Global Medical Device Nomenclature (GMDN)

Update for UkrMedCert

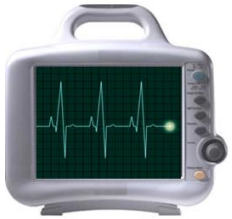
Edward Glenn
GMDN Agency
Feb 2019

- GMDN introduction
- Using the data
- Implementation and UDI
- Data quality

GMDN

What does the GMDN do?

|A DEVICE| is assigned to |A GMDN Term| which creates |A GENERIC DEVICE GROUP|



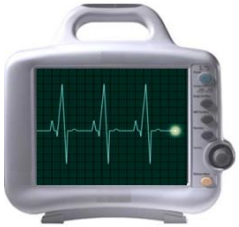
GMDN Code: 35195
GMDN Term Name: Electrocardiographic monitor
GMDN Term Definition: A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart 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.

within |A DATABASE| and allows for |HARMONIZED NAMING|

What's the GMDN Process?

|THE GMDN Term| is assigned to |THE DEVICE| by |THE MANUFACTURER|

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.



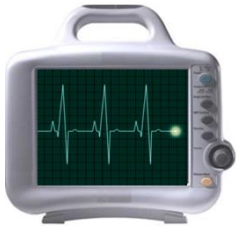
for |REGULATORS| and |HOSPITALS|

What's UDI?

|A UDI ISSUING AGENCY| provides |THE MANUFACTURER| with |A UNIQUE NUMBER| to be put in |A BARCODE|

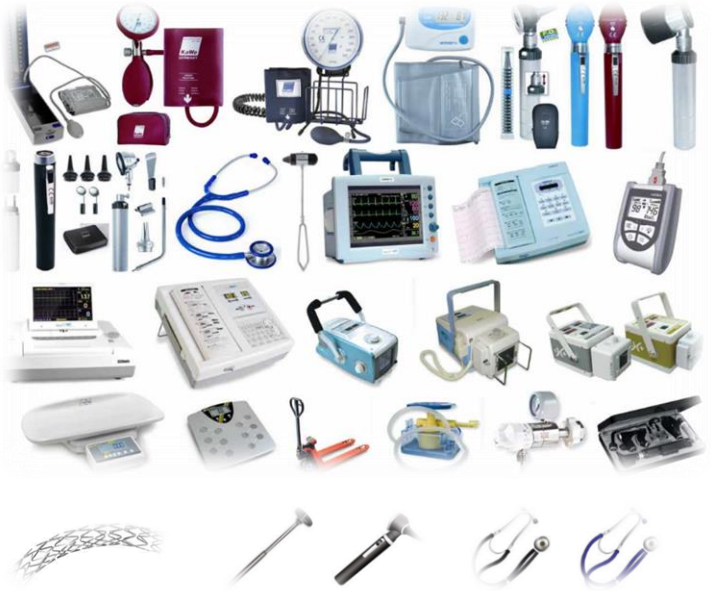
(01) 1 0614141 012345678

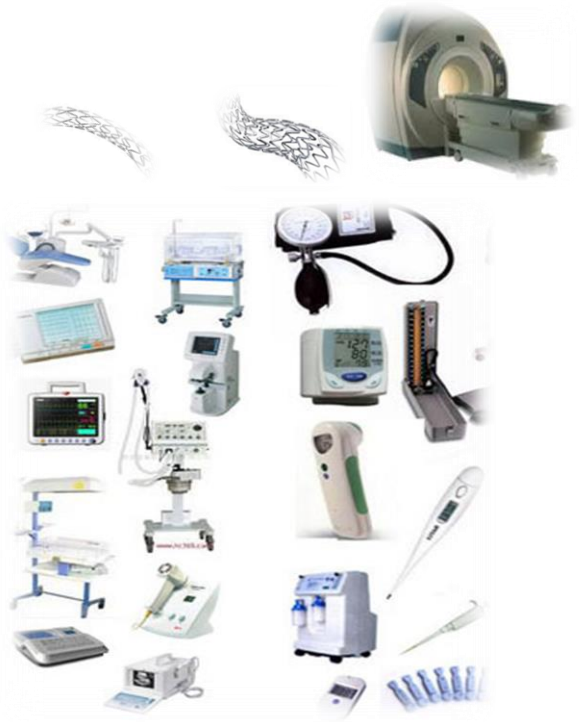
for |THE DEVICE| allowing accurate |RETRIEVAL| of |DEVICE DATA| from |A DATABASE|



DI number
GMDN code
SIZE
Company info
Brand name

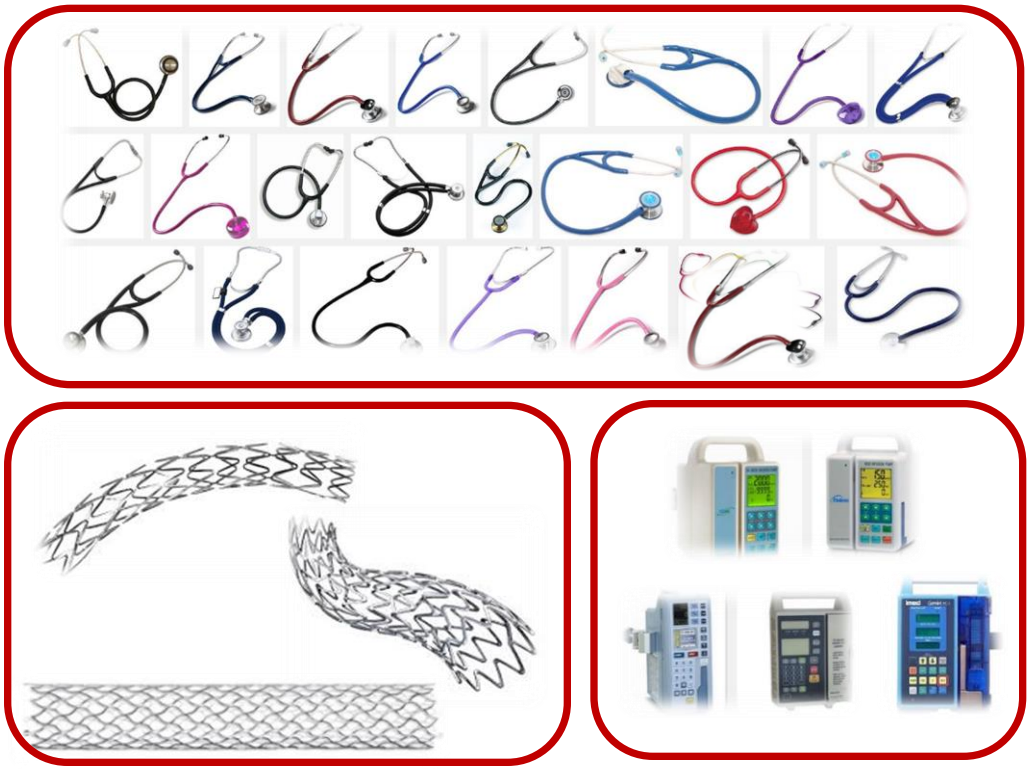
Get from this:





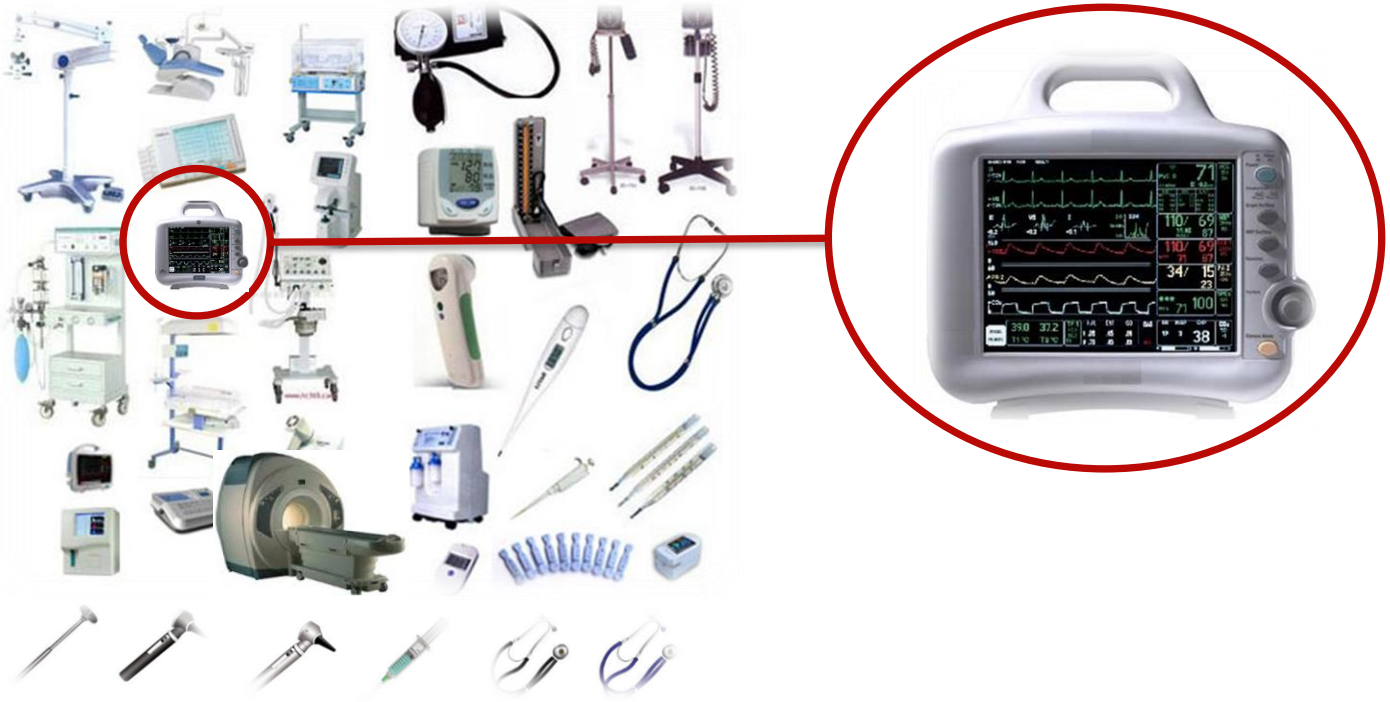
GMDN

To this ?



Naming and grouping – The role of GMDN

Device Group



The GMDN term

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.

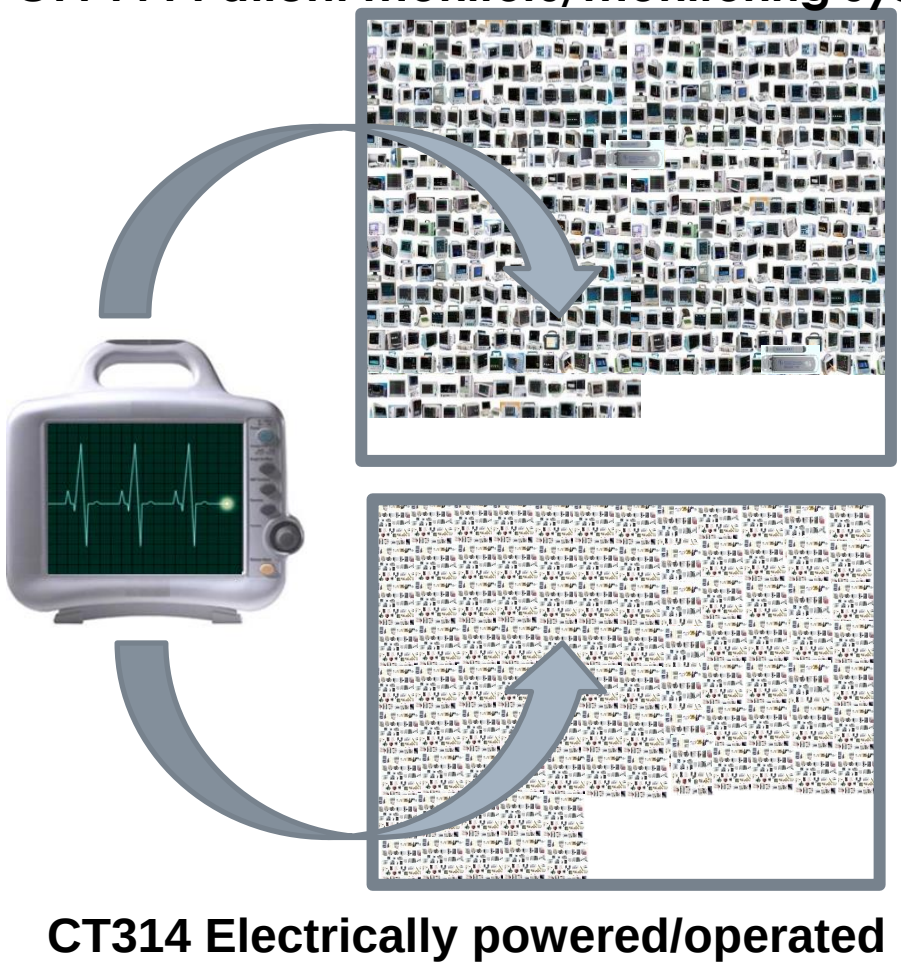
The GMDN term

- Names the group
- Defines scope of the generic device group
- Many Products assigned to 1 GMDN term

Products assigned to **35195 Electrocardiographic monitor**

GMDN higher level grouping (CT's)

- Each GMDN term is linked to many higher level (broader) Collective terms (CT's)
- CT's arranged in a (multi-) hierarchy
- Therefore each Collective term creates a broader group of devices



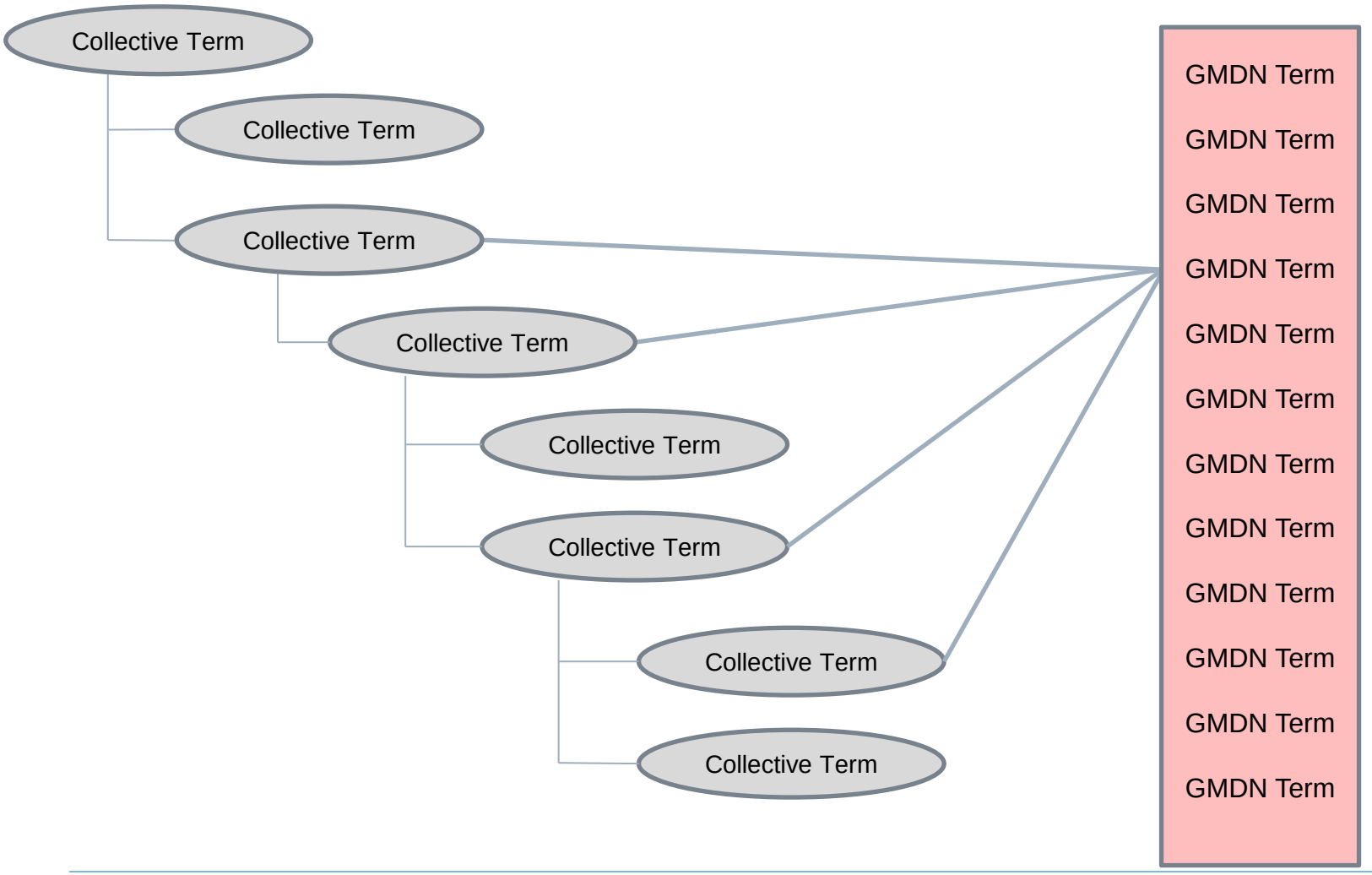
GMDN higher level grouping (CT's)

- **CT's** group/organize:
  - By clinical application (e.g., cardiovascular devices)
  - By name (e.g., prosthesis, scissors, catheter)
  - By attribute (e.g., Material, Invasiveness, sterility, Use frequency)

- A hierarchical categorisation …

Hierarchical classification
Collective Terms

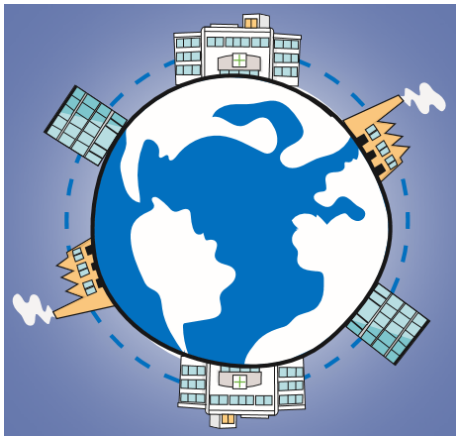
Nomenclature
GMDN terms



What does GMDN give the user

The GMDN data gives the user (Regulator, Registry, Hospital, Manufacturer):

- A name and definition that describes the device clearly and succinctly without proprietary jargon (in up to 20 languages)
- A way to group the device at many levels (e.g., for inventory management, regulatory risk trending, recall analysis)
- A global solution:
  - Only one code needed worldwide
  - Allows for global analysis of data
  - Consistent communication of data across borders



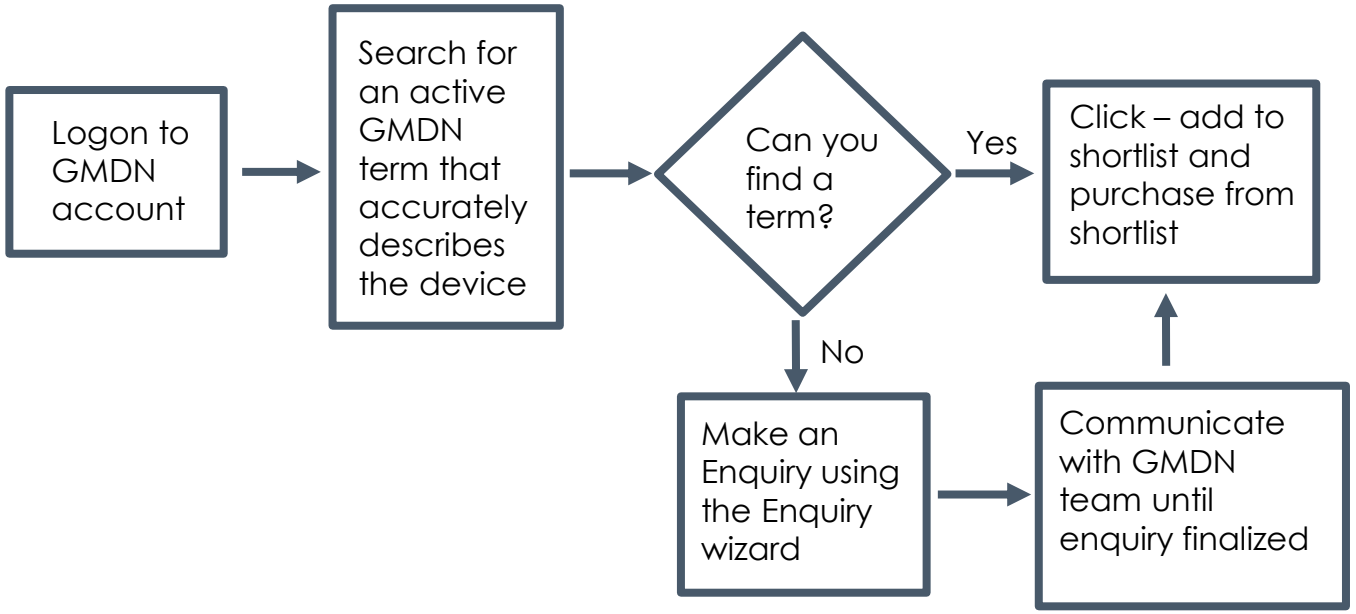
GMDN Uses

- Used by:
  - 118 national medical device Regulators members
  - 50+ using regular download options
  - 4500+ manufacturers worldwide
  - Medical engineering e.g Scandinavia (MTPReg), UK hospitals

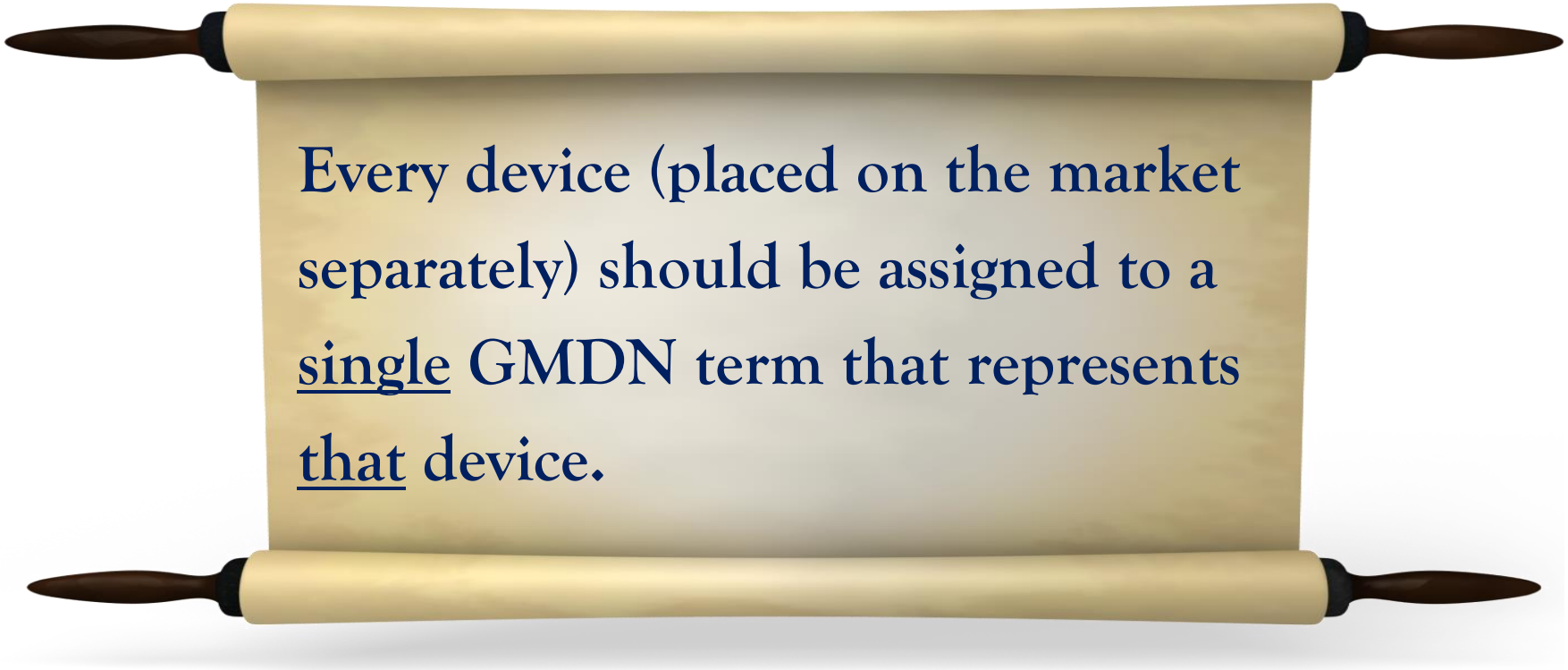
- US FDA implementation of UDI Rule
  - All medical devices sold in the US will need a GMDN code

GMDN

The Process for Manufacturer members

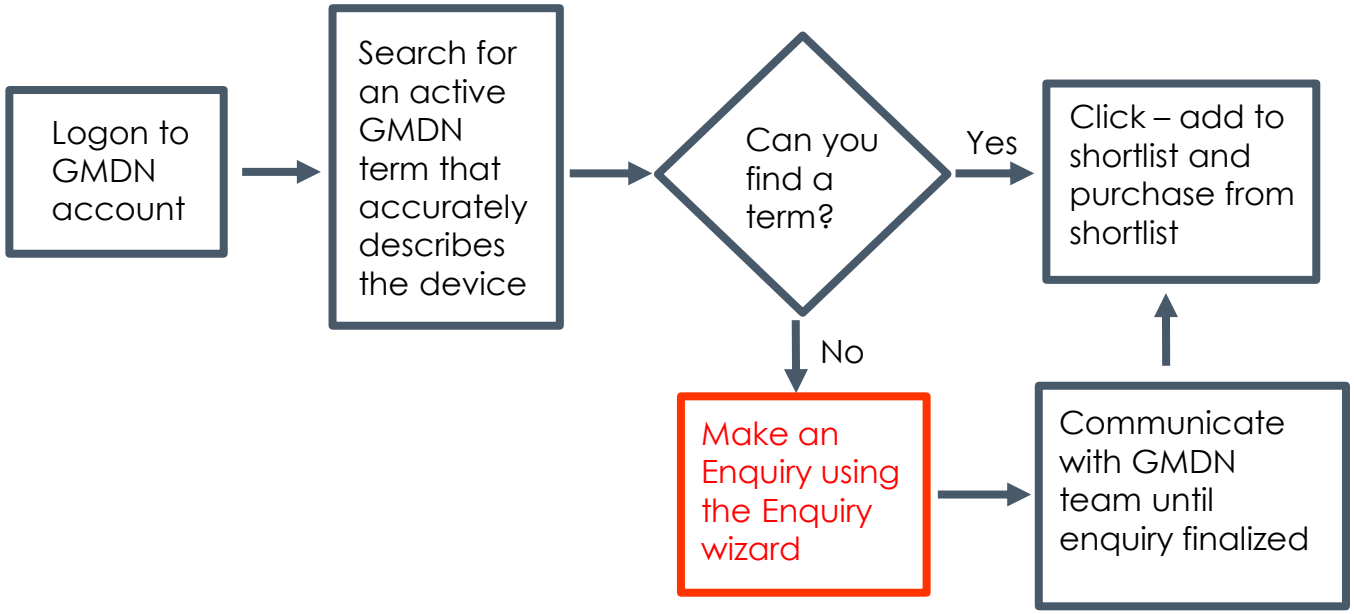


Golden rule



- ***A thought:*** *If you have the device in front of you and someone asked "What is that?" – would the GMDN term be a reasonable answer? Hopefully yes.*

The Process for Manufacturer members



GMDN Website - Enquiry

- Search first – if cant find suitable term use Enquiry.
- Enquiry is the only way to get help from the GMDN Agency for assigning Terms to products. The outcome will be:
  - An appropriate existing Term.
  - Modification of an existing Term to include the new product's characteristics.
  - A new GMDN Term is created.

Changes to GMDN data

- Develop new terms (average 2-3 day)
- We only modify existing Terms (average 3-4 day)
  - To increase the scope / improve the definitions
- We obsolete Terms (average 10/m or 0.5% per year)
  - To remove ambiguity / term overlap
- GMDN is dynamic and current to keep up with innovation
- Members are notified about changes…

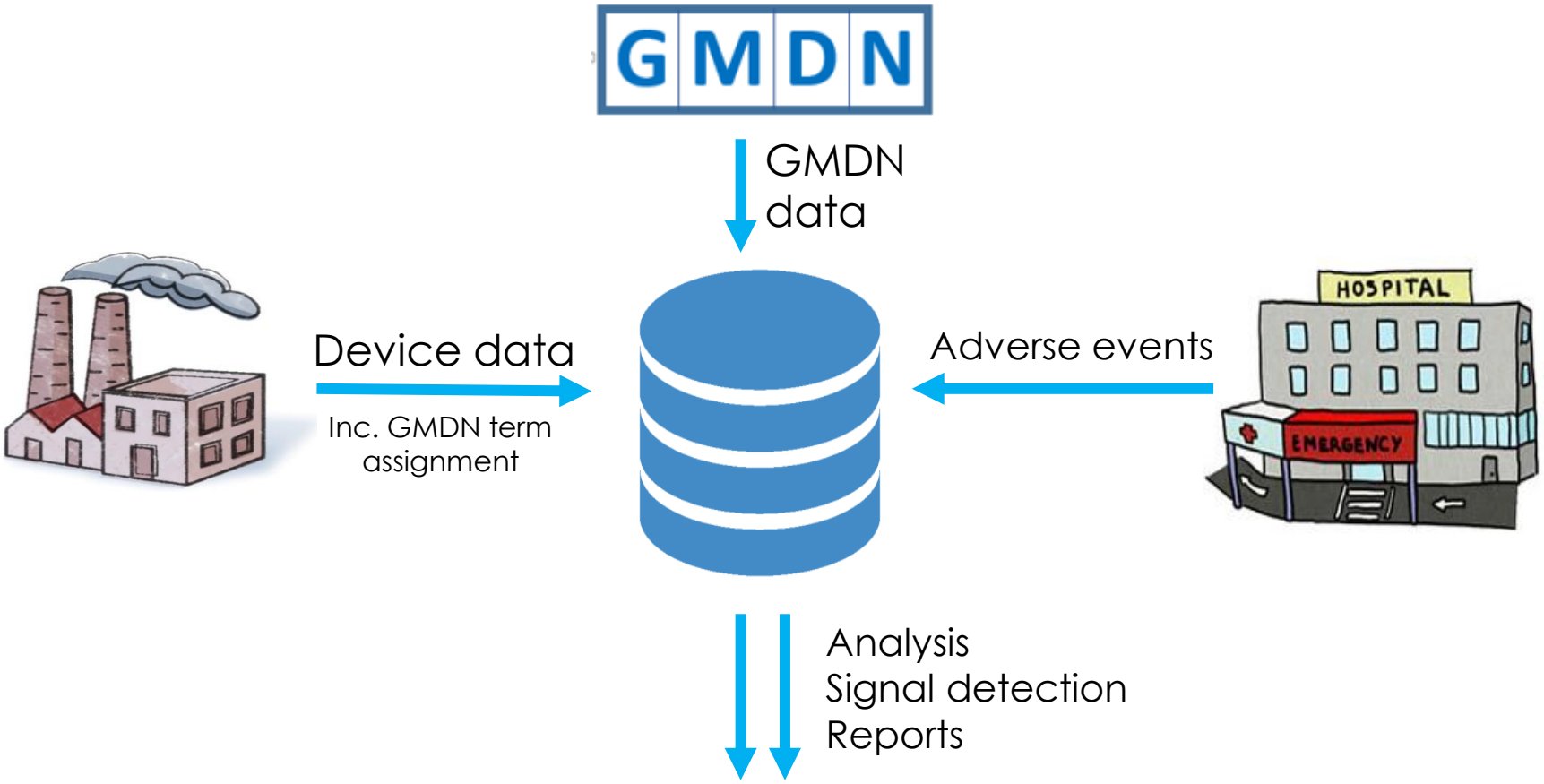
Notifications to manufacturers

- Manufacturers will receive alerts relating to any changes
  - All changes will be seen at the alerts page on their account
  - Notification e-mails will be sent out
  - Manufacturers will receive a monthly newsletter by e-mail detailing these changes

GMDN dataset availability:

- Website download
  - Monthly full and delta
- FTP
  - Daily full and delta
  - Monthly full and delta
  - Monthly CTs
- All in English, French and Spanish
- API in development

Integrating GMDN



GUDID

- US FDA UDI
- Database = GUDID
  - GMDN code is mandatory field on record submission

FDA GUDID April 2018

- DI records: 1,623,452
- Unique GMDN codes: 8,450

  (Active GMDN = 8,239)
- Therefore ratio = 1:192
- Unique companies: 4705
- DIs using GMDN (rather than FDA PT) = 83 %
- Active implantable device records: 3,515
- Non-active implantable device records: 638,623
- IVD device records: 32,218

  (2864 GMDN IVD terms used, therefore ratio = 1:11)

GMDN Agency working with the FDA

- ‘Learning UDI Community (LUC)’
  - FDA initiated and participant
  - Managed by AHRMM – trade association for supply chain
  - Objectives
    - Help stakeholders understand UDI
    - Identify and explore non-regulatory uses for UDI
- GMDN involved in:
  - Device Categorisation
  - High Risk Implants
- Helping to improve GMDN definitions and user assignment of terms.

Learning UDI Community – Use cases/projects

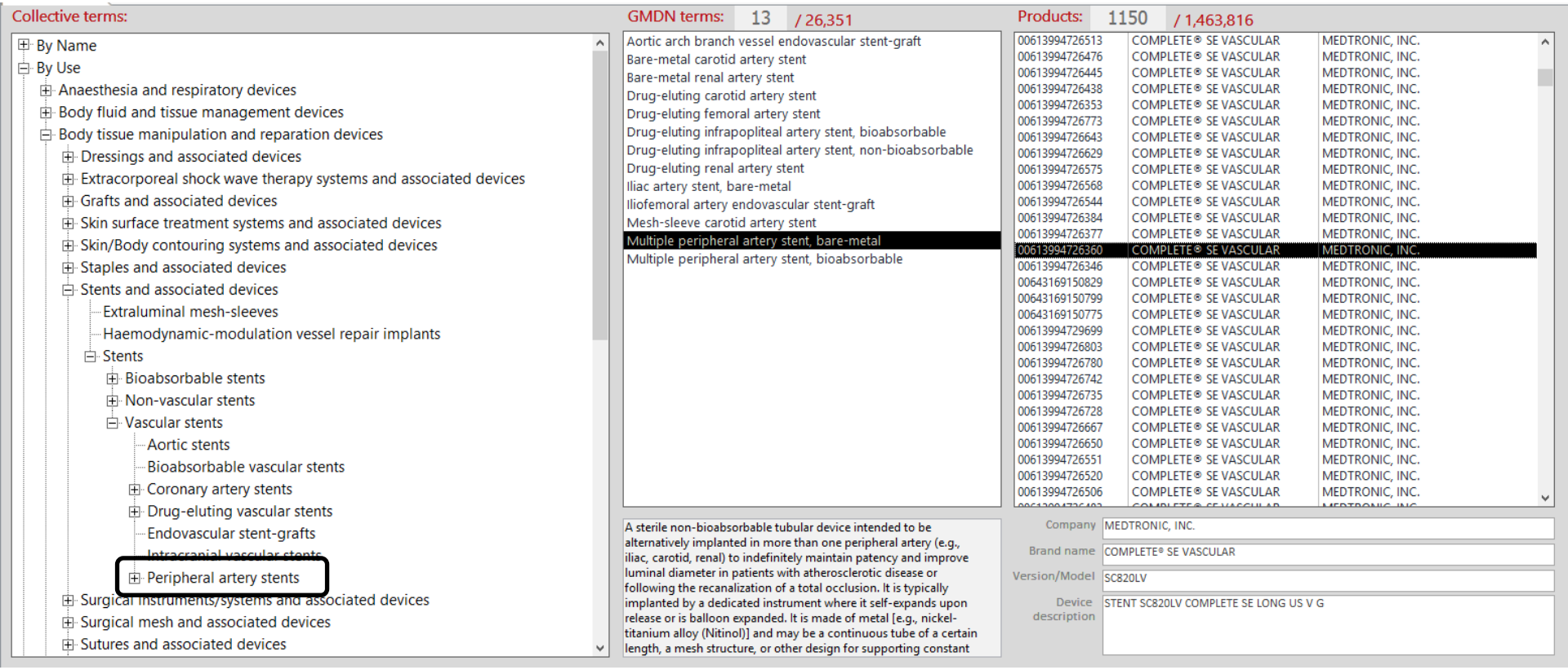
- RAPID (vascular implant clinical evaluation project)/VQI (vascular implant registry)
- Augmented UDI Data (AUDI)
- Breast Implant registry

RAPID/VQI use case

- RAPID project (Pilot study MDEpiNet – academic group)
- Phase 2 completed
- Use GMDN to get data from GUDID for:
  - Peripheral vascular stents
  - Atherectomy/Angioplasty – 15 terms
  - Vascular grafts
  - Vascular guidewires
- Clinicians analysed results - GMDN grouping achieved and level of granularity required

GMDN

Device Identification



GMDN CTs ⟶ GMDN Terms ⟶ Devices

Issues

- Poor assignment
  - Multiple GMDN
  - Systems/components
  - Not using definition
  - PT code finder
  - Lazy?
- Initial assessment (cardiovascular implants) ~ 20% assigned poorly

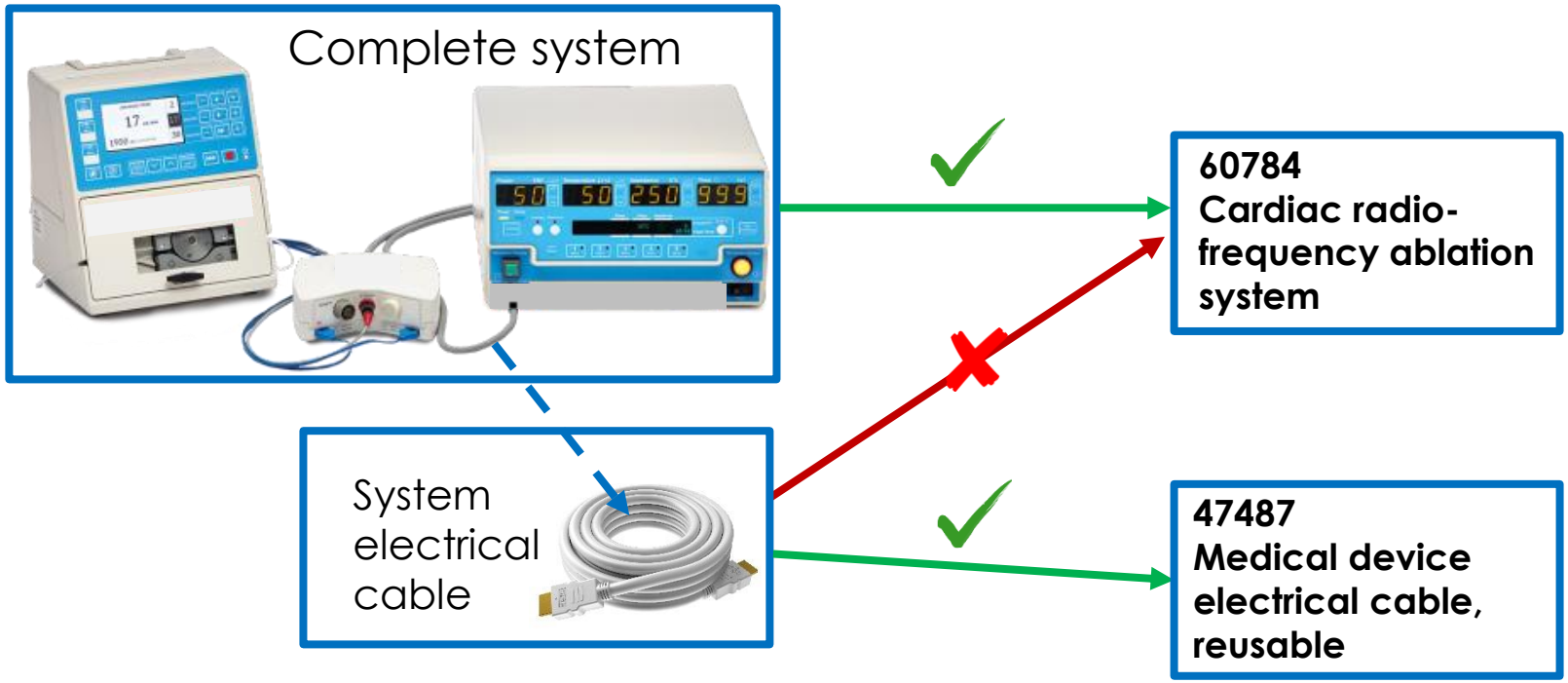
Common mistakes

- Poorly assigned GMDN terms leads to poor data
- Data quality is key

Systems/components

A GMDN term for a system term applied to a component of the system

Example:



GMDN

Not using definition

Judging the term by the name without review of the definition

Ophthalmic use

[redacted] 752SS11170071

CUSTOM **SURGICAL** KIT EYE PACK

Company Name: [redacted] **Version or Model:** [redacted]

Device IDs:

- [redacted] (Primary)

GMDN Terms:

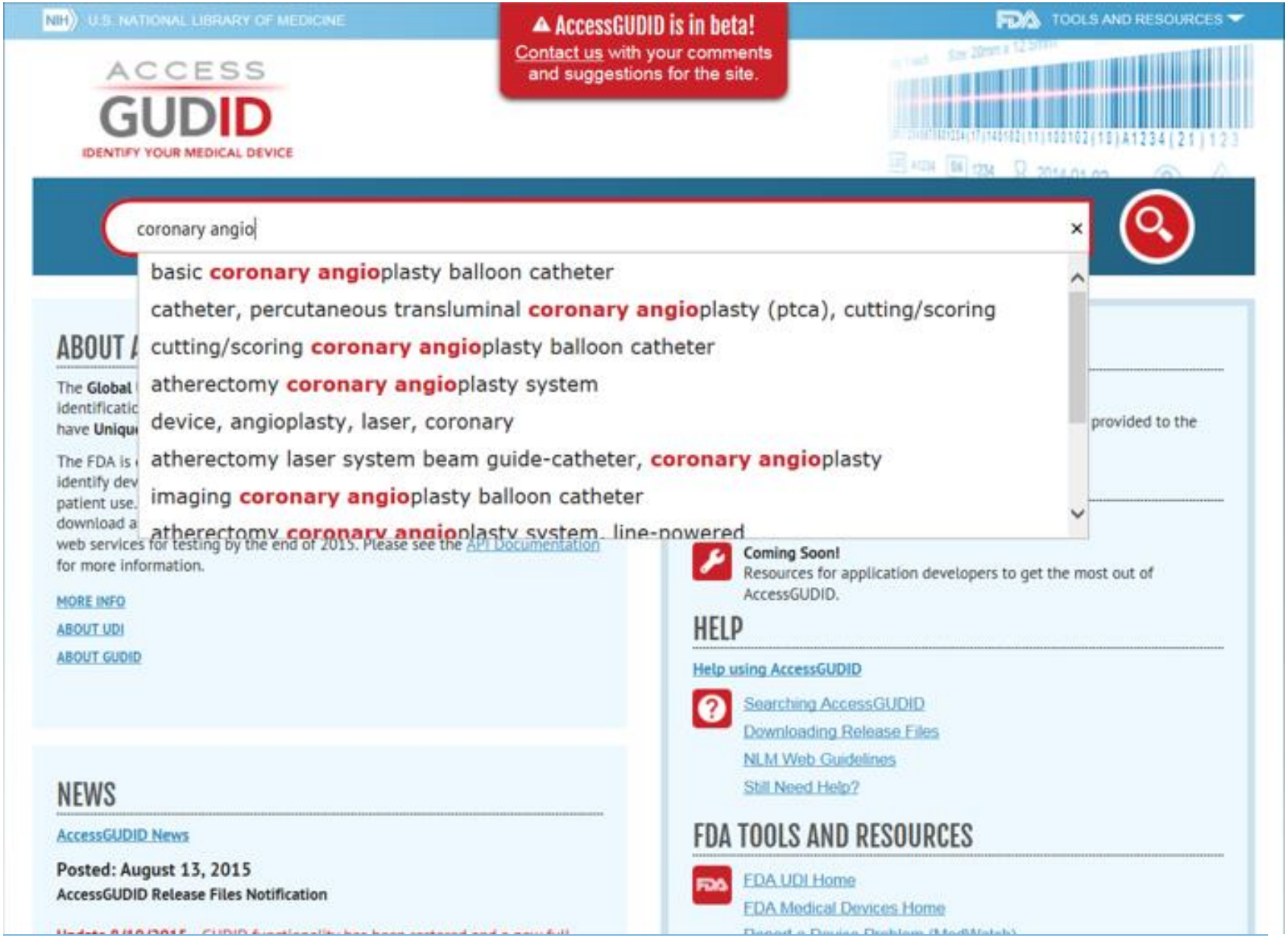
- General **surgical** procedure kit, non-medicated, **single-use**

33961
General surgical procedure kit, non-medicated, single-use

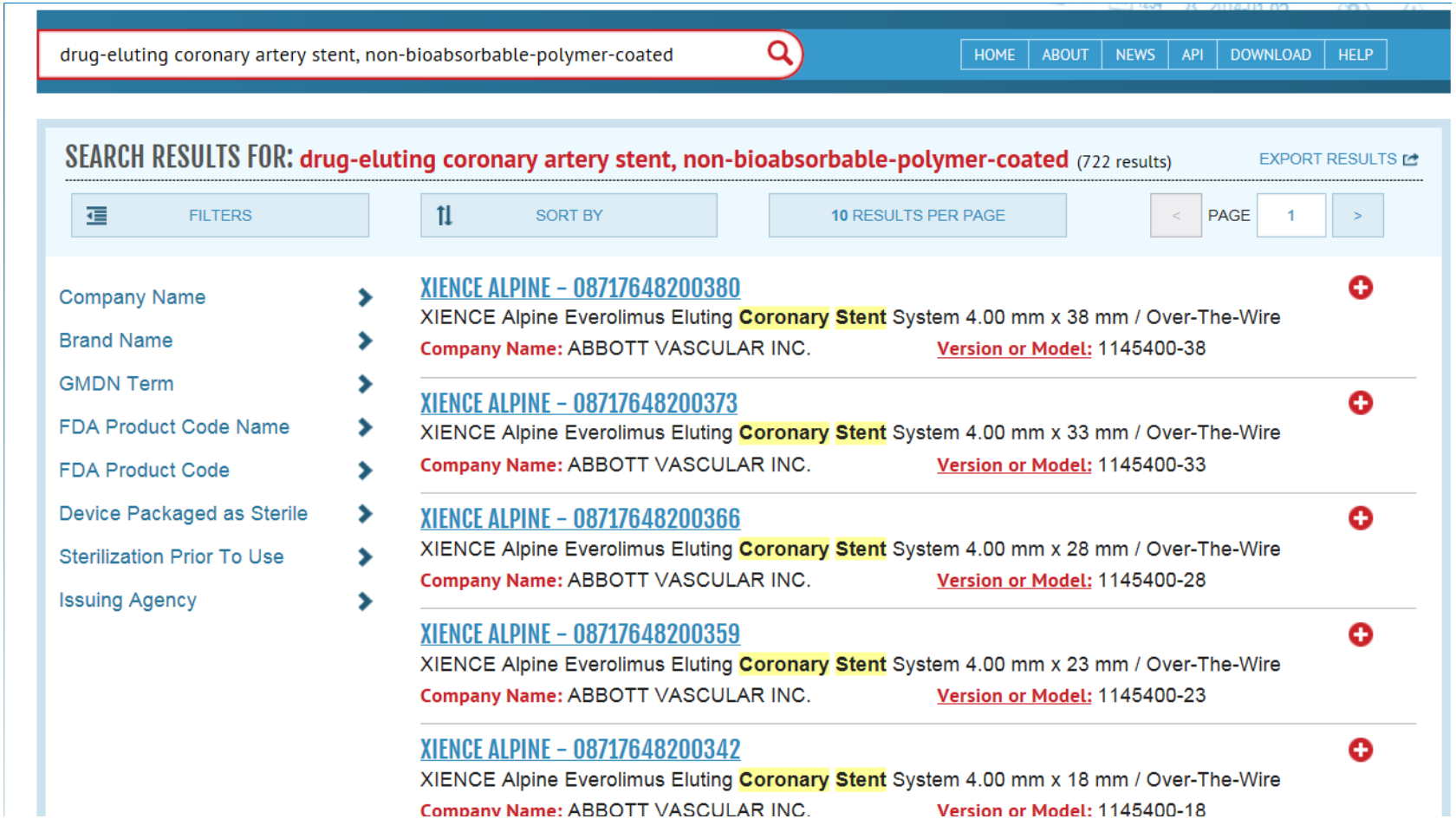
A general-purpose collection of various sterile surgical instruments, dressings, and materials **intended to be used to assist a range of surgical procedures across multiple clinical specialities**. It does not contain pharmaceuticals. This is a single-use device.

Is this term more appropriate?
Ophthalmic surgical procedure kit, non-medicated, single-use

GMDN

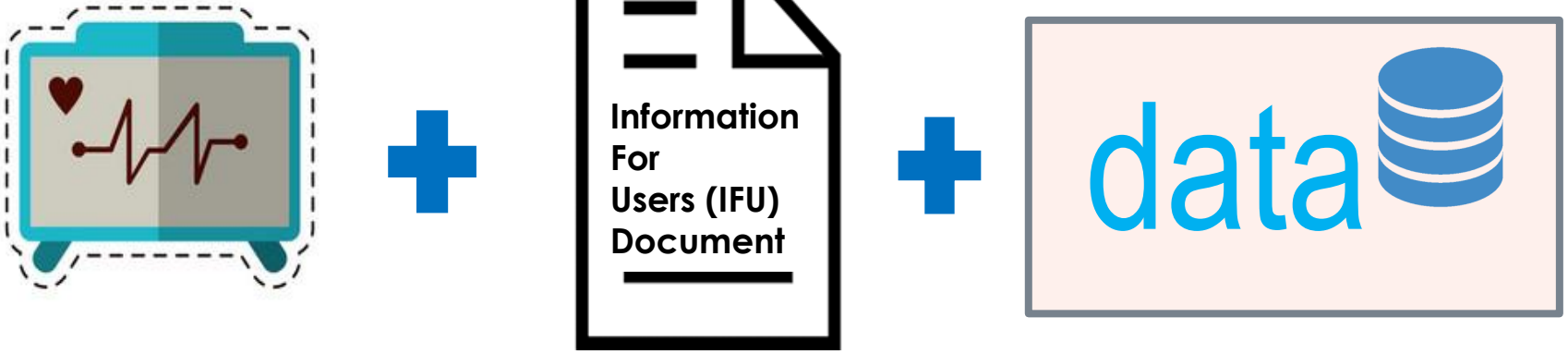

U.S. NATIONAL LIBRARY OF MEDICINE
AccessGUDID is in beta!
Contact us with your comments and suggestions for the site.
TOOLS AND RESOURCES
ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE
coronary angio
basic coronary angioplasty balloon catheter
catheter, percutaneous transluminal coronary angioplasty (ptca), cutting/scoring
cutting/scoring coronary angioplasty balloon catheter
atherectomy coronary angioplasty system
device, angioplasty, laser, coronary
atherectomy laser system beam guide-catheter, coronary angioplasty
imaging coronary angioplasty balloon catheter
atherectomy coronary angioplasty system, line-powered
ABOUT
The Global
identificatic
have Uniqu
The FDA is
identify dev
patient use.
download a
web services for testing by the end of 2015. Please see the API Documentation
for more information.
MORE INFO
ABOUT UDI
ABOUT GUDID
provided to the
Coming Soon!
Resources for application developers to get the most out of AccessGUDID.
HELP
Help using AccessGUDID
Searching AccessGUDID
Downloading Release Files
NLM Web Guidelines
Still Need Help?
NEWS
AccessGUDID News
Posted: August 13, 2015
AccessGUDID Release Files Notification
FDA TOOLS AND RESOURCES
FDA UDI Home
FDA Medical Devices Home

GMDN


drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated
HOME
ABOUT
NEWS
API
DOWNLOAD
HELP
SEARCH RESULTS FOR: drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated (722 results)
EXPORT RESULTS
FILTERS
SORT BY
10 RESULTS PER PAGE
PAGE 1
Company Name
Brand Name
GMDN Term
FDA Product Code Name
FDA Product Code
Device Packaged as Sterile
Sterilization Prior To Use
Issuing Agency
XIENCE ALPINE – 08717648200380
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 38 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC.
Version or Model: 1145400-38
XIENCE ALPINE – 08717648200373
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 33 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC.
Version or Model: 1145400-33
XIENCE ALPINE – 08717648200366
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 28 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC.
Version or Model: 1145400-28
XIENCE ALPINE – 08717648200359
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 23 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC.
Version or Model: 1145400-23
XIENCE ALPINE – 08717648200342
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 18 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC.
Version or Model: 1145400-18

GMDN

A device has a new component – Shared Data



Publically shared data (inc. GMDN term assignment) sent to Regulators and Customers (e.g., via GDSN)

GMDN

GMDN in Hospitals

- **Asset Management**
  - Support equipment commissioning
  - Help identify equipment location
  - Support maintenance programmes

- **Inventory Control**
  - Reduce wastage
  - Translate product labels with poor descriptions
  - Improve stock control

- Replace existing inventory classification with an externally managed globally recognized nomenclature

GMDN

GMDN is improving communication

- GMDN is now the global language

Thank you for listening

Questions?