FDA AND POST-MARKET SURVEILLANCE

Post-Marketing Activities

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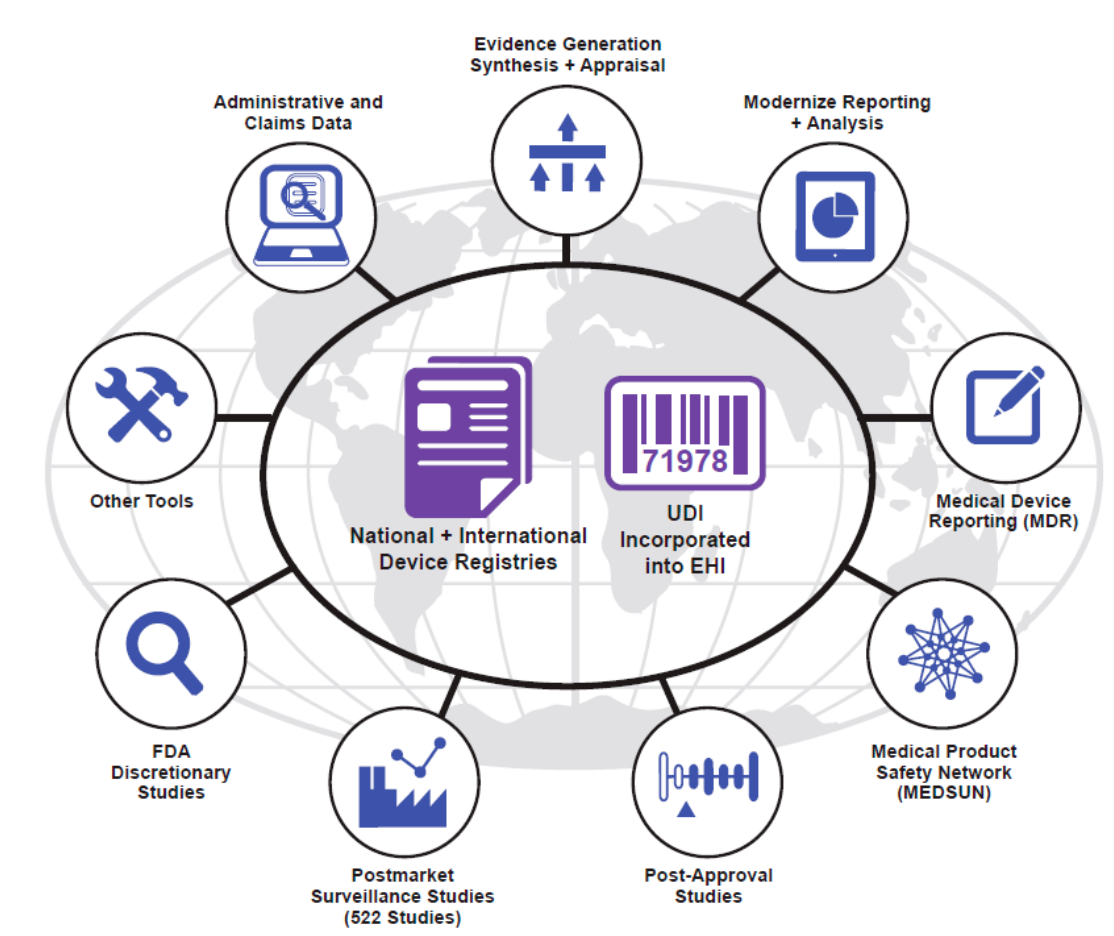
Purpose of this Talk

- To show what FDA expects for post-market surveillance activities
- To discuss actions FDA takes to respond to post-market issues
- To understand the implications of changes to an approved product

Overview



From: Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps Center For Devices And Radiological Health U.S. Food And Drug Administration. April 2013

Manufacturer's Responsibilities (1)

- As part of compliance with the QSRs, manufacturers must have:
  - Adequate complaint handling system
  - Adequate corrective and preventive action procedures to determine the root cause of problems and implement changes to prevent them from happening in the future

Manufacturer's Responsibilities (2)

- Regulatory requirement for mandatory reporting to FDA of certain device-related adverse events and product problems (Medical Device Reporting)
  - Required of manufacturers, importers, and users
  - When device may have caused or contributed to a death or serious injury
  - When device malfunctions and would likely contribute to a death or serious injury if that malfunction were to recur
- Voluntary reporting

The Public's Responsibilities

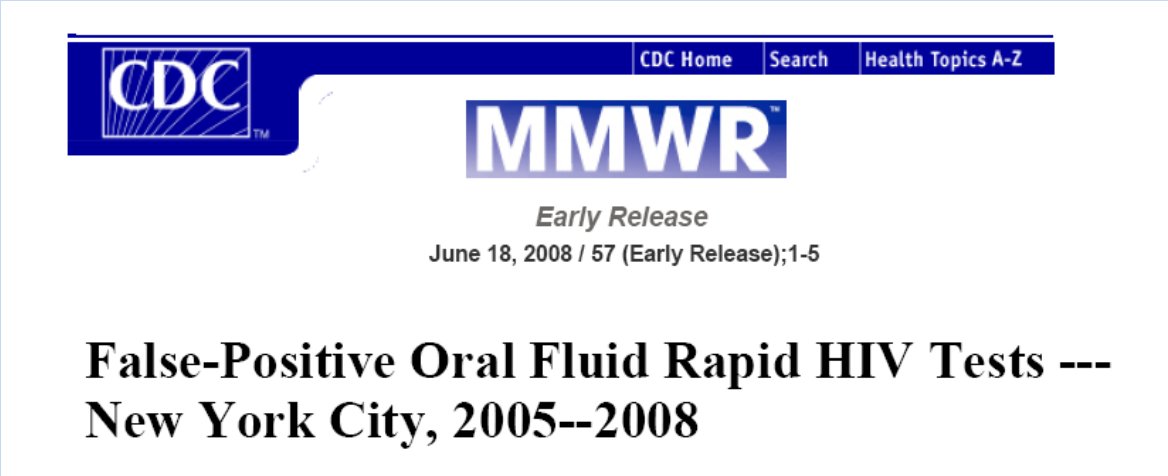
- Register complaints to manufacturer and to FDA
  - Test performance not consistent with claims in package insert/instructions for use
  - Quality issues
- MedWatch reporting

Triggers for Reporting: Test Performance

- False positive results
  - Reactive rapid HIV test result must be confirmed
  - Higher than expected rate of results that do not confirm positive
- False negative results
  - Typically identified through research studies

Examples

- Reports of sporadic, localized increased rate of false positive results



- Reports of false negative results
  - Window period testing
  - Documented false negatives with oral fluid specimens from individuals on anti-retroviral therapy

FDA Responsibilities

- Routine inspections for Class III IVDs (at least every 2 years) to monitor for continued QSR compliance
- Follow up with manufacturer on issues reported to FDA
  - Contact manufacturer
  - Ensure investigation conducted, root cause identified, and corrective action taken
  - For-cause inspection, if necessary
- Compliance actions, if necessary

FDA Enforcement Tools (1)

- Approved/cleared tests
  - Letters to manufacturers
  - Recalls
    - Voluntary action to carry out manufacturer's responsibility to protect the public health with respect to its products
  - Injunction and seizure (judicial actions for US manufacturers)
  - Application integrity policy (action taken in the event of fraud and misrepresentation)

FDA Enforcement Tools (2)

- Unapproved/uncleared tests (*e.g.*, marketed through the Internet)
  - Letters (made public)
  - Import alert (for non-US manufacturers)
  - Court action to prevent sale (for US manufacturers, after gathering evidence)

Changes to an Approved Product

- Manufacturers make changes to their products to
  - Improve efficiency of the manufacturing process
  - Change suppliers of materials/components
  - Correct errors
  - Address problems
  - Other reasons

Changes to the IVD

Guidance for Industry and FDA Staff

Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process

Document Issued on: December 11, 2008

This document supersedes "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" dated March 9, 2007.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm

Assessing Changes

What is the potential for the change to affect the safety and effectiveness of the product?

Thank You