



# The ISoP Star

NEWS AND REPORTS FROM ISoP – No 24. August 2012

## ISoP went to Berlin



This year on 11 -12 June, ISoP conducted two parallel training courses in Berlin, Germany. It was decided to have these training courses in the European Union because of the July implementation date of the new EU pharmacovigilance legislation.

'New EU Post-licensing Legislation and Benefit-Risk Management' and 'Future perspectives for EU Pharmacovigilance' were therefore the themes of the courses. With 50 participants and a group of international speakers, these were very successful meetings.

The ISoP workshops provided a forum for intense discussion on major legal changes and methodological challenges. Apart from work, attendees enjoyed the wonderful atmosphere at the meeting venue and in the vibrant city of Berlin in the summer time.

ISoP offered 4 bursaries to young researchers in pharmacovigilance and who are members of ISoP to attend the training courses. Here is an extract from one of their reports:

*"Having a bursary from ISoP to attend this course gave me a great opportunity to get clear understanding of the rationale behind the changes of this EU post-marketing legislation, the major changes, the modular structure of the new PV guidelines entitled "Good Vigilance Practice - GVP", the course also gave special focus to the Risk Management Plans including the newly introduced Post Authorization Efficacy Studies, Benefit optimization and Risk minimization.*

*.... Furthermore I had a chance to communicate directly with colleagues from other regulatory authorities and from industry as well, the discussions that took place during the breaks were fruitful to benefit from their experiences and on the other hand to familiarize them*

*with the Egyptian Pharmacovigilance experience and to exchange contacts for future co-operation."*

Hadir Mamdouh Ahmed, Team leader of EPVC & rapporteur of the pharmacovigilance committee

More information about both these courses can be found at <http://www.isoponline.org/index.php?page=training>



Course participants and faculty in Berlin

## Mid-year Training courses

The next ISoP training courses will take place in March 2013 in Asia with a basic Pharmacovigilance course to be held back-to-back with an advanced course as on previous occasions. Venue and details about next year's training will be provided in due course.

## ISoP 2013 Italy

*"The Renaissance of Pharmacovigilance"*. Pisa is the venue for next year's Annual Meeting (1-4 October 2013) with pre conference courses on the agenda. The local organizer (LOC) is Dr Marco Tuccori from the University of Pisa and Dr Hervé Le Louet (France) will chair the scientific committee.

The 13<sup>th</sup> ISoP Annual Meeting (ISoP 2013) will follow the Annual Meeting of the WHO Programme (to be held in Rome). More information in September at [www.isop2013pisa.org](http://www.isop2013pisa.org)



M Tuccori (LOC), H Le Louet (EC), U Moretti (EC)

## Call for Annual Meeting bids

If you (or colleagues) would like your country to host the 2014 ISoP Annual Meeting, please contact the Administration Office and ask for the guidelines for bids.

## More News from ISoP

★ 12<sup>th</sup> Annual Meeting – Cancun, ISoP 2012  
30 Oct-02 Nov 2012 - [www.isop2012.org](http://www.isop2012.org)

★ The ISoP Italian Chapter will organize a training course (in Italian): *"Management of Spontaneous reports of adverse reactions in health System Units"* on 22 September 2012 - Pisa, Italy. More information at: [drugs.pisa@gmail.com](mailto:drugs.pisa@gmail.com)

★ With ISoP Swiss-Austrian Chapter endorsement, a scientific conference on *"Psychotropic Medication: Risks and Risk Management"* (in German) will be held on 26-28 September 2012 - Königsfelden, Brugg, Switzerland. Programme and information: [www.tagung2012.ch](http://www.tagung2012.ch)

★ In planning for next year's Annual Meeting, are there any current issues or scientific topics/symposia you feel should be included in the forthcoming scientific programme? It would help us if you could provide us with your suggestions as we would like the content of our Annual Meeting to reflect our members' wishes (see Questionnaire section).

★ Most of the presentations from the ISoP Annual Meeting held in Istanbul last October are posted on the website of the society. To view them, please log-on  
at: <http://www.isoponline.org/index.php?page=me>

members-section

To gain access to the presentations, you will have to register in the Members Section and kindly follow instructions on screen.

★ 2011 ISoP General Assembly, during the 11th Annual Meeting, Istanbul – Turkey. Minutes are posted on the ISoP website [at :  
http://www.isoponline.org/general-assembly.html](http://www.isoponline.org/general-assembly.html)

★ 2012 ISoP General Assembly will be held during the 12th ISoP Annual Meeting in Cancun, Mexico and the ISoP General Assembly will take place from 13.45 to 14.30 on Thursday 01 November 2012 (JW Marriott)

★ Statutes and by-laws of the Society are posted on the ISoP website  
<http://www.isoponline.org/statutes.html>

★ National Chapters: We look forward to the launch of the Balkan Chapter during the 12<sup>th</sup> Annual Meeting in Cancun, Mexico.

★ June 2012 issue of "Pharmacology International" [www.iuphar.org/pdf/Pharmacology International  
2012 June.pdf](http://www.iuphar.org/pdf/Pharmacology%20International%202012%20June.pdf)

This issue of "Pharmacology International" announces the upcoming position paper describing clinical pharmacologists and their roles in health care, teaching and research, which was prepared by representatives of IUPHAR for the World Health Organization and the Council for International Organizations of Medical Sciences.

★ A book to read: "First, do less harm: Confronting the Inconvenient Problems of Patient Safety (2012)". Edited by Suzanne Gordon and Ross Koppel. <http://suzannegordon.com/books-resources/>

★ Pharmacovigilance tool kit: a collection of resources and information needed for the practice of pharmacovigilance <http://www.pvtoolkit.org/>

## ISoP 2012 Mexico

12<sup>th</sup> Annual Meeting – Cancun, ISoP 2012 on 30 October – 02 November, 2012 (Cancun, Mexico, JW Marriott) ' *New Landscapes for Pharmacovigilance*'  
[www.isop2012.org](http://www.isop2012.org)



**CANCÚN 2012**  
New Landscapes for Pharmacovigilance  
12<sup>th</sup> ISoP ANNUAL MEETING

The scientific programme is ready with 3 pre-conference courses on the agenda, and an exciting social programme included in the registration fee offering an affordable occasion for ISoP members to come to Cancun.

**Registration** (discount for ISoP members): Save money and register now!

Early bird registration until 15 August

**Information** : ISoP 2012 Conference Secretariat

E-mail: [isop2012@grupodestinos.com.mx](mailto:isop2012@grupodestinos.com.mx)

Please check the Ministry of Foreign Affairs website for updated information and information on which passport holders may require a visa  
<http://portal3.sre.gob.mx/english/>

## Programme ISoP 2012

### Tuesday 30 October (08.30-17.30)

Pre-conference courses / Full Day

Registration

- Basics in Pharmacovigilance  
(Chair: Eugene van Puijenbroek)
- Vaccines (Chair: tbc)
- New EU-post licensing legislation - EU and beyond  
(Chairs: Deirdre McCarthy, Ulrich Hagemann)

Welcome reception

### Wednesday 31 October (9.00-17.30)

Registration

Welcome and opening ceremony

Plenary session 'Improving the safety of Drugs: opportunities and challenges » (Munir Pirmohamed, UK)

Coffee-break / Posters

Parallel sessions

Session 1: Signal detection

Session 2: Pharmacovigilance in Paediatrics

Lunch

Parallel sessions

Session 3: Studies in Pharmacovigilance (Part I)

Session 4: ISoP/FIP joint session

Coffee-break / Posters

Session 5: Studies in Pharmacovigilance (Part II)

Session 6: Pharmacogenetics and personalized treatments

Thursday 01 November (9.00-17.30)

Parallel sessions

Session 7: ISoP/ISPE joint session

Session 8: Pharmacovigilance in Neglected Diseases

Coffee-break / Posters

Session 9 : Concepts and Methodology

Session 10: Ecopharmacovigilance and Herbal Pharmacovigilance

Lunch

ISoP General Assembly (13.45-14.30)

CIOMS Lecture (Risk Minimisation Tools)

Coffee-break/Posters

Bengt-Erik Wiholm Lecture (Michael Rawlins, NICE)

Round table discussion : Lessons learned from recent safety issues

Conference Dinner

Friday 02 November (09.00- 15.00)

Parallel sessions

Session 11: Regional and Global Developments in Pharmacovigilance (Peter Arlett, EMA)

Session 12 : Pharmacovigilance in Hospitals

Coffee-break

Parallel sessions

Session 13 : Communication

Session 14: Pharmacovigilance of women's medicines and reproductive health

Lunch

Poster Prize Awards Presentation for ISoP 2013 and Closing Ceremony of ISoP 2012



Cancun panoramic view

## Dr. Jeremy Labadie



ISoP learnt with great shock and sadness the tragic death of Dr. Jeremy Labadie (Jerry) after a road traffic accident on Wednesday 1<sup>st</sup> August 2012 in Uppsala Sweden. Jerry's death has sent shockwaves through the global vaccine safety community. Until his untimely and unexpected death, Jerry was the Vaccine Safety Specialist at the Uppsala Mentoring Centre providing great expertise to the UMC and WHO where he was heavily involved in the PMS Network of Countries. Jerry was actively working on the vaccine dictionary; leading efforts on how to ensure that Vigibase (the WHO ICSR database) is able to receive and manage data on Adverse Events Following Immunization and travelling to regularly to member countries to provide training and expertise in vaccine safety. He was one of those physicians who chose to devote their working life to the care for and study of patients suffering from adverse effects of their treatments, skillfully integrating clinical, pharmacological and epidemiological reasoning. His passing away has left a huge void that will be most difficult to fill.

For ISoP, Jerry has been a constant support and active participant and was a presenter at the 2011 ISoP meeting in Istanbul. At the time of his death, Jerry was the chosen chairman and coordinator of the ISoP pre-conference course on Vaccine Pharmacovigilance scheduled for 30<sup>th</sup> October 2012 in Cancun. ISoP will surely miss him.

On a personal level, I met Jerry in 2001 at the UMC Pharmacovigilance Course in Uppsala and have since remained very close friends with him.

We have undertaken vaccine safety studies in Ghana and co-authored a paper on our findings. His change of jobs from the Netherlands Pharmacovigilance Centre, LAREB, to the UMC where I am a Senior Fellow means that our friendship and professional interactions increased greatly especially over the past three years. Dr Jeremy Labadie was a warm, thoughtful, caring and open-minded person and an excellent scientist, public health specialist and teacher. The World Health Organisation, the UMC, ISoP and LAREB have been enriched by his skills and services and will all miss him. I still find his passing away difficult to believe and accept. He was a very good person.

ISoP will like to extend deepest commiserations to his wife Inger, his four children and one granddaughter, his close family and relatives as well as to all his friends, co-workers, colleagues and collaborators. May he rest in peace.

Alex Dodoo, ISoP President

(On behalf of the Executive Committee and entire membership of ISoP)

## Executive Committee Elections

The new Executive Committee has just been elected. Congratulations to all!

The result of the election will be announced publicly during the ISoP General Assembly in Cancun (Mexico), 1st November 2012.

In the meantime, a call for candidates for presidency has been put forth, and the new president will be elected this summer, as well as the officers, so the new EC can have a running start in Cancun at the 12<sup>th</sup> ISoP Annual Meeting.

## ISoP Strategic Meeting

Executive Committee (EC) members and the 3 past presidents of ISoP met on the 09 and 10 June for a strategy meeting. The purpose of this ambitious meeting was to define the wider ISoP strategy –its short, medium and long-term goals as well as how to achieve those goals.

The meeting was facilitated by Bruce Hugman and the idea was to get to a point where there would be a view of the future direction for ISoP (development plan) to hand over to the next generation of EC members.

The outline of the development plan will be presented at the General Assembly in Cancun in November.



B Hugman, R Edwards, E Brown, H Le Louet, N Moore, U Hagemann, M Lindquist, E van Puijenbroek, D McCarthy, U Moretti, G Velo

## Questionnaire

ISoP members will receive a short questionnaire during the summer, based on a list agreed at the strategic meeting, seeking input on priority areas in pharmacovigilance and specific regional needs, to be taken into account when planning future annual meetings and training and education activities. Another aim is to take the Society forward in raising its profile

## isoponline

The website with its layout has a Members section page which will allow you to facilitate the exchange of information between members only. It will give you access to the ISoP online archive of materials used for the various ISoP conferences and presentations.... and because ISoP is on LinkedIn you will enjoy a forum for discussion of pharmacovigilance related issues, and keep in touch with ISoP colleagues.

## LinkedIn ISoP group

Members of the LinkedIn ISoP Group can post questions to the membership - for example, asking how others have handled a particular safety concern, or interpreted safety data or regulations. Make suggestions for research projects, training courses, put questions to the Executive Committee, make known to ISoP members your views on topical issues. You can also post job vacancies and tell members when and where you are travelling in order to meet up with friends and colleagues in different parts of the world.

In the wider context, LinkedIn allows you to publicise your *curriculum vitae*, to make and receive

recommendations for work performed and to create and grow your personal network of acquaintances and colleagues.

So, if you have not already joined, do so today! Just visit <http://www.linkedin.com> and sign up for a free LinkedIn account. Then, when you have joined LinkedIn,

1. Visit the ISoP Online members' section and generate your password at:  
<http://www.isoponline.org/index.php?page=members-section>
2. To generate your new password simply click the link which says "New Users / If you have forgotten your password (or don't have one) click here".
3. Follow the simple instructions which will come up on screen (If you have any problems please contact our webmaster at [simon@seofoundry.co.uk](mailto:simon@seofoundry.co.uk))

When you log in to ISoP Online members section the link to the LinkedIn group will be present. Simply follow that link, submit a request to join and we will welcome you to our Group within a day or two and then you are part of our very special interest group (already 113 members)!

## Have you moved?

If there is a mistake in our database, or you have changed your address e-mail, do let us know as soon as possible!

Please send your letters, comments and contributions for ISoP Star to:

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