ENGELBERG CENTER for Health Care Reform at BROOKINGS

Identifying Steps for Implementation and Integration of UDI within Electronic Data Infrastructure of Care Delivery Sites

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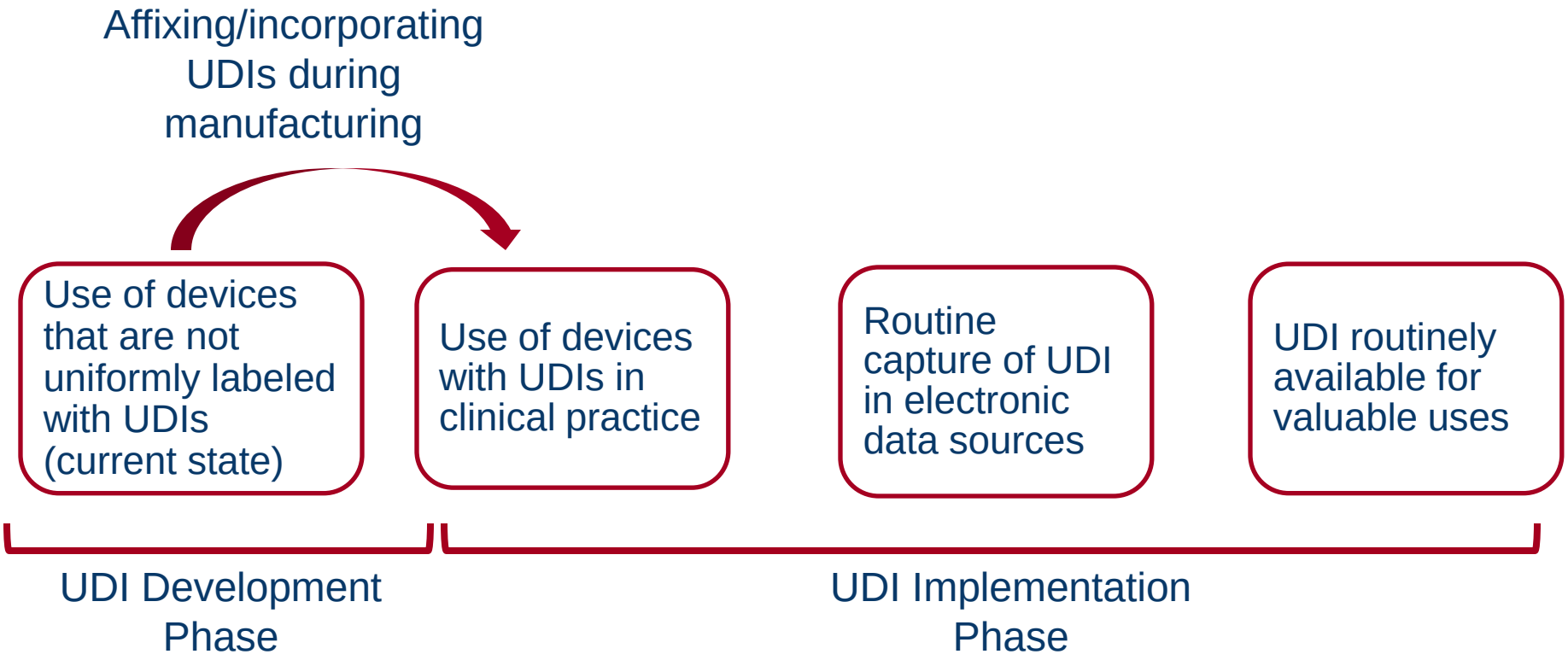
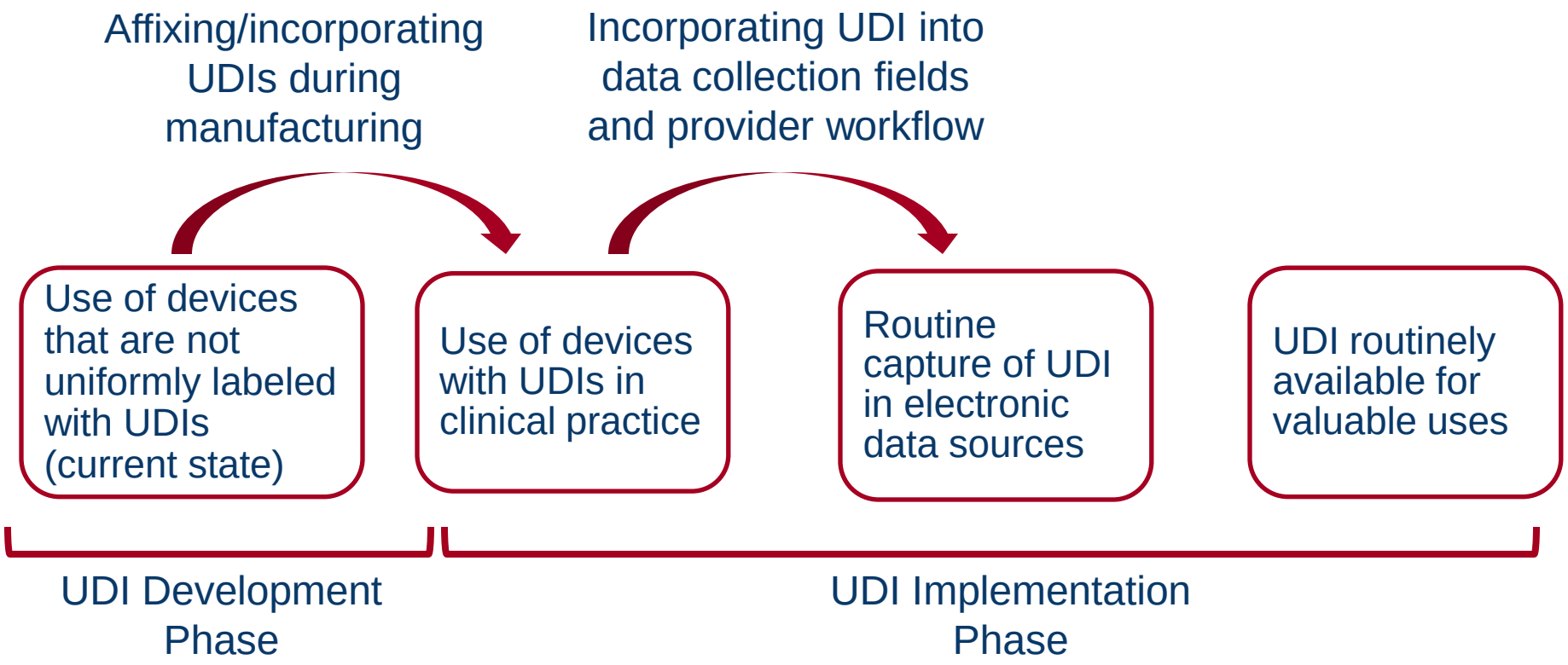
Background and Timeline

- 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*

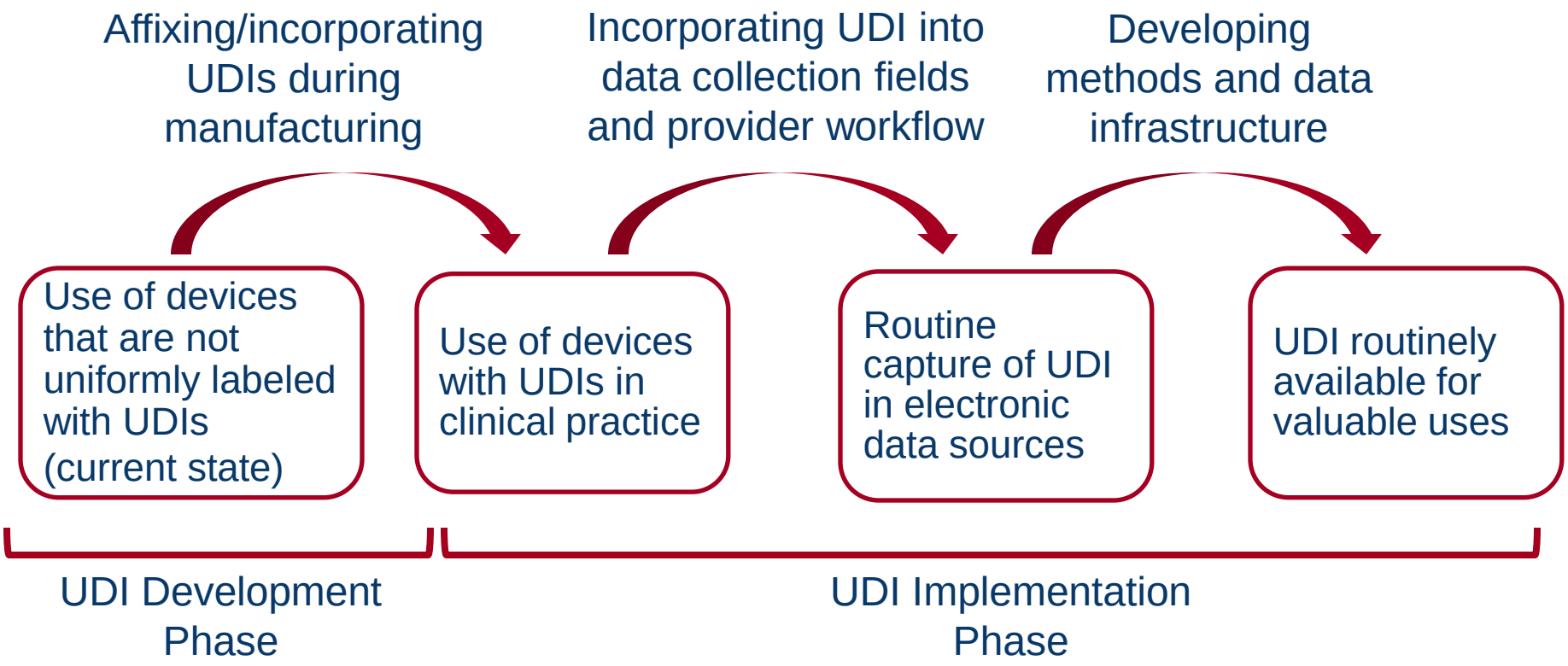
UDI Development and Implementation



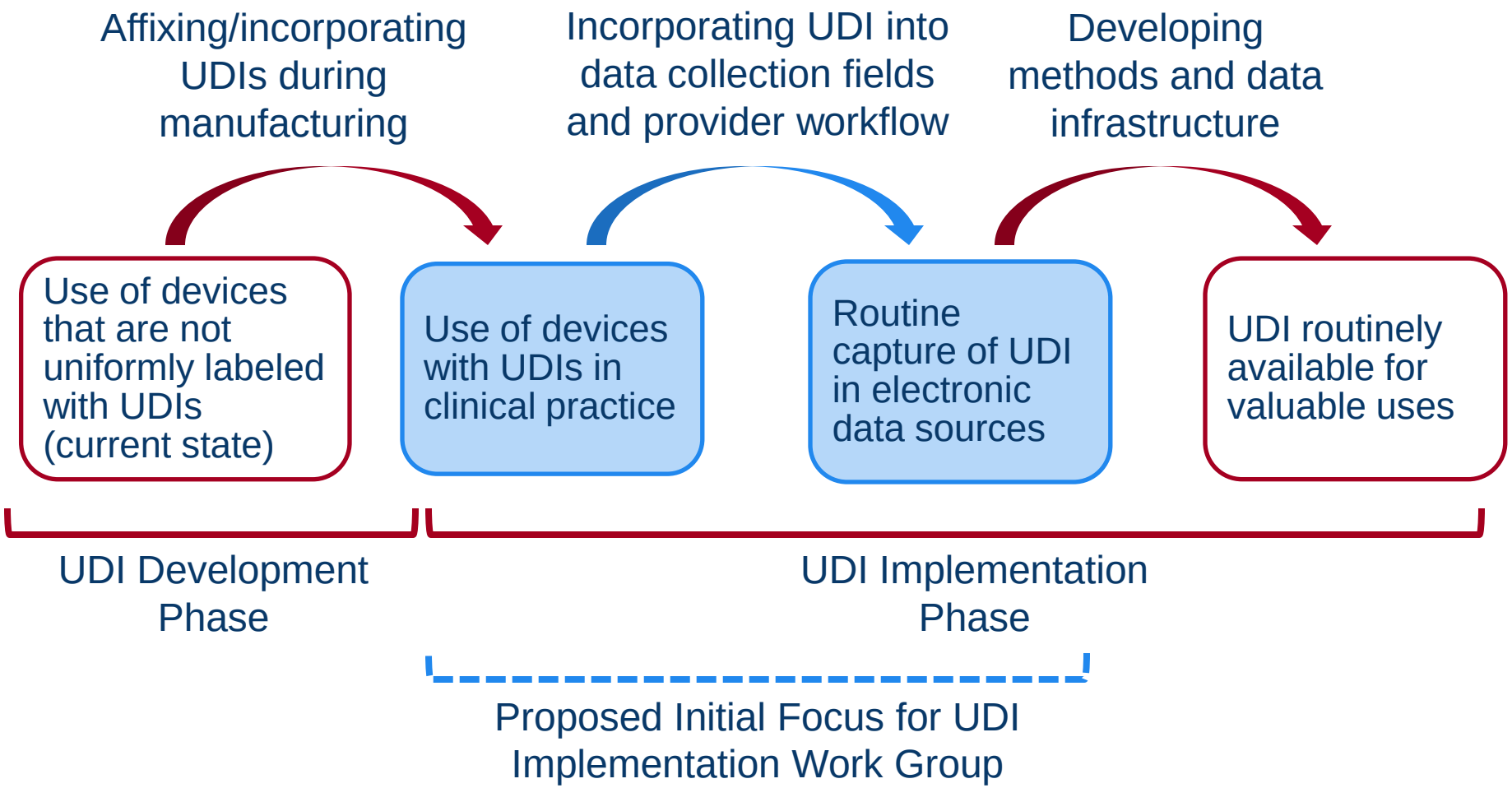
UDI Development and Implementation



UDI Development and Implementation



UDI Development and Implementation



Meeting Agenda

Overview of Proposed UDI Rule

Piloting Efforts to Implement UDI

Session 1: Tracking UDIs throughout the Administrative Systems: Incorporating UDI into the Internal Supply Chain and Billing Processes

Session 2: Understanding Device Use and Patient Outcomes: Capturing UDIs in Clinical Data Sources

Session 3: Leveraging Information: Integrating Across the Electronic Data Infrastructure