

1st Information Day on the use of MedDRA including Medication Errors

Course #13542

22 October 2013

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



Programme Committee

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Medical Director, GSK, Global Clinical Safety and
Pharmacovigilance, UK

Overview

The Medical Dictionary for Regulatory Activities (MedDRA) terminology is designed for sharing regulatory information for human medicinal products. The latest versions of two ICH-Endorsed Guides for MedDRA users were published beginning of April 2013: "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider". Both were developed by a working group consisting of experts from the MedDRA MSSO, regulatory and industry representatives of the EU, Japan and the US, as well as representatives from the Canadian regulatory authority and were updated based on MedDRA version 16.1.

This Information Day will focus specifically on the use of MedDRA for coding and retrieving clinical and pharmacovigilance data including medication errors. Discussions will be led by experts from regulatory authorities, the MedDRA MSSO and pharmaceutical industry. The use of MedDRA in the context of EudraVigilance and other international databases will be also addressed.

Key Topics

- Practical use of MedDRA for coding purposes including those associated with medication errors
- Practical use of MedDRA for coding of overdose, misuse, abuse, off label use, and occupational exposure
- Practical use of MedDRA for data retrieval, signal detection and evaluation including the use of Standardised MedDRA Queries (SMQs)
- Use of MedDRA in the context of EudraVigilance and other large databases

Learning Objectives

At the end of this Information day, participants should be able to

- Identify the latest developments in MedDRA
- Apply MedDRA to code clinical and pharmacovigilance data including medication errors
- Evaluate the use of MedDRA for signal detection
- Recognize the use of MedDRA in the context of EudraVigilance and other large databases
- Improve MedDRA coding and analysis based on specific examples

Who Will Attend

This programme will benefit Qualified Persons Responsible for Pharmacovigilance (QPPVs) and individuals involved in:

- Pharmacovigilance
- MedDRA coding
- Signal detection and evaluation
- Clinical development
- Safety databases

**Attendees are invited to submit specific coding or data retrieval questions
by 4 October to EudraVigilance@ema.europa.eu,
subject 1st MedDRA Information Day**

EudraVigilance

TUESDAY | 22 OCTOBER 2013

08:15 REGISTRATION

08:45 WELCOME NOTE

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

09:00 Session 1

HIGHLIGHTS OF MEDDRA AND THE DEVELOPMENTAL ACTIVITIES

Patrick Revelle, MedDRA MSSO, USA

Session 1 will provide a brief overview of the evolution of MedDRA to meet the needs of users. This includes a discussion of several initiatives including medication error terms, device terms, product quality issue terms, vaccine terms, microorganism terms, terms related to chemical health threats, pharmacogenetic terms, and neoplasm terms. A brief discussion of the process to add these various types of terms within the scope of MedDRA will also be discussed.

09:30 Session 2

MEDDRA TERMS SELECTION FOR CODING OF ICSRS

Co-Chairs:

Sabine Brosch, EMA, EU

Patrick Revelle, MedDRA MSSO, USA

Session 2 will focus on the use of MedDRA to code clinical data. Following an overview of the “key principles in the ICH-endorsed MedDRA Term Selection: Points to Consider” document, the practical use of MedDRA in coding will be discussed based on various examples from both an industry and regulatory perspective. Specific questions from the audience will be addressed as part of a panel discussion.

Overview of the MedDRA Term Selection Points to Consider Document and Key Coding Principles

Judy Harrison, MedDRA MSSO, USA

A Pharmaceutical Industry Perspective in Coding Clinical Trials and Post-authorisation Data

Christina Winter, Glaxo Smith Kline, UK

A Regulator's Perspective in Coding with MedDRA and Practical Examples

Sarah Vaughan, MHRA, UK

Discussant

Barry Hammond, European MedDRA Users Group, UK

Gaby Danan, Pharmacovigilance expert, FR

10:30 COFFEE BREAK

11:00 Session 3

USE OF MEDDRA FOR SIGNAL DETECTION AND DATA ANALYSIS

Co-Chairs:

Georgy Genov, EMA, EU

Sarah Vaughan, MHRA, UK

Session 3 will provide important insight into the use of MedDRA for signal detection and data analysis including an overview of the key aspects described in the ICH-endorsed “MedDRA Data Retrieval and Presentation: Points to Consider” document. Various approaches to data analysis such as the use of the MedDRA hierarchy and secondary System Organ Class (SOC) analyses will be presented. Standardised MedDRA Queries and their application in case identification and signal detection will be discussed. Specific questions from the audience will be addressed as part of a panel discussion.

Overview of the MedDRA Data Retrieval and Presentation: Points to Consider document including Standardised MedDRA Queries (SMQs)

Judy Harrison, MedDRA MSSO, USA

MedDRA for signal detection in EudraVigilance

Aniello Santoro EMA, EU

MedDRA for signal detection by FDA

Sonja Brajovic, FDA, US

12:30 SANDWICH LUNCH

13:30 Session 4

USE OF MEDDRA FOR CODING AND ANALYSIS OF MEDICATION ERRORS – PART 1

Co-Chairs:

Sabine Brosch, EMA, EU

Thomas Goedecke, EMA, EU

Session 4 will focus on challenges in coding patient safety data based on specific examples of medication error reports and how this can be addressed using MedDRA. Important considerations in relation to handling of medication errors and product quality issues will be presented from an FDA perspective. Coding, analysis and data presentation of medication errors in the context of risk management and pharmacovigilance will be also addressed. Actions agreed as a result of the Medication Error Workshop held at the EMA in February 2013 will conclude the discussions of this Information Day. Specific questions from the audience will be addressed as part of a panel discussion.

A Patient Safety Perspective of Medication Error Incident Reports and Coding Challenges

David Cousins, NHS, UK

MedDRA Coding of Medication Error Incident Reports Based on Practical Examples

Sarah Vaughan, MHRA, UK

Victoria Newbould, EMA, EU

Medication Errors versus Product Quality Issues

Sonja Brajovic, Food and Drug Administration, USA

15:00 COFFEE BREAK

15:30 Session 4 Continued

USE OF MEDDRA FOR CODING AND ANALYSIS OF MEDICATION ERRORS – PART 2

Co-Chairs:

Sabine Brosch, EMA EU

Thomas Goedecke, EMA, EU

Coding, Analysis and Data Presentation of Medication Errors from a Pharmaceutical Industry Perspective

Christina Winter, Glaxo Smith Kline, UK

Follow up from EMA Medication Error Workshop and Next Steps

Thomas Goedecke, EMA, EU

Discussant

Barry Hammond, European MedDRA Users Group, UK

Gaby Danan, Pharmacovigilance expert, FR

16:30 End of this Information Day

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HOTEL INFORMATION

Attendees have to make their own reservation. Recommended hotel close to the European Medicines Agency:

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

DIA was able to negotiate a special rate for participants of the Information Day:

Room rate is **GBP 139.00** per room (2013 rate) incl. breakfast excl. VAT

To book a room, please send an email to Ms. Liane Lopes at Liane.Lopes@Hilton.com or call +44 203 002 2350.

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).

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■ Benefit/Risk Management

26-27 September 2013 | Prague, Czech Republic | ID 13524

■ Diagnosis and Management of Drug-Induced Liver Injury (DILI)

19-20 September 2013 | Paris, France | ID 13563

■ How to Prepare for Pharmacovigilance Audits and Inspections

7-8 November 2013 | Paris, France | ID 13556

■ ICH Endorsed Pharmacovigilance

22-23 September 2013 | Muscat, Sultanate of Oman | ID 13568
28-29 November 2013 | Zagreb, Croatia | ID 13569

■ Pre-Marketing Clinical Safety

Next recurrence of this course to be announced

■ Signal Management in Pharmacovigilance

6-7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses

■ Excellence in Pharmacovigilance: Clinical trials and post-marketing

18-22 November 2013 | London, United Kingdom | ID 13522

■ EudraVigilance Information Day

10 December 2013 | London, United Kingdom | ID 13530

■ EudraVigilance courses:

- EudraVigilance – Electronic reporting of ICSRs in the EEA
- eXtended EudraVigilance Medicinal Product Dictionary
- Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses.

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professional networking

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REGISTRATION FORM

1st EudraVigilance Information Day on the use of MedDRA including Medication Errors
22 October 2013 | European Medicines Agency, London, United Kingdom



ID #13542

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52 or email to: diaeuropa@diaeuropa.org

FEES

Standard fee	€ 365.00	☐
Reduced fee for Academia/Non-profit (Full-time)	€ 180.00	☐
Reduced fee for Government	€ 150.00	☐

The registration fee includes meeting material, sandwich lunch and refreshments.

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

TOTAL AMOUNT DUE: _____

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

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*(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°

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

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

If you do not cancel five working days 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.