



International Society of Pharmacovigilance

Guidelines for ISO P Communities

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1. What is an ISoP Community?

A Community is a group of ISoP members, approved by the ISoP Executive Committee (EC) and Advisory Board (AB), united by shared interests and needs, working collaboratively to advance pharmacovigilance and further the objectives of ISoP (Article 3 section ix ISoP By-laws). Communities are not confined by geographical boundaries and are global. Upon mandate and approval from the EC, and in line with the strategic plan, communities can collaborate on global ISoP activities with experts, other groups, associations, or societies outside of ISoP. After discussion within the AB, and with the written agreement of the EC, a community could start formal communication with external organisations to explore collaboration and share knowledge that could be useful for ISoP.

Communities must agree in writing to abide with ISoP bylaws and the constitution.

2. How Can Communities Impact ISoP's mission?

ISoP Communities are expected to support and contribute to the Society's strategic plan. Communities should channel their energies intentionally toward execution of the strategic plan's priorities so that community activity reinforces Society-level goals. This can be achieved in multiple ways including:

- 2.1 Promoting Collaboration and Networking:** Communities facilitate networking among members with shared interests, fostering collaboration that can lead to innovative solutions and partnerships. This collective effort strengthens ISoP's Community including the ISoP Scientific Board (SB) and enhances its ability to address complex challenges in drug safety.
- 2.2 Advancing Research and Knowledge:** Communities focus on a variety of operational topics within pharmacovigilance and drug safety that may interest members and may encourage them to conduct targeted operational research and share findings that contribute to the broader understanding of these fields. This research should be consistent with ISoP's strategic plan, and every reasonable effort made not to conflict with SIG activities.
- 2.3 Developing Standards and Guidelines:** By bringing together experts in particular areas, Communities can input into developing scientific standards and guidelines under the direction and in consultation with the AB and SB.
- 2.4 Developing Education and Training:** Communities can identify gaps and unmet needs in the education and training of ISoP members in a Community. They can propose to the AB and the academic coordinator workshops, seminars, and training courses that disseminate knowledge and skills related to their specific interests in line with ISoP's strategic plan.
- 2.5 Contributing to Policy Development:** Communities can suggest and contribute to position papers, statements, and recommendations that influence policy and regulatory frameworks related to pharmacovigilance and drug safety. Consultation with the SB is advisable where appropriate. However, such proposals require EC approval. By providing expert insights Communities help shape discussions that align with ISoP's mission to promote safe and optimal medication and device use.
- 2.6 Engaging External Experts:** Communities can attract external experts who may not be ISoP members but possess valuable knowledge and experience required to contribute and advance certain topics. Where relevant and possible, these experts should be invited to join ISoP.
- 2.7 Increasing Visibility and Outreach:** Through presentations at conferences, publications, and participation in external events, Communities can raise awareness about ISoP and its objectives. This visibility can attract new members and stakeholders, furthering ISoP's mission. As regards social media strategy, Communities should liaise with the ISoP secretariat who can inform the EC who in turn can arrange for the social media consultant to be involved where appropriate.

3. Advantages of Joining a Community

Membership of a Community offers numerous benefits, including the opportunity to discuss research ideas, contributions to publications, development and promotion of scientific standards, integration into a professional Community and expansion of one's network.

ISoP Communities provide members the opportunity to actively participate in the development of documents, opinions and statements which may become official and public ISoP documents. The proposal and the production of **such documents must receive approval from the EC prior to their development and prior to their release or publication.**

Communities could also propose specific support programs, such as conferences, symposia, training courses, or workshops. Communities may also have an opportunity to present their activities at the Global Meetings, Symposiums or other ISoP events, with prior approval of the meeting's scientific committee (see below).

Communities should be sufficiently structured to take care of meetings minutes and communication with community coordinator, academic coordinator and EC from their own.

4. Establishing a Community and Duration of Term

A Community can be initially created to discuss and work on a specific and relevant topic which is within the scope and aims of ISoP. The EC must formally approve communities. The duration of a Community is not limited.

During the regular reviews of Community activities by the EC, the continuation of a Community's work will be assessed and confirmed, or, if justified and legitimate, it may be terminated by the EC.

Once approved, and after agreement with the Communities coordinator, the ISoP Secretariat may support the proposed Community efforts to recruit more ISoP members through the dissemination of an invitation to all ISoP members.

Community members are encouraged to collaborate in recruiting sufficient members to ensure the viability of Communities. A starting target for recruitment would be to aim to recruit 20% of the members that theoretically belong to that community.

All Communities must provide at least one annual reports to the ISoP Community Coordinator, who will integrate the information and submit to the EC. The Community coordinator may request other reports.

5. New Community Approval

The EC is responsible for the official approval of new Communities, while the AB can review and provide its opinion to the EC.

ISoP members who are proposing the Community should:

- Justify the need for the new Community
- Demonstrable experience in pharmacovigilance
- Demonstrate determination, diligence and competence on the specific topic and the discipline of pharmacovigilance through scientific publications, presentations, or other scientific, regulatory or teaching activity.
- Be willing to adhere to the ISoP strategic plan, policies and procedures.
- Fulfils the requirements enlisted in the next section

5.1 Requirements

- At least five ISoP members are needed to initiate discussion of a new Community. However, the EC reserves the right to set the minimum number required to establish a Community based on the needs of ISoP and its members.
- The proposed Community should have clearly defined objectives, deliverables, and timelines, and provide a summary in its application to the EC. This submission may be organised and supported by the ISoP Communities Coordinator (see description below).
- The new Community must be organized to fulfil its objectives and extend its activities, such as meetings and training courses under the supervision of the AB Community coordinator.
- The pre-approval set up of a Community should take place only once there has been agreement from the EC and AB and timelines will be set for a full proposal. Formal launch of the community requires full approval from the EC and AB.

5.2 Approval Process for a New Community

- ISoP Members who share the same background or work profile not covered by existing Communities should prepare a written proposal and a PowerPoint presentation.
- The proposal for a Community should be sent to the ISoP Community Chair, who will review and work with the new Community to fulfil the requirements and send to the ISoP Secretariat who will distribute to the AB and EC.
- The AB members will review, and they will send their comments to the EC. The EC can or not consider the AB comments. Only the EC is responsible for the approval of a new Community.
- Once the proposed Community is approved, the new Community Coordinator will receive the official approval letter from the President of ISoP or delegate.
- After the approval, the new ISoP Community will be able to announce itself to members, but it may not, unless specifically authorized by the EC, speak on behalf of ISoP.
- The formation of a specific Community will be officially launched during the General Assembly (GA) (Figure 1).

6. Community Structure and Process

Members of the proposed Community will designate the Community leaders, which include the Community Chair, Co-Chair, and Secretary (Other position can be designated depending on the needs of each Community). Their decision will be incorporated into the proposal submitted to the EC. Community Leaders will serve a term of three years, after which a transparent voting process will be conducted, as instructed by the AB and if required, ISoP secretariat. All Community members with an active membership in ISoP will be allowed to vote. The Community leaders will be eligible to participate as candidates in the election for another 3-years term only.

Community leaders will not be allowed to lead more than one Community, Special Interest Group or Chapter simultaneously. All elected Community leaders must be members in good standing of the Society. If a member of the Community leadership group resigns, is excluded, expelled, or leaves for any other reason, their position will be filled by another member of the Community until the next election. The newly chosen individual will serve until the normal term of the person they are replacing, ensuring that the regular replacement schedule is maintained. This “partial tenure” will not count toward the re-election limits.

The Chair, Co-Chair and Secretary will ensure that all members of the specific Community adhere to the ISoP Code of Conduct and Bylaws.

7. ISO P Executive Committee (EC) and Advisory Board

The ISO P EC will appoint an AB Member to act as the ISO P Community Coordinator whose role will be to mentor, monitor, support and encourage activities of each Community.

The EC is responsible for ensuring that Communities adhere to acceptable principles of Code of Conduct as defined in the Bylaws. The EC reserves the right to withdraw recognition from Communities and to revoke permission for the Community to use the ISO P name.

The EC is the official approver of a Community.

8. ISO P Community Coordinator

According to Article 9.4 of the By-Laws, a Communities Coordinator is appointed by the ISO P AB, for a three-year cycle, renewable once.

Key responsibilities of this role include:

- Exploring areas that may benefit from the establishment of a Community.
- Supporting Community creation proposals submitted by ISO P members.
- Submitting evaluated creation proposals for a Community to the ISO P AB.
- Assisting the establishment of new communities approved by the EC until they are formally launched and fully operational.
- Overseeing Communities and providing feedback following periodic updates to the EC.
- Encouraging Communities to write articles for the Society's Official Journal "*Drug Safety*."
- Ensuring there is an election of a Chair, Co-Chair, and Secretary of a Community.
- Providing ongoing support and guidance to Communities during their establishment and operation.
- Ensuring regular communication with Communities through scheduled meetings (e.g., quarterly, or biannually), reporting back to the EC.
- Providing verbal or written updates as necessary at AB or EC meetings.
- Delivering a written update at mid-year training if unable to attend in person.
- Collaborating with the ISO P Secretariat to update Community information on the website and ISO P Communication team for information on social media.

Chair

Key responsibilities of the Community Chair:

- Ensuring that ISO P objectives are met during their tenure within the Community.
- Provide leadership and establish an annual plan for the Community based on the ISO P strategic plan.
- Organise regular Community meetings and ensure effective communication among members.
- Foster a collaborative environment by encouraging member participation and input in decision-making processes.
- Identify and engage potential speakers or experts for Community events and activities.
- Propose, monitor, and evaluate the progress of Community activities and initiatives, adjusting as necessary to meet objectives.
- Represent the Community at ISO P meetings and events, advocating for the group's interests and needs.
- Collaborate with other Communities, SIGs and Chapter to identify opportunities for joint initiatives or projects.

- Ensure the Community adhere to ISoP Code of Conduct and By Laws.
- Provide mid-year and annual reports to the ISoP Community Coordinator.

Co-Chair

In agreement with the ISoP Community Coordinator, and approval from the EC, a Community can have a maximum of two co-Chairs.

Key responsibilities of the Community Co-Chair:

- Assume the Chair's responsibilities in case of Chair resignation.
- Assist the Chair in developing and implementing the strategic plan for the Community.
- Take the lead in specific projects or initiatives as assigned by the Chair.
- Support the organization of Community events, including webinars, workshops, or conferences.
- Help maintain a positive and productive environment within the Community by resolving conflicts or addressing member concerns.

Secretary

Key responsibilities of the Community Secretary:

- Maintain an up to date the Community membership roster and ensure all Community members receive relevant information and updates.
- Organize and coordinate Community events, including scheduling meetings and managing logistics.
- Assist in the preparation of reports and documentation for ISoP meetings and activities.
- Ensure that all Community communications are clear, timely, and accessible to all members.
- Track action items and follow up on outstanding tasks from meetings to ensure accountability.
- Facilitate onboarding for new Community members, providing them with essential information about the group and its activities.
- Collaborating with the ISoP Secretariat to update Community information on the website and ISoP Communication team for information on social media

9. Oversight of Communities and regular review by ISoP EC

The ISoP Community Coordinator will periodically review Communities activities to ensure that their quality and integrity remain high and will inform the EC, and report to the AB. Such procedures aim to empower meaningful activities while maintaining a commitment to ISoP's mission and strategic plan. The EC will ensure that elections, where required, are adequately arranged and resourced.

The ISoP Community Coordinator will assist Communities in any reasonable manner to facilitate their functioning to ensure effective and accountable Communities. If weaknesses are identified, they should be addressed collaboratively and constructively, with a focus on strengthening the Community's position and work. In case of any issue, the ISoP Community Coordinator will escalate it to the EC, and inform the AB.

10. Closing Communities

Communities that do not engage in any activities during the year and fail to provide the mid-year and annual reports will be placed on probation for one year. If the Community remains inactive and does not submit the required reports during this probationary period, the EC will close it.

11. Contributions of external experts to Communities

While it is preferred that all Community members are paid-up ISoP members, certain subject matter experts who are not ISoP members may support the goals and activities of a Community for a one-year term. After this period, they are required to become ISoP members.

12. Contribution of Communities to the Annual Meeting

Communities could contribute to the annual meeting in various ways. Discussions on specific Community topics can generate interest and engagement from new ISoP members and other experts, supporting the continued growth of the Community. Under the direction of the Scientific committee for the annual meeting, contributions may include pre-conference training courses, standalone podium presentations, proposing and/or chairing entire sessions.

As are all ISoP Members, Community members are encouraged to submit abstracts for oral or poster presentations for the annual meeting, following the normal abstract submission process.

The ISoP annual meeting also serves as an excellent opportunity to launch new Communities in the GA.

Anyone wishing to join a Community should feel free to contact the respective Community leader or the ISoP contact person by email (administration@isoponline.org) and wait for confirmation that they have been enrolled. Further information is also available on the ISoP website (<http://isoponline.org/communities/>).