

Core PV Activities

- AE/ADR event and signal detection
- AE/ADR verification
- AE/ADR data reporting
- AE/ADR data synthesis and analysis
- Generation of hypotheses on new AE/ADR signals
- Dissemination and feedback on AE/ADR
- Supervision and monitoring of PV system



Organizational Issues

- Vertical disease-specific approach vs. integration of all PV under one agency
- Role of research institutions and universities
- Administrative structure
- Role of industry

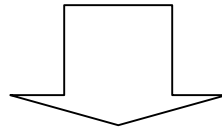


Monitoring Issues

- How to detect events?
- How to grade severity?
- How to classify relationship?
- How to determine expectedness?
- What events to report?
- Pathway for reporting?

Individual Issues

- Motivation/incentives schemes for reporting
- Education/motivation for high quality reporting
- Job satisfaction



Improved PV

- Prompt and timeliness of ADR reports
- ADR data utilization
- Rapid feedback and follow up

Support functions

- Training
- Communication
- Resources
- Logistics

