



Guideline on ISoP Special Interest Groups (SIG)

Introduction and rationale for establishing Special Interest Groups

Over recent years, a few **specific or outstanding topics** emerged from presentations and discussions at ISoP Annual Meetings or training courses, which are related to pharmacovigilance and which need more attention, but have not yet been in the centre of debates so far. Around such topics, ISoP members created, or proposed to create working groups within ISoP, so called 'Special Interest Groups' – SIG.

What is a Special Interest Group?

A SIG is a group of ISoP members acting as volunteers and working on a specific and relevant topic which is within the scope and aims of ISoP. SIGs are not regionally limited and may engage non-ISoP members with special expertise on the topic concerned. A SIG may work together on its specific topic with other groups, associations or societies outside of ISoP, after agreement by the Executive Committee (EC).

SIGs **are considered as working groups** and do not have own statutes but shall agree in writing to abide with ISoP bylaws and the constitution.

SIG members designate **by common agreement** a coordinator and contact person who has to co-operate closely with the ISoP Education&Training Programm group (ETP; for details see website) and the ISoP Secretariat.

The SIG can use the name and emblem of ISoP.

Conditions for establishing a SIG and duration of term

A SIG can be created by at least five ISoP members to discuss and work on a specific and relevant topic which is within the scope and aims of ISoP. SIGs should be established formally by the EC, their duration of term is not limited.

Within the regular review of SIG activities by the EC, continuation of work of a SIG should be confirmed, or, if justified and legitimate, be terminated by agreement through the EC.

Deliverables

ISoP SIGs enable ISoP members to be personally involved in developing documents, opinions, statements which may become official and public ISoP documents. **Such documents must be adopted by the EC prior release or publication.** In some cases it may be appropriate for ISoP that SIGs develop specific programmes of support, e.g. supporting conferences, symposia, training courses or workshops. SIGs are encouraged to present their activities or other topics of interest at Annual Meetings or other ISoP events, with prior approval of the meeting's scientific committee.

SIGs may receive administrative support through the ISoP Secretariat, e.g. organizing tele/video-conferences.

Members of SIGs are encouraged to collaborate in the recruitment of members in sufficient numbers to make SIGs viable. They retain an overall commitment to act as important sources of the information that helps achieve ISoP's mission.

How can the ISoP EC approve a SIG?

For the ISoP EC, in order to approve a SIG, the following points need to be addressed in a submission to the ISoP EC either by affirming commitment or demonstrating evidence:

1. The proposed SIG must be able demonstrate its determination, diligence and competence to work on their specific topic and the discipline of pharmacovigilance.
- 2. The proposed SIG should have clearly defined objectives and give a summary in the submission to the ISoP EC.**
3. At least 5 ISoP members are needed to form a SIG.
4. The SIG must be organised to be able to fulfil its deliverables. The SIG must be able to extend its activities to such as meetings and training courses.
5. Each SIG designates **by common agreement** a coordinator who ensures the SIG's activities, and keep its records, for communication with the EC. These SIG Officers are typically appointed within the SIG, and the EC is informed accordingly.
6. The SIG and its members adhere to and continuously act in accordance with the active ISoP constitution and bylaws. As the first step, an understanding is reached between the ISoP EC and a group of persons (individuals or an existing organization) that a group will work towards forming a SIG of ISoP. The SIG will receive a letter from the President of ISoP recognizing this group as the "SIG xy" of ISoP. At this stage, the SIG coordinator may use the ISoP name or logo, but may not, unless specifically authorised to do so by the EC,

speak on behalf of ISoP. Subsequently, the formation of a specific SIG will be announced in ISoP Star and at the Annual General Assembly.

Oversight and regular review by ISoP EC

The ISoP EC will at **its regular meetings** review the activities of SIGs to ensure that the quality and integrity of SIGs is acceptably high. Such procedures are developed to empower meaningful activities while retaining an overall commitment to the joint achievement of ISoP's common mission. The objective is to achieve effective and accountable SIGs.

The EC will assist in any reasonable way in the functions of SIGs. Where weaknesses are identified, at any time, they should be addressed jointly and constructively, with a primary view to strengthening the position and work of the SIG.

Expectations of SIGs

The activities of SIGs should strengthen ISoP as a whole by being consistent with the stated aims of ISoP.

The EC retains the responsibility of checking that SIGs abide by acceptable standards of conduct as defined in the bylaws. The EC reserves the right to withdraw recognition of SIGs and permission for the SIG to use the ISoP name.

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