CBI's 2nd Forum on

REGISTER BY 26 MARCH 2010 AND RECEIVE £200 OFF OF YOUR REGISTRATION FEE!

Clinical Trial Registries and Results Databases

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

1-2 June 2010 • Le Meridien Piccadilly • London, UK

"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**

Featuring Presentations and Case Studies Exploring

- Eudrapharma, ClinicalTrials.gov and ClinicalStudyResults.org
- Anticipated changes from EudraCT Versions 8 and 9
- Strategies for adverse event disclosure
- National requirements for clinical data disclosure
- International harmonization efforts
- Managing patient inquiries
- The IRB perspective on clinical data disclosure
- Policies and processes for clinical data disclosure

Conference Chairperson

Diane Fuell, M.D., Vice President, Clinical Submissions, Policies and Standards, **GlaxoSmithKline UK**

Elite Speakers

Tomáš Boráň, M.D., Clinical Trial Unit, **State Institute for Drug Control, Czech Republic**

Francis P. Crawley, Executive Director, **Good Clinical Practice Alliance – Europe,**

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

Gabriele Dreier, M.D., German WHO-Primary Registry DRKS, Head of Clinical Trial Registries, **ZKS – Clinical Trials Center, University Medical Center Freiburg**

Trish Groves, M.D., Deputy Editor, ***British Medical Journal***

Nicholas Ide, Chief Architect, ClinicalTrials.gov, **National Institutes of Health** *(via telecommunications resource)*

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

Pierre-Yves Lastic, Ph.D., Senior Director, Data Privacy and Healthcare Interoperability Standards, **sanofi-aventis R&D**

Karine Le Malicot, Biostatistician, Global Biometrics, **Fournier Pharma, Member of Solvay Group**

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

John McKenney, President, **SEC Associates**

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

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

photo by: Getty Images

Organized By:

The Center for Business Intelligence — Presenting Industry Opportunities & Solutions — A Subsidiary of Advanstar Communications

Lead Media Partner:

Applied Clinical Trials

Outstanding Support Provided by:

Pharma Voice · Clinical Trials

"This conference addressed the very latest information on requirements and challenges from knowledgeable speakers."

— 2009 Attendee, Gerard Lynch, Global Manager, AstraZeneca Clinical Trials Website, **AstraZeneca**

MAIN CONFERENCE

Day One — Tuesday 1 June 2010

7:30 *Conference Registration and Continental Breakfast*

8:30 *Chairperson's Opening Remarks*

Diane Fuell, M.D., Vice President, Clinical Submissions, Policies and Standards, **GlaxoSmithKline UK**

Dr. Fuell is currently Vice President, Clinical Submissions Policies and Standards at GlaxoSmithKline (GSK) in which capacity she is responsible for Medical Writing and the publishing of documents and support material for submission to regulatory authorities; disclosure of protocols and clinical study results on appropriate databases and registers; and writing and governance of cross functional process documents. She has worked for GSK for twenty-five years, most of this time as a Clinical Scientist in Neurosciences (depression, anxiety and Parkinson's disease) and Metabolism (type 2 diabetes) at company locations in the UK, Belgium and the U.S. Prior to that, Dr. Fuell spent sixteen years as a Hospital Pharmacist, which included work in clinical pharmacy and drug information.

Regulations and Standards Governing Clinical Trial Registries and Results Databases

8:45 **Identify and Discuss Emerging EMEA and EudraCT Requirements**

The last few years have brought about significant changes to the disclosure of clinical trial information. Fraught with the challenge of publicizing sensitive information, those responsible for clinical trial registries and results databases have been forced to juggle a myriad of evolving requirements. During this session, the speakers explore the most challenging EMEA and EudraCT requirements and offer suggestions for remaining compliant.

- Identify and discuss the three Eudra systems related to clinical trials
- Understand the implications of changes to EudraCT and the implementation of the paediatric regulation
- Anticipate the impact of EudraCT Versions 8 and 9
- Discuss early experience of submitting data to EudraCT/Eudrapharm and ensuring consistency with FDA
- Review early experience with EudraCT Version 8 and the new process of submitting paediatric studies via the EMA (dependent on the release date of Version 8)
- Review the most recent efforts of the EudraCT Joint Operations Group

Merete Jorgensen, 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**

10:15 *Networking, Refreshment Break*

10:45 **Analyse the Efforts of the HL7 Clinical Trials Registries and Results Project**

The HL7 Clinical Trials Registries & Results (CTR&R) project was launched in order to "feed" the various registries and results databases using a standard structured message. The outcome of this project should allow clinical trial sponsors to save a great deal of resources and should also help harmonize worldwide regulatory requirements. During this session, a member of the Leadership Team discusses the status of the project to-date.

Pierre-Yves Lastic, Ph.D., Senior Director, Data Privacy and Healthcare Interoperability Standards, **sanofi-aventis R&D**

Explore the Roles and Responsibilities of Key Stakeholders to Ensure Compliance and Transparency when Disclosing Clinical Trial Information

11:30 **Publication Planning and Results Disclosure**

Submitting manuscripts for publication is a key component of the clinical disclosure process. However, understanding the necessary components of a manuscript is a complex task. As a result, journal editors are an essential resource for all clinical trial registries and results stakeholders. During this session, the Deputy Editor of the *British Medical Journal* discusses ICMJE requirements and what an editor is looking for in a manuscript submitted for publication.

- Review a brief history of the journal editor's involvement in clinical data disclosure
- Understand what is considered pre-publication of results
- Discuss evolving legislative requirements
- Analyse the impact results posting could have on medical journals

Trish Groves, M.D., Deputy Editor, **British Medical Journal**

12:15 *Luncheon*

13:30 **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
- The role and expectations of ECs/IRBs with regard to transparency in clinical research
- Experiences in Europe and the U.S. regarding relations between clinical trial databases, researchers and regulatory authorities
- 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)**

14:15 **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 federal 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.

- Status update on FDAAA implementation at ClinicalTrials.gov
- Implementation of the Adverse Event module in ClinicalTrials.gov

Nicholas Ide, Chief Architect, ClinicalTrials.gov, **National Institutes of Health** *(via telecommunications resource)*

15:00 *Networking, Refreshment Break*

15:30 **Implement a Simple Process to Manage a Global Disclosure Operation**

The myriad of clinical trial registration and results disclosure requirements have created a great deal of ambiguity for sponsors striving to remain compliant on a global scale. If not managed correctly, the extensive nature of these requirements can lead to internal disconnect and an inability to adhere to the evolving regulatory framework. In order to overcome these challenges, a simple and clear internal process for disclosure must be created. During this session, the speaker reviews AstraZeneca's process and explains how it was created.

- Understand how EU regulations have impacted existing processes for handling FDA regulations
- Review early experiences with submitting data to EudraCT/Eudrapharma and ensuring consistency with FDA
- Develop an internal policy that promotes global compliance
- Discuss the role technology has played in clinical data disclosure at AstraZeneca

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

16:15 **Clinical Data Disclosure at Solvay Pharmaceuticals**

In order to meet the evolving demands for clinical data disclosure, Solvay Pharmaceuticals implemented a project called "Clinical Trial Information." During this session, the project leader discusses her experience to-date and offers suggestions to others responsible for protocol posting and results disclosure

- Organize/train staff members to enable a global compliance program
- Utilise biostatistics expertise to post study results
- Future perspective of study results analyses
- Explore the challenges of working with FDA, Maine and ClinicalTrials.gov

Karine Le Malicot, Biostatistician, Global Biometrics, **Fournier Pharma, Member of Solvay Group**

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 — Wednesday 2 June 2010

8:00 *Continental Breakfast*

8:30 *Chairperson's Review of Day One*
Diane Fuell, M.D., Vice President, Clinical Submissions, Policies and Standards, **GlaxoSmithKline UK**

Country Specific Requirements for Clinical Data Disclosure

8:45 **Building a Global Compliance Program — Surveying Transparency Requirements in Key Countries and Linking it All Together**

There are already many national clinical trial registries in existence, but 2010 is going to see the launch of several more. Harmonization of trial registration requirements is an important and much-desired goal, but success in that endeavor is still a long way off. In order to achieve compliance with emerging and evolving transparency requirements around the world, one must know what the rules are. This session focuses on several key clinical trial markets, providing essential information about their public disclosure requirements.

- Identify the similarities and differences between disclosure requirements for Eudrapharm and ClinicalTrials.gov
  - * what elements are required by both databases?
  - * what elements are different?
  - * how do you reconcile differences and minimize risk for inconsistencies?
- Develop internal workflows, processes and tools to ensure compliance with Eudrapharm, ClinicalTrials.gov as well as local/regional registries
- Review the sanofi-aventis approach for global compliance

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

9:30 **Analyse the Unique Requirements of the German Clinical Trial Register**

In order to provide a central portal for information on clinical research in Germany and to facilitate the search of planned, ongoing and completed clinical trials, the German Clinical Trials Register (GermanCTR) was implemented in cooperation with the WHO's registries network. It is an open access online register of clinical trials conducted in Germany, which allows all users to search for, register and share information on clinical trials. The project is funded by the Federal Ministry of Education and Research and is implemented at the Institute for Medical Biometry and Medical Informatics of the University Medical Center Freiburg as a joint project of the Clinical Trials Center Freiburg and the German Cochrane Center. Since October 2008, the GermanCTR is an approved WHO Primary Registry and allows clinical trial registration in Germany according to the requirements of the International Committee of Medical Journal Editors (ICMJE). During this session, the speaker explores the unique characteristics of the GermanCTR and fields questions from the audience.

- Discuss specific details on the GermanCTR
- Understand the role of country-specific registries and how they will work with the EudraCT publication
- What harmonisation efforts are being made among country specific registries to avoid redundant work?

Gabriele Dreier, M.D., German WHO-Primary Registry DRKS, Head of Clinical Trial Registries, ZKS — Clinical Trials Center, **University Medical Center Freiburg**

10:15 *Networking and Refreshment Break*

10:45 **Clinical Trial Disclosure Developments in Latin America**

Case Study

Over the past decade, Latin America has become an increasingly popular region for conducting clinical trials. In order to promote greater transparency in clinical trials, several Latin American countries have taken steps to establish clinical trial registries and results databases. Although most are in various stages of drafting and implementing laws and regulations, at least one Latin American country currently has an online public registry. This session reviews regional and national efforts for public registry requirements and databases in Latin America.

- Explore regional efforts promoting clinical trial registration in Latin America
- Review current and future transparency initiatives in selected countries
- Identify potential challenges that could be encountered when registering trials in Latin America

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

11:15 **Explore the Requirements of the SUKL Clinical Trial Registry**

Case Study

The Czech Republic launched their clinical trial registry on January 1, 2008. Designed to provide patients with access to clinical trial information, the public can search for indications, study sites, age groups of patients, etc. During this session, a representative from the Czech registry explores the registration process, reviews the landscape of clinical research in the Czech Republic and explains what is and isn't posted on the registry.

- Identify and discuss the public and secure sections of the Czech database for clinical trials
- Obtain tips for working with the Czech database

Tomáš Boráň, M.D., Clinical Trial Unit, **State Institute for Drug Control, Czech Republic**

12:00 *Luncheon*

13:00 **Identify and Discuss the Myriad of Country-Specific Registry and Result Posting Requirements**

PANEL

New global regulations and standards for clinical trial registration and results databases are forcing companies that conduct clinical trials internationally to re-evaluate their approach to global clinical trial transparency. Global harmonisation of requirements has not occurred. In addition, specific clinical trial websites/databases for particular regions of the world are now common. During this session, the panelists review the varying international requirements and explain how a company can approach the challenges of compliance with global clinical trial transparency requirements.

- Identify the countries with the most complicated requirements for posting clinical trial information
- Suggestions on how to manage varying international requirements at a global company
- Discuss the potential for harmonisation between EU member states and FDA

Moderator: Diane Fuell, M.D., Vice President, Clinical Submissions, Policies and Standards, **GlaxoSmithKline UK**

Panelists: Tomáš Boráň, M.D., Clinical Trial Unit, **State Institute for Drug Control, Czech Republic**
Gabriele Dreier, M.D., German WHO-Primary Registry DRKS, Head of Clinical Trial Registries, **ZKS – Clinical Trials Center, University Medical Center Freiburg**
John C. McKenney, President, **SEC Associates, Inc.**

13:45 **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 a brief history of transparency in clinical research and analyses 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 optimise 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.

14:30 *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:

Clinical Trial Registry/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 results databases.

Welcome Interested Sponsors:

CBI Research, Inc.'s corporate sponsors represent select companies that share a common mission: business advancement through thought leadership, strategic interaction and innovation. Companies that sponsor with CBI carefully select messaging, branding or positioning sponsorships which result in the successful communication of their quality products and/or services available to the conference's targeted attendees. Opportunities ranging from strategic Co-Sponsor positioning, to the simple power of a single Exhibit are available.

If you are interested in sponsorship or exhibit opportunities, please call Stuart Steller at 00+1-339-298-2111, fax 00+1-781-939-2458 or email stuart.steller@cbinet.com





Join us in Arlington, VA for our U.S. Forum

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.**

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**

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

REGISTER BY 26 MARCH 2010 AND RECEIVE £200 OFF OF YOUR REGISTRATION FEE!

CBI's 2nd Forum on

Clinical Trial Registries and Results Databases

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

1-2 June 2010 • Le Meridien Piccadilly • London, UK

TOP REASONS TO ATTEND:

- Prepare for the release of EudraCT Versions 8 and 9
- Explore the requirements of the major national registries
- 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

CD-Rom Compendiums

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 £98 (+VAT UK @ 17.5%) 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:**

Advantage Pricing	£1250 **(+VAT UK @ 17.5%)**
Early Bird Rate	£1050 **(+VAT UK @ 17.5%)**

Advantage Pricing Discount — Register by 26th March 2010 and SAVE £200.
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.

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

- **Discount Accommodations & Travel:**
To receive CBI's special discounted hotel rate on line or by phone, go to:
— *On line:* www.cbinet.com/clinicaltrialregistries
— *Phone reservations:* +44 207 734 8000 and mention CBI's Clinical Trial Registries.

Cut-off date is Monday, 17th May. 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 subject to availability.

- **Venue:**
Le Meridien Piccadilly
21 Piccadilly
London, UK W1J OBH
Hotel reservations: 44 207 734 8000

- **Substitution & Cancellation:**
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 Tuesday, 18th May 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 30 days 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.

- **Satisfaction Guaranteed:**
CBI stands behind the quality of its conferences. If you are not satisfied with the quality of the conference, a credit will be awarded towards a comparable CBI conference of your choice. Please contact 800-817-8601 for further information. Advanced preparation for CBI conferences is not required.

CBI
600 Unicorn Park Drive • Woburn, MA 01801 • USA

TO REGISTER
CALL Roberts Apse 00+1-339-298-2290
OR EMAIL roberts.apse@cbinet.com

Registration Card

DO NOT REMOVE MAILING LABEL. PLEASE RETURN ENTIRE FORM. **PC10007**

◯ **Yes! Please register me for CBI's 2nd Forum on Clinical Trial Registries and Results Databases.**

◯ I am registering for ADVANTAGE PRICING ◯ 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.

Do you have any special needs?_____

KEY CODE (appears above mailing address): _____

Register 3 Get 1 FREE

1. NAME _____ POSITION _____
2. NAME _____ POSITION _____
3. NAME _____ POSITION _____ FREE
4. NAME _____ POSITION _____

COMPANY _____ DIVISION _____

ADDRESS _____

CITY _____ STATE/COUNTRY _____ ZIP/POSTAL CODE _____

TELEPHONE _____ FAX _____ E-MAIL _____

AUTHORIZED SIGNATURE _____

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: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

◯ Amex: ☐☐☐☐ ☐☐☐☐☐☐ ☐☐☐☐☐

Please photocopy this form for additional delegates.

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

CARDHOLDER SIGNATURE _____