INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Clinical Trial Safety

Training Course, 27th – 28th May 2010, Belgrade, Serbia

(Faculty of Pharmacy, University of Belgrade - 450, Vojvode Stepe Street - 11221 Belgrade)

Day 1: Thursday 27th May 2010

Chairpersons: Brian Edwards and Vid Stanulovic

8.30 to 9.00 am Registration

9.00 to 9.10 am
Joint Welcome remarks
Introduction Course objectives
Marija Petronijević, Medicines and Medical Devices Agency of Serbia (ALIMS)
Viola Macolić-Sarinić, Croatian Agency for Medicinal Products and Medical Devices
Natália Kocánková, PharmaSwiss, Prague, Czech Republic

9.10 - 9.50 am
Current legal requirements in South-East Europe: application of EU CTD
Maja Lovrek, WorldWide Clinical Trials, Croatia
Zorica Vucinic, Medicines and Medical Devices Agency of Serbia (ALIMS)

9.50 – 10.20 am
Essentials of GCP and ethics:
basis of Declaration of Helsinki and importance of informed consent
Sinisa Radulović, National Cancer Research Center, Belgrade

10.20 – 11.00 Panel discussion

11.00 – 11.30 am
Coffee-break

11.30 – 12.30 pm
Good investigator site practice: Role of the chief investigator/ principal investigator; Role of the coordinating centre and trials unit
Role of the trial coordinator, Hervé Le Louet, ISoP

12.30 – 1.00 pm
Team work exercises
Brian Edwards, ISoP

1.00 - 2.00 pm
Lunch

2.00 pm to 5.00 pm

2.00 – 2.30 pm
Role of ethics committees and regulatory agencies in Clinical trial authorisation and monitoring
Brian Edwards, ISoP

2.30 – 3.00 pm
Regulatory Reporting and Other Communication of Safety Information from Clinical Trials
Natália Kocánková, PharmaSwiss, Prague, Czech Republic

3.00 – 3.30 pm
Coffee-break

3.30 – 4.30 pm
Medical Monitoring in Clinical trials
CRO perspective
Pavle Vukojević , Pharm-Olam Group Ltd, Belgrade, Serbia

4.30 – 5.00 pm
Discussions and open forum and Close of Day 1

Day 2: Friday 28th May 2010

Chairperson: Vid Stanulovic

Welcome to Day 2

8.30 am to 1.00 pm

8.30 – 9.10 am
Expectedness, Collection & Management of safety data
Brian Edwards, ISoP

9.10 – 10.30 am
Causality assessment in hepatotoxicity
Milena Miljkovic, Medicines and Medical Devices Agency of Serbia (ALIMS)

10.30 – 11.00 am
Coffee-break

11.00 – 12.00
Examples to work on
Brian Edwards, ISoP
Natália Kocánková, PharmaSwiss, Prague, Czech Republic
Deirdre McCarthy, ISoP

12.00 – 1.00 pm
Feedback on examples from groups

1.00 – 2.00 pm
Lunch

2.00 pm – 5.15 pm

2.00 – 3.00 pm
Signal detection and Risk Management in clinical trials
Brian Edwards, ISoP
Hervé Le Louet, ISoP

3.00 – 3.30 pm
Coffee-break

3.30 – 4.15 pm
Clinical trials in Oncology and HIV
Katarina Ilic, School of Pharmacy, Belgrade, Serbia

4.15 – 5.15 pm
Pulling it all together: panel discussion and open forum
Closing remarks

***

The International Society of Pharmacovigilance gratefully acknowledges assistance from ALIMS (Medicines and Medical Devices Agency of Serbia) and the Faculty of Pharmacy in Belgrade as partners co-organizers