Charge for the AccessGUDID Committee

US Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)

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FDA UDI Rule – 9/24/2013

- ***Unique device identifier (UDI)*** means an identifier that *adequately* identifies a device through its distribution and use.. A unique device identifier is composed of:
  - (1) A ***device identifier***—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

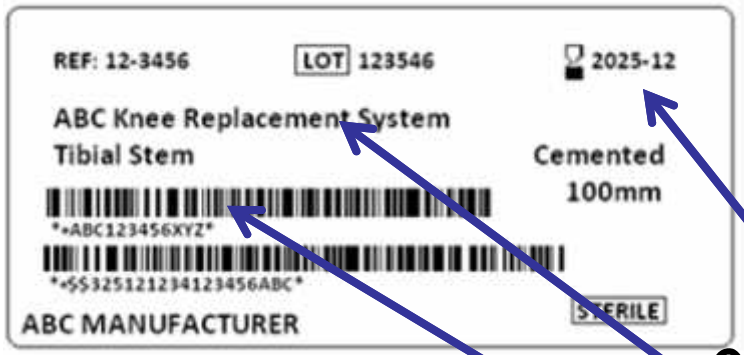
  - (2) A ***production identifier***—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
    - (i) **The lot or batch within which a device was manufactured;**
    - **(ii) The serial number of a specific device;**
    - **(iii) The expiration date of a specific device;**
    - **(iv) The date a specific device was manufactured;**
    - **(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter**.

Compliance Dates for UDI Requirements

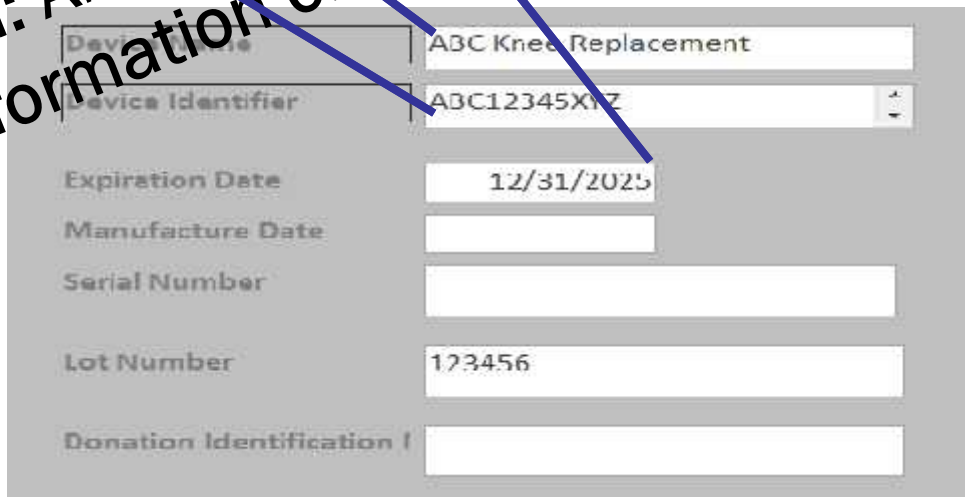
Device	Compliance Date
Class III (including class III LS/LS) Devices licensed under the PHS Act	September 24, 2014
Implantable, Life-Supporting and Life-Sustaining (class II, class I & unclassified)	September 24, 2015
Class II (other than I/LS/LS)	September 24, 2016
Class I or unclassified (other than I/LS/LS)	September 24, 2018

Link: Details on Compliance Dates

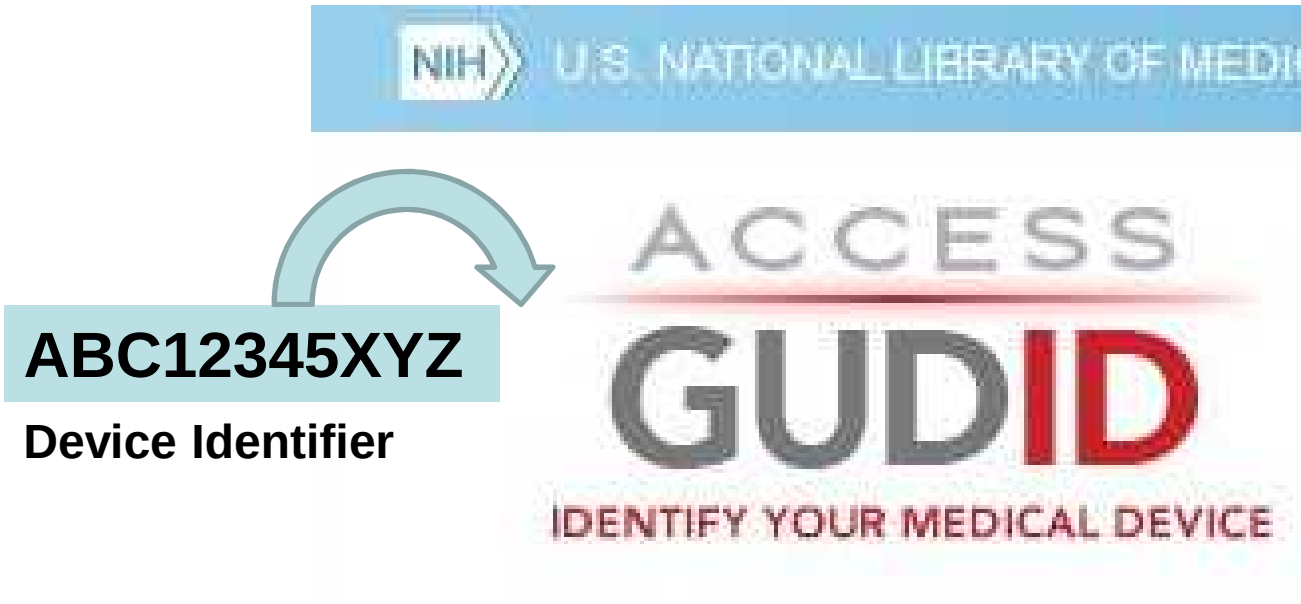
#1 Add UDI to Label



Assumption: Able to scan and verify scan by reading information on the label

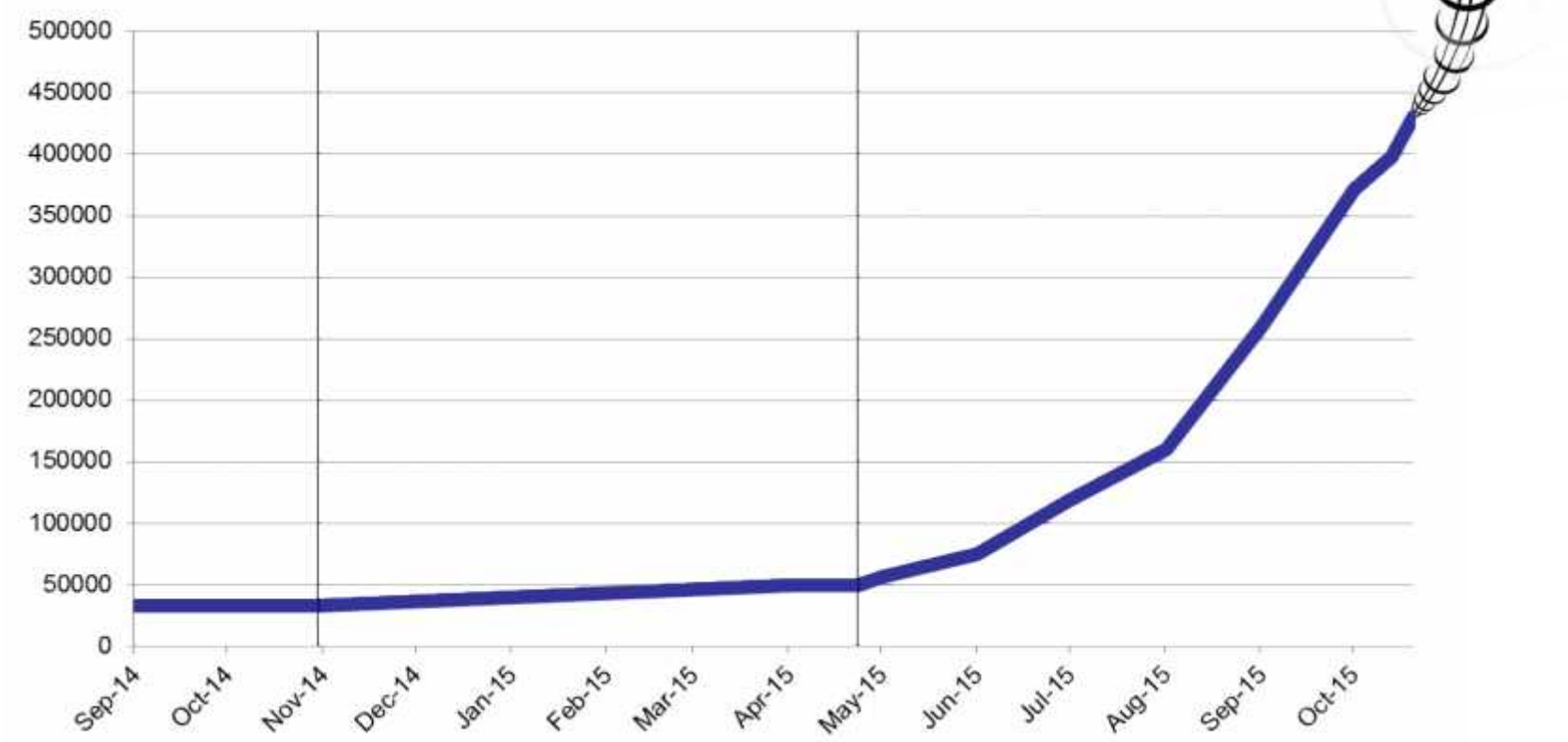


#2 Populate accessGUDID with DI Records



http://accessgudid.nlm.nih.gov/

GUDID DI Records



10/16/15 - ONC and CMS Rules

- Established UDI Requirements for EHRs
- 2015 Edition Health IT Certification Criteria
  - **Implantable Device List – UDI and core attributes**
- Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3
  - **UDI in Common Clinical Data Set (CCDS)**

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Discharge Summary

Active Implantable Device List

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DI Lot Serial Expiration Mfr Date DIC	Description (GMDN or SNOMED)	Company Name	Brand Name	Model or Version	MRI Safe	Labeled Containing Latex
ABC12345XYZ 123456 12/31/2025	ABC Knee Replace-ment System	ABC Manufacturer	Tibial Stem	Cemented	Y	N

Common Clinical Data Set

Putting the I in HealthIT
www.HealthIT.gov

Core Data accessible and available for exchange.

Patient name	Lab tests
Sex	Lab values/results
Date of birth	Vital signs (changed from proposed rule)
Race	Procedures
Ethnicity	Care team members
Preferred language	Immunizations
Problems	Unique device identifiers for implantable devices
Smoking Status	Assessment and plan of treatment
Medications	Goals
Medication allergies	Health concerns

ONC Interoperability Roadmap Goal

2015-2017

Send, receive, find and use priority data domains to improve health and health quality

Red = New data added to data set (+ standards for immunizations)
Blue = Only new standards for data

UDI Use in Peripheral Device Registries

- Same as other Data Sources
  - Scan device for UDI number- direct entry into EHR
  - Pull data from EHR to Registry – to include GUDID data from ONC rule
- Current reality:
  - Still a lot of text and custom entry of device data
  - Huge number of ever changing devices makes maintenance of drop down menus difficult and expensive for registries

RAPID - Access GUDID Project

– Issues:

- Stents approved for coronary, biliary, trachea-bronchial applications are used off-label in peripheral vascular Rx
- Current FDA **product codes for** vascular devices includes only those with specific indication
- Assessing completeness of GUDID and usefulness of GMDN as a categorization scheme to include all relevant devices is an early goal

RAPID - Access GUDID Project

Key Actions:

– Work with FDA and NLM to **use** APIs or other automated methods to periodically extract specific device data from Access GUDID to populate relevant registries.

– Assess usefulness of **Global Medical Device Nomenclature (GMDN) to meet peripheral vascular categorization goals**

– **Assess quality of UDI data for your purposes – complete, accurate, etc**