FDA Regulation of Medical Devices
Postmarket Requirements

Prof. Steven S. Saliterman
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

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 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

Landscape

Postmarket Requirements
◦ Postmarket 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

Johnson, J. A., FDA Regulation of Medical Devices, 2010
Postmarket Surveillance Studies...

- 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.
  - 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...

![Image](NMDES_Duke_Margolis_Center_Planning_Center_Report_April_2016.png)
Table 1: Objectives of the NMDES Coordinating Center

<table>
<thead>
<tr>
<th>Coordinating Center Objectives</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish a coordinated, centrally managed system for the evaluation of medical devices</td>
<td>The Coordinating Center establishes a centralized system for the evaluation of medical devices, ensuring consistency and efficiency across all centers.</td>
</tr>
<tr>
<td>Promote the adoption of best practices for device evaluation</td>
<td>The Coordinating Center promotes the adoption of best practices for device evaluation, ensuring that all centers follow the same standards and procedures.</td>
</tr>
<tr>
<td>Develop a transparent and accessible process for evaluating and documenting adverse events and warning information</td>
<td>The Coordinating Center develops a transparent and accessible process for documenting adverse events and warning information, allowing for easy access and analysis.</td>
</tr>
</tbody>
</table>

Further information can be found in the NMDES and the Coordinating Center report. A detailed description of the Coordinating Center's objectives and goals can be found in the NMDES planning center report. 

**Figure 1: Concept of a National Medical Device Evaluation System**

- Safety surveillance to support evidence-based decision-making, recall management, and facility management
  - Active safety surveillance
  - Passive safety surveillance
  - Recall management
  - Safety communication
- Activities to meet specific FDA regulations
  - Studies to support premarket submissions
  - Post-Authorization Studies
  - 510(k) Premarket Surveillance Studies
  - Minimally invasive studies

**Unique Device Identification...**

*What is a UDI?*
### 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