ENCePP Information Day

Event #10115
26 November 2010
De Vere Venues Canary Wharf, London, United Kingdom

Programme Co-Chairs

Noël Wathion
Head of Patient Health Protection, Regulatory Affairs and Pharmacovigilance, European Medicines Agency, EU

Jytte Lyngvig
Chief Executive Officer, Danish Medicines Agency, Member of ENCePP Steering Group, Denmark

About the Drug Information Association (DIA)

DIA serves more than 30,000 biopharmaceutical professionals from industry, academia and regulatory agencies worldwide. Through its domestic and international meetings, training courses, workshops and webinars, DIA provides a neutral global forum for the exchange of information critical to the advancement of the drug discovery and lifecycle management processes.

Headquartered in Horsham, PA, USA, and with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China, the Association is led by its volunteer-based Board of Directors and executive management team. For more information, visit www.diahome.org or call DIA in Europe +41 61 225 51 51.

Background

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 scattered across Europe in a Network of Excellence, comprising research and medical-care centres, healthcare databases, electronic registries and existing networks. The number of centres collaborating with ENCePP has risen from 56 in 2007 to around 90 research organisations and data sources in 20 European countries and currently registered in a publicly accessible and fully searchable Resource Database.

The aim of the ENCePP project is to further strengthen the postauthorisation monitoring of medicinal products in Europe by facilitating the conduct of high quality, multicentre, independent postauthorisation studies focusing on safety and benefit risk. In order to achieve this ENCePP collaborating centres have developed, together with the EMA, the concept of an ENCePP study. Briefly, ENCePP studies are any pharmacoepidemiology or pharmacovigilance study carried out by an ENCePP collaborating centre that signs up to the following principles before the study commences:

- An ENCePP Code of Conduct for scientific independence and transparency, which is essentially a set of business rules between the study funder and the investigator
- A checklist of methodological standards for study protocols
- Registration of the study in the ENCePP electronic registry of pharmacoepidemiology and pharmacovigilance studies before the study commences

The ENCePP Steering Group has recently been established. It includes representatives from the EMA, the Committee for Medicinal Products for Human Use (CHMP), the PharmacoVigilance Working Party (PhVWP), Heads of Medicines Agencies, Patients and Consumers Working Party, learned societies (ISPE and ISoP) and ENCePP collaborating centres. They have recently adopted the ENCePP Code of Conduct and the checklist of methodological research standards for study protocols following extensive public consultation.

Who Will Attend

The target audience of this event is primarily pharmaceutical industry staff responsible for risk management plans and post-authorisation studies (e.g. pharmacovigilance, pharmacoepidemiology and regulatory affairs professionals), as well as other interested professionals including academics, regulatory, editors of medical journals and other professionals specialising in the field of observational research.

SwAPP and SGPM Credits

DIA meetings are generally approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available on request from the registration desk.

FINAL PROGRAMME

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA®
www.diahome.org

FRIDAY |26 NOVEMBER, 2010

08:00 **Registration and welcome coffee**

08:45 **Welcome Address and Introduction**
Thomas Lönngren, Executive Director, European Medicines Agency, European Union

09:00 **SESSION 1**
INTRODUCING ENCePP

Session Chairperson:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU

Importance of Post-authorisation Studies
Valerie Simmons, Lilly QPPV Executive, Global Patient Safety, Eli Lilly and Company Ltd., UK and European Federation of Pharmaceutical Industries and Associations (EFPIA)

The EMA and Drug Safety Studies: Overview and history of ENCePP
Stella Blackburn, Business Coordination and Scientific Projects Pharmacovigilance and Risk Management, Patient Health Protection Unit, European Medicines Agency, EU

Research Centres, Networks and Data Sources
Camilla Smeraldi, Pharmacovigilance and Risk Management, Patient Health Protection Unit, European Medicines Agency, EU

Panel discussion
With all speakers and Hans-Ulrich David Haerry, European AIDS Treatment Group, Belgium

10:30 **Coffee break**

11:00 **SESSION 2**
PILLARS of ENCePP

Session Chairperson:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency, EU

Common Issues with Pharmacoepidemiology Studies: Standards and transparency
Bert Leufkens, Chairman, Medicines Evaluation Boards (MEB), The Netherlands

Checklist of Methodological Standards for ENCePP Study Protocols
Kevin Blake, Scientific Administrator, Pharmacovigilance and Risk Management, Patient Health Protection Unit, European Medicines Agency, EU

ENCePP Code of Conduct
Stefanie Prilla, Pharmacovigilance and Risk Management, Patient Health Protection Unit, European Medicines Agency, EU

Panel discussion
With all speakers

12:30 **Lunch break**

13:30 **SESSION 3**
REGISTRATION AND ENCePP STUDIES

Session Chairperson:
Jytte Lyngvig, Chief Executive Officer, Danish Medicines Agency, Member of ENCePP Steering Group, Denmark

Post-authorisation Studies: New legislation
Peter Arlett, Head of Pharmacovigilance and Risk Management, European Medicines Agency, EU

The Need to Register Studies before They Start
Ingemar Persson, Senior Expert, Medical Products Agency, Sweden

The ENCePP Electronic Registry of Studies
Rocio Fernandez, Pharmacovigilance and Post-authorisation Safety and Efficacy of Medicines, European Medicines Agency, EU

15:00 **Coffee break**

15:30 **SESSION 4**
BRAVE NEW WORLD

Session Chairperson:
Jytte Lyngvig, Chief Executive Officer, Danish Medicines Agency, Member of ENCePP Steering Group, Denmark

ENCePP: Future developments
June Raine, Chair of PhVWP, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Concept of "ENCePP Study" - How will ENCePP change the way we work?
Peter Arlett, Head of Pharmacovigilance and Risk Management, European Medicines Agency, EU

Panel discussion
With all speakers and Hans-Ulrich David Haerry, EATG Representative, European AIDS Treatment Group, Belgium

17:00 **Conclusions**
Stella Blackburn, Business Coordination and Scientific Projects Pharmacovigilance and Risk Management, Patient Health Protection Unit, European Medicines Agency, EU

17:10 **End of Information Day**

ENCePP INFO DAY LOCATION

DE VERE Canary Wharf
1 Westferry Circus,
London E14 4HA, UK
Tel. +44 (0)844 980 2327
Fax. +44 (0)20 7353 9291
www.devere.co.uk

TRAVEL INFORMATION

The De Vere venue in Canary Wharf is located in one of London's premier business areas. There are fast links to central London by Westferry DLR station and the Jubilee Underground line is just a five-minute walk away. For more details on the DLR go to:

http://www.tfl.gov.uk/assets/downloads/dlr-route-map.pdf

REGISTRATION FORM

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ID# 10115

www.diahome.org

Registration includes participant material, coffee breaks and lunch.

Standard Fee Industry	**EUR 500.00** ❑
Reduced Fee for Academia and Full Government	**EUR 250.00** ❑

Special discount for SME (status confirmed by EMA) available. Please contact DIA Europe.

Note: Payment of registration fees must be received before commencement of the event.

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.

10115DIA

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__ Document Management/eSubmissions
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__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Affairs
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❑ **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# 10515 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.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

All cancellations must be in writing and received at the DIA office by 17:00 CET on 19 November 2010

Cancellations received by this date are subject to an administrative fee of EUR 100.00.

Registrants who do not cancel five working days prior to the course start date and do not attend, 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 registrants. Registrants 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 registrants 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. If you have not received your confirmation within five working days, please contact DIA.**

HOW TO REGISTER

The DIA 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 European Office Postfach, 4002 Basel, Switzerland