IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

European Commission

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Postmarket Vigilance Industry Perspectives

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Overview

- Post-market surveillance is **essential** to **ensure that medical devices continue to be safe, perform as intended, and remedial actions and improvements are undertaken**, as necessary
- Critical **need to harmonize** across regulatory jurisdictions
  - Implement IMDRF harmonized **coding system** for **adverse events**
  - Harmonized **terminology** and **definitions** for **corrective actions**
  - Propose **updates to outstanding GHTF Study Group 2 PMS documents** and adoption as IMDRF documents

Post Market Data

- Reactive information
- Proactive information
- Surveillance Management - Process/systems to collect, analyze, study, act, report, take action, etc.
- Master data to study, detect, evaluate, report, track, understand and innovate and develop

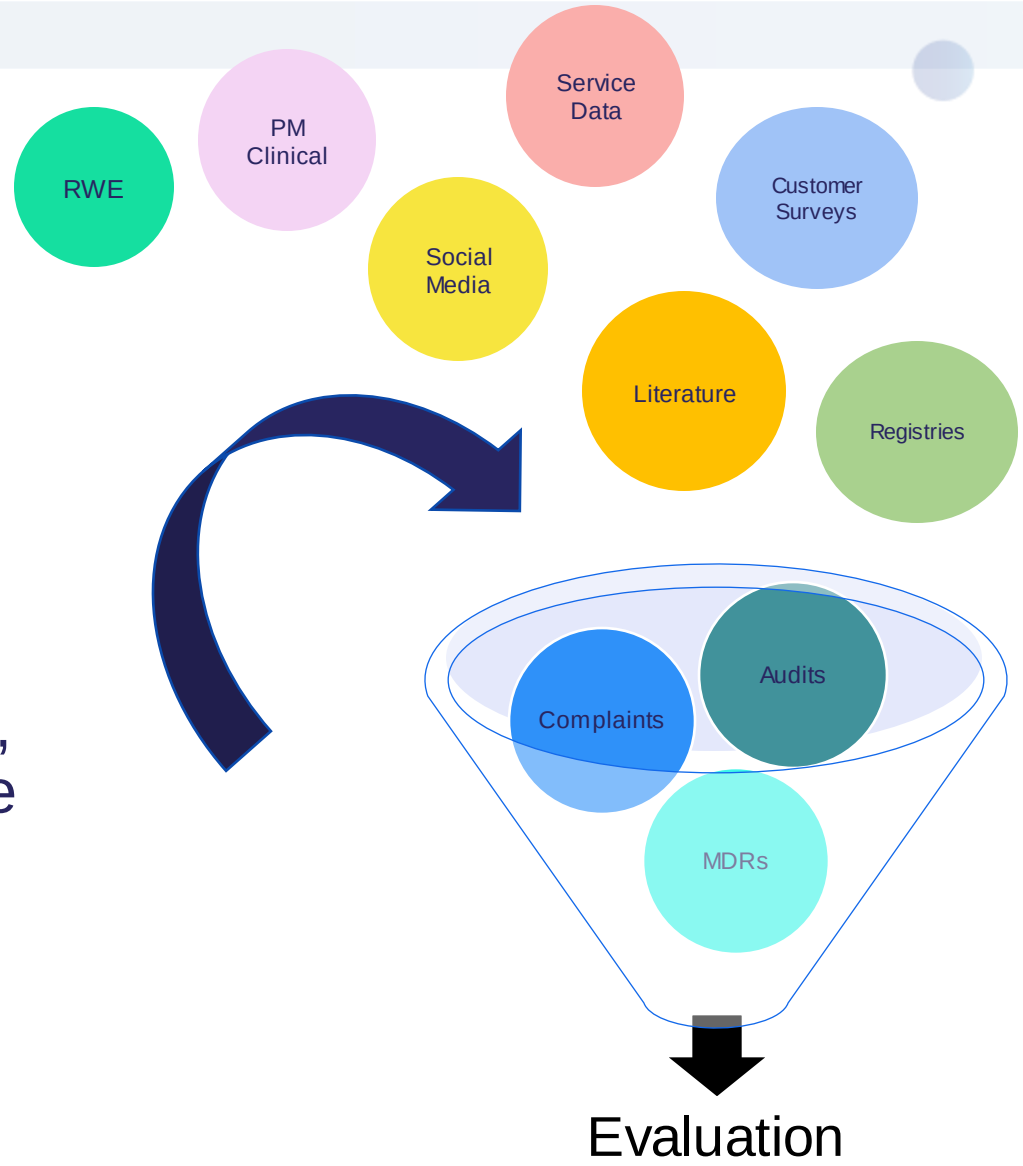
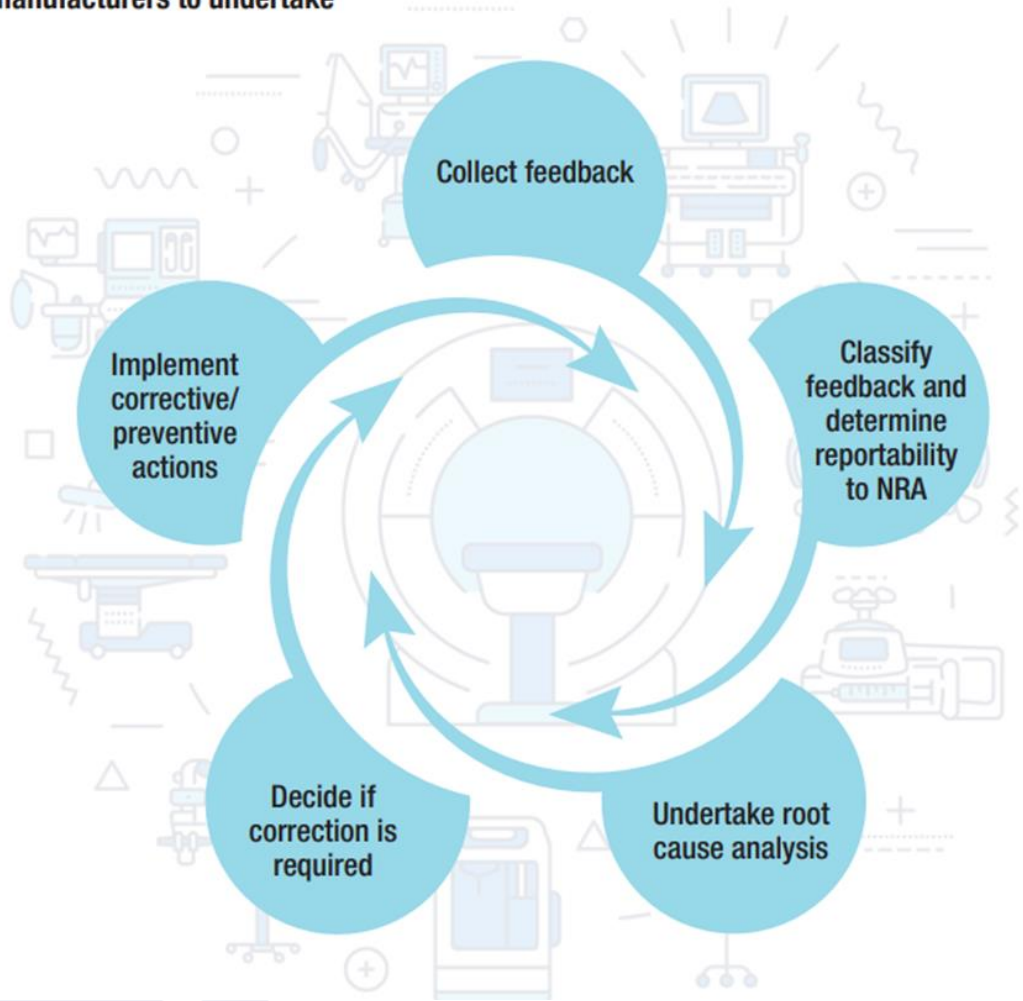
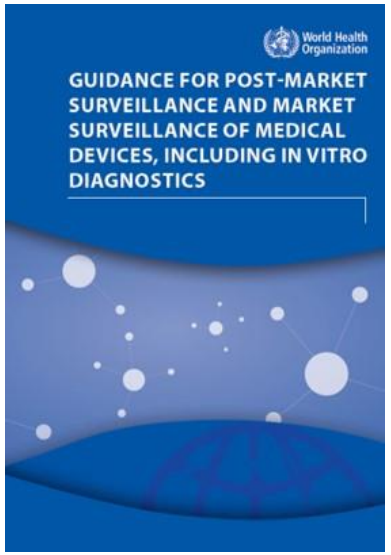


Fig. 3.
Actions for manufacturers to undertake
Page 25





Feedback

- Variations **challenge** our ability to collate and compare and **track data across the world**
- Difficult **to study global data** and accurately **predict and prevent patient harm**
- Impair ability to clearly **communicate** information and **understand impact**
- Less likely to **collaborate** and **rely** on another analysis
- Lack of clarity on how to interpret data due to **unharmonized adverse event codes** and **field corrective action terminology**
- Need for **harmonized reporting/notification template**

Importance of Harmonized Approaches

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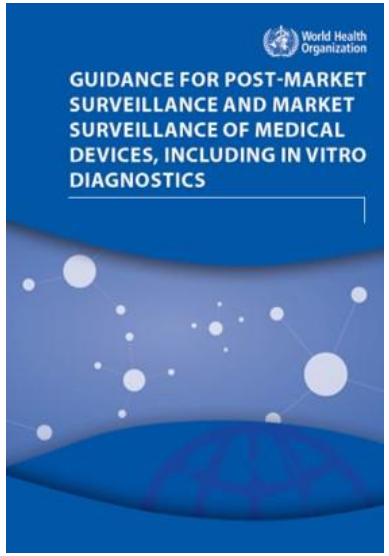

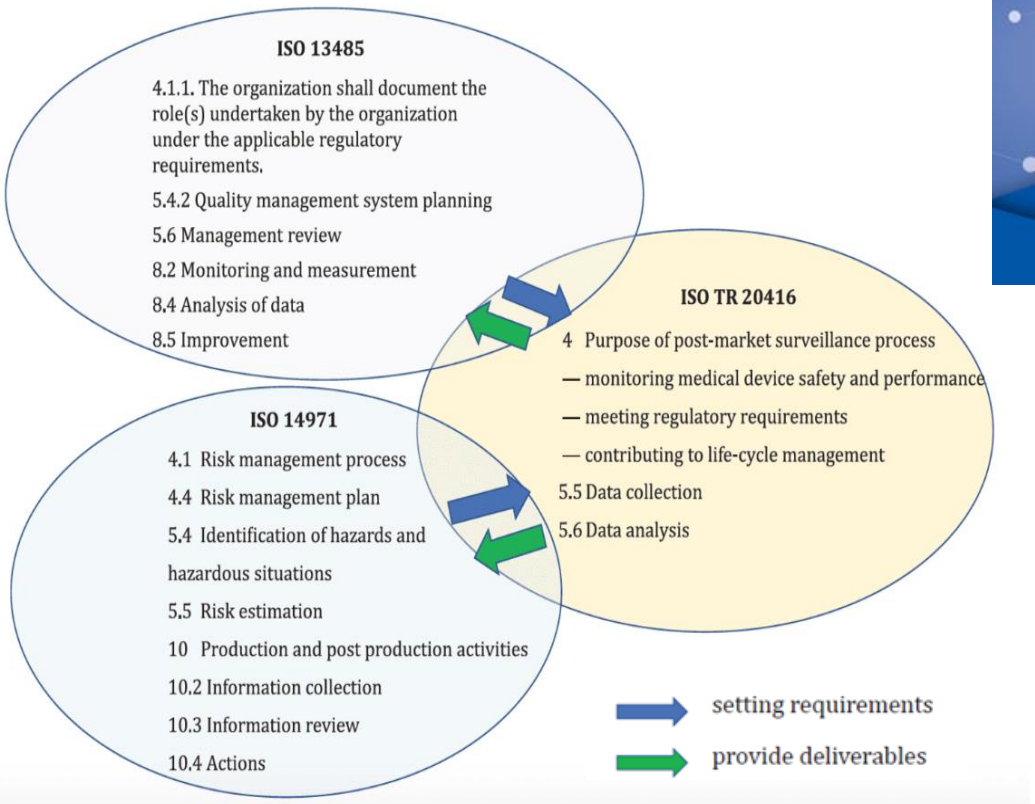

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Proposed Solutions

Harmonized Terminology for Reporting Adverse Events - **IMDRF AE Codes**

- Improve signal detection by adverse event management systems enabling a faster response by both industry and regulatory authorities
- Improves accuracy of capturing and reporting device related adverse events
- Reduces ambiguity which increases effectiveness of the evaluation process
- Readily usable (vs. narrative text) by management systems.

Proposed Solutions

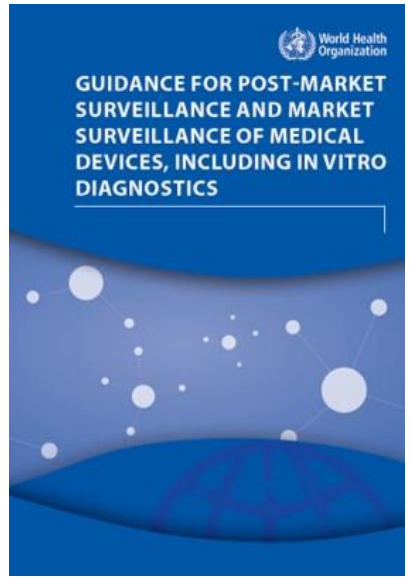
- Additional jurisdictions join **IMDRF MDSAP** as member or affiliate

- Propose IMDRF to update/adopt **outstanding GHTF Study Group 2 PMS documents**
  - N79: Medical Devices Post Market Surveillance
  - N57: Content of Field Safety Notices
  - Harmonization of terminology across jurisdictions
  - Harmonized template for safety reporting

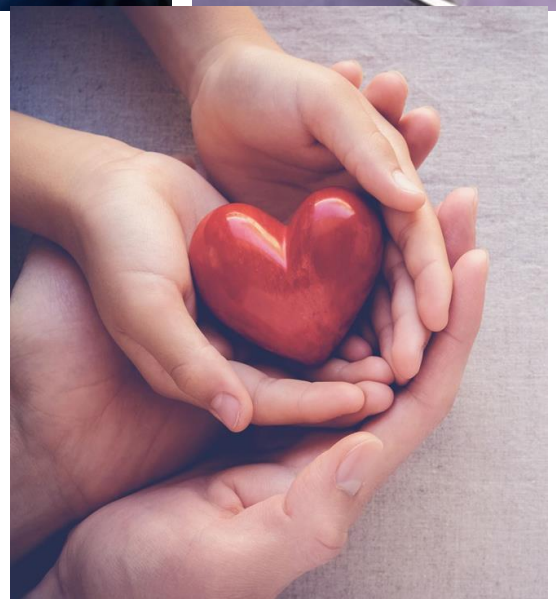
- Support for **new work item related to QMS** – joint work group for IMDRF, GHWP, and ISO

Proposed Solutions

- **Harmonized Unique Device Identifier (UDI)** for post-market surveillance
- *WHO Guidance for Post-Market Surveillance:*
  - **Implementation** of International Medical Device Regulators Forum **(IMDRF) guidance on unique device identification (UDI)** systems for medical devices will **aid documenting user feedback**, and onward **reporting to NRAs** by manufacturers
  - IMDRF's UDI is intended to "**facilitate unambiguous identification** of the medical device… used to **link and integrate existing government, clinical, hospital, and industry databases**"
  - UDI allows more **rapidly identify medical devices** implicated by user feedback.
  - UDI allows **traceability of the medical device throughout distribution and use**



Connected by our common goal… Patients



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THANK YOU / QUESTIONS

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