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Florentine East-West Medical Congress

Latest advances in clinical trials: from clinical trial to clinical practice

Florence (Italy), February 12th, 2009
Galleria Luca Giordano, Palazzo Medici Riccardi, Via Cavour, 1

Florence (Italy), February 13th – 14th, 2009
Vivahotel Alexander Novoli, Viale Guidoni, 101

Organized by
FACULTY OF MEDICINE AND SURGERY - UNIVERSITY OF FLORENCE

FONDAZIONE ROMUALDO DEL BIANCO
FONDAZIONE INTERNAZIONALE MENARINI

PROGRAM

Under the Auspices of



Associazione Italiana
di Oncologia Medica



Associazione Medici
Endocrinologia



Società Italiana
di Cardiologia



Associazione Nazionale
Medici Cardiologi Ospedalieri
Sezione Regione Toscana



Società Italiana
di Endocrinologia



Società Italiana di
Medicina Interna



Azienda USL11
Empoli

Supported by:



Contract Research Organisation Medical

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Dean of the Faculty of Medicine and Surgery
of the Florence University (Italy)

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Professor, Post-Graduate School of Endocrinology, Florence University

Prof. Vladimir Popov

MD, PhD, DrScMed

Head of Clinical Pharmacology, Central Hospital № 6
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Leading Researcher of Cardiology Department
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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.

The Scientific Committee

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Thursday, February 12th, 2009 – Afternoon
Galleria Luca Giordano – Palazzo Medici Riccardi

Opening Ceremony

17.00 Welcome addresses of the **Authorities**

17.30 Welcome and Introduction

Gian Franco Gensini (Dean, Faculty of Medicine and Surgery, Florence University)

Riccardo Gionata Gheri (Chief, Endocrine Unit, AUSL11, Tuscany Region, National Health Service)

Vladimir Popov (Moscow Medical Academy named after I.M. Sechenov)

Alessandro Casini (President, Fondazione Internazionale Menarini)

Paolo Del Bianco (President, Fondazione Romualdo Del Bianco)

Oriana Zerbini (Medical Director, CROM)

19.00 Welcome cocktail

Friday, February 13th, 2009 – Morning
Meeting Hall - Vivahotel Alexander

08.30 **Registration** – Each speaker is requested to leave a copy of his/her presentation at the registration desk

Plenary Session I

09.00 **Breakfast workshop: “Country Updates on Clinical Trial Regulations and Compliance (Russia, Italy, Ukraine)”**

Co-Presidents: **Deputy of Tuscany Region** (Florence, I)
 V. Popov (Moscow, Russia)

09.15 **O. Verstakova** (Moscow, Russia)

- Clinical trials in Russia in 2008
- 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?

09.35 **G. Rasi** (Rome, I)

- Clinical trials in Italy in 2008
- 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

09.55 **I.V. Nizhenkovskaya** (Kiev, Ukraine)

- Clinical trials in Ukraine in 2008
- Overview of Ukrainian drug law
- Current regulatory requirements for clinical trials

10.15 **D. Agnusdei** (Florence, I)

Main Lecture on: “Future of medical education for healthcare professionals: partnership between industry & academia”

10.50

Coffee break

Friday, February 13th, 2009 – Morning
Primavera Hall - Vivahotel Alexander

Parallel Session II - Statistics and Data Management

- President: **P. Morelli** (Verona, I)
- 11.30 **P. Morelli** (Verona, I)
Statistical planning – hypothesis formulation and sample size
- 11.50 **A. Conti** (Florence, I)
Electronic trial and the ‘Caveats’ for a correct hypothesis formulation
- 12.10 **L. Comarella** (Verona, I)
Statistical and Data Management issues in respiratory and cardiovascular
drug development
- 12.30 General discussion
- 13.00 Lunch

Friday, February 13th, 2009 – Morning
Venere Hall - Vivahotel Alexander

Parallel Session III - Clinical Safety & Pharmacovigilance

- President: **A. Mugelli** (Florence, I)
- 11.30 **E. Serrotti** (Florence, I)
Pharmacovigilance in clinical practice
- 11.50 **A. Mugelli** (Florence, I)
The Tuscan pharmacovigilance system
- 12.10 **A.P. Viktorov** (Kiev, Ukraine)
Pharmacovigilance in Ukraine: formations and challenges
- 12.30 **V. Popov** (Moscow, Russia)
Drug safety: Drug-related QT interval prolongation
- 12.50 General discussion
- 13.00 Lunch

Friday, February 13th, 2009 – Afternoon
Primavera Hall - Vivahotel Alexander

Parallel Session IV - Drug Discovery and New Technologies

President: **T. Mazzei** (Florence, I)

14.30 **A. Khokhlov** (Yaroslavl, Russia)
Association between adherence and effectiveness, safety to drug therapy
of arterial hypertension

14.50 **G. Lisova** (Kharkiv, Ukraine)
The methodological peculiarities of the usage of peritoneal dialysis in patients
with diabetic kidney affections

15.10 **F. de Braud** (Milan, I)
Early clinical trials for new drugs development in comparison with traditional
cytotoxics

15.30 **A.E. Dorofeyev** (Donetsk, Ukraine)
Clinical trials experience of biologic agents in inflammatory bowel disease patients

15.50 **I. Sarvilina** (Rostov on Don, Russia)
Technological platform for molecular diagnostics of drug reactions

16.10 General discussion

Friday, February 13th, 2009 – Morning
Venere Hall - Vivahotel Alexander

Parallel Session V

- 14.30 *Workshop: “How to Initiate and Manage Clinical Trials in CEE (Regulatory, Operational and Clinical Challenges): CRO and sponsor experience”*
- President: **O. Zerbini** (Verona, I)
- 14.45 **V. Popov** (Moscow, Russia)
Attractiveness and difficulties of running Clinical Trials in Russia
- 15.00 **L. Krzysztofa** (Warsaw, Poland)
Experience from Clinical Research in Poland
- 15.15 **M. Mosconi** (Verona, I)
Patient recruitment: also the Sponsor / CRO can play an important role
- 15.30 **V.N. Nelyubin** (Moscow, Russia)
System of external quality assessment of clinical laboratory
- 15.45 **S. Colazzo** (Verona, I)
Quality of data from Central Eastern Europe: the Auditor’s Experience
- 16.00 **L. Cantini** (Livorno, I)
Quality of data from CEE - independent Medical expert experience
- 16.15 **A.V. Kabanov** (Yaroslavl , Russia)
Controversial points of Clinical Trials
- 16.30 General discussion

Saturday, February 14th, 2009 – Morning
Meeting Hall - Vivahotel Alexander

Plenary Session VI - State of the Art Lectures

- 09.00 **A. Zanchetti** (Milan, I)
How to interpret clinical Guidelines. Their implications, and new clinical evidence
- 09.20 **P. Zagnoni** (Ferrara, I)
Critical evaluation of guidelines in the treatment of the epilepsies
- 09.40 **V. Zaporozhan** (Odessa, Ukraine)
Clinical trials in the context of Nooethics
- 10.00 Coffee break

Saturday, February 14th, 2009 – Morning
Primavera Hall - Vivahotel Alexander

Parallel Session VII: “Latest Advances in Clinical Trials – Cardiology & Hypertension”

- President: **G.F. Gensini** (Florence, I)
- 10.30 **C. Borghi** (Bologna, I)
How to manage hypertension in high risk patients: the evidence from clinical trials
- 11.15 **N. Bulanova** (Moscow, Russia)
Stroke prevention in patients with atrial fibrillation
- 11.55 **R. Abbate** (Florence, I)
New antiplatelet and anticoagulant drugs
- 12.40 **N. Gorovenko** (Kiev, Ukraine)
Pharmacogenetics in the clinical trials
- 13.00 General discussion
At the conclusion:
Yong-Seok Lee (Seoul, South Korea)
Antiplatelet Trial in Acute Ischemic Stroke: Feasibility of Non-inferiority Test (*)

(*) Presented as a poster

13.15 Lunch

Saturday, February 14th, 2009 – Morning
Venere Hall - Vivahotel Alexander

Parallel Session VIII: “Latest Advances in clinical trials – Endocrinology, Obesity and Bone Metabolism”

President: **R.G. Gheri** (Empoli - Florence, I)

10.30 **R.G. Gheri** (Empoli – Florence, I)
Endocrine clinical trials in internet

10.50 **C.M. Rotella** (Florence, I)
Comparison among different pre-treatment predictors of weight loss in the medical treatment of obesity

11.20 **M.L. Brandi** (Florence, I)
Osteoporosis: when clinical trials can last 10 years

11.40 **A. V. Dreval** (Moscow, Russia)
Seven subtypes of diabetes mellitus revealed in IVGTT

12.00 **J.G. Pokramovich** (Moscow, Russia)
Oktreotid-depot therapy of acromegaly with long action somatostatin analogue

12.20 **N. Pertseva** (Dniepropetrovsk, Ukraine)
Problems in clinical trials in diabetic patients

12.40 General discussion

13.15 Lunch

Saturday, February 14th, 2009 – Afternoon
Primavera Hall - Vivahotel Alexander

Session IX: “Latest Advances in Clinical Trials – Pulmonology & Asthma Treatment”

President: **M. Pistolesi** (Florence, I)

14.30 **P. Paggiaro** (Pisa, I)

Latest advances in clinical trials – pulmonology & asthma treatment

14.50 **Y.I. Feshchenko** (Kiev, Ukraine)

Predicaments, which we collided in our practice during conducting of clinical trials

15.10 **Z.R. Aisanov** (Moscow, Russia)

Major problems of clinical trials in respiratory medicine

15.30 **T.V. Kobets** (Simferopol, Crimea, Ukraine)

Efficacy Polysim - 4 in children with recurrent bronchitis

15.50 **T.A. Pertseva** (Dniepropetrovsk, Ukraine)

Patients with COPD: randomized clinical trials and patient’s adherence to the national and international treatment guidelines

16.10 **L.A. Iashyna** (Kiev, Ukraine)

Ways of improvement of compliance during clinical trials with the use of modern technologies in patients with respiratory diseases

16.30 General discussion

Saturday, February 14th, 2009 – Afternoon
Venere Hall - Vivahotel Alexander

Session X: “Latest Advances in Clinical Trials – Clinical Oncology”

President: **F. de Braud** (Milan, I)

14.30 **F. Di Costanzo** (Florence, I)

Adjuvant treatment in early gastric cancer: yes or not?

15.00 **E. Mini** (Florence, I)

Latest advances in the treatment of colorectal cancer: results from clinical trials and pharmacogenomic research

15.30 **G. Fiorentini** (Empoli - Florence, I)

Integrated and locoregional approaches in oncology

16.00 **N. Berdnikova** (Moscow, Russia)

Study of safety and efficiency of indol-3-carbinol (I-3-C) at benign breast diseases

16.30 General discussion

GENERAL INFORMATION

Meeting venues

The venues for the Meeting will be

- **Florence (Italy), February 12th, 2009**
Galleria Luca Giordano, Palazzo Medici Riccardi, Via Cavour, 1.
- **Florence (Italy), February 13th – 14th, 2009**
Vivahotel Alexander Novoli, Viale Guidoni, 101 - Tel.: +39 055 4378951 – Fax: +39 055 416818.

Secretariat during the Meeting

The Secretariat will be open at the following times:

Friday, February 13th, from 08.00 a.m. to 17.00 p.m.

Saturday, February 14th from 08.00 a.m. to 18.00 p.m.

Official language

The official language of the Meeting will be English.

CME Credits

The Meeting earned n° 8 credits from the Italian Health Authorities for Physicians.

European CME credits (ECMEC's)

European CME credits have been applied for from the European Accreditation Council for Continuing Medical Education (EACCME).

Registration fee = 200 Euro

The registration fee includes:

- welcome reception, the first day
- 2 coffee breaks, lunch-break and dinner for the second day
- 2 coffee breaks, lunch-break and dinner for the third day
- full conference (badge of recognition, folder, program, abstract book)

Applicants are requested to fill the Registration Form on the web page of the conference:

http://www.fondazione-delbianco.org/seminari/progetti_prof/progview_PL.asp?start=1&idprog=76

or write directly to info@fondazione-delbianco.org.

Accommodation

Due to the significant involvement of the Romualdo Del Bianco Foundation and Florentine Vivahotels Company, **participants will obtain very favourable conditions at following specially reduced accommodation rate.**

- Hotel 4 stars (Vivahotel Alexander Novoli, 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.

Technical facilities

Facilities will be available for computer presentations and overhead projections.

Each speaker is requested to leave a copy of his/her presentation at the registration desk (only Powerpoint presentation for Windows available) will be possible to check and preview the presentations. It is essential that speakers take their presentation at the registration desk at least one hour before the session starts.

Lunches, coffee breaks and dinners

Lunches, coffee breaks and dinners will be served in the Meeting area.

Abstracts book

Participants will receive the Abstract book at the Meeting.

LIST OF THE PRESIDENTS OF THE SESSIONS, SPEAKERS AND MEMBERS OF THE SCIENTIFIC COMMITTEE

Rosanna Abbate

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