ISoP General Assembly
14/15 October 2020

Dr Mira Harrison-Woolrych
ISoP President

International Society of Pharmacovigilance
Welcome to our General Assembly!

- A very warm welcome to all our wonderful ISoP members!
- Thank you for participating in ISoP meetings & events worldwide this year.
- In this annual General Assembly, we will report back to ISoP members on the society’s work since November 2019.
- Thank you for all your input and support!
1. The GA will be chaired by Mira Harrison-Woolrych with Deirdre McCarthy as co-chair, especially in the event of a connection issue in New Zealand;

2. Jean-Christophe Delumeau and Sophie Spence will manage the videoconferencing technology;

3. Presentations will be given by EC & AB members as “panelists”;

4. Attendees, apart from panelists are welcome to ask questions and make comments via the Q&A functionality (not the chat functionality);

5. Questions and comments will be responded at the end of each topic within the limit of reasonable time frame;

6. If we haven’t been able to answer your questions according to your expectation please email them to Sophie Spence at: administration@isoponline.org, we will do our best to respond.
1.1. Introducing the ISoP Executive Committee

Mira Harrison-Woolrych
President - New Zealand

Rebecca Chandler
Vice-President - Sweden

Jean-Christophe Delumeau
Treasurer - Singapore

Deirdre McCarthy
Secretary General - USA
1.2. Introducing the ISoP Advisory Board

Zhang Li
China

Manal Younus
Iraq

Angela Caro-Roja
Colombia

Mónica Tarapués
Ecuador

Jan Petraček
Czech Republic

Gianluca Trifirò
Italy

Sten Olsson
Past-President
## 2.0 Approval of Agenda

<table>
<thead>
<tr>
<th>Section</th>
<th>Topic</th>
<th>Presenter</th>
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</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Welcome, introductions, housekeeping</td>
<td>by Mira Harrison-Woolrych</td>
</tr>
<tr>
<td>2.0</td>
<td>Approval of Agenda</td>
<td>by Mira Harrison-Woolrych</td>
</tr>
<tr>
<td>2.1</td>
<td>Approval of 2019 GA Minutes (Bogota)</td>
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<tr>
<td>3.0</td>
<td>ISoP Activities in 2020</td>
<td>by Mira Harrison-Woolrych</td>
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<tr>
<td>3.1</td>
<td>Moving to online/webinar concept</td>
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<td>3.2</td>
<td>Patient Safety Day events</td>
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<td>3.3</td>
<td>ISoP Infographic Project</td>
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<td>4.0</td>
<td>Communications Strategy</td>
<td>by Deirdre McCarthy</td>
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<td>5.0</td>
<td>Financial Report</td>
<td>by Jean-Christophe Delumeau</td>
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<td>6.0</td>
<td>Membership Report</td>
<td>by Deirdre McCarthy</td>
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<tr>
<td>7.0</td>
<td>Report from Chapters</td>
<td>by Rebecca Chandler</td>
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<tr>
<td>8.0</td>
<td>Report on SIGs</td>
<td>by Angela Caro</td>
</tr>
<tr>
<td>9.0</td>
<td>Report from CIOMS</td>
<td>by Manal Younus</td>
</tr>
<tr>
<td>10.0</td>
<td>Fellowship Awards</td>
<td>by Mira Harrison-Woolrych</td>
</tr>
<tr>
<td>11.0</td>
<td>Looking Forward – plans for next year</td>
<td>by Mira Harrison-Woolrych</td>
</tr>
</tbody>
</table>
2.1. Approval of 2019 GA Minutes (Bogota)

- Minutes have been posted on the ISoP website: 
  [https://isoponline.org/about-isop/general-assembly-reports/](https://isoponline.org/about-isop/general-assembly-reports/)

- Request for ISoP members’ approval of 2019 GA minutes

- Please message Sophie Spence (ISoP Secretary) if you do not approve the 2019 GA minutes.
3. ISoP Activities since April 2020

Mira Harrison-Woolrych
ISoP President

International Society of Pharmacovigilance
3.1. ISoP in the time of COVID

- ISoP was founded on the concept of face-to-face meetings.
- Annual and mid-year meetings every year since 1993!
- We remain committed to supporting our members and colleagues, especially in challenging times.
- In 2020 we have found new ways to keep ISoP proactive and interactive around the world.
- Pharmacovigilance never sleeps!
3.1 Move to online platforms and webinar concept

- ISoP has purchased 3 Zoom-Pro licenses – we may add 2 more licenses, if needed. Regular Zoom-Pro licenses may connect up to 100 participants.

- The Isoponline1 license has Webinar capability and may connect up to 500-1000 participants.

- Our Zoom platform allows reaching an unlimited audience via live streaming or post-event Facebook or YouTube broadcasting as well as Vimeo access.

- Each of the 3 accounts has a Virtual Events Manager and a preferred geographic scope. This allows any ISoP member to host ISoP meetings or record presentations from their region.

- Applications for using the Zoom platform requires joining the Isoponline135 WhatsApp group. Requests should be emailed to Sophie or Jean-Christophe.
3.1. Virtual ISoP meetings in 2020 (so far!)

- Pharmacovigilance Journal Club
- Africa Chapter meeting
- Israel Chapter Hot Summer of Drug Safety Webinars
- Egypt and Middle East Chapter webinars
- NASoP meetings
- Prague Pharmacovigilance meeting (hybrid)
- Western Pacific Chapter Meeting
- World Patient Safety Day events
  - Boston seminar/webinar (December)
3.2. World Patient Safety Day: 17 September 2020

- Founded by WHO in 2019 to recognise patient safety as a global health priority; increase public awareness and promote actions worldwide.

- ISoP events organised by Angela Caro and the Med Error SIG.

- Supported by ISoP using Zoom Pro, Facebook livestreaming and ISoP YouTube channel (https://www.youtube.com/channel/UCojtROXZbiDk_1GLxzThzQ/videos)

- 34 presentations in 4 different time zones.

- Offered to anyone interested as free events.
# AGENDA
## ISoP PATIENT SAFETY DAY 2020

### 16 SEPTEMBER

<table>
<thead>
<tr>
<th>UK Time</th>
<th>Speaker</th>
<th>Conference</th>
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<tbody>
<tr>
<td>11:00 am</td>
<td>Irene R. Ferman</td>
<td>Combining tools, methods, AI and IT to prevent medication errors: the ISoP hawk multidisciplinary strategy</td>
</tr>
<tr>
<td>12:00 pm</td>
<td>Gidi Stein</td>
<td>AI solution to prevent medication error: Results of the Harvard study</td>
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<tr>
<td>12:00 pm</td>
<td>Gil Millokovsky</td>
<td>Patient empowerment: how to get out of a hospital alive</td>
</tr>
<tr>
<td>12:00 pm</td>
<td>Gideon Koren</td>
<td>Treating the Mother, Protecting the Unborn and the Newborn</td>
</tr>
<tr>
<td>1:00 pm</td>
<td>Ghita Benabdallah</td>
<td>Detecting preventable drug related problems through AdIs in Pharmacovigilance: The use of a specific tool: the IP Method</td>
</tr>
<tr>
<td>2:00 pm</td>
<td>Sefiani Houda</td>
<td>Management of patient safety during Covid-19 disease</td>
</tr>
<tr>
<td>3:00 pm</td>
<td>Brian Edwards</td>
<td>World Patient Safety Day</td>
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<tr>
<td>4:00 pm</td>
<td>Sten Olsson</td>
<td>Patient involvement in the development and safe use of medicines: GOMS XI Project</td>
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<tr>
<td>5:00 pm</td>
<td>Alem Zekarias and Loubna Alj</td>
<td>The importance to report medication errors</td>
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<tr>
<td>6:00 pm</td>
<td>Mariano Madurga</td>
<td>El Farmacéutico y el Uso Seguro de los Medicamentos</td>
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<tr>
<td>7:00 pm</td>
<td>Shannon Brownlee</td>
<td>Medication overload: Why overprescribing is a patient safety issue</td>
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<td>8:00 pm</td>
<td>Alpina Mal</td>
<td>Addressing Polypharmacy targeting high risk medicines</td>
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<tr>
<td>9:00 pm</td>
<td>Helaine Carneiro Capucho</td>
<td>Segurança do Paciente e Valor em Saúde</td>
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<tr>
<td>10:00 pm</td>
<td>Aaron Padilla</td>
<td>Fundamentos de la Seguridad del Paciente y relación con la Farmacia hospitalaria</td>
</tr>
<tr>
<td>11:00 pm</td>
<td>Liliana Vargas Neri</td>
<td>Acciones para prevenir riesgos asociados con el uso de medicamentos</td>
</tr>
<tr>
<td>12:00 am</td>
<td>Monica Tarapues</td>
<td>Importancia de la farmacovigilancia y el reporte como estrategia para vigilar medicamentos recientemente comercializados</td>
</tr>
<tr>
<td>1:00 am</td>
<td>Angela Caro Rojas</td>
<td>Yo hablamos: Comunicación para la medicación segura</td>
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</table>

### 17 SEPTEMBER

<table>
<thead>
<tr>
<th>UK Time</th>
<th>Speaker</th>
<th>Conference</th>
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<tbody>
<tr>
<td>8:00 am</td>
<td>Thamir Alshammari</td>
<td>The third WHO Global Patient Safety Challenge: Medication without harm</td>
</tr>
<tr>
<td>9:00 am</td>
<td>Sameh Al-Zubedi</td>
<td>Drug safety in pediatrics: healthcare professional awareness and ADRs reporting</td>
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<tr>
<td>10:00 am</td>
<td>Libby Roughhead</td>
<td>Medicines Safety in Aged Care: Our role and our responsibility</td>
</tr>
<tr>
<td>11:00 am</td>
<td>Malal Younous</td>
<td>A New COVID-19 related medication error</td>
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<tr>
<td>12:00 pm</td>
<td>Long Chau Ming</td>
<td>Medication Errors in Hospitals</td>
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<tr>
<td>1:00 pm</td>
<td>Loubna Alj</td>
<td>Managing Medication Errors within Pharmacovigilance Centres: Moroccan experience</td>
</tr>
<tr>
<td>2:00 pm</td>
<td>Michael Cohen</td>
<td>Medication safety</td>
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<tr>
<td>3:00 pm</td>
<td>Albert Wu</td>
<td>Supporting Health Care Workers During the COVID-19 Pandemic</td>
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<tr>
<td>4:00 pm</td>
<td>Helen Haskell</td>
<td>Unsafe use of medications: What happens to the patient?</td>
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<tr>
<td>5:00 pm</td>
<td>Gun-Ying Yue</td>
<td>Pharmacogenomics in Pharmacovigilance</td>
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<tr>
<td>6:00 pm</td>
<td>Jan Petricek</td>
<td>Clever medication process design with built-in risk management</td>
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<tr>
<td>7:00 pm</td>
<td>Elza Nikoleishvili</td>
<td>Drug safety (pharmacovigilance) involvement in Academy</td>
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<tr>
<td>8:00 pm</td>
<td>Helaine Capucho</td>
<td>Como un medicamento puede causar daño</td>
</tr>
<tr>
<td>9:00 pm</td>
<td>Carlos Aceves</td>
<td>Aplicación de la Ergonomía para la seguridad del paciente</td>
</tr>
<tr>
<td>10:00 pm</td>
<td>Mariano Jiménez Mendez</td>
<td>Medicación sin daños</td>
</tr>
<tr>
<td>11:00 pm</td>
<td>Patricia Zuluaga Arias</td>
<td>Farmacogenética en términos sencillos: ¿Qué debemos enseñar a los pacientes?</td>
</tr>
<tr>
<td>12:00 am</td>
<td>Todos</td>
<td>Conversatorio con los Speakers</td>
</tr>
</tbody>
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More Info
isoponline.org

@ISoPOnline
3.2. World Patient Safety Day
3.2. Summary of ISoP WPSD Activities

- 1677 people registered (172 ISoP members, 1505 non-members)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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<tbody>
<tr>
<td>Academic</td>
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<tr>
<td>Healthcare</td>
<td>760</td>
</tr>
<tr>
<td>Industry</td>
<td>380</td>
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<tr>
<td>Not stated</td>
<td>261</td>
</tr>
<tr>
<td><strong>Total registered</strong></td>
<td><strong>1677</strong></td>
</tr>
</tbody>
</table>

- Approximately 3000 views in first 9 hours
- Approximately 5000 views in total
- Huge opportunity to invite new applications for ISoP membership
- Next year – WPSD 2021 – key day for ISoP - bigger and better!
Thanks to the Med Error SIG and their fantastic team!

- Angela Caro, Brian Edwards and the Med Error SIG
- Melissa Bernal: Coordinator of European region and co-host of whole event
- Daniel Castellanos: Technological support
- Constanza Moreno Fernández: Coordinator of Africa region
- Andrea Gonzalez: Coordinator of Latam region
- Patricia Zuluaga: Coordinator of Asia region

*ISoP will gift ISoP memberships (1 year, excluding access to Drug Safety) to the above volunteers, as a mark of our gratitude for their help with this important event.*

*ISoP will also offer ISoP membership to speakers not already ISoP members.*
3.3. World Pharmacist Day 2020

- Friday 25th September 2020
- Aim is to recognise the role of pharmacists worldwide
- ISoP drafted a statement in support of pharmacists
- Statement posted on ISoP website and on social media
- Article in NZ Pharmacy Today magazine
- Plans to build on this next year with an international article
- Many thanks to Prof Jo Barnes, Head of Western Pacific Chapter, for suggesting ISoP supports this day each year.
3.4. ISoP Infographic Project

- Infographics team: Mira Harrison-Woolrych, Deirdre McCarthy, Priya Bahri, Angela Caro, Gabriela Durán and Sophie Spence.

- Thanks to Risk Comms SIG for their input (via Priya Bahri)

- Aims of group:

1. Develop easily understandable information about medicines utilization and key safety issues (e.g. for prevention of medication error).

2. Design infographics for patients, prescribers and other health professionals, in all regions of the world.

3. Translate infographics into different languages for international use.

4. Work with Comms team to promote ISoP infographics worldwide.
Using medicines safely during the COVID-19 pandemic

Get your medicines from trusted sources

Products from non-trusted places and internet sellers could be fake and severely endanger your health. Stick to licensed pharmacies or other trusted sources.

Act on side effects to medicines

If you experience an unwanted effect, seek medical help and mention your medicine. Your country may offer online reporting of side effects. Please state if you have had COVID-19.

Stay safe and healthy

Continue to take your usual medicines as prescribed and if you have any concerns contact your healthcare provider.

Beware of wrong information

Fake news about possible treatments for COVID-19 has spread in many countries. Check the reliability of information with trusted sources, for example, national health agencies, or the WHO*.

*World Health Organization

© ISoP - May 2020 - Please acknowledge source when disseminating further
3.4. ISoP COVID-19 infographic in use by ISoP members

ISoP distributing information around the world

3.4. ISoP COVID-19 infographic in use by ISoP members

ISoP Infographic Project

Annual General Assembly 2020
3. ISoP Activities in 2020

Any questions or comments?
4. ISoP Communications Strategy

Deirdre McCarthy
ISoP Secretary General and Comms Leader

International Society of Pharmacovigilance
4.1. Communications Strategy: Key Team Achievements

- Employment of a Social Media Manager (Gabriela Durán) & establishment of a dedicated ISoP COMMS team.

- Infographic on safe use of medicines in COVID-19 disseminated widely including to key global organisations. Six primary and several non-primary languages available online.

- Strong social media presence: Twitter & LinkedIn, with Facebook and Instagram added in 2020.

- Strong framework for promotion of Patient Safety Day.

- Membership email newsletter launched – 2 editions – positive feedback.

- Membership benefit poster published.

- Logo and ISoP slide template refresh.
4.1. Social Media

**TOTAL FOLLOWERS**

- **Facebook**: 1,335
- **Twitter**: 2,271
- **Instagram**: 245
- **LinkedIn**: 436
- **YouTube Subscribers**: 119

**TOTAL INTERACTIONS**

- **Likes, Comments, Shares**: 14,265

**TOTAL REACH**

- **People reached**: 108,604

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This number includes the followers and subscribers on all of ISoP’s social media.

The interactions include likes, comments and shares made on all the publications of ISoP.

Reach includes the number of people that have seen the content of ISoP’s social media.
4.2. Drug Safety Journal Articles

2020 Publications

- **Feb** - A New President’s Vision for International Pharmacovigilance
- **April** - ISoP Fellowships: Recognising Contributions to the Goals of ISoP
- **June** - The Role of Pharmacovigilance and ISoP During the Global COVID-19 Pandemic
- **July** - The International Society of Pharmacovigilance (ISoP) SIG on Herbal and Traditional Medicines: Towards Progress in Pharmacovigilance for Herbal and Traditional Medicines and Other “Natural Health” Products
- **November** – The work of the International Council for International Organizations of Medical Sciences (CIOMS) in Global Pharmacovigilance.

January 2021 onwards – potential articles:

ISoP activities in China; NASoP activities; Risk Comm SIG article
Communications Strategy Summary

- Social Media Manager adding substantial value to ISoP visibility worldwide.
- In September 2020, ISoP EC and AB approved a 6-month extension to Social Media Manager’s contract.
- Good COMMS outputs, including infographic and DS articles.
- Aim to continue to leverage international visibility post WPSD and build on FB & IG presence.

Thanks to Sophie, Gaby, Angela and Monica!
5. Financial Report

Jean-Christophe Delumeau
ISoP Treasurer
Driving ISoP’s financial risk throughout COVID-19 pandemic

**Overall goal:** Sustain ISoP’s assets until capable of organising profitable events again

- Envisage new sources of revenue in the so-called New Normal context.
- Use the Zoom platform extensively to in a way which can generate income,
  - Restart organising chargeable events using the Zoom platform (Training in Prague),
  - Get used to the platform with non-chargeable events (Africa Chapter, Patient Safety Day),
  - Set-up a flexible open Zoom Webinar platform capable of supporting such events,
  - Design a new operating model based upon so-called Virtual or Hybrid Events,
  - Observe closely how other event organisers are adapting to the new context,
  - Post-pone planned events early enough to avoid cancellation fees or low attendance losses
  - Monitor closely the evolution of the pandemic and its impact anticipating further impact,
  - Recognise early the risk of an impactful pandemic,
Past 12-month Income analysis compared to previous years

- Pre-Covid: 4 months, Post-Covid: 8 months
- Income from the Bogota meeting not yet received as of 2020.09.30
- Flat income from the ISoP-UMC training in Guangzhou
- Mid-year training income and membership refill was missed
- Boston meeting provided profit as usual

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<tr>
<td>EUR</td>
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<td>68'390</td>
<td>Regular: 93'900</td>
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<td>Discount: 22'548</td>
<td>Discount: 34'574</td>
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<td>ISoP Events</td>
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<td>24'016</td>
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<td>136'535</td>
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<td></td>
<td></td>
<td>+26% vs 2017</td>
<td>- 23% vs 2019</td>
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<td>-3.8% vs 2017</td>
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Income decreased Income increased Income increased Income decreased
### Past 12-month Expenses analysis compared to previous years

#### 2016.10.01 – 2020.09.30 period

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<tbody>
<tr>
<td>Payroll expenses</td>
<td>44’444</td>
<td>42’298</td>
<td>46’357</td>
<td>50’938</td>
<td>51’282</td>
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<td>Travel expenses &amp; Promotion fund</td>
<td>2’540</td>
<td>2’413</td>
<td>2’232</td>
<td>2’404</td>
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<tr>
<td>Subscription Drug Safety (Adis)</td>
<td>18’306</td>
<td>15’996</td>
<td>20’162</td>
<td>29’799</td>
<td>30’956</td>
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<tr>
<td>ISoP secretariat expenses &amp; running cost</td>
<td>1’872</td>
<td>2’977</td>
<td>2’280</td>
<td>2’820</td>
<td>2’410</td>
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<tr>
<td>Legal &amp; professional fees</td>
<td>13’007</td>
<td>12’183</td>
<td>14’085</td>
<td>7’289</td>
<td>8’667</td>
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<tr>
<td>General &amp; administration expenses</td>
<td>12’746</td>
<td>11’996</td>
<td>8’014</td>
<td>9’142</td>
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<td>Depreciation</td>
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<td>VAT expenses</td>
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<td>2’377</td>
<td>2’838</td>
<td>3’790</td>
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<tr>
<td>Bank charges, Financial costs Loss/benefits on currency exchange</td>
<td>15’952</td>
<td>5’342</td>
<td>3’810</td>
<td>2’442</td>
<td>3’126</td>
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<tr>
<td><strong>Total expenses</strong></td>
<td><strong>117’778</strong></td>
<td><strong>102’115</strong></td>
<td><strong>103’635</strong></td>
<td><strong>110’442</strong></td>
<td><strong>118’583</strong></td>
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+6.7% +7.3%
## Income, Expenses and Taxes | 2019.09.30 vs previous periods

- No loss of assets despite 9 months of Covid crisis
- Assets increased by EUR.15'636
- However not sustainable beyond this year

Resuming profitable activities mainly consisting in organising virtual events using the ISoP Zoom platform is a necessity to avoid a loss of assets next year.

### Income, Expenses and Taxes

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<tbody>
<tr>
<td>Total income</td>
<td>+ 99’105</td>
<td>+ 96’100</td>
<td>+140’464</td>
<td>+177’539</td>
<td>+136’535</td>
</tr>
<tr>
<td>Total expenses</td>
<td>-117’778</td>
<td>-102’115</td>
<td>-103’636</td>
<td>-110’442</td>
<td>-118’583</td>
</tr>
<tr>
<td>Profit before taxes</td>
<td>-18’673</td>
<td>-6’015</td>
<td>+36’828</td>
<td>+67’097</td>
<td>+17’952</td>
</tr>
<tr>
<td>Taxes</td>
<td>-512</td>
<td>-242</td>
<td>-589</td>
<td>-898</td>
<td>-2’316</td>
</tr>
<tr>
<td>Balance after tax</td>
<td>-19’185</td>
<td>-6’257</td>
<td>+36’239</td>
<td>+66’199</td>
<td>+15’636</td>
</tr>
</tbody>
</table>
Total Assets | 2020.09.30 vs previous periods

- No loss of assets despite 9 months of Covid crisis
- Assets increased by EUR.15'636
- However not sustainable beyond this year

➢ Resuming profitable activities mainly consisting in organising virtual events using the ISoP Zoom platform is a necessity to avoid a loss of assets next year.

<table>
<thead>
<tr>
<th>EUR</th>
<th>2015.10.01 2016.09.30</th>
<th>2016.10.01 2017.09.30</th>
<th>2017.10.01 2018.09.30</th>
<th>2018.10.01 2019.09.30</th>
<th>2019.10.01 2209.09.30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Asset</td>
<td>148’298</td>
<td>153’160</td>
<td>200’056</td>
<td>+256’187</td>
<td>+273’461</td>
</tr>
<tr>
<td>Liabilities</td>
<td>+4’449</td>
<td>- 6’670</td>
<td>-17’327</td>
<td>-7’259</td>
<td>-8’897</td>
</tr>
<tr>
<td>Net Assets</td>
<td>152’747</td>
<td>146’490</td>
<td>182‘729</td>
<td>+248’928</td>
<td>+264’564</td>
</tr>
<tr>
<td>Asset variation vs</td>
<td>- 19’185</td>
<td>- 6’257</td>
<td>+36’239</td>
<td>+66’199</td>
<td>+15’636</td>
</tr>
<tr>
<td>previous period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ISoP Membership | Update versus previous years

Compared to 2020.09.30, ISoP membership decreased from 826 to 792 (-32) essentially due to the lack of new membership from the postponed Moscow meeting initially scheduled in April 2020, otherwise membership would likely have continued on the increasing curve.

<table>
<thead>
<tr>
<th>EUR</th>
<th>As of 2015.09.30</th>
<th>As of 2016.09.30</th>
<th>As of 2017.09.30</th>
<th>As of 2018.09.30</th>
<th>As of 2019.09.30</th>
<th>As of 2019.09.30</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIC (EUR.215)</td>
<td>293</td>
<td>328</td>
<td>264</td>
<td>415</td>
<td>401</td>
<td>315</td>
</tr>
<tr>
<td>LMIC (EUR.95)</td>
<td>79</td>
<td>116</td>
<td>194</td>
<td>218</td>
<td>388</td>
<td>455</td>
</tr>
<tr>
<td>LMIC Groups [EUR.70]</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Free (e.g. Speakers, EC)</td>
<td>18</td>
<td>14</td>
<td>15</td>
<td>22</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>Total N members</td>
<td>390</td>
<td>458</td>
<td>473</td>
<td>661</td>
<td>826</td>
<td>792</td>
</tr>
<tr>
<td>Paid to Adis annually</td>
<td>14’920</td>
<td>17’760</td>
<td>16’000</td>
<td>25’717</td>
<td>29’276</td>
<td>30’956</td>
</tr>
</tbody>
</table>
ISoP Membership Fees | regular fees unchanged in 2021

- Full rate: EUR.215 (including EUR.40 to Adis) applicable to:
  - High Income Countries (HIC) according to World Bank (WB)
- Reduced rate: EUR.95 (including EUR.40 to Adis) applicable to:
  - Medium and Low Income Counties (MIC and LIC)
  - Retired
- Drug Safety fee unchanged (EUR.40)

- Membership fees stable since 2013 will remain unchanged in 2021
- Additional membership options will be proposed
- Approved by the GA?
### Institutional Membership Program | non-HIC only | already in place for 3 years

<table>
<thead>
<tr>
<th>Individual non-HIC standard</th>
<th>Package For 5 subscribers from the same institution</th>
<th>Per additional subscriber from the same institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUR.95</td>
<td>EUR.350</td>
<td>EUR.70</td>
</tr>
<tr>
<td>ISoP: Eur.55</td>
<td>ISoP: Eur.30x30=Eur.150</td>
<td>ISoP: Eur.30</td>
</tr>
<tr>
<td>Eur.95/member/year</td>
<td>Eur.70/member/year</td>
<td>Eur.70/member/year</td>
</tr>
</tbody>
</table>

### Chapter Membership Program | non-HIC only | NEW

1. Eligibility criteria:
   - Resident of a LIC or MIC according to World Bank categories
   - Joining a chapter where a quorum of members have already paid EUR.95
2. Membership fee
   - EUR.55 *(EUR.95 previously)*
3. Access to DS
   - Not included.
4. Quorum required
   - Varying from 10 to 50 members depending upon the size of the population covered by the Chapter and strength of the local currency

### Global Students Membership program | any country | NEW

1. Eligibility criteria:
   - Being a student in a health care whatever the Chapter or Country
2. Membership fee
   - EUR.75
3. Access to DS
   - Included.
The International Society of Pharmacovigilance
2020 General Assembly On-line

Thank you for your attention

Jean-Christophe Delumeau
Board & EC member (2016-2022)
Treasurer of ISoP, Singapore

Sophie Spence
ISoP Administration
London, UK

Committed to safer use
of medicines worldwide
6. Membership Report

Deirdre McCarthy
Secretary General

International Society of Pharmacovigilance
Total membership is growing year-on-year
Membership summary 2020 – since October 2019
ISoP Membership Update vs categories

Who are the 792 members as of 2020.09.30?

- **253** Renewals
- **77** Renewals from previous Annual meetings
- **21** Renewals from previous trainings since 2013
- **8** Renewals from Nairobi Symposium & Training (vs 95 attendees)
Total renewal: 359

- **241** Joined at the Bogota 2019 annual meeting
- **48** Joined at the Guangzhou ISoP-UMC training
- **19** Joined at the Boston 2019 Seminar
Total joined at the occasion of an event: 308

- **103** Joined not at occasion of a meeting (115 last year)
- **11** Board members
- **11** Honorary members

**Membership Report**

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Americas</td>
<td>43.0 %</td>
</tr>
<tr>
<td>Europe</td>
<td>26.0 %</td>
</tr>
<tr>
<td>Asia</td>
<td>14.5 %</td>
</tr>
<tr>
<td>Africa</td>
<td>7.0 %</td>
</tr>
<tr>
<td>Middle East</td>
<td>7.0 %</td>
</tr>
<tr>
<td>Oceania</td>
<td>2.5 %</td>
</tr>
</tbody>
</table>
Membership report 2020 – since October 2019

Renewals and new applications

<table>
<thead>
<tr>
<th>Month</th>
<th>Oct-Dec 19</th>
<th>Jan-20</th>
<th>Feb-20</th>
<th>Mar-20</th>
<th>Apr-20</th>
<th>May-20</th>
<th>Jun-20</th>
<th>Jul-20</th>
<th>Aug-20</th>
<th>Sep-20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>44</td>
<td>136</td>
<td>109</td>
<td>34</td>
<td>22</td>
<td>26</td>
<td>37</td>
<td>24</td>
<td>18</td>
<td>16</td>
</tr>
</tbody>
</table>
7. Report from Chapters

Rebecca Chandler
ISoP Chapters Coordinator

International Society of Pharmacovigilance
Summary of ISoP Chapters & current membership numbers

<table>
<thead>
<tr>
<th>Date of creation</th>
<th>Chapter</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>Italy</td>
<td>14</td>
</tr>
<tr>
<td>2007</td>
<td>Western Pacific region</td>
<td>55</td>
</tr>
<tr>
<td>2008</td>
<td>Mexico</td>
<td>34</td>
</tr>
<tr>
<td>2009</td>
<td>Switzerland</td>
<td>17</td>
</tr>
<tr>
<td>2009</td>
<td>LATAM</td>
<td>229</td>
</tr>
<tr>
<td>2010</td>
<td>Africa</td>
<td>58</td>
</tr>
<tr>
<td>2012</td>
<td>South Eastern Europe</td>
<td>12</td>
</tr>
<tr>
<td>2013</td>
<td>North America/NASoP</td>
<td>85</td>
</tr>
<tr>
<td>2014</td>
<td>Israel</td>
<td>2</td>
</tr>
<tr>
<td>2015</td>
<td>Middle East</td>
<td>28</td>
</tr>
<tr>
<td>2016</td>
<td>China</td>
<td>46</td>
</tr>
<tr>
<td>2017</td>
<td>Indonesia</td>
<td>10</td>
</tr>
<tr>
<td>2020</td>
<td>* Egypt - Official launch GA 2020</td>
<td>17</td>
</tr>
</tbody>
</table>

* South Asia Chapter is currently dormant
ISoP Chapters: Activity in 2020

- **Africa** – Kick off Chapter meeting (September 2020) & publication in Drug Safety
- **Egypt** – Multiple webinars on the theme of PV during the pandemic
- **Israel** – “Hot Summer in Drug Safety” series
- **Middle East** – Webinar “Business continuity of pharmacovigilance in COVID-19 era” and Medication Error Safety Program
- **North America (NASoP)** – Am2P, Executive Committee election, COVID-19 panel organized jointly by NASoP, ISoP Italy and ISoP Israel Chapters to cover “The Impact of COVID-19 Pandemic on Pharmacovigilance, Drug-development and Healthcare practices” (to be held virtually in December at the NASoP Annual meeting)
ISoP Chapters: Activity in 2020

- **Western Pacific** - Chapter meeting by Zoom in September: topics included medicines utilization & safety issues during the COVID-19 pandemic

- **Switzerland** – Website creation, spring symposium in planning stages

- **China** – ISoP infographic translation to Chinese, creation of official chapter WeChat account as tool to share information from ISoP webpage; joint ISoP-UMC training planned for early 2021

- **Latin America** - publication and review on hydroxychloroquine in COVID-19, LATAM chapter Facebook page; interaction/networking with other ISoP chapters

- **Italy** – active Facebook page and collaborating with North American chapter for joint covid-19 webinar in December
Posibles terapias para COVID-19: revisión narrativa de seguridad I. Cloroquina/hidroxicloroquina y azitromicina

Raquel Herrera Comoglioa (0000-0002-2810-1749)

Facultad de Ciencias Médicas, Universidad Nacional de Córdoba, Argentina.

Autor para correspondencia: Raquel Herrera Comoglio, Facultad de Ciencias Médicas, Universidad Nacional de Córdoba, Pabellón Perú, Ciudad Universitaria, Blvd. de la Reforma s/n, X5000 Córdoba, Argentina. Números telefónicos: (+54) 9 351 650 1331; e-mail: rherrera@fcm.unc.edu.ar; raquelherrera.comoglio@gmail.com
ISoP Chapters: Activity in 2020

The challenging times and opportunities for pharmacovigilance in Africa during the COVID-19 pandemic

C. Ope\textsuperscript{1}, W. Mathenge\textsuperscript{2}, C. Khamzina\textsuperscript{3}, H. Haldorset\textsuperscript{4}

Published online: 30 May 2020
© Springer Nature Switzerland AG 2020

Introduction
It is now > 4 months since the COVID-19 outbreak started with the first suspected cases reported in China. At the start of the pandemic, Africa seemed “safe” and isolated in its watched by many high-income countries across the world grapple with the devastating effects of the coronavirus. Sadly, this “safe” state only lasted until February when Egypt reported the first case of COVID-19 in Africa\textsuperscript{1}. The viral infection has since spread to 40 of the 55 countries in the World Health Organization (WHO) African region, with 223,746 confirmed cases and 8910 deaths as at 29 April 2020\textsuperscript{2}. With the declaration of the situation as a global pandemic, everything from the global economy, financial markets, and manufacturing industries to tourism, travel, and hospitality industries and even the educational sector have come to a grinding halt worldwide.

This commentary seeks to highlight the challenges for pharmacovigilance (PV) posed by the COVID-19 pandemic and how PV practitioners in Africa can use this opportunity to strengthen patient safety.

Suggested remedies lack clinical evidence ...

World leaders, out of a sense of desperation to bring an end to the pandemic, with its catastrophic negative economic consequences, have made premature proclamations on a possible vaccine or other strategies such as chloroquine or a combination of hydroxychloroquine + azithromycin\textsuperscript{3}. While publications from the global scientific community indicate that there is insufficient evidence to support widespread use of the medicines for treatment of COVID-19\textsuperscript{4–7}, social media, as expected, has further spread such claims. Remedies claimed to treat or prevent COVID-19 by boosting the immune system include vitamin, natural herbs, alternative medicines, and other methods, and range from the sublime to the ridiculous (e.g., from using a mixture of some “super foods” such as lemon, ginger, garlic, black tea, turmeric, or anything that contains vitamin C and D to the use of moon lights, hair dryers, steam inhalation, and exposing patients to the sun).

... and are potentially dangerous

Unverified and unqualified claims for some remedies can have dire consequences, particularly in Sub-Saharan Africa where literacy levels are still relatively low (60\% in 2018)\textsuperscript{8}, and where beliefs that anything herbal is safe and minor of government institutions and science-based evidence are widespread. Furthermore, in an environment where there is low international access to all classes of medicines without professional guidance and emotional use of medicines is high and enforcement of medicine use regulations is low, there is a glaring need for extreme caution and for (PV) practitioners to highlight the dangers of these unverified claims.

Based on reports of individuals self-medication with chloroquine and causing themselves serious harm\textsuperscript{9}, the WHO cautions against physicians and medical associations recommending or administering, or patients self-administering, unproven treatments for COVID-19 until there is sufficient evidence.

Meanwhile, the WHO and its partners have launched a Solidarity Clinical Trial for COVID-19 Treatments\textsuperscript{10}. This international randomized controlled trial (RCT) aims to evaluate the relative effectiveness of four COVID-19
Previously the ISoP Mexico and LATAM Chapters have operated separately.

In late 2019, ISoP members from several LATAM countries proposed formation of a united and inclusive LATAM Chapter.

Consultation undertaken with Chapter Heads in 2020, EC produced a report recommending the formation of a single LATAM Chapter. Decision supported and approved by ISoP Advisory Board

All ISoP LATAM members informed in October 2020

General elections for LATAM chapter leadership to be held in first quarter of 2021
ISoP Chapters: New Developments

- New life to the dormant South Asia Chapter
- Proposal to start a Central Asian Chapter from Kazakhstan
New ISoP Chapter: Official Launch

- Egypt Chapter, headed by Hadir Rostom

Welcome!

Webinars

Since its creation, the Chapter has conducted several successful webinars:

- **Effective Pharmacovigilance outsourcing: Pharmaceutical company perspective**
  2nd of September 2020
  ISoP Egypt Chapter posted on LinkedIn

- **Lessons learned from COVID-19 in pharmacovigilance practice**
  19th of August 2020
  ISoP Egypt Chapter posted on LinkedIn

- **Effect of COVID pandemic on pharmacovigilance: updates & expectations**
  9th of June 2020
  ISoP Egypt Chapter posted on Facebook

- **Pharmacovigilance Measures Update During & post-COVID 19**
  1st of June 2020
  ISoP Egypt Chapter posted on LinkedIn

Current coordinating group:

Chapter President: Hadir Rostom

Chapter Vice-President: Moataz Elwarwary

Chapter Committee:
- Marianne Mounir
- Ahmed Bassar
- Gehan Hefny
- Rania Aly
- Lana Osman
- Yomna Tarek
8. Report from SIGs

Angela Caro-Roja
ISoP Board member

International Society of Pharmacovigilance
Special Interest Group (SIG) updates from 2020

Established SIGs are working as usual in their topics

- **Herbal and Traditional Medicines** SIG published article in Drug Safety: Towards Progress in Pharmacovigilance for Herbal and Traditional Medicines and Other “Natural Health” Products

- **Medication Errors** Group leaded the Patient Safety Day event

- **CommSIG** contributed to the development of the ISoP infographic regarding COVID-19 and has an article summarising the learnings of the first five years of the ISoP CommSIG under preparation

- **PV Professional Qualification Framework** Group developed a proposal for PV development

- **Women’s Medicines SIG** continues to communicate by email and provides expert comment on key papers and proposals

- We have a new SIG!!! **Pharmacogenomics**
ISoP Pharmacogenomics SIG: key objectives

- To be led by Qun-Ying Yue (senior PV expert at UMC)
- To create opportunities for those researching and investigating pharmacogenomics to network
- To exchange experiences and provide support to healthcare professionals and/or organizations
- To organise and/or support training and tutorials for pharmacovigilance centres to increase understanding while focusing on aspects of pharmacovigilance.
- To organise (when possible) a session at the ISoP annual meeting each year on the topic of pharmacogenomics in pharmacovigilance.
- To advise the ISoP Executive Committee, where required, on issues relating to pharmacogenomics in pharmacovigilance.
9. Report from CIOMS

Manal Younus
ISoP Board Member
ISoP CIOMS representative
Aim: The guidance will provide a comprehensive overview of present knowledge and existing initiatives and will address a wide range of the remaining challenges and practice gaps.

Participants: patient organizations, industry, regulators, academia and the World Medical Association.

ISoP has been invited to join this WG and ISoP is represented by Sten Olsson, Brian Edwards and Manal Younus though out the project.
The work was initially divided into several groups and the early discussions decided to present the guidelines in ten different chapters and a glossary.

ISoP representatives have actively contributed to the draft text of several chapters.

Attending and participating in the discussions of the F2F and virtual meetings.

The work is now at an advanced stage with the help of an editorial team and implementation strategy team.

For more details: https://cioms.ch/working-groups/working-group-xi-patient-involvement/
CIOMS WG XI on Patient Involvement
More details around the chapters ISoP taking part in

- Chapter 1: Introduction
- Chapter 2: The landscape of patient engagement in the development and safe use of medicines.
- Chapter 3: Guiding principles for patient engagement.
- Chapter 4: Patient involvement in advancing treatments for their disease.
- Chapter 5: Guiding principles for patient involvement in patient product labelling.
- Chapter 6: Opportunities for patient involvement in additional risk minimisation.
- Chapter 7: Guiding principles for patient engagement in the development and use of safety and effectiveness data.
- Chapter 8: Patient involvement in developing time-bound safety communications regarding medicinal products.
- Chapter 9: Challenges and opportunities for patient involvement in resource-limited settings (RLS).
10. ISoP Fellowship Awards 2020

Mira Harrison-Woolrych
ISoP President
Fellowship Nominations Sub-Committee 2020

- Chaired by Deirdre McCarthy, ISoP Secretary General
- Other FNSC members: Sten Olsson and Brian Edwards
- 14 applications received by 31 May 2020
- All applications assessed against ISoP Fellowship eligibility criteria
## Congratulations to the 2020 ISoP Fellows!

<table>
<thead>
<tr>
<th></th>
<th>Title</th>
<th>First Name</th>
<th>Surname</th>
<th>Organisation</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dr</td>
<td>Joanne</td>
<td>Barnes</td>
<td>School of Pharmacy</td>
<td>New Zealand</td>
</tr>
<tr>
<td>2</td>
<td>Dr</td>
<td>Jean-Christophe</td>
<td>Delumeau</td>
<td>Bayer / ISoP</td>
<td>Singapore</td>
</tr>
<tr>
<td>3</td>
<td>Dr</td>
<td>Brian</td>
<td>Edwards</td>
<td>NDA Regulatory Science Ltd.</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>4</td>
<td>Prof Dr</td>
<td>Joerg</td>
<td>Hasford</td>
<td>IBE</td>
<td>Germany</td>
</tr>
<tr>
<td>5</td>
<td>Dr</td>
<td>Véronique</td>
<td>Kugener</td>
<td>Takeda Pharmaceuticals International</td>
<td>USA</td>
</tr>
<tr>
<td>6</td>
<td>Mr</td>
<td>Sten</td>
<td>Olsson</td>
<td>ISoP</td>
<td>Sweden</td>
</tr>
<tr>
<td>7</td>
<td>Dr</td>
<td>Jan</td>
<td>Petracek</td>
<td>ISoP, Independent consultant</td>
<td>Czech Republic</td>
</tr>
<tr>
<td>8</td>
<td>Dr</td>
<td>Victoria</td>
<td>Rollason</td>
<td>Hôpitaux Universitaires de Genève</td>
<td>Switzerland</td>
</tr>
<tr>
<td>9</td>
<td>Dr</td>
<td>Santiago</td>
<td>Schiaffino</td>
<td>Boehringer Ingelheim</td>
<td>Argentina</td>
</tr>
<tr>
<td>10</td>
<td>Dr</td>
<td>Saad</td>
<td>Shakir</td>
<td>Drug Safety Research Unit</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>11</td>
<td>Dr</td>
<td>Marco</td>
<td>Tuccori</td>
<td>University of Pisa</td>
<td>Italy</td>
</tr>
<tr>
<td>12</td>
<td>Prof</td>
<td>Li</td>
<td>Zhang</td>
<td>Dongfang Hospital /ISoP</td>
<td>China</td>
</tr>
</tbody>
</table>
11. Looking Forward

Mira Harrison-Woolrych
ISoP President

International Society of Pharmacovigilance
ISoP meetings to October 2021

- Boston Seminar December 2020 (virtual)
- More chapter meetings expected in 2021
- Mid-year meeting in Moscow April 2021
- World Patient Safety Day September 2021
- ISoP annual meeting in Oman October 2021

- PLEASE NOTE: we need to find a venue for ISoP 2022!
Other ISoP activities for 2021

- Retaining and growing ISoP membership (invite a colleague to join!)
- Inviting FISoP applications (apply in May!) and developing FISoP roles
- Supporting chapter and regional meetings worldwide
- Continuation of infographics project in collaboration with SIGs
- International article for World Pharmacist Day in September 2021
- Continuing input to other stakeholder projects, e.g. ENCePP, CIOMS
- Collaborating with other international centres; e.g. UMC, DSRU
- Continuing to communicate key messages from ISoP worldwide
Jean-Christophe Delumeau suggested ISoP create a Scientific Board (in addition to the existing AB) to provide training and education resources.

Jan Petraček suggested ISoP should create a globally-recognised Pharmacovigilance Professional Development Certification system.

Mira Harrison-Woolrych suggested maintaining ISoP’s focus on patient safety; the science of Pharmacovigilance and the needs of ISoP members worldwide, while retaining democratic, accountable, affordable and transparent processes.

Rebecca Chandler suggested there is an opportunity for ISoP to become the “Medicines Safety Science Organisation” (less bureaucratic/industry exercise, more evidence generation for issues relevant to clinicians and academics).

Other AB members commented on the importance of both academic and professional development for members in ISoP’s regional chapters and the need for any future projects to be relevant to people in all countries.
Overview of Future Purposes and Missions of ISoP

**ISoP Member benefits**

1. Provide high-quality educational events and resources.
2. Offer a Professional Development scheme for ISoP members.
3. Networking, education & support via Chapters and SIGs.
4. Other benefits e.g. access to Drug Safety.

**Wider influence and international roles**

1. Develop tools to directly help protect patients from harm caused by medicines.
2. Provide expert advice to non-ISoP members including clinicians, patients/carers.
3. Provide evidence-based statements on key issues: Act as the voice of our specialty
4. Work with other international bodies concerned with patient safety
Next Steps

- Establish a Scoping Group from Advisory Board members
- Co-chaired by Jean-Christophe Delumeau and Jan Petraček
- 3 other AB members: Mónica Tarapués, Manal Younus and Li Zhang
- Supported and coordinated by Sophie Spence, ISoP Secretary
- To report directly to Mira Harrison-Woolrych, ISoP President
- Scoping Group will consider all issues raised in AB discussions, including administrative requirements and issues relating to ISoP statutes/bylaws.
- To prepare a paper for consideration by the EC and AB in early 2021
- Conclusions will be reported at the ISoP GA in October 2021
Thank you for your attention