



The ISoP Star

NEWS AND REPORTS FROM ISoP – No 32. June 2016

ISoP in Manila

The recent mid-year training course was held in Manila-Makati (AIM), 25th-27th April, 2016.

Coordinators: K. Hartigan-Go and U. Hagemann

ISoP Mid Year Training Course
Makati-Manila 25-27 April 2016

PV Management: Devising and organizing effective operations for ensuring safe and appropriate use of medicinal products.



This three day-course was attended by 68 participants from 16 countries, with both private and public organizations represented.

The course was particularly designed for interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used, where strengthening pharmacovigilance translates to better patient care.

Highlights of the course included: a site-visit to the Makati Medical Center exploring hospital drug management systems in the Philippine context; and a lecture series covering topics on organizational management approaches to pharmacovigilance, health technology assessment, fundamental aspects of adverse drug reports and SRSs, new sources of data/information and signal detection and management, and a panel on the Dengue fever vaccine.



Participants and Speakers of the ISoP Training Course with the medical staff of Makati Medical Center, 25 April 2016

More information about this course can be found at

<http://isoponline.org/training/training-courses-mid-year-manila-2016/>

Venue and details about next mid-year's training course will be provided in due course.

Call for Annual Meeting bids

If you (or colleagues) would like your country to host an ISoP Annual Meeting, please contact the Administration Office and ask for the guidelines for bids.

ISoP 2016 Agra

16th Annual Meeting – Agra, ISoP 2016

16th – 19th October 2016

(Hotel Mughal ITC)

in association with Society of Pharmacovigilance India

'Pharmacovigilance for safer tomorrow'

www.isop2016agra.org



Closing date for submission of oral and poster abstracts is 7th June 2016. When submitting an abstract, presenters must register to attend the meeting before an abstract can be accepted by the Scientific Committee. Abstracts must be submitted in ENGLISH.

The scientific programme is almost completed with 2 pre-conference courses on the agenda and a panel of international experts. An exciting social programme is included in the registration fee offering an affordable occasion for ISoP members to come to India.

Registration (discount for ISoP members)

Save money and register now! Early bird registration can be made until 31st July.

Information : ISoP 2016 Conference Secretariat

E-mail: isop2016@gmail.com



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Sunday 16th October

2 Pre-conference courses / Full Day (08.00-18.00)

Registration

- Course 1- Essential elements and solutions for advancing risk management and risk communication
- Course 2- Advanced Signal detection

Welcome reception

Provisional programme/ Main conference

Monday 17th October (08.00- 19.00)

Registration, welcome and opening ceremony

Opening lecture: CIOMS lecture - Ethics in pharmacovigilance

Coffee-break / Posters viewing

Plenary sessions : 21st Century Pharmacovigilance: Intuition, Science, and the Role of Artificial Intelligence (*Peter Pitts, Center for Medicine in the Public Interest- USA*)

Big Data, Smart Data, fast Data - a paradigm shift (*Andrew Bate, Pfizer-UK*)

Lunch

Session A: Risk Communication and Management (re CommSIG)

Session B: Medicines for women

Coffee-break / Posters

Session C: Evidence Based PV decision making

Session D: Catch them young - providing

opportunities and a career path for young scientists to undertake research in pharmacovigilance and epidemiology)

Plenary session: Chapters meeting

Tuesday 18th October (8.30-17.30)

Symposium: Monitoring of drugs of Indian Systems of Medicine (ISM)

Coffee-break / Posters viewing

Session E: Challenges of Complementary Medicines and pharmacovigilance

Session F: Integration of pharmacovigilance in Public Health Programmes

Lunch

ISoP General Assembly (13.30-14.45)

PRAC session-round table (Pharmacovigilance Risk Assessment Committee) "The impact of PRAC, and global PV regulations; how this affect countries around the world" (*Brian Edwards- UK*)

Coffee-break/Posters viewing

Session G: Medication errors Vs medical negligence

Session H: Financial burden of pharmacovigilance
Conference Dinner

Wednesday 19th October (09.00-14.00)

Session I: Emerging and re-emerging diseases and role of PV

Session J: Clinical aspect of pharmacovigilance (Antidiabetic, Oncology/cancer, critically ill-patients)

Coffee-break

Bengt Erik Wiholm Lecture (plenary session) (*Ralph Edwards, UMC*)

Poster Prize Awards - Presentation for ISoP 2017 and Closing Ceremony of ISoP 2016.

Visit regularly the conference website for updates
<http://www.isop2016agra.org/scientific-program>



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ISoP 2017 Liverpool



Liverpool, city of North West England, will host the 2017 Annual Meeting. More details will be available in due course.

3rd ISoP-UMC Training

In January 2016, a revised Memorandum of Understanding establishes a strategic framework for a training collaboration. It was signed by ISoP and UMC officials. After the Asia continent, UMC and ISoP have identified a capacity building need in the Latin America region and a need to further strengthen pharmacovigilance systems. Therefore, it was decided that the third pharmacovigilance training course jointly organized by ISoP and UMC will take place in **Lima, Peru from 7 to 9 September 2016.**



Register now!

This three day-course entitled “*From case reports to benefit harm assessment and risk communication*” is aimed to engage all interested pharmacovigilance

professionals in a regulatory, industry, hospital, university or community setting. More information about programme and registration at <http://isoponline.org/training/isop-umc-training-courses/>

Statutes and Elections

The recommendations of the task force strategic review were examined and discussed with the membership during the ISoP 2015 General Assembly in Prague on the 29th October 2015 with one of the main objectives being to mandate the President to consult upon and establish the new governance of ISoP.

The Executive Committee of ISoP has now finalized the modifications of the ISoP Statutes with the main goal of having a smaller and more compact Executive Committee within an Advisory Board structure. This will give ISoP a more agile operational structure which will be more appropriate for enabling efficient operations for an international Society. The President commends to the membership that these changes are necessary in order to move forward to create a Society which can efficiently lead the future development of pharmacovigilance globally.

Following our current Statutes (Articles 15.1; 15.2), the modified Statutes must be submitted to and approved by the General Assembly. At least half plus one of the active paid-up members must be present at this Assembly.

An ISoP General Assembly has therefore been convened in London, at 19h00 on **Wednesday 8 June 2016** at the UCL School of Pharmacy 29-39 Brunswick Square, London WC1N 1AX, UK.

In the event of this General Assembly not being quorate, the vote will be held during a further extraordinary General Assembly which will take place in London, on **Friday 8 July 2016** at 14h00 at the UCL School of Pharmacy 29-39 Brunswick Square, London WC1N 1AX, UK.

This decision will then be valid whatever the



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number of members present. Preparation to the Elections of the new Board will then follow (online vote).

You should have received with a letter e-mailed to you on 8 May the propositions for modification of our Statutes. For consultation, please visit our website www.isoponline.org where you will find the current statutes under the section 'Statutes & by-laws' <http://isoponline.org/statutes-and-by-laws/>

**Please check your Spam box regularly if you have not received any message from administration@isoponline.org*

ISoP Board Elections

As you know, the leadership arrangements for ISoP has changed with the coming in force of new ISoP Statutes that aim to make the running of the society more efficient. What used to be the Executive Committee is now changed to be known as the ISoP Board (please see the new statutes).

Elections of eligible members to the new ISoP Board will take place in the first week of September. The vote would be done on-line. There will be 10 vacancies that need to be filled.

As soon as elected, the ISoP Board will propose and elect a President from amongst the Board members by online ballot. The new President and the officers (Executive Committee) will be in place for the Annual Meeting in Agra in October to have its first meeting.

Would you have the time and the opportunity to commit to undertaking the role of a member of the (new) ISoP Board?

Would you like an opportunity to contribute and help ISoP to become a robust, professional and leading society in Pharmacovigilance?

... then we are interested in hearing from you!
Paid-up members with appropriate skills and experience who would like to put themselves

forward as a candidate are invited to contact the Nominating Committee directly by 10 July 2016 (please contact Alex Dodoo at alex.dodoo@who-pvafrica.org or alexooo@yahoo.com with any queries).

PV Curriculum

Contributors to the crowdsourcing pilot <http://isoponline.org/training/pv-curriculum/> developed a draft article describing the purpose, content, and functionalities of the crowdsourcing tool. The article will be submitted to the Editor mid-year and published in *Drug Safety*. Thereafter the crowdsourcing tool will be enriched, announced and propagated for wider use. A presentation will be given at the ISoP 2016 Annual Meeting in Agra.

isoponline.org survey



Thank you for your responses!

Initiated by Y Moride, the web-based application Survey monkey was used to design a questionnaire about the ISoP website. Members were asked to rate the ISoP website (launched last year), as it is important for the Society to understand what has been their experience in order to plan further improvements and make sure that the website meets the members' needs and interests.

On 22 March, 580 ISoP members, whose e-mail addresses were known, received an invitation to complete the short questionnaire. On 8 April, a reminder was sent. Deadline for completing the survey was 18 April. 10% responses were received and we would like to thank you again for your votes and interesting comments.

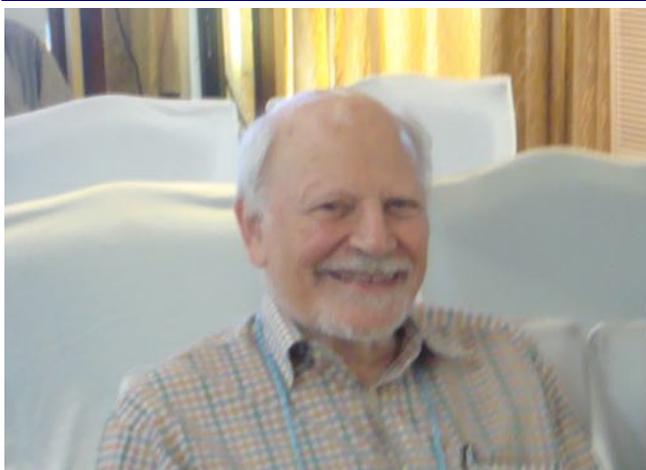


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The survey report outlining the main priorities from the members, with possible and reasonable improvements to be implemented on the website will be posted on our website and presented at the next Annual Meeting in Agra, India in October 2016.

Dr Andrew Herxheimer 1925-2016



A Herxheimer in ISoP 2010 Accra (November 2010)

Dr Andrew Herxheimer, honorary member of ISoP, died on 22 February 2016.

ISoP and the global public health community have lost a dear colleague and friend who showed unwavering lifelong passion in protecting and acting in the interests of patients especially those whose voices went unheard.

Dr Andrew Herxheimer was a clinical pharmacologist in the Cochrane Collaboration, Emeritus Fellow of the UK Cochrane Centre, a convenor of the Cochrane Collaboration Adverse Effects Methods Group, and the founding member of International Society of Drug Bulletins (ISDB).

Dr Herxheimer became a honorary member of ISoP in October 2010, at the General Assembly in Accra, Ghana. Always active, he was a keen supporter of ESOP (European Society of Pharmacovigilance) and thoroughly enjoyed

attending the Society meetings and welcomed the opportunity for lively debate in a way that will be fondly missed.

More News from ISoP

★ **ISoP monograph:** 'Pharmacovigilance: critique and ways forward' will be published by September by Springer. Thank you to the 17 contributors!

★ If ISoP members or ISoP chapters feel a strong need for PV training in their country, please contact us at training@isoponline.org

★ **Most of the presentations from the ISoP 2015 Annual Meeting** held in Prague last October are posted on the ISoP website. To view them, please log-on <http://isoponline.org/members/isop-annual-meeting-presentations/> To gain access to the presentations, you will have to register in the Members' Section and follow instructions on screen (if you have forgotten or lost your password, you can generate a new password; to generate your password simply click on the link which says 'Forgot your password?' you may copy and paste the password when received)

★ Important dates / Revised statutes

General Assembly at 19h00 on Wednesday 8 June 2016 at the UCL School of Pharmacy 29-39 Brunswick Square, London WC1N 1AX, UK (Maplethorpe lecture Hall)

In the event of this General Assembly not being quorate, the vote will be held during a further extraordinary General Assembly which will take place in London, on Friday 8 July 2016 at 14h00 at the UCL School of Pharmacy 29-39 Brunswick Square, London WC1N 1AX, UK.

(The UCL School of Pharmacy is located just a three minute walk to Russell Square tube station and only a ten minute walk to Kings Cross, Euston and St Pancras International train stations)



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★ **2016 ISoP Annual General Assembly** will be held during the 16th ISoP Annual Meeting in Agra, India and will take place from 13h30 to 14h45 on Tuesday 18th October (Hotel Mughal ITC)

★ **Chapters:** We look forward to the launch of the Chinese Chapter during the 16th ISoP Annual Meeting in Agra, next October. Find out more about chapters at <http://isoponline.org/chapters/>

★ **Joint session ENTIS-ISoP:** The European Network of Teratology Society (ENTIS) together with the International Society of Pharmacovigilance (ISoP) organized a joint training meeting entitled “Risk assessment of drug use during pregnancy – human teratogens” in Berlin, Germany, on the 2 and 3 June 2016 at the Berlin Brandenburg Academy of Science (BB-A)



C Weber-Schoendorfer (ENTIS President) and H Le Louet (ISoP President) opening the meeting in Berlin/BB-A

★ **CIOMS** (the Council for International Organizations of Medical Sciences) is pleased to announce the appointment of Dr Lembit Rägo as its new Secretary-General

★ **32nd International Conference on Pharmacoepidemiology & Therapeutic Risk Management**

25 – 28 August 2016 – Dublin, Ireland

Organized by ISPE

<https://www.pharmacoepi.org/meetings/32ICPE/>

Drug Safety Journal

As part of their membership, all ISoP members receive an electronic access to the journal *Drug Safety*, and therefore the printed version of the *Drug Safety* journal is not anymore available.

The link to the journal *Drug Safety* must be clicked from within the ISoP Members Section on the ISoP website in order to obtain online access (and not from the Springer/*Drug Safety* website).

Only members who are paid-up will have access to membership benefits and voting rights.

(if / when you have forgotten or lost your password, you can generate a new password; to generate your password simply click on the link which says ‘Forgot your password?’. You may copy and paste the password when received).

Send your letters, comments and contributions for ISoP Star to:

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