Welcome to today’s FDA/CDRH Webinar

Thank you for your patience while we register all of today’s participants.

If you have not connected to the audio portion of the webinar, please do so now, dial:

U.S. Callers: 877-891-6976
International Callers: 1-212-287-1678
Participant Passcode: 6211806
Optimizing GUDID Data Quality

Thursday, August 3, 2017
Agenda

- **Target audience:** Labelers with GUDID accounts for all classes of devices

- **Goal:**
  - Share observations/impacts of data quality (DQ) issues in GUDID
  - Identify “best practices” for GUDID data submission
  - Encourage dialog about GUDID data quality to better understand challenges
GUDID Status

- Total DI Records ~1,500,000#
- GUDID Production Accounts ~4500*

#Includes Published & Unpublished DI records
*Data as of August 1, 2017
GUDID Data --> EHR Information

Patient Medical Record

Implant List

<table>
<thead>
<tr>
<th>Lot</th>
<th>Serial</th>
<th>Exp. Date</th>
<th>DI</th>
<th>Company Name</th>
<th>Brand Name</th>
<th>Model</th>
<th>MRI Safe</th>
<th>Latex</th>
<th>GMDN/SNOMED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Recent Lab Results

<table>
<thead>
<tr>
<th>Vitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>T 99 F</td>
</tr>
<tr>
<td>P 82</td>
</tr>
<tr>
<td>R 18</td>
</tr>
<tr>
<td>BP 136/70</td>
</tr>
<tr>
<td>HT 71 in</td>
</tr>
<tr>
<td>WT 175 lb</td>
</tr>
<tr>
<td>PN 1</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Appointments/Visits/Admissions

No data found.
FDA’s Focus

• Data in GUDID is of acceptable quality to realize public health benefits and a return on investment across the entire healthcare ecosystem.

• Sufficient confidence in the accuracy and completeness of the data to ensure UDI integration from manufacturing through supply chain to patients, electronic health records (EHRs) and registries.

• Engage with stakeholders to address challenges and optimize data quality and utility for higher-risk devices
### Value of UDI

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Value</th>
<th>Registry1</th>
<th>Registry2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier</td>
<td>08714729805885</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand Name</td>
<td>Epic™ Vascular</td>
<td>Device Type</td>
<td>Epic Vascular Self Expanding Stent (120 CM shaft)</td>
</tr>
<tr>
<td>Company Name</td>
<td>BOSTON SCIENTIFIC CORPORATI</td>
<td>Device Manuf.</td>
<td>Boston Scientific</td>
</tr>
<tr>
<td>Catalog Num.</td>
<td>H749392000910 20</td>
<td>Product Num.</td>
<td>39200-09102</td>
</tr>
<tr>
<td>Model or Version</td>
<td>H749392000910 20</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Brand Name</td>
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<td>Epic Vascular Self Expanding Stent (120 CM shaft)</td>
<td>Epic Vascular Stent System 9.0 mm x 100 mm</td>
</tr>
<tr>
<td>Company Name</td>
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<td>Boston Scientific</td>
<td>Boston Scientific Corporation</td>
</tr>
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Data Profiling

• The process of analyzing the data for
  – Correctness
  – Completeness
  – Uniqueness
  – Consistency
  – Reasonability
Internal/External Checks

- Look for logical inconsistencies within the database
- Check related fields together
  - GMDN and Device Description
  - GMDN and FDA Product code
  - Version/Model and Catalog #

### Pro-code | GMDN Term                                      | Count |
------------|-------------------------------------------------|-------|
**OVD**     | Polymeric spinal fusion cage, sterile           | **475** |
**OVD**     | Composite-polymer surgical glove, non-powdered  | **1**  |

FDA Product code aligns with GMDN term except in one case – likely mistake
Key Data Elements
(Short-Term Focus)

- Device Identifier (DI)
- Brand Name
- Version/Model
- Catalog Number
- Description
- Size
- MRI Safety
- Latex
- DUNS Number/Company Name
- GMDN/FDA Product Code
GUDID Data Elements Reference Table (DERT)

- **GUDID Data Element Reference Table (DERT)**
  - Understand GUDID data element definitions and business rules

When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.
Device Identifiers in GUDID

- **GS1 Healthcare GTIN Allocation Rules**
  
  Indicator Digit + GS1 Company Prefix + Item Reference + Check Digit

- **HIBCC 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
Multiple DIs

• **DQ Issue**: Records with the same ‘Brand Name’, ‘Version and Model’, but different DIs

• **Steps to address**: Proposed Learning UDI Community (LUC) workgroup to address multiple DI issue
  – Issuing Agency DI rules
  – Labeler’s internal processes
  – FDA DI triggers
Brand Name

• **DQ Issue:** ‘Brand Name’ field contains more than the brand name of the device
  – Including size, version, model and other data that is collected in other fields in GUDID is not recommended

• **Steps to address:** Include only device brand name
  – If the device does not have a brand name, or any name on the label of the device, enter “NA”
Version or Model

• **DQ Issue:** Entries in ‘Version or Model’ field not sufficient to help identify the product

• **Steps to address:**
  – Distinguish the product from its family
  – Do not repeat the words “Model” or “Version” in the entry
  – Easy to remember and use

Example: long strings or calculated numbers may be a challenge for users

**Version or Model:** 580.9062999999999999
Catalog Number

• **DQ Issue**: ‘Catalog Number’ field is often left blank
  – Although an optional entry in GUDID, catalog number is a legacy identifier and is necessary to link to the DI for lookup

• **Steps to address**: LUC Working Group to discuss and address with best practices
Clinically Relevant Size

- **DQ Issue**: Clinically relevant size entries inconsistent within a device group
  - Avoid using “Device Size Text, Specify” rather than List of Values in GUDID
- **Steps to address**: Requires effort to define size for each device group
  - RAPID WG – Stent
  - LUC WG

<table>
<thead>
<tr>
<th>Size Type Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length: 12 Millimeter</td>
</tr>
<tr>
<td>Needle Gauge: 29 Gauge</td>
</tr>
<tr>
<td>Total Volume: 0.3 Milliliter</td>
</tr>
</tbody>
</table>
Device Description

• **DQ Issue**: ‘Device Description’ is often left blank or not descriptive
  – Although an optional entry in GUDID, ‘Device Description’ is displayed on the search results screen of AccessGUDID
  – Including data from other GUDID fields (e.g., size) not recommended

• **Steps to address**: Enter device description. Recommend using:
  – Cleared/approved indications for use
  – Links to labels or more information
GMDN and Product Code

• **DQ Issue**: GMDN and FDA Product Code information is inconsistent

• **Steps to address**: Ensure GMDN and FDA Product Code align and are consistent with the device
  – Device Categorization LUC WG
  – GMDN/SNOMED
# Data Quality Recap

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Data Quality Best Practices</th>
</tr>
</thead>
</table>
| Device Identifier          | Ensure DI is correct – validate check digits  
One Primary DI per version/model of device                                                   |
| Brand Name                 | Do not include data from other fields (e.g., size)                                            |
| Version or Model           | Enter value only, do not restate field name                                                  |
| Catalog Number             | Include catalog number, if available                                                          |
| Clinically Relevant Size   | Do not include size in ‘Device Description’ or ‘Brand Name’  
Use List of Values in GUDID vs. “Device Size Text, Specify”                                 |
| Device Description         | Include device description. Recommend approved/cleared indications for use                   |
| GMDN Code                  | One code sufficient for most medical devices                                                  |
Future: Enter Once and Reuse

Labeler -> Registries

Payers <-> GUDID

Hospitals

Distributors

REUSE
We want to hear from you...

• What are your challenges with identifying and correcting data quality issues?

• What changes do you recommend to help improve GUDID data quality?

• How do you solicit and use feedback from your customers on their use of your GUDID data?
Thank you for participating!

Please send your comments to:
FDA UDI Help Desk at [www.fda.gov/udi](http://www.fda.gov/udi)
Subject: Aug 3 Webinar Comments

Slide Presentation, Transcript and Webinar Recording will be available at:
[http://www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn)
Under the Heading: UDI System

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