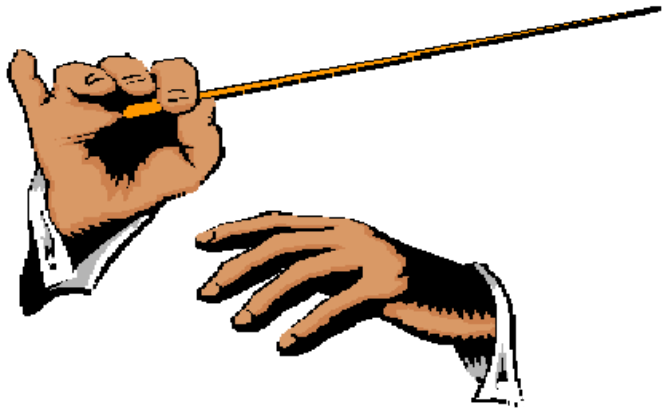
The Global Language of Business

UDI in the US

Ms. Terrie Reed, Senior Advisor for UDI Adoption
U.S. Food and Drug Administration

19 October 2017



U.S. FOOD & DRUG ADMINISTRATION

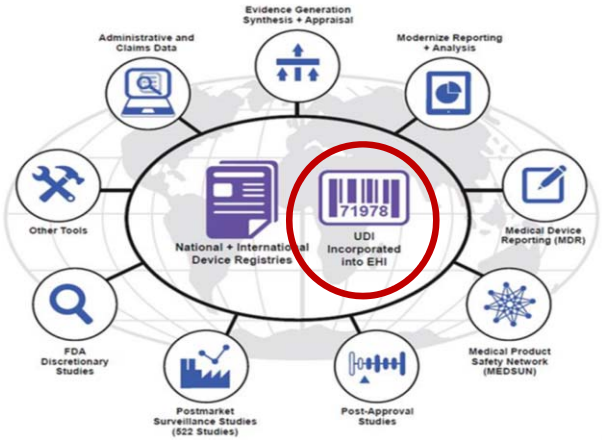
UDI: Regulatory Update

Terrie L. Reed, MS. Ind. Engineering
Center for Devices and Radiological Health
Senior Advisor for UDI Adoption

Core Strategy: Leverage Real-World Evidence

National Evaluation System for health Technology (NEST)

- Real World Evidence Final Guidance
- Medical Device Innovation Consortium NEST Coordinating Center



Data sources:

- Registries
- Medical Claims
- Electronic Health Records (EHR)
- Others

Work collaboratively with:

- Patients/consumers
- Professional societies and Registries
- Academia
- Payers/Health care industry
- Device industry

The Value Proposition for NEST

Patients / Clinicians

- More timely access to safer, more effective devices
- Better information about the use of a given device in practice

Hospitals, Health Systems

- Improved quality
- Reliable assurances of safety
- Possibly, reduced reporting requirements

Payers

- Access to high-quality evidence on device performance in clinical practice

Medical Device Industry

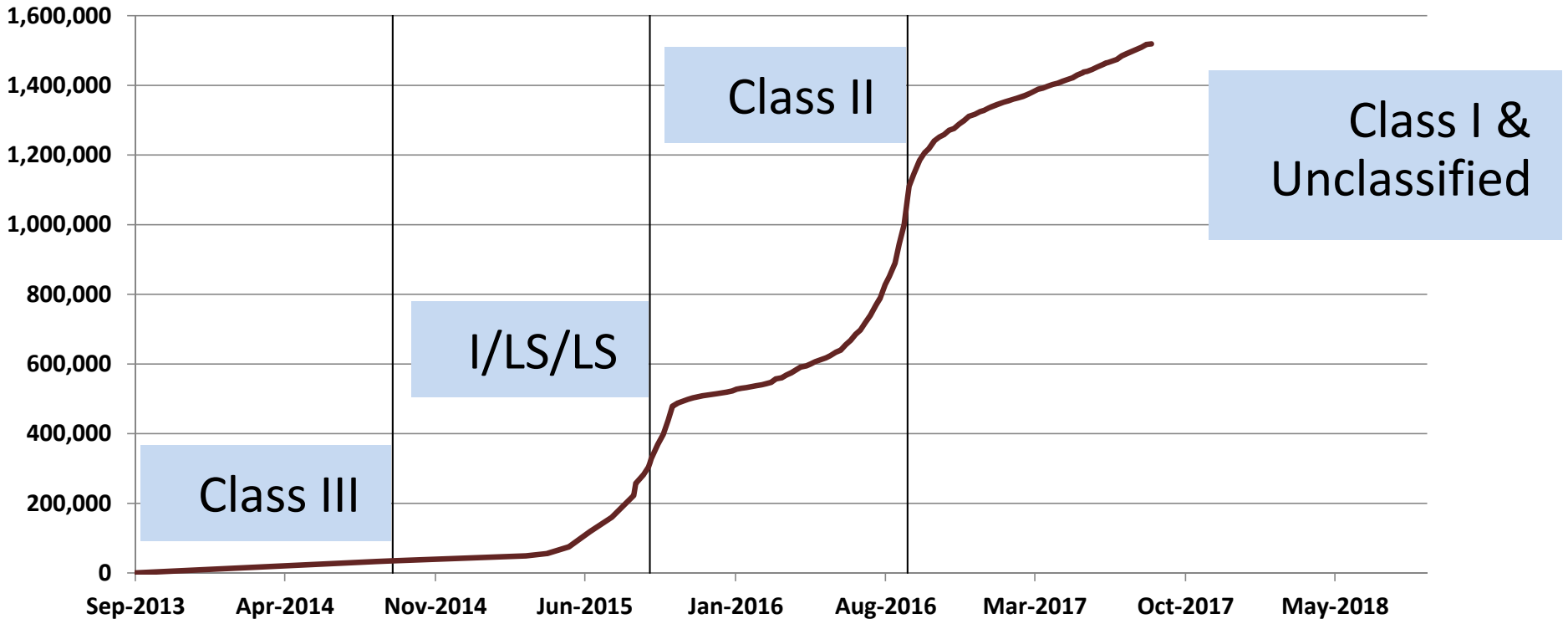
- High-quality evidence at lower cost, in less time, to support premarket approval/clearance, payer coverage
- Meet or reduce the need for postmarket study and adverse event reporting requirements
- Potential for premarket-postmarket shift owing to strong assurances that postmarket RWE would be generated
- May obviate the need for FDA premarket review of some device modifications because more timely and informative routine data collection

UDI

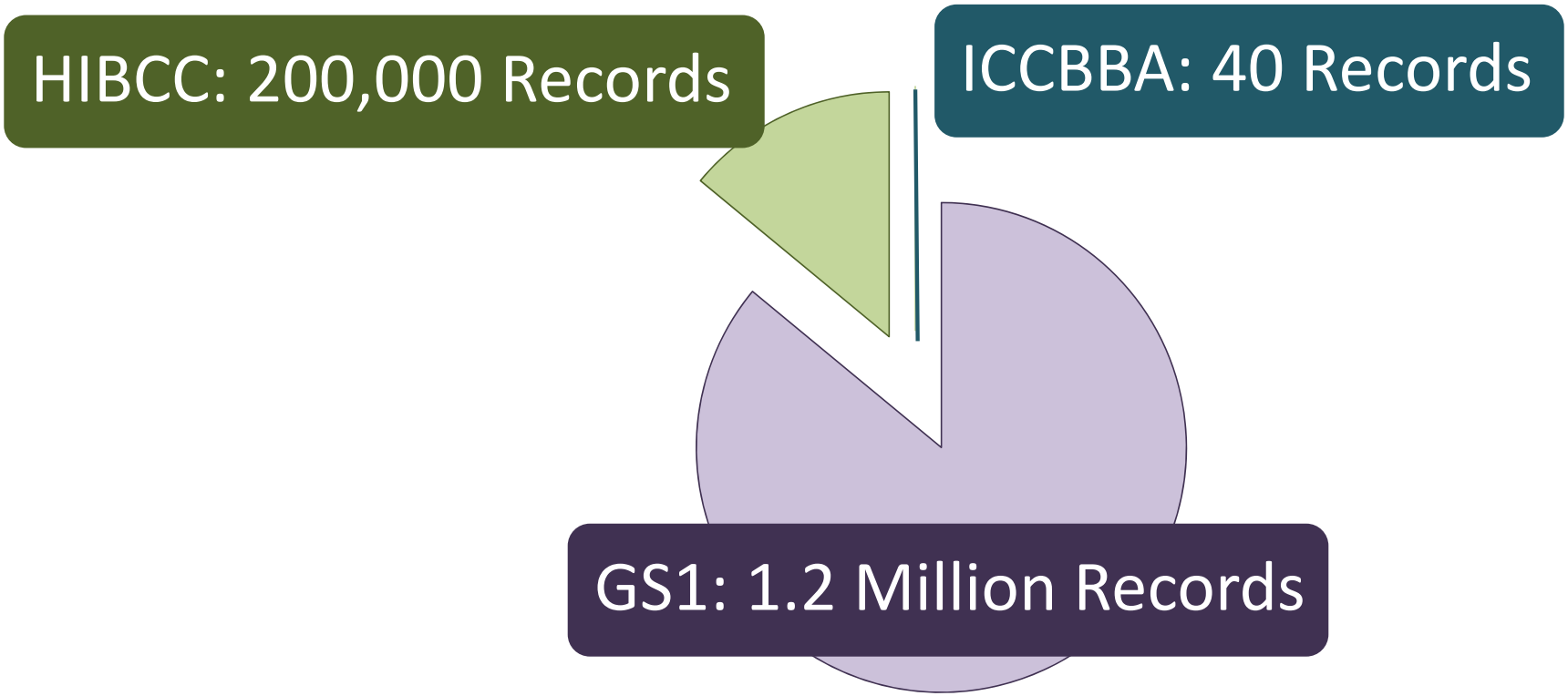
UDI & AccessGUDID

- **Standard reference source for FDA regulated devices**
- **Manufacturer submits DI data once for multiple purposes**
- **Replaces text, non-standard data with meta-data in AccessGUDID**

GUDID Records and
Submission Compliance Deadlines
Data Current as of September 5, 2017

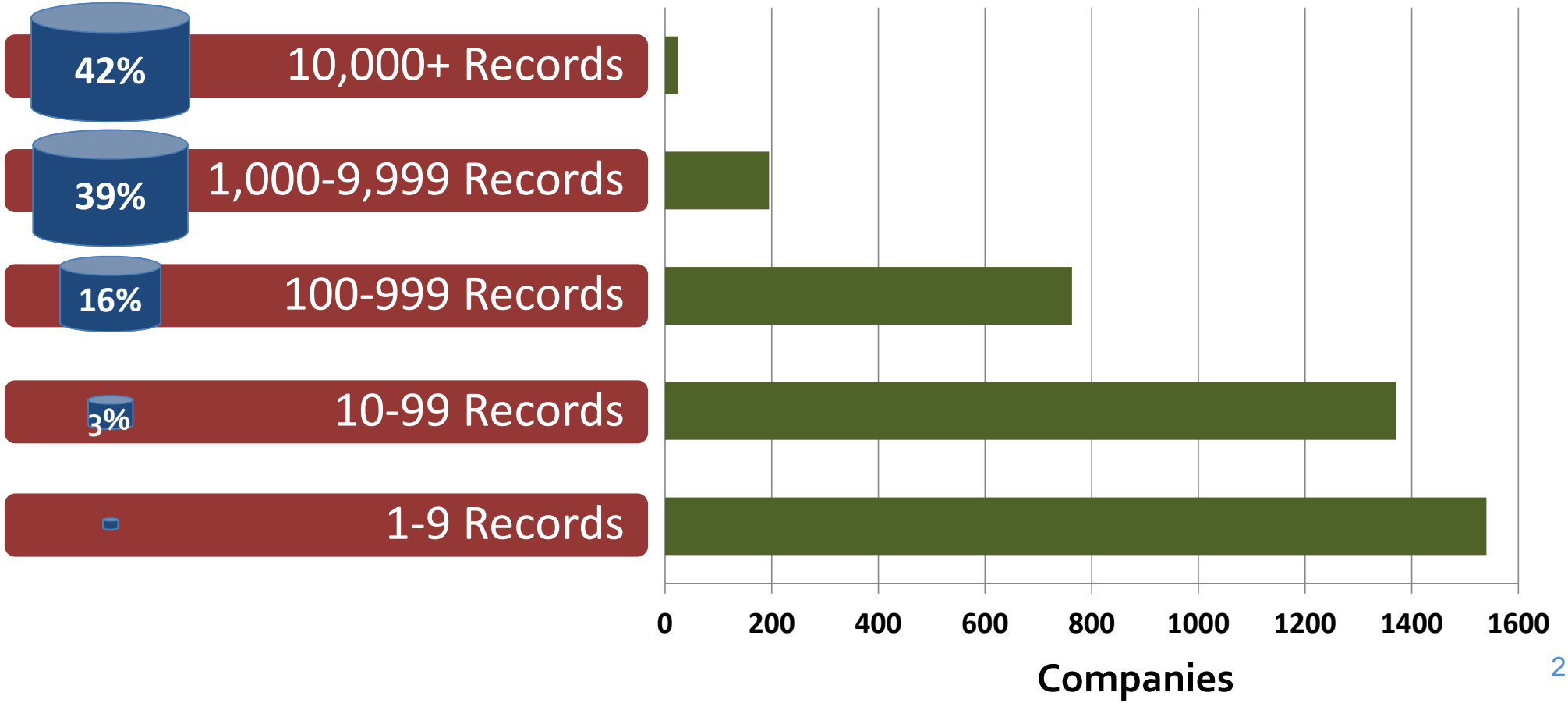


Most Primary DIs
Have Been Issued by GS1
Data Current as of September 6, 2017



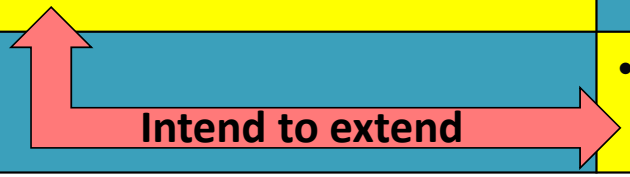
219 Companies Have Submitted 80% of GUDID Records

Data Current as of September 1, 2017

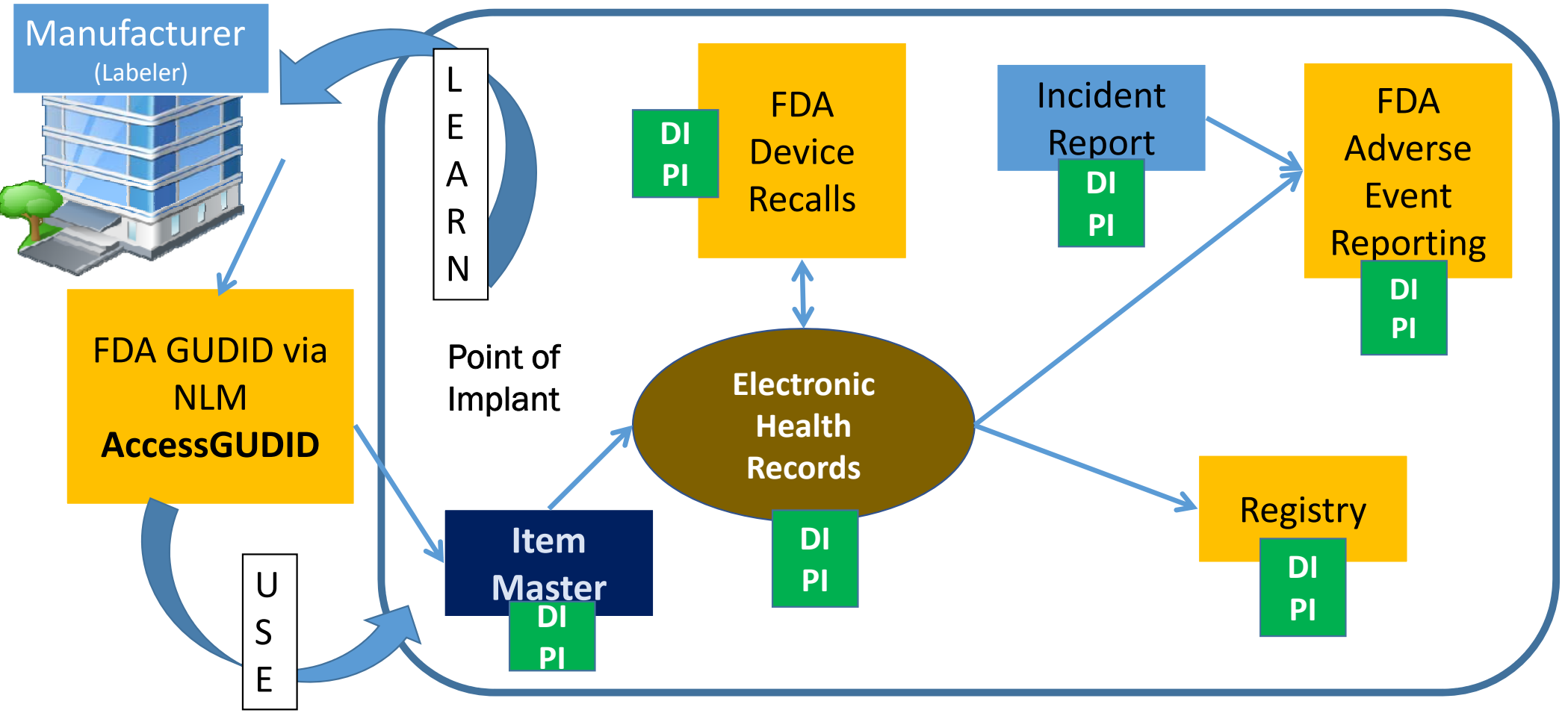


UDI Regulatory Dates

Compliance Date	Must bear a UDI & submit data to GUDID	Direct Marking (for certain intended uses)
September 24, 2014	• Class III devices • Devices licensed under the PHS Act	
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices	• LS/LS devices
September 24, 2016	• Class II devices	• Class III devices and devices licensed under the PHS Act
September 24, 2018	• Class I devices and unclassified devices	• Class II devices
September 24, 2020		• Class I devices and unclassified devices



UDI Adoption: Linking and Learning



Regulations: Adoption in EHRs

Vendor	Software
Allscripts	Allscripts Professional EHR
Allscripts	Allscripts TouchWorks EHR
CureMD.com, Inc.	CureMD SMART Cloud
Epic Systems Corporation	EpicCare Ambulatory EHR Suite
Epic Systems Corporation	EpicCare Ambulatory EHR Suite
Epic Systems Corporation	EpicCare Inpatient EHR Suite
Epic Systems Corporation	EpicCare Inpatient EHR Suite
Cerner Corporation	FirstNet (Clinical)
MEDHOST	MEDHOST Enterprise
Henry Schein Medical Systems	MicroMD

Vendor	Software
Netsmart Technologies	myAvatar Certified Edition
McKesson	Paragon® for Hospitals 2015 Certified EHR
Cerner Corporation	PowerChart (Clinical)
SRS-Health	SRS EHR
Greenway Health, LLC	SuccessEHS
Allscripts	Sunrise Acute Care
Allscripts	Sunrise Ambulatory Care
Medical Transcription Billing Corporation (MTBC)	TalkEHR
Evident	Thrive EHR
Evident	Thrive Provider EHR

Early Adopters

Vendor	Software
Allscripts	Allscripts Professional EHR
A	
C	
Epic Systems Corporation	EpicCare Ambulatory EHR Suite
E	
Epic Systems Corporation	EpicCare Inpatient EHR Suite
E	
C	
MEDHOST	MEDHOST Enterprise
Henry Schein Medical Systems	MicroMD

Materials Management:
Improved Recall Management

Nursing:
Operating Room Efficiency

Clinical Engineers:
Improved Tracking

Vendor	Software
Nets	
McKesson	Paragon® for Hospitals 2015 Certified EHR
Cerr	
SRS-	
Greenway Health, LLC	SuccessEHS
Allsc	
Allsc	
Medical Transcription Billing Corporation (MT	TalkEHR
Evid	
Evident	Thrive Provider EHR

Quality:
Workflow Improvements

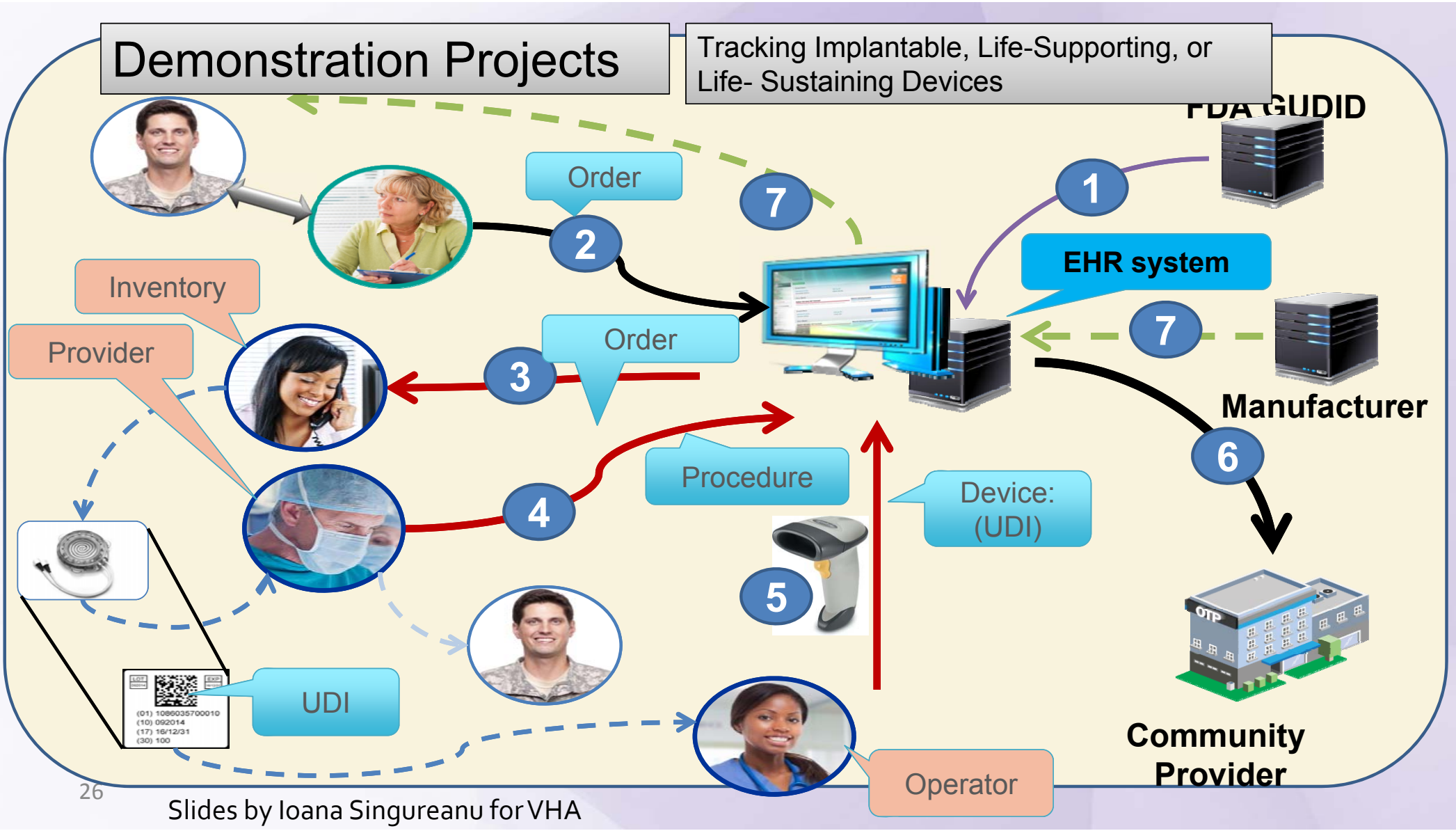
Information Systems:
Meaningful Use

Risk Management:
Patient Safety Projects

Researchers:
Medical Device Registries

Demonstration Projects

Tracking Implantable, Life-Supporting, or Life- Sustaining Devices

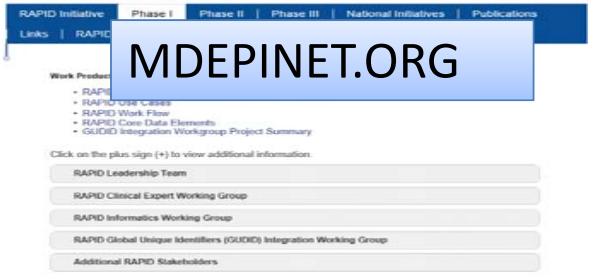


Slides by Ioana Singureanu for VHA

Demonstration Projects

Medical Device Epidemiology Network (MDEpiNET)
Registry Assessment of Peripheral Interventional Devices (RAPID)

- ✓ Develop UDI registry team that includes Manufacturers, Registry Owners, Vendors, FDA, Clinicians
- ✓ Educate on known UDI gaps and issues
- ✓ Identify medical devices covered by registry using:
  - ✓ Product code x Company x Brand x GMDN /SNOMED terms
- ✓ Run AccessGUDID reports to pull DI device records
- ✓ Identify gaps, improve GUDID
- ✓ Use UDI and GUDID data in Registry



RAPID – UDI Core Data Elements

Primary Device Identifier	GMDN term	Clinically Relevant Size Type
Secondary Device Identifier	SNOMED CD/Term *Mapped from GMDN*	Clinically Relevant Size Value
Company Name	Device Description	Clinically Relevant Size Unit of Measure
Brand	Version or Model	Catalog Number

RAPID: Integration of UDI

Enter data ONCE to support data capture and device evaluation

WL GORE

Vascular Quality Initiative

DEVICE: GORE VIABAHN Endoprosthesis (00733132614394)

DOWNLOAD: XML | JSON

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: GORE VIABAHN Endoprosthesis
Version or Model: VBC050502
Catalog Number:
Company Name: W. L. Gore & Associates, Inc.
Device Description: No description.

Primary DI Number: 00733132614394
Issuing Agency: GS1
Device Count: 1

Treatment Type: Stent Graft
Product Number or DI: VBC
Manufacturer
Type
GUDID Diameter
GUDID Length

VBC050202 DI:00733132614387
VBC050502 DI:00733132614394
VBC051002 DI:00733132614400
VBC051502 DI:00733132614417
VBC060202 DI:00733132614424
VBC060501 DI:00733132614431
VBC060502 DI:00733132614448

Device 1

Treatment Type: Stent Graft
Product Number or DI: VBC050502 DI:00733132614394
Manufacturer: W. L. Gore & Associates, Inc.
Type: GORE VIABAHN Endoprosthesis
GUDID Diameter: 5 Millimeter
GUDID Length: 5 Centimeter

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

SCANH
Supply Chain Advancement Network in Health

NEW

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

IMDRF International Medical Device Regulators Forum

New Work Item:
UDI Harmonized Unique Device Identification (UDI) Application Guide

UDI as a Global Standard

Consistent, universal approach to UDI will facilitate:

- Traceability of medical devices through distribution and use
- Identification of specific medical devices and device attributes associated with adverse events
- Reduction of medical errors
- Documentation of specific device data in the course of patient care

Summary

- **UDI –** standard that opens up ability to scan and identify devices more accurately in electronic supply chain, device maintenance and clinical sources. Foundational to National Evaluation System for health Technology
- **AccessGUDID** - reference data source that associates DI of UDI with standard meta-data that can be shared across care continuum
- **Value of Demonstration projects** – cross-stakeholder demonstration projects show value and will lead to improved patient and device safety and innovation
- **Global Harmonization** – a founding principle of the IMDRF UDI Working group was establishment of a global standard. This requires commitment.

UDI Resources

- Association for Healthcare Resources and Materials Management (AHRMM) Learning UDI Community
  - UDI Resources
  - Workgroups to address adoption challenges
- Medical Device Epidemiology Network (MDEPINET)
  - UDI and National Education System education, case studies, bibliographies
- Medical Device Innovation Consortium (MDIC) National Evaluation System for health Technology (NEST) Coordinating Center
  - Status of Center
  - Demonstration projects

UDI Resources

- FDA UDI Website
  - AccessGUDID, UDI Help Desk, Regulations and Guidance, Benefits of UDI
- Office of National Coordinator for Health IT (ONC)
  - Implantable Device List
  - Common Clinical Data Set
  - Meaningful Use
- Office of the Assistant Secretary for Planning and Education (ASPE)
  - Strategically Coordinated Registry for Women's Health Technologies and other projects