EudraVigilance Information Day

Course #10534
22 June 2010
European Medicines Agency, London, UK

Programme Committee

Prof. Kent Woods
- Chief Executive, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
- Co-Chair EudraVigilance Steering Committee (EV-SC)

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

Sabine Brosch, M Pharm, Pharm D
- Business Lead EudraVigilance and International Standardisation in Pharmacovigilance, European Medicines Agency, EU

Gaby Danan, MD, PhD
- Pharmacovigilance Expert, Global Pharmacovigilance and Pharmacoepidemiology, sanofi-aventis, France

EudraVigilance Information Day Audience

This programme will benefit Qualified Persons Responsible for Pharmacovigilance and individuals involved in:
- Pharmacovigilance
- Clinical Data Management
- Clinical Development
- Information Management
- Safety databases

Details of the EudraVigilance Information Day

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

Capacity: The event is limited to 120 participants

NEED OF EUDRAVIGILANCE INFORMATION DAYS

The further development of EudraVigilance supporting the EU pharmacovigilance and risk management strategy remains one of the priorities of the European Medicines Agency's work programme. This includes the achievement of high quality of Individual Case Safety Reports (ICSRs) and the preparation for the implementation of the EudraVigilance Access Policy. In addition, the electronic exchange of adverse reaction data and their analysis in the pre- and post-authorisation phase, a regulatory requirement in line with Volume 9A and Volume 10 of Eudralex, remains a key activity for EudraVigilance.

The international standardisation in the area of the new Individual Case Safety Reports (ICSR, ICH E2B) and the Identification of Medicinal Products (IDMP, ICH M5) is also rapidly progressing and the implementation at EU level needs to be planned for by all stakeholders in a timely and harmonised manner.

Pharmacovigilance capacity and knowledge building in the context of the Innovative Medicines Initiative (IMI) and the European Network of Centres of Excellence in Pharmacovigilance and Pharmacoepidemiology (ENcEPP) are also new projects that have been initiated by the Agency.

The EudraVigilance Information Day will provide a forum for medicines regulatory authorities, marketing authorisation holders and sponsors of clinical trials to gain updates on the key activities of the EudraVigilance-Expert Working Group in line with their work programme for 2010 (see http://eudravigilance.emea.europa.eu) and the recent developments in pharmacovigilance and international standardisation.

The detailed programme will be made available several weeks before the EudraVigilance Information Day, the main areas that will be addressed are as follows:

- EudraVigilance project planning 2010 and beyond
- Practical implementation questions from stakeholders with focus on electronic reporting of ICSRs and EudraVigilance data quality management
- Recent developments and updates on the ICH topics E2B (eElectronic Transmission of ICSRs), M5 (Identification of Medicinal Products), E2F (Development Safety Update Report -DSUR) and M1 (MedDRA)
- Signal detection and risk management
- New projects related to capacity and knowledge building in pharmacovigilance (e.g. ENCePP and IMI)

Panel discussions will provide the opportunity for extensive Q&As with the speakers, chairpersons and Programme Committee members

EudraVigilance Information Day Goals

Desired Outcomes
- Share knowledge about the ongoing pharmacovigilance and EU risk management activities in the context of EudraVigilance
- Operate the electronic reporting of ICSRs within a company/organisation in line with the regulatory requirements across the Community
- Share implementation experience in adverse reaction reporting in the pre- and post-authorisation phase
- Share knowledge about the current implementation status of EudraVigilance and future developments.

EudraVigilance

EUROPEAN MEDICINES AGENCY
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TUESDAY | 22 JUNE 2010

08:00 **Registration**

08:45 **Welcome**
Peter Arlett, European Medicines Agency, EU

09:00 **Session 1**

FURTHER STRENGTHENING OF EUDRAVIGILANCE TO MEET CHALLENGES TO COME

Session chair:
Peter Arlett, European Medicines Agency, EU

EudraVigilance has become a key tool in supporting the EU pharmacovigilance and risk management activities. The system now processes and average of 40.000 ICSRs per month. With the growing size of the database the expectations of stakeholders are rising.
Furthermore, the proposed new pharmaceutical legislation and the international standardisation activities in pharmacovigilance will add new challenges towards the further development of EudraVigilance over the next years to come. This session will provide participants with a unique opportunity to discuss their views and expectations with the co-chairs of the EudraVigilance Expert Working Group and the chair of the EFPIA Pharmacovigilance Working Group.

EudraVigilance: milestones 2010 and beyond
Sabine Brosch, European Medicines Agency, EU

EudraVigilance: Expectations from Member States
Anja van Haren, Medicines Evaluation Board, NL

EudraVigilance: Expectations from Pharmaceutical Industry
Margaret Walters, EFPIA, UK

Panel discussion

10:30 **Coffee Break**

11:00 **Session 2**

INTERNATIONAL STANDARDISATION IN PHARMACOVIGILANCE

Session Chairs:
Andrew Marr, ICH M2 Rapporteur, UK and
Sabine Brosch, European Medicines Agency, EU

The international standardisation related to the development of the new Individual Case Safety Report (ICSR) and the Identification of Medicinal Products – an integrated part of the new ICSR – is rapidly progressing requiring coordinated planning for implementation at EU and international level. This session will provide an overview of the latest developments including an update from the Food and Drug Administration (FDA) in the US on their implementation approach and the collaboration with the European Medicines Agency.

International standardisation of Identification of Medicinal Products (IDMP, ICH M5): current status and implementation by FDA
Vada Perkins , Office of the Director, CBER, FDA, USA

The new Individual Case Safety Report (ICSR) standard and ICH E2B Implementation Guide
Nick Halsey, Pharmacovigilance and Risk Management,
European Medicines Agency, EU

Panel discussion

12:30 **Lunch**

13:30 **Session 3**

PRACTICAL ASPECTS IN PHARMACOVIGILANCE

Session Chairs:
Gaby Danan, sanofi-aventis, FR and
Sabine Brosch, European Medicines Agency, EU

This session will focus on the release of new Questions and Answers in the context of Volume 9A and Volume 10 of the Rules Governing Medicinal Products in the EU. An update on the outcome of the MedDRA Important Medical Events (IME) pilot testing and the ongoing improvements of the IME List will be also presented.

New Questions and Answers on Volume 9A and Volume 10
Gilles Touraille, European Medicines Agency, EU
Subhash Mistry, GSK, UK

MedDRA Important Medical Events (IME) in the EU
Patricia Mozzicato, MedDRA MSSO
European Medicines Agency, EU

Panel discussion with speakers and Aniello Santoro, European Medicines Agency, EU

15:00 **Coffee Break**

15:30 **Session 4**

SCIENTIFIC KNOWLEDGE AND CAPACITY BUILDING AT THE AGENCY

Session Chair:
Peter Arlett, European Medicines Agency, EU

In the context of the Innovative Medicines Initiative (IMI), the Agency has taken an active role in supporting and managing the Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium (PROTECT) project, which focuses on improving and strengthening the monitoring of the benefit/risk of medicines marketed in the EU. In the context of IMI, the EU2P project was also launched, focusing on the development of a comprehensive and flexible pan-European training and education programme in the area of pharmacovigilance and pharmacoepidemiology. The ENCePP project is another example, where the European Medicines Agency is taking a leading role in strengthening the post-authorisation monitoring of medicinal products in Europe. This session will give a unique opportunity to gain an overview of the current developments, the next steps in the projects and their impact on the
pharmacovigilance activities and stakeholders.

Innovative Medicines Initiative and PROTECT project
Xavier Kurz, Business Coordination and Scientific Projects,
European Medicines Agency, EU

Innovative Medicines Initiative: EU2P project
Deborah Szafir, Safety Risk Management Strategy,
Roche, FR

European Network of Centres of Excellence in Pharmacovigilance and Pharmacoepidemiology (ENCePP)
Henry Fitt, Coordination and Networking,
European Medicines Agency, EU

17:00 **End of Course**

DIA UPCOMING TRAINING COURSES IN 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

The New Individual Case Safety Report (ICSR) International Standard and ICH E2B/M2 Information Day at the European Medicines Agency
25 June 2010 | London, United Kingdom | ID 10568

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

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

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

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

REGISTRATION FORM

EudraVigilance Information Day

22 June 2010 | European Medicines Agency, London, UK

ID# 10534

Registration includes participant material, coffee breaks and sandwich lunch. Each event is limited to 120 participants.

Standard Fee	**EUR 300.00** ❑
Reduced Fee for Academia and Full Government	**EUR 150.00** ❑

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

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. **10534DIA**

__ Advertising & Promotion
__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Eff ectiveness/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 Aff airs
__ Research & Development
__ Statistics
__ Strategic Planning
__ IT/Validation

REGISTRANT

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

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Job Title

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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

❑ **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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Card Number

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Date Cardholder's Signature

❑ **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# 10534 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.

Hotel and Travel Information

Recommended hotels near the European Medicines Agency. Attendees must make their own hotel reservation. Ask for available EMA rate at:

Hilton London Docklands Riverside
265 Rotherhithe Street, London , SE16 5HW, UK
Telephone: +44 20 7231 1001 - Fax: +44 20 7231 0599
Email: reservations.docklands@hilton.com

London Marriott Hotel West India Quay
22 Hertsmere Rd, Canary Wharf
London, E14 4ED, United Kingdom
Phone: +44 20 70931000 - Fax : +44 20 70931001

CANCELLATION POLICY

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

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