30 September 2010

Dear Colleague,

The regulatory framework for clinical trial transparency continues to evolve globally. The highly anticipated release of EudraCT Version 8 and the continued proliferation of national registries around the globe are expected to greatly impact processes in 2011 and beyond.

Those involved with clinical trial registration and results disclosure must utilise valuable opportunities to interact with likeminded professionals and develop best practices for a global compliance program. Such benchmarking and compliance best practices are paramount to ensuring compliance and developing efficient processes for results posting.

CBI's **3rd Annual Forum on Clinical Trial Registries and Results Databases** provides a timely opportunity to learn the latest regulatory updates, as well as a forum for discussion on how to seamlessly incorporate these ever-changing processes into practice.

This annual forum provides expert insight from **Abbott, Novo Nordisk, Johnson & Johnson, Novartis, GlaxoSmithKline, Ipsen** and **F. Hoffmann-La Roche Ltd.** Attendees at this important meeting hear from industry thought leaders about best practices for maintaining compliance when dealing with emerging global registries, as well as exploring the potential implications of reporting results of unapproved products. The forum also provides an opportunity to hear the perspective of a patient advocacy group. Additionally, hear practical approaches for ensuring publication deadlines are met and learn the impact results posting has on publication planning.

Please join this group of distinguished experts on 10 and 11 February 2011 in London, to discuss these important topics during CBI's annual event. It is an invaluable opportunity to network with your peers and learn more about practical procedures for managing clinical trial registries and results databases.

I look forward to seeing you in February!

Sincerely,

Jacqueline

Dr. Jacqueline Sayers,
Quality Projects Manager, Product Development Quality
Roche Products Ltd

PS. Don't miss the opportunity to learn about new registry initiatives around the world!

MAIN CONFERENCE

Day One — Thursday 10 February 2011

7:30 *Conference Registration and Continental Breakfast*

8:30 *Chairperson's Opening Remarks*

Jacqueline Sayers, Ph.D., Quality Projects Manager, Product Development Quality, **Roche Products Ltd**

Dr. Sayers completed a Sports Science Degree (BSc Hons), and then a Ph.D. in Physiology at the Royal London Hospital Medical College. She then began work in the pharmaceutical industry with ***ICI****. She has also worked for* ***Roche, ML Laboratories*** *and* ***BOC****. She has held various roles in clinical research, marketing, training, regulatory affairs, drug safety, computerized systems validation, GCP auditing and most recently in quality project management in the Roche Clinical QA Department. She has also completed a MBA and been accepted as a Chartered Quality Professional of the Institute of Quality Assurance and a Member of the Association of Project Management.*

Evaluate the European and United States Regulatory Landscape

8:45 **Prepare for the Highly Anticipated EudraCT Version 8 Updates**

As companies prepare for version 8 updates to the EudraCT database, they must be aware of the difficulties they may face when the new version is implemented. The updating of the EudraCT database requires companies to assess their current process and manage any difficulties resulting from the new database. This session addresses the latest trends and issues resulting from the EudraCT version 8 update.

- Review the latest initiatives and updates
- Understand the issues that have resulted from these updates
- Discuss experience with submitting data
- Anticipate the implications for 2011

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

9:30 **Implications of the Proposed EudraCT Version 9 Results Databases**

While presently the elements of the proposed EudraCT Results Database version 9 will likely not be implemented until the end of 2011 at the earliest, the elements were out for public comment during September 2010. The proposal of the EMA and the feedback on this proposal greatly impact the results posting process. This session addresses the future implications of the process and the differences from the process for ClinicalTrials.gov.

- Understand what the EMA is proposing to collect and make public
- Discuss the potential implications of the public results database
- Review any feedback from the public consultation on the results data elements
- Compare and contrast the proposed EudraCT results database to the ClinicalTrials.gov results database

Merete Jorgensen, MSc., MBA, Director, Global Clinical Registry, **Novo Nordisk A/S**

10:15 *Networking and Refreshment Break*

10:45 **Managing and Meeting ClinicalTrials.gov and Food and Drug Administration Amendments Act (FDAAA) Requirements**

Many companies do not understand, or do not have the resources to keep up with, the evolving FDAAA requirements. Best practices are emerging allowing companies to meet the requirements of FDAAA and ClinicalTrials.gov. This session discusses recent updates to ClinicalTrials.gov and offers an overview of the best of the best practices.

- Review changes to ClinicalTrials.gov in the past few months
- Discuss best practices for meeting FDAAA requirements within the growing challenge of global clinical trial disclosure
- Review potential impact on industry for proposed FDAAA expansion
- Participate in collaborative discussion with industry peers and colleagues

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

11:30 **Implications for Reporting the Study Results of Unapproved Products**

The global regulatory requirements for posting the study results of unapproved products has yet to be defined. EudraCT version 9 will require the reporting of study results, irrespective of a product's Marketing Authorisation status. The FDA Amendments Act of 2007, requires that regulations be issued by 27 September 2011 to address whether or not results for unapproved products need to be posted on ClinicalTrials.gov. An understanding of what these processes may entail and how they will affect your company's portfolio is now a crucial part of product development strategy. During this session, the following is addressed:

- What are the implications of reporting study results for unapproved products?
- What impact is this additional reporting likely to have on company processes?
- What are the evolving global regulatory initiatives?
- What might the unintended consequences of these initiatives be?

Malcolm Barratt-Johnson, Managing Director, **PharmaMedic Consultancy Ltd**

12:15 *Luncheon*

Transparency, Compliance and Communication Strategies for Clinical Trials

13:30 **International Federation of Pharmaceutical Manufacturers and Associations Priorities and Accomplishments in Supporting Transparency**

The International Federation of Pharmaceutical Manufacturers and Associations 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 organisations, national institutions, governments and non-governmental organisation 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 a set of voluntary principles to clarify 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 the implementations including which clinical trials should be published and/or disclosed
- Determine where the IFPMA will go from here

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

14:15 **Ensuring Compliance from Registration to Results**

In order to remain compliant, companies must continue to evaluate their processes and make necessary changes to meet global disclosure requirements. This case study illustrates how a company modifies internal policies and procedures to ensure alignment, consistency and transparency in disclosing information for industry-sponsored clinical trials.

Case Study

- Hear one company's approach to best practices for disclosure
- Learn the challenges of adapting requirements to ensure alignment, consistency and transparency in a global environment

Mary Alesci, Associate Director, Clinical Trial Registration & Results Disclosure, **Abbott Laboratories**

15:00 *Networking and Refreshment Break*

15:30 **Results Posting and the Effect on Publication Planning**

The requirement for posting results one year after study completion and 6 months for pediatric trials brings about new challenges for publications. The session addresses what impact this has on publishing results of clinical trials in medical journals.

- Understand how authors, publication managers, statisticians, medical writers and regulatory affairs professionals collaborate
- Analyse results posting on medical journals
- Discuss evolving regulatory initiatives
- Review the future implications

Susan Scott, Ph.D., CMPP, Director Publications and Communications, **Ipsen**

16:15 **Practical Approaches to Meeting Publication Deadlines in the Current Environment**

Working to good publications practices helps ensure transparency, accuracy and ownership of publications. However, these practices inevitably take time and impact on the development timeline of publications. In parallel with this, publications would ideally be out before results posting. Companies, therefore, face a huge challenge to ensure guidelines and good practices are followed, whilst meeting strict deadlines. This session reviews statistics around the industry to assess if companies are getting publications out prior to results posting, review appropriate metrics for assessing the efficiency of publication development and discuss practical measures to refine and streamline processes.

- Determine if publication deadlines are being achieved with metrics
- 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

Russell Traynor, Strategic Business Unit Head, **UBC-Envision Group;**
Executive Committee Member, **ISMPP**

17:00 *Close of Day One*

17:00-18:00
Networking, Wine & Cheese Reception
Join colleagues and friends in a relaxed setting.

Photo by: Photolink / Getty Images

Day Two — Friday 11 February 2011

8:00 *Continental Breakfast*

8:30 *Chairperson's Review of Day One*
Jacqueline Sayers, Ph.D., Quality Projects Manager, Product Development Quality, **Roche Products Ltd**

8:45 **Successful Implementation of Results Posting into Business**

As regulatory framework for clinical trial transparency continuously evolves throughout the world, companies face the challenge of how to integrate results disclosure into practice. This process can be time consuming, and therefore costly, so establishing the best practice for implementing results posting into their process is essential for a company's success. This case study provides an example of practical implementation and how it was achieved.

Case Study

- Discuss integration of results posting into the main stream business
- Hear best practices that need to be embraced from a case study
- Review challenges surrounding the disclosure arena and consider the changing nature of the requirements
- Understand the benefits of not considering results posting as a silo activity
- Determine risks of non-integration of disclosure into business

Tatjana Poplazarova, Head of Scientific and Public Disclosure, **GlaxoSmithKline Biologicals**

9:30 **Examine Available Information and Utilisation Strategies of Public Databases**

In recent years, there has been an explosion of pharmaceutical data freely available from the web. Companies have the opportunity to review what competitors are currently working on. This also presents challenges for information providers. This session explores the ways in which publicly available information can be used and by what groups and explores the relationship between publicly available information and proprietary information.

Case Studies

- Hear highlights of important public database resources
- Review the type of content that is available and of interest
- Hear examples of how publicly available information is being used and by which groups
- Discuss different ways the information could be used
- Determine the relationship between publicly available information and proprietary information
- Hear a case study — Putting data from ClinicalTrials.gov to use

David Owler, Data Architect, **IMS Health**

10:15 *Networking and Refreshment Break*

Patient Utilisation, Anticipated Registry Emergence and Associated Challenges

10:45 **Registries — Are They Serving Their Intended Purpose?**

PANEL

Clinical trial registries were originally developed with the purpose of providing information to the public. As new registries emerge and regulations increase, many sponsors question whether we have lost sight of the original intent of these registries and if the target has shifted. During this discussion the panel addresses the following questions:

- Who are the main customers of the current registries and results databases and do they differ from the original customer groups?
- What information does each of these groups need and are the needs in alignment?
- Consider whether the current registries and results databases are fit for purpose. If not, why not? What needs to be done to put it right and who needs to do it?

Moderator: Jacqueline Sayers, Ph.D., Quality Projects Manager, Product Development Quality, **Roche Products Ltd**
Panelists: Merete Jorgensen, MSc., MBA, Director, Public Access to Clinical Trials, **Novo Nordisk A/S**
Nikos Dedes, WorldCAB Coordinator, **ITPC (International Treatment Preparedness Coalition)**
Beat Widler, Global Head of Clinical Quality, **F. Hoffmann-La Roche Ltd.**
Detlef Niese, Head, Global Development External Affairs, **Novartis**

11:45 **The Importance of Registries — A Patient Advocacy Perspective**

As the call for transparency increases and sponsors spend more resources to meet the requirements of different registries, the question arises whether the targeted audience is utilising this information. During this session, hear the perspective of the patient advocate and learn if the efforts to increase transparency have been and continue to be successful.

- Discuss the transparency expectations of the EudraCT database
- Determine if postings are understood by the public
- Discuss if the information is sufficient and useful
- Review if patient needs are being met by the information disclosed

Nikos Dedes, WorldCAB Coordinator,
ITPC (International Treatment Preparedness Coalition)

12:30 *Luncheon*

13:45 **Examine Global Transparency Initiatives and Emerging Registries**

Countries and organisations around the world continue to develop new clinical trial registries and results databases. In order to ensure a company is compliant, it is necessary to know what new registries are going to be mandatory. Explore the status of these initiatives and understand their implications for sponsors.

- Examine specific countries' current transparency initiatives
- Analyse which registries are mandatory and which are voluntary
- Review future initiatives on the horizon
- Discuss the impact of these registries for sponsors

John McKenney, President, **SEC Associates**

14:30 **Coping with the Impact of Emerging Registries**

The increasing number of emerging registries requires companies to review their processes and determine how they can be updated to better manage impacts resulting from these new registries. This session discusses how companies can best mange as registries continue to emerge and reviews a real scenario of a company revising their standard operating procedures (SOPs) and implementing them into practice.

- Determine the impact multiple registries have on company processes
- Understand how companies are coping from a process perspective
- Case Study — Hear an example of how a company reviewed and revised their SOP and incorporated these new procedures into process

Rob Middel, Head of Operations, Quality Management Center of Excellence, **Johnson & Johnson Pharmaceuticals Research & Development**

15:15 *Close of Conference*

WHO SHOULD ATTEND:

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

- Regulatory Affairs
- Disclosure
- Quality Management
- Medical Affairs
- Policy
- Publication
- Clinical Trial Information
- Clinical Communications/Marketing
- Clinical Science
- Global Development
- Outcomes Research
- Project Management
- Scientific Communications
- Clinical Trial Registries
- Medical Information
- Clinical Research
- Medical Business Operations
- Clinical Trials
- Medical Writing
- Clinical Affairs
- Clinical Operations
- Business Development
- Information Management
- Transparency
- Strategic Operations/Planning
- World Wide Development

This conference will also interest contract research organisations and technology vendors and supporting registries and results.

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Clinical Trial Registries and Results Databases

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

10 and 11 FEBRUARY 2011 • ANDAZ LIVERPOOL STREET • LONDON, UK

Conference Highlights:

- Discuss if patient needs are being met by the information disclosed
- Learn if publication deadlines are being achieved with metrics
- Compare and contrast the propsed EudraCT results database to the ClinicalTrials.gov results database
- Understand the benefits of not considering results posting as a silo activity

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Cut-off date is 17 December 2010. Reservations made after the cut-off date or after group room block has been filled (whichever comes first) will be accepted on a space and rate availability basis. Rooms are limited so please book early. All travel arrangements are subject to availability.

- **Venue:**
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Clinical Trial Registries and Results Databases

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

10 and 11 FEBRUARY 2011 • ANDAZ LIVERPOOL STREET • LONDON, UK

Conference Chairperson:

Jacqueline Sayers, Ph.D.,
Quality Projects Manager,
Product Development Quality,
Roche Products Ltd

Unique Perspectives from:

- Abbott Laboratories
- F. Hoffmann-La Roche Ltd.
- GlaxoSmithKline Biologicals
- IMS Health
- Ipsen
- ITPC (International Treatment Preparedness Coalition)
- Johnson & Johnson Pharmaceuticals Research & Development
- Novartis
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- PharmaMedic Consultancy Ltd
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Program Highlights:

- Understand what the EMA is proposing to collect and make public
- Determine the implications of reporting study results for unapproved products and what the unintended consequences might be
- Learn about the challenges of adapting requirements to ensure alignment, consistency and transparency in a global environment
- Evaluate IFPMA implementations including which clinical trials should be published and/or disclosed
- Understand how authors, publication managers, statisticians, medical writers and regulatory affairs professionals collaborate to publish results
- Assess the relationship between publicly available information and proprietary information
- Discuss the integration of results posting into mainstream business
- Identify the primary customers of the current registries and results databases and if they differ from the original customer groups
- Review which emerging registries are mandatory and which are voluntary

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