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

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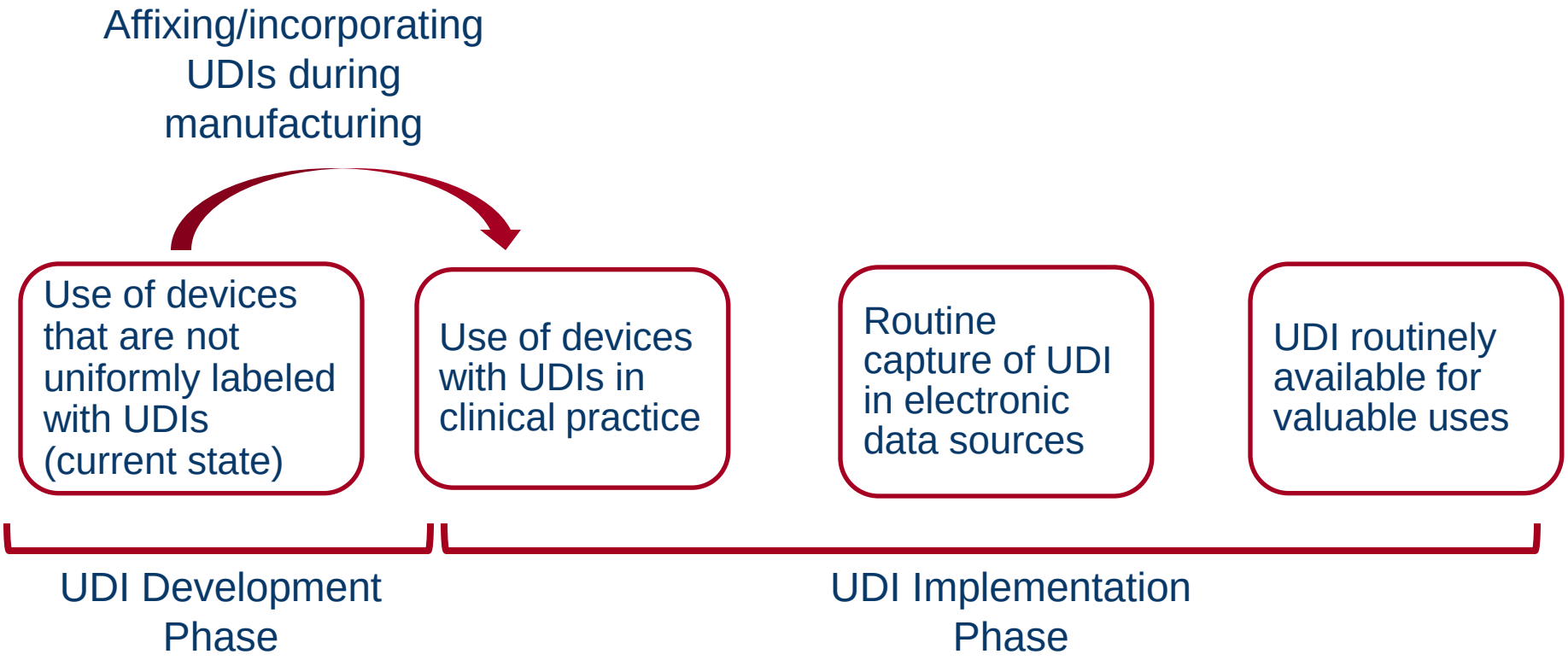
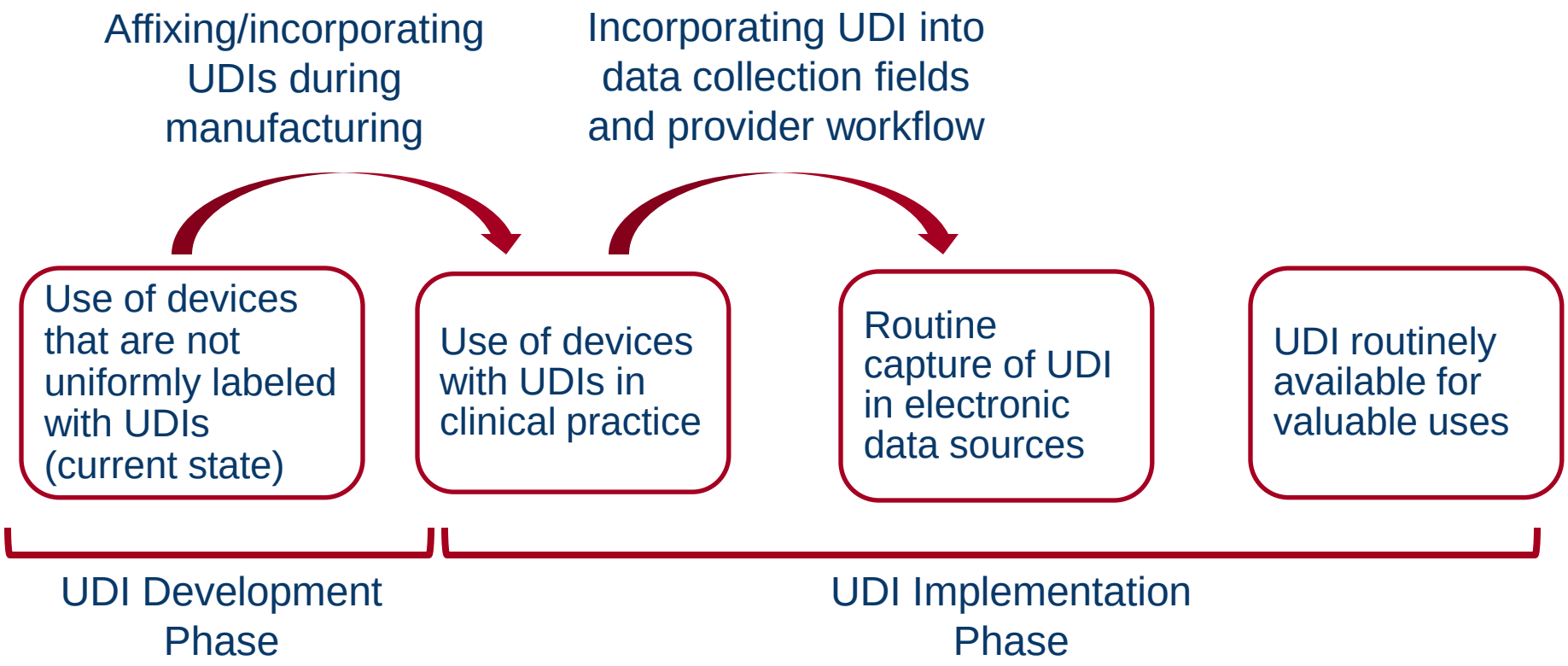
Background and Timeline

- 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*

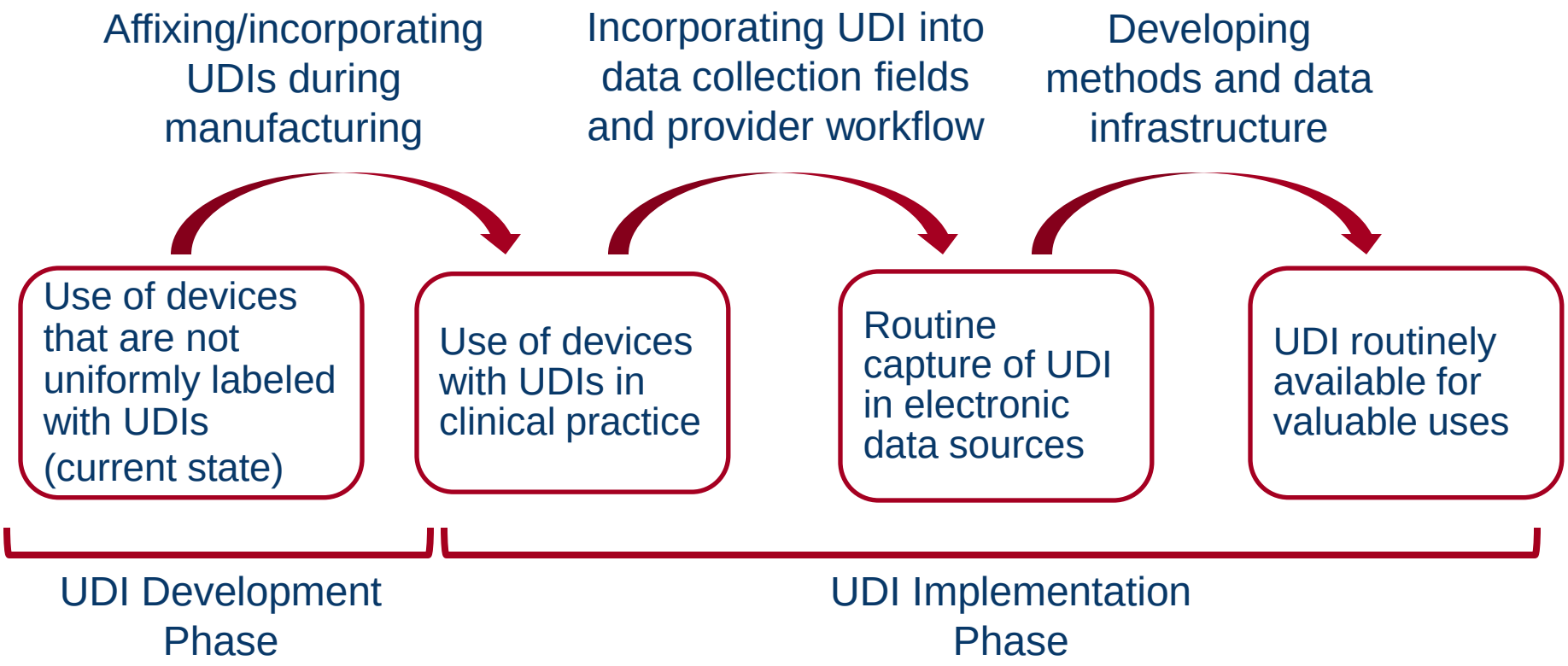
UDI Development and Implementation



UDI Development and Implementation



UDI Development and Implementation



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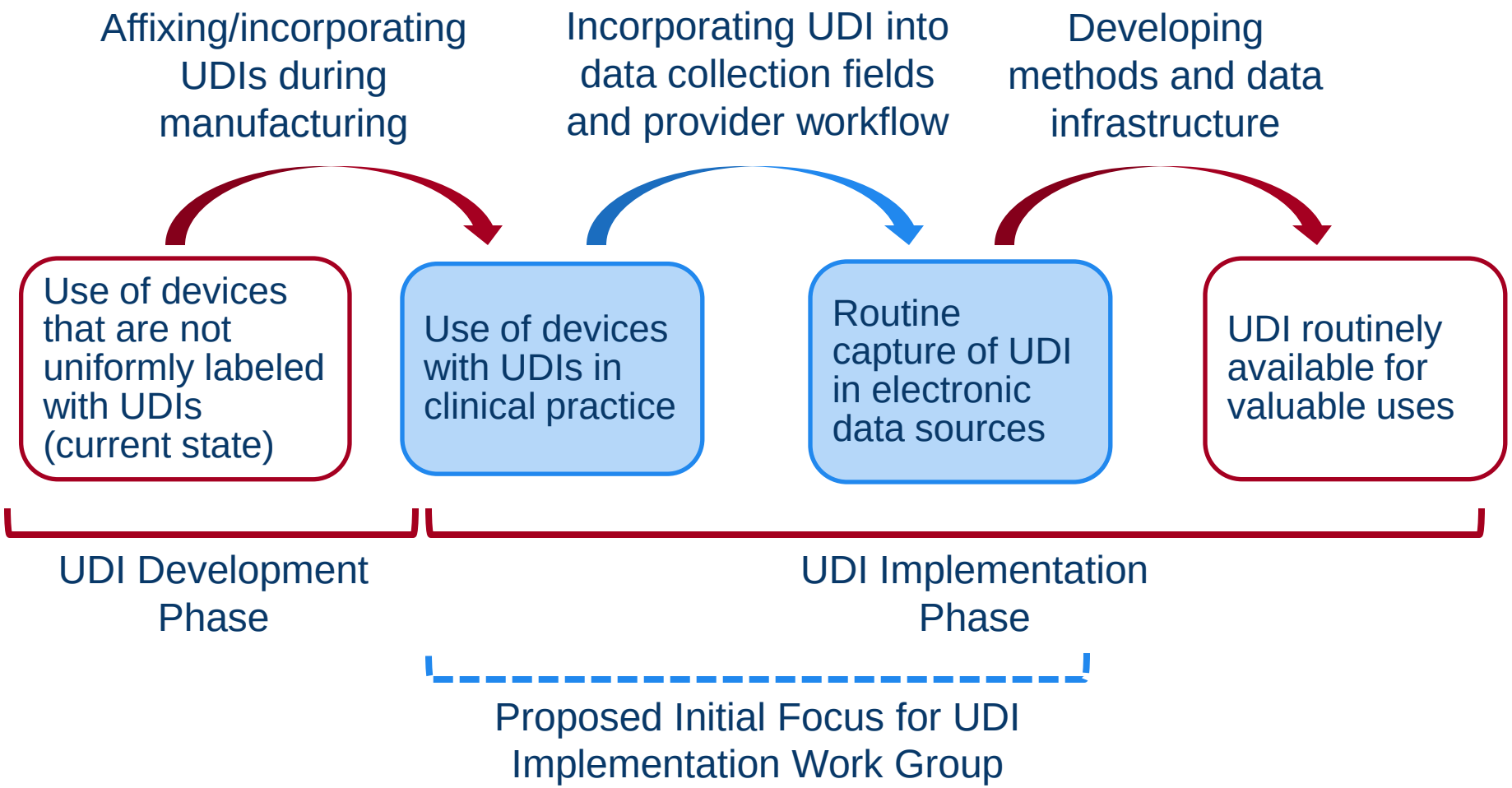

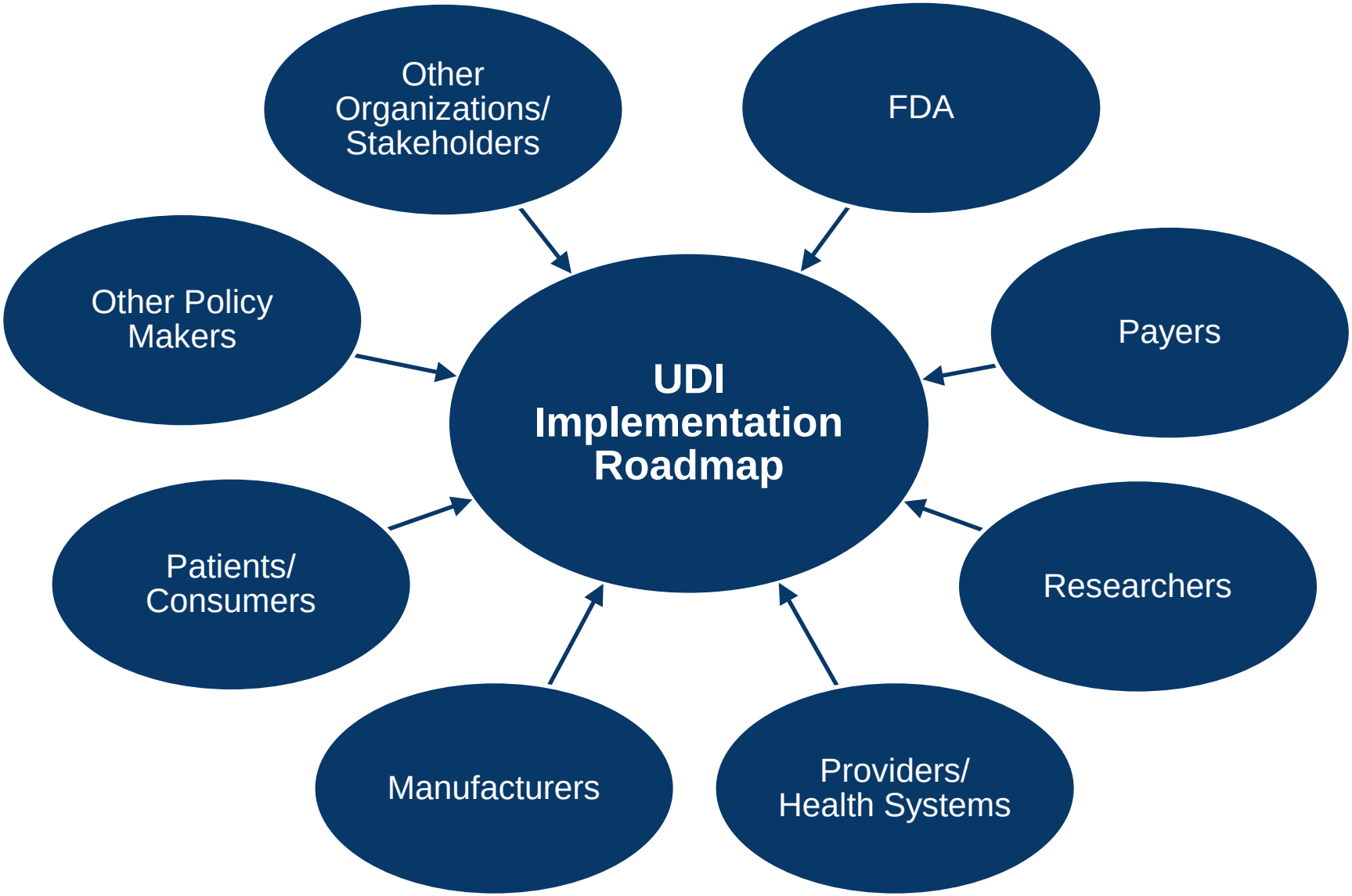

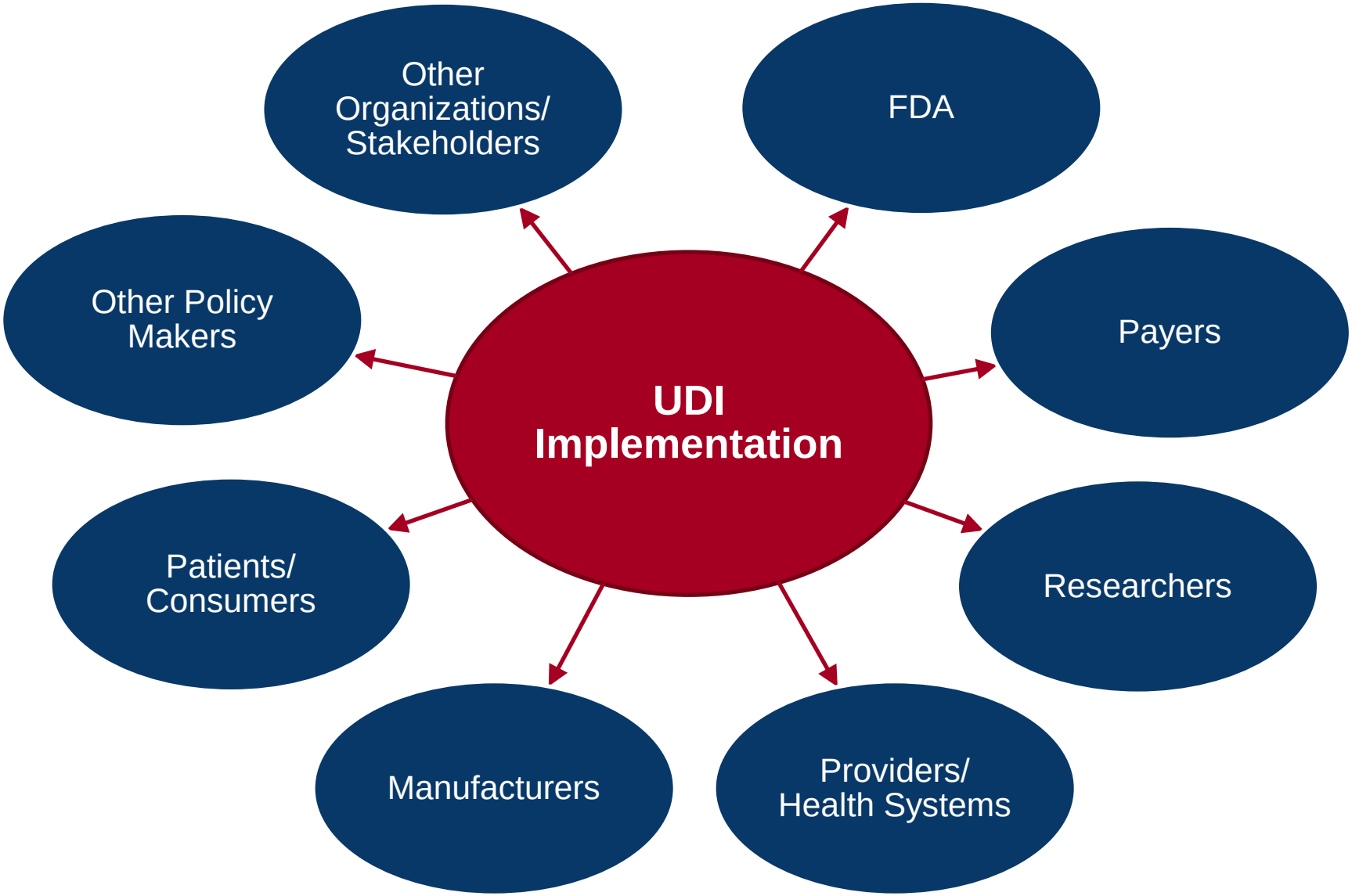

Meeting Agenda

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