Unique Device Identification (UDI)
Status, Learnings, Next Steps

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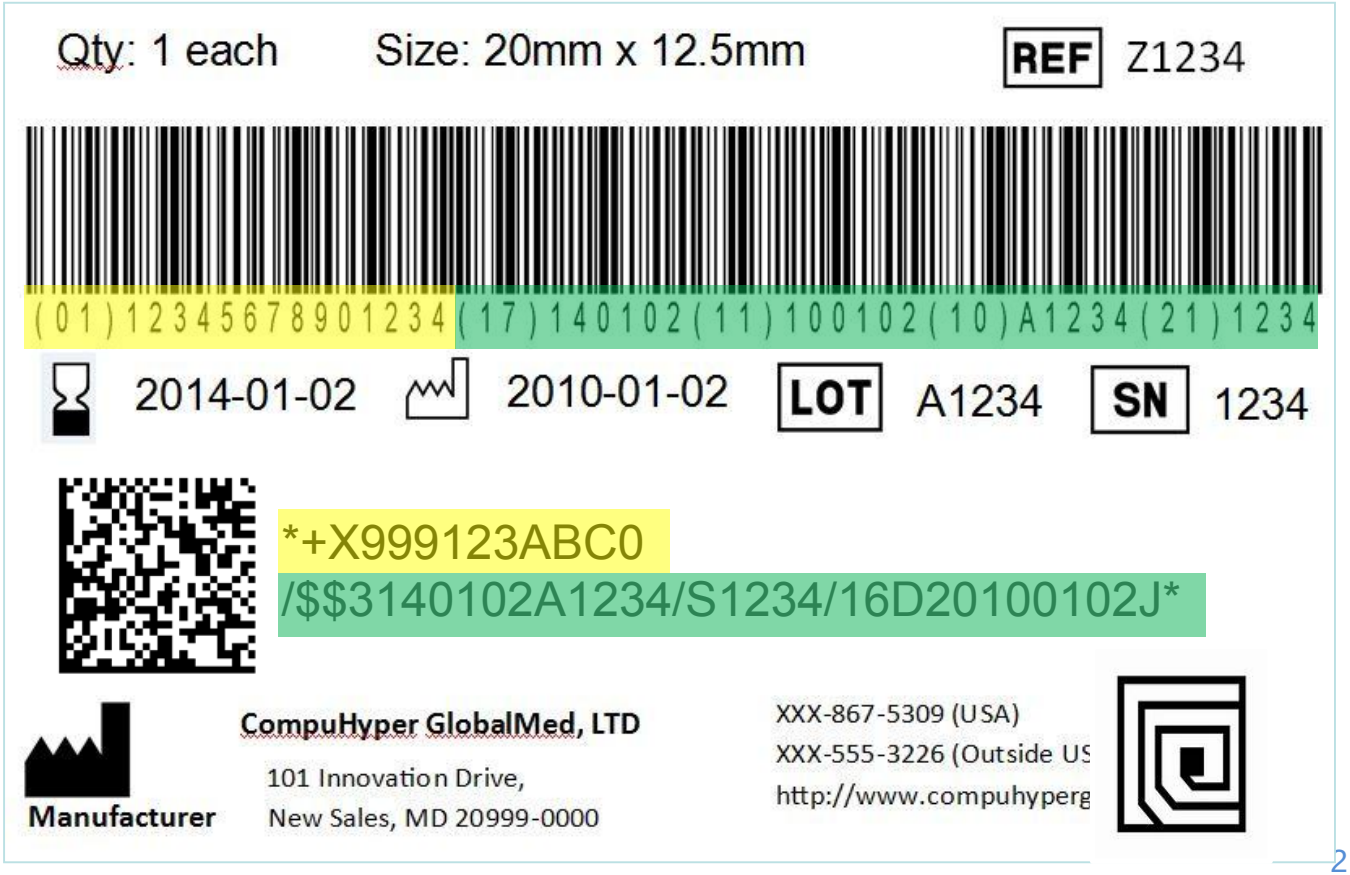
IMDRF – September 2016

What is a UDI?

Required on the device label, packages or, in some cases, on the device itself

Code in plain text and machine readable format (AIDC)

UDI = DI + PI



Benefits of UDI

Improve Patient Safety

- Collect and analyze more detailed and accurate device information to detect product problems
- Identify and remove unsafe products
- Increase likelihood of identifying counterfeit products

More Accurate Understanding of Device Benefit-Risk Profile

- Better evaluate product performance
- Improve device selection by providers and patients

Facilitate Device Innovation and Patient Access

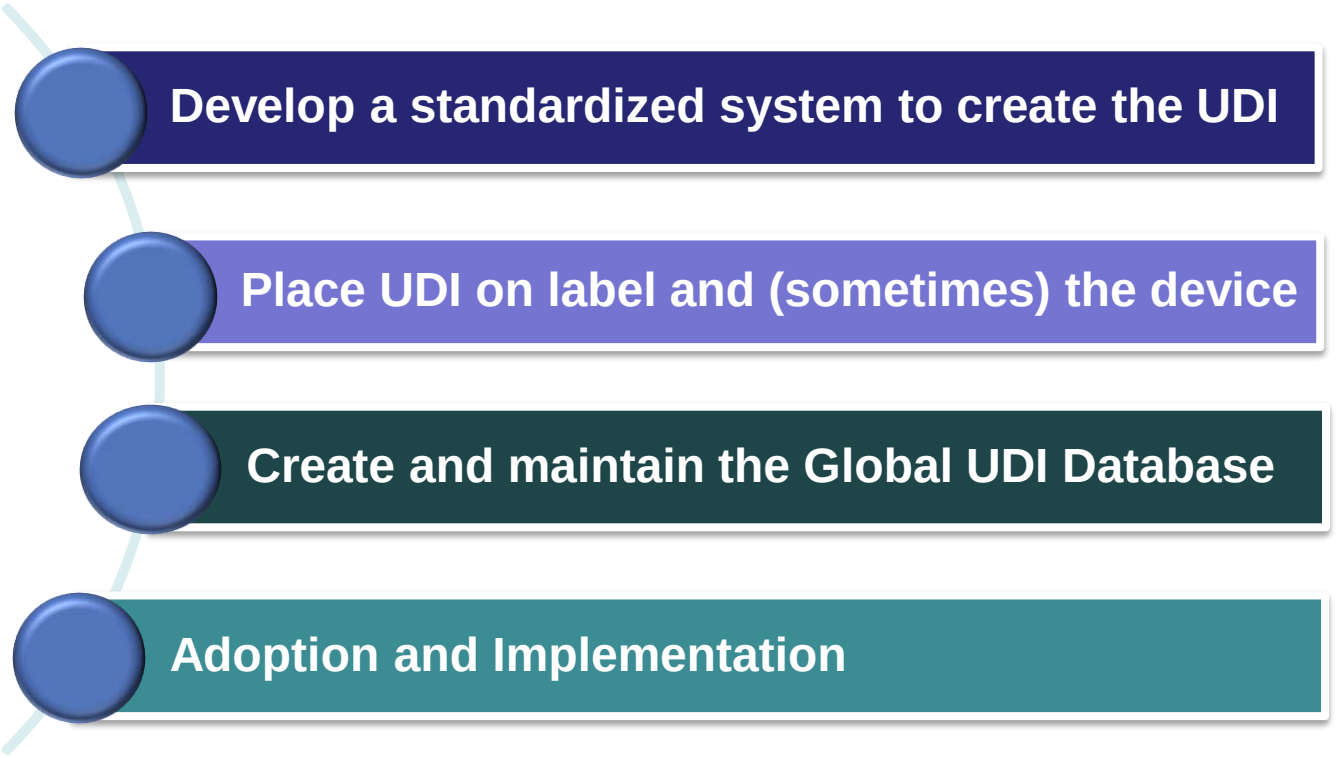
- Understand patient-device characteristics to improve device design
- Inform regulatory decisions (e.g. expand indications, new device approvals, PAS)

Establishing a UDI System

UDI Final Rule

[78 FR 58786]

Sept 24, 2013



Implementation Timeframe

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	• Class III devices, incl. class III stand alone software • Devices licensed under the PHS Act
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software • Direct Marking of I/LS/LS for certain intended uses
September 24, 2016	• Class II devices • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	• Class I devices and devices not classified class I, II or III • Direct Marking of class II devices for certain intended uses
September 24, 2020	• Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

Data Collection

Repository of key device identification information

Contains ONLY the DI; PIs are not submitted to nor stored in the GUDID

Contains only PI flags to indicate which PIs are on the device UDI

Adoption and Data Use

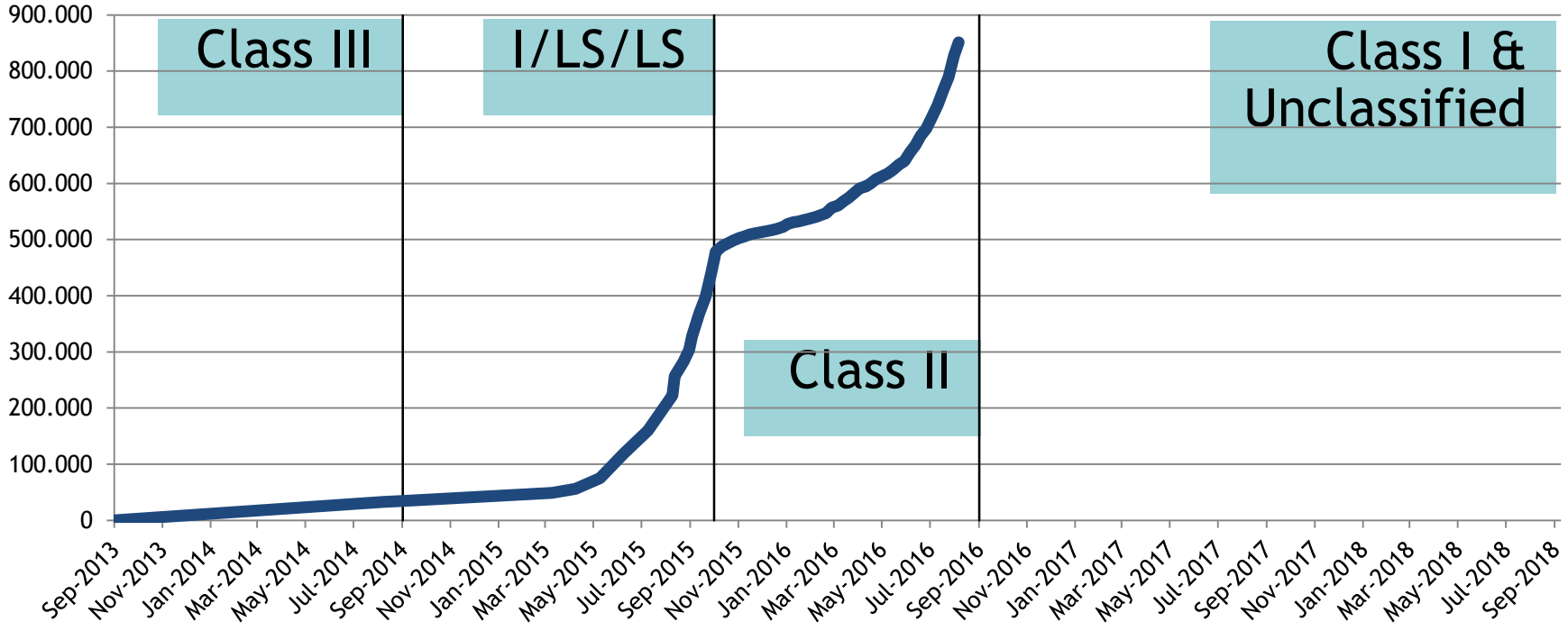
Public Access to GUDID data

High quality public search, download and web services (APIs)

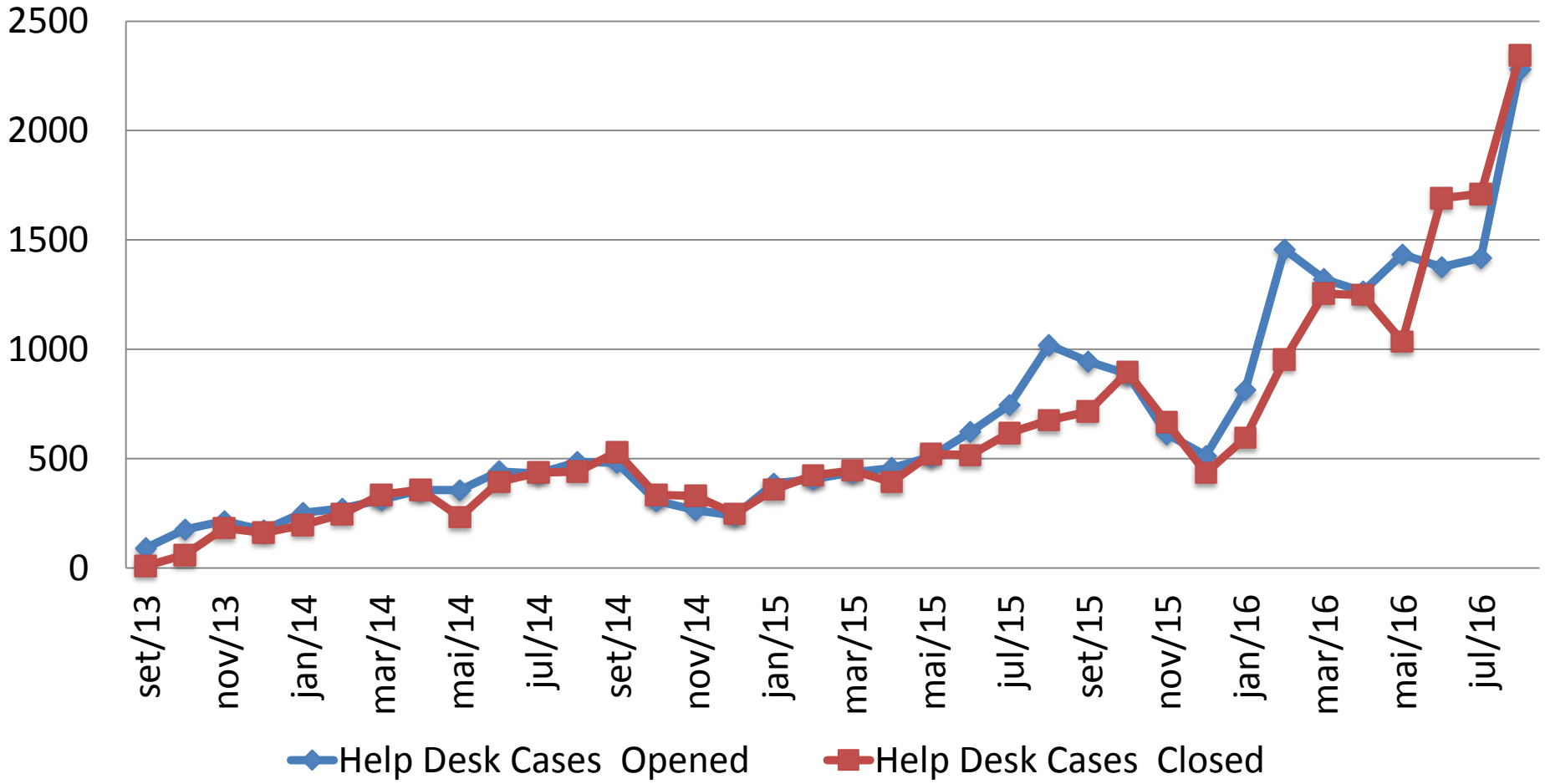
Provides link to health IT expertise and initiatives

GUDID Records and Submission Compliance Deadlines

Data Current as of September 1, 2016



Helpdesk Statistics



September 2013 to 2016

LESSONS LEARNED

Subject Matter Expert Resources

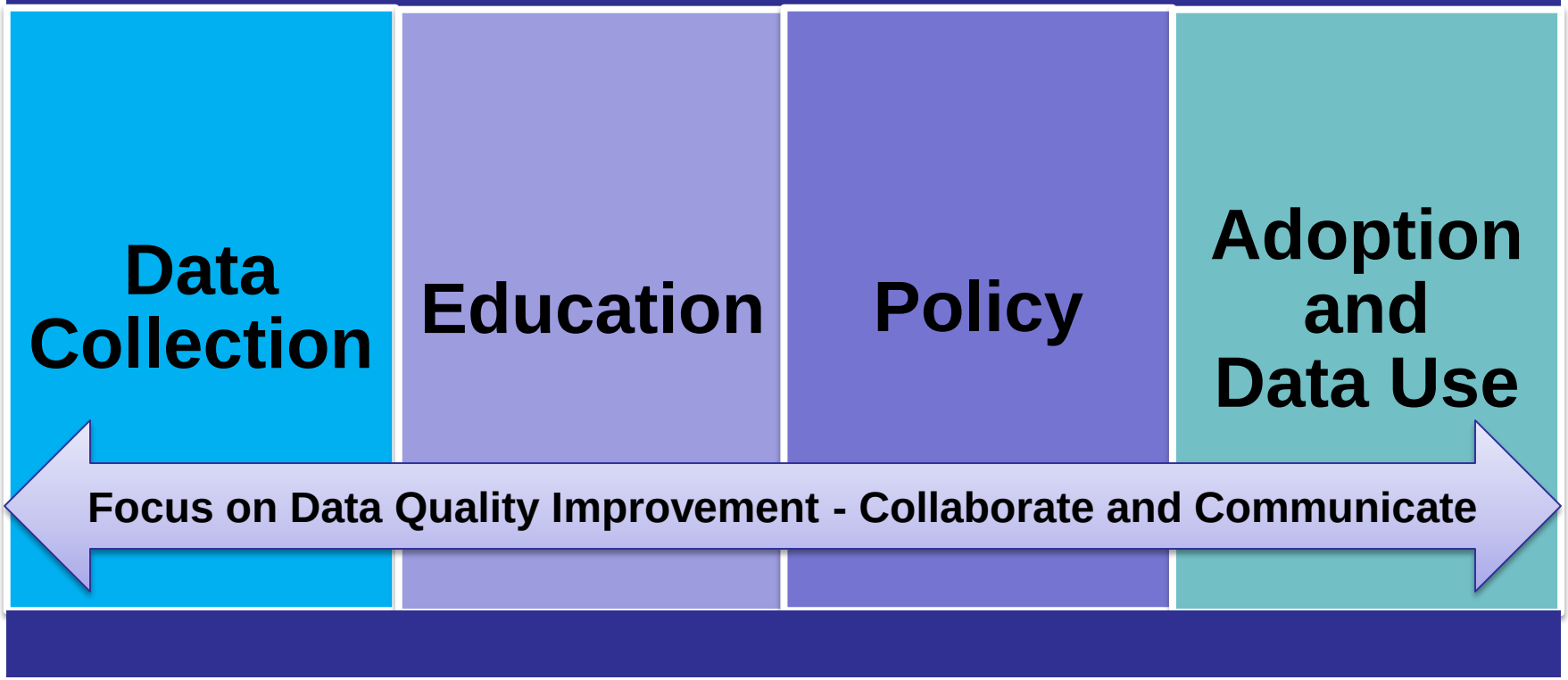
UDI Team

- Technical
- Regulatory
- Adoption
- Data Quality
- Standards
- UDI Helpdesk

Collaborators

- Internal (Premarket, MDR, Compliance, CBER, CDER, ORA)
- External (device and healthcare industry)
- Government (NLM, ONC, CMS, VA)
- Healthcare Systems
- Registries

UDI Program Components



Lessons Learned

Data Collection

- Use data standards; focus on downstream data use
- Set expectation of continuous improvement
- Provide public access to database in multiple forms
- Plan for challenging device types (kits, device systems, consigned devices)

Lessons Learned

Education

- Automate help desk tools; consider chat or phone option
- Early and often – website, webinars, guidances, FAQs
- Staff for cyclical ups and downs
- Leverage issuing agencies and other external groups to multiply common messages

Lessons Learned

Policy

- Leverage available vetted policies/standards
  - IMDRF UDI Guidance
  - Issuing Agency Standards
  - Guidances by other countries
- Establish firm deadlines and extend as needed
- Base policy and technical decisions on real world use of UDI data

Lessons Learned

Adoption and Data Use

- Emphasize value of DI + 5 PI fields – DI is key in database and link across data sources.
- Learning UDI Community framework for shared best practices
- Integrate in National & International device initiatives – NEST, Registries, EHR Certification
- Demonstrate benefit of UDI adoption through pilots, ROI analysis and early adopters

Labeler Challenges

UDI is New

- Setting best practices for adding UDI to label
- Difficult to collect data across Enterprise and submit to GUDID
- Combining regulatory and healthcare uses

Heterogeneity of devices

- Wide variety of characteristics
- Implantables, instruments, orthopedic trays, software, etc.
- UDI rule can't cover it all

Variability in UDI use

- GUDID fields vary by context of use
- Difficult to coordinate development of consensus-based best practices
- Best source to improve UDI in practice

Questions?

FDA UDI Website (including Helpdesk):
www.fda.gov/udi

Slide Presentations, Transcripts and Webinar Recordings are available at:
www.fda.gov/CDRHWebinar
Under Heading: Unique Device Identification (UDI) System