



# The ISO P Star

No 39. December 2019

## Reports from the world of pharmacovigilance

### ISO P reaches the heights

Bogotá, capital and largest city in Colombia is located on a high plateau in the Andes at an altitude of 2,640 metres. In October 385 professionals from all round the world headed to the Grand Hyatt there for the annual forum of updates, research reports, networking and some fun.

The well-attended pre-conference courses - on medication errors and human factors, active surveillance in pharmacovigilance including pharmacoepidemiology tools, and biological and biotechnological product safety - set the scene for a packed programme in the following two-and-a-half days.



*Packed plenary at ISO P 2019*

There was little neglected using the parallel session format, and major plenaries put the spotlight on the patient's role in pharmacovigilance, the importance of human factors in pharmacovigilance, and the work of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance in assessing the impact of pharmacovigilance. Other main topics included strengthening the capacity for signal detection and management for national centres and 'Smart Safety Surveillance': what, why and how.



*Brian Edwards introduces one of the courses*

The increasing role of ISO P Chapters was on view in a session where each geographical group gave a brief sketch of their activities, from Africa to North America and with stops in the Middle East, Italy, South East Europe, the Pacific Rim, Indonesia and Latin America. Likewise the ISO P Special Interest Groups showcased their work in a dedicated session, offering good reasons to join one or more and get involved.

The annual Bengt Erik Wiholm Lecture was given by the tireless advocate for pharmacovigilance, Mariano Madurga Sanz from Spain, whose topic was 'Which are the new opportunities for new generations?'; the CIOMS lecture was an update on hepatotoxicity and drug-induced liver injury (DILI) from Dr Alexandre Olry, France.

From the wide range of posters displayed this year, prizes went to:

- ★ 1st Prize: R. Soulaymani, H. Sefiani, G. Benabdallah, A. Tebaa (Morocco)  
#54 Promoting Spontaneous Adverse Event Reporting in Morocco. The national Reporting Day.

- ★ 2nd Prize: T. P. Pacheco (Colombia)  
#67 Parkinsonism associated with Gabapentinoid drugs: an observational post marketing study.
  - ★ 3rd Prize: M. Tuccori/S. Ferrano, L. Leonardi, C. Blandizzi, I. Convertino (Italy)  
#2 Antibiotic Drugs and unresolved sensory side effects: analysis of Eudravigilance database of suspected adverse drug reaction reports.
- (#number indicates the abstract number in *Drug Safety* Vol.42 No.10, 2019)



Raquel Comoglio (chair of the poster prize committee) and Amina Tebaa (first prize)

Each winner will receive a one-year subscription to the journal of their choice kindly donated by Adis Premier journals. As ever thanks are due to all who took time and trouble to present their work and research at the meeting.

The conference dinner was in the lively surroundings of a typical Colombian cabaret restaurant, the Café Gaita, where, as well as the food, a music and dance show entertained delegates for the evening.



Fun at the ISoP 2019 welcome reception with Colombian dancers

## All change on the Executive and Board

The results of the ISoP Advisory Board Elections in 2019 were announced during the annual meeting, and for 2019-22 the Executive Committee and Advisory Board will be:

**President :** Mira Harrison-Woolrych  
**Vice-President :** Rebecca Chandler  
**Secretary General :** Deirdre McCarthy  
**Treasurer :** Jean-Christophe Delumeau  
 Angela Caro Rojas (Colombia)  
 Jan Petracek (Czech Republic)  
 Gianluca Trifirò (Italy)  
 Mónica Tarapués (Ecuador)  
 Manal Younus (Iraq)  
 Li Zhang (China)



Members of the new Board with some past members, from left back row: Mónica Tarapués, Manal Younus, Rebecca Chandler, Hervé Le Louët, Brian Edwards, Gianluca Trifirò, Angela Caro Rojas, Phil Tregunno, Jean-Christophe Delumeau; in front: Sten Olsson, Mira Harrison-Woolrych, Deirdre McCarthy.

The following EC/AB members have agreed to undertake other roles for ISoP:

Chair of Fellowship Nominations Committee: Deirdre McCarthy  
 Chapters Co-ordinator: Rebecca Chandler  
 CIOMS representatives: Manal Younus and Sten Olsson  
 Communications Team: Deirdre McCarthy, Angela Caro Rojas and Mónica Tarapués  
 ISPE and EnCePP liaison: Gianluca Trifirò  
 SIGs Co-ordinator: Angela Caro Rojas  
 UMC/WHO liaison: Rebecca Chandler

## Message from new ISoP President



I am honoured and delighted to have been elected as President of ISoP – as announced on 28th October 2019 at our Annual General Meeting in Bogotá – and am especially proud to be the first woman to ever hold this role in our professional society. I would like to thank all ISoP members who voted for me and the other members of our new Executive Committee and Advisory Board. Worldwide, women constitute approximately 70% of the pharmacovigilance workforce: it is therefore both gratifying and appropriate that membership of the ISoP Advisory Board for 2019-2022 reflects this distribution.

I would like to summarise my vision for ISoP and pharmacovigilance during the next three years, following on from my first presidential address in Bogotá. If this is the first time you have read about ISoP, welcome to our professional society! For those of you who have been members for a long time (as I have) please accept my personal thanks for your commitment and enthusiasm for pharmacovigilance worldwide and I look forward to working with you in my new role.

**We are all pharmacovigilantes!**

ISoP now includes over 800 members from 100 countries, and the key elements that unite us are

much stronger than any of our individual differences. I live and work in New Zealand, where the indigenous Maori people have a saying “*He waka ake noa!*” – “*We are in this canoe together*”, and more broadly encouraging a unity in purpose. This is my philosophy for how we should operate in pharmacovigilance. Whether we come from a clinical or academic background; from medicines regulation or other governmental bodies; from NGOs or charitable organisations; or from the pharmaceutical industry, within ISoP we must all paddle in the same direction to achieve safer use of medicines worldwide. Our professional society is a place where we can educate, collaborate, network and support each other in conducting the essential tasks of monitoring the safety of pharmaceutical products, whatever our personal or professional backgrounds.

### Patient-centred pharmacovigilance

We must never forget that patients are at the heart of our work. In my experience as a clinical doctor, having also been employed in academic research, medicines regulation, pharmacoepidemiology (as former Director of the New Zealand Intensive Medicines Monitoring Programme) and working as a writer (see <https://www.miraharrison.com/>), I have learned that in order to maximise the safe use of medicines/devices, and to conduct appropriate risk management in any environment – including drug development in clinical trials – we must understand how products are used in real life. This includes knowing how drugs are obtained by patients; how they are taken, inserted or applied (or not!), and – in addition to the clinical factors which may affect safety (e.g. personal medical history; concomitant medicines) – how societal or cultural environments may affect efficacy or safety in each individual. Including and consulting with patients, and helping to better integrate pharmacovigilance with clinical medicine and public health systems, should be fundamental parts of the ISoP mission.

### Special Interest Areas

International pharmacovigilance has broadened in scope to include study of medication error, medical devices, herbal and traditional medicines, vaccine safety, women's medicines and risk minimisation

methods. This is reflected in our ISoP Special Interest Groups which I encourage all ISoP members to join and participate in, depending on your area of interest. There are plans to develop common themes across all the ISoP SIGs, for example, patient involvement in pharmacovigilance, risk communication practices, with presentation of this work at future ISoP conferences. Our leadership team also has ideas for new SIGs, for example on biologicals and advanced medicines, and would like to include more pharmacoepidemiology into ISoP courses and conferences. We will reach out to colleagues worldwide to assist and collaborate with us.

### New ISoP leadership team for 2019-2022



Members of the new Board, from left: Manal Younus, Mónica Tarapués, Rebecca Chandler, Mira Harrison-Woolych, Deirdre McCarthy, Jean-Christophe Delumeau, Angela Caro Rojas, Sten Olsson, Gianluca Trifirò.

The new ISoP Executive Committee (EC) and Advisory Board (AB) include pharmacovigilance experts from a wide range of countries, backgrounds and workplaces. All have been democratically elected by ISoP members worldwide and conduct their work for ISoP as volunteers. I would like to acknowledge their generosity in donating so much time to our society: the enthusiasm and support which every EC/AB member provides to our leadership team is inspiring! I am extremely lucky to have such a hard-working and diligent team behind me.

## Mid-year in Moscow

The 27-29 April 2020 ISoP mid-year meeting in Moscow will be the first to be organised by ISoP in the Russian Federation and will address the needs of stakeholders from the Eurasian Economic Union (EAEU) interested in pharmacovigilance methods and activities.

Healthcare professionals from national regulatory authorities, academia, medical institutions, health care industries and service providers are welcome. Come and network and contribute to the success of this event where the audience will be invited to interact with the presenters and panellists.

The 2020 ISoP mid-year course will be happening at a crucial time for the EAEU region. After implementing a common Good Vigilance Practice several years ago, the different national pharmacovigilance systems are moving toward maturity – but at different speeds. The safety-regulatory harmonisation process is incomplete and substantial challenges remain and a revision of the EAEU-GVP is underway. We look forward to meeting members old and new in Moscow!

## Membership renewal system change

Members who joined ISoP before January 2019 or after should be aware that the existing method for annual subscriptions has changed. Our new membership management system automatically takes the annual payment by credit card on a rolling 365-day membership cycle; so if you join on the 1st of December your membership will run until the following 30th of November, and so on. We believe this will be easier to administer for the Society, a fairer system, and better understood by members.

**Please note:** Members will receive a reminder email 28 days and 1 day before we automatically take payment from your card. If your card has expired or your details have changed please login at <https://isoponline.org/members/> and update your account within the 'Members Profile' or 'Update your Information' within the 'Members' menu.

If you no longer wish to benefit from being an ISoP Member please login and select 'Cancel' in the Members Profile page.

Or contact [administration@isoponline.org](mailto:administration@isoponline.org) who will be happy to help.

## Oman annual meeting

The 2020 ISoP Annual Meeting will take place in Muscat, Oman from 12th to 15th October 2020. The theme will be 'Integrating pharmacovigilance for safer patients - activities and stakeholders coming together for more effective systems'. The planned programme will focus on:

- ★ integrating safety data and knowledge from different information sources
- ★ coordinating key stakeholders of national pharmacovigilance systems
- ★ harmonizing safety surveillance across different groups of health products
- ★ making safety data and knowledge relevant to meet local, regional and global needs
- ★ managing languages, nomenclature and terminologies for interoperability of information.



### Important dates:

Abstracts submission and registration will open on 3rd March 2020

Deadline for submission of abstracts: 20th May

Early-Bird Registration: 15th July

Pre-conference courses: 12th October

## Success in China

The ISoP-UMC training event planned for Shenzhen, China in September was postponed and moved to Guangzhou, on 11-12 November 2019. The training was jointly sponsored by the

International Society of Pharmacovigilance, the Uppsala Monitoring Centre (UMC). It was also supported by the ISoP China Chapter and The University of Hong Kong - Shenzhen Hospital.

There were 71 participants from all levels, mostly from Chinese drug regulatory administrations, commercial enterprises, medical institutions, and scientific research academies in the region.



Panel discussion in Guangzhou

The two-day course levered pharmacovigilance expertise drawn from UMC and ISoP, the National Medical Products Administration (NMPA) (formerly the China Food and Drug Administration or CFDA), as well as local organizations and was designed to address both practical and theoretical aspects of pharmacovigilance. The programme covered topics such as:

- ★ ICH related topics such as E2B and its implementation as well as Periodic Safety Update Reports (PSUR) and Development Safety Update Reports (DSUR) submissions
- ★ Terminologies used in pharmacovigilance: WHODrug and MedDRA
- ★ Experience sharing about good quality case reports in China
- ★ Safety evaluation and risk management covering signal detection and serious organ toxicity
- ★ Introduction to the new Chinese PV 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.

Based on the feedback, the course was deemed very beneficial and we would like to thank the organisers and the participants for contributing to this successful outcome.

## AI in Boston

December brought the third edition of ISoP's North American Seminar on Intelligent Automation in PV. Fast becoming a fixture of the pharmacovigilance calendar, these two days brought together a group of 50 representatives from US FDA, MHRA, UMC, companies, technology and service providers.



*The participants in Boston*

Topics discussed included experience gained with AI and machine learning to date, new approaches, pros and cons, regulatory expectations and approaches to identifying opportunities for AI across the lifecycle. A panel discussion with regulatory and industry participants was a major highlight.

During the afternoon of the second day, there was a joint programme with the Annual Meeting of North America's Chapter of ISoP (NASoP) allowing pharmacovigilance professionals to conveniently attend the annual meeting as well as the seminar. The International Society of Pharmacovigilance would like to extend its gratitude to Biogen for hosting the meeting at its premises for the third time in a row.

Next year's seminar is already on the books for December 2020 – see you there!

## MoU renewed

The memorandum of understanding (MoU) between ISoP and the Uppsala Monitoring Centre (UMC) has been renewed for another three years. It principally covers collaboration in the field of training events in Asia and Latin America.

## 2021 annual meeting in Barcelona

Discussions over the year have led to a successful bid from colleagues at the Fundació Institut Català de Farmacologia organization to hold the 2021 annual meeting in Barcelona, Spain.

## Chapters building networks

Sameh Al-Zubiedi coordinated the 4th ISoP Middle East Chapter symposium in Amman in partnership with Acdim Biocentre.

The ISoP Middle East Chapter held their 5th Pharmacovigilance Workshop in November, a two-day meeting in collaboration with MSSO who provided MedDRA training. Many thanks to all involved for a very successful course!

### Regional ISoP leaders

Regional Leaders for each of the eight areas of the world where ISoP has members have been appointed:

- ★ Africa (African Chapter) – *Helen Ndagije, Sten Olsson*
- ★ Asia (China Chapter, Indonesia Chapter, South East Asia Chapter) – *Jean-Christophe Delumeau, Li Zhang*
- ★ Europe, North West (Italian Chapter, Swiss-Austria Chapter) – *Rebecca Chandler, Gianluca Trifirò*
- ★ Europe, South East (South East Europe Chapter) – *Katarina Ilic, Jan Petracek*
- ★ Latin America (Latin American Chapter, Mexican Chapter) – *Angela Caro Rojas, Mónica Tarapués*
- ★ North America (North American Chapter) – *Deirdre McCarthy, Jan Petracek*
- ★ Middle East (Middle East Chapter, Israel Chapter) – *Manal Younus, Magnus Ekelo*
- ★ Western Pacific (Western Pacific Chapter) – *Jo Barnes, Mira Harrison-Woolrych.*

All members are encouraged to contact the Regional Leaders for their area, informing them of how our Society can serve your needs. Please e-mail the ISoP Secretariat and we will put you in touch with the best person to help.

## First Fellows

The first cohort of Fellows of the International Society of Pharmacovigilance was announced at the meeting in Bogotá.

They are:

Deirdre McCarthy, BSc, MSc

Luis Alesso, MD

Priya Bahri, BSc, PhD

Giovanni Furlan, BSc

Mira Harrison-Woolrych, BM, DM, FRCOG

Ian C. K. Wong, PhD

Katarina Ilic, MD, MSc, PhD, MPH

Raquel Herrera Comoglio, MD, MSc

The Fellowship of the International Society of Pharmacovigilance is for ISoP members with five years membership, who have demonstrated significant achievement and distinction in their field, including peer recognition in pharmacovigilance. Fellows will have made substantial contributions to the discipline of pharmacovigilance through their work – including publications or similar outputs – and have also shown service to ISoP, for example by involvement in ISoP conferences and meetings, and/or by leadership of ISoP Chapters and Special Interest Groups.

Applications are assessed each year by the Fellowship Nominations Sub-Committee and new Fellows will receive their certificate at the ISoP Annual General Meeting. Their profile, including contributions to ISoP, will be published in the AGM minutes and in a subsequent print edition of Drug Safety. In recognition of their contribution to ISoP, Fellows may be invited to undertake additional leadership roles within the society.

## Membership jumps again

As of the meeting in Colombia, ISoP had 830 members from 101 countries. This is another significant marker of the Society's growth in recent years. Both in terms of individuals who are part of our pharmacovigilance movement and the geographical coverage they represent, this is impressive!

## The medium and our message

ISoP's presence online is enhanced by an active Twitter feed - @ISoPonline. There are now around 1,500 people following ISoP on this platform – do join them if you have not already!

Our website <https://isoponline.org/> continues to be updated regularly, and the members-only section is where you will find presentations from the annual meeting and have the chance to update your personal information.

## CIOMS working group XI

ISoP representatives Sten Olsson and Brian Edwards have attended consultations for the Patient Involvement in the Development and Safe Use of Medicines working group which CIOMS is organizing at present.

Following the meeting in Geneva in May, they were present in Basel last October. Their next meeting will be next April in Utrecht, Netherlands.

## Get in touch

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

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**\* Wishing Season's Greetings and a Happy New Year to all ISoP members!**