



The ISoP Star

NEWS AND REPORTS FROM ISoP – No 30. May 2015

ISoP went to São Paulo

The recent training course was held in São Paulo, 26th-28th March, 2015, in partnership with Anvisa and Sindusfarma.

Coordinator: Ulrich Hagemann

For the first time, ISoP held a training course in Brazil.

Some 110 representatives from pharmaceutical companies, academia, all mainly from Brazil, and from the Brazilian national drug agency Anvisa attended the meeting.

'Basics in pharmacovigilance and new developments' have been the topics of the course.

The scientific programme was aligned with the new WHO-ISoP Pharmacovigilance Curriculum, as far as possible, supplemented by two intermezzi on 'Medical assessment of ADRs' in specific system organ classes. The course started on day 1 with an overview on the history of pharmacovigilance, the pharmacovigilance system in Brazil, both to provide a basis for more specific items like spontaneous reporting and use of ADR data bases, developing Periodic Benefit Risk Evaluation Reports (PBRER), Risk Management Plans, and to elucidate existing international concepts and requirements.

Signal detection, methods in post licensing observational studies, benefit-to-harm assessment of drug related risks as well as medication errors were in the centre of day 2, supplemented by talks about safety of biosimilars, personalized medicine, the work of the WHO Global Vaccine Safety Initiative (GVSI) and consumer reporting.

A lively discussion happened around transparency, openness and communication with patients and the media. The meeting was closed with a strong unanimous plea of the participants to strengthen pharmacovigilance in Brazil by various activities in the near future with the possibility of creating a Brazilian Society of Pharmacovigilance.



Course participants and faculty in São Paulo

More information about this course can be found at <http://isoponline.org/training/isop-training-courses/>

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

ISoP 2016 in USA

There are currently talks to organize next year's Annual Meeting (ISoP 2016) in Boston (USA) in October 2016. Dr Yola Moride (University of Montreal) would chair the scientific committee. More information in due course at www.isoponline.org

Call for Annual Meeting bids

If you (or colleagues) would like your country to host the ISoP 2018 Annual Meeting, please contact the Administration Office and ask for the guidelines for bids.

ISoP 2015 Prague

15th Annual Meeting – Prague, ISoP 2015

27th – 30th October 2015

(Clarion Congress Hotel Prague)

'Cubism in pharmacovigilance'

www.isop2015prague.org



Call for Abstracts You are invited to submit an abstract(s) for presentation as a poster or

oral presentation at the ISoP 2015 Annual Meeting <http://www.isop2015prague.org/abstract-submission-guidelines.htm>

Closing date for submission of oral and poster abstracts is 1st June 2015. When submitting an abstract, presenters must register to attend the meeting and before an abstract can be accepted by the Scientific Committee. Abstracts must be submitted in ENGLISH.

The scientific programme is almost completed with 3 pre-conference courses on the agenda and a panel of international experts, an exciting social programme included in the registration fee offering an affordable occasion for ISoP members to come to Czech Republic.

Registration (discount for ISoP members)
Save money and register now! Early bird registration can be made until 31st July.

Information : ISoP 2015 Conference Secretariat
E-mail: info@isop2015prague.org



Tuesday 27th October

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

Registration

- 1- Risk Management and risk minimization
- 2- Methodologies in Pharmacovigilance
- 3- Pharmacovigilance in MENA (Middle East and North Africa) region

Welcome reception

Provisional programme

Wednesday 28th October (08.00- 19.00)

Registration, Welcome and opening ceremony
Opening lecture: Patient safety today - From identifying problems to implementing solutions (*Nick Sevdalis, King's College London*)
Coffee-break / Posters

Plenary sessions : Future of Pharmacovigilance (*Peter Arlett, EMA*)

Big data including social media. Global perspectives (*Marie Lindquist, UMC*)

Lunch

Session A : Risk Management in Pharmacotherapy

Session B: Vaccines

Coffee-break / Posters

Session C: Risks and benefits of medicines for women

Session D : Benefit/burden of Pharmacovigilance

Plenary session: Chapters meeting

Thursday 29th October (8.30-17.30)

Session E: The roles of PV centers and community involvement

Session F: Emerging sources of PV data

Coffee-break / Posters

CIOMS lecture: Beyond protection: The integrity of science as a fundamental ethical concern (*Alex London, USA*)

Lunch

ISoP General Assembly (12.45-14.45)

PRAC session (Pharmacovigilance Risk Assessment Committee) and roundtable (*June Raine, UK and Hervé Le Louet, France*)

Coffee-break/Posters

Session G: Hospital pharmacovigilance and clinical epidemiology (Swiss-Austrian Chapter session)

Session H: Herbals

Conference Dinner

Friday 30th October (09.00- 14.00)

Session I: Hot topics around the cube

Session J: Methodologies in Signal detection and Safety surveillance

Keynote lecture: Role of genomics in Pharmacovigilance (*Ondrej Slanar, Czech Republic*)

Coffee-break

Bengt Erik Wiholm Lecture (plenary session) : Patient safety through dialogue - how to better connect pharmacovigilance and healthcare? (Round table) *see ISoP CommSIG below

Poster Prize Awards - Presentation for ISoP 2016 and Closing Ceremony of ISoP 2015.



Visit regularly the conference website for updates
<http://www.iso2015prague.org/tentative-programme.htm>

Executive Committee Elections

Following the announcement at the last ISoP General Assembly in Tianjin of an extensive review of ISoP's organisation, policies and procedures, this has now started and the task force producing this strategic review is led by Ralph Edwards. Because roles and responsibilities of the Executive Committee (EC) may change and because of the need to maintain continuity of the EC to deliver change, the current ISoP EC has decided to postpone this year's elections for a new EC for up to a year.

This will enable the recommendations of the strategic review to be examined, discussed and then shared with the membership for their opinion during the upcoming ISoP 2015 General Assembly in Prague on the 29th October.

New isoponline.org



We are very pleased to announce the release of our new website isoponline.org redesigned with a more modern look and a new server and features. We hope you like it!

Visit our website regularly to stay informed about ISoP and its many activities!

An email with 'joining instructions' to set up your new account in the Members' Section has been sent to your registered e-mail address; **as member of ISoP, if you have not received the e-mail, please contact ISoP Administration as soon as possible.**

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

ISoP CommSIG

From Priya Bahri, ISoP CommSIG coordinator

The ISoP CommSIG, the special interest group on medicinal product risk communication, has been very productive since its launch and first meeting in Tianjin last year!

It now counts 20 members from different continents, representing stakeholders from industry, academia, healthcare as well as regulatory and other public bodies, including the UMC at international level. The founding members have just been notified by *Drug Safety* that their paper, outlining why and how the CommSIG came into being and summarising its mandate and planned activities, will be published soon. Watch out for it! The most important ongoing activities relate to the planning of the Beje Wiholm lecture at ISoP 2015, which was allocated to a 90-minutes session sponsored by the SIG. There will be short presentations by Viola Macolic and Peter Mol on latest initiatives regarding communication in Europe and brief lectures from two invited special experts, namely Wolfgang Gaissmaier, communication psychologist from the University of Konstanz, Germany, and Simon Jones, healthcare researcher from the University of Surrey, UK, followed by an interactive debate with the audience on challenges and best practices when communicating about risk factors for adverse reactions. See you in Prague!

Swiss-Austrian chapter

From Stefan Russmann on behalf of the Swiss-Austrian ISoP chapter

Report on the ISoP chapter meeting in Zurich, 15 March 2015

On 15 March 2015 the Swiss-Austrian ISoP chapter held its 4th annual drug safety symposium. After its foundation the Chapter started an annual series of half-day meetings on special topics of interest. This year's meeting was once more dedicated to innovative trends in drug safety and was organized under the title "BIG DATA - Driving Evidence for Healthcare".

The increasing implementation of electronic drug prescription provides the foundation for the analysis of drug safety issues through pharmacoepidemiological studies in a regulatory and industry context, which was the focus of the first session. Although primarily organized as a national symposium this session featured a rather

international board of speakers. Susanna Perez from Barcelona gave an introductory overview on Big Data real-life studies and available databases, followed by a presentation from Marcel Zwahlen, Berne, on promises and pitfalls of Big Data research. Madé Wenten from Boston concluded the session with a presentation of practical applications of Big Data research in the field of multiple sclerosis therapies from an industry point of view.

The second afternoon session then switched the focus to new opportunities for the detection of adverse drug reactions and improvement of drug safety in clinical practice, particularly in hospitals. André Sander from ID Berlin presented innovative solutions for medical quality management, followed by a collaborative demonstration from 4solutions, David Niedrig and Stefan Russmann on their latest drug safety software development for hospitals. Mario Bertazzoli concluded the symposium with an overview on current and future reporting requirements and electronic data exchange.

New board elections were also due this year, and we welcome David Niedrig and Victoria Rollason as new board members, thereby extending our activities (including in Prague at the 15th ISoP Annual Meeting) and maybe also future ISoP symposia to the French speaking part of Switzerland. We would like to thank Eveline Jaquenoud-Sirot and Jan-Willem van der Velden who stepped down from the board.

More News from ISoP

★ **ISoP monograph:** There is now a final agreement and a contract to sign from the Springer Global Editorial Meeting that we should go ahead with the book/monograph, under the title, 'Pharmacovigilance: critique and ways forward' (printing early 2016)

★ **CIOMS** is happy to invite ISoP members to submit proposals of relevant topics for new working groups within the drug safety area that would benefit from global harmonisation.

ISoP is an International Member of CIOMS
<http://www.cioms.ch/>

★ 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 2014**

Annual Meeting held in Tianjin last October are posted on the website of the society. 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

★ **2015 ISoP General Assembly** will be held during the 15th ISoP Annual Meeting in Prague, Czech Republic and will take place from 12.45 to 14.45 on Thursday 29th October (Clarion Congress Hotel Prague)

★ **Special Interest Group (SIG):** We look forward to the launch of the Risk Minimization Methods in Asia during the 15th ISoP Annual Meeting in Prague, next October

<http://isoponline.org/special-interest-groups/risk-minimisation-methods-for-asian-countries/>

Other SIGs are in development (SIG on Ethics)

★ **2nd African Society of Pharmacovigilance (ASoP) conference – Accra 2015**

Pharmacovigilance in Africa: New methods, New opportunities, New challenges

25 - 27 November 2015 – Accra, Ghana

Organized by ASoP/ISoP African chapter

<http://asop2015.com/>

★ **World Immunization Week 2015**

The Vaccine Confidence Project

London School of Hygiene and Tropical Medicine

Visit www.vaccineconfidence.org

★ **Esher project** involving product and batch traceability in case management of ADRs with biological medicines

<http://escher.tipharma.com/projects/current-projects/escher-launches-new-project-pharmacovigilance-of-biologics.html>

Please contact ISoP if as a member you would like to explore the work of Esher and any similar initiatives and look to move the science forward in this rapidly evolving area on behalf of ISoP

★ **Joint session ENTIS-ISoP:** The European Network of Teratology Society (ENTIS) together with the International Society of Pharmacovigilance (ISoP) will organize 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). More information later on www.isoponline.org

★ **EMA Consultation:** Preventing medication errors in the European Union.

- The good practice guide on risk minimisation and prevention of medication errors open for consultation is available
- The good practice guide on recording, coding, reporting and assessment of medication errors open for consultation is available
- The risk minimisation strategy for high strength and fixed combination insulin products, addendum to the good practice guide on risk minimisation and prevention of medication errors, open for consultation is available. Please contact medicationerrors2013@ema.europa.eu or website at <http://www.ema.europa.eu/ema/>

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.

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

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