

Statisticians in the Pharmaceutical Industry Limited



Business Plan 2010 – 12

Engage with PSI

The Board of Directors wishes to encourage all members of PSI to help in further defining and implementing this business plan. Please contact any member of the Board for more information on how to contribute to the activities of PSI.

Board Members

Stephen Pyke (Pfizer)	Chair
Sara Hughes (GSK)	Vice Chair / Secretary
John Davies (GSK)	Chair, Scientific Committee
Jim Ditchburn (Takeda)	Chair, Statistical Computing Committee
Chrissie Fletcher (Amgen)	Regulatory Committee
Andy Grieve (King's College, London)	External Affairs Committee
Nigel Howitt (PRA International)	Representative to EFSPi
Katherine Hutchinson (Quanticate)	Contracts
Mark Jones (Takeda)	Website Committee
Stephen Jones (Covance)	Publications Committee
Peter Lane (GSK)	Treasurer
Colin Neate (Roche)	Careers & Academic Liaison
Ann Smith (AstraZeneca)	Training Committee
Mike Williams (GSK)	Conference

Introduction

PSI is a UK-based, non-profit-making membership organisation that exists to serve, support, represent and promote the interests of statisticians, statistical programmers and all others with an interest in the application of statistics in the pharmaceutical industry. PSI seeks to further its aims by partnering with other organisations in the UK, in Europe and elsewhere. PSI is a member organisation of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI).

PSI is governed by a Board of Directors. The Board comprises 10-14 Directors representing various committees and office holders. All Directors of the Board are required to be Ordinary Members elected by the membership.

This document represents the Board's views on how the Society should position itself, and what it should focus on, over the coming three years.

Our Purpose & Strategic Objectives

PSI's purpose is to:

**Promote and lead statistical thinking
in the Pharmaceutical Industry**

We fulfil our purpose guided by our strategic objectives:

- 1. Promote professional standards in the application, understanding and communication of statistics in the pharmaceutical industry.**
- 2. Create and sponsor forums where statistical topics relevant to the pharmaceutical industry are discussed, and innovation can be championed**
- 3. Influence and lead statistical aspects of science and regulatory debate relating to drug discovery and development.**
- 4. Promote statistics and statistical programming as a profession of choice.**

We believe that these strategic objectives represent a natural evolution of those set out in our 2007-9 Business Plan with particular emphasis now added in the areas of understanding and communication, innovation, and statistical programming as a career choice, while maintaining a strong focus on those areas previously recognised as important.

Our Services & Activities

PSI fulfils its purpose by:

1. Arranging a large annual **conference**, at least 5 **scientific meetings** and a quarterly **journal club** where members have the opportunity to share new ideas, consider best practices, and explore new applications in the areas of statistics and statistical computing. In addition, our Special Interest Groups (SIGs) host meetings typically aimed at a more targeted audience than can easily be accommodated within our general programme.
2. Arranging 5-6 **training courses** each year, with the aim of bringing PSI members up-to-date in a particular area without having to commit to a lengthy period away from the office or to extensive follow-up reading. Our popular Introduction to Industry training (**ITIT**) course is run each year for new entrants to the pharmaceutical industry.
3. Exploiting the opportunity provided by new **e-learning** tools to allow members unable to attend our meetings and training courses in person to learn at their desk.
4. Providing an industry viewpoint on **regulatory** issues. This includes input on regulatory guidelines (co-ordinated with EFSPi), driving debate on future guidance, and meeting with statisticians in European regulatory agencies.
5. Promoting **careers** within the industry by: publishing careers materials and forging links with schools and universities; and by establishing and

maintaining contact with academic statistical groups and professional organisations to further the use and study of statistics. A discretionary Grants Fund has been established to support postgraduate students studying Statistics at UK universities.

6. Proactively engaging with topics of the day through our **External Affairs** committee. The committee is charged with a remit to promote, amongst members of the pharmaceutical industry and the general public, a proper understanding of risks, benefits and associated statistical issues as they relate to pharmaceutical research, development, manufacturing & marketing.
7. Sponsorship of **Pharmaceutical Statistics**, the official journal of PSI, published by Wiley. The journal objectives are to promote discussion of statistical applications in drug development.
8. Publishing **SPIN**, our lively quarterly magazine that aims to inform members about, and solicit feedback on, PSI activities and other events of interest.
9. Providing a **website** for sharing and exchanging information with both members and non-members with an interest in pharmaceutical statistics.
10. Establishing ad hoc **Expert Groups** to investigate and report on issues of current interest to pharmaceutical statisticians.
11. Carefully managing our **finances**. Our Treasurer works closely with our Executive Office to ensure efficient administration of our finances and to ensure adequate reserves are prudently maintained.

What we will do during 2010-12

During the fourth quarter of 2009, the Board of Directors undertook a strategic review of the means by which we will meet our strategic objectives. Our selection of targets was driven by reflections on progress made through our 2007-9 Business Plan, perspectives on important current and future challenges for our industry and for our members, and consideration of factors that enable or constrain our ability to deliver successfully in a reasonable timeframe. In formulating targets we were also mindful of the need to make changes in direction should the external environment evolve.

Strategic Objective 1

Promote professional standards in the application, understanding and communication of statistics in the pharmaceutical industry

- Develop a programme of events and activities that encourage the transition of more statisticians from being simply enablers and technicians, to being instead contributors and leaders in the drug discovery and development effort
- In partnership with relevant parties, explore the benefits and costs associated with regulated accreditation of professional pharmaceutical statisticians
- Influence small companies to make better use of appropriately trained and experienced statisticians as they plan their development programmes and seek to register new drugs

Strategic Objective 2

Create and sponsor forums where statistical topics relevant to the pharmaceutical industry are discussed, and innovation can be championed

- Partner with EFSPI to create a forum for industry statisticians and regulatory statisticians to debate hot topics
- Reorganise and augment website resources to improve accessibility and usefulness for members
- Grow the journal club and online education
- Promote the role of Special Interest Groups and provide increased support for their activities

Strategic Objective 3

Influence and lead statistical aspects of science and regulatory debate relating to drug discovery and development

- Promote, among members of the pharmaceutical industry and the public, a proper understanding of risks, benefits and associated statistical issues related to pharmaceutical research, development, manufacturing & marketing
- Create and implement a rolling plan to ensure that, at any one time, there is a minimum of one Expert Group working on a significant topical issue
- Develop and implement a strategic framework for partnering with organisations with whom we share common purpose

Strategic Objective 4

Promote statistics and statistical programming as a profession of choice

- Influence political, educational and other organisations to provide financial support for postgraduate study in statistics
- In partnership with other interested organisations, develop resources suitable for use by schools that become nationally known and accessible