Registry Assessment of Peripheral Interventional Devices (RAPID) project: A report from the GUDID (Global Unique Device Identification) Integration Working Group

Introduction

The Registry Assessment of Peripheral Interventional Devices (RAPID) project was designed to standardize core data elements required to assess peripheral interventional devices in different registries, to implement these variables in 2 major existing registries (SVS VQI and ACC NCDR), and conduct a device evaluation project using these 2 registries to demonstrate the value of multi-specialty device data collection for industry and the FDA. To successfully manage the enormity of such a project, RAPID was divided into the three (3) phases listed below to allow for a progressive and step-wise approach.

a. Phase 1: This phase consists of identifying the minimal set of core data elements for registry assessment of peripheral arterial interventional devices, including a method for registries to extract Unique Device Identifier (UDI)[1] data for relevant peripheral arterial vascular intervention devices.
b. Phase 2: This phase consists of incorporating the standardized data elements into existing registries, EHR systems, and demonstrating the ability to extract data for studies from multiple sources.
c. Phase 3: This phase consists of the use of interoperable data extraction to conduct a prospective device evaluation project in the peripheral arterial treatment space.

The FDA's Informatics team that supports the adoption of Unique Device Identifiers (UDIs) in electronic health information was tasked with leading the Global Unique Device Identification Database integration workgroup (GUDID WG). RAPID stakeholders have expressed enthusiasm and recognize value in using the data in GUDID as the source of structured device identification that will eventually be stored as part of a patient's record in Health IT systems but is now currently available to use as reference data in device registries. Since device registries currently do not have an efficient or consistent mechanism for storing structured device identification data and there is no existing recognized standard identifier that links device records across registries, there is interest in understanding the opportunities for using the GUDID for that purpose. The work of the GUDID WG is aimed at promoting knowledge sharing across FDA, device manufacturers, clinicians and registries that will result in strategies for pulling data from GUDID and facilitate the transition from existing non-standardized device identification in device registries to one based upon the DI as a standard linking identifier and a key to extracting core standard device identification data elements from the GUDID.

The goal of the GUDID WG is to create a mechanism whereby PVI (Peripheral Vascular Intervention) registries can download relevant information about all medical devices used to treat peripheral arterial

[1] For further information on UDI refer to the FDA UDI website at http://www.fda.gov/udi

disease from the GUDID database, so that these devices can be precisely specified in the registries. Throughout the text the acronym GUDID will be used as a generic reference to the data originally submitted into FDA's GUDID and transmitted on a daily basis to National Library of Medicine for public use via accessGUDID (For a link to AccessGUDID see http://accessgudid.nlm.nih.gov).

Current Challenge: UDIs associated with particular peripheral vascular devices are not currently captured in PVI device registries making it difficult to clearly and unambiguously track peripheral vascular device performance and use. These devices are available in different diameters, lengths, and delivery shaft configurations, all of which would be identified by thousands of unique UDIs potentially available to improve device identification. Further, new devices are constantly being cleared or approved and added to the list or older devices eliminated and many of the devices are used both on and off-label. Without a mechanism to extract UDI from the EHR and link the patient with the given device(s) being used in a procedure, registries are forced to develop and maintain their own mechanism for device specification. Even then, the challenge is to maintain an accurate, current list of manufacturers and devices available in the PVI space. Therefore, the current model is inefficient, burdensome, resource demanding and prone to lack of data accuracy due to human error.

Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) Example: For its registries concerning endovascular abdominal or thoracic aortic treatment, VQI maintains a look-up table of the product number and 4 characteristics of each device (manufacturer name, manufacturer sub-type, diameter and length) such that users can enter a product number and the look-up table populates the other 4 device characteristics, or users can enter the other 4 device characteristics, and the table populates the product number. This is tedious, but possible because the number of devices available in the aortic space is in the hundreds, not thousands like the peripheral devices, so the drop down menus are manageable for users. Given the thousands of UDIs available for peripheral devices, VQI determined that it was impractical to maintain such a look-up table for each manufacturer name, device sub-type, diameter and length (and resulting product number) because the drop down menus required would be excessively long and cumbersome. Until UDI bar code scanners are widely available, and such data can be extracted from EHRs, this will continue to be the case.

American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR) Example: For the Carotid Artery Stenting and Lower Extremity portions of the PVI Registry™, NCDR maintains a searchable table of products by manufacturer and/or product name. The list is manually maintained and includes all devices used in the treatment of the lesion as well as distal protection devices, IVUS, FFR and re-entry devices. Device diameter and length (not catheter length or product number) are included in the device description. Currently the list has over 5,500 devices used in the treatment of chronic and acute limb ischemia and carotid artery stenting. The list includes products approved for the treatment of the Carotid and Lower Extremity as well as coronary balloons and stents, biliary balloons and stents, embolization products and imaging products used to aid in the treatment of the lesion. The PVI Registry

was built to collect UDI; however until scanning capability is available as well as interfaces from EHRs, it is felt impractical to enter the UDI numbers manually.

Society of Interventional Radiology (SIR) Example: The majority of device-oriented IR registries and trials today utilize web-based forms for data collection (examples: Pharmacomechanical catheter directed thrombolysis for DVT (ATTRACT); IVC filter study (PRESERVE)). The next generation of Interventional Radiology registries is designed to automatically capture data transmitted from structured procedure and post-procedure reports, either through voice recognition/dictation systems or from EHRs. Topic-specific and performance measure registry data will be aggregated and reported using the American College of Radiology's *National Radiology Data Registry* or other vendor platform. The technical details module of structured procedure reports includes device names, manufacturers and (dictation or manual entry of) UDIs, if available. A pilot study of structured procedural reporting, limited to a small number of non-arterial interventional procedures, has been completed will be used to create new reports applicable to a wider set of interventions available for download to any practitioner performing these procedures. Maintaining an up-to-date and accurate list of all potential devices and specifications for inclusion in structured reports remains a challenge, as previously described.

Proposal for the GUDID WG: RAPID would work with the FDA UDI Informatics and National Library of Medicine AccessGUDID team to accomplish the following steps:

1. Review and provide feedback about the existing classification scheme (i.e. Global Medical Device Nomenlature) linked to records in GUDID for use with peripheral vascular devices.
2. Develop a mechanism to evaluate the GMDN terms used to categorize all existing and new devices based on both their indications for use and their clinical use.
3. Agree on a common set of GMDN terms that could be used by each registry to download and extract the information needed from GUDID for common analysis across registries. The set of terms should be as complete as possible and developed in collaboration with clinicians and informaticians as subject matter experts.
4. Agree on a common set of core device information available in GUDID that each registry could download and then extract the information needed for their registry.
5. Provide ongoing feedback to manufacturers participating in registries to ensure that that data entered into GUDID (i.e. the common data elements and GMDN terms)is consistent.

Methodology

The GUDID WG established the following parameters to narrow the scope of the work so that we could achieve tangible results that could be generalized more broadly. Participation in this workgroup was limited to the US FDA Global Unique Device Identification Database (GUDID) and two of the three device registries mentioned in the introduction – the Society for Vascular Surgery Quality Initiative and the American College of Cardiology National Cardiovascular Data Registry. The scope was further narrowed by focusing on 'stents' and "stent grafts" Even within this device type it is difficult to generate an

accurate complete list of all stents in each of the three data sources noted above was a key challenge. Identifying a stent in GUDID could be through its product code, Global Medical Device Nomenclature (GMDN) term, or device description. Likewise each of the other data sources has groupings for device types.

Appendix 1 outlines the specific steps and data used by the FDA and staff at SVS and ACC in the first attempt to integrate device identification records from the GUDID into each of the two peripheral vascular registries. GMDN terms that contained stents were tested as a potential controlled vocabulary to extract data from each of the data sources. Two major challenges were identified as the team attempted to select appropriate terms applicable to PVI devices. First, the initial list of potential GMDN search terms used in the exercise only included relevant active GMDN terms. Since this list was used to extract data from GUDID data, DI records that were relevant but had obsoleted GMDN terms assigned to the DI records were not identified in the extracted record results.
Second, the GUDID WG recognized that GMDN terms are based upon approved indications for use and so would not take into account the real world use of the devices in medical practice. The team recommended exploring options identifying actual use in order to compare effectiveness of approved use vs. real world use of the devices. Since we could not be sure the GMDN term alone would successfully identify all relevant devices, the project leaders used a combination of the keyword 'stent' and relevant GMDN terms as the basis of their queries. Each team (FDA, SVS, ACC) ran separate queries and attempted mappings to GUDID to obtain independent query results and provide the best opportunity to identify relevant records and improve mapping results between data sources. The detailed steps and relevant files generated by each data source are located in Appendix 1.

The following are the major insights from the initial mapping exercise:

- Brand and size were the only data elements that could be used to map between GUDID and the ACC's National Cardiovascular Device Registry because NCDR did not include catalog number in their initial data.
- "Catalog Number" and "Version or Model" were significant fields to map between GUDID and VQI's product number but mapping was limited by inconsistent data entry for these fields (e.g. use of '-' or ',' or no delimiter to separate parts of the product number)
- It was extremely difficult to identify any combination of elements that would allow for significant mapping between the registry device data and the data in GUDID without a direct link between the DI and the reference/catalog number.

After several attempts the project leaders recognized that there was no single unique attribute to further match data between the registries and GUDID and so the subgroup engaged willing manufacturers who offered resources to add the device identifier (DI) from the GUDID to the products in the ACC and SVS registries. This collaboration provided the most comprehensive matching and led to identification of gaps that will help inform a generalizable registry transition plan that can be used and modified by registries covering all device types.

Currently registries rely on manual entry of customized device identification data elements collected from a variety of sources (e.g. manufacturer catalogs and voluntary submissions to registries, hospital data, general Internet sites). The future vision is to populate the registries by using GMDN terms to extract data from one source, the FDA's GUDID. Boston Scientific and Cook Medical staff volunteered to participate and provided staff familiar with the GUDID to add device identifiers to ACC and VQI records for their individual stent products. The steps involved and files generated are listed in Appendix 2. Major insights from this exercise included:

- Importance of knowing the identifier used most consistently to identify a device prior to the integration of the UDI. Feedback from the DI exercise indicated that both product numbers and catalog numbers are important pre-UDI numbers to use as the basis for linking the DI to device registries. Neither catalog number nor product number is currently required in GUDID leading to a potential gap for effective matching.
- Importance of capturing clinically relevant size in distinct fields for size type, unit of measure and quantifier. GUDID has separate fields for each of these elements but currently allows users an option to enter data as text. A query of GUDID found that the majority of size data is being entered in an unstructured text field. This will be a barrier to mapping from GUDID to device registries.
- Need for a more common understanding of how clinically relevant size is captured in GUDID (see Appendix 3 for basic information on how clinically relevant size is captured)
- Need for additional measurement type categories (e.g. catheter effective length) because stents of the same size may be loaded on multiple delivery systems
- Need for additional clinically relevant measurement types and units of measure to promote use of structured standard data vs. text for these fields
- Importance of the role of GMDN as the potential term set that could be used to pull data from GUDID via enhanced APIs.
- Since GMDN could be such an important tool, the need to evaluate GMDN term assignment, access, and use across stakeholder groups. Initial observations of the group are outlined below:
    - GMDN terms may be too specific to allow for effective grouping. GMDN has collective terms that will be evaluated for their use in pulling data.
    - Devices may have multiple indications for use. There is a need for discussion on effective ways to represent the multiple indications for use in GUDID records.
    - The frequency of GMDN changing the status of a term to obsolete combined with the inability to enter obsolete codes in GUDID could potentially impact usefulness of GMDN as a standard for use in APIs
- Variability of brand name across data sources. Note that use of the standard Brand name linked to the DI of the GUDID will reduce that variability
- Additional device identification records were found and added to the VQI and ACC registry library based upon the Boston Scientific and Cook mapping exercise indicating that current

manual data entry and reliance on sources other than a master list like GUDID likely miss key device product data.

- Records were found in the registries that were not available from the device manufacturers indicating that there may have been errors in manual data entry into the registry data libraries.
- Registries may store devices regulated by Canada or other regulatory authorities outside North America. These data will not be available via GUDID.
- Unless the approved site of use is clearly identified in GUDID, there may be ambiguity between devices appearing in registries that are approved for one use by one regulatory authority and for another use by another (e.g. biliary vs. vascular stent).
- Consideration should be given to the impact of International Registries on the development of UDI databases in those countries
- Registries may include devices that are no longer commercially available. Records in the GUDID may not be available for those products. Submission to UDI is limited to products in commercial distribution at the time of the UDI regulatory compliance date
- Registry and Manufacturer representatives recognize that the source of the DI for patient implant data should be patient electronic health data and that the DI from that data could be used to link and extract core elements from GUDID.

Subgroup members identified and agreed upon the core GUDID data elements that should be pulled for each Stent DI identified in the participating registries. These are noted in Table 1.

Table 1. List of GUDID Common Data Elements Recommended for a Device Registry

GUDID Data Element[2]	Definition
Primary Device Identifier	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.
Secondary Device Identifier	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.
Company Name	Company name associated with the labeler DUNS Number entered in the DI Record.

[2] For further information on GUDID data elements see http://google2.fda.gov/search?q=data+elements+reference+table&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&requiredfields=-archive%3AYes&output=xml_no_dtd&getfields=*

Brand	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or TM symbol.
Catalog/Product Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.
GMDN term	Name of the generic device group
SNOMED CD/Term	As applicable, the SNOMED term that is mapped to a GMDN term for a particular model/version of a device. Note this is a derived field not directly entered into GUDID
Device Description	Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.
Clinically Relevant Size Type	Dimension type for the clinically relevant measurement of the medical device
Clinically Relevant Size Value	Numeric value for the clinically relevant size measurement of the medical device.
Clinically Relevant Size Unit of Measure	The unit of measure associated with each clinically relevant size
Version or Model	The version or model found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.

These terms will need to be further evaluated during the RAPID pilot study to determine:

- Relevance of these terms to meet the goals of registry analysis
- Usefulness across the entire device ecosystem
- Generalizability to other device type registries (e.g. orthopedic devices, central venous devices)

Following the mapping of DI to stent data by device manufacturers, the GUDID staff used the DI's to pull core standard data from GUDID to demonstrate the value of the DI in providing the same data to multiple registries. The steps followed to perform this task are outlined in Appendix 2.

The processes of matching DI's and extracting data from GUDID were completed manually in this exercise, but the goal of the workgroup is to create a mechanism whereby PVI registries could download relevant information about all medical devices used to treat peripheral arterial disease from the GUDID. The registries successfully used the learnings and observations from the mapping exercise to provide recommendations for enhancements to the GUDID as well as outline activities that can serve as a roadmap for any device registry that is considering integration of GUDID data.

GMDN terms are used as the source of device type for pulling device identification records available at http://accessgudid.nlm.nih.gov via an API specifically developed for that purpose. Without this, the burden to downloading the entire GUDID database, extracting the desired devices, and optimizing formats might be too high for most registries especially those with limited IT resources. For example VQI staff was able to strip the records of unneeded data while organizing and formatting the information they needed. They encountered challenges because the downloaded data did not have a standard template – e.g. if a field had multiple values it repeated on a new line. VQI staff overcame this by using dimensional attribute tags to sort what they needed from the list of details. They also developed a workflow for the remaining tasks. However, workgroup members recognized that an API specific to GMDN terms and core data elements would greatly increase the value of GUDID for registry purposes.

While the group was clear that GMDN could be used as a GUDID data extraction tool, further work is needed to evaluate GMDN for as a recommended device type codes set to be used by all registries. As a foundation for future work, the GUDID WG identified the following key characteristics of a device type code set:

- Integration of a change control and versioning process that proactively communicates change details to allow more effective use of terms within downstream systems (Health IT, registries, etc.).
- Documentation of best practice guidelines to establish unambiguous ways to assign device types
- Alignment with or improvement of on existing device type code sets – e.g. product code, UNSPSC, UMDNS, etc.
- Capability to incorporate a range of regulatory requirements associated with a particular model/version of a device.
- Inclusion of all existing device types and up-to-date with those in commercial distribution

The group also thought it was important to for future evaluation of GMDN as a device type code set, to better understand and specify how GMDN terms are developed and assigned. Appendix 4 provides a pictorial overview of the life history of a GMDN term from the perspective of the GMDN Agency which develops and maintains the GMDN terminology. The GMDN WG representative indicated that there is version control over each preferred term. Appendix 5 shows the GMDN assignment process for a sample manufacturer. The workgroup discovered during review of the workflows that there were differences in understanding in the following areas:

- purpose of GMDN assignment for GUDID
- how GMDN terms linked to regulatory approval of a device
- whether GMDN term assignment in one country could be applied for use in another
- level of granularity that would be useful to stakeholders, especially FDA

Workgroup participants identified that manufacturers are making assumptions about the appropriate assignment of GMDN terms for purposes of entry into the GUDID. Some manufacturers are reusing terms assigned for device approval in other countries while others believe it is appropriate to obtain a new term based upon US FDA approved use and even to assign multiple GMDN terms for a single device when multiple indications for use apply to a single product even though multiple indications are allowed within a single GMDN term. It is clear from discussions that there is failure to achieve international harmonization of GMDN assignment and that there needs to be further clarification and potentially a best practice developed for GMDN assignment to reduce variation in term assignment and improve the value of GMDN as a device type code set. It was not decided whether the tie to indications for use would make the use of GMDN preferred terms more difficult for registries to use GMDN terms across countries. The group saw possibilities for using GMDN Collective Terms as a way of 'rolling up' groups of devices that have individual preferred term assignments. The challenge in this approach would be matching the preferred terms in GUDID to GMDN Collective Terms not stored or accessible in GUDID. The GMDN code is also not available in GUDID due to proprietary requirements of the GMDN Agency. Only the preferred term and definition are available, resulting in further barriers to linking to other datasets like registries.

Another issue to be resolved is notification of when terms are changed or obsoleted by the GMDN Agency. These notifications are currently not made public and are only detected by backend systems that would monitor changes in GUDID. Registries specified that identifying changes to the approved use of a product and getting that information based upon GMDN terms changes would be of value to them. The GMDN agency representative provided demonstrations of tools that could be used to link GMDN terms to GUDID device identifier records and to GMDN collective terms. The GMDN Agency is also willing to work with registry owners to provide matching to GUDID records and to alert registries of changes to GMDN terms in GUDID. Appendix 6 shows a screen shot of an application that could provide such matching. The WG discussions did not lead to a resolution of how this service would be provided or how tools such as those shown in Appendix 6 would be made publicly available to all users.

The GUDID WG learned that GMDN terms are mapped to SNOMED terms by the International Health Terminology Standards Development Organization (IHTSDO) and are made publicly available to citizens of several countries (e.g. USA) via country based subscriptions. Since SNOMED updates occur every 6 months and GMDN terms are revised on an ongoing basis there can be a significant gap) for devices with GMDN terms but not SNOMED term assignments. The workgroup did not explore use of the SNOMED ontology, links of GUDID records to SNOMED codes, version control, use of SNOMED as a recognized standard in EHRs, use of SNOMED to identify anatomical sites for actual device use and how those issues

would inform registry use. The groups did recommend further evaluation of these issues and further review of GMDN services to determine their usefulness to registry and other data users.

In addition to GMDN issues, the matching and merging of registry data to device identifier records is currently limited by gaps in two critical fields that have already been mentioned –catalog number and clinically relevant size in GUDID. Ensuring that manufacturers understand the importance of entering catalog numbers into GUDID will greatly enhance the matching of existing medical device data to GUDID data in all data sources that currently collect medical device information. Because catalog number is currently used as a major reference for ordering products directly from manufacturers, providing this information will increase the ability to match to GUDID data. One caveat is that downstream systems (distributors, hospital) may create and store their own ordering numbers and not have visibility into the original manufacturer catalog number. The use of device identifier by all downstream users is meant to address this lack of visibility.

Clinically relevant size became a key topic for the GUDID WG and resulted in a recommendation for further analysis by a group composed of supply chain experts, clinicians and researchers to better understand the current GUDID functionality and need for data quality improvement. Appendix 3 provides an overview of the GUDID functionality for entering clinically relevant size. Currently, there not enough measurement types and units of measure in the allowable GUDID size values. There are also ways to bypass structured measurement type or unit of measure when entering data in GUDID even for devices that could take advantage of this information. Feedback from this group reinforces that of other early UDI adopters and highlights the need to explain current UDI clinically relevant size functionality to device manufacturers and to base future enhancements upon experts who rely on clinically relevant size for activities across the device ecosystem (e.g. purchasing, device selection for clinical care, measurement of patient outcomes).

While the WG identified these key challenges it should be noted that both ACC and SVS are incorporating the knowledge gained from their workgroup participation and downloading of GUDID data to inform the design of their registries. For example, VQI envisions that during a peripheral vascular procedure the registry user will rely on GMDN terms to populate the correct device list, and then user selection will guide which device identification data options are available. The new registry will also be extensible so that it can easily incorporate additional GMDN terms to cover devices beyond the stent or stent graft devices that were the focus of this workgroup. Once downloaded from the GUDID the VQI records will be loaded into a “master” device database using a match and merge with existing devices that are already in VQI data libraries. Both SVS and ACC registries are capturing the existing GUDID data using semi-automated processes and limitations in field values and expect to gain value from each GUDID enhancement that improves the capture of complete, structured data.

Recommendations

The value of bringing FDA, GMDN Agency, NLM, registry owners, clinicians, researchers, manufacturers, and software vendors together to identify and work through the detailed operational and technical issues related to GUDID integration in registries is reflected in the number of insights and recommendations that resulted from workgroup activities. Participants were engaged, open and constructive in identifying issues and making recommendations that they believe can be used not only by their organizations but by those who choose to learn from the GUDID WG findings. The original steps used to guide GUDID WG activity provide the framework for summarizing the group's outputs and recommendations.

1. **Review and provide feedback about the existing classification scheme (i.e. Global Medical Device Nomenclature) linked to records in GUDID for use with peripheral vascular devices.**

    - Linking GMDN terms to GUDID Device identifiers has the potential to be a powerful tool for extracting device identification data by device type. Registries in this WG demonstrated the ability of GMDN terms to identify records by device type. Specific outputs and recommendations include:
        - FDA and NLM received feedback on and have plans to implement a new API service to use GMDN terms to return device identification records from GUDID.
        - Pictorial workflows and descriptions of device assignment differences by manufacturer are included in the appendix of this report to highlight the nature of GMDN term development and use. Reducing variability in GMDN assignment and updates of codes, separating device attribute terminology from indications for use and reducing the version control differences between GMDN and SNOMED are recommended to improve the value of both code sets for registry and other downstream users.
        - Proactively communicating versioning of GMDN terms would allow more effective use of terms within downstream systems.
        - The specific issues raised in this document could form the basis of an AHRMM Learning UDI Community Workgroup to develop GMDN-SNOMED user guides and best practices and to generalize learning to a broader community. Specific enhancements to GUDID data entry and linkages to collective or other terms could be discussed.

2. **Agree on a common set of GMDN terms that could be used by each registry to download and extract the information needed from GUDID for common analysis across registries. The set of terms should be as complete as possible and developed in collaboration with GMDN Agency, clinicians and informaticians as subject matter experts.**

- Since GMDN terms are being created, updated, and obsoleted on a regular basis and registries contain different product types it remains challenging to identify a common set of GMDN terms for use by each registry.
- Instead, the group recommends making more use of GMDN Collective Terms and working with GMDN Agency to link GMDN Collective Terms and changes to preferred terms to GUDID data.
- Further discussion and resolution of effective ways to represent the multiple indications for use in GUDID records should be undertaken by a GMDN-SNOMED workgroup.

3. **Agree on the common set of core device information available in GUDID that each registry could download and then extract the information needed for their registry**.
    - Table 1 provides the agreed upon core device information that is expected to form the basis for all registries linking to GUDID.
    - At a minimum all device registries should contain the device identifier (DI) of the UDI in order to link to GUDID data and to other data sources
    - Catalog number should be entered by all manufacturers submitting data to GUDID in order to link existing data sources to GUDID.
    - Registries should use the catalog number or other registry identification number as the effective link for mapping to GUDID
    - Clinically relevant size is a key field for registries and for purchasing and selecting medical devices for procedures. The GUDID WG has highlighted a need that has been reinforced by multiple UDI early adopters that are interested in improving the quality (structure and completeness) of the clinically relevant size data captured in the GUDID. It is recommended that MDEpiNet and the AHRMM Learning UDI community work across their respective memberships to form a workgroup to look specifically at clinically relevant size and to make recommendations on the size types (e.g. length, width) and units of measure (e.g. cm, in, ft.) that would provide the most benefit across the device ecosystem.

4. **Provide ongoing feedback to manufacturers participating in registries to ensure that that data entered into GUDID (i.e. the common data elements and GMDN terms) is consistent.**
    - Workgroup exercises and discussions engaged all participants but especially opened up a dialog between registry owners and manufacturers to better understand how the data entered into the GUDID by manufacturers would be used by registries.
    - Registry owners may consider joining AHRMM's Learning UDI Community in order to participate in further efforts aimed at improving UDI adoption in electronic health information and the usefulness of data in GUDID

Conclusions

The GUDIG WG was facilitated by the FDA Informatics team and included members from medical device industry, registries, clinicians, and health IT vendors. The workgroup achieved its goals to evaluate the feasibility of integrating UDI into existing peripheral vascular device registry data and to identify gaps

and functional improvements that could be made in the GUDID to meet the specific needs of the identified registries as well as to develop general functionality that could improve the usefulness of GUDID for all device registries. While the GUDID has over 72 standard attributes, this workgroup limited its evaluation to a small subset that included identification of a core set of device identification data for registries, a review and evaluation of the existing classification scheme (i.e. GMDN and SNOMED CT), identification of GMDN/SNOMED terms relevant to PVI devices, and identification of key fields in GUDID that will require further development to increase the value of the GUDID for device registry owners and users. The insights and learnings from the WG are meant to raise general awareness of the value and capabilities of the UDI and GUDID, to share insights and recommendations for improvement to this national resource and to promote effective adoption of UDI in individual and coordinated registry networks. As UDI integration across data sources increases it is expected that the foundational work of this group will be further expanded and refined to meet the needs of a more mature level of device registry development.

Despite challenges, the workgroup retained their goal to promote knowledge sharing across FDA, device manufacturers, clinicians and registries that will result in strategies for pulling data from GUDID and facilitate the transition from existing non-standardized device identification in device registries to one based upon the DI as a standard linking identifier and a key to extracting core standard device identification data elements from the GUDID. RAPID stakeholders have expressed enthusiasm and recognize value in using the data in GUDID as the source of structured device identification as well as our registry partners for this project. Engagement of willing manufacturers who offered resources to add the device identifier (DI) from the GUDID to the products in the ACC and VQI registries, provided the most comprehensive matching and led to identification of gaps that will help inform a registry transition plan generalized to all registries. The future vision is to populate the registries by pulling standard data from GUDID using a standard device type code set and to work with and in support of the subgroups that will take this work forward.

Appendix 1
Identification and Linking between GUDID and Registries

GUDID: Stent Query and Mapping to VQI and ACC stent data

The following steps were taken by the FDA Informatics team to support linking between GUDID and registries.

1. Queried all GMDN terms with word Stent which resulted in 99 terms (Column B of the attached). Also queried the terms that were used to date in GUDID (37 terms Column A of the attached). VQI reviewed the list and provided the relevant terms for RAPID project. Provided in sheet 2 of attached

T03 - GMDN Terms with _stent_used in da

2. Queried GUDID to find the DI's submitted with GMDN term with word "stent". (Resulted in 10508 records – attached below)

t01 - stents.xlsx

3. Received "stent" data from ACC. Added a column to the file, copied the device name, removed size from the name. Matched against the list that was produced in step 2. From 86 unique names in ACC file, only 6 automatically matched the update device name.

   Same steps were taken for the VQI file – from 68 unique device name, 12 automatically matched the updated device name.
   The attached document, the above results is in separate sheets, to which matches to GUDID brands were added manually if automatically not found.

Compare GUDID ACC VQI- Stents.xls

VQI: Linking to GUDID PVI Stents

The following steps were taken by the staff at VQI to link to GUDID stents.

1. Generated the list of stents that existed in current VQI database (both branch devices and iliac limb devices), which contains 1777 devices with the following characteristics:
    a. Product Number
    b. Device Manufacturer
    c. Device Type
    d. Device Diameter
    e. Device Length

2. Generated the list of 22 new PVI stents (only with Device Manufacturer and Device Type, no Device Diameter or Device Length) that VQI is planning to add in the following categories:
    a. Balloon-Expanding Stents
    b. Self-Expanding Stents
    c. Drug-Eluting Stents

3. Combined the two sources into a single list, and shared with FDA

4. Received GMDN terms from FDA. Reviewed the list of 99 GMDN terms and identified 15 relevant terms for RAPID project

5. Spot-checked 11 manufacturers' "Product Number" in VQI against GUDID, and found that some manufacturers had their Product Numbers entered as "Catalog Number" in GUDID but some entered as GUDID "Version or Model"

    Manufacturers checked:

    Abbott
    Atrium
    Bard
    Boston Scientific
    Cook
    Cordis
    Covidien
    Gore
    Medtronic
    Merit
    Terumo

Appendix 2
Device Manufacturer – Adding DI to Registry Data

Boston Scientific – Adding DI to VQI data

The following steps were taken by BSCI to review VQI stent data set and add the Device identifier of the UDI. Attached is the file with 366 unique DI's

BSC Filled PVI Stent Boston Scientific Devic

The list was merged with GUDID data and the following data elements were pulled in the next attached document: Brand Name, Model/Version, Catalog, Description, Product Code, GMDN Term. This file includes 420 rows since some DI's had multiple Product Codes or GMDN Term.

t07- bsci vqi DI match with GUDID.xlsx

GUDID – Standard population of VQI registry data using DI lookup

The next file is the merge of DI's on BSCI file with GUDID size data. This file has 1048 rows since each DI has 3 measurements (Stent Length, Effective Length, and Diameter). The matched DI's size is different from the size in VQI data set.

t07- bsci vqi DI match with GUDID size.xlsx

Boston Scientific – Insights and Lessons Learned

PVI/VQI Registry:

- The Catalog number is not entered into the UDI database, and is thus not going to be searchable. However, both the "Version or Model" and "Catalog-Product Number" fields in the GUDID Database will supply the UPN for BSC, unique to each of BSC's products.
- Having the Device sizes separated is helpful for pulling the information—separate columns for Length and Diameter
    - For a number of products, It is also important to note the Catheter Effective length, as stents of the same size may be loaded on multiple delivery system lengths
- Brand Name may differ slightly from what was on the spreadsheet, but is entered into the GUDID database, so may still be extrapolated from a GUDID Report.

- There were many PI Stents missing; I added those

ACC Registry:

- Without separating the length/diameter into separate columns, making a spreadsheet sortable, it makes it very time consuming to add additional information.
- Additionally, delivery system length is not specified. Because the same stent size is used with multiple delivery systems, there may be multiple Device Identifiers associated with a device and stent size. Effective Catheter length is required to specify—or else the registry owners should pull data from Both Device identifiers

"Core Data Elements" by Registry Owner	Where does BSC enter this data in GUDID	Additional Notes
Device Identifier	Primary Device Identifier	"GTIN"
Brand Name	Brand Name	
Company Name	Company Name	
Catalog/Product Number	"Catalog Number"	UPN entered into both fields; Identical field
Version or Model	"Version or Model"	
GMDN Term/SNOMED	"GMDN Preferred Term Name"	Autopopulates in FDA database from submitted GMDN Term
Device Description	"Device Description"	Note*: Could also use GMDN Definition, as it autopopulates in FDA database from submitted GMDN Term
Clinically Relevant Size	"Size Type Text" in Clinically Relevant Size	Submits as three rows to the field as Effective Length, Stent Length, and Stent Diameter Note*: Field does not populate as only a number (i.e. "7"), but rather an entire numerical/text field (i.e. "7 mm Stent Diameter")

Cook Medical – Adding DI to VQI

PVI Cook Stent Devices_VQI_CM_Upd

Cook Medical – Adding DI to ACC

ACC RAPID Cook Stents_with DI.xlsx

Cook Medical – Insights and Lessons Learned

PVI/VQI Registry

There were a few issues identified during the process, mainly relating to the different availability of devices within or outside the US. This becomes even more confusing when there are similar/same devices with slightly different names and different availability depending on geography. I have tried to summarize the points below:

- Formula 535 Vascular stent is not currently available in the US, therefore there is no DI.
- The Zilver Flex 35 vascular stent is not currently available in the US. However, there is a Zilver Flex 35 Biliary stent available in the US. The size range in the spreadsheet reflects the vascular stent, although it is unclear exactly which device was intended to be included. Since there is a DI for the biliary stents we have included the corresponding product # and DI when possible. I think it would be good to also update the device name to indicate biliary or vascular so that there is a clear distinction.
- The various Zilver stents are available with both an 80 cm and 125 cm delivery system; only the 125 cm system was included in the spreadsheet.
- The Zilver 635 Vascular is not available in 100 mm length or 12 mm diameter since there were a couple of entries with these dimensions.

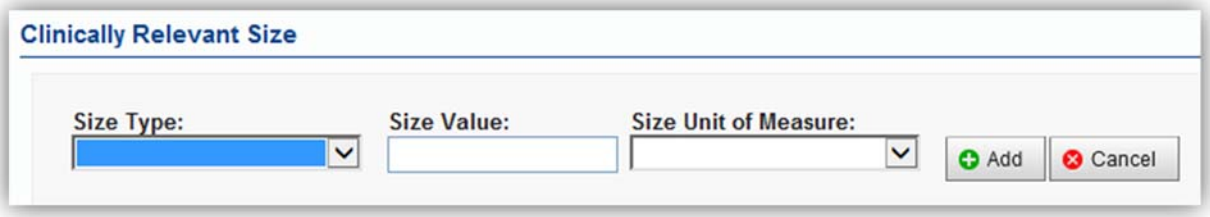
ACC Registry

The key piece to matching was having the product/catalog number available. This was already in the VQI dataset, which made it very simple to match up. The ACC dataset did not have product number and so we had to match up the device name and dimensions (stent diameter, stent length, catheter length) to hopefully the correct product number before being able to match product number to GUDID. Some of the additional challenge within this process was trying to make sure we were identifying the correct device since there are some similarly named and sized devices within the dataset (with potentially differing availability within and outside the US).

Appendix 3

Overview of Capture of Clinically Relevant Size in GUDID

The following is a screen shot showing the data entry fields and drop downs available to users entering data into the Global Unique Device Identification Database from the web interface.



Features of the Clinically Relevant Size field:

- Designed to capture a minimum data set
- Drop-down lists for Size Type and Size Unit of Measure help standardize data entry
    - For those using xml submission, C-codes for each size type (see below) and appropriate units of measure are provided in HL7 SPL implementation documents.
- Labelers can enter more than 1 size per DI record
- The following cannot be entered: Size Value as a range, Size Value as a fraction
- Edit Rules: after the DI record is published, labelers can only 'Add' new sizes; existing sizes cannot be edited or deleted

Size Type list:

The list of size types needs to be –

- Generic enough to represent the variety of medical devices
- Specific enough to capture a relevant size for a specific device type
- Represent common or standard metrics of a specific device (or device type)
- A manageable list of options; a list that's too long will discourage use

NCIt Code	CDRH-GUDID Preferred Term	FDA CDRH-GUDID definition
C67505	Angle	The inclination of one line to another or the plane of one object to another.
C25244	Area/Surface Area	The extent of a 2-dimensional surface enclosed within a boundary.
C64265	Circumference	The length of the closed curve of a circle; the size of something as given by the distance around it.

C25333	Depth	The extent downward or inward; the perpendicular measurement from the surface downward to determine deepness.
C106041	Device Size Text	Additional undefined device size not represented in the GUDID clinically relevant size list.
C101680	Catheter Gauge	A number representing the outer diameter of a catheter where each integer represents 1/3 of a millimeter.
C96684	Outer Diameter	The greatest possible length of a straight line passing through the center of a circular or spheroid object that connects two points on the circumference.
C25347	Height	The vertical measurement or distance from the base to the top of an object; the vertical dimension of extension.
C25334	Length	The linear extent in space from one end of something to the other end, or the extent of something from beginning to end.
C101685	Lumen/Inner Diameter	The length of a straight line passing through the center of the inner open space or cavity of a tubular organ and connecting two points on the circumference.
C101687	Needle Gauge	A number representing the outer diameter of a hypodermic needle.
C112332	Pore size	A quantitative or qualitative measurement of the physical dimensions of the pores in a material.
C25195	Pressure	The force applied to a unit area of surface.
C25335	Total Volume	The total amount of three dimensional space occupied by an object or the capacity of a space or container.
C25208	Weight	The vertical force exerted by a mass as a result of gravity.
C25345	Width	The extent or measurement of something from side to side.

Size Units of Measure list

(List can be found in the HL7 SPL implementation files, SPLCodeList.xls; units of measure are excerpts from Unified Code for Units of Measure (UCUM))

Description	Code
Degree	deg
Square centimeter	cm2
Square foot	[sft_i]
Square inch	[sin_i]
Square meter	m2
Square millimeter	mm2
French	[Ch]
Gauge *	G
Centimeter	cm
Decimeter	dm
Feet	[ft_i]
Femtometer	fm
Inch	[in_i]
Kilometer	Km
Meter	M
Micrometer	Um
Millimeter	Mm
Nanometer	Nm
Picometer	Pm
Yard	[yd_i]
Hertz	Hz
KiloPascal	kPa
millibar	mbar
Pound per Square Inch	[psi]
Centiliter	cL
Cubic Inch	[cin_i]
Cup	[cup_us]
Deciliter	dL
Femtoliter	fL
Fluid Ounce	[foz_us]
Gallon	[gal_us]
Kiloliter	kL
Liter	L
Microliter	uL
Milliliter	mL
Nanoliter	nL

* Unit not represented in the UCUM standard; unit is specific to GUDID implementation

Picoliter	pL
Pint	[pt_us]
Quart	[qt_us]
Gram	G
Kilogram	Kg
Metric Ton	T
Microgram	ug
Milligram	mg
Pound	[lb_av]
Ton	[ston_av]

Mapping of Size Type to Size Unit of Measure

Description	Code
Degree	deg
Square centimeter	cm2
Square foot	[sft_i]
Square inch	[sin_i]
Square meter	m2
Square millimeter	mm2
French	[Ch]
Gauge	G
Centimeter	cm
Decimeter	Dm
Feet	[ft_i]
Femtometer	Fm
Inch	[in_i]
Kilometer	Km
Meter	M
Micrometer	Um
Millimeter	Mm
Nanometer	Nm
Picometer	Pm
Yard	[yd_i]
Hertz	Hz
KiloPascal	kPa
millibar	mbar
Pound per Square Inch	[psi]
Centiliter	cL
Cubic Inch	[cin_i]
Cup	[cup_us]
Deciliter	dL
Femtoliter	fL
Fluid Ounce	[foz_us]
Gallon	[gal_us]
Kiloliter	kL
Liter	L

To promote data quality, Units of Measure are mapped to appropriate Size Types, listed below:

Angle

Area/Surface Area

Catheter Gauge

Needle Gauge

Circumference
Depth
Height
Length
Lumen/Inner Diameter
Outer Diameter
Pore Size
Width

Pressure

Volume

Microliter	uL
Milliliter	mL
Nanoliter	nL
Picoliter	pL
Pint	[pt_us]
Quart	[qt_us]
Gram	g
Kilogram	Kg
Metric Ton	T
Microgram	ug
Milligram	mg
Pound	[lb_av]
Ton	[ston_av]

Volume, con't

Weight

OR as it appears in the GUDID SPLCodeList.xls:

Angle Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Angle	C67505	Degree	deg
Area Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Area/Surface Area	C25244	Square centimeter	cm2
		Square foot	[sft_i]
		Square inch	[sin_i]
		Square meter	m2
		Square millimeter	mm2
Gauge - French Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Catheter Gauge	C101680	French	[Ch]
Gauge - Needle Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Needle Gauge	C101687	Gauge	G
Note: This unit of measure is not provided in UCUM. The code value is one specific to the GUDID implementation			
Length Size Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Circumference	C64265	Centimeter	cm

Depth	C25333	Decimeter	dm
Height	C25347	Feet	[ft_i]
Length	C25334	Femtometer	fm
Lumen/Inner Diameter	C101685	Inch	[in_i]
Outer Diameter	C96684	Kilometer	km
Pore Size	C112332	Meter	m
Width	C25345	Micrometer	um
		Millimeter	mm
		Nanometer	nm
		Picometer	pm
		Yard	[yd_i]
Pressure Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Pressure	C25195	Hertz	Hz
		KiloPascal	kPa
		millibar	mbar
		Pound per Square Inch	[psi]
Volume Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Total Volume	C25335	Centiliter	cL
		Cubic Inch	[cin_i]
		Cup	[cup_us]
		Deciliter	dL
		Femtoliter	fL
		Fluid Ounce	[foz_us]
		Gallon	[gal_us]
		Kiloliter	kL
		Liter	L
		Microliter	uL
		Milliliter	mL
		Nanoliter	nL
		Picoliter	pL
		Pint	[pt_us]
		Quart	[qt_us]
Weight Units of Measure			
Size Types	**Size Type C-Code**	**Description**	**Code**
Weight	C25208	Gram	g
		Kilogram	kg

		Metric Ton	t
		Microgram	ug
		Milligram	mg
		Pound	[lb_av]
		Ton	[ston_av]

Above is all information from the data entry perspective.
What you see from AccessGUDID looks like this:

Example 1: one size entered using standard values ‘Length’ and one size entered as text ‘Diameter’

Size Type Text
Device Size Text, specify: Diameter: 8.5 Millimeter
Length: 65.0 Millimeter

When entered using standard options, this is how ‘Size’ should be formatted

Example 2: all sizes entered as text

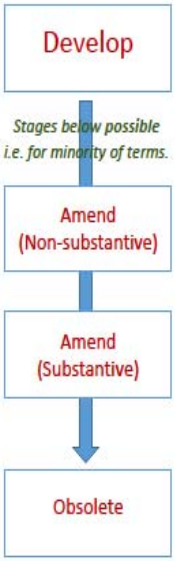
Size Type Text
Device Size Text, specify: 20 mm, Proximal Diameter
Device Size Text, specify: 0 mm, Uncovered Extension Length
Device Size Text, specify: 88 mm, Covered Extension Length
Device Size Text, specify: 13 mm, Distal Diameter

Example 3: size entered as text, but no Size Type or Units of Measure

Size Type Text
Device Size Text, specify: 7.0 X 55

Appendix 4

Life History of a GMDN term



1. Request received from member who cannot find existing GMDN term to adequately describe a product. The member provides details (including product documentation eg IFU) and an image of the product.
2. GMDN review request and make decision as to whether a new term required, or an amendment to an existing term.
3. If new term is developed, there is consultation and status updates with the member.
4. The final draft Term is linked to the appropriate Collective Terms in the nomenclature.
5. When complete and on approval, the Term is finalized (allocated a unique GMDN code) and is immediately available for use by all members.

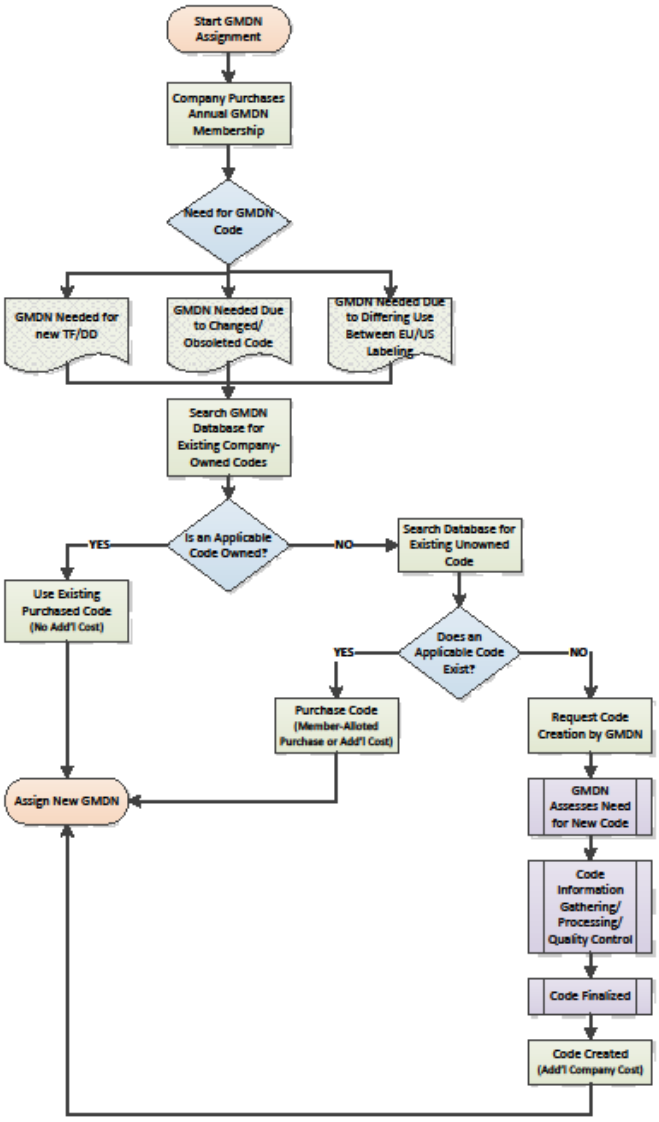
Minor amends to Term i.e no change of scope, usually to link to more Collective Terms. May be editorial (grammar) correction. Members will be unaware that this has happened.

Amends to Term name and/or definition with a broadening of scope, typically identified as necessary during development process. Usually to maintain consistency in the nomenclature, to define boundaries and/or to align with industry.
NO CHANGE to GMDN code.
Members using the term are notified. Translations flagged as requiring re-translation and details included in update files exported to regulators etc.

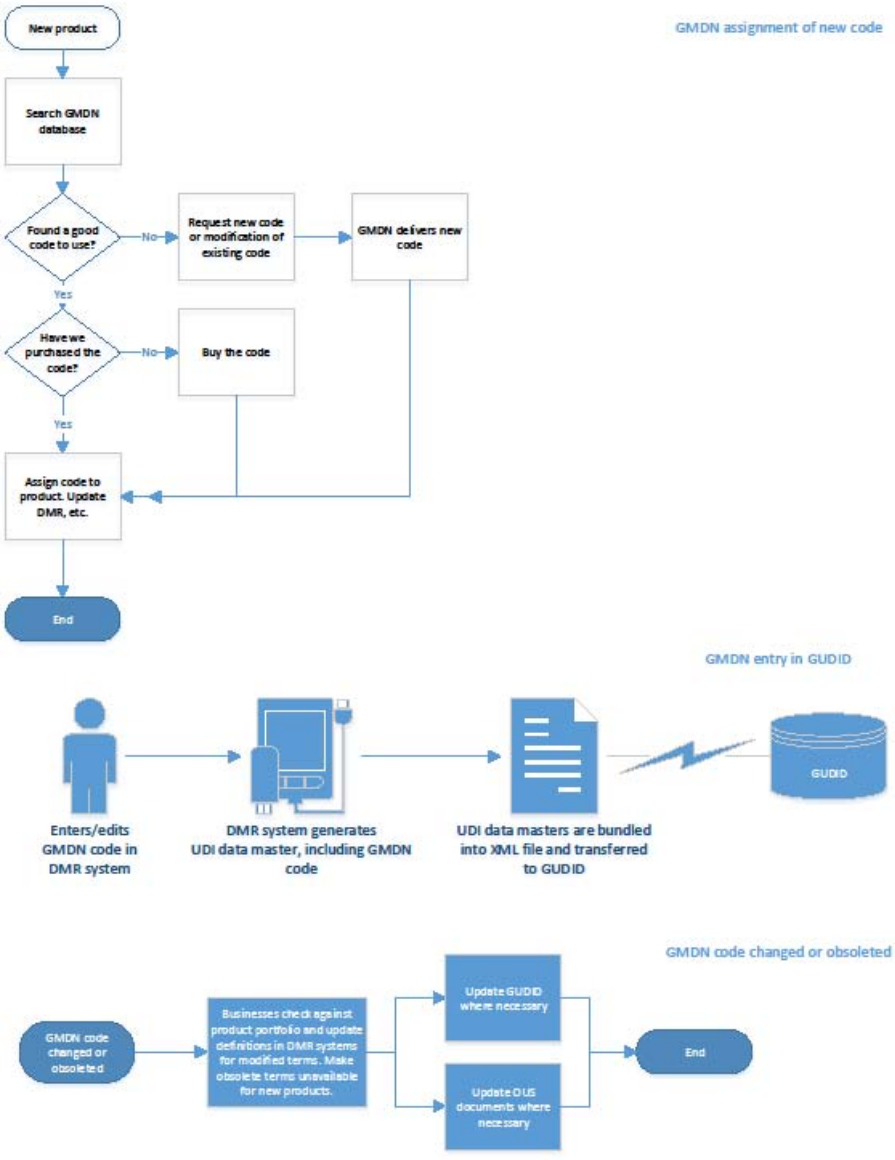
As obsoletion of GMDN Terms causes considerable disruption to regulators and manufacturers there is consultation and consideration before implementing.
Typically for 'older' terms that are poorly defined, ambiguous, overlap with other term(s) and/or too general for practical use.
Members using the term are notified with guidance for selecting appropriate alternative term.

Barry Daniels GMDN Agency May 2016

Appendix 5
Example - Manufacturer Assignment of GMDN

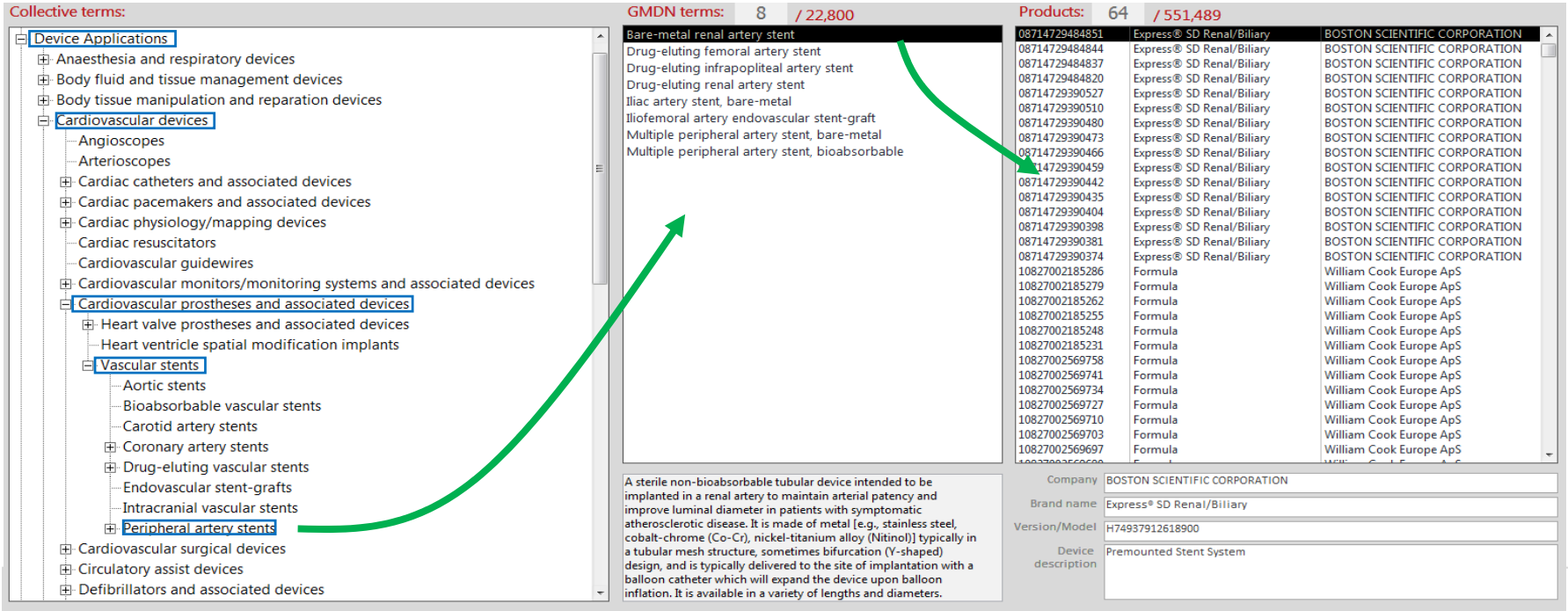


Appendix 5 (cont'd)
Example - Manufacturer Assignment of GMDN



Appendix 6

Sample: Use of the GMDN Collective Terms to link GMDN Terms to GUDID records



In the left-hand box above shows the navigation down through logical nodes to a collective term ‘Peripheral artery stents’. Once selected the middle list is populated with corresponding GMDN Terms (i.e. all Terms for peripheral artery stents). On selection of one of the GMDN Terms, the corresponding records in the GUDID populate the right-hand list.

This demonstrates how the ‘Collective Terms’ can be used to find the appropriate products in the GUDID.

The Collective Term explorer is available on the GMDN website for members. It can be used to identify appropriate GMDN Terms – we can develop a means for that data to be used by members e.g. exports of lists of Terms or a more sophisticated API.