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Clinical Trial Registries and Results Databases

Clinical Data Transparency and Disclosure Techniques for Compliance in an Evolving Regulatory Framework

3rd and 4th February, 2009 • Waldorf Hilton • London, UK

"Excellent overview of the factors that have led to recent legislation on disclosure of clinical trial results. A great mix of speakers and topics that provided up-to-date and relevant information that will help companies comply with these regulations."

— Previous Attendee, Harry J. Sacks, M.D., Vice President, Medical and Scientific Affairs, **Meda Pharmaceuticals**

Essential Perspectives Include:

JOURNAL EDITOR:

Ana Marusic, M.D., Ph.D., Co-Editor, ***Croatian Medical Journal;*** President, **Council of Science Editors**

NIH:

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

WHO:

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

CDISC:

Niels Both, CDISC Consultant, **S-Cubed;** Member, **CDISC e3c**

PATIENT:

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

photo by: Getty Images

Conference Chairperson

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

2009 Industry Perspectives

Gerard Lynch, Global Manager, AstraZeneca Clinical Trials Website, **AstraZeneca**

Merete Jørgensen, MSc, MBA, Director, Public Access to Clinical Trials, **Novo Nordisk A/S**

Detlef Niese, M.D., Ph.D., Head, External Affairs, Global Development, **Novartis Pharmaceuticals AG, Switzerland**

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

Catherine Papillon-Downey, Director, Clinical Trial Information Disclosure, International Clinical Development, **sanofi-aventis**

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

Organized By: The Center for Business Intelligence, Presenting Industry Opportunities & Solutions — A Subsidiary of ADVANSTAR COMMUNICATIONS

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"This meeting provides critical information for anyone involved in clinical trials disclosure." — *Previous Attendee, Allan Drew, Editorial Manager,* **Wolters Kluwer**

MAIN CONFERENCE

Day One — Tuesday, 3rd February 2009

7:30 *Conference Registration and Continental Breakfast Hosted by:* NNIT

8:30 *Chairperson's Opening Remarks*

Jacqueline Sayers, Ph.D., Head, Quality Projects, **Roche**

Dr. Sayers completed a Ph.D. in Physiology at the Royal London Hospital Medical College and then began work in the pharmaceutical industry with ***ICI****. In a varied career 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. During this time she has also completed a MBA and been accepted as a member of the Institute of Quality Assurance and the Association of Project Management. Dr. Sayers is also a fellow of the Royal Society of Medicine.*

OPENING ADDRESS

8:45 **Access and Transparency in Clinical Research — The Patient's Point of View**

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

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

KEYNOTE ADDRESS

9:30 **Transparency and Clinical Trials — Are We Setting the Right Priorities?**

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 a brief history of 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 of Clinical Quality,
F. Hoffmann-La Roche Ltd.

Dr. Widler joined Hoffmann-La Roche in 1986 as an International Drug Regulatory Affairs officer. Three years later he moved into the International Clinical Research department where he assumed the position of a Senior Research Scientist participating in the planning and conduct of a major international drug development program. During this time, he also acted as a coordinator for the review of clinical safety data. In 1993 he joined the International Clinical Quality Assurance department where he was primarily responsible for clinical trial centres and adverse event reporting system audits. In November 1994, Dr. Widler became Head of the CQA group in Basel, responsible for 5 international clinical auditors located in Switzerland, and in January 1997 he was promoted to Head of the CQA group Europe.
In September 1997, Dr. Widler was appointed International Head of Clinical Quality Assurance. Since 2002 he has been the Head of the Department for Quality, Ethics and Systems in Roche Pharma Development. In addition to his functional responsibilities, he was nominated head of the Welwyn Garden City (UK) Development site in September 2002, giving leadership to a group of about 600 development professionals.

10:30 *Networking Refreshment Break*

International Regulations and Standards Governing Clinical Trial Registries and Results Databases

11:00 **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 for companies that conduct clinical trials. Global harmonization of transparency requirements is no closer now than it was in 2005.
If anything, nationalistic demands for unique clinical trial websites/databases are increasing. This session examines international public disclosure requirements, explains similarities and differences and offers ideas on how to approach the challenges of compliance with international clinical trial transparency requirements as well as challenges to ensure consistency of clinical trial information being provided in the public domain.

- Identify countries that currently have requirements for clinical trial registration or posting results
- Analyze the approach used by mid-sized pharma companies to ensure consistent clinical trial information is being provided across various public venues
- Elevate the impact of transparency on existing procedures

Robert Paarlberg, MS., Director, Global Regulatory Policy and Intelligence,
UCB, Inc.
Catherine Papillon-Downey, Director, Clinical Trial Information Disclosure, International Clinical Development, **sanofi-aventis**
John McKenney, President, **SEC Associates, Inc.**

12:30 *Luncheon*

13:45 **Management and Governance of Clinical Trial Registries Globally**

Regulations and standards for clinical trial registration and results databases are developing rapidly in Europe, the United States and globally. At the same time there are a growing number and types of registries. This proliferation of regulation and guidance, alongside the growth of registries and results databases challenge companies in their attempts to conduct high quality clinical trials internationally. While transparency remains a generally recognized and agreed objective, the way to achieve such transparency is fraught with confusion and hurdles. Global harmonization of requirements, while generally thought to be needed, has not occurred. This session reviews the varying international requirements and explains how a sponsor might best approach the challenges of compliance among a variety of national and global clinical trial transparency requirements.

- Examine the current international landscape for clinical trial registries and results databases
- Suggestions on how to manage varying international requirements for global and regional sponsors

Francis P. Crawley, Executive Director, **European Forum for Good Clinical Practice;** *Member of the former Scientific Advisory Group, International Clinical Trials Registry Platform, (ICTRP),* **World Health Organization**

14:30 **Trial Disclosure Requirements for Pediatric Studies in Europe and Beyond**

- Analyze and interpret the EudraCT extension
- Identify requirements for European and global studies
- Understand the impact on clinical trial registries and results disclosure
- Review the broad scope of the pediatric extension beginning with Phase I

Detlef Niese, M.D., Ph.D., Head, External Affairs, Global Development, **Novartis Pharmaceuticals AG, Switzerland**

15:15 **ClinicalTrials.gov — NIH Update and In-Depth Discussion with the Chief Architect**

ClinicalTrials.gov contains nearly 50,000 trials sponsored by the National Institutes of Health, other U.S. agencies and private industry (clinicaltrials.gov). Because of evolving regulatory guidelines, clinical trial protocol posting requirements can appear very complex. The audience has the opportunity to interact with and ask questions directly to the Chief Architect of ClinicalTrials.gov.

NIH Perspective

- Understand the impact of FDAAA
- Discuss FDAAA's requirement for an estimated date of study completion
- Understand NIH strategy in relation to CDISC

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

16:15 *Networking and Refreshment Break*

16:45 **Understand How CDISC and HL7 are Collaborating with Industry and Other Stakeholders to Develop Common Standards for Clinical Trial Registries and Results Databases**

As various registries continue to emerge, the need for industry standards becomes increasingly important. CDISC and HL7 have already had a major impact on clinical data management and current initiatives should prove beneficial for posting trial protocols and study results. Hear directly from a member of the CDISC e3c as he discusses how standards can be applied to transparency in clinical trials.

CDISC Address

- Introduction to the CDISC organization
- Short overview of the CDISC Standards Landscape
  - * electronic protocol representation
  - * Trial Design representation model
  - * ADaM, the statistical data and results model
- Understand how the models above have been and can be utilised to transfer information regarding clinical trials and clinical protocols and the results of clinical trials
- Discuss the future impact of CDISC and HL7 on clinical study transparency

Niels Both, CDISC Consultant, **S-Cubed;** *Member,* **CDISC e3c**

17:30 *Close of Day One*

17:30-18:30 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

photo by: Photolink / Getty Images

Day Two — Wednesday, 4th February 2009

8:00 *Continental Breakfast Hosted by:* NNIT

8:30 *Chairperson's Review of Day One*
Jacqueline Sayers, Quality Projects Manager, **Roche**

Best Practices for Posting and Publishing Clinical Study Results

8:45 **Understand the Impact of the Evolving Requirements for Posting Clinical Study Results**

From the World Health Organization (WHO) to the International Committee of Medical Journal Editors (ICMJE) to the Maine legislative requirements to the Food and Drug Administration Amendments Act (FDAAA) to specific non-U.S. country regulations, the requirements to post clinical trial results data are diverse as are the potential ramifications from this diversity.