Postmarket Surveillance for Medical Devices

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Objectives

- Differentiate FDA postmarket surveillance from device manufacturer surveillance activities
- Responsibilities as Medical Device Manufacturer
- Risk management
- Sources of data
- Procedures supporting postmarket surveillance
- Trending and analysis
- FDA vision for a National Postmarket Surveillance System

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Postmarket Surveillance – An FDA Vigilance Activity

Postmarket surveillance is the systematic

- collection,
- analysis,
- interpretation, and
- dissemination

of health-related data to

- improve public health and
- reduce morbidity and mortality

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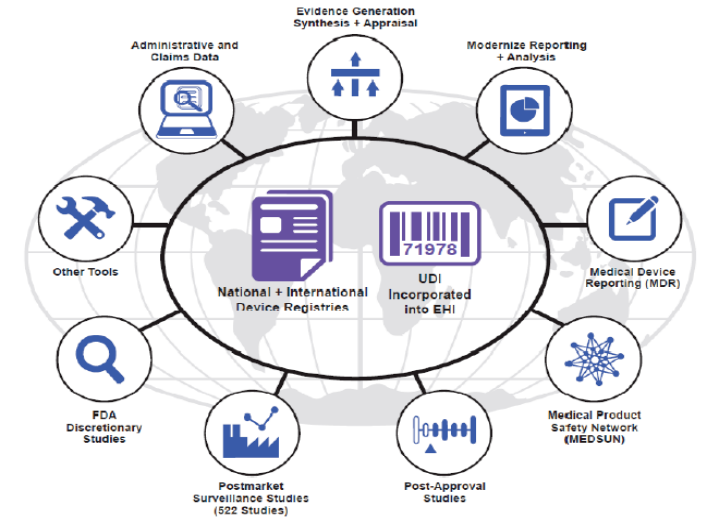
FDA Vision for Postmarket Surveillance



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Postmarket Surveillance – A Manufacturer's Vigilance and Risk Management Activity

Postmarket surveillance is the systematic

- collection,
- analysis,
- interpretation, and
- review

of product-related data to

- ensure distributed products meet specified performance and safety requirements

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Postmarket surveillance

MANUFACTURER RESPONSIBILITIES

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Premarket Activities

- Establish a quality management system that ensures products meet requirements and specifications (FDA QSR and ISO Standards)
- Starts with Design Controls
  - Clinical and nonclinical studies ensure
    - Product is safe and effective
    - Meets user needs
- Purchasing Controls
  - Defined component and service specifications
  - Defined quality requirements for suppliers
  - Suppliers are qualified and monitored

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Postmarket Surveillance: Monitoring and Controlling Risks

- A key requirement of ISO 14971 is to manage risk throughout the product lifecycle
  - Starts during Design Control phase
- ISO 14971 defines risk as the "combination of the probability of occurrence of harm and the severity of that harm."
- Risk management is "the systematic application of management policies, procedures and practices, to the tasks of analyzing, evaluating, monitoring and controlling risk."
- Companies must have processes and procedures for monitoring and controlling product-related risks

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Risk Management

- Establish a Risk Management File for each device or group of similar devices
- The first step in establishing a risk management process is performing a full risk assessment.
  - Risk analysis – Identify hazards and estimate risk
  - Risk evaluation – Examine each hazard to determine acceptability or need for risk reduction
  - Risk Control – Implement measures that reduce or eliminate risks
- Repeat risk assessment throughout the product lifecycle
  - Review of production and post-production information
  - Update Risk Management File based on new information

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Post-market surveillance of medical devices (or post-production monitoring as described in ISO 14971) should include:

- Determination if changes must be made to the original medical device risk assessment;
- A systematic process to evaluate product (not just customer complaints);
- Evaluation of any new hazards;
- Determining whether there have been changes in the acceptability of risks as originally defined;
- Inclusion of objective evidence in the risk management file;

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Process for Postmarket Surveillance/Risk Management

- Identify sources of data
- Establish procedures for data collection and evaluation
- Analyze and trend data
- Determine actions required

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Sources of Postmarket Data

- Customer feedback (complaints, inquiries, surveys)
- Published literature
- Device servicing activities
- Nonconforming product reports
- Manufacturing deviations
- CAPA
- Post-Approval Studies or Postmarket Surveillance Studies (if required)
- Marketing studies
- Others

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FDA ordered postmarket studies may be required for certain devices

Post-Approval Studies (PAS)

- Can be a condition of approval under a Class III PMA order
- Used to assess device safety and effectiveness or long term performance

Postmarket Surveillance Studies (522 Studies) – 21CFR822

- Limited to certain types of class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be-

  (1) implanted in the human body for more than one year, or

  (2) a life sustaining or life supporting device used outside a device user facility. ”

- Vary widely. May include non-clinical testing, observation, analysis of clinical databases and, rarely, controlled trials

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Key Procedures Supporting Postmarket Surveillance and Risk Management

- Complaint Handling
- Medical Device Reporting
- Recalls - Corrections and Removals
- Manufacturing Deviations/Nonconformances
- Quality Audits (Internal and Supplier)
- CAPA
- Quality data trending and review
- Management Review

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Procedures for Postmarket Surveillance

Design procedures and documentation systems with the end in mind

- Determine the data elements required for trending and analysis
  - *What are the Key Performance Indicators (KPIs)?*
  - *What do you need to measure in order to manage risk?*
- Build system documentation for easy retrieval and analysis of data
  - *You cannot effectively analyze and trend data that is not readily accessible*

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Procedures for Postmarket Surveillance

<u>Considerations for e-Systems:</u>

- Build data analysis and reporting requirements should besystem configuration
- Key trending data should not be buried in free text fields
- Use unique fields for each key data element
  - Date Occurred / Date Discovered
  - Device Name / Product Code
  - Lot/ID
  - Problem Code
  - Cause Code
  - Etc.

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Procedures for Postmarket Surveillance

Considerations for e-Systems:

- Use predefined, field-dependent data entries, e.g. drop-down lists or look up tables, to ensure accuracy and consistency.
- Establish meaningful predefined categories that describe each event, e.g. Problem Codes, Root Cause Codes, etc.
  - Avoid creating too many codes. It dilutes your analytical power.
  - Nested or dependent codes are helpful
    - Primary codes facilitate high level trending
    - Secondary codes support more in-depth pareto analysis

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Procedures for Postmarket Surveillance

Complaint Handling procedures

- Evaluate each complaint to determine cause and if product did not perform as intended
- Determine if the event requires regulatory reporting (MDR or Vigilance Reporting)
- If device is nonconforming, determine need for Correction or Removal

Medical Device Reporting

- Define product specific criteria for what is reportable vs. not reportable

Recalls - Corrections and Removals

- Establish an escalation process for evaluation of events indicating nonconforming product or serious adverse events

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Important Note on Training

All personnel that may be involved in collection of customer data (complaints, adverse events) must be trained to ensure events are captured in the quality system!

This includes all field personnel such as:

Sales Representatives

Service Representatives

Distributors

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Procedures for Postmarket Surveillance

Deviations/Nonconforming Product

- All events must be investigated and, if necessary escalated to CAPA

CAPA System

- A robust CAPA system is key to an effective postmarket surveillance and risk management system
- Process for identifying, investigating and correcting product
- Process includes:
  - Identifying the problem
  - Investigating for root cause
  - Identifying corrective/preventive actions
  - Verifying/validating
  - Communicating
  - Monitoring effectiveness

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Procedures for Postmarket Surveillance

Quality Data Trending and Review

- Define sources of data and KPIs for trending
- Identify methods for analysis – Allow flexibility to utilize different tools/approaches
  - Don't get locked in to a single approach for data analysis
- Define criteria for what constitutes an potentially adverse trend that requires further analysis or CAPA

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Procedures for Postmarket Surveillance

Quality Data Trending and Review

- Analyze data – Determine need for CAPA
  - CAPA could include: Manufacturing change
    Labeling Change
    Training
    Design Change
- Frequency – Typically monthly or quarterly. Once annually is not usually considered adequate for most data
- *Use trending as a management tool to move from Reactive to Proactive control of product quality and risk*

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FDA Inspection Trends

- Inadequate Procedures, esp. complaint handling
- CAPA
  - Inadequate documentation
  - Corrective actions implemented without initiating CAPA; No effectiveness checks performed
- Trending and Analysis
  - Inadequate or lack of procedures for statistical analysis
  - CAPA not initiated in response to trends
  - Lack of criteria for adverse trends that require further action or CAPA
  - Inadequate frequency of management review
- Purchasing Controls
  - Inadequate or lack of procedures
  - Inadequate control of supplier quality

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Summary

- Device Manufacturer Postmarket Surveillance is part of Risk Management process
- Conducted throughout product lifecycle
- Important to identify sources of data and KPIs
- Establish procedures and documentation systems for easy data retrieval and analysis
- Support a robust CAPA system
- Track and trend to go from reactive to proactive

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Current System

FDA SYSTEM FOR POSTMARKET SURVEILLANCE

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Current System – Key Elements and Data Sources

- Medical Device Reporting (MDR)
- Medical Product Safety Network (MedSun)
- Post-Approval Studies
- Postmarket Surveillance Studies (522 Studies)
- FDA Discretionary Studies
- Other Tools and Authorities

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FDA's Other Tools and Authorities supporting Postmarket Surveillance

- Registration and Listing
- Recalls
- Device Tracking
- Withdraw of PMA Approval or 510(k) Clearance
- Restrict Devices
- Enforcement Actions
- Removal of a Device as a Predicate

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Challenges

- Diversity and complexity of medical devices
- Rapid technological change
- Incomplete or inaccurate MDR reporting data
- Disparate systems for collecting and analyzing data

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National Postmarket Surveillance System

FDA FUTURE VISION

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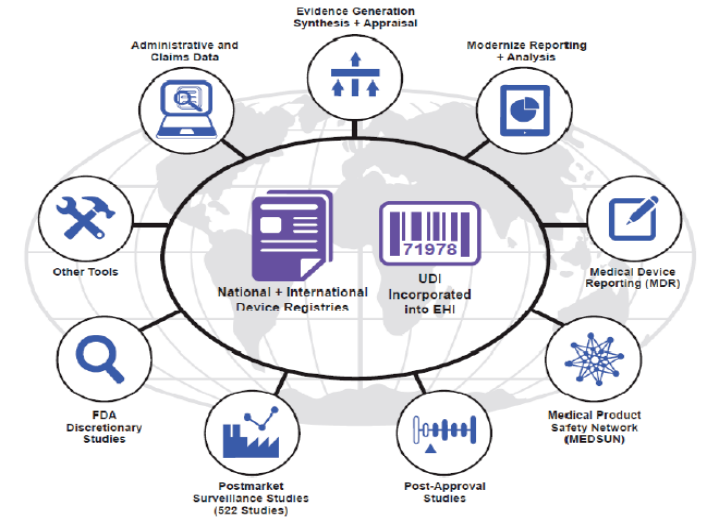
FDA Vision for Postmarket Surveillance



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National System – Key Actions

1. Unique Device Identifier (UDI) system and promote its incorporation into electronic health information;
2. Promote the development of national and international device registries for selected products;
3. Modernize adverse event reporting and analysis; and
4. Develop and use new methods for evidence generation, synthesis, and appraisal.

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Unique Device Identifier (UDI) system

- Establishes a standard, unambiguous system for identifying devices
  - Two components – Device Identifier and Product Identifier
  - Phased in over 7 years. UDI is required for Class III devices and licensed biological devices as of 9/24/2014
- UDI applied to labeling of most devices
  - Plain text
  - Barcoded - automatic identification and data capture (AIDC) technology
- Product information entered in to FDA's Global Unique Device Identification Database (GUDID)
- Improves accuracy of devices identification and reporting

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UDI Benefits to Postmarket Surveillance

- Allowing more accurate reporting, reviewing and analyzing of adverse event reports
- Reducing medical errors by enabling health care professionals to more rapidly and precisely identify a device and obtain characteristics of the device.
- Providing a standard way to document device use in electronic health records, clinical information systems, claim data sources and registries.
- A more robust postmarket surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Providing a standardized identifier to more effectively manage medical device recalls.
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Leading to the development of a globally recognized medical device identification system

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Summary/Conclusion

- Device company reporting of MDRs, recalls, postmarket studies and enforcement actions are inputs to FDA surveillance efforts
- FDA's vision for National Surveillance System
- Relies on UDI implementation and national/international registries
- Requires collaboration from stakeholder throughout the distribution chain
- When fully integrated will allow more rapid assessment of device benefits vs. risks

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