IRV Service Scope

- Comparison with Competitor Products
- Check Class Effects
- Aggregation of AE Cases
- Signal Detection
- Stratified Comparison with Aggregated Cases
- AE Trend Charts

Communication Tool to Support the Management of Safety Measures

Safety Database

JADER (PMDA)

AERS (FDA)

Detect Safety Signals and Visualize with Alert Function

Display Safety Specifications (SS) which match the set alert criteria. Two levels of alerts can be defined and is represented by the two colors red and orange. A summary of signals detected using the four analytical methods (ROR, PRR, BCPNN, GPS) is available on the signals column.

Compare Adverse Event Trends between Drugs with Same Indications (Class Effect)

AE trend graphs for the first year after marketing authorization, the past 1, 5 or 10 years are available for comparison. Important events and information such as package insert updates and shipment quantity can also be included.

Confirm Signals using Four Analytical Methods (ROR, PRR, BCPNN and GPS) which are also used by Regulatory authorities

Confirm whether or not signals are detected for all AEs and AE groups (e.g. MedDRA SMQ). Click on the graph icon to display a signal chart which compares your product against other drugs for a particular AE. The BCPNN signal graph provides you with the time-series trend of the signal.

Analyze Adverse Event Trends using Stratified Data

Use multiple filters (age, gender, primary disease, concomitant drug etc) to stratify data and analyze AE trends in specific groups. Line list can be accessed by clicking on the numbers displayed. Stratified data and the line list can be exported into Excel spreadsheets for storing, organizing and further analysis of data.

Five Key Benefits

1. Signal Detection with Alert Function (Analytical methods: Reporting Odds Ratio (ROR), Proportional Reporting Ratio (PRR), Bayesian Confidence Propagation Neural Network (BCPNN), Gamma-Poisson Shrinker (GPS))
2. Compare Adverse Events (AE) trends between drugs with same indications (class effect)
3. Analyze AE trends using chronological and/or stratified data
4. Assist in timely communication between PV managers and staff members to monitor the progress of safety measures implementation
5. Avoid increased costs in safety operations