



The ISoP Star

No 36. June 2018

A busy 6 months – with another to follow

Countdown to Geneva



Lake Geneva

The 18th ISoP Annual Meeting will take place on 11th-14th November 2018 at the International Conference Centre Geneva (CICG), located near the United Nations, 10 minutes from the airport and the city centre on a convenient bus route. ISoP will follow the WHO's National Centres Annual Meeting, also in Geneva, and marking the 50-year anniversary of the international pharmacovigilance programme.

ISoP (formerly ESOP - European Society of Pharmacovigilance) will also celebrate its 25-year anniversary, as ESOP organised its very first annual meeting in Geneva in 1993!

The theme of this year's conference will be "Pharmacovigilance without borders", underlining ISoP's mission that no scientific borders, nor any geographic borders should impede the study of drug safety or the prevention and management of adverse drug reactions throughout the world.

The ISoP 2018 conference will run for three full days and include some exciting new ideas, keynote lectures, parallel sessions and symposia.

We are delighted to welcome international speakers on a range of key topics within the field of pharmacovigilance, including:

- ★ Two pre-conference courses "Pharmacovigilance in the aging population" and "Pharmacovigilance in pre-approval phases" on Sunday 11th November
- ★ WHO-ISoP joint session on WHO Coalition of Interested Partners (CIP) [Monday 12th November]
- ★ CIOMS lecture "New use of Clinical Concepts in MedDRA: Can MedDRA Labelling Groupings help to standardise Safety Labelling?" [Tuesday 13th November]
- ★ Keynote lectures and expert panel "Putting Patients First in Pharmacovigilance" [Tuesday 13th November]
- ★ Four parallel sessions including i) Risk communication ii) Role of the pharmaceutical industry in pharmacovigilance iii) Medical devices iv) Benefit-Risk assessment
- ★ Twelve symposia organised by ISoP members, covering a range of key topics in pharmacovigilance
- ★ Plenary lecture "Artificial intelligence in pharmacovigilance and machine learning" [Wednesday 14th November]
- ★ Poster presentations selected from over 380 abstracts submitted.

We look forward to seeing you in Geneva!

Register now! Early bird registration: 12 September
<https://www.isop2018geneva.org/>



Call for sponsors for ISoP 2018

If any members know of companies and organizations wishing to support ISoP 2018 in Geneva, please enquire via e-mail isop@mci-group.com

Our annual conference is an excellent chance for organizations to get in touch with an international

News from the International Society of Pharmacovigilance

audience of pharmacovigilance experts and decision makers. There are opportunities for promotion before, and during the event through a range of digital and print media channels and sponsorship packages. The meeting environment itself will bring together leading researchers and innovators to kick-start the next wave of ideas and innovation.



STOP PRESS

The 19th ISoP Annual Meeting in 2019 will be held in Bogotá, Colombia - more details to follow in due course.

September 2018 ISoP-UMC course in Ecuador

The 6th pharmacovigilance training course jointly organized by ISoP and UMC will take place on 24-26 September 2018 at the Courtyard Marriott in Guayaquil, Ecuador. The course will include experts from UMC and ISoP and offer teaching in pharmacovigilance, including management of individual case safety reports, signal detection, and risk management and communication.

The target audience is professionals from regulatory agencies, hospitals, universities and industry. Lectures, working groups and panel discussions between regulators and industry will be the main training method.

The programme will cover:

- ★ Individual case safety reports and spontaneous reporting systems
- ★ Signal detection and management
- ★ PV Inspections
- ★ Assessment of risks and benefits
- ★ Risk communication
- ★ Pharmacovigilance on vaccines
- ★ Biotherapeutics
- ★ Pharmacovigilance in public health programmes
- ★ Harmonization of pharmacovigilance.

Some main lectures will be in Spanish, while others will have a simultaneous translation.

Register now!

<https://isoponline.org/training/isop-umc-training-courses/>



Mid-Year training in Australia



The participants at Canberra, with, in the front centre (L→R) Richard Hill, Mira Harrison-Woolrych, Phil Tregunno and Jan Petracek

In March this year, over 40 people attended the first ever ISO_P training course in Australia “Pharmacovigilance in the Western Pacific: Global approaches to risk-management of medicines.” This course took place in the capital city Canberra, in collaboration with the Western Pacific chapter.

The faculty consisted of international and national experts in pharmacovigilance, representing government, academia, and industry. ISO_P were delighted to welcome speakers and delegates from the Australian Therapeutic Goods Administration (TGA), Medsafe New Zealand and the Singapore Health Sciences Authority (HSA). All attendees at ISO_P courses become members of our professional society and we warmly welcome them.

The training course in Canberra addressed the specific needs and interests of those working in pharmacovigilance in the Western Pacific region, including regulatory agencies, pharmaceutical companies, academia, hospitals and community settings. The programme covered topical pharmacovigilance and risk-management issues – both international and in the context of the Australian and New Zealand health systems.

The first day consisted of lectures with opportunities for discussion, while the second day focused on interactive tasks in smaller workshop groups. The second part of the course looked at risk management and minimization approaches. Participants gained hands-on experience of development of Risk Management Plans (RMPs) and the conduct of benefit-risk assessments and

how they should be adapted to local settings. This course had a strong focus on practical examples and real-life solutions.

The next ISO_P Mid-Year training will be in Kenya, Africa (spring 2019); more information available soon.

Shenyang course



The participants at Shenyang

The 5th ISO_P – UMC pharmacovigilance joint training course took place in the north-eastern city of Shenyang, in collaboration with the ISO_P China chapter and the International Food and Drug Policy and Law Research Center (IFDPL), Shenyang Pharmaceutical University on 11-12 January 2018.

There were over 50 participants from Chinese drug regulatory departments, commercial enterprises, medical institutions and scientific research academies in the region. The main topic was ‘How does harmonization of active surveillance and signal detection evaluated by PV inspection lead to better safety governance?’.

The training was delivered through lectures, working groups and panel discussions, and related to the context of real-world practice in China, for example in the attention paid to safety problems related to Traditional Chinese Medicine. Case study and small group discussion teaching was used: there were four groups split into two case studies (chemical drug and bio-similar product) each group sharing their discussion results on RMPs for their respective products.

Brian Edwards and Pia Caduff answered questions and gave feedback on each group presentation. Chinese and overseas scholars freely exchanged hot

topics and research progress in the field of pharmacovigilance.

There was simultaneous interpretation arranged to enhance the training experience and the training was much appreciated both for its content and the teaching methods used.

Check the ISoP website regularly for the next ISoP-UMC training in China, dates to be announced soon.

President on the move

ISoP President Sten Olsson has been flying the flag for the Society around the world in the last few months.

In early December 2017 he was a guest speaker at the Symposium of the Latin American Chapter, Mexico City, then in the first week of 2018 he went to the Euro-Asian Pharmacoepidemiology Congress, in Shiraz, Iran, and in April he participated in the Hamad Medical Corporation Medication Safety Symposium 2018, in Doha, Qatar.

The Iran meeting, endorsed by ISoP, attracted 250 pharmacoepidemiology, drug safety, pharmacovigilance and pharmacoconomics experts, researchers and students. Very interesting panel discussions on the second day focused on how to get access to drug utilization and patient health record data for the performance of useful pharmacoepidemiological studies. There were also lively exchanges about the undergraduate pharmacy curriculum.

Blog on ISoP in Boston

For another angle on ISoP's first US meeting last December, do read the blog post 'Why rise of the machines will be beneficial in the pharmacovigilance world' by Suzanne Berresford. <https://adisintouch.com/2018/02/08/report-from-isop-seminar-on-intelligent-automation-in-pv-feb-18/>

Check the ISoP website regularly for details of the next ISoP seminar in Boston, to be announced soon.

Remembering Ana Maria



Dr. Ana Maria Corrêa Nunes (1947-2017)

It is with great sadness that we report the passing of our colleague and friend Dr. Ana Maria Corrêa Nunes on 24th of December 2017. Ana obtained her medical degree in Lisbon in 1972 and specialized in Internal Medicine and Cardiology. After a few years of clinical work she switched to the pharmaceutical industry and later to INFARMED, the Portuguese national medicines authority. But Ana's work went beyond the borders of Portugal.

Ana was the first Secretary-General of the International Society of Pharmacovigilance (ISoP) (2000-2003), under Prof. Ralph Edwards's presidency. Many of us knew Ana from ESOP and then ISoP and will treasure fond memories from ISoP conferences in different parts of the world.

A full obituary may be found on the ISoP website: <https://isoponline.org/about-isop/in-memoriam/>

Indonesia Chapter

Having already held a well-attended scientific meeting, the Indonesia Chapter has clear plans for the next three years, with:

- * local training to increase and enhance pharmacovigilance capacity building among hospital pharmacists, medical practitioners and the pharmaceutical industry.
- * an annual scientific meeting incorporating all experts, sciences, and capabilities
- * engagement and partnership with other pharmacovigilance stakeholders such as local regulatory authorities, organizations of clinical

pharmacy and health professionals, hospitals, universities and communities.

Anyone interested in joining ISoP and the Indonesia Chapter is invited to contact administration@isoponline.org, or contact the Indonesia Chapter coordinator at Indonesia.isop@gmail.com, or visit their website at <https://sites.google.com/view/isop-indonesia>

Second ISoP Middle East Chapter Workshop

35 participants from the pharma industry, research institutions and academia across Arab countries attended the second pharmacovigilance training workshop arranged by the ISoP Middle East Chapter 18-19 April 2018 in Dubai.

The main focus area of the training was the Arab Guidelines, and the workshop was conducted by ISoP members Dr. Mayada Alkhakany (Head of PV - Boehringer Ingelheim), Dr. Thamir Alshammari (Dean of College of Pharmacy, University of Hail), Dr. Nasser Al-Qahtani - Advisor, Vice-President for Drug Sector Saudi Food and Drug Authority (SFDA), Dr. Nidaa Brwarsheeh - Head of Jordan Rational Drug Use and Pharmacovigilance Department - JFDA. Dr. Manal Younus, Head of the Iraq Pharmacovigilance center- Iraq Ministry of Health and Dr. Hussain Al Ramimmy, Head of Pharmacovigilance - Oman Ministry of Health were also present.

The 2nd ISoP Middle East Chapter and Iraq Ministry of Health joint pharmacovigilance training will be held on 30-31 August 2018 in Baghdad (Iraq).

ISoP webinars

Thanks to the success of the first ISoP webinar last year, another free webinar was offered to members on 6 February 2018, with the assistance of Springer Nature. In this presentation, Nitin Joshi, Editor-in-Chief of *Drug Safety* talked about choosing the right journal for your research, starting with some strategies on how to produce a strong manuscript and then discussed in detail the steps for choosing the right journal.

You can now find these webinar videos on our website (Member section).

ISoP 2017 presentations

ISoP webinars and most of the Liverpool ISoP 2017 presentations are posted on the ISoP website; to view them, please log-on to <https://isoponline.org/members>. To get access to the annual meetings presentations, ISoP webinars and ISoP Board meeting minutes, please go to the 'Member section' in 'Member Login' enter your registered e-mail address and password.

ISoP Privacy Policy

To reflect the recent changes in data protection law (GDPR), and our commitment to transparency, we have updated our Privacy Policy.

Please take some time to read our updated privacy policy which explains what data we collect, why we collect it, how we use it and other information relevant to the privacy of your data. From now, we will ask your consent to email you about the Society activities, including training and annual meetings, events and newsletter (ISoP Star), learning opportunities (webinars), membership and other benefits (member section on our website and access to the journal *Drug Safety*) through your membership.

If you would like to update your settings or if you no longer wish to hear from us then you can unsubscribe using the link <https://isoponline.org/isop-privacy-policy/> or you can e-mail us at: administration@isoponline.org

New Special Interest Group (SIG): Medical devices

ISoP SIG on Safety Surveillance of Medical Devices: finding solutions and moving forward.

This new SIG will provide a forum for members to share experiences and suggest best practices and policy in the field of medical device performance monitoring and safety surveillance.

The SIG leader is Dr. Jitendar Sharma (Executive Director, Kalam Institute of Health Technology

MD&CEO, Andhra Pradesh MedTech Zone, India).

This SIG will be officially launched during the ISoP General Assembly in Geneva on 13 November, during the 18th ISoP Annual Meeting where a dedicated parallel session on Medical devices is part of the ISoP 2018 scientific programme.

List of current ISoP chapters

Africa	Mexico
China	Middle East
Indonesia	South Eastern Europe
Israel	Swiss-Austrian
Italy	North America
Latin America	Western Pacific

Want to get involved?

Visit <https://isoponline.org/chapters/>

List of current special interest groups (SIGs)

Women's Medicines
Risk Communication
Risk Minimisation Methods for Asian Countries
Herbal and Traditional Medicines
PV Professional Qualification Framework
Medication Error

Want to get involved? Visit

<https://isoponline.org/special-interest-groups/>

Teratology Education Course

The Women's Medicines SIG is pleased to inform ISoP members about the upcoming 3rd International Joint Meeting of the European Network of Teratology Information Services (ENTIS) and Organization of Teratology Information Specialists (OTIS) meeting in Newcastle upon Tyne, UK, 4-6 September 2018.

Don't miss this unique opportunity to hear state-of-the-art lectures from UK and international experts on:

- * Fetal development
- * Principles of human teratology
- * Known and emerging human teratogens of relevance today
- * Effects of maternal illness on pregnancy outcome
- * Risk-benefit analysis of medicine use in pregnancy and lactation

- * Pregnancy pharmacovigilance and clinical application of pregnancy safety data
- * Risk communication in the context of human teratogens.

<http://www.uktis.org/html/education-course.html>

How to get in touch

Please send your comments and contributions for ISoP Star to:

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Contact details

As member of ISoP, the way we keep you informed and updated about the Society and its activities is solely through emails.

If you have changed your e-mail address, do let us know as soon as possible. Please e-mail your correct address to us, we will be able to update our lists.

