Careers for Statisticians and Statistical Programmers within the Pharmaceutical Industry

www.psiweb.org/newcareers

CONTENTS

The careers booklet is a simplification of the drug development process compiled from several statisticians and statistical programmers contrbutions.

1. The Pharmaceutical Industry

The pharmaceutical industry is concerned with the research, development, manufacture and marketing of products for the prevention, diagnosis and treatment of diseases. The industry is made up of a wide range of companies - large and small, local, national and international, some with manufacturing and marketing facilities, others concentrating solely on research and development - as well as Contract Research Organisations (CROs).

CROs frequently provide their research and development services to the mainstream pharmaceutical companies. They often work in tandem with the manufacturing companies to achieve product approval from the regulatory authorities around the world. The links between CROs and pharmaceutical companies have strengthened over recent years.

The pharmaceutical industry is a successful and growing professional environment. It rises to the varying challenges of the health care industry, not just research, development and manufacturing of new treatments and devices, but also improving the effectiveness of medicines in a broader way. Drugs with fewer side effects and improved devices, for example, pre-filled syringes (easy to inject at home) result in shorter hospital stays. In addition, vaccines and health education improve people's quality of life. See table below for the ten largest pharmaceutical companies.

Top 10 pharmaceutical companies by 2008 sales (in millions of dollars)

1. Pfizer	43,363	6. Hoffmann–La Roche	30,336
2. GlaxoSmithKline	36,506	7. Johnson & Johnson	29,425
3. Novartis	36,506	8. Merck & Co.	26,191
4. Sanofi-Aventis	35,642	9. Abbott	19,466
5. AstraZeneca	32,516	10. Eli Lilly and Company	19,140

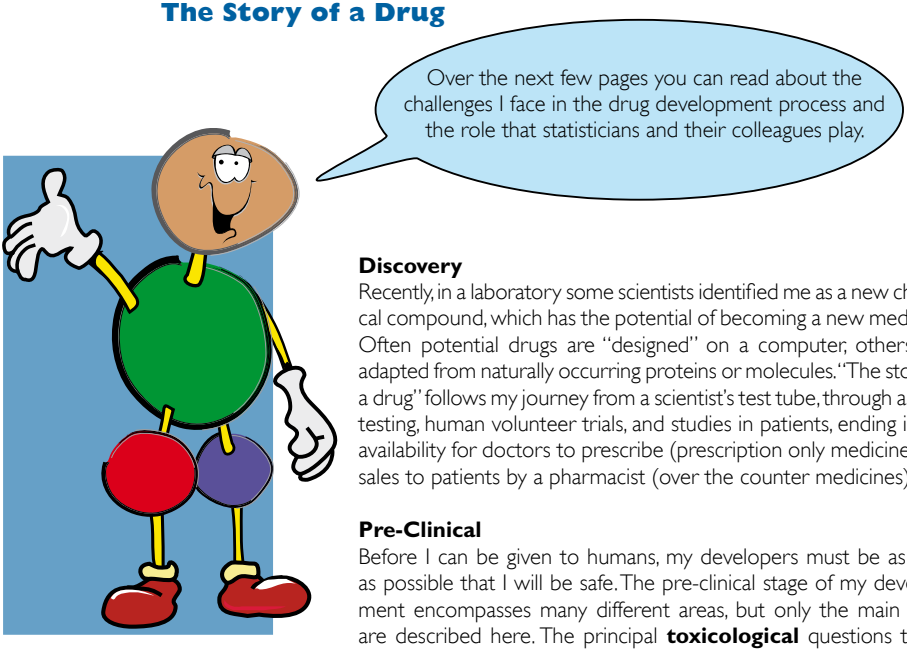
Source: www.imshealth.com (as of July 2009).

2. Qualifications

Each year the demand for qualified statisticians increases. The large majority of new graduates recruited into this role have an MSc in Statistics. MSc courses are seen to provide statisticians with a strong background in statistics as well as the ability and confidence to apply the knowledge to a wide range of problems. Some pharmaceutical companies sponsor MSc students with the aim of ensuring that high standards of academic training within the industry are maintained. The Royal Statistical Society (RSS) also offers the opportunity for career progression with professional examinations, as do some universities, with part-time and correspondence MSc courses. Graduates with BScs are also recruited, and it is not uncommon for statisticians in the industry to have PhDs.

A large number of statistical programmers are also employed in the industry. These are also graduates, with at least a BSc in mathematics, statistics or computing. Like statisticians, statistical programmers need to be able to think logically, write reports, communicate well, have strong interpersonal skills and an eye for detail.

3. The Role of Statistics in Drug Development: The Story of a Drug



Discovery

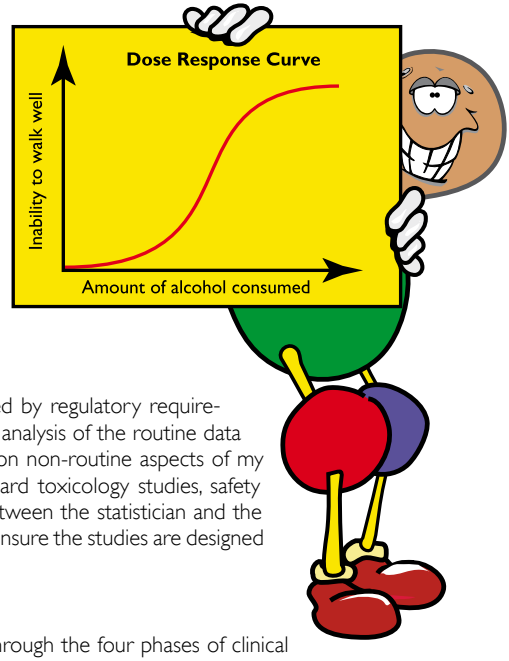
Recently, in a laboratory some scientists identified me as a new chemical compound, which has the potential of becoming a new medicine. Often potential drugs are "designed" on a computer, others are adapted from naturally occurring proteins or molecules. "The story of a drug" follows my journey from a scientist's test tube, through animal testing, human volunteer trials, and studies in patients, ending in my availability for doctors to prescribe (prescription only medicines) or sales to patients by a pharmacist (over the counter medicines).

Pre-Clinical

Before I can be given to humans, my developers must be as sure as possible that I will be safe. The pre-clinical stage of my development encompasses many different areas, but only the main ones are described here. The principal **toxicological** questions to be answered are:

- *What is my maximum tolerated dose?*
  This will help establish the dose levels to be tested in the next stage of my development.
- *Will I have any adverse effects on the patients?*
  Any potential harmful effects can be evaluated and monitored closely in future studies and/or clinical trials. When given to patients, any adverse effects must be outweighed by the benefits.
- *Is it likely that I will cause cancer when used long-term?*
  The importance of this type of study is obvious. However, it is not necessarily the end of the road for me; for example, I may only be a **carcinogen** (cause cancer) at dose levels higher than those to be used in patients.
- *Do I have an adverse effect on unborn foetuses?*
  If I am shown to be a **teratogen** (cause birth defects), my ultimate use will be restricted and I will not be given to pregnant women or women likely to become pregnant.

To answer these questions, I need to be tested on animals, typically rats and mice. Large amounts of data are collected on relatively small numbers of animals; such data include body weights, food consumption, a range of blood sample tests, urine analysis and organ weights. It is important in this stage of my development to collect large volumes of data to fully explore drug effects. Steps are being taken to try to reduce the number of animals used, but it is still necessary to do some animal testing during early development.



The design of many of these studies and the sample size used (number and breed of animals) are governed by regulatory requirements. For the most part, data collection and statistical analysis of the routine data are automated. Statisticians spend more of their time on non-routine aspects of my development, such as analysis of data from non-standard toxicology studies, safety pharmacology and molecular toxicology. Interaction between the statistician and the scientists is paramount, as they must work as a team to ensure the studies are designed and analysed appropriately.

Clinical Trials

Conventionally, the next stage of my development is through the four phases of clinical trials. At this stage in my development my developers will know my effect in tissues and animals. However, it is still unclear as to how safe I am in humans, or if I am effective in the whole body system. Statisticians play an important part in the team that designs my development programme. They also play an integral part in the design of the overall clinical summaries as well as in the analyses which may lead to submission for a drug licence.

In Phase I, I am normally first tested on a small group of healthy, male volunteers (typically 8 to 24). I am not tested on female subjects at this early stage, even if I was not shown to be a teratogen in the pre-clinical studies. The healthy male volunteers, conventionally known as "**subjects**", are paid to participate in these trials. The amount of money they receive depends on the duration of the study and invasiveness of the procedures.

Once my developers are satisfied that I am safe I can move into Phase II. The studies in Phase II involve **patients** rather than subjects and include **dose finding** studies that aim to find my most effective and safe dose. There will be a range of Phase II studies, often involving a total of 100-200 patients, which will collect **safety** and **efficacy** data. Early Phase II studies may aim to investigate the effect of a single dose of me, in great detail, over just a few hours and, later on, multiple doses.

If the Phase II studies showed that I am safe and provided evidence that one or two of my doses are effective then I can go into a Phase III programme. The aim of Phase III is to find out if I am **efficacious** in large numbers of patients in real life situations. The evidence from Phases I-III, plus pre-clinical results, will be used to submit a dossier to the regulatory authorities for a licence to market me as a drug. Phase IV studies continue to collect data after licensing with the aim of gathering information from a larger group of patients. The data are also analysed and published in scientific journals.'

During development data are collected about the total cost of the illness, known as **Health Economics** data. Health Economics, sometimes known as **Pharmacoeconomics**, identifies, measures, and compares the costs and consequences (e.g. quality of life) of medical interventions, using epidemiological, economic and clinical methodologies and concepts for examining the impact of alternative medical interventions. Economic evaluation of healthcare aims to demonstrate the most efficient use of scarce resources.

Phase I

In Phase I studies, a wide range of **safety** data are collected. If any serious adverse events are reported, these need to be carefully looked at, to ensure I do not cause them. Besides the safety data, other types of data commonly collected in phase I studies include **pharmacodynamics**: what I do to the body, and **pharmacokinetics**: what the body does to me

The statistician will work with their clinical colleagues in designing the **protocol,** which specifies not only the procedures that the investigator and subject undertake, but also how the data will be analysed. They will have spent time writing statistical programs to perform the analyses, before producing tables and graphs to include in the study report.

When all the data have been entered into the database and cleaned (ensuring accuracy and consistency), the randomisation codes are broken and the data analysed. All modelling **assumptions** are checked and results are **quality controlled** before they are released outside the statistical team. The statisticians may then write a **Statistical Report** and/or work with medical writers to produce a **Study Report**. Statisticians need to have good report writing skills, and be able to communicate the results found from the study.

Phase II

The statistician in the Phase II group responsible for my development needs to consider several issues with his/her colleagues, when planning the Phase II studies:- design, randomisation, blinding, comparisons and endpoints. The analyses performed, most often using a statistical package called **SAS** (a common package used in the industry), may need to be performed quickly so programs will have to be written in advance and the statistician needs to manage his/her time effectively.

Study Designs

Parallel group design: Each patient takes me or one of the other drugs.

Cross-over design: Each patient takes me and the other drugs being studied in a random order with a period in-between to ensure no effects are carried forward. Cross-over design studies often need fewer patients in them to see the same treatment difference compared to a Parallel group design. However, such a design can only be used to test treatments that are reversible and short-lived. The disease must be chronic or at least relatively stable.

Adaptive design: Methods are available which allow designs to be modified on the basis of data collected so far. For example, the trial can be stopped early if there is enough evidence that the drug is much better, or much worse, than the other drugs being studied. Extreme care must be taken to preserve the integrity and reliability of the trial.

The statistician and his/her clinical colleagues have to decide with which other drug(s) I should be compared. If there is nothing else on the market that treats patients in my disease area then I will be compared with a dummy drug - a **placebo**. A placebo is usually an inactive substance which tastes and looks exactly the same as me, ensuring that the **blinding** put in place can work successfully. Sometimes there are drugs already on the market, one of which might be considered as the best possible treatment, known as the **gold standard**, which can be used as a comparison instead.

Phase III

The statistician in the Phase III group, and his/her clinical colleagues, may search the published literature and use Phase II information to estimate the necessary **sample size** (number of patients) needed to obtain a reasonably accurate estimate of my effect versus another drug, in each Phase III study.

Analysis groups

Intention To Treat (ITT): All patients who are randomised into the study are included in the analysis, which reflects "real life".

Per Protocol (PP): Patients who do comply with the protocol, representing an "ideal situation".

Safety: Patients who are randomised into the study and take at least one dose of study medication. This allows the effects of the study medication to be seen.

The statistician will have worked with his/her team writing the protocol, including details of the proposed analyses, for example whether one or more analyses will be performed before the study has finished and, if so, what adjustments will be made to the overall p-values to account for multiple analyses. However, before any analyses can be performed, he/she needs to write a **Statistical Analysis Plan** that explicitly states, among other things, what the primary and secondary endpoints are and how they will be analysed. Alternative methods of analysing the data are sometimes proposed in case the assumptions underlying the preferred method of analysis do not hold.

A statistical programmer may help the statistician to write programs in SAS to analyse the data. They will do this well in advance of the study being completed, making sure that they fully understand the data.

After the completion of the Phase III studies the regulatory authorities will be approached with a licence application. If a licence to sell me is granted then post-marketing Phase IV studies will be initiated.

Bias, randomisation and blinding

The importance of randomisation and blinding becomes clear if the patient or investigator, or anyone working with them, already believes that the drug works - this may introduce bias.

Bias: Systematic allocation of drugs, for example personal judgements about how the effectiveness of a drug can influence the data and results.

Randomisation: Allocating treatments to patients in an unpredictable way so that the treatment allocated can not be predicted by the patient or the doctor.

Blinding: Concealing the identification of the treatment, either single blind (from the patient) or double blind (from the patient and investigating doctor), to help to reduce bias in the conduct and assessment of a trial.

Phase IV

The main driving force behind the clinical trials in this phase of research is the marketing strategy which has been put together for my launch, which contrasts with the aims in the previous phases. Unlike Phase III trials inferences need to be made about my use in a wide population, rather than on a tightly defined patient population. The data collected in a marketing study may differ from those in an earlier phase study as patients are often asked to express a preference for different formulations of me, or for different inhaler devices, or for different drugs. At the end of a marketing study the statistician working with the marketing team would like to conclude that I have superior efficacy as well as being safe and part of a cheaper healthcare package for each patient.

Licence Extensions could also be an aim of a marketing study. This can involve proving that a new formulation or dosing regimen is equally effective as the one originally approved, or extending the licence to new patient groups. The same strict regulations guide statisticians working within marketing departments as in the clinical phases, and internal reports are still written. However, the main documents produced from marketing studies are **publications** in medical journals, rather than registration submissions.

Pharmacy and Production

Fewer statisticians work in the pharmacy and production department compared to the clinical trials area, but the number is growing each year. When I am introduced into clinical trials, the statistician supports a variety of aspects of the production process, including its development and the development of quality control methods, validation of the operating parameters, and production of the material required for clinical trials. Later on when I am on the market and being produced by large-scale manufacturing techniques, statisticians are involved in developing and optimising the production process, the transfer to alternative plants, quality control and process monitoring.

During my **development** there are many questions that the statistician can help answer. For example, what are the ranges of temperatures, times, quantities and qualities of raw materials over which I am produced with an acceptable quality? What conditions give the best yield with an acceptable quality? How can the properties the scientists know about me be measured? How can the process be scaled up from a laboratory bench level to large quantity manufacturing?

There are three main statistical techniques which statisticians use in the pharmacy and production department, which differ in their use, depending on the phase of development. **Design of Experiments (DOE)** is used in the development of laboratory experiments which define the processes in optimising yields, as well as in pilot plant experiments to validate the parameter ranges and to validate the production plant. **Statistical Modelling** can also be used for defining, for example, how much variability in the purity of the raw materials can be tolerated. The aim is to establish the tolerance limits for manufacturing, ensuring that important differences in my purity between batches are discernible. **Statistical Process Control (SPC)** is used for validating processes and establishing limits, process capability analysis and control charts.

Later on, when I am in the **production** phase, the questions are different: How will the new process be validated to ensure that I am produced as I was for testing in the clinical trials? How can my quality be monitored so as to ensure that acceptable levels are maintained? How will the statistician ensure that two quality control laboratories will obtain acceptably close measurements of the quality of a product? In production, **factorial experimental designs** can be used to answer questions such as: What impact do changes in the manufacturing process have on me? **Multivariate statistical modelling** investigates the relationships and links between the stages in a manufacturing process.

Regulatory

When all the Phase I-III are complete, the whole history of my development is brought together in the pharmacy, pre-clinical and clinical reports. These form the basis of the **regulatory dossier**. These are submitted to the regulatory authorities, for example the MHRA or FDA.

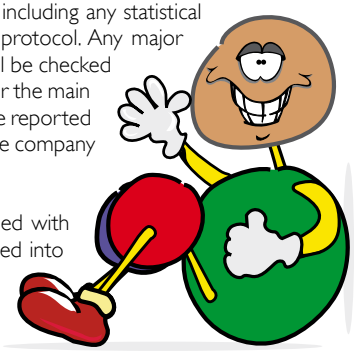
Regulatory Agencies	
USA: Food and Drug Administration	(FDA)
European Union: European Medicines Evaluation Agency	(EMEA)
UK: Medicines and Healthcare Products Regulatory Agency	(MHRA)
Japan: Ministry of Health & Welfare	(MHW)

My assessor at the regulatory authority starts by reading the proposed details of my product labelling along with the clinical summary. Then the guidelines that may be applicable to my development are reviewed. To assess my efficacy, he/she takes particular interest in the CPMP guidelines that summarise underlying medical issues and recommend how trials should be designed and interpreted.

Guidelines	
European Committee for Proprietary Medicinal Products	(CPMP)
International Conference on Harmonisation	(ICH)

The assessor always reads the trial protocol before reading any documents. He/she establishes the planned objectives, the variables that are specified as primary and secondary, the analysis procedures and checks the sample size specification. A review of the randomisation procedure and whether any interim analyses were planned is also undertaken.

The next step is the review of the main study report, including any statistical analysis plan which has been used in addition to the protocol. Any major deviations from the protocol that may affect efficacy will be checked and discussed in the assessment. The statistical output for the main analyses will be checked to assess whether the results are reported appropriately, and whether the conclusions drawn by the company are supportable.



For each trial, the statistical assessment will be discussed with the medical assessor and the results will be incorporated into the medical assessment. In the medical assessment the evidence for efficacy and safety will be judged and a recommendation made about my **risk: benefit** ratio.

The pharmacy, pre-clinical and medical assessments are then combined with the company's reports into one assessment report. The assessment report is reviewed by **CSM**. A **Marketing Authorisation** can be granted if the risk:benefit ratio is favourable.

Committee on Safety of Medicines (CSM):

An independent advisory group of experts. This committee advises on the quality, safety and efficacy, in terms of the risk:benefit in the clinical setting.

However, that is not the end of the regulatory process. Now that I have a national authorisation from the UK, the MHRA will help to take the regulatory dossier to other Member States of the European Union, co-ordinated by the **EMEA**. My sponsoring company may also want to approach the FDA and the Japanese regulatory authorities.

A truck taking a regulatory submission to the MHRA

4. Other statistical roles in the Pharmaceutical Industry

Statistical roles with drug discovery, pre-clinical and clinical trials, pharmacy and production, and regulatory agencies have been described in **The Story of a Drug**. Some roles within other areas of the Pharmaceutical Industry are explained in this section.

Positions for statisticians, within research, development and manufacturing are less common compared to those in clinical development. Some statisticians outside of these areas work closely with scientists and write specific programs so that the scientists can analyse their own data for regular experiments; these programs can be used to implement the principles of experimental design. There is also a great deal of involvement in training scientists in statistical ideas and methods as well as statistical software, so that they can understand and perhaps utilise these methods themselves in consultation with a qualified and experienced statistician.

Biology (Pharmacology)

Experiments are often performed to determine the relative effects of compounds and identify their modes of action. Most experiments are done in cell cultures and tissues; others may involve watching an animal and recording its behaviour. The goals of the experiment may be clear scientifically but more difficult to state as statistical hypotheses. Often the statistician finds a general linear model, a mixed model, a non-linear model or logistic regression most suitable and the challenge is to explain the results when the scientist was expecting a Student's t-test. The ED50 (estimated dose having a 50% effect) is a concept which can bridge the gap between the scientists expectations and the best statistical practice. For example, if a standard compound is known to cause contraction of the pupils and if adding the test compound at several doses reverses this effect, the estimated dose causing 50% reversal would be presented together with a confidence interval.

Developing Devices

Statisticians support scientists in a variety of areas, including the development of equipment which represents the human respiratory system and is used to ascertain how the drug, e.g. from an asthma inhaler device, moves through the system. Such equipment may consist of a number of stages where each stage represents a specific part of the respiratory system. The scientists measure the size of the particles that accumulate at each stage. The results are then analysed by the statistician to determine whether the new device is more effective than an old one at distributing the drug to the appropriate place.

Diagnostics

The diagnosis of a disease is also an essential part of clinical practice, and much medical research is carried out in an attempt to develop and improve methods of diagnosis. Statisticians have a role to play in identifying the important diagnostic question(s) and ensuring that the data collected in the study and the statistical methodology applied will lead to useful and clinically meaningful conclusions.

An example of a diagnostic study is as follows: The results of a liver scan (the test method) are to be compared with a diagnosis based on either autopsy, biopsy or surgical inspection (a reference method). A question asked is: How accurate is the liver scan in predicting abnormal pathology?

Statistical methods for assessing diagnostic accuracy include calculations of **sensitivity** - the proportion of patients with abnormalities who are correctly diagnosed - and, **specificity** - the proportion of patients who are normal and who are correctly diagnosed as normal. Depending on the study, the relative importance of sensitivity and specificity may differ. Other issues, more pertinent to diagnostic studies, are **repeatability and reproducibility**. A diagnostic test should be repeatable and provide consistent results for different assessors.

5. Careers for Statisticians and Statistical Programmers

Statisticians are key players in a drug development project team within the research, development and manufacturing of a pharmaceutical product. Statisticians can be involved in a wide range of activities, including experimental design, sample size and power calculations, data collection, and the analysis, interpretation and presentation of results. To perform well, statisticians need a variety of skills, such as effective communication, computer literacy, good time management and the willingness to learn new scientific areas.

Statisticians almost never work in isolation in the pharmaceutical industry. Project teams are made up of a variety of disciplines. More experienced colleagues will often support a junior statistician. This lends itself to continual learning and will be backed up with more formal training. The future for statisticians who want to progress can go in several directions - as a manager, of people or projects, or as a technical statistical specialist.

Many pharmaceutical companies and contract research organisations (CROs) employ statistical programmers who work closely with the statisticians to carry out a wide range of activities. Their main role is to help design and then program the tables, listings and figures that summarise the data collected during a clinical trial. Statistical programmers are also responsible for developing and validating computer software and macros, both in-house and externally purchased, used by both statisticians and statistical programmers. Career progression opportunities are similar to those for statisticians.

Graduates looking for a career as a statistician or statistical programmer may want to consider joining Statisticians in the Pharmaceutical Industry (PSI) or Royal Statistical Society (RSS) to find out more about the industry and to receive newsletters which advertise jobs. Statistical programmers can join Pharmaceutical Users Software Exchange (PhUSE), a European forum for programmers in the pharmaceutical industry.

6. Working Environment

Statisticians and statistical programmers enjoy a status comparable with other scientific disciplines in the pharmaceutical industry. They also enjoy good working conditions. Most offices in the pharmaceutical industry have modern equipment and very comfortable settings. There are many opportunities to travel abroad to discuss the design of trials, collect information, discuss results and meet with the regulatory authorities. There are also opportunities for temporary or permanent employment abroad as most companies are international. The salaries and benefits are very competitive with statistical posts in other industries.

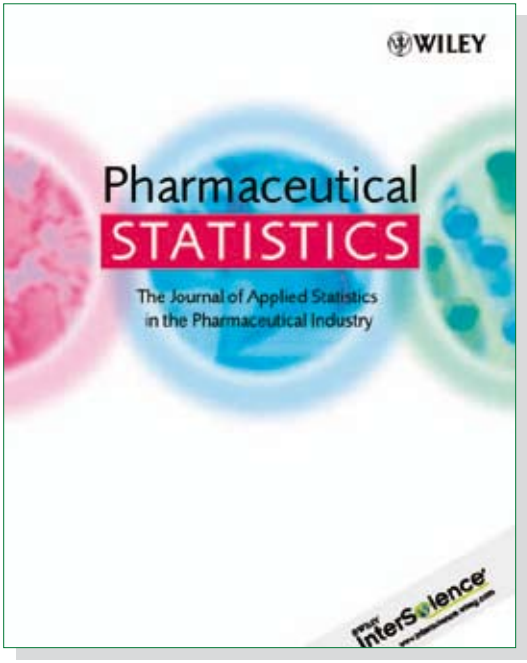
7. PSI - Statisticians in the Pharmaceutical Industry

PSI was formed in 1977 for statisticians, by statisticians, working within the pharmaceutical industry. Its major objectives are to provide a forum for regular discussion on matters relating to the practice of statistics in the pharmaceutical industry, and promote professional standards of statistics in matters pertinent to the pharmaceutical industry. Membership grew quickly, from around 30 in the early years, to over 1100 at present. Members include statisticians and statistical programmers drawn from many pharmaceutical companies and CROs in the UK and mainland Europe. Academic statisticians, consultants and others interested in the application of statistics within the industry are also included as associate members.

The lively and active organisation achieves its objectives in a number of ways. There are scientific meetings held throughout the year, providing ideal opportunities for practising statisticians to meet with their peers from other companies to listen and discuss topics of common interest. This is augmented by the 3-day Annual Conference to which speakers from academia and industry come together to present on statistical methods. PSI acknowledges the need to provide training for new recruits to the industry through its "Introduction to Industry Training" programme consisting of 11 days of training spread over 12 months introducing different aspects of pharmaceutical research. Other ongoing training in statistics is provided through short courses on specific topics organised by PSI in conjunction with other groups. PSI also works closely with organisations such as the RSS and PhUSE to organise and promote joint events.

An example of PSI's proactive involvement in the industry is its journal 'Pharmaceutical Statistics', in collaboration with Wiley. The aim of the journal is to be practical and applied, quite different from many of the other published journals.

There are several sub-committees within PSI which share the responsibility for, amongst other things, co-ordinating scientific meetings and training, giving careers talks, organising the annual conference and publishing the newsletter.



There is regular professional communication within the lively environment of PSI and outside the industry with regulatory authorities, universities, the Medical Research Council (MRC) and other research workers. Industry statisticians play their part in organising and directing the activities of professional societies such as RSS and the Association for Clinical Data Management (ACDM). They also take part in the general research activities by sitting on technical working parties and through the supervision and direction of students at colleges and universities. PSI members are active with other statistical and scientific organisations.

8. Are you up for the challenge?

Pharmaceutical research and development is changing fast and the roles of statisticians and statistical programmers are changing with it. As the innovative new drugs of the last decade go off patent and become established as low cost, safe and effective medicines, so the bar rises for new entries. At the same time, the cost of research and development is rising year on year, while government budgets have come under increasing pressure, making them less willing to pay for new drugs without proof of cost-effectiveness.

For these reasons, the industry is turning to some of the following innovative approaches to drug discovery and development:

- Furthering our knowledge and understanding of the target diseases and the biology of the body, to better pinpoint treatments that may be successful.
- Screening large numbers of molecules for candidates for development using high power computing.
- Systematic review (meta-analyses and data-mining) of any prior research and available data for the disease area and drug class.
- Modelling and simulation based approaches which link information from pre-clinical species and clinical trials.
- Bayesian statistics which allow prior information from expert knowledge or other clinical trials to be used.
- Routine use of efficient trial designs which allow ineffective drugs to be spotted and stopped earlier on. Valuable resources can then be re-directed towards more promising drugs.
- Close partnerships throughout the drug development process to allow fast and efficient development programmes from target identification through to regulatory approval.

In almost all these areas, the role of statistics and statisticians is growing.

Are you up for the challenge?

9. Useful Addresses and Additional Information

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Macclesfield
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http://www.psiweb.org/

Association of the British Pharmaceutical Industry
12 Whitehall
London SW1A 2DY
Tel: 0207 930 3477
http://www.abpi.org.uk/

The Royal Statistical Society
12 Errol Street
London EC1Y 8LX
Tel: 0207 638 8998
http://www.rss.org.uk/

PhUSE Office
64 High Street
BROADSTAIRS
Kent
CT10 1JT
Tel: +44 (0) 1843 608099
http://www.phuse.eu/

Other useful websites	
Food and Drug Agency:	http://www.fda.gov/default.htm
European Medicines Evaluation Agency:	http://www.eudra.org/en_home.htm
Medicines and Healthcare products Regulatory Agency:	http://www.mhra.gov.uk
The European Federation of Statisticians in the Pharmaceutical Industry:	http://www.efspi.org
International Society for Clinical Biostatistics:	http://www.iscb-homepage.org/

Most companies in the pharmaceutical industry will have their own websites

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