



The ISoP Star

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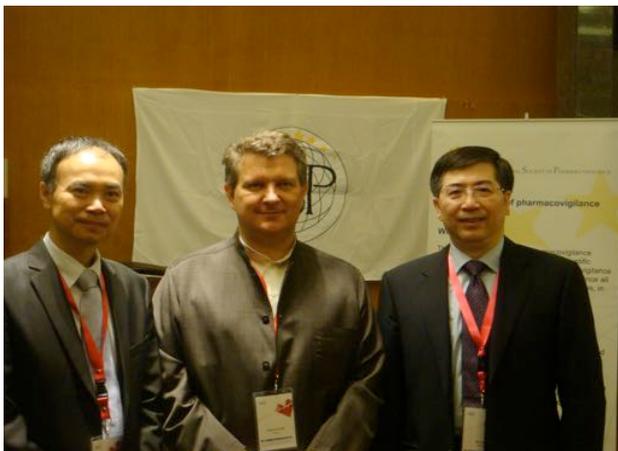
From Tianjin to Prague via Mysore and Sao Paulo

Tianjin conference report and AGM

The 14th ISoP Annual Meeting took place in Tianjin, China from 19th to 22nd October 2014.

It was the first time that ISoP held an Annual Meeting in China, and this event was considered to be a milestone for the development of Pharmacovigilance in the region.

The Scientific Committee chaired by Ian Wong, University of Hong Kong, and the Local Organizing Committee with Lili Cao from the Chinese national agency CFDA had developed an inspiring programme under the headline 'New ideas in ancient cultures: advancing Pharmacovigilance in Asia'. Around 230 pharmacovigilantes and international experts from 41 countries attended the meeting and the pre-conference courses.



(L → R) Ian Wong, Hervé Le Louet, and Bin Xue (CFDA)

The most important plenary lectures and sessions are summarized below (see report from Ulrich Hagemann). Most of the ISoP 2014 presentations and the winning posters are on the website of the Society. The instructions to allow access to them on the Members Section was sent by e-mail with your renewal membership notice.

President Hervé Le Louet announced at the General Assembly of ISoP members (AGM) the launch of the new ISoP chapter of Israel with Irene Fermont as coordinator, and encouraged members to join the Special Interest Group on 'Risk Communication' leading by Priya Bahri (see section SIGs).

On behalf of the Executive committee, Ralph Edwards, President of ISoP from 2000 to 2003 proposed the nomination of Cheng Jinhua as honorary member which the General Assembly unanimously approved. Cheng Jinhua is the pioneer of the pharmacovigilance in China, and among many achievements, he has collaborated to the creation of the Chinese agency CFDA in 1998. Finally, the General Assembly agreed to the proposal to establish an internal task force to appraise ISoP's current performance and internal rules and governance, and to consider how more activities of ISoP could be implemented and promoted in the future to patients and health professionals, in line with the ISoP strategic meeting in 2012.



Season's Greetings to ISoP members!

Tianjin Poster Prizes

118 abstracts were accepted as posters (67) or oral presentations (51), and as always, an ISoP Poster Prize was given to the three best posters. The winners are:

* First prize: *The Association between Oral Fluoroquinolone use and the development of retinal detachment: a systematic review and meta-analysis of observational studies*- CSL Chui, ICK Wong, LYL Wong, EW Chan (Abstract no P039)

* Second prize: *High dose methotrexate: Drug-drug interaction and toxicity*- J Mahe, G Veyrac, C Tourillon, P Jolliet (Abstract no P050)

* Third prize: *The value of patient reporting in signal generation*- D Darko, G Sabblah, K Amponsa-Achiano, KO Antwi-Agyei (Abstract no P086)

The winners will receive a one-year electronic subscription to an Adis journal of their choice.

ISoP 2014 Report

(from Dr Ulrich Hagemann – Secretary General of ISoP)

The conference started on Sunday 19 Oct with three training courses in parallel on ‘Principles of meta-analyses’, ‘Core and emerging issues in ADR reporting and Pharmacovigilance’ and ‘Communication in Pharmacovigilance’. The courses aimed on informing and discussing in an interactive manner current problems and practice.

On the 20th October, Marie Lindquist, Alex Dodoo and Gang Cheng gave a report on the Annual Meeting of the WHO Monitoring programme that took place in Tianjin the week prior to the ISoP meeting. The opening lecture of the ISoP 2014 conference was given by Parthasarathi Gurusurthy, India, on ‘Harmonization and essential differences in Pharmacovigilance approach’. The main subject of his talk was the major differences in concepts and regulations in Pharmacovigilance across Asian countries and the approach to harmonize requirements and procedures in this region where a third of the global population lives. Then, Juergen Beckmann presented briefly the WHO-ISoP Pharmacovigilance Curriculum, now published in *Drug Safety* and online accessible via SpringerLink, and Priya Bahri outlined the

mandate, aims and objectives of the new ISoP Special Interest Group (SIG) on ‘Communication’.



June Raine who is the chairperson of the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicine Agency in London (UK), gave a talk about the Committee’s experiences and achievements since being established in July 2012. On the second day, the CIOMS talk, following an agreement on collaboration between the two societies, was given by Panayiotis Tsintis reporting on the recent CIOMS IX Report on ‘Practical Approaches to Risk Minimisation for Medicinal Products: Report of CIOMS Working Group IX’, undoubtedly a useful guidebook for practical Pharmacovigilance. ‘Clinical trials, information technologies and benefit assessment - current challenges for Pharmacovigilance’ has been the title of this year Beje Wiholm Lecture given by Joerg Hasford from Germany, highlighting some major problems, needs and shortcomings in clinical research particularly in the post-licensing phase. On the 22nd October, at the final conference day, Kenneth Hartigan-Go from the Philippines, elaborated how important collaboration and mutual information is within one country and internationally to early identify and efficiently manage safety problem, all based on practical experiences from his work and position.

In between the plenary lectures, ten sessions with different main items and many numbers of short presentations took place with discussions and questions. A special session was held for young scientists where they had the opportunity to present results from their research in an unburdened atmosphere and to learn to defend

A Happy New Year to all members!

their results within a collegial and convivial scientific discussion.

Wallis Lau from Hong Kong University received the ISoP 2014 Junior Prize for best presentation for her talk about "*The unmet needs of antithrombotic treatment in patients with non valvular atrial fibrillation in real world clinical practice*" (P045)

On the first day, a meeting of the chapter's coordinators and chapter members were held at the margins of the conference day which was very effective. It was decided that such meetings will be held regularly at future Annual Meetings.

2nd ISoP UMC Training

After Manila last June, the second Pharmacovigilance training course jointly organized by ISoP and UMC is scheduled for **12-14 January 2015 in Mysore, India**: '*Risk Management through fostering good Pharmacovigilance practice in emerging markets*'



This three day-course is conducted with expertise from ISoP and Uppsala Monitoring Centre, and designed for interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used. The programme is focused on providing expert perspective and guidance on key elements of Pharmacovigilance for the provision of risk management with a focus on signal detection and activities in emerging markets. This course will take place at the JSS Hospital in Mysore (India) and 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://www.isoonline.org/index.php?page=isop-umc-training>

Book now!

ISoP course in Brazil



ISoP is organizing in collaboration with the Brazilian national agency ANVISA and ISoP's Latin America chapter, a training course on 26-27 & 28 March 2015 in Sao Paulo, Brazil.

This training course is dedicated to 'Basics in Pharmacovigilance and new developments' and will thereby address the specific needs and interests of people working on the field of Pharmacovigilance.

Over two and half days, experts from Brazil and an international faculty will present a mixture of talks, interactive discussions and practical exercises. ISoP intends to address particularly Pharmacovigilance items in the context of the Brazilian national health system and the specific situation of emerging and rapidly growing countries and health economies.

Register now!

More details about programme and registrations are available from the ISoP Administration office (administration@isoponline.org), or visit

<http://www.isoonline.org/index.php?page=training>.

ISoP Joint sessions

ISoP is much interested in co-organizing joint symposia with other scientific societies aimed at improving the culture of Pharmacovigilance all over the world. Scientific societies interested in such co-operations can contact the ISoP Secretariat: administration@isoponline.org

ISoP joint session with Greek scientific societies in Athens, Greece

The 1st International congress "From Drug Discovery to Drug Delivery" took place in Athens, Greece from 13 to 15 November 2014. The congress was organized by The Hellenic Pharmaceutical Society, The Hellenic Society of

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Medicinal Chemistry and the International Liposome Society, and it was chaired by Prof. Gregory Gregoriadis (University of London, UK), Prof. Costas Demetzos (University of Athens, Greece) and Prof. Anna Tsantili-Kakoulidou (University of Athens, Greece). ISoP was requested to participate in the organization of a joint session during the congress dedicated to hot topics in Pharmacovigilance and entitled "Drug safety monitoring and beyond". The session was attended by about 70 participants from several countries, mostly European. During the session, Marco Tuccori (University Hospital of Pisa, Italy) provided a presentation entitled "General overview on the safety of antidiabetic drugs". The second presentation by Nicole Baker (Quintiles, Ireland) was about "Post Authorization Safety Studies and Post Authorization Efficacy Studies in Line with the 2012 European Pharmacovigilance legislation". The session was closed by Giannis Papadopoulos (National and Kapodistrian University of Athens, Greece), with a presentation entitled "The adverse drug reactions of biotechnological medicines for rheumatoid arthritis and the role of healthcare professionals". The session had a participatory and lively debate, and the joint session was a success.

ISoP 2015 Prague

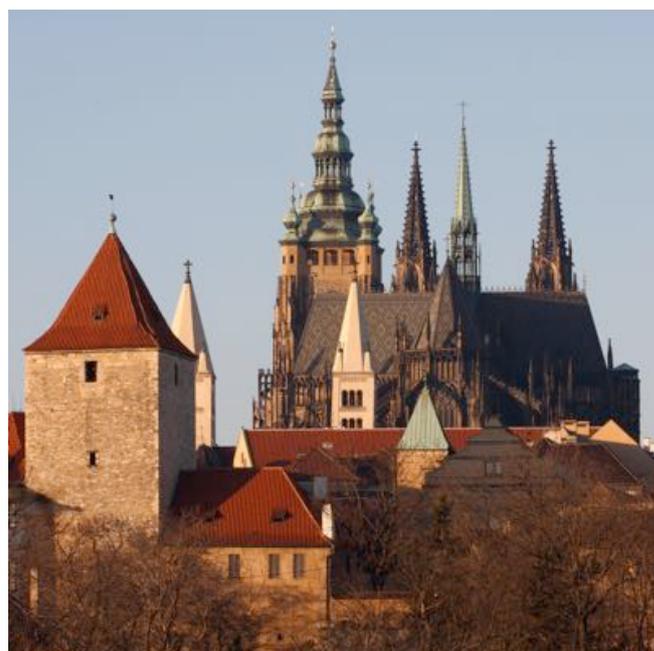
'Cubism in Pharmacovigilance'

27th -30th October 2015, Clarion Congress Hotel Prague

The 15th ISoP Annual Meeting is hosted by the Charles University in Prague and the Czech Pharmaceutical Society and the chairman of the Local Organizing Committee is Prof Jiří Vlček and Dr Gunilla Sjölin-Forsberg (CIOMS) is chairing the Scientific Committee.

Back-to-back training courses will be held on 27th October.

The organisers look forward to welcome you to the ISoP 2015 Annual Meeting!



Call for abstracts

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

More information on ISoP 2015 will be available soon on the conference website or from the secretariat: info@isop2015prague.org
Website: www.isop2015.org

Call for Annual Meetings bids

If you would like your country to host the 2016 or 2017 Annual Meeting, please do contact the Administration Office and ask for guidelines for your bid.

WHO ISoP PV Curriculum

The WHO-ISoP PV Curriculum is now public!

ISoP is very pleased to inform you that the Pharmacovigilance Curriculum, developed by experts from ISoP, WHO and institutions dedicated to Pharmacovigilance, is available electronically on the Springer website. As member of ISoP, you have access to the document via the ISoP website at the members section. The curriculum contains a theoretical part in a comprehensive modular form, practical tasks

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and some key literature references. The PV curriculum can be used by everyone who needs to plan and conduct training courses in Pharmacovigilance. The printed version is in the conference volume of *Drug Safety* at the occasion of the 14th ISoP Annual Meeting in Tianjin last October. The authors would be interested in receiving your comments by contacting ISoP at training@isoponline.org or the corresponding author directly. The authors would like to know about any experience you made when using the curriculum in practice.

Special Interest Groups - SIGs

A SIG is a group of ISoP members (min. 5) and non-ISoP members acting as volunteers and working on a specific and relevant topic within the scope and aims of the Society.

Two SIGs, i.e. 'Women's Health' and 'Risk Communication' have been established and already approved by the Executive Committee. The EC will continue to be very supportive with the creation of SIGs. If members want to create resp. establish a SIG, please contact the ISoP administrative secretariat.

Chapters

The International Society of Pharmacovigilance is proud of the rapidly growing number of regional chapters. Currently, nine chapters are active in ISoP: Italy, Western Pacific Region, Mexico, Latin America, Switzerland/Austria, Africa, South Eastern European, and North America chapters. We welcome the new chapter from Israel <http://www.isoponline.org/index.php?page=israeli-chapter> and look forward to the creation of other chapters in Asia and Middle East.

The chapters can communicate with the ISoP website (www.isoponline.org under *Chapters*) and also directly via the LinkedIn ISoP group (follow: www.linkedin.com)

ISoP Monograph : an ISoP baby is in gestation

(from Prof Ralph Edwards –ISoP Past President)

The world changes continuously and Pharmacovigilance, as a new discipline also changes, perhaps even faster, striving to make its mark and its voice for better patient care heard. There are new fields opening with novel challenges facing the discipline, whilst we are still perfecting ways to manage the basic situations we all recognise.

New stakeholders come into the field not knowing the history of Pharmacovigilance. Their ideas must be sifted and the good incorporated and the duplications and irrelevancies managed. ISoP must show the way.

ISoP is a society dedicated to the broadest look at patients using medicines in society: we want to limit medicines' harms as much as possible and maximise their benefits.

Following discussions at the last ISoP meeting in Tianjin, it was agreed to go ahead with the proposed monograph: our baby. You have all been asked to contribute *your* ideas, *your* critical thoughts, *your* experience and *your* wisdom to make this ISoP baby fit and well for the next decade of Pharmacovigilance and beyond.

We have had 23 expressions of interest with 15 giving a clear outline of what they wish to present and in a couple of cases complete papers. And there are a few of you who have said they would like to write something after the Tianjin meeting.

Final agreement by Springer to go ahead (they have agreed to be the publisher), as well as the final format (book, web publication or special edition of *Drug Safety*) will be dependent on your submissions on topics and their number and quality. **What we need urgently from you is a SUMMARY DESCRIPTION of your contribution to see where it will fit into the overall outline. If it does not fit into the outline already prepared, we will add a new section but we do need your contribution NOW. This really is your last chance to make your views for the future live.**

A Happy New Year to all members!

Don't miss out, your thoughts count - and the only things you really regret are those you never tried.

In summary, the ISoP gestation is going well so far, but *your* contributions will be very valuable so that Pharmacovigilance will continue to be a lively, interesting and, more than anything, useful subject for all stakeholders and particularly patients.

Send your contributions or queries to ISoP (administration@isoponline.org)

2015 Membership renewal

Renewal forms have been sent out by electronic mail. Only members who are paid-up will have access to incentives and voting rights.

This year the membership fees have been frozen and students, retired and emerging countries will still be able to subscribe to the journal *Drug Safety* for the price of 95 EUR (online subscription).

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

Non-members who registered at the ISoP 2014 Tianjin Annual Meeting and paid full registration fees, will become ISoP members from 1 January to 31 December 2015. A very warm welcome to these 98 newcomers!

Benefits for members

20% discount on Wiley-Blackwell Pharmacology and Pharmaceutical Medicine books for all ISoP members!

Fast, simple and secure ordering! You can order books online at www.wiley.com (this offer is not available through bookstores). The promotion code to allow access to the 20% discount has been sent with your renewal membership notice.

More discounts for books at

<http://www.isoponline.org/index.php?page=membership>

Drug Safety Journal

As part of their membership, all ISoP members will receive an electronic access to the journal *Drug Safety*, and therefore the printed version of the



Drug Safety journal is not anymore available to members.

The link to the journal *Drug Safety* must be clicked from within the ISoP Members' Area 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.

ISoP Privacy Policy

Your contact details are kept on a computer at the Administration Office, but will not be released to any other organisation or individual outside ISoP except to Springer publishers (*Drug Safety*). For the purpose of electronic distribution of the *Drug Safety* journal as part of membership and based on a contract between ISoP and Springer publishers, ISoP Administration will forward your registered e-mail address to Springer publishers. The processing of the data itself and rendering of the e-mail services can be performed by a non-Springer company or its related companies. Information about relevant *Drug Safety* journal activities (like e.g. so-called TOC - Table of Content - or other alerts) will be sent to ISoP members by e-mail, unless you ask for them not to be sent.

More about the ISoP privacy policy can be seen on www.isoponline.org.

www.isoponline.org

We are very pleased to announce the release on the 26th February 2015 of our new website [isoponline.org](http://www.isoponline.org), redesigned with a more modern look and a new server and features.

Our current site has a lot of content and with the

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passing of time the platform became obsolete. We hope that the new ISoPonline website will show how much, as a society, we are committed to evolving and changing.

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

Please send your letters, comments, ideas and contributions for ISoP Star to:
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Telephone and fax: +44 (0)20 3256 0027
E-mail: administration@isoponline.org
Internet: www.isoponline.org

Contact details

If you have changed your address, and most importantly your address e-mail, do let us know as soon as possible. Some members don't receive accurate information because of not providing their e-mail address. We would like to keep members informed of Society news with an easy access to the journal *Drug Safety*, and electronic mail is the way of sending certain types of information. Please e-mail your correct details to us, we will be able to update our address lists. Thank you!



**Have
you
moved?**

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