Global Medical Device Nomenclature (GMDN)

An Introduction

Mark Wasmuth – CEO, GMDN Agency
What we will be discussing

- Why do we need GMDN?
- What is GMDN?
- GMDN and UDI?
- How can we use the GMDN?
- Benefits for Researchers
Why the need for Device names?

Large variety of devices!
Why the need for Device names?

And all these too!
Why is consistent naming important?

- Medical Devices are traded internationally
  - Regulators need to
    - Identifying the product groups
    - Approve devices efficiently
    - Identify individual and ‘systematic’ failure types
  - Healthcare Providers need to
    - Identify the products they use
    - Use their inventory more efficiently
    - Identify more effective devices
Why was the GMDN needed?

Existing (national) nomenclatures:
- Not suitable for international harmonisation
- Too vague / poor definitions
- Too rigid – difficult to include new technology
- Can’t keep up with volume of innovation
- Too many duplicates / overlaps
- Single language
- Uncontrolled – no update method for users

The GMDN is a harmonizing standard.
What about trade descriptions?

Example - A recent study to find all **Peripheral Stents** sold in the USA found Manufacturer’s descriptions confusing:

- Self-Expanding Stent System
- Self-Expanding Peripheral Stent System
- STENT COMPLETE SE LONG US
- Self-Expanding Stent
- Trade name Stent System

We need a name we can all use
What is the GMDN?

Global Medical Device Nomenclature (GMDN)

- Used by over 80 national Medical Device Regulators
- Over 7500 Manufacturers worldwide
- Translated into 25 languages
- 24,000 descriptions with detailed definitions
- Controlled distribution and updating
- International acceptance
- Up to date with latest technology
Global use of GMDN

- European Commission uses the GMDN for their **EUDAMED** (market surveillance database)
- Widely supported by device **Trade Associations** (Advamed, MedTech Europe, GMTA, DITTA, etc)
- The **WHO** use GMDN in their field guide for developing countries
- **US FDA** are using GMDN in their national implementation of Unique Device Identification (UDI)
GMDN Term Structure

Each GMDN Term consists of 3 parts:

- **Term Name:** General-purpose syringe, single-use

- **Definition:** “A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both)…”

- **Code:** 47017
GMDN Agency publish the GMDN

GMDN Agency

The GMDN Agency is responsible for the Global Medical Device Nomenclature (GMDN) used to identify medical devices.

News

UDIs and Traceability for Medical Devices Forum, 17-18 May 2017
17 Feb 2017 - The GMDN Agency will be presenting at UDIs and Traceability for Medical Devices Forum in Brussels, Belgium on 17-18 May 2017. Discover key lessons learned from...

GMDN Agency to support the UDI Conference 7 & 8 June 2017 in Baltimore, USA
03 Feb 2017 - As an educational authority on UDI, the 9th annual UDI Conference will once again bring industry stakeholders together with the FDA UDI Team to ensure accurate...

GMDN expert at UDI Workshop in London, 24th November 2016
27 Oct 2016 - Edward Glenn will give a presentation at the UDI Workshop at the Hilton Metropole in London, UK, on 24th November 2016. The event is free of charge for register...

Welcome GMDN test

Start Page
Help file to get you started.

Membership
Information about your account membership.

Alerts
Notifications about your account and purchased terms.

Orders
Manage your orders.

Users
Manage your users.

My Terms
View your purchased GMDN Codes for your devices.

Enquiry
Can't find a term for your product?
Search using key words

| Abdominal aorta endovascular stent-graft |
| Abdominal aorta endovascular **stent-graft** deployment aid |
| Antibody-coated coronary artery **stent** |
| Antibody-coated coronary artery **stent**, drug-eluting |
| Aortic transcatheter heart valve bioprosthesis, **stent-like framework** |
| Bare-metal aortic **stent** |
| Bare-metal biliary **stent** |
| Bare-metal carotid artery **stent** |
Search using ‘high level’ groups

Explorer

Browse device definitions by group.

CT2566: Haemodynamic-modulation vessel repair implant
- CT2090: Stents
  - CT2177: Bioabsorbable stents
  - CT513: Non-vascular stents
  - CT485: Vascular stents
    - CT2250: Aortic stents
    - CT2137: Bioabsorbable vascular stents
  - CT1102: Coronary artery stents
    - CT1812: Drug-eluting coronary artery stents
- CT2269: Drug-eluting vascular stents
- CT2270: Endovascular stent-grafts
- CT2249: Intracranial vascular stents

1-6 of 6 term(s)
- Drug-coated-metal coronary artery stent
- Drug-eluting coronary artery stent, antibody-coated
- Drug-eluting coronary artery stent, bioabsorbable-polylactic acid (58771)
- Drug-eluting coronary artery stent, carbon-coated
- Drug-eluting coronary artery stent, fully-bioabsorbable coated
- Drug-eluting coronary artery stent, non-bioabsorbable coated
When we can’t find a GMDN Term?

- Our aim is to include a description for all medical devices
- Free on-line enquiry process
- We provide updates for manufactures
- Bulk data services for:
  - Regulators
  - Hospitals
  - Researchers
What is the Trend?

GMDN Term Changes Monthly

- Red: Obsolete
- Blue: Amended
- Green: New Terms
## Term changes - new this week!

<table>
<thead>
<tr>
<th>GMDN Code</th>
<th>GMDN Term Name</th>
<th>CT Name (higher level group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>63286</td>
<td>Inpatient motion surveillance software</td>
<td>General hospital devices</td>
</tr>
<tr>
<td>63285</td>
<td>Nasal/eye irrigation saline solution</td>
<td>Ophthalmic devices</td>
</tr>
<tr>
<td>63284</td>
<td>Ingrowing toenail splint/brace</td>
<td>Body tissue manipulation and reparation devices</td>
</tr>
<tr>
<td>63283</td>
<td>Transcatheter heart valve prosthesis implantation catheter</td>
<td>Cardiovascular devices</td>
</tr>
<tr>
<td>63282</td>
<td>Cotton wool ball, sterile</td>
<td>General hospital devices</td>
</tr>
<tr>
<td>63281</td>
<td>Cotton wool ball, non-sterile</td>
<td>General hospital devices</td>
</tr>
<tr>
<td>63280</td>
<td>CD26 cell marker IVD, antibody</td>
<td>In vitro diagnostic medical devices (IVDs)</td>
</tr>
<tr>
<td>63279</td>
<td>Pressure bandage, Hevea-latex, reusable</td>
<td>Body tissue manipulation and reparation devices</td>
</tr>
<tr>
<td>63278</td>
<td>Tongue/lip exerciser</td>
<td>Physical therapy devices</td>
</tr>
</tbody>
</table>
GMDN is not the same as the UDI!

The GMDN and UDI work together

Device Type = Unique Device Identifier
From a single supplier
(e.g. 12345678909874)

Device Group = GMDN Term
All suppliers
(e.g. GMDN Code 47017)

Hudson

12345678909874

Brooks

19876543218976

Woods

32345678908765
The USA are using GMDN now

- Collecting data in US FDA GUDID
  - Nearly 1.5 million device records so far and growing - see https://accessgudid.nlm.nih.gov/
  - Search by UDI and GMDN Term Name
  - Quality checking of UDI data

- Evaluating UDI (MD EpiNet)
  - Registry Assessment of Peripheral Interventional Devices - mdepinet.org/rapid
  - Building UDI into Longitudinal Data for Medical Device Evaluation - mdepinet.org/build
UDI: 0613994868268

**Device Description:** THV 1000-29 3F AORTIC BIO 29MM

**Primary DI Number:** 0613994868268
**Issuing Agency:** GS1
**Device Count:** 1

---

**GMDN**

<table>
<thead>
<tr>
<th>GMDN Preferred Term Name</th>
<th>GMDN Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic heart valve bioprosthesis</td>
<td>A sterile xenograft (e.g., porcine or bovine heart valve) intended to be implanted in a patient during open heart surgery to repair or replace a dysfunctional aortic heart valve. It is processed to render the tissue in the valve non-viable, it may be tissue only, or tissue attached to a metal or synthetic polymer framework. The device is typically used to treat acquired or congenital valvular disease.</td>
</tr>
</tbody>
</table>

---

**Related Links:**
https://accessgudid.nlm.nih.gov/
AccessGUDID downloads may be most useful for hospitals and other health care systems, researchers, registries, and third-party data aggregators, providing GUDID data to users in near "real time". This page contains the latest database release files.

If you need help downloading the GUDID data or understanding the AccessGUDID file schema, please visit the Download Section of the Help Page.

**DAILY RELEASES**

- **gudid_daily_update_20180413.zip** [HTTP / FTP]
  - Date Created: Apr 13, 2018
  - Number of Device Identifier Records: 894
  - File Size: 126 KB
  - MD5 Checksum: 732501883ecce1c2ed6b9c467cf808a2

**LATEST FULL RELEASE**

- **gudid_full_release_20180402.zip** [HTTP / FTP]
  - Date Created: Apr 02, 2018
  - Number of Device Identifier Records: 1623452
  - File Size: 145 MB
  - MD5 Checksum: 17111da53ab9ed8e8999a9110c5295589e

AccessGUDID also provides Delimited Files of the FDA Full Release. These files contain reorganized data from the FDA release files in a pipe delimited format meant for importing into relational models.
Examples of using GMDN in Regulation

- Better Regulation
  - Speed up Pre-market approval
  - Identify products quickly
  - Detailed information on imports and exports
  - Quickly identify trends about new equipment use and problems

- Post Market surveillance
  - Identify systematic (generic) product failure
  - Support rapid product recall
GMDN identifying systematic problems

**Product Failure**

**Regulator Device Register**

<table>
<thead>
<tr>
<th>GMDN</th>
<th>Make</th>
<th>UDI [GTIN]</th>
<th>Date</th>
<th>Recall</th>
</tr>
</thead>
<tbody>
<tr>
<td>38501</td>
<td>Hudson</td>
<td>12345678909874</td>
<td>2011</td>
<td>✔</td>
</tr>
</tbody>
</table>
GMDN identifying systematic problems

Product Failure

Hudson

Jones

Regulator Device Register

<table>
<thead>
<tr>
<th>GMDN</th>
<th>Make</th>
<th>UDI [GTIN]</th>
<th>Date</th>
<th>Recall</th>
</tr>
</thead>
<tbody>
<tr>
<td>38501</td>
<td>Hudson</td>
<td>12345678909874</td>
<td>2011</td>
<td>✓</td>
</tr>
<tr>
<td>38501</td>
<td>Woods</td>
<td>32345678908765</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>38501</td>
<td>Brooks</td>
<td>19876543218976</td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>38501</td>
<td>Jones</td>
<td>58746528415424</td>
<td></td>
<td>?</td>
</tr>
</tbody>
</table>

Investigate this product too? Is it a systematic failure?
# Failure Mode – GMDN Group

## Example - Metal-on-Metal Hip Implants

<table>
<thead>
<tr>
<th>GMDN CT</th>
<th>GMDN</th>
<th>UDI</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>W</td>
<td>X</td>
<td>A</td>
<td>1.3</td>
</tr>
<tr>
<td>W</td>
<td>X</td>
<td>B</td>
<td>1.5</td>
</tr>
<tr>
<td>W</td>
<td>X</td>
<td>C</td>
<td>1</td>
</tr>
<tr>
<td>W</td>
<td>X</td>
<td>D</td>
<td>1.75</td>
</tr>
<tr>
<td>W</td>
<td>X</td>
<td>E</td>
<td>1.2</td>
</tr>
<tr>
<td>W</td>
<td>Y</td>
<td>F</td>
<td>3.2</td>
</tr>
<tr>
<td>W</td>
<td>Y</td>
<td>G</td>
<td>4.1</td>
</tr>
<tr>
<td>W</td>
<td>Y</td>
<td>H</td>
<td>4.5</td>
</tr>
<tr>
<td>W</td>
<td>Y</td>
<td>I</td>
<td>3.8</td>
</tr>
<tr>
<td>W</td>
<td>Y</td>
<td>J</td>
<td>3.5</td>
</tr>
<tr>
<td>W</td>
<td>Z</td>
<td>K</td>
<td>1.8</td>
</tr>
<tr>
<td>W</td>
<td>Z</td>
<td>L</td>
<td>1.6</td>
</tr>
<tr>
<td>W</td>
<td>Z</td>
<td>M</td>
<td>1.2</td>
</tr>
<tr>
<td>W</td>
<td>Z</td>
<td>N</td>
<td>1.4</td>
</tr>
<tr>
<td>W</td>
<td>Z</td>
<td>O</td>
<td>1.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Failure Mode - GMDN Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
</tr>
<tr>
<td>X</td>
</tr>
</tbody>
</table>

---

**G•M•D•N**
### Failure Mode – Manufacturer Group

<table>
<thead>
<tr>
<th>Type GMDN</th>
<th>Make</th>
<th>Type GMDN</th>
<th>Failure rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>Jones</td>
<td>A</td>
<td>1.3</td>
</tr>
<tr>
<td>Y</td>
<td>Jones</td>
<td>B</td>
<td>1.5</td>
</tr>
<tr>
<td>Y</td>
<td>Jones</td>
<td>C</td>
<td>1</td>
</tr>
<tr>
<td>Y</td>
<td>Jones</td>
<td>D</td>
<td>1.75</td>
</tr>
<tr>
<td>Y</td>
<td>Jones</td>
<td>E</td>
<td>1.2</td>
</tr>
<tr>
<td>Y</td>
<td>Smith</td>
<td>F</td>
<td>3.2</td>
</tr>
<tr>
<td>Y</td>
<td>Smith</td>
<td>G</td>
<td>4.1</td>
</tr>
<tr>
<td>Y</td>
<td>Smith</td>
<td>H</td>
<td>4.5</td>
</tr>
<tr>
<td>Y</td>
<td>Smith</td>
<td>I</td>
<td>3.8</td>
</tr>
<tr>
<td>Y</td>
<td>Smith</td>
<td>J</td>
<td>3.5</td>
</tr>
<tr>
<td>Y</td>
<td>Brown</td>
<td>K</td>
<td>1.8</td>
</tr>
<tr>
<td>Y</td>
<td>Brown</td>
<td>L</td>
<td>1.6</td>
</tr>
<tr>
<td>Y</td>
<td>Brown</td>
<td>M</td>
<td>1.2</td>
</tr>
<tr>
<td>Y</td>
<td>Brown</td>
<td>N</td>
<td>1.4</td>
</tr>
<tr>
<td>Y</td>
<td>Brown</td>
<td>O</td>
<td>1.7</td>
</tr>
</tbody>
</table>

#### Failure Mode - Manufacturer Group

---

**Example – PIP Breast Implants**

![PIP Breast Implants Chart]
Benefits for Researchers

- The UDI identifies the device and GMDN identifies the Group of devices
- The UDI will be recorded in the electronic patient record
- The GMDN is cross-referenced to the UDI by the Manufacturer
- The Manufacturer is driven by regulation to improve accuracy and maintain data quality and consistency
- The volume of device data available will be large
- The GMDN Collective Term attributes are independent of the GMDN Term structure
Who is the GMDN Agency?

- The GMDN Agency is an independent, non-profit, UK Charity
- Set-up by Regulators (GHTF / IMDRF)
- Responsibility for maintaining the GMDN

Governance

- Board of Trustees
- Policy Advisory Group – guided by:
  - Regulators
  - Manufacturers
  - Healthcare Providers
It’s all about sharing information!
Thank you for listening

Any questions?

Contact us at

www.gmdnagency.org