The Worldwide Melding of Regulatory, Commercial, & Patient Safety Information Needs

Terrie L. Reed, MS
FDA CDRH
Senior Advisor for UDI Adoption
Collect Once - use many times

Consider what is required for secondary data use and integrate those requirements in UDI primary data collection

Provided by courtesy of
Donald T. Mon, PhD
Adapted by T. Reed
IMDRF UDI Guidance

• Showed commitment across jurisdictions and industry to develop a harmonized approach for a Global UDI System
• Published 12/2013
• Role of Industry and Regulators in UDI System
• Set Global foundation for a UDI system
• 19 pages
US FDA UDI Regulation

- 21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830
- Statutory requirement to substantially reduce existing obstacles to the adequate identification of medical devices used in the United States
- Published 9/2013
- Responsibilities of FDA and labeler, issuing agency accreditation, label and database requirements
- 44 pages
ONC Regulation §170.315(a)(14) Implantable Device List Capability to Record UDI by 190+ EHR Vendors

Adopting UDI in Health IT; Role of EHR vendors and Providers

1. Implant with UDI
2. Production Identifier
3. Lot, Serial, Expiration Date, Mfr Date, DIC
4. Device Identifier
5. Record

Description (GMDN or SNOMED)  Company Name  Brand Name  Model  MRI Safe  Labeled as containing latex

UDIconference.com
ONC/CMS: UDI-DI and UDI-PI in US Core Data for Interoperability

- Patient name
- Sex
- Date of birth
- Race
- Ethnicity
- Preferred language
- Problems
- Smoking Status
- Medications
- Medication allergies
- Lab tests
- Lab values/results
- Vital signs (changed from proposed rule)
- Procedures
- Care team members
- Immunizations
- UDI-DI + UDI-PI (implantable devices)
- Assessment and plan of treatment
- Goals
- Health concerns

ONC and CMS commitment to UDI’s inclusion in REAL WORLD DATA
Testing and Implementation

- UDI is on label of high and medium risk devices esp. Implantable/Life Supporting/Life Sustaining
- APIs are available to link to AccessGUDID
- Testing and Implementation identifies barriers
- Need for community conversations and shared best practice
AHRMM Learning UDI Community

- Address issues impacting the implementation and use of UDIs
- Developing a common understanding and approach to UDI adoption within the healthcare setting.
- Establishing a consistent and unbiased platform for collaboration, communication, and education between all healthcare stakeholders
- LUC membership and content is open to all those who are interested in advancing UDI adoption within the healthcare field.
- Seek. Solve. Share.
US FDA
GUDID
updates

Do not delete records in AccessGUDID when de-activated or Unpublished records for the purpose of editing

Add a status to indicate the record states:

- Added (when newly added)
- Edit (record being edited)
- Updated (record has been updated)
- Deleted (record has been deleted)
Ongoing Improvement - Categorization

Categorization fit for purpose - Clinical care

Consistency of assignment

Multiple Nomenclatures

- GMDN
- SNOMED
- CND (CLASSIFICAZIONE NAZIONALE DISPOSITIVI MEDICI)

Additional challenges detailed in AHRMM LUC Device Categorization workgroup paper
<table>
<thead>
<tr>
<th>Added Size Dimensions</th>
<th>How often used (DI records)?*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atherectomy Cutter Diameter</td>
<td>2</td>
</tr>
<tr>
<td>Balloon Diameter</td>
<td>15</td>
</tr>
<tr>
<td>Balloon Length</td>
<td>17</td>
</tr>
<tr>
<td>Balloon Nominal (Inflation) Pressure</td>
<td>12</td>
</tr>
<tr>
<td>Balloon Proximal Outer Diameter (OD)</td>
<td>12</td>
</tr>
<tr>
<td>Balloon Rated Burst Pressure</td>
<td>12</td>
</tr>
<tr>
<td>Catheter Inner Diameter</td>
<td>1</td>
</tr>
<tr>
<td>Catheter Length</td>
<td>39</td>
</tr>
<tr>
<td>Catheter Working Length</td>
<td>15</td>
</tr>
<tr>
<td>Guidewire Diameter</td>
<td>30</td>
</tr>
<tr>
<td>Guidewire Length</td>
<td>16</td>
</tr>
<tr>
<td>Introducer Sheath Compatibility</td>
<td>16</td>
</tr>
<tr>
<td>Shaft Length</td>
<td>31</td>
</tr>
<tr>
<td>Stent Diameter</td>
<td>94</td>
</tr>
<tr>
<td>Stent Length</td>
<td>92</td>
</tr>
</tbody>
</table>

* As of June 5 2019
US FDA Top 10

• Device Identifier (DI)
• Brand Name
• Version/Model
• Catalog Number
• Description

• Size
• MRI Safety
• Latex Information
• DUNS Number/Company Name
• GMDN/FDA Product Code
IMDRF UDI Application Guide

IMDRF/UDI WG/N48 FINAL: 2019
UDI system application guide

IMDRF/UDI WG/N53 FINAL: 2019
UDI data elements across different jurisdictions

IMDRF/UDI WG/N54 FINAL: 2019
Systems requirements related to use of UDI in health care including special use cases

Available to Public as of 5/24/2019
http://imdrf.org/ Documents
Overall
• Build on foundation of UDI Guidance
• Incorporation of learning
• Harmonization total agreement
• Use Cases
• Pictures and Diagrams
• Need for further learning

IMDRF/UDI WG/N48 FINAL: 2019
UDI system application guide

Australia  Brazil  Canada  GMTA
China  EU  Japan  DITTA
Russian Federation  Singapore  South Korea  WHO
US

UDI Regulatory Work  Regulatory Member  Manufacturer Rep  Observer
IMDRF/UDI WG/N48 FINAL: 2019

UDI system application guide – Sections 1-8

1.0 – Scope
2.0 – References – IMDRF, ISO, IA/IE,
3.0 – Definitions – improve clarity on terms not defined in UDI Guidance
4.0 – Fundamental Elements of Harmonized UDI System
5.0 – Guiding principles for UDI system design and operations

“This system is emerging across various regulatory authorities at varying levels of system maturity based on IMDRF/UDI WG/N7Final:2013.”
6.0 – The UDI
6.1 - Content, Structure and representation of a UDI (UDI-DI and UDI-PI)
6.2 - The UDI carrier “may also contain other identifiers not considered part of the UDI”
6.3 - UDI Human Readable Interpretation (HRI) Format, Structure and Content of Each Issuing Agency/Entity; refer to Appendix A
6.4 - Automatic Identification Data Capture (AIDC) representation of UDI – Follow ISO standards; refer to Appendix B/C (RFID)
6.5 - How to place a UDI carrier on the label of the device or on the device itself - avoid Figures of UDI on device, device label and packaging
   6.5.1 - Direct Marking; refer to Appendix F for feasibility issues
6.6 - Considerations on the UDI contents of the Medical Device Label
6.7 - Considerations on AIDC readers
7.0 - Application of UDI to packaging levels

7.1 – Applying UDI to medical device package level hierarchy; refer to Appendix D

7.2 – Unit of Use DI; refer to Appendix E (AHRMM LUC)
8.0 – The Unique Device Identification Database (UDID)

8.1 – Expectations for an effective UDID design
  • 18 Recommendations for regulatory authorities – public, focus on data quality, acknowledge receipt of submission

8.2 – UDID Data Specifications
  • 10 general specifications
  • Point to IMDRF/UDI WG/N53 FINAL: 2019 collects information on UDI data elements as collected in National UDI databases (UDID) across jurisdictions

8.3 – Submission of UDID by third-party submitter – formal process

8.4 – UDI-DI triggers – list and identification of issues with multiple device identifiers
IMDRF/UDI WG/N53 FINAL:2019

UDI data elements across different jurisdictions

Procedural/information Document - identify how common UDID data are collected by the different jurisdictions and identify additional data elements
Update - IMDRF Management Committee will consider processing and publishing updated versions of the Annex
### UDI data elements across different jurisdictions - Annex

<table>
<thead>
<tr>
<th>Data Element #</th>
<th>Data Element</th>
<th>UDDID Requirement</th>
<th>EUDAMED Requirement</th>
<th>Data Element</th>
<th>GUDID Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>UDI-DI (UDI type, e.g. GS1 GTIN, HIBC-LIC, ISBT-128 PPIC)</td>
<td>R</td>
<td>--</td>
<td>UDI-DI</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td>Issuing Entity (UDI-DI)</td>
<td>R</td>
<td>--</td>
<td>Issuing Agency</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td>Issuing Entity (Basic UDI-DI)</td>
<td>R</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>9</td>
<td>Brand Name</td>
<td>C</td>
<td>--</td>
<td>Name or Trade name (name of product)</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td>Device model or version</td>
<td>R</td>
<td>--</td>
<td>Name or, if applicable, device model that identifies the BASIC UDI-DI Group in the technical documentation and/or certificate and declaration of conformity</td>
<td>R</td>
</tr>
<tr>
<td>12</td>
<td>Reference and/or catalogue number</td>
<td>C</td>
<td>--</td>
<td>Reference, article or catalogue number</td>
<td>R</td>
</tr>
<tr>
<td>15</td>
<td>Additional product Description (optional) - Additional clinically relevant information, e.g. radio-opaque</td>
<td>O</td>
<td>--</td>
<td>Additional product Description</td>
<td>O</td>
</tr>
</tbody>
</table>
9.0 - Recording Unique Device Identifiers into forms, databases (other than UDID), registries and other health information

“To take advantage of the structured data embedded in a UDI it is recommended that the UDI be parsed into discrete fields in database entries and forms in order to have the UDI data properly catalogued.”
Systems requirements related to use of UDI in health care including special use cases

General system requirements for recording the UDI - utilize the UDI available at the point of care and transmit the UDI across health systems
• capture the data in the UDI Carrier
• capture all formats of the UDI as established by accredited issuing agencies/entities
• capture and save the UDI, the UDI-DI and all the UDI-PIs in distinct fields.
• use the UDI-DI as a real-time look-up to the appropriate UDID. pull and auto-populate relevant UDID attributes in the UDID record

“UDI benefits are more likely be achieved when the UDI is recorded in real world electronic health systems ...”
IMDRF/UDI WG/N54 FINAL:2019

Systems requirements related to use of UDI in health care
including special use cases

Examples of recording UDI in Healthcare Use cases
• Use Case 1: Recording of UDI in EHR
• Use Case 2: Adverse Event Reporting: US FDA Medical Product Safety Network (MedSun)
• Use Case 3: Medical Device Registry: Society for Vascular Surgery Vascular Quality Initiative (VQI)
a. Scan or manually record UDI found on label of device

b. Use software to parse the UDI into UDI-DI + UDI-PIs, and use the UDI-DI as a key to pull data from AccessGUDID (the publicly available version of U.S. FDA UDID). Use the data in the AccessGUDID record to automatically populate the corresponding field in the MedSun report.

NOTE: MedSun does not display all elements available in an AccessGUDID record. MedSun only extracts the elements from AccessGUDID that are captured in MedSun.
Vascular Quality Initiative

VQI uses the UDI-DI as a means to identify products at the model/company level. A user can enter the initial letters of a product number or catalog number and see the relationship between the product number or catalog number and the UDI-DI as listed below.

The VQI auto-populates data from AccessGUDID into appropriate fields (manufacturer, type, size) by using the UDI-DI to return data from AccessGUDID.
10.0 - Establishing Responsibility for Creating and Maintaining a UDI System
10.1 – Regulatory Authority
10.2 - Manufacturer
   10.2.1 - Own brand or private labelers
10.3 – Issuing Agency/Entity
10.4 – Stakeholders related to UDI
   10.4.1 – Distributors and importers
   10.4.2 – Healthcare providers and retail pharmacies
   10.4.3 – Other stakeholders – reviewers, researchers, professional societies
   10.4.4 – International standards and terminology development organizations – ISO, IEC, AIM, LOINC, SNOMED, HL7, GMDN, CND

IMDRF/UDI WG/N48 FINAL: 2019
UDI system application guide – Sections 10-13
11.0 - General Considerations to facilitate an effective UDI implementation

11.1 – Transitional period: effective implementation period

11.2 – UDI implementation arrangements

- Public forms
- Engagement with trade and healthcare professional associations
- UDI System Conferences
- Help desk
- Guidance documents
- Process to apply for exceptions/alternatives
- UDID education webinars
- UDID user groups
- Learning communities with expert clinical and supply chain groups
UDI system application guide - Sections 10-13

12.0 – Special cases – clarify Section 10 of UDI guidance based upon implementation knowledge gained

12.1 - Implantable Devices – generally not required to have UDI and should be able to be scanned and link to electronic system

12.2 - Reusable devices

12.3 – Non-IVD Kits
   12.3.1 – Placement of UDI carrier on the medical device contents of kits; refer to Appendix G
   12.3.2 – Exemption for non-IVD kits - clarification of original IMDRF Guidance exemption

12.4 – IVD Kits
   12.4.1 – Medical device contents of IVD Kits
   12.4.2 – Placement of UDI on IVD kits; refer to Appendix G

12.5 Configurable medical devices; refer to Appendix H

12.6 Software as a medical device
   12.6.1 - UDI Assignment Criteria
   12.6.2 –UDI Placement Criteria
13.0 - Emerging issues with UDI which are not specifically covered by this Guide.

**What is not covered**—
- Contact lens attributes
- Harmonization of UDI-DI triggers and other multiple UDI-DI use cases
- Use of UDI along supply chain
- SaMD deployment
- Device categorization
- Harmonized value sets (e.g. clinically relevant size dimensions)
- Low unit of measure
- Issues related to data quality management in UDIDs
Don’t judge each day by the harvest you reap, but by the seeds that you plant.
– Robert Louis Stevenson