Quality Control and Post-Market Data Collection

FDA View

Ellen Pinnow, MS

Division of Epidemiology

Office of Surveillance and Biometrics

Food and Drug Administration

Background

Goal of establishing a PAS Registry

- Gather essential post-market information
- Longer-term performance including effects of re-treatments & product changes
  - Evaluate real-world device performance (patients and clinicians)
  - Evaluate sub-group performance
  - Outcomes of concern (safety and effectiveness)

What works well: FDA View

Benefits of having a comprehensive registry

- PAS with standard definitions of baseline characteristics, outcomes, and adverse events
- Clinical sites are identified
- IRB approval for the existing registry may be completed
- Case report forms developed
- Data entry processes defined and validated

Current Challenges: FDA View

- No standard definitions of baseline characteristics, outcomes, and adverse events
- Variable quality which is dependent on data collection criteria
  - Patient reported outcomes
  - Required clinical visits
- Variability in data quality of current PAS
  - Data entry personnel and training
  - Few or no validity checks
- Variable amount of missing data

Short Term Priorities: FDA View

- Agreement of standard definitions of baseline characteristics, outcomes, and adverse events
- Agreement of case report form elements
- Validation of data being collected
- Design a good base registry that can evolve with changing technology and data collection requirement

Long Term Priorities: FDA View

- Streamlined implementation of PAS
- Use of study designs, data sources, and innovative tools to address post-approval study questions