



MedDRA: Safety Data Analysis and SMQs

Objective:

For participants to review and understand the principles described in the MedDRA Data Retrieval and Presentation: Points to Consider document and to gain an understanding of how and why SMQs have been developed and to appreciate their utility when using databases of MedDRA-coded information.

Description:

This highly interactive 1-day course is designed to provide an overview of the features of MedDRA that relate to the analysis and retrieval of MedDRA-encoded data. The course 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. Participants will benefit from interactive individual and group exercises in which they will learn how to develop medically meaningful queries for use in their daily work. The course 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. The class also features a demonstration of MedDRA browser-based tools which can be used to analyse data sets. Examples of practical applications of SMQs for case identification, safety signal detection, product labeling review, and safety data reporting are presented.

This course is designed for:

- Drug safety/pharmacovigilance professionals
- Clinical monitors
- Medical writers
- Data coordinators
- Clinical programmers
- Statisticians

Course outline:

- MedDRA overview
- MedDRA Data Retrieval and Presentation: Points to Consider document
- Developing queries using MedDRA
- Examples and hands-on exercises
- SMQ background and definition
- SMQs development status
- SMQ data characteristics
- SMQ testing, production maintenance, and versioning
- Analysis of a data set using SMQs
- SMQ applications
- Customised searches