MANAGEMENT OF ADRS

Adverse drug reaction (ADR) is an unintended and potentially harmful response to a medicinal product. ADRs may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure. Conditions of use outside the marketing authorisation include off-label use, overdose, misuse, and medication error.

CASE COLLECTION

- Safety call centre reported cases
- Clinical trials SAEs
- Spontaneous reports
- Literature and Internet review

SAFETY DATA PROCESSING

TRIAGE

- Origin of the source
- Assess AE terms
- Assess case for validity
- Serious/Not serious
- Expected/Unexpected

15 DAYS OR 90 DAYS

QUERY PROCESS

- Medical Concepts
- Causality

DATA ENTRY

- Assign case ID number
- Duplicate case ID
- Generate narrative
- Code case

MEDICAL REVIEW

Complete verification against source data

- ✓ Accuracy
- ✓ Completeness
- ✓ Consistency

SUBMISSION TO HEALTH AUTHORITIES

Learn more at http://www.elc-group.com/en/Pharmacovigilance