

**General Assembly
4 October 2024**

Centre Mont-Royal Symposia Theatre
Montreal, Canada
13:30 – 15:30 (EDT)

Present: Angela Caro-Rojas (Society President), Brian Edwards (Vice-President), Mónica Tarapués (Secretary General), and Omar Aimer (Treasurer). Advisory Board members: Mayada Alkhakany, Ghita Benabdallah, Maribel Salas, Francesco Salvo, Manal Younus and Li Zhang.

Approximately 150 members of the Society and 45 Society members connected online.

Chairs: Society President Angela Caro-Rojas and Secretary General Mónica Tarapués.

Agenda

- 1. Welcome, introductions, housekeeping**
- 2. Approval of Agenda**
- 3. Approval of Minutes GA 2023**
- 4. Overview of the ISO P Strategic Plan Introduction**
 - 4.1 Goal 1 - Long-term financial and organisational sustainability and stability of ISO P
 - 4.1.1 Administrative Report
 - 4.1.2 Financial Report
 - 4.1.3 Membership Report
 - 4.2 Goal 2. Create and build a community for optimising the safer use of medicine
 - 4.2.1 Overview of ISO P activities 2024
 - 4.2.2 Communication Team Report
 - 4.2.3 Partnership and Alliances
 - 4.3. Goal 3- Maintain and enhance scientific knowledge and competencies in the global pharmacovigilance community
 - 4.3.1. Report from Chapters
 - 4.3.2. Report on SIGs
 - 4.3.3 Report on Communities: Students, Scientific Board, Fellows

- 4.3.4. Fellowship and Honorary Awards 2024
- 4.3.5. Pool of Speakers and Abstract Reviewers Proposal

5. Looking forward

- 5.1. First Certification of the Global PV Professional program (GPPC)
- 5.2. Planned events in 2025 and 2026
- 5.3. Advisory Board Elections

6. Q&A

1. Welcome

ISoP President Angela Caro-Rojas opened the General Assembly by warmly welcoming all members around the world. The ISoP General Assembly was held as a hybrid Zoom event, with online attendance free for all ISoP members. The meeting was streamed live from Montreal during the 23rd ISoP Annual Meeting.

2. Approval of Agenda

ISoP Secretary General Mónica Tarapués requested approval of the agenda, which was accepted by the General Assembly.

3. Approval of Minutes GA 2023

Mónica Tarapués requested approval of the 2023 General Assembly minutes, which were accepted by the General Assembly (the General Assembly minutes have been posted on the ISoP website: <https://isoponline.org/about-isop/general-assembly-reports/>).

4. Overview of the ISoP Strategic Plan

Short Introduction

The President gave an overview of ISoP, founded in 1992 as ESOP (European Society of Pharmacovigilance) and became ISoP (International Society of Pharmacovigilance) in 2000, a non-profit, independent organization, funded by membership fees. Angela Caro-Rojas explained ISoP's Mission. In 2025 ISoP will be recognized as the leading global champion for education and research in pharmacovigilance and the safe use of medical products and devices.

After introducing the Executive Committee and Advisory Board and the three communities (Honorary/Fellow members, Students group, and Scientific Board), the President outlined the following three main goals.

4.1 Goal 1- Long-term financial and organisational sustainability and stability of ISoP

To define ISoP Strategy, identify improvement opportunities and strategic alliances.

In order to reach goal 1, the following activities were presented at the general assembly

4.1.1 Administrative Report

ISoP Secretary General Monica Tarapués described that the Advisory Board (AB) members are actively collaborating within the Committees to achieve the objectives outlined in the 2023-2025 Strategic Plan. Internal ISoP processes are securely stored on the ISoP Shared Drive, and the administrative support team currently consists of Sophie Spence and Antoinette Ivins. It was also mentioned that the ISoP President, is conducting regular one-on-one meetings with AB members to enhance communication and collaboration. She outlined the internal functioning of the administration department, which includes defining the roles of Advisory Board members., The meeting also addressed the redesign of the ISoP Scientific Board Terms of Reference (ToR) and Project Procedure, ISoP Chapter Guidelines, and the ISoP Sponsorship Policy.

4.1.2 Financial Report

ISoP Treasurer Omar Aimer presented his treasury interim accounts report as of August 31, 2024, with various key financial developments. There has been an increase in website maintenance fees and payroll expenses, including costs for administrative support and communication leadership, amounting to an additional EUR 9,990. The successful Barcelona Mid-Year Symposium and Africa Chapter meeting welcomed new members, contributing to a profit. The Intelligent Automation Boston seminar also generated a profit from both in-person attendance and recordings. However, this year, there was a decrease in income from the AM2P project with EU2P.

Compared to September 30, 2023, revenue from membership fees and event profits has increased, despite higher expenses related to website amortization, payroll, and general operating costs as the current budget cycle concludes. The organization maintains good control over budgets and expenses considering rising operating costs and inflation, aligning with the Executive Committee's financial goals and strategies. The introduction of numerous webinars, including free options, along with travel support for the Executive Committee and Advisory Board, aims to enhance visibility and attract new members. The successful meetings in Bali, Boston, and Barcelona further illustrate this growth.

	2022	2023	2024
	In a world which has irreversibly changed	Increasing inflation and expenses despite an increase of income	Increasing expenses despite an increase of income
EUR	2021.10.01 2022.08.31	2022.10.01 2023.09.30	2023.10.01 2024.09.30
Current Asset	269'256	278'446	259'121
Liabilities	-11'056	-7'849	-19'325
Net Assets	262'457	242,419	237'630
Variation vs previous period	- 10'221 - 3.8%	-20'038 -7.6%	-4'789 -1.98%

4.1.3 ISoP Membership Report

The Secretary General Mónica Tarapués presented the current membership figures as of 1 September 2024, totalling 1281 members in 111 countries which represents a 42% increase for this year in membership (with 378 new members). 631 members (50.75%) come from High Income Countries and 650 (49.25%) Lower-Middle Income Countries. Mónica Tarapués also highlighted the 83 new memberships from our recent meeting in Kampala and from the Montreal Annual Meeting to be a total of about +150 new members (not yet listed in the ISoP database or accounts) and welcomed all these new members.

4.2 Goal 2- Create and build a community for optimising the safe use of medicine.

In order to reach goal 2, the following activities were presented at the general assembly

4.2.1 Overview of ISoP activities 2024

All ISoP Chapters and Special Interest Groups (SIGs) have remained actively engaged.

ISoP Academic Coordinator Ghita Benabdallah outlined the ISoP activities that occurred around the world during the year:

- ISoP Mid-Year Symposium 2024 Barcelona
- Africa Chapter meeting
- Patient Safety Day 2024
- 4 Chapter external meetings
- 2 Special Interest Groups Joined Webinars
- Medical Devices 2 webinars
- 2 Pharmacovigilance Journals Webinars
- Intelligent Automation in Pharmacovigilance Seminar 2024
- Training course webinar for Health Care Providers (HCPs) and Pharmacists

The ISoP Mid-Year Symposium for 2024 was successfully organized in collaboration with IDIAP Jordi Gol, attracting over 130 participants.

Other activities included the Pharmacovigilance Journal Club and the highly impactful Patient Safety Day 2024, which featured 7 sessions (Middle East, Africa, Europe, Western Pacific, Asia, North America and LATAM) with 15 speakers + 8 Chairpersons (Chapters leaders and guests). This event spanned 14 hours of transmission and garnered the participation of more than 1850 individuals registered through live streaming on YouTube (793 views) and Facebook (1405 views)

4.2.2 Communication Team Report

Under the leadership of the ISoP Secretary General Mónica Tarapués, the communications team is dedicated to enhancing the communication strategy.

Highlights:

- With a new ISoP Events account on LinkedIn, ISoP currently has a strong presence on several social media platforms, including LinkedIn with 7,853 followers, X with 3,530 followers, Facebook with 2,707 followers, and YouTube with 638 followers, totalling 15,662 followers (with 2,485 new followers in 2024).
- The ISoP brochure and newsletters have been rebranded, along with all forms of social media and digital communications.
- ISoP Website: a dynamic Member only section

Mónica Tarapués encouraged members to explore the ISoP website, brochures, and newsletters, which are sent to all members via Mailchimp.

4.2.3 Partnership and Alliances

As part of the strategic plan, ISoP is now in partnership with the following organisations:

- International Ergonomic Association (IEA)
- Council for International Organizations of Medical Sciences (CIOMS)
- World Health Organization (WHO) & Coalition of Interested Parties/CIP Network
- Institute for Safe Medication Practices (ISMP)
- Uppsala Monitoring Centre (UMC)
- European programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P)
- European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) Steering Group
- Rabat Collaborating Center
- International Medication Safety Network (IMSN)
- ARCS Australia Limited

4.3 Goal 3- Maintain and enhance scientific knowledge and competencies in the global pharmacovigilance community.

4.3.1 ISoP Chapters Report

All ISoP Chapters have been active during the year, and the Chapters Co-ordinator Francesco Salvo briefly provided a number of updates:

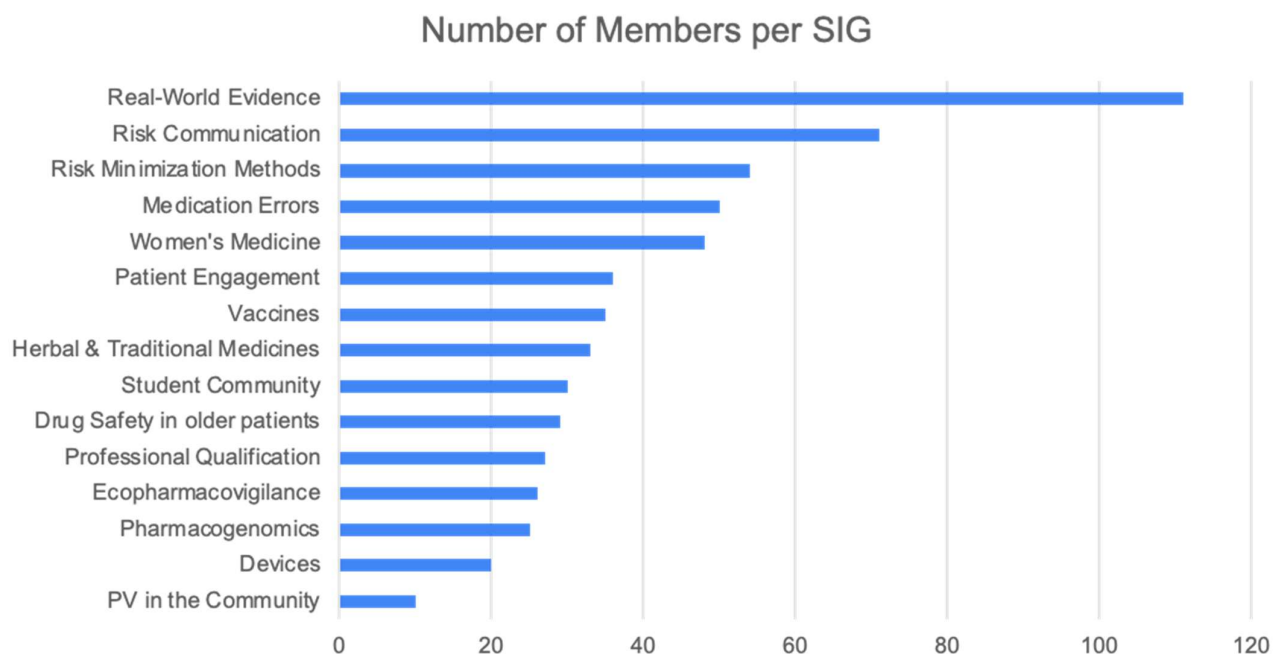
- ISoP Africa Elections results. ISoP Africa Chapter Elections with Comfort Ogar (President) Helen Byomire Ndagile (Vice-President) Jayesh Pandit (Treasurer) and George Sabblah (Secretary-General)
- Several Chapters held successful webinars throughout the year with good social media interaction. Highlighting the ISoP Africa Chapter Meeting in Kampala, Mid-Year Symposium in Barcelona, and Latam Chapter 1st Pharmacovigilance online course
- Collaboration of Chapters to mark Patient Safety Day in September
- Revision of the Chapter guidelines

The first chapter, created by GP Velo, was established 18 years ago in Italy. As ISoP has grown in recent years, Francesco Salvo explained the importance to reorganizing the chapters and subsequently to update the Chapter guidelines:

- A minimum of 50 members is required to establish a new chapter.
- Consider merging smaller chapters into larger regional ones to create a federated structure.
- Centralize financial management within ISoP.
- Conduct chapter elections every 3-4 years.

Additionally, future considerations include promoting the sharing of best practices across chapters and notifying ISoP about any promotional materials used for events. For revised guidelines, members are encouraged to visit the ISoP website at <https://isoponline.org/chapters/chapters-overview/>

4.3.2 ISoP SIGs Report



The SIGs Co-ordinator, Maribel Salas provided updates and contribution from the SIG's and welcomed the new SIG's Pharmacovigilance in the Community and Artificial Intelligence in Pharmacovigilance to the group.

During the timeframe from September 1, 2023, to August 31, 2024, there were a total of 15 Special Interest Groups (SIGs) involved in various activities (abstract submission, manuscripts, and webinars).

For further information about SIGs visit <https://isoponline.org/special-interest-groups/sigs-overview/>

4.3.3 Report on Communities

Student Community

Manal Younus, Chair of the Student Group, presented the Student Community, which was established in February 2023 with well-defined goals and a strategic plan. The group has specific objectives aimed at enhancing the student experience.

Internally, the Student Group is involved in various activities, including the ISoP Mid-Year Training, the ISoP Annual Meeting, and the ISoP Patient Safety Day (PSD). Additionally, student meet-and-greet events are organized during the annual meetings, such as the Meet &

Greet at ISoP 2023 in Bali and the Meet & Greet with the Fellows at ISoP 2024 in Montreal. Externally, the group participates in significant events like the IFMSA General Assembly and the IPSF Career Fair & Exhibition. For further information about the Student Community visit <https://isoponline.org/communities/student-group/>

Report from the ISoP Scientific Board

An overview on the ISoP Scientific Board was presented by Veronique Kugener, Chair of the Scientific Board.

The mission of the ISoP Scientific Board (SB), which was established in 2022, is to support ISoP's scientific, educational, and professional enhancement activities while providing expert consultation on pharmacovigilance matters internationally.

During the 2022-2023 period, the focus was on supporting ISoP in the Global Pharmacovigilance Professional Certification (GPPC), culminating in a Memorandum of Understanding (MoU) with the Institute of Pharmacovigilance (IPV) to form a partnership for the GPPC and launch a dedicated Task Force.

In 2024, efforts shifted towards revamping the Scientific Board's operating model, including revising the Terms of Reference (ToR), introducing new internal procedures, and redesigning membership to enhance resource utilisation and ensure active engagement within a smaller group.

The Scientific Board's scope included providing expert consultation to the ISoP Advisory Board while collaborating with SIGs and chapters to engage ISoP members across all regions.

For further information about the Scientific Board visit <https://isoponline.org/communities/scientific-board/>

Report from the Fellows

Presented by Vice-President Brian Edwards on behalf of Kenneth Hartigan-Go and Santiago Schiaffino, Honorary and Fellow members Coordinators, ISoP Fellowships recognize members who have been active for at least five consecutive years, demonstrated significant achievements in pharmacovigilance, and contributed meaningfully to ISoP's work. The purpose of the fellowship is to honour professional excellence and outstanding contributions to the ISoP community. Fellows serve as ambassadors to the broader pharmacovigilance community, gaining international exposure, leadership opportunities, and networking connections that support both their careers and the global pharmacovigilance community.

For further information about the Fellows visit <https://isoponline.org/communities/fellowship/>

4.3.4 Fellowship and Honorary Awards 2024

ISoP Fellows have made substantial contributions to the discipline of pharmacovigilance through their work (including publications or similar outputs) and have also shown services to the Society, for example, by involvement in ISoP meetings, and/or by leadership of ISoP Chapters and Special Interest Groups (SIG's).

Mónica Tarapués, Secretary General and Chair of the Fellowship Nominations Sub-Committee (FNSC), and Angela Caro-Rojas, ISoP President announced the 2024 cohort of ISoP Fellows.

They are (in alphabetic order):

- Omar Aimer, Innovigilance (Canada)
- Nitin Joshi, Drug Safety/Adis Journals (New Zealand)
- Katarina Kralova, Sanofi (France)
- Comfort Ogar, Pharmacopeia (USA)
- Patricia Zuluaga Arias, Pontificia Universidad Javeriana (Colombia)

Congratulations to all our new fellows!

The new fellows received their certificates from President Angela Caro-Rojas. Katarina Kralova was not able to attend the General Assembly in Montreal, and her certificate will be forwarded to her.

Honorary Membership Awards 2024

President Angela Caro-Rojas, on behalf of the Executive Committee, proposed to the General Assembly the nominations of Jeffrey K Aronson MA DPhil FRCP HonFBPhS HonFFPM (United Kingdom) and Michael R. Cohen RPh, MS, ScD (hon.), DPS (hon.) (USA) as honorary members. The Assembly unanimously approved the nominations.

Congratulations to both our new Honorary Members!

Jeffrey Aronson received his certificate from President Angela Caro-Rojas, while Michael Cohen joined the General Assembly via Zoom and will have his certificate mailed to him.

4.3.5. Pool of Speakers and Abstract Reviewers Proposal

Strategy and Innovation coordinator, Mayada Alkhakany presented the Pool of Speakers and Abstract Reviewers Proposal.

The primary goal of this proposal is to establish a diverse and dynamic pool of speakers and

abstract reviewers composed of ISoP members. Key phases for implementing the speaker pool and abstract reviewer program include defining general requirements for speakers and reviewers and establishing a selection procedure. This initiative will provide ISoP members with opportunities for professional development by sharing their expertise, while also fostering a sense of community and active participation within ISoP.

5. Looking forward

5.1 First Certification of the Global PV Professional Program (GPPC)

the [GPPC Pilot Launch](#), presented by Jan Petracek, chair of the Special Interest Group (SIG) on PV Professional Qualification Framework, is set for October 2024. This initiative aims to implement a certification program accessible for pharmacovigilance professionals across all regions. This initiative will test the WHO's pharmacovigilance guidelines to ensure consistency with global standards. A nominal fee will be charged to cover technology costs, keeping the program affordable for participants. The Special Interest Group (SIG) on PV Professional Qualification Framework will continuously generate and review test questions to ensure their relevance and accuracy, while the ISoP Scientific Committee Task Force will oversee the process, approving all test questions to ensure alignment with the project's goals.

For further information visit <https://isoponline.org/special-interest-groups/pv-professional-qualification-framework/>

5.2 Planned events

The President outlined the ISoP meetings planned for the year ahead (2024 - 2025) as follows:

- Continuation of ISoP webinars, chapters and SIG meetings
- Intelligent Automation Seminar in Boston (USA): December 2024
- Intelligent Automation Seminar in Basel (Switzerland): February 2025
- ISoP mid-year symposium in Uppsala (Sweden): May 2025
- World Patient Safety Day: September 2025
- ISoP annual meeting in Cairo, Egypt: November 2025

5.3 Advisory Board Elections 2025

The election of members to the new ISoP Advisory Board (AB) will take place in 2025, organized by the Past President, Mira Harrison-Woolrych. There will be ten vacancies to fill, with a call for nominations issued in May 2025. Voting will occur online, starting in September 2025, followed by the election of the President by the newly elected board later that month. The first meeting of the new Advisory Board is scheduled for November 3-6, 2025, during ISoP 2025 in Cairo.

Final Acknowledgments

President Angela Caro-Rojas expressed appreciation to the Executive Committee and Advisory Board members for their dedication and support. Special thanks were given to the NASoP Chapter and the ISoP 2024 Local Organizing Committee for their efforts. Additional recognition was provided to Omar Aimer and Maribel Salas for their significant contributions. President Caro-Rojas also thanked Sophie Spence and Antoinette Ivins from ISoP Administration, and all involved in ISoP for their support and contribution.

6. Q&A and AOB

Due to time constraints, there were no opportunity for questions from the audience, both in-person and virtual. However, everyone was encouraged to email any questions they may have to administration@isoponline.org for a response.

The meeting was subsequently concluded, and all members and other colleagues were warmly invited to the next ISoP Annual Meeting in Cairo, Egypt, 3-6 November 2025.

The meeting closed at 15:30 (EDT).

Date:

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Angela Caro-Rojas
President

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Mónica Tarapués MD. PhD
Secretary General