FDA Activities Update

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Center for Devices and Radiological Health (CDRH)
US Food and Drug Administration (FDA)
FDA CDRH 2016-2017 Priority
Establish a National Evaluation System for Medical Devices

GOAL: ACCESS and USE of Real-World Evidence To Support Regulatory Decision Making
FDA CDRH 2016-2017 Priority

Establish a National Evaluation System for Medical Devices

Obtain Access to Real World Data from:

• Electronic patient records, national and international clinical registries, and claims data – UDI, as available

To Generate Real World Evidence
FDA CDRH 2016-2017 Priority
Establish a National Evaluation System for Medical Devices

Use of Real World Evidence for:

- Identifying and clarifying potential safety signals
- Leveraging current registry infrastructures to study iterative improvements to approved devices
- Expansion of label/indications
What is a UDI?

1st requirement... *the label of every medical device shall bear a unique device identifier (UDI)*...

2nd requirement... *the labeler of a device must provide the information required ... for each model or version required to bear a unique device identifier (UDI)*...

[QR Code]

[Website]

accessgudid.nlm.nih.gov
What is a UDI?

1st requirement ... the label of every medical device shall bear a unique device identifier (UDI)...

2nd requirement ... the labeler of a device must provide the information required ... for each model or version required to bear a unique device identifier (UDI)...

>1,100,000 DI Records

accessgudid.nlm.nih.gov
<table>
<thead>
<tr>
<th>Compliance Date</th>
<th>Must bear a UDI &amp; submit data to GUDID</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 24, 2014</td>
<td>• Class III devices, incl. class III stand alone software</td>
</tr>
<tr>
<td></td>
<td>• Devices licensed under the PHS Act</td>
</tr>
<tr>
<td>September 24, 2015</td>
<td>• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software</td>
</tr>
<tr>
<td></td>
<td>• Direct Marking of I/LS/LS for certain intended uses</td>
</tr>
<tr>
<td>September 24, 2016</td>
<td>• Class II devices</td>
</tr>
<tr>
<td></td>
<td>• Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses</td>
</tr>
<tr>
<td>September 24, 2018</td>
<td>• Class I devices and devices not classified class I, II or III</td>
</tr>
<tr>
<td></td>
<td>• Direct Marking of class II devices for certain intended uses</td>
</tr>
<tr>
<td>September 24, 2020</td>
<td>• Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses</td>
</tr>
</tbody>
</table>
Principles for UDI Adoption in EHI

- UDI is part of Real World Data – need to understand
- Data resides at source of truth - GUDID
- Use APIs to access data
- Focus on developers and users
- Include rigorous informatics principles
- Design for the 80% rule; supplemental data later
- Everything is free
- UDI and the data in GUDID will be adopted when it provides value and is USEFUL
Building Infrastructure:

**UDI as Standard and UDI in Standards**

- **HL7 CCDA** - Consolidated Clinical Document Architecture
- **HL7 FHIR** - Fast Health Care Interoperability Resources
- **NCPDP** - National Council for Prescription Drug
- **IHE** - Integrating the Healthcare Enterprise
- **ANSI X12** – American National Standards Institute X12
- **National Library of Medicine** – Terminology services
- **Various data models** – e.g. OMOP, Sentinel
OpenFDA allows public users to merge the GUDID device identification data with other FDA data sets. You will currently find an association from GUDID to FDA Classification data with plans to link to other FDA data sets in the future.
Building Infrastructure: Access to Standard Device Identification Data: AccessGUDID

Accessgudid.nlm.nih.gov
### Device Identifier (DI) Information

- **Brand Name:** Blender
- **Version or Model:** 10501
- **Catalog Number:**
- **Company Name:** Carefusion Corporation
- **Device Description:** MBLENDER, LOFLO, EME
- **Primary DI Number:** 10846446001969
- **Issuing Agency:** GS1
- **Device Count:** 1

### Device Characteristics

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What MRI safety information does the labeling contain?</td>
<td>MR Unsafe</td>
</tr>
<tr>
<td>Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):</td>
<td>No</td>
</tr>
<tr>
<td>Device labeled as &quot;Not made with natural rubber latex&quot;:</td>
<td>No</td>
</tr>
<tr>
<td>For Single-Use:</td>
<td>No</td>
</tr>
<tr>
<td>Prescription Use (Rx):</td>
<td>Yes</td>
</tr>
<tr>
<td>Over the Counter (OTC):</td>
<td>No</td>
</tr>
<tr>
<td>Kit</td>
<td>No</td>
</tr>
<tr>
<td>Combination Product:</td>
<td>No</td>
</tr>
<tr>
<td>Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):</td>
<td>No</td>
</tr>
</tbody>
</table>

- **GMDN**
- **FDA Product Code**
- **Sterilization**
MORE DI RECORD ATTRIBUTES

GMDN Names and Definitions: © Copyright GMDN Agency 2015. Reproduced with Permission from the GMDN Agency.

<table>
<thead>
<tr>
<th>GMDN Preferred Term Name</th>
<th>GMDN Definition</th>
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</thead>
<tbody>
<tr>
<td>Oxygen/air breathing gas mixer</td>
<td>An independent mechanical device designed for accurate mixing of air and oxygen (O2) with O2 concentrations ranging from 21% to 100% (oxygen/air proportioner) that are appropriated for breathing in patients who need a concentration of O2 above the normal concentration in air. The mixer receives air and oxygen from either the hospital gas pipeline or from compressed gas cylinders; it may include a pressure-regulating mechanism. The mixer may deliver the gas to the patient through devices such as ventilators, tracheostomy tubes, endotracheal (ET) tubes, oxygen tents, and/or masks.</td>
</tr>
</tbody>
</table>

CLOSE

FDA PRODUCT CODE

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Code Name</th>
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</thead>
<tbody>
<tr>
<td>BZR</td>
<td>Mixer, Breathing Gases, Anesthesia Inhalation</td>
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</table>

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STERILIZATION

STORAGE AND HANDLING

CLINICALLY RELEVANT SIZE

<table>
<thead>
<tr>
<th>Size Type Text</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>No Device Sizes</td>
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</table>

CLOSE

DEVICE STATUS

ALTERNATIVE AND ADDITIONAL IDENTIFIERS
Test the Infrastructure
UDI as part of CDEs in RWD

BUILD
Building UDI Into Longitudinal Data Sets for Medical Device Evaluation
CARDIOVASCULAR DEVICES
See http://mdepinet.org/build/

RAPID
Registry Assessment of Peripheral Interventional Devices
PERIPHERAL VASCULAR DEVICES
See http://mdepinet.org/rapid/
RAPID project Work Products
Testing and Evaluating the Infrastructure

VQI Registries:

- Carotid Artery Stent
- Carotid Endarterectomy
- Endovascular AAA Repair
- Hemodialysis Access
- Infra-Inguinal Bypass
- IVC Filter
- Lower Extremity Amputations
- Open AAA Repair

**Peripheral Vascular Intervention:** 100,700 procedures

- Supra-Inguinal Bypass
- Thoracic and Complex EVAR
- Varicose Vein
**Procedure Variables**

**Common Data Elements**

<table>
<thead>
<tr>
<th>Procedure Information</th>
<th></th>
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<tbody>
<tr>
<td><strong>Access</strong></td>
<td></td>
</tr>
<tr>
<td>Number Access Sites</td>
<td>2</td>
</tr>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Procedure</strong></td>
<td></td>
</tr>
<tr>
<td>Fluoro Time</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Heparin</td>
</tr>
<tr>
<td>Treatment Details</td>
<td></td>
</tr>
<tr>
<td>Number of Arteries Treated</td>
<td>1</td>
</tr>
<tr>
<td></td>
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Integrate UDI in PSO/Device Registry
Vascular Quality Initiative

VQI offers three ways to enter stents/stent grafts:

1. **Product number or Catalog Number**
2. **Manufacturer**
3. **Device Identifier (GUDID)**

*See VQI website for more information: [http://www.vascularqualityinitiative.org/](http://www.vascularqualityinitiative.org/)*
### Vascular Quality Initiative

**Product Number**

<table>
<thead>
<tr>
<th>Artery 1</th>
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<tbody>
<tr>
<td>Number Treatment Types</td>
</tr>
<tr>
<td>Device 1</td>
</tr>
<tr>
<td>Treatment Type</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Type</td>
</tr>
<tr>
<td>Product Number or UDI</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Type</td>
</tr>
<tr>
<td>Diameter</td>
</tr>
<tr>
<td>Length</td>
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<tr>
<td>Concomitant</td>
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</tbody>
</table>
Vascular Quality Initiative
Auto Populates Company/Brand/Size:

Artery 1

Number Treatment Types 1

Device 1

Treatment Type Stent
Product Number or UDI PRB35-05-100-080 UDI:00821684033746
Manufacturer Covidien LP
Type Protege EverFlex
Diameter 5 Millimeter
Length 100 Millimeter
Vascular Quality Initiative
Selecting by Length

Selecting by Length

Number Treatment Types: 1
Device 1
Treatment Type: Stent
Product Number or UDI: 
Manufacturer: Covidien LP
Type: Protege EverFlex
Diameter: 5 Millimeter
Length: 100 Millimeter

Multiple Device Matches

There are multiple devices which match your selection. Please choose the specific device which was used for this treatment by clicking on the radio button.

- **UDI: 00821684033746**
  - Description: Self-Expanding Biliary Stent System
  - Model or Version: PRB35-05-100-080
  - Catalog Number: PRB35-05-100-080
  - Brand: Protege EverFlex
  - Device Sizes:
    - Outer Diameter: 5 Millimeter
    - Length: 100 Millimeter

- **UDI: 00821684034156**
  - Description: Self-Expanding Biliary Stent System
  - Model or Version: PRB35-05-100-120
  - Catalog Number: PRB35-05-100-120
  - Brand: Protege EverFlex
  - Device Sizes:
    - Length: 100 Millimeter
    - Outer Diameter: 5 Millimeter

Final Technical Result: Select
Improving the data: AHRMM
Leading a Learning UDI Community
AHRMM
Leading a Learning UDI Community

Active Workgroups
Understanding the Meaning

- Unit of Use
- Recognition of AIDC
- Clinically Relevant Size
- Product Categorization
UDI Adoption
Continuous Quality Improvement

- HL7
- X12
- NCPDP
- UDI Rule
- ONC Rule

- Pilots
- Early Adoption
- Mapping to Existing Data Sources (Inventory Systems, Registries)

- AHRMM LUC
- Guidances
- GUDID updates
- Standards updates

- Run Analytics
- Feedback from Pilots and early adopters
- DQ Steward Work
Other ideas?