AGENDA
ADVISORY BOARD MEETING
Wednesday 25 January 2023, 13.00 UTC (duration: 75 mins)

Board meeting 25 January	Bogota, Quito Boston, Montreal	London UTC/GMT	Bordeaux Rabat	Bagdad	Dubai	Beijing
	UTC-5	UTC+0	UTC+1	UTC+3	UTC+4	UTC+8
Start	08:00	13:00	14:00	16:00	17:00	21.00

1. Welcome from the President to the Board members

2. Approval of the agenda and last AB minutes (30 Nov 2022)

3. Review of the Strategic plan for AB 2022-2025
   3.1. Long-term financial and organizational sustainability and stability of ISoP (Goal 1)

   Follow-up:
   a) *ISoP Budget*
      Finances: Budget and guidelines about chapters/SIG activities (Omar, Ghita, Francesco and Maribel)
   b) *Administrative Committee: members survey and membership payment process for applicant (Mayada)*

   3.2. Create and build a community for optimising the safer use of medicines (Goal 2)
   a) Updates and Chapters-SIGs activities road map (Ghita)

   3.3 Maintain and enhance scientific knowledge and competencies in the global ISoP pharmacovigilance community (Goal 3)
   a) Strategic plan for the student group (Manal)
   b) Criteria for Annual Meeting bids: Scientifically attractive place, important for developing PV activities in the area, with a positive financial balance
   c) Real-World Evidence and Big Data Special Interest Group (RWE SIG) approval and SIGs guidelines updates (process for the SIGs review/approval by the EC/AB)
   d) Scientific Board updates
   e) Honorary members and Fellowship group

4. AoB

   Timeslot for EC (every two months) and AB meetings (every two months) (each third Monday of the month) and closing remarks

MINUTES- ISoP Advisory Board meeting

Wednesday, 25 January 2023, 13.00 UTC

Present: Angela Caro Rojas (Chair), Brian Edwards, Mónica Tarapués, Omar Aimer, Mayada Alkhakany, Ghita Benabdallah, Manal Younus, and Li Zhang.
Apologies: Mira Harrison-Woolrych and Francesco Salvo
Not present: Maribel Salas
In attendance: S Spence (ISoP Secretariat Ltd)

1. Welcome from the President to the Board members

President Angela Caro Rojas welcomed the Executive Committee (EC) and Advisory Board (AB 'the Board') members to the meeting.

2. Approval of the agenda and last AB meeting minutes

All Board members approved the proposed agenda.

The minutes of the last meeting of the Advisory Board held on 30 November were approved as a correct record.

Action:	
Sophie Spence to post the AB approved minutes on the website	End of January

3. Review of the Strategic plan for AB 2022-2025

3.1 Long-term financial and organizational sustainability and stability of ISoP (Goal 1)

a) ISoP budget - Finances: Budget and guidelines about chapters/SIG activities

Omar reported that he met Angela to discuss the global budget, including the membership fees and meeting incomes. He will prepare a draft of the 2023 budget projection for EC consideration.

Omar also met Ghita, Francesco, and Maribel to define the financial part of the SIGs/Chapters and academic events. They discussed how to encourage the SIG and chapter leaders to engage more and organize events with registration fees. The income generated from these events will be managed centrally by ISoP and redistributed among chapters or SIGs.
In this regard, on 21st February, Ghita, Francesco, Maribel, and Omar will meet the SIG/Chapter leaders to explain the new ISoP strategy. Angela may attend this meeting.

Mayada informed the AB that she has just organized an event with the Middle East (ME) chapter and the Patient engagement SIG, managed by a third party, and there would be a deficit. She explained the reason for the deficit due to fees between members and non-members and the absence of a budget. Mayada then asked if ISoP would cover this deficit eventually.

While Omar regretted the situation, he explained that there was no information regarding this chapter's meeting where ISoP was not engaged since the beginning.

On a separate issue, he also confirmed that the ISoP 2021 Oman profit was available for the ME chapter.
From experience with previous meetings and ISoP 2021 Oman, Mayada recommended preparing a clear process with chapters or SIGs if the event would result in a financial deficit; for instance, will the burden of this deficit be equally divided? As the strategic coordinator, Mayada would also like to be involved in the financial discussions for the SIGs and chapters. She suggested organising a meeting to discuss this issue and how better engage the SIGs and Chapters to generate income and increase membership.

Angela acknowledged Mayada's views and agreed to have a robust and transparent financial structure for the future, reminding that chapters and SIGs should not pay any deficit with their own money or receive any ISoP money into their personal account.

Outlining the importance of having specific standards for the chapters and SIGs ('the way to work'), Angela has asked Omar to define the financial guidelines and invited Ghita to coordinate the scientific agenda for each event/activity.

b) Administrative Committee: members survey) and membership payment process for applicant

Mayada confirmed that the member survey was finalized and all AB had the chance to test the questionnaire.

Mayada, Monica, and Sophie met last week to discuss the online membership application and how to simplify the application and payment process for new applicants.

Mayada highlighted the following points:

- Remove the vetting step currently undertaken by the Secretary, allowing the applicant to join ISoP and pay the fees at the same time.
- Reinforce the application procedure with the ISoP criteria resulting automatically in the membership payment by simplifying the fields in the application form and guiding the applicants using the drop lists and completing the payment directly.

This new procedure will be incorporated into the new website, which will go live at the end of April 2023. Sophie will check with Dan, our webmaster if there is any additional cost for this new procedure.

Mayada also mentioned the job description for an ISoP assistant, prepared by Sophie and Mayada. Sophie will post the job advert on LinkedIn with Gaby's help after receiving Omar's financial approval.

Angela appreciated Sophie, Monica and Mayada's work and welcomed the member survey and the new procedure to ease the application and payment process with stronger algorithms. As suggested by the EC, the AB agreed to remove the reviewing period (vetting step).

Angela extended thanks to the Administrative Committee for its efforts in implementing a better administrative organization.

Action:	Responsible	Deadline
To release the survey for ISoP members	Sophie and Monica	Next EC meeting 20 Feb

3.2 Create and build a community for optimising the safer use of medicines (Goal 2)

a) Updates and Chapters-SIGs activities and roadmap

Sophie confirmed that Ghita, Francesco, and Maribel would organize a meeting with all the Chapters and SIGs leaders to explain the new ISoP strategy and action plan. The meeting is planned for 21st February, and Omar will participate in presenting the financial aspects of the strategy.

Angela also noted that Maribel, as SIG Coordinator, sent a short survey to the SIGs to organize ISoP SIGs meetings. The idea is to increase collaboration and plan ISoP scientific activities across SIGs.

Brian informed the AB of new developments as follows:

- ISoP officially joined the ECAMET alliance (no legal documentation required). The ISoP logo will be appearing on the ECAMET website (https://ecamet.eu/), and Brian is in liaison with ECAMET regarding the medicine errors SIG.
- Brian was also introduced to the European Healthcare Management Association (https://ehma.org/) of those who manage different healthcare systems. The association is interested in the digitalization of healthcare; it could be a good opportunity for the new Real-World Evidence and Big Data Special Interest Group (RWE SIG) to meet this association as PV needs to be represented in discussions around digitalization.
- The Healthcare Safety Investigation branch (HSIB) (https://www.hsib.org.uk/) - to improve patient safety through professional safety investigations in the UK, focusing on medication errors- has developed courses, and Brian will introduce HSIB to Ghita to develop these courses internationally and introduce the topic for ISoP training.

Angela thanked Brian for the updates and invited the AB members to suggest ideas for potential collaboration between ISoP and other scientific organisations.

Actions:	Responsible	Deadline
To liaise with Maribel and the Real-World Evidence and Big Data Special Interest Group (RWE SIG) for possible collaboration with the European Healthcare data management Association	Brian	Next AB meeting 20 March
To introduce the Healthcare safety investigation branch (HSIB) to Ghita for possible collaboration in developing training courses	Brian	Next AB meeting

3.3 Create and build a community for optimising the safer use of medicines (Goal 2)

a) Updates and Chapters-SIGs activities road map

Ghita informed the AB that she confirmed her support to the South Asia Chapter to conduct a day on-site PV Workshop at Jamia Hamdard University in New Delhi in February; this event is free and will give visibility to ISoP in a university setting.

Brian added that Moin Don (South Asia Chapter leader), as one of the chairpersons of the forthcoming DIA India PV Conference held in Mumbai in May 2023, would like to invite a speaker from ISoP. It was agreed to receive more details regarding this request before any decision from the treasurer.

Action:	Responsible	Deadline
To liaise with Moin Don regarding a possible ISoP involvement in the DIA India summit next May	Sophie, Ghita, and Brian	End of January

3.4 Maintain and enhance scientific knowledge and competencies in the global ISoP pharmacovigilance community (Goal 3)

a) Strategic plan for the student group

The student group proposal was previously approved, and the AB is overall supportive of the strategic plan and agreed to move forward with the proposal.

Manal presented the next steps to establish an ISoP student groups committee that would work on the strategic plan for 2023-2025 and recommended having a meeting with the strategic group involving Mayada, Ghita, Francesco, and Maribel.

As we need to define guidelines for this new group, Manal questioned the specificity of the group (as a special SIG?), the possible need for financial support such as free membership for students, and the eligibility for all students to be part of the group or for only a specific category.

The AB discussed these issues, and Brian suggested having a third category called 'Communities' which could cover the FISoP fellows, students, and honorary members. He encouraged Manal to put ideas (including bursaries) on a proposal for EC's consideration.

Omar also recommended engaging students in all SIGs and Chapters to interact, write articles, etc., and Monica suggested organising fellows mentoring in the student group and offering scholarships if budget permitted.

Angela pointed out the creation of a new initiative led by Kenneth Hartigan Go, an ISoP honorary member, regarding the involvement of the ISoP fellows and honorary members, which could collaborate with the student group (see Point 3) e) below).

Angela thanked Manal for her efforts and was very pleased with the progress of this important group for the renewal of the Society. She invited Manal to proceed and draft well-documented guidelines for this specific group.

Actions:	Responsible	Deadline
To draft guidelines for the student group, and Sophie to liaise with Manal to post information about this new group on the website	Manal	Next AB meeting 20 March
To liaise with Manal to create new webpage and post information about this new group on the website	Sophie	Next AB meeting 20 March

b) Criteria for Annual Meeting bids: Scientifically attractive place, important for developing PV activities in the area, with a positive financial balance

Applications to host the ISoP Annual Meeting are welcomed from any regional pharmacovigilance centre, university, association, or ISoP Chapter, worldwide. Angela explained that the decision on the venue (location and date) for a conference is usually made two years before the date in question.

Criteria for Annual meeting bid selection could be sent to the chapter leaders as well as ISoP contacts, allowing receiving within the timeline more proposals to host the next ISoP conference.

Angela asked Monica and Sophie to check the current SOPs for annual meetings, including the Bid information, update the guidelines, and create a checklist for the chapters with clear timelines, MedTech registration for sponsorship, involvement of the SIGs and SB, etc.

Brian and Sophie reviewed the MedTech code, and Brian pointed out the importance to emphasize scientific and educational needs when registering for MedTech (https://www.ethicalmedtech.eu/) to get funding from the pharmaceutical industry. While facilities and transportation links are important, the venue should not be too touristic. Brian recommended making this point clear in the criteria for bids.

Omar informed the AB that Montreal could be a suitable venue for 2024, and he was currently liaising with the convention centre and universities in Montreal for a possible collaboration. Nicole Baker is keen to explore a training or an annual meeting in Dublin (Ireland). Manal informed the AB that the Egypt chapter could also be interested to host an annual conference.

It was agreed during the last EC meeting to scrap the unwritten rule of having an annual meeting every two years in Europe and to assess each bid on its own merit.

Actions	**Responsible**	**Deadline**
To prepare checklists with criteria selection inviting chapters for annual meeting and training bids	Sophie	EC meeting 20 February
To update the guidelines and SOPs for meetings	Monica and Sophie	AB meeting 20 March

c) Real-World Evidence and Big Data Special Interest Group (RWE SIG) approval and SIGs guidelines updates (process for the SIGs review/approval by the EC/AB)

The AB discussed the Real-World Evidence and Big Data Special Interest Group (RWE SIG) proposal, which was approved.
While the new SIG can start the process, Brian will follow up with Gianluca and Maribel to to prepare an action plan for EC's approval.

SIGs guidelines updates (process for the SIGs review/approval by the EC/AB):
Item not discussed due to Maribel's absence.

Actions:	**Responsible**	**Deadline**
To inform Maribel about the RWE SIG approval by the AB and information on the website	Sophie	1st week of February
To follow up with Maribel and Gianluca to shape the SIG action plan	Brian	Next AB meeting 20 March

d) Scientific Board updates

There have been recent correspondence and meetings related to the progress of the Global Pharmacovigilance Professional Certification (GPPC) program between the Scientific Board (SB) chairs, the GPPC chair, Angela, Brian, Monica, and the Institute of Pharmacovigilance (IPV).

One of the meeting outcomes was the creation of an explanatory document defining transparent processes and clear roles of the SB, IPV, the ISoP Special Interest Group on Pharmacovigilance Professional Qualification Framework and setting timelines.

Angela was happy with these positive discussions and outcomes from the two meetings previously organised with all the parties. She asked Omar to look at the Memorandum of Understanding (MoU) between ISoP and IPV, signed last year.
Sophie informed the AB about a meeting on 31st January for the follow-up on the status of the GPPC project and the latest update on the relationship between ISoP, the Scientific Board (SB), and the Institute of Pharmacovigilance (IPV).

e) Honorary members and Fellowship group

Further to the Verona meeting where a Fellows breakfast was organised last September, Angela informed the AB that she asked Kenneth Hartigan Go to write a concept note for the strategic engagement of ISoP Fellows and honorary members to actively pursue the development of ISoP. Kenneth, who will coordinate this new group, has made some suggestions for EC's consideration.

This group could work together to assist/mentor ISoP student members and junior colleagues (work with new student group via Manal) and Angela invited the AB to send their comments or ideas.

Action:	**Responsible**	**Deadline**
To upload Kenneth Hartigan Go's proposal on the SharePoint Drive for AB to comment by 20 February	Sophie	Next EC meeting 20 February

4. AoB

a) EC and AB meetings 2023

At Angela and Monica's request, Sophie presented a proposal summarizing all EC and AB meetings for 2023 (during each third Monday of the month).
Save the dates! timeslots for EC and AB meetings (every two months) were agreed upon as follows:

2023	EC meeting | Date & Time	Duration	AB meeting | Date & Time
January	20 Jan 12.00 UTC with Linda/Lareb & Ghita for Leiden	1.30	25 Jan 13.00 UTC
February	20 Feb 19.00 UTC with Mira & Ghita for Bali	1.00	
March	N/A	1.30	20 March 12.00 UTC
April	17 April 12.00 UTC	1.00	N/A
May	N/A	1.30	22 May 12.00 UTC
June	19 June 12.00 UTC	1.00	N/A
July	N/A	1.30	24 July 19.00 UTC with Mira
August	21 August 12.00 UTC	1.00	N/A
September	N/A	1.30	18 September 12.00 UTC
October	23 October 12.00 UTC	1.00	N/A

November	N/A	1.30 1.30	7 November in Bali (after sessions) 8 November GA
December	11 December 12.00 UTC	1.00	

b) Meeting updates

Ghita gave an update on the following meetings organised by ISoP:

- ISoP mid-year symposium Leiden

The next ISoP mid-year symposium will be held in Leiden (Netherlands) from 1 to 2 June 2023 in collaboration with Lareb. The meeting venue is the Rijksmuseum Boerhaave.
Ghita and Francesco are part of the scientific committee (SC) with Linda Harmark, Eugene van Puijenbroek (Lareb), Rebecca Chandler, and Sophie is involved in the organisation.

The latest programme is available on the SharePoint at ISoP Advisory Board 2022-2025_Documents.

- Advanced course (Theme: Pharmacovigilance: where science meets clinical practice)
- Eight sessions of 1h30 (2 x 25(+5) minutes followed by 30 minutes plenary/panel discussion)
- European speakers with Dutch predominance
- Introduction of oral abstracts presentations (Flash presentations)
- European Chapter meeting after the sessions

The AB is invited to advertise the course among colleagues and on their social networks.

Action:	**Responsible**	**Deadline**
To promote the ISoP Mid-Year Symposium	AB	

- ISoP 2023 Bali (6-9 November 2023) www.isop2023bali.org

The programme is very interesting with experts in different fields and the involvement of the SIGs and Chapters.

- Four pre-conference courses on 6 November (half-day courses)
- Four plenary sessions: 1) Protecting patients from harm 2) Patient Engagement 3) Risk Communication 4) Improving PV in LMICs. Details of the proposed speakers are in the latest version of the programme.
- In collaboration with the SIGs, there will be eight parallel sessions: all sessions are being organised and chaired by a member of the Scientific Committee with a SIG representative.
- Chapters feedback session, chaired by Angela and the Chapters coordinator.
- There will be a meet-and-greet social for students on Tuesday 7th November at 18.00 (outside the scientific programme).

Ghita will send suggestions to Mira regarding the plenary session “Improving pharmacovigilance in low- & middle-income countries”, and the vaccine session.

Angela asked AB members to use the SharePoint drive organised via folders (for reviewing, sharing, and uploading documents) and reminded everyone to read all documents before each AB meeting, in particular the Strategic Plan, where monthly actions/tasks are highlighted in red.

She welcomed comments and suggestions from the AB on this new way to work.

All EC/AB documents are posted on SharePoint at ISoP Advisory Board 2022-2025_Documents.

Next AB meeting
The next AB meeting is scheduled on 20 March 2023 at 12.00 UTC.

The meeting closed at 14.15 UTC.

Date:

Signature …………………….   ………………………….

Angela Caro Rojas
President

Mónica Tarapués
Secretary General