

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.

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:

Noël Wathion, Head of Patient Health Protection, Regulatory Affairs and Pharmacovigilance, 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

Henry Fitt, Head of Coordination & Networking Section, 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:

Noël Wathion, Head of Patient Health Protection, Regulatory Affairs and Pharmacovigilance, 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

Xavier Kurz, Principal 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

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

The Need to Register Studies before they start

Ingemar Persson, Senior Assessor, MPA and Adjunct Professor in Pharmacological Epidemiology at the Department of Medical Epidemiology and Biostatistics, Karolinska Institute, Sweden

The ENCePP Electronic Registry of Studies

Rocio Fernandez, Pharmacovigilance and Risk Management, Patient Health Protection Unit, European Medicines Agency, EU

Concept of “ENCePP Study” - How will ENCePP change the way we work?

Peter Arlett, Head of Pharmacovigilance and Risk Management, European Medicines Agency, EU

15:00 Coffee break

16:00 SESSION 4

BRAVE NEW WORLD

Session Chairperson:

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

Post-authorisation Studies: New legislation

Els Geeraerts, Pharmaceutical Inspection, Belgian Federal Agency for Medicines and Health Products, Belgium

ENCePP: Future developments

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

Other EMA Activities in the Field of Pharmacoepidemiology

Henry Fitt, Head of Coordination & Networking Section, Pharmacovigilance and Risk Management, Patient Health Protection Unit, 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

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>

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation 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.

HOTEL INFORMATION

Attendees must make their own hotel reservation, we have blocked rooms at the following two Hotels:

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

at the rate of:

GBP 133.19 per room incl. breakfast exclusive of VAT

To book a room, please click here:

https://secure.hilton.co.uk/HiWayWeb/appmanager/portals/reservation?_nfpb=true&_pageLabel=reservationPortal_mainBook_reservationBook_reservationPage&ctyhocn=LONNDHI&portalFrom=hotel.

Please fill in corporate account number: 481223696.

The hotel is situated opposite of Canary Wharf conveniently connected by a shuttle boat. The landing stage is in walking distance to the European Medicines Agency (2 min). The three day ferry ticket is included in the room rate. Please make sure you receive it when checking in.

For further information, please go to http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

De Vere Venue Devonport House

King William Walk

Greenwich - London SE10 9JW

Tel: 020 8269 5400 - Fax: 020 8269 5422

www.deverevenues.co.uk

at the rate of:

£ 149.00 inclusive of breakfast, exclusive of VAT

Please book your room at the Devonport House directly by contacting Eileen Murnane at emurnane@deverevenues.co.uk or by phone 020 8269 5443 and use the reservation no. 50300086. Rooms are available on a first-come first-serve base.

Important: Please complete your reservations before 14 October at the latest. Reservations requested after this date will be subject to hotel availability and room rate may vary.

The Devonport House is situated on the World Heritage Site in Greenwich and Greenwich station is only a short walk away with easy access to London city by tubes and trains. Travel time is approx. 20 minutes.

Register for upcoming DIA events in Europe

1st joint DIA/EMA Workshop on Statistical Methodology in Clinical R&D

27-29 September 2010 | Vienna, Austria

Joint EFGCP Children's Medicines Working Party 6th Annual Conference and DIA 4th Paediatric Forum

Current and Future Medical Child Care: Visions, Daily Challenges, Ways Forward

28-29 September 2010 | London, UK

Joint DIA/EFGCP Pharmacovigilance Audit and Inspection Workshop - Opportunities for Patient Safety

1 October 2010 | London, UK

4th Annual Clinical Forum and Exhibition

Navigating the Future

11-13 October 2010 | Lisbon, Portugal

4th European Cardiac Safety Conference and Exhibition

25-26 October 2010 | Nice, France

Future Direction for Orphan Drugs in Europe

3 November 2010 | Paris, France

2nd Health Technology Assessment Conference

Building a new system to get effective treatment to European patients

4-5 November 2010 | Paris, France

Combination Products - Finding the Right Regulatory Strategy

9 November 2010 | Zurich, Switzerland

2nd Joint DIA/EMA/CMD(h) Conference on Variations

23 November 2010 | London, UK

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2nd Joint DIA/European Medicines Agency Innovation Forum: Is the EU Regulatory Framework Ready?

29-30 November 2010 | London, UK

11th Conference and Exhibition on European Electronic Document Management - *The New Frontiers*

1-3 December 2010 | Nice, France

9th Middle East Regulatory Conference MERC 2011

1-2 February 2011 | Amman, Jordan

DIA/IFAH Global Animal Health Conference

March 2011 | London, UK

23rd Annual EuroMeeting

28-30 March 2011 | Geneva, Switzerland

REGISTRATION FORM

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26 November 2010 | De Vere Venues Canary Wharf, London, United Kingdom

ID# 10115



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.

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| ☐ Advertising & Promotion | ☐ Medical Communications | ☐ Pharmacology | ☐ Regulatory Affairs |
| ☐ CMC | ☐ Medical Writing | ☐ Pricing/Reimbursement | ☐ Research & Development |
| ☐ Clinical Data Management/eClinical | ☐ Nonclinical | ☐ Project Management | ☐ Statistics |
| ☐ Clinical Research | ☐ Outsourcing | ☐ Professional Education, Training & Development | ☐ Strategic Planning |
| ☐ Clinical Safety/Pharmacovigilance | ☐ Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine | ☐ Public Policy/Law/Corp. Compliance | ☐ IT/Validation |
| ☐ Document Management/eSubmissions | | ☐ Quality Assurance/Quality Control | |
| ☐ Manufacturing | | | |

REGISTRANT

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

☐ Prof. ☐ Dr. ☐ Ms. ☐ Mr.

Last Name

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Job Title

Street Address / P.O. Box

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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 our 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.

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Date

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☐ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:

D.I.A., 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# 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 diaeuropa@diaeuropa.org

Mail DIA European Office
Postfach, 4002 Basel, Switzerland