

SMi Presents their 2014 masterclass on

Risk Minimisation Measures: Implementation, Evaluation and Results of EU Studies

15th
JULY
2014
Central London

Hosted by: Dr Nawab Qizilbash, Head, Geriatrician
and Epidemiologist, Oxon Epidemiology and
Dr Sabine Straus, Member of the Pharmacovigilance Risk Assessment
Committee (PRAC) of the EMA

Hosted by:



Overview:

Learn about risk minimization studies, their implementation and evaluation in Europe from two EMA experts: a regulator on the EMA PRAC committee and a clinical pharmacoepidemiologist at ENCePP.

Why should you attend this masterclass::

- Discuss your challenges in risk minimisation
- Evaluate effectiveness of planned and ongoing risk minimisation
- Learn from real-life case studies and exercises
- Analyse the principles of risk management
- Increase effective alignment of risk studies and regulators
- Gain insights into the benefits of using an evidence-based toolkit

Who should attend:

Staff involved in risk management plans, PASS studies and risk minimisation studies:
Departments of Pharmacovigilance, Epidemiology, Medical Affairs, Regulatory Affairs and
Statistics.

www.smi-online.co.uk/xxxxx.asp

Register online and receive full information on all of SMi's conferences
Alternatively fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711
GROUP DISCOUNTS AVAILABLE

MC380



www.smi-online.co.uk/xxxxx.asp

Register online and receive full information on all of SMI's conferences
Alternatively fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711
GROUP DISCOUNTS AVAILABLE

FULL DAY PROGRAMME

09.00	Context and regulatory background	15.00	Review of the results of risk minimisation measures
09.30	GVP regulations for risk minimisation	15.30	Afternoon Coffee
09.40	Levels of risk minimisation measures for regulators	15.45	Usefulness of benefit-risk analysis
11.00	Morning coffee	16.15	Challenges and ways forward
11.20	Available tools and guidance at the EU level	16.45	How to discuss risk minimisation measures and studies with regulators
13.00	Lunch	17.05	Using an evidence based tool kit
14.00	How to select risk minimisation measures	17.30	End of masterclass
	- Designs and data sources to evaluate the effectiveness of risk minimisation measures		

About your masterclass leader:



Dr Nawab Qizilbash MBChB MRCP(UK) BSc MSc DPhil(Oxon.) 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 nominated '**EMA Expert**'.

Co-author of x5 Lancet, x1 JAMA and x3 BMJ publications in epidemiology, trials and meta-analysis. Chief editor of: 'Evidence-based Dementia Practice'.

Nawab was formerly: Director of Epidemiology at GSK (1997-2005); Honorary Consultant Physician, Radcliffe Infirmary, Oxford; and chief editor of the Cochrane Dementia Group.

Dr Sabine Straus, Member of the **Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA** since 2012 and Staff Member of the Medicines Evaluation Board, Utrecht.

Sabine was **formerly Head of Pharmacovigilance at the Medicines Evaluation Board**, Utrecht; Associate Professor, Erasmus Medical Centre, Rotterdam; Senior Assessor Pharmacovigilance Medicines Evaluation Board.

Memberships include: European Medicines Agency (EMA) working parties: Member Incident Review Network (IRN) and European Risk Management Facilitation Group (ERMS).



About OXON:

OXON is a consultancy and CRO based in London and Madrid that specialises in 'real word data'(HYPERLINK "<http://www.oxonepi.com>" www.oxonepi.com): Epidemiology (field and database studies and patient registries), Safety (statistical signal analysis, benefit-risk analysis, risk management), HEOR, Meta-analysis and Evidence strategy for pre-and post-approval products. OXON provides the highest standards: an HYPERLINK "<http://www.encepp.eu/encepp/viewResource.htm?id=3657>" ENCePP centre of the European Medicines Agency with: a nominated 'EMA Expert', membership of the Steering, the Multi-data Source and the HTA Groups, and Chair of the Data Integration Group; co-authors of (x6) Lancets; an academic affiliation with the London School of Hygiene & Tropical Medicine; world renowned consultants with EMA and FDA experience: medical statistician HYPERLINK "http://en.wikipedia.org/wiki/Stuart_Pocock" Professor Stuart Pocock. A 5-year alliance with the 10th largest global CRO provides operations for pan-European, Asian and Latin American projects.

RISK MINIMISATION MEASURES: IMPLEMENTATION, EVALUATION AND RESULTS OF EU STUDIES

Tuesday 15th July 2014, Central London

4 WAYS TO REGISTER

ONLINE www.smi-online.co.uk/xxxxx.asp

FAX your booking form to +44 (0) 870 9090 712

PHONE on +44 (0) 870 9090 711

POST your booking form to: Events Team, SMi Group Ltd, 2nd Floor
South, Harling House, 47-51 Great Suffolk Street, London, SE1 0BS

--	--

Unique Reference Number	
Our Reference	MC380

DELEGATE DETAILS

Please complete fully and clearly in capital letters. Please photocopy for additional delegates.

Title: Forename: _____

Surname: _____

Job Title: _____

Department/Division: _____

Company/Organisation: _____

Email: _____

Address: _____

Town/City: _____

Post/Zip Code: Country: _____

Direct Tel: Direct Fax: _____

Mobile: _____

Switchboard: _____

Signature: Date: _____

I agree to be bound by SMi's Terms and Conditions of Booking.

ACCOUNTS DEPT

Title: Forename: _____

Surname: _____

Email: _____

Address (if different from above): _____

Town/City: _____

Post/Zip Code: Country: _____

Direct Tel: Direct Fax: _____

Terms and Conditions of Booking

Payment: If payment is not made at the time of booking, then an invoice will be issued and must be paid immediately and prior to the start of the event. If payment has not been received then credit card details will be requested and payment taken before entry to the event. Bookings made within 7 days of the event require payment on booking.

Substitutions/Name Changes: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. Two or more delegates may not 'share' a place at an event. Please make separate bookings for each delegate.

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. Regrettably 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.

Data Protection: The SMi Group gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. Unless you tick here we may also share your data with third parties offering complementary products or services. If you have any queries or want to update any of the data that we hold then please contact our Database Manager databasemanager@smi-online.co.uk or visit our website www.smi-online.co.uk/updates quoting the URN as detailed above your address on the attached letter.

MASTERCLASS PRICE

I would like to attend:	Fee	Total
<input type="checkbox"/> Masterclass:	£599.00 +VAT	£718.80

FUTURE MASTERCLASSES

I would be interested in attending a Masterclass on the following topic or area:

PAYMENT

Payment must be made to **SMi Group Ltd**, and received before the event, by one of the following methods **quoting reference MC380 and the delegate's name. Bookings made within 7 days of the event require payment on booking, methods of payment are below. Please indicate method of payment:**

UK BACS Sort Code **300009**, Account **00936418**

Wire Transfer Lloyds TSB Bank Plc, 39 Threadneedle Street,
London, EC2R 8AU
Swift (BIC): **LOYDGB21013**, Account **00936418**
IBAN **GB48 LOYD 3000 0900 9364 18**

Cheque We can only accept Sterling cheques drawn on a UK bank.

Credit Card Visa MasterCard American Express

All credit card payments will be subject to standard credit card charges.

Card No:

Valid From /

Expiry Date /

CVV Number 3 digit security on reverse of card, 4 digits for AMEX card

Cardholder's Name: _____

Signature: Date: _____

I agree to be bound by SMi's Terms and Conditions of Booking.

Card Billing Address (if different from above): _____

VENUE

Please contact me to book my hotel

Alternatively call us on +44 (0) 870 9090 711,
email: hotels@smi-online.co.uk or fax +44 (0) 870 9090 712

VAT

VAT at 20% is charged on the attendance fees for all delegates.