



The ISoP Star

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*Reports from the world of
pharmacovigilance*

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President's Message

Dear ISoP members

As we bid farewell to another remarkable year, I am thrilled to share the astounding achievements and milestones our Society has attained throughout 2023.

This year has been a tremendous success, marked by significant strides in enhancing our visibility, forging strategic alliances, and enriching our academic endeavours. Our community has expanded to nearly **10,000 followers** across various social media platforms such as LinkedIn and YouTube (if you haven't joined us yet, find us www.isoPONline.org). Collaborating with esteemed partners including the **World Health Organization, Uppsala Monitoring Centre, the International Medication Safety Network**, among many others, has been pivotal. Keep an eye on our new webpage for the latest documents, projects, and training opportunities.

Our calendar was adorned with stellar events, each contributing to the dissemination of invaluable knowledge on medication safety. From the **Mid-Year Training in Leiden** to the virtual **ISoP World Patient Safety Day**, the resounding success of the Annual Meeting in Bali, and the recent **ISoP Seminar on Intelligent Automation**, these gatherings not only welcomed over 200 new members but also fostered collaborative learning and engagement.

Throughout the year, our Special Interest Groups (SIGs) and Chapters diligently organized **25 webinars**, imparting specialized insights. For those not yet part of any SIG or Chapter, I encourage you to explore these valuable resources on our website.

During our General Assembly at the **#ISoP2023Bali Annual Meeting**, we shared comprehensive updates and insights, providing a glimpse into our dynamic journey. Stay connected with us on social media for further updates.

Looking ahead, I urge you to mark your calendars for our upcoming events in the coming year:

- ✓ Barcelona ISoP Mid-Year Training 2024: **June 3rd to 4th**
- ✓ ISoP World Patient Safety Day 2024: **September**
- ✓ ISoP 2024 Montreal Annual Meeting: **October 1st to 5th**
- ✓ ISoP Seminar on Intelligent Automation 2024: **December**

These events promise to be extraordinary opportunities to further our collective mission in ensuring medication safety.

I eagerly anticipate our continued collaboration and participation in these forthcoming events, further enriching our shared commitment to excellence in pharmacovigilance.

Angela Caro-Rojas, ISoP President 2022-2025



Bali Conference Report

The 22nd Annual Meeting of the International Society of Pharmacovigilance, entitled “Putting Patients First in Pharmacovigilance: International Perspectives from Global South” took place in Prime Plaza Hotel Sanur Bali from 6th - 9 November 2023.

The Local Organising Committee was chaired by **Grace Wangge of the Monash University, Indonesia**, and the Scientific Committee was chaired by **Mira Harrison-Woolrych (New Zealand) and Jarir Atthobari (Indonesia)**.

The four pre-conference courses were all well attended on November 6th, then the next day kicked off with a traditional and very engaging opening ceremony led by **Angela Caro-Rojas, Mira Harrison Woolrych, and Grace Wangge**, alongside a virtual address by the **Head of National Drug and Food Agency (BPOM) Indonesia**.

With around **315 people attending**, the programme had 40 international speakers and chairpersons, and with truly global attendance. The five plenaries and eight parallel sessions (mainly around SIGs) were well-received. In addition, 188 posters have been successfully accepted for this year's 22nd ISoP Annual Meeting with all the abstracts published in *Drug Safety* journal.

On the first day, key plenary sessions highlighted the importance of patient safety, featuring discussions on international pharmacovigilance improvements, monitoring

medicine safety during pregnancy, and the pivotal role of patient engagement in safety decisions.

In parallel sessions, topics ranged from Southeast Asia and Western Pacific pharmacovigilance insights to ecopharmacovigilance strategies. Attendees delved into case studies, including the environmental impact of medications and considerations for older patients' drug safety. Vaccine pharmacovigilance methods and COVID-19 vaccine safety were pivotal themes, exploring global perspectives, lessons from Australia's pandemic response, and intriguing research findings on persistent health issues post-vaccination.

The day concluded with specialized interest group meetings, including Pharmacogenomics and **Real-World Evidence**, followed by a vibrant **Student Meet and Greet**, fostering connections among future professionals.

The second day of the conference, insightful sessions were presented regarding effective communication strategies for medication safety. The plenary session explored bridging the gap between scientific information and media interpretation, emphasizing communication policies and engaging discussions led by experts **Priya Bahri (Chair of the Risk Communication SIG), Grace Wangge**, and others.

Parallel sessions highlighted critical areas, including medicines for women and professional development in pharmacovigilance, fostering discussions on global perspectives, access, and safety issues surrounding contraceptive medicines and devices.

The day culminated with the ISoP General Assembly, providing a platform for updates and discussions on the Society's strategy. It concluded with an enriching plenary session on updates from ISoP chapters, fostering collaboration and knowledge-sharing.

The day ended on a social note with a Networking Dinner, offering attendees a chance to unwind and network in a relaxing and lively atmosphere.

The last day brought focus on critical areas like medical devices and clinical aspects of pharmacovigilance. Discussions centred on real-world examples, patient-centric solutions in surgical trials, and insights into Indonesia's data landscape regarding acute kidney injury cases.

A pivotal plenary session discussed enhancing pharmacovigilance in low and middle-income countries (LMICs), featuring the Bengt Erik Wiholm Lecture by **Shanthi Pal** from the World Health Organization, delving into the efficacy of spontaneous reporting systems in LMICs.

Most of the presentations have been uploaded to the members section of the ISoP website, and all the abstracts are published in *Drug Safety*, Vol 46 Issue 12, December 2023. <https://doi.org/10.1007/s40264-023-01350-z>

Remember that all ISoP members have free access to *Drug Safety Journal* as part of their membership!

A warm welcome to all the new members who joined for this year's meeting!

Bali poster prizes

In a scientific society, the poster prize represents a significant event. Katarina Ilic (Takeda, USA) chaired this year's poster prize committee, which was assisted by Ian Wong (University of Hong Kong, Hong Kong) and Manal Younus (Iraqi Pharmacovigilance Center, Iraq). The winners were:

First Place

Safety, immunogenicity, and effectiveness of COVID-19 vaccines for pregnant persons: A living systematic review and meta-analysis by Andy Stergachis et al.



Second Place

Association between mortality and warfarin comparing with direct oral anticoagulants: a population-based cohort study by Wang Zixuan et al.

Third Place

Association between maternal antibiotics use during pregnancy and child autistic behaviour from the TMM BirThree Cohort Study by Abe Miyu et al.

Sten Olsson Award

African Union Smart Safety Surveillance (AU-3S) Joint Signal Management: African-owned safety data integration and signal detection for COVID-19 vaccines by Meyer Hannelie et al.

Congratulations to all the winners, and thanks to all the poster presenters.

General Assembly 2023



The ISoP General Assembly (GA) was held on 8 November 2023 during the Bali meeting with approximately 200 members of the Society and 45 Society members connected online.

During the ISoP General Assembly, President Angela Caro-Rojas led discussions on the society's strategic plan. Highlights included financial stability initiatives, and a 12% increase in membership globally.

The meeting showcased ISoP's active engagement through chapters, SIGs, and innovative activities, including a survey to enhance member satisfaction. The assembly outlined a rich schedule of planned events for 2024, culminating in the annual meeting in Montreal in 2024. Discussions also addressed online security, multilingual sessions, and member-led initiatives, setting an inclusive tone for the community's vibrant future.

The GA minutes are referenced on the [ISoP website](#) for all members to access.

New membership fees 2024:

As approved by the ISoP General Assembly 2023 in Bali, the membership fees will increase in January 2024 for the [new applicants](#) as follows:

Standard membership

249 EUR

(Individual members from High-Income Countries (HICs) affiliated to a commercial organisation)

Reduced membership

99 EUR

(Individual members from High-Income Countries (HICs) affiliated to a not-for-profit organisation including Students and Individual members from Low and Middle-Income Countries (LMICs) affiliated to a commercial organisation)

Special Reduced membership

49 EUR

(Individual members from Low and Middle-Income Countries (LMICs) affiliated to a not-for-profit organisation including Students)

Current membership fees will remain for our active members providing the renewal within the **3-month deadline**.



International Society
of Pharmacovigilance



ISoP Mid-Year Symposium The value of real-world data for ensuring patient safety.

In collaboration with IDIAP Jordi Gol

3 & 4 June 2024 - Barcelona, Spain

isoponline.org/training/symposium/

#ISoPBarcelona2024

Mid-Year Symposium 2024

The [ISoP mid-year symposium](#) will be hosted by the **Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAP Jordi Gol)** on **3-4 June 2024, in Barcelona, Spain**. Discussions will be focused on the “The value of real-world data for ensuring patient safety”. Leveraging real-world data in pharmacovigilance is pivotal for continuously assessing and ensuring the safety and efficacy of medications and treatments as they are used in everyday clinical practice, ultimately improving patient care and outcomes.

The symposium is aimed at healthcare professionals working in a regulatory, industry, or university setting as well as persons working in clinical or epidemiological settings with an Interest in pharmacovigilance.

Stay tuned for more info!

ISoP Fellowship 2023

We are delighted to announce that the following ISoP members received fellowships at the 2023 General Assembly.

- ✓ Dr Helen Byomire Ndagije, National Drug Authority (Uganda)
- ✓ Dr Maribel Salas, Daiichi Sankyo Inc (USA)
- ✓ Dr Qun-Ying Yue, Uppsala Monitoring Centre (Sweden)

Congratulations to all our new fellows!

Patient Safety Day 2023

ISoP World Patient Safety Day took place on 7 & 8 September 2023 with the topics “Engaging Patients for Patient Safety”. In collaboration with the Chapters, ISoP arranged five sessions, with twelve speakers and seven chairpersons (Chapter leaders and guests).

9 hours of transmission

1,000 people registered



Seminar on Intelligent Automation

7th ISoP Boston Seminar

Intelligent Automation in Pharmacovigilance

4-5 December 2023

Cambridge, MA, USA

2024 heralds a transformative era for pharmacovigilance. Emerging evidence robustly supports that the synergy of humans and Artificial Intelligence (AI) surpasses the capabilities of either alone. This paradigm shift necessitates that all pharmacovigilance professionals enrich their skill sets to stay ahead. In recognition of this pivotal change, ISoP continues to host its Boston Seminars on intelligent automation in pharmacovigilance.

This event is not just another conference; it's a mission-driven, non-profit gathering dedicated to scientific rigor and transparency. Here, participants gain deep insights and practical knowledge to navigate the evolving landscape of pharmacovigilance.

The 7th ISoP Seminar on Intelligent Automation was enlightening two-day journey brimming with cutting-edge information and invaluable perspectives. Participants confirmed it dramatically expanded their understanding and prepared them for the future of pharmacovigilance. Speakers were senior members of industry, leading regulators and academics from the most developed organizations around the world.

This year was the best so far. Participants confirmed the quality of insights has surpassed all other events on this topic in 2023. **You can access all materials and recordings by registering on the [ISoP website](https://www.isoPONline.org).**

Academic Events Strategy for 2024

ISoP's Academic events new strategy effective January 2024 aims to **minimize "webinar burn-out"** among members by reducing the number of webinars while maintaining robust scientific content with increased ISoP members engagement.

To achieve this, merging efforts with chapters and SIGs is planned. Suggestions for topics are encouraged, aiming to consolidate similar themes for extended or training sessions. Proposed topics will undergo review to prevent event clashes. ISoP will back one annual members-only webinar per Chapter or SIG, encouraging non-members to join ISoP for access.

Chapters and SIGs have autonomy for additional internal webinars, and a structured process will be in place such as speaker and chair endorsements.



We are pleased to announce that the 23rd ISoP Annual Meeting will be in Montreal, on **1-5 October 2024** “Global Perspectives on Pharmacovigilance in the Digital Age and Advanced Therapeutics”. The ISoP 2024 Scientific Committee is by Dr Maribel Salas, ISoP Advisory Board member and SIG coordinator. The Local Organizing Committee is chaired by Dr Omar Aimer, President of the North America Chapter (NASoP).

With two days pre-conference courses and 2.5 days of main meetings, the draft list of pre-conference courses includes:

- Introduction to Pharmacovigilance (PV)
- RWE in Pharmacovigilance
- Approach for Signal Detection & assessment
- Regulatory Framework for Pharmacovigilance
- Practical Applications of Evidence-Based Medicine Tools in Drug Safety
- Risk management plans
- Benefit/Risk Assessment from different perspectives
- Examples of Risk Minimization
- Measures and assessment of their effectiveness (REMS, PASS, PMS)

The deadline for abstract submission will be 1st April 2024. All abstracts are reviewed by an international committee, with accepted abstracts published in Drug Safety, the official journal of ISoP.

The pre-conference courses will be provided by highly experienced professionals and leaders from: regulatory authorities and international organisations (Health Canada, US FDA, EMA, UMC, PAHO), Academia (Beijing University, British Columbia University, University of Cape Town and McGill University) and from pharmaceutical industry.

Delegates attending the Annual Meeting of ISoP will be guaranteed a memorable event in Montreal in 2024. The North America Chapter of ISoP, believes that Montreal's rich history of academic excellence, research centres and experts, regulatory environment, and cultural diversity make it the ideal host city for the 2024 ISoP Annual Meeting.

More information at the conference website: [ISoP 2024 Montreal](https://www.isoPONline.org)

