FDA Regulation of Medical Devices
Postmarket Requirements

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Landscape

- FDA Authority
  - Medical Device Act of 1976
  - FDA Modernization Act of 1997
  - Federal Food, Drug and Cosmetic Act (FFDCA)
  - Medical Device User Fee Act (MDUFA)
- Premarket Requirements
  - A Premarket Approval (PMA) application or 510(k) must be submitted. Approval or clearance depends on risk!
- Postmarket Requirements
  - National Medical Device Evaluation System
- Labeling and Manufacturing
- Compliance and Enforcement
Postmarket Requirements

- Postmarketing Surveillance and the National Evaluation System for Health Technology (NEST)
  - Postmarket Surveillance Studies ("522 Studies")
  - Adverse Event Reporting
  - Medical Device Tracking
  - The Sentinel Initiative
  - Unique Device Identification (UDI) System
Monitors the on-going safety.

Corrective actions
- Changing the device labeling.
- Changing the instructions for use.
- Improving user training.
- Removal of the device from the market if appropriate.

Issues
- Some foreign surveillance systems have identified serious device safety concerns sooner than in the United States.

Additional Benefit
- Understanding and measuring device innovation and cost-effectiveness
Information sources:

- **Medical Device Reporting (MDR).**
  - *Adverse Event Reporting* within 30 Days by manufacturer.
  - Annually hundreds of thousands of reports of confirmed or possible medical device related malfunctions, serious injuries, and deaths.

- **Medical Product Safety Network (MedSun).**
  - Network of 280 US hospitals ~5,000 reports annually.

- **Post–Approval Studies –**
  - May be a condition of PMA approval.
- **522 Postmarket Surveillance Studies (Class II and III Devices).**
  - If failure may cause serious consequences.
  - If intended for significant use in pediatrics.
  - Intended to be implanted >1 year.
  - Life-supporting or sustaining outside a device user facility.
- **FDA Discretionary Studies.**
  - FDA conducts its own research
  - Use of privacy-protected data—National registry, Medicare & Medicaid, EHR and literature.
- **National Evaluation System for health Technology (NEST)**
- **Real World Data (RWD)**
  - Data collected outside of traditional clinical trials.
Medical Device Tracking...

- FDA may issue a *tracking order* for any Class II or Class III device if:
  - If failure may cause serious consequences
  - Intended to be implanted <1 year
  - Life-supporting or sustaining outside a device user facility.
The Sentinel Initiative…

- Launched in 2008
- **Postmarket risk identification system**
  - Monitoring all FDA regulated products – drugs and medical devices after they have reached the market.
  - As of 2012 there was secure access to data from ~126 million patients.
  - Health partners: academic medical centers, healthcare systems and health insurance companies.
National Medical Device Evaluation System...

Figure 1. NMDES as a Coordinated Network of Partners

- Patient Communities
- CMS
- PCORnet
- Manufacturers
- Contract Research Organizations (CROs)
- Device Registries
- Coordinated Registry Networks (CRNs)
- MDEpiNet
- Integrated Delivery Systems
- Methods Partners
- Sentinel Initiative
- Sentinel
- Private Health Plans
- FDA
- Coordinating Center
- Best Practices
- DUAs
- Coordination

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<table>
<thead>
<tr>
<th>Coordinating Center Objectives</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Functional Objectives</strong></td>
<td></td>
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<tr>
<td>Optimize the cost of, access to, quality of, and sharing of data related to the evaluation of medical devices</td>
<td>The Coordinating Center should create a coordinated network of data partners by promoting UDI adoption, standardized data sharing agreements, interoperability, and automated data collection and extraction while committing to rigorous privacy, ethical, and data security protections.</td>
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<td>Promote the adoption of best practices for device evaluation</td>
<td>The Coordinating Center should develop a clearinghouse of best practices for evaluating the safety and efficacy of medical devices that is easily accessible to researchers and the public.</td>
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<td>Develop a transparent and streamlined process for evaluating and disseminating medical device safety and effectiveness information</td>
<td>The Coordinating Center should promote methods for evaluating emerging safety signals and the dissemination of accurate and informative safety information to patients, clinicians, and policymakers in a responsible, timely, and accurate manner.</td>
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<td><strong>Organizational Objectives</strong></td>
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<td>Establish governance components for NMDES and the Coordinating Center</td>
<td>A governing board, expert committees, and an executive director will need to be identified and selected by the Coordinating Center early on. The governing components will be critical towards setting the policy agenda for NMDES activities.</td>
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<td>Develop a sustainable business model for a national medical device evaluation system</td>
<td>The Coordinating Center should be the central body responsible for promoting the long-term sustainability of NMDES through both public and private funding sources.</td>
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Figure A1. Essential Uses of a National Medical Device Evaluation System

- Safety surveillance to support evidence-based decision-making, recall management, and safety communication.
  - Active safety surveillance
  - Passive safety surveillance
  - Recall management
  - Safety communication

- Activities to meet specific FDA evidentiary requirements
  - Studies to support premarket submissions
  - Post-Approval Studies
  - 522 Postmarket Surveillance Studies
  - Discretionary studies
  - Indication expansions
  - Label changes
  - Fostering appropriate shifts of premarket data collection to the postmarket setting
Unique Device Identification...

What is a UDI?

Found on the device label, packaging or, in some cases, on the device itself. Both in plain text and machine readable format (AIDC).

UDI = DI + PI

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## Compliance Dates for UDI Requirements

<table>
<thead>
<tr>
<th>Device</th>
<th>Label/GUID/Date Format</th>
<th>Direct Mark (When Required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class III (including class III LS/LS)</td>
<td>September 24, 2014</td>
<td>Class III LS/LS devices must bear a permanent UDI by September 24, 2015. All other class III devices must bear a permanent UDI by September 24, 2016.</td>
</tr>
<tr>
<td>Devices licensed under the PHS Act</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implantable (class II, class I &amp; unclassified)</td>
<td>September 24, 2015</td>
<td>N/A</td>
</tr>
<tr>
<td>LS/LS (class II, class I &amp; unclassified)</td>
<td>September 24, 2015</td>
<td>September 24, 2015</td>
</tr>
<tr>
<td>Class II (other than I/LS/LS)</td>
<td>September 24, 2016</td>
<td>September 24, 2018</td>
</tr>
<tr>
<td>Class I or unclassified (other than I/LS/LS)</td>
<td>September 24, 2018</td>
<td>September 24, 2020</td>
</tr>
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Other Requirements

- **Labeling:**
  - All labels and accompanying printed matter – *including advertising.*

- **Manufacturing**
  - *Good Manufacturing Practice (GMP)* (as described in the *Quality System (QS)* regulations)

- **Compliance and Enforcement**
  - Inspection
  - Warning Letter
  - Product Recall

Summary

Postmarket Requirements

- Postmarket Surveillance Studies.
  - Adverse Event Reporting, Medical Device Tracking, UDI (Unique Device ID)
- National Medical Device Evaluation System.
- Labeling and Manufacturing
- Compliance and Enforcement