

# PHARMACOVIGILANCE

## INTRODUCTION TO PHARMACOVIGILANCE

### WEEK 1 SATURDAY



#### PV in the Real World

- What is PV and why does it matter?
- Basic terminologies: ADRs, AEs, SAE, MedDRA, ICH, CIOMS
- Activity: Quiz game – Match the PV terms

### Drug Lifecycle & Role of PV

- Regulatory framework (USFDA, EMA, CDSCO)
- Where PV fits in the pharma value chain
- Activity: Map a drug's lifecycle from discovery to post-marketing

### WEEK 1 SUNDAY



## CASE PROCESSING FUNDAMENTALS

### WEEK 2 SATURDAY



#### Intro to Case Processing

- Types of safety reports (spontaneous, solicited, literature)
- Seriousness, expectedness, causality, validity
- Activity: Breakdown a sample case report

### Source Documents & Narrative Writing

- MedWatch, CIOMS I, and E2B formats
- Writing a case narrative
- Activity: Write a narrative for a mock AE case

### WEEK 2 SUNDAY



# PHARMACOVIGILANCE

## SAFETY DATABASES & TOOLS

### WEEK 3 SATURDAY



#### Tools of the Trade

- Overview of Argus, ArisG, Veeva Vault (with screenshots)
- Intro to MedDRA coding – How to classify events
- Activity: Practice MedDRA coding with sample AEs

### Hands-On Case Simulation

- Simulated case intake to submission workflow
- Group role-play: Case processor, reviewer, QC analyst
- Activity: Review & QC a peer's case form

### WEEK 3 SUNDAY



## AGGREGATE REPORTING & SIGNAL DETECTION

### WEEK 4 SATURDAY



#### Safety Reports Beyond Case Level

- PSUR, PADER, DSUR, RMP – Intro only
- Role of PV in ongoing safety monitoring
- Activity: Summarize a public PSUR or PADER (template)

### Signal Management

- What is signal detection?
- Real examples (e.g., Ranitidine, COVID vaccines)
- Activity: Group discussion – What triggers a label change?

### WEEK 4 SUNDAY



# PHARMACOVIGILANCE

## CAREER PREP & SOFT SKILLS

### WEEK 5 SATURDAY



#### Resume & Role Fit

- Drug safety resume teardown
- Keywords, structuring for non-traditional candidates
- Activity: Peer review resumes in breakout groups

#### Soft Skills for PV Success

- Communication, attention to detail, time management
- Email writing, narrative polishing, QC checklists
- Activity: Write & edit a Med info response email

### WEEK 6 SUNDAY



## PORTFOLIO, PRACTICE, AND PITC

### WEEK 4 SATURDAY



#### Portfolio Case Presentation

- Present your end-to-end case (simulated)
- Sections: Case intake, coding, narrative, QC, summary
- Activity: Present to the class + peer feedback

#### AMA + Industry Insights

- Guest speaker: PV Lead or Safety Physician
- Transition stories + Q&A
- Tips: Internships, fresher-friendly firms, freelancing

### WEEK 4 SUNDAY

