Simposio Nazionale
Bergamo, Italy | Saturday 6 May 2017

The UDI Experience: From a US Perspective

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Presentation Objectives

- Unique Device Identifier (UDI) Basics – US & MDR
- 5 Stages of a Sustainable UDI Program
- Benefits to Stakeholders
- Implementation in the EU
- UDI Data Element Requirements
- Next Steps – Industry to Hospitals

Intent of UDI

- Provide standard device identification
- Track medical devices from manufacturer to patient
- Support post-market surveillance (PMS) activities
  - Adverse event reporting of specific devices
  - Aggregate reporting of adverse events
- Inclusion of devices in both device and disease-specific registries
- Collection of device information in large population-based data sets

UDI – What Is It?

Method of clearly, distinctly and unambiguously identifying medical devices, components, sets, kits and systems within the healthcare supply & use chains

Unique Device Identification – the Process

- general term for a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard
  - i.e. GS1, HIBCC, ICCBBA
- allows the unambiguous identification of a specific device on the market
- “unique" does not imply serialization of individual production units

Unique Device Identifier – the Tool

- unique numeric or alpha-numeric code that includes:

Device Identifier (UDI-DI)

+ Production Identifier (UDI-PI)

Unique Device Identifier (UDI)

Static Information: Identifies Company & Product

Variable Information: Contains production & control information

UDI – Why Do We Need It?

- Provide more efficiency, accuracy and automation of capturing device information through automation
  - Supply chain
  - Electronic health records
  - Global device registries
- Better visibility of device supply & movement through the supply & distribution chain, use in healthcare organizations, through to the patient
- Improved visibility & management of adverse events, recalls and post-market surveillance

Basic UDI-DI

- primary identifier of a device model
- assigned at the level of the device unit of use
- main key for records in the UDI database to be referenced in certificates and Declarations of Conformity
- associates use of device on a patient to data related to the patient

Device Identifier (UDI-DI)

- Static portion of the UDI
- Included in UDID database & serves as Primary Key for looking up device
- Contains Company & Device Information:
  - *Company*
    - Name & Address
  - *Product*
    - Product Name
    - GMDN Code & Term

Critical for IDENTIFICATION of DEVICE and the DEVICE MANUFACTURER

Production Identifier (UDI-PI)

- Variable portion of the UDI
- NOT included in UDID database
- Contains Dynamic Information Specific to Production:
  - *Lot/Batch/Serial Data*
  - *Expiration Date*
  - *Manufactured Date*

Critical for TRACEABILITY of DEVICE to the PATIENT LEVEL

UDI Carrier | Barcode Format

- means to convey the UDI by using AIDC and, if applicable, its HRI

- may include 1D/linear bar code, 2D/Matrix bar code, RFID, etc.

AIDC + HRI = UDI Carrier

UDI Carrier | Barcode Format
GS1

- (AI) codes = Application Identifiers

- Used to identify different pieces of data
  - (01) = GTIN (Global Trade Identification Number)
  - (10) = Lot/Batch Number
  - (17) = Expiration Date

http://www.idautomation.com/barcode-properties/definitions/gs1-application-identifiers.html

http://www.gs1.org/healthcare/udi

UDI Carrier | Barcode Format
HIBCC

- "+" indicates HIBC barcode structure

- Primary Data Structure includes:
  - LIC = Labeler Identification Code (4 characters)
  - PCN = Product/Catalog Number (1-13 characters)
  - U/M = Unit of Measure Identifier (1 digit)

- Secondary Data Structure may include:
  - Quantity/Date Fields
  - Lot/Batch/Serial Number fields
  - Link Character

http://www.neodynamic.com/Products/Help/BarcodeWPF4.0/barcodes/HibcLic128.htm

http://www.hibcc.org/udi-resources/

Automatic Identification & Data Capture (AIDC)

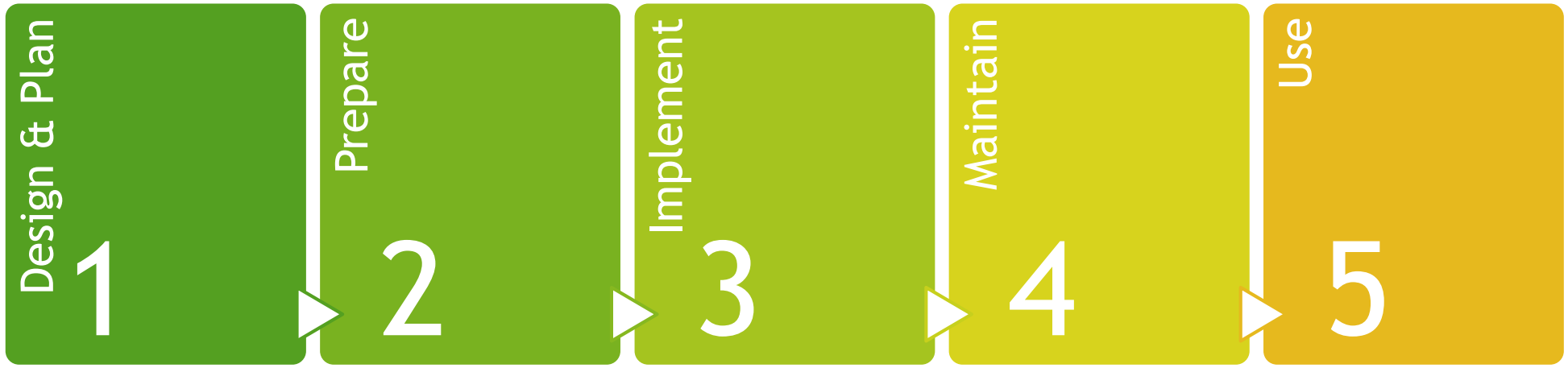
- technology used to automatically capture data
- includes barcodes, smart cards, biometrics and RFID

Human Readable Interpretation (HRI)

- a legible interpretation of the data characters encoded in the UDI Carrier

- HRI format shall follow the rules of the UDI code issuing organization
  - i.e. GS1, HIBCC, ICCBBA

Five Stages of a Sustainable UDI Program



1. Design & Plan – ALL STAKEHOLDERS

Design & Plan

Top Level

- Regulators / Manufacturers / Healthcare Organizations

Flexible

- Allow for growth, change & sustainability

Time Consuming

- Avoid excessive & lengthy delays

Buy-In = Support

- Won't make everyone happy
- Listen to all voices

Lessons Learned

- 2005 – 2013 (Concept to Realization)
- Prolonged process led to doubts and skepticism by manufacturers
- Necessary to involve as many manufacturers & users (healthcare organizations) as possible
- Communicate consistent information
- Solicit feedback
- General enough to apply to all products but still provide clear requirements
  - Not a consensus program like standards organizations

2. Prepare – Government Agencies, Regulators

Prepare

Communication to industry

- Don’t assume everyone has been listening

Enforcement plans

- Accountability
- Consequences of noncompliance
- Auditing
- Customs / Border Control

Highlight benefits

- Include healthcare organizations

Lessons Learned

- Final Rule – 24 Sept 2013
- Class III – 1 year to implement!
- Phased in approach
  - GOOD – prevented overloading FDA system
  - BAD – confusing & difficult to manage
- Many smaller companies still not aware of UDI requirements
- Communication of enforcement plans was/is lacking

US Compliance Date: Sept 24, 20xx

Compliance Year	Labels/Packages Must Have a UDI	Date Formatting (YYYY-MM-DD)	Data Submitted to the GUDID	Direct Marking (DM)
2014 ✓	Class III	Class III	Class III	
2015 ✓	Implantable, life-supporting & life-sustaining devices	Implantable, life-supporting, life-sustaining devices	Implantable, life-supporting, life-sustaining devices	Life-supporting, life-sustaining devices
2016 ✓	**Class II**	**Class II**	**Class II**	Class III
 **2018**	Class I & Non-Classified	Class I & Non-Classified	Class I & Non-Classified	**Class II**
2020				Class I

Examples:
Class III: pacemakers, heart valves, cerebral stimulators
Class II: Infusion pumps, needles, surgical drapes, powered wheelchairs
Class I: general instruments, examination gloves, bandages

3. Implement – Manufacturers, Distributors

Implement

Process versus Project

- Look beyond the requirements

Allow as much time as possible

- Encourage early adoption

Data gathering & cleansing

- Single Source of Truth

Lessons Learned

- Don’t underestimate the time & expense required
- Data gathering – major challenge for manufacturers
  - Make requirements very clear
  - You don’t know your data until you start pulling it together
- Load testing of system
  - Can it support massive volumes of data?
- Prevent bottlenecks
  - Delays in creating accounts
  - Slow response time from Help Desk

4. Maintain – Government Agencies, Regulators, Manufacturers & Distributors

Maintain

Routine review of data

- Coordination between departments

Changes to requirements

- Communication – internal & external

Dedicated resource

- Controls the data
- Restricts the change

Lessons Learned

- Still learning!
- Don’t underestimate the impact of UDI – every department needs to be involved
- Communication is key
- UDI is not implemented and then done – it’s a living process

5. Use – ALL STAKEHOLDERS

Use

Unlimited possibilities

- Internal & external uses

Incentives / Benefits for use

- Compliance - legal
- Financial – reimbursement, discounts, cost savings
- Streamline processes

Requires change

- Workflows, systems, other processes
- Technology

Lessons Learned

- Still learning!
- UDI is not just about patient safety
  - Supply chain efficiencies & security
  - Customs
- Technology is prohibitive and/or not available
  - Electronic health record (EHR) vendors expect to offer software with UDI capture capabilities by 2018
- Centers for Medicare and Medicaid Services (CMS)
  - Want UDI on universal health insurance claims forms
  - Provide for better value-based reimbursement based on device performance
- Improve device evaluation and post-market surveillance

Benefits for All Stakeholders

Regulatory Bodies

- Improved data on product performance
- More accurate Adverse Event reporting
- Increased understanding of device risks & benefits

Manufacturers

- Increased visibility of products throughout supply chain
- Improved purchasing processes
- Identify & prevent counterfeit products

Patient Safety

Healthcare Providers

- Improved inventory management
- Reduction of human errors through transaction automation
- Interconnectivity of data
- Improved device recalls

Consumers/Patients

- Easy access to device information
- Reliable availability of products
- Reduced costs
- Awareness of devices & options

Implementation in the EU

MDR UDI Requirements:

- Article 24
- Annex V, part B & C

UDI in EU expected to closely follow the FDA UDI program

UDI on all levels of packaging for all device classes

Human readable and AIDC

Eudamed database

Hurdles to Harmonization

- Decentralization of Medical Device Regulations in EU vs Centralized in US
- Device Classifications
- Multiple Databases
- Data Attributes
- Agreement on Terms & Concepts
- No Global Mandate

Comparison of Data Element Requirements

33 MDR EUDAMED Data Elements

vs

62 FDA GUDID Data Elements

3 Buckets of Data

- Device Information – 28 possible
- Device Status – 12 possible
- Device Characteristics – 30 possible

Core Elements = the minimum requirements

Device Information

DATA ELEMENT	FDA	EC
Primary DI Issuing Agency	FDA	
Primary DI Number	FDA	EC
Device Count	FDA	
Unit of Use DI Number	FDA	EC
Labeler DUNS number	FDA	
Company Name	FDA	EC
Company Physical Address	FDA	EC
Brand Name	FDA	EC
Version or Model	FDA	EC
Catalog Number	FDA	EC
Device Description	FDA	EC
DI Record Publish Date	FDA	
Commercial Distribution End Date	FDA	
Commercial Distribution Status	FDA	
Device Subject to DM, but Exempt?	FDA	
DM DI Different from Primary DI	FDA	
DM DI Number	FDA	
Secondary DI Issuing Agency	FDA	
Secondary DI Number	FDA	EC
Package DI Number	FDA	
Quantity per Package	FDA	EC
Contains DI Package	FDA	
Package Type	FDA	
Package Discontinue Date	FDA	
Package Status	FDA	
Customer Contact Phone	FDA	
Customer Contact Email	FDA	
Additional Trade Names		EC

Device Information

DATA ELEMENT	FDA	EC
HCT/P?	FDA	
Kit?	FDA	
Combination Product?	FDA	
Device Exempt from Premarket Submission	FDA	
FDA Premarket Submission Number	FDA	
FDA Supplement Number	FDA	
FDA Product Code	FDA	
FDA Product Code Name	FDA	
FDA Listing Number	FDA	
GMDN Code	FDA	**EC**
GMDN Name	FDA	
GMDN Definition	**FDA**	

Device Information

DATA ELEMENT	FDA	EC
For Single Use?	FDA	EC
Lot or Batch Number Control?	FDA	EC
Manufacturing Date Control?	FDA	EC
Serial Number Control?	FDA	EC
Expiration Date Control?	FDA	EC
Donation ID Number Control?	FDA	
Labeled as Containing Natural Rubber?	FDA	EC
Labeled as Not Made with Natural Rubber?	FDA	
Prescription Use (Rx)?	FDA	
Over the Counter (OTC)?	FDA	
What MRI safety information does the labeling contain?	FDA	
Size Type	FDA	EC
Size Value	FDA	EC
Size Unit of Measure	FDA	EC
Size Type Text	FDA	
Storage & Handling Type	FDA	EC
S & H Low Value	FDA	EC
S & H High Value	FDA	EC
S & H Unit of Measure	FDA	EC
Special Storage Conditions	FDA	
Device Packaged as Sterile?	FDA	EC
Requires Sterilization Prior to Use?	FDA	EC
Sterilization Method	FDA	
Authorized Representative's Name		EC
Authorized Rep. Contact Information		EC
SaMD Version		
Restricted Number of Reuses		EC
URL for Additional Information		EC
Labeled as Containing DEHP?		EC
Critical Warnings or Contraindications		EC

Impact of UDI

Improved efficiencies to global trade

Data is now an integral component of a medical device

- Must be considered at all stages of life-cycle

Product cost

- Initial increase?
- Savings over time

Future: eliminates need for part numbers?

Conclusion

No definitive timelines

Resource & labor intensive

- Leads to “wait & see” approach

Plan for change

- Dedicated resource to monitor UDI regulations

Build a sustainable UDI program

Have Questions? Need Help?

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“Quality in Everything”