Keys to Success: Systems and Programs to Manage Complex Master Data Management

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Terrie Reed – US Food and Drug Administration
Dennis Black – Becton, Dickinson and Company
Grant Hodgkins – USDM Life Sciences
Terrie Reed
Senior Advisor for UDI Adoption
US Food and Drug Administration

- Leads FDA UDI adoption efforts by coordinating with FDA UDI program staff, UDI data submitters and data users through multi-stakeholder initiatives, early adoption efforts and demonstration projects focused on improving and harmonizing data standards to support device evaluation efforts across the total product lifecycle.

- Prior to working in academia and government, she worked for 13 years at a healthcare facility in Indianapolis in various positions as a process engineer, IT System analyst, quality analyst, and medical informatics specialist.
Introductions

Dennis Black
Director, e-Business, Solutions Group
Becton, Dickinson and Company

- Over 25 years of experience within the medical device industry in a variety of different roles. Currently in the BD Solutions Group developing and implementing solutions for supply chain processes, implementation of data standards, and other collaborative solutions.

- Active in implementing FDA’s Unique Device Identification (UDI) regulation within BD and collaborating with leading healthcare systems on UDI implementation processes.

- Serves on the GS1 Healthcare Global Leadership Team, and participates in many industry work groups including AHRMM, SMI, and AdvaMed.
Introductions

Grant Hodgkins  
VP Commercial Services and Solutions  
USDM Life Sciences

• Three decades of Pharmaceutical and Medical Device manufacturing experience including Track and Trace, Medical Device UDI, GS1 standards adoption, ERP, MES, Master Data Management, and other enterprise solutions.

• Drove UDI and Master Data Management initiatives for over 75 engagements during tenure at USDM.

• Active in several industry initiatives including the GS1 Healthcare Leadership Team and GS1 Data Excellence Board.
What You Should Takeaway from this Session

- Understand industry challenges for high-quality data to feed Global UDI initiatives
- “Business as Usual”, spreadsheets, and manual labor no longer good enough
- MDM strategies and tools are needed, sooner rather than later
- Here’s what an ‘MDM Strategy’ looks like
- And, here’s what you need to do, starting now
Agenda / Topics

• Current state of FDA GUDID adoption and lessons learned
• What would we have done if we had a crystal ball? What gaps have we identified?
• Compare and contrast FDA and EU EUDAMED data requirements
• What we would like to know about EUDAMED requirements
• What should device manufacturers do differently to meet Global UDI data needs?
• What should device manufacturers do right now?
• Question and Answer period
State of UDI Adoption in US
Lessons Learned
Key Messages and Desired Outcomes

• **Regulators** are committed to coordinating the implementation of UDI as a global standard that adequately identifies a device through distribution and use across the global supply chain, not just within their own regulatory jurisdiction.

• **Manufacturers** are able to create a UDI implementation program based upon master data principles that allow for the ongoing improvement of UDI and data attributes to better meet the requirements of the device ecosystem.

• **Users** have sufficient confidence in the accuracy and completeness of the data to be willing to incorporate UDI into their own IT systems – item masters, EHRs, claims and device registries.
<table>
<thead>
<tr>
<th>GUDID Data Element(s)</th>
<th>Data Quality Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary DI, Package DI Number</td>
<td>DI construct does not follow the issuing agency’s specifications such as wrong check digit</td>
</tr>
<tr>
<td>GMDN Code/Term</td>
<td>GMDN code not consistent with other information on record; codes not available</td>
</tr>
<tr>
<td>Product Code</td>
<td>Product Code does not match with Premarket data set</td>
</tr>
<tr>
<td>Brand Name</td>
<td>DI record Brand Name completely different than names provided in premarket application or Registration and Listing)</td>
</tr>
<tr>
<td>Version or Model Number</td>
<td>Many DI records with the same data values including same Version and Model, but different DI’s</td>
</tr>
<tr>
<td>Size Value</td>
<td>contains an erroneous and/or is missing a Size Value in structured way</td>
</tr>
<tr>
<td>Description</td>
<td>No description given or inconsistent</td>
</tr>
<tr>
<td>Catalog Number</td>
<td>No catalog or order number; reduces match rate to current item masters</td>
</tr>
</tbody>
</table>
What we’ve learned so far

Increase trust in UDI as standard identifier

• Focus on downstream data use – clinical, researchers, patients
• Set expectation of continuous improvement and going beyond compliance
• Offer public access to GUDID database in multiple usable forms
What we’ve learned so far

- Partner with supply chain and clinical community to set up Learning UDI Community framework for shared best practices
- Align across government agencies to establish harmonized and standards-based implementation
- Rely on early adopters and demonstration projects for harmonization, ROI analysis, and incorporation into real world data sources

Increase trust in UDI as standard identifier
Share Learning: UDI as a Global Standard

- ISO/IEC - HL7- GMDN – SNOMED – Issuing Agencies
- Scan4Safety - UK National Heath System

EU Final Regulation April 2017
- UDI assignment and submission of UDI core data elements to EUDAMED
- Linking of DI information across jurisdictions

**Funded:** Government of Canada, Networks of Centers of Excellence

**Hosted:** University of Windsor Odette School of Business

**Participation:** Representations from Canada, Australia, Netherlands, UK, US

Adopt and scale best practices in healthcare supply chain

**New Work Item:**
UDI Harmonized Unique Device Identification (UDI) Application Guide
UDI Adoption: Basis of Learning
UDI in U.S. Real World Data

Demonstrations and Early Adoption

• 18 Major EHRs – Cerner, Epic, McKesson, Allscripts
  – 100+ hospitals implementing on their own
• 450+ members of Association for Healthcare Resource & Materials Management (AHRMM) Learning UDI Community
• VA Implant Tracking and IHE Patient Care Devices
• CDC/FDA/ASPE Study
• Demonstration Projects in 5+ device areas – Cardiovascular, Gastrointestinal, Prostate, Peripheral Artery, Women’s Health Technology
• 1 Registry includes UDI (Vascular Quality Initiative) as core data
<table>
<thead>
<tr>
<th>Vendor</th>
<th>Software</th>
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<th>Software</th>
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<tr>
<td>Allscripts</td>
<td>Allscripts Professional EHR</td>
<td>Netsmart Technologies</td>
<td>myAvatar Certified Edition</td>
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<td></td>
<td>Allscripts TouchWorks EHR</td>
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<td></td>
<td>Sunrise Acute Care</td>
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<td>Sunrise Ambulatory Care</td>
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<td>NextGen Healthcare</td>
<td>NextGen Ambulatory EHR</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>EpicCare Ambulatory EHR Suite</td>
<td>McKesson</td>
<td>Paragon® for Hospitals 2015 Certified EHR</td>
</tr>
<tr>
<td></td>
<td>EpicCare Inpatient EHR Suite</td>
<td></td>
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<tr>
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<td></td>
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<td>SRS-Health</td>
<td>SRS EHR</td>
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<td>Centricity Practice Solution</td>
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<td>SuccessEHS</td>
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<td>MEDHOST Enterprise Clinicals</td>
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<td>Medical Transcription</td>
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<td>Billing Corporation</td>
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<td>Thrive EHR</td>
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<td></td>
<td>Thrive Provider EHR</td>
</tr>
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<td>Bizmatics Inc</td>
<td>PrognoCIS</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>Practice Fusion EHR</td>
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# Early Adopters

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**Information Systems:** Meaningful Use

**Materials Management:** Improved Recall Management
Gaps Identified from US
What Would We Do Differently?
Gaps and What We Wish We Had Known

• Focus was (necessarily) on US regulatory requirements; global needs were low priority
• Over-reliance on non-scalable UDI / GUDID solutions (e.g., spreadsheets)
• Under-estimating the effort to cleanse GUDID data (and gather missing data)
• Insufficient focus on Data Quality – ensuring the data for GUDID is accurate, complete, and meets the needs of intended users (not just FDA)
• Result – for many items, data quality does not meet intended use for end-users (clinicians)
• Going forward: formal, robust data modeling and architecture needed…
What Do We Know about EUDAMED Requirements?
<table>
<thead>
<tr>
<th>EU Common Attributes</th>
<th>US Common Attributes</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDI-DI</td>
<td>Primary DI number (and issuing agency)</td>
</tr>
<tr>
<td>Name and address of the manufacturer (as on the label)</td>
<td>Labeler company name and physical address (as represented by labeler DUNS)</td>
</tr>
<tr>
<td><strong>Name or trade name (if labeled)</strong></td>
<td>Brand name</td>
</tr>
<tr>
<td>Device model, reference, or catalogue number (optional)</td>
<td>Version or Model</td>
</tr>
<tr>
<td>Additional product description (optional)</td>
<td>Catalog number (optional)</td>
</tr>
<tr>
<td>Clinical size – volume, length, gauge, diameter (if labeled)</td>
<td>Clinically relevant size</td>
</tr>
<tr>
<td>Manner in which production of the device is controlled</td>
<td>Production identifier(s)</td>
</tr>
<tr>
<td>Labeled as a single-use device (y/n)</td>
<td>For single-use (y/n)</td>
</tr>
<tr>
<td>Device labeled sterile (y/n)</td>
<td>Device packaged as sterile (y/n)</td>
</tr>
<tr>
<td>Need for sterilisation before use (y/n)</td>
<td>Requires sterilization prior to use (y/n)</td>
</tr>
<tr>
<td>Containing latex (y/n)</td>
<td>Device labeled as containing natural rubber latex or dry natural rubber (y/n)</td>
</tr>
<tr>
<td><strong>Storage and/or handling conditions – as indicated on the label or in the instructions for use</strong></td>
<td>Storage and handling</td>
</tr>
<tr>
<td>Quantity per package configuration</td>
<td>Device Count (for primary DI)</td>
</tr>
<tr>
<td>The unit of use UDI-DI</td>
<td>Unit of use DI number</td>
</tr>
<tr>
<td>Status of the device (on the market, no longer on the market)</td>
<td>DI record publish date</td>
</tr>
<tr>
<td></td>
<td>Commercial distribution end date</td>
</tr>
<tr>
<td>EU-Specific Attributes</td>
<td>US-Specific Attributes</td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>The Basic UDI-DI</td>
<td>Labeler DUNS Number</td>
</tr>
<tr>
<td>The Single Registration Number (SRN)</td>
<td>Device subject to direct marking (DM), but exempt</td>
</tr>
<tr>
<td>Name and address of the Authorised Representative</td>
<td>DM DI different from primary DI (and DM DI number)</td>
</tr>
<tr>
<td>Additional trade names of the device</td>
<td>Secondary DI Number (and Issuing Agency)</td>
</tr>
<tr>
<td>Risk class of the device</td>
<td>Customer Contact – phone and email</td>
</tr>
<tr>
<td>The medical device nomenclature code</td>
<td>Device is also a HCT/P, kit and/or combination product</td>
</tr>
<tr>
<td>Maximum number of reuses</td>
<td>Premarket submission number</td>
</tr>
<tr>
<td>Information labelled in accordance with Section 10.4.5 of</td>
<td>FDA product code</td>
</tr>
<tr>
<td>Annex I</td>
<td>FDA listing number</td>
</tr>
<tr>
<td>URL for additional information</td>
<td>GMDN code</td>
</tr>
<tr>
<td>Critical warnings or contra-indications</td>
<td></td>
</tr>
<tr>
<td>Status – recalled, field safety corrective action initiated</td>
<td>Device labeled as &quot;Not made with natural rubber latex&quot;</td>
</tr>
<tr>
<td></td>
<td>Prescription use (Rx) and/or Over the Counter (OTC)</td>
</tr>
<tr>
<td></td>
<td>MRI safety status</td>
</tr>
<tr>
<td></td>
<td>Special storage conditions</td>
</tr>
<tr>
<td></td>
<td>Sterilization method</td>
</tr>
<tr>
<td></td>
<td>Package type</td>
</tr>
</tbody>
</table>
What We Would Like to Know about EUDAMED…

- Complete data definitions for every attribute – just received 2 weeks ago!
- Multi-language requirements – 26 different descriptions? What other attributes might be subject to multiple languages? How will this all work exactly?
- How exactly will data be uploaded to EUDAMED?
- When will the system be available for modeling, testing and education?
- When will pilots or other joint regulator/industry deeper-dives happen?
What Do Device Manufacturers Need to Do Differently to Meet Global UDI?
The Challenge – Growing UDI Requirements…

- EU MDR and IVDR regulations – approved and in-force (starting 26-May-2017)
- Several additional countries in progress
- Every new regulation introduces additional complexities:
  - New attributes (additional to GUDID)
  - Local language translations of existing attributes (e.g., Description)
  - Conversions of attributes (e.g., imperial to metric, True/False to Y/N)
  - Different mechanisms to upload UDI data to government databases
- UDI is no longer a project, it is a PROGRAM
- MDM (Master Data Management) is a key enabler to address this complexity
The Evolving UDI Landscape

**Extending UDI in US to**
--IDNs (hospitals)
--GPOs
--ONC/EHRs, CMS

**EU Requirements**
- Re-registrations
- Re-classifications
- BUDI-DI
- EUDAMED
- Implant Cards
- Traceability

“Commercial” or (Ministry of) Health/Cost/Import Control Requirements

China – any day...?
2018-2020 – Saudi Arabia
2018-2020 – Taiwan
2019-2022 – South Korea
2022+ - India
Canada – “IMDRF”? Singapore – coming...
What Is Needed to Succeed

• Deep understanding of the specifics of the regulations and how they affect you

• Re-assess current UDI program vs. new requirements and Gaps from US experience

• One Source of Truth to house and easily share your key attribute data
  • Highly-flexible data models, workflows, uploads to government databases
  • Scalable solutions with fast deployment, validation, and startup
  • Foundation to provide high-quality, meaningful data

• Meet requirements while maximizing business operations and reducing costs

• Your Destination: A UDI ‘Capability’, not perpetual UDI projects
What is Master Data Management, Anyway?
The Digital Representation of the Physical World…
Navigating the Alphabet Soup of MDM, PIM, PLM, PDM…

- **Master Data Management (as a discipline)**
  - Processes to define, collect, manage, share master data
  - Goal: Single Source of Truth or ‘Golden Record’ – shareable

- **PLM – Product Lifecycle Management**
  - Manage product development lifecycle process and assets
  - BOM’s, versioning, CAD, approvals, hand-off to Commercial
  - Examples: PTC Windchill, Oracle Agile, Siemens Teamcenter

- **PIM – Product Information Management**
  - Master data in Commercial operations to market, sell, support
  - Unlimited attribution to feed ERP, customers, catalogs, etc.
  - Examples: Oracle PDH, SAP MDM/MDG, Stibo, Innovit

Focus:
- **Engineering / Product Development**
- **Commercial / Post-Market Operations**
Single Source of Truth Model

- Global UDI
- Internal Ops
- Customer Requirements
- US UDI

Common Attributes
### Example – Data Model Considerations

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>UOM</th>
<th>Description (EN)</th>
<th>Description (FR)</th>
<th>Description (ES)</th>
<th>US S10K</th>
<th>EU SRN</th>
<th>EU BUDI-DI</th>
<th>US Rx</th>
<th>EU Max Re-Uses</th>
<th>US Device Class</th>
<th>EU Risk Class</th>
<th>US Name &amp; Address</th>
<th>EU Name &amp; Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>1006</td>
<td>FA</td>
<td>Cannula 15mm</td>
<td>Canule 15mm</td>
<td>Aguja 15mm</td>
<td>K10000</td>
<td>19054-934</td>
<td>0123456000009</td>
<td>Rx</td>
<td>25</td>
<td>II</td>
<td>Eb</td>
<td>MedDev Partners 2000 Main Street Anytown, MM 99001</td>
<td>MedDev Group Inc. 1402 Production Way Smalltown, YY 00089</td>
</tr>
<tr>
<td>1006</td>
<td>BX</td>
<td>Cannula 15mm</td>
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- One product may have multiple entries (by packaging level)
- Name and Address may differ – based on differing requirements
- Registration numbers will differ – across jurisdictions
- Descriptions may differ – 26 approved EU languages – only 3 modeled here
- Some attributes only for US (US Rx), some only for EU (EU Max Re-Uses)
The Holy Grail of MDM – The ‘Barney’ Solution

MDM Solution
- Consolidation / Review / Approval
- Master Data Repository
- Translator / Integrator

Operations
- ERP
- WMS
- Finance
- Others

BI / Data Warehouse / Decision Support / Reporting

Trusted Data Sources
- GUDID
- GDSN
- Others

Internal Data Sources
- R&D
- Mfg / Supply Chain
- Supplier Feeds
- Other Sources

Purple Power!
What Do Device Manufacturers Need to Do NOW?
## Choose an MDM Strategy

### Integrated
- Extend Pre-Market PLM → Commercial Ops
- PLM = Single Source of Truth
- Benefit – one platform
- Tradeoff – not optimized for Commercial and UDI

### Best of Breed
- PLM for Pre-Market
- PIM for Commercial
- PIM = Single Source of Truth
- Benefit – Optimized for Commercial and UDI
- Tradeoff – complexity and interfaces

### Hybrid
- 2 or more systems share UDI data (ERP, PLM, others)
- Designate one = Single Source of Truth
- Benefit – leverage existing solutions
- Tradeoff – scalability, lack of functionality

### Data Mart / BI
- UDI Data consolidated into one 'Slave' repository
- Data Mart = Single Source of Truth
- Benefit – easier and cheaper to deploy
- Tradeoff – functionality, integrations
How to Get Started

We suggest a structured approach such as:

**Strategy Workshop(s) / Roadmap(s)**
- Strategy and direction
- Gap Analysis
- Roadmaps
- Solution Stacks
- High-Level Budget
- Project Planning
- Vendor Selection
- Validation Planning

**Requirements**
- Workshops
- Business and Technical Requirements

**Design / Build**
- Design
- Process Re-Engineering
- Build
- Test

**Validate / Deploy**
- Validation
- Data Migration
- Training
- Startup and Cutover
- Go-Live
- Hypercare

**Improve**
- Metrics
- Operational Reviews
- Improvements List
- Launch
- Improvements
Why Now?

• Current UDI compliance programs were (necessarily) quickly enacted to meet aggressive FDA timelines

• Data Quality in GUDID is proving to be more challenging than anyone expected – we must all get better quickly before the next wave of regulations

• For EU and other countries, we have (a little) time to re-evaluate, optimize, and convert UDI initiatives into sustainable, operational capabilities – and that meet user’s needs
Takeaways from this Session

• Understand industry challenges for high-quality data to feed Global UDI initiatives
• “Business as Usual”, spreadsheets, and manual labor no longer good enough
• MDM strategies and tools are needed, sooner rather than later
• Here’s what an ‘MDM Strategy’ looks like
• And, here’s what you need to do, starting now
Summary

• Upcoming Global UDI initiatives present significant challenges to data modeling and therefore data quality
  • Product Master Data is one of the most serious challenges
• A robust, scalable strategy and supporting systems are needed to cope with this complexity
• Keeping the needs of the ultimate end-users is of utmost importance
• The window of time for re-evaluation is quickly closing and should not be missed (once in a career opportunity)
GREAT QUESTION!
Where to Learn More

• Gartner “Magic Quadrant” reports
• Forrester WAVE Reports
• DAMA – Data Management Association – www.dama.org
• The Data Governance Institute – www.datagovernance.com
• Master Data Management Maturity Assessment - Katharina Pietzka, Univerity of Utrecht, 19-Aug-2012, Master’s Thesis (good for basic understanding of key issues)
• Multiple sources for Master Data Management Maturity Models – good overview of some at https://www.slideshare.net/alanmcsweeney/review-of-data-management-maturity-models
• LinkedIn – Master Data Management group
THANK YOU for your ATTENTION!
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