



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

## Clinical Trial Safety

Training Course, 27<sup>th</sup> – 28<sup>th</sup> May 2010, Belgrade, Serbia

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

Enquiries: ISoP Phone and Fax +44 (0)20 3256 0027  
[www.isoonline.org](http://www.isoonline.org)      [administration@isoonline.org](mailto:administration@isoonline.org)

This is a two day learning program and consists of a collection of talks and interactive workshops given by international pharmacovigilance experts. The clinical trial safety program is dedicated to introduce important basic concepts around what is a Safe Clinical Trial. It is aimed at all interested health professionals and participants with a basic background in clinical trials and drug safety.

The programme will be held in the historic city of Belgrade, one of the oldest in Europe.

### TARGET AUDIENCE:

- Physician investigators and clinical research coordinators wherever based.
- Medical directors, project managers, CRAs, Clinical trial coordinators or administrators in the pharmaceutical industry and CROs wherever based.
- Members of ethics committees.

**AIM:** The effective use of all available resources - people, equipment and procedures - to enhance safety of clinical research and remain focused on how safety matters to research participants.

### OBJECTIVES:

Understand the importance of team-working in delivering safety and its application to decision-making; situational awareness; leadership; communication; error management; personality and behaviour,

Derive meaning from the Declaration of Helsinki to develop core standards for behaviour,

How to apply ICH and CIOMS to Clinical Trial safety,

Application of EU Clinical Trial Directive,

How to prioritise and develop appropriate documentation of safety,

Apply best practice in expectedness assessment and how it is extrapolated from reference safety information: IB/CCSI/SPC,

Recognising all forms of safety evidence from trials and how to collect it.

## Day 1: Thursday 27 May 2010

**Chairpersons: Brian Edwards**

8.30 to 9.00 am      Registration and Coffee

**9.00 to 9.10 am**

**Joint Welcome remarks**

**Introduction Course objectives**

Marija Petronijevic, Medicines and Medical Devices Agency of Serbia (ALIMS)

Viola Macolic-Sarinic, Croatian Agency for Medicinal Products and Medical Devices

Natalia Kocankova, PharmaSwiss, Prague, Czech Republic

**9.10 - 9.50 am**

**Current legal requirements in South-East Europe: application of EU CTD**

Maja Lovrek, ALMP, Croatia

Zorica Vucinic, Medicines and Medical Devices Agency of Serbia (ALIMS)

**20 mins each**

**9.50 – 10.20 am**

**Essentials of GCP and ethics:**

**basis of Declaration of Helsinki and importance of informed consent**

Sinisa Radulovic, National Cancer Research Center, Belgrade

**30 mins**

**10.20 – 11.00 Panel discussion**

**20 mins**

**11.00 – 11.30**

**Coffee-break**

**30 minutes**

**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, Herve Le Louet, ISoP

**1 hour**

**12.30 – 1.00 pm**

**Team work exercises**

Brian Edwards, ISoP

**(30 minutes)**

**Lunch**

**1.00 - 2.00 pm**

**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**

Deirdre McCarthy, ISoP

**(30 minutes)**

**2.30 – 3.00 pm**

**Regulatory Reporting and Other Communication of Safety Information from  
Clinical Trials** (30 minutes)

Natalia Kocankova

**3.00 – 3.30 pm**

**Coffee-break**

**30 minutes**

**3.30 – 4.30 pm**

**Medical Monitoring in Clinical trials**

**(1 hour)**

CRO perspective

Pavle Vukojevic, Pharm-Olam Group Ltd, Belgrade, Serbia

**4.30 – 5.00 pm**

**Discussions and open forum and Close of Day 1**

**(20 minutes)**

## Day 2: Friday 28 May 2010

### *Chairpersons:*

**Welcome to Day 2**

**8.30 am to 1.00 pm**

**8.30 – 9.10**

**Expectedness, Collection & Management of safety data**

Brian Edwards, ISoP

**(50 minutes)**

**9.10 – 10.30 am**

**Causality assessment in hepatotoxicity**

Milena Miljkovic, ALIMIS

**(50 minutes)**

**10.30 – 11.00 pm**

Coffee-break

**(30 minutes)**

**11.00 – 12.00 am**

**Examples to work on**

Brian Edwards, ISoP

Natalia Kocankova, PharmaSwiss, Prague, Czech Republic

Deirdre McCarthy, ISoP

**(1 hour)**

**12.00 – 1.00 pm**

**Feedback on examples from groups**

**(1 hour)**

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 (1 hour)**

Herve Le Louet, ISoP

**3.00 – 3.30 pm**

Coffee-break

**(30 minutes)**

**3.30 – 4.15 pm**

**Clinical trials in Oncology and HIV**

Katarina Ilic, School of Pharmacy, Belgrade, Serbia

**(45 minutes)**

**4.15 – 5.15 pm**

**Pulling it all together: panel discussion and open forum**

**(45 minutes)**

Closing remarks

**(10 minutes)**