Joint DIA/EMA Information Day on Post-Authorisation Studies (PAS)

5 June 2015
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Morten Andersen*
Karolinska Institutet, Centre for Pharmacoepidemiology/Department of Medicine, Sweden

Peter Arlett*
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Agencija za Lijekove i Medicinske Proizvode (HALMED), Croatia

Susana Perez-Gutthann*
RTI Health Solutions, Spain

FACULTY

Marieke De Bruin*, College ter Beoordeling van Geneesmiddelen, The Netherlands

Pierre Engel*, Quintiles RWLPR (Real World & Late Phase Research), France

David Haerry*, European Aids Treatment Group (EATG), Belgium

Teresa Herdeiro*, Unidade de Farmacovigilância do Norte, Faculdade de Medicina da Universidade do Porto, Portugal

Xavier Kurz, European Medicines Agency (EMA), EU

Nawab Qizilbash*, Oxon Epidemiology Ltd., Spain & London School of Hygiene and Tropical Medicine, UK

Patrice Verpillat, EFPIA Observer to ENCePP Steering Group, Boehringer Ingelheim, Germany

* ENCePP Steering Group member

WHY AN INFORMATION DAY ON PAS?

This information day on post-authorisation studies (PAS) and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is targeted to industry, academia and CROs as main stakeholders. The objective is to explore regulatory procedures and requirements and scientific guidelines on the conduct of both safety and efficacy studies and to explore the benefits of the ENCePP network in supporting stakeholders in the conduct of PAS for regulatory decision making.

This information day will be an opportunity to introduce new methodological guidance for pharmacoepidemiology studies investigating safety outcomes and regulatory guidance on post-authorisation efficacy studies in advance of the public consultation.

The information day will provide insight into the current regulatory thinking about joint studies and how projects such as ADVANCE and PROTECT could enhance a lifecycle approach to product development and benefit risk management.

KEY TOPICS

- ENCePP contribution to capacity building for (joint) PAS
- Update on methodological and regulatory guidances for PAS
- EMA initiatives to support regulatory decision making
- EU PAS Register and GVP VIII requirements – lessons learnt

TARGET AUDIENCE

This program is being developed for scientists in pharmaceutical industry, academia and contract research organisations involved in the planning and conduct of post-authorisation safety or efficacy studies in the context of EU risk management planning and post-approval benefit-risk assessment of medicines.

Professionals working in the area of:

- Pharmacoepidemiology
- Drug Safety/Pharmacovigilance
- Risk Management/REMS
- Post-marketing activities
- Statistics
- Comparative Effectiveness/HTAs/Health Outcomes
- Regulatory Affairs
- Medical Affairs
- Quality Assurance/Compliance

LOCATION

European Medicines Agency
30 Churchill Place - Canary Wharf
London E14 5EU - United Kingdom

Capacity: The event is limited to 110 participants

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1995 2015 EMA

DIA DEVELOP INNOVATE ADVANCE

08:30 **REGISTRATION**

08:45 **WELCOME NOTE**

Peter Arlett

08:50 **SESSION 1**

CONTRIBUTION OF PAS TO INNOVATION AND HEALTH

Co-chairs:
Viola Macolić Šarinić, HALMED and **Morten Andersen**, Karolinska Institutet

This session will explore how PAS contribute to benefit monitoring of medicines and are critical to the support of innovation. The session will discuss the experience with PAS in regulatory evaluation.

Life-cycle planning: collection of data is key to success
Peter Arlett, EMA

PRAC experience with PAS
June Raine, MHRA

Panel discussion
Joined by Giampiero Mazzaglia, EMA

10:10 **COFFEE BREAK**

10:30 **SESSION 2**

ENABLING EXCELLENT PAS – BUILDING CAPACITY

Co-chairs:
Patrice Verpillat, Boehringer Ingelheim, and **David Haerry**, EATG

This session looks at key enablers for conducting PAS. It draws from the experience from the ENCePP network as an interface between pharmaceutical industry, CROs and academia for the conduct of PAS. The session will also look at other initiatives which hold promise in building capacity for PAS.

Contribution of ENCePP
Susana Perez-Gutthann, RTI Health Solutions

Regulatory initiatives on joint PAS and registries
Peter Mol, College ter Beoordeling van Geneesmiddelen

Good governance is key-learning from ENCePP survey and ADVANCE project
Laurence Pagnon, Sanofi Pasteur MSD

Panel discussion
Joined by Teresa Herdeiro, Unidade de Farmacovigilância do Norte, Faculdade de Medicina da Universidade do Porto, and Corinne de Vries, EMA

HOTEL INFORMATION

Attendees are kindly requested to make their own hotel reservation.

Recommended hotel:
Hilton London Docklands Riverside
265 Rotherhithe Street
London SE16 5HW

Tel: +44 20 7231 1001
Fax: +44 20 7231 0599
Email: reservations.docklands@hilton.com

Please contact the hotel directly for the best available rate.

12:20 **SANDWICH LUNCH**

13:00 **SESSION 3**

GETTING IT RIGHT: UNDERSTANDING THE REGULATORY REQUIREMENTS

Co-chairs:
Xavier Kurz, European Medicines Agency (EMA), EU, and **Susana Perez-Gutthann,** RTI Health Solutions

This session will discuss the regulatory requirements for both safety and efficacy studies in the context of stakeholder experience with GVP requirements and the EU PAS Register. This session will also discuss how the planning of studies to support the evaluation of the benefits and risks of medicines is improved through the EMA scientific advice procedure.

Overview of regulatory requirements for PAS
Thomas Goedecke, EMA

Registration and transparency - experience with the EU PAS Register
Pierre Engel, Quintiles RWLPR

Key role of EMA Scientific Advice for the conduct of PAS
Jane Moseley, EMA

Panel discussion
Joined by Viola Macolić Šarinić, HALMED, and Maria Boulos, EMA

14:50 **COFFEE BREAK**

15:10 **SESSION 4**

GETTING IT RIGHT: OPTIMISING SCIENTIFIC METHODS

Co-chairs:

Nawab Qizilbash, Oxon Epidemiology and and **Marieke De Bruin,** College ter Beoordeling van Geneesmiddelen

This session provides an overview of recent updates on methodological guidance for the conduct of pharmacoepidemiological studies for both safety and efficacy outcomes.

The role of registries in European post-marketing surveillance: a retrospective analysis of new centrally approved products, 2005-2013
Jacoline Bouvy, EMA

The ENCePP methods guide
Alejandro Arana, RTI Health Solutions

Draft scientific guidance on post-authorisation efficacy studies (PAES)
Kevin Blake, EMA

Panel discussion
Joined by Nawab Qizilbash, Oxon Epidemiology and June Raine, MHRA

16:50 **CLOSING REMARKS**

Susana Perez-Gutthann, RTI Health Solutions and **June Raine,** MHRA

17:00 **END OF INFORMATION DAY**

REGISTRATION FORM

Joint DIA/EMA Information Day on Post-Authorisation Studies (PAS)
5 June 2015, European Medicines Agency, London, United Kingdom

ID#15524

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,
E-mail: diaeurope@diaeurope.org Fax: +41 61 225 51 52 For more information please call +41 61 225 51 51

Attendees are invited to submit questions to speakers and panellists in relation to post-authorisation studies (PAS) by 31st May 2015 to ENCePP_Secretariat@ema.europa.eu, subject: 'Information Day on PAS – panel discussion'

Registration fees*	Fees*
Industry	400.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	200.00 EUR ❑

Registration fee includes: refreshments, sandwich lunch and delegate material.

Payment is due 30 days after registration and must be paid in full by commencement of the event.

Attendees are invited to submit questions to speakers and panellists in relation to post-authorisation studies (PAS) by 31st May 2015 to: ENCePP_Secretariat@ema.europa.eu, subject: 'Information Day on PAS – panel discussion'

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **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." Please include your name, company, Event ID #15524 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event 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 or postponed, 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.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
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