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Global UDI Database (GUDID) Best Practices Guide

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GLOBAL UDI DATABASE (GUDID) BEST PRACTICES GUIDE

BACKGROUND:

The AHRMM LUC chartered a Transactional Efficiency work group to identify opportunities to promote adoption and expand use of the Unique Device Identifier (UDI). As the work group evaluated the current situation and looked for barriers to maximizing the use of the UDI, data quality issues within the Global Unique Device Identifier Database (GUDID) were identified as an area that needed to be addressed.

Manufacturers are required by the FDA to submit medical device data to the GUDID[1]. The database serves as the reference catalog for every device with a Unique Device Identifier (UDI) and contains both required and optional data elements. The GUDID contains the Device Identifier (UDI-DI) component of the UDI and flags that indicate which UDI-PI attributes (e.g., lot, serial number, expiration date, manufacture date, donation identification number) are included in the UDI. Data elements are populated by and updated by the device labeler. Furthermore, the FDA has data monitoring authority and can remove fraudulent data.

GUDID data is available for access via two public portals, AccessGUDID, (https://accessgudid.nlm.nih.gov/) and OpenFDA (https://open.fda.gov/). AccessGUDID provides a user-friendly tool to search and retrieve GUDID data for specific medical devices. The AccessGUDID portals also allows for GUDID data download and includes helpful Application Programming Interfaces (APIs) information. OpenFDA is geared more to programmers and data aggregators and provides APIs and data downloads of GUDID data.

Health care providers are required to use Electronic Health Record (EHR) systems that are certified by the Office of the National Coordinator for Health Information Technology (ONC) to qualify for Medicare's Promoting Interoperability Program. The certification process (referred to as CEHRT) requires specific data elements related to implantable devices to be validated against the GUDID and populated into the EHR. A list of CEHRT requirements is included in the appendix.

CHALLENGE:

Hospitals, software application providers, consultants, and others want to rely on device identification data in GUDID for standardizing their own device data. However, known data quality issues within the GUDID database impede integration of device information into the various third-party applications systems, ERP, and EHR systems. As the use of GUDID information expands, nuances regarding its use for supply chain and clinical purposes have become apparent resulting in the need for better clarity and enhanced definitions for data elements and the associated guidance for data submission. Additionally, the FDA is interested in ways to further enhance the value the GUDID brings to patients and the health care industry.

[1] 21 CFR 830.300

PROCESS:

The work group was comprised of representatives from health care providers, manufacturers, group purchasing organizations, software application providers, data platforms, consultants, issuing agencies (GS1, HIBCC, and ICCBBA), and the FDA. The group reviewed all the data elements contained in GUDID and compared the required data elements in GUDID with those for CEHRT. They identified the data elements that had the most impact on patient safety and operational efficiency as well as those that frequently contained inaccurate or missing data. The work group identified how each of the data elements were used by providers and developed the best practice recommendations outlined below.

BEST PRACTICE RECOMMENDATIONS:

To better meet the needs of all the various stakeholders that use information from GUDID, AHRMM LUC makes the following recommendations:

General Requirement:

GUDID data element reference table states "When a GUDID attribute appears in the medical device labeling, the values submitted to GUDID should match the values in the labeling."

- Manufacturers should follow this guidance and update the GUDID when they make label changes. (Note that if the change impacts a 'DI Trigger' element, then a new Device Identifier must be assigned. Please refer to the GUDID Data Elements Reference Table (DERT) for more information)

Catalog Number:

Current GUDID Definition: The catalog, reference (REF), reorder, or product number used by the labeler (generally the company whose name is on the product) for business and clinical transactions to identify a particular product; this number can usually be found on the device label or labeling.

Current GUDID Requirement: Optional

- Manufacturers *should always* populate this data element in the GUDID.
- The catalog number is important in that it serves as a link between the manufacturer submitted UDI-DI and the provider's internally defined item master. This linkage is critical in providers transition to and adoption of UDIs.
- Alignment of manufacturer and provider internal item master catalog numbers is critical in the successful use of UDI-DI in EDI transaction data sets (e.g., purchase order, invoice, etc.,) clinical documentation and inventory management systems.

Version/Model Number:

Current GUDID Definition: 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.

Current GUDID Requirement: Required

Current CEHRT Requirement: Required

- If the medical device does not have a version/model number, the GUDID reference table notes state, "enter a concept that can be used to identify all devices that have specifications, performance, size, and composition within limits set by labeler."
- If the manufacturer's medical device lacks a version/model number, then the manufacturer catalog number should be populated in both the GUDID Catalog and GUDID Version/Model number data elements.

Device Description:

Current GUDID Definition: Device description should include any description found on the device label, package insert, or approved or cleared indications for use to support user identification. If you have multiple device records with similar information, this field should help users differentiate among the device records.

Current GUDID Requirement: Optional

- Manufacturers *should always* populate this data element in the GUDID as it is a critical field for providers to identify medical devices and distinguish between similar devices. It is also critical for patient documentation and must be included in EHRs for implantable devices.
- Description in GUDID should match the description on the medical device packaging.
- If size is a critical factor in differentiating the medical device (e.g., French size for catheters) it should be included in the description as well as in the clinically relevant size field.

GMDN Preferred Term (PT) Name:

Current GUDID Definition: Name of the common device type associated with the GMDN Preferred Term Code.

Current GUDID Requirement: Required

Current CEHRT Requirement: Required

- GMDN names are used by providers to group products for analytical purposes, to identify potential product substitutions, and classify products as implantable (see High Risk Implantable Device LUC report at: https://www.ahrmm.org/system/files/media/file/2019/11/high-risk-implants-work-group-report-102019.pdf).
- In many cases GMDN names for implantable devices are parsed from GUDID and populated in the patient's EHR.
- Since providers are the primary users of the GMDN Preferred Term Name, their input should be considered by the GDMN Agency and manufacturers.
- The GUDID will begin displaying the GMDN code along with the name, anticipated around October 2023.
- Manufacturers should assign only one name per medical device.
- If manufacturers are unsure which GMDN Preferred Name is most applicable, they may want to get input from their customers. Likewise, if providers disagree with an assigned name, they are encouraged to talk with the manufacturer and share their rationale for using a different GDMN Preferred Name. The GMDN Agency can also provide guidance.
- When notified that a GMDN is obsolete manufacturers should update this information in the GUDID.

Clinically Relevant Size:

Current GUDID Definition: Dimension type for the clinically relevant measurement of the medical device.

Current GUDID Requirement: Required if the medical device is available in more than one size.

- Clinically relevant size is very important when selecting which medical device to use or purchase (e.g., Regular versus Extra Large blood pressure cuffs).
- Providers document the clinically relevant size of implantable devices in the patient's EHR. If it cannot be parsed from GUDID, it must be manually documented. Since this isn't a required field in the EHR, it can easily be missed, leaving important information undocumented in the patient record.
- Medical device registries use clinically relevant size in their analysis of patient outcomes and device performance. What is considered "clinically relevant" can vary based on the medical device type. Therefore, it is important for device registry representatives, medical researchers, providers, and manufacturers of specific types of medical devices (e.g., peripheral vascular devices) collaborate to determine the specific requirements.
- The Clinically relevant size is a drop-down list in GUDID that can be modified based on manufacturer's request once specific requirements have been determined.
- More information regarding clinically relevant size can be found in the Clinically Relevant Size LUC Report at: https://www.ahrmm.org/sites/default/files/ahrmm/gudid-clinically-relevant-size-workgroup-report-082017.pdf

Customer Contact Information:

Current GUDID Definition: Phone number or email address of Customer contact; to be used by patients and consumers for device-related questions.

Current GUDID Requirement: Conditional – if phone number is entered, then email is required. If email is entered, then a phone number is required.

- Manufacturers *should always* populate these two data elements in the GUDID.
- At least one field should contain valid contact information. If there is not a Customer Contact phone number, please enter '9999999999'. If there is not a Customer Contact email, please enter 'xx@xx.xx'.
- Since the launch of the GUDID it has become apparent that contact information is required in circumstances beyond the initial intent that it would be used for Medical Device Reporting or for patients or consumers with questions about the device.
- Keeping the data in GUDID updated and accurate is everyone's responsibility. Since manufacturers control their data, email and phone numbers that connect to knowledgeable contacts should always be included in the GUDID.
- Providers, their representatives, and other 3rd party entities find errors in the GUDID data and must be able to contact the manufacturer to get the information corrected.
- The FDA and issuing agencies would also benefit from correct contact information being included in the GUDID.

SUMMARY:

GUDID has the potential to be the foundational source of truth for medical device information. It is publicly available data that can be used by a wide variety of end users including health care providers, medical researchers, data cleansing and management services, software applications companies, patients, manufacturers, government agencies, and other interested parties. The key to achieving this vision is the quality and completeness of the data contained within the GUDID.

This report focused on six data elements that are of critical importance but are frequently missing or inaccurate in the GUDID. Accurately populating these fields improves patient safety by ensuring that the data parsed from GUDID and populated in the patient's medical record is accurate and will support follow up care and facilitate patient contact in the event of a recall.

Additionally, there are several ways manufacturers directly benefit from having complete and accurate data in GUDID. For example:

- Including the catalog number facilitates updating provider ERP systems with the UDI-DI which in turn allows trading partners to use it in EDI transactions. Utilization of UDI-DI instead of proprietary internal numbers and reference tables has been demonstrated to significantly reduce errors and associated reconciliation costs.

- Inclusion of descriptions and clinically relevant size makes it easier for providers to order the correct product and enhances clinical documentation. It also reduces product returns and creates customer goodwill. Additionally, it allows health care teams not involved in the original case to know the exact medical device used in the event of adverse events or if additional follow-up appointments are needed.
- Accurately assigning the GMDN preferred term name ensures that when providers are looking for product substitutions or new contracting opportunities, all relevant medical devices are included.
- Accurate data tied to the unique device identifier provides a clean audit trail in conjunction with end-to-end transaction processing which includes (but not limited to) ordering, shipping, receiving, invoicing, remitting, post sales, and ultimate product usage.

Everyone has a role to play in continuously improving the data quality in GUDID. The FDA should consider making catalog number, description and contact information required data elements, enhance their data maintenance efforts, and require all manufacturers update the GUDID when their information changes. All users of GUDID data should contact manufacturers when they find inaccurate or missing data. They can also submit a ticket to the UDI help desk at https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/fda-udi-help-desk

Data maintenance within GUDID is an ongoing challenge. However, using the GUDID data and sharing reports and subsequent actions taken based on that data with all stakeholders is a powerful way to improve data quality and expand adoption.

APPENDIX

CEHRT REQUIREMENTS

§170.315(a)(14)Implantable Device List

Regulation	Test Steps	Expected Result	Testing Comments	# of Data Elements	Field Association
170.315(a)(14)(i) and 170.315(a)(14)(ii) are the only items showing as tested by Cerner and review ONCs Certified Health IT Product List.					
(i)Record Unique Device Identifiers associated with a patient's Implantable Devices.					
	Record Unique Device Identifiers: Select patient's record & enter medical device manufacturer supplied test data for unique device identifiers for a patient's implantable device in all formats (1D, 1D-Stacked, 2D) established by the 3 UDI Issuing Agencies (GS1, HIBCC, ICCBBA).	Entered unique device identifiers for a patient's implantable device in all formats established by the 3 UDI Issuing Agencies.	Completed. GS1, HIBCC, ICBBA accredited agencies and associated 1D, 1D-Stacked and 2D tested; UDI-DI and UDI-PI parsed into patients EHR. Three barcodes per agency validated.	1	UDI
(ii)Parse identifiers from a Unique Device Identifier (UDI):					
	Parse Unique Device Identifiers: Select patient's record & parse medical device manufacturer's supplied UDIs in all formats established by the 3 UDI Issuing Agencies for the patient's implantable device (A) Device Identifier; (B) Production Identifiers; 1. lot or batch the device was manufactured in; 2. serial number of a specific device; 3. expiration date of a specific device; 4. date a specific device was manufactured; & 5. For an HCT/P (human cell, tissue, or cellular & tissue-based product) regulated as a device, the distict identification code required by: 21 CFR § 1271.290(c).	Parsed unique device identifiers in all formats established by the 3 UDI Issuing Agencies for a patient's implantable device (A) Device Identifier; (B) Production Identifiers: 1. lot or batch the device was manufactured in; 2. serial number of a specific device; 3. expiration date of a specific device; 4. date a specific device was manufactured; & 5. For an HCT/P regulated as a device, the distinct identification code required by: 21 CFR § 1271.290(c).	Completed. UDI-DI, UDI-PI and all GUDID data parsed into the patients implant log of the EHR including the GMDN-PT Name, Manufacturing Date, DI, HCT/P. All GS1, HIBCC, ICBAA formats and 1D, 1D-stacked, 2D barcodes tested including Non-sterile inventory sheets and barcodes that only contained the UDI-DI parsed with GUDID data and validated.	6	UDI-DI UDI-PI • Lot Number • Serial Number • Expiration Date • Manufacturing Date • HCT/P?
170.315(a)(1-4)(iii), 170.315(a)(1-4)(iv), 170.315(a)(1-4)(v), 170.315(a)(1-4)(vi) appear untested/certified by Cerner and review ONCs Certified Health IT Product List.					
(iii) Obtain and associate a description of the implantable device with each Unique Device Identifier (UDI):					
	(A) Obtain & Associate Description of Implantable Device: Cause SUT to obtain a description in all formats established by the 3 UDI Issuing Agencies & associate it with the patient's implantable device: (A) A description of the implantable device referenced by at least one of the following: 1. "GMDN PT Name" attribute associated with the Device Identifier in the Global Unique Device Identification Database. OR 2. The "SNOMED CT Description" mapped to the attribute "GMDN PT Name" referenced above.	Obtained in all formats established by the 3 UDI Issuing Agencies & associated description of Implantable Device for a patient's implantable device referenced by either: 1. "GMDN PT Name" attribute associated with the Device Identifier in the Global Unique Device Identification Database. OR 2. The "SNOMED CT Description" mapped to the attribute "GMDN PT Name" referenced above. (Note: Step A & B may be done simultaneously)	Completed. GMDN PT Name parsed from the GUDID into the patients implant log on scan of any GS1, HIBCC or ICBBA label Testing lab stated Alternate Functionality: (A)(1) "GMDN PT Name"	1	GMDN Part Name

Regulation	Test Steps	Expected Result	Testing Comments	# of Data Elements	Field Association
	(B) Obtain & Associate Description of Implantable Device: Cause SUT to obtain description attributes in all formats established by the 3 UDI Issuing Agencies & associate it with the patient's implantable device: (B) The following Global Unique Device Identification Database attributes: 1. "Brand Name"; 2. "Version or Model"; 3. "Company Name" ; 4. "What MRI safety information does the labeling contain?"; & 5. "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)."	Obtained in all formats established by the 3 UDI Issuing Agencies & associated description attributes for patient's implantable device as follows: 1. "Brand Name"; 2. "Version or Model"; 3. "Company Name" ; 4. "What MRI safety information does the labeling contain?"; & 5. "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)."	Completed. GS1, HIBCC, ICBBA accredited agencies and associated 1D, 1D-Stacked and 2D tested. Three barcodes per agency validated. Real-time scan of barcode returns all GUDID data and parsed all details into patients EHR.	5	Brand Version Manufacturer (Company Name) MRI Safety Natural Rubber
(iv) Display to a user an implantable device list consisting of: (A)The active Unique Device Identifiers recorded for a patient; and (B) For each active Unique Device Identifier, the description of the implantable device specified by subparagraph (iii)(A) of this paragraph.					
	Display Implantable Device List: Verify the implantable device lists consist of: (A)The active UDI recorded for a patient. (B) For each active UDI, the description of the implantable device (C) A method to access all Unique Device Identifiers recorded for a patient	Verified: the displayed implantable device lists consist of: (A)The active UDI recorded for a patient. (B) For each active UDI, the description of the implantable device (C) A method to access all Unique Device Identifiers recorded for a patient.	Completed. Real-time scan of barcode returns all GUDID data and parsed all details into patients history with the active UDI, description allowing for access and removal "explant" of recorded UDI medical device.	1	Active Indicator
(v) For each Unique Device Identifier for a patient, enable a user to access:The Unique Device Identifier;The description of the implantable device, The identifiers associated with the Unique Device Identifier,The attributes associated with the Unique Device Identifier					
	Access Unique Device Identifiers: Select patient's record & access vendor supplied test data for UDI for a patient's implantable device: (A) Unique Device Identifier; (B) description of the implantable device (from Obtain & Associate step A above) (C) identifiers associated with the UDI, (from Parse Unique Device Identifiers step above) (D) attributes associated with the UDI (from Obtain & Associate step B above)	Accessed unique device identifiers for a patient's implantable device & verified each data element was accessible	Completed. Real-time scan of barcode returns all GUDID data and parsed all details into patients implant log and displays in the patients history with the active UDI, description with GMDN Name and GMDN description in the patients implant documentation and viewable in reports and clinical renderings of the surgical record.	1	User Access (no field)
(v) For each Unique Device Identifier for a patient, enable a user to access:The Unique Device Identifier;The description of the implantable device, The identifiers associated with the Unique Device Identifier,The attributes associated with the Unique Device Identifier					
	Change Status of Unique Device Identifier: Select patient's record & change vendor supplied test data for unique device identifier status for a patient's implantable device	Changed unique device identifier status for a patient's implantable device	Completed. Real-time scan of barcode returns all GUDID data and parsed all details into patients implant log. Any changes by the manufacturers GUDID reported data is updated in real-time. The GUDID takes 7 days to update manufacturer data.	1	Explant

TRANSACTIONAL EFFICIENCY WORK GROUP MEMBERS:

- Eric Abbott, BJC HealthCare
- Melissa Amell, Infor
- Robert Badzinski, Mayo
- Devin Bobulski, Epic
- Carrie Bosela, Symmetric
- Kraig Butts, BJC HealthCare
- Kevin Carr, Director Enterprise Architecture, Owens & Minor
- Karen Conway, GHX
- Mike Crabb, Syndigo
- Jay Crowley, USDM
- Scott Everett, OSF Health Care
- Dawn Fowler, Director UDI/Master Data Management, Masimo
- Alex Garlets, ICCBBA
- Brittany Goganzer, Director Procurement and Analytics, AtlaniCare
- Carl Gomberg, Lead Solution Analyst, Premier
- Tasha Gowin, Geisinger
- Angelie Grant, HIBCC
- Emily Haas, CDC
- Carl Henshaw, Director Standards Implementation, Vizient
- Alexis Hull-Stone, GHX
- Tom Jones, JnJ
- Keegan Jones, Oracle
- Michelle Keller, Supply Chain Coordinator, FMLOHS
- Jack Koczela, Director Supply Chain, Froedtert
- Indira Konduri, FDA
- Rich Kucera, Symmetrich Health Solutions
- David Kunz, Premier
- DeJuana Lane, Director, Materials Management, FMLOHS
- Nancy LeMaster, Consultant, AHRMM
- Alex Lentini

- Keith Lohkamp, Workday
- Ellenmary Martin, Dukal (HMMS)
- Jeff Martin, Intermountain Health Care
- Becky Mashmann, Workday
- Bob Matthews, Workday
- Allison Mehr, Communication Director, HIBCC
- Joan Melendez, President, Xcelrate UDI
- Kristin Miles, Oracle
- Nichole Monahan, EPIC
- Karen Moniz, ICCBBA
- Scott Motschenbacher, Syndigo
- Stanley Nachimson, Nachimson Advisors
- Trent Pierce, Clinical Advisor, Kermit PPI
- Chaun Powell, Group Vice President, Premier
- Mack Preston, Symmetric
- Terrie Reed, Symmetrich Health Solutions
- Rachel Richardson, Symmetric
- Dan Rutz, EPIC
- Mike Schiller, Senior Director of Supply Chain, AHRMM
- Matt Shimshock, Premier
- Cynthia Shumway, Intermountain Health Care
- Michael Simpson, FDA
- Josh Skiba, GHX
- Mark Terranova, Vice President Supply Chain Management, Grady
- John Terwilliger, Abbott
- Beth Wells, Senior Director Community Engagement, GS1
- Barbara Young, AtlaniCare