1st ISoP-UMC Training course

Ensuring Safe Medicines:
How harmonisation underpins international pharmacovigilance

5-7 June 2014, Makati (Manila) – Philippines

Asian Institute Management (ABS-CBN Case room), 123 Paseo de Roxas St, Makati City

Programme

Day 1 Thursday June 5	
08:30	*Registration*
	Chairperson: Kenneth Hartigan-Go (ISoP EC Member)
09:00-09:15	Opening words and introduction Introduction of ISoP: History, vision and mission and programmes *By Hervé Le Louet (President of ISoP)*
09:15-09:30	Introduction of the UMC: history, vision and mission and activities *By Anki Hagström (UMC)*
	Harmonization and adherence to international standards for Adverse Drug Reaction reporting systems
09:30-09:50	The WHO Programme for International Drug Monitoring *By Anki Hagström (UMC)*
09:50-10:10	National Centre ADR Reporting Systems *By Siti Asfijah Abdoellah (National Agency of Drug and Food Control, Indonesia)*
10:10-10:30	ICRS submission from Industry: Current practice and issues. How harmonization can improve the quality of safety data. (Lecture and panel discussion) *By Jean-Christophe Delumeau (Bayer, Asia-Pacific)*
10:30-11:00	Panel and open forum
11:00-11:30	*Coffee Break*
	Individual Case Safety Reports (ICSRs) *Chairperson: Maria Victoria Calub (FDA Philippines)*
11:30-12:00	What is an ICSR? Advantages of structured data and the importance of the narrative *By Pia Caduff (UMC)*
12:00-12:30	New regulatory initiatives employing Pharmacogenetics; the Singapore's experience *By Cheng Leng Chan (HSA Singapore)*
12:30-13:30	*Lunch*
	Risk Management *Chairperson: Sonia Bongala (Makati Medical Center)*
13:30-14:30	Drug Risk Management, an European perspective *By Hervé Le Louet (President, ISoP)*
14:30-15:00	Detection of possible risks related to the use of medicines *By Minerva Calimag (University of Santo Tomas Faculty of Medicine and Surgery, Philippines)*
15:00-15:30	*Coffee Break*
15:30-16:30	Risk minimization strategies: what is risk management planning and how is this related to product safety and undertaken by both regulators and industry? *By Hervé Le Louet (President, ISoP), Jean-Christophe Delumeau (Bayer, Asia-Pacific) and Cheng Leng Chan (HSA Singapore)* (Panel discussion)
16:30-17:00	Open forum and Concluding remarks

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Day 2 Friday June 6		
	PV Methodologies (part I) *Chairperson: Ian Boyd (ISoP EC member)*	
09:00-10:00	Industry pharmacovigilance practices: Organisation, systems, operations, governance, and interface with Health Authorities. *By Jean-Christophe Delumeau (Bayer, Asia-Pacific)*	
10:00-10:30	*Coffee Break*	
10:30-11:30	Effective data analysis and causality assessment protocols. How to detect and analyze biases and make better analysis. *Chairperson: Minerva Calimag (University of Sto Tomas Faculty of Medicine and Surgery, Philippines)* Practical exercises in causality assessment for medicine products, and vaccines. Understanding the real problems of therapeutic failures, interactions, programme errors in assessment. *By Ian Boyd (ISoP EC member) and Suzette Lazo (Philippine Society of Experimental and Clinical Pharmacology)*	
11:30-12:00	Application of PV methods for Clinical Trials: Experience with local industry *By Herbert Ho (President of the Philippine Society of Experimental and Clinical Pharmacology)*	
12:00-13:00	*Lunch*	
13:00-15:30	**Session A** **PV methodologies (part II)** For the National PV Centers participants	**Session B** **Clinical and pharmacological assessment of adverse drug reactions**
	ICSR management software tools (a discussion on home built, vendor provided or WHO standard tools i.e. - VigiFlow™ and VigiLyze). Hands-on session: VigiLyze introduction *By Pia Caduff and Anki Hagström (UMC)*	What is the contribution of Clinical Trials in providing information about safety profile of a drug? How can clinical trials be improved to capture data needed by both industry and regulators? (panel discussion with case examples). *By Ian Boyd (ISoP EC member) and Minerva Calimag (University of Sto Tomas Faculty of Medicine and Surgery, Philippines)*
15:30-16:00	*Coffee Break*	
16:00-17:00	Data analysis management and what is considered efficient best practice. (webinar) *By Tomas Bergvall (UMC)*	

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Day 3 Saturday June 7	
	Chairpersons: Pia Caduff, Anki Hagström (UMC)
09:00-10:00	Assessment of Pharmacovigilance Systems in Five Asian Countries. *By Michael Gabra, Management Sciences for Health (MSH)*
10:00-10:30	*Coffee Break*
10:30-12:00	**Regulatory decision-making** Panel discussion chaired by Kenneth Hartigan-Go (ISoP EC member), Cheng Leng Chan (HSA Singapore), Siti Asfijah Abdoellah (National Agency of Drug and Food Control, Indonesia) 1. How are ADRs, Signals translated into policy and into regulatory actions? 2. Reactions to the earlier presentation in the morning.
12:00-13:00	*Lunch*
13:00-15:00	Communication and dissemination of pharmacovigilance information towards the public and other stakeholders. An analysis and discussion of the vaccine AEFI misinformation case study. *By Kenneth Hartigan-Go (ISoP EC member)*
15:00-15:30	*Coffee Break*
15:30-16:00	Concluding remarks. Joint-statement from UMC and ISoP. *By the Chairpersons and Presenters*
16:30	*End of the meeting*

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