



CAIRO 2025
ANNUAL MEETING

24th ISoP Annual Meeting

Pharmacovigilance: Back to the Future

October 24–27, 2025

Conference Programme



International Society of Pharmacovigilance
24th ISoP Annual Meeting in Cairo, Egypt
isoponline.org

#ISoP2025Cairo



International Society of Pharmacovigilance
24th ISO P Annual Meeting in Cairo, Egypt
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Contents

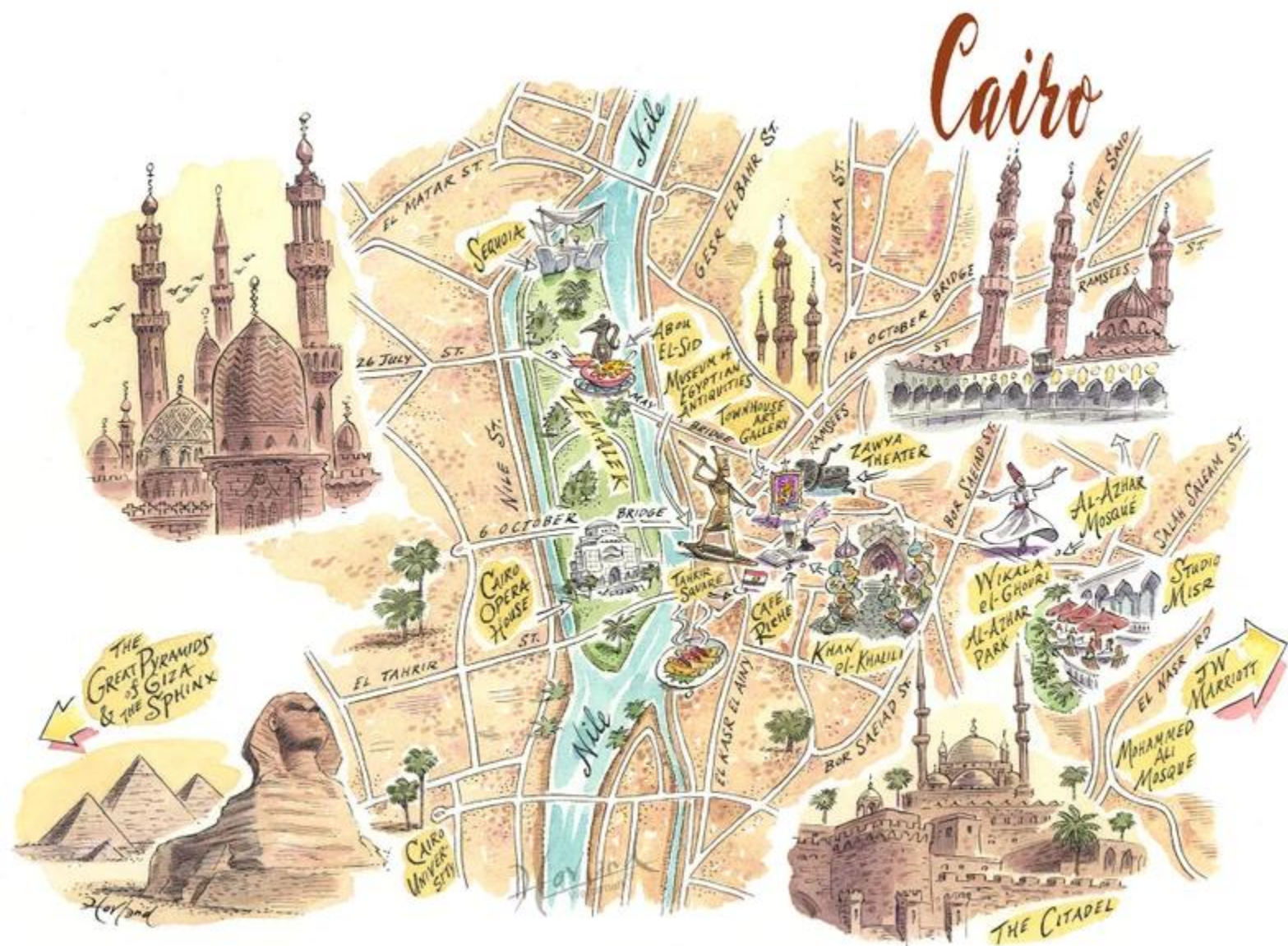
<u>Venue Floor Plan</u>	4
<u>Cairo Map</u>	5
<u>Welcome Message</u>	6
<u>About ISoP</u>	7
<u>Committees</u>	8
<u>General Information</u>	9
<u>Pre-Conference Programme</u>	11
<u>Conference Programme</u>	17
<u>List of Chairpersons and Speakers</u>	25
<u>Networking</u>	28
<u>Cairo</u>	29
<u>Companies Profiles</u>	31
<u>Supporters</u>	37
<u>Testimonial</u>	38



Venue Floor Plan



Cairo Map





Welcome Message

Dear ISoP Participant,

Welcome to the **24th Annual Meeting of the International Society of Pharmacovigilance (ISoP)**, taking place in the dynamic and historic city of **Cairo, Egypt!**

This year's theme, "**Pharmacovigilance: Back to the Future**," invites us to reflect on how our past continues to shape our future. From foundational documents such as the CIOMS reports to the latest advances in digital technologies, the evolution of pharmacovigilance is deeply rooted in both legacy and innovation. In Cairo—a city that bridges millennia of civilization with a vibrant present—we are reminded that progress is always built on the wisdom and dedication of those who came before us.

Our **Scientific Committee** has curated a rich and diverse program, **featuring over 30 scientific sessions and panel discussions** covering global updates, digital transformation, regulatory convergence, antimicrobial resistance, patient-centered safety, and more. These sessions highlight pharmacovigilance as a truly **interdisciplinary field**, uniting perspectives from regulators, academia, industry, public health institutions, and patient communities worldwide.

This year's meeting also marks several unique milestones:

- **The ISoP–WHO** Joint Session will focus on the WHO Global Smart Pharmacovigilance Strategy, exploring how to operationalize smarter, risk-based approaches across varied regulatory contexts, with emphasis on lessons learned, reliance, and systems strengthening.
- **The ISoP–UMC** Session will spotlight the Global MedSafetyWeek Campaign, emphasizing the importance of stakeholder engagement in promoting medication safety awareness.
- **A high-level panel discussion**, "Driving the Future of Pharmacovigilance: Global Strategies and Perspectives," will bring together thought leaders from regulatory authorities, major public health organizations (including WHO, UMC, and the Gates Foundation), and the pharmaceutical industry to explore forward-looking strategies for medicine safety.

The meeting begins with **five parallel pre-conference training courses**, designed to meet the diverse learning needs of our global community—covering topics from community healthcare to pharmacoepidemiology, vaccine safety, benefit–risk assessment, and advanced pharmacovigilance practices in the digital age.

As always, ISoP remains committed to fostering learning, collaboration, and innovation across all continents. Whether you are a regulator, healthcare professional, academic, industry representative, or student, your role in advancing medication safety is vital—and your presence here strengthens our shared mission.

We are delighted to welcome you to Cairo and hope this meeting inspires renewed commitment, shared learning, and meaningful connections as we explore the **future of pharmacovigilance through the lens of its impactful past**.

Warm regards,

Brian Edwards (Scientific Committee Chair)

Hadir Rostom (Local Committee Chair)

About ISoP

International Society of Pharmacovigilance

ISoP is a global professional, independent, not for profit society, open to anyone with an interest in the safe and effective use of medicinal products.

ISoP aims to foster science, learning and research in pharmacovigilance in all countries.

These objectives are met by providing:

- Collegial and convivial support among fellow pharmacovigilance professionals
- An open and impartial forum for sharing experience, knowledge, and solutions
- A platform for discussion and generation of new research and ideas
- Meetings, education, and affordable training
- Regional Chapters and Special Interest Groups
- Opportunities for networking in a friendly environment

ISoP Advisory Board

Executive Committee

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Vice President

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Annual Meetings (ESOP and ISoP)*

ESOP Annual Meetings

- 1993 Geneva, Switzerland
- 1994 Rouen, France
- 1995 Cambridge, England
- 1996 Lisbon, Portugal
- 1997 Berlin, Germany
- 1998 Budapest, Hungary
- 1999 Ankara, Turkey
- 2000 Verona, Italy

ISoP Annual Meetings

- 2001 Carthage-Tunis, Tunisia
- 2002 Amsterdam, The Netherlands
- 2003 Marrakech, Morocco
- 2004 Dublin, Ireland
- 2005 Manila, Philippines
- 2006 Liège, Belgium
- 2007 Bournemouth, UK
- 2008 Buenos Aires, Argentina
- 2009 Reims, France
- 2010 Accra, Ghana
- 2011 Istanbul, Turkey
- 2012 Cancun, Mexico
- 2013 Pisa, Italy
- 2014 Tianjin, China
- 2015 Prague, Czech Republic
- 2016 Agra, India
- 2017 Liverpool, UK
- 2018 Geneva, Switzerland
- 2019 Bogota, Colombia
- 2020 Postponed
- 2021 Muscat, Oman
- 2022 Verona, Italy
- 2023 Bali, Indonesia
- 2024 Montreal, Canada

* In 2000, the European Society of Pharmacovigilance (ESOP) became the International Society of Pharmacovigilance (ISoP)



Committees

Local Organizing Committee

Chair

Hadir Rostom

Co-Chair

Mohamed A. Elhawary

Scientific Programme Committee

Chair

Brian Edwards

Co-Chair

Hadir Rostom

Committee

Hadir Rostom
Heba Ibrahim
Christina Saad
Mohamed A. Elhawary
Gehan El-Hefney
Denny Van Liew
Amira Shehata
Ahmed Hegazy

Committee

Hadir Rostom
Mayada Alkhakany
Mohamed A. Elhawary
Jimmy Jose
Viola Macolic Sarinic
Santiago Schiaffino
Eugene van Puijenbroek
Alem Zekarias
Jayesh Pandit

General Information



Venue

InterContinental Cairo Semiramis
Cairo, Egypt

Accommodation

For help booking accommodation or if you have any queries about your hotel reservation, please visit the registration desk where one of the organisers will be able to assist you.

Cloakroom

A cloakroom is available for participants on the second floor next to the stairs ([see floorplan](#)).

Certificate of Attendance

A certificate of attendance will be provided for all attendees of the pre-conference training course and main conference and will be available for downloading on the registration portal once the online survey has been completed. A link to the survey will be emailed on the last day of the conference.

Emergency Procedures

In the event of an emergency in the Hotel building, please follow the instructions from the staff.

First Aid

In the event of an accident or an emergency, contact a member of the organization at the registration. Please be as accurate and as concise as possible with any information you are providing, especially the exact location of the emergency.

Internet Access

Every delegate will get a personal wi-fi login details at the registration desk.

Insurance

The conference organising committee or its agents will not be responsible for any medical expenses, loss or accidents incurred during the conference. Delegates are strongly advised to arrange their own personal insurance to cover medical and other expenses including accident or loss. Where a delegate has to cancel for medical reasons, the normal cancellation policy will apply.

Lost and Found

If you have misplaced any personal items or found an item to hand in, please visit the registration desk located on the second floor.

Exhibition, Posters and Catering

The exhibition is taking place on the second floor, right in front of the main hall. Poster Area is in the Kahrmana room. Refreshments will be served at the following times:

Date	Coffee break	Lunch	Coffee break
Friday 24 October	11:30–12:00	13:30–14:30	16:30–17:00
Saturday 25 October	11:30–12:00	13:30–14:30	16:30–17:00
Sunday 26 October	10:15–10:45	13:00–14:00	16:00–16:45
Monday 27 October	10:15–10:45	13:00–14:00	



Mobile Phones

Delegates are kindly requested to keep their mobile phones on silent in all rooms where scientific and educational sessions are being held, as well as in and around the poster exhibition area.

Names Badge

A name badge will be provided on arrival to the conference upon presentation of the relevant registration documents. The name badge must always be worn and is to be visible both inside the meeting rooms and sessions, as well as at all events organised during the meeting, including the supporting social programme.

Registration Times

The registration desk will be open at the following times:

October 23: 15:00–20:30
October 24: 07:00–18:00
October 25: 07:00–18:00
October 26: 07:00–18:00
October 27: 08:00–15:00

Smoking and Electric Cigarettes

Smoking is forbidden in all the indoor public areas, such as bars, restaurants, hotels, offices, shops, etc. except for the places with reserved smoking areas, provided with a suitable ventilation system.

Social Media

Follow @ISoPonline on twitter, LinkedIn, Instagram, and Facebook and get all the latest updates. We encourage you to tweet and post your highlights during the conference using the hashtag #ISoPCairo2025

Share with ISoP your experience!

Take photos during the conference, when networking, or even enjoying time with friends and colleagues, and tag us at @ISoPonline on Facebook, Instagram, Twitter, and LinkedIn – we will repost all photos and make a collage with the best highlights of the Cairo event!

Speaker Preview Room Times

The Speaker Preview room is located on the Nefertiti room and is open at the following times:

Friday 24 October	07:00–17:00
Saturday 25 October	07:00–17:30
Sunday 26 October	07:00–17:30
Monday 27 October	08:00–13:00

Useful Telephone Numbers

Egypt country code is 20. For international calls, dial 00 + national code + area code + personal number.

123	Main Ambulance
126	Tourist Police
128	Traffic Police
122	Emergency Police
180	Fire Department

Cairo Tourism

Maps and tours information are available at the registration desk.

Networking

Please see [page 28](#) for details of the official networking events.

Delegates

The event will host a diverse group of 552 delegates representing various sectors within the pharmaceutical and healthcare fields..

Pre-Conference Training Courses



Friday 24 October 2025

Pre-Conference Course 1: Pharmacovigilance in the Community and Healthcare.

Cleopatra 3 (Morgana) ,08:30 – 17:00

Objectives of the course:

1. Explain pharmacovigilance in healthcare settings and highlight the role of healthcare professionals.
2. Explore approaches to enhance clinical practice knowledge as an ideal clinical explorer.

Sessions:

- **08:30 – 09:30** Introduction: Place of HCPs in the system / Angela Caro
- **09:30 – 10:30** Human factors and safety of medicines and devices / Angela Caro & Brian Edwards
- **11:00 – 12:00** Medication errors and Medication Safety Officer / Loubna Alj
- **12:00 – 12:45** Spontaneous reporting / Monica Tarapues and Alem Zekarias
- **12:45 – 13:00** Questions and Answers
- **14:00 – 15:00** The Role of Pharmacoepidemiology and Real-World Studies in Pharmacovigilance / Saad Shakir
- **15:00 – 16:00** Managing risks around medicines and vaccines in clinical practice / Mark Perrott
- **16:30 – 16:55** ISoP-SIG Pharmacovigilance in the Community/ Mohamed A. Elhawary
- **16:55 – 17:00** Conclusion / Alem Zekarias

Training Includes Two Breaks & One Lunch



Pre-Conference Course 2: Advanced Course in Pharmacovigilance for the Industry

Cleopatra 1 (Blue Nile) ,08:30 – 17:30

Objectives of the course:

1. Identify the key differences and common findings between audits and inspections.
2. Describe effective preparation strategies for regulatory inspections and outline current industry best practices.

Sessions:

- **09:00 – 10:00** Inspection vs. Auditing: Strengthening PV Compliance/ Mayada Alkhakany & Santiago Schiaffino
- **10:00 – 11:00** Quality of Safety Information Governance/ Deborah Layton & Santiago Schiaffino
- **11:30 – 12:30** Medical Literature Review & Its Impact on Signal Detection/ Nicole Baker, Deborah Layton & Ban Abdul Ameer
- **12:30 – 13:30** Risk Minimization Measures: From Challenge to Opportunity/ Thamer Alshammari
- **14:30 – 15:30** Crisis Management in Pharmacovigilance/ Thamer Alshammari & Felix Arellano
- **15:30 – 16:30** Future of Pharmacovigilance: Leveraging Innovation & Digital Transformation / Felix Arellano
- **17:00 – 17:30** Interactive Case Study & Closing Remarks / Maria Bantouna, Santiago Schiaffino & Joanne Holley

Training Includes Two Breaks & One Lunch



Pre-Conference Course 3: Challenges and Strategies for Strengthening Vaccine Safety

Pavilion 3 (Floor M), 08:30 – 17:30

Objectives of the course:

1. Understand the principles of vaccine safety, including risk assessment, adverse event monitoring, and safety evaluation throughout the vaccine lifecycle.
2. Apply best practices in detecting, reporting, and managing vaccine-related adverse events to strengthen immunization program safety and public confidence.

Sessions:

- **09:00 – 11:00** Introduction to pharmacovigilance of vaccines: Key concepts and international frame / Ghita Benabdallah, Houda Sefiani & Rebecca Chandler
- **11:30 – 13:30** Bridging tools for vaccine safety: MedDRA and Brighton collaboration / Miriam Strurkenboom, Andy Stergachis & Heba Ibrahim
- **14:30 – 16:30** AEFI investigation and causality assessment: strengthening evidence for vaccine safety / Ghita Benabdallah, Houda Sefiani & Rebecca Chandler
- **16:45 – 17:30** Panel of discussion: AEFI management during health crisis / All speakers

Training Includes Two Breaks & One Lunch



Pre-Conference Course 4: Introduction to Pharmacoepidemiology

Cleopatra 2 (White Nile), 08:30 – 13:00

Objectives of the course:

1. Understand the fundamental concepts, methods, and applications of pharmacoepidemiology in assessing the use and effects of medications in large populations.
2. Develop the ability to interpret pharmacoepidemiologic data and apply study findings to improve medication safety and public health decision-making.

Sessions:

- **08:00 – 08:10** Welcome and introduction to the course / Gianluca Trifirò
- **08:10 – 08:55** Principles for Observational Real-World Studies including their Strengths and Weaknesses / Saad Shakir
- **08:55 – 09:40** Data sources and study design / Gianluca Trifirò & Salvatore Crisafulli
- **10:10 – 11:10** Sources of bias and confounding / Gianluca Trifirò & Salvatore Crisafulli
- **11:10 – 12:00** Role of Observational Data in Regulatory Decision Making: The Drug Safety Paradigm / Tarek Hammad

**Training Includes One
Break & Lunch**



Pre-Conference Course 5: Benefit-Risk Assessment for Medicinal Products

Cleopatra 2 (White Nile), 13:00 – 17:00

Objectives of the course:

1. Understand the principles and methodologies used to evaluate the benefit-risk profile of medicinal products across the product life cycle.
2. Apply structured benefit-risk assessment frameworks to support evidence-based regulatory and clinical decision-making in pharmacovigilance.

Sessions:

- **13:10 – 13:40** Regulatory Landscape: What “Good” Looks Like / Tarek Hammad
 - ICH Recommendations and Implications
 - FDA Benefit-Risk Framework
 - EMA Adoption of BR Approaches
 - Comprehension Checkpoint
- **13:40 – 14:10** Methods Primer (with live demo) / Adel Abou Ali
- **14:10 – 15:10** Hands-On Lab 1: Build the Framework / Uwe Niehaus
- **15:40 – 16:45** Hands-On Lab 2: Build the Framework / Uwe Niehaus
- **16:45 – 17:15** Panel Q&A Take-Home Kit

**Training Includes One
Break & Lunch**

Conference Programme



Saturday 25 October 2025

8:00– 9.00	Registration		
9:00– 9.30	S1-Pl: Opening Session: Dignitaries Hadir Rostom (Local Chair ISoP 2025, President of ISoP Egypt Chapter, MSA University, Egypt) / Brian Edwards (Scientific Chair ISoP 2025, Vice President of ISoP, Husoteria Ltd, UK) / Angela Caro Rojas (President of ISoP, Pontificia Universidad Javeriana, Colombia)		
9:30 – 11:30	S2-PL: Panel Discussion: Driving the Future of pharmacovigilance: Global Strategies and Perspectives Chairs: Hadir Rostom (President of ISoP Egypt Chapter, Pharmacovigilance consultant, Lecturer at MSA University, Egypt) Brian Edwards (Vice President of ISoP, Managing Director of Husoteria Ltd, UK) Panelists : Maha Mohamed (General Manager of the Egyptian Pharmaceutical Vigilance Center – Egyptian Drug Authority (EDA), Egypt) Ali Al Shaharani (Executive Director of Pharmacovigilance at Saudi Food & Drug Authority (SFDA), Saudi Arabia) Florah Matlala (Pharmacovigilance Manager at South African Health Products Regulatory Authority (SAHPRA), South Africa) Georgy Genov (Head of Pharmacovigilance Office at the European Medicines Agency (EMA), Netherlands) Phil Tregunno (Deputy Director of Patient Safety Monitoring at the Medicines & Healthcare products Regulatory Agency (MHRA), UK) Victoria Prudence Nambasa (Senior Programme Officer – Health Product Safety at the African Union Development Agency-NEPAD, South Africa) Shanthi Pal (Team Lead, Pharmacovigilance, Regulation and Prequalification at the World Health Organization (WHO), Switzerland) Deirdre McCarthy (Pharmacovigilance Lead at Gates Foundation , USA) Peter Hjelmsström (Director of Uppsala Monitoring Centre (UMC), Sweden) Marcin Kruk (EUAfME Regional Head Worldwide safety, Pfizer, USA)		
	Break Poster and Exhibition		
11:30– 12:00	S3– Parallel session: What's new from North America and EU? Chair: Viola Macolic-Sarinic (Scientific adviser on safety of medicines at the European Medicines Agency (EMA), Netherlands)	S4– Parallel session: Stepping back into the future of signal detection Chairs: Michele Fusaroli (Senior Pharmacovigilance Scientist and Deputy Chief Medical Officer, UMC, Sweden) Co-Chair: Brian Edwards	S5–Parallel session: Medical device and combination products safety Chair: Omar Aimer (ISoP Executive Committee member- NASoP President, ISoP/ InnoVigilance, Canada)
12:00 – 13:30	S3.1 Back to the Future of EU Pharmacovigilance: Shaping the Next Era of Drug Safety Exploring the latest projects, priorities, and EMA's vision for innovation, shaping smarter safety surveillance Georgy Genov (Head of Pharmacovigilance Office at the European Medicines Agency (EMA), Netherlands)	S4.1 Ronnie Meyboom lecture Charting the Pitfalls of Disproportionality Analysis Michele Fusaroli (Senior Pharmacovigilance Scientist and Deputy Chief Medical Officer, UMC, Sweden)	S5.1 (Abstract presentation- 197) Medical Device Vigilance Survey on Incidents Associated with Blood Glucose Meters in Patients with Diabetes Nouzha Zhor Lazli (Algiers Pharmacy Faculty, Algeria)
	S3.2 North American perspective on Pharmacovigilance Myriam Salem (Health Canada , NASoP, Canada)	S4.2 (Abstract presentation- 94) Sexual dysfunctions associated with proton pump inhibitors: insights from vigiBase, the WHO pharmacovigilance database Salvatore Crisafulli (University of Verona, Italy)	S5.2 (Abstract presentation-284) Impact of social determinants of health on patient safety in clinical trials with combination products Marina Malikova (Boston University, USA)

S3.3 (Abstract presentation- 241) European Framework for Post-Authorisation Vaccine Safety Monitoring Using Real-World Data (SAFETY-VAC project) Fabio Riefolo on behalf of Sima Mohammadi (Senior Scientific Officer, Teamit Institute, Spain)	S4.3 (Abstract presentation- 113) Evaluating Liver-Related Risks of Nitazoxanide: Findings from Egyptian Post marketing PV Case Reports Lobna Kilany (Pharmacovigilance General Administration, EDA, Egypt)	S5.3 (Abstract presentation- 141) Medical Device Surveillance Gaps in Uganda: A Case Study of Dental Devices Douglas Mwesigwa (National Drug Authority, Uganda)
		Q&A for Oral Presentations
	S4.4 (Abstract presentation- 38) Exploring Venetoclax-Associated Pericardial Effusion: A Signal for Cardio-Oncology Vigilance Ban Al Shimran (Pharmacovigilance Center, Iraq)	S5.4 Panel Discussion: Chair: Omar Aimer (ISoP Executive Committee member- NASoP President, ISoP /InnoVigilance, Canada) Panelists: Tomas Bergvall (UMC, Sweden) Mohammed Majrashi (SFDA, Saudi Arabia) Maha Mohamed (EDA, Egypt) Marina Malikova (NASoP, USA)
	S4.5 (Abstract presentation- 137) Post-Authorisation Safety Studies (PASS) in United Arab Emirates (UAE):Current situation, Challenges and Regulatory vision Alina Panourgia (Composite Pharma, UAE)	
Lunch		
S6- Parallel session: What's new from the Middle East ? Chairs: Thamer M. AlShammary (President of ISoP Middle East Chapter, Associate Professor, Jazan University, Saudi Arabia) Maha Mohamed (General Manager Pharmaceutical Vigilance Center – Egyptian Drug Authority (EDA), Egypt)	S7- Parallel session:Pharmacogenomics and Drug Safety Chair:Qun-Ying Yue (Chair of the Pharmacogenomics SIG, Senior Pharmacovigilance Expert, UMC, Sweden)	S8- Parallel session: Pharmacovigilance: Bridging the Gap with Digital Healthcare Chair: Felix Arellano (Global Head of Pharmacovigilance and Drug Safety, Roche, Switzerland)
S6.1 PV updates from Egypt Maha Mohamed (General Manager Pharmaceutical Vigilance Center, EDA, Egypt)	S7.1 Why Pharmacogenomics is important for ISOP members? Qun-Ying Yue (Chair of the Pharmacogenomics SIG, Senior Pharmacovigilance Expert, UMC, Sweden)	S8.1 Innovation in Pharmacovigilance Felix Arellano (Global Head of Pharmacovigilance and Drug Safety, Roche,Switzerland)
S6.2 PV updates from Lebanon Abeer Zeitoun (National Pharmacovigilance Program, MoPH, Lebanon) S6.3 PV updates from Saudi Arabia Abdullatif Alotaibi (Head of Pharmacovigilance inspection section, SFDA, Saudi Arabia) S6.4 (Abstract presentation- 225) The Role of the Jordan Food and Drug Administration (JFDA) in Establishing a National Pharmacovigilance System Jaber Jaber, (Head of Pharmacovigilance, JFDA, Jordan)	S7.2 (Abstract presentation- 307) Genome-Wide Association Study of cases of Venous Thromboembolism after SARS-CoV-2 vaccination Sofia Attelind (Swedish Medical Products Agency, Sweden) S7.3 (Abstract presentation- 238) NSAID-Induced Fixed Drug Eruption: Utility of allergy work-up in diagnosis and cross-reactivity Haifa Ben-Romdhane (Fatouma Bourguiba University Hospital, Tunisia) S7.4 (Abstract presentation- 85) Epidemiology and Awareness of Drug Allergies and Anaphylaxis among the Egyptian Pharmacists Geham Elhefny (Medical Union Pharmaceuticals, Egypt)	S8.2 (Abstract presentation-294) Individual Pharmacotherapy Management Applying Defined Electronic IPM Patient Scores Prevents Multidimensional Risks from Polypharmacy and Enables Verified Reliable AI-Based Implementation Ursula Wolf (University Hospital Halle, Germany) S8.3 (Abstract presentation- 232) Advancing Harmonization in Pharmacovigilance: MedDRA Interoperability Marina Dimov Di Giusti (MedDRA Maintenance and Support Services Organization (MSSO), USA) S8.4 (Abstract presentation- 81) Digitally Mediated Self-Medication in Young People: A New Signal for Pharmacovigilance in the Age of Artificial Intelligence & Social Media Pragna Roy (JNMCH, India)

15:30 – 16:30	S9– Parallel session: What’s new from Latin America and Asia? Chair: Mónica Tarapués (ISoP Executive Committee member, Pharmacovigilance Scientist, UMC, Ecuador)	S10– Parallel session: Safe use of Vaccines and pandemic planning Chair: Rebecca Chandler (Chair of the Vaccines SIG, Senior Vaccine Safety Lead at the Coalition for Epidemic Preparedness Innovations (CEPI), UK)	S11– Parallel session: Pharmacovigilance and Market Access: From Safety to Safe Availability Chair: Ibrahim Altamawy (Regional Medical & Compliance Head (MENA) at SAJA Pharmaceuticals, Egypt)
15:30–15:50	S9.1 Standardizing information in pharmacovigilance: Impact across Latin America Patricia Zuluaga (UMC Regional Specialist Outreach team, Colombia)	S10.1 Strengthening vaccine safety surveillance in Africa: Lessons from Mpox Cohort Event Monitoring in the DRC and DRC’s participation in the BRAVE project Trésor Bodjick (University of Kinshasa, DR Congo)	S11.1 (Abstract presentation-131) Pharmacovigilance: Where does it rank on the agenda for local manufacturing of medical products in Africa? Comfort Ogar (United States Pharmacopeia, USA)
15:50–16:10	S9.2 What new in South Asia? Dr Jamal Baig (Multi-country Safety head for Sanofi, India) S9.3 (Abstract presentation- 376) Strengthening the Pharmacovigilance System in Lima, Peru Gelida Barboza (Sociedad Peruana De Farmacovigilancia, Peru)	S10.2 (Abstract presentation- 91) Generation of Safety Evidence in the Context of Public Health Emergency: Scoping Review of Mpox Vaccines Active Safety Surveillance Protocols Andy Stergachis (University of Washington, USA)	S11.2 Abstract presentation- 65) Evaluation of Pharmacoeconomic Parameters and Adverse Drug Reactions Associated with Topical Steroid Misuse among Patients Attending a Tertiary Care Hospital Neil Patel (Aligarh Muslim University, Aligarh, India)
16:10–16:17	S9.4 (Abstract presentation- 338) Spotlight on Asia Pacific Risk Management Plan: A Descriptive Survey Jamal Baig , (Sanofi, India)	S10.3 (Abstract presentation- 63) Risk Assessment of 32 Adverse Events of Special Interest Following COVID- 19 Vaccination in the French Population Nicolas H Thurin (PharmacoEpi, INSERM CIC-P 1401, Université de Bordeaux, France)	S11.3 Pharmacovigilance as a Strategic Partner in Value-Based Healthcare Aya Anis (Operation Manager, Baupharma, Czech Republic)
16:20–16:30		S10.4 (Abstract presentation- 161) A Pharmacovigilance Experience by a Public Vaccine Laboratory: The Case of the Influenza Vaccine Vera Lúcia Gattás (Instituto Butantan, Brazil)	S11.4 Pharmacovigilance as a Strategic Enabler: Driving Safe and Equitable Patient Access Jean-Marc Häusler (Global Head International Patient Safety, Roche, Switzerland)
16:30 – 17:00	Break (Poster and Exhibition)		
17:00 – 18:00	S12– Parallel session: PV regulatory convergence, reliance and PV system strengthening Chair: Shanthi Pal (Team Lead, Pharmacovigilance, Regulation and Prequalification, WHO,Switzerland)	S13–Parallel session: Herbal, traditional medicines and cosmetics Chair: Houda Sefiani (Director, Centre Anti Poison et de Pharmacovigilance, Morocco)	S14– Parallel session: Ecoparmacovigilance and Antimicrobial resistance (inc.TB) Chair: Jayesh Pandit (Pharmacovigilance Country Head- NW and E Africa and QPPV Coordination Lead, Bayer, Kenya)
	S12.1 Bringing Pharmacovigilance to the Next Level by Leveraging Global IDMP: A Joint Effort for Global Impact Malin Fladvad (Portfolio Officer, UMC, Sweden)	S13.1 Building a framework for herbal vigilance: methods, standards, and partnership Houda Sefiani (Director, Centre Anti Poison et de Pharmacovigilance,Morocco)	S14.1 From Lab to Nature: An Introduction to EcoPharmacovigilance Jayesh Pandit (ISoP EcoPV SIG)
	S12.2 Medicines for all (M4all): EMA’s pathway to global access Viola Macolic-Sarinic (Scientific advisor on safety of medicines at the European Medicines Agency (EMA), Netherlands)	S13.2 (Abstract presentation-324) Enhancing Pharmacovigilance for Herbal and Traditional Medicines (HTMs) in MENA: UAE, Saudi Arabia, Egypt, and Beyond Ahmed Hegazy and Ingy Zamzam (PVigilant Health, UAE)	S14.2 (Abstract presentation-134) Designing an Algorithm to differentiate Clinical Antibiotic Ineffectiveness from Antimicrobial Resistance Fabio De Gregorio (Shionogi Europe, UK)
	S12.3 (Abstract presentation- 357) Visualizing Proxy Indicators for Pharmacovigilance Maturity in Africa Julie Doherty (Akros Research, Zambia)	S13.3 (Abstract presentation-120) Strengthening pharmacovigilance of herbal medicines in Côte d’Ivoire: Issues, challenges, and perspectives Gniénéferétien Nounaféri (Université Félix Houphouët Boigny, Côte d’Ivoire,Country)	S14.3 (Abstract presentation-268) 17:24– 17:36 Environmental Exposure to Medicinal Products: A Pharmacovigilance Analysis of the EudraVigilance Database Andreia Lopes (INFARMED – National Authority of Medicines and Health Products, Portugal)
	S12.4 (Abstract presentation- 264) Information Sharing as a Strategy to Enhance Regulatory Reliance: Lessons from Stringent Regulatory Authorities for East African National Regulatory Authorities Allan Serwanga (National Drug Authority, Uganda)	S13.4 (Abstract presentation- 331) Call for the development of phytovigilance in French-speaking West Africa by Kampadilemba Ouoba Medicines Regulatory Authority – Burkina Faso)	S14.4 (Abstract presentation- 349) Reducing Environmental Hazards: Ecopharmacovigilance Risk MinimizationMeasures for Safer Drug Use in Egypt Amira Selim (AstraZeneca, Egypt)



Conference Programme

Sunday 26 October 2025

8:00 – 9:00

Poster and Exhibition Session

9:00 – 10:15

S15– Parallel session:

Importance of Communication in Pharmacovigilance

Chair: Priya Bahri (Senior Lead Pharmacovigilance and Risk Management Guidance and Policy at the European Medicines Agency (EMA))

S15.1 Applying mixed methods for tailoring risk communication and minimisation materials to target populations

Priya Bahri (Senior Lead Pharmacovigilance and Risk Management Guidelines and Policy, EMA, Netherlands)

S15.2 (Abstract presentation- 40) Using Generative Artificial Intelligence to create abridged Patient Medication Information focused on essential messages in patient's preferred language

Jean-Christophe DELUMEAU (Institute of Pharmacovigilance, Canada)

S15.3 (Abstract presentation-383) Application of Human Factors for Designing Information That Keeps Patients Safe

Rabih Dabliz (AmanViva, UAE)

S16– Parallel session:

Biotechnology and biosimilars including haemovigilance

Chair:

Brian Edwards (Vice President of ISO P, Managing Director of Husoteria Ltd, UK)

S16.1 (Abstract presentation- 102)

A European Surveillance Study On Cognitive Decline With Incretin Agonists **Annamaria Mascolo** (Link Campus University, Italy)

S16.2 (Abstract presentation- 213) Monitoring and assessment of adverse effects of targeted neoplasia's therapy and immunotherapy

Nouzha Zhor Lazli (Algiers Pharmacy Faculty, Algeria)

S16.3 (Abstract presentation- 286) Safety Profile of Biologic Drugs for Type-2 High Allergic Conditions in Pediatric Patients: an Analysis of VigiBase

Nicoletta Luxi (University of Verona, Italy)

S16.4 (Abstract presentation-126) Safety of Immune Checkpoint Inhibitors for Cancer Treatment: Real-World Retrospective Data Analysis from a Single-Center Experience in Qatar. (SAFE- ICI-Q Study)

Nabil Elhadi (Hamad Medical Corporation, Qatar)

S17– Parallel session:

Falsified and substandard medicines

Chairs:

Lubna Merchant (Head of Risk Management Strategy, AbbVie, USA)
Alem Zekarias (Senior Pharmacovigilance Scientist, UMC, Sweden)

S17.1 Significance and global impact of Substandard and Falsified Medicinal Products (SFMP) **Pernette BOURDILLON ESTEVE** (WHO, Switzerland)

S17.2 Identification of gaps and weaknesses in global PV systems in detecting SFMP **Alem Zekarias** (Senior Pharmacovigilance Scientist, UMC, Sweden)

S17.3 (Abstract presentation-4) Community Pharmacists' Knowledge And Practices In Detecting And Reporting Substandard And Falsified Medicines In A Large Metropolitan City Southwest Nigeria **Ibrahim Oreagba** (African Centre of Excellence for Drug Research, University of Lagos, Nigeria)

S17.4 (Abstract presentation-329) Trend Analysis of Substandard and Falsified Medicinal Products Reports Submitted to the Iraqi Pharmacovigilance Center 2016–2024 **Manal Younus** (Pharmacovigilance Center, Iraq)

Panel discussion and questions from audience

10:15 – 10:45

Break (Poster and Exhibition Session)

10:45 – 12:00

S18– Parallel session: Risk management and measurement of RMM effectiveness

Chairs:

Jean-Christophe Delumeau (Chair of the Risk Minimisation Methods SIG, Institute of Pharmacovigilance, Canada)

Fawaz Alharbi (Director of Drug Safety and Risk Management Department at SFDA, Saudi Arabia)

S18.1 Risk minimisation measures (RMM) and Methods for Effectiveness Evaluation **Thomas Goedecke** (Senior Pharmacovigilance Specialist, EMA, Netherlands)

S18.2 Can a digital risk minimisation control tool be successfully implemented across multiple countries?

Mark Perrott (Axian Consulting, UK)

S19– Parallel session: Women's medicines

Chair:

Viola Macolic-Sarinic (Scientific adviser on safety of medicines at the European Medicines Agency (EMA), Netherlands)

S19.2 Good Pharmacovigilance Practice population-specific considerations: Pregnant and breastfeeding women **Viola Macolic-Sarinic** (Scientific adviser on safety of medicines, EMA, Netherlands)

S19.1 Minimising embryo-fetal risks of medicines proactively - new EU guidance **Priya Bahri** (Senior Lead Pharmacovigilance and Risk Management Guidelines and Policy, EMA, Netherlands)

S20– Parallel session: PV education and qualification

Chair:

Francesco Salvo (ISO P Board Member, Director of the Bordeaux Pharmacovigilance Center, Coordinator of Eu2P, France)

Ryan Walker (University of Birmingham, UK)

S20.2 WHO-ISO P PV curriculum **Jürgen Beckmann** (Director & Professor (Ret.), University of Göttingen, Germany)

S20.1 ISO P Global Pharmacovigilance Professional Certification program **Jan Petracek** (ISO P Qualification SIG president, CEO iVigee, Czech)



12:00 – 13:00

S18.3 (Abstract presentation- 179) Phased Integration of Additional Risk Minimization Measures (aRMMs) into Hospital Information Systems in Saudi Arabia: A National Safety Initiative Aljawharah ALBABTAIN (SFDA, Saudi Arabia) S18.4 (Abstract presentation-281) 11:45– 12:00 U.S. Risk Evaluation and Mitigation Strategies with Elements to Assure Safe Use: A longitudinal analysis of REMS modifications Elaine Morrato (Loyola University Chicago, USA)	S19.3 (Abstract presentation-181) Medication related problems in women correctional facilities, Thailand: A cross-sectional observational study Chuenjid Kongkaew (Naresuan University, Thailand) S19.4 (Abstract presentation-185) Valproate Use by Fathers During Spermatogenesis and Risk of Neurodevelopmental Disorders in Children: A Cross-National Study from Norway and Taiwan Hedvig Nordeng (Department of Pharmacy, Faculty of Mathematics and Natural Sciences, University of Oslo, Oslo, Norway) S19.5 (Abstract presentation-234) Use of the Tree-based Scan statistics for surveillance of pregnancy and infant outcomes following paternal medication use during spermatogenesis Nhung Trinh (University of Oslo, Norway)	S20.3 (Abstract presentation-231) Strengthening Pharmacovigilance Capacities in Southern African countries – Current Practices, Challenges and Proposed Strategies Hazel Bradley (University of the Western Cape, South Africa) S20.4 (Abstract presentation- 381) Mapping Resources to Support Pharmacovigilance Research: A Review of Online, Open- Access Materials Ryan Walker (University of Birmingham, UK)
S21- Parallel session: PV compliance, audit and inspection Chair: Hadir Rostom (President of ISoP Egypt Chapter, Pharmacovigilance consultant, MSA University, Egypt)	S22- Parallel session: Active Monitoring/surveillance Chair: Santiago Schiaffino (Senior Director, Patient Safety Biopharma at AstraZeneca, Spain)	S23- Parallel session: Medication errors Chairs: Brian Edwards (Chair of the Medication Error SIG, Vice President of ISoP, Managing Director of Husoteria Ltd, UK) Lubna Merchant (Head of Risk Management Strategy, AbbVie, USA)
S21.1 AI Assistance during Audits and Inspections in Pharmacovigilance. Jan Petracek (ISoP Qualification SIG president, CEO iVigee, Czech) S21.2 The impact of Pharmacovigilance inspection on Drug Safety and Compliance for Pharmaceutical companies- SFDA perspective Hammad A. Al Dali (Senior Expert Pharmacovigilance Inspector at SFDA, Saudi Arabia) S21.3 (Abstract presentation- 292) Navigating the Lifecycle of Pharmacovigilance Agreements: Practical Considerations and Lessons Learned Marion Mueller (Akademie Heidelberg, Germany) S21.4 (Abstract presentation-371) Global Pharmacovigilance Blind Spots in Out-Licensing Agreements Hadir Rostom (President of ISoP Egypt Chapter, Pharmacovigilance consultant, MSA University, Egypt)	S22.1 Staying Ahead of the Curve: Active Surveillance in a Rapidly Evolving Therapeutic Landscape Marco Tuccori (Associate Professor of Pharmacology, University of Verona, Italy) S22.2 (Abstract presentation-116) Paediatric Drug Safety in Europe: Ten Years of PRAC Safety Signal Evaluation 2014–2024) Maria Galiulo (Italian Medicines Agency (AIFA) Italy) S22.3 (Abstract presentation-104) Impact of different data prompts on the identification of ulcerative colitis patients and flares in four European healthcare data sources Giuseppe Roberto (Agenzia regionale di sanità della Toscana, Italy) S22.4 (Abstract presentation- 133) Evaluation of Potential Medicine-Related Symptom Burden and Health-Related Quality of Life Among Patients Using Regular Medicines: A Cross-sectional Study Abebe Basazn (University of South Australia, Australia)	S23.1 Medication Error Pharmacovigilance Lubna Merchant (Head of Risk Management Strategy, AbbVie, USA) S23.2 Can we prevent what we don't see? Medication Error handling in the EU regulatory network – From detection to action – A 20-Minute Dive into Current Strategies, Challenges, and Future Directions Viola Macolic-Sarinic (Scientific adviser on safety of medicines at the European Medicines Agency (EMA), Netherlands) S23.3 (Abstract presentation-52) Prevention of pediatric iatrogenesis through prospective medication prescription analysis Oumaima EL Qabissi (Mohammed V University, Morocco) S23.4 (Abstract presentation- 145) Co-Designing actions to prevent iatrogenesis in older patients: a collective intelligence approach in the Portuguese central region Fátima Roque (University of Guarda, Portugal)



13:00 - 14:00

Lunch (SIGs Get Together – Informal Meeting)

14:00 - 16:00

S24–PL: ISoP Assembly: Introducing new Advisory Board

16:00 - 16:45

**Break
Poster & Exhibition Session**

S25– PL: What's new from Africa?

Chairs:

Comfort Ogar (*President of ISoP Africa Chapter, Senior Pharmacovigilance Manager at the US Pharmacopeia (USP), USA*)
Jayesh Pandit (*Pharmacovigilance Country Head- NW and E Africa and QPPV Coordination Lead, Bayer, Kenya*)

S25.1 Africa's Progress in Pharmacovigilance and the AMA establishment

Victoria Prudence Nambasa (*Senior Programme Officer – Health Product Safety at the African Union Development Agency- NEPAD, South Africa*)

S25.2 The Moroccan Agency for Medicines and Health Products: an overview

Loubna Alj (*Agence Marocaine du Médicament et des produits de Santé (AMMPS), Morocco*)

S25.3 Building sustainable Pharmacovigilance systems in Africa: the role of Global Health EDCTP3 and partners **Jean Marie Vianney Habarugira** (*Senior Scientific Officer at Global Health EDCTP3, Belgium*)

S25.4 (Abstract presentation- 272)

Strengthening Pharmacovigilance in Kenya: Capacity Building through AU-3S Implementation **Pamela Nambwa** (*Pharmacy and Poisons Board, Kenya*)

S25.5 (Abstract presentation-289)

Enhancing Patient Safety in South Africa's Medicinal Cannabis Sector: The Role of Pharmacovigilance Integration
Pfunzo Collins Mukoma (*South African Health Products Regulatory Authority (SAHPRA), South Africa*)

19:30- 20:30

Travel to the Conference dinner venue

20:30- 00:00

Conference Dinner

Conference Programme

Saturday 25 October 2025



8:00 – 9:00	Poster and Exhibition	
9:00 – 10:15	S26-Parallel session: AI and digitalization in PV Chair: Mohamed Fouda (<i>Chair of the Artificial Intelligence in PV SIG, Head of Signal Detection Section, SFDA,Saudi Arabia</i>) S26.1 (Abstract presentation-351) AI as a Signal Assessor – Can a Large Language Model Assess a Signal? Alem Zekarias (<i>Senior Pharmacovigilance Scientist, UMC, Sweden</i>) S26.2 (Abstract presentation-186) Artificial Intelligence-Assisted Causality Assessment of Serious Adverse Events in Clinical Trials JeaWoo Kim (<i>Hanmi Pharm Co.,Ltd., Korea</i>) S26.3 Tailoring solutions to real-world needs Charles Kumar (<i>Director, Nextrove LLC, India</i>) S26.4 (Abstract presentation-280) A Multidimensional Framework for AI Readiness in LMIC Cross-Country Pharmacovigilance: Lessons from AfriVigilance Design under the AU-3S Programme Kudakwashe Dandajena (<i>African Union Development Agency (AUDA-NEPAD), Johannesburg, South Africa</i>) S26.5 (Abstract presentation-343) Leveraging Digital Transformation and Artificial Intelligence for Enhanced Pharmacovigilance Compliance at Local Affiliates Level: The I-Vigilance Initiative Ibrahim Altamawy (<i>SAJA Pharmaceuticals, Egypt</i>)	S27- Parallel session: MedSafetyWeek: Building a global PV campaign Chairs: Angela Caro (<i>President of ISO-P, Colombia</i>) Jayesh Pandit (<i>Pharmacovigilance Country Head- NW and E Africa and QPPV Coordination Lead, Bayer, Kenya</i>) S27.1 10 years of #MedSafetyWeek: from regional experiment to global movement Federica Santoro (<i>Communications Officer, UMC, Sweden</i>) S27.2 (Abstract presentation- 295) Communicating for the Safe Use of Medicines: ISO-P Egypt Chapter's MedSafetyWeek Experience Mohamed A. Elhawary (<i>General Secretary of ISO-P Egypt Chapter, MOH, Egypt</i>) S27.3 (Abstract presentation-321) Iraq MedSafetyWeek: A Comprehensive Overview of Campaign Evolution Ban Al Shimran (<i>Iraqi Pharmacovigilance Center, Iraq</i>) S27.4 Group activity: Workshop – Communications case challenge Federica Santoro (<i>Communications Officer, UMC, Sweden</i>) Workshop Moderators: Rania Aly (<i>Patient Safety Lead at Roche</i>) Yomna Abdelgayed (<i>Global Safety Manager at Amgen</i>)
10:15 – 10:45	Break (Poster and Exhibition)	
10:45 – 12:00	S28- Parallel session: RWE (Adaptive pharmacovigilance in the Age of Accelerated Drug Approvals) Chairs: Gianluca Trifirò (<i>Chair of the Real-World Evidence and Big Data SIG, Evidence Professor of Clinical Pharmacology, University of Verona, Italy</i>) Maribel Salas (<i>ISO-P Board Member, Executive Medical Director and Oncology Therapeutic Area Lead in Benefit-Risk Management at Bayer, USA</i>) Introduction Gianluca Trifirò (<i>University of Verona, Italy</i>) S28.1 Adaptive Pharmacovigilance in the Age of Acceleration: Challenges at the Intersection of Speed and Safety Tarek Hammad (<i>Vice President, Global Head of Medical Safety, MPD, PDT, & MDS, Takeda, USA</i>) S28.2 Observational Study Methods which Support Early Access to Medicines Saad Shakir (<i>Consultant – Pharmacovigilance & Pharmacoepidemiology at ADROITVIGILANCE, and Former Director of DRSU, UK</i>)	S29- Parallel session: From Silent Sufferers to Safety Partners: Elevating Patient Voices in Pharmacovigilance Chairs: Mayada Alkhakany (<i>Chair of ISO-P Pat-EG SIG & ISO-P Board Member, Iraq</i>) Manal Younus (<i>Co-Chair of ISO-P Pat-EG SIG & Head of Iraqi PV Centre</i>). Introduction Mayada Alkhakany (<i>Chair of ISO-P Pat-EG SIG & ISO-P Board Member, Iraq</i>) S29.1 Role of patients in Pharmacovigilance Hussain Jafri (<i>CEO of the World Patients Alliance</i>) S29.2 From Policy to People An authority perspective Manal Younus (<i>Co-Chair of ISO-P Pat-EG SIG & Head of Iraqi PV Centre, Iraq</i>) .



	S28.3 Turning RWE into Actionable Risk-Mitigation Post-Accelerated Approval Adel Abou Ali (Vice President & Strategy Lead for Global Risk Management and REMS at Syneos Health, USA) S28.4 How can AI transform the role of RWE in pharmacovigilance? Andrew Bate (VP, Head of Safety Innovation & Analytics at GSK, UK) Q&A Maribel Salas (ISoP Board Member, Executive Medical Director and Oncology Therapeutic Area Lead in Benefit-Risk Management at Bayer, USA)	S29.3 What matters? Different perspectives and needs of pharmacovigilance Linda Harmark (Director of Drug Safety Research Unit, UK) S29.4 (Abstract presentation-143) How is the health literacy and medication adherence of low-income older adults? Fátima Roque (Polytechnic University of Guarda, Portugal) S29.5 Narratives that matter : Patient Trust and the Future of pharmacovigilance Helen Ndagije (Vice President of ISoP Africa, Director Product Safety at National Drug Authority, Uganda) Mohamed A. Elhawary (General Secretary of ISoP Egypt Chapter, MOH, Egypt)
12:00 – 12:30	S30– PL: Pharmacovigilance and the forgotten: the riddle of missing information Chair: Brian Edwards (Vice President of ISoP, Managing Director of Husoteria Ltd, UK) Brent Gibson (General Partner at Avocet Health Partners, USA)	
12:30 – 13:00	S31-PL Bengt Erik Wiholm Lecture Chair: Brian Edwards (Vice President of ISoP, Managing Director of Husoteria Ltd, UK) Speaker: Qun-Ying Yue (Senior Pharmacovigilance Expert, UMC, Sweden)	
13:00 – 14:00	Lunch Poster and Exhibition	
14:00 – 17:00	S32-PI: Joint ISOP –WHO meeting	
	 International Society of Pharmacovigilance  World Health Organization ISoP – WHO Joint Session Operationalizing the WHO Global Smart Pharmacovigilance Strategy	
17:00 – 18:00	S33-PI: Closing Ceremony: Sten Olsson & Poster Awards and ISOP 2026 Host presentation	
18:00 – 18:30	Networking Break	

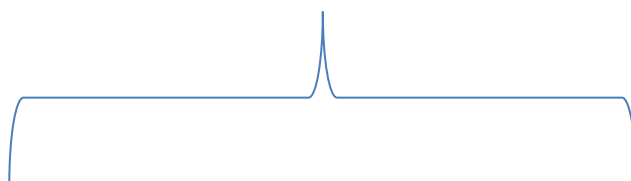


Total Number of Registered Participants

552

Total Number of Accepted Abstract

382



Oral Abstracts

32

Posters

350

To get access to these abstract click the link below

<https://link.springer.com/article/10.1007/s40264-025-01605-x>



ISoP 2025 Poster Prize Committee

- **Jimmy Jose**, University of Nizwa, Sultanate of Oman (Chair)
- **Salvatore Crisafulli**, University of Verona, Italy
- **Christina Saad**, Bayer, Egypt
- **Ryan Walker**, University of Birmingham, UK



Poster Prize & Sten Olsson Award Results

1 st Poster Prize Winner	Sarah Banholzer	Poster Topic: Positive Side Effect of Drug Safety Screening: Contribution to National Pharmacovigilance Efforts
2 nd Poster Prize Winner	Michele Fusaroli	Poster Topic: Pregnancy Report Retrieval in VigiBase: Differences and Commonalities of Three Different Algorithms
3 rd Poster Prize Winner	David Ryan	Poster Topic: OpenPV: Development and Validation of an Open-Access, Code-Free Online Platform to Conduct Pharmacovigilance Studies
Sten Olsson Award Winner	Lucila Isabel Castro Pastrana	Poster Topic: A First-Generation AI Tool for Antidepressant Pharmacovigilance: Addressing Data Accessibility Gaps in Mental Health Care



List of Chair Persons, Speakers and Instructors

- Brian Edwards (Scientific Chair ISoP 2025, Vice President of ISoP, Husoteria Ltd, UK)
- Angela Caro Rojas (President of ISoP, Pontificia Universidad Javeriana, Colombia)
- Maha Mohamed (General Manager of the Egyptian Pharmaceutical – Vigilance Center – Egyptian Drug Authority (EDA), Egypt)
- Ali Al Shaharani (Executive Director of Pharmacovigilance at Saudi Food & Drug Authority (SFDA), Saudi Arabia)
- Florah Matlala (Pharmacovigilance Manager at South African Health Products Regulatory Authority (SAHPRA), South Africa)
- Georgy Genov (Head of Pharmacovigilance Office at the European Medicines Agency (EMA), Netherlands)
- Phil Tregunno (Deputy Director of Patient Safety Monitoring at the Medicines & Healthcare products Regulatory Agency (MHRA), UK)
- Victoria Prudence Nambasa (Senior Programme Officer – Health Product Safety at the African Union Development Agency-NEPAD, South Africa)
- Shanthi Pal (Team Lead, Pharmacovigilance, Regulation and Prequalification at the World Health Organization (WHO), Switzerland)
- Deirdre McCarthy (Pharmacovigilance Lead at Gates Foundation, USA)
- Peter Hjelmström (Director of Uppsala Monitoring Centre (UMC), Sweden)
- Marcin Kruk (EUAFME Regional Head Worldwide Safety, Pfizer, USA)
- Viola Macolić Sarinić (Scientific adviser on safety of medicines at the European Medicines Agency (EMA), Netherlands)
- Michele Fusaroli (Senior Pharmacovigilance Scientist and Deputy Chief Medical Officer, UMC, Sweden)
- Omar Aimer (ISoP Executive Committee member- NASoP President, ISoP / InnoVigilance, Canada)
- Myriam Salem (Health Canada, NASoP, Canada)
- Thamer M. AlShammary (President of ISoP Middle East Chapter, Associate Professor, Jazan University, Saudi Arabia)
- Qun-Ying Yue (Chair of the Pharmacogenomics SIG, Senior Pharmacovigilance Expert, UMC, Sweden)
- Felix Arellano (Global Head of Pharmacovigilance and Drug Safety, Roche, Switzerland)



- Abeer Zeitoun (National Pharmacovigilance Program, MoPH, Lebanon)
- Abdullatif Alotaibi (Head of Pharmacovigilance inspection section, SFDA, Saudi Arabia)
- Mónica Tarapués (ISoP Executive Committee member, Pharmacovigilance Scientist, UMC, Ecuador)
- Rebecca Chandler (Chair of the Vaccines SIG, Senior Vaccine Safety Lead at the Coalition for Epidemic Preparedness Innovations (CEPI), UK)
- Ibrahim Altamawy (Regional Medical & Compliance Head (MENA) at SAJA Pharmaceuticals, Egypt)
- Patricia Zuluaga (UMC Regional Specialist Outreach team, Colombia)
- Trésor Bodjick (University of Kinshasa, DR Congo)
- Aya Anis (Operation Manager, Baupharma, Czech Republic)
- Jean-Marc Häusler (Global Head International Patient Safety, Roche, Switzerland)
- Houda Sefiani (Director, Centre Anti Poison et de Pharmacovigilance, Morocco)
- Jayesh Pandit (Pharmacovigilance Country Head- NW and E Africa and QPPV Coordination Lead, Bayer, Kenya)
- Malin Fladvad (Portfolio Officer, UMC Sweden)
- Lubna Merchant (Head of Risk Management Strategy, AbbVie, USA)
- Alem Zekarias (Senior Pharmacovigilance Scientist, UMC, Sweden)
- Jean-Christophe Delumeau (Chair of the Risk Minimisation Methods SIG, Institute of Pharmacovigilance, Canada)
- Fawaz Alharbi (Director of Drug Safety and Risk Management Department at SFDA, Saudi Arabia)
- Francesco Salvo (ISoP Board Member, Director of the Bordeaux Pharmacovigilance Center, Coordinator of Eu2P, France)
- Ryan Walker (University of Birmingham, UK)
- Jan Petracek (ISoP Qualification SIG president, CEO iVigee, Czech)
- Santiago Schiaffino (Senior Director, Patient Safety Biopharma at AstraZeneca, Spain)



- Comfort Ogar (President of ISoP Africa Chapter, Senior Pharmacovigilance Manager at the US Pharmacopeia (USP), USA)
- Loubna Alj (Agence Marocaine du Médicament et des produits de Santé (AMMPS), Morocco)
- Jean Marie Vianney Habarugira (Senior Scientific Officer at Global Health EDCTP3, Belgium)
- Mohamed Fouda (Chair of the Artificial Intelligence in PV SIG, Head of Signal Detection Section, SFDA, Saudi Arabia)
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- Adel Abou Ali (Vice President & Strategy Lead for Global Risk Management and REMS at Syneos Health, USA)
- Andrew Bate (VP, Head of Safety Innovation & Analytics at GSK, UK)
- Helen Ndagije (Vice President of ISoP Africa, Director Product Safety at National Drug Authority, Uganda)
- Brent Gibson (General Partner at Avocet Health Partners, USA)



Networking

Welcome Reception

Friday 24th of October 2025 ,18:00 – 20:00

Venue: InterContinental Cairo Semiramis ,2nd floor

Attendees will have the opportunity to network with friends, colleagues and industry partners in a relaxed atmosphere whilst enjoying refreshments.

ISoP 25th Anniversary Celebration

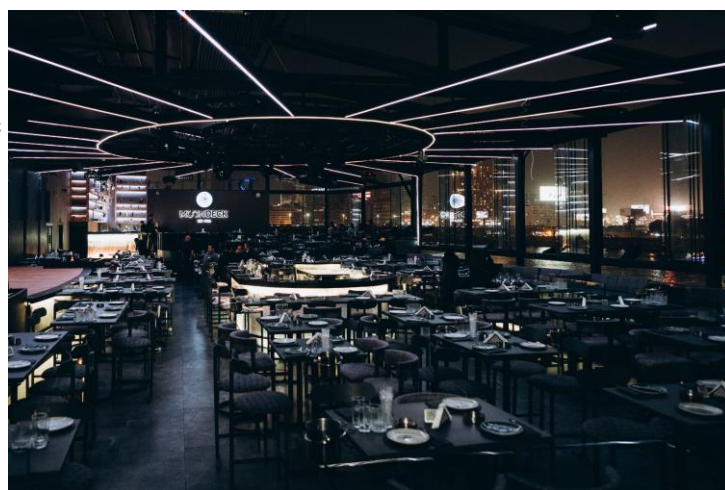
Saturday 25th of October 2025 ,18:00 – 21:00

Join us as we celebrate the 25th Anniversary of ISoP on 25 October 2025, during the ISoP Annual Meeting in Cairo, Egypt.

It will be a magic night by the Nile River, bringing together our global community to mark 25 years of advancing pharmacovigilance and patient safety.

Where: Nile Boat

Dress code: Smart casual, Blue, White & Yellow
transfer: walking distance from the conference venue



Conference Dinner

Sunday 26th of October 2025

Time

19:30- 20:30 Transportation from the conference venue to the dinner

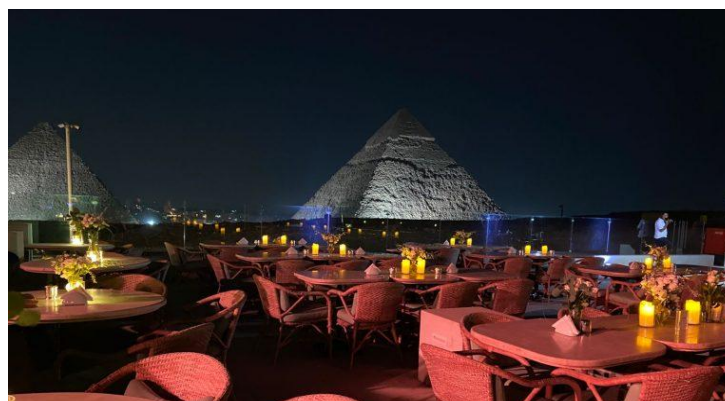
20:30- 23:30 Conference Dinner

23:30 – 24:00 Transportation back to the conference venue

Where: Laduree The Great Pyramids of Giza Restaurant

Dress code: Smart casual

Free Transfer to and from dinner venue will be provided by the conference.





International Society
of Pharmacovigilance

JOIN US TO CELEBRATE OUR



anniversary

25th October 2025

19:00h - 21:00h

Blue Nile Boat,
9 A Saray Algazeera st-Zamalek

Dress code: Blue, white, or gold

24th ISoP Annual Meeting





CAIRO 2025
ANNUAL MEETING

24th ISoP Annual Meeting
Pharmacovigilance: Back to the Future
October 24-27, 2025

Conference Dinner
at The Great Pyramids of Giza





Cairo

Cairo Downtown: The Heart of the City

Cairo Downtown is the historic and commercial heart of the city, known for its grand 19th and early 20th-century architecture, lively streets, and cultural landmarks. Developed during Egypt's modernization under Khedive Ismail, it features Parisian-style boulevards, iconic squares like Tahrir Square, and a mix of Belle Époque, Art Deco, and Islamic architectural styles. Home to business centers, renowned cafés, restaurants, and shopping streets, it remains a bustling hub of activity.

Walking through Downtown is the best way to soak in its rich history and vibrant energy. Its broad avenues and pedestrian-friendly streets make it ideal for exploring landmarks, discovering local shops, and enjoying the city's dynamic street life.

Top Attractions in Cairo:

- The Pyramids of Giza & The Sphinx
- The Grand Egyptian Museum (GEM)
- The Nile River & Felucca Ride
- Abdeen Palace
- Cairo Tower
- The National Museum of Egyptian Civilization (NMEC)
- Khan El Khalili Bazaar
- Al-Muizz Street & Islamic Cairo
- Coptic Cairo & The Hanging Church
- Saladin Citadel & The Mosque of Muhammad Ali
- Gastronomic Tour

Language

Arabic is the official language of Egypt.

English is commonly spoken in hotels, restaurants, tourist areas, shops and by younger generations. Some people also speak French, German, or Italian, especially in the tourist areas.

Weather and time

Late October in Cairo offers pleasant and warm temperatures, making it an ideal time for sightseeing.

Daytime: Around 25–30°C (77–86°F) with plenty of sunshine.

Evenings: Cooler, around 18–22°C (64–72°F).

Rainfall: Rare, with mostly dry and clear skies.

Humidity: Low to moderate, making the weather comfortable for outdoor activities.

Egypt standard time is Eastern European Time (EET, UTC+2).

However, Daylight Saving Time (DST) UTC+3 will be operating from end of April till last Thursday of October.

Weekends: Friday and Saturday.

Taxes and Tips

VAT (Value-Added Tax): A 14% VAT is applied to most goods and services, usually included in the price.

Service Charges: Many restaurants and hotels add a 12% service charge, but it does not go directly to staff, so additional tipping is appreciated.



Hospitals and pharmacies

Hospitals: Cairo has modern private hospitals and clinics with high-quality healthcare.

Pharmacies: Open late or 24/7 in major areas. Well-known chains include Seif, El Ezaby, and Misr Pharmacies.

Emergency Number: Call 123 for medical emergencies.

Shopping

Cairo is a shopper's paradise, offering everything from bustling bazaars to modern malls.

Cairo's Downtown (Wust El Balad) is a lively district known for its historic architecture, bustling streets, and diverse shopping options. Popular shopping streets like Talaat Harb Street and Qasr El Nil Street offer everything from local boutiques and bookshops to fashion stores and souvenir stalls, making it a great place to experience the city's vibrant commercial scene.

Modern Malls: Cairo boasts several modern malls, offering a mix of international brands, dining, and entertainment, with popular options like City Stars, Cairo Festival City Mall, and The First Mall.

Traditional Markets (Souks): Khan El Khalili Bazaar – The most famous market, ideal for souvenirs, jewelry, spices, and handmade crafts. Bargaining is expected!

Useful Numbers

Egypt country code is +20.

We wish you a pleasant stay, but just to be extra safe, keep these numbers handy for quick and easy access in case of inquiries, suggestions, or emergencies!

Ministry of Tourism and Antiquities	19654
Tourist Police	126
Ambulance	123
Air Hospital Service	+(202) 377 66392/3
Telephone Guide	140
Cairo Airport Shuttle Bus	19970
Gas Emergency	129
Fire services	180



ROCHE

SPONSOR

Roche is a global pioneer in pharmaceuticals and diagnostics committed to advancing scientific discoveries to enhance human health. Originating in Basel, Switzerland in 1896, the Roche Group has grown into a multinational corporation active in over 100 countries. Roches' core business revolves around developing and delivering innovative medicines and diagnostic tools. They are also increasingly focused on leveraging data-driven medical insights to facilitate personalized healthcare. Roche collaborates with partners across the healthcare spectrum with the ultimate goal of providing the best possible care for each individual. For more information, please visit www.roche.com.



Baupharma

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Baupharma, headquartered in Prague, is a premier pharmaceutical service provider with over 25 years of industry experience. Our international team offers comprehensive services—including pharmacovigilance, regulatory affairs, medical writing, batch release and distribution, translations, and clinical research—across the EU, MENA region, CIS, Africa, USA, LATAM, and beyond. With offices in Czech Republic, Saudi Arabia, UAE and Egypt, we ensure efficient project management and collaboration, delivering tailored solutions that meet the unique needs of each market.

<https://www.baupharma.com>



African Union Development Agency

SPONSOR

The mandate of AUDA-NEPAD is to: coordinate and execute priority regional and continental projects to promote regional integration towards the accelerated realisation of Agenda 2063, strengthen capacity of African Union (AU) Member States and regional bodies, advance knowledge-based advisory support, undertake the full range of resource mobilisation and serve as the continent's technical interface with all Africa's development stakeholders and development partners

www.nepad.org





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Pfizer is one of the world's leading biopharmaceutical companies. Our diversified health care portfolio includes some of the world's best known and most prescribed medicines and vaccines. At Pfizer, we apply science and our global resources to bring therapies to people that help extend and improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time.

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Uppsala Monitoring Centre

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UMC was established in 1978 through an agreement between the World Health Organization (WHO) and the government of Sweden as a WHO Collaborating Centre for International Drug Monitoring. UMC is custodian of the WHO global database of adverse event reports for medicines and vaccines and strengthens global safety surveillance through science and innovation, signal monitoring, development of pharmacovigilance tools, standardisation with the WHODrug dictionary, and education and communication.

www.who-umc.org



AB-Cube
Making Safety Easy

AB Cube

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AB Cube is the developer of the most efficient drug safety database software for life sciences organizations – enabling effortless pharmacovigilance, materiovigilance, cosmetovigilance and nutriviigilance operations in one unified platform. Founded in 2006, Paris-based AB Cube pioneered the industry's with the first SaaS vigilance application. Now with a presence in 43 countries and serving over 220 international clients, today pharmaceutical laboratories, CROs, academics and health authorities trust AB Cube's best-in-class SafetyEasy® Suite to support their global Multivigilance needs at every scale.

www.ab-cube.com



MedDRA

MedDRA

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The International Conference on Harmonization (ICH) created MedDRA in the late 1990s as a detailed, standardized medical terminology to support global sharing of regulatory information for human medical products. MedDRA is used internationally for product registration, documentation, and safety monitoring across pharmaceuticals, biologics, vaccines, and drug-device combinations. Its widespread adoption by regulators, pharmaceutical companies, CROs, and healthcare professionals enhances global patient safety.

To manage MedDRA, ICH established the Maintenance and Support Services Organization (MSSO). The MSSO serves as the central repository, maintains the accuracy and integrity of the terminology, and distributes updates. Since receiving the original “Golden Master” version in 1998, the MSSO has kept MedDRA under strict quality control. The Quality System Manual (QSM) outlines the MSSO’s responsibilities, processes, and quality management system for maintaining and supporting MedDRA.

PhV LATAM

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PhV LATAM is a company that provides specialized services in pharmacovigilance, technovigilance, cosmetovigilance, regulatory affairs, and medical information.

PhV LATAM supports pharmaceutical companies and distributors in complying with local and international regulations through standardized processes and a multidisciplinary team.

The company is the first in LATAM region to be ISO 9001:2015 certified for pharmacovigilance services.

PhV LATAM offers operational coverage in Latin America, Africa, Asia, and the Middle East, with solutions tailored to the clients’ needs.

<https://phvlatam.com/>



Qinecsa

Qinecsa

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Qinecsa are redefining drug safety with our technology enabled, end-to-end pharmacovigilance services, designed to help pharmaceutical companies stay ahead in an evolving regulatory landscape.

<https://qinecsa.com/>



PharmaKnowl Consulting

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PharmaKnowl Consulting is an SFDA-licensed Pharmacovigilance and Regulatory Affairs service provider. PharmaKnowl supports pharmaceutical, biotechnology, clinical research, and MedTech companies in achieving and maintaining compliance with Saudi Food and Drug Authority (SFDA) requirements.

Pharmacovigilance services include the appointment of licensed Saudi QPPV and Deputy QPPV, establishment and maintenance of local PV systems, development of regulatory documentation (PMSF, PSSF, SOPs), local literature monitoring, signal detection, and SFDA inspection readiness. Services also cover case intake, reconciliation, safety variation tracking, and regulatory intelligence updates, with full operational integration into global MAH systems.

In addition to pharmacovigilance, PharmaKnowl Consulting provides end-to-end regulatory support, including product registration, SFDA submission management, and licensing coordination, serving as a single point of contact for companies operating in the Saudi market.

With on-ground expertise and a structured, compliance-focused approach, PharmaKnowl ensures that all activities align with SFDA guidelines and international safety standards.

PharmaKnowl is an SFDA licensed, EU Audited, and ISO certified Pharmacovigilance Service Provider in Saudi Arabia.

<https://pharmaknowl.com/>



PVigilant Health

SPONSOR

PVigilant Health is dedicated to advancing patient safety and innovation in healthcare. Established to provide expert support, tailored solutions, and strategic consultations, the company specializes in Pharmacovigilance, Medical Affairs, and a wide range of Research & Development services. With a commitment to quality and scientific excellence, PVigilant Health partners with organizations to strengthen systems, optimize compliance, and drive better outcomes across the healthcare and life sciences sectors.



SPONSOR

Nextrove is a global consulting and technology firm with deep-rooted expertise in pharmacovigilance system optimization and safety operations.

With decades of experience in the Life Sciences sector, our team delivers end-to-end solutions across the entire safety chain from implementation, upgrades, cloud hosting and data migration to regulatory intelligence.

We provide full-service support for leading PV platforms including validated migrations and complex system integrations. Our proprietary Progressive Suite extends core safety systems with interoperable modules that enable automation, case intake optimization, and advanced reporting capabilities.

As a trusted partner to top pharmaceutical companies, CROs, and biotechs, we combine technical depth with industry expertise to drive digital transformation and operational excellence, empowering pharma to improve patient safety.

<https://nextrove.com/>



Eu2P

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Eu2P stands for “European program in Pharmacovigilance and Pharmacoepidemiology”. This consortium, coordinated by the university of Bordeaux, offers an innovative and academic web-based education & training offer in Pharmacovigilance and Pharmacoepidemiology at the worldwide level:

An accredited Master of Science program :

This curriculum includes mandatory and optional course modules, possibly leading to a Master Specialisation Track

32 individual accredited Certificates courses :

They can be attended on a single basis during the Master curriculum calendar

91 individual Short courses :

They are bite-sized courses which have been designed out of the Master and Certificate modules’ course material and can be attended at anytime, any-pace.

Eu2P has recently been extended to the Am2P program dedicated to North American stakeholders in collaboration to the NaSOP chapter. Am2P also provides accredited postgraduate certificates and short courses in Pharmacovigilance and Pharmacoepidemiology and can be attended online at anytime, any-pace

<https://www.eu2p.org/>



Frontiers in Drug Safety and Regulation

A journal by  frontiers

Frontiers

SPONSOR

Frontiers in Drug Safety and Regulation is a PubMed Central and Scopus-indexed journal, that investigates emerging issues in pharmacovigilance, pharmacoepidemiology, regulatory science and public health. Led by Gianluca Trifirò, the journal aims to address potentially emerging issues concerning pharmacovigilance, with special emphasis on how the post-marketing surveillance drives informed regulatory decision process and vice-versa.

SPRINGER NATURE Springer Nature

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Springer Nature supports global research by publishing high-quality work, expanding knowledge, and promoting open access. Their goal is to offer excellent service to the entire research community. Among their products is AdisInsight Safety, a platform designed to streamline pharmacovigilance (PV) literature monitoring. It enables efficient tracking of ICSRs, adverse events, special situations, and the latest drug safety news, ensuring strong and compliant PV processes. The tool covers all pharmaceutical products. With over 40 years of industry experience, Springer Nature provides trusted expertise and a deep understanding of the challenges in drug development.



International Society of Pharmacovigilance (ISoP)

Organizer

The International Society of Pharmacovigilance (ISoP) is a global professional, independent, not-for-profit society, open to anyone with an interest in the safe and effective use of medicinal products. ISoP aims to foster science, learning and research in pharmacovigilance in all countries.

administration@isoponline.org

www.isoponline.org

Supporters



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Qinecsa

Frontiers in
Drug Safety
and Regulation

A journal by  frontiers



NEXTROVE



testimonial



Samila Macedo

Sun, Oct 26, 2025, 10:55

From Cabo Verde to Vietnam, Uganda, Serbia, and Egypt — united through ISoP.
That's what ISoP is all about — bringing people together from all over the world! 🌍



2 Comments

17 Likes



Nyende Sophia

Mon, Oct 27, 2025, 15:49

🇺🇬 ✨ The Ugandan Squad joined by many other great minds at #ISoPCairo2025 — all smiles, ideas, and global pharmacovigilance energy! 💚 Probably the biggest and most vibrant crew around, still flying the flag high on the final day! 🎉 Drop a like for Team Uganda and all the amazing professionals making safety science shine! 🌍🔥 #ISoP25Years #TeamUganda #Pharmacovigilance #ISoP



0 Comments

23 Likes



Samar Allam

Mon, Oct 27, 2025, 14:54

A wonderful example of a tiny campaign workshop that showed teamwork, creativity, and collaboration in action.
Proud to have been part of this inspiring experience!



1 Comments

13 Likes



Marwa Zaki

Mon, Oct 27, 2025, 13:01



0 Comments

11 Likes



Amneh Abu Qamar

Sat, Oct 25, 2025, 18:47

Uppsala team and Amman Arab University team from Jordan. 🤗❤️



0 Comments



19 Likes



Rabih Dabliz

Sun, Oct 26, 2025, 12:20

Going back with all of them !!!



1 Comments



30 Likes



Rabih Dabliz

Sat, Oct 25, 2025, 17:11

🚨 Signal Detection Alert 🚨

We found the Med Safety Blobs unconscious and overdosed on candy 🍬

How do you categorize this in your PV system ??

Only wrong answers allowed !



2 Comments



20 Likes





The day concluded with the Gala Dinner held at the charming Pyramids of Giza, offering attendees a memorable and magical Cairo evening. According to Marco Tuccori, Associate Professor of Pharmacology at the University of Verona and one of the attendees at the conference, the conference dinner made him feel “genuinely privileged”. “As always, it was wonderful to reconnect with colleagues from around the world,” he said.



View of the Gala Dinner.



Highlights in the International Press

1- Global Perspective on the Evolution and Future of Pharmacovigilance: Deliverables from the 24th Annual Meeting of the International Society of Pharmacovigilance Celebrating 25 Years of Excellence. (Meeting Reports)
<https://doi.org/10.1007/s40264-026-01680-8>

2- ISoP 2025 Cairo: A Global Perspective on the Evolution and Future of Pharmacovigilance
Authors: Saad, C, Onsy, A. SH & Elhawary, M.A
<https://uppsalareports.org/articles/isop-2025-cairo-a-global-perspective-on-the-evolution-and-future-of-pharmacovigilance/>

3- Pharmacovigilance: Back to the Future with ISoP 2025. (March 19, 2025)
Authors: Onsy, A. SH, Elhawary, M.A & Brian Edwards
<https://uppsalareports.org/articles/pharmacovigilance-back-to-the-future-with-isop-2025/>

4- CIOMS Newsletter Issue No. 50 (Q2 2025)
https://cioms.ch/.../2025/07/CIOMS_Newsletter50-Q2-2025.pdf



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