



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Basic Concepts in Pharmacovigilance

Training Course, 26-27 March 2009, Verona, Italy
(University of Verona - Via Paradiso 6 – 37100 Verona)

Day 1: Thursday 26 March 2009

Chairpersons: Ugo Moretti and Kenneth Hartigan-Go

8.30 to 9.00 am Registration

9.00 am to 1.00 pm Basic Principles

9.00 to 9.10 am
Introduction- Course objectives
Kenneth Hartigan Go, ISoP

9.10 – 9.50 am
Principles and Mechanisms of adverse drug reactions
Important lessons
Alexander Dodoo, ISoP

9.50 – 10.30 am
Vaccino-vigilance
Kenneth Hartigan-Go, ISoP

10.30 – 11.00 am
Coffee-break

11.00 – 11.45 am
Pharmacovigilance of herbal medicines
Francesca Menniti- Ippolito, Istituto Superiore di Sanità, Roma

11.45 – 12.45 pm
Pharmacogenetics: basic aspects and recent advances
Munir Pirmohamed, University of Liverpool, UK

12.45 pm to 1.00 pm
Open Forum for Questions and Answers

Lunch



2.00 pm to 5.30 pm Methodologies and Tools for Pharmacovigilance

2.00 – 2.30 pm

Individual case safety reports: building blocks of the system

Brian Edwards, ISoP

2.30 – 3.00 pm

Spontaneous reporting: biases, benefits and limits

Part I : Eugene van Puijenbroek, ISoP

3.00 – 3.30 pm

Spontaneous reporting: biases, benefits and limits

Part II : Ugo Moretti, University of Verona

3.30 – 4.00 pm

Coffee-break

4.00 – 4.30 pm

Working with individual and aggregate cases:

Causality assessment I

Nicholas Moore, ISoP

4.30 – 5.30 pm

Causality Assessment II : exercises

John McEwen, ISoP

Close of Day 1



Day 2: Friday 27 March 2009

Chairpersons: Thierry Trenque and Alex Dodoo

Welcome to Day 2

9.00 am to 1.00 pm Translational Pharmacovigilance

9.00 am to 9.50 am

Independent information needed to assist in causality assessment and evaluation – a critical utilization of medical literature

Francesco Salvo, University of Messina, Italy and University of Bordeaux, France

9.50 – 10.40 am

From safety signal to action

Marie Lindquist, ISoP

10.40 – 11.10 am

Coffee-break

11.10 – 12.00 pm

Medication errors

Jeffrey Aronson - Oxford University, UK

Open Forum for Questions and Answers

Lunch

2.00 pm – 5.30 pm Basic Risk Management Principles

2.00 – 3.00 pm

Risk management and the prevention of adverse drug reactions: a panel discussion with regulatory, industry, research organization, clinical, and public health experts.

Ambrogio Bottoni, Pfizer International Pharmacovigilance, Milan

Ralph Edwards, UMC, Sweden

John McEwen, ISoP

Nicholas Moore, ISoP

(facilitator: Kenneth Hartigan-Go)

3.00 – 4.00 pm

Workshop on how the System should Manage Risk

Developing processes for PV within the Industry – requirements, techniques and evaluation

(facilitators: Brian Edwards, Eugene van Puijenbroek, John McEwen)



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Coffee-break

4.00 – 5.30 pm

Movie screening: The Legal aspects of pharmacovigilance

(facilitator: Kenneth Hartigan-Go)

Closing remarks