



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 how SMQs are used to query MedDRA-coded information to generate medically meaningful safety data 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. Examples of practical applications of SMQs for case identification, safety signal detection, product labelling 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 and production maintenance
- SMQ versioning
- SMQ applications
- Customised searches