Florentine East-West Medical Congress: Latest advances in clinical trials - From clinical trial to clinical practice

Vivahotel Alexander, 12th - 15th February 2009

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CALL FOR PARTICIPATION

An average of 4,000 people are needed to test a new drug before it can be sold. According to several studies, hundreds of drugs are developed each year, creating intense competition for test subjects. The US & EU are actively involved in Clinical Trials; therefore, the hopes for a widening market are now limited. Each day's delay getting a major drug on the market costs $1.3 million in unrealized sales, according to industry estimates. In this case, Eastern European countries are now more attractive for Western Pharmaceuticals Companies. Several factors influence the decision to conduct phase II & III Clinical Trials in the CEE and CIS regions.

The conference will provide a forum for people responsible for managing European clinical trials at the institutional level to discuss and work through the various challenges they face in their work in a supportive environment with peers and colleagues. Particular emphasis will be placed on the practicalities of ensuring patient safety by adhering to Good Clinical Practice (GCP) whilst complying both with "local", national, and European legislation.

Tentative Program

DAY ONE – THURSDAY, FEBRUARY 12TH 2009

Vivahotel Alexander Meeting Hall

h. 16.00: Registration

h. 18.00: Welcome and introduction by the promoting and sponsoring organizations

Fondazione Romualdo Del Bianco
Fondazione Internazionale Menarini
Crom
Florence Faculty of Medicine

h. 19.00: Welcome cocktail

DAY 02 – FRIDAY, FEBRUARY 13TH 2009

Vivahotel Alexander – Meeting Hall

h. 9.00 – 10.50:

PLENARY SESSION I

h. 9.00 – 10.10: Breakfast workshop: *Country Updates on Clinical Trial Regulations and Compliance (Italy, Ukraine, Russia)*

Chair: Mr **Enrico Rossi** (Alderman of Tuscany Region for the Public Health) and Dr. **Vladimir Popov** (Moscow Medical Academy named after Sechenov, Head of Clinical Pharmacology , Central Hospital № 6 of Russian Railways, Moscow, Russia)

h. 9.15 – 9.30: Russia

Prof. **Elena Yu. Barmanova** (Deputy Director, Office for Registration of Drugs and Medical Devices, Federal department for Surveillance in Healthcare, Roszdravnadzor, Russia)

- Clinical trials in Russia in 2007
- Overview of Russian federal drug law
- Current regulatory requirements for clinical trials
- Principle criteria for choosing hospitals to conduct clinical trials
- Certification of hospitals
- Russian Healthcare System reform – How will this Impact on trials?

h. 9.35 – 9.50: Italy

Prof. **Guido Rasi** (Director of AIFA – Agenzia del Farmaco, Italy)

- Clinical trials in Italy in 2007
- Overview of Italian federal drug law
- Current regulatory requirements for clinical trials
- Principle criteria for choosing hospitals to conduct clinical trials
- Certification of hospitals
- Italian Healthcare System reform – How will this Impact on trials?
- Italian Healthcare System

h. 9.55 – 10.10:

Prof. **Irina Nizhenkovskaya** (State Pharmacological Center of the Ministry of Health of Ukraine – Kiev, Ukraine)

- Clinical trials in Ukraine in 2007
- Overview of Ukrainian drug law
- Current regulatory requirements for clinical trials

h. 10.15 – 10.45:

Prof. Donato Agnusdei (Director, Global Medical External Relations - Eli Lilly & Company, Florence)

Future of Medical Education for Healthcare Professionals: partnership between industry & academia

h. 10.50 – 11.20: coffee break

Vivahotel Alexander - Primavera Hall

h.11.30 – 13.00:SESSION II: Statistics and Data Management

Electronic Trial and Document Management
Statistical Planning – Hypothesis Formulation & Sample Size
Statistical and Data Management Issues in Respiratory and Cardiovascular Drug Development
Developing a Protocol for a Randomised Controlled Trial
Statistical Planning – Hypothesis Formulation & Sample Size

Chair: **Dr. Paolo Morelli (CROSnt** Verona, Italy)

Prof. **Antonio Conti** (Coordinator of the Presidents of the CC.dd.LL., Faculty of Medicine and Surgery, Dep. Pathophysiology Clinic – University of Florence)

Dr. **Lisa Comarella**, (CROSnt Verona Italy).

Questions time

Vivahotel Alexander - Venere Hall
h.11.30 – 13.00:SESSION III: Clinical Safety & Pharmacovigilance

Pharmacovigilance - beyond 2009
Clinical Safety in Clinical Trials: The New EU Directive and Guidance
Pharmacovigilance and adverse event reporting
The management of adverse drug reactions: from diagnosis to signals.

Chair: Prof. **Alessandro Mugelli** (Director of the Department of Preclinical and Clinical Pharmacology, Florence University, Italy)
Pharmacovigilance and adverse event reporting: the experience in Tuscany

Dott. **Alessandro Casini** (President of the Fondazione Internazionale Menarini)

Prof. **Vladimir Lipakhin** (Head of Pharmacovigilance Dept of Russian Drug Agency Moscow, Russia)

Prof. **Victorov Olexey Pavlovich** (doctor of medicine, professor, head of Department of Clinical pharmacology and laboratory by functional diagnostic National Scientifical Center "Institute of Cardiology by name of acad. N.D. Stragesko" AMSc Ukraine)
Pharmacovigilance in Ukraine: formations and challenges

Prof. **Vladimir Popov** (Leading Researcher, Moscow Medical Academy named after Sechenov Central Hospital № 6 of Russian Railways, Moscow, Russia)
Drug safety: Drug-Related QT Interval Prolongation

Questions Time

13.15 – 14.15: Lunch break

Vivahotel Alexander - Meeting Hall
h. 12.30 - 15.30: POSTER PRESENTATION
Will be selected among the abstracts submitted by participants. There will be a poster session during lunch-time of each day . During that time posters should be attended by the Authors.

Vivahotel Alexander Primavera Hall
h. 14.30 – 17.00: SESSION IV : Drug Discovery and New Technologies
Chair: Prof. **Teresita Mazzei** (Department of Preclinical and Clinical Pharmacology, Faculty of Medicine and Surgery, University of Florence, Italy)

Prof. **Sergey Martsevich** (Head of Department of Preventive Pharmacology with phase I Unit and Pharmacokinetics lab. National Research Center of Preventive Medicine, Moscow, Russia)

Dr. **Anna Lesovay** (Scientific worker of the Regional Clinical Center of the Urology and Nephrology. Oncourological Department, Kharkiv, Ukraine)
The methodological peculiarities of the usage of peritoneal dialysis in patients with diabetic kidney affections.

Prof. Filippo De Braud (Director Unit Clinical Pharmacology and New Drugs of the European Institute of Oncology)

Prof. **Piergiuseppe Zagnoni** (Professor of Neurology, University Ferrara, Italy)
Department of Neurology Ferrara, Italy)
Critical Evaluation of Guidelines in the treatment of the Epilepsies

Professor **Andriy Dorofyeyev** (Professor of the Department of Internal Medicine No 2 of Donetsk State Medical University named after M. Gorkiy, Donetsk, Ukraine)
Clinical trials experiences of biologic agents in inflammatory bowel disease patients

Prof. **Irina Sarvilina** Director, of Novomedicina Medical Centre Ltd Rostov on Don Russia
Technological platform for molecular diagnostics of drug reactions

Vivahotel Alexander - Venere Hall
h. 14.30 - 16.00: SESSION V - Workshop: How to Initiate and Manage Clinical Trials in CEE (: Regulatory, Operational and Clinical Challenges CRO and sponsor experience.

CEE is emerging as an increasingly interesting and attractive place to conduct clinical trials. However, the industry still has more questions than answers about the regulatory, customs and operational environment in this region. This workshop will provide an introduction and practical advice about the initiation and management of clinical trials in CEE and how to take advantage of the benefits this region offers and how to overcome the challenges and obstacles. Issues to be covered:

- Attractiveness and difficulties of running Clinical Trials in CEE
- FDA and EMEA acceptance of data from CEE
- Quality of data from CEE
- Patient recruitment – feasibility and recruitment
- Monitoring and auditing trials in CEE
- Logistics and customs issues .
- GCP compliance

Chair: **Oriana Zerbini** (**Medical Director -** CROM Srl, Verona, Italy)

Prof. Vladimir Popov (Leading Researcher, Moscow Medical Academy named after Sechenov Central Hospital № 6 of Russian Railways, Moscow, Russia)
Attractiveness and difficulties of running Clinical Trials in Russia and Ukraine

Luczak Krzysztofa (Clinical Research Operation Assistant - CROM Polska – Warsaw, Poland)
Experience from Clinical Research in Poland

Margherita Mosconi (Client Project Operations Director .- CROM Verona)
Patient recruitment - feasibility and recruitment

Prof. **Vladimir Nikolaevich Neliyubin** (Head of department of Laboratory Diagnostics Central Hospital n. 6 OAO "RZD" Moscow, Russia)
Local lab experience in running clinical trials (QC/QA issues)

Simona Colazzo (Head of Quality Assurance Department - CROM Verona) :
Quality of Data From CEE- auditor experience

Dr. Luca Cantini (Independent Consultant , Livorno, Italy)
Quality of data from CEE - independent Medical expert experience.

Prof . **Vladimir V. Yakusevich , Dr. Andrey V. Kabanov**
Yaroslavl Municipal Health Care Institution Clinical Hospital for Emergency Care n.a. N.V. Solovyov, Yaroslavl, Russia)
Unresolved problems of Good Clinical Practice

Prof. **Yurj I. Feschenko** (Director of State Organisation "National Institute of Phthisiology and Pulmonology named after . F.G. Yanovsky (AMS of Ukraine", Head of Pulmonology department)
Predicaments, which we collided in our practice during conducting of clinical trials

Questions and Discussion

h.17.00: possibility of visiting the Uffizi Gallery offered by the Romualdo Del Bianco Foundation (under confirmation)

DAY 03 – SATURDAY, FEBRUARY 14TH 2009

Vivahotel Alexander Meeting Hall

h. 9.00 – 10.00
PLENARY SESSION VI

STATE-OF-THE-ART LECTURE: How to interpret clinical Guidelines. Their Implications, and New Clinical Evidence.
Prof. **Ettore Ambrosioni** (President of the Italian Society hypertension and clinical medical director - University of Bologna, , Italy)

h. 10.00 – 10.30: coffee break

Vivahotel Alexander Primavera Hall
h. 10.30 – 13.00: SESSION VII: Latest Advances in clinical trials – Cardiology & Hypertension
Chair: **Prof. Gian Franco Gensini** (Prorector for the Relationships with the National Health System, Faculty of Medicine and Surgery, University of Florence, Italy)

Prof: **Claudio Borghi** (Department of Internal Medicine, Faculty of Medicine and Surgery, Bologna University, Italy)

Prof.ssa **Rosanna Abbate** (Director of the Department of Medical Surgical Critical Area, Faculty of Medicine and Surgery, University of Florence, Italy)

Dr. **Nataliya Bulanova** (Medical Centre of General Management Department of the President of the Russian Federation; Moscow, Russia)
Clinical trials on Atrial Fibrillation

Vivahotel Alexander Venere Hall
h. 10.30 – 13.00: SESSION VIII: Latest Advances in clinical trials – Endocrinology, Obesity and Bone Metabolism
Chair: Prof.. **Riccardo Gionata Gheri** (S. Giuseppe Hospital, Empoli, Italy)
Endocrine Clinical Trials in Internet

Prof. **Carlo Maria Rotella** (Department of Clinical Pathophysiology, Faculty of Medicine and Surgery, University of Florence, Italy)
Comparison among different pre-treatment predictors of weight loss in the medical treatment of obesity

Prof. **Maria Luisa Brandi** (Department of Internal Medicine, Faculty of Medicine and Surgery, University of Florence, Italy)
Osteoporosis: When Clinical Trials Can Last 10 Years

Professor **A. V. Dreval** (Head of Department of Endocrinology Moscow Regional Clinical Research Institute, Moscow, Russia)
Seven subtypes of diabetes mellitus revealed in IVGTT

J.G. Pokramovich, A.V. Dreva1, O.A. Nechaeva1, V. S. Pronin, D.E. Koloda, E. P. Gitel (The Moscow Regional Research Clinical Institute of M.F. Vladimirsky, Moscow Medical Academy of I.M. Sechenov, Russia)
Oktreotid-depot therapy of acromegaly with long action somatostatin analogue

Dr. **Nataliya Pertseva** (Faculty Therapy and Endocrinology Department of Dnepropetrovsk State Medical Academy, Ukraine)
Problems in conducting of clinical trials in diabetic patients

13.30 – 14.20: Lunch break

Vivahotel Alexander Meeting Hall
h. 12.30 - 15.30: POSTER PRESENTATION
Will be selected among the abstracts submitted by participants. There will be a poster session during lunch-time of each day. During that time posters should be attended by the Authors.

Vivahotel Alexander Primavera Hall
h. 14.30 – 17.00: SESSION IX: Latest Advances in clinical trials – Pulmonology & asthma treatment
Chair: Prof. **Massimo Pistolesi** (Department of Internal Medicine, Faculty of Medicine and Surgery, University of Florence, Italy)

Prof. **Pieluigi Paggiaro** (Department Cardio Thoracic and Vascular, Faculty of Medicine and Surgery, Pisa University, Italy)

Prof. **Zaurbek R. Aisanov** (Head of the Clinical Physiology and Clinical Trials Department, Moscow Scientific Research Pulmonology Institute MoH RF, Moscow, Russia)
Major problems of clinical trials in respiratory medicine

Prof. **Tatyana Kobets** (Head of Department of propedeutics of paediatrics of the Crimean State Medical University named after S. I. Georgievsky Simferopol, Ukraine)
Efficacy Polysim - 4 in children with recurrent bronchitis

Prof. **Tatyana Alexeevna Pertseva** (Chief of Department of Internal Medicine of the Dniepropetrovsk State Medical Academy, Ukraine.)
Patients with COPD: randomized clinical trials and patient's adherence to the national and international treatment guidelines

Prof. **Liudmyla Iashyna** (Chief of the department of Diagnostic, Therapy and Clinical Pharmacology of Lung Diseases, Ukraine)
Ways of improvement of compliance during clinical trials with the use of modern technologies in patients with respiratory diseases

Prof. **Natalia Grigorievna Gorovenko**(Chief of the Department of Medical Genetics, National Medical Academy of Postdiploma Education, Ukraine)
Pharmacogenetics in the clinical trials

Vivahotel Alexander Venere Hall
h. 14.30 – 17.00: SESSION X: Latest Advances in clinical trials – Clinical Oncology
Chair: Prof. **Filippo De Braud** (Director Unit Clinical Pharmacology and New Drugs of the European Institute of Oncology)

Prof. **Mikhail Davidov** (Director of Russian National Cancer Research Center of AMS , Moscow, Russia)

Prof. **Francesco Di Costanzo** (School of Specialization of Oncology, Faculty of Medicine and Surgery, Perugia University, Italy)
Adjuvant treatment in early gastric cancer: yes or not?

Prof. **Enrico Mini** (Department of Pharmacology, University of Florence)
Latest advances in the treatment of colorectal cancer: results from clinical trials and pharmacogenomic research

Prof..**Gianmaria Fiorentini** (San Giuseppe Hospital, Empoli, Florence, Italy)
Integrated and locoregional approaches in Oncology

h.18.00: possibility of visiting the Academia Gallery (David of Michelangelo) offered by the Romualdo Del Bianco Foundation (under confirmation)

DAY 04 – SUNDAY, FEBRUARY 15TH 2009

Departure or post conference tour (upon request)

Economic conditions of participation

Registration fee = 200 Euro including:

- welcome reception, the first day
- 2 coffee breaks, lunch-break and dinner for the first day (the Vivahotel Alexander has rooms, bar and restaurant)
- 2-coffee breaks, lunch-break and dinner for the first day
- full conference (badge of recognition, folder, program)

Accommodation:

- Hotel 4 stars (Vivahotel Alexander, Viale Guidoni, 101) = **235 Euro** per person for 3 nights in room DUS; **135 Euro** per person for 3 nights in single room
- Hotel 3 stars (Vivahotel Fleming, Viale Guidoni, 87) = **220 Euro** per person for 3 nights in room DUS; **130 Euro** per person for 3 nights in single room

How to apply

Applicants are requested to fill the Registration Form on
http://www.fondazione-delbianco.org/seminari/progetti_prof/progview_PL.asp?start=1&idprog=76
or write directly to info@fondazione-delbianco.org
The deadline for the registration and payment of the fee, December 10th, 2008