



The ISoP Star

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Reports from the world of pharmacovigilance

PV systems in China

China's pharmacovigilance regulations have changed significantly since 2018, with high standards and requirements for new pharmacovigilance systems and electronic data transmission (e.g. E2B R3). These updated regulations cover activities from the clinical trial to post-marketing surveillance.

This two-day course '**Pharmacovigilance systems in China: Moving to the next step**' is a great opportunity to hear the views of global pharmacovigilance specialists, learn from their experience about harmonization of safety reporting requirements and pharmacovigilance systems, and optimizing the benefit–risk ratio of medicinal products for patients in China and beyond.

This course will be conducted with expertise from UMC and ISoP as well as local organizations, and is designed to address the practical and theoretical aspects of pharmacovigilance throughout life-cycle surveillance.

The target audience includes those working in regulatory agencies, hospitals, and universities, plus industry professionals in all areas of pharmacovigilance and related functions, such as clinical trials, medical information, regulatory affairs, and audits.

The programme will cover:

- ★ E2B and its implementation, Periodic Safety Update Report (PSUR), and Development Safety Update Report (DSUR) submissions
- ★ Terminologies used in pharmacovigilance: WHODrug and MedDRA
- ★ Good quality case reports in China
- ★ Safety evaluation and risk management, signal detection and serious organ toxicity
- ★ New Chinese regulations and their application in clinical trials and post-market surveillance
- ★ ISoP special interest groups with focus on herbal and traditional medicines, and medication errors.

The main lectures will be given in English with simultaneous translation into Chinese; in addition there will be working groups and panel discussions.

This course, on 20-21 September in the city of Shenzhen, Southeast China, is in collaboration with the ISoP China chapter and the University of Hong Kong – Shenzhen Hospital.

[Register now!](#)



SAVE THE DATE

7th ISoP-UMC PV Training
Shenzhen, China
20-21 September 2019



Are you coming to ISoP 2019 in Colombia?

The 19th Annual Meeting of ISoP 'New opportunities for new generations', will be in Bogotá, Colombia from the 26th to 29th October 2019 at the Grand Hyatt Hotel in Bogotá.

This is a fantastic opportunity for professionals, researchers, students, and patients to come together and examine interesting and challenging topics, such as risk communication and management, medication errors, education, social network impact and patient perspectives, and more! The meeting will see the convergence of ideas, topics, and experiences.

Pharmacovigilance is rapidly developing in regions such as Latin America. In Colombia patient safety and pharmacovigilance have gained a privileged position on the national health agenda. It is exciting to have an ISoP Annual Meeting in the region for the third time in two decades.

Two pre-congress courses are being offered on 26th October: Medication errors prevention and Active Surveillance in pharmacovigilance.

The plenaries and parallel sessions will cover a broad range of current issues including:

- ★ Impact in real life: are we making a difference? (hospital/community vision, industry vision)
- ★ National systems in developing countries - ISoP chapters from the Middle East, Indonesia, South Asia, China
- ★ Herbal and traditional medicines
- ★ Medical devices safety
- ★ Importance of communication in pharmacovigilance.



More information about the programme is at www.isop2019bogota.org/. The call for abstracts is now closed.

Finally, an authentic and memorable social programme will be arranged, including a complimentary conference dinner with traditional Colombian hospitality.

The ISoP meeting is directly followed in the same city by the 42nd Annual Meeting of the WHO Programme for International Drug Monitoring, from 28 October to 1 November.

Take advantage of the early bird reduced registration fee for the 19th ISoP Annual Meeting [by registering before 6th August 2019](#).

We look forward to seeing you in Bogotá!

ISoP webinar

The 3rd webinar "Value of Narrative Reviews", broadcast on 27th March in collaboration with *Drug Safety* was a success with 45 attendees. You can view all the videos of our webinars on the ISoP website (Members section).

ISoP Chapter news

One advantage of being an ISoP member is being able to act locally by volunteering and contributing to an ISoP chapter. Currently, chapters are in varying states of maturity. Meetings tailor-made to local customs and language are popular. Examples include annual symposiums arranged by the Latin-American chapter, workshops arranged by the Indonesia, Mexico and Middle East chapters, a conference this June by the Israel chapter, a risk communication workshop in Italy and a benefit-risk meeting by the North American chapter.

Future plans include rebuilding the African chapter by arranging elections for chapter officers, and potential new chapters in Russia, Turkey and Egypt. We thank all those who have made the ISoP chapters a success!

To get involved, contact ISoP Administration [or go to our website](#).

Enthusiastic turnout in Kenya



The participants in Kenya

ISoP wants to support and be a part of the current dynamic development of pharmacovigilance in Africa, and so decided to organize a symposium and training course in Nairobi, Kenya, on 6th-8th May 2019, with the theme '**Pharmacovigilance in Africa beyond spontaneous reports**'. The programme assembled primarily African pharmacovigilance experts as faculty members with the hope of attracting pharmacovigilance professionals from across the continent working in regulatory agencies, pharmaceutical companies, academia, hospitals and community settings.

The turnout was better than expected, with 94 participants representing 19 countries. The wide range of topics included the global scenario and gaps in African pharmacovigilance. The plans and ambitions for regulatory harmonization through the African Medicines Agency were presented by AUDA*. Other sessions explored the role of QPPVs, technology development, benefit versus risk assessments and the use of VigiFlow/VigiLyze for data management and analysis. Discussions were lively throughout and also covered how to revive an active ISoP chapter, the African Society of Pharmacovigilance, ASoP.

*African Union Development Agency (formerly NEPAD)

Broad discussions in Israel

The ISoP meeting in Herzliya (3rd-4th June) aimed to reach out beyond specialists to gather in the same place several disciplines, and environments – with the strong belief that risk management can be successful only if it is fully multidisciplinary. It takes time for people to understand that drug

safety is also in their hands and that we have plenty of space for improvement – and especially for communication between stakeholders.

36 speakers and 120 participants eventually assembled for the meeting. The organizers had as one objective to enrol pilot centres to implement the strategy they had designed, something achieved in Maayanei Hayeshua Hospital which presented its one-year results. Also reported were the results of the campaign by community pharmacy chain Superpharm to advise patients with anticoagulants; a fascinating drug-use snapshot. Healthcare professionals from hospitals and community, from industry, Ministry of Health and HMOs were brought together. Solutions: tools, methods, artificial intelligence and IT were discussed, and patient communication and transparency explored. A range of therapeutic classes were covered: anticoagulants, bio-pharmaceuticals, opioids. Other hospitals in Israel have shown interest, among them Sheba medical centre; a session was dedicated to their drug safety engineering.

Over the next five years ISoP Israel will be on the Advisory Board of the Ministry of Health campaign on polypharmacy in elderly people. This was introduced by project leader Prof Elliot Berry, Public Health Hebrew University. The hope is that all these projects and pilots will build towards a real think-tank to improve drug safety in Israel.

First ISoP Fellowships

A new ISoP Fellowship status has been established to recognise significant contributions from those who have been members of our society for more than five years. [Details are available here.](#)

On 5th June 2019, the ISoP Fellowship Nominations Subcommittee (FNSC) met to discuss applications received before the deadline of 31st May. The FNSC is chaired by Associate Professor Mira Harrison-Woolrych (ISoP Secretary General) and includes Ms Deirdre McCarthy (ISoP Board member) and Professor Ian Wong (ISoP Vice-President).

The committee received several strong applications and will be making recommendations to the ISoP Executive Committee later this month.

Candidates will be contacted after 30th June and ISoP's first Fellowships will be announced at the ISoP General Assembly in Bogotá (13.30-14.45 on 28th October) at the ISoP 2019 Annual meeting.

News from SIGs

There are currently [seven active SIGs in ISoP](#):

- ★ Women's Medicines
- ★ Risk Communication
- ★ Risk Minimisation Methods for Asia
- ★ Herbals and Traditional Medicines
- ★ Medication Errors
- ★ PV Career Framework
- ★ Medical Devices.

The remit of the Risk Minimisation Asia SIG is being expanded to include a multi-disciplinary group looking at pharmacovigilance systems in a more regional way, building on the work of a previous initiative; a vaccines SIG is in planning.

Key on-going activities include preparation of a paper on herbal hepatotoxicity, social media strategy for medication errors, and a draft global pharmacovigilance career framework.

Do contact ISoP should you wish to become involved in any of the above SIGs, and come to Bogotá in October to hear directly from the SIGs!

ISoP Board elections

Elections to the new ISoP Board will take place in the first week of September. The vote will be conducted on-line. There will be 10 vacancies to be filled. As soon as the new ISoP Board is elected, it will propose and elect a President from among the Board members by on-line ballot. The new President and the officers (Executive Committee) will be in place for the Annual Meeting in Bogotá in October to have its first meeting.

At the end of July, the list of candidates will be posted on the Members section on the website with their personal statements. More information about voting procedures will be e-mailed to all members at the end of August.

Get ready to vote for the new ISoP Board!

ISoP Seminar Boston

The ISoP Seminar in Boston, USA, on Intelligent automation in Pharmacovigilance will come back for a third edition on 9th and 10th December 2019.

[Register your interest on the website.](#)

Oman in 2020

Muscat is the venue for the 2020 ISoP annual meeting. The 20th ISoP Annual Meeting will take place on 12th-15th October 2020 at the Grand Millennium Hotel. Sten Olsson (Sweden) will chair the Scientific Committee, and its other members will be announced later.



The local organisers are Thamer Alshammary and Mayada Alkhakany, President of the ISoP Middle East Chapter.

Obituary for David Finney

Honorary member of ISoP, Emeritus Professor David Finney, one of the trail-blazers for pharmacovigilance, died last November aged 101, and we are pleased to be able to reproduce on the ISoP website the obituary written by Ralph Edwards, and first published earlier this year in Uppsala Reports.

“David was a remarkable, modest person and wonderful as a friend. His scientific achievements in mathematics and statistics are numerous and are well recorded at the James Lind Library, but he was also a traveller, a raconteur, kind, and yet determined. He had a profound interest in people and their welfare and happiness, certainly not as an amorphous statistical group.”

[Read on at the ISoP website.](#)