

Charge to the UDI Implementation Work Group

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The Brookings Institution • Washington, DC
Monday, July 16, 2012

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

Affixing/incorporating UDIs during manufacturing

Incorporating UDI into data collection fields and hospital workflow

Use of devices without UDIs in clinical practice (current state)

Use of devices with UDIs in clinical practice

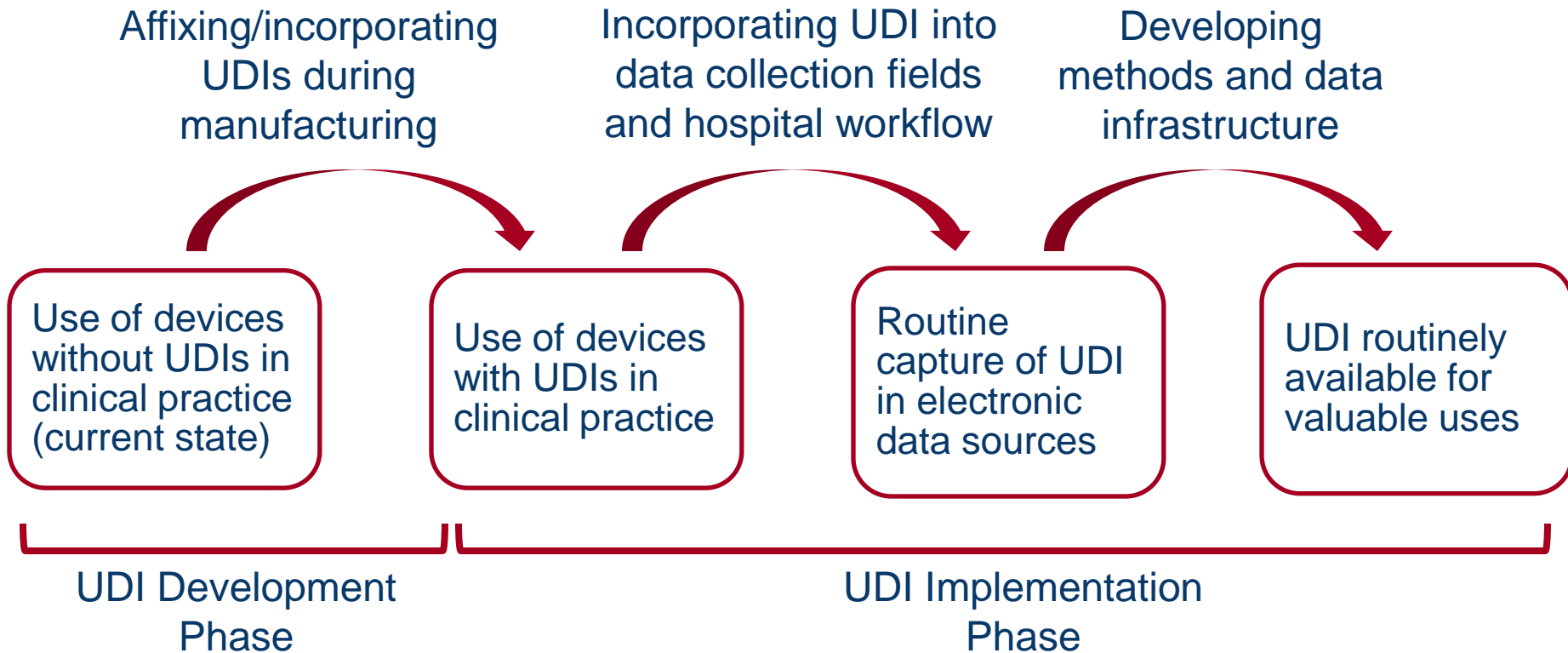
Routine capture of UDI in electronic data sources

UDI routinely available for valuable uses

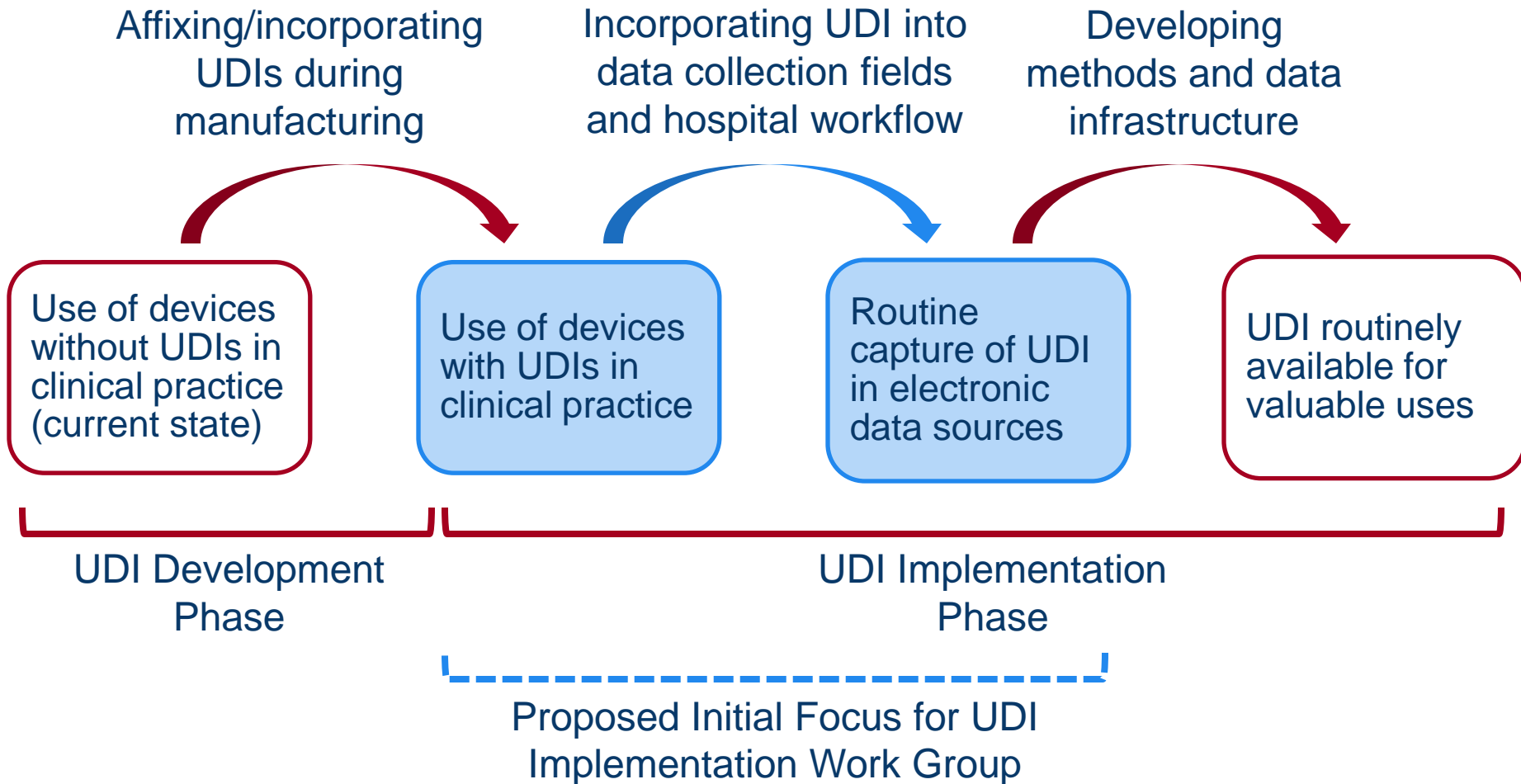
UDI Development Phase

UDI Implementation Phase

UDI Development and Implementation



UDI Development and Implementation



Developing a Roadmap for Successful UDI Implementation

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

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

