



Safety professionals in today's rapidly changing global regulatory environment must have a strong foundation in safety surveillance and pharmacovigilance, which requires ongoing, comprehensive, and up-to-date training and education.

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## COURSE 6: MedDRA AND WHODrug CODING

Course 6 covers adverse event (AE) and medical diagnosis coding using the Medical Dictionary for Regulatory Activities (MedDRA®\*), a standardized coding dictionary required by regulation for use by clinical study sponsors and license/marketing authorization holders. The course describes the development, scope, and structure of the terminology. The course focuses on and provides a comprehensive discussion of MedDRA coding conventions, including interactive, case study-driven application exercises. Other coding dictionaries, such as WHODrug for suspect medication and concomitant medication coding, are also covered.

**COURSE 6: MEDDRA AND WHODRUG CODING**

**MedDRA Scope**

*It includes:*

1. Diseases
2. Diagnosis
3. Signs
4. Symptoms
5. Therapeutic indications
6. Medical and surgical procedures
7. Medical and social history
8. Terms from COSTART, WHO-ART, ICD dictionaries.

*Not included:*

1. Numerical values of lab results.
2. Severity description
3. Clinical study design terms
4. Patient demographic terms

The diagram shows four concentric circles representing coding systems: MEDDRA (outermost), WHO-ART, COSTART, and ICD (innermost).

Navigation: HOME, GLOSSARY, HELP, EXIT, BACK, NEXT

**Length:** 4 hours

**Audience:** Individuals interested in entering the field of drug safety and pharmacovigilance; professionals already in the biopharmaceutical industry practicing in the areas of clinical research, drug safety, regulatory affairs, and GCP compliance.

### LEARNING OBJECTIVES:

- Describe the role of coding in Adverse Event (AE) collection, processing, and regulatory reporting throughout the lifecycle of a medical product, including premarketing safety surveillance and postmarketing pharmacovigilance
- Trace the development and evolution of coding conventions in the medical product regulatory environment
- Differentiate between the various coding conventions in play globally, including MedDRA, WHODrug, and the Systematized Nomenclature of Medicine (SNOMED)
- Recognize the importance of accuracy, sensitivity, and specificity in coding in terms of medical product regulatory reporting
- Describe the use and application of MedDRA coding in clinical safety surveillance and postmarketing pharmacovigilance
- Describe the application of MedDRA SMQs for defining medical concepts and for safety signal detection
- List and describe the hierarchical structure and elements of MedDRA terminology, including SOC, HLT, HLT, PT, and LLT
- Allocate codes using MedDRA, including primary and secondary SOC allocations (using case study examples)
- Describe the structure, formats, and key elements of WHODrug, including Anatomical Therapeutic Chemical (ATC) classification and coding
- Allocate WHODrug codes for suspect medication and concomitant medication coding (using case study examples)

\* MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).