SMi MASTERCLASS SERIES 2014

SMi LINKING BUSINESS *with* INFORMATION

SMi presents its 2014 masterclass on

Quantitative Benefit – Risk Assessment for the New PSUR and Risk Minimisation

2nd DEC 2014
Central London

Hosted by:
Andrew Maguire, Director, Global Epidemiology & Database Services
Ignacio Mendes, Director, Outcomes & Statistics,
Nawab Qizilbash, Head,
OXON Epidemiology Ltd.

About the Masterclass:

The EMA expects MAHs to submit the new PSUR (PBRER) which marks a paradigm shift. The PSUR will change from being largely a document based online listings, narratives and simple sales-based incidence statistics to a benefit-risk tool with a much more statistical and quantitative approach to adverse event data, and including the incorporation of efficacy data. Risk minimisation measures have negative as well as positive consequences and these should be evaluated. The masterclass will provide attendees with the necessary exposure to approach the elements of benefit-risk analysis for the new PSUR in their company for new and old drugs and approaches to evaluate the positive and negative effects of risk minimisation measures.

Key benefits of attending:

- Understand the requirements of the European GVP legislation for the New PSUR
- Appreciate the concepts behind quantitative BRA and why and when quantification is necessary
- Understand the process for undertaking BRA and the evidence and data requirements
- Describe the role of quantitative models in BRA and understand regulatory expectations including the current opinion of the European working groups
- Understand methodological options available and their pros and cons
- Appreciate the principles and practice of statistical BRA including the advantages and disadvantages of the principal methods
- Discuss how to implement/optimise BRA for the new PSUR in your company for old and new products, and learn what other companies are implementing
- Learn approaches to evaluate the negative and positive effects of risk minimisation measures.

In association with:

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MC389

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MASTERCLASS AGENDA

09.00 Registration and Coffee

09.30 Welcome and introductions

09.45 Regulatory expectations for the new PSUR (PBRER)
- Implementation
- Compliance
- System tracking
- Quality
- Auditability
- Links with RMP & Signal detection

10.30 Understanding quantitative concepts (1)

11.00 Morning Coffee

11.20 Understanding quantitative concepts (2)

12.00 Methodologies of benefit-risk assessment
- Approaches with advantages and disadvantages

13.10 Lunch

14.00
- Statistical methods
- Data requirements
  - Clinical efficacy/effectiveness data
  - Safety data
  - Patient reported outcome efficacy data
  - Meta-analysis of efficacy and safety data
  - Statistical signal analysis
  - Preferences and values

15.20 Afternoon Tea

15.40 Discussion: Planning for the new PSUR for new and old products in your company

16.15 Evaluation of the positive and negative effects of additional risk minimisation plans

17.15 Review of the day

17.30 End of Masterclass

About your masterclass leaders:

Andrew Maguire BSc MSc FSS, Director of Global Epidemiology & Database Services at OXON Epidemiology's Centre for Real World Secondary Data, London. Andy is a statistical epidemiologist who has specialised in databases and quantitative benefit-risk analysis. He worked in the epidemiology departments of Pharmacia and Pfizer and subsequently at GPRD and THIN in the UK. Andy's last post was as Director of Epidemiology and Database Analytics for Europe for a US multinational scientific service provider. In this role he led a group of epidemiologists and programmers undertaking real world pharmacoepidemiological research using medical databases, epidemiological modelling as well as epidemiological and burden of disease support for the pharmaceutical sector. He has developed a benefit-risk model with ex-European regulators. He has published in Lancet, among many other journals. He has recently authored a book chapter on quantitative benefit risk analysis and has used BRA models in regulatory submissions (FDA and EMA).

Ignacio Mendez VMD MPH, Director of HEAOR & Field Analytics at OXON Epidemiology's Centre for Real World Field Studies, Madrid. Ignacio has more than 17 years of experience in epidemiology, health economics, patient-reported outcomes and associated statistical methodologies. He specialises in the application and analysis of PROs and health economic measures in observational and PASS studies. He is currently a member of the ENCePP HTA task force of the EMA.

Nawab Qizilbash MBChB MRCP(UK) BSc MSc DPhil(Oxon.) Clinical Epidemiologist & Head at OXON Epidemiology and; Honorary Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine; Honorary Consultant Geriatrician, Madrid; Member of Green-Templeton College, Oxford University and ENCePP-nominated 'EMA Expert'. Co-author of x5 Lancet, x1 JAMA and x3 BMJ publications in epidemiology, trials and meta-analysis. Chief editor of the internationally authored textbook: ´Evidence-based Dementia Practice´ published by Blackwells, Oxford. Nawab was formerly: Director of Epidemiology & EBM at GlaxoSmithKline (1997-2005); Honorary Consultant Physician, Radcliffe Infirmary, Oxford; and chief editor of the Cochrane Dementia Group.

About OXON

OXON is a consultancy and CRO based in London and Madrid that specialises in ´real word data´(www.oxonepi.com): Epidemiology (field and database studies and patient registries), Safety (PASS studies, statistical signal analysis, benefit-risk analysis, risk management), HEOR, Meta-analysis, development of concept protocols, and Evidence strategy for pre-and post-approval products. OXON provides the highest standards: an **ENCePP centre** of the European Medicines Agency with: a nominated **'EMA Expert'**, membership of the Steering, Multi-data Source and HTA Groups, and Chair of the Data Integration Group; co-authors of (x6) Lancets; an academic affiliation with the London School of Hygiene & Topical Medicine; world renowned consultants with EMA and FDA experience: medical statistician, **Professor Stuart Pocock.** A 5-year alliance with the **10th largest global CRO** provides operational support for pan-European, Asian and Latin American projects.

QUANTITATIVE BENEFIT –RISK ASSESSMENT FOR THE NEW PSUR AND RISK MINIMISATION

2nd December 2014, Central London

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Cancellation: If you wish to cancel your attendance at an event and you are unable to send a substitute, then we will refund/credit 50% of the due fee less a £50 administration charge, providing that cancellation is made in writing and received at least 28 days prior to the start of the event. Regretfully cancellation after this time cannot be accepted.

Alterations: It may become necessary for us to make alterations to the content, speakers, timing, venue or date of the event compared to the advertised programme.

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I would like to attend:	Fee		Total
☐ Masterclass:	**£599.00**	**+VAT**	**£718.80**

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