2nd DIA Conference on Signal Detection and Data Mining: 
International Perspectives on Individual Case Safety Reports 
and Other Healthcare Data Sets

Event #09029
November 17-18, 2009  Tutorial: November 16
New York Marriott Marquis, New York, NY, USA

PROGRAM COMMITTEE
Andrew Bate, PhD, MA
Director, Quantitative Epidemiologist
Pfizer Inc, United States

Manfred Hauben, MD, MPH
Senior Director, Risk Management Strategy
Pfizer Inc, United States

François Maignen, PharmD (Internship), MSc (Paris), MSc (London)
Principal Scientific Administrator
European Medicines Agency (EMEA), European Union

Niklas Norén, PhD
Manager, Research and Development
Uppsala Monitoring Centre, WHO, Sweden

CONTACT INFORMATION
Conference:  Ben Zaitz, Phone +1-215.293.5803
email  Benjamin.Zaitz@diahome.org
Exhibits: Jeff Korn, Phone +1-215.442.6184
email  Jeff.Korn@diahome.org

CONFERENCE OVERVIEW
There is a growing interest in using screening of other sources of real
world medical information such as insurance claims data and elec-
tronic patient records for emerging safety issues, developing computa-
tional methods which do not rely on disproportionality analysis
such as self-controlled case series or temporality techniques.
This conference will address all aspects of signal detection and data
mining (covering the methodological aspects, the clinical interpreta-
tion as well as the international harmonization initiatives).

WHO SHOULD ATTEND
Professionals involved in:
• Pharmacovigilance and safety
• Risk management
• Clinical safety assessment
• Pharmacoepidemiology
• Clinical development of medicines
• Statistics
• Regulatory affairs
• Labeling

FEATURED TOPICS
• Future for analysis of spontaneous reports and other healthcare
data with potential applicability to pharmacovigilance
• Signal detection successes resulting from data mining sponta-
neous reports, with a discussion on the pitfalls, evaluation and
validation of the methods and real-world implementation
• Update on the networks of pharmacoepidemiology and the use of
longitudinal/ observational databases for signal detection purposes
• Update on CIOMS VIII working group on signal detection and
management
• FDA Sentinel Initiative and the Observational Medical Outcomes
Partnership (OMOP)
TUTORIAL DAY | MONDAY, NOVEMBER 16

12:30-1:30 PM  TUTORIAL REGISTRATION

1:30-5:00 PM  TUTORIAL
Data Mining in and Beyond Individual Case Safety Reports – What it is, Why it is Done and Common Pitfalls and Misunderstandings

This tutorial will provide theoretical and methodological review of the application of data mining techniques to signal detection/safety surveillance, and the critical role of clinical case assessment. An overview of strategies and specific situation applications will be presented.

LEARNING OBJECTIVES
- Understand the basic concepts of data mining and principles of signal detection;
- Identify specific applications of data mining technology;
- Describe how drug safety issues will be detected faster and more effectively in the future;
- Explain and apply the skills needed to make real-world strategic decisions in signal detection in your respective institution;
- Develop a skill set/knowledge base to adapt to situations presenting new aspects that don’t fit the usual “textbook” data mining illustrations; and
- Develop a basic understanding of new methods and data sets such as electronic patient records.

TARGET AUDIENCE
This tutorial is designed to prepare you for the rest of the conference – specifically for those professionals new to or experienced in pharmacovigilance and whose responsibilities require a detailed understanding of data mining and signal detection. This tutorial will be beneficial for the individuals involved in the areas of pharmacovigilance, risk management and clinical safety assessment, pharmacoepidemiology, clinical development of medicines, statisticians, regulatory affairs and labeling.

Manfred Hauben MD, MPH
Senior Director, Risk Management Strategy
Pfizer Inc

Niklas Norén PhD
Manager, Research and Development
Uppsala Monitoring Centre, WHO
Sweden

DAY 1 | TUESDAY, NOVEMBER 17

7:00-8:00 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:05 AM  WELCOME AND OPENING REMARKS
Andrew Bate, PhD, MA
Director, Quantitative Epidemiologist
Pfizer Inc

Manfred Hauben, MD, MPH
Senior Director, Risk Management Strategy
Pfizer Inc

8:05-10:30 AM
Signal Detection and Data Mining: Where We Are Today

SESSION CHAIRPERSONS
Andrew Bate, PhD, MA
Director, Quantitative Epidemiologist
Pfizer Inc, United States

Francois Maignen, PharmD, MSc, MSc
Principal Scientific Administrator
European Medicines Agency (EMEA), EU

This session will present the state of the art in terms of quantitative signal detection strategies in Individual Case Safety Reports. Major pharmacovigilance organizations will present their most up-to-date experience including a presentation of the significant adverse drug
reactions identified as a result of data mining Individual Case Safety Reports. Results of two major research initiatives will be presented along with discussion of how to gauge signal detection quality/performance. The possibility of major improvements in signal detection capability in Individual Case Safety Reports with further methodological innovation will also be considered.

**Data Mining Successes and the Results from the PhRMA-Funded Evaluation of Data Mining Methods**

**Manfred Hauben, MD, MPH**  
Senior Director, Risk Management Strategy  
Pfizer Inc

**The Public Health Evaluation of Quantitative Methods of Signal Detection: Results of a Performance Study Conducted on EudraVigilance - Future Challenges and Perspectives**

**Jim Slattery**  
Scientific Administrator, Pharmacovigilance and Risk Management  
European Medicines Agency (EMEA), EU

**State of the Art**

**Andrew Bate, PhD, MA**  
Director, Quantitative Epidemiologist  
Pfizer Inc

10:30-11:00 AM  REFRESHMENT BREAK

11:00 AM -12:30 PM  
**New Challenges: Methods, Data Sets, and Paradigms**

This session will discuss new and emerging methods, paradigms, procedures and data sets to allow for more effective identification of safety issues than is possible with the standard range of signal detection methods currently in routine use to screen Individual Case Safety Reports.

**Use of Temporality Techniques in Signal Detection: Parametric Modeling of Time to Onset of Adverse Drug Reactions**

**Francois Maignen, PharmD (Internship), MSc (Paris), MSc (London)**  
Principal Scientific Administrator, Pharmacovigilance and Risk Management  
European Medicines Agency (EMEA), EU

**Novel Bayesian Methods**

**Stephen Evans, BA, MSc, CStat, FRCP (Edin)**  
Professor, London School of Hygiene and Tropical Medicine, UK

3:00-3:30 PM  BREAK

3:30-5:00 PM  
**New Challenges: Methods, Data Sets, and Paradigms – continued**

**The Self-Controlled Case Series for Adverse Drug Reaction Surveillance**

**Carlos Vallarino, PhD**  
Manager, Post-Marketing Safety Statistics  
Takeda Global Research & Development

**Temporal Pattern Discovery in Longitudinal Patient Records**

**Niklas Norén, PhD**  
Manager, Research and Development  
Uppsala Monitoring Centre, WHO, Sweden

5:00-6:00 PM  RECEPTION

DAY 2 | WEDNESDAY, NOVEMBER 18

7:30-8:30 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM  
**Current and Changing Practices in Data Mining**

**Session Chairpersons**

**Niklas Norén, PhD**  
Manager, Research and Development  
Uppsala Monitoring Centre, WHO, Sweden

**Manfred Hauben, MD, MPH**  
Senior Director, Risk Management Strategy  
Pfizer Inc

Pharmacovigilance practice may be optimized by a holistic approach utilizing a comprehensive suite of clinical and quantitative methods and data sets. This involves numerous decisions about what, how and where to implement the different components of a signal detection program, including the relative positioning of clinical versus quantitative surveillance, how to choose from the various available software solutions, specific regional requirements and whether and how organizations should commence using additional data sets for routine signal detection. This session will provide information to facilitate such decision making.

The FDA Sentinel Initiative: Overview, Challenges and Future Directions

**Judy Racoosin, MD, MPH**  
Sentinel Initiative Scientific Lead, Office of Critical Path Programs, Office of the Commissioner, FDA
Clinical Aspects of Signal Detection: The Need for Qualitative Methods
Professor Saad A.W. Shakir, MD, FRCP, FISPE
Director
Drug Safety Research Unit

The Evaluation of Off-the-Shelf Data Mining Products: Points to Consider
Vaishali Patadia, MPH, RD
Director & Head, Pharmacoepidemiology Product Safety and Pharmacovigilance
Astellas Pharma

How Is and Does Signal Detection Need to Change in the Asia Pacific?
E. Stewart Geary, MD
Vice President
Eisai Co., Ltd., Japan

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM
Good Practices in Signal Detection
With over a decade of intense attention to the application of quantitative signal detection methods to Individual Case Safety Reports by large organizations, smaller organizations continue to ponder whether and how to implement data mining, and other readily available data sets are being increasingly considered as potentially fertile targets for quantitative signal detection. This session will address initiatives in this area – specifically with an international perspective and with real-world examples.

Signal Triaging
Aparna Mohan, MD, PhD
Senior Director, Pharmacovigilance Analytics
Johnson & Johnson Pharma R&D

Improving the Analysis of Clinical Safety Data from Interventional Clinical Trials: From the Signal Detection to the Safety Specification
Pamela J. Bradt, MD, MPH
Senior Medical Director, Global Health Economics and Outcomes Research and Clinical Epidemiology
Abbott Laboratories

From Data Mining to Product Safety Profile: The Safety Signal Sojourn at Genzyme
Margaret (Meg) Richards, PhD
Director, Global Patient Safety and Risk Management
Genzyme Corporation

12:00-1:00 PM LUNCHEON

1:00-2:30 PM
Good Practices in Signal Detection (continued)

CIOMS VIII: Recommendations on Signal Detection
Meredith Y. Smith, PhD, MPA
Senior Scientific Director, Risk Management Pain Care and Immunology
Global Pharmaceutical Research & Development
Abbott Laboratories

A Vision for the Future of Signal Detection
Ivor Ralph Edwards, MB ChB (Birmingham), MRCS, LRCP (London), MRCP (UK), FRCP (London), FRACP
Medical Advisor
Uppsala Monitoring Centre, WHO, Sweden

2:30-3:00 PM QUESTION AND ANSWER PERIOD

3:00-3:15 PM CLOSING REMARKS AND MEETING ADJOURNMENT

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.
2nd DIA Conference on Signal Detection and Data Mining: 
*International Perspectives on Individual Case Safety Reports and Other Healthcare Data Sets* 

**Event #09029 • Tutorials: November 16 • Workshop: November 17-18, 2009** 
New York Marriott Marquis, New York, New York, USA

**Contact Information**  
See page 2 for event and exhibit contacts.

**Registration Fees**  
If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

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Join DIA now to qualify for the early-bird member fee!  
www.diahome.org/Membership

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonmember members.

**Nonmember Fee**  
US $1635 □

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

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**Discount Fees**  
**MEMBER**  
Government (Full-time)  
US $395 □  
US $535 □

Charitable Nonprofit/Academia (Full-time)  
US $755 □  
US $895 □

If paying a nonmember fee, please check one box above, indicating whether you want membership.

**TUTORIAL: MONDAY, NOVEMBER 16**  
1:30-5:00 pm

Data Mining in and Beyond Individual Case Safety Reports  
What it is, Why it is Done and Common Pitfalls and Misunderstandings

**TO RECEIVE A TABLETOP EXHIBIT APPLICATION, PLEASE CHECK □**

**GROUP DISCOUNTS**  
Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does not include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.

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**PAYMENT OPTIONS:**  
Register online at www.diahome.org or check payment method.

- **CREDIT CARD** number may be faxed: +1.215.442.6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

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- **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 950000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

- **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. if applicable, will be included on the transfer document to ensure payment to your account.

**TRAVEL AND HOTEL**  
La Guardia, Kennedy, and Newark Airports are conveniently located and airline reservations should be made as early as possible to ensure availability. Amtrak’s Penn Station is located several blocks from the New York Marriott Marquis. For Amtrak reservations, call 1-800-USARAIL. The New York Marriott Marquis is holding a block of rooms at the reduced rate below until October 23, 2009, for DIA meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

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Please contact the New York Marriott Marquis by telephone at 212-398-1900 and mention the DIA event. The hotel is located at 1535 Broadway, New York, NY 10036, USA.

**CANCELLATION POLICY:**  
On or before NOVEMBER 9, 2009

Administrative fee that will be withheld from refund amount:  
Member or Nonmember = $200  
Government or Academia or Nonprofit (Member or Nonmember) = $100  
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for non-member fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

**Please check the applicable category:**

- Academia  
- Government  
- Industry  
- CSO  
- Student  

(Call for registration information)

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