have a constantly evolving landscape. Learn how to utilize technology to achieve consistency, compliance and sustainability in supporting your organization's clinical trials and study results posting solutions.

- Create a governing structure for posting so employees and vendors know responsibilities
- Partner with technology vendors to collaborate on scope, development and implementation
- Use technology to track and report performance registry metrics
- Determine the compliance and business needs for sustainability in ongoing training and support of posted clinical information

Jacob Lee, Director, Planning and Technical Services, **Amgen Inc.**
Carolyn Severns, Senior Planning and Technical Services Specialist, **Amgen Inc.**
Laura Miolla, Director, Business Development, **Veritas Medicine**

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4:45 **Learn How Clinical Trial Registries and Results Databases are Being Used as a Means of Competitive Intelligence**

Posting information on clinical trial registries and results databases allows competitors to view future plans for your product pipelines and also allows you to be informed about your competitor's pipeline as well. This session educates attendees on how to prepare for competitors to view internal clinical research information. Also, there is a discussion regarding best practices your competitive intelligence team should be using when viewing other posted clinical information.

Case Study

- Know which information is best to post to protect your company and clinical pipeline
- Learn how to balance posting with regulatory requirements and your competitive intelligence strategy
- Use data from competitors' websites as a tool in future strategy and development

Mark Little, Vice President of Business Intelligence, **Covance**

5:30 **Position Clinical Trial Data Efficiently within the Dynamic Registry and Results Database Environment**

This session provides a view of the complex landscape of key current clinical trial registries and results databases and those that are in development. There is also an emphasis on various clinical trial portals and primary databases that are becoming very popular and more frequently used.

- Understand where clinical trial data may be posted and the established links between various portals and databases
- Learn about key web sites upon which clinical trial data may currently be posted and the types of trial information posted on each
- Discover new clinical database initiatives
- Hear about the strategic differences between various databases

Sandra Raff, M.D., MBA, FACP, FACE, Senior Director, Clinical Research, **AstraZeneca**

6:00 **Learn about Business Processes and Regulations that Impact Clinical Trial Registries and Results Databases**

Panel

Prior to participation in the interactive panel, attendees are asked to submit questions to be addressed by the panelists. Please pass your written, confidential questions to a CBI representative by the 3:30 networking break.

Due to the market's need to openly discuss issues, ideas and concerns regarding clinical trial registries and results databases, this panel discussion allows attendees and panelists to do so. Leaders within registries and results databases convene to address the most pressing issues for implementing, maintaining and remaining compliant when posting to clinical trial registries and results databases. Since this topic area is reasonably new to the industry there are many different and innovative strategies available to succeed that are discussed from different perspectives in this panel. Topics to be addressed include:

- Technologies that assist in building and maintaining clinical trial registries and results databases
- Medical device registries and results databases
- The impact of PhRMA's ClincialStudyResults.org website on results posting

Moderator: Laura Miolla, Director, Business Development, **Veritas Medicine**

Panelists: Michael Rubison, Ph.D., Senior Director, Global Medical Research and Registration, Global Medical Affairs, **Abbott**

Margaret M. Cobb, M.D., Ph.D., Senior Director, Global Leader of Clinical Registry, **Johnson & Johnson Medicines and Nutritionals**

Jodi Scott, Legal Counsel for FDA Regulatory Matters, Legal Regulatory, **Medtronic, Inc.**

Natalie Jones, Associate Director, Clinical Trial Disclosure Group, Safety and Risk Management, **Pfizer Inc**

Alan Goldhammer, Ph.D., Associate Vice President, Regulatory Affairs, **PhRMA**

Pamela A. Rose, RN, FNP, ASQ-CMQOE, Director, Clinical Trial Information Registries, Research and Development, **TAP Pharmaceuticals**

6:45 *Close of Day One*

6:45-7:45 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

Day Two — Tuesday, May 1, 2007

7:30 *Continental Breakfast*

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

Pamela A. Rose, RN, FNP, ASQ-CMQOE, Director, Clinical Trial Information Registries, Research and Development, **TAP Pharmaceuticals**

8:15 **The WHO International Clinical Trials Registry Platform — Update and Current Priorities**

Since its launch in 2005, the WHO International Clinical Trials Registry Platform has become a leading force in clinical trial registration and reporting. The WHO Registry Platform has defined policies to coordinate trial registers worldwide into an integrated accurate and useful Registers Network. In addition, the Registry Platform is defining a minimum set of results information that should be reported for all registered trials. The Registry Platform works with clinical trials professionals around the world to introduce policies and standards that benefit public health. Attendees take an in-depth look at the most influential clinical trial registry and results database regulatory organization.

Case Study

- Learn the mandate of, and the basic principles behind, the International Clinical Trials Registry Platform at the WHO
- Know about the current structure, policies, interactions and composition of the WHO Registers Network
- Hear about the WHO's assessment of the state of trial registration worldwide

- Understand the Minimum Trial Report and its objective
- Appreciate the importance of complete registration and results reporting for maintaining public trust in clinical research

Ida Sim, M.D., Ph.D., Past Project Coordinator, International Clinical Trials Registry Platform (RPC/EIP), **World Health Organization**

8:55 **SearchClinicalTrials.org — A Coordinated Site for Registries, Results Databases and News, All in One Place**

Learn the results of a survey of 4,500 registry users that was conducted in August 2005 and how that information led the Center for Information and Study on Clinical Research Participation to create SearchClinicalTrials.org. SearchClinicalTrials.org is the first clinical trial search engine to appease many of the concerns and frustrations registry users have. SearchClinicalTrials.org is the most comprehensive web portal for locating clinical trials, clinical trial results and clinical trial news in the U.S. and Canada. Attendees learn how to apply the survey's feedback into current posting methods and what resources are best to use when creating registries and results databases.

- Hear survey results from registry users on the ease of using registries
  - * what information is most important?
  - * what is done with the information found on registries?
  - * what are registry readers looking for?
- Learn about the inception and creation of SearchClinicalTrials.org
- Discover how SearchClinicalTrials.org increases transparency and public access to clinical trials, clinical trial results and news about clinical research

Rachel Stanley, Marketing and Communications Director,
Center for Information and Study on Clinical Research Participation

9:40 **IFPMA — The Sole Search Portal Connecting All Major Registries and Results Databases**

IFPMA built a search engine that crawls all major sites where sponsors (academia, industry, patient groups and sponsors) can post trial information. This search portal enables patients, researchers and physicians to quickly and effectively find information about registered trials. This session addresses how IFPMA is improving utilization in a large user community which allows viewers to choose between different languages (English, French, German, Spanish and Japanese) that should further promote transparency. This IFPMA tool also promotes endeavors for an improved transparency of clinical trials activities. Additionally, attendees discuss how the IFPMA actively manages the site to ensure that links are kept up-to-date and new search features are added.

- Understand the IFPMA Portal and its impact on the registration of trials globally
- Learn the best methods to use the search engine
- Hear how the IFPMA is promoting access to trial information for patients and physicians

Beat E. Widler, Ph.D., Global Head of Clinical Quality,
F. Hoffmann-La Roche

10:25 *Networking and Refreshment Break*

10:55 **ClinicalTrials.gov — Updates and Future Expectations of this Key Registry**

The ClinicalTrials.gov registry is sponsored by the United States (U.S.) government and provides information regarding all different types of trials from around the world. Sponsors post their trials at ClinicalTrials.gov in order to comply with a number of different policy initiatives on increasing transparency. Discuss how ClinicalTrials.gov continues to adapt to changes in the U.S. environment, as well as, meets the needs of other country requirements.

- Status update — What is new and what is happening globally that has impacted ClinicalTrials.gov
- Hear a statistics update on who is using ClinicalTrials.gov
- Understand how the implementation of the Best Pharmaceuticals for Children's Act is affecting the registry
- Learn about user interface changes and features on ClinicalTrials.gov

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

FEATURED FDA PRESENTATION

11:40 **FDAMA Section 113 — An FDA Update**

In January 2002, the Food and Drug Administration (FDA) Office of Special Health Issues (OSHI) initiated a program to educate private-sector sponsors about the statutory reporting requirements under Section 113 of FDAMA and to assess sponsor compliance with the law. Additional compliance studies were completed in 2004, 2005 and 2006. Attendees hear an update of FDAMA 113 and where the FDA stands on trial registration.

- Review compliance trends from the four-year period of 2002 to 2006
- Discuss sponsor compliance in 2006 for research and commercial-sponsored protocols for cancer drugs
- Hear a status report on current activities

Theresa Toigo, R.Ph., MBA, Director, Office of Special Health Issues,
Food and Drug Administration

In the OSHI, Ms. Toigo works with patients and their advocates to encourage and support their active participation in the formulation of FDA policy and decision-making. Ms. Toigo has held various FDA positions since joining FDA in 1984. She has worked in hospital and retail pharmacy and continues to serve as a preceptor for pharmacy students. Ms. Toigo received her pharmacy (BS) and business (MBA) degrees from Rutgers University.

12:10 *Networking Luncheon*

1:15 **Understand and Prepare for the Passage of the Enzi-Kennedy Bill**

Senators Michael Enzi (R-Wyo) and Edward Kennedy (D-Mass) have recently introduced a bipartisan bill designed to provide FDA with more power to monitor the safety and clinical information regarding prescription drugs. The bill would mandate registration of clinical trials and disclosure of their results, including both a scientific and public summary. This session addresses the content of the bill and the outlook for its passage, including disclosure requirements and common concerns that sponsors fear to ensure registration is done properly.

- Understand the requirements for clinical trial registration in the Enhancing Drug Safety and Innovation Act
- Learn the criteria for clinical trial results disclosure under the Act
- Evaluate areas of controversy, including the balance between transparency and confidential commercial information
- Review the 2007 legislative outlook for this and other proposals

Amy Muhlberg, Professional Staff Member, **Senate Committee on Health, Education, Labor and Pensions, Ranking Minority Member Michael B. Enzi** *(R-WY) (invited)*

George Neyarapally, Pharm.D., MPH, Pharmacy Healthcare Policy Fellow, **Virginia Commonwealth University; American College of Clinical Pharmacy; American Society of Health System Pharmacists**

1:50 **Learn Why Certain States Are Requiring and Enforcing Trial Registration and Results Posting Requirements**

Panel

With controversies surrounding clinical registry and results posting individual states are now taking initiative in this space. In this panel discussion, attendees are educated on what requirements various states currently have in place or are working on putting together, regarding trial registration and posting results.

- Learn why states have taken clinical trial posting regulations into their own hands
- Hear which states currently have and are working on clinical information posting regulations
- Understand how state regulations impact trial posting and transparency

Moderator: John Patrick Oroho, Esq., Principal, **Porzio Bromberg and Newman;** *Executive Vice President,* **Porzio Pharmaceutical Services, LLC**

Panelists: Paula C. Hollinger, **Maryland State Senator**

Christopher J. Badgley, Vice President, State Government Affairs, **PhRMA**

Marjorie E. Powell, Senior Assistant General Counsel, **PhRMA**

Jude Walsh, Special Assistant, Governor's Office of Health Policy and Finance, **State of Maine**

2:25 **Journal Editors' Views and Impact on Clinical Trial Registries**

Journals are taking a firm stand on the issue of registering clinical trials. Many journals now do not allow publication of clinical trial results in their journals unless they have been registered on a clinical trial registry that meet specific criteria. This session discusses why journal editors have adopted this policy and how to post to ensure clinical trials can be published in these journals.

- Understand the reasons why journal editors have adopted this policy
- Identify who journal editors feel is responsible for registration
- Evaluate the benefits associated with adhering to these requirements

Kamran Abbasi, Editor, **Journal of the Royal Society of Medicine;** *Chief Executive,* **OnMedica.net**

3:05 **Public and Patient Perspectives on Trial Transparency and Data Disclosure**

Regulators, sponsors and journals base clinical reporting and registering decisions on their relative perspectives. This leads the public to wonder what would happen if decisions were made based on the ultimate metric — health outcomes. Explore the tensions within trial registration, results reporting and data disclosure, while focusing on and balancing the patient perspective.

- Balance registration systems to attain a win-win for all
- Learn what patients look to gain from registries
- Understand what information is critical to informed decision making
- Consider novel ways to construct registries to gain attention from patients and the public
- Address both positive and negative results from a patient perspective

Sharon Fontaine Terry, President and Chief Executive Officer, **Genetic Alliance**

3:45 *Close of Conference*

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CBI's 2nd Premier Forum on Clinical Trial Registries and Results Databases Advisory Board

CBI would like to thank our esteemed advisory board for their contributions to the program. The professionals below used their vast knowledge regarding clinical trial data disclosure to help provide attendees with a conference that is timely and compelling to the clinical industry.

Francis P. Crawley, Director General,
Good Clinical Practice Alliance, Europe;
Member, Scientific Advisory Group,
International Clinical Trials Registry Platform,
World Health Organization

*Mr. Crawley is a philosopher that specializes in ethical, legal and regulatory issues concerning biomedical research. He is the past Secretary General, Ethics Officer and Chairman of the Ethics Working Party at the **European Forum for Good Clinical Practice** (EFGCP). He has acted as an author for the leading international and European ethics guidelines, as well as for several in-country guidelines in Asia, Africa, the Americas and Europe. He is currently Chairman of the Ethical Review Committee of the International Network for Cancer Treatment and Research (INCTR), a member of the INCTR Tissues Committee and a member of the Ethics Committee of the European Organization for Research and Treatment of Cancer (EORTC). He also served for four years on the UNAIDS Ethical Review Committee.*

Beat E. Widler, Ph.D., Global Head of Clinical Quality,
F. Hoffmann-La Roche

Dr. Widler obtained his Ph.D. in Microbiology from the Swiss Institute of Technology in Zurich, Switzerland. He then gained experiences as a research scientist in a microbiology research laboratory and then for the past 22 years in the pharmaceutical industry. His experience covers Drug Regulatory Affairs and Clinical Science where he participated in the planning and conduct of a major international drug development program. In addition to his functional responsibilities, he was nominated head of the Welwyn Garden City (UK) Development site giving leadership to a group of about 600 development professionals.

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

Dr. Karol holds a BS in biology and chemistry from Valparaiso University, an MS in biochemistry and an MBA from Fairleigh Dickinson University and a Ph.D. in biochemistry from Rutgers University. During her lengthy career in the global pharmaceutical industry, she has had hands-on experience in all phases of drug development, from discovery through registration and post-marketing trials. Throughout Dr. Nauss Karol's 24 years in clinical research, she has been involved in 12 NDAs and, although the majority of her clinical experience has been in developing antiviral agents, she has also developed drugs in the metabolic, gastrointestinal, local anesthetic and oncology therapeutic areas and conducted clinical pharmacology studies for a variety of drugs.

Rick Ward, Director, Business Development,
Veritas Medicine

*Mr. Ward has been involved with business development for 17 years, the past 7 years he focused specifically on the pharmaceutical and biotech industries. Prior to joining Veritas Medicine in 2003, Mr. Ward held a senior sales position for 8 years with **Medical Copy Services**. Prior to entering the professional services arena Rick worked in the medical device industry. Mr. Ward is a member of the ACRP. Having received his B.S. in Marketing from Penn State University in 1990, he is currently pursuing a specialized MBA in Biotechnology and Healthcare Industries at Penn State's Great Valley Campus.*

Who Should Attend

You will benefit from this event if you are a Vice President or Director/Manager at a pharmaceutical or biotech company with responsibilities in the area of:

Medical Writing
Medical Information
Medical Knowledge
Clinical Trial Information
Registration/Registry
Information Management
Strategic Communication
Business Development
World Wide Development
Strategic Operations/Planning
Medical Affairs
Business Operations
Project Management
Regulatory Affairs
Clinical Affairs
Clinical Communications/Marketing
Clinical Operations
Clinical Research

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

CBI's Upcoming Events

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Vaccine Development Summit
May 24-25, 2007 • Philadelphia, PA

3rd Annual
Obesity Drug Development Summit
July 26-27, 2007 • Washington, DC

2nd Annual Forum on
Clinical Supply Chain Management
July 26-27, 2007 • Philadelphia, PA

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April 30 – May 1, 2007 • DoubleTree Hotel • Washington, D.C.

Learn About These Leading Clinical Trial Registries, Results Databases and Portals:

- PhRMA's ClinicalStudyResults.org
- FDA's and NIH's ClinicalTrials.gov
- The IFPMA Portal
- CISCRP's SearchClinicalTrials.org
- WHO's Registry Platform Search Portal

Plus! Best Practices for Trial Registration and Results Posting, Including Insights on:

- Registering and posting Phase I data
- Third party audits
- Competitive intelligence
- Leading technologies

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Your organization may send 1 executive **FREE** for every 3 delegates registered. All registrations must be made at the same time to qualify.

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Your registration may be **transferred** to a member of your organization up to 24 hours in advance of the conference. **Cancellations** received in writing on or before April 16, 2007 will be refunded, less a $195 administrative charge. No refunds will be made after this date; however, the registration fee less the $195 administrative charge can be credited to another CBI conference if you register within 6 months from the date of this conference. In case of **conference cancellation**, CBI's liability is limited to refund of the conference registration fee only.
CBI reserves the right to alter this program without prior notice.
Please Note: Speakers and agenda are subject to change without notice.
In the event of a speaker cancellation, every effort to find a suitable replacement will be made. The opinions of the conference faculty do not necessarily reflect those of the companies they represent or The Center for Business Intelligence.

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- ◯ **Yes! Please register me for CBI's 2nd Premier Forum on Clinical Trial Registries and Results Databases**
- ◯ I am registering for the EARLY BIRD DISCOUNT ◯ I am registering for the ACADEMIC RATE
- ◯ We would like to take advantage of the TEAM DISCOUNT (see left for details).
- ◯ I cannot attend. Please send me a Conference CD-Rom Compendium.

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Payment Options: Payment in full is required to process registration. Please call with any payment questions.

- ◯ Enclosed is a check for payment in full (No personal checks accepted)
- ◯ MC/Visa: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐
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Please photocopy this form for additional delegates.

NAME (AS APPEARS ON CARD) _____ EXP. DATE _____

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