A Conference on

Clinical Trials in Serbia: Looking upon GCP, Regulatory Issues and Bio-ethics

5-6 September, 2006
Media Centre, Belgrade, Serbia

organised by

European Forum for Good Clinical Practice

EF
GCP

‘where science & ethics meet’

In collaboration with

VEIO Research
SIEPA
Medicine and Medical Device Agency of Serbia
Programme Committee

Sinisa Radulovic  Head, Clinical Trial Approval Committee, Serbia
Tomislav Solarevic  Director, Serbian Medicine and Medical Devices Agency, Serbia
Milica Prostran  Chief of Clinical Pharmacology Dpt for Post-graduates, School of Medicine of Belgrade, Serbia
Ljiljana Kulic  Head of Medical Dpt, Serbian Medicine and Medical Devices Agency, Serbia
Slobodan Jankovic  Faculty of Medicine, Kragujevac, Serbia
Vojko Dukic  Director of the Clinical Centre of Serbia
Mirjana Zivkovic  Head of Ethics Committee, Nis, Serbia
Ana Sabo  Head of Pharmacology Dpt, Faculty of Medicine, Novi Sad; Secretary General, Ethics Committee, Serbia
Darinka Boskovic  Member of Ethics Committee, Serbian Agency
Ljiljana Vuckovic  Pharmacovigilance expert, Serbia

Faculty

Regulatory and ethics committee professionals, educators and QA/QS, representatives of pharmaceutical companies, CROs, and EFGCP.

Darinka Boskovic  Scientific Advisor, Clinical Trial Approval Committee, Serbia
Srdjan Boskovic  Clinical Centre of Serbia, Clinic for Internal Medicine, Serbia
Elmar Doppelfeld  Permanent Working Party of the German Ethics Committees, Germany
Christiane Druml  Ethics Committee, Medical University of Vienna, Austria
Jozef Glasa  Slovak Medical University/ Institute of Medical Ethics & Bioethics, Slovakia
Slobodan Jankovic  Pharmacovigilance Commission of Medicine and Medical Device Agency, Serbia
Ingrid Klingmann  Pharmaplex / EFGCP, Belgium
Olga Kubar  Pasteur Institute / EFGCP, Russia
Branka Krunic  Ethics Committee, Clinical Centre of Serbia
Ljiljana Pitic  Pfizer Belgrade, Serbia
Biljana Putnikovic  Clinical Centre ‘Zemun’, Serbia
Mariana Resnicoff  European Science Foundation, France
Sinisa Radulovic  Clinical Trial Approval Committee, Serbia
Ana Sabo  Head of Pharmacology Dpt, Faculty of Medicine, Novi Sad; Secretary General, Ethics Committee, Serbia
Tomislav Solarevic  Medicine and Medical Device Agency, Serbia
Jean-Pierre Tassignon  PSI Pharma Support / EFGCP, Switzerland
Ivana Timotijevic  Institute for Mental Health, Belgrade, Serbia
Aleksandra Vikadovic-Lazic  Roche, Belgrade, Serbia
Zorica Vucinic  Medicine and Medical Device Agency, Serbia
Vesna Vujaklija  Veio Research / EFGCP, Belgium
Frank Wells  Consultant / EFGCP, United Kingdom
Conference Description

The Conference is aiming to disseminate awareness of the current practice of clinical trials in Serbia and Montenegro, reflecting on its recent past and anticipating its nearest mid-term future! Insights are to be shared among professionals who take an active role and part in clinical trials within Serbia, as well as from neighbouring countries and EU member states.

The SEE region has the highest growth in Europe. For companies that seek to start or expand their clinical trials business in this region, Serbia is a cardinal place to be, for a number of reasons. Apart from already well known and well exploited ones, such as reputation for historically solid strong medical schools, high standards, easy administration, high patient recruitment, dedicated investigators and in most cases, significantly lower costs, there are others, not less important:

- As State Union with Montenegro, Serbia is the only country outside of CIS that enjoys a free Trade Agreement with the Russian federation, thus customs-free access to its market of 150 million people;
- the local Serbian market is among the largest in the region (7.5 million people)
- Familiarity with English language is highest among selected 5 CEE countries (source Gallup International)
  
<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Serbia</td>
<td>42%</td>
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<tr>
<td>Poland</td>
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<tr>
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<td>Romania</td>
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<tr>
<td>Hungary</td>
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<td>Bulgaria</td>
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- Bordering Hungary, Serbia is at the doorstep of the EU, as a gateway between South East Europe, Western and Central Europe, while also an intersection of the two most important corridors connecting Western Europe and the Middle East.
- Serbia possesses a skilled and productive workforce with a wealth of experience, along the tradition of cooperation with foreign companies during decades of openness towards Western culture and values.

Conference Auditorium

Representatives of pharmaceutical companies, CROs, regulatory authorities, competent authorities, ethics committees, Medical School of Belgrade, legal advisors from applicable sector, investors and banking service providers, journalists

Conference Scheme

Two-day conference with plenary sessions, 6 interactive workshops and exhibition of service providers.
The EFGCP Education Working Party will hold ‘open doors’ on the occasion of the Conference. The EFGCP Ethics Working Party and Education Working Party chairs will be available to answer all questions about Working Parties activities and registrations as members.

Conference Language

The language of the conference is English.
Conference on
Clinical Trials in Serbia: Looking upon GCP, Regulatory Issues and Bio-ethics
5-6 September 2006, Media Centre, Belgrade, Serbia
(Preliminary Programme version 16, 20 July 2006)

Conference Venue

Media Centre
Milentija Popovića 9 (Sava Centre)
11070 Belgrade, Serbia and Montenegro
Phone: +381 11 220-69-00
Fax: +381 11 220-64-00

For further information

On the programme, please contact Mrs. Vesna Vujaklija:
Tel.: +32 2 385 29 01, Fax.: +32-2-654 14 80, E-mail: vesna.vujaklija@veio-research.com

On registration and EFGCP activities & membership, please contact Ms Fanny Senez:
Tel: +32 2 732 87 83, Fax: +32 2 503 31 08, E-mail: conferences@efgcp.be

On travel and accommodation details and other ‘on-site’ information, please contact MrPh. Milena Samardzic of VEIO Research Serbia, Belgrade:
Tel/fax: + 381 11 456 767, Mob.: + 381 63 27 41 45, E-mail: milena.samardzic@veio-research.com

Special service

EFGCP is providing assistance in setting up one-to-one meetings, as well as a visit to research sites and hospitals. Should you be interested, please contact MrPh Milena Samardzic of VEIO Research Serbia, Belgrade:
Tel/fax: + 381 11 456 767, Mob.: + 381 63 27 41 45, E-mail: milena.samardzic@veio-research.com
Conference Programme

Day 1

GCP and Regulatory Requirements

Objectives
The primary objective of the first day of the conference is to compare EU and Serbian regulatory requirements, in order to place local performance in the context of current international standards and practices. The morning sessions will be dedicated to the present and expected future situation for clinical trials in Serbia. In the afternoon session areas of special interest, and the way forward for clinical trials in Serbia will be discussed. The new EU Directives, on Clinical Trials and GCP will be reviewed, and the maintenance of scientific & ethical values and principles in clinical trial practice will be emphasised.

Who are the speakers?
Representatives from Serbian RA / CA*, other regulatory authorities, SEDP of USAid, health sector government representative, representatives of key investigative sites, and EFGCP

Who should attend?
Professionals from the Pharmaceutical Industry and CROs (including monitors, regulatory affairs specialists and medical directors), investigators who conduct clinical research, members of Ethics Committees, regulatory authorities, academia members and the legislators.

Why to attend?
With the implementation of the new EU Directive on Clinical Trials as from May 1, 2004, in EU member states, all clinical research professionals face new challenges and a new set of working practices. Directives are already prerogatives in all countries of the old continent, EU as well as non-EU states. The Serbian auditorium, as an integral part of the European and international clinical research arena, needs to understand, comply and eventually implement Directives in their daily work. In order to be able to do so, conferences such as this one and exchange of experiences are very valuable. Training on the current and on the forthcoming regulatory framework is imperative for everyone who works on clinical research.

* Competent Authorities
AGENDA

08.00  Registration

Plenary Session 1
GCP & Clinical Trials in Serbia

Chairpersons: Dr Aleksandra Vikadovic-Lazic, Country Medical Manager, Roche Belgrade, Serbia  
Mr.Ph Tomislav Solarevic, Prim Dr, Director, Medicine and Medical Device Agency, Serbia

08:30  Introduction of EFGCP and brief overview of the Serbian regulatory framework for clinical trials  
Mrs. Vesna Vujaklija, President, Veio Research & Chairperson, Education Working Party, EFGCP, Belgium

08:45  Clinical Trial standards in Serbia 2005: Present situation and expectations for the future - Industry perspective  
Dr Ljiljana Pitic, Medical Director, Pfizer Belgrade, Serbia

09:15  Clinical Trials standards in Serbia 2005: Present situation and expectations for the future – The Competent Authorities’ perspective  
Dr Sinisa Radulovic, Scientific Advisor & Head, Clinical Trial Approval Committee, Serbia

09:45  Review of Clinical Research activities in Serbia from Phase I to Phase IV for drugs, medical devices and in-vitro diagnostics  
Dr Darinka Boskovic, Scientific Advisor, Clinical Trial Approval Committee, Serbia

10:15  An investigator’s view  
Prof. Dr Ivana Timotijevic, Prof MD, Deputy Director, Scientific Affairs, Institute for Mental Health, Belgrade, Serbia

10:45  Coffee-break

11:05  Clinical Investigator training - the European Syllabus  
Dr. Mariana Resnicoff, EUROCORES Programme Coordinator in Medical Sciences, European Science Foundation (ESF), France

11:35  How will Bulgaria develop towards the EU regulatory requirements?  
Speaker invited

12:05  Neighbouring country experience: Review on the situation in Hungary  
Speaker invited

12:35  Neighbouring country experience: Review on the situation in Romania  
Speaker invited

13:05  Neighbouring country experience: Review on the situation in Croatia  
Speaker invited

13:35  Lunch
Workshops

Areas of special interest in Clinical Research

Chairperson: Chairperson invited

14:30 Workshop 1:
“Tasks and responsibilities in clinical trials”
Moderator: Prof. Olga Kubar, Head, Clinical Department, Pasteur Institute, FECCIS & Education Officer, EFGCP, Russia
Rapporteur: invited

15:15 Workshop 2:
“Pharmacovigilance”
Moderator: Prof. Slobodan Jankovic, Head, Pharmacovigilance Commission of Medicine and Medical Device Agency, Serbia
Rapporteur: invited

16:00 Workshop 3:
“Clinical trials in special populations & Investigator initiated clinical trials”
Moderator: invited
Rapporteur: invited

16:45 Coffee-break

Plenary Session 2

17:05 Forum Discussion on “How should Serbia prepare for Clinical Trials and GCP Directives?”
Chairperson: invited

17:50 End of Day one
Day 2

Good Ethical Review Practice

Objectives
The second day of the conference aims to present requirements regarding ethical standards that are necessary conditions for CTs. The EU Directives will be used as standards, along with other available tools, such as Declaration of Helsinki, EFGCP Guidelines and Recommendations for European Ethical Committees, WHO Draft SOP for ECs. Current experiences within the region, with perspective on training and education will bring the conclusion for the day.

Who are the speakers?
Ethics experts, Developers of ethical guidelines and EC members.

Who should attend?
The content of the day will be relevant for all parties involved in managements and placement of a CT: EC members, monitors, project managers, for those responsible for training and for quality assurance and for those with responsibility for company policy and strategy – heads of clinical research, medical directors and general managers. No company, pharmaceutical or CRO, can afford not to be prepared in this area. Much more so for ECs!

Why to attend?
The implementation of the EU Directive on clinical trials has given clinical research in Europe a new mandatory framework, which defines roles and responsibilities vis-à-vis ethical considerations. Professionals working in clinical research must be aware of all current Ethical requirements and also of the consequences of non-compliance.
AGENDA

Plenary Session 3
Good Ethical Review Practice

Chairperson: Prof. Olga Kubar, Head, Clinical Department, Pasteur Institute, FECCIS & Education Officer, EFGCP, Russia

09:00  The development of Modern Research Ethics
       Prof. Dr Jozef Glasa, Deputy Head, Slovak Medical University & Head, Institute of Medical Ethics & Bioethics, Slovakia

09:30  Ethics Committees and ethical review in the EU Clinical Trials Directive
       Dr. Ingrid Klingmann, CEO, Pharmaplex & Co-Chairperson, Ethics Working Party, EFGCP, Belgium

10:00  How did EU countries implement the new ethics committee requirements?
       Dr Frank Wells, Consultant & Co-Chairperson, Ethics Working Party, EFGCP, United Kingdom

10:30  Coffee-break

11:00  Report on Serbian EC practice and policy
       Dr. Branka Krunic, Ethics Committee, Clinical Centre of Serbia

11:30  The need for GCP training and implementation of quality standards in Serbian ethics committees
       Dr. Christiane Druml, Managing Director, Ethics Committee of the Medical University of Vienna, Austria

12:00  The role of ethics committees in the management of research misconduct
       Dr Frank Wells, Consultant & Co-Chairperson, Ethics Working Party, EFGCP, United Kingdom

12:30  Lunch

Workshops
Challenges for Ethics Committees in Serbia

13:30  Workshop 1:
       “How to optimize the efficiency of ethics committees?”
       Moderator: Dr Srdjan Boskovic, MD, MSc, Clinic for Cardiovascular Diseases «Dedinje», Belgrade, Serbia
       Rapporteur: Mrs. Vesna Vujaklija, President, Veio Research & Chairperson, Education Working Party, EFGCP, Belgium

14:15  Workshop 2:
       “How to ensure best practices in the ethical review?”
       Moderator: Dr. Christiane Druml, Managing Director, Ethics Committee of the Medical University of Vienna, Austria
       Rapporteur: Dr. Ana Sabo, Head of Pharmacology Dpt, Faculty of Medicine, Novi Sad; Secretary General, Ethics Committee, Serbia
15:00 **Workshop 3:**
“The Informed Consent Process”
**Moderator** - *Prof. Elmar Doppelfeld*, Permanent Working Party of the German Ethics Committees, Germany
**Rapporteur:** *Dr. Biljana Putnikovic*, Clinical Centre ‘Zemun’, Serbia

15:45 Coffee-break

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**Plenary Session 4**

16:15 **Reports from the Workshops** by the Rapporteurs

16:45 **Forum Discussion** on “Which ethics committee system would be the best for Serbia?”

**Chairperson:** *Dr Sinisa Radulovic*, Head, Clinical Trial Approval Committee, Serbia

**Workshop Rapporteurs**

17:15 Closing remarks

*Dr Jean-Pierre Tassignon*, Executive Vice President, PSI Pharma Support & Chairman, EFGCP, Switzerland

17:30 End of day two - Exhibition free time