



The ISO P Star

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Reports from the world of pharmacovigilance

Sten Olsson



It was with deep sadness in April this year that ISO P's Executive Committee (EC) members learned of the passing of Sten Olsson, our beloved Past-President, valued colleague and treasured friend. Many ISO P members worldwide who knew Sten have been devastated by this news. Sten had a long and outstanding career at the WHO-UMC and directly contributed to improving pharmacovigilance and patient safety worldwide over several decades. He was also a trusted mentor to many ISO P members, and we will miss him greatly. Rebecca Chandler, representing the ISO P EC and Advisory Board, attended Sten's funeral on 19 May 2022 in Uppsala.

A floral tribute was sent on behalf of all ISO P members. Thank you for your messages of condolence received from members all over the world. We will include them on the ISO P website at the end of July.



ISO P 2022 in Verona

The 21st Annual Meeting of the International Society of Pharmacovigilance (ISO P 2022), "A New Era of Pharmacovigilance: challenges and opportunities" will take place in Verona, Italy from 20th to 23rd September 2022.



ISO P | International Society of Pharmacovigilance
2022 | 21ST ANNUAL MEETING

We warmly invite you to attend the ISO P annual conference in Verona – our first in-person meeting for three years!

Home to a legacy of great traditions, from opera to food and wine, Verona is one of the most visited places in Italy. A UNESCO world heritage city and the home of Romeo and Juliet, it is a centre of history, culture, music, and architecture, waiting to be explored. Verona is an inspiring landscape in which to discuss the importance of international pharmacovigilance to health professionals and patients, medicines regulatory agencies, scientific organizations and universities, state authorities worldwide, and the pharmaceutical industry. Verona can be easily reached by train from Rome and Milan and by flights from Europe and beyond. It is a popular destination, and you are urged to book your hotel as soon as possible.

News from the International Society of Pharmacovigilance

The meeting will take place at the University of Verona, in “Polo Zanotto” - a new university building close to the historical city centre. The Local Organising Committee is chaired by Gianluca Trifirò from the University of Verona.



University of Verona, Polo Zanotto

The ISoP 2022 Annual Meeting will offer the chance to discuss current challenges and future opportunities in pharmacovigilance, to exchange ideas and experiences between international experts, engaging ISoP's special interest groups (SIGs) and global participants with many areas of expertise.

Angela Caro, Chair of the Scientific Committee, has announced the programme and more information is available on [the dedicated website](#).

There will be three pre-conference courses on 20 September:

- ★ Course 1 is **Advanced signal detection** (Coordinators: Marco Tuccori and Ugo Moretti)
- ★ Course 2 is **Introduction to pharmacoepidemiology studies and their role in pharmacovigilance** (Coordinators: Rebecca Chandler and Gianmario Candore)
- ★ Course 3 is **Regulatory Updates across the Continuum of Spontaneous Reporting to Risk Minimization** (Coordinators: Deirdre McCarthy and Giampiero Mazzaglia).

The main conference will be held on 21 to 23 September, with eight parallel sessions involving most of the ISoP SIGs. There will be four plenary sessions covering a broad range of current issues including:

- ★ Lessons learned from COVID-19 pandemic
- ★ Traditional and innovative approaches for post-marketing surveillance of COVID-19 vaccines

- ★ Artificial Intelligence, machine learning, and big data
- ★ Medication errors prevention
- ★ Medicines for women
- ★ PV of biotechnology drugs: from advanced therapy medicine products to biosimilars
- ★ Risk communication
- ★ Clinical decision supporting pharmacovigilance
- ★ Training and professional framework of pharmacovigilance
- ★ Herbal and traditional medicines
- ★ Ecopharmacovigilance

The plenary sessions will include presentations from:

Bernard Bégaud, University of Bordeaux

Miriam Sturkenboom, University of Utrecht

Karina Top, Canadian Center for Vaccinology

Andrej Segec, European Medicines Agency

Saad Shakir, Drug Safety Research Unit (Beje Wiholm lecture)

Ralph Edwards, Sweden (Lecture in memory of Prof Giampaolo Velo).

Finally, a memorable social programme will be arranged, including a conference dinner in the beautiful Palazzo Verità-Poeta.

We are delighted to have received over 450 submitted abstracts; authors should now have received a notification of abstract acceptance or rejection.

Take advantage of the early bird reduced registration fee by registering by 20 July (deadline for early bird) [via this link](#).

General Assembly 2022

The ISoP General Assembly will be held on Thursday, 22 September 2022 at 13:00 CET during the Verona meeting at the main venue. ISoP members will be emailed an online link for those not attending in person, but please note this Zoom access will not permit attendance at any other conference session. The agenda for the General Assembly will be posted online soon and includes many interesting items! This is an important event in the life of our society and all members are encouraged to participate, either in person or online.

Committed to safer use of medicines worldwide

New UK–Ireland Chapter

We are excited to announce the new ISoP UK–Ireland Chapter (UKIREC), launched by President Mira Harrison-Woolrych on 9 May 2022 prior to the mid-year symposium at the Drug Safety Research Unit, Bursledon Hall, Southampton.

This becomes the 13th Chapter of ISoP and is dedicated to members in the UK and Ireland. The launch was well attended by the chapter’s founding members and honoured by the presence of ISoP EC members Deirdre McCarthy (Secretary General) and Rebecca Chandler (Vice-President).

The rationale, goals and future strategy of the chapter were presented by Dr Brian Edwards, Dr Walter-Rodney Nagumo, Mr Ryan Walker and Dr Nicole Baker, which generated a lot of discussion. The aim of the chapter is to bridge the gap between pharmacovigilance and patient safety activities within this key strategic geographical location through capacity building, training and stakeholder collaborations.

Currently the UKIREC consists of 18 members, with plans to expand. It intends to hold committee elections, identify key themes and organisations for collaboration and allocate responsibilities to key individuals at an inaugural in-person meeting on July 4th, at the University of Birmingham Medical School, Birmingham, UK.



Walter-Rodney Nagumo, Brian Edwards, Mira Harrison-Woolrych, Ryan Walker at the launch of the UK-Ireland Chapter in Southampton

ISoP-DSRU mid-year training

“Beyond spontaneous reporting: integrating data from multiple sources to ensure medicines safety”

In May, ISoP joined forces with the Drug Safety Research Unit (DSRU) in Southampton UK, to organize our annual mid-year meeting. With the participation of 80 delegates from 35 countries, the training webinar was successfully conducted online on 10 and 11 May, co-ordinated by Rebecca Chandler (ISoP Vice-President), with other EC and Advisory Board members chairing sessions.



Symposium organizers Rebecca Chandler and Saad Shakir

Non-members who registered at the ISoP-DSRU mid-year symposium and paid full registration fees become ISoP members for one year. A very warm welcome to these newcomers!

New ISoP Scientific Board

The new ISoP Scientific Board has now been established. As outlined at the ISoP General Assembly in 2021, the ISoP Scientific Board’s mission is to support ISoP’s scientific and educational activities and to offer expert advice on pharmacovigilance worldwide. It will collaborate with the Institute of Pharmacovigilance (IPV) in delivering the Global Pharmacovigilance Professional Certification (GPPC) for ISoP. Scientific Board members were appointed by the ISoP Advisory Board in March.

Committed to safer use of medicines worldwide

The core members are: Thamir Alshammari (Saudi Arabia), Priya Bahri (Netherlands), Rebecca Chandler (Sweden), Jean-Christophe Delumeau (Singapore), Birgitta Grundmark (Sweden), Veronique Kugener (USA), Ishak Mansi (USA), Maja Mockenhaupt (Germany), Hadir Rostom (Egypt), Shui Ki Henry Seto (USA), Marco Tuccori (Italy), Eugene Van Puijenbroek (Netherlands), Li Zhang (China).

The first meeting of the ISoP Scientific Board was held on 20 April 2022, chaired by ISoP President, Dr. Mira Harrison-Woolrych. Subsequently new board members elected Veronique Kugener as Chair and Marco Tuccori as Co-chair.

Associate members to be consulted on specific topics include Nicole Baker (Ireland), Yasmine Boulkroun (France), Katarina Ilic (USA), Albert Figueras (Spain), Navinisha Lee (Australia), Marina Litvienko (Russia), Yola Moride (Canada), Xiao Hui Yang (China) and Zhi Gang Zhao (China).

ISoP GPPC on its way

An essential mission of the ISoP Scientific Board includes overseeing the Global Pharmacovigilance Professional Certification (GPPC), which is being developed as a collaboration between the Institute of Pharmacovigilance (a non-profit organization) and ISoP, following on from the work of the ISoP SIG on Pharmacovigilance Professional Qualification Framework.

The aim of the GPPC is to provide a framework to support colleagues working in pharmacovigilance worldwide and assist their professional development. By defining expected competences for each role and seniority in pharmacovigilance and testing against them, the GPPC shall increase the recognition of pharmacovigilance, as well as improve professional competence to serve public health, industry and patients better than ever before.

A large part of the certification programme will include regional Examination Boards with a special geographical focus acting as advisory and assessment bodies. As GPPC Examination Boards are appointed for specific regions, the IPV sees this as an opportunity to invite ISoP members to become members of the regional Examination Board.

Examination Board members should meet the following criteria:

- ★ ISoP high contributor – e.g., FISoP, former Board member, SIG Chairperson/Coordinator, and/or
- ★ recognized academic with scientific/educational profile predominantly related to pharmacovigilance, and/or
- ★ well-known and respected member of the pharmacovigilance community, with a high level of scientific, operational, or regulatory competency in pharmacovigilance.

Please email nominations for the GPPC Examination Boards (name and brief professional details), before 31st July 2022, to Kamil Uhlir at kamil.uhlir@pharmacovigilance.institute.

Advisory Board Elections



Get ready to vote! The ISoP Board elections are approaching fast!

Nominations have now been received for the ten new ISoP Advisory Board members who will serve from 2022 to 2025. Details of

candidates have been placed [on the ISoP website](#). **The online voting period will be from 11 to 25 July 2022.**

All paid-up ISoP members will receive an e-mail from administration@isoponline.org at the beginning of July, explaining how to vote. Remember to check your spam folder in case your voting e-mail ends up there!

Results of these elections (including the new ISoP President and Executive Committee, who are elected by the new AB members) will be announced at the end of August. The new Advisory Board members will take up their positions in September at ISoP 2022 in Verona and will hold these positions for three years.

Special Interest Groups news

Angela Caro, ISoP SIGs co-ordinator, is in regular contact with these groups, and SIG activities and developments are very positive this year!

Highlights over the last six months include:

- ★ A new leadership group for the Herbal and Traditional Medicines SIG. From March 2022 the Chair is Souad Skalli, Co-chair is Florence van Hunsel, and Project Manager Jia Bo Wang.
- ★ A webinar series hosted by the Medical Devices SIG
- ★ A proposal for a new “Ecopharmacovigilance” SIG has been approved by the Executive Committee.

Details on how to join any ISoP SIG may be found on our website – [do go and have a look!](#)

World Patient Safety Day 2022

We are delighted to announce the third annual ISoP online event to mark World Patient Safety Day. The main topics will be “Medication Without Harm” and “Patient Engagement”.

Join us for free webinars and activities with ISoP chapters and other international experts on 7 and 8 September.



Patient Safety Day 2022



7-8 September

We are delighted to announce the third version of the free online event ISoP Patient Safety Day.

Join us for free webinars and activities with worldwide experts



@ISoPOnline

more info: isoponline.org



6th annual Boston Seminar



We are going to be back to the east coast of the US for the 6th ISoP Boston Seminar, to take place on 5 and 6 December 2022 with the title 'Intelligent Automation in Pharmacovigilance'.

International experts from pharma and various technology services will be invited to contribute and debate this hot topic online.

Coordinator: Dr Jan Petracek (ISoP Board member).

More information available soon on the [training seminars page of the website](#).

Drug Safety articles 2022

ISoP members have continued to contribute to the following publications in the front pages of our affiliated journal *Drug Safety*:

- ★ Medication Errors Special Interest Group of the International Society of Pharmacovigilance and the Trends in International Collaboration for Patient Safety (January 2022)
- ★ The International Society of Pharmacovigilance Vaccines Special Interest Group: Challenges and Opportunities (May 2022)
- ★ An Update on the ISoP China Chapter (July 2022)

An informative video about the collaboration between ISoP and the journal *Drug Safety* is [available on YouTube here](#).

A themed edition of *Drug Safety* on the ‘Role of Artificial Intelligence and Machine Learning in Pharmacovigilance’ edited by former Board member Andrew Bate and Yuan Luo was published in May 2022.

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New ISoP website

We are currently building a new ISoP website and are conducting a short survey to gain a better understanding of how ISoP members use the ISoP website.

[Please take the survey here](#); all feedback will be much appreciated.

Code of Conduct

Some important new developments within our professional society include a new Code of Conduct and revised Chapter Guidelines.

The ISoP Code of Conduct is intended to be a user-friendly guide for individual ISoP members to ensure that we always communicate and cooperate in a respectful, inclusive and professional way.

You may view this new document on the ISoP website [here](#).

The revised Chapter Guidelines document is also now available [on the ISoP website](#).

Webinars for ISoP members

If you have missed our latest webinars organised from March to June 2022 by the Medical Devices SIG or the Western Pacific Chapter, please check our [webinars section on the ISoP website](#).

ISoP representative on CIOMS



Congratulations to Manal Younus, ISoP Advisory Board member, who has recently been appointed to the Executive Committee of the Council for International Organizations of Medical Sciences (CIOMS).

ISoP Fellowships

The ISoP Fellowship Nominations Subcommittee (FNCS) met to discuss applications received before the deadline of 31st May.

Candidates will be contacted in August and new ISoP Fellowships will be announced at the ISoP General Assembly in Verona (13.00-14.30 on 22 September) at the ISoP 2022 annual meeting.

ISoP 2023

The ISoP Advisory Board has approved a proposal from the Indonesia Chapter to hold the 22nd ISoP Annual Meeting in Bali. Provisional dates are 6 to 9 November 2023: please save the dates!



Bali Sanur Prime Hotel, meeting venue

The ISoP 2023 Scientific Committee will be chaired by Dr Mira Harrison-Woolrych. The committee will be co-chaired by Dr Jarir At Thobari, President of the Indonesian Chapter and will include ISoP experts from Indonesia and the Western Pacific region.

Stay in the loop

Do follow us on Facebook, Twitter, Instagram or LinkedIn @ISoPonline.

Our website <https://isoponline.org/> is updated regularly, and the Members-Only section is where you will find access to the journal *Drug Safety*, presentations from the annual meetings, and have the chance to update your personal information.

As always, please send your comments, ideas and contributions for ISoP Star to:

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