

Scoping group report

This is a report of the Scoping Group dedicated to the discussion on future possibilities of development in relation to International Society of Pharmacovigilance. The paper is accompanied by a comprehensive slide-deck and serves as a basis for discussion of Advisory Board on 20 April 2021.

Introduction

To expand ISoP globally and continue to support the needs of members, President Mira Harrison-Woolrych informed the General Assembly on 14 October 2020 of the establishment of a **Scoping Group** which will consider all concepts and ideas regarding future developments in our professional society. Ideas proposed by Board members include building a globally-recognised PV certification process, or the creation of a multidisciplinary Scientific Board to provide training and education resources for ISoP members.

This Scoping Group was co-chaired by Jean-Christophe Delumeau and Jan Petráček, along with Advisory Board members Mónica Tarapués, Manal Younus and Li Zhang as members.

The Group has prepared a report in a form of presentation, which is the bases for this paper. The report was presented and considered by the Executive Committee in early 2021 with conclusions to be reported at the ISoP General Assembly in October 2021.

Scoping Group meetings

The Scoping Group has met three times:

1. Meeting on 22 October 2020
 - a. Discussed status of ISoPs Special Interest Group (SIG) on Pharmacovigilance Professional Qualification Framework
 - b. Investigated ways to build a globally-recognised PV certification process, potentially requiring the creation of a multidisciplinary Board.
2. Meeting on 01 December 2020
 - a. Further to the last meeting of the Scoping Group, the main item on the agenda was presentation on the draft of the strategy for creating a global PV certification program, followed by a discussion among the members of the Scoping Group.
3. Meeting on 05 March 2021
 - a. Update on the Strategy Presentation, final paper for EC

Executive committee meeting on 16th March 2021

Executive committee welcomed the report and asked for the following questions to be considered for the presentation to the Advisory Board:

1. Administrative support and resources of the new Scientific Board and the certification programme (including term of office, appointment process for the SB, and remunerations)
2. Roll-out of the Professional Development Programme (details as to how the scheme would be piloted and rolled-out, with approximate numbers in each cohort and draft timelines pilot phase, and the relationship between the Institute of Pharmacovigilance and ISoP in delivering this programme/MoU).
3. Broader goals of ISoP to offer free training/expert advice to the wider public health community (How do the Scoping Group proposals fit with the broader aims of ISoP to deliver webinars/advice free-of-charge to non-ISoP members?)

Problem statement for the Scoping Group

ISoP so far is mainly financed through membership fees. Recruitment of new members of ISoP is mainly done through annual meetings and various trainings. Variable and relatively small proportion of participants to these events renew membership for the consecutive years. Therefore, ISoP depends on attracting new and new participants to its events.

Covid-19 pandemics removed all in person meetings and therefore seriously impacted recruitment of new members as well as renewal of membership via this traditional approach. This situation has uncovered a major weakness of the ISoP business model.

ISoP is still perceived as a society providing education in pharmacovigilance, often in collaboration with UMC and universities. As such, it is just “one of many”, with a very uncertain Unique Selling Points to offer to pharmacovigilance community. This limits significantly the potential for ISoPs further development.

Scoping Group should find a way how to sustainably increase attractiveness of membership and improve positioning of ISoP in the community.

Brainstorming on strategic objectives

Scoping Group members were asked to brainstorm on the possibilities of addressing the problems described above. The two strategic objectives were defined:

1. Improve wide recognition of ISoP as a scientific society with high authority in education
2. Position ISoP as a global professional organization, supporting professional qualifications on top of its scientific and educational activities

The two objectives are complementary and in line with ISoP mission.

The scoping group further discussed how to achieve those strategic objectives and have agreed to further elaborate on two tools :

1. Establishment of a Scientific Board
2. Establishment of a Global Professional Certification Program for pharmacovigilance professionals

ISoP Scientific Board

A Scientific Board is a typical body of any learned, scientific, or academic organization/society. It usually serves the society in support of its scientific and academic objectives and significantly supports its authority in the community.

The Scoping Group would see two major missions for the Scientific Board of ISoP:

1. Support ISoP's Scientific and Educational activities
2. Support Global PV Professional Certification project

There are three major groups of pharmacovigilance professionals to choose the members of the Scientific Board from:

1. Well-known and respected members of the Pharmacovigilance community, with high level of scientific competency
2. ISoP high contributors – e.g. FISoP, Former Board members, SIG Chairpersons/Coordinators
3. Academics upon proposal of Advisory Board members, based on their highly recognized academic profile related to pharmacovigilance.

Candidates should be proposed by the Advisory Board members, then screened by the Executive Committee, and then approved by the whole Advisory Board by qualified majority of at least 2/3 of members. Appointment shall be limited in time. It should be longer than the functional period of the

elected Advisory Board to ensure continuity in between the Advisory Boards in function. 5-year period seems to be optimal. The position in the Scientific Board can be renewed only once. Executive committee should ensure equality and diversity in the appointment process. Performance of the members of the Scientific Board shall be evaluated regularly by the Advisory Board. Should any member of the Scientific Board fail to meet the performance standards and expectations, Advisory Board can dismiss that member and appoint another member instead.

Scientific Board members will be electing their chairperson every 3 years (renewable once). The nominated chair should be approved by the EC. The Scientific Board Charter to be elaborated by Scoping Group (initially) and approved by Advisory Board. Consecutive updates to the SB Charter can be suggested by the Scientific Board and approved by the Advisory Board.

As examples of practical roles of the Scientific Board, the following can be expected:

- Provide scientific and academic authority to ISoP supporting all its projects
- Assist Scientific Committees in organization of Conferences and Training contents for ISoP events
- Take responsibility/Support/contribute to the Professional Certification Project, in particular in review and approval process, support examination Boards, and ensuring support by significant stakeholders in pharmacovigilance community

Administrative support of the Scientific Board can be provided by the Institute of Pharmacovigilance based on the memorandum of understanding. This will be a contribution in kind. ISoP can run the secretariat of the Scientific Board when sufficient funds are collected through increased membership.

It is expected the newly created Scientific Board of ISoP will improve recognition of the society as scientifically competent, would improve educational activities with wider audience, and will potentially grow membership by about 30% in two years and will have a synergic effect for the Global PV Certification Project.

Global PV Certification Project

Every major learned society is serving its constituents by making standards regarding expectations in terms of the competence required for members of the profession they represent. Many of these societies also developed certification programs, continuous professional development programs, and similar standards of self-governance.

The Scoping Group is of the opinion that the time is right for International Society of Pharmacovigilance to serve its community by more than just educational and advisory offerings. The program should have the following characteristics:

Aim: Elevate Pharmacovigilance Profession

Purpose: By improving competency of pharmacovigilance professionals, we improve performance and recognition of pharmacovigilance discipline

Mission: Define expected competence at each role and seniority step, and test candidates against it

By defining expectations, we improve education, competence development and quality of work.

The Global Pharmacovigilance Professional Certification should sit on top of existing academic qualifications, and various certification projects of training organisations. There is currently no such certification available and therefore the creation of this system would fill a gap that is so far representing an unmet need or pharmacovigilance professionals.

The Institute of Pharmacovigilance and the Special Interest Group have developed the basic outline of the certification project.

First, we need to define so-called Career Framework. That means a definition of roles and seniority steps in pharmacovigilance career making sure we all use the same terminology.

The second component is a Competence Framework, a standard defining expectations of competence for each pharmacovigilance professional role and for each seniority step. Competence consists of knowledge, skills, and attitudes.

The third component is the professional certification. It is a system for testing the candidates against the career and competence framework standards so to see whether the candidate meets the expectations for competence in a particular role and seniority.

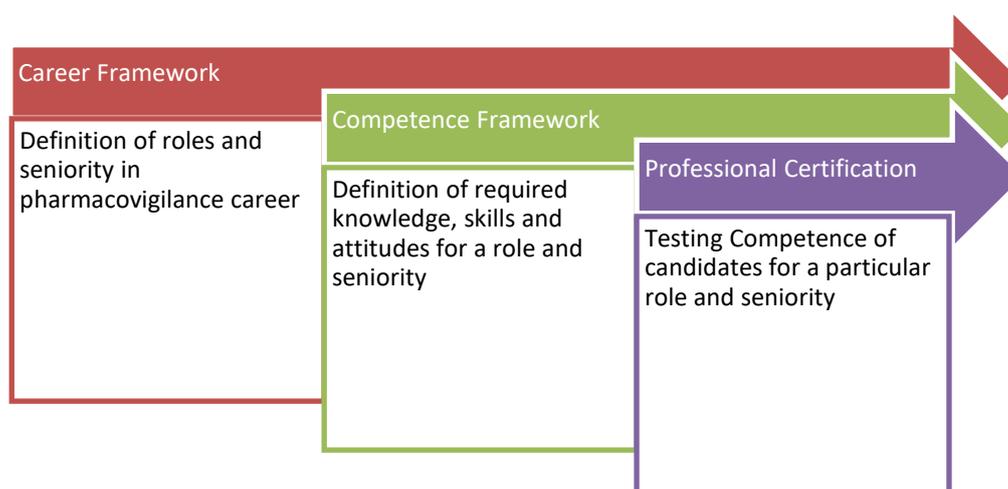


FIGURE 1 THREE MAJOR COMPONENTS OF THE GLOBAL PHARMACOVIGILANCE PROFESSIONAL CERTIFICATION

The Scoping Group expects the Global PV Professional Certification will have the following effect on the International Society of Pharmacovigilance:

- Significantly improving recognition of ISoP as the professional organization
- ISoP would become the source of standards for education, training, and career development in all pharmacovigilance roles

- Additional revenue from continuous professional education activities
- Growth of ISO-P membership, as being a member of ISO-P would be a condition of a valid certificate

In the accompanying slide-deck more details about the strategy of deployment and various subcomponents of the global professional certification project are provided.

The program is designed as global in English and will have local components focusing on local or regional specifics and will be available in language of the region. The first two localization will be Mandarin for China and Spanish for Latin America, based on the preliminary discussions about the demand for these certifications. Other regions, such as Africa, will likely accept English as a working language and localization will focus on local pharmacovigilance regulatory intelligence.

Roll-out of the Global Pharmacovigilance PV Certification Program

The Program requires significant investment to deliver first class service to the pharmacovigilance community. Based on Memorandum of Understanding, Institute of Pharmacovigilance may deliver the program for International Society of Pharmacovigilance. Institute has received financial donation from Jan Petracek, and will use it for the kick start of this project. Further funds may be available through various grants and government programs. The program will be self-sustainable and self-funded from the certification fees once established.

The draft hierarchy is depicted on the Figure 2.

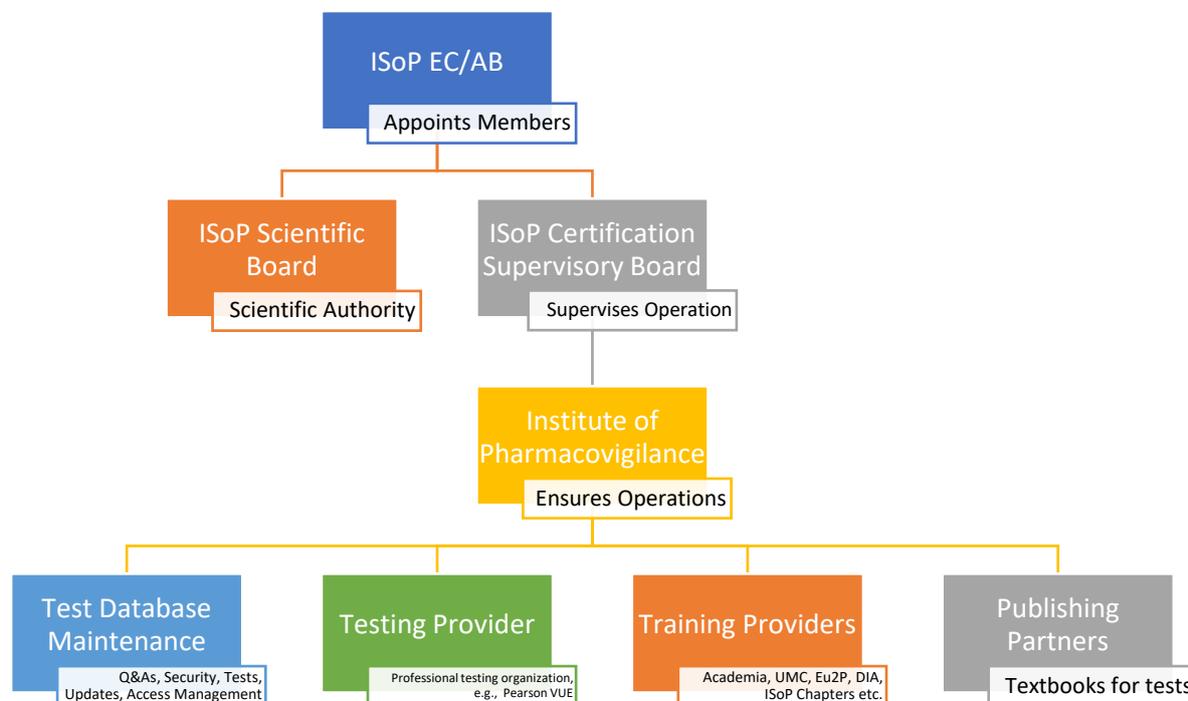


FIGURE 2 BASIC HIERARCHY FOR THE GLOBAL PHARMACOVIGILANCE CERTIFICATION PROGRAM

The project will be delivered in collaboration with organisations of proven track record in the area of professional certification. Example may be Pearson Vue, www.pearson.com .

The work on the program has commenced, and as of the 1. 4. 2021, Institute of Pharmacovigilance has hired first two project managers and rented offices in Prague. The draft timelines are depicted on the Figure 3.

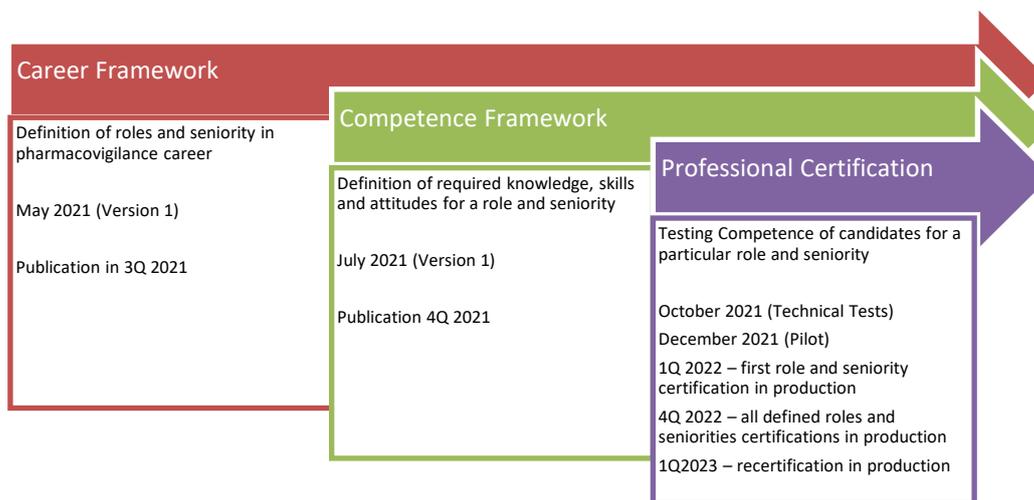


FIGURE 3 DRAFT TIMELINE FOR THE ROLL-OUT

Developing, testing and piloting methodology

The Global Pharmacovigilance Professional Certification program will respect the established methodology and technology that has been tested and validated already. Example of the Process of the test development is provided in the Figure 4.

Institute of Pharmacovigilance is working/planning to work with:

1. SIG on PV Career Framework and with the ISO P community in developing the standards and questions for the certifications.
2. Brand identity specialists for development of dedicated website, logo, brand, and communication campaign. www.pharmacovigilance.institute .
3. Top psychologists for development of the didactic tests of the certification project, development of mind-sets/attitude tests, and overall psychology of certification process.
4. Global network of experts for development of knowledge management system holding up to date regulatory intelligence in a form of mind maps, wiki, document archive, educational materials, and potential use of AI.
5. Testing provider, such as Pearson VUE.
6. Educational providers, such as EU2P, DIA, and other universities and established training providers.
7. CPD credit providers to align standards.
8. Stakeholders, in particular regulatory authorities and pharmaceutical industry, for definition of expectations, feedback, and potential codification of the developed standards in regulatory requirements.

9. ISO P partners, WHO UMC, ISPE, various national pharmacovigilance societies and institutes, pharmacotherapeutic bulletins, patient organisations, for their input, feedback and endorsement.

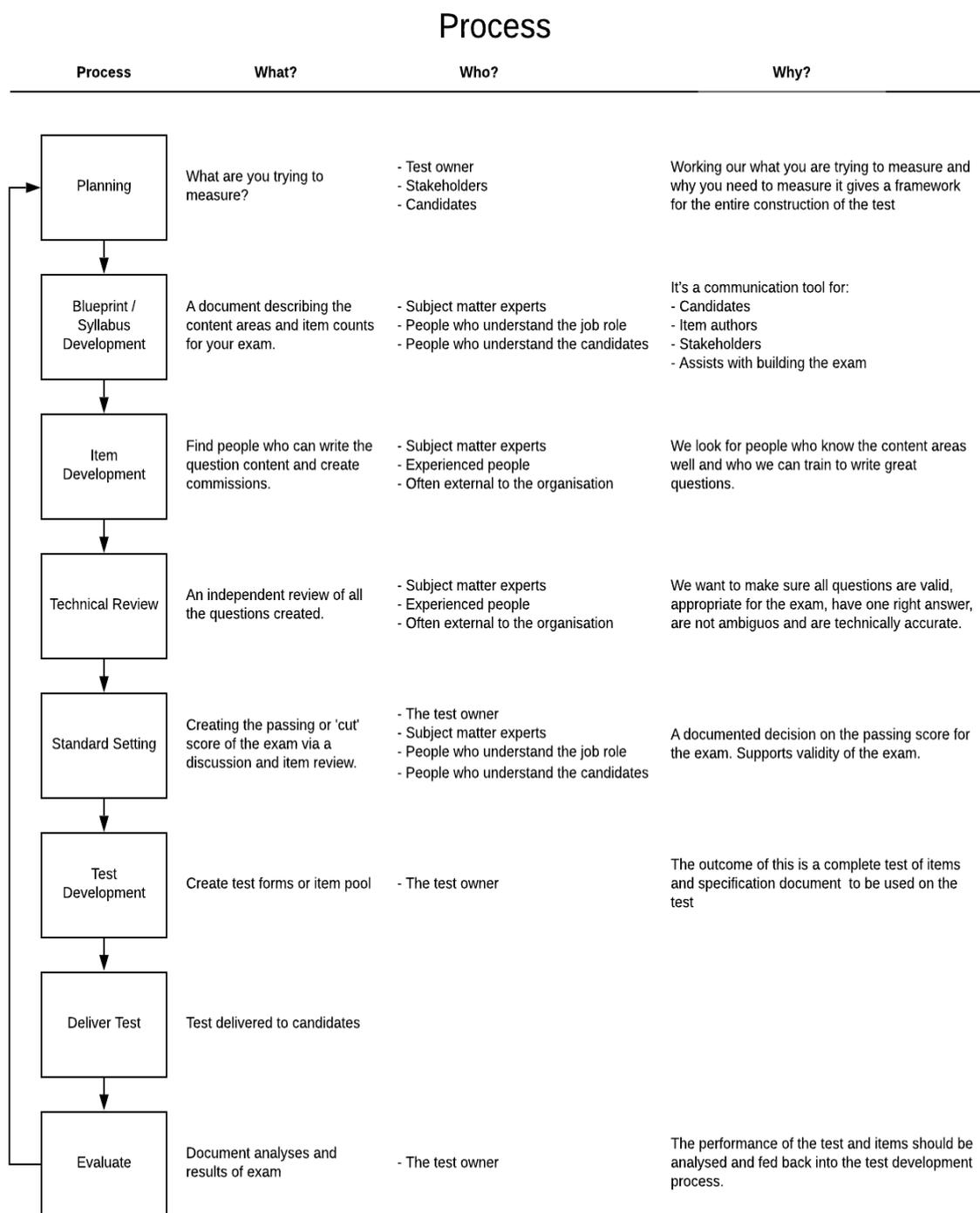


FIGURE 4 STANDARD HIGH LEVEL PROCESS FOR THE TEST DEVELOPMENT

Conclusion

The proposals from the Scoping Group have potential to significantly improve the standing, positioning and impact of ISoP through improvement of services to its members, and to pharmacovigilance overall.

The Global Pharmacovigilance Professional Certification program will create a new ecosystem, based on win-win relationships, that has potential of delivering a quantum change in quality of pharmacovigilance work worldwide. This can bring better satisfaction of pharmacovigilance professionals with their careers, status, recognition, and life.

When implemented, ISoP's delivery on its mission will significantly improve. These proposals represent a bold and modern way forward, and an outstanding opportunity for ISoP future.