Charge to the UDI Implementation Work Group

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Background and Timeline

• 2007 - Food and Drug Administration Amendments Act directed the FDA to establish a 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
UDI Development and Implementation

Affixing/incorporating UDIs during manufacturing

Use of devices without UDIs in clinical practice (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
UDI Development and Implementation

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Incorporating UDI into data collection fields and hospital workflow

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UDI Implementation Phase

Incorporating UDI into data collection fields and hospital workflow

Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

Developing methods and data infrastructure

UDI routinely available for valuable uses
UDI Development and Implementation

**UDI Development Phase**

- Affixing/incorporating UDI during manufacturing
- Use of devices without UDIs in clinical practice (current state)

**UDI Implementation Phase**

- Incorporating UDI into data collection fields and hospital workflow
- Use of devices with UDIs in clinical practice
- Routine capture of UDI in electronic data sources
- UDI routinely available for valuable uses

Proposed Initial Focus for UDI Implementation Work Group
Developing a Roadmap for Successful UDI Implementation

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Work Group Meetings</td>
<td>Small meetings that focus on developing the UDI implementation roadmap and identifying important issues that require broader stakeholder consideration</td>
<td>1 initial full-day, in-person meeting, followed by monthly conference calls</td>
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<tr>
<td>Expert Workshops</td>
<td>Workshops to focus on specific issues identified by the Work Group</td>
<td>3 full-day in-person meetings</td>
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<tr>
<td>Roundtable Webinars</td>
<td>Webinars to cover a diverse range of initiatives that are relevant to UDI – intended as semiannual updates for all interested stakeholders</td>
<td>2 webinars</td>
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Role of UDI Implementation Work Group

Members will:

• Attend initial meeting and monthly conference calls

• Engage in discussions of issues related to the implementation of UDI, explore potential strategies for resolving them, and inform development of a roadmap for successful UDI implementation

• Guide the content of three expert workshops and two webinars to be held over the next year, participating as appropriate in these events
UDI Implementation Roadmap

Other Organizations/Stakeholders

FDA

Payers

Researchers

Manufacturers

Providers/Health Systems

Patients

Other Policy Makers

Other Policy Makers

Other Policy Makers

Other Policy Makers