The Expanding and Evolving Global UDI Imperative

Understanding the Future Nexus of Regulatory, Commercial, & Patient-Safety Information
Workshop Facilitators

- Karen Conway, Vice President, Healthcare Value, GHX
- Jay Crowley, Vice President, UDI Solution and Services, USDM Life Sciences
- Marti Velezis, UDI Practice Lead, USDM Life Sciences
Workshop Overview

- Overview of various regulatory and commercial product data requirements and the drivers behind those demands
- Discuss how the use of UDI data in the future should drive the foundational data management strategies of today
Jay Crowley, Vice President, UDI, USDM Life Sciences

UDI OVERVIEW
Medical Device Sector

The Evolving Global Landscape

Commercial (Market Requirements)
- US IDNs (Kaiser, others)
- US GPOs
- US ONC/EHRs, CMS
- Canadian GPOs
- Abu Dhabi, Cleveland Clinic
- Qatar, Hamad Medical
- Netherlands (implants)
- Hospitals

Postmarket Requirements
- MDIC/NEST
- RWD/RWE
- Case for Quality
- Registries, Sentinel
- EU MDR/IVDR

Country Requirements
(Ministry of Health Others)
- UK NHS
- Taiwan
- Japan MHLW

Regulatory Requirements
- Turkey
- India
- Saudi Arabia
- China
- Singapore
- Health Canada
- Columbia

Traceability Requirements
- EU class III implants
- Turkey
- Saudi Arabia
- Brazil
- Columbia
The Visibility and Control Imperative

**WHO**
Economic Operators and Other Stakeholders
- Is manufacturer/labeler
- Is Notified Body
- Is responsible (AR)
- Is country of origin
- Is reg. contact
- Is prescribing
- Is trained/using

**WHAT**
Global Product Attributes
- GUDID/Eudamed/Others
- Basic UDI-DI
- Classification
- GDSN
- Price
- Commercial
- Is it (device, accessory)
- Parent-child relationships (kits)
- Labeling, pictures, IFUs, implant card

**HOW**
Regulatory and Commercial
- Regulated
- On to market
- Into country
- Performing (PMS)
- Paid (reimbursed)
- Distributed (SC)
- Recalled
- Traceability
- Safety and Performance
The Evolving Device Data Model

- AE Reports
- Complaint Handling
- Clinical Evaluation
- IFU/Labeling/Pictures
- Regulatory Contact
- Own Brand/Private Label
- Contract Manufacturer
- Authorized Representative, Importer, Distributor
- Parent-Child Relationships (e.g., kits)
- Implant Card
- Patients and HC Providers
- Market Authorization
- Risk Class
- GMDN
- Device Attributes (UDIDs)
- Basic UDI-DI
- Registration and Listing
- Country of Origin
- Recalled/Discontinued
- Price

For each country/region
Whereas: (41/38) The *traceability of devices* by means of a Unique Device Identification (UDI) system … should significantly enhance the effectiveness of the *post-market safety-related activities* for devices, which is owing to *improved incident reporting, targeted field safety corrective actions* and *better monitoring* by competent authorities. It should also help to *reduce medical errors* and to *fight against falsified devices*. Use of the UDI system should also *improve purchasing* and *waste disposal policies* and *stock-management* by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.
US UDI Implementation – Lessons Learned

1. Existing regulatory foundation need to be robust (device, label)
2. Data needs to be electronic, computable (not spreadsheets)
3. Need to adhere to MDM practices (owner, change rules)
4. Shared visibility and control (all users/owners engaged)
5. Same data needs to shared internally and externally
6. Reuse SAME data for all needs (regulatory, commercial, pt safety)
7. This is a global initiative – but there are regional differences/needs
8. Information needs to be internally consistent and aligned
9. CONTROL (and limit/understand) change
10. This is only the beginning….
Where is all of this going...?

1. MANY parent-child relationships (actors, kits, accessories)
2. (Global) Track and trace (serialization)
3. Larger influence of payors
4. Focus on patients (home care, telemedicine, other models)
5. (and therefore more focus on) COST effectiveness
6. Capture of all devices used
7. Blurring of lines between regulated products (drugs, devices, biologics)
8. Integration of (non-regulated) “data” (e.g., wearables, apps)
9. MUCH more product data …
10. Devices won’t be distributed, used or reimbursed if data doesn’t align
GLOBAL DATA VARIATIONS
Technical Similarities and Differences

• Examples of similarities and differences based on known patterns
• Link back to data usage – why is data reporting and data usage so important
As UDI Goes Global...

- Managing various business processes
- Handling complex business rules
- Preparing for Global and Regional data elements
- Navigating multiple databases / source of truth systems
- Supporting multiple exchange standards
...A Globally-Focused Solution is needed

- Single platform for UDI services and support
- Streamline and simplify the submission process
- Submit more data to more places globally
- Leverage data commonalities and manage the differences
- Future-proof business process to prepare for global scale
A look at the constants and variants

• Specifically with regulations in US, EU, KSA
• Implementation details are still forthcoming
• Additional authorities coming soon...
The UDID Constants

• Harmonized data elements
• Issuing Agencies (updated last Friday)
  – GS1
  – Health Industry Business Communications Council (HIBCC)
  – International Council for Commonality in Blood Banking Automation (ICCBBA)
  – Informationsstelle für Arzneispezialitäten (IFA) (EU only)
The UDID Variants

• Data attribute variations (i.e., region-specific data elements, MDR versus IVDR)
• Different business rules (e.g., DI triggers, cross attribute validations, etc.)
• Different data types across regions
• Cardinality (required versus optional)
• Variation in value sets and external vocabularies
• Submission format (Exchange message format and/or upload method)
• Data reuse from regulatory databases Cardinality (required versus optional)
Data Attributes

• Basic UDI-DI Construct and its attributes (inherited by UDI-DI)
• Risk Class
• Indicators (e.g. Implantable Device)
• Variation in Safety Elements
• Reuse information
Different Business Rule Types

- Update rules for attributes (i.e., DI Triggers)
- Cross-attribute business rules
- Value provided rather than derived (e.g., status)
- Production level information (e.g., imports and device traceability)
Different Data Types

• One Regulatory Authority versus another
  – A coded value may be a text string (vice versa)
  – A structured data field with multiple parts (type, value, unit of measure) may be a text string
  – Boolean value may be a coded value or text string
Boolean Data

• Implementation Warning – values must be collected for all of these data elements
  – Unknown responses complicate data usage
Cardinality

• One Regulatory Authority versus another
  – Required versus Optional
  – Conditionally required based on device class or type
  – Single value versus Multiple
Variation in Value Sets

- Region-specific codes (for region-specific attributes)
- Different External Vocabularies (e.g., GMDN versus CND)
- Message codes
Submission Formats

- Web-based data entry
- Web-based Upload (e.g. proprietary structure(s))
- Electronic Submissions with different exchange formats (e.g., HL7 SPL, proprietary structure(s))
Data Reuse of regulatory database

• Key Data may be submitted to link to data in separate premarket database (e.g., premarket authorization and/or listing number)

• Company ID may be used to pull name and address from separate regulatory database
How do the variations affect the use of data locally and globally?

• Differences in vocabulary will require additional maintenance to use across regulatory authorities

• Difficulty with queries against text string attributes – i.e., inconsistency in terms/values

• Comparisons in data characteristics
How will data be used given variation?

• Use within regional domains should be more consistent than across those domains
Karen Conway, Vice President, Healthcare Value, GHX

VALUE BEYOND COMPLIANCE
The Growing Demand for YOUR PRODUCT Data

UDI is a primary driver....

...but do not forget about your customers and other regulatory and commercial “requirements”
MUST HAVE IDEA

UDI in the US.
UDI in Europe
UDI in the Rest of the World

Customer Demands from Hospitals, GPOs, Others?

Dutch Implant Registry?
Scan4Safety?
Agreements on the Uniform Coding of Medical Devices (ADC)- Signed on July 21, 2017

- Manufacturers to furnish medical implants with a “UDI” and make the corresponding product data available to the LIR.

- Healthcare institutions are obliged to enter data about the inserted implants into Electronic Health Records and to supply data on their clients’ implants to the LIR.

A Requirement for Hospitals….
But What about Manufacturers?
Lord Carter Report on Acute Trust Productivity and Performance
Published February 2016

NHS eProcurement Strategy
Published May 2014

“ A radical new blueprint for how the NHS buys and funds everything”
Published Sept. 2013

Launched 2016 with £12 million in funding for six demonstration sites
Scan4Safety Moving to NHS X
Suppliers being invited to join a new workspace

Driving forward the digital transformation of health and social care

Who we are
From 1 July, NHSX will bring together teams from the Department of Health and Social Care, NHS England and NHS Improvement.

What we do
We’re here to improve health and social care by giving people the technology they need.
Releasing TIME to CARE by:
The automation and simplification of non clinical tasks, from administration to locating inventory.

Leveraging Global Standards (GS1), Barcodes and Transaction Automation through Certified PEPPOL Access Point to improve operational performance and enable clinicians to spend more time on patient care and reduce errors.
A Closer Look at Leeds and Scan4Safety

Catalogue Management

Our work with GHX and two other demonstrator sites (Plymouth and Salisbury) has given us access to over 130,000 GTINs

Presentation by David Berridge, Deputy Chief Medical Officer and Vascular Surgeon, Leeds NHS Teaching Hospital
Ability to scan at the point of care enables identification of expired inventory

Reducing Waste, Improving Patient Safety

Presentation by David Berridge, Deputy Chief Medical Officer and Vascular Surgeon, Leeds NHS Teaching Hospital
UDI and Device Recalls

“Our preliminary analysis found that firms initiated about 700 recalls per year. However, we found that firms were unable to correct or remove all recalled devices even though subject to the highest risk or Class 1 recalls…”

GAO Healthcare director Marcia Crosse
UDI and Device Recalls

GAO showed that device firms do not remove all unsafe medical devices from the market because:
• The firm cannot locate all customers or devices, or
• Customers cannot locate the devices subject to recall.

In a review of class I recalls, in 53% of the cases – firms were unable to correct or remove all of the faulty devices from the market.
A Closer Look at Leeds and Scan4Safety: Managing Recalls

From Manual Processes... To Automated and Digitized Processes

- 194 books
- 800 records/book
- 155,000 potential records

2 months work checking we had no cases

17,000+ patients / 22,000 implanted items checked in under 30 minutes

Presentation by David Berridge, Deputy Chief Medical Officer and Vascular Surgeon, Leeds NHS Teaching Hospital
Use Case: UDIs and Recalls

“Delays in identifying recalled devices can result in the continued use of those devices on patients and involves an increased risk for patient harm. A device labeled with a UDI can be identified rapidly and with great precision.”

...to more effectively target and manage medical device recalls
• For the third consecutive quarter, more than one million Class I units were recalled during 2019’s Q1

• Average number of Class I units recalled per quarter increased more than 64 percent from 2016 to 2017.

• McKinsey estimates manufacturers can experience as much as a 10% decrease in shares after a major recall, along with damage to the company’s reputation.

Source: Stericycle Expert Solutions
MANUFACTURER RESPONSES: In what areas do you believe use of unique device identifiers will deliver benefits to your company? (Check all that apply)
Value of UDIs to Your Organization

<table>
<thead>
<tr>
<th></th>
<th>Operational Efficiencies</th>
<th>SKU Rationalization/Product Standardization</th>
<th>Better Evidence on Product Performance for Marketing and Sourcing</th>
<th>Earlier Visibility to Adverse Events</th>
<th>Improved Recall Management</th>
<th>Improved Demand Planning and/or Inventory Management</th>
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MANUFACTURER RESPONSES: In which of the following systems or processes has your company incorporated unique device identifiers (UDIs)? (Check all that apply)
MANUFACTURER RESPONSES: In what areas do you believe unique device identifiers (UDIs) will improve your relationship with your healthcare provider customers? (Check all that apply)
Value of UDIs to your Trading Partner Relationships
Challenges and UDI Impact Points

Product Recalls

• Challenges
  • Lack of master data file in Healthcare Organization (HCO) leads to suppliers and multiple HCO staff in many departments looking for recalled product without support in HCO systems. As a result, healthcare product recalls are relatively unsuccessful.

• UDI Impact Points
  • Master data file used to inform hospital ERP and EHR on all devices purchased, held, and used with specific patients.
Product Recalls - Future Process

• UDI Impact Points
  • Use of Clean or Virtual Item Master with ASN gives HCO specific knowledge of all products purchased to exact internal locations.
  • Interoperability of ERP to EHR gives HCO knowledge of all products used with patients.
  • 3rd party recall management organization provides timely recall information that HCO can match to all internal product data.
  • HCO data management for medical devices is responsible to share internally to conduct recall.

Business Case for the UDI
Report at www.ahrmm.org/luc
UDI Adoption – Product Recalls

• Benefits
  • Improves the ability to identify a specific recalled device within inventory management systems.
  • Documentation of device use in EHRs, reimbursement, and other clinical information system allows connection to specific patients.

• Investments
  • Scanning capabilities at device acquisition and point of use/care.
  • Updates to EHRs, clinical information, and inventory management systems to capture device logistics/use.
Product Recalls
Benefits of Future Process

• Savings
  • Labor now used “hunting” for recalled product will decline as recalls will be focused specifically on known purchases to exact locations within an HCO. Savings two days per recall for a typical hospital. (McKinsey, 2012)

• Patient Safety
  • Recalls along supply chain will be successful and recalled products will be unavailable to purchase and removed from all inventories.
  • Recalls found in EHR allow HCO patient communication to patient record as necessary.
Recalled Product(s): See full list below
• Manufacturing Dates: March 1, 2017 to March 31, 2019
• Distribution Dates: March 1, 2017 to March 31, 2019
• Devices Recalled in the U.S.: 24,587
• Date Initiated by Firm: April 8, 2019
Recalled Product
• SOLOPATH® Balloon Expandable TransFemoral System and Re-Collapsible Balloon Access System
• All model and lot numbers are affected. (See full list of affected devices in Terumo recall noticeExternal Link Disclaimer.)
• Manufacturing Dates: June 22, 2016 to January 30, 2019
• Distribution Dates: July 22, 2016 to March 13, 2019
• Devices Recalled in the U.S.: 3,474
• Date Initiated by Firm: April 26, 2019

Full List of Affected Devices

<table>
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<tr>
<th>Product Name</th>
<th>SOLOPATH® Balloon Expandable TransFemoral System</th>
<th>SOLOPATH® Re-Collapsible Balloon Access System</th>
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<td>STFI-2135</td>
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Lot Numbers: All lots within expiry

All lots within expiry
Recall data today and in the future with UDI

• Data from Regulator or Manufacturer
• Identify location of medical device supply
• Hospital/Provider receives notification and determines necessary action
What Recall Data is Available?

- Manufacturer
- Product or Affected Product(s) by Name/Description*
- Model or Catalog Number
- Reason
- Actions/Instructions ‡
- Lot Expiration Range
- Serial Number (if available, or contact MFR)
- Premarket Info (e.g., Authorization Number, Product Code) ‡
- Quantity in Distribution‡
- Distribution Locations‡

* May include model or catalog number
‡ Region-specific
Data Across Systems (FDA)

**FDA Recall Data**
- **Product:** Device A, xx mm diameter, Model AAAXXA
- **Procode:** XXW
- **Exp. Date Range:** February 2023 - March 2024

**GUDID Data**
- **Name:** N/A
- **Description:** Device A, YY adjustable
- **Model:** AAAXXA
- **Procode:** YYW
- **UDI-DI:** 12345678901234

**Premarket Database**
- KYY1234, KYY9999 (also listed in Recall)
- **Procode:** XXW
- **Device Name:** Device A

Anonymized Data (from actual recall)
Data Across Systems (HC)

HC Recall Data

- Affected Product(s): Device A
- Model: AAAXXA
- Serial Number: Greater than 100, Contact MFR

UDID Data

- Not available

Active Licence Search by Device A Name (listed in recall)

- Licence No.: NNNN
- Device Name: Device A

Anonymized Data (from actual recall)
What Data is sent in Notification?

• Actions/Instructions to providers regarding the medical device
• Identifying information (e.g., manufacturer, name/description of medical device, model or catalog number)
• Others?
Focus on moving to UDI-DI as the key

• Using the UDI-DI allows for more accurate data and identification of the medical devices in the supply chain and/or implanted/used on patients
• Queries on various data sources to locate medical devices:
  – Catalog/Inventory data
  – Electronic health records, patient records, claims data
Discussion

• Questions/Comments/Wrap-up