A. The Medical Dictionary for Regulatory Activities (MedDRA) for coding medical history and adverse events
B. WHO Drug dictionary for coding drugs
C. EudraVigilance Medicinal Product Dictionary (EVMPD

IV. Discuss the development, maintenance and use of the safety database
A. Key components of the safety database
B. Differentiate the clinical studies database and the safety database
C. Data reconciliation between systems
D. Discuss the setup of different systems
E. MSSO: Standardized MedDRA Queries
F. Monitoring of "Medically Important" predefined events
G. Trend Analysis

V. Understand the functions needed for a compliant product safety/pharmacovigilance department
A. ICSR Processing
B. Aggregate Reporting
C. Signal Detection
D. Risk Management
E. Quality Management
F. Training
G. Compliance
H. QPPV Office (EU)

The textbook and other instructional material will be determined by the instructor.