



## **Device Categorization: GMDN/SNOMED Terminologies Learning UDI Community Workgroup Summary Statement**

Device categorization is a data element that allows for analysis of device behavior at a higher level than that provided by a device identifier, Company name or Brand name. It provides the ability to search across a device type or category (containing like devices) to see trends or signals you couldn't otherwise see.

Global Medical Device Nomenclature (GMDN) is a system of internationally agreed terms used to identify medical devices of the same type (device types) used by regulators and manufacturers to group like devices. GMDN has been selected by the US FDA to categorize medical devices in their Unique Device Identification (UDI) Rule.

Systematized Nomenclature of Medicine & Clinical Terminology (SNOMED CT) is a terminology for clinical documentation and reporting endorsed by the Office of the National Coordinator (ONC) for Health IT as the clinical terminology to be used in certified electronic health record (EHR) technology.

With respect to medical devices, manufacturers/labelers and regulators are speaking in GMDN, while clinicians, supply chain and other healthcare practitioners are speaking in SNOMED CT. In order for the UDI Program and broader National Evaluation System for Medical Devices in Health IT (NEST) to bring value to the healthcare enterprise, all parties along the medical device spectrum (manufacturer/labeler through end user) need to be speaking the same language. NLM's AccessGUDID website has developed API's that provide the GMDN to SNOMED mapping for end users, but is this appropriate and sufficient to the needs of healthcare users?

This work group should review the pro's and con's of GMDN and SNOMED terminologies and review findings of preliminary pilot exercises (RAPID), while also recognizing that additional vocabularies for medical devices, such as UMDNS, UNSPSC, or others, may provide value to GUDID device data and NEST priorities.

As an example, the RAPID GUDID Integration workgroup identified the following key characteristics of a device categorization code set:

- Includes a transparent change control and versioning process that proactively communicates change details to allow effective use of terms within downstream systems (Health IT, registries, etc.).
- Includes best practice guidelines that define unambiguous ways to assign device categories
- Aligns with or improves existing device type code set.
- Has ability to include reference to regulatory requirements associated with a particular model/version of a device.
- Includes representation of all existing device types and is up-to-date with those in commercial distribution