CRA Academy

Advanced level PV

3rd and 4th March 2020

1st day

- Introduction speech
- CIOMS: seriousness, expectedness, listedness
- CCSI
- Coffee break
- Signal management
- DDPS vs. PSMF
- Safety Update Reports (DSUR, PSUR, PBRER)
- aRMM and effectiveness check break
- PhV audits and inspections

2nd day

- Introduction speech
- XEVMPD
- EudraVigilance - Modules
- Data Entry (DrugVisor – Asseco Safety Database)
- Data Entry (cont.), Data Review, Medical Review
- Duplicate reports management, valid report
- ICSR Statistical data analysis and interpretation
- Quality Assurance

Course syllabus

CIOMS: seriousness, expectedness, listedness	□ Definitions □ Importance of Expectedness & Unexpectedness Assessment □ Reference Safety Information as a resource for Expectedness & Unexpectedness □ Assessment Showing examples of Expectedness & Unexpectedness □ Determining Expectedness using the Investigator Brochure □ Determining Expectedness using the SmPC □ Helpful CIOMS Rules
Signal management	□ Monitoring EudraVigilance: legal basis and guidance □ Transitional arrangements for MAHs □ Member State signal management work-sharing □ Recommendations on signals □ Designated medical events
DDPS vs. PSMF	□ What is DDPS □ Variations required for DDPS updates Introduction of the PSMF □ Registration and maintenance of PSMF □ Transfer from DDPS □ Article 57 database
Safety Update Reports (DSUR, PSUR, PBRER)	□ Definitions (DSUR, PSUR, PBRER) □ DLP □ Risk-benefit analysis □ Link to Regulatory Actions □ Work-sharing procedure □ PSUR submissions – frequencies, submission portal
aRMM and effectiveness check	□ Risk Minimization Plan □ Routine vs. Additional Risk Minimization □ Educational Materials □ Effectiveness of Risk Minimization Measures o Examples o Social media impact
PhV audits and inspections	□ Types and dynamics □ Preparation □ Conduct □ Post Audit & Inspection □ CAPA Management □ Audit & Inspection Findings/Scenarios

XEVMPD	□ Regulatory controlled vocabularies (XEVMPD, IDMP, SPL) □ Role of XEVMPD in EudraVigilance □ Database Architecture □ Product Report Database □ Scientific Database □ Product Index □ Example
EudraVigilance - Modules	□ Registration with EV □ EV post-authorization module (EVMP) □ EV clinical trials module (EVCTM) □ EVWEB vs. Gateway
Data Entry (DrugVisor – Asseco Safety Database)	Real database case processing
Data Entry (cont.), Data Review, Medical Review	Real database case processing
Duplicate reports management, valid report	□ EV Data Processing □ Dictionary coding (MedDRA) □ Pharmacovigilance Case Processor (repetition of steps)
ICSR Statistical data analysis and interpretation	□ EVDAS queries for MAHs □ EVDAS queries for clinical trial sponsors □ EVDAS queries for PhV inspectors □ Data Mining Methods □ Proportional Reporting Ratio (PRR) method □ Bayesian Methods
Quality Assurance	□ Scope of Quality System □ Performance Indicators □ Difference between GCP and PV QA □ Management of Human Resources □ Compliance Management □ Record Management and Data Retention