U.S. FOOD & DRUG ADMINISTRATION

State of the UDI Regulation

aim Virtual Seminar

UDI Beyond the Basics

December 6, 2021

But First, The Basics

Unique Device Identifier (UDI) Program Objectives

Establish a system to adequately identify devices through distribution and use

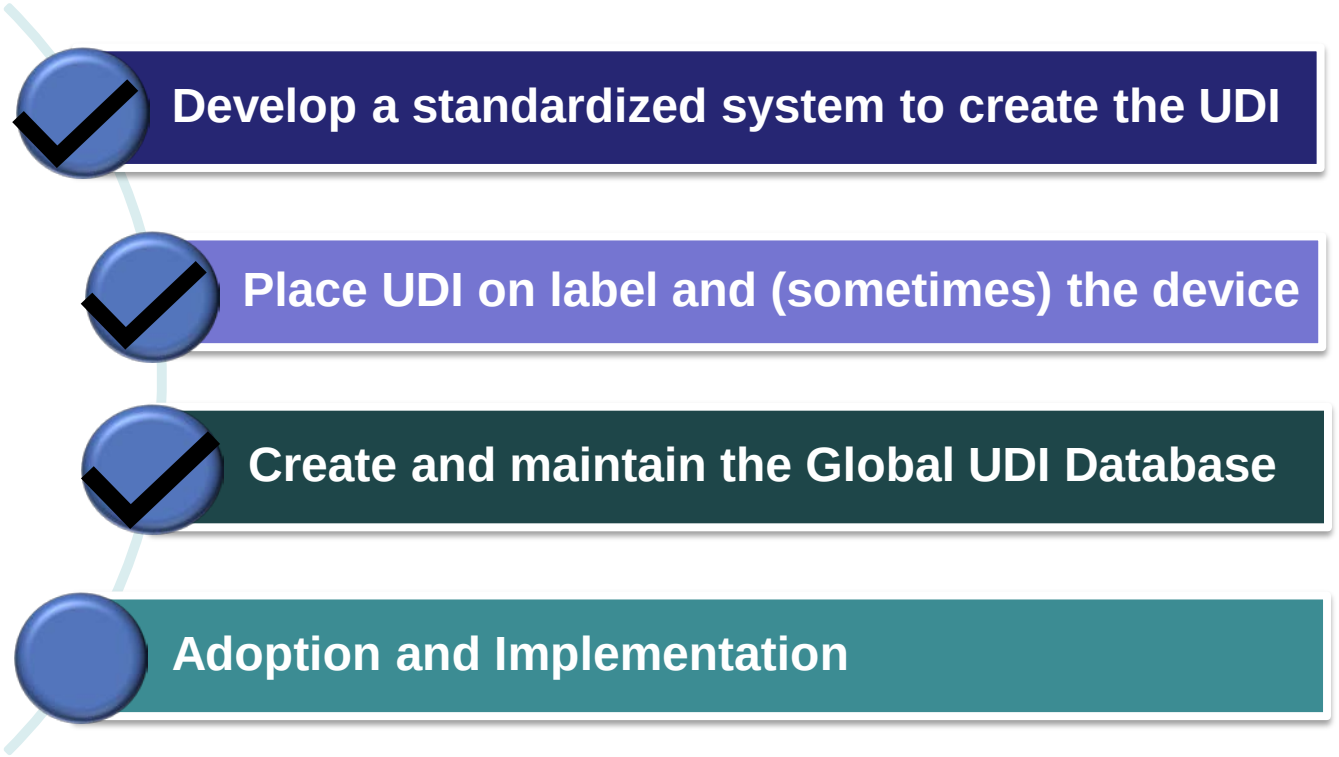
- Facilitate the rapid and accurate identification of a device
- Provide a standard and clear way to document device use in real world data sources such as electronic health records, clinical information systems, claims data sources and registries
- Allow for more accurate reporting, reviewing, and analyzing of adverse event reports to evaluate devices over time
- Enable more effective management of medical device recalls

Establishing a UDI System

UDI Final Rule

[78 FR 58786]

Sept 24, 2013

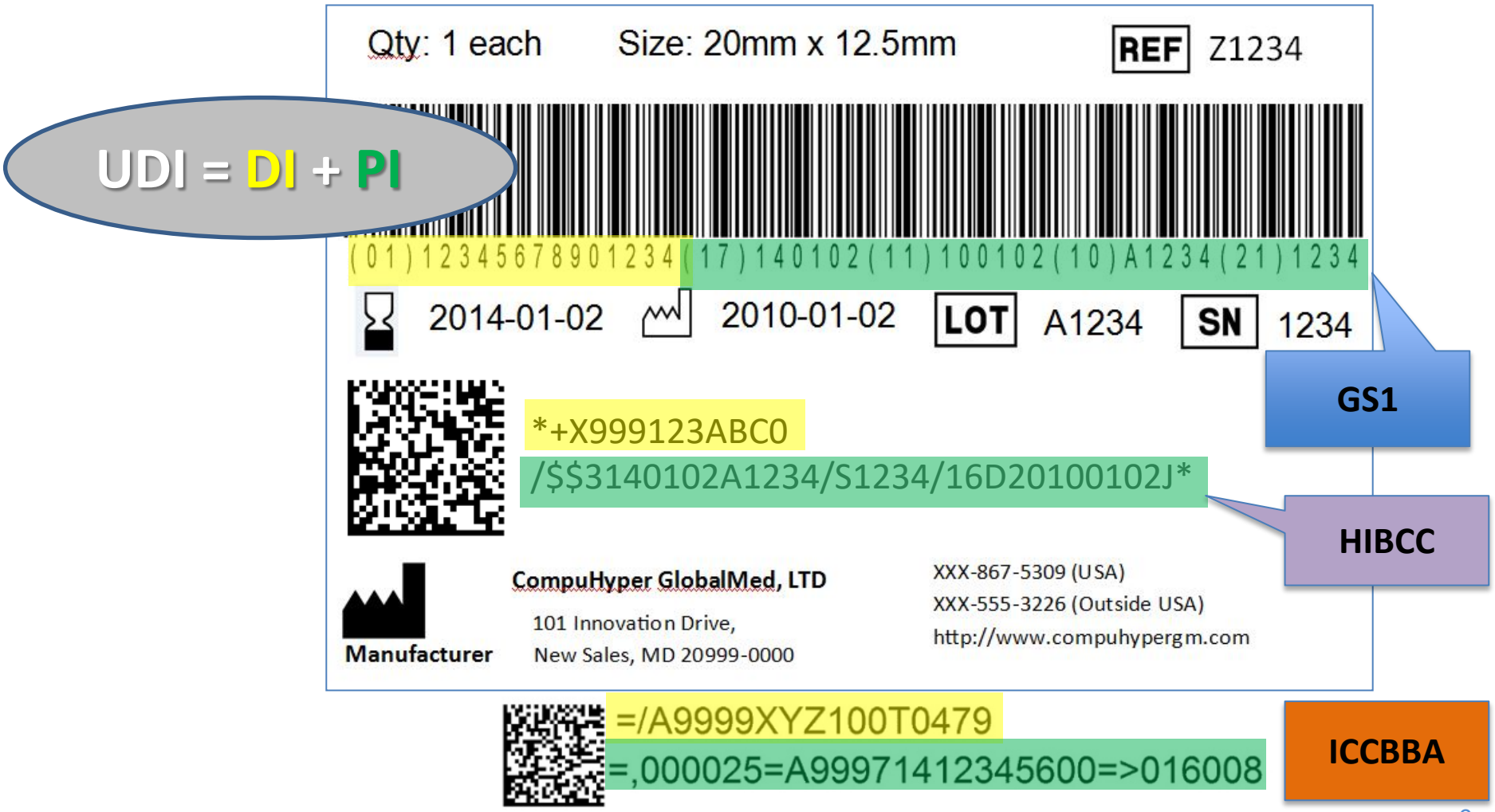


UDI Final Rule Requirement

Device label and device packages must bear a UDI

Key data must be submitted to GUDID

UDI Examples



UDI ISO 15223-1:2021

- Medical devices — Symbols to be used with information to be supplied by the manufacturer
- Devices already in the field do not require updates to their labeling
- Not mandatory unless specifically required to meet national regulations and standards

UDI Implementation Timeframes

Compliance Date	Must bear a UDI and Submit data to GUDID	Direct Marking (for certain intended uses)
✓ Sep 24, 2014	Class III devices Devices licensed under the PHS Act	
✓ Sep 24, 2015	Implantable, life-supporting and life-sustaining (I/LS/LS) devices	LS/LS devices
✓ Sep 24, 2016	Class II devices	Class III devices and devices licensed under the PHS Act
Sep 24, 2018*	Class I & Unclassified devices	✓ Class II devices
Sep 24, 2020*	⇩	⇩ Class I devices Unclassified devices
Sep 24, 2022**	Class I devices Unclassified devices	Class I devices Unclassified devices

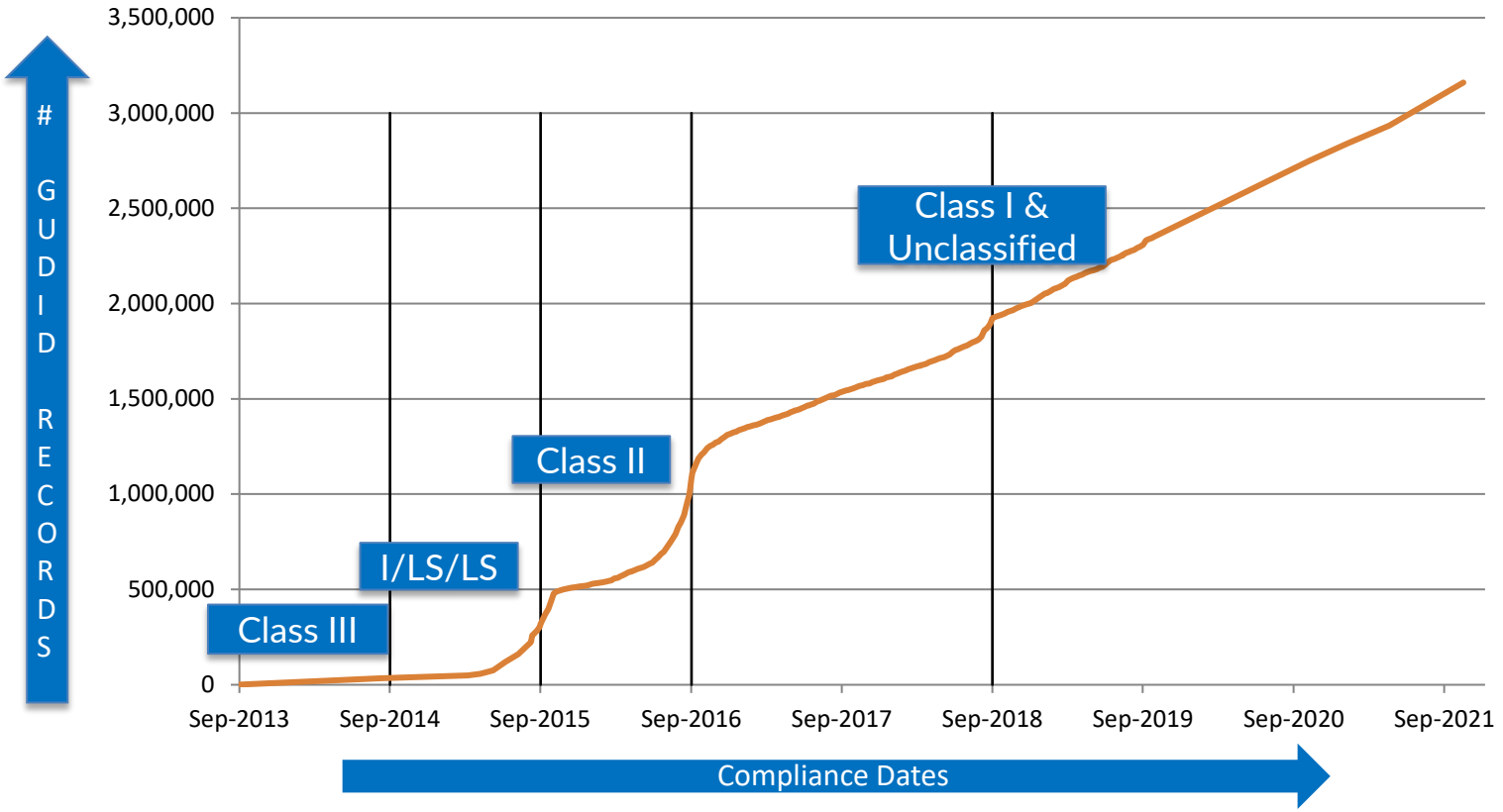
*UDI Rule Compliance Date
**Compliance policy regarding enforcement via Guidance

UDI Program – By The Numbers

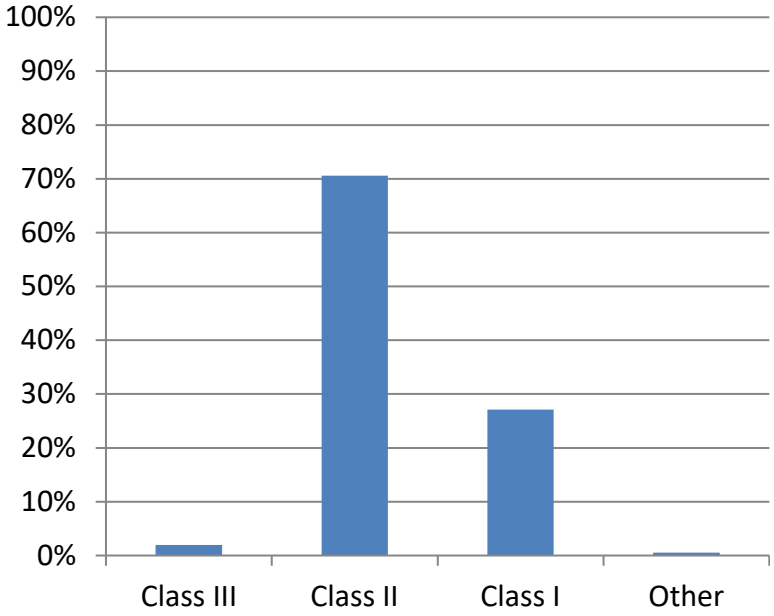
- GUDID platform - > 3.1M records from 6300+ companies
- AccessGUDID platform – avg. 4600+ sessions/day
- Guidances – 10 published since 2013
- Help Desk - ~400 tickets/month, with TAT average of ~2 days
- Learning UDI Community – 13 workgroups to date with completed deliverables
- IMDRF – 4 UDI publications
- Issuing Agencies – 3 accredited
- UDI incorporation in HL7, X12, & US Core Data for Interoperability
- Industry training – 9 modules available on UDI website
- MDRs – ~80% include UDI
- Utilization in clinical registries
- Incorporation in FDA/ORA inspection activities
- Workstream in MDIC NEST Collaborative Community

>3.15 Million Records in GUDID

Data Current as of Nov 1, 2021

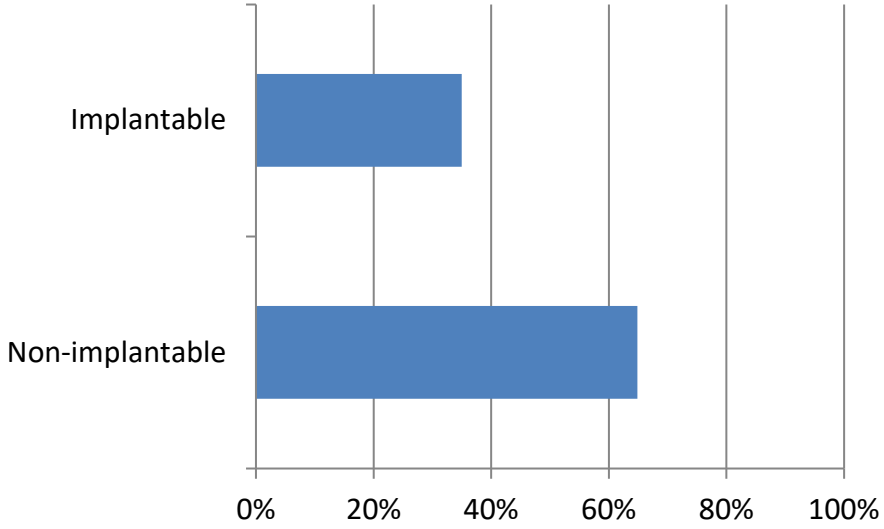


Most GUDID Records are Class II



~35% are Associated with Implantables

"Implantable" devices are those assigned FDA Product Codes associated with Implantable Devices, Systems, and Accessories

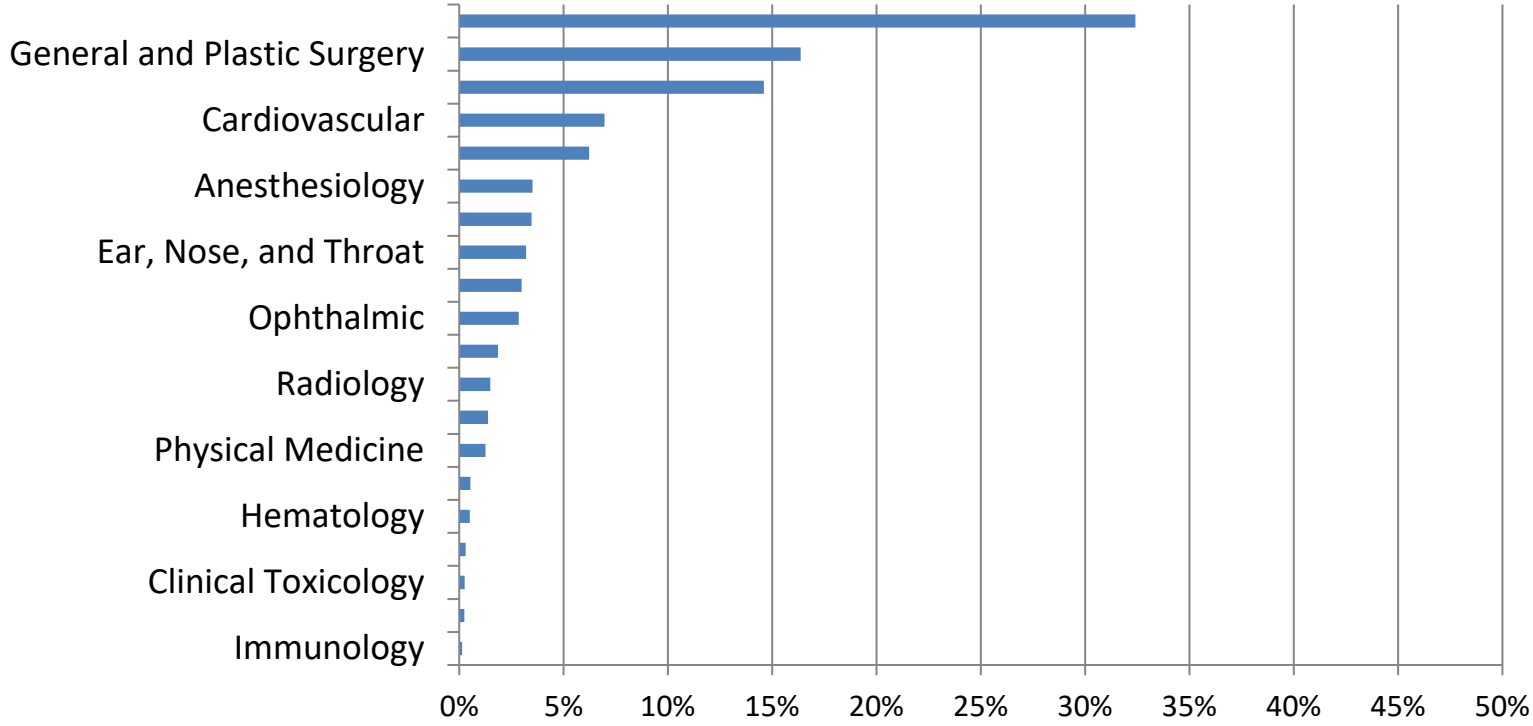


Data Current as of Nov 1, 2021

Medical Specialties in GUDID

Data Based on FDA Product Codes

Data Current as of Nov 1, 2021



CDRH Activity
During The
Public Health Emergency (PHE)

Unprecedented COVID-19 response in addition to normal operating conditions

- 38% overall increase in premarket submissions in 2020 alone
- >1600 new medical devices for COVID-19
- Outreach to >1,000 manufacturing sites across 12 countries
- Development of >300 FAQs
- Outreach including >90 webinars and Town Halls
- Development of 13 EUA templates (diagnostic tests, antibody tests, PPE, etc.)
- 28 guidances
- Over 400,000 public inquiries
- Shortage mitigation & realignment of staff to COVID activities
- And much more

(September 2021 data)

UDI Regulatory Activity During The PHE

UDI Website

UDI Rule and Guidances, Training, Resources, and Dockets

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This page provides a comprehensive list of links to:

- UDI rule and guidances
- UDI training for industry
- UDI and GUDID technical documents
- UDI dockets

www.fda.gov/udi

July 2020 Guidance: Compliance Dates for Class I and Unclassified Devices

- Publication Date: July 2020
- FDA does not intend to enforce standard date formatting, UDI labeling, and GUDID data submission requirements for class I and unclassified devices, other than I/LS/LS devices before September 24, 2022

Enforcement Policy Regarding Use of NHRIC and NDC Numbers on Device Labels and Packages

- Publication Date: May 2021
- FDA does not intend to object to the use of legacy NHRIC and NDC numbers on device labels and device packages, with respect to finished devices that are manufactured and labeled prior to September 24, 2023

UDI Form & Content Final Guidance

- Publication Date: July 2021
- Intended to assist labelers and FDA-accredited issuing agencies in complying with unique device identifier (UDI) labeling requirements
- Added references to internationally used terms from recent IMDRF UDI guide
- Issuing agencies or other entities may refer to the easily readable plain-text form of the UDI as the human readable interpretation (HRI)

Draft Guidance: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices

- Publication date: 10/13/21
- Comments due: 12/13/21
- Select update of July 2020 UDI Compliance Policy Guidance (referenced three slides prior)
- FDA generally does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I consumer health products

UPC Alternative Extension

- Extended the following alternatives:
  - UDI-A160001
  - UDI-A160002
- Certain nonprescription, over-the-counter devices intended to be sold exclusively through retail establishments may continue to bear a UPC as their DI
- Expire on September 24, 2023
- UDI Exceptions, Alternatives and Time Extensions | FDA

Regulatory Harmonization Efforts During The PHE

IMDRF/DITTA*

- Joint Workshop on COVID-19 – March 2021
  - members shared their experiences and challenges during the pandemic
  - emergency use or other systems to expedite access and supply of essential medical devices
  - flexible and pragmatic approaches to regulatory processes such as remote inspections
  - publishing information about approval pathways and availability of critical medical devices

*International Medical Device Regulators Forum/Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association

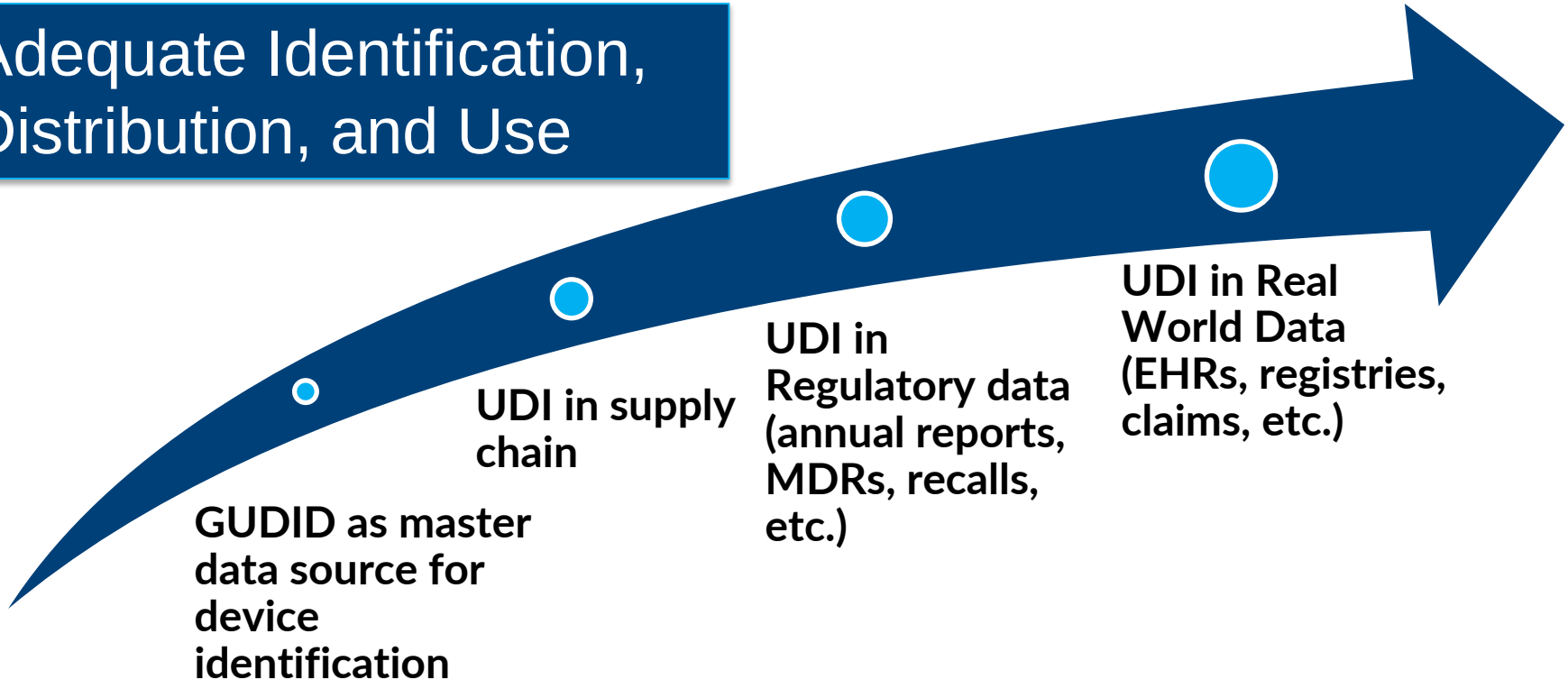
IMDRF/DITTA

- Joint Workshop on UDI - September 2021
  - provided an opportunity for stakeholders to discuss challenges and opportunities with UDI
  - recognition of the importance of global harmonization in realizing the benefits of UDI and our experience with the global nature of device supply and usage during the pandemic

Moving Forward

Focus on ensuring the objectives of the UDI Rule are realized

Adequate Identification, Distribution, and Use



UDI Use & Adoption

- UDI in Claims:
  - Latest version (8020) of X12 standard includes UDI-DI for "high-risk" devices

- UDI in Real World Data:
  - ONC-certified EHR systems include ability to capture UDI
  - Many hospitals systems are using UDI/GUDID information
  - MDEpiNet demonstration projects

UDI Use & Adoption

- Collaboration and continued engagement
  - MDIC/NESTcc
  - AHRMM Learning UDI Community (LUC)
  - IMDRF

- UDI for device Total Product Life Cycle (TPLC)
  - Improved effectiveness of device recalls
  - Utilization in adverse event review

UDI Program Resources

- FDA UDI Website: www.fda.gov/udi
- Public access to GUDID data:
  - AccessGUDID: https://accessgudid.nlm.nih.gov/
  - Open FDA: https://open.fda.gov/apis/device/udi/
- UDI Help Desk: GUDIDSupport@fda.hhs.gov

It always seems impossible until it’s done.

- Nelson Mandela

THANK YOU!

Any questions?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