



## **Guideline on ISoP National and Regional Chapters**

### **Rationale for chapters**

ISoP should aim to contribute to the development of national or regional chapters, taking into account the needs, opportunities and benefits that may be involved in particular areas. In some cases, in discussion with the ISoP Executive Committee, it may be appropriate for ISoP itself to develop specific programmes of support, e.g. supporting conferences and workshops at a local level to stimulate or further develop national chapters.

### **What is an ISoP Chapter?**

ISoP Chapters are independent, locally-established organisations that actively address the needs arising from the whole range of pharmacovigilance activities in their respective countries (e.g. Italy) or regions (e.g. Africa), implement their own national or regional programmes as well as agreed global and regional strategies. Chapters enable ISoP members to be personally involved in the future development of pharmacovigilance in their country or region. ISoP Chapters are also instrumental in shaping ISoP's strategy and policies, and can work together on regional priorities as well as promote and support regional initiatives. Chapters provide a mechanism for national and regional issues to be recognized globally. Members of established chapters are encouraged to collaborate in the recruitment of members in sufficient numbers to make new chapters viable. They retain an overall commitment to the joint achievement of ISoP's common mission as well as acting as important sources of the information that helps achieve that mission.

Chapters are ambassadors for ISoP, in that they contribute to the achievement of ISoP's goals and aims, and in turn inform ISoP of the local needs towards achieving that aim.

They are encouraged to propose specific events or symposia presenting their activities or other topics of interest at the annual meeting, with prior approval of the meeting's scientific committee.

### **Oversight by ISoP EC**

The members of the Application Committee, appointed by the EC, are responsible and have a co-ordinating function for the network of chapters to ensure they stay in line with ISoP's global vision and aims while remaining organisationally

autonomous at the national or regional level. They are not responsible for chapters' internal and organizational matters.

A system of Chapter review by the ISoP executive committee helps ensure that the quality and integrity of Chapters is acceptably high around the world. Such procedures are developed to empower locally meaningful activity while retaining an overall commitment to the joint achievement of ISoP's common mission. The objective is to assure/achieve a movement of strong, effective and accountable Chapters. The Executive Committee will assist in any reasonable way in the functions of the Chapters such as, on request, by providing teaching materials or speakers. Where weaknesses are identified, at any time, they should be addressed jointly and constructively, with a primary view to strengthening the position of the National or Regional Chapter and thus of the Society as a whole.

### **Expectations of chapters**

Within their own countries or region, Chapters are standalone organisations working with ISoP members acting as volunteers. They do not have their own statutes and shall agree in writing to abide with ISoP bylaws and the constitution.

ISoP retains the responsibility of checking that all Chapters abide by acceptable standards of conduct as defined in the bylaws. ISoP reserves the right to withdraw recognition of Chapters and permission for the Chapter to use the ISoP name.

ISoP Chapters act to develop pharmacovigilance in their territory of influence and help those in need of assistance. Their activities should strengthen ISoP as a whole by being consistent with the stated global aims of ISoP.

National and regional chapters can organize themselves in any way that they see fit and can meet at a periodicity of their own choosing. National or regional chapters shall inform the ISoP Secretariat on any scheduled events such as meetings, symposia, conferences etc.

### **How can ISoP EC approve a chapter?**

In order for the ISoP EC to approve a national or regional chapter, the following points need to be addressed in a submission to the ISoP EC either by affirming commitment or demonstrating evidence as follows:

1. The proposed Chapter must be able demonstrate its determination, diligence and competence to represent ISoP and the discipline of pharmacovigilance in its own country and act as a member of ISoP.
2. At least 10 ISoP members are needed to form a chapter
3. There can only be one ISoP Chapter within a defined territory. Typically this will represent one country. If a Chapter is to represent more than one country, or wishes to represent a region within a country, it must state its

reasons, generally in relation with numbers of ISoP members available to start a chapter, local or regional interests, or geographical constraints.

4. Chapters need to have an autonomous status which allow them to operate in conformity with the fundamental principles of ISoP. Chapters agree to be guided in their work by internationally acceptable ethical principles of ISoP although details of how such principles are implemented vary across the world. The specific legal nature of the status, such as a charity status, may vary from country to country. It may not be necessary to have any specific legal status, but such a legal status may be desirable, e.g. to declare and manage funding by any organizations or companies involved in meetings, courses and travel or other activities.

5. The Chapter must be organized to be able to fulfil the tasks consistent with intent of ISoP statutes, and members must follow the ISoP policy in regards to the declaration of Conflicts of Interest (CoI). A form to be filled is annexed.

6. Each Chapter designates a coordinator and a deputy, a treasurer and a Secretary, which ensures the Chapter's activities, financial management, and keep its records, for communication with the EC. The term of the chapter coordinators to be mentioned in the records or files. These Chapter Officers are typically elected within the chapter, and a record is kept of the voting mechanism and results. Chapters' Officers or/and coordinators must be current members of ISoP.

Chapters sessions should be held regularly at the ISoP Annual Meetings (a proposal for the session and its agenda should be sent prior to the EC for evaluation and adoption by February 1<sup>st</sup> of the year of the Annual Meeting).

7. The Chapter can use the name and emblem of ISoP. It takes all necessary steps to protect the name and logo of ISoP under the laws and regulations of the NC's country or territory.

8. The Chapter must be able to extend its activities such as meetings and training courses within its defined territory.

9. The Chapter adheres to and continuously acts in accordance with the active ISoP constitution and bylaws, and shares its values.

10. Where appropriate, the Chapter will share regular financial and activity reports with the Application Committee and ISoP Executive Committee.

At all stages the documentation submitted to ISoP EC is first screened by the Application Committee and then submitted through to the EC and President with recommendations for action for the EC.

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 Chapter of ISoP in its country. The chapter will receive a letter from the President of ISoP recognizing this group as the "Chapter" of ISoP. At

this stage, the National Contact 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 chapter will be officially launched at the next upcoming Annual General Assembly and announced in ISoP Star and website.

### **Regular Review by ISoP EC**

To help strengthen ISoP chapters, and to assure that a chapter continues to comply with the intent and basic principles of ISoP and is contributing to the goals of the movement, an annual review of chapters should take place. Approximately every year after approval by ISoP EC, chapters prepare an annual report based on criteria numbered 1.to 10. above, which concludes with a statement of its own strengths and weaknesses, and the identification of areas where strengthening efforts will be directed, if any. Criteria for the evaluation of a chapter will among others be the number of its members, and their activity, especially in teaching, education, research and promotion of the safe use of medicines.

The chapters will submit their report to the Application Committee for consideration which in turn will inform the EC about its conclusions. A form with predefined criteria for use of the coordinators should be made available (online) to report to the EC.