DI Record

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Today’s Presentation

• GUDID Show & Tell!
• GUDID Data Elements – Vocabulary
• GUDID Data Quality
Device Identifier = mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device

Production Identifier = a conditional, variable portion of a UDI that identifies one or more of the following when included in the UDI:

Lot or batch number, Serial number, Expiration date, Manufacturing date, and, for an HCT/P regulated as a device, the distinct identification code
Repository of key device identification information

Contains ONLY the DI; PIs are not submitted to nor stored in the GUDID

Contains only PI flags to indicate which PIs are on the device UDI
GUDID Overview

Labelers - GUDID Submission Options

GUDID HL7 SPL Submission

GUDID Web Interface

FDA Electronic Submissions Gateway

FDA ESG

GUDID

Global Unique Device Identification Database

Public Users - GUDID Search & Retrieval Options

accessgudid.nlm.nih.gov

Public Users

Search

Download

Web Services

U.S. NATIONAL LIBRARY OF MEDICINE
DI Record Pop Quiz!

- Each packaging level requires a UDI. Each Package DI must be entered as a separate device record in GUDID.
  - True
  - False

Each packaging level requires a UDI. Higher level Package DIs are entered as part of the same base package DI record.
SHOW & Tell
Let's start with....

- Data Element walk through
- GUDID DI Record Life Cycle
  - Draft DI Record
Show....
Let's look at... Moving Between DI Record States

- **Draft**
  - Business rules pass
  - Publish Date in future
  - Business rules pass
  - Publish Date is today
  - Nightly automated check
    - If Publish Date = today

- **Unpublished**
- **Published**
Show....
How to use the DI Record Grace Period

<table>
<thead>
<tr>
<th>Publish Date</th>
<th>Grace Period Start Date</th>
<th>Grace Period End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friday, January 15, 2016</td>
<td>Saturday, January 16, 2016</td>
<td>Monday, February 15, 2016</td>
</tr>
</tbody>
</table>

Grace Period = 30 calendar days*

*Grace period subject to change

During Grace Period

- Unlimited Editing, except for Publish Date
- Please review your data in GUDID!

After Grace Period

- Record released to AccessGUDID
- New DI Trigger Data Elements – no edits
- Limited Editing

*Grace period subject to change
Recap

• GUDID Data Element walk through
• GUDID DI Record Life Cycle
  – moving between DI record states
    • Draft → Unpublished, Draft → Published, Unpublished → Published
• GUDID DI Record Management
  – Editing DI Records
  – Using the grace period
• Copying DI records
DI Record Pop Quiz!

• Unpublished records automatically get published by the system on the DI Record Publish Date.
  – True
  – False
Vocabulary of the DI record
DI Record Vocabulary

- DUNS
- FDA Classification Product Codes (Procodes)
- GMDN
- MRI Safety Information (ASTM F2503-13)
- Sterilization methods (FDA Guidance)
GMDN

• Global Medical Device Nomenclature
• Provides a way to group or categorize devices
• Internationally recognized vocabulary for medical devices
• Required element in GUDID
Purpose of GMDN

Courtesy of B. Daniels, GMDN Agency
Anatomy of a GMDN term

• Each term has 3 parts
  – Code
  – Term name
  – Term definition

• Device groups can be defined by:
  – Intended Use
  – Technology
  – Anatomy
  – Add’l featured
    • Use frequency, power source, etc.

GMDN Code: 35195
GMDN Term Name: Electrocardiographic monitor
GMDN Term Definition: A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

Courtesy of B. Daniels, GMDN Agency
Value of GMDN in GUDID

All devices have a different DI

All devices have 1 GMDN term
GMDN Data Entry

- GMDN Code is a required element of DI record
  - Term name and definition will be auto-populated
- DI Record will only accept Active GMDN Codes
- It is the labelers responsibility to update obsolete GMDN Codes in a DI record
- See Final GUDID Guidance
Additional GMDN Questions

• How do I find the right terms for my device?
• How do I build a new GMDN term?
• How do I get a GMDN Membership?

• See Dr. Barry Daniels, GMDN Agency
Vocabulary Challenges to Data Entry
Data Element: Size – 1

- Designed to capture minimum data set
- Web-data entry designed to capture 3 distinct attributes
- >1 Size Type can be added per DI record
Data Element: Size – 2

- Labelers are encouraged to use pull-down lists, when possible
- When size type is not represented in the list, use **C106041 Device Size Text**
- Remember to include type, value and unit of measure

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C67505</td>
<td>Angle</td>
</tr>
<tr>
<td>C25244</td>
<td>Area/Surface Area</td>
</tr>
<tr>
<td>C64265</td>
<td>Circumference</td>
</tr>
<tr>
<td>C25333</td>
<td>Depth</td>
</tr>
<tr>
<td>C101680</td>
<td>Catheter Gauge</td>
</tr>
<tr>
<td>C96684</td>
<td>Outer Diameter</td>
</tr>
<tr>
<td>C25347</td>
<td>Height</td>
</tr>
<tr>
<td>C25334</td>
<td>Length</td>
</tr>
<tr>
<td>C101685</td>
<td>Lumen/Inner Diameter</td>
</tr>
<tr>
<td>C101687</td>
<td>Needle Gauge</td>
</tr>
<tr>
<td>C112332</td>
<td>Pore size</td>
</tr>
<tr>
<td>C25195</td>
<td>Pressure</td>
</tr>
<tr>
<td>C25335</td>
<td>Total Volume</td>
</tr>
<tr>
<td>C25208</td>
<td>Weight</td>
</tr>
<tr>
<td>C25345</td>
<td>Width</td>
</tr>
</tbody>
</table>

UDIconference.com
Data Element: Size – 3

• Catheter:
  • Bone screw:
    • Stent system:
      • Surgical template:

※ CLINICALLY RELEVANT SIZE [2]

<table>
<thead>
<tr>
<th>Size Type Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Size Text, specify: 7.0 X 55</td>
</tr>
</tbody>
</table>
Data Element: Sterilization

- Designed to provide information to a healthcare professional or patient/consumer
- Not intended to capture manufacturer’s sterilization procedures
Data Element: Single-Use

Definition
• Device is intended for one use or on a single patient during a single procedure

Implementation
• If device does not meet the definition, Single-Use = ‘No’
• Device reviewed as single-use, but base package contains >1 single use
  – Ex: cement powder
• GUDID ‘Single-Use’ does not affect pre-market review
Data Elements: Direct Mark

- ONLY devices subject to 21 CFR 801.45
- Exceptions are listed in 801.45 of UDI Rule
- Do not submit a request for exception per 21 CFR 801.55
- Enter DM DI only if different from Primary DI
Data Element: Secondary DI

- NDC/NHRIC on retail products can be captured in the DI record
Device Type: Unclassified

- Unclassified ≠ Exempt
- Unclassified devices may be reviewed by 510k or PMA process
- All devices should have a FDA listing number
Device Type: Kit

- Kit = 2 or more different devices
- When entering DI record for a kit, some data elements are difficult to complete:
  - Device Count
  - Device Description
  - GMDN
  - Size
  - Sterilization
  - Storage & Handling
Device Type: Kit - 2

• Device Count
  – Kit as a device = 1

• Device Description
  – Use to describe contents of the kit

• GMDN Code(s)
  – Paradigm is one GMDN Code per DI record
  – However, GMDN could be used to identify constituent devices
    • GUDID record (kit) – 7 GMDN Codes
Device Type: Kit - 3

- **Size**
  - When using pull-downs, cannot attribute size type to constituent devices
  - ‘Size Type Text’ is an option to assign size to constituent devices
    - Enter constituent device, size type, value and unit of measure

- **Sterilization**
  - Applies to the whole kit
  - IF whole kit is sterile, Packaged as Sterile = YES
  - IF only 1 or 2 devices are sterile (not whole kit), Packaged as Sterile = NO
Device Type: Kit - 4

• Storage & Handling
  – Like Size, cannot attribute conditions to a specific constituent device
  – ‘Special Storage Conditions’ is also an option
Data Quality
National Evaluation System

• Establishing a national evaluation system for medical devices is one of FDA’s 2016-2017 strategic priorities

• A national evaluation system is a collaborative system that monitors, links, and analyzes real-world data from many different sources—including clinical registries, electronic health records, and medical billing claims—across the medical device landscape with the goal of better understanding how medical devices perform.
GUDID – How will it serve?

GUDID - Separated

- Hospital
- Registries
- Labeler
- Other Request

GUDID - Integrated

- Labeler
- GUDID
- Hospital
- Registries
- Other entities
GUDID and Data Quality

• Start with GOOD Data

• Review your data in GUDID BEFORE Publish Date
  – Export your records from GUDID and review/validate

• Do not wait until after records show up on AccessGUDID
  – This happens AFTER the grace period passes when editing is limited
Data Profiling

• The process of analyzing the data for
  – correctness
  – completeness
  – uniqueness
  – consistency
  – reasonability
## Review your Data

**Manage Device**

<table>
<thead>
<tr>
<th>DI Number:</th>
<th>Company Name:</th>
<th>Brand Name:</th>
<th>Version or Model Number:</th>
<th>DI Record Status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeler DUNS Number:</td>
<td>Last Name:</td>
<td>First Name:</td>
<td>User Name:</td>
<td>Filter</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*UDIconference.com*
Compare Data

Source System Data

Data submitted to GUDID
GUDID – FDA R&L

Product Codes in GUDID:
- MNI
- MNH
- KWP
- NKB
- KWQ
- HWC
- HRS
- JWH
- OSH
- MAX

Product codes in Registration and Listing:
- MNI
- MNH
- KWP
- HWC
- KWQ
- GEI
- HRS
- JWH
- NKB
- HQY
- LPH
- JDI
- LZO
- DZE
- ITX
- GEX
Product Code

• Procode must match the Procode assigned to the device Listing
  – FGE in R&L MIR & MAF in GUDID
  – FGE Catheter, Biliary, Diagnostic in R&L
  – MAF Stent, Coronary in GUDID
## Review Summarized Data

### Example 1

<table>
<thead>
<tr>
<th>ISSUING AGENCY</th>
<th># of Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS1</td>
<td>338</td>
</tr>
<tr>
<td>HIBCC</td>
<td>1</td>
</tr>
</tbody>
</table>

### Example 2

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>GMDN TERM NAME</th>
<th># of Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVD</td>
<td>Polymeric spinal fusion cage, sterile</td>
<td>475</td>
</tr>
<tr>
<td>OVD</td>
<td>Composite-polymer surgical glove, non-powdered</td>
<td>1</td>
</tr>
</tbody>
</table>
GUDID Data Reference Table

- GUDID Data Elements Reference Table - May 1, 2015 (XLS - 104KB)
  - Data Element Name
  - Description
  - Data Entry Notes
  - Edit rule after Grace Period
  - Required
  - Data Type and Length
  - Entry List of Values
  - New DI Trigger
Publish Date

• Use the Publish Date as the deadline for ensuring the data is correct
• Set the Publish Date in the future but before your compliance deadline
• Make use of the 30-day Grace Period after the Publish Date
Device Identifier

- **GS1 Healthcare GTIN Allocation Rules** (Indicator Digit + GS1 Company Prefix + Item Reference + Check Digit)
- **HIBCCs-Guide-to-GUDID-Device-Identifiers** (Labeler Identification Code (LIC) + Product/Catalog Code + Unit of Measure)
- **ICCBBA - Processor Product Identification Code** (Facility Identification Number (FIN) + Facility Product (FPC) + Product Description Code)
Brand Name

• Brand Name must be limited to the name of the device
  – Including Size, Version, Model and other data that is collected in other fields in the database is not recommended
• If the device does not have a Brand Name, use refer to DERT for recommendation
Model Version

• Model or Version of a product is supposed to further help identify the product.
  – It should be set up in a way to distinguish the product from its family
  – When entering the value, do not repeat the word Model or Version
  – It should be easy to remember and use

Version or Model: 580.906299999999999
Consistency?

- Are related data elements such as GMDN and Product code consistent?
- Does the data make sense?
Completeness

• Non-required elements:
  – Description
  – Catalog Number
GUDID Data Quality Community

• Suggestions to start a collaborative public space to share the questions and concerns about the data in GUDID
Call to Action

• Utilize the resources available on our website
• Do not forget data quality
• Be sure to understand the DI record edit rules
• Use the Publish Date effectively
• Make sure the CONTACT information in GUDID is accurate
Thank you for your attention!