

Accessing and Communicating Device Information: UDI as a Tool for Improved Patient and Provider Connectivity

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Background and Timeline

- 2007 Food and Drug Administration Amendments Act directed the FDA to establish a unique device identification (UDI) system
- 2010 Medical Device Epidemiology Network (MDEpiNet) established as a public-private partnership between FDA and academic medical institutions
- 2011 Chickasaw Nation Industries, Inc. awarded contract from FDA as part of the MDEpiNet initiative to advance innovative methodologies and medical device-specific infrastructure for regulatory science and surveillance
- 2012 Proposed Rule for UDI System published in Federal Register



Affixing/incorporating UDIs during manufacturing



Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

UDI routinely available for valuable uses

UDI Development Phase UDI Implementation Phase



Affixing/incorporating UDIs during manufacturing

Incorporating UDI into data collection fields and provider workflow



Use of devices that are not uniformly labeled with UDIs (current state)

Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

UDI routinely available for valuable uses

UDI Development Phase UDI Implementation
Phase



Affixing/incorporating UDIs during manufacturing

Incorporating UDI into data collection fields and provider workflow

Developing methods and data infrastructure



Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

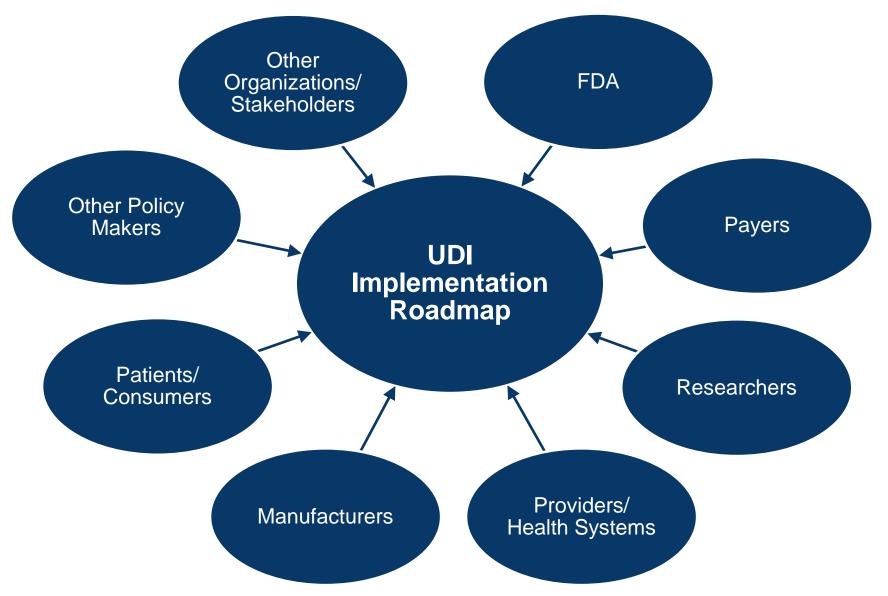
UDI routinely available for valuable uses

UDI Development Phase UDI Implementation
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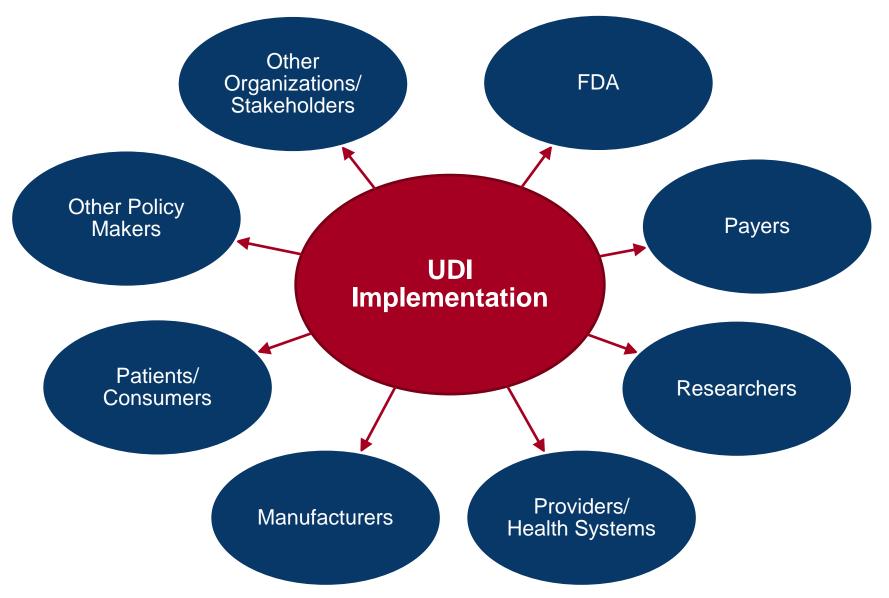


Incorporating UDI into Affixing/incorporating Developing **UDIs** during data collection fields methods and data and provider workflow manufacturing infrastructure Use of devices Routine that are not Use of devices **UDI** routinely capture of UDI with UDIs in available for uniformly labeled in electronic with UDIs valuable uses clinical practice data sources (current state) **UDI** Development **UDI** Implementation Phase Phase Proposed Initial Focus for UDI Implementation Work Group











Meeting Agenda

Overview of Proposed UDI Rule

Session 1: Communicating Device Safety Information to Patients and Providers Using UDI

Session 2: Information Needs for Ongoing Care of Patients with Devices

Session 3: Facilitating Enhanced Connectivity of Patients, Providers and Others Using UDI

