C·D·R·H Center for Devices and Radiological Health

FDA CDRH Informatics Update

Terrie Reed
Associate Director, Informatics

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About CDHR Informatics Staff

- **Small Team; Formally Initiated 5/2010**
  - **Latousha Leslie, Nurse Informaticist**
- **Identify *Informatics* role as part of "Information" team**
  - **Agency Information Management and Data Standards Council**
  - **CDRH Information Technology Group**
  - **CDRH Information Analysts**
  - **Data Sharing Partners/Regulated Entities**

Health Informatics

- For CDRH
  - Data Standards
    - Data Exchange
    - Data Format
    - Terminology
- Vision of Health Informatics
  - Facilitate sharing and aggregating of data across device total product life cycle and with other stakeholders. Result is improved data quality – foundation for effective analysis.

CDRH Activities to Meet Goals

- Coordinate with Agency and Center Initiatives
- Collaborate with Data Sharing Partners - Regulated Industry, Healthcare facilities, AHRQ, CDC, and other Federal Health Architecture Members
- Standards Development –HL7, ISO, IEEE, AAMI, GMDN, SNOMED
- Apply Standards to CDRH Initiatives (e.g. UDI, eMDR)

Examples of CDRH Informatics Projects

Standard Vocabularies

- **Event Problem Codes – Fully Live 4/2/2010**
- **Evaluation Codes**
- **Product Dictionary – Unique Device Identifier (UDI) + Global Medical Device Nomenclature (GMDN)+ Procode + Other Attributes**

Examples of CDRH Informatics Projects

Data Standards

- **Supported by FDA Data Standards Council**
  - **HL7**
    - ***Study Data***
    - ***Clinical Trial meta-data: Clinical Trials Registration and Results (CTR&R)***
    - ***Structured Documentation: CDA (Clinical Document Architecture)***
    - **Adverse Event Reporting: Individual Case Safety Report (ICSR)**
    - **UDI - Product Information +** ***Content of Labeling*** **Structure Product Labeling (SPL)**

UDI: Important for Informatics Efforts

Using UDI as source of Product Information:

- **Improves ability to link internal CDRH databases**
  - **Greater level of specificity in postmarket oversight**
    - **Facilitates analysis of AE Reports**
    - **Improves effectiveness of device recalls**

EHR and Supply chain adoption of UDI:

- **Allows CDRH to use EHR as a rich data source for device-specific safety surveillance/observational study**
  - ***Level of detail - device data to pull from EHR?***
  - ***Best method***

UDI Update

- Finalizing Proposed Rule
- Working on requirements for development of a UDI Database
  - Pilots
  - Collaboration with CDRH IT
- Establishing Internal Team to include IT and Business

GHTF Attributes

- Device Identifier – base + higher levels
- Manufacturer Name (on label)
- Manufacturer Address
- Contact Information
- Nomenclature code and term (GMDN)
- Trade Name (Brand Name)
- Device Model Number
- Controlled by – serial, lot, exp date, mfr date
- Size
- Short Product Description
- Storage and Handling Conditions
- Labeled as Single Use
- Sterility
- Labeled as containing latex

GHTF Attributes (cont'd)

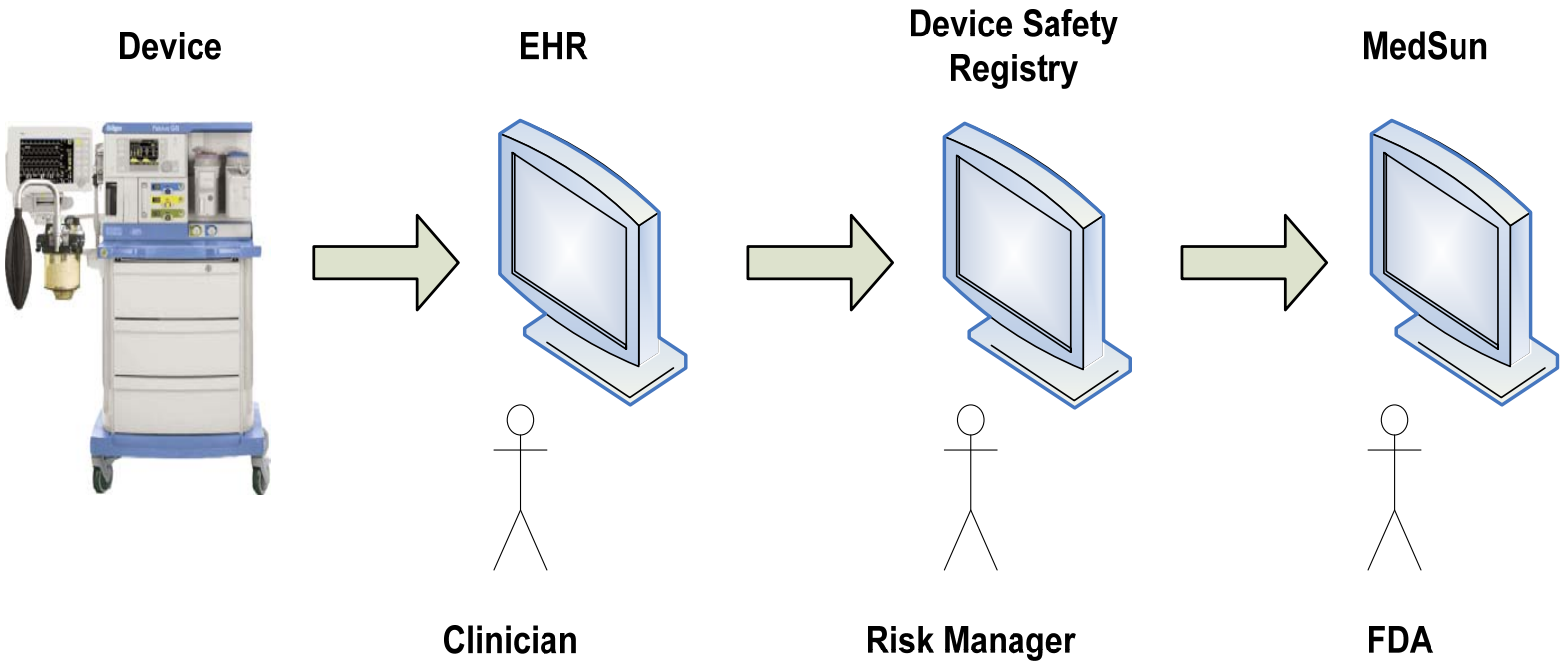
- Authorised Representatives (OOUS)
- Licensing Number (OOUS)
- URL for Additional Information
- Critical Warnings or Contraindications

ASTER-D

- **Objective:**
  - **Determine the risks and benefits that result when the reporting requirements change from a reliance on manual data entry after an event to real-time, automated data capture, storage, and transmission using standard vocabularies and open data transmission methods.**

Aster-D

- **Member of ASTER-D Project on IHE PCD group**
  - **Created a Scenario Use Case for capturing AE**



Questions?