Discover the latest regulatory and international developments at SMi’s...

Conducting Clinical Trials in Europe

25th & 26th October 2006, Crowne Plaza Hotel - The City, London

Hear cutting edge contributions from senior industry practitioners, including:

- Dr Brian O’Neill, Global Head, CQA Management External Alliances, F. Hoffmann-La Roche
- Professor Heinrich Klech, Senior Medical Director, Eli Lilly
- Dr Hartwig Gajek, Medical Director, Baxter Europe
- Dr Agnieszka Zareba, Regional Director, Clinical Research & Development, Wyeth
- Pierre Mermet-Bouvier, Director, Wyeth Research
- Dr Michael Herschel, Director, Clinical Research, GlaxoSmithKline
- Dr Gerhard Fortwengel, Director & Head, Quality Systems, Actelion Pharmaceuticals
- Dr Ian Thomson, Medical Quality Assurance Advisor, Eli Lilly
- Dr Richard Sullivan, Director, Clinical & Translational Directorate, Cancer Research UK
- Dr Milen Vrabevski, Chief Executive Officer, Comac Medical

Key issues to be addressed at the conference include:

- EU CLINICAL TRIAL DIRECTIVE TWO YEARS ON: See what has changed from early implementation of the directive and its affect on academics and the pharmaceutical industry
- QUALITY ASSURANCE: Learn from key industry experts what it takes to prepare, host and survive regulatory inspections
- HAS EUROPE BECOME A BETTER PLACE FOR TRIALS? Hear lessons learned and practical solutions to overcome the financial concerns that companies deal with when conducting clinical trials
- CLINICAL TRIAL SUPPLY: Discover its implications for conducting studies in EU member states and how this is affecting major pharmaceutical companies whilst learning how to ensure maximum participation in trials
- EUROPEAN PERSPECTIVES: Listen as leading experts discuss the impact of the directive from various European countries including Germany, France, UK and Central Europe
- NETWORKING OPPORTUNITIES: Collaborate with industry peers in an environment promoting information exchange

PLUS AN ASSOCIATED HALF-DAY POST-CONFERENCE EXECUTIVE BRIEFING

Good Clinical Practice - An Overview of Regulations and Principles

27th October 2006, Crowne Plaza Hotel - The City, London

In association with: Clinrex

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GROUP DISCOUNTS AVAILABLE
is an independently owned and managed Phase I-IIa CRO. Our 40-bed unit is staffed by highly experienced personnel.

1.50 EFFECTS OF THE DIRECTIVE ON PUBLICLY FUNDED TRIALS
- Complying with new regulations
- Taking advantage of the requirements that simplify the initiation and conduct of trials
- What influence do clinical researchers hold? Can they sway the decision-making process?
- Unnecessary delays or stoppages when conducting trials
- Inadequate financial support for academic groups
- Clarifying the precise requirements of the legislation for sponsors and investigators conducting non-commercial trials

Dr Richard Sullivan, Director, Clinical & Translational Directorate. Cancer Research UK

PANEL DISCUSSION

2.30 Survival of the fittest - how are regulations affecting the industry?
- How can we achieve harmonisation across member states?
- Does Europe still suffer from a lack of uniformity?
- Are there too many differences?

Participants:
- Professor Heinrich Klech, Senior Medical Director, Eli Lilly
- Dr Michael Herschel, Director, Clinical Research, GlaxoSmithKline
- Pierre Mermet-Bouvier, Director, Wyeth Research
- Dr Ian Thomson, Medical Quality Assurance Advisor, Eli Lilly

3.10 Afternoon Tea

EUROPEAN PERSPECTIVES

3.40 IMPLEMENTATION OF THE DIRECTIVE
- The UK perspective
- Significant variations in reporting procedures
- The main benefits and disadvantages of the Directive
- Good Clinical Practice (GMP) guidelines
- Good Manufacturing Practice (GMP) standards for medicines used in trials
- The responsibility of sponsors
- Regulatory guidelines
- Impact of the directive on members of the public

Dr John Bolodeoku, Senior Director, Medical Affairs & Health Economics Europe, Astellas Pharma Europe

4.20 IMPLEMENTING THE EU CLINICAL TRIALS DIRECTIVE IN GERMANY
- A focus on Investigator Initiated Trials (IITs)
- Highlights and lowlights of the German drug law after the transposition of the Directive
- Impact of the new law on IITs
- Where are the simplifications?
- GCP in IITs
- How much support can a pharmaceutical company provide for an IIT without becoming the sponsor?

Dr Dagmar Chase, Managing Director, Clinrex

5.00 Chairman’s Closing Remarks and Close of Day One

Bio-Kinetic Europe is an independently owned and managed Phase I-IIa CRO. Our 40-bed unit is staffed by highly experienced personnel with an unrivalled track record for delivering high quality studies. With over thirty years combined experience in over 200 clinical trials, across a full range of study designs and therapeutic areas, our reputation is our key company asset and our client base has been carefully built by personal attention to detail and a relationship-focused approach. We pride ourselves on our ability to build long-term sustainable relationships with our clients by providing a superior, flexible service virtually unknown in the industry. For more information please visit www.biokineticeurope.com

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9.00 Chairman’s Opening Remarks
Pierre Mermet-Bouvier, Director, Wyeth Research

9.50 IMPACT OF THE DIRECTIVE ON EASTERN EUROPE
- An attractive location for trials?
- Cost issues - can it lead to the loss of commercial research to Eastern Europe?
- What does the directive mean for Eastern Europe?
- Understanding the various local governments and communities
- The impact of EU regulations on clinical trials in Eastern Europe
- Encouraging the co-operation of EU member states

Dr Agnieszka Zareba, Regional Director, Clinical Research & Development, Wyeth

10.30 Morning Coffee

11.00 GUARANTEES FOR QUALITY
- Clinical Trial Management (CTM)
- Clinical Research (CR)
- Experiences from candidates - Romania, Macedonia & Bulgaria

Dr Milen Vrabevski, Chief Executive Officer, Comac Medical

11.40 HAS EUROPE BECOME A BETTER PLACE FOR CLINICAL TRIALS?
- Key issues and problems
- Concerns over the Directive
- Practical solutions to meet the challenges of working to the Directive
- Lessons learned from FDA inspections
- Investment in clinical trials in Europe and the world

Dr Jean-Pierre Tassignon, Chairman, European Forum for Good Clinical Practice (EFGCP) & Executive Vice President, PSI Pharma Support International

12.20 Networking Lunch

NEW REGULATORY SYSTEMS (EXPERIENCES SHARED AND LEARNED)
Case Study - an example from Bio-Kinetic Europe
- The MHRA and CTA applications
- COREC the new ethics committee systems:
- Regulatory approvals within the NHS trusts
- Input from the CRSC

Dr David Bell, Medical Director, Bio-Kinetic Europe

CLINICAL TRIAL SUPPLY
A new dimension to clinical trials that is creating waves in the industry
- Overview of relevant European regulatory framework and its implications for conducting clinical studies in EU member states
- Managing the movement, control, and release of investigational medicinal product (IMP) into and within Europe
- Role of the QP(s) and the importance of formalised agreements related to breakdown of responsibilities between centralised QP, national QPs, heads of local QA and responsible persons, and between sponsor and third party contractors acting on their behalf
- Identifying and agreeing responsibilities at the GCP-GMP interface

Dr Brian O’Neill, Global Head, CQA Management External Alliances, F. Hoffmann-La Roche

3.10 Afternoon Tea

MAXIMISING TRIAL PARTICIPATION

PATIENT RECRUITMENT
- Ensuring maximum participation
- Always an issue?
- What is the real cost of resources and services?
- Differentiating treatment costs
- Ensuring that decision makers are consulted early in the costing and resource process

Dr Hartwig Gajek, Medical Director, Baxter Europe

4.20 Focusing on patients
- Involving patients upfront
- Learning how they think
- Patients and investigators - contrasting views on recruitment
- Putting an effective programme into place

Richard Anderson, Chief Executive Officer, De Facto Communications

5.00 Chairman’s Closing Remarks and Close of Conference
About the SMi Pharmaceutical Team

SMi have been involved in the Pharmaceutical industry since 1993 and have developed a series of informative and niche events, covering the latest issues and developments surrounding the industry.

Events bring together senior industry professionals and serving companies who have a focus on being at the forefront of developments in this area. SMi aim to generate informed and topical discussion through the medium of both Conferences and Executive Briefings.

Our Pharmaceutical events are research-based and content driven with regular contact with major industry personnel and cover a wide range of industry sectors. For more information please visit www.smi-online.co.uk/pharma.asp

Pharmaceutical Forward Planner

JUNE 2006
26/27 Clinical Trials in Cancer
28/29 Depression & Anxiety

SEPTEMBER 2006
20/21 Pharmaceutical Stability Testing
20/21 Drug Delivery Global Summit

OCTOBER 2006
02/03 Metabolic Diseases Forum - A Focus on Diabetes, Obesity & Related Disorders
04/05 European Pharmaceutical Wholesale & Distribution 2006
23/24 Medical Devices - Regulation, Clinical Evaluation & Post-Market Surveillance
25/26 Conducting Clinical Trials in Europe
30/31 Nutraceuticals & Functional Foods 2006

NOVEMBER 2006
01/02 HIV & AIDS - Novel Therapeutics & Strategies to Beat the Pandemic
01/02 European Pharmaceutical Pricing & Reimbursement
13/14 Clinical Trials in CNS
20/21 Advances in Anti-Inflammatory Therapeutics
29/30 Outsourcing for Clinical Trials
Good Clinical Practice - An Overview of Regulations and Principles

27th October 2006, Crowne Plaza Hotel - The City, London

In association with:

About the Executive Briefing:
The successful implementation of the GCP standards is crucial for all companies and professionals involved in clinical trials. This briefing will provide you with the latest requirements in Good Clinical Practice implementation with a special focus on the most recent developments in the EU. Emphasis is given to the exchange of experiences and discussions and a comparison of EU requirements with ICH-GCP and FDA regulations will complete the picture of this Executive Briefing on GCP.

8.30 Registration & Coffee

9.00 Regulatory requirements in the field of clinical trials
   - Declaration of Helsinki
   - ICH - GCP (CPMP/ICH/135/95)
   - EU Clinical Trials Directive (2001/20/EC)
   - EU GCP Directive (2005/28/EC)
   - Guidance documents (ENTR CT1 - 5)
   - How does it all tie together? What are the differences and where are the overlaps?

9.45 Principles of GCP
   - ICH-GCP
   - EU GCP Directive

10.30 Morning Coffee

10.45 Overview of GCP obligations for:
   - Ethics Committees (IRB/IEC)
   - Investigators
   - Sponsors
   - Sponsor-Investigators

11.30 FDA requirements
   - Are there any peculiarities to watch out for if my EU trial is planned to be part of a FDA NDA?

12.15 Discussion and questions - review of the session

12.30 Close of Executive Briefing

About your Briefing Leader:
Dr Dagmar Chase graduated in Computer Science with a secondary focus on Theoretical Medicine at the Technical University in Munich and has a PhD in Human Biology from the Medical Faculty of the University in Ulm, Germany. Dr Chase co-founded gmi, a full service CRO for clinical trials phases II - IV, in 1983. In parallel, Dr Chase concentrated on the development of training programmes for the pharmaceutical industry covering the full spectrum from planning a clinical trial to writing the clinical study report. In order to be able to offer international services to gmi’s clients, she was instrumental in the merger of gmi with the US-based CRO Kendle International Inc in 1997, holding the position of Vice President until the beginning of 2004.

In March 2004, Dr Chase started up Clinrex, a consultancy firm for clinical research. Besides providing training, she focuses on global project management, for example, advising non-EU companies, which need support in the conduct of clinical trials in Europe.
CONDUCTING CLINICAL TRIALS IN EUROPE  
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