UDI and Meaningful Use – Are you ready for January 2018?

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AGENDA

- What is the UDI?
- UDI and Meaningful Use Stage 3
- UDI Update
- Benefits of the UDI
- What is the Learning UDI Community (LUC)
- Recent Workshop Breakout Sessions
- Key Take-aways

What is the UDI?

Risk-based Compliance Deadlines

- September 24, 2014 - Class III devices (implants)
- September 24, 2015 - "…*devices that are implantable, life-saving, and life sustaining" (DPM for required devices in this category))*
- September 24, 2016 – Class II devices *(DPM for Class III)*
- September 24, 2018 – non-exempt Class I devices, unclassified *(DPM for Class II if required)*
- September 24, 2020 – *(DPM for Class I and unclassified, if required)*

The Need for UDI

Business Name	Item Number Type	Item Number
BD	Mfg Catalog Number	329461
BD	GTIN	00382903294619
Cardinal Health	PV Order Number	BF329461
Owens & Minor	PV Order Number	0722329461
American Medical Depot	Vendor Catalog Number	777127217
Government Sci Source	Vendor Catalog Number	FSC1482679CS
Alliance Joint Venture	Vendor Catalog Number	888021932
Thomas Scientific	Vendor Catalog Number	8938M25
VWR International	Vendor Catalog Number	BD329461

Only UDI compliant code on list

UDI = Unique Device Identifier

- Device Identifier(**DI**) + Production Identifier(s)(**PI**)
- **DI**= mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device
  - Issued by FDA-accredited Issuing Agencies
- **PI**= a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
  - Lot or batch number
  - Serial number
  - Expiration date
  - Manufacturing date

UDI and Meaningful Use Stage 3

Meaningful Use Stage 3 and UDI- Expanded Common Clinical Data Set

- Meaningful Use Stage 3 takes affect January 2018
- Providers will be required to submit information to the Electronic Health Record
- How will this information be captured?

Meaningful Use Stage 3 and UDI- Expanded Common Clinical Data Set

Common Clinical Data Set Definition- The "Common Clinical Data Set" would replace the "Common MU Dataset" including:

Patient Name
Date of Birth
Ethnicity
Smoking Status
Medications
Laboratory Test(s)
Vital Signs
Procedures
Immunizations
Health Concerns
Sex
Race
Preferred Language
Problems
Medication Allergies
Laboratory Value(s) / Results (s)
Care Plan Field(s) including goals and instructions
Care Team Member(s)
Device(s) Assessment and Plan of Treatment

Unique Device Identifier(s) for a Patient's Implantable

What are the patient safety challenges?

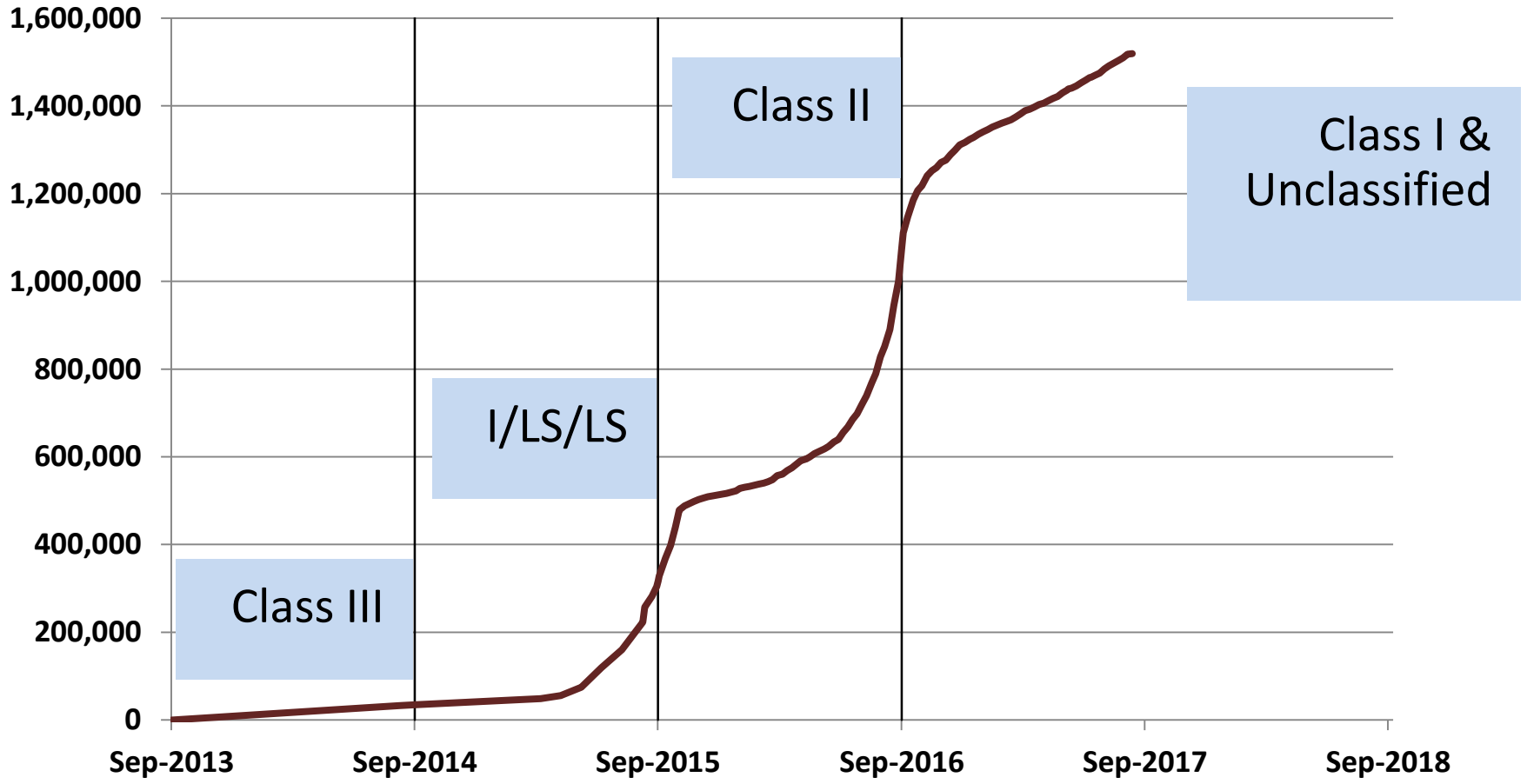
- Medical error is 3rd leading cause of death in US
- Life changing
- Preventable
- Reactive
- Little improvement in 10 years of focus

Where supply chain works well

UDI Update

GUDID Records and Submission Compliance Deadlines

Data Current as of September 5, 2017



24 Companies Have Submitted 10,000+ Records to GUDID

Data Current as of September 1, 2017

- Cardinal Health, Inc.
- Biomet, Inc.
- Medtronic, Inc.
- Stryker Corporation
- Smith & Nephew, Inc.
- Medline Industries, Inc.
- Zimmer, Inc.
- Smiths Medical MD, Inc.
- Synthes GmbH
- Globus Medical, Inc.
- Dentsply International Inc.
- Owens & Minor Distribution, Inc.
- Bauerfeind AG
- Nuvasive, Inc.
- Aesculap, Inc.
- Integra Lifesciences Corporation
- L&K Biomed Co., Ltd.
- Medos International Sàrl
- Covidien LP
- Microport Orthopedics Inc.
- Seaspine Orthopedics Corporation
- BSN Medical GmbH
- K2M, Inc.
- Boston Scientific Corporation

What is the Learning UDI Community (LUC)

The Learning UDI Community

What is the Mission of the Learning UDI Community?

The Learning UDI Community was established to develop a common understanding and approach to UDI adoption within the healthcare setting

Work Groups in Action

Active:

- Bar Code Logistics
- Business Case for the UDI (Adoption, Education)
- Device Categorization
- High Risk Implants (Adoption)
- Low Unit of Measure (Compliance)
- *Human Cell Tissue Products (Education/ Data Quality)*

Multiple Device Identifiers

Completed:

- *Catalog Number field in the GUDID (Data Quality)*
- *Clinically Relevant Size (Data Quality)*
- UDI Capture (Adoption)
- *Unit of Use (Data Quality)*

Pending:

- UDI 101

Key Takeaways

- UDI Supports
  - Improved patient outcomes
  - Improved Device Quality
  - Visibility across the ecosystem
  - New and innovative evidence-based models
  - Focus on outcomes
- Begins with Meaningful Use 3
- To come: Medicare will require information for reimbursement, so will other payers

Thank you for attending.

Please direct questions to

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