IMDRF International Medical Device Regulators Forum

Challenges in Current Post-Market Surveillance

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Setting the Scene: IMDRF and GHTF Foundations

Risk-Based Surveillance Approach
- IMDRF and GHTF promote a risk-based approach to prioritize surveillance efforts based on medical device risks.

Timely Adverse Event Reporting
- Emphasis on prompt reporting of adverse events facilitates rapid safety signal detection and patient protection.

Collaborative Data Sharing
- Comprehensive data sharing among regulators, manufacturers, and healthcare providers enhances transparency and safety.

Non-Harmonised Practices

- Variations in reportable events
- Diverse reporting timelines
- Inconsistent reporting formats
- Language and Translation

Impact of non-harmonisation

- **Delayed Safety Issue Detection** - Inconsistent data reporting may delay safety concern identification, risking patient health and timely interventions.
- **Inefficient Surveillance Systems** - Fragmented global data limits effectiveness of post-market surveillance, reducing medical device safety assurance.
- **Limited Regulatory Decision Making** - Fragmented data may hinder regulators' ability to make informed decisions, leading to suboptimal policies.
- **Increased Regulatory Burden** - complex, inconsistent duplicated regulatory requirements increase costs and resource diversion both for manufacturers and regulators

Opportunities for improvement

Promoting Standardized Global Tools

- Utilizing IMDRF tools like NCAR and AET improves data consistency across regions for adverse event reporting.

Enhancing Collaboration

- Strengthening cooperation between regulators and industry fosters aligned expectations and streamlined processes.

Consistent Guideline Implementation

- Encouraging uniform interpretation of PMS guidelines/documents reduces variability and enhances surveillance effectiveness.

Evaluate older GHTF PMS documents for adoption, updates or retirement

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Thank you/Questions

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