

IBC's 4th International Conference on

Clinical Trials in Central and Eastern Europe

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21 & 22 October 2003

Renaissance Penta Hotel, Vienna, Austria

In-depth Analysis of the Latest Developments in Clinical Trials in Central and Eastern Europe

Programme highlights include:

- ▶ Update on European Clinical Trials Directive and ICH GCP
- ▶ The Future of Clinical Trials in Central and Eastern Europe
- ▶ A Project Manager's View of Improving Quality of Conduct of Clinical Trials in Central and Eastern Europe
- ▶ Globalisation of Clinical Trials: Acceptance of Central and Eastern European Trials by the FDA
- ▶ Using CROs: Global or Local?
- ▶ The Role and Management of Site Management Organisation in Central and Eastern Europe
- ▶ Patient Recruitment in Clinical Trials
- ▶ Country Updates on Clinical Trial Regulations and Compliance: Theory and Practice
 - Hungary • Poland • Russia • Ukraine
 - Slovakia • Bulgaria • Baltics • Serbia and Montenegro

Co-located Event

Parallel Trade, Patents and Generics in Central and Eastern Europe

23 & 24 October 2003, Renaissance Penta Hotel, Vienna, Austria
See inside for further details

Chair:

Dr Jean Pierre Tassignon, PSI Pharma Support International, Belgium

Learn from the Experiences of our Expert Panel of Speakers:

An J Baeyens, European Commission, Belgium

Dr Mikhail Samsonov, Bristol-Myers Squibb, Belgium

Dr Davorka Tomic-Wallis, Procter and Gamble Pharmaceuticals, UK

Dr B Lillian Natorff, Independent Consultant in Pharmaceutical Medicine, UK

Prof. Dr. János Borvendég, National Institute of Pharmacy, Hungary

Michal Pirozynski, Office of Medicinal Products, Medicinal Devices and Biocides, Poland

Alexandere Roumiantsev, Scientific Centre of the Ministry of Health, Russia

Dr Tetyana Efimtseva, State Pharmacological Centre of the Ministry of Health, Ukraine

Dr Heinrich Klech, Eli Lilly Regional GmbH, Austria

Dr Otto Skoran, Goodwill Research Ltd, Hungary

Dr Tamás Bölcsvölgyi, Diagnostic Units Hungary SMO, Hungary

Prof. Ludevít Martinec, State Institute for Drug Control, Slovak Republic

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Chair: Dr Jean Pierre Tassignon, Executive Vice President, PSI Pharma Support International, Belgium

09.00 Registration and Coffee

09.30 Chair's Introduction

09.40 **Update on European Clinical Trials Directive and ICH GCP**

- General introduction
- Comparison between Clinical Trials Directive and ICH/GCP: scope, ethical review, GCP and GMP compliance, etc...
- Preparation of additional Directive

Speaker: **An J Baeyens, DG Research – Unit C3 Ethics and Science, European Commission, Belgium**

10.20 **The Future of Clinical Trials in Central and Eastern Europe**

- 10 years experience in CEE
- Current legal and economical environment
- EU accession and EU Directive: new red tapes or speed up of study initiations in CE
- Clinical trials in Eastern Europe after May 2004: more or less

Speaker: **Dr Mikhail Samsonov, Medical Director CEE Region, Bristol-Myers Squibb, Belgium**

11.00 Coffee

11.30 **A Project Manager's View of Improving Quality of Conduct of Clinical Trials in Central and Eastern Europe**

- Overview of recent developments in CEE clinical research environment
- Diversifying clinical research in CEE countries
- Ethical considerations
- Regulatory challenges
- Dynamic market changes - emerging of CEE based CROs and SMOs
- What the future may bring

Speaker: **Dr Davorka Tomic-Wallis, Senior Project Manager, Procter and Gamble Pharmaceuticals, UK**

12.10 **Globalisation of Clinical Trials: Acceptance of Central and Eastern European Trials by the FDA**

Regulatory dossiers of several new drugs registered by FDA in recent years contained data from clinical trials run in CEE countries in addition to data obtained from Western Europe or USA. According to FDA's spokesman, Murray Lampkin, it is the quality of the data not the location of clinical trials that matters. Analysis of the results of FDA GCP Inspections, as found on the Freedom of Information website, implies that the quality of data obtained from clinical trials performed in CEE is as good as the quality of data obtained from clinical trials run in traditional locations

Speaker: **Dr B Lillian Natorff, Independent Consultant in Pharmaceutical Medicine, UK**

12.50 Lunch

COUNTRY UPDATES ON CLINICAL TRIAL REGULATIONS AND COMPLIANCE: THEORY AND PRACTICE

14.00 **Hungary**

- Impact of the EU Directive 2001/20/AC on the clinical trial regulation in Hungary
- What does the Directive say? What has already been

CLINICAL TRIALS IN CENTRAL

21 & 22 October 2003, Renaissance

The countries of Central and Eastern Europe continue to play a very important and large role in providing clinical trials of high quality, and they compete successfully with countries which are already members of the EU. The main attraction of CEE countries is the large pool of potential patients, low costs of conducting trials, highly qualified local medical professionals and implementation of GCP and ICH guidelines.

In May 2004, eight CEE countries will become members of the EU, and clinical trials are being conducted increasingly in many other countries in the region.

This 4th IBC conference on Clinical Trials in Central and Eastern Europe aims to take a practical view of the current state and future prospects for clinical trials in the CEE region.

There will be updates from the following EU accession countries:

- Poland • Hungary • Baltics

done in the field of regulation, ethics, pharmacovigilance and concerning the reinforcement of GCP/GMP rules?

- How are the principles and requirements of the Directive transposed into Hungarian legislation (Min. Decree 24/2002. 05.09.)?
- Presentation and clarification of the present legislative process of clinical trial authorisation and ethical approval in Hungary
- How to solve the practical problems (e.g. compliance to the new regulations) being raised by the implication of the new regulation

Speaker: **Prof. Dr. János Borvendég, Chief Counsellor, National Institute of Pharmacy, Hungary**

14.40 **Poland**

Speaker: **Michal Pirozynski, Director, Office of Medicinal Products, Medicinal Devices and Biocides, Poland**

15.20 Tea

15.50 **Russia**

- Overview of Russian federal drug law
- Current regulatory requirements for clinical trials
- Principle criteria for choosing hospitals to conduct clinical trials
- Certification of hospitals

Speaker: **Alexandere Roumiantsev, Chief of Information and Analytics Division, Scientific Centre of the Ministry of Health, Russia**

16.30 **Ukraine**

Speaker: **Dr Tetyana Efimtseva, Senior Research Assistant, Deputy Chief of Section for Coordination and Control of Medicinal Products Clinical Trials, State Pharmacological Centre, Ministry of Health, Ukraine**

17.10 Questions and Discussion

17.30 Cocktail Reception 

There will also be additional updates from these CEE countries:

- Slovakia • Bulgaria • Russia
- Ukraine • Serbia & Montenegro

Speakers include regulatory authorities from the countries listed above and practical experiences will be presented by sponsor companies and CROs, who have considerable experience and expertise in conducting clinical trials in CEE.

Why you should attend this event

Attending this conference should be a priority for pharmaceutical company personnel from R&D, medical, regulatory and marketing departments involved in running clinical trials in CEE. CROs already working in CEE, or considering doing so, will also benefit greatly from attending this conference, as will the drug regulatory authorities from CEE. The opportunities for networking are always cited as invaluable by delegates attending these IBC conferences.

- Further challenges during and after the Directive's transposition
- CROs in CEE - impact of Annex 13 and Annex 16
- Important regulatory issues - the role of population pharmacokinetics; trials based on rare disease/indications; biomarkers and biowaivers
- Clinical trials in paediatrics

Speaker: **Dr Borislav Borissov, Director, Bulgarian Drug Agency**

14.35 Tea

14.50 Baltics

Speaker to be announced
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15.30 Serbia and Montenegro

Speaker: **Dr Zoran M Pavlovic, Private Practitioner**

16.10 End of Conference

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Parallel Trade, Patents and Generics in Central and Eastern Europe

23 - 24 October 2003, Renaissance Penta Hotel, Vienna, Austria

Conference Agenda

- Parallel Trade in EU - Current Situation And Prospects
 - CEE-EU Parallel Trade Issues For The Future
- Parallel Trade and Trade Mark Protection In CEE-EU
 - Parallel Trade - Potential Benefits For CEE/EU
- Pharmaceutical Patent and IP Issues in EU and CEE
 - Prospects For The World Generics Market
 - Opportunities For The EU/CEE Generics Market
- Opportunities in The EU and CEE Generics Markets - An Asian Perspective
 - Generics and EU Enlargement - Implications for EU And CEE
 - Views of Foreign Companies, Views of Domestic Companies, Views of Distributors

Visit www.ibc-lifesci.com/LY1235 for full programme details

DAY TWO 22 October 2003

08.45 Coffee

09.00 Using CROs: Global or Local?

Speaker: **Dr Heinrich Klech, Professor of Medicine Area Medical Director Central Eastern Europe, Middle East, Africa, Eli Lilly Regional GmbH, Austria**

09.45 The Role and Management of Site Management Organisation in Central and Eastern Europe

Speaker: **Dr Otto Skoran, General Manager, Goodwill Research Ltd, Hungary**

10.30 Coffee

11.00 Patient Recruitment in Clinical Trials

The presentation reviews the most popular recruitment approaches in CEE countries and the legal background of patient recruitment, and gives in-depth information about the relevant Hungarian regulations and international ethical standards concerning advertising clinical trials. The effectiveness of different enrolment methods will be compared as well as successful recruitment techniques based on our practice

Speaker: **Dr Tamás Bölcsvölgyi, Director, Diagnostic Units Hungary SMO, Hungary**

11.45 Questions and Discussion

12.00 Lunch

COUNTRY UPDATES ON CLINICAL TRIAL REGULATIONS AND COMPLIANCE: THEORY AND PRACTICE

13.15 Slovakia

Speaker: **Prof. Ludevít Martinec, Director, State Institute for Drug Control, Slovak Republic**

13.55 Bulgaria

- Why is Dir 2001/20/EC is particularly important for the EU Accession countries?



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CLINICAL TRIALS IN CENTRAL AND EASTERN EUROPE

21 & 22 October 2003, Renaissance Penta Hotel, Vienna

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