

Exploring the Opportunities and Challenges Associated with Capturing UDIs in Claims

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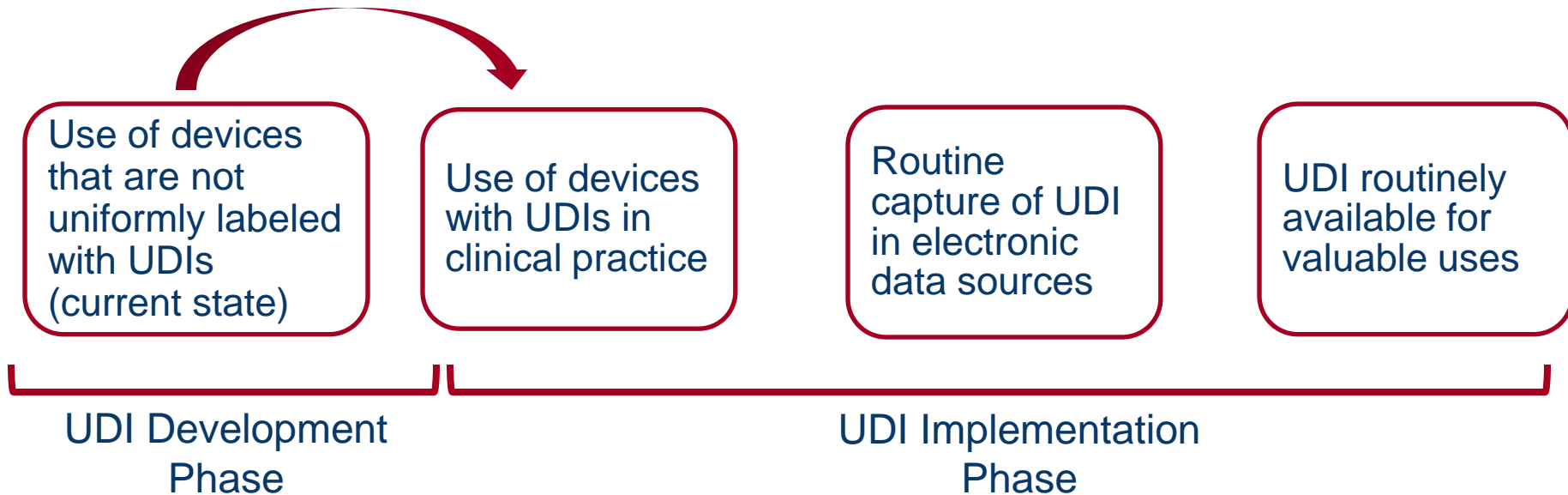
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Background and Timeline

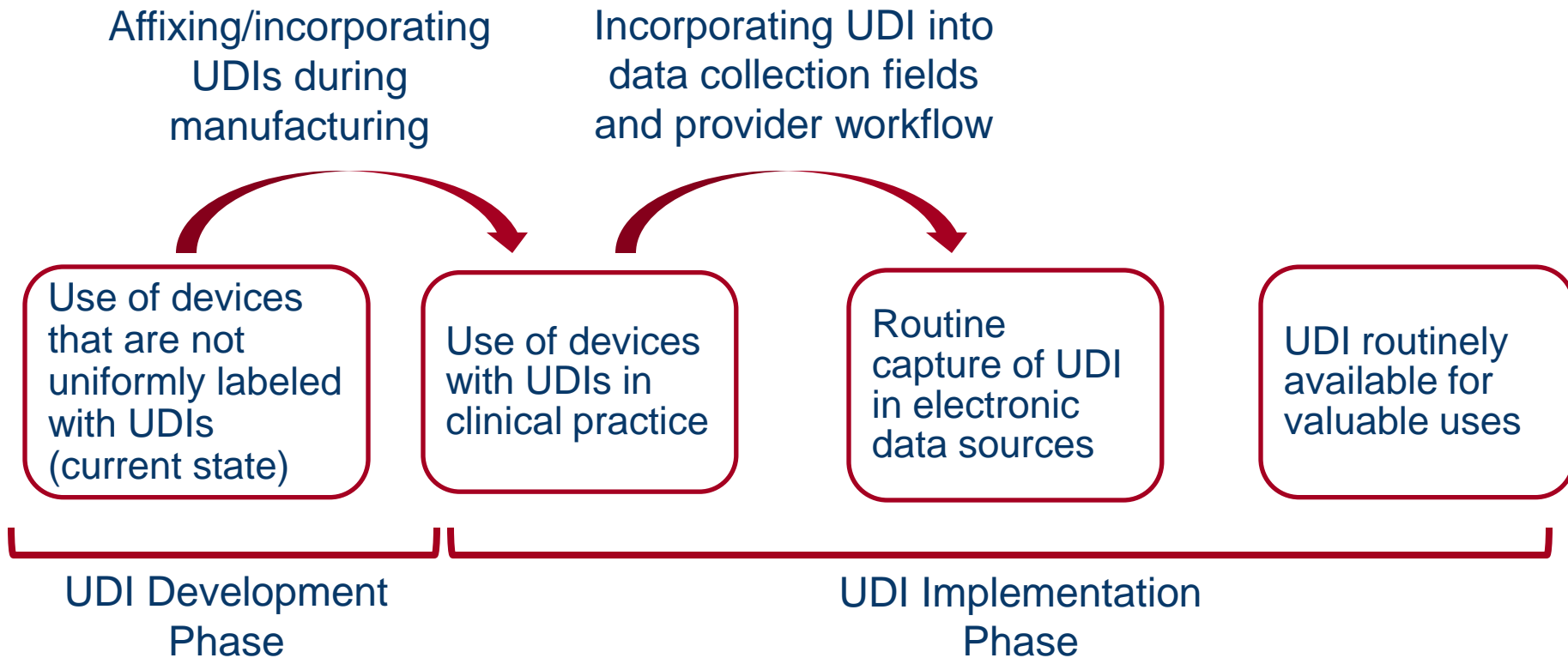
- 2007 - Food and Drug Administration Amendments Act directed the FDA to establish a UDI System
- 2010 - Medical Device Epidemiology Network (MDEpiNet) established as a public-private partnership between FDA and academic medical institutions
- 2011 - Chickasaw Nation Industries, Inc. awarded contract 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

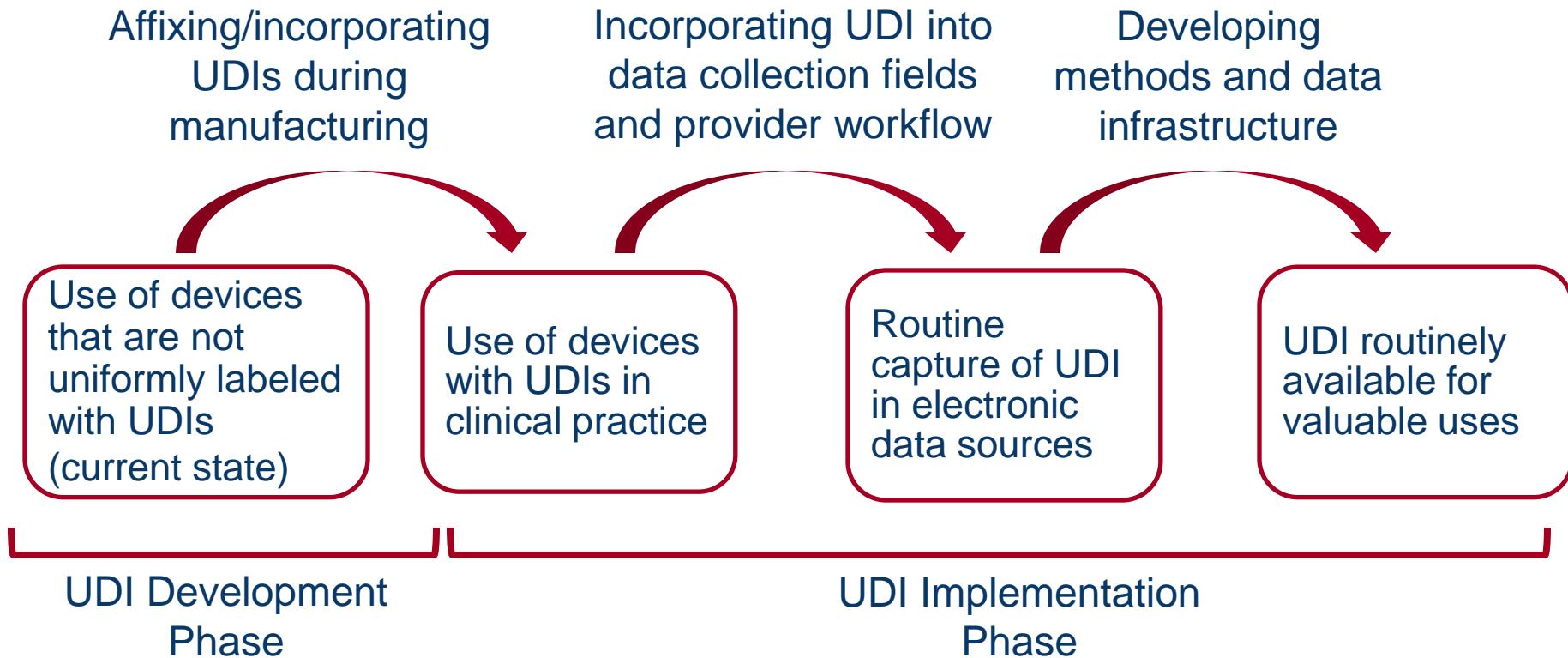
Affixing/incorporating
UDIs during
manufacturing



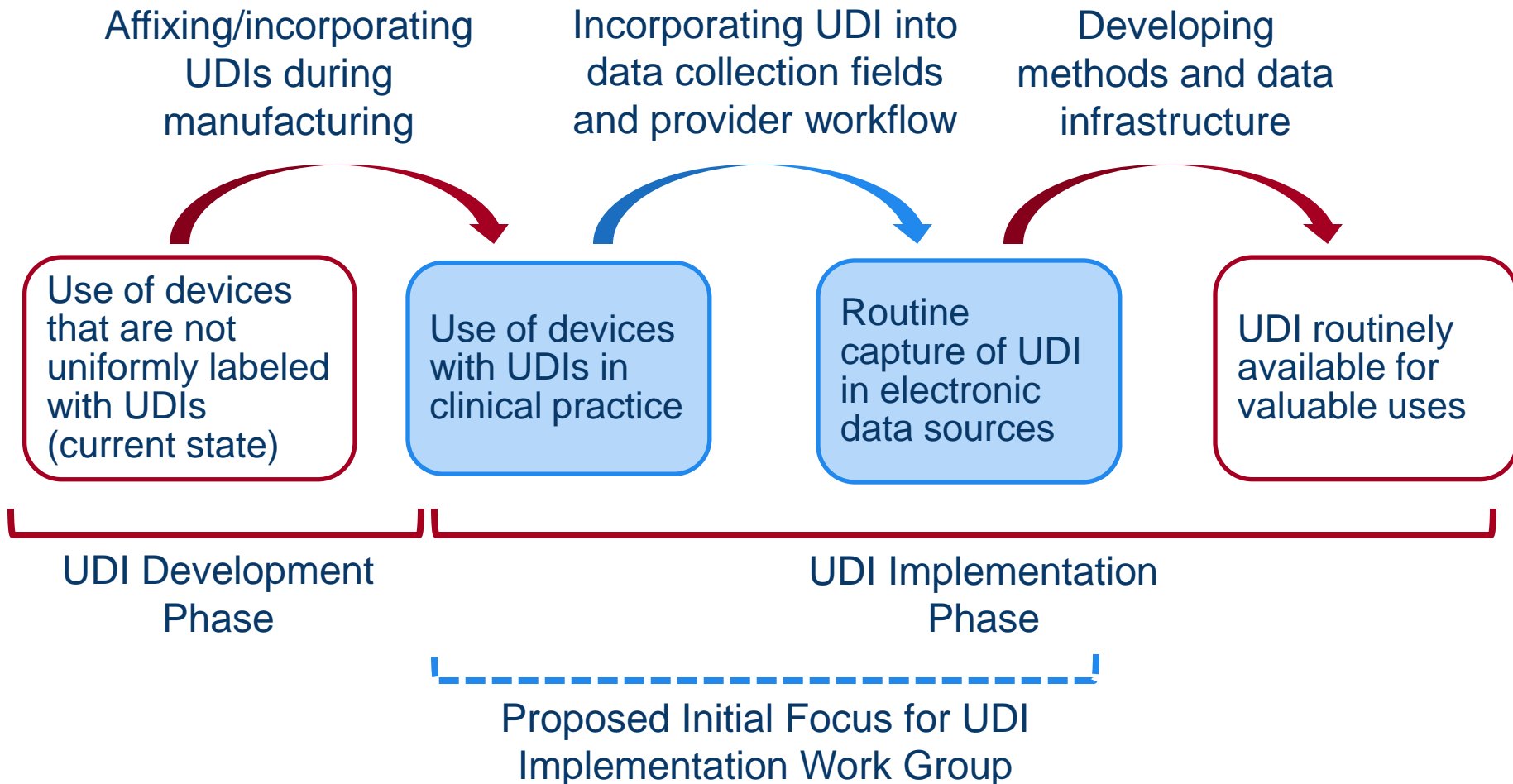
UDI Development and Implementation



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Meeting Agenda

Overview of Proposed UDI Rule

Overview of Universal Product Number Pilot

Panel 1: Potential Benefits of Including UDI in Claims

Panel 2: Technical Steps Necessary to Create UDI
Recording and Transmission Capabilities

Panel 3: Appropriate Policies for Enabling Consistent UDI
Recording