2nd Joint DIA/EMA ENCePP Information Day

Event #11118
7 November 2011
European Medicines Agency, London, UK

Programme Committee

Arlett Peter
ENCePP Steering Group Chair, Head of Pharmacovigilance and Risk Management Sector, European Medicines Agency (EMA), EU

Persson Ingemar
ENCePP Steering Group Vice Chair, Senior Expert, Medical Products Agency (MPA), SE

Faculty

Stella Blackburn, Risk Management Development and Scientific Lead, European Medicines Agency (EMA), EU

Kevin Blake, Scientific Administrator, European Medicines Agency (EMA), EU

Corinne de Vries, Professor of Pharmacoepidemiology, Department of Pharmacy & Pharmacology University of Bath, UK

Henry Fitt, Head of Coordination and Networking Section, European Medicines Agency (EMA), EU

Klaas Heinemann, Managing Director, Center for Epidemiology and Health Research (ZEG), DE

Jytte Lyngvig, Chief Executive Officer, Danish Medicine Agency, DK

Susana Perez-Gutthann, Head Epidemiology, RTI Health Solutions, ES

Stefanie Prilla, Scientific Administrator, European Medicines Agency (EMA), EU

Annalisa Rubino, Scientific Administrator European Medicines Agency (EMA), EU

Gabriel Schnetzler, Director, Prism Ideas, CH

Jim Slattery, Scientific Administrator, European Medicines Agency (EMA), EU

Miriam Sturkenboom, Professor Pharmacoepidemiology, Erasmus University, NL

Overview

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is a project led by the European Medicines Agency (EMA) to bring together the available expertise and research experience in the fields of pharmacoepidemiology and pharmacovigilance across Europe in a Network of Excellence. There are now over 100 partners registered in ENCePP including academic research and medical care centres, healthcare databases, electronic registries and existing networks. The details of all these partners are public and are readily accessible to all parties with an interest in post authorisation medicines research in the fully searchable ENCePP Resources Database.

The aim of the ENCePP project is to further strengthen post authorisation medicines research in Europe by facilitating the conduct of high quality, multicentre, independent studies focusing on safety and benefit/risk. To encourage this, ENCePP has developed the concept of an 'ENCePP Study', which is any pharmacoepidemiology or pharmacovigilance study that fulfils a number of requirements in terms of transparency, independence and methodological standards and is carried out in collaboration with an ENCePP partner.

In addition, ENCePP has launched an electronic Register of Studies which provides a free and publicly accessible site for the registration of all pharmacoepidemiological and pharmacovigilance studies, including non-interventional studies and clinical trials.

Key Topics

The key topics will relate to the consolidation of ENCePP as the network for non-interventional research in Europe and will cover aspects of pharmacoepidemiology and pharmacovigilance of most current interest.

The principles contained in the ENCePP Code of Conduct will be illustrated with a special focus on the provisions that have been revised to take account of the experience gained so far with its application.

This Information Day will also give the opportunity to hear how the ENCePP Guide on Methodological Standards in Pharmacoepidemiology will serve as an important tool for learning and assuring high quality pharmacoepidemiological studies that benefit public health.

This event represents an occasion to receive feedback from representatives from regulatory authorities, industries and academia on the role of ENCePP in post authorisation research.

Learning Objectives

The audience will become familiar with the key ENCePP principles and associated tools and their applicability throughout the whole research process.

ENCEPP

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA®
www.diahome.org

Who Will Attend

This programme will benefit

- All pharmaceutical industry staff, in particular those responsible for risk management plans and post authorisation studies (e.g. pharmacovigilance, pharmacoepidemiology and regulatory affairs).
- Academics, regulators, editors of medical journals, funding bodies and other professionals specialising in the field of observational research.

Details of the Information Day

Location: European Medicines Agency
Canary Wharf
7 Westferry Circus
London E14 4HB, UK

Capacity: The event is limited to 135 participants

What is ENCePP?

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®) is a project led by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. Its goal is to further strengthen the postauthorisation monitoring of medicinal products in Europe by facilitating the conduct of multi-centre, independent, post authorisation studies focusing on safety and on benefit/risk, using available expertise and research experience across Europe. This network of excellence comprises relevant research centres, medical care centres, healthcare databases, electronic registries and existing European networks covering certain rare diseases, therapeutic fields and adverse drug events of interest.

ENCePP Steering Group

Peter Arlett (Chair),
European Medicines Agency, London / UK

Ingemar Persson (Vice Chair),
Karolinska Institutet, Stockholm / SE

Stella Blackburn,
European Medicines Agency, London / UK

Corinne de Vries,
University of Bath / UK

Hans-Georg Eichler,
European Medicines Agency, London / UK

Henry Fitt,
European Medicines Agency, London / UK

David Haerry,
European AIDS Treatment Group, Brussels / BE

Joan-Ramon Laporte,
Fundació Institut Català de Farmacologia, Barcelona / ES

Hubert Leufkens,
College ter Beoordeling van Geneesmiddelen / NL

Jytte Lyngvig,
Lægemiddelstyrelsen - Danish Medicines Agency / DK

Nicholas Moore,
Université Victor Segalen, Bordeaux / FR

Yola Moride,
Faculty of Pharmacy, Université de Montréal / CA

June Raine,
Medicines and Healthcare Products Regulatory Agency, London / UK

Miriam Sturkenboom,
Erasmus University, Rotterdam / NL

Giuseppe Traversa,
Istituto Superiore di Sanità, Rome / IT

MONDAY | 7 NOVEMBER 2011

08:30 **Registration**
Welcome coffee

09:15 **Welcome Note and Introduction**
Noel Wathion, Head of Patient Health Protection, EMA, EU

Chairpersons for the whole day:
Jytte Lyngvig, Ingemar Persson

09:30 **Session 1**

INTRODUCING ENCePP

This session will provide background information on the ENCePP initiative, how it has started, its evolution and the current status.

09:45 **Topic 1**
Importance of post authorisation studies as a means for risk management of products
Ingemar Persson, MPA, SE

Survey of PASS requested by the CHMP
Henry Fitt, EMA, EU

ENCePP Studies sponsored by industries: the experience so far
Klaas Heinemann, ZEG, DE

Panel Discussion

11:00 **COFFEE BREAK**

11:15 **Session 2**

ENCePP GUIDING PRINCIPLES: INDEPENDENCE, TRANSPARENCY, STANDARDS

A key element of ENCePP is to uphold high standards throughout the research process based on the principles of transparency and scientific independence. To this end, the concept of an 'ENCePP Study' is introduced to identify those studies which are conducted in line with the 'ENCePP Code of Conduct'. The E-Register of Studies was released in November 2010 and provides a publicly accessible resource for the registration of studies. Over the past year ENCePP has produced further important tools to assist in the implementation of these standards.

ENCePP Code of Conduct
Stefanie Prilla, EMA, EU

Role of ENCePP in fostering methodological aspects of research
Susana Perez-Gutthann, RTI Health Solutions, ES

Research Centres, Networks & Data Sources
Kevin Blake, EMA, EU

Panel Discussion

12:45 **SANDWICH LUNCH**

13:20 Session 3

ADDRESSING CHALLENGES TO CONDUCTING RESEARCH

The declared goal of ENCePP is to further strengthen the post authorisation monitoring of medicinal products in Europe by facilitating the conduct of multi-centre, independent, post authorisation studies. In addition to providing a publicly accessible platform gathering the expertise in pharmacovigilance and pharmacoepidemiology scattered across Europe, over the last year ENCePP has also been used as an influential voice on a number of policies directly affecting the conduct of research such as the upcoming revision of Directive 2001/20 on clinical trials and the review of Directive 95/46/EC on data protection.

Strength of the network
Miriam Sturkenboom, Erasmus University, NL

Definition of non-interventional trial
Gabriel Schnetzler, Prism Ideas, CH

Data protection: challenges to the conduct of multi-national studies
Corinne de Vries, University of Bath, UK

Panel Discussion

15:00 COFFEE BREAK

15:15 Session 4

ENCePP IN A CHANGING SCENARIO

July 2012 will see the application of the new EU pharmacovigilance legislation requiring important changes to the existing regulatory processes both for Competent Authorities and Marketing Authorisation Holders. This new public health legislation will have an important impact on the future development of ENCePP and will contribute in shaping the agenda of post authorisation research of medicines. During this session the implementing measures foreseen by the new legislation will be presented alongside the future direction of ENCePP in this changing scenario.

Implementing the new pharmacovigilance legislation
Kevin Blake, EMA, EU

Oversight of non-interventional safety studies
Annalisa Rubino, EMA, EU

ENCePP's role in future action: HTA, paediatrics, rare diseases
Jim Slattery, EMA, EU

Panel Discussion

16:45 Conclusions
Stella Blackburn, EMA, EU

17:00 END OF INFORMATION DAY

Upcoming DIA Training Courses on Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing
3-7 October 2011 | Zagreb, HR | ID 11548

How to Prepare for Pharmacovigilance Audits and Inspections
November 2011 | Location to be confirmed | ID 11570

Introduction to Signal Detection and Data Mining in Pharmacovigilance
November 2011 | Location to be confirmed | ID 11569

Medical Approach in Diagnosis and Management of ADRs
19-20 September 2011 | Paris, FR | ID 11530

EudraVigilance Information Day at the European Medicines Agency
15 November 2011 | London, UK | ID 11522

Information Day on the Development Safety Update Report (DSUR) Guidelines ICH E2F
04 July 2011 | London, UK | ID 11591

IDMP Information Day at the European Medicines Agency
22-23 September 2011 | London, UK | ID 11524

ICSR Information Day at the European Medicines Agency
16 November 2011 | London, UK | ID 11525

ICSR Technical Implementation Training at the European Medicines Agency
17 November 2011 | London, UK | ID 11526

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
13 September 2011 | London, UK | ID 11552
6 December 2011 | London, UK | ID 11553

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org
> Training > EudraVigilance > Click on > Related Courses

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.

HOTEL INFORMATION

Recommended Hotel:

Hilton London Docklands Riverside
265 Rotherhithe Street, London , SE16 5HW, UK

Telephone: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599

Email: reservations.docklands@hilton.com

DIA was able to negotiate a special rate for participants of the Information Day: Room rate is GBP 129.00 per room incl. breakfast excl. VAT

Please book before 6 October 2011.

REGISTRATION FORM

2nd Joint DIA/EMA ENCePP Information Day
7 November 2011 | European Medicines Agency, London, UK

ID # 11118

DIA www.diahome.org

Registration includes participant material, coffee breaks and sandwich lunch. The event is limited to 135 participants.
FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52 OR EMAIL TO DIAEUROPE@DIAEUROPE.ORG

Standard fee	€ 300.00 ❑
Reduced Fee for Academia and Full Government	€ 150.00 ❑

NOTE: PAYMENT OF REGISTRATION FEES MUST BE RECEIVED BEFORE COMMENCEMENT OF THE COURSE

TOTAL AMOUNT DUE: €_____ NOTE: PAYMENT IS DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION 11118DIA

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ Please charge my credit card - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ VISA ❑MC ❑ AMEX

Card Number

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ **Bank transfers**: 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. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 11118 as well as the invoice number to ensure correct allocation of your payment.
Payments must be net of all charges and bank charges must be borne by the payer.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00
Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA Europe Postfach, 4002 Basel, Switzerland