

# **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 90 DAYS

#### **QUERY PROCESS**

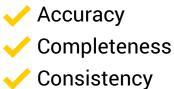
- Medical Concepts
- Causality

**DATA ENTRY** 

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

MEDICAL **REVIEW** 

Complete verification against source data





**SUBMISSION TO HEALTH AUTHORITIES** 





