ISoP Five-Year Strategic Plan

Five-Year Vision

By 2023, the International Society of Pharmacometrics (ISoP) will be the premier organization advancing the discipline of pharmacometrics throughout the world. ISoP will actively champion the expanding role of pharmacometrics in protecting and improving human health, by:

- Broadening ISoP’s outreach to become a truly international society, increasing membership by 50%, and sponsoring pharmacometrics meetings worldwide.
- Increasing the awareness of key decision-makers, such as regulators, clinicians, payers (anyone setting pricing or reimbursement policies), patient advocates, and industry leadership, to the impact of pharmacometrics on drug discovery, development, and clinical practice.
- Strengthening core pharmacometric capabilities through research support and educational initiatives, while increasing the exposure of society members to new areas, such as health economics and machine learning.
- Improving development of and access to educational resources, pharmacometrics tools, and open-science resources for society members at every stage of their career.

Core Activity Areas

We have identified the following six areas for our core activity under the Five-Year Strategic Plan. Working groups will be established to plan and implement each of these.

- Scientific Expertise and Innovation
- Influence
- Education
- Tools and Resources
- Internationalization
- Organizational Effectiveness
Scientific Expertise and Innovation

Chair: Jin Jin (jin.jin@gene.com)

**Objective:** To encourage further research and innovation in pharmaceutometrics.

Initial priority will be placed on strengthening our core capabilities in order to demonstrate value to our membership in the near term. Beginning in parallel, efforts to expand ISoP into new scientific frontiers will focus initially on opportunity assessment and prioritization, with the long term goal of partnering with other organizations to bridge scientific disciplines, and then positioning the society to drive science forward in a cohesive and sustainable manner.

### Capabilities vs. Potential Applications

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### Areas of Potential Expansion

**Five-year goals**

- ISoP is fostering strong, sustainable partnerships in the areas of clinical pharmacology, statistics and health economics, with a demonstrated and articulated understanding of how tools such as real world data and AI/machine learning can enable better decision making, when coupled with pharmaceutometrics.
- Membership in ISoP is viewed as a valued investment for access to cutting edge educational resources, tools and collaborations with other quantitative disciplines, providing depth of experience in pharmaceutometrics, as well as broader engagement with new technologies, capabilities and applications in the realms of drug discovery, real world patient care, and the payer environment.
Influence

Chair: Heather Vezina (heather.vezina@bms.com)

**Objective:** To enable the use of pharmacometrics to inform decision making within drug discovery, development and clinical practice.

Initial priority will be placed on development of a communications package designed to describe the science of pharmacometrics to external audiences and communities. In parallel to this, the working group will identify key stakeholders for increased engagement over the next 3-5 years. Engagement with the identified stakeholders, such as clinical societies, regulatory agencies, and healthcare payer organizations, is prioritized to first deeply understand their perspective, followed by a systematic and sustainable engagement with those areas.

**Five-year goals**

- By 2023, key stakeholders including regulators, clinicians and other technical disciplines have a robust understanding of the value of pharmacometrics for quantitative decision making.
- In the 1-2 therapeutic areas that have been prioritized for engagement, pharmacometrics is embraced as a core discipline in modern drug development, and is more routinely observed in clinical journals and meetings, thus enabling sustainable contributions beyond this strategic plan.
- By 2023 ISoP has leveraged these experiences to develop a playbook for engaging with additional therapeutic areas following this strategic plan.
Education

Chair: Brenda Cirincione (brenda.cirincione@vrtx.com)

Objective: To improve consistency, quality, and availability of educational resources for society members in every stage of their career.

Initial priority will be focused on establishing a recommended curriculum for pharmacometrics degree programs. In parallel to this, a formal mentoring program will be established for junior ISoP members, and a central index of educational materials will be established. Finally, a comprehensive series of tutorial webinars will be collected and developed to support continuing education of ISoP members.

Five-year goals

- ISoP has established recommended standards for pharmacometrics education to improve consistency of academic education.
- Quality and availability of educational resources for pharmacometrics have been improved through the creation of mentoring programs, online indices of education materials, and tutorial webinars.
Tools and Resources

Chair: Justin Wilkins (justin.wilkins@go-isop.org)

Objective: To increase visibility and facilitate development of and access to pharmacometric tools, as well as open science resources for pharmacometrics.

Initial priority will be focused on a comprehensive review of available pharmacometrics tools, followed by dissemination of information through a web-based registry. Continuing efforts will be made to promote the use and maintenance of publicly available resources for model and data sharing, as well as to support the development of new tools and methodologies.

Five-year goals

- ISoP is fostering a healthy, inclusive and diverse ecosystem of software tools and resources, arranging for gaps in functionality to be filled, new tools to be developed, and existing tools to be maintained and expanded.
- ISoP website is the global hub of information and resources pertaining to model development and algorithms for parameter estimation, and all commercial and open source tools, for pharmacometrics, QSP and PBPK.
Internationalization

Chair: Siv Jönsson (siv.jonsson@farmbio.uu.se)

**Objective:** To expand ISoP’s outreach to pharmacometrics community members across the globe.

Initial focus will be on maintaining current international outreach efforts and identifying opportunities for expanding outreach beyond US/Europe. Subsequent efforts will be focused on increasing the value proposition of ISoP membership to potential international members, via means such as expanding support for local meetings/training events or partnering with other international organizations.

*Five-year goals*

- ISoP has a presence at all global meetings.
- ISoP can support student attendance at most if not all global meetings.
- ISoP supports annual trainings in emerging regions in Africa, South America and Asia.
- 50% of ISoP membership is based outside the continental US.
Organizational Effectiveness

Chair: Pete Bonate (peter.bonate@astellas.com)

Objective: To ensure ISoP has the resources and staffing needed to implement the five-year plan.

Organizational support is vital in achieving all of the core activity areas identified above. Initial priority will be placed on supporting infrastructure and staffing needs to provide sustainable organizational support as a relatively mature society. Continuing efforts will be made to maintain and enhance messaging across various platforms, partnership with other scientific organizations, and exploring sources that can provide financial support.

Five-year goals

- ISoP operations and communications are smooth and integrated.
- Adequate sustained funding sources are identified to provide financial support required for all the core activity areas.