

Management of Clinically Significant Device Attributes not Contained in the GUDID:

Augmented Unique Device Identifier Data – AUDI

Report of the MDEpiNet AUDI Workgroup

MISSION:

Provide the framework for best practices in expanding the UDI-associated device system to manage clinically significant attributes not currently found in the GUDID.

GUIDING PRINCIPLES

- Start small and move forward gradually
- Recognize the steep learning curve of stakeholders
- Leverage device attribute data that are already published
- Organize device attribute data into a more readily accessible (and interoperable) platform
- Plan for incremental improvement in AUDI data use (rather than striving for perfection)
- Anticipate that AUDI requires and self-defines a device classification system (AUDI attributes describe families or types of devices)
- No patient identifiers / PHI will be in the AUDI database (i.e., same as GUDID)
- AUDI will raise awareness of issues with the GUDID - but the goal is not to 'fix' the GUDID
- AUDI may identify issues that will need a separate working group to address
- Certain recommendations will be applicable across all devices while other recommendations will pertain to the handling of data by device class (and will be identified as such)

BACKGROUND:

FDA's Global Unique Device Identification Database (GUDID) currently does not include fields for all of the clinically-relevant attributes needed to optimize clinical utility of the data or to assess device performance. Currently these data are either maintained with the labeler or combined with the Device Description in the GUDID.

ASSUMPTIONS:

Clinically-relevant attributes are needed to more clearly identify key clinical performance characteristics of devices.

- Examples of clinically relevant attributes are size, composition, and risk for cyberterrorism
- Fields recommended for inclusion in AUDI may also be proposed for eventual inclusion in the GUDID
- Manufacturers, distributors, supply chain managers, providers, clinicians, solution companies, patients, GPOs, information technology systems, and others are all potential users and consumers of AUDI data
- AUDI data fields may be specific to certain types of devices / certain classes of devices
- AUDI and GUDID will be closely coordinated
- Access to AUDI data via a single pathway (AccessGUDID) will be the optimal approach
- The AUDI database is a reference database containing current attributes that may be accessed in real time or near-real time. Attributes pulled from GUDID following movement

of those attributes from the AUDI database to GUDID will have a definition and specification identical to what it had when it was in AUDI. This is another reason the 2 databases need to be closely connected—at least functionally.

- Attributes that are created for AUDI and become included in GUDID will be deprecated from AUDI and will not be duplicated in the two databases
- Attributes that exist within GUDID are not in scope for AUDI
- AUDI is not covered under regulation and represents a voluntary database under multi-stakeholder governance. Attributes should be contained in GUDID or AUDI data so that new device identifiers are not generated for the same device but with different attributes. The current system could potentially require the development of parent identifiers to group DIs of the same device in order to evaluate device performance or monitor safety.
- Attributes that are identified for inclusion in the AUDI data set are added or deleted by the multi-stakeholder organization and not through the regulatory process.
- Ultimately, GUDID should evolve to subsume AUDI.

USE CASE EXAMPLES:

The following are examples of circumstances in which AUDI data would be valuable.

1. *Cyber-risk/cyber-terrorism*
Devices that have vulnerabilities due to communication with another device could be identified via an AUDI True/False field to indicate the vulnerability exists. Example: Defibrillators that communicate with a home transceiver and care provider could be vulnerable to hacking or acts of cyber-terrorism.
 2. *Device selection at the time of implantation based on clinically relevant characteristics*
Where multiple variations of a device exist (e.g., drug-eluting coronary stents), clinical selection of a specific brand of stent could be predicated on the drug specifically eluted, particularly in cases of stent failure (restenosis) following implantation of a stent eluting a different drug, along with capture of those attributes as data in a patient's medical record.
 3. *Comparative Effectiveness Research (CER)*
Comparison across different devices by specific attributes to determine if there is a clinically relevant shared attribute that is the driver of device performance or safety.
 4. *Patient education and engagement*
Consumer Case Study: Patient A gets a bioabsorbable anchor in her shoulder. She is unsure if it is safe to get an MRI. If AUDI or, eventually GUDID, contains an attribute for bio-absorbable devices that is publicly available, it would allow her to look up the device that was implanted to learn if it is metal or bioabsorbable.
 5. *Implanted devices that are subsequently removed and discarded*
Identification of clinically relevant attributes shared by devices from multiple manufacturers where there is premature failure or other unexpected / unexplained clustering of explantation, such as metal on metal hips, and the potential association with device failure
 6. *Black Box Warnings and Labeling Changes*
Consideration should also be given to whether AUDI should include an indicator when devices are labeled with critical warnings or contraindications since there is no indicator in GUDID to accommodate black box warnings.
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GOVERNANCE

Leadership of AUDI should be provided by a multi-stakeholder, user community governing body because the information gathered in the database will be used for many purposes other than post-market surveillance. The governing body should be comprised of representatives from the following groups:

1. Manufacturers
2. FDA (and potentially international regulators)
3. Clinicians (e.g., physicians, nursing, cath lab / OR technicians)
4. Health system administration (e.g., supply chain, cath lab / OR administration)
5. Supply chain IT vendors (e.g., Becton Dickinson, Omnicell)
6. Group Purchasing Organizations
7. Registries (at least three – VQI, NCDR, Ortho, other)
8. Healthcare data analytics (e.g., Leidos, IBM Watson)
9. EHR and procedure documentation IT vendors (e.g., Epic, Cerner, Lumedx, Wolters Kluwer)
10. Patients (e.g., patient advocacy groups)
11. Legislative liaisons (US Congress, state government)
12. GMDN
13. Snomed
14. Learning UDI Community
15. NEST Coordinating Center

Governance issues to be addressed:

- Ideally, AUDI will be an integral part of NEST; AUDI governance will be linked to the NEST Coordinating Center.
- An over-arching responsibility of governance will be determining how AUDI and the entire device data ecosystem are to be used in device evaluation and post-market surveillance.
- Governance will be responsible for crafting a business plan, including resourcing requirements, budget estimates, etc.

FUNDING OPTIONS:

A substantial amount of seed funding will be needed to establish and resource the AUDI Operations Center, and to build the AUDI database and the cloud implementation thereof. Cost of long-term operations will largely be dependent on the rate of transfer of AUDI data fields into the GUDID.

- Manufacturers – Many are willing to pay but need return on investment. Manufacturers will also necessarily make internal investments to provide well-formed data to AUDI.
- Federal Agencies
 - FDA – Funding is limited and focused on post-market surveillance. MDUFA funds are available but were spent on NEST Coordinating Center in FY17. Significant MDUFA funds may be available in subsequent years through the NEST Coordinating Center.
 - NIH – Some funding might be available but will likely be limited to NIH research priorities.
- Direct congressional funding through an earmark or legislation such as the Twenty-first Century Cures Act.

- Non-U.S. sources – PMDA (Japan), UK, EU, UN agencies that are becoming data centric and may have surveillance data systems.
 - Other – Private investment or donations possibly through a public private partnership to set up and prove system.
 - One option for ongoing support would be a not-for-profit corporation subsidized by subscription fees from users.
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OPERATIONS AND INFORMATICS

The development of AUDI device data elements is intentionally separate from FDA regulatory processes, following a multi-stakeholder model. Similarly, development and management of the AUDI database, while closely and carefully aligned with GUDID, will be separate from the “rules” governing the GUDID to facilitate adjustment, correction, expansion, and scalability of the AUDI system.

1. AUDI operations should be overseen by a group separate from GUDID administration. This group must be funded and resourced adequately to accomplish its missions, very likely independently from GUDID.
 2. The AUDI group must stay coordinated and synchronized with GUDID administration.
 3. AUDI data will be gathered based on standards built from within the community that generates, stores, analyzes, compiles, reviews, distributes, and uses the database for research, regulatory, and clinical purposes as well as other unforeseen, decision making purposes.
 4. AUDI will be responsible for bringing together subject matter experts (SME) from clinical medicine, professional societies, industry, the public, and hospital systems to identify parsimonious sets of clinically relevant device data elements for specific device types / specific device classes.
 5. AUDI will have a permanent professional staff to oversee continuing managerial operations, and these will serve a coordinating role in assembling the relevant SME panels.
 6. The SME panels will be assembled periodically by device class as necessary to identify AUDI elements and will dissolve once the work is completed.
 7. AUDI elements will be configured in an appropriate informatics structure to be completely interoperable with GUDID. This will depend in large measure on the informatics of the GUDID.
 8. The GUDID currently uses Global Medical Device Nomenclature (GMDN) as a device classification system that is based on manufacturer intended use devices. AUDI will require a device classification system as well, but one that is based on actual clinical uses of devices, not just intended (or labeled) use. The development of such a system is being addressed by the Learning UDI Community/MDEpiNet Device Classification Workgroup. AUDI must work in parallel with this workgroup, and make appropriate plans for a clinical device classification system.
 9. AUDI professional staff along with knowledgeable members of SME panels will work with each panel to configure AUDI elements in the appropriate formats for interoperability.
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HOSTING AND STRUCTURE

As already noted, the AUDI hosting model is not premised on an expectation of FDA management of the collection, review and routing of additional device attribute information; an independent repository permits greater flexibility and would not require the regulatory and administrative efforts that would be required for the Agency to expand its device attribute collection .

Additionally, this model presumes the creation of a consolidated hosting entity. Whoever ultimately utilizes the data – clinicians at the point of care, clinical registries, manufacturers, or academic researchers – a unified locus to which manufacturers could forward AUDI data and from which all data users can access it is the fundamental design. A single source for access to the data is likely a practical necessity for active clinical uses; a fragmentation of responsibilities between collector and distributor would require significant efforts to coordinate content, vocabulary and technology standards that will not be required with a common repository. Employing the same entity for data-in and data-out responsibilities not only eliminates a data handoff, but also facilitates normalization and quality review of the submitted information.

Based on these premises, the high-level design of AUDI hosting is readily defined: a host (“the Warehouse”) would accept submitted information from manufacturers, collect what is needed but has not been submitted, conduct identified validations, normalize and organize the data, and make it available for access by users.

- *Organization of the hosting agency* – The extensive responsibilities of maintaining the AUDI database will be a full-time occupation for a staff of several individuals. The AUDI Warehouse will require continuity, given the importance of consistency and the value of acquired expertise, and clinical users seeking point-of-care device information will require a stable resource with reliable access. Estimates of the required staffing are difficult to state precisely at this point, but several data analysts, an IT development and maintenance group and available clinical resources provide an outline of likely Warehouse needs.
- *Receipt of manufacturer AUDI data* – A manufacturer’s submission of AUDI data will parallel as much as possible the GUDID device listing process. Preferably at the same point at which a manufacturer was completing a GUDID filing, the AUDI attributes, where relevant, could also be collected and delivered to a separate portal. Since those attributes will vary among different classes of devices, the process could involve a system prompt, based on a device’s listed GMDN or other device classification, that identified devices with requested AUDI attributes. This could be as simple as a website, maintained by the Warehouse, in which entry of a GMDN or other description would result in presentation of any AUDI template that was relevant for a given category of device. These templates would be developed and made available by the Warehouse staff to facilitate delivery of the attributes defined and determined to be clinically meaningful by the AUDI Operations SME team.
- *Independent data collection* – Ideally all required AUDI attributes will be submitted to the Warehouse by all manufacturers completely and accurately, but there will inevitably be gaps, errors and transmission issues that result in a less than comprehensive file. Consequently, when a manufacturer does not provide some or all AUDI elements, Warehouse staff will contact the manufacturer to address incomplete listings, and staff will consequently need to monitor and

evaluate new FDA device filings. Staff could also undertake independent efforts to populate missing data fields by, *e.g.*, researching available product documentation.

- *Data quality assurance* – In view of the data variability evident in GUDID filings, validation reviews of AUDI data will be required – at a minimum to address non-compliant data entries (alpha data in a numeric field) or reported values outside a normative range. Similarly, effective use of the AUDI data will require that it be presented consistently, both within a category of devices and across categories. Common descriptive attribute vocabularies and well-defined terminology will be necessary for both clinical and research uses, and the standardization of submitted information will be a primary responsibility of the Warehouse.
- *Data delivery and access* – The final obligation of the Warehouse would be to make the compiled and cleaned data available to users electronically. While this function could be accomplished via an API, a web service lookup, or as a deliverable file that could be integrated into an EHR, the envisioned approach will complement and cleanly integrate with AccessGUDID. Critically, if high quality data can be properly collected, none of these options requires more than currently available technology solutions.

The simplified schematic drawing below outlines the information flow envisioned by this proposal: from manufacturers to the Warehouse and from the Warehouse to all interested users. Optimally, the query mechanism would be via AccessGUDID (solid lines). Alternatively, a separate mechanism for access and delivery of AUDI data could be created (dotted lines). While not depicted on the schematic, It is also expected that users will provide feedback, both specific to a device and more generally, to the Warehouse and the AUDI governance organization.

