Unique Device Identification (UDI)-Key to Interoperability

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What is a UDI?

Required on the device label, packages or, in some cases, on the device itself (in plain text and machine readable format (AIDC))

The labeler of a device must provide the information required for each model or version

UDI = DI + PI

Access GUDID
IDENTIFY YOUR MEDICAL DEVICE

www.fda.gov
GUDID Records and Submission Compliance Deadlines

*Data Current as of April 3, 2017*
Who made it?
What brand is it?
What model?
Has it been recalled?
Impact on other care?
Did it hasten other conditions?
What was expected life of the device?
Did it last longer than that?
How to analyze UDI data to support innovation?
2015 Edition §170.315(a)(14) Implantable Device List
January 2018

As of 4/5/2017
2017 – Realizing UDI Value

Goal: UDI in data sources of acceptable data quality such that it realizes public health and economic return on investment across the device ecosystem

Demonstrate and improve value through device initiatives such as:

- Medical Device Innovation Consortium (MDIC) National Evaluation System for health Technology (NEST)
- Medical Device Epidemiology Network (MDEpiNET)
- MDIC Case for Quality (CFQ) – dashboards for purchase decisions
- Association for Healthcare Resources and Materials Management (AHRMM) Learning UDI Community (LUC)
- International Medical Device Regulators Forum (IMDRF)
AHRMM LUC
Learning UDI Community

- Major Objectives:
  - Identify UDI adoption hurdles
  - Identify UDI adoption solutions
  - Host in the LUC Resource Center
International Medical Device Regulatory Forum

**2013 – UDI principles and attributes created by IMDRF**

<table>
<thead>
<tr>
<th>IMDRF code</th>
<th>Document title</th>
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</thead>
<tbody>
<tr>
<td>IMDRF/REGISTRY</td>
<td>Principles of International System of Registries Linked to Other Data Sources</td>
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<td>WG/N33 FINAL:2016</td>
<td>and Tools - PDF (873kb)</td>
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<td>Common Data Elements for Medical Device Identification - DOCX (135kb)</td>
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**2017 - New EU MDR Regulations Approved. Time to revisit Global implementation of UDI**
Comparison of 3 Data Sources

GUDID

- Device Identifier
- Brand Name
- Company Name
- Catalog Number
- Model or Version
- Product Code
- GMDN Term
- Description
- Size (Dimension, value, UOM)

R1

- Product Number
- Device Manufacturer
- Device Type
- Device Diameter
- Device Length

R2

- Device Name
- Device Manufacturer
- Device Diameter
- Device Length
- Shaft Length
## Analysis of One Record

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<th>Field Value</th>
<th>Registry 2 Filed Name</th>
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GUDID as Source of Truth

DI Record can be used to auto-populate EHRs, Registries etc

WL GORE

Vascular Quality Initiative
What Can you Do?

Assessing the quality and consistency of data requires data standards.

Be guided by common sense and pragmatism To benefit patient care.