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:

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U.S. FOOD & DRUG ADMINISTRATION

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

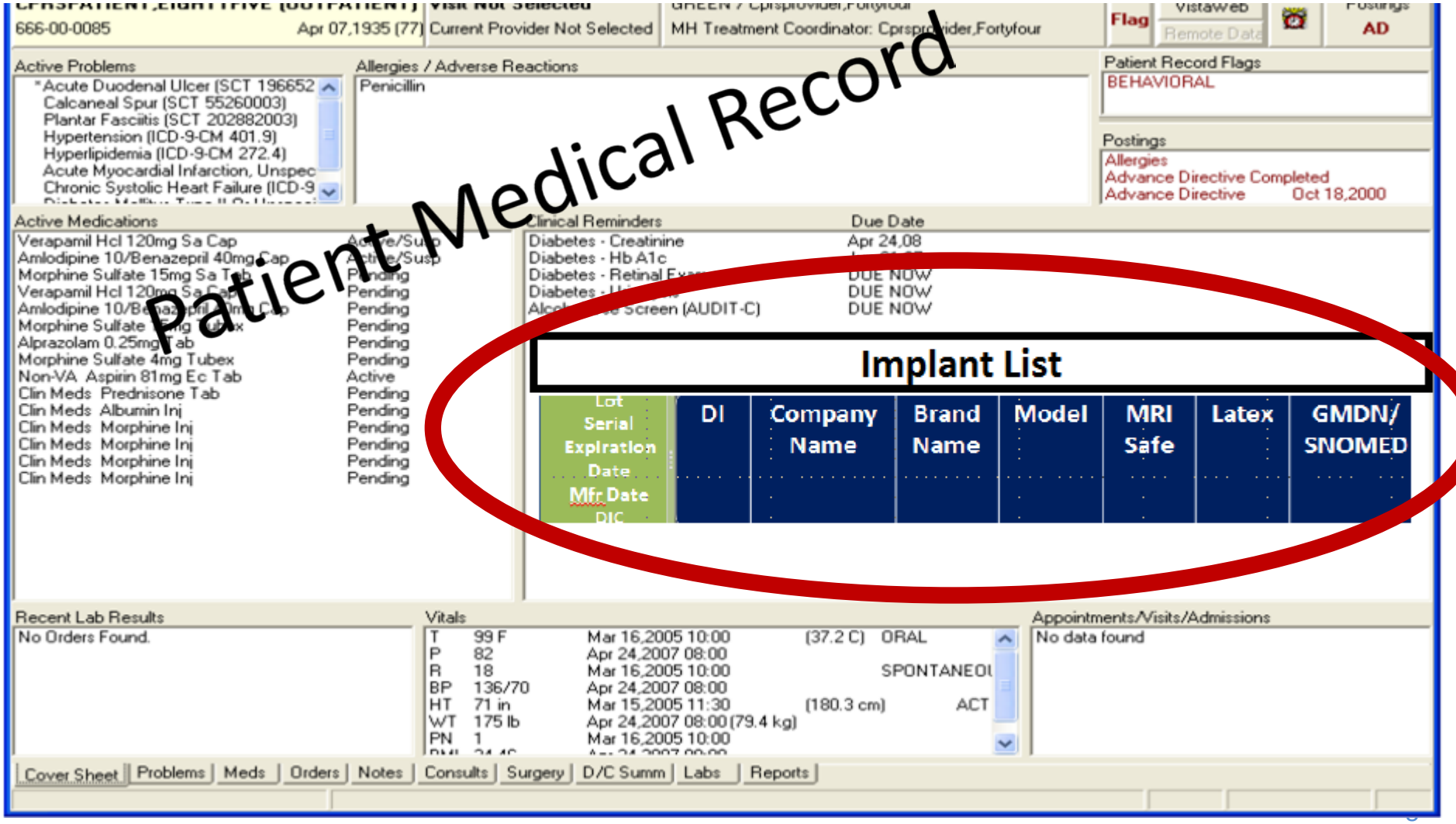
GUDID Status

- 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#Includes Published & Unpublished DI records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



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

GUDID		Registry1		Registry2	
Field Name	**Field Value**	**Field Name**	**Field Value**	**Field Name**	**Field Value**
Device Identifier (DI)	08714729805885				
Brand Name	**Epic™ Vascular**	Device Type	**Epic Vascular Self Expanding Stent (120 CM shaft)**	Device Name	**Epic Vascular Stent System 9.0 mm x 100 mm**
Company Name	**BOSTON SCIENTIFIC CORPORATI**	Device Manuf.	**Boston Scientific**	Device Manuf.	**Boston Scientific Corporation**
Catalog Num.	H74939200091020	Product Num.	**39200-09102**		
Model or Version	H74939200091020				

Data Sources Not Consistent

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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 #

FDA Product code aligns with GMDN term except in one case – likely mistake

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

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

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger	Publicly Released?
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: 580.90629999999999

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

CLINICALLY RELEVANT SIZE [?]

Size Type Text
Length: 12 Millimeter
Needle Gauge: 29 Gauge
Total Volume: 0.3 Milliliter

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

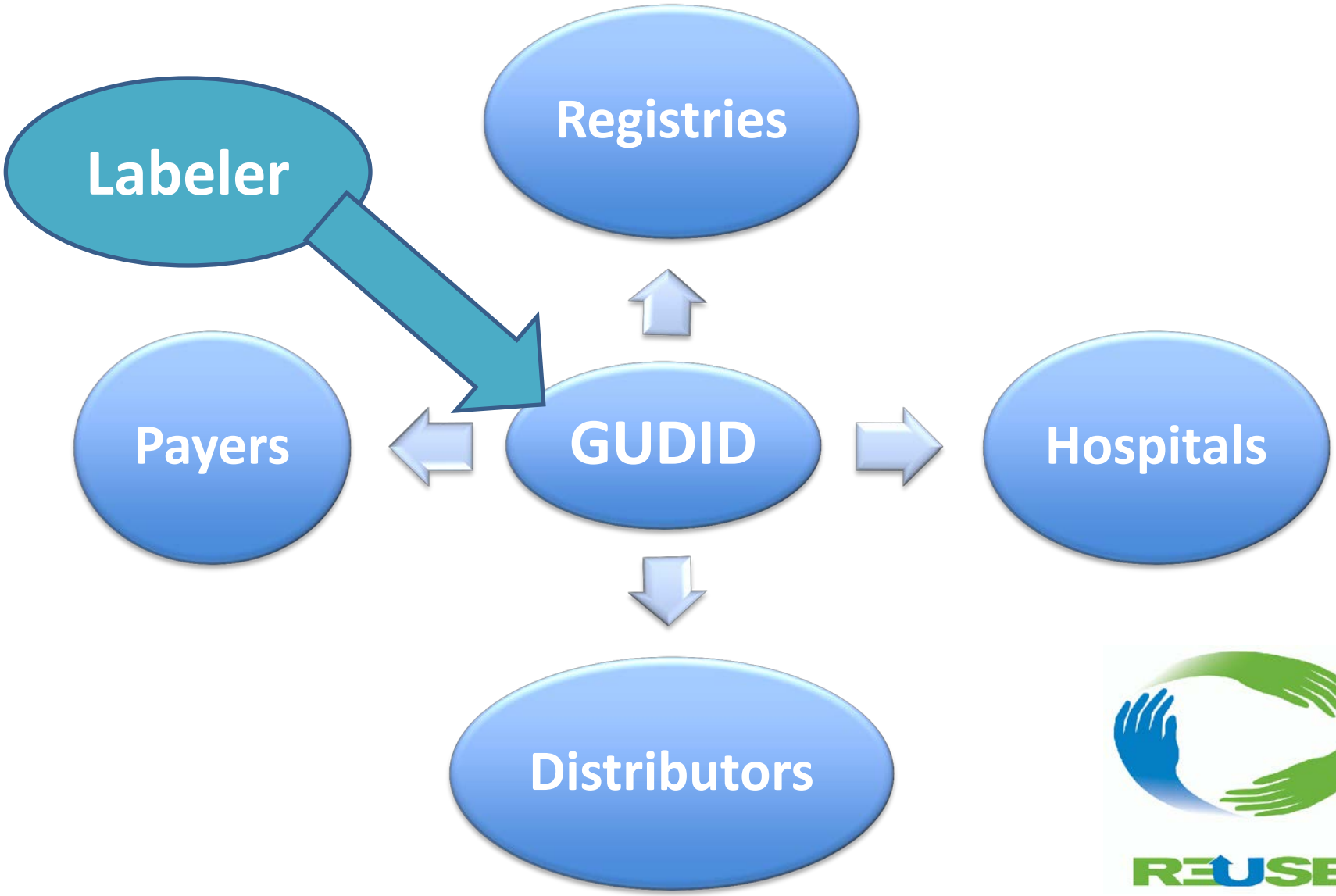
GMDN and Product Code

- **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

Data Element	Data Quality Best Practices
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



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
Subject: Aug 3 Webinar Comments

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http://www.fda.gov/training/cdrhlearn
Under the Heading: UDI System

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