



STATISTICIANS IN THE  
PHARMACEUTICAL  
INDUSTRY LIMITED

# PSI Annual Conference | 10



**PSI Conference 2010**  
PSI 33rd Annual Conference  
16th-19th May 2010  
Midland Hotel, Manchester, England

**CALL FOR REGISTRATION**



## **INVITATION**

We invite everyone to join us for the 33rd PSI Annual conference, to be held in Manchester. We have developed the program this year to reflect some of the major issues facing us in the industry today, as well as providing an opportunity to meet with colleagues and old friends from academia. The plenary session and parallel session topics cover issues from meta-analysis to multiplicity, and the role of NICE to ethical issues in clinical trials. We also have a focus in the statistical computing session on CDISC and how they affect the role of the statistician.

Once again, the conference has a full social program planned, including a trip to Old Trafford for dinner on the Monday night, and there will be plenty of opportunities to meet and greet during the meal breaks and outside the main conference program.

This is your conference, and we want you to take part by submitting abstracts for presentations or posters during the conference. If this is something that will interest you, then contact [sharon.richards@i3statprobe.com](mailto:sharon.richards@i3statprobe.com) or [caroline.warman@quintiles.com](mailto:caroline.warman@quintiles.com)

The Conference Committee look forward to seeing you in Manchester next May.

Mike Williams  
Chair, Conference Committee

## **LOCATION & FACILITIES**

The Midland Hotel is situated in Manchester City Centre. The hotel is a short walk or taxi ride from Manchester Piccadilly and Victoria Stations. Up to six trains an hour run from Manchester airport to the city centre, taking just over twenty minutes. Manchester is easily accessible by road (M56 and M61) and the hotel has ample parking on site (charges apply).

PSI conference delegates have access to the hotel's leisure facilities including swimming pool, gym and spa. We hope you will enjoy the extensive and comfortable conference and catering facilities that are included on site for all conference delegates, but if you need to take in some fresh air, you can stroll around Manchester City Centre located right on the doorstep!

## **CONFERENCE REGISTRATION**

Conference registration is open at [www.psiweb.org](http://www.psiweb.org). The full conference fee includes accommodation on the Sunday, Monday and Tuesday nights and all meals taken at the hotel and at Old Trafford, plus entertainment. If you require a paper registration form, please contact the Executive Office. Please note that registration forms need to be submitted by **5pm on Friday 5<sup>th</sup> March 2010 to avoid paying the penalty for late registration.**

Refund policy: All delegates who cancel their booking before 5pm on 5<sup>th</sup> March 2010 will receive a refund less the cost of the hotel charges and an administration charge of £50.00. No refunds will be given for cancellations made after 5pm on 6<sup>th</sup> March 2010, although substitutions may be made. All changes/cancellations must be made in writing to Jenny Butterworth at the PSI Executive Office.

## **PROMOTIONAL OPPORTUNITIES**

For information on our exhibition and sponsorship opportunities at the conference please contact Jenny Butterworth at the Executive Office. This year's exhibition will also host all our lunches, tea and coffee breaks.

## **CONTACT POINT**

Any queries about the conference should be directed to:

Jenny Butterworth  
PSI Executive Office  
Kingston Smith Association Management  
South Park Road  
Macclesfield  
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SK11 6SH

Tel: +44 (0)1625 267882 Fax: +44 (0)1625 267879  
Email: [psiconference@kingstonsmith.co.uk](mailto:psiconference@kingstonsmith.co.uk)

## **SUNDAY 16<sup>th</sup> MAY**

**13.30 – 17.00**

**½ DAY WORKSHOP: MULTIPLE IMPUTATION FOR MISSING DATA IN CLINICAL TRIALS**  
**Speaker: James Carpenter (London School of Hygiene and Tropical Medicine)**

Missing data are ubiquitous in medical research, and raise particular issues as the validity of any analysis depends on inherently untestable assumptions. The aim of this course is to familiarize participants with these issues, and to focus particularly on mixed models and multiple imputation methods for missing data. This will include a discussion of recent and potential future developments.

Specifically the course will:

- \* Introduce the issues involved in analysing missing data, review common jargon and argue for a principled, systematic approach
- \* Review the implications for ITT and 'on- treatment' analysis of clinical trials
- \* Introduce multiple imputation and mixed models for the analysis of partially observed data and discuss their relative merits
- \* Discuss methods for sensitivity analysis

<b>If you wish to register for this ½ day workshop please ensure you complete the relevant section of the registration form.</b>
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**16.00 – 21.00**

**Registration**

**18.00 – 19.30**

**Welcome Drinks Reception**

**19.30 – 21.30**

**Dinner**

## **MONDAY 17<sup>th</sup> MAY**

**08.00 – 09.00**  
**Registration**

**09.15 – 09:30**  
**STEPHEN PYKE – Chair, PSI**  
**Opening Remarks**

**09.30 – 11.00**  
**PLENARY 1**

**THREE QUESTIONS OF META-ANALYSIS**  
**Chair: Stephen Pyke, Pfizer and PSI Chairperson**

**Speakers: Julian Higgins (Medical Research Council), Peter Lane (GlaxoSmithKline), Stephen Senn (University of Glasgow)**

**What makes a good meta-analysis?**  
**Julian Higgins (Medical Research Council)**

Meta-analyses have become established as an influential type of research. However, they have encountered considerable criticism over the years. Much of this is appropriate, since some meta-analyses are better than others. A few tools have been developed to assess the quality of a meta-analysis or systematic review, but none seems to address some of the key statistical issues. I will overview the attributes of what I consider to be a 'good' meta-analysis, and describe the development of a new checklist for assessing the extent to which its results should be believed.

**How has meta-analysis been changing?**  
**Peter Lane (GlaxoSmithKline)**

The PSI Expert Group on Meta-analysis was set up in 2009 to investigate perceived changes in the way meta-analysis is being used. Of particular interest is the quality of analyses carried out by academic and industry groups, and the effect of the move to make trial results available on the Internet. The Group planned a structured search of published analyses, and assessed them using the statistical checklist that they developed. I will present the results of the analysis of these assessments, and relate them to trends in the use of and increasing reliance on this methodology for summarizing evidence about the safety and efficacy of pharmaceuticals.

**What is a random-effects meta-analysis?**  
**Stephen Senn (University of Glasgow)**

The term 'random effect' is used in two different ways in connection with meta-analysis, more usually to indicate that the treatment by trial interaction varies randomly from trial to trial but also sometimes to indicate random variation in the main effect of trial. It is not always appreciated, however, that models that feature the latter permit the recovery of inter-trial information. In doing this they abandon the principle of concurrent control. To avoid this happening it is necessary to treat the trial effect as fixed. Furthermore, even in the case where the trial effect is treated as fixed, random interactions raise the possibility of different definitions of the main effect of treatment. I consider various published approaches to meta-analysis in order to fit them into this framework and conclude that it would be helpful if authors were explicit about models when using such terms.

**11.00 – 11.30**  
**Coffee Break**

**11.30 – 12:30**  
**Annual General Meeting**

**12.30 – 13.30**  
**Lunch**

**13.30 – 15.00  
PARALLEL SESSIONS**

**SESSION 1A                    STATISTICAL COMPUTING: THE FUTURE OF CLINICAL TRIAL REPORTING – IT’S NOT ALL ABOUT THE DATA!**

The Pharmaceutical industry has changed vastly over the last decade. What is the future direction? The increasing industry regulation and focus on reporting quality has increased the pressure for improved speed to market for drug approvals. The development of standards which allow procedures and tools to aid submission review times without compromising quality have been steadily evolving by CDISC (Clinical Data Interchange Standards Consortium) in partnership with both the FDA and Sponsor companies. Until now, most people have associated these standards as data standards; however other key sections of the submission package are known to be under review for standardisation, in particular the protocol, which is likely to be followed by the Statistical Analysis Plan. Currently, the focus has predominately been on the raw and derived data standards. This session will aim to provide thought provoking discussion to highlight the direction of CDISC, and how this will impact on the statistician.

**SESSION 1B                    PRACTICAL APPROACHES TO PHARMACOGENETICS**

Pharmacogenetics is the study of efficacy and/or side-effects of therapeutic agents due to genetic factors. The use of pharmacogenetic testing is viewed by many as a promising opportunity to improve patient care, particularly in the area of drug safety through reducing serious events caused by adverse reactions. However, there are a number of challenges associated with undertaking pharmacogenetic studies, both in terms of design and analysis. This session will take a practical look at some recent work undertaken in the field.

**SESSION 1C                    CONTRIBUTED PAPERS**

**15.00 – 15.30  
Coffee Break**

**15.30 – 17.00  
PARALLEL SESSIONS**

**SESSION 2A                    STATISTICAL COMPUTING: THE REALITY OF CLINICAL TRIAL REPORTING, BACK FROM THE FUTURE**

They say the best way to learn is to observe other people’s experiences! At present, the FDA are stating that they will mandate the use of CDISC standards in electronic submissions from 2013. What does this mean for clinical trial reporting? In the second session devoted to CDISC (Clinical Data Interchange Standards Consortium), this session hopes to share knowledge of other’s submission experiences using CDISC standards, the strategies they undertook, the education required for a new approach, the effect on internal and partnership resource, technologies assessed and implemented, as well as the key areas that the statistician has to concentrate on.

**SESSION 2B                    BIOSIMILARS**

Session details to be confirmed

**SESSION 2C                    CONTRIBUTED PAPERS**

**17:00  
Close**

**19.30  
Evening event at Old Trafford**

## TUESDAY 18<sup>th</sup> MAY

09.15 – 10.45  
PLENARY 2

### **PHARMACEUTICAL STATISTICS: THE PEOPLES' CHOICE.**

**Chair: Alan Ebbutt**

**Speakers: Professor Andy Grieve (Kings College) and Kevin Carroll (Chief Statistical Expert, AstraZeneca)**

This session will build on the very successful previous "editor's choice" sessions at previous conferences. The top 2 downloaded papers from Pharmaceutical Statistics have been chosen and will be presented by their authors. These papers are "**25 years of Bayesian methods in the pharmaceutical industry: a personal, statistical bummel**" by Professor Andy Grieve and "**Biomarkers in drug development: friend or foe? A personal reflection gained working within oncology**" by Kevin Carroll. Initially an overview of these papers will be presented, followed by a discussion facilitated by Alan Ebbutt. So why not read the papers prior to the session and join in the discussion at the end.

References:

**25 years of Bayesian methods in the pharmaceutical industry: a personal, statistical bummel.** *Pharmaceutical Statistics Volume 6, Issue 4, Date: October/December 2007, Pages: 261-281.* Andrew P. Grieve.

**Biomarkers in drug development: friend or foe? A personal reflection gained working within oncology.** *Pharmaceutical Statistics Volume 6, Issue 4, Date: October/December 2007, Pages: 253-260.* Kevin J. Carroll.

10.45 – 11.15  
Coffee Break

11.15 – 12.45  
PARALLELSESSIONS:

SESSION 3A

### **MULTIPLE COMPARISON AND GATE KEEPING PROCEDURES (TUTORIAL)**

**Presenters: Frank Bretz and Willi Maurer (Novartis)**

The first part of this tutorial starts with a general introduction to the problem of multiple comparisons. Explanations of some basic concepts are given (experiment-wise and family-wise error rate, false discovery rate, etc.), as well as an overview of some common methods for dealing with multiple comparisons. At the end of this session, the audience should be able to identify when it is necessary to adjust for multiple comparisons, and select an appropriate adjustment. In the second part, we introduce iterative graphical approaches to construct and extend powerful multiple testing procedures, including fixed sequence tests, gate keeping and fallback procedures. The graphical approach is illustrated with several examples from real clinical trials.

SESSION 3B

### **ETHICS AND STATISTICS IN CLINICAL TRIALS**

**Chair: Dr Les Huson (Imperial College/London Research Ethics Committee)**

**Speakers: Rosemary Hill CStat (Chair, Outer North London Research Ethics Committee), Professor Jane Hutton (University of Warwick), Professor Diana Kornbrot (University of Hertfordshire) Professor Stephen Senn University of Glasgow)**

Compliance with the standards set out in the ICH E6 Guideline on Good Clinical Practice "provides public assurance that the rights, safety and well-being of trial subjects are protected", and this fundamental ethical requirement should underlie all of the work done by statisticians in clinical trials. The talks in this session will deal with some of the key ethical considerations that impact on statistical work, and will outline some of the principles and concerns of IRBs and Research Ethics Committees.

**SESSION 3C****STATISTICAL COMPUTING: KNOWLEDGE MANAGEMENT STREAM**

What is Knowledge Management (KM), and why is it so important to each and every one of us? It allows us all to have ready access to knowledge within our companies, via the sharing and therefore exploitation of information and expertise. A knowledge-sharing culture enables us to improve productivity and collaboration, facilitate learning and innovation and so improve performance.

But, what does this mean in practice? e.g. an I.T. system, such as a data mining facility or a search engine from which information can be retrieved and utilised; the sharing of 'lessons learned' across projects within a central repository, or a knowledge directory to store knowledge embodied in experts/experienced colleagues. By adopting KM as an integrated way of working, the approach can help individuals and groups to share valuable information which can lead to continuous improvement of organisational strategy, to reduce redundant work, to avoid 're-inventing the wheel', to reduce training time for new employees, to retain intellectual capital in spite of employee turnover, and to adapt to changing environments and markets.

This session will look at the issues, challenges and benefits of implementing KM within the Pharma industry.

**12:45 – 13:45****Lunch****13.45 – 15.15****PARALLEL SESSIONS****SESSION 4A****MULTIPLE COMPARISON AND GATE KEEPING PROCEDURES (TUTORIAL CONTINUED)****SESSION 4B****GETTING YOUR RESULTS ACROSS – WHAT MAKES A GOOD POSTER?****Speaker: Donald Patterson (Amgen)**

Posters are a great way of communicating ideas or results at a conference. At many medical and scientific conferences the majority of presentations are in poster form. So how can you ensure that your poster stands out from the rest and ensures the maximum exposure to your ideas or study results? In this session, we will be looking at what makes a good poster, including breaking down some of the design elements such as readability, legibility, organization and succinctness.

**SESSION 4C****STATISTICAL COMPUTING: THE CHANGING FACE OF STATISTICAL SOFTWARE IN THE INDUSTRY**

There is an abundance of statistical software available within the industry today. The reasons for software application development include usability, increasing industry regulation and compliance requirements, improving data/output quality, available technologies and the format type of our clinical data. If you think that SAS is the only application used within the pharmaceutical industry, you'd be mistaken. This session will highlight some of these applications, identify the associated pros and cons and specialist areas that they were developed for, and how they have evolved over the years.

**15.15 – 15.45****Coffee Break**

**15.45 – 17.15  
PARALLEL SESSIONS**

**SESSION 5A                    AS OTHERS SEE US: SOFT SKILLS FOR STATISTICIANS**  
**Chair: Rebecca Sudlow, (Roche Products Ltd)**

This session will focus on the non-technical skills that a statistician needs to possess in order to be effective in the medical research / pharmaceutical development. Speakers (non-statisticians) from industry and recruitment will share their perspectives on what makes an effective statistician.

**SESSION 5B                    CONTRIBUTED PAPERS**

**SESSION 5C                    SHOULD I SPLIT OR SHOULD I POOL? SUBGROUPS AND INTERACTIONS IN CLINICAL TRIALS**  
**Chair: Stephen Senn (University of Glasgow)**

**Speakers: Willi Sauerbrei (Institut fuer Medizinische Biometrie), Beat Neuenschwander, Michael Branson (Novartis Pharma AG),**

The old joke goes that a statistician is someone who with one foot in ice and the other in boiling water says that on average (s)he is comfortable. Scientists in many other disciplines, in particular clinicians, are convinced that statisticians are far too ready to put together that which should be kept apart. In this session we shall consider what statisticians should do in order to steer a sensible middle course between a 'one size fits all' mentality and data dredging.

Presentations to include:

Bayesian shrinkage approaches to subgroup analysis in clinical trials  
Beat Neuenschwander, Michael Branson (Novartis Pharma AG)

**17.15  
Close**

**18.00 – 19.30  
Poster Session & Drinks Reception**

For more information about submitting a poster, please email Sharon Richards at [sharon.richards@i3statprobe.com](mailto:sharon.richards@i3statprobe.com) or Caroline Warman at [caroline.warman@quintiles.com](mailto:caroline.warman@quintiles.com).

**19:30  
Gala Dinner, Midland Hotel**

## **WEDNESDAY 19th MAY**

**09.30 – 11.00**  
**PLENARY 3**

### **RISK MANAGEMENT PLANS** **Chair: Dr Lesley Wise (MHRA)**

Ongoing regulatory initiatives and stories in the popular press highlight the importance of sponsor companies actively planning and conducting an ongoing assessment of the risk profile of their products. This management of risk should be conducted throughout development and through the product's marketed life. This session will combine case studies of methods to manage the risk of pharmaceutical products from different stages of development with informed discussion on the requirements of formal risk management plans and will seek to describe the contribution that statisticians can make to the appropriate evaluation of risk.

**11.00 – 11.30**  
**Coffee Break**

**11.30 – 12.45**  
**PLENARY 4**

### **REIMBURSEMENT V REGULATORY SUBMISSIONS: HOW THEY DIFFER AND WHY** **STATISTICIANS NEED TO BE INVOLVED WITH BOTH**

Speakers from both NICE and the regulatory authorities will share on the use of HTA tools in the assessment of cost effectiveness assessment for new drugs, and provide insights into the issues that arise in this controversial area. Speaker names and abstracts will appear on the PSI website as they are confirmed.

**12:45 - 13:00**  
**Closing remarks**  
Stephen Pyke: Chair, PSI

**13.00**  
**Lunch and Close**

## **EXHIBITION SPACE**

This year's exhibition will be held in a spacious area near the main conference rooms at the Hilton Hotel. This year we are offering two-day stands – available on the Monday and Tuesday of the conference.

The cost of a stand for two days is £1750. These prices include day-exhibitor passes for up to two stand members – stand space costs are VAT exempt. Dinner, bed and breakfast costs are additional. Companies must provide their own public liability insurance.

## **SPONSORSHIP**

By sponsoring or exhibiting at the conference, you will have the opportunity to promote your product or service to around 200 delegates from industry representatives from across the UK and Europe. Regular attendees at our conference include senior managers and influential decision-makers from all major pharmaceutical companies and CROs in the UK and Europe. As ever, we anticipate attracting a good cross-section of younger statisticians, keen to learn and progress within the industry.

There are a number of ways in which you can become involved. If you're looking for broad exposure, platinum sponsorship is the ideal way to ensure delegates are constantly aware of your brand. Spaces in the busy exhibition area are always keenly sought-after with coffee breaks and lunches taking place in the same area to give you maximum interaction with delegates. This year sees some new sponsorship options for the PSI conference including wireless internet/room key wallets for each delegate, promotional gifts and student place sponsorship.

For all sponsorship and exhibition enquiries, contact Jenny Butterworth at the PSI Executive Office – Email: [admin@psiweb.org](mailto:admin@psiweb.org), Tel: +44 (0) 1625 267882, Fax: +44 (0) 1625 267879

## **ADVERTISING**

PSI provides a monthly mailing to all its members and a quarterly magazine, in both of which advertising space is also available. In addition, advertising is available on the PSI website, [www.psiweb.org](http://www.psiweb.org). For further information about advertising please email [admin@psiweb.org](mailto:admin@psiweb.org).



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