IMDRF International Medical Device Regulators Forum

Leveraging Automation to Enhance PMS Data Integration

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BD Corporate Overview

70,000 +
BD associates worldwide
3 Segments, 9 Business Units

34B +
devices made annually:
RUO, LUO, IVDs, MDs, Pharma Devices
Class I to III implantables MDs

190 +
countries served

Regulated Countries
112 with 59 official languages

$1B +
annual R&D investment & five global enterprise R&D centers of excellence

31,000 +
active patents

2,000+
data scientists and software engineers

~$1B
pharmacy and lab robotics business

BD technology critical in many
Nobel Prize winning discoveries

"BD is a dynamic global medical technology leader that touches billions of patients around the world."

Industry Challenges in Managing PMS Data

PMS Data Sources

- **Digital tools** are transforming post-market surveillance into a proactive discipline.
- However, companies often use **multiple systems** to track different aspects of product safety & performance.
- This **fragmentation** creates silos, limits visibility, and complicates signal detection.

Industry Challenges

- **Fragmented systems** with large volume and complex data
- **Regulatory pressure** to maintain compliance for traceable, auditable, and timely post-market data.
- Need to balance **cost-efficiency** with the need for robust surveillance capabilities

Strategic Goals

- **Unified Surveillance**: Create a single view of product post-market performance.
- **Automated Observations**: Enable real-time, consistent data capture.
- **Early Signal Detection**: Identify emerging issues faster.
- **Regulatory Alignment**: Meet global post-market surveillance requirements.

Considerations for Data Integration

Stepped Approach?

- You already have **multiple systems** (e.g., complaint and service systems) that capture valuable data.
- You can use **automation tools** (like bots) to bridge gaps between systems.
- You want to **minimize cost and disruption** while still improving data flow and visibility.
- You're aiming for **incremental improvements** and learning before committing.

New Digital Tool?

- Your current systems are **incompatible, outdated, or lack key functionality** (e.g., analytics, traceability).
- You need to meet **complex regulatory requirements** that demand unified, auditable data.
- You're **scaling globally** and need a centralized platform for consistent surveillance across regions.
- You want to leverage AI or machine learning for predictive insights, which may require structured, integrated data.

Hybrid Approach?

- Start with automation and integration of existing systems.
- Use that experience to define requirements for a future-ready platform.
- Transition gradually to a new tool if and when the business case supports it.
- Can AI tools be used to aid current systems?

BD Case Study – Automation to Bridge PMS Systems

- BD uses two major systems for post-market feedback:
  - **Complaint System** – Proactive, customer-initiated reports.
  - **Service System** – Reactive, engineer-recorded service events and spare parts usage.
- Each system tracks different process elements and requires different data inputs.
- Both systems provide valuable post-market data (~35k data points annually for a single product line) and must be monitored together.

- BD **deployed a bot** to transfer structured data from the Service System to the Complaint System.
- The bot helps bridge the gap without a full system overhaul.
- Human oversight is still required, especially for contextual observations.

Outcomes & Benefits

- **Proactive Risk Management**: Enables earlier detection and continuous improvement.
  - Linking the systems utilizing the bot enabled service data to feed into the PMS reviews
- **Holistic Insights**: Combines customer feedback with field service intelligence.
- **Cost Efficiency**: Lower initial cost with bot vs. building a new system.

- **Cost Trade-offs:** Initial savings with bot, but increased resource needs for manual oversight.
- **Data Standardisation/Management**: Systems record different types of data; manual enrichment is needed so can be difficult to make fully automated.
- **Change Management:** Training and workflow adaptation required.
- **Scalability**: Infrastructure and process must support future automation and analytics and roll-out to other business areas

Key Learnings and Considerations

How Can AI Enhance PMS Processes? – Industry/BD Example:

- **Case Creation**: AI helping to translate local-language complaints into globally understandable formats.
- **Customer Communication**: AI used to generate problem summaries from customer interactions.
- **Reportability Decisions**: AI analyses data against vigilance criteria.
- **IMDRF Code Selection**: AI assists in coding for adverse events and trending.
- **Predictive Analytics and Signal Detection:** AI can identify emerging safety signals and trends from large datasets, enabling early intervention before issues escalate.
- **Automating Complaint Handling and Intake:** AI can automatically classify complaints as valid or invalid, flag missing information, and triage them for follow.-up, reducing manual workload and errors.
- **Enhancing Proactive PMS:** AI supports proactive data collection beyond traditional complaint channels, including user interaction data, device usage patterns, and clinical outcomes, including published data.

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ありがとう Thank you – Questions?