GMDN

GMDN INTRODUCTION

DENIZ BRUCE – CEO

14/03/2024

STANDARDISED NOMENCLATURE IS ESSENTIAL FOR MAINTAINING PATIENT SAFETY AND PROMOTING BETTER HEALTHCARE OUTCOMES.

THE GMDN HISTORY

- Since **1991,** medical device experts worldwide have worked together to create the Global Medical Device Nomenclature (**GMDN**)

- This work was requested by the inter-governmental body, the Global Harmonisation Task Force (GHTF) to help accelerate international medical device regulatory harmonisation and convergence

- The **GHTF** has now been superseded by the **IMDRF**

GHTF

First international workshop on harmonisation of medical devices nomenclature. (EU AUS, CA, USA)

1991

2002

The first issue of GMDN is published on CD-ROM.

2019

Free GMDN membership launched to all users.

GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN)
A NON-PROFIT, CHARITY

Name and Group All Medical Devices

- ~25,000 Terms for all medical device
- All systematically named to reduce duplication and ambiguity
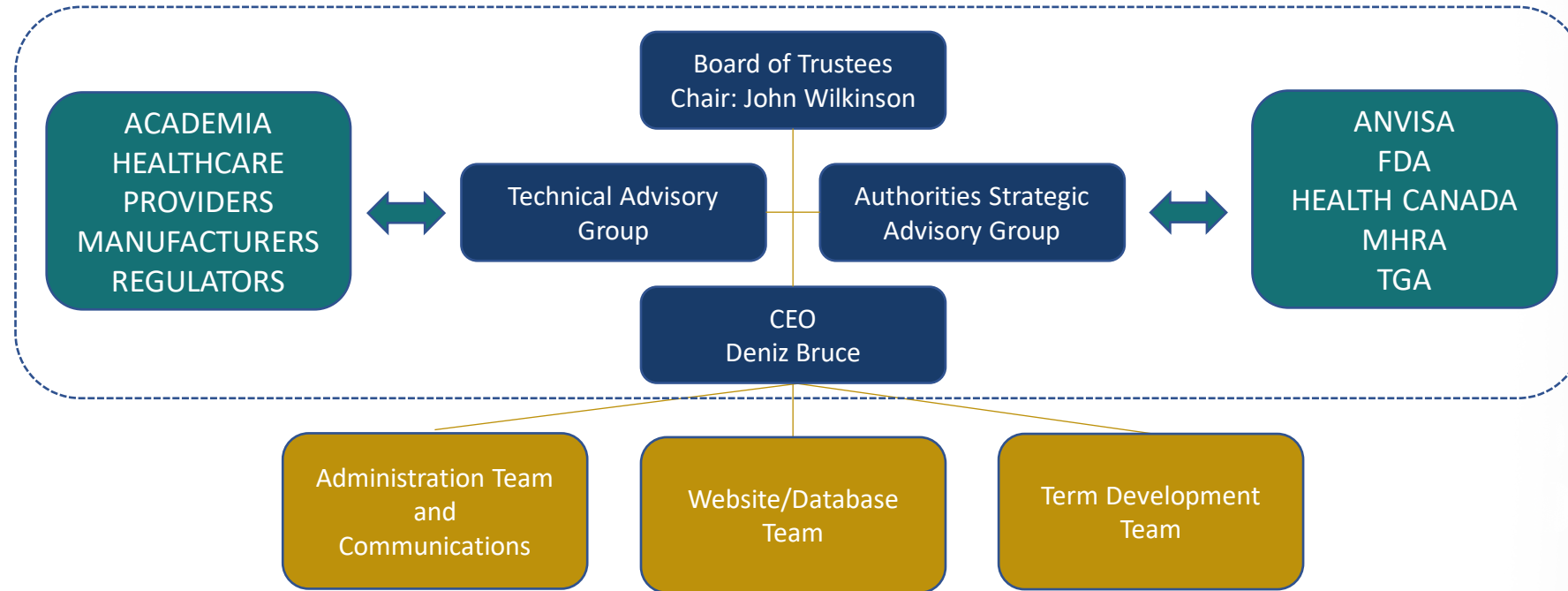- ~12,000 manufacturers

Fully Up-to-Date Free Access to All

- Free access to Codes
- Free to update
- Representing the current supply of all medical devices, dynamic nomenclature

Globally Recognised and Independent

- ~ 13,000 users , >70 Regulatory users in all continents, >145 countries
- UDID used since 2013 (FDA's GUDID)
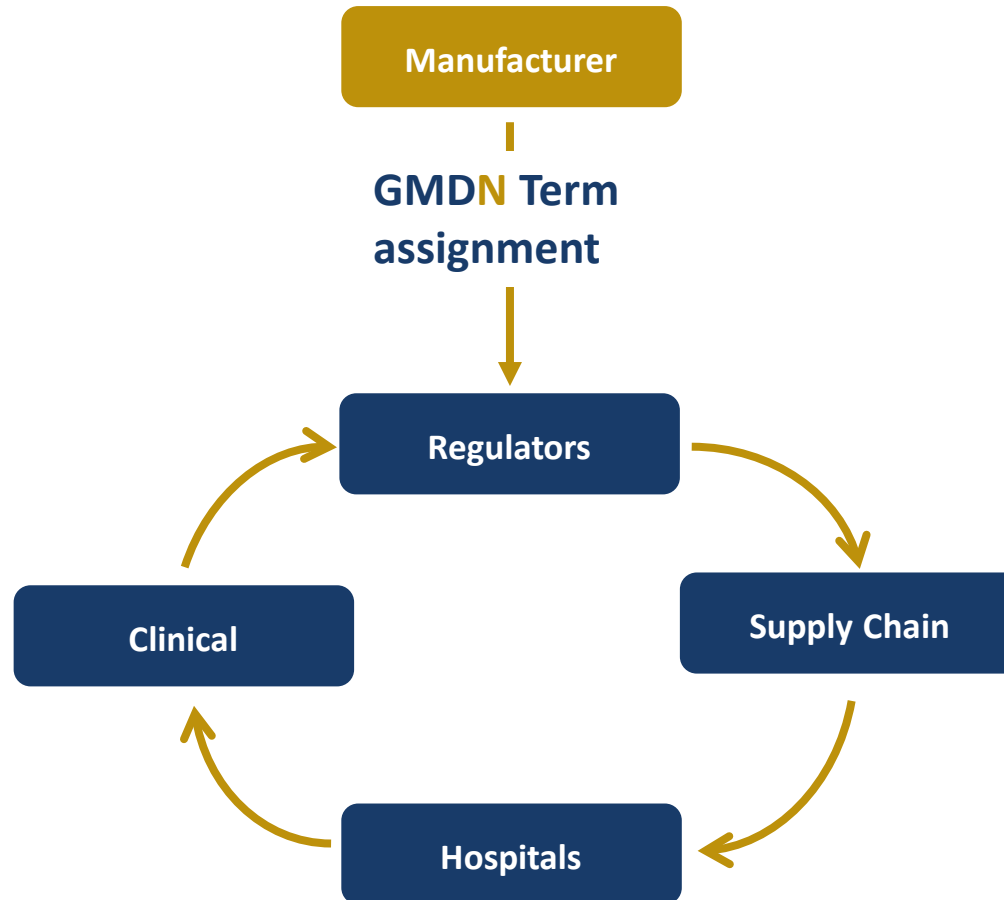- Self-funding, independent and guided by Regulators

THE GOVERNANCE OF GMDN

Board of Trustees
Chair: John Wilkinson

ACADEMIA HEALTHCARE PROVIDERS MANUFACTURERS REGULATORS

Technical Advisory Group

Authorities Strategic Advisory Group

ANVISA FDA HEALTH CANADA MHRA TGA

CEO Deniz Bruce

Administration Team and Communications

Website/Database Team

Term Development Team

Confidential – All Advisory Groups are providing advice to the Board of Trustees, and all members are volunteers and are not funded for activity linked with GMDN Agency governance.

Confidential – GMDN Agency reserves the right to change the organizational structure as needed.

GMDN DATA IN USE

```
                  ┌──────────────────┐
                  │   Manufacturer   │
                  └──────────────────┘
                           │
                   GMDN Term
                   assignment
                           ↓
                  ┌──────────────────┐
                  │    Regulators    │
                  └──────────────────┘
          ↗                              ↘
  ┌──────────────┐              ┌──────────────────┐
  │   Clinical   │              │   Supply Chain   │
  └──────────────┘              └──────────────────┘
          ↑                              ↓
                  ┌──────────────────┐
                  │    Hospitals     │
                  └──────────────────┘
```

- Pre-market approval
- Market Analysis
- Purchase and Tender
- Inventory/Asset management
- Safety signal detection
- Real-world evidence

GMDN
Terms

Non-proprietary groups are defined by:

- **Name** – Unique, nearly full-descriptive

- **Definition**

  - Scope of devices covered by name, including

    - Intended use

    - Technology/material

    - Form/components

    - Significant attributes (e.g., use-frequency, pharmaceutical inclusion, device power)
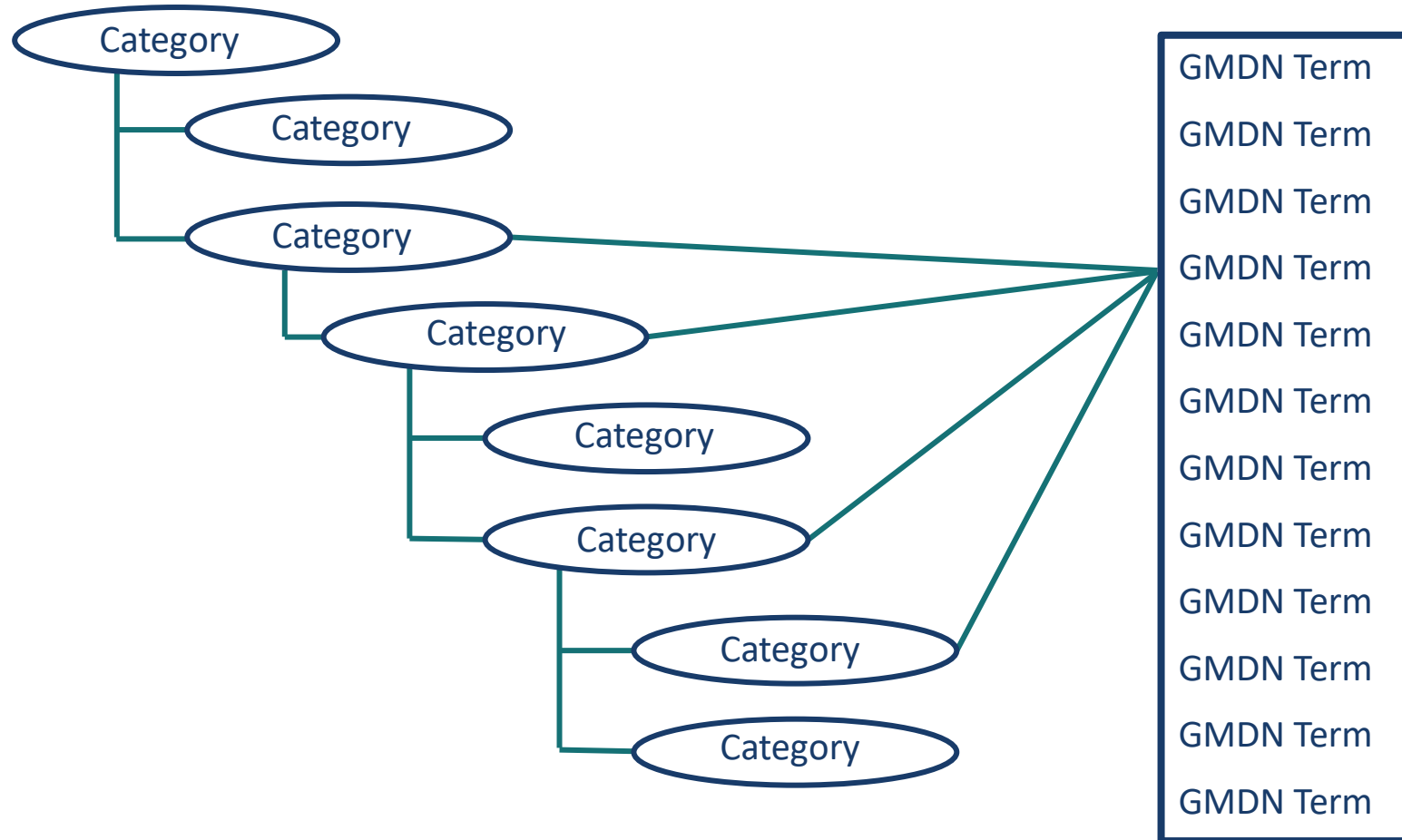
- **Code (ID)**
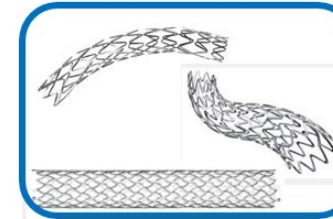
CATEGORIES

- Device Function
  - CT1007 Tissue reparation devices
    - CT2775 Tissue dressing/stabilization devices
      - CT554 Dressings
        - CT2148 Dermal dressings
          - CT1352 Wound-nonadherent dressings
- Anatomical Specialty
  - CT775 Dermatological and soft-tissue reconstructive/cosmetic devices
    - CT2148 Dermal dressings
      - CT1352 Wound-nonadherent dressings
- Names Index
  - CT124 Dressings and associated devices
    - CT554 Dressings
      - CT2148 Dermal dressings
        - CT1352 Wound-nonadherent dressings
- Use Frequency
  - CT981 Single use
- Power
  - CT2986 Non-active
- Featured Attributes
 - CT315 Home-use patient/layperson
  - CT233 Surgical

TERMS

Wound-nonadherent dressing, absorbent, non-antimicrobial
46854
A wound covering typically in the form of a multi-layered pad having a material or substance on its skin-contact surface (e.g., silicone gel), or designed to be soaked in saline prior to application, to prevent adherence to the wound bed thereby decreasing wound trauma potential; it does not contain an antimicrobial agent. It is typically used to absorb wound blood/exudates while protecting the wound from external contamination and maintaining a moist internal environment. It may be used as a primary or secondary dressing to treat chronic and postoperative wounds, burns, ulcers, abrasions, cuts, or puncture sites; it is not a dedicated burn dressing. This is a single-use device.

WHAT MAKES GMDN THE MOST WIDELY USED NOMENCLATURE ACROSS THE WORLD?

Exactly 10 years of use in the FDA UDI database – the GUDID!
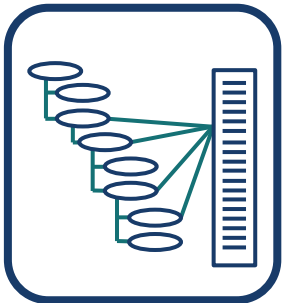
1. **Assignment** is key

Requires fully defined, unambiguous, mutually exclusive Terms, consistent granularity

2. **Data integrity** is key

Continuous communication with all stakeholders. Terms are created/expanded in real time to capture the latest technology with Manufacturers' feedback based on regulatory requirements, and all can comment

3. Data consumers have **different requirements** according to the use case

GMDN users consist of manufacturers, Regulators, and downstream users such as hospitals, NGOs, data distributors, clinical groups, registries, etc.
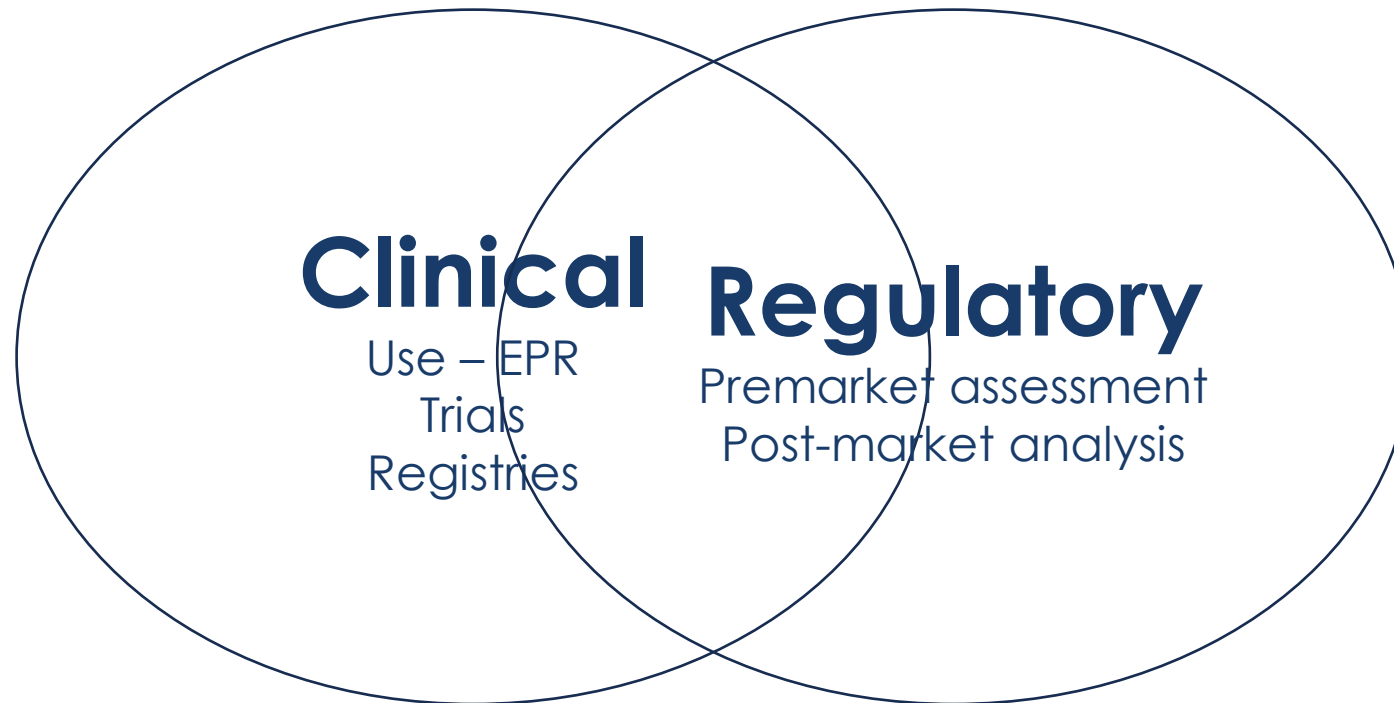
GMDN
Innovation

- To keep up with innovation in the Med Tech industry and new regulatory requirements, a nomenclature has to evolve quickly i.e. to be dynamic

- Otherwise, it becomes:

  o out of date

  o uncomprehensive

  o inaccurate

GMDN USE-CASES

Safety signal detection
and vigilance reports
Post-market surveillance

Regulators

Pre-market approval
(Planning, Innovation)

Manufacturers

Clinical

Supply Chain

Inventory
Purchasing

Hospitals

Tendering
Market Analysis
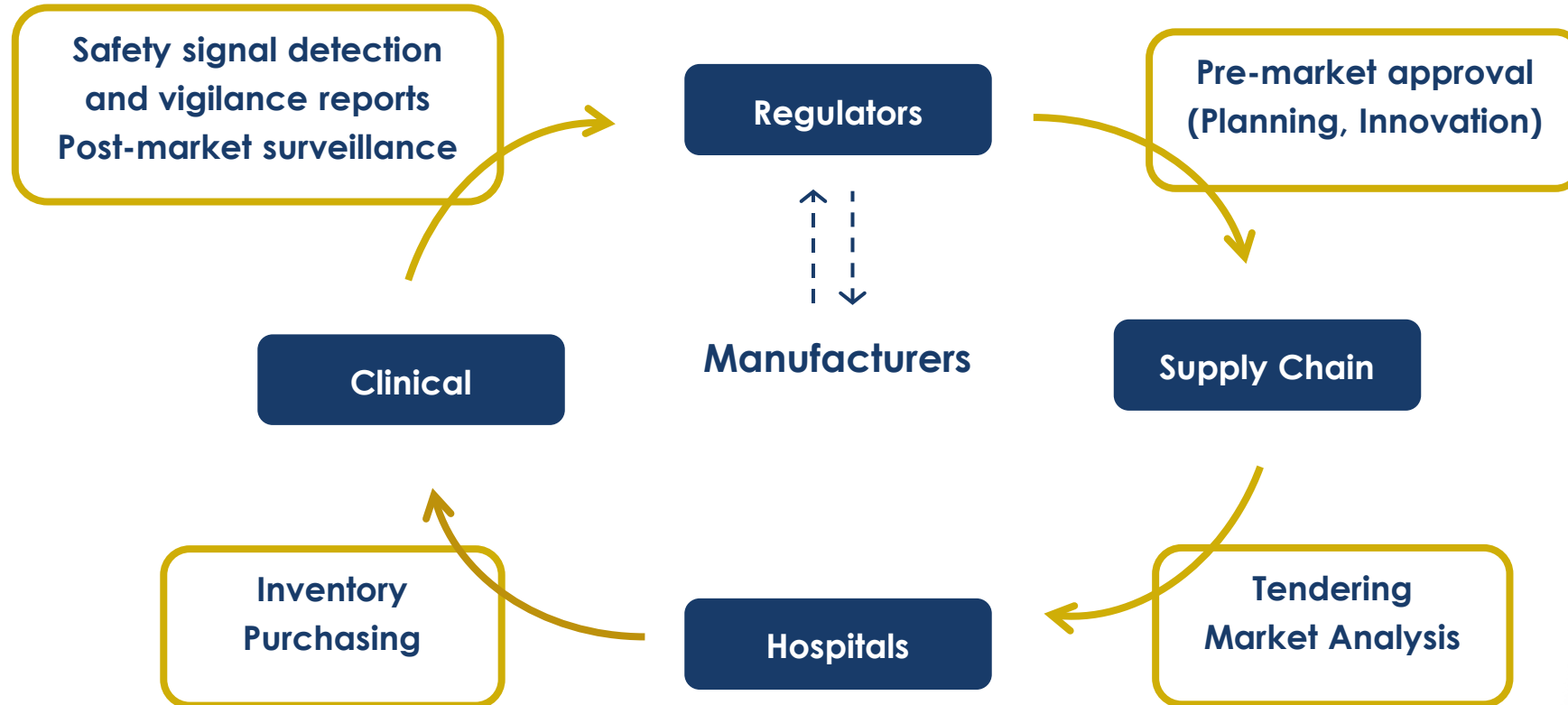
RWE – COLLABORATION
DATA AND RESOURCES

Clinical
Use – EPR
Trials
Registries

Regulatory
Premarket assessment
Post-market analysis

RWE
DATA LEVELS

- Product level – UDI

  - Adverse incidence > recalls

- Category level – GMDN

  - Does issue have significant reporting ratio within the group of similar devices ie 'signal'?

  - Assignment and data integrity are key

RECENT ACTIVITIES/PROJECTS

GMDN Agency

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

Trainings & Workshops

Regulators Workshops

Manufacturers Workshops

Manufacturers New Training Tools

Bespoke Training Sessions for Medical Device Manufacturers

Bespoke Training Sessions for Clinical Engineers

Medical Device Regulatory Convergence Project – African Medical Device Forum Advancing Regulatory Convergence & Reliance/Kenya

27th GHWP/Virtual presentation

New Users/Government Departments/Regulators: Mozambique, Iceland, Ethiopia, Mongolia, Vietnam, Iran, Uganda, Ukraine

Projects

FDA – Access GUDID

MHRA – Public Access Database (PARD)

ANVISA – UDI

TGA – UDI

INVIMA – Registration Database

Translations project (Arabic)

GHC – Taawon Portal

NHS UK Supply Chain & DHSC Projects

Innovate UK Project – Discovery Phase: "Transforming post-market intelligence to safely accelerate medical device innovation and adoption"

Collaboration with the WHO

Other

Term Development Team – New training programme

Teaming up with the Universities to expand technical capabilities

New Report for Regulators and Healthcare Providers: "Implantables" and New Service Design – "My Custom Categories" – In development

GMDN Database/Software Technology Upgrade Phase II

New Trustee

GMDN use-cases

GHC – JOINT PROCUREMENT PROGRAM

GMDN USE-CASE/US

4 March 2024

Guest Blog

How Strata Decision Technology is using the GMDN to improve cost analysis speed for healthcare providers

Co-authored by Ron Iller, Senior Director of Product Management at Strata Decision Technology and Tim Cleary, Consulting Manager and Solution Architect, Data & Intelligence Services at Strata Decision Technology

Here at Strata, we're empowering organizations to fuel their missions. We support hospitals, health systems, and other healthcare providers with a portfolio of software and data solutions that help them develop achievable budgets and effective strategic plans. We enable them to leverage data to discover market opportunities and new areas for growth, and gain insights into patient care delivery and cost and revenue drivers for healthcare organizations across the United States.

Helping organizations sort through, categorize, and analyze the immense amounts of valuable data they generate daily to drive sustainable improvements is key. The Global Medical Device Nomenclature (GMDN) Agency is our valued partner in helping these critical organizations group and classify complex medical device data so that they can quickly conduct analyses that enhance patient care.

The struggle to manage mounds of data

Healthcare leaders are continually looking for ways to enhance their organizations' financial, operational, and quality outcomes, which ultimately come down to how they deliver care. This often requires deep data analysis down to the specific items that went into the care delivery for a cohort of patients.

https://www.gmdnagency.org/guest-blog-how-strata-decision-technology-is-using-the-gmdn-to-improve-cost-analysis-speed-for-healthcare-providers/

NEW PROJECT
INNOVATE UK/DISCOVERY PHASE
PARTNERING WITH UCL, GSTT, GS1, PANAROMIC DIGITAL HEALTH

UK Regulatory Science and Innovation
Networks – Discovery phase

Application name
Transforming post-market intelligence
to safely accelerate medical device
innovation and adoption

Project summary

Project summary

**We propose to transform post-market intelligence; unlocking and
connecting richer sources of real-world data to safely accelerate medical
device innovation and adoption.**

Medicines & Healthcare products
Regulatory Agency

UK Regulatory Science and
Innovation Networks –
Discovery phase webinar

Getting ready for fast-paced innovations

25 January 2024

- The group is exploring how IMDRF adverse event categorisation can be implemented more widely in medical device asset management databases, enabling more standardised data for post-market intelligence.
- This will be like the FDA MAUDE database but with IMDRF codes applied along with other categorisation schemes.
- Looking at whether modern technology can help us augment this categorisation with some product architecture information to describe failure location. This would be a product-specific (manufacturer-curated) but standardised description.

THE WHO – GMDN COLLABORATION

- The collaboration scope includes the essential in vitro diagnostic list, publication, and electronic platforms, as well as the priority medical devices List, publication, electronic platforms, training, and consultations.

- GMDN Database and website registration for 52 WHO personnel have been completed

- The rights granted to the WHO shall include using 3,000 Codes, Terms and Definitions in the above-listed WHO publications and electronic platforms (Creative Commons Licence, Non-Commercial)

GMDN IS HERE FOR YOU

BETTER UNDERSTAND YOUR NEEDS

HELP YOU TO GET THE BEST OUT OF GMDN DATA

DEVELOP TOOLS THAT WILL SUPPORT YOUR WORK

Q&A