ADVANCED MATERIALS

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PV MATERIAL SOLID
https://allaboutpharmacovigilance.org/pharmacovigilance-guidance-material/icsr-processing-aggregate-reporting-and-signal-management/

LISTEDNESS/EXPECTEDNESS/LABELLED/UNLABELLED
https://allaboutpharmacovigilance.org/18-i-listedness-expectedness-assessment-introduction/

https://allaboutpharmacovigilance.org/18-ii-listedness-expectedness-assessment-reference-safety-information-documents/

https://allaboutpharmacovigilance.org/19-1-guidelines-and-examples-of-expectedness-assessment/

CAUSALITY ASSESSMENT
https://allaboutpharmacovigilance.org/19-causality-assessment/
https://allaboutpharmacovigilance.org/20-scale-for-causality-assessment/

NARRATIVE WRITING
https://allaboutpharmacovigilance.org/21-narrative-writing/

ICSR/CASE FOLLOW-UP – LIST OF ITEMS THAT MUST BE INCLUDED
https://allaboutpharmacovigilance.org/22-case-follow-up/

AGGREGATE REPORTING (PADER, PBRER)/ IND ANNUAL REPORT
https://allaboutpharmacovigilance.org/23-aggregate-reporting-introduction/

https://allaboutpharmacovigilance.org/24-aggregate-reporting-ind-annual-reports/

https://allaboutpharmacovigilance.org/30-periodic-adverse-drug-experience-report-pader-paer/

CLINICAL STUDY REPORT (CSR) – MUST BE SUBMITTED TO FDA WITHIN 1 YEAR OF THE END OF STUDY IN ADULTS AND 6 MONTHS IN CHILDREN
https://allaboutpharmacovigilance.org/25-csr-reports/

NDA/ANDA ANNUAL REPORT
https://allaboutpharmacovigilance.org/26-nda-and-anda-annual-reports/

DEVELOPMENT SAFETY UPDATE REPORT
https://allaboutpharmacovigilance.org/27-development-safety-update-report-dsur/

PERIODIC SAFETY UPDATE REPORT (PSUR) OR PERIODIC BENEFIT RISK EVALUATION REPORT, PERIODIC ADVERSE DRUG EXPERIENCE REPORT
https://allaboutpharmacovigilance.org/28-periodic-safety-update-reports-psurs-periodic-benefit-risk-evaluation-reports-pbrer-and-periodic-adverse-drug-experience-report-pader-introduction/

https://allaboutpharmacovigilance.org/29-periodic-safety-update-reports-psurs-periodic-benefit-risk-evaluation-reports-pbrer/

SIGNAL MANAGEMENT

SIGNALS:
https://allaboutpharmacovigilance.org/31-signal-introduction/

SIGNAL DETECTION:
https://allaboutpharmacovigilance.org/32-signal-management-signal-detection/

SIGNAL VALIDATION:
https://allaboutpharmacovigilance.org/33-signal-validation/

SIGNAL PRIORITIZATION
https://allaboutpharmacovigilance.org/34-signal-prioritisation/

SIGNAL ASSESSMENT – EVALUATION OF RISK
https://allaboutpharmacovigilance.org/35-signal-assessment-evaluation-of-risk/

RECOMMENDATION OF ACTION AND INFORMATION EXCHANGE
https://allaboutpharmacovigilance.org/36-recommendation-for-action-and-exchange-of-information/

BENEFIT-RISK ASSESSMENT
https://allaboutpharmacovigilance.org/introduction-to-benefit-risk-assessment/

https://allaboutpharmacovigilance.org/38-risk-benefit-evaluation-process-overview/

RISK MANAGEMENT PLAN
https://allaboutpharmacovigilance.org/40-medicine-safety-plans-rmp-and-rems/

SAFETY SIGNAL DETECTION AND DATA MINING
https://allaboutpharmacovigilance.org/41-safety-signal-detection-methods-data-mining-approach/

PROPORTIONAL REPORTING RATIO
https://allaboutpharmacovigilance.org/42-data-mining-proportional-reporting-ratio/

REPORTING ODDS RATIO
https://allaboutpharmacovigilance.org/43-reporting-odds-ratio-ror/

RELATIVE REPORTING RATIO
https://allaboutpharmacovigilance.org/44-relative-reporting-ratio-rrr/

CHI SQUARE
https://allaboutpharmacovigilance.org/45-chi-square-%CF%872/

INFORMATION COMPONENT
https://allaboutpharmacovigilance.org/46-the-information-component/

BAYESIAN CONFIDENCE PROPAGATION NEURAL NETWORK
https://allaboutpharmacovigilance.org/47-bayesian-confidence-propagation-neural-network/

MULTI-ITEM GAMMA SHRINKER
https://allaboutpharmacovigilance.org/48-multi-item-gamma-poisson-shrinker-mgps-algorithm/

TRADITIONAL METHODS OF SIGNAL DETECTION
https://allaboutpharmacovigilance.org/traditional-methods-of-signal-detection/

ADVERSE EVENT OF SPECIAL INTEREST (AESI)
https://allaboutpharmacovigilance.org/adverse-event-of-special-interest-aesi/