Pharma IQ's 2nd Annual

Including brand new product specific case studies!

Signal Detection & Data Mining Strategies

Providing practical know-how for detecting and assessing adverse reactions in post-marketed drugs

Pre-conference workshops • 5th December 2006
Two day conference • 6th & 7th December 2006
Swissotel The Howard • London

Network and learn with Europe's leading signal detection experts and discover innovative ways of improving your signal detection systems:

- Discover novel statistical approaches from the GPRD
- Learn from AstraZeneca's experience in signal detection for cancer therapies
- Compare new automated systems with more traditional methods of data mining
- Gain insight into signal detection in the real life of mid-sized pharma companies
- Develop successful long term strategies for signal detection

Pre-conference workshops: 5th December 2006

New for 2006!

09.00 – 12.00
A Practical Guide to Writing a Risk Management Plan
Led by Nawab Qizilbash, Director of OXON Clinical Epidemiology Ltd.

13.00 – 16.00
Signal Detection Strategies for Paediatric Treatments
Led by Steve Simon, Biostatistician, Childrens Mercy Hospitals

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Wolfgang Schumann, Head of Global Medical Safety Surveillance, **Schering AG**

Steve Simon, Biostatistician, **Childrens Mercy Organisation**

Nawab Qizilbash, Director, **OXON Clinical Epidemiology Ltd**

Pauline H. Gerritsen-van Schieveen, Senior Director Drug Safety and Pharmacovigilance European Qualified Person for Pharmacovigilance, **Astellas Pharma Europe BV**

Phillip Berry, Global Medical Director, Reckitt Benckiser Healthcare International Ltd

Larry Gould, Senior Director Scientific Staff, **Merck Inc**

Antoni Wisniewski, Senior Drug Safety Scientist, **AstraZeneca**

Tjeerd van Staa, Head of GPRD Research, **MHRA**

William Maier, Director of Epidemiology, **Elan Ltd**

Ulrich Vogel, Medical Advisor Corporate Safety Evaluation, **Boehringer Ingelheim GmbH**

Hans Mosberg, Head of Corporate Drug safety and Pharmacovigilance, **Altana Pharma**

Dona M. Ely, Associate Director, Safety Surveillance, Global Product Safety, **Cephalon**

Alfonso Carvajal, Professor of Pharmacology,Instituto de Farmacoepidemiología, **Universidad de Valladolid**

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Signal Detection & Da

Workshops: 5th December 2006

09.00- 12.00

A Practical Guide to Writing a Risk Management Plan

You know how important risk management is and not having a thorough understanding of it increases your company's regulatory risk. But how do you formulate accurate and compliant developmental and post-approval risk management plans for every new product?

This workshop will dissect the risk management plan and discuss strategies for developing standard operating procedures and planning to plug important data gaps for your product. A series of case examples will teach you how to overcome obstacles, proactively seek the information needed, including gathering observational data on potential signals, and allow you to discuss the best approaches to solve problems in an open forum.

Led by Nawab Qizilbash *MD MSc DPhil (Oxon.)* **Director of OXON Clinical Epidemiology Ltd**, Nawab is Director of OXON Clinical Epidemiology Ltd.; and consultant geriatrician/honorary senior lecturer in epidemiology, St. Mary's Hospital, Imperial College, London University; and Member of Green College, University of Oxford. His consultancy and contract research company specialises in epidemiology and risk management and safety, using EU/US databases, EU/US registries, and spontaneous reporting databases, and carrying out EU/US post-marketing surveillance studies, and safety-related related training and multimedia products. Each area draws on people with experience.
Dr Qizilbash was Director of Epidemiology at GlaxoSmithKline, 1997-2005 and formerly honorary consultant physician/senior research fellow, Oxford University, where he worked and published with Sir Richard Peto in epidemiology, phase IV trials and meta-analysis.

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12.00 – 15.00

Signal Detection Strategies for Paediatric Treatments

Signal detection and pharmacovigilance are already highly regulated and challenging fields, but once you factor in children as your patient group these challenges become even greater. There are physiologic, ethical, and statistical questions that you must consider for some (but not all) efforts in post marketing surveillance.

Discuss openly with your peers the issues that complicate drug safety studies in children and recognise when these issues apply and when they don't apply. Look at and debate the merits of alternative data sources, research designs, and statistical analyses to balance the sometimes conflicting needs of regulators, drug companies, and ethical review boards.

Led by Steve Simon, *Biostatistician,* **Childrens Mercy Hospitals**, Steve earned a Ph.D. in Statistics from the University of Iowa in 1982. He currently works as a research biostatistician at Childrens Mercy Hospitals and Clinics in Kansas City, MO. He has co-authored over 60 peer reviewed publications in a variety of medical, scientific, and statistical journals. He recently published a book, Statistical Evidence in Medical Trials, through Oxford University Press. He is the architect and designer of StATS (Steve's Attempt to Teach Statistics) a widely cited web site with over one thousand pages and has contributed material to two other prominent web sites: Chance News and Wikipedia.

Conference Day One: December 6th 2006

08.30 **Coffee and Registration**

09.00 **Opening Remarks from the Chair**

09.05 **Developing Successful Long-Term Drug Safety Strategies for an Uncertain Future**
Post market surveillance is not a recent phenomenon but the events of the past 2 years have thrown it into the limelight. A more stringent regulatory landscape, increased media and customer scrutiny is driving significant changes in the pharmaceutical industry. This opening presentation will discuss the challenges currently faced by industry and what the future holds for the field of medical surveillance and pharmacovigliance.
Wolfgang Schumann, Head of Global Medical Safety Surveillance, **Schering AG**

09.50 **A Combinatorial Approach to Signal Detection for Respiratory Adverse Reactions**
So much work has gone on in the field over the last few years concerning the potential link between serious/fatal adverse events and use of different drugs.
This talk discusses the alternative approaches and outcomes of different studies and highlights the benefits and flaws of a specific study.
- Which databases are more appropriate for respiratory studies
- Integrating epidemiological studies
- Combining the different studies already done what pieces are we still missing? Where do we go from here?
- What are the regulatory implications of the findings?

William Maier, Director of Epidemiology, **Elan Ltd**

10.35 **Refreshment Break**

11.00 **Best Practices for Combining Manual and Medical Opinion with Statistical Analysis**
- Aligning your early statistical analysis and computational findings with medical opinion on signal detection and prioritisation
- Determining the most relevant information for medical analysis
- What aggregate spontaneous data can contribute - and what it can't
- Looking beyond in-house data: cross-database signal detection

Ulrich Vogel, Medical Advisor Corporate Safety Evaluation, **Boehringer Ingelheim GmbH**

11.45 **Control Charts for Continuous Monitoring of the Number Needed to Harm**
While most of the efforts in signal detection use newly developed data mining algorithms that are both complex and computer intensive, there is still room in your research arsenal for simpler approaches that have withstood the test of time, like the statistical process control chart. By applying a straightforward data transformation, you can use the control chart to monitor the Number Needed to Harm (NNH), an easily interpreted measure of absolute risk.
- Identify those situations where simple control charts are preferable, but also recognize their risks and limitations
- Adapt different decision rules and alternate control chart formats to increase your sensitivity for small but consistent shifts in risk
- Establish rational targets for the NNH that balance the benefits of a new drug against its risks

Steve Simon, Biostatistician, **Childrens Mercy Organisation**

12.30 **Lunch**

13.45 **Signal matching: Effectively Managing and Monitoring Databases**
- Key Factors when determining which database to use: Severity, rarity and potential adverse effect, class and mode of drug use and geographical representation
- A comparative look at accessible medical and claims databases
- Matching signal types to the most appropriate database
- Requirements for properly utilising databases
- Maintaining knowledge and training to make informed decisions

Nawab Qizilbash, Director, **OXON Clinical Epidemiology Ltd**; and Honorary Consultant Geriatrician and Honorary Senior Lecturer in Epidemiology, St Mary's Hospital, **Imperial College, London**

14.30 **Strategies for Improving Data Quality**
Internally collected data is the most meaningful source for signal detection. No matter what the size of the database the quality can always be improved and increasing the quality of data ensures better evaluation results.

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ta Mining Strategies

- Data quality: Individual and in numbers
- Data from studies vs. other reports
- Data repositories: Accessibility, data selection and queries
- Presentation / Visualisation

Hans Mosberg, Head of Corporate Drug safety and Pharmacovigilance, **Altana Pharma**

15.15 **Refreshment Break**

15.45 **Risk Management and Signal Detection in the Real Life of a Middle Sized Company**
Past presentations from the big pharma companies provided lots of theory and brilliant ideas. But how can you implement these in smaller companies, especially those with a big portfolio of older products or generic products? The role of headquarters has been explained, but what is the role of the local DSO?
- How should we document risk management and signal detection?
- What procedures are needed?
- How should we be prepared for inspections?

Pauline H. Gerritsen-van Schieveen, Senior Director Drug Safety and Pharmacovigilance, European Qualified Person for Pharmacovigilance, **Astellas Pharma Europe BV**

16.30 **Signal Detection at Reckitt Benckiser Healthcare International**
Even if products are well established in the market and the potential for adverse reactions is low it is still important to show due diligence and devise a compliant process for signal detection.
- How regulatory compliance was achieved and how the inspection was passed
- What are the methods for evaluating signals and what are the thresholds for evaluation
- What people are involved in the process

Philip Berry, Global Medical Director, **Reckitt Benckiser Healthcare International Ltd**

17.15 **Close of Day One**

Conference Day Two: December 7th 2006

08.30 **Coffee and registration**

09.00 **Chair's Opening Comments and Recap of Day One**

09.05 **Post-marketing Reports of Seizure in Non-epileptic Patients Using an Antileptic Off-label**
In this case series, we will present an interesting situation in which the safety signal was in fact, an expected event in the treated population. The use of the product off-label resulted in a difficult case series analysis.

Evolution of a signal resulting from an expected event:
- Individual case review
- Internal pharmacogivilance data base review and preliminary case series development
- Standard analyses including event frequency, analysis by body system etc.
- Multivariate analysis undertaken of preliminary case series

Pharmacovigilance analysis of identified signal to evaluate strength of hypothesis:
- Pharmacokinetic and pharmacodynamic statistical analysis of confounders in population of those with event of interest and those without event of interest
- Longitudinal analyses – Dose, time to onset, duration
- Case cluster by reporter
- Demographic analysis – Age, sex, comorbidities
- FOI analysis of product and comparator medications
- Reporting rate and increased frequency analysis

Risk management of identified risk:
- Labeling Changes
- Educational Campaign
- Risk Map Development

Dona M. Ely, Associate Director, Safety Surveillance & **Robert M. Gordon,** Manger, Global Product Safety, **Cephalon**

10.00 **Refreshment Break**

10.30 **Dealing with Uncertainty: A Breast Cancer Case Study**
Not all safety signals will provoke unequivocal responses or obvious courses of action. Confounding by indication is a common problem in evaluating safety signals, not least in the breast cancer setting. How do we deal with weak signals and the uncertainty that surrounds them? The answer is not to rely on a single source of information but to make use of all the available evidence. In this case study, we follow the processes and considerations involved, from detecting a weak signal to an eventual change in the reference safety information.
Antoni Wisniewski, Senior Drug Safety Scientist, **AstraZeneca**

11.15 **Case Study: Hepatotoxicity signals found in new antidepressants**
Through national databases and spontaneous reporting systems specific new Antidepressant drugs were found to be hepatotoxic. This case study discusses how the signals were identified and evaluated.
- What methods were used?
- Who was involved in the process?
- How were comparisons made and conclusions drawn?
- How were the findings relayed to physicians and what effect did they have of the safety information?

Alfonso Carvajal, Professor of Pharmacology, Instituto de Farmacoepidemiología, **Universidad de Valladolid**

12.00 **Product and purpose breakout brain storming session**
Conference tables will breakout to discuss the specific challenges facing them. The benefits of national, international and internal databases and varying statistical approaches will be analysed. This session provides interactive learning for specific challenges depending on the product and company size.
Points to be raised:
- Challenges facing different sized companies
- Automated vs. traditional approaches
- Specific obstacles involved with off label use, Generics and drug/drug interactions

12.30 **Feedback from brain storm session**
Each table leader will present the most interesting and valuable points from their discussions to the whole group, allowing all delegates further insight into each topic and allowing for more debate.

12.45 **Lunch**

14.00 **Case study: Novel Approach to Signal Strengthening**
Current approaches to signal detection do not evaluate the possible impact of safety signals and the methods for interpreting safety signals are often based on "gut feeling". A novel approach has been developed to improve our understanding of the signals that need further evaluation.
- What were the challenges that needed to be overcome?
- How was the approach developed and what are the tangible improvements?
- What is the regulators view of this approach and what developments continue?

Tjeerd van Staa, Head of GPRD Research, **MHRA**

14.45 **A New Statistical Approach Using Bayesian Screening Principles**
There is increasing interest in statistically-based quantitative data mining techniques for identifying potential drug toxicities from large spontaneous reporting databases, among other sources. There is, however, no consensus in the pharmacovigilance community as to how they might be used most effectively. Part of the difficulty is that there is no "gold standard" against which the diagnostic properties of these methods can be evaluated. This presentation describes a statistical approach using Bayesian screening principles that has attractive properties, in particular:
- Straightforward interpretation: the metric is the probability that the finding for a drug-event pair represents a 'signal'
- Diagnostic properties can be determined analytically and by simulation
- Good control of diagnostic error rates, especially False Discovery

Larry Gould, Senior Director Scientific Staff, **Merck Inc**

15.30 **Refreshment Break**

16.00 **Signal Detection in Prescription-Event Monitoring**
The Drug Safety Research Unit (DSRU) is dedicated to monitoring the safety of newly marketed drugs in England using Prescription-Event Monitoring (PEM) primarily and other techniques when appropriate. This presentation will describe the methods and techniques used for the detection of drug safety signals in PEM.
- How the data is collected, coded and stored
- What monitoring and analysis techniques are used to detect signals
- How can signals be evaluated in the framework of PEM?
- Specific case study examples and findings

Germano Ferreira, Research Fellow, **Drug Safety Research Unit (DSRU)**

16.45 **Chair's closing remarks and end of conference**

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