NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH MALAYSIA

ASEAN Workshop on MedDRA and its Application in Safety Drug Monitoring

Date:
17/03/2010–19/03/2010

Venue:
Le Meridien, KL

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Fee:
- RM 1,500/person
- Limited places, first come first serve basis

Closing date:
25/02/2010

Trainers:
1. Dr Judy Harrison, Senior Physician, MedDRA MSSO
2. Dr Christina Winter, MedDRA Board Member, OR

   Dr William Gregory, ICH expert and Member of CIOMS Working Group on SMQs to provide industry perspective
3. Dr Sonja Brajovic, Physician, Office of Surveillance and Epidemiology in US FDA's Center for Drug Evaluation

Note:
Each Participant has to bring their own laptop during the workshop

DAY 1

LEARNING OBJECTIVE: DAY 1 WILL PROVIDE AN UNDERSTANDING OF THE SCOPE, STRUCTURE, AND CHARACTERISTICS OF MedDRA AND THE APPLICATION OF THE TERMINOLOGY IN CODING CLINICAL DATA. IT IS DESIGNED FOR INDIVIDUALS INVOLVED WITH CODING AND THOSE AFFECTED BY CODING GUIDELINES AND ASSOCIATED STANDARD OPERATING PROCEDURES. PARTICIPANTS WILL BE GIVEN AN OVERVIEW OF THE "MedDRA TERM SELECTION: POINTS TO CONSIDER" DOCUMENT AND WILL PERFORM HANDS-ON CODING EXERCISES TO DEMONSTRATE THE PRINCIPLES DESCRIBED IN THE DOCUMENT.

Outline:
- ASEAN introduction
- Introduction and Coding with MedDRA
1. Overview of MedDRA's development and regulatory mandate for its use
2. Overview of MedDRA's scope, structure, and characteristics
3. MedDRA maintenance
4. Coding conventions
5. Synonym lists
6. QA of coding
7. Review of selected topics from the "MedDRA Term Selection: Points to Consider" document
8. Demonstration of the MSSO Desktop Browser
9. Hands-on coding exercises

DAY 2

LEARNING OBJECTIVE: DAY 2 WILL PROVIDE AN OVERVIEW OF THE FEATURES OF MedDRA THAT RELATE TO THE ANALYSIS AND RETRIEVAL OF MedDRA-ENCODED DATA. IT FOCUSES ON THE USE OF MedDRA TO RETRIEVE AND PRESENT AGGREGATED DATA, BASED ON THE PRINCIPLES OUTLINED IN THE "MedDRA DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER" DOCUMENT. A FEW REAL-LIFE EXAMPLES AND HANDS-ON QUERY DEVELOPMENT EXERCISES ARE INCLUDED. DAY 2 ALSO INCLUDES A THOROUGH OVERVIEW OF STANDARDISED MedDRA QUERIES (SMQs) AND THEIR APPLICATION IN THE INVESTIGATION OF DRUG SAFETY ISSUES. PARTICIPANTS LEARN ABOUT THE DEVELOPMENT, TESTING AND MAINTENANCE OF SMQs AND SEE DETAILED EXAMPLES OF INDIVIDUAL SMQs. EXAMPLES OF PRACTICAL APPLICATIONS OF SMQs FOR CASE IDENTIFICATION AND SAFETY SIGNAL DETECTION ARE PRESENTED.

Outline:
- "MedDRA Data Retrieval and Presentation: Points to Consider" document
- Developing Queries using MedDRA
- Examples and Hands-on Exercises
- SMQ Data Characteristics
- SMQs Development Status
- SMQ Testing and Production Maintenance
- SMQ Versioning
- SMQ Applications
- Customized Searches

DAY 3

LEARNING OBJECTIVE: DAY 3 WILL PROVIDE CASES STUDIES OF MedDRA IMPLEMENTATION AND UTILIZATION FROM INDUSTRY AND REGULATORY AUTHORITIES

Outline:
- MedDRA coding and analysis from industry perspective – An experiences MedDRA industry expert will discuss the implementation and use of MedDRA in their organization. This presentation will include the use of MedDRA within clinical trials and with marketed products. The presentation will discuss the challenges presented during initial implementation (e.g. training, data conversion, SOP revision) as well as current production use to support safety reporting.
- MedDRA data analysis from the regulatory perspective – An experienced MedDRA regulatory authority will present their agency's use of MedDRA. This presentation will focus on data analysis of MedDRA coded data but will also include a discussion of coding quality and specific tools used by the agency to support the use of MedDRA.
- Panel Discussion and Open Question and Answer
- ASEAN Wrap-up

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Ministry of Health, Malaysia

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