EudraVigilance Information Day

Course #10535
19 October 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 Sector Pharmacovigilance and Risk Management, European Medicines Agency (EMA), EU

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

Gaby Danan, MD, PhD
- Pharmacovigilance Expert, France

EudraVigilance Information Day Audience

This programme will benefit Qualified Persons Responsible for Pharmacovigilance and individuals involved in:
- Pharmacovigilance
- 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.

In June 2010, the European Commission initiated a review of the detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use ('CT-3'), which will require adaptations to the business processes as regards safety reporting in the EU.

Furthermore, the new pharmaceutical legislation will have a major impact on the conduct of pharmacovigilance in the EU and will require careful strategic planning to ensure that the new provisions can be implemented by all stakeholders successfully.

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. 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, clinical trials and international standardisation.

The programme will address the following areas:
- Changes in the EU regulatory environment in relation to clinical trials
- The new pharmaceutical legislation and the impact on the conduct of pharmacovigilance in the EU
- The new data quality management in EudraVigilance and impact on stakeholders
- Practical implementation questions from stakeholders with focus on electronic reporting of ICSRs and pharmacovigilance

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 anticipated update of the clinical trial guideline CT-3
- Operate the electronic reporting of ICSRs within a company/organisation in line with the regulatory requirements across the Community
- Share knowledge about the new legislation and its impact on the conduct of pharmacovigilance in the EU
- Share knowledge on the initiatives of the European Medicines Agency to improve the quality of pharmacovigilance data held in EudraVigilance and the anticipated impact on stakeholders

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TUESDAY | 19 OCTOBER 2010

08:00 **Registration**

08:45 **Welcome**
Peter Arlett, EMA, EU

09:00 **SESSION 1**
LATEST DEVELOPMENTS IN SAFETY REPORTING AND CLINICAL TRIALS

Session chair:
Chantal Belorgey, AFSSAPS, FR

In June 2010, the European Commission initiated a review of the detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use ('CT-3'). This initiative is a response to many calls from stakeholders during the public consultation on the functioning of the Clinical Trials Directive for short-term improvements/clarifications of the detailed rules for safety reporting. These improvements have to be necessarily limited to what is possible under the current legal framework. The revision of the Clinical Trials Directive is a medium/long-term project, conducted in parallel to this public consultation and aiming at more structural improvements of the situation for investigators and sponsors. This session will provide an update on the key areas that are being likely to be affected by the revision of CT-3.
The current experience in conducting clinical trials from an academic sponsor perspective will be also addressed. Finally, the finalisation of the ICH E2F guideline and its impact on safety reporting in the EU will be presented.

Experience of an academic sponsor regarding the safety reporting process for clinical trials in Europe
Nathalie Dubois, European Organisation for Research and Treatment of Cancer, EORTC, BE

Anticipated changes to the detailed guidance CT-3 and impact on sponsors and investigators
Chantal Belorgey, Chair of the Clinical Trials Facilitation Group (CTFG), AFSSAPS, FR

ICH E2F DSUR and its impact on annual safety reporting in the EU
Brian Davis, Consultant in Clinical Trials, Former MHRA, UK

Panel discussion

10:30 **Coffee Break**

11:00 **SESSION 2**
THE NEW PHARMACEUTICAL LEGISLATION AND THE IMPACT ON THE CONDUCT OF PHARMACOVIGILANCE IN THE EU

Session Chair:
Peter Arlett, EMA, EU

On 10 December 2008, the Commission adopted two legislative proposals as part of the pharmaceutical package aimed at amending the current legal framework. Key changes will refer to the strengthening of the rules on transparency relating to pharmacovigilance data, assessment, decision-making and stakeholder involvement, the establishment of Good Vigilance Practices (GVP) for the conduct of pharmacovigilance and simplifying the reporting of suspected adverse drug reactions (ADRs) making the best use of current information technology (including EudraVigilance). The focus will also be on stimulating innovation by establishing a clear legal requirement to conduct post-authorisation safety studies, including those in risk management systems. This session will provide the opportunity for participants to familiarise with the key changes anticipated for the conduct of pharmacovigilance in the EU and the potential impact on regulators and pharmaceutical industry.

Impact of new pharmaceutical legislation on EU pharmacovigilance activities
Margaret Walters, EFPIA, UK

Opportunities for New Ways of Working - A regulator's view
Mick Foy, MHRA, UK

EudraVigilance and simplification of adverse reaction reporting
Sabine Brosch, EMA, EU

Panel discussion

12:30 **Sandwich lunch**

13:30 **SESSION 3**
EUDRAVIGILANCE AND EMA'S INITIATIVE TO IMPROVE DATA QUALITY

Session Chairs:
Sabine Brosch and Gaby Danan

In June 2010, the revised EudraVigilance business rules became effective for electronic reporting of Individual Case Safety Reports (ICSRs) in the EU. Further enhancements of the business rules, with focus on SUSAR reporting in clinical trials are expected to enter into force in January 2011. The session will provide stakeholders with an update of the key changes to be applied in improving ICSR data quality. Furthermore, in agreement with Heads of Medicines Agencies, EMA launched a tender in October 2009 to support the data quality management in EudraVigilance. A framework contract was signed by the Agency in August 2010 allowing to initiate a major review of the quality of ICSRs and medicinal product information reported to EudraVigilance. The session will provide an overview of the four main work streams that focus on the retrospective and prospective data quality improvement in EudraVigilance and the impact for stakeholders as regards electronic adverse reaction reporting, data analysis and signal detection as well as the implementation of the EudraVigilance Access Policy. Aspects in relation to the improvement of expedited reporting compliance and the submission of copies of literature articles will be also addressed.

The new EudraVigilance business rules and the impact on the processing of ICSRs
Gilles Touraille, EMA, EU

Improving the quality of ICSRs in EudraVigilance
Tom Paternoster, EMA, EU

Improving the quality of medicinal products in the EVMPD
Ilaria del Seppia, EMA, EU

15:00 **Coffee Break**

15:30 **SESSION 4**
PRACTICAL ASPECTS IN PHARMACOVIGILANCE

Session Chairs:
Sabine Brosch and Gaby Danan

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.

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

16:30 **End of Course**

DIA UPCOMING TRAINING COURSES IN 2010

Clinical Research

Advanced GCP Study Monitoring
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
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

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
6-8 October 2010 | Prague, Czech Republic | ID 10573

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
5-7 December 2010 | Dubai, United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
10-12 November 2010 | Zurich, Switzerland | ID 10547

Quality by Design: A Hands-on Short Course for Pharma
4-5 November 2010 | Graz, Austria | ID 10565

Training Course for eCTD Submissions in Switzerland
9 December 2010 | Zurich, Switzerland | ID 10572

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

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
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
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
1-3 December 2010 | Paris, France | ID 10526

IDMP Information Day at the European Medicines Agency
17 September 2010 | London, United Kingdom | ID 10577

EudraVigilance Information Day at the European Medicines Agency
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

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
19 October 2010 | European Medicines Agency, London, UK

ID# 10535

DIA www.diahome.org

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. **10535DIAWEB**

__ 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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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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❑ **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# 10535 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