Joint MHRA/MedDRA Information Day MedDRA in the Pharmacovigilance Regulatory Process

Event #14505
08 December 2014
Holiday Inn Kensington Forum

Programme Committee

Sabine Brosch
Monitoring and Incident Management
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MedDRA Maintenance and Support Services Organization (MSSO), Director, USA

Overview

The Medical Dictionary for Regulatory Activities (MedDRA) terminology is designed to assist the sharing, assessment and evaluation of medical information in relation to the authorisation, the safety monitoring and continuous benefit risk assessment of medicines.

This Information Day will provide attendees with a highlight of the latest MedDRA initiatives and developments. This will includes an outline of various efforts of the MedDRA MSSO to support interoperability of MedDRA with other terminologies specifically in the healthcare domain and the use of MedDRA in coding and analysing medication errors.

The use of social media and other emerging technologies in pharmacovigilance and the potential role of MedDRA in facilitating data capture and analysis will be one of the key topics of the meeting.

In addition, practical aspects on the use of MedDRA in the context of the new ICH E2B(R3) ICSR format will be outlined thus allowing participants to obtain a better understanding of the impact on their future coding processes. This will be complimented by an outline of MHRA of frequently observed coding mistakes as part of the current ICSR reporting practices. The Information Day will conclude with a session that is dedicated to the use of MedDRA for signal detection and data analysis both from a regulator's and industry perspective.

Key Topics

- MedDRA in the context of the use of social media and other emerging technologies in pharmacovigilance
- MedDRA and interoperability efforts in the healthcare domain
- Review of MedDRA scope and potential impact on MedDRA users
- Use of MedDRA for coding of medication errors
- Frequently observed coding errors by MHRA as part of ICSRs reporting
- Use of MedDRA for signal detection and data analysis
- Practical MedDRA coding aspects in the context of the new ICH E2B(R3) ICSR

Who Will Attend

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

- Pharmacovigilance
- Coding of ICSRs
- Signal detection and evaluation
- Clinical development
- Safety databases

Details of the Information Day

Location:
Holiday Inn London – Kensington Forum
97 Cromwell Road
London SW7 4DN
United Kingdom

Session Co-chairs for this Information Day:
Mick Foy, MHRA and **Patrick Revelle**, MSSO

08:45 **REGISTRATION**

09:00 **WELCOME NOTE**
Mick Foy, MHRA

09:15 **Session 1**

MEDDRA DEVELOPMENTS TO MEET NEW PHARMACOVIGILANCE NEEDS

This session will provide an update on recent activities to ensure the continuing development of MedDRA to meet evolving pharmacovigilance needs and will focus on the coding and analysis of medication errors, off label use, and product quality issues.

Scope of MedDRA – Update on Blue Ribbon Panel Meeting
Judy Harrison, MSSO, US

Use of MedDRA for coding Medication Errors in ICSRs
Victoria Newbould, EMA , EU

How the MedDRA Hierarchy Can Help – retrieving Medication Errors, Off Label Use, and Product Quality Issues
Judy Harrison, MSSO, US

10:45 **COFFEE BREAK**

11:00 **SESSION 2**

CAPTURING NEW DATA RESOURCES IN PHARMACOVIGILANCE

This session will look at the possibilities of harnessing social media data to inform pharmacovigilance activities and address the activities taking place to ensure natural language from these data can be mapped to the MedDRA hierarchy.

Building a dictionary to translate internet vernacular to MedDRA
Nabarun Dasgupta, University of North Carolina, US

How MedDRA could support data analytics in the context of the IMI WEB RADR project
Patrick Revelle, MSSO, US

Harnessing Social Media for Pharmacovigilance – view from the industry
Tjark Reblin, VP Safety Evaluation and Risk Management – UK Development GlaxoSmithKline, UK

12:45 **LUNCH BREAK**

ABOUT DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation headquartered in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

13:30 **SESSION 3**

NEW ICH E2B(R3) ICSR AND MEDDRA CODING

This session will provide explanations on how to use MedDRA in the new ICH E2B (R3) format in the context of the electronic reporting of adverse reactions in the EU. The expected benefits and the impact on the pharmacovigilance business processes will be highlighted. This will be followed by a discussion MedDRA coding best practices from a regulatory perspective and will include the highlights of a survey of industry users on MedDRA coding practices.

How to use MedDRA in the new ICH ICSR E2B(R3) format
Gaby Danan, pharmacovigilance expert, FR

MedDRA coding best practices from a regulatory perspective
Tahira Jan, MHRA, UK

Results of MedDRA Coding Practices Survey
Barry Hammond, Terminologeze Ltd, UK

15:00 **COFFEE BREAK**

15:30 **SESSION 4**

MedDRA FOR SIGNAL DETECTION AND DATA ANALYSIS

This session 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. The presentations will provide both a regulatory and industry perspective on this topic.

Use of MedDRA in signal detection and evaluation
Phil Tregunno, Signal Management Unit Manager, MHRA, UK

Safety signals, data retrieval and analysis – Industry Perspective
Christina Winter, Medical Director, GSK, Global Clinical Safety and Pharmacovigilance, UK

17.00 **END OF INFORMATION DAY**

HOTEL INFORMATION

DIA has blocked a limited number of rooms at the following hotel:

Holiday Inn London – Kensington Forum
97 Cromwell Road
SW7 4DN London
United Kingdom

Tel.: +44 207 341 8000
Website: http://www.hikensingtonforumhotel.co.uk/

at the rate of:
GBP 157.00 per room/night inclusive of breakfast and VAT.

In order to make your reservation, please contact the hotel directly at + 44 (0) 207 341 3355 and quote the booking reference P0N.

Important: The room rate is available until 20 October 2014 or until the group block is sold-out, whichever comes first.

REGISTRATION FORM

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DIA DEVELOP INNOVATE ADVANCE

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

FEES

Standard fee	€ 500.00 ❑
Reduced fee for Academia/Non-profit (Full-time)	€ 250.00 ❑
Reduced fee for Government	€ 250.00 ❑

TOTAL AMOUNT DUE: _____

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.

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.

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

Card N°

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❑ **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 #14504 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

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

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