



The ISoP Star

News and reports from the International Society of Pharmacovigilance

No 37. December 2018

Over 600 members!!



A plenary at the 2018 annual meeting, in Geneva - welcoming some of the many new members

ISoP now has over 600 members, its highest membership total ever. Recent years have seen a consistent increase in the number of Society members reported each year. With more attention to the various benefits of membership and extra training courses all around the world attracting new members, the Society hopes to consolidate this number even more.

If you have a colleague who would be interested in joining, why not get them signed up? All the details on how to become a member can be found on the Society website.

In view of the considerable increase in membership, and to reduce the administrative costs, a new, more automated system for membership renewal will begin in the New Year, and from then each annual membership will run from the date of joining/renewal.

Further information on this rolling 12-month membership will be sent out soon. See the last page of this ISoP Star for more about membership.

Welcome to all new members - and to those who have been here for some time, thanks for your loyal support!

Back in Geneva 25 years on

In 1993 a group of pharmacovigilance professionals from around Europe came together in Geneva for the inaugural meeting of the European Society of Pharmacovigilance. A quarter of a century later, a handful of those people were among the 430 delegates from 72 countries who packed the pleasant surroundings of the International Conference Centre Geneva (CICG) for three days of discussion and learning at ISoP2018.

The 2018 organizing committee had set out their aim to 'optimise pharmacovigilance, so that it can operate without borders, offering us greater efficiency, clarity of reporting and thus enable us to analyse the latest information to better care for patients on a worldwide basis'.

From the diverse programme it was clear that the 'borders' were not only geographical and disciplinary but conceptual, pushing the boundaries of habitual pharmaco-vigilance into neglected areas of patient safety.



Down memory lane at the ISoP 2018 dinner in Geneva - a projected photo of Rafe Edwards, Nicolas Moore and Ronald Meyboom planning the European Society in 1993.



A rare quiet moment for Sophie Spence on the ISO P desk in Geneva

Programme

A new process for devising the programme, by inviting proposals from members for topics and sessions, resulted in ten varied symposia to complement the main plenaries.

Symposium 1: Taking advantage of new data and technologies to facilitate the collection of safety data and to enhance their value for contributing to decision making

Symposium 2: The impact of adverse drug reactions on public health – how to get relevant and reliable data as the basis for preventive measures and the assessment of their success?

Symposium 3: Pavia and Proforma projects increasing pharmacovigilance readiness in Sub-Saharan Africa

Symposium 4: Teaching pharmacovigilance to undergraduates and pharmacovigilance beginners

Symposium 5: Need for a joined-up strategy to optimize use of medicines for HIV/AIDS, TB, and diabetes

Symposium 6: Professional pharmaceutical service: the experience of joint work between academia, pharmaceutical associations and the pharmaceutical industry

Symposium 7: Why do so many people receive treatments they do not need and what can we do about it?

Symposium 8: Current challenges in data collection on safety regarding drug use during pregnancy and breastfeeding

Symposium 9: The case narrative and artificial intelligence

Symposium 10: Practical aspects of pharmacovigilance in resource-limited countries.

The annual Bengt Erik Wiholm Lecture also expanded its scope to include patient perspectives and a round table panel.

2018 poster prizes

284 posters were accepted for the 18th ISO P Annual Meeting, and were displayed in two rounds in the airy exhibition hall and refreshments area. Abstracts are available on pages 1124 to 1263 of the special edition of *Drug Safety* to coincide with conference Vol 41. No.11 (which also has the abstracts of the oral presentations). The Poster Prize winners were:

1st prize: Anca Butucă, of the Universitatea 'Lucian Blaga' din Sibiu, in central Romania, for 'A Study regarding the frequency of adverse reactions in the infertility treatment'.

2nd prize: Irma Convertino of the University of Pisa, Italy, for 'A model-based analysis on direct costs of adverse drug events and related cost-savings achievable by their prevention in Tuscany, Italy'.

3rd prize: Octavio Alejandro Enríquez Lara of the Federal Commission for Health Risk Protection, Mexico, for 'Frequency of regulatory breach of risk management plans in Mexico'.



Sten Olsson, Anca Butucă and Pia Caduff (chair of the poster prize committee)

Congratulations to all three poster prize winners, and thanks to everyone who took trouble to submit their work to the poster sessions.

A Happy New Year to all members!

Two pre-meeting courses on topical areas of pharmacovigilance considered issues related to the ageing population, and phases of the pre-approval of medicines.

The Conference Dinner, enjoyed by around 250 delegates, featured – as well as excellent food and wine – short reminiscences from those who were at the conception of the society in 1992, and the cutting of a suitably festive 25th birthday cake. The more energetic ISoP members stayed after the meal for an anniversary disco.



ISoP 25th birthday cake

In November with winter drawing on the city of Geneva still has its charms with its famous lake, the cobbled streets of the old town and endless enticing chocolatiers for those necessary gifts to take home. Local organizers led by Victoria Rollason, of the University Hospitals of Geneva, ensured the large group had an attentive welcome and a smooth-running programme.

ISoP 2018 presentations

ISoP webinars and most of the Geneva ISoP 2018 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, Chapters sections and ISoP Board meeting minutes, please go to the 'Member section' in 'Member Login' enter your registered e-mail address and password.

Non-members who registered at the Geneva Annual Meeting and paid full registration fees become ISoP members from 1st January to 31st December 2019. A very warm welcome to these newcomers!

New medical devices SIG



Sten Olsson with Dr Jitendar Sharma, convenor of the new SIG on the Pharmacovigilance of Medical Devices

The Geneva meeting saw the launch of a new Special Interest Group (SIG) on the Pharmacovigilance of Medical Devices.

With recent revelations from the International Consortium of Investigative Journalists on shortcomings in the safety monitoring of medical devices, this will be a timely and important addition to the Society's activity.

Session C of the conference heard from a patient representative as well as academic research on the problems facing the sector.

Any member of ISoP with an interest in medical device technology and safety is welcome to join this SIG. We are expecting and hoping the group will attract members from different countries and continents and a good representation from countries who are strong in medical technology.

If you would like to join the medical devices SIG please contact Mr Santhosh Kumar at santhosh.kumar@amtz.in

A Happy New Year to all members!

A SIG is a group of ISoP members acting as volunteers and working on a specific and relevant topic which is within the scope and aims of ISoP. Currently there are SIGs on:

'Risk communication', 'Women's medicines', 'Risk Minimisation Methods for Asian countries', 'Herbal and Traditional Medicines', 'PV Professional Qualification Framework', 'Medication Errors', and the new one described here.

Future events

Pharmacovigilance in Africa beyond spontaneous reports

ISoP-ASoP Symposium & Training Course
Sarova PanAfrica Hotel, Nairobi, Kenya;
6 (Symposium), 7-8 (Training course) May 2019

The programme of this combined symposium and mid-year training event will include:

- Current pharmacovigilance landscape in Africa
- Pharmacovigilance during the pre-approval phase in Africa
- Pragmatic active methodology applicable to pharmacovigilance in Africa - pharmacoepidemiological and other methods designed to fit Africa's unique challenges
- Strengthening pharmacovigilance regulations in Africa - the concept of Qualified Person in Pharmacovigilance (QPPV), African Medicines Regulatory Harmonisation Programme, EAC Initiatives, PV inspections, PV System Master File (PSMF)
- Risk Management Planning - Benefit versus Risk evaluation methods, Risk minimisation methods. Safety communication methods in African contexts.

Practical information, the programme and registration forms are available on the website; <https://isoponline.org/training/midyear-training-nairobi-6-8-may-2019/>.



ISoP Israel Chapter

International Symposium 'Drug Safety from All Angles, multidisciplinary and solution-oriented'
Herzliya, Israel, 3-4 June 2019

Keynote speakers will be world-leading safety experts from EU, US and Israel.

Day 1 will cover key tools and methods: to prevent medication errors and improve communication, to combine dual risk management approaches of pharma industry and hospitals. Day 2 will consist of a case study: new tools for managing anticoagulants treatment, current initiatives: what works?

Participants will leave with a tool-box to use in their own environment.

Please send your abstracts and share your experience in medication error, risk communication on any medication or anticoagulants, to isopisrael@gmail.com.

Go to

<http://www.ortra.com/events/isop2019/Home.aspx>
or, <https://www.linkedin.com/company/isopisrael>.



ISoP Board Elections

Would you have the time and the opportunity to commit to undertaking the role of a member of the ISoP Board?

Would you like an opportunity to contribute and help ISoP to be a robust, professional and leading society in pharmacovigilance? ... then we are interested in hearing from you!

Paid-up members with appropriate skills and experience who would like to put themselves forward as a candidate are invited to contact the Nominating Committee (contact Sophie Spence administration@isoponline.org with any queries).

A Happy New Year to all members!

ISoP Fellowship

A new membership category was announced at the annual general assembly of ISoP in Geneva: Fellows of the International Society of Pharmacovigilance - members who have demonstrated significant achievement and distinction in their field, including peer recognition in pharmacovigilance. They may have made substantial contributions to the discipline of pharmacovigilance through their work (publications, for instance) and have shown service to the Society, through involvement in ISoP meetings, or leadership of ISoP Chapters and Special Interest Groups.

Members wishing to apply for Fellowship must demonstrate distinction and peer recognition in the practice, research and/or education of pharmacovigilance. Applicants will be asked to complete an application form and a statement outlining how they meet the criteria for Fellowship. All applications will be considered by a sub-committee, which will recommend Fellows to the other members of the Executive Committee and Advisory Board who will then decide on Fellowship awards.

ISoP collaborations

ISoP representatives Sten Olsson and Brian Edwards will be taking part in the CIOMS working group XI on 'Patient Involvement in the Development and Safe Use of Medicines'. They have already attended the meetings in Geneva in April and Berlin in October. You can follow the progress of the group, and read about their objectives, on the webpage https://cioms.ch/working_groups/working-group-xi-patient-involvement/. ISoP is affiliated as an International Member of CIOMS.

There is also a potential partnership with the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP); here the ISoP representative is Hervé Le Louët. The ENCePP steering group has invited proposals from ISoP for further activities to strengthen EU pharmacovigilance. A draft memo from ISoP was discussed within the ISoP Advisory Board and submitted to ENCePP, followed by further contact; there is a possibility for closer collaboration in specific areas.

WHO involvement

ISoP was represented in the Pre-ICDRA (International Conference of Drug Regulatory Authorities) meeting in Dublin in September 2019, where the President moderating a panel discussion on the WHO-led Smart Safety Surveillance initiative.

ISoP has also submitted comments on the vigilance section of the WHO Global Benchmarking Tool; this is a means by which WHO will evaluate a country's regulatory system through comprehensive and systematic benchmarking, to identify strengths and weaknesses leading to the formulation of an institutional development plan.

North America chapter

The NASoP Annual Meeting 2018 was held on 2nd November 2018 at Takeda, Boston. "Structured benefit-risk assessment across the therapeutic product lifecycle" was presented by the Benefit Risk Framework NASoP sub-group composed of experts from academia, industry and FDA.

The meeting was a great success, triggered high interest and was very well attended with more 90 participants.

Members of NASoP can access the meeting presentations on the ISoP website via the Members section.



NASoP in Boston - Veronique Kugener, Sara Eggers, Abimbola Cole, Yola Moride, Carmit Strauss, Laura Peppers, and Rania Mouchantaf

A Happy New Year to all members!

Second Boston seminar

The 2nd “Intelligent Automation in Pharmacovigilance” ISoP Seminar, held on December 3-4 in Boston, once again brought together forward-thinking representatives of industry, government and academia at the Biogen Auditorium to share their success stories and provide actionable insights into the advances and challenges of bringing Artificial Intelligence and Automation in pharmacovigilance to reality.

While maintaining last year’s level of thought-provoking ideas, this year’s seminar has also provided its 50 participants with an abundance of real examples of business process automation and artificial intelligence applications within pharmacovigilance.

Special mention should be made of Sameen Desai’s presentation on Celgene’s AI endeavor that championed knowledge dissemination by sharing a detailed blueprint for machine learning development and validation. Eva-Lisa Meldau’s presentation on UMC’s approach to automated patient deidentification, provided a comprehensive overview of the proposed ensemble method and plain explanations of constituent AI techniques. Shaun Comfort (Genentech-Roche) gave a live demonstration of the MONARCSi Causality Assessments Decision Support system prototype, and explained the underlying algorithms to the audience.

It was also great to see video demonstrations of automation. Sameer Thapar (Oracle) offered a glimpse of the upcoming capabilities of automated Adverse Drug Reaction report intake and data extraction in Argus, while a demo of automated safety database data entry using Robotic Process Automation came in Jeffrey Philip’s presentation on Biogen’s “foray” into this technology.



An alternative approach to safety data collection streamlining using WEB-RADR and similar platforms was discussed by Phil Tregunno (MHRA), who outlined some legal requirements and potential regulatory challenges with AI solution validation. This simplified and user-friendly reporting solution was congruent with Anton Rachmanov’s (PrimeVigilance) stance on automation risk management, inspired by systems theory’s notion of complexity.

Undoubtedly, Touchless Case Management was biggest topic of the Seminar, and Eric Sandor (Genpact), Aman Wasan (ArisGlobal) and Sidd Bhattacharya (PwC) showcased their companies’ products and provided an outline of automation possibilities available today. Uwe Trinks (Foresight, an IQVIA company) has adopted the same approach, but went the extra mile and supplied the audience with an overview of commercially available technologies, as well as a list of expected characteristics of a hypothesized next generation zero-touch safety system.

Kristof Huysentruyt (UCB) reminded the audience about the impact on and the role of human resources and skillsets in automation implementation, as well as the necessity of developing a vision for automation and AI, which was aligned with Sean Darcy’s (Alnylam) presentation on holistic and purpose-driven innovation.

All the aforementioned issues were summarized within panel discussion sessions, prepared in advance by Jan Petracek’s (ISoP Board Member, PrimeVigilance) stimulating and even provocative presentations on the future of pharmacovigilance ecosystems and analysis of the potential impact of automation on our industry.

The International Society of Pharmacovigilance would like to extend its gratitude to Biogen for hosting the meeting at its premises, and to PrimeVigilance for their organizational support.

The seminar received very positive feedback and ISoP is hopeful that a third can be held in due course.

◀ *Intelligent Automation participants in Boston*

A Happy New Year to all members!

2019 membership renewal

As part of the ongoing process of improving the ISoP website we are currently making some changes to the membership renewal process. Renewals notices will be sent out from the first week of January 2019, when members will be able to renew online by completing a renewal form and make payment (or ask for an invoice if payment is by bank transfer).

New >>

All ISoP membership subscriptions are now annually recurring with payment being taken electronically every year. Membership subscriptions will be renewed 365 days from the date of registration, with payment automatically debited from your card unless you choose to cancel your membership subscription.

Please remember to renew your membership! Only members who are paid-up will have access to incentives, Chapters and SIGs.

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

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.

Drug Safety journal

As part of their membership, all ISoP members will receive electronic access to the journal *Drug Safety*. The link to *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.

As a member of ISoP, the way we keep you informed and updated about the Society and its activities is solely through e-mails. If you have changed your e-mail address, do let us know as soon as possible.

2019 meeting in Colombia

Our next annual meeting will return for a third time to Latin America, in Bogotá, Colombia, the theme “New opportunities for new generations”.



The poster for the ISO P 19th Annual Meeting in Bogotá, Colombia, features a colorful logo with a stylized bird and the text 'ISO P 19th ANNUAL MEETING Bogotá 2019'. It includes the dates '06 - 09 November' and the tagline 'New opportunities for new generations'. Below the logo is a collage of images showing various scenes from Bogotá, including a park, a street, and a building. The bottom section of the poster lists 'Topics of conference:' and 'Register your interest for ISO P 2019'. The topics include Medication Errors, Risk Communication, Risk Management Plans and Signal Detection, Pharmacovigilance Education throughout the System, Herbal Medicines, Women's Medicines, Social Network Impact in Pharmacovigilance, Patients and Pharmacovigilance, and more. Contact information is provided: Email at: contacto@isop2019bogota.org and Web: isop2019bogota.org. Logos for sponsors like Best Cities and Bogotá are also present.

So 'save the date' for the ISoP 2019 Annual Meeting, on 6-9 November 2019, and keep an eye out for the first announcement and deadlines for submissions of abstracts at

www.isop2019bogota.org

Visit the ISoP website for all new training courses (including the ISoP-UMC training course in China) and updates.

Webinars – stay tuned

Two ISoP webinars were offered to members last year, with the assistance of Springer Nature. For your convenience, you can find these webinar videos on our website (Members section).

Thanks to the success of these webinars, a new free webinar will be organised with Nitin Joshi, Editor-in-Chief of *Drug Safety* in February or March 2019 on 'The value of review articles'.

A Happy New Year to all members!

Annual meeting 2020

At its meeting in Geneva in November the ISoP Advisory Board decided to accept the invitation received from the Middle East chapter to organize the 2020 Annual ISoP Meeting in Muscat, Oman.

ISoP Privacy Policy

To reflect the 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 on, we will ask your consent to e-mail you about the Society's activities, including training and annual meetings, events and the newsletter (ISoP Star), learning opportunities (webinars), membership and other benefits (Members section on our website and access to the journal Drug Safety) through your membership.

In addition, a new section 'Terms of service' describes the new membership management and auto-renewal with payment being taken electronically every year (available from the first week of January).

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

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

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Get in touch

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A Happy New Year to all members!